PERFORMANCE MANAGEMENT IN CLINICAL RESEARCH

DELIVER NEW DRUGS FASTER AND AT LOWER COST

COGNOS®

THE NEXT LEVEL OF PERFORMANCE™

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WHAT DRIVES THE NEED TO IMPROVE CLINICAL RESEARCH AND DEVELOPMENT

Pharmaceutical companies are under intense pressure to deliver new drugs in record time. Yet the reality is that drug development is an expensive, lengthy, and increasingly regulated process. The challenges from competition, compliance, and the market underscore the value of optimizing clinical performance. As a result, drug companies need to find ways to drive both costs and time out of the process.

"Conducting clinical development activities in an efficient and regulatory-compliant manner is a challenging endeavor," Life Science Insights wrote in a recent white paper, sponsored by Cognos. "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."[1]

Early adopters of technology have implemented systems to increase operational efficiency in clinical R&D. The most common systems, EDC and CTMS applications, aggregate the large volumes of data used in clinical trials. But these are point solutions and 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.

Market realities have increased the requirement for greater management oversight. You need to see the big picture—the relationships, connections, and direction—to make informed decisions. This is the promise of clinical performance management.

[1] Judy Hanover, Alan Susser. *The Performance Management Imperative for Clinical Research*. White paper sponsored by Cognos. Life Science Insights, April 2005.

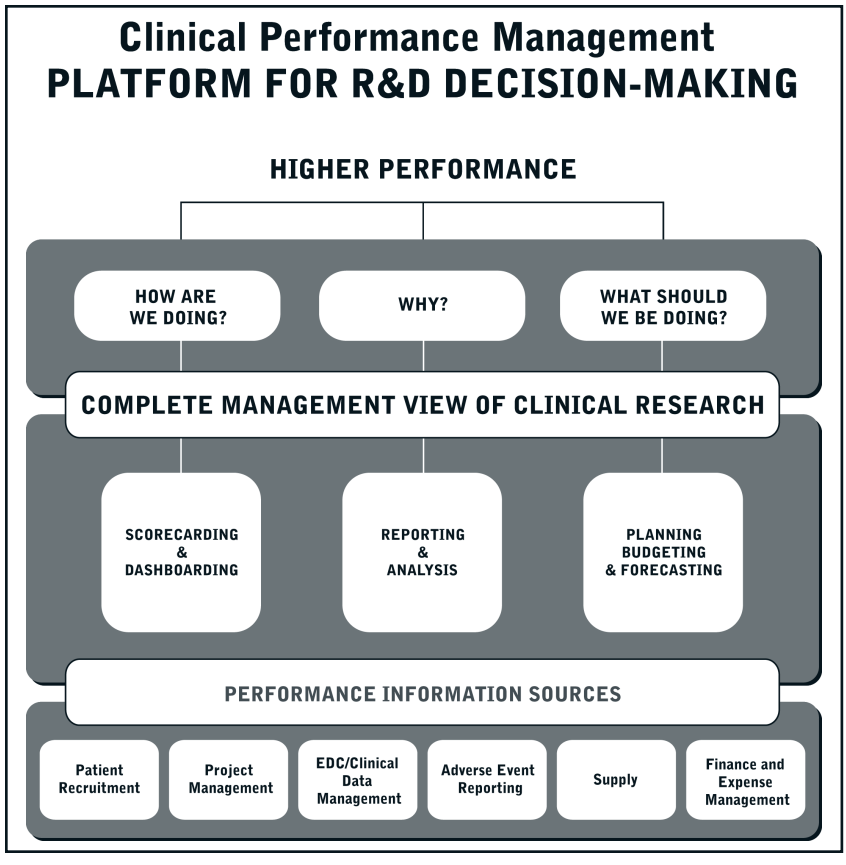
WHY CLINICAL PERFORMANCE MANAGEMENT

With clinical performance management, you gain access to the reliable, timely information that drives better decisions. While you may have any number of decisions to make, they depend on answers to these fundamental questions:

- **What is happening—**A gauge of the most critical indicators for your organization.
- **Why—**The ability to dig deeper into current issues, successes, or problems in order to understand what led to the results.
- **What should happen—**The facility to set plans, allocate resources, monitor them, and adapt.

