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.

Design Once, Execute Everywhere: Leveraging AI and PwC's Digital Trial Core Vision to Orchestrate Modern Trials

Full Video Here

Matthew Markman, Manager, Pharma & Life Sciences R&D Analytics, PwC
Joe Ricks, Senior Associate, Pharma & Life Sciences R&D Analytics, PwC

Clinical development remains heavily document-driven, creating friction as teams translate and reconcile Word and Excel files across protocols, budgets, and contracts. This "split-screen reality" slows execution and introduces risk as documents drift from their original intent. (00:00:00–00:01:18)

The speakers explained how protocol optimization efforts often erode over time as documents change without visibility or feedback loops. As amendments accumulate, patient and site burden can creep back in, undermining enrollment goals without teams realizing it. (00:01:18–00:02:44)

While standards efforts like CDISC and TransCelerate have improved data consistency, the challenge has shifted from defining digital data flow to actually implementing it. Advances in AI, mature data standards, and greater organizational readiness have created a practical window to embed digital data flow into daily workflows. (00:02:44–00:05:30)

They introduced the concept of a Digital Trial Core, a continually updated, modular, single source of truth that extends beyond the protocol to include operational data like vendors, geographies, and sites. By enabling parallel work and downstream automation, this approach reduces rework, shortens startup timelines, and lowers amendment risk. (00:05:30–00:08:26)

Key Takeaways

- Document-based workflows remain a major drag on trial speed and consistency.
- Protocol intent often degrades as documents change without transparency.
- Digital data flow now benefits from mature standards, AI, and organizational readiness.
- A Digital Trial Core can reduce startup time, rework, and amendment risk.

Why Robust Standards Are Critical to Leveraging AI to Accelerate Clinical Research

Full Video Here

Chris Decker, Chief Executive Officer, CDISC

The speaker argued that AI does not eliminate the need for standards and instead depends on them to produce reliable results. Structured, well-defined data enables AI to work effectively, while poorly defined data increases the risk of error and hallucination. (00:00:00–00:01:19)

He explained that the challenge with standards is not over-complexity, but visibility. Standards need to become more sophisticated under the hood, while remaining easy for end users to consume without exposing the "plumbing." (00:01:19–00:02:26)

The presentation described how CDISC is refactoring its standards to support digitized study design rather than focusing solely on submission outputs. Models like USDM are intended to connect information from study design through analysis, enabling end-to-end traceability. (00:02:26–00:06:55)

He concluded by outlining CDISC's 360i initiative, which uses AI to accelerate standards development and enable automation across the trial lifecycle. This approach positions standards as active AI enablers rather than static compliance artifacts. (00:06:55–00:15:51)

Key Takeaways

- AI relies on robust data standards to function reliably.
- Standards must become more sophisticated but easier to consume.
- Digitizing study design is critical for downstream automation and traceability.
- CDISC is repositioning standards as active enablers of AI-driven workflows.

Evaluating Generative AI Output: Toward Robust Assessment with Human and Automated Methods

Full Video Here

Rogier Landman, PhD, Associate Director Data Science, Pfizer

The speaker outlined the central role of statistical analysis plans and the time-intensive effort required to draft them manually. At scale, even small efficiency gains can significantly reduce workload across large portfolios. (00:00:00–00:01:42)

He described an AI-assisted approach that maps protocol templates to SAP templates, using structured prompts and prior documents as inputs. Large language models generate SAP sections one at a time and assemble them into a complete first draft. (00:01:42–00:03:21)

Different generation modes are used depending on the section, including copying, summarizing, inserting dynamic variables, or generating new text. Care is taken to preserve original wording where precision matters most. (00:03:21–00:07:11)

The presentation emphasized the importance of rigorous evaluation using both subject matter expert review and AI-based semantic assessment. This combination reduced drafting time from days to minutes while maintaining accuracy and trust. (00:07:11–00:11:34)

Key Takeaways

- SAP drafting is a high-effort, high-volume activity well suited to AI support.
- Mapping protocol and SAP templates enables structured automation.
- Multiple generation modes help balance accuracy and efficiency.
- Rigorous evaluation is essential for trustworthy AI adoption.

