

ICH Press Release

Geneva, Switzerland, November 2017

ICH decision on multi-regional clinical trials aims to benefit public health

Geneva, 30 November 2017

The International Council for Harmonisation (ICH) met in Geneva, Switzerland on 11 to 16 November 2017. Among other decisions, the ICH Assembly approved the Health Sciences Authority, Singapore (HSA), as a new Regulatory Member. The Assembly also approved the Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Colombia (INVIMA), and the Bill & Melinda Gates Foundation as new Observers.

With these new parties, there are now 15 members and 24 observers, and full details are available on the ICH website www.ich.org.

The ICH Assembly re-elected Ms. Lenita Lindström-Gommers (EC, Europe) and Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan) as Chair and Vice-Chair until November 2019. Dr. Theresa Mullin (FDA, US) and Dr. Toshiyoshi Tominaga (MHLW/PMDA, Japan) were re-elected as Chair and Vice-Chair of the association's Management Committee.

There are 23 ICH working groups focusing on the development and maintenance of global harmonisation Guidelines and technical guidance, with the participation of some 513 scientific and technical experts. Only a subset of working groups meets face-to-face at ICH meetings, with the majority of work done through teleconferences and written exchange. Details of the membership of each working group are available on the ICH website, and a breakdown of membership is given in annex to this press release.

Planning and designing multi-regional clinical trials

With the increasing globalisation of medicines development, ICH adopted a major Guideline on the planning and design of multi-regional clinical trials (MRCTs). It is intended that the E17 Guideline will facilitate the acceptability of MRCTs as part of global regulatory submissions in ICH and non-ICH regions, as well as making it easier to seek approval of global trials.

Facilitating the conduct and acceptability of MRCTs is expected to have a direct public health benefit, in particular by encouraging more predictability around the approval of trials and the use of clinical trial data from a greater variety of countries and regions. It is hoped that this will decrease the delay in marketing authorization often caused by requirements to conduct trials in local populations, and promote earlier access to innovative medicines. Avoidance of duplicative regional or national trials will also avoid unnecessary trial subjects' exposure.

Dedicated training and implementation materials will be prepared to accompany the Guideline, including the development of case studies to aid harmonised implementation. The Assembly agreed to create an Implementation Working Group (IWG) to maintain momentum for the implementation of this important Guideline and the development of any additional guidance including Question & Answer (Q&A) documents, based on a Concept Paper to be agreed.

Draft Guideline on lifecycle management goes for public consultation

There was agreement to begin an extended 12-month public consultation of stakeholders on the draft ICH Q12 Guideline on pharmaceutical product lifecycle management, following ICH Assembly adoption of the draft Guideline. The purpose of Q12 is to provide guidance on a framework to facilitate the management of chemistry, manufacturing and control (CMC) changes to approved medicines.

In addition to providing more predictability for handling CMC changes, the Q12 Guideline is intended to contribute to public health by promoting innovation and the continual improvement of medicines. Strengthened quality assurance is also expected to lead to better reliability of product supply, including proactive supply chain planning, that should help reduce shortages.

Focus on pediatric medicines

Following agreement earlier in 2017 on the ICH E11 Guideline on clinical investigation of medicinal products in the pediatric population, ICH decided to establish a standing Pediatric Expert Working Group. The purpose of the group is to provide centralized and consistent cross-functional and multi-regional pediatric expertise to other ICH expert working groups as issues and questions arise on existing and new Guidelines.

Following the completion of the concept paper and business plan, work began on the new Guideline on pediatric extrapolation that was announced at the 27 May to 1 June 2017 Montreal meeting.

GCP renovation package

As part of the GCP renovation package announced at the November 2016 Osaka meeting, work on revising the 1997 ICH E8 Guideline on general considerations for clinical trials progressed, with the adoption of the concept paper and business plan by the Assembly. Approval of these key foundation documents clears the path for the Expert Working Group to move forward, including its plans for appropriate stakeholder engagement during the Guideline development.

Other achievements

The Assembly agreed on a Q&A document on the ICH S3A note for guidance on toxicokinetics, which focuses on micro-sampling techniques in toxicokinetic assessment that have been enabled by the recent technological development of analytical methods. By promoting the use of these new techniques, the Q&A contributes to the improvement of animal welfare, for example by reducing pain and distress in animals and the number of animals used in studies. The Q&A also contributes to the more precise evaluation of the relationship between safety data and drug exposure in animals in drug development.

Technical decisions include harmonised guidance on submission of PDF files. This was a joint effort by the M2 (Electronic standards) and M8 (eCTD) Expert Working Groups and will be published on the ESTRI website <http://estri.ich.org>. The Assembly adopted v1.1 of the eCTD v4.0 Change Request and Q&A document prepared by the M8 group, and also finalised the E2B(R3) EDQM Dose Form and Route of Administration Term User Guide.

The next ICH meeting takes place on 2-7 June 2018 in Kobe, Japan.

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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Figure 1. Number of experts in ICH Expert Working Groups, by ICH nominating party (data as at 9 November 2017).

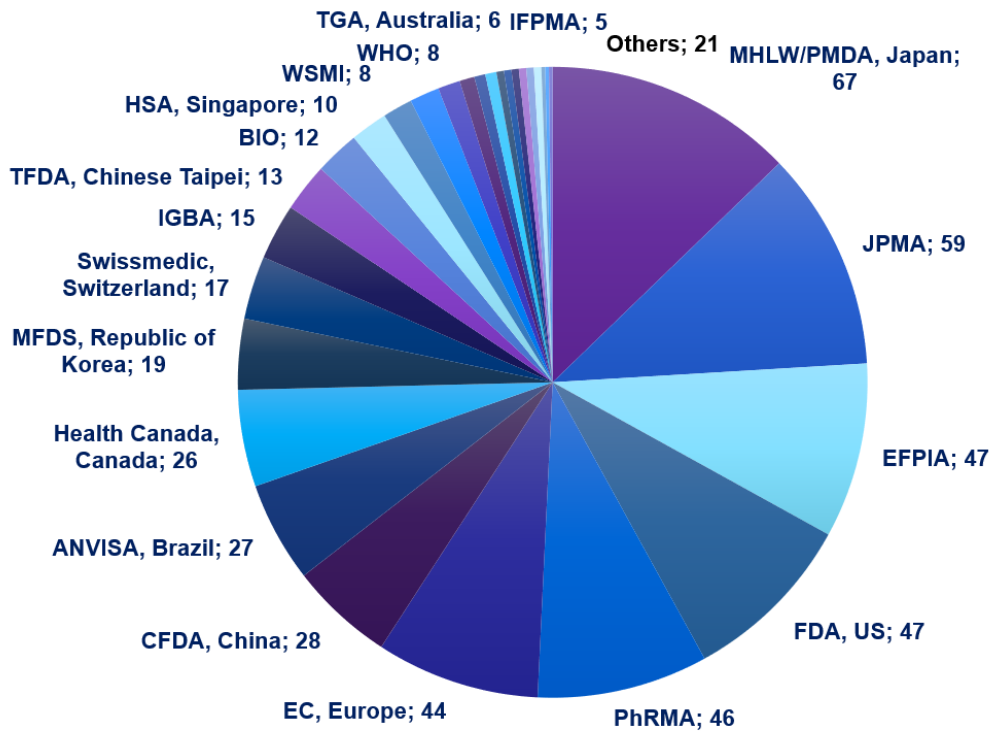


Figure 2. Proportion of experts in ICH Expert Working Groups, by category of ICH nominating party (data as at 9 November 2017).

