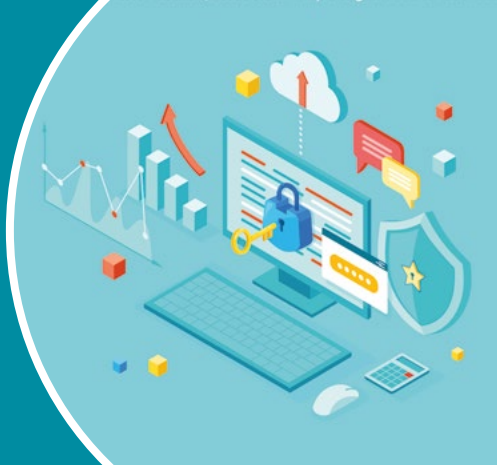
DIA

Clinical Trial Disclosure & Data Transparency Conference

Evolving Requirements and New Challenges

4-5 December 2019 | Amsterdam, the Netherlands



Get ready to gain insights on different approaches to navigate and comply with global clinical trial disclosure and transparency requirements for medicinal products and medical devices

Programme Committee

Julie Holtzople
Director Clinical Trial Transparency Operations AstraZeneca

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Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

Scott Feiner
Clinical Trial Disclosure Specialist Allergan

Robert Paarlberg
Principal, Paarlberg & Associates LCC, United States of America

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

Overview

This conference aims to bring 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.

Join us in exploring the latest challenges and opportunities resulting from EMA, Health Canada and National Institutes of Health data disclosure & transparency policies, and gain insights on different approaches to navigate and comply with global disclosure and transparency requirements for medicinal products and medical devices.

Additionally, we will discuss the impact of the EU General Data Protection Regulation (GDPR) on data sharing; various strategies for preparing for the implementation of the EU Clinical Trials Regulation; the impact of Brexit on MHRA and disclosure requirements; how new ICMJE data sharing requirements are being implemented; what approaches sponsors are taking for redaction and anonymization; and updates on sponsor compliance.

This 2019 Conference builds on prior conference discussions and leverages learnings from Regulators and international experts in the field.

Key Objectives

- Learn about the latest developments relating to EMA's Clinical Data Publication (Policy 0070), Health Canada's Clinical Data Publication Policy, EU CTR, Patient Centric Transparency, Publication Data Sharing requirements (such as ICMJE), EU MDR, EU GDPR, Brexit and MHRA, and ClinicalTrials.gov from regulators, legal experts as well as industry experts.
- 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 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

Key Topics

- Legal Requirements for disclosure of Clinical Research Information
- Legal impact of the EU General Data Protection Regulation (GDPR) on data sharing
- The implementation of EU Clinical Trial Regulation
- Transparency implications of the EU Medical Device Regulations and ISO14155
- Operationalizing publication driven data sharing requirement - How sponsors are approaching data sharing/Experience to date from the publications such as ICMJE
- Explore progress in the sharing of individual patient level data, consider platforms, progress and usability for all stakeholders
- Latest update from FDA and NIH on topics such as ClinicalTrials.gov
- Planning for submission of clinical documents to Health Canada and EMA
- Understanding approaches sponsors are taking on redaction/pseudonomisation/ anonymisation for clinical data and documents
- Impact of Brexit on MHRA and clinical trial disclosure requirements
- Discuss the evolution of Lay Language Summaries/Trial Result Summaries with a focus on best practices in authoring, translations and review processes
- Transparency consideration for complex clinical study designs, when we should disclose during a study that continues to evolve, new arms, etc.
- Considerations for the preparation of applications and notifications by sponsors

PRE-CONFERENCE DAY | TUESDAY, 3 DECEMBER 2019

WORKSHOP: THE EVOLVING DISCLOSURE/ TRANSPARENCY LANDSCAPE

13:00-17:30

Limited Places Available.

Workshop Instructors:

Merete Jørgensen, Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk, Denmark
Robert Paarlberg, Principal, Paarlberg & Associates LLC

This course will cover the key global clinical trial disclosure and transparency requirements and background information on how the requirements have evolved from 2004-2019. The course will also provide an underpinning of the policies and regulations in order to give participants a firm foundation and tools in which to successfully work in this space.

