Article

A Sponsor's Perspective: Why Digital Adoption Lags in Clinical Trials

Pharmaceutical outsourcing: By Sara Liu, Director, Client Delivery, Patient Centered Technology, IQVIA

Clinical trial sponsors face increasing pressure to adopt innovative technology solutions to improve operations and information gathering. While the potential benefits of these advances are clear — such as enhanced data harmonization and streamlined trial processes — navigating rapid technological innovation presents unique challenges. For instance, a 2024 McKinsey report found that the average number of Phase II and III endpoints, has continually grown. To capture these vital endpoints, more equipment must be integrated, often five or more systems, along with site-specific training, resulting in an increased level of overall complexity. This underscores the need for thoughtful approaches to technology adoption that prioritize integration and alignment across systems. Addressing these factors is essential to achieving operational efficiency and ensuring seamless clinical trial execution.

While stakeholders recognize the potential benefits of new technologies, sponsors often fear that implementing them will increase complexity. These apprehensions are not unfounded, as poorly integrated systems can lead to challenges, such as delayed trial start times, overly complex user acceptance training and unnecessary redundancy in workflows. The root of these challenges often lies in a lack of integration and unified delivery, which can disrupt trial operations and compromise overall efficiency.

Unintegrated solutions exacerbate these issues by creating siloed systems that often require sites to navigate multiple devices and applications, leading to inconsistent data and increased administrative burden. For instance, separate systems for eConsent and Interactive Response Technology can force sites to manage redundant documentation, duplicated data entry and misaligned processes. These inefficiencies detract from trial quality by increasing site workload, delaying timelines and potentially impacting patient care. By contrast, integrated solutions that unify technology and delivery can streamline workflows, eliminate redundancy and ultimately improve both site and sponsor experiences.

A sponsor's perspective: Making the case for digital adoption

From a sponsor's perspective, change promises support of decentralization, increase in compliance, reduced patient burden and improved patient retention. But this promise alone is often not enough to convince sponsors to make the transition from one solution to another. This justifies the case for digital adoption in clinical trials requiring comprehensive solutions that include consolidated documentation, a unified process and a delivery strategy that includes a singular or unified user acceptance training program, as well as a central point of communication for both sites and sponsors.

Of course, a successful integration strategy requires the coordinated development of integrated workflows that establish a data flow that surfaces insights quickly and helps teams make critical decisions about the trial quicky. However, the creation of a quality integration between solutions not only involves the integrated build but requires a unified and coordinated approach to system implementation and aligned user acceptance training. Supporting a successful integration between solutions also requires coordinated training sessions that maintain stakeholder alignment while relieving the burden of multiple, uncoordinated solution trainings.

Successful orchestration of operational delivery ensures alignment across stakeholders while reducing the amount of time involved in the execution of system build and delivery. It involves synchronized implementation planning, shared risk management and coordinated change management, which are essential for seamless integration.

Implementation planning and design considerations

Rigorous implementation planning is essential to the success of integrated solutions. This involves gathering requirements, designing workflows to ensure seamless data flow and deciding on configuration versus customization. These steps, paired with validation efforts during the build phase, optimize system requirements and reduce errors. UAT sessions also play a central role, consolidating scripts and processes for streamlined execution. Training sessions not only align stakeholders but also prepare teams for efficient system adoption.

A recent case study demonstrates the value of integrated solutions through eConsent and IRT. This integration addresses key barriers to technology adoption by showcasing how an integrated platform that is supported by a unified delivery team can streamline operations. For instance, it provides a single sign-on for users, consolidates documentation to prevent redundancy and harmonizes data entry points to minimize error. Through robust, yet unified, training programs, both sponsors and sites experienced smoother implementation and reduced start-up times.

The benefits of this integration extend to reducing patient burden by providing an interactive experience that improves comprehension and flexibility. Digital solutions like eConsent enhance patient understanding by allowing individuals to proceed at their own pace, making the process less overwhelming and more engaging. This approach also supports the move to decentralization by delivering consistent information across systems, regardless of whether the trial is conducted on-site or remotely. Additionally, these solutions leave a comprehensive audit trail, which is critical as global audits of clinical trials become more frequent.

Key benefits of integration: A sponsor's perspective

Integration of eConsent and IRT solutions enhances the participant experience by automating workflows. Data from activities like recording consent and entering demographics seamlessly flows into IRT systems, reducing manual effort and potential errors. This ensures more consistent delivery of information and quicker access to data for decision-making. The integration fosters unified reporting capabilities, automated decision-making and streamlined medication allocation processes. Sponsors benefit from improved compliance, better patient retention and reduced regulatory submission complexities.

For sponsors, integrating digital tools into clinical trials ensures that data quality and availability are significantly improved. This improvement enables real-time decision-making, enhances reporting efficiency and supports compliance across diverse

trial types. In addition, digital solution adoption delivers complete traceability of data collection and correction through system audit trails. In one case, the platform optimization at build and delivery stages ensured that both eConsent and IRT systems went live ahead of schedule, demonstrating the potential of digital integration to positively impact timelines and trial execution.

Looking to the future

Future integrations should focus on applying lessons learned, particularly in areas like site training and system optimization. Reflecting on these integrations reveals opportunities to further refine processes and ensure scalability, ultimately driving quality and efficiency across clinical trials.

Looking to the future, the integration of patient-centric digital tools aligns with broader trends in clinical trials. Precision medicine and the decentralization of trials underscore the importance of adaptable and efficient technologies. These tools not only facilitate hybrid trial models but also provide quicker access to actionable data, fostering improved patient retention and site engagement. Sponsors hesitant to adopt these technologies should consider how integrated solutions can address their primary concerns — implementation complexity, data silos and delayed trial starts — while delivering substantial benefits in efficiency and patient outcomes.

As the clinical trial landscape evolves, embracing integrated digital solutions will be essential to overcoming the complexities of modern trials. By selecting responsible technology partners, streamlining training and ensuring unified data management, sponsors can successfully navigate the technology transition and achieve significant gains in trial efficiency and patient care.

About the author

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Sara Liu has over 16 years of experience in the eClinical Technology industry, specializing in IRT/RTSM, eCOA and eConsent. She is experienced with developing and leading global teams that deliver managed services spanning Operations, Project Management, Client Partnerships and Business Transformation. Sara is passionate about simplifying the patient's journey and improving patients' healthcare by utilizing technology that makes a real difference to patients' lives. Sara holds a Master of Science degree in Computer Science from New Jersey Institute of Technology in the U.S. and Bachelor of Science degree in Medicine Science in China.

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