

Clinical Trial Enrollment Forecasting Performance Blueprint



Introduction

Clinical trial enrollment forecasting challenges

Patient enrollment is a major headache for life science organizations. Failure to enroll adequate numbers of patients is a primary reason why some clinical trials fail. Sponsors and CROs need robust forecasting and enrollment analytics that involve collaboration between managers, analysts, and the individual investigator sites.

The ability to collect and model enrollment trends and make decisions to shut down or set up additional sites is key to managing a development portfolio as study designs become more complex and resources become more scarce.

Key questions:

- Am I forecasting sufficient patient numbers to meet study goals?
- Are patients being enrolled quickly enough to meet end-points?
- Which sites are underperforming?
- What are the leading indicators that would provoke a decision to shut down a site?
- Do I have the right balance between cost and performance?
- How much will it cost to get enrollment back on target?

Limitations of transactional systems

Custom-designed or commercial Clinical Trials Management Systems (CTMS) often lack the flexibility and forecasting capability to effectively model the entire enrollment picture across the development portfolio. CTMS are designed to be good at recording transactions and storing data so their modeling capabilities lack robust functionality and predictive capabilities.

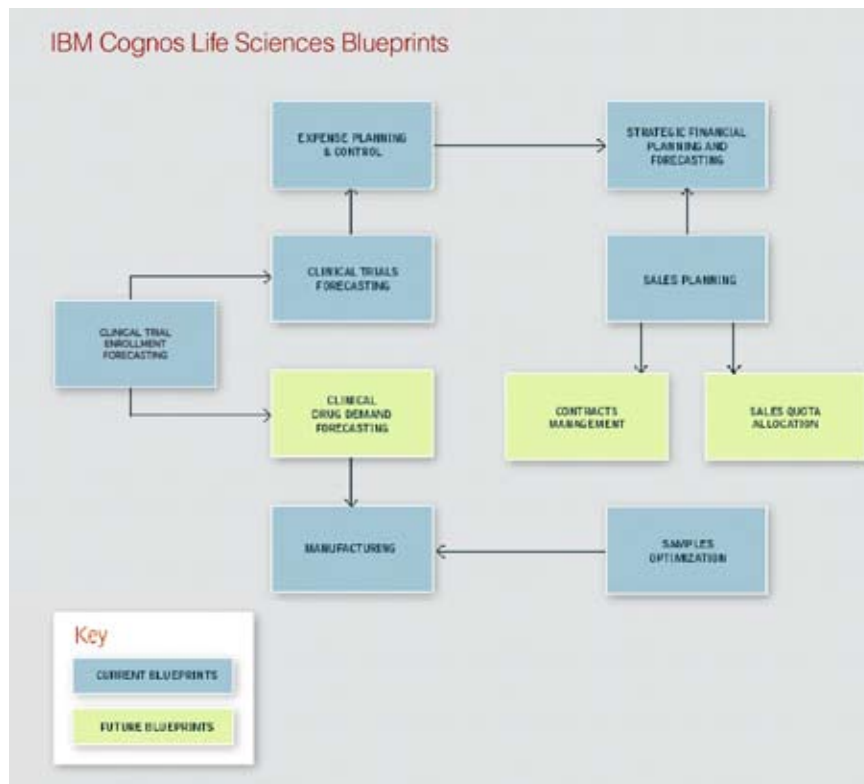
Consequently, spreadsheets are used for modeling and forecasting. While they are great desktop productivity tools, spreadsheets introduce substantial control risks and do not incorporate enterprise-class functionality such as managed workflow and the ability to push template changes out to hundreds of users simultaneously.

The combination of CTMS for collecting actual enrollment and spreadsheets for forecasting or scenario modeling leads to problems of data integrity and information silos. Keeping multiple systems up to date and synchronized is frustrating, time-consuming, and error-prone.

The IBM Cognos Clinical Trial Enrollment Forecasting Blueprint

Utilizing the IBM Cognos 8 suite of performance management products, the *IBM Cognos Clinical Trial Enrollment Forecasting (CTEF) 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. Customers are not wasting time “re-inventing the wheel” and can focus on applying the technology to solve business problems rather than fundamental process analysis and technical design.

