ICH Press Release

Charlotte, NC, USA, November 2018

Advancement of Harmonisation Efforts in an Increasingly Global ICH

Geneva, 23 November 2018

The International Council for Harmonisation (ICH) met in Charlotte, NC, USA on 10-15 November 2018. Three years on from the reform of ICH, all organisational changes have been implemented, with the Charlotte meeting being illustrative of ICH's steady evolution to a more global initiative.

ICH is now constituted by sixteen Members and twenty-eight Observers, with the Assembly approving in Charlotte its newest Regulatory Observer with the appointment of NRA, Iran.

Further appointments in Charlotte, included election of Dr. Petra Doerr (Swissmedic, Switzerland) as Assembly Vice-Chair, while Dr. Theresa Mullin (FDA, United States) was re-elected as Chair of the ICH Management Committee alongside newly elected Vice-Chair Dr. Nobumasa Nakashima (MHLW/PMDA, Japan). All will serve a one year term until November 2019.

Managing the continued success and efficiency of the ICH process in view of ICH's expansion was an important focus of ICH Management Committee discussions in Charlotte. Charlotte also marked the first face-to-face meeting of the expanded Management Committee, with elected Management Committee Representatives from HSA, Singapore; MFDS, Republic of Korea; NMPA, China; BIO and IGBA joining ICH's Founding and Standing Members to play an active role in overseeing the Association's administrative, financial, and Working Group operations.

Full details on the composition of ICH and its governing bodies are available on the ICH website www.ich.org.

Significant progress on new and existing ICH Guidelines

The global orientation of ICH's harmonisation efforts is well evidenced in ICH's current twenty-five Working Groups which currently involve over six hundred experts (see Annex 1 for supplementary information). Thirteen of these Working Groups met in Charlotte to progress their activities, including three recently established informal Working Groups and a Discussion Group:

- Analytical Procedure Development and Revision of Q2(R1) Analytical Validation (Q2(R2)/Q14);
- Continuous manufacturing (Q13);
- Clinical electronic Structured Harmonised Protocol ('CeSHarP') (M11);
- Discussion Group on Clinical and non-Clinical Evaluation of QT/QTc Interval Prolongation (E14/S7B).

These groups made good progress resulting in the approval by the ICH Management Committee of Concept Papers and Business Plans as well as the establishment of formal ICH Expert Working Groups. Approved Concept Papers and Business plans can be found on the ICH website.

The Charlotte meeting also saw the timelines established for the initiation of work on two additional new topics adopted at the last meeting in Kobe in June 2018. Work on Adaptive Clinical Trials (E20) and Drug Interaction Studies (M12) is now expected to get underway in mid-2019.

Future strategic areas for harmonisation by ICH were also considered, with the Assembly updated on the development of Reflection Papers which included one on "Further Opportunities for Harmonization of Standards for Generic Drugs". This Reflection Paper received endorsement by the ICH Assembly and is intended for publication on the ICH website shortly. The remit of a new Informal Quality Discussion Group was also approved in Charlotte and is detailed in the Reflection Paper on "Advancing Pharmaceutical Quality Standards" which was approved by the ICH Assembly in June 2018 and will be made available on the ICH website. Another future strategic area was also discussed as a potential new work area: "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".

Additionally, the Assembly approved a new maintenance process for the Q4B Annexes which cover pharmacopoeial texts to be considered as interchangeable. This process will be coordinated by the Pharmacopoeial Discussion Group, which includes ICH Observers EDQM and USP, who will keep the ICH Assembly updated on the need for ICH approval of any updated annexes.

Training recognised as key to successful implementation

The increasing number of ICH Members and Observers has further underlined the importance of training in ensuring a globally consistent approach to ICH Guideline implementation. Consideration of training resources is therefore high on ICH's agenda, with several Working Groups tasked with development of training materials and/or Questions & Answers documents to support understanding of the new concepts and approaches of the guidelines they have developed. In Charlotte, the Assembly was updated on several important training related activities, including the development of training videos to accompany the ICH E9 Guideline Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses, and work to develop further training materials for the ICH E17 Guideline on General Principles for Planning and Design of Multi-Regional Clinical Trials which was adopted in 2017. Updates were also made on ongoing ICH work with training providers, in addition to recent considerations on how ICH might further leverage the expertise of such providers as it tries to ensure the availability of training on priority ICH Guidelines.

