Business Value Guide

CLINICAL TRIAL FORECASTING

A WEB-BASED PERFORMANCE MANAGEMENT APPLICATION

COGNOS | INNOVATION CENTER
for Performance Management™

CLINICAL TRIAL FORECASTING HELPS COMPANIES BETTER ANTICIPATE RESOURCE AND EXPENDITURE NEEDS TO OPTIMIZE INVESTMENT IN THEIR DEVELOPMENT PROGRAMS

The importance of managing the drug development process cannot be overstated. Costs can exceed $800 million, and it can take 12 years to bring a drug to market. Clinical Trials are the largest component of that investment. Companies face increasing budget pressures and growing study designcomplexity, both of which heighten the importance of robust budgeting and forecasting.

Clinical trial forecasting is complex and challenging.

Understanding and predicting the exact performance of a large Phase 3 trial can be challenging, since programs are often run globally and involve the manual collection and consolidation of visit data. Multiple data versions for enrollment- and finance forecast models are maintained in far-flung spreadsheet systems. Dedicated clinical trials management systems (CTMS) often lack robust financial forecasting functionality, since they are focused on transaction recording, rather than activity-based forecasting or scenario modeling—both essential for finance- and resource management functions.

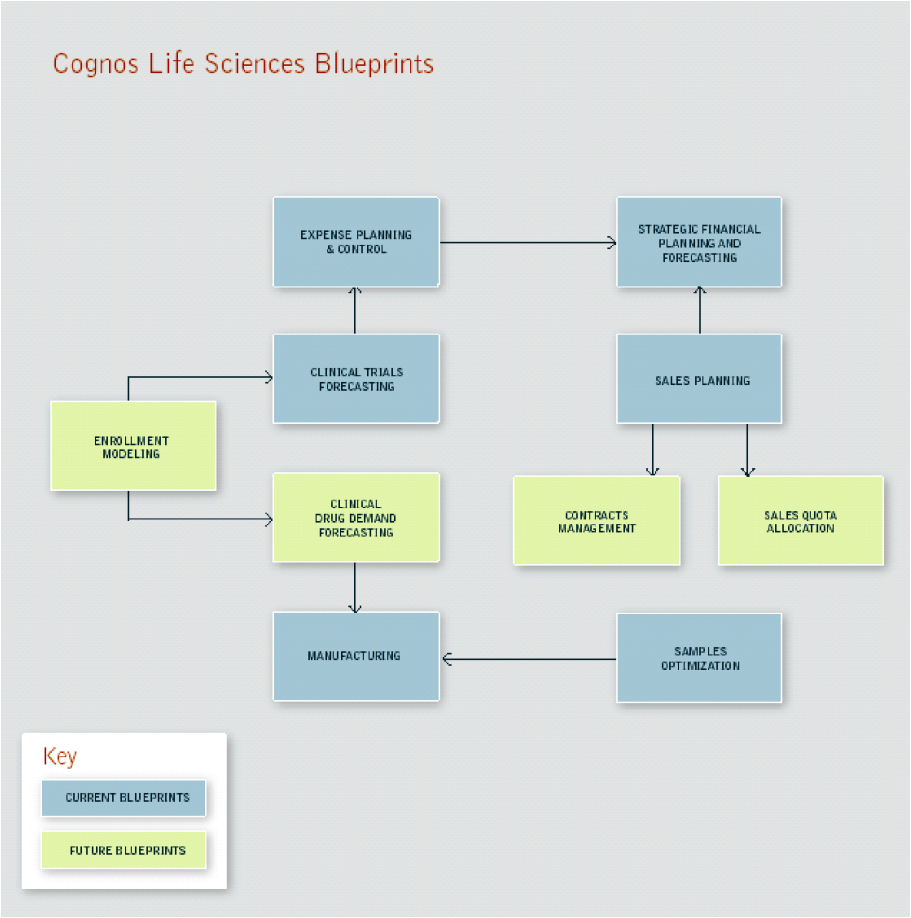
Forecasting with CTMS presents a number of challenges:

- Inability to link-in and update the plan based on actual spending.
- Phasing based on a representative patient across the entire study, rather than on individual visits and their associated costs for forecast generation.
- 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.
- Lack of up-to-date accounting information.

