Evaluation Guide

Clinical Trial Resource Planning Performance Blueprint

Information Management

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Reining in the costs of clinical trial staffing

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]

Furthermore, clinicians and regulatory agencies are requiring more and more data from clinical trials, especially regarding the pharmacodynamic behavior of drugs. This results in increased complexity in each trial phase, further driving up costs while lengthening the delays before a new drug reaches the market–and extending the time a drug developer remains out of pocket.

Increasing trial complexity has had a profound impact on human resource costs. Larger staffs, combined with rising salaries for physicians, clinical investigators and registered nurses, are making staffing costs the biggest expense in the clinical trial process.

As one project leader put it, "It takes a lot of people to do a clinical trial–getting regulatory approval, setting up with hospitals, ensuring hospitals are recruiting the right people for the right treatment, ensuring documents are all filed and all project data is finalized. We need to show we are managing those people costs."

Strategies for reducing staffing costs

Not surprisingly, clinical research organizations (CROs) are seeking strategies to reduce HR costs, both for salaried full-time employees (FTEs), part-time employees, contractors and outsourced staffs.

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 or even overseas, 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. Cutting Edge Information, a research firm, surveyed dozens of leading pharmaceutical and biotech firms about their clinical development spending and staffing practices for Phase 1, 2, 3 and 4 studies, and found outsourcing ranges from 54% to 64% for trials in these development phases, on average.[3]

Clinical trial resource planning

Increasing budget pressures and growing study design complexity have heightened the need for robust budgeting and forecasting capabilities for clinical trial resource management.

Today resource planning models are often maintained in spreadsheet systems–an approach that is error-prone and inflexible for rapid, accurate clinical trial resource planning. Since information cannot be easily shared and consolidated with other financial forecast or budget data, different departments find themselves with conflicting numbers, and precious time is spent debating, reconciling and re-keying data between systems.

Dedicated clinical trials management systems (CTMS) often lack robust forecasting functionality, since they are focused on transaction recording, rather than activity-based forecasting or scenario modeling–both essential for financial and resource management functions. Forecasting with CTMS presents a number of other challenges:

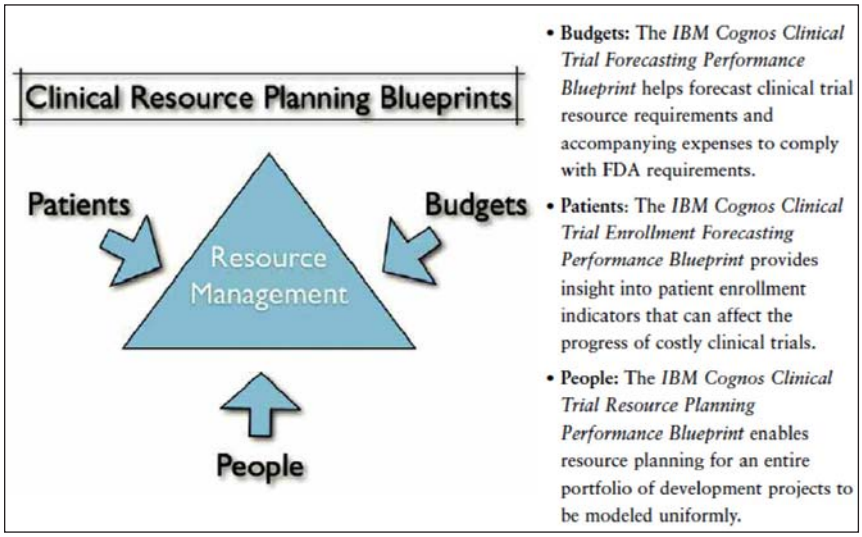
- Inability to link-in and update the plan based on actual spending.
- Difficult integration with other financial forecasts to present a consolidated view of the overall department.
- Finance requirements such as accounting periods and foreign exchange rates not well supported.

The IBM Cognos Clinical Trial Resource Planning Performance Blueprint

To address these resource management challenges, the *IBM Cognos® Clinical Trial Resource Planning Performance Blueprint* provides immediate insight for forecasting both the short- and long-term staffing requirements for a successful clinical trial. It helps clinical trial operations departments, trial managers, financial managers, business analysts and clinical development function heads plan, budget and forecast their staffing needs for clinical trials.

