Exclusivity or Collaboration in Clinical Trials: What's the Best Formula for Success?

Exploring the people, process, data and technology challenges and choices facing clinical trials operators

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OVERVIEW

Clinical research is undergoing rapid change, spurred by the challenges of operating in an environment shaped by a global pandemic and continuing industry pressure for faster more efficient clinical trials. Exclusivity—better known as siloed people, processes and technology—is a now making way for more cross-functional and collaborative approaches. Siloed point solutions, typical of many current clinical operations, create closed environments that offer limited integration or interoperability. Consequent vulnerabilities, including lack of transparency, data integrity issues, and delays translate into increased costs and patient and site dissatisfaction. This article examines how a more open environment that promotes inclusivity and collaboration offers a pathway to standardization and harmonization for the entire clinical trial ecosystem and lifecycle.

EXCLUSIVE OR COLLABORATIVE?

There is much discussion around what exclusive or inclusive really means, especially with the emergence of new technologies and increasing shift to decentralized clinical trials. A generic definition of exclusive would be "limiting or limited to possession or control or use by a single individual or group." In the context of clinical trials, this typically means "siloed areas." An example is where only one company can provide the services for a particular system, as sometimes seen in functions such as interactive response technology (IRT) or clinical trials management systems (CTMS). Exclusivity in

clinical trials generally means having a system that is not open and does not work well with other systems, companies, or technologies.

In contrast, inclusive means "not excluding any of the parties or groups involved in something." With the advent of open platforms and services, companies are gaining the opportunity to work more closely together, share systems data, and operate in a more collaborative manner. This inclusive environment has the potential to make clinical trials more efficient and effective for clinical research organizations (CROs), technology companies, sponsors, sites, and regulatory agencies.

THE CHALLENGES OF EXCLUSIVITY

Exclusivity presents several challenges for clinical trials management, affecting the people, process, data, and technology involved.

People. With respect to the people involved, designating control to an individual or to a specific group runs the risk of limiting opportunities for consensus and deprives project teams of the ability to align on goals and to agree on the strategy needed to get the job done. Consequences such as disorganized or distorted hand-offs, or unclear priorities, can mean a disjointed workflow and a detrimental impact on timelines. Equally, communicating in a vacuum or in an exclusive environment can create a lack of transparency and affect trust. The absence of any opportunity to align and share common goals and priorities can have a real impact on a team and its performance.

Process. When it comes to process, in an exclusive environment people often repeat the same tasks and there may be redundancy and duplication. This can mean significant efficiency and productivity losses. In addition, any reliance on tasks being carried out sequentially in a process essentially turns everything into a critical path, whereas defining those tasks that really should be on the critical path is better carried out in an inclusive environment. Bottlenecks, where one group is waiting for another to complete a task before they can move ahead, can become a significant issue. The result can be missed milestones or extended timelines, both of which are critically important in clinical development, and such failure to perform is costly.

Data. Areas of challenge around the data in exclusive environments include its quality, completeness, and timeliness. If a dataset can be viewed only in its own silo, there is no opportunity to see it in the context of other data, and data rarely stands alone. Traceability of the data is also an issue—knowing where all those pieces of exclusive data actually come from—and perhaps most important of all, ease of access to that data. Accessing high-quality data in a timely manner is critical. In exclusive systems, siloed data might appear convenient at first, as it is located in one place. However, working with others across all facets of clinical trial soon highlights the need for real-time data sharing.

Technology. Going hand in hand with the data challenge is the technology challenge. Siloed data and siloed technology both restrict sharing. Siloed technology that performs only for its functional area of operation is usually rigid and narrow in its application, and there

is a risk that it will become disconnected from the whole process, together with the data it generates. The operation of multiple siloed systems also results in considerable redundancy and data duplication. Redundancy is probably one of the most visible consequences of working this way and also has implications with respect to data quality. Moving to an inclusive approach for clinical trials offers several potential solutions to the issues that result from an exclusive, more siloed way of working.

