



Clinical Trial Regulation and Clinical Trial Disclosure & Data Transparency Conferences

6-8 December 2016

Amba Hotel Marble Arch, London, United Kingdom

CLINICAL TRIAL REGULATION CONFERENCE

While publication of the Clinical Trial Database is delayed, the endorsement of the Clinical Trial Regulation is moving forward in other areas. The Clinical Trials Regulation Conference will focus on the differences between, the present and new requirements on managing clinical trials in the face of forthcoming changes.

This 2-day 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?

CLINICAL TRIAL DISCLOSURE & DATA TRANSPARENCY CONFERENCE

Transparency of clinical trial information is taking on new dimensions, resulting in trial sponsors and research organisations facing a host of **new requirements in the EU and the US**. This 2016 Conference leverages learnings from European and US experts as well as prior conference discussions, providing the opportunity to gain insights on how to meet new challenges. The programme is assembled around key themes:

- Impact of the **EU Clinical Trial Regulation and EMA Policy 0070 on trial disclosure** business processes
- Upcoming legal requirements related to disclosure of **clinical research information for medicinal products and medical devices**
- **Real-world experiences** on implementation of the regulations, including fine-tuning and optimising processes to meet the requirements for **disclosure, data sharing and data transparency**

Attendees will participate in the collaborative discussions through lectures, panel discussions and interactive sessions, and will learn from case studies and experiences of experts and their peers.

PROGRAMME COMMITTEES

Nick Sykes

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

Surendra Gokhale

Head of Clinical Trial Regulatory Management,
F. Hoffmann-La Roche Ltd, Switzerland

Elke Stahl

Clinical Trial Unit, BfArM, Germany

Robert Paarlberg

Principal, Paarlberg & Associates LLC, US

Merete Jorgensen

Director, Global Clinical Registry,
Novo Nordisk A/S, Denmark

Matthias Zerm

Sr. Expert Clinical Trial Disclosure and R&D Processes,
Merz Pharmaceuticals GmbH, Germany

Gerard Lynch

Associate Director, Clinical Operations, Biogen Idec Inc.,
United Kingdom

FINAL PROGRAMME



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CONTACT US

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Clinical Trial Regulation and Clinical Trial Disclosure & Data Transparency Conferences

HALF DAY PRE-CONFERENCE WORKSHOP 5 December 2016 | 13:00–17:30

EU Clinical Trials Regulation: Anticipating the Changes

This pre-conference short course will bring you up-to-date with current developments and preparations for the implementation of the new clinical trial regulation so far. The course will complement the knowledge and information you'll receive within the following conference days. It is recommended to take part if you did not attend last year's clinical trial regulation conference.

Learning objectives

- You will be up to date on current preparations for the implementation of the new clinical trial regulation
- Understand the top line implementation challenges faced by sponsors, CROs, and member states

Workshop Chair:

Sini Eskola, Director Regulatory Affairs, EFPIA

12:00 Registration

13:00 Introduction including Roadmap for EU CTR implementation

Sini Eskola, Director Regulatory Affairs, EFPIA

13:30 EU CTR: preparing the organisation for change - a Sponsor perspective

Adam Smith, Development Excellence Leader; Roche, Switzerland

14:45 Refreshment Break

15:15 EU CTR: preparing for change - a CRO perspective

John Poland, Association of Clinical Research Organizations, UK

16:00 EFPIA CTiMonitor

Sini Eskola, Director Regulatory Affairs, EFPIA

16:40 Voluntary Harmonization Procedure (VHP) as a stepping stone to CT Reg: Sponsor perspective

Claire Berry, Roche, Switzerland

17:20 Wrap Up

Sini Eskola, Director Regulatory Affairs, EFPIA

17:30 End of the Workshop

Separate registration required

DAY ONE | 6 December 2016

08:30 REGISTRATION AND WELCOME COFFEE

09:00 WELCOME & INTRODUCTIONS AND KEYNOTE SPEAKER

Session Chair:

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

09:30 SESSION 1

CTREG IMPLEMENTATION STATUS IN MEMBER STATES

Session Chair:

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

Implementation Status in Denmark

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

Implementation Status in Italy

Sandra Petraglia, Head of Independent Research Office, AIFA - Agenzia Italiana Del Farmaco, Italy

Implementation Status in UK

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

11:00 Coffee Break

11:30 SESSION 2

EXPERIENCES FROM PILOTS

Session Chair:

Elke Stahl, Clinical Trial Unit, BfArM, Germany

Experience with German Pilot

Elke Stahl, Clinical Trial Unit, BfArM, Germany

Experience with Spanish Regulation for Clinical Trials- Sponsor perspective

Elena Bolanos, Senior Director of Clinical Operation, Eli Lilly and Company, Spain

Panel Discussion with Q&A

12:30 Lunch

13:45 SESSION 3

TECHNICAL ISSUES

Session Chair:

Judith Creba, Head EU Liaison and Policy, Novartis Pharma AG, Switzerland

Annex VI : Discussion of the Key Issues and How to Address Them

Sini Eskola, Director Regulatory Affairs, EFPIA, Belgium

Implementation Guidance and Delegated Acts - Awareness of and the Key Identified Issues from the Draft Guidance

Isabelle Clamou, Regulatory Affairs Director - EU Policy, Amgen Ltd, Belgium

Current Thinking on Transition from CT Directive to CT Regulation

Maja Leon-Grzymkowska, Legal Officer, European Commission

Panel discussion with Q&A



Clinical Trial Regulation and Clinical Trial Disclosure & Data Transparency Conferences

15:00 Coffee Break

15:30 SESSION 4

RISK-ADAPTED TRIALS/ LOW-INTERVENTIONAL TRIALS / OBSERVATIONAL TRIALS

Session Chair:

Surendra Gokhale, Head of Clinical Trial Regulatory Management, F. Hoffmann-La Roche Ltd, Switzerland

Overview of the Guideline on Risk-Adapted Trials and Key Issues

Camelia Mihaescu, Scientific Administrator, European Medicines Agency

Case Study on a Low-Interventional Trial under the EU Directive – Issues Encountered and how These may be Addressed/made worse by the CTReg

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

Real World Studies: Navigating the grey Between Interventional and Observational

Emma Du Four, Head of International Regulatory Policy, AbbVie, UK

Panel discussion with Q&A

16:45 SESSION 5

SAFETY REPORTING

Session Chair:

Esteban Herrero-Martinez, Director Regulatory Policy and Intelligence, AbbVie Ltd, United Kingdom

Interactive question and answer session between industry and regulators (CTFG rep and EMA rep) to discuss recent developments, outstanding issues and current thinking on clinical trial safety reporting.

Elke Stahl, Clinical Trial Unit, BfArM, Germany

Amanda Joseph, Case Management Consultant, Eli Lilly and Company, UK

Camelia Mihaescu, Scientific Administrator, European Medicines Agency

17:45 END OF DAY ONE

DAY TWO | 7 December 2016

08:30 REGISTRATION AND WELCOME COFFEE

09:00 WELCOME & INTRODUCTIONS

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

Robert Paarlberg, Principal, Paarlberg & Associates LLC, US

09:15 SESSION 6

EU PORTAL & DATABASE

Anne DeBock, Sr Regional Director, AstraZeneca, Belgium

What is the status quo and what can you expect to happen in 2017? This session will answer these questions in form of high-level presentations followed by a panel discussion that focuses on the learnings so far from user-acceptance testing.

The EU Portal and Database: What to Expect. Demo of the draft Portal

Noémi Manent, Scientific Administrator, Compliance and Inspection European Medicines Agency, UK

A Stakeholder's Perspective of the EU Clinical Trials Portal and Database

John Poland, Regulatory Affairs Consultant for ACRO, UK

10:30 Coffee Break

11:00 SESSION 7

KEY ELEMENTS OF CT DATA TRANSPARENCY IN THE EU

Session Chair:

Matthias Zerm, Sr. Expert Clinical Trial Disclosure and R&D Processes; Merz Pharmaceuticals GmbH, Germany

Get an overview of how transparency is reflected in all regulations and policies - EU CTReg, Paediatric Regulation, Data Protection Regulation and Policy 70 – and how it all comes together.

Implementation of the Clinical Trial Disclosure provisions of the CTReg

Emma Du Four, Head of International Regulatory Policy, AbbVie, UK

Mandatory Disclosure of Clinical data in the EU

Christian Fulda, Lawyer, Jones Day, Germany

12:00 Lunch

13:10 SESSION 8

EMA POLICY 0070: FIRST EXPERIENCES AND IMPLICATIONS

Session Chair:

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

You will hear about the rules for Policy 70, and the experiences with it so far, followed by discussions how the policy can translate into actual data availability under the CTReg

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EMA Perspective on Policy 0070 and 0043: First Experience of Phase 1 (Submission of Clinical reports) and Plans for Phase 2 (Submission of IPD), Similarities and Differences

Anne-Sophie Henry-Eude, Head of Access to Documents Service, European Medicines Agency

Challenges Protecting Sponsors' Commercial Interests and Patients' Privacy (Legal (Patent Attorney/Data Privacy).

