Clinical Data Disclosure, Transparency & Plain Language Summaries

Navigate Regulatory Changes, Develop Strategies for Sharing Patient Data and Elevate Medical Writing

JANUARY 22-24, 2020 | HYATT REGENCY CORAL GABLES | CORAL GABLES, FL

CURATED CONTENT FOR CLINICAL TRIAL SPONSORS DRIVEN BY INDUSTRY EXPERTS AND THOUGHT-LEADERS

FEATURED SPEAKERS FOR THE 2020 PROGRAM INCLUDE:

Jo Anne-Marie Blyskal, Head of Global Regulatory Medical Writing & Data Transparency and Disclosure, Teva
Richard White, Chief Operating Officer, Oxford PharmaGenesis
Deborah Collyar, Founder & President, Patient Advocates in Research (PAIR)
Jean-Marc Ferran, Director, Qualiance
Jessica S. Scott, M.D., JD, Head of R&D Patient Engagement Office, Takeda Pharmaceutical Company

JOIN US FOR COMPELLING DISCUSSIONS AND CRITICAL INSIGHTS, INCLUDING:

- Bridge the Gap — Working Together to Enhance Clinical Data Disclosure, Dissemination and Discoverability
- Hear Critical Insights on Health Canada’s PRCI, EU Policy 0070 and Global Harmonization of Disclosure Regulations
- Discuss Ethical and Moral Imperatives to Increase Clinical Transparency and Data Sharing in Response to Clear Needs and Expectations from Patients
- Explore Upcoming Changes in The NIH Review Process and Recommendation for Preparedness
- Elevate Patient Engagement through Improved Access of Clinical Information

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• Three Days of Comprehensive Content and Luminary Plenary Conversations
• Three Targeted Tracks:
  A. Clinical Disclosure & Anonymization
  B. Plain Language Summaries
  C. Regulatory & Medical Writing
• Nine À La Carte Interactive Breakouts
• And much more!

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Join us this January in Coral Gables as Informa Connect-CBI's Clinical Data Disclosure, Transparency & Dissemination Conference celebrates its 7th year and expands content on plain language summaries and medical writing. Driven by audience feedback, this program convenes industry thought leaders and experts to discuss the most pressing issues facing clinical trial transparency and dissemination teams today. Participate in interactive sessions, working groups and strategic discussions to benchmark with peers and elevate your clinical data disclosure operations. Don't miss your opportunity to join this innovative and growing community and tackle critical challenges impacting your daily work. Benefit from high-level discussions of regulatory developments, strategize to streamline processes and procedures and leverage innovative insights to drive progress within your organization.

THANK YOU TO THE 2020 ADVISORY BOARD!

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

Julie Holtzople,
Director, Clinical Trial Transparency Operations,
AstraZeneca

Nate Root,
Associate Director
Clinical Disclosure and Transparency,
Ionis Pharmaceuticals

Liz Roberts,
Global Public Policy Lead, External Engagement Practice,
UCB

Paul Ngai, M.S.,
Co-founder & Chief Executive Officer,
Xogene

AUDIENCE SNAPSHOT:

48% Disclosure/Transparency
32% Medical Writing/Publications
13% Medical/Scientific Affairs
7% Clinical Affairs and Operations

TITLES NOTED:
• Medical Transparency
• Disclosure and Transparency
• Documentation and Submissions
• Plain Language Summaries
• Clinical Document Transparency

TITLES NOTED:
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• Clinical Content Standards
• Principal Scientist

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Clinical Transparency Operations • Documentation & Submissions • Data Transparency/Data Sharing
Plain Language/Lay Summaries • Regulatory Affairs • Scientific Reviewer • Patient Engagement • Health Literacy

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DAY ONE  WEDNESDAY, JANUARY 22, 2020

7:15  Conference Registration and Continental Breakfast
8:15  Conference Chair’s Opening Remarks

8:30  KEYNOTE ADDRESS
Discuss Ethical and Moral Imperatives to Increase Clinical Transparency and Data Sharing in Response to Clear Needs and Expectations from Patients

Jessica S. Scott, M.D., JD, Head of R&D Patient Engagement Office, Myokardia

8:45  Track A
Achieving Balance — Approaching Anonymization with Quantified Risk

Oladayo Oyelola, Ph.D., SC (ASCP), Director, Clinical Trial Information Disclosure Regulatory Management Operations, Daiichi Sankyo, Inc.

9:15  Bridge the Gap — Working Together to Enhance Clinical Data Disclosure, Dissemination and Discoverability

Cathal Gallagher, Senior Life Sciences Consultant, d-wise

10:00 Networking and Refreshment Break

10:30 Clinical Document Anonymization and Disclosure, a Global Perspective

The session will provide updates on EMA Policy 0070 and Health Canada’s PRCI process.

