CLINICAL TRIAL ENROLLMENT FORECASTING

A WEB-BASED PERFORMANCE MANAGEMENT APPLICATION

PERFORMANCE BLUEPRINT IMPLEMENTATION GUIDE

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INTRODUCTION

This implementation guide demonstrates the design and functionality of the IBM Cognos Clinical Trial Enrollment Forecasting Performance Blueprint, *a web-based planning and reporting process model for clinical trial enrollment forecasting using IBM Cognos 8 Planning and IBM Cognos 8 Business Intelligence. It provides immediate insight into both the short- and long-term requirements for a successful clinical trial.*

This Clinical Trial Enrollment Forecasting Blueprint *can be used to manage the resources and expenditures of a company's clinical trial program. Utilizing the IBM Cognos 8 suite of performance management products, this* Blueprint *provides out-of-the box functionality including dashboards, analytical reports, and a pre-configured data model to facilitate rapid time-to-value. Customers benefit from proven practices in model design that greatly reduce investment in implementation time and resources, and can focus on applying the technology to solve business problems, rather than fundamental process analysis and technical design.*

Key aspects of the Blueprint *model's operation are explained, followed by a section-by-section explanation of function, purpose, and operation. Users should have a basic understanding of the IBM Cognos 8 Planning Analyst and Contributor tools.*

BLUEPRINT OBJECTIVES

The *Clinical Trial Enrollment Forecasting Blueprint* meets a number of objectives:
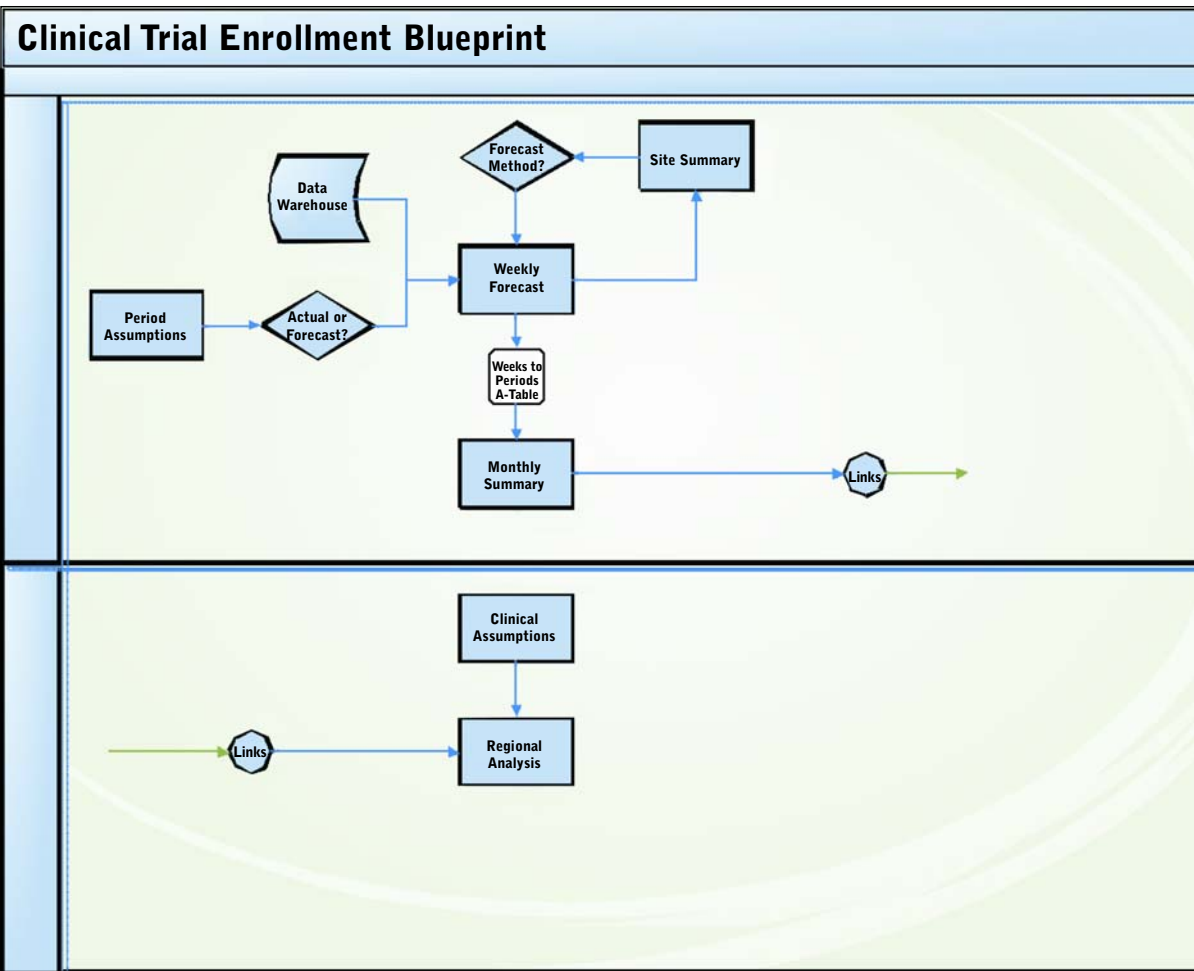
1. Establishes clear and concise targets for each regional manager for specific clinical studies

