Westin Arlington

Sep 23, 2024 7:00 AM - Sep 24, 2024 7:00 PM

801 North Glebe Road, , Arlington, VA 22203 , USA

Global Clinical Trial Disclosure and Data Transparency Conference

Learn about the latest requirements in clinical trial disclosure and data transparency, share best practices, and engage in in-depth discussions on hot topics.

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Early Bird Rates Expire

13	22	29	14
DAYS	HOURS	MINUTES	SECONDS

Print Agenda

Day 1 Sep 23, 2024

7:30 AM — 5:00 PM

Conference Registration

Networking Breakfast

8:30 AM — 8:45 AM

Opening Remarks

Track: General Session

Session Chair(s)

Sorcha McCrohan, MS, MSc

Specialist, Scientific Programs
DIA, United States

Sorcha McCrohan is a Specialist of Scientific Programs for the Americas Region at DIA. In her current role, she focuses on content development and strategy for DIA's meetings to improve and facilitate innovation in clinical research, drug development, and the fields of devices and diagnostics. Before joining DIA, she conducted COVID-19 research in Chiapas, Mexico, and worked in marketing within Pfizer's Global Vaccines Meningococcal franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.

Robert Paarlberg, MS

Principal
Paarlberg & Associates LLC, United States

Robert Paarlberg is Principal of Paarlberg & Associates LLC, a consultancy specializing in regulatory policy, regulatory intelligence and global clinical trial disclosure strategy and operations. Prior to founding Paarlberg & Associates LLC, Bob worked at Pharmacia (Upjohn) and UCB. Bob is former Chair of DIA's Clinical Trial Disclosure Community. Bob has more than 40 years of pharmaceutical industry experience with the vast majority of his experience in US and international regulatory affairs. Bob has been active in the clinical trial disclosure and transparency space since 2005.

8:45 AM — 10:00 AM

Session Chair(s)

Kelly Coulbourne, MS

Director, Clinical Trial Transparency and Disclosure
Pfizer Inc, United States

Kelly is the Director of Clinical Trial Transparency and Disclosure at Pfizer where she provides strategic and operational expertise to support the disclosure of clinical regulatory documents pertaining to Pfizer-sponsored interventional trials on public websites.

Speaker(s)

How Can Value Be Added to Registration and Results Postings?

Representative Invited

Center For the Study of Drug Development, United States

Ken Getz is the Executive Director and a Professor at the Tufts Center for the Study of Drug Development, Tufts University School of Medicine. He is also the chairman of CISCRP – a nonprofit organization that he founded to educate and raise public and patient awareness of the clinical research enterprise. A well-known speaker at conferences, symposia, universities, investor meetings and corporations, Ken also holds a number of board appointments in the private and public sectors. He received an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, Phi Beta Kappa, from Brandeis University.

Enabling Individual Participant Data Return (iPDR)

Representative Invited

TransCelerate BioPharma Inc., United States

Update on ClinicalTrials.gov Modernization Effort

Representative Invited

National Institutes of Health (NIH), United States

Dr. Stacey Arnold is a Subject Matter Expert for the Results Quality Control Team, ClinicalTrials.gov, at the National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health in

10:00 AM — 10:30 AM

Refreshment and Networking Break

10:30 AM — 12:00 PM

Session 2: EU Clinical Trials Information System (CTIS)

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Track: General Session

Session Chair(s)

Scott Feiner

Senior Manager, Trial Disclosure
AbbVie, United States

Scott has over a decade of experience with clinical trial disclosure, initially working for smaller sponsors as a one-person clinical trial disclosure department, to later operating in larger organizations, serving as an expert in summary results reporting and clinical document redaction/anonymization for public disclosure. As part of implementation planning for the EU Clinical Trials Regulation, Scott is AbbVie's representative in the EMA CTIS sponsor master trainer programme.

Speaker(s)

Speaker

Christopher Pfitzer, MA

Clinical Trial Transparency Strategy Lead
Biogen, United States

Christopher Pfitzer is the Transparency Operations Lead at UCB BioSciences in Raleigh, North Carolina but today he is representing the TransCelerate Clinical Research Access Initiative. Chris earned his Master's degree from NC State University and a Bachelor's degree from the University of Alabama at Birmingham. Prior to joining UCB, Chris worked extensively with healthcare and nonprofit organizations supporting policy and communications activities.

