20 YEARS | Cmed

The secret to achieving a smarter long-term clinical data strategy

Where technology meets expertise

D&A ARTICLE

Investing in the right partner can pay dividends

There is a tendency for Sponsors to view data management and analysis as a commodity business – something that one Contract Research Organization (CRO) can do as well as another. But the truth is, it demands a level of expertise and attention that is not always available in CROs for whom it is not the core component and specialty of their business.

However, emerging and mid-sized biopharma companies often tend to turn to a single CRO partner to manage all aspects of their clinical trials to include recruitment, monitoring and site management, as well as data management, analytics and biostatistics (although they often select different full-service vendors for different trials). The rationale for choosing this full-service outsourcing model can be summed up in one word: convenience. Contracting and oversight is simplified, and Sponsors have but "one throat to choke" should issues arise.

Even so, there are compelling reasons for Sponsors to carve out the data management and analytics responsibilities from the full-service contract and assign them to an organization specializing in those functions. Investing up front in the right advisors and systems, which form part of a proactive, bespoke data strategy, can pay dividends that outweigh and outlast the initial convenience factor. In providing the most appropriate data strategy for the trial or program, the right CRO who specializes in data and analytics can deliver efficiencies that ensure the integrity of the data collected, support clinical and medical monitoring processes in real time, enable robust data analysis, and speed database lock.

Thus, it often makes sense to have one vendor focused on patient recruitment, clinical monitoring, and site management and another focused on the systems and processes surrounding the management and reporting of trial data. Sponsors need not settle for second best in either area of expertise, instead seeking 'best-in-class' support and guidance from a specialized CRO can make all the difference.

Challenges of a full-service outsourcing model

When a single CRO is tasked with managing all aspects of a trial via the full-service outsourcing model, those areas that consume the largest portions of the trial budget – patient recruitment, clinical monitoring, and site management – naturally receive the most attention. Despite being affectionately known as the 'back-bone' of a trial, fewer resources are devoted to the detailed aspects of data capture, management, and analysis, while the critical aspects of data quality, timeliness, visibility, and reliability can be missed. The importance of data integrity is, of course, key to the trial's ultimate success (and absolutely required by ICH E6 (R2)); there is no shortcut or economy worth risking "dirty" data at the end of a trial.

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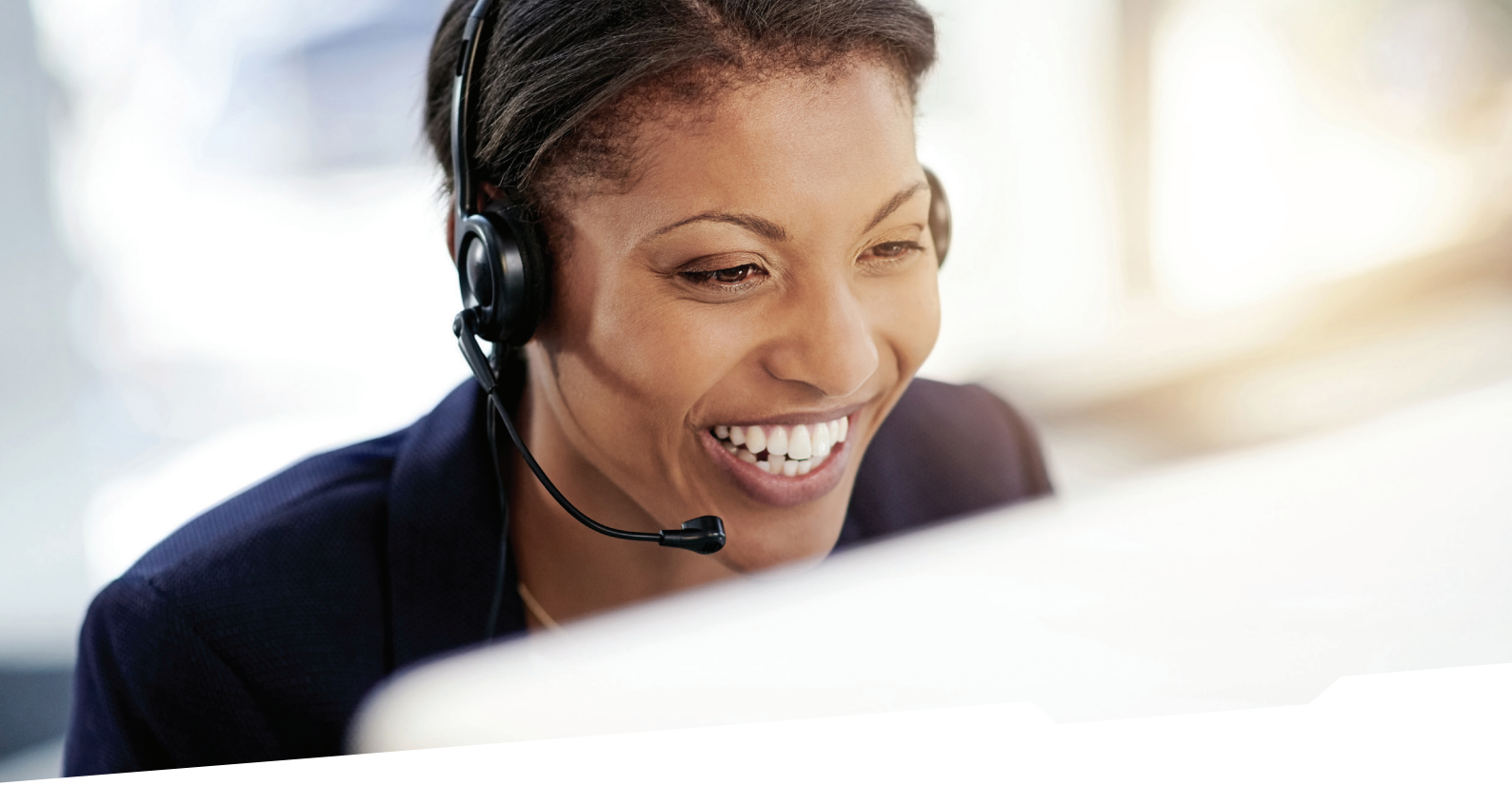
Turning to trial generalists rather than data management and analytics specialists can yield less than ideal results, especially when:

- The study design is highly complex
- The study captures data from multiple sources
- The results will impact subsequent trials, or
- The target population is small, and no lost or missing data can be tolerated.

Furthermore, data challenges are most often addressed reactively, when an issue has already occurred. In these situations, all members of the CRO team must be experts in their fields; the trial cannot be a training ground for junior staff nor can strategic data decisions be entrusted to those who are not data scientists or do not have the "end game in mind", i.e., the trial data output.



The value of a specialized data and analytics CRO

In contrast, CROs who specialize in data and analytics have the skills needed to collect, manage and analyze clinical trial data, and offer several advantages to Sponsors through their knowledge and expertise in:

- **Strategic planning.** The data strategy, technology platform, and statistical analysis plan must all be created with a clear view of the end goal: what will be required in the evidence dossier. The specialized data and analytics CRO will be capable of consulting on the design of the trial so that the data collected will answer the questions that the study is intended to address. Working backwards from an understanding of the trial goals, the CRO can ensure that the system that is built will deliver on those goals and that the data will be structured to support regulatory approval. Furthermore, they should understand today's trial complexity and deliver efficient and effective solutions, no matter the volume, type or source, in order to unleash the full potential for your valuable data. This can only come from data experts who have amassed experience over hundreds of trials in numerous therapeutic areas.

- **Data stewardship.** They will take ownership of implementing the data strategy and ensuring data integrity on behalf of the Sponsor for the trial or program. This involves reviewing the protocol to anticipate the system needs and identifying the system that will afford full, real time access to all the data. It also involves defining the strategies for reviewing data so that they are aligned with the needs of the trial and with the standards for risk-based quality management. It entails working with eClinical vendors to see that data are structured correctly in the database, captured at the right time (quickly and ideally in real time) and in forms which are interactive and customized for the user and are available for review on an on-going basis.

  When data are managed properly in one place, synergies are created and analyses can be conducted across trials. Standards should be developed for how the data are imported, structured and reported, and these standards should apply across studies. This disciplined approach creates efficiencies, saving time and money. It allows for integrated reporting with program-level data, minimizing the need to re-format data in order to integrate it. Thus, it speeds data analysis, and ultimately, submission and go-to-market.

- **Proactive risk management.** This type of specialized CRO, who focus on trial data, have the wherewithal to be proactive in foreseeing potential issues and forestalling them; they consult with the Sponsor and carefully develop the requirements while recommending the best way to apply data science, including technology, to meet the customer's needs. They bring their years of data-agnostic expertise to the process having overcome the most complex and unique data challenges across all phases and therapy areas, often uncovering potential problems that the client had not anticipated.

- **Creating a personalized approach.** These experts, who have your best interest at heart, develop custom solutions in order to be able to adapt to your needs and any study design changes. Efficiently employing templates and standards is important when it comes to time savings, as well as giving you real time visibility and system adaptability.

- **Responsive service.** You deserve special attention to your trial's data to ensure that nothing is missed or misunderstood. The right specialized data and analytics CRO partner can do just that and also escalate issues rapidly and provide quick, reliable answers to requests at any time. A request to "see my most problematic site," "see where my study currently is" or review and track enrollment rates across global sites, understand outliers in study data, and pinpoint patient-specific data points should all be easy to address.

- **Breaking down a silo mentality.** The ability to respond quickly stems from the fact that within a specialized data and analytics CRO, functions are not siloed; teams are composed of intimate groups who understand the full development cycle and can ensure smooth hand offs across functions. The teams also typically have experience working with multiple eClinical vendors and other CROs – experience that translates into solid working relationships, good communications, and effective coordination.

