# ICH Press Release

**Continued ICH Growth and Advancement**

Geneva, 10 June 2021

The International Council for Harmonisation (ICH) met virtually on 2-3 June 2021 in place of face-to-face meetings that were to take place in Incheon, Republic of Korea. The meeting was preceded by virtual meetings of the ICH Management Committee and MedDRA Management Committee.

**Further expansion of ICH Membership**

The ICH Assembly welcomed SFDA, Saudi Arabia as a new ICH Member, in addition to two new ICH Observers: AEC, Azerbaijan and MHRA, UK, bringing ICH to a total of 18 Members and 33 Observers.

**ICH Management Committee elections**

In line with ICH procedures, new elections were held for Elected Representatives to the ICH Management Committee, welcoming for a 3-year term Representatives from Regulatory Members: ANVISA, Brazil; MFDS, Republic of Korea; and NMPA, China and Industry Members: BIO and IGBA.

**Results of new implementation survey**

The Assembly was presented with the results of the second third-party survey to understand the current level of implementation and adherence to ICH Guidelines within Regulatory Member and Observer countries/regions. The survey results demonstrate good progress made by Regulatory Authorities in implementing ICH Guidelines since the first survey in 2019. The results also provided a firm basis for confirming Regulatory Member eligibility in the Management Committee elections, and allowing participating ICH Observers to confirm their eligibility to apply for ICH Membership if they would so wish.

**Progress on existing ICH Guidelines**

ICH's Working Groups have also continued to progress their virtually. The Assembly was updated on the status of ICH's current thirty-four Working Groups, and the dedicated efforts of ICH experts to progress their harmonisation activities in the face of pandemic related challenges. The Assembly noted significant milestones reached by several Working Groups including:

- *Step 3* Working Group consensus and *Step 4* Regulatory Member endorsement reached for the Q3C(R8) Guideline on Impurities: Guideline for Residual Solvents, revised to include the Permitted Daily Exposure (PDE) levels for 2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether and Tertiary Butyl Alcohol.
- *Step 3* Working Group consensus and *Step 4* Regulatory Member endorsement reached for the M8 eCTD v4.0 Question and Answer (Q&A) Document v.1.5, Specification for Submission Format for eCTD v.1.3, and eCTD v4.0 Implementation Package v.1.4.
- *Step 1* Working Group consensus and *Step 2* Assembly and Regulatory Member endorsement reached for the draft ICH S1B(R1) Addendum to the Guideline on Testing for Carcinogenicity of Pharmaceuticals.
- *Step 1* Working Group consensus and *Step 2* Assembly and Regulatory Member endorsement reached for the new, draft ICH S12 Guideline on Nonclinical Biodistribution Considerations for Gene Therapy Products.

The Assembly additionally noted significant progress made on the revision of the ICH E6 Guideline on Good Clinical Practice with the recent publication of a draft principles document, which were subsequently presented at two global public web conferences in May 2021. ICH hopes that sharing the draft version of the principles will facilitate transparency and better understanding on the revision

of this important guideline which is widely used by clinical trial researchers and has significant impact for trial participants and patients.

**New areas of ICH harmonisation**

The Assembly discussed New Topic Proposals and supported the following topics as new areas of ICH harmonisation, noting the need for further discussion on the timeframe for their initiation:

- Revision of ICH Q1 Guidelines on Stability Testing and related ICH Q5C Guideline on Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products.
- Revision of ICH Q6A and Q6B on Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances and Biotechnogical/Biological Products.
- New ICH Guideline on General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of a Medicine.

The ICH Assembly supported an updated version of the ICH Reflection Paper on Patient-Focused Drug Development (PFDD) endorsed in November 2020. The paper presents opportunities for development of new ICH Guidelines to provide a globally harmonised approach to the inclusion of the patient's perspective in a way that is methodologically sound and fit-for-purpose for both regulated industry and regulatory authorities. The updated version reflects modifications based on public stakeholder comments received during the recent public consultation and which are summarized in an Outcome of Public Consultation Document which will be published shortly on the ICH website.

**Training**

The Assembly was also updated on ICH training related activities, including work with ICH's two Training Associates to develop online training materials on ICH Q1 Stability Guidelines, ICH M4 Common Technical Document Guidelines, and ICH E2 Pharmacovigilance Guidelines. The Assembly additionally welcomed finalisation of training modules on the ICH Q12 Guideline on Regulatory and Technical Considerations for Pharmaceutical Product Lifecycle Management, which aim to provide a comprehensive training programme to facilitate an aligned interpretation and a harmonised implementation of ICH Q12 globally.

**MedDRA**

The Assembly was updated about the steady increase in the number of MedDRA subscribers, noting over 540 new subscribers in the last year, bringing the total number to 6,800 organisations in more than 127 countries. Work is ongoing on targeted mappings with other terminologies, as well as on efforts to support the language needs of users: with plans to develop an Arabic translation, and continuing work to translate MedDRA into the remaining languages of the European Economic Area. User support is also being further extended with new IT developments, including MedDRA Application Programming Interfaces which will allow users more flexibility in developing their own tools or extending existing tools. These Interfaces are in a phase of testing by users with a view to official release towards the end of 2021.

**Communication**

The Assembly noted an upcoming publication to be made available on the ICH website to celebrate ICH's important 30$^{th}$ Anniversary milestone reached in 2020.

The next ICH Assembly meeting is planned as a virtual meeting on 17-18 November 2021.

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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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