OVERVIEW

This year’s Information Day will review the ICH reform following the key developments agreed to at the Steering Committee meeting in November 2014. Participants will also get the opportunity to hear directly from regulators and industry representatives about a selection of important new topics that are being addressed as part of the ICH process.

ABOUT ICH

The success of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is largely due to its unique model that brings together regulatory authorities and pharmaceutical industry from Europe, Japan and the US to discuss scientific and technical aspects. Since its launch in 1990, ICH has evolved and responded to the increasing globalisation of pharmaceutical development and the need for international regulators outside the initial 3 regions to work together to respond to these new challenges.
08.00  REGISTRATION

08.30  SESSION 1

Session Chairpersons: Lenita Lindström Gommers, European Commission and Emer Cooke, European Medicines Agency

The ICH Steering Committee meeting of 8-13 November 2014 agreed on some key reforms of ICH in terms of governance, new membership and funding. This session will provide an overview of these reforms, including implications for pharmaceutical industry and mechanisms for wider involvement of regulatory partners outside the original three ICH regions.

ICH reforms
Lenita Lindström Gommers, European Commission

Industry perspectives on ICH reform
Pär Tellner, EFPIA

Questions & Answers, Panel Discussion
Session participants and Sarah Adam, ICH Secretariat

09.30  SESSION 2

Session Chairperson: Tomas Salmonson, European Medicines Agency

This session includes a look at the new ICH quality topic (Q12) being developed to facilitate post-approval changes, promote innovation, quality management and continual improvement throughout the lifecycle. It will also review of initiatives in the area of nonclinical rodent carcinogenicity studies, where an effort to introduce a more comprehensive and integrated approach to address the risk of human carcinogenicity of small molecule pharmaceuticals is being made (SI).

Q12 Pharmaceutical Product Lifecycle Management
Graham Cook, Pfizer Global Quality Intelligence and Compendial Affairs

S1 Regulatory Notice Document on the Proposed Change to Rodent Carcinogenicity Testing of Pharmaceuticals
Jan-Willem van der Laan, Medicines Evaluation Board

Questions & Answers

10.30  COFFEE BREAK

11.00  SESSION 3

Session Chairperson: Tomas Salmonson, European Medicines Agency

This session will look at 3 key ICH efficacy topics. It includes scientific and technical advances in paediatric drug development being addressed in the context of the Addendum to E11, including methodological aspects, commonality of content in plans for paediatric drug development, considerations on extrapolation, and paediatric formulations. It will also review the innovative approaches to good clinical practices (GCP), which are currently being harmonized as an Addendum to Guideline E6. The final topic looks at advances made in harmonising multi-regional clinical trials (MRCTs). This work stream has the final goal of promoting appropriate conduct of MRCTs, resulting in further use of data from MRCTs in the various regions and better regulatory decisions.

E11 Clinical Investigation of Medicinal Products in the Paediatric Population
Dirk Mentzer, Paul-Ehrlich-Institut

E6 Addendum on Good Clinical Practice
Fergus Sweeney, European Medicines Agency

E17 Multi-Regional Clinical Trials
Yoshiaki Uyama, Pharmaceuticals and Medical Devices Agency

Questions & Answers

12.30  END OF INFORMATION DAY

STAY CONNECTED

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REGISTRATION FORM
Information Day on ICH
13 April 2015, Le Palais des Congrès, Paris, France

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,
E-mail: diaeurope@diaeurope.org  Fax: ++41 61 225 51 52   For more information please call +41 61 225 51 51

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