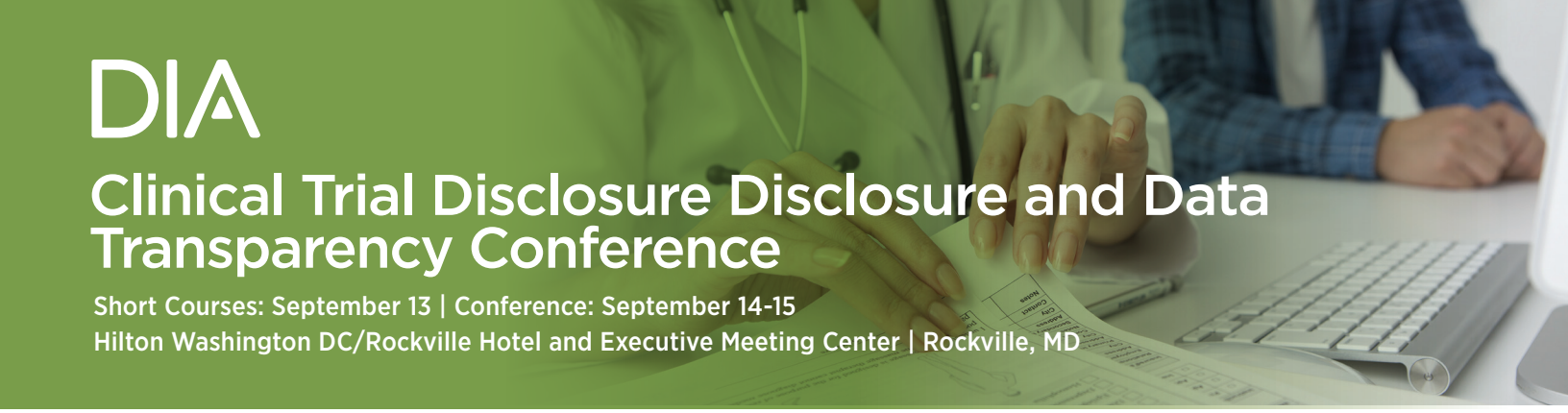

Clinical Trial Disclosure Disclosure and Data Transparency Conference

Short Courses: September 13 | Conference: September 14-15
Hilton Washington DC/Rockville Hotel and Executive Meeting Center | Rockville, MD

PROGRAM CHAIR

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

PROGRAM COMMITTEE

Marla Jo Brickman, PhD
Senior Director/Team Leader Clinical Trial Disclosure Group
Pfizer Inc

Merete Jørgensen, MSc, MBA
Director, Clinical Trials Registry
Novo Nordisk A/S, Denmark

Erik Lakes, MSc, MScRA
Associate Director, Global Clinical Study Disclosure
Takeda Development Center Americas, Inc.

Melanie North, PhD
Consultant
Melanie North Consulting

Patricia A. Teden, MBA
President and Principal
Teden Consulting LLC

Matthias Zerm, PhD
Corporate R&D, Senior Expert Clinical Trial Disclosure and R&D Processes
Merz Pharmaceuticals GmbH

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 and the EU. With evolving requirements comes a host of new challenges, creating additional opportunities for knowledge-sharing and necessitating more interaction with peers. This conference will provide critical and timely information relating to clinical trial disclosure and data transparency from those on the front lines. Engage with speakers who will provide expert insight into how study sponsors from industry, academia, and government are addressing these changes and putting them into practice.

