2. 非対照試験報告書

2.1 EP0012 試験［発作コントロールが得られていない強直間代発作を有するてんかん患者を対象とするラコサミド併用療法における安全性及び有効性を評価する多施設共同、非盲検、長期継続投与試験、第 2 回中間報告］（5.3.5.2.4：評価資料）

治験方法の概略（表 2.1-1）及び結果の要約を示した。

表 2.1-1　試験方法の概略

項目	内容
標題	発作コントロールが得られていない強直間代発作を有するてんかん患者を対象に、併用療法としてラコサミドを経口投与した時の安全性及び有効性を評価する多施設共同、非盲検、長期継続投与試験
開発の相	第 III 相
目的	主要目的： 発作コントロールが得られていない強直間代発作を有するてんかん患者を対象に、併用療法としてラコサミドを長期経口投与した時の安全性及び忍容性を評価する 副次目的： ・ 発作コントロールが得られていない強直間代発作を有するてんかん患者を対象に、併用療法としてラコサミドを長期経口投与した時の有効性を評価する ・ SP0982 試験を完了した被験者及び本治験で適格となる SP0982 試験をベースライン脱落した被験者に、ラコサミド投与の機会を提供する
治験デザイン	多施設共同、非盲検、長期継続投与
治験方法	本治験の対象は、以下のとおりとした。 SP0982 試験を完了した被験者： ・ SP0982 試験の治療期間（24 週間）に強直間代発作回数が 2 回未満であった被験者 SP0982 試験で無作為割付けされ、SP0982 試験の完了基準を満たした被験者 ・ SP0982 試験の治療期間の最初の 6 週間に 2 回以上の強直間代発作を発現した被験者、又は治療期間の最初の 6 週間を経過後に 2 回目の強直間代発作を発現した被験者 SP0982 試験をベースライン脱落した被験者： ・ SP0982 試験の Prospective ベースライン期間を完了し、無作為割付けの適格性基準（強直間代発作の発現頻度の基準を除くすべての基準）を満たしている被験者

表 2.1-1 試験方法の概略（続き）

項目	内容
治験方法（続き）	本治験は、治療期間（最長 5 年間）、減量期間（最長 4 週間）及び安全性追跡調査期間（30 日間）から構成された。 SP0982 試験を完了した被験者は、SP0982 試験の最終来院を本治験の第 1 回来院とした。SP0982 試験を強直間代発作の発現頻度の基準でベースライン脱落した被験者は、SP0982 試験の第 2 回来院時に本治験の第 1 回来院を実施した。第 1 回来院の 2 週間後に第 2 回来院を実施し、第 2 回来院の 4 週間後に第 3 回来院を実施した。その後、1 年目は 8 週間ごと、2 年目は 16 週間ごとに来院を実施した。3 年目以降も本治験を継続した場合は、3 年目から治験終了まで 24 週間ごとに来院を実施した。来院が予定されていない場合は、8 週間ごとに電話調査を実施した。体重 50 kg 未満の小児被験者は、3 年目以降の 24 週間ごとの各来院から 12 週間後に追加の治験薬処方来院を実施した。 第 1 回来院時に、SP0982 試験の参加状況ごとに、年齢及び体重に応じた用量で治験薬の投与を開始した。本治験の最低投与量は 4 mg/kg/日［経口液（シロップ）］又は 200 mg/日（錠剤）とし、最高投与量は体重 50 kg 未満の小児被験者で 12 mg/kg/日［経口液（シロップ）］、体重 50 kg 以上の小児被験者で 600 mg/日（錠剤）、及び成人被験者で 800 mg/日（錠剤）とした。治療期間を通じて、被験者の忍容性及び発作コントロールが最適となるように、治験責任医師の判断により治験薬の用量調整（増減）を可能とした。増減は初回投与後から可能としたが、SP0982 試験を強直間代発作の発現頻度の基準でベースライン脱落した被験者は、第 1 週の投与が完了するまで治験薬の用量調整（増減）を不可とし、第 1 回来院から 14 日以内に最低投与量に到達することとした。治験薬の用量調整（増減）は段階的に実施し、1 回の調整量が 2 mg/kg/日［経口液（シロップ）］又は 100 mg/日（錠剤）を超えないこととした。体重 50 kg 未満の小児被験者の 10 mg/kg/日超への初回増量時並びに体重 50 kg 以上の小児及び成人被験者の 400 mg/日超への初回増量時は、増量から 1 週間後に規定外の電話調査を実施し、忍容性を確認した。 治療期間中に最低投与量に到達することを必須とし、到達しないことが判明した被験者は減量期間に移行し、治験を中止した。 本治験を中止する場合は、早期中止来院を実施した。その後、減量期間（最長 4 週間）に移行し、推奨された減量スケジュールに従って減量した。減量期間完了時に減量完了来院を実施し、安全性追跡調査期間（30 日間）に移行した。 安全性追跡調査期間では、来院（減量完了来院から 2 週間後）及び電話調査（治験薬の最終投与から 30 日後）を実施した。
併用薬及び併用療法	併用抗てんかん薬： 治療期間中に治験薬の投与による最適又は十分な効果が認められない場合等は、被験者の疾患に対してその被験者の国で承認された抗てんかん薬の新規投与を可能とした。 臨床的に適切と判断された場合は、治験責任医師がメディカルモニターと相談した上で併用抗てんかん薬を慎重に減量及び中止し、治験薬の単剤投与を可能とした。

表 2.1-1　試験方法の概略（続き）

項目	内容
併用薬及び併用療法（続き）	併用可能薬： 神経遮断薬（クロザピン以外）、バルビツール酸系薬及び麻薬性鎮痛薬の使用を可能とした。 併用制限薬及び併用制限療法： ベンゾジアゼピン系薬剤：てんかん以外の治療を目的とし、用法・用量を変更せずに使用する場合は、併用を可能とした。 緊急処置薬： ベンゾジアゼピン系薬剤の頓用使用は、てんかんに対する緊急処置を目的とし、1 週間に 1 回の頻度で使用する場合のみ可能とした。 併用禁止薬： 治験期間中に felbamate の投与を開始することを禁止した。 クロザピン、モノアミンオキシダーゼ A 阻害薬及びビガバトリンの使用を原則禁止した。
被験者数	計画例数：最大 250 例 登録例数：240 例（外国人 203 例、日本人 37 例） 安全性解析対象集団（SS）：239 例（外国人 202 例、日本人 37 例）、 最大の解析対象集団（FAS）：238 例（外国人 201 例、日本人 37 例） 【被験者数設定の根拠】 先行試験である SP0982 試験に基づいて決定した。SP0982 試験は event-driven 試験であるため、必要なイベント件数を満たすために最大 250 例を登録する可能性があった。
対象	発作コントロールが得られていない強直間代発作を有する 4 歳以上のてんかん患者
主な選択/除外基準	選択基準： 1) SP0982 試験を完了した被験者、又は本治験で適格となる SP0982 試験をベースライン脱落した被験者。なお、SP0982 試験でスクリーニングされた他の被験者で、本治験に参加することが有益であると治験責任医師が判断した場合は、治験依頼者のメディカルドクターとの事前協議及び承認の下、本治験への移行が検討される 除外基準： 1) SP0982 試験の中止基準に該当する、又は重篤な有害事象が継続中の被験者 2) 現在、自殺念慮が認められる被験者［コロンビア自殺評価スケール（C-SSRS）（「前回の来院以降」版）の質問 4 又は質問 5 のいずれかに「はい」と回答］。なお、当該基準に該当する場合は、速やかに精神科医に紹介すること

表 2.1-1　試験方法の概略（続き）

項目	内容
主な選択/除外基準（続き）	除外基準（続き）： 3)　ALT、AST 若しくは ALP が基準範囲上限値の 2 倍以上、又は総ビリルビンが基準範囲上限値超（ジルベール症候群を有する場合は、基準範囲上限値の 1.5 倍以上）の被験者。総ビリルビンのみが高値（基準範囲上限値超～基準範囲上限値の 1.5 倍未満）の場合は、ビリルビン分画を測定し、未診断のジルベール症候群（すなわち、直接ビリルビンが 35%未満）の可能性を特定した。 無作為割付けされた被験者の ALT、AST、ALP 又は総ビリルビンのベースライン値が基準範囲上限値超の場合は、ベースライン時の診断及び／又は臨床的に意味のある高値の原因を確認し、電子症例報告書に記録した。 被験者の ALT、AST 又は ALP が基準範囲上限値超でも、スクリーニング時の除外基準に抵触しない場合は、可能な限り投与開始前に再検査を実施し、臨床的に意味のある高値が更に悪化していないことを確認した。臨床的に意味のある高値が更に悪化している場合は、当該被験者の組入れについてメディカルモニター又は治験依頼者のメディカルドクターと相談した。 ALT、AST 又は ALP の検査結果が除外基準を最大 25%上回っていた場合は、確認のため再検査を 1 回実施することを可能とした（再スクリーニングを含む）。
治験薬、投与量及び投与方法	治験薬： ラコサミド経口液（シロップ）10 mg/mL ラコサミド 50 mg 錠 ラコサミド 100 mg 錠 投与量及び投与方法： 治験薬は、朝・夕 1 日 2 回、約 12 時間の間隔を空けて経口投与した。 経口液（シロップ）で投与開始した被験者は、治験責任医師の判断により錠剤に変更することを可能とした。 1)　治療期間 <u>開始用量</u> 第 1 回来院時に以下の用量で治験薬の投与を開始した。 SP0982 試験を完了した被験者： · 体重 30 kg 未満の小児被験者：10 mg/kg/日 · 体重 30 kg 以上 50 kg 未満の小児被験者：8 mg/kg/日 · 体重 50 kg 以上の小児及び成人被験者：400 mg/日 SP0982 試験をベースライン脱落した被験者： · 体重 50 kg 未満の小児被験者：2 mg/kg/日 · 体重 50 kg 以上の小児及び成人被験者：100 mg/日

表 2.1-1　試験方法の概略（続き）

<table>
<tr><th>項目</th><th>内容</th></tr>
<tr><td>治験薬、投与量及び投与方法（続き）</td><td>用量調整
治験薬の最低投与量及び最高投与量を下表に示した。治療期間を通じて、被験者の忍容性及び発作コントロールが最適となるよう、治験責任医師の判断により下表の範囲内で治験薬の用量調整（増減）を可能とした。ただし、SP0982 試験をベースライン脱落した被験者は、第 1 週の投与が完了するまで治験薬の用量調整（増減）を不可とし、第 1 回来院から 14 日以内に最低投与量に到達することとした。この間も、治験薬の減量又は維持は回数の制限なく実施可能とした。
治験薬の用量調整（増減）は段階的に実施し、1 回の調整量が 2 mg/kg/日［経口液（シロップ）］又は 100 mg/日（錠剤）を超えないこととした。また、増量は増量前の用量で 7 日間以上投与を継続した後に実施した。体重 50 kg 未満の小児被験者の 10 mg/kg/日超への初回増量時並びに体重 50 kg 以上の小児及び成人被験者の 400 mg/日超への初回増量時は、増量から 1 週間後に規定外の電話調査を実施し、忍容性を確認した。
治療期間中に最低投与量に到達することを必須とし、到達しないことが判明した被験者は減量期間に移行し、治験を中止した。

治験薬の最低投与量及び最高投与量
<table><tr><th>剤形（体重）</th><th>最低投与量</th><th>最高投与量</th></tr><tr><td>経口液（シロップ）（50 kg 未満の小児被験者）</td><td>4 mg/kg/日</td><td>12 mg/kg/日</td></tr><tr><td>錠剤（50 kg 以上の小児被験者）</td><td>200 mg/日</td><td>600 mg/日</td></tr><tr><td>錠剤（成人被験者）</td><td>200 mg/日</td><td>800 mg/日</td></tr></table>
2)　減量期間
治験薬の推奨減量スケジュールを下表に示した。早期中止来院又は中止来院を実施後、本治験を中止した被験者又は治療期間を完了し本治験終了後に市販のラコサミドを用いた継続治療を実施しない被験者は、下表に従って減量することを推奨した。医療上必要な場合は、本治験の中止を決定する前に可能な限りメディカルモニターに相談した上で、緩やかな減量を可能とした。また、緊急の場合は、メディカルモニターに相談した上で、より速やかな減量を可能とした。減量完了後に減量完了来院を実施した。
中止来院時に、治験責任医師が被験者及び／又はその親若しくは法的保護者と相談した上で選択した治療方針によっては、治験薬を漸減せずに、治験薬の投与を中止することも可能とした。</td></tr>
</table>

表 2.1-1　試験方法の概略（続き）

<table>
<tr><th colspan="2">項目</th><th>内容</th></tr>
<tr><td>治験薬、投与量及び投与方法（続き）</td><td></td><td>治験薬の推奨減量スケジュール
<table>
<tr><th>早期中止来院時又は中止来院時の用量[a]</th><th>第 1 週</th><th>第 2 週</th><th>第 3 週</th><th>第 4 週</th></tr>
<tr><td>11 又は 12 mg/kg/日</td><td>9 mg/kg/日</td><td>6 mg/kg/日</td><td>4 mg/kg/日</td><td>2 mg/kg/日</td></tr>
<tr><td>9 又は 10 mg/kg/日</td><td>8 mg/kg/日</td><td>6 mg/kg/日</td><td>4 mg/kg/日</td><td>2 mg/kg/日</td></tr>
<tr><td>7 又は 8 mg/kg/日</td><td>6 mg/kg/日</td><td>4 mg/kg/日</td><td>2 mg/kg/日</td><td>—</td></tr>
<tr><td>5 又は 6 mg/kg/日</td><td>4 mg/kg/日</td><td>2 mg/kg/日</td><td>—</td><td>—</td></tr>
<tr><td>3 又は 4 mg/kg/日</td><td>2 mg/kg/日</td><td>—</td><td>—</td><td>—</td></tr>
<tr><td>800 mg/日</td><td>600 mg/日</td><td>400 mg/日</td><td>200 mg/日</td><td>100 mg/日</td></tr>
<tr><td>700 mg/日</td><td>500 mg/日</td><td>300 mg/日</td><td>200 mg/日</td><td>100 mg/日</td></tr>
<tr><td>600 mg/日</td><td>500 mg/日</td><td>300 mg/日</td><td>200 mg/日</td><td>100 mg/日</td></tr>
<tr><td>500 mg/日</td><td>400 mg/日</td><td>300 mg/日</td><td>200 mg/日</td><td>100 mg/日</td></tr>
<tr><td>400 mg/日</td><td>300 mg/日</td><td>200 mg/日</td><td>100 mg/日</td><td>—</td></tr>
<tr><td>300 mg/日</td><td>200 mg/日</td><td>100 mg/日</td><td>—</td><td>—</td></tr>
<tr><td>200 mg/日</td><td>100 mg/日</td><td>—</td><td>—</td><td>—</td></tr>
</table>
a.　減量は早期中止来院時又は中止来院時に開始した</td></tr>
<tr><td colspan="2">投与期間</td><td>本治験は、治験を実施している国でラコサミドが強直間代発作を有するてんかん患者の治療薬として承認を受ける日まで、又は治験依頼者が本適応症に対するラコサミドの開発中止を決定する時点まで若しくは本治験の中止を決定する時点までとした。
· 治療期間 2 年以上
· 減量期間 最長 4 週間
· 安全性追跡調査期間 30 日間</td></tr>
<tr><td>評価項目</td><td>安全性</td><td>主要評価項目：
· 被験者及び／又は介護者の自発的報告又は治験責任医師の観察により報告された有害事象
· 有害事象による中止例
· 治療期間の 28 日あたりの欠神発作及びミオクロニー発作発現日数が Prospective ベースライン期間と比較して 25%以下、25%超 50%以下、50%超 75%以下及び 75%超増加した被験者の割合
· 治療期間中に新たな発作型を発現した被験者の割合</td></tr>
</table>

表 2.1-1　試験方法の概略（続き）

項目		内容
評価項目（続き）	安全性（続き）	副次評価項目： · 臨床検査値（血液学的検査、血液生化学検査、尿検査）の変化 · 12 誘導心電図の変化 · バイタルサイン（血圧及び脈拍数）、体重及び身長、並びに身体所見（神経学的検査を含む）の変化 · 血液学的検査及び血液生化学検査における治験薬投与後の顕著な異常値の割合 · 12 誘導心電図における治験薬投与後の顕著な異常値の割合 · バイタルサイン（血圧及び脈拍数）における治験薬投与後の顕著な異常値の割合 その他の評価項目： · タナー分類を用いた判定 · Achenbach の子どもの行動チェックリスト（CBCL）/1½-5 版又は 6-18 版を用いた評価（小児被験者のみ） · 実行機能に関する行動評価尺度（BRIEF／BRIEF-P）を用いた認知機能評価（小児被験者のみ） · C-SSRS を用いた自殺傾向の評価
	有効性	特に記載のない限り、SP0982 試験のベースラインを本治験のベースラインとした。 副次評価項目： · Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率 その他の評価項目： · Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作発現日数の変化量 · Prospective ベースライン期間に対する治療期間の 28 日あたりのミオクロニー発作発現日数の変化量
統計解析方法		本治験は継続中であり、本報告書は 2019 年 8 月 28 日でカットオフしたデータに基づく第 2 回中間報告書である。 解析対象集団の定義： SS：本治験に登録され、本治験の治験薬を 1 回以上投与された被験者 FAS：SS のうち、本治験中に発作日誌の評価が 1 回以上得られた被験者 安全性及び有効性のその他の評価項目の解析は SS、有効性の副次評価項目の解析は FAS を対象とした。

表 2.1-1　試験方法の概略（続き）

項目	内容
統計解析方法（続き）	安全性： 治験薬投与開始後に認められた有害事象の発現例数及び発現率を集団、年齢グループ、投与量及び曝露量別に求めた。治験薬投与開始後に認められた有害事象は、本治験の治験薬初回投与日から最終投与 30 日後までに認められた事象、又は本治験の治験薬初回投与日から最終投与 30 日後までに悪化した事象と定義した。 臨床検査、バイタルサイン及び 12 誘導心電図について、測定値及びベースラインからの変化量の記述統計量を来院時別に求めた。また、12 誘導心電図は治験薬投与後の顕著な異常値の割合を年齢グループ別に集計した。 有効性： Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率の記述統計量を求めた。 Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作及びミオクロニー発作発現日数の変化量の記述統計量を求めた。
治験責任医師	87 名
治験実施医療機関	87 医療機関（アジア・太平洋・その他、東欧州、中南米、北米、西・中央欧州）
公表文献	なし
治験実施期間	2015 年 8 月 [redacted] 日～継続中

2.1.1 被験者の内訳

本治験の SS での被験者の内訳及び中止理由を年齢グループ別に表 2.1-2（全集団）及び表 2.1-3（日本人集団）に示した。

全集団では、第 2 回データカットオフ時点で 240 例が登録され、うち 239 例が本治験の治験薬を 1 回以上投与された。このうち、109 例（45.6%）が 94 週を超えて治験薬を投与された。本治験を継続中の被験者は 187 例（78.2%）で、52 例（21.8%）が本治験を中止した。主な中止理由は、同意撤回（7.5%）、効果不十分（6.3%）及び有害事象（4.6%）であった。

日本人集団では、データカットオフ時点で 37 例が登録され、本治験の治験薬を 1 回以上投与された。このうち、8 例（21.6%）が 94 週以内で治験を継続中で、25 例（67.6%）が 94 週を超えて治験を継続中であった。4 例（10.8%）が本治験を中止した。中止理由は、同意撤回（5.4%）、有害事象及びその他（各 2.7%）であった。

表 2.1-2　全集団の被験者の内訳及び中止理由：SS

Table 1.2.1
Disposition and Discontinuation Reasons by Baseline Age in SP0982
Analysis Set: Safety Set

	Baseline Age in SP0982				
	>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Disposition	n (%)	n (%)	n (%)	n (%)	n (%)
Started Study	16 (100)	36 (100)	186 (100)	1 (100)	239 (100)
Ongoing Within 94 Weeks of Treatment	9 (56.3)	14 (38.9)	60 (32.3)	0	83 (34.7)
Completed >94 Weeks of Treatment	6 (37.5)	15 (41.7)	88 (47.3)	0	109 (45.6)
Discontinued Within 94 Weeks of Treatment	1 (6.3)	7 (19.4)	38 (20.4)	1 (100)	47 (19.7)
Primary Reason for Discontinuation					
ADVERSE EVENT	1 (6.3)	2 (5.6)	6 (3.2)	1 (100)	10 (4.2)
LACK OF EFFICACY	0	2 (5.6)	11 (5.9)	0	13 (5.4)
PROTOCOL VIOLATION	0	0	1 (0.5)	0	1 (0.4)
LOST TO FOLLOW-UP	0	0	2 (1.1)	0	2 (0.8)
CONSENT WITHDRAWN	0	3 (8.3)	14 (7.5)	0	17 (7.1)
OTHER	0	0	4 (2.2)	0	4 (1.7)

[a] Subjects who have not completed or discontinued from EP0012 prior to the clinical cut-off date.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Ongoing Within 94 Weeks of Treatment are those subjects still ongoing who have not reached Visit 11 (Week 94). Completed >94 Weeks of Treatment are those subjects who have completed Visit 11. Discontinued within 94 Weeks of Treatment are those subjects who discontinued prior to Visit 11.
Note: Completed study are those subjects who the investigator has indicated have completed the study.
Note: Discontinuation are those subjects who discontinue the study.

Reference: Listings 1.3, 2.7

表 2.1-2　全集団の被験者の内訳及び中止理由：SS（続き）

Table 1.2.1
Disposition and Discontinuation Reasons by Baseline Age in SP0982
Analysis Set: Safety Set

	Baseline Age in SP0982				
	>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Disposition	n (%)	n (%)	n (%)	n (%)	n (%)
Ongoing [a]	15 (93.8)	28 (77.8)	144 (77.4)	0	187 (78.2)
Completed study	0	0	0	0	0
Discontinued	1 (6.3)	8 (22.2)	42 (22.6)	1 (100)	52 (21.8)
Primary Reason for Discontinuation					
ADVERSE EVENT	1 (6.3)	2 (5.6)	7 (3.8)	1 (100)	11 (4.6)
LACK OF EFFICACY	0	2 (5.6)	13 (7.0)	0	15 (6.3)
PROTOCOL VIOLATION	0	0	2 (1.1)	0	2 (0.8)
LOST TO FOLLOW-UP	0	0	2 (1.1)	0	2 (0.8)
CONSENT WITHDRAWN	0	4 (11.1)	14 (7.5)	0	18 (7.5)
OTHER	0	0	4 (2.2)	0	4 (1.7)

[a] Subjects who have not completed or discontinued from EP0012 prior to the clinical cut-off date.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Ongoing Within 94 Weeks of Treatment are those subjects still ongoing who have not reached Visit 11 (Week 94).
Completed >94 Weeks of Treatment are those subjects who have completed Visit 11. Discontinued within 94 Weeks of Treatment are those subjects who discontinued prior to Visit 11.
Note: Completed study are those subjects who the investigator has indicated have completed the study.
Note: Discontinuation are those subjects who discontinue the study.

Reference: Listings 1.3, 2.7

表 2.1-3　日本人集団の被験者の内訳及び中止理由：SS

Table 1.2.1.1
Disposition and Discontinuation Reasons by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

	Baseline Age in SP0982				
Disposition	>=4 to <12 years N=2 n (%)	>=12 to <18 years N=9 n (%)	>=18 to <65 years N=26 n (%)	>=65 years N=0 n (%)	All Subjects N=37 n (%)
Started Study	2 (100)	9 (100)	26 (100)	0	37 (100)
Ongoing Within 94 Weeks of Treatment	0	3 (33.3)	5 (19.2)	0	8 (21.6)
Completed >94 Weeks of Treatment	2 (100)	5 (55.6)	18 (69.2)	0	25 (67.6)
Discontinued Within 94 Weeks of Treatment	0	1 (11.1)	3 (11.5)	0	4 (10.8)
Primary Reason for Discontinuation					
ADVERSE EVENT	0	0	1 (3.8)	0	1 (2.7)
LACK OF EFFICACY	0	0	0	0	0
PROTOCOL VIOLATION	0	0	0	0	0
LOST TO FOLLOW-UP	0	0	0	0	0
CONSENT WITHDRAWN	0	1 (11.1)	1 (3.8)	0	2 (5.4)
OTHER	0	0	1 (3.8)	0	1 (2.7)

[a] Subjects who have not completed or discontinued from EP0012 prior to the clinical cut-off date.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Ongoing Within 94 Weeks of Treatment are those subjects still ongoing who have not reached Visit 11 (Week 94).
Completed >94 Weeks of Treatment are those subjects who have completed Visit 11. Discontinued within 94 Weeks of Treatment are those subjects who discontinued prior to Visit 11.
Note: Completed study are those subjects who the investigator has indicated have completed the study.
Note: Discontinuation are those subjects who discontinue the study.
Reference: Listings 1.3, 2.7

表 2.1-3　日本人集団の被験者の内訳及び中止理由：SS（続き）

Table 1.2.1.1
Disposition and Discontinuation Reasons by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

	Baseline Age in SP0982				
	>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Disposition	n (%)	n (%)	n (%)	n (%)	n (%)
Ongoing[a]	2 (100)	8 (88.9)	23 (88.5)	0	33 (89.2)
Completed study	0	0	0	0	0
Discontinued	0	1 (11.1)	3 (11.5)	0	4 (10.8)
Primary Reason for Discontinuation					
ADVERSE EVENT	0	0	1 (3.8)	0	1 (2.7)
LACK OF EFFICACY	0	0	0	0	0
PROTOCOL VIOLATION	0	0	0	0	0
LOST TO FOLLOW-UP	0	0	0	0	0
CONSENT WITHDRAWN	0	1 (11.1)	1 (3.8)	0	2 (5.4)
OTHER	0	0	1 (3.8)	0	1 (2.7)

[a] Subjects who have not completed or discontinued from EP0012 prior to the clinical cut-off date.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Ongoing Within 94 Weeks of Treatment are those subjects still ongoing who have not reached Visit 11 (Week 94). Completed >94 Weeks of Treatment are those subjects who have completed Visit 11. Discontinued within 94 Weeks of Treatment are those subjects who discontinued prior to Visit 11.
Note: Completed study are those subjects who the investigator has indicated have completed the study.
Note: Discontinuation are those subjects who discontinue the study.
Reference: Listings 1.3, 2.7

2.1.2 被験者背景

2.1.2.1 人口統計学的特性及び疾患特性

本治験の SS での人口統計学的特性を年齢グループ別に表 2.1-4（全集団）及び表 2.1-5（日本人集団）に、ベースラインの疾患特性を年齢グループ別に表 2.1-6（全集団）及び表 2.1-7（日本人集団）に示した。

全集団の性別の割合は男性 43.9%及び女性 56.1%で、男性の割合がわずかに低かった。多くの被験者（74.5%）は白人であった。本治験のベースラインの年齢では、小児（4 歳以上 18 歳未満）が 44 例（18.4%）で、成人（18 歳以上）が 195 例（81.6%）であった。

日本人集団の性別の割合は男性 45.9%及び女性 54.1%であった。本治験のベースラインの年齢では、小児（4 歳以上 18 歳未満）が 9 例（24.3%）で、成人（18 歳以上）が 28 例（75.7%）であった。

全集団では、ほとんどの被験者（99.6%）の発作型の既往は強直間代発作であった。欠神発作及びミオクロニー発作の発作型の既往を有する被験者の割合は、それぞれ 36.4%及び 38.1%であった。SP0982 試験の Combined ベースライン期間での強直間代発作回数の平均値は 1.74 回（範囲：0.3～19.4 回）で、多くの被験者（81.2%）の 28 日あたりの発作回数は 2 回以下であった。

日本人集団では、すべての被験者の発作型の既往は強直間代発作であった。欠神発作及びミオクロニー発作の発作型の既往を有する被験者の割合は、それぞれ 18.9%及び 43.2%であった。SP0982 試験の Combined ベースライン期間での強直間代発作回数の平均値は 2.40 回（範囲：0.5～19.4 回）で、多くの被験者（83.8%）の 28 日あたりの発作回数は 2 回以下であった。

表 2.1-4　全集団の人口統計学的特性：SS

Table 3.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=16 n (%)	>=12 to <18 years N=36 n (%)	>=18 to <65 years N=186 n (%)	>=65 years N=1 n (%)	All Subjects N=239 n (%)
Age (years)	n	16	36	186	1	239
	Mean	8.6	15.8	31.7	66.0	27.9
	SD	2.5	2.0	11.0	-	12.6
	Q1	6.0	14.0	23.0	66.0	19.0
	Median	10.0	16.0	28.5	66.0	26.0
	Q3	10.5	17.0	38.0	66.0	35.0
	Min	4	12	18	66	4
	Max	11	18	60	66	66

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-4　全集団の人口統計学的特性：SS（続き）

Table 3.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=16 n (%)	>=12 to <18 years N=36 n (%)	>=18 to <65 years N=186 n (%)	>=65 years N=1 n (%)	All Subjects N=239 n (%)
Age (years) [a]						
≥4-<12	n (%)	16 (100)	0	0	0	16 (6.7)
12-<18	n (%)	0	28 (77.8)	0	0	28 (11.7)
18-<65	n (%)	0	8 (22.2)	186 (100)	0	194 (81.2)
≥65	n (%)	0	0	0	1 (100)	1 (0.4)
<=18 [b]	n (%)	16 (100)	36 (100)	5 (2.7)	0	57 (23.8)
19-<65	n (%)	0	0	181 (97.3)	0	181 (75.7)
≥65	n (%)	0	0	0	1 (100)	1 (0.4)
Gender						
M	n (%)	8 (50.0)	11 (30.6)	86 (46.2)	0	105 (43.9)
F	n (%)	8 (50.0)	25 (69.4)	100 (53.8)	1 (100)	134 (56.1)

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-4　全集団の人口統計学的特性：SS（続き）

Table 3.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=16 n (%)	>=12 to <18 years N=36 n (%)	>=18 to <65 years N=186 n (%)	>=65 years N=1 n (%)	All Subjects N=239 n (%)
Weight (kg)	n	16	36	186	1	239
	Mean	33.69	63.20	76.80	96.90	71.95
	SD	12.48	14.62	19.84	-	21.87
	Q1	24.15	53.85	63.10	96.90	56.80
	Median	31.95	60.65	74.35	96.90	70.50
	Q3	41.05	75.80	90.00	96.90	84.90
	Min	15.8	33.2	40.2	96.9	15.8
	Max	57.0	102.0	154.3	96.9	154.3

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-4　全集団の人口統計学的特性：SS（続き）

Table 3.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=16 n (%)	>=12 to <18 years N=36 n (%)	>=18 to <65 years N=186 n (%)	>=65 years N=1 n (%)	All Subjects N=239 n (%)
Height (cm)	n	16	36	186	1	239
	Mean	134.03	164.84	169.07	165.00	166.07
	SD	15.01	10.76	10.26	-	13.76
	Q1	121.35	155.95	162.20	165.00	158.00
	Median	136.50	164.65	167.55	165.00	166.00
	Q3	146.00	171.25	177.40	165.00	175.00
	Min	105.0	147.8	144.0	165.0	105.0
	Max	154.0	190.0	203.2	165.0	203.2

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-4　全集団の人口統計学的特性：SS（続き）

Table 3.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=16 n (%)	>=12 to <18 years N=36 n (%)	>=18 to <65 years N=186 n (%)	>=65 years N=1 n (%)	All Subjects N=239 n (%)
BMI (kg/m²)	n	16	36	186	1	239
	Mean	18.06	23.12	26.76	35.59	25.67
	SD	3.31	4.27	6.22	-	6.29
	Q1	15.81	20.64	22.22	35.59	21.33
	Median	16.90	23.22	25.76	35.59	24.61
	Q3	19.88	26.01	29.79	35.59	28.85
	Min	14.2	14.6	15.0	35.6	14.2
	Max	24.3	31.4	50.0	35.6	50.0

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-4　全集団の人口統計学的特性：SS（続き）

Table 3.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Race from SP0982						
American Indian/Alaskan Native	n (%)	0	0	1 (0.5)	0	1 (0.4)
Asian	n (%)	3 (18.8)	13 (36.1)	32 (17.2)	0	48 (20.1)
Black	n (%)	0	1 (2.8)	3 (1.6)	0	4 (1.7)
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0
White	n (%)	13 (81.3)	21 (58.3)	143 (76.9)	1 (100)	178 (74.5)
Other/Mixed	n (%)	0	1 (2.8)	7 (3.8)	0	8 (3.3)
Ethnicity from SP0982						
Hispanic or Latino	n (%)	5 (31.3)	5 (13.9)	18 (9.7)	0	28 (11.7)
Not Hispanic or Latino	n (%)	11 (68.8)	31 (86.1)	168 (90.3)	1 (100)	211 (88.3)

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-5　日本人集団の人口統計学的特性：SS

Table 3.1.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

		Baseline Age in SP0982				
		>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Age (years)	n	2	9	26	0	37
	Mean	9.5	16.2	26.7		23.2
	SD	2.1	1.9	8.5		9.1
	Q1	8.0	16.0	21.0		18.0
	Median	9.5	17.0	24.0		21.0
	Q3	11.0	17.0	32.0		26.0
	Min	8	13	18		8
	Max	11	18	50		50

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.s
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-5　日本人集団の人口統計学的特性：SS（続き）

Table 3.1.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

		Baseline Age in SP0982				
		>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Age (years) [a]						
>=4-<12	n (%)	2 (100)	0	0	0	2 (5.4)
12-<18	n (%)	0	7 (77.8)	0	0	7 (18.9)
18-<65	n (%)	0	2 (22.2)	26 (100)	0	28 (75.7)
>=65	n (%)	0	0	0	0	0
<=18 [b]	n (%)	2 (100)	9 (100)	2 (7.7)	0	13 (35.1)
19-<65	n (%)	0	0	24 (92.3)	0	24 (64.9)
>=65	n (%)	0	0	0	0	0
Gender						
M	n (%)	0	2 (22.2)	15 (57.7)	0	17 (45.9)
F	n (%)	2 (100)	7 (77.8)	11 (42.3)	0	20 (54.1)

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-5　日本人集団の人口統計学的特性：SS（続き）

Table 3.1.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=2 n (%)	>=12 to <18 years N=9 n (%)	>=18 to <65 years N=26 n (%)	>=65 years N=0 n (%)	All Subjects N=37 n (%)
Weight (kg)	n	2	9	26	0	37
	Mean	35.55	54.94	65.48		61.30
	SD	20.44	6.24	14.57		15.08
	Q1	21.10	50.00	57.00		52.70
	Median	35.55	53.20	64.55		59.80
	Q3	50.00	59.80	70.30		67.00
	Min	21.1	46.5	40.2		21.1
	Max	50.0	63.8	108.0		108.0
Height (cm)	n	2	9	26	0	37
	Mean	132.50	156.37	164.78		160.99
	SD	15.27	3.55	6.95		10.18
	Q1	121.70	154.30	162.20		155.30
	Median	132.50	155.30	165.10		162.40
	Q3	143.30	159.40	168.00		166.60
	Min	121.7	152.1	152.3		121.7
	Max	143.3	162.5	182.0		182.0

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-5　日本人集団の人口統計学的特性：SS（続き）

Table 3.1.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=2 n (%)	>=12 to <18 years N=9 n (%)	>=18 to <65 years N=26 n (%)	>=65 years N=0 n (%)	All Subjects N=37 n (%)
BMI (kg/m²)	n	2	9	26	0	37
	Mean	19.30	22.44	24.03		23.39
	SD	7.14	2.09	4.70		4.38
	Q1	14.25	20.70	21.28		20.99
	Median	19.30	21.87	23.29		23.28
	Q3	24.35	24.16	26.28		24.82
	Min	14.2	19.9	15.0		14.2
	Max	24.3	25.5	36.3		36.3
Race from SP0982						
American Indian/Alaskan Native	n (%)	0	0	0	0	0
Asian	n (%)	2 (100)	9 (100)	26 (100)	0	37 (100)
Black	n (%)	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0
White	n (%)	0	0	0	0	0
Other/Mixed	n (%)	0	0	0	0	0

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-5　日本人集団の人口統計学的特性：SS（続き）

Table 3.1.1
Demographics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

		Baseline Age in SP0982				
		>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Ethnicity from SP0982						
Hispanic or Latino	n (%)	0	0	0	0	0
Not Hispanic or Latino	n (%)	2 (100)	9 (100)	26 (100)	0	37 (100)

BMI=body mass index, F=female, M=male, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
[a] EudraCT age categories.
[b] clinicaltrials.gov age categories.

Reference: Listings 2.1, 2.7

表 2.1-6　全集団のベースラインの疾患特性：SS

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Combined Baseline PGTCS frequency from SP0982	n	16	36	186	1	239
	Mean	2.87	1.05	1.75	5.89	1.74
	SD	4.78	0.45	1.81	-	2.06
	Q1	0.88	0.75	0.76	5.89	0.76
	Median	1.01	1.00	1.24	5.89	1.02
	Q3	1.75	1.24	2.00	5.89	1.75
	Min	0.8	0.5	0.3	5.9	0.3
	Max	19.4	2.8	15.0	5.9	19.4

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=16 n (%)	>=12 to <18 years N=36 n (%)	>=18 to <65 years N=186 n (%)	>=65 years N=1 n (%)	All Subjects N=239 n (%)
Combined Baseline PGTCS categories from SP0982 (from IRT)						
<=2 per 28 days	n (%)	12 (75.0)	25 (69.4)	129 (69.4)	0	166 (69.5)
>2 per 28 days	n (%)	3 (18.8)	3 (8.3)	31 (16.7)	1 (100)	38 (15.9)
Missing	n (%)	1 (6.3)	8 (22.2)	26 (14.0)	0	35 (14.6)
Combined Baseline PGTCS categories from SP0982 (from CRF)						
<=2 per 28 days	n (%)	13 (81.3)	35 (97.2)	146 (78.5)	0	194 (81.2)
>2 per 28 days	n (%)	3 (18.8)	1 (2.8)	40 (21.5)	1 (100)	45 (18.8)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Time since first diagnosis at SP0982 entry (years)	n	16	36	186	1	239
	Mean	3.42	4.98	17.83	60.74	15.11
	SD	2.14	4.41	12.23	-	12.60
	Q1	1.79	1.63	8.45	60.74	5.07
	Median	3.23	3.01	14.77	60.74	11.93
	Q3	4.50	6.63	24.78	60.74	21.18
	Min	0.5	0.5	0.8	60.7	0.5
	Max	9.0	16.0	54.9	60.7	60.7

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Age at diagnosis of epilepsy (years)	n	16	36	186	1	239
	Mean	5.53	11.04	14.08	5.00	13.01
	SD	3.44	4.28	6.20	-	6.24
	Q1	2.43	9.19	10.83	5.00	9.34
	Median	6.03	12.18	14.23	5.00	13.22
	Q3	8.83	14.21	17.76	5.00	16.91
	Min	0.4	1.3	0.0	5.0	0.0
	Max	11.2	18.0	39.8	5.0	39.8

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Lifetime AEDs and Benzodiazepines at SP0982 entry						
0	n (%)	7 (43.8)	18 (50.0)	113 (60.8)	1 (100)	139 (58.2)
1-3	n (%)	9 (56.3)	17 (47.2)	54 (29.0)	0	80 (33.5)
4-6	n (%)	0	1 (2.8)	17 (9.1)	0	18 (7.5)
>=7	n (%)	0	0	2 (1.1)	0	2 (0.8)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Concomitant AEDs at SP0982 entry[a]						
0	n (%)	1 (6.3)	0	3 (1.6)	0	4 (1.7)
1	n (%)	8 (50.0)	18 (50.0)	54 (29.0)	0	80 (33.5)
2	n (%)	6 (37.5)	13 (36.1)	94 (50.5)	1 (100)	114 (47.7)
3	n (%)	1 (6.3)	5 (13.9)	35 (18.8)	0	41 (17.2)
4	n (%)	0	0	0	0	0

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Concomitant AEDs at EP0012 entry[a]						
0	n (%)	1 (6.3)	0	0	0	1 (0.4)
1	n (%)	8 (50.0)	16 (44.4)	57 (30.6)	0	81 (33.9)
2	n (%)	6 (37.5)	14 (38.9)	97 (52.2)	1 (100)	118 (49.4)
3	n (%)	1 (6.3)	6 (16.7)	31 (16.7)	0	38 (15.9)
4	n (%)	0	0	1 (0.5)	0	1 (0.4)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Concomitant benzodiazepine use at SP0982 entry						
Yes	n (%)	1 (6.3)	4 (11.1)	37 (19.9)	0	42 (17.6)
No	n (%)	15 (93.8)	32 (88.9)	149 (80.1)	1 (100)	197 (82.4)
Concomitant benzodiazepine use at EP0012 entry						
Yes	n (%)	1 (6.3)	8 (22.2)	41 (22.0)	0	50 (20.9)
No	n (%)	15 (93.8)	28 (77.8)	145 (78.0)	1 (100)	189 (79.1)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-6　全集団のベースラインの疾患特性：SS（続き）

Table 3.2
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set

		Baseline Age in SP0982				
		>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
LCM Study Drug Status						
Continuing LCM Treatment	n (%)	7 (43.8)	14 (38.9)	76 (40.9)	0	97 (40.6)
New LCM Treatment	n (%)	9 (56.3)	22 (61.1)	110 (59.1)	1 (100)	142 (59.4)
SP0982 exit criteria						
Baseline failure	n (%)	0	7 (19.4)	23 (12.4)	0	30 (12.6)
24-week completer	n (%)	9 (56.3)	12 (33.3)	73 (39.2)	0	94 (39.3)
Met exit criteria	n (%)	6 (37.5)	16 (44.4)	86 (46.2)	1 (100)	109 (45.6)
Incomplete Screener[b]	n (%)	1 (6.3)	1 (2.8)	3 (1.6)	0	5 (2.1)
SP0982 Safety Follow-up[c]	n (%)	0	0	0	0	0
SP0982 Early Discontinuation	n (%)	0	0	1 (0.5)	0	1 (0.4)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject's history and stopped at least 28 days prior to Visit 1.
Note: Baseline failures subjects of SP0982 have missing baseline PGTCS categories information (from IRT).
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After the 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.

