Westin Arlington

Sep 23, 2024 7:30 AM - Sep 24, 2024 3:30 PM

801 North Glebe Road, Arlington, VA 22203

Global Clinical Trial Disclosure and Data Transparency Conference

Untangle the complexities of global disclosure practices, learn about recent regulatory modernization, and discuss cross-regional strategic considerations.

Print Agenda

Day 1 Sep 23, 2024

7:30 AM — 5:00 PM — Ballroom Foyer

Conference Registration

7:30 AM — 8:30 AM — Ballroom Foyer

Networking Breakfast

8:30 AM — 8:45 AM — F. Scott Fitzgerald Ballroom CDE

Opening Remarks

Track: General Session

Session Chair(s)

Sorcha McCrohan, MS

Scientific Projects Manager
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 F. Scott Fitzgerald Ballroom CDE

Session 1: Increase Value of Publicly Disclosed Clinical Trial Information

The focus of this session is to discuss how companies and regulators can increase the value of trial information being communicated to clinical trial participants and the public. There are ongoing efforts to enhance the end user experience with public registries and sponsor organizations have started piloting returning individual data to trial participants.

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

- Measure the value of registration and results information to clinical trial participants and the public
- Apply existing solutions to implement processes for returning individual participant level data
- Discuss the impact on the modernization efforts to the public's experience with ClinicalTrials.gov information

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?

Zack Fey

Manager, Medical Writing
CISCRP, United States

Zack Fey is a manager on the medical writing team at CISCRP, an organization widely recognized as a pioneer in the field of plain language clinical trial results summaries. Through innovative practices and a deep commitment to patient-centered communication, CISCRP has been instrumental in setting the standard for plain language summaries, shaping industry guidelines, and promoting clinical trial transparency. Zack helps lead a talented team of writers that work together to create plain language results summaries, protocol synopses, and other patient education materials. Since early 2024, Zack has also been guiding a CISCRP and industry collaboration to assess and leverage AI-enabled approaches in patient communication.

Enabling Individual Participant Data Return (iPDR)

Jean Sposaro, MHS, LLM

Director, Global Drug Development Operations, Industry Collaborations
Bristol-Myers Squibb Company, United States

Healthcare Provider, Researcher, Patient Advocate, Bioethics, Pharmaceutical Law & Policy Professional advancing science through impactful collaboration with stakeholders across the R&D ecosystem to "co-create a healthier future". Optimizing global collaborations as enablers of innovation, inclusion, health equity and access. Never compromising scientific integrity, patient safety, confidentiality, privacy or quality to ensure a future where patients can access clinical research at their point of care, are provided more personalized and flexible options to access their health data and enables more informed decision making.

Update on ClinicalTrials.gov Modernization Effort

Stacey Arnold, PhD

Results Team Subject Matter Expert

National Institutes of Health (NIH), United States

Dr. Arnold is a staff scientist at the National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health in Bethesda, MD, and a results subject matter expert for ClinicalTrials.gov. She is participating in efforts to modernize the ClinicalTrials.gov website and the Protocol Registration and Results System (PRS) database. She also contributes to the development of educational materials and trainings intended to facilitate the successful completion of results submissions to ClinicalTrials.gov. She received her PhD in Biological Chemistry from the University of Michigan, Ann Arbor, and conducted post-doctoral research at the Institute of Genetic Medicine at Johns Hopkins in Baltimore, MD.

10:00 AM — 10:30 AM Ballroom Foyer

Refreshment and Networking Break

10:30 AM — 12:00 PM F. Scott Fitzgerald Ballroom CDE

Session 2: EU Clinical Trials Information System (CTIS)

The implementation of the revised transparency rules on June 18th 2024 removed all deferrals in CTIS, immediately making public thousands of clinical trials, but limited to structured data only. Beginning June 18th 2024, applications submitted in CTIS lead to publication of study documents, but with different publication rules for historical and non-historical trials. This session brings together sponsor experiences navigating these challenges with experts on the operational details of CTIS for discussions on best practices under the new transparency rules.

Learning Objective :

- Explain how CTIS will disclose documents for historical trials and non-historical trials
- Recognize how the same action in CTIS can produce different publication behaviors
- Develop best practices for sponsors to plan SM, NSMs and AMSC applications with transparency considerations in mind
- Understand how operational details in CTIS impact public disclosure for both applications and summary results

Track: General Session

Session Chair(s)

Scott Feiner

Senior Manager, Trial Disclosure
AbbVie, United States

Scott has 15 years 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. Scott is designated as a CTIS subject matter expert by the EMA and serves as EuropaBio representative for the EU Clinical Trials Regulation.