Highlights

- Two exclusive short courses on Wednesday to enhance your learning experience
- In-depth discussions on the implementation of US Final Rule 0070, EMA Policy 0043, data sharing, and lay language summaries
- Engage with the DIA CTD Community
- Hear firsthand from colleagues from ClinicalTrials.gov and the EMA on regulatory changes
- Patient-level data sharing of best practices, challenges, and data protection

Who Should Attend

Professionals involved in:

- Compliance
- 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

Schedule At-A-Glance

SHORT COURSES | WEDNESDAY, SEPTEMBER 13	
7:30AM-4:30PM	Short Course Registration
8:30AM-12:00PM	**Short Course 1:** Disclosures 101
1:00-4:30PM	**Short Course 2:** Preparing Documents for Disclosure and Public Sharing
DAY ONE | THURSDAY, SEPTEMBER 14	
7:30AM-5:00PM	Registration
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking
8:30-8:45AM	**Welcome and Opening Remarks**
8:45-10:30AM	**Session 1:** Access to Regulatory Clinical Documents: Hear from the Regulators
10:30-11:00AM	Refreshments, Exhibits, and Networking Break
11:00AM-12:00PM	**Session 2:** Access to Regulatory Clinical Documents: Sponsors' Experiences
12:00-12:30PM	**Keynote Address: Changing Directions in NIH Stewardship Over Clinical Trials**
12:30-1:30PM	Luncheon, Exhibits, and Networking
1:30-2:30PM	**Session 3:** FDAAA Final Rule: Latest Updates from ClinicalTrials.gov
2:30-3:00PM	Refreshments, Exhibits, and Networking Break
3:00-4:30PM	**Session 4:** FDAAA Final Rule: Results
4:30-5:00PM	**Featured Oral Abstract:** Using Systems Integration and a Central Approach to Achieve Compliance with ClinicalTrials.gov
5:00-6:00PM	Poster Session and Networking Reception
DAY TWO | FRIDAY, SEPTEMBER 15	
7:00AM-2:30PM	Registration
7:00-8:00AM	Continental Breakfast, Exhibits, and Networking
7:30-8:00AM	**DIA Clinical Trials Disclosure Community Open Meeting**
8:00-9:00AM	**Session 5:** EU Portal: The Gateway to the Implementation of Clinical Trial Regulations
9:00-10:30AM	**Session 6:** Data Transparency: How Do We Measure Up?
10:30-11:00AM	Refreshments, Exhibits, and Networking Break
11:00AM-12:00PM	**Session 7:** Sharing Patient Level Data: Where Are We Headed?
12:00-1:00PM	Luncheon, Exhibits, and Networking
1:00-2:30PM	**Session 8:** Oral Abstract Presentations
2:30-2:45PM	**Closing Remarks**

Learning objectives

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

- Explain present and upcoming requirements for clinical trial disclosure and data transparency requirements globally
- Identify IT systems and tools that can facilitate clinical trial data disclosure compliance
- Describe best practices for operationalizing new provisions to be compliant with the new regulations for clinical trial disclosure and data transparency

Continuing Education Credit

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET). As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer 1.8 CEUs for the program. Participants must attend the entire conference in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

- Short Course 1: .3 CEUS
- Short Course 2: .3 CEUs
- Conference: 1.2 CEUs

If you would like to receive a statement of credit, you must attend the conference (Short Courses if applicable), sign in at the DIA registration desk each day, 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 on Friday, September 22, 2017.

This event is approved by the Regulatory Affairs Professionals Society for 12 RAC credits.

View DIA's Grievance Policy at DIAglobal.org/Grievance

ACCESS MY TRANSCRIPT

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the course

ACCESS PRESENTATIONS

- Visit DIAglobal.org
- Select 'Sign in' at the top right
- Enter your User ID and Password
- View 'My Presentation'

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder.

Presentations will be available for six months post conference.

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

SHORT COURSES | WEDNESDAY, SEPTEMBER 13

7:30AM-4:30PM — **Short Course Registration**

8:30AM-12:00PM

Short Course 1
Disclosures 101

Instructors

Merete Joergensen, MBA, MSc
Director, Global Clinical Registry
Novo Nordisk A/S, Denmark

Patricia A. Teden, MBA
President and Principal
Teden Consulting LLC

Are you new to clinical trial disclosure operations? Perhaps you are a bit confused as to the different processes, websites, outside influences? We have a course for you! As clinical trial disclosure requirements expand, new colleagues are flooding into this discipline and there is much to absorb. Let us help!