The topics to be covered are:

- The evolution from ICMJE requirements in 2004 to today's requirements for sharing of clinical study documents/data in relation to regulatory submissions, and sharing of data for secondary use
- The outside influencers and internal stakeholders – who are they? As disclosure responsible when and what topics do you need to consider/discuss internally in your organization.
- A deeper dig into the EU and US requirements, similarities and differences
- Highlights of the FDA Amendments Act Final Rule expanding reporting requirements in ClinicalTrials.gov
- The global environment of local and primary WHO registers

Learning Objectives

At the conclusion of this short course, attendees will be able to:

- Explain the evolution of transparency requirements
- Identify influencers and internal stakeholders
- Recognize the differences between EU and US requirements

Target Audience

- Professionals from industry and academia relatively new to the disclosure and transparency area or who want to have a refresher on the policies and regulations underpinning the disclosure/transparency landscape.
- Professionals working with:
  - Disclosure, Trial and Results Registration Activities
  - Clinical Operations
  - Publication Planning
  - Medical Writing
  - Regulatory Submissions
  - Biostatistics
  - Compliance

Separate Registration Required

WORKSHOP AGENDA

13:00 REGISTRATION

13:30 INTRODUCTION AND WELCOME

14:15 CLINICAL TRIAL DISCLOSURE AND DATA TRANSPARENCY:

- The evolution timeline
- Trial registration and results reporting
- FDAAA Final Rule
- EudraCT/EU Clinical Trials Register and ICMJE requirements

16:00 COFFEE AND TEA BREAK

16:30 CLINICAL TRIAL DISCLOSURE AND DATA TRANSPARENCY – CONTINUED

- Clinical study documents sharing
- Lay Summary results
- Patient level data sharing

17:30 CLOSE OUT

| 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.

| Conference Venue

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

DAY ONE | WEDNESDAY, 4 DECEMBER 2019

08:00 REGISTRATION AND WELCOME COFFEE

08:45 SESSION 1

LATEST UPDATES ON CLINICAL TRIAL PORTAL AND ITS FUNCTIONALITIES

Session Chair:

Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

An overview of the EU Regulatory scene seen in the perspective of Clinical Transparency and Disclosure. The presentations will focus on the status and recent development in EU, including the upcoming EU Clinical Trials Regulation, the development of the IT system CTIS (Clinical Trials Information System), the latest and upcoming development initiatives for the EudraCT system, and Brexit implications on its future functionality. The industry perspective on preparation for the new requirements including also the new database for device trials.

Objectives

At the conclusion of this session, participants should be able to:

- Analyze and prepare for their organization's process for the upcoming Clinical Trials Regulation
- Describe the changes in EudraCT and the practical implications

Updates on EU Clinical Trial Regulation from Member States

Lene Grejs, Petersen Senior Adviser, Danish Medicines Agency, Denmark

Updates on EU Clinical Trials Portal

Noemie Manent, Scientific Administrator, Compliance and Inspection, European Medicines Agency, European Union

CTIS Project Update from an Industry Perspective

Milagros Blazquez, EFPIA Process Owner in relation to CTIS, BMS

Panel discussion with Q&A

10:15 VENDOR PRESENTATION - PRIVACY ANALYTICS

10:30 COFFEE BREAK

11:00 SESSION 2

GLOBAL HARMONIZATION FOR CLINICAL TRIAL TRANSPARENCY AND DISCLOSURE

Session Chair:

Karla Childers, Senior Director, Strategic Projects, Office of the Chief Medical Officer Johnson & Johnson, USA

In this session we will look at emerging goals and opportunities sponsors view as possibilities for global harmonization in Clinical Trial Transparency. We will discuss the ideology along with the risks, benefits and opportunities for harmonization in Clinical Trial Transparency globally.

