

A new day for Clinical Trial Management

Pharmaceutical companies are under constant pressure to increase the pace of clinical trials. Business intelligence solutions can help them make the most of every hour.

8:00 a.m. list the challenges

Simon Goodall, clinical trials manager, has a full plate of challenges ahead. He needs to pinpoint which clinical research organizations (CROs) are best qualified to handle Phase II trials of a promising new compound. There's budget pressure from the top, especially since a clinical trial has recently failed in late-stage development. Plus, he has to make sure sales and marketing are ready for a full commercial launch as the company's blockbuster drug prospect enters Phase III. Simon also risks FDA audits and fines if his work doesn't include enough detail or isn't completed on time.

10:00 a.m. streamline interactions with CROs.

Simon knows firsthand that longer clinical trials cost more to run. Now he's discovered a way to improve interactions with CROs to compress timelines and control expenses. Simon uses Cognos business intelligence software to evaluate the performance of the CROs on his approved vendor list. He finds answers to key questions: "Which CROs get their sites initiated quickest?" "Which deliver the cleanest data and trial results?" "And which have proven track records for meeting deadlines?"

Cognos, an IBM company, gives him the answers. He uses the data to build a shortlist of external resources he can rely on to deliver on time and on budget. With Cognos, Simon is able to gather metrics from nearly a dozen CROs using disparate systems and still generate reports that offer a coordinated, customized view to anyone who needs it. This gives him the freedom to choose the best CROs for the job—regardless of what tools they use. And it dramatically simplifies and streamlines his dealings with the vendors he's chosen for this trial. Next.

1:15 p.m. track budgets to manage priorities

Clinical trials can be affected by any number of pitfalls. Safety concerns could derail a new drug at a late stage of development. Or an FDA ruling could force you to put a study on the shelf. Your R&D budget is already spent and priorities have to be shifted. But where? Simon has just had a \$300 million study put on hold. So he uses his Cognos financial solutions to integrate data from R&D, Finance, Sales and Marketing and quickly builds a case for shifting funding and resources to another priority project. He calls on Cognos to identify which drugs in the company's pipeline offer the greatest promise in the least amount of time. He knows that if he can get on doctors' pads even a month earlier than the competition, it could mean millions in sales.

Next, Simon publishes a report of his analysis on a secure Web site and solicits feedback from the organization's financial stakeholders. His report is filled with the kind of detailed, up-to-the-minute financial data that upper management needs to give the green light—with detail down to the site, patient, and CRO costs. While he's waiting for stakeholders to respond, Simon begins an analysis of site costs for another ongoing clinical trial.

He compares the cost of a single procedure at a variety of hospitals, clinics, and doctors' offices to develop a clear picture of where money is being spent and why.

2:30 p.m. prepare for commercial launch.

Time is short and Simon has to make sure sales and marketing are in the loop as a potential blockbuster cancer drug enters Phase III. Everyone in the field and on staff needs to understand the changing priorities and tight schedules. What's going on? Should they be spending time

on the allergy study? Or does this new oncology drug take precedence? What's the window of opportunity? Simon uses Cognos to automatically alert the sales force and marketing team of this shift in priorities, so they can give it their immediate attention. His notice and accompanying reports encourage them to focus their efforts on this new oncology drug—a product that will have tremendous impact on the bottom line.

Naturally, doctors are going to have questions, too. How long has this new cancer drug been tested? Were there any adverse events on patient health? Did age or ethnicity come into play? Cognos enterprise reporting allows Simon to pool all the sales, marketing, clinical, and technical information into a single, integrated source of data, and make it available to everyone who needs it. Now everyone sales rep and marketing manager can access the information they need to provide quick and accurate answers with confidence.

4:50 p.m. monitor regulatory compliance.

Simon's company faces two questions as it ushers new compounds from the lab to the real world: Are they safe? And will they work? Rigorous corporate standards and increasingly stringent government requirements like Part 11 demand that these questions be answered as thoroughly and completely as possible. But getting there isn't always easy. The FDA is conducting more audits, with fines attached for non-compliance. Simon understands that his company must stay one step ahead—by providing the detailed, comprehensive reports that give regulators the confidence that his company is in compliance.

To ensure compliance, Simon uses Cognos to track metrics and view the progress of clinical study reports. So he knows exactly when they're due and when they're completed.

He takes a quick look at the status of his Monitor Trip Reports to see how many reports have been written by Clinical Research Associates and how many are in the central file. Then he drills down to view performance metrics by study, site, and geographic location. He triggers another report to compare the number of patients in a study versus the number of case report form pages collected—to see if

one month is heavier than another. That way he can evaluate workloads and decide whether the company needs to increase or decrease staff to meet upcoming deadlines. He even runs a report to ensure that the people using these compliance tools are properly trained—meeting yet another regulatory requirement.

5:50 p.m. getting started.

When a colleague of Simons calls to ask him about the best way to start implementing intelligent performance management solutions, Simon makes a few suggestions. Begin by gathering your company's requirements. What do you need to know? What kind of reports would help you better manage clinical trials? What kind of output and access are essential to success? Create a solid set of qualifications and requirements so you have a benchmark to judge available tools against. Next, identify a champion, someone in your organization who understands the challenges and believes in the power of business intelligence tools—like those available from Cognos—to drive performance. Simon submits that once you build a vision and establish value, you'll open other people's minds to the possibilities.

About Cognos, an IBM company

Cognos, an IBM company, is the world leader in business intelligence and performance management solutions. It provides world-class enterprise planning and BI software and services to help companies plan, understand and manage financial and operational performance. Cognos was acquired by IBM in February 2008. For more information, visit www.cognos.com.



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