

BRIEF



Clinical Modeling and Resource Tracking Performance Blueprint

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Introduction

This application brief demonstrates a Web-based planning and reporting process for forecasting clinical trials recruitment, resource requirements, profitability and cash flows using IBM Cognos® 8 Planning and IBM Cognos 8 Business Intelligence. Key aspects of the operation of the *IBM Cognos Clinical Modeling and Resource Tracking Performance Blueprint* model are explained, followed by a section-by-section explanation of function, purpose and operation.

Managing a portfolio of clinical trials is particularly challenging; the size and complexity of studies continues to grow while budgets are under ever increasing scrutiny. The *Clinical Modeling and Resource Tracking Blueprint* provides a streamlined, best-practice planning, forecasting, analysis and reporting tool for clinical trial forecasting of recruitment, enrollment, resource requirements, and profitability and cash flows. The *Blueprint* can be used to track income, costs and cash flows by clinical trial or geographical area and to manage staff resources by individual clinic

IBM Cognos Performance Blueprints are pre-defined data, process and policy software models developed in partnership with IBM Cognos customers and partners. Utilizing the IBM Cognos 8 suite of performance management products, Blueprints provide out-of-the-box functionality including dashboards, analytical reports and a preconfigured 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 utilizing the Blueprint can focus on applying the technology to solve business problems, rather than on fundamental process analysis and technical design.

Blueprint Objectives

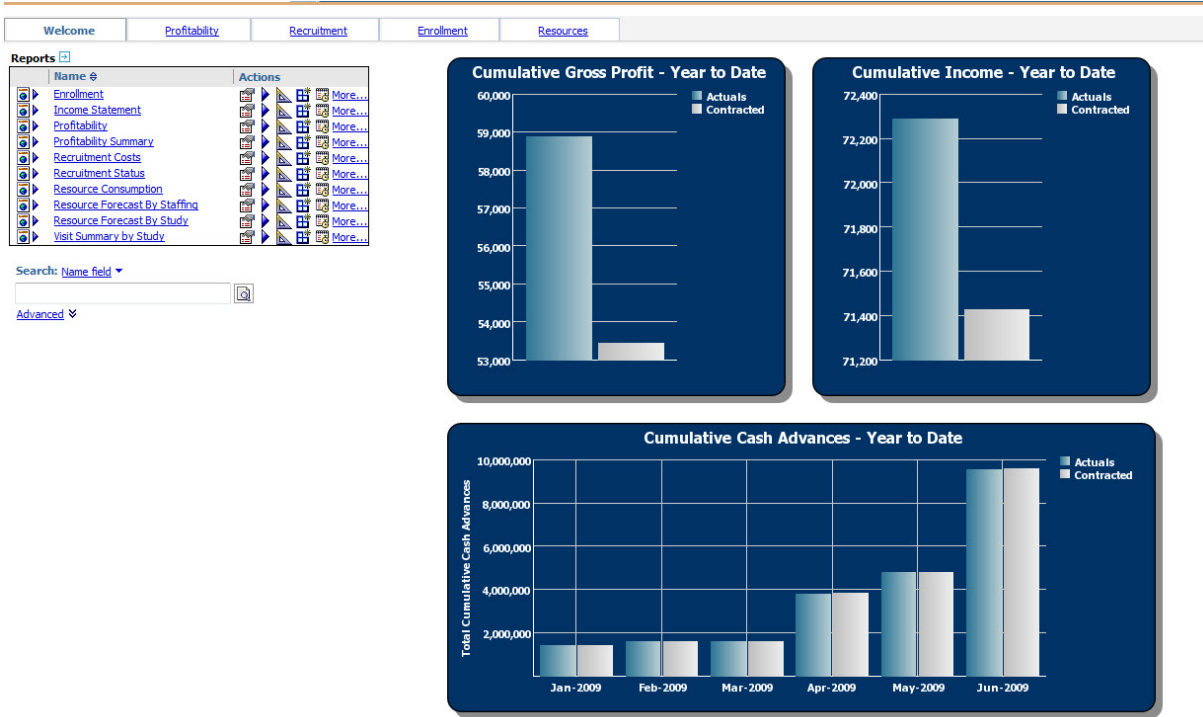
The *Clinical Modeling and Resource Tracking Blueprint*, together with IBM Cognos performance management software, provides a reliable, consistent modeling tool that helps organizations run their clinical trial studies more efficiently. The Blueprint uses drivers and study timelines to efficiently predict study income, costs and resource requirements over the life of a study. The Blueprint includes functionality to:

- Update patient numbers and see immediate impact on study profitability.
- Allocate patients to countries and specific sites within each country.
- Allow for flexibility in updating and evaluating the profitability of using various recruiting methods.
- Enter individual visit start dates to drive accurate profitability and resource requirement projections across the study timeline.
- Enter staff time requirements by visit to calculate very detailed and accurate forecasts of resource requirements by site.
- Evaluate resource requirements at the position and clinic level by month to ensure that the right mix of staff is in place to avoid potential bottlenecks.

This application brief describes the functionality and processes built into the *Clinical Modeling and Resource Tracking Blueprint*. Although the Blueprint was designed to meet the needs of most CROs and sponsor organizations, this model can easily be configured to support alternative and specific requirements to accommodate planning in any organization.

