DIA

Global Clinical Trial Disclosure and Data Transparency Conference

Conference: September 13-14 | Virtual Event

PROGRAM COMMITTEE CHAIR

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Principal
Paarlberg & Associates, LLC

PROGRAM COMMITTEE

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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

Upon completion of registration, participants will gain access to the following:

- Live Event Access
- Presentation Slides
- Access to recorded sessions, on demand for 4 months post event

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

Sessions are held in ET

DAY ONE | MONDAY, SEPTEMBER 13

10:00-10:45AM	**Welcoming Remarks and Session 1:** Keynote Address
10:45-11:00AM	BREAK / Visit the Virtual Exhibit Hall
11:00AM-12:15PM	**Session 2:** ClinicalTrials.gov - Enforcement and Compliance Landscape
12:15-1:00PM	BREAK / Visit the Virtual Exhibit Hall
12:15-1:00PM	**BONUS -** Round Table Session Hosted by Privacy Analytics: 3 Trends for 2022 (Start Planning Now) (**RSVP Required**)
1:00-2:00PM	**Session 3:** EU CTIS and Organizational Readiness
2:00-2:30PM	BREAK / Visit the Virtual Exhibit Hall
2:00-2:30PM	**BONUS -** Case Study Hosted by Real Life Sciences: Roadmap to Success – Navigating a PRCI Regulatory Submission with `Quantitative Communication' (**RSVP Required**)
2:30-3:45PM	**Session 4:** ClinicalTrials.gov Updates and Modernization Highlights
3:45-4:00PM	BREAK / Visit the Virtual Exhibit Hall
4:00-5:00PM	**Session 5:** ClinicalTrials.gov Modernization Focus Group
5:00-5:45PM	**BONUS -** Happy Hour Hosted by Privacy Analytics: Trends, Truths and Trivia Happy Hour! (**RSVP Required**)

DAY TWO | TUESDAY, SEPTEMBER 14

9:15-10:00AM	**BONUS -** Round Table Session Hosted by d-Wise: Transparency Resourcing: Meeting Compliance No Matter Your Size or Structure (**RSVP Required**)
10:00-11:15AM	**Welcome to Day Two and Session 6:** International Regulations and the Impact on Global Clinical Research
11:15-11:45AM	BREAK / Visit the Virtual Exhibit Hall
11:45AM-1:00PM	**Session 7:** Patient Focus in Disclosure: From Intent to Action
1:00-2:00PM	BREAK / Visit the Virtual Exhibit Hall
1:30-2:00PM	**BONUS -** Case Study Hosted by Synchrogenix: Plain Language Summaries, Patient Engagement, & the EU Clinical Trails Regulation: Meeting the Challenge (**RSVP Required**)
2:00-3:15PM	**Session 8:** The Evolution of Health Canada's Public Release of Information & Closing Remarks
3:15PM	Conference Adjourns

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
- Discuss the interplay between clinical data disclosure and transparency requirements

DAY ONE | MONDAY, SEPTEMBER 13

Sessions are held in ET

10:00-10:45AM

Welcoming Remarks and Session 1: Keynote Address

An-Wen Chan, MD, PhD, FRCPC, Chair, SPIRIT Initiative; Phelan Scientist, Women's College Research Institute; Associate Professor, Department of Medicine, University of Toronto, Canada

10:45-11:00AM

BREAK / Visit the Virtual Exhibit Hall

11:00AM-12:15PM

Session 2: ClinicalTrials.gov - Enforcement and Compliance Landscape

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

On April 27, 2021, FDA issued the first ever Notice of Noncompliance to a sponsor for failure to submit the required information to ClinicalTrials.gov. As of April 28, 2021, the agency has also sent Pre-Notices of Noncompliance to more than 40 sponsors to encourage voluntary compliance with the ClinicalTrials.gov requirements. NIH has also notified academic institutions to encourage voluntary compliance.

