

CLINICAL TRIAL ENROLLMENT FORECASTING



A WEB-BASED
PERFORMANCE
MANAGEMENT
APPLICATION

PERFORMANCE BLUEPRINT
IMPLEMENTATION GUIDE

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:

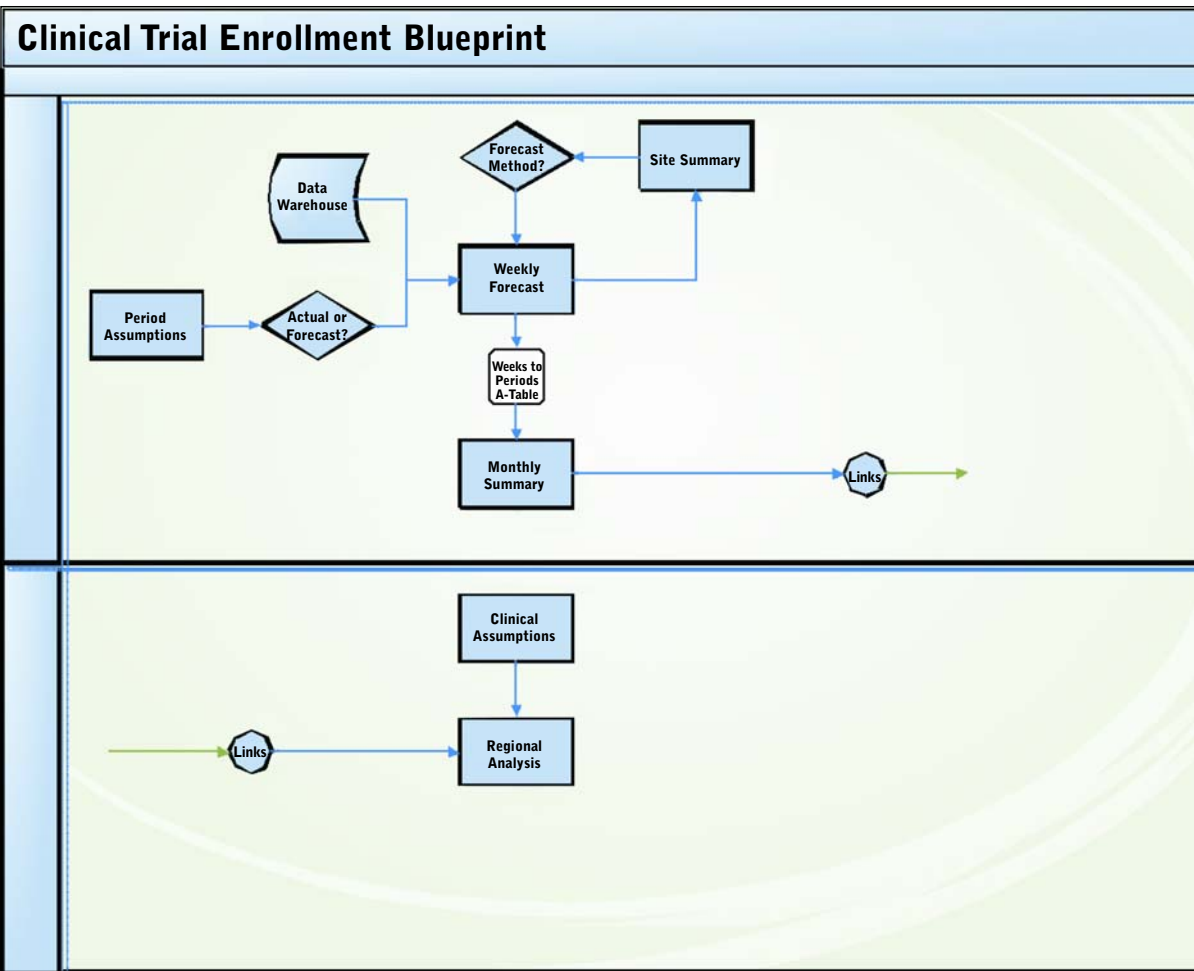
1. Establishes clear and concise targets for each regional manager for specific clinical studies
2. Provides the ability to create what-if scenarios
3. Evaluates historical data in order to evaluate the effectiveness of the plan
4. Provides immediate feedback on planning decisions
5. Allows reporting 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.