Reference: Listings 2.1, 2.3.3

表 2.1-7　日本人集団のベースラインの疾患特性：SS

Table 3.2.1
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

		Baseline Age in SP0982				
		>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Combined Baseline PGTCS frequency from SP0982	n	2	9	26	0	37
	Mean	10.45	0.95	2.29		2.40
	SD	12.66	0.16	3.02		3.86
	Q1	1.50	0.75	1.00		1.00
	Median	10.45	1.00	1.36		1.25
	Q3	19.40	1.01	2.00		1.75
	Min	1.5	0.8	0.5		0.5
	Max	19.4	1.2	15.0		19.4
Combined Baseline PGTCS categories from SP0982 (from IRT)						
<=2 per 28 days	n (%)	1 (50.0)	7 (77.8)	17 (65.4)	0	25 (67.6)
>2 per 28 days	n (%)	1 (50.0)	0	4 (15.4)	0	5 (13.5)
Missing	n (%)	0	2 (22.2)	5 (19.2)	0	7 (18.9)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject history and stopped at least 28 days prior to Visit 1.
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After then 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.
Reference: Listings 2.1, 2.3.3

表 2.1-7　日本人集団のベースラインの疾患特性：SS（続き）

Table 3.2.1
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Variable	Statistic	Baseline Age in SP0982: >=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
		n (%)	n (%)	n (%)	n (%)	n (%)
Combined Baseline PGTCS categories from SP0982 (from CRF)						
<=2 per 28 days	n (%)	1 (50.0)	9 (100)	21 (80.8)	0	31 (83.8)
>2 per 28 days	n (%)	1 (50.0)	0	5 (19.2)	0	6 (16.2)
Time since first diagnosis at SP0982 entry (years)	n	2	9	26	0	37
	Mean	1.15	6.02	13.06		10.70
	SD	0.93	4.60	9.51		9.06
	Q1	0.49	2.90	8.14		3.87
	Median	1.15	5.59	10.10		9.42
	Q3	1.80	7.66	15.19		13.33
	Min	0.5	0.7	0.8		0.5
	Max	1.8	14.8	42.1		42.1

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject history and stopped at least 28 days prior to Visit 1.
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After then 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.
Reference: Listings 2.1, 2.3.3

表 2.1-7　日本人集団のベースラインの疾患特性：SS（続き）

Table 3.2.1
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Variable	Statistic	Baseline Age in SP0982 >=4 to <12 years N=2 n (%)	>=12 to <18 years N=9 n (%)	>=18 to <65 years N=26 n (%)	>=65 years N=0 n (%)	All Subjects N=37 n (%)
Age at diagnosis of epilepsy (years)	n	2	9	26	0	37
	Mean	8.61	10.49	13.72		12.66
	SD	3.62	3.81	5.25		5.06
	Q1	6.05	9.67	11.56		10.50
	Median	8.61	11.26	12.73		12.33
	Q3	11.16	13.11	15.52		14.35
	Min	6.0	2.6	1.7		1.7
	Max	11.2	14.4	28.8		28.8
Lifetime AEDs and Benzodiazepines at SP0982 entry						
0	n (%)	0	2 (22.2)	8 (30.8)	0	10 (27.0)
1-3	n (%)	2 (100)	7 (77.8)	13 (50.0)	0	22 (59.5)
4-6	n (%)	0	0	5 (19.2)	0	5 (13.5)
>=7	n (%)	0	0	0	0	0

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject history and stopped at least 28 days prior to Visit 1.
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After then 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.
Reference: Listings 2.1, 2.3.3

表 2.1-7　日本人集団のベースラインの疾患特性：SS（続き）

Table 3.2.1
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

		Baseline Age in SP0982				
		>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Concomitant AEDs at SP0982 entry[a]						
0	n (%)	0	0	0	0	0
1	n (%)	1 (50.0)	4 (44.4)	5 (19.2)	0	10 (27.0)
2	n (%)	1 (50.0)	3 (33.3)	11 (42.3)	0	15 (40.5)
3	n (%)	0	2 (22.2)	10 (38.5)	0	12 (32.4)
4	n (%)	0	0	0	0	0
Concomitant AEDs at EP0012 entry[a]						
0	n (%)	0	0	0	0	0
1	n (%)	1 (50.0)	4 (44.4)	5 (19.2)	0	10 (27.0)
2	n (%)	1 (50.0)	4 (44.4)	12 (46.2)	0	17 (45.9)
3	n (%)	0	1 (11.1)	8 (30.8)	0	9 (24.3)
4	n (%)	0	0	1 (3.8)	0	1 (2.7)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject history and stopped at least 28 days prior to Visit 1.
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After then 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.
Reference: Listings 2.1, 2.3.3

表 2.1-7　日本人集団のベースラインの疾患特性：SS（続き）

Table 3.2.1
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

		Baseline Age in SP0982				
		>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
Concomitant benzodiazepine use at SP0982 entry						
Yes	n (%)	0	1 (11.1)	12 (46.2)	0	13 (35.1)
No	n (%)	2 (100)	8 (88.9)	14 (53.8)	0	24 (64.9)
Concomitant benzodiazepine use at EP0012 entry						
Yes	n (%)	0	1 (11.1)	12 (46.2)	0	13 (35.1)
No	n (%)	2 (100)	8 (88.9)	14 (53.8)	0	24 (64.9)
LCM Study Drug Status						
Continuing LCM Treatment	n (%)	0	3 (33.3)	8 (30.8)	0	11 (29.7)
New LCM Treatment	n (%)	2 (100)	6 (66.7)	18 (69.2)	0	26 (70.3)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject history and stopped at least 28 days prior to Visit 1.
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After then 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.
Reference: Listings 2.1, 2.3.3

表 2.1-7　日本人集団のベースラインの疾患特性：SS（続き）

Table 3.2.1
Baseline Characteristics by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

		Baseline Age in SP0982				
		>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Variable	Statistic	n (%)	n (%)	n (%)	n (%)	n (%)
SP0982 exit criteria						
Baseline failure	n (%)	0	2 (22.2)	5 (19.2)	0	7 (18.9)
24-week completer	n (%)	0	2 (22.2)	9 (34.6)	0	11 (29.7)
Met exit criteria	n (%)	2 (100)	5 (55.6)	11 (42.3)	0	18 (48.6)
Incomplete Screener[b]	n (%)	0	0	0	0	0
SP0982 Safety Follow-up[c]	n (%)	0	0	0	0	0
SP0982 Early Discontinuation	n (%)	0	0	1 (3.8)	0	1 (2.7)

AED=antiepileptic drug, CRF=case report form, IRT=interactive response technology, Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Combined Baseline includes the 16 weeks prior to randomization.
Note: Lifetime AEDs and benzodiazepines are taken in the subject history and stopped at least 28 days prior to Visit 1.
[a] Note: Count includes benzodiazepines.
[b] Note: After the 125th event, subjects who were in SP0982 screening could directly enroll into EP0012.
[c] Note: After then 125th event, subjects in SP0982 could complete their safety follow-up in EP0012.
Reference: Listings 2.1, 2.3.3

2.1.2.2 抗てんかん薬

本治験の SS での治療期間中に併用していた抗てんかん薬を表 2.1-8（全集団）及び表 2.1-9（日本人集団）に示した。

全集団では、ほとんどの被験者が抗てんかん薬を併用していた。また、多くの被験者はベンゾジアゼピン系薬剤を併用していなかった。最も多く併用していた抗てんかん薬はバルプロ酸製剤（58.2%）で、次いでレベチラセタム（44.4%）及びラモトリギン（31.4%）であった。

日本人集団では、すべての被験者が抗てんかん薬を併用していた。また、多くの被験者はベンゾジアゼピン系薬剤を併用していなかった。最も多く併用していた抗てんかん薬はバルプロ酸製剤（70.3%）で、次いでレベチラセタム（48.6%）及びラモトリギン（35.1%）であった。

表 2.1-8　全集団の治療期間中の併用抗てんかん薬：SS

Table 5.2
Concomitant AEDs and Benzodiazepines During the Treatment Period
Analysis Set: Safety Set

WHODD (Version SEP/2013) Chemical Subgroup [Level 4] Preferred Term	All Subjects N=239 n (%)
Any AED and/or Benzodiazepine	238(99.6)
ALDEHYDES AND DERIVATIVES, N05CC	1(0.4)
CHLORAL HYDRATE	1(0.4)
BARBITURATES AND DERIVATIVES, N03AA	10(4.2)
PHENOBARBITAL	8(3.3)
PRIMIDONE	2(0.8)
BARBITURATES, PLAIN, N05CA	1(0.4)
BENZOBARBITAL	1(0.4)
BENZODIAZEPINE DERIVATIVES, N03AE	53(22.2)
CLOBAZAM	27(11.3)
CLONAZEPAM	26(10.9)
LORAZEPAM	4(1.7)

AED=antiepileptic drug, WHODD=World Health Organization Drug Dictionary.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Concomitant medications are those taken on or after the date of the first dose of study medication.
Note: Phenytoin use includes phenytoin, phenytoin sodium, ethotoin, fosphenytoin, fosphenytoin sodium, and zentronal.
Note: Valproate use includes valproic acid, valproate semisodium, valproate sodium, valproate magnesium, ergenyl chrono, and valpromide.
Note: Phenobarbital use includes phenobarbital, phenobarbital sodium, methylphenobarbital, and primidone.
Reference: Listing 2.6.2

表 2.1-8　全集団の治療期間中の併用抗てんかん薬：SS（続き）

Table 5.2
Concomitant AEDs and Benzodiazepines During the Treatment Period
Analysis Set: Safety Set

WHODD (Version SEP/2013) Chemical Subgroup [Level 4] Preferred Term	All Subjects N=239 n (%)
BENZODIAZEPINE DERIVATIVES, N05BA	20(8.4)
DIAZEPAM	16(6.7)
CLOBAZAM	2(0.8)
LORAZEPAM	2(0.8)
ALPRAZOLAM	1(0.4)
BENZODIAZEPINE DERIVATIVES, N05CD	9(3.8)
MIDAZOLAM	6(2.5)
TEMAZEPAM	2(0.8)
BROTIZOLAM	1(0.4)

AED=antiepileptic drug, WHODD=World Health Organization Drug Dictionary.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Concomitant medications are those taken on or after the date of the first dose of study medication.
Note: Phenytoin use includes phenytoin, phenytoin sodium, ethotoin, fosphenytoin, fosphenytoin sodium, and zentronal.
Note: Valproate use includes valproic acid, valproate semisodium, valproate sodium, valproate magnesium, ergenyl chrono, and valpromide.
Note: Phenobarbital use includes phenobarbital, phenobarbital sodium, methylphenobarbital, and primidone.
Reference: Listing 2.6.2

表 2.1-8　全集団の治療期間中の併用抗てんかん薬：SS（続き）

Table 5.2
Concomitant AEDs and Benzodiazepines During the Treatment Period
Analysis Set: Safety Set

WHODD (Version SEP/2013) Chemical Subgroup [Level 4] Preferred Term	All Subjects N=239 n (%)
CARBOXAMIDE DERIVATIVES, N03AF	18(7.5)
CARBAMAZEPINE	14(5.9)
OXCARBAZEPINE	3(1.3)
ESLICARBAZEPINE ACETATE	1(0.4)
FATTY ACID DERIVATIVES, N03AG	139(58.2)
VALPROATE	139(58.2)
HYDANTOIN DERIVATIVES, N03AB	7(2.9)
PHENYTOIN	7(2.9)
OTHER ANTIEPILEPTICS, N03AX	183(76.6)
LEVETIRACETAM	106(44.4)
LAMOTRIGINE	75(31.4)
TOPIRAMATE	32(13.4)

AED=antiepileptic drug, WHODD=World Health Organization Drug Dictionary.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Concomitant medications are those taken on or after the date of the first dose of study medication.
Note: Phenytoin use includes phenytoin, phenytoin sodium, ethotoin, fosphenytoin, fosphenytoin sodium, and zentronal.
Note: Valproate use includes valproic acid, valproate semisodium, valproate sodium, valproate magnesium, ergenyl chrono, and valpromide.
Note: Phenobarbital use includes phenobarbital, phenobarbital sodium, methylphenobarbital, and primidone.
Reference: Listing 2.6.2

表 2.1-8　全集団の治療期間中の併用抗てんかん薬：SS（続き）

Table 5.2
Concomitant AEDs and Benzodiazepines During the Treatment Period
Analysis Set: Safety Set

WHODD (Version SEP/2013) Chemical Subgroup [Level 4] Preferred Term	All Subjects N=239 n (%)
OTHER ANTIEPILEPTICS, N03AX	
ZONISAMIDE	17(7.1)
PERAMPANEL	15(6.3)
LACOSAMIDE	3(1.3)
PREGABALIN	3(1.3)
FELBAMATE	2(0.8)
GABAPENTIN	1(0.4)
RETIGABINE	1(0.4)
OTHER GENERAL ANESTHETICS, N01AX	1(0.4)
PROPOFOL	1(0.4)

AED=antiepileptic drug, WHODD=World Health Organization Drug Dictionary.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Concomitant medications are those taken on or after the date of the first dose of study medication.
Note: Phenytoin use includes phenytoin, phenytoin sodium, ethotoin, fosphenytoin, fosphenytoin sodium, and zentronal.
Note: Valproate use includes valproic acid, valproate semisodium, valproate sodium, valproate magnesium, ergenyl chrono, and valpromide.
Note: Phenobarbital use includes phenobarbital, phenobarbital sodium, methylphenobarbital, and primidone.
Reference: Listing 2.6.2

表 2.1-8　全集団の治療期間中の併用抗てんかん薬：SS（続き）

Table 5.2
Concomitant AEDs and Benzodiazepines During the Treatment Period
Analysis Set: Safety Set

WHODD (Version SEP/2013) Chemical Subgroup [Level 4] Preferred Term	All Subjects N=239 n (%)
PHENYLPIPERIDINE DERIVATIVES, N02AB	1(0.4)
FENTANYL	1(0.4)
SUCCINIMIDE DERIVATIVES, N03AD	12(5.0)
ETHOSUXIMIDE	7(2.9)
BRIVARACETAM	5(2.1)

AED=antiepileptic drug, WHODD=World Health Organization Drug Dictionary.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Concomitant medications are those taken on or after the date of the first dose of study medication.
Note: Phenytoin use includes phenytoin, phenytoin sodium, ethotoin, fosphenytoin, fosphenytoin sodium, and zentronal.
Note: Valproate use includes valproic acid, valproate semisodium, valproate sodium, valproate magnesium, ergenyl chrono, and valpromide.
Note: Phenobarbital use includes phenobarbital, phenobarbital sodium, methylphenobarbital, and primidone.
Reference: Listing 2.6.2

表 2.1-9　日本人集団の治療期間中の併用抗てんかん薬：SS

Table 5.2.1
Concomitant AEDs and Benzodiazepines During the Treatment Period
Analysis Set: Safety Set - Japanese

WHODD (Version SEP/2013) Chemical Subgroup [Level 4] Preferred Term	All Subjects N=37 n (%)
Any AED and/or Benzodiazepine	37(100)
OTHER ANTIEPILEPTICS, N03AX	33(89.2)
LEVETIRACETAM	18(48.6)
LAMOTRIGINE	13(35.1)
PERAMPANEL	4(10.8)
ZONISAMIDE	3(8.1)
TOPIRAMATE	1(2.7)
FATTY ACID DERIVATIVES, N03AG	26(70.3)
VALPROATE	26(70.3)
BENZODIAZEPINE DERIVATIVES, N03AE	14(37.8)
CLOBAZAM	8(21.6)
CLONAZEPAM	6(16.2)

AED=antiepileptic drug, WHODD=World Health Organization Drug Dictionary.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Concomitant medications are those taken on or after the date of the first dose of study medication.
Note: Phenytoin use includes phenytoin, phenytoin sodium, ethotoin, fosphenytoin, fosphenytoin sodium, and zentronal.
Note: Valproate use includes valproic acid, valproate semisodium, valproate sodium, valproate magnesium, ergenyl chrono, and valpromide.
Note: Phenobarbital use includes phenobarbital, phenobarbital sodium, methylphenobarbital, and primidone.

Reference: Listing 2.6.2

表 2.1-9　日本人集団の治療期間中の併用抗てんかん薬：SS（続き）

Table 5.2.1
Concomitant AEDs and Benzodiazepines During the Treatment Period
Analysis Set: Safety Set - Japanese

WHODD (Version SEP/2013) Chemical Subgroup [Level 4] Preferred Term	All Subjects N=37 n (%)
BENZODIAZEPINE DERIVATIVES, N05BA	7(18.9)
DIAZEPAM	7(18.9)
CARBOXAMIDE DERIVATIVES, N03AF	2(5.4)
CARBAMAZEPINE	2(5.4)
HYDANTOIN DERIVATIVES, N03AB	2(5.4)
PHENYTOIN	2(5.4)
ALDEHYDES AND DERIVATIVES, N05CC	1(2.7)
CHLORAL HYDRATE	1(2.7)
BARBITURATES AND DERIVATIVES, N03AA	1(2.7)
PHENOBARBITAL	1(2.7)

AED=antiepileptic drug, WHODD=World Health Organization Drug Dictionary.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Concomitant medications are those taken on or after the date of the first dose of study medication.
Note: Phenytoin use includes phenytoin, phenytoin sodium, ethotoin, fosphenytoin, fosphenytoin sodium, and zentronal.
Note: Valproate use includes valproic acid, valproate semisodium, valproate sodium, valproate magnesium, ergenyl chrono, and valpromide.
Note: Phenobarbital use includes phenobarbital, phenobarbital sodium, methylphenobarbital, and primidone.

Reference: Listing 2.6.2

2.1.3 安全性

2.1.3.1 曝露状況

本治験での治験薬の曝露期間、最高投与量及び最頻投与量を年齢グループ別に表 2.1-10（全集団）及び表 2.1-11（日本人集団）に示した。また、治験薬の曝露期間別の曝露状況を表 2.1-12（全集団）及び表 2.1-13（日本人集団）に示した。

全集団では、第 2 回データカットオフ時点で治験薬を 1 回以上投与された 239 例（100%）に対する治験薬の曝露期間の中央値は 595.0 日（範囲：20～1416 日）であった。また、最頻投与量の中央値は経口液（シロップ）が 8.0 mg/kg/日、錠剤が 400.0 mg/日であった。

日本人集団では、データカットオフ時点で治験薬を 1 回以上投与された 37 例（100%）に対する治験薬の曝露期間の中央値は 898.0 日（範囲：191～1259 日）であった。また、最頻投与量の中央値は経口液（シロップ）が 7.0 mg/kg/日、錠剤が 300.0 mg/日であった。

表 2.1-10　全集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS

Table 9.4
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set

	Baseline Age in SP0982				
Variable	>=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Study Medication Duration (days)					
n	16	36	186	1	239
Mean	517.1	609.3	651.1	190.0	633.9
SD	327.8	383.7	370.8	-	370.6
Q1	187.0	263.5	323.0	190.0	316.0
Median	497.5	541.5	629.5	190.0	595.0
Q3	821.0	946.5	966.0	190.0	955.0
Min	92	61	20	190	20
Max	1010	1231	1416	190	1416

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-10　全集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS（続き）

Table 9.4
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Baseline Age in SP0982 >=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Total study medication duration (subject-years)	22.65	60.05	331.56	0.52	414.78
Maximum Daily Dose (mg/kg/day)					
n	12	4	0	0	16
Mean	8.7	7.5			8.4
SD	1.3	1.0			1.3
Q1	8.0	7.0			8.0
Median	8.0	8.0			8.0
Q3	10.0	8.0			10.0
Min	6	6			6
Max	10	8			10

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-10　全集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS（続き）

Table 9.4
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Baseline Age in SP0982 >=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Maximum Daily Dose (mg/day)					
n	10	34	185	1	230
Mean	325.0	408.8	433.2	500.0	425.2
SD	113.7	96.5	115.7	-	114.7
Q1	300.0	400.0	400.0	500.0	400.0
Median	300.0	400.0	400.0	500.0	400.0
Q3	350.0	400.0	400.0	500.0	400.0
Min	200	200	200	500	200
Max	600	600	800	500	800

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-10　全集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS（続き）

Table 9.4
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Baseline Age in SP0982 >=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Modal Dose (mg/kg/day)					
n	12	4	0	0	16
Mean	8.0	6.8			7.7
SD	2.1	1.9			2.1
Q1	8.0	5.5			7.5
Median	8.0	7.5			8.0
Q3	10.0	8.0			9.0
Min	3	4			3
Max	10	8			10

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-10　全集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS（続き）

Table 9.4
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set

Variable	Baseline Age in SP0982 >=4 to <12 years N=16	>=12 to <18 years N=36	>=18 to <65 years N=186	>=65 years N=1	All Subjects N=239
Modal Dose (mg/day)					
n	10	34	185	1	230
Mean	290.0	354.4	373.8	200.0	366.5
SD	110.1	101.8	105.8	-	106.8
Q1	200.0	300.0	300.0	200.0	300.0
Median	300.0	400.0	400.0	200.0	400.0
Q3	300.0	400.0	400.0	200.0	400.0
Min	100	100	100	200	100
Max	500	550	800	200	800

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-11　日本人集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS

Table 9.4.1
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Variable	Baseline Age in SP0982 >=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Study Medication Duration (days)					
n	2	9	26	0	37
Mean	831.5	836.9	822.4		826.4
SD	181.7	309.7	358.0		333.6
Q1	703.0	542.0	555.0		555.0
Median	831.5	919.0	849.5		898.0
Q3	960.0	1115.0	1178.0		1175.0
Min	703	457	191		191
Max	960	1231	1259		1259
Total study medication duration (subject-years)	4.55	20.62	58.54	0	83.72

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-11　日本人集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS（続き）

Table 9.4.1
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Variable	Baseline Age in SP0982 >=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Maximum Daily Dose (mg/kg/day)					
n	1	1	0	0	2
Mean	10.0	6.0			8.0
SD	-	-			2.8
Q1	10.0	6.0			6.0
Median	10.0	6.0			8.0
Q3	10.0	6.0			10.0
Min	10	6			6
Max	10	6			10
Maximum Daily Dose (mg/day)					
n	2	8	26	0	36
Mean	275.0	487.5	448.1		447.2
SD	106.1	112.6	106.3		114.0
Q1	200.0	400.0	400.0		400.0
Median	275.0	500.0	400.0		400.0
Q3	350.0	600.0	500.0		500.0
Min	200	300	300		200
Max	350	600	800		800

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-11　日本人集団の治験薬の曝露期間、最高投与量及び最頻投与量：SS（続き）

Table 9.4.1
Study Medication Duration by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

	Baseline Age in SP0982				
Variable	>=4 to <12 years N=2	>=12 to <18 years N=9	>=18 to <65 years N=26	>=65 years N=0	All Subjects N=37
Modal Dose (mg/kg/day)					
n	1	1	0	0	2
Mean	10.0	4.0			7.0
SD	-	-			4.2
Q1	10.0	4.0			4.0
Median	10.0	4.0			7.0
Q3	10.0	4.0			10.0
Min	10	4			4
Max	10	4			10
Modal Dose (mg/day)					
n	2	8	26	0	36
Mean	150.0	381.3	296.2		306.9
SD	70.7	125.2	99.9		114.7
Q1	100.0	300.0	200.0		200.0
Median	150.0	400.0	300.0		300.0
Q3	200.0	450.0	400.0		400.0
Min	100	200	200		100
Max	200	550	500		550

LCM=Lacosamide, Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Modal dose is defined as the daily LCM dose the subject received for the longest duration during the Treatment Period.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.

Reference: Listings 2.7, 5.3

表 2.1-12　全集団の治験薬の曝露期間別の曝露状況：SS

Table 9.1
LCM Overall Exposure
Analysis Set: Safety Set

LCM Exposure[a]	Number of Subjects n (%)	Subject-Years Exposed Total
>0 months	239(100)	414.78
>=6 months	207(86.6)	406.14
>=12 months	174(72.8)	382.86
>=18 months	138(57.7)	340.74
>=24 months	108(45.2)	292.71
>=30 months	72(30.1)	214.17
>=36 months	49(20.5)	154.55
>=42 months	22(9.2)	74.91
>=48 months	2(0.8)	7.62
>=54 months	0	
>=60 months	0	

LCM=Lacosamide.
[a] LCM exposure for ongoing subjects is calculated up to and including the date of clinical cut-off.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.
Note: A month is defined as 28 days.

Reference: Listings 5.3

表 2.1-13　日本人集団の治験薬の曝露期間別の曝露状況：SS

Table 9.1.1
LCM Overall Exposure
Analysis Set: Safety Set - Japanese

LCM Exposure[a]	Number of Subjects n (%)	Subject-Years Exposed Total
>0 months	37(100)	83.72
>=6 months	37(100)	83.72
>=12 months	32(86.5)	80.12
>=18 months	31(83.8)	78.87
>=24 months	25(67.6)	69.74
>=30 months	19(51.4)	57.34
>=36 months	11(29.7)	36.49
>=42 months	9(24.3)	30.22
>=48 months	0	
>=54 months	0	
>=60 months	0	

LCM=Lacosamide.
[a] LCM Exposure for ongoing subjects is calculated up to and including the date of clinical cut-off.
Note: Study medication duration=(date of last dose-date of first dose)+1.
Note: Subject-years of exposure is the total treatment duration in days divided by 365.25.
Note: A month is defined as 28 days.

Reference: Listing 5.3

2.1.3.2 主要評価項目

2.1.3.2.1 有害事象

本治験では MedDRA version 16.1 を用いて有害事象を集計した。

治験薬との因果関係は、治験責任医師が「関連なし（Not related）」又は「関連あり（Related）」のいずれかで評価し、「関連あり」の有害事象を「治験薬との因果関係が否定できない有害事象」として取り扱った。

2.1.3.2.1.1 有害事象発現例数の概要

本治験の治験薬投与開始後に認められた有害事象発現例数の概要を年齢グループ別に表 2.1-14（全集団）及び表 2.1-15（日本人集団）に示した。

全集団では、治験薬投与開始後に有害事象が 197 例（82.4%）に 1097 件認められた。

日本人集団では、治験薬投与開始後に有害事象が 36 例（97.3%）に 245 件認められた。

表 2.1-14　全集団の有害事象発現例数の概要：SS

Table 10.1
Incidence of TEAEs by Baseline Age in SP0982 - Overview
Analysis Set: Safety Set

	Baseline Age in SP0982														
	>=4 to <12 years N=16			>=12 to <18 years N=36			>=18 to <65 years N=186			>=65 years N=1			All Subjects N=239		
Category	n	(%)	[#]	n	(%)	[#]	n	(%)	[#]	n	(%)	[#]	n	(%)	[#]
Any TEAEs	10	(62.5)	[56]	31	(86.1)	[148]	155	(83.3)	[890]	1	(100.0)	[3]	197	(82.4)	[1097]
Serious TEAEs	2	(12.5)	[5]	8	(22.2)	[12]	28	(15.1)	[48]	0			38	(15.9)	[65]
Subject discontinuations due to TEAEs	0			2	(5.6)	[2]	7	(3.8)	[15]	1	(100.0)	[1]	10	(4.2)	[18]
Drug-related TEAEs	3	(18.8)	[6]	11	(30.6)	[24]	68	(36.6)	[164]	1	(100.0)	[2]	83	(34.7)	[196]
Severe TEAEs	1	(6.3)	[1]	3	(8.3)	[7]	21	(11.3)	[38]	1	(100.0)	[1]	26	(10.9)	[47]
All Deaths	0			0			0			0			0		
Deaths (TEAEs leading to death)	0			0			0			0			0		

TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE in that category.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE in that category. Note: An AE with missing intensity is treated as severe; an AE with missing drug relationship is treated as related.

Reference: Listing 2.7, 7.2

表 2.1-15　日本人集団の有害事象発現例数の概要：SS

Table 10.1.1
Incidence of TEAEs by Baseline Age in SP0982 - Overview
Analysis Set: Safety Set - Japanese

	Baseline Age in SP0982													
	>=4 to <12 years N=2			>=12 to <18 years N=9			>=18 to <65 years N=26			>=65 years N=0			All Subjects N=37		
Category	n	(%)	[#]	n	(%)	[#]	n	(%)	[#]	n	(%)	[#]	n	(%)	[#]
Any TEAEs	2	(100)	[16]	9	(100)	[61]	25	(96.2)	[168]	0			36	(97.3)	[245]
Serious TEAEs	0			1	(11.1)	[1]	1	(3.8)	[2]	0			2	(5.4)	[3]
Subject discontinuations due to TEAEs	0			0			1	(3.8)	[2]	0			1	(2.7)	[2]
Drug-related TEAEs	2	(100)	[4]	4	(44.4)	[11]	6	(23.1)	[12]	0			12	(32.4)	[27]
Severe TEAEs	0			0			1	(3.8)	[2]	0			1	(2.7)	[2]
All Deaths	0			0			0			0			0		
Deaths (TEAEs leading to death)	0			0			0			0			0		

TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE in that category.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE in that category.
Note: An AE with missing intensity is treated as severe; an AE with missing drug relationship is treated as related.

Reference: Listing 2.7, 7.2

2.1.3.2.1.2 有害事象の発現状況

本治験の治験薬投与開始後に認められた重症度別の有害事象を表 2.1-16（全集団）及び表 2.1-17（日本人集団）に示した。

全集団では、ほとんどの有害事象の重症度は軽度（72.8%）又は中等度（45.6%）で、高度の有害事象が 26 例（10.9%）に認められた。最も多く認められた有害事象（SOC）は神経系障害（50.6%）で、次いで感染症および寄生虫症（43.5%）及び傷害、中毒および処置合併症（27.6%）であった。また、最も多く認められた有害事象（PT）は鼻咽頭炎（19.7%）で、次いで頭痛（18.4%）及び浮動性めまい（14.6%）であった。

日本人集団では、ほとんどの有害事象の重症度は軽度（97.3%）又は中等度（37.8%）で、高度の有害事象は 1 例（2.7%）に発現した各種物質毒性及び自殺企図のみであった。最も多く認められた有害事象（SOC）は感染症および寄生虫症（70.3%）で、次いで神経系障害（54.1%）、傷害、中毒および処置合併症（48.6%）及び胃腸障害（35.1%）であった。精神障害の発現率は 10.8%で低かった。また、最も多く認められた有害事象（PT）は鼻咽頭炎（51.4%）で、次いで傾眠（27.0%）、インフルエンザ（24.3%）、挫傷（21.6%）、悪心及び頭痛（各 18.9%）並びに浮動性めまい（16.2%）であった。精神障害の SOC で認められた PT の発現率は低かった。

表 2.1-16　全集団の重症度別の有害事象：SS

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
Any TEAE	Any	197	(82.4)
	Mild	174	(72.8)
	Moderate	109	(45.6)
	Severe	26	(10.9)
血液およびリンパ系障害	Any	12	(5.0)
	Mild	11	(4.6)
	Moderate	2	(0.8)
	Severe	0	
貧血	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
血液およびリンパ系障害			
鉄欠乏性貧血	Any	3	(1.3)
	Mild	2	(0.8)
	Moderate	1	(0.4)
	Severe	0	
白血球減少症	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	1	(0.4)
	Severe	0	
好中球減少症	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
血液およびリンパ系障害			
白血球増加症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
リンパ節症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
リンパ球減少症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
血液およびリンパ系障害			
血小板減少症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
心臓障害	Any	7	(2.9)
	Mild	6	(2.5)
	Moderate	1	(0.4)
	Severe	0	
動悸	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
心臓障害			
洞性頻脈	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
第一度房室ブロック	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
徐脈	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
心臓障害			
右脚ブロック	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
耳および迷路障害	Any	17	(7.1)
	Mild	12	(5.0)
	Moderate	5	(2.1)
	Severe	1	(0.4)
回転性めまい	Any	16	(6.7)
	Mild	10	(4.2)
	Moderate	5	(2.1)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
耳および迷路障害			
耳痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
乗物酔い	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
内分泌障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
内分泌障害			
甲状腺機能低下症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
眼障害	Any	17	(7.1)
	Mild	13	(5.4)
	Moderate	6	(2.5)
	Severe	1	(0.4)
複視	Any	8	(3.3)
	Mild	5	(2.1)
	Moderate	3	(1.3)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
眼障害			
霧視	Any	5	(2.1)
	Mild	4	(1.7)
	Moderate	1	(0.4)
	Severe	0	
視力障害	Any	4	(1.7)
	Mild	4	(1.7)
	Moderate	0	
	Severe	0	
眼乾燥	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
眼障害			
眼瞼湿疹	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
変視症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
視神経乳頭浮腫	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
眼障害			
斜視	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
胃腸障害	Any	53	(22.2)
	Mild	50	(20.9)
	Moderate	12	(5.0)
	Severe	2	(0.8)
悪心	Any	17	(7.1)
	Mild	16	(6.7)
	Moderate	3	(1.3)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
嘔吐	Any	17	(7.1)
	Mild	13	(5.4)
	Moderate	5	(2.1)
	Severe	0	
下痢	Any	14	(5.9)
	Mild	13	(5.4)
	Moderate	3	(1.3)
	Severe	0	
腹痛	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
口の感覚鈍麻	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	
腹部不快感	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
下腹部痛	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	0	
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
上腹部痛	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
便秘	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
齲歯	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
口内乾燥	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
胃炎	Any	2	(0.8)
	Mild	0	
	Moderate	1	(0.4)
	Severe	1	(0.4)
過敏性腸症候群	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
嚥下痛	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
口内炎	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
口唇炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
セリアック病	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
胃食道逆流性疾患	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
痔核	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
口の錯感覚	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
歯周病	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
小腸穿孔	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
胃腸障害			
埋伏歯	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
歯の脱落	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
歯痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
一般・全身障害および投与部位の状態	Any	36	(15.1)
	Mild	32	(13.4)
	Moderate	2	(0.8)
	Severe	3	(1.3)
発熱	Any	9	(3.8)
	Mild	9	(3.8)
	Moderate	0	
	Severe	0	
疲労	Any	7	(2.9)
	Mild	6	(2.5)
	Moderate	1	(0.4)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
一般・全身障害および投与部位の状態			
易刺激性	Any	6	(2.5)
	Mild	6	(2.5)
	Moderate	0	
	Severe	0	
非心臓性胸痛	Any	3	(1.3)
	Mild	2	(0.8)
	Moderate	0	
	Severe	1	(0.4)
無力症	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
一般・全身障害および投与部位の状態			
歩行障害	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	0	
	Severe	1	(0.4)
局所腫脹	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
末梢性浮腫	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
一般・全身障害および投与部位の状態			
胸痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
悪寒	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
低体温	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
一般・全身障害および投与部位の状態			
炎症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
インフルエンザ様疾患	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
倦怠感	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
一般・全身障害および投与部位の状態			
粘膜びらん	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
疼痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
評価不能の事象	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
肝胆道系障害	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
脂肪肝	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
免疫系障害	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
免疫系障害			
薬物過敏症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
季節性アレルギー	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
感染症および寄生虫症	Any	104	(43.5)
	Mild	75	(31.4)
	Moderate	50	(20.9)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
鼻咽頭炎	Any	47	(19.7)
	Mild	43	(18.0)
	Moderate	4	(1.7)
	Severe	0	
インフルエンザ	Any	17	(7.1)
	Mild	8	(3.3)
	Moderate	9	(3.8)
	Severe	0	
上気道感染	Any	14	(5.9)
	Mild	6	(2.5)
	Moderate	8	(3.3)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
胃腸炎	Any	8	(3.3)
	Mild	5	(2.1)
	Moderate	4	(1.7)
	Severe	0	
咽頭炎	Any	7	(2.9)
	Mild	5	(2.1)
	Moderate	2	(0.8)
	Severe	0	
尿路感染	Any	7	(2.9)
	Mild	3	(1.3)
	Moderate	4	(1.7)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
ウイルス性気道感染	Any	5	(2.1)
	Mild	1	(0.4)
	Moderate	4	(1.7)
	Severe	0	
扁桃炎	Any	4	(1.7)
	Mild	2	(0.8)
	Moderate	2	(0.8)
	Severe	0	
急性扁桃炎	Any	3	(1.3)
	Mild	0	
	Moderate	3	(1.3)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
気管支炎	Any	3	(1.3)
	Mild	1	(0.4)
	Moderate	2	(0.8)
	Severe	0	
膀胱炎	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	
肺炎	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
鼻炎	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	
耳感染	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
歯肉炎	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
咽頭扁桃炎	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
気道感染	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
皮下組織膿瘍	Any	2	(0.8)
	Mild	0	
	Moderate	2	(0.8)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
歯感染	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
ウイルス性上気道感染	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
四肢膿瘍	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
カンジダ感染	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
蜂巣炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
大腸菌性尿路感染	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
ウイルス性胃炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
消化管感染	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
蜂窩部膿瘍	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
帯状疱疹	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
麦粒腫	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
腎感染	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
大葉性肺炎	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
ライム病	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
口腔カンジダ症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
口腔ヘルペス	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
外耳炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
中耳炎	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
乳頭腫ウイルス感染	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
歯冠周囲炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
歯周炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
毛巣嚢胞	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
副鼻腔炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
皮膚細菌感染	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
細菌性扁桃炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
気管炎	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
気管気管支炎	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
腟感染	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
ウイルス感染	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
外陰腟真菌感染	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
感染症および寄生虫症			
外陰部腟炎	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
傷害、中毒および処置合併症	Any	66	(27.6)
	Mild	48	(20.1)
	Moderate	24	(10.0)
	Severe	5	(2.1)
挫傷	Any	16	(6.7)
	Mild	14	(5.9)
	Moderate	2	(0.8)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
頭部損傷	Any	10	(4.2)
	Mild	6	(2.5)
	Moderate	6	(2.5)
	Severe	0	
裂傷	Any	8	(3.3)
	Mild	5	(2.1)
	Moderate	3	(1.3)
	Severe	0	
歯牙破折	Any	6	(2.5)
	Mild	5	(2.1)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
擦過傷	Any	5	(2.1)
	Mild	5	(2.1)
	Moderate	0	
	Severe	0	
転倒	Any	4	(1.7)
	Mild	4	(1.7)
	Moderate	0	
	Severe	0	
靭帯捻挫	Any	4	(1.7)
	Mild	4	(1.7)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
顔面損傷	Any	3	(1.3)
	Mild	1	(0.4)
	Moderate	2	(0.8)
	Severe	0	
顔面骨骨折	Any	3	(1.3)
	Mild	0	
	Moderate	2	(0.8)
	Severe	1	(0.4)
手骨折	Any	3	(1.3)
	Mild	2	(0.8)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
節足動物咬傷	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
鎖骨骨折	Any	2	(0.8)
	Mild	0	
	Moderate	2	(0.8)
	Severe	0	
脳振盪	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
足骨折	Any	2	(0.8)
	Mild	0	
	Moderate	2	(0.8)
	Severe	0	
関節損傷	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
肋骨骨折	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
交通事故	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
皮下血腫	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
舌損傷	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
各種物質毒性	Any	2	(0.8)
	Mild	0	
	Moderate	1	(0.4)
	Severe	1	(0.4)
アルコール中毒	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
動物咬傷	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
節足動物刺傷	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
背部損傷	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
第２度熱傷	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
腓骨骨折	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)
骨折	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)
上腕骨骨折	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
損傷	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
関節脱臼	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
下肢骨折	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
肉離れ	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
過量投与	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
処置による疼痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
刺創	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
硬膜下血腫	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
サンバーン	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
熱傷	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
外傷性頭蓋内出血	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
創傷	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
傷害、中毒および処置合併症			
手首関節骨折	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
臨床検査	Any	31	(13.0)
	Mild	25	(10.5)
	Moderate	8	(3.3)
	Severe	1	(0.4)
γ－グルタミルトランスフェラーゼ増加	Any	6	(2.5)
	Mild	6	(2.5)
	Moderate	1	(0.4)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
臨床検査			
アラニンアミノトランスフェラーゼ増加	Any	5	(2.1)
	Mild	4	(1.7)
	Moderate	2	(0.8)
	Severe	0	
体重減少	Any	5	(2.1)
	Mild	3	(1.3)
	Moderate	2	(0.8)
	Severe	0	
体重増加	Any	4	(1.7)
	Mild	3	(1.3)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
臨床検査			
血圧上昇	Any	3	(1.3)
	Mild	2	(0.8)
	Moderate	1	(0.4)
	Severe	0	
白血球数増加	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
アスパラギン酸アミノトランスフェラーゼ増加	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
臨床検査			
血中アルカリホスファターゼ増加	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
血中クレアチンホスホキナーゼ増加	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
血中ブドウ糖増加	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
臨床検査			
拡張期血圧上昇	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
血中尿酸増加	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
薬物濃度増加	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
臨床検査			
心電図ＰＲ延長	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
尿中蛋白陽性	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
サイロキシン減少	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
臨床検査			
トリヨードチロニン減少	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
遊離トリヨードチロニン減少	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
代謝および栄養障害	Any	15	(6.3)
	Mild	8	(3.3)
	Moderate	6	(2.5)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
代謝および栄養障害			
糖尿病	Any	3	(1.3)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	1	(0.4)
ビタミンD欠乏	Any	3	(1.3)
	Mild	1	(0.4)
	Moderate	2	(0.8)
	Severe	0	
脱水	Any	2	(0.8)
	Mild	0	
	Moderate	2	(0.8)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
代謝および栄養障害			
鉄欠乏	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
食欲減退	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
脂質異常症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
代謝および栄養障害			
高アンモニア血症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
高血糖	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
高トリグリセリド血症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
代謝および栄養障害			
高尿酸血症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
低カリウム血症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
低ナトリウム血症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

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表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
代謝および栄養障害			
過体重	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
ビタミンA欠乏	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
筋骨格系および結合組織障害	Any	32	(13.4)
	Mild	27	(11.3)
	Moderate	7	(2.9)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
筋骨格系および結合組織障害			
背部痛	Any	13	(5.4)
	Mild	10	(4.2)
	Moderate	3	(1.3)
	Severe	0	
関節痛	Any	6	(2.5)
	Mild	5	(2.1)
	Moderate	2	(0.8)
	Severe	0	
筋骨格痛	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
筋骨格系および結合組織障害			
筋肉痛	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
四肢痛	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
側腹部痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
筋骨格系および結合組織障害			
関節腫脹	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
混合性結合組織病	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
筋肉疲労	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
筋骨格系および結合組織障害			
頚部痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
顎痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
脊柱変形	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
筋骨格系および結合組織障害			
脊椎障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
滑液嚢腫	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
腱鞘炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	Any	5	(2.1)
	Mild	2	(0.8)
	Moderate	3	(1.3)
	Severe	1	(0.4)
乳腺線維腺腫	Any	2	(0.8)
	Mild	0	
	Moderate	2	(0.8)
	Severe	0	
膀胱癌	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）			
甲状腺新生物	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
子宮平滑筋腫	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
神経系障害	Any	121	(50.6)
	Mild	96	(40.2)
	Moderate	47	(19.7)
	Severe	16	(6.7)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
頭痛	Any	44	(18.4)
	Mild	31	(13.0)
	Moderate	15	(6.3)
	Severe	3	(1.3)
浮動性めまい	Any	35	(14.6)
	Mild	26	(10.9)
	Moderate	9	(3.8)
	Severe	1	(0.4)
傾眠	Any	25	(10.5)
	Mild	23	(9.6)
	Moderate	1	(0.4)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
大発作痙攣	Any	17	(7.1)
	Mild	4	(1.7)
	Moderate	9	(3.8)
	Severe	4	(1.7)
片頭痛	Any	10	(4.2)
	Mild	3	(1.3)
	Moderate	8	(3.3)
	Severe	1	(0.4)
錯感覚	Any	7	(2.9)
	Mild	7	(2.9)
	Moderate	2	(0.8)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
小発作てんかん	Any	7	(2.9)
	Mild	4	(1.7)
	Moderate	4	(1.7)
	Severe	0	
振戦	Any	7	(2.9)
	Mild	5	(2.1)
	Moderate	2	(0.8)
	Severe	0	
平衡障害	Any	5	(2.1)
	Mild	3	(1.3)
	Moderate	2	(0.8)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
ミオクローヌス性てんかん	Any	5	(2.1)
	Mild	2	(0.8)
	Moderate	2	(0.8)
	Severe	1	(0.4)
健忘	Any	4	(1.7)
	Mild	4	(1.7)
	Moderate	0	
	Severe	0	
てんかん重積状態	Any	4	(1.7)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	4	(1.7)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
失語症	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	
感覚鈍麻	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	1	(0.4)
	Severe	0	
ミオクローヌス	Any	3	(1.3)
	Mild	1	(0.4)
	Moderate	2	(0.8)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
運動失調	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
痙攣	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	1	(0.4)
	Severe	0	
注意力障害	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
発作後頭痛	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	0	
	Severe	1	(0.4)
緊張性頭痛	Any	2	(0.8)
	Mild	0	
	Moderate	2	(0.8)
	Severe	0	
咬舌	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
脱力発作	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
自律神経失調	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
良性頭蓋内圧亢進	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
頚髄神経根障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
認知障害	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
複雑部分発作	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
協調運動異常	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
構語障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
味覚異常	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
統合運動障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
てんかん	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
反射亢進	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
反射減弱	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
嗜眠	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
意識消失	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
記憶障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
二次性全般化を伴う部分発作	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
姿勢時振戦	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
神経系障害			
失神	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
強直性痙攣	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
精神障害	Any	29	(12.1)
	Mild	22	(9.2)
	Moderate	8	(3.3)
	Severe	3	(1.3)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
うつ病	Any	6	(2.5)
	Mild	3	(1.3)
	Moderate	3	(1.3)
	Severe	0	
不眠症	Any	5	(2.1)
	Mild	5	(2.1)
	Moderate	0	
	Severe	0	
攻撃性	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
不安	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
失見当識	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
心因性発作	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
精神緩慢	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
妄想	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
抑うつ気分	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
初期不眠症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
学習障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	0	
大うつ病	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
精神状態変化	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
パニック発作	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)
心的外傷後ストレス障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
精神運動制止遅滞	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
睡眠時驚愕	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
身体表現性障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
ストレス	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
自殺念慮	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
自殺企図	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
精神障害			
早朝覚醒型不眠症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
腎および尿路障害	Any	4	(1.7)
	Mild	3	(1.3)
	Moderate	1	(0.4)
	Severe	0	
排尿困難	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
腎および尿路障害			
遺尿	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
糖尿	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
腎仙痛	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
腎および尿路障害			
腎不全	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
生殖系および乳房障害	Any	15	(6.3)
	Mild	13	(5.4)
	Moderate	4	(1.7)
	Severe	1	(0.4)
月経困難症	Any	7	(2.9)
	Mild	7	(2.9)
	Moderate	1	(0.4)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
生殖系および乳房障害			
月経過多	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	1	(0.4)
	Severe	1	(0.4)
無月経	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
子宮内膜症	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
生殖系および乳房障害			
不規則月経	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
卵巣嚢胞	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
多嚢胞性卵巣	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
生殖系および乳房障害			
前立腺腫大	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
性機能不全	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
子宮出血	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
呼吸器、胸郭および縦隔障害	Any	22	(9.2)
	Mild	18	(7.5)
	Moderate	4	(1.7)
	Severe	1	(0.4)
口腔咽頭痛	Any	7	(2.9)
	Mild	7	(2.9)
	Moderate	0	
	Severe	0	
咳嗽	Any	5	(2.1)
	Mild	5	(2.1)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
呼吸器、胸郭および縦隔障害			
鼻出血	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
過換気	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
誤嚥性肺炎	Any	2	(0.8)
	Mild	0	
	Moderate	1	(0.4)
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
呼吸器、胸郭および縦隔障害			
呼吸障害	Any	2	(0.8)
	Mild	1	(0.4)
	Moderate	2	(0.8)
	Severe	0	
急性呼吸不全	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)
喘息	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
呼吸器、胸郭および縦隔障害			
労作性呼吸困難	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
喀血	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
鼻乾燥	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
呼吸器、胸郭および縦隔障害			
呼吸時疼痛	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
湿性咳嗽	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
鼻漏	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
呼吸器、胸郭および縦隔障害			
いびき	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
皮膚および皮下組織障害	Any	16	(6.7)
	Mild	15	(6.3)
	Moderate	1	(0.4)
	Severe	0	
脱毛症	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
皮膚および皮下組織障害			
嵌入爪	Any	3	(1.3)
	Mild	3	(1.3)
	Moderate	0	
	Severe	0	
皮膚炎	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
湿疹	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
皮膚および皮下組織障害			
蕁麻疹	Any	2	(0.8)
	Mild	2	(0.8)
	Moderate	0	
	Severe	0	
ざ瘡	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
皮膚乾燥	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
皮膚および皮下組織障害			
紅斑	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
逆むけ	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
爪破損	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
皮膚および皮下組織障害			
そう痒症	Any	1	(0.4)
	Mild	0	
	Moderate	1	(0.4)
	Severe	0	
血管障害	Any	10	(4.2)
	Mild	7	(2.9)
	Moderate	2	(0.8)
	Severe	1	(0.4)
高血圧	Any	4	(1.7)
	Mild	2	(0.8)
	Moderate	2	(0.8)
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
血管障害			
毛細血管障害	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
血腫	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
低血圧	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
血管障害			
起立性低血圧	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	
末梢性虚血	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)
末梢血管障害	Any	1	(0.4)
	Mild	0	
	Moderate	0	
	Severe	1	(0.4)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-16　全集団の重症度別の有害事象：SS（続き）

Table 10.3
Incidence of TEAEs by Intensity
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=239 n	(%)
血管障害			
血管炎	Any	1	(0.4)
	Mild	1	(0.4)
	Moderate	0	
	Severe	0	

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
Any TEAE	Any	36(97.3)
	Mild	36(97.3)
	Moderate	14(37.8)
	Severe	1(2.7)
血液およびリンパ系障害	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
貧血	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
心臓障害	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
心臓障害		
徐脈	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
耳および迷路障害	Any	4(10.8)
	Mild	4(10.8)
	Moderate	0
	Severe	0
回転性めまい	Any	4(10.8)
	Mild	4(10.8)
	Moderate	0
	Severe	0
眼障害	Any	3(8.1)
	Mild	3(8.1)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
眼障害		
眼乾燥	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
眼瞼湿疹	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
霧視	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
胃腸障害	Any	13(35.1)
	Mild	13(35.1)
	Moderate	1(2.7)
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
胃腸障害		
悪心	Any	7(18.9)
	Mild	7(18.9)
	Moderate	0
	Severe	0
下痢	Any	3(8.1)
	Mild	3(8.1)
	Moderate	0
	Severe	0
齲歯	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
口内炎	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
胃腸障害		
嘔吐	Any	2(5.4)
	Mild	1(2.7)
	Moderate	1(2.7)
	Severe	0
腹痛	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
下腹部痛	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
口唇炎	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
胃腸障害		
便秘	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
歯周病	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
埋伏歯	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
一般・全身障害および投与部位の状態	Any	9(24.3)
	Mild	9(24.3)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
一般・全身障害および投与部位の状態		
発熱	Any	5(13.5)
	Mild	5(13.5)
	Moderate	0
	Severe	0
末梢性浮腫	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
悪寒	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
疲労	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
一般・全身障害および投与部位の状態		
炎症	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
倦怠感	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
粘膜びらん	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
免疫系障害	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
免疫系障害		
季節性アレルギー	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
感染症および寄生虫症	Any	26(70.3)
	Mild	25(67.6)
	Moderate	9(24.3)
	Severe	0
鼻咽頭炎	Any	19(51.4)
	Mild	19(51.4)
	Moderate	0
	Severe	0
インフルエンザ	Any	9(24.3)
	Mild	1(2.7)
	Moderate	8(21.6)
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
感染症および寄生虫症		
膀胱炎	Any	3(8.1)
	Mild	3(8.1)
	Moderate	0
	Severe	0
咽頭炎	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
胃腸炎	Any	1(2.7)
	Mild	0
	Moderate	1(2.7)
	Severe	0
歯肉炎	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
感染症および寄生虫症		
帯状疱疹	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
麦粒腫	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
外耳炎	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
歯冠周囲炎	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
感染症および寄生虫症		
肺炎	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
皮膚細菌感染	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
扁桃炎	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
傷害、中毒および処置合併症	Any	18(48.6)
	Mild	16(43.2)
	Moderate	3(8.1)
	Severe	1(2.7)

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
傷害、中毒および処置合併症		
挫傷	Any	8(21.6)
	Mild	8(21.6)
	Moderate	0
	Severe	0
擦過傷	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
頭部損傷	Any	2(5.4)
	Mild	1(2.7)
	Moderate	1(2.7)
	Severe	0
皮下血腫	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
傷害、中毒および処置合併症		
歯牙破折	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
靭帯捻挫	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
動物咬傷	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
節足動物咬傷	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
傷害、中毒および処置合併症		
顔面損傷	Any	1(2.7)
	Mild	0
	Moderate	1(2.7)
	Severe	0
裂傷	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
下肢骨折	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
肋骨骨折	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
傷害、中毒および処置合併症		
熱傷	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
各種物質毒性	Any	1(2.7)
	Mild	0
	Moderate	0
	Severe	1(2.7)
創傷	Any	1(2.7)
	Mild	0
	Moderate	1(2.7)
	Severe	0
臨床検査	Any	6(16.2)
	Mild	6(16.2)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
臨床検査		
γ－グルタミルトランスフェラーゼ増加	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
白血球数増加	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
アラニンアミノトランスフェラーゼ増加	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
尿中蛋白陽性	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
臨床検査		
体重増加	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
代謝および栄養障害	Any	3(8.1)
	Mild	3(8.1)
	Moderate	0
	Severe	0
高尿酸血症	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
高アンモニア血症	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
代謝および栄養障害		
高トリグリセリド血症	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
筋骨格系および結合組織障害	Any	8(21.6)
	Mild	8(21.6)
	Moderate	0
	Severe	0
背部痛	Any	4(10.8)
	Mild	4(10.8)
	Moderate	0
	Severe	0
関節痛	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
筋骨格系および結合組織障害		
関節腫脹	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
筋肉痛	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
滑液嚢腫	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
腱鞘炎	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
神経系障害	Any	20(54.1)
	Mild	18(48.6)
	Moderate	4(10.8)
	Severe	0
傾眠	Any	10(27.0)
	Mild	10(27.0)
	Moderate	0
	Severe	0
頭痛	Any	7(18.9)
	Mild	7(18.9)
	Moderate	0
	Severe	0
浮動性めまい	Any	6(16.2)
	Mild	5(13.5)
	Moderate	2(5.4)
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
神経系障害		
小発作てんかん	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
振戦	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
健忘	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
複雑部分発作	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
神経系障害		
大発作痙攣	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
感覚鈍麻	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
意識消失	Any	1(2.7)
	Mild	0
	Moderate	1(2.7)
	Severe	0
ミオクローヌス性てんかん	Any	1(2.7)
	Mild	0
	Moderate	1(2.7)
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
精神障害	Any	4(10.8)
	Mild	4(10.8)
	Moderate	0
	Severe	1(2.7)
心因性発作	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
不安	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
身体表現性障害	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
精神障害		
自殺企図	Any	1(2.7)
	Mild	0
	Moderate	0
	Severe	1(2.7)
早朝覚醒型不眠症	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
生殖系および乳房障害	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
月経困難症	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
呼吸器、胸郭および縦隔障害	Any	8(21.6)
	Mild	8(21.6)
	Moderate	0
	Severe	0
口腔咽頭痛	Any	3(8.1)
	Mild	3(8.1)
	Moderate	0
	Severe	0
咳嗽	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
鼻出血	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
呼吸器、胸郭および縦隔障害		
過換気	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
鼻乾燥	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
皮膚および皮下組織障害	Any	8(21.6)
	Mild	8(21.6)
	Moderate	0
	Severe	0
皮膚炎	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1 Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
皮膚および皮下組織障害		
湿疹	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
蕁麻疹	Any	2(5.4)
	Mild	2(5.4)
	Moderate	0
	Severe	0
ざ瘡	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
脱毛症	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

表 2.1-17　日本人集団の重症度別の有害事象：SS（続き）

Table 10.3.1
Incidence of TEAEs by Intensity
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Intensity	All Subjects N=37 n (%)
皮膚および皮下組織障害		
嵌入爪	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
血管障害	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0
起立性低血圧	Any	1(2.7)
	Mild	1(2.7)
	Moderate	0
	Severe	0

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the intensity for all TEAEs within that System Organ Class or Preferred Term.
Note: An AE with missing intensity is treated as severe.

