White Paper
January 2009

Top Ten Reports in Clinical Performance Management

Information Management

Cognos software

Contents

Abstract

Finding ways to reduce the cost of clinical trials is on the agenda of every pharmaceutical company striving to remain profitable. Many are turning to clinical performance management software to manage and optimize their clinical trial activities. This platform unites critical data in one place. It lets you set goals and fix plans through budgeting and planning tools, track metrics through scorecarding and reporting, and understand results through analysis. This white paper outlines the ten critical CPM reports every pharmaceutical organization needs to gain a complete view of all clinical trial activities.

Overview

The era of the blockbuster drug has come to an end. And in its wake, the pharmaceutical industry is undergoing massive restructuring to remain profitable in the face of patent expirations, limited research pipelines, regulatory constraints, safety concerns and more.

Clinical trials have been identified as the greatest source of escalating costs in the drug development industry. Drug development costs may range from $500 million to over $2 billion[1], depending on the therapy area, including capitalized losses through time spent out of pocket. For every day a drug is delayed from reaching the market, the company stands to lose an average of $775,000 in revenues per day, plus approximately $37,000 daily in development costs.[2]

Meanwhile, clinicians and regulatory agencies are requiring more and more data from clinical trials, resulting in increased complexity in each trial phase, escalating costs and longer delays before a new drug reaches the market—while extending the time a drug developer remains out of pocket.

To ensure continued profitability, you need to:

- Boost lagging R&D productivity
- Reduce drug development cycle time
- Speed time to market
- Improve product quality and safety
- Control costs
- Manage regulatory issues

The Solution

Clinical Performance Management

Clinical performance management (CPM) is a term pioneered by IBM to describe a comprehensive reporting, analytic and planning/budgeting solution for the entire clinical trial process. CPM spans all the activities that are required as a part of study execution and across multiple departments and transactional systems.

CPM based on IBM Cognos performance management software provides a holistic view that helps clinical research organizations set goals and metrics, fix plans and understand results. Our integrated, best-practices platform for clinical performance management gives you access to all your critical data—clinical trials, 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.

The following is a description of 10 critical CPM reports every pharmaceutical organization needs to gain a complete view of all activities associated with clinical R&D. We begin with an area of strategic importance: clinical resource planning.

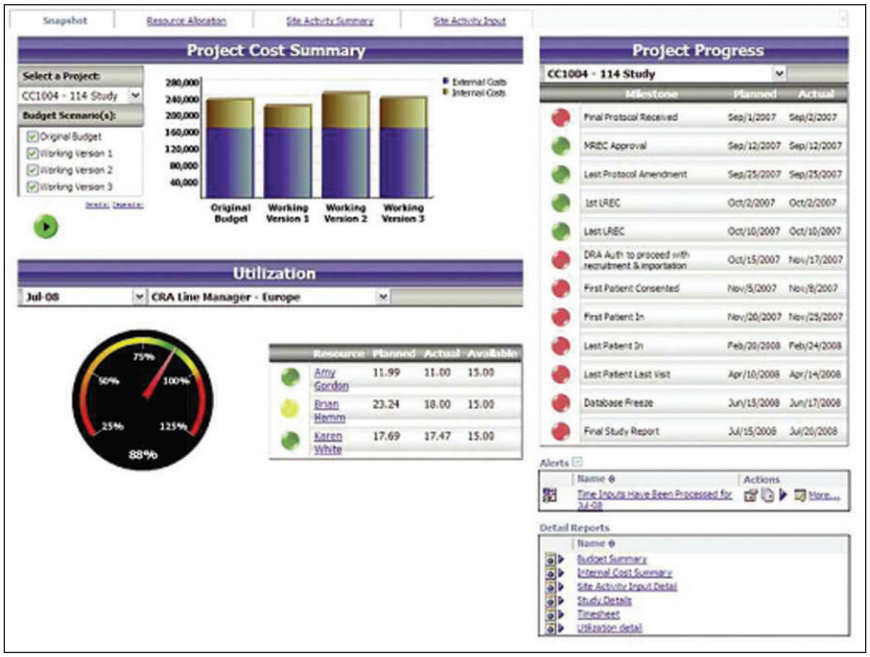
Clinical Trial Resource Planning Reports