Speaker(s)

Speaker

Christopher Pfitzer, MA

Head of Clinical Trial Transparency Strategy
Biogen, United States

Christopher Pfitzer is the Head of Clinical Trial Transparency Strategy at Biogen where he oversees all plain language and disclosure activities. 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 pharma, Chris worked extensively with healthcare and nonprofit organizations supporting policy and communications activities.

Speaker

Ruediger Pankow, DrSc

Clinical Regulatory Affairs Expert, CTIS SME
Independent Consultant, Germany

Ruediger Pankow holds a university degree in Biology and is a Regulatory Affairs professional with more than 17 years of experience in the clinical research and trials regulatory space, mostly in the CRO industry. His specific area of expertise is the EU Clinical Trials Regulation 536/2014 (EU CTR) and EU CTR implementation at industry level, including for his past employer Parexel. Since 2019 he has been continuously involved for ACRO as an industry stakeholders' representative (sponsor product owner / external SME) in EMA's Clinical Trial Information System (CTIS) delivery project, and is DIA instructor of EMA's CTIS sponsor end user training programme.

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

Stuart Donald, PhD

Co-CEO
Krystelis Ltd., United Kingdom

Stuart holds a First-Class Honours degree in Pharmacology and a PhD in Cardiovascular Pharmacology. His extensive experience in the UK and USA spans academic research, pharmaceutical project and portfolio management, management consultancy, and executive roles in contract research organisations, reaching board level. Stuart is passionate about building environments where individuals and teams can thrive and achieve their full potential.

Speaker

Representative Invited

European Medicines Agency, Netherlands

Francesca Scotti is a pharmaceutical chemist, who worked for pharmaceutical industries before joining EMA in 2016, as a procedure manager in the Human medicines division. In 2019 she joined the clinical trials team, becoming first the business responsible of the EudraCT database, and then taking the lead of the implementation of the revised CTIS transparency rules in the new CTIS public portal, which was launched in June 2024.

12:00 PM — 1:00 PM Ballroom Foyer

Networking Luncheon

1:00 PM — 2:15 PM F. Scott Fitzgerald Ballroom CDE

Session 3: Global Perspectives on Disclosure

The focus of this session is to consider the ever-changing clinical trials disclosure and transparency requirements in a global perspective. How trial sponsors can stay aware of the requirements from all countries and regions where they conduct clinical research and market products. Strategic considerations and questions to consider for trial sponsors in order to meet global clinical trials transparency requirements will be shared.

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

- Recognize how and where to find sources for global clinical trials transparency requirements
- Appraise and evaluate the transparency requirements in global perspective
- Integrate experience from different sponsor organizations approach to strategic considerations for clinical research

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 A/S. She is now working as independent Clinical trials transparency expert. 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)

What in the World is Going on? Navigating Evolving Disclosure Mandates

Thomas Wicks, MBA

Head of Transparency Operations
Citeline, United States

Thomas Wicks is an experienced strategic leader with over 20 years in life sciences. As Head of Transparency Operations at Citeline, he spearheads strategy for TrialScope's industry-leading disclosure solutions. Thomas is an established thought leader, having spoken at over 60 conferences and authored over 40 publications on disclosure requirements and transparency trends. Thomas is motivated by empowering teams to accelerate solutions that honor trial participants through transparency.

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

Lora Killian, MBA

Clinical Trial Transparency and Disclosure Lead
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.

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

Julie Holtzople

President
Holtzople Consulting, United States

Julie Holtzople is a seasoned Clinical Trial Transparency professional. She spent 10 years building Clinical Transparency and Data Sharing at AstraZeneca, becoming an expert in Plain Language Summaries, Clinical Document Anonymization and Clinical Data Sharing. She also led the implementation and readiness for EU CTR Transparency requirements. Julie has been an active member of numerous CTT working groups and organizations contributing to CTT standards and best practices. Prior to AstraZeneca, she started her career as a management consultant working at Ernst & Young and then Booz Allen. Julie has recently returned to consulting as an independent. She specializes in Clinical Trial Transparency, process optimization and program delivery.