Designed in collaboration with industry leaders and some of our most successful customers, IBM Cognos Performance Blueprints are pre-configured planning, reporting and policy templates based upon IBM Cognos 8 Planning and IBM Cognos 8 Business Intelligence.

The *IBM Cognos Clinical Trial Resource Planning Performance Blueprint* is one of a series of IBM Cognos performance blueprints for clinical resource planning, as illustrated by the figure below.



Designed to work together, these *Blueprints* enable customers to make changes in resource planning projections and update financial projections seamlessly. By linking patient enrollment, budgeting and resource planning data to financial data, decision-making is greatly simplified, letting managers understand the cost of changes and the dollar effect of their projections.

All IBM Cognos Blueprints are pre-populated with common operational drivers and business structures, dramatically reducing the time required to deploy a new performance management process. These flexible templates are intended as a starting point, and can easily be adapted and modified to the individual clinical trial. Customers benefit from proven practices in model design that greatly reduce investment in implementation time and resources. Rather than wasting time "reinventing the wheel," customers can focus on applying the technology to solve business problems rather than fundamental process analysis and technical design.

"We don't have the luxury of spending days on duplicative data entry processes or dealing with data corruption and discrepancy reports. With the Clinical Trial Resource Planning Blueprint, we'll save two man-days a month just on double-checking our data alone. Over time, the savings could be substantial. It will help with morale as well, by eliminating a lot of frustration."

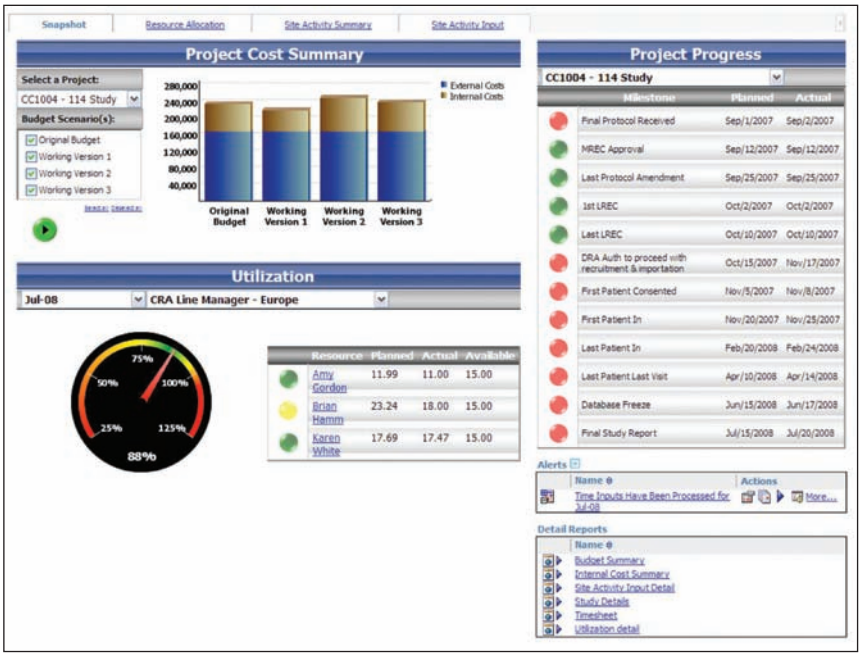
~ Project leader for leading clinical research organization

Evaluation guide

This evaluation guide provides an overview of the *IBM Cognos Clinical Trial Resource Planning Performance Blueprint*. Utilizing the IBM Cognos 8 suite of performance management products, this Blueprint provides out-of-the box functionality including dashboards, analytical reports and a preconfigured 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. The screenshot below is a dashboard illustrating a range of charts relevant to a project manager. From this dashboard, the manager can access the full range of relevant reports, analyses, and plans.