Understanding and predicting staffing needs, say, for a large and complex Phase 3 trial, can be challenging, especially since programs are often international in scope. While outsourcing provides some relief to clinical staffing budgets, it also adds a layer of complexity. Forecasting, budgeting and planning for staff resources working from far-flung locations, in combination with in-house staff, presents a resource management challenge that strains existing systems. Forecasting must take into account diverse HR policies and regulations, local holiday schedules, varying pay scales and many other variables in each country.

The first three critical CPM reports are included in the IBM Cognos Clinical Trial Resource Planning Performance Blueprint, which provides out-of-the box functionality including dashboards, analytical reports and a pre-configured data model to facilitate rapid time-to-value. Since clinical trial project managers need critical data readily available, the blueprint presents information as a customized array of reports.

Report #1 - Clinical Trial Project Overview

The dashboard below is a collection of reports that create a snapshot view of information a clinical trial project manager needs to make more effective resource management decisions. From here, the manager can access the full range of relevant reports, analyses and plans.

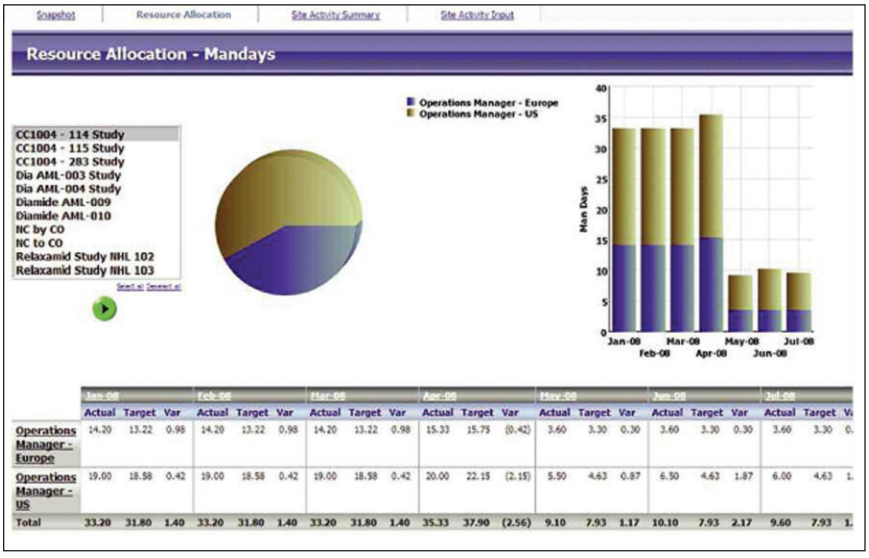


The sections of this dashboard (clockwise from top left) are **1) Project Cost Summary monitor**, **2) a report on Project Progress** and **3) Utilization**, in this case showing clinical research associate (CRA) line managers in Europe. A list of detail reports is shown on the lower right portion of the screen, and a drill-down example is shown later on.

All the charts allow drill-through to more detailed analyses and include up-to-date information from multiple transactional and planning systems. Dashboards are customized to the different roles and responsibilities found within a clinical development organization and show only the data that the manager has permission to access.

