SCDM Live

SCDM 2027
EMEA Conference

18-21 April, 2027
Athens, Greece

Call for Abstracts

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INFLUENCING WITH AUTHORITY

As pioneers in clinical data science, we understand that bridging ideas and defining the future of our field requires collaboration at every level. Proudly hosted by **Pfizer**, the SCDM 2027 EMEA Conference is the place where leaders across clinical data science, clinical operations, regulatory affairs, patient advocacy, and beyond come together to influence the direction of our industry.

This is where transformative conversations happen. Where industry and regulatory authorities engage openly. Where diverse perspectives challenge conventional thinking and spark new solutions.

By joining us, you will enter a safe space where leaders share actionable insights, navigate the complexities of modern clinical research, and unlock new ways to integrate data, streamline processes, and strengthen cross-disciplinary partnerships. Will you be in the room when it happens?

Our attendees enjoy hearing from their mentors, from industry leaders and from their peers. They like to be inspired, challenged and motivated. Our session chairs and speakers make the SCDM EMEA Conference and we look forward to seeing your ideas.

WHAT DO THE MOST SUCCESSFUL PRESENTATIONS HAVE IN COMMON?

HAVE ONE BIG IDEA

Develop an idea worth sharing and express it clearly and simply. Your idea may be an assumption that you wish to challenge, or, a unique perspective on a common topic, or even an innovative concept that has the power to advance the profession. Remember to summarise your idea in one clear message.

DEVELOP A TWIST

If your idea can be stated in a catchy or provocative way, our attendees will pay more attention and remember it easily. Be thought-provoking and not afraid to offer a slightly contrary challenge to what is expected.

OFFER REAL VALUE

Our attendees want to be inspired, but they also want valuable, practical takeaways. Make sure you answer the key questions relating to your topic and prepare a virtual handout for the attendees to use in the office.

WE ARE LOOKING FOR THE BEST SPEAKERS IN THE INDUSTRY

ENGAGING

Our best speakers tell personal stories and carefully use humour to emphasise a key point they wish to make.

HONEST

Typically, they are very open and transparent, particularly when revealing data and other relevant information. They ensure that the truth prevails, even when it may not be particularly attractive.

OPINIONATED

Rarely do they sit on the fence. Instead, they voice a clear opinion - and, always in a respectful and humble way.

RELAXED

Being relaxed, but passionate about your topic, goes down very well with the SCDM audience. The best speakers do not use gimmicks or appear stuffy and excessively formal.

5 PRINCIPLES

1. All content must be original and not a rehash of a presentation given at another industry event.

2. If your submission is successful, the cost to cover any fees (such as registration) must be covered by you.

3. There is no additional charge to speak at the SCDM EMEA Conference. On the contrary, you benefit from a reduction on the standard registration fee.

4. Successful abstracts are selected by the session chairs on the merit of the idea and the speaker.

5. You are responsible for the concept, creation and delivery of your presentation and you will be working with the session chair to ensure your presentation is a fit for the session. The SCDM Team is on hand to guide you and is the official contact point for confirmations and changes.

