SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

PROOF AT THE SPEED OF LIFE

WINNING TOGETHER

CHARACTERIZING SUCCESSFUL PARTNERSHIPS WITH eCLINICAL PROVIDERS

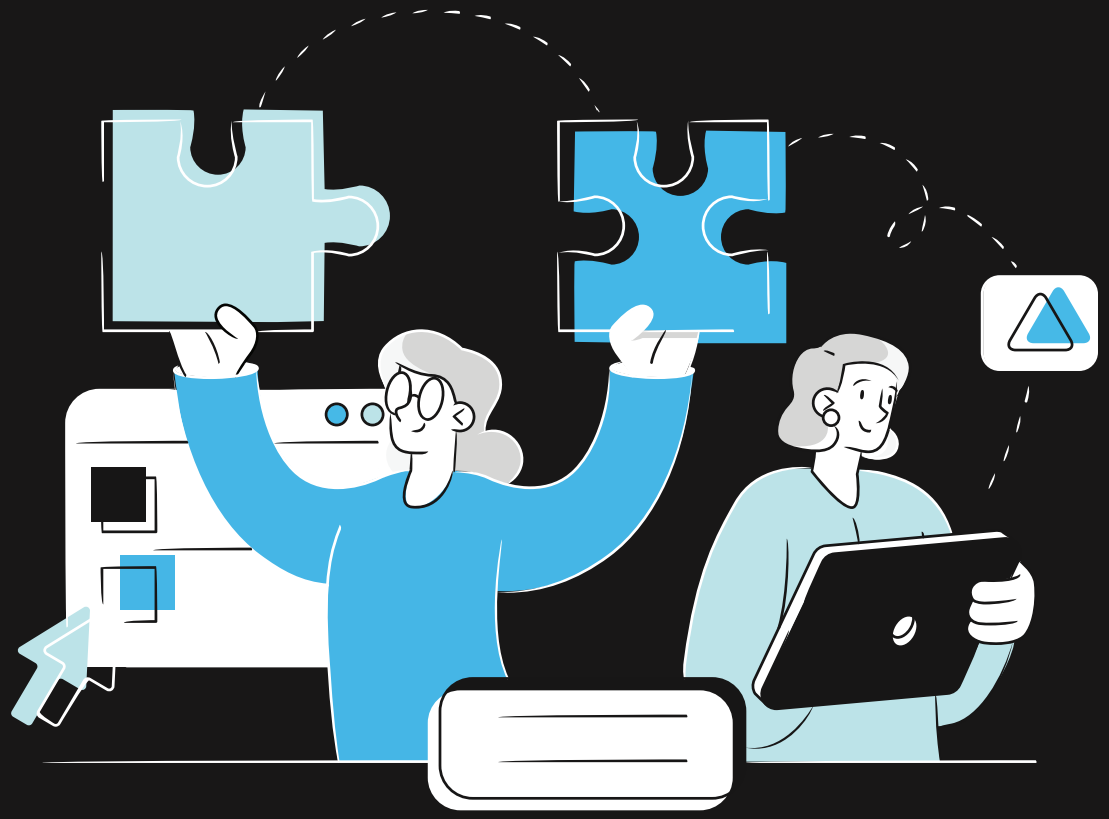


TABLE OF CONTENTS

INTRODUCTION

In the dynamic realm of clinical research, change is a reliable constant. Breakthroughs in science and technology propel the field forward at an unprecedented pace. The pandemic accelerated the adoption of new technologies and new methods of trial conduct. Evolving regulatory requirements shape nearly every aspect of clinical trial design, execution, and interpretation.

Within this context, the role of contract research organizations (CROs) has become even more pivotal. CROs serve as strategic partners, empowering sponsors to navigate the complexities of clinical research with agility, expertise, and efficiency. In today's fast-paced and highly regulated environment, the contributions of CROs are indispensable to the success of drug development programs and the advancement of medical science.

CROs who best understand the challenges, embrace opportunities, and establish enduring relationships with strategic, symbiotic partners will be poised to achieve continued growth and sustainable success.

RESEARCH SPONSORS' TOP CHALLENGES

Whether they are developing a molecule, biologic, or a medical device, research sponsors face a myriad of challenges in navigating the complex landscape of clinical development and clinical trials. **Some of these challenges include:**

01

Patient Recruitment and Retention

Studies may face difficulties achieving enrollment goals as a result of limited patient awareness, stringent eligibility criteria, geographic distribution, increasing diversity expectations, patient burden for protocol assessments and competition for participation across multiple studies.

