More Data, More Challenges:

The Value of Specialty & FSP Partnerships for Biometrics in a Data-Rich Environment

A Playbook for Choosing the Right Partner at Every Stage of Growth

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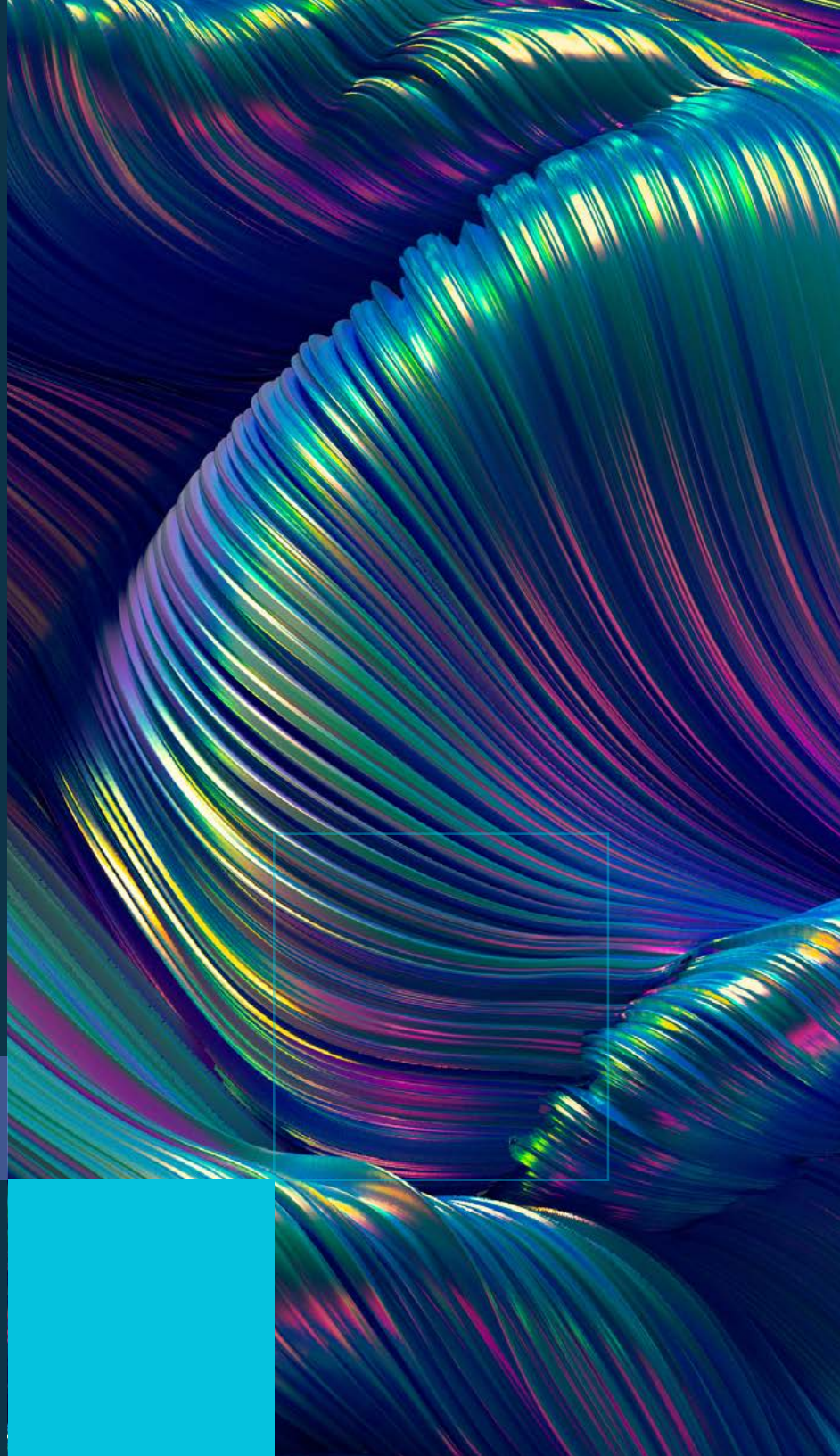


