DIA Global Clinical Trial Disclosure and Data Transparency Conference

This virtual live conference is a must-attend for anyone involved in clinical trials!

Dec 05, 2023 1:30 PM – Dec 07, 2023 5:00 PM

Virtual

REGISTER

Print Agenda

Day 1 Dec 05, 2023

1:30 PM — 1:45 PM

Welcome and Introduction by DIA

1:45 PM — 2:00 PM

Opening Keynote

2:00 PM — 3:00 PM

Session 1: Current Developments in Clinical Trial Disclosure - Europe

In March 2023 the UK MHRA announced that it will streamline clinical trial approvals in the biggest overhaul of trial regulation in 20 years. Learn about the latest developments regarding the new legal framework, new clinical trial

disclosure requirements, and new comprehensive guidance to accompany the new legislative measures.

The implementation of EUDAMED in the context of the EU MDR has been delayed, with the new go-live date expected in Q2 2024. Mandatory use of the database will begin in Q4 2024 for registration, clinical investigations, performance studies, vigilance and post-market surveillance. Hear the latest updates on EUDAMED's Clinical Investigations and Performance Studies module and the related transparency aspects.

Session Chair(s)

Matthias Zerm, PhD

Lead Expert, Clinical Trial Disclosure and R&D Processes
Merz Therapeutics Gmbh, Germany

Matthias Zerm is a Lead Expert Clinical Trial Disclosure and R&D Processes at Merz Therapeutics located in Frankfurt/Germany. In this role he coordinates and oversees all clinical trial disclosure activities including registration and results submissions. He is also involved in a wide range of organizational and process-related projects at Merz Therapeutics, such as preparing for the EU-CTR. He is a biologist by training and has >15 years of global experience in the clinical research arena.

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)

EU MDR CIPS Module - An Update

Joyce Swart

Clinical Disclosure Lead
Alcon Research, LLC, United States

Joyce Swart is the Clinical Disclosure Lead at Alcon Research, LLC, a major eye care device company operating in the global marketplace. For over 10 years she has been responsible for understanding disclosure requirements specific to medical device trials, developing disclosure practices and processes for companywide implementation, and overseeing the registration of medical device trials on ClinicalTrials.gov and other public registries. She is also skilled in registering drug studies and posting results on ClinicalTrials.gov and EudraCT. Joyce received her B.S. from Rutgers University, New Brunswick, New Jersey.

UK Update

Speaker Invited

United Kingdom

3:00 PM — 3:30 PM

Coffee Break

3:30 PM — 4:30 PM

Session 2: Current Developments in Clinical Trial Disclosure

The National Library of Medicine (NLM) previously launched an effort to modernize ClinicalTrials.gov to deliver an improved user experience on an updated platform that will accommodate growth and enhance efficiency. Hear from ClinicalTrials,gov about the latest updates on the Modernization initiative.

In February 2023 Health Canada announced a public consultation on 'Registration of Clinical Trials and Public Disclosure of Results: Draft Guidance and Public Search Portal'. Hear from Health Canada regarding the latest developments on this initiative as well as an update on Health Canada's Proactive Release of Clinical Information which entered into its last stage in March 2023 (now including all NDS, SNDS, ANDS, SANDS + Class III & IV devices).

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Speaker(s)

CTgov Update

Anna Fine, PharmD, MS

Interim Director for ClinicalTrials.gov
National Institutes of Health (NIH), United States

Dr. Anna M. Fine joined the National Library of Medicine, NIH in 2018 and is Acting Director of CinicalTrials.gov. She leads the scientific, policy, regulatory and outreach activities related to the operation of ClinicalTrials.gov, including the modernization initiative. Her previous experience includes over a decade of service in stakeholder engagement, adverse drug event reporting, and supervisory roles at the U.S. Food and Drug Administration. Prior to that, she was Chief of Pharmacy Services at Hanscom Air Force Base in Massachusetts. Dr. Fine has a PharmD from Northeastern Univ. and an MS in psychopharmacology from William James College. She completed a postgraduate year two drug information residency at Stanford Hospital.