02

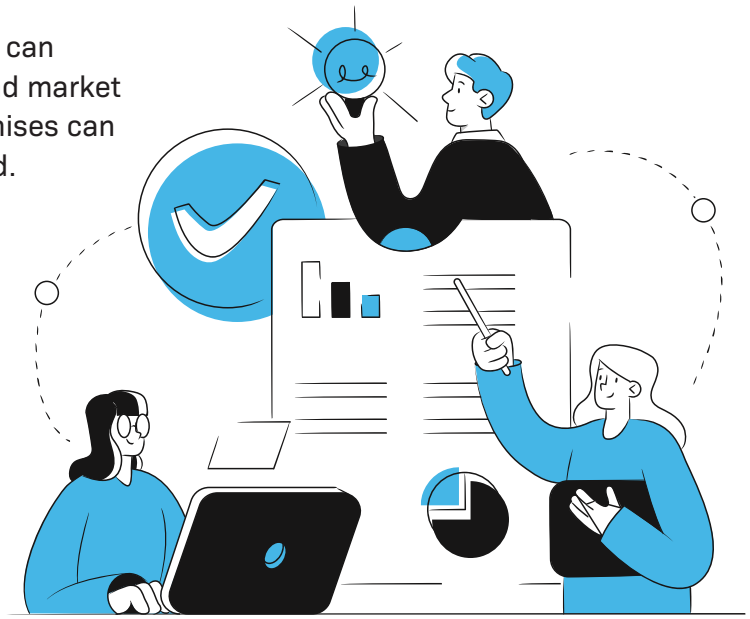
Rising Costs

The cost of conducting clinical trials continues to increase, driven by many factors. Managing budgets effectively, including those of partner organizations, driving efficiency, and maintaining quality is a constant challenge.

03

Timelines and Delays

Delays in the clinical trial start up and inefficient management processes can have significant implications for clinical development timelines, costs, and market competitiveness. Sponsors and CROs need partners whose timeline promises can be relied upon, and who respond quickly when study changes are needed.



04

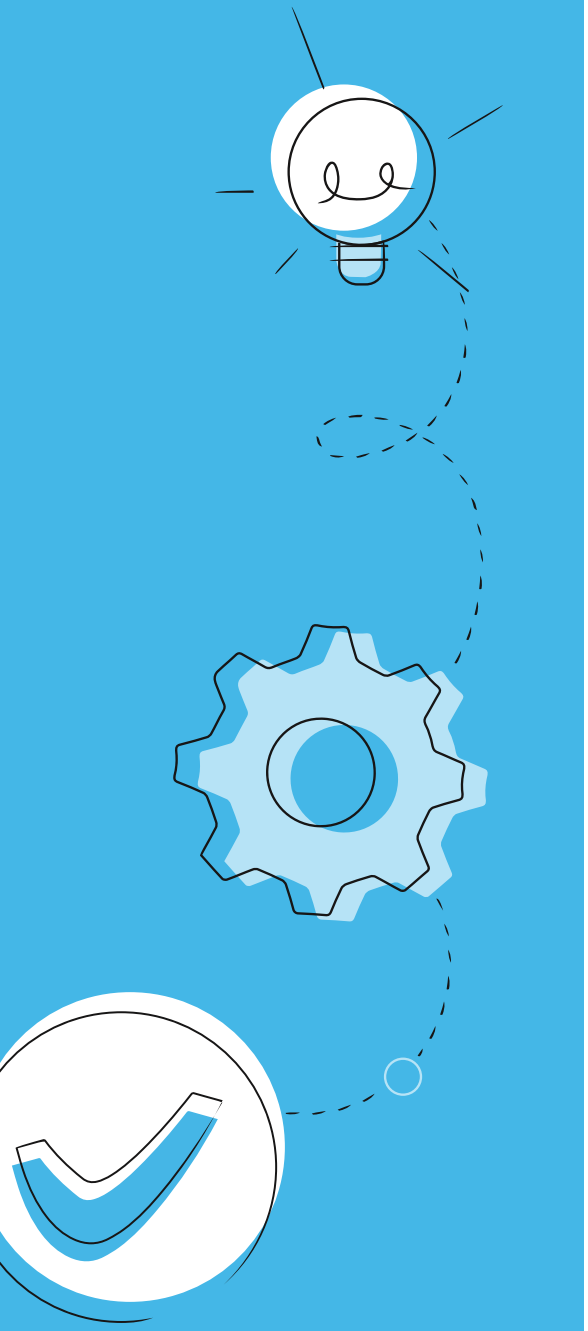
Regulatory Compliance

Sponsors must keep abreast of evolving regulations set forth by agencies globally such as the FDA, EMA, and others, as well as ensuring protocol compliance.

05

Data Quality and Integrity

Ensuring the accuracy, consistency, completeness, and integrity of clinical trial data is paramount for robust decision making and regulatory approval.



06

Optimal Selection of Investigative Sites

Effective and efficient trial site identification, activation, and management are critical for the successful execution of clinical trials. Challenges such as site staffing and resourcing, competing priorities, and previous site performance can impact study timelines and outcomes.

