1.24.2.2　死亡および重篤な有害事象

死亡および重篤な有害事象［Source: Listing 14.3.2.4 および Listing 14.3.2.2］

MedImmune
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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.4
Treatment-emergent Adverse Events Resulting in Death - Safety Population

Treatment Group (Safety): Placebo

Subject	Date of Death	Study Day of Death	Number of Doses Received	Days Since Last Dose Until Death	Cause of Death	Adverse Event Contributing to Death: Preferred Term (Days Since AE Onset)	Adverse Event Contributing to Death: Relationship to Investigational Product
[redacted]	[redacted]20[redacted]	119	4	24	Due to disease	多臓器不全 (24)	Not related
[redacted]	[redacted]20[redacted]	240	5	110		特発性肺線維症 (110)	Not related

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/teae_dth1.sas (teae_dth1.rtf)
Standard Template SL_DTH_001

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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.4
Treatment-emergent Adverse Events Resulting in Death - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg

						Adverse Event Contributing to Death	
Subject	**Date of Death**	**Study Day of Death**	**Number of Doses Received**	**Days Since Last Dose Until Death**	**Cause of Death**	**Preferred Term (Days Since AE Onset)**	**Relationship to Investigational Product**
[redacted]	[redacted]20[redacted]	304	11	22	Not due to disease	肺炎 (22)	Not related
[redacted]	[redacted]20[redacted]	208	7	15	Due to disease	肺炎 (15)	Not related
[redacted]	[redacted]20[redacted]	502	16	56	Due to disease	特発性肺線維症 (56)	Not related
[redacted]	[redacted]20[redacted]	40	2	4	Due to disease	特発性肺線維症 (4)	Not related
[redacted]	[redacted]20[redacted]	196	7	30	Not due to disease	心停止 (30)	Not related

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/teae_dth1.sas (teae_dth1.rtf)
Standard Template SL_DTH_001

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CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.4
Treatment-emergent Adverse Events Resulting in Death - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg

Subject	Date of Death	Study Day of Death	Number of Doses Received	Days Since Last Dose Until Death	Cause of Death	Adverse Event Contributing to Death: Preferred Term (Days Since AE Onset)	Adverse Event Contributing to Death: Relationship to Investigational Product
[redacted]	[redacted]20[redacted]	49	1	40	Due to disease	特発性肺線維症 (40)	Related
[redacted]	[redacted]20[redacted]	93	4	2	Not due to disease	呼吸不全 (2)	Not related
[redacted]	[redacted]20[redacted]	143	5	20	Not due to disease	脳梗塞 (20)	Not related

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/teae_dth1.sas (teae_dth1.rtf)
Standard Template SL_DTH_001

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 72/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (337) **Total number of doses:** 13

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](301) [redacted]20[redacted]320) 20	11 [redacted]20[redacted](281)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](308) [redacted]20[redacted](311) 4
[redacted]20[redacted](364) [redacted]20[redacted](367) 4	13 [redacted]20[redacted](337)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](364) [redacted]20[redacted](367) 4
[redacted]20[redacted](386)	13 [redacted]20[redacted](337)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED UNKNOWN	Yes: [H] [redacted]20[redacted](388)

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 76/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (479) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](86) [redacted]20[redacted](334) 249	3 [redacted]20[redacted](59)	VT: 単径ヘルニア PT: 単径ヘルニア SOC: 胃腸障害	Not related Grade 1	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](333) [redacted]20[redacted](334) 2

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 63/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (372) **Total number of doses:** 13

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](26) [redacted]20[redacted](50) 25	1 [redacted]20[redacted](1)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](37) [redacted]20[redacted](50) 14
[redacted]20[redacted](84) [redacted]20[redacted](120) 37	2 [redacted]20[redacted](57)	VT: 左頬扁平上皮癌 PT: 皮膚有棘細胞癌 SOC: 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）	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](120) [redacted]20[redacted](120) 1
[redacted]20[redacted](384) [redacted]20[redacted](389) 6	13 [redacted]20[redacted](372)	VT: 直腸出血 PT: 直腸出血 SOC: 胃腸障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](384) [redacted]20[redacted](389) 6