This session will explore the enforcement and compliance initiatives taken by FDA and NIH to sponsors for failure to submit required information to ClinicalTrials.gov as required by Section 801 of the FDA Amendments Act of 2007. The session will also provide an update of industry's most recent clinical trial transparency and data-sharing performance.

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

- Describe the current enforcement and compliance disclosure landscape in the US
- Identify actions taken by FDA and NIH for noncompliance
- Discuss how companies are being evaluated for disclosure performance

Speakers
Jennifer Miller, PhD, Assistant Professor, Yale School of Medicine

David Peloquin, JD, Senior Advisor, MRCT Center; Associate, Health care Group, Ropes & Gray LLP

12:15-1:00PM

BREAK / Visit the Virtual Exhibit Hall

12:15-1:00PM

BONUS - Round Table Session Hosted by Privacy Analytics: 3 Trends for 2022 (Start Planning Now) (RSVP Required)

Our industry is changing so rapidly, it can be hard to stay on top of what's coming next. From the impending enforcement of EU-CTR (EU Clinical Trial Regulation) to the increased attention on safely sharing clinical trial data as a way to drive pharmaceutical innovation, you need to start planning ahead.

In this roundtable, we'll hear from industry insiders as they share their insights into three key trends for 2022. Each segment will include an opportunity for participants to engage in an interactive discussion on the importance of each trend as trial sponsors prepare for the year ahead.

- **Trend 1: Re-Using Clinical Trial Data for Innovation**
  (Introduced by Aaron Mann, Senior Vice President, Data Science, Clinical Research Data Sharing Alliance)

- **Trend 2: Turning Clinical Trial Documents into Insight with NLP**
  (Introduced by Jane Reed, Director, Life Sciences, Linguamatics)
- **Trend 3: Considerations for EU-CTR and EMA Policy 0070**
  (Introduced by Vivien Fagan, Director, Global Medical Writing, IQVIA)

Moderators
Sarah Lyons, Head of Privacy Analytics, Privacy Analytics

Rebecca Li, Executive Director, Vivli, Center for Global Data Research

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1:00-2:00PM

Session 3: EU CTIS and Organizational Readiness

Session Chair
Kelly Coulbourne, MS, Director, Clinical Trial Disclosure and Data Transparency, Arena Pharmaceuticals

In January 2022, the EU Clinical Trial Regulation 536/2014 will come into effect when the EU Clinical Trial Information System (CTIS) goes live. The CTIS "will be the single-entry point for submitting clinical trial information in the EU" and clinical documents submitted to the CTIS will be made public per the EMA's transparency rules. In this session, hear about experiences with the EMA's Master Trainer Program, understand how organizations are preparing for go-live, and managing the challenges of the differences in disclosure obligations between the US and the EU and its member states.

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

- Differentiate how organizations of various sizes are preparing for go-live of the EU CTIS
- Evaluate the EMA Master Trainer Program
- Discuss the differences between the EU and the US approaches to disclosure of trial information

Speakers
Scott Feiner, Senior Clinical Trial Data Registries Associate II, Abbvie

Ruediger Pankow, DrSc, Principal Consultant, Regulatory Affairs, Parexel International, Germany

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

2:00-2:30PM

BREAK / Visit the Virtual Exhibit Hall

2:00-2:30PM

BONUS - Case Study Hosted by Real Life Sciences: Roadmap to Success – Navigating a PRCI Regulatory Submission with 'Quantitative Communication' (RSVP Required)

Guidance on today's key challenges, solutions, and communication strategies to successfully navigate your Health Canada PRCI submissions. Effectively manage the regulatory evolution from Qualitative to Quantitative disclosure methodologies.