Clinical Modeling and Resource Tracking Dashboard

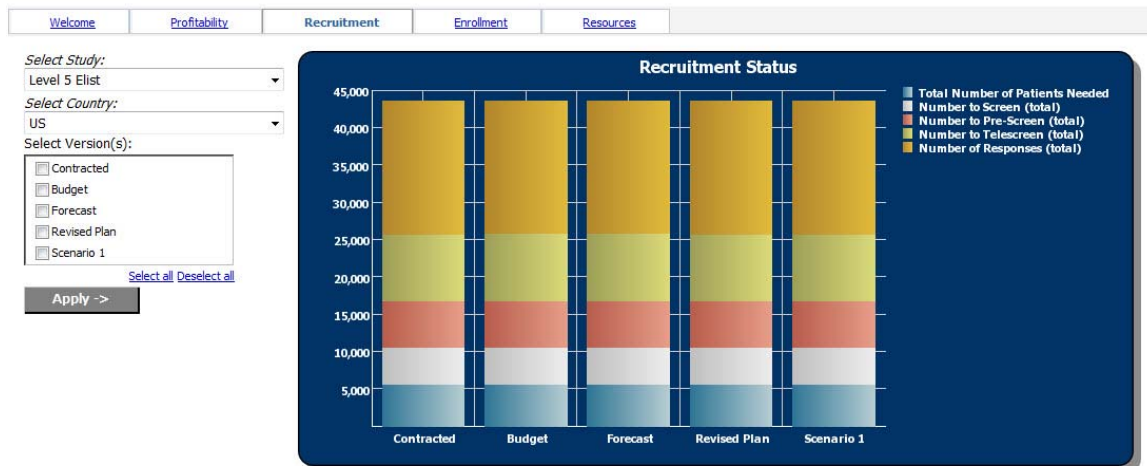
The *Blueprint* includes a comprehensive collection of pre-defined dashboards and analytical charts. The following chart shows an overview of Cumulative Gross Profit, Income and Cash Advances for the year to date. Links to additional reports are available on the left side of the dashboard to enable the user to delve deeper into the forecast detail.



The next chart 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 for Actuals vs. Budget and Forecast. This report can be used to analyze whether actual recruitment is on target with the budget and the latest forecast and enables the organization to drill into the detail and react quickly if necessary to adjust recruitment for the remainder of the year.



Another critical aspect of the *Blueprint* 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. Once updates are made to any of the scenarios, the updated forecasts are immediately available for review using IBM Cognos enterprise-class reporting capabilities.



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

Keep this version | Add 1

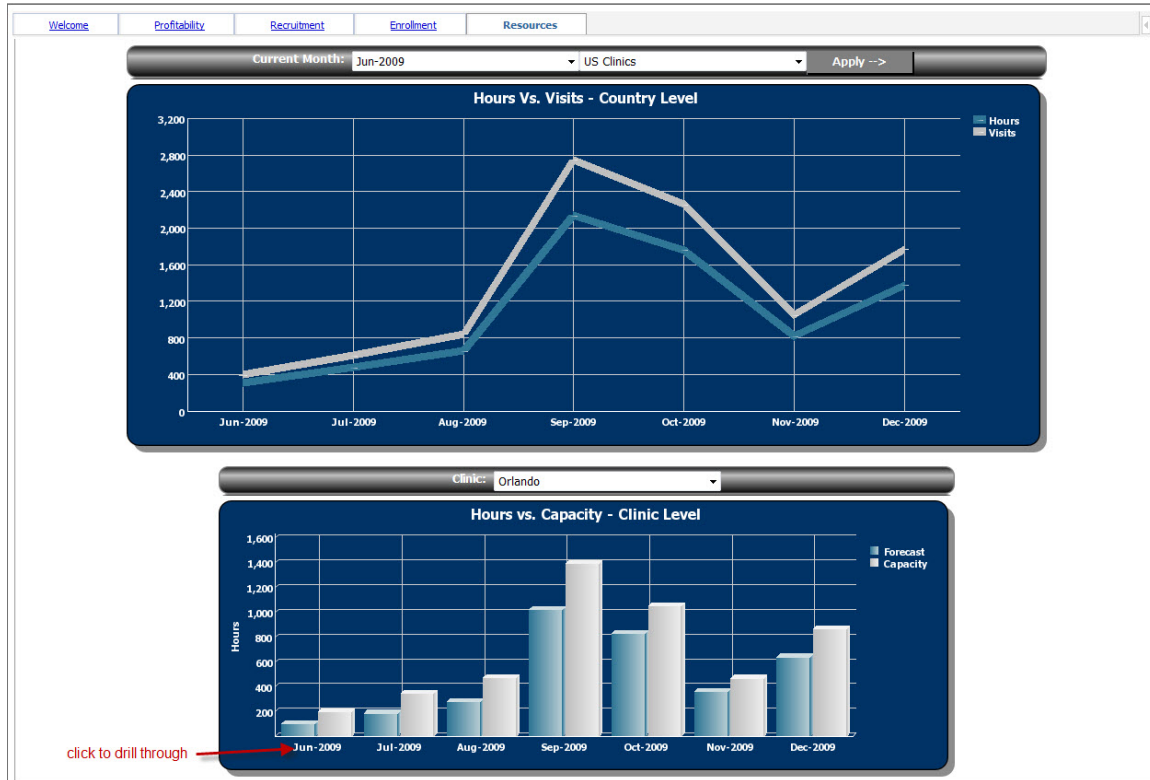
Income Statement						
	Jun-2009	Jul-2009	Aug-2009	Sep-2009	Oct-2009	Nov-2009
INCOME						
Miscellaneous Income			295,254	306,999	404,625	447,684
Prescreen Income	15,316	93,588	175,414	135,287	75,607	24,744
Screen Income	50,376	420,952	1,179,947	1,941,514	1,398,785	761,500
Rand Income				8,232	77,845	162,580
Set Up Fee Income			576,836	431,915	432,157	360,000
Project Management Income				225,157	599,834	831,069
Total Direct Income	65,692	514,540	2,227,451	3,049,105	2,988,853	2,587,576
Prescreen Patient Travel Income				6		
Screen Patient Travel Income				62,416	31,225	
Run in Patient Travel Income				6		
Rand Patient Travel Income				2,760	14,964	31,967
Prescreen Procedure Income				6		
Screen Procedure Income				6		
Run in Procedure Income				6		
Rand Procedure Income				6		
GP SDV's Income				47,186	95,762	80,531
Advertising Income	363,735	3,796,348	9,103,150	15,542,815	9,251,785	3,330,387
Total Pass Through Income	363,735	3,796,348	9,103,150	15,655,215	9,393,736	3,442,885
Total Income	429,428	4,310,888	11,330,601	18,704,320	12,382,589	6,030,461

Resource staffing requirement charts are available by either study or resource type. Any months where the forecast exceeds capacity will be highlighted to alert the user to consider either reallocating or adding resources or adjusting the forecast to alleviate some of the resource demands for that period.

