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The Performance Management Imperative for Clinical Research

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WHITE PAPER

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LIFE SCIENCE INSIGHTS OPINION

In recent years, pharmaceutical and biotech companies have been faced with challenges to the traditional approach to drug development. These approaches have failed to produce a pipeline of new blockbuster drugs to replace profits associated with products that now face expiring patents. New technology, regulatory requirements, and poor productivity have led to a rise in clinical development costs. With pressure from both the top and bottom lines, organizations are being forced to look for efficiencies in their clinical development process that will bring new compounds to market more cost-effectively. This situation has led to an industrywide push for tools to improve clinical development processes.

Life Science Insights has identified a progression of technology for clinical development that encompasses a number of critical technologies, including electronic data capture (EDC), clinical trial management systems (CTMS), and clinical performance management (cPM) systems, the subject of this white paper:

- **EDC.** EDC on its own addresses only the basic automation issues of regulatory data entry in clinical trials, but it does not address larger process or operational issues.
- **CTMS.** CTMS reaches the next level, allowing tactical management of the different sites, investigators, technologies, and processes in a clinical trial.
- **cPM.** cPM operates at a strategic level, looking at clinical data in the aggregate alongside other data on the progress of clinical trial programs, such as operational, financial, supply, and regulatory data. It allows corporate managers to look across multiple trials at the performance of entire clinical programs, identifying and targeting problem sites, issues, and personnel while encouraging the propagation of the environments that lead to success.

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cPM allows users to realize more of the promised benefits of clinical development process automation that are recognized at either the EDC or CTMS level. In our opinion, this high-level approach to the management of clinical performance represents the next level in achieving value from clinical research. This document details the business case for cPM systems — along with an overview of the cPM — space, the issues confronting users, and the solutions they have undertaken to solve them.

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This white paper provides an overview of the compelling case for clinical performance management (cPM) in the drug development environment. The Situational Overview section of the white paper provides an overview of the uses of cPM systems and presents the background of the issues that have led pharmaceutical executives to recognize the need for cPM in clinical development. The market drivers for cPM are also discussed. The Case Studies section presents the feedback from a series of detailed interviews with cPM system users and early adopters. The advantages associated with using the Cognos system are provided alongside a discussion of Cognos' competitive position in the space.

The Challenges section presents key issues facing Cognos and other business intelligence (BI) providers, while the Future Outlook section of the paper presents our expectations for adoption of BI in clinical development. This information focuses on the needs of life science stakeholders who seek to improve their organizations' clinical performance. The Essential Guidance section of this document should be taken into account by pharmaceutical and biotech executives making decisions related to the use of cPM systems in their own strategic clinical performance analysis environments.

SITUATIONAL OVERVIEW

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 in the press and by pharmaceutical companies themselves 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.

Efforts to contain costs and speed drug development have necessitated the incorporation of technology into clinical trial processes. As the level of automation in clinical development increases and the tools mature, clinical trial sponsors have access to increasing amounts of data from first-generation point solutions such as EDC that focus on specific activities in the process. Second-generation CTMS applications focus on managing the entire process — from beginning to end — of clinical trials. CTMS manages the clinical projects themselves and provides aggregate operational data. EDC and CTMS data together provide a wealth of operational data on trial processes.

Although the operational improvements delivered by EDC and CTMS are important, a new priority has emerged: the examination of trial processes to improve overall clinical development performance beyond the initial automation benefits associated with EDC and CTMS decision making.

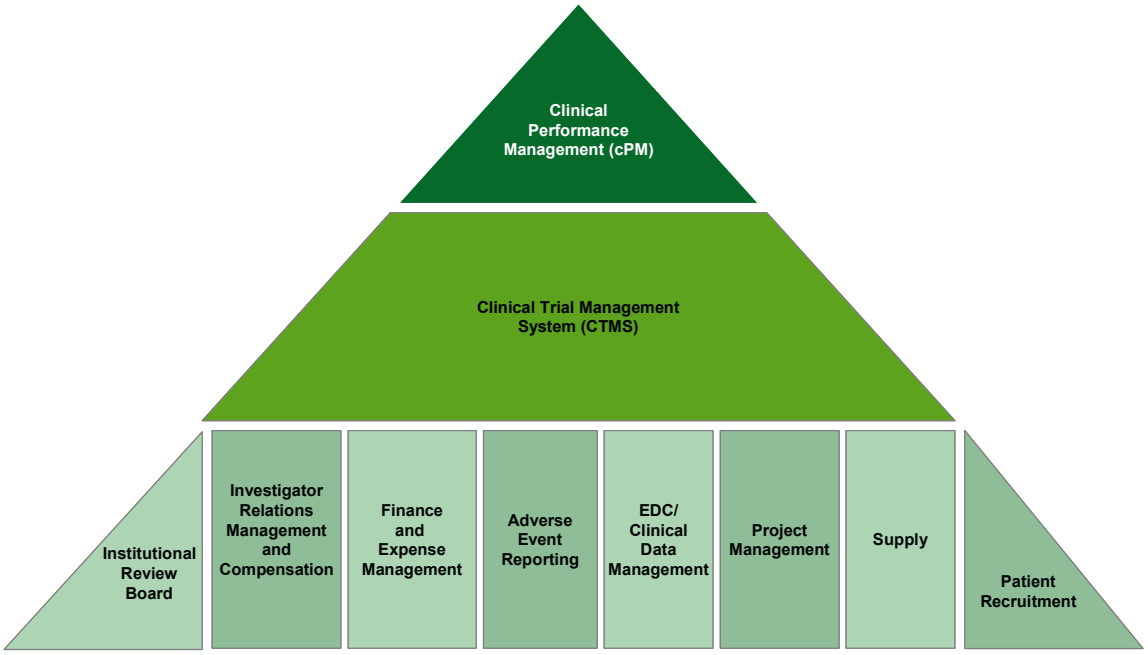
Although the operational improvements delivered by EDC and CTMS are important, a new priority has emerged: the examination of trial processes to improve overall clinical development performance beyond the initial automation benefits associated with EDC and CTMS decision making. This is both a natural progression of the industry and a result of the increasingly competitive clinical development environment for pharmaceutical companies. Forward-thinking clinical trial sponsors have slowly come to realize the opportunity to leverage available technologies combined with improved business processes.

