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The Virtual R&D Operating Model

How Innovative Outsourcers Are Using Advanced Cloud Technologies to Collaborate with CROs

Faced with increasing trial complexity and tight budget strings, many sponsors choose to partner with clinical research organizations (CROs) to conduct study research and development. However, clinical operations teams know all too well that handing over trial management and execution to a third party is risky, given the many obstacles that can arise during a study.

To minimize the risk of obstacles resulting in non-compliance or timeline delays, sponsors rely on their CROs to keep them informed on trial progress. CROs typically extract data from their clinical trial management system (CTMS) on a weekly basis and use it to report on ongoing studies. However, today's sponsors need data that can be consumed easily and efficiently. With complex operating models (many sponsors outsource to multiple CROs at once, and a number of them conduct some stages of a single trial in-house but other parts in collaboration with a third party), data is collected in multiple systems, resulting in the dispersion of data relevant to a single trial across disparate clinical systems.

The high cost of CTMS integration, as well as the lack of industry-wide data and integration standards for CTMS, have inhibited partners from easily and effectively centralizing operational data despite the importance of information sharing between CRO and sponsor. Without the ability to aggregate data, sponsors are challenged to deduce trends and make data-driven, actionable decisions that keep trial progress on track.

Today's life science companies want to be better outsourcers, and they need solutions that support collaboration and compliance (for less than they were spending five years ago). As sponsors strive to be proactive rather than reactive, R&D leaders across life science organizations are evaluating tools available to support virtual coordination between partners. This paper seeks to explore effective ways for exchanging information between CROs and sponsors.

Clinical R&D Outsourcing Is on the Rise

There's no question that clinical research outsourcing is here to stay. According to a Kalorama Information report, the proportion of clinical trial dollars allocated by sponsors to pay CROs for outsourced research increased by 6.6 percent annually between 2009 and 2011, from $31.8 billion in 2009 to $36.6 billion in 2011.[1] As the proportion of outsourced R&D to in-house R&D increases along the trajectory shown in Figure 1, sponsors demand greater coordination and better methods for collaboration, calling for CROs to adapt their partnership models.

Figure 1: Global R&D expenditures outsourced: 2003-2010 by percent

What Is Driving the Need for Greater Collaboration?

First, sponsors are no longer outsourcing purely transactional activities like site monitoring and data management; they are beginning to outsource more complex activities, such as statistical services, regulatory interactions and headquarter operations. CROs today are carrying out a greater percentage of the total trial than in the past, blurring the line between when a sponsor process starts and a CRO process ends. To further complicate the outsourcing model, sponsors do not outsource everything—they are still conducting some activities in-house, which means data collected on trial operations is dispersed between sponsor and CRO systems.

In many studies, sponsors carry out clinical operation functions before any work is outsourced, as shown in Figure 2. For example, sponsors often start collecting operational data while planning trial milestones during the study design stage, before a CRO is even selected.

Secondly, CROs are finding niche markets focused on specific geographies, therapeutic areas and functional areas in which to offer their services. Sponsors are taking advantage of these targeted services, and as a result are working with an increasing number of CROs (in fact, some sponsors work with more than four CROs at once). However, managing multiple CRO relationships is complex. Sponsors rely heavily on their CROs to provide frequent and proactive information, but they are challenged to keep up with trial progress without the ability to have a single view of all of the data aggregated across all CROs.

Lastly, increased economic pressure means more frequent mergers, acquisitions and licensing deals, which lead to greater funding variability. Thus, sponsors need to be able to quickly scale project resources to match the peaks and troughs of resource availability. The flexibility and leverage required to make quick changes to project resources requires strong ties and partnerships between sponsors and CROs.

