August 7-8, 2017 // The Rittenhouse Hotel // Philadelphia, PA

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Disclosure and Transparency for Clinical Data Summit

Balance Your Commercial Values and Ethical Responsibilities Through the Vigilant Execution of National and Global Data Transparency

Keynote Session:

Open Patient Data Access and Sharing: Where Are We on the Journey and Is the Destination Worth the Cost of the Trip?

Frank Rockhold, Ph.D., *Professor of Biostatistics and Bioinformatics, Duke Clinical Research Institute,* **DUKE UNIVERSITY MEDICAL CENTER**

Strategic and Practical Disclosure Considerations Regarding the EMA Policy 0070 Update

René Allard, *Public Disclosure Lead,* **GRÜNENTHAL GMBH**

Enable Next Generation Smart Processes Through Federated Informatics Technology

Greg Koski, M.D., Ph.D., *President and CEO,* **ALLIANCE FOR CLINICAL RESEARCH EXCELLENCE AND SAFETY (ACRES);** *Associate Professor,* **MASSACHUSETTS GENERAL HOSPITAL, HARVARD MEDICAL SCHOOL;** *Senior Scientist,* **MONGAN INSTITUTE FOR HEALTH POLICY**

Align Timelines, Communication Resources and Data Across Silos to Optimize Transparency and Disclosure

Oladayo Oyelola, Ph.D., *Director, Clinical Trial Information Disclosure,* **DAIICHI SANKYO**

Standardize Manual Processes to Accomplish Data Disclosure and Clinical Trial Registry

Laura Troast, M.S., *Associate Director, Clinical Data Disclosure and Transparency,* **MERCK**

Event Highlights:

- Accomplish transparency through **collaboration across all sectors of science**
- Progress in precision medicine through **individual patient data access**
- Streamline and **coordinate disclosure processes** across functions
- **Examine the FDA and EMA rollouts** to successfully navigate the regulatory landscape
- Explore best practices for **managing growth from a transparency perspective**
- **Encourage sprightly adaptation,** regardless of company size, to new regulations through **novel infrastructure**

Conference Chair

Liz Roberts, *Senior Director, Global Lead Transparency and Data Sharing,* **UCB**

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Disclosure and Transparency for Clinical Data Summit

Dear Colleague,

Regulations for clinical data disclosure and transparency are no longer on the horizon — they are underfoot. Competing timelines, nonexistent standardization processes, inadequate government support and ever-changing regulatory guidelines define the chaotic data disclosure landscape. In response to Policy 0070 and The Final Rule, life science organizations have been tripping over themselves in this aptly coined regulatory quicksand to achieve data transparency on a global and national scale.

To combat the burden of new regulatory requirements, operational challenges and renewed infrastructure needs, the life science industry must take a holistic and collaborative approach to achieving data disclosure compliance. Through data disclosure and transparency, life science organizations decrease the chances of clinical trial duplication, ensure public understanding and access, and ultimately promote brand integrity.

At the **Disclosure and Transparency for Clinical Data Summit**, the star-studded speaking faculty will define standardization processes for disclosure and registry, provide best practices to balance commercial confidentiality and public access, and examine proven tactics that preserve data utility while ensuring adequate anonymization. This summit will provide you with the tools to ultimately maximize the benefits of clinical data from the inherent risks of clinical trials, all while complying with national and global compliance regulations.

I look forward to welcoming you to Philadelphia this summer!

Sincerely,

Mercy Lister

Mercy Lister
Conference Production Director
ExL Events, a division of Questex, LLC

WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, clinical research organizations and biotechnology companies with responsibilities in the following areas:

- Clinical Trial Disclosure and Transparency
- Clinical Trial Information Disclosure/ Management
- Clinical Operations
- Data Management/Standards
- Regulatory Affairs
- Clinical Trial Registration
- Publication Planning
- Medical Writing
- Information/Knowledge Management
- Strategic Projects Management
- Medical Communications
- Patient Engagement
- Biostatistics/Bioinformatics

This conference is also of interest to:

- Data Reporting/Transparency Solution Providers
- Medical Writing/Publication Services
- Discrepancy Management/Data Management Service Providers
- Legal Consultants

VENUE INFORMATION

The Rittenhouse Hotel
210 West Rittenhouse Square
Philadelphia, PA 19103

To make reservations, please call 1-800-635-1042 or 215-546-9000 and request the negotiated rate for **ExL's August Meetings**. The group rate is available until **July 18, 2017**. Please book your room early, as rooms available at this rate are limited. You may also make reservations online at http://bit.ly/2nH4yjj.