Keep this version | Add this report

Orlando																					
Beginning Forecast Month: Jun-2009																					
Total	Jun-2009		Jul-2009		Aug-2009		Sep-2009		Oct-2009		Nov-2009		Dec-2009		Jan-2010		Feb-2010		Mar-2010		Apr-2010
	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	Forecast	Capacity	
CC10004 - 114 Study - Ph III Double Blind - Rand	0.0	3.2	0.0	5.5	17.2	17.2	83.1	0.0	0.0	0.0	8.2	8.2	40.4	40.4	24.5	0.0	0.0	10.2	48.4	48.4	7
CC10004 - 115 Study - Ph2b	3.2	0.0	0.0	0.0	7.6	0.0	22.1	22.1	0.0	0.0	7.3	13.7	13.7	0.0	13.3	9.3	9.3	0.0	0.0	0.0	
CC10004 - 283 Study - A Phase III, Open-Label, Extension Study Transfusion Dependent PNH	0.0	22.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	44.7	0.0	0.0	0.0	0.0	0.0	0.0	73.1	
Dia AML-003 Study	0.0	0.0	0.0	0.0	0.0	0.0	0.0	22.1	0.0	0.0	7.3	7.3	0.0	13.7	13.3	0.0	9.3	9.3	21.7	0.0	
Dia AML-004 Study	0.0	3.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	16.4	0.0	0.0	0.0	13.7	13.3	0.0	0.0	9.3	0.0	0.0	
Diamide AML-009	0.0	0.0	5.5	0.0	16.4	16.4	0.0	0.0	112.1	112.1	48.9	48.9	77.2	77.2	0.0	76.8	38.0	38.0	85.1	85.1	
Diamide AML-010	3.2	3.2	5.5	0.0	7.6	7.6	22.1	22.1	16.4	0.0	7.3	0.0	13.7	13.7	0.0	0.0	0.0	0.0	0.0	0.0	
Relaxamid Study NHL 102	3.2	3.2	0.0	0.0	7.6	0.0	22.1	22.1	0.0	16.4	0.0	0.0	13.7	0.0	13.3	13.3	9.3	0.0	21.7	0.0	4
Relaxamid Study NHL 103	0.0	0.0	0.0	0.0	14.1	14.1	28.6	28.6	0.0	22.9	13.8	0.0	0.0	0.0	0.0	0.0	15.8	15.8	0.0	0.0	21
Staff Capacities	28.9	28.9	49.8	0.0	0.0	0.0	0.0	211.2	162.3	162.3	0.0	0.0	0.0	130.8	0.0	106.6	0.0	70.8	0.0	0.0	39

Another report enables the user to compare resource hours to the number of visits over time.

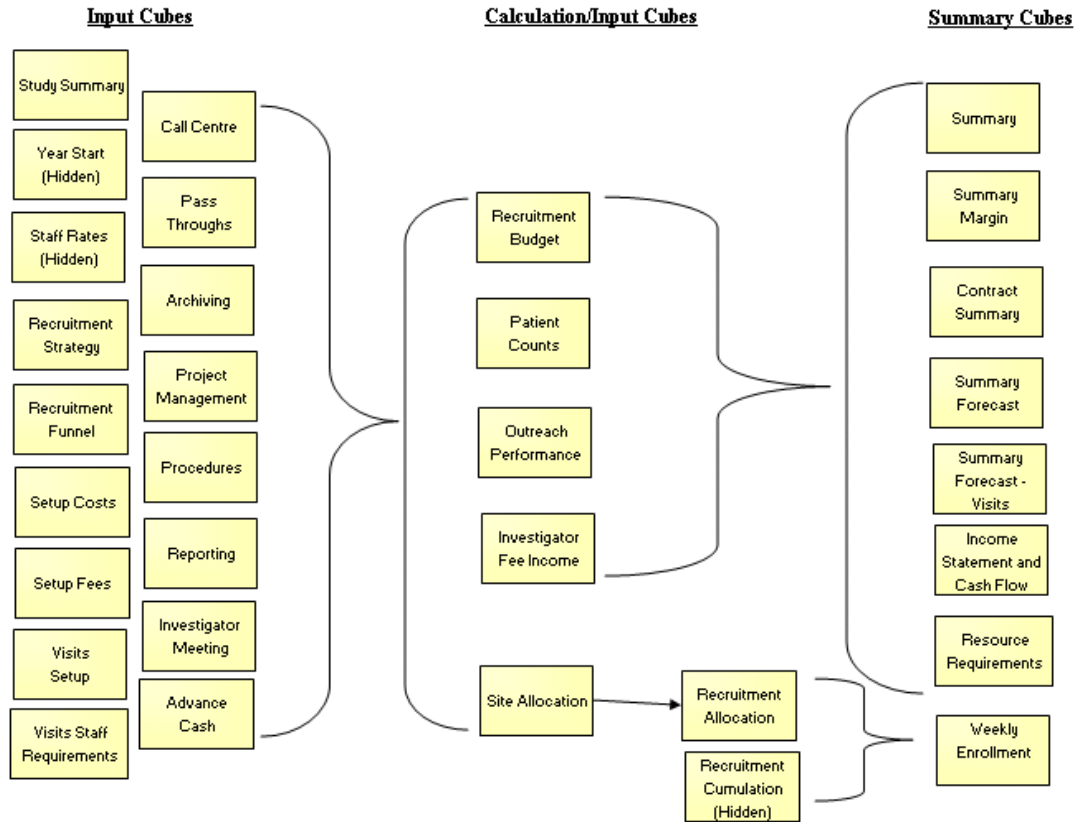


Planning Model Overview

The *Clinical Modeling and Resource Tracking Blueprint* forecasting model consists of 32 d-cubes and 104 d-links. Several assumption and calculation d-cubes are hidden from the users resulting in the Contributor view showing 28 different d-cubes or tabs. Five forecast versions are available throughout the model and they are Contracted, Budget, Forecast, Revised Plan, and Scenario 1. The majority of the forecast is collected by country, with the country data being broken down further by clinic for the recruitment and enrollment calculations and the resource requirement calculations.

