Redefining sponsor/CRO/ site collaboration: Integrating document platforms and portals to optimize startup from protocol to recruitment

An opportunity for better quality and expedited timelines in clinical trials

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In the high-stakes world of clinical trials, quality is key to successful regulatory approval, but meeting timelines is a prerequisite to commercial success. Delays in protocol finalization, poor site engagement and patient recruitment, and lack of real-world feasibility insights are key contributors to costly setbacks. At the core of these issues is often the lack of early involvement of external stakeholder groups, e.g., investigators and patients—patient and public involvement (PPI), in the protocol development process. Moreover, document-based clinical studies, while long-standing in the industry, present a range of pitfalls that hinder efficiency, quality and compliance. One of the most significant risks is the misalignment of information—documents are often stored in disparate systems, leading to version control issues, duplication of effort, compounding of errors and delays in communication. Manual document handling increases the likelihood of human error, such as outdated templates being used or critical updates being missed. These inefficiencies not only slow down study startup and execution but also compromise data integrity and regulatory readiness.

The opportunity

What if feasibility wasn't an afterthought, but an integrated, parallel activity? What if sponsors could involve sites (and patients) earlier in the protocol development process? What if documents were not created in isolation but connected and available together in real time?

With a strategic workflow between **Trialynx™** and **Cognizant® Shared Investigator Platform (SIP),** that vision can become a reality. Launched in 2024, Trialynx (a commercially available, AI-powered study development and document authoring platform) provides a disruptive approach to core document creation and management. This approach brings sites into the process when it matters most—before the protocol is finalized—empowering sponsors to build better studies faster, while strengthening site relationships and improving patient outcomes. Furthermore, study documents are digitally connected and can be authored, reviewed, revised, approved and circulated consistently, automatically and in a fraction of the time, making them readily available for downstream use.

The traditional process: Sequential, siloed and slow

In the traditional study startup process, protocol development begins in a vacuum. Sponsors draft protocols internally or with principal investigators and consultants, sometimes referencing historical data or broad feasibility reports. At the same time, studies have become more challenging and timely input more crucial. As clinical study designs get more complex, with more dynamic elements and clinical endpoints (between 2015 and 2021, phase 3 clinical trials saw a 37% increase in endpoints, reaching an average of 25.8 per study. Similarly, the average number of phase 2 and 3 endpoints rose from 17 (2013–2016) to 21 (2017–2020). Stakeholder groups are also becoming more diverse. Growing focus on patient-centered design and patient outcomes is driving a need for sponsors and investigators to gather and implement input from an increasing number of stakeholder groups, ensuring a 360-degree perspective during study design and protocol development. The necessity to reach out to more remote patients and include more decentralized elements in studies means the capabilities and needs of these, e.g., local healthcare providers and labs, monitors, etc., must be considered. Asking for feedback only after a draft is finalized can negatively impact the feasibility process, delaying sites in determining whether a protocol can be operationalized and causing costly amendments.

Major drawbacks that occur when sites are not included in protocol design include:

- **Feasibility is reactive**, not proactive
- **Sites have little to no input** on inclusion/exclusion criteria, visit schedules or operational burdens
- **Late feedback triggers amendments**, which delay timelines and add cost

- **Engaged sites aren't identified until too late** in the process
- **Lack of investigator/patient awareness** of clinical trials available to them
- **Language and cultural gaps**, particularly in global trials, preventing participation of diverse populations

Simply put: The current system asks for feedback when it's too late to do much about it. Even when actively soliciting feedback earlier in protocol development, sponsors often rely on a few, often very experienced or specialized sources of input, ensuring perhaps that studies can be conducted at those and similar sites, but potentially not accounting for the aforementioned stakeholder diversity. According to McKinsey, the biggest opportunity for sponsors to accelerate clinical trials is to increase the speed and improve the efficiency of clinical trial enrollment. With growing evidence and examples of benefits of PPI, there are still significant challenges to its effective implementation. How to maintain efficiency while sequestering and managing a broader swath of stakeholder input?

Bringing the right tools together

Isolated documents and systems in clinical research create significant inefficiencies by fostering silos, increasing the risk of errors and delaying trial timelines. In contrast, open APIs and standardized data models offer a scalable solution by enabling seamless interoperability across platforms, reducing duplication and improving data integrity.