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Australia
Subject:[redacted] **Age/Sex/Race[a]:** 63/M/W **First Dose Date:**[redacted]20[redacted] **Final Dose Date (day):**[redacted]20[redacted](372) **Total number of doses:** 13

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](393) [redacted]20[redacted](412) 20	13 [redacted]20[redacted](372)	VT: 血栓性静脈炎 PT: 血栓性静脈炎 SOC: 血管障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](393) [redacted]20[redacted](412) 20
[redacted]20[redacted](399) [redacted]20[redacted](412) 14	13 [redacted]20[redacted](372)	VT: 肺塞栓症 PT: 肺塞栓症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [L], [H] [redacted]20[redacted](393) [redacted]20[redacted](412) 20
[redacted]20[redacted](429) [redacted]20[redacted](441) 13	13 [redacted]20[redacted](372)	VT: 深部静脈血栓症 PT: 深部静脈血栓症 SOC: 血管障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](429) [redacted]20[redacted](441) 13

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 63/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (372) **Total number of doses:** 13

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (457) [redacted]20[redacted] (460) 4	13 [redacted]20[redacted] (372)	VT: インフルエンザ菌胸部感染症 PT: ヘモフィルス感染 SOC: 感染症および寄生虫症	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted] (457) [redacted]20[redacted] (460) 4

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 61/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (481) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](256) [redacted]20[redacted](257) 2	9 [redacted]20[redacted](234)	VT:低血圧虚脱(失神) PT: 失神 SOC: 神経系障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](256) [redacted]20[redacted](257) 2
[redacted]20[redacted](313) [redacted]20[redacted](316) 4	11 [redacted]20[redacted](285)	VT: 失神 PT: 失神 SOC: 神経系障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](313) [redacted]20[redacted](316) 4

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 75/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](458) **Total number of doses:** 15

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](5) [redacted]20[redacted](12) 8	1 [redacted]20[redacted](1)	VT: 尿路感染 PT: 尿路感染 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](6) [redacted]20[redacted](9) 4
[redacted]20[redacted](131) [redacted]20[redacted](132) 2	4 [redacted]20[redacted](110)	VT: 市中感染性肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](131) [redacted]20[redacted](132) 2
[redacted]20[redacted](152) [redacted]20[redacted](367) 216	5 [redacted]20[redacted](138)	VT: 間欠性両下肢腫脹 PT: 末梢腫脹 SOC: 一般・全身障害および投与部位の状態	Not related Grade 1	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](155) [redacted]20[redacted](156) 2

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Canada
Subject: [redacted] **Age/Sex/Race**[a]**:** 71/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (477) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] [redacted]20[redacted](575)		VT: 排尿困難 PT: 排尿困難 SOC: 腎および尿路障害	Not related Grade 1	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](538) [redacted]20[redacted](539) 2

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Canada
Subject: [redacted] **Age/Sex/Race[a]:** 70/F/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (174) **Total number of doses:** 7

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](204) [redacted]20[redacted]	7 [redacted]20[redacted](174)	VT:脳卒中 PT: 脳血管発作 SOC: 神経系障害	Not related Grade 4	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](204) [redacted]20[redacted](229) 26

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Israel
Subject: [redacted] **Age/Sex/Race[a]:** 65/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](57) **Total number of doses:** 3

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](78) [redacted]20[redacted](87) 10	3 [redacted]20[redacted](57)	VT: 乾癬増悪再燃 PT: 乾癬 SOC: 皮膚および皮下組織障害	Not related Grade 2	DRUG WITHDRAWN RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](78) [redacted]20[redacted]87) 10

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Israel
Subject: [redacted] **Age/Sex/Race[a]:** 78/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](83) **Total number of doses:** 4

