White Paper
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A 4-Step Guide to Optimizing Clinical Development

Information Management

Cognos software

Contents

Abstract

Better results, faster than ever.

Overview

The need to show more and more progress in less and less time captures the increasing pressure in the pharmaceutical industry. Drug development is expensive, time-intensive, and increasingly regulated. In addition, competitive pressure, shrinking patent life, compliance issues, and market forces continue to increase the demand for faster delivery. As a result, drug companies need to find ways to cut both costs and time from the clinical development process.

Business Problems

A recent IBM Cognos® white paper notes that, "Conducting clinical development activities in an efficient and regulatory-compliant manner is a challenging endeavor… In recent years, maturing patents and a decline in the pipeline of 'blockbuster' drugs in the industry have led to the problem characterized as…'the research and development productivity crisis.' Companies are forced to examine drug development processes with an eye toward efficiency, cost-effectiveness, and cost containment."

Perhaps no other single factor is as critical to cost containment as managing the clinical trial process. Currently, pharmaceutical company budgets exceed $400 million in total expenses, which accounts for 37 percent of total research and development costs (according to Cutting Edge Information). While trial costs are increasing, so is the complexity of the process.

Increasing operational and process efficiencies in the face of that complexity (both in and out of the laboratory environment) is crucial to speeding time-to-market. Early adopters of technology have implemented systems like EDC and CTMS that aggregate the large volumes of data used in clinical trials. But these are point solutions that offer limited decision support. The information necessary to manage clinical performance—metrics, plans and budgets, and detailed actual results—have been difficult to integrate and report against. As a result, organizations are undertaking these efforts with complex people-intensive processes based on inadequate systems.

The risks of this approach are large, growing, and global. Business press from North America, Europe, and Asia continually chronicle legal judgments rising out of patient privacy and compliance failures that continue to weigh on pharma's reputation, financial strength, and culture.

In this increasingly regulatory environment, everything from sales and marketing, to pricing, accounting practices, and science are under scrutiny. The case for timely, accurate, and shared data has never been greater. Management needs to know what is happening, why, and what is expected. What are the key performance indicators? Does the data support root-cause analysis and decision-making?

Business Drivers

Clinical program performance management – link planning to performance and vice versa

Clinical trial planning is critical to successful clinical performance. Effective planning optimizes areas such as expense forecasting and tracking, and has a significant impact on factors including reporting accuracy, costs, and the time it takes to get drugs approved.

Incorporating Clinical Performance Management lets managers understand and compare performance of sites or regions and conduct "what-if" scenario analysis to ensure best use of resources. Accurate, real-time views of clinical trial forecasts and budgets give team members the critical information they need to make key decisions and allows them to collaboratively assess performance. Ultimately, goals are reached sooner, and the entire process is more cost-efficient.

Executed effectively, planning, and performance work hand-in-hand, with each trial leveraging those that came before it, and helping to guarantee the success of those that follow.

The Solution

A 4-STEP Guide to Optimizing Clinical Development

1 Get the team on the same page: Clinical development draws on complex processes, multiple constituencies, and various data sources. While integration of all these components is essential, it is often difficult to achieve. Yet, it is only when conflicting reports are eliminated, and one version of the truth is accepted, that productive collaboration can take place.

Collaboration begins with an easy-to-use interface that routinely draws on and relays multiple data sources in multiple formats—a major drawback to conventional spreadsheets. Once data is aggregated, it must be made readily accessible via an open framework and Web browser that allows for statistical analysis, modeling and reporting across the organization.

For complicated processes with many people involved, work needs to be saved or submitted for multiple reviews and updates. At any point, designated stakeholders need to monitor workflow status, identifying uninitiated, work in progress, or ready-for-review research cycles and data.

Connecting and transforming data from multiple sources into meaningful useful reports enables more objective and timely analysis, scorecarding, managed and ad hoc reporting, dashboards, and greater process efficiencies.

Real-time collaboration, across multiple research departments within and outside the organization and across regulators and reviewers, achieves dramatic cost reductions as discrepancies are caught earlier when their consequences are less pronounced.

