ICH Press Release

ICH Assembly Meeting, Incheon, Republic of Korea, November 2022

Excellent Progress by ICH Expert Working Groups, with Recognition of Significant Expert Contributions with New ICH Award

Geneva, 22 November 2022

The Assembly of the International Council for Harmonisation (ICH) met in-person on the 15 - 16 November 2022, in Incheon, Republic of Korea in parallel of meetings of ten Working Groups, and preceded by meetings of the ICH Management Committee and the MedDRA Management Committee.

The meeting provided an important opportunity to advance work of ICH's thirty-three Working Groups and key activities including training.

The ICH Assembly also welcomed DPM, Tunisia as a new ICH Observer, bringing ICH to a total of 20 Members and 36 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 and with the adoption (*Step 4)* of a new guideline, ICH Q13 "Continuous Manufacturing of Drug Substances and Drug Products". This new guideline describes scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of continuous manufacturing (CM) specific to drug substances and drug products.

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

- The guideline ICH E19 "A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval or Post-Approval Clinical Trials" was adopted (*Step 4*) in September 2022. This new guideline is intended to provide internationally harmonised guidance on the use of selective safety data collection - by tailoring the method of safety data collection, it may be possible to carry out clinical trials with greater efficiency by streamlining the approach to data collection with a controlled, risk-based approach. This may facilitate the conduct of large-scale efficacy and safety clinical trials with large numbers of participants and long-term follow-up;

- The Draft ICH Guideline M11 "Clinical electronic Structured Harmonised Protocol (CeSHarP), Technical Specification and Template" was agreed in September 2022 (*Step 2*). This new draft guideline is proposed to provide comprehensive clinical protocol organisation with standardised content, with 1) a Template which presents the format and structure of the protocol, including the table of contents, common headers, and contents; and 2) a Technical Specification which presents the conformance, cardinality, and other technical attributes that enable the interoperable electronic exchange of protocol content;

- The Draft ICH Guideline Q5A(R2) "Viral Safety Evaluation of Biotechnology Products" was agreed in September 2022 (*Step 2*). The revision retains key principles of the original guideline and provides additional recommendations on the established and complementary approaches to control the potential viral contamination of biotechnology products;

- An addendum to ICH S1B(R1) was adopted (*Step 4*) in August 2022, that was integrated with the original guideline and published as ICH S1B(R1) "Testing for Carcinogenicity of Pharmaceuticals". The new addendum expands the evaluation process for assessing human carcinogenic risk of pharmaceuticals by introducing an additional approach that is not described in the original ICH S1B Guideline. Application of this integrative approach reduces the use of animals in accordance with

the 3R (reduce/refine/replace) principles and shifts resources to focus on generating more scientific mechanism-based carcinogenicity assessments, while continuing to promote safe and ethical development of new pharmaceuticals.

Training

The Assembly was also updated on ICH training related activities, including the recent creation of a new Training Library on the ICH website to house in a single location ICH's growing portfolio of training materials. This library will be further grown with the addition of a significant number of new online materials currently being developed by four ICH Training Associates, and will include training on ICH E2, E6(R3), E8(R1), E17, M4, Q1, Q3, Q5 and the ICH Q8 to Q12 series of Guidelines.

ICH Award

At its meeting, the ICH Assembly inaugurated a new ICH Award for Outstanding Contribution to ICH Harmonisation for Better Health, with recipients of the 2022 award recognised for their significant and sustained contributions in ICH leadership roles in ICH Working Groups. The names of the awardees will be published on the ICH website.

MedDRA

In view of the increasing number of MedDRA users worldwide, currently reaching over 8,200 users in 134 countries, the MedDRA Management Committee is working actively to ensure support. This includes provision of additional new MedDRA translations, such as the release of Greek and Polish, making MedDRA available in 18 languages, with these foreseen to be followed closely by a new Arabic MedDRA translation. Additionally, local in-country/in-region support, including training and helpdesk services, is set to be further enhanced in the Latin America region, and through addition newly of support in Arabic.

Communication

The Assembly was also updated on considerations related to patient stakeholder engagement in ICH and supported the forthcoming publication on the ICH website of a principles document on ICH patient engagement.

The next ICH Assembly meeting is planned on 12 – 13 June 2023 in Vancouver, Canada.

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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

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