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Do you want to spread the word about your organization's solutions and services to potential clients who will be attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

8:00 Registration Opens and Continental Breakfast

8:45 Chairperson's Opening Remarks

Liz Roberts, *Senior Director, Global Lead Transparency and Data Sharing,* **UCB**

9:00 **Open Patient Data Access and Sharing: Where Are We on the Journey and Is the Destination Worth the Cost of the Trip?**

- Understand that providing access to patient data is just one step toward the goal of transparency
- Accomplish transparency through collaboration between researchers across all sectors of science
- Progress in precision medicine through individual patient data access

Frank Rockhold, Ph.D., *Professor of Biostatistics and Bioinformatics, Duke Clinical Research Institute,* **DUKE UNIVERSITY MEDICAL CENTER**

10:00 **A Holistic Approach to the Evolving Transparency Landscape**

- Review key transparency requirements, including EU CTR536, EMA Policy 0070 and The Final Rule (42 CFR Part 11)
- Highlight transparency collaborations across industry, including TransCelerate and Clinical Study Data Request Site (CSDR)
- Define next steps on the transparency journey

Liz Roberts, *Senior Director, Global Lead Transparency and Data Sharing,* **UCB**

10:45 Networking Break

11:15 **EMA Policy 0070 Lessons Learned & Best Practices Gained from 3 Case Studies**

- Proactively prepare your team's T&D processes for upcoming submissions
- Learn how to avoid common Policy 0070 process pitfalls
- Understand how to prepare for the EMA consultation round

Lora Killian, *Director, Transparency and Disclosure,* **SYNCHROGENIX**

12:00 **Strategic and Practical Disclosure Considerations Regarding the EMA Policy 0070 Update**

- Examine practical considerations and the impact of EMA Policy 0070 and EU access to public administration files on national registries
- Propose best practices for clinical development planning that include effective collaboration leading to practical disclosure solutions
- Understand decision-making processes in EMA Policy 0070 document preparation

René Allard, *Public Disclosure Lead,* **GRÜNENTHAL GMBH**

1:45 **Examine Data Disclosure Methods to Achieve Full Transparency and to Ensure Credibility**

- Discuss how to ensure organizational discipline that is true to transparent compliance practices
- Consider the different uses of clinical data in a transparent environment

Debra Mayo, *Vice President, Global Scientific Communications,* **TEVA**

12:45 Luncheon

2:30 **Implement and Manage a Clinical Disclosure Group or Process for Your Organization**

- Review the advantages and disadvantages of an in-house versus an outsourced disclosure model
- Consider the documentation needed to manage transparency in this evolving field
- Debate the merits of a disclosure system
- Explore best practices for managing growth from a transparency perspective

Frantz Derilus, *Associate Director, Clinical Trial Transparency,* **SHIRE**

3:15 Networking Break

3:45 **Align Timelines, Communication Resources and Data Across Functions to Optimize Transparency and Disclosure**

- Limit internal data discrepancies by merging resources across data integrity, validation and transparency departments
- Engage employees cross-functionally in the preparation of data reports to reduce delays and increase the validity of submitted data
- Streamline and coordinate disclosure processes across functions for consistency and efficient disclosure operations

Oladayo Oyelola, Ph.D., *Director, Clinical Trial Information Disclosure,* **DAIICHI SANKYO**

4:30 **Standardize Manual Processes to Accomplish Data Disclosure and Clinical Trial Registry**

- Explore manual documentation strategies that protect the validity of your data
- Consider the roles of different departments when gaining approval for manual processes
- Review challenges in and solutions for ensuring organizational discipline

Laura Troast, M.S., *Associate Director, Clinical Data Disclosure and Transparency,* **MERCK**

5:15 **Case Study: Johnson & Johnson's Yale Open Data Access (YODA) Project**

- Walk through J&J's implementation of an independent body that reviews requests from investigators and physicians seeking access to clinical data
- Consider third-party collaborators to make final, objective decisions in authorizing data access