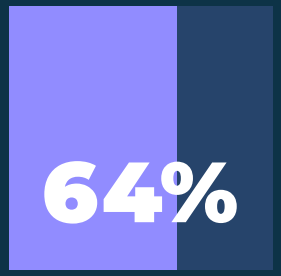
The use of data in life sciences research has reached all-time highs. According to a 2019 Tufts study, clinical trial data grew 183 percent within 10 years,[1] in part because more data types are readily available: A 2022 survey found that 64 percent of sponsors consider six or more different data sources for their protocols,[2] marking a pace so fast that demand for data scientists and data managers has well exceeded candidate pools.

Combine that rapidly growing data volume with a few other R&D priorities—such as trial diversity, patient safety, cost efficiency, therapeutic complexity, and the pandemic-era urgency to make breakthroughs faster—and it's clear that sponsors have a mountain of challenges ahead.

As they navigate them, many companies are finding that the traditional full-service partner model, in which one CRO manages everything, no longer meets modern demands. Sponsors need resources that are more adaptable and adept at addressing the evolving data complexities of this new moment. That, in turn, has ushered in a new generation of outsourcing models, including specialty provider, specialty end-to-end provider, and functional service provider partnerships.

These data providers and the flexible models they bring to the market stand to revolutionize product pipelines by transforming how companies collect, manage, interpret, and activate clinical trial data. And they can deliver value even in early phases, sooner than most sponsors may think.

Inside, we speak with experts from both perspectives—the partner's and the sponsor's—to explore how these various models and providers can meaningfully improve research workflows, and how, when, and why sponsors should consider them in the context of traditional full-service partnerships.



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1. https://www.appliedclinicaltrialsonline.com/view/enabling-digital-transformation-managing-external-clinical-data-sources-to-advance-drug-development
2. https://www.eclinicalsol.com/7018Y000001JheTQAS/

Understanding Different Models and Why They Matter

The many trends of the modern era have led to a moment of reckoning for clinical trial sponsors. As they contend with the expanding volume of biometrics data and therapy sophistication, they're also encountering urgency and pressure from investors to get to market faster, while also heeding regulators' calls to promote diversity, equity, and inclusion after the 2022 FDA draft guidance.[3]

This pace and amount of transformation create a landscape that requires real-time changes to the protocol and specialized expertise. But working with a single CRO—something sponsors have traditionally done for decades—doesn't necessarily deliver on those crisscrossing needs of the current moment, emphasizes Erika Vento-Gaudens, Director, Global Clinical Study Operations at Guardant Health.

"Engaging CROs as a full-service singular provider, assuming little to no sponsor oversight, isn't the best route to take in my opinion for many reasons, but the biggest reason could be regulatory-related," she said. "When you get audited, they'll usually ask you how you provided sponsor oversight to that CRO. You must be able to show evidence as well as defend the roles and responsibilities of the partnership. If you can't dedicate the sponsor oversight resources required for that single full-service partner, you risk study- or people-related problems going undetected. This could lead to potential red flags for auditors."

3. https://www.fda.gov/media/157635/download

That's why, upon joining Guardant Health, Vento-Gaudens worked hard to transform her organization's model from full-service to a more diversified vendor approach. It's a move that stakeholders at eClinical Solutions are seeing more often as sponsors evolve how they work with potential partners.