Objectives:

- Highlight incremental steps that can lead towards successful global harmonization
- Look at additional opportunities for increased harmonization
- Discuss global CTT harmonization opportunities as they relate to all stakeholders

Panellists:

Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service European Medicines Agency (EMA), EU
Anne Cutting, Director, Human Subject Research Governance GSK, UK
Nate Root, Associate Director, Disclosure and Transparency Ionis Pharmaceuticals, United States
Andre Molgat, Senior Regulatory Affairs Officer, Resource Management and Operations Directorate, HPFB, Health Canada, Canada
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

12:30 LUNCH

14:00 SESSION 3

HEALTH CANADA AND EMA PUBLICATION POLICIES

Session Chair:

Robert Paarlberg, Principal, Paarlberg & Associates, United States of America

Health Canada newly implemented its regulation on Public Release of Clinical Information. These new requirements covers both drug and device applications. As of 1 August 2018 EMA, suspended all new activities related to clinical data publication. This is a result of the implementation of the third phase of EMA's Business Continuity Plan. It is anticipated that EMA will resume publishing clinical data 4Q2019.

Objectives:

At the conclusion of this session, participants should be able to:

- Analyze and prepare for their organization's process for the disclosure according to the Health Canada initiative.
- Discuss EMA's most current update on Policy 0070.
- Share information on best practice to ensure the process will run as smooth as possible both for industry and regulators.
- Discuss best practices in order to avoid double work when submitting clinical packges to Health Canada and EMA

Process Improvement

Scott Feiner, Clinical Trial Disclosure Specialist Allergan

Status of EMA Clinical Publication Policy

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

Health Canada and Their Publication Policy

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

15.30 VENDOR PRESENTATION - d-wise

15:45 COFFEE BREAK

16:15 SESSION 4

CLINICAL TRANSPARENCY IN THE UK, THE FOCUS ON THE IMPORTANCE FOR PATIENT CENTRICITY, AND THE POSSIBLE IMPACT OF BREXIT

Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

The UK has been on the forefront of transparency requirements. The HRA/MHRA transparency strategy and initiatives for ensuring a patient focussed information will be presented, and the possible impact of Brexit.

Objectives:
At the conclusion of the session the participants will be able to:
- Know the content of the ABPI approach – from publication, through open access to summaries that are understandable for patients
- Explain the cross-sector approach (with funders, charities, regulators and government)
- Appreciate what is happening in the UK environment – outcome of select committee and HRA consultation
- Obtain an overview of the work on lay summaries (reference session 7 in the conference)
- Be informed about the possible impact of Brexit – also in case an equivalent portal will be needed in case UK will not have access to the EU Clinical Trials Information System.

Why Clinical Trial Transparency is Important for Patient Centricity
Sheuli Porkess, Executive Director, Research, Medical & Innovation, The association of the British Pharmaceutical Industry (ABPI), UK

The Complexity of Transparency in the UK and How Brexit Might Impact on this
Amanda Hunn, Freelance consultant and medical writer, formerly Head of Policy and Public affairs at the Health Research Authority, UK

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

DAY TWO | THURSDAY, 5 DECEMBER 2019

08:00 RECAP

08:15 SESSION 5

TRANSPARENCY IMPLICATIONS OF THE EU MEDICAL DEVICE REGULATIONS (MDR)

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

The EU Medical Device Regulation (Regulation (EU) 2017/745) in conjunction with the upcoming new version of EN ISO 14155 introduces many new clinical trial disclosure and transparency requirements relating to clinical investigations with medical devices in the EU as from May 2020. The clinical module in Eudamed will serve as the central system for submitting, exchange of information, and reporting of clinical investigations and will be accessible to Regulatory Authorities, notified bodies, industry, and the public.

Objectives:
- Gain first hand insights on how information/documents relating to clinical investigations will be made publicly available in Eudamed:
  - What information/documents?
  - Publicly available at what point in time over the course of a clinical investigation?
  - What criteria and measures are foreseen to ensure protection of personal data and commercially confidential information potentially contained therein?
- Learn about the new public disclosure provisions in the upcoming new version of EN ISO 14155:2018 and how they relate to the MDR and may become applicable beyond.

