CONQUER STUDY START-UP DELAYS WITH A DATA-DRIVEN APPROACH

By: Jill Johnston

For over 25 years, study start-ups have plagued the pharmaceutical industry. These delays keep potentially lifesaving drugs from the patients who need them and increase costs for the R&D industry.

With so much at stake, why hasn't the problem been solved? It hasn't been from a lack of effort, but rather from the lack of comprehensive data and analytic tools that help operational teams predict outcomes and develop risk mitigation strategies. Gaps in key performance and quality data plus a lack of optimal processes have made it difficult to access and aggregate data into a usable format to inform decisions and improve outcomes.

Today, advances in computing and analytic capabilities enable aggregation of various public and licensed data sources to provide insights that simply did not exist before. A new approach to solving start-up delays is built on this foundation of advanced data analytics and **accelerates study start-up timelines by 33 percent.**

What Sponsors Need

Sponsors realize they need data and insights to make better decisions. But many times, they only have access to in-house data, and/or their CRO's data and public sources of less-robust trial information. Licensed solutions are another option, yet an expensive one. All of these sources of fragmented data are still insufficient to provide the insights needed to make important study start-up predictions.

For data to be useful for predictive analytics, it needs to have three elements:

- Volume - broad base of many data points
- Velocity - quick accessibility and current, and
- Variety - large number of types of data

Without a comprehensive dataset that addresses all of these factors, analytical models cannot generate accurate insights or predictions.

Fortunately, volume, velocity, and variety of data are all becoming more accessible today due to advances in technology. Data that was once isolated in legacy systems and other disconnected sources can now be normalized and connected, thereby providing a rich source of investigator and site performance information. Data coming in from a variety of sources can be processed and accessed quickly to provide current insights. With a more complete view of industry data and the right analytical tools, we can start to address the four biggest start-up challenges and accurately predict outcomes, such as:

- When will my first site be activated?
- When can we enroll the first patient?

- Which are the best sites for a study?
- When will my study complete enrollment?

The 4 Key Areas Of Start-Up Delays

Addressing a problem of this magnitude starts with identifying and focusing on the key drivers of delays. With literally hundreds of variables impacting trial timelines, delays rarely have a single cause. Analysis of global trial data points to four key reasons for start-up delays.

1. *Site selection and feasibility* - Sponsors often use the same sites over and over for their studies. This is a problem because they miss out on the opportunity to select the best sites for a study, which may include ones previously unknown to them. To choose sites, sponsors habitually refer to the same licensed sources that happen to be incomplete and not always current because they are populated with self-reported data (i.e., not mandated to be reported by regulations). The sources also provide no insight into site feasibility. How can this be improved? What if you could use historical data to accurately predict the highest-performing investigators for your protocol? What if you could further refine that list by ranking the highest performing sites by turnaround time for feasibility? What if the source data came from more current and complete FDA-mandated reports?

2. *Site contracting* - The investigational site contracting process is the most common reason for study delays, responsible for 49 percent of study delays.[1] What if you could use sites' contract timing history as a factor in site selection? What if you could reuse a site's previously approved language to prepopulate site contracts as a starting point for future contracts?

3. *IRB review and approval* - The decision of whether to use a local or centralized Institutional Review Board (IRB) can impact your start-up timing. Can you afford to use local IRBs that average five weeks or more to reach a decision on final protocols compared to a centralized IRB that reaches a decision in seven days on average?[2]

4. *Patient enrollment* — Overburdened sites have a difficult time finding appropriate patients for the studies. Often at least a quarter of the sites, and sometimes more in certain clinical indications, end up never enrolling a single patient in the trial. This is another key area of delay, causing 41 percent of study delays.[1] What if you had visibility into sites' upcoming workloads and you also had analytics to know the maximum workload each can handle without a performance decline? What if you could avoid overburdened sites? What if you could accurately predict the patient enrollment time for each study based on history of previous studies?

Because of the dependencies that exist, the above causes must be managed simultaneously and holistically. Focusing on one or two causes and ignoring the others is a risky approach since any one of these causes can delay the entire trial. Admittedly, this is a big job. The sponsor or CRO often cannot provide the level of intense focus and expertise needed for the start-up process while also managing and monitoring the many details of the trial. What does a solution look like?

A Game-Changing Start-Up Plan

How can you accelerate the start-up timeline by 33 percent? The plan has multiple components:

- Address each of the four key causes of delay in your start-up planning process.
- Build in accountability and metrics to drive intense focus in all four areas in parallel.
- Use technology to streamline burdensome and redundant documentation processes such as feasibility and CTAs.
- Close data gaps and use predictive analytics to improve site selection and patient enrollment.