07

Emerging Technologies and Methodologies

Keeping pace with advancements in eClinical technology and methodologies, such as remote source data verification (rSDV), eSource data capture, increasing decentralization, and adaptive trial designs, presents both opportunities and challenges for sponsors in optimizing trial efficiency and data quality.

08

Patient-Centricity and Diversity

Ensuring representative trial participant populations is essential for the generalizability of study results and addressing unmet medical needs. Challenges may include reaching underrepresented populations, addressing language and cultural barriers, and accommodating patient preferences and needs.

09

Supply Chain Management

Managing the supply chain for investigational products, including manufacturing, distribution, and storage, requires meticulous planning and coordination to ensure adequate and timely supply throughout the duration of the trial.

10

Competitive Landscape

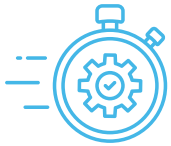
The competitive landscape in drug development is intense, with multiple stakeholders vying for limited resources and market share. Sponsors must navigate intellectual property considerations, patent timelines, competition for sites and patients, competitor strategies, and market dynamics to maximize the success of their drug candidates.

OPPORTUNITIES FOR CROs

CROs can leverage these challenges by strategically aligning their offerings with sponsors' needs and priorities to win more business. There are additional opportunities to differentiate, add value, and drive growth by capitalizing on these market trends:

Overall Pharma R&D Market Expansion + Growth in Outsourcing

Most biopharmaceutical and medical device organizations continue to invest significant resources into developing new treatments. They increasingly rely on outsourcing research and development functions to optimize internal cost structures. As a result, the global CRO market is projected to grow from $82.60 billion in 2023 to $188.52 billion by 2030, a compound annual growth rate (CAGR) of 12.5%[1].



Need for Optimized Trials

CROs can capitalize on growing demand for optimized trials by offering innovative solutions and services to help sponsors reduce costs, improve efficiency, and maximize the value of clinical research investments for sponsors. Thoughtfully chosen and applied eClinical technologies (such as eCOA, RTSM, EDC/DDC, eConsent, and data quality-monitoring solutions) can optimize trial protocols through digitalization to improve data quality, minimize patient and site burden, accelerate decision-making throughout the trial lifecycle, and maximize the likelihood of success, particularly in complex therapeutic areas or challenging patient populations.

Emerging Biopharma Opportunities

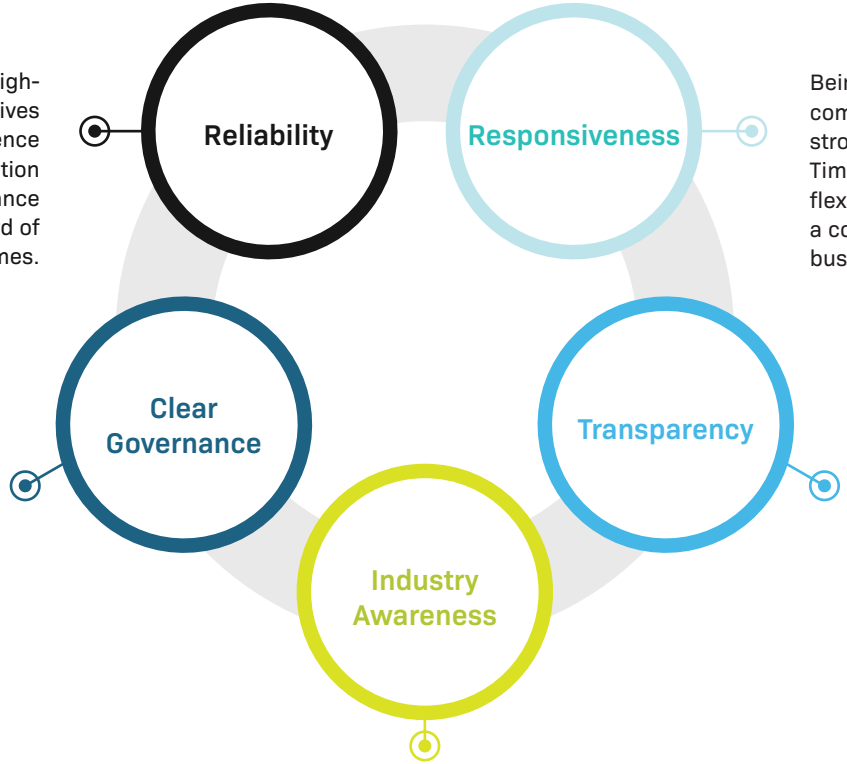
CROs can capitalize on the opportunities presented by rapid growth in the emerging biopharma sector by strategically aligning their services and capabilities with the unique needs of smaller biotech and pharma companies. With a growing emphasis on innovation and agility, emerging biopharma firms require CRO partners who can adapt quickly to evolving research objectives, timelines, and resource constraints. CROs can differentiate themselves by offering flexible and scalable solutions where speed, efficiency, and data quality are paramount.