Furthermore, investigator payments—which typically comprise 60-80 percent of trials costs—are often made without invoices, since the investigators do not issue them. Without an invoice or purchase order, deriving an accurate and timely information from accounting systems is highly problematic.

The trouble with spreadsheets.

Although companies try to apply best practices for clinical trial management, spreadsheet-based corporate budgeting and forecasting tools are typically used for modeling clinical trials—an approach much too rigid for rapid, accurate clinical trial management. 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.



THE COGNOS CLINICAL TRIALS FORECASTING BLUEPRINT

Cognos Performance Blueprints are pre-configured planning, reporting, and policy templates based upon Cognos 8 Planning and Cognos 8 Business Intelligence. The *Clinical Trials Forecasting Blueprint* is one of a rich suite of performance management solutions for the life sciences, as illustrated by the figure above. The *Clinical Trials Blueprint* is robust, flexible, scalable, and enables an entire portfolio of development projects to be modeled uniformly. The *Blueprint* helps users identify key pain points and facilitates more effective trials expense management by mapping expenses to activities, rather than using time-based accrual.

Use of project management data

Bio-pharma R&D businesses are driven by projects. Traditional clinical project management systems, whether home-grown or commercial, contain the source data needed to build financial models. But typical budgeting and finance applications are cost-center focused and do not take into account multi-year project and portfolio management processes. Typical project management systems cannot or do not use this valuable data at the project level.

The patient visit is the underlying driver for the majority of costs in a large clinical trial. By predicting when patient visits occur, the *Clinical Trials Blueprint* creates a robust forecast by modeling visit attributes such as per-patient costs, retention, or drop rates between visits and the timing of visits relative to each patient enrolled in the study.

Portfolio modeling

When resources are constrained and it is necessary to optimize investments, the abilities to model *what-if* scenarios and to assess the performance of cross-portfolio sites or regions across the portfolio are critical. The *Clinical Trials Blueprint* enables such functionality, and builds a robust performance data repository as a base for future decisions such as site selection for prospective studies.

For example, by modeling per-patient costs by study type and by region, it is possible to compare costs with other metrics such as retention and enrollment rates. This gives visibility to the complete cost performance picture across the portfolio to answer critical questions. For example, a multi-national generics manufacturer might wonder:

> *"Per-patient costs for running studies in Russia are low, but patient enrollment always undershoots and we end up spending more by adding additional centers. What would be the impact of running more of the study in France, where costs are higher, but patient drops are lower?"*

Early-stage and concept studies

The *Clinical Trials Forecasting Blueprint* is perfect for larger, more material studies—typically Phase 2b onwards with a spending excess of $1-2 million. But what about smaller studies and concept studies, where underlying patient enrollment data is not available? The early-stage portfolio is different in nature and typically comprises many smaller and shorter duration projects. For such projects, the *Clinical Trial Blueprint* offers a streamlined approach that uses project start- and end-dates along with an anticipated task-level budget or forecast.

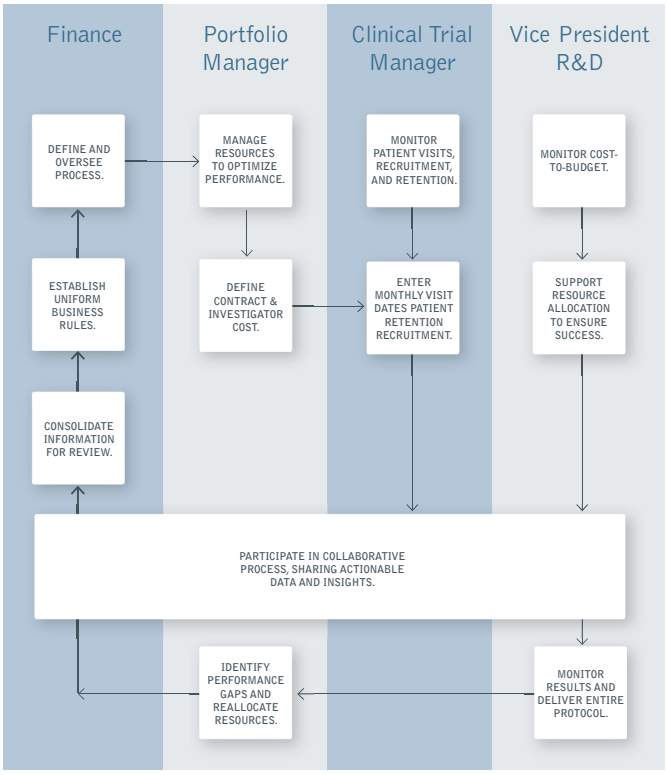
Data is sourced from an in-place project or portfolio management system. The data is linked into the *Blueprint* and used as basis for a phasing calculation. Pre-defined formulas update the forecast for the actual activity and re-forecast based on a range of assumptions, such as:

- Average monthly spend projected forward
- Cumulative percent variance to budget projected forward
- Accumulated variance to budget spread over the remaining months or project lifespan
- Existing forecast projected forward so that variances to data are considered permanent

A Typical Workflow Supporting Clinical Trial Forecasting

In many companies, the clinical trial process is managed by four primary stakeholders:

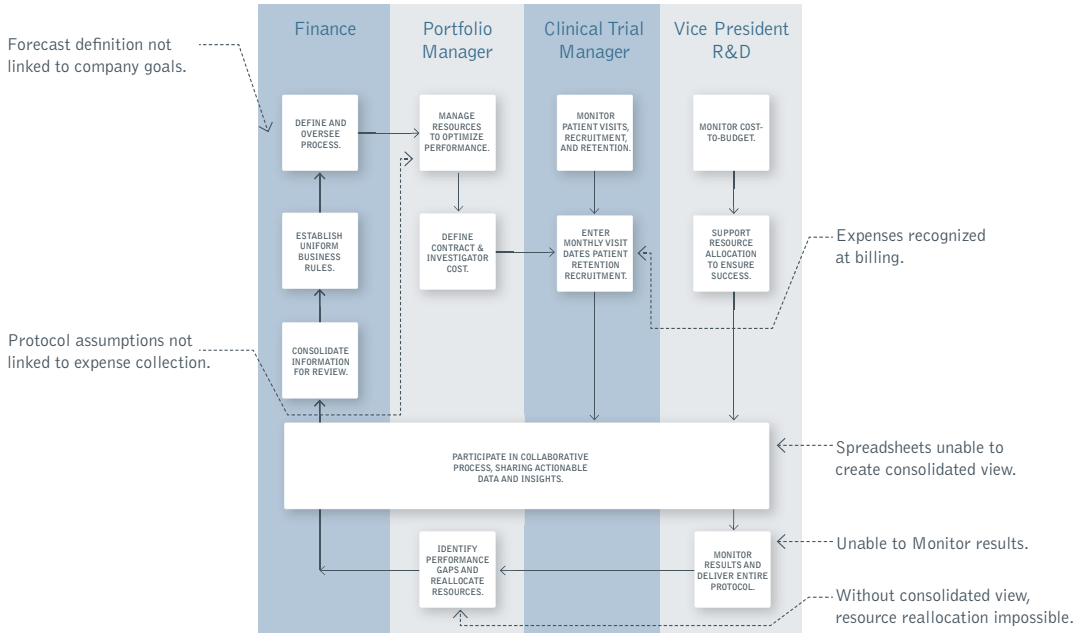
- *Finance* defines the trial forecasting process.
- *Portfolio Manager* defines protocol assumptions and fixed/variable costs, which can include contract and investigator costs. [Note that, even within, it is important to note that even within the same protocol or study, these costs can vary by site location.]
- *Clinical Trial Manager* enters monthly costs associated with enrollees across all protocols.
- *R&D Executive Team* reviews consolidated information from Finance to monitor trial results.



Most companies manage the clinical trials process using spreadsheets, which leads to error and difficulty in arriving at a consolidated forecast plan with sufficient detail to improve forecast accuracy. The process is complicated further because spreadsheets lack the consistent business rules needed to communicate process intricacies.