The Performance Blueprint map



The second in a series of clinical trial IBM Cognos Performance Blueprints, CTEF complements the *Clinical Trial Forecasting Blueprint*. Designed to work together, the *Blueprints* enable customers to have changes in enrollment projections update financial projections seamlessly. By linking enrollment data to financial data, decision-making is greatly simplified, letting managers understand the cost of changes and the dollar effect of enrollment projections.

What is important to see?

Since clinical managers need critical data readily available, *Clinical Trial Enrollment Forecasting* presents information as a customized array of reports. The screenshot below is a dashboard illustrating a range of charts relevant to a portfolio manager. From this dashboard, the manager can access the full range of relevant reports, analyses, and plans.



All the charts have the capability to drill through to more detailed analyses and include up-to-date information from multiple transactional and planning systems. Dashboards are customized to the different roles and responsibilities found within a clinical development organization and show only the data that the manager has permission to access.

The IBM Cognos 8 Planning environment

The *Clinical Trial Enrollment Forecasting* data model is built using IBM Cognos® 8 Planning – a flexible, scalable modeling environment. The following are some examples of the out-of-the-box functionality included in IBM Cognos 8 Planning and the *Blueprint*.

Workflow and control

The *Clinical Trial Enrollment Forecasting* data model features a workflow that represents the clinical site hierarchy, consolidating – in real time – data from the individual investigator-site level up through regions and countries. The tree-view displayed in the graphic below indicates the status of contributors to the plan.



Note that for the US North East region, two Boston site plans have been started, two of the three New York plans have not been started, and one plan has been finished or submitted. From this workflow screen, a user can click links to see more detail or e-mail contributors as needed.

This hierarchy would be updated automatically from the CTMS or whichever system was the source of record for the site lists.

Forecasting and performance metrics

The *Clinical Trial Enrollment Forecasting* data model calculates and presents for analysis a range of metrics such as:

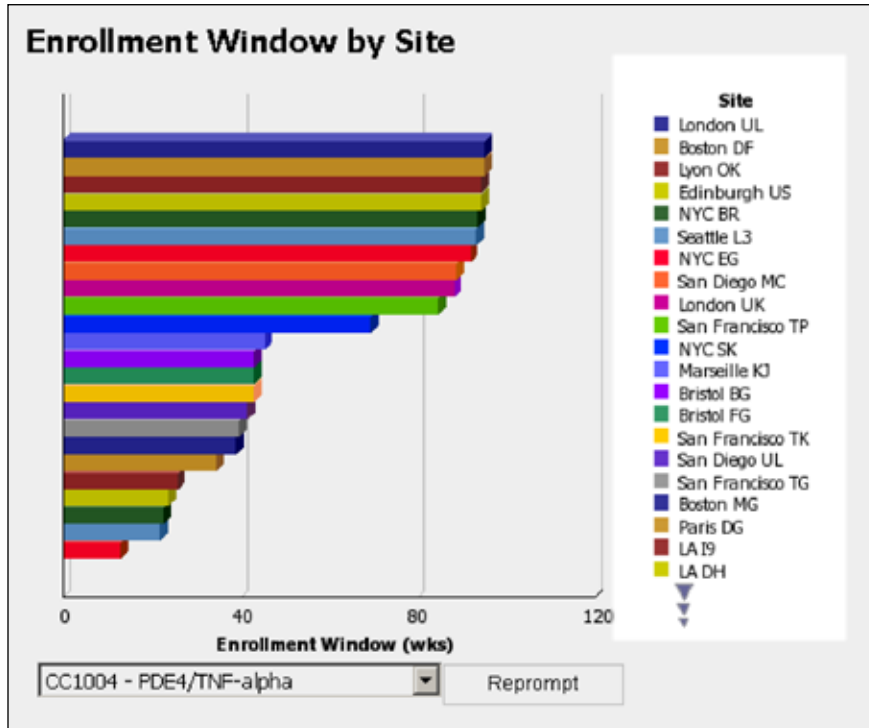
- Enrollment Windows – actual versus planned
- Actual rates against planned enrollment rates
- Site activations
- Screen failure percentages

Since there are so many data points in a clinical trial process, it is vital to highlight only the data that is most important and most relevant. The IBM Cognos 8 suite provides a rich environment for creating exception reports and color coding that focuses managers' attention on the most critical data.