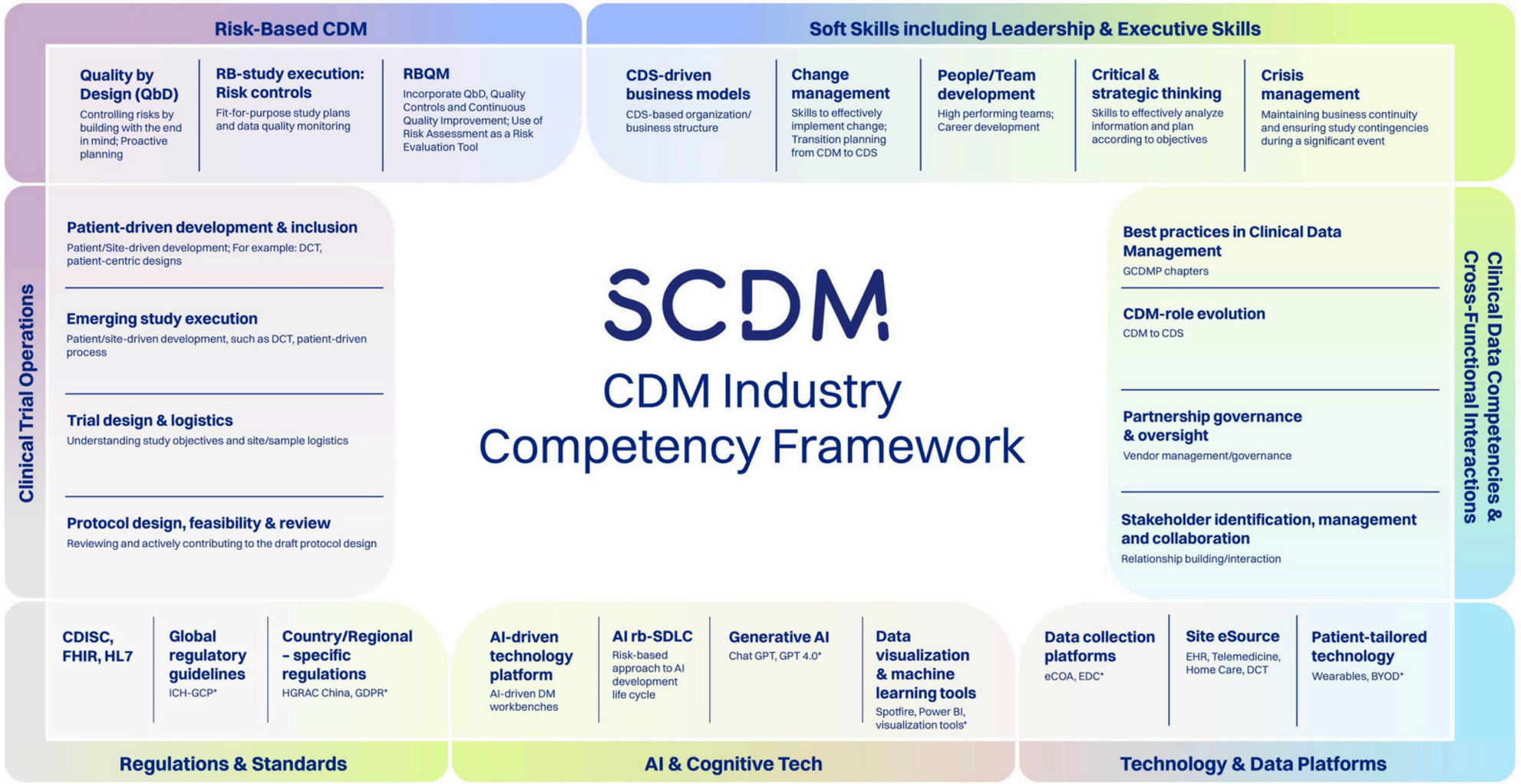
CONDITIONS

Presentations from vendors are welcome, however **vendors are asked to respect the educational nature of this meeting and not to promote their products** and services during their presentation (with the exception of product showcases).

In order to provide attendees with a broad range of perspectives, SCDM reserves the right to limit the number of presentations chosen from a single company.

Presenters are required to attend several conference calls with the conference co-chairs and session chairs during the preparation process.

CONFERENCE COMPETENCIES



*This is not an exhaustive list.

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SESSION FORMATS

SCDM accepts submissions within sessions of the following formats:



Storytelling



Panel Discussions



Oral Presentations



Roundtable Discussion



Debate

By 4 December

Submit your abstract

You should do this through the online portal. Proposals submitted directly to SCDM Team will not be considered.

4 December - End of January

Review Process & Selection

1. The conference co-chairs will review all abstracts to ensure their quality and commercial-free nature.

2. Once the abstracts have been reviewed, they will be presented to the session chairs for their final selection

End of January

Confirmation

If your proposal is selected by the session chair, a member of the SCDM Team will contact you with an initial offer of a slot, in the session you submitted for. Once everything has been finalised, we will list the conference speakers online and in marketing communications.

End of January & onwards

Ongoing and Final Preparations

The SCDM Team will work with all session chairs and speakers to ensure you deliver a successful session and that there is no overlap between different presentations.

ABSTRACT SUBMISSION

REQUIREMENTS

For standardization, the acceptable format of the abstract is limited to a maximum of 350 words. This number does not include abstract title (100 characters) and presenter biography (600 characters).

ABSTRACT REVIEW AND NOTIFICATION OF ACCEPTANCE

- The conference co-chairs will review the abstracts according to the relevance to their proposed topic and the **session chairs will select the most appropriate ones for their session expectations**.
- All abstract submitters should be prepared to present the abstract as an oral communication within the corresponding session format.
- The Programme Committee reserves the right to assign the abstract to one or the other presentation formats without any reservation.

STORYTELLING SESSION

SESSION DURATION

60-75 minutes
Q&A Included

THE BIG IDEA

Bring technical concepts to life through real-life case studies.

HOW IT WORKS

2-3 case studies (15 minutes each; 10 minute Q&A) themed around the same scenario/ issue are told as engaging stories.

The case studies should reflect the authentic experience of an individual, a team, or a community.

WHAT IT'S NOT

It is not a corporate sales presentation

A series of boring or aloof presentations.

Similarly, they should not lack practical guidance on the application of the topic being discussed.

Proposed Sessions

- The Most Valuable Data Point May Be the One We Never Collect - Moving Clinical Data Management Upstream: From Data Cleaning to Data Strategy
- USDM in the Real World: Implementation and the Evolving Role of Data Management
- Who's Driving? Trust, Control and Accountability for Agentic AI in Clinical Data Lifecycle

THE MOST VALUABLE DATA POINT MAY BE THE ONE WE NEVER COLLECT - MOVING CLINICAL DATA MANAGEMENT UPSTREAM: FROM DATA CLEANING TO DATA STRATEGY

Clinical Data Management has spent decades becoming better at collecting, reviewing, reconciling and cleaning increasingly complex clinical trial data. But one of the most important questions should be asked much earlier: do we need to collect this data at all?

Clinical trials generate data to support scientific, regulatory, safety and operational decisions. Yet data collection can also reflect historical practice, established templates and a tendency to add rather than remove. Every additional data point has a downstream consequence for participants and sites asked to provide it, for systems and vendors that transport it, and for teams that review, reconcile, query and interpret it.

This interactive storytelling session challenges Clinical Data Management to move further upstream. Instead of receiving a finalized protocol and determining how to operationalize its requirements, what if CDM became an active partner in defining a purposeful data strategy before those requirements were fixed?

In “The Data Point on Trial,” three anonymized, composite stories will unfold from protocol design through collection, transfer, review, analysis and decision use. At the start of each story, the audience will receive only the original rationale for collecting the data and vote: KEEP, SIMPLIFY, PROVE IT or STOP. Cross-functional contributors representing Clinical or Medical, Data Management, Statistics or Data Science, and ideally a sponsor, site or patient perspective will then reveal further consequences and challenge the initial decision.

Each story will apply four practical questions: What decision will this data support? Who will use it? What happens if we do not collect it? Is its value greater than the burden it creates?

The objective is not simply to collect less data. It is to collect the right data, for a clear purpose, with an intentional path from collection to decision. The session positions CDM not only as the function managing data after collection, but as a strategic partner in defining, orchestrating and preparing data for their intended use.

Participants will leave with a practical challenge for their own protocol and study teams: if nobody can explain what decision a data point supports, why are we collecting it?