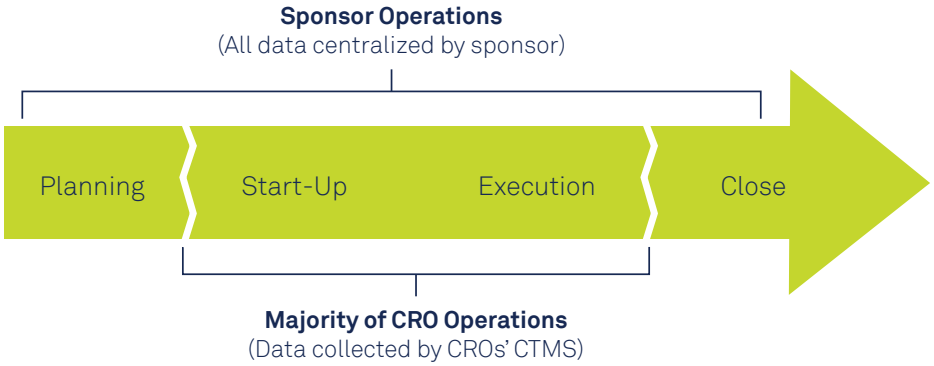


Figure 2: Where data is established at different trial stages

Collaboration Is Paramount in Today's Outsourcing Environment

Sponsors and CROs are in agreement that today's outsourcing environment demands stronger partnerships. The need for more efficient interactions, improved communication tactics and greater transparency has the life science industry challenging the status quo of sponsor-CRO partnerships. R&D leaders across life science organizations are evaluating how to improve collaboration and what innovative technology solutions are available to support them in this effort.

While a sponsor can greatly benefit, for example, from outsourcing regulatory interactions in an unfamiliar region to a geographically niche CRO with strong ties to the regional health authorities, the complexity of managing these interactions and the impact of approvals or denials on future commercialization means that the sponsor needs to put a lot of trust in their CRO partner (or incur the risk and cost if the collaboration is unsuccessful). Similarly, a merger or acquisition can force a sponsor to scale down on the resources committed to one outsourced project and quickly reallocate them to another outsourced project. However, this is a difficult and cumbersome task when working with multiple CROs at one time. Consistent and accurate information, as well as frequent communication about trial progress, allow sponsors to be more agile.

A Relationship Management Strategy Is Critical

Not only is the FDA interested in how sponsors oversee the compliance of their partner organizations, but sponsors also have a vested interest to both track trial progress and communicate effectively with their CROs. Sponsors need to oversee activities to ensure that decisions about trial progress are made at critical time points and that CROs are in compliance with all regulations. CROs, in turn, need a method for proactively identifying issues and sharing concerns with their sponsor at the earliest stage possible in order to meet study milestones.

Partnership is a two-way street; sponsors need to be equally as involved as their CRO throughout the outsourcing process. The more upfront and open the sponsor is about their development plans, portfolio and pipeline, the better they enable their CROs to keep them abreast of issues early on, not just at a time of trouble.

"Sharing individual goals, and then together creating the team's goals, truly make a winning combination," states Sally Osmond, executive vice president and general manager of cardiovascular and endocrinology, and executive vice president of post-approval and strategic services at INC Research. "When embarking on a project, partners need to find commonality and build a shared mission so that everyone knows the milestones and goals ahead." Partners today are driving to achieve greater alignment by co-defining expectations for timelines, deliverables, issue resolution and metrics. Yet, at a time when collaboration is paramount and the virtual sponsor is more common than ever, today's manual processes and disparate clinical systems make interactions between partners increasingly difficult.

"Improved interactions, interfaces and access to data lower the sponsor's risk in an outsourced model. Sharing data also improves trust. Better interfaces to support that, with access to quality data, need to be the life blood of our industry."

– James Sandy,
SVP Development,
Creabilis

Figure 3: Key elements for a sucessful CRO–sponsor partnership

Turning to Advanced Cloud Technology Solutions

To support these efforts, innovative life science companies are using advanced technology to improve information exchange frequency and data transparency within shared cloud-based ecosystems. Clinical operations teams are turning to solutions that break the silos between CRO and sponsor data, while point-to-point system connections—which require a lot of resources, time and budget—are becoming a thing of the past. These organizations are using interoperable solutions that are connected in the cloud—systems that can support proactive data exchange across sponsor and CRO systems—and are developed using agile methods so that they are easy to upgrade (enabling frequent enhancements to meet ever-evolving needs).

