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SCOPE 2026

Conference Track Summary

AI in Clinical Research

SCOPE365, a Cambridge Healthtech Institute Company
Accelerating fit-for-purpose and flexible clinical trial research partnerships with confidence

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AI in Clinical Research - Track Overview

Track Overview

This track examined how artificial intelligence is moving from experimentation to practical application across the clinical research lifecycle. Rather than focusing on abstract potential, speakers emphasized where AI is already delivering measurable value, where it is creating new operational risks, and where human judgment remains essential.

Most Frequently Covered Issues

- 1. From pilots to production-scale AI**
Moving beyond proofs of concept to deploy AI systems that operate reliably in regulated, real-world environments.
- 2. Agentic AI and workflow orchestration**
Using AI agents to coordinate multi-step processes across design, activation, monitoring, and reporting, rather than optimizing isolated tasks.
- 3. Data readiness and digital foundations**
The need for digitized protocols, harmonized data, and strong data engineering as prerequisites for effective AI.
- 4. Human oversight, trust, and governance**
Balancing automation with explainability, auditability, and clear accountability in highly regulated settings.
- 5. Adoption and change management**
Addressing cultural resistance, user training, and workflow redesign to ensure AI tools are actually used and trusted.

Recurring Takeaways

- AI delivers the most value when embedded directly into existing workflows, not layered on top as a separate tool.
- Agentic approaches enable continuous decision loops, but humans remain central to oversight and final judgment.
- Strong data foundations matter more than model sophistication.
- Trust, transparency, and validation are competitive differentiators, not just compliance requirements.
- The path forward is incremental and modular, focusing on high-impact use cases rather than end-to-end replacement.



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Building AI-Enabled Clinical Control Towers for Real-Time Oversight

[Full Video Here](#)

Francis Kendall, Head of Statistical Programming, Digital and Data Sciences, Biogen

The speaker introduced clinical control towers as centralized platforms for real-time trial oversight across recruitment, quality, and performance. Disconnected tools limit insight, while integrated platforms enable proactive decision-making. (00:00:00–00:01:38)

He described how different user groups, from executives to trial managers and data scientists, require tailored views into the same underlying data. Unified access supports faster and more consistent decisions. (00:01:38–00:03:58)

Using Biogen's BEACON example, he showed how forecasting, site ranking, and portfolio dashboards can guide resourcing and risk mitigation. Embedded AI improves prediction accuracy and scenario planning. (00:03:58–00:10:54)

He closed by emphasizing data quality as the foundation for any control tower. AI amplifies insight only when built on trusted, integrated data sources. (00:10:54–00:16:53)

Key Takeaways

- Control towers unify trial oversight in real time.
- Embedded AI enables forecasting and risk detection.
- Different users need different operational views.
- High-quality data is essential for AI value.

Agentic AI in Clinical Data Management: From Promise to Practice

[Full Video Here](#)

Prasanna Rao, Chief Products and Innovation Officer, Saama

The speaker positioned agentic AI as the next step beyond RPA, ML, and generative AI, arguing that real impact comes from agents that can think, plan, and act across systems. Clinical data management, rich with SOPs and tribal knowledge, is well suited for this shift. (00:00:00–00:01:19)

He defined agents in terms of goals, tasks, and skills, drawing parallels to autonomous systems like self-driving cars. The emphasis was on intent-based execution rather than rigid commands. (00:01:19–00:02:32)

A live demo showed a persona-based “junior data manager” agent performing continuous data review, detecting anomalies, and proposing queries with full protocol traceability. Human approval remained central to decision-making. (00:02:32–00:11:16)

Measured impact focused on left-shifting data review from end-of-study to continuous oversight. This approach reduces late surprises while preserving human-in-the-loop governance. (00:11:16–00:12:35)

Key Takeaways

- Agentic AI enables continuous, role-based data review.
- Goals, tasks, and skills form the backbone of effective agents.
- Human oversight remains essential for trust and compliance.
- Early deployment shifts data quality work earlier in the trial.

From Automation to Agentic AI: A Clinical Trial Inflection Point

[Full Video Here](#)

Krishna Cheriath, VP Digital and AI, Thermo Fisher Scientific

The speaker framed agentic AI as a pivot beyond traditional automation, driven by the growing complexity of clinical trials. While automation improved efficiency, many risks are still detected too late. (00:00:01–00:04:02)

He introduced a staged model of AI augmentation, from human-led work to selective autonomy with audit-based oversight. Most clinical roles are expected to remain in augmented, not fully autonomous, modes. (00:04:02–00:09:08)

Four opportunity areas stood out: smarter trial design, faster site activation, better patient identification, and continuous data monitoring. Progress requires multiple coordinated improvements rather than a single solution. (00:09:08–00:14:31)

He closed by emphasizing trust, governance, and human experience as competitive differentiators. AI succeeds when it augments people and shortens the path to patients. (00:14:31–00:22:55)

Key Takeaways

- Automation has reached its ceiling for complex trials.
- Agentic AI extends optimization across silos.
- Most roles will see augmentation, not autonomy.
- Governance and trust are critical to adoption.