The Pyramid of Clinical Development Technology Evolution

The interrelationship of clinical trial technologies is depicted in Figure 1. The lowest level involves representatives from a host of point solutions that automate specific steps in clinical development. For example, EDC is at the bottom level of the pyramid. The middle level of the pyramid shows the aggregation of these systems into CTMS. CTMS includes larger-scale systems that manage multiple processes either directly or via monitoring of underlying systems from the bottom level of the pyramid. However, CTMS is still mainly operational in nature as it manages the multiple point solutions, project management, and financial management tools that control clinical trial operations.

FIGURE 1

The Pyramid of Clinical Development Technology Evolution



Source: Life Science Insights, 2005

At the highest level of the pyramid is cPM. We now find organizations leveraging point solutions and CTMS to create more strategically focused decision support systems. Data sources such as CRFs and EDC forms, enrollment information, and central lab and supply systems provide the information that cPM solutions use to begin measuring performance. When combined with relevant performance indicators, cPM enables managers to set goals and track metrics that measure progress toward these goals and identify opportunities for improvements in efficiency. This takes clinical process improvement to the next level, truly enabling the organizational change that has the potential to alleviate the research and development productivity crisis.

Clinical Development Industry

In the area of process automation, as in many other areas, the clinical development market has been slow to adopt technology to improve efficiency and create competitive advantage from operations. Although the tools themselves may not be problematic, the bottlenecks for most pharmaceutical and biotech companies include:

For many clinical trial processes, data issues go far beyond those in other industries that bemoan difficulties related to the integration of multiple, disparate databases.

- **Data availability.** For many clinical trial processes, data issues go far beyond those in other industries that bemoan difficulties related to the integration of multiple, disparate databases. In clinical trials, the databases themselves may not exist because data often resides in combinations of paper medical charts, spreadsheets, and paper and electronic documents.

- **Human factors and scientific resistance.** The need to create data for analysis is often complicated by organizational resistance to recognizing and accepting the need for improvements in R&D productivity and collecting the data needed to measure the problem. People are accustomed to the paper-based systems in place and resist change.

- **Clinical measurements.** The nature of clinical measurements is another confounding factor. Even for trials that have electronic databases of information associated with them, clinical data consolidation needs to take into account equipment nature and calibration, and even subjective data such as interpretation of images.

- **Nature of drug development.** There is also a serendipity factor in drug development. 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. The scientific workforce can resent efforts to "productionize" its work if it is not approached sensitively. It is possible to make R&D more productive, but those implementing changes must be careful not to compromise the image of the scientist as unencumbered by fiscal policy concerns.

When done right, cPM is used to institute programs that drive efficiency and create competitive advantage from operations.

Although the clinical development industry may be slower than most to use the available technologies — data warehouses, planning applications, or business intelligence reporting tools — the situation is now changing. Data availability issues can be resolved, and the human and clinical factors can be addressed. Tools can be structured so that as many elements of independence can be maintained as possible for a scientific workforce.

In other industries such as healthcare and manufacturing, executives have embraced cPM solutions that allow them to track and measure the success or failure of business processes. When done right, cPM is used to institute programs that drive efficiency and create competitive advantage from operations.

Clinical Trial Management and Clinical Performance Management Systems

There is some confusion about the difference between CTM and cPM systems. They both collect data from various sites, subsidiaries, salespeople, and monitors into a single tool, although their end use of the data is quite different. Table 1 details key differences between CTM and cPM systems.

TABLE 1

Clinical Trial Management and Clinical Performance Management: Differentiators

Area	CTM	cPM
Purpose	Operational	Strategic and Tactical
Functions	Management of aspects of a trial including project timelines and tasks, financial performance and compensation of participants including contractors, data collection and management, and supply management	Measurement of long-term metrics associated with trial performance, high-level graphical reporting and query
Data	Transactional data store for day-to-day management of trial processes	Reporting warehouse for near real-time analysis
Users	Clinical operations staff and managers	Clinical operations staff and managers at all levels, CRO and corporate executives in pharmaceutical and biotech companies

Source: Life Science Insights, 2005

In essence, cPM solutions represent a convergence of planning and budgeting applications, business intelligence tools, and business process automation systems. They provide many benefits to organizations, but the greatest value is in presenting a single version of the truth upon which effective decisions can be made in a timely fashion.

cPM is a decision-making platform that helps people find answers to the following questions:

- What is happening with the organization, and how well are goals being met? Scorecarding allows the company to monitor current and past performance. This data provides the intelligence to help people make good decisions and to modify strategy going forward.
- Retrospectively, what happened with a given project, and why? Reporting and analysis allow the organization to understand its performance and even create a snapshot of the project from a particular past date, providing a clear picture into the conditions that existed at that particular time.
- Going forward, what should happen? Planning, forecasting, and budgeting allow an organization to drive performance. By providing model scenarios of future outcomes, cPM can help an organization make intelligent decisions for future planning.

