EXECUTIVE SUMMARY

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From Data Collection To Decision-Making in Clinical Trials

Panelists:

Kim Boericke, Chief Executive Officer, Veristat

Anita DiFrancesco, Senior Vice President, Clinical Operations, Endeavor BioMedicines

Robert Goldman, Global Head of Clinical Operations, Contraline

Emilio Neto, Global Head, Country & Site Operations and Executive Director, Biogen

Phillip Stanford, Vice President, Research Technology, EmVenio Clinical Research

Moderator:

Izabela Chmielewska, Editor in Chief, Custom Content, Citeline

KEY TAKEAWAYS

- Despite an abundance of data, there is often a disconnect between data collection and decision-making.
- Real-time insights are key to good decision-making, but their use depends on site maturity and protocol design.
- AI is another potential pathway to accelerate decision-making, but needs reliable guardrails.

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OVERVIEW

Clinical trials produce more data than ever before. The challenge is ensuring that this data benefits all stakeholders, including patients, by translating it into actionable insights for better decision-making.

To harness the potential of trial data, especially as technology becomes standard across trial execution, sponsors are taking a closer look at how data is collected, how it moves between systems, and how it can better support day-to-day operational choices.

CONTEXT

In a roundtable discussion held during the 2026 SCOPE Summit in Orlando, Florida, the participants discussed the practical journey that data takes—from data capture to decision-making in modern clinical trials, which are increasingly characterized by complex technology environments. They highlighted where data quality issues tend to arise, and how these issues might affect timelines, oversight, and confidence in the outputs, as well as how technology, process, and human judgment intersect in real trial settings.

KEY TAKEAWAYS

Despite an abundance of data, there is often a disconnect between data collection and decision-making.

At the core of this disconnect is the need for better data literacy among trial team members, so they can be more discerning as to which data points represent signal and which are just noise. Being able to make this distinction is critical for assessing data quality related to endpoints and biomarkers.

> "The challenge today isn't a lack of data, but potentially too much of it. A critical skill and exercise comes from focusing on the right data, which enables better decisions."
>
> – *Emilio Neto, Biogen*

In this context, researchers should be wary of adding superfluous data requirements to trial protocols, which can overcomplicate things and may trigger avoidable institutional review board (IRB) queries. "The most complicated process you have in a protocol is what's going to be focused on the most, so that should align with your primary endpoint. And if you don't need it, don't require it, because then you're going to drown in data," Anita DiFrancesco, senior vice president for clinical operations at Endeavor BioMedicines, said.

> "The protocols should only be as complicated as they absolutely have to be."
>
> – *Anita DiFrancesco, Endeavor BioMedicines*

One way to avoid collecting irrelevant data—which places unnecessary burden for sites and patients, often simply because a captive cohort is available—is for sponsors to collaborate with principal investigators (PIs) and clinical research coordinators (CRCs) from the outset. Doing so can help clarify what a trial's clinically relevant primary endpoints should be and discard decisions about unnecessary data collection—in DiFrancesco's words: "Get rid of the noise."

Robert Goldman, global head of clinical operations at Contraline, which is developing the first male contraceptive, said one of his priorities is asking the PIs leading the company's trial what elements of the trial protocol might be most difficult for patients. He poses this question at the protocol design stage:

> "What I want them to tell me is, 'What will keep you up at night with this protocol?' Because if I can change the patient burden [by requiring] one less on-site visit, home health, or DCT component . . . this is data we need to use to inform the future and what our teams need to absorb."
>
> – *Robert Goldman, Contraline*

Ultimately, paring collection requirements down to the minimum essentials reduces the burden on patients and sites caused by excessive data variation. Involving sponsors, clinical research organizations (CROs), and sites in this process also helps define the most efficient way to gather information so it aligns with sites' electronic data capture (EDC) systems.

Real-time insights are key to good decision-making, but their use depends on site maturity and protocol design.

Real-time insights can accelerate clinical development by revealing what factors help recruit and retain trial participants from certain patient populations or communities. They can also streamline operations by shedding light on how efficiently collected data is being entered into EDC systems and highlighting areas for improvement.

The group agreed that real-time visibility into trial performance is becoming increasingly important, particularly in hybrid and community-based models where oversight extends beyond the traditional site. In that context, maintaining disciplined data collection processes is critical.

> "We're working with a lot of our principal investigators and some of our senior clinical staff to make sure that we've got a real good discipline around the way we collect data."
>
> – *Phillip Stanford, EmVenio Clinical Research*

Further, real-time insights enable adaptive trial designs, where a protocol can be modified in response to new information. DiFrancesco acknowledged that this function has limited applicability in the context of orphan drug research due to small patient populations that are usually dispersed globally and whose national jurisdictions may impede spontaneous protocol adjustments.

However, better decision-making depends not only on improving team members' data literacy and enabling access to real-time insights, but also on having integrated systems, processes, and workflow ownership. At many sponsor organizations, those components are fragmented. Combined with rising trial costs—and the temptation to "cram" multiple objectives into a single study—this fragmentation may lead to the creation of *unicorn protocols*.

