DIA

Global Clinical Trial Disclosure and Data Transparency Conference

Short Course September 18 | Conference September 19-20
DoubleTree Bethesdan | Bethesda, MD

PROGRAM CHAIR

Robert Paarlberg, MS
Principal
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Vice President, Global Transparency,
TrialScope

Nathaniel Root, MSc
Associate Director, Disclosure and Transparency
Ionis Pharmaceuticals

Overview

Clinical trial information transparency is taking on new dimensions. Clinical trial sponsors and academia are facing a host of new registration requirements in the US, EU, and elsewhere. With evolving requirements comes new challenges, creating additional opportunities for knowledge-sharing and necessitating more interaction with peers. This conference will provide critical and timely information relating to global clinical trial disclosure and data transparency from those on the front lines.

Highlights

- Exclusive short courses to enhance your learning experience
- Exhibits to learn about the latest solutions and services

Who Should Attend

Professionals involved in:

- 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

Schedule At-A-Glance

SHORT COURSE | WEDNESDAY, SEPTEMBER 18		ROOM
7:30AM-4:30PM	Short Course Registration	Del Ray Foyer
8:30AM-12:00PM	**Short Course 1:** Clinical Trial Disclosure 101	Del Ray
1:00-4:30PM	**Short Course 2:** Practical Approaches to Using the ClinicalTrials.gov PRS	Del Ray

DAY ONE | THURSDAY, SEPTEMBER 19		ROOM
7:00AM-4:30PM	Registration	Bethesdan AB Foyer
7:00-8:15AM	Continental Breakfast, Exhibits, and Networking	Bethesdan CD
8:00-8:15AM	**Welcome and Opening Remarks**	Bethesdan AB
8:15-8:45AM	**Keynote Address:** Data of, by, and for the People: How Sharing Data with Participants will Save Clinical Research	Bethesdan AB
8:45-9:30AM	**Session 1:** Implementation of the Health Canada Requirements of Public Release of Clinical Information	Bethesdan AB
9:30-9:45AM	Refreshment, Exhibits, and Networking Break	Bethesdan CD
9:45-11:00AM	**Session 2:** Global Approaches of Data Sharing and ICMJE Data Sharing Requirements	Bethesdan AB
11:00-11:15AM	Refreshment, Exhibits, and Networking Break	Bethesdan CD
11:15AM-12:30PM	**Session 3:** Good Compliance is Good Business	Bethesdan AB
12:30-1:30PM	Luncheon, Exhibits, and Networking Break	Bethesdan CD
1:30-2:30PM	**Session 4:** Disclosure of Innovative Trial Designs: Adaptive Designs and Master Protocol	Bethesdan AB
2:30-3:00PM	Refreshments, Exhibits, and Networking Break	Bethesdan CD
3:00-3:30PM	**Session 5:** Featured Oral Abstract	Bethesdan AB
3:30-4:30PM	**Session 6:** Overview of Disclosure Requirements for Federally Funded Trials	Bethesdan AB
4:30-5:30PM	Poster Presentations and Networking Reception	Bethesdan CD

DAY TWO | FRIDAY, SEPTEMBER 20		ROOM
7:00AM-3:00PM	Registration	Bethesdan AB Foyer
7:00-8:00AM	Continental Breakfast and Networking	Bethesdan CD
7:30-7:55AM	DIA Clinical Trials Disclosure Community Open Meeting	Bethesdan AB
7:55-8:00AM	**Welcome to Day Two**	Bethesdan AB
8:00-9:15AM	**Session 7:** Status and Latest News on the EU Regulatory Requirements Related to Disclosure of Clinical Data	Bethesdan AB
9:15-10:15AM	**Session 8:** Oral Abstract Presentations	Bethesdan AB
10:15-10:30AM	Refreshments, Exhibits, and Networking Break	Bethesdan CD
10:30-11:30AM	**Session 9:** Protecting Confidential Information in Summaries of Trial Results	Bethesdan AB
11:30-11:45AM	Refreshments, Exhibits, and Networking Break	Bethesdan CD
11:45AM-1:00PM	**Session 10:** US Regulatory and Policy Updates: FDA and ClinicalTrials.gov Developments	Bethesdan AB
1:00-2:00PM	Luncheon, Exhibits, and Networking Break	Bethesdan CD
2:00-3:00PM	**Session 11:** Valuing Patient Input into Clinical Trials	Bethesdan AB
3:00-3:15PM	Closing Remarks	Bethesdan CD

