Clinical Trials Workshop

Are we ready for the Implementation of the new Clinical Trial Regulation in 2016?

26-27 October 2015

Holiday Inn Bloomsbury, London, UK

PROGRAMME CO-CHAIRS

Clare Lavery, Director, Policy, Chief Medical Office, AstraZeneca, UK

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

PROGRAMME COMMITTEE

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

Elke Stahl, Clinical Trial Unit, BfArM, Germany

ABOUT DIA

In 1964, 30 visionary pharmaceutical research professionals came together with a noble mission – to increase communication and collaboration in drug development in order to improve safety and advance therapeutic success.

Over the next 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: to improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

CONTINUING EDUCATION

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. This conference has been accredited with 10 credits. All participants are eligible for these credits.

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 and panel discussions. There will be a particular focus on the critical issues affecting sponsors and Member States as they consider the impact and changes needed to implement the Regulation.

KEY TOPICS

Key aspects of and differences between the present and new requirements on managing clinical trials including:

- Member States preparedness for the Regulation, including plans for co-operation between agencies and ethics committees and coordinated assessment.
- Considerations for the preparation of applications and notifications by sponsors.
- Role of the European Commission and proposals for implementing measures.
- EMA Status report - Development of the EU Clinical Trials Portal and Database.
- Impact of new requirements for disclosure and transparency of data from clinical trials.

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, clinical trial sponsors, patients and other stakeholders.

FINAL PROGRAMME

DIA DEVELOP INNOVATE ADVANCE

DIA Europe, Middle East and Africa
Kuechengasse 16
4051 Basel, Switzerland
+41 61 225 51 51 | emea@DIAglobal.org

DAY ONE | MONDAY, 26 OCTOBER 2015

08:30 **REGISTRATION AND WELCOME COFFEE**

09:30 **PRE-WORKSHOP SESSION**

OVERVIEW OF THE CLINICAL TRIAL REGULATION AND CURRENT KNOWLEDGE

An optional training session at the start of the Workshop outlining the key provisions of the Clinical Trial Regulation and the knowledge about the CTReg that is widely known, for example a review of latest knowledge concerning the proposed CT database and portal, including potential transparency rules, and potentially any released delegated acts (GMP and/or GCP) and implementing guidance.

Clare Lavery, Director, Policy, Chief Medical Office, AstraZeneca, UK

Fabienne Zeegers, Associate Director, Global Clinical Trial Submission Unit GCT-SU, Bristol Myers Squibb, Belgium

10:30 **REGISTRATION AND COFFEE**

11:00 **SESSION 1**

WORKSHOP OFFICIAL OPENING

Welcome Remarks

Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, UK

Clare Lavery, Director, Policy, Chief Medical Office, AstraZeneca, UK

Keynote Speech

Lidia Retkowska-Mika, Director Legal DPT, Office For Registration of Medicinal Products, Medical Devices and Biocides, Poland

11:30 **SESSION 2**

CONSIDERATIONS BY MEMBER STATES AS THEY WORK TOWARDS IMPLEMENTATION OF THE REGULATION

Session Co-Chairs:

Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, UK

Clare Lavery, Director, Policy, Chief Medical Office, AstraZeneca, UK

The different Member States (MS) and EMA discuss their views on key challenges for implementation of the CTReg.

Panelists:

Lidia Retkowska-Mika, Director Legal DPT, Office For Registration of Medicinal Products, Medical Devices and Biocides, Poland

Kristof Bonnarens, Head of Division R&D, Federal Agency For Medicines and Medicinal Products, Belgium

Janet Messer, Director of Systems & Development and Programme Director - HRA Approval, Health Research Authority, UK

Lene Grejs Petersen, Senior Adviser, Clinical Trials, Danish Health and Medicines Agency, Denmark

Elke Stahl, Nonclinical Assessor, Clinical Trial Unit, BfArM, Germany

Noemie Manent, Scientific Administrator, Compliance and Inspection, European Medicines Agency, European Union

13:00 **LUNCH**

14:00 **SESSION 3**

WHAT IS NECESSARY FOR EFFICIENCY AND STANDARDISATION IN SAFETY REPORTING FROM CLINICAL TRIALS

Session Chair:

Esteban Herrero-Martinez, Director, Regulatory Intelligence, Daiichi Sankyo Development Ltd., UK

Session 3 aims to highlight the key issues and concerns identified for safety reporting from different stakeholders (commercial and academic sponsors).

The session will also outline the role of CTFG in developing practices around co-ordinated safety assessment and provide an update from the EMA on the progress towards a clinical trial safety database.

Implementing Safety Reporting Provisions in the EU-CTR – the Industry View

Esteban Herrero-Martinez, Director, Regulatory Intelligence, Daiichi Sankyo Development Ltd., UK

Towards Implementation – Member States Cooperation in Safety Assessment

Elke Stahl, Nonclinical Assessor, Clinical Trial Unit, BfArM, Germany

EU-CT Regulation – Update on Safety Reporting Systems

Sophia Mylona, Clinical and Non-Clinical Compliance Service, European Medicines Agency, European Union

15:30 **REFRESHMENT BREAK**

16:00 **SESSION 4**

CHALLENGES ANTICIPATED FOR THE TRANSITION PERIOD

Session Chair:

Juliette Kirk, Director, Business Process Owner – Clinical Trial Applications, European Regulatory Strategy, Pfizer Global Research & Development, UK

There are a series of transition periods for the CTReg - use of the CTDir and CTReg for one year after entry into force of the CTReg, trials approved under the CTDir continuing to run under the CTDir for three years after entry into force of the CTReg. Running trials and ensuring their compliance with relevant requirements during this period may be a challenge.