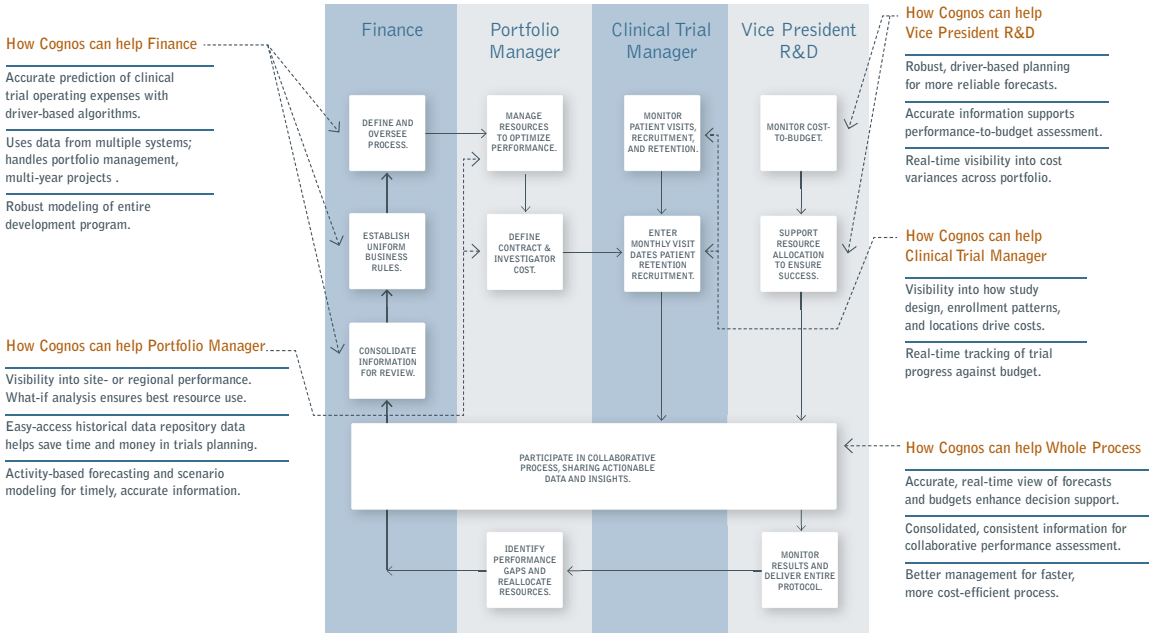
Typically, forecast goals are not linked to protocol assumptions. Expenses have to be recorded when billed, as apposed to being derived through enrollment figures.

And most importantly, due to the sheer volume of spreadsheets typically generated, a consolidated view across all protocols is difficult. Effective performance monitoring and resource reallocation becomes nearly impossible.



Farewell to Spreadsheets

The clinical trial process requires combined central business rule management with driver-based planning in a collaborative decision-support environment that allows participation by "all the right people." High-performance companies replace spreadsheets with robust multi-dimensional modeling and integrated workflows that limit error, improve control, enhance visibility, and boost accountability. Through such an approach, expenses can be better anticipated and results can be consolidated instantly to facilitate monitoring. A consolidated view also enhances analysis and resource allocation to improve overall protocol performance.



The *Cognos Clinical Trials Forecasting Blueprint* offers benefits a spreadsheet-based system never could.

For Finance, the *Blueprint*

- Provides accurate prediction of clinical trial operating expenses, using driver-based algorithms.
- Pulls together data from multiple systems; accommodates multi-year projects and portfolio management processes.
- Enables robust modeling of an entire development program.

For Portfolio Managers, the *Blueprint*

- Provides visibility into performance of sites or regions and allows managers to conduct "what-if" scenario analysis to ensure best use of resources.
- Creates a data repository, allowing easy access to historical data that can help save time and money when planning trials.
- Provides activity-based forecasting and scenario modeling for timely, accurate information.

For Clinical Trial Managers, the *Blueprint*

- Provides visibility into how study design, enrollment patterns and locations are driving costs.
- Delivers real-time tracking of trial progress against budget.

