DIA

Clinical Trial Regulation Conference

5-6 December 2017
Millennium Hotel London Mayfair, London, UK

PROGRAMME CHAIR

Nick Sykes
Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

PROGRAMME COMMITTEE

Surendra Gokhale
Senior Director, Global Regulatory Affairs and Capability Development Lead, F. Hoffmann-La Roche, Switzerland

Elke Stahl
CTFG co-chair; Clinical Trial Unit, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Conference Venue

Millenium Hotel London Mayfair
44 Grosvenor Square, Mayfair
London W1K 2HP
United Kingdom

Meeting room: Ballroom

OVERVIEW

While the implementation date of the Clinical Trial Database is delayed, work is progressing on the implementation of the Clinical Trial Regulation in other areas. The Clinical Trial Conference will focus on the differences between the present and new requirements for managing clinical trials in the face of forthcoming changes.

This Conference will provide a forum for **information exchange** on both **conceptual** and **practical** questions of:

- How will the new legislation change the **processes and the format of the trial application**?
- What are the impacts on how a clinical trial is managed after approval has been granted?
- What are the **critical issues affecting sponsors and Member States** as they consider changes needed to implement the regulation?
- How will the new provisions for public access to an EU Clinical Trials Database enforce disclosure of clinical trial data and information?

Attendees will participate in the collaborative discussions through lectures, panel discussions and interactive sessions.

OBJECTIVES

- Understand the new requirements along with the practical and operational considerations for implementation by authorities and clinical trial sponsors
- Identify the key challenges and opportunities of the new requirements and policies
- Leverage insights on how companies and research institutions are fine-tuning and optimising processes to meet the requirements of the Clinical Trial Regulation
- Exchange views between regulators, clinical trial sponsors, patients, and other stakeholders

KEY TOPICS

- Member States preparedness for the regulation, including plans for co-operation between agencies and ethics committees and coordinated assessment
- Development of the EU clinical trials portal and database
- Considerations for the preparation of applications and notifications by sponsors
- Impact of new requirements for disclosure and transparency of data from clinical trials

DAY ONE I TUESDAY, 5 DECEMBER

08:30 REGISTRATIONS AND WELCOME COFFEE

09:30 OPENING REMARKS

Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

09:35 SESSION 1

OVERVIEW OF THE CLINICAL TRIALS REGULATION ENVIRONMENT

Session Chair:
Karina Griffiths, Director - Clinical Trial Application (CTA) Lead, Pfizer, United Kingdom

- Current Clinical Trial Directive & rationale for change
- Why a new Regulation
- What is the new EU Clinical Trial Regulation
- What supports the new Regulation
- Differences between Directive & Regulation
- Submissions process part I & part II
- What are the current timelines for implementation

Karina Griffiths, Director - Clinical Trial Application (CTA) Lead, Pfizer, United Kingdom

11:00 COFFEE BREAK

11:30 SESSION 2

HOW THE CLINICAL TRIAL REGULATION HAS EVOLVED

Session Chair:
Karina Griffiths, Director - Clinical Trial Application (CTA) Lead, Pfizer, United Kingdom

- CTR implementation progress – setting the scene
- IMP and GMP guidelines
- Transition phase
- Interactions between sponsors and regulators

Karina Griffiths, Director - Clinical Trial Application (CTA) Lead, Pfizer, United Kingdom

Sini Eskola, Director, Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

12:30 LUNCH

13:30 SESSION 3

STATUS OF THE EU PORTAL AND DATABASE

Session Chair:
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

A key pillar for implementation of the Regulation is the availability of the EU Portal and Database. EMA have been working to deliver the system and will provide the latest updates alongside the perspective of a user involved in testing. Following the release of the auditable version, the portal and database will be further developed, industry's perspectives on what needs to be included in the 'go live' portal and database will also be discussed.

Updates from the EMA
Noemi Manent, Scientific Administrator, Compliance and Inspection, European Medicines Agency (EMA), European Union

Learning Experience from User Acceptance Tests
Stéphanie Kromar, Regulatory Affairs Manager, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Development Priorities for Post-Audit
Judith Creba, Executive Director, EU Regulatory Strategy, Novartis Pharma, Switzerland

Panel Discussion with Q&A
All speakers and
Elke Stahl, CTFG co-chair; Clinical Trial Unit, Federal Institute for Drugs and Medical Devices (BfArM), Germany

15:00 COFFEE BREAK

15:30 SESSION 4

IMPLEMENTATION AND READINESS

Session Chair:
Elke Stahl, CTFG co-chair; Clinical Trial Unit, Federal Institute for Drugs and Medical Devices (BfArM), Germany

How ready are the member states for the upcoming CT Regulation? There are different approaches to implement the CT Regulation throughout EU/EEA, with resulting challenges to solve. First experiences on national pilot projects, where the cooperation between national competent authority and ethics committees is being tested, are gained. A general overview on the national implementation status in EU will be given. Selected NCAs and ECs will give an inside in their MS's approach, first experiences and challenges from their viewpoint. In addition an update on sponsor's changes to CT application and also managing of an approved trial, identified critical issues and experiences with national pilots from a sponsor's view will be presented.

