Driving Clinical Trial Performance

THE IMPORTANCE OF MEASURING CLINICAL RESEARCH

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Why measuring performance is important

Introduction

To drive better R&D, we must first learn how to properly measure our performance. It is only by measuring our performance that we are able to set goals and drive for improvement. This has been found to be just as true in business as in sports, and ultimately will prove itself in the Research & Development world of life sciences organizations.

At first glance scientific research may seem to defy measurement. For how can something that has never been done before be compared to anything that has preceded? Yet there is the opportunity for performance measurement as drug compounds move through the pipeline into Clinical development. The key is in properly defining the metrics of performance. The compound may be new, the protocol may be totally unique, the indication might be rare. But shared with other research is the fact that protocols are written, studies are initiated, treatment is completed, data analyzed and study reports written. These are all milestones along the path of research that are objective and meaningful markers of progress. So even with the most esoteric research, it is possible to define metrics such that performance can be measured.

Once the metrics for Clinical research have been determined, the next step is to collect the measurements. The way this is done can be the key difference between improving performance or actually hindering it. You cannot expect study managers, site monitors, and data managers to believe their performance will improve simply by having them spend more time reporting progress to management. To minimize the negative impact on performance, you must effectively leverage the data points already collected during the course of Clinical trials in order.

Some good sources of data

Some of the most readily available data points relate to the actual treatment phase of the trials. The CRFs and edc forms tell us when studies enrolled their first patients, when sites completed treatment, and when all discrepancies were resolved. But performance in Clinical research can be driven by more timely measurements as well. For example, randomization centers are an ideal source for up-to-the minute enrollment metrics. Central labs are great for patient progress metrics as kits are shipped in from the investigator sites. And often tapping into the clinical data management system will yield timely data discrepancy metrics. Beyond patient progress, many organizations have clinical trial management systems that capture milestones such as investigator selection, IRBs, and site initiations. Clinical supply systems may provide key metrics such as drug availability and supply shipments to sites. By spending some time analyzing current research processes, often ways can be found to capture performance metrics without adversely impacting the team.

Uniting disparate data into a central source

Once the organization has identified the metrics and methods to collect measurements, the next step is to aggregate this information into a single source for reporting and analysis. This aggregation has a clear benefit of pulling information together from multiple sources into one central source of business intelligence. This step has the added benefit of providing a level of isolation between the operational Clinical systems and the metrics that will be used to drive the business. This is critical to allow the underlying research systems to be replaced with improved technologies as they become available, without fear of disrupting the entire organization.

Once these steps have been completed, Cognos, an IBM company, can unlock the Clinical business intelligence embedded in the metrics of the data mart. You can build data cubes to support ad hoc analysis of the Clinical metrics and show correlations between performance for a given metric and performance of the study. For example, you might discover that the study will be faster than a paperbased trial as long as setting up an edc database takes less than 68 days.

Identifying key performance indicators

The next step is to identify the Key Performance Indicators, or KPIs. Identifying KPIs focuses the business on the specific metrics that affect final outcome. Cognos lets you delivered them to every level of the R&D organization. Users can look at KPIs just for their sites; study managers can get a global view for an entire study or just one country; medical directors can keep track of their compounds; and Clinical operations can identify top performers across all products and therapy areas.

Five key focus areas

The business intelligence needs of Clinical organizations can be categorized into five key areas: speed, timeliness, data quality, investigator performance, and sponsor staff performance.

Speed

Speed is the performance differentiator of development organizations. Clinical has little direct influence over the safety or efficacy of a drug. Regulatory bodies set standards for delivering drug to market. But what Clinical can affect is the speed at which drugs get to market. Cognos can help. By looking at the durations of a particular study, or a project that combines multiple studies for regulatory approval, the Clinical organization answer key questions: Based on comparisons to our other programs, how long will it take to develop this drug for market? Are the EDC studies really saving us the time we had hoped? Which countries complete enrollment more quickly for this indication? What will be the effect on our submission date if we amend the protocol? The study and project duration metrics can drive decision-making for the entire organization.

