IBM Cognos Software Demo Transcript
Clinical Forecasting Performance Blueprint

HOST: Cognos Life Sciences Performance Management Solutions are designed to help pharmaceutical and biotech institutions align corporate objectives with operating plans so they can operate more profitably and efficiently.

Cognos planning coordinates plans, budgets and forecasts across your institution so everyone accountable for business results has visibility into how their role supports the company's strategic initiatives and financial goals.

Cognos 8 Business Intelligence provides world class reporting and analysis, allowing you to track your progress against forecasts and plans and access critical information with ease.

In the latest breakthrough from the Cognos Innovation Center for Performance Management, Cognos Planning and Cognos 8 Business Intelligence are combined into Performance Blueprints that will accelerate your implementation of performance management capabilities.

The Performance Blueprints are predefined data process and policy models designed to help you improve two key processes: planning, budgeting and forecasting and reporting and analysis.

A blueprint prepopulates your plan with common operational drivers and business structures, dramatically reducing the time required to deploy a new performance management process. The Performance Blueprints were developed by the Cognos Innovation Center for Performance Management in collaboration with some of our most successful customers and industry thought leaders. They are designed to help customers adopt best practices in performance management.

Plans that are driver-based developed with the participation of all the right stakeholders and updated as frequently as needed to capture the most current view of the business, coupled with the robust dashboards, reporting and analysis capabilities needed to remain informed about your business operations.

Blueprints help you reduce time and risk in a new performance management implementation, and so accelerate the time to results. Best of all, these blueprints are free to existing customers. Customers can apply for free membership to the Innovation Center and then download the models right from our Web site. It's that easy.

If you're not yet a customer but are considering Cognos planning or Cognos 8 Business Intelligence, the blueprints will deliver value right out of the box.

The Performance Blueprints cover many key financial and operational processes across multiple industries. Today's demonstration will focus on the Clinical Performance

Blueprint, which is intended for use by finance and clinical managers to improve their ability to understand performance and make better resource allocation decisions.

The clinical Performance Blueprint includes two primary components: Cognos Planning and Cognos 8 Business Intelligence. With the Clinical Performance Blueprint, we will demonstrate how clinical trials resource and finance managers can create forecasts and budgets for the entire portfolio using a robust and scalable process that is driven by the underlying patient enrollment and study level data...

Analyze performance across the portfolio and identify key performance issues early through a series of dashboards and reports...

Facilitate portfolio modeling, what-if analysis and improved decision making. And, use a common tool that connects the clinical budgets and forecasts with the other financial and resource management processes.

With that, I'd like to introduce [Paul Hake], a Director with the Cognos Innovation Center for Performance Management, and welcome you to this short demonstration on how the Cognos Clinical Forecasting Performance Blueprint can help you move to best practices.

[HAKE]: Welcome to the Clinical Trials Performance Blueprint. In this example, I am playing the role of a therapeutic area manager responsible for managing a selection of clinical trials supporting the FDA filings for a number of new drug candidates within my therapeutic area.

When I sign on to the Cognos portal, I'm presented with a dashboard that has comprised a number of reports that summarize information about my portfolio as well as an exception report that notifies me of studies that may be facing critical enrollment issues.

The data presented on the dashboard are sourced from a driver-based Cognos planning model that creates budgets and resource forecasts from the underlying study and data metrics, the most important being the patient enrollment data.

The Cognos Planning Model that is the heart of this blueprint contains a best-in-class algorithm that generates reliable and accurate budget and forecast data that is then easy to integrate with other financial data forming the core of the financial forecast and budget submissions for the clinical area.

By connecting the operational clinical data with the financial data in this way, a unique value proposition is realized in that clinical and finance colleagues are both working from the same set of data and assumptions, eliminating time wasting caused by having information silos and debating the correct numbers.

We will start by reviewing the information presented in the dashboard. The top left report shows us high-level budget projects and forecasts that are grouped by study status. It is important as a portfolio manager to be able to understand the resource position by status grouping studies with projects by whether they are ongoing, concept or approved.

Having this information readily available for my entire portfolio will help greatly when I'm making trade-off or resource reallocation decisions. Because I can see the current forecast against budget for the entire portfolio, I can quickly gain insight for the potential for freeing up resources.