2:20 PM — 3:20 PM F. Scott Fitzgerald Ballroom CDE

Session 4: Enforcement Initiatives by FDA and a UK Research Funding Agency

Sponsors are required to register and report results of clinical trials according to regional laws and regulations. This session will focus on the enforcement initiatives by health authorities to ensure that sponsors are complying with clinical trial data disclosure requirements, while also highlighting the legal consequences of non-compliance. Note: Rachel Knowles will be participating virtually

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

- Describe the initiatives health authorities are taking to encourage compliance
- Understand the potential civil and monetary penalties for non-compliance

Track: General Session

Session Chair(s)

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.

Speaker(s)

ClinicalTrials.gov: Meeting FDA Registration and Reporting Requirements

Representative Invited

FDA, United States

Dr. Laurie Muldowney serves as the Deputy Director of the Office of Scientific Investigations (OSI) in the Center for Drug Evaluation and Research (CDER) at the U.S. FDA. In this role, she manages the development and implementation of patient focused, risk-based inspection, compliance, and enforcement activities under the Agency Bioresearch Monitoring Program. Before joining OSI in 2019, Dr. Muldowney served in multiple positions across CDER, including clinical team leader with the Office of New Drugs and associate director for medical policy in the Office of Translational Science. Dr. Muldowney received a B.S. in chemistry from the College of William and Mary and earned her medical doctorate from Jefferson Medical College.

Compliance with Funder Requirements for Clinical Trials Transparency

Rachel Knowles

Lead for Clinical Research Policy, Ethics and Government
Medical Research Council, United Kingdom

3:20 PM — 4:00 PM

Ballroom Foyer

Refreshment and Networking Break

3:25 PM — 3:55 PM

F. Scott Fitzgerald Ballroom B

Exhibitor Event: Case Study Spotlight hosted by TrialAssure

We will explore the effectiveness of TrialAssure ANONYMIZE® 3.0 to perform data, document, and image anonymization and redaction using machine learning (ML), natural language processing (NLP), and artificial intelligence (AI) to protect patient and company confidential information. The tool automates anonymization, balancing the need for data privacy while maintaining the utility of the data. ANONYMIZE reduces the time and effort required for data preparation and minimizes re-identification risks, supporting both regulatory compliance and the integrity of clinical research. TrialAssure ANONYMIZE 3.0 gives users the ability to anonymize PDFs and other document types, including emails and Microsoft Office documents (Word, Excel, and PowerPoint). For data, ANONYMIZE 3.0 supports SAS, XPT, Excel, and CSV file formats.

Learning Objective : Featured Topics:

- AI
- Anonymization
- CCI
- EU CTR/CTIS

Track: Exhibitor Case Study

Session Chair(s)

Sponsored Sessions

United States

EXHIBITOR

Speaker(s)

The Role in AI Safeguarding Privacy and Confidential Company Information (CCI)

Zach Weingarden, MS

Director, Product Solutions
TrialAssure, United States

Zach Weingarden is a Product Solutions Manager in Project and Account Management with over eight years of project management experience, currently leading the design and implementation of the TrialAssure Disclosure Management System. He has experience across a wide range of sponsors focusing in all areas of clinical trial transparency, including registry disclosure, plain language summaries, document redaction, and data anonymization. Mr. Weingarden holds a Master of Science in Biomedical Engineering, concentrating in Biotechnology, and a Bachelor of Science in Industrial and Operations Engineering from the University of Michigan.

4:00 PM — 5:25 PM F. Scott Fitzgerald Ballroom CDE

Session 5: Clarity in Clinical Trials

This comprehensive session explores the critical role of Plain Language Summaries (PLS) in clinical trial disclosure, addressing the EU CTR requirement and global best practices. Attendees will gain insights into developing effective summaries that adhere to health literacy principles, navigate regulatory requirements, and overcome common challenges in the field. The session will also delve into the value of plain language writing in clinical research operations and explore the patient perspective plain-language summaries.

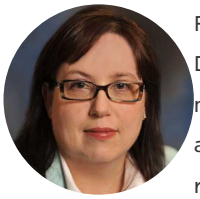
Learning Objective :

- Develop a toolkit of industry-proven strategies for crafting Plain Language Summaries (PLS)
- Explain key challenges in maintaining consistency and protecting participant privacy when reporting clinical trial endpoints and safety data in plain language formats
- Identify and evaluate the primary sources where patients find and access clinical trial information

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 stakeholders – including sponsors, investigators, regulators, and transparency and patient advocates – to help align the goals and expectations of these groups, as well as help identify more consistent ways sponsors can meet industry standards. Prior to her current role, Francine served as Director of Product Management at TrialScope.