For R&D Executive Teams, the *Blueprint*

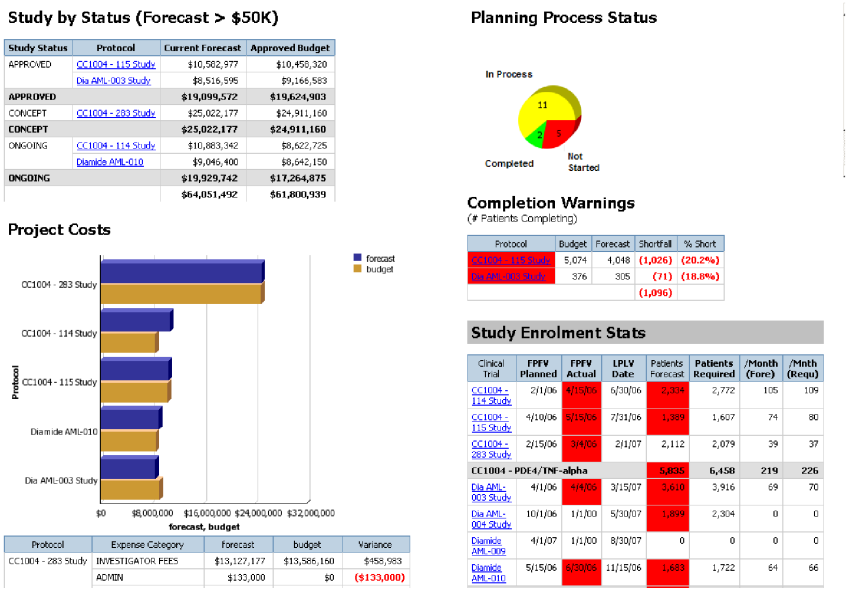
- Delivers robust, driver-based planning for a more reliable forecast.
- Accurate information supports confident assessment of performance to budget.
- Offers real-time visibility into cost variances across portfolio.

Across the clinical trials process, the *Blueprint*

- Delivers an accurate, real-time view of clinical trials forecasts and budgets, giving team members the critical information they need to make key decisions.
- Provides consolidated, consistent information —i.e. "one version of the truth" —allowing the team to collaboratively assess performance, make decisions and reach goals.
- Facilitates better management at every level, for a faster, more cost-efficient process.

Blueprint Detail

The *Clinical Trials Blueprint* consists of both Cognos 8 Planning models and Cognos 8 Business Intelligence reports.



Study by Status (Forecast > $50K)

Study Status	Protocol	Current Forecast	Approved Budget
APPROVED	CC1004 - 115 Study	$10,562,977	$10,458,320
	Dia AML-003 Study	$8,516,595	$9,166,583
APPROVED		**$19,099,572**	**$19,624,903**
CONCEPT	CC1004 - 283 Study	$25,022,177	$24,911,160
CONCEPT		**$25,022,177**	**$24,911,160**
ONGOING	CC1004 - 114 Study	$10,883,342	$8,622,725
	Diamide AML-010	$9,046,400	$8,642,150
ONGOING		**$19,929,742**	**$17,264,875**
		$64,051,492	**$61,800,939**

Project Costs

Protocol	Expense Category	Forecast	budget	Variance
CC1004 - 283 Study	INVESTIGATOR FEES	$13,127,177	$13,586,160	$458,983
	ADMIN	$133,000	$0	($133,000)

Planning Process Status

Completion Warnings

(# Patients Completing)

Protocol	Budget	Forecast	Shortfall	% Short
CC1004 - 115 Study	5,074	4,048	(1,026)	(20.2%)
Dia AML-003 Study	376	305	(71)	(18.8%)
			(1,096)	

