DIA
Clinical Trial Regulation Conference

18-19 November | Virtual

PROGRAMME CHAIR

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

PROGRAMME COMMITTEE

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

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 | WEDNESDAY, 18 NOVEMBER 2020

14:30 LOG-IN AND CONNECT

14:40 WELCOME AND INTRODUCTION TO DIA

Elena Popa, Scientific Program Manager, DIA, Switzerland

14:50 CLINICAL TRIAL DISCLOSURE & DATA TRANSPARENCY: LOG-IN AND CONNECT

Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

15:00 SESSION 1: JOINT SESSION

OVERVIEW OF THE CTIS

Session Chair:
Rose-Marie Swallow, Senior Manager, EU Regulatory Policy & Intelligence, Bayer, United Kingdom
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

Overview of CTIS as it is about to undergo audit to confirm that it is ready for CTR implementation.
This session will demonstrate the functionality of CTIS for Sponsors and Regulators. This is an opportunity for EMA to showcase the CTIS and how far its development has progressed as it stands on the brink of being audited and found to be ready for implementation.

CTIS – a system ready for audit and implementation of the CTR
Fergus Sweeney, Head of Clinical Studies and Manufacturing Task Force, European Medicines Agency, EU

CTIS – a system ready for audit and implementation of the CTR – a Sponsor view
Christopher Price, Senior Manager, Global Regulatory Affairs Oncology, Merck, Germany

Panel Discussion with Q&A

16:00 BREAK

16:15 SESSION 2: JOINT SESSION

PRACTICAL IMPLICATIONS OF TRANSPARENCY IN CTIS

Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Transparency, Novo Nordisk, Denmark
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

The session aims to cover the below topics through presentations and ample opportunity to ask questions and discuss with the panel:

- CTIS Publication Rules: how CTIS supports access to clinical trial data – explanation and demonstration of the related CTIS functionality for sponsors and for public access
- How sponsors are approaching the challenge of managing the deferral rules and preparing for the redaction/anonymisation of the 'for publication' documents.
- Ensuring consistency of redaction/anonymisation between documents for publication via CTIS and via other EMA disclosure policies (Policy 70 and Policy 43).

CTIS Publication Rules: How CTIS Supports Access to Clinical Trial Data
Laura Pioppo, Scientific Administrator, CTIS Expert, European Medicines Agency

Preparing for the redactions of the 'for publication' documents and challenges of managing the deferral rules: A Sponsors' Perspective
Sameer Sharma, Manager, Clinical Trial Transparency, Merck KGaA,Germany

Panel discussion with Q&A, with additional participation:
Claudia Riedel, Head of the Clinical Trial Unit, Division of Scientific Services, Federal Institute for Drugs and Medicinal Devices (BfArM), Germany

17:15 BREAK

17:30 SESSION 3: JOINT SESSION - PANEL DISCUSSION & KEY TAKEAWAYS

5 YEARS OF CTR, FUTURE STRATEGY, POSSIBLE CHANGES

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

The Clinical Trials Regulation was finalised in 2014 but is to be implemented more than seven years later. During that time the design and conduct of clinical trials has evolved; complex innovative design trials have become more mainstream, use of digital technologies have shown the potential for great efficiencies in the running, monitoring and the collection of data without compromising the rights or safety of participants. This session will convene a panel of experts who will consider how the clinical trial ecosystem has evolved and will continue to evolve and how the provisions outlined in the Clinical Trials Regulation and the structures developed to support the implementation of the Regulation may need to be adapted to maintain Europe's competitiveness as a location for clinical research.

Speakers:

Kristof Bonnarens, Policy Officer - Pharmaceuticals, Directorate-General for Health and Food Safety, DG SANTE, European Commission, Belgium
Pieter Vankeerberghen, Head of Clinical Trials, European Medicines Agency, EU
Judith Creba, Executive Director, EU Regulatory Strategy, Novartis Pharma AG, Switzerland
Ruediger Pankow, Principal Consultant, Regulatory Affairs, Parexel International GmbH, Germany

18:30 CLOSING REMARKS DATA TRANSPARENCY CONFERENCE

Robert Paarlberg, Principal, Paarlberg & Associates LLC, USA
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

18:40 VIRTUAL NETWORKING

19:30 END OF DAY 1

DAY TWO | THURSDAY, 19 NOVEMBER 2020

13:45 LOG-IN AND CONNECT

14:00 SESSION 4

1 YEAR COUNTDOWN: ARE YOU READY? SPONSORS PREPAREDNESS FOR CTR INCLUDING NON-COMMERCIALS SPONSORS

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

This session will present the thoughts of three Sponsor Product Owners who are working with EMA and the IT Developers preparing CTIS for audit and then go-live on: how things are proceeding, what practicalities Sponsors of all types and sizes might need to consider in this final countdown stage; and what tips and pitfalls they might want to consider when preparing for the implementation of the CTR in late 2021.

Practicalities of using CTIS in the future
Ruediger Pankow, Principal Consultant, Regulatory Affairs, Parexel International GmbH, Germany

Operational considerations of an Academic Institution or a Small Sponsor
Andrea Seidel-Glaetzer, Project Manager, Coordination Centre For Clinical Trials, Heidelberg (KKS), Germany

Operational considerations of a Large Organisation
Pierre Omnes, , Executive Director, Site Start-Up & Regulatory, Syneos Health, France

Panel discussion with Q&A

15:00 BREAK

15:15 SESSION 5

1 YEAR COUNTDOWN: ARE YOU READY? OR WHAT IS NEEDED? MEMBER STATES PERSPECTIVE/FEEDBACK

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

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

Readiness in Belgium
Greet Musch, General Director, FAMHP, Belgium

Readiness in Sweden
Anne Marie Jansen Lang, CTFG co-chair; Clinical Assessor, Swedish Medical Products Agency, Sweden

Readiness in Austria
Stefan Strasser, Head of Clinical Trials, Institute Surveillance, Austrian Federal Office for Safety in Health Care / Medicines & Medical Devices, Austria

Readiness in Denmark
Lene Grejs Petersen, Senior Adviser, Clinical Trials, Danish Medicines Agency, Denmark

Panel discussion with Q&A

16:45 BREAK

17:00 SESSION 6

CTIS TRAINING MODULES

Session Chairs:
Christopher Price, Senior Manager, Global Regulatory Affairs Oncology, Merck, Germany
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, United Kingdom

This session aims to provide an overview of EMA's plans to develop and deliver training materials for users of the CTIS. It will also include some initial perspectives from Member States and sponsors on the materials delivered to date and the approach being taken to ensure users can interact correctly with the system. A Q&A session will also provide participants with opportunities to seek answers to outstanding questions they may have on CTIS training.

EMA CTIS Training Programme – concept and content
Fia Westerholm, Programme Assurance Manager, European Medicines Agency, EU

Development of the training materials
Marieke Meulemans, Member of the CTIS Expert Group (EMA) and Founder & CEO, GCP Central, the Netherland
Fatima Simoes, Pharm.D, Senior Service Coordinator, Infarmed, Portugal
Stephanie Kromar, Senior Regulatory Affairs Manager & Clinical Trial Sponsor CTIS Product Owner, European Organisation for Research and Treatment of Cancer (EORTC)

Panel discussion with Q&A.

18:30 END OF THE CONFERENCE