Ruediger holds a university degree in Biology and is a clinical regulatory affairs professional with history of more than 16 years in the CRO industry at Parexel, where he last was Principal Consultant in the clinical trial regulatory services. He was involved in his company's EU Clinical Trials Regulation 536/2014 (EU CTR) readiness implementation, and has contributed for ACRO to EU CTR stakeholder activities with EU Regulators and EMA. Since 2019 he has been a sponsor product owner for ACRO in EMA's Clinical Trials Information System (CTIS) delivery project providing input on design and development of system functionalities and guidance material, and is DIA instructor of EMA's CTIS sponsor user training programme.

End-to-End Experience with EU CTR 536/2014 Transparency Requirements Representative Invited

Krystelis Ltd., United Kingdom

12:00 PM — 1:00 PM

Networking Luncheon

1:00 PM — 2:15 PM

Session 3: Global Perspectives on Disclosure

Session 3: Global Perspectives on Disclosure

Track: General Session

Session Chair(s)

Merete Joergensen, MBA, MSc

Clinical Disclosure and Transparency Expert
Merete-J Consulting, Denmark

Merete Joergensen holds an MSc in Statistics and an MBA in Management of Technology. She has more than 30 years of experience in Clinical Research. From 2004 she has been building up the

Speaker(s)

Value of CTT Disclosure Channels and Thoughts about What Purposeful Transparency Look Like

Representative Invited

AstraZeneca, United States

Julie Holtzople is the Sr. Director of Clinical Transparency & Data Sharing for AstraZeneca and co-lead of the CREG CTT group. Julie received her Bachelors of Science in Business Administration at Virginia Polytechnic Institute. Julie has been with AstraZeneca for 14 years. Prior to her time in AstraZeneca Julie was a management consultant in health care. Today, Julie if focused on the implementation and delivery of new transparency policies, regulations, tools and the general best practices as they emerge across the industry. As part of her role Julie is actively involved in several industry organizations focused on establishing best practices in Clinical Trial Transparency.

Assessment of the Impact of Disclosure Platforms, Study with EFPIA and Pharma

Representative Invited

Pfizer, United States

Lora has 20+ years of business experience, including more than a decade of pharmaceutical industry experience. She started her career in the military serving four years of active duty in the Medical Service Corp for the U.S. Army. In her first pharmaceutical industry position, Lora served for 4 years as Director of Operations for a small medical writing company. She transitioned to Transparency and Disclosure in 2014. During her 8 years in Transparency and Disclosure, Lora has overseen delivery of 5500+ redacted and anonymized documents to support European Medicines Agency Policy 0070, Health Canada Public Release of Clinical Information, other global disclosure regulations and broader corporate transparency policies for many sponsors.

What in the world is going on?

Representative Invited

Citeline, United States

Thomas Wicks is the Head of Data and Partnerships at Citeline, where he is responsible for the organization's data governance and interoperability as well as tracking regulatory requirements and clinical data sharing trends that shape the company's clinical transparency solutions and services. He has over 25 years of experience with compliance management solutions, specializing in applications for life sciences with a focus on clinical trial disclosure and transparency since 2007.

Session 4: Enforcement Initiatives by Health Authorities to Ensure Compliance with Clinical Trial Transparency Requirements

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Session Chair(s)

Robert Paarlberg, MS

Principal
Paarlberg & Associates LLC, United States

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Speaker(s)

Speaker

Representative Invited

FDA, United States

Dr. Laurie Muldowney is a Clinical Team Leader within the FDA's Division of Gastroenterology and Inborn Error Products. In this role, Dr. Muldowney focuses primarily on the review of products to treat inborn errors of metabolism. Dr. Muldowney previously served as a medical officer in the Office of Pharmaceutical Science, where she led Center-wide working groups charged with evaluating drug quality issues with potential impact on the safety and efficacy of drug products. Dr. Muldowney received a B.S. in chemistry from the College of William and Mary and earned her medical doctorate from Jefferson Medical College in Philadelphia, PA.

Representative Invited

Saudi Food and Drug Authority, Saudi Arabia

Clinical Trial Regulation, Enforcement, How Member States Think about Harmonization of Transition Trials Representative Invited

Danish Medicines Agency, Denmark

Lene Grejs Petersen is Senior Adviser at the Danish Medicines Agency, Clinical Trial Unit. Lene has been member of the Clinical Trials Facilitation Group (CTFG) member since 2008 and the Danish representative of the EU Commission's expert group concerning clinical trials since 2001. Lene has been an employee at the Danish Medicines Agency since 2000 and she is involved in the implementation of the EU Clinical Trials Regulation into Danish legislation and works as a regulatory assessor and coordinator of clinical trial applications including VHP. Lene has a background as Master in Pharmacy.