Karla Childers, *Senior Director, Strategic Projects,* **JOHNSON & JOHNSON**

6:00 Chairperson's Closing Remarks

Liz Roberts, *Senior Director, Global Lead Transparency and Data Sharing,* **UCB**

6:15 Day One Concludes

8:00 Continental Breakfast

9:00 Chairperson's Recap of Day One

Liz Roberts, *Senior Director, Global Lead Transparency and Data Sharing,* **UCB**

9:15 **Enable Next Generation Smart Processes Through Federated Informatics Technology**

- Discuss why high-performance computing and analytic algorithms are available but their power is largely untapped
- Realize that a new generation of smart tools can enhance performance and safety, but only if data can be safely accessed, aggregated and analyzed in real time
- Explore the benefits of a secure, federated environment for data connectivity and interoperability

Greg Koski, M.D., Ph.D., *President and CEO,* **ALLIANCE FOR CLINICAL RESEARCH EXCELLENCE AND SAFETY (ACRES);** *Associate Professor,* **MASSACHUSETTS GENERAL HOSPITAL, HARVARD MEDICAL SCHOOL;** *Senior Scientist,* **MONGAN INSTITUTE FOR HEALTH POLICY**

10:00 **SHRINE (Shared Health Research Information Network): Enable Patient Cohort Identification for Accrual to Clinical Trials**

- Review the Accrual of Patients to Clinical Trials project to understand the underlying enabling components
- Use standardized vocabularies to represent data elements
- Examine open-source i2b2 software tools for establishing local data repositories
- Consider software tools to perform queries across the federated network to obtain cohort counts from each participating hospital

Bhanu Bahl, Ph.D., *Director, Clinical and Translational Science Center,* **HARVARD MEDICAL SCHOOL**

10:45 Networking Break

11:15 **Strategies and Resources for Sharing Clinical Research Data in Academia**

- Determine best practices for navigating mandates for data sharing for all stakeholders, particularly regarding funders, publications and resources
- Discuss the culture shift of data sharing from a data vault to open science
- Define the value of data transparency to academia

Kristen Bolt, *Program Manager, Data Sharing and Transparency,* **MULTI-REGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD**

12:00 Luncheon

1:00 **Best Practices for Balancing Your Organization's Commercial Value and Data Sharing**

- Illustrate processes that protect commercial confidentiality while authorizing data access
- Detail standardization methods that simplify assessing CCI material

Pranab Mitra, Ph.D., *Principal Biostatistician,* **BRISTOL-MYERS SQUIBB**

1:45 **The Challenges of Medical Writing in Clinical Trial Disclosure**

- Review the registration requirements for international and national registries
- Define the challenges you must face to achieve compliance
- Explore best practices in streamlining workflow and assigning responsibility

Sulochanda Gawande, Ph.D., *Director, Oncology Medical Writing and Publications,* **EISAI**

2:30 **Implement Disclosure Infrastructure to Facilitate Rapid Changes to Preexisting Data**

- Innovate large pharmaceutical companies with dexterity and new technologies
- Encourage sprightly adaptation, regardless of company size, to new regulations through novel infrastructure

Nathaniel Root, *Global Clinical Trial Registration and Results Disclosure Lead,* **TAKEDA**

3:15 **Lay Language Summaries as Tools for Patient Engagement: Driving Patient Engagement Through Sharing Overall Trial Results.**

- Explore best practices for engaging patients before, during, and after participation
- Understand the cycle of patient engagement, and the challenges it presents
- Discuss the importance of providing overall trial results to patients in an easy-to-understand format.

Julia Farides-Mitchell, MA, *Senior Project Manager, Center for Information & Study on Clinical Research Participation (CISCRP)*

4:00 Chairperson's Closing Remarks

Liz Roberts, *Senior Director, Global Lead Transparency and Data Sharing,* **UCB**

4:15 Conference Concludes

"ExL Events never disappoints! They provide a collaborative environment."

—Chief Operating Officer, **AVOCA GROUP**

"The speakers were excellent choices; the content was interesting and intellectually challenging."

—Director, Biostatistics, **KV PHARMACEUTICALS**

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Register by Friday, June 23, 2017

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Register after Friday, June 23, 2017

ONSITE PRICING — **$2,195**

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Questions? Comments?

Do you have a question or comment that you would like to be addressed at this event? Would you like to get involved as a speaker or discussion leader?

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