"Unicorn protocols" refer to study designs that incorporate multiple ambitious but poorly aligned inclusion and exclusion criteria, creating requirements that may be difficult—or sometimes impossible—to satisfy in real-world patient populations. For example, an oncology trial might require participants to have normal liver function while also enrolling patients with advanced-stage disease. In practice, these criteria can be incompatible, as the liver is often among the first organs affected as cancer progresses. Conversely, when investigating novel indications where biomarkers have yet to be established, sponsors must strike a careful balance between maintaining scientific rigor and minimizing operational burden on patients and trial sites. In these situations, sponsors may rely on indirect clinical measures—such as liver function tests—to assess safety or potential drug activity, inadvertently introducing additional complexity into protocol design.

"There are some indications where it's difficult to evaluate drug effectiveness through simple measures. Part of the development journey is understanding how the drug should be measured in the first place," said Emilio Neto, global head of country and site operations and executive director at Biogen.

Neto noted that better integration across clinical trial systems could help address some of these challenges.

> "AI could help connect disparate systems, automate certain processes, and ultimately reduce the operational conflicts we see today."
>
> – *Emilio Neto, Biogen*

AI is another potential pathway to accelerate decision-making, but needs reliable guardrails.

Sponsors recognize AI's potential to accelerate data analysis and development timelines, but they are equally mindful of its limitations, including the risk of unreliable outputs. As a result, many sponsors remain wary of using trial-related AI technologies without first ensuring robust data privacy protections.

According to Kim Boericke, CEO of Veristat, trial sponsors are increasingly looking for specific AI clauses in the master service agreements with their CRO partners: "Some of them will not even let you use AI for anything in their drug development processes," she explained.

Veristat uses AI in some of its biostatistical processes by deploying R and Python via Claude—the family of proprietary large language models—instead of via the legacy programming environment SAS. Still, the company ensures there is a human biostatistician at the front of the cycle to define the analysis and at the end of the cycle to interpret the resulting data.

> "Tools developed using [Claude] provides the data a little bit faster, so instead of waiting a month to get your full output, you can start getting it in real time. But there has to be a gate that you go through to review the results before you proceed to the next step."
>
> – *Kim Boericke, Veristat*

This level of attention to the governance surrounding AI implementation contrasts with some industry stakeholders' eagerness to dive into AI without creating guardrails around them. Referencing one of the biggest mistakes of using AI in a trial environment, Phillip Stanford, vice president of research technology at EmVenio Clinical Research, stated: "[Sites] realize that AI is the new wave and don't want to get left behind. But do they have a strategy around it or are they loading protocols into the public version of ChatGPT?"

AI vendors also carry responsibility for promoting technologies that may not yet be sufficiently mature for use in sensitive settings such as clinical trials. At the same time, sites must ensure that eagerness to innovate does not supersede the due diligence required to critically assess and validate these solutions.

CONCLUSION

For trial data to consistently support faster, more confident operational and clinical decision-making across studies, trial sites need capabilities to better integrate and automate data transfer between electronic source (eSource) systems, such as EHRs, and EDC systems. Having such capabilities requires a standard for the flow of information from eSource to EDC systems and a common technology environment that is affordable for small, lean biotechs—something the clinical trial industry has yet to establish.

"It's going to [require] some bridging between industry with regard to what is and isn't considered confidential information, and how we can standardize that through the whole process. That's aspirational, but that's where we're going to see disruption and real change," Boericke said.

> "We need guidance from regulators, but we also have to play nice in the sandbox [amongst us]. Everybody's got different tools—different shovels, different buckets. Everyone's building a different type of sandcastle, but we're all in this together . . . so we have to integrate with one another."
>
> – *Robert Goldman, Contraline*

In the meantime, some technology vendors are trying to help sponsors and sites address these gaps by offering data integration solutions, but these solutions are often not tailored to the unique and changing parameters of clinical trials. To minimize these data challenges for sites in a generally unharmonized environment, EmVenio is developing a solution that maps data fields across eSource technology and clinical trial EDCs for easier, faster integration.

Ultimately, sponsors and sites can contribute to solutions by collaborating on big, non-IP issues such as secure data exchange, as well as by developing more thoughtfully designed and internally aligned trial protocols.

> "We all have the dream of more standardization and easy integration . . . but that's not going to happen tomorrow. When I think about what can we do today, it's about design—truly understanding your population up front, talking to your sites [and] stakeholders, understanding what they're going to need from us, and really what that trial needs."
>
> – *Anita DiFrancesco, Endeavor BioMedicines*

BIOGRAPHIES

Kim Boericke

Chief Executive Officer,
Veristat.

Kim Boericke is the Chief Executive Officer of Veristat and a member of the company's Executive Leadership Team. She is responsible for developing and implementing the global strategy for the organization which is focused on providing data analytics and insights to accelerate research and development and approvable regulatory submissions. She is known for rigorous standards and an execution-focused approach that supports regulatory clarity and operational consistency across complex development programs. She brings a leadership approach that is grounded in accountability and collaboration with a sharp focus on client and patient outcomes.