In the clinical trials setting, managers want to know, in near real time, how their trials are progressing. Common information needs include enrollment progress, site performance, sales force effectiveness, and comparisons of current clinical data to past data from similar trials. These are some of the real issues pharmaceutical executives face in their day-to-day work and need to measure to make the decisions that drive their success or failure. Access to reports that provide this information in a timely manner and easy-to-read format enables these intelligent decisions. Managers need to view data in a manner that allows them to go through steps including comparing sets of data, creating metrics, measuring progress, and evaluating past performance. Without such tools, managers are at a disadvantage. This tactical information is available from within a cPM system.

cPM Market Drivers

The success of a pharmaceutical company is based on the success of its drugs — sales, safety profile, size of target population, market share, and other factors. However, the driving factor behind many product successes in the industry is the ability of a pharmaceutical company to leverage enormous amounts of data to create a competitive advantage in clinical research and ultimately in drug development and sales.

The driving factor behind many product successes in the industry is the ability of a pharmaceutical company to leverage enormous amounts of data to create a competitive advantage in clinical research and ultimately in drug development and sales.

One tool that helps organizations to achieve this goal and, as a result, become more competitive is a BI system. It allows managers to collect, organize, and analyze data on past performance, and they can then focus on the changes that will make the most difference.

BI has been applied with great success in many areas of large pharmaceutical companies. Commonly, these companies have experience with metric-based management in their manufacturing, finance, marketing, or sales departments. The market drivers for adding this application to the clinical development environment include:

- Present single version of the truth/data integrity (provide a repository for data from multiple internal and external sources)
- Add an analytical environment for financial, operational, and performance comparisons across projects, departments, and regions — engaging entire organization in consumption and contribution
- Provide visibility through multiple development efforts in many therapeutic areas and with a variety of CROs and contractors
- Take control of data by creating actionable reports that give managers the information they need to make decisions
- Improve execution of strategy

Although BI has proven invaluable, additional requirements emerged for tools that would enhance and extend decision-making abilities across the clinical development process. Applications were needed to support the development and management of metrics that, in turn, would allow the organization to measure performance, set goals, and drive improvement. Similarly, clinical trial managers

required planning and budgeting tools to deliver projects on time and within budgets. The driving forces included:

- Visualize and understand data
- Leverage existing information assets, derive new value
- Forecast financial requirements and allocate funding
- Make decisions about the future of compounds and drug development projects
- Improve the overall efficiency and productivity of R&D

cPM Challenges

Consolidating data from multiple divisions and external sources is never simple, and clinical data has its own challenges.

The first hurdle for pharmaceutical and biotech companies implementing cPM is to identify the data that will be used to measure performance and then locate and collect all the data together in a warehouse. Consolidating data from multiple divisions and external sources is never simple, and clinical data has its own challenges. For clinical development operations, the problem goes beyond consolidation, because some of the necessary data may not be collected or may not be collected in a relational database. Instead, the data may reside on paper and in spreadsheets and even be buried within documents. Some data sources may be external to the organization, such as clinical trial data that lies within a CRO. The data consolidation portion of the project can be extensive and typically requires support from internal IT groups that manage the data involved as well as third-party implementation services assistance.

Once all the data is collected, companies can go through an implementation process that integrates the various data feeds into a data warehouse, using an architecture that supports the analysis and reporting requirements. In addition, this architecture allows subsequent report writers to determine how they want to aggregate the data and which variables they want to report on later. This architecture also allows report writers to adjust and reaggregate data at any time. Once the database is available and has been loaded with historical information, the actual BI application is ready for configuration.

Cognos Clinical Performance Management

Cognos' cPM solution is a set of tools built around the issues and concerns of using BI to support performance management activities in the clinical development environment. Cognos provides software and services that assist pharmaceutical and biotech users in the installation, training, implementation, and use of the applications in their specialized environments.

Cognos product offerings in the cPM space are described in Table 2.

TABLE 2

Cognos Product Summary

Product	Function	Benefits and Applications in Biopharma
Platform		Secure access to information and reporting from any place, at any time, via a configurable, Web-based interface
		Advanced and scalable technology is simple enough for use by clinical and business staff, but capable enough for IT
ReportNet	Enterprise reporting and analysis functionality	Intuitive, out-of-the-box report creation for clinical trials, sales, finance, and budgeting
		Comprehensive coverage of all types of reports
		Allow user autonomy
		Works with existing applications
		Scalable and multi-lingual
Metrics Manager	Measures business process performance	Allows for standardized measurement of metrics across the organizations, including clinical trial milestones, drug safety/adverse event trends and sales performance
		Tracks performance against planned strategy and budgeted spending
		Clearly visualizes trends with colored arrows and change alerts
		Taps into multiple data sources in near real time
Planning	Enterprise planning	Defines goals and plan for performance
		Engages the clinical trial team with real-time feedback on progress toward goals
		Distills high-level strategy into plans and goals, down to the individual CRA level
		Continuous planning of clinical development processes with daily, weekly, and monthly updating
Controller	Measures financial performance	Consolidates multiple sources of accounting information into a single view of the truth
		Secure access to information from any place at any time
		Improves planning and forecasting of clinical development costs
		Sophisticated consolidation application allows comparisons of costs in different countries, currencies, and financial reporting environments

Source: Life Science Insights, 2005

Planning and Budgeting

Pharmaceutical executives readily admit they have no idea what the true costs of clinical development programs are in many cases.

Planning progress and budgeting costs for clinical trials are notoriously difficult tasks. The length of a clinical trial depends on external factors beyond the control of managers, including investigator participation, subject enrollment, and even, increasingly, the interim results from meta-analysis of clinical data. Slower-than-expected enrollment often requires clinical operations managers to add sites and investigators or increase recruitment efforts in midstream. When clinical data reflects that a trial has reached its endpoints, data collection may end early, and conversely, trials that fail to reach endpoints may be prolonged. The best efforts of managers at trial planning and budgeting commonly fail to predict outcomes, yet financial markets and clinical observers are quick to react when pharmaceutical companies are forced to reveal delays and cost overruns. Pharmaceutical executives readily admit they have no idea what the true costs of clinical development programs are in many cases.