Speaker(s)

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

Oladayo Oyelola, PhD

SENIOR DIRECTOR and HEAD GLOBAL CLINICAL TRIAL INFORMATION DISCLOSURE
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

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

Maureen Kashuba, BSN

Assoc. Director, Plain Language Summaries Program Lead
Merck Sharp & Dohme LLC, United States

Maureen Kashuba has over 20 years of Pharma experience. She leads the Plain Language Summary (PLS) program at Merck Sharp & Dohme LLC, United States. She led the development of the company's > 1250 term Health Literate Glossary which has been reviewed, tested for cultural competency and approved for use internally. She's led Patient Panel and Cultural Competency reviews to engage diverse insights on terms and concepts. Maureen co-chairs the DIA PLS Working Group is a member of the MRCT Center Glossary Development Review Team and the EFPIA CREG joint subteam on patient friendly language. She is passionate about clear communication of research information to empower patients to make informed health choices for themselves and their families.

PLS Strategies That Work for Patients, Sites, & Sponsors

Deborah Collyar

President
Patient Advocates In Research (PAIR), United States

Deborah Collyar is founder and president of Patient Advocates in Research (PAIR), “where research meets reality.” Her leadership in patient engagement and advocacy started in the 1990s after her first cancer diagnosis. She applies business leadership, IT, communication and strategic skills to bridge gaps between scientists, medical providers, payers, governments, and patients. Deborah has vast research experience in translational, clinical, epidemiology, health outcomes, and health delivery fields while working with academia, federal agencies, companies, non-profits, and patient communities. Key patient insights are delivered throughout development, clinical trials, results reporting, data-sharing, standards, genomics, and into practice.

5:25 PM — 6:30 PM Ballroom Foyer

Networking and Poster Reception

Day 2 Sep 24, 2024

8:00 AM — 8:30 AM Ballroom Foyer

Networking Breakfast

8:00 AM — 5:00 PM Ballroom Foyer

Registration

8:30 AM — 9:45 AM F. Scott Fitzgerald Ballroom CDE

Session 6: Results Reporting according to EU Clinical Trials Regulation

The EU Clinical Trials Regulation defines requirements for submission and disclosure of summaries of results of clinical trials for trials conducted according to the EU Clinical Trials Regulation. For the Clinical Study For trialreports used in a MAA that meet one or more of the three sets of requirements, this double session aims at presenting and clarifying how these requirements overlap, where they differ, and how they interact. The mutual recognition of submissions between EU and Canada has the benefit of having same documents made public at both places. How will the processes be impacted when the CSR is going to be made public via CTIS. Note: Marianne Luzner, Elizabeth Lieu, and Radu Popescu and will be participating virtually

Learning Objective :

- Obtain knowledge of the most recent changes in the requirements for clinical trials result summaries disclosure in EU
- Appraise similarities and differences in the three different sets of disclosure requirements for the Clinical Study Report (EU Clinical Trials Regulation, EU Policy 0070 and Health Canada's Public Release of Clinical Information)

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 A/S. She is now working as independent Clinical trials transparency expert. 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)

Requirements in CTIS for Results Summaries, Lay Summaries and Interim Results, and CSRs Submissions

Marianne Lunzer, DrMed

Assessor, Dept of Clinical Trials, Federal Office for Safety in Health Care
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.

Health Canada’s Public release of clinical Information (PRCI) and collaboration with EMA

Elizabeth Lieu

Senior Regulatory Affairs Officer
Health Canada, Canada

Main Differences between CSR Submission in CTIS and Policy 0070

Representative Invited

European Medicines Agency, Netherlands

Radu Popescu has been with the European Medicines Agency (EMA) for more than 10 years and worked in various positions. Currently, he is a member of the Documents Access and Publication Service. Following the completion of his medical training he was attracted by clinical research. He worked for several CROs before joining the EMA. His career path followed the clinical data trail from its source (the research centre) to where the final review is performed (the regulator). He had the opportunity to work in several countries: Romania his home country, Sweden, The UK and now The Netherlands. This path satisfied his quest for new challenges and allowed him to experience the multiple connotations of the EU motto: ‘United in Diversity’.