Harnessing Gen AI for Clinical Development

Full Video Here

Scott Chetham, Chief Executive Officer and Co-Founder, Faro Health

The speaker described how protocol design remains a major bottleneck due to fragmented workflows and document-based processes. Faster decision-making enables better science, but only if design quality improves alongside speed. (00:00:00–00:01:32)

He introduced an AI-driven protocol review workflow that analyzes objectives, endpoints, and schedules of activities using natural language. The system provides transparent, evidence-based recommendations without forcing teams to change how they work. (00:01:32–00:07:06)

The approach enables teams to identify over-collection, reduce patient and site burden, and resolve design debates using objective data. Reviews that once took weeks can be completed in hours with full traceability. (00:07:06–00:11:20)

A blinded case study showed how phased adoption and peer-led rollout drove enterprise-scale adoption. The result included faster protocol lock, reduced amendments, and significant cost avoidance. (00:11:20–00:16:51)

Key Takeaways

- AI can support faster, higher-quality protocol design decisions.
- Natural language workflows reduce disruption to existing processes.
- Transparent, traceable recommendations build trust and adoption.
- Scaled deployment can reduce timelines, amendments, and costs.

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.

Agentic AI: Driving Business Value Through Implementation, Change Management While Navigating Compliance & IP Challenges

Full Video Here

Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Angela Radcliffe, Founder, How Mighty We Ventures
Nagaraja Srivatsan, Chief Executive Officer, Endpoint Clinical

Panelists outlined four AI categories, from knowledge assistants to agentic automation, with compliance considerations increasing as autonomy grows. Human accountability remains central regardless of automation level. (00:00:00–00:02:20)

They discussed pharma's shift from AI exploration to execution, emphasizing FAIR data principles and clean, interoperable foundations. Agentic strategies require early alignment between innovation, operations, and compliance teams. (00:02:20–00:05:27)

Speakers warned against over-reliance on AI outputs, highlighting risks like "AI slop" and automation bias. Best practice includes human-in-the-loop review, checker-the-checker models, and rigorous training. (00:05:27–00:16:02)

The session concluded with a call for mindset change, experimentation, and psychological safety. Leaders must create space for learning while anchoring AI use to patient impact and regulatory responsibility. (00:16:02–00:24:14)

Key Takeaways

- Compliance responsibility always sits with humans, not AI.
- FAIR data foundations enable scalable AI adoption.
- Guardrails prevent automation bias and low-quality outputs.
- Culture and mindset matter as much as technology.

From Insights to Outcomes: A Practical AI Playbook for Trial Teams

Full Video Here

Suzanne Caruso, GM, Clinical and Regulatory and SI, CiteLine

The speaker positioned AI as a set of targeted tools rather than a single solution, each suited to specific workflow problems. Fragmentation across the trial lifecycle creates gaps that humans have traditionally bridged manually. (00:00:00–00:03:33)

She walked through practical AI use cases, including predictive enrollment models, anomaly detection, and NLP for unstructured data. These tools deliver value when matched deliberately to the right task. (00:03:33–00:07:11)

Generative AI was framed as a strong starting point for documents, not a replacement for expert judgment. Early ROI depends on defining success criteria such as time savings, accuracy, or decision support. (00:07:11–00:08:27)

The session emphasized AI agents as the next evolution, automating repeatable workflow steps while preserving human expertise for final decisions. Agents enable flexibility without removing accountability. (00:08:27–00:12:10)

Key Takeaways

- AI value comes from matching tools to specific problems.
- Predictive models improve forecasting but require iteration.
- Generative AI accelerates starts, not final outputs.
- Agents automate routine work while preserving expert judgment.

Who's Training on Your Trial? Where Your Data Goes When You Use AI

Full Video Here

Storm Stillman, Chief Executive Officer, Curebase

The speaker opened by highlighting how casually clinical teams now paste sensitive trial data into public AI tools, often without understanding where that data is stored or who can access it. What feels like a simple query can expose protocols, patient information, and competitive strategy. (00:00:00–00:01:14)

He explained that many AI interactions involve multiple vendors behind the scenes, each with its own retention and security policies. A single voice or chat interaction can route data through several services, multiplying exposure risk. (00:01:14–00:03:30)

The presentation outlined a security spectrum, ranging from on-device and private cloud deployments to direct use of public AI providers. The farther data travels from controlled environments, the higher the risk of reuse or unintended training. (00:03:30–00:07:16)

He concluded with practical guidance, including data minimization and asking vendors hard questions about retention, training, and deployment options. Sponsors should assume responsibility for controlling where AI touches their data. (00:07:16–00:10:30)

Key Takeaways

- Public AI tools can expose sensitive clinical data.
- AI workflows often involve multiple unseen vendors.
- Local and private deployments reduce data risk.
- Sponsors must actively govern AI data usage.

