Let's Bring Visibility and Real-Time Collaboration to Clinical Trials

By Venkat Sethuraman, Aaron Mitchell and Bazgha Qutab

It's no industry secret that clinical trials are inefficient. In his parting message, outgoing FDA Commissioner Scott Gottlieb said, "Efforts to streamline medical product development based on advancing science can be frustrated by legacy business models that discourage collaboration and data-sharing, and the adoption of disruptive technologies that make clinical research more effective." He went on explain that unless we can make clinical trials more efficient, we won't be able to support the rapid trial process needed for personalized therapies. But clinical trial inefficiency isn't just a threat to personalized medicine. The longer a trial takes, the longer patients have to wait for life-saving treatment—and many don't have time to lose.

What's causing these delays? In many cases, they can be traced back to poor decisions that were made during trial design. What's frustrating is that these decisions are typically made by some of the most experienced people in the company who are highly committed to their work. The problem isn't the decision-makers but the ecosystem that they're operating in. Many are hampered from the very start with a lack of data visibility and insufficient cross-team collaboration. While pharma companies have access to large amounts of clinical trial data, leveraging that data often requires major investments in big data infrastructure and hiring people with specialized skill sets. Furthermore, even companies that can leverage this data often do so in silos: The scientific protocol review committee gathers data for the scientific aspects of protocol design. An operations review committee looks at operational data, such as clinical trial enrollment and site selection. The budget and finance committee looks at trial budget data. It's impossible for teams to collaborate effectively if they're each looking at only one piece of a larger data puzzle. And it's difficult to gain a clear portfolio view of multiple clinical trials and how they're performing, which makes it difficult to manage clinical trials at a program level.

While pharma companies have been working to improve clinical trials for years, progress has been slow. However, we believe that clinical trials can become dramatically more efficient by changing the organizational mindset, pulling trial data together and leveraging technology to increase collaboration between teams.

Setting the Stage for Clinical Trial Efficiency

While improving organization-wide data visibility and enabling collaboration might seem like a daunting undertaking for pharma companies, these changes will have a broad impact. Teams will be better equipped to make data-driven decisions on clinical trial design and operations, and gain more clarity into clinical trials' likely challenges and outcomes. As a result, companies will dramatically improve their trial efficiency and accelerate their clinical programs—ultimately improving access to patients in need of better therapies, faster.

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Here's what pharma companies should do in order to set the stage for more efficient clinical trials:

1. **Shift the organizational mindset.** Leadership must be on board to guide the organization to break down silos and become more data-driven. These are change management challenges that require ongoing attention. Across scientific teams, there's a pervasive mindset that their focus is the science alone and operations teams can worry about the human element. Meanwhile, the operations side can feel that the scientists are out of touch with on-the-ground realities and make unrealistic requests. This cultural gap contributes to a practical gap between the two teams, which must be bridged by bringing them together in collaborative forums with an integrated agenda.

   Second, leadership must enable the organization to effectively leverage data in its decision-making. Decisions based on instinct and past experiences should be discouraged. Assertions like "I think the patient influence is going to be 10%" or "I don't think we'll find patients in this country" need to be backed up by data or challenged. Get your teams comfortable with analytics and the technology they need to make data-driven decisions. Hire a data science or analytics ambassador who can help teams navigate the overwhelming amount of data they'll need to draw insights from. It can also help to encourage the creation of reusable reporting templates to make it easier for teams to report KPIs in a consistent way.

2. **Invest in a clinical and real-world data foundation.** Make the necessary investments in your infrastructure to combine all internal data and external data sources. Give stakeholders visibility into the same data, united under a single platform, so that any team member can monitor the landscape and clinical trial progress in real time, and any team can leverage the massive real-world data and clinical trial data sets that have been so difficult to leverage in the past due to their size. For instance, you can use historical clinical data to understand disease progression along with real-world data to extrapolate and better predict how your trial design will perform. You can make necessary tweaks in your protocol design by leveraging these disparate data sources. It can also help clinical design and operations teams

respond quickly to changes in the competitive landscape. Furthermore, teams can leverage advanced analytics and AI to predict the potential impact of their design decisions on the operations team before they make them.

3. **Find innovative ways to bring teams together.** The whole clinical trial journey must be visible to all teams, from the portfolio level to the individual study design level. Some teams have taken an "event approach" to trial design, where the core team members get away from the office and work together on key design decisions. We have even seen a rise in facilitators that specialize in leading these collaborative meetings, with a standardized approach to preparing, running and documenting the outcomes of these meetings. Such events are useful but high-effort. One of the more successful solutions we've seen is an advisory board model that brings all clinical trial organizations together. Pharma companies can't bring all stakeholders to a single meeting, so in these models, those who design the trials and those who execute them are separated, but an advisory board sits between them organizationally and ensures that information flows between the two groups. Without technology, this type of collaboration can be somewhat slow, but it results in fewer costly mistakes.

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While not practical in real life, imagine how useful a NASA-like command center would be to bring stakeholders together for real-time collaboration. What's missing in the advisory board model is a collaborative space for all teams to work together, with ways to monitor real-time information and the ability for all teams to respond immediately to unexpected developments, just as they would in a NASA command center that's filled with monitors and cross-functional support at the ready.

This kind of collaboration is possible with the aid of technology that enables a sophisticated connection between design and operations. Each team needs different insights, so a series of tailored applications specific to each team's needs—and that leverages the same data—would be useful. From these interfaces, each stakeholder should be able to understand what a decision will cost, how trials are projected to succeed in the real world and what pain points to anticipate. When one team makes a change that impacts another, imagine an intelligent alert that could notify them so that they're forced to stop and collaborate with other teams at the time that the decision is made, not after the consequences have been felt. For example, if the budget team reaches out to operations with a request to find sites that are less costly, ordinarily the operations team would look for these new sites without consulting the design team. This simple decision might lead to a trial failure if the trial results show that a drug is less effective than anticipated. However, the real problem could be that the patient population in the new location was healthier than expected due to its advanced medical care. With technology-enabled real-time collaboration, an alert could notify the design team of the site change and they would have an opportunity to prevent a trial failure by selecting sites with more appropriate patient populations.

These capabilities are made possible by today's technology, AI and data science techniques. If design and operations teams collaborate in real time with the help of a solution that allows them to collaborate virtually, both design and operations teams could design protocols together. Both teams

would have the opportunity to identify and address concerns they foresee during the design phase. They could examine data from similar trials to determine whether the proposed protocol would reduce patient burden and, when they see that it won't, they can work together to optimize protocols to be more patient-centric.

It's important to remember that expertise in all areas of clinical trial design should be represented in such a solution so that it doesn't become operations- or design-centric. Otherwise, the entire premise of bringing teams together is missed and the solution will fail because it will function as though it was designed for one team and not all teams.

The Way Forward

Ultimately, pharma companies need to undergo a radical transformation to improve how they leverage data and insights during clinical trial design. However, this transformation won't take place overnight. Rather, the way forward is by initiating a series of small changes over time, ensuring that change management is easier on all stakeholders and that pharma companies feel a measurable impact more quickly.

While changing the organizational mindset, driving a data-driven culture and encouraging the adoption of new methods of collaboration won't be easy, the patient benefits and economic drivers are too great not to try.

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