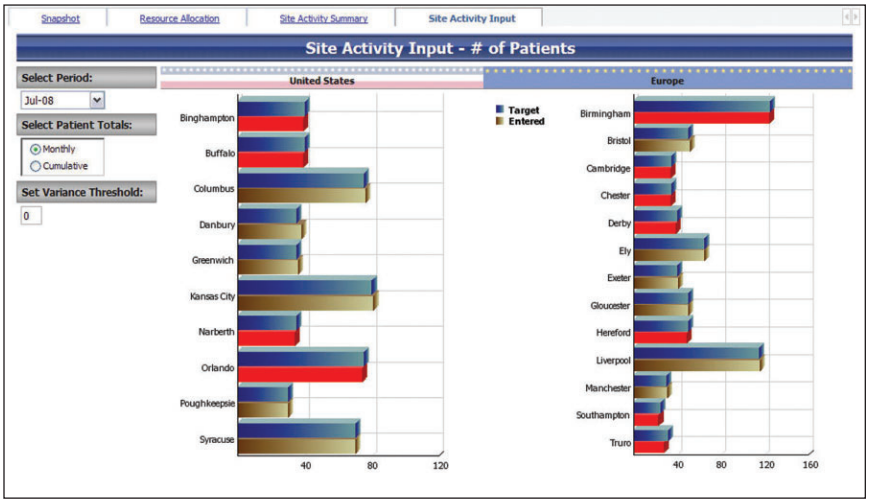
Report #2 - Resource Allocation

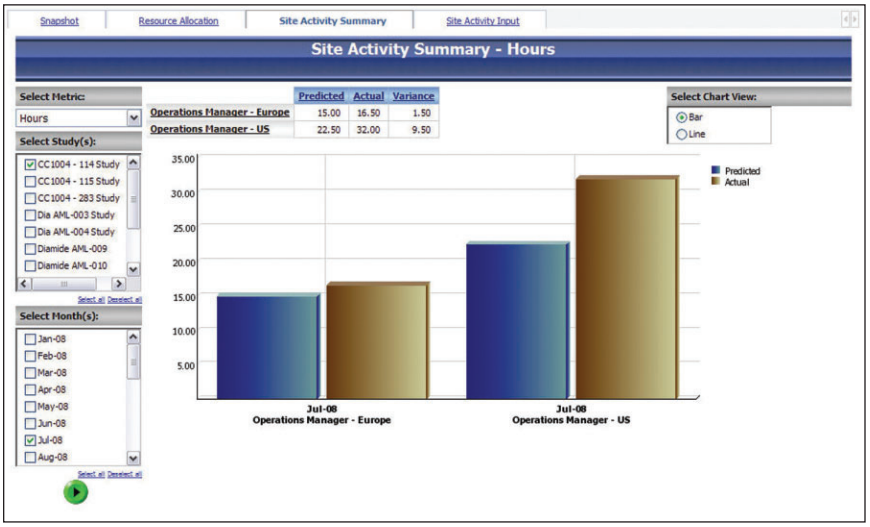
In this and the following figures, we see some of the tabs underlying the Project Cost Summary. In this Resource Allocation report, we can compare man-day allocations for operations managers in the U.S. and Europe, including actual hours, target hours and variance.



Report #3 – Site Activity

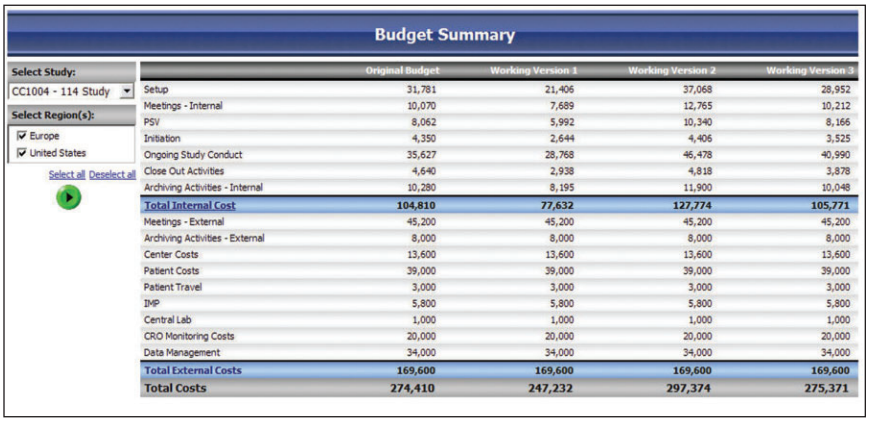
Next, we can see the Site Activity summary report for each city in the clinical trial, in the U.S. and Europe. The first of these is expressed in numbers of patients for each site. In the second view, the Site Activity Summary presents a recruitment perspective, showing activity for the same sites expressed in numbers of hours for operations managers in the U.S. and in Europe.