9:45 AM — 10:30 AM Ballroom Foyer

Refreshment and Networking Reception

10:30 AM — 11:45 AM F. Scott Fitzgerald Ballroom CDE

Session 7: Continuation of Session 6: Results Reporting according to EU Clinical Trials Regulation

In continuation of the Session 6 on Results Reporting via CTIS (EU), Policy 0070 (EU) and PRCI (Canada) this Session aims to provide further information such as visions for future collaboration, and mutual collaboration for ensuring harmonized documents being made available. For the panel discussion central representatives from Regulators in EU and Canada, from sponsor organizations and CROs aims to give ample opportunities for asking questions. Note: Marianne Luzner, Elizabeth Lieu, and Radu Popescu and will be participating virtually

Learning Objective :

- Recognize the value and opportunities in visions for increased collaboration and mutual recognition of same documents for disclosure via different platforms
- Express your views on opportunities and challenges in relation to the current experience with Policy 0070 and the PRCI
- Ask your questions and obtain clarification from Regulators and Sponsor organizations

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 A/S. She is now working as independent Clinical trials transparency expert. 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.

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.

Speaker(s)

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

Honz Slipka, MSc

Senior Transparency Specialist
Certara, Canada

With a background in neuroscience, and experience working with health information technology, I have a thorough understanding of health data management, global regulatory standards, and best practices in the field of clinical data privacy. I lead and manage a portfolio of global pharmaceutical companies and strive for innovation by leading

the field of science, healthcare, and research into the modern age of technological efficiency, clinical transparency, and data utility.

Redacted Document Challenges. / Panelist.

Laura Dodd, MSc

Director, Clinical Trial Transparency
Instem, United States

Laura Dodd is the Director of Clinical Trial Transparency at Instem. Laura heads the DIA subgroup on EMA's Policy 0043/FOIAs, which also covers redactions needed for Policy 0070 and Health Canada's Public Release of Clinical Information. Laura started working in Data Sharing in 2014, which quickly required her to interact with many functional areas to obtain internal sponsor approval to share AND to fully protect both the intellectual property rights and protected personal data found in the documents. Prior positions include writing CSRs and submission summary documents for 20 years and coordinating research studies for industry, NIH, and the National Cancer Institute.

Panel Discussion: Addressing questions in relation to Requirements, Challenges & Complexities of Submitting Results Summaries, CSR's via CTIS, Policy 0070 EU, and the PRCI (Canada)

Francesca Scotti

CTIS Transparency Lead
European Medicines Agency, Netherlands

Francesca Scotti is a pharmaceutical chemist, who worked for pharmaceutical industries before joining EMA in 2016, as a procedure manager in the Human medicines division. In 2019 she joined the clinical trials team, becoming first the business responsible of the EudraCT database, and then taking the lead of the implementation of the revised CTIS transparency rules in the new CTIS public portal, which was launched in June 2024.

Panel Discussion: Addressing questions in relation to Requirements, Challenges & Complexities of Submitting Results Summaries, CSR's via CTIS, Policy 0070 EU, and the PRCI (Canada)

Radu Popescu, MD

Scientific Administrator
European Medicines Agency, Netherlands

Radu Popescu has been with the European Medicines Agency (EMA) for more than 10 years and worked in various positions. Currently, he is a member of the Documents Access and Publication Service. Following the completion of

his medical training he was attracted by clinical research. He worked for several CROs before joining the EMA. His career path followed the clinical data trail from its source (the research centre) to where the final review is performed (the regulator). He had the opportunity to work in several countries: Romania his home country, Sweden, The UK and now The Netherlands. This path satisfied his quest for new challenges and allowed him to experience the multiple connotations of the EU motto: 'United in Diversity'.

Panel Discussion: Addressing questions in relation to Requirements, Challenges & Complexities of Submitting Results Summaries, CSR's via CTIS, Policy 0070 EU, and the PRCI (Canada)

Elizabeth Lieu

Senior Regulatory Affairs Officer
Health Canada, Canada

Panel Discussion: Addressing questions in relation to Requirements, Challenges & Complexities of Submitting Results Summaries, CSR's via CTIS, Policy 0070 EU, and the PRCI (Canada)

Marianne Lunzer, DrMed

Assessor, Dept of Clinical Trials, Federal Office for Safety in Health Care
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.

11:45 AM — 12:45 PM Ballroom Foyer

Networking Luncheon

12:45 PM — 2:00 PM F. Scott Fitzgerald Ballroom CDE

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

While the EMA has provided updated guidance on the protection of CCI in CTIS, it is Member States that assess applications and raise RFIs on redactions and sponsor justifications to protect CCI. This session will cover both sponsor approaches to protecting CCI and Member States assessment of these approaches. Special considerations for protecting CCI in Complex Clinical Trials, Pre-CTA advice from Member States, and Interim CSRs will be discussed. Note: Marianne Lunzer and Silvia Garrido-Lestache will be participating virtually

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

- Prepare applications that protect CCI
- Explain the publication of dosing information in the EU
- Anticipate the special considerations of Complete Clinical Trials and Interim CSRs
- Plan CCI protection approaches in line with Member State expectations

Track: General Session

Session Chair(s)

Scott Feiner

Senior Manager, Trial Disclosure
AbbVie, United States

Scott has 15 years 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. Scott is designated as a CTIS subject matter expert by the EMA and serves as EuropaBio representative for the EU Clinical Trials Regulation.