3:35 PM — 4:10 PM

Refreshment and Networking Break

4:10 PM — 5:25 PM

Session 5: Clarity in Clinical Trials: Unlocking the Potential of Plain Language Summaries for Patients and the Public

Session 5: Clarity in Clinical Trials: Unlocking the Potential of Plain Language Summaries for Patients and the Public

Session Chair(s)

Francine Lane, MBA

Senior Director of Product Management
Citeline, United States

Francine Lane is the VP of Global Transparency at TrialScope and the Chair of the DIA Clinical Trial Disclosure Community. In her day job, Francine is responsible for helping TrialScope customers meet and exceed current disclosure expectations globally, giving them the tools they need to meet all the requirements in this evolving industry. Francine also dedicates her time building relationships with external

Navigating EU CTR: Mastering Effective Lay Protocol Synopses (LPS) and Plain Language Summary (PLS) Development

Representative Invited

Merck Sharp & Dohme LLC, United States

The Value of Plain Language Writing in Clinical Research Operations and Medical Communication

Representative Invited

Daiichi Sankyo, Inc. , United States

Dr. Oladayo Oyelola is Senior Director and Head, Clinical Trial Information Disclosure at Daiichi Sankyo. He oversees corporate clinical trial transparency/data sharing strategies and compliance activities; coordinates internal disclosure operations' training, process improvements and trial transparency policy intelligence.He holds a PhD in Clinical Chemistry from Obafemi Awolowo Univ. Ile-Ife, Nigeria, 1990 and received The Rockefeller Foundation Postdoctoral Fellowship, 1991 and National Mentor Role Model Award of Minority Access Inc/Office of Minority Health, NIH, 2001. Dr. Oyelola has over 35 years' experience in biomedical R&D, and certifications by National Registry of Certified Chemists and American Society for Clinical Pathologists

5:25 PM — 6:30 PM

Networking Reception

Day 2 Sep 24, 2024

7:30 AM — 5:00 PM

Registration

8:30 AM — 9:45 AM

Session 6: Results Reporting via CTIS and Policy 0070

Session 6: Results Reporting via CTIS and Policy 0070

Track: General Session

Session Chair(s)

Merete Joergensen, MBA, MSc

Clinical Disclosure and Transparency Expert
Merete-J Consulting, Denmark

Merete Joergensen holds an MSc in Statistics and an MBA in Management of Technology. She has more than 30 years of experience in Clinical Research. From 2004 she has been building up the area of Clinical Trials Disclosure in Novo Nordisk. She is now working as a senior specialist for the area of clinical disclosure. Prior she headed up Biostatistics in Novo Nordisk A/S for 15 years and worked 7 years as a Clinical Statistician at the medical faculty at Copenhagen University. Further she has served as Clinical Trials Transparency pillar lead, under the Clinical Research Expert Group in EFPIA.

Speaker(s)

Speaker

Representative Invited

European Medicines Agency, Netherlands

Francesca Scotti is a pharmaceutical chemist, who worked for pharmaceutical industries in the field of compliance of clinical trials. She joined EMA in 2016 first as procedure manager in the Human medicines division. In 2019, she joined the clinical trials team as a business responsible of the EudraCT database, where she particularly focused on supporting sponsors in raising their compliance with clinical trials' results posting requirements. Since the last year, she is also leading the implementation of the revised transparency rules in the CTIS public portal.

Speaker

Representative Invited

European Medicines Agency, Netherlands

Examination of Risk-Based Clinical Document Anonymization Techniques and Related Processes

Representative Invited

Real Life Sciences, United States

Approach to Clinical Trial Transparency & Disclosure is Changing – EMA's Policy 0070 is a Large Contributor

Representative Invited

Certara, Canada

With a background in Neuroscience research, and experience working with several of PharmExec's Top 10 global pharmaceutical companies, I have an extensive understanding of clinical research, regulatory standards and best practices in the field of clinical data privacy, including the anonymization of patient data, as well as confidential business information. I'm using my experiences to lead the field of science, healthcare and research into the modern age of data transparency and digital privacy.

