DIA
Clinical Trial Disclosure & Data Transparency Conference

Evolving requirements and new challenges

16-18 November 2020 | Virtual Event

(Central European Time)

Programme Committee

Merete Jørgensen
Senior Trial Disclosure Director, Clinical Transparency, Novo Nordisk, Denmark

Scott Feiner
Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA

Robert Paarlberg
Principal, Paarlberg & Associates LCC, USA

Nate Root
Associate Director, Disclosure and Transparency Ionis Pharmaceuticals, USA

Matthias Zerm
Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

Programme Advisor

Julie Holtzople
Director Clinical Trial Transparency Operations AstraZeneca, USA

Workshop

Limited Places Available

Pre-Conference Day
Thursday, 12 November

Workshop: Best Practices for the Redaction and Anonymization of Clinical Documents

This short course will cover:

- Redacting and Anonymizing Clinical Documents
- Writing Justifications for Redactions
- Responding to Feedback from Regualtory Agencies
- Writing Anonimzation Reports

Overview

2020 Conference builds on prior very successful conference series and leverages learnings from Regulators and international experts in the field. Clinical trial sponsors and academia are facing a host of new registration requirements in the EU, USA, and elsewhere. With evolving requirements comes new challenges, creating additional opportunities for knowledge-sharing and necessitating more interaction with peers. This event will provide essentials and timely information about global clinical trial disclosure and data transparency. It brings leading study sponsors from Industry and Academia to exchange knowledge and share their experiences with the implementation of Clinical Trial and Data Transparency from an academic and an industry viewpoint.

The program is assembled around key themes:

- Approaches to navigating and complying with global disclosure and transparency requirements
- Upcoming implementation of the **EU Clinical Trial Regulation**: CTIS Status/Updates
- Legal requirements related to **disclosure of clinical research information** for **medicinal products** and **medical devices**
- The **data sharing requirements and initiatives**
- Impact of the **EU General Data Protection Regulation (GDPR)** on data sharing
- Latest developments from ClinicalTrials.gov and Health Canada
- Patient Perspective
- Global harmonisation – benefits and barriers
- Compare and contrast qualitative and quantitative data anonymisation techniques for sharing of individual participant data
- Learnings for the future from COVID-19

Key Objectives

- Benefit from the various perspectives on regulatory, legal aspects and practical challenges from large to smaller sponsor organisations
- Leverage best practices on the practical implementation through case studies by the exchanging of views between regulators, industry, patients, academia and other stakeholders
- Use a unique opportunity for networking and asking questions to your own specific situation and area of responsibility

Who Will Attend

- Legal Requirements for disclosure of Clinical Research Information
- Compliance/Legal
- Clinical trial disclosure
- Transparency policies and compliance
- Clinical operations
- Medical writing, medical affairs, and medical communications
- Regulatory
- Publications
- Biometrics
- Data management
- Disclosure
- Data transparency/data sharing
- Academia
- Clinical/Medical Research
- Patient Advocacy

WORKSHOP: BEST PRACTICES FOR THE REDACTION AND ANONYMIZATION OF CLINICAL DOCUMENTS

15:50-18:00 CET

Limited Places Available.

Workshop Instructors:

Lora Killian, Clinical Trial Transparency and Disclosure Lead, Pfizer, USA
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA
Lukasz Kniola, Principal Analyst, Data Sharing, Biogen, UK

This short course will cover:

- Redacting and Anonymising Clinical Documents
- Writing Justifications for Redactions
- Responding to Feedback from Regulatory Agencies
- Writing Anonymisation Reports
- How Quantitative Risk Assessment works
- Transition to Quantitative to Qualitative Risk Assessment

| PRE-CONFERENCE WORKSHOP

15:50 LOG-IN AND CONNECT. WELCOME AND INTRODUCTION

DIA & Scott Feiner, Clinical Trial Disclosure Specialist , Abbvie (from Allergan), USA

16:00 SESSION 1

REDACTING AND ANONYMISING CLINICAL DOCUMENTS

Session Chair:
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA

General Landscape
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA

Qualitative Review
Lora Killian, Clinical Trial Transparency and Disclosure Lead, Pfizer, USA

16:45 BREAK

16:50 SESSION 2

QUANTITATIVE RISK ASSESSMENT

Session Chair:
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA

CCI review
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA

How quantitative risk assessment works
Lukasz Kniola, Principal Analyst, Data Sharing, Biogen, UK

18:00 END OF THE WORKSHOP

DAY ONE | MONDAY, 16 NOVEMBER 2020 (CENTRAL EUROPEAN TIME)

15:00 LOG-IN AND CONNECT

15:10 WELCOME AND INTRODUCTION DIA

Elena Popa, Scientific Program Manager, DIA, Switzerland
Robert Paarlberg, Principal, Paarlberg & Associates LLC, USA

15:20 OPENING KEYNOTE: GLOBAL REGULATORY CHANGES IN RELATION TO TRANSPARENCY

Merete Jørgensen, EFPIA CREG Clinical Trials Transparency pillar Lead

15:45 SESSION 1

LATEST DEVELOPMENTS AND FUTURE PERSPECTIVES FROM REGULATORS ON SHARING OF CLINICAL DOCUMENTS

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

The COVID-19 pandemic has increased the demand for global access to clinical information. In this session we will hear from regulators from EU, US and Canada on their take of the growing importance of sharing access to clinical documents. What impact the COVID-19 situation might have on the already available processes of clinical document sharing, and plans for the future including considerations for the future process and benefits from global collaboration. What are the pros and cons seen from a regional/country regulatory perspective of an added global collaboration?