Report #4 – Budget Summary

The Project Manager can also drill down from the Project Overview dashboard to several pre-configured detail reports (listed at the lower right portion of dashboard). For example, the following Budget Summary Report provides a detailed comparison report of several variations of the budget. Other detail reports include Internal Cost Summary, Site Activity Input Detail, Study Details, Timesheet and Utilization Detail.



Budget Summary

Select Study: CC1004 - 114 Study

Select Region(s): Europe, United States

Select all Deselect all

	Original Budget	Working Version 1	Working Version 2	Working Version 3
Setup	31,781	21,406	37,068	28,952
Meetings - Internal	10,070	7,689	12,765	10,212
PSV	8,062	5,992	10,340	8,166
Initiation	4,350	2,644	4,406	3,525
Ongoing Study Conduct	35,627	28,768	46,478	40,990
Close Out Activities	4,640	2,938	4,818	3,878
Archiving Activities - Internal	10,280	8,195	11,900	10,048
Total Internal Cost	**104,810**	**77,632**	**127,774**	**105,771**
Meetings - External	45,200	45,200	45,200	45,200
Archiving Activities - External	8,000	8,000	8,000	8,000
Center Costs	13,600	13,600	13,600	13,600
Patient Costs	39,000	39,000	39,000	39,000
Patient Travel	3,000	3,000	3,000	3,000
IMP	5,800	5,800	5,800	5,800
Central Lab	1,000	1,000	1,000	1,000
CRO Monitoring Costs	20,000	20,000	20,000	20,000
Data Management	34,000	34,000	34,000	34,000
Total External Costs	**169,600**	**169,600**	**169,600**	**169,600**
Total Costs	**274,410**	**247,232**	**297,374**	**275,371**

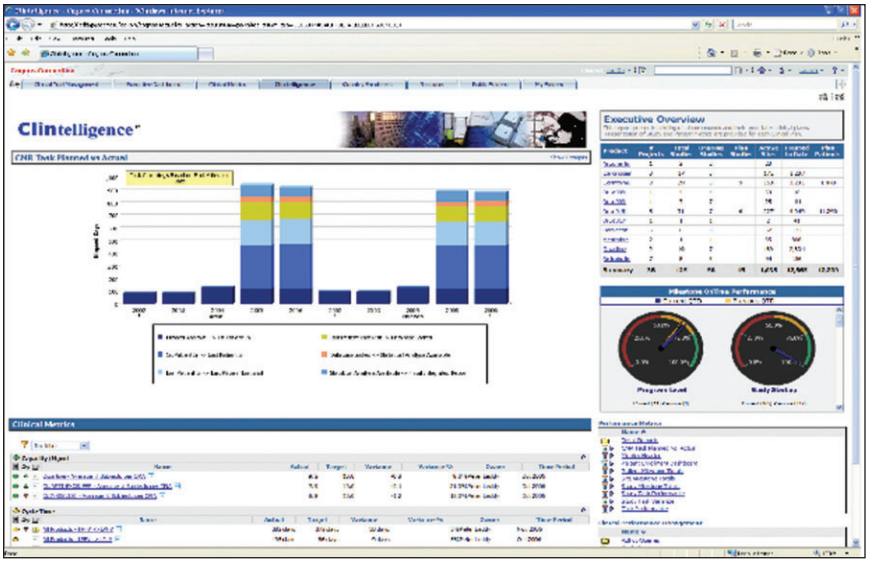
Report #5 – Executive Overview Dashboard

Developed in partnership with 3C Pharma, developers of Clintelligence, and using IBM Cognos performance management software, this dashboard provides senior management with high-level oversight of ongoing activities in the clinical organization. The Executive Overview in the top right provides summary metrics of the portfolio of products, showing the number of programs, studies and active versus planned patients for each product. These summary metrics are often difficult to get from clinical trial management systems (CTMS), which typically have a single-study focus and often require cobbling together a variety of unwieldy spreadsheets.