TOPIC

3. Clinical Data Competencies & Cross-Functional Interactions

SESSION LEVEL

Advanced

LOOKING FOR

- Clinical or Medical representative: scientific intent and patient-safety context.
- Statistics or Data Science representative: analysis value and interpretability.
- Sponsor, investigator/site or patient representative: feasibility and burden perspective.
- Optional Regulatory or Quality representative if the final panel allows five participants.

USDM IN THE REAL WORLD: IMPLEMENTATION AND THE EVOLVING ROLE OF DATA MANAGEMENT

ICH M11's move toward structured, machine-readable protocols has increased interest in the USDM standard and its potential to support greater automation, traceability, and consistency across the clinical trial lifecycle. A growing number of organizations have begun exploring USDM through pilots, proofs of concept, and partial implementations. Much of the discussion around USDM has focused on what the standard can enable, however, less attention has been given to what happens when USDM moves from a conceptual model into the operational reality of a clinical study.

This session explores that reality through the experiences of professionals involved in USDM implementation from different perspectives. Presenters will examine the challenges that have emerged when a standardized model encounters the complexity of real-world clinical research, including gaps between the standard and existing processes, technology limitations, regulatory and regional considerations, organizational readiness, and the practical difficulty of transforming unstructured source information into structured data. Greater standardization may eliminate some manual effort while introducing new challenges in governance, process, technology, or cross-functional coordination. The session will explore the adaptations, workarounds, and decisions required when the expected path does not unfold as planned.

These experiences raise a broader question for Data Management: Does greater standardization and automation actually make Data Management simpler, and if so, what does a simpler Data Management function look like? As activities traditionally performed by Data Management move upstream, become more automated, or are shared across functions, responsibilities may be redefined in ways the field is still working out. USDM may therefore change not only how clinical data is managed, but also what Data Managers and their cross-functional partners are responsible for, where their expertise is applied, and which skills become increasingly important.

Drawing on real-world implementation experiences, whether complete or still underway, the session will examine both the obstacles encountered and the approaches developed in response. Where there is no clean solution, the discussion will examine the alternative approaches taken instead, including what was learned and how those lessons influenced subsequent decisions.

Attendees will leave with a clearer understanding of the realities of USDM adoption at any stage, the trade-offs that can accompany increased standardization and automation, and the ways implementation may reshape Data Management. The session will provide practical insight for organizations at different points along their own road ahead, while encouraging a broader conversation about what Data Management should become as clinical research moves toward increasingly structured and automated processes.

TOPIC

3. Clinical Data Competencies & Cross-Functional Interactions

SESSION LEVEL

Intermediate

LOOKING FOR

Looking for speakers who are current or former Data Managers, or someone who has worked closely with a Data Management team during USDM implementation, who have had direct involvement in a full-scale or pilot USDM implementation effort. Speakers must be able to describe a specific obstacle faced during implementation and the result or tradeoff/workaround that occurred. Questions that should be answered include:

- What did we think USDM would change?
- What actually happened when implementation began?
- What does a Data Manager do differently in a USDM-enabled environment?
- What DM tasks were removed or added?
- What tasks became more technical?
- What skills become more/less important?
- What would we do differently?

WHO'S DRIVING? TRUST, CONTROL AND ACCOUNTABILITY FOR AGENTIC AI IN CLINICAL DATA LIFECYCLE

The era of rules-based automation in clinical data management is ending. The next inflection point is agentic AI like systems that do not simply execute a predefined pipeline step but reason, plan and act autonomously across ingestion, validation, anomaly detection and preliminary analysis. As these systems take on more decision-making, data managers face a harder question than "how do we automate this?" It becomes: "who is driving, and can we trust them?"

This session moves the conversation from what agentic AI could theoretically do to how organizations are actually standing it up in a regulated environment. We will examine real architecture choices behind agentic clinical data platforms, the governance guardrails required to keep autonomous systems audit-ready and the redefined role of the data manager as orchestrator and exception handler rather than manual operator.

Speakers will share grounded case studies from building agentic capabilities into modern clinical data platforms, covering how autonomy is bounded and escalated when agents encounter uncertainty what audit trail, traceability and "human in the loop" controls are non-negotiable under GxP expectations and how teams are managing the cultural shift of trusting a system that increasingly makes first pass decisions on their behalf.

The session is deliberately structured to surface tension, not just celebrate innovation. We will directly address where agentic AI adds genuine value today, where it still requires significant human oversight and where organizations have been burned by over-automating too early. Attendees will leave with a practical framework for evaluating agentic AI investments in their own organizations plus concrete questions to ask vendors and internal technology partners before handing any part of the data lifecycle to an autonomous agent.

This is a conversation for data managers, technology leads and quality/regulatory professionals who are being asked to evaluate, govern or defend agentic AI initiatives right now, not in five years.

TOPIC

5. AI & Cognitive Tech

SESSION LEVEL

Advanced

LOOKING FOR

Individuals who have directly built, deployed or governed agentic AI capabilities within a clinical data platform or pipeline, not just evaluated the concept theoretically. Ideal speakers include a technology/platform lead who has architected agentic or autonomous components into a clinical data lifecycle, a sponsor or CRO side data management leader who can speak to a real deployment, including what worked, what failed and what guardrails were added as a result and a quality, regulatory, or compliance professional who has worked through audit-trail, traceability or human in the loop requirements for AI-driven decision-making in a GxP environment. We are prioritizing speakers who can share specific, grounded experience over generalized industry commentary and who are comfortable discussing both successes and limitations openly.

PANEL DISCUSSION

SESSION DURATION

60-90 minutes
Q&A Included

THE BIG IDEA

Being the primary format, content here should be inspirational, future-facing and highly memorable.

HOW IT WORKS

SCDM Panel Discussion is facilitated by the Session Chair who guides the panel and the audience through the topic.

