

ICH Press Release

Amsterdam, the Netherlands, June 2019

Significant advancements in global harmonisation efforts at ICH's largest biannual meeting to-date

Geneva, 14 June 2019

The International Council for Harmonisation (ICH) met in Amsterdam, the Netherlands from 1 – 6 June 2019. The meeting marked ICH's largest biannual meeting to-date, bringing together almost 500 participants from ICH's sixteen Members and twenty-eight Observers. ICH's global constituency also further grew in Amsterdam, with ICH Assembly approval of four new Regulatory Observers: ANMAT, Argentina; CPED, Israel; JFDA, Jordan and SFDA, Saudi Arabia, bringing the total number of ICH Observers to thirty-two. Full details are available on the ICH website www.ich.org.

At the meeting, the Assembly reviewed the excellent progress made by ICH Working Groups both at and prior to the meeting, approved new areas for harmonisation, and took decisions in support of the recognised importance of training in ensuring a globally consistent approach to ICH Guideline implementation.

In Amsterdam, the Assembly also welcomed a new Assembly Vice Chair, with the election of: Dr. Celia Lourenco (Health Canada, Canada) succeeding Dr. Petra Doerr (Swissmedic, Switzerland) for a 6 months term until November 2019.

Progress on existing ICH Guidelines

A record number of sixteen ICH Working Groups met in Amsterdam to progress their activities.

Two groups made substantial progress resulting in the adoption of the following documents by the Assembly at and just prior to the Amsterdam meeting (*Step 4* of the ICH process):

- Revised E2B(R3) Question & Answer (Q&A) regarding Implementation: Transmission of Individual Case Safety Reports;
- Revision of the Cadmium Inhalation Permitted Daily Exposure (PDE) (Q3D(R1)) in March 2019.

Moreover, the following draft guidance documents were adopted for public consultation (*Step 2b* of the ICH process) prior to the meeting:

- Optimization of Safety Data Collection (E19) in April 2019;
- Bioanalytical Method Validation (M10) in February 2019;
- Revision on General Considerations for Clinical Trials (E8(R1)) in May 2019.

Training to Support Implementation of ICH Guidelines

Significant progress was made in the development of Q&A documents and training materials, to support understanding of the guidelines developed. In Amsterdam, the Assembly was updated on the development of training materials, including the progress towards finalising seven training modules and an animated video on ICH E17 General Principles for Planning and Design of Multi-Regional Clinical Trials, and the publication of a training video on ICH Q11 Q&As on the Selection & Justification of Starting Materials. These will be available on the ICH website shortly after the meeting.

The Assembly was also updated on the outcome of the call for expression of interest for training associates conducted by ICH prior to the Amsterdam meeting. The Assembly gave its support for ICH

to proceed with efforts to engage appropriate accredited non-profit training organisations to assist ICH in its efforts to address the training needs of its Regulatory and Industry Members and Observers in a strategic manner.

Global ICH Public Stakeholder Meeting

The Assembly was also updated on plans for a global ICH meeting with public stakeholders regarding the ICH E8 Guideline Revision on General Considerations for Clinical Trials which recently reached *Step 2b* of the ICH process. The meeting, which will be held on 31 October 2019 at Silver Spring, MD, USA, will serve to discuss planned next steps for the guideline's development and its role in ICH's [Good Clinical Practice \(GCP\) Renovation](#). Further details regarding the meeting will be made available shortly on the ICH website, with the opportunity to be given for stakeholders to also participate in-person or via a webcast. Additional public stakeholder meetings in ICH Member countries/regions will also be held, notably in Tokyo, Japan on 25 July 2019.

Agreement on new ICH harmonisation activities

The Assembly took the decision to begin work on four new topics for ICH harmonisation:

- **Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin**, which is proposed to update the ICH Q5A Guideline on technologies for virus detection and quantification, and validation approaches for virus clearance, and expand the scope of the Guideline to include new biotechnology products such as viral-like particles and viral-vectored particles.
- **E6(R3) Guideline for Good Clinical Practice**, which is proposed to revise the existing ICH E6(R2) Guideline to address the increasing diversity of study types and data sources that are being employed to support regulatory and other health policy decisions in line with the ICH Reflection Paper on GCP Renovation.
- **E2D(R1) Post Approval Safety Data Management: Definition and Standards for Expedited Reporting**, which is proposed to update the existing ICH E2D Guideline to incorporate pragmatic potentially risk-based approaches of the management of information from existing and any new data sources, to enable a greater focus on the data sources that will optimize signal detection activities and public health.
- **A new Guideline on Non-clinical Biodistribution Studies for Gene Therapy Products**, which will recommend types of the non-clinical studies with which collection of biodistribution data is considered informative and/or necessary to support dosing in early clinical trials, and which will provide guidance on the design of the studies. This will result in streamlined development of the gene therapy products with higher scientific rigor while minimising the unnecessary use of animals.

Once the Informal Working Groups are established, they will begin the work on developing formal concept papers and business plans, which will be subsequently made available on the ICH website.

Another new topic was also adopted with a delayed starting timeframe which will be determined at a later point:

- **Guideline on Impurity: Assessment and Control of Extractables and Leachables (E&L) for Pharmaceuticals and Biologics**, which will establish a workflow for assessment of leachables in all drug product dosage forms, aligned to the acceptable levels of risk to patients from the impurity and the route of exposure. The workflow would include evaluation and reporting thresholds linked to the route of administration, duration of exposure and dose-response concepts.

The Assembly also advanced future strategic areas for harmonisation by endorsing a strategic reflection paper entitled Strategic Approach to International Harmonization of Technical Scientific

Requirements for Pharmacoepidemiological Studies Submitted to Regulatory Agencies to Advance More Effective Utilization of Real-World Data. This paper will be published on the ICH website and a discussion group will be established after the meeting.

Monitoring ICH Guideline implementation

The Amsterdam meeting marked the conclusion of an important initial ICH effort to better understand the state of implementation of ICH Guidelines by ICH Regulatory Members and Observers. With the help of an independent third-party, a survey was conducted in early 2019 monitoring adequacy of implementation and adherence to ICH Guidelines. The results of the survey were presented during the Amsterdam meeting, with communication of aggregated survey results to be made available on the ICH website later in 2019.

The next ICH meeting will take place on 17 - 21 November 2019 in Singapore.

NOTES FOR EDITORS

This press release, together with more information on the 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

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