Industry Joins Forces to Improve Collaboration Between Sponsors and CROs

As the complexity, size, length, and globalisation of clinical trials have steadily increased, so too have trial costs. A recent study estimated the average cost of bringing a drug to market at around $2.6 billion.[1] And with pressure mounting to reduce these costs – while accelerating time to market, expanding pipelines, improving drug quality and safety, and meeting ever-more-stringent expectations – sponsors are increasingly relying on contract research organisations (CROs).

With highly concentrated expertise in the latest technologies, clinical design, geographical areas, therapeutic areas, and regulations, CROs have emerged as effective providers of an increasing array of services – and key to achieving greater efficiencies. As a result, more sponsors are outsourcing various aspects of their clinical development processes, with a recent report predicting clinical outsourcing to increase to 50% by 2020.[2]

Clinical outsourcing is nothing new. It has played an increasingly important role in supporting drug development since the late 1970s, growing from a few small players providing niche services to biopharmaceutical companies, to a highly competitive global market predicted to be worth $51.3 billion by 2024.[2] Today, the CRO market constitutes an estimated several hundred small and medium-sized limited-service providers, plus a small number of large, full-service global CROs with capabilities spanning drug discovery to regulatory filings.

As the CRO market continues to evolve, one of the driving forces is the need to handle the growing amount of data generated by clinical trials. A typical Phase III protocol, for example, now has many more endpoints, procedures, and data points collected compared to a decade ago.[1] At the same time, data management processes have become more complicated, as CROs and sponsors manage a variety of clinical trial data, including real-world evidence, electronic clinical outcome assessments, mobile device-driven data, social media communities, and electronic health and medical records.

In a recent survey of 50 pharmaceutical and biotech companies, around three-quarters of respondents say access to global data will be increasingly important in their choices of CROs over the next three to five years.[4] As a result, streamlining how data is shared between CROs and sponsors is fast becoming the new imperative. But with many different systems, applications, and data structures used across the sponsor-CRO landscape, that remains a challenge.

Improving Collaboration through Common Standards

Now the industry is coming together to tackle that challenge. In March, six leading CROs formed Align Clinical CRO, a new industry-standards group dedicated to making it easier for sponsors and CROs to work together during clinical trials. Founding members, with input across the industry, plan to help create open technology standards that will improve trial execution, increase sponsor and CRO productivity, reduce operational costs, and run faster trials.

"One of the biggest challenges is that there are different processes and systems across sponsors and CRO partners, making collaboration and real-time decision-making difficult," explains Henry Levy, president of Align Clinical CRO and chief strategy officer for Veeva Systems. "This will only get more challenging as the ecosystem of stakeholders continues to expand and outsourcing remains a core part of trial strategies. Standards organisations like Align Clinical CRO will make it easier for the industry to adopt common operational processes and technologies."

A Market Vocabulary for Data

The group's first standard will be Operational Data Exchange to facilitate seamless information sharing between sponsors and CROs. It is expected to include the definition of a technical standard for data to be exchanged between a sponsor and a CRO relating to the operational execution of a trial. This will include key metrics and milestone information.

Data exchange is one of the biggest challenges impacting working relationships between CROs and sponsors. "Today there are many different data formats and structures that manufacturers and their partners develop and share," says Brett Husselton, senior VP of commercial strategy at UBC, one of the founding members of Align Clinical CRO. "In order to make this data usable, it often requires extensive time and effort from IT teams, business analysts, operations teams, and other quality teams involved in testing/release management. In addition, sponsors must take time to load and integrate that operational data about their studies into their internal systems and databases."

By establishing a common framework for this data that defines its attributes, operational value, and other variables that can travel with that data and need to be understood across platforms, Align Clinical CRO will create a market vocabulary that can be used across the industry. It will help to reduce the amount of time and resources wasted on non-strategic activities, and contribute to faster, more efficient drug development processes.

"CROs and sponsors are investing heavily in new capabilities to better integrate and analyse the ever-increasing volume of data that plays a role within and around the execution of clinical trials," notes Levy. "Align Clinical CRO is focused on pre-competitive areas where efficiencies can be driven, and therefore, a focus on the operational data exchange, which is a subset of overall data, is a strong fit for our first collaboration across CROs."

A Shared Commitment to Faster Trials

Align Clinical CRO represents a shared commitment between sponsors and CROs to overcome common challenges and delays in clinical trials and make drug development more efficient and productive.

The sponsor-CRO partnership model has been successful in accelerating innovation, with the number of trials continuing to rise. However, the time required to bring new medicines to market remains long and the effort to develop them has

become increasingly complex, especially as more partners are added to the mix. Founding members of Align Clinical CRO believe that open technology standards will help to remove some of the common roadblocks and speed overall timelines.

"By creating a vehicle for CROs to collaborate and share actionable insight with sponsors, we can improve operational delivery and streamline the increasingly complex trial process for everyone involved," says Rachel Stahler, chief information officer at Syneos Health, a founding member of Align Clinical CRO.

Open technology standards will also help to strengthen the sponsor-CRO partnership model, as Levy explains: "The goal of Align Clinical CRO is not to disrupt traditional outsourcing, but to help improve the way CROs and sponsors work together. Outsourcing will continue to rise as a way for sponsors to augment their available resources and leverage the best trial practices from CROs to complete activities faster, with greater efficiency and more predictable fixed-price costs. Align Clinical CRO brings leading CROs together in a pre-commercial environment to create common standards that benefit the entire industry."

There is tremendous potential to enhance clinical trial execution with common technology standards. The assembly of Align Clinical CRO represents an important industry collaboration to improve not only the trial process, but also how the industry works together to accelerate drug development.

Align Clinical CRO will post its Operational Data Exchange standard for public review and input later this year, which will also be reviewed and considered as part of the adoption of proposed standards.

REFERENCES

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