BI the Way

The potential of eClinical technologies can be optimised through the use of cloud-based tools for analysing business intelligence, with actionable visual reports helping to identify study bottlenecks and improve performance

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The clinical trials sector is heavily invested in technologies that track how studies unfold, but putting that information to good use requires turning real-time visibility into actionable data. It is not enough for a sponsor to know that one site enrols quicker or is speedier than others at turning around the study budget. Instead, it is more effective to understand what it takes for all sites to complete those tasks in a timely manner and where the bottlenecks are, so steps can be taken to turn more sites into high achievers.

This requires access to critical information that, when quickly spotted in reports, is actionable – allowing project managers and other stakeholders to be proactive in making decisions faster and better, based on fact. Putting this data in a useful format requires processes regularly referred to as business intelligence (BI).

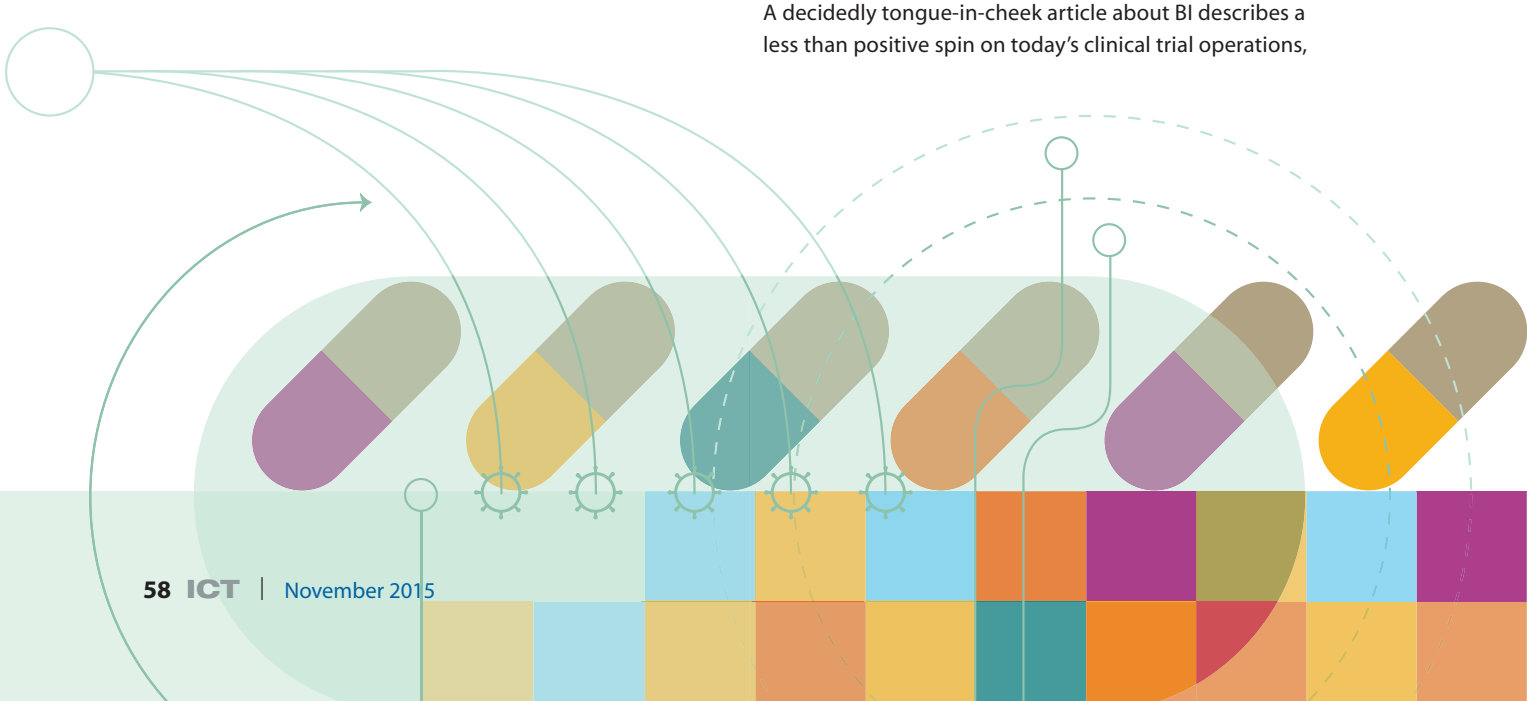
Business Transformation

Until recently, use of BI in clinical trials has been far from commonplace, but that is beginning to change, driven largely by a need to revamp how studies are conducted in today's ultra-competitive global marketplace. In an insightful piece, Kramer *et al*, acknowledged that while clinical trial technology has become routine, the supporting business model has not evolved alongside it (1). The continued use of obsolete methods to track study conduct reflects ties to processes shaped by previous generations of paper-based business models for clinical research. Business transformation is a must if the sector is to benefit from what new technologies have to offer – which is where BI comes in.

At a time when it takes an estimated eight months to move from pre-visit through site initiation – and the cost of initiating one site is in the range of $20,000 to $30,000 – altering how study information is collected and used is a transformation way long overdue (2,3). For starters, BI is best when gathered by robust reporting tools that offer visualisations, making it easy for sponsors and CROs to hone in on which tasks are behind schedule, which countries are struggling, and which sites are yet to be activated. Not long ago, this reporting capability had been missing from many of the available electronic clinical trial technologies, but newer solutions are now addressing this gap.

Breaking-Down BI

A decidedly tongue-in-cheek article about BI describes a less than positive spin on today's clinical trial operations,



Box: Re-Thinking Patient Recruitment

For a long time, speeding patient recruitment has been a key focus of SSU, given the dismal statistics that half of investigative sites under-enrol, 11% of sites fail to enrol a single patient in a clinical trial, and just 13% exceed their enrolment target. Also, Tufts Center for the Study of Drug Development reports that timelines are sometimes doubled to meet a study's enrolment goals.