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](103) ONGOING	4 [redacted]20[redacted](83)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 4	DOSE DELAYED	Yes: [L], [H], [P] [redacted]20[redacted](107)
[redacted]20[redacted](107) [redacted]20[redacted](119) 13	4 [redacted]20[redacted](83)	VT: 多臓器不全 PT: 多臓器不全 SOC: 一般・全身障害および投与部位の状態	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D], [H] [redacted]20[redacted](107) [redacted]20[redacted](119) 13
[redacted]20[redacted](110) ONGOING	4 [redacted]20[redacted](83)	VT: 呼吸不全 PT: 呼吸不全 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 4	DOSE NOT CHANGED	Yes: [L], [H], [P] [redacted]20[redacted](107)

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Peru
Subject: [redacted] **Age/Sex/Race[a]:** 71/F/O **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (93) **Total number of doses:** 4

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (115) [redacted]20[redacted] (156) 42	4 [redacted]20[redacted] (93)	VT:急性呼吸促迫 PT: 呼吸窮迫 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED WITH SEQUELAE	Yes: [H], [S] [redacted]20[redacted] (121) [redacted]20[redacted] (122) 2

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** Peru
Subject: [redacted] **Age/Sex/Race[a]:** 56/M/O **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (249) **Total number of doses:** 10

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (261) [redacted]20[redacted] (276) 16	10 [redacted]20[redacted] (249)	VT: 特発性肺線維症急性増悪の疑い PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted] (261) [redacted]20[redacted] (267) 7

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** United States of America
Subject: [redacted] **Age/Sex/Race**[a]**:** 66/F/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (223) **Total number of doses:** 9

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (160) ONGOING	6 [redacted]20[redacted] (139)	VT: 肺高血圧症 PT: 肺高血圧症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED	Yes: [H] [redacted]20[redacted] (175) [redacted]20[redacted] (180) 6

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 68/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](113) **Total number of doses:** 5

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](27) [redacted]20[redacted]41) 15	1 [redacted]20[redacted](1)	VT: 特発性肺線維症の増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](27) [redacted]20[redacted](30) 4
[redacted]20[redacted](125) [redacted]20[redacted](132) 8	5 [redacted]20[redacted](113)	VT: 失神 PT: 失神 SOC: 神経系障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](125) [redacted]20[redacted](132) 8
[redacted]20[redacted](148) [redacted]20[redacted](152) 5	5 [redacted]20[redacted](113)	VT:急性失神 PT: 失神 SOC: 神経系障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](148) [redacted]20[redacted](152) 5

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 68/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](113) **Total number of doses:** 5

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](175) [redacted]20[redacted](192) 18	5 [redacted]20[redacted](113)	VT: 特発性肺線維症の増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H], [P] [redacted]20[redacted](175) 20[redacted](180) 6
[redacted]20[redacted](206) [redacted]20[redacted](210) 5	5 [redacted]20[redacted](113)	VT: 急性拡張機能障害 PT: うっ血性心不全 SOC: 心臓障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H], [P] [redacted]20[redacted](206) 20[redacted](210) 5
[redacted]20[redacted](206) [redacted]20[redacted](210) 5	5 [redacted]20[redacted](113)	VT: 発作性上室性頻拍 PT: 上室性頻脈 SOC: 心臓障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H], [P] [redacted]20[redacted](206) 20[redacted](210) 5

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Placebo **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 68/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](113) **Total number of doses:** 5

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](223) [redacted]20[redacted](240) 18	5 [redacted]20[redacted](113)	VT: 特発性肺線維症の進行 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D], [H], [P] [redacted]20[redacted](223) [redacted]20[redacted](240) 18

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 77/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (477) **Total number of doses:** 17

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](41) [redacted]20[redacted](64) 24	2 [redacted]20[redacted](29)	VT: 左胸痛NOS PT: 胸痛 SOC: 一般・全身障害および投与部位の状態	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](62) [redacted]20[redacted](64) 3
[redacted]20[redacted](102) [redacted]20[redacted](133) 32	4 [redacted]20[redacted](83)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](116) [redacted]20[redacted](119) 4
[redacted]20[redacted](194) [redacted]20[redacted](237) 44	6 [redacted]20[redacted](169)	VT: 右変形性股関節症悪化 PT: 変形性関節症 SOC: 筋骨格系および結合組織障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](229) [redacted]20[redacted](237) 9

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 77/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](477) **Total number of doses:** 17