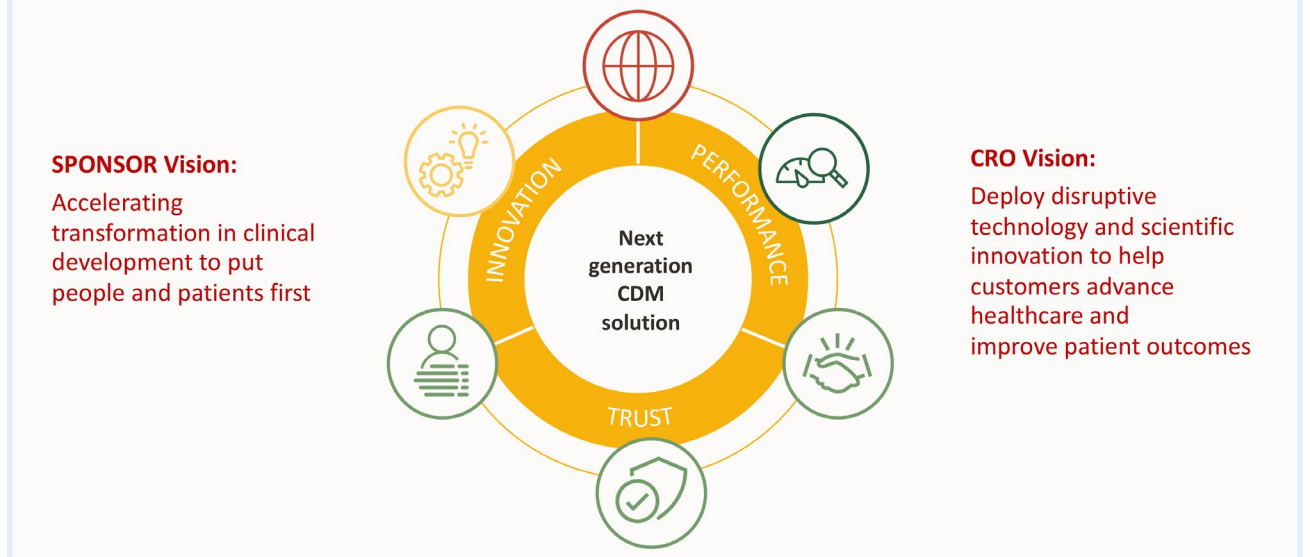
INGREDIENTS FOR SUCCESS IN INCLUSIVITY

Important ingredients for success in developing an inclusive environment are collaboration, communication, standardization, harmonization, and parallelization.

Collaboration. Collaboration is a key factor. Greater inclusivity, with a broader project team in which everyone is working toward a common endpoint, means that people are operating in a collaborative environment and can establish shared goals. Given this, it is important to set clear performance goals, for the team to be successful. Transparency is essential in ensuring open communication within and between project teams, CROs, sponsors and vendors, all of whom play an important role in the clinical development process. This starts right from the beginning, during the request for information (RFI) or request for proposal (RFP), and is about setting that common goal. When considering providers and partners, whether as a sponsor, vendor or CRO, aligning on a shared vision is critical to building a successful team.

FIGURE 1 illustrates how this may operate in terms of a CRO working to understand a sponsor's vision for a broad partnership, in which the CRO would be the only data services provider. Here, the sponsor's vision of accelerating transformation to put people and patients first closely aligns with the

Figure 1: Collaboration means aligning on a common vision to achieve success.



CRO's vision of using disruptive technology and innovation to accelerate transformation and improve the lives and healthcare of patients. While these may appear to be broad goals, which are common to all in clinical development, a deeper look revealed that, both companies had specific performance goals in place for team leaders and team members. Setting common performance goals down to an individual level drives the teams to make the partnership successful.