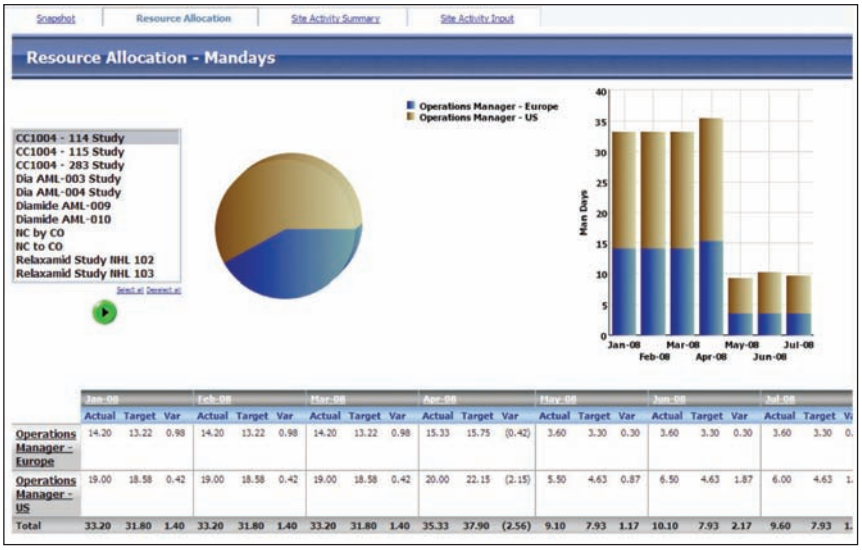
The dashboard, shown below, provides a snapshot view that serves as the starting point for a clinical trial project manager. The sections of this dashboard (clockwise from top left) are: 1) Project Cost Summary monitor; 2) a report on Project Progress; and 3) Utilization, in this case showing CRA Line Managers in Europe. A list of detail reports is shown on the lower right portion of the screen.



All the charts have the capability to drill through to more detailed analyses and include up-to-date information from multiple transactional and planning systems.

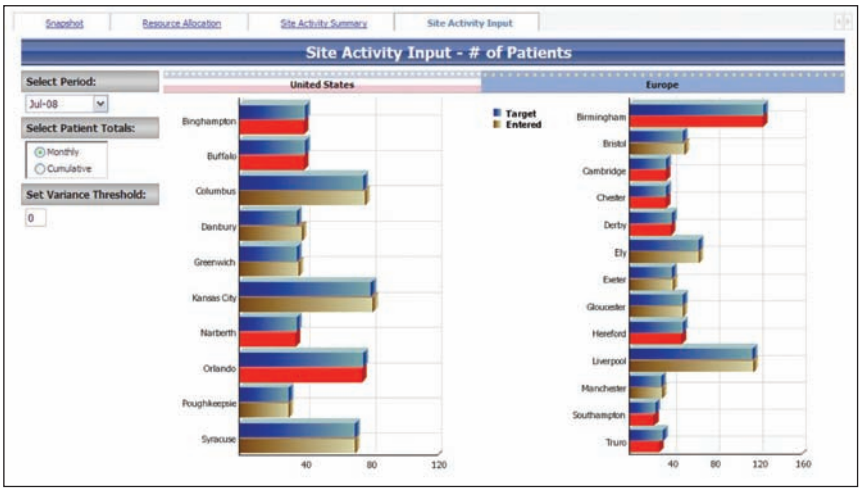
Dashboards are customized to the different roles and responsibilities found within a clinical development organization and show only the data that the manager has permission to access.

The following three figures show the tabs underlying the Project Cost Summary. First, let's take a look at Resource Allocation, where we can compare man-day allocations for operations managers in the U.S. and Europe, including actual hours, target hours and variance:

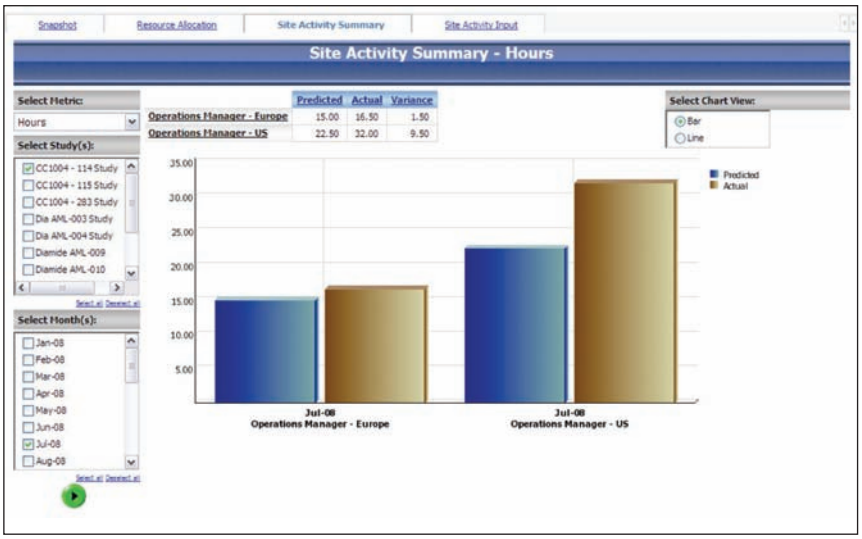


	Jan-08			Feb-08			Mar-08			Apr-08			May-08			Jun-08			Jul-08		
	Actual	Target	Var	Actual	Target	Var	Actual	Target	Var	Actual	Target	Var	Actual	Target	Var	Actual	Target	Var	Actual	Target	Var
Operations Manager - Europe	14.20	13.22	0.98	14.20	13.22	0.98	14.20	13.22	0.98	15.33	15.75	(0.42)	3.60	3.30	0.30	3.60	3.30	0.30	3.60	3.30	0.
Operations Manager - US	19.00	18.58	0.42	19.00	18.58	0.42	19.00	18.58	0.42	20.00	22.15	(2.15)	5.50	4.63	0.87	6.50	4.63	1.87	6.00	4.63	1.
Total	33.20	31.80	1.40	33.20	31.80	1.40	33.20	31.80	1.40	35.33	37.90	(2.56)	9.10	7.93	1.17	10.10	7.93	2.17	9.60	7.93	1.

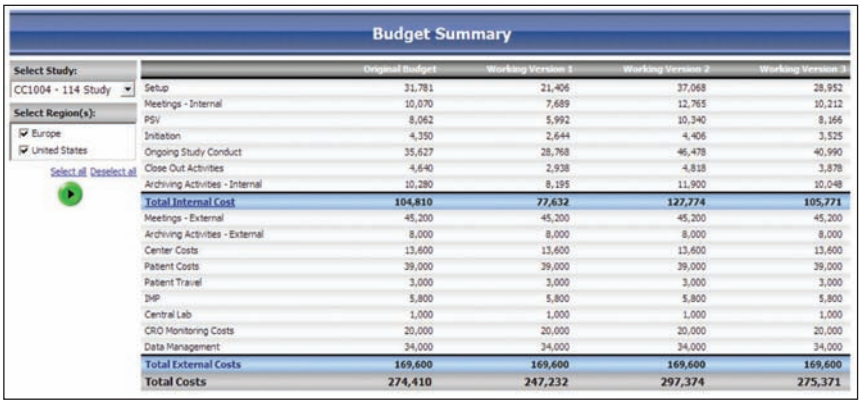
Next, we can see the site activity summary for each city in the clinical trial, in the U.S. and Europe, expressed in numbers of patients.