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](234) [redacted]20[redacted](254) 21	8 [redacted]20[redacted](225)	VT:右臀部血腫 PT: 血腫 SOC: 血管障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](249) [redacted]20[redacted](254) 6
[redacted]20[redacted](313) [redacted]20[redacted](316) 4	11 [redacted]20[redacted](309)	VT: 脳振盪 PT: 脳振盪 SOC: 傷害、中毒および処置合併症	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](313) [redacted]20[redacted](314) 2

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 76/F/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](423) **Total number of doses:** 16

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](138) [redacted]20[redacted](138) 1	5 [redacted]20[redacted](113)	VT: 失神 PT: 失神 SOC: 神経系障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](138) [redacted]20[redacted](139) 2
[redacted]20[redacted](479) [redacted]20[redacted](502) 24	16 [redacted]20[redacted](423)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D], [H] [redacted]20[redacted](480) [redacted]20[redacted](502) 23

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 69/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](429) **Total number of doses:** 15

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](307) [redacted]20[redacted](324) 18	11 [redacted]20[redacted](282)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H], [I] [redacted]20[redacted](307) [redacted]20[redacted](324) 18
[redacted]20[redacted](431) [redacted]20[redacted](448) 18	15 [redacted]20[redacted](429)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](431) [redacted]20[redacted](448) 18
[redacted]20[redacted](457) [redacted]20[redacted](477) 21	15 [redacted]20[redacted](429)	VT:頚椎症 PT: 変形性脊椎症 SOC: 筋骨格系および結合組織障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](457) [redacted]20[redacted](477) 21

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 69/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (429) **Total number of doses:** 15

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (480) [redacted]20[redacted] (499) 20	15 [redacted]20[redacted] (429)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED WITH SEQUELAE	Yes: [H], [I] [redacted]20[redacted] (480) [redacted]20[redacted] (499) 20

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 77/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (204) **Total number of doses:** 7

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (82) [redacted]20[redacted] (82) 1	3 [redacted]20[redacted] (56)	VT:失神エピソード PT: 失神 SOC: 神経系障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted] (82) [redacted]20[redacted] (85) 4
[redacted]20[redacted] (82) [redacted]20[redacted] (129) 48	3 [redacted]20[redacted] (56)	VT: 鼻骨折(外傷性) PT: 顔面骨骨折 SOC: 傷害、中毒および処置合併症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted] (82) [redacted]20[redacted] (85) 4
[redacted]20[redacted] (85) ONGOING	3 [redacted]20[redacted] (56)	VT:右心不全 PT: 右室不全 SOC: 心臓障害	Not related Grade 3	DRUG WITHDRAWN	Yes: [H] [redacted]20[redacted] (217) [redacted]20[redacted] (228) 12

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Canada
Subject: [redacted] **Age/Sex/Race[a]:** 74/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](57) **Total number of doses:** 3

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](8) ONGOING	1 [redacted]20[redacted](1)	VT: 肺腺癌 PT: 肺腺癌 SOC: 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）	Not related Grade 4	DRUG WITHDRAWN	Yes: [L], [I]
[redacted]20[redacted](8) ONGOING	1 [redacted]20[redacted](1)	VT: 副腎結節転移 PT: 副腎転移 SOC: 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）	Not related Grade 4	DRUG WITHDRAWN	Yes: [L], [I]

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
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CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Israel
Subject: [redacted] **Age/Sex/Race**[a]**:** 54/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (84) **Total number of doses:** 4

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] ONGOING		VT: 肺移植後の敗血症 PT: 処置後敗血症 SOC: 感染症および寄生虫症	Not related Grade 4	DOSE NOT CHANGED	Yes: [H] [redacted]20[redacted](115)
[redacted]20[redacted](59) [redacted]20[redacted](124) 66	2 [redacted]20[redacted](30)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 4	DRUG WITHDRAWN RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](115)

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Israel
Subject: [redacted] **Age/Sex/Race[a]:** 63/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (479) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (253) [redacted]20[redacted] 256) 4	9 [redacted]20[redacted] (226)	VT: 慢性閉塞性肺疾患増悪 PT: 慢性閉塞性肺疾患 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted] (253) [redacted]20[redacted] (256) 4