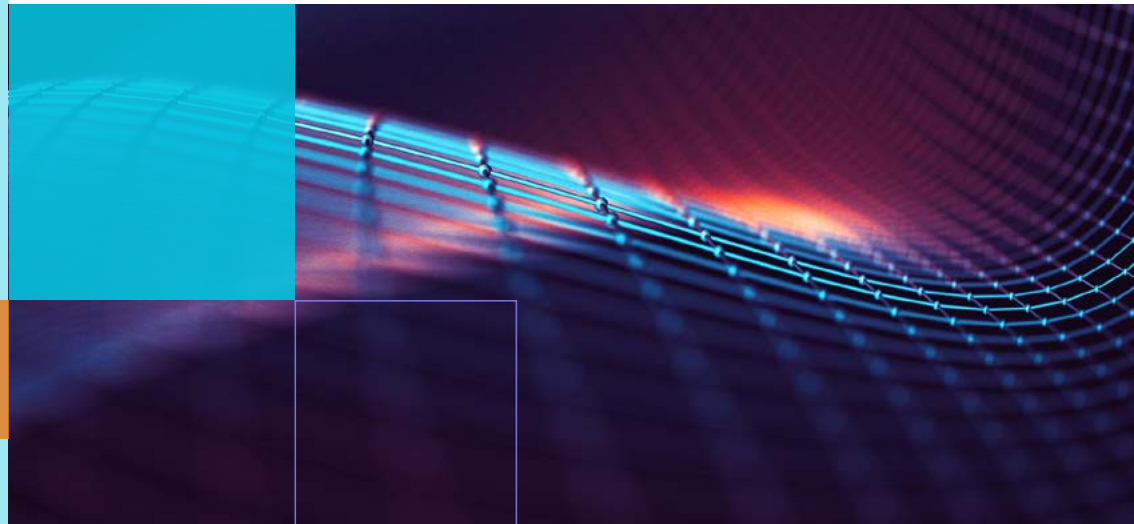
In turn, those developments have created new categories of collaboration that span the following spectrum:

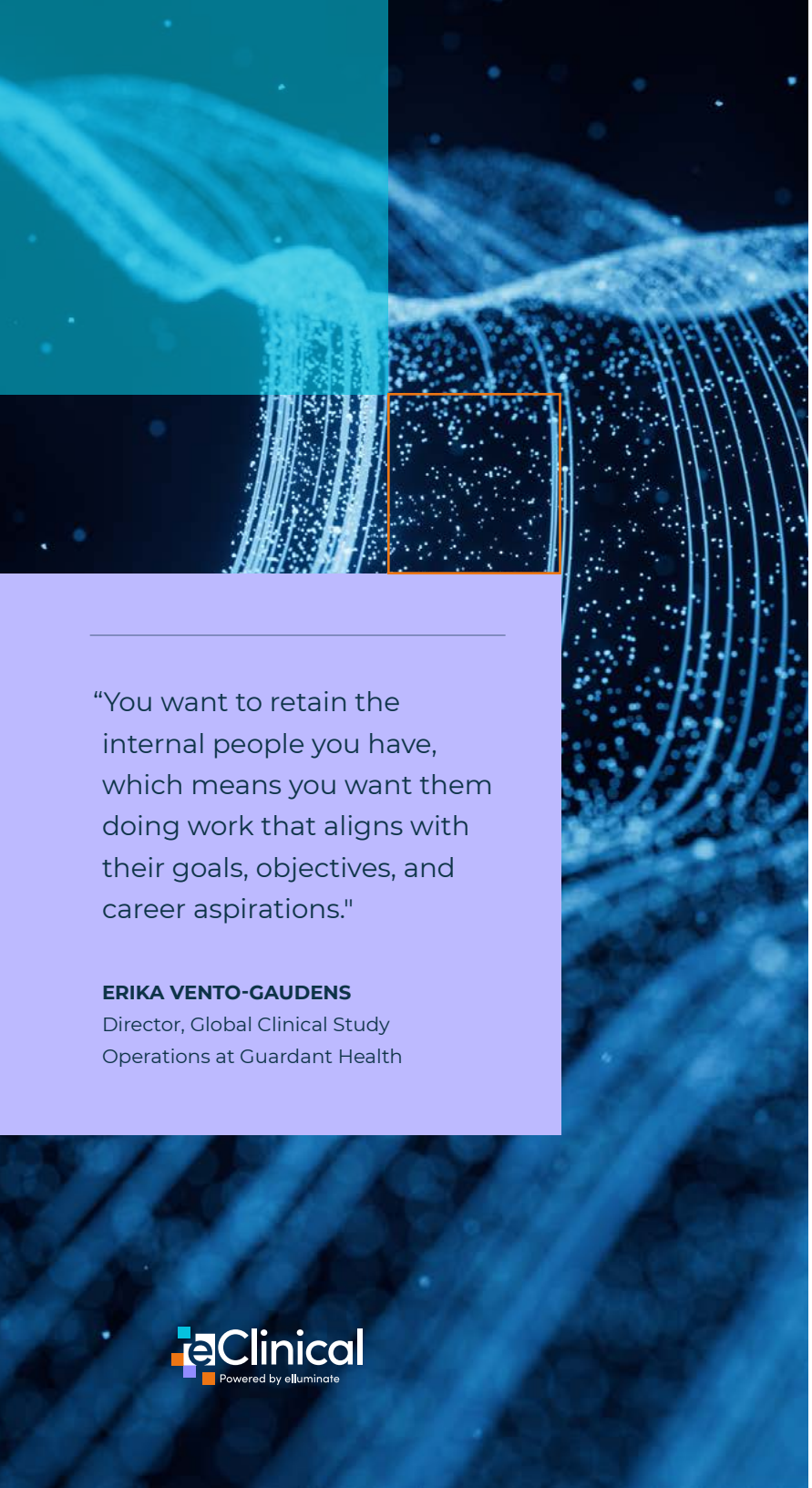
- **Full-service CRO:** One CRO handles everything
- **Specialty provider:** Different providers take on different isolated functions, such as for EDC builds, eCOA, data management, clinical operations, submissions, IVR, etc.
- **Specialty end-to-end:** Different providers take on different categories, such as one data provider for all things data
- **Functional service partnership:** Different providers take on functional service areas at scale, including management of employees, training, and SOPs