Industry View: Disclosure of clinical investigation information in Eudamed – what, when, how?"
Céline Bourguignon, Head of Quality, Regulatory & Clinical Affairs, Cardinal Health, Brussels Chair of the Eudamed Taskforce

New Version of ISO14155:2018
Danielle Giroud, CEO MD-CLINICALS SA, Switzerland

Panel discussion with Q&A

10:00 COFFEE BREAK

10:30 SESSION 6

SHARING OF INDIVIDUAL PATIENT DATA FROM CLINICAL TRIALS
ICMJE DATA SHARING REQUIREMENTS: IMPLICATIONS FOR CLINICAL TRIAL SPONSORS

Session Chair:
Kathy B Thomas-Urban, Medical and Scientific Writer Medical & Technical Writing & Publication Services

Various data sharing initiatives are prompting trial sponsors to share clinical data in the public domain. Indeed, some ICMJE member journals have stated that lack of a positive data sharing statement, upon submission of the manuscript, will prevent manuscript acceptance for publication. The EU General Data Protection Regulation (EU GDPR) is also influencing the data sharing environment, especially for rare diseases.

Concepts regarding data sharing that are part of the considerations for sponsors of clinical trials include: i) processes and conditions that could be used to share data including the impact of GDPR, and ii) types of collaborative research that could evolve through data sharing.

Sponsor preparedness for data sharing should be an essential component at the early stage of clinical trial planning. This implies communicating and explaining the data sharing requirements within the organization as well as revising internal processes and procedures for data sharing of clinical data.

ICMJE Data Sharing Requirements: Brief Overview
Kathy B Thomas-Urban, Medical and Scientific Writer Medical & Technical Writing & Publication Services, Germany

Scientific Collaboration and Data Sharing
Slavka Baronikova, Director, Scientific Publications, Galapagos NV, Belgium

ICMJE Data Sharing Requirements and EU GDPR
Grant Strachan, Senior Associate, Brodies LLP Solicitors Capital House, UK

11:45 VENDOR PRESENTATION - PA CONSULTING

12:00 LUNCH

13:00 SESSION 7

LAY SUMMARIES AND REGULATORY

Session Chair:
Caragh Murray, Plain Language Summary Manager, Data Transparency, Jansen R&D, UK

Lay Summaries are required for all studies sponsors will run in the EU after the EU CTR effective date. Sponsors have begun implementation and many early successes have led to lessons learned in delivery. In this session sponsors with different perspectives will present their experiences to date through a panel discussion.

Objectives
- Discuss experience in the implementation for each sponsor
- Share lessons learned during the implementation as early adopters
- Discuss key topics that have presented a challenge during the implementation
- Discuss current hot topics sponsors are facing during their implementation journeys

User Testing Perspective
D.K.Theo Raynor, Professor of Pharmacy Practice University of Leeds School of Healthcare Leeds

Industry Perspective
Anne Cutting, Director, Clinical Data Transparency GSK, UK

Medical Writing Perspective
Tom Rees, Communications Director, Oxford PharmaGenesis Ltd, UK

Panel discussion with Q&A

14:30 COFFEE BREAK

15:00 SESSION 8

PRACTICAL STRATEGIES FOR IMPLEMENTING GDPR ACROSS THE ENTIRE PRODUCT DEVELOPMENT LIFECYCLE

Session Chair:
Scott Feiner, Clinical Trial Disclosure Specialist Allergan

While sponsors are gaining experience in protecting individual privacy in Policy 0070 and Health Canada submissions, new reidentification techniques are challenging currently employed anonymization practices. Recent research shows that reidentification of individuals, even in fully anonymized data sets, is becoming a practical concern. The upcoming Clinical Trials Information System (CTIS) and Eudamed databases will greatly enhance the amount of clinical data that sponsors are to anonymize and make public. This session explores these challenges and discusses practical approaches to fulfilling the requirements of the GDPR and ensuring individual privacy protection.

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

Overall Challenge in Implementing GDPR in the Lifecycle of a Product
Hannah Crowther, Senior Associate for Bristows LLP, UK

Risk of Reidentification from Anonymized Datasets
Scott Feiner, Clinical Trial Disclosure Specialist Allergan, Canada

16:15 WRAP UP

EXHIBITOR FLOORPLAN