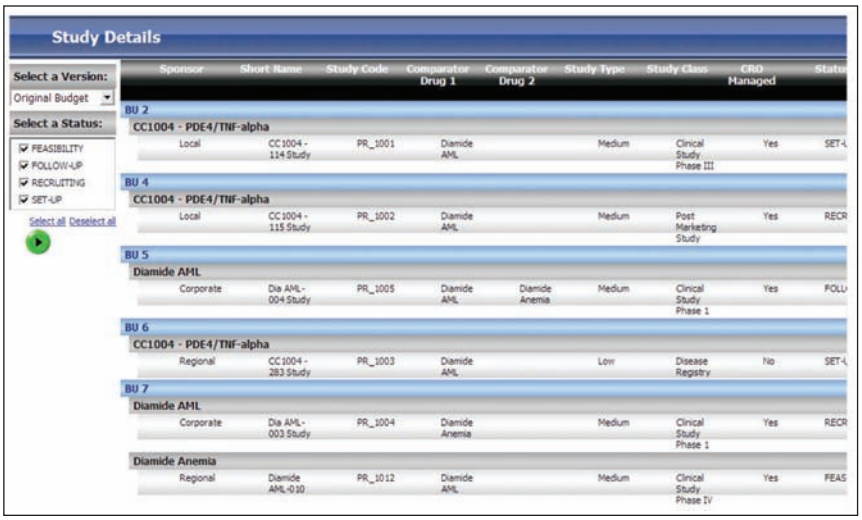
In the next view, the Site Activity Summary shows site activity expressed in numbers of hours.



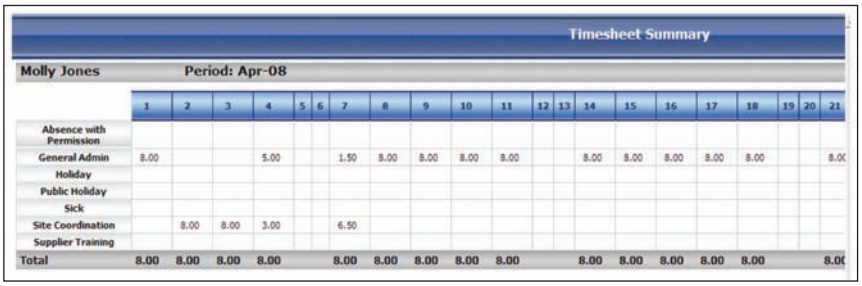
The Project Manager can also drill down from the dashboard to several pre-configured detail reports (listed at the lower right portion of dashboard). For example, the following are detail reports for the Budget Summary and Study Details.



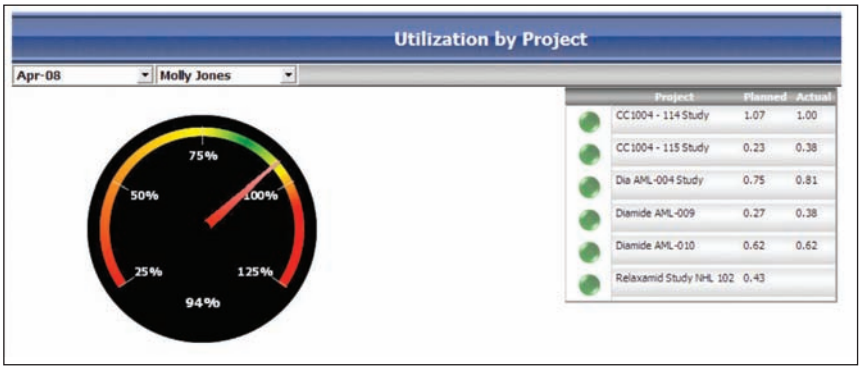
	Original Budget	Working Version 1	Working Version 2	Working Version 3
Setup	31,781	21,406	37,068	28,952
Meetings - Internal	10,070	7,689	12,765	10,212
PSV	8,062	5,992	10,340	8,166
Initiation	4,350	2,644	4,406	3,525
Ongoing Study Conduct	35,627	28,768	46,478	40,990
Close Out Activities	4,640	2,938	4,818	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**



The Timesheet Summary in this example shows the summary time report for an employee, Molly Jones, and her hours by category such as holiday, administrative time and so on.



The last detail report, Utilization by Project, shows the same employee's actual hours were well aligned with planned hours, and the green light indicator confirms this visually. Red light indicators show when a resource is either seriously under-utilized or over-utilized, while the yellow light is a warning indicator.



