Overview

The new EU Clinical Trials Regulation is expected to become applicable in 2016. The new legislation will have implications on clinical trial sponsors preparing and submitting clinical trial applications. Member States will have to adapt their procedures for the assessment of clinical trial applications by competent authorities and review by ethics committees. Additionally, the new Regulation will impact how the conduct of a clinical trial is managed after approval has been granted. New provisions for public access to an EU clinical trials database will enforce disclosure of clinical trials data and information.

This 2-day workshop will provide a forum for information exchange and discussion on conceptual and practical questions through lectures, panel discussions, and interactive break-out sessions. Day 1 will focus on the new provisions for submission, assessment and decision-making of clinical trial applications, and the management and monitoring of trials. Day 2 will focus on the new transparency provisions for clinical trials.

An adjacent 2-day workshop, on clinical data transparency, will focus on practical considerations for the disclosure of clinical trials data. 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.

There will be an introductory session at the beginning of the workshop for those attendees, who feel they need an overview on the new legislation to enable them to participate in discussions throughout the event.

Key Topics Include

• Key aspects of the present and new requirements on managing clinical trials including disclosure and transparency of data from trials
• Coordinated assessment by Member States
• Developments in the Member States – Cooperation between Agencies and Ethics Committees
• Impact on preparation of submissions by sponsors, including redacted CSRs and lay summaries
• Role of European Commission and EMA and implementing measures
• 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 implementation is being considered 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 of the clinical trials Regulation.
• 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 science and clinical operations
  • Monitors, auditors of clinical trials
  • Regulatory affairs personnel
  • Pharmacovigilance staff
• 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.
DAY ONE | TUESDAY | 23 SEPTEMBER 2014

07:30  REGISTRATION AND WELCOME COFFEE

08:00  Pre-Workshop Session

WHAT IS NEW IN THE CLINICAL TRIALS REGULATION – OVERVIEW OF THE KEY CHANGES

Clare Laverty, Director, Janssen Pharmaceutical Companies of Johnson & Johnson, UK
Fabienne Zeegers, Associate Director, Global Clinical Trial Submission Unit GCT-SU and EU CT External Policies, Global Development Operations, Bristol Myers Squibb International, Belgium

09:30  REGISTRATION AND WELCOME COFFEE

10:00  Tuesday | Session 1

WELCOME AND INTRODUCTION TO THE NEW CLINICAL TRIALS LEGISLATION

Session Chair:
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer Inc., UK

Introduction to the Workshop
Sabine Atzor, Head of EU Regulatory Policies, F. Hoffmann-La Roche Ltd, Switzerland

Keynote speech: The New Regulation – How will the outcome reflect the need of Europe?
Speaker invited

Keynote speech: Does the new Regulation meet the needs of the innovative industry in a global environment?
Susan Forda, Vice President, International Regulatory Affairs, Eli Lilly & Company Ltd, UK

11:00  Tuesday | Session 2

SUBMISSION, ASSESSMENT, DECISION OF A CLINICAL TRIAL APPLICATION – A NEW PARADIGM – PERSPECTIVE FROM THE MEMBER STATES

Session Chair invited

From Voluntary Harmonisation Procedure to Clinical Trials Regulation: How long is the way to go?
Hartmut Krafft, Head, Section Clinical Trials, Paul Ehrlich-Institut

Challenges Faced by MS for Implementation
Stefan Strasser, Department for Clinical Trials, Institute Surveillance, BASG/AGES, Austria

Integration of Ethics Committees into the Process – A model example
Joerg Hasford, President of the Working Group of Medical Ethics Committees, Ludwig-Maximilians University, Germany

12:15  LUNCH

13:30  Tuesday | Session 3

SUBMISSION, ASSESSMENT, DECISION OF A CLINICAL TRIAL APPLICATION – A NEW PARADIGM – PERSPECTIVE FROM COMMERCIAL SPONSORS

Session Chair:
Ingrid Klingmann, European Forum for Good Clinical Practice (EFGCP), Belgium

14:30  Panel Discussion with Speakers from Sessions 1 - 3

Facilitator:
Ingrid Klingmann, European Forum for Good Clinical Practice (EFGCP), Belgium

15:00  COFFEE BREAK

15:30  Tuesday | Session 4

PROTECTION OF THE SUBJECT

Session Chair:
Esteban Herrero-Martinez, Director of Regulatory Intelligence, Daiichi Sankyo Development Ltd, UK

Informed Consent – What matters to patients?
Kaisa Immonen-Charalambous, Senior Policy Adviser at European Patients’ Forum, Belgium

Safety Reporting – How to ensure cooperation between member states
Elke Stahl, Federal Institute for Drugs and Medicinal Devices (BfArM), Division of Scientific Services, Clinical Trial Unit, Preclinical Section, Germany

Panel discussion with Q&A

16:45  Tuesday | Session 5

PERSPECTIVE OF OTHER STAKEHOLDERS

Session Chair:
Isabelle Clamou, Regulatory affairs Director, EU Policy, Amgen Ltd, Belgium

How will Academia Manage New Processes in the Future?
Daniel Bridge, Policy Manager, Cancer Research, UK

Where do CROs need to re-adjust their processes?
John Poland, PhD, FTOPRA, Chair ACRO EU Scientific & Regulatory Committee, UK

17:45  NETWORKING RECEPTION

18:45  END OF TUESDAY PROGRAMME WORKSHOP I

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.

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe. Speakers and agenda are subject to change without notice. Recording during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.
DAY TWO | 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, GlaxoSmithKilne, 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

NETWORKING RECEPTION IN THE EXHIBITION AREA FOR WORKSHOP II

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

EXHIBIT AT THIS WORKSHOP
For more information on opportunities to showcase your company to this focused audience, please contact Roxann Schumacher, DIA Exhibits Manager on +41 61 225 51 38 or email: roxann.schumacher@diaeurope.org
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: €130.00

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 availability – 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.

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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 #14111 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.