The panel format allows for a brief introduction and then discussion among the panellists and audience.

The panel, composed of 3-4 experts or practitioners in the field, shares facts, offers opinions and responds to audience questions either through questions curated by the moderator or taken from the audience directly.

The panel aims to offer the audience a thought-provoking discussion thatanalyses a topic from different angles.

WHAT IT'S NOT

We want to avoid having a set of presentations, one after another.

Similarly, it should not be a one-on-one interview conducted with each panellist in turn.

Many untrained moderators simply ask questions of each panellist, one after another, rather than build the dialogue into a conversation.

Proposed Sessions

- Beyond Signatures: Demonstrating PI Data Oversight Through Risk-Based Evidence
- In a World of Infinite Data, How Do We Decide What Matters? Navigating Standardization, Flexibility, and Trust in Clinical Trials
- Beyond Data Access: Making Secondary Use of Clinical Trial Data Routine
- The Hidden Cost of Reuse: When Similar Studies Stop Being the Same
- Who Audits the Algorithm? Accountability in the Age of Autonomous Clinical Data Operations
- Between Scylla and Charybdis: Steering Human Oversight of AI in Clinical Data Management
- From Bedside to Database: How AI at the Site Level Is Reshaping Downstream Data Quality
- The Odyssey of an Idea: How Conference Learning can lead to transformations in organisations
- Before the Window Closes: An ePRO Data Quality Odyssey

BEYOND SIGNATURES: DEMONSTRATING PI DATA OVERSIGHT THROUGH RISK-BASED EVIDENCE

As clinical trials become increasingly digital and data-rich, principal investigators are often expected to review and attest to growing volumes of information across multiple systems and processes. While signatures and attestations have traditionally served as evidence of oversight, organizations are increasingly looking beyond signatures to identify alternate evidence for demonstrating meaningful oversight of critical trial data and activities.

Find out how sponsors, informed by engagement with sites, service providers, and other stakeholders, are re-examining traditional oversight practices through the lens of ICH E6(R3), risk-based quality management, and fit-for-purpose trial execution. Speakers will share practical examples of oversight evidence available today, including metadata, workflow records, and system-generated indicators that may provide a more complete picture of investigator engagement.

TOPIC

1. Risk-Based CDM

SESSION LEVEL

Advanced

LOOKING FOR

Individuals with experience in PI Data Oversight from Industry, Regulatory and Site Perspectives.

IN A WORLD OF INFINITE DATA, HOW DO WE DECIDE WHAT MATTERS? NAVIGATING STANDARDIZATION, FLEXIBILITY, AND TRUST IN CLINICAL TRIALS

Clinical trials are becoming increasingly complex. Protocols are expanding, the volume and variety of data continue to grow, and advances in technology make it possible to collect, review, and analyze more data than ever before. At the same time, organizations face increasing pressure to standardize processes, accelerate study startup, improve efficiency, and reduce costs.

But are we always collecting the right data? Are we standardizing the right things? And how do we balance consistency with the flexibility needed to support increasingly complex protocols?

These questions are no longer solely operational or technical challenges. They require sound judgment, cross-functional collaboration, and the ability to build trust among diverse stakeholders. Clinical Data Management, Clinical Operations, Biostatistics, Medical, Regulatory, Standards, and Technology teams often bring different perspectives on risk, quality, compliance, efficiency, and scientific value. Finding the right balance requires collaboration, influence, and a willingness to challenge long-held assumptions.

TOPIC

2. Soft Skills including Leadership & Executive Skills

SESSION LEVEL

Advanced

LOOKING FOR

- Clinical Data Manager or Leader (sponsor) with experience in standards, data strategy, or trial execution.
- Clinical Operations Leader who can discuss site burden, protocol complexity, and operational feasibility.
- Biostatistics and/or Medical representative who can address scientific value and evidence generation.
- Patient-centricity, protocol design, or RBQM expert who can provide perspectives on patient impact and risk-based decision making.

The panel should include individuals who have experience leading cross-functional discussions and making trade-off decisions between standardization, flexibility, efficiency, scientific value, and patient/site burden. Diverse perspectives and practical experience navigating organizational change would be more valuable than purely technical expertise, reinforcing the conference theme of Navigating Change, Guided by Trust.

BEYOND DATA ACCESS: MAKING SECONDARY USE OF CLINICAL TRIAL DATA ROUTINE

Clinical trials generate rich participant-level data, yet much of their value remains tied to the original study objectives. As clinical data environments become increasingly harmonised and accessible, Clinical Data Science creates an opportunity to responsibly reuse historical trial data to answer new scientific and development questions.

This session will explore how organisations can move from one-off secondary analyses toward a more systematic capability for generating decision-relevant insights from existing clinical trial data.

Using practical industry examples, the session will examine the journey from a new scientific question to usable evidence: discovering relevant studies and variables, assessing data fitness-for-purpose, harmonising information across trials, applying appropriate analytical approaches, and translating results into insights that scientific and development teams can act upon.

Importantly, the session will also explore situations where historical data cannot fully answer the new question. These limitations can themselves create value by identifying gaps in endpoints, metadata or data collection that should be addressed in future clinical trials.

The discussion will focus on three recurring challenges: How do we determine whether historical clinical trial data are fit for a new purpose? How can reusable data and analytical patterns reduce repeated effort? And what competencies and cross-functional partnerships are required to translate secondary analyses into trusted decision support?

The session will bring together perspectives from Clinical Data Science, data standards/platforms and scientific or statistical stakeholders to discuss practical lessons for moving from data availability to data reuse, and ultimately to better-informed development decisions.

TOPIC

3. Clinical Data Competencies & Cross-Functional Interactions

SESSION LEVEL

Advanced

LOOKING FOR

We are looking for experienced practitioners who have implemented, scaled, governed or evaluated the secondary use of historical clinical-trial data and can share practical lessons rather than theoretical perspectives.