EMA
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency (EMA), EU

FDA/CDER: Globalization Perspective
Nancy B. Sager, Director, Division of Information Disclosure Policy, ORP, CDER, FDA, USA

Health Canada
Andre Molgat, Senior Regulatory Affairs Officer, Resource Management and Operations Directorate, HPFB, Health Canada, Canada

Panel discussion with Q&A

16:45 SPONSORED SESSION

DRIVERS FOR TRANSPARENCY ADOPTION: RESEARCH COMPARING TODAY'S EXPECTATIONS AGAINST THE FUTURE

Kristin McDougall, Director of Clinical Transparency, D-Wise

Discover what driving factors are pushing disclosure forward at global sponsors and what challenges are holding progress back based on key results from industry research study and focus groups. We'll also take a look at what the future of transparency looks like, including Health Canada's phased approach and what that means for sponsors.

17:00 SESSION 2

GLOBAL HARMONISATION – BENEFITS AND BARRIERS

Session Chair:
Nate Root, Associate Director, Disclosure and Transparency Ionis Pharmaceuticals, USA

The global harmonization session will cover a brief history of the ongoing harmonization efforts to date and an introduction to the new PHUSE Best Practice guide. Industry experts will be discussing how the COVID-19 pandemic has changed the global collaboration of regulators and opportunities to where this can translate into disclosure and data sharing, as there has been an increasing demand in transparency. In these challenging times, we want to ensure that information is being disclosed timely and appropriately, while abiding by current regulations and maintaining trial integrity on a global scale.

Global Harmonisation – An Industry Perspective
Julie Holtzople, Director Clinical Trial Transparency Operations AstraZeneca, USA

Global Harmonisation – An Industry Perspective
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Transparency, Novo Nordisk, Denmark

Panel discussion with Q&A with speakers from both Session 1 & 2.
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency (EMA), EU
Nancy B. Sager, Director, Division of Information Disclosure Policy, ORP, CDER, FDA, USA
Andre Molgat, Senior Regulatory Affairs Officer, Resource Management and Operations Directorate, HPFB, Health Canada, Canada

18:15 NETWORKING

19:00 END OF DAY ONE

DAY TWO| TUESDAY, 17 NOVEMBER 2020 (CENTRAL EUROPEAN TIME)

15:00 LOG-IN AND CONNECT

15:10 SESSION 3

LATEST INFORMATION FROM CLINICALTRIALS.GOV

Session Chair:
Robert Paarlberg, Principal, Paarlberg & Associates, USA

This session will include an update from ClinicalTrials.gov regarding National Library of Medicine's Modernization initiative as well as other recent developments. It will also include an industry perspective regarding: Modernization initiative; National Institutes of Health's July 28th letter to sponsors on submitting results for pACTs; enforcement actions following FDA's final guidance on Civil Monetary Penalties; and, ClinicalTrials.gov's new practice of publishing results without review.

Updates on Modernisation Initiatives & COVID – 19 Activities in ClinicalTrials.gov
Rebecca J. Williams, Acting Director, ClinicalTrials.gov, National Library of Medicine, NIH, USA

Industry Experience
Gregory Shear, Clinical Trial Transparency Manager, PRAHealthSciences, USA

Panel discussion and Q&A.

16:10 BREAK

16:25 SESSION 4

UK MHRA AND BREXIT – NEXT STEPS. CONCRETE CLINICAL TRIALS DISCLOSURE ASPECTS

Session Chair:
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA

Overview of Latest MHRA Guidance for Clinical Trials Post-Brexit
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA

Presentation Title (to be confirmed)
Amanda Hunn, Self-employed Advisor, Formerly Head of Policy and Public Affairs At the HRA, UK

Panel discussion with Q&A

17:25 BREAK

17:40 SESSION 5

MEDICAL DEVICES: CLINICAL TRIAL DISCLOSURE REQUIREMENTS IN THE EU MEDICAL DEVICE REGULATION AND IN ISO 14155:2020

Session Chair:
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany
The EU Medical Device Regulation (MDR) (Regulation (EU) 2017/745) and the new version of ISO 14155:2020 introduce many new clinical trial disclosure and transparency requirements relating to clinical investigations with medical devices in the EU and beyond. We will look at the MDR and ISO 14155 requirements and provide an update on the progress of the clinical module in Eudamed which is scheduled to become available in May 2022.

EudaMed Updates
Celine Bourguignon, Head of Quality, Regulatory & Clinical Affairs, Cardinal Health, Belgium

ISO 14155 Requirements
Matthias Zerm, , Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

Panel discussion with Q&A

18:10 DAY 2 HIGHLIGHTS

Merete Jørgensen, Senior Trial Disclosure Director, Clinical Transparency, Novo Nordisk, Denmark
Scott Feiner, Clinical Trial Disclosure Specialist, Abbvie (from Allergan), USA
Robert Paarlberg, Principal, Paarlberg & Associates, USA
Nate Root, Associate Director, Disclosure and Transparency Ionis Pharmaceuticals, USA
Matthias Zerm, , Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.

DAY THREE| WEDNESDAY, 18 NOVEMBER 2020 (CENTRAL EUROPEAN TIME)

18:20 NETWORKING

19:20 END OF DAY TWO

14:30 CLINICAL TRIAL REGULATION CONFERENCE: LOG-IN AND CONNECT

14:40 WELCOME AND INTRODUCTION 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 Chairs:
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany
Rose-Marie Swallow, Senior Manager, EU Regulatory Policy & Intelligence, Bayer PLC, UK

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 Chairs:
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Transparency, Novo Nordisk, Denmark
Nick Sykes, Senior Director, Worldwide Safety & Regulatory, Pfizer, UK

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, EU

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 of:
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, UK

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