Clinical Trial Disclosure & Data Transparency – The Expanding Global Environment

Tutorial: September 16 | Conference: September 17-18

Hyatt Regency Bethesda | Bethesda, MD

As of August 27 , 2015

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 Jorgensen, MSc, MBA
Director
Clinical Trials Registry
Novo Nordisk A/S

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

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

Sarah A White, MPH
Director
Partners Human Research Quality Improvement Program
Partners Healthcare

OVERVIEW:

Transparency of clinical trial information is taking on new dimensions, including the release of anonymized participant-level data and return of results to study participants. Clinical trial sponsors and academia are facing a host of new registration requirements in the US and EU. Organizations, such as the Institute of Medicine, World Health Organization (WHO), National Institutes of Health (NIH) are calling on both industry and academia to share their clinical trial data. Industry's initiatives on data sharing are also expanding. This increased transparency and use of information from clinical trials brings with it new data use opportunities and operational challenges for industry and academia.

The continuing expansion of disclosure requirements in the US and EU leave many sponsors and academia considering disclosure strategy, developing operational measures, and looking for efficient ways to manage dissemination of clinical trial protocol information and results data. The users of clinical trial information is varied which provides both opportunities and challenges for how the information is provided.

FEATURED TOPICS:

- US Requirements and EU Regulations
- Tools and Registries
- Academic Perspective
- Harmonization
- Responsible Data Sharing
- CTD Hacks

LEARNING OBJECTIVES:

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

- Identify the current clinical trial disclosure requirements in the US and EU
- Describe the impact of greater transparency, ie, clinical trial data sharing, in the clinical trial disclosure environment on industry and academia
- Discuss the practical implications of data sharing and how it affects government, industry and academia
- Recognize the challenges of providing consistent information and identify the tools available to facilitate consistent disclosure

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WEDNESDAY, SEPTEMBER 16

12:00–1:00PM REGISTRATION

**Please note: Lunch is not provided by DIA.

1:00–4:30PM TUTORIAL: RESULTS DISCLOSURE 101: OPERATIONAL BASICS

INSTRUCTOR:

Suzanne Heyd, MA, MFA
Clinical Trial Disclosure Specialist/Medical Writer
ABSD Associates, LLC

This half-day tutorial will introduce the operational basics of results disclosure on ClinicalTrials.gov and EudraCT, with the goal of providing participants with practical content, resource material, and time-saving tips to assist them as they begin a results disclosure project within their organization. Topics include posting requirements, data sources and formats, internal roles and responsibilities, an overview of some nuances of the ClinicalTrials.gov and EudraCT systems (no hands-on training), and strategies for posting, planning, and tracking the work. Along with content presentation, there will be opportunity for facilitated peer interaction and extended Q&A.

LEARNING OBJECTIVES:

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

- Define what's in scope, timing, and requirements for posting results on EudraCT and ClinicalTrials.gov
- Identify data sources for the modules in each system, including study documents, ad-hoc tables, xml files
- Describe definitions, ambiguities, differences and similarities of some of the fields of the EudraCT and ClinicalTrials.gov systems
- Determine internal stakeholders and appropriate levels of responsibility, review, and approval
- Discuss how to develop proactive strategies for posting, planning and tracking the disclosure process

TARGET AUDIENCE:

Newcomers to the results disclosure space who are tasked with managing, creating, processing and/or submitting results records to EudraCT and/or ClinicalTrials.gov.

*Tutorial requires registration and are an additional fee.

THURSDAY, SEPTEMBER 17

7:30-8:30AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:45AM WELCOME AND OPENING REMARKS

PROGRAM CHAIR

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

8:45-10:30AM SESSION 1: UPDATE ON NEW CLINICAL DISCLOSURE REQUIREMENTS IN THE EU AND US

SESSION CHAIR

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

New legislation is coming into force in both US and EU. This session will give the latest updates on the status of the new requirements and their way to implementation seen from EMA and NIH perspective.

Future Requirements for ClinicalTrials.gov per the Proposed Rule Making

Deborah A. Zarin, MD
Director
ClinicalTrials.gov
National Library of Medicine
National Institutes of Health (NIH)

Overview of the Clinical Trials Regulation

Noemi Manent
Scientific Administrator
Compliance and Inspection
European Medicines Agency

10:30-11:00AM REFRESHMENT BREAK

11:00AM–12:30PM SESSION 2: CLINICALTRIALS.GOV AND EUDRACT – AN UPDATE BY NIH AND EMA

SESSION CHAIR

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

This session featuring representatives from NIH and EMA will provide an update on the requirements and status of ClinicalTrials.gov and EudraCT highlighting overlaps and differences. The session will also have a panel for questions & answers.

