

ICH M1 Points to Consider EWG Work Plan

14 July 2026

Topic Adoption Date: 1999

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. The two main documents are “MedDRA Term Selection” PtC and “MedDRA Data Retrieval and Presentation” PtC updated annually in line with the March release of MedDRA. The PtC “Companion Document” provides additional guidance on high level topics pertaining to the use of MedDRA and may be updated as needed. The initial version of the “Companion Document” was released in June 2018, covering data quality and medication errors. A new section on distributed/manufactured ‘Product quality issues’ was available in October 2020, and a new section on “Manufacturing and quality system issues” was available in September 2024. This WG also provides guidance on ICH MedDRA initiatives when requested by the MedDRA Steering Committee (SC), as well as recommendations for development or not related to requests for new Standardised MedDRA Queries (SMQs).

Rapporteur: *Martin Menke, EFPIA*

Regulatory Chair: *Mary Doi, FDA, United States*

Last Face-to-Face Meeting: *Madrid, Spain. May 2025*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>Jun. 2018</i>	<i>First release of the ‘MedDRA Points to Consider, Companion Document’</i>
<i>Nov. 2018</i>	<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.</i>

Jul. 2020	<i>Release of v1.1 of the ‘Companion document’, incorporating changes.</i>
Oct. 2020	<i>Release of v2.0 of the ‘Companion document’, with a new section on product quality issues, focusing on distributed (marketed/manufactured) products.</i>
Oct. 2020	<i>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)</i>
Oct. 2021	<i>Release of Russian translation of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2021)</i>
Sep. 2024	<i>Release of v3.0 of the “Companion document”. with a new section on “Manufacturing and Quality System Issues” and revised sections on Introduction, Data quality, Medication errors, and Product quality issues</i>
Mar. 2025	<i>Annual releases “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2022-2025) in English, Japanese, Chinese, Korean, Russian, and Spanish</i>
Sep./Oct. 2025	<i>Release of French and Brazilian Portuguese translations of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents.</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
2020	<i>Annual release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2027)</i>
Nov. 2024	<i>Release of Companion document v4.0 with additional guidance on terms relating to Manufacturing and Quality System Issues relevant to large molecule, biologics, vaccines, and drug delivery devices. Other amendments to existing sections of the Points to Consider Companion Document v3.0</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Sep. 2026	<i>Release of Companion document v4.0 with additional guidance on terms relating to Manufacturing and Quality System Issues relevant to large molecule, biologics, vaccines, and drug delivery devices. Other amendments to existing sections of the Points to Consider Companion Document v3.0</i>
Mar. 2027	<i>Annual release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents (2027) in English, Japanese, Chinese, Korean, Russian, Spanish, Brazilian Portuguese, and French.</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
Jun. 2025	Sep. 2026	<i>Companion Document: Update to the Companion document: Manufacturing and Quality System Issues Section. Amendments to other existing sections of the Points to Consider Companion Document v3.0</i>	<i>Collate comments from F2F draft proposal, review and discuss during several teleconferences.</i>
Mar. 2026	Nov. 2026	<i>Existing MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents: Collate and review user comments.</i>	<i>Collate and review user comments and create draft proposals for discussion during Sep-Nov 2026.</i>
Sep. 2026	Sep. 2026	<i>Release of Companion document v4.0.</i>	<i>Release of Companion document v4.0.</i>