Reference: Listing 7.2

2.1.3.2.1.3 治験薬との因果関係が否定できない有害事象

本治験の治験薬投与開始後に認められた治験薬との因果関係別の有害事象を表 2.1-18（全集団）及び表 2.1-19（日本人集団）に示した。

全集団では、治験薬投与開始後に治験薬との因果関係が否定できない有害事象が 83 例（34.7%）に認められた。最も多く認められた治験薬との因果関係が否定できない有害事象（SOC）は神経系障害（22.6%）で、次いで胃腸障害（7.1%）、一般・全身障害および投与部位の状態（5.0%）であった。また、最も多く認められた治験薬との因果関係が否定できない有害事象（PT）は浮動性めまい（10.9%）で、次いで傾眠（5.9%）並びに回転性めまい及び悪心（各 3.8%）であった。

日本人集団では、治験薬投与開始後に治験薬との因果関係が否定できない有害事象が 12 例（32.4%）に認められた。治験薬との因果関係が否定できない有害事象は、神経系障害（27.0%）、胃腸障害（10.8%）及び耳および迷路障害（8.1%）の SOC で認められた。また、最も多く認められた治験薬との因果関係が否定できない有害事象（PT）は傾眠（18.9%）で、次いで浮動性めまい（13.5%）、悪心（10.8%）及び回転性めまい（8.1%）であった。

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
Any TEAE	Any	197	(82.4)	[1097]
	Related	83	(34.7)	[196]
	Not Related	183	(76.6)	[901]
血液およびリンパ系障害	Any	12	(5.0)	[22]
	Related	4	(1.7)	[11]
	Not Related	10	(4.2)	[11]
白血球減少症	Any	3	(1.3)	[6]
	Related	2	(0.8)	[4]
	Not Related	2	(0.8)	[2]
貧血	Any	3	(1.3)	[4]
	Related	0		
	Not Related	3	(1.3)	[4]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
血液およびリンパ系障害				
鉄欠乏性貧血	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
好中球減少症	Any	2	(0.8)	[4]
	Related	2	(0.8)	[4]
	Not Related	0		
血小板減少症	Any	1	(0.4)	[2]
	Related	1	(0.4)	[2]
	Not Related	0		
白血球増加症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
血液およびリンパ系障害				
リンパ節症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
リンパ球減少症	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
心臓障害	Any	7	(2.9)	[9]
	Related	2	(0.8)	[2]
	Not Related	5	(2.1)	[7]
洞性頻脈	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
心臓障害				
動悸	Any	2	(0.8)	[2]
	Related	1	(0.4)	[1]
	Not Related	1	(0.4)	[1]
徐脈	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
第一度房室ブロック	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
右脚ブロック	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
耳および迷路障害	Any	17	(7.1)	[27]
	Related	9	(3.8)	[9]
	Not Related	10	(4.2)	[18]
回転性めまい	Any	16	(6.7)	[25]
	Related	9	(3.8)	[9]
	Not Related	8	(3.3)	[16]
耳痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
乗物酔い	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
内分泌障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
甲状腺機能低下症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
眼障害	Any	17	(7.1)	[27]
	Related	10	(4.2)	[14]
	Not Related	8	(3.3)	[13]
複視	Any	8	(3.3)	[11]
	Related	6	(2.5)	[9]
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
眼障害				
霧視	Any	5	(2.1)	[6]
	Related	3	(1.3)	[3]
	Not Related	3	(1.3)	[3]
視力障害	Any	4	(1.7)	[4]
	Related	2	(0.8)	[2]
	Not Related	2	(0.8)	[2]
視神経乳頭浮腫	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
眼乾燥	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
眼障害				
眼瞼湿疹	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
変視症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
斜視	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
胃腸障害	Any	53	(22.2)	[101]
	Related	17	(7.1)	[28]
	Not Related	43	(18.0)	[73]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
胃腸障害				
悪心	Any	17	(7.1)	[23]
	Related	9	(3.8)	[11]
	Not Related	9	(3.8)	[12]
嘔吐	Any	17	(7.1)	[23]
	Related	6	(2.5)	[10]
	Not Related	12	(5.0)	[13]
下痢	Any	14	(5.9)	[16]
	Related	1	(0.4)	[1]
	Not Related	13	(5.4)	[15]
腹痛	Any	3	(1.3)	[4]
	Related	0		
	Not Related	3	(1.3)	[4]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
胃腸障害				
口の感覚鈍麻	Any	3	(1.3)	[3]
	Related	2	(0.8)	[2]
	Not Related	1	(0.4)	[1]
嚥下痛	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
腹部不快感	Any	2	(0.8)	[2]
	Related	2	(0.8)	[2]
	Not Related	0		
下腹部痛	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
胃腸障害				
上腹部痛	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
便秘	Any	2	(0.8)	[2]
	Related	1	(0.4)	[1]
	Not Related	1	(0.4)	[1]
齲歯	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
口内乾燥	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
胃腸障害				
胃炎	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
過敏性腸症候群	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
口内炎	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
口の錯感覚	Any	1	(0.4)	[2]
	Related	1	(0.4)	[1]
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
胃腸障害				
口唇炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
セリアック病	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
胃食道逆流性疾患	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
痔核	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
胃腸障害				
歯周病	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
小腸穿孔	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
埋伏歯	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
歯の脱落	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
胃腸障害				
歯痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
一般・全身障害および投与部位の状態	Any	36	(15.1)	[47]
	Related	12	(5.0)	[13]
	Not Related	25	(10.5)	[34]
発熱	Any	9	(3.8)	[9]
	Related	0		
	Not Related	9	(3.8)	[9]
疲労	Any	7	(2.9)	[9]
	Related	3	(1.3)	[3]
	Not Related	4	(1.7)	[6]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
一般・全身障害および投与部位の状態				
易刺激性	Any	6	(2.5)	[7]
	Related	5	(2.1)	[6]
	Not Related	1	(0.4)	[1]
非心臓性胸痛	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
局所腫脹	Any	2	(0.8)	[4]
	Related	0		
	Not Related	2	(0.8)	[4]
無力症	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
一般・全身障害および投与部位の状態				
歩行障害	Any	2	(0.8)	[2]
	Related	2	(0.8)	[2]
	Not Related	0		
末梢性浮腫	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
胸痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
悪寒	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
一般・全身障害および投与部位の状態				
低体温	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
炎症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
インフルエンザ様疾患	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
倦怠感	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
一般・全身障害および投与部位の状態				
粘膜びらん	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
疼痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
評価不能の事象	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
肝胆道系障害	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
肝胆道系障害				
脂肪肝	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
免疫系障害	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
薬物過敏症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
季節性アレルギー	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症	Any	104	(43.5)	[207]
	Related	1	(0.4)	[3]
	Not Related	103	(43.1)	[204]
鼻咽頭炎	Any	47	(19.7)	[69]
	Related	0		
	Not Related	47	(19.7)	[69]
インフルエンザ	Any	17	(7.1)	[20]
	Related	1	(0.4)	[1]
	Not Related	16	(6.7)	[19]
上気道感染	Any	14	(5.9)	[15]
	Related	0		
	Not Related	14	(5.9)	[15]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
胃腸炎	Any	8	(3.3)	[10]
	Related	0		
	Not Related	8	(3.3)	[10]
尿路感染	Any	7	(2.9)	[9]
	Related	1	(0.4)	[1]
	Not Related	6	(2.5)	[8]
咽頭炎	Any	7	(2.9)	[7]
	Related	0		
	Not Related	7	(2.9)	[7]
ウイルス性気道感染	Any	5	(2.1)	[5]
	Related	0		
	Not Related	5	(2.1)	[5]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
扁桃炎	Any	4	(1.7)	[4]
	Related	0		
	Not Related	4	(1.7)	[4]
気管支炎	Any	3	(1.3)	[5]
	Related	0		
	Not Related	3	(1.3)	[5]
急性扁桃炎	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
膀胱炎	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
肺炎	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
鼻炎	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
耳感染	Any	2	(0.8)	[4]
	Related	0		
	Not Related	2	(0.8)	[4]
気道感染	Any	2	(0.8)	[4]
	Related	0		
	Not Related	2	(0.8)	[4]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
咽頭扁桃炎	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
歯肉炎	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
皮下組織膿瘍	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
歯感染	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
ウイルス性上気道感染	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
四肢膿瘍	Any	1	(0.4)	[3]
	Related	0		
	Not Related	1	(0.4)	[3]
毛巣嚢胞	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
カンジダ感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
蜂巣炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
大腸菌性尿路感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
ウイルス性胃炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
消化管感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
蜂窩織炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
帯状疱疹	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
麦粒腫	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
腎感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
大葉性肺炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
ライム病	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
口腔カンジダ症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
口腔ヘルペス	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
外耳炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
中耳炎	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
乳頭腫ウイルス感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
歯冠周囲炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
歯周炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
副鼻腔炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
皮膚細菌感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
細菌性扁桃炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
気管炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
気管気管支炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
腟感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
ウイルス感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
感染症および寄生虫症				
外陰腟真菌感染	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
外陰部腟炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
傷害、中毒および処置合併症	Any	66	(27.6)	[125]
	Related	5	(2.1)	[5]
	Not Related	63	(26.4)	[120]
挫傷	Any	16	(6.7)	[21]
	Related	1	(0.4)	[1]
	Not Related	15	(6.3)	[20]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
頭部損傷	Any	10	(4.2)	[13]
	Related	1	(0.4)	[1]
	Not Related	9	(3.8)	[12]
裂傷	Any	8	(3.3)	[9]
	Related	0		
	Not Related	8	(3.3)	[9]
歯牙破折	Any	6	(2.5)	[6]
	Related	0		
	Not Related	6	(2.5)	[6]
擦過傷	Any	5	(2.1)	[10]
	Related	0		
	Not Related	5	(2.1)	[10]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
転倒	Any	4	(1.7)	[6]
	Related	0		
	Not Related	4	(1.7)	[6]
靭帯捻挫	Any	4	(1.7)	[5]
	Related	0		
	Not Related	4	(1.7)	[5]
顔面損傷	Any	3	(1.3)	[3]
	Related	1	(0.4)	[1]
	Not Related	2	(0.8)	[2]
顔面骨骨折	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
手骨折	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
鎖骨骨折	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
足骨折	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
節足動物咬傷	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
脳振盪	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
関節損傷	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
肋骨骨折	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
交通事故	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
皮下血腫	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
舌損傷	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
各種物質毒性	Any	2	(0.8)	[2]
	Related	1	(0.4)	[1]
	Not Related	1	(0.4)	[1]
腓骨骨折	Any	1	(0.4)	[3]
	Related	0		
	Not Related	1	(0.4)	[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
上腕骨骨折	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
アルコール中毒	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
動物咬傷	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
節足動物刺傷	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
背部損傷	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
第２度熱傷	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
骨折	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
損傷	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
関節脱臼	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
下肢骨折	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
肉離れ	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
過量投与	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
処置による疼痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
刺創	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
硬膜下血腫	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
サンバーン	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
傷害、中毒および処置合併症				
熱傷	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
外傷性頭蓋内出血	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
創傷	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
手首関節骨折	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
臨床検査	Any	31	(13.0)	[44]
	Related	5	(2.1)	[6]
	Not Related	27	(11.3)	[38]
ｙ－グルタミルトランスフェラーゼ増加	Any	6	(2.5)	[11]
	Related	1	(0.4)	[1]
	Not Related	5	(2.1)	[10]
アラニンアミノトランスフェラーゼ増加	Any	5	(2.1)	[6]
	Related	1	(0.4)	[1]
	Not Related	4	(1.7)	[5]
体重減少	Any	5	(2.1)	[5]
	Related	0		
	Not Related	5	(2.1)	[5]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
臨床検査				
体重増加	Any	4	(1.7)	[4]
	Related	2	(0.8)	[2]
	Not Related	2	(0.8)	[2]
血圧上昇	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
白血球数増加	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
アスパラギン酸アミノトランスフェラーゼ増加	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
臨床検査				
血中アルカリホスファターゼ増加	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
血中クレアチンホスホキナーゼ増加	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
血中ブドウ糖増加	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
拡張期血圧上昇	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
臨床検査				
血中尿酸増加	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
薬物濃度増加	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
心電図ＰＲ延長	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
尿中蛋白陽性	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
臨床検査				
サイロキシン減少	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
トリヨードチロニン減少	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
遊離トリヨードチロニン減少	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
代謝および栄養障害	Any	15	(6.3)	[21]
	Related	2	(0.8)	[2]
	Not Related	13	(5.4)	[19]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
代謝および栄養障害				
糖尿病	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
ビタミンD欠乏	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
脱水	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
鉄欠乏	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
代謝および栄養障害				
高尿酸血症	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
食欲減退	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
脂質異常症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
高アンモニア血症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
代謝および栄養障害				
高血糖	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
高トリグリセリド血症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
低カリウム血症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
低ナトリウム血症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
代謝および栄養障害				
過体重	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
ビタミンA欠乏	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
筋骨格系および結合組織障害	Any	32	(13.4)	[37]
	Related	1	(0.4)	[1]
	Not Related	31	(13.0)	[36]
背部痛	Any	13	(5.4)	[14]
	Related	0		
	Not Related	13	(5.4)	[14]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
筋骨格系および結合組織障害				
関節痛	Any	6	(2.5)	[7]
	Related	0		
	Not Related	6	(2.5)	[7]
筋骨格痛	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
筋肉痛	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
四肢痛	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
筋骨格系および結合組織障害				
側腹部痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
関節腫脹	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
混合性結合組織病	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
筋肉疲労	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
筋骨格系および結合組織障害				
頚部痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
顎痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
脊柱変形	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
脊椎障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
筋骨格系および結合組織障害				
滑液嚢腫	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
腱鞘炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	Any	5	(2.1)	[6]
	Related	0		
	Not Related	5	(2.1)	[6]
乳腺線維腺腫	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）				
膀胱癌	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
甲状腺新生物	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
子宮平滑筋腫	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
神経系障害	Any	121	(50.6)	[288]
	Related	54	(22.6)	[88]
	Not Related	99	(41.4)	[200]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
頭痛	Any	44	(18.4)	[74]
	Related	6	(2.5)	[6]
	Not Related	40	(16.7)	[68]
浮動性めまい	Any	35	(14.6)	[50]
	Related	26	(10.9)	[35]
	Not Related	14	(5.9)	[15]
傾眠	Any	25	(10.5)	[33]
	Related	14	(5.9)	[16]
	Not Related	13	(5.4)	[17]
大発作痙攣	Any	17	(7.1)	[18]
	Related	2	(0.8)	[2]
	Not Related	15	(6.3)	[16]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
片頭痛	Any	10	(4.2)	[14]
	Related	0		
	Not Related	10	(4.2)	[14]
小発作てんかん	Any	7	(2.9)	[11]
	Related	2	(0.8)	[2]
	Not Related	5	(2.1)	[9]
錯感覚	Any	7	(2.9)	[9]
	Related	3	(1.3)	[4]
	Not Related	5	(2.1)	[5]
振戦	Any	7	(2.9)	[8]
	Related	2	(0.8)	[2]
	Not Related	5	(2.1)	[6]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
平衡障害	Any	5	(2.1)	[7]
	Related	4	(1.7)	[6]
	Not Related	1	(0.4)	[1]
ミオクローヌス性てんかん	Any	5	(2.1)	[5]
	Related	1	(0.4)	[1]
	Not Related	4	(1.7)	[4]
てんかん重積状態	Any	4	(1.7)	[10]
	Related	1	(0.4)	[2]
	Not Related	3	(1.3)	[8]
健忘	Any	4	(1.7)	[4]
	Related	1	(0.4)	[1]
	Not Related	3	(1.3)	[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
感覚鈍麻	Any	3	(1.3)	[4]
	Related	1	(0.4)	[1]
	Not Related	2	(0.8)	[3]
失語症	Any	3	(1.3)	[3]
	Related	1	(0.4)	[1]
	Not Related	2	(0.8)	[2]
ミオクローヌス	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]
痙攣	Any	2	(0.8)	[4]
	Related	0		
	Not Related	2	(0.8)	[4]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
運動失調	Any	2	(0.8)	[2]
	Related	1	(0.4)	[1]
	Not Related	1	(0.4)	[1]
注意力障害	Any	2	(0.8)	[2]
	Related	2	(0.8)	[2]
	Not Related	0		
発作後頭痛	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
緊張性頭痛	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
咬舌	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
構語障害	Any	1	(0.4)	[2]
	Related	1	(0.4)	[2]
	Not Related	0		
脱力発作	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
自律神経失調	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
良性頭蓋内圧亢進	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
頚髄神経根障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
認知障害	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
複雑部分発作	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
協調運動異常	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
味覚異常	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
統合運動障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
てんかん	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
反射亢進	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
反射減弱	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
嗜眠	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
意識消失	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
記憶障害	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
二次性全般化を伴う部分発作	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
姿勢時振戦	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
失神	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
神経系障害				
強直性痙攣	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
精神障害	Any	29	(12.1)	[38]
	Related	5	(2.1)	[8]
	Not Related	25	(10.5)	[30]
うつ病	Any	6	(2.5)	[6]
	Related	1	(0.4)	[1]
	Not Related	5	(2.1)	[5]
不眠症	Any	5	(2.1)	[5]
	Related	0		
	Not Related	5	(2.1)	[5]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
精神障害				
心因性発作	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
攻撃性	Any	2	(0.8)	[2]
	Related	2	(0.8)	[2]
	Not Related	0		
不安	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
失見当識	Any	2	(0.8)	[2]
	Related	1	(0.4)	[1]
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
精神障害				
抑うつ気分	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
学習障害	Any	1	(0.4)	[2]
	Related	1	(0.4)	[2]
	Not Related	0		
精神緩慢	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
妄想	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
精神障害				
初期不眠症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
大うつ病	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
精神状態変化	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
パニック発作	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
精神障害				
心的外傷後ストレス障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
精神運動制止遅滞	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		
睡眠時驚愕	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
身体表現性障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
精神障害				
ストレス	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
自殺念慮	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
自殺企図	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
早朝覚醒型不眠症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
腎および尿路障害	Any	4	(1.7)	[5]
	Related	0		
	Not Related	4	(1.7)	[5]
排尿困難	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
遺尿	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
糖尿	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
腎および尿路障害				
腎仙痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
腎不全	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
生殖系および乳房障害	Any	15	(6.3)	[25]
	Related	1	(0.4)	[3]
	Not Related	15	(6.3)	[22]
月経困難症	Any	7	(2.9)	[13]
	Related	0		
	Not Related	7	(2.9)	[13]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
生殖系および乳房障害				
月経過多	Any	2	(0.8)	[4]
	Related	1	(0.4)	[3]
	Not Related	1	(0.4)	[1]
無月経	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
子宮内膜症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
不規則月経	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
生殖系および乳房障害				
卵巣嚢胞	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
多嚢胞性卵巣	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
前立腺腫大	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
性機能不全	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
生殖系および乳房障害				
子宮出血	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
呼吸器、胸郭および縦隔障害	Any	22	(9.2)	[31]
	Related	0		
	Not Related	22	(9.2)	[31]
口腔咽頭痛	Any	7	(2.9)	[7]
	Related	0		
	Not Related	7	(2.9)	[7]
咳嗽	Any	5	(2.1)	[5]
	Related	0		
	Not Related	5	(2.1)	[5]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
呼吸器、胸郭および縦隔障害				
呼吸障害	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
鼻出血	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
過換気	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
誤嚥性肺炎	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
呼吸器、胸郭および縦隔障害				
喀血	Any	1	(0.4)	[2]
	Related	0		
	Not Related	1	(0.4)	[2]
急性呼吸不全	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
喘息	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
労作性呼吸困難	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
呼吸器、胸郭および縦隔障害				
鼻乾燥	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
呼吸時疼痛	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
湿性咳嗽	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
鼻漏	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
呼吸器、胸郭および縦隔障害				
いびき	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
皮膚および皮下組織障害	Any	16	(6.7)	[19]
	Related	2	(0.8)	[3]
	Not Related	14	(5.9)	[16]
脱毛症	Any	3	(1.3)	[3]
	Related	2	(0.8)	[2]
	Not Related	1	(0.4)	[1]
嵌入爪	Any	3	(1.3)	[3]
	Related	0		
	Not Related	3	(1.3)	[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
皮膚および皮下組織障害				
皮膚炎	Any	2	(0.8)	[3]
	Related	0		
	Not Related	2	(0.8)	[3]
湿疹	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
蕁麻疹	Any	2	(0.8)	[2]
	Related	0		
	Not Related	2	(0.8)	[2]
ざ瘡	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
皮膚および皮下組織障害				
皮膚乾燥	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
紅斑	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
逆むけ	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
爪破損	Any	1	(0.4)	[1]
	Related	1	(0.4)	[1]
	Not Related	0		

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
皮膚および皮下組織障害				
そう痒症	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
血管障害	Any	10	(4.2)	[13]
	Related	0		
	Not Related	10	(4.2)	[13]
高血圧	Any	4	(1.7)	[4]
	Related	0		
	Not Related	4	(1.7)	[4]
血腫	Any	1	(0.4)	[3]
	Related	0		
	Not Related	1	(0.4)	[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
血管障害				
毛細血管障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
低血圧	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
起立性低血圧	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
末梢性虚血	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-18　全集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4
Incidence of TEAEs by Relationship
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class / Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=239 n	(%)	[#]
血管障害				
末梢血管障害	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]
血管炎	Any	1	(0.4)	[1]
	Related	0		
	Not Related	1	(0.4)	[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
Any TEAE	Any	36(97.3)[245]
	Related	12(32.4)[27]
	Not Related	35(94.6)[218]
血液およびリンパ系障害	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
貧血	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
心臓障害	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
心臓障害		
徐脈	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
耳および迷路障害	Any	4(10.8)[11]
	Related	3(8.1)[3]
	Not Related	1(2.7)[8]
回転性めまい	Any	4(10.8)[11]
	Related	3(8.1)[3]
	Not Related	1(2.7)[8]
眼障害	Any	3(8.1)[3]
	Related	0
	Not Related	3(8.1)[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
眼障害		
眼乾燥	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
眼瞼湿疹	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
霧視	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
胃腸障害	Any	13(35.1)[24]
	Related	4(10.8)[5]
	Not Related	10(27.0)[19]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
胃腸障害		
悪心	Any	7(18.9)[9]
	Related	4(10.8)[4]
	Not Related	3(8.1)[5]
下痢	Any	3(8.1)[3]
	Related	0
	Not Related	3(8.1)[3]
齲歯	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
口内炎	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
胃腸障害		
嘔吐	Any	2(5.4)[2]
	Related	1(2.7)[1]
	Not Related	1(2.7)[1]
腹痛	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
下腹部痛	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
口唇炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
胃腸障害		
便秘	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
歯周病	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
埋伏歯	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
一般・全身障害および投与部位の状態	Any	9(24.3)[12]
	Related	0
	Not Related	9(24.3)[12]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
一般・全身障害および投与部位の状態		
発熱	Any	5(13.5)[5]
	Related	0
	Not Related	5(13.5)[5]
末梢性浮腫	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
悪寒	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
疲労	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
一般・全身障害および投与部位の状態		
炎症	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
疲労	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
粘膜びらん	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
免疫系障害	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
免疫系障害		
季節性アレルギー	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
感染症および寄生虫症	Any	26(70.3)[61]
	Related	0
	Not Related	26(70.3)[61]
鼻咽頭炎	Any	19(51.4)[37]
	Related	0
	Not Related	19(51.4)[37]
インフルエンザ	Any	9(24.3)[10]
	Related	0
	Not Related	9(24.3)[10]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
感染症および寄生虫症		
膀胱炎	Any	3(8.1)[3]
	Related	0
	Not Related	3(8.1)[3]
咽頭炎	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
胃腸炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
歯肉炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
感染症および寄生虫症		
帯状疱疹	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
麦粒腫	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
外耳炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
歯冠周囲炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
感染症および寄生虫症		
肺炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
皮膚細菌感染	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
扁桃炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
傷害、中毒および処置合併症	Any	18(48.6)[30]
	Related	0
	Not Related	18(48.6)[30]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
傷害、中毒および処置合併症		
挫傷	Any	8(21.6)[11]
	Related	0
	Not Related	8(21.6)[11]
擦過傷	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
頭部損傷	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
皮下血腫	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
傷害、中毒および処置合併症		
歯牙破折	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
靭帯捻挫	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
動物咬傷	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
節足動物咬傷	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
傷害、中毒および処置合併症		
顔面損傷	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
裂傷	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
下肢骨折	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
肋骨骨折	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
傷害、中毒および処置合併症		
熱傷	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
各種物質毒性	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
創傷	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
臨床検査	Any	6(16.2)[7]
	Related	0
	Not Related	6(16.2)[7]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
臨床検査		
γ－グルタミルトランスフェラーゼ増加	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
白血球数増加	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
アラニンアミノトランスフェラーゼ増加	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
尿中蛋白陽性	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
臨床検査		
体重増加	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
代謝および栄養障害	Any	3(8.1)[4]
	Related	0
	Not Related	3(8.1)[4]
高尿酸血症	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
高アンモニア血症	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
代謝および栄養障害		
高トリグリセリド血症	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
筋骨格系および結合組織障害	Any	8(21.6)[9]
	Related	0
	Not Related	8(21.6)[9]
背部痛	Any	4(10.8)[4]
	Related	0
	Not Related	4(10.8)[4]
関節痛	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

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表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
筋骨格系および結合組織障害		
関節腫脹	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
筋肉痛	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
滑液嚢腫	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
腱鞘炎	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
神経系障害	Any	20(54.1)[48]
	Related	10(27.0)[19]
	Not Related	16(43.2)[29]
傾眠	Any	10(27.0)[15]
	Related	7(18.9)[8]
	Not Related	5(13.5)[7]
頭痛	Any	7(18.9)[12]
	Related	0
	Not Related	7(18.9)[12]
浮動性めまい	Any	6(16.2)[11]
	Related	5(13.5)[9]
	Not Related	2(5.4)[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
神経系障害		
小発作てんかん	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
振戦	Any	1(2.7)[2]
	Related	0
	Not Related	1(2.7)[2]
健忘	Any	1(2.7)[1]
	Related	1(2.7)[1]
	Not Related	0
複雑部分発作	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

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表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
神経系障害		
大発作痙攣	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
感覚鈍麻	Any	1(2.7)[1]
	Related	1(2.7)[1]
	Not Related	0
意識消失	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
ミオクローヌス性てんかん	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
精神障害	Any	4(10.8)[7]
	Related	0
	Not Related	4(10.8)[7]
心因性発作	Any	2(5.4)[3]
	Related	0
	Not Related	2(5.4)[3]
不安	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
身体表現性障害	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
精神障害		
自殺企図	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
早朝覚醒型不眠症	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
生殖系および乳房障害	Any	2(5.4)[3]
	Related	0
	Not Related	2(5.4)[3]
月経困難症	Any	2(5.4)[3]
	Related	0
	Not Related	2(5.4)[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
呼吸器、胸郭および縦隔障害	Any	8(21.6)[10]
	Related	0
	Not Related	8(21.6)[10]
口腔咽頭痛	Any	3(8.1)[3]
	Related	0
	Not Related	3(8.1)[3]
咳嗽	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
鼻出血	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

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表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
呼吸器、胸郭および縦隔障害		
過換気	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
鼻乾燥	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
皮膚および皮下組織障害	Any	8(21.6)[10]
	Related	0
	Not Related	8(21.6)[10]
皮膚炎	Any	2(5.4)[3]
	Related	0
	Not Related	2(5.4)[3]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

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表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
皮膚および皮下組織障害		
湿疹	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
蕁麻疹	Any	2(5.4)[2]
	Related	0
	Not Related	2(5.4)[2]
ざ瘡	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
脱毛症	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

表 2.1-19　日本人集団の治験薬との因果関係別の有害事象：SS（続き）

Table 10.4.1
Incidence of TEAEs by Relationship
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	Relationship to Study Drug per Investigator	All Subjects N=37 n (%) [#]
皮膚および皮下組織障害		
嵌入爪	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
血管障害	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]
起立性低血圧	Any	1(2.7)[1]
	Related	0
	Not Related	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.
Note: Each subject is counted once within each System Organ Class and Preferred Term according to the relationship for all TEAEs within that System Organ Class or Preferred Term. An AE with missing drug relationship is treated as related.

Reference: Listing 7.2

2.1.3.2.1.4 死亡

本治験では、死亡は認められなかった。

2.1.3.2.1.5 重篤な有害事象

本治験の治験薬投与開始後に認められた重篤な有害事象を年齢グループ別に表 2.1-20（全集団）及び表 2.1-21（日本人集団）に示した。また、重篤な有害事象の詳細を本まとめ（その他の重篤な有害事象）及び EP0012 試験第 2 回中間報告書（5.3.5.2.4）12 項に示した。

全集団では、治験薬投与開始後に重篤な有害事象が 38 例（15.9%）に 65 件認められた。重篤な有害事象の発現率は、本治験の被験者集団の年齢グループ別及び治験薬の投与量において予想された結果であった。

65 歳未満の被験者で多く認められた重篤な有害事象（SOC）は神経系障害で、年齢グループ別では 4 歳以上 12 歳未満が 2 例（12.5%）、12 歳以上 18 歳未満が 6 例（16.7%）及び 18 歳以上 65 歳未満が 16 例（8.6%）であった。本治験では 65 歳以上の被験者は 1 例であったが、重篤な有害事象は認められなかった。神経系障害の SOC のうち、多く認められた PT は大発作痙攣（12 歳以上 18 歳未満：8.3%、18 歳以上 65 歳未満：4.8%）、てんかん重積状態（4 歳以上 12 歳未満：6.3%、12 歳以上 18 歳未満：2.8%、18 歳以上 65 歳未満：1.1%）であった。

日本人集団では、治験薬投与開始後に重篤な有害事象が 2 例（5.4%）に 3 件（各種物質毒性、大発作痙攣及び自殺企図）認められた。いずれの事象も治験薬との因果関係は「関連なし」と評価された。これらの事象発現時の治験薬投与量は、400 mg/日以上 600 mg/日未満であった。大発作痙攣は 12 歳以上 18 歳未満、各種物質毒性及び自殺企図は 18 歳以上 65 歳未満の年齢グループで発現した。

表 2.1-20　全集団の重篤な有害事象：SS

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
Any serious TEAE	38(15.9)[65]
胃腸障害	4(1.7)[6]
嘔吐	2(0.8)[2]
腹痛	1(0.4)[1]
下腹部痛	1(0.4)[1]
セリアック病	1(0.4)[1]
小腸穿孔	1(0.4)[1]
一般・全身障害および投与部位の状態	1(0.4)[1]
非心臓性胸痛	1(0.4)[1]
感染症および寄生虫症	3(1.3)[3]
大腸菌性尿路感染	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
感染症および寄生虫症	
尿路感染	1(0.4)[1]
ウイルス性上気道感染	1(0.4)[1]
傷害、中毒および処置合併症	11(4.6)[15]
頭部損傷	2(0.8)[4]
顔面骨骨折	2(0.8)[2]
鎖骨骨折	1(0.4)[1]
顔面損傷	1(0.4)[1]
腓骨骨折	1(0.4)[1]
骨折	1(0.4)[1]
手骨折	1(0.4)[1]
刺創	1(0.4)[1]
硬膜下血腫	1(0.4)[1]
各種物質毒性	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
傷害、中毒および処置合併症	
外傷性頭蓋内出血	1(0.4)[1]
臨床検査	1(0.4)[2]
薬物濃度増加	1(0.4)[1]
体重減少	1(0.4)[1]
代謝および栄養障害	2(0.8)[2]
脱水	1(0.4)[1]
糖尿病	1(0.4)[1]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1(0.4)[2]
膀胱癌	1(0.4)[2]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
神経系障害	24(10.0)[28]
大発作痙攣	12(5.0)[13]
てんかん重積状態	4(1.7)[7]
良性頭蓋内圧亢進	1(0.4)[1]
痙攣	1(0.4)[1]
浮動性めまい	1(0.4)[1]
てんかん	1(0.4)[1]
片頭痛	1(0.4)[1]
ミオクローヌス性てんかん	1(0.4)[1]
小発作てんかん	1(0.4)[1]
強直性痙攣	1(0.4)[1]
精神障害	2(0.8)[2]
精神状態変化	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
精神障害	
自殺企図	1(0.4)[1]
呼吸器、胸郭および縦隔障害	2(0.8)[3]
誤嚥性肺炎	2(0.8)[2]
急性呼吸不全	1(0.4)[1]
血管障害	1(0.4)[1]
末梢性虚血	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=4 to <12 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=16 n (%) [#]
Any serious TEAE	2(12.5)[5]
神経系障害	2(12.5)[5]
てんかん重積状態	1(6.3)[4]
強直性痙攣	1(6.3)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=12 to <18 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=36 n (%) [#]
Any serious TEAE	8(22.2)[12]
胃腸障害	2(5.6)[3]
嘔吐	2(5.6)[2]
下腹部痛	1(2.8)[1]
一般・全身障害および投与部位の状態	1(2.8)[1]
非心臓性胸痛	1(2.8)[1]
感染症および寄生虫症	2(5.6)[2]
尿路感染	1(2.8)[1]
ウイルス性上気道感染	1(2.8)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=12 to <18 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=36 n (%) [#]
神経系障害	6(16.7)[6]
大発作痙攣	3(8.3)[3]
痙攣	1(2.8)[1]
浮動性めまい	1(2.8)[1]
てんかん重積状態	1(2.8)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=186 n (%) [#]
Any serious TEAE	28(15.1)[48]
胃腸障害	2(1.1)[3]
腹痛	1(0.5)[1]
セリアック病	1(0.5)[1]
小腸穿孔	1(0.5)[1]
感染症および寄生虫症	1(0.5)[1]
大腸菌性尿路感染	1(0.5)[1]
傷害、中毒および処置合併症	11(5.9)[15]
頭部損傷	2(1.1)[4]
顔面骨骨折	2(1.1)[2]
鎖骨骨折	1(0.5)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=186 n (%) [#]
傷害、中毒および処置合併症	
顔面損傷	1(0.5)[1]
腓骨骨折	1(0.5)[1]
骨折	1(0.5)[1]
手骨折	1(0.5)[1]
刺創	1(0.5)[1]
硬膜下血腫	1(0.5)[1]
各種物質毒性	1(0.5)[1]
外傷性頭蓋内出血	1(0.5)[1]
臨床検査	1(0.5)[2]
薬物濃度増加	1(0.5)[1]
体重減少	1(0.5)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=186 n (%) [#]
代謝および栄養障害	2(1.1)[2]
脱水	1(0.5)[1]
糖尿病	1(0.5)[1]
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1(0.5)[2]
膀胱癌	1(0.5)[2]
神経系障害	16(8.6)[17]
大発作痙攣	9(4.8)[10]
てんかん重積状態	2(1.1)[2]
良性頭蓋内圧亢進	1(0.5)[1]
てんかん	1(0.5)[1]
片頭痛	1(0.5)[1]
ミオクローヌス性てんかん	1(0.5)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=186 n (%) [#]
神経系障害	
小発作てんかん	1(0.5)[1]
精神障害	2(1.1)[2]
精神状態変化	1(0.5)[1]
自殺企図	1(0.5)[1]
呼吸器、胸郭および縦隔障害	2(1.1)[3]
誤嚥性肺炎	2(1.1)[2]
急性呼吸不全	1(0.5)[1]
血管障害	1(0.5)[1]
末梢性虚血	1(0.5)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-20　全集団の重篤な有害事象：SS（続き）

Table 10.5.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=1 n (%) [#]

There are no AEs that meet this criteria.

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-21　日本人集団の重篤な有害事象：SS

Table 10.5.1.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=37 n (%) [#]
Any serious TEAE	2(5.4)[3]
傷害、中毒および処置合併症	1(2.7)[1]
各種物質毒性	1(2.7)[1]
神経系障害	1(2.7)[1]
大発作痙攣	1(2.7)[1]
精神障害	1(2.7)[1]
自殺企図	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-21　日本人集団の重篤な有害事象：SS（続き）

Table 10.5.1.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=4 to <12 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=2 n (%) [#]

There are no AEs that meet this criteria.

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-21　日本人集団の重篤な有害事象：SS（続き）

Table 10.5.1.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=12 to <18 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=9 n (%) [#]
Any serious TEAE	1(11.1)[1]
神経系障害	1(11.1)[1]
大発作痙攣	1(11.1)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-21　日本人集団の重篤な有害事象：SS（続き）

Table 10.5.1.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=26 n (%) [#]
Any serious TEAE	1(3.8)[2]
傷害、中毒および処置合併症	1(3.8)[1]
各種物質毒性	1(3.8)[1]
精神障害	1(3.8)[1]
自殺企図	1(3.8)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

表 2.1-21　日本人集団の重篤な有害事象：SS（続き）

Table 10.5.1.1
Incidence of Serious TEAEs by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=0 n (%) [#]

There are no AEs that meet this criteria.

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one serious TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the serious TEAE.

Reference: Listing 7.3

2.1.3.2.1.6 治験薬の投与中止に至った有害事象

本治験で認められた治験薬の投与中止に至った有害事象を年齢グループ別に表 2.1-22（全集団）及び表 2.1-23（日本人集団）に示した。

全集団では、治験薬の投与中止に至った有害事象が 10 例（4.2%）に 18 件認められた。18 件のうち、8 件は治験薬との因果関係が「関連なし」と評価された。最も多く認められた治験薬の投与中止に至った有害事象（PT）は、健忘及びミオクローヌス性てんかん（各 2 例、0.8%）であった。その他の治験薬の投与中止に至った有害事象は、いずれも 1 例ずつ発現した。

日本人集団では、治験薬の投与中止に至った有害事象が 1 例（2.7%）に 2 件（各種物質毒性及び自殺企図）認められた。

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
Any TEAE	10(4.2)[18]
眼障害	2(0.8)[2]
複視	1(0.4)[1]
霧視	1(0.4)[1]
一般・全身障害および投与部位の状態	2(0.8)[2]
歩行障害	1(0.4)[1]
易刺激性	1(0.4)[1]
傷害、中毒および処置合併症	1(0.4)[1]
各種物質毒性	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
神経系障害	6(2.5)[10]
健忘	2(0.8)[2]
ミオクローヌス性てんかん	2(0.8)[2]
失語症	1(0.4)[1]
平衡障害	1(0.4)[1]
痙攣	1(0.4)[1]
浮動性めまい	1(0.4)[1]
頭痛	1(0.4)[1]
てんかん重積状態	1(0.4)[1]
精神障害	2(0.8)[2]
うつ病	1(0.4)[1]
自殺企図	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
生殖系および乳房障害	1(0.4)[1]
子宮出血	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=4 to <12 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=16 n (%) [#]

There are no AEs that meet this criteria.

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=12 to <18 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=36 n (%) [#]
Any TEAE	2(5.6)[2]
神経系障害	2(5.6)[2]
痙攣	1(2.8)[1]
てんかん重積状態	1(2.8)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=186 n (%) [#]
Any TEAE	7(3.8)[15]
眼障害	2(1.1)[2]
複視	1(0.5)[1]
霧視	1(0.5)[1]
一般・全身障害および投与部位の状態	2(1.1)[2]
歩行障害	1(0.5)[1]
易刺激性	1(0.5)[1]
傷害、中毒および処置合併症	1(0.5)[1]
各種物質毒性	1(0.5)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=186 n (%) [#]
神経系障害	3(1.6)[7]
ミオクローヌス性てんかん	2(1.1)[2]
健忘	1(0.5)[1]
失語症	1(0.5)[1]
平衡障害	1(0.5)[1]
浮動性めまい	1(0.5)[1]
頭痛	1(0.5)[1]
精神障害	2(1.1)[2]
うつ病	1(0.5)[1]
自殺企図	1(0.5)[1]
生殖系および乳房障害	1(0.5)[1]
子宮出血	1(0.5)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-22　全集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set

Baseline Age in SP0982: >=65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=1 n (%) [#]
Any TEAE	1(100)[1]
神経系障害	1(100)[1]
健忘	1(100)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-23　日本人集団の治験薬の投与中止に至った有害事象：SS

Table 10.6.1.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: All Subjects

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=37 n (%) [#]
Any TEAE	1(2.7)[2]
傷害、中毒および処置合併症	1(2.7)[1]
各種物質毒性	1(2.7)[1]
精神障害	1(2.7)[1]
自殺企図	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-23　日本人集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=4 to <12 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=2 n (%) [#]

There are no AEs that meet this criteria.

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-23　日本人集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=12 to <18 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=9 n (%) [#]

There are no AEs that meet this criteria.

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-23　日本人集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=18 to <65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=26 n (%) [#]
Any TEAE	1(3.8)[2]
傷害、中毒および処置合併症	1(3.8)[1]
各種物質毒性	1(3.8)[1]
精神障害	1(3.8)[1]
自殺企図	1(3.8)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

表 2.1-23　日本人集団の治験薬の投与中止に至った有害事象：SS（続き）

Table 10.6.1.1
Incidence of TEAEs Leading to Discontinuation by Baseline Age in SP0982
Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=65 years

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=0 n (%) [#]

There are no AEs that meet this criteria.

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one TEAE leading to discontinuation of study drug within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.4

2.1.3.2.1.7 その他の注目すべき有害事象

本治験の治験薬投与開始後に認められたその他の注目すべき有害事象を表 2.1-24（全集団）及び表 2.1-25（日本人集団）に示した。

本治験では、治験薬投与開始後に認められた有害事象のうち、その他の注目すべき有害事象として、心臓障害関連、自殺関連、並びに失神、意識消失、食欲障害、食欲減退、拒食、過小食、食物嫌悪及び異常行動の有害事象の有無を確認した。

本治験では、徐脈、意識消失、失神、自殺念慮及び自殺企図が各 1 例に認められた。このうち、徐脈（2 件）、自殺企図及び意識消失は日本人での発現であった。また、治験薬投与開始前に洞性徐脈が 2 例（このうち、日本人 1 例）に認められた。

本治験では、薬物性肝障害に関する有害事象の発現は少なかった（8 例、10 件）。10 件中 9 件は治験薬投与開始後に認められ、このうちアラニンアミノトランスフェラーゼ増加 1 件は、治験薬との因果関係が否定できないと判断された。

表 2.1-24　全集団のその他の注目すべき有害事象：SS

Table 10.7
Incidence of Other Significant TEAEs
Analysis Set: Safety Set

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=239 n (%) [#]
Any Other Significant TEAE	5(2.1)[6]
心臓障害	1(0.4)[2]
徐脈	1(0.4)[2]
神経系障害	2(0.8)[2]
意識消失	1(0.4)[1]
失神	1(0.4)[1]
精神障害	2(0.8)[2]
自殺念慮	1(0.4)[1]
自殺企図	1(0.4)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one other significant TEAE within System Organ Class/ Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.2

表 2.1-25　日本人集団のその他の注目すべき有害事象：SS

Table 10.7.1
Incidence of Other Significant TEAEs
Analysis Set: Safety Set - Japanese

MedDRA v16.1 System Organ Class Preferred Term	All Subjects N=37 n (%) [#]
Any Other Significant TEAE	3(8.1)[4]
心臓障害	1(2.7)[2]
徐脈	1(2.7)[2]
神経系障害	1(2.7)[1]
意識消失	1(2.7)[1]
精神障害	1(2.7)[1]
自殺企図	1(2.7)[1]

MedDRA=Medical Dictionary for Regulatory Activities, TEAE=Treatment-Emergent Adverse Event.
Note: n=number of subjects reporting at least one other significant TEAE within System Organ Class/Preferred Term.
Note: Percentages are based on the number of subjects in the Safety Set.
Note: [#] is the number of individual occurrences of the TEAE.