Learning Objectives

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

- Discuss best practices to achieve good compliance
- Assess the operational challenges and considerations in executing Innovative Trial Designs
- Describe the changes in EudraCT and the practical implications
- Describe the current status of Clinical Data Summary Pilot Program and any findings related to the program implementation to date

Continuing Education Credit

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If you would like to receive a statement of credit, you must attend the entire primer, short course and/or all three days of the forum, sign in each day at the DIA registration desk upon arrival and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, October 2, 2019**.

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7:30AM–4:30PM **Short Course Registration**

8:30AM–12:00PM **Short Course 1:** Clinical Trial Disclosure 101

Instructor
Merete Joergensen, MBA, MSc, Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk A/S, Denmark

Jennifer Houser, MS, Senior Manager, Medical Writing, Seattle Genetics, Inc.

This short course presents 'the big picture' of clinical trial disclosure for those new to this growing profession or experienced professionals who may still be struggling to understand how all the pieces fit. We will offer an overview of study registration, posting of summary study results, sharing of participant-level data, lay summary results and public posting of study documents such as protocols, SAPs and clinical study reports. 'Old' regulations (US FDAAA and EU CTD) will be compared to updated regulations/policies (US Final Rule and EU CTR and Policy 0070), with a bit of time spent on the newly enacted Canadian regulation. We will also cover the influencers of clinical trial disclosure and the impact they have had and will continue to have on the public, WMA, WHO, ICMJE, MRCT, AllTrials, others. Let's put all these pieces together.

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

- Describe the full range of clinical trial disclosure activities and scope of colleagues who need to coordinate their activities
- Analyze prior "old" regulations and updated regulations and describe differences
- Identify different audiences who are influenced by disclosure activities and how best to communicate with them

1:00-4:30PM **Short Course 2:** Practical Approaches to Using the ClinicalTrials.gov PRS

Instructors
Kristina Elliott, MLS, ClinicalTrials.gov Web Content and Outreach Coordinator, ICF

Annice Bergeris, Research Information Specialist, ClinicalTrials.gov/National Library of Medicine

Sarice Boston, PhD, Results Team Manager, ICF

Elisa Golfinopolous, PhD, Results Team Manager, ICF

This short course covers the basics of using the ClinicalTrials.gov Protocol Registration and Results System (PRS) and is intended for newer PRS users who want to quickly get up to speed on PRS functions and best practices. Attendees will be given a guided tour of PRS features and learn key principles and approaches for submitting high-quality registration and results information. To maximize practical application, instructors will draw on examples from real study submissions.

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

- Utilize the PRS Planning Report to identify studies in their PRS account that may require attention
- Discuss best practices for describing primary and secondary outcome measures
- Identify key informational resources that are intended to support the submission process

DAY ONE | THURSDAY, SEPTEMBER 19

7:00AM-4:30PM — **Registration**

7:00-8:15AM — **Continental Breakfast, Exhibits, and Networking**

8:00-8:15AM — **Welcome and Opening Remarks**

8:15-8:45AM — **Keynote Address:** Data of, by, and for the People: How Sharing Data with Participants will Save Clinical Research

Session Chair
Robert Paarlberg, MS, Principal, Paarlberg & Associates LLC

Speaker
Donna R. Cryer, JD, Interim Executive Director, People-Centered Research Foundation

8:45-9:30AM — **Session 1:** Implementation of the Health Canada Requirements of Public Release of Clinical Information

Session Chair
Merete Joergensen, MBA, MSc, Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk A/S, Denmark

Health Canada recently implemented new regulations around the Public Release of Clinical Information. These new requirements cover both retroactive and proactive drug and device applications. Sharing information on best practices to ensure the process will run as smooth as possible both for industry and regulators. How might double work be avoided in relation to almost identical requirements in EU and Canada.