Cognos 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 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.



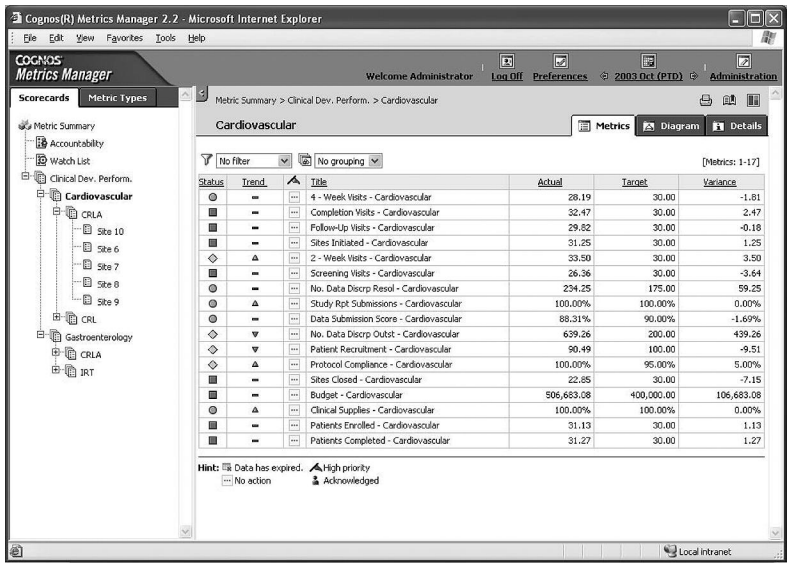
Scorecarding

Scorecarding, using Cognos Metrics Manager, communicates your strategy and objectives through a metrics-based method of management. It answers "What is happening" by providing people with the information they need to take ownership of their performance—visibility into strategy, understanding the part they play in making the strategy succeed, and the metrics to measure their success.

By enabling the strategic alignment of clinical development objectives against performance metrics, you can answer at any time the key question: Are we making progress on the things that must be done?

Use Cognos Metrics Manager to:

- Create and track clinical trial milestones, drug safety and adverse event trends, and sales performance.
- Monitor the progress of New Chemical Entities (NCEs) from discovery through regulatory approval.
- Monitor and measure regulatory activities, including regulatory warnings and sanctions, and the speed and quality of regulatory approvals for new products and new medicines.
- Track actual performance against planned strategy and budgeted spending.



Business Intelligence Reporting and Analysis

The drug development process amasses large amounts of data that reside in many sources and systems, often across multiple sites. Consolidating this information for analysis and reporting is a huge challenge. It is especially difficult given that there can be as many tools used to analyze and report on the data, creating further islands of information.

Cognos Business Intelligence (BI) consolidates and leverages your critical data, and turns it into meaningful analysis and reports that everyone can use. You can spot broader trends and drill down to discover underlying causes and issues. The flexible, user-friendly reporting of Cognos ReportNet™ means everyone has the right information delivered in the right way across all departments and roles.

With a single, standardized BI platform for reporting and analysis, you can accurately assess the "Why" behind operational activity and performance. This provides the necessary context against which decisions can be made.

Use Cognos BI to:

- Understand which CROs, investigators, and staff are performing optimally.
- Track the completeness and accuracy of patient information as it is collected.
- Monitor patient recruitment to identify sites on track as well as those encountering problems so action can be taken to avoid delays.
- Identify innovations and competencies that aren't being fully exploited.
- Provide the detailed reports that give regulators confidence that your organization is in compliance; or develop internal reports to update sales and marketing on the progress of a new compound as it enters Phase III.

In addition, adopting Cognos as the BI standard across all your validated systems can reduce the costs and risks involved in complying with FDA CFR 21 requirements.