We will review the status of Policy 0070 in the context of the ever-evolving global landscape of data sharing and discuss:
- Policy 0070 status up to the pause
- EMA Technical Anonymisation Group (TAG) progresses
- Synergies with Health Canada Public Release of Clinical Information policy
- Learnings from the FDA Clinical Data Summary Pilot Program

Jean-Marc Ferran, Director, Qualiance

Health Canada Update
Hear updates, insights and lessons learned from Health Canada’s Public Release of Clinical Information Initiative.

Melissa Jean, Scientific Reviewer – Public Release of Clinical Information, Health Canada

Followed by an Open Q&A Discussion Facilitated by:
Sanjay Bagani, Director, Clinical Trials Transparency, Xogene

11:15  Track B
Delve Into the Complexities of Pediatric Lay Summaries and Determine Best Practices

Kelsey Brown, Medical Writing Manager, Syneos Health

11:45  Track C
Explore Lean Medical Writing and Other Opportunities to Streamline Processes

Jo Anne-Marie Blyskal, Head of Global Regulatory Medical Writing & Data Transparency and Disclosure, Teva

12:15 Networking Luncheon

1:30  CHOOSE BETWEEN ONE OF THREE CONCURRENT TRACKS (A - C)

1:30  TRACK A
Clinical Disclosure & Anonymization

1.30  Track Chair’s Opening Remarks

Oladayo Oyelola, Ph.D., SC (ASCP), Director, Clinical Trial Information Disclosure Regulatory Management Operations, Daiichi Sankyo, Inc.

1:45  Achieving Balance — Approaching Anonymization with Quantified Risk

- Technology has made it possible to go beyond redaction into risk-based anonymization.
- Still, sponsors have to exercise discretion.
- Explore strategies that achieve balance when enabling sharing, preserving privacy, and operating with the reality of time and resource constraints.

Cathal Gallagher, Senior Life Sciences Consultant, d-wise

2:45  Delve into Prospective and Retrospective Analyses of Clinical Disclosure and Data Sharing Requirements

- Examine where challenges may arise in retrospective data requests.
- Discuss the potential to proactively approach data sharing with evolving Health Canada requirements.

Jo Anne-Marie Blyskal, Head of Global Regulatory Medical Writing & Data Transparency and Disclosure, Teva

1:30  TRACK B
Plain Language Summaries & Dissemination Strategies

1.30  Track Chair’s Opening Remarks

Behtash Bahador, MS, Associate Director, Relationship Management and Development, Center for Information & Study on Clinical Research Participation (CISCRP)

1:45  Delve into the Complexities of Pediatric Lay Summaries and Determine Best Practices

- Understand key differences in medical writing for pediatric studies.
- Examine how to best reach pediatric patients and caregivers.
- Include the patient and caregiver perspective in document development.

Kelsey Brown, Medical Writing Manager, TransPerfect

2:45  Discover Patient Perspective of Clinical Research and Plain Language Summaries

- Understand the patient perspective on clinical research.
- Listen to patient feedback on plain language summaries.
- Discuss how effective patient engagement early on helps in creating patient-relevant plain language summaries.

Vidhi Vashisht, Associate Director, Kinapse, a Syneos Health Company

1:30  TRACK C
Regulatory & Medical Writing

1:30  Track Chair’s Opening Remarks

Jo Anne-Marie Blyskal, Head of Global Regulatory Medical Writing & Data Transparency and Disclosure, Teva

1:45  Explore Lean Medical Writing and Other Opportunities to Streamline Processes

- Define lean medical writing and its key components.
- Analyze the benefit of lean writing vs. other tactical approaches.
- Examine roadblocks to effective implementation.
- Streamline medical writing processes and operations to ensure optimal resource allocation and reduce costs.

Jo Anne-Marie Blyskal, Head of Global Regulatory Medical Writing & Data Transparency and Disclosure, Teva

MEDICAL WRITING ATTENDEES ARE WELCOME TO ATTEND EITHER OF THE OTHER SESSIONS FROM 2:45-5:00
3:45 Networking and Refreshment Break

3:45 Explore New Technology and Advancements for Clinical Trial Transparency and Health Literacy
- Hear how CISCRP is advancing health literacy and clinical trial transparency, as well as dissemination to patients and caregivers
- Discuss howplainlanguage summaries have evolved and what can be expected to come next
- Benefit from a discussion of case studies and lessons learned
- Benchmark with peers to identify opportunities for improvement