The report in this example is prefiltered to exclude smaller studies that have a small budget under $50,000. I do not want to see these on the dashboard, as they will provide unnecessary clutter.

The next report shows me a chart showing graphically the performance against budget for my key studies. A table showing more detail is presented below. The table shows more detail and the performance by category of expense with the variances.

All the reports and charts on the dashboard are drillable to provide more detail and perhaps a different perspective. If I take a closer look at Study No. 283, for example, I notice that there appear to be a number of issues with its resource forecast that warrant further investigation.

Of particular concern is its appearance in the exception report completion warnings. This report lists those studies that are projected to not meet their budget criteria for the number of completions.

Study 283 is showing in this list, and it also has a number of odd variances that we can see in the project cost report that we just looked at.

If we now drill down on Study 283 we drill into a new report that may help explain the shortfall on the number of completions. The chart that I drilled to shows the projected enrollment against the original plan and I can see straight away that there's an alarming and persistent undershooting of the enrollment target, together with an erratic dip in the October and November, 2005, periods.

This would appear to be the chief cause of the problem, and at this point I could go straight into report of the enrollment for that study by country or site to further explain the variance and to see more detail.

At this point we will drill through into the planning model to further our investigation, and in doing so will highlight how the driver-based enrollment algorithm works.

The planning model opens, and I can see my hierarchy of projects. In this example, we have two therapeutic areas, hematology and oncology, comprising drug candidates or

molecules and then the individual clinical trials or studies that support the filings. The hierarchy is totally customizable and is tailored to the needs of each organization and would typically be sourced from existing corporate data.

I can also see the process status of the individual projects as they are represented as color-coded icons: red means not started, yellow is work in process and green means completed. Notice also the padlock icon for study AML 010. This has been submitted and its data is now locked.

The planning model has real-time consolidation. So if I were the reviewer for the entire therapeutic area, I would see the changes of my contributing projects as soon as the data are saved.

I do not have to wait for back-end process to run before I can see the results of those contributions. In practice, the blueprint would enable even the largest pharma companies that exist today to model their entire late stage portfolio in one place.

Having a real time view of the global portfolio is a powerful decision-making prospect and avoids the data collection and consolidation headaches associated with the traditional spreadsheet-based approach.

If I open up the 283 study, I download the entire driver-based model for that study and all calculations and their impact are performed locally within my Web browser. This is very powerful in that I can perform what-if analysis and see the result of those calculations without sending any data back and forth to the server or without having to wait if I have a slow connection.

This also means that the server will not slow at critical windows when planning deadlines are approaching and everyone is using the system at the same time. I'm also free to take my model offline if I need to work on my forecast while traveling.

I'll now move to the study details tab. This tab contains the high level header style information about the study, and contains some very useful metrics that are calculated within the model and summarized here.

Most of the detailed information about the study such as its description, start date, status, et cetera, would be sourced from other systems and linked into the model. We can see the summary level budget and forecasts that are calculated online from the driver data within the model.

I can also see the budgeted and forecast number of completions and a corresponding warning message if the completion forecast falls short of the budgeted number of patients to complete.

The model is also calculating a forecast for drug supply that I can use to predict the quantity of drug I will need together with the timing of when it will be needed.

The fixed costs contract screen gives me the flexibility to input costs in a date and percent spread fashion that is a common feature of many clinical trial expenditure patents. I do not need to navigate a date grid to find the right month and key the values in; instead I can pick a date from a drop-down and assign a dollar value and a percent of that amount to the spread in the months selected.

In this example you will note that the investigator meeting is planned for October, 2006. The model calculates the correct phasing and feeds the data into the next screen where I can also enter data in free form.

The central fixed cost screen here I can input in either local or U.S. dollar currencies. The level of detail can be sub ledger and down to the line item of detail.

I can also employ the standard Cognos data input shortcuts. For example, if I want to increase advertising to $133,000, I don't need to key in the 13300, I can use a shortcut key. I can also quickly see the impact of these changes in blue, and by reorienting the cube I can compare the budget with the forecast.

So that is very good for overheads that do not vary directly with the number of patients in my study. The greatest value of this model is in the way that those variable costs -- principally payments to investigators -- are driven by the patient enrollment and the actual protocol design itself in terms of the procedure costs for each visit and the relative timing of those visits themselves.

