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Moving beyond clinical and operational metrics in study startup

By Craig Morgan

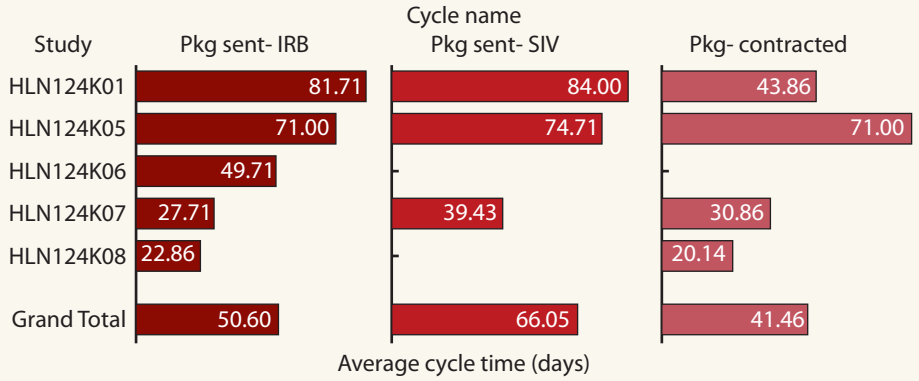
Metrics are central to efforts to rein in clinical trials that are either poorly initiated or have incurred unforeseen events, which place the original timelines and/or budgets at risk of overages. They also drive competitive performance among those organizations performing trials.

Business Intelligence (BI) has become an increasingly popular topic in clinical trials. Clinical project managers are expected to make smarter decisions on intelligence derived from clinical trial data and sponsors/CROs are looking for ways to incorporate BI into the eClinical systems they are using to empower oversight—turning raw trial data into actionable information.

Having technology that can automate or assist in the timely monitoring of trials is a huge improvement over current manual methods such as spreadsheets, which are cumbersome and erroneous, not to mention only provide a dated snapshot of trial performance. But how do metrics drive performance competitiveness?

Benchmarking of trial data allows research teams to gauge their performance and progress against internal data, as well as externally run trials. Are they on par with past trials of a similar size, geographic footprint, therapeutic area, indication, etc? If not, why not? But arguably the more important question is: How is the team performing against other organizations? This is particularly important with regard to maintaining or justifying a continued sponsor/CRO relationship. A review of benchmarking data may indicate red flags not otherwise raised during the monitoring of the trial, and may be country-specific.

Example of a report that allows teams to understand the study startup performance of sites and their investigator, including cycle time for completion of study startup packages.



Note: Not included are institution and PI name columns

From an internal perspective, organizations can capture cycle-time metrics on whichever artifacts they deem important to measure; as long as these metrics have clear definitions and are measured consistently between trials, these measurements become internal benchmarks upon which future trials can be gauged. For external purposes, clear, consistent and concise industry-wide standards are required. This ensures a true "apples to apples" comparison that has the added benefit of improving trial data quality, because data that might not have been previously recorded, such as certain start or stop dates, is now required.

With standards in place that can be applied across all studies, global milestones need to be utilized. Global milestones are important because they recognize that the nomenclature of artifact naming conventions is not consist across organizations or even countries, nor will it ever be. For example, these are dependent on an organization's SOPs where the events Activated, IP Release, and Site Initiated could be synonymous. Global milestones ensure that cycle-time metrics can be accurately measured and mapped to an industry-defined standard.

By applying industry standards and global milestones, the goal of industry benchmarking in clinical trials is achievable. But this is not the end of the story. In reality, it is just the beginning.

In the context of clinical trials, gamification presents an excellent opportunity to improve performance efficiencies. There

are a number of areas that hold promise, including patient and CRA retention, disease research, investigator and site training, patient recruitment and improving site performance.

Benchmarking would also allow for efficient resource allocation. A review of subpar performance may indicate that this is simply due to staffing issues, affording executives the option of either allocating more staff to critical steps in the progress or opting to incur the subsequent financial ramifications from a delayed launch to the market.

Lastly, benchmarking is the precursor to predicative analytics or forecasting, enabling clinical research teams to estimate future outcomes based on their current state of progress—critical to risk mitigation and a preemptive weapon in the fight against the dreaded rescue study.

CROs, often seen as the bastions of innovation, are leading this charge into the BI foray. Top CROs have been aggressively acquiring data sources to leverage in data mining. In 2013, PPD acquired Acurian to gain analytics-driven feasibility capabilities; LabCorp acquired Covance for collective data resources to drive greater R&D productivity; and Quintiles merged with IMS Health last year to improve clinical trial execution using patient data.

What is the common thread? We now operate in a data-driven environment.

Craig Morgan is a technology and life sciences management professional with more than 15 years' experience in the application of informatics to drug discovery. He leads the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times, improve collaboration and oversight in clinical trials. Email cmorgan@gobalto.com or tweet @goBalto.