Are We Ready for a Unified Clinical Platform?

A unified clinical platform that supports the end-to-end clinical development process can increase trial quality, promote efficient decision-making, reduce time to market, and meet a greater number of clinical needs for patients.

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INTRODUCTION

The clinical development technology platform market, including related services, is expected to reach more than $15 billion by 2026. The interest in this market is driven by pharmaceutical companies that are looking to address challenges in the orchestration of the many complex activities that are a part of the clinical development process. Clinical development and IT leaders currently rely on a mix of technology platforms offered by various software providers to manage this complexity, but the gaps between these systems lead to data latency, process fragmentation, added costs, and administrative delays. In response, the life sciences industry may be ready to tackle one of its most important questions: Are market forces finally aligned to deliver a unified clinical platform (UCP) to support the end-to-end clinical development process?

To gain perspective, it is important to discuss the process and technology building blocks needed to build an end-to-end clinical development solution, the requirements for a viable UCP, and the benefits and challenges that would accrue post-adoption.

THE CURRENT STATE OF TECHNOLOGY DEPLOYMENT IN CLINICAL RESEARCH

The current technology deployment model is a complex system in which layer upon layer of point solutions are implemented across major clinical development activities, including decision support, candidate selection, protocol draft development, study initiation, clinical outcomes assessment, data quality checks, regulatory submission support, and regulatory follow-up.

There are also optional paths that create more complexity, such as decentralized clinical trials (DCTs). On average, a clinical site utilizes about seven to eight major platform technologies to set up and implement a single clinical trial, and to collect and report the data. Under that umbrella of overarching technologies are large numbers of additional smaller, sometimes bespoke, platforms and connections. These point-solution-oriented platforms manage one or a handful of activities, each with complex data flow, document management, human-to-human interactions, human-to-device interactions, continuous management of quality, data protection, and the generation of various tables, lists, figures, and reports.

While each platform has developed solutions for specific problems, the complexity of stringing multiple technologies together creates transactional and inertial inefficiencies. Until recently, the need to bridge multiple dominant platforms complemented by smaller platforms has created a discussion about efficiency and effectiveness that revolves around the nuts and bolts of making these platforms work end-to-end. This is not sustainable in the long term.

The inefficiencies and process fragmentation in the current model add substantially to trial administrative costs. There has been exponential growth in the type and number of data sources that are now being gathered in clinical research studies due to the rise in popularity of DCTs. These data sources include electronic health records (EHRs), wearables, the internet of things (IOT) devices, personalized medicine, and study designs that require genomics and other types of omics data.

To use a concrete example of the cost challenges, Tufts Center Study of Drug Development has found that almost 11% of clinical study sites that are selected are never activated, and this is primarily due to the budget and contract issues.[1] Another cost challenge is the expense of clinical procedures, which has been estimated to account for almost 22% of the total cost of the average study.[2] Indeed, because of long cycle times and complex and sequential trial designs, the cost of administering clinical procedures has been escalating rapidly in recent years. The significant roadblocks described above strain the sustainability of these ecosystems.

Over the past two decades, the industry has evolved rapidly, from building individual databases for each study, to software capable of managing multiple studies simultaneously, to integration across systems, and most recently, the journey to the cloud and the reduction of temporal barriers in data storage, and tools that derive insights from cloud-sourced data. When the COVID-19 pandemic hit, technological advancements accelerated at a remarkable pace in order to implement DCTs on a large scale, and drive development of vaccines and pharmaceuticals at seemingly warp speed. Thus, there has never been a better time to develop a UCP. The industry no longer considers academic medical center trials as the rule. DCTs, digital trials, and connected trials are establishing a new standard. UCPs can be a cornerstone to this next wave of possibility.