[1] "Contract Research Organization Services Market Size...and Regional Forecast," Fortune Business Insights. https://www.fortunebusinessinsights.com/industry-reports/contract-research-organization-cro-services-market-100864

CHARACTERISTICS OF SUCCESSFUL PARTNERSHIPS WITH eCLINICAL PROVIDERS

CROs expect their vendor partners to be responsive, reliable, transparent, aware of industry trends, and to implement a clear governance structure. Technology providers who prioritize these foundational aspects of relationship management will help CROs differentiate in a competitive field, build strong client relationships, and position themselves for sustained growth and success.

Reliability is paramount for CROs to deliver high-quality services, and achieve client objectives consistently. Reliability encompasses adherence to timelines, accuracy in data collection and reporting, consistency in performance across multiple projects, and a track record of successful outcomes.



Being responsive to client needs and meeting timeline commitments are essential for building and maintaining strong relationships with pharmaceutical sponsors. Timely communication, prompt resolution of issues, and flexibility in accommodating client requests demonstrate a commitment to client satisfaction and can lead to repeat business and positive referrals.

Establishing clear governance structures, processes, and roles within each organization ensures effective decision-making, accountability, and risk management. Clear governance frameworks help CROs streamline operations, mitigate conflicts, and maintain compliance with regulatory requirements and industry standards.

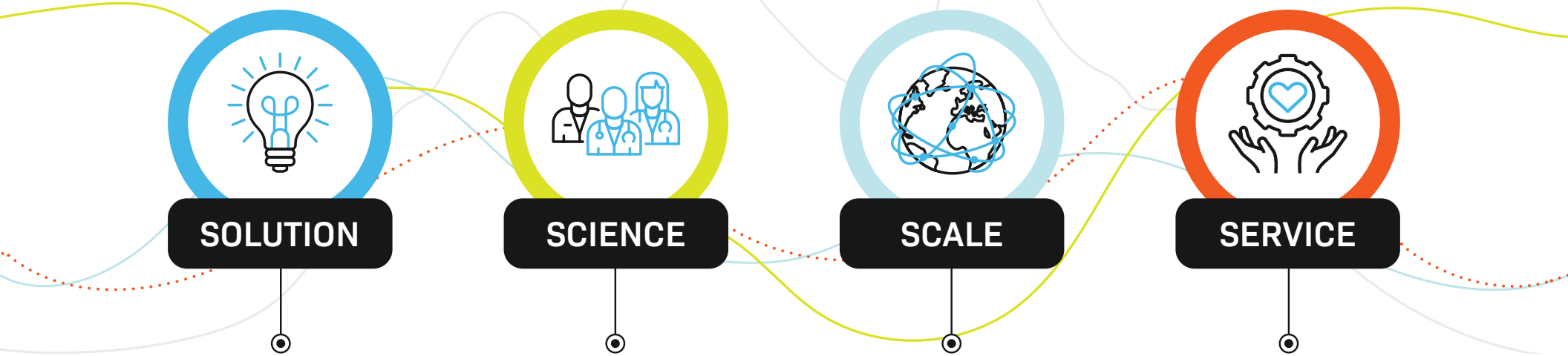
Transparency in all aspects of trial operations, including project timelines, budgets, KPIs, data management processes, and potential risks fosters trust and confidence with sponsors. Transparent communication ensures that sponsors are fully informed and empowered to make decisions throughout the duration of the partnership.

Understanding industry trends, regulatory developments, competitor strategies, and emerging technologies is essential for CROs to remain competitive and relevant in the dynamic clinical research landscape. CROs should select partners who can anticipate client needs, identify growth opportunities, and adapt their services to meet evolving industry demands.

QUALIFYING & SELECTING PRODUCTIVE, EFFECTIVE ENABLEMENT PARTNERS

Signant Health understands that selecting a vendor in today's marketplace is not always straightforward. CROs should go beyond surface-level assessments and thoroughly understand how prospective vendors' capabilities and experience align with sponsors' needs. Using a detailed question set early in the discovery and qualification process provides a more nuanced understanding of a vendor's strengths, weaknesses, and overall sustainability as a partner who can contribute to successful trial outcomes.

While the capabilities of the technology solutions offered are of vital importance, evaluations should encompass all four pillars of eClinical success: solution, science, scale, and service.



Partners should provide high-quality eClinical solutions that streamline processes, enhance data accuracy, and accelerate decision-making throughout the trial lifecycle. These may include EDC, eCOA, eConsent, RTSM, data analytics, Telemedicine, endpoint quality solutions, and more. Solutions should be complete, without capability gaps.

