SPOTLIGHT

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As clinical trial sites struggle to cope with disparate data sets and fragmented systems, intelligent solutions that automate workflows, fuel collaboration, and scale compliance will transform how they operate in the future.

Clinical Trial Operations Platforms: Expediting Study Start-Up, Controlling Risk, and Unleashing Collaboration

December 2025

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Breaking Through Burnout: The Secret Is Operational Data and Site Intelligence

The top priority for the life sciences industry is accelerating time to market for therapies; just one lost day can prove very expensive. A single day's delay can cost up to $500,000 in unrealized or lost prescription drug sales and $40,000 in direct daily clinical trial costs, according to a June 2024 study from the Tufts Center for the Study of Drug Development (Tufts CSDD). Therefore, sponsors, contract research organizations (CROs), and clinical trial sites need to collaborate to simplify processes and automate workflows to scale efficiencies.

Sponsors and CROs do everything possible to quickly get a site up and running. However, Tufts CSDD reports that 40% of clinical trial sites in North America will not activate and a percentage of those that do will have difficulty enrolling a single patient. Not surprisingly, 70% of site staff have reported that trials have become much more difficult to manage in the past five years. Study designs are growing more complex, the number of protocol amendments is increasing, and data sources are becoming increasingly varied and complex. There is also a huge technology burden on sites. Most use over 20 disparate systems on a daily basis, according to the Society for Clinical Research Sites, and that number is increasing every day. The swivel-chair effect — manually entering data from electronic health records (EHRs) to the electronic data capture (EDC) database — only adds to the burden on staff. The actual priority of sites is enrolling patients, but administrative demands and technology burnout take a toll. As a result, 85% of all clinical trials fail to recruit enough patients, and 80% are delayed due to recruitment problems, according to Tufts CSDD. Bottom line — we need to address site staff burnout.

AT A GLANCE

KEY STATS

- According to IDC's July 2024 *Global Knowledge Management Solutions Survey,* 51% of the life sciences industry cited the numerous unconnected silos of data and the inability to collaborate using that knowledge as their organization's top process challenges.
- In addition, 49% of the life sciences industry considered mobile access and 42% considered content traceability to be the most important user experience features of knowledge management solutions.

WHAT'S IMPORTANT

The life sciences industry has never been more focused on doing more with less. The ability to drive the intelligent automation of clinical workflows, the integration of data pipelines, and the use of GenAI to generate intelligent insights holds enormous promise for the life sciences industry.

In addition, the latest ICH E6(R3) guidance, released in January 2025, emphasizes the importance of sponsor oversight and the responsibility of sites in ensuring data integrity and quality.

What the life sciences industry urgently needs is a bidirectional platform that digitizes all operational workflows and offers smarter and integrated technology via open APIs, resulting in better oversight, compliance, and collaboration between sponsors, CROs, and clinical trial sites, ultimately driving down costs and reducing risk. There is a distinct paucity of such solutions in the market.

Beyond the Grind: Collaboration Redefined

There are multiple opportunities for the life sciences industry to enhance efficiencies and reduce the highly laborious, time-consuming, and error-prone manual processes that frustrate both the clinical research coordinator (CRC) at the site and clinical operations managers at sponsors.

These efficiencies can be designed to address challenges that both sponsors and sites face:

- **Controlling risk and ensuring compliance:** Inspection readiness is a critical requirement for clinical trial sites. Poor documentation issues routinely stand out as a prominent issue in FDA inspections and frequently appear as observations on Form 483s. Having organized and auditable electronic investigator site files (eISFs)/ebinders helps ensure that sites are well prepared for inspections by regulatory authorities and supports monitoring visits conducted by clinical research associates (CRAs).
- **Reducing costs through automated workflows:** Sponsors, CROs, and sites spend a huge amount of time on administrative paperwork and data processing activities. A paper by the Memorial Sloan Kettering Cancer Center indicates that over 50% of clinical trial data is duplicated between research systems and hospital EHRs, with around 20% of total study costs typically allocated to data duplication and verification. The paper references a retrospective analysis conducted by AstraZeneca and Sanofi, which indicated that since study personnel spend at least 3 minutes per data point, an oncology study involving 10 patients, each with 10,000 data points, would require about 5,000 hours of work (source: *Applied Clinical Trials,* August 2024). CRCs work across multiple sponsors and multiple large studies. Automating workflows and centralizing data could significantly reduce site burden, allowing for efficient query resolution and seamless document access.
- **Expediting start-up through site feasibility:** Site feasibility is a core metric for clinical trial sites that is increasingly critical as competition for repeat sponsor business increases. Providing access to intelligent databases of potential trial sites and automating site selection and participation surveys with AI-enabled feasibility scoring help sponsors stay on track and allow sites to position their capabilities effectively.
- **Enhancing access:** Mobile apps can provide site staff with ready, real-time access to documents, allowing CRCs and investigators to quickly process and sign documents in a secure and compliant manner.