2 Ask the right questions: Optimizing clinical performance management requires a clear understanding of all the metrics involved, how they relate to one another, and the questions that need to be asked. In developing a strategy for better information leverage, the key questions to ask yourself include:

1. What critical development questions are we consistently trying to answer—and consistently have trouble answering?
2. How are costs affected by study-type, region, patient retention and enrollment rates, and other metrics?
3. How do costs compare across sites? Across regions?
4. What if? (How would various scenarios, such as reallocating resources to different sites or regions, play out?)
5. Which users do these questions apply to?
6. Where does the data reside to answer these questions?
7. What further questions could this metric or key performance indicator (KPI) raise?
8. What actions or decisions could be completed based on this information?
9. What specific measure, dimension, and target of the metric or KPI is needed to create action?
10. What historical data could help answer these questions?

By organizing your data collection in this way, and combining it with the right team and tools, you'll be well on your way to getting better results, faster.

3 Shatter the silos: In this context, silos may refer to data located in different physical locations or systems, or a single spreadsheet living on someone's desktop. When data is stored this way, decision-making is often delayed or, more often, based on incomplete and inaccurate information.

By contrast, pulling data into a centralized repository allows you to:

- Respond in real-time to both external and internal changes
- Catch errors in and/or validate data earlier
- Provoke discussion based on shared data and information
- Enhance reporting, using key performance indicators, scorecarding, and dashboards to achieve ongoing efficiencies
- Reduce both data-management and personnel costs

When you break down silos and support data with a high-speed, bi-directional calculation engine, managers can evaluate models and test assumptions in minutes to support truly informed business decisions. Real-time aggregation, break-back, multidimensional analysis, and drilling-down from general data to detail help you explore information fully and efficiently. This in turn enables flexible rolling forecasts and greater visibility into future operating performance.

4 Update your tools: Making objective business decisions is impossible without data that is widely accepted as timely and accurate. Add real-time capability, and decisions can be made in response to immediate changes in the market, regulatory environment, or financial circumstance.

Most companies manage R&D using spreadsheets, which leads to error and difficulty in arriving at a consolidated forecast plan. This already-complex process is further complicated by the use of spreadsheets that—although flexible—lack the consistent business rules needed to communicate process intricacies. Typically, forecast goals are not linked to research assumptions. And most importantly, due to the sheer volume of spreadsheets typically generated, a consolidated view across all research is difficult. This makes effective performance monitoring and resource reallocation nearly impossible.

Tracking, reporting, and predictability are the building blocks of decision-making. Too often, however, critical data is out of date, locked away in proprietary systems, or just plain inaccurate. A catch-22 results, as the time taken to build the required dataset pushes decision deadlines beyond what is practical and diverts personnel from other equally vital tasks. Regulatory pressures and time-to-market compound the situation.

Monitoring the entire research process gives you the status of every stage and participant; reducing time and promoting dialogue through shared data and analysis. Drilling down from summary reports, graphs, and charts to the underlying detail for reporting and analysis allows and accelerates root-cause analyses.

In addition to your data gathering and monitoring capabilities, review your planning and business-intelligence tools. Today's advanced tools are able to:

- Provide accurate predictions of clinical trial operating expenses, using driver-based algorithms
- Enable robust modeling of an entire development program
- Provide data and forecasts based on actual activity and spending rather than time-based accrual
- Integrate seamlessly with other financial and operations software

• Automatically adjust for foreign exchange rates

• Update accounting information real-time

• Facilitate better management at every level, for a faster, more cost-efficient process

