Global Clinical Trials Transparency Conference
19-20 September 2018

Pre-Conference Workshop: The Evolving Disclosure/Transparency Landscape
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 industry 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
- Approaches to navigating and complying with global disclosure and transparency requirements
- 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
- Strategies for preparing for implementation of the EU Clinical Trials Regulation

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: 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 and Lunch
13:00 Introduction and Welcome
13:15 Clinical Trial Disclosure and Data Transparency:
  • The evolution of Clinical Trails Disclosure Requirements
  • FDAAA and Final Rule
  • ICMJE Sharing Patient level data and Who is watching?
  • General Discussions
15:00 COFFEE BREAK
15:30 Clinical Trial Disclosure and Data Transparency – continued
  • Operational Aspects of Policy 0070 – sharing documents
  • ICMJE Sharing Patient level data and Who is watching?
  • General Discussions
17:00 Close out

Disclosure Policy

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<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>08:00</td>
<td>REGISTRATION AND WELCOME COFFEE</td>
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<tr>
<td>09:00</td>
<td>SESSION 1</td>
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<tr>
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<td><strong>SHARING CLINICAL STUDY REPORTS</strong></td>
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<td>Session Chair:</td>
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<td></td>
<td>Francine Lane, VP, Global Transparency, TrialScope, United States of America</td>
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<td>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?</td>
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<td><strong>Interactions with the FDA Clinical Data Summary Pilot Program</strong></td>
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<td></td>
<td>Olivia Shopshear, Senior Director, Science and Regulatory Advocacy, PhRMA, United States of America</td>
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<td>EMA Clinical Data Publication Policy 0070</td>
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<td></td>
<td>Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency (EMA), European Union</td>
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<td>Health Canada Initiative:</td>
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<td>Health Canada’s draft guidance on Public Release of Clinical Information</td>
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<td>Andre Molgat, Senior Regulatory Affairs Officer, Resource Management and Operations Directorate, HPFB, Health Canada, Canada</td>
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<td>Panel discussion with Q&amp;A</td>
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<td>11:00</td>
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<td><strong>SHARING AND USING DEIDENTIFIED INDIVIDUAL PARTICIPANT DATA (IPD)</strong></td>
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<td>Rebecca J. Williams, Acting Director, ClinicalTrials.gov, National Library of Medicine, NIH, United States of America</td>
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<td>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.</td>
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<td><strong>Sponsors/Funders Providing Access to IPD through ClinicalStudyDataRequest.com</strong></td>
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<td></td>
<td>Ben Rotz, Senior Advisor, Global Medical Strategy and Operations, Eli Lilly, United States of America</td>
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<td><strong>Vivli – A global data sharing platform</strong></td>
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<td>Rebecca Li, Executive Director, Vivli, United States of America</td>
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<td><strong>Requesting, Preparing, and Using IPD in Academic Research</strong></td>
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<td>Sarah Nevitt, Department of Biostatistics, University of Liverpool, UK</td>
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<td><strong>GDPR AND DATA TRANSPARENCY REQUIREMENTS</strong></td>
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<td>Session Chair:</td>
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<td>Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor &amp; Disclosure, Novo Nordisk, Denmark</td>
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<td>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?</td>
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<td><strong>Legal aspects of GDPR and Data Transparency Requirements</strong></td>
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<td>David J. Peloquin, Associate, Ropes &amp; Gray LLP, United States of America</td>
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<td><strong>Patients’ perspectives on Data Privacy versus Data Transparency</strong></td>
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<td>Deborah E. Collyar, President, Patient Advocates In Research (PAIR), United States of America</td>
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<td><strong>GDPR and Data Transparency: An Industry Perspective’</strong></td>
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<td>Anne Cutting, Director Human Subject Research Governance and Disclosure, GSK</td>
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**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 devices 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
Anabela Marcal, Head of Committees and Inspections Department, European Medicines Agency (EMA), European Union

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

**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.

Transcelerate Initiative to Improve Data Quality in Clinical Trial Registries
Munther Baara, Senior Director, Development Business Technology, Pfizer, United States of America

Results Submission “Success”: An Update
Heather Dobbins, ClinicalTrials.gov Lead Results Analyst, NCBI/NLM, National Institutes of Health (NIH), United States of America

Improving GSK's first time acceptance record for Results submissions on ClinicalTrials.gov
Smita Shukla, Director Clinical Disclosure Reporting, Clinical Governance and Data Transparency, GSK, United States of America

Managing Submissions to Global Registries
Thomas Wicks, Chief Strategy Officer, Trialscope, United States of America

Panel discussion with Q&A

**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.

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

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?
Trish Groves, Associate Editor, British Medical Journal (BMJ), United Kingdom

Making Publications, Disclosure and Data Sharing Commitments go Hand in Hand
Lise Baltzer, Director for Global Publications, Novo Nordisk, Denmark

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

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

15:00 COFFEE BREAK

15:20 SESSION 8

WHERE ARE WE HEADING? THE US AND EU INDUSTRY ASSOCIATIONS’ PERSPECTIVE
Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

Speakers:
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

15:40 SESSION 9

PANEL DISCUSSION WITH Q&A: LAST CHANCE FOR QUESTIONS
Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Clinical Reporting Anchor & Disclosure, Novo Nordisk, Denmark

Panellists:
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
Lise Baltzer, Director for Global Publications, Novo Nordisk, Denmark
Jennifer Miller, Founder, Bioethics International and Good Pharma Scorecard, Assistant Professor, Yale University School of Medicine, United States of America
Ben Goldacre, Senior Clinical Research Fellow, CEBM, Department of Primary Care Health Sciences, University of Oxford, United Kingdom

17:00 END OF CONFERENCE

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