We particularly welcome speakers with experience in enterprise clinical-data reuse and harmonisation; cross-company data-sharing initiatives; data standards and interoperability; Clinical Data Science and reproducible cross-study analytics; and regulatory or statistical assessment of secondary-use evidence.

Ideal speakers will have addressed real challenges around data discoverability, fitness-for-purpose, metadata, privacy, traceability, reproducibility and evidence acceptance, and can discuss both successful applications and situations where historical data were not sufficient for the intended purpose.

We especially encourage perspectives from pharmaceutical R&D, industry collaborations such as TransCelerate/DataCelerate, standards organisations such as CDISC/PHUSE, Biostatistics/Clinical Data Science, and regulatory authorities or regulatory data-science experts.

The aim is to bring complementary perspectives across the journey from sharing and standardising data to reusing it responsibly and determining when the resulting evidence is trusted enough to inform decisions.

THE HIDDEN COST OF REUSE: WHEN SIMILAR STUDIES STOP BEING THE SAME

Organizations frequently launch parallel studies using a shared foundation of protocols, CRFs, edit checks, data standards, specifications, and operational processes. The expectation is clear: reuse should accelerate delivery, reduce effort, and promote consistency. Yet experience shows that even studies designed to be highly aligned can diverge rapidly as development progresses.

Drawing on lessons learned from managing parallel studies, this session explores how small, well-intentioned decisions can gradually create substantial differences across study documentation, system builds, data review strategies, and operational processes. Attendees will see how protocol amendments, regional requirements, vendor interpretations, timeline pressures, and study-specific decisions can result in unexpected divergence despite a common starting point.

Studies often begin more than 95% aligned, but differences emerge through protocol amendments, regional requirements, and vendor decisions. Over time processes diverge. Eventually, teams may continue to assume harmonization exists, even when important differences have accumulated.

Through real-world examples, participants will explore divergence across protocols, CRFs, data standards, specifications, edit checks, training materials, and data transfer requirements, and learn practical approaches for maintaining governance without sacrificing the efficiency benefits of reuse.

While AI will be discussed, this is not an AI session. It is a session about study governance, reuse strategy, and proactive Clinical Data Management oversight. AI will be presented as an emerging capability that can help identify inconsistencies across study documentation and systems before they translate into operational issues, rework, or data quality risks.

TOPIC

7. Clinical Trial Operations

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

Individuals from Clinical Data Management, Clinical Operations, Study Management, Clinical Development, Biostatistics, Data Standards, and Clinical Technology/IRT implementation.

WHO AUDITS THE ALGORITHM? ACCOUNTABILITY IN THE AGE OF AUTONOMOUS CLINICAL DATA OPERATIONS

Artificial intelligence is moving rapidly from assisting clinical data professionals to recommending actions, prioritising risks and potentially executing parts of the clinical data lifecycle. But when an AI agent identifies an anomaly, closes a review loop or recommends that no action is required, who remains accountable for the decision?

This panel will confront the governance questions that arise when clinical data operations become increasingly autonomous. Panellists will debate whether traditional validation, audit trails and human review models remain adequate when systems learn, adapt and operate across multiple data sources. The discussion will examine what evidence organisations should retain, when human intervention is meaningful rather than ceremonial, and whether every automated decision must remain fully explainable.

The panel will also explore a difficult possibility: excessive human oversight may create the appearance of control while preventing organisations from realising the benefits of intelligent automation. Conversely, insufficient oversight could make critical decisions impossible to reconstruct or defend.

Rather than asking whether AI can automate clinical data work, this session asks a more urgent question: What new accountability model is needed when the work is performed by humans and machines together?

TOPIC

6. Regulations & Standards

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

Indivduals with experience in deplyment and monitoring from CRO, sponsor and Pharma.

BETWEEN SCYLLA AND CHARYBDIS: STEERING HUMAN OVERSIGHT OF AI IN CLINICAL DATA MANAGEMENT

As AI moves deeper into clinical data management workflows such as data review, cleaning, reconciliation, coding, and query management, and beyond, organisations must steer between two hazards. On one side is Scylla: heavy re-verification of AI outputs, absorbing the cost of automation without realising its benefits and without clear evidence that quality improves as a result. On the other side is Charybdis: over-reliance on AI outputs that no one can fully explain to stakeholders.

Our industry has navigated a similar passage before, in the shift from 100% SDV to the risk-proportionate approaches now embedded in ICH E6(R3). This cross-functional panel (sponsor, CRO, technology, and regulatory/inspector perspectives) will explore how to apply the same thinking to AI. Topics include matching the level of human oversight to the risk and context of use, considering how much the AI influences a decision, and the consequences if it is wrong for critical data, participant safety, or primary endpoints.

The panel will also discuss the evidence needed to demonstrate fitness for purpose and inspection readiness, such as intended use, as well as how to recognise when AI is not the right tool. Each panelist will bring a short example from practice to ground the discussion. The session will draw on ICH E6(R3) and the January 2026 EMA–FDA Guiding Principles of Good AI Practice. Attendees will leave with a practical, defensible course for oversight that keeps the people accountable for AI in clinical data management.

TOPIC

6. Regulations & Standards

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

- EMA / EU inspector (regulatory speaker)
- CRO/Sponsor CDM SME (ideally two distinct sponsors/CROs)
- Technology Service Provider

FROM BEDSIDE TO DATABASE: HOW AI AT THE SITE LEVEL IS RESHAPING DOWNSTREAM DATA QUALITY

Clinical research has spent decades optimizing what happens after data leaves the site - cleaner EDC builds, smarter query management, and more sophisticated risk-based monitoring. What if we could impact what happens at the site at the time of the patient encounter? Addressing data quality issues earlier in the data collection process the less we will have to build quality into the process after the fact.

