

ICH M1 PtC EWG/IWG Work Plan

October 18, 2018

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 also updating twice a year in line with new MedDRA versions. This WG also provides guidance on ICH MedDRA initiatives (remit extended April 2014). In November 2016, the MedDRA Management Committee endorsed production of a Companion Document. The Companion document aims to provide additional guidance on high level topics pertaining to the use of MedDRA (e.g. data quality issues, detailed examples and Q & As for topics such as medication errors and product quality issues). The first version was released in June 2018.

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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>Mar. 2018</i>	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (updated for MedDRA Version 21.0)
<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)

1.b. Future anticipated key milestones

Expected future completion date	Milestone
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)
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)

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Apr. 2017	Dec. 2018	Translation of Condensed Versions of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider”	Translation into all MedDRA languages (except English and Japanese)
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