9:45 AM — 10:30 AM

Refreshment and Networking Reception

10:30 AM — 11:45 AM

Session 7: Panel Discussion: Challenges and Complexities of Submitting CSR's via CTIS in EU, Policy 0070 in EU and Results Reporting via CTIS and the PRCI (Canada)

Session 7: Panel Discussion: Challenges and Complexities of Submitting CSR's via CTIS in EU, Policy 0070 in EU and Results Reporting via CTIS and the PRCI (Canada)

Track: General Session

Merete-J Consulting, Denmark

Merete Joergensen holds an MSc in Statistics and an MBA in Management of Technology. She has more than 30 years of experience in Clinical Research. From 2004 she has been building up the area of Clinical Trials Disclosure in Novo Nordisk. She is now working as a senior specialist for the area of clinical disclosure. Prior she headed up Biostatistics in Novo Nordisk A/S for 15 years and worked 7 years as a Clinical Statistician at the medical faculty at Copenhagen University. Further she has served as Clinical Trials Transparency pillar lead, under the Clinical Research Expert Group in EFPIA.

Speaker(s)

Speaker

Representative Invited

United States

Laura has worked in Voluntary Data Sharing since 2015. She has experience sharing data with Clinical Study Data Request, Vivli, and C-PATH. Voluntary Data Sharing requires her to interact with many functional areas to obtain approval to share and fully protect both the intellectual property rights and personal patient data found in the documents. Laura heads the DIA subgroup on EMA's Policy 0043/FOIAs, and is the subject matter expert at PRA for Public Release of Clinical Information and Policy 0070 redactions. Prior positions include writing CSRs and submission summary documents for 20 years and coordinating research studies for industry, NIH, and NCI.

11:45 AM — 12:45 PM

Networking Luncheon

12:45 PM — 2:00 PM

Session 8: Information (CCI) in Clinical Trial Applications and Documents

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Track: General Session

Senior Manager, Trial Disclosure
AbbVie, United States

Scott has over a decade of experience with clinical trial disclosure, initially working for smaller sponsors as a one-person clinical trial disclosure department, to later operating in larger organizations, serving as an expert in summary results reporting and clinical document redaction/anonymization for public disclosure. As part of implementation planning for the EU Clinical Trials Regulation, Scott is AbbVie's representative in the EMA CTIS sponsor master trainer programme.

Speaker(s)

Speaker

Representative Invited

AGES, Austria

Marianne is a medical doctor by training and joined AGES in 2008 as a pharmacovigilance assessor. She was an alternate PRAC member between 2015 and 2017. In 2017, she joined the clinical trial unit at AGES as a safety assessor and has since been part of the Clinical Trials Facilitation and Coordination Group (CTFG) group. Since 2022 she is chairing the group now called Clinical trials coordination group (CTCG). Marianne contributed to the CTFG best practice guidelines for safety assessors for clinical trials and is a member of the drafting team for the Commission implementing regulation for the cooperation in safety assessment of clinical trials.

Accelerating Clinical Trials Publication by Proactively Protecting CCI: Adapting to EU-CTIS Revised Transparency Rules

Representative Invited

MMS Holdings, India

2:05 PM — 3:20 PM

Session 9: Use of Artificial Intelligence in Clinical Trial Transparency

Session 9: Use of Artificial Intelligence in Clinical Trial Transparency

Paarlberg & Associates LLC, United States

Robert Paarlberg is Principal of Paarlberg & Associates LLC, a consultancy specializing in regulatory policy, regulatory intelligence and global clinical trial disclosure strategy and operations. Prior to founding Paarlberg & Associates LLC, Bob worked at Pharmacia (Upjohn) and UCB. Bob is former Chair of DIA's Clinical Trial Disclosure Community. Bob has more than 40 years of pharmaceutical industry experience with the vast majority of his experience in US and international regulatory affairs. Bob has been active in the clinical trial disclosure and transparency space since 2005.

Speaker(s)

Leveraging AI Agents to Enhance Clinical Trial Transparency and Efficiency

Representative Invited

Xogene, United States

Woo Song is a co-founder of Xogene Services LLC, a leader in innovative solutions for clinical transparency. Prior to Xogene, Woo co-founded Intrasphere Technologies, Inc., a technology and services provider to the biopharmaceutical industry, which was acquired by Deloitte Consulting in 2011. While at Intrasphere, Woo created PharmaCM, a leading clinical disclosure platform, now owned by TrialScope. A former derivatives trader, Woo is also a founder of Reval, a Software-as-a-Service platform for treasury and risk management with over 650 corporate clients globally. Reval was sold to Ion Investment Group in 2016.

Patient and Public Perceptions on the Use of AI in Creating Clinical Trial Documents

Representative Invited

CISCRP, United States

Modernizing the BMS PLS process, accelerating with AI support

Representative Invited

Bristol-Myers Squibb, United States

3:20 PM — 3:30 PM

3:30 PM — 3:30 PM

Conference Adjourns