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US SUMMIT 2026 ▪ Princeton, NJ

BioForum THE DATA MASTERS

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DELEGATE GUIDE

CONTENTS

INTRODUCTION

It is my pleasure to welcome you to Princeton for this important new event for the clinical data management community. We are delighted to have you with us and hope this Delegate Guide helps you make the most of the programme, discussions, and networking opportunities over the next two days.

For nearly 40 years, the Association for Clinical Data Management (ACDM) has served the clinical data management community, guided by its mission: "Empowering Excellence in Clinical Data Management." It does so by fostering continuous learning, enabling collaboration, and supporting professionals as they help shape the future of clinical research.

This year's Summit highlights many of the themes shaping the future of our profession, including artificial intelligence in healthcare and drug development, modern data workflows from source to submission, new approaches to clinical data review, the convergence of centralized monitoring with risk-based data review, and the role of standards and automation in accelerating clinical development. Together, these sessions reflect the growing impact of clinical data management in driving trust, innovation, and better outcomes across clinical research.

My sincere thanks go to the Steering Group for their hard work, expertise, and commitment in shaping this inaugural Summit. Their efforts have helped create a programme that is timely, relevant, and forward-looking, and we see this event as only the beginning. We hope it will be the first of many ACDM summits in the years ahead, providing a lasting platform for connection, collaboration, and continued progress across our profession.

Thank you for joining us. I wish you a productive, enjoyable, and successful Summit.

Robert King | ACDM Chair & Anita Kratchmarov | ACDM US Summit Chair

PROGRAMME

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18th May 17:00 - 18:00

Registration

18th May 18:00 - 21:00

Networking Evening

The Networking Evening is the perfect chance to meet with fellow attendees and members of the ACDM Board ahead of the scientific and practical sessions.

19th May 08:00 - 09:00

Registration, Breakfast & Networking

19th May 09:00 - 09:15

Welcome & Launch of US Summit

Robert King | ACDM Chair

Robert King kicks off the launch of the US Summit with a warm welcome to attendees.

19th May 09:15 - 09:45

Keynote: Integrated. Intelligent. Accelerated: The New Era of Clinical Data Management

Joe Sasarak | Genmab

"Integrated. Intelligent. Accelerated: The New Era of Clinical Data Management" explores how the function is evolving to meet the demands of increasingly complex trials. The talk offers a spirited reflection on both traditional ways of working and the shifts now underway—driven by integration, advanced analytics, and closer cross-functional collaboration. It provides a forward-looking perspective on where clinical data management is heading and how teams can adapt to deliver faster, more meaningful insights.

19th May 09:45 - 10:15

Keynote: The AI Revolution in Health and Drug R&D

Ulo Palm | R&D AI Consultant

This keynote will explore how artificial intelligence—particularly generative and agentic AI—is transforming healthcare and pharmaceutical R&D. Dr. Ulo Palm will discuss the implications for core functions such as Clinical, Biostatistics, Programming, and Data Management, and how these disciplines are likely to operate differently in an AI-enabled future.

19th May 10:15 - 10:45

Coffee Break

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19th May 10:45 - 11:15

Automating Data Workflows: From Source to Submission

Manny Vazquez | Veeva

Traditional clinical data management has long been hindered by fragmentation—multiple sources translated to multiple places, manual transcription, delayed access to data which obscures the real-time health of a study. To evolve, the industry must shift from passive data collection to active data connection. This presentation will discuss a modern framework for automated data flows from source to submission that will streamline and accelerate the journey from patient interaction to statistical insight.

19th May 11:15 - 11:45

Reimagining Clinical Data Review: A Unified Framework Using R/Shiny

Christine Kanalis & **Nicole Panunzio** | Atorus Research

Clinical data management sits at the center of trust, quality, and decision-making in clinical trials, yet data review practices remain largely fragmented. Many organizations still depend on static listings, delayed exports, and function-specific tools that limit transparency, slow issue detection, and weaken confidence in the data.

19th May 11:45 - 12:00

Q&A

19th May 12:00 - 13:00

Lunch & Networking

19th May 13:00 - 14:00

AI at Scale: Transforming Study Design and Data Review from Build to Insight

Olek Czepla & **Alex Liu** | Taiho Oncology

The era of theoretical AI in clinical data management is coming to an end. The question facing data management leaders today is not whether to adopt AI, but how to do so in a way that delivers real, sustainable value.

19th May 13:00 - 14:00

Beyond Boundaries to One Control Tower: When Centralized Monitoring Meets Risk Based Data Review from Build to Insight

Tanya du Plessis | Bioforum the Data Masters, **Joe Fitzgerald** | Whitehawk Therapeutics, **Terry Katz** | Daiichi Sankyo, **Lana McLaren** | Genmab & **Kasey Bumber** | CluePoints

Centralized monitoring (CM) and data management (DM) risk based data reviews began as neighbouring disciplines: CM focused on operational and site performance signals, while DM focused on data validity, consistency, and cleaning. Today, those boundaries are dissolving. The same realities are forcing convergence—hybrid execution, multi source data volumes, and expectations for early insight into patient safety and trial integrity.