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Peru
Subject: [redacted] **Age/Sex/Race[a]:** 75/M/O **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (280) **Total number of doses:** 11

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (302) [redacted]20[redacted] (304) 3	11 [redacted]20[redacted] (280)	VT:重症肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D], [H] [redacted]20[redacted] (302) [redacted]20[redacted] (304) 3

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** Peru
Subject: [redacted] **Age/Sex/Race[a]:** 51/M/A **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](164) **Total number of doses:** 7

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](179) [redacted]20[redacted](208) 30	7 [redacted]20[redacted](164)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D], [H] [redacted]20[redacted](179) [redacted]20[redacted](208) 30

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country: South Korea**
Subject: [redacted] Age/Sex/Race[a]: 62/M/A First Dose Date: [redacted]20[redacted] Final Dose Date (day): [redacted]20[redacted] (480) Total number of doses: 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](360) [redacted]20[redacted](367) 8	13 [redacted]20[redacted](338)	VT: 急性咽頭炎 PT: 咽頭炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](360) [redacted]20[redacted](361) 2
[redacted]20[redacted](360) [redacted]20[redacted](363) 4	13 [redacted]20[redacted](338)	VT:斑状丘疹状皮疹 PT: 斑状丘疹状皮疹 SOC: 皮膚および皮下組織障害	Related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](360) [redacted]20[redacted](360) 1

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity, [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** South Korea
Subject: [redacted] **Age/Sex/Race[a]:** 71/M/A **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](28) **Total number of doses:** 2

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](5) [redacted]20[redacted](59) 55	1 [redacted]20[redacted](1)	VT: 特発性肺線維症急性増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](5) [redacted]20[redacted](10) 6
[redacted]20[redacted](5) [redacted]20[redacted](59) 55	1 [redacted]20[redacted](1)	VT: 異型肺炎 PT: 異型肺炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](5) [redacted]20[redacted](10) 6
[redacted]20[redacted](39) ONGOING	2 [redacted]20[redacted](28)	VT: 薬疹 PT: 薬疹 SOC: 皮膚および皮下組織障害	Related Grade 3	DRUG WITHDRAWN	Yes: [H] [redacted]20[redacted](45) [redacted]20[redacted](52) 8

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** South Korea
Subject: [redacted] **Age/Sex/Race[a]:** 73/M/A **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](470) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](521) [redacted]20[redacted](525) 5	18 [redacted]20[redacted](470)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](521) [redacted]20[redacted](525) 5

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** South Korea
Subject: [redacted] **Age/Sex/Race[a]:** 69/M/A **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](115) **Total number of doses:** 5

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](130) [redacted]20[redacted]164) 35	5 [redacted]20[redacted](115)	VT:薬剤性瘙痒 PT: アレルギー性そう痒症 SOC: 皮膚および皮下組織障害	Related Grade 3	DRUG WITHDRAWN RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](130) [redacted]20[redacted](137) 8

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 77/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](419) **Total number of doses:** 16

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](244) [redacted]20[redacted](245) 2	9 [redacted]20[redacted](223)	VT: 虫垂炎 PT: 虫垂炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](244) [redacted]20[redacted](245) 2
[redacted]20[redacted](424) ONGOING	16 [redacted]20[redacted](419)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED	Yes: [H] [redacted]20[redacted](424)
[redacted]20[redacted](424) ONGOING	16 [redacted]20[redacted](419)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED	Yes: [H] [redacted]20[redacted](424)

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 69/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (29) **Total number of doses:** 2

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](33) [redacted]20[redacted](40) 8	2 [redacted]20[redacted](29)	VT: 特発性肺線維症の急性増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D], [H] [redacted]20[redacted](33) [redacted]20[redacted](40) 8
[redacted]20[redacted]33) ONGOING	2 [redacted]20[redacted](29)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 4	DOSE NOT CHANGED	Yes: [H] [redacted]20[redacted](33) [redacted]20[redacted](40) 8

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 400 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 78/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](166) **Total number of doses:** 7