Planning and Budgeting

Many pharmaceutical executives and managers admit they have no idea of the true cost of clinical development. The traditional planning process, involving annual budgets and infrequent adjustments, often relies on guesswork instead of certainty. And traditional planning tools—such as spreadsheets—do little to support collaboration or dynamic planning cycles.

What's required is a solution that replaces a fragmented process with continuous, collaborative planning that delivers up-to-date insight into clinical performance. Cognos Planning helps you build a foundation for higher performance by connecting strategy to plans, targets, and operational objectives. It addresses "What should happen" by allowing you to define goals, and turn them into discrete plans and budgets for the entire clinical team, down to the CRO level. Plans can be built to maximize operational effectiveness, and they can be realigned as conditions change.

Use Cognos Planning to:

- Engage the entire clinical development team with real-time feedback on progress toward goals.
- Provide daily, weekly, or monthly updating of clinical development costs.
- Forecast the revenues and net income contribution of each entity in the R&D pipeline.
- Make go/no go decisions early on so funding and resources can be diverted from unpromising candidate compounds to successful ones.
- Compare costs in different countries and financial reporting environments.

YOUR PATH TO CLINICAL PERFORMANCE MANAGEMENT WITH COGNOS

Where companies begin on the path to clinical performance management will differ, and how quickly they implement the platform will vary. The bottom line is that you can take an incremental approach, starting with one performance management component and building from there. Every time you address one element in the system, you strengthen your decision-making and clinical performance.

Starting Point 1—The One Thing

If you were to do one thing to improve your organization's performance, what would it be? For some, it is managing costs, perhaps through better tracking of CROs. For others, it is improving clinical standards to address regulatory requirements. Cognos technologies let you understand the information to do the one important thing, and then grow from there.

Starting Point 2—The Data

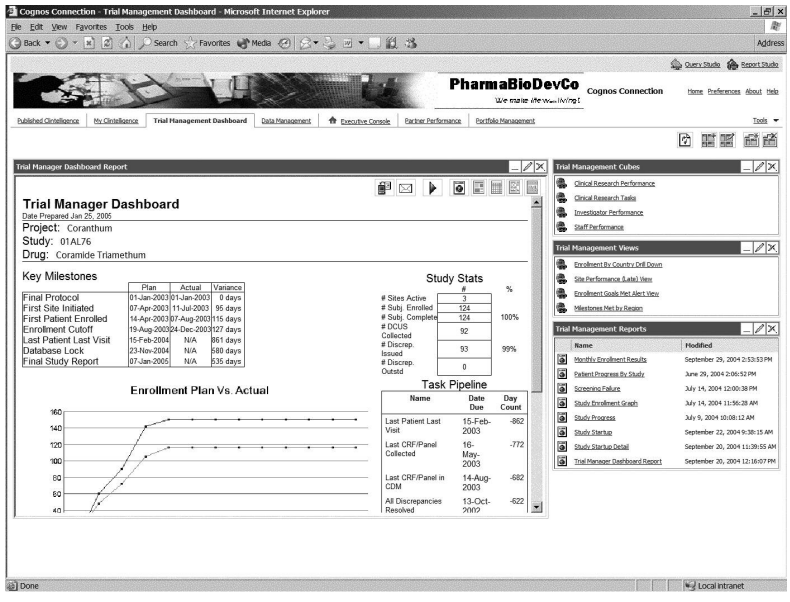
Leverage your existing data resources. You may have data locked away in a variety of databases, spreadsheets, and other systems, with no effective way to report against them. Access and integrate this data, and then let everyone from front-line managers to executives generate their own timely, meaningful reports. With a firm grasp on the 'Why' behind performance, you are ready to move forward.

Starting Point 3—The Scorecard

Take advantage of a clinical scorecard or other method to drive your performance agenda. Monitor the key metrics that map to your organizational strategy. Leverage your existing data resources to deliver this information into a scorecard that shows you status, trends, relationships, and interdependencies and gives you the ability to drill through to the business intelligence layer for more information.

