Global Clinical Trials Transparency Conference
19-20 September 2018

Pre-Conference Workshop 1: The Evolving Disclosure/Transparency Landscape
Pre-Conference Workshop 2: Operationalizing Policy 0070
18 September 2018

Doubletree by Hilton Docklands Riverside London, United Kingdom

PROGRAMME COMMITTEE

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

Merete Jørgensen
Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk, Denmark

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

Rebecca J. Williams
Acting Director, National Library of Medicine, NIH, United States of America

Overview

Disclosure and 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, US, and other places in the world. This 2018 Conference builds on prior conference discussions and leverages learnings from International experts, providing the opportunity to gain insights on how to meet the new challenges and opportunities. The program is assembled around key themes:

- Upcoming implementation of the EU Clinical Trial Regulation: Portal and Database Status/Updates
- Operational tools and strategies sponsors are using to comply with EMAs Clinical Data Publication Policy 0070
- Best practices in meeting the expanded requirements of the NIH Final Rule for FDAAA (42 CFR Part 11)
- Legal requirements related to disclosure of clinical research information for medicinal products and medical devices
- How the new ICMJE data sharing requirements are being implemented
- Impact of the EU General Data Protection Regulation (GDPR) on data sharing
- Approaches to navigating and complying with global disclosure and transparency requirements

Attendees will learn from case studies and the experiences of experts and their peers.

Objectives

- Learn about the latest developments relating to the implementation of the EMA Clinical Data Publication Policy 0070, FDAAA Final Rule, ICMJE Data Sharing Statement Requirement, EU GDPR, Health Canada’s new clinical publication regulation and EU MDR from regulators, legal experts as well as medical device experts
- Benefit from the various perspectives on regulatory, legal aspects and practical challenges from large, mid-sized, and 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 of the option for networking and asking questions to your own specific situation and area of responsibility

Key Topics

Developments in relation to implementation of EMAs Clinical Data Publication Policy 0070, NIH Final Rule for FDAAA, ICMJE Data Sharing Requirement, EU GDPR, EU Medical Device Regulation, Health Canada’s draft guidance on Public Release of Clinical Information, and FDAs new initiatives on sharing clinical documents publicly: Member States preparedness for the regulation, including plans for co-operation between agencies and ethics committees and coordinated assessment

- Latest updates from EMA and NIH (on ClinicalTrials.gov)
- Best practices for operationalizing EMAs Clinical Data Publication Policy 0070 submissions including risk assessments
- Compare and contrast qualitative and quantitative data anonymisation techniques for sharing of individual participant data
- Utility of redacted/anonymized clinical data
- Planning for submissions to ClinicalTrials.gov
- Planning and thinking ahead for submission of documents for EMAs Clinical Data Publications Policy 0070 and documents for inclusion of results submission for ClinicalTrials.gov
- Understand the legal impact of the EU General Data Protection Regulation (GDPR) on data sharing
- Clinical trial disclosure and transparency requirements in the upcoming EU Medical Device Regulation
- Compare and contrast EMA, FDA and Health Canada’s clinical data publication policies
- Operationalizing ICMJE’s new data sharing statement requirement – How Sponsors are Approaching this new requirement/Experience to date from the ICMJE
- Experiences with FDA’s Pilot Clinical Data Publication Project
- Strategies for preparing for implementation of the EU Clinical Trials Regulation
- Company strategies regarding returning trial results to participants and meeting the EU
- Clinical Trial Regulation requirements for trial results summaries for laypersons.

Who Should Attend

- Professionals and experts from areas affected by public clinical trial disclosure requirements across drug and medical device development (regulatory affairs, scientific affairs, medical writing, clinical operations, medical communication, biostatisticians/biometrics, project management, medical affairs, legal, patent departments, etc.)
- Consultants, CROs and companies that offer services for submitting to clinical trial registries, publication planning and medical writing
- Patient organisations
- Regulatory agencies
- Academic institutions

Find out more at DIAglobal.org/Transparency
WORKSHOP 1: THE EVOLVING DISCLOSURE/TRANSPARENCY LANDSCAPE

Instructors:
Robert Paarlberg, Principal, Paarlberg & Associates, United States of America
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

The workshop will cover the key disclosure and transparency requirements and background information on how the requirements have evolved from 2004-2018. The topics to be covered are:

• The evolution from ICMJE requirements in 2004 to today’s requirements for sharing of clinical study documents in relation to regulatory submissions.
• Who are the outside influencers and the internal stakeholders
• 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
• A few words as to the future requirements – a teaser for the topics to be covered during the conference

Audience: People relatively new to the disclosure and transparency area.
People working with:
• Disclosure, Trial and Results Registration Activities
• Publications
• Medical Writing
• Regulatory Submissions

Level: Audience with limited or beginner’s knowledge of the disclosure requirements.

