ICH PRESS RELEASE

Reformed ICH advances work on several key new guidelines

Jacksonville, Florida, USA, 5-10 December 2015

The new International Council for Harmonisation (ICH) met in Jacksonville, USA, from 5 to 10 December 2015. In addition to its Expert Working Groups and Management Committee, the new ICH Assembly met in person for the first time, bringing together regulators and industry members, including observers from WHO, other regulators and industry associations.

As part of increasing the international outreach and inclusiveness of ICH, one of the first points of business was to review the application process for new Members and Observers. More information about the procedure, including application forms, will be published on the ICH website.

The Assembly also encouraged members of the former Global Cooperation Group to take the opportunity to automatically become Observers before 23 January 2016, a privilege provided by the Articles of Association. The Southern African Development Community (SADC), the Gulf Cooperation Council (GCC), the Agência Nacional de Vigilância Sanitária (ANVISA) of Brazil, the Pan American Network for Drug Regulatory Harmonization (PANDRH), and the Asia-Pacific Economic Cooperation (APEC) were welcomed as the first Observers under these new rules.

The Assembly finalised its rules of procedure, which reflect the new emphasis on clearer governance, transparency and openness in the operation of the reformed ICH, and will be published shortly.

Key advances for public health

ICH aims to improve health through harmonisation of global regulatory requirements. Some of the key achievements at this meeting include progress made on developing a draft guideline for multi-regional clinical trials (ICH E17), advances on developing a Questions and Answers document to clarify requirements for non-clinical studies for anti-cancer drugs (ICH S9 Q&A) and agreement on a draft guideline on genomic sampling and management of genomic data (ICH E18).

A draft revision to the Questions and Answers document on clinical evaluation of QT prolongation (ICH E14 Q&A (R2)) was approved. This Q&A aims to clarify and improve the use of concentration-response analysis principles for regulatory decision-making and possibly reduce the number of early phase trials.

As part of ongoing work to revise the current ICH S1 guideline on rodent carcinogenicity testing, progress was made in clarifying regulators' expectations for carcinogenicity assessment documents (CADs). Pharmaceutical companies planning to conduct carcinogenicity studies are encouraged to continue submitting CADs.

It is hoped that these efforts will lead to changes in requirements for carcinogenicity studies by allowing waivers of such studies under certain circumstances. This can potentially accelerate the approval of new, safe, effective, and high-quality drugs, while reducing the use of animals and not compromising patient safety.

To facilitate the application process for new medicines the ICH Assembly adopted the implementation package for the next major version of the electronic Common Technical Document (eCTD, ICH M8).

Details about the progress of each working group that met in Jacksonville are outlined below. All concept papers and work plans for each topic are available on the ICH website (www.ich.org).

Progress in ICH safety guidelines

In addition to the call for submission of more CADs, the ICH S1 Expert Working Group reviewed the 25 CADs received to date and the process for reviewing CADs. It also worked on improving quality of data currently included in CAD submissions.

Progress was made on a Questions and Answers document related to non-clinical evaluation of anti-cancer products (ICH S9 Q&A). Given the rapidly changing field of anti-cancer therapies, the Implementation Working Group will continue to work towards completing the draft document by the June 2016 ICH meeting.

The Expert Working Group developing a new guideline on non-clinical safety testing in support of development of pediatric medicines (ICH S11) worked on drafting text for the guideline.

The Expert Working Group revising the ICH S5(R3) guideline on detection of toxicity to reproduction for medicinal products and toxicity to male fertility continued its work on an extensive revision of this guideline to address advancements in a number of areas.

Progress in ICH efficacy guidelines

The Assembly adopted the draft guideline on genomic sampling and management of genomic data (ICH E18) for public consultation. The guideline sets out harmonised principles for genomic sampling and addresses issues relating to patient privacy and informed consent.

The draft Questions and Answers document aiming at clarifying the use of concentration-response to evaluate the risk of QT/QTc interval prolongation was approved (ICH E14 Q&A (R2)).

Progress was made on the draft addendum to the guideline on statistical principles for clinical trials (ICH E9) on providing a structured framework for improved clinical trial planning, conduct, analysis, and interpretation.

Progress was made towards completing a draft of the guideline on multi-regional clinical trials (ICH E17) and ICH anticipates that the draft document will be signed-off for public consultation prior to the next face-to-face meeting in June 2016. Multi-regional clinical trials are generally the preferred option for investigating a new drug. This guideline will facilitate acceptance of multi-regional clinical trials in global regulatory submissions.

Progress in ICH quality guidelines
Work progressed on the draft guideline on pharmaceutical product lifecycle management (ICH Q12) and creation of a framework for effective quality management systems, and management of post-approval chemistry manufacturing and controls changes in a more predictable and efficient manner across the product lifecycle. This aims to optimise industry and regulator resources, to ensure continual improvement and contribute to assuring drug quality and availability.

The next ICH meetings will be held from 11-16 June 2016 in Europe, and 5-10 November 2016 in Japan.

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NOTES FOR EDITORS

1. For more details on the ICH reforms, see the ICH press release of 26 October 2015 here.
2. This press release, together with more information on the guidelines mentioned above, can be found on its website: www.ich.org

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