Fit-for-Purpose AI Applications in Clinical Trials

Full Video Here

Henry Wei, Executive Director, Development Innovation, Regeneron
Amy Chowansky, Sr. Director, AI Strategy Lead, Pfizer
Nareen Katta, Head of Data Science and Analytics, AbbVie

Panelists shared firsthand experiences applying AI to protocol design, site strategy, and recruitment challenges. Early efforts focused on reducing protocol burden, preventing amendments, and simplifying execution. (00:00:00–00:03:06)

Regeneron described using AI to deconstruct protocols into structured components, enabling analysis of burden and amendment risk. External design-led approaches helped reframe problems before applying AI. (00:03:06–00:04:53)

AbbVie and Pfizer emphasized site activation and recruitment as priority bottlenecks. AI-assisted document generation and patient identification showed early signs of cycle-time reduction and site satisfaction. (00:04:53–00:10:32)

The discussion stressed that value realization depends on process change and adoption, not tools alone. Change management and early adopters play a critical role in scaling impact. (00:10:32–00:18:12)

Key Takeaways

- AI can reduce protocol burden and amendment risk.
- Recruitment and site activation show early AI gains.
- Design thinking strengthens AI effectiveness.
- Adoption hinges on process integration, not pilots.

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.

Using Knowledge Graphs to Unify Clinical Intelligence

Full Video Here

Ankit Singh, MS, Senior AI Scientist, IR, AbbVie
Bryan Feldman, Sr. Director, Business Technology, AbbVie

The speakers explained how knowledge graphs sit between structured databases and data lakes, creating context-rich connections across clinical content. Protocols, endpoints, visits, and procedures become linked rather than siloed. (00:00:00–00:02:49)

They described building a graph-first foundation by extracting complex protocol elements, including tables and images, into structured nodes and relationships. This enabled rapid querying and reuse across studies. (00:02:49–00:08:50)

The Magellan platform demonstrated how AI agents use the graph to assist trial designers in real time. Suggestions for endpoints, eligibility criteria, and schedules are grounded in historical trials and literature. (00:08:50–00:14:47)

Rather than replacing experts, the system acts as a knowledgeable collaborator. The goal is fewer amendments and more informed decisions before protocols are finalized. (00:14:47–00:19:28)

Key Takeaways

- Knowledge graphs provide context AI models need to reason.
- Protocols become reusable, connected assets.
- Agents guide designers with evidence-based suggestions.
- Early insight reduces downstream amendments.

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.

Agentic AI for Risk-Based Quality Management

Full Video Here

Nicolas Huet, Machine Learning Sr. Manager, CluePoints
Usama Dar, Chief Product and Technology Officer, CluePoints

The speakers described how recent advances in large language models now enable context-aware reasoning across complex clinical workflows. This shift allows AI to move beyond static rules into continuous, adaptive decision loops. (00:00:01–00:01:41)

They framed risk-based quality management as an ideal fit for agentic AI because it is inherently cyclical and context driven. Planning, monitoring, acting, and documenting can now be executed continuously rather than episodically. (00:01:41–00:05:45)

A key theme was consolidating fragmented signals into a single, explainable view of risk. Agents can integrate structured data, unstructured documents, and protocol context to identify root causes instead of isolated alerts. (00:05:45–00:11:05)

The presentation emphasized auditable-by-design workflows with human oversight. AI recommends actions with full traceability, while humans retain control over final decisions. (00:11:05–00:22:02)

Key Takeaways

- Agentic AI enables continuous, context-aware RQM loops.
- Consolidation reduces signal overload and duplication.
- Explainability and traceability are essential for trust.
- Humans remain central to final risk decisions.

Production-Grade Agentic AI for Clinical Trial Compliance

Full Video Here

Shuba Simha, Sr. Director, Engineering and Operations, Bristol Myers Squibb
Sujan Gowda, Sr. Manager, Engineering, Global Clinical Development, Bristol Myers Squibb

The speakers introduced PAAR, an agentic AI system built to manage protocol amendment impact reviews for clinical trial disclosure. The goal was to reduce manual effort while ensuring regulatory compliance. (00:00:17–00:03:17)

They explained how multi-agent orchestration replaces a highly manual, multi-handoff process. Specialized agents extract content, compare amendments, validate outputs, and prepare structured submissions. (00:03:17–00:09:34)

Human review remains embedded at critical checkpoints, allowing experts to override AI decisions and provide feedback. This feedback loop improves future agent behavior and accuracy. (00:09:34–00:16:18)

Since deployment, the system has achieved full compliance with clinical trial reporting requirements and reduced operational risk. The architecture is modular, enabling expansion to other compliance workflows. (00:16:18–00:21:18)

Key Takeaways

- Agentic AI can safely automate high-risk compliance workflows.
- Review agents reduce hallucination and error.
- Human feedback improves long-term performance.
- Modular agents support reuse across processes.