Marie Isabel Manley, Partner, Head of the Regulatory Practice Solicitor, Bristows, UK

14:00 SESSION 9

EMA POLICY 0070: CHALLENGES AND TECHNIQUES FOR SPONSORS

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

Industry Experience with Preparing Documents for Submission

Nicole Hinton, Data Transparency / Clinical Trial Results Manager, Biogen Inc., USA

Mats Ericson, Regulatory Policy Director, Amgen, France

Technical Solutions to Ease the Process of Redaction/Anonymisation/Justification

Janice Branson, Novartis Pharma AG, Switzerland

Q&A

15:15 Coffee Break

15:45 SESSION 10

PROVISION OF RESULTS TO PATIENTS

Session Chair:

Angelika Joos, Executive Director, Global Regulatory Policy, MSD (Europe) Inc., Belgium

Overview of Industry and Regulatory Initiatives (CT Regulation, UK Health Research Authority, Harvard MRCT, TransCelerate)

Angelika Joos, Executive Director, Global Regulatory Policy, MSD (Europe) Inc., Belgium

Patient Perspective – Will the Proposals Meet Patient Needs?

Richard Stephens, Chair of the Consumer Liaison Group, UK National Cancer Research Institute, UK

Patients at the Centre of Peer Review and Reporting of Research

Trish Groves, Deputy Editor, British Medical Journal, UK

Q&A

17:00 Networking Reception

18:00 END OF DAY TWO

DAY THREE | 8 December 2016

08:00 REGISTRATION AND WELCOME COFFEE

08:30 OPENING, RECAP FROM DAY 1

Merete Jorgensen

Director, Global Clinical Registry Novo Nordisk A/S, Denmark

08:45 SESSION 11 - PART 1

STATUS AND CHANGES IN RELATION TO CURRENT DISCLOSURE REQUIREMENTS IN EU AND THE USA

Session Chair:

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

Update of EU Country Registries/Requirements

Tom Bosch, Director, Clinical Registry, Johnson & Johnson, Netherlands

EU PASS/PAES Requirements for Disclosure

Thomas Goedecke, Principal Scientific Administrator, Surveillance and Epidemiology, European Medicines Agency

09:45 Coffee Break

10:15 SESSION 11 - PART 2

STATUS AND CHANGES IN RELATION TO CURRENT DISCLOSURE REQUIREMENTS IN EU AND THE USA

Session Chair:

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

The Final Rule for FDAAA and ClinicalTrials.gov Requirements

Rebecca J. Williams, Assistant Director, ClinicalTrials.gov, NCBI, National Library of Medicine, NIH, US

Q&A

11:15 SESSION 12

EU: PUBLIC DISCLOSURE IN UPCOMING NEW EU MEDICAL DEVICE REGULATION (MDR) AND IN-VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (IVDR)

Session Chair:

Matthias Zerm

Sr. Expert Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals GmbH, Germany

New Clinical Trial Disclosure Requirements for Medical Devices Trials

Erik Vollebregt, Attorney, Axon Lawyers, The Netherlands

The Practical Side of Entering Data in the New MDR Eudamed

Ronald Boumans, EMERGO, Senior Global Regulatory Consultant, The Netherlands

12:00 Lunch



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13:30 SESSION 13 - PART 1

CLINICAL TRIAL DATA SHARING: STATUS AND BENCHMARKING

Session Chair:

Robert Paarlberg, Principal, Paarlberg & Associates LLC, US

Good Pharma Scorecard

Jennifer E. Miller, President, Bioethics International, US

Clinical Trial Transparency and the AllTrials Campaign

Sile Lane, Director of Campaigns and Policy, Sense about Science, UK

Delivering Transparency: A Research-based Approach to Confirming industry's Commitment

Virginia Acha, Executive Director – Research, Medical & Innovation, The Association of the British Pharmaceutical Industry, UK

Panel discussion with Q&A

14:45 Coffee Break

15:00 SESSION 13 - PART 2

CLINICAL TRIAL DATA SHARING: STATUS AND BENCHMARKING

Session Chair:

Robert Paarlberg

Principal, Paarlberg & Associates LLC, US

ICMJE Policy on Clinical Trial Data Sharing: From the Horse's Mouth

Trish Groves, Deputy Editor, British Medical Journal, UK

Data Sharing and Data Protection Regulation

Martin Dræbye Gantzhorn, Life Sciences & Healthcare Expert, Horten, Denmark

Future Framework for Data Sharing

Jennifer O'Callaghan, Clinical Data Sharing Manager, Wellcome Trust, UK

16:15 END OF THE CONFERENCE

Conference Venue

Amba Hotel Marble Arch

Bryanston Street

London

W1H 7EH

United Kingdom

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Evaluation

We value your feedback on the content and organisation of this conference. The link to the online evaluation will be sent to you after the conference.