To address this issue, there has been a shift in thinking away from patient recruitment as an isolated SSU activity. There is a growing realisation that if sites can be initiated faster, patient enrolment seems to happen faster (11).

Barry Milton, Director of Pre-Sales at goBalto, and previously Director of Project Management Planning and Regulatory Document Management at Novartis Pharmaceuticals, comments that while at Novartis, many observed how sites that open quicker go on to recruit patients faster: "We know this historically. A site that is open and able to recruit their patient is far more likely to recruit a second patient into that study; so if we delay their study start-up, they may miss recruiting their first patient. In fact, they may not recruit any patients."

In gathering data that speeds SSU, and linking those data to greater patient recruitment success, processes can be implemented to repeat the success in future studies. Those milestones can be built into the BI history.

referring to the processes around study execution and analysis as a 'slavish, box-ticking Sisyphean nightmare'. And this is before factoring in the problems caused by older, so-called 'lead-footed tools and technologies' (4).

Fortunately, newer technology enables BI, which is all about the flow of captured data from patient, to the investigator to management, and then onto analysis. In simple terms, BI is a widely accepted, technology-driven process for analysing data and presenting actionable information to help make informed business decisions faster (5). BI – a term first coined in 1989 – is meant to optimise processes that support users in identifying and addressing business problems (6). In its early days, this approach was used to tackle prevalent business problems, such as how to accelerate check-out lines or improve inventory control.

Dashboard Metrics

BI processes are developed from an array of tools, applications and methodologies that allow organisations to collect data from internal systems and external sources, prepare them for analysis, and create reports, data visualisations and dashboards to make the resulting analytics usable for stakeholders (5). In applying this general definition to the clinical trials market, it is important to ask: with volumes of data being generated, which ones are needed for BI?

For clinical trial operations, data that is to be collected and analysed for BI are characterised by the protocol and statistical analysis plan (4). A BI solution is able to plug into one or more data sources, such as the clinical trial management system (CTMS), electronic data capture (EDC), safety, and financial systems. The solution then aggregates and summarises data, and displays key performance indicators usually accessed through a dashboard (7).

Using this data, it is possible to lay out the roadmap for identifying bottlenecks and other risk factors that may throw the study off course. For trials, the promise offered by BI is in its capacity to foresee those risks, compare results to milestones and, ultimately, reduce cycle time. By comparison, traditional spreadsheets – still widely in use – lack the ability to link critical data, creating a void when it comes to the visualisation of data and decision-making.

