Information Day on ICH

13 April 2015 | Le Palais des Congrès, Paris, France

PROGRAMME COMMITTEE

Lenita Lindström Gommers,
DG SANTE, European Commission, EU
Member of ICH Steering Committee

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European Medicines Agency, EU
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EMA Technical Coordinator,
European Medicines Agency, EU

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SPEAKERS

Sarah Adam
ICH Manager,
ICH Secretariat, Switzerland

Graham Cook
Senior Director, Pfizer Global Quality Intelligence and Compendial Affairs,
United Kingdom

Dirk Mentzer
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Head of Inspections and Human Medicines Pharmacovigilance Division,
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EFPIA, Belgium
EFPIA ICH Coordinator

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Director, Division of Epidemiology, Office of Safety I, Pharmaceuticals and Medical Devices Agency, Japan

Jan Willem van der Laan
Section on Pharmacology, Toxicology and Biotechnology (FTBB), Medicines Evaluation Board, The Netherlands
Chair of CHMP Safety Working Party,

DIA DEVELOP INNOVATE ADVANCE

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.

In collaboration with :

EUROPEAN MEDICINES AGENCY
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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 (S1).

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

Event venue

Le Palais des Congrès
2 Place de la Porte Maillot
75017 Paris, France
Registration will be located on level 3

Hotel Information

DIA has negotiated special hotel rates with K.I.T. Group GmbH for participants of the Information Day on ICH (EuroMeeting/Clinical Forum room block).
For more information on hotels and to book your room please use the link on DIA website.

For any question concerning your booking, please contact K.I.T. Group GmbH directly. Tel: +49 30 24 603 226 | Fax: +49 30 24 603 399
E-mail: dia2015@kit-group.org

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 harmonised as an Addendum to Guideline ICH 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

REGISTRATION FORM

Information Day on ICH
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ID# 15116

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

Registration fees*	Fees*
Industry	300.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	FREE ❑
DIA Membership	130.00 EUR ❑

***ALL REGISTRATION FEES ARE SUBJECT TO FRENCH VAT AT 20%**
PLEASE ENTER YOUR COMPANY'S FRENCH VAT NUMBER HERE: _____

Registration fee includes: morning Coffee Break and delegate material

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

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• Industry (Member/Non-member) € 200.00

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Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

Photography Policy

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The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
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