Scientific and technical expertise, as well as domain knowledge, are indispensable for navigating complex therapeutic areas, ensuring high quality and reliable clinical evidence, optimizing study design, and interpreting clinical data accurately. Thus, CROs should seek technology and enablement partners that support their solutions with deep scientific and technical expertise.

Global reach and scalability are crucial to accommodate fluctuations in study volumes, resource demands, and geographic expansion effectively. Therefore, partnering with technology providers offering scalable solutions and infrastructure as well as fully resourced project teams in all time zones is paramount.

Finally, comprehensive services, including COA scale management, experienced project delivery teams, global 24/7 site and patient helpdesks, and mature operational processes can help CROs differentiate and win more opportunities.

PROTOCOL DIGITALIZATION & TRIAL OPTIMIZATION SOLUTIONS

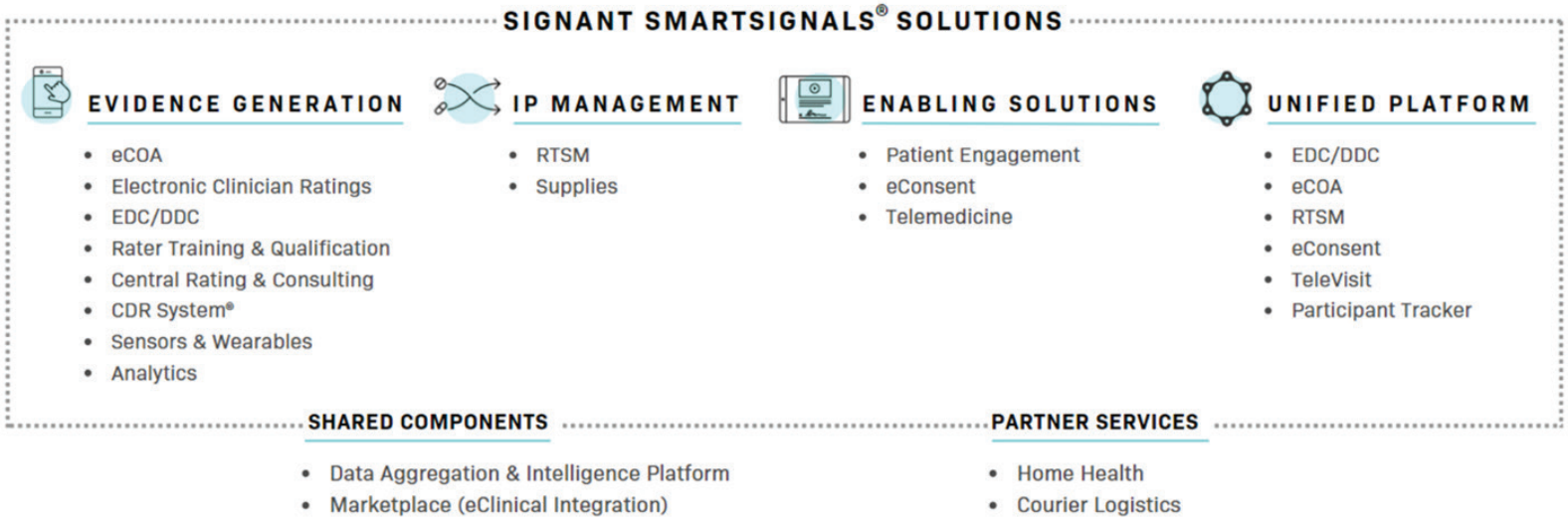
With a wide array of eClinical technologies available today, it is important to seek a partner with a comprehensive trial optimization solution suite.

✓ *Fully featured, best-in-class technologies to supplement your tech and service offerings*

CROs who can offer a broad suite of trial optimization solutions provide sponsors with access to a wider range of tools and capabilities that can address diverse needs and challenges throughout the clinical trial lifecycle. Having access to an array of best-in-class solutions is advantageous in three ways:

1. They can be integrated into and supplement CROs' existing solution suite.
2. They can provide a comprehensive solution for CROs without their own solutions.
3. They offer routes to develop new service revenue lines by leveraging self-service capabilities.