This session examines how AI-enabled tools at the site level - structured eSource, automated transcription/integration, real-time edit checks - are beginning to change not just how quickly data moves, but how clean it is by the time it reaches sponsors and data management teams. Rather than treating data quality as something to be caught and corrected downstream, these tools raise the possibility of preventing errors at their origin: the moment a coordinator documents a visit, a vital sign, or a protocol deviation.

Drawing on recent survey data and real-world implementation experience across global research sites, panelists will explore what's actually happening on the ground today, separating genuine capability from vendor hype. Topics will include: where AI is already demonstrating measurable impact on source data accuracy and completeness; the operational and workflow barriers that slow adoption at the site level; how data management teams should rethink query rates, monitoring plans, and risk-based quality approaches as source data quality improves; and what sponsors, CROs, and technology providers each need to do differently to capture this opportunity.

The panel will bring together perspectives from site operations, clinical data management, and technology development to give attendees a grounded, cross-functional view - not just of what's technically possible, but of what's realistic to expect over the next 2-3 years. Attendees will leave with a clearer framework for evaluating AI-enabled site tools, practical questions to ask vendors and sites, and a sharper sense of where their own data quality investments might be better placed upstream rather than downstream.

This session is especially relevant for data managers, biostatisticians, site relationship leads, and technology strategists looking to move beyond incremental EDC-side improvements toward structural gains in data quality.

TOPIC

7. Clinical Trial Operations

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

- Individuals with experience in AI and its use within a site setting
- Individuals with an understanding as to how direct collection of source data should impact the way that we manage and clean data
- Individuals from a clinical research site (I have names of people)
- Individuals from a sponsor or a CRO
- Individuals from a vendor related to this session abstract

THE ODYSSEY OF AN IDEA: HOW CONFERENCE LEARNING CAN LEAD TO TRANSFORMATIONS IN ORGANISATIONS

Every year, clinical data professionals leave the SCDM conferences with new learnings, fresh perspectives, innovative ideas, and ambitious plans. Yet many of those insights never progress beyond conference notes, post-event discussions, and individual reflections. This session explores the gap between learning and implementation, seeking to understand what enables some ideas to create lasting organisational impact while others never move beyond initial inspiration.

SCDM conferences are designed to promote knowledge sharing, collaboration, professional development, and the exchange of innovative approaches across the clinical data science community. Attendees return to their organisations energised by new concepts, technologies, methodologies, and ways of working that have the potential to improve processes, strengthen cross-functional collaboration, and drive meaningful change. However, the transition from inspiration to implementation is rarely straightforward.

Competing priorities, limited resources, organisational culture, change fatigue, regulatory considerations, and the challenge of gaining stakeholder support can all influence whether an idea succeeds or stalls. As a result, many professionals find themselves months after a conference reflecting on the same question: what happened to all those great ideas?

Through an interactive discussion and real-world examples, this session aims to explore how conference learnings have been translated into tangible initiatives, process improvements, new capabilities, and different ways of working. Equally important, it will create space to discuss ideas that were never implemented and the barriers that prevented progress. By examining both successes and failures, participants will gain a more complete understanding of the realities involved in turning learning into action.

The session will explore questions such as: What helps new ideas gain traction within organisations? What are the most common obstacles that prevent implementation? How can attendees become effective advocates for change? What role do leadership, stakeholder engagement, timing, and organisational readiness play in transforming inspiration into sustainable impact?

Rather than focusing on a specific technology, methodology, or organisation, this discussion will focus on a challenge that affects the entire clinical data science community: how to maximise the value of professional learning. Attendees will leave with practical insights, relatable experiences, and actionable strategies to help ensure that the knowledge gained at future conferences can translate into meaningful and lasting change.

TOPIC

8. Wild Cards

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

Speakers who have attended SCDM conferences or similar professional forums and have experience bringing conference learnings back to their organisations. This could include individuals who have been involved in translating new ideas, methodologies, technologies, or best practices into actionable initiatives, process improvements, capability-building efforts, or organisational change. The session welcomes perspectives from professionals across different levels and functions, and would benefit from speakers who can share both successful implementation stories and examples where promising ideas failed to gain traction. Finally, the speakers of this session should be willing to reflect openly on lessons learned, common obstacles and practical approaches for turning professional learning into meaningful organisational impact.

BEFORE THE WINDOW CLOSES: AN EPRO DATA QUALITY ODYSSEY

Time-sensitive ePRO and eCOA data present a unique challenge for Clinical Data Management. When an expected assessment is not completed within its intended collection window, identifying the missing data during a later reconciliation or data review may be too late. Unlike many other clinical data issues, a query cannot necessarily recover an assessment that should have been completed contemporaneously.

This session will explore how we can shift our approach from retrospective detection of missing ePRO data to prospective prevention of data loss. Drawing on practical experience with both vendor-managed and sponsor-configured eCOA solutions, we will examine where and why data may be lost throughout the collection process and what can be done while there is still an opportunity to intervene.

Topics will include questionnaire scheduling and availability windows, participant reminders, site and sponsor alerts, compliance dashboards, trigger and stop logic, monitoring strategies, escalation pathways, and the roles of Data Management, Clinical Operations, sites and eCOA providers. The session will also explore the sometimes difficult balance between maximizing data completeness and preserving the validity and contemporaneous nature of patient-reported data.

Through real-world scenarios and audience discussion, we will challenge a traditional assumption: should missing ePRO be treated as a data-cleaning issue at all, or should it be managed primarily as a data-collection risk before the data become irretrievably missing?