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the Clinical Trial Regulation Conference with 13 credits and the Clinical Trial Disclosure & Data Transparency Conferences with 9.5 credits each.



DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

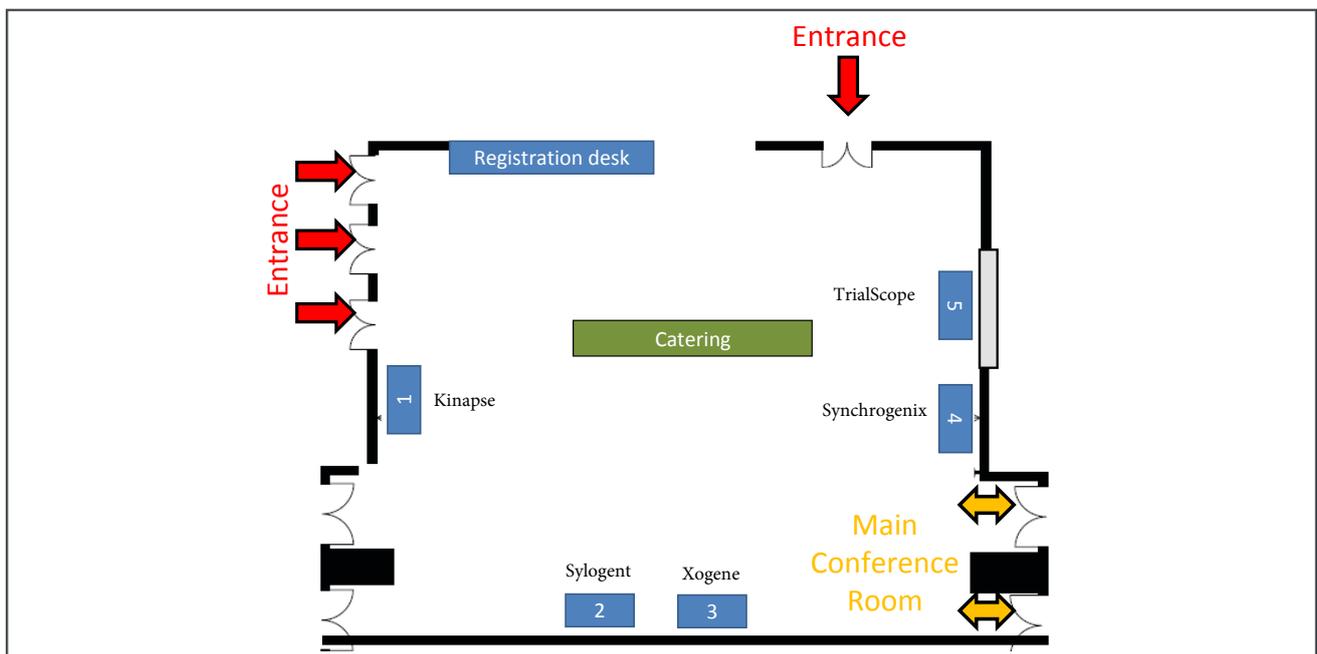


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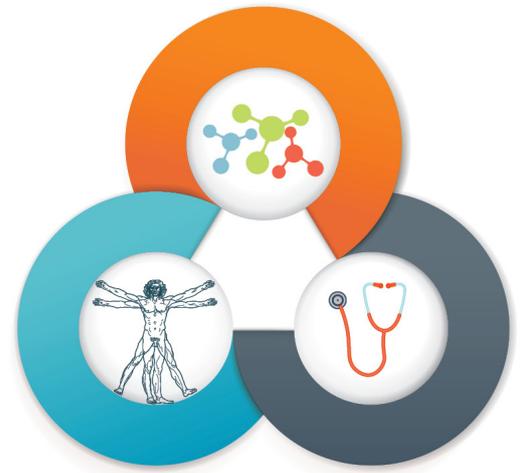
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