Clinical Trial Disclosure:

Towards a More Transparent World

Tutorials: September 30 | Conference: October 1-2
Bethesda, MD

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Clinical Trial Disclosure Group
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Transparency of clinical trial information is taking on new dimensions including the release of participant-level data. Discussion is now focused on the different mechanisms for transparency, their scope, objectives, and audiences. This increased transparency changes availability and use of information from clinical trials, and brings with it new data use opportunities and operational challenges for industry and academia.

The continuing proliferation of national and industry sponsored registries leave many sponsors considering disclosure strategy, developing operational measures, and looking for efficient ways to manage dissemination of clinical trial protocol information and results data. The audience for registers containing clinical trial information is expanding from patients to readers of the medical literature to clinical investigators and researchers.

LEARNING OBJECTIVES

At the conclusion of this meeting, participants will:

- Identify the current clinical trial disclosure requirements in the US and EU
- Discuss the interrelationships between medical writing, regulatory affairs, and clinical trials disclosure teams to maintain consistency for protocol registration and results reporting
- Describe the impact of greater transparency in the clinical trial disclosure environment on industry and academia
- Discuss the advantages and implications of availability of clinical trial disclosure databases

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Continuing Education Credit Allocation
Tutorial 1: A Sane Approach to Entering Results in ClinicalTrials.gov: IACET .7 CEUs
Tutorial 2: Is Your Protocol Ready to be Published on a Public Registry: IACET .4 CEUs
Clinical Trial Disclosure: Towards a More Transparent World: IACET 1.2 CEUs

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TUTORIALS | MONDAY, SEPTEMBER 30

8:00 AM – 1:30 PM TUTORIAL REGISTRATION

9:00 AM – 5:00 PM FULL-DAY TUTORIAL

A Sane Approach to Entering Results in ClinicalTrials.gov

Co-Instructors:

Melanie North, PhD
Clinical Trial Data Disclosure Consultant
Melanie North Consulting

Barbara Godlew, RN
President
The FAIRE Company, LLC

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

New to results data entry or need additional assistance in navigating the ClinicalTrials.gov results data entry system? This one-day tutorial will provide an overview of FDAAA and ClinicalTrials.gov requirements and teach you the ins and outs of results data entry, from navigating the system to practical advice on entering data. Experienced instructors will guide you through each section of results entry, providing examples and showing common mistakes to avoid. Participants will have the opportunity for hands-on data entry with guidance from the tutorial instructors.

All participants will receive a copy of the tutorial presentation and a quality control checklist to take home.

Tutorial objectives:

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

- Describe the requirements per FDAAA and ClinicalTrials.gov and how to navigate the ClinicalTrials.gov results data entry system. Identify how to streamline results entry to minimize repeat entry, reduce review comments, and maximize efficiency
- Analyze common mistakes to avoid by trouble-shooting system errors and warning messages
- Recognize how to minimize ClinicalTrials.gov review comments and get results accepted the first time
- Discuss approaches that are used for different study designs

Target Audience:

Clinical research professionals from academic research organizations and industry who may be new to and responsible for clinical trial results data entry into ClinicalTrials.gov.

Laptop required. Limited to 20 participants.

1:00 – 5:00 PM HALF-DAY TUTORIAL

Is Your Protocol Ready to Be Published on a Public Registry?

Instructor:

Pat Teden, MBA
President and Principal
Teden Consulting LLC

Co-Instructor

Laura Hagan
Head Clinical Disclosure Office
Clinical Policy and Scientific Office
Chief Medical Office
Novartis Pharmaceuticals Corporation

Despite many years of publicly registering trials based on protocol information, many companies have not modified how they write protocols to make study registration as efficient, accurate and traceable as possible. Now there is considerable pressure to require public access to protocols, new guidance on writing protocols SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials), and new requirements from the EU Pharmacovigilance regulations for observational PASS protocols. Are you ready?

Tutorial objectives:

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

- Discuss clinical trial disclosure trends that point to the need to prepare protocols for public registration
- List tips in protocol writing that facilitate efficient and traceable study registration
- Summarize the proposal from SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) and the requirements from the new EU PV regulations for observational PASS protocols.

