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Fomenting A Culture Of Analytical Excellence in Clinical Development

In the dynamic landscape of clinical research, optimizing data management is paramount for ensuring efficient, cost-effective, and successful clinical development programs. Despite advancements in technology, clinical researchers continue to grapple with challenges related to data quality, timelines, and the proactive identification of emerging safety signals within a clinical trial. To address these hurdles and maximize the value of clinical data, innovative strategies are needed to streamline processes, reduce costs, and enhance insights.

The adoption of fast, flexible clinical analytics can revolutionize a trial team's approach to clinical research. By providing near real-time insights into patient data, researchers can proactively address emerging issues and make informed decisions throughout the trial. Implementing an end-to-end clinical data science platform empowers teams with high-quality, accessible data, fostering complex cross-study analysis and optimizing trial effectiveness. This ultimately benefits both data management and the clinical team, accelerating the development of transformative treatments for devastating diseases.

What Builds An Analytics Culture?

When it comes to understanding what makes an "analytics culture" in clinical research, it can help to look for indicators of its absence. Tools alone cannot create this culture — ultimately, there are many examples of approaches or workflows that stymie access to data, undermining decision-making and creating informational bottlenecks that can slow progress and result in undue risk. How much time does a trial team spend preparing data? Building reports? Waiting for data or input from other teams or researchers? The right culture addresses all of these questions and provides value at every stage of a trial, giving researchers the framework to effectively leverage past learnings, understand current trends, and predict future issues. The right solutions enable this through:

- Key Performance Indicator (KPI) evaluation

- Post-mortem lessons learned

- Accessible, streamlined dashboards

- Consistent tracking of key metrics

- Machine learning (ML) and pattern recognition

With more than 35 years of experience working with companies from early discovery through market acceptance, Revvity Signals has established a broad portfolio of technology solutions to facilitate research and development for life sciences companies. Revvity's approach to clinical analytics is centered on more than its offerings, however; its comprehensive support in building a "culture of analytics," one that can drive optimization, is core to its value proposition.

From bolstering change management and resourcing to deploying software and building and managing bespoke solutions, Revvity offers SaaS solutions and accessible support that fosters this culture cohesively and comprehensively. It does so by leveraging methods built around three key pillars: people, processes, and technology. Its people possess the clinical domain and analytics expertise; its processes are adaptive and feature highly flexible change management and deployment models; and its technologies, built around Signals™ Clinical and Spotfire™, are highly collaborative and persona-driven.

Laying The Foundation For A Culture Of Analytics

Establishing a robust analytics culture is essential for optimizing clinical research and driving data-driven decision-making. By creating an environment where data is accessible, utilized effectively, and integrated into daily workflows, organizations can unlock valuable insights and improve outcomes. This begins with a clear vision and goals, which requires organizations to define the desired outcomes of implementing analytics and then communicate this vision to stakeholders, thereby positioning themselves to reap the full benefits of embracing a data-driven approach.

Building consensus is crucial for establishing an analytics culture. This means addressing potential concerns and resistance from stakeholders early and often, as well as emphasizing the

value that analytics can bring to an organization. Engaging key influencers and champions to promote the adoption of data-driven practices is likewise essential to achieving the right analytical paradigm, as is developing the necessary skills essential for effective analytics implementation. By accessing training programs and resources to equip team members with the skills needed to use data analysis tools and interpret results, or hiring data scientists or analysts to provide expertise and support, trial teams can ensure their analytical tools are complemented by an analytical mindset.

Incentivizing data-driven decision-making is essential to foster an analytics culture; this includes recognizing and rewarding individuals who utilize data to improve outcomes and make informed decisions, creating a culture where data-driven insights are valued and celebrated. Implementing appropriate technology is another key component of building an analytics culture; clinical researchers should choose analytics tools that are relevant to a study or program's specific needs, and which facilitate collaboration through user-friendly and accessible interfaces.