Study Enrolment Stats

Clinical Trial	FPFV Planned	FPFV Actual	LPLV Date	Patients Forecast	Patients Required	/Month (Fore)	/Mnth (Requ)
CC1004 - 114 Study	2/1/06	4/15/06	6/30/06	2,334	2,772	105	109
CC1004 - 115 Study	4/10/06	5/15/06	7/31/06	1,389	1,607	74	80
CC1004 - 283 Study	2/15/06	3/4/06	2/1/07	2,112	2,079	39	37
CC1004 - PDE4/TNF-alpha				**5,835**	**6,458**	**219**	**226**
Dia AML-003 Study	4/1/06	4/4/06	3/15/07	3,610	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	8/30/06	11/15/06	1,683	1,722	64	66

The sample dashboard above is populated with data from the *Blueprint* model. It is designed for a clinical or finance manager who has financial and project management responsibilities responsibility for a range of clinical trials.

The charts on the left display portfolio summaries comparing budgeted performance to actual and forecasted performance. All the charts on the dashboard have drill-down or drill-through capabilities.

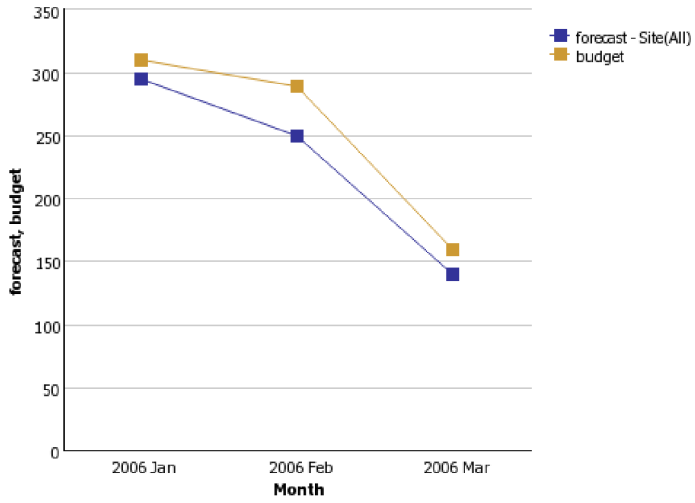
The right side of the dashboard displays operational and process data for the clinical trials. The top-right chart, “Planning Process Status,” shows in real time that five studies have not been updated this month.

"Completion Warnings" is an exception report showing which studies are predicted to under-complete, based on the protocol requirements for the number of patients needed to finish the study. One can quickly drill through to an enrollment trend chart revealing the under-enrollment that may be causing the problem.

Completion Warnings
(# Patients Completing)

Protocol	Budget	Forecast	Shortfall	% Short
CC1004 - 115 Study	5,074	4,048	(1,026)	(20.2%)
Dia AMI -003 Study	376	305	(71)	(18.8%)
			(1,096)	