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](122)	5 [redacted]20[redacted](110)	VT: 肺塞栓症 PT: 肺塞栓症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED UNKNOWN	Yes: [H] [redacted]20[redacted](122) [redacted]20[redacted](125) 4
[redacted]20[redacted](196) [redacted]20[redacted](196) 1	7 [redacted]20[redacted](166)	VT: 心停止 PT: 心停止 SOC: 心臓障害	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D]

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race**[a]**:** 69/F/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](478) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](155) [redacted]20[redacted](175) 21	6 [redacted]20[redacted](138)	VT: 重症脱水 PT: 脱水 SOC: 代謝および栄養障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](158) [redacted]20[redacted](162) 5

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race[a]:** 72/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](488) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](41) [redacted]20[redacted](45) 5	2 [redacted]20[redacted](29)	VT: 下痢 PT: 下痢 SOC: 胃腸障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED WITH SEQUELAE	Yes: [H], [P] [redacted]20[redacted](41) [redacted]20[redacted](45) 5
[redacted]20[redacted](41) [redacted]20[redacted](45) 5	2 [redacted]20[redacted](29)	VT: 敗血症 PT: 敗血症 SOC: 感染症および寄生虫症	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H], [I] [redacted]20[redacted](41) [redacted]20[redacted](45) 5
[redacted]20[redacted](41) [redacted]20[redacted](43) 3	2 [redacted]20[redacted](29)	VT:心房性頻脈性不整脈 PT: 頻脈性不整脈 SOC: 心臓障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](41) [redacted]20[redacted](43) 3

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race**[a]**:** 72/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](488) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](41) [redacted]20[redacted](45) 5	2 [redacted]20[redacted](29)	VT: 嘔吐 PT: 嘔吐 SOC: 胃腸障害	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED WITH SEQUELAE	Yes: [H], [P] [redacted]20[redacted](41) [redacted]20[redacted](45) 5
[redacted]20[redacted](261) [redacted]20[redacted](262) 2	10 [redacted]20[redacted](250)	VT: 心房粗動 PT: 心房粗動 SOC: 心臓障害	Not related Grade 1	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](261) [redacted]20[redacted](262) 2

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Australia
Subject: [redacted] **Age/Sex/Race**[a]**:** 72/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](478) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](533) ONGOING	18 [redacted]20[redacted]478)	VT:右下肢黒色腫 PT: 悪性黒色腫 SOC: 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）	Not related Grade 2	DOSE NOT CHANGED	Yes: [I]

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Canada
Subject: [redacted] **Age/Sex/Race[a]:** 63/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](141) **Total number of doses:** 6

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](159) ONGOING	6 [redacted]20[redacted](141)	VT: 胃腺癌 PT: 胃腺癌 SOC: 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）	Not related Grade 3	DRUG WITHDRAWN	Yes: [I]

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Israel
Subject: [redacted] **Age/Sex/Race[a]:** 72/F/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (477) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (385) [redacted]20[redacted] (406) 22	14 [redacted]20[redacted] 365)	VT: 急性気管支炎 PT: 気管支炎 SOC: 感染症および寄生虫症	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted] (401) [redacted]20[redacted] (406) 6

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Israel
Subject: [redacted] **Age/Sex/Race**[a]**:** 68/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (224) **Total number of doses:** 8

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](30) [redacted]20[redacted](37) 8	1 [redacted]20[redacted](1)	VT: 上気道感染 PT: 上気道感染 SOC: 感染症および寄生虫症	Not related Grade 1	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](34) [redacted]20[redacted](37) 4
[redacted]20[redacted](64) [redacted]20[redacted](65) 2	2 [redacted]20[redacted](57)	VT: 咳嗽 PT: 咳嗽 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 1	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](64) [redacted]20[redacted](65) 2
[redacted]20[redacted](129) [redacted]20[redacted](132) 4	4 [redacted]20[redacted](112)	VT:心臓性胸痛 PT: 狭心症 SOC: 心臓障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](129) [redacted]20[redacted](132) 4

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf)
Standard Template SL_AE_002
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12MAY2016 7:47

