Final Concept Paper
Extension of the Remit for the Points to Consider Working Group (M1 PtC) to Develop and Maintain a Companion Document to the PtC Documents
Endorsed by the ICH MedDRA Management Board on 6 November 2016

Type of Harmonization Action Proposed

The proposal is to extend the remit of the Points to Consider (PtC) Working Group (WG) beyond the development and maintenance of the *MedDRA Term Selection: Points to Consider* and *MedDRA Data Retrieval and Presentation: Points to Consider* documents to allow the WG to develop and maintain an additional companion document to the existing PtC documents.

Statement of the Perceived Problem

The PtC documents provide valuable guidance to MedDRA users worldwide on general term selection and data retrieval principles as well as providing specific examples of approaches to coding and analysis. However, there are certain topics where users could benefit from having more detailed information and guidance pertaining to the use of MedDRA than can be covered in the existing documents. One topic is that of data quality in regulatory submissions - both in clinical trials and postmarketing -where it is recognized that poor quality in the initial data collection and subsequent coding and analysis steps can compromise the ability to evaluate safety issues with regulated products. In addition, there is considerable demand from MedDRA users for detailed examples and "Questions and Answers" (Q&As) on special topics of regulatory importance such as medication errors and product quality issues.

Issues to be Resolved

The PtC WG seeks approval for the extension of its remit by the ICH MedDRA Management Board to develop and maintain the companion document; however, it is proposed that the document itself would not need to be approved by the ICH MedDRA Management Board prior to initial release or prior to subsequent updates. The PtC WG proposes that the companion document would follow the same sign-off procedure as the existing PtC documents which are approved by the Rapporteur and Regulatory Chair for each twice yearly release.

In the case of situations where the PtC WG does not possess the necessary expertise and consultation with outside experts, including from other ICH Working Groups, is needed, consideration has to be given as to how to accommodate those persons within the existing communication and meeting structure of the WG on an *ad hoc* basis.

Background to the Proposal

The ICH Points to Consider Working Group was established in 1999 with the scope of developing a Points to Consider document on MedDRA Term Selection. In late 2003, the ICH Steering Committee agreed to extend the remit of the PtC WG from their role of advising on coding standards to a broader role to include advising on standards for data output. The current remit of the PtC WG is to use the ICH platform to develop best practices on the use of MedDRA and to maintain the *MedDRA Term Selection: Points to Consider* and *MedDRA*

Data Retrieval and Presentation: Points to Consider documents in parallel with each MedDRA release.
In 2013, the remit of the PtC WG was extended to allow the WG to provide guidance on MedDRA initiatives on an as-needed basis. With this new remit, the WG provided input on the EU Good Practice Guides on Medication Errors which were published in 2015.

With this proposal to develop and maintain a companion document to the existing PtC documents, the PtC WG is responding to users' needs for more detailed information and guidance on special topics pertaining to the use of MedDRA. These guidance and examples will be agreed by all ICH parties rather than regulator-specific examples as provided for instance by the EU in their Good Practice Guides on medication errors or the FDA's Data Standards. The PtC WG proposes that the companion document would be a dynamic, "living" document that would be updated on a frequent basis, according to users' needs and thus it would not be tied to the biannual update of the PtC documents that is performed with each MedDRA release.

The section on data quality would obviate the need for a separate MSSO Best Practice document on data quality that was approved as an action by the MedDRA Management Board at its meeting in June 2016. The PtC WG notes that there are several sources of material available for consideration for the companion document including: Q&As developed by the European Industry MedDRA User Group following their 2015 webinar on medication error coding; questions received by the MSSO/JMO Help Desk; and issues identified by FDA in their FAERS Coding QA review. This material can serve as a starting point to be reviewed for applicability to the ICH regions, expanded as needed, and subsequently placed in the companion document where it will be easily accessible as a valuable resource for users.

The PtC WG proposes that this companion document will be in English and Japanese ; but if it is not considered necessary, or even feasible, to translate some examples or Q&As into Japanese these may be ommited.

Type of Expert Working Group and Resources
The existing PtC WG has the expertise and resources available to develop and maintain the proposed companion document.

Timing
The PtC WG seeks approval for the extension of its remit by the ICH MedDRA Management Board at its meeting in November 2016 in Osaka, Japan. If approved, the PtC WG will ask to meet in 2017 and aim to publish the initial version of the document within one year.