ICH M1 PtC EWG/IWG Work Plan
April 21, 2022

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: *Christina Winter, EFPIA*

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

Interim regulatory chair*: Suranjan De, 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

1.b Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2022	Release of v3.0 of the 'Companion document', with a new section on manufacturing product quality issues (focus on product during manufacturing process). **SUSPENDED**
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	*Jul. 2021*	Form team of appropriate (manufacturing quality) experts and review draft of new section of companion document on product quality issues (during manufacturing).	Ad hoc experts accepted by ICH as Ad hoc members of WG. Draft of new section of Companion document on product quality issues (during manufacturing) reviewed by relevant experts.

Aug. 2021	*Mar. 2022*	Collate comments from ad hoc experts	Unable to achieve alignment with experts on content of second draft. No agreement on way forward for section on product quality issues during manufacturing. Awareness of potential overlap with ICH Q9 WG.
Mar. 2022	*Apr. 2022*	Discussion at MedDRA Management Committee: companion document section on product quality issues during manufacturing.	MedDRA Management committee decided to suspend further work on companion document section on product quality issues during manufacturing pending ICH Q9 outcome.