DRUG DISCOVERY & DEVELOPMENT©

Study Startup: New Battleground in CRO Differentiation Strategy

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The drug development process is long, arduous, and costly, driving many sponsors to consider greater use of contract research organizations (CROs). This move reflects sponsors' sharper focus on core competencies and the shifting of management and conducting of clinical trials to CROs. One recent CRO survey reported that 80 percent of respondents expect increasing demand for CRO services this year. Other research anticipates a 7.4 percent compound annual growth rate for the CRO market through 2019, and a market penetration rate of 72 percent by 2020. Yet, at the same time, there are clues that this significant market penetration indicates a maturing market, leading to eventual slowing of revenue growth, possible reduction in the number of CROs, and fewer new customers.

With the CRO market approaching tipping point, forward-thinking CROs are looking to differentiate themselves as competition stiffens. Differentiation is an opportunity for CROs as they move away from commoditized, tactical service offerings emphasizing lowest price, in favor of becoming risk-sharing strategic partners in the race for faster and higher quality clinical trials. At a time when study startup (SSU) remains a perpetual bottleneck, CROs that embrace solutions that confront this challenge may be positioning themselves as a step ahead of the competition.

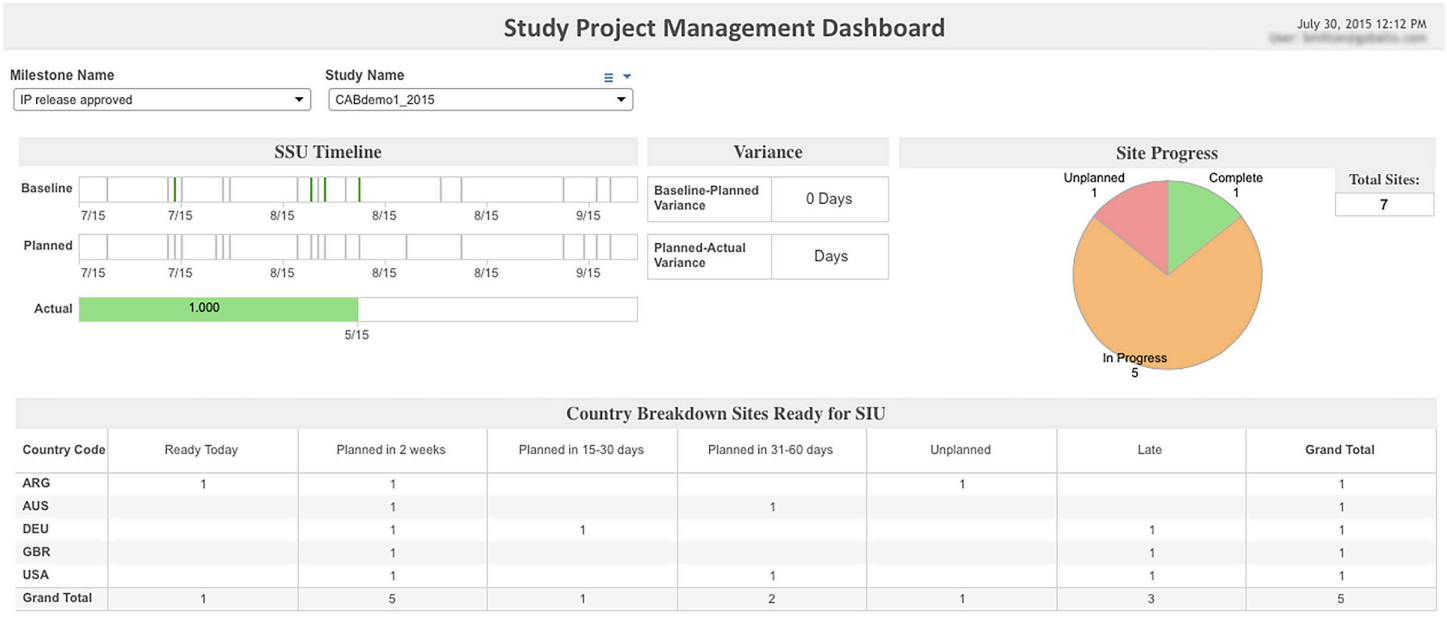
The SSU bottleneck

SSU is an array of activities performed to launch a clinical trial. This early stage of development is complicated by the rising globalization of clinical trials, in addition to traditional tasks such as site selection and initiation, regulatory document submission, contract and budget negotiations, and enrolling the first patient. It is a slow process, taking an estimated eight months to move from pre-visit through site initiation. A 2014 report sponsored by the U.S. Department of Health and Human Services cites the already sluggish SSU process as stalled further by sponsor-imposed barriers, such as complex internal review methods and highly restrictive inclusion/exclusion criteria. Adding to the list of slowdowns are insufficient recruitment planning, issues of poor case report form design, and delays in site initiation. Much of the inefficiency stems from the fact that many SSU tasks are either paper-based or rooted in spreadsheets, making it difficult to track activity in real-time and view trends.

