Reducing Study Team and Site Burden through an Integrated eClinical Platform Solution

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If you survey most biopharmaceutical clinical study teams and site personnel regarding their main frustration with eClinical solutions, their response will inevitably be, "we have too many user names and passwords for all the different systems we need to use." While this frustration is usually categorized as a "user credential issue," many users don't realize that working between different systems is not just a source of annoyance but a structure that results in extra administrative burden and mistakes that cause significant study delays. But change is happening across the clinical research industry, as more sponsors are moving toward eClinical Platform Solutions to streamline and facilitate their clinical research programs.

The Current System

It is clear from discussions at major industry and site-focused meetings that we are overwhelming study teams and sites with too many technologies that don't talk to each other. Adding a new technology with the latest features and gadgets might be the right decision for a study team, but careful consideration should be given to the additional workload this could place on the end users who may be supporting 10 to 20 trials at a time. A major reason why more than 40% of investigators who conduct one study decide to never conduct another study is that they underestimated the complexity of clinical trial conduct.[2] Unless it can reduce the burden on new researchers, the clinical research

Problems in working with multiple systems, cited by users include: [1]

- Double and triple data entry into as many as ten systems per study is cumbersome and increases probability for errors.

- Printing, scanning, uploading and faxing hundreds of documents into multiple systems each day is time consuming and takes time away from seeing study participants.

- Learning new technologies that are added onto each study, some of which may only be used once, is inefficient and difficult.

- Managing and learning how to use multiple hardware devices (tablets, laptops, cameras, etc.) provided by each vendor is complicated and time-consuming.

- Activating user accounts in multiple systems for multiple studies is riddled with errors.

- Excel "trackers" that track multiple applications creates complications and inevitably, errors, as they require manual data entry from multiple stakeholders.

industry is setting itself up for losing promising new investigators.

In order to develop a solution to this problem, it is helpful to understand how we got to this point in the first place. Over the last 15 years, biopharmaceutical companies began to license individual Clinical Trial Management, Regulatory Management, Drug Safety Management and/or Learning Management Systems from separate eClinical vendors. The common practice was to implement those solutions on premise, and customize them to a point where they became more client-centric than product-centric. The significant customization made it difficult for the vendors to integrate their own products within a single biopharmaceutical sponsor, let alone across the studies of multiple sponsors. The cost of implementing, integrating, maintaining and upgrading these products became extraordinarily expensive as each sponsor had highly customized versions of multiple point solutions – with sponsors paying more for implementation and maintenance than the software license itself. Contract Research Organizations (CROs) typically followed the same practice and utilization patterns as sponsors, and ran into the same challenges.

Economic pressure on pharmaceutical companies to reduce technology budgets and operating costs just reinforced the challenges caused by these initial patterns. Instead of investing in new cloud-based platforms with integrated workflow applications and application program interfaces (APIs) for third-party software integrations and single-sign-on, budgets were focused on supporting the highly customized software that had already been purchased. Technology vendors quickly moved from promoting their solutions to technology departments to working directly with the individual study teams. These teams managed study budgets with available funds, had less stringent decision-making processes, and had the autonomy to select the vendors they liked best. While study team budgets were not able to support the purchase of an enterprise platform solution, they could support the addition of a new point solution for a single study. Consequently, the number of new point solutions and new vendors developing them has grown exponentially over the past 10 years.

Change is Happening

While a large number of major pharmaceutical companies and CROs still rely on those point solutions today, there is a major shift by midsize biopharmaceutical companies and CROs to adopt a cloud-based eClinical platform or Clinical Trial Portal solution. These solutions provide integrated workflow applications for site selection, study start-up, study team training, management of the Institutional Review Board (IRB) submissions, electronic Trial Master Files (eTMF), site communication/messaging, and participant recruitment/engagement. Major pharmaceutical companies are starting to follow suit, using a more cautious and planned approach. Based on surveys conducted by ePharmaSolutions clients, the feedback from those study teams and sites who have implemented and used these integrated solutions on

multiple studies is overwhelmingly positive.[3] Features that stakeholders cite most frequently include:

- One user credential to access most, if not all, of the systems needed to complete tasks across all studies.