By aggregating information from throughout the organization and organizing it along common accounting principles for individual trials and development programs, Cognos Planning and Controller applications put costs in perspective and give clinical program managers the power they need to make closer predictions of timelines and budgets. Throughout the business cycle, organizations are empowered to improve future projects, monitor ongoing projects, and understand current issues. As circumstances change, data is updated in near real time, and estimates can be revised instantly to reflect current circumstances. This allows managers to anticipate problems and act accordingly before things get out of control.

Analysis and Reporting

On-demand reporting is a requirement for pharmaceutical executives.

On-demand reporting is a requirement for pharmaceutical executives. The Cognos reporting environment provides on-demand reporting and enables end users to design and generate reports based on the data access permissions and business rules of the organization. The Cognos reporting environment is by no means static; rather, it provides the flexibility to produce both ad hoc and production reports. ReportNet allows users:

- Self-service, single-point access to the information they need
- An easy-to-use authoring environment with the ability to select and customize data views
- On-demand creation of graphics and visual data depictions that can be integrated into reports

The report environment allows users to create new reports without knowledge of the underlying data and use the functionality without misinterpreting or misusing the data. More sophisticated reports can be designed and built by professional authors within the Report Studio component.

The key functions of BI in pharmaceutical and biotech companies include:

- Analytics, queries, and graphical representation of data, trends, and metrics
- Balanced scorecarding and other formalized performance management methods

The analytics in the Cognos ReportNet environment include queries, reports, and graphical representations of data. Users access the analytics functions via either preconfigured reports or ad hoc queries. Even when using preconfigured reports, users have the ability to interact with and customize their view of the data on the fly as follows:

- Drilling down or aggregating specific data elements
- Sorting, grouping, and filtering data to get the desired cuts
- Performing calculations
- Creating graphics and visual depictions based on the data

The query environment is user-friendly enough so that even nontechnical users with a basic understanding can use the tools, but powerful enough to meet the demands of IT staff and other demanding users. Organizations have the ability to give wide groups of users access to the information while also maintaining a secure environment for sensitive data. Organizations can control access in a role-based security environment to individual fields in the database. This empowers users at all levels to draw their own insights from the data. Figure 2 provides an example of the analytical environment using Cognos tools.

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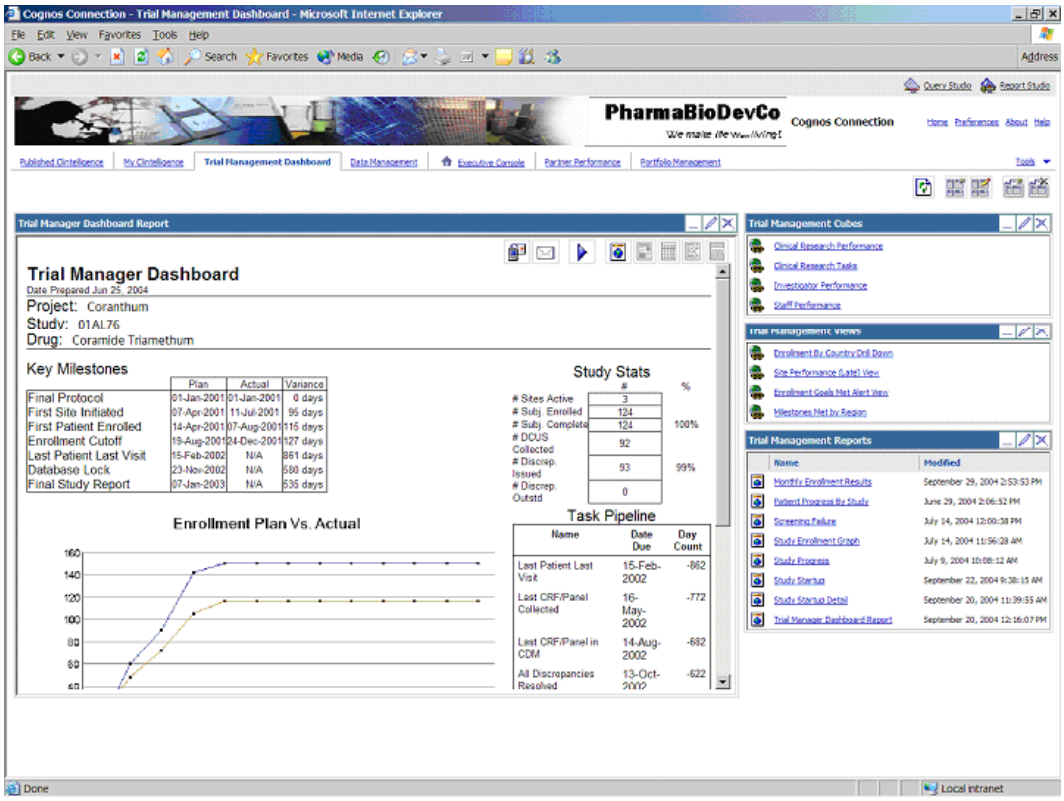
FIGURE 2

Analytical Environment Screenshot



Source: Cognos, 2005

Clinical Scorecarding

One of the most common cPM applications is clinical scorecarding, whereby predetermined metrics are assessed on a regular basis, usually quarterly or annually, to measure the progress of the organization's teams toward strategic goals. The metrics are carefully selected as representative of progress toward the agreed-upon goals. Although the business process work that is involved in identifying the metrics to be studied is the bulk of the work in the process of the balanced scorecard method, having a tool in place to generate the scorecards can also be invaluable.

Predetermined metrics are assessed on a regular basis, usually quarterly or annually, to measure the progress of the organization's teams toward strategic goals.