The Sponsor and CRO Edge: Strategic Oversight for Expedited Start-Up and Trial Operations

While both sponsors and CROs have focused on scaling efficiencies and accelerating clinical trials, as a result of the COVID-19 pandemic, there is increasing acceptance of pursuing remote site oversight and fueling collaboration and compliance at scale across sponsors, CROs, and sites. Further:

- **Reducing costs and controlling risk through operational intelligence:** The Association of Clinical Research Professionals has reported that onsite monitoring alone accounts for 25% to 30% of total clinical trial costs. Tools that will enable remote access to sites can enable rapid site activation, reduce CRA burnout, increase CRA productivity, and improve study oversight.
- **Operating with intelligence at a global scale:** A well-designed electronic trial master file (eTMF) with direct connectivity to the site eISF enables seamless document exchange and allows for faster issue resolution. In addition, it enables sponsors/CROs to have an overarching view of the documentation compliance across multiple sites, considerably scaling efficiency and improving compliance.

Considering Florence Healthcare

Florence Healthcare, founded in 2014, pioneered the electronic investigator site file with ebinders and has evolved into a comprehensive trial operations platform that connects sponsors, CROs, and research sites to accelerate cures for diseases.

Florence's Trial Operations Platform encompasses the complete trial life cycle from start-up to closeout, including AI-enabled site selection and feasibility scoring, automated document exchange, role-based training, remote monitoring capabilities, and real-time eTMF synchronization. The platform leverages AI throughout to provide operational intelligence, early risk detection, and next best action recommendations.

Florence connects over 65,000 study sites across 90 countries, providing global operational visibility and supporting large global multicentric clinical trials. Its tools are FDA 21 CFR Part 11, EU Annex 11, General Data Protection Regulation (GDPR), and Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant, addressing the needs of the highly regulated life sciences industry.

Challenges

While Florence's Trial Operations Platform offers comprehensive integration capabilities through Open APIs and a connected eclinical ecosystem, seamless integration with complex, multivendor technology stacks remains an ongoing consideration for enterprise deployments.

As the regulatory landscape continues to evolve with new ICH E6(R3), European Union Clinical Trial Regulation (EU CTR), and FDA Decentralized Clinical Trials (DCT) guidance, the life sciences industry must keep a close eye on ensuring that Florence continues to advance its compliance framework to help sponsors navigate these changes while maintaining the global operational intelligence and risk detection capabilities across diverse regulatory environments.

Conclusion

By creating automated data and document workflows, CROs and sponsors can not only help accelerate trial timelines but also reduce the burden on sites and incentivize them to perform better. Intelligent workflows and operational data that facilitate communication and collaboration across sites, sponsors, and CROs can play a key role in transforming the way the life sciences industry conducts clinical trials.

To the extent that Florence Healthcare can drive interoperability with legacy technology platforms at sponsors/CROs and can demonstrate that it can continue to drive compliance with the evolving global standards and regulations, the company is well positioned for success in the marketplace.

About the Analyst

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Dr. Nimita Limaye provides strategic advisory and market analysis on key topics related to life sciences R&D strategy and technology and is IDC's primary Life Sciences AI analyst. An executive business leader with over three decades of life sciences leadership experience, spanning pharma, CRO, and tech consulting, she has led business strategy and managed large global operations. An extremely well-networked thought leader and sought-after speaker, she has been ranked among the top 50 analysts in the AR100 Market Amplifiers Power 100 list in 4Q25.

MESSAGE FROM THE SPONSOR

About Florence Healthcare

Florence offers the fastest-growing clinical trial operations platform, connecting 65,000+ trial sites and 600+ sponsors worldwide through the industry's largest site intelligence network. With AI-first workflows that speed startup, operational intelligence that reduces risk, and automation that cuts costs, Florence is changing the way sponsors, sites and CROs operate to bring cures to patients faster.

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