ICH Press Release

ICH Assembly Meeting, Montréal, Canada, November 2024

Ongoing Progress in ICH's Global Harmonisation Initiatives

Geneva, 13 November 2024

The Assembly of the International Council for Harmonisation (ICH) met in-person on 5 & 6 November 2024, in Montréal, Canada in parallel of meetings of 11 Working Groups and 1 Discussion Group, and preceded by meetings of the ICH Management Committee (MC) and the MedDRA MC.

The ICH continues to expand and welcomed with great pleasure CPPS, Uzbekistan; DIGEMID, Peru and Thai FDA, Thailand as new ICH Observers, bringing ICH to a total of 23 Members and 38 Observers.

Progress on ICH Guideline Development and Important Revisions

The Assembly was updated on the MC approval of the Concept Paper for the new ICH S13 Guideline on *"Nonclinical Safety Studies for Oligonucleotide-based Therapeutics".* In addition to receiving reports on progress made at ICH Working Group meetings in Montréal, the Assembly also noted significant milestones reached by several Working Groups since the last ICH meeting, which included awaited important updates to some older ICH Guidelines, as well as some new ICH Guidelines:

- The Draft ICH E6(R3) Annex 2 Guideline on "*Good Clinical Practice (GCP)*" reached *Step 2a/b* and was endorsed by the ICH Assembly. This Annex addresses the GCP considerations that arise from the increased use of a wider range of design elements and data sources and focuses on examples of trials that incorporate decentralised elements, pragmatic elements and/or real-world data (RWD).

- The Draft ICH M15 Guideline on "*General Principles for Model-Informed Drug Development (MIDD)*" reached *Step 2a/b* and was endorsed by the ICH Assembly. The overarching Guideline is expected to cover the general principles and good practices for the use of MIDD and will harmonise expectations regarding documentation standards, model development, data used in the analysis, model assessment, and its applications.

- The ICH M13A Guideline and associated Questions and Answers (Q&As) on "*Bioequivalence for Immediate-Release Solid Oral Dosage Forms*" reached *Step 4* of the ICH Process prior to the Montréal, Canada meeting on 23 July 2024. This Guideline provides recommendations on conducting bioequivalence studies during both development and post approval phases for orally administered immediate-release solid oral dosage forms. The Q&As document is intended to provide additional clarification and improve harmonisation of bioequivalence study design and data analysis.

- The ICH E11A Guideline on "*Pediatric Extrapolation*" reached *Step 4* of the ICH Process prior to the Montréal, Canada meeting on 21 August 2024. The E11A Guideline provides a framework for using extrapolation to support paediatric drug development. The framework describes an iterative process for understanding the existing information available, the gaps in information needed to inform development, and ways to generate additional information when required and recommends approaches to assessing factors that influence the determination of similarity of disease, drug pharmacology, and response to treatment between a reference and paediatric target population.

Monitoring ICH Guideline implementation

With monitoring the progress of international harmonisation and coordinating efforts in this regard being an important ICH focus, the Assembly welcomed ICH's publication in October 2024 on the ICH website of the results of the recent survey conducted in 2024, building on the previous 2019 and 2021 assessments. The main objective of this survey was to monitor progress of international harmonisation, identify regulatory training and capacity building needs, assist the ICH MC in determining whether the Regulatory Members would meet the eligibility criteria for the June 2024 ICH MC elections, and to allow participating Observers interested in future ICH Membership to reference the survey findings to confirm their eligibility.

MedDRA

MedDRA Management Committee Vice-Chair election was held during the meeting which saw the appointment of Dr. Craig Simon, Health Canada, Canada to serve for a two-year term.

With the recent release of MedDRA Version 27.1, MedDRA is now available in 24 languages, including the newly added Croatian, Lithuanian, and Icelandic. The MedDRA Management Committee is also pleased to announce the publication of the MedDRA Points to Consider Companion Document Version 3.0, which features a new section on Manufacturing and Quality System Issues. Collaboration with international organizations is ongoing, focusing on targeted mappings with MedDRA to enhance the availability of MedDRA-coded data for analysis, interoperability, supporting patient safety efforts and promoting public health.

Training

The Assembly was updated on ICH training related activities, including the recent publication on the ICH website of ICH E8(R1) "General Considerations for Clinical Studies" Introductory Training Video developed by the ICH Training Associate, as well as the updated training materials on ICH Q8/Q9/Q10 Guidelines developed by the Q9(R1) Implementation Working Group.

Communication

A most welcome news has been shared with the Assembly during the meeting as the ICH has been awarded by DIA Europe the 2025 DIA Regional Inspire Award for Outstanding Contribution to Global Health for its significant and innovative contribution to advancing global health.

The next ICH Assembly meeting is planned on 13 and 14 May 2025 in Madrid, Spain.

****

NOTES FOR EDITORS

This press release, together with more information on the ICH Guidelines mentioned above and the work of ICH, can be found on its website: www.ich.org

For further information, please contact the ICH Secretariat at pressrelease@ich.org

Follow ICH on X (formerly Twitter) @ICH_News