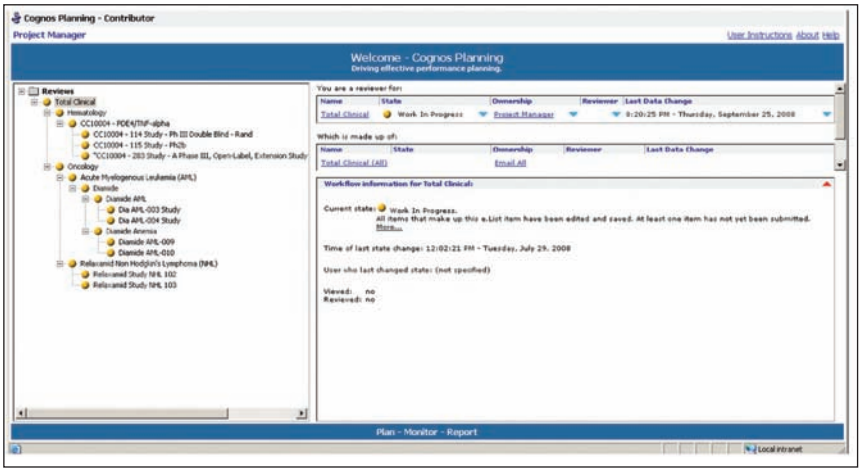
The *Blueprint* also pre-populates the hours needed to complete the activities or tasks required to set up and execute the trial. By assigning specific named resources to these tasks, the *Blueprint* calculates utilization metrics. As the *Blueprint* supports multiple scenarios, it is easy for a portfolio planner to work up different scenarios and view the impact on resource availability for the portfolio across geographies.

Model overview

There are two components to the *Clinical Trials Resource Planning Blueprint*. They are the Project Budgeting module, where the forecast for the trial is created and resources are assigned to work on that trial; and the Timesheet module, where the resources are able to enter their Actual time worked and these Actuals are then compared to the forecast and target chargeable hours for that employee. The timesheet module can be bypassed and data loaded from existing time reporting systems, if desired.

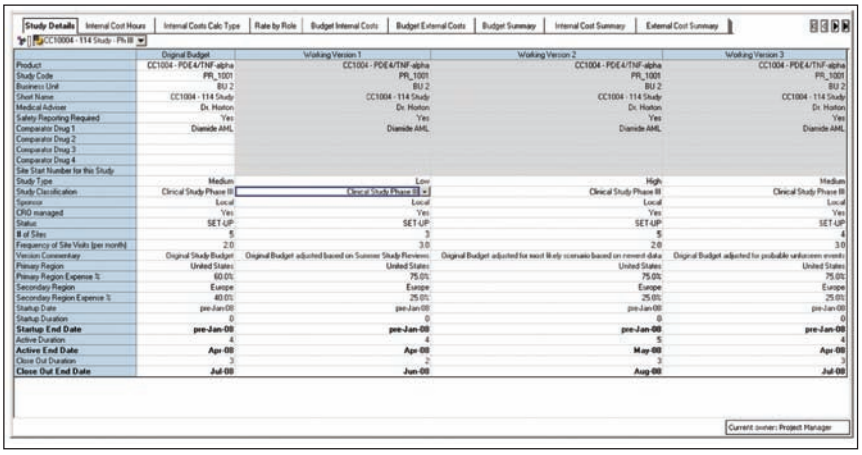
Let's take a look at the forecasting process for the Project Budgeting component. The Project Budgeting input is assigned by study, as can be seen in the contribution hierarchy below. A forecast reviewer can see the consolidated results of all clinical trials or drill down and look into specific detail for individual clinical trials. Reviewers can see the workflow status of each clinical trial. As co-owners of that information, they can also make edits, if required. All workflow status changes, data consolidations, and aggregations occur in real time, allowing for frequent planning iterations.

Before a user enters data, the state of the plan is Not Started. Once a user saves a plan, the state becomes Work in Progress and remains accessible for further editing. When a user submits an item, the plan is Locked, and permits no further changes. The Locked state indicates that the plan is ready for review. A reviewer can see a plan in any state, but can only reject a Locked item. When a reviewer rejects a Locked plan, the plan returns to a state of Work in Progress, which means it is again editable.