2. Provides the ability to create what-if scenarios

3. Evaluates historical data in order to evaluate the effectiveness of the plan

4. Provides immediate feedback on planning decisions

5. Allows reporting and analysis by clinical study and region.

MODEL OVERVIEW

The *Blueprint* employs a weekly forecast for a number of clinical trials and a choice of forecast methods to determine whether the trial can be a success. Actual data is used to measure the success of the original forecast. It is expected that changes in forecast methodology and factors will be made on an ongoing basis.

The workflow intended for this model assumes that each site analyst will input and track a number of clinical trials. Regional Managers will receive daily updates and may track all trials in their region. The actual data will be updated on a weekly basis.

Blueprint contributors start the process by entering the targets for each clinical study, then selecting the best Forecast Method to determine future enrollment. Once forecasts have been submitted, the information will be linked to a regional analyst. The analyst will evaluate whether additional investment is necessary to ensure that target enrollments for each clinical study can be met. Examples of further investment may include increased advertising or the creation of additional sites. The analyst will recommend to the regional manager that the investments be made. The model flow is shown below.

Clinical Trial Enrollment Blueprint

```
Forecast          Site Summary
Method?

Data
Warehouse
                  Weekly
                  Forecast

Period     Actual or
Assumptions Forecast?

                  Weeks to
                  Periods
                  A-Table

                  Monthly                    Links
                  Summary


                  Clinical
                  Assumptions


         Links     Regional
                   Analysis
```

CLINICAL TRIAL ENROLLMENT, ANALYSIS, DASHBOARDS, AND SCORECARDS

In addition to the planning functionality previously described, the *Clinical Trial Enrollment Forecasting Blueprint* includes reporting and analysis using IBM Cognos 8 Business Intelligence. These reports can be created from the IBM Cognos 8 Planning Contributor model or any external source. The examples below provide a hierarchy of dashboards and reports designed to give users a clear understanding of clinical trial enrollment outcomes.