- **Future-proof approach.** The landscape of clinical trials is changing and becoming ever-more dynamic with respect to clinical trial data and different data collection solutions, such as ePRO, eSource and wearable technologies. When this is considered alongside other technology or software that is available, such as key risk indicator dashboards and central statistical analysis tools and the evolution of artificial intelligence/machine learning, one begins to understand not only the requirement for technical capabilities of a data and analytics management team, but also the wider understanding of RBQM principles and how to operationalize this within a study setting as part of a cross-functional team.

- **Leveraging the right technologies.** The ability to conduct trials intelligently and effectively cannot be underestimated, and specialized teams must have an appreciation of how all of this fits together to deliver data integrity, reliability of trial results and above all, human subject protection.

When all of these qualities are demonstrated in a specialized data and analytics CRO, Sponsors have the comfort of knowing that their data are in the right hands, can feel confident that trial risks will be mitigated, and that the proactive solutions provided will deliver the intended results, efficiently.

Cmed has quickly adapted with Clinical Trials 2.0, which provides trial Sponsors with one integrated technology platform, known as encapsia®, to collect, review, and share relevant data from site systems, patient-home systems and other external sources in real time.

The appropriate blend of data and analytics experts and innovative clinical technologies now gives Sponsors the ability to monitor data quality, track study progress and site performance at any given time, irrespective of the data source.

Helpful checklist:
What to look for in a specialist data and analytics CRO partner

Sponsors should expect all the above from their CRO solutions partner. But, how can they know if a given CRO will deliver? Here's a list of questions and considerations that can help sponsors in making the award decision and in preparing to work with a Data and Analytics specialist...

	What is the scope of your need? Will the approach be needed for a single trial, or for a program? Or, is this the birth of your overall data library? As your trial begins, it's good to think about your end goal. The need to keep your data clean and ready for the next step should be a top priority.
	Where do you need efficiencies and what is the expected gain?
	While you own the data, can your CRO provider be trusted to bring the right processes and systems to ensure its integrity? Recognizing that the output of the trial is its data.
	Is it obvious that the CRO partner's team understands the overall clinical data flow and not just the data management process?
	Will you be able to access the data when, where, and how you want? Does the CRO provide advanced analytical tools? The technology solutions offered should be able to be customized around the trial design.
	Will the team be responsive? Does the CRO partner have a history of presenting options and offering solutions – not just cataloging problems?
	Will the CRO partner build a team that can take ownership and deliver cross-functionally? What organizational steps will ensure efficient operations?
	What are their project management skills like? Do you have to coordinate them, or do they drive the project and keep you informed? Do they liaise effectively with all eClinical vendors on your behalf?
	Will the CRO partner commit to managing third-party data providers, or leave you to sort out data transfer specifications?
	How will you provide oversight? Have you put governance models in place? Will the CRO partner provide regular and accurate performance metrics against established Key Performance Indicators (KPIs)?
	Has the CRO partner passed your qualification audit?

Case study

Handling an expanded scope of data: Cmed to the rescue

A Phase IV clinical trial in Europe was outsourced to a single CRO partner in a full-service model. The initial purpose for the data were within the capabilities of the selected CRO, however as the core study neared completion, it became apparent that the data being collected would need to support a pivotal study. As the Sponsor requirements rapidly changed, the deficiencies in the existing data management processes became clear.

It was at that point when the Sponsor decided to invite Cmed's Data Science and Analytics Team to assume all of the data management and statistics responsibilities to support the extension phase of the trial.

> There is value in establishing a long-term data strategy early-on with a CRO who specializes in data and analytics.

Cmed Data Science and Analytics initially insourced 12 staff members to work with the original CRO and tasked with importing all of the existing datasets and building an extension database. Cmed Data Science and Analytics then performed data management and statistics for the extension study, delivering the locked extension database on time and on budget.

The decision to move a project from one CRO partner to another is never easy and comes at a cost to the Sponsor that could have been avoided. In this case, the transition was handled with empathy and speed, however it highlights the value of establishing a long-term data strategy early-on with a CRO who specializes in data and analytics.

Conclusion

The prospect of working with two CROs rather than one sounds more complicated at first. However, the need to rely on a best-in-class partner that can devote sufficient resources to and has the required experience in data management and analytics often demands such an approach. Furthermore, most full-service models have multiple vendors for services such as central laboratories and other ancillary needs. A CRO specializing in data management and analytics can see that the right long-term data strategy is developed, the best technology adopted, and the right processes followed to ensure the trial goals are met. Since the product of any clinical trial is data, Sponsors should entrust its collection, management, and analysis to experienced specialists.

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Let's talk

Get in touch with us today to ensure you have the right data strategy and experts in place to unleash the full potential of your trial data.

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