4 Modernized Functions Every Sponsor Needs for Study Startup

WHITE PAPER

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For many sponsors, study startup is a process everyone strives to make more efficient. Often reliant on manual workflows across site identification, contracting, submissions, and beyond, startup activities can be painfully sluggish and prone to unexpected bumps, delaying timelines, driving up costs, and shifting launches.

Those concerns feed into global challenges across site activation, enrollment, study budget fluctuations, and ultimately, getting therapies to patients faster. When external forces such as labor shortages and market competition are at play—an ongoing reality in this economic landscape—manual processes can further complicate pipelines and set sponsors back.

Fortunately, the long and winding pathway through study startup doesn't have to be so burdensome. Technologies are increasingly becoming more sophisticated and purpose-driven in automating administrative tasks and providing oversight, which helps sponsors and contract research organizations (CROs) standardize and operationalize their programs for a more seamless startup journey.

This white paper explores four of these modern tech capabilities designed to help decrease cycle times, improve processes and compliance, and mitigate site burdens:

- Standardized documentation
- Intelligent notifications
- Dashboard visibility
- Technology interoperability

With more intention around those essential areas—plus investments in the systems powering them—sponsors can realize a more fluid, functional, and faster startup workflow.

Standardized Documentation and Exchange

> *The information exchange requirements of any research program can be enormous. A standardized and repeatable process to generate and exchange documents makes it much easier to systemize programs for faster startup.*

You likely already know every trial has a set of essential documents to collect and establish in two consolidated areas: the trial master file (TMF) for the sponsor and the investigator file (ISF) for the site. With standards underlining the process, including the TMF reference models and ICH-enumerated essential documents, information exchange workflows rely heavily on standardized templates.

Even so, not all "standardizations" are created equally. Many programs use spreadsheets as stand-ins for templates, to their own detriment. Especially for large and complex programs involving multiple sites across multiple countries, standard-order grids don't account for the many "middle points" along the way.

Here's an example: On its surface, completing the confidential disclosure agreement (CDA) and other contracts culminates in a single signature event. But in reality, the process involves a great deal of back and forth with multiple reviews. And a static spreadsheet doesn't necessarily support those many "in-between" activities.

By contrast, sophisticated technology enables a more dynamic workflow-based exchange system than the flatness of a one-off grid. By including pre-defined templates within an enterprise research collaboration system, it supports a repeatable (and better) process. This saves time for everyone, triggers assignable tasks and milestone statuses, provides a centralized oversight dashboard for all stakeholders to reference, and automates key functions of study startup workflows.

Once a system gets configured for one study, sponsors can then copy the structure across their entire pipeline, with the freedom and flexibility to modify templates, project milestones, or other activities as needed. This standardizes a more functional process so stakeholders can expect a more predictable flow and clearly measure innovative changes to the process across time from project to project.

Additionally, consider the institutional review board (IRB) implications: IRB documents are frequently stored in disparate systems, far removed from regular platforms. Enterprise documentation solutions provide the benefit of immediate visibility through a central and shared space—avoiding compliance missteps, optimizing startup, and reducing site burdens.

Real-time Notifications

> *More isn't necessarily better. A successful program sends only the right updates to only the right people at only the right times. This avoids notification fatigue so alerts are more actionable and actioned.*

In this always-on era, so much effort goes into ensuring stakeholders stay current and informed. But in all the messages, emails, pop-ups, and notifications, recipients can become numb to the volume of communications flying back and forth.

A big problem is sending notifications to the wrong people, such as teams receiving an alert and then passing that information along to someone else.

To make more effective use of real-time notifications, sponsors can benefit from enterprise solutions making these updates more targeted, contextualized, and delegable.

Targeted notifications only get routed to the people who need to see them. Advanced systems let sponsors specify to whom, where, and when messages get delivered without spamming an entire user contact list with every notification. Stakeholders should align on the correct recipients at the outset to make the most of this function.

Take, for example, the common tendency to send everything to the already-overloaded principal investigator (PI). If notifications instead were routed to the people who could act on the alert immediately—a central contracting team, central regulatory team, or local IRB, for instance—those updates become more purposeful. While PIs should be kept in the loop, they don't necessarily need to be accountable for every update.

Contextualized notifications allow for more information within every update. With this capability, platform users can add details about timelines and expectations so every notification matters—including specifying when a notification is FYI only or requires action.

And finally, **delegable** notifications can be reassigned to someone else. When platforms have that capability built in, it naturally provides a more seamless and efficient workflow experience without the need for extra coordination (and extra messaging) to align on who's doing what.