The dashboard, shown below, serves as the starting point for a Regional Manager. The sections of this dashboard (clockwise from top left) are: **1**) Site Activation Performance monitor for USA and Europe; **2**) a report on Program Enrollment Statistics; **3**) Regional Analyzer graphic showing Enrollment and Screen Fail Statistics; **4**) a selection of reports.
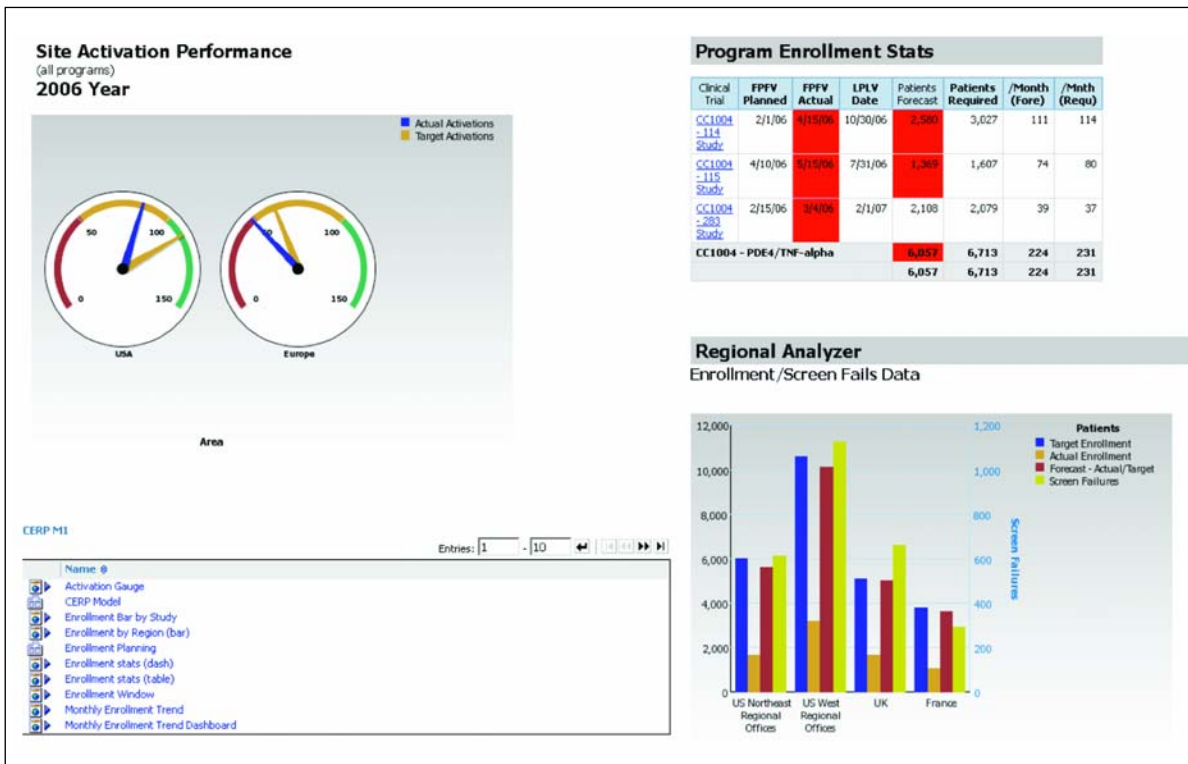
The graph below shows a detailed view of enrollment by week for each territory. The drop-down at the bottom allows a user to select a specific clinical trial.
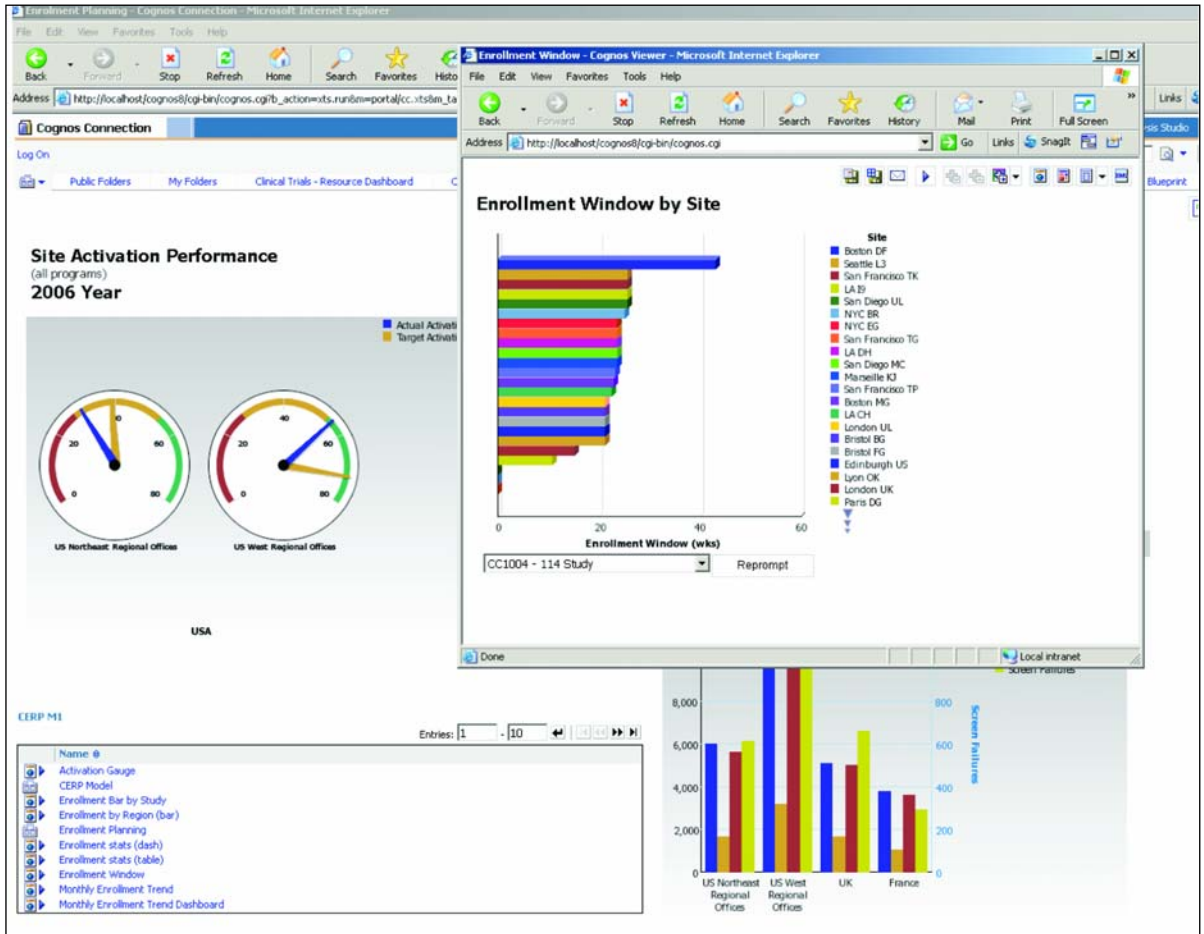
This report displays statistics for each study on actual vs. planned enrollment, patient data, and dates of planned completion for each of the clinical trials.