Reference: Listing 7.2

2.1.3.2.1.8 発作に関連する有害事象

全集団では、発作に関連する有害事象（PT）として大発作痙攣が 17 例（7.1%）、小発作てんかんが 7 例（2.9%）、うつ病が 6 例（2.5%）、ミオクローヌス性てんかんが 5 例（2.1%）及びてんかん重積状態が 4 例（1.7%）に認められた。

日本人集団では、発作に関連する有害事象（PT）として大発作痙攣、ミオクローヌス性てんかん及び小発作てんかんが各 1 例（2.7%）に認められた。

2.1.3.2.1.9 治療期間における欠神発作及びミオクロニー発作発現日数が増加した被験者の割合

全集団では、Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作及びミオクロニー発作発現日数が増加した被験者の割合は低く、50%増悪した被験者は、それぞれ 1 例（1.1%）及び 4 例（4.3%）であった。

日本人集団では、Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作及びミオクロニー発作発現日数が 50%増悪した被験者はいなかった。

2.1.3.2.1.10 治療期間中に新たな発作型を発現した被験者の割合

Combined ベースライン期間と比較して本治験の治療期間中に新たな発作型を発現した被験者の割合を表 2.1-26（全集団）及び表 2.1-27（日本人集団）に示した。また、発作歴又は Combined ベースライン期間と比較して本治験の治療期間中に新たな発作型を発現した被験者の割合を表 2.1-28（全集団）及び表 2.1-29（日本人集団）に示した。

全集団では、治療期間中に欠神発作及びミオクロニー発作を発現した被験者は、それぞれ 50 例（20.9%）及び 48 例（20.1%）であった。また、発作歴又は Combined ベースライン期間に欠神発作及びミオクロニー発作を発現せず、治療期間中に新たな欠神発作及びミオクロニー発作を発現した被験者は、それぞれ 3 例（1.3%）及び 4 例（1.7%）であった。なお、発作歴又は Combined ベースライン期間に欠神発作及びミオクロニー発作を発現せず、治療期間中も欠神発作及びミオクロニー発作を発現しなかった被験者は、それぞれ 147 例（61.5%）及び 145 例（60.7%）であった。

日本人集団では、Combined ベースライン期間、又は Combined ベースライン期間及び治療期間中に欠神発作及びミオクロニー発作を発現した被験者は、それぞれ 2 例（5.4%）及び 7 例（18.9%）であった。また、発作歴又は Combined ベースライン期間に欠神発作を発現せず、治療期間中に新たな欠神発作を発現した被験者は 1 例（2.7%）で、新たなミオクロニー発作を発現した被験者はいなかった。

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
All subjects				
Partial onset seizures				
Simple partial (IA)	Yes	1(0.4)	0	1(0.4)
	No	1(0.4)	237(99.2)	238(99.6)
	Total	2(0.8)	237(99.2)	239(100)
Complex partial (IB)	Yes	0	0	0
	No	2(0.8)	237(99.2)	239(100)
	Total	2(0.8)	237(99.2)	239(100)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	239(100)	239(100)
	Total	0	239(100)	239(100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
All subjects				
Generalized seizures				
Absence (IIA)	Yes	34(14.2)	9(3.8)	43(18.0)
	No	16(6.7)	180(75.3)	196(82.0)
	Total	50(20.9)	189(79.1)	239(100)
Myoclonic (IIB)	Yes	33(13.8)	10(4.2)	43(18.0)
	No	15(6.3)	181(75.7)	196(82.0)
	Total	48(20.1)	191(79.9)	239(100)
Clonic (IIC)	Yes	1(0.4)	2(0.8)	3(1.3)
	No	1(0.4)	235(98.3)	236(98.7)
	Total	2(0.8)	237(99.2)	239(100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
All subjects				
Generalized seizures				
Tonic (IID)	Yes	1(0.4)	1(0.4)	2(0.8)
	No	0	237(99.2)	237(99.2)
	Total	1(0.4)	238(99.6)	239(100)
Tonic-clonic (IIE)	Yes	167(69.9)	71(29.7)	238(99.6)
	No	0	1(0.4)	1(0.4)
	Total	167(69.9)	72(30.1)	239(100)
Atonic (IIF)	Yes	2(0.8)	0	2(0.8)
	No	0	237(99.2)	237(99.2)
	Total	2(0.8)	237(99.2)	239(100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
All subjects				
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	2(0.8)	237(99.2)	239(100)
	Total	2(0.8)	237(99.2)	239(100)
Continuing LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	1(0.4)	0	1(0.4)
	No	0	96(40.2)	96(40.2)
	Total	1(0.4)	96(40.2)	97(40.6)
Complex partial (IB)	Yes	0	0	0
	No	1(0.4)	96(40.2)	97(40.6)
	Total	1(0.4)	96(40.2)	97(40.6)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Partial onset seizures				
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	97(40.6)	97(40.6)
	Total	0	97(40.6)	97(40.6)
Absence (IIA)	Yes	13(5.4)	3(1.3)	16(6.7)
	No	3(1.3)	78(32.6)	81(33.9)
	Total	16(6.7)	81(33.9)	97(40.6)
Myoclonic (IIB)	Yes	14(5.9)	5(2.1)	19(7.9)
	No	6(2.5)	72(30.1)	78(32.6)
	Total	20(8.4)	77(32.2)	97(40.6)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Clonic (IIC)	Yes	0	2(0.8)	2(0.8)
	No	0	95(39.7)	95(39.7)
	Total	0	97(40.6)	97(40.6)
Tonic (IID)	Yes	0	0	0
	No	0	97(40.6)	97(40.6)
	Total	0	97(40.6)	97(40.6)
Tonic-clonic (IIE)	Yes	72(30.1)	24(10.0)	96(40.2)
	No	0	1(0.4)	1(0.4)
	Total	72(30.1)	25(10.5)	97(40.6)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Atonic (IIF)	Yes	1(0.4)	0	1(0.4)
	No	0	96(40.2)	96(40.2)
	Total	1(0.4)	96(40.2)	97(40.6)
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	2(0.8)	95(39.7)	97(40.6)
	Total	2(0.8)	95(39.7)	97(40.6)
New LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	1(0.4)	141(59.0)	142(59.4)
	Total	1(0.4)	141(59.0)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Partial onset seizures				
Complex partial (IB)	Yes	0	0	0
	No	1(0.4)	141(59.0)	142(59.4)
	Total	1(0.4)	141(59.0)	142(59.4)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	142(59.4)	142(59.4)
	Total	0	142(59.4)	142(59.4)
Absence (IIA)	Yes	21(8.8)	6(2.5)	27(11.3)
	No	13(5.4)	102(42.7)	115(48.1)
	Total	34(14.2)	108(45.2)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Generalized seizures				
Myoclonic (IIB)	Yes	19(7.9)	5(2.1)	24(10.0)
	No	9(3.8)	109(45.6)	118(49.4)
	Total	28(11.7)	114(47.7)	142(59.4)
Clonic (IIC)	Yes	1(0.4)	0	1(0.4)
	No	1(0.4)	140(58.6)	141(59.0)
	Total	2(0.8)	140(58.6)	142(59.4)
Tonic (IID)	Yes	1(0.4)	1(0.4)	2(0.8)
	No	0	140(58.6)	140(58.6)
	Total	1(0.4)	141(59.0)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-26　全集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Generalized seizures				
Tonic-clonic (IIE)	Yes	95(39.7)	47(19.7)	142(59.4)
	No	0	0	0
	Total	95(39.7)	47(19.7)	142(59.4)
Atonic (IIF)	Yes	1(0.4)	0	1(0.4)
	No	0	141(59.0)	141(59.0)
	Total	1(0.4)	141(59.0)	142(59.4)
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	142(59.4)	142(59.4)
	Total	0	142(59.4)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
All subjects				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)
Complex partial (IB)	Yes	0	0	0
	No	1 (2.7)	36 (97.3)	37 (100)
	Total	1 (2.7)	36 (97.3)	37 (100)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
All subjects				
Generalized seizures				
Absence (IIA)	Yes	2 (5.4)	0	2 (5.4)
	No	3 (8.1)	32 (86.5)	35 (94.6)
	Total	5 (13.5)	32 (86.5)	37 (100)
Myoclonic (IIB)	Yes	6 (16.2)	1 (2.7)	7 (18.9)
	No	1 (2.7)	29 (78.4)	30 (81.1)
	Total	7 (18.9)	30 (81.1)	37 (100)
Clonic (IIC)	Yes	0	1 (2.7)	1 (2.7)
	No	0	36 (97.3)	36 (97.3)
	Total	0	37 (100)	37 (100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

		Present During Treatment Period		
	Present During Combined Baseline	All Subjects N=37		
		Yes	No	Total
Seizure Type		n (%)	n (%)	n (%)
All subjects				
Generalized seizures				
Tonic (IID)	Yes	1 (2.7)	0	1 (2.7)
	No	0	36 (97.3)	36 (97.3)
	Total	1 (2.7)	36 (97.3)	37 (100)
Tonic-clonic (IIE)	Yes	30 (81.1)	7 (18.9)	37 (100)
	No	0	0	0
	Total	30 (81.1)	7 (18.9)	37 (100)
Atonic (IIF)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
All subjects				
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)
Continuing LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Complex partial (IB)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Partial onset seizures				
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Generalized seizures				
Absence (IIA)	Yes	0	0	0
	No	1 (2.7)	10 (27.0)	11 (29.7)
	Total	1 (2.7)	10 (27.0)	11 (29.7)
Myoclonic (IIB)	Yes	2 (5.4)	0	2 (5.4)
	No	1 (2.7)	8 (21.6)	9 (24.3)
	Total	3 (8.1)	8 (21.6)	11 (29.7)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 — Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Clonic (IIC)	Yes	0	1 (2.7)	1 (2.7)
	No	0	10 (27.0)	10 (27.0)
	Total	0	11 (29.7)	11 (29.7)
Tonic (IID)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Tonic-clonic (IIE)	Yes	8 (21.6)	3 (8.1)	11 (29.7)
	No	0	0	0
	Total	8 (21.6)	3 (8.1)	11 (29.7)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Atonic (IIF)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
New LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Partial onset seizures				
Complex partial (IB)	Yes	0	0	0
	No	1 (2.7)	25 (67.6)	26 (70.3)
	Total	1 (2.7)	25 (67.6)	26 (70.3)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)
Generalized seizures				
Absence (IIA)	Yes	2 (5.4)	0	2 (5.4)
	No	2 (5.4)	22 (59.5)	24 (64.9)
	Total	4 (10.8)	22 (59.5)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Generalized seizures				
Myoclonic (IIB)	Yes	4 (10.8)	1 (2.7)	5 (13.5)
	No	0	21 (56.8)	21 (56.8)
	Total	4 (10.8)	22 (59.5)	26 (70.3)
Clonic (IIC)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)
Tonic (IID)	Yes	1 (2.7)	0	1 (2.7)
	No	0	25 (67.6)	25 (67.6)
	Total	1 (2.7)	25 (67.6)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-27　日本人集団の Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.1.1
Incidence of New Seizure Types During Treatment Period
Analysis Set: Safety Set - Japanese

Seizure Type	Present During Combined Baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Generalized seizures				
Tonic-clonic (IIE)	Yes	22 (59.5)	4 (10.8)	26 (70.3)
	No	0	0	0
	Total	22 (59.5)	4 (10.8)	26 (70.3)
Atonic (IIF)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

Seizure Type	Present in History or Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
All subjects				
Partial onset seizures				
Simple partial (IA)	Yes	1(0.4)	0	1(0.4)
	No	1(0.4)	237(99.2)	238(99.6)
	Total	2(0.8)	237(99.2)	239(100)
Complex partial (IB)	Yes	0	0	0
	No	2(0.8)	237(99.2)	239(100)
	Total	2(0.8)	237(99.2)	239(100)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	239(100)	239(100)
	Total	0	239(100)	239(100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

		Present During Treatment Period		
		All Subjects N=239		
Seizure Type	Present in History or Combined Baseline	Yes n (%)	No n (%)	Total n (%)
All subjects				
Generalized seizures				
Absence (IIA)	Yes	47(19.7)	42(17.6)	89(37.2)
	No	3(1.3)	147(61.5)	150(62.8)
	Total	50(20.9)	189(79.1)	239(100)
Myoclonic (IIB)	Yes	44(18.4)	46(19.2)	90(37.7)
	No	4(1.7)	145(60.7)	149(62.3)
	Total	48(20.1)	191(79.9)	239(100)
Clonic (IIC)	Yes	1(0.4)	4(1.7)	5(2.1)
	No	1(0.4)	233(97.5)	234(97.9)
	Total	2(0.8)	237(99.2)	239(100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

		Present During Treatment Period		
		All Subjects N=239		
Seizure Type	Present in History or Combined Baseline	Yes n (%)	No n (%)	Total n (%)
All subjects				
Generalized seizures				
Tonic (IID)	Yes	1(0.4)	4(1.7)	5(2.1)
	No	0	234(97.9)	234(97.9)
	Total	1(0.4)	238(99.6)	239(100)
Tonic-clonic (IIE)	Yes	167(69.9)	71(29.7)	238(99.6)
	No	0	1(0.4)	1(0.4)
	Total	167(69.9)	72(30.1)	239(100)
Atonic (IIF)	Yes	2(0.8)	3(1.3)	5(2.1)
	No	0	234(97.9)	234(97.9)
	Total	2(0.8)	237(99.2)	239(100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

Seizure Type	Present in History or Combined Baseline	Present During Treatment Period All Subjects N=239 Yes n (%)	 No n (%)	 Total n (%)
All subjects				
Unclassified epileptic seizures (III)	Yes	1(0.4)	1(0.4)	2(0.8)
	No	1(0.4)	236(98.7)	237(99.2)
	Total	2(0.8)	237(99.2)	239(100)
Continuing LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	1(0.4)	0	1(0.4)
	No	0	96(40.2)	96(40.2)
	Total	1(0.4)	96(40.2)	97(40.6)
Complex partial (IB)	Yes	0	0	0
	No	1(0.4)	96(40.2)	97(40.6)
	Total	1(0.4)	96(40.2)	97(40.6)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

Seizure Type	Present in History or Combined Baseline	Present During Treatment Period All Subjects N=239 Yes n (%)	 No n (%)	 Total n (%)
Continuing LCM Treatment				
Partial onset seizures				
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	97(40.6)	97(40.6)
	Total	0	97(40.6)	97(40.6)
Absence (IIA)	Yes	14(5.9)	22(9.2)	36(15.1)
	No	2(0.8)	59(24.7)	61(25.5)
	Total	16(6.7)	81(33.9)	97(40.6)
Myoclonic (IIB)	Yes	17(7.1)	20(8.4)	37(15.5)
	No	3(1.3)	57(23.8)	60(25.1)
	Total	20(8.4)	77(32.2)	97(40.6)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

Seizure Type	Present in History or Combined Baseline	Present During Treatment Period: All Subjects N=239 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Clonic (IIC)	Yes	0	3(1.3)	3(1.3)
	No	0	94(39.3)	94(39.3)
	Total	0	97(40.6)	97(40.6)
Tonic (IID)	Yes	0	2(0.8)	2(0.8)
	No	0	95(39.7)	95(39.7)
	Total	0	97(40.6)	97(40.6)
Tonic-clonic (IIE)	Yes	72(30.1)	24(10.0)	96(40.2)
	No	0	1(0.4)	1(0.4)
	Total	72(30.1)	25(10.5)	97(40.6)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

Seizure Type	Present in History or Combined Baseline	Present During Treatment Period All Subjects N=239 Yes n (%)	 No n (%)	 Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Atonic (IIF)	Yes	1(0.4)	1(0.4)	2(0.8)
	No	0	95(39.7)	95(39.7)
	Total	1(0.4)	96(40.2)	97(40.6)
Unclassified epileptic seizures (III)	Yes	1(0.4)	1(0.4)	2(0.8)
	No	1(0.4)	94(39.3)	95(39.7)
	Total	2(0.8)	95(39.7)	97(40.6)
New LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	1(0.4)	141(59.0)	142(59.4)
	Total	1(0.4)	141(59.0)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

		Present During Treatment Period		
		All Subjects N=239		
Seizure Type	Present in History or Combined Baseline	Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Partial onset seizures				
Complex partial (IB)	Yes	0	0	0
	No	1(0.4)	141(59.0)	142(59.4)
	Total	1(0.4)	141(59.0)	142(59.4)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	142(59.4)	142(59.4)
	Total	0	142(59.4)	142(59.4)
Absence (IIA)	Yes	33(13.8)	20(8.4)	53(22.2)
	No	1(0.4)	88(36.8)	89(37.2)
	Total	34(14.2)	108(45.2)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

Seizure Type	Present in History or Combined Baseline	Present During Treatment Period All Subjects N=239 Yes n (%)	 No n (%)	 Total n (%)
New LCM Treatment				
Generalized seizures				
Myoclonic (IIB)	Yes	27(11.3)	26(10.9)	53(22.2)
	No	1(0.4)	88(36.8)	89(37.2)
	Total	28(11.7)	114(47.7)	142(59.4)
Clonic (IIC)	Yes	1(0.4)	1(0.4)	2(0.8)
	No	1(0.4)	139(58.2)	140(58.6)
	Total	2(0.8)	140(58.6)	142(59.4)
Tonic (IID)	Yes	1(0.4)	2(0.8)	3(1.3)
	No	0	139(58.2)	139(58.2)
	Total	1(0.4)	141(59.0)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-28　全集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2
Incidence of New Seizure Types During Treatment Period As compared to Seizure History
Analysis Set: Safety Set

		Present During Treatment Period		
		All Subjects N=239		
Seizure Type	Present in History or Combined Baseline	Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Generalized seizures				
Tonic-clonic (IIE)	Yes	95(39.7)	47(19.7)	142(59.4)
	No	0	0	0
	Total	95(39.7)	47(19.7)	142(59.4)
Atonic (IIF)	Yes	1(0.4)	2(0.8)	3(1.3)
	No	0	139(58.2)	139(58.2)
	Total	1(0.4)	141(59.0)	142(59.4)
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	142(59.4)	142(59.4)
	Total	0	142(59.4)	142(59.4)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

		Present During Treatment Period		
	Present in history or combined baseline	All Subjects N=37		
		Yes	No	Total
Seizure Type		n (%)	n (%)	n (%)
All subjects				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)
Complex partial (IB)	Yes	0	0	0
	No	1 (2.7)	36 (97.3)	37 (100)
	Total	1 (2.7)	36 (97.3)	37 (100)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
All subjects				
Generalized seizures				
Absence (IIA)	Yes	4 (10.8)	4 (10.8)	8 (21.6)
	No	1 (2.7)	28 (75.7)	29 (78.4)
	Total	5 (13.5)	32 (86.5)	37 (100)
Myoclonic (IIB)	Yes	7 (18.9)	9 (24.3)	16 (43.2)
	No	0	21 (56.8)	21 (56.8)
	Total	7 (18.9)	30 (81.1)	37 (100)
Clonic (IIC)	Yes	0	1 (2.7)	1 (2.7)
	No	0	36 (97.3)	36 (97.3)
	Total	0	37 (100)	37 (100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period All Subjects N=37 Yes n (%)	 No n (%)	 Total n (%)
All subjects				
Generalized seizures				
Tonic (IID)	Yes	1 (2.7)	0	1 (2.7)
	No	0	36 (97.3)	36 (97.3)
	Total	1 (2.7)	36 (97.3)	37 (100)
Tonic-clonic (IIE)	Yes	30 (81.1)	7 (18.9)	37 (100)
	No	0	0	0
	Total	30 (81.1)	7 (18.9)	37 (100)
Atonic (IIF)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
All subjects				
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	37 (100)	37 (100)
	Total	0	37 (100)	37 (100)
Continuing LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Complex partial (IB)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Partial onset seizures				
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Generalized seizures				
Absence (IIA)	Yes	0	3 (8.1)	3 (8.1)
	No	1 (2.7)	7 (18.9)	8 (21.6)
	Total	1 (2.7)	10 (27.0)	11 (29.7)
Myoclonic (IIB)	Yes	3 (8.1)	2 (5.4)	5 (13.5)
	No	0	6 (16.2)	6 (16.2)
	Total	3 (8.1)	8 (21.6)	11 (29.7)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Clonic (IIC)	Yes	0	1 (2.7)	1 (2.7)
	No	0	10 (27.0)	10 (27.0)
	Total	0	11 (29.7)	11 (29.7)
Tonic (IID)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Tonic-clonic (IIE)	Yes	8 (21.6)	3 (8.1)	11 (29.7)
	No	0	0	0
	Total	8 (21.6)	3 (8.1)	11 (29.7)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
Continuing LCM Treatment				
Generalized seizures				
Atonic (IIF)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	11 (29.7)	11 (29.7)
	Total	0	11 (29.7)	11 (29.7)
New LCM Treatment				
Partial onset seizures				
Simple partial (IA)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Partial onset seizures				
Complex partial (IB)	Yes	0	0	0
	No	1 (2.7)	25 (67.6)	26 (70.3)
	Total	1 (2.7)	25 (67.6)	26 (70.3)
Partial evolving to secondarily generalized (IC)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)
Generalized seizures				
Absence (IIA)	Yes	4 (10.8)	1 (2.7)	5 (13.5)
	No	0	21 (56.8)	21 (56.8)
	Total	4 (10.8)	22 (59.5)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Generalized seizures				
Myoclonic (IIB)	Yes	4 (10.8)	7 (18.9)	11 (29.7)
	No	0	15 (40.5)	15 (40.5)
	Total	4 (10.8)	22 (59.5)	26 (70.3)
Clonic (IIC)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)
Tonic (IID)	Yes	1 (2.7)	0	1 (2.7)
	No	0	25 (67.6)	25 (67.6)
	Total	1 (2.7)	25 (67.6)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

表 2.1-29　日本人集団の発作歴又は Combined ベースライン期間と比較して治療期間中に新たな発作型を発現した被験者の割合：SS（続き）

Table 8.3.2.1
Incidence of New Seizure Types During Treatment Period As Compared to Seizure History
Analysis Set: Safety Set - Japanese

Seizure Type	Present in history or combined baseline	Present During Treatment Period: All Subjects N=37 Yes n (%)	No n (%)	Total n (%)
New LCM Treatment				
Generalized seizures				
Tonic-clonic (IIE)	Yes	22 (59.5)	4 (10.8)	26 (70.3)
	No	0	0	0
	Total	22 (59.5)	4 (10.8)	26 (70.3)
Atonic (IIF)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)
Unclassified epileptic seizures (III)	Yes	0	0	0
	No	0	26 (70.3)	26 (70.3)
	Total	0	26 (70.3)	26 (70.3)

Note: n=number of subjects reporting at least one new seizure in that type.
Note: Percentages are based on the number of subjects in the Safety Set.

Reference: Listing 6.1

2.1.3.3 副次評価項目

2.1.3.3.1 臨床検査、バイタルサイン（体重及び身長を含む）、12 誘導心電図及び身体所見（神経学的検査を含む）

本治験でのベースライン及び各来院時の測定値、並びにベースラインからの変化量について、血液学的検査を表 2.1-30（全集団）及び表 2.1-31（日本人集団）に、血液生化学検査を表 2.1-32（全集団）及び表 2.1-33（日本人集団）に示した。また、バイタルサイン（体重及び身長を含む）のベースライン及び各来院時の測定値、並びにベースラインからの変化量を表 2.1-34（全集団）及び表 2.1-35（日本人集団）に示した。

全体的に、臨床検査のベースラインからの変化量（平均値又は中央値）にラコサミド投与に起因すると考えられる臨床的又は一貫した結果は認められなかった。血液学的検査及び血液生化学検査では、全体的にベースラインからベースライン後の最大値に悪化傾向が認められた被験者の割合は5%以下で低かった。全体的に、治験薬投与開始後の顕著な異常値、及び米国国立がん研究所-共通毒性規準のグレード 2 以上の血液学的検査値及び血液生化学検査値に該当する被験者は少なかった。

全体的に、バイタルサインの平均値は、ベースライン及びベースライン後のすべての測定時において予想できる範囲であった。最終来院時に 10%以上の体重増加／減少及び 7%以上の体重増加／減少を認めた被験者が、17 歳以上の年齢グループでそれぞれ 208 例中 35 例（16.8%）及び 208 例中 60 例（28.8%）認められたが、その他の治験薬投与開始後の顕著な異常値が認められた被験者の割合は、いずれの年齢グループでも最終来院時には全体的に低かった（10.0%以下）。

12 誘導心電図は、すべての測定時においてベースラインからの変化量（平均値及び中央値）が小さかった。最終来院時に治験薬投与開始後の顕著な異常値が認められた被験者の割合は、17 歳以上の年齢グループで QRS 間隔の 100 msec 超が 25.0%、3 歳から 12 歳未満の年齢グループで PR 間隔のベースラインから 25%超延長が 18.2%、12 歳以上 17 歳未満の年齢グループで QTcB の 450 msec 超が 10.5%であったが、その他の治験薬投与開始後の顕著な異常値が認められた被験者の割合は、いずれの年齢グループでも最終来院時には全体的に低かった（10%未満）。

神経学的検査は、ほとんどの被験者でベースラインから最終来院時まで安定した結果であった。1 例で、ベースラインで正常であったが最終来院時に臨床的に顕著な異常値が認められ、当該被験者は治験を中止した。

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hemoglobin (g/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	139.2	14.3	139.0	92	173						
V1, Wk 0	27	138.2	14.9	141.0	92	163	27	0.0	5.2	1.0	-13	9
V2, Wk 2	229	138.7	14.4	140.0	88	170	229	-0.6	6.5	0.0	-27	20
V5, Wk 22	200	139.9	13.9	139.0	105	176	200	0.7	7.6	0.5	-19	41
V8, Wk 46	169	139.8	14.1	140.0	104	172	169	1.3	8.3	2.0	-29	40
V9, Wk 62	145	139.8	14.4	140.0	104	173	145	1.9	9.1	2.0	-30	38
V10, Wk 78	62	137.6	14.4	138.0	92	169	62	1.8	11.2	1.0	-42	48
V11, Wk 94	107	140.9	15.0	140.0	102	183	107	2.0	10.2	2.0	-31	45
V12, Wk 118	80	139.8	15.6	140.0	106	170	80	1.0	10.9	2.0	-39	26
V14, Wk 166	21	139.4	15.2	137.0	108	168	21	2.7	8.9	1.0	-13	28

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hemoglobin (g/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	45	140.0	13.7	139.0	108	168	45	0.6	7.1	1.0	-11	24
Termination Visit	4	153.0	21.5	148.0	133	183	4	8.3	9.1	6.0	0	21
Min Post-BL	237	134.3	14.5	134.0	88	172	237	-4.9	7.7	-4.0	-42	13
Max Post-BL	237	145.2	13.9	144.0	115	183	237	6.0	8.5	5.0	-14	48
Last Visit	237	139.9	14.2	140.0	106	183	237	0.7	9.1	1.0	-39	38

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hematocrit (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	42.74	4.49	42.60	31.1	56.5						
V1, Wk 0	27	42.69	4.13	42.80	33.0	50.5	27	0.41	2.29	0.40	-3.5	4.1
V2, Wk 2	229	42.94	4.73	42.80	31.7	57.5	229	0.15	3.12	0.40	-11.5	8.3
V5, Wk 22	200	43.38	4.63	43.00	33.3	60.0	200	0.52	3.35	0.20	-9.0	15.7
V8, Wk 46	169	43.21	4.52	42.50	32.0	57.5	169	0.63	3.12	0.70	-10.4	10.2
V9, Wk 62	145	43.66	4.97	43.00	33.8	58.2	145	1.23	3.83	1.20	-10.4	10.9
V10, Wk 78	62	42.44	4.43	42.50	30.6	55.0	62	0.87	3.64	0.85	-12.0	13.3
V11, Wk 94	107	43.59	4.56	43.50	36.1	56.2	107	0.94	3.41	0.60	-6.5	11.0
V12, Wk 118	80	44.01	5.24	43.45	32.6	55.0	80	1.48	4.31	1.50	-11.4	12.7
V14, Wk 166	21	45.34	5.47	44.10	37.6	56.6	21	3.19	3.68	2.70	-4.0	12.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Hematocrit (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	45	42.83	4.36	42.60	35.0	52.9	45	0.35	3.11	0.40	-5.9	10.1
Termination Visit	4	47.10	8.43	44.75	39.7	59.2	4	1.62	6.64	0.40	-5.0	10.7
Min Post-BL	237	41.07	4.28	41.00	30.6	53.2	237	-1.69	2.90	-1.40	-12.0	4.9
Max Post-BL	237	45.83	4.79	45.40	35.2	60.0	237	3.07	3.41	2.70	-9.0	15.7
Last Visit	237	43.84	4.84	43.30	32.6	59.2	237	1.08	3.63	1.20	-11.4	12.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Platelets (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	238	247.8	67.1	244.0	79	494						
V1, Wk 0	27	261.3	56.3	256.0	154	397	27	4.2	35.6	16.0	-78	87
V2, Wk 2	227	248.0	59.5	244.0	87	480	226	-1.3	39.5	-2.0	-156	209
V5, Wk 22	197	245.1	58.4	242.0	92	394	196	-2.0	37.2	-1.5	-173	116
V8, Wk 46	167	246.7	60.6	241.0	83	449	166	-1.8	52.1	-1.5	-187	221
V9, Wk 62	142	247.9	63.0	242.5	91	476	141	-2.1	47.8	-2.0	-170	194
V10, Wk 78	62	249.6	65.8	247.5	115	373	62	-5.0	54.1	-10.5	-142	166
V11, Wk 94	106	246.0	60.9	241.0	125	463	106	-4.3	45.0	-8.0	-134	138
V12, Wk 118	79	244.5	58.8	241.0	136	393	79	-3.5	50.3	-9.0	-110	175
V14, Wk 166	21	260.5	60.7	274.0	159	377	21	-0.0	48.2	13.0	-122	97

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Platelets (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	254.0	70.5	255.0	80	396	44	-7.7	39.4	-5.0	-123	76
Termination Visit	4	283.8	74.4	284.5	195	371	4	17.8	17.4	14.5	2	40
Min Post-BL	237	220.6	53.5	217.0	80	381	236	-26.5	39.4	-24.5	-187	96
Max Post-BL	237	275.4	65.7	267.0	92	480	236	28.3	43.8	22.0	-122	221
Last Visit	237	245.9	61.3	242.0	80	476	236	-1.3	47.1	1.5	-170	194

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Erythrocytes (10^12/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	4.633	0.435	4.630	3.74	6.47						
V1, Wk 0	27	4.657	0.355	4.730	3.91	5.54	27	0.046	0.188	0.050	-0.34	0.43
V2, Wk 2	229	4.611	0.435	4.590	3.56	6.04	229	-0.026	0.227	-0.010	-0.75	0.79
V5, Wk 22	200	4.649	0.453	4.635	3.75	6.46	200	0.008	0.246	0.010	-0.68	0.63
V8, Wk 46	169	4.649	0.431	4.650	3.75	5.83	169	0.020	0.264	0.020	-1.14	0.72
V9, Wk 62	145	4.647	0.425	4.630	3.64	5.66	145	0.034	0.283	0.040	-1.11	0.95
V10, Wk 78	62	4.627	0.460	4.665	3.83	5.58	62	0.053	0.305	0.015	-0.65	1.38
V11, Wk 94	107	4.683	0.426	4.660	3.78	6.04	107	0.046	0.316	0.020	-0.58	1.35
V12, Wk 118	80	4.633	0.479	4.650	3.72	5.51	80	-0.008	0.362	0.010	-1.63	0.80
V14, Wk 166	21	4.576	0.527	4.630	3.59	5.65	21	-0.012	0.234	-0.010	-0.50	0.39

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Erythrocytes (10^12/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	45	4.583	0.508	4.510	3.40	5.61	45	0.009	0.232	-0.040	-0.34	0.66
Termination Visit	4	4.880	0.583	4.830	4.22	5.64	4	0.260	0.253	0.230	0.00	0.58
Min Post-BL	237	4.451	0.443	4.450	3.40	6.43	237	-0.183	0.262	-0.170	-1.63	0.47
Max Post-BL	237	4.815	0.462	4.830	3.90	6.46	237	0.181	0.275	0.160	-0.51	1.38
Last Visit	237	4.622	0.466	4.610	3.40	6.46	237	-0.012	0.290	-0.010	-1.63	0.80

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Leukocytes (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	6.69	1.88	6.40	2.9	14.9						
V1, Wk 0	27	6.90	1.87	6.60	4.1	11.0	27	0.53	1.44	0.50	-3.0	3.5
V2, Wk 2	227	6.64	1.85	6.40	3.1	14.4	227	-0.04	1.55	0.00	-6.9	5.6
V5, Wk 22	200	6.80	1.78	6.40	3.5	12.0	200	0.09	1.73	0.15	-8.2	5.5
V8, Wk 46	168	6.68	1.81	6.55	3.3	13.5	168	0.01	1.64	0.00	-6.2	5.7
V9, Wk 62	145	6.64	2.02	6.30	3.0	14.0	145	0.01	1.92	0.00	-9.0	7.2
V10, Wk 78	62	6.69	1.97	6.30	3.2	12.6	62	0.03	1.76	0.15	-5.6	4.4
V11, Wk 94	107	6.45	1.73	6.10	3.7	11.0	107	-0.19	1.45	-0.10	-4.9	3.7
V12, Wk 118	80	6.49	1.99	6.15	3.9	14.2	80	-0.07	1.83	-0.25	-4.1	7.2
V14, Wk 166	21	6.38	1.89	6.00	3.9	12.0	21	0.25	1.11	0.10	-2.0	2.6

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Leukocytes (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	7.18	2.13	7.30	3.4	12.3	44	0.22	1.84	0.30	-4.2	4.5
Termination Visit	4	7.55	1.80	6.90	6.2	10.2	4	1.50	1.43	1.80	-0.5	2.9
Min Post-BL	237	5.67	1.44	5.50	2.4	10.6	237	-1.00	1.46	-0.70	-9.0	2.7
Max Post-BL	237	7.90	2.19	7.60	3.6	14.4	237	1.24	1.79	1.10	-6.2	7.2
Last Visit	237	6.65	1.97	6.20	3.4	14.2	237	-0.02	1.77	-0.10	-9.0	7.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	0.02	0.04	0.00	0.0	0.2						
V1, Wk 0	27	0.02	0.04	0.00	0.0	0.1	27	0.00	0.05	0.00	-0.1	0.1
V2, Wk 2	227	0.02	0.05	0.00	0.0	0.4	227	-0.00	0.05	0.00	-0.2	0.4
V5, Wk 22	199	0.03	0.05	0.00	0.0	0.2	199	0.00	0.05	0.00	-0.1	0.1
V8, Wk 46	167	0.03	0.05	0.00	0.0	0.2	167	0.00	0.05	0.00	-0.1	0.2
V9, Wk 62	145	0.03	0.05	0.00	0.0	0.2	145	-0.00	0.05	0.00	-0.2	0.1
V10, Wk 78	62	0.03	0.05	0.00	0.0	0.1	62	0.00	0.04	0.00	-0.1	0.1
V11, Wk 94	107	0.04	0.05	0.00	0.0	0.2	107	0.01	0.05	0.00	-0.1	0.1
V12, Wk 118	80	0.03	0.04	0.00	0.0	0.1	80	0.00	0.05	0.00	-0.1	0.1
V14, Wk 166	21	0.08	0.08	0.10	0.0	0.3	21	0.03	0.06	0.00	0.0	0.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	0.03	0.05	0.00	0.0	0.1	43	0.00	0.04	0.00	-0.1	0.1
Termination Visit	4	0.10	0.08	0.10	0.0	0.2	4	0.05	0.10	0.00	0.0	0.2
Min Post-BL	237	0.01	0.03	0.00	0.0	0.1	237	-0.02	0.04	0.00	-0.2	0.1
Max Post-BL	237	0.05	0.06	0.00	0.0	0.4	237	0.03	0.06	0.00	-0.1	0.4
Last Visit	237	0.03	0.05	0.00	0.0	0.3	237	0.01	0.05	0.00	-0.1	0.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	0.53	0.37	0.40	0.0	2.0						
V1, Wk 0	27	0.55	0.60	0.40	0.2	3.3	27	0.07	0.47	0.00	-0.6	2.1
V2, Wk 2	227	0.57	0.54	0.40	0.1	5.6	227	0.03	0.50	0.00	-1.4	5.2
V5, Wk 22	199	0.60	0.51	0.50	0.0	3.4	199	0.04	0.41	0.00	-1.0	2.6
V8, Wk 46	167	0.60	0.52	0.40	0.0	4.1	167	0.05	0.46	0.00	-1.1	3.8
V9, Wk 62	145	0.62	0.51	0.50	0.1	3.2	145	0.05	0.46	0.00	-1.3	2.4
V10, Wk 78	62	0.57	0.31	0.50	0.1	1.5	62	-0.03	0.36	0.00	-1.2	0.7
V11, Wk 94	107	0.67	0.58	0.50	0.0	3.7	107	0.10	0.46	0.10	-1.1	2.1
V12, Wk 118	80	0.55	0.40	0.40	0.0	2.0	80	-0.02	0.37	0.00	-1.2	1.0
V14, Wk 166	21	1.23	1.31	0.70	0.2	5.2	21	0.43	1.10	0.20	-0.7	4.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Basophils/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	0.53	0.33	0.50	0.1	1.3	43	0.02	0.30	0.00	-1.1	0.9
Termination Visit	4	1.43	1.24	1.05	0.4	3.2	4	0.70	1.41	0.10	-0.2	2.8
Min Post-BL	237	0.36	0.26	0.30	0.0	2.0	237	-0.17	0.30	-0.10	-1.4	0.8
Max Post-BL	237	0.91	0.84	0.60	0.2	5.6	237	0.38	0.70	0.20	-1.0	5.2
Last Visit	237	0.63	0.64	0.40	0.1	5.2	237	0.10	0.54	0.00	-1.2	4.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	0.18	0.15	0.10	0.0	1.2						
V1, Wk 0	27	0.16	0.06	0.10	0.1	0.3	27	0.01	0.07	0.00	-0.1	0.2
V2, Wk 2	227	0.18	0.16	0.10	0.0	1.6	227	0.00	0.13	0.00	-0.6	0.8
V5, Wk 22	199	0.16	0.15	0.10	0.0	1.2	199	-0.01	0.15	0.00	-0.9	1.0
V8, Wk 46	167	0.16	0.14	0.10	0.0	1.1	167	-0.02	0.14	0.00	-0.8	0.6
V9, Wk 62	145	0.16	0.16	0.10	0.0	1.3	145	-0.01	0.14	0.00	-0.5	0.8
V10, Wk 78	62	0.16	0.17	0.10	0.0	1.2	62	-0.01	0.12	0.00	-0.4	0.4
V11, Wk 94	107	0.16	0.14	0.10	0.0	1.3	107	-0.02	0.11	0.00	-0.4	0.4
V12, Wk 118	80	0.13	0.09	0.10	0.0	0.4	80	-0.02	0.11	0.00	-0.3	0.4
V14, Wk 166	21	0.12	0.07	0.10	0.0	0.2	21	-0.03	0.12	0.00	-0.4	0.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	0.15	0.13	0.10	0.0	0.7	43	0.01	0.14	0.00	-0.3	0.6
Termination Visit	4	0.25	0.06	0.25	0.2	0.3	4	-0.00	0.18	-0.00	-0.2	0.2
Min Post-BL	237	0.11	0.10	0.10	0.0	1.1	237	-0.07	0.11	0.00	-0.9	0.3
Max Post-BL	237	0.23	0.19	0.20	0.0	1.6	237	0.06	0.17	0.00	-0.6	1.0
Last Visit	237	0.15	0.13	0.10	0.0	1.3	237	-0.02	0.13	0.00	-0.8	0.6

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	2.55	2.43	2.00	0.0	26.4						
V1, Wk 0	27	2.21	1.02	2.10	0.7	4.8	27	0.11	0.86	0.00	-2.3	2.1
V2, Wk 2	227	2.60	2.51	1.90	0.0	28.3	227	0.05	1.71	0.00	-8.8	10.1
V5, Wk 22	199	2.40	2.35	1.90	0.1	26.8	199	-0.16	1.92	-0.10	-12.8	9.9
V8, Wk 46	167	2.37	2.41	1.70	0.1	21.9	167	-0.28	2.08	-0.20	-10.7	10.6
V9, Wk 62	145	2.41	2.54	1.90	0.0	25.5	145	-0.17	1.79	-0.20	-7.9	8.6
V10, Wk 78	62	2.48	2.97	1.70	0.1	22.4	62	-0.15	1.78	-0.05	-7.2	4.7
V11, Wk 94	107	2.41	2.62	1.80	0.1	25.1	107	-0.17	1.62	0.00	-7.3	5.1
V12, Wk 118	80	2.14	1.32	2.00	0.1	7.2	80	-0.07	1.62	0.10	-4.6	6.3
V14, Wk 166	21	1.87	0.92	1.80	0.4	3.6	21	-0.67	1.89	-0.20	-7.5	0.9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Eosinophils/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	2.13	1.82	1.60	0.2	10.8	43	0.13	1.87	-0.20	-4.4	9.0
Termination Visit	4	3.15	0.31	3.05	2.9	3.6	4	-0.98	2.35	-0.90	-3.5	1.4
Min Post-BL	237	1.58	1.68	1.30	0.0	21.9	237	-0.96	1.59	-0.60	-12.8	3.5
Max Post-BL	237	3.50	2.75	2.90	0.2	28.3	237	0.96	2.14	0.60	-8.8	10.6
Last Visit	237	2.31	2.13	1.90	0.1	25.3	237	-0.23	1.78	-0.20	-10.7	9.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	2.32	0.72	2.20	1.0	4.9						
V1, Wk 0	27	2.18	0.53	2.20	1.2	2.9	27	0.12	0.50	0.00	-0.8	1.0
V2, Wk 2	227	2.30	0.74	2.20	0.9	5.7	227	0.00	0.53	0.00	-1.8	1.4
V5, Wk 22	199	2.26	0.66	2.10	0.8	4.6	199	-0.06	0.54	0.00	-2.3	1.4
V8, Wk 46	167	2.27	0.65	2.20	0.9	4.0	167	-0.03	0.55	-0.00	-1.9	1.5
V9, Wk 62	145	2.24	0.60	2.10	0.9	4.5	145	-0.06	0.59	0.00	-2.5	2.0
V10, Wk 78	62	2.26	0.88	2.10	1.1	5.7	62	-0.01	0.60	-0.00	-1.6	2.3
V11, Wk 94	107	2.20	0.65	2.10	1.0	4.2	107	-0.08	0.53	-0.10	-1.5	1.5
V12, Wk 118	80	2.08	0.69	1.95	1.0	5.3	80	-0.18	0.59	-0.10	-1.8	1.3
V14, Wk 166	21	2.18	0.62	2.00	1.3	4.1	21	-0.01	0.70	0.20	-2.1	1.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	2.30	0.77	2.20	1.3	4.1	43	-0.07	0.46	-0.00	-1.8	0.8
Termination Visit	4	2.95	0.26	3.00	2.6	3.2	4	0.45	0.68	0.60	-0.5	1.1
Min Post-BL	237	1.93	0.59	1.80	0.8	4.1	237	-0.37	0.53	-0.30	-2.5	1.1
Max Post-BL	237	2.63	0.78	2.50	1.3	5.7	237	0.33	0.50	0.30	-1.0	2.3
Last Visit	237	2.24	0.63	2.20	0.9	4.2	237	-0.06	0.57	-0.00	-2.1	2.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	35.46	9.47	34.70	13.4	74.3						
V1, Wk 0	27	32.54	8.07	30.30	19.8	50.6	27	-0.76	4.23	-1.20	-7.9	12.5
V2, Wk 2	227	35.52	9.53	34.70	14.7	75.4	227	0.18	7.85	-0.20	-29.0	24.8
V5, Wk 22	199	34.21	9.02	33.80	9.1	57.0	199	-1.25	8.40	-1.30	-27.8	33.4
V8, Wk 46	167	34.90	8.60	35.10	16.3	57.4	167	-0.37	7.71	-1.50	-18.4	19.1
V9, Wk 62	145	35.12	8.91	35.00	12.4	53.1	145	-0.38	8.66	-0.70	-39.1	22.8
V10, Wk 78	62	34.26	8.75	35.15	13.4	52.3	62	-0.60	8.15	-0.55	-21.2	18.4
V11, Wk 94	107	34.96	9.14	34.50	14.4	61.4	107	-0.08	8.95	0.30	-28.1	20.5
V12, Wk 118	80	33.40	9.89	33.25	10.3	60.4	80	-1.65	9.45	-0.80	-28.1	15.7
V14, Wk 166	21	34.52	6.75	35.20	21.6	47.8	21	-1.21	8.94	-1.00	-25.5	13.9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Lymphocytes/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	33.28	10.58	31.50	18.9	61.9	43	-2.33	8.24	-2.50	-25.6	16.1
Termination Visit	4	40.10	7.21	41.15	31.2	46.9	4	-1.23	5.72	-3.05	-5.9	7.1
Min Post-BL	237	29.47	9.10	29.40	9.1	59.8	237	-5.94	8.28	-5.30	-39.1	15.0
Max Post-BL	237	40.11	8.74	40.10	20.4	75.4	237	4.70	6.91	3.80	-14.6	33.4
Last Visit	237	34.97	9.44	35.30	10.3	61.9	237	-0.44	8.15	-0.10	-27.7	22.8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	0.55	0.20	0.50	0.0	1.3						
V1, Wk 0	27	0.53	0.18	0.50	0.2	0.9	27	0.02	0.18	0.00	-0.2	0.4
V2, Wk 2	227	0.54	0.20	0.50	0.2	1.6	227	-0.01	0.17	0.00	-0.5	0.6
V5, Wk 22	199	0.54	0.20	0.50	0.0	1.2	199	-0.02	0.22	0.00	-0.9	1.0
V8, Wk 46	167	0.54	0.18	0.50	0.2	1.3	167	-0.02	0.18	0.00	-0.6	0.7
V9, Wk 62	145	0.53	0.20	0.50	0.2	1.4	145	-0.02	0.23	0.00	-0.8	0.8
V10, Wk 78	62	0.51	0.18	0.50	0.2	1.2	62	-0.05	0.21	0.00	-0.9	0.9
V11, Wk 94	107	0.51	0.16	0.50	0.2	0.9	107	-0.04	0.20	0.00	-0.9	0.6
V12, Wk 118	80	0.52	0.17	0.50	0.2	1.0	80	-0.03	0.22	0.00	-0.8	0.7
V14, Wk 166	21	0.43	0.16	0.40	0.2	0.8	21	-0.05	0.17	-0.10	-0.4	0.3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	0.57	0.22	0.60	0.2	1.1	43	0.03	0.19	0.00	-0.4	0.5
Termination Visit	4	0.68	0.24	0.60	0.5	1.0	4	0.20	0.24	0.15	0.0	0.5
Min Post-BL	237	0.43	0.15	0.40	0.0	0.9	237	-0.12	0.18	-0.10	-0.9	0.3
Max Post-BL	237	0.67	0.21	0.60	0.2	1.6	237	0.11	0.20	0.10	-0.5	1.0
Last Visit	237	0.53	0.19	0.50	0.2	1.4	237	-0.02	0.20	0.00	-0.8	0.8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	8.35	2.45	8.00	0.3	18.9						
V1, Wk 0	27	7.70	2.30	7.30	4.8	13.5	27	-0.14	1.69	-0.10	-3.3	4.5
V2, Wk 2	227	8.30	2.44	8.10	2.6	16.5	227	-0.00	2.00	0.00	-4.8	6.3
V5, Wk 22	199	8.02	2.41	7.80	0.2	17.2	199	-0.36	2.41	-0.40	-12.0	11.3
V8, Wk 46	167	8.08	2.12	7.70	3.1	14.3	167	-0.37	2.34	-0.30	-10.3	9.4
V9, Wk 62	145	8.03	2.30	7.80	2.8	17.2	145	-0.31	2.31	-0.20	-7.3	7.5
V10, Wk 78	62	7.73	2.28	7.75	2.9	15.7	62	-0.76	2.40	-0.70	-7.2	7.4
V11, Wk 94	107	7.95	2.20	7.90	4.4	15.3	107	-0.42	2.09	-0.30	-5.9	6.0
V12, Wk 118	80	8.08	2.43	7.60	3.3	14.8	80	-0.47	2.23	-0.30	-5.6	5.3
V14, Wk 166	21	6.92	2.60	6.90	3.0	14.7	21	-1.35	2.43	-0.90	-5.7	2.9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Monocytes/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	7.94	2.43	7.30	4.4	14.3	43	0.03	2.53	-0.10	-6.3	7.9
Termination Visit	4	8.80	1.05	9.05	7.4	9.7	4	1.15	2.21	1.60	-1.8	3.2
Min Post-BL	237	6.70	1.97	6.60	0.2	12.6	237	-1.64	2.13	-1.30	-12.0	3.0
Max Post-BL	237	9.67	2.46	9.60	4.4	17.2	237	1.33	2.10	1.10	-4.0	11.3
Last Visit	237	8.01	2.35	7.80	3.0	17.2	237	-0.33	2.28	-0.30	-10.3	7.9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	3.63	1.51	3.30	1.2	10.6						
V1, Wk 0	27	4.00	1.54	3.80	1.5	7.6	27	0.35	0.99	0.30	-2.0	2.7
V2, Wk 2	227	3.59	1.49	3.30	1.3	10.5	227	-0.05	1.32	0.00	-6.2	4.8
V5, Wk 22	199	3.79	1.47	3.40	1.0	8.9	199	0.16	1.49	0.20	-8.2	5.5
V8, Wk 46	167	3.69	1.44	3.40	1.0	8.6	167	0.08	1.37	0.10	-5.9	4.4
V9, Wk 62	145	3.69	1.70	3.20	1.5	9.9	145	0.09	1.65	0.10	-7.7	7.1
V10, Wk 78	62	3.72	1.46	3.45	1.6	7.6	62	0.09	1.47	0.05	-4.9	4.7
V11, Wk 94	107	3.57	1.41	3.20	1.0	8.1	107	-0.05	1.31	-0.10	-3.7	3.4
V12, Wk 118	80	3.74	1.83	3.20	1.7	11.8	80	0.16	1.66	0.00	-3.7	7.5
V14, Wk 166	21	3.60	1.50	3.20	1.9	8.6	21	0.34	1.04	0.20	-1.2	2.8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils (10^9/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	4.13	1.79	4.10	1.6	8.4	43	0.25	1.61	0.40	-4.2	3.7
Termination Visit	4	3.58	1.39	3.10	2.5	5.6	4	0.80	0.78	0.55	0.2	1.9
Min Post-BL	237	2.88	1.10	2.70	1.0	6.8	237	-0.74	1.19	-0.50	-8.2	2.0
Max Post-BL	237	4.72	1.89	4.30	1.5	11.8	237	1.10	1.64	0.90	-5.9	7.5
Last Visit	237	3.70	1.71	3.20	1.5	11.8	237	0.08	1.51	0.00	-7.7	7.5