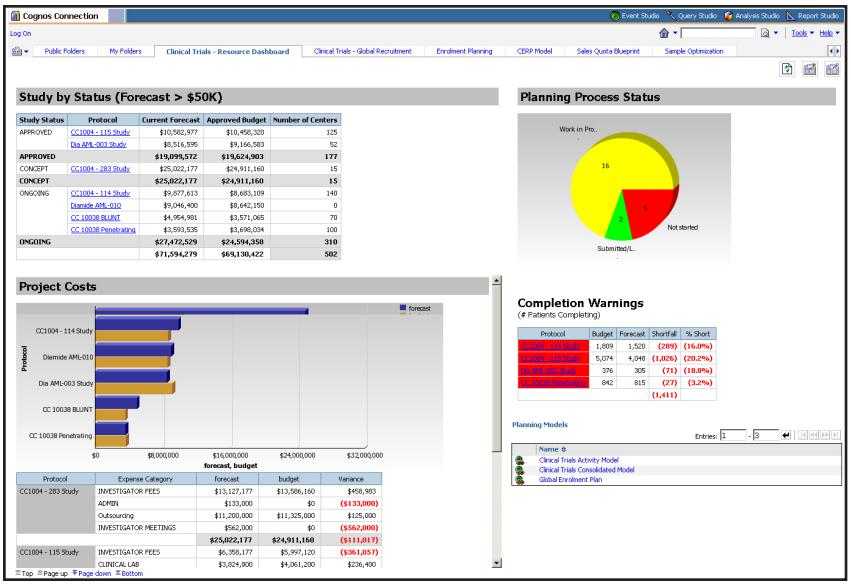
Beyond reports to Scorecards and Dashboards

Scorecards and dashboards are far more sophisticated than spreadsheets and simple reports, and they have a far greater impact on the quality and speed of decision-making.

Scorecards are primarily used to help align operational execution with the clinical development strategy. The goal of the scorecard is to keep the team focused on a common strategic path by monitoring real-world execution and mapping results of that execution back to the strategy. The primary measurements used in the scorecard are KPIs. These are often a composite of several metrics or other KPIs that measure the team's ability to execute against the specific clinical development objective.

Dynamic scorecards that quickly and clearly communicate the strategic priorities of the research show how metrics connect with each other, and link them with underlying reports and information. Calculated metrics summarization and linkage to scorecards and reports allows users to measure key expenses and related performance indicators for all operations.

A dashboard falls one level down in the decision-making process from a scorecard: it is less focused on a strategic objective and more tied to specific operational goals within the clinical development process. An operational goal may directly contribute to one or more higher-level strategic objectives. Within a dashboard, execution of the operational goal itself becomes the focus, not the higher-level strategy. The purpose of the dashboard is to provide users with actionable information in a format that is both intuitive and insightful.



Dashboard

Pulling it all together

High-performance companies replace manual spreadsheets with robust multi-dimensional modeling and integrated workflows that limit error, improve control, enhance visibility, and boost accountability. The clinical trial process requires an approach that combines central business rules management with driver-based planning in a collaborative decision-support environment that allows all the right people to participate. Through such an approach, expenses can be better anticipated and results can be consolidated instantly to better facilitate monitoring. The consolidated view also allows for better analysis and resource allocation to improve overall protocol performance.

Conclusion

IBM Cognos software can help

IBM Cognos software provides an integrated, best-practices platform for Clinical Performance Management. It gives you access to all your critical data – clinical trials and operations, financial and regulatory information – and delivers the scorecarding, business intelligence reporting and analysis, and the planning and budgeting tools you need to manage and optimize performance. With integrated plans, analysis, and performance metrics, you can dramatically improve your understanding of the entire clinical trials process, and improve your ability to make intelligent, informed decisions. IBM Cognos Performance Blueprints enable organizations to apply proven best practices quickly, with less risk, and without having to "reinvent the wheel."

For example, the IBM Cognos Clinical Trials Performance Blueprint helps pharmaceutical companies better anticipate clinical trial resource requirements and accompanying expenses in order to comply with FDA filing requirements. It also provides the level of detail needed to improve forecast accuracy by quickly capturing expense requirements at the Clinical Trial Manager level – the point closest to the study.

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About IBM Cognos BI and Performance Management

IBM Cognos business intelligence (BI) and performance management solutions deliver world-leading enterprise planning, consolidation and BI software, support and services to help companies plan, understand and manage financial and operational performance. IBM Cognos solutions bring together technology, analytical applications, best practices, and a broad network of partners to give customers an open, adaptive and complete performance solution. Over 23,000 customers in more than 135 countries around the world choose IBM Cognos solutions.

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