Considerations to Improving Information Exchange

Regulations

Although regulatory authorities have conditioned sponsors to oversee the work of their outsourcing partners, the non-explicit nature of this guidance results in sponsors adding project management resources in an attempt to boost oversight. Yet these resources tend to add only unproductive and unconstructive levels of management, and their impact does not correlate with improved compliance. Throwing resources at a problem is not the answer, but unfortunately this practice has become precedence and perpetuates with each new study and partner.

Cost

Despite the benefits of information exchange, the high cost of system integration and maintenance often prohibits sponsors and CROs from allocating budget to integration projects. So rather than embracing technology, they resort to emailing reports and rekeying data into spreadsheets, which can be burdensome and inefficient for time-sensitive information. The task for technology vendors has been to make it easier for sponsors to access and CROs to deliver operational data.

Additionally, the adoption of CTMS—which both establish and aggregate operational data from other systems—has been limited to smaller organizations that cannot afford technology investments. However, with the availability of cloud solutions, the adoption of CTMS is expected to grow, as pay-as-you-go pricing is compelling to smaller organizations because they limit up-front investment without having to compromise on functionality. According to a MarketsandMarkets (M&M) report, the adoption of CTMS in the CRO market between 2010 and 2016 is expected to grow at a CAGR of 16.7% and among sponsors at a CARG of 12.8%.[2] The availability of CTMS data that is structured and standardized can facilitate the exchange of information on trial operations between partners.

Risk

There's a misconception within the life science industry that CROs are apprehensive about sharing data with their sponsors. The truth of the matter is that their concern doesn't stem from exposing the content of the data itself, but rather in the errors that are introduced if the CRO uses manual processes and does not use a CTMS; in this scenario, the CRO will need to scrub the data before sending it to their sponsor. However, what is not commonly noted is the second point at which errors are easily introduced: when the sponsor must reenter the CROs report into their own CTMS. This leaves room for human error during reentry and copy and pasting, not to mention time wasted by duplicating work that the CRO already completed. The use of data transfer standards with self-describing structures, such as XML imports, changes the game. This allows for data to be retrieved by the sponsor directly from their own systems.

"Although sharing data is a valuable first step, what truly supports decision making is the ability to interpret what the data means. Having standardized, aggregated data allows you to do that. CROs can add great value to the clinical operations process by using information contained within a centralized CTMS view to deduce trends and find alerts in order to promote discussion."

– Sally Osmond,
EVP and GM, Cardiovascular and Endocrinology, and EVP, Post-Approval and Strategic Services, INC Research

Today's Data Exchange Methods Are Costing Both Sponsors and CROs

Manual methods of information exchange make sharing data a lot more costly and time-consuming than one might think. For the CRO, it is an administrative burden to produce and email reports. And, without a standard reporting format, sponsors that outsource to multiple CROs must comb through every piece of information shared by their CRO to determine what's important and eliminate what is not.

Alternatively, some CROs give sponsors direct login access to their CTMS. Although these proprietary systems ensure that information is accessible on a regular basis, it can be tedious for sponsors with multiple partners to check and keep track of data in different systems. And, if CROs do not readily have access to dedicated engineering resources, they may not have the capability to consistently upgrade systems to meet customers' evolving needs. There is a reverse scenario that can also occur when the sponsor requests that the CRO uses their CTMS, thus freeing them from bothering with the CRO's system or with CRO reports. The question then becomes: is the efficiency gained by outsourcing to a CRO with their own CTMS the same as the efficiency gained if they use the sponsors' CTMS that is unfamiliar to them? Arguably, the answer is no; a sponsor hires a CRO to improve efficiency, but if the sponsor takes away the tool that makes them most efficient, they are losing the value gained by outsourcing.

Additionally, CROs incur a significant cost to produce data reports for their sponsor—nearly $40,000 per study—which increases as the frequency of the requests for reports increases. Sponsors also outlay nearly $10,000 in full-time employee (FTE) expenses to reenter data into their spreadsheets or CTMS and keep it up-to-date during each study. Industry leaders have cited that sponsors spend 20–25 percent of their time duplicating the work that their CRO has already done. This is not only an inefficient use of a sponsor's time and resources, but reentering or copying and pasting data can also introduce errors.