Featured Topics

- Illustrative Submission Timeline: Key Challenges
- Illustrative Submission Timeline: Key Optimizations
- Potential Road Bumps with Regulatory Submissions
- Optimizing around the Process Initiation Meetings (PIM)
- Enabling 'Quantitative Communication' with Regulators
- Common Pressure Points with SAEs in Submission Processes
- Anonymization Options
- Proactive Communication Strategy

Speakers
Stephen Doogan, Product Strategy – Disclosure, Anonymization and Outcomes Research, Real Life Sciences

Ahmed Eldafrawy, Disclosure Risk Specialist, Real Life Sciences

2:30-3:45PM

Session 4: ClinicalTrials.gov Updates and Modernization Highlights

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

Learn about ClinicalTrials.gov approach to Modernization and see a demonstration of the new PRS features. Members of the National Library of Medicine's Modernization team will share an overview of the insights gained from user feedback, what issues will be addressed in the system, and what industry should know.

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

- List recent updates to ClinicalTrials.gov and convey the plans for and progress of modernization efforts
- Describe features of the updated PRS modules
- Summarize the upcoming changes for the ClinicalTrials.gov public site modernization

What's New at ClinicalTrials.gov and Modernization Overview
Anna Fine, PharmD, MS, Assistant Director for ClinicalTrials.gov, National Institutes of Health (NIH), National Library of Medicine

Modernization of PRS (Protocol Registration and Results System)
Stacey Arnold, PhD, Results Team Subject Matter Expert, National Institutes of Health (NIH), National Library of Medicine

Modernization of ClinicalTrials.gov
Christina Robinson, MA, Product Manager for ClinicalTrials.gov Modernization, National Institutes of Health (NIH), National Library of Medicine

3:45-4:00PM

BREAK / Visit the Virtual Exhibit Hall

4:00-5:00PM

Session 5: ClinicalTrials.gov Modernization Focus Group

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

Learn about ClinicalTrials.gov approach to Modernization and see a demonstration of the new PRS features. Members of the National Library of Medicine's Modernization team will share an overview of the insights gained from user feedback, what issues will be addressed in the system, and offer the opportunity to provide feedback on prototypes.

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

- Identify features of the updated PRS modules
- Express changes desired by Users for the ClinicalTrials.gov public site
- Understand how data submitted to PRS is used by patients and clinical trial data researchers

Speakers
Jolie Dobre, Product Manager for PRS Modernization, ClinicalTrials.gov

Wendy Harman, UX Lead for Modernization, ClinicalTrials.gov

5:00-5:45PM

BONUS - Happy Hour Hosted by Privacy Analytics: Trends, Truths and Trivia Happy Hour! (RSVP Required)

Looking for a fun way to end Day 1 of the conference (and flex your CTT, data, and analytics skills)? Join host Niamh McGuinness, CTT Anonymization Expert at Privacy Analytics, and your fellow attendees in this not-so-serious interactive Happy Hour trivia event. Top scorers get Day 2 bragging rights!

Speaker
Niamh McGuinness, CTT Anonymization Expert, Privacy Analytics

9:15-10:00AM

BONUS - Round Table Session Hosted by d-wise: Transparency Resourcing: Meeting Compliance No Matter Your Size or Structure (RSVP Required)

As clinical trial disclosure regulations continue to expand and evolve, maintaining compliance will become embedded in your organization's teams and processes. Who will handle all the elements of a successful transparency program? Does your organization have the resources and expertise to create a team for this purpose, or will other teams add additional responsibilities to current roles?

In this roundtable we'll discuss:

- Internal vs external resourcing: when does either option make sense?
- Delegation: should existing teams handle transparency requirements or should new teams be created?
- Role types: whether going in-house or outsourcing, what types of roles should be considered?

Moderator
Cathal Gallagher, Senior Consultant, d-wise

10:00-11:15AM

Welcome to Day Two and Session 6: International Regulations and the Impact on Global Clinical Research

Session Chair
Merete Joergensen, MBA, MSc, Senior Director, Clinical Transparency, Novo Nordisk A/S, Denmark

In a landscape of global clinical research attention to international regulations play an important role. Harmonization to the extent possible has an impact on making research conduct more ethical i.e. less need for repeat of trials/randomization of patients into trials already conducted elsewhere. Bringing products to patients earlier when trials are globally acceptable for new medical product approval. This session's presentations will provide insight into some of the international regulations such as playing a role in achieving transparency of the landscape of clinical research, efficiency by harmonization and collaboration of regulators review and approval of new drugs/devices, and considerations for options for harmonization of data privacy rules and consequences related to data sharing across borders