Speaker Invited

China

4:30 PM — 5:00 PM

Coffee Break

5:00 PM — 6:00 PM

Session 3: European Health Data Space: What you need to know

This session is an opportunity for you to learn about the EUs vision for and status of the European Health Data Space (EHDS). What are the legal issues to take into account? How will this regulation impact protection of Personal Data and Commercially Confidential Information? This session will provide answers to these questions and more. You will have the

opportunity to submit your own questions as well. Questions can be submitted in advance or during the session. The option to submit questions anonymously will be available.

Session Chair(s)

Merete Joergensen, MBA, MSc

Clinical Disclosure and Transparency Expert, Former EFPIA, CREG Clinical Trials
Merete-J Consulting CVR: 34920818, 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 is Clinical Trials Transparency pillar lead, under the Clinical Research Expert Group in EFPIA.

Lora Killian, MBA

Clinical Trial Transparency and Disclosure Lead
Pfizer Inc, 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.

Speaker(s)

European Health Data Space Overview

Kristof Van Quathem

Data Protection Advisor
Covington and Burling, Belgium

EFPIA's EHDS Advocacy Efforts: secondary use of health data

Thomas Brookland, MSc

EU Data and AI Policy Lead
F. Hoffmann-La Roche Ltd, Switzerland

Thomas (Tom) Brookland has worked in the Pharma industry for the last 15 years, combining interests in regulatory science, health technology and policy research. He joined Hoffmann La Roche in 2008 and in this time has held

multiple roles within regulatory product development across molecules and therapeutic areas, in addition to globally and regionally focused policy lead roles in the emerging areas of RWD/RWE, big data, digital health and AI/ML. His current work and passion is focused on strategy and external engagement in the European policy landscape for data, digital and AI, supporting the development of new policy options as the convergence of medical knowledge, technology and data science is revolutionising patient care.

EHDS from a Disclosure Perspective

Julie G. Holtzople

Senior Director Clinical Transparency and Data Sharing
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.

Day 2 Dec 06, 2023

1:30 PM — 1:40 PM

Introduction and Welcome from DIA

1:40 PM — 2:40 PM

Session 4: CTIS with One Transition Year Ahead: The new and final EU CTR transparency implementation

Overview of the July 2023 EMA Guidance document on how to approach the protection personal data (PPD) and commercial confidential information (CCI) in CTIS by EMA, with updates from Member States and Ethics Committees perspective on the implementation of this latest guidance.

Session Chair(s)

Scott Feiner

Senior Manager, Clinical Records Management, Strategic Clinical Operations
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.

Ruediger Pankow, DrSc

Regulatory Affairs Expert, CTIS SME and PO
Germany

Ruediger Pankow joined Parexel in 2007 in Regulatory Consulting. He is Principal Consultant Regulatory Affairs in the clinical trials regulatory service leadership with responsibility for regulatory process, compliance and policy. As Industry Associations liaison he supports stakeholder initiatives with EU Regulators and EMA on implementation of the EU Clinical Trials Regulation, since 2019 as Sponsor Product Owner in the EMA Clinical Trials Information System (CTIS) delivery project and as EMA/DIA CTIS sponsor user trainer. Ruediger obtained a university degree in Biology in 1995, holds a scientific doctorate degree and was a post-doctoral research scientist prior to joining the CRO business in 2007.

Speaker(s)

Opening

Laura Pioppo

Scientific Administrator, CTIS expert
European Medicines Agency, Netherlands

Laura qualified as pharmacist before joining the EMA in 2009 in the Compliance and Inspection Department where she was responsible for the coordination and follow up of GCP and Pharmacovigilance inspections requested by CHMP. Since 2017 she has been working on the development of the Clinical Trial Information system (CTIS), defining and testing the system functionalities in collaboration with the MS and sponsors product owners and the European Commission.

Member States /CA Perspective

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.