The following diagram of the forecast model shows the cubes in the model and the general data flow for the cubes. Due to the volume of links in the model (104 total), the individual links are not depicted in the diagram.

Clinical Trials Modeling and Resource Tracking Blueprint



Workflow

As planners are updating the clinical trial forecasts, managers and executives need real-time visibility to the workflow status of that information.

In this *Blueprint*, individual forecasts are entered for each clinical trial. Clinical Trials then roll up to product groups and a total clinical view. Reviewers can view the consolidated results of the clinical trials and the effect of those trials on overall profitability, cash flows and resource requirements. These reviewers can see the workflow status of each clinical trial that is their responsibility and they can also be co-owners of that information, which enables them to make edits, if required. All workflow status changes, data consolidations and aggregations occur in real-time as the information is saved by the end user, making frequent planning iterations possible.

Before data is entered, the state of the plan is designated as **Not Started**. Once a plan is saved, the state becomes **Work In Progress** and remains accessible for further editing. When an item is submitted, the plan is **Locked** and no more changes can be made. The Locked state indicates that the plan is ready for review. A reviewer can review the plan in any state, but can only reject a Locked plan item. When a Locked plan is rejected, it returns to a state of Work In Progress, making it editable once again for the owner of that plan.

The following example shows the workflow from the perspective of the final reviewer of Total Clinical data. This individual has review views of Total Clinical, Hematology, and Oncology and is able to view detail down to the lowest (clinical trial) level of the hierarchy. This individual is also the owner of Staff Capacities and is responsible for its input.

The screenshot shows the Contributor application interface. The top navigation bar includes the user name 'Haley Roberts', a 'Log off' link, and navigation icons. The left sidebar shows a tree view of 'Contributions' and 'Reviews' under 'Total Clinical', 'Hematology', and 'Oncology'. The main content area displays a review workflow for 'CC10004 - PDE4/TNF-alpha'.

You are a reviewer for:

Name	State	Ownership	Reviewer	Last Data Change
CC10004 - PDE4/TNF-alpha	Incomplete	Email All	Mike Smith	11:24:35 PM - Tuesday, June 23, 2009

Which is made up of:

Name	State	Ownership	Reviewer	Last Data Change
CC10004 - 114 Study - Ph III Double Blind - Rand	Work In Progress	Contributor Submit	Mike Smith	11:24:32 PM - Tuesday, June 23, 2009
CC10004 - 115 Study - Ph2b	Locked	Contributor Submit	Mike Smith	11:19:05 PM - Tuesday, June 23, 2009
CC10004 - 283 Study - A Phase III, Open-Label, Extension Study Transfusion Dependent PNH	Not Started	None	Mike Smith	11:13:30 PM - Tuesday, June 23, 2009

Workflow information for CC10004 - PDE4/TNF-alpha:

Current state: Incomplete.
Some items that make up this e>List item are not started. [More...](#)

Time of last state change: 11:18:22 PM - Sunday, April 19, 2009

User who last changed state: [Contributor Submit](#)

Viewed: no
Reviewed: no
Document Attached: no
Size limit: 1 MBs

Study Summary

The Study Summary tab is used to collect high level data about each forecast version. Required inputs on this tab include Version Number; the Date of the Latest Forecast; and Dates for Start PreScreens, Start Screens, Start Run ins, Start Recruitment and Stop Recruitment. Other inputs include Length of Recruitment, Study Duration, Total Number of Patients Needed and Total Number of Sites Needed.

Several calculations needed to feed later tabs are hidden from the users on this screen using Access Tables in Contributor. The dates collected for this tab are used to drive calculations that allocate income and costs for the appropriate months on the Summary Forecast tab. The Patient and Site numbers are fed into the Recruitment Funnel tab where the user can then allocate patients and sites across countries.

	Contracted	Budget	Forecast	Revised Plan	Scenario 1
Version Number					
Date of Latest Forecast	01-01-2009	01-01-2009	01-01-2009	01-01-2009	01-01-2009
Start Pre Screens	15-07-2009	15-07-2009	15-07-2009	15-07-2009	15-07-2009
Start Screens	31-07-2009	31-07-2009	31-07-2009	31-07-2009	31-07-2009
Start Run ins	15-08-2009	15-08-2009	15-08-2009	15-08-2009	15-08-2009
Start Recruitment	01-09-2009	01-09-2009	01-09-2009	01-09-2009	01-09-2009
Stop Recruitment	16-10-2009	16-10-2009	16-10-2009	16-10-2009	16-10-2009
Length of Recruitment	1.50	1.50	1.50	1.50	1.50
Length of Recruitment (Days)	45	45	45	45	45
Study Duration (Months)	12.00	12.00	12.00	14.00	12.00
Estimated Study End Date	11-10-2010	11-10-2010	11-10-2010	10-12-2010	11-10-2010
Total Study Length (Weeks)	57.86	57.86	57.86	66.43	57.86
Total Number of Patients Needed	100	100	120	100	100
Total Number of Sites Needed	4	4	4	4	4

Year Start (*hidden*)

Year Start is a hidden tab that is used to capture the starting date for each year. This tab is needed in order to appropriately pull the correct year's staff rates into Visits Staff Requirements. The calculations in Visits Staff Requirements compare each visit's Visit Begin Date to the Year Start field to determine which year's staff rates will be used to calculate income and costs for each visit.