Communication. Having clear communication during a clinical trial may seem like common sense, but this mind-set can result in failure to take all the steps necessary for real success. Open communication is vital and must be clear, direct, and honest, with a balance between needs and priorities. Most important, however, is putting in place a comprehensive communications strategy (see FIGURE 2). This entails understanding

Figure 2: Components of a comprehensive communication strategy.

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and outlining the goals of all parties working in an inclusive environment, making sure that requirements and objectives align, that everyone has common priorities, and that everyone understands their role in delivering on the goals. Identifying the target audiences, the most effective way of communicating with them and the frequency of those communications, are critical success factors.

Over-communication can result in losing the audience. It is also important to fully understand the communication pathways, especially around escalation points. Finally, establishing governance around the entire communications process is essential to define who is responsible, how often to review and check that the strategy remains aligned to the goals, to ensure the right audiences receive the right communications at the right time and frequency. Communications are not something that can be set up once and left; they must be revisited regularly.

Standardization. Operating in an inclusive environment, a holistic view of standardization is important. This means taking account not only of industry standards, but also having benchmarks and quality metrics, and setting

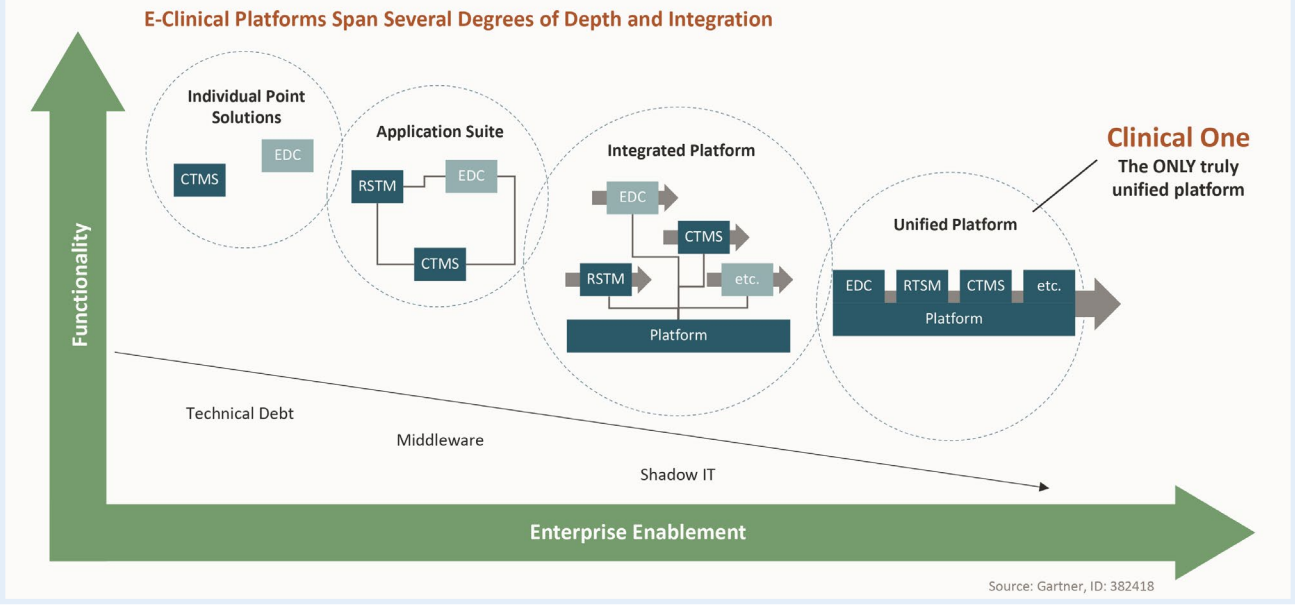
Figure 3: Key industry groups working toward standardization.