2:40 PM — 3:00 PM

Coffee Break

3:00 PM — 4:00 PM

Session 5: CTIS with One Transition Year Ahead: Sponsor End User Operational and Disclosure Aspects

This session provides general experiences with new trials but also with transition trials on the operational use of the system. Views from commercial and academic sponsors, CROs as well as from the Member States perspective will be shared and discussed.

Session Chair(s)

Scott Feiner

Senior Manager, Clinical Records Management, Strategic Clinical Operations
AbbVie, United States

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Speaker(s)

Opening: How is CTIS doing after 2 Years?

European Medicines Agency Speaker Invited

European Medicines Agency, Netherlands

Industry Perspective

Gabriella Di Matteo

Director CTRO Team Manager
Pfizer, Belgium

Working in Early Clinical Research for more than 25 years, and leading the implementation of the CT Directive and Belgian law on Clinical Trials for the Pfizer Clinical Research Unit (Brussels) as Regulatory Manager. Member of Pfizer internal workstreams on EU CTR and active tester of the portal since UAT 1 in early 2016. Currently Global Clinical Trial Application Submission Manager in Pfizer Global Regulatory Operations, managing submissions in various European countries as well as outside Europe. Strong advocate of the EU CTR and its portal.

CRO Experience

Fatima Pimentel

Director, Regulatory Consulting
Syneos Health, Spain

Fatima Pimentel joined Syneos Health in 2021 as an Associate Director, Site Start-Up & Regulatory and is also responsible for the training and development of the new CTIS Portal Team. She worked as a Regulator in the Portuguese Agency INFARMED, I.P, between 2005-2021 in the Clinical Trial Unit, as a senior CT coordinator. Fatima was part of several EMA CT groups as well as CTFG. Fátima studied Industrial Pharmacy and obtained a POS-degree in Clinical trials Monitoring. Joining the EMA-CTIS project almost from start as a MS Product Owner and master trainer. Currently she is a trainer in the EMA/DIA CTIS sponsor trainings.

Academia Perspective

Andrea Seidel-Glaetzer, MA, RN

Head of Project Management
Coordination Centre For Clinical Trials Heidelberg (KKS), Germany

Prior to joining the University Hospital Heidelberg (KKS) 10 years ago, she gained some years' experience in the pharmaceutical industry. KKS acts with more than 80 staff members as a kind of CRO and provides services to support mainly investigator initiated clinical trials in academic institutions, but also for smaller industries. Since March 2020 Andrea joins EMA´s Clinical Trial Information System testing as a representative of the academia on behalf of the German KKS-Network. This is an association of 26 clinical trial centers, all located at medical faculties and university hospitals with the common task to strengthen activities in clinical trials.

CA Experience – As panelist

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.

4:00 PM — 4:15 PM

Coffee Break

4:15 PM — 5:15 PM

Session 6: IMPD-Q Only Trials : Operational and Disclosure Aspects

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Speaker(s)

Sponsor Experience Considerations in CTIS

Invited Speaker

Switzerland

IMPD-Q Owner Experience

Raquel Vaquer Pérez

EU CTR implementation lead
Bristol-Myers Squibb, Belgium

5:15 PM — 5:30 PM

Coffee Break

5:30 PM — 6:30 PM

Session 7: Transitional Trials: less than a year to get it done!

In case your company has ongoing trials in scope for transition, now is the time to start considering how and when to get it done. To ensure trials can continue under the regulation the transition must be completed before end of January 2025 I.e. expected latest submission September 2024. Presentations cover practical examples of transitions completed. What obstacles have sponsors/CROs met and what is important to consider when planning and performing the transitions. Use your option to ask questions directly to those who have tried it and maybe join and contribute your own experience.

Session Chair(s)

Matthias Zerm, PhD

Lead Expert, Clinical Trial Disclosure and R&D Processes
Merz Therapeutics Gmbh, Germany

Matthias Zerm is a Lead Expert Clinical Trial Disclosure and R&D Processes at Merz Therapeutics located in Frankfurt/Germany. In this role he coordinates and oversees all clinical trial disclosure activities including registration and results submissions. He is also involved in a wide range of organizational and process-related projects at Merz Therapeutics, such as preparing for the EU-CTR. He is a biologist by training and has >15 years of global experience in the clinical research arena.