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	53.05	10.51	54.20	18.1	78.7						
V1, Wk 0	27	56.99	9.31	58.10	35.1	74.1	27	0.73	5.01	1.00	-12.3	9.2
V2, Wk 2	227	53.01	10.75	53.70	17.7	79.1	227	-0.21	8.78	-0.40	-24.7	33.3
V5, Wk 22	199	54.77	10.37	55.40	24.3	82.3	199	1.78	9.49	1.00	-42.0	32.8
V8, Wk 46	167	54.06	9.71	54.30	29.3	75.3	167	1.04	8.11	1.40	-20.8	20.1
V9, Wk 62	145	53.84	10.15	53.30	29.9	83.0	145	0.89	9.50	1.10	-24.4	44.3
V10, Wk 78	62	54.96	10.60	53.50	32.0	78.9	62	1.73	9.30	1.50	-15.7	24.8
V11, Wk 94	107	54.01	10.72	54.60	21.6	76.7	107	0.69	9.89	-0.60	-26.5	28.2
V12, Wk 118	80	55.82	11.14	54.70	30.6	83.3	80	2.36	9.95	0.85	-16.1	29.9
V14, Wk 166	21	55.46	8.53	56.80	39.7	71.6	21	3.35	10.54	3.30	-11.2	33.6

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-30　全集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Neutrophils/Leukocytes (%)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	56.12	12.15	57.30	25.1	74.7	43	2.15	8.71	3.10	-15.7	31.8
Termination Visit	4	46.53	6.87	45.20	40.3	55.4	4	0.35	7.12	2.40	-9.5	6.1
Min Post-BL	237	47.97	9.82	48.70	17.7	72.7	237	-5.16	7.81	-3.90	-42.0	14.3
Max Post-BL	237	60.17	10.75	61.10	25.1	83.3	237	7.04	9.27	7.00	-15.1	44.3
Last Visit	237	54.07	10.97	53.90	25.1	83.3	237	0.94	8.87	0.40	-24.4	33.6

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Hemoglobin (g/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	137.4	17.8	138.0	92	169						
V1, Wk 0	2	137.5	7.8	137.5	132	143	2	-0.5	6.4	-0.5	-5	4
V2, Wk 2	37	137.0	18.4	139.0	98	170	37	-0.4	6.0	0.0	-19	14
V5, Wk 22	37	138.9	16.3	134.0	114	170	37	1.5	9.5	0.0	-18	41
V8, Wk 46	32	139.7	17.8	139.0	110	169	32	2.5	10.2	3.0	-17	35
V9, Wk 62	31	137.8	18.0	142.0	104	166	31	0.9	9.2	2.0	-15	30
V10, Wk 78	13	136.5	15.8	138.0	109	160	13	0.6	8.4	-3.0	-10	21
V11, Wk 94	25	142.1	15.5	142.0	107	167	25	0.7	9.9	0.0	-13	32
V12, Wk 118	19	142.0	16.3	144.0	114	170	19	1.9	7.9	1.0	-12	25
V14, Wk 166	10	137.2	18.2	136.5	108	168	10	3.7	10.6	0.5	-6	28
Early Termination Visit	4	129.0	22.3	126.5	108	155	4	-3.8	6.7	-4.0	-10	3
Min Post-BL	37	131.6	17.5	133.0	98	162	37	-5.8	5.9	-6.0	-19	6
Max Post-BL	37	145.0	15.9	143.0	118	170	37	7.6	9.0	6.0	-7	41
Last Visit	37	138.3	17.5	138.0	108	170	37	0.9	9.1	0.0	-13	30

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Hematocrit (%)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	44.38	5.66	44.10	31.1	55.0						
V1, Wk 0	2	44.50	4.53	44.50	41.3	47.7	2	0.30	5.37	0.30	-3.5	4.1
V2, Wk 2	37	44.59	6.46	43.00	33.5	57.5	37	0.21	3.92	-0.70	-6.2	8.3
V5, Wk 22	37	46.08	5.62	46.00	34.0	60.0	37	1.69	5.01	0.50	-6.4	15.7
V8, Wk 46	32	45.45	6.26	44.30	36.3	57.5	32	1.29	3.78	1.55	-5.4	8.0
V9, Wk 62	31	46.15	6.11	46.40	33.8	57.7	31	2.07	4.76	2.40	-6.6	10.9
V10, Wk 78	13	45.30	5.31	45.90	34.6	55.0	13	2.66	3.29	2.40	-2.8	7.7
V11, Wk 94	25	45.72	5.36	45.30	37.0	56.2	25	0.77	3.59	0.50	-4.7	8.1
V12, Wk 118	19	47.57	4.43	47.60	40.3	55.0	19	3.32	3.97	2.80	-2.6	12.7
V14, Wk 166	10	47.74	6.03	47.95	39.0	56.6	10	5.63	3.34	5.45	-0.4	12.2
Early Termination Visit	4	44.00	6.51	42.20	38.7	52.9	4	0.10	1.43	0.40	-1.7	1.3
Min Post-BL	37	42.29	5.40	42.50	33.5	52.8	37	-2.09	2.89	-2.30	-6.6	4.2
Max Post-BL	37	48.96	5.65	48.20	38.7	60.0	37	4.57	4.27	4.20	-2.3	15.7
Last Visit	37	46.29	5.47	46.40	38.4	56.6	37	1.90	3.90	1.30	-4.1	12.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Platelets (10^9/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	264.5	83.5	261.0	81	494						
V1, Wk 0	2	296.5	57.3	296.5	256	337	2	-10.5	37.5	-10.5	-37	16
V2, Wk 2	37	258.1	69.9	248.0	110	480	37	-6.4	37.3	-5.0	-72	90
V5, Wk 22	37	255.8	67.1	249.0	100	394	37	-8.7	41.0	-9.0	-173	73
V8, Wk 46	32	255.3	55.7	249.0	149	401	32	-15.2	53.8	-11.0	-187	144
V9, Wk 62	30	258.5	69.6	244.0	143	469	30	-8.4	55.0	-8.5	-170	109
V10, Wk 78	13	258.0	75.3	266.0	157	368	13	-23.9	41.5	-23.0	-123	35
V11, Wk 94	25	246.7	72.5	238.0	141	428	25	-14.4	50.5	-27.0	-134	107
V12, Wk 118	19	250.3	66.8	241.0	142	365	19	-16.8	43.1	-25.0	-99	67
V14, Wk 166	10	252.6	71.6	249.5	159	377	10	-24.7	52.5	-21.5	-122	46
Early Termination Visit	4	271.0	60.8	272.5	196	343	4	-14.0	34.0	-10.0	-58	22
Min Post-BL	37	222.9	57.7	208.0	100	340	37	-41.6	43.1	-43.0	-187	35
Max Post-BL	37	291.8	78.0	265.0	110	480	37	27.3	41.7	19.0	-32	144
Last Visit	37	237.6	62.9	231.0	100	377	37	-26.9	45.5	-26.0	-170	46

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Erythrocytes (10^12/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	4.615	0.481	4.610	3.74	5.65						
V1, Wk 0	2	4.660	0.467	4.660	4.33	4.99	2	0.010	0.226	0.010	-0.15	0.17
V2, Wk 2	37	4.599	0.478	4.550	3.80	5.58	37	-0.016	0.245	0.030	-0.71	0.53
V5, Wk 22	37	4.614	0.496	4.700	3.75	5.64	37	-0.002	0.259	-0.000	-0.67	0.60
V8, Wk 46	32	4.674	0.512	4.660	3.75	5.55	32	0.031	0.293	0.090	-0.52	0.48
V9, Wk 62	31	4.574	0.466	4.570	3.64	5.49	31	-0.036	0.246	-0.030	-0.46	0.51
V10, Wk 78	13	4.563	0.513	4.570	3.84	5.37	13	-0.085	0.209	-0.080	-0.38	0.37
V11, Wk 94	25	4.637	0.471	4.660	3.78	5.33	25	-0.077	0.258	-0.090	-0.55	0.42
V12, Wk 118	19	4.668	0.527	4.660	3.86	5.45	19	-0.064	0.215	-0.010	-0.59	0.29
V14, Wk 166	10	4.495	0.591	4.575	3.59	5.46	10	-0.062	0.247	-0.055	-0.50	0.37
Early Termination Visit	4	4.308	0.762	4.415	3.40	5.00	4	-0.085	0.234	-0.090	-0.34	0.18
Min Post-BL	37	4.362	0.473	4.360	3.40	5.10	37	-0.254	0.221	-0.270	-0.71	0.18
Max Post-BL	37	4.794	0.481	4.880	3.95	5.68	37	0.179	0.222	0.180	-0.35	0.60
Last Visit	37	4.519	0.528	4.520	3.40	5.46	37	-0.096	0.211	-0.090	-0.59	0.37

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Leukocytes (10^9/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	5.98	1.58	5.60	3.8	10.4						
V1, Wk 0	2	4.55	0.35	4.55	4.3	4.8	2	-0.30	0.42	-0.30	-0.6	0.0
V2, Wk 2	37	6.00	1.45	6.00	3.1	10.6	37	0.01	1.30	0.00	-3.7	2.7
V5, Wk 22	37	6.16	1.53	5.90	3.6	10.0	37	0.17	0.99	0.20	-2.3	1.8
V8, Wk 46	32	5.90	1.38	5.85	3.9	9.2	32	-0.27	1.28	-0.20	-3.3	2.7
V9, Wk 62	31	5.95	1.63	5.60	4.0	10.9	31	-0.28	1.94	-0.50	-4.9	6.5
V10, Wk 78	13	6.12	1.53	5.90	3.5	9.5	13	0.66	1.73	0.60	-1.8	4.4
V11, Wk 94	25	5.55	1.47	5.10	3.9	9.1	25	-0.36	1.36	-0.40	-2.9	2.8
V12, Wk 118	19	5.68	1.33	5.20	3.9	7.9	19	0.01	1.06	0.00	-1.6	2.1
V14, Wk 166	10	5.52	0.75	5.45	4.4	7.0	10	-0.05	0.61	-0.10	-1.2	1.0
Early Termination Visit	4	6.40	1.40	6.40	5.0	7.8	4	0.18	0.97	0.45	-1.2	1.0
Min Post-BL	37	4.88	1.23	4.80	2.4	9.1	37	-1.11	1.16	-0.80	-4.9	0.5
Max Post-BL	37	7.15	1.69	6.80	4.6	10.9	37	1.16	1.47	1.10	-2.3	6.5
Last Visit	37	5.66	1.19	5.40	3.9	9.1	37	-0.32	1.25	-0.20	-4.9	2.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Basophils (10^9/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	0.07	0.05	0.10	0.0	0.1						
V1, Wk 0	2	0.05	0.07	0.05	0.0	0.1	2	-0.05	0.07	-0.05	-0.1	0.0
V2, Wk 2	37	0.06	0.05	0.10	0.0	0.1	37	-0.01	0.06	0.00	-0.1	0.1
V5, Wk 22	37	0.06	0.06	0.10	0.0	0.2	37	-0.00	0.07	0.00	-0.1	0.1
V8, Wk 46	32	0.08	0.05	0.10	0.0	0.2	32	0.01	0.06	0.00	-0.1	0.1
V9, Wk 62	31	0.07	0.04	0.10	0.0	0.1	31	0.01	0.06	0.00	-0.1	0.1
V10, Wk 78	13	0.06	0.05	0.10	0.0	0.1	13	-0.02	0.06	0.00	-0.1	0.1
V11, Wk 94	25	0.07	0.05	0.10	0.0	0.1	25	0.00	0.07	0.00	-0.1	0.1
V12, Wk 118	19	0.05	0.05	0.10	0.0	0.1	19	-0.02	0.06	0.00	-0.1	0.1
V14, Wk 166	10	0.12	0.08	0.10	0.0	0.3	10	0.03	0.07	0.00	0.0	0.2
Early Termination Visit	3	0.10	0.00	0.10	0.1	0.1	3	0.00	0.00	0.00	0.0	0.0
Min Post-BL	37	0.03	0.05	0.00	0.0	0.1	37	-0.04	0.06	0.00	-0.1	0.1
Max Post-BL	37	0.12	0.04	0.10	0.1	0.3	37	0.05	0.06	0.00	0.0	0.2
Last Visit	37	0.09	0.06	0.10	0.0	0.3	37	0.02	0.06	0.00	-0.1	0.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Basophils/Leukocytes (%)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	1.02	0.41	1.00	0.2	2.0						
V1, Wk 0	2	1.95	1.91	1.95	0.6	3.3	2	0.85	1.77	0.85	-0.4	2.1
V2, Wk 2	37	1.03	0.66	0.80	0.3	3.2	37	0.01	0.61	0.00	-1.1	1.6
V5, Wk 22	37	1.05	0.69	0.70	0.3	3.4	37	0.04	0.72	-0.10	-1.0	2.6
V8, Wk 46	32	1.08	0.50	1.10	0.2	2.2	32	0.05	0.53	0.00	-1.1	1.1
V9, Wk 62	31	1.20	0.54	1.10	0.3	2.6	31	0.17	0.69	0.10	-1.0	1.8
V10, Wk 78	13	0.92	0.30	0.90	0.4	1.5	13	-0.38	0.55	-0.50	-1.2	0.5
V11, Wk 94	25	1.16	0.54	1.00	0.4	2.2	25	0.15	0.59	0.20	-0.9	1.4
V12, Wk 118	19	0.95	0.48	0.80	0.4	2.0	19	-0.19	0.52	-0.40	-1.0	1.0
V14, Wk 166	10	2.02	1.53	1.35	0.6	5.2	10	0.69	1.56	-0.00	-0.7	4.1
Early Termination Visit	3	1.10	0.17	1.00	1.0	1.3	3	0.07	0.12	0.00	0.0	0.2
Min Post-BL	37	0.66	0.38	0.60	0.2	2.0	37	-0.35	0.46	-0.30	-1.2	0.8
Max Post-BL	37	1.94	0.95	1.80	0.9	5.2	37	0.92	0.91	0.70	-0.5	4.1
Last Visit	37	1.39	0.98	1.10	0.4	5.2	37	0.37	0.96	0.20	-1.0	4.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Eosinophils (10^9/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	0.19	0.18	0.10	0.0	0.9						
V1, Wk 0	2	0.10	0.00	0.10	0.1	0.1	2	0.00	0.00	0.00	0.0	0.0
V2, Wk 2	37	0.16	0.13	0.10	0.0	0.5	37	-0.03	0.13	0.00	-0.5	0.2
V5, Wk 22	37	0.17	0.10	0.20	0.0	0.4	37	-0.02	0.14	0.00	-0.6	0.2
V8, Wk 46	32	0.17	0.16	0.10	0.0	0.6	32	-0.03	0.15	0.00	-0.6	0.4
V9, Wk 62	31	0.18	0.16	0.10	0.0	0.8	31	-0.03	0.15	0.00	-0.5	0.3
V10, Wk 78	13	0.13	0.08	0.10	0.0	0.3	13	-0.02	0.08	0.00	-0.2	0.1
V11, Wk 94	25	0.16	0.10	0.10	0.0	0.4	25	-0.02	0.10	0.00	-0.3	0.2
V12, Wk 118	19	0.14	0.10	0.10	0.0	0.4	19	-0.02	0.14	0.00	-0.3	0.4
V14, Wk 166	10	0.14	0.07	0.15	0.0	0.2	10	-0.02	0.09	0.00	-0.2	0.1
Early Termination Visit	3	0.17	0.12	0.10	0.1	0.3	3	-0.10	0.17	0.00	-0.3	0.0
Min Post-BL	37	0.11	0.09	0.10	0.0	0.3	37	-0.09	0.13	-0.10	-0.6	0.1
Max Post-BL	37	0.25	0.17	0.20	0.0	0.8	37	0.05	0.15	0.00	-0.5	0.4
Last Visit	37	0.16	0.11	0.10	0.0	0.4	37	-0.03	0.14	0.00	-0.5	0.3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Eosinophils/Leukocytes (%)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	2.90	2.05	2.30	0.3	8.8						
V1, Wk 0	2	2.80	0.42	2.80	2.5	3.1	2	0.75	0.78	0.75	0.2	1.3
V2, Wk 2	37	2.51	1.78	2.40	0.2	6.4	37	-0.38	1.59	-0.30	-4.9	4.1
V5, Wk 22	37	2.78	1.53	2.50	0.7	6.4	37	-0.11	1.72	0.10	-5.1	2.5
V8, Wk 46	32	2.82	2.79	1.90	0.2	13.0	32	-0.22	2.55	-0.25	-4.9	10.6
V9, Wk 62	31	2.94	2.36	2.30	0.4	10.6	31	-0.12	1.84	-0.30	-4.2	5.6
V10, Wk 78	13	2.39	1.63	1.80	0.5	6.4	13	-0.25	1.29	0.10	-3.2	1.3
V11, Wk 94	25	2.76	1.93	2.10	0.3	7.8	25	-0.09	1.40	-0.10	-4.2	3.7
V12, Wk 118	19	2.52	1.62	2.10	0.7	7.2	19	-0.07	2.04	0.00	-4.0	6.3
V14, Wk 166	10	2.22	1.01	2.20	0.9	3.6	10	-0.60	1.39	-0.05	-3.7	0.9
Early Termination Visit	3	3.17	1.00	2.80	2.4	4.3	3	-0.73	1.64	-0.10	-2.6	0.5
Min Post-BL	37	1.68	1.15	1.60	0.2	3.9	37	-1.22	1.58	-0.60	-5.1	1.6
Max Post-BL	37	4.21	2.73	3.50	0.9	13.0	37	1.31	2.23	0.80	-1.6	10.6
Last Visit	37	2.81	1.80	2.70	0.3	8.0	37	-0.08	1.58	0.00	-3.7	5.6

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Lymphocytes (10^9/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	2.15	0.41	2.20	1.3	2.9						
V1, Wk 0	2	1.75	0.64	1.75	1.3	2.2	2	-0.20	0.00	-0.20	-0.2	-0.2
V2, Wk 2	37	2.01	0.52	2.10	1.0	3.0	37	-0.14	0.46	-0.20	-1.1	0.9
V5, Wk 22	37	2.06	0.50	2.10	1.1	3.0	37	-0.09	0.51	-0.00	-1.2	0.7
V8, Wk 46	32	2.07	0.44	2.20	1.2	2.9	32	-0.11	0.39	-0.10	-1.0	0.7
V9, Wk 62	31	2.08	0.49	2.10	1.4	3.2	31	-0.13	0.46	-0.20	-0.9	0.7
V10, Wk 78	13	1.91	0.46	2.00	1.1	2.6	13	-0.11	0.47	-0.20	-0.8	0.8
V11, Wk 94	25	2.02	0.67	2.00	1.0	3.8	25	-0.11	0.57	-0.10	-1.3	1.5
V12, Wk 118	19	2.06	0.62	1.80	1.3	3.6	19	-0.00	0.60	-0.10	-0.9	1.3
V14, Wk 166	10	2.03	0.49	1.90	1.3	2.9	10	0.03	0.46	-0.00	-0.7	0.7
Early Termination Visit	3	1.93	0.55	2.20	1.3	2.3	3	-0.40	0.44	-0.20	-0.9	-0.1
Min Post-BL	37	1.67	0.45	1.60	0.8	2.5	37	-0.48	0.38	-0.50	-1.3	0.5
Max Post-BL	37	2.39	0.55	2.40	1.3	3.8	37	0.24	0.47	0.30	-0.9	1.5
Last Visit	37	2.07	0.52	2.10	1.3	3.6	37	-0.08	0.49	-0.10	-0.9	1.3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Lymphocytes/Leukocytes (%)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	37.01	8.17	36.70	22.7	53.0						
V1, Wk 0	2	37.70	11.46	37.70	29.6	45.8	2	-2.90	2.40	-2.90	-4.6	-1.2
V2, Wk 2	37	34.04	7.93	33.00	17.3	47.5	37	-2.96	8.84	-3.50	-29.0	16.3
V5, Wk 22	37	34.45	8.10	33.50	16.9	50.3	37	-2.56	8.16	-1.10	-22.1	12.6
V8, Wk 46	32	35.85	7.87	35.60	21.9	51.2	32	-0.47	7.68	-1.80	-13.0	16.8
V9, Wk 62	31	36.14	8.13	36.50	12.4	53.1	31	-0.40	9.08	-0.40	-30.1	20.4
V10, Wk 78	13	32.26	8.99	32.90	13.4	48.5	13	-4.81	9.55	-5.40	-21.2	10.8
V11, Wk 94	25	37.17	10.94	37.60	14.4	61.4	25	0.65	10.91	1.40	-28.1	16.0
V12, Wk 118	19	36.64	7.39	38.10	20.0	53.0	19	0.14	8.52	0.60	-15.5	11.2
V14, Wk 166	10	36.52	6.44	35.35	28.1	47.8	10	0.09	8.31	1.65	-14.8	10.2
Early Termination Visit	3	33.37	10.63	29.90	24.9	45.3	3	-9.13	14.87	-5.10	-25.6	3.3
Min Post-BL	37	28.81	7.91	29.50	12.4	45.1	37	-8.20	8.20	-6.60	-30.1	8.2
Max Post-BL	37	41.00	7.83	39.80	24.2	61.4	37	3.99	7.38	4.50	-14.6	20.4
Last Visit	37	37.26	8.51	35.70	20.0	56.1	37	0.26	8.01	0.20	-25.6	13.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Monocytes (10^9/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	0.50	0.19	0.50	0.3	1.1						
V1, Wk 0	2	0.25	0.07	0.25	0.2	0.3	2	-0.05	0.07	-0.05	-0.1	0.0
V2, Wk 2	37	0.47	0.17	0.40	0.2	0.8	37	-0.03	0.15	0.00	-0.4	0.2
V5, Wk 22	37	0.45	0.17	0.40	0.0	0.8	37	-0.05	0.21	0.00	-0.9	0.4
V8, Wk 46	32	0.46	0.13	0.50	0.2	0.7	32	-0.06	0.17	0.00	-0.6	0.2
V9, Wk 62	31	0.43	0.15	0.40	0.2	0.8	31	-0.09	0.20	-0.10	-0.7	0.2
V10, Wk 78	13	0.44	0.16	0.40	0.2	0.7	13	-0.03	0.13	0.00	-0.3	0.1
V11, Wk 94	25	0.42	0.15	0.40	0.2	0.7	25	-0.06	0.16	-0.10	-0.4	0.3
V12, Wk 118	19	0.41	0.10	0.40	0.2	0.6	19	-0.07	0.13	-0.10	-0.3	0.1
V14, Wk 166	10	0.36	0.11	0.30	0.2	0.5	10	-0.12	0.10	-0.10	-0.3	0.0
Early Termination Visit	3	0.37	0.21	0.30	0.2	0.6	3	-0.17	0.06	-0.20	-0.2	-0.1
Min Post-BL	37	0.32	0.12	0.30	0.0	0.6	37	-0.18	0.19	-0.10	-0.9	0.1
Max Post-BL	37	0.58	0.16	0.60	0.3	0.8	37	0.08	0.15	0.10	-0.3	0.4
Last Visit	37	0.40	0.12	0.40	0.2	0.7	37	-0.09	0.18	-0.10	-0.7	0.2

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Monocytes/Leukocytes (%)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	8.25	2.66	7.70	4.5	15.0						
V1, Wk 0	2	5.35	0.78	5.35	4.8	5.9	2	-0.20	1.41	-0.20	-1.2	0.8
V2, Wk 2	37	7.84	2.31	8.00	3.7	12.3	37	-0.41	2.16	-0.10	-4.8	3.7
V5, Wk 22	37	7.22	2.63	7.00	0.2	17.2	37	-1.03	2.68	-1.00	-12.0	5.1
V8, Wk 46	32	7.70	1.95	7.25	4.6	11.6	32	-0.72	2.18	-0.75	-4.4	3.1
V9, Wk 62	31	7.32	2.66	7.00	3.2	17.2	31	-0.98	3.01	-1.00	-7.3	7.5
V10, Wk 78	13	7.39	3.25	7.00	2.9	15.7	13	-1.35	2.88	-1.90	-7.2	3.6
V11, Wk 94	25	7.60	2.47	6.50	4.4	13.7	25	-0.77	2.05	-0.60	-4.0	3.0
V12, Wk 118	19	7.32	2.44	6.90	3.3	13.1	19	-1.33	2.04	-0.70	-5.0	1.9
V14, Wk 166	10	6.24	1.83	6.65	3.0	9.4	10	-2.44	2.19	-3.05	-5.7	1.1
Early Termination Visit	3	5.87	1.51	5.20	4.8	7.6	3	-2.97	2.89	-1.40	-6.3	-1.2
Min Post-BL	37	5.57	1.85	5.40	0.2	10.6	37	-2.68	2.62	-2.20	-12.0	1.2
Max Post-BL	37	9.30	2.65	9.00	5.9	17.2	37	1.05	2.29	1.00	-3.5	7.5
Last Visit	37	7.09	2.77	6.70	3.0	17.2	37	-1.16	2.67	-1.20	-6.3	7.5

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Neutrophils (10^9/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	3.12	1.20	3.00	1.5	6.0						
V1, Wk 0	2	2.35	0.21	2.35	2.2	2.5	2	-0.10	0.57	-0.10	-0.5	0.3
V2, Wk 2	37	3.31	1.09	3.20	1.5	7.0	37	0.19	1.11	0.20	-2.5	2.2
V5, Wk 22	37	3.41	1.23	3.20	1.7	6.5	37	0.28	0.84	0.40	-1.5	2.2
V8, Wk 46	32	3.16	1.12	3.00	1.5	6.0	32	-0.09	1.05	0.10	-2.6	2.2
V9, Wk 62	31	3.20	1.49	2.80	1.6	9.1	31	-0.08	1.76	-0.10	-2.9	7.1
V10, Wk 78	13	3.60	1.53	3.10	1.7	7.5	13	0.80	1.68	0.10	-1.8	4.7
V11, Wk 94	25	2.92	1.27	2.70	1.0	6.2	25	-0.19	1.27	-0.10	-2.2	3.4
V12, Wk 118	19	3.03	1.01	3.00	1.7	5.7	19	0.08	0.91	-0.10	-1.4	2.6
V14, Wk 166	10	2.92	0.54	2.90	1.9	3.8	10	0.02	0.69	0.15	-1.2	0.9
Early Termination Visit	3	3.43	1.06	3.60	2.3	4.4	3	0.60	1.41	0.40	-0.7	2.1
Min Post-BL	37	2.40	0.89	2.20	1.0	6.0	37	-0.72	0.89	-0.60	-2.9	0.7
Max Post-BL	37	4.30	1.54	4.00	1.9	9.1	37	1.18	1.45	0.90	-1.0	7.1
Last Visit	37	2.95	1.01	2.90	1.6	6.2	37	-0.18	1.00	0.00	-2.9	2.6

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-31　日本人集団の血液学的検査の測定値及びベースラインからの変化量：SS（続き）

Table 11.1.1
Hematology Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Neutrophils/Leukocytes (%)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	50.83	8.40	51.80	34.4	67.9						
V1, Wk 0	2	52.20	8.34	52.20	46.3	58.1	2	1.50	6.36	1.50	-3.0	6.0
V2, Wk 2	37	54.57	7.89	53.80	39.5	73.1	37	3.75	9.30	3.30	-15.9	33.3
V5, Wk 22	37	54.49	8.84	54.10	40.2	71.2	37	3.66	9.19	1.00	-15.9	24.3
V8, Wk 46	32	52.55	8.42	53.45	37.6	70.1	32	1.35	7.76	1.80	-16.2	16.7
V9, Wk 62	31	52.40	9.45	51.70	35.2	83.0	31	1.32	10.93	-0.10	-23.3	37.2
V10, Wk 78	13	57.04	10.56	54.30	41.3	78.9	13	6.78	11.77	6.10	-14.9	24.8
V11, Wk 94	25	51.30	11.98	50.30	21.6	74.0	25	0.07	11.63	-2.00	-15.1	28.2
V12, Wk 118	19	52.58	8.43	51.70	36.3	73.3	19	1.46	9.34	-0.40	-13.3	19.1
V14, Wk 166	10	53.00	7.75	53.90	39.7	62.0	10	2.26	9.46	0.85	-8.9	20.8
Early Termination Visit	3	56.50	10.07	57.20	46.1	66.2	3	12.77	16.68	5.80	0.7	31.8
Min Post-BL	37	46.48	8.19	47.30	21.6	65.7	37	-4.34	7.97	-4.20	-23.3	14.3
Max Post-BL	37	61.24	8.80	61.10	45.6	83.0	37	10.41	9.41	8.00	-5.0	37.2
Last Visit	37	51.45	9.73	53.10	34.9	73.3	37	0.62	9.53	-0.30	-13.8	31.8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.1

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Calcium (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	2.328	0.097	2.330	2.07	2.69						
V1, Wk 0	26	2.306	0.101	2.280	2.15	2.53	26	-0.007	0.089	-0.005	-0.17	0.16
V2, Wk 2	233	2.321	0.098	2.330	2.02	2.63	233	-0.007	0.094	-0.000	-0.26	0.26
V5, Wk 22	202	2.317	0.094	2.330	1.98	2.56	202	-0.008	0.102	0.005	-0.31	0.18
V8, Wk 46	170	2.323	0.095	2.325	2.10	2.53	170	-0.003	0.094	0.000	-0.29	0.28
V9, Wk 62	146	2.314	0.096	2.310	2.07	2.61	146	-0.011	0.104	0.000	-0.42	0.20
V10, Wk 78	64	2.314	0.106	2.300	2.05	2.59	64	-0.009	0.115	-0.020	-0.23	0.26
V11, Wk 94	108	2.308	0.098	2.290	2.05	2.67	108	-0.011	0.094	-0.015	-0.22	0.21
V12, Wk 118	81	2.300	0.094	2.310	1.93	2.49	81	-0.020	0.124	0.000	-0.55	0.18
V14, Wk 166	21	2.326	0.100	2.330	2.18	2.52	21	-0.004	0.086	-0.010	-0.19	0.19

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Calcium (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	2.315	0.102	2.330	2.10	2.63	44	-0.028	0.103	-0.010	-0.26	0.18
Termination Visit	4	2.363	0.064	2.370	2.28	2.43	4	-0.020	0.120	-0.035	-0.15	0.14
Min Post-BL	238	2.246	0.085	2.250	1.93	2.47	238	-0.082	0.090	-0.070	-0.55	0.14
Max Post-BL	238	2.390	0.091	2.390	2.06	2.67	238	0.063	0.089	0.070	-0.20	0.28
Last Visit	238	2.313	0.093	2.315	2.04	2.63	238	-0.014	0.102	-0.010	-0.55	0.21

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Phosphate (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	1.227	0.228	1.210	0.54	1.94						
V1, Wk 0	26	1.215	0.185	1.260	0.84	1.52	26	0.072	0.247	0.090	-0.32	0.77
V2, Wk 2	230	1.235	0.229	1.230	0.70	1.86	230	0.007	0.185	0.000	-0.52	0.95
V5, Wk 22	199	1.210	0.209	1.200	0.72	1.84	199	-0.015	0.211	-0.020	-0.53	0.95
V8, Wk 46	166	1.219	0.215	1.200	0.71	1.84	166	-0.005	0.204	-0.010	-0.52	0.75
V9, Wk 62	144	1.208	0.206	1.205	0.72	1.84	144	-0.006	0.195	0.000	-0.55	0.62
V10, Wk 78	64	1.211	0.221	1.200	0.78	1.93	64	0.010	0.244	-0.015	-0.66	0.79
V11, Wk 94	104	1.218	0.222	1.190	0.58	1.91	104	0.007	0.199	-0.005	-0.68	0.57
V12, Wk 118	78	1.166	0.248	1.165	0.48	1.87	78	-0.030	0.244	-0.040	-0.49	0.54
V14, Wk 166	21	1.114	0.158	1.140	0.68	1.39	21	-0.070	0.215	-0.100	-0.42	0.37

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Phosphate (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	1.248	0.212	1.240	0.74	1.76	43	-0.017	0.215	0.020	-0.55	0.33
Termination Visit	4	1.215	0.204	1.270	0.93	1.39	4	0.172	0.174	0.205	-0.05	0.33
Min Post-BL	238	1.093	0.211	1.090	0.48	1.76	238	-0.134	0.179	-0.125	-0.68	0.25
Max Post-BL	238	1.356	0.204	1.360	0.80	1.93	238	0.129	0.193	0.110	-0.39	0.95
Last Visit	238	1.221	0.223	1.210	0.48	1.87	238	-0.006	0.207	-0.005	-0.55	0.54

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Sodium (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	141.6	2.0	141.0	135	149						
V1, Wk 0	26	141.0	1.8	140.5	139	145	26	-0.8	2.1	-1.0	-5	4
V2, Wk 2	233	141.6	2.1	142.0	133	150	233	0.0	2.3	0.0	-5	10
V5, Wk 22	202	141.5	2.0	142.0	136	148	202	-0.1	2.3	0.0	-5	11
V8, Wk 46	170	141.2	2.2	141.0	134	151	170	-0.5	2.4	0.0	-9	11
V9, Wk 62	146	141.0	2.2	141.0	134	147	146	-0.8	2.4	-1.0	-8	5
V10, Wk 78	64	140.6	2.2	141.0	133	145	64	-0.8	1.9	-1.0	-7	3
V11, Wk 94	108	141.1	2.0	141.0	135	148	108	-0.6	2.1	0.0	-7	6
V12, Wk 118	81	140.9	2.5	141.0	131	147	81	-0.9	2.3	-1.0	-9	4
V14, Wk 166	21	141.0	1.7	142.0	138	143	21	-0.6	2.4	-1.0	-5	3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Sodium (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	140.9	1.8	141.0	136	144	44	-0.4	2.2	0.0	-7	4
Termination Visit	4	141.0	1.8	141.0	139	143	4	-1.0	1.4	-1.5	-2	1
Min Post-BL	238	139.6	2.4	140.0	121	146	238	-2.0	2.4	-2.0	-14	8
Max Post-BL	238	142.9	2.0	143.0	136	151	238	1.3	2.3	1.0	-5	11
Last Visit	238	141.2	1.9	141.0	133	148	238	-0.4	2.2	0.0	-7	8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Potassium (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	4.40	0.39	4.30	3.4	5.8						
V1, Wk 0	26	4.50	0.40	4.50	3.9	5.5	26	0.04	0.42	0.10	-0.7	0.9
V2, Wk 2	229	4.41	0.40	4.40	3.3	6.7	229	0.01	0.44	0.00	-1.1	2.1
V5, Wk 22	199	4.41	0.35	4.40	3.7	5.5	199	0.00	0.45	0.00	-1.4	1.4
V8, Wk 46	166	4.40	0.35	4.40	3.8	5.7	166	-0.01	0.44	0.00	-1.1	2.1
V9, Wk 62	145	4.32	0.32	4.30	3.5	5.4	145	-0.08	0.41	0.00	-1.8	0.9
V10, Wk 78	64	4.30	0.39	4.25	3.6	5.4	64	-0.09	0.41	-0.10	-1.1	0.7
V11, Wk 94	105	4.38	0.37	4.30	3.6	5.6	105	-0.00	0.46	0.10	-1.2	1.2
V12, Wk 118	79	4.29	0.32	4.30	3.6	5.1	79	-0.11	0.45	-0.10	-1.3	0.8
V14, Wk 166	21	4.24	0.26	4.10	3.9	4.8	21	-0.03	0.37	0.00	-0.8	1.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Potassium (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	4.34	0.35	4.30	3.2	5.2	43	-0.06	0.50	0.00	-1.3	0.8
Termination Visit	4	4.30	0.34	4.30	3.9	4.7	4	-0.17	0.24	-0.10	-0.5	0.0
Min Post-BL	238	4.14	0.31	4.10	3.2	5.5	238	-0.26	0.42	-0.20	-1.8	1.3
Max Post-BL	238	4.67	0.38	4.60	3.8	6.7	238	0.28	0.42	0.30	-0.8	2.1
Last Visit	238	4.36	0.31	4.30	3.2	5.5	238	-0.04	0.43	0.00	-1.3	1.3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Chloride (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	105.8	2.9	106.0	97	115						
V1, Wk 0	26	106.4	2.2	106.0	101	111	26	-0.0	1.9	0.0	-4	4
V2, Wk 2	233	106.1	2.8	106.0	96	116	233	0.3	2.5	0.0	-8	8
V5, Wk 22	202	106.2	3.0	106.0	96	115	202	0.4	3.0	1.0	-15	11
V8, Wk 46	170	105.9	3.0	106.0	96	114	170	0.2	2.9	0.0	-9	11
V9, Wk 62	146	106.1	2.8	106.0	98	116	146	0.3	2.8	0.0	-11	7
V10, Wk 78	64	105.7	3.1	106.0	96	115	64	0.5	2.2	1.0	-6	4
V11, Wk 94	108	106.2	2.9	106.0	98	114	108	0.8	2.7	1.0	-8	6
V12, Wk 118	81	106.5	3.5	106.0	98	118	81	1.1	2.9	1.0	-8	12
V14, Wk 166	21	107.1	2.1	107.0	103	111	21	1.1	2.8	1.0	-5	7

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Chloride (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	105.5	2.8	105.0	96	114	44	-0.1	2.6	0.0	-8	4
Termination Visit	4	106.3	2.5	106.5	103	109	4	1.0	3.4	1.0	-3	5
Min Post-BL	238	104.1	3.2	104.0	83	114	238	-1.7	2.9	-1.0	-17	6
Max Post-BL	238	108.1	2.5	108.0	101	118	238	2.3	2.5	2.0	-6	12
Last Visit	238	106.4	2.8	107.0	96	118	238	0.7	2.8	1.0	-8	9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bicarbonate (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	226	25.5	3.2	25.0	17	34						
V1, Wk 0	24	24.3	3.3	24.0	19	30	24	-1.5	2.9	-2.0	-8	3
V2, Wk 2	213	25.3	3.6	25.0	16	36	208	-0.2	2.9	0.0	-8	6
V5, Wk 22	184	25.1	3.4	25.0	17	35	181	-0.4	2.9	0.0	-10	7
V8, Wk 46	163	25.2	3.7	25.0	16	36	161	-0.1	3.1	0.0	-8	13
V9, Wk 62	136	25.4	3.3	25.0	17	35	134	-0.3	2.8	0.0	-7	8
V10, Wk 78	57	25.5	3.5	25.0	18	35	56	0.1	3.4	0.0	-8	7
V11, Wk 94	100	25.4	2.9	25.0	17	32	98	-0.3	2.7	0.0	-10	5
V12, Wk 118	75	24.5	3.0	25.0	19	31	73	-1.0	2.7	-1.0	-8	5
V14, Wk 166	19	24.9	3.0	25.0	19	29	19	-0.8	2.7	-1.0	-6	3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bicarbonate (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	25.0	3.2	25.0	19	32	42	-1.5	3.0	-1.5	-6	5
Termination Visit	3	26.0	1.7	27.0	24	27	3	-3.0	1.7	-4.0	-4	-1
Min Post-BL	224	22.9	2.9	23.0	16	32	218	-2.6	2.7	-3.0	-10	5
Max Post-BL	224	27.1	3.4	27.0	18	36	218	1.6	2.7	2.0	-6	13
Last Visit	224	24.4	3.0	24.0	18	32	218	-1.1	2.6	-1.0	-7	5

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Creatinine (umol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	64.8	15.8	64.0	27	114						
V1, Wk 0	26	66.9	12.1	62.5	53	89	26	-0.4	8.6	1.5	-29	11
V2, Wk 2	233	64.8	14.6	65.0	24	119	233	0.3	8.6	0.0	-33	34
V5, Wk 22	202	65.8	14.4	65.0	25	110	202	0.5	9.0	1.0	-30	26
V8, Wk 46	170	65.1	13.3	64.0	30	104	170	0.1	8.5	1.0	-35	21
V9, Wk 62	146	65.2	13.9	64.0	30	110	146	0.4	9.6	1.0	-40	19
V10, Wk 78	64	66.3	13.6	65.0	32	110	64	1.4	8.3	1.0	-23	20
V11, Wk 94	108	66.5	13.4	67.0	31	95	108	1.6	8.2	2.0	-17	27
V12, Wk 118	80	67.9	13.7	68.0	32	101	80	2.1	10.8	3.0	-26	37
V14, Wk 166	21	64.5	7.9	67.0	45	76	21	2.7	8.2	3.0	-16	18

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Creatinine (umol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	67.0	12.0	67.0	42	112	44	0.9	8.9	1.5	-25	14
Termination Visit	4	88.8	18.2	93.0	63	106	4	2.8	16.9	8.5	-22	16
Min Post-BL	238	59.3	12.6	59.0	24	91	238	-5.3	8.6	-4.0	-40	18
Max Post-BL	238	71.8	14.9	72.5	29	119	238	7.2	8.0	7.0	-23	37
Last Visit	238	66.6	14.2	67.0	29	112	238	2.0	9.2	2.0	-26	37

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urea Nitrogen (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	4.62	1.28	4.50	1.5	8.0						
V1, Wk 0	26	4.77	1.43	4.70	2.5	7.1	26	0.14	0.96	0.00	-1.5	2.6
V2, Wk 2	233	4.65	1.34	4.50	1.8	10.5	233	0.06	1.14	0.00	-3.2	3.9
V5, Wk 22	202	4.71	1.31	4.60	1.9	8.6	202	0.07	1.16	0.00	-2.5	4.0
V8, Wk 46	170	4.69	1.37	4.50	1.5	8.6	170	0.01	1.24	-0.00	-3.4	4.0
V9, Wk 62	146	4.50	1.27	4.30	2.1	8.6	146	-0.04	1.12	-0.05	-4.0	2.5
V10, Wk 78	64	4.45	1.22	4.20	2.4	8.8	64	-0.15	0.96	-0.15	-2.2	2.2
V11, Wk 94	108	4.69	1.42	4.50	1.9	9.6	108	0.08	1.39	0.00	-2.9	5.7
V12, Wk 118	80	4.54	1.18	4.45	2.8	10.2	80	-0.14	1.18	-0.30	-2.3	3.8
V14, Wk 166	21	4.15	1.01	4.00	2.3	6.1	21	-0.29	1.21	-0.50	-1.9	2.5

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urea Nitrogen (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	4.86	1.52	4.55	1.8	8.4	44	0.22	1.17	0.15	-1.5	4.0
Termination Visit	4	5.90	1.40	6.25	4.0	7.1	4	2.10	1.79	2.40	-0.1	3.7
Min Post-BL	238	3.87	1.08	3.70	1.5	7.0	238	-0.74	0.99	-0.70	-4.0	2.1
Max Post-BL	238	5.61	1.45	5.40	1.8	10.5	238	1.00	1.20	0.90	-2.1	5.7
Last Visit	238	4.73	1.41	4.50	1.8	10.2	238	0.12	1.24	0.05	-4.0	4.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Aspartate Aminotransferase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	22.8	7.7	21.0	8	57						
V1, Wk 0	26	22.6	9.7	19.5	13	63	26	1.1	7.8	0.0	-9	35
V2, Wk 2	233	22.2	7.9	21.0	7	93	233	-0.7	8.6	-1.0	-37	78
V5, Wk 22	202	23.0	8.8	21.0	7	73	202	0.2	8.8	0.0	-32	49
V8, Wk 46	170	23.0	8.6	21.0	9	94	170	0.2	9.7	1.0	-29	79
V9, Wk 62	145	22.3	7.4	20.0	4	56	145	-0.3	8.5	0.0	-34	30
V10, Wk 78	64	22.3	7.5	21.0	12	50	64	-0.3	9.3	0.5	-34	26
V11, Wk 94	105	22.4	6.8	22.0	11	44	105	-0.3	7.6	0.0	-28	23
V12, Wk 118	80	23.2	8.8	21.0	11	67	80	-0.1	8.4	0.0	-26	25
V14, Wk 166	21	20.3	5.2	19.0	14	34	21	-2.9	8.3	0.0	-22	9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Aspartate Aminotransferase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	23.8	10.8	21.0	14	78	44	1.7	7.4	1.0	-11	38
Termination Visit	4	23.0	8.0	20.5	17	34	4	0.3	9.7	0.0	-11	12
Min Post-BL	238	18.8	4.9	18.0	4	40	238	-4.0	6.3	-2.0	-37	9
Max Post-BL	238	28.5	12.1	26.0	9	94	238	5.7	11.3	3.5	-29	79
Last Visit	238	22.8	7.8	21.0	8	78	238	-0.1	7.7	0.0	-34	38

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alanine Aminotransferase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	22.6	12.2	19.0	6	89						
V1, Wk 0	26	25.5	15.8	19.0	12	74	26	1.8	12.2	-1.5	-13	52
V2, Wk 2	233	23.9	23.4	19.0	7	319	233	1.2	20.8	0.0	-36	285
V5, Wk 22	202	23.3	14.4	19.0	6	128	202	0.5	10.7	0.0	-36	40
V8, Wk 46	170	23.3	15.2	19.0	5	132	170	0.6	13.2	0.0	-37	105
V9, Wk 62	145	23.4	16.3	19.0	6	133	145	1.1	13.8	0.0	-36	88
V10, Wk 78	64	21.3	12.8	17.5	7	64	64	0.1	12.6	0.0	-37	30
V11, Wk 94	106	23.2	15.2	17.5	7	118	106	0.6	12.5	1.0	-36	58
V12, Wk 118	80	23.6	14.7	19.0	9	92	80	0.4	13.0	2.0	-33	35
V14, Wk 166	21	18.0	7.6	17.0	7	45	21	-2.6	10.6	-1.0	-32	12

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alanine Aminotransferase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	25.0	13.5	22.5	10	77	44	1.8	8.6	1.0	-17	23
Termination Visit	4	29.0	16.9	22.5	17	54	4	4.5	11.9	4.0	-9	19
Min Post-BL	238	17.7	9.1	15.5	5	77	238	-4.9	8.5	-3.0	-37	21
Max Post-BL	238	32.1	27.1	25.0	9	319	238	9.4	23.1	5.0	-27	285
Last Visit	238	23.1	13.5	19.0	7	92	238	0.4	11.2	0.0	-32	64

