ICH M1 PtC (Points to Consider) EWG Work Plan
4 August 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). 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
2018	Condensed Versions of the "MedDRA Term Selection: Points to Consider" and "MedDRA Data Retrieval and Presentation: Points to Consider" documents in all MedDRA languages (except English and Japanese) to be posted on MedDRA website
1 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
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
July - August 2017	Update PtC documents for MedDRA Version 20.1	➢ Relevant changes to PtC documents based on user feedback have been agreed. Translation into Japanese is ongoing. PtC documents for MedDRA Version 20.1 will be released via MedDRA and JMO websites on 1st September 2017

July 2017 - 2018	Translation of Condensed PtC documents into 9 MedDRA languages	➢ English master of Condensed documents has been signed off by Rapporteur and Regulatory Chair. MSSO will send Condensed documents to translation vendors. Translation work on MedDRA release documents and completion of translation review takes priority over translation of Condensed documents. (Translation into French has been completed by in-house MSSO staff in July 2017). Anticipated release date is in 2018.
April – November 2017	Create draft of initial version of Companion document to the PtC	➢ 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.
November 2017 – 1Q 2018	Finalise Companion document to the PtC	➢ Finalise the initial version of the companion document for sign – off by MedDRA Management Board and subsequent translation to Japanese. Anticipated release in 2018.