Enrolment Analysis

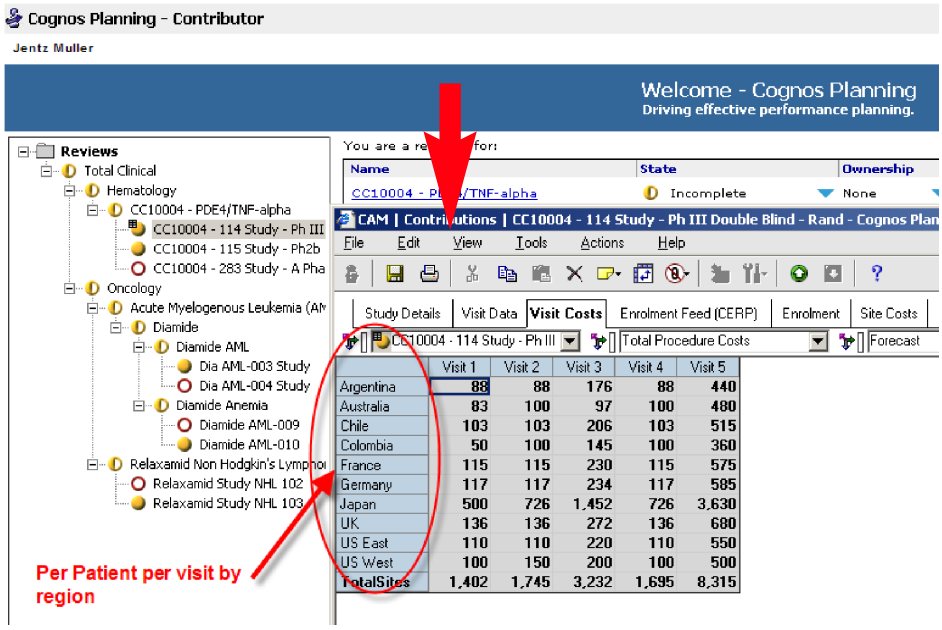


Of course, the problem may be one of patient retention aside from (or in addition to) one of enrollment. It is just as easy to drill into an analysis of retention trends for this study, or to compare the study with others in the portfolio using the same regions.

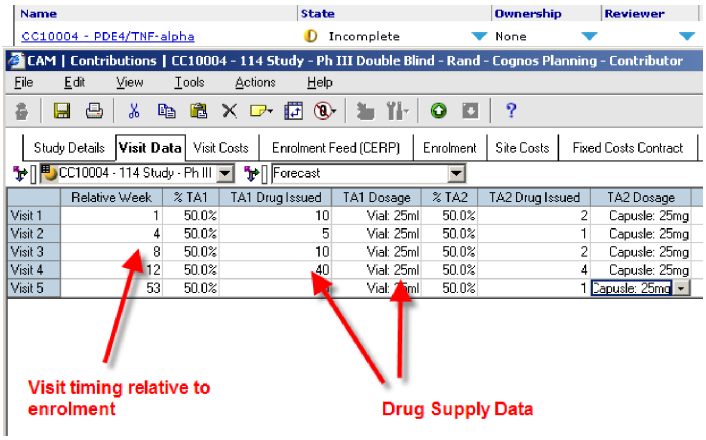
Blueprint Planning Model Details

The algorithm that predicts visits, number of patients in the study, and costs has four parts, which are explained below:

1. Per-patient per-visit costs are captured from the protocol design and loaded into the model. The *Blueprint* offers full FX support for global studies; the sites/regions lists are fully customizable.

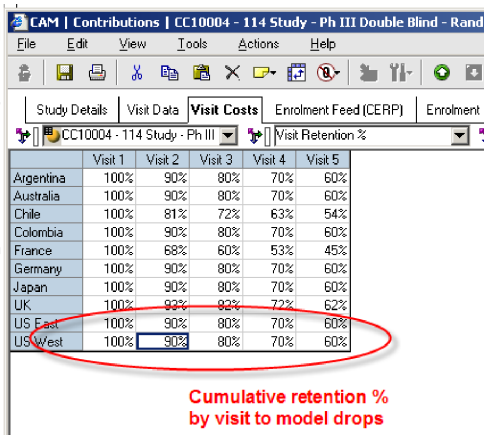


2. Relative visit dates are also captured from the protocol design, breaking out the costs and timing of each visit, providing a more accurate phasing calculation for the individual visit cost drivers.

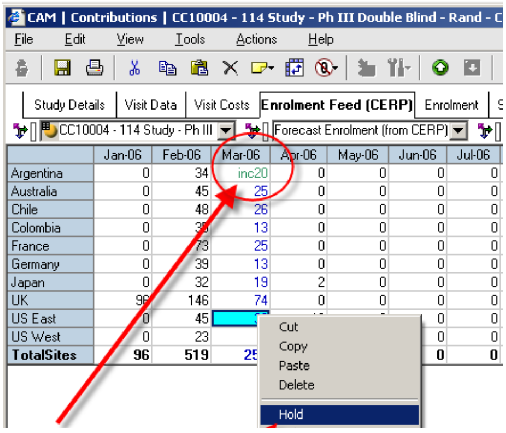


One can also model the drug demand while forecasting the number of patients for each visit at given times. [This functionality is being expanded in a *Drug Demand Forecasting Blueprint* designed for a range of study types and logistical business requirements.]