Overview of the Requirements and the Latest Feedback on the Response to the Received Comments (Remote Presentation)
Andre Molgat, DrSc, Senior Regulatory Policy and Risk Management Officer, HPFB, Health Canada

Industry Experience of Health Canada Submission
Julie Holtzople, Director, Clinical Trial Transparency Operations, AstraZeneca

9:30-9:45AM — **Refreshment, Exhibits, and Networking Break**

9:45-11:00AM — **Session 2:** Global Approaches of Data Sharing and ICMJE Data Sharing Requirements

Session Chair
Robert Paarlberg, MS, Principal, Paarlberg & Associates LLC

The ICMJE's new data sharing requirements, requiring manuscripts contain a data sharing statement became effective July 1, 2018. The ICMJE also requires clinical trials that begin enrolling participants on or after January 1, 2019 must include a data sharing plan in the trial's registration as requirement of manuscript acceptance by a journal. This session will provide an update from a journal editor regarding the journal's experience with manuscripts they have received regarding the new data sharing requirement as well as experience from industry and academia regarding these new requirements.

PhUSE Update and Industry Perspective on ICMJE's Data Sharing Requirements
Liz Roberts, MSc, Global Public Policy Lead, External Engagement Practice, UCB BioSciences, Inc.

Data Sharing Statements
Pamela Miller, Assistant to the Editor, New England Journal of Medicine

Data Sharing Statements: Considerations for Academic Medical Centers
Anthony Keyes, MBA, PMP, Project Manager, Clinical Research Projects, Johns Hopkins University

11:00-11:15AM — **Refreshment, Exhibits, and Networking Break**

11:15AM-12:30PM — **Session 3:** Good Compliance is Good Business

Session Chair
Francine Lane, MBA, Vice President, Global Transparency, TrialScope

The public continues to pay close attention to clinical trial disclosures. Large pharma is no longer the primary focus of analyses by transparency advocates but studies from organizations from all sizes and shapes are highlighted when study results are not shared in a timely manner.

In this session, we'll hear from funders and transparency advocates to understand why disclosure is important, what is 'good' compliance, and some best practices to help your organization become better with clinical trial disclosures and compliance.

Why Transparency is Important to Us (Remote Presentation)
Georgina Humphreys , MSc, PhD, Clinical Data Sharing Officer, Wellcome Trust, United Kingdom

Trends and Best Practices in Trial Disclosure
Thomas Wicks, MBA, Chief Strategy Officer, Trialscope

Presentation Title TBD (Remote Presentation)
Till Bruckner, PhD, Founder, TranspariMED & Transparify, United Kingdom

12:30-1:30PM — **Luncheon, Exhibits, and Networking Break**

1:30-2:30PM — **Session 4:** Disclosure of Innovative Trial Designs: Adaptive Designs and Master Protocol

Session Chair
Tabassum "Tab" Y. Hoda, Senior Manager, Clinical Trials Disclosure, Amgen Inc.

Awareness of such Innovative Clinical Trial designs and Master Protocols can be complex and are a challenge in operationalizing for disclosure. These are innovative methods, with no definitive guidance on how trial results should be disclosed in registries, while maintaining a balance between transparency and trial integrity. This session will discuss how the recent FDA guidance documents on Adaptive Designs for Clinical Trials and Master Protocols affect clinical trial disclosure, cover definitions of these methods, provide an overview of how these methods can benefit patients and research, and help to address the gaps while gaining insights from the expert speakers.