Speaker(s)

Speaker

Marianne Lunzer, DrMed

Assessor, Dept of Clinical Trials, Federal Office for Safety in Health Care
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.

Speaker

Silvia Angela Garrido-Lestache, MSc

Clinical Data Publication Manager, Transparency Department
EMA, Netherlands

Clinical Data Publication Officer in the Transparency team at the European Medicines Agency. Silvia started to work in Glaxo Wellcome as clinical trial monitor before moving into international clinical development research as clinical research manager in GlaxoSmithKline. Since joining EMA in 2002, she has fulfilled several positions, initially as project manager for centralised marketing authorisations applications in a wide range of therapeutic areas. Thereafter, I joined the Transparency department first as an Access to Documents manager and since 2016 as Clinical Data Publication Officer.

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

Raina Agarwal, MPharm

Associate Director, Clinical Trial Disclosure and Transparency
MMS Holdings Pvt Ltd., India

Raina Agarwal holds 15+ years of experience in Clinical Trial Transparency and Disclosure Domain. She is working as Associate Director, Transparency, at MMS holdings and specializes in anonymization of regulatory packages for EU-CTR, EMA P0070 and HC-PRCI submissions. Raina is hands-on with disclosure regulations for US, EU, and several international registries. Raina has continuously involved in developing and reviewing standard operating procedures, work-instructions, quality checklists for transparency, templates for clinical documents, deploying of automated technology platforms for anonymization of documents. Raina is a strong advocate of cross-functional integration for successful implementation of transparency requirements.

2:05 PM — 3:20 PM F. Scott Fitzgerald Ballroom CDE

Session 9: Use of Artificial Intelligence in Clinical Trial Transparency

Artificial Intelligence (AI) is having a major impact on life sciences. Its ability to process vast quantities of data and information faster than humans has numerous valuable applications in the sector, from creating new drugs and targets, to preparing documents for regulatory submissions to health authorities. This session will explore the use of leveraging AI in creating documents, using AI to modernize the Plain Language Summary process, and hearing about patient and public perceptions on the use of AI in crating clinical trial documents.

Learning Objective :

- Understand how AI agents can automate mundane tasks in clinical trial documentation and disclosure
- Identify opportunities for implementing AI agents in clinical trial transparency processes

- Explore the integration of AI technology into the PLS writing process
- Describe patient and public perceptions and preference on the use of AI to create plain language clinical trial documents

Session Chair(s)

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.

Speaker(s)

Leveraging AI Agents to Enhance Clinical Trial Transparency and Efficiency

Woo Song

Co-Founder
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 Citeline. 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.

Modernizing the BMS PLS Process, Accelerating with AI Support

Lauren Haggerty

Clinical Trial Manager II
Bristol-Myers Squibb, United States

Lauren Haggerty brings nearly a decade of experience in the pharmaceutical industry to her role as a Clinical Trial Manager at Bristol Myers Squibb. In this capacity, she oversees global trial disclosure and ensures compliance with data transparency regulations. Lauren specializes the production of Plain Language Summaries and the disclosure of clinical trial results. She holds a Bachelor of Arts degree from Villanova University.

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

Zack Fey

Manager, Medical Writing
CISCRP, United States

Zack Fey is a manager on the medical writing team at CISCRP, an organization widely recognized as a pioneer in the field of plain language clinical trial results summaries. Through innovative practices and a deep commitment to patient-centered communication, CISCRP has been instrumental in setting the standard for plain language summaries, shaping industry guidelines, and promoting clinical trial transparency. Zack helps lead a talented team of writers that work together to create plain language results summaries, protocol synopses, and other patient education materials. Since early 2024, Zack has also been guiding a CISCRP and industry collaboration to assess and leverage AI-enabled approaches in patient communication.

3:20 PM — 3:30 PM F. Scott Fitzgerald Ballroom CDE

Closing Remarks

Speaker(s)

Sorcha McCrohan, MS

Scientific Projects Manager
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
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3:30 PM — 3:30 PM

Conference Adjourns