

ICH M1 PtC (Points to Consider) EWG Work Plan

8 March 2017

Topic Adopted: This Working Group is charged with the continuing development and maintenance of the MedDRA Points to Consider (PtC) documents. As new areas of MedDRA are developed, refinements to the PtC documents are necessary. In addition, the documents are routinely updated in line with MedDRA version releases twice a year. This WG also provides guidance on ICH MedDRA initiatives (remit extended April 2014 per EU/EMA request for PtC expert consultation). In November 2016 the MedDRA Management Board endorsed the extension to the remit of the WG to produce an additional companion document to the existing PtC documents. The companion document would provide additional guidance on high-level topics pertaining to the use of MedDRA such as data quality issues in regulatory submissions, as well as detailed examples and Q&A's for special topics such as medication errors and product quality issues.

Last Face-to-Face Meeting: Lisbon, Portugal – June 2016

1. Anticipated Milestones

Completion Date	Deliverable
Q2 2017	Condensed Versions of the “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents available in all MedDRA languages (except English and Japanese)
1 st September 2017	Release of “MedDRA Term Selection: Points to Consider” and “MedDRA Data Retrieval and Presentation: Points to Consider” documents, including updates for MedDRA Version 20.1 via MedDRA and JMO websites
Q1 2018	Release of initial version of new Companion Document to the existing PtC documents via MedDRA and JMO websites

2. Timelines

Date	Task / Activity	Details
May – July 2017	Review and update PtC documents for MedDRA Version 20.1.	➤ Decide on relevant changes to be made to PtC documents based on user feedback. Release of PtC documents for MedDRA Version 20.1 via MedDRA and JMO websites on 1 st September 2017.

February – March 2017	Finalise Condensed PtC documents in preparation for translation into 9 MedDRA languages.	➤ MSSO finalises English master of Condensed documents including any relevant changes from v20.0 update of full PtC documents. Rapporteur and Regulatory Chair sign off. MSSO sends Condensed documents to translation vendors. Anticipated release date is Q2 2017.
April November 2017	– Create Companion document to the PtC for finalisation in November 2017.	➤ This companion document will provide additional guidance on high-level topics pertaining to the use of MedDRA such as data quality issues in regulatory submissions, as well as detailed examples and Q&A's for special topics such as medication errors and product quality issues.
November 2017	Finalise Companion document to the PtC.	➤ Finalise the initial version of the companion document for translation to Japanese. Anticipated release in Q1 2018.