Innovative Clinical Trial Designs and Considerations for Disclosure
Michelle Detry, PhD, Director, Adaptive Trial Execution & Senior Statistical Scientist, Berry Consultants LLC

Registering Master Protocols
Deborah A. Zarin, MD, Program Director, MRCT Center

Patient Perspective: Patient Interest in Trials and How These Trials Make Sense to Patients
Deborah E. Collyar, President, Patient Advocates In Research (PAIR)

2:30-3:00PM — **Refreshments, Exhibits, and Networking Break**

3:00-3:30PM — **Session 5:** Featured Oral Abstract

Session Chair
Suzanne Carlson, Consultant, ABSD Associates, LLC

Keeping the End in Mind: Case Studies Demonstrating the Importance of Thinking about Transparency During Protocol Design
Sudipta Chakraborty, PhD, Senior Medical Writer, PRA Health Sciences

3:30-4:30PM

Session 6: Overview of Disclosure Requirements for Federally Funded Trials

Session Chair
Patrick Fawcett, Information Disclosure Administrator, Office for ClinicalTrials.gov, University of Pittsburgh

Obligations to publicly disclose clinical trial information are rooted in law, ethics and organizational policy. Like many other major funders of clinical trials research, the United States federal government has numerous such policies in place. This session will primarily focus on policies requiring disclosure of registration information, summary results information and/or study documents, and which apply to trials funded in whole or in part by the US government. These include: 1) NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information; 2) Revised Federal Policy for the Protection of Human Subjects ("Common Rule"); and 3) Other US Government Funding Agency Policies.

Overview of Disclosure Requirements for Federally Funded Trials
Anthony Keyes, MBA, PMP, Project Manager, Clinical Research Projects, Johns Hopkins University

Overview of Disclosure Requirements for Federally Funded Trials
Diane Wilson, MPP, MA, JD, Regulatory Affairs Manager, University of Michigan Medical School Office of Regulatory Affairs

4:30-5:30PM

Poster Presentations and Networking Reception

Redaction Impact and Efficiencies Assessed for Optimal Transparency Preparation for the EU Clinical Trial Regulation 536/2014
Michelle Hellstern, BSN, Manager, Clinical Trial Disclosure & Transparency, CSL Behring

Assessment of Anonymization Methods, Processes and Challenges for Clinical Information Submissions to Health Canada
Raina Agarwal, MPharm, Senior Manager, Kinapse Ltd.

Do You Know Your Risk?
Cathal Gallagher, Senior Life Science Consultant, d-wise, United Kingdom

Experiences Generating Synthetic Clinical Trial Data
Lucy Mosquera, Lead Statistician, Replica Analytics, Canada

Automating Data Anonymization Procedures with Software
Veera Thota, MMS Holdings

Actionable Insights for Plain Language Summary Implementation
Pooja Phogat, PhD, Vice President, Head of Development Operations, Kinapse, A Syneos Health Company, India

The Future of Transparency: How Global Regulatory Authorities May Expect Patient and HCP Engagement During the Drug Approval Process
Nirpal Virdee, MSc, Director, Client Services, Technology, Synchrogenix, United Kingdom

DAY TWO | FRIDAY, SEPTEMBER 20

7:00AM-3:00PM

Registration

7:00-8:00AM

Continental Breakfast and Networking

7:30-7:55AM

DIA Clinical Trials Disclosure Community Open Meeting

Session Chair
Francine Lane, MBA, Vice President, Global Transparency, TrialScope

7:55-8:00AM — **Welcome to Day Two**

8:00-9:15AM — **Session 7:** Status and Latest News on the EU Regulatory Requirements Related to Disclosure of Clinical Data

Session Chair
Merete Joergensen, MBA, MSc, Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk A/S, 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.

Regulatory Update: Status of the Implementation of EU Clinical Trials Regulation, Clinical Trials Information System (CTIS), and Other Important EU Clinical Transparency News (Remote Presentation)
Noemi Manent, Scientific Administrator, Compliance and Inspection, European Medicines Agency, European Union, United Kingdom

Industry Update: Clinical Disclosure Requirements in Europe
Matthias Zerm, PhD, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals GmbH, Germany

9:15-10:15AM — **Session 8:** Oral Abstract Presentations

Session Chair
Kelly Coulbourne, Associate Director, Clinical Trial Data Registries, Allergan

When Innovation Meets Regulation: Patient Centric Study Registration
Chris Pfitzer, MA, Transparency Operations Lead, UCB Biosciences

Managing Privacy Obligations in Global Clinical Trial Transparency and Data Sharing Compliance Operations
Oladayo Oyelola, PhD, Director, Clinical Trial Information Disclosure, Daiichi Sankyo, Inc.