AI Digital Twins for Clinical Decision Support

Full Video Here

Yifan Zhu, PhD, Director, Clinical Statistical Modeling, Sanofi

The speaker explored AI-based digital twins as a way to simulate patient outcomes under alternative treatment scenarios. These models extend traditional prognostic and simulation approaches. (00:00:00–00:01:38)

Digital twins were positioned as especially valuable in settings like Alzheimer's and rare diseases, where sample sizes are constrained. Early applications show potential for meaningful sample size reduction. (00:01:38–00:04:52)

A Sanofi case study in asthma demonstrated how deep learning models can improve long-term outcome prediction. Transfer learning across related diseases enhanced model performance. (00:04:52–00:13:12)

The talk highlighted ongoing challenges, including data requirements, extrapolation limits, and lack of built-in causality. Future progress will depend on integrating AI with mechanistic and causal modeling. (00:13:12–00:22:43)

Key Takeaways

- Digital twins simulate alternative patient outcomes.
- AI models can improve trial efficiency and power.
- Data quality and comparability remain limiting factors.
- Causal integration is key to future adoption.

Evaluating End-to-End Agentic AI Workflows in Clinical Trials

Full Video Here

Michael Cohen-Wolkowiez, Faculty, Duke University; Director, iC³, Duke Clinical Research Institute

The speaker introduced Project Loom, a proof-of-concept study that tested whether agentic AI could execute an entire clinical trial workflow with human oversight. A previously completed Duke trial was used as a benchmark to compare AI-generated outputs against human-produced artifacts. (00:00:00–00:02:15)

A network of specialized agents generated core study documents, submitted IRB packets, identified and engaged participants, collected PROs, and ingested synthetic EHR data. Existing systems such as EDC were deliberately kept in the loop to avoid creating a black-box environment. (00:02:15–00:05:51)

The full simulated trial ran in roughly 7.5 days of agent work and 14 days total when accounting for human interaction. Participants responded positively to voice-based agents for consent and data collection, citing convenience and clarity. (00:05:51–00:08:26)

Limitations included handling off-script participant questions and tailoring tone to different personas. The team emphasized the need for ongoing evaluation of accuracy, compliance, and ROI before real-world deployment. (00:08:26–00:11:45)

Key Takeaways

- End-to-end agentic trials are technically feasible.
- Time compression was substantial compared to human workflows.
- Human oversight remains essential for quality and trust.
- Independent evaluation is critical before production use.

Data Engineering for Speed and Trust with AI Agents

Full Video Here

Arnab Roy, Associate Principal, R&D, ZS Associates
Sunanda Teeparti, Assoc. Director, BTS R&D, AbbVie
Rajiv Harpalani, Associate Director, Data Governance, AbbVie
Jinit Shah, Assoc. Principal, ZS Associates

Panelists discussed how speed, quality, and cost must be balanced when scaling clinical data platforms. Reliable, harmonized data pipelines were positioned as the foundation for trustworthy AI agents. (00:00:08–00:03:10)

AbbVie described using agentic approaches to accelerate data ingestion, profiling, and pipeline development across dozens of systems. Early automation focused on areas with clear ROI rather than end-to-end replacement. (00:03:10–00:07:57)

Validation emerged as a major bottleneck, prompting the use of agents to generate test scripts, evidence, and dry runs. This reduced testing effort by up to 60 percent while preserving GxP rigor. (00:07:57–00:13:40)

Panelists stressed modular design, standardized inputs, and human-in-the-loop review as keys to sustainable adoption. AI was framed as an enabler of better decision-making, not a substitute for accountability. (00:13:40–00:20:28)

Key Takeaways

- Trustworthy AI depends on strong data foundations.
- Agentic automation can significantly reduce validation effort.
- Modular use cases ease change management.
- Humans remain accountable in regulated environments.