Transforming A Culture: Revvity and Replimune

For Replimune, an early-stage biotechnology company focused on novel oncolytic immunotherapy development, its initial approach to analytics mirrored that of many small biotechs: a collection of disparate Excel sheets with siloed data and stiff competition for resources. "Often with emerging biotechs, we're focused on our registrational pathways or new

study development, we're working lean with as few resources as possible, and we're watching that budget closely," said Regina Norelli, Senior Director of Clinical Data Management at Replimune. "What we've learned, and as many oncology and emerging biotechs are finding out, is that the data is coming in fast and furious, and we need to consume it and understand it a lot faster than before."

When Norelli arrived at Replimune, its development pipeline included five active Phase I trials and two more ongoing complex oncology trials. "Our study teams were struggling to consume that amount of data from the number of sources it was being generated from, let alone draw conclusions on that data's quality," Norelli said. This was due, in part, to utilizing tools like Excel which, though it offers filtering and formatting that can reveal data outliers, lacks the sophistication necessary to ensure comprehensive data insights. "Often, we get what's called data blur, and we're left with more questions than answers," she said. "I knew Replimune needed a pathway to more transparent awareness of data outliers, as well as a more ready pathway to answering questions we had as we looked at the data."

To address the gaps in its data collection and curation, Replimune partnered with Revvity Signals, which set the company up with solutions that could position it for deeper data insights. But overcoming this hurdle presented a new one: now that Replimune had access to the data and tools it needed to drive decision-making, how would it ensure that it could effectively consume that data? Having adopted several Revvity Signals solutions, including its Clinical Data Review and Line Listing Review Modules, Replimune's team began, with Revvity's help, to encourage its team to embrace a more integrated, visual, collaborative platform for data. "Adoption is an exercise, one that requires leadership, a lot of one-on-one time, and a demystification of the data review process that aligns with a unified goal."

Ultimately, Revvity opted to embed one of its own senior software service specialists, Anna Billiard, with Replimune to support the company's platform adoption. "Our relationship has worked so smoothly and has provided Replimune with the support it needed to be a data-driven company," Norelli said. Revvity helped Replimune establish internal technical guides not only for Spotfire, the visual data science platform Revvity leverages, but also guidance on more efficient data consumption and comprehension. "We needed to know how to understand the analytics, how to interrogate our data more efficiently, how to understand the answers to our questions, and how to dig deeper," Norelli added.

With access to expert help, Replimune was able to shift its focus from foundational data science understanding to pursuing customizations that more optimally support the emerging considerations it has as an early-stage biotech. "With [Billiard] on our team in the analytic project manager role, it makes immediate concept exploration more achievable," Norelli said. "We don't have to form a new contract or put more budget together; I can simply say 'let's tag in [Billiard] to explore this question.'" Having this access to support has enabled Replimune to model new approaches in just days and move to implement them, as needed, across programs or studies.

> "The additional benefit of working with Revvity is that, if you ask for something that I don't know how to do or it needs to be deployed quickly across every active study, we have a team of developers that can be brought in to help build it out," Billiard said.

This support is truly comprehensive, as Billiard manages Replimune's Remedy development pathway, coordinating timelines, services, and cost scoping as the organization continues to build out its information infrastructure. "Often, what people want out of a tool and its support is to feel heard and to understand," Billiard said. "I may have built the tool, but I can understand users might be frustrated, especially transitioning from something they've used for years to something

completely new. So sitting down with them, understanding their goals, and showing them how to achieve part of that with the tools Revvity has built is important."

Conclusion

Without the right understanding, even the best analytical platform in the world is useless. By successfully integrating data analytics across its organization, Replimune has demonstrated the transformative power of a data-driven culture. As Replimune continues to expand its use of analytics, they are poised to unlock even greater value from their data and drive further advancements in clinical research.

From clinical development to manufacturing, analytics has enabled the company to optimize processes, improve decision-making, and accelerate the development of innovative therapies. Revvity's Signals Clinical solution is a clinical data science platform that streamlines workflows for clinical data review and medical review, reducing the time spent preparing data for analytics. Signals Clinical helps clinical researchers access and understand clinical data and accelerates clinical and operational study decisions.

With a centralized and searchable interface that offers automated data tracking and collaborative workflow integration, Signals Clinical enables rapid, comprehensive clinical insights. To learn more about how Revvity can help organizations foster a culture of analytics, watch the webinar with Regina Norelli and Revvity's clinical analytics experts here.