Behtash Bahador, MS, Associate Director, Relationship Management and Development, Center for Information & Study on Clinical Research Participation (CISCRP)
Sudipta Chakraborty, Ph.D., Plain Language Summaries Lead, PRA Health Sciences

4:15 Examine the Evolution of Clinical Disclosure and Transparency in Japan
- Hear key lessons learned from working with Japanese transparency requirements
- Explore the similarities and differences between Japanese and other country-specific/regional requirements
- Discuss common roadblocks in effective disclosure to Japanese regulatory bodies
Jenny Petersen, Director, Aplylam

4:15 Networking and Refreshment Break

5:00 Close of Day One

D AY T W O TH U R SD AY, J A N U A R Y 2 3, 2 0 2 0

8:00 Continental Breakfast

8:30 Chair’s Review of Day One
Iwona Bucior, Director Medical Communications, Myokardia

8:45 Patient Perspectives on Clinical Data Sharing, Disclosure and Dissemination
Benefit from patient perspectives on the evolving landscape for dissemination and disclosure of clinical data and study information:
- Discuss common roadblocks to patient access of clinical information
- Understand what is most critical to patients and caregivers during clinical research
- Explore channels and strategies for optimal dissemination
- Establish trust through partnerships with patient advocacy groups and co-development

MODERATOR:
Deborah Collyar, Founder & President, Patient Advocates in Research (PAIR)

CONVERSATION CONTRIBUTORS:
Jamie Tyrone, CEO and Founder, Beating Alzheimer’s By Embracing Science (B.A.B.E.S)
Amy Leitman, Director of Policy & Research, NTM Info & Research

9:30 KEYNOTE ADDRESS
Discuss Ethical Standards for Clinical Research and the Responsibilities of the Life Sciences Industry
- Review transparency and data-sharing standards in clinical research
- Learn about clinical trial transparency for new drugs and by large companies as related to the Good Pharma Scorecard
- Identify common risk areas and best practices in ethical design, conduct and dissemination of research
Jennifer Miller, Founder, Bioethics International and the Good Pharma Scorecard; Assistant Professor, Yale University School of Medicine

10:15 Networking and Refreshment Break

10:45 Analyze the Evolution Clinical Disclosure and Transparency and the Potential for Harmonization of Global Standards
Examine evolving regulations and requirements related to clinical data disclosure and transparency, including Health Canada’s Public Release of Clinical Information Initiative, ClinicalTrials.gov and EU CTR and Policy 0070.
- Compare and contrast the approach of diverse global regulatory bodies

12:30 Networking Luncheon

1:45 À La Carte Breakouts and Skills Labs
**Disclosure 101**
The first part of this short course serves as part one of an introductory study of data disclosure regulations and transparency requirements for life sciences companies.
- NIH Rule for FDAAA
- Explore ClinicalTrials.gov and EudraCT Platforms
- Summary of local registries
- Understand FDA CSR Pilot

*Iwona Bucior, Director Medical Communications, Myokardia*

**Explore Advances in Transparency through TransCelerate’s Clinical Research Access Initiative**
Hear an update on the project and understand how registration data quality can be improved by enabling adherence with registry requirements while reflecting key information desired by patients.
- Understand the key information patients value when searching for clinical trials on public registries based on a global patient survey of over 1,000 patients
- Interact to see how sponsors can leverage the free Clinical Trial Registration Tool to proactively evaluate the quality of the clinical trial registration data, specifically for the “Brief Title” and the “Brief Summary” fields, that they submit to government-owned registries

*Chris Pfitzer, MA, Transparency Operations Lead, UCB Biosciences*

**Global Harmonization of CTT requirements — Opportunities, Challenges and Ideas**
A Discussion on How to Advance This Global Need
In this session, come prepared to dig deeper into the current opportunities for global harmonization and share ideas for how to pursue this as an industry.

*Julie Holtzople, Director, Clinical Trial Transparency Operations, AstraZeneca*

**Disclosure 102**
The second part of the short course serves as an introductory study of data disclosure regulations and transparency requirements for life sciences companies and further explores global regulations.
- Overview and evolution of EU Policy 0070
- EU Clinical Trials Registration (CTR)
- ICMJE requirements
- Introduction to data sharing

*Oladayo Oyelola, Ph.D., SC (ASCP) Director, Clinical Trial Information Disclosure Regulatory Management Operations, Daiichi Sankyo, Inc.*

**Advance Disclosure of Biostatistics through Streamlined Programming and Processes**
Hear insights learned from the implementation of new programming techniques to optimize disclosure of clinical biostatistics data.
- Discuss common challenges in disseminating biostatistics
- Review current best practices and opportunities for improvement
- Delve into operational and statistical challenges of effectively communicating this data