Agentic AI to Accelerate Clinical Data Management Artifacts

Full Video Here

Jeremy Zhang, PhD, Sr. Director, Data Science, Otsuka

The speaker presented a production-ready agentic AI system that generates CRFs and edit-check specifications directly from digitized protocols. The goal was to shorten study startup by several weeks. (00:00:00–00:01:46)

A multi-agent architecture digitizes protocols in minutes, maps schedules of assessments to CRFs, and streams artifact generation for review. Microsoft Word was intentionally used as the interface to minimize user retraining. (00:01:46–00:05:59)

Historical CRFs and standards were treated as vectorized “semantic assets,” allowing agents to reuse institutional knowledge. Accuracy approached near-complete coverage, with human review required for non-standard protocols. (00:05:59–00:10:24)

The system also generates edit-check specifications and supports CRO collaboration through clear, standardized outputs. Change management and user adoption were cited as equally important as technical performance. (00:10:24–00:16:15)

Key Takeaways

- Agentic AI can compress study startup timelines.
- Historical standards are critical differentiators.
- Familiar tools improve adoption and trust.
- Human review is still required for GxP readiness.

Human-Centered AI for Patient Access and Enrollment

Full Video Here

Ramita Tandon, Chief Biopharma Officer, Walgreens

The speaker emphasized that while AI can identify and match patients to trials at scale, enrollment still hinges on human trust and engagement. A matched patient does not automatically become an enrolled patient. (00:00:03–00:05:19)

From Walgreens' perspective, AI works best as an enabler that removes friction from workflows rather than as a replacement for human systems. Deep community presence and long-standing relationships allow technology to be paired with education and trust. (00:05:19–00:08:53)

She highlighted that bias already embedded in healthcare data cannot be solved by algorithms alone. Human systems are required to uncover, address, and correct those biases. (00:08:53–00:12:06)

The talk concluded with a call for community-based research models where AI, people, and access points work together. Enrollment improves when patients see trials as a care option within their everyday healthcare journey. (00:12:06–00:15:09)

Key Takeaways

- Patient matching is not the same as patient enrollment.
- Trust and education remain essential for participation.
- AI should augment, not replace, human engagement.
- Community-based access expands trial inclusion.

Using GenAI to Accelerate Trial Activation at the Site Level

Full Video Here

Karen Hartman, Vice Chair Research Administration, Mayo Clinic

The speaker shared a site-level view on applying AI across trial activation, from protocol intake through budgeting, contracting, and logistics. Not every problem requires agentic AI; simpler automation often delivers value faster. (00:00:00–00:01:11)

Mayo Clinic implemented an internal LLM-based protocol ingestion tool that abstracts key study details from uploaded PDFs in minutes. This replaces hours of manual data entry and reduces downstream errors. (00:01:11–00:04:55)

The system flags inconsistencies within protocols, enabling earlier correction before activation delays occur. Staff are freed to focus on higher-value work such as negotiation and critical review. (00:04:55–00:07:17)

Adoption success was tied to involving frontline users in design and prioritizing high-impact bottlenecks. Change management and ROI considerations were stressed as critical to sustainable AI deployment. (00:07:17–00:12:30)

Key Takeaways

- Trial activation contains repeatable automation opportunities.
- Protocol abstraction significantly reduces manual effort.
- User-driven design improves adoption.
- ROI should guide AI investment decisions.

Applying AI Thoughtfully in eCOA Design and Patient Engagement

Full Video Here

Paul O'Donohoe, Sr. Director, eCOA Product and Science, Medidata

The speaker traced the evolution of patient-reported outcomes from paper to eCOA and now toward AI-enabled workflows. Each technological shift faced early skepticism before becoming standard practice. (00:00:00–00:02:45)

Medidata's current AI focus is on back-end study build activities rather than direct patient interaction. AI automates schedule-of-activities generation, form recommendations, and UAT script authoring. (00:02:45–00:11:48)

These capabilities reduce manual effort by up to 50 percent in eCOA setup while improving consistency. Study teams retain control over nuances that are not captured in protocols. (00:11:48–00:15:34)

Looking ahead, the speaker highlighted adaptive notifications and conversational assessments as emerging opportunities. Patient-facing AI must balance innovation with trust, validity, and regulatory acceptance. (00:15:34–00:21:58)

Key Takeaways

- AI delivers strong value in eCOA study setup.
- Back-end automation reduces effort and errors.
- Patient-facing AI requires careful validation.
- Adoption mirrors earlier eCOA evolution patterns.