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5.4.2 CTD 2.7.2で引用した文献又は報告書

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5.4.2-4	Dynamometry testing in spinal cord injury.	J Rehabil Res Dev. 2007;44(1):123-36.	-	参考	-
5.4.2-5	Reference values for extremity muscle strength obtained by hand-held dynamometry from adults aged 20 to 79 years.	Arch Phys Med Rehabil 1997;78:26-32.	-	参考	-
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5.4.2-9	Reference values for a multiple repetition 6-minute walk test in healthy adults older than 20 years.	J Cardiopulm Rehabil 2001;21(2):87-93.	-	参考	-
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5.4.3 CTD 2.7.3で引用した文献又は報告書

資料番号	タイトル	報告書／文献	国内外別	評価／参考	実施場所
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5.4.3-2	Muscular weakness assessment: use of normal isometric strength data.	Arch Phys Med Rehabil. 1996 Dec;77(12):1251-5.	-	参考	-
5.4.3-3	Reference values for extremity muscle strength obtained by hand-held dynamometry from adults aged 20 to 79 years.	Arch Phys Med Rehabil. 1997 Jan;78(1):26-32.	-	参考	-
5.4.3-4	Maximal isometric muscle strength: normative values and gender-specific relation to age.	Clin Rheumatol. 2000;19(2):105-13.	-	参考	-
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5.4.3-8	Comparison of the Sit-to-Stand Test with 6 min walk test in patients with chronic obstructive pulmonary disease.	Respir Med. 2007 Feb;101(2):286-93. Epub 2006 Jun 27.	-	参考	-

5.4.4 CTD 2.7.4で引用した文献又は報告書

資料番号	タイトル	報告書／文献	国内外別	評価／参考	実施場所
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5.4.4-3	Sialylation is essential for early development in mice.	Proc Natl Acad Sci U S A. 2002 Apr 16;99(8):5267-70.	-	参考	-

1.12.2 提出すべき資料がない項目一覧

3.2.R	各極の要求資料
3.3	参考文献
4.2.1.2	副次的薬理試験
4.2.1.4	薬力学的薬物相互作用試験
4.2.2.7	その他の薬物動態試験
4.2.3.4	がん原性試験
4.2.3.6	局所刺激性試験
5.3.1.1	バイオアベイラビリティ（BA）試験報告書
5.3.1.2	比較 BA 試験及び生物学的同等性（BE）試験報告書
5.3.1.3	In Vitro-In Vivo の関連を検討した試験報告書
5.3.2	ヒト生体試料を用いた薬物動態関連の試験報告書
5.3.3.1	健康被験者における PK 及び初期忍容性試験報告書
5.3.3.3	内因性要因を検討した PK 試験報告書
5.3.3.4	外因性要因を検討した PK 試験報告書
5.3.3.5	ポピュレーション PK 試験報告書
5.3.4	臨床薬力学（PD）試験報告書
5.3.6	市販後の使用経験に関する報告書