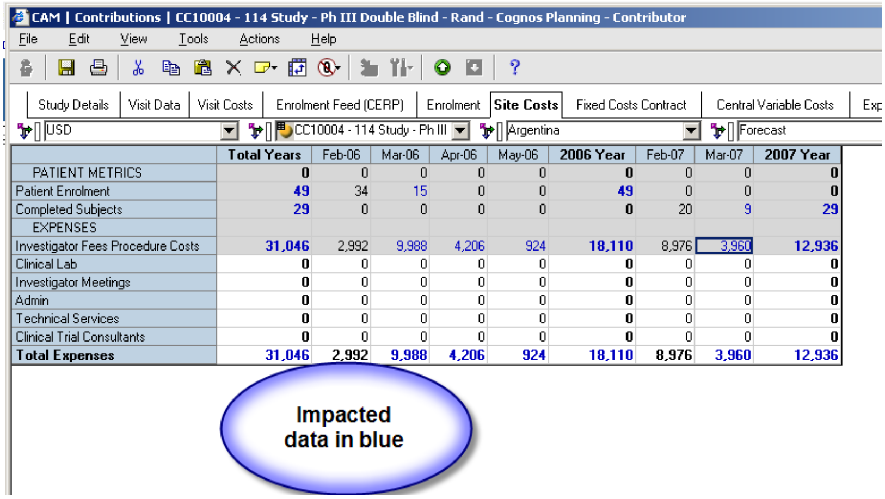
3. Patient retention is modeled on cumulative percentage basis for each study by region and by visit.



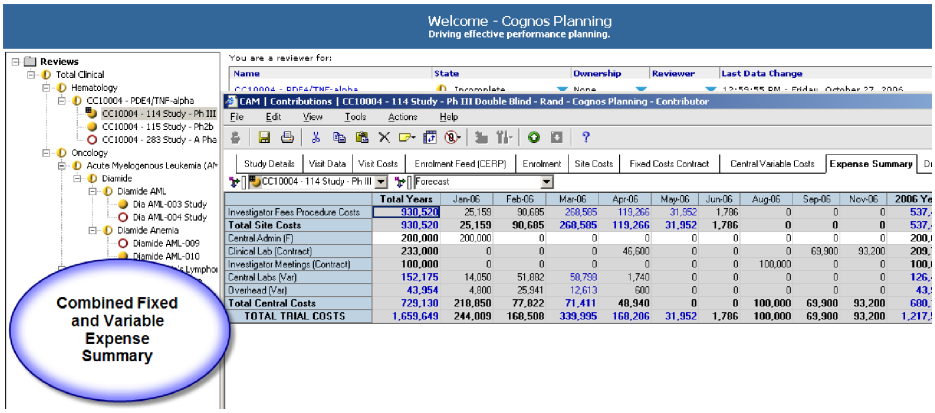
4. Enrollment data is loaded from a CTMS or input directly into the model. As part of the routine forecast update cycle, data is updated for actual enrollment as it occurs. The screenshot below illustrates how easy it is to perform *what-if* modeling using the *Blueprint*. There are a variety of other shortcuts that greatly simplify data entry and eliminate the need for an off-line spreadsheet to perform goal-seeking or similar functions.



The impact of these changes on the forecast is immediately visible. All impacted data is displayed in BLUE.



Fixed Costs—such as meetings, administration overheads, or advertising—do not vary directly with patient visits. Fixed costs are also captured by the *Blueprint* and combined with variable-cost data to present a complete picture of the clinical trial, both in financial and operational terms.



A Final Word

The *Cognos Clinical Trial Forecasting Blueprint* offers the visibility and control you need to respond quickly to changing conditions and pursue performance goals with confidence. It enables finance and R&D to focus resources on the protocols that are missing key dates in their FDA filing process. The *Blueprint* maximizes insight into enrollment indicators that can affect the progress of a costly study. And it provides the structure R&D needs to ensure that the protocols are aligned with corporate targets.

To learn more about the *Cognos Clinical Trial Forecasting Blueprint* or other life science *Blueprints* like *Samples Optimization*, *Enrollment Modeling*, or *Drug Demand Forecasting*, please visit http://www.cognos.com/innovationcenter.

ABOUT THE COGNOS INNOVATION CENTER FOR PERFORMANCE MANAGEMENT

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.

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