Start-Up Improvements

Study start-up (SSU) is widely acknowledged as an aspect of clinical trials in dire need of improvement. Bringing a higher level of predictability and quality to this multi-step process is of critical importance to industry stakeholders (8). In particular, SSU activities – for example, site identification and feasibility, contract and budget negotiations, patient recruitment activities, and managing regulatory documents and drug accountability – have traditionally been handled via laborious manual or siloed processes. Because these

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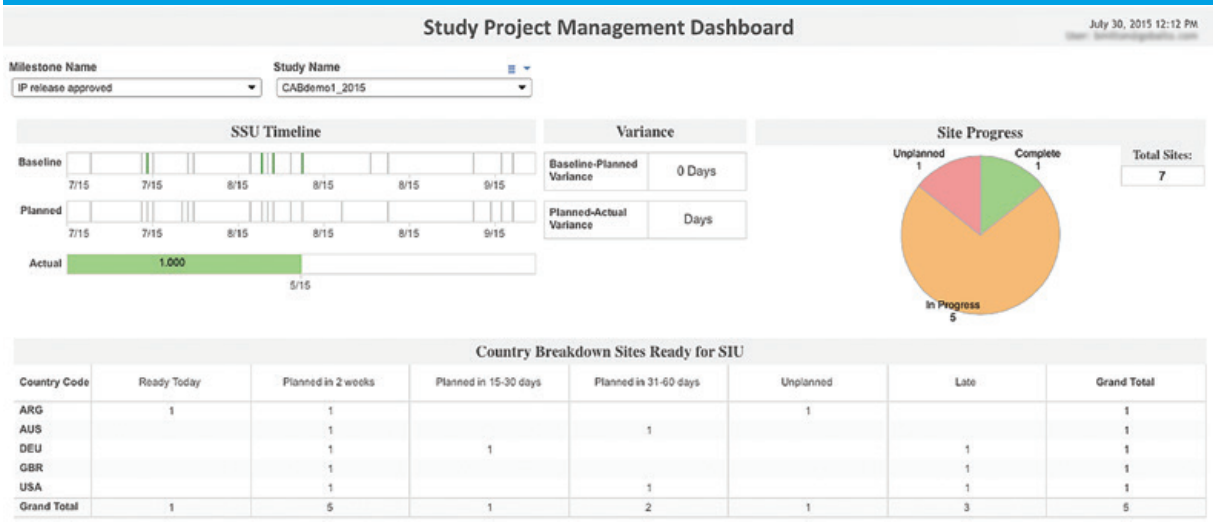
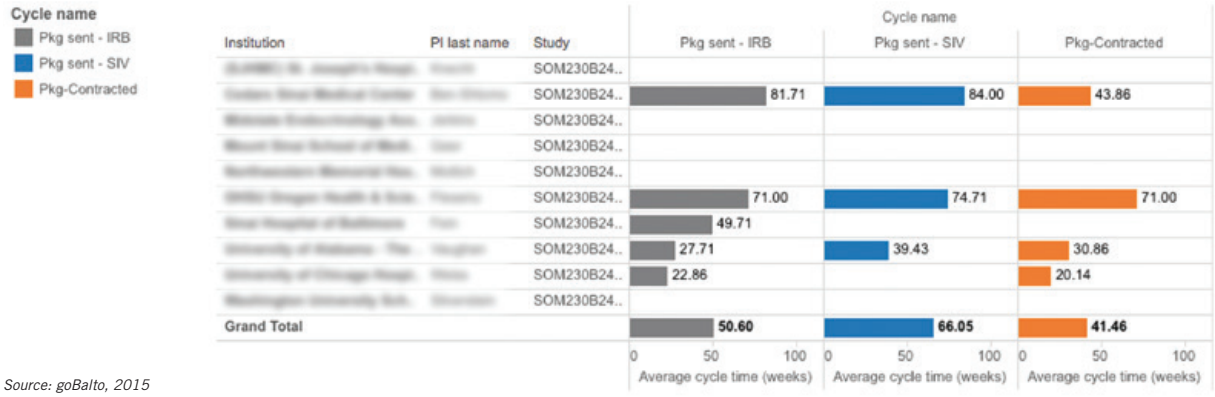
Figure 1: Dashboards showing SSU visualisations



Above: This is a high-level executive view of study progress by country with projected work to be completed. The 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.

