Disclosure and Transparency for Clinical Data Summit

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

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

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

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

Sponsors

Legal Regulations
Clinical Trials Registry
Change Management
Interoperable Technologies
Medical Writing
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
Conference Production Director
ExL Events, a division of Questex, LLC
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
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, DAII 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
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
Monday, August 7, 2017
Day One
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
Registration Fees for Attending ExL’s Disclosure and Transparency for Clinical Data Summit

<table>
<thead>
<tr>
<th>EARLY BIRD PRICING — $1,895</th>
<th>Register by Friday, June 23, 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANDARD PRICING — $2,095</td>
<td>Register after Friday, June 23, 2017</td>
</tr>
<tr>
<td>ONSITE PRICING — $2,195</td>
<td></td>
</tr>
</tbody>
</table>

TERMS AND CONDITIONS: By registering for an ExL Events (“ExL”) event, you agree to the following set of terms and conditions listed below:

REGISTRATION FEE: The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

PAYMENT: Make checks payable to ExL Events and write C895 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

**Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.**

CANCELLATION AND REFUND POLICY: If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
- Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email cancel@exlevents.com or fax your request to 888-221-6750.

CREDIT VOUCHERS: Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees’ behalf, the credit voucher will no longer be valid.

ExL Events does not and is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.

SUBSTITUTION CHARGES: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.

ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants.

Group Discount Program

Save 25% per person when registering four

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

Save 15% per person when registering three

Can only send three? You can still save 15% off of every registration.

Offers may not be combined. Early bird rates do not apply. To find out more about how you can take advantage of these group discounts, please call 201 871 0474.

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?

ExL Events’ liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.

*The opinions of ExL’s conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events.

Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL’s designated speakers and is designed for informational purposes for its attendees. It is NOT INTENDED for purposes of copywriting or redistribution to other outlets without the express written permission of ExL’s designated speaking parties. Neither ExL nor its content providers and/or speakers and attendees shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. ExL EVENTS EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL presentations may point to other websites that may be of interest to you, however ExL does not endorse or take responsibility for the content on such other sites.
August 7-8, 2017 // The Rittenhouse Hotel // Philadelphia, PA

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

Standardize Manual Processes to Accomplish Data Disclosure and Clinical Trial Registry

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

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

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

Method of Payment: ☐ Check ☐ Credit Card
Make checks payable to PMA Conference Management
Card Type: ☐ MasterCard ☐ Visa ☐ Discover ☐ AMEX
Card Number: ____________________________________________________________
Exp. Date: __________/__________ CVV: __________
Name on Card: __________________________________________________________
Signature: _______________________________________________________________

Please contact me:
☐ I'm interested in marketing opportunities at this event.
☐ I wish to receive email updates on ExL Pharma's upcoming events.
CONFEREENCE CODE: C895