WORKSHOP OUTLINE:
12:00 Registration
13:00 Introduction and Welcome
13:15 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

15:00 COFFEE BREAK

15:30 Clinical Trial Disclosure and Data Transparency – continued
• Clinical study documents sharing
• Lay Summary results
• Patient level data sharing

17:00 Close out

WORKSHOP 2: OPERATIONALIZING POLICY 0070

Approach, Challenges, and Solutions from Experience Gained in Preparing and Submitting 3 MAA’s and 1 Type 2 Variation.
Instructor:
Kelly Vaillant, President, Vaillant Consulting LLC, United States of America

This workshop will cover some of the key considerations and challenges associated with planning for and preparing Policy 0070 packages for submission to the EMA. The topics to be covered include:

• Overview of Policy 0070 Regulation and the evolution of Policy 0070 Guidance from 1st implementation (2016) to its current state (2018)
  - Documents in scope and not in scope.
  - PPD vs. CCI
• Important considerations when planning your first Policy 0070 package
  - Lead Time
  - Process(es) / Technologies
  - What activities can/should be outsourced vs. insourced
• Internal cross-functional engagement and coordination
  - Awareness, Awareness, Awareness
  - Training, Training, Training
• Engagement with the EMA – Timing, Setting Expectations, Commitments
• Implementing a rational, robust, and scalable Redaction Process
  - EMA vs. Internal Expectations
  - What is already in the Public Domain...What is REALLY in the public domain? The importance of internal Due Diligence
  - CCI – Is it Commercially Confidential Information...Really?
• The future of Policy 0070 and ‘Policy 0070 like’ regulations
  - Health Canada Implementation of ‘Public Release of Clinical Information’ regulation update (analogous to EMA Policy 0070
  - Policy 0070 vs. the GDPR: Alignment or misalignment?
• Moving toward true Anonymization
  - Redaction vs. Anonymization – a general overview, current practice, and discussion

Audience: Individuals / Sponsors who have not yet prepared a Policy 0070 Package.
People working with:
• Disclosure, Trial and Results Registration Activities
• Publications
• Medical Writing
• Regulatory Submissions

Level: Audience with limited or beginner’s knowledge of Policy 0070 and associated requirements / guidance.

WORKSHOP OUTLINE:
12:00 Registration
13:00 Introduction and Welcome
13:15 Overview of Policy 0070 and Associated Guidance
14:00 Important Considerations When Planning for Your First Policy 0070 Package

15:00 COFFEE BREAK

15:30 Putting Together Your First Policy 0070 Package
16:30 The Future Policy 0070 and ‘Policy 0070 Like’ Regulations
17:00 Close out
08:00 REGISTRATION AND WELCOME COFFEE
08:30 KEY NOTE SPEECH
09:00 SESSION 1

SHARING CLINICAL STUDY REPORTS
Session Chair:
Robert Paarlberg, Principal, Paarlberg & Associates, United States of America

The FDA, EMA and Health Canada will all share clinical study information in the public domain. What are the differences between the Regulators on what clinical information will be shared? How does this impact industry?

Interactions with the FDA Clinical Data Summary Pilot Program
Olivia Shopshear, Senior Director, Science and Regulatory Advocacy, PhRMA, United States of America

EMA Clinical Data Publication Policy 0070
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency (EMA), European Union

Health Canada Initiative: Health Canada’s draft guidance on Public Release of Clinical Information
Andre Molgat, Senior Regulatory Affairs Officer, Resource Management and Operations Directorate, HPFB, Health Canada, Canada

Panel discussion with Q&A
Additional Panellist:
Sini Eskola, Director, Regulatory, Drug Development and Manufacturing, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

10:30 COFFEE BREAK
11:00 SESSION 2

SHARING AND USING DEIDENTIFIED INDIVIDUAL PARTICIPANT DATA (IPD)
Session Chair:
Rebecca J. Williams, Acting Director, ClinicalTrials.gov, National Library of Medicine, NIH, United States of America

Learn how data repositories such as Vivli and ClinicalStudyDataRequest.com are advancing access to IPD for research purposes and how specific companies are using this resource to support their own disclosure policies. This session will also include a case study describing how academic researchers are using IPD to address questions intended to have clinical impact. Specific features of these data sharing platforms, as well as issues in using IPD will be described.

