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

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

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 practice.

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.
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:
Fergus Sweeney, Head, Inspections and Human Medicines, Pharmacovigilance Division, European Medicines Agency, EU

The new EU Portal and Database – What to be expected by when?
Ana Rodriguez, Head, Clinical and Non-Clinical Compliance Service, European Medicines Agency, EU

Expectations by Member States for Competent Authorities and Ethics Committees
Stefan Strasser, Department for Clinical Trials, Institute Surveillance, BASG/AGES, Austria

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 AND MAAS– HOW TO MOVE TO THE FUTURE?
Session Chair:
Noël Wathion, Chief Policy Adviser, European Medicines Agency, EU

EMA’s vision for Availability of Clinical Trial Information from Marketing Authorisation Applications and How it is to be Achieved
Noël Wathion, Chief Policy Adviser, European Medicines Agency, EU

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?
Meindert Boysen, Programme Director Technology Appraisals, PASLU and HST NICE, UK

12:30  LUNCH

14:00  Wednesday | Session 3

EXPECTATIONS – WHAT STAKEHOLDERS EXPECT FROM THE NEW TRANSPARENCY REQUIREMENTS
Session Chair:
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
Kaisa Immonen-Charalambous, Senior Policy Adviser at European Patients’ Forum, Belgium

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, 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

17:30  END OF WEDNESDAY PROGRAMME FOR WORKSHOP II

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
Nicola Perrin, Head of Policy, Welcome Trust, London, UK

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

How can patient confidentiality be maintained?
Robert Frost, Policy Director, Medical Policy, Office of the Chief Medical Officer, GlaxoSmithKline, UK

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

EU-CTR and National registers - way into the future?
Thorsten Ruppert, Verband Forschender Arzneimittelhersteller e.V., Berlin, Germany

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?
Azin Shahzamani, Senior Director Global Head, Disclosures, Regulatory Affairs Genentech, F.Hoffmann-La Roche, Switzerland

EMA – Practical considerations of EudraCT and EU CTR postings - and international context
Noemie Manent, Clinical and Nonclinical Compliance Service, European Medicines Agency, EU

US Requirements on Results Reporting – and international context
Rebecca J. Williams, Assistant Director, ClinicalTrials.gov, National Library of Medicine, NIH, USA

15:30  END OF WORKSHOP

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 interdisciplinary 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.

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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 | 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)

FEES (after 12 August 2014)

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Join DIA now to qualify for the member rate

€ 150.00

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 canceling 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.