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bilirubin (umol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	8.04	4.24	6.80	1.7	30.8						
V1, Wk 0	26	6.96	2.27	6.45	3.2	12.0	26	-0.93	2.72	-0.75	-6.2	5.3
V2, Wk 2	233	7.47	3.04	6.80	1.7	20.9	233	-0.55	3.14	-0.10	-15.4	9.4
V5, Wk 22	202	7.71	3.85	6.80	1.7	35.5	202	-0.25	3.43	0.00	-22.2	10.6
V8, Wk 46	170	7.62	3.42	6.80	3.4	27.4	170	-0.15	3.17	-0.00	-11.1	9.1
V9, Wk 62	145	7.40	3.42	6.70	3.0	26.4	145	-0.38	3.64	0.00	-13.5	18.2
V10, Wk 78	64	6.79	2.52	6.80	2.9	16.3	64	-0.03	2.91	0.45	-9.8	6.7
V11, Wk 94	106	7.30	3.06	6.50	3.0	18.9	106	-0.33	3.15	-0.00	-11.2	8.7
V12, Wk 118	80	7.41	3.62	6.75	1.7	23.7	80	-0.11	3.13	0.10	-10.4	8.1
V14, Wk 166	21	7.27	2.91	7.30	3.4	17.8	21	0.49	2.30	0.20	-3.4	5.9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Bilirubin (umol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	7.46	3.19	6.80	3.4	18.5	44	-1.46	3.65	-0.25	-12.2	6.3
Termination Visit	4	8.53	6.08	7.10	3.4	16.5	4	0.50	2.03	0.45	-1.9	3.0
Min Post-BL	238	5.83	2.41	5.30	1.7	16.9	238	-2.23	3.27	-1.70	-22.2	9.4
Max Post-BL	238	9.65	4.05	8.70	3.4	35.5	238	1.59	3.64	1.70	-15.4	18.2
Last Visit	238	7.56	3.31	6.80	1.7	23.7	238	-0.50	3.57	-0.00	-22.2	9.4

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alkaline Phosphatase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	88.2	53.9	71.0	29	320						
V1, Wk 0	26	68.6	20.4	65.5	35	132	26	1.9	8.6	0.0	-10	24
V2, Wk 2	233	89.7	63.7	71.0	30	631	233	1.4	26.5	0.0	-108	311
V5, Wk 22	202	85.9	57.0	69.0	25	520	202	-1.1	23.3	-1.0	-74	200
V8, Wk 46	170	86.6	63.6	69.0	31	594	170	-3.0	33.8	-2.0	-118	274
V9, Wk 62	146	86.3	64.2	71.0	33	575	146	-3.6	34.1	-1.5	-151	255
V10, Wk 78	64	83.2	50.2	71.5	37	405	64	-9.7	33.0	-4.0	-119	89
V11, Wk 94	108	84.0	62.7	68.5	27	539	108	-7.7	37.7	-3.5	-153	219
V12, Wk 118	81	81.4	55.7	67.0	32	390	81	-12.0	39.0	-5.0	-176	74
V14, Wk 166	21	65.4	18.6	67.0	30	104	21	-15.6	31.7	-6.0	-112	23

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Alkaline Phosphatase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	86.2	59.3	69.5	37	370	44	0.8	34.2	0.0	-102	185
Termination Visit	4	79.5	27.2	71.0	57	119	4	8.3	9.8	9.5	-4	18
Min Post-BL	238	74.7	46.8	62.0	25	367	238	-13.4	26.9	-7.0	-176	47
Max Post-BL	238	97.2	68.1	76.5	33	631	238	9.1	30.0	6.0	-108	311
Last Visit	238	82.4	53.2	69.0	25	390	238	-5.7	30.8	-3.0	-176	185

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Gamma Glutamyl Transferase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	34.1	53.3	19.0	3	557						
V1, Wk 0	26	32.1	32.3	20.0	8	165	26	-3.0	18.3	0.5	-64	25
V2, Wk 2	233	34.4	50.1	20.0	6	460	233	0.5	16.0	1.0	-97	89
V5, Wk 22	202	35.0	56.1	20.0	6	482	202	0.6	21.2	1.0	-75	211
V8, Wk 46	170	35.8	51.8	21.0	7	486	170	-0.7	17.8	1.0	-96	73
V9, Wk 62	146	37.8	56.6	21.0	7	445	146	0.1	22.9	0.0	-113	115
V10, Wk 78	64	30.2	42.7	17.0	6	318	64	1.9	24.5	1.5	-111	112
V11, Wk 94	108	38.9	63.4	19.5	6	386	108	-0.4	26.9	1.0	-171	128
V12, Wk 118	80	41.4	75.6	19.5	7	494	80	1.4	28.1	1.5	-116	136
V14, Wk 166	21	39.3	79.3	21.0	11	380	21	-7.4	39.3	2.0	-177	11

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Gamma Glutamyl Transferase (U/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	53.7	126.2	28.0	8	853	44	13.0	93.1	0.0	-45	607
Termination Visit	4	26.0	16.7	18.5	16	51	4	4.8	10.2	0.5	-2	20
Min Post-BL	238	26.0	36.4	16.0	6	380	238	-8.2	20.9	-3.0	-177	22
Max Post-BL	238	46.3	76.0	27.0	7	853	238	12.2	44.0	5.0	-63	607
Last Visit	238	35.8	66.8	21.0	7	853	238	1.7	45.1	1.0	-177	607

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Glucose (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	4.99	1.20	4.80	2.6	18.0						
V1, Wk 0	26	4.93	0.54	4.90	3.7	6.3	26	0.08	0.61	0.10	-1.6	1.0
V2, Wk 2	230	5.16	1.60	4.90	2.2	23.2	230	0.18	1.59	0.10	-6.9	17.2
V5, Wk 22	199	5.22	1.39	4.90	2.9	17.3	199	0.22	1.31	0.10	-7.1	7.7
V8, Wk 46	166	5.14	1.29	4.90	3.8	16.3	166	0.09	1.54	0.10	-7.5	13.7
V9, Wk 62	145	5.24	1.93	4.90	3.3	21.3	145	0.25	1.71	0.10	-5.6	11.2
V10, Wk 78	64	5.75	3.80	5.10	3.7	32.7	64	0.56	3.28	0.15	-4.2	22.6
V11, Wk 94	106	5.11	1.79	4.90	3.6	21.7	106	-0.01	1.63	0.00	-9.3	11.6
V12, Wk 118	78	5.41	3.04	5.00	2.5	30.5	78	0.28	2.69	0.10	-9.2	20.4
V14, Wk 166	21	4.93	0.61	4.90	3.4	5.9	21	0.09	0.76	0.10	-1.7	1.3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Glucose (mmol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	43	5.37	2.34	4.90	3.1	19.0	43	0.55	2.83	0.20	-6.7	16.4
Termination Visit	4	4.53	0.69	4.65	3.7	5.1	4	-0.28	0.22	-0.30	-0.5	-0.0
Min Post-BL	238	4.54	0.80	4.50	2.2	8.9	238	-0.45	1.11	-0.30	-9.3	2.3
Max Post-BL	238	5.90	2.64	5.40	3.7	32.7	238	0.91	2.39	0.50	-4.2	22.6
Last Visit	238	5.08	1.25	4.90	3.1	19.0	238	0.09	1.55	0.00	-9.2	16.4

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Albumin (g/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	45.0	2.7	45.0	36	53						
V1, Wk 0	26	45.2	2.4	45.5	40	50	26	0.3	1.9	0.5	-3	5
V2, Wk 2	233	44.8	2.8	45.0	37	52	233	-0.2	2.3	0.0	-6	7
V5, Wk 22	202	45.2	2.7	45.0	36	53	202	0.2	2.3	0.0	-6	7
V8, Wk 46	170	44.9	2.7	45.0	38	51	170	-0.1	2.5	0.0	-7	6
V9, Wk 62	146	45.1	2.9	45.0	32	53	146	0.2	2.6	0.0	-11	7
V10, Wk 78	64	44.8	3.5	45.0	33	54	64	0.3	3.5	0.0	-10	10
V11, Wk 94	108	45.1	3.0	45.0	36	54	108	0.5	2.5	1.0	-7	6
V12, Wk 118	81	45.1	3.6	45.0	29	53	81	0.4	3.1	1.0	-14	7
V14, Wk 166	21	45.8	2.4	45.0	42	50	21	0.6	3.2	1.0	-7	8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Albumin (g/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	44.5	3.1	45.0	35	50	44	-0.8	2.8	-0.5	-8	5
Termination Visit	4	45.5	3.1	44.5	43	50	4	0.5	4.2	0.0	-4	6
Min Post-BL	238	43.2	2.8	43.5	29	52	238	-1.8	2.4	-2.0	-14	5
Max Post-BL	238	46.7	2.8	47.0	37	54	238	1.7	2.5	2.0	-6	10
Last Visit	238	45.1	2.9	45.0	34	53	238	0.1	2.7	0.0	-8	8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Protein (g/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	72.5	4.1	72.0	63	84						
V1, Wk 0	26	72.2	3.8	71.5	65	81	26	-0.4	3.2	-1.0	-6	7
V2, Wk 2	233	71.9	4.3	72.0	60	83	233	-0.6	3.9	-1.0	-11	12
V5, Wk 22	202	72.0	4.2	72.0	60	82	202	-0.7	4.2	-1.0	-15	12
V8, Wk 46	170	71.6	4.3	71.0	62	84	170	-1.2	4.6	-1.0	-13	14
V9, Wk 62	146	71.7	4.2	71.0	61	86	146	-1.3	4.6	-1.0	-17	13
V10, Wk 78	64	72.4	4.5	72.0	63	82	64	-0.7	5.2	-1.0	-15	11
V11, Wk 94	108	71.2	4.2	71.0	62	81	108	-1.7	4.7	-1.5	-17	11
V12, Wk 118	81	70.5	5.4	71.0	50	81	81	-2.6	6.1	-2.0	-27	8
V14, Wk 166	21	69.5	3.9	68.0	65	79	21	-4.0	4.9	-5.0	-10	10

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Protein (g/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	70.7	5.1	71.5	61	81	44	-2.5	4.6	-2.0	-12	10
Termination Visit	4	72.8	7.3	70.5	67	83	4	2.0	6.3	1.5	-5	10
Min Post-BL	238	67.9	3.9	68.0	50	79	238	-4.6	4.3	-4.0	-27	5
Max Post-BL	238	74.1	4.5	74.0	62	86	238	1.6	4.2	2.0	-9	14
Last Visit	238	69.4	4.4	69.0	50	83	238	-3.2	4.8	-3.0	-22	10

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urate (umol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=239)												
Baseline	239	295.0	88.5	285.0	89	626						
V1, Wk 0	26	300.0	92.2	273.5	175	542	26	-6.7	60.4	-13.5	-109	145
V2, Wk 2	233	303.1	85.1	298.0	107	590	233	6.9	44.0	1.0	-157	168
V5, Wk 22	202	302.3	92.8	296.0	115	619	202	7.5	56.0	3.0	-107	344
V8, Wk 46	170	301.6	87.9	294.0	144	561	170	7.4	50.6	2.5	-144	216
V9, Wk 62	146	295.5	85.4	288.5	99	513	146	7.6	53.9	3.0	-216	158
V10, Wk 78	64	289.0	80.4	274.5	135	472	64	11.0	55.7	5.5	-75	335
V11, Wk 94	108	295.2	88.4	285.0	138	622	108	7.9	58.9	1.5	-119	304
V12, Wk 118	81	294.9	84.1	286.0	155	523	81	8.6	58.4	19.0	-198	125
V14, Wk 166	21	300.8	89.7	298.0	167	457	21	-6.0	36.2	-15.0	-72	65

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-32　全集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Urate (umol/L)

Visit, Week Number (Descriptor)	Observed Result						Change From Baseline Result					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Early Termination Visit	44	287.5	81.2	285.0	167	535	44	5.5	64.0	2.0	-161	126
Termination Visit	4	350.3	69.0	345.5	290	420	4	-7.3	84.3	6.0	-122	81
Min Post-BL	238	266.3	78.2	256.0	90	555	238	-28.7	46.5	-25.0	-216	111
Max Post-BL	238	338.7	91.4	333.0	165	622	238	43.7	55.3	40.0	-122	344
Last Visit	238	302.2	85.0	298.0	116	588	238	7.3	54.2	6.0	-198	126

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Calcium (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	2.322	0.086	2.340	2.17	2.51						
V1, Wk 0	1	2.290	-	2.290	2.29	2.29	1	-0.050	-	-0.050	-0.05	-0.05
V2, Wk 2	37	2.326	0.077	2.330	2.18	2.50	37	0.004	0.082	-0.000	-0.13	0.17
V5, Wk 22	37	2.324	0.097	2.320	2.16	2.56	37	0.002	0.084	0.020	-0.18	0.15
V8, Wk 46	32	2.350	0.089	2.365	2.18	2.50	32	0.019	0.086	0.010	-0.16	0.17
V9, Wk 62	31	2.329	0.093	2.340	2.07	2.58	31	-0.004	0.090	0.010	-0.18	0.14
V10, Wk 78	13	2.308	0.139	2.300	2.05	2.57	13	-0.025	0.131	-0.030	-0.21	0.26
V11, Wk 94	25	2.332	0.081	2.340	2.22	2.52	25	-0.001	0.068	0.000	-0.12	0.13
V12, Wk 118	19	2.318	0.072	2.320	2.21	2.49	19	-0.014	0.076	-0.010	-0.21	0.10
V14, Wk 166	10	2.325	0.112	2.340	2.18	2.50	10	0.011	0.083	0.000	-0.13	0.19
Early Termination Visit	4	2.328	0.045	2.330	2.27	2.38	4	-0.007	0.093	-0.020	-0.09	0.10
Min Post-BL	37	2.243	0.075	2.260	2.05	2.43	37	-0.079	0.072	-0.080	-0.21	0.07
Max Post-BL	37	2.402	0.088	2.400	2.25	2.58	37	0.080	0.073	0.080	-0.07	0.26
Last Visit	37	2.308	0.074	2.300	2.16	2.50	37	-0.014	0.081	-0.010	-0.21	0.19

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Phosphate (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	1.279	0.215	1.220	0.94	1.75						
V1, Wk 0	1	1.020	-	1.020	1.02	1.02	1	-0.280	-	-0.280	-0.28	-0.28
V2, Wk 2	37	1.267	0.234	1.230	0.70	1.83	37	-0.013	0.182	0.010	-0.51	0.32
V5, Wk 22	37	1.240	0.209	1.230	0.76	1.78	37	-0.039	0.240	-0.050	-0.48	0.60
V8, Wk 46	32	1.210	0.202	1.220	0.77	1.84	32	-0.065	0.205	-0.040	-0.49	0.28
V9, Wk 62	31	1.225	0.188	1.230	0.89	1.67	31	-0.055	0.214	-0.030	-0.47	0.42
V10, Wk 78	13	1.201	0.204	1.220	0.78	1.56	13	-0.048	0.166	-0.030	-0.41	0.16
V11, Wk 94	25	1.222	0.152	1.190	1.03	1.74	25	-0.040	0.168	-0.030	-0.38	0.23
V12, Wk 118	19	1.175	0.211	1.120	0.86	1.66	19	-0.087	0.293	-0.100	-0.49	0.54
V14, Wk 166	10	1.138	0.160	1.150	0.90	1.39	10	-0.076	0.264	-0.155	-0.39	0.37
Early Termination Visit	4	1.368	0.216	1.445	1.05	1.53	4	-0.000	0.282	-0.040	-0.25	0.33
Min Post-BL	37	1.092	0.184	1.090	0.70	1.67	37	-0.188	0.189	-0.170	-0.51	0.16
Max Post-BL	37	1.416	0.174	1.420	1.12	1.84	37	0.136	0.195	0.120	-0.21	0.60
Last Visit	37	1.234	0.191	1.200	0.90	1.74	37	-0.046	0.232	-0.040	-0.44	0.54

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Sodium (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	141.5	1.5	141.0	139	145						
V1, Wk 0	1	140.0	-	140.0	140	140	1	0.0	-	0.0	0	0
V2, Wk 2	37	142.1	2.5	142.0	137	150	37	0.5	2.7	0.0	-4	10
V5, Wk 22	37	141.7	1.9	142.0	138	145	37	0.2	2.0	-1.0	-3	5
V8, Wk 46	32	141.3	1.7	141.0	138	146	32	-0.3	1.9	-0.5	-4	3
V9, Wk 62	31	140.7	2.2	141.0	135	145	31	-0.9	2.2	-1.0	-6	3
V10, Wk 78	13	140.8	2.1	142.0	136	143	13	-0.5	2.0	0.0	-4	3
V11, Wk 94	25	141.2	2.2	141.0	135	146	25	-0.6	2.2	0.0	-5	4
V12, Wk 118	19	140.4	2.2	140.0	136	144	19	-1.5	1.5	-1.0	-5	0
V14, Wk 166	10	140.8	1.7	141.5	138	143	10	-0.9	2.1	-1.0	-4	3
Early Termination Visit	4	140.5	2.9	140.5	137	144	4	-0.3	2.2	0.0	-3	2
Min Post-BL	37	139.2	1.8	140.0	135	142	37	-2.3	2.0	-2.0	-6	1
Max Post-BL	37	143.5	2.2	143.0	138	150	37	1.9	2.2	2.0	-1	10
Last Visit	37	141.1	1.7	142.0	137	144	37	-0.4	1.7	-1.0	-4	3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Potassium (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	4.22	0.25	4.20	3.8	4.7						
V1, Wk 0	1	4.50	-	4.50	4.5	4.5	1	0.10	-	0.10	0.1	0.1
V2, Wk 2	37	4.20	0.26	4.20	3.8	4.8	37	-0.02	0.31	0.00	-0.6	0.7
V5, Wk 22	37	4.34	0.27	4.30	3.8	4.8	37	0.12	0.34	0.10	-0.7	0.6
V8, Wk 46	32	4.28	0.31	4.20	3.8	5.1	32	0.04	0.37	0.00	-0.8	0.8
V9, Wk 62	31	4.21	0.26	4.20	3.6	4.8	31	-0.03	0.31	0.00	-0.5	0.6
V10, Wk 78	13	4.08	0.29	4.10	3.6	4.6	13	-0.15	0.24	-0.10	-0.5	0.4
V11, Wk 94	25	4.21	0.29	4.20	3.6	4.8	25	-0.03	0.37	-0.10	-0.7	0.7
V12, Wk 118	19	4.17	0.33	4.10	3.6	4.8	19	-0.06	0.40	-0.10	-0.7	0.7
V14, Wk 166	10	4.25	0.31	4.10	4.0	4.8	10	0.06	0.42	-0.05	-0.3	1.0
Early Termination Visit	4	4.33	0.25	4.20	4.2	4.7	4	0.13	0.30	0.10	-0.2	0.5
Min Post-BL	37	3.98	0.23	4.00	3.6	4.4	37	-0.24	0.32	-0.30	-0.8	0.4
Max Post-BL	37	4.52	0.25	4.50	4.1	5.1	37	0.30	0.31	0.30	-0.4	1.0
Last Visit	37	4.23	0.26	4.20	3.7	4.8	37	0.01	0.40	0.00	-0.6	1.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Chloride (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	105.3	2.6	105.0	101	115						
V1, Wk 0	1	106.0	-	106.0	106	106	1	1.0	-	1.0	1	1
V2, Wk 2	37	105.5	3.2	105.0	99	114	37	0.2	2.7	1.0	-6	8
V5, Wk 22	37	105.7	2.7	106.0	98	111	37	0.4	2.9	1.0	-7	6
V8, Wk 46	32	105.6	2.6	105.5	100	111	32	0.3	2.1	0.0	-5	5
V9, Wk 62	31	106.1	2.5	106.0	101	113	31	0.7	2.6	1.0	-7	7
V10, Wk 78	13	105.6	3.7	105.0	100	115	13	0.1	2.2	0.0	-3	4
V11, Wk 94	25	105.9	3.0	106.0	98	111	25	0.6	2.1	1.0	-5	5
V12, Wk 118	19	106.3	3.2	107.0	100	114	19	0.8	1.6	1.0	-1	4
V14, Wk 166	10	106.7	2.5	107.0	103	110	10	0.4	2.7	1.0	-5	3
Early Termination Visit	4	105.3	1.3	105.0	104	107	4	0.0	1.6	0.0	-2	2
Min Post-BL	37	103.5	2.5	104.0	98	110	37	-1.8	2.2	-1.0	-7	3
Max Post-BL	37	108.0	2.4	107.0	104	115	37	2.7	1.9	3.0	-2	8
Last Visit	37	106.5	2.2	107.0	100	110	37	1.2	2.2	1.0	-5	5

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Bicarbonate (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	28.7	3.0	29.0	22	34						
V1, Wk 0	1	24.0	-	24.0	24	24	1	-8.0	-	-8.0	-8	-8
V2, Wk 2	37	28.9	3.1	28.0	23	36	37	0.2	3.4	1.0	-8	6
V5, Wk 22	37	27.9	3.0	28.0	22	35	37	-0.7	3.3	-1.0	-10	7
V8, Wk 46	32	28.1	3.3	28.0	22	35	32	-0.6	3.5	-0.5	-7	7
V9, Wk 62	31	27.4	3.0	27.0	20	32	31	-1.5	3.1	-2.0	-7	5
V10, Wk 78	12	28.4	3.8	29.5	19	33	12	0.3	3.5	0.0	-5	5
V11, Wk 94	24	27.1	2.9	27.5	19	32	24	-1.8	2.4	-2.0	-7	4
V12, Wk 118	19	26.4	2.3	27.0	21	31	19	-1.7	2.0	-1.0	-6	2
V14, Wk 166	10	26.8	2.1	27.0	23	29	10	-0.5	2.8	0.0	-5	3
Early Termination Visit	4	27.3	3.0	27.0	24	31	4	-3.8	2.2	-4.0	-6	-1
Min Post-BL	37	24.9	2.1	25.0	19	28	37	-3.8	2.6	-4.0	-10	2
Max Post-BL	37	30.9	2.7	31.0	24	36	37	2.2	2.9	2.0	-6	7
Last Visit	37	26.8	2.1	27.0	22	31	37	-1.9	2.6	-2.0	-7	3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Creatinine (umol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	58.4	11.1	59.0	33	79						
V1, Wk 0	1	57.0	-	57.0	57	57	1	-6.0	-	-6.0	-6	-6
V2, Wk 2	37	58.7	11.4	59.0	31	83	37	0.3	6.9	0.0	-21	16
V5, Wk 22	37	60.5	12.7	63.0	25	84	37	2.1	8.2	2.0	-20	14
V8, Wk 46	32	58.8	10.7	61.0	30	77	32	1.0	5.8	1.5	-11	19
V9, Wk 62	31	58.4	11.3	60.0	30	75	31	0.5	7.1	0.0	-18	14
V10, Wk 78	13	61.5	9.0	61.0	53	87	13	3.5	8.0	3.0	-13	19
V11, Wk 94	25	60.5	10.3	61.0	31	79	25	1.2	5.1	2.0	-9	15
V12, Wk 118	19	63.8	9.4	61.0	49	86	19	4.5	6.3	4.0	-9	18
V14, Wk 166	10	62.4	8.4	65.0	45	72	10	5.2	5.1	4.5	-4	15
Early Termination Visit	4	62.0	7.8	59.5	56	73	4	3.0	4.3	2.0	-1	9
Min Post-BL	37	52.8	9.3	54.0	25	71	37	-5.6	6.1	-4.0	-21	4
Max Post-BL	37	65.6	11.5	68.0	31	87	37	7.2	6.5	7.0	-10	19
Last Visit	37	59.9	11.1	59.0	31	86	37	1.5	5.6	1.0	-10	15

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Urea Nitrogen (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	4.59	0.97	4.50	2.2	6.2						
V1, Wk 0	1	3.50	-	3.50	3.5	3.5	1	-0.60	-	-0.60	-0.6	-0.6
V2, Wk 2	37	4.72	0.91	4.60	2.6	6.6	37	0.13	1.06	0.10	-1.8	2.8
V5, Wk 22	37	4.58	1.09	4.40	2.4	6.5	37	-0.01	1.08	-0.10	-2.0	1.9
V8, Wk 46	32	4.16	1.11	4.05	2.3	6.9	32	-0.33	1.24	-0.30	-3.4	3.1
V9, Wk 62	31	4.36	0.98	4.30	2.9	6.1	31	-0.13	1.12	-0.30	-1.9	2.3
V10, Wk 78	13	4.14	0.90	4.10	3.0	5.6	13	-0.49	0.95	-0.30	-2.2	1.0
V11, Wk 94	25	4.57	1.04	4.70	1.9	6.6	25	-0.01	0.98	-0.20	-1.8	2.8
V12, Wk 118	19	4.07	0.73	4.20	2.8	5.0	19	-0.46	0.87	-0.50	-2.0	1.0
V14, Wk 166	10	4.22	0.98	4.25	2.3	5.6	10	-0.49	1.25	-1.00	-1.9	1.5
Early Termination Visit	4	4.73	0.83	4.90	3.7	5.4	4	-0.25	0.91	-0.20	-1.3	0.7
Min Post-BL	37	3.54	0.80	3.50	1.9	5.9	37	-1.05	0.83	-1.10	-3.4	0.8
Max Post-BL	37	5.38	0.82	5.50	3.6	6.9	37	0.80	0.86	0.90	-1.5	3.1
Last Visit	37	4.40	1.00	4.40	2.3	6.5	37	-0.19	0.94	0.00	-1.9	1.5

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Aspartate Aminotransferase (U/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	20.6	5.1	21.0	12	32						
V1, Wk 0	1	20.0	-	20.0	20	20	1	2.0	-	2.0	2	2
V2, Wk 2	37	20.4	4.3	19.0	13	30	37	-0.2	3.4	0.0	-7	9
V5, Wk 22	37	20.8	6.3	20.0	11	42	37	0.2	5.5	1.0	-14	16
V8, Wk 46	32	21.6	5.6	20.5	11	38	32	1.0	3.9	2.0	-9	9
V9, Wk 62	31	22.2	8.4	20.0	11	56	31	1.8	7.0	1.0	-10	24
V10, Wk 78	13	17.8	4.2	18.0	12	25	13	-1.1	5.1	0.0	-12	4
V11, Wk 94	25	21.6	5.3	21.0	15	32	25	1.0	5.4	0.0	-12	14
V12, Wk 118	19	20.7	4.0	21.0	16	33	19	0.9	5.0	1.0	-9	10
V14, Wk 166	10	17.5	2.8	17.5	14	22	10	-0.8	6.2	0.0	-10	9
Early Termination Visit	4	19.3	3.6	18.5	16	24	4	1.5	0.6	1.5	1	2
Min Post-BL	37	18.1	3.8	18.0	11	26	37	-2.5	3.8	-2.0	-14	6
Max Post-BL	37	25.9	7.6	24.0	18	56	37	5.3	6.3	3.0	-5	24
Last Visit	37	20.9	4.2	20.0	14	33	37	0.4	4.3	1.0	-10	9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Alanine Aminotransferase (U/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	17.8	11.4	14.0	6	52						
V1, Wk 0	1	16.0	-	16.0	16	16	1	4.0	-	4.0	4	4
V2, Wk 2	37	18.6	11.0	16.0	7	57	37	0.8	6.0	0.0	-16	14
V5, Wk 22	37	18.1	8.9	15.0	6	41	37	0.3	9.9	1.0	-33	24
V8, Wk 46	32	18.8	12.1	16.0	5	70	32	0.4	10.1	1.0	-29	25
V9, Wk 62	31	21.0	22.0	16.0	6	133	31	2.7	19.0	3.0	-29	88
V10, Wk 78	13	13.6	6.2	12.0	7	29	13	-4.2	13.1	0.0	-33	8
V11, Wk 94	25	19.7	11.7	16.0	7	54	25	0.0	11.7	2.0	-32	20
V12, Wk 118	19	19.1	9.5	17.0	9	49	19	0.2	11.2	3.0	-26	25
V14, Wk 166	10	13.8	3.7	14.0	7	19	10	-4.8	13.9	0.0	-32	7
Early Termination Visit	4	15.0	4.4	15.0	10	20	4	2.3	2.6	2.0	0	5
Min Post-BL	37	13.9	5.5	13.0	5	32	37	-3.9	9.1	-1.0	-33	4
Max Post-BL	37	26.5	21.3	20.0	12	133	37	8.8	15.2	5.0	-16	88
Last Visit	37	17.7	8.5	16.0	7	49	37	-0.1	9.3	2.0	-32	25

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Bilirubin (umol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	7.92	3.31	6.70	4.1	15.6						
V1, Wk 0	1	4.90	-	4.90	4.9	4.9	1	-6.20	-	-6.20	-6.2	-6.2
V2, Wk 2	37	7.15	2.42	6.80	3.4	14.9	37	-0.77	3.27	-0.40	-7.2	8.1
V5, Wk 22	37	7.28	3.18	6.20	3.0	17.4	37	-0.64	3.52	-0.30	-8.9	10.6
V8, Wk 46	32	8.04	3.30	7.40	4.4	19.8	32	0.24	3.28	0.25	-8.3	7.5
V9, Wk 62	31	7.62	4.53	6.60	3.0	26.4	31	-0.22	4.51	0.10	-8.3	18.2
V10, Wk 78	13	6.11	1.97	5.40	3.5	10.2	13	-1.08	2.09	-0.50	-6.3	1.2
V11, Wk 94	25	7.43	3.38	7.00	3.0	15.8	25	-0.54	3.25	-0.50	-8.4	8.1
V12, Wk 118	19	8.46	4.25	7.20	4.3	23.7	19	0.19	3.06	0.20	-6.2	8.1
V14, Wk 166	10	7.88	3.74	7.30	4.8	17.8	10	0.86	1.99	1.05	-2.9	3.2
Early Termination Visit	4	6.68	1.79	6.00	5.4	9.3	4	-2.83	4.17	-2.45	-7.7	1.3
Min Post-BL	37	5.32	1.54	5.20	3.0	9.3	37	-2.60	2.89	-1.90	-8.9	1.3
Max Post-BL	37	9.85	4.55	8.10	6.0	26.4	37	1.93	4.41	1.90	-6.1	18.2
Last Visit	37	7.75	3.60	7.00	4.7	23.7	37	-0.17	3.27	0.40	-7.7	8.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Alkaline Phosphatase (U/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	83.7	55.4	66.0	29	290						
V1, Wk 0	1	71.0	-	71.0	71	71	1	11.0	-	11.0	11	11
V2, Wk 2	37	82.4	48.2	71.0	33	255	37	-1.3	13.0	-1.0	-39	24
V5, Wk 22	37	78.1	44.5	67.0	25	235	37	-5.6	18.7	-2.0	-55	29
V8, Wk 46	32	76.2	38.1	67.5	37	217	32	-11.0	29.9	-2.5	-118	23
V9, Wk 62	31	75.0	37.2	71.0	34	225	31	-11.4	35.2	-1.0	-151	29
V10, Wk 78	13	66.2	21.1	65.0	37	113	13	-19.5	29.6	-9.0	-88	12
V11, Wk 94	25	75.0	38.7	65.0	35	223	25	-19.3	39.7	-7.0	-153	20
V12, Wk 118	19	69.6	21.8	62.0	38	116	19	-21.9	46.6	-4.0	-176	18
V14, Wk 166	10	61.0	16.4	58.0	30	89	10	-23.8	40.9	-13.0	-112	23
Early Termination Visit	4	53.5	15.3	47.0	44	76	4	-0.8	13.6	-1.5	-16	16
Min Post-BL	37	63.3	31.7	56.0	25	215	37	-20.4	36.9	-8.0	-176	11
Max Post-BL	37	87.4	47.7	75.0	33	255	37	3.6	15.5	4.0	-39	29
Last Visit	37	67.6	33.0	60.0	25	223	37	-16.2	39.2	-5.0	-176	23

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Gamma Glutamyl Transferase (U/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	29.1	52.7	14.0	3	301						
V1, Wk 0	1	13.0	-	13.0	13	13	1	4.0	-	4.0	4	4
V2, Wk 2	37	29.8	43.5	17.0	7	242	37	0.7	12.1	1.0	-59	24
V5, Wk 22	37	28.9	40.5	16.0	6	235	37	-0.1	15.2	2.0	-66	24
V8, Wk 46	32	33.0	50.8	17.0	9	278	32	2.4	8.7	2.5	-23	18
V9, Wk 62	31	28.8	42.7	13.0	7	188	31	-2.6	22.8	0.0	-113	28
V10, Wk 78	13	20.3	19.1	14.0	6	82	13	1.0	5.3	2.0	-10	8
V11, Wk 94	25	36.4	51.3	18.0	7	242	25	1.9	20.3	4.0	-59	51
V12, Wk 118	19	24.4	17.8	19.0	12	75	19	5.1	7.8	4.0	-3	33
V14, Wk 166	10	17.5	4.5	18.0	12	24	10	1.6	4.9	3.0	-5	11
Early Termination Visit	4	24.3	21.0	17.0	8	55	4	6.0	6.2	8.5	-3	10
Min Post-BL	37	22.6	33.4	12.0	6	188	37	-6.5	20.3	-2.0	-113	6
Max Post-BL	37	38.8	51.7	20.0	11	278	37	9.7	12.0	8.0	-23	51
Last Visit	37	29.0	41.4	16.0	7	242	37	-0.1	15.1	3.0	-59	33

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Glucose (mmol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	5.12	0.99	4.90	4.0	9.9						
V1, Wk 0	1	5.20	-	5.20	5.2	5.2	1	0.70	-	0.70	0.7	0.7
V2, Wk 2	37	5.14	0.91	4.90	3.9	8.2	37	0.02	0.79	0.10	-1.7	1.8
V5, Wk 22	37	5.18	0.74	5.00	4.2	7.3	37	0.06	0.94	0.10	-2.6	1.9
V8, Wk 46	32	5.13	0.76	4.95	3.8	7.6	32	-0.01	1.21	0.05	-4.5	2.4
V9, Wk 62	31	5.09	0.67	5.10	3.8	6.9	31	-0.05	1.27	0.10	-5.6	1.8
V10, Wk 78	13	5.29	0.96	5.10	3.7	7.1	13	0.25	1.16	0.40	-1.7	2.4
V11, Wk 94	25	4.97	0.63	4.80	4.0	6.8	25	-0.08	0.66	-0.10	-1.2	1.5
V12, Wk 118	19	5.24	0.92	5.10	4.0	8.4	19	0.24	0.82	0.10	-1.0	2.5
V14, Wk 166	10	5.09	0.43	4.90	4.7	5.8	10	-0.07	0.59	-0.15	-1.0	0.9
Early Termination Visit	4	4.95	0.35	4.95	4.6	5.3	4	0.43	0.71	0.30	-0.2	1.3
Min Post-BL	37	4.47	0.36	4.40	3.7	5.5	37	-0.65	1.07	-0.50	-5.6	1.0
Max Post-BL	37	5.89	0.97	5.60	4.7	8.4	37	0.76	0.97	0.90	-1.7	2.5
Last Visit	37	5.09	0.61	4.90	4.0	6.9	37	-0.04	1.19	0.10	-5.6	1.3

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Albumin (g/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	44.4	2.3	44.0	39	49						
V1, Wk 0	1	46.0	-	46.0	46	46	1	2.0	-	2.0	2	2
V2, Wk 2	37	44.6	2.4	45.0	39	48	37	0.2	1.9	-1.0	-3	5
V5, Wk 22	37	45.3	2.8	45.0	40	53	37	0.9	2.2	1.0	-3	7
V8, Wk 46	32	45.3	2.7	46.0	39	49	32	0.7	2.3	1.0	-5	4
V9, Wk 62	31	44.8	3.3	45.0	32	49	31	0.2	2.9	0.0	-11	7
V10, Wk 78	13	44.5	2.8	45.0	39	49	13	0.4	2.6	-1.0	-2	7
V11, Wk 94	25	45.0	2.6	45.0	40	50	25	0.6	1.7	0.0	-2	5
V12, Wk 118	19	45.5	2.2	46.0	40	49	19	1.2	1.5	1.0	-1	4
V14, Wk 166	10	45.4	2.3	45.0	42	50	10	1.7	2.7	2.0	-3	8
Early Termination Visit	4	45.3	1.3	45.0	44	47	4	0.0	2.9	0.0	-3	3
Min Post-BL	37	43.0	2.8	44.0	32	47	37	-1.4	2.4	-1.0	-11	2
Max Post-BL	37	46.9	2.4	47.0	42	53	37	2.5	2.0	2.0	-1	8
Last Visit	37	45.0	2.3	45.0	40	50	37	0.6	2.0	1.0	-3	8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Protein (g/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	72.4	3.8	72.0	63	80						
V1, Wk 0	1	77.0	-	77.0	77	77	1	2.0	-	2.0	2	2
V2, Wk 2	37	72.4	4.1	73.0	62	83	37	-0.1	3.8	-1.0	-6	8
V5, Wk 22	37	72.7	4.6	73.0	60	81	37	0.3	4.1	1.0	-10	11
V8, Wk 46	32	72.9	4.2	72.5	64	81	32	0.2	4.1	-0.5	-10	9
V9, Wk 62	31	73.0	4.5	72.0	67	86	31	0.3	4.3	0.0	-8	13
V10, Wk 78	13	72.2	3.7	72.0	66	78	13	-1.6	4.4	-3.0	-6	8
V11, Wk 94	25	71.5	4.1	71.0	64	79	25	-1.0	3.0	-2.0	-5	8
V12, Wk 118	19	73.1	4.3	73.0	67	81	19	-0.3	3.1	1.0	-6	5
V14, Wk 166	10	70.8	4.5	68.5	67	79	10	-2.7	5.3	-4.5	-7	10
Early Termination Visit	4	71.8	6.1	74.0	63	76	4	-3.0	5.9	-1.5	-11	2
Min Post-BL	37	68.5	3.8	68.0	60	76	37	-3.9	3.3	-4.0	-11	5
Max Post-BL	37	75.6	4.4	76.0	62	86	37	3.2	3.9	3.0	-5	13
Last Visit	37	69.9	4.8	69.0	60	79	37	-2.5	3.6	-3.0	-11	10

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-33　日本人集団の血液生化学検査の測定値及びベースラインからの変化量：SS（続き）

Table 12.1.1
Clinical Chemistry Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Urate (umol/L)

Visit, Week Number	Observed Result						Change From Baseline Result					
(Descriptor)	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)												
Baseline	37	312.7	83.4	290.0	175	480						
V1, Wk 0	1	269.0	-	269.0	269	269	1	-5.0	-	-5.0	-5	-5
V2, Wk 2	37	317.3	85.1	301.0	172	515	37	4.6	44.2	5.0	-102	114
V5, Wk 22	37	314.5	82.1	322.0	180	464	37	1.8	55.4	7.0	-90	163
V8, Wk 46	32	304.7	78.8	298.0	144	448	32	-10.4	42.8	-15.0	-123	78
V9, Wk 62	31	310.6	80.2	301.0	159	452	31	-4.9	47.2	-5.0	-105	112
V10, Wk 78	13	310.7	84.9	297.0	164	454	13	-9.7	38.1	-7.0	-71	78
V11, Wk 94	25	314.4	78.3	308.0	145	447	25	-11.7	45.5	-27.0	-101	122
V12, Wk 118	19	326.6	83.8	334.0	173	523	19	17.2	49.7	26.0	-80	121
V14, Wk 166	10	319.1	101.0	302.0	167	457	10	-16.6	19.9	-21.5	-39	19
Early Termination Visit	4	288.3	88.6	264.0	214	411	4	-27.0	32.3	-38.0	-52	20
Min Post-BL	37	274.4	70.4	269.0	144	427	37	-38.3	41.9	-32.0	-123	73
Max Post-BL	37	347.5	81.6	342.0	195	523	37	34.9	47.2	32.0	-56	163
Last Visit	37	309.3	77.7	301.0	167	457	37	-3.4	40.7	-9.0	-83	121

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a laboratory value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 8.1.2

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Baseline													
Supine 3 min	3	239	116.2	13.0	118.0	86	155						
Standing 1 min	1	235	116.9	13.7	117.0	82	158						
Standing 3 min	3	233	117.1	12.7	117.0	88	159						
V1, Wk 0													
Supine 3 min	3	4	113.3	10.8	114.0	100	125	3	4.7	4.6	2.0	2	10
Standing 1 min	1	4	111.8	17.6	113.5	90	130	3	2.7	4.6	0.0	0	8
Standing 3 min	3	4	108.0	10.6	104.5	100	123	3	-1.3	13.3	2.0	-16	10
V2, Wk 2													
Supine 3 min	3	235	118.1	13.2	119.0	81	160	235	1.8	10.8	1.0	-27	47
Standing 1 min	1	233	117.8	13.4	117.0	82	158	231	0.9	11.6	1.0	-36	46
Standing 3 min	3	232	118.2	12.9	118.0	82	167	229	1.1	10.7	0.0	-37	37

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V3, Wk 6													
Supine 3 min	3	231	118.3	12.7	118.0	87	153	231	2.1	10.6	1.0	-32	39
Standing 1 min	1	231	119.0	12.8	119.0	85	157	229	2.2	11.4	1.0	-37	52
Standing 3 min	3	231	118.4	12.8	119.0	84	152	227	1.3	10.5	1.0	-30	43
V4, Wk 14													
Supine 3 min	3	225	117.7	12.3	118.0	89	151	225	1.4	10.6	1.0	-27	35
Standing 1 min	1	223	119.0	12.3	119.0	94	155	220	2.0	12.1	1.5	-39	37
Standing 3 min	3	223	119.0	12.2	120.0	84	157	218	1.7	11.0	1.0	-40	35
V5, Wk 22													
Supine 3 min	3	203	117.4	13.3	118.0	90	156	203	1.1	11.1	0.0	-25	40
Standing 1 min	1	203	118.5	13.2	118.0	90	159	200	1.3	11.8	0.0	-35	36
Standing 3 min	3	203	118.2	12.6	118.0	90	150	198	0.5	11.0	0.0	-44	37

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V6, Wk 30													
Supine 3 min	3	138	118.4	13.4	118.0	89	150	138	2.3	10.9	1.5	-29	34
Standing 1 min	1	138	119.2	13.0	120.0	90	157	137	1.4	12.2	1.0	-41	49
Standing 3 min	3	138	119.7	13.1	119.0	90	153	135	1.5	11.6	2.0	-53	35
V7, Wk 38													
Supine 3 min	3	122	118.4	12.9	118.5	88	150	122	1.1	10.7	0.0	-37	33
Standing 1 min	1	121	120.3	13.1	121.0	88	157	119	0.9	12.0	1.0	-34	38
Standing 3 min	3	121	120.3	12.6	120.0	90	156	117	0.9	12.1	1.0	-46	34
V8, Wk 46													
Supine 3 min	3	175	117.7	13.3	117.0	84	156	175	1.1	10.7	1.0	-30	34
Standing 1 min	1	175	119.1	13.7	120.0	57	163	172	1.2	12.7	0.0	-76	37
Standing 3 min	3	175	118.8	12.2	118.0	87	162	170	0.9	10.5	0.0	-43	36

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V9, Wk 62													
Supine 3 min	3	153	118.3	13.0	119.0	89	151	153	1.8	10.9	1.0	-29	29
Standing 1 min	1	153	119.1	12.6	120.0	85	150	150	0.8	12.6	0.0	-48	28
Standing 3 min	3	153	118.6	12.6	120.0	88	152	148	0.0	11.6	0.0	-44	29
V10, Wk 78													
Supine 3 min	3	67	116.3	12.1	115.0	90	145	67	-0.2	10.0	0.0	-21	24
Standing 1 min	1	67	118.8	12.4	120.0	99	152	66	0.1	14.5	0.0	-40	31
Standing 3 min	3	67	117.6	12.2	118.0	90	144	64	-1.3	12.4	-2.0	-36	33
V11, Wk 94													
Supine 3 min	3	109	118.7	12.8	120.0	90	148	109	1.7	10.6	0.0	-30	28
Standing 1 min	1	109	119.9	13.2	120.0	90	154	108	0.3	12.5	0.5	-38	43
Standing 3 min	3	109	119.6	12.7	119.0	92	148	106	0.3	11.7	0.0	-42	29

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V12, Wk 118													
Supine 3 min	3	65	119.4	13.2	119.0	92	164	65	2.3	11.7	1.0	-35	28
Standing 1 min	1	64	119.1	12.8	120.0	90	158	64	0.5	15.0	0.5	-47	38
Standing 3 min	3	64	119.1	13.4	119.0	93	170	63	0.7	13.8	0.0	-54	32
V13, Wk 142													
Supine 3 min	3	34	117.8	11.4	118.0	99	142	34	-0.6	10.5	-1.0	-25	28
Standing 1 min	1	34	117.1	12.3	119.0	94	148	33	-1.7	11.3	-1.0	-25	23
Standing 3 min	3	34	118.2	11.1	119.5	97	140	32	-0.6	10.6	-1.0	-19	23
V14, Wk 166													
Supine 3 min	3	9	122.6	13.7	121.0	98	146	9	2.9	12.2	5.0	-17	19
Standing 1 min	1	9	123.3	16.2	127.0	99	150	9	3.3	7.4	4.0	-12	12
Standing 3 min	3	9	124.4	14.5	125.0	100	141	9	2.2	9.8	5.0	-18	12

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Early Termination Visit													
Supine 3 min	3	49	115.8	11.6	115.0	95	141	49	0.6	13.2	2.0	-32	34
Standing 1 min	1	48	116.6	13.0	116.0	90	142	45	2.5	14.8	3.0	-30	46
Standing 3 min	3	48	116.3	11.6	118.0	90	136	43	0.7	13.7	0.0	-34	40
Termination Visit													
Supine 3 min	3	1	140.0		140.0	140	140	1	-10.0		-10.0	-10	-10
Standing 1 min	1	1	130.0		130.0	130	130	1	-10.0		-10.0	-10	-10
Standing 3 min	3	1	140.0		140.0	140	140	1	-5.0		-5.0	-5	-5
Min Post-BL													
Supine 3 min	3	238	108.6	10.9	108.0	81	133	238	-7.8	9.2	-8.0	-37	14
Standing 1 min	1	238	108.5	11.3	108.5	57	136	234	-8.5	11.3	-8.0	-76	30
Standing 3 min	3	238	109.2	10.7	109.0	82	139	232	-7.8	9.8	-8.0	-54	22

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Max Post-BL													
Supine 3 min	3	238	127.0	12.9	125.5	99	164	238	10.7	11.1	10.0	-18	47
Standing 1 min	1	238	128.1	12.8	128.0	98	163	234	11.2	11.8	10.0	-19	52
Standing 3 min	3	238	127.9	13.0	128.0	98	170	232	10.6	10.5	10.0	-28	43
Last Visit													
Supine 3 min	3	238	117.9	12.4	118.0	90	151	238	1.6	11.0	2.0	-32	34
Standing 1 min	1	238	118.1	12.8	118.0	90	151	234	1.1	12.4	2.0	-42	46
Standing 3 min	3	238	118.0	12.0	118.5	90	150	232	0.7	11.0	0.0	-39	40

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Baseline													
Supine 3 min	3	239	72.0	10.0	72.0	39	97						
Standing 1 min	1	235	76.1	11.2	75.0	48	121						
Standing 3 min	3	233	76.4	10.4	76.0	48	110						
V1, Wk 0													
Supine 3 min	3	4	70.5	7.3	72.5	60	77	3	-0.3	3.5	0.0	-4	3
Standing 1 min	1	4	75.3	13.4	77.0	60	87	3	7.3	7.5	7.0	0	15
Standing 3 min	3	4	73.0	10.4	74.0	60	84	3	1.0	4.6	0.0	-3	6
V2, Wk 2													
Supine 3 min	3	235	73.5	9.2	74.0	44	98	235	1.6	8.0	0.0	-23	31
Standing 1 min	1	233	77.4	10.4	78.0	46	126	231	1.4	9.2	0.0	-44	26
Standing 3 min	3	232	77.8	9.7	77.5	42	116	229	1.4	8.8	1.0	-34	24

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V3, Wk 6													
Supine 3 min	3	231	73.0	10.1	73.0	47	104	231	1.1	9.4	0.0	-23	33
Standing 1 min	1	231	77.2	10.3	77.0	50	114	229	1.1	10.2	2.0	-51	35
Standing 3 min	3	231	77.4	10.3	78.0	43	118	227	0.9	8.7	1.0	-40	20
V4, Wk 14													
Supine 3 min	3	225	73.3	9.1	74.0	52	103	225	1.4	9.1	2.0	-30	34
Standing 1 min	1	223	77.4	10.5	77.0	50	120	220	1.1	10.4	2.0	-49	42
Standing 3 min	3	223	77.4	10.1	78.0	54	122	218	0.8	9.2	2.0	-32	27
V5, Wk 22													
Supine 3 min	3	203	72.7	9.8	72.0	50	104	203	0.7	9.1	1.0	-23	30
Standing 1 min	1	203	76.6	10.9	77.0	42	103	200	0.2	10.2	1.0	-42	29
Standing 3 min	3	203	76.5	11.0	77.0	50	107	198	-0.3	9.9	1.0	-26	27