This course will cover:

- The evolution of disclosure
- Outside Influencers
- Internal Stakeholders
- EU vs US comparisons
- Highlights of the Final Rule in the US
- What is happening in the rest of the world?
- What might the future look like?

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

- Explain the evolution of data disclosure
- Compare EU and US disclosure requirements
- Summarize highlights of the Final Rule in the US

1:00-4:30PM

Short Course 2
Preparing Documents for Disclosure and Public Sharing

Instructor

Eileen M. Girten, MS
Principal Medical Writer
inVentiv Health Clinical

Recent clinical trial transparency regulations have been developed to provide greater access to clinical trial information. As a result, the pharmaceutical industry is changing its approach to responsibly, sharing the results of clinical trials and addressing what information needs to be released, when, and how in order to comply with these recent regulations. This short course will focus on the European Medicine Agency's (EMA) Publication Policy 0070 and the US Department of Health and Human Services (HHS) Final Rule for Section 801 of the US Food and Drug Administration Amendments Act (FDAAA) of 2007. We will discuss how these recent US and EU regulations related to data disclosure are being implemented and will also focus on the application of preparing such documents for disclosure. This short course is appropriate for medical writers who will be preparing documents for disclosure.

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

- Define what is in scope, the timing, and requirements of the EMA Policy 0070 and HHS Final Rule
- Discuss how regulatory documents can be prepared for disclosure
- Apply best practices in developing layperson summaries
- Discuss the impact of clinical trial disclosure regulations and initiatives on publication deliverables

DAY ONE | THURSDAY, SEPTEMBER 14

7:30AM-5:00PM

Registration

7:30-8:30AM

Continental Breakfast, Exhibits, and Networking

8:30-8:45AM

Welcome and Opening Remarks

Sudip Parikh, PhD
Senior Vice President and Managing Director,
DIA Americas
DIA

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

8:45-10:30AM

Session 1
Access to Regulatory Clinical Documents: Hear from the Regulators

Session Chair
Merete Jørgensen, MSc, MBA
Director, Clinical Trials Registry
Novo Nordisk A/S, Denmark

This first session on Access to Regulatory Documents will focus on the regulators' perspectives while highlighting similarities and differences among the different approaches in EU, US, and Canada. A proactive approach to access to regulatory clinical documents submitted under the centralized procedure has been implemented by EMA's launch of a specific website. EMA has issued further guidance on the implementation of its Policy 0070 - EMA/240810/2013, and EMA/90915/2016. In March 2017 Health Canada published its intent of a similar approach in the *Public release of Clinical Information in Drug Submissions and Medical Device Applications.*

Virtual Presentation

Anne-Sophie Henry-Eude
Head of Documents Access and Publication Service,
Office of the Deputy Executive Director
European Medicines Agency, United Kingdom

André Molgat, DrSc
Scientific Reviewer, Health Products and Food Branch
Health Canada

Nancy Sager
Director, Division of Information Disclosure Policy, Office of Regulatory Policy
CDER, FDA

Panel Discussion

10:30-11:00AM

Refreshments, Exhibits, and Networking Break

11:00AM-12:00PM

Session 2
Access to Regulatory Clinical Documents: Sponsors' Experiences

Session Chair
Patricia A. Teden, MBA
President and Principal
Teden Consulting LLC

The second session on Access to Regulatory Clinical Documents will focus on the Sponsors' experience. Both the EU and US require regulatory documents be made available on public portals, and Canada announced their intention to do the same. These requirements raise issues regarding protecting personal confidentiality and corporate confidential information. Initial standards have been documented by a few groups, and 'tested' by actual experience posting documents on the EMA's website. This session will focus on the experience of sponsors who have prepared and posted regulatory clinical documents, including technical issues (such as redaction), corporate process issues, and communication with regulators.

