DIA

Clinical Trial Regulation

Status, what do we still need to know and the way forward

2-3 December 2019 | Amsterdam, the Netherlands

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

Rose-Marie Swallow
Senior Manager, EU Regulatory Policy & Intelligence, Bayer, United Kingdom

Vladimir Vujovic
Regulatory and Safety Manager, Optimapharm, Belgrade, Serbia

Join experts from regulatory, ethics bodies, sponsors and patients to discuss latest developments of Clinical Trial Regulation and ensure its successful launch.

Overview

This conference will focus on the differences between the present and new requirements for managing clinical trials in the face of forthcoming changes, including the new EU clinical trials Regulation but also conducting novel complex innovative design trials. Regulators and other decision-makers, together with various experts in the field, will debate how the new legislation will impact the processes for the design, submission and approval, and managing European clinical trials in the future.

Key Objectives

- Understand the impact of the new requirements on running clinical trials in Europe along with the practical and operational considerations for implementation by authorities and clinical trial sponsors
- Identify the opportunities and consider how to overcome the key challenges of the requirements particularly for novel clinical trial approaches
- Leverage insights on how companies and research institutions are fine-tuning and optimising processes to meet the requirements of the Clinical Trials Regulation
- Exchange views between regulators and other decision-makers, clinical trial sponsors, patients, and other stakeholders

Key Topics

- Status of the CTR
- Ethics Committee preparedness for CTR
- Update on national pilots from MS
- Innovative Trial Designs and their Management
- GDPR and its consequences for Clinical Trials
- 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

Who Should Attend

- Regulatory agencies (assessors, reviewers, inspectors)
- Sponsors of non-commercial clinical trials
- The pharmaceutical industry and contract research organisations, including:
  - Regulatory affairs personnel in clinical research
  - Professionals in charge of clinical trial strategy
  - Regulatory intelligence and policy professionals
  - Change managers for clinical trials business processes
  - Clinical research professionals working with submission, data, information sharing
  - Clinical safety professionals

DAY ONE | MONDAY, 2 DECEMBER 2019

08:30 REGISTRATION AND WELCOME COFFEE

09:30 SESSION 1

STATUS ON IMPLEMENTATION OF THE CTR AND HOW TO KEEP MOMENTUM

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

Latest Status of the CTReg
Judith Creba, Executive Director, EU Regulatory Strategy Novartis Pharma AG, Switzerland

Panel Discussion with Q&A from Audience
Elke Stahl, CTFG co-chair; Clinical Trial Unit, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Judith Creba, Executive Director, EU Regulatory Strategy Novartis Pharma AG, Switzerland
Sini Eskola, Director Regulatory Affairs European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
Stéphanie Kromar, Senior Regulatory Affairs Manager, European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Monique Al, Team Coordinator National Clinical Trial Office at Central Committee on Research Involving Human Subjects (CCMO), the Netherlands

10:30 COFFEE BREAK

11:00 SESSION 2

INNOVATIVE TRIAL DESIGNS AND THEIR MANAGEMENT

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

Industry's Thinking on the CTFG's Recommendations on Complex Clinical Trials
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

The Latest Thinking from CTFG on Supporting the Conduct of Complex Innovative Design Trials in Europe
Elke Stahl, CTFG co-chair; Clinical Trial Unit, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Running Complex Innovative Design Trials in a Non-Commercial Setting – Experiences and Challenges
Stéphanie Kromar, Senior Regulatory Affairs Manager, European Organisation for Research and Treatment of Cancer (EORTC), Belgium

Panel discussion with Q&A

12:30 LUNCH

14:00 SESSION 3

EXPERIENCES FROM NATIONAL PILOTS INFORMATION AND LEARNINGS

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

Feedback from Pilots from Selected National Pilots

Germany
Claudia Riedel, Head CT Unit, Federal Institute for Drugs and Medicinal Devices (BfArM), Division of Scientific Services, Clinical Trial Unit, Germany

Czech Republic
Lucie Kravackova, Senior Clinical Assessor, State Institute for Drug Control (SUKL), Czech Republic

Sweden
Ann Marie Janson Lang, CTFG co-chair; Expert, Clinical Assessor, Clinical Trials and Special Permissions, the Swedish Medical Products Agency (MPA), Sweden

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

Panel discussion with Q&A

15:30 COFFEE BREAK

16:00 SESSION 4

CLINICAL TRIAL REGULATION AND ETHICS COMMITTEE PREPAREDNESS

Session Chair:
Monique Al, Team Coordinator National Clinical Trial Office at Central Committee on Research Involving Human Subjects (CCMO)

Panel discussion with Q&A
Netherlands
Monique Al, Team Coordinator National Clinical Trial Office at Central Committee on Research Involving Human Subjects (CCMO), the Netherlands
Germany
Joerg Hasford, Ludwig-Maximilians Univ Institut fur Med. Inf. Ver. Biometry and Epidemiology, Germany
Belgium
Katelijne Anciaux, Quality expert Healthcare for the Clinical trial College, Belgium
Finland
Outi Konttinen, General Secretary, National Committee on Medical Research Ethics (TUKIJA), Finland

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

DAY TWO | TUESDAY, 3 DECEMBER 2019

08:30 WELCOME COFFEE

09:00 SESSION 5

SAFETY REPORTING – GUIDANCE ON USE OF NEW RSI AND OUTSTANDING ISSUES

Session Chair:
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations Bristol-Myers Squibb, Belgium

Regulators Perspective
Massimiliano Sarra, CTFG Secretary, Italian Medicine Agency (AIFA), Italy

Industry Perspective
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations Bristol-Myers Squibb, Belgium

Panel discussion with Q&A

10:00 SESSION 6

GDPR AND ITS CONSEQUENCES FOR CLINICAL TRIALS

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

GDPR
Loes Markenstein, Senior Inspector, Dutch Data Protection Authority, the Netherlands

Implications of the GDPR on the Conduct of Clinical Trials
Jaspreet Takhar, Associate, Healthcare | Tech | Commercial, Baker & McKenzie LLP, UK

Panel discussion with Q&A

11:00 COFFEE BREAK

11:30 SESSION 7

UPDATE ON THE EU PORTAL FROM USERS PERSPECTIVE

Session Chair:
Rose-Marie Swallow, Senior Manager, EU Regulatory Policy & Intelligence, Bayer, United Kingdom

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

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

Sponsors Perspective
Pierre-Frédéric Omnes, Sr Director, Site Start-Up & Regulatory, Syneos Health, France

Panel discussion with Q&A
Stéphanie Kromar, Senior Regulatory Affairs Manager, European Organisation for Research and Treatment of Cancer (EORTC), Belgium
Monique Al, Team Coordinator National Clinical Trial Office at Central Committee on Research Involving Human Subjects (CCMO), the Netherlands

13:00 END OF THE CONFERENCE

| Conference Venue

Hotel Mercure Amsterdam City
Joan Muyskenweg 10
1096 CJ
AMSTERDAM
NETHERLANDS
Tel: +31207219176
Hotel Location

The perfect location of the hotel makes it easy to reach and to get to other parts of Amsterdam. The metro is easily accessible and will take you to the centre of Amsterdam, the RAI and the Zuid-As business district in few minutes.

EXHIBITORS

EVALUATION

We value your feedback on the content and organisation of this conference. Please complete the electronic survey after the conference.

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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 the presentation. Updated versions of the slides will be made available shortly after the conference.

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.

About DIA

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