Cultivating a Culture of Compliance with Clinical Trials Disclosure on ClinicalTrials.gov
Niem-Tzu Rebecca Chen, Med, MS, Human Subjects Protection Senior Analyst, Rutgers, The State University of New Jersey

VIVLI - Experiences in Data Sharing of Participant Level Data
Rebecca Li, PhD, Executive Director, Vivli Center for Global Clinical Research Data

10:15-10:30AM — **Refreshments, Exhibits, and Networking Break**

10:30-11:30AM — **Session 9:** Protecting Confidential Information in Summaries of Trial Results

Session Chair
Robert Paarlberg, MS, Principal, Paarlberg & Associates LLC

Global clinical data disclosure and transparency requirements and initiatives have resulted in massive amounts of clinical data in the public domain. Local county and regional data protection regulations safe guard personal identifiable information from public disclosure. This session will explore how patient identifiable data are being protected in this global clinical disclosure/transparency ecosystem.

Protecting Confidentiality: Public and Patient Perceptions and Best Communication Practice
Behtash Bahador, Associate Director, Relationship Management and Development, Center for Information & Study on Clinical Research Participation (CISCRP)

Common Challenges Under GDPR for Data Disclosure and Transparency
Michael A. DiMaio, JD, Associate, Ropes & Gray LLP

Anonymisation and Public Trust (Remote Presentation)
Brendan Barnes, Director, Multilateral Issues and Health Policy, EFPIA, Belgium

11:30-11:45AM — **Refreshments, Exhibits, and Networking Break**

11:45AM-1:00PM — **Session 10:** US Regulatory and Policy Updates: FDA and ClinicalTrials.gov Developments

Session Chair
Suzanne Carlson, MA, Consultant, ABSD Associates, LLC

In 2018, the FDA issued a draft guidance on Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank. This guidance addresses how violations of the requirements of the Final Rule would be identified, under what circumstances civil monetary penalties would be sought, what procedures would apply, and what penalty amounts would be assessed. This session will present on the current status of this initiative, and provide a regulatory and policy update from ClinicalTrials.gov.

ClinicalTrials.gov Civil Money Penalty Draft Guidance
Patrick J. McNeilly, PhD, Senior Health Policy Analyst, FDA

ClinicalTrials.gov Program Updates
Rebecca Williams, Acting Director, ClinicalTrials.gov, NCBI, National Library of Medicine, NIH

FDA Federal Register Notice New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication – PhRMA's Perspective
Olivia Shopshear, MS, Senior Director, Science and Regulatory Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA)

Secret Keeper: Do Harry Potter and the FDA Have Similar Powers?
Anne K. Walsh, Director, Hyman, Phelps & McNamara

1:00-2:00PM — **Luncheon, Exhibits, and Networking Break**

2:00-3:00PM — **Session 11:** Valuing Patient Input into Clinical Trials

Session Chair
Deborah E. Collyar, President, Patient Advocates In Research (PAIR)

Historical approaches to clinical trials created challenging issues, including exceedingly low patient participation and too many uncompleted trials. There are many reasons for this, including focus on advancing the market instead of science, ultimately relegating real patient priorities to talking points rather than representing the true goal. Patients and their organizations are changing this by taking a more direct role in clinical trial development and implementation.

How Patients are Influencing Clinical Trials
Deborah E. Collyar, President, Patient Advocates In Research (PAIR)

Why Patient-Provided Data is Critical and How it Effects Clinical Trials
Patty Spears, Research Patient Advocate, UNC, Chapel Hill

Opportunities to Use Health Literate Information for People and Providers
Catina O'Leary, PhD, LMSW, President and CEO, Health Literacy Media

Panelist
Liz Roberts, MSc, Global Public Policy Lead, External Engagement Practice, UCB BioSciences, Inc.

3:00-3:15PM — **Closing Remarks**