Timeliness

Capturing the planned completion date of milestones in the research process and the actual completion dates provides insight into organizational effectiveness and allows for improved product delivery forecasting. With Cognos, Clinical can then ask questions such as How timely has this product area been at completing submissions? Is our Pre-Clinical team completing their study reports on time? Are we getting better at planning? Are protocol translations delaying study startup in our subsidiaries? Based on past performance, what is the likelihood we will meet our target dates, with how much variance? Analyzing on time performance metrics within Clinical Research will result in better performance management.

Data quality

Data quality is a third area of focus for leveraging Cognos to drive R&D performance. Clearly Clinical trials are not complete until the study data is clean, and the rate at which this happens directly affects the time it takes to get a product to market. Capturing metrics on this aspect of Clinical research allows the business to ask questions like What percent of our queries to the sites are resolved vs. outstanding right now? How much of a delay is there between a patient's visit and entry of the data into the EDC system? How long does it take to collect CRFs from the site? What percent of data collected has initial discrepancies? Which studies have cleaner data? By focusing on the critical issue of Clinical data quality, Cognos helps organizations these metrics to drive process and performance improvements.

Staff performance

Different team members are going to excel in different areas. Looking at individual performance the organization can place people in the roles that will most effectively leverage their strengths. Additionally, programs of Best Practice will provide opportunities to mentor poor performers while properly recognizing high performers. With Cognos, it becomes possible to ask What study monitors are better at getting top performance from sites? What percent of the time do our medical writers meet their dates versus the timeliness of our data managers? Which teams are best at resolving discrepancies? What countries consistently meet their enrollment quotas? Which CROs get better results? The metrics of on-time performance, when applied to staff or contractors, can have an immediate effect on overall performance improvement.

Investigator performance and data quality

Historically, the sole metric available for choosing research partners has been an investigator's ability to recruit patients. But quicker recruitment with more data problems may not be a tradeoff worth making. Analyzing metrics of investigator timeliness and quality not only asks the basic question Which investigators recruit faster?, but also Can an investigator data quality rating help manage performance? What institutions meet dates? Does faster recruitment lead to more discontinuations and discrepancies? Who manages patient compliance to the protocol more effectively? Capturing investigator performance metrics such as these enable Clinical to reach another level of sophistication in their approach to developing drugs.

How Cognos can help

Cognos effectively delivers Clinical business intelligence to the R&D organization when strategically aligned with metrics focusing on speed, timeliness, quality and performance of staff and investigators. KPIs specific to Clinical R&D will let the organization know where their performance stands, and will drive improvement. This alone is more than enough to warrant action, but the benefits do not stop here. Scorecarding with IBM Cognos 8 BI lets you interconnect these performance indicators and model your entire drug development plans and strategies. Coupling these Clinical metrics with metrics from Cognos solutions for Sales & Marketing, IBM Cognos 8 BI is the first scorecarding software product to deliver drug portfolio management to the desktops of decision-makers across your organization. Factoring drug development time into patent life to arrive at projected sales and marketing forecasts using near real-time metrics lets Pharmaceutical & Biotechnical organizations put together sophisticated product strategies and then monitor corporate performance against these plans.

About the writer

Peter Oudheusden is President of 3C Company, a Cognos partner and Pharma R&D software organization specializing in packaged and custom business intelligence solutions. 3C Pharma developed the first "out of a box" data warehouse for Clinical Research, Clintelligence, focusing on milestones & metrics of the entire drug development process. Peter has presented throughout North America on creating strategic business advantage through technology. You may learn more at: www.3cpharma.com

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 http://www.cognos.com.

Pharmaceutical organizations worldwide choose Cognos for our unsurpassed expertise in delivering the information and insight they need to reduce costs, streamline processes, and increase profitability. Cognos has delivered solutions to 25 of the top 30 pharmaceutical firms, along with many leading life sciences and biotech companies.

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GLOBAL

Cognos ULC

3755 Riverside Drive

P.O. Box 9707, Station T

Ottawa, Ontario

Canada K1G 4K9

ASIA/PACIFIC

Cognos PTY Limited

Level 2 110 Pacific Highway

St. Leonards, NSW 2065

Australia

EUROPE

Cognos Limited

Westerly Point

Market Street

Bracknell, Berkshire

UK RG12 1QB

NORTH AMERICA

Cognos Corporation

15 Wayside Road

Burlington, MA

USA 01803

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