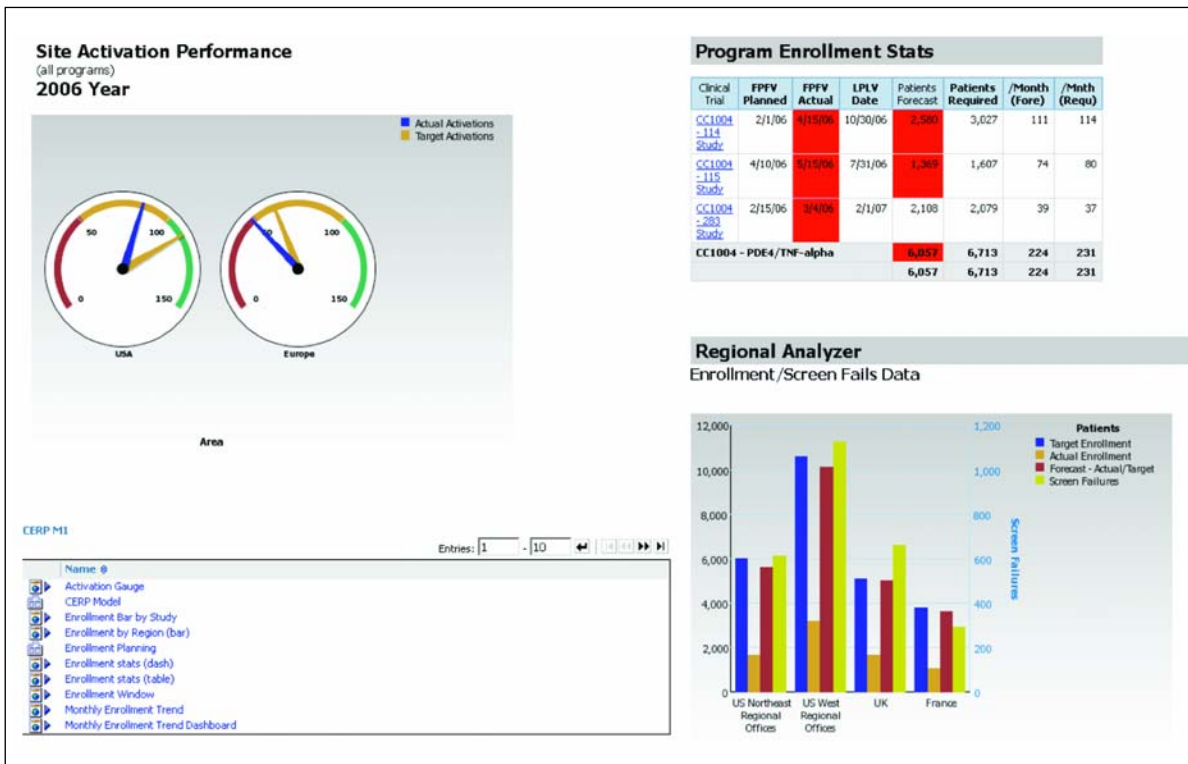
Blueprint contributors start the process by entering the targets for each clinical study, then selecting the best Forecast Method to determine future enrollment. Once forecasts have been submitted, the information will be linked to a regional analyst. The analyst will evaluate whether additional investment 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.