Sponsors/Funders Providing Access to IPD through ClinicalStudyDataRequest.com
Ben Rotz, Senior Advisor, Global Medical Strategy and Operations, Eli Lilly, United States of America

Experience With Existing IPD Repositories
Rebecca Li, Executive Director, Vivli, United States of America

Requesting, Preparing, and Using IPD in Academic Research
Sarah Nevitt, Department of Biostatistics, University of Liverpool, UK

Panel discussion with Q&A

12:30 LUNCH
14:00 SESSION 3

GDPR AND DATA TRANSPARENCY REQUIREMENTS
Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

How to ensure Data privacy and being Transparent at the same time gives rise to some considerations and concerns. What does this mean from a patient perspective, what are the considerations from industry trying to manoeuvre the requirements and what are the legal reality when working in this field.

Legal aspects of GDPR and Data Transparency Requirements
Mark Barnes, Partner, Ropes & Gray LLP, United States of America

Patients perspectives on Data Privacy versus Data Transparency
Deborah E. Collyar, President, Patient Advocates In Research (PAIR), United States of America

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.
GLOBAL CLINICAL TRIALS TRANSPARENCY CONFERENCE

15:30 COFFEE BREAK

16:00 SESSION 4

LATEST UPDATES ON CLINICAL TRIAL DISCLOSURE IN THE EU AND USA

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

Are you aware of the latest clinical trial disclosure updates in the USA and the EU? This session will present updates from ClinicalTrials.gov, inform about the implementation of the EU Portal and Database in the context of the EU Clinical Trial Regulation, and provide insights into the ongoing expansion of the Eudamed database to accommodate the functionalities around clinical studies with medical device along with pertinent transparency provisions as required by the EU Medical Device Regulation.

Updates from NIH/ClinicalTrials.gov
Rebecca J. Williams, Acting Director, ClinicalTrials.gov, National Library of Medicine, NIH, United States of America

Updates on EU Clinical Trials Regulation
Noemi Manent, Scientific Administrator, Compliance and Inspection European Medicines Agency, European Union

Updates on MDR: Transparency Provisions and Eudamed Expansion (Clinical Module)
Ronald Boumans, Senior Global Regulatory Consultant, Emergo, The Netherlands

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

THURSDAY, 20 SEPTEMBER

08:30 HIGHLIGHTS FROM DAY ONE AND OVERVIEW OF DAY TWO

08:45 SESSION 5

SUMMARY PROTOCOL AND RESULTS INFORMATION: CLINICALTRIALS.GOV & EUDRACT

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

Are you prepared to posting results in both registries? How do you ensure consistency across registries considering differences in data fields, process (quality review versus purely automated validation) and timing? This session will address procedural aspects, will give insights around the quality control review at ClinicalTrials.gov and provide an outlook on how information contained in clinical trial registries may become more aligned and more meaningful for patients.

How to Approach Submissions to Each Database
Thomas Wicks, Chief Strategy Officer, Trialscope, United States of America

Issues Related to Quality Control Review
Heather Dobbins, ClinicalTrials.gov Lead Results Analyst, NCBI/NLM, National Institutes of Health (NIH), United States of America

Quality Control Review at NIH - Industry Experience
Smita Shukla, Director Clinical Disclosure Reporting, Clinical Governance and Data Transparency, GSK, United States of America

Transcelerate Initiative to Improve Data Quality in Clinical Trial Registries
Paulo Moreira, Clinical Research Access Team Program Leader, Transcelerate, United States of America

Panel discussion with Q&A

10:20 COFFEE BREAK

11:10 SESSION 6

CLINICAL TRIAL RESULTS SUMMARIES FOR PATIENTS AND THE PUBLIC

Session Chair:
Rebecca J. Williams, Acting Director, ClinicalTrials.gov, National Library of Medicine, NIH, United States of America

There has been recent progress towards making the results of clinical trials available in a format and language that can be readily understood by the general public. This session will cover the patient experience and expectations for summaries, the EU expert group recommendations on summaries of clinical trial results for laypersons, and experience with returning results to research participants.

