Evaluation Guide

# Clinical Modeling and Resource Tracking Performance Blueprint

Information Management

Cognos. software

## Introduction

Clinical trials are often the biggest line item in research and development budgets and can be the most critical component in getting new drugs to market on time and at a reasonable cost.

Managing a portfolio of clinical trials is particularly challenging; the size and complexity of studies increases relentlessly and budgets are under ever increasing scrutiny.

Tracking and monitoring the various phases of the study–from establishing the protocol design to close out and controlling costs–are the critical challenges facing clinical operations and finance teams in both contract research organizations (CROs) and sponsor organizations. Data is spread throughout multiple source systems, including clinical trial management systems (CTMS), electronic data capture (EDC) and spreadsheets. The myriad of data sources and manual processes restricts visibility into the performance of the study and obscures accurate forecasting and data-driven decision making.

What is needed is a model that can tie all the parts of the study together, linking cost drivers such as advertising, patients and staff so that sponsors and CROs can create and track costs and performance for clinical trials. By combining all these moving parts into a comprehensive model, they can better anticipate resource requirements, avoid bottlenecks and control costs.

The *IBM Cognos® Clinical Modeling and Resource Tracking Performance Blueprint* is the tool that can be used to create that model. It provides a clear picture of a clinical trial upfront, making it easier for sponsors and CROs to see where costs can be reduced. It also helps optimize investments and improves decision making.

## Introducing the IBM Cognos Clinical Modeling and Resource Tracking Performance Blueprint

The *IBM Cognos Clinical Modeling and Resource Tracking Blueprint* helps organizations answer a question that is both simple and powerful: How can we run this study more efficiently?

To do this, the *Blueprint* takes all the information about a study that is probably scattered over different spreadsheets and in different formats and puts it all in one place for better budgeting, planning, decision making and performance monitoring. Unlike existing spreadsheet and clinical trial management systems, the *Blueprint* combines historical data from source transactional systems with planned data to create a robust forecasting and tracking model.

Using the *Blueprint*, clinical trial organizations can build a model of the planned study based on historical profiles and performance. This can help them more accurately price contracts, understand resource requirements, prevent delays in the trial process and make sure that they have the right mix of staff in place to avoid potential bottlenecks.

The *Blueprint* is also flexible; business rules can be added as needs arise and the basics of calculating costs can be changed. For example, a sponsor could decide to change the way it recruits patients for a study from advertising to using an existing mailing database. This change is very simple in the model, which adjusts the calculations based on the change.


The *Blueprint* includes a comprehensive collection of pre-defined dashboards and analytical charts. The chart in this illustration is a view of the “recruitment funnel” for a particular study, showing the number of patients at each stage and highlighting the cumulative enrollment performance to date.

Another critical aspect is the ability to run "what-if" scenarios, changing key assumptions and dates to determine a range of likely outcomes. The following chart displays the patient enrollment for a range of scenarios. All the scenario forecasts are immediately available for distribution to all decision makers in the organization using IBM Cognos enterprise-class reporting capabilities.


Using the *Blueprint*, organizations can model:

- How the clinical trial outreach will perform
- Patient allocation over sites
- How the trial might be affected when patient numbers change
- Income and cost allocation based on the role of the staff
- Resource effort required for site visits and other activity associated with the trial

*Blueprint* capabilities include:

- A hierarchy that enables instant calculation of groups of trials
- Cross-scenario or what-if analysis
- Automated population of actual data from source systems
- Daily or hourly updates
- Integrated business, profit and loss and cash flow reporting
- Dashboard metrics calculated automatically

Resource allocations and costs are easily calculated and all aspects of the study are clearly visible for analysis and reporting.

## How the IBM Cognos Clinical Modeling and Resource Tracking Blueprint works

To prepare a budget and forecast for a clinical trial, most organizations start by manually inputting data into a spreadsheet. Those initial assumptions inevitably change as the plan is developed, so the organization must go back and update that spreadsheet. Not only is this manual process very cumbersome and labor intensive, but it also introduces risks and inaccuracies as the original assumptions are probably being used elsewhere in another spreadsheet for another part of the planning process. Now we have multiple versions of the data without all the associated confusion and risk.