- Adding a user to one system automates account activation and permissions across all of the systems used on the study.

- The ability to track and complete tasks across all studies eliminating the need for redundant processes like completing Good Clinical Practice (GCP) training for each study, filling out the same site qualification survey questions for multiple sponsors, and acknowledging the same safety letter across multiple studies with the same product.

- Auto-population of study documents and allowing for eSignatures eliminate mistakes and the need to print, scan and fax documents.

- Time stamps and tracking features that provide study teams and sites with real-time reports on what has been completed and is still outstanding.

- Solutions are standard and user-friendly, allowing study teams and sites to accelerate adoption and improve usability.

Raleigh Neurology Associates (RNA), one of the largest neurology sites in the world, has carefully studied the benefit of these solutions on over 100 studies working in a paperless environment.

Rigorous time motion studies conducted by RNA management suggests a 30% overall improvement in productivity, cost, and enrollment over two and a half years.[4] Sean Walsh, Director of Clinical Trials at RNA stated that, "By eliminating paper, double data entry, and the mistakes of a paper-driven process, our coordinators spend more time recruiting, consenting and maintaining relationships with our patients. This has resulted in our ability to conduct a third more studies, with less staff and achieve 30% higher enrollment metrics than before we used the portal."

The less time site personnel spend double-entering data, shuffling paper, and fixing mistakes, the more time they can spend on the most important stakeholder in the process- the study participant. Sponsor study teams are reporting equally impressive results in terms of better and faster site selection/activation, improved site training, quality and oversight.

Developing eClinical platforms that facilitate many of the workflow tasks mentioned in this paper is a complex undertaking. Many of the larger eClinical companies are still struggling to fully operationalize a complete system. Biopharmaceutical companies' collaborative efforts are years behind their original goals to launch the most simple workflow applications. Database structures must be architected properly; security models for user permissions must be considered; complex document management workflow applications must be configurable; and the system must be scalable, reliable and validated to meet regulatory requirements. The list is extensive, but it can and must be achieved. Other industries have resolved these issues for the benefit of all stakeholders. The banking industry solved it years ago—many people probably can't remember the last time they visited a bank branch to deposit a check, or even mailed a check to pay a bill. The cellphone industry developed the "app" model with standards that require all apps to operate within a given operating system (or platform). How many daily tasks do you complete on your smartphone today?

The emerging eClinical platform-based companies are paving the way for significant improvements across the clinical trial landscape that can have a transformational impact if biopharmaceutical companies move away from the point solution model.

It should be noted that technology alone may not provide the transformational impact our industry requires to streamline and accelerate study start-up and/or participant enrollment and retention. We can apply the best platform-based eClinical solution to any study, but if sites are not selected who cannot negotiate site contracts effectively, or obtain IRB approval in a timely and efficient manner, most of the time-saving is lost. For the foreseeable future, the right mix of eClinical technologies with integrated clinical services to support site selection decision making, contract negotiation, and IRB approvals has the highest likelihood to make a transformational impact on the study start-up process. Helping sites to reduce administrative burdens and redundant tasks with those same solutions, to work in a paperless environment, will also play a major role in improving productivity and site performance.

Biopharma decision-makers at both the corporate and study level should consider the following questions during the eClinical vendor selection process;

- Can I accept a platform-based solution that meets 90% of my needs vs. multiple point solutions that meet 100% of my needs?

- Are my requirements "nice to haves" or "must haves"? What is the trade-off of making changes that are "nice to have"?

- How will the selection of a new technology affect my study team users, vendors and sites? Will it cost more to integrate and reduce workload for the end-users? How will they be trained on the technology and the process?

- Does the point solution have open APIs for integration or will it require customization (and therefore, validation) for each study.

- How simple is it to use for study teams and sites? Simple always wins.

Conclusions

The biopharmaceutical industry is facing immense pressure to reduce friction and delays within the clinical trials process. The industry needs to start thinking differently—and acting differently—to make these changes. Single sign-on platform technologies with integrated workflow applications that operate in a paperless environment are available and affordable today. The right combination of these technologies with supplemental services that help accelerate manual processes is the key to transformational change in study start-up, efficient clinical trial conduct, and productive, satisfied sites.

About the Author

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