PERIOD ASSUMPTIONS

The **Period Assumptions** tab is hidden from users. This tab is maintained by the administrator. It contains information on Actual and Forecast periods.

2006 - Wk 7	Actual Period
2006 - Wk 8	Actual Period
2006 - Wk 9	Actual Period
2006 - Wk 10	Actual Period
2006 - Wk 11	Actual Period
2006 - Wk 12	Actual Period
2006 - Wk 13	Actual Period
2006 - Wk 14	Actual Period
2006 - Wk 15	Actual Period
2006 - Wk 16	Actual Period
2006 - Wk 17	Actual Period
2006 - Wk 18	Actual Period
2006 - Wk 19	Actual Period
2006 - Wk 20	Actual Period
2006 - Wk 21	Actual Period
2006 - Wk 22	Actual Period
2006 - Wk 23	Actual Period
2006 - Wk 24	Actual Period
2006 - Wk 25	Actual Period
2006 - Wk 26	Forecast Period
2006 - Wk 27	Forecast Period
2006 - Wk 28	Forecast Period
2006 - Wk 29	Forecast Period
2006 - Wk 30	Forecast Period
2006 - Wk 31	Forecast Period

2006 - Wk 1

The data is used in the **Weekly Forecast** tab to provide information on whether the period is Actual or Forecast.