Interpreting Data Should Be Straightforward

Sponsors rely on CRO data to keep outsourced operations on track, make critical decisions, answer internal queries about trial progress, track milestones and report to executives. However, interpreting this data is not as straightforward as it should be. Data is only as valuable as its utility ("utility" is defined here as the ability to use data to deduce trends, gain insights and make data-driven decisions). To a sponsor's clinical operations team, the utility of CRO data is a factor of the frequency with which it is shared and the ease with which it can be consumed and interpreted.

Using Standards to Operationalize CTMS Data Exchange

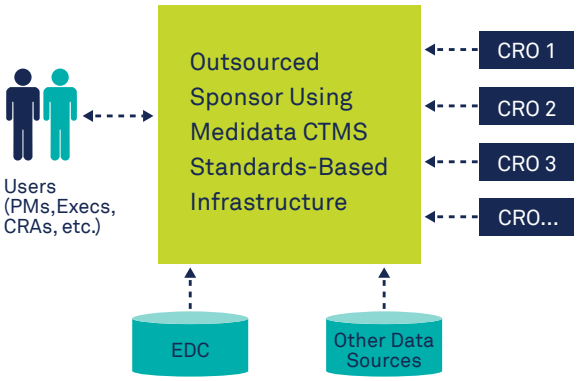
It has not been easy for sponsors to aggregate in-house and CRO-established data in a way that is centralized within a single CTMS. Integrations are like a handshake between two systems that require technical and subject matter expertise on both sides. Both partners need to fully understand their systems in order to come together and determine how to connect the data.

However, Medidata's approach to CTMS is to create an open system that can accept clinical data from any source using standards-based infrastructure. Sponsors using Medidata CTMS™ can bring in data from any number of external CROs' CTMS, regardless of the brand or vendor. The seamless flow of data between the CRO's CTMS and the sponsor's Medidata CTMS removes redundant steps across site management workflows and feeds the robust built-in reporting tool, providing high visibility into trial progress.

Medidata's connection is built so that the clinical operations team has enhanced visibility into mappings. In fact, the clinical operations user can easily map data through the user interface—there is no need to rely on IT teams to set up mappings. Putting the clinical operations team in control of the mappings reduces the complexity of ongoing management, reduces the reliance on IT and saves more than 50 percent of the professional service costs typically incurred. (Medidata also supports multiple import and export formats to support different client needs.)

By centralizing operational data established by the sponsor and aggregating it with operational data established by their CRO(s), both parties have greater visibility into trial progress. While this provides the sponsor more control over their outsourced studies, it also allows their CRO partners to reduce some of their own administrative burdens and saves time for more value-add activities. Additionally, it is quick and simple for the sponsor to add subsequent studies with their CRO once the standards-based infrastructure is set up, making the partnership strongly integrated.

Figure 4: An outsourcing ecosystem built with standards based CTMS infrastructure



Sponsor's CTMS is open to accept and centralize data from any CRO system:

- With configurations that are built for the end-user, the clinical operations team can control the connection.
- Using standards reduces professional service costs by more than 50 percent.
- It's quick and easy to add additional studies, so partnerships are strongly integrated.

Innovative Outsourcers Are Capitalizing on Standards-Based CTMS Infrastructure

When sponsors do not have proactive information from their CRO partners, critical information about trial operations can be overlooked. And every day that important data is overlooked it adds time and costs to trial completion by lengthening the road to commercialization. As sponsors continue to outsource more and conduct fewer clinical operations in-house, they have an even greater need to aggregate data created and collected in disparate systems.

As clinical outsourcing models grow in complexity, the high cost of point-to-point system integrations is too costly to sustain. The virtual sponsor, commonly seen today, needs solutions that make them more effective outsourcers—solutions that support collaboration without added cost. Innovative leaders in R&D operations are capitalizing on standards-based CTMS infrastructure—building their own network of interoperable systems that facilitates information exchange between their CROs' CTMS and their own CTMS, allowing them to centralize CRO data and increase trial visibility.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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