Cognos' Metrics Manager is designed to calculate and display organizational and other performance metrics and can be customized to suit the requirements of the clinical development environment. Balanced scorecards are one of the most popular performance management approaches, but Metrics Manager can be configured to other methodologies, including Baldridge, Six Sigma, and the European Foundation for Quality Management tools.

Some common uses of metrics in clinical development include:

- **Making decisions about external resources.** Scorecarding can be used to create objective measures of the performance of clinical entities such as research sites, individual investigators, or CROs used in clinical research. This information can then be used to make decisions when planning future clinical trials.

- **Comparing the efficiency of multiple development programs.** Individual development programs often have their own internal systems that drive day-to-day operations in pharmaceutical and biotech companies. As a result, data from these programs can be difficult to compare at the organizational level. The Cognos data warehouse provides a single reporting environment for storing, accessing, and using metrics to compare this information across the company.

- **Measuring cost and allocating resources.** The true cost of clinical research is an elusive figure for many pharmaceutical and biotech companies. Pulling together the financial information from all of the company's projects provides a unified view of the truth.

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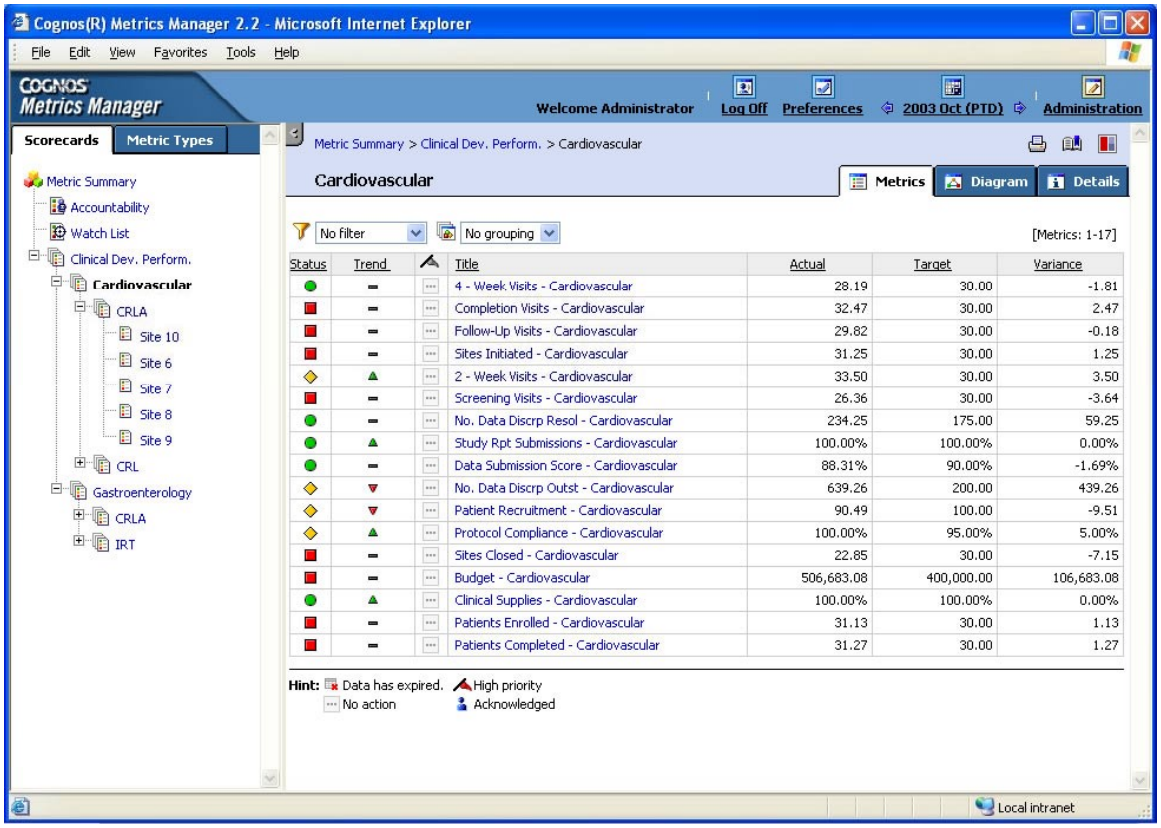
The screenshot from the Cognos application in Figure 3 provides an example of a Metric Summary Report built in Metrics Manager. It uses simple, graphical indicators to depict the status of trial activities as well as the trend in the status metric over the reporting period.

FIGURE 3

Clinical Scorecard in Metrics Manager



Source: Cognos, 2005

Vendor Strengths

Cognos has a long history of providing applications for business intelligence, planning, financial, and performance management to multiple industries. The company has brought this experience into the clinical development arena, although its time-tested tools have been recently updated to reflect the latest technology. Strengths of the Cognos solution include:

- **Capabilities.** For pharmaceutical and biotech companies, a rapidly changing operating environment is the rule. The flexibility of the Cognos cPM application allows pharmaceutical companies to:
  - Make changes to the metrics, reports, and analyses in response to changes in regulatory requirements, the product and project portfolio, and staff and strategy changes
  - Adapt the user environment and the available tools to differing user roles and responsibilities as well as varying levels of computing expertise
  - Configure the application to meet the requirements of the clinical development environment

- **Flexibility.** Many cPM users we spoke with are moving Cognos into the clinical development area following a positive experience with the product in other areas of their organizations. In the largest pharmaceutical organizations, corporate "standards" for IT products are often in place, and when clinical development groups look to add performance management, they quite often look to the tools their organizations have experience with and trust, such as Cognos. Many of the largest pharmaceutical companies in the world use Cognos as a corporate standard for BI, and adding an implementation in the clinical development space makes sense.

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- **Web-based platform.** With development programs and staff spanning multiple continents, the Web-based platform allows all team members to access a single version of the truth from data and reporting available online, in a secure environment, from any location.