SIGNANT HEALTH'S COMPREHENSIVE SOLUTION SUITE

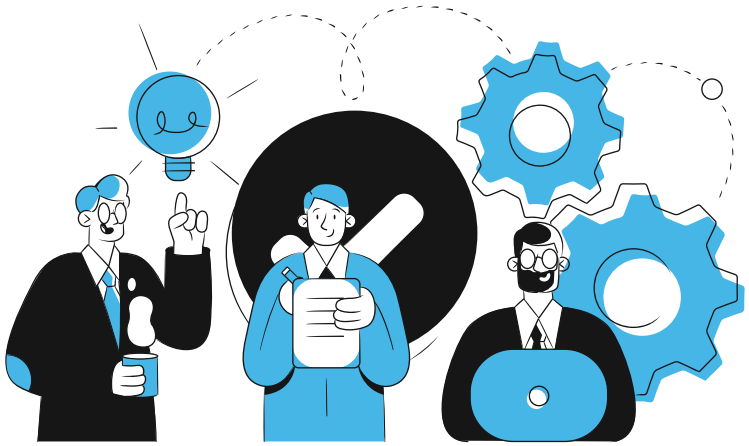


✓ *Reliable and trustworthy implementation and support*

Reliable and trustworthy implementation and support from a technology vendor partner are essential for CROs to ensure trial efficiency, data integrity, regulatory compliance, client confidence, cost efficiency, and scalability. By partnering with a vendor that prioritizes reliability and quality in its solutions and services, CROs can enhance their operational capabilities, deliver superior trial outcomes, and maintain a competitive edge in the clinical research landscape.

✓ *Self-service options*

Vendors who can provide self-service capabilities for their eClinical technologies empower CROs to offer full-service solutions to sponsors while also creating opportunities for additional service revenue through customized offerings, value-added services, and streamlined operations. By leveraging self-service capabilities effectively, CROs can enhance sponsor engagement, differentiate themselves in the market, and drive revenue growth in an increasingly competitive clinical research landscape.



We work together as ONE team with Signant Health in the development of best-in-class solutions for eCOA and central rating. Partnering with Signant Health provides us with a one-stop-shop for effective data quality management solutions for our trials including access to a global network of independent raters as well as an eCOA platform with data capture and protocol adherence tools that can be implemented rapidly.

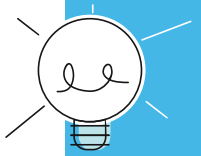
- Senior Director, Global CRO

SCIENTIFIC & MULTIDISCIPLINARY EXPERTISE

Clinical trials often require multidisciplinary expertise spanning diverse therapeutic areas, disease indications, and regulatory and operational conditions. While a CRO has clinical, regulatory, and operational expertise, partnering with a provider that offers complementary scientific and technical expertise ensures sponsors have access to specialized knowledge, insights, and best practices relevant to the specific requirements of each trial.

✓ *eCOA Science Expertise & Early Engagement*

Complex trials may necessitate specialized capabilities or methodologies that go beyond the core competencies of a traditional CRO. These may include COA selection and measurement strategy; protocol design elements, such as rater training and limiting the influence of placebo response; and modality/assessment setting considerations. By collaborating with a partner who has COA and digital health sciences expertise, and doing so early in the protocol development process, CROs can help sponsors optimize trial designs, enhance patient engagement, ensure data quality and integrity, and facilitate regulatory compliance, ultimately leading to more successful trials and greater value for sponsors.



DID YOU KNOW?

Signant has more than 50 full-time clinical and digital health science experts whose expertise spans all therapeutic areas. They also advise on study design, COA measure selection and implementation, PRO dossier support, novel endpoints, data quality monitoring, rater training, and more.

✓ *Clinical Supply Management*

Leveraging a vendor's expertise in randomization methodology consulting, complex trial designs (platform, basket, adaptive trial designs), and biostatistics enables CROs to optimize clinical trial supply utilization and management for sponsors by tailoring trial designs, implementing adaptive supply management strategies, facilitating data-driven decisions, developing robust risk mitigation strategies, and driving continuous improvement in trial operations. By collaborating with vendors who offer specialized expertise in these areas, CROs can deliver more efficient, cost-effective, and successful trials that meet sponsors' objectives and expectations.

✓ *Data Analytics*

Offering a blinded data analytics solution alongside risk-based quality management (RBQM) solutions/services enhances value to sponsors by providing deeper insights into trial data and enabling study teams implement proactive risk mitigation strategies. For example, in-study data quality checks can reveal trends, anomalies, and potential risks. Corrective actions can then be implemented to prevent poor-quality data from proliferating throughout a study. Collaborating with a vendor that offers such analytics solutions and expertise helps CROs drive optimal data quality and complements their own RBQM solutions.

EXAMPLES OF SIGNANT'S THOUGHT LEADERSHIP & THERAPEUTIC AREA EXPERTISE

Signant conducts original research to enhance the value of our scientific services by providing insights, innovation, validation, continuous improvement, and thought leadership, resulting in the delivery of higher-quality products and services that better serve the needs of the clinical research community.

Sample Research Summary 1: Exploring the Impact of MMSE Assessment Duration on Scoring and Administration Errors

Therapeutic Area	CNS - Neurology
Disease Indications	Mild Cognitive Impairment (MCI), Mild Alzheimer's Disease (AD)
Measures	Mini-Mental State Examination (MMSE)
Method	The study, conducted retrospectively using data from large clinical trials, analyzed 38,584 MMSE assessments conducted by 1,203 unique raters to identify relationships between interview durations, total scores, and error occurrences.

Objectives

This research investigated the association between Mini-Mental State Examination (MMSE) interview duration and the presence of administration and/or scoring errors in patients with Mild Cognitive Impairment (MCI) or mild Alzheimer's Disease (AD).

Findings

Results revealed a positive relationship between interview duration and the probability of errors, with longer interviews associated with higher error rates. Surprisingly, shorter interviews did not show fewer errors as expected.

Impact

The findings suggest that raters who are less familiar with the MMSE may take longer to administer it and make more errors. These results have significant implications for data quality monitoring programs, suggesting the importance of considering interview duration in error detection and prevention strategies.

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EXAMPLES OF SIGNANT'S THOUGHT LEADERSHIP & THERAPEUTIC AREA EXPERTISE

Sample Research Summary 2: Assessment of Completion Time of Common Patient-Reported Outcome Measures (PROMs) in Oncology Clinical Trials

Therapeutic Area	Oncology
Disease Indications	Breast Cancer & Non-Small Cell Lung Cancer
Patients	2,881
Measures	European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Core Questionnaire (QLQ C30). EORTC Breast Cancer Module (QLQ BR23), EORTC Lung Cancer Module (QLQ LC13), Patient Reported Outcomes Common Terminology Criteria for Adverse Events (PRO CTCAE), Single item side effects measure, EuroQol EQ 5D 5L
Method	The study analyzed PROM completion times for 2,881 patients across 7 global studies on breast and lung cancer. Data from various PROMs were used, completed electronically via tablet during clinic visits. Completion times were estimated from electronic timestamps at baseline and end-of-treatment assessments.

Objectives

To explore the impact on patients when switching from in-clinic assessments to at-home, more frequent assessments during their treatment, per FDA draft guidance recommendations.

Findings

We found completion times for core patient-reported outcomes in cancer trials to be within acceptable ranges for patients, even those very impacted by the effects of treatment.

Impact

These results provide confidence that a measurement strategy utilizing core PROM sets may not be over-burdensome or too time consuming to patients. Careful PROM selection and scheduling in oncology trials are essential for the management of patient time and PROM completion burden.

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GLOBAL REACH & SCALABILITY

> We knew from past experience with Signant on several vaccine studies over the years that their eCOA platform and global team could handle large, complex protocols. What we didn't know is whether they would be able to meet our highly compressed schedule and aggressive milestone deadlines. Our study team was beyond impressed by the level of commitment, responsiveness, collaboration, and above-and-beyond efforts from the entire team throughout the course of our first COVID-19 vaccine studies. They responded to change requests, amendments, and all of our emails, phone calls, and texts immediately even in the middle of the night. We trust Signant as our reliable partner for global, complex studies and programs.
>
> **- Senior Scientist, Large Pharmaceutical Sponsor**

A partner with global reach and infrastructure can provide significant benefits to CROs looking to implement multinational trials.

✓ *Geographic Reach*

A partner with a global presence can offer project teams in your time zones to simplify trial management. In addition, with access to global operational infrastructure, mature project delivery processes, seamless international logistics, and trial management resources in multiple countries and regions, CROs can support more clients as well as easily scale trials from early-phase, regional studies to multinational pivotal trials. By leveraging economies of scale, CROs can also optimize trial efficiency, minimize costs, and mitigate operational risks for sponsors.

✓ *Regulatory Compliance*

Conducting trials across multiple countries requires navigating complex regulatory landscapes, cultural differences, and local requirements. A partner with global regulatory expertise can provide guidance, support, and oversight to ensure compliance with relevant regulations and streamline regulatory submissions, approvals, and reporting processes.

✓ *Flexibility and Scalability*

Global partners offer flexibility and scalability to accommodate fluctuations in study volumes, resource demands, and geographic expansion. Whether providing full-service support or niche services on-demand, global partners can adapt to CROs' evolving needs and preferences, enabling them to scale trials efficiently and effectively.

SERVICE

By providing comprehensive, high-quality services that meet client needs, CROs can differentiate themselves, build lasting client relationships, and drive business growth. CROs rely on similarly high quality services from their chosen partner providers, so they should evaluate potential partners' capabilities in these areas:

✓ *Operational Best Practices*

Mature operational processes delivered by experienced and highly responsive project teams ensure consistency, predictability, and quality across trial execution, from study startup to closeout. This allows CROs to deliver trials on time, within budget, and to the highest standards of quality, meeting or exceeding sponsor expectations.

✓ *Responsive Project Delivery Teams*

Highly responsive multidisciplinary project delivery teams enable rapid communication, decision-making, and problem-solving throughout the trial lifecycle. This agility ensures timely responses to sponsor queries, proactive issue resolution, and effective risk management, enhancing trial efficiency and success.

✓ *24/7 Site & Patient Helpdesk*

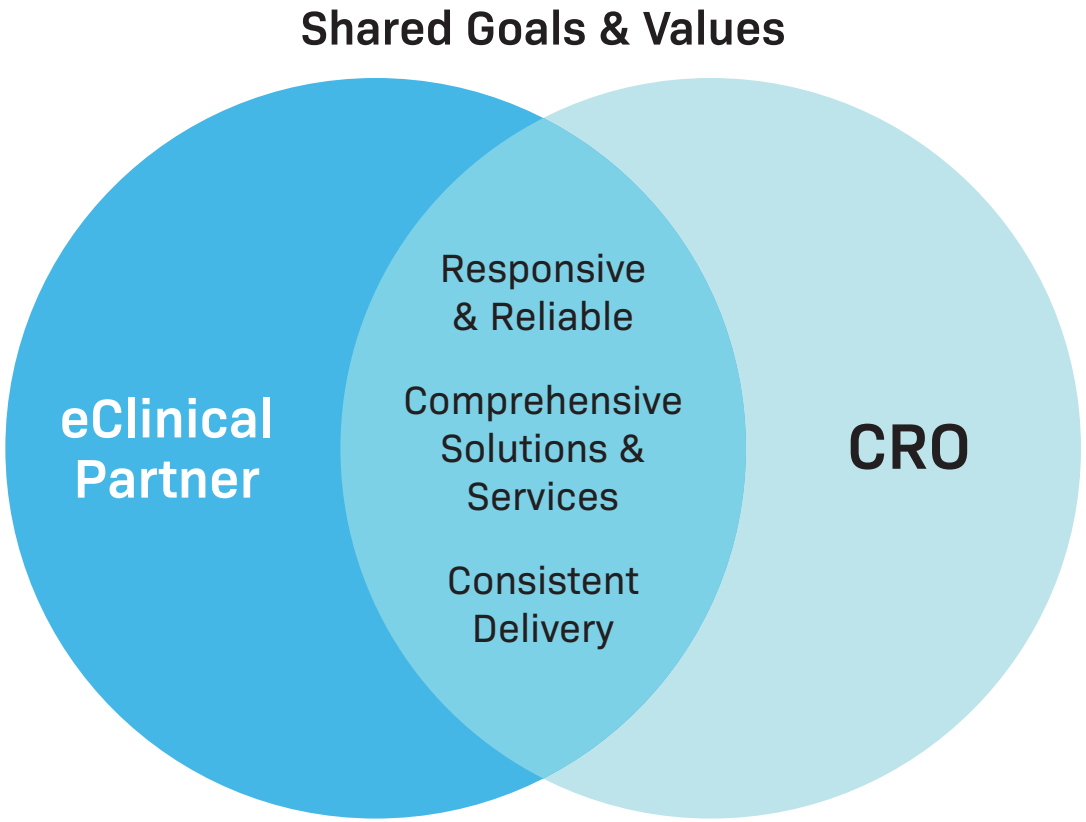
CROs can minimize costs by leveraging their partner's site- and patient-facing support infrastructure. 24/7 patient and site help desks, available in all languages, facilitate seamless trial operations across different time zones, geographies, and languages. This ensures continuous support to patients, investigators, and sites, addressing enquiries, resolving issues, and minimizing disruptions to trial activities.

CONCLUSION

In the rapidly evolving landscape of clinical research, characterized by continuous advancements in science and technology as well as evolution in trial design and conduct methodologies, CROs serve as crucial strategic allies in the development of new and better treatments. Sponsors rely on the essential services and expertise they provide to support planning, execution, and completion of clinical trials. Their contributions are instrumental in advancing medical knowledge, evaluating therapeutic interventions, and ultimately improving patient care and outcomes.

Similarly, CROs rely on strategic partnerships for access to complementary expertise, resources, and technologies that can address specific trial requirements as well as enhance the overall quality and efficiency of trial execution. When qualifying and selecting an eClinical vendor, CROs should seek a company with shared goals and values that is committed to responsiveness, transparency, reliability, clear governance, and industry awareness.

A vendor should also be sufficiently resourced with well-established and comprehensive solutions, scalability, expertise, as well as clearly defined operational infrastructure and processes.



With experienced eClinical technology partners, CROs position themselves as invaluable partners to a sponsor, aiding in overcoming the challenges of modern clinical research and establishing a solid foundation for winning together through sustained growth and success.

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

ABOUT SIGNANT HEALTH

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant Health solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics.

Learn more at www.signanthealth.com.

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