In particular, the need to manage so much data variety has pushed this evolution of partnership models, as well as the need for experienced providers to take on certain service areas. Within those broader categories of functions, data hasn't historically gotten the attention it deserves, particularly in early phases, but it's too significant now to overlook, says Katrina Rice, Chief Delivery Officer, Biometrics Services, at eClinical Solutions.

"The volume of data is just continuously increasing," she said. "The complexity of that data is also increasing. And all the while, the expectation of the market is getting more complex, which means it's even more important to have people with specialized insight."

She adds that's why companies like eClinical started with this model in mind: to focus on the data. In turn, specialty and FSP outsourcing models have gained momentum with data aggregation and management, but it's also a trend that's seen in other service areas, like medical writing and clinical operations.





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ERIKA VENTO-GAUDENS
Director, Global Clinical Study Operations at Guardant Health

The benefits of a diversified partner model are many. In addition to the regulatory piece which Vento-Gaudens mentions, there are also labor and upskilling trends to consider. The demand for data scientists and data managers often exceeds candidate pools, and keeping pace with technology is challenging.

Meanwhile, sponsors are also keen to keep their own internal teams engaged in meaningful work, which Vento-Gaudens says her organization has been able to do with its evolution away from only full-service CRO relationships.

"You want to retain the internal people you have, which means aligning them with work which supports their goals, objectives, and career aspirations," she said. "When we were working with a CRO, many of the team had been doing work that wasn't necessarily stimulating, nor was it providing the level of sponsor oversight required. However, that changed when we switched to a diversified model because the team was refocused on high-skill areas they enjoyed and we were able to better align with the providers on study-related responsibilities."

However, there are challenges to a diversified partner model. One tendency is to go with the "devil you know"—the behemoth CRO—and also stick with the simplicity of a single contract. But this approach can limit sponsors to prescribed workflows that don't necessarily hold up to modern needs, Rice adds. And companies can certainly benefit from a willingness to try new models, and embrace what works best to easily overcome these challenges.

