3rd ICH Information Day

ICH Goes Global
ICH Reforms & How They Affect You

Jointly Organised by EC/EMA/DIA

6 April 2016 | 08:00 - 12:30
CCH Congress Centre Hamburg, Germany

PROGRAMME COMMITTEE

Martin Harvey Allchurch
International Affairs, European Medicines Agency, EU

Lenita Lindström Gommers
DG SANTE, European Commission, EU
ICH Assembly Chair

Tomas Salmonson
Chair CHMP, Senior Scientific Advisor, MPA, Sweden

SPEAKERS

Richard Bergström
Director-General, EFPIA, Belgium

Emer Cooke
Head of International Affairs European Medicines Agency, European Union

Corina Dana Dota
AZ ECG Centre Director, AstraZeneca, Sweden

Joris Kampmeijer
Information Processing Department Medicines Evaluation Board, Netherlands

Filip Mussen
Vice President, Regional Regulatory Affairs
Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium
Dawn Ronan, Director of the ICH Secretariat, Switzerland

Toshiyoshi Tominaga
Associate Executive Director (for International Programs)
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Steven Teerenstra, Statistician
Medicines Evaluation Board, the Netherlands

Jan-Willem Van der Laan
Section on Pharmacology, Toxicology and Biotechnology (FTBB), Medicines Evaluation Board, the Netherlands
Chair of CHMP Safety Working Party, European Medicines Agency, EU

OVERVIEW

This year's Information Day will focus on the recent reforms by ICH and what this means for global development of medicines. Participants will hear how ICH is moving towards being a truly global platform for regulators and industry to achieve the objective of 'Harmonisation for Better Health'.

Learn directly from the experts: Sessions include Q&A with *Dawn Ronan, ICH, Switzerland, Tomas Salmonson EMA, EU and Richard Bergström, EFPIA, Belgium*

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. Following the reforms, ICH has become "the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use" and established as an international non-profit Association under Swiss law on 23 October 2015. The reforms mean that ICH becomes a truly global initiative, expanding beyond the current ICH members. Regulatory authorities and international pharmaceutical industry organisations that are affected by ICH guidelines may apply to become Members or Observers of the Association.

Organised by: DIA DEVELOP INNOVATE ADVANCE

In collaboration with: EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

08:30 SESSION 1

Session Chairpersons:
Lenita Lindström Gommers, European Commission and **Emer Cooke**, EMA, EU

This session will illustrate that ICH is a platform for regulators and industry to engage and debate, and where they can work together to deliver on the promise of ICH – "Harmonisation for Better Health". Overview of the reforms, what was achieved, where we are today and future plans.

A reformed ICH: Better equipped for global harmonisation and regulation of technical requirements for medicines
Lenita Lindström-Gommers, European Commission, EU

Harmonisation for Better Health: Making sure ICH addresses the right topics
Tomas Salmonson, MPA, Sweden

Questions & Answers, Panel Discussion with Dawn Ronan, ICH, Switzerland

09:30 SESSION 2

Session Chairperson:
Tomas Salmonson, MPA, Sweden

This session will talk about how the M2 expert group will impact on drug development and on other ICH guidelines. Translation of standards to real impact for drug discovery and impacts on public health. This session will focus on the changes that S1, S5, and S11 will introduce.

M2 Electronic Standards
Joris Kampmeijer, Medicines Evaluation Board, the Netherlands

S Series: Changing paradigms in non-clinical drug development
Jan-Willem Van der Laan, Medicines Evaluation Board, the Netherlands

Questions & Answers

10:30 COFFEE BREAK

11.00 SESSION 3

Session Chairperson: Toshiyoshi Tominaga, PMDA, Japan

E9 Improving Planning, Conduct, Analysis and Interpretation of Clinical trials
Steven Teerenstra, Medicines Evaluation Board, the Netherlands

E14 Clinical Evaluation of QT/QTc
Corina Dana Dota, AstraZeneca, Sweden

M4E (CTD) Benefit-Risk Information
Filip Mussen, Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium

Panel Discussion with Tomas Salmonson MPA, Sweden and Richard Bergström, EFPIA, Belgium

12:30 CLOSING COMMENTS AND REMARKS AND END OF ICH DAY

Event venue

CCH - Congress Center Hamburg
Am Dammtor / Marseiller Str.
20355 Hamburg
Deutschland

Hotel Information

DIA has negotiated special hotel rates with K.I.T. Group GmbH for participants of the Information Day on ICH (EuroMeeting 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
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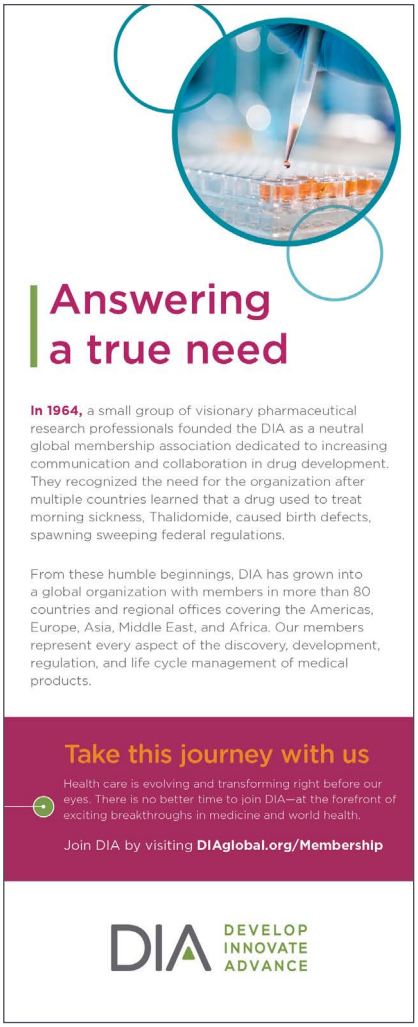

REGISTRATION FORM

ICH Information Day | ID#16120
6 April 2016 | CCH Congress Centre Hamburg, Germany

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FEES	Fees*
Industry	€ 450.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	Free ❑

*All fees are subject to 19% German VAT.

Registration fee includes: morning Coffee Break and delegate material. Payment 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 MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

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Please provide your European VAT number

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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, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here.**

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TERMS AND CONDITIONS

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All cancellations must be in writing and received at the DIA EMEA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00
Academia/Charitable/Government /Non-profit (Member/Non-member) = € 100.00
For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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 EMEA office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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

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