# Clinical Trials Workshop II – Translating the New Transparency Requirements into Practice

Event #14116
24-25 September 2014
Millennium Gloucester Hotel London Kensington, UK

## Programme Co-Chairs

**Sabine Atzor**
Head of EU Regulatory Policies, F. Hoffmann-La Roche Ltd, Switzerland

**Nick Sykes**
Senior Director, Worldwide Safety & Regulatory, Pfizer Inc., UK

## Programme Committee

**Merete Joergensen**
Director, Global Clinical Registry, Novo Nordisk A/S, Denmark

**Hanns-Georg Leimer**
Head of Processes and Systems Coordination in Corporate Division Quality, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

**Robert Paarlberg**
Principal, Paarlberg & Associates LLC, USA

## UPGRADE TO THE FULL THREE DAYS!

Add the extra day from ***Workshop I - Translating the New Clinical Trials Regulation into Practice*** (23 September) to your registration.

See the registration form at the back for rates.

## Overview

New EU requirements are expected to come into force during 2014, impacting clinical trial processes including informed consent as well as the provision of public access to information and results of clinical trials. This workshop will review the new transparency requirements and voluntary commitments and, describe how these will impact current disclosure procedures. There will be a focus on sharing experiences on how the requirements are being implemented in practise.

The two day workshop will address the Transparency aspects of the new Clinical Trials Regulation expected to become applicable in 2016, the EMA clinical data transparency policy expected to be published in its final version for implementation later in 2014, and implementation of the clinical trials results submission to EudraCT for public disclosure via the EU Clinical Trials Register. The EU results requirements via EudraCT is to come in force by the finalisation of the next version update of EudraCT, expected mid 2014. The workshop will also address how these initiatives relate to the EFPIA-PhRMA "Principles for Responsible Data Sharing" and how industry is implementing the Principles.

An adjacent 2-day workshop on the new Clinical Trials Regulation, will offer an opportunity for attendees to focus on conceptual and practical aspects of implementation of the new Regulation. Attendees can participate in either one workshop or in the entire 3-day program. The two workshops will overlap with a day addressing the Transparency aspects of the Clinical Trials Regulation.

## Key Topics Include

- Key aspects of the present and new requirements on clinical trials with respect to disclosure and transparency of clinical trial information
- Impact on preparation and update of CTA submissions by sponsors
- Preparing redacted Clinical Study Reports (CSRs) and lay summaries in response to the EFPIA-PhRMA Principles, the new EMA policy, and the new Clinical Trials Regulation
- Role of European Commission and EMA and implementing measures
- Entering study results into the EudraCT database versus ClinicalTrials.gov
- Public information in the EU Clinical Trials Register from the EudraCT database.
- Industry scheme for clinical trial data sharing

## Objectives

- Understanding the new requirements and the way they are being implemented by authorities and clinical trial sponsors including their practical and operational impact
- Discuss and identify the key challenges and opportunities of the new requirements and policies
- Recognise how companies and research institutions are fine-tuning and optimising processes to meet the requirements for disclosure of clinical trial information and data sharing initiatives.
- Exchange views between regulators, industry, patients, academia and other stakeholders

## Who Will Attend

This workshop is aimed at intermediate and experienced professionals from

- Regulatory agencies
- The pharmaceutical industry and Contract Research Organisations including
  - Staff from clinical data disclosure, clinical science, and clinical operations
  - Regulatory affairs personnel
  - Pharmacovigilance staff
  - Staff from Legal, Patent departments and Scientific Intelligence
- Academic institutions
- Physicians
- Patient organisations

This workshop is currently in development. Please contact mara.canova@diaeurope.org or visit www.diahome.org for more information.

FIFTY YEARS 1964-2014 DIA®
www.diahome.org

# JOINT DAY FOR WORKSHOPS I AND II

## DAY ONE | WEDNESDAY, 24 SEPTEMBER 2014

**08:00** **REGISTRATION AND WELCOME COFFEE**

**08.45** **WELCOME AND INTRODUCTION**

**09:00** Wednesday | Session 1

**PROVISIONS UNDER THE NEW REGULATION – REQUIREMENTS FOR THE EU DATABASE AND PORTAL**
Session Chair invited

**The new EU Portal and Database – What to be expected by when?**
EMA speaker invited

**Expectations by Member States for Competent Authorities and Ethics Committees**
MHRA speaker invited

**Learning From Experience – Industry's hopes and concerns?**
Angelika Joos, Executive Director, Global Regulatory Policy, MSD (Europe) Inc., Belgium