Recruitment Strategy

The Recruitment Strategy tab enables the user to input data about the various recruiting costs. Total Projected Cost for each line item is calculated as $(\text{Cost}/\text{Units Covered by Cost}) * \text{Planned Units}$. Any items that are collected or calculated elsewhere in the model are linked in and are displayed in read-only or grayed out cells.

	Cost	Units covered by Cost	Planned Units	Total Projected Cost
Fulfillment (Database Mailshots)	320.00	1,000	1,953	625.00
Paper (Database Mailshots)	110.00	2,000	1,953	107.42
Envelopes (Database Mailshots)	14.35	1,000	1,953	28.03
Postage (Database Mailshots)	0.34	1	1,953	664.06
Total Database Mailshots - Per Site				1,424.51
GP Stafftime (cost and letters per hour)	13.16	50	1,302	342.71
Paper (GP Mailshots)	2.00	500	1,302	5.21
Envelopes (GP Mailshots)	15.00	1,000	1,302	19.53
Postage (GP Mailshots)	0.31	1	1,302	403.65
Total GP Mailshots - Per Site				771.09
Telescreener - Call Center	290.77	30	130	1,262.02
Telescreener - Admin	64.62	50		0.00
Fulfillment Charges	1.00	1	65	65.10
Total Telescreening - Per Site				1,327.12
Responses			521	0.00
Doctor	181.73			0.00
Senior Nurse	100.96			0.00
Nurse	88.85			0.00
Administration	64.62			0.00

Recruitment Funnel

The Recruitment Funnel tab is used to allocate Patients, Sites and Recruitment over different countries. The Recruitment Funnel also enables the creation of a subset (for example, a group of patients starting the trial at a later date) and will calculate recruitment requirements in total and for the subset, if used.

The screenshot shows the 'Recruitment Funnel' tab in the 'Clinical Trials - MART' application. The interface includes a menu bar (File, Edit, View, Workflow Actions, Help), a toolbar with various icons, and a navigation pane with tabs for Study Summary, Recruitment Strategy, Recruitment Funnel (selected), Recruitment Budget, Patient Counts, Setup Costs, Setup Fees, and Visits Setup. The main area displays a table with the following data:

	Total Countries	UK	US	France	Germany
Total Number of Patients Needed	100				
Total Number of Sites Needed	4				
Number of Patients	100	25	50	25	0
Number of Sites	4	1	2	1	0
Number of patients at each site	75	25	25	25	0
Run-in success rate %	80%	80%	80%	80%	80%
Number to Run-in (per site)	94	31	31	31	0
Number to Run-in (total)	125	31	63	31	0
Screening success rate %	80%	80%	80%	80%	0%
Number to Screen (per site)	117	39	39	39	0
Number to Screen (total)	156	39	78	39	0
Pre Screen success rate %	60%	60%	60%	60%	60%
Number to Pre-Screen (per site)	195	65	65	65	0
Number to Pre-Screen (total)	260	65	130	65	0
Telescreen success rate %	50%	50%	50%	50%	0%
Number to Telescreen (per site)	391	130	130	130	0
Number to Telescreen (total)	521	130	260	130	0
Responses success rate %	25%	25%	25%	25%	25%
Number of Responses (per site)	1,563	521	521	521	0
Number of Responses (total)	2,083	521	1,042	521	0
Database Mailshots	30.0%	30.0%	30.0%	30.0%	0.0%
GP Mailshots	25.0%	25.0%	25.0%	25.0%	0.0%

The interface also shows a 'Context' dropdown set to 'CC10004 - 114 Study - Ph III Double Blind - Rand' and a 'Contracted [Version]' dropdown. The current owner is listed as 'rvanier'.

Recruitment Budget

The Recruitment Budget tab summarizes the previously entered Recruiting Costs. It is also where the user can enter Recruiting Income, which is intended to be entered into the Total cell for Income per Site Input, enabling it to appear to break back equally against recruiting methods. In reality, calculations in the cube automatically run to allocate the recruiting income proportionately to match the allocation of the recruiting costs. The results can be seen in the Income per Site field.

	Length of Recruitment	# of Campaigns	Cost per Campaign	Number of Sites	Income per Site Input	Income per Site	Cost per Site	Total Income	Total Cost
Total Recruitment	1.5	3		1	160,000	160,000	10,673	160,000	10,673
Press Advertising	1.5	1	1,000	1	20,000	14,991	1,000	14,991	1,000
Radio Advertising	1.5	2	3,000	1	20,000	89,949	6,000	89,949	6,000
Database Mailshots	1.5			1	20,000	21,356	1,425	21,356	1,425
GP Mailshots	1.5			1	20,000	11,560	771	11,560	771
Telescreening	1.5			1	20,000	19,896	1,327	19,896	1,327
Responses	1.5			1	20,000	0	0	0	0
Other	1.5			1	20,000	0	0	0	0
Call Centre Service Charge	1.5			1	20,000	2,249	150	2,249	150

Staff Rates *(hidden)*

The Staff Rates cube holds Cost and Charge out rates for each type of staff by year. This data is used to calculate cost and income for visits, setup and meetings based how much time each type of staff will spend on activities.

Patient Counts

The Patient Counts cube calculates patient counts by country based on data in the Recruitment Funnel tab.