Outsourcing model decision framework

Fully Insourced Model → **Full-Service CROs**

Fully Insourced Model	Combination Approach: Speciality Provider/FSP Outsourcing	Traditional Full Service Outsourcing Model
Minimal Outsourcing Company resources, company-owned technology and infrastructure	**Combination Approach: Speciality Provider/FSP Outsourcing** Combination of company resources and outsourced provider infrastructure	**Traditional Full Service Outsourcing Model** Large contract with one CRO for horizontally integrated services
Maximum Flexibility Company-owned, long-term focused, vendor agnostic	**Moderate Flexibility** Requires insourced resources, systems for specialty provider setup, management & oversight	**Less Flexibility** High switching costs, CRO-owned and managed technology infrastructure
Highest Cost Internal resource needs & commitment, reduced strategic focus & scalability	**Medium Cost** Breaking up work across providers spreads risk, builds long-term value	**Lowest Short-Term Cost** Increased long-term cost, largest single point of failure

Advantages of Specialty Providers and FSP Models Across Development Stages and Portfolio Growth

With respect to data, specialty providers and FSP models provide obvious advantages: expertise, adaptability, improved quality and cost, and the ability to take advantage of more data streams—something increasingly important with remote or hybrid trials.

With decentralized trial models, there is an opportunity to bring more aspects of trial conduct to the patient, easing participation burden and broadening trial access to more populations," says Sheila Rocchio, Chief Marketing Officer at eClinical Solutions. "These models also increase the diversity of the data environment. The challenge is how to collect different data sources and data streams in a way that is convenient for participants, without significantly increasing the noise in the data and or bottlenecks in the data management and medical clinical review processes."

These newer specialized partnership models have the benefit of providing sponsors with access to best practices and lessons learned from previous trials across indications, geographies, and populations. The value of this expertise may potentially be overlooked, as these providers help sponsors avoid collecting too much data or measures that are error-prone, which is costly to process and can negatively impact patient and site experience.

No matter which model gets chosen, engaging partners earlier on helps to ensure the right data is being included to drive higher-quality findings. And FSP partnerships don't have to involve large-scale engagements with hundreds of resources. They can be more purpose-built and focused with smaller teams to support specific areas of need during specific areas of growth.

STAGE OR PORTFOLIO SIZE	GOALS
Early-stage or small portfolio →	Optimize resources, get earlier insights, fail/succeed faster
Mid-stage or larger portfolio →	Scale more efficiently, benefit from experience/expertise, optimize the patient experience/participant centricity

“As companies grow and have multiple products in their pipeline, there are opportunities to establish FSP models early on that expand with the portfolio and deliver increased value with every additional project, especially with data-focused providers,” Rocchio said. “The opportunities to standardize trial designs and data formats and reuse those assets to accelerate cycle times for study startup and last patient last visit to clinical study report are significant and especially important in the post-Covid era of drug development.”

These scalable benefits of FSP and specialty models become even more pronounced in the context of tech evolution. Well-diversified partner models can deliver the best portfolio of tools for the protocol, many of them automated. Moreover, technologies can also support governance and associated oversight.

The Power of a Specialty Partnership: Karyopharm

When Karyopharm needed outside support to manage its complex and disparate data, it turned to eClinical Solutions as a specialty partner. By using an agile, consolidated data management approach, Karyopharm's partnership with eClinical provided greater efficiency across its portfolio of tight-timeline trials.

Source data from Medidata Rave along with data from numerous lab providers and other sources all flowed into eClincal's elluminate Clinical Data Cloud - a single tool, allowing Karyopharm to expedite their data collection, cleaning, and analysis processes.

These process enhancements alongside a productive partnership with eClinical enabled Karyopharm to accelerate development and maximize the value of their clinical data moving forward. In doing so, the partnership enabled four phase II studies to be deployed within four months—as well as an expedited build of 15 days for Covid-19 research—with five additional studies and 25 protocol amendments delivered.

Getting Started with an Outsourcing Model for Biometrics

FSP and specialty models are something to consider at every growth stage, even if you have an existing relationship with a CRO. In other words, you're not locked into the model you originally select, Rocchio adds.

"Consider data partners as an accelerator for growth who can supplement the contributions of the clinicial CRO, not just another vendor you have to manage," she said. "First assess how your current CRO is treating the biometrics piece and identify if there are opportunities to improve or optimize."