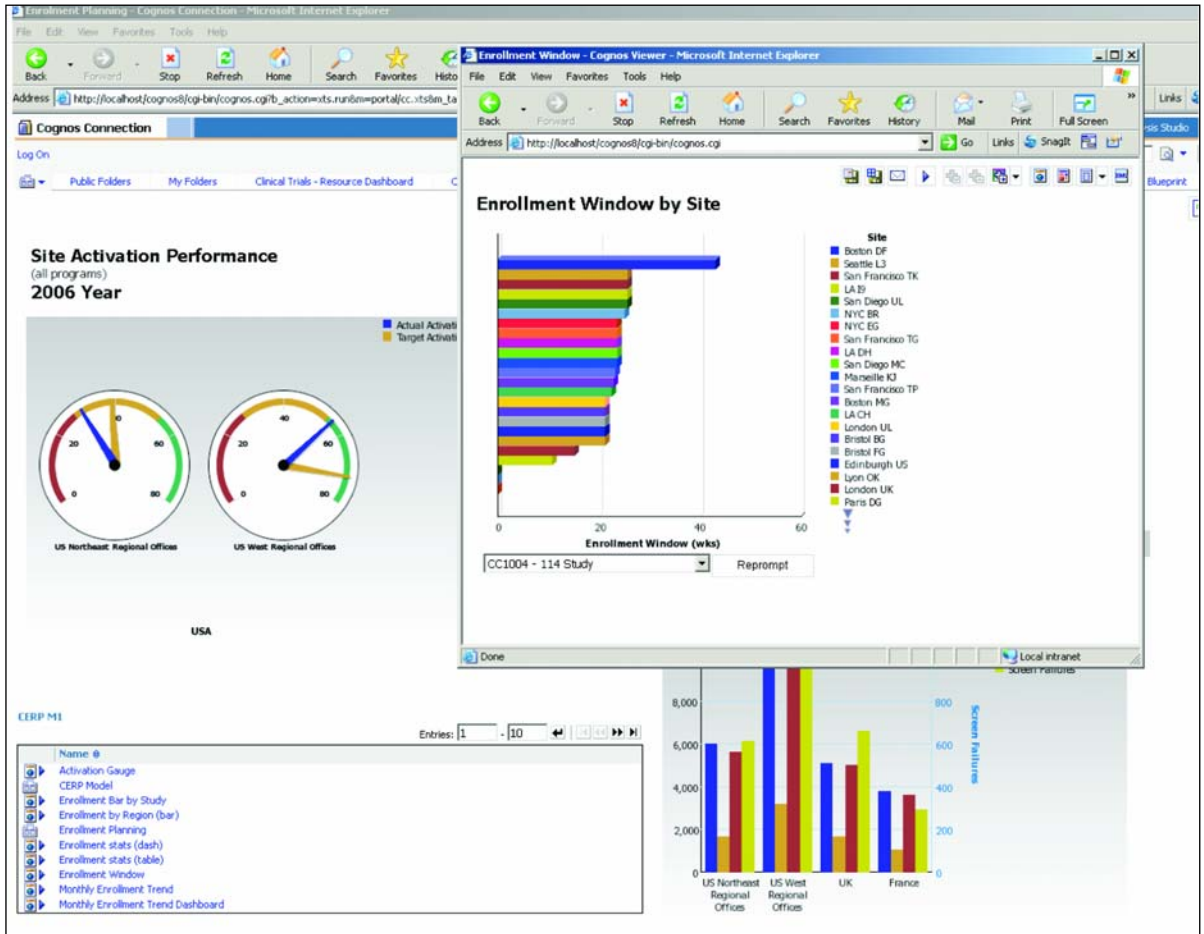
CLINICAL TRIAL ENROLLMENT, ANALYSIS, DASHBOARDS, AND SCORECARDS

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.

The screenshot displays a Cognos dashboard with two main sections: 'Site Activation Performance' and 'Enrollment Stats'.

Site Activation Performance (all programs) 2006 Year

Two gauges show 'Actual Activation' (blue) and 'Target Activation' (yellow) for 'US Northeast Regional Offices' and 'US West Regional Offices'. The US West gauge shows a higher percentage of target activation compared to the US Northeast.