**10:30** **COFFEE BREAK**

**11:00** Wednesday | Session 2

**CLINICAL TRIAL DATA TRANSPARENCY – HOW TO MOVE TO THE FUTURE?**
EMA Session Chair invited

**EUDRACT to the CT Regulation – EMA's vision for availability of clinical trial information and how it is to be achieved?**
EMA speaker invited

**What changes will new transparency provisions bring for researchers?**
Catrin Tudur Smith, Reader in Medical Statistics, Liverpool University, Liverpool

**What does greater availability of clinical trial information mean for HTA?**
Speaker invited

**12:30** **LUNCH**

**14:00** Wednesday | Session 3

**EXPECTATIONS – WHAT STAKEHOLDERS EXPECT FROM THE NEW TRANSPARENCY REQUIREMENTS**
Facilitator:
**Ingrid Klingmann,** European Forum for Good Clinical Practice (EFGCP), Belgium

Extended panel discussion with Speakers from Session 1 and 2 involving Ethics Committee, Patient Representatives and Academia, with questions from the audience

**Patient Organisation Representative**
EURORDIS speaker invited

**Ethics Committee Representative**
Joerg Hasford, President of the Working Group of Medical Ethics Committees, Ludwig-Maximilians University, Germany

**15:00** **COFFEE BREAK**

**15:30** Wednesday | Session 4

**INDUSTRY COMMITMENT – FROM DATA SHARING POLICY TO IMPLEMENTATION**
Session Chair:
**Hanns-Georg Leimer,** Head of Transparency, Disclosure, and Application Governance within Medical, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

**How does the new policy translate for the industry? A company approach**
Robert Frost, Policy Director, Medical Policy, Office of the Chief Medical Officer, GlaxoSmithKline, UK

**Commercially Confidential Information – Where to draw the line?**
Victoria Kitcatt, Vice President and Assistant General Counsel, European Regulatory Law, Pfizer Ltd, UK

**How may data transparency contribute to improving the development of medicines?**
Rebecca Sudlow, Associate Director (Biostatistics Manager), Roche Products Ltd, UK

**17:00** **END OF WORKSHOP I**

## HOTEL INFORMATION

A limited number of rooms are available a special rate at the event hotel:

Millennium Gloucester Hotel London Kensington
Address: 4-18 Harrington Gardens, London SW7 4LH, UK
Tel: +44(0) 207 331 6105 Fax: +44(0) 207 331 6123

To make your booking, go to www.millenniumhotels.co.uk/millennium-gloucester/Booking Code: LOND230914 (insert the code into the CORP/ PROMO CODE box)
Single GBP 140.00/Double GBP 150.00 including breakfast and VAT

DIA rate is guaranteed until 11 August 2014, or until room block is filled. After this rooms are subject to availability and prices may vary. Attendees should make reservations as soon as possible.

## TRAVEL INFORMATION

The Millennium Gloucester Hotel London Kensington is situated next to Gloucester Road underground station served by Circle, District and Piccadilly Lines. For details on public transport please visit http://www.tfl.gov.uk

## DAY TWO | THURSDAY, 25 SEPTEMBER 2014

**08:00** **REGISTRATION AND WELCOME COFFEE**

**09:00** Thursday | Session 1

**OPERATIONAL ASPECTS OF DATA SHARING: CLINICAL STUDY RESULTS AND PATIENT LEVEL DATA**
Session Chair:
**Holger Maria Rohde**, Director, Strategy Implementation Lead, Merck Serono Strategy and Business Operations Global R&D, Germany

**Independent Review Panel – different models**
Speaker invited

**Perspectives from academia**
Catrin Tudur Smith, Reader in Medical Statistics, Liverpool University, Liverpool

**How can patient confidentiality be maintained?**
Speaker invited

**10:30** **COFFEE BREAK**

**11:00** Thursday | Session 2

**A PERSPECTIVE OUT OF EUROPE – REGIONAL AND LOCAL REGISTRIES - CONSIDERATIONS OF TRANSPARENCY**
Session Chair:
**Robert Paarlberg**, Principal, Paarlberg & Associates LLC, USA

**Overview of Regional/Country Registries and Results Disclosure**
John C. McKenney, President, SEC Associates, Inc., USA