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19th May 15:00 - 15:30

Coffee Break

19th May 15:30 - 16:15

The Priests of Process vs The Wizards of Why

Sarah Clark | AstraZeneca, **Carolina Cubillos** | Genmab, **John Acampado** | Veeva & **Rishi Raj** | SENSAN Biosciences Pvt. Ltd.

Panel Discussion, moderated by Sarah Clark

This panel debate will explore the fundamental differences between these two critical roles, examining their respective contributions to clinical development and the unique value each brings to modern drug development. We will investigate how evolving business requirements—including real-world evidence integration, decentralized trials, AI-driven analytics, and regulatory expectations around data transparency—are reshaping both positions and potentially blurring the boundaries between them.

19th May 16:15 - 16:45

Keynote: From Protocol to SDTM in Seconds: Building the Future of Clinical Data Flow with CDISC 360i and AI

Tamer Chowdhury | Chair of ACDM Technology DMEG

Clinical data management has long been plagued by manual mapping, disconnected systems, and weeks of reconciliation efforts. The CDISC 360i initiative—encompassing USDM, Biomedical Concepts, Dataset Specializations, promises to revolutionize this landscape through end-to-end automation. This presentation demonstrates how these standards work in practice.

19th May 16:45 - 17:00

Summit Wrap Up & Takeaways

Robert King | ACDM Chair & **Sverre Bengtsson** | ACDM Vice-Chair

ACDM Chair Robert King and Vice-Chair Sverre Bengtsson close the Summit with reflections on the key themes and insights shared.

SPEAKERS

John Acampado - Sr. Director, Clinical Strategy | Veeva

With more than 20 years of experience in data management, clinical research, project management, and product management, John has a steadfast commitment to optimizing processes to enable compliant, end-to-end clinical trial execution and evidence generation. He holds an MBA and MPH, and has served in leadership roles in medtech and biopharma prior to joining Veeva MedTech.

Sverre Bengtsson - CEO | DTC

Sverre has been working with clinical trials since the early 1990's. His first job was what the global first electronic patient diary MiniDoc. He later started working as a statistician and data manager for two different local CROs. In 2003 he co-founded a CRO who later, through many transformations later became the eClinical technology company Viedoc. At Viedoc, Sverre focused on making the company a global company, all over the globe.

Sverre is nowadays a consultant, advisor and board member to companies in their Go To Market and overall company strategies. He is an active investor in the field since many years, especially looking for clinical trials technologies who stand a chance to make a real impact in the industry.

Sverre is the Vice Chair of ACDM.

Kasey Bumber - Senior Strategic Consultant | CluePoints

Kasey has 19 years of experience in life sciences, starting as a Clinical Project Associate at ClinPhone in 2006 and later managing IVR/IWR projects at United BioSource Corporation. She then transitioned to sponsor roles at Novartis and Merck before expanding her expertise at Medidata, where she spent a decade as a Subject Matter Expert delivering strategic clinical trial technologies and solution design. Kasey then moved to Signant Health to lead the Unified Platform initiative, focusing on EDC, eCOA, and RTSM, with an AI-first, patient-centric vision. She now serves as a Senior Strategic Consultant at CluePoints, continuing her mission to advance AI-first clinical trial technology and evangelizing innovative approaches to both internal teams and external clients.

SPEAKERS

Tamer Chowdhury - Chair of ACDM Technology DMEG

With over 25 years of pharmaceutical experience, Tamer uniquely bridges business vision with technical implementation. He currently serves as Chair of the ACDM Technology Data Management Expert Group (DMEG), where he champions the modernization of clinical data flow from protocol to clinical trial reports. Tamer is the lead author of ACDM's white paper "Modernization of Clinical Data Flow: Leveraging CDISC 360i Standards for End-to-End Data Flow Automation" and actively develops AI-powered products, demonstrating how modern data standards and AI can transform clinical trial design and execution.

Sarah Clark - Global Head of Clinical Data Management | AstraZeneca

Sarah has provided stability to the organisation, whilst progressing forward key initiatives and deliverables and building an internal Data Management capability. As business sponsor for one of AstraZeneca's key transformation projects, Redefining Clinical Data Flow, she has championed the programme as it entered the critical implementation phase.

Prior to this Sarah led the Clinical Data and Insights (CDI) team. Sarah led the expansion of AZ's CDI footprint to Bangalore, India, and has helped to pave the way for other data and related functions. During her tenure at AstraZeneca, she has reduced operating costs, amassed over $15 million in savings, and helped drive innovative ways of working that are reducing our carbon footprint.