Target Audience:

Medical Writers; Heads of clinical trial disclosure groups; Clinical Research; Clinical Operations; Regulatory

CONFERENCE DAY 1 | **TUESDAY, OCTOBER 1**

8:00 – 8:45 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:45 – 9:00 AM WELCOME AND OPENING REMARKS

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

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

9:00 – 10:30 PM SESSION 1

Clinical Trial Registries and Results Disclosure in the EU and US – An Update

Session Chair:

Hanns-Georg Leimer, PhD
Head of Processes and Systems Coordination in Corporate Division Quality, Regulatory, Pharmacovigilance, Epidemiology
Boehringer Ingehleim (Germany)

In 2014, sponsors, who conduct trials globally, will have to comply with new requirements for disclosing clinical trial results in Europe in addition to the widely-known requirements of ClinicalTrials.gov. At the same time, there is more and more discussion about the target and actual audience of the different registries, and how they relate to each other. This session will provide an update on the requirements and status of ClinicalTrials.gov and the EU Clinical Trials Register, highlighting overlaps and differences

EudraCT V9 - Publication of result-related information in Europe

Ana Rodriguez , PhD
Head of Clinical and Non-Clinical Compliance
European Medicines Agency, European Union

ClinicalTrials.gov: A General Update

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

EudraCT V9 – What to Expect. An Industry Perspective

Merete Joergensen, MSc, MBA
Director, Global Clinical Registry
Novo Nordisk

10:30 – 11:00 AM MORNING BREAK

11:00 AM – 12:00 PM SESSION 2

Opportunities and Challenges Faced by Academia and Industry in Meeting Disclosure Obligations: An Overview of Policy, Process, and Technology

Session Co-Chairs:

Karen Hartman, RN, MSN
Research Compliance Officer
Mayo Clinic

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

With the ever expanding requirements for study registration and results postings across multiple registries, the need for clearly defined institutional policies and efficient processes to ensure timely compliance with regulations, as well as, consistency of content is of critical importance to study sponsors. While the requirements are the same, academia and industry face unique challenges in meeting these disclosure obligations. This session will provide an overview of how academia and industry approach policy development, process implementation and their use of technology.

Sarah White, MPH
Director, Human Research Quality Improvement Program
Partners HealthCare

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

Thomas Wicks, MBA
Pharma CM Leader
Deloitte Analytics LLC

Chris Dedels
Director, Product Management
Virtify, Inc.

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12:30 – 1:30 PM LUNCHEON

1:30 – 2:45 PM SESSION 3

Meeting Regional Disclosure Requirements While Aiming for a Global Standard

Session Chair:

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

While disclosure of clinical trials information must meet national/regional legislation requirements, the information is accessed and used in a global world. Standardised information is supporting transparency by providing consistent information. How might a global standard be developed, and maintained? What are the challenges seen from the registry owners and the industry and academia who are providing the information?

Panelists:

Barbara Godlew, RN
President
The FAIRE Company, LLC

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

Hanns-Georg Leimer, PhD
Head of Processes and Systems Coordination in Corporate Division Quality, Regulatory, Pharmacovigilance, Epidemiology
Boehringer Ingehleim (Germany)

2:45 – 3:00 PM AFTERNOON BREAK

3:00 – 4:15 PM SESSION 4

Impact of Increasing Regulatory Transparency on Publications

Session Chair:

Laura Hagan
Head Clinical Disclosure Office
Clinical Policy and Scientific Office
Chief Medical Office
Novartis Pharmaceuticals Corporation

This session will consist of a panel of journal editors, academic clinical researchers, and industry publication coordinators discussing the impact of increasing regulatory disclosure requirements.

Panelists:

Christine Laine, MD, MPH
Editor of Annals of Internal Medicine
Senior Vice President of American College of Physicians

Joseph Solomon Ross, MD
Assistant Professor of Medicine (General Medicine)
Yale School of Medicine

Michael Krumenacker, MD
Publication Compliance Officer
Sanofi

4:15 – 4:30 PM BREAK

4:30 – 6:00 PM SESSION 5

Disclosing Participant-level Data: Goals and Challenges

Session Chair:

Patricia Teden, MBA
President and Principal
Teden Consulting LLC

The EMA has stated their intent to make participant-level datasets for clinical trials studying products approved in the EU available to the public by January 2014. Draft policies and processes should be available by conference time. The U.S. Office of Science and Technology Policy recently asked federal agencies that fund more than $100 million in research annually to craft proposals for disclosing results (publications, datasets) of federally-funded research to the public. This session will explore the goals and challenges of sharing granular data with the public, e.g. participant-level data from clinical trials.