Study Summary Recruitment Strategy Recruitment Funnel Recruitment Budget Patient Counts Setup Costs S					
Rows:	[Patient Counts]	Columns:	[Country]	Context:	CC10004 - 114 Study - Ph III Double Blind - Rand [Elist]
	Total Countries	UK	US	France	Germany
Total Patients	100	25	50	25	0
Total to Run in	125	31	63	31	0
Total to Screen	156	39	78	39	0
Total to Pre Screen	260	65	130	65	0
Total to Telescreen	521	130	260	130	0
Total Responses	2,083	521	1,042	521	0
Subset Patients	0	0	0	0	0
Subset to Run in	0	0	0	0	0
Subset to Screen	0	0	0	0	0
Subset to Pre Screen	0	0	0	0	0
Subset to Telescreen	0	0	0	0	0
Subset Responses	0	0	0	0	0
Total less Subset Patients	100	25	50	25	0
Total less Subset to Run in	125	31	63	31	0
Total less Subset to Screen	156	39	78	39	0
Total less Subset to Pre Screen	260	65	130	65	0
Total less Subset to Telescreen	521	130	260	130	0
Total less Subset Responses	2,083	521	1,042	521	0

Setup Costs

The number of minutes per site that each type of staff spends on the different setup activities is collected on the Setup Costs tab. The cost per site is calculated based on the minutes input.

Rows: [Setup Costs Calc] [Staff Positions] [Setup Activity] Context: CC10004 - 114 Study - Ph III Double Blind - Rand [Elist] Contracted [Version] UK [Country]

	Total	Ethics	Recruitment Planning	Internal Training	Prestudy Visits	Initiations	Protocol Review	Jobsheet	Telescreen	GP Informati
Number of minutes per site	3,405	90	195	210	90	1,200	725	105	60	
Research Physician	340	0	0	30	0	180	120	0	0	
Site Director	540	30	45	30	90	120	120	15	30	
Senior Nurse	330	0	0	30	0	120	120	60	0	
Research Nurse	440	0	0	30	0	240	120	0	0	
Clinical Trials Technician	150	0	0	30	0	120	0	0	0	
Data Coordinator	420	0	0	30	0	180	120	0	0	
Administrator	270	0	0	30	0	240	0	0	0	
Project Manager	605	60	60	0	0	0	60	30	30	
Projects Director	180	0	15	0	0	0	45	0	0	
Medical Director	40	0	15	0	0	0	20	0	0	
Head of Administration	45	0	45	0	0	0	0	0	0	
Operations Director	45	0	15	0	0	0	0	0	0	
Cost per site	947	29	65	52	37	283	214	28	20	
Research Physician	139	0	0	12	0	74	49	0	0	
Site Director	221	12	18	12	37	49	49	6	12	
Senior Nurse	75	0	0	7	0	27	27	14	0	
Research Nurse	88	0	0	6	0	48	24	0	0	
Clinical Trials Technician	24	0	0	5	0	19	0	0	0	
Data Coordinator	73	0	0	5	0	31	21	0	0	
Administrator	39	0	0	4	0	35	0	0	0	

Current Owner: rvanlier

Setup Fees

Income per Site is input by version and country on the Setup Fees tab and combined with the Cost per Site that was collected and calculated on the previous tab to generate the Setup Margin calculations.

Rows: [Per Site Margin Calc] [Setup Fees] Context: CC10004 - 114 Study - Ph III Double Blind - Rand [Elist] Contracted [Version] UK [Country]

Pre Study Activities Sites	
Number of Sites	1
Income per Site	2,000
Cost per Site	947
Income	2,000
Costs	947
Margin	1,053
Margin %	52.7%

Visits Setup

In the Visits Setup tab, a user can enter information about up to 25 different visits. Inputs include a Visit Description, Day of Visit, Visit Type, Select Number of Patients, % of Patients and Patient # Override. The Day of Visit Selected is used to calculate the start and end date for that particular visit and to allocate income and costs to the corresponding months later in the model. The Visit Type is used to consolidate by visit type on the P&L and Cash Flow tab. The remaining fields enable the selection of the appropriate number of patients attending each visit. A selection can be made from the Select Number of Patients drop down, thus pulling in the patient number corresponding to that selection from the Patient Counts tab. Patient counts can be further customized using the % of Patients field and the Patient # Override field.

The screenshot shows the 'Visits Setup' tab in a software application. The interface includes a menu bar with options like 'Recruitment Funnel', 'Recruitment Budget', 'Patient Counts', 'Setup Costs', 'Setup Fees', 'Visits Setup', and 'Visits Staff Requirements'. Below the menu, there are filters for 'Rows' (set to '[Generic Numbers 1-25]'), 'Columns' (set to '[Visits Input and Patient Calc]'), and 'Context' (set to 'CC10004 - 114 Study - Ph III Double Blind - Rand [Elist]'). There are also dropdowns for 'Contracted [Version]' and 'UK [Country]'. The main data table has the following columns: Visit Description, Day of Visit (from Recruitment Start Date), Visit Type, Start Recruitment, Visit Begin Date, Visit Duration (Days), Select Number of Patients, Selected # of Patients, and % of. The table contains 21 rows of visit data, with a total of 4,071 patients and 1,125 selected patients across all visits.

	Visit Description	Day of Visit (from Recruitment Start Date)	Visit Type	Start Recruitment	Visit Begin Date	Visit Duration (Days)	Select Number of Patients	Selected # of Patients	% of
Total		4,071					1,125	354	
1	VisitPreScreen	(14)	Pre Screen	01-09-2009	18-08-2009	45	Total to Pre Screen	65	
2	Visit1	0	Screen	01-09-2009	01-09-2009	45	Total to Screen	39	
3	Visit2	90	Randomization	01-09-2009	30-11-2009	45	Total Patients	25	
4	Visit3	180	Randomization	01-09-2009	28-02-2010	45	Total Patients	25	
5	Visit4	225	Randomization	01-09-2009	14-04-2010	45	Total Patients	25	
6	Visit5	270	Randomization	01-09-2009	29-05-2010	45	Total Patients	25	
7	Visit6	365	Randomization	01-09-2009	01-09-2010	45	Total Patients	25	
8	Visit7	455	Randomization	01-09-2009	30-11-2010	45	Total Patients	25	
9	Visit8	545	Randomization	01-09-2009	28-02-2011	45	Total Patients	25	
10	Visit9	590	Randomization	01-09-2009	14-04-2011	45	Total Patients	25	
11	Visit10	635	Randomization	01-09-2009	29-05-2011	45	Total Patients	25	
12	Visit11	730	Randomization	01-09-2009	01-09-2011	45	Total Patients	25	
13		0		01-09-2009	01-09-2009	45		0	
14		0		01-09-2009	01-09-2009	45		0	
15		0		01-09-2009	01-09-2009	45		0	
16		0		01-09-2009	01-09-2009	45		0	
17		0		01-09-2009	01-09-2009	45		0	
18		0		01-09-2009	01-09-2009	45		0	
19		0		01-09-2009	01-09-2009	45		0	
20		0		01-09-2009	01-09-2009	45		0	
21		0		01-09-2009	01-09-2009	45		0	