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

- Recognize the importance of focus on global harmonized approach to clinical research and the bene fit for society
- Appraise the roles and rules behind of Global Clinical Trials registries versus the National Clinical Trials registries
- Assess and organize in relation to global data privacy rules

Speakers
Ghassan Karam, Manager International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO), Switzerland

Jenny Peterson, Director, Clinical Trial Disclosure and Transparency, Alnylam Pharmaceuticals

Jeppe Guilford Manual, MLIS, Principal R&D Data Privacy Specialist, Novo Nordisk, Denmark

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11:15-11:45AM

BREAK / Visit the Virtual Exhibit Hall

11:45AM-1:00PM

Session 7: Patient Focus in Disclosure: From Intent to Action

Session Co-Chairs
Patrick Fawcett, Information Disclosure Administrator, Office of Research Protections, University of Pittsburgh

Deborah Collyar, President, Patient Advocates in Research (PAIR)

This session will help attendees turn intent into action concerning patient focused clinical trial disclosure practices. The US FDA's Patient-Focused Drug Development (PFDD) Program will be highlighted as a

systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation. Implications for clinical trial disclosure will be introduced, followed by a panel discussion covering the sponsor, regulator, and patient perspectives.

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

- Apply the principles of PFDD to clinical trial disclosure practices
- Use disclosure as a tool for achieving the global aims of PFDD
- Adapt disclosure practices to achieve greater diversity of clinical trial participant populations.

Speakers

Dyan Bryson, MBA, Patient Engagement Strategist/Patient Advocate, Inspired Health Strategies

Robyn Bent, MS, RN, Director, Patient Focused Drug Development Program, OCD, CDER, FDA

Catina O'Leary, PhD, President and Chief Executive Officer, Health Literacy Media (HLM)

Ting Pun, PhD, Volunteer Stanford Healthcare Patient Partner, Iconquerms

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1:00-2:00PM — **BREAK / Visit the Virtual Exhibit Hall**

1:30-2:00PM — **BONUS - Case Study Hosted by CertaraSynchrogenix: Plain Language Summaries, Patient Engagement, & the EU Clinical Trails Regulation: Meeting the Challenge (RSVP Required)**

As the EU clinical trials regulation goes into effect at the end of the year, Sponsors will be faced with the challenge of efficiently and accurately producing large volumes of plain language summaries (PLS). Additionally, an increased demand is expected for patient engagement during PLS authoring. In this session, we will present our solutions to these challenges, which include our Smart Template and our patient engagement tool, Podium.

Speaker

Theresa Shalaby, Sr Regulatory Services Manager, Plain Language Summaries Functional Lead, Certara Synchrogenix

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2:00-3:15PM — **Session 8:** The Evolution of Health Canada's Public Release of Information & Closing Remarks

Session Chair

Nancy Williams, Associate Director, RSMO, Document Publishing Solutions, Janssen Pharmaceuticals

Health Canada Public Release of Information (PRCI) was released in March of 2019 and was temporarily paused in 2020 in order to focus on COVID-19 efforts. However, Health Canada has resumed PRCI and is moving forward with implementation of Stage 2 for proactive release, which includes all NDS-type submissions. Industry has also had to implement, pause, and re-start their internal processes to deliver PRCI submissions. The session will provide lessons learned and refinement of process both from the very first to the more seasoned PRCI experience.

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

- Understand PRCI guidance and scope moving forward
- Identify actions to prepare for initial PRCI submissions
- Considerations for refinement of existing PRCI processes

Speakers

George Allan, PhD, Associate Director, Regulatory Document Lead, Janssen Research & Development

Nicole Hinton, Director, Clinical Trial Transparency, Ultragenyx Pharmaceutical

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3:15PM — **Conference Adjourns**