Updates from Member States: General Overview and 'Traffic Lights' on Readiness
Elke Stahl, CTFG co-chair; Clinical Trial Unit, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Feedback from Pilots from Selected European Countries: Belgium and Czech Republic
Greet Musch, General Director, DG Pre-Authorisation, Federal Agency for Medicines and Health Products (FAMHP), Belgium
Lucie Kravackova, Senior Clinical Assessor, State Institute for Drug Control (SUKL), Czech Republic

Ethics Perspective: The Netherlands and Denmark
Monique Al, Senior Scientific Staff Member, Central Committee on Research Involving Human Subjects (CCMO), The Netherlands
Karen Kiilerich, Special Legal Consultant, National Committee on Health Research Ethics, Denmark

CTR Implementation Readiness – Sponsor's Perspective
Rose-Marie Swallow, Senior Manager, EU Regulatory Policy & Intelligence, Bayer, United Kingdom

Panel Discussion with Q&A

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

Continuing Education

SwAPP and SGPM Credits

DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for applicable credits.

This conference has been accredited with 12.0 credits.

DAY TWO IWEDNESDAY, 6 DECEMBER

09:00 SESSION 5

CHALLENGES OF THE IMPLEMENTATION

Session Chair:
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

This session will take the form of a panel discussion involving commercial and non-commercial sponsors, member state representatives, and service providers. Panellists will respond to specific questions set by the chair along with questions being posed from the audience. Key considerations to be discussed include the challenges that exist with implementing the Regulation and actions that can be taken to maintain momentum in the face of delays in the final implementation date.

Panel Discussion with Q&A

Panellists:
Elisna Maree, Associate Director - Regulatory Affairs, Vectura Limited, United Kingdom
Stéphanie Kromar, Regulatory Affairs Manager, European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Leona Fitzgerald, Senior Director, Regulatory Affairs, PPD, United Kingdom
Judith Creba, Executive Director, EU Regulatory Strategy, Novartis Pharma, Switzerland
Lucie Kravackova, Senior Clinical Assessor, State Institute for Drug Control (SUKL), Czech Republic
Karen Kiilerich, Special Legal Consultant, National Committee on Health Research Ethics, Denmark

10:30 COFFEE BREAK

11:00 SESSION 6

CTR – SAFETY RELATED INFORMATION EXCHANGE

Session Chair:
Surendra Gokhale, Senior Director, Global Regulatory Affairs and Capability Development Lead, F. Hoffmann-La Roche, Switzerland

This session will focus on the progress made on different elements of the safety reporting. This will include regulators' and sponsors' viewpoint on recently published Q&A from CTFG related to Reference Safety information [RSI], sponsors' viewpoint on GCP breaches guidance draft published mid-2017 and need for further clarifications, and status update on Clinical Trials Safety reporting [CTSR] under CTR.

Reference Safety Information [RSI] and Management of Changes to RSI for Clinical Trials
Elena Prokofyeva, Head of Drug Safety Unit, Federal Agency for Medicines and Health Products (FAMHP), Belgium
Esteban Herrero-Martinez, Director, Regulatory Policy and Intelligence, AbbVie, United Kingdom

Management of Serious Breaches Under Clinical Trial Regulation – Sponsors' Perspective
Michael Smith, Quality Strategy Lead, Merck Serono, United Kingdom

Clinical Trials Safety Reporting [CTSR] – Status Update
Sophia Mylona, Scientific Administrator, Compliance and Inspection, European Medicines Agency (EMA), European Union

Panel Discussion with Q&A

All speakers and
Elke Stahl, CTFG co-chair; Clinical Trial Unit, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Nektaria Varela, Lead Business Analyst for EMA Technology and Architecture Business Analysis Service, Lead BA for CT Programme, European Medicines Agency (EMA), European Union

12:30 LUNCH

14:00 SESSION 7

IMPLEMENTATION STATUS FOR THE EMA CLINICAL DATA PUBLICATION: SETTING THE SCENE

Session Chairs:
Robert Paarlberg, Principal, Paarlberg & Associates, United States
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

The public availability of clinical trial information on the EU Portal and Database is a key element of the Clinical Trial Regulation (CTReg). While Policy 0070 differs from the CTReg in scope, redacted/anonymised versions of clinical study reports (CSRs) of at least some studies will be published under both rules. Apart from references to Policy 0070, no details are yet available on standards and processes for redacted/anonymised versions of CSRs and other clinical documents to be submitted to the EU Portal under the CTReg framework.

This session will focus on the transparency provisions in the CTReg as well as the implementation status of Policy 0070 {backlog, phase II, Technical Anonymisation Group (TAG)} and the status of the Portal used for sharing documents and the technicalities of the process of submitting and accessing documents. The future of the Policy 0070 requirements and process when the CTReg is fully implemented will also be addressed.