A scientifically astute executive with more than 25 years in the clinical research industry, Boericke is recognized for expertise in clinical trial design and the implementation of decentralized clinical trials across global regions and therapeutic areas, with an execution-focused style that supports regulatory clarity and operational consistency. She joined Veristat in 2024 as Chief Operating Officer (COO) and previously served as COO at THREAD, with additional executive and senior leadership roles at ICON, IQVIA, ClinTrials, INC Research, Duke Clinical Research Institute and i3 Research. She also served on the board of Mapi Trust as the Chairwoman and an independent director.

Boericke graduated from Duke University with a degree in biology and is the author of more than 15 published articles. She is an active mentor within the clinical operations community and a strong advocate for patient centricity, inclusion, and STEM education.

Anita DiFrancesco

Senior Vice President,
Clinical Operations,
Endeavor BioMedicines

Anita DiFrancesco is Senior Vice President of Clinical Operations at Endeavor BioMedicines. Over her 25 years in the biotech industry she has designed and managed numerous clinical trials from Phase 1 to Phase 3 in therapeutic areas including oncology, pulmonology, musculoskeletal disorders and pain. DiFrancesco previously served as Vice President of Clinical Operations at Samumed, LLC, and served as a team member at Huya Bioscience, Cypress Bioscience and Chiron Corporation. She earned her Bachelor of Science from Georgetown University.

Robert Goldman

Global Head of Clinical Operations,
Contraline

As Global Head of Clinical Operations, Robert Goldman oversees the performance of all global clinical trials, ensuring delivery to scope, timeline, budget, and quality standards. With more than 16 years of experience across sites, CROs, and sponsors, he brings deep therapeutic expertise spanning analgesia, gastroenterology, pulmonology, hepatology, cardiovascular disease, dermatology, endocrinology, rare disease, oncology, women's health, men's health, infectious disease, and CNS disorders.

What sets Goldman apart is not only his experience but his refusal to accept the status quo. A self-described disruptor, he is redefining how clinical trials are managed, designed, and delivered, with a sharp focus on operational efficiency and an uncompromising commitment to the patient experience.

Emilio Neto

Global Head, Country & Site Operations and Executive Director, Biogen

Emilio Neto is a clinical research and drug development executive with over 23 years of global experience leading clinical trial operations and country management, with deep expertise in Neuroscience and Rare Diseases, as well as Vaccines, Respiratory, Cardiovascular, and Oncology. His work spans the full clinical development lifecycle, operating at the intersection of global operations, strategy, and execution.

Neto is passionate about a true global perspective, having initiated his career in Brazil, expanded his leadership scope across Latin America, and later progressed into global roles managing internationally distributed teams. This trajectory has shaped a deep understanding of regional regulatory environments, cultural dynamics, and health system variability across both emerging and established research markets. From 2014 to 2017, he served as Board Director and President of ABRACRO, the Brazilian Association of CROs, supporting innovation, regulatory modernization, and collaborative growth within Brazil's clinical research ecosystem.

In his current role as Global Head of Country & Site Operations at Biogen, Neto leads global site and country operations, with accountability for clinical monitoring models, the implementation of the EU Clinical Trials Regulation (EU CTR), and the patient-centric execution of clinical trials from Phase I through Phase IV. His scope includes driving operational excellence, regulatory readiness, and scalable global delivery across regions.

He holds a PharmD from the University of São Paulo, an MBA from Fundação Getulio Vargas (FGV–EAESP), and a Certification in International Business Management from UCD Smurfit School of Business. Emilio is currently pursuing a Doctor of Public Health (DrPH) at the UNC Gillings School of Global Public Health, with a focus on leadership, health systems, and improving representation of underrepresented populations in U.S. clinical trials.

Phillip Stanford

Vice President, Research Technology, EmVenio Research

Nick Patterson is an accomplished leader in clinical trial project management, patient recruitment, and clinical trial technology implementation. He combines operational expertise with strategic insight to drive efficiency and compliance across the clinical development lifecycle. With certifications in Project Management and Six Sigma, Patterson applies proven methodologies to optimize trial execution through data, technology, and best practices. He is deeply committed to improving patient access and ensuring each eligible individual has the opportunity to receive the treatments they need.

Izabela Chmielewska

(Moderator)

Editor in Chief, Custom Content, Citeline

Izabela Chmielewska is an experienced writer and editor with a robust background in B2B journalism. Currently, at Citeline, she produces custom content across various mediums and platforms, focusing on pharmaceutical and biotechnology news and insights.

Chmielewska is responsible for creating partnered content and Norstella thought leadership. She collaborates closely with commercial teams to develop topical themes and content solutions that resonate with clients. Additionally, she manages the creation and moderation of live sponsored webinars, in-person roundtables, as well as writing new content such as articles, whitepapers, research reports and conducting interviews with SMEs.