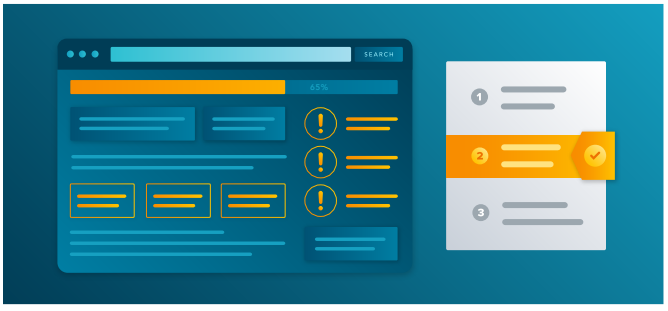
Global Program Visibility and Oversight

> *Giving sites and sponsor stakeholders common visibility into startup activities can make collaboration more sustainable—and meaningful, too. Creating a shared space through a global dashboard supports that need.*

When everyone is working toward a shared goal, not giving contributors shared visibility into it does a disservice to the research program. Ultimately, transparency gives contributors an understanding not only of the progress made on study startup steps, but also the ability to dive into the finer nuances of a program's inevitable obstacles—such as: To whom do I escalate problems? Who are the points of contact if things aren't getting done?

For global visibility to work, though, it requires centralized reporting and visible dashboards of the study activation process. Sites need to know where they sit in comparison with others, from document management to training to IRB approval. If clinical research coordinators (CRCs) and PIs see they're on track with their counterparts at other sites, it restores confidence that everyone is on the same page. If they see they're behind, for example, it can mobilize action to catch up.

A best-in-class dashboard provides optics into where any document is at any point in the process. This would include details on what action items are needed for any given site by providing a command center dashboard where a site and sponsor can visit first with all questions.



Dashboard essentials include:

- Feasibility status
- Training compliance and completion
- Essential document collection
- IRB review status

Enterprise Integration

> *Clinical trials involve an ecosystem of many different people exchanging information across many different systems. Integration involves not just the underlying technology, but also the people and processes powering those systems. By fostering more automated connections from point to point, the better and more supported that broader ecosystem becomes.*

Integration is a term used, and maybe misused, often. True integration between clinical trial systems is more than just plugging two systems together. In reality, purpose-built connections involve much more pre-implementation planning and coordination than most people may think.

As early as possible in the startup journey, sponsors need to understand which platforms (such as document storage systems) the selected sites, CROs, and vendors plan to use throughout the duration of the partnership. Look for opportunities to accommodate and integrate with those systems—and then outline a site-specific plan to gather and exchange information during the trial.

In that plan, aim for bidirectional exchange relationships from platform to platform. This means documents can easily pass back and forth between sender to recipient and vice versa through a secure and validated exchange. Recent technologies have become more supportive of these relationships through Application Programming Interface (APIs) and other capabilities.

Remember: You don't have to integrate everything. Just implementing a few high-priority connection points can improve efficiency. In the hierarchy of what matters most from an integration standpoint, many sponsors typically find connections between these systems to be the most worthwhile:

- **IRB to eTMF and eISF** connections enable an automated and secure transfer of IRB-related materials directly from the IRB portal to the eTMF and electronic investigative site files (eISF). With this integration in place, users can avoid the error-prone manual processes of manipulating, loading, and exporting documents between each of these points.
- **Training certification integrations** allow for a centralized source of truth for training operations and records. With this capability, users can track, store, and report training updates without the need to repeat requirements like good clinical practice (GCP).
- **Regulatory packet sharing** between sites and sponsors provides the ability to securely and seamlessly exchange, maintain, store, and sign regulated documents without cumbersome processes such as frequent communications more common in manual workflows.
- **Participant information integrations** between systems create a single and centralized spot to keep patient details, study status, and associated documents and information. With this integration, sponsors can reduce risks of compromised security and inaccurate recordkeeping, potentially jeopardizing participant privacy and study outcomes.
- **Single sign-on** has become common for most clinical trial platforms, particularly for site users—often clinicians—who are asked to engage in multiple systems per day. With this capability, users can more easily complete research workflows from their platform of choice without having to individually log in and out of each system during each session.

A More Efficient Path to Study Startup

By design, study startup should be a comprehensive process, but that doesn't mean it must be slow. With modernized functions such as standardized documentation, improved notifications, dashboard visibility, and enterprise integration, stakeholders can more effectively sail through workflows and meet program objectives—without getting stuck in the cycle of manual activities.

If you'd like support getting started, reach out to Advarra to see how purpose-built technology can help you and your sites achieve a more efficient pathway to study startup: ***advarra.com***

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