Lay Summaries
Juan Garcia Burgos, Head of Public Engagement Department, European Medicines Agency (EMA), European Union

Writing Lay Summaries- A Survivor’s Guide
Lisa Chamberlain James, Senior Partner, Trilogy Writing & Consulting, United States of America
Patient Expectations for Results Summaries  
**Deborah E. Collyar**, President, Patient Advocates In Research (PAIR), United States of America

Returning Research Results To Participants  
**Rikke Gøbel**, Senior Medical Writer, Novo Nordisk, Denmark  
**Ann Olling**, Principle Medical Writer, Novo Nordisk, Denmark

Panel discussion with Q&A

12:40  LUNCH

13:50  SESSION 7 (PART 1)

PUBLIC ACCOUNTABILITY AROUND DISCLOSURE AND WHERE ARE WE HEADING  
Session Chair:  
**Merete Jørgensen**, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

New initiatives on how to improve, enforce and measure Data Sharing activities are being implemented and published. How are these measured? What has the impact been? How have organisations worked with these new initiatives? Future transparency ambitions, and how can we even get more out of these new initiatives?

Data Sharing: What are Journals Doing?  
**Fiona Godlee**, Editor in Chief, British Medical Journal (BMJ), United Kingdom

Data sharing the new initiative under the Good Pharma Score Card  
**Jennifer Miller**, Founder, Bioethics International and Good Pharma Scorecard, Assistant Professor, Yale University School of Medicine, United States of America

Making Publications and Data Sharing commitments go hand in hand  
**Lise Baltzer**, Director for Global Publications, Novo Nordisk, Denmark

Auditing Policy and Performance on Transparency: the TrialsTracker Programme  
**Ben Goldacre**, Senior Clinical Research Fellow, CEBM, Department of Primary Care Health Sciences, University of Oxford, United Kingdom

15:30  COFFEE BREAK

15:50  SESSION 7 (PART II) - PANEL DISCUSSION WITH Q&A: LAST CHANCE FOR QUESTIONS

FINAL PANEL DISCUSSION AND KEY TAKEAWAYS: WHERE ARE WE HEADING IN TERMS OF TRANSPARENCY?  
Session Chair:  
**Merete Jørgensen**, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

Panellists:  
**Fiona Godlee**, Editor in Chief, British Medical Journal (BMJ), United Kingdom  
**Andre Molgat**, Senior Regulatory Affairs Officer, Resource Management and Operations Directorate, HPFB, Health Canada, Canada  
**Olivia Shopshear**, Senior Director, Science and Regulatory Advocacy, PhRMA, United States of America  
**Sini Eskola**, Director, Regulatory, Drug Development and Manufacturing, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium  
**Jennifer Miller**, Founder, Bioethics International and Good Pharma Scorecard, Assistant Professor, Yale University School of Medicine, United States of America  
**Lise Baltzer**, Director for Global Publications, Novo Nordisk, Denmark  
**Ben Goldacre**, Senior Clinical Research Fellow, CEBM, Department of Primary Care Health Sciences, University of Oxford, United Kingdom

17:00  END OF CONFERENCE
Early-bird rate
To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird applies to industry representatives with active DIA membership only.

**Early bird discount: register by 7 August 2018**

| CATEGORY | Member | Non-Member
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Optional Pre-Conference Workshops | 18 September 2018 | Half day

Pre-Conference Workshop 1: The Evolving Disclosure/Transparency Landscape
Pre-Conference Workshop 2: Operationalizing Policy 0070

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Group discount/SME rates available. Special rates for students and patient representatives offer, subject to availability. Please contact DIA in Basel for more information.

Registration fee includes: refreshments and lunches.

Payment methods:
- Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

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    - Card Number
    - Exp. Date
  - Cardholder’s Name

- Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to “Account Holder: DIA.” Please include your name, company, Event ID 18119 as well as the invoice number to ensure correct allocation of your payment.

  Payments must be net of all charges and bank charges must be borne by the payer. If you have not received your confirmation within five working days, please contact DIA in Basel.

  By signing below, I confirm that I agree with DIA’s Terms and Conditions of booking. These are available from the office or online by clicking here.

  Date
  Signature

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- I would like to receive a one year complimentary DIA membership at no additional cost.

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- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation: € 50.00

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You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office in Basel of any such substitutions as soon as possible.

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You agree that your personal data will be transferred to DIA in the US

The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CET.

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