MARGINAL COST TYPE

This assumption tab is hidden, and indicates whether the cost is per-person or total.

WEEKLY FORECAST

This is an input tab for the site contributor. It is used to input Target Enrollment, Manual Forecast Override, and Screen Failures for each clinical study. Final Forecast Enrollment will be calculated based on the Forecast Method chosen in the Site Summary tab.

SITE SUMMARY

This tab is used to input the investigator, the planned and actual first visit dates, the last visit date, the forecast method chosen, the number of weeks used if the Average Forecast Method is chosen, and the expected weekly Enrollment rate. The forecast methods and descriptions include:

Act/Bud	Uses Actual Enrollment for historic periods, and Target Enrollment for future periods.
Override	Same as above with ability to override the Target Enrollment with the data in the Manual Forecast Override field
Trend %	Follows the trend to date by using Actual Enrollment to date as a percentage of the Target Enrollment, and applying it to future periods.
Goal	Scales future periods to meet the Target Enrollment goals.
Average	This uses the # of Wks for Avg Method field.
Manual Rate	Uses Input Weekly Enrollment Rate from the Site Summary Tab.

MONTHLY SUMMARY

This tab does not require input. The information in the tab summarizes the forecast for each clinical trial enrollment by month. Variance to Target indicates whether or not enrollment is on target for the study displayed.

When all sites in the region have completed and submitted their forecasts, the administrator may run an Admin Link to the regional analyst. This data aggregates the targets and variances for each site in the region for each of the clinical trials. The regional analyst may also run a System Link at any time to gather this information.