MedImmune
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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Israel
Subject: [redacted] **Age/Sex/Race[a]:** 68/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](224) **Total number of doses:** 8

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](232) [redacted]20[redacted]234) 3	8 [redacted]20[redacted](224)	VT:心臓性胸痛 PT: 狭心症 SOC: 心臓障害	Not related Grade 1	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](232) [redacted]20[redacted](234) 3

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Peru
Subject: [redacted] **Age/Sex/Race**[a]**:** 74/M/O **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](150) **Total number of doses:** 5

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](166) [redacted]20[redacted](190) 25	5 [redacted]20[redacted](150)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 2	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](166) [redacted]20[redacted](169) 4

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** Peru
Subject: [redacted] **Age/Sex/Race**[a]**:** 64/M/O **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](91) **Total number of doses:** 4

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](93) [redacted]20[redacted](93) 1	4 [redacted]20[redacted]91)	VT: 呼吸不全 PT: 呼吸不全 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 5	DOSE NOT CHANGED FATAL	Yes: [D]

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** South Korea
Subject: [redacted] **Age/Sex/Race[a]:** 75/M/A **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (337) **Total number of doses:** 13

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (83) [redacted]20[redacted] (87) 5	3 [redacted]20[redacted] (55)	VT: 市中感染性肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted] (83) [redacted]20[redacted] (87) 5
[redacted]20[redacted] (365) ONGOING	13 [redacted]20[redacted] (337)	VT:特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DRUG WITHDRAWN	Yes: [H] [redacted]20[redacted] (365)

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

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CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** South Korea
Subject: [redacted] **Age/Sex/Race[a]:** 53/F/A **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](29) **Total number of doses:** 2

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted]56) ONGOING	2 [redacted]20[redacted](29)	VT:咳嗽増加 PT: 咳嗽 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 3	DOSE NOT CHANGED	Yes: [H] [redacted]20[redacted](56)
[redacted]20[redacted]56) ONGOING	2 [redacted]20[redacted](29)	VT: 股関節痛 PT: 関節痛 SOC: 筋骨格系および結合組織障害	Not related Grade 3	DOSE NOT CHANGED	Yes: [H] [redacted]20[redacted](56)

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** South Korea
Subject: [redacted] **Age/Sex/Race[a]:** 79/M/A **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](119) **Total number of doses:** 5

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](139) [redacted]20[redacted](143) 5	5 [redacted]20[redacted](119)	VT: 脳梗塞 PT: 脳梗塞 SOC: 神経系障害	Not related Grade 5	DRUG WITHDRAWN FATAL	Yes: [D], [H] [redacted]20[redacted](139) [redacted]20[redacted](143) 5

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 59/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](1) **Total number of doses:** 1

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](41) [redacted]20[redacted](49) 9	1 [redacted]20[redacted](1)	VT: 病態悪化による特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Related Grade 5	DRUG WITHDRAWN FATAL	Yes: [D], [H] [redacted]20[redacted](42) [redacted]20[redacted](45) 4

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race**[a]**:** 67/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted] (477) **Total number of doses:** 17

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted] (278) [redacted]20[redacted] (281) 4	10 [redacted]20[redacted] (251)	VT: 急性右後頭脳血管発作 PT: 脳血管発作 SOC: 神経系障害	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED WITH SEQUELAE	Yes: [H] [redacted]20[redacted] (278) [redacted]20[redacted] (281) 4

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 73/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](420) **Total number of doses:** 16

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](440) [redacted]20[redacted](453) 14	16 [redacted]20[redacted](420)	VT: 肺炎 PT: 肺炎 SOC: 感染症および寄生虫症	Not related Grade 3	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](440) [redacted]20[redacted](453) 14

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
Standard Template SL_AE_002 12MAY2016 7:47

MedImmune
CD-RI-CAT354-1066
CSR, DB lock [redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 62/M/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted]476) **Total number of doses:** 18