Drilling into the Compound allows users to see detailed information about programs and studies, down to the site level of information, bringing together data from multiple systems including clinical data management systems (CDMS), electronic data capture (EDC), enterprise resource planning (ERP), CTMS and others.

The bar chart provides comparative metrics to gauge performance in various stages of the clinical trial process. Utilizing standardized phases as defined by CMR International, a clinical benchmarking organization, this report provides insight on performance towards a goal of reducing cycle time.

Metrics such as On-Time Performance provide executives with performance and trending of key measures that support the organization's clinical strategy. The On-Time Performance gauges provide a trending of current period versus previous period and allow management to quickly see where the organization may be underperforming.



Report #6 – Clinical Trials Dashboard

This dashboard, developed in partnership with ISA Consulting, allows you to continually monitor clinical trials performance to alert you to situations needing attention. It provides the depth of understanding to correct issues at the source. It leverages IBM Cognos 8 Business Intelligence and extracts data from existing CTMS, EDC and ERP systems to populate the data warehouse. Analytic pathways within the Clinical Trials Dashboard bring important information to the surface and focus users' attention on high-priority areas. The user experience is maximized through multiple tables, charts and prompts.

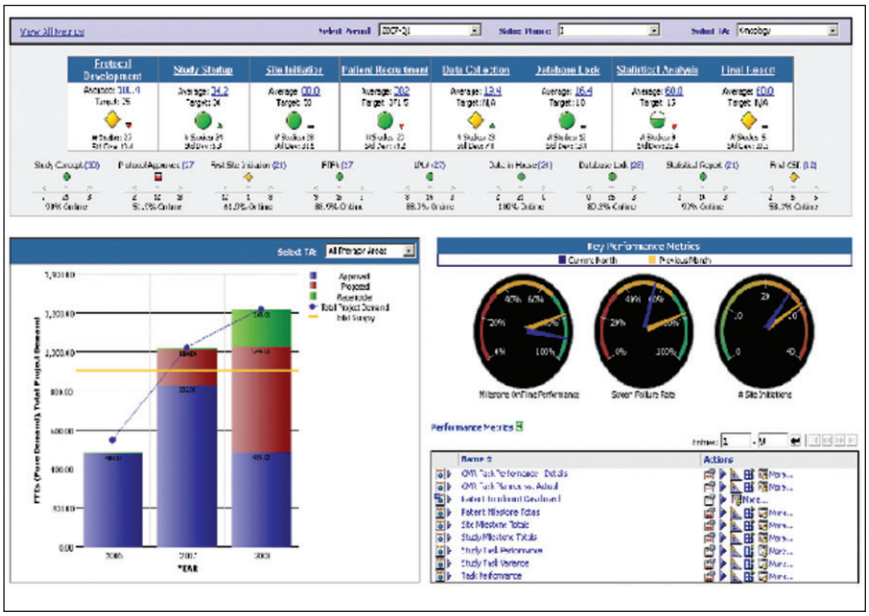
In this dashboard, one can filter on, say, Trial 48 and see what has changed. Notice there are three green lights that show trial initiation status by country, by percentage of sites that are ready and by percentage enrolled, over-enrolled or under-enrolled. There are countries within the target green, including Italy, which is indicating within the over-enrollment threshold. You can sort the countries by percentage of sites ready, and then by percentage of target enrolled.

