Simplify to Accelerate: Perspectives on Moving Toward a More Collaborative Clinical Trial Ecosystem

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Introduction

There is a significant opportunity for the life sciences industry to bring together trial stakeholders, simplify information exchange, and improve collaboration across all study partners. This paper presents perspectives from three parties—a sponsor, a site, and a technologist—to understand how they currently perceive the issue and the steps they are taking to make clinical trials more efficient, streamlined, and collaborative.

A Sponsor's Perspective

A global Top 50 pharma company has taken has taken great strides in operationalizing virtual, decentralized trial models to drive better outcomes in collaboration, patient engagement, and trial quality.

They describe three guiding principles to consider when creating trial designs that work best for all trial stakeholders.

Design for Choice

"We feel very passionate about [designing for choice] and putting that power in the hands of the participants and the investigators. To do that, it is going to hinge on our usage of technologies that sponsors (like ourselves) have been lagging in adopting and perfecting."

– Director of technology & operations

The first step is to provide options for how sites want to engage with sponsors, rather than dictating that all meetings are virtual or in person. Depending on the time, need, and circumstance, sites should be able to choose the method that works best for them. This means that the sponsor organization needs to be flexible to accommodate either option, which may require a change to the sponsor's traditional expectations.

The company uses several tools to help minimize the need for personal interaction with patients, such as ePRO, eConsent, telemedicine solutions, and wearable devices that can track patient activities and status. However, they caution, "When you think about those technologies, consider what types of challenges they may introduce into the clinical trial infrastructure. Is it something that's going to create more burden for our sites and patients, or will those technologies create added value?" If a solution requires too much back-end support to get off the ground, the investment may not be worth it. Organizations should make sure they understand the cost vs. benefit of new technologies, especially around patient interactions.

Simplify to Accelerate

"This is the concept of addition by subtraction—make things easier or do more work in one place versus spreading the work across three to four different systems—essentially, how to do more with less."

The company focuses specifically on the concept of "a single point of data capture," that is, enabling the data to be captured once and then propagated seamlessly to all of the stakeholders without having to repeat data entry at different stages of the study.

This could be achieved through potential integrations to internal or external systems to partners. It may mean identifying mundane tasks that can be reduced or eliminated through automation or technology. "You shouldn't be working for your data. Your data should be working for you." The director goes on to say,

"There's a great opportunity when you look at how much data redundancy there is out there and how many high-volume, low-value interactions are happening, be it with the sponsor, the site, or the patient. You can [find ways to] free up their time, be more productive, and have higher value interactions together."

You shouldn't be working for your data. Your data should be working for you

Find Your Waste

"Everyone's running a million miles an hour and trying to put their best effort into the trials. If you don't hit the pause button and take a step back to think about the way that you're doing the work, you may not be able to improve your operations in the way that you intend to."

While there is some overlap in this concept with the prior one, "It's [about] having the perspective of the site and developing an approach that has a shared purpose - to improve collaboration. How can you make changes that make life easier for you and the site, so that everyone gets what they need, things work faster, and you stay compliant at the same time?"

For instance, physical documents, like safety letters, need to be distributed to sites consistently and tracked by sponsors. Portals may work for a singular trial, but they provide little direct benefit to sites around their trial operations. If a site is running several studies for various sponsors, imposing a proprietary portal may simply push the burden of tracking and collating data from the sponsor onto the site.

Instead, think about if there places where the sponsor and site can merge technologies. Are there overlaps that can be eliminated? What opportunities present themselves? If sites are juggling multiple systems for multiple sponsors, where can solutions be implemented to streamline from the site's perspective and the sponsor's?

A Clinical Research Site's Perspective

With Rachel Sheppard, clinical regulatory director at the University of Louisville

Sheppard observes an increase in sponsors pushing for operational efficiency around data flow from site to sponsor, especially after the pandemic started. Thankfully, she has found that sponsors are collaborating with sites on this and that her site is getting a voice in achieving that goal successfully. An essential aspect of this is helping sponsors recognize that it's not just about the sponsors' needs but also that sites want technology to fit their needs.

Understanding the Needs of Clinical Research Sites

> *"One of my coordinators manages about ten active clinical trials with different sponsors. Each of these trials utilizes about four different technologies. If you think about [a different] EDC, IVRS, image uploading, etc. and you multiply that for ten trials … that becomes a huge burden on her to learn all those different systems and to track which system goes with which project."*
>
> **– Rachel Sheppard**

Juggling multiple projects that utilize different systems is perhaps one of her department's most significant operational challenges. However, as a state-run university, several purchasing hurdles must be addressed when assessing new systems. Cost, IT security around student data, and state and federal regulations all play into what solutions her department can even consider, making it even more challenging to leverage systems that benefit her team.

A key strategy they have embraced is digitizing paper documents into digital files. Doing so allows them much more flexibility in collaborating with sponsors and eliminates a lot of manual effort. One of the main goals of any new technology purchase is to not buy a system to just meet a sponsor's requirements, but that can also address some operational challenges they face on site.