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](482) ONGOING	18 [redacted]20[redacted](476)	VT: 虫垂膿瘍 PT: 虫垂膿瘍 SOC: 感染症および寄生虫症	Not related Grade 4	DOSE NOT CHANGED	Yes: [L], [H], [I] [redacted]20[redacted](483) [redacted]20[redacted](500) 18
[redacted]20[redacted](487) [redacted]20[redacted](500) 14	18 [redacted]20[redacted](476)	VT: 特発性肺線維症増悪 PT: 特発性肺線維症 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 4	DOSE NOT CHANGED RECOVERED/RESOLVED WITH SEQUELAE	Yes: [L], [H], [P], [I] [redacted]20[redacted](483) [redacted]20[redacted](500) 18

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** United States of America
Subject:[redacted] **Age/Sex/Race[a]:** 71/M/A **First Dose Date:**[redacted]20[redacted] **Final Dose Date (day):**[redacted]20[redacted](484) **Total number of doses:** 17

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](388) [redacted]20[redacted]391) 4	14 [redacted]20[redacted](365)	VT: 気胸 PT: 気胸 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 4	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [L], [H], [I] [redacted]20[redacted](388) [redacted]20[redacted](391) 4
[redacted]20[redacted](396) [redacted]20[redacted](408) 13	14 [redacted]20[redacted](365)	VT: 気胸 PT: 気胸 SOC: 呼吸器、胸郭および縦隔障害	Not related Grade 4	DOSE NOT CHANGED RECOVERED/RESOLVED	Yes: [L], [H], [I] [redacted]20[redacted](396) [redacted]20[redacted](408) 13

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

Program (Output): /SASDATA/cars/prod/cat354/cd1066/csr/listings/tesae1.sas (tesae1.rtf) Validated
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MedImmune
CD-RI-CAT354-1066
CSR, DB lock[redacted]20[redacted]

Listing 14.3.2.2
Treatment-emergent Serious Adverse Events - Safety Population

Treatment Group (Safety): Tralokinumab 800 mg **Country:** United States of America
Subject: [redacted] **Age/Sex/Race[a]:** 73/F/W **First Dose Date:** [redacted]20[redacted] **Final Dose Date (day):** [redacted]20[redacted](471) **Total number of doses:** 17

Date (Day) of AE Onset/ AE Stop/ Duration[b]	Previous Dose # /Date (Day) of Previous Dose	AE Verbatim Term (VT)/ Preferred Term (PT)/ System Organ Class (SOC) (MedDRA version 18.1)	Relation to Study Drug/ Severity[c]	Study Drug Action Taken/ Outcome	Serious/ SAE Criteria[d]
[redacted]20[redacted](124) [redacted]20[redacted](143) 20	5 [redacted]20[redacted](108)	VT:左股関節脱臼 PT: 関節脱臼 SOC: 傷害、中毒および処置合併症	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED	Yes: [H] [redacted]20[redacted](125) [redacted]20[redacted](127) 3
[redacted]20[redacted](190) [redacted]20[redacted]206) 17	7 [redacted]20[redacted](164)	VT: 左股関節後方脱臼 PT: 関節脱臼 SOC: 傷害、中毒および処置合併症	Not related Grade 3	DOSE DELAYED RECOVERED/RESOLVED WITH SEQUELAE	Yes: [H] [redacted]20[redacted](190) [redacted]20[redacted](192) 3

[a] Age=Years; Race: W=White, B=Black, A=Asian, N=American Indian or Alaskan Native, H=Native Hawaiian or Other Pacific Islander, M=Multiple, O=Other.
[b] Duration is presented in days and is only calculated when both onset and stop dates are present (eg, AE onset and AE stop or Admission and Discharge).
[c] Grade 1= Mild, Grade 2=Moderate, Grade 3= Severe, Grade 4= Life-threatening, Grade 5= Fatal.
[d] Serious adverse event criteria: [D]=death, [L]=life-threatening, [H]=required inpatient hospitalization, [P]=prolongation of existing hospitalization, [S]=persistent or significant disability/incapacity; [I]=important medical event; [C]=congenital anomaly/birth defect (in the offspring of the subject).If at least one of the serious event criteria is hospitalization, then hospital admission and discharge dates and hospital duration will also be displayed.

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Standard Template SL_AE_002 12MAY2016 7:47