Visits Staff Requirements

The Visits Staff Requirements tab is used to enter the number of minutes each staff type is expected to spend on each visit. In the view below, the visits are set up as the columns with the Visit Description and the Day of Visit showing up as the first two rows on the tab. When the user enters the number of minutes required from each staff type for each visit, the Staff Costs and Staff Income calculate below for each visit.

Recruitment Budget		Patient Counts		Setup Costs		Setup Fees		Visits Setup		Visits Staff Requirements		Investigator Fee Income		
Rows: [Visits Staff Reqs Calc]		[Staff Positions]		Columns: [Generic Numbers 1-25]		Context: CC10004 - 114 Study - Ph III Double Blind - Rand [Elist]		Contracted [Version]		UK [Country]				
		Total	1	2	3	4	5	6	7	8	9	10	11	1
Visit Description	Research Physician		VisitPreScreen	Visit1	Visit2	Visit3	Visit4	Visit5	Visit6	Visit7	Visit8	Visit9	Visit10	Visit
Day of Visit (from Recruitment Start Date)	Research Physician	4,071	(14)	0	90	180	225	270	365	455	545	590	635	
Time (Mins.)	Total	1,075	60	155	40	125	125	125	40	135	45	70	85	
	Research Physician	160	30	30	0	20	20	20	0	30	0	0	10	
	Research Nurse	305	0	60	10	40	40	40	10	40	15	20	10	
	Data Coordinator	400	20	40	20	40	40	40	20	40	20	40	40	
	Administrator	210	10	25	10	25	25	25	10	25	10	10	25	
Staff Costs	Total	226	17	35	7	27	27	27	7	31	8	12	17	
	Research Physician	65	12	12	0	8	8	8	0	12	0	0	4	
	Research Nurse	61	0	12	2	8	8	8	2	8	3	4	2	
	Data Coordinator	69	3	7	3	7	7	7	3	7	3	7	7	
	Administrator	31	1	4	1	4	4	4	1	4	1	1	4	
Staff Income	Total	353	24	53	12	42	42	42	12	47	13	21	27	
	Research Physician	84	16	16	0	11	11	11	0	16	0	0	5	
	Research Nurse	97	0	19	3	13	13	13	3	13	5	6	3	
	Data Coordinator	116	6	12	6	12	12	12	6	12	6	12	12	
	Administrator	55	3	7	3	7	7	7	3	7	3	3	7	

Investigator Fee Income

The Investigator Fee Income tab combines the number of visits (entered on the Visits Setup tab) with the income and cost per visit data (calculated on the Visits Staff Requirements tab) to calculate income and cost per visit. The user can override or adjust the Income per Visit, if desired.

Visit Description	Number of Visits	Income per Visit	Adjustment	Adjusted Income per Visit	Cost per Visit	Total Income	Total Costs	Total Margin	Margin %
Total	329	353.33	0.00	353.33	226.21	9,945	6,403	3,542	443.9%
1 VisitPreScreen	40	24.29	0.00	24.29	17.19	971	688	284	29.2%
2 Visit1	39	53.17	0.00	53.17	34.84	2,077	1,361	716	34.5%
3 Visit2	25	11.64	0.00	11.64	6.91	291	173	118	40.6%
4 Visit3	25	41.52	0.00	41.52	26.74	1,038	669	370	35.6%
5 Visit4	25	41.52	0.00	41.52	26.74	1,038	669	370	35.6%
6 Visit5	25	41.52	0.00	41.52	26.74	1,038	669	370	35.6%
7 Visit6	25	11.64	0.00	11.64	6.91	291	173	118	40.6%
8 Visit7	25	46.80	0.00	46.80	30.83	1,170	771	399	34.1%
9 Visit8	25	13.23	0.00	13.23	7.91	331	198	133	40.2%
10 Visit9	25	20.65	0.00	20.65	12.37	516	309	207	40.1%
11 Visit10	25	26.70	0.00	26.70	16.65	667	416	251	37.7%
12 Visit11	25	20.65	0.00	20.65	12.37	516	309	207	40.1%

Call Centre

The Call Centre tab calculates call center income and cost by seven different call center activities. The user can enter either a number of calls or number of centers and the associated costs and income per each call or center.

	Number of Calls/Centres	Income per Call/Centre	Cost per Call/Centre	Total Income	Total Cost
Total Call Centre				3,625.00	2,918.75
Protocol Calls	50	1.00	0.75	50.00	37.50
Attempted Protocol Calls	25	1.00	0.75	25.00	18.75
Telescreen	500	1.00	0.75	500.00	375.00
Appointment Confirmation	500	1.00	0.75	500.00	375.00
DNA Calls	50	1.00	0.75	50.00	37.50
Retention Calls	100	1.00	0.75	100.00	75.00
Call Centre Set-up	1	2,400.00	2,000.00	2,400.00	2,000.00

Pass Throughs

In the Pass Throughs tab, the user can enter pass throughs for Patient Expenses, Patient Payments or GP SDVs for any visits. A percentage of total patients attending a visit can be selected or 100% can be input to apply the pass through to all patients. Income per Visit and Cost per Visit are inputs for each visit.