** ISA Clinical Dashboard is the property of ISA Consulting*

Report #7 – Clinical Cycle-Time Metrics Dashboard

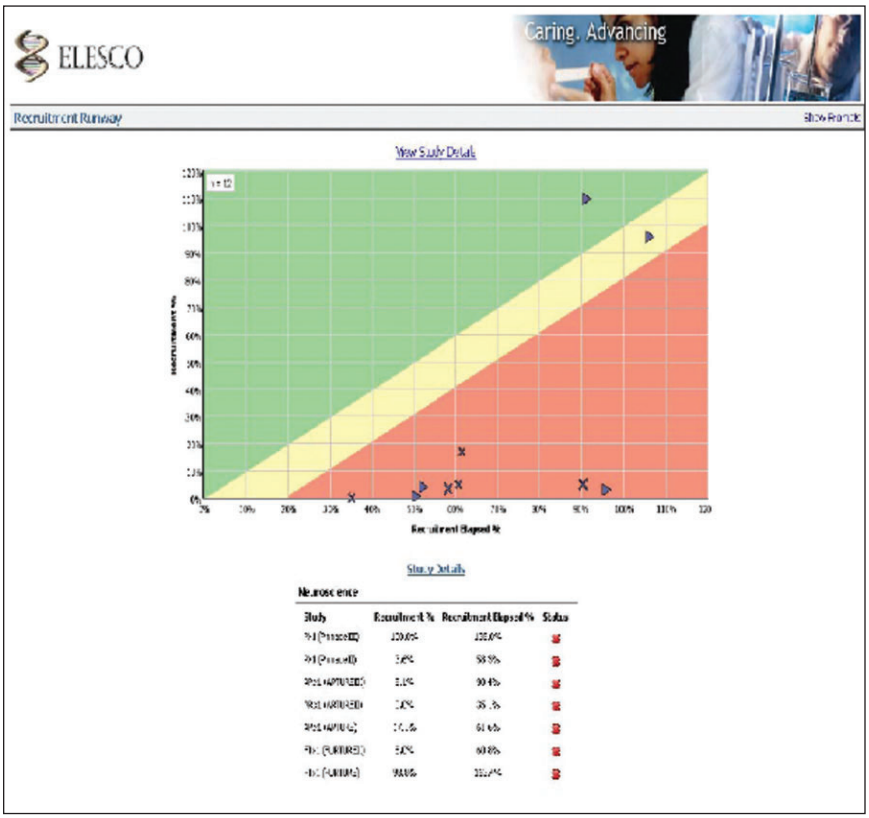
This Clinical Cycle-Time Metrics dashboard provides an at-a-glance view of the key phases of the clinical trial workflow. It is an industry best practice to manage and monitor the time between key milestones. As an example, the Study Startup Phase is the duration between Protocol Approval and First Site Initiated (FSI) milestones. By monitoring the duration of phases as well as the individual milestone counts and on-time performance, we can identify and remedy the bottlenecks in the process. Drop-downs let the user look at a particular slice of the organization, for example, Phase I Oncology Studies. Users can also look at a Resource Allocation chart showing the resource requirements projected to complete planned trials. This can be compared to a defined or planned future supply of resources for better planning.

Lastly, various gauges provide a snapshot of key performance metrics, showing planned versus actual, with the ability to drill down into details.



Report #8 - Recruitment Performance

One of the most challenging tasks in clinical trial management is determining when studies are not progressing appropriately toward planned goals. The Recruitment Performance report spotlights a hypothetical clinical research organization called Elesco. By providing an at-a-glance view of all studies and their current performance in recruiting patients versus the elapsed recruitment time, this report clearly shows the outliers and where remedial action may be needed, such as initiating new sites or follow-up with primary investigators. The studies are drillable to provide more information about the study status.