Julie Holtzople
Clinical Trial Transparency Operations Director
AstraZeneca

Milena Vakrilova
Regulatory Intelligence Manager
Novartis Pharmaceuticals Corporation, Switzerland

Panel Discussion

12:00-12:30PM

Keynote Address
Changing Directions in NIH Stewardship Over Clinical Trials

Keynote Speaker
Michael S Lauer, MD, FACC
Deputy Director for Extramural Research
National Institutes of Health

Dr. Lauer will review NIH's suite of clinical trials reforms, including requirements for registration and reporting. He will also touch on data sharing and inclusion.

12:30-1:30PM

Luncheon, Exhibits, and Networking

DAY ONE | THURSDAY, SEPTEMBER 14

1:30-2:30PM

Session 3
FDAAA Final Rule: Latest Updates from ClinicalTrials.gov

Session Chair
Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

The Final Rule expanding the registry and results data bank specified in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 was published in the Federal Register on September 21, 2016. The Final Rule had an effective date of January 18, 2017 and a compliance date of April 18, 2017. This session will provide the latest update from NLM on the Final Rule including how the new requirements for results reporting.

Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, NCBI
National Library of Medicine, NIH

2:30-3:00PM

Refreshments, Exhibits, and Networking Break

3:00-4:30PM

Session 4
Preparing for Results Submission Under Final Rule and Other Global Requirements - Panel Discussion

Session Chair
Erik Lakes, MS, MSc
Associate Director, Global Clinical Study Disclosure
Takeda Pharmaceuticals, Inc.

Are you prepared for submitting results under the new Final Rule requirements? How do the final regulations impact your company's disclosure timelines? Are your protocols and SAPs ready for public disclosure? What actions do you need to take now to ensure compliance in 2018? This panel discussion will include perspectives from both industry and legal, and will include impact on other global requirements.

Panelists
René Allard, PhD
Public Disclosure Lead
Grünenthal GmbH, Germany

Ramona Rorig
Associate Director Clinical Trial Disclosure
Astellas Pharma Global Development

David J. Peloquin
Associate
Ropes & Gray LLP

4:30-5:00PM

Featured Oral Abstract
Using Systems Integration and a Central Approach to Achieve Compliance with ClinicalTrials.gov

Issis J Kelly Pumarol, MD
Research Subject Advocate
Wake Forest Baptist Health

Changes, including new results reporting rules and NIH policy on clinical trials registration, present compliance challenges for investigators and institutions. We performed a compliance review revealing the need for institutional awareness of these requirements, how to navigate the ClinicalTrials.gov system, and hands-on support for study teams in managing the records. This central approach of monitoring, education, and support could be replicated at any institution. By providing investigators with resources to comply with regulations and ethical obligations, we hope to facilitate research.

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

- Apply the use of systems currently in place to obtain and maintain compliance with ClinicalTrials.gov requirements
- Evaluate the current status of your organization/department compliance with ClinicalTrials.gov regulations
- Predict what level of risk your organization will have in relation with the number of trials in the database and FTE's maintaining an institutional account

5:00-6:00PM

Poster Session and Networking Reception

DAY TWO | FRIDAY, SEPTEMBER 15

7:00AM-2:30PM — **Registration**

7:30-8:00AM — **Continental Breakfast, Exhibits, and Networking**

7:30-8:00AM — **DIA Clinical Trials Disclosure Community Open Meeting**

Attend to learn more or meet fellow members, hear about what's happening in the Community, and learn how to join in the latest discussions on the latest hot topics!

8:00-9:00AM

Session 5

EU Portal: The Gateway to the Implementation of Clinical Trial Regulations

Session Chair

Matthias Zerm, PhD
Corporate R&D, Senior Expert Clinical Trial Disclosure and R&D Processes
Merz Pharmaceuticals GmbH, Germany

Interested in the EU Portal and Database? What is it about and how will it work? What is the current status? What is the implementation strategy and related timelines? Address these questions and gain insight into the clinical trial disclosure provisions in the EU Clinical Trial Regulation EU (No) 536/2014 and how they are implemented in the EU Portal.

