

Tooling up for Smarter Studies

Two industry studies found need for appropriate trial planning and tools.

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Separate industry surveys by information technology research and advisory firm Gartner and global software company ClearTrial make a strong case for clinical resource management tools in the cost-cutting arsenal of biopharmaceutical and medical device companies.

The Gartner survey of industry sponsors and their technology partners late last year identified several clinical study best practices.

For starters, study-related activities need to get appropriately planned up-front to the right level of depth and detail, says Gartner analyst Steven Lefebure. Companies don't always devote sufficient time to planning, creating costly mid-study surprises. Project managers also need a firm understanding of the study schedule and required resources so that information can be used to better plan studies and keep them on track.

Third, companies need to better match protocol design and study. Many protocols get "very ambitious" in terms of clinical measures and endpoints without an understanding of the downstream consequences, Lefebure says. "It's essential to balance out cost and complexity with...the scientific factors."

Studies require technology-based support at every stage, from data capture to regulatory document management and submission, continues Lefebure. Productivity improvements and cost reductions have already been seen in this arena, but the technology itself has introduced issues. "We find seams between systems, handoff complications between EDC [electronic data capture] systems and data management tools at the sponsor organization, access problems, and...issues in terms of how medical information gets coded across a study." The multitude of systems employed to do discrete study



ClearTrial CEO Mike Soenen says the platform excels at planning, forecasting, and tracking.

tasks only adds to the complexity.

Study information with real-time visibility is yet another industry-identified best practice, says Lefebure, although this is still not the case at many organizations. As suggested by earlier Gartner research, cross-organizational information sharing by the sponsor and its clinical research organization (CRO) partners is another favored practice, especially since their operations and activities can be highly interwoven. Ideally, sponsors are collaboratively engaged with CRO partners in "honest and real communication about study status."

Finally, the industry-best planning process involves both the sponsor and its CRO partners in protocol design and budgeting. This gets all collaborating organizations "on the same page" at study launch, says Lefebure.

Purpose-Built Tools Needed

These best practices are "necessary but not sufficient" to improve study performance, says Lefebure. Also vital are clinical resource management tools "tailored to the job at hand" that can turn information into actionable insights. "Business intelligence tools are not enough."

EDC technology will "fade a bit into the background...because it's not necessarily vital to achieving the next breakthrough in future operational efficiency. A lot of gains have already been achieved in that category."

Lefebure advises companies to seek out clinical resource management tools whose planning and budgeting features "reveal all assumptions" from protocol development through study execution. The software should allow a collaborative environment for transparent information sharing to get "more eyeballs" on problems, he adds.

Linked study planning and execution tools will ensure study plans aren't "obsolete" once trials get underway, Lefebure continues. Gaps between plan and practice can be immediately identified, along with needed actions to ensure the best possible outcomes in terms of resource use.

Although industry opinion is mixed on whether or not systems integration helps with study execution, Gartner research indicates integrated systems and approaches more effectively "move the needle" on performance, Lefebure says. Industry is likewise split on the value of

simulation and optimization tools. Software that enables what-if analysis and scenario planning, in Lefebure's view, is "essential to the future" because it allows assumptions and plans to be tested before real resources are expended – notably, on costly protocol amendments once a study is underway.

ClearTrial's Supportive Technology

ClearTrial has the only fully integrated system for clinical planning, forecasting, outsourcing, and project and financial tracking, notes CEO Mike Soenen. The clinical study operational plan and detailed study budget also get built from the "bottom up" based on assumptions from clinical operations professionals.

Multiple operational scenarios can be quickly developed based on timeline, cost, or resource objectives, says Soenen. Once a study is underway, heads of clinical development and operations can "easily view project status and trends," and project managers can "quickly drill down to pinpoint underlying problems putting the study at risk." New assumptions can

be entered into the system "based on the problems identified to determine the best operational plan for getting the study back on track—in a matter of hours."

The technology also further supports the kind of strategic, long-range planning advocated by Lefebure

In a separate survey of industry professionals with clinical study budget responsibilities, ClearTrial found the use of "old tools" and "wrong tools" hampering the efforts of life science companies to improve operational efficiency, says Soenen. Well over half of respondents rely on Excel as their primary tool for study budgeting.

The same survey revealed serious operational inefficiencies. Only one in ten surveyed are able to keep their cost variances, from forecast to actual, at 5% or below. "What was surprising is that this pattern applies across the board, regardless of company size."

Among other disturbing survey findings:

- 65% of respondents take five weeks or more to complete the review and revision

cycle for a single study.

- 62% of respondents require three weeks or more to roll up individual study budgets into a budget portfolio
- 79% of respondents are only "somewhat confident" or "not confident" in their budget forecasts.
- 88% of respondents have a typical budget variance of at least 6%, with more than half of this number experiencing a variance of 11% or more.

At least some ClearTrial customers are having a decidedly difference experience, says Soenen. One top-20 sponsor using the software reports that annual cost variance is less than 1% across its clinical portfolio.

A small biotech customer successfully negotiated cost savings of \$2 million with its CRO for a single phase II oncology study. And a mid-size customer reduced its contract closure time from 2.5 months to 2.5 weeks for outsourced studies using ClearTrial as the common platform for negotiations with its CRO. "This proves that operational efficiency gains are indeed possible," observes Soenen. ●