*Paul Ngai, Co-Founder and CEO, Xogene*

**Analyze Disclosure and Registry Challenges in Socio Behavioral Studies**
- Delve into the specific challenges of working with registries for socio behavioral studies
- Consider opportunities to address common roadblocks in disclosing socio-behavioral data
- Compare and contrast clinical transparency for medical vs. socio behavioral studies
- Exchange best practices and identify areas for continued improvement

*Yolanda P. Davis, Clinical Disclosure Manager, University of Miami*

**EMA Policy 0070 — An Exploratory Review of Data Utility in Clinical Study Reports for Academic Research**
The session will present a review of thirteen secondary-purpose research academic manuscripts based on CSRs and discuss:
- How Data Utility is defined in Policy 0070
- A classification of the different research purposes academics are looking to address
- Which CSR sections and data entities are required for their research
- Recommendation to optimize and justify Data Utility in anonymized CSRs

*Jean-Marc Ferran, Director, Qualiance*

**Changing Processes and Attitudes Towards Risk-assessment and Anonymization after Implementation of Health Canada PRCI**
- HC’s preference for evaluation of quasi identifiers and reference population for risk-assessment
- Shift in sponsors’ attitude — Moving from qualitative to quantitative risk-assessment
- Preparation before submitting the package to HC

*Shalini Dwivedi, Director, Kinapse, a Syneos Health Company*

**Rare Disease Working Group — Explore the Challenges of Disclosure and Transparency in Small Populations**
- Identify and discuss the biggest pain points in disclosure for rare disease professionals
- Benchmark with peers on how to best manage the deidentification of patient-level data
- Analyze ethical roadblocks comply with disclosure and transparency requirements while protecting the patient and furthering science

*Nate Root, Associate Director Clinical Disclosure and Transparency, Ionis Pharmaceuticals*
7:45  Continental Breakfast

8:15  Chairman’s Review of Day Two
Iwona Bucior, Director Medical Communications, Myokardia

8:30  Upcoming Changes in the NIH Review Process and Recommendation for Preparedness
• Summary of upcoming changes
• Discuss impact on how disclosure arena will change
• Recommendations for Sponsors to consider minimum review rounds
Sonali Parmar, Associate Director, Kinapse, a Syneos Health Company

8:45  Research Participant/Patient Perspective of Genetic and Biomarker Disclosure
• Hear a Research Participant and her personal journey of genetic disclosure
• Discuss Insights on Disclosure, the Needs of Research Participants, and Motivations to Volunteer
• Understanding Disclosure and Informed Consent
• Discuss the Pro’s and Con’s of Genetic or Biomarker Disclosure
Jamie Tyrone, CEO and Founder, Beating Alzheimer’s By Embracing Science (B.A.B.E.S)

9:15  Explore Effective Ways to Engage with Patients through TransCelerate’s Patient Experience Initiative
Hear an update on the Patient Experience initiative and understand how the initiative tools provide more effective ways to engage with patients in the design and execution of clinical studies.
• Learn more about the Patient Protocol Engagement Toolkit (P-PET) and the Study Participant Feedback Questionnaire (SPFQ) toolkits
Sean Ludlam, Clinical Trial Registrries, Allergan

9:45  Partnering with Patients and Participants to Develop Clinical Research Materials and Plain Language Summaries
• Identify the opportunities for participant input throughout the clinical research process
• Describe how co-development can elevate document quality and impact
Sylvia Baedorf Kassis, MPH, Program Manager, Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard

10:30  Networking and Refreshment Break

11:00  Elevate the Quality of Clinical Submissions and Documentation through Strategic Medical Writing
Delve into opportunities to leverage strategic medical writing to enhance the quality of clinical documentation and accessibility of clinical trial information.
• Analyze common risk areas and improve compliance
• Identify key metrics for evaluating document quality
• Leverage strategic process management to streamline operations and resource allocation
Jo Anne-Marie Blyskal, Head of Global Regulatory Medical Writing & Data Transparency and Disclosure, Teva
Robert Stumpo, Director of Medical Writing and Submission Management, Teva Pharmaceuticals

11:45  Conference Closing Remarks & Close of Conference

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“Getting updated on guidelines and learning real-life solutions from lively conversations and networking in a smaller venue that allows for more interactions.”
— Director, Medical Communications, Myokardia

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CHOOSE YOUR SESSION

Day One Track  □ A □ B □ C
Day Two 1:30 Session  □ 1 □ 2 □ 3
Day Two 2:30 Session  □ 4 □ 5 □ 6
Day Two 4:00 Session  □ 7 □ 8 □ 9

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7th Annual Clinical Data Disclosure, Transparency & Plain Language Summaries

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