Visit Description	Number of Patients this Visit	% of Patients	Number of Patients	Income per Visit	Costs per Visit	Total Income	Total Costs	Margin	Margin %
Total	329	200%	64	150	140	5,156	4,906	250	20%
1 VisitPreScreen	40	0%	0	0	0	0	0	0	0%
2 Visit1	39	100%	39	100	100	3,906	3,906	0	0%
3 Visit2	25	0%	0	0	0	0	0	0	0%
4 Visit3	25	0%	0	0	0	0	0	0	0%
5 Visit4	25	0%	0	0	0	0	0	0	0%
6 Visit5	25	0%	0	0	0	0	0	0	0%
7 Visit6	25	100%	25	50	40	1,250	1,000	250	20%
8 Visit7	25	0%	0	0	0	0	0	0	0%
9 Visit8	25	0%	0	0	0	0	0	0	0%
10 Visit9	25	0%	0	0	0	0	0	0	0%
11 Visit10	25	0%	0	0	0	0	0	0	0%
12 Visit11	25	0%	0	0	0	0	0	0	0%

Archiving

The Archiving tab enables a user to calculate Archiving Income and Cost either by patient or by site. If ECRF is set to **Yes**, the calculation is by site, if ECRF is set to **No**, the calculations are by patient. The user enters an Income by patient or site and Costs per patient or site are automatically set to equal the Income by patient or Site.

Total Countries	UK	US	France	Germany	
# of patients at each site	75	25	25	25	0
# of sites	4	1	2	1	0
ECRF					
Income per patient/site	400	100	100	100	100
Costs per patient/site	400	100	100	100	100
Total Income	10,000	2,500	5,000	2,500	0
Total Costs	10,000	2,500	5,000	2,500	0
Margin	0	0	0	0	0
Margin %	0%	0%	0%	0%	0%

Project Management

The Project Management tab is where Project Management costs and income are calculated. There is a flag to set Project Management to chargeable. Until this field is set to **Yes**, the project management income and costs do not roll forward into any of the Summary tabs or the P&L. Inputs required are the Months (enter the number of months the project manager is needed on the study) and FTE Days/Week (the number of days/week utilization during the time the Project Manager is being utilized for the Study). Staff salaries and charge out rates link in from the hidden Staff Rates cube for the year recruitment started for the study.

	Set-up phase	Recruitment	Study Duration	Close out	
Chargeable	Yes	Yes	Yes	Yes	
Months	16.5	2.0	1.5	12.0	1.0
Weeks	66.0	8.0	6.0	48.0	4.0
FTE days/Week	9.0	3.0	2.0	2.0	2.0
Total Days	140	24	12	96	8
Income per Day		174	174	174	174
Costs per Day		121	121	121	121
Total Income	24,311	4,168	2,084	16,670	1,389
Total Costs	16,962	2,908	1,454	11,631	969
Margin	7,349	1,260	630	5,040	420
Margin %	121%	30%	30%	30%	30%

Procedures

Up to 10 different procedures can be entered against each study on the Procedures tab. Each procedure is entered against the visit (columns in the example below) that the procedure relates to. Required inputs include Procedure Description (which allows selection from a drop down list of procedure types), Number of Procedures, Cost per Procedure and Charge Out per Procedure.

	Total	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Visit Description	VisitPreScreen	Visit1	Visit2	Visit3	Visit4	Visit5	Visit6	Visit7	Visit8	Visit9	Visit10	Visit11			
Day of Visit		(14)	0	90	180	225	270	365	455	545	590	635	730	0	0
Number of Patients	329	40	39	25	25	25	25	25	25	25	25	25	25	0	0
Procedure Description						CT									
Number of Procedures	25	0	0	0	0	0	25	0	0	0	0	0	0	0	0
Cost per Procedure	250	0	0	0	0	0	250	0	0	0	0	0	0	0	0
Procedure Cost	6,250	0	0	0	0	0	6,250	0	0	0	0	0	0	0	0
Charge Out per Procedure	350	0	0	0	0	0	350	0	0	0	0	0	0	0	0
Procedure Income	8,750	0	0	0	0	0	8,750	0	0	0	0	0	0	0	0
Margin	2,500	0	0	0	0	0	2,500	0	0	0	0	0	0	0	0
Margin %	29%	0%	0%	0%	0%	0%	29%	0%	0%	0%	0%	0%	0%	0%	0%
3 Procedure Description	Psychiatrist Close out														

Reporting

On the Reporting tab, required Inputs for all items, except CI reporting, include Description, Number of, Income per and Cost per. The required inputs for CI include Description, One-off Fee Income and One-off Fee Costs.

	SAE's	Pregnancy	CI	Endpoints	Ad Hoc	Ad Hoc 2	Ad Hoc 3
Total Reporting							
Description							
Number of	30	0	0	5	25	0	0
Income per	300	0	0	200	100	0	0
Costs per	250	0	0	200	50	0	0
One-off Fee Income	4,200	0	4,200	0	0	0	0
One-off Fee Costs	0	0	0	0	0	0	0
Total Income	7,700	0	4,200	1,000	2,500	0	0
Total Costs	2,250	0	0	1,000	1,250	0	0
Margin	5,450	0	4,200	0	1,250	0	0
Margin %	150%	0%	100%	0%	50%	0%	0%

Investigator Meeting

The Investigator Meeting tab enables the entry of how many of each staff type must attend the investigator meeting and how many days they must attend. Cost per day and Charge out rate per day feed in from the Staff Rates cube.

	Number of Employees	Total Days	Income per Day	Total Income	Cost per Day	Total Cost	Margin	Margin %
Total	2	4	2,824.50	541.17	3,204.05	331.15	210.02	78%
Research Physician			234.23	0.00	181.73	0.00	0.00	0%
Site Director			234.23	0.00	181.73	0.00	0.00	0%
Senior Nurse			153.46	0.00	100.96	0.00	0.00	0%
Research Nurse	1	2	141.35	282.70	88.85	177.69	105.01	37%
Radiographer			153.46	0.00	100.96	0.00	0.00	0%
Clinical Trials Technician			122.