The Data & AI Imperative: Transforming Clinical Operations for the Next Decade

[Full Video Here](#)

Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb

The speaker framed clinical operations' biggest challenge as insight latency, the gap between when something happens and when teams can act on it. AI offers a way to close that gap, but only if organizations rethink how work is structured. (00:00:00–00:02:31)

He outlined four pillars for 2030, starting with autonomous clinical workflows that plan, execute, and monitor multi-step processes across systems. The value comes not from adding AI to existing workflows, but from redesigning processes with AI as a core participant. (00:02:31–00:08:33)

The second and third pillars focused on adaptive, machine-readable protocols and predictive site and patient experiences. Continuous simulation, digital twins, and privacy-preserving learning could shift trial design from retrospective fixes to proactive optimization. (00:08:33–00:15:23)

The final pillar emphasized zero-latency data and continuous quality, paired with a redefined human role. As AI handles more execution, humans focus on judgment, ethics, and relationship leadership. (00:15:23–00:21:54)

Key Takeaways

- Insight latency remains a core limitation in clinical operations.
- AI delivers value only when workflows are redesigned from the ground up.
- Digital protocols and predictive models enable proactive trial optimization.
- Human judgment becomes more critical, not less, in AI-enabled operations.

AI in Clinical Development: Shaping the Regulatory Environment to Enable Transformative Innovation

[Full Video Here](#)

Kevin Bugin, PhD, Head of Global Regulatory Policy and Intelligence, Amgen

Anindita “Annie” Saha, Associate Director for Strategic Initiatives, FDA

Tala Fakhouri, Vice President, AI and Digital Policy Consulting, Parexel

Panelists discussed how FDA and regulators are encouraging responsible AI use while maintaining human oversight. Current policy supports innovation, provided sponsors apply risk-based thinking and transparency. (00:00:00–00:03:52)

The discussion emphasized reimagining evidence generation rather than optimizing isolated steps. AI’s greatest potential lies in transforming how data is used across development, not in incremental efficiency gains. (00:03:52–00:08:01)

Speakers cautioned against over-validation and misapplying legacy system validation rules to AI. Excessive process burden can slow adoption without improving safety or credibility. (00:08:01–00:10:59)

They highlighted the importance of early and frequent regulatory engagement, clear definitions, and global alignment. Consistency across FDA, EMA, and other agencies is critical for multinational trials. (00:10:59–00:14:02)

Key Takeaways

- Regulators support AI when applied transparently and responsibly.
- Transformative value comes from rethinking evidence generation end to end.
- Over-validation can hinder AI adoption without adding protection.
- Early engagement and global alignment reduce regulatory uncertainty.

Designing with Foresight: Turning Operational Data into Protocol Performance

[Full Video Here](#)

Ian Bailey, Managing Director, AI and Data Science, Advarra

Jamie Bendrick-Peart, Senior Director, Innovation and Strategic Projects, Novartis

The speakers described how many trial issues emerge only after execution begins, often resulting in costly amendments. Operational data has historically been difficult to access, limiting early insight. (00:00:00–00:01:10)

They explored how AI can unlock historical protocol and amendment data to pressure-test assumptions before site activation. This enables teams to identify operational risks earlier and reduce avoidable amendments. (00:01:10–00:06:26)

The discussion highlighted the disconnect between scientifically sound protocols and real-world site and patient experience. Amendments frequently stem from overlooked operational and experiential factors. (00:06:26–00:11:22)

A retrospective case example showed how benchmarking against prior studies can predict amendment risk. Early visibility allows sponsors to adjust design decisions and avoid downstream disruption. (00:11:22–00:18:15)

Key Takeaways

- Many protocol issues are operational, not scientific, in nature.
- AI can surface amendment risk before trials reach execution.
- Patient and site experience must be considered early in design.
- Predictive insights reduce cost, churn, and trial delays.

AI as the Catalyst: Re-Imagining Clinical Trial Delivery

[Full Video Here](#)

Rob Goodwin, COO, Parexel

The speaker argued that most AI initiatives today simply make existing silos faster rather than fundamentally better. True value comes from reimagining workflows end to end, deciding what to stop doing, simplify, or eliminate. (00:00:00–00:02:12)

He traced how clinical trials have layered technology over decades without reducing complexity, leaving roles like CRAs overwhelmed by growing data volume. AI creates an opportunity to rethink roles, decision-making, and how information flows across functions. (00:02:12–00:05:39)

The talk emphasized shifting from function-driven models to purpose-driven orchestration, enabled by open data and real-time insight. Cross-functional “orchestrators” replace rigid handoffs and static governance. (00:05:39–00:12:28)

He closed by reframing AI as a catalyst for patient-centric redesign, not just automation. Simplifying experiences for patients, sites, and teams ultimately determines whether innovation delivers real impact. (00:12:28–00:20:41)

Key Takeaways

- AI often accelerates silos instead of transforming workflows.
- Layering technology without redesign increases complexity.
- Purpose-driven orchestration can replace rigid functional models.
- Patient experience should anchor all AI-enabled change.