Perspective of a Non-Commercial Sponsor

Anastassia Negrouk, Head of International Regulatory and Intergroup Office, EORTC, Belgium

Perspective of a Commercial Sponsor

Juliette Kirk, Senior Associate, European Regulatory Strategy, Pfizer Global Research & Development, UK

Perspective of a Member State
Kristof Bonnarens, Head of Division R&D, Federal Agency For Medicines and Medicinal Products, Belgium

17:30 NETWORKING RECEPTION

DAY TWO | TUESDAY, 27 OCTOBER 2015

08:30 **SESSION 5**

CLINICAL TRIALS DATABASE AND PORTAL – A KEY PILLAR NECESSARY FOR SUCCESSFUL OPERATION OF THE CLINICAL TRIALS REGULATION

Session 5 aims to cover a number of topics relating to the ongoing development of the CT Portal and database which includes obtaining an update from the EMA on the status and current development of the database aiming to provide Workshop attendees with an oversight of what to expect and when covering the EMA's thinking on submission of CTAs, notifications and user registration.

Database and Portal
Session Chair: Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, UK

The EU Portal and Database: EMA Updates
Fergus Sweeney, Head of Inspections and Human Medicines, Pharmacovigilance (Division), European Medicines Agency, European Union

The EU Portal and Database: a Non-Commercial Sponsor Perspective
Anastassia Negrouk, Head of International Regulatory and Intergroup Office, EORTC, Belgium

The EU Portal and Database: a Member State Perspective
Martin O'Kane, Acting Head of Clinical Trials, Medicines and Healthcare Products Regulatory Agency, UK

The EU Portal and Database: a Commercial Sponsor Perspective
Florina Prundaru, Senior Clinical Operation Manager, MSD Merck Research Laboratories, Romania

10:00 FLEXIBLE REFRESHMENT BREAK

10:30

TRANSPARENCY

Session Chair: Susan Forda, Vice President, International Regulatory Affairs, Eli Lilly & Company Ltd, UK

EMA Perspective
Fergus Sweeney, Head of Inspections and Human Medicines, Pharmacovigilance (Division), European Medicines Agency, European Union

Industry Perspective
Susan Forda, Vice President, International Regulatory Affairs, Eli Lilly & Company Ltd, UK

Panel Discussion

Additional Panelists:

Anastassia Negrouk, Head of International Regulatory and Intergroup Office, EORTC, Belgium

Martin O'Kane, Acting Head of Clinical Trials, Medicines and Healthcare Products Regulatory Agency, UK

12:00 **SESSION 6**

PANEL DISCUSSION ON LAY SUMMARIES: HOW CAN WE MEET PATIENTS' EXPECTATIONS?

Chair:
Sini Eskola, Director Regulatory Affairs, EFPIA, Belgium

Patient representatives will share their expectations for the lay persons' summary. Stakeholders from industry and Member States will reflect on the topic and share their views on how to ensure optimisation of information to be provided to the patient.

Panelists:

Antonio Ferrari, Clinical Safety and GCP Compliance Unit Head, Corporate Cardiac Leader, Chiesi Farmaceutici S.P.A., Italy

Amanda Hunn, Engagement and Policy Manager, Health Research Authority, UK

Marleen Kaatee, President, PSC PATIENTS EUROPE

Lidia Retkowska-Mika, Director Legal DPT, Office For Registration of Medicinal Products, Medical Devices and Biocides, Poland

13:00 LUNCH

14:00 **SESSION 7**

HOW ARE SPONSORS OF CLINICAL TRIALS WORKING TOWARDS IMPLEMENTATION AND THE ISSUES THEY ARE FACING?

Session Chair: Mark Rutter, Director, Regulatory Policy & Intelligence, AbbVie Ltd., UK

Session 7 will give insights on the work conducted, approaches taken, and the challenges faced by sponsors as they are considering steps to ensure they implement the CTReg.

Clinical Trial Regulation Readiness – Insight From the CRO Perspective
John Poland, Regulatory Affairs Consultant, Consultant to ACRO, UK

Connecting the EU Jigsaw: Creating the CTR Mindset
Adam Smith, Development Excellence Leader, Pharma Portfolio Management F. Hoffmann-La Roche Ltd, UK

Company Readiness for the CTR: Key Considerations
Mark Rutter, Director, Regulatory Policy & Intelligence, AbbVie Ltd., UK

Panel discussion with Q&A

15:30 **WRAP-UP SUMMARY**

15:45 END OF WORKSHOP

EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference and can also be accessed through the following link:

https://www.surveymonkey.com/r/15111

PRESENTATION ACCESS

As a benefit of registration, presentations are available on the DIA website. Please sign in to DIA Website and select "My Presentations" under "My account" and you will be able to download all presentations that have been submitted by speakers.

Note: You will need to enter your DIA User ID and password to verify your status. If you have forgotten your DIA User ID and password, use the Login Reminder.

After logging in to the website, you will see presentation PDFs from all the DIA offerings you have attended in the past 6 months. Simply choose the presentation you would like to view or download.

Please note that if a presentation is not available on the website, it is because:

- The presenter has not supplied us with a presentation file
- There was no slide presentation planned by the speaker
- The speaker did not agree to share it with other participants
- You have not yet paid the registration fee

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be e-mailed to all attendees after they have filled in the evaluation. Please note certification requires full attendance to the event.

For more information please contact DIA EMEA Contact Center on

EMEA@DIAglobal.org or call +41 61 225 51 51.