Enrollment Stats						
Candidate	Clinical Trial	FPVY Planned	FPVY Actual	LPLV Date	Patients Forecast	Patients Required
CC1004 - PDE4/TNF-alpha	CC1004 - 114 Study	2/1/06	4/1/06	6/30/06	2,772	2,772
	CC1004 - 115 Study	4/10/06	3/1/06	7/31/06	1,581	1,607
	CC1004 - 283 Study	2/15/06	3/3/06	2/1/07	2,112	2,079
CC1004 - PDE4/TNF-alpha					5,835	6,458
Diamide AML	Dia AML-003 Study	4/1/06	4/1/06	3/15/07	3,610	3,916
	Dia AML-004 Study	10/1/06	1/1/00	5/30/07	1,699	2,304
	Diamide AML-009	4/1/07	1/1/00	8/30/07	0	0
	Diamide AML-010	5/15/06	3/23/06	11/15/06	1,605	1,722
Diamide AML					7,193	7,942
Relasamid NHL	Relasamid Study NHL 102	4/10/06	3/23/06	12/31/06	2,126	2,344
	Relasamid Study NHL 103	7/30/06	7/30/06	4/1/07	1,711	1,764
Relasamid NHL					3,844	4,108
					16,072	10,500

Better decisions

Data is of greatest value when it helps managers make better decisions. The *Clinical Trial Enrollment Forecasting Blueprint* facilitates creation of reports like the one below, which ranks all sites in a study by enrollment windows.



The report enables quick identification of sites with excessively long enrollment windows, as well as easy drill-down into underlying detail.

The Clinical Trial Enrollment Forecasting model

The *Clinical Trial Enrollment Forecasting* model is arranged as a series of tabs similar to a spreadsheet, where changes to one of the assumptions will recalculate all the impacted data instantly—there is no time-consuming processing on the network server. Impacts are visible immediately, facilitating *what-if* and scenario analysis.

	2006 - wk. 25	2006 - wk. 26	2006 - wk. 27	2006 - wk. 28	2006 - wk. 29	2006 - wk. 30	2006 - wk. 31
Target Enrollment	21	21	10	6	7	4	
Actual Enrollment	16	16	0	0	0	0	
Cum Actual Enrollment	392	408	408	408	408	408	
Cum Target Enrollment	532	553	563	569	576	580	
Cum Forecast Enrollment	390	420	429	439	450	458	
Manual Forecast Override	0	0	0	0	0	0	
Screen Failures	6	6	0	0	0	0	
% Screen Failures	27%	27%	0%	0%	0%	0%	
Forecast (Act/Bud)	16	21	10	6	7	4	
Forecast (Override)	16	0	0	0	0	0	
Forecast (Trend)	16	15	9	6	7	4	
Forecast (Goal)	16	85	17	6	7	4	
Forecast (Avg)	16	16	3	3	3	3	
Forecast (M Rate)	16	22	4	4	4	4	
Final Forecast	16	22	9	10	11	8	

The “Weekly Forecast” screen shown above is the heart of the model. The Target or initial plan is either input or data-loaded from another system to create the initial projection or forecast. This plan is updated for actual enrollment as it occurs. The CTEF model then calculates a range of scenarios by combining the two data sets under a given range of assumptions.

The forecasting assumptions cover all possible scenarios and avoid the need for manual off-line number crunching. Standard forecast scenarios include:

- **Actual/Budget.** This scenario assumes original plan for all forecast periods but locks historic weeks at the actual enrollment numbers, combining the two data sets to produce a forecast that is always updated for the actual enrollment.
- **Forecast (Trend).** Calculates the percent difference between the target and the actual enrollment and applies that percentage to all future open enrollment weeks to generate the forecast

- **Forecast (Avg).** Simply the average of the actual enrollment projected forward, the user can pick the number of historic weeks to use in the average calculation
- **Forecast (M Rate).** Use a manually entered enrollment rate and use that for the duration of the planned enrollment window until last patient first visit.

Note that all the scenarios above are generated automatically allowing a regional or site analyst to visualize possible outcomes.

There are several other forecast assumptions in addition to the four explained above. All these functions and other customized versions are available as pre-defined formulae and require no programming or customization. A “best guess” forecast is selected for each site and those are aggregated as a combined forecast for the entire study.

It is important to note that the description above relates to a customer wanting to forecast at quite a low level of detail. The *Blueprint* is designed to enable forecasting at a higher level of detail if required. For example, the data can be entered at the monthly level just as easily.