Multi-Regional Clinical Trials (MRCT) Center Data Sharing Working Group

Rebecca H. Li, PhD
Executive Director
Multi-Regional Clinical Trials (MRCT) Center

"Yale Open Data Access" (YODA)

Joseph Solomon Ross, MD
Assistant Professor of Medicine (General Medicine)
Yale School of Medicine

Peter Doshi, PhD
Postdoctoral Fellow in Comparative Effectiveness Research
Divisions of General Pediatrics and General Internal Medicine
Johns Hopkins University School of Medicine

6:00 PM NETWORKING RECEPTION

CONFERENCE DAY 2 | **WEDNESDAY, OCTOBER 2**

8:00 – 8:45 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:45 – 9:00 AM OVERVIEW OF DAY 1

9:00 – 10:30 AM SESSION 6

The Right to Know: Patients and Clinical Trial Results

Session Chair:

Barbara Godlew, RN
President
The FAIRE Company, LLC

Industry and academia spend valuable time and resources on interpreting regulations and determining how to publicly convey clinical trial data in a patient-friendly, but nonpromotional manner. However, in many cases, clinical development programs and academic research organizations overlook the benefit of engaging patient advocacy organizations to provide insight and constructive criticism in developing understandable summaries containing clinical trial results. This session will focus on the patients' perspective and experience in receiving trial results, concerns over publicly releasing patient-level data, and thoughts on making clinical trial results understandable to patients and their families.

Patient Experience in Receiving Trial Results from Sponsors

Jessica B. Gilbart, MS, CHES
Director of Patient Services
Lupus Foundation of America

Making Clinical Trial Results Understandable for Patients and Their Families

Cheryl Jernigan
Advocates in Science Steering Committee
Susan G. Komen for the Cure

Food for Thought: Rare Disorders and Patient-Level Data Disclosure

Barbara Godlew, RN
President
The FAIRE Company, LLC

10:30 – 11:00 AM MORNING BREAK

11:00 – 12:30 PM SESSION 7

Non-interventional Studies: The Next Wave of Disclosure Requirements

Session Chair:

Erik Lakes, MSc, MScRA
Clinical Trial Disclosure Strategy Manager
Strategic Partnerships & Initiatives
Takeda Global Research & Development Center, Inc.

This session will discuss non-interventional studies (NIS), current international disclosure requirements and the EU pharmacovigilance directive. Learn the various types of NIS research and what goes into making a NIS study. Also hear from a member of the DIA NIS Working Group and their ongoing analysis of non-interventional study requirements and posting on ClinicalTrials.gov. Special focus on audits and other issues impacting academia will round out the discussion.

Non-interventional Study Design & Types

Ahmed R. Selah, PhD, MS, CCRP
Director, Clinical Trials
Laboratory of Viral Diagnostics
University of Maryland

Overview of International NIS Disclosure Laws & PASS Studies

Erik Lakes, MSc, MScRA
Clinical Trial Disclosure Strategy Manager
Strategic Partnerships & Initiatives
Takeda Global Research & Development Center, Inc.

DIA NIS Working Group & ClinicalTrials.gov Database

Shannon Tyson
Manager,
Clinical Trial Disclosure Group
Pfizer, Inc.

12:30 – 1:30 PM LUNCHEON

1:30 – 2:45 PM SESSION 8

Clinical Trial Disclosure – FDA Enforcement Activities

Session Chair:

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

In the September 26, 2012 *Federal Register* notice, the US Department of Health and Human Services delegated to FDA authority pertaining to "expansion of the Clinical Trial Registry and Results Data Bank". The notice gives FDA the authority to pursue "...any clinical trial information (that) was not submitted as required under (federal law) or was submitted but is false or misleading in any particular, and to notify the responsible party and give such party an opportunity to remedy non-compliance by submitting required revised clinical trial information not later than 30 days after such notification." This session will focus on FDA's perspective on compliance inspection audits and enforcement activities of clinical trial disclosure requirements.

Panelists:

Jarilyn Dupont, Esquire
Director of Regulatory Policy
FDA

Mark Barnes, Esquire
Partner
Ropes & Gray LLP

Chris Galvin, M.B.A.
Department of Health and Human Services,
Office of Inspector General,
Office of Evaluation and Inspection

3:00 – 3:30 PM SUMMARY & CLOSING REMARKS

Robert Paarlberg, MS
Principal
Paarlberg & Associates LLC

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

3:30 PM END OF CONFERENCE

US Conference on Rare Diseases and Orphan Products: The New Era in Health Care

October 7-9 | North Bethesda, MD

Call for poster abstracts submission deadline: Friday, July 12

The meeting will include four major themes:

- Research & Regulation
- Access and Reimbursement
- The Role of the Patient in the Research and Regulatory Process
- The Implementation of the Affordable Care Act

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