As competition intensifies, CROs can bring value to the clinical trial process by emphasizing differentiation and operational efficiencies that address these very real SSU challenges. To date, CROs have stepped up by implementing eClinical solutions, such as clinical trial management systems (CTMS), electronic data capture (EDC), and the electronic trial master file (eTMF), but bringing differentiation to SSU operations could be the next battleground, and might involve adopting a purpose-build cloud-based solution.

This technology allows for the collection of SSU data on individual site performance, country performance and submission activities. Using an application program interface (API), the solution integrates with eClinical functions to optimize data flow among the integrated components. The information can be accessed through a dashboard using a single sign-on, a major improvement over having to logon to each solution separately.

With its reporting tool, the SSU solution creates reports with actionable information and data analytics that help the CRO and stakeholders view study status in real time, including presence of bottlenecks. This functionality helps identify bottlenecks by evaluating completion of documents on the critical path, such as site contracts or an informed consent form (ICF), and tracks cycle times amongst individual sites as well as countries (Figure 1). If a report signals a trend toward longer completion time for contracts, for example, the CRO can act quickly to steer lagging sites back on track, or consider adding new sites.



Country Code	Ready Today	Planned in 2 weeks	Planned in 15-30 days	Planned in 31-60 days	Unplanned	Late	Grand Total
ARG	1	1			1		1
AUS		1		1			1
DEU		1	1			1	1
GBR		1				1	1
USA		1		1		1	1
Grand Total	1	5	1	2	1	3	5

Figure 1. This is a high level executive view of study progress by country with projected work to be completed. This dashboard allows a functional manager and study manager to know the resource needs for the upcoming weeks and months based on work completed to date. (Credit: goBalto 2015)

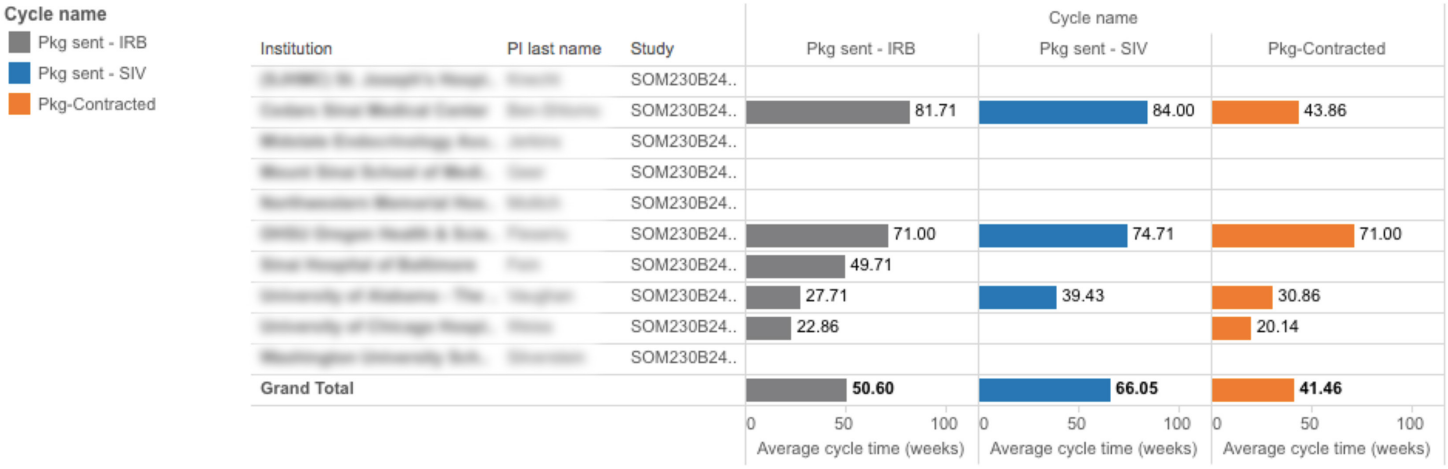


Figure 1. This report allows teams to understand the SSU performance of sites and their investigator, including cycle time for completion of SSU packages. (Credit: goBalto 2015)

A More Competitive Future

The issue of competition is destined to loom large for CROs, so developing a strategy of adopting an SSU solution is a smart way to handle this inevitability. In taking this approach, CROs are aligning with sponsors' efforts to refine their selection progress for the right CRO. As explained in a survey on CRO selection, there are a whole host of deciding factors, such as experience and sound management of the CRO/sponsor relationship, but use of disruptive technology and ability to execute the project plan are also key. For example, the survey defined "execute the project plan" as including country and site selection capability, features that can be tracked with a purpose-built SSU solution.

The process of initiating clinical trials is cumbersome, challenging, and often behind schedule, making SSU one of the poorest performing aspects of clinical trials. As CROs fight to maintain market share and ensure long-term survival, the next battleground may be the improvement of SSU operations, and those companies able to take those steps may be well positioned to reap the rewards.

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