If I look at the cost matrix screen, it represents per patient, per visit cost by country or region. We are going to model the study using relative date math where all the cost events are relative to the enrollment date for each group of patients. Modeling this way provides a very accurate phasing calculation, as the timing and separation of the visits is captured and represented in the model.

This view tells me that for visit one for Argentina, the procedure cost for each patient are $753. The next thing I need to know is when the visits occur relative to enrollment and also to each other.

For this study I can see that Visit 7 occurs 52 weeks or one year after the enrollment. The algorithm recognizes this, and will not apply the Visit 7 cost to each patient until 52 weeks after enrollment and Visit 1.

Also note that this data can be used for drug supply forecasting, as I may be dispensing drug substance to the patients at each visit in which case I can record the expected issue quantities and thereby generate a drug supply forecast that will also be accurately phased.

Of course not all patients will complete the study, and this varies by country or region. I capture those data by indicating the percentage retention for each visit in the study.

These data are particularly valuable when making location decisions for future studies, as I can gain visibility of performance by region in terms of retention for all my studies and start creating a reliable repository of valuable data to help me make future decisions.

The final thing I need to record is the actual recruitment plans to complete the data required by the model to calculate the forecast. On this screen I can see when the recruitment is planned to occur and the forecast version would be updated for the actual activity.

You can easily see that I have a persistent shortfall across the entire enrollment window, but it is especially bad in November, 2005, and especially bad in the U.S.A. where I only enrolled 50 patients against the planned 200.

After discussing the performance of this study with the individual managers concerned, we have a plan of action. We will commit an additional $1 million of investment with the CRO to set up more centers in the U.S.A. and will plan to enroll an additional 1,000 patients in the U.S.A. from August, 2005, through the end of the study.

Using the Cognos bidirectional break back technology I can achieve this adjustment to my forecast very easily. I can simply hold the first column as it is July and I do not wish to change it, and I can then simply type in plus 1k in the total for the number of patients. And the Cognos tool will calculate the phasing adjustment and spread the increase back proportionately in terms of the original forecast. And I can notice all changes that are now in blue, and I can easily see the difference comparing the budget to the new forecast.

I may also wish to enter comments or annotations to explain what I have done in terms of the increased forecast for this particular study, and I can do that easily by right clicking and selecting to insert annotation. All of the annotations are easily viewable in the Cognos reports.

That completes my forecast updates; now, I would like to save and submit the data. By doing this, the data is then fed back to the server and so my managers in the therapeutic area directors above me in the hierarchy would now be able to see my updated forecasts online.

When I go back to my dashboard, I notice the changes. The forecast for Study 283 has now increased. Study 283 has now also disappeared from my exception report as the forecasted number of completions now exceed the budget.

I can also get a view of global recruitment patterns for my studies. This chart tells me globally where enrollment is occurring, and I can drill into any country to see a list of studies enrolling in that country.

The Clinical Performance Blueprint lets me model my entire portfolio in one place and captures the valuable operational study level data. This approach offers great visibility into the performance of my clinical trials and provides the right information to help make better decisions.

The outputs of this process can be fed into other upstream processes, streamlining my entire approach to clinical budgeting and forecasting.

HOST: Thank you, Paul. The Clinical Forecasting Performance Blueprint accelerates the realization of performance management in life sciences by providing tools, disciplines and industry best practices that help institutions synchronize and coordinate financial and operational planning processes and by ensuring that they remain informed with world-class reporting and analysis.

With these capabilities the life sciences organization can quickly see the impact of changes in operational plans on corporate financial projections. At the same time, departments and functions can intelligently reallocate resources to support corporate objectives. The blueprint also helps communication between finance and clinical managers, right across the organization, down to all those contributing to the plan.

Finally, it delivers value right out of the box. Our customers can quickly adopt best practices and performance management with reduced risk and faster results.

For more information on our performance management solutions for life sciences, visit the life sciences resource center. More information on other Performance Blueprints is available at www.cognos.com/innovationcenter.

If you are an existing customer, we encourage you to apply for a free membership to the Innovation Center. You will then be able to download the blueprints for use with your Cognos planning application.

If you are not a Cognos customer, you'll find materials that describe the value and use of the blueprint models, and you'll find articles by industry experts and Web seminars with more detail on using the Performance Blueprints.
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