TOPIC

7. Clinical Trial Operations

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

- eCOA technology/provider expert (someone who understands alerts, dashboards, notifications, collection windows, questionnaire scheduling, system configuration; to answer: "What can technology realistically prevent?")
- Clinical Operations / Site perspective (to answer: "What is operationally realistic when a patient hasn't completed today's questionnaire?")
- COA/endpoints or biostatistics specialist (to answer: "When does extending the opportunity to collect data improve completeness but potentially undermine the intended timing or interpretation of the assessment?")

ORAL PRESENTATION

SESSION DURATION

60-75 minutes
Q&A Included

THE BIG IDEA

A connected series providing a coherent deep-dive.

HOW IT WORKS

SCDM Oral Presentation sessions, which consist of 3-4 presenters per session covering practical, skills-based content.
Each presentation lasts 20-25 minutes.

It is an ideal session for capable speakers presenting more specialised presentations.

WHAT IT'S NOT

It is not a corporate sales presentation.

Proposed Sessions

- Execution Beyond Detection: Dynamic Governance, Interim Locks, and Deviation Management Under ICH E6(R3)
- Two Truths and a Lie About AI

EXECUTION BEYOND DETECTION: DYNAMIC GOVERNANCE, INTERIM LOCKS, AND DEVIATION MANAGEMENT UNDER ICH E6(R3)

The shift toward Clinical Data Science has improved how teams identify and monitor risk, but many aspects of trial execution remain highly manual. Protocol deviation management, preparation for interim safety and efficacy analyses, and updates to trial quality plans often rely on spreadsheets, manual reconciliation, and last-minute effort.

With ICH E6(R3) placing greater emphasis on ongoing quality management, this vendor-neutral panel will look at how sponsors and CROs are changing the way these activities are managed in practice.

The discussion will focus on three areas: moving from static Integrated Quality Management Plans to more dynamic and actionable quality frameworks; shifting protocol deviation management from manual, retrospective tracking toward more continuous and rule-based approaches; and improving readiness for interim analyses through ongoing data governance rather than relying on intensive data-cleaning efforts immediately before a freeze or lock.

Attendees will gain insight into how clinical operations, data management, data science, and biostatistics can work together more effectively to reduce manual effort, improve visibility, and maintain data and quality readiness throughout the study.

TOPIC

1. Risk-Based CDM

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

- Sponsor VP of Clinical Operations/Data Strategy
- CRO Head of Biostatistics/Data Management
- Quality Assurance/Compliance Officer.

TWO TRUTHS AND A LIE ABOUT AI

Conversations about Artificial Intelligence in clinical data management are filled with claims. Some are true, some partly true, and others could place data integrity, patient safety, or inspection readiness at risk. This interactive session will turn the familiar game of “Two Truths and a Lie” into a practical reality check for the clinical data industry. The audience will be presented with 3 statements: AI can accelerate clinical data review without transferring accountability away from people; when an AI output is accurate and repeatable, it is ready for regulated use; and as AI automates more tasks, experienced DM judgement becomes more important, not less. Two of these statements are true, and one is a potentially dangerous lie.

Participants will vote before each statement is examined through realistic industry scenarios like query generation, cross-source reconciliation, anomaly detection, coding support, report generation and AI-enabled workflow execution. Each reveal will explore what the AI was asked to do, what its output appears to show, what may have been missed and where human judgement must intervene. The session will distinguish between automation, augmentation, and autonomy which are concepts that are often treated as interchangeable despite requiring very different levels of control and oversight. It will also examine why accuracy alone does not establish trust. An AI system may produce a correct answer for the wrong reason, repeat the same error consistently or perform well in one study context while failing in another. Traceability, intended use, validation boundaries, privacy, explainebility, change control and ongoing performance monitoring must therefore form part of the assessment.

The session will connect these principles to the realities faced by sponsors, CROs, technology providers, and clinical data teams. Attendees will leave with a practical TRUTH Check for assessing AI-enabled workflows: the Task and intended use are defined; the Risk is assessed; the Underlying data and provenance are understood; Testing, traceability, and change control are documented; and Human authority and accountability are explicit. The learning outcomes for the session will focus on distinguishing automation, augmentation, and autonomy; recognizing AI failure modes that may affect data integrity or inspection readiness; and applying a practical framework to determine whether an AI-enabled workflow is controlled, traceable, and fit for purpose. The main idea I want to leave with the audience is: “The most dangerous AI output is not the one that looks wrong; it is the one that looks right and is trusted too quickly.”

TOPIC

5. AI & Cognitive Tech

SESSION LEVEL

Novice (CCDA)

LOOKING FOR

Individuals with practical experience implementing, validating, governing, or using AI-enabled solutions within clinical data management. Ideally, speakers should represent different perspectives, such as sponsors, CROs, technology providers, and clinical data professionals, and be able to share real-world lessons on AI adoption, human oversight, validation, risk management, and regulatory or inspection readiness.

ROUNDTABLE DISCUSSION

SESSION DURATION

60-75 minutes
Q&A Included

THE BIG IDEA

A space for speakers to deliver CDM best practice and actionable ideas.

HOW IT WORKS

A flexible format to presentations. Sessions may look quite different from each other, but they have one thing in common: it allows for extended discussion among a small group. Roundtables are an ideal forum for having the speakers very accessible to the SCDM audience, for giving and receiving targeted feedback, and for engaging in in-depth discussions.

WHAT IT'S NOT

Roundtables are not Panel Discussions conducted in long-play format.

Equally, the discussion should not be lacking in focus or in learner outcomes.

Proposed Session

- Acknowledged Is Not Resolved: Earning Trust Through Cross-Functional Follow-Through in CDM

ACKNOWLEDGED IS NOT RESOLVED: EARNING TRUST THROUGH CROSS-FUNCTIONAL FOLLOW-THROUGH IN CDM

A data quality issue is identified, raised and acknowledged. Months later, the same issue is still open. In global, outsourced and functional service provider (FSP) models, data managers are accountable for data readiness but rarely own the fix. Sites enter and correct data, CRAs follow up, Medical interprets requirements and study leaders allocate resources. When "we will follow up" is recorded as progress, confidence in the data, and in each other, starts to erode.