Most importantly, align stakeholders to determine the best way to work together in consideration of the greater clinical strategy, adds Rice.

"Think about your entire clinical strategy and how your data strategy fits in," she said. "Sponsors benefit from the expertise of someone who can look across and make sure all these parts fit together cohesively within that overarching strategy, from the data and technologies to the processes that support that, and even the people. FSPs should be more about the partnership and not transactional on a study-by-study basis."

After that initial assessment, sponsors will then want to identify their current needs and strengths before comparing partners, piloting with selected protocols, and eventually engaging in an enterprise-wide model shift.

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Chief Marketing Officer at eClinical Solutions.

That stepwise approach is what Vento-Gaudens embraced at Guardant Health when she shifted her organization to a specialty-focused partner model:

"I first had to understand exactly what the CRO was doing and also what our internal team had been doing and whether their responsibilities lined up to their own professional preferences," she said. "Once we assessed all the contracts and dashboard reports, we could then segment our efforts and oversight into service areas like data management, TMF support, monitoring and study startup. After that, we could be more intentional about specialty functions and contracting such that our partners could be set up for success as well as our people."

Once the Guardant Health team ironed out that process—which Vento-Gaudens says took about six months—they started to see the advantages of a diversified partner model, she adds.

"We moved a lot faster and more efficiently," she said. "It was also very good for my internal team because they were given new opportunities to do work that directly aligned with their interests. And we were able to reallocate some functions away from the CRO which, honestly, the CRO was happy about because it made everything operate more effectively. The goal is to utilize our resources properly and execute the study on time."