How can you close the data gaps? WCG is uniquely positioned to close the data gaps. While best known for its IRB leadership, WCG's additional clinical services divisions are a rich resource of the much-needed volume and variety of clinical trial data. WCG has proprietary access to site performance data for 90 percent of FDA-regulated protocols, global site budgets, contracts, payments, operational metrics, quality data, and enrollment rates, just to name a few. These proprietary data assets provide the most comprehensive source of clinical trial data in the industry. All of this data, when aggregated and aligned with advances in computing power and analytical capabilities, provides valuable insights and uniquely positions WCG to help pharmaceutical companies streamline start-up processes.

How can your company resource a start-up plan? WCG provides a study start-up solution called Study Fast Start. The goal is to assist clients with minimizing the time to "last patient first visit." This is done by identifying and qualifying proven high-performing sites and significantly reducing low- or non-enrolling sites and managing patient enrollment through to evaluation of patients for randomization. WCG provides the data, analytics capabilities, services, and resources to achieve this.

Is WCG attempting to be a CRO? The Study Fast Start solution is not to be confused with the role of the CRO, as WCG does not conduct full program outsourcing. Rather, this start-up

service provides key insights, unique services and solutions to better enable the execution of critical clinical trial processes. In doing this, WCG enables biopharmaceutical companies, CROs, and institutions to more effectively plan and run clinical trials and speed delivery of new treatments and therapies to patients, while maintaining the highest standards of human subject protections.

Quick start-up of investigational sites maximizes the amount of time each site has to enroll patients before the "last patient in" (LPI) deadline. To achieve this, a start-up solution needs to proactively address the roadblocks that keep sites from reaching their potential, while capitalizing on experiential knowledge, technology, and data to help customers meet their intended enrollment goals and objectives.

Learn more about WCG's Clinical Study Fast Start Solutions. To understand how WCG can help with your study timeline, contact Jill Johnston at jjohnston@wcgclinical.com.

Sources

1. Tamkar, Priya, Accelerating Study Start-Up: The Key to Avoiding Trial Delays, Clinical Researcher, February 1, 2017, https://www.acrpnet.org/2017/02/01/accelerating-study-start-up-the-key-to-avoiding-trial-delays/

2. Abbott D., Califf R., Morrison BW, Pierre C, Bolte J, Chakraborty S. Cycle Time Metrics for Multisite Clinical Trials in the United States. Therapeutic Innovation & Regulatory Science. 2013;47(2)152-60.

About The Author

As President of WCG's Site Activation Solutions, Jill is responsible for developing strategy, driving the vision, and delivering for customers as WCG continues to drive ingenuity in the clinical research space as it relates to site identification, selection, and activation. The aim is to deliver transformational site activation solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials. With over 25 years in clinical research, Jill is an expert in clinical business strategy, transformation, innovation, pharmaceutical efficiency, and clinical research operations.

Prior to WCG, Jill was the vice president of Vault Clinical at Veeva. Jill was responsible for providing thought leadership, driving development of product and market strategy, and coordinating resources across the customer life cycle from sales to delivery for eMF, study start-up and CTMS.

Before joining Veeva, Jill spent the majority of her career at Covance, where she held a variety of strategic roles in clinical operations, project management, and as a Six Sigma Black Belt. She spent the early part of her career running large global clinical trials in oncology, cardiovascular, metabolic, and neurology compounds. As she moved into more strategic roles, she provided executive level guidance and led a team of scientific, operational, and medical experts to bring about customized, practical, and evidence-based solutions.

Jill holds a BSc in biology from SUNY – Environmental Science and Forestry and is an instructor for clinical monitoring at Mercer County College, supporting Drexel University's Clinical Development Master program. She was previously the founding president of the ACRP Chapter in the Greater Philadelphia area, and she is a frequent speaker at industry conferences.

About WCG

The pioneer of independent ethical review, WCG continues to drive ingenuity in the clinical research space. Today, WCG's solutions are built upon the foundation of ethical review, but have grown to include a suite of complementary services and technologies that expand the capabilities of the modern research professional. WCG delivers transformational solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials.

WCG is proud to serve the individuals on the front lines of science and medicine and the organizations that strive to develop new products and therapies to improve the quality of human health. It is our role to empower them to accelerate advancement, while ensuring that the risks of progress never outweigh the value of human life.