Below: Predictive analytics are key to site selection. This report enables teams to understand the SSU performance of sites and their investigators. It allows for risk management, especially where the contracted dates at one site are 71 days versus the average of 41 days for the remaining sites.



Source: goBalto, 2015

tasks have frequently been performed without an organised approach, resulting inefficiencies have led to missed timelines and cost overruns.

However, there have been significant improvements to SSU tied to electronic, real-time document collection and data reporting systems. Stakeholders are starting to align these technologies with critical path project management and resource centralisation initiatives, in a bid to reduce trial initiation times (8). Still, much work is needed to implement greater use of reporting tools that bring BI to study start-up.

Reporting Tool

The BI reporting tool is a cloud-based technology that permits the collection of SSU data – once consolidated – and enables users to pre-populate standard text and devise ad hoc reports, with drag and drop visualisations an added extra. The SSU data include information about individual site performance, country performance and submission activities, and are collected from existing cloud-based solutions such as SSU, CTMS, EDC and the electronic trial master file. The SSU solution uses an application program interface that integrates with the various eClinical functions to optimise this data flow among the integrated components (9). Access to the information is through a dashboard using a single sign-on – a significant improvement over having to access each solution separately.

The ensuing reports contain a wealth of data, and serve as the basis for analytics that help stakeholders determine study status, as well as identifying and resolving bottlenecks. Reports can either be a standard part of the solution or ad hoc. Importantly, they can be shared quickly with members of the clinical team in a simple, secure method that generally entails clicking 'share' and providing an e-mail address to authorise team members to see the dashboard and one of more reports. Information is available at the site, country or regional level, and can reflect individual studies or groups of studies across the portfolio.

Understanding how the reporting tool identifies a bottleneck may involve looking at documents on the

Table 1: Various cycle time reports available through a BI reporting tool

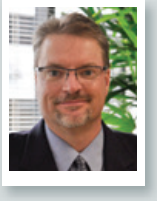
Cycle times	
Report	Description
Site milestone cycle times	The amount of time (in days) spent on each milestone at each site
Average cycle times by study	The average cycle time (in days) for each selected site milestone in all selected countries, listed by study
Study average cycle times side by side	The average time (in days) spent on each milestone (at both the country and site levels) across studies, to compare study efficiency and averages
Planned vs actual cycle times	A side-by-side comparison between planned cycle time and actual cycle time for milestones (at both the country and site levels), for selected studies, countries and cycles
Country actual vs average cycle times	Site and country milestone actual cycle times and averages, rolled up to the country level
Site actual vs average cycle times	Site milestone cycle times (in days) to compare site performance, and the average

Source: goBalto, 2015

critical path, such as site contracts or an informed consent form (ICF). As a study is unfolding, stakeholders can track how long it takes individual sites, as well as countries, to complete those contracts or ICFs. As new sites are initiated, it is also possible to monitor their progress. Is it taking them five weeks on average, or eight weeks? Is this longer than the established benchmark? If a report shows a trend toward longer completion time for contracts, stakeholders can take action to steer sites back on track. Another example illustrating the value of BI is how actionable data that speeds SSU can ultimately accelerate patient recruitment – a long-time bottleneck (see box on page 59).

A high-level view of study progress by country and a predictive analytics report appear in Figure 1, showing how reports can be clearly visualised using pie charts, bar charts or tables. Examples of items that can be tracked, analysed and reported might include: cycle times for various activities; length of time since cycle-start activities were completed; individuals responsible for completing tasks; and leading indicators. Table 1 lists various cycle time reports available through the reporting tool.

About the author



Craig Morgan is a technology and life sciences management professional with more than 15 years experience in the application of informatics and bioinformatics to drug discovery. He currently heads up the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times, and improve collaboration and oversight in clinical trials.

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Meaningful Patterns

Improved SSU has the potential for overhauling how large quantities of study-related data are collected, handled and parsed. If those data are consolidated and flow into a robust reporting tool that allows study team members to aggregate data, view standard reports or create ad hoc ones and customise data visualisations, it becomes possible to uncover meaningful patterns within the data (10). This analytical approach defines BI, and is a major step forward in ensuring visibility of real-time data sets that help stakeholders be proactive in identifying bottlenecks and take action based on facts. The intent is to use the technology to build a competitive edge and deliver promising therapies to patients sooner.

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