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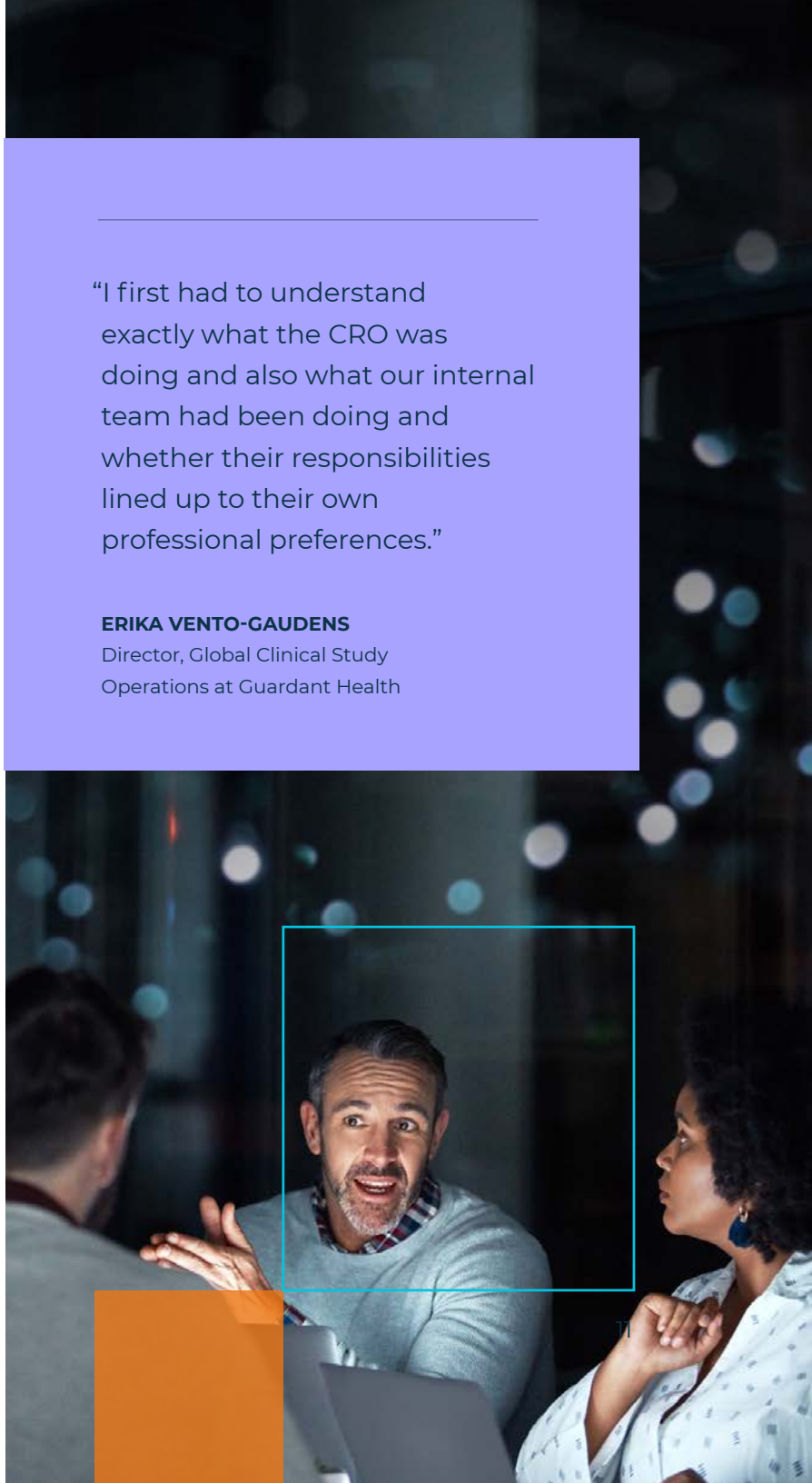
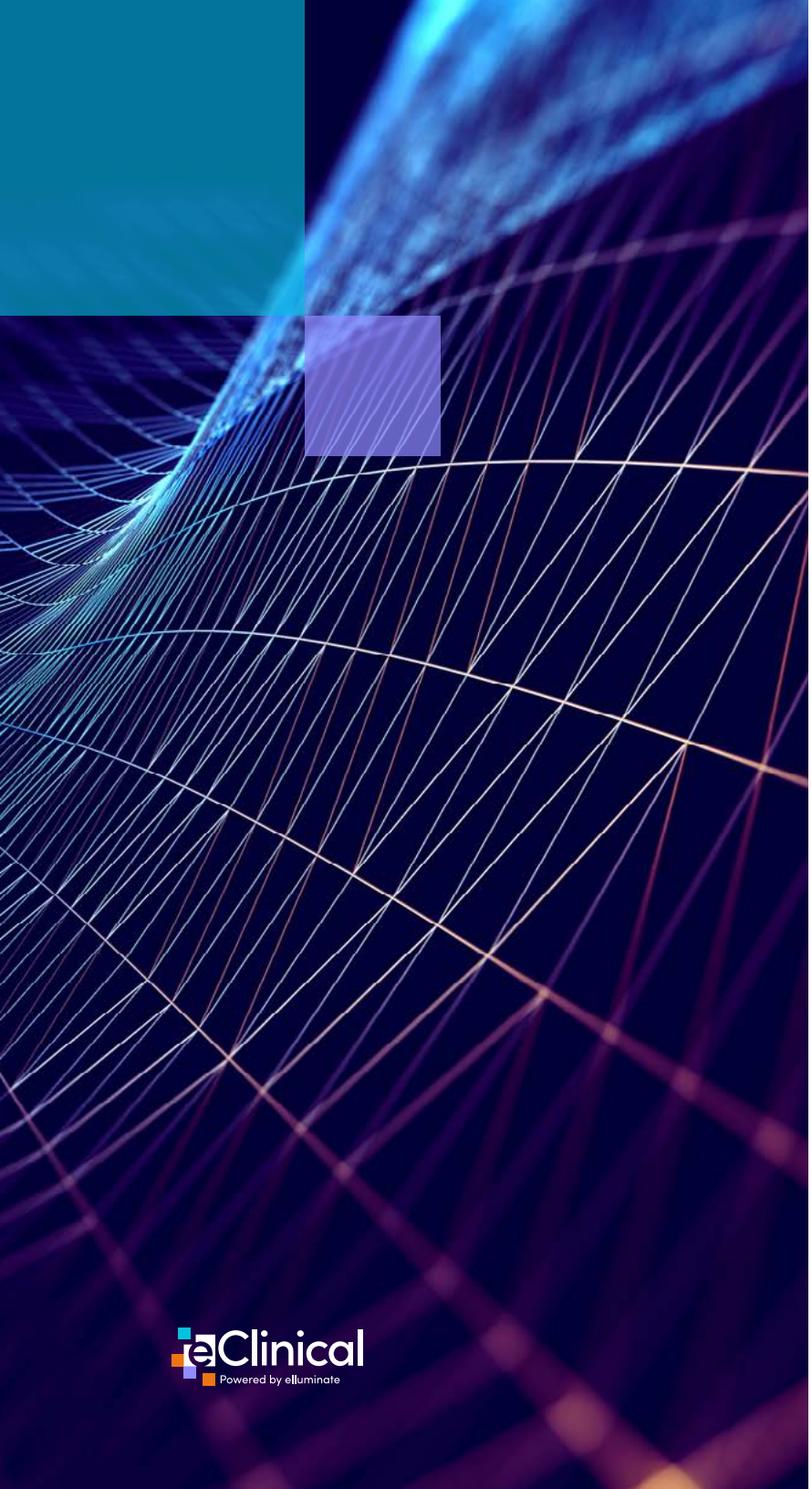