BENEFITS AND CHALLENGES OF A UNIFIED CLINICAL PLATFORM

There are numerous benefits for sponsors and sites to leveraging a well-designed, secure, and compliant UCP. First, the platform will provide a single work environment where all of the stakeholders across the clinical ecosystem are able to collaborate and perform their tasks as an integrated whole, instead of working in silos. The platform will offer a uniform user interface and bring together modular solutions for functionality, including eConsent, data capture, the clinical trial management system (CTMS), the electronic trial master file (eTMF), and payments. Centralized data storage will allow for very robust data flows, and interoperability will be key. The ideal UCP will enable the connection and integration of aligned vendor

solutions. Second, the UCP will support more rapid evidence generation and thus faster regulatory review. This is due to the overall reduction in trial complexity, reduction in latency between steps or across platforms, standardization of data, reduction in quality control challenges, and the use of automation from the protocol to the clinical study report. These features reduce the overall cycle time and drive faster decision making. UCPs provide all of the above benefits in the context of higher user satisfaction and a lower overall total cost of the technology system.

On the patient side, UCPs can improve patient centricity in clinical studies in several ways. They facilitate the implementation of DCTs, which are known to reduce recruitment challenges and decrease dropout rates. In addition, UCPs bring an added level of data security to all data sources, including EHRs, RWD, images, device sensors, IOTs, and wearables. Lastly, they facilitate the use of adaptive trial designs, by providing the ability for real-time data collection, cleaning and analysis, and secure handling of blinded data.

On the other hand, there are several challenges facing the industry during the development and implementation process for a well-designed, secure, and compliant UCP. First, a single vendor is unlikely to have the capability, expertise, or financial aspiration to manage it alone. Significant inter-vendor collaboration and co-investment will be required to bring software capabilities and expertise together to build an end-to-end UCP solution. Second, it will be a challenge to achieve speed and agility in the UCP that can keep pace with the emerging changes in science and medicine. Vendor developments in automation for process, data, and systems will be critical to overcome this challenge. Lastly, sponsors will need to prepare for the significant investment in resources that will be required when migrating over from legacy systems, especially when managing legacy data.

REQUIREMENTS FOR A VIABLE UNIFIED CLINICAL PLATFORM

In considering what would be required for a viable UCP, first and foremost is a human-centered interface. This is taken for granted in consumer technology and applications, but historically it has been lacking in the clinical trial platform industry. This has been referred to as the "Monday morning effect", in which industry professionals over the weekend use personal devices and applications that have highly intuitive and human-centered interfaces that are a delight to work with. On Monday morning, however, those professionals open up the clinical platform interface to a jarring, archaic legacy experience. This needs to change.

A viable UCP should also support an end-to-end clinical development process in a way that can drive the decision-making process in real time. Obviously early models will focus first on the core functionality, but with inter-vendor collaboration and co-investment, the goals of interoperability and the ability to easily integrate the end-to-end process should be very achievable. This collaborative approach to UCP development will need a design model that promotes open-source technology versus proprietary technologies, is cloud-platform-agnostic, offers software-as-a-service, and uses single-sign-on authentication.

A modular technical design would allow for maintenance and improvements to be made at an affordable cost and with relative ease. There must be a significant element of automation so that the UCP can operationalize with great efficiencies that are not based on prior expert-driven relationships. Data aggregation, analytics, and insights will allow the UCP to drive decision-making processes in real time.

Scalability is another critical feature necessary for a viable UCP. The solution must be able to manage the various needs and desires of smaller boutique or niche clinical trial sites and sponsors, all the way up to site and sponsor needs

that are large and highly complex. The UCP should be able to grow with the organization and meet any increasingly complex needs that arise. To that end, the UCP must be able to handle all types of data, both structured and unstructured, across multiple data domains, from omics to images. It must be compatible with any system or subsystem for tables, listings, and figures generation.

The UCP should be a living, evolving system. It should provide all core capabilities out of the box and not require extensive customization, with an ideal ratio of standard to custom around 80:20.

CONCLUSION

This is an exciting time of technological revolution in the clinical development ecosystem, with rising use of DCTs, cloud technology, mobile devices, artificial intelligence, and machine learning all leading to new design-driven development opportunities. Within the next several years, the UCP is likely to be at the core of the digital ecosystem for both sponsors and sites, enabling users to gather high-quality, actionable trial data more efficiently and at a lower cost than can be achieved with the point-solution oriented model in use today. This will result in substantial changes to clinical research. A well-designed, user-friendly, and compliant UCP will help sponsors increase trial quality, come to decisions quicker, bring more therapies to market, and ultimately meet a greater number of unmet clinical needs for patients.

REFERENCES

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