

Annex 6: MedDRA Points to Consider (PtC) Working Group

The MedDRA Points-to-Consider (PtC) Working Group (WG) was established with the scope of developing a PtC document on Good MedDRA Selection Practices and advising on standards for data output. The PtC WG develops and maintains the *MedDRA Term Selection: Points to Consider* and the *MedDRA Data Retrieval and Presentation: Points to Consider* documents synchronized with MedDRA version updates; its remit was later extended to enable the WG to provide guidance on ICH MedDRA initiatives on an as-needed basis.

The MedDRA Management Committee provides oversight of the MedDRA PtC WG for matters that relate to the improved operation and use of MedDRA (*i.e. PtC documents, Acronyms & Abbreviations, etc.*). However, the ICH Management Committee oversees any activities that relate to Guideline development (*Guideline, Q&As, Addendum, etc.*). When proposing any new work activities, the PtC WG will be asked to develop a Concept Paper with detailed information on the scope, need, benefits, deliverables, cost, timeframe, and membership, for the support of either the MedDRA Management Committee or the ICH Management Committee, depending on the type of work to be completed. For work activities related to Guideline development, the Assembly will be asked to approve a Concept Paper outline and the ICH MC should approve the final Concept Paper. For work activities not related to Guideline development, the MedDRA MC will be asked to approve a Concept Paper. Additionally, the Assembly should be notified of all ongoing work activities of the MedDRA PtC WG and the WG should provide a report at each face-to-face meeting of the Assembly.

I. Endorsement of PtC documents

The PtC documents are not subject to regional implementation, but provide a best practice approach. Generally, the PtC WG releases a new version of the PtC documents for every version of MedDRA. PtC documents with major changes (*i.e.*, significant new documents, new concepts in existing documents) will be signed off by the ICH Members of the PtC WG and endorsed by the MedDRA MC and the ICH Assembly will be informed of the changes. PtC documents with minor changes (*e.g.*, simple revisions) will be agreed between the Rapporteur/Co-Rapporteur and Regulatory Chair for publication if there is consensus in the PtC WG.

Once signed-off, the PtC documents are available for public consultation. Any comments are forwarded to the PtC WG and will be taken into consideration for the release of the next version of the documents.

II. Membership

The PtC WG is established in line with the procedure outlined in section [1.4 Establishment of EWG/IWG](#) of this SOP. Additionally, the MedDRA PtC WG usually also includes a representative from both MSSO and JMO.

III. Working Procedures

The PtC WG has an on-going mandate to work by tele/web conference and e-mail. The group is asked to report at MedDRA Management Committee tele/web conferences when there is a need for a face-

to-face meeting. Justification will need to be provided for all face-to-face meetings, for ICH Management Committee approval.

The PtC WG usually meets every 18 months during the week of the ICH face-to-face meeting; however, the WG may need to meet every 12 months, as the necessity for holding meetings depends on the feedback received from users and the time of release of MedDRA (March and September). The usual maintenance of both PtC documents on term selection and on data retrieval & presentation does not require frequent face-to-face meetings. A large part of the work is done by correspondence, and major and only complex changes to MedDRA are discussed during face-to-face meetings. The Rapporteur with support of the Regulatory Chair is asked to report on progress and issues to both the MedDRA MC and ICH Assembly on a regular basis. Unresolved issues will be brought to the attention of the MedDRA MC as appropriate.

IV. Designation of the Rapporteur / Co-Rapporteur and Regulatory Chair

The nomination of a Rapporteur/Co-Rapporteur and a Regulatory Chair proceeds in line with [section 1.4.2](#) of this SOP. The PtC WG should also be consulted and invited to discuss their leadership. Additionally, the MedDRA MC will be asked to support the nomination(s) prior to the official designation of the Rapporteur/Co-Rapporteur by the Assembly and the Regulatory Chair by the MC.

The MedDRA MC will reassess the term of the Rapporteur and Regulatory Chair, as needed and consult with the ICH MC regarding any need to rotate the Rapporteur or Regulatory Chair.