Understanding ICH Member Guideline implementation

Linked with these efforts, it is an important ICH undertaking to understand the level of implementation of ICH Guidelines and the level of adherence to ICH Guidelines within the Regulatory Member and Observer countries/regions. Important progress was made in Charlotte in this regard, with the Assembly supporting new terminology with respect to consistent definitions of the degrees of implementation of ICH Guidelines. The Assembly also took note of the progress towards the finalisation of an ICH-driven independent third party survey aimed at mapping the implementation of ICH Guidelines by ICH Regulatory Members and Observers. The survey is targeted for completion mid-2019, with outcomes to be published in the second half of 2019.

The next ICH meeting will take place on 1-6 June 2019 in Amsterdam, the Netherlands.

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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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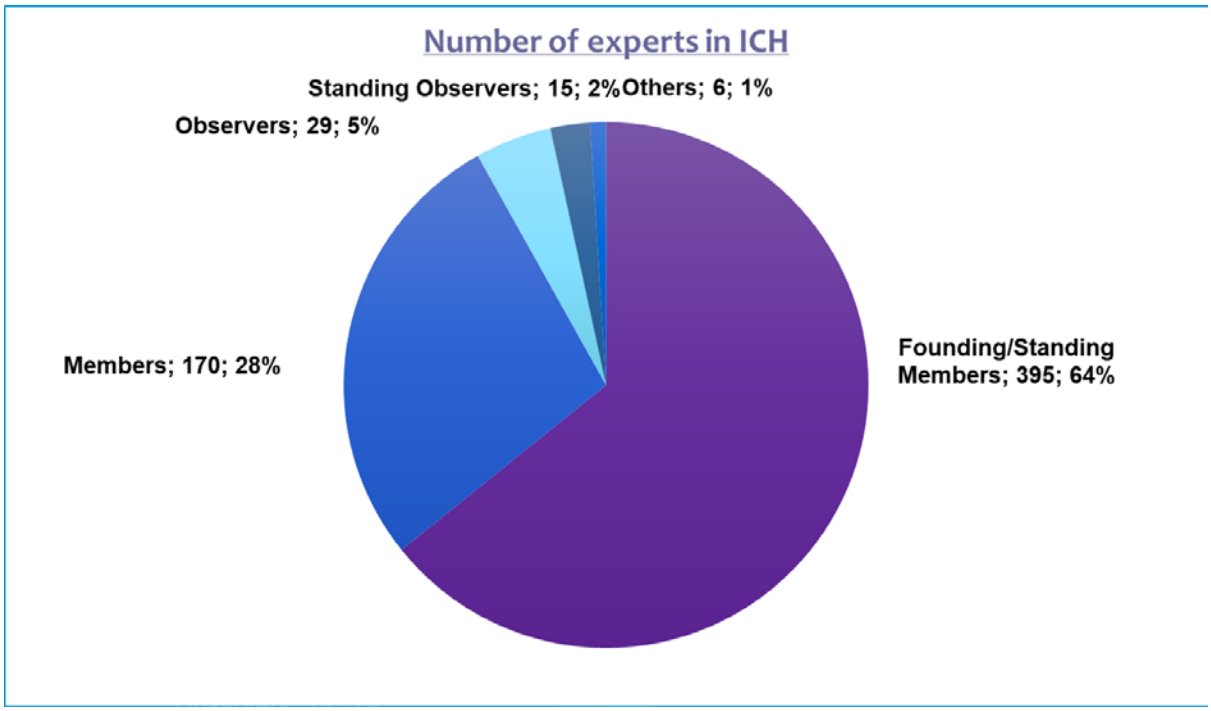
Annex 1

ICH Press Release Charlotte, November 2018, Supplementary Information



Number of experts in ICH per Members and Observers, as of 15 October 2018.