Starting Point 4—The Plan

Change your budget into a rolling, responsive forecast. Go beyond the unwieldy spreadsheet-based system. Use technology to engage all cost and revenue centers in preparing realistic forecasts that take into account your organization's overall strategy. Save time and resources usually committed to this process, and turn them into better analysis and forward-looking thinking.



THE HUMAN SIDE OF R&D

Human endeavor is at the center of clinical research and development. Life Science Insights points to the "serendipity factor" in this process. "Scientific research, by nature, involves a certain amount of luck driving its direction and success. Scientists are more successful when they operate in an environment that fosters independence and innovation." [2]

Technology can never replace the human and creative side of research. But by addressing the supporting processes—helping organizations maximize operational efficiency, make better decisions, and minimize costs—it can foster collaboration and further the efforts of the research community.

In effect, less administrative paperwork means more time for pure research. Technology solutions like clinical performance management can provide a working environment that gives scientists more time and opportunity to devote to what they do best—finding a new cure or discovering the next innovative therapeutic solution.

DRIVING DOWN TIME AND COSTS

It is expected that each new approved drug must return $300 to $600 million to cover the overall cost of research. In an industry where costs are becoming so prohibitive, making timely, well-informed R&D decisions is absolutely critical. Effective decision-making depends on having access to accurate, up-to-the-minute information you can act on—you need to know what is happening, why, and what should happen.

Whether you have to manage budgets and expenses, evaluate CRO performance, allocate resources, or track lab results, Cognos performance management delivers the deep insight you need. Our decision-making platform helps your R&D organization leverage your information and resources—to gain efficiencies, streamline operations, speed the development cycle, and reduce the costs of bringing new products to market.

[2] Judy Hanover, Alan Susser. *The Performance Management Imperative for Clinical Research*. White paper sponsored by Cognos. Life Science Insights, April 2005.

PHARMACEUTICAL CUSTOMERS IMPROVE THEIR PERFORMANCE WITH COGNOS

Cognos offers greater depth and breadth of experience in the life science industry than any other performance management vendor. Twenty-four of the top 30 pharmaceutical firms and a broad range of companies across life sciences and health care already choose Cognos performance management solutions.

These organizations recognize Cognos for its innovation, vision, ability to execute, and technology leadership in performance management.

Proven ROI

Independent research into Cognos customers at various stages of deployment confirmed that 80 percent had already achieved a positive return on investment from our software and services.

Completeness of Vision

Cognos has built a holistic, integrated technology framework. In addition to planning, analysis, and scorecarding, we provide common user portals, common data definitions, and standards-based technologies to simplify your business and IT environment.

Enterprise Scale

Cognos built its technology to handle the data volumes, level of activity, and complex business and IT environments of the Fortune 1000 and other large enterprises. Our technical capabilities streamline administration, support, security, and validation requirements, which reduces costs and risk.

Support

Cognos supports its integrated performance management capabilities with award-winning Global Customer Services. We consistently top the list for best software support and services innovation with customers and support professionals. Our consultants can design and implement a solution that grows as your organization grows to deliver value for years to come.

Leverage Existing Investments

Reports, analysis, plans, budgets, and scorecards from Cognos work within your existing data and IT environment to increase the value of your investments.

ABOUT COGNOS

Cognos is the world leader in delivering an integrated performance management solution—reporting, analysis, scorecarding, consolidation, and enterprise planning. Industry analysts and experts point to the breadth and excellence of Cognos performance management software as the source of this leadership.

Cognos backs up this leadership with the highest awards for customer service in the industry. More importantly, the ROI Cognos delivers to its customers is proven by independent industry watchers, and backed up by customers across all major industries, around the world.

Founded in 1969, Cognos today serves more than 23,000 customers in over 135 countries. Cognos performance management solutions and services are also available from more than 3,000 worldwide partners and resellers.

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