The source tab is the **Monthly Summary** for each site and the target is the **Regional Analysis** tab for the regional analyst view. Pair the dimensions as shown below. Match items for Clinical Trial to Clinical Trial and Monthly Summary to Regional Analysis.
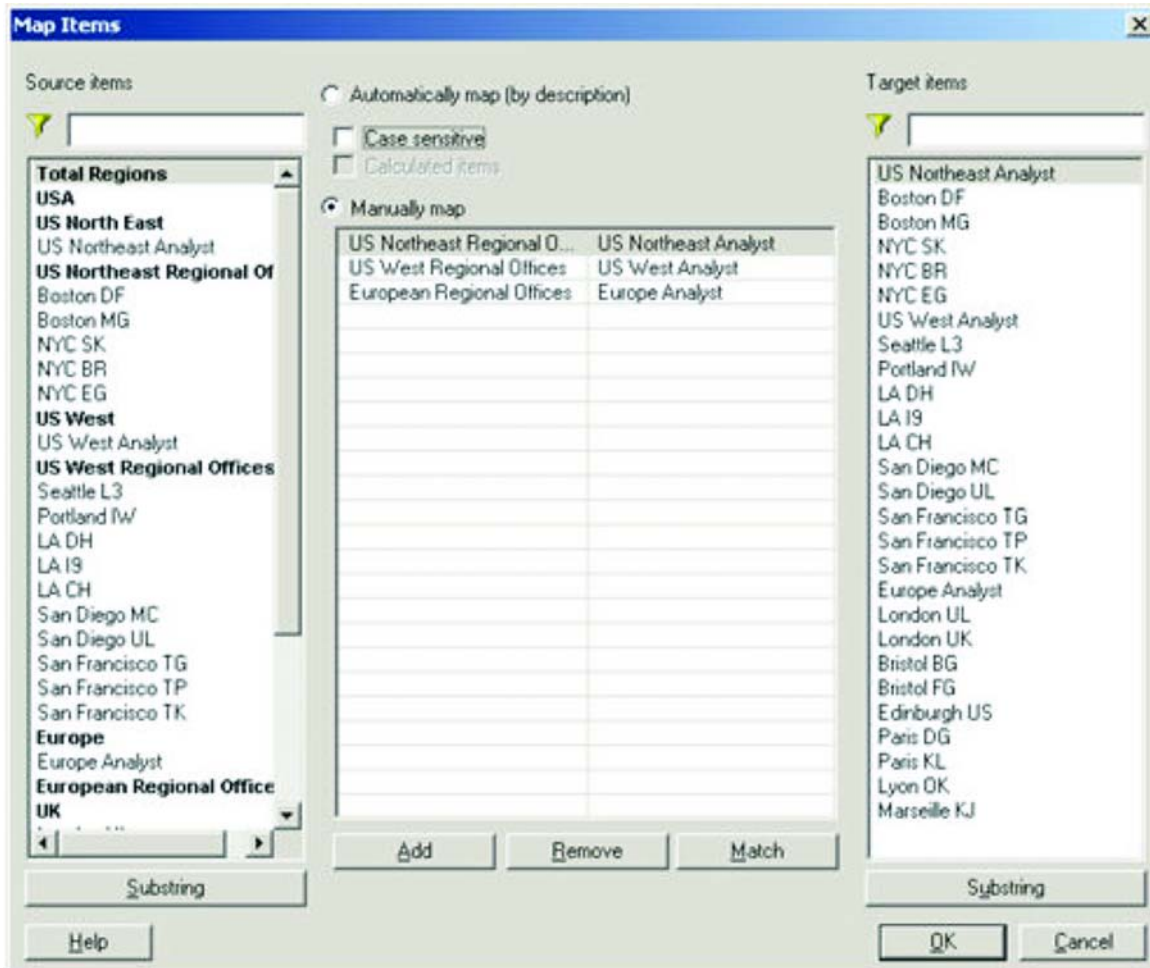
For **Periods to Regional Costs,** allocate items as shown below:
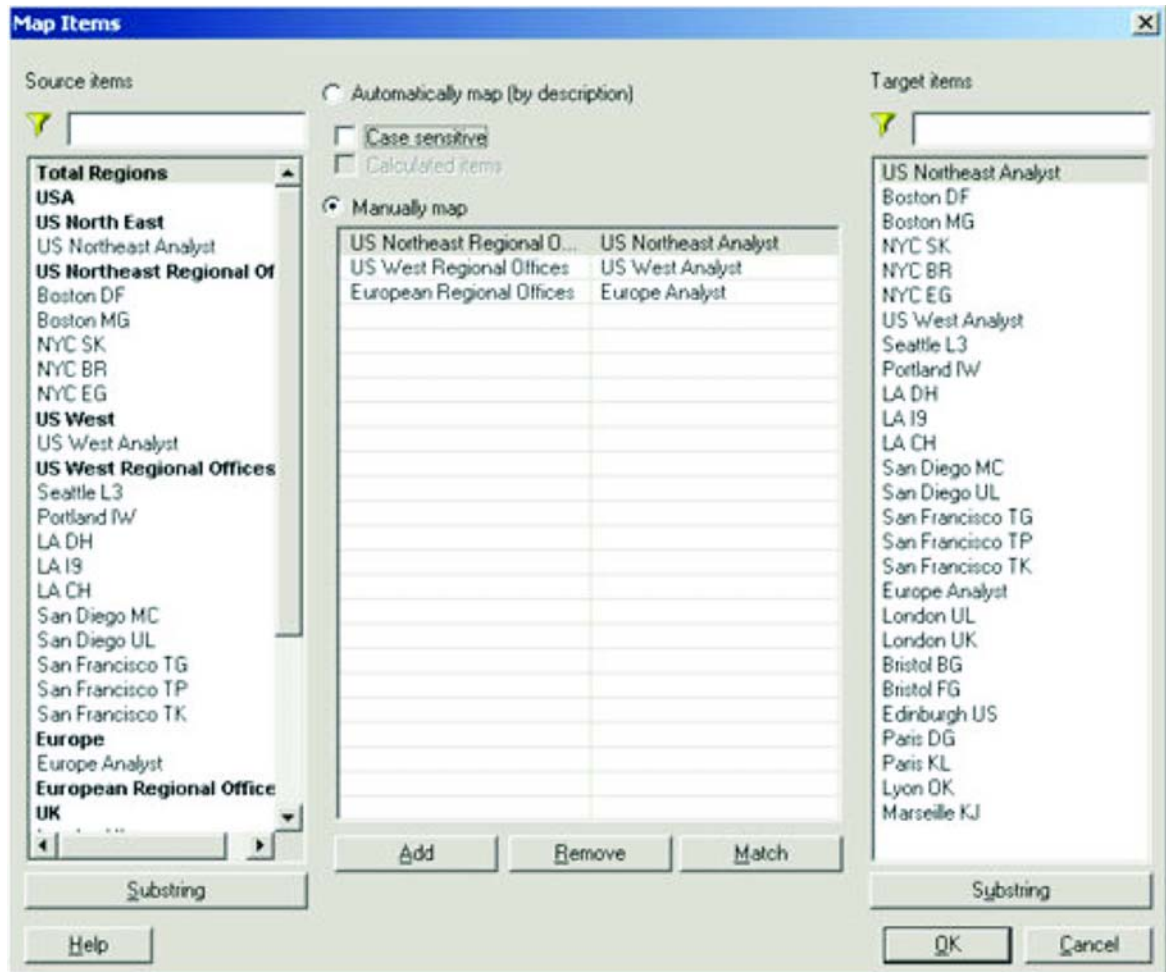
For the **Elist** to **Elist** dimensions, allocate items as shown below:

Regional analysts also make a number of assumptions for each trial study in their regions. For this *Blueprint*, we have used variable advertising costs, the cost to open an additional site, and miscellaneous costs. Costs may be modified or added to accommodate individual company requirements.

This data in the **Clinical Assumptions** tab above and data from each of the regional sites' **Monthly Summary** tab is linked to the **Regional Analysis** tab.

REGIONAL ANALYSIS

This tab will give analysts insight into each of the trials and cost options that can be used to improve any negative variances. Regional managers also have access to this data.

SUMMARY

Performance management systems allow management to articulate goals and provide a measurement process so that performance against the goals can be tracked and feedback provided. At a corporate level, an effort is made to manage the overall clinical trial enrollment process. At a regional level, managers make decisions to optimize the factors necessary to create a successful forecast for a number of clinical trials and their associated costs. Collaboration must occur on a forward-looking basis so that decisions are aligned with corporate expectations, and so that variances can be evaluated.

Regional managers need clear targets and goals, and need to understand how these are defined. These managers must be able to forecast enrollment, and have feedback on their performance against these forecasts to determine the success of a number of specific clinical trials. The *IBM Cognos Clinical Trial Enrollment Forecasting Blueprint* meets these needs.

To learn more about the *IBM Cognos Clinical Trial Enrollment Forecasting Performance Blueprint* or other *Blueprints*, please visit **http://www.cognos.com/innovationcenter.**

ABOUT COGNOS, AN IBM COMPANY

Cognos, an IBM company, is the world leader in business intelligence and performance management solutions. It provides world-class enterprise planning and BI software and services to help companies plan, understand and manage financial and operational performance. Cognos was acquired by IBM in February 2008. For more information, visit **http://www.cognos.com**.

Pharmaceutical organizations worldwide choose Cognos for our unsurpassed expertise in delivering the information and insight they need to reduce costs, streamline processes, and increase profitability. Cognos has delivered solutions to 25 of the top 30 pharmaceutical firms, along with many leading life sciences and biotech companies.

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