

# Learning to Fish in Data Lakes

**Companies should look to optimise their clinical operations by using monitoring technology, analytical dashboards, and operational metrics to gain powerful insights**

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Today, clinical operations teams are drowning in data but starving for information, at a time of intense pressure to speed up clinical trials and restrain costs (1). The massive volumes of data generated during clinical trials are woefully inadequate at helping stakeholders spot risk factors and bottlenecks that can disrupt cycle times and budgets, primarily due to the inefficient ways in which operational data are captured and analysed, often relying on outdated methods such as Excel. Excel was not designed to collect and analyse clinical trial data as it lacks project management capability, yet its extensive use persists (2-3).

Having technology that can automate or assist in the timely monitoring of trials is a huge improvement over the current status quo of manual methods such as spreadsheets, which are cumbersome and erroneous, not to mention they only provide a dated view of trial performance.

The use of business intelligence (BI) in clinical trials was not always as common, but now, due to the demand for more optimised studies in today's ultra-competitive global marketplace, things are starting to change (4). Kramer *et al* acknowledged that clinical trial technology has become routine, but the supporting business model has not evolved alongside it (5). Obsolete methods to track study conduct is shaped by the use of paper-based models for clinical research, and transformation is essential if the sector is to reap the benefits of new technology. This is where BI comes in.

Technologies that track how studies unfold are essential, but putting that information to good use requires turning real-time visibility into actionable data. Therefore, risk mitigation is optimal, using systems that can provide timely, preferably real-time data on trial bottlenecks, which indicate red flags to be reviewed and addressed, or at least tracked carefully throughout the trial. The power conferred by such real-time intelligence directly impacts the efficiency, cost, and reliability of clinical operations (6). This requires access to critical information that allows stakeholders to be proactive in making decisions faster, better, and based on fact. BI incorporated into eClinical

systems is empowering this oversight by turning raw trial data into actionable information.

An effective study startup process (encompassing the activities associated with site identification, feasibility assessment, selection, and activation) is fundamental to the overall operational success of a clinical trial as it is the most impactful phase of the trial's lifecycle. As stakeholders are increasingly aware that better study startup processes are linked to shorter clinical timelines, the emphasis has been shifting in that direction (7-8).

Purpose-built study startup systems that utilise advances in data analytics and visualisation have now become an integral component of decision support systems, aiding compliance and affording clinical research teams an opportunity to intervene before the effects of a risk have been incurred. Of paramount importance to project managers in this endeavor are analytical dashboards, but like the data they display, dashboards alone do not provide value; it's up to experienced clinicians to distill insights.

Analytical dashboards represent a logical evolution from earlier practices of using control charts, scorecards, metrics-based snapshots, and other measurement techniques to gauge progress. The advantages of dashboards to monitor the progression of a trial and compliance with budget/timeline goals cannot be overstated – aiding important communication and planning activities among all stakeholders.

When utilising operational metrics, dashboards capture and display metrics associated with an increasingly smaller slice of time/artifact activity, which is critical when reviewing processes for optimisation and providing an organisation with a competitive edge. The risk posed, however, is that detailed and elaborate dashboards may lead to suboptimal decisions being made due to information overload.

Smaller slices of information that populate dashboards can make them more susceptible to outliers. While it is critical to investigate the causes of these outliers – outside

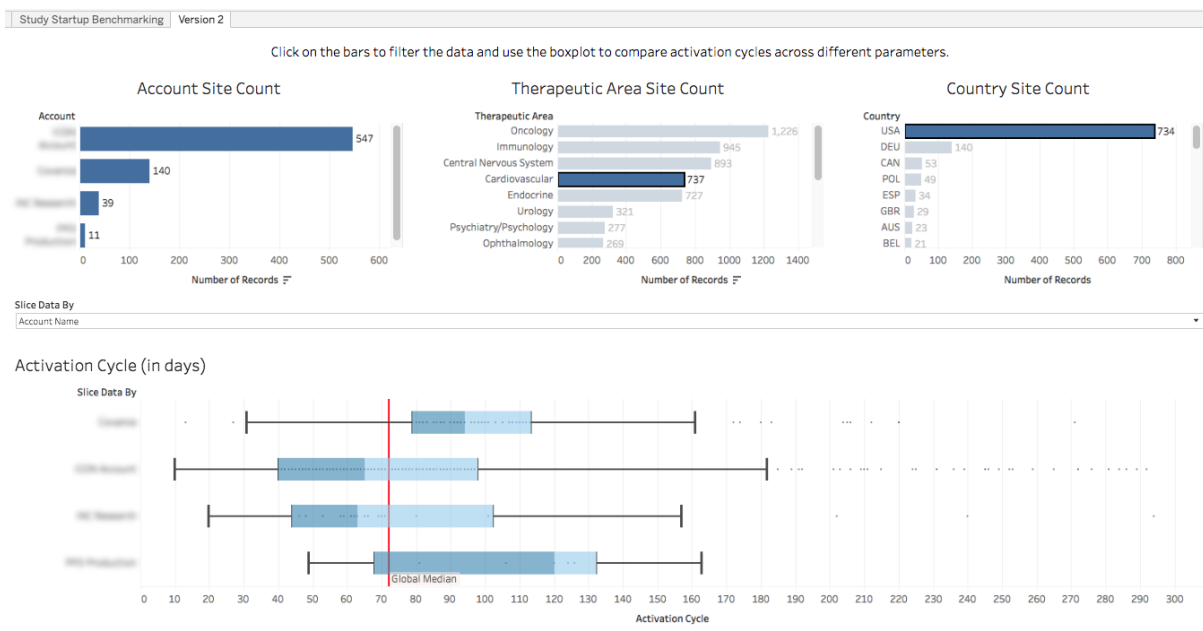


Figure 1: Benchmarking report showing activation cycle times of cardiovascular studies in US

of a confidence range based on an internal or industry benchmark – focusing on spikes can make managers reactive.