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V6, Wk 30													
Supine 3 min	3	138	73.9	9.8	74.0	53	104	138	2.0	9.3	2.0	-22	27
Standing 1 min	1	138	77.6	11.4	78.0	54	137	137	0.2	11.6	0.0	-49	63
Standing 3 min	3	138	77.8	9.7	78.0	54	112	135	0.2	8.9	0.0	-25	20
V7, Wk 38													
Supine 3 min	3	122	72.7	9.9	71.5	51	100	122	-0.0	10.1	0.0	-32	29
Standing 1 min	1	121	77.7	11.0	80.0	53	105	119	-0.8	12.5	0.0	-58	27
Standing 3 min	3	121	77.4	10.6	78.0	56	103	117	-1.2	10.5	0.0	-43	25
V8, Wk 46													
Supine 3 min	3	175	73.1	10.0	72.0	50	100	175	1.1	9.2	1.0	-30	30
Standing 1 min	1	175	77.2	10.6	78.0	39	109	172	0.3	11.6	0.5	-72	22
Standing 3 min	3	175	78.0	10.6	78.0	52	110	170	0.6	10.4	1.0	-43	27

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V9, Wk 62													
Supine 3 min	3	153	73.7	10.0	73.0	52	106	153	1.6	9.9	2.0	-22	36
Standing 1 min	1	153	78.1	10.5	79.0	50	110	150	0.6	12.1	1.0	-58	40
Standing 3 min	3	153	77.3	9.4	78.0	55	103	148	-0.6	9.7	0.0	-27	30
V10, Wk 78													
Supine 3 min	3	67	72.1	9.0	72.0	50	93	67	0.5	8.9	0.0	-22	21
Standing 1 min	1	67	76.2	10.3	76.0	56	107	66	-0.8	11.5	0.0	-29	26
Standing 3 min	3	67	76.7	9.6	76.0	60	101	64	-1.0	10.1	0.0	-28	17
V11, Wk 94													
Supine 3 min	3	109	73.7	9.1	73.0	52	99	109	1.4	10.1	1.0	-22	26
Standing 1 min	1	109	77.6	10.1	78.0	56	101	108	-0.7	12.6	0.0	-50	25
Standing 3 min	3	109	78.7	9.9	80.0	56	107	106	-0.0	10.4	0.5	-30	22

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V12, Wk 118													
Supine 3 min	3	65	74.9	8.3	74.0	57	97	65	2.4	9.4	2.0	-29	24
Standing 1 min	1	64	78.2	10.2	80.0	60	104	64	0.4	12.4	0.5	-51	28
Standing 3 min	3	64	77.5	10.1	78.0	59	102	63	0.0	10.9	0.0	-29	24
V13, Wk 142													
Supine 3 min	3	34	74.3	9.5	74.5	52	92	34	1.3	10.7	1.0	-24	24
Standing 1 min	1	34	77.0	11.4	76.5	58	105	33	0.5	12.4	0.0	-25	23
Standing 3 min	3	34	75.5	11.5	74.5	53	99	32	-1.6	11.3	-1.0	-29	21
V14, Wk 166													
Supine 3 min	3	9	76.3	11.8	75.0	54	93	9	7.6	12.1	7.0	-18	23
Standing 1 min	1	9	79.6	12.6	80.0	52	97	9	3.2	13.3	7.0	-27	19
Standing 3 min	3	9	84.1	12.9	90.0	58	100	9	8.2	15.5	10.0	-24	32

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Early Termination Visit													
Supine 3 min	3	49	73.1	9.6	73.0	57	103	49	0.2	9.8	1.0	-21	25
Standing 1 min	1	48	76.5	10.9	76.0	56	101	45	1.2	10.5	0.0	-19	28
Standing 3 min	3	48	78.5	11.5	75.0	59	106	43	1.0	10.6	0.0	-15	51
Termination Visit													
Supine 3 min	3	1	85.0		85.0	85	85	1	-5.0		-5.0	-5	-5
Standing 1 min	1	1	90.0		90.0	90	90	1	0.0		0.0	0	0
Standing 3 min	3	1	90.0		90.0	90	90	1	0.0		0.0	0	0
Min Post-BL													
Supine 3 min	3	238	65.8	8.5	66.0	44	86	238	-6.2	8.2	-6.0	-32	22
Standing 1 min	1	238	68.5	9.1	69.0	39	93	234	-7.6	10.1	-6.0	-72	11
Standing 3 min	3	238	68.8	8.9	70.0	42	92	232	-7.6	9.4	-7.0	-43	14

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Max Post-BL													
Supine 3 min	3	238	80.9	8.5	81.0	61	106	238	8.9	8.5	9.0	-12	36
Standing 1 min	1	238	85.1	10.6	84.5	59	137	234	9.0	10.1	9.0	-36	63
Standing 3 min	3	238	85.1	10.1	85.0	59	122	232	8.5	8.5	8.5	-24	51
Last Visit													
Supine 3 min	3	238	73.0	9.0	72.0	50	103	238	0.9	9.1	1.0	-24	30
Standing 1 min	1	238	76.3	10.2	76.0	50	101	234	0.1	11.2	0.0	-51	28
Standing 3 min	3	238	77.0	10.2	76.5	54	106	232	0.3	10.3	0.0	-29	51

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Baseline													
Supine 3 min	3	239	72.1	11.5	72.0	44	120						
Standing 1 min	1	235	79.7	13.4	78.0	40	122						
Standing 3 min	3	233	79.1	13.7	78.0	38	120						
V1, Wk 0													
Supine 3 min	3	4	70.8	7.8	70.0	62	81	3	9.3	13.6	2.0	1	25
Standing 1 min	1	4	75.0	9.9	75.0	64	86	3	16.0	7.2	14.0	10	24
Standing 3 min	3	4	78.8	10.4	77.0	69	92	3	15.7	7.1	17.0	8	22
V2, Wk 2													
Supine 3 min	3	235	73.8	11.8	73.0	41	101	235	1.7	9.5	2.0	-32	28
Standing 1 min	1	233	81.5	13.0	81.0	50	122	231	1.8	11.6	2.0	-38	48
Standing 3 min	3	232	81.1	12.8	81.0	52	114	229	1.8	11.5	2.0	-38	43

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V3, Wk 6													
Supine 3 min	3	231	74.7	12.5	74.0	35	117	231	2.7	9.6	2.0	-38	24
Standing 1 min	1	231	81.8	13.5	81.0	52	125	229	2.3	10.5	2.0	-37	34
Standing 3 min	3	231	81.6	13.6	80.0	50	129	227	2.7	10.8	2.0	-29	42
V4, Wk 14													
Supine 3 min	3	225	73.2	11.7	73.0	39	116	225	1.5	9.5	1.0	-35	26
Standing 1 min	1	223	80.2	13.2	80.0	36	123	220	1.2	10.6	1.0	-54	30
Standing 3 min	3	223	80.0	13.2	80.0	38	124	218	1.7	11.0	1.0	-51	37
V5, Wk 22													
Supine 3 min	3	203	73.3	12.1	72.0	45	102	203	1.7	9.7	2.0	-37	26
Standing 1 min	1	203	79.4	13.6	78.0	40	124	200	0.4	10.1	1.0	-29	29
Standing 3 min	3	203	79.1	12.7	77.0	38	112	198	0.9	11.1	1.0	-35	38

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V6, Wk 30													
Supine 3 min	3	138	73.7	11.6	73.0	48	100	138	1.0	10.3	1.0	-32	27
Standing 1 min	1	138	81.0	12.7	81.5	54	110	137	0.7	12.6	3.0	-33	31
Standing 3 min	3	138	80.7	12.6	80.0	52	116	135	1.7	11.2	2.0	-40	36
V7, Wk 38													
Supine 3 min	3	122	75.0	11.5	76.0	48	99	122	2.4	10.1	2.5	-27	28
Standing 1 min	1	121	83.2	13.3	83.0	57	112	119	3.2	12.5	4.0	-33	35
Standing 3 min	3	121	82.5	13.0	82.0	55	113	117	3.5	11.8	5.0	-35	36
V8, Wk 46													
Supine 3 min	3	175	72.6	11.9	72.0	48	110	175	0.9	10.8	0.0	-29	37
Standing 1 min	1	175	80.8	14.0	80.0	42	130	172	1.8	12.4	2.0	-30	43
Standing 3 min	3	175	80.3	13.0	79.0	50	115	170	1.9	11.7	2.0	-31	42

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V9, Wk 62													
Supine 3 min	3	153	72.8	11.8	72.0	46	113	153	0.5	9.9	0.0	-27	33
Standing 1 min	1	153	79.6	13.1	80.0	48	115	150	-0.7	12.5	-0.5	-41	36
Standing 3 min	3	153	78.9	12.2	79.0	49	115	148	-0.1	11.4	1.0	-34	30
V10, Wk 78													
Supine 3 min	3	67	73.2	12.0	75.0	52	104	67	1.8	10.0	0.0	-25	28
Standing 1 min	1	67	80.8	14.1	81.0	50	118	66	2.5	12.8	3.5	-40	30
Standing 3 min	3	67	80.7	13.6	80.0	51	112	64	3.7	11.8	2.5	-34	40
V11, Wk 94													
Supine 3 min	3	109	73.2	11.2	72.0	49	105	109	0.6	11.3	0.0	-35	28
Standing 1 min	1	109	80.7	11.0	81.0	56	112	108	0.6	13.3	2.0	-37	34
Standing 3 min	3	109	80.9	10.8	81.0	54	104	106	2.0	13.0	2.0	-34	27

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V12, Wk 118													
Supine 3 min	3	65	75.9	11.9	75.0	57	110	65	3.4	12.1	3.0	-31	33
Standing 1 min	1	63	81.1	13.1	81.0	60	116	63	2.6	13.6	3.0	-36	37
Standing 3 min	3	63	80.8	13.6	82.0	58	115	62	3.4	13.3	3.0	-39	30
V13, Wk 142													
Supine 3 min	3	34	78.6	14.3	78.5	57	121	34	4.2	14.5	2.0	-27	47
Standing 1 min	1	34	85.9	16.0	85.0	59	124	33	5.2	15.7	4.0	-28	45
Standing 3 min	3	34	84.6	16.7	81.5	60	122	32	4.7	16.6	6.5	-39	47
V14, Wk 166													
Supine 3 min	3	9	85.6	11.1	81.0	71	109	9	3.4	11.1	9.0	-22	12
Standing 1 min	1	9	90.1	12.4	92.0	71	107	9	-0.9	16.6	4.0	-38	19
Standing 3 min	3	9	92.0	13.8	90.0	76	113	9	5.0	18.4	11.0	-39	24

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Early Termination Visit													
Supine 3 min	3	49	76.1	13.5	76.0	49	118	49	4.9	11.4	5.0	-19	46
Standing 1 min	1	48	83.2	16.3	81.0	55	144	45	2.4	11.8	2.0	-27	37
Standing 3 min	3	48	84.3	18.0	82.0	58	155	43	4.5	12.3	3.0	-15	46
Termination Visit													
Supine 3 min	3	1	72.0		72.0	72	72	1	0.0		0.0	0	0
Standing 1 min	1	1	72.0		72.0	72	72	1	0.0		0.0	0	0
Standing 3 min	3	1	72.0		72.0	72	72	1	0.0		0.0	0	0
Min Post-BL													
Supine 3 min	3	238	65.5	9.6	65.0	35	95	238	-6.6	8.6	-6.0	-38	12
Standing 1 min	1	238	70.6	11.2	70.0	36	110	234	-9.0	10.3	-8.0	-54	18
Standing 3 min	3	238	71.2	11.0	70.0	38	103	232	-8.0	10.4	-7.0	-51	27

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Max Post-BL													
Supine 3 min	3	238	83.2	12.3	82.0	55	121	238	11.2	10.1	11.0	-32	47
Standing 1 min	1	238	91.8	14.6	91.0	57	144	234	12.0	11.4	11.0	-29	60
Standing 3 min	3	238	91.2	14.6	90.0	56	155	232	12.0	11.9	11.0	-24	67
Last Visit													
Supine 3 min	3	238	73.9	11.7	74.0	44	118	238	1.8	11.3	1.0	-36	46
Standing 1 min	1	238	80.9	13.5	81.0	42	125	234	1.0	12.7	1.0	-38	60
Standing 3 min	3	238	81.0	13.8	80.5	44	140	232	1.6	12.6	2.0	-39	67

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Weight (kg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Baseline		239	71.98	21.85	69.90	16.2	154.1						
V1, Wk 0		3	73.40	22.91	76.00	49.3	94.9	3	1.20	3.16	-0.10	-1.1	4.8
V4, Wk 14		224	72.76	20.85	70.25	17.0	144.2	224	0.93	4.33	1.00	-23.0	17.6
V6, Wk 30		138	72.35	22.84	67.35	17.2	146.4	138	1.10	4.83	0.45	-21.2	17.0
V8, Wk 46		175	73.55	21.67	70.50	20.2	143.8	175	1.43	5.57	1.00	-15.9	25.0
V9, Wk 62		153	74.35	23.61	70.30	19.8	160.0	153	2.85	12.72	1.00	-15.0	109.0
V10, Wk 78		71	73.34	23.39	67.50	20.0	141.8	71	0.32	5.97	0.00	-17.0	13.1
V11, Wk 94		109	73.58	22.25	70.90	19.8	139.5	109	1.42	7.09	1.10	-22.7	36.0
V12, Wk 118		64	73.24	21.28	69.15	37.2	135.0	64	2.32	8.91	2.05	-27.1	34.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Weight (kg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
V13, Wk 142		35	73.22	21.07	68.00	39.2	126.0	35	2.28	6.88	1.30	-12.0	16.1
V14, Wk 166		10	77.46	22.15	71.40	52.8	120.2	10	1.95	7.26	-0.40	-10.3	14.0
V15, Wk 190		1	66.40		66.40	66.4	66.4	1	-5.20		-5.20	-5.2	-5.2
Early Termination Visit		49	76.76	24.85	71.00	27.2	156.0	49	3.33	15.11	1.10	-21.8	92.0
Termination Visit		1	112.10		112.10	112.1	112.1	1	5.60		5.60	5.6	5.6
Min Post-BL		236	71.48	20.78	69.90	17.0	139.9	236	-0.78	5.33	-0.05	-27.1	14.0
Max Post-BL		236	76.84	23.80	73.55	20.2	160.0	236	4.59	12.12	2.50	-23.0	109.0
Last Visit		236	74.70	22.48	72.00	19.8	160.0	236	2.44	11.27	1.30	-23.0	109.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Height (cm)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Baseline		239	166.07	13.76	166.00	105.0	203.2						
V1, Wk 0		3	167.33	10.07	166.00	158.0	178.0	3	0.00	0.00	0.00	0.0	0.0
V9, Wk 62		151	165.00	16.80	166.00	50.0	191.0	151	-0.46	11.75	0.00	-110.0	15.4
V12, Wk 118		60	165.78	16.80	166.90	66.0	191.0	60	-0.44	13.90	0.00	-101.6	19.0
V14, Wk 166		10	169.32	9.87	167.65	156.4	188.0	10	1.10	2.21	0.00	-0.6	6.0
Early Termination Visit		46	165.44	18.37	166.50	64.0	188.0	46	-1.60	14.34	0.00	-96.0	8.0
Min Post-BL		183	164.40	18.96	166.00	50.0	191.0	183	-1.51	14.82	0.00	-110.0	15.4
Max Post-BL		183	165.33	17.49	166.00	50.0	191.0	183	-0.58	12.96	0.00	-110.0	19.0
Last Visit		183	164.70	18.94	166.00	50.0	191.0	183	-1.22	14.96	0.00	-110.0	19.0

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-34　全集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set

Variable: Body Mass Index (kg/m)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Observed Result Mean	Observed Result SD	Observed Result Median	Observed Result Min	Observed Result Max	Change From Baseline Result n	Change From Baseline Result Mean	Change From Baseline Result SD	Change From Baseline Result Median	Change From Baseline Result Min	Change From Baseline Result Max
All Subjects (N=239)													
Baseline		239	25.67	6.30	24.67	14.3	50.0						
V1, Wk 0		3	26.06	7.56	23.99	19.7	34.4	3	0.46	0.87	0.08	-0.2	1.4
V9, Wk 62		151	32.29	56.70	24.83	14.1	640.0	151	6.55	56.70	0.38	-5.2	620.1
V12, Wk 118		60	27.57	12.94	24.82	15.4	114.6	60	2.09	12.39	0.76	-13.0	93.7
V14, Wk 166		10	26.77	6.28	25.55	18.9	40.3	10	0.26	1.75	-0.06	-2.9	2.3
Early Termination Visit		46	34.02	52.67	25.61	17.0	380.9	46	7.55	52.54	0.13	-10.1	355.9
Min Post-BL		183	32.82	57.71	24.62	14.1	640.0	183	7.15	57.72	0.08	-13.0	620.1
Max Post-BL		183	33.79	57.98	24.96	14.1	640.0	183	8.12	58.00	0.52	-5.2	620.1
Last Visit		183	33.57	57.99	24.87	14.1	640.0	183	7.89	58.04	0.25	-10.1	620.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value. Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value. For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Baseline													
Supine 3 min	3	37	110.7	14.3	107.0	86	142						
Standing 1 min	1	37	115.7	19.1	111.0	82	157						
Standing 3 min	3	37	116.2	15.5	113.0	93	151						
V2, Wk 2													
Supine 3 min	3	37	112.4	13.6	114.0	81	149	37	1.7	11.8	3.0	-25	23
Standing 1 min	1	37	115.6	16.0	114.0	82	158	37	-0.1	15.8	1.0	-36	46
Standing 3 min	3	37	115.5	12.8	116.0	82	146	37	-0.7	10.8	-2.0	-28	32
V3, Wk 6													
Supine 3 min	3	37	114.7	13.6	116.0	87	151	37	4.0	11.7	3.0	-21	39
Standing 1 min	1	37	117.4	14.0	120.0	90	157	37	1.6	16.6	4.0	-37	29
Standing 3 min	3	37	114.6	13.8	114.0	88	152	37	-1.6	11.7	0.0	-30	21

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V4, Wk 14													
Supine 3 min	3	37	111.9	11.5	110.0	89	141	37	1.2	11.8	1.0	-26	20
Standing 1 min	1	37	118.1	14.6	116.0	94	155	37	2.4	14.9	5.0	-39	25
Standing 3 min	3	37	119.5	15.5	118.0	84	157	37	3.4	11.8	2.0	-26	24
V5, Wk 22													
Supine 3 min	3	37	112.5	11.3	113.0	95	139	37	1.8	10.7	1.0	-19	22
Standing 1 min	1	37	115.6	14.3	113.0	90	159	37	-0.2	14.5	1.0	-35	26
Standing 3 min	3	37	115.4	12.6	113.0	98	146	37	-0.8	11.4	0.0	-23	34
V6, Wk 30													
Supine 3 min	3	27	114.4	12.3	110.0	94	139	27	1.8	11.3	4.0	-20	27
Standing 1 min	1	27	119.7	15.7	119.0	92	157	27	0.1	16.6	1.0	-25	49
Standing 3 min	3	27	119.1	14.8	119.0	90	153	27	-0.3	12.7	4.0	-32	30

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V7, Wk 38													
Supine 3 min	3	23	114.7	13.3	110.0	96	140	23	-0.7	13.9	2.0	-37	33
Standing 1 min	1	23	119.4	13.0	119.0	96	155	23	-2.4	15.0	0.0	-27	31
Standing 3 min	3	23	118.4	12.3	119.0	102	152	23	-2.9	11.8	0.0	-30	18
V8, Wk 46													
Supine 3 min	3	32	111.7	13.8	110.0	84	140	32	0.7	14.5	3.0	-30	34
Standing 1 min	1	32	114.8	15.6	117.0	57	139	32	-2.1	20.4	1.5	-76	37
Standing 3 min	3	32	118.6	13.6	117.0	87	152	32	1.3	12.7	4.5	-29	23
V9, Wk 62													
Supine 3 min	3	32	113.8	10.7	112.0	95	144	32	2.9	13.6	4.0	-22	26
Standing 1 min	1	32	115.1	10.8	116.0	85	131	32	-1.8	18.4	-2.5	-48	24
Standing 3 min	3	32	115.7	10.1	116.5	99	137	32	-1.6	13.5	-1.5	-32	21

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V10, Wk 78													
Supine 3 min	3	13	115.2	8.8	115.0	105	139	13	2.4	12.1	3.0	-17	24
Standing 1 min	1	13	116.0	10.7	113.0	104	136	13	-5.5	20.6	-6.0	-40	26
Standing 3 min	3	13	115.2	7.6	113.0	106	129	13	-7.7	14.1	-8.0	-33	12
V11, Wk 94													
Supine 3 min	3	25	112.2	12.6	110.0	91	134	25	0.6	10.1	-2.0	-17	22
Standing 1 min	1	25	114.5	13.1	112.0	93	142	25	-4.8	14.5	-2.0	-38	18
Standing 3 min	3	25	115.0	13.6	114.0	92	142	25	-4.0	12.6	-4.0	-32	17
V12, Wk 118													
Supine 3 min	3	8	117.4	5.8	116.5	110	126	8	5.3	11.5	5.5	-9	26
Standing 1 min	1	8	115.6	9.7	117.0	102	130	8	-5.4	25.0	-3.5	-42	38
Standing 3 min	3	8	116.5	6.2	117.5	108	126	8	-2.1	13.5	2.0	-21	15

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V13, Wk 142													
Supine 3 min	3	2	100.5	2.1	100.5	99	102	2	-8.0	11.3	-8.0	-16	0
Standing 1 min	1	2	102.0	11.3	102.0	94	110	2	-8.0	12.7	-8.0	-17	1
Standing 3 min	3	2	110.5	16.3	110.5	99	122	2	-5.0	19.8	-5.0	-19	9
V14, Wk 166													
Supine 3 min	3	2	109.5	16.3	109.5	98	121	2	1.0	25.5	1.0	-17	19
Standing 1 min	1	2	105.0	8.5	105.0	99	111	2	-5.0	9.9	-5.0	-12	2
Standing 3 min	3	2	108.5	12.0	108.5	100	117	2	-7.0	15.6	-7.0	-18	4
Early Termination Visit													
Supine 3 min	3	4	117.8	8.2	116.0	110	129	4	0.3	27.8	-0.5	-32	34
Standing 1 min	1	4	123.5	14.8	125.0	104	140	4	8.5	30.8	8.5	-29	46
Standing 3 min	3	4	121.5	8.2	119.5	114	133	4	3.0	27.2	-2.0	-24	40

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Systolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Min Post-BL													
Supine 3 min	3	37	101.5	9.6	102.0	81	127	37	-9.2	10.3	-8.0	-37	9
Standing 1 min	1	37	102.6	12.2	104.0	57	125	37	-13.2	17.4	-12.0	-76	15
Standing 3 min	3	37	104.6	9.4	104.0	82	123	37	-11.6	10.2	-10.0	-33	14
Max Post-BL													
Supine 3 min	3	37	124.0	11.6	123.0	103	151	37	13.2	11.1	13.0	-13	39
Standing 1 min	1	37	128.7	15.0	125.0	98	159	37	12.9	15.4	14.0	-16	49
Standing 3 min	3	37	127.8	14.9	129.0	100	157	37	11.6	10.7	11.0	-7	40
Last Visit													
Supine 3 min	3	37	113.0	10.2	112.0	91	133	37	2.2	12.8	2.0	-32	34
Standing 1 min	1	37	114.7	12.5	114.0	90	142	37	-1.0	18.4	0.0	-42	46
Standing 3 min	3	37	114.3	10.8	116.0	92	142	37	-1.9	14.4	-2.0	-32	40

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Baseline													
Supine 3 min	3	37	66.5	11.5	66.0	39	91						
Standing 1 min	1	37	80.2	16.0	79.0	57	121						
Standing 3 min	3	37	79.8	14.1	80.0	51	110						
V2, Wk 2													
Supine 3 min	3	37	67.2	10.3	66.0	44	91	37	0.7	10.4	0.0	-23	24
Standing 1 min	1	37	79.7	15.1	78.0	46	126	37	-0.5	12.9	0.0	-44	26
Standing 3 min	3	37	78.7	13.8	78.0	42	116	37	-1.1	12.4	-1.0	-34	21
V3, Wk 6													
Supine 3 min	3	37	67.0	11.0	65.0	47	100	37	0.5	13.2	0.0	-23	33
Standing 1 min	1	37	76.2	13.4	74.0	51	114	37	-4.1	13.9	-3.0	-51	18
Standing 3 min	3	37	76.4	14.4	74.0	43	118	37	-3.3	12.1	-2.0	-40	17

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V4, Wk 14													
Supine 3 min	3	37	67.8	9.3	68.0	52	86	37	1.3	12.5	3.0	-30	34
Standing 1 min	1	37	77.1	13.6	76.0	50	120	37	-3.2	14.4	0.0	-49	23
Standing 3 min	3	37	78.5	13.2	80.0	55	122	37	-1.3	12.1	0.0	-32	20
V5, Wk 22													
Supine 3 min	3	37	66.6	9.1	67.0	50	82	37	0.1	9.3	0.0	-22	16
Standing 1 min	1	37	73.6	12.6	75.0	42	99	37	-6.6	11.7	-5.0	-42	10
Standing 3 min	3	37	75.1	13.0	74.0	50	107	37	-4.7	11.1	-3.0	-26	23
V6, Wk 30													
Supine 3 min	3	27	69.3	9.2	69.0	53	91	27	2.3	11.5	3.0	-22	26
Standing 1 min	1	27	79.9	17.1	78.0	59	137	27	-3.4	19.4	-2.0	-49	63
Standing 3 min	3	27	78.9	12.9	77.0	61	112	27	-3.5	11.1	-6.0	-25	19

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V7, Wk 38													
Supine 3 min	3	23	64.7	7.7	66.0	51	78	23	-3.9	13.7	0.0	-32	29
Standing 1 min	1	23	74.7	12.0	75.0	53	105	23	-11.0	16.8	-10.0	-58	16
Standing 3 min	3	23	75.0	10.1	72.0	56	93	23	-9.3	13.2	-8.0	-43	14
V8, Wk 46													
Supine 3 min	3	32	66.2	9.4	63.5	52	84	32	0.2	12.9	2.0	-30	30
Standing 1 min	1	32	75.4	12.1	75.5	39	96	32	-5.6	18.3	-2.5	-72	22
Standing 3 min	3	32	77.0	11.6	78.0	52	102	32	-3.6	15.3	0.0	-43	22
V9, Wk 62													
Supine 3 min	3	32	68.6	7.7	68.0	56	93	32	2.6	13.3	3.0	-21	36
Standing 1 min	1	32	76.4	10.8	77.5	50	102	32	-4.5	17.3	-1.0	-58	26
Standing 3 min	3	32	76.8	9.6	76.0	55	103	32	-3.8	13.3	2.0	-27	17

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V10, Wk 78													
Supine 3 min	3	13	67.5	8.5	66.0	50	82	13	0.2	10.1	3.0	-22	12
Standing 1 min	1	13	73.8	11.2	71.0	59	99	13	-12.2	13.8	-18.0	-29	21
Standing 3 min	3	13	76.4	7.8	75.0	62	87	13	-9.5	12.6	-14.0	-28	10
V11, Wk 94													
Supine 3 min	3	25	67.6	8.0	69.0	52	80	25	1.3	10.7	1.0	-17	23
Standing 1 min	1	25	75.2	11.7	73.0	61	101	25	-7.9	17.1	-6.0	-50	24
Standing 3 min	3	25	76.1	11.9	74.0	58	107	25	-6.0	13.6	-6.0	-28	22
V12, Wk 118													
Supine 3 min	3	8	72.1	4.6	72.0	66	80	8	2.1	8.3	2.5	-12	16
Standing 1 min	1	8	78.5	12.0	81.0	60	99	8	-10.5	20.1	-3.5	-51	8
Standing 3 min	3	8	76.1	10.0	75.0	61	95	8	-9.8	12.7	-10.0	-29	5

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V13, Wk 142													
Supine 3 min	3	2	55.5	4.9	55.5	52	59	2	-6.0	19.8	-6.0	-20	8
Standing 1 min	1	2	61.0	4.2	61.0	58	64	2	-16.0	7.1	-16.0	-21	-11
Standing 3 min	3	2	58.5	7.8	58.5	53	64	2	-18.0	15.6	-18.0	-29	-7
V14, Wk 166													
Supine 3 min	3	2	63.0	12.7	63.0	54	72	2	1.5	27.6	1.5	-18	21
Standing 1 min	1	2	65.5	19.1	65.5	52	79	2	-11.5	21.9	-11.5	-27	4
Standing 3 min	3	2	69.5	16.3	69.5	58	81	2	-7.0	24.0	-7.0	-24	10
Early Termination Visit													
Supine 3 min	3	4	68.8	7.4	68.5	60	78	4	-5.8	11.2	-4.0	-21	6
Standing 1 min	1	4	76.0	9.4	76.5	64	87	4	-7.0	9.4	-5.0	-19	1
Standing 3 min	3	4	81.0	2.2	80.5	79	84	4	-3.8	11.2	-4.5	-15	9

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Diastolic Blood Pressure (mmHg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Min Post-BL													
Supine 3 min	3	37	57.5	7.2	56.0	44	74	37	-9.0	9.8	-8.0	-32	8
Standing 1 min	1	37	64.7	10.6	66.0	39	81	37	-15.5	14.5	-11.0	-72	3
Standing 3 min	3	37	66.3	10.4	68.0	42	84	37	-13.5	12.4	-15.0	-43	9
Max Post-BL													
Supine 3 min	3	37	78.0	8.4	79.0	62	100	37	11.5	12.3	10.0	-12	36
Standing 1 min	1	37	89.1	15.1	87.0	64	137	37	8.8	16.0	8.0	-36	63
Standing 3 min	3	37	86.8	12.9	86.0	66	122	37	7.1	10.7	7.0	-24	23
Last Visit													
Supine 3 min	3	37	67.4	7.9	69.0	50	80	37	0.8	10.7	0.0	-21	23
Standing 1 min	1	37	74.0	10.0	73.0	52	99	37	-6.2	15.4	-1.0	-51	24
Standing 3 min	3	37	75.0	8.8	77.0	58	95	37	-4.7	12.8	-5.0	-29	22

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Baseline													
Supine 3 min	3	37	66.9	13.2	68.0	44	102						
Standing 1 min	1	37	82.0	16.1	81.0	40	117						
Standing 3 min	3	37	80.2	15.5	79.0	38	115						
V2, Wk 2													
Supine 3 min	3	37	70.2	12.0	71.0	41	95	37	3.3	9.2	4.0	-18	20
Standing 1 min	1	37	85.6	11.3	85.0	51	115	37	3.6	16.0	2.0	-38	48
Standing 3 min	3	37	86.1	10.0	87.0	53	113	37	5.9	14.1	6.0	-31	43
V3, Wk 6													
Supine 3 min	3	37	69.8	12.3	69.0	35	92	37	2.9	9.0	4.0	-18	19
Standing 1 min	1	37	83.4	11.3	83.0	61	112	37	1.4	13.8	1.0	-37	29
Standing 3 min	3	37	84.2	11.3	85.0	63	119	37	4.0	14.1	4.0	-29	40

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V4, Wk 14													
Supine 3 min	3	37	68.8	11.8	70.0	39	96	37	1.9	9.8	1.0	-19	23
Standing 1 min	1	37	80.6	13.0	82.0	36	108	37	-1.4	15.2	-3.0	-54	30
Standing 3 min	3	37	81.1	12.9	84.0	38	107	37	0.9	14.2	1.0	-51	27
V5, Wk 22													
Supine 3 min	3	37	71.6	13.5	72.0	49	101	37	4.6	10.5	5.0	-37	26
Standing 1 min	1	37	83.1	14.7	84.0	40	114	37	1.1	11.0	1.0	-18	22
Standing 3 min	3	37	82.8	12.2	83.0	38	105	37	2.7	12.5	4.0	-30	24
V6, Wk 30													
Supine 3 min	3	27	70.2	13.0	70.0	48	96	27	2.3	13.7	2.0	-32	26
Standing 1 min	1	27	81.6	12.4	83.0	56	105	27	-1.4	16.1	3.0	-33	26
Standing 3 min	3	27	82.2	12.4	81.0	55	105	27	-0.1	13.8	0.0	-40	24

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V7, Wk 38													
Supine 3 min	3	23	70.6	11.0	71.0	51	88	23	3.5	11.6	6.0	-27	23
Standing 1 min	1	23	82.9	10.5	85.0	57	101	23	1.6	15.2	4.0	-33	23
Standing 3 min	3	23	82.8	10.9	83.0	55	100	23	1.0	14.5	2.0	-35	21
V8, Wk 46													
Supine 3 min	3	32	70.6	11.1	72.0	48	93	32	2.5	11.8	4.0	-29	21
Standing 1 min	1	32	85.2	13.5	86.5	58	130	32	1.6	14.9	0.5	-29	43
Standing 3 min	3	32	84.2	10.0	85.0	61	103	32	1.8	12.4	4.5	-31	24
V9, Wk 62													
Supine 3 min	3	32	69.1	10.5	72.0	46	97	32	1.0	11.3	2.5	-27	25
Standing 1 min	1	32	78.7	12.0	81.0	48	93	32	-4.8	16.7	-6.5	-41	29
Standing 3 min	3	32	80.8	10.9	82.0	49	105	32	-1.6	14.7	2.0	-33	20

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V10, Wk 78													
Supine 3 min	3	13	71.5	11.2	75.0	53	94	13	5.2	13.3	6.0	-25	27
Standing 1 min	1	13	84.3	13.3	81.0	68	118	13	3.5	18.8	9.0	-40	30
Standing 3 min	3	13	83.4	10.7	81.0	71	110	13	3.2	15.2	6.0	-34	21
V11, Wk 94													
Supine 3 min	3	25	67.1	9.7	68.0	51	85	25	-1.6	12.4	1.0	-23	24
Standing 1 min	1	25	82.1	9.7	83.0	68	101	25	-1.7	16.0	1.0	-37	17
Standing 3 min	3	25	82.3	9.0	84.0	66	98	25	-1.1	15.3	3.0	-34	21
V12, Wk 118													
Supine 3 min	3	8	79.1	15.6	79.0	58	102	8	6.9	14.6	7.5	-21	29
Standing 1 min	1	8	87.0	13.1	88.0	65	102	8	3.8	20.6	11.5	-36	31
Standing 3 min	3	8	89.0	13.3	86.0	70	110	8	3.8	20.7	5.0	-39	27

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result						Change From Baseline Result					
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
V13, Wk 142													
Supine 3 min	3	2	78.5	4.9	78.5	75	82	2	-9.0	25.5	-9.0	-27	9
Standing 1 min	1	2	86.0	2.8	86.0	84	88	2	-14.0	19.8	-14.0	-28	0
Standing 3 min	3	2	83.0	9.9	83.0	76	90	2	-15.5	33.2	-15.5	-39	8
V14, Wk 166													
Supine 3 min	3	2	75.5	6.4	75.5	71	80	2	-12.0	14.1	-12.0	-22	-2
Standing 1 min	1	2	74.5	4.9	74.5	71	78	2	-25.5	17.7	-25.5	-38	-13
Standing 3 min	3	2	76.0	0.0	76.0	76	76	2	-22.5	23.3	-22.5	-39	-6
Early Termination Visit													
Supine 3 min	3	4	62.3	12.1	62.0	49	76	4	3.0	5.9	2.0	-3	11
Standing 1 min	1	4	73.3	16.2	72.5	55	93	4	-2.0	4.9	-1.0	-8	2
Standing 3 min	3	4	75.0	17.2	72.0	60	96	4	5.8	14.4	2.5	-8	26

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Pulse Rate (beats/min)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Min Post-BL													
Supine 3 min	3	37	61.0	9.5	62.0	35	77	37	-5.9	9.0	-4.0	-37	10
Standing 1 min	1	37	69.1	11.9	71.0	36	86	37	-12.9	14.0	-10.0	-54	11
Standing 3 min	3	37	71.8	10.6	74.0	38	90	37	-8.4	13.9	-5.0	-51	12
Max Post-BL													
Supine 3 min	3	37	81.2	11.5	80.0	60	102	37	14.3	8.6	14.0	-6	29
Standing 1 min	1	37	96.6	11.2	94.0	70	130	37	14.6	14.3	15.0	-12	48
Standing 3 min	3	37	96.0	10.0	95.0	70	119	37	15.8	14.2	17.0	-15	52
Last Visit													
Supine 3 min	3	37	68.1	11.1	69.0	44	93	37	1.2	12.0	3.0	-22	29
Standing 1 min	1	37	79.9	12.3	80.0	43	101	37	-2.1	16.1	-1.0	-38	31
Standing 3 min	3	37	80.7	11.6	82.0	44	106	37	0.5	16.6	3.0	-39	27

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Weight (kg)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Baseline		37	61.34	15.29	60.20	20.9	109.5						
V4, Wk 14		37	61.92	15.33	60.00	22.0	106.3	37	0.58	3.13	0.70	-6.2	9.0
V6, Wk 30		27	63.35	16.42	61.50	23.0	105.7	27	1.20	3.59	0.30	-5.3	7.0
V8, Wk 46		32	62.38	15.16	60.80	21.7	105.1	32	0.60	3.51	0.00	-6.8	7.8
V9, Wk 62		32	62.29	14.43	60.85	23.6	103.8	32	0.51	4.20	0.30	-13.1	8.9
V10, Wk 78		13	64.51	10.50	61.90	46.2	83.4	13	0.26	5.41	-0.30	-13.3	8.2
V11, Wk 94		25	64.74	17.59	61.00	24.1	106.3	25	1.92	6.66	1.50	-14.1	22.3
V12, Wk 118		8	62.93	15.41	59.50	46.5	98.0	8	4.52	6.90	2.70	-3.5	17.1
V13, Wk 142		2	58.45	3.04	58.45	56.3	60.6	2	5.10	3.82	5.10	2.4	7.8
V14, Wk 166		2	57.25	0.49	57.25	56.9	57.6	2	3.90	6.36	3.90	-0.6	8.4
Early Termination Visit		4	61.40	13.23	58.20	50.2	79.0	4	1.22	6.25	1.10	-6.3	9.0
Min Post-BL		37	60.31	14.66	59.50	21.7	103.8	37	-1.03	3.83	-0.40	-14.1	6.0
Max Post-BL		37	64.39	15.85	61.50	24.1	106.3	37	3.05	4.90	1.70	-3.6	22.3
Last Visit		37	62.55	15.45	61.00	24.1	106.3	37	1.21	5.27	1.00	-14.1	17.1

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Height (cm)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Baseline		37	160.99	10.18	162.40	121.7	182.0						
V9, Wk 62		32	162.04	9.55	163.40	129.3	181.6	32	0.60	1.85	0.25	-1.8	7.6
V12, Wk 118		7	156.86	5.69	155.40	150.3	168.4	7	1.53	2.72	0.30	-0.6	7.0
V14, Wk 166		2	157.60	1.70	157.60	156.4	158.8	2	1.85	3.46	1.85	-0.6	4.3
Early Termination Visit		4	159.25	6.42	159.10	153.5	165.3	4	0.10	1.81	-0.65	-1.1	2.8
Min Post-BL		34	161.83	9.43	163.40	129.3	181.6	34	0.56	1.84	0.25	-1.8	7.6
Max Post-BL		34	161.99	9.30	163.60	129.3	181.6	34	0.72	2.02	0.25	-1.3	7.6
Last Visit		34	161.94	9.34	163.60	129.3	181.6	34	0.67	2.03	0.25	-1.3	7.6

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

表 2.1-35　日本人集団のバイタルサインの測定値及びベースラインからの変化量：SS（続き）

Table 15.1.1
Vital Signs Observed Results and Changes from Baseline
Analysis Set: Safety Set - Japanese

Variable: Body Mass Index (kg/m²)

Visit, Week Number (Descriptor) Position	Time (min)	Observed Result n	Mean	SD	Median	Min	Max	Change From Baseline Result n	Mean	SD	Median	Min	Max
All Subjects (N=37)													
Baseline		37	23.39	4.38	23.28	14.3	36.3						
V9, Wk 62		32	23.49	4.16	22.73	14.1	34.2	32	0.09	1.52	0.00	-5.1	3.8
V12, Wk 118		7	23.56	2.61	23.23	19.1	27.2	7	0.91	1.61	1.36	-1.5	2.8
V14, Wk 166		2	23.05	0.30	23.05	22.8	23.3	2	0.82	2.15	0.82	-0.7	2.3
Early Termination Visit		4	24.01	3.42	22.91	21.3	28.9	4	-0.03	2.72	0.52	-3.8	2.6
Min Post-BL		34	23.47	4.11	22.68	14.1	34.2	34	-0.06	1.57	0.00	-5.1	2.6
Max Post-BL		34	23.71	4.15	23.06	14.1	34.2	34	0.18	1.72	0.08	-5.1	3.8
Last Visit		34	23.60	4.11	23.06	14.1	34.2	34	0.07	1.63	0.08	-5.1	2.8

BL=Baseline, LCM=Lacosamide, Max=maximum, Min=minimum, SD=standard deviation.
Note: Last Visit=Last post-baseline visit (including unscheduled visits) during the Treatment Period with a vital signs value.
Min (Max) Post-Baseline=Minimum (maximum) of all reported values (including unscheduled visits) during the Treatment Period.
Note: For Baseline failures from SP0982, data collected at Visit 1 prior to the first dose of LCM was used as the Baseline value.
For non-Baseline failures from SP0982, the last non-missing value prior to the first dose of study medication in the SP0982 study was used as the Baseline value.

Reference: Listing 9.1

2.1.3.4 その他の評価項目

2.1.3.4.1 タナー分類、子どもの行動チェックリスト及び実行機能に関する行動評価尺度

タナー分類を用いた判定、CBCL/1½-5 版又は 6-18 版を用いた評価、BRIEF／BRIEF-P を用いた認知機能評価において、臨床的に意味のある異常が認められた被験者はいなかった。

2.1.3.4.2 コロンビア自殺評価スケール

ベースラインの C-SSRS の回答が陽性（質問 4 及び質問 5 に「はい」と回答）であった被験者は 3 例であった。2 例に自殺関連の有害事象（自殺念慮及び自殺企図）が認められたが、C-SSRS では自殺企図の報告はなかった。

2.1.3.5 全集団のまとめ

全集団では、ラコサミドを投与した強直間代発作を有する 4 歳以上のてんかん患者において、忍容できる安全性プロファイルが示され、安全性上の新たな懸念事項は認められなかった。全集団では 197 例（82.4%）に有害事象が認められたが、ほとんどの有害事象の重症度は軽度又は中等度で、高度の有害事象の発現率は 10.9%であった。治験薬の投与中止に至った有害事象は 10 例（4.2%）に認められた。治療期間中に新たな欠神発作及びミオクロニー発作を発現した被験者は、それぞれ 16 例及び 15 例であった。臨床検査のベースラインからの変化量（平均値又は中央値）にラコサミド投与に起因すると考えられる臨床的又は一貫した結果は認められなかった。バイタルサインの平均値は、ベースライン及びベースライン後のすべての測定時において予想できる範囲であった。12 誘導心電図は、すべての測定時においてベースラインからの変化量（平均値及び中央値）が小さかった。

2.1.3.6 日本人集団のまとめ

日本人集団では、ラコサミドを投与した強直間代発作を有する 4 歳以上のてんかん患者において、忍容できる安全性プロファイルが示された。日本人集団では、全集団と比べて有害事象の発現率が高かった（全集団：82.4%、日本人集団：97.3%）。高度の有害事象が 2 件（各種物質毒性及び自殺企図）認められたが、その他の有害事象の重症度は軽度又は中等度であった。治験薬の投与中止に至った有害事象が 1 例に認められた。治療期間中に新たな欠神発作を発現した被験者は 3 例で、新たなミオクロニー発作を発現した被験者は 1 例であった。臨床検査値、バイタルサイン、12 誘導心電図、及びその他の評価項目の結果は、全集団の結果と同様であり、安全性上の新たな懸念事項は認められなかった。

2.1.4 有効性

2.1.4.1 副次評価項目

2.1.4.1.1 強直間代発作回数の変化率

本治験の FAS での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率を期間別に表 2.1-36（全集団）及び表 2.1-37（日本人集団）に示した。また、各期間の試験完了例の集団での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率を期間別に表 2.1-38（全集団）及び表 2.1-39（日本人集団）に示した。

全集団では、Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率の中央値は、−88.52%であった。以下に示した各期間の試験完了例の集団間の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率の中央値は同程度であり、治療期間の長さに関わらず、一貫して減少した（0〜22 週：−88.20%、0〜46 週：−86.32%、0〜94 週：−89.45%）。全集団では、94 週超〜142 週の被験者は 100 例で、Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率の中央値は、−93.50%であった。Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率の中央値は、94 週以内の被験者と 94 週超の被験者で同程度であった。

日本人集団の有効性の結果は、全集団の結果と同様であった。Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率の中央値は、−81.82%であった。Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率は、治療期間の長さに関わらず一貫して減少した。日本人集団では、94 週超〜142 週の被験者は 23 例で、Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率の中央値は、−88.48%であった。

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
0 to 22 Weeks	n	238
	Mean	-64.67
	SD	68.39
	Median	-88.18
	Min	-100.0
	Max	473.8
>22 to 46 Weeks	n	204
	Mean	-67.16
	SD	69.77
	Median	-96.16
	Min	-100.0
	Max	429.3

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
>46 to 94 Weeks	n	170
	Mean	-72.02
	SD	61.19
	Median	-93.26
	Min	-100.0
	Max	349.4
>94 to 142 Weeks	n	100
	Mean	-77.63
	SD	44.06
	Median	-93.50
	Min	-100.0
	Max	239.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
>142 to 190 Weeks	n	34
	Mean	-75.85
	SD	37.03
	Median	-86.21
	Min	-100.0
	Max	95.2
>190 to 238 Weeks	n	1
	Mean	-100.00
	SD	-
	Median	-100.00
	Min	-100.0
	Max	-100.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
0 to 46 Weeks	n	238
	Mean	-63.18
	SD	69.59
	Median	-87.07
	Min	-100.0
	Max	465.4
0 to 46 Weeks (> 22 Weeks)	n	204
	Mean	-68.37
	SD	58.45
	Median	-87.50
	Min	-100.0
	Max	465.4

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
0 to 94 Weeks	n	238
	Mean	-63.98
	SD	69.90
	Median	-88.83
	Min	-100.0
	Max	465.4
0 to 94 Weeks (> 46 Weeks)	n	170
	Mean	-72.08
	SD	44.68
	Median	-87.58
	Min	-100.0
	Max	203.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
0 to 142 Weeks	n	238
	Mean	-64.14
	SD	69.64
	Median	-88.68
	Min	-100.0
	Max	465.4
0 to 142 Weeks (> 94 Weeks)	n	100
	Mean	-74.95
	SD	39.22
	Median	-85.77
	Min	-100.0
	Max	166.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
0 to 190 Weeks	n	238
	Mean	-64.20
	SD	69.63
	Median	-88.52
	Min	-100.0
	Max	465.4
0 to 238 Weeks	n	238
	Mean	-64.20
	SD	69.63
	Median	-88.52
	Min	-100.0
	Max	465.4

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-36　全集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set

Time Period	Statistic	All Subjects N=238
Treatment Period	n	238
	Mean	-64.20
	SD	69.63
	Median	-88.52
	Min	-100.0
	Max	465.4

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.

Note: Results are based upon average seizure frequency over 28 days.

Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-37　日本人集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS

Table 8.1.1.2.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set - Japanese

Time Period	Statistic	All Subjects N=37
0 to 22 Weeks	n	37
	Mean	-72.12
	SD	52.00
	Median	-85.64
	Min	-100.0
	Max	193.5
>22 to 46 Weeks	n	36
	Mean	-67.19
	SD	59.89
	Median	-99.14
	Min	-100.0
	Max	228.9
>46 to 94 Weeks	n	32
	Mean	-69.01
	SD	57.03
	Median	-87.84
	Min	-100.0
	Max	195.2

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-37　日本人集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set - Japanese

Time Period	Statistic	All Subjects N=37
>94 to 142 Weeks	n	23
	Mean	-62.64
	SD	76.11
	Median	-88.48
	Min	-100.0
	Max	239.0
>142 to 190 Weeks	n	11
	Mean	-66.05
	SD	55.78
	Median	-85.45
	Min	-100.0
	Max	95.2
>190 to 238 Weeks	n	0
	Mean	
	SD	
	Median	
	Min	
	Max	

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-37　日本人集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set - Japanese

Time Period	Statistic	All Subjects N=37
0 to 46 Weeks	n	37
	Mean	-69.75
	SD	53.87
	Median	-88.44
	Min	-100.0
	Max	211.1
0 to 46 Weeks (> 22 Weeks)	n	36
	Mean	-69.41
	SD	54.60
	Median	-89.75
	Min	-100.0
	Max	211.1
0 to 94 Weeks	n	37
	Mean	-69.86
	SD	51.45
	Median	-82.95
	Min	-100.0
	Max	203.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-37　日本人集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set - Japanese

Time Period	Statistic	All Subjects N=37
0 to 94 Weeks (> 46 Weeks)	n	32
	Mean	-67.93
	SD	54.35
	Median	-80.15
	Min	-100.0
	Max	203.0
0 to 142 Weeks	n	37
	Mean	-68.98
	SD	50.36
	Median	-81.82
	Min	-100.0
	Max	166.0
0 to 142 Weeks (> 94 Weeks)	n	23
	Mean	-62.68
	SD	60.41
	Median	-77.43
	Min	-100.0
	Max	166.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-37　日本人集団の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.2.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Treatment Period

Analysis Set: Full Analysis Set - Japanese

Time Period	Statistic	All Subjects N=37
0 to 190 Weeks	n	37
	Mean	-68.85
	SD	50.85
	Median	-81.82
	Min	-100.0
	Max	166.0
0 to 238 Weeks	n	37
	Mean	-68.85
	SD	50.85
	Median	-81.82
	Min	-100.0
	Max	166.0
Treatment Period	n	37
	Mean	-68.85
	SD	50.85
	Median	-81.82
	Min	-100.0
	Max	166.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-38　全集団の試験完了例の集団での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS

Table 8.1.1.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Completer Cohort

Analysis Set: Full Analysis Set

Completer Cohort	Time Period	Statistic	All Subjects N=238
22 Weeks	0 to 22 Weeks	n	207
		Mean	-69.27
		SD	59.66
		Median	-88.20
		Min	-100.0
		Max	473.8
46 Weeks	0 to 22 Weeks	n	176
		Mean	-73.35
		SD	41.19
		Median	-88.18
		Min	-100.0
		Max	193.5
	>22 to 46 Weeks	n	176
		Mean	-70.18
		SD	55.51
		Median	-90.27
		Min	-100.0
		Max	318.5

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-38　全集団の試験完了例の集団での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.1
PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Completer Cohort
Analysis Set: Full Analysis Set

Completer Cohort	Time Period	Statistic	All Subjects N=238
46 Weeks	0 to 46 Weeks	n	176
		Mean	-71.31
		SD	43.76
		Median	-86.32
		Min	-100.0
		Max	211.1
94 Weeks	0 to 22 Weeks	n	107
		Mean	-73.01
		SD	44.41
		Median	-90.54
		Min	-100.0
		Max	193.5
	>22 to 46 Weeks	n	107
		Mean	-68.85
		SD	54.35
		Median	-88.69
		Min	-100.0
		Max	262.2

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-38　全集団の試験完了例の集団での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.1
PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Completer Cohort
Analysis Set: Full Analysis Set

Completer Cohort	Time Period	Statistic	All Subjects N=238
94 Weeks	>46 to 94 Weeks	n	107
		Mean	-78.47
		SD	39.08
		Median	-93.19
		Min	-100.0
		Max	195.2
	0 to 46 Weeks	n	107
		Mean	-70.86
		SD	46.69
		Median	-86.09
		Min	-100.0
		Max	211.1
	0 to 94 Weeks	n	107
		Mean	-74.70
		SD	39.87
		Median	-89.45
		Min	-100.0
		Max	203.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-39　日本人集団の試験完了例の集団での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS

Table 8.1.1.1.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Completer Cohort

Analysis Set: Full Analysis Set - Japanese

Completer Cohort	Time Period	Statistic	All Subjects N=37
22 Weeks	0 to 22 Weeks	n	37
		Mean	-72.12
		SD	52.00
		Median	-85.64
		Min	-100.0
		Max	193.5
46 Weeks	0 to 22 Weeks	n	32
		Mean	-70.57
		SD	55.23
		Median	-88.09
		Min	-100.0
		Max	193.5
	>22 to 46 Weeks	n	32
		Mean	-65.28
		SD	62.42
		Median	-96.45
		Min	-100.0
		Max	228.9

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-39　日本人集団の試験完了例の集団での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.1.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Completer Cohort

Analysis Set: Full Analysis Set - Japanese

Completer Cohort	Time Period	Statistic	All Subjects N=37
46 Weeks	0 to 46 Weeks	n	32
		Mean	-67.80
		SD	57.01
		Median	-87.41
		Min	-100.0
		Max	211.1
94 Weeks	0 to 22 Weeks	n	25
		Mean	-65.03
		SD	61.21
		Median	-83.24
		Min	-100.0
		Max	193.5
	>22 to 46 Weeks	n	25
		Mean	-61.21
		SD	68.49
		Median	-94.61
		Min	-100.0
		Max	228.9

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

表 2.1-39　日本人集団の試験完了例の集団での Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率：FAS（続き）

Table 8.1.1.1.1

PGTCS Frequency Percent Changes from Combined Baseline per 28 Days by Completer Cohort

Analysis Set: Full Analysis Set - Japanese

Completer Cohort	Time Period	Statistic	All Subjects N=37
94 Weeks	>46 to 94 Weeks	n	25
		Mean	-64.38
		SD	62.39
		Median	-83.38
		Min	-100.0
		Max	195.2
	0 to 46 Weeks	n	25
		Mean	-63.03
		SD	63.04
		Median	-81.62
		Min	-100.0
		Max	211.1
	0 to 94 Weeks	n	25
		Mean	-63.71
		SD	60.34
		Median	-73.25
		Min	-100.0
		Max	203.0

Max=maximum, Min=minimum, PGTCS=primary generalized tonic-clonic seizure, SD=standard deviation.
Note: Results are based upon average seizure frequency over 28 days.
Note: Combined Baseline is the combined 12-week Historical and 4-week Prospective Baseline from SP0982.

Reference: Listings 2.7, 6.2

2.1.4.2 その他の評価項目

2.1.4.2.1 欠神発作及びミオクロニー発作発現日数の変化量

本治験の SS での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量を年齢グループ別及び期間別に表 2.1-40（全集団）及び表 2.1-41（日本人集団）に示し、試験完了例の集団での欠神発作発現日数及び Prospective ベースライン期間に対する変化量を年齢グループ別及び期間別に表 2.1-42（全集団）及び表 2.1-43（日本人集団）に示した。また、治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量を年齢グループ別及び期間別に表 2.1-44（全集団）及び表 2.1-45（日本人集団）に示し、試験完了例の集団でのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量を年齢グループ別及び期間別に表 2.1-46（全集団）及び表 2.1-47（日本人集団）に示した。

全集団の Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作発現日数の変化量は、平均値及び中央値がそれぞれ−2.0 及び 0.0 日（範囲：−27～22 日）であった。

日本人集団の Prospective ベースライン期間に対する治療期間の 28 日あたりの欠神発作発現日数の変化量は、平均値及び中央値がそれぞれ−0.1 及び 0.0 日（範囲：−4～4 日）で、全集団と比べて変化は小さかった。日本人集団では欠神発作を発現した被験者は 9 例で、全集団と比べて被験者数が少なかったことが影響している可能性があり、結果の解釈には注意が必要である。

全集団の Prospective ベースライン期間に対する治療期間の 28 日あたりのミオクロニー発作発現日数の変化量は、平均値及び中央値がそれぞれ−1.0 及び 0.0 日（範囲：−27～27 日）であった。

日本人集団の Prospective ベースライン期間に対する治療期間の 28 日あたりのミオクロニー発作発現日数の変化量は、平均値及び中央値がそれぞれ−1.9 及び 0.0 日（範囲：−9～1 日）で、試験完了例の集団も含め一貫して減少した。

表 2.1-40　全集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.1.2

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=92)														
Prospective Baseline	92	5.5	9.0	0.0	0.0,8.1	0	28							
0 to 22 Weeks	92	3.8	7.3	0.0	0.0,5.3	0	28	92	-1.7	6.2	0.0	-2.3,0.0	-27	28
0 to 46 Weeks	92	3.8	7.3	0.1	0.0,5.0	0	28	92	-1.6	6.7	0.0	-2.6,0.1	-27	28
0 to 46 Weeks (> 22 Weeks)	72	3.7	6.8	0.2	0.0,5.1	0	28	72	-1.9	7.5	0.0	-3.4,0.1	-27	28
0 to 94 Weeks	92	3.6	6.8	0.1	0.0,3.9	0	28	92	-1.9	6.6	0.0	-2.5,0.1	-27	22
0 to 94 Weeks (> 46 Weeks)	56	3.6	6.1	0.2	0.0,4.4	0	26	56	-2.1	7.8	0.0	-4.2,0.1	-27	22
Treatment Period	92	3.5	6.7	0.1	0.0,3.9	0	28	92	-2.0	6.8	0.0	-2.5,0.1	-27	22

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-40　全集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=4 to <12

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=8)														
Prospective Baseline	8	1.0	2.1	0.0	0.0,1.0	0	6							
0 to 22 Weeks	8	0.8	2.3	0.0	0.0,0.0	0	7	8	-0.2	0.8	0.0	0.0,0.0	-2	1
0 to 46 Weeks	8	1.1	2.4	0.0	0.0,1.1	0	7	8	0.1	1.2	0.0	0.0,0.3	-2	2
0 to 46 Weeks (> 22 Weeks)	5	0.5	1.0	0.0	0.0,0.0	0	2	5	0.5	1.0	0.0	0.0,0.0	0	2
0 to 94 Weeks	8	1.3	2.6	0.0	0.0,2.0	0	7	8	0.3	1.7	0.0	0.0,0.3	-2	4
0 to 94 Weeks (> 46 Weeks)	3	1.3	2.3	0.0	0.0,4.0	0	4	3	1.3	2.3	0.0	0.0,4.0	0	4
Treatment Period	8	1.3	2.6	0.0	0.0,2.0	0	7	8	0.3	1.7	0.0	0.0,0.3	-2	4

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-40　全集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=12 to <18

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=20)														
Prospective Baseline	20	2.8	7.2	0.0	0.0,1.0	0	28							
0 to 22 Weeks	20	2.0	5.6	0.0	0.0,0.5	0	22	20	-0.7	2.0	0.0	-0.5,0.1	-6	2
0 to 46 Weeks	20	1.9	5.3	0.0	0.0,0.5	0	22	20	-0.8	2.3	0.0	0.0,0.2	-7	1
0 to 46 Weeks (> 22 Weeks)	15	1.1	2.9	0.0	0.0,0.8	0	11	15	-0.5	2.1	0.0	0.0,0.3	-7	1
0 to 94 Weeks	20	1.8	5.3	0.0	0.0,0.5	0	22	20	-0.9	2.3	0.0	-0.2,0.0	-7	1
0 to 94 Weeks (> 46 Weeks)	13	1.1	3.0	0.1	0.0,0.6	0	11	13	-0.8	2.2	0.0	0.0,0.1	-7	1
Treatment Period	20	1.8	5.3	0.0	0.0,0.4	0	22	20	-1.0	2.2	0.0	-0.5,0.0	-7	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-40　全集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=64)														
Prospective Baseline	64	6.9	9.7	0.9	0.0,10.0	0	28							
0 to 22 Weeks	64	4.8	8.0	0.2	0.0,6.5	0	28	64	-2.1	7.3	0.0	-3.2,0.0	-27	28
0 to 46 Weeks	64	4.8	8.0	0.2	0.0,6.0	0	28	64	-2.1	7.9	0.0	-3.4,0.1	-27	28
0 to 46 Weeks (> 22 Weeks)	52	4.8	7.6	0.2	0.0,6.6	0	28	52	-2.6	8.7	0.0	-4.7,0.1	-27	28
0 to 94 Weeks	64	4.4	7.5	0.2	0.0,6.1	0	28	64	-2.4	7.8	0.0	-3.9,0.1	-27	22
0 to 94 Weeks (> 46 Weeks)	40	4.5	6.8	0.4	0.0,7.8	0	26	40	-2.7	9.0	0.0	-7.5,0.1	-27	22
Treatment Period	64	4.3	7.3	0.2	0.0,6.1	0	28	64	-2.6	8.0	0.0	-3.9,0.1	-27	22

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-40　全集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=65

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
0 to 22 Weeks	0							0						
0 to 46 Weeks	0							0						
0 to 46 Weeks (> 22 Weeks)	0							0						
0 to 94 Weeks	0							0						
0 to 94 Weeks (> 46 Weeks)	0							0						
Treatment Period	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-41　日本人集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.1.2.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: All Subjects

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=9)														
Prospective Baseline	9	0.7	1.5	0.0	0.0,0.0	0	4							
0 to 22 Weeks	9	0.2	0.4	0.0	0.0,0.2	0	1	9	-0.5	1.4	0.0	0.0,0.0	-4	0
0 to 46 Weeks	9	0.6	1.1	0.1	0.0,0.3	0	3	9	-0.1	1.7	0.0	0.0,0.3	-4	2
0 to 46 Weeks (> 22 Weeks)	9	0.6	1.1	0.1	0.0,0.3	0	3	9	-0.1	1.7	0.0	0.0,0.3	-4	2
0 to 94 Weeks	9	0.7	1.4	0.1	0.0,0.4	0	4	9	-0.0	2.1	0.0	0.0,0.1	-4	4
0 to 94 Weeks (> 46 Weeks)	9	0.7	1.4	0.1	0.0,0.4	0	4	9	-0.0	2.1	0.0	0.0,0.1	-4	4
Treatment Period	9	0.6	1.3	0.1	0.0,0.4	0	4	9	-0.1	2.1	0.0	0.0,0.1	-4	4

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-41　日本人集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=4 to <12

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=1)														
Prospective Baseline	1	0.0	-	0.0	0.0,0.0	0	0							
0 to 22 Weeks	1	0.0	-	0.0	0.0,0.0	0	0	1	0.0	-	0.0	0.0,0.0	0	0
0 to 46 Weeks	1	2.3	-	2.3	2.3,2.3	2	2	1	2.3	-	2.3	2.3,2.3	2	2
0 to 46 Weeks (> 22 Weeks)	1	2.3	-	2.3	2.3,2.3	2	2	1	2.3	-	2.3	2.3,2.3	2	2
0 to 94 Weeks	1	4.0	-	4.0	4.0,4.0	4	4	1	4.0	-	4.0	4.0,4.0	4	4
0 to 94 Weeks (> 46 Weeks)	1	4.0	-	4.0	4.0,4.0	4	4	1	4.0	-	4.0	4.0,4.0	4	4
Treatment Period	1	4.0	-	4.0	4.0,4.0	4	4	1	4.0	-	4.0	4.0,4.0	4	4

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-41　日本人集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=12 to <18

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=5)														
Prospective Baseline	5	0.4	0.9	0.0	0.0,0.0	0	2							
0 to 22 Weeks	5	0.3	0.4	0.2	0.0,0.4	0	1	5	-0.1	0.5	0.0	0.0,0.2	-1	0
0 to 46 Weeks	5	0.6	1.2	0.1	0.0,0.3	0	3	5	0.2	0.3	0.1	0.0,0.3	0	1
0 to 46 Weeks (> 22 Weeks)	5	0.6	1.2	0.1	0.0,0.3	0	3	5	0.2	0.3	0.1	0.0,0.3	0	1
0 to 94 Weeks	5	0.4	0.7	0.1	0.0,0.4	0	2	5	0.0	0.3	0.0	0.0,0.1	-0	0
0 to 94 Weeks (> 46 Weeks)	5	0.4	0.7	0.1	0.0,0.4	0	2	5	0.0	0.3	0.0	0.0,0.1	-0	0
Treatment Period	5	0.3	0.4	0.1	0.0,0.4	0	1	5	-0.1	0.6	0.0	0.0,0.1	-1	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-41　日本人集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=18 to <65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=3)														
Prospective Baseline	3	1.4	2.5	0.0	0.0,4.3	0	4							
0 to 22 Weeks	3	0.1	0.1	0.0	0.0,0.2	0	0	3	-1.4	2.4	0.0	-4.1,0.0	-4	0
0 to 46 Weeks	3	0.0	0.1	0.0	0.0,0.1	0	0	3	-1.4	2.4	0.0	-4.2,0.0	-4	0
0 to 46 Weeks (> 22 Weeks)	3	0.0	0.1	0.0	0.0,0.1	0	0	3	-1.4	2.4	0.0	-4.2,0.0	-4	0
0 to 94 Weeks	3	0.0	0.0	0.0	0.0,0.1	0	0	3	-1.4	2.4	0.0	-4.2,0.0	-4	0
0 to 94 Weeks (> 46 Weeks)	3	0.0	0.0	0.0	0.0,0.1	0	0	3	-1.4	2.4	0.0	-4.2,0.0	-4	0
Treatment Period	3	0.0	0.0	0.0	0.0,0.1	0	0	3	-1.4	2.5	0.0	-4.2,0.0	-4	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-41　日本人集団の治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.2.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
0 to 22 Weeks	0							0						
0 to 46 Weeks	0							0						
0 to 46 Weeks (> 22 Weeks)	0							0						
0 to 94 Weeks	0							0						
0 to 94 Weeks (> 46 Weeks)	0							0						
Treatment Period	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-42　全集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=92)														
Prospective Baseline	92	5.5	9.0	0.0	0.0,8.1	0	28							
22 Weeks	70	3.8	6.9	0.2	0.0,5.4	0	28	70	-2.0	7.0	0.0	-3.4,0.0	-27	28
46 Weeks	57	3.9	6.8	0.2	0.0,5.1	0	28	57	-1.6	7.8	0.0	-3.4,0.2	-27	28
94 Weeks	35	2.4	4.4	0.1	0.0,3.4	0	18	35	-3.2	7.6	0.0	-5.6,0.1	-27	10

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-42　全集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=4 to <12

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=8)														
Prospective Baseline	8	1.0	2.1	0.0	0.0,1.0	0	6							
22 Weeks	5	0.0	0.0	0.0	0.0,0.0	0	0	5	0.0	0.0	0.0	0.0,0.0	0	0
46 Weeks	4	0.6	1.1	0.0	0.0,1.1	0	2	4	0.6	1.1	0.0	0.0,1.1	0	2
94 Weeks	3	1.3	2.3	0.0	0.0,4.0	0	4	3	1.3	2.3	0.0	0.0,4.0	0	4

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-42　全集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=12 to <18

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=20)														
Prospective Baseline	20	2.8	7.2	0.0	0.0,1.0	0	28							
22 Weeks	14	1.3	3.7	0.1	0.0,0.6	0	14	14	-0.4	1.7	0.0	0.0,0.4	-4	2
46 Weeks	13	1.3	3.1	0.1	0.0,0.8	0	11	13	-0.6	2.3	0.0	0.0,0.3	-7	1
94 Weeks	8	0.4	0.6	0.1	0.0,0.6	0	2	8	-0.4	1.5	0.0	-0.2,0.3	-4	1

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-42　全集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=64)														
Prospective Baseline	64	6.9	9.7	0.9	0.0,10.0	0	28							
22 Weeks	51	4.8	7.6	0.4	0.0,7.0	0	28	51	-2.7	8.1	0.0	-5.3,0.0	-27	28
46 Weeks	40	5.1	7.6	0.3	0.0,7.6	0	28	40	-2.2	9.2	0.0	-4.7,0.1	-27	28
94 Weeks	24	3.2	5.1	0.2	0.0,4.2	0	18	24	-4.7	8.8	-0.3	-8.5,0.0	-27	10

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-42　全集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=65

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
22 Weeks	0							0						
46 Weeks	0							0						
94 Weeks	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-43　日本人集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.1.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: All Subjects

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=9)														
Prospective Baseline	9	0.7	1.5	0.0	0.0,0.0	0	4							
22 Weeks	9	0.2	0.4	0.0	0.0,0.2	0	1	9	-0.5	1.4	0.0	0.0,0.0	-4	0
46 Weeks	9	0.6	1.1	0.1	0.0,0.3	0	3	9	-0.1	1.7	0.0	0.0,0.3	-4	2
94 Weeks	6	1.0	1.6	0.0	0.0,1.6	0	4	6	-0.1	2.6	0.0	-0.4,0.0	-4	4

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-43　日本人集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=4 to <12

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=1)														
Prospective Baseline	1	0.0	-	0.0	0.0,0.0	0	0							
22 Weeks	1	0.0	-	0.0	0.0,0.0	0	0	1	0.0	-	0.0	0.0,0.0	0	0
46 Weeks	1	2.3	-	2.3	2.3,2.3	2	2	1	2.3	-	2.3	2.3,2.3	2	2
94 Weeks	1	4.0	-	4.0	4.0,4.0	4	4	1	4.0	-	4.0	4.0,4.0	4	4

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-43　日本人集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=12 to <18

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=5)														
Prospective Baseline	5	0.4	0.9	0.0	0.0,0.0	0	2							
22 Weeks	5	0.3	0.4	0.2	0.0,0.4	0	1	5	-0.1	0.5	0.0	0.0,0.2	-1	0
46 Weeks	5	0.6	1.2	0.1	0.0,0.3	0	3	5	0.2	0.3	0.1	0.0,0.3	0	1
94 Weeks	2	0.8	1.1	0.8	0.0,1.6	0	2	2	-0.2	0.3	-0.2	-0.4,0.0	-0	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-43　日本人集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=18 to <65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=3)														
Prospective Baseline	3	1.4	2.5	0.0	0.0,4.3	0	4							
22 Weeks	3	0.1	0.1	0.0	0.0,0.2	0	0	3	-1.4	2.4	0.0	-4.1,0.0	-4	0
46 Weeks	3	0.0	0.1	0.0	0.0,0.1	0	0	3	-1.4	2.4	0.0	-4.2,0.0	-4	0
94 Weeks	3	0.0	0.0	0.0	0.0,0.1	0	0	3	-1.4	2.4	0.0	-4.2,0.0	-4	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-43　日本人集団の試験完了例の集団での治療期間における 28 日あたりの欠神発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.1.1.1

Days with Absence Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
22 Weeks	0							0						
46 Weeks	0							0						
94 Weeks	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 6.3.1

表 2.1-44　全集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.4.2

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=94)														
Prospective Baseline	94	3.6	6.1	0.0	0.0,5.2	0	28							
0 to 22 Weeks	94	2.9	6.7	0.0	0.0,1.6	0	28	94	-0.6	7.0	0.0	-1.2,0.0	-25	28
0 to 46 Weeks	94	2.7	6.5	0.0	0.0,1.6	0	28	94	-0.9	7.0	0.0	-1.9,0.0	-26	28
0 to 46 Weeks (> 22 Weeks)	82	2.9	6.7	0.0	0.0,2.1	0	28	82	-0.7	7.1	0.0	-1.9,0.0	-26	28
0 to 94 Weeks	94	2.6	6.2	0.0	0.0,1.7	0	28	94	-1.0	6.8	0.0	-2.0,0.0	-27	27
0 to 94 Weeks (> 46 Weeks)	66	1.3	3.4	0.0	0.0,1.3	0	22	66	-1.9	5.8	0.0	-3.3,0.0	-27	22
Treatment Period	94	2.5	6.2	0.0	0.0,1.5	0	28	94	-1.0	6.8	0.0	-2.0,0.0	-27	27

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-44　全集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=4 to <12

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=2)														
Prospective Baseline	2	0.0	0.0	0.0	0.0,0.0	0	0							
0 to 22 Weeks	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0
0 to 46 Weeks	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0
0 to 46 Weeks (> 22 Weeks)	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0
0 to 94 Weeks	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0
0 to 94 Weeks (> 46 Weeks)	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0
Treatment Period	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-44　全集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=12 to <18

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=11)														
Prospective Baseline	11	3.8	6.3	0.0	0.0,10.0	0	17							
0 to 22 Weeks	11	1.5	3.6	0.2	0.0,1.3	0	12	11	-2.3	5.6	0.0	-0.9,0.1	-17	1
0 to 46 Weeks	11	1.3	3.0	0.1	0.0,1.2	0	10	11	-2.5	5.6	0.0	-1.9,0.0	-17	1
0 to 46 Weeks (> 22 Weeks)	8	1.6	3.5	0.0	0.0,1.1	0	10	8	-1.5	3.0	0.0	-1.5,0.0	-9	0
0 to 94 Weeks	11	1.0	2.2	0.1	0.0,1.3	0	8	11	-2.8	5.6	0.0	-4.6,0.0	-17	1
0 to 94 Weeks (> 46 Weeks)	7	1.3	2.8	0.1	0.0,1.3	0	8	7	-2.1	3.3	-0.5	-4.6,0.0	-9	0
Treatment Period	11	0.8	1.5	0.1	0.0,1.2	0	5	11	-3.0	5.7	0.0	-7.0,0.0	-17	1

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-44　全集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=80)														
Prospective Baseline	80	3.7	6.2	0.0	0.0,5.7	0	28							
0 to 22 Weeks	80	3.2	7.1	0.0	0.0,2.1	0	28	80	-0.5	7.3	0.0	-1.7,0.0	-25	28
0 to 46 Weeks	80	3.0	6.9	0.0	0.0,2.0	0	28	80	-0.7	7.2	0.0	-2.0,0.0	-26	28
0 to 46 Weeks (> 22 Weeks)	71	3.1	7.1	0.0	0.0,2.4	0	28	71	-0.7	7.6	0.0	-2.0,0.0	-26	28
0 to 94 Weeks	80	2.8	6.7	0.0	0.0,2.0	0	28	80	-0.9	7.0	0.0	-2.0,0.0	-27	27
0 to 94 Weeks (> 46 Weeks)	57	1.3	3.5	0.0	0.0,1.4	0	22	57	-1.9	6.2	0.0	-3.3,0.0	-27	22
Treatment Period	80	2.8	6.7	0.0	0.0,1.7	0	28	80	-0.9	7.0	0.0	-2.1,0.0	-27	27

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-44　全集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=65

Treatment Group / Time Period	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=1)														
Prospective Baseline	1	0.0	-	0.0	0.0,0.0	0	0							
0 to 22 Weeks	1	5.4	-	5.4	5.4,5.4	5	5	1	5.4	-	5.4	5.4,5.4	5	5
0 to 46 Weeks	1	5.5	-	5.5	5.5,5.5	5	5	1	5.5	-	5.5	5.5,5.5	5	5
0 to 46 Weeks (> 22 Weeks)	1	5.5	-	5.5	5.5,5.5	5	5	1	5.5	-	5.5	5.5,5.5	5	5
0 to 94 Weeks	1	5.5	-	5.5	5.5,5.5	5	5	1	5.5	-	5.5	5.5,5.5	5	5
0 to 94 Weeks (> 46 Weeks)	0							0						
Treatment Period	1	5.5	-	5.5	5.5,5.5	5	5	1	5.5	-	5.5	5.5,5.5	5	5

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-45　日本人集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.4.2.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: All Subjects

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=16)														
Prospective Baseline	16	3.2	4.7	0.0	0.0,7.1	0	12							
0 to 22 Weeks	16	2.5	4.9	0.0	0.0,2.3	0	16	16	-0.7	3.5	0.0	-0.4,0.0	-7	8
0 to 46 Weeks	16	1.7	3.2	0.0	0.0,1.8	0	10	16	-1.5	2.9	0.0	-1.5,0.0	-7	1
0 to 46 Weeks (> 22 Weeks)	15	1.8	3.3	0.0	0.0,2.5	0	10	15	-1.6	3.0	0.0	-1.9,0.0	-7	1
0 to 94 Weeks	16	1.4	2.8	0.0	0.0,1.2	0	8	16	-1.7	3.1	0.0	-2.8,0.0	-8	1
0 to 94 Weeks (> 46 Weeks)	13	1.1	2.3	0.0	0.0,0.5	0	8	13	-2.2	3.3	0.0	-4.6,0.0	-8	0
Treatment Period	16	1.2	2.5	0.0	0.0,1.0	0	8	16	-1.9	3.4	0.0	-4.0,0.0	-9	1

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-45　日本人集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=4 to <12

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
0 to 22 Weeks	0							0						
0 to 46 Weeks	0							0						
0 to 46 Weeks (> 22 Weeks)	0							0						
0 to 94 Weeks	0							0						
0 to 94 Weeks (> 46 Weeks)	0							0						
Treatment Period	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-45　日本人集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=12 to <18

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=4)														
Prospective Baseline	4	3.6	5.7	1.0	0.5,6.6	0	12							
0 to 22 Weeks	4	3.5	5.9	0.9	0.1,6.9	0	12	4	-0.1	0.6	0.1	-0.4,0.3	-1	1
0 to 46 Weeks	4	2.8	4.9	0.6	0.0,5.6	0	10	4	-0.7	0.9	-0.5	-1.5,0.0	-2	0
0 to 46 Weeks (> 22 Weeks)	4	2.8	4.9	0.6	0.0,5.6	0	10	4	-0.7	0.9	-0.5	-1.5,0.0	-2	0
0 to 94 Weeks	4	2.0	3.7	0.3	0.0,4.0	0	8	4	-1.5	2.1	-0.7	-2.8,-0.2	-5	0
0 to 94 Weeks (> 46 Weeks)	4	2.0	3.7	0.3	0.0,4.0	0	8	4	-1.5	2.1	-0.7	-2.8,-0.2	-5	0
Treatment Period	4	1.4	2.5	0.3	0.0,2.8	0	5	4	-2.1	3.2	-0.8	-4.0,-0.3	-7	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-45　日本人集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=18 to <65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=12)														
Prospective Baseline	12	3.0	4.6	0.0	0.0,7.1	0	12							
0 to 22 Weeks	12	2.2	4.8	0.0	0.0,1.5	0	16	12	-0.9	4.0	0.0	-2.3,0.0	-7	8
0 to 46 Weeks	12	1.3	2.6	0.0	0.0,1.3	0	8	12	-1.7	3.4	0.0	-3.5,0.0	-7	1
0 to 46 Weeks (> 22 Weeks)	11	1.4	2.7	0.0	0.0,2.5	0	8	11	-1.9	3.5	0.0	-7.0,0.0	-7	1
0 to 94 Weeks	12	1.2	2.6	0.0	0.0,1.0	0	8	12	-1.8	3.5	0.0	-3.5,0.0	-8	1
0 to 94 Weeks (> 46 Weeks)	9	0.7	1.5	0.0	0.0,0.0	0	4	9	-2.5	3.8	0.0	-7.0,0.0	-8	0
Treatment Period	12	1.2	2.6	0.0	0.0,0.7	0	8	12	-1.9	3.6	0.0	-3.5,0.0	-9	1

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-45　日本人集団の治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.2.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Time Period and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
0 to 22 Weeks	0							0						
0 to 46 Weeks	0							0						
0 to 46 Weeks (> 22 Weeks)	0							0						
0 to 94 Weeks	0							0						
0 to 94 Weeks (> 46 Weeks)	0							0						
Treatment Period	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period.

Reference: Listing 6.3.1

表 2.1-46　全集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.4.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: All Subjects

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=94)														
Prospective Baseline	94	3.6	6.1	0.0	0.0,5.2	0	28							
22 Weeks	84	3.2	7.1	0.0	0.0,2.5	0	28	84	-0.4	7.2	0.0	-1.1,0.0	-25	28
46 Weeks	68	1.8	5.0	0.0	0.0,1.3	0	28	68	-1.1	6.8	0.0	-1.5,0.0	-26	28
94 Weeks	38	0.7	1.5	0.0	0.0,0.7	0	8	38	-2.2	4.9	0.0	-3.3,0.0	-27	1

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listings 2.7, 6.3.1

表 2.1-46　全集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=4 to <12

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=2)														
Prospective Baseline	2	0.0	0.0	0.0	0.0,0.0	0	0							
22 Weeks	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0
46 Weeks	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0
94 Weeks	2	0.0	0.0	0.0	0.0,0.0	0	0	2	0.0	0.0	0.0	0.0,0.0	0	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listings 2.7, 6.3.1

表 2.1-46　全集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=12 to <18

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=11)														
Prospective Baseline	11	3.8	6.3	0.0	0.0,10.0	0	17							
22 Weeks	9	1.7	4.0	0.2	0.0,1.3	0	12	9	-2.9	6.1	0.0	-0.9,0.0	-17	1
46 Weeks	7	1.8	3.7	0.1	0.0,1.2	0	10	7	-1.7	3.2	0.0	-1.9,0.0	-9	0
94 Weeks	5	1.9	3.2	0.5	0.0,1.3	0	8	5	-2.8	3.9	-0.5	-4.6,0.0	-9	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listings 2.7, 6.3.1

表 2.1-46　全集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=18 to <65

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=80)														
Prospective Baseline	80	3.7	6.2	0.0	0.0,5.7	0	28							
22 Weeks	72	3.5	7.5	0.0	0.0,2.7	0	28	72	-0.2	7.4	0.0	-1.2,0.0	-25	28
46 Weeks	59	1.9	5.3	0.0	0.0,1.6	0	28	59	-1.0	7.2	0.0	-2.0,0.0	-26	28
94 Weeks	31	0.6	1.0	0.0	0.0,0.7	0	4	31	-2.2	5.3	0.0	-3.3,0.0	-27	1

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.
Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listings 2.7, 6.3.1

表 2.1-46　全集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set

Baseline Age in SP0982: >=65

Treatment Group / Completer Cohort	Observed Result							Change from Prospective Baseline						
	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=1)														
Prospective Baseline	1	0.0	-	0.0	0.0,0.0	0	0							
22 Weeks	1	5.4	-	5.4	5.4,5.4	5	5	1	5.4	-	5.4	5.4,5.4	5	5
46 Weeks	0							0						
94 Weeks	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported myoclonic seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listings 2.7, 6.3.1

表 2.1-47　日本人集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS

Table 8.2.4.1.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: All Subjects

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=16)														
Prospective Baseline	16	3.2	4.7	0.0	0.0,7.1	0	12							
22 Weeks	16	2.5	4.9	0.0	0.0,2.3	0	16	16	-0.7	3.5	0.0	-0.4,0.0	-7	8
46 Weeks	13	1.4	3.0	0.0	0.0,1.0	0	10	13	-1.9	3.1	0.0	-1.9,0.0	-7	0
94 Weeks	11	0.9	2.3	0.0	0.0,0.5	0	8	11	-1.8	3.1	0.0	-4.6,0.0	-8	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 2.7, 6.3.1

表 2.1-47　日本人集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=4 to <12

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
22 Weeks	0							0						
46 Weeks	0							0						
94 Weeks	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 2.7, 6.3.1

表 2.1-47　日本人集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=12 to <18

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=4)														
Prospective Baseline	4	3.6	5.7	1.0	0.5,6.6	0	12							
22 Weeks	4	3.5	5.9	0.9	0.1,6.9	0	12	4	-0.1	0.6	0.1	-0.4,0.3	-1	1
46 Weeks	4	2.8	4.9	0.6	0.0,5.6	0	10	4	-0.7	0.9	-0.5	-1.5,0.0	-2	0
94 Weeks	3	2.7	4.2	0.5	0.0,7.5	0	8	3	-1.7	2.5	-0.5	-4.6,0.0	-5	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 2.7,6.3.1

表 2.1-47　日本人集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=18 to <65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=12)														
Prospective Baseline	12	3.0	4.6	0.0	0.0,7.1	0	12							
22 Weeks	12	2.2	4.8	0.0	0.0,1.5	0	16	12	-0.9	4.0	0.0	-2.3,0.0	-7	8
46 Weeks	9	0.8	1.7	0.0	0.0,0.0	0	5	9	-2.4	3.6	0.0	-7.0,0.0	-7	0
94 Weeks	8	0.2	0.7	0.0	0.0,0.0	0	2	8	-1.9	3.5	0.0	-3.5,0.0	-8	0

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 2.7,6.3.1

表 2.1-47　日本人集団の試験完了例の集団での治療期間における 28 日あたりのミオクロニー発作発現日数及び Prospective ベースライン期間に対する変化量：SS（続き）

Table 8.2.4.1.1

Days with Myoclonic Seizures Observed Results and Change from Prospective Baseline per 28 Days by Completer Cohort and Baseline Age in SP0982

Analysis Set: Safety Set - Japanese

Baseline Age in SP0982: >=65

Treatment Group	Observed Result							Change from Prospective Baseline						
Completer Cohort	n	Mean	SD	Median	Q1,Q3	Min	Max	n	Mean	SD	Median	Q1,Q3	Min	Max
All Subjects (N=0)														
Prospective Baseline	0													
22 Weeks	0							0						
46 Weeks	0							0						
94 Weeks	0							0						

Max=maximum, Min=minimum, Q1=lower quartile, Q3=upper quartile, SD=standard deviation.

Note: Results are based upon average seizure days over 28 days for those subjects who have a history of or reported absence seizures in Combined Baseline or the Treatment Period. For the completer cohort rows, only the data for the implied time for the cohort is included in the analyses.

Reference: Listing 2.7,6.3.1

2.1.5 結論

第 2 回データカットオフ時点では、強直間代発作を有する 4 歳以上のてんかん患者に対する併用療法としてラコサミドの良好な忍容性が示され、安全性上の新たな懸念事項は認められなかった。

第 2 回データカットオフ時点での結果は、強直間代発作を有する 4 歳以上のてんかん患者に対するラコサミドの長期併用療法を支持するものであった。全集団では、各期間の試験完了例の集団間及び期間別の Combined ベースライン期間に対する治療期間の 28 日あたりの強直間代発作回数の変化率に一貫した減少が認められた。

新たな欠神発作及びミオクロニー発作を発現した被験者の割合、並びに欠神発作及びミオクロニー発作発現日数が増悪した被験者の割合は低かった。

日本人集団と全体集団の結果に大きな違いは認められなかった。日本人集団でもラコサミドの長期併用療法の忍容性と有効性が示された。

重篤な有害事象の詳細

死亡

該当なし。

その他の重篤な有害事象

被験者番号：[redacted]

重篤な有害事象一覧

基本語	医師記載用語	発現日/ 発現までの日数 a	発現時の投与量/ 持続期間	重症度/ 因果関係	転帰/ 治験薬の処置
大腸菌性尿路感染	大腸菌性尿路感染	2016 年 7 月 9 日/ 20 日	200 mg/日/ 10 日間	軽度/ 関連なし	回復/ 用量変更なし

a 本治験の治験薬初回投与日を 1 日目とした発現時の日数

基本語、医師記載用語：MedDRA ver. 16.1

本被験者は、24 歳の黒人女性で、体重は 52.6 kg、BMI は 19.8 kg/m^2、10 歳にてんかんと診断された。既往歴・合併症はアレルギー性鼻炎、１型糖尿病、手根管症候群、ビタミンD欠乏、貧血、尿路感染、腎結石症、便秘及びウイルス感染であった。報告（CIOMS# 2016025943）によると、この他の既往歴として家族性危険因子、子宮内避妊具挿入及び高コレステロール血症があった。

本被験者は、2016 年 6 月 20 日に本治験に組み入れられ、2016 年 6 月 20 日にラコサミド 100 mg/日で投与を開始した。被験者は、同意撤回のため本治験を中止した（有害事象が理由ではない）。治験薬の最終投与日は 2018 年 2 月 4 日、最終来院日は 2018 年 3 月 31 日であった。

大腸菌性尿路感染（CIOMS# 2016025943）：

2016 年 7 月 9 日、被験者は右側腹部痛のため救急治療室を受診し、右側腹部痛によって誘発される症状はないと述べた。被験者は、会社から帰宅後に突然、不快感を覚えた。右側腹部に局所的で広がりのない強い圧迫を認め、体を動かすと痛みは悪化した。右側腹部痛は、薬理学的介入によって軽減した。同日、大腸菌性尿路感染と診断された（大腸菌数：100000 超）。被験者は救急治療室の受診中に 39.3°C の発熱があり、重度の鉄欠乏、排尿困難及び全身性の脱力が認められた。治療薬として insulin glargine、paracetamol、magnesium sulfate、prednisone、Gas-X、thomapyrin N、famotidine、simeticone、cefalexin、methylprednisolone、morphine、ondansetron、potassium、sodium chloride、ceftriaxone 及び tamazepam が投与された。被験者には、糖尿、高血糖、低ナトリウム血症、高血圧及び低カリウム血症も認められ、血液量減少症及び経口摂取減少と診断された。輸液の吸収は良好で、20 mEq のカリウムを含有する生理食塩液の投与が継続された。同日の臨床検査の結果は、白血球数が 8.2 K/UL（基準範囲：4.0～12.0 K/UL）、グルコース（随時血糖値）が 365 mg/dL（基準範囲：74～118 mg/dL）、尿素窒素が 9 mg/dL（基準範囲：8～26 mg/dL）、クレアチニンが 1.09 mg/dL（基準範囲：0.70～1.40 mg/dL）、ナトリウムが 128 mEq/L（基準範囲：136～144 mEq/L）、カリウムが 3.5 mEq/L（基準範囲：3.6～5.1 mEq/L）、クロールが 98 mEq/L（基準範囲：101～111 mEq/L）、尿中白血球数が 51～100/HPF であった。腹部及び骨盤のコンピュータ断

層撮影（CT）検査で、右腎の中央から下部に不規則で非対称な陰影が認められ、腎盂腎炎が示唆された。被験者は、hydrocortisone sodium succinate（240 mg/日）を 2 日間投与され、血糖値が上昇した（投与前：102、投与後：360）。また、治療薬として insulin glargine を 27 単位投与された。同日の尿検査の結果、蛋白尿及び血尿を認めたが、これらは大腸菌性尿路感染の診断に対して臨床的に影響を与えるものではなかった。被験者は「月経周期の過程」に起因する可能性のある子宮内疾患（子宮内避妊具の挿入によって子宮内膜が薄くなる症状）を有していた。直近の婦人科の受診は約 2 年前で、男児を出産したときであった。被験者は症状を訴えなかったが、悪臭尿が認められた。2016 年 7 月 10 日、好中球は 71.4%（基準範囲：31.0%～76.0%）であった。2016 年 7 月 11 日、グラム陰性桿菌は抗生物質（ampicillin、cefazolin、ceftriaxone、ciprofloxacin、gentamicin、nitrofurantoin、tobramycin、amikacin、ampicillin with sulbactum、cefepime、ceftazaidime、levofloxacin、trimethoprim with sulfamethoxazole 及び piperacillin with tazobactam）の耐性を持つ大腸菌であった。2016 年 7 月 12 日、白血球数は 6.0 K/UL であった。2016 年 7 月 13 日、臨床検査の結果は、グルコース（随時血糖値）が 273 mg/dL、尿素窒素が 9 mg/dL、クレアチニンが 0.82 mg/dL、ナトリウムが 135 mEq/L、カリウムが 3.8 mEq/L、クロールが 105 mEq/L であった。大腸菌性尿路感染の発現時、被験者はラコサミド 200 mg/日を 4 日間服用していた。なお、大腸菌性尿路感染の発現時の併用抗てんかん薬は lamotrigine で、その他の併用薬は ergocalciferol、insulin glargine 及び insulin human であった。更に、大腸菌性尿路感染の発現日と同日に iopamidol が投与された。

被験者番号：[redacted]

重篤な有害事象一覧

基本語	医師記載用語	発現日/ 発現までの日数 [a]	発現時の投与量/ 持続期間	重症度/ 因果関係	転帰/ 治験薬の処置
良性頭蓋内圧亢進	頭痛及び霧視を伴う偽性脳腫瘍	2017 年 2 月 12 日/ 179 日	200 mg/日/ 2 日間	中等度/ 関連なし	回復/ 用量変更なし

a　本治験の治験薬初回投与日を 1 日目とした発現時の日数

基本語、医師記載用語：MedDRA ver. 16.1

本被験者は、21 歳の白人女性で、体重は 96.2 kg、BMI は 39.8 kg/m^2、14 歳にてんかんと診断された。既往歴・合併症はカタプレキシー、片頭痛、ナルコレプシー、うつ病、不安、月経困難症、及び脱水であった。報告（CIOMS# 2017006449）によると、この他の既往歴として月経性痙攣、毛巣嚢胞、肥満、軽度貧血、多発性硬化症の家族歴及びアルコール症があった。

本被験者は、2016 年 8 月 17 日に本治験に組み入れられ、2016 年 8 月 18 日にラコサミド 50 mg/日で投与を開始した。被験者は本治験を継続した。

良性頭蓋内圧亢進（CIOMS# 2017006449）：

2017 年 2 月 12 日、被験者は進行中の頭痛（約 1 ヵ月間）及び霧視（約 2 週間）を有していた。被験者は、軽度の視力障害のため眼鏡を使用していた。検眼医を受診時に、視神経乳頭浮腫が認められた。被験者は、重度の頭痛により入院した。治療薬として lidocaine が投与され、症状が軽快した。2017 年 2 月 13 日、腰椎穿刺を実施し、磁気共鳴画像（MRI）検査で視神経乳頭浮腫を確認した。血清グルコースは 108 mg/dL（基準範囲：60～100 mg/dL）であった。治療薬として Diamox が投与された。2017 年 2 月 14 日、被験者は安定した状態で退院した。退院時の診断は、頭痛及び霧視を伴う偽性脳腫瘍、てんかん及び鉄欠乏性貧血の疑いであった。良性頭蓋内圧亢進の発現時、被験者はラコサミド 200 mg/日を 172 日間服用していた。なお、良性頭蓋内圧亢進の発現時の併用抗てんかん薬は eslicarbazepine 及び levetiracetam で、その他の併用薬は amoxicillin、ibuprofen 及び Midol であった。更に、良性頭蓋内圧亢進の発現日と同日に lidocaine が投与された。

2016 年 9 月 11 日、被験者は非重篤な毛巣嚢胞（1 回目）を発現した。毛巣嚢胞の治療薬として Bactrim、cefalexin 及び hydrocodone が投与された。2016 年 9 月 22 日、毛巣嚢胞は消失した。治験薬との因果関係は「関連なし」と評価された。

2017 年 1 月 13 日、被験者は非重篤な頭痛（1 回目）及び視力障害を発現した。2018 年 4 月 14 日時点で、頭痛（1 回目）は未消失であった。第 2 回データカットオフ時点で、視力障害は未消失であった。治験薬との因果関係は、いずれも「関連なし」と評価された。

2017 年 1 月 23 日、被験者は非重篤な毛巣嚢胞（2 回目）を発現した。毛巣嚢胞の治療薬として Bactrim 及び hydrocodone が投与された。第 2 回データカットオフ時点で、毛巣嚢胞は軽快していた。治験薬との因果関係は「関連なし」と評価された。

2017 年 1 月 26 日、被験者は非重篤な軽度の視神経乳頭浮腫を発現した。第 2 回データカットオフ時点で、視神経乳頭浮腫は軽快していた。治験薬との因果関係は「関連なし」と評価された。

2017 年 1 月 26 日、被験者は非重篤な中等度の視神経乳頭浮腫を発現した。第 2 回データカットオフ時点で、視神経乳頭浮腫は未消失であった。治験薬との因果関係は「関連なし」と評価された。

2017 年 2 月 12 日、被験者は良性頭蓋内圧亢進の発現日と同日に、非重篤な血圧上昇を発現した。第 2 回データカットオフ時点で、血圧上昇は未消失であった。治験薬との因果関係は「関連なし」と評価された。

2018 年 4 月 15 日、被験者は非重篤な頭痛（2 回目）を発現した。第 2 回データカットオフ時点で、頭痛（2 回目）は軽快していた。治験薬との因果関係は「関連なし」と評価された。