Carolina Cubillos - Director, Team Lead, Clinical Data Management | Genmab

Carolina is a Biologist by training and a leader in global clinical data management with more than 25 years of experience shaping data strategy and operations across various pharmaceutical organizations. She has built and led high-performing global teams, optimizing data operations, and implementing innovative processes and technologies across major pharmaceutical organizations. Carolina is known for her strategic approach to data quality, regulatory compliance, vendor partnerships, and operational excellence in complex, matrixed environments.

She currently heads a Clinical Data Management team at Genmab, supporting the company's growing oncology portfolio. Prior to Genmab, Carolina held senior data management leadership roles at Bayer, Novartis, and Schering-Plough, driving global operating model transformations and establishing dedicated data management units internationally.

SPEAKERS

Olek Czepla - Executive Director, Data Management | Taiho Oncology

Olek has nearly 30 years of experience in clinical research and pharmaceutical development. He specializes in clinical data strategy, digital transformation, and the implementation of advanced technologies that support modern clinical trials. Throughout his career, Olek has focused on leveraging innovative data platforms, analytics, and emerging AI capabilities to improve data quality, efficiency, and decision-making in clinical development.

At Taiho Oncology, he leads initiatives that advance the use of technology and data science within clinical data management. Olek is particularly interested in the growing role of artificial intelligence and automation in clinical research and how these technologies can reshape the future of clinical trial operations and data-driven drug development.

Tanya du Plessis - Chief Data Strategist & Solutions Officer | Bioforum the Data Masters

Tanya is currently Chief Data Strategist & Solutions Officer of Bioforum, she has over 20 years industry experience. Throughout her career, Tanya has worked with multinational pharmaceutical companies as well as small-to-mid size biotechs and startups. She has led various data management operations and programs, heading numerous innovation teams and spearheading the development of strategies for customized data delivery solutions, focusing on timely, quality data. After working for IQVIA (legacy Quintiles) for nearly 14 years, she left her role as Director for a opportunity with Bioforum as VP, Data Strategies and Solutions. Thereafter moving into the role of Chief Data Strategist and Solutions officer, Tanya is directly involved in the companies innovative strategies for customised data delivery solutions. Additionally, ensuring that Bioforum is driving excellence through partnerships and solutions to industry challenges.

Joe Fitzgerald - Vice President, Clinical Data and Evidence | Whitehawk Therapeutics

Joe is Head of Data and Evidence at Whitehawk Therapeutics, a clinical-stage biotech focused on antibody–drug conjugates (ADCs). He leads data strategy and analytics capabilities with a focus on data quality, inspection readiness, and operational efficiency through risk-based quality management (RBQM) and centralized data monitoring.

He has 27+ years in clinical data management, most recently serving as Head of Data Management at Regeneron Pharmaceuticals, where he built scalable operations and applied data-driven approaches to proactively identify risk and improve trial execution.

SPEAKERS

Christine Kanalis - Executive Director, Clinical Data Management | Atorus Research

Christine leads strategy and execution for modernizing clinical data operations across the life sciences. With more than 30 years of industry experience, she operates at the intersection of clinical data management, programming, and emerging technologies, driving high-quality data delivery and cross-functional collaboration to enable efficient and compliant clinical research. Christine has watched an industry grow into its potential, moving from paper studies to electronic solutions to the advent of AI. She draws on her broad experience, providing a unique perspective on data strategy and technological innovation, and breaking down clinical data silos to accelerate research impact.

Terry Katz - Daiichi Sankyo

Terry is a Statistical Leader with over 40 years of experience. He retired in 2026 as Sr Dir of Biostatistics and Data Management Functional Excellence at Daiichi Sankyo, emphasizing processes, compliance with guidelines, and proactive tool-based data review including Risk-Based Quality Management. Previously he was Head of Global Data Management and Biostatistics for Merck Animal Health, VP of Biometrics at ImClone Systems (Eli Lilly), Senior Manager of Analysis and Reporting for PRA International, and a Statistical Manager for Schering-Plough. He is an Accredited Professional Statistician (ASA), a Certified Quality Engineer (ASQ), a Certified Six Sigma Green Belt (ASQ), and Certified in Pharmaceutical Quality Control (NJPQCA).

Robert King - Executive Director | PPD (Thermo Fisher Scientific)

Robert has over 29+ years of industry experience and for the last 17 years he's had global leadership roles in Data Management/ Statistics and Clinical Development support functions. Where he's been key a driver in developing and implementing corporate strategic direction across clinical development and eClinical technologies as well as gathering significant experience in the FSP marketplace.