Understanding the Needs of Trial Patients

> *"Many of our participants have limited resources and don't have a smartphone or a computer at home. Even if they do, their ability to use the technology may be very limited. Some of these solutions, while they seem elegant, may be very inaccessible to someone who's not used to utilizing technology."*
>
> **– Rachel Sheppard**

Finding a way to monitor patients when the shutdown began was of critical concern. "We didn't have fully capable remote monitoring. We had the investigative site file available, but we still didn't have a good efficient way for sponsors to be able to review our source documents for our participants," Sheppard confesses.

Sheppard cautions that while solutions like e-consent and telehealth are available, they may not solve all of the hurdles with patient care and follow up. In addition to the potential lack of access to tools like smartphones, computers, or the internet, there's also the challenge of accessibility. "We have participants who have visual issues or hearing issues. All of those issues have to be addressed with any technology that we roll out. This means more selectivity in our adoption of technology and a slightly slower process. This is a truth that we need to hold on to, that we have to make trials more accessible to our participants and more convenient to our participants."

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A Technologist's Perspective

With Jason Methia, vice president of Veeva Site Connect and Vault eTMF at Veeva Systems

Methia's approach to the collaboration issues during clinical trials is to provide solutions that benefit all three of the primary constituents: sponsors, sites, and patients. He's seen large strides on the sponsor side, with eTMF, CTMS, and eReg solutions gaining momentum. His next area of focus is developing solutions for site efficiency and engagement and looking towards potential solutions for better patient experiences.

Methia discusses how solutions for collaboration in the life sciences industry have lagged across the industry as a whole. "How sponsors and research sites interact is very outdated. It's manual, and it's very paper-oriented. There's a lot of administrative burdens that come out of this disjointed way in which we communicate. And so this process quite simply needs to improve."

Methia defines manual effort as downloading, attaching, sending, receiving information in one system, processing that information, putting it into another system, etc. This series of steps done repeatedly can bog down the process and presents its own challenges. Information in transit is difficult to report on, and there are quality concerns due to so many potential points of failure. This can result in missing or misfiled documents, which can impact inspection-readiness, compliance, and result in downstream work before regulatory submission and regulatory approval.

Site Engagement is Key to Successful Collaboration

"Today, the traditional mode of supporting sites is for sponsors to push technology down to clinical research sites for a particular project or a study. But often, these portals do little to support site operations."

– Jason Methia

While current solutions, such as investigator portals, are intended to facilitate site engagement, a big problem with sponsor-mandated technologies is that they are typically focused on the sponsor's benefit and do not provide any meaningful impact on site operations. Standalone portals don't eliminate the manual effort required to transition information from site ISF solutions to those portals. And when these portals are used for multiple studies, the burden on a site multiplies.

Technology has advanced to the point where sites should be able to leverage an eISF solution that helps them comply with regulatory requirements and digitally transfer documents and data to sponsors securely. Having separate solutions for each of these steps is unreasonable and unsustainable in the long term. Consolidating these capabilities should help sites become more efficient by reducing the amount of high-volume, low-value manual workaround document and information exchange.

When sponsors invest in solutions that help sites succeed, it can provide lasting value for sponsors as well:

1. Reduced manual effort in document sharing and tracking
2. Stronger oversight of site progress and results
3. Simplified consolidation of data at the end of the study
4. Overall higher engagement with contracted clinical research sites

The Patient Experience

"What if patients could actually find studies more easily? What if once they found those studies they weren't forced into one mode of participating in a clinical trial? What if a study coordinator could spend more time with patients and improve what the patient experience looks like?"

– Jason Methia

The patient experience is the third, and in some ways, the most important part of any successful clinical trial. While accessibility to technology is a problem that technology itself cannot fix, there are still many opportunities to simplify and improve the hurdles that patients who are part of clinical trials face today.

With COVID-19, the need for and ability to establish virtual engagements with patients has grown quickly. But solutions for specific tasks are still disjointed; data capture solutions (eSource), patient-reported outcomes (ePRO), and consent protocols (eConsent) all work to track data digitally but require separate training for each system, and all that data must be collated to get an understanding of a patient's status.

While each of these capabilities is fairly straightforward, there is no reason why they cannot work together and serve the needs of sites and patients holistically.

A unified patient system can improve the experience for the patients themselves. Rather than having to deal with multiple documents, systems, or emails, patients should be able to have a single access point where they can see everything they need to know about the next steps. This will significantly reduce the patient burden by putting everything they need to know and do in one place and help consolidate patient data in a comprehensive view for further study.

Conclusion

The clinical trial operating model is rapidly changing as the industry reimagines how trials are conducted. Sponsors, CROs, and sites are looking for simpler ways to share information and make it easier for patients to participate in trials, from enrollment through treatment.

Technology has matured to the point where it can enable a more collaborative clinical trial environment by seamlessly connecting trial partners, systems, and processes throughout study execution.

Looking ahead, the modern trial of the future will reduce the patient burden, speed drug development, and improve how stakeholders work together during clinical trials.

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