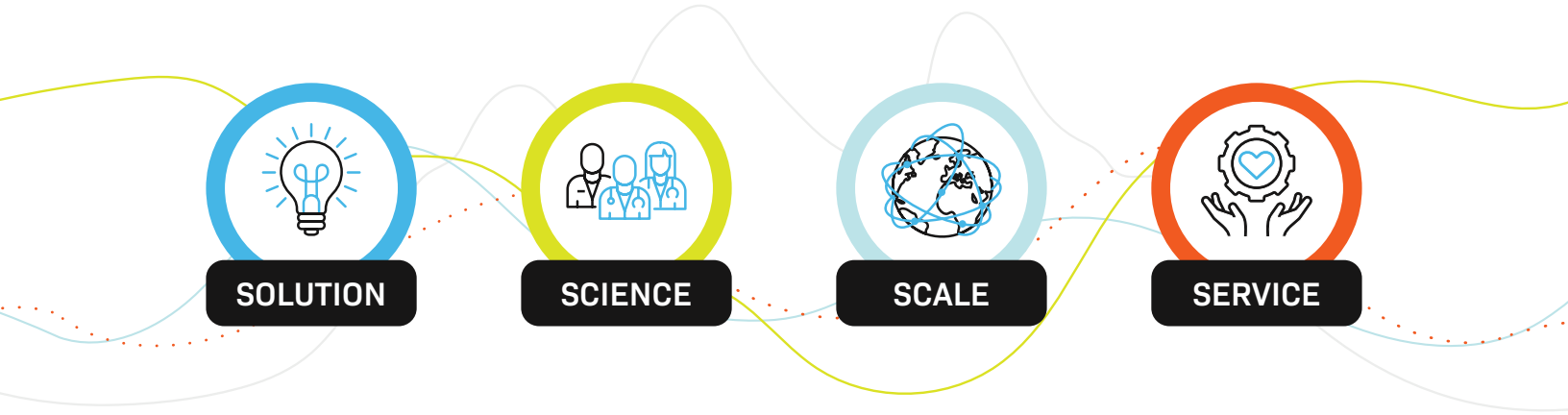
SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

PERSPECTIVE

SUCCESSFUL eCOA DEPENDS ON THE FOUR S's

Choosing to collect clinical outcome assessments data electronically is not usually a difficult decision. Compared to pen-and-paper, electronic collection ensures data quality and integrity, and helps satisfy the ALCOA+ principles required for source records. Selecting a vendor in today's marketplace can be less straightforward.

eCOA requires a solid technology solution that meets all the needs of modern clinical trials. But successful eCOA implementation also requires a vendor that meets requirements in terms of scientific expertise, scale, and service. Along with technology solution, these are the four pillars, the four S's, that are all individually important in a successful eCOA implementation: Solution, science, scale, and service.



SOLUTION

What are the table stakes in terms of eCOA technology features and capabilities? Sometimes, these are difficult to determine in enough granularity before contracts are signed, and the full details of the study solution begin to be specified. Capability gaps at this stage mean difficult decisions and time delays for the study team – what workarounds can be implemented to meet the study's key requirements?

Despite promises and handsome looks, some vendors have only basic technical capabilities and so sponsors can be faced with the need to shoehorn their protocols to fit the limitations of the solution provider. This isn't limited to the capabilities of the patient-facing application, but also the tools, interfaces, and reporting solutions available to sites and sponsors to manage and oversee their studies.

At Signant Health, our eCOA is built from our experience implementing solutions for over 20 years and across around 5,000 clinical trials. Our technical capabilities are drawn from this experience, and our solution contains all the features and know-how to navigate all study requirements frictionlessly. With Signant, there are no surprise gaps in capabilities compromising implementations.

SCIENCE

eCOA, including electronic patient-reported outcomes (ePRO) and electronic clinician-reported outcomes (eClinRO), requires thoughtful implementation to provide high quality clinical evidence that can be relied upon in regulatory submissions.