Updates to the ClinicalTrials.gov Protocol Registration and Results System (PRS)

Nicholas C. Ide, MS
Chief Architect
ClinicalTrials.gov
National Library of Medicine
National Institutes of Health (NIH)

Rebecca Williams, PharmD., MPH
Assistant Director
ClinicalTrials.gov
National Library of Medicine
National Institutes of Health (NIH)

Updates to the EudraCT Database

Noemi Manent
Scientific Administrator
Compliance and Inspection
European Medicines Agency

12:30-1:45PM LUNCHEON AND NETWORKING

1:45-2:30PM SESSION 3: CTD HACKS

SESSION CHAIR

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

This session will include a collection of quick anecdotes that organizations feel have a lot of payback as far as efficiency (include small/mid-size companies, academia, and big pharma). The session will be high-energy and interactive with audience participation.

2:30-3:00PM REFRESHMENT BREAK AND NETWORKING

3:00-4:30PM SESSION 4: A NON-INDUSTRY PERSPECTIVE

SESSION CHAIR

Sarah A White, MPH
Director
Partners Human Research Quality Improvement Program
Partners Healthcare

This session will focus on the challenges of managing registration and results reporting requirements at an academic institution. Information regarding common models of infrastructure and oversight will be presented.

Managing Disclosure in an Academic Environment – Challenges, Infrastructure, Operations

Sarah A White, MPH
Director
Partners Human Research Quality Improvement Program
Partners Healthcare

Common Challenges to Submitting ClinicalTrials.gov Basic Results: A Non-Industry Perspective

Heather Dobbins, PhD
ClinicalTrials.gov Lead Results Analyst
NCBI
National Library of Medicine
National Institutes of Health (NIH)

4:30-5:00PM SESSION 5: ALL GROWN UP? THE MATURING OF CLINICAL TRANSPARENCY

SESSION CHAIR:

Sarah A White, MPH
Director
Partners Human Research Quality Improvement Program
Partners Healthcare

An assessment of current approaches to trial transparency, looking at issues such as policies and data governance, SOPs, and task management, as well as automation and organizational approaches.

All Grown Up? The Maturing of Clinical Transparency

Thomas Wicks, MBA
Chief Strategy Officer
TrialScope

5:00-6:00PM NETWORKING RECEPTION AND NETWORKING

FRIDAY, SEPTEMBER 18

7:00-8:00AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:05AM WELCOME TO DAY 2

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

8:05-9:30AM SESSION 6: IS THERE ANY HOPE FOR HARMONIZATION?

SESSION CHAIR:

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

With so many different regulations, formats, locations and target audiences for public information about clinical trials, is there any hope for harmonization? Join this expert panel discussion of potentials and opportunities to make all our efforts at disclosing clinical trial information as productive, efficient and useful as possible. Help us identify what we can do to encourage harmonization in a fractured environment.

MODERATOR:

Rebecca Li, PhD
Executive Director
Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital

PANELISTS:

Deborah A. Zarin, MD
Director
ClinicalTrials.gov
National Library of Medicine
National Institutes of Health (NIH)

Nina M. Hill, Ph.D
Vice President
Science Policy & Advocacy
Global Policy and International Public Affairs
Pfizer Inc

9:30-10:00AM REFRESHMENT BREAK AND NETWORKING

10:00-11:30AM SESSION 7: RESPONSIBLE DATA SHARING

SESSION CHAIR:

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

Data sharing is here to stay. This session will go beyond the "how to share data" and will discuss some of the more practical implications of data sharing and what this means for the research community, government, industry and academia.

Data Sharing: It's In Our DNA

Ira Shoulson, MD
Professor Neurology, Pharmacology & Human Science
Director, Program for Regulatory Science & Medicine (PRSM)
Georgetown University

Human Genomic Data, Privacy and Oversight

Debra JH Mathews, PhD, MA
Assistant Director for Science Programs
BERMAN INSTITUTE OF BIOETHICS
Associate Professor, Pediatrics

Clinical Data Sharing – Maximizing Benefits, Minimizing Risk

Timothy Coetzee, PhD
Chief Advocacy
Services and Research Officer
National Multiple Sclerosis Society

11:30-12:30PM LUNCHEON AND NETWORKING

12:30-2:00PM SESSION 8: KEEPING IT CONSISTENT!

SESSION CHAIR:

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

How do sponsors ensure the same story is repeated across different databases and other avenues? What are the challenges when collaborating with partners in making sure consistent information is disclosed publicly? What tools and initiatives are available to facilitate consistent disclosure?

Consistency Across the Expanding Disclosure Environment—Operational Considerations

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

Consistency Across the Expanding Disclosure Environment—Consistency Across Registries

Pooja Phogat, PhD
Vice President
Global Head of Clinical Trial Disclosure
Kinapse Ltd.

Consistency Across the Expanding Disclosure Environment—Registries and Beyond

Benjamin Rotz, RPh
Director
Office of Medical Transparency
Eli Lilly and Company

2:00-3:15PM SESSION 9: KEYNOTE ADDRESS AND CLOSING

SESSION CHAIR:

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

Keynote Address

Robert M. Califf, MD, MACC
Deputy Commissioner
Office of Medical Products and Tobacco
FDA

3:15PM CONFERENCE ADJOURNED