expectations. All of which is intended to allow reliable replication, enable real learning, and avoid continual reinventing of processes. Many industry groups have emerged in recent years, working toward similar standardization goals. They have already enabled advances in areas such as submitting to regulatory agencies and sharing data between different companies (FIGURE 3). The Society for Clinical Research Sites (SCRS), for example, is working on standardizing the ways CROs, sites and sponsors work together to ensure consistency between clinical studies. The Metrics Champion Consortium (MCC) supports organizations with their own metrics to ensure appropriate measurements that facilitate continual improvement, while the Avoca Quality Consortium helps ensure that quality is built in. The Clinical Data Interchange Standards Consortium (CDISC) is driving data sharing and, with moves toward decentralized clinical trials, the Decentralized Trials and Research Alliance (DTRA) is coming to the fore. As mentioned previously, standardization also includes setting specific benchmarks and goals. For example, asking how long it should take to set up a study or a site, and how long before data reporting starts. In an inclusive environment, this approach ensures everyone moves together towards the same goals and avoids silo'ed activity that is not aligned with overall strategy. Quality metrics are built-in, and expectations set.

As mentioned previously, standardization also includes setting specific benchmarks and goals.

Harmonization. Harmonization is the key to unifying systems and processes, providing interoperability, and having a "single source of truth." A truly unified platform that

Figure 4: Technological aspects of harmonization.



standardizes hosting, operating systems, and data entry is critical in achieving inclusivity and data sharing. As the number of open systems and open processes grows, harmonization enables organizations to collaborate, bringing together individual systems, technologies and solutions, and eliminating the need to collect, clean and reconcile data in multiple locations.

FIGURE 4 illustrates the technological aspects of harmonization that have now culminated in the development of one unified platform. Thirty years ago, everything was collected on paper for clinical trials. Then, software providers emerged with point solutions to address specific business processes, which resulted in EDC, CTMS, and RTSM, to name a few. These solutions were better than paper, but they were all developed independently, which resulted in a mess of silo'ed point solutions that don't work together. Eventually, some of these point solutions that related to the same business process were bundled together into an application suite to allow some data to be shared. Then the integration was expanded to include all systems, to create an integrated platform, which was a move in the right direction, but requires a lot of IT support to maintain the integration between all the separate systems. But now, what the industry demands is a unified platform—one in which people, processes and data are all build in the same environment—not in separate databases and systems. With the shift to decentralized trials and the introduction of new technologies to collect data directly from patients, the number of integrations required to run a trial has increased substantially.

The need for a different environment that can support this has driven the development of a unified platform in which the processes supported by EDC, RTSM, CTSM, and all the other e-clinical systems can be supported together by a single platform. An important distinction is that data is truly shared rather

than being integrated. This unification paves the way for meeting the demands of clinical trials over the coming decade. Oracle Health Sciences' Clinical One is the only truly unified platform available today, delivering on the industry's need to unify people, process, and data in one environment.

Parallelization. While parallelization may feel like a novel concept, in fact it has already been used in several areas of drug development. The general premise is that by having parallel rather than sequential workflows, you can shorten the time required to complete a task or process. While sequential operation has perhaps been the industry norm as a way of managing risk, the global pandemic has made study teams challenge traditional ways of doing things and pushed them to try new approaches. Clear benefits of parallelization are the ability to get product to market sooner and often at lower cost. It is also being used in scenario planning and simulation modelling for moving compounds through drug discovery and in predictive analytics for risk alerts. Parallelization in computing enables access to artificial intelligence and increased computing power for faster processing.

In a parallel, workflow tasks overlap and provide opportunities to complete other tasks at the same time, enabling faster movement to the next step in a process and, ultimately, compressing overall timelines.

SUMMARY

An inclusive approach to clinical trials enables stronger, more strategic partnerships that are aligned to common goals that is built for the long term. Inclusivity enables a strategic approach to data handling, which in turn allows the application of adaptive and predictive analytics for greater insight into the entire process and provides the necessary support for informed decision-making. A unified e-Clinical environment brings together people, process and data in clinical trials, and encourages streamlined workflow and running many things in parallel,accelerating activity and efficiency. Ultimately, this means optimized delivery for faster, better clinical trials and bringing therapies to market faster