

ICH M1 PtC WG Work Plan

February 21, 2023

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 once a year in line with the March release of MedDRA. 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). A new section on distributed/manufactured 'Product quality issues' was available in October 2020. This WG also provides guidance on ICH MedDRA initiatives when requested by the MedDRA Management Committee.

Rapporteur: Dr. Christina Winter, EFPIA

Regulatory Chair: Dr. Sonja Brajovic, FDA, United States

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2018	First release of the 'MedDRA Points to Consider, Companion Document '
Nov. 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)
Jul. 2020	Release of v1.1 of the 'Companion document', incorporating changes.
Oct. 2020	Release of v2.0 of the 'Companion document', with a new section on product quality issues, focusing on distributed (marketed/manufactured) products.
Oct. 2020	Release of Chinese, Korean, and Spanish translations of "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents (based on MedDRA Version 23.0)

Mar. 2021	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2021) in English, Japanese, Chinese, Korean and Spanish. [Documents numbered by year instead of MedDRA version following change to annual release in Mar2020.]
Oct. 2021	Release of Russian translation of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2021)
Mar. 2022	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2022) in English, Japanese, Chinese, Korean, Russian and Spanish
Jun. 2022	Release of v3.0 of the ‘Companion document’ was planned on completing a new section on manufacturing product quality issues (focus on product during manufacturing process). The new section was SUSPENDED in 1H2022 and the WG is exploring whether this can be restarted.

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Mar. 2023	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2023) in English, Japanese, Chinese, Korean, Russian and Spanish

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2021	Aug. 2023	Team of appropriate (manufacturing quality) industry experts reviewed draft of new section of companion document on product quality issues (during manufacturing).	Ad hoc industry expert members of WG reviewed draft of new section of companion document on product quality issues (during manufacturing) and were unable to agree on content. They also stated potential overlap with ICH Q9 WG. In March 2022, MedDRA Management Committee (MMC) decided to suspend work on this section. Subsequent analysis (by PtC members) of ICH Q9R1 and the

			<i>ICH PtC work-product confirmed alignment between the two with no conflict or dependencies. Since there is no potential overlap, the WG is submitting a justification to the MMC to re-activate the task.</i>
Mar. 2022	<i>Mar. 2023</i>	<i>Annual update of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider”.</i>	<i>Review user comments and impact of MedDRA version updates and revise accordingly for annual release in March.</i>