Major advantages of early involvement of external stakeholders:

- **Heightened awareness of and early identification of study opportunity**
- **Fewer amendments, lower costs and reduction of retraining need** by reducing amendments
- **Improved recruitment, retention and adherence** through patient-informed, realistic protocols
- **Higher data quality** with engaged sites and patients able to follow protocols accurately
- **Regulatory and ethical strength** through demonstrable compliance with ICH and ethical standards, improving regulatory confidence

By curating the right tools in a more intelligent process, investigator portals like Cognizant SIP can evolve from static document repositories into intelligent coordination hubs when integrated with upstream planning tools, allowing for proactive engagement, streamlined operations, and integration and communication with downstream systems. Embedding these tools within a unified ecosystem allows for automated downstream availability, while structured protocol data can drive automated feasibility assessments and early site identification. Early access to study materials also promotes mock scenario and time-motion analyses, providing early insight into feasibility. Digital connections between systems can eliminate weeks of lost time between protocol approval and site activation by automating document flow and task initiation. Platforms like SIP and Trialynx are well positioned to support this future state, offering modular architectures and API readiness that enable interconnectivity.

Connecting documents and systems end-to-end

The clinical research industry is undergoing a significant transformation, driven by initiatives like Transcelerate's digital data flow (DDF) and CDISC's unified study definitions model (USDM). These efforts aim to move clinical trials from a document-centric to a data-centric model, enabling automation, interoperability and real-time insights across the study lifecycle. At the core of this transformation is the need for robust digital infrastructure that can ingest, interpret and distribute structured protocol data and documents across diverse stakeholders and systems. This is where document generation platforms and site portal and integration hubs—such as Trialynx SIP—play a pivotal role. SIP supports interoperability by integrating

with sponsor CTMS, eTMF, study design tools, site-facing systems (e.g., EISF) and regulatory platforms. Through API-based data exchange, it enables seamless flow of structured data, minimizing manual reentry and reconciliation. This not only improves data quality but also enhances operational efficiency. SIP serves as a digital integration hub that facilitates the implementation of DDF by acting as a central access point for digitized protocol definitions. It can host structured protocol data conforming to USDM standards and distribute this metadata to sites in real time, enabling automated configuration of downstream systems like EDC and ETMF. This capability significantly reduces the lag between protocol approval and study startup, one of the key goals of the DDF initiative. By connecting systems and workflows, we can bridge the gap between protocol digitization and operational execution, enabling faster, smarter and more connected clinical trials.

Parallel workflows, structured feedback and downstream efficiency with SIP and Trialynx

By leveraging the combined strengths of **Trialynx** and **Cognizant SIP**, sponsors can create a more intelligent, integrated protocol development process. Here's how it works:

1. **Draft protocol or synopsis in Trialynx**
   Trialynx allows sponsors to quickly generate a first-draft protocol or protocol synopsis using structured data and automation. These drafts are not static documents—they're dynamic, editable blueprints that automatically populate downstream documents like consent forms, study plans and site packets. The comprehensive 360-degree study builder helps teams identify and flush out the operational aspects of the trial alongside the scientific aspects.

2. **Share early draft with select sites via Cognizant SIP**
   Instead of waiting for full finalization, the sponsor can share the synopsis, early-stage protocol and other documents directly with select, trusted sites that are already onboarded through SIP as they develop, when feedback is needed. These may be high-performing sites from past trials, geographic targets for enrollment or locations with diverse patient populations. By bringing stakeholders together, sponsors can stack the deck in their favor—ensuring trials are both scientifically and operationally sound.

3. **Collect structured feedback**
   Through SIP's document exchange functionality and workflows, investigators, site staff and other site-facing stakeholders can provide targeted feedback:

   - Are the eligibility criteria too narrow?
   - Is the visit schedule realistic?
   - Are there barriers to recruitment in their setting?
   - Are there cultural, demographic or logistical challenges?

Because Trialynx uses structured fields, feedback from SIP can be automatically ingested and maps directly back to the protocol sections, allowing sponsors to quickly see where changes are needed.

Revise protocol in Trialynx with real-world insights

Based on the site feedback, sponsors update the protocol in Trialynx. Changes cascade automatically to related study documents, keeping everything aligned and eliminating manual rework, and avoiding additional error introduction. Final documents/document package is pushed to SIP for automatic circulation recirculation or kicking off site feasibility/selection.

