

ICH M1 PtC WG Work Plan

14 February 2018

Topic Adoption date: 1999

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Regulatory Chair: *Dr. Sonja Brajovic (FDA, US)*

Last Face-to-Face Meeting: *Geneva, Switzerland - November 2017*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2016	The MedDRA Management Committee endorsed the production of a Companion Document to existing Points to Consider documents.
Mar. 2017	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (updated for MedDRA Version 20.0)
Sep. 2017	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (updated for MedDRA Version 20.1)
Nov. 2017	Companion Document (draft) agreed by M1 PtC WG.

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Mar. 2018	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (updated for MedDRA Version 21.0)
Jun. 2018	Release of initial version of new Companion Document to the existing PtC documents
Sep. 2018	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (updated for MedDRA Version 21.1)
Dec. 2018	Release of Condensed Versions of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” into all MedDRA languages (except English and Japanese)

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Feb. 2018	Mar. 2018	New Companion document	Final editorial work
Mar. 2018	Apr. 2018	New Companion Document	Endorsement by the MedDRA Management Committee
May. 2018	Jun. 2018	New Companion Document	Finalise and post on MedDRA and Japanese Maintenance Organisation websites
Jul. 2018	Aug. 2018	“MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents	Discuss user feedback and update both documents for MedDRA version 21.1