- **Standards-based architecture.** The clinical informatics industry is increasingly relying on standards for data interoperability. Cognos is built on a service oriented architecture that is the basis for emerging requirements in the clinical informatics space, including XML. Cognos' BI tools communicate with other industry-leading sales force automation, enterprise resource planning, and supply chain management systems, enabling organizations to leverage these investments.

- **Regulatory compliance.** The zero-footprint architecture, incorporation of data interoperability standards, and security of the system aid in validation when system data is used in regulatory submissions.

Competitive Landscape

In the clinical development environment, performance management is a new concept. Many pharmaceutical and biotech companies are still in the early stages of enabling trials for the use of EDC. More advanced organizations may have EDC in place and are embarking on the next step, which is usually CTMS. Most companies that are ready to start moving on to cPM are just beginning to ask the difficult questions about clinical trial processes and assemble the data they need to find the answers.

As interest in addressing problems in the clinical development process grows, driven by initiatives such as the FDA's Critical Path, organizations will look to BI as a necessary tool. cPM is a logical extension of BI and a number of Cognos' traditional competitors also serve their own customers' cPM needs.

Business intelligence competitors include Oracle, SAS, Hyperion, and Business Objects. Oracle and SAS provide clinical trial management system applications to their customers in addition to the analytical environment that assists users in maximizing the impact of their data. All of these vendors offer business intelligence platforms that work with multiple data sources, but the sophistication of the solutions and the content and expertise offered in the life science vertical vary.

Demand for BI software is robust across multiple industries, and BI continues to remain a top-priority segment within the enterprise software market. In 2003, BI market growth accelerated to 4.9%, reaching $3.9 billion in worldwide license and

maintenance revenue, according to IDC. This growth represents an improvement over the 1.8% increase in 2002. Additionally, unlike other enterprise software markets, the BI tools market never decreased during the 2000–2002 period, whereas the IT market and the economy as a whole went through an adjustment. (See *Worldwide Business Intelligence Tools 2004–2008 Forecast Update and 2003 Vendor Shares*, IDC #31472, July 2004.) This trend speaks to the increased importance of BI software in the corporate setting, and we expect life science to continue to be a growth area for BI.

CASE STUDIES

Cognos' customers have seen demonstrable results and value from the ReportNet, Metrics Manager, Planning, and Controller applications. The case studies that follow present several notable user experiences with the Cognos applications.

Enterprise Reporting Manager, Top 10 Biotech

The value of organizational standards is clear, and pharma and biotech IT managers see the same total cost of ownership benefits from enterprisewide deployment as their counterparts in other industries. A manager of enterprise reporting services stated that his company has used "nearly every reporting tool on the market" prior to Cognos. As his company adopted Cognos, he found that "there's a lot of business value in converting reports from one technology to the other [Cognos]." He added:

> From our perspective, the biggest savings is in the standard. Before, there were a lot of custom-built reports, whereas now the solution is entirely out of the box with ReportNet. So our overall cost of maintenance from an IS perspective is significantly less. And the turnaround time to be able to meet a client need is faster. We find that the speed of development with ReportNet is significantly faster than with other comparable BI tools. So that's a competitive advantage.

From the IT manager's perspective, implementing BI software adds value to his organization. Standardization of technologies under the Cognos umbrella alleviates many technical and support issues. By empowering users to customize their own reports, the application frees up IS time spent customizing reports for business users. cPM is the biggest winner in this case as the company moves to standardized terminology, costs are reduced, and time is saved in the overall clinical development program.

Senior Project Manager, R&D, Biotech

Control over reporting is a common theme for business and clinical users. A senior project manager within the R&D organization at a leading biotech company, which recently began rolling out ReportNet and Metrics Manager, stated that "we want [our users] to take control over our reporting." In the current situation, data users requesting reports need to involve the IT staff, which requires lengthy documentation

and a long lead time. According to the senior project manager, in addition to these headaches, "At the end of the day when you get the report back, you say 'This is kind of what I was looking for but not quite.'" In the new scenario, the entire team working on a clinical trial is empowered — clinical trial scientists, data analysts, operations specialists, and financial specialists. These people and many others will benefit from better data, leading to more productive meetings and more intelligent decisions within drug development.

Senior Project Manager, R&D, Biotech

Even when a custom report-building service is kept in place, IS staff report that the combination of the report-building tool in ReportNet with the user-friendly interface still saves them time over traditional reporting processes:

> Having a certain level of savvy in building the underlying data model is something we can accomplish. Once that data model is built, we can publish so much easier, since it's then just drag and drop. It's really putting the reporting capability back in the hands of the end user, and we can control our own destiny from a reporting standpoint.

Ultimately, Cognos software puts control in the hands of the end users and allows them to actually access their data. End users are also using the query capabilities for filtering and rearranging the data in preconfigured reports:

> I can say 'Here's the published report, and here is a way to pull what you need and save your own query.' Particularly powerful in both ad hoc and Report Studio is the ability to create custom filters on every column in the data field. [With the old tool,] we would have to tell the programmers to create a filter for each query, and they would have to custom-code the query. That's a pretty powerful feature — the users can just put whatever they want in the data area and filter it how they want. So once people see they can start using their data more efficiently, it's going to be a wonderful thing.

End users are empowered by the capability to manage their data and create their own reports to optimize the direction of current and future clinical trials.

Senior Project Manager, R&D, Biotech

> I think we will be able to deploy many more reports, and it will snowball. At our company, people have accepted the fact that they put a lot of data into systems and they can't get it out. As I show them early reports, they're starting to realize that this would be great, that they won't have to reenter all their data.

This manager, currently in the implementation stage, expects widespread adoption of Cognos' products by end users who will become more efficient with their time, data, and report management.