Merete Joergensen, MBA, MSc

Clinical Disclosure and Transparency Expert, Former EFPIA, CREG Clinical Trials
Merete-J Consulting CVR: 34920818, 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 is Clinical Trials Transparency pillar lead, under the Clinical Research Expert Group in EFPIA.

Speaker(s)

Opening

Caroline Correas, MA

Associate Director, Global Regulatory Policy
Bristol Myers Squibb , Switzerland

Caroline is Associate Director in Global Regulatory Policy at Bristol Myers Squibb, based in Switzerland. She holds a Masters Degree in Political Sciences from Sciences Po Paris with a specialization in European Law. She has been working in the pharmaceutical industry for the past ten years. She has been working on preparing her organization and the industry in general for the implementation of the Clinical Trials Regulation since 2017. In particular, she has been leading the industry's efforts relevant to transitioning clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation since 2021, through cross-trade associations (representing big and small companies, commercial & academic sponsors) advocacy activities.

Sponsor Experience

Sameer Sharma, MPharm

Associate Director, Clinical Trial Transparency
Merck KGaA, Germany

Sameer Sharma works as a Clinical Trial Transparency Manager at Merck KGaA, Darmstadt, Germany since 2015. He has 10+ years of experience in the Clinical Trial Transparency and Medical Writing domain. At Merck, he is responsible for setting up the processes and overseeing redactions and anonymizations as per worldwide redaction regulations not limited to EMA policy 0070, Health Canada-PRCI, Japan PMDA, EMA Policy 0043, and ad hoc redaction requests. He holds a Masters in Pharmaceutical science and a registered Pharmacist.

Sponsor Experience

Chris Bamford

Director, Regulatory Affairs
IQVIA Ltd, United Kingdom

Sponsor Experience

Seán Kilbride, PhD

Director, Regulatory Affairs
Regeneron Ireland DAC, Ireland

Day 3 Dec 07, 2023

1:30 PM — 1:40 PM

Welcome and Introduction from DIA

1:40 PM — 2:40 PM

Session 8: Management of Commercially Confidential Information (CCI) in Clinical Trial Applications (CTA) under the EU Clinical Trial Regulation (CTR)

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Session Chair(s)

Lora Killian, MBA

Clinical Trial Transparency and Disclosure Lead
Pfizer Inc, United States

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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.

Thomas Schindler, PhD

Director Global Regulatory Affairs - Regulatory Operations
BioNTech SE, Germany

Thomas M. Schindler, PhD, has studied biology and linguistics, was a member of the TransCelerate Return of Results and Clinical Research Access work streams, is contributing to the Good Lay Summary Practice initiative and the Plain Language Summary Guidance of PFMD. He has some 25 years of experience in both medical affairs and regulatory medical writing, and leads the plain language and lay summary initiatives as head of Innovation Medical Writing at Boehringer Ingelheim Pharma.

Speaker(s)

Risks posed by CTIS to the protection of clinical trial innovation

Polyana Bastos

Senior Legal Counsel
Switzerland

CCI management in EU Clinical Trial Applications

Wendy M Wimmer, MS

Director, Clinical Data Disclosure and Transparency
Merck & Co., Inc., United States

Wendy Wimmer is a Director in the Clinical Data Disclosure & Transparency department at Merck Sharp & Dohme. She has over 25 years of clinical research experience and over the last 6 years has created and currently manages a centralized document transparency functional area for her company. Most recently, she has been responsible for the implementation of the transparency processes accompanying the initiation of the EU Clinical Trial Regulation.