**Regulatory and Policy Issues in the USA**
Rebecca J. Williams, Assistant Director, ClinicalTrials.gov, National Library of Medicine, NIH, USA

**Future Situation with EU and National Registries**
Speaker invited

**12:30** **LUNCH**

**14:00** Thursday | Session 3

**OPERATIONAL ASPECTS OF DATA SHARING: EUDRACT**
Session Chair:
**Merete Joergensen**, Director, Global Clinical Registry, Novo Nordisk A/S, Denmark

**How to cope with the posting back to 2004?**
Speaker invited

**Practical Considerations in Posting Future Trial Results on ClinicalTrials.gov and EudraCT – An industry perspective**
Speaker invited

**EU and US Requirements on Results Reporting - A comparison**
Rebecca J. Williams, Assistant Director, ClinicalTrials.gov, National Library of Medicine, NIH, USA
and EMA speaker invited

## About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation headquartered in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

## DIA EUROPE CONFERENCES AND WORKSHOPS 2014-2015

- **Achieving Improved Regulatory Efficiency within the current Framework: Lessons from the Escher Project – jointly organised by DIA and TOPRA**
  Mid-September 2014 | Brussels, Belgium
- **8th Annual European Medical Information and Communication Conference and Exhibition**
  23-24 September 2014 | London, United Kingdom | ID 14103
- **Joint DIA/FIP European Workshop on Biorelevant Performance Testing of Orally Administered Dosage Forms**
  24-25 September 2014 | Amsterdam, the Netherlands
- **EFGCP/DIA/EMA Annual Conference on Better Medicines for Children – Exploring ways to enhance collaboration between key players**
  30 September – 1 October 2014, EMA Headquarters, London, UK
- **Joint DIA/ICOS Conference on Cardiac Toxicity Resulting from Cancer Chemotherapy: Strategies for Early Detection, Risk Mitigation and Clinical Prevetion and Exhibition**
  9-10 October 2014 | Prague, Czech Republic | ID14108
- **4th African Regulatory Conference and Exhibition**
  22-23 October 2014 | Dakar, Senegal | ID 14105
- **Workshop on HTA and Access to Medicines Status and Future**
  End October 2014 | location to be confirmed
- **Joint DIA/AEMPS Statistics Workshop**
  10-11 November 2014 | Barcelona, Spain | ID 14107
- **Maghreb Regulatory Conference and Exhibition**
  November 2014 | Algiers, Algeria | ID 14113

For more information and a complete listing of all DIA conferences, please visit: www.diahome.org > click on Meetings & Training

Call DIA Europe on +41 61 225 51 51 or email:
diaeurope@diaeurope.org

# REGISTRATION FORM
## Clinical Trials Workshop II
24-25 September 2014 I Millennium Gloucester Hotel London Kensington, UK

**ID #14116**

## Early-bird rates available for members: Register by 12 August 2014

Join DIA now to qualify for the Early-bird member fee! The Early-bird registration form and accompanying payment must be received by the date above. Early-bird fee applies to industry members only. *(www.diahome.org/membership)*

**€ 1'220.00** ❑

## FEES (after 12 August 2014)

| | Member | Non-Member |
|---|---|---|
| Industry | € 1'420.00 ❑ | € 1'550.00 ❑ |
| Academia/Charitable/Government/Non-profit (Full-time) | € 710.00 ❑ | € 840.00 ❑ |
| Join DIA now to qualify for the member rate | € 130.00 ❑ | |

### OPTIONAL DAY:

Upgrade and add a third day (23.9.) of the adjacent #14111 "Clinical Trials Workshop II – Translating the New Clinical Trials Regulation into Practice" for a special fee:

| | |
|---|---|
| Industry | €550.00 ❑ |
| Academia/Charitable/Government/Non-profit (Full-time) | €275.00 ❑ |

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information. Registration fee includes: refreshments, lunches and meeting material.

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

**TOTAL AMOUNT DUE:** _____

## 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.

## PAYMENT METHODS

**Credit cards:** Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date / 

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID #14116 as well as the invoice number to ensure correct allocation of your payment.

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 |
|---|---|
| | |

### Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
Email diaeurope@diaeurope.org Tel. +41 61 225 51 51 Fax +41 61 225 51 52 Web www.diaeurope.org Mail DIA Europe, Küchengasse 16, 4051 Basel, Switzerland