Robert first started supporting the ACDM back-in 1993 on the Technical and Conference sub-committee, which included helping organise the ACDM's first ever conference and he also joined the ACDM board in 2000. After 11 years of supporting the ACDM in 2004 he decided it was time to "retire" from the ACDM to spend a little more time with his young twins.

SPEAKERS

Alex Liu - Associate Director, Clinical Systems | Taiho Oncology

Alex is the AD, Clinical Systems at Taiho Oncology, where he leads in-house EDC study builds and the implementation of data review tools to support high-quality clinical trial execution. His work focuses on enabling effective data review through CRF standardization, consistent study builds, and the integration of AI into practical, scalable workflows that surface actionable insights earlier. With over a decade of experience programming custom functions and tediously testing edit checks in Medidata, Alex is a long-time advocate of "AI is kool" and continues to work toward a future of more automated data review and "one-click" study builds.

Lana McLaren - Senior Manager, Risk Based Quality Management | Genmab

Lana leads the implementation and oversight of risk-based approaches across clinical trials. Her work focuses on alignment with regulatory expectations, including ICH E6(R2), E6(R3), and E8(R1), with an emphasis on quality by design and fit-for-purpose risk management. She partners with cross-functional teams and CROs to identify and monitor critical data and processes, supporting data integrity, subject safety, and inspection readiness. Lana has contributed to advancing Genmab's RBQM framework through the development of risk assessments, Key Risk Indicators (KRIs), Quality Tolerance Limits (QTLs), and targeted monitoring approaches.

Ulo Palm - R&D AI Consultant

Dr. Ulo Palm is an independent R&D AI consultant focused on digital transformation in pharmaceutical research and development. He brings more than 30 years of industry experience across clinical development, operations, quality, data management, biostatistics, and programming. Over his career, he has contributed to more than 30 successful New Drug Applications and has led the strategy and implementation of innovative technologies to improve clinical research and drug development.

Dr. Palm previously served as Chief Medical Officer of Vaxxinity and was Co-Founder and Chief Medical Officer of Ordaos Bio, an AI-driven drug design company. Earlier, he held senior leadership roles at Allergan, Forest Laboratories, Novartis, Schering-Plough, and Bayer.

SPEAKERS

Nicole Panunzio - Director, Clinical Data Management | Atorus Research

Nicole, with over 25 years of experience, is a strategic thinker with a hands-on approach. She has extensive experience with operationalizing critical tasks and excels in turning around high-risk or under-performing projects. She brings expertise in "rescue" scenarios by bringing order, clarity, and direction to clinical data workflows and team dynamics. Throughout her career, she has partnered with global pharma, biotech, and CRO organizations to improve quality oversight and foster a culture of accountability and collaboration. Her leadership style emphasizes transparency and mentorship, which help deliver projects on time and within scope. She is passionate about leveraging technology, talent, and proven methodologies to ensure data integrity and operational success.

Rishi Raj - Strategic Partnerships & Clinical Innovation | Sensan Biosciences PVT Ltd

With over 10 years of experience in optimizing data operations for global clinical trials, Rishi is an accomplished professional in the field of Clinical Data Management (CDM). In his current role, he is responsible for overseeing the full data lifecycle, from eCRF design and database setup to database lock, ensuring alignment with regulatory standards and study protocols.

Joe Sasarak - Vice President, Head of Clinical Data Management | Genmab

Joe is a clinical data management leader with extensive experience in oncology drug development and risk-based quality management. As VP of Clinical Data Management & RBQM at Genmab, he leads global data strategies, oversees outsourced study execution, and drives innovative approaches to data review and quality. Throughout his career, Joe has held leadership roles across clinical data management, consistently delivering complex programs and shaping scalable, high-quality data operations. He is known for building and leading high-performing teams that deliver operational excellence and enable faster, data-driven decision-making in clinical development.

SPEAKERS

Manny Vazquez - Senior Director, Clinical Data Strategy | Veeva

Manny has spent the last 20 years in Clinical Data Management leading teams in biopharma & CRO organizations before joining Veeva in 2022 to support Clinical Data product strategy. Manny currently sits on the Board of Trustees of the Society for Clinical Data Management (SCDM).

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Bioforum THE DATA MASTERS

Bioforum The Data Masters is a leading global clinical research organization (CRO) that specializes in biometric services and solutions for the pharmaceutical, biotech and medical device industries. With a team of experienced professionals and state-of-the-art technology, Bioforum provides a range of services including data management, biostatistics, statistical programming and medical writing to help companies bring new drugs and therapies to market faster.

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Zelta is a clinical trials solution business that offers a cloud-based unified clinical data management and acquisition platform with customizable modules that can be tailored to the unique needs of your clinical trials. Zelta's unified cloud-hosted platform has supported over 4,500 trials to date across all phases and complexities of research, including more than 550 phase III and 20 pivotal trials.

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