Need to meet capability

In addition to functionality described above it is also important to be able to answer the question:

“If this study is under-enrolling, what would it cost me to bring the enrollment back on track and give me a couple of scenarios?”

The *Clinical Trial Enrollment Forecasting Blueprint* is ideally suited to this form of flexible modeling. Assuming I have an expectation or a business rule to relate enrollment to cost, I can answer this type of question easily. For example, my assumptions are as follows:

Site setups involve a setup cost. CTEF calculates the average number of patients forecasted to enroll for each active site, estimates the forecasted under-enrollment, and derives the additional number of sites needed and how much that will cost in terms of setup costs.

	Avg Patients per Site	Total Patient Enrollment	Total Enrollment	Budget to meet Target	Cost per Person	Additional Cost to meet Target	Actual Advertisements	Total Incremental
CC104 - US Northeast Analyst	133	133	133	488		0	0	6,7548
CC104 - T15 Study	63	303	303	45		25,800	4	5,7426
CC104 - T20 Study	203	603	772	(28)		0	4	3,0456
CC104 - PDR 4/TNF alpha	133	1,830	2,120	422		95,800	13	16,3448
Hematology	133	1,830	2,120	422		95,800	13	16,3448
US-AML, 021 Study	266	780	1,116	352		0	1	4,1729
US-AML, 024 Study	8	396	1,188	220		0	1	3,0000
US-AML, 043	8	400	500	100		0	1	3,0000
US-AML, 053	72	360	450	48		0	1	3,0000
Disease AML	145	2,516	3,215	639		0	0	9,8200
Personalized Study 044, 022	67	186	62	74		0	1	4,7052
Personalized Study 044, 023	67	204	300	76		0	1	6,2500
Personalized 044	77	632	842	150		0	0	11,0152
Personalized 044	109	3,200	4,057	849		0	17	20,2462
Personalized 044	118	4,300	5,177	1,221		95,800	20	37,1952

Average patients per site determines # of additional sites, converted into a cost

In addition to site setup costs, assume that there are fixed and variable enrollment advertising campaign costs. CTEF calculates the average advertising spend per patient, backs out fixed components, and applies tiers or curves to calculate the extra advertising needed to put enrollment back on track.

	Avg Patients per Site	Total Patient Enrollment	Total Enrollment	Budget to meet Target	Cost per Person	Additional Cost to meet Target	Actual Advertisements
CC104 - T14 Study	143	562	730	156	236.49	27,432	4
CC104 - T15 Study	63	303	340	45	811.89	40,899	5
CC104 - T20 Study	203	603	772	(28)		0	4
CC104 - PDR 4/TNF alpha	133	1,830	1,828	130	1,327.58	67,531	13
Hematology	133	1,830	1,828	130	1,327.58	67,531	13
US-AML, 021 Study	266	780	1,116	352		0	3
US-AML, 024 Study	8	396	1,188	220		0	0
US-AML, 043	8	400	500	100		0	0
US-AML, 053	72	360	450	48		0	0
Disease AML	145	2,516	3,215	639		0	0
Personalized Study 044, 022	67	186	62	74		0	4
Personalized Study 044, 023	67	204	300	76		0	5
Personalized 044	77	632	842	150		0	9
Personalized 044	109	3,200	4,057	849		0	17
Personalized 044	118	4,300	5,895	979	1,520.08	67,531	20

Calculates average patients per site, advertising cost per patient and suggested incremental advertising spend

The *Clinical Trial Enrollment Forecasting* model is very flexible: Business rules are open, extensible, and can be changed or modified by business users without costly developers and complex coding. The fact that business users are building and adapting the models is perfect in this situation where the rules and the underlying assumptions are constantly changing. New assumptions and rules can be quickly tested and pushed out to the end-users and analysts performing the forecasting and scenario modeling.

A final word

The *IBM Cognos Clinical Trial Enrollment Forecasting Blueprint* offers the robust forecasting and enrollment analytics you need to help ensure adequate patient participation, and facilitates collaboration between managers, analysts, and individual investigator sites.

The *Blueprint* maximizes insight into enrollment indicators that can affect the progress of a costly study. It provides the ability to collect and model enrollment trends and make decisions to shut down or set up additional sites, which is vital to managing a development portfolio as study designs become more complex and resources become increasingly scarce.

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

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