Breaking New Ground: How Industry Collaboration is Transforming Clinical Trials

An increasingly complex clinical trial landscape is driving the life sciences industry to support broad collaborations to define and implement common approaches that make running a trial easier. These collaborations are becoming a strategic priority for many companies hoping to create greater efficiencies in the race to deliver innovative therapies, drugs, and medicines to market faster.

TransCelerate BioPharma, Inc., a non-profit organisation whose members consist of some of the world's most successful biopharmaceutical companies, has played a significant role in bringing the industry together to accelerate research and development efforts.

The importance of such industry collaborations is increasing as the complexity of clinical trials rises dramatically. The industry is working together to collectively define approaches that could create greater efficiencies in trial processes, especially as sponsors increasingly outsource their research and development work to CROs. With more stakeholders in the mix, as well as different processes and systems used across the clinical trial ecosystem, the ability to share information and make timely decisions has become burdensome. For example, study teams regularly use manual processes to manage documents and data – often sharing information via email – which limits collaboration, creates redundant work, and significantly lengthens trial timelines.

To address some of these challenges, TransCelerate introduced the Shared Investigator Platform (SIP) initiative, with the aim of providing the industry with a centralised platform focused on collaborating with investigational sites that is interoperable with various clinical solutions. The SIP's goal is to streamline communications between investigators and sponsors and reduce duplicate information requests during trials.

As part of this effort, TransCelerate recently announced it will integrate a cloud-based content management solution, Veeva Vault SiteExchange, with the SIP to enable clinical teams to easily access and exchange information with sites before, during, and after trial execution. The cloud application will help sites consolidate study-document requests, alerts, and notifications in the TransCelerate-sponsored SIP, allowing sites to spend less time on tedious administrative tasks and focus more on clinical research.

Centralising information-sharing and establishing an easy, consistent process for document access and information exchange, sites, and sponsors has the potential to dramatically reduce administrative burden in trials and increase operational efficiency. In addition, companies gain visibility across all of their studies, and investigator sites can have a consolidated view across multiple trials with multiple sponsors. This level of visibility hasn't been possible before within SIP.

A centralised model of information exchange, such as the TransCelerate SIP, is a good example of how the life sciences industry is transforming the clinical model in four key areas:

1. Creating a universal and flexible operating model
2. Enabling a collaborative clinical ecosystem
3. Gaining better insight from metrics and measurement
4. Shifting to modern, unified systems

Standardising on a Common Operating Model

Creating a common framework that standardises trial processes, while still enabling flexibility to support individual study needs, will help to eliminate the rework that takes place with each new trial and reduce the time to full study optimisation.

To date, rigid information systems have exacerbated the challenges in embracing a common model because they limit the flexibility of a business process and force people to find workarounds to complete their tasks at hand. For example, today's trials require more data collection and protocol amendments, and include novel therapeutic areas and multiple partnerships. Clinical study teams often must adjust to mid-study changes, and if the systems they work within are not flexible enough to easily accommodate change of any sort, people revert to managing activities and tasks outside the system, creating manual processes and information silos, and ultimately extending the duration of a trial.

A common industry process for exchanging documents and information can drive significant operational improvements in running trials and ultimately speed time to market. With sponsors, partners, investigators, and others working on one centralised platform, the need to seek non-standard workarounds is greatly reduced. Investigator sites no longer need to log in and out of multiple systems to share important information with sponsors. And sponsors gain a complete view across all their studies, and can post and retrieve documents quickly and easily.

Improving Collaborative Processes

Operational and information silos between functional areas, as well as sponsors and partners, have historically made collaboration difficult. As clinical trials expanded in scope and complexity, sponsors built dedicated teams internally, with specialised functions to handle specific parts of trials. Over time, these functions developed their own organisational structures, processes, and systems. Teams drove toward efficiency in their areas of specialisation, with limited visibility into end-to-end trial processes and inability to conduct effective handoffs between groups.

Similar challenges exist between sponsors and partners. Each commonly has its own processes and systems in place, which makes information harder to share and difficult to access. Functional and operational silos have created barriers to effective trial collaboration.

Creating a more collaborative ecosystem requires a cultural shift. Companies must be willing to move away from specialised and siloed processes to ones that fit into a common framework across all trial activities.