Conclusion: A blueprint for the future

The potential to transform clinical trial activation by enabling parallel processes at the site level has been previously demonstrated. Here we explored the opportunity to support and develop that potential through early engagement, upstream from a process perspective.

Involving sites after the protocol is finalized is like asking engineers to approve a bridge after it's built. Instead, sponsors should bring sites into the design process early—when their insights can shape the outcome.

Involving sites early (and often) facilitates better insights and enables better external stakeholder engagement and study quality.

By combining the Trialynx 360-degree study builder and instant documentation platform and Cognizant SIP's site engagement capabilities, sponsors unlock a smarter, faster, more collaborative trial development process. This isn't just innovation for its own sake—it's a practical path to better studies, faster approvals and stronger site partnerships.

Bring sites in early. Build better trials. Drive downstream efficiency. That's the future of protocol development.

Benefits for sponsors

- **Improve protocol quality**
  Protocols that reflect real-world site realities are more likely to be executable, compliant and successful.
- **Start feasibility sooner**
  Sponsors don't have to wait for a polished protocol. Feasibility can begin from the synopsis phase, enabling earlier engagement and faster site selection.
- **Identify engaged, high-performing sites**
  By watching which sites respond and how thoughtfully, sponsors can build a shortlist of committed, informed sites. This data can also accelerate site qualification, contracting and activation.
- **Reduce risk of amendments**
  By addressing feasibility concerns early, sponsors avoid costly amendments that can delay study startup and require IRB reapprovals.
- **Increase site satisfaction and retention**
  Sites want to be heard. When sponsors ask for their input and actually incorporate it, site relationships improve—along with compliance, recruitment and retention.
- **Ensure end-to-end document alignment**
  Static, siloed documents are replaced by structured, interoperable data enabling machine-readable protocol elements to flow seamlessly across documents and systems—from study design to site activation, supporting automation, real-time updates and consistent data reuse, enhancing traceability, accelerating decision-making and laying the foundation for scalable, high-quality research operations.

Benefits for sites

- **Voice in protocol design**
  Sites get to weigh in on criteria that directly affect their ability to recruit and retain participants.
- **Earlier visibility into studies**
  Rather than receiving finalized protocols cold, sites can begin planning earlier and decide if a trial is right for them.
- **Influence without administrative burden**
  Because SIP is already integrated into site workflows, providing feedback is straightforward and efficient.
- **Stronger sponsor-site relationships**
  This process fosters mutual respect and collaboration, which sites value deeply.
- **Securely creating, sharing and managing documents for the site**
  Source document templates, but also a number of others, are often created and maintained by sponsors on behalf of sites to support harmonized and consistent study processes and data collection, requiring local site modification. Sites will be able to leverage their own template/local standards to automatically create and manage documents based the protocol and other sponsor documents.

Benefits for patients

- **Feasible and patient-friendly protocols**
  Early involvement of investigators and site staff ensures that study procedures are practical and considerate of patient needs. Their operational insights help reduce patient burden and improve adherence.
  Example: Site staff may recommend replacing frequent in-person visits with telehealth options to accommodate patients with mobility or transportation challenges.
- **Patient-centered endpoints and procedures**
  Patient advocacy groups amplify the patient voice by identifying what matters most to participants—such as managing fatigue, pain or emotional well-being—and advocating for their inclusion in study endpoints.
  Result: Trials become more ethically sound and yield data that better reflects real-world outcomes.
- **Greater trust and transparency**
  Advocacy groups help tailor communication strategies and address cultural sensitivities, especially in underrepresented communities. This fosters trust and reduces barriers to participation, improving recruitment and retention.
- **Sustained patient engagement**
  Advocacy groups often remain involved beyond the trial phase, contributing to post-market surveillance, real-world evidence generation and adherence initiatives.
  Impact: Advocacy groups ensure that patient needs continue to be addressed throughout the product lifecycle.
- **Faster access to innovative treatments**
  Stakeholder-informed protocols are more robust, require fewer amendments and move through regulatory and recruitment phases more efficiently.
  Benefit: Patients gain quicker access to potentially life-changing therapies.

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