THEN AND NOW:
Is Clinical Trial Technology Selection and Implementation Becoming Easier?

Quanticate
The Clinical Data Experts

The drug development industry has seen significant changes in the last ten years. Amongst those changes, pharmaceutical and biotechnology sponsor companies are outsourcing more drug development activities to third-party clinical research organisations (CROs)[1]. Alongside this, clinical trial technology is playing an increasingly critical role in drug development, as the range of technologies in the market increases and as those technologies become more effective and refined[2]. As technology choices expand and relationships between sponsors and CROs deepen, CROs need to alter their technology provider selection process to consider market drivers that didn't exist just a few years ago, including:

Go Big or Go Home – The era of CROs implementing a technology on a "study-by-study" basis is over, as the industry realises the advantages of developing a truly strategic partnership between CROs and technology providers. The resulting cost and time-saving benefits drive CROs instead to find a technology partner who can deliver on an enterprise-level commitment—regardless of phase or speciality—with a scalable product solution and shared investment in a mutually beneficial, long-term relationship.

It Takes a Village – Developing a strategic relationship between a CRO and a technology provider involves a range of stakeholders from many functions. Not only must technical and operational specialists address their functional needs and concerns, but C-level management must also guide the strategic needs of the discussions. Involving executive-level players is the only way to ensure that each party's longer-term visions are accounted for and become aligned.

Plays Well with Others – Implementing multiple technologies should be synergistic; however, this is only possible if those technologies can be integrated. The degree of integration with other systems should be one of the central success factors when evaluating technology providers. This paper will examine the planning, communication, and support required for successful clinical trial technology implementation in the current state of the industry compared to previous years. The paper will also outline keys to success for a mutually beneficial CRO and technology-provider relationship.

A BRIEF HISTORY

When the use of electronic data capture (EDC) systems as a means of collecting clinical trial data was in its infancy, many CROs created, developed, and implemented their own in-house systems. The scope and functionality of such systems ranged from the most basic setups featuring data capture via the web to fully functional data management systems that incorporated import/export facilities, dictionary coding tools, and laboratory management modules. The increasing need to incorporate additional functionality to manage ancillary trial-related activities—such as randomisation, trial supply management, and automatic medical event and concomitant medication coding—and the challenge of maintaining and upgrading these systems has fostered an environment that rewards CROs taking a renewed focus on their core business area: conducting clinical trials.

Thus, many CROs have strategically decided to abandon their in-house EDC systems in favour of those offered by commercial technology providers[3]. This shift has enabled CROs to encourage customers to use a preferred technology choice—one that may be more favourable to the specific study. Many CROs have evaluated the commercial EDC systems available and selected one or more technology providers as preferred partners. Following the selection process, successful implementation of the technology

becomes the next critical step.

COLLABORATION FACILITATES A PAINLESS AND EFFICIENT PROCESS OF TECHNOLOGY IMPLEMENTATION

The partner selection process tends to be driven by higher-level management or a technology expert, with the more "hands-on" operational staff having little, if any, involvement. In some cases, a consultant may have been brought in for the short term as the latter role, their contract coming to an end once the formal agreement between the CRO and technology provider has been established.

So once a partner has been selected, how does the CRO implement the solution? The process followed may differ according to company size. In substantial organisations such as a large pharmaceutical company or CRO, a team might then be assigned to coordinate the necessary training, determine the workflow to be adopted within the organisation's clinical and data management teams, and conduct the steps necessary to achieve either a fully operational system or accredited partnership status. A member of the training department manages scheduling webinars and e-learning modules that should be attended by an appropriate mix and number of members of each department.

This group should include a member of the quality assurance (QA) department—who then updates the standard operating procedures (SOPs) and ensures due diligence—and data managers and programmers assigned to perform necessary validation. The team may be allowed to concentrate all their attention to these tasks until they are completed.

A smaller CRO or virtual pharmaceutical company might not have the necessary dedicated resources for such a formal in-depth process. In such scenarios, assistance from the technology provider can provide invaluable support and guidance for the new partner to facilitate a smooth pathway toward full adoption of the system.

As an example of a formal implementation process for CRO partners, a dedicated individual may be appointed by the EDC vendor to oversee the process, leading a team of personnel to guide the CRO through the implementation process—analogous to the support that a CRO would provide to a sponsor when implementing a full clinical trial. In such a partnership, the teams hold a kick-off meeting to set expectations, establish timelines, assign tasks, and draw up a communication plan. Following this, the EDC vendor and the CRO partner's core development team meet weekly to discuss status updates, capturing agendas and minutes just as they would for any important project. Thus, both parties remain focussed on their respective part of contributing to the ultimate goal of conducting an effective clinical trial. During these meetings, the team organises the sequence and timing of webinars and the release of e-learning modules, maintaining a comprehensive tracker to ensure that staff attend the training most appropriate to their functional role, be it data management, medical monitoring, QA, or biostatistics. The EDC vendor should offer guidance as to the workflow the partner should adopt with a master template in place as a starting model, which can be taken on-board in its entirety if so desired. However, the final decision rests with the partner to determine how they will operate according to their SOPs and infrastructure.

EFFECTIVE SYSTEM INTEGRATION IS A KEY SUCCESS FACTOR

As more and more clinical data in the clinical research environment is captured electronically, the benefits of automatic integration of ancillary data into electronic case report forms (eCRFs) become increasingly apparent.The ancillary data may arise from a multitude of sources: interactive voice response systems (IVRS), interactive web response systems (IWRS), serious adverse event (SAE) reports, clinical notes, patient diaries, electrocardiography (ECG), and imaging technology, to name a few. A successful EDC solution is one which can, when required, provide an interface with other electronic sources, enabling all data to be integrated, viewed, and interrogated from a single point of access. Such an integrated system will facilitate the reconciliation of data on an ongoing basis, reducing the workload for investigative sites, CROs, and sponsor stakeholders.

CONCLUSION

In conclusion, the relative size of the company will dictate the best approach for the implementation process. Such formal partnerships between CROs and clinical technology providers enable an environment in which clinical data acquisition, entry, and access are effected in the most efficient, cost-effective, and mutually beneficial way.

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ABOUT QUANTICATE

Quanticate, headquartered in the UK and USA, is a leading global Clinical Research Organization (CRO) primarily focused on the management, analysis, and reporting of data from clinical trials and post-marketing surveillance. As The Clinical Data Experts, our team provides high quality, efficient outsourcing solutions for companies who need additional capacity or who want to outsource certain activities in their entirety. Clinical and post-marketing services include scalable on-site and off-site clinical data management, biostatistics, clinical programming, PK/PD analysis, medical writing, pharmacovigilance, and consultancy. Quanticate was announced as a five category winner at the annual CRO Leadership Awards for Quality, Reliability, Productivity, Regulatory, and Innovation. Quanticate was the first CRO to introduce the Centralized Service Provision (CSP) approach to outsourcing supported by its data centralization and visualization tool for both single-study and cross-study data analysis.

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