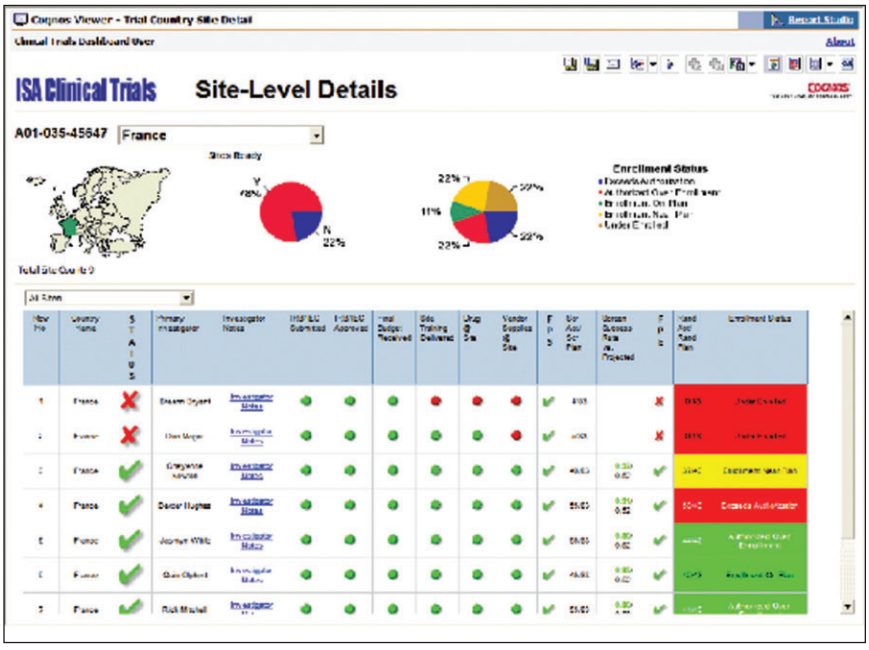


Report #9 – Site-Level Details

This report, developed by ISA Consulting, delivers site status and performance metrics around recruitment within the selected country and trial. It provides CRAs with a consolidated and simplified view of sites that helps them easily identify where they may need to engage.

Country summary information provides a breakdown of the current enrollment status and overall site status. For example, filtering on "Trial 47" and drilling through on France using the drop-down filter for country allows examination of trial data by this country. The data is sorted by those sites not ready, but filtering the data by a variety of categories is also possible.

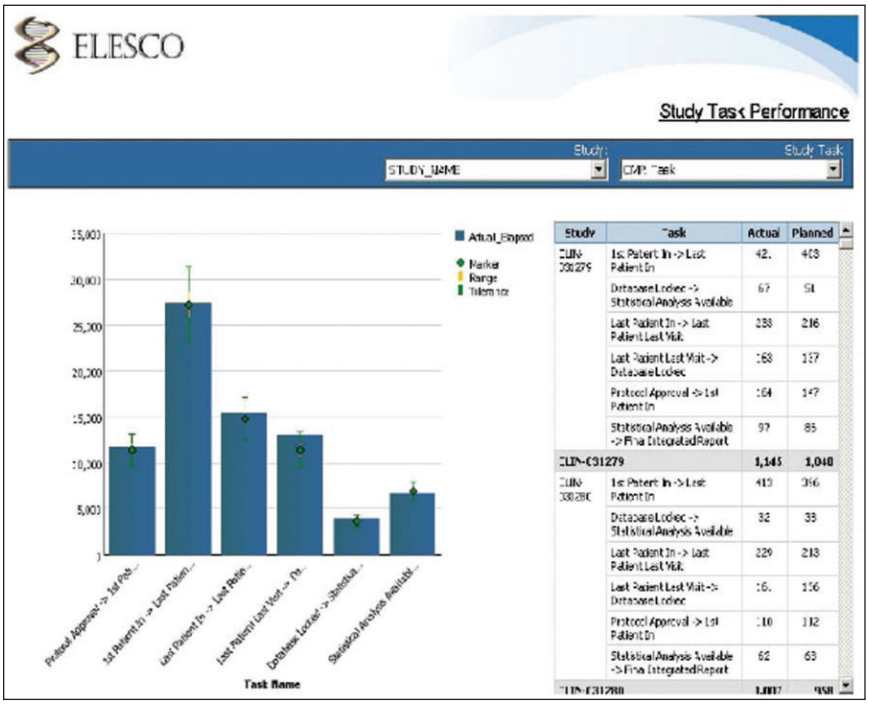
Note that the pie chart displays are affected only by the "country" filter and are not affected by the "All Sites" filter. We can then go back to France and drill-through on "Investigator Notes."