Enrollment Stats

Candidate	Clinical Trial	FPFV Planned	FPFV Actual	LPLV Date	Patients Forecast	Patients Required	Patients/month Forecast	Patients/month Required
CC1004 - PDE4/TNF-alpha	CC1004 - 114 Study	2/1/06	4/15/06	10/30/06	2,500	3,027	111	114
	CC1004 - 115 Study	4/10/06	5/15/06	7/31/06	1,364	1,607	74	80
	CC1004 - 283 Study	2/15/06	3/4/06	2/1/07	2,108	2,079	39	37
CC1004 - PDE4/TNF-alpha Diamide AML	Dia AML-003 Study	4/1/06	4/4/06	3/15/07	3,605	3,916	69	70
	Dia AML-004 Study	10/1/06	1/1/00	5/30/07	1,899	2,304	0	0
	Diamide AML-009	4/1/07	1/1/00	8/30/07	0	0	0	0
	Diamide AML-010	5/15/06	6/30/06	11/15/06	1,682	1,722	64	66
Diamide AML Relaxamid NHL	Relaxamid Study NHL 102	4/10/06	5/25/06	12/31/06	2,122	2,344	75	77
	Relaxamid Study NHL 103	7/30/06	7/30/06	4/1/07	1,712	1,764	44	43
	Relaxamid NHL				3,834	4,108	119	119
					17,077	18,763	476	486

CERP M1

Navigation menu: Name: @, Entries: 1 - 10

- Activation Gauge
- CERP Model
- Enrollment Bar by Study
- Enrollment by Region (bar)
- Enrollment Planning
- Enrollment stats (dash)
- Enrollment stats (table)
- Enrollment Window
- Monthly Enrollment Trend
- Monthly Enrollment Trend Dashboard

Bar Chart: Screen Features

Y-axis: Screen Features (0 to 8,000). X-axis: US Northeast Regional Offices, US West Regional Offices, UK, France.

Region	Screen Features
US Northeast Regional Offices	~6,000
US West Regional Offices	~8,000
UK	~5,000
France	~4,000

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.

The screenshot shows the 'Marginal Cost Type' tab selected in the software. The window title is 'CERP | Contributions | Boston DF - Cognos Planning - Contributor'. The menu bar includes File, Edit, View, Tools, Actions, and Help. The toolbar contains various icons for file operations and help. Below the menu and toolbar are four tabs: 'Marginal Cost Type' (selected), 'Clinical Cost Assumptions', 'Weekly Forecast', 'Site Summary', and 'Monthly Summary'. The main content area displays a table with the following data:

	Marginal Cost Type
Advertising Variable	Per Person
Site setup Cost	Total Cost
Other Enrolment Cost	Per Person

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.

The screenshot shows the 'Weekly Forecast' tab selected in the software. The window title is 'CERP | Contributions | Boston DF - Cognos Planning - Contributor'. The menu bar includes File, Edit, View, Tools, Actions, and Help. The toolbar contains various icons for file operations and help. Below the menu and toolbar are three tabs: 'Weekly Forecast' (selected), 'Site Summary', and 'Monthly Summary'. The main content area displays a table with the following data:

	2006 Year	2006 - Wk 1	2006 - Wk 2	2006 - Wk 3	2006 - Wk 4	2006 - Wk 5	2006 - Wk 6	2006 - Wk 7	2006 - Wk 8
LPFV - Date		06/30/06	06/30/06	06/30/06	06/30/06	06/30/06	06/30/06	06/30/06	06/30/06
FPFV - Planned		01/01/06	01/01/06	01/01/06	01/01/06	01/01/06	01/01/06	01/01/06	01/01/06
Target Enrollment	270	20	20	10	10	10	10	10	10
Actual Enrollment	245	19	19	9	9	9	9	9	9
Manual Forecast Override	6	0	0	0	0	0	0	0	0
Screen Failures	23	0	0	0	1	1	1	1	1
% Screen Failures	9%	0%	0%	0%	10%	10%	10%	10%	10%
Actual/Forecast Period		Actual Period	Actual Period	Actual Period	Actual Period	Actual Period	Actual Period	Actual Period	Actual P
ENROLMENT FORECASTS									
Forecast Method		Manual Rate	Manual Rate	Manual Rate	Manual Rate	Manual Rate	Manual Rate	Manual Rate	Manual

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.