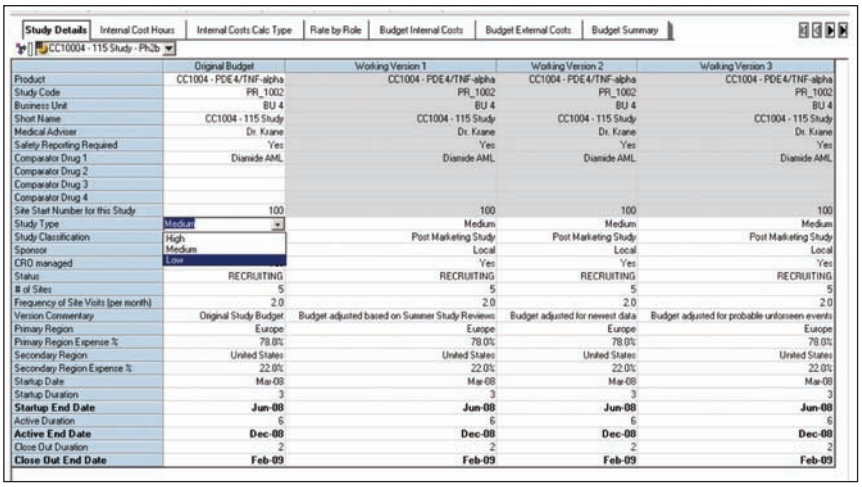
Project budgeting module

The first tab in this module is the Study Details tab. It holds various information about the study, including Study Type (low, medium or high), which drives the number of predicted hours per task for the study. This tab also holds start and end dates for each phase of the trial, and these dates drive the allocation of cost and hours for each task across the appropriate months for that phase of the trial. The Study Details tab also includes inputs for percentages of expenses and hours that should be allocated to each region.



Changing the “study type” drop-down (highlighted in the screenshot below) will pre-populate the tasks and resources for internal and external costs. In addition, setting the dates for the three different stages of the study (setup, execution and close-out) will calculate phasing for the costs. All the assumptions are preconfigured, but are easily changed by business users without having to rely on IT staff or complex scripting languages.

In addition, all the assumptions within the *Blueprint* are easy to override manually if a study has unique characteristics that do not fit a standard model. By inputting a few simple assumptions, you can quickly populate an entire resource plan that calculates and phases both internal and external costs.



A full walk-through of both the Project Budgeting and Timesheet modules of the *Clinical Trial Resource Planning Blueprint* is available separately in an Implementation Guide. Further information is available at www.cognos.com/innovationcenter.

Summary

Performance management systems allow clinical trial managers to forecast staffing resources and provide a measurement process so that performance against the goals can be tracked and updated. Manual spreadsheet-based systems are error-prone and consume valuable staff time to reconcile and re-key information. The *IBM Cognos Clinical Trial Resource Planning Performance Blueprint* addresses these inefficiencies and allows clinical trial managers to effectively forecast, manage and track staffing costs. It provides a flexible template that can be easily adapted and modified to meet the needs of the individual clinical trial manager.

To learn more about the *IBM Cognos Clinical Resource Planning Performance Blueprint* or other Blueprints, please visit www.cognos.com/innovationcenter.

About the IBM Cognos Innovation Center for Performance Management

The IBM Cognos Innovation Center for Performance Management was established in North America and Europe to advance the understanding of proven planning and performance management techniques, technologies and practices. The Innovation Center is dedicated to transforming routine performance management practices into "next practices" that help cut costs, streamline processes, boost productivity, enable rapid response to opportunity and increase management visibility. Staffed globally by experts in planning, technology and performance and strategy management, the Innovation Center partners with more than 600 IBM Cognos customers, academics, industry leaders and others seeking to accelerate adoption, reduce risk and maximize the impact of technology-enabled performance management practices. To join, visit www.cognos.com/innovationcenter.

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Endnotes

1 *Datamonitor Report, "Trends in Clinical Trials"* [DMHC2445], September 2008.

2 *Datamonitor Report, "Launch Strategies"* [DMHC2304], August 2007.

3 "*Clinical Operations: Accelerating Trials, Allocating Resources and Measuring Performance,"* by Cutting Edge Information, reported in Lab Business Week, November 5, 2006.

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