European R&D Program Manager, Top 10 Pharma

The reporting data warehouse that underlies the Cognos application is a benefit to large pharmaceutical users. In one pharmaceutical company we spoke to, the warehouse replaces an older environment in which there were many sources of data, each with its own format, owner, and perspective. Questions would stream into the IT department and each question generated a static report: "Every time [we had a request], we had to rebuild the query," said the program manager. In fact, the company even had dedicated a full-time person to fulfilling data requests and running laborious queries that required culling data from disparate excel sheets, PowerPoint presentations, and many other sources. "We needed just one place where all the data would live," said the program manager.

Metrics Manager provided a solution for both her department and the entire European subsidiary that put all their relevant information in one easily accessible location. The implementation process also put standard data definitions and interpretations in place across all the groups at their facility, further complementing the benefits they reaped from Metric Manager's single source of data.

European R&D Program Manager, Top 10 Pharma

This program manager of information management at a top 10 pharmaceutical company has been working with Metrics Manager for a year. Over a year ago, her group was looking to improve its measurement capabilities. "We were looking for a good solution in scorecarding" and chose Cognos as the solution. At her company, Metrics Manager is heavily applied to measuring and monitoring progress within drug development, particularly in drug discovery.

With Metrics Manager, the company is able to "move forward in the different phases" of discovery. For example, this manager is able to answer key questions such as:

- How many projects do I have in target identification phase?
- How many are moving along within assay development?
- How many projects have gone from hit to lead?

Every year, each project team sets annual targets for its drug development goals. "Throughout the year, we measure the goals against the actuals, which produce key performance indicators (KPIs)," said the manager. With Metrics Manager, team members are able to build one collective report, enhanced by an action plan and traffic lights to guide and monitor progress.

From an IT perspective, the value emerges from the simplicity of having one place where the data lives, collected from every source required. This design allows for real access to all data in drug discovery. This manager also finds value in the ease of tracking milestones. With many projects running, Metrics Manager makes it easy to follow the status of each project at each quarter.

Global Head of Clinical Operations, Novartis

The global head of clinical operations in the Oncology division at Novartis Pharmaceuticals is a relatively new user of Cognos products. His division oversees a significant number of clinical trials and, therefore, was in need of a product to help monitor trials as well as make important, strategic decisions based on good data. He stated, "We have a need to stay on top of all these trials."

In discussing his expectations, he conveyed that he was excited about the strength of the tool and how it would complement the clinical trial operations. "We're just now implementing it, but I expect it to increase visibility into our trials, increase transparency. I also expect a significant improvement in the area of clinical start-up times, an increased focus on enrollment, and improvement in our trial closeouts," he said. "Of course, Cognos will not make this all happen, but it's a contributing tool." He stated that although Cognos is an essential component, "There are many other steps we've taken to improve our performance."

As an early user, he discussed his vision of his company's future use of Cognos' products: "At this point, I think Cognos is a very helpful tool to generate basic, standard reports. In terms of data mining and coming up with new insights, I think that is the future. At this point, I think it's important that we can design easy-to-understand reports. The true test will be how easily we'll be able to drill down into the data to come up with new combinations."

Thinking about his introduction to Cognos and the future of Cognos' products, he stated, "Initially, I was very intrigued when I saw a presentation by Cognos when they showed how BMW was using Cognos — how they were able to pull together information from their business worldwide in almost real time, to generate almost real-time reports for management. And that is my vision, that one day Cognos could help us with reporting capabilities for the pharmaceutical industry."

In summary, these users of Cognos' products have seen, or are beginning to see, the benefits associated with improved transparency of the data, visual representations of the data, and collecting the data in one location. cPM is at the heart of these benefits. Clinical performance is completely centered on all the key aspects of clinical trials — study start-ups, clinical trial budget management, AE reporting, enrollment, site management, and study closeouts. These are the milestones and measurable activities in the clinical trials arena that ultimately save the sponsors time and money. Information-based, intelligent decisions are enabled with these cPM tools, and the strength of the trial data is the ultimate predictor of success. Biotech and pharmaceutical companies that have the tools accessible and on their users' desktops to capture, share, and analyze this data will see the benefits throughout the drug discovery and development chain.

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CHALLENGES

This white paper documents the business case for cPM and the features of Cognos' services and tools that assist pharmaceutical and biotech companies in establishing cPM processes in their organizations. However, Cognos is one of many vendors offering performance management tools. Challenges for Cognos in the cPM market include:

- **Brand recognition.** Although Cognos is well-known in the IT space and is the standard for BI at many big pharmaceutical companies, it is relatively unknown in the clinical development space.
- **Market timing.** cPM is a progression from underlying technology that still awaits adoption in many pharmaceutical organizations. Although it is possible to manually institute performance management without the precursor technologies identified, it is more difficult due to the expected paucity of available data for analysis in the performance management process. Cognos and similar BI applications may be a bit ahead of market readiness for some pharmaceutical and biotech companies. However, the level of preparedness for performance management varies with individual pharmaceutical organizations.
- **Clinical development customizations.** Although Cognos successfully markets a standard product in all of its existing verticals, the clinical development space is highly specific and its participants often prefer applications specifically built for this space. Cognos is a horizontal IT vendor that does not offer a customized version of the applications discussed for the life science industry; however, industry partners are available to support life science companies implementing the Cognos technology.
- **Implementation issues.** Implementation processes, time, and costs are a hurdle for any IT application, but implementation of cPM can be especially challenging given the nature and basic lack of source applications in many cases. This situation may create a barrier to adoption as companies wait for the underlying IT environments to mature.

FUTURE OUTLOOK

Today's market environment puts pressure on pharmaceutical and biotech companies to bring safer, more effective drugs to market faster than ever before. Generic competition and pricing pressure have lowered margins, just as critical blockbuster drug patents are expiring. To remain competitive, pharmaceutical companies need the information to make critical R&D decisions earlier, reduce spending on failed compounds, and focus their companies' resources on the best candidates for success, whether or not they are developed internally. Information is an essential tool for making these difficult decisions, and the decentralized governance structure of most major pharmaceutical companies makes getting the data to create this information difficult.