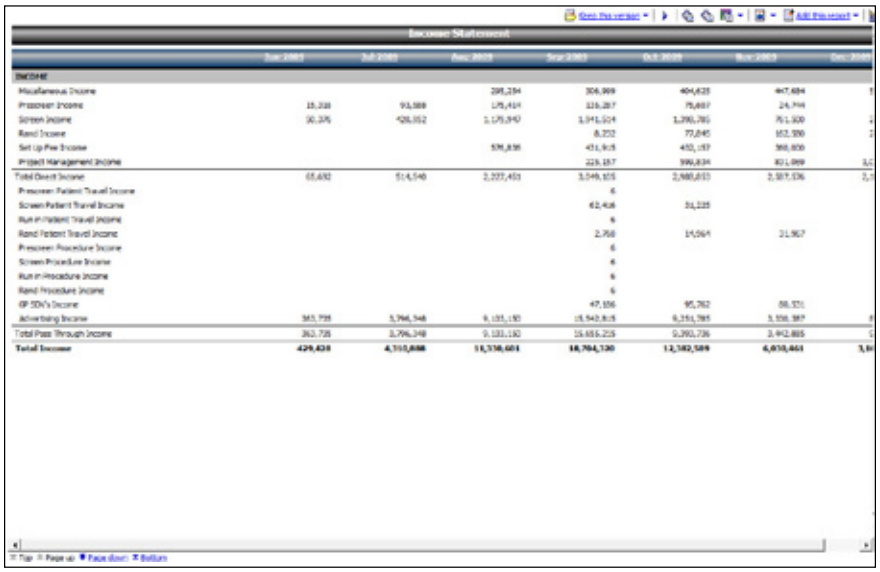
Activities such as project management are typically tracked separately and are not integrated or correlated with the spreadsheets. It is very difficult, in this scenario, to create a reliable and timely forecast for the entire study. The result of these different and separate processes and sources of information is that senior management has difficulty assessing performance trends and identifying subsequent actions because there is no central location for all of the data. This makes it difficult for them to assess the organization's position in regard to achieving strategic goals.

The *IBM Cognos Clinical Modeling and Resource Tracking Blueprint* was developed to help organizations create realistic and comprehensive study budgets and track performance to budget by providing a centralized view of all elements of a clinical trial.

Powered by IBM Cognos 8 Planning and IBM Cognos 8 Business Intelligence software, the *Blueprint* features templates for detailed modeling of the entire clinical portfolio that can be used to build a consolidated Clinical Trial Income, Expense Statement and Cash Flow Analysis. Organizations can also monitor, review and analyze this data with business intelligence dashboards and reports that are ready to use.

Using the mechanics of a costing model as the basis for preparing a study forecast, the *Blueprint* combines all elements of a clinical trial and emphasizes the relationships between them. Costs are modeled utilizing drivers–advertising, patients, laboratory and equipment, clinical support staff and more–to determine the planned costs. The *Blueprint* not only helps organizations track costs, but it also helps them weigh the quality of scientific data versus costs, so that they can make better decisions about the study.

For CROs, the Blueprint comes equipped with study-level Income and Expense Statement and Cashflow reporting.



**Understand costs, improve planning and track performance: Blueprint benefits**

With the *Blueprint*, organizations can understand their clinical trial costs, which can help them find areas of savings and improvement. Because it uses pre-defined planning templates, management dashboards and analytical reports, the process of planning and tracking clinical trials is streamlined. Project management of the planning process is improved for organizations and senior management can quickly assess performance to see if strategic goals are being met.

The *Blueprint* enables more accurate costing because it brings together all the moving parts of a clinical trial in one location. It also easily integrates with transactional systems to update for actuals and provides visibility into the execution of portfolio plans with costs, cash flow and resource demands.

Other benefits of the *Blueprint* include:

- Populating the model can be completed electronically, reducing manual keying to a minimum.
- Data silos and multiple versions of the truth can be avoided.
- A standardized planning process can be controlled with built-in workflow.
- Several scenarios for contract, budget and forecast are available online, in real time.
- Forecasts can be updated easily and regularly.

- Reports are instantly available at any hierarchical level and can be easily shared throughout the organization.
- Performance trends and relevant, detailed information about the study are more visible.
- The data repository can be used for future study planning and costing.


**Conclusion**

Planning for a new clinical trial can be a challenge. You must create budgets, allocate resources, find patients and determine the efficacy of one study site over another.

The *IBM Cognos Clinical Modeling and Resource Tracking Blueprint* can significantly improve this process by modeling your study based on all aspects of a study: costs, resources, time and geography. It creates visibility into the overall clinical trial process so that you can plan appropriately, reduce costs and make better decisions.

### About the IBM Cognos Innovation Center for Performance Management

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

### 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.

For further information or to reach a representative: www.ibm.com/cognos

### Request a call

To request a call or to ask a question, go to www.ibm.com/cognos/contactus.
An IBM Cognos representative will respond to your enquiry within two business days.



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

Produced in Canada
July 2009


IBM Cognos
**Innovation Center**
**for Performance Management**

IML14172-CAEN-00