Before hunting for insights, project managers must have a clear idea of what is actionable. Organisations that travel down the rabbit hole of data exploration will lose time and waste employee energy unless they can set parameters on what they want to achieve.

A useful dashboard can help set goals, monitor performance, and provide implementation metrics and strategic insights. Project managers must also decide on the frequency and granularity of data used in dashboards.

According to Jeff Kasher, President of Patients Can't Wait, and formerly Vice President of Clinical Innovation and Implementation at Eli Lilly and Company, "Turning big data into big insights requires analytics that are actionable. Performance metrics must be data-driven, standardized across studies, indication, and therapeutic areas, and timely. They must also, importantly, facilitate a forum for discussion".

Big Data and automated processes are giving hope that actionable insights will automatically appear, as if by magic. However, finding actionable insights is driven as much by smart humans as it is by actual data (9). Nevertheless, a paradigm shift in the consumption of insights generated from clinical trial data is omnipresent, driven by the marriage of dashboard analytics embedded within applications at critical decision-making points.

Benchmarking of trial data allows clinical research teams to gauge their performance and progress against historical data, as well as externally (i.e., trials run by other organisations). It is this ability to see at a glance if they are on par with trials of a similar size, geographic footprint, or therapeutic area that provides powerful insights. This is particularly important in the case of a CRO vying for a pharmaceutical outsourced study contract or for the pharma's need to justify the continued outsourcing relationship. A review of benchmarking data may indicate red flags not otherwise raised during the monitoring of the trial and may be country specific.

Benchmarking is the precursor to predictive analytics or forecasting, enabling clinical research teams to estimate future outcomes based on their current state of progress (10). This is critical to risk mitigation and a pre-emptive weapon in the fight against the dreaded rescue study. By leveraging predictive analytics, clinical operations teams

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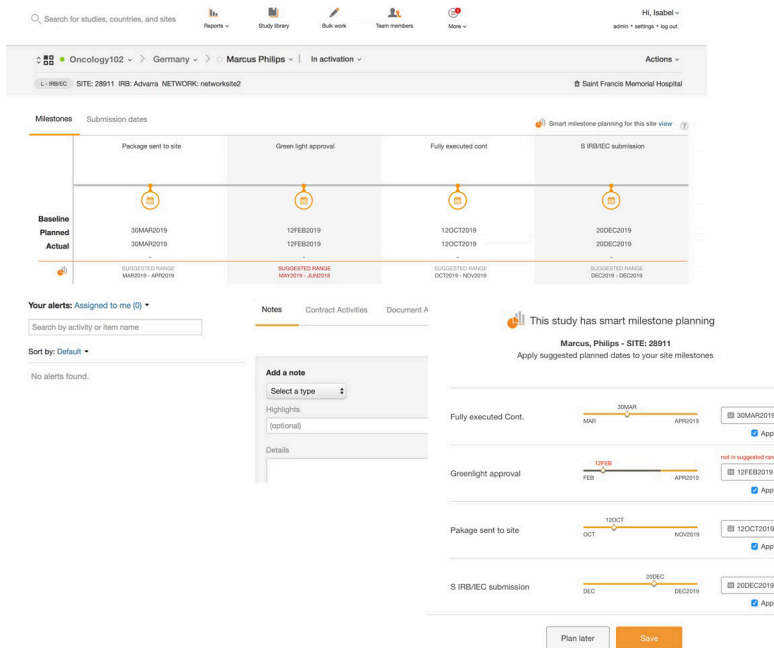


Figure 2: Predictive analytics used in milestone planning can flag milestone dates outside of expected data ranges

can be guided in milestone planning with in-application planning assistance.

This proactive planning assistance can alert teams to unforeseen issues, which allow for discussions and decisions to be made before studies incur risk due to missed timelines. For example, in Figure 2, the planned completion data for greenlight approval was 12 February, but the system alerts the clinical operations team that this date is outside of the anticipated range. The system, using machine learning and based on dynamically updated metrics in real-time on study and site metadata, recommends a suggested range of May-June. This is in stark contrast to using static cycle times from outdated printed industry reports or an organisation's own historical data.

Analytic dashboards are essential tools for shedding light on process bottlenecks and offering insights into complex, multi-site, global, and concurrently run clinical trials in real time. They relegate descriptive, static status reports to the archives and empower data-based decision making – driving a competitive advantage and optimal proactive planning in study execution. They also provide an opportunity for in-depth internal reviews of organisational processes, resource allocations, study costs, and quality assessments (11). High-quality data means data that are complete, consistent, and correct (12). What degree of confidence do you have that your data have been entered correctly? What auditing do you have in place for not just regulatory data, which are subject to audits, but also performance data? After all, if your competitive advantage

is built on poor quality data, it might be more perception than reality (13).

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## About the author



**Craig Morgan** is responsible for directing the global marketing strategy and team for the Oracle Health Sciences suite of study startup applications, working with sponsors, CROs, medical device manufacturers, and sites to reduce cycle times and

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