

ICH M1 PtC EWG/IWG Work Plan

January 18, 2019

Topic Adoption date: 1999 (Approximately)

This working group develops and maintains the MedDRA Points to consider (PtC) documents. As new areas of MedDRA are developed, the documents require refinement and updating twice a year in line with new MedDRA versions. This working group has also developed a Companion Document. The first version, released in June 2018, provides additional guidance on high level topics pertaining to the use of MedDRA (e.g. data quality issues and detailed examples for medication errors). Examples for product quality issues are planned for a later version. This WG also provides guidance on ICH MedDRA initiatives when requested by the MedDRA Management Committee.

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2018</i>	Release of 'Companion Document' version 1.0
<i>Sep. 2018</i>	Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (updated for MedDRA Version 21.1)
<i>Nov. 2018</i>	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)

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Feb. 2019	Collation of user comments, discussion of potential changes to the 'Companion document'
Mar. 2019	Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (updated for MedDRA Version 22.0)
Sep. 2019	Release of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (updated for MedDRA Version 22.1)

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jul. 2018	Feb. 2019	"MedDRA Points to Consider, Companion document"	Collation of user comments, discussion of potential changes to the 'Companion document'
Sep. 2018	Feb. 2019	"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 22.0 (planned release Mar2019).
Mar. 2019	Aug. 2019	"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 22.1 (planned release Sep2019).