ICH Press Release

ICH Assembly Meeting, Athens, Greece, May 2022

A Successful Hybrid Meeting

Geneva, 1 June 2022

The International Council for Harmonisation (ICH) met on the 21 – 25 May, in Athens, Greece, for the first time in a hybrid format, with both in-person and virtual participation across the meetings of seven Working Groups, the ICH Management Committee, the MedDRA Management Committee and the ICH Assembly.

At the meeting, the Assembly reviewed the status of activity of all thirty-one of ICH's Working Groups; received a report from the MedDRA Management Committee; and was updated on several important recent ICH activities in relation to training and communication.

Further expansion of ICH Membership and Observership

The ICH Assembly welcomed MHRA, UK as a new ICH Member, in addition to ANPP, Algeria as a new ICH Observer, bringing ICH to a total of 20 Members and 35 Observers.

Progress on existing ICH Guidelines and harmonisation activities

ICH's Working Groups have continued to progress their activities, with many groups making significant progress. The following milestones were reached in Athens:

- *Step 4* was reached for the ICH M7(R2) Q&As on "Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk". The Q&As will be published alongside the M7(R2) revised ICH Guideline and Addendum which are also expected to reach *Step 4* shortly;
- *Step 4* was reached for the ICH M8 eCTD "v4.0 Q&As and Specification Change Request Document v1.7" and "eCTD v4.0 Implementation Package v1.5";
- *Step 4* was reached for the ICH M10 Guideline on "Bioanalytical Method Validation and Study Sample Analysis", providing recommendations for the validation of bioanalytical assays and outlining principles to improve the quality of bioanalytical data in the development and market approval of chemical and biological drugs;
- *Step 2* was reached for the draft ICH M12 Guideline on "Drug Interaction Studies". This guideline is intended to provide a consistent approach in designing, conducting, and interpreting drug-drug interaction studies during the development of a therapeutic product.

The Assembly also noted significant milestones reached by several Working Groups since the last ICH meeting:

- *Step 4* was reached in February 2022 for the ICH E14/S7B updated Q&A document on "Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential" that provide recommendations on considerations for an integrated risk assessment combining nonclinical and clinical data – in particular, at later stages of drug development when clinical data are available. The guideline is intended to provide a harmonised approach to integrate nonclinical and clinical

information for proarrhythmia risk assessment to streamline drug development and provide clarity on regulatory decision-making;

- *Step 2* was reached in March 2022 for the revised ICH Q2(R2) draft Guideline on "Validation of Analytical Procedures", which is intended to continue to provide a general framework for the principles of analytical procedure validation, adding validation principles that cover analytical use of spectroscopic or spectrometry data (e.g., NIR, Raman, NMR or MS);
- *Step 2* was reached in March 2022 for the ICH Q14 draft Guideline on "Analytical Procedure Development", intended to harmonise scientific approaches and provide principles relating to the description of Analytical Procedure Development, facilitating more efficient, sound scientific and risk-based approval as well as post approval change management of analytical procedures;
- *Step 2* was reached in April 2022 for the ICH E11A draft Guideline on "Paediatric Extrapolation", which is intended to support the incorporation of paediatric extrapolation into overall drug development plans – aligning terminology related to paediatric extrapolation, providing information on various approaches that can be utilised, and providing information on study designs and statistical analysis methods.

New areas of ICH harmonisation

The ICH Assembly endorsed the development of a new ICH Efficacy Guideline on the "Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials" to provide for a globally accepted framework and best practices. The COVID-19 pandemic has illustrated the importance to develop a well-defined harmonised international guideline which will benefit this underserved population, regulators, healthcare providers and the pharmaceutical industry globally.

Training

The Assembly was also updated on ICH training related activities, and status of activities to expand work with three ICH Training Associates as part of a 5-year strategic plan to develop online training materials on ICH Guidelines, in addition to offering tailored training. Over the next few years, it is expected that the Training Associates will develop online training materials for the ICH E6(R3), E8(R1), E17, Q3, Q5 and ICH Q8 to Q12 series of Guidelines.

MedDRA

The Assembly was updated on the recent release of Swedish and Latvian MedDRA translations in Version 25.0, making MedDRA available in 16 languages in support of users' language needs. Ongoing work to translate MedDRA into Arabic, Greek, Polish, Maltese, Estonian, Icelandic and Norwegian was also noted. These translations support MedDRA's steady uptake which is close to 7,500 organisations in almost 130 countries. Collaborative work on targeted mappings with other terminologies continues. In May 2022, the second production of the SNOMED CT – MedDRA mappings was released. A new Standardised MedDRA Query (SMQ) on Noninfectious myocarditis/pericarditis has been included in the MedDRA Version 25.0 March release.

Communication

The Assembly noted the recent publication of the ICH 30th Anniversary Publication and informative leaflet on the ICH website, providing an overview of ICH's history and current work, as well as views of different stakeholders on how ICH has contributed to better health and ICH's future directions in the next 10 years.

The Assembly was additionally informed of a new feature on the ICH website which allows stakeholders to register to be kept up-to-date on new publications and press releases with an email notification.

The next ICH Assembly meeting is planned on the 15 – 16 November 2022 in Incheon, Republic of Korea.

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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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