	CC1004 - 114 Study				CC1004 - 115 Study				CC1004 - 283 Study			
Investigator	SMITH	1.006	1.006	1	SMITH	1.006	1.006	1	SMITH	1.006	1.006	1
FPFV - Planned			01/01/06				04/01/06				02/01/06	
FPFV - Actual			01/01/06				04/01/06				02/01/06	
LPPV - Date			06/30/06				07/31/06				02/01/07	
Enrolment Window			26				17				52	
# Patients Forecast			70				65				200	
# Patients Required			200				77				181	
Site Activated?			Yes				Yes				Yes	
Forecast Method			Manual Rate				Act/Bud				Act/Bud	
# of Wks for Avg method												
Missing Data Warning												
Input - Weekly Enrolment Rate			3				0				0	

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.

	Total Years	Prior Years	2005 Year	Jan-06	Feb-06	Mar-06	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06	106 Ye
Target Enrollment	200	0	0	45	28	35	28	28	35	0	0	0	0	0	0	0
Actual Enrollment	70	0	0	10	12	9	12	12	15	0	0	0	0	0	0	0
Screen Failures	23	0	0	1	4	5	4	4	5	0	0	0	0	0	0	0
Final Forecast Enrollment	70	0	0	10	12	9	12	12	15	0	0	0	0	0	0	0
Variance to Target	(130)	0	0	(35)	(16)	(26)	(16)	(16)	(20)	0	0	0	0	0	0	0
Actual Activations	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Target Activations	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0

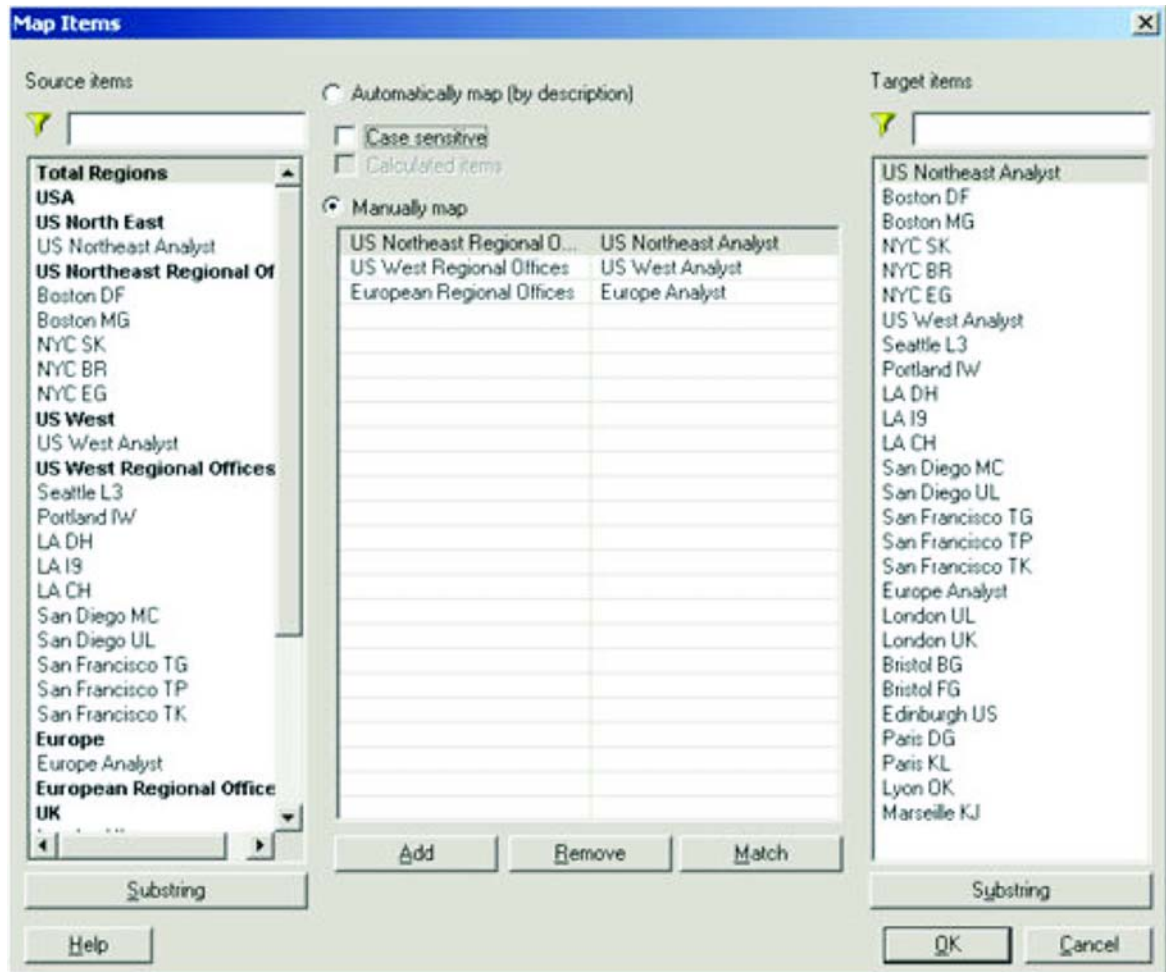
When all sites in the region have completed and submitted their forecasts, the administrator may run an Admin Link to the regional analyst. This data aggregates the targets and variances for each site in the region for each of the clinical trials. The regional analyst may also run a System Link at any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