This session treats that gap as a leadership problem that structure can solve, not one that needs a firmer tone. It builds on the change-management and executive-communication themes of the SCDM EMEA 2025 session Beyond Data: Developing Leadership and Strategic Agility in Clinical Data Management, and moves from broad leadership capability to one recurring, practical situation: how a data manager influences action on an issue they do not own.

The session works through anonymized situations from global study delivery: follow-up on recurring site data issues that stalls at acknowledgment for months, different interpretations of the same visit requirement, and a targeted data review request that has to turn a metrics report into specific site actions by a set date. Data management, Clinical Operations and sponsor study-lead perspectives show why the same issue looks different from each seat, and what each function needs before it can act.

In small groups, participants apply three tools to one case: a stakeholder and decision map that separates who decides from who acts, a concise decision request (issue, consequence, options, recommendation, owner and decision needed), and a closure definition that distinguishes acknowledgment, commitment and verified completion. The debrief compares how each function would respond, without assigning blame.

Participants leave with a one-page worksheet to use on a recurring issue in their own study, a structure for escalations that ask for a decision rather than another update, and one first action to take back to their team.

TOPIC

3. Clinical Data Competencies & Cross-Functional Interactions

SESSION LEVEL

Intermediate (CCDM)

LOOKING FOR

We are looking for people with hands-on experience moving data quality issues to resolution across functional or organizational boundaries in global studies. We want three perspectives on the same problem:

Clinical Operations: CRA line managers or Clinical Operations leads who have balanced data management requests against site and monitoring workload.
Sponsor study leadership: global study leads or study managers who make decisions when issues are escalated to them.
Sites: research coordinators or site data leads who can describe how follow-up requests look from the site.

Speakers should be willing to share real, anonymized examples of follow-up that stalled or succeeded, including what helped an issue reach verified closure. Experience in outsourced or FSP delivery models is especially welcome.

DEBATE

SESSION DURATION

45-60 minutes
Q&A Included

THE BIG IDEA

A dynamic, structured debate that brings opposing viewpoints to the forefront in an engaging and thought-provoking format.

HOW IT WORKS

Debate sessions are designed to encourage critical thinking, present contrasting perspectives, and stimulate meaningful discussion.
A debate features two speakers or teams presenting opposing arguments on the same topic.
• Each side has a set amount of time to present their position.
• Rebuttals follow, allowing each side to respond to arguments raised.
• A moderated Q&A or audience interaction segment concludes the session.
The moderator ensures balance, keeps timing on track, and guides the flow of the discussion to maintain clarity and engagement.

WHAT IT'S NOT

It is not a casual conversation or an unstructured panel.
It focuses on presenting clear, contrasting viewpoints rather than broad, general commentary.

Proposed Session

- Order in the Court! The Trial of Clinical Data Science: Sponsor vs. CRO vs. Tech Provider

ORDER IN THE COURT! THE TRIAL OF CLINICAL DATA SCIENCE: SPONSOR VS. CRO VS. TECH PROVIDER

The shift from Clinical Data Management (CDM) to Clinical Data Science (CDS) is a fundamental paradigm shift: moving from transactional, post-hoc eCRF cleaning toward holistic, real-time surveillance and predictive analytics across complex data streams. Benchmark research shows that while biopharma organizations aspire to this risk-proportionate, AI-enabled model, real-world execution is stalled by legacy SOPs, commercial inertia, and trust boundaries. Who holds the key to operational transformation, and who stands in the way?

Welcome to the "Court of Clinical Data Science." In this high-stakes SCDM debate, three heavyweights representing Sponsors, CROs, and Tech Providers argue that their group is the primary architect (or the biggest bottleneck) of the industry's future. The motion before the court: Which stakeholder group holds the ultimate power and responsibility to drive the transformation from traditional CDM to true CDS?

Presided over by the Session Chair as "Chief Justice," each debater defends a distinct position. Their exact positions will be defined upon recruitment, but could include:

The Sponsor Advocate: Argues that transformation is governed by Sponsor risk appetite, quality management systems, and budget allocation, asserting neither CROs nor Tech Providers can innovate beyond what a Sponsor's risk tolerance permits.

The CRO Advocate: Argues that transformation is defined by operational scale and delivery models, contending that because CROs execute most global trials, modernization lives or dies in how CRO workforces, FTE structures, and clinical operations adapt.

The Tech Provider Advocate: Argues that transformation is dictated by digital infrastructure, asserting that without modern platform architecture, continuous ingestion engines, and AI automation, Sponsors and CROs are simply applying legacy manual review to modern data volumes.

The format ensures high energy, rapid debate, and rigorous analysis:

Opening Salvos: Each advocate delivers a 5-minute uninterrupted argument outlining their core thesis.

Cross-Examination & Rebuttals: The Chief Justice interrogates each debater on operational blind spots and commercial contradictions, followed by rapid-fire cross-examination among debaters.

The Jury's Turn: The floor opens for direct audience interrogation.

This is an unvarnished examination of the commercial friction, SOP inertia, and reskilling required to modernize clinical trial execution. The audience serves as the jury, voting via live poll before and after the session. The debater who most effectively sways the audience's sentiment wins the trial.

TOPIC

8. Wild Cards

SESSION LEVEL

Novice (CCDA)

LOOKING FOR

- A Head of Clinical Data Science/Data Management from a Leading European Sponsor to advocate for the Sponsor perspective.
- A VP of Clinical Data Science/Clinical Data Management/Data Operations/Innovation from a leading CRO to advocate for the CRO perspective.
- A senior technology product leader/strategist from a technology provider to advocate for the technology provider's perspective.

QUESTIONS?



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