Virtual Presentation

Ana Rodriguez Sanchez Beato, PhD
Head of Clinical and Non-Clinical Compliance
European Medicines Agency, European Union, United Kingdom

Matthias Zerm, PhD
Corporate R&D, Senior Expert Clinical Trial Disclosure and R&D Processes
Merz Pharmaceuticals GmbH, Germany

Panel Discussion

9:00-10:30AM

Session 6

Data Transparency: How do We Measure Up?

Session Chair

Melanie North, PhD
Consultant
Melanie North Consulting

In this session we will hear from prominent commentators on the status of clinical trial data disclosure in 2017. We will start with a discussion about the reporting of outcome measures and hear the latest on the All Trials TrialsTracker and the Good Pharma Scorecard. As a late-breaking addition we will hear industry's response and analysis of compliance with clinical trial registration and reporting requirements.

April Clyburne-Sherin
AllTrials USA Campaign Manager
Sense About Science USA

Henry Drysdale, BSc, BM BCh (Oxon)
Researcher, Centre for Evidence-Based Medicine
University of Oxford, United Kingdom

Jennifer Miller, PhD
Assistant Professor
NYU School of Medicine

Olivia M. Shopshear, MS
Director, Science and Regulatory Advocacy
Pharmaceutical Research and Manufacturers of America (PhRMA)

Panel Discussion

10:30-11:00AM — **Refreshments, Exhibits, and Networking Break**

11:00AM-12:00PM

Session 7

Sharing Patient Level Data: Where Are We Headed?

Session Chair

Marla Jo Brickman, PhD
Senior Director - Clinical Data Transparency/Compassionate Access Lead
Pfizer Inc

The sharing of patient-level data has now become the new norm. Provisions for sponsors of clinical research (industry, academia, government) are being added to regulations and guidelines requiring these sponsors to make the de-identified/anonymized data supporting this clinical research available to other researchers. Discuss in-depth the practical implications of current data sharing models, as well as explore future models and what this means for the research community, government, industry, and academia.

Sean Khozin, MPH, MD
Associate Director (Acting), Oncology Center of Excellence
FDA

Rebecca Li, PhD
Executive Director, Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital; Instructor in Medicine, Harvard Medical School; Division of Global Health Equity, Department of Medicine
Brigham and Women's Hospital

Panel Discussion

12:00-1:00PM — **Luncheon, Exhibits, and Networking**

DAY TWO | FRIDAY, SEPTEMBER 15

1:00-2:30PM

Session 8
Oral Abstract Presentations

Session Chair
Erik Lakes, MSc, MSc
Associate Director, Global Clinical Study Disclosure
Takeda Development Center Americas, Inc.

Clinical trial sponsors and academia are facing a multitude of new registration requirements in the US and the EU. With evolving requirements come new challenges, creating additional opportunities for knowledge-sharing and necessitating more interaction with peers. Seize this opportunity to engage with and gain insights from your fellow attendees by attending this abstract session showcasing research, best practices, and practical applications related to the implementation of the new clinical trial regulations in the US and EU, anonymizing data, and data-sharing.

Clues into Diverse Patient and Public Needs for Clinical Trial Summaries
Deborah Collyar
President
Patient Advocates In Research (PAIR)

Leveraging Lay Summaries as a Meaningful Approach to Patient Engagement and Not Just a Regulatory Requirement
Jill McNair, MBA
Senior Director, Patient Engagement
CISCRP

Using TransCelerate's Common Protocol Template to Enable Disclosure to Trial Registries
Mitzi Allred
Director, R&D Technical Information, Management Clinical Sciences
Sanofi

Anonymizing Individual Patient Data - Data Utility Focus
Denise Qyqja
Project Manager, Clinical Trial Transparency
Shire Pharmaceutical

The Global Transparency Challenge
Representative Invited
Trialscope

Getting Ahead of the EU CTR Lay Summary Requirement: Strategies for Success
Margaret Zorn, MBA, MS
Senior Manager, Regulatory Affairs and Submissions
MMS Holdings, Inc.

2:30-2:45PM

Closing Remarks

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

2:45PM

Conference Adjourned