Questions to Ask Potential Data Partners

- What technologies do you use? Why do they add value?
- How do technologies and services work together?
- In what ways do you automate to be more efficient?
- How do you build efficiencies over multiple studies and programs?
- How will you collaborate with my internal team?
- How will you collaborate with my CROs?
- What is your experience in working with my protocol type?
- How can you ensure quality?
- How flat is your client service model? Will I be speaking directly to the people doing the work?
- How will you standardize and reuse data assets?
- How do you optimize flexibility while also standardizing?
- How do you support innovative and adaptive protocols such as master and basket designs?
- What is your onboarding process?
- How do you approach resource management?
- How do you approach governance?



Diversity of Data, Diversity of Data Partners

As sponsors wrestle with the many challenges of a changing environment, one thing has become abundantly clear: The traditional CRO model doesn't always give the flexibility required for today's clinical development landscape.

By pivoting to an FSP or specialty model, sponsors stand to realize several advantages, from readying their pipelines for regulatory scrutiny to improving costs, resources, staff satisfaction, and speed-to-market by way of accessing the strengths and technologies of more specialized vendor partners.

Anyone can start a journey toward optimizing this model and integrating it with current workflows and partners to ensure good outcomes. Start by aligning your internal stakeholders, assessing your CRO's current reach, and determining functional areas—including data—that may benefit the most from a reimagined approach.

If you'd like help with that process, we're here for you. Reach out to eClinical at eclinicalsol.com to start your journey toward a diversified—and more effective— data strategy.

eClinical Solutions helps life sciences organizations around the world accelerate clinical development initiatives with expert biometrics services and the elluminate® Clinical Data Cloud – the foundation of digital trials. Together, the elluminate platform and eClinical Biometrics Services give clients self-service access to all their data from one centralized location plus advanced analytics that help them make smarter, faster business decisions.

Leveraged by 100+ biopharmaceutical companies, elluminate is a purpose-built clinical data cloud designed to accelerate digitization efforts that proactively manage the exponential growth of clinical data volume, variety, and velocity.

eClinical's Biometrics Services combine top talent with best-in-class technologies, rigorous processes and the power of elluminate, to deliver efficient, high-quality clinical data solutions fit for the new era of digital trials. From acquisition to submission, we enable sponsors to execute an end-to-end data strategy that embeds standardization and streamlines oversight.

Whether partnering with us for study-based biometrics services, functional service outsourcing, or specialized clinical data consultancy, sponsors of all sizes rely on eClinical Solutions for agile, expert support with the right skills and technology for today's speed-driven, complex trials.

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