CTReg Transparency Provisions and Their Implementation
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

EMA Updates on Policy 70
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency (EMA), European Union

How the Portal Works
Noemie Manent, Scientific Administrator, Compliance and Inspection, European Medicines Agency (EMA), European Union

Panel Discussion with Q&A

15:30 COFFEE BREAK

16:00 SESSION 8

LEGAL CONSIDERATIONS FOR CLINICAL DATA PUBLICATION

Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk, Denmark

Publication of Clinical Documents requires a lot of considerations about legal aspects, about Private Personal Data, Company Confidential Information, Copy Rights, and Terms of use of the information made available. Presentations will cover an overview of the different legislation requirements, as they are applicable to the release of documents as specified in EMA's Policy 0070 on proactive data sharing, and on Policy 0043 on Requested Data Access. Views from the aspect of industry as well as from the regulatory authority perspective will be presented.

Drawing the Boundaries of Data Disclosure in Clinical Trials – the Industry Perspective
Marie Manley, Partner and Head of the Regulatory Practice, Bristows, United Kingdom

Drawing the Boundaries of Data Disclosure in Clinical Trials – the EMA's Perspective
Aleksandar Rusanov, Legal Adviser, European Medicines Agency (EMA), European Union

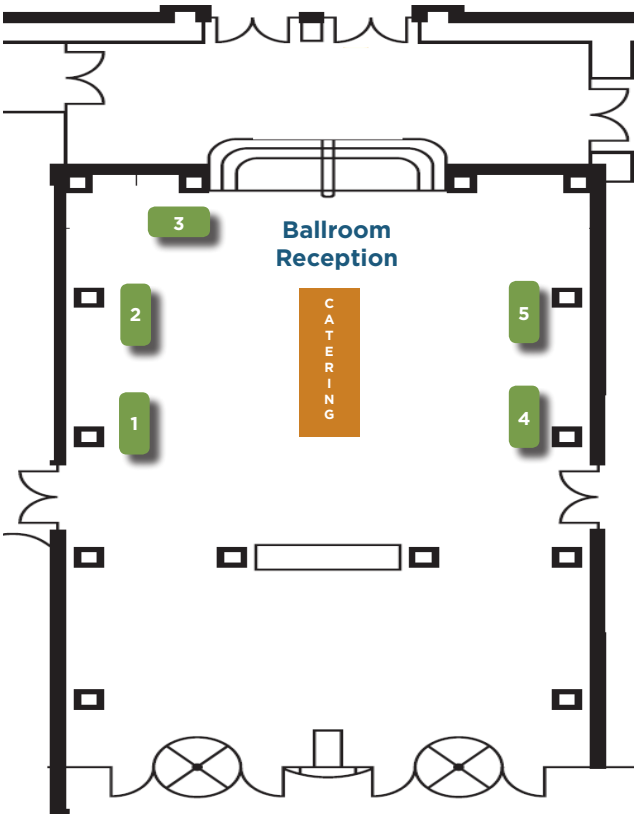
Panel Discussion with Q&A
All speakers and
Karen Quigley, Clinical Data Publication Manager, European Medicines Agency (EMA), European Union
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency (EMA), European Union

17:30 NETWORKING RECEPTION

18:30 END OF CONFERENCE

Clinical Trial Regulation Conference

Exhibitor Floorplan



Exhibiting Companies

1. Privacy Analytics
2. d-Wise Technologies
3. Trialscope
4. Sylogent
5. Xogene

Evaluation

We value your feedback on the content and organisation of this conference. The electronic survey can be accessed through the following link: http://bit.ly/2z3naMc.

Access Presentations

As a benefit of your registration, presentations are made available on www.diaglobal.org.

- Presentations are made available to full conference attendees only (Attendee, Exhibitor, Speaker, and Press badges).
- To access presentations, go to *My Presentation Downloads* and log in when prompted
- No paper copies of the presentations will be provided

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with their presentation. Updated versions of the slides will be made available shortly after the conference.

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 our Login Reminder.

In *My Presentation Downloads* 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.

Certificate of Attendance

A Certificate of Attendance will be sent to all attendees electronically after the conference. Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on Basel@DIAglobal.org or call +41 61 225 51 51.

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- Download & Install: type "DIA GLOBAL" in the App store or in Google Play
- Sign in with the email address you used to register for the event
- If needed, use the reset password link to set your password
- Need assistance? Please feel free to ask one of our staff.

REGISTRATION FORM | ID# 17111

Clinical Trial Regulation Conference | 5-6 December 2017 | London, UK

DIA

Early-bird discount and Advance rate

To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird/Advance rate applies to industry members only.

Early bird discount: register by 12 September 2017 **€ 1'230.00** ❑

Advance rate: register by 24 October 2017 **€ 1'330.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'430.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑

Upgrade and **add a third day** of the adjacent "**Clinical Data Publication: Evolving from Policy 0070**" Meeting for a special fee:

Industry	€ 585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 293.00 ❑

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. Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to the applicable VAT. Payment 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 MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

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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#17111 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 in Basel.**

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**.

Date	Signature

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DIA offers one year complimentary membership against event registration at non-member rate

❑ **I do not want complimentary membership**

TERMS AND CONDITIONS

Cancellations

All cancellations must be made in writing and be received at the DIA office in Basel four weeks 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

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 reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA 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 in Basel of any such substitutions as soon as possible.

Photography and Video 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 will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CET.

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