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R&D, and its largest spending category, clinical trials, are increasingly coming under the microscope when pharmaceutical companies look at drug development costs. Clinical operations managers on the ground are heavily focused on the day-to-day issues that can slow the pace of a trial. These issues are important, as trial delays play a major role in an environment where time is money. At the organizational level, managers increasingly seek information that can address process issues at the strategic level.

A higher-level focus on clinical development brings the process into the light and reveals opportunities for efficiencies and making better decisions. Pharmaceutical companies are increasingly focusing on the overall conduct of investigators, sites, and CROs and looking for objective data on experiences to make decisions for future clinical research. BI tools meet this need for data and analysis and will play an increasing role in management of clinical operations in the future.

BI and cPM adoption are in the early stages in all sectors of the pharmaceutical and biotech industries. A number of determining factors will affect the speed of adoption of BI in clinical development, including:

- The acceptance of underlying technologies that provide the data for BI warehouses, including EDC and CTMS
- Developments on regulatory initiatives such as the FDA's Critical Path and data interoperability standards
- Urgency of the push for R&D efficiency by small and medium-sized pharmaceutical companies and biotech organizations
- Growing data integration challenges for drug development projects
- Increasing demand for solutions such as data warehousing and analytical environments, alongside the ongoing trend toward partnering and in-licensing of compounds

ESSENTIAL GUIDANCE

Pharmaceutical and Biotech Companies

A number of factors have led pharmaceutical and biotech companies to seek process improvements and the tools that enable them to make headway against the challenges facing the industry. Pharmaceutical and biotech companies that want to implement cPM need to start with a BI reporting agenda. BI systems allow better access to information within disparate systems and provide an entry point for high-level, decision-enabling scorecarding. This will also complement any ongoing corporate scorecard initiatives. The guided analytics provide a perspective for decision making, while the BI platform gives easy access to the underlying information. cPM solutions provide a valuable tool for performance assessment and improvement and can address issues such as:

- **Clinical development costs and time.** Clinical development costs have grown exponentially over the past decade, and the pressure has built for clinical operations professionals to deliver better trials faster with more accurate data. The first step in making this happen is clearly and objectively examining the current status of operations. Implementing a BI tool can help companies to accomplish this first step.
- **R&D productivity.** Measuring current productivity levels allows R&D managers to set goals for future productivity and monitor progress toward these goals.

- **Better decision making.** Accurate performance data allows for objective decision making about the future of specific projects and allows managers to focus resources on the opportunities that are most likely to bring success.

- **Organizational process improvement.** cPM can be used to identify the processes that are most in need of improvement and suggest those areas within these processes that should be targeted.

The business case for implementing cPM is clear, but the actions that must be taken to get there often are not. At its core, BI is only a tool for providing information about current processes, and it should be taken to the next level which includes performance assessment and subsequent improvement efforts. Target areas for improvement in clinical development programs include speed, timeliness, data quality, and staff and investigator performance. To improve performance, drug development organizations need to change their processes, which is always a difficult task. A high level of organizational commitment, appropriate leadership, and dedicated resources are necessary for successful performance improvement programs. Besides the tools, organizations need to have the resources and drive to implement solutions.

The business case for implementing cPM is clear, but the actions that must be taken to get there often are not.

Beginning a project without this commitment is fraught with peril. However, even without this commitment, measuring the problem can demonstrate the necessity for change, thereby increasing the organizations' readiness and easing further process improvements.

cPM System Selection

In an assessment of the capabilities required to perform cPM, we find that most of the major BI products on the market are capable of being configured to perform cPM successfully. Differences between potential cPM applications lie in their architecture, flexibility, scalability, and ability to meet both users' needs and the regulatory requirements of the pharmaceutical industry. Pharmaceutical and biotech companies should identify their organizations' needs and look to meet them when selecting a solution. Only the benefits of the Cognos solution are covered in this paper; no attempt is made to compare it with other available solutions.

We expect that existing organizational standards will play an important role in cPM system selection. In most organizations, clinical development is one of the last areas to adopt BI, and existing organizational standards and IT expertise will drive adoption.

Life Science Insights feels strongly about the need to address inefficiencies in clinical development and the relevance of performance management to this problem. However, this white paper is not intended to specifically recommend the Cognos solution; it only points out the strengths of this particular solution when applied to the business issues of pharmaceutical and biotech companies.

LEARN MORE

Methodology

This white paper was sponsored by Cognos Corporation. The majority of the primary research component of the paper consists of eight formal interviews with users of Cognos' ReportNet or Metrics Manager at pharmaceutical and biotech companies. Representatives of two Cognos integration partners, Phase Forward and 3C Pharma, were also interviewed: Stacy Humphrey, director of product marketing at Phase Forward; and Peter Oudheusden, president, and Karen Briegs, director of marketing/product development at 3C Pharma. All of the interviews were conducted by telephone, and all of the formal interview subjects were referred to Life Science Insights by Cognos. Additional primary research was done with independent sources provided by Life Science Insights. Primary research data is presented in the Case Studies section of the paper and was used to develop the background information and analysis throughout the document.

Extensive secondary research was also performed by Life Science Insights in the course of preparing this white paper.

Glossary of Acronyms

AE: Adverse event

BI: Business Intelligence

cPM: Clinical performance management

CRA: Clinical research associate

CRF: Case report form

CRO: Clinical research organization

CTMS: Clinical trial management system

EDC: Electronic data capture

FDA: Food and Drug Administration

OLAP: Online analytical processing

R&D: Research and development

XML: eXtensible Markup Language

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