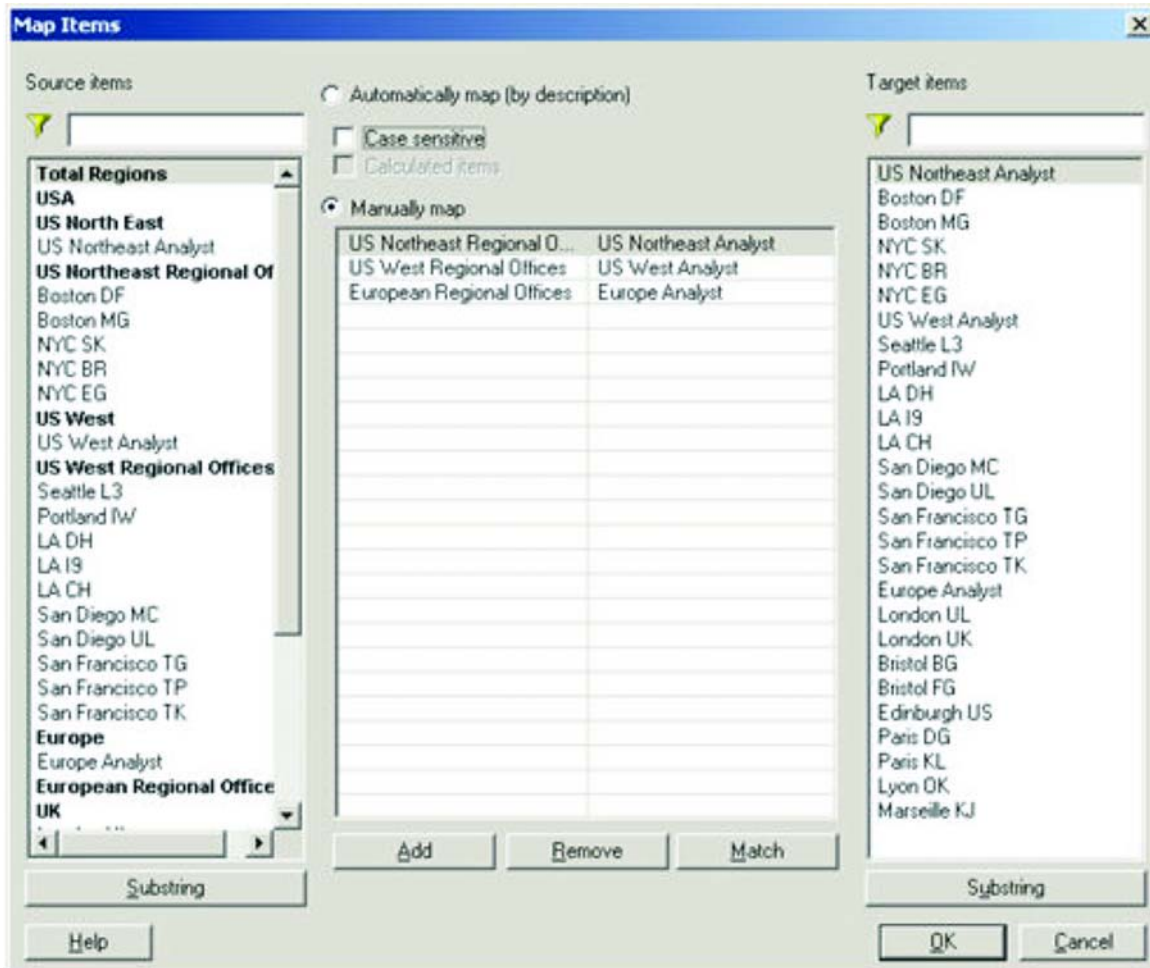
The image shows a software configuration window titled "Administration Link - Element". It contains several sections for setting up data links:

- Description:** A text area for entering a description.
- Pick the source and target applications:**
 - Source application: Clinical Trial Planning
 - Target application: Clinical Trial Planning
 - From application state: Production
 - To application state: Production
- Source cube:** Monthly Summary
- Target cube:** Regional Analysis
- Map source to target dimensions:**
 - Source dimensions: Clinical Trial, Monthly Summary, Periods, Elist
 - Target dimensions: Clinical Trial, Regional Analysis, Regional Costs, Elist
 - Mapping: Lines connect "Clinical Trial" to "Clinical Trial", "Monthly Summary" to "Regional Analysis", and "Elist" to "Elist".
 - Buttons: Map, Map All, Edit, Clear, Clear All
- Navigation:** Help, Cancel, < Back, Next >, Finish

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.

	Advertising Variable	Site setup Cost	Other Enrolment Cost
CC1004 - 114 Study	17,500	10,000	2,000
CC1004 - 115 Study	50,000	10,000	0
CC1004 - 283 Study	80,000	10,000	0
CC1004 - PDE4/TNF-alpha	147,500	30,000	2,000
Hematology	147,500	30,000	2,000
Dia AML-003 Study	25,000	8,000	0
Dia AML-004 Study	30,000	8,000	0
Diamide AML-009	50,000	8,000	0
Diamide AML-010	47,500	8,000	0
Diamide AML	152,500	32,000	0
Relaxamid Study NHL 102	17,500	12,000	0
Relaxamid Study NHL 103	21,000	12,000	0
Relaxamid NHL	38,500	24,000	0
Oncology	191,000	56,000	0
Total Clinical	338,500	86,000	2,000

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.

	Advertising Variable	Site setup Cost	Other Enrolment Cost
Value	17,500	10,000	2,000
Additional Cost to meet Target	10,805	10,000	1,235
Cost per Person	42.37		4.84
Final Forecast Enrolment	413	413	413
Target Enrolment	668	668	668
Reqd to meet Target	255	255	255

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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The Cognos Innovation Center 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 Cognos customers, academics, industry leaders, and others seeking to accelerate adoption, reduce risk, and maximize the impact of technology-enabled performance management practices.