2:40 PM — 3:00 PM

Coffee Break

3:00 PM — 4:00 PM

Session 9: Transparency Aspects of Trial Results

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Speaker(s)

Introduction

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BioNTech SE, Germany

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Plain language Synopsis Protocol

Julia Anna Hild

Boehringer Ingelheim Pharma GmbH & Co.KG, Germany

4:00 PM — 4:30 PM

Coffee Break

4:30 PM — 5:30 PM

Session 10: Update on Clinical Document Disclosure policies/restart activities: EU and Canada

This session will provide an update on EMA Policy 0070 and Health Canada's Public Release of Clinical Information (PRCI). Speakers will provide EMA's and sponsor perspectives regarding the restart of Policy 0070 scheduled for Sep 2023, its scope, related organisational adaptations, alignment with Health Canada's PRCI, and first practical experiences. Health Canada will present on status and progress of PRCI which reached its final implementation stage in March 2023 and now encompasses dossiers of class III and IV medical devices.

Session Chair(s)

Thomas Schindler, PhD

Director Global Regulatory Affairs - Regulatory Operations
BioNTech SE, Germany

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Speaker(s)

PRCI Update Devices

Andre Molgat, PhD

Head of Operations, Public Release of Clinical Information
Health Canada, Canada

André Molgat is the Head of Operations for Health Canada's Public Release of Clinical Information initiative. He was previously a core member of the team responsible for the initiative's regulatory and policy development. André has a PhD in biochemistry and post-doctoral training in biochemistry and stem cell biology.

Update and Relaunch of EMA Clinical Data Publication (Policy 0070)

Anne-Sophie Henry-Eude, PharmD

Head of Documents Access and Publication Department
European Medicines Agency, Netherlands

Dr Anne-Sophie Henry-Eude has a degree in pharmacy from the University of Lille in France and postgraduate degrees in Regulatory Affairs and in Pharmacovigilance & Pharmacoepidemiology. She worked in the pharmaceutical industry before joining EMA as product team leader for anti-infectives and later as paediatric coordinator in the HIV and vaccines field. In 2013 she put in place a Service to centralised activities linked to access to documents (Policy 0043) and later Clinical Data Publication (Policy 0070). Since 2021, she is Head of Documents Access & Publication, a Department, which manages transparency activities at EMA.

Sponsor Experience Submitting to EMA Policy 0070 Post-Restart

Catherine Brown

Clinical Trial Transparency and Disclosure Manager
Pfizer Inc., United States

Catherine has 9 years of experience in the transparency and disclosure space. As an anonymization specialist for contract research organizations, she supported the anonymization of protected data for several mid-sized to top tier pharmaceutical clients. In 2021, Catherine joined Pfizer as a Clinical Trial Transparency and Disclosure Manager and oversees the delivery of anonymized clinical documents prepared for Health Canada Public Release of Clinical Information, European Medicines Agency Policy 0070 and other global regulations.

5:30 PM — 5:45 PM

Coffee Break

5:45 PM — 7:00 PM

Session 11: Bitesize Topics & Open Community Forum

Your Voice, Your Topics! We're thrilled to bring you a session featuring topics proposed by the DIA Disclosure Community. We've listened to your suggestions, and this session is designed to address your most pressing concerns and interests in the field of disclosure and transparency. Join us for an engaging and interactive discussion shaped by your input!

Session Chair(s)

Session Chair Invited

Switzerland

Speaker(s)

Update on Privacy Methodology

Boris Grimm

Global Biostatistics & Data Sciences
Boehringer Ingelheim Pharma GmbH & Co. , Germany

Update on Privacy Methodology

Jeppe G. Manuel, MLIS

Principal R&D Data Privacy Specialist
Novo Nordisk, Denmark

Jeppe G. Manuel works as the Principal R&D Data privacy Specialist in Novo Nordisk A/S and is responsible for driving and aligning Novo Nordisk's privacy by design/default efforts across the global R&D organisation. Hereunder, support managers & employees in Clinical Drug Development on implementing data privacy and ensuring the clinical processes and systems are aligned with personal data protection regulations. Furthermore, as the R&D subject matter expert on Personal Data Protection, Jeppe supports communication, training, and knowledge sharing activities across the R&D organisation and advise the Novo Nordisk on issues related to Data Privacy.

Complex Clinical Trials

Scott Feiner

Senior Manager, Clinical Records Management, Strategic Clinical Operations
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

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