CWeekly
A CenterWatch Publication

The Pulse on Study Startup Article Reprint • December 11, 2017

Dismantling silos key to improving the clinical trial continuum

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The focus on technology as a driver of performance improvement in clinical trials is intense, but despite years of valiant efforts, study execution remains far from optimal. For study startup, the data are dismal: Contract cycle times have doubled from an industry median of 1.5 months in 2009–2011 to more than three months in 2014–2015.[1] Nearly 50% of clinical trials are behind schedule, with slow patient enrollment cited as the top reason.[2] Research also suggests a lengthy 16.7 months is typically required to initiate all approved sites for phase II–III trials.[3]

While technology remains critical, as emphasis shifts to process optimization it may be only part of the solution. Point solutions can hinder the flow of data across the continuum,[4] causing already entrenched silos to dig in further. To improve performance quality in study startup, two factors are needed: an end-to-end solution and support from top management.

An end-to-end solution with workflows that aggregate data from disparate sources can identify the documents needed to conform to downstream regulatory requirements, and can also signal bottlenecks or breakdowns in study execution. This approach helps to avoid rework, delays and cost overruns; improves cycle times; and facilitates audit readiness. It can also break down silos that have long performed in isolation with little understanding of what the next department needs to fulfill its regulatory obligations and achieve targets measured by performance metrics.

As for the C-suite, the importance of buy-in from upper management cannot be overstated. Without management direction, efforts to jump-start overall performance optimization tend to flounder as departments retreat to their silos.

In short, tools are essential, but they don't create a master craftsman. Real expertise comes from combining experience with the authority and talent to influence the way studies are conducted from an operational perspective. Research suggests that organizational issues become strategic and of interest to upper management once they have proven relevance to performance.[5]

Recent research by Tufts CSDD determined that a mere 8% of sponsors and 14% of CROs are extremely satisfied with their study startup processes. By comparison, approximately 40% are either somewhat or completely unsatisfied with those processes.[6] Not surprisingly, respondents reporting that they are extremely satisfied have cycle times 57.5% shorter than those that claim to be completely unsatisfied.

While the industry tries to implement processes that improve study startup quality, regulatory efforts may be the driving force. The November 2016 release of ICH-GCP E6(R2)[7] includes a new section focused exclusively on risk-based quality management. It states that the sponsor should implement a system to manage quality from the start, and throughout all stages of the trial process.

Unfortunately, entrenched silos such as site identification, clinical development, data management, contracting and regulatory affairs have long stymied these data flow efforts because they often have minimal understanding of what is needed downstream.

This awkward management style is a root cause of problems with the TMF. Information about the standardized taxonomy and metadata provided in the TMF reference model is not typically shared with study startup team members, so they are frequently unaware of which documents are needed or the required

SSU process cycle time: A three-year perspective

	Sites	Very or somewhat shorter, %	Very or somewhat longer, %
Sponsors	Repeat	18.9%	27.5%
	New	15.9%	35.0%
CROs	Repeat	36.1%	15.3%
	New	23.9%	15.5%
Centralized SSU	Repeat	35.9%	17.1%
	New	27.9%	20.7%
Decentralized SSU	Repeat	17.7%	27.9%
	New	13.5%	33.3%

Source: Tufts Center for the Study of Drug Development, 2017

format for release into the TMF. Since startup generates almost half of the artifacts found in the TMF—data files, documents, digitized content and media—this can create challenges for the regulatory group tasked with mapping documents to the TMF and indexing the metadata.[8]

Fortunately, technology provides the opportunity to rethink the inefficiencies of silos. Some stakeholders want to move away from vertical silos and "think horizontally." This method uses automation and workflows to integrate operational data across all functions, making it easier to extract meaningful insights from those data.[9] Some also believe that bringing interdependent functions together using technology and critical teams will help navigate the highly complicated global regulatory maze.[10]

References:

1. KMR Group. "Site Contracts from Weeks to Months: Results from KMR Group's Site Contracts Study." Press release. August 24, 2016.
2. Gwinn B. "Metrics for Faster Clinical Trials." PharmaVoice, June 2011.
3. goBalto and Tufts Center for the Study of Drug Development. "'START' (Start-up Time and Readiness Tracking) Study."
4. Goldsmith J. "It's Time to Transform Clinical Trials Operations." Applied Clinical Trials, 1 August 2016.
5. Dutton JE, Ashford SJ. Selling issues to top management. Academy of Management Review. 1993;18(3):397-428. Accessed May 31, 2017.
6. goBalto. START II (Start-up Time and Readiness Tracking) Study. 2017.
7. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Guideline. "Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)." 9 November 2016.
8. Trial Master File Reference Model. "Version 3.0 of the Trail Master File Is Here!" 16 June 2015.
9. Fassbender M. "The Rise of 'technology-enabled' Clinical Research Companies. Outsourcing-pharma.com. 17 January 2017.
10. Pisani J., and M. Lee. "A Critical Makeover for Pharmaceutical Companies. Overcoming Industry Obstacles with a Cross-Functional Strategy." Strategy&. 10 January 2017.

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