The growing call for information to be shared across both company and geographic lines is driving the need to collaborate and contribute information that can be easily accessed and disseminated. In TransCelerate's example of site-document exchange, investigator sites have a channel to exchange information across multiple sponsors and trials, instead of working in one way with one sponsor and another way with another. Sites can simply log in once and find out exactly what tasks are outstanding and what tasks need attention, across multiple trials. Communication is streamlined and the administrative burden is greatly reduced.

Linking all stakeholders together on a common platform provides greater visibility across the end-to-end trial process. Enabling real-time access to information, and the ability to transfer knowledge more easily, engenders trust that all parties are working towards the same goals and outcomes – which, in turn, fosters greater collaboration.

Enabling Better Metrics and Measurement

Visibility into how trials are performing relative to other studies is another common challenge among investigators, sponsors, and CROs. Lack of comparable data makes it tough to judge what is working or how to improve trial performance.

Increasingly, sponsors and CROs want to have single, consolidated views of their clinical trials across their portfolios, regardless of which specialised providers have participated in contributing data or documents to trials. But inconsistent metrics and varying means of measurement often make it impossible to harmonise the data to gain the insight they need.

Investigators typically deal with multiple sponsors and requests for documentation and information that they manually track. When the collection of documents and the data around these documents is easier to manage and track, sponsors can better understand the progression of their trials and where delays may be occurring. Sponsors can also benchmark their trials as they relate to the timeliness and quality of how sites are executing.

Setting common operational metrics and measurements is an important aspect of a more unified, collaborative clinical landscape. With a standard set of metrics and measures, the ability to extract quality insight and identify trends across the industry is greatly improved. For example, a clinical team can determine whether a problem is isolated to one study, one site, one therapeutic area, or another common denominator. This type of information then becomes a strategic asset to perform predictive analysis across multiple sites and studies, using real-world evidence and historical operational metrics to better inform trials moving forward.

Modernising and Unifying Information Systems

Limitations in available technology created the silos that companies are now trying to eliminate. Systems were implemented to support specific functional activities, not end-to-end trial processes. As a result, most clinical teams work in many different systems, and often without the benefit of direct collaboration between teams, either internally or externally. The systems also have very different purposes. While one system may manage content, another manages the data being produced. Therefore, content and data are collected and managed from multiple sources, even though the information is all associated with the same study.

Now life sciences companies are bringing together previously disparate systems in the cloud to support the end-to-end trial process. Open APIs, standards, and emerging native cloud solutions allow companies to better support a unified clinical environment and sustain collaboration among internal and external partners. In addition, next-generation cloud applications can manage both content and data to eliminate information and process silos. Clinical information systems that are inherently integrated by leveraging a single platform will be essential in propelling the industry toward a unified clinical environment.

Groups such as TransCelerate BioPharma Inc. are also establishing approaches to facilitate better engagement and collaboration between sponsors and their partners by using technology platforms. Now clinical and other functional groups can access much of the same information and data throughout the drug development lifecycle with cloud technologies and sharing tools, helping to foster more collaborative working processes. The flexibility and collaborative nature of next-generation clinical systems creates an environment where people are enabled to work within their processes, as well as ensure information can be traced and viewed across the trial.

Industry Collaboration and the Patient Effect

Cultural barriers, organisational structures, and functional and operational siloes still exist across life sciences – but the boundaries for collaboration between companies and their partners are expanding. Collaborations are building greater understanding among clinical trial stakeholders and the industry is focused on finding new ways of working together for the benefit of the patient.

With a common framework supported by technologies designed to enable greater sharing and information exchange, collaboration among sponsors, CROs, IRBs, investigator sites, and others in the trial process becomes easier.

Cloud technology is helping to drive the transition from traditional operating models to more efficient, agile, and collaborative processes – empowering life sciences to innovate faster and accelerate new drugs, targeted therapies, and speciality medicines to market. For the industry – and for patients – that's a breakthrough.

Jennifer Goldsmith

Senior Vice President of Veeva Vault Strategy. She leads the Vault initiative for Veeva Systems, overseeing the product vision, implementation, and marketing. She has honed her skills for regulated content management over the last 15 years by working with clients such as Johnson and Johnson, Pfizer, Shire, BMS and Roche, and has created strategies and solutions in business areas across the life sciences value chain, including research and development, regulatory submissions, manufacturing and promotional materials. Following the launch of Veeva Vault in 2011, PharmaVOICE named Goldsmith one of the top 100 most inspirational leaders in life sciences and, in 2015, was invited to serve on the editorial advisory board of RAPS Regulatory Focus.