** ISA Site-Level Details report is the property of ISA Consulting*

Report #10 – Study Task Performance

The Study Task Performance report, also created in partnership with 3C Pharma and based on its clinical data mart, provides an aggregate view of the trial phases and tasks, as well as details about those trials, as a part of its filtering capabilities.

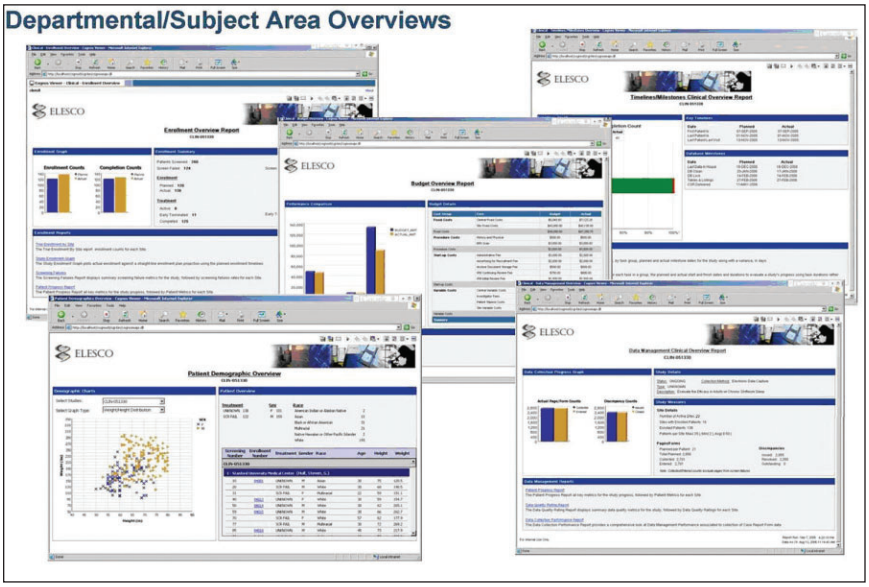


Departmental/Subject Area Overviews

IBM Cognos performance management solutions provide a consolidated view of trial information across multiple transactional systems. The sampling of screenshots below demonstrates the variety of functional areas and associated departments that interact with trials:

- Enrollment
- Budget overview
- Patient demographics
- Data management
- Timelines and milestones

By delivering personalized views of the data based on topic area and also consolidated views for management, IBM Cognos solutions provide complete reporting capabilities for clinical performance management within a single environment.



Conclusion

Performance management systems empower clinical trial managers to forecast, plan, measure and report on key performance indicators. They provide a measurement process and best practices so that performance against goals can be tracked and decisions can be made to improve results.

Manual spreadsheet-based systems are error-prone and consume valuable staff time to reconcile information. With IBM Cognos clinical performance management software, Performance Blueprints and partner solutions, these inefficiencies are eliminated. Clinical trial managers can effectively forecast, manage and track key milestones. And all of the reports described in this white paper can be easily adapted and modified to meet the needs of the individual clinical trial manager.

Clinical research organizations worldwide already use IBM Cognos solutions, including 25 of the top 30 global pharmaceutical firms. Small and midsize organizations also choose IBM to provide flexible software solutions that fit their needs and budgets, and can grow with their business. Large or small, these organizations recognize our innovative capabilities, vision, ability to deliver and technology leadership in the field of performance management.

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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IBM Canada
3755 Riverside Drive
Ottawa, ON, Canada K1G 4K9

Produced in Canada
January 2009

End notes

1 Datamonitor Report, “Trends in Clinical Trials” [DMHC2445], September 2008.

2 Datamonitor Report, “Launch Strategies” [DMHC2304], August 2007.