ICH PRESS RELEASE
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First new regulatory Members of ICH, key global good clinical practice guideline revisions agreed

The International Council for Harmonisation (ICH) met in Osaka, Japan on 5-10 November 2016. As part of the objective to extend its global outreach, ICH is pleased to welcome the Agência Nacional de Vigilância Sanitária (ANVISA) from Brazil and the Ministry of Food and Drug Safety (MFDS) from South Korea as the first new regulatory Members, together with the Biotechnology Innovation Organization (BIO) as a new industry association Member.

In addition, the following regulatory authorities and international pharmaceutical industry organisation were agreed as ICH Observers:

- Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED), Cuba
- National Center for the Expertise of Drugs, Medical Devices and Equipment (National Center), Kazakhstan
- Medicines Control Council (MCC), South Africa
- Active Pharmaceutical Ingredients Committee (APIC)

There are now 13 members and 22 observers, and full details are available on the ICH website www.ich.org.

Global good clinical practice (GCP) guideline amendment adopted

The 1996 ICH guideline on GCP is one of the most significant achievements of the ICH process, establishing harmonised standards for clinical trials. The ICH Assembly adopted an important amendment (ICH E6(R2)) that aims to encourage sponsors to implement improved oversight and management of clinical trials, while continuing to ensure protection of human subjects participating in trials and clinical trial data integrity. This amendment will now be implemented by ICH members through national and regional guidance.

In parallel, the Assembly agreed to look at renewing the wider package of guidelines that relate to GCP and clinical trial design. This will include updating current guidance on interventional trials and expand on novel trial methodologies for drug registration such as non-interventional trials, including use of new data sources such as real world evidence, patient registries, etc.

A reflection paper is expected to be published on the ICH website in early 2017, which will include an outline of the long-term work planning, beginning with revision of the ICH E8 guideline in 2017. ICH recognises the high level of interest in GCP guidance and is committed to working with concerned stakeholders and will be seeking views as work goes forward.

Optimising safety data collection

Recognising the increased interest in collecting data on the long-term effects of drugs, the Assembly also decided to begin work on development of a new guideline on optimisation of safety data collection.

The new guideline (future ICH E19) is expected to harmonise requirements on the optimal collection of safety data during late stage pre-market and post-approval clinical investigations of new drugs and new indications for approved drugs. This will improve global health by encouraging study on long-term effects, rare events and new indications of drugs through reducing resources required for these studies. ICH Members will also seek to work closely with stakeholders, especially patient representatives, in the development of this guideline.

Other decisions

Individual case safety reports (ICSRs) have an important role in supporting drug safety surveillance by regulators around the world. The Assembly agreed to an update on the implementation guide for the ICH ICSR guideline (ICH E2B(R3)) as well as the Q&A document. These documents will be published on the ICH website shortly. The Assembly acknowledged the positive collaboration with the European Directorate for Quality of Medicines (EDQM) in the use of terminologies for routes of administration and dose forms.

Following on from the adoption of the 2012 guideline on development and manufacturing of drug substances (ICH Q11), a question and answer document has been developed to clarify a number of implementation issues, particularly focusing on chemical entity drug substances. The draft document will now be released for stakeholder consultation.

A new update of the ICH guideline on residual solvents (ICH Q3C(R6)) was finalised and adopted for implementation by ICH members. There were also decisions relating to the eCTD guideline (ICH M8), with adoption of a new ICH eCTD v4.0 Implementation Package v1.2 and related documents.

For further details on progress made on other guidelines at the meeting, please see the ICH Assembly Report published on the ICH website.

Next ICH meeting will take place on 27 May – 1 June 2017 in Montreal, Canada.

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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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