Not all vendors can support the questions that study teams face during implementation (Box 1) or smooth the processes around scale owner approvals and translations.

At Signant, our dedicated science and medicine specialists enable us to work with customers to make the best solutions for each study, ensuring industry best practices are followed. We imbue a full understanding of best eCOA implementation, combined with an understanding of the patients and their condition for optimal design and measurement strategy. We provide credible client support, including helping to decide whether to use BYOD, developing eCOA strategies, co-designing custom instruments, providing input into the submission PRO dossier, and more (Box 1).

Our scientific services, such as rater training and qualification, placebo response mitigation training, and in-study statistical quality monitoring, ensures our eCOA software produces the highest quality of clinical evidence.

Our scale management team leverage our relationships and credibility with authors and license holders to help us to navigate each study's electronic implementations successfully. And, our scientists are up to date with current regulatory and industry thinking so that you can rely on best practice implementations at all times, with no last minute issues when it is time to submit your data.

BOX 1.

QUESTIONS OUR SCIENTISTS ARE ASKED

- Can you help us develop an eCOA strategy?
- Can you provide input for our PRO dossier to support how we have implemented ePRO?
- What is best for this study - BYOD or using provisioned devices?
- Can you help us select the best measures for this study?
- What is the current regulatory thinking?
- Why not use paper?
- Is this implementation following best practice, and will it support a regulatory submission?
- What evidence of measurement comparability do I need when using this PROM electronically? Can you help us provide this?
- Can you help us design a custom diary for this condition?
- Can you provide scientific input into our study design?
- Can you manage the scale approvals and licensing for us?
- Can you help us adapt and validate our ClinROs for assessment over video?

SCALE

What matters when moving from an in-country, early phase study to a multinational pivotal trial? Accommodating scale matters, and is a vital element in the implementation of studies designed for regulatory decision making. There are many different elements to accommodating scale that are important as we consider eCOA implementation.

First: Including the languages and localisations needed for all countries and patients, and ensuring that translations and approvals are conducted in a way that does not introduce unplanned delays.

Second: Managing the logistics of configuring and exporting/importing provisioned devices on a global basis. Even BYOD studies need provisioned devices to ensure patients are not denied inclusion based on smartphone ownership.

Third: Supporting patients and sites with effective, local-language help desk support at any time of the day or week.

Fourth: The operational capacity to build, test, implement, and manage multiple studies in parallel. Not all providers have the capacity to manage large volumes of studies, and short-staffing operations leads to unplanned delays to study implementations and study starts.

And finally: Infrastructure. Does the solution have sufficient architectural capacity to ensure the performance and protection of many studies concurrently?

At Signant, we have the scale to support large numbers of studies across all corners of the world. We operate in over 135 countries, with support from internal logistics capabilities that ensure all studies can operate at all times. Through these facilities we process around 1,500 eCOA devices each week. We currently support around 600 live eCOA studies on our platform, with more added each month. Signant are proud to have conducted the industry's largest BYOD study in over 44,000 participants.

SERVICE

Service excellence is the fourth of the 4 S's important in successful eCOA implementation.

Good service means responsive and informed staff. It also means having the service components that are important to trouble-free implementations. This includes the ability to manage COA version selection and licensing on behalf of the sponsor, to ensure successful compliance with license holder requirements. It includes preferred partnerships and frictionless processes with leading translation providers to simplify and accelerate localizations. It includes a comprehensive logistics service that procures, configures, and ships devices ready for use for all studies across the globe. It includes local language patient- and site-facing helpdesk that is available at any time of day or week to troubleshoot with patients and sites. And, it includes experienced project teams who understand best practices and can ensure implementations will stand up to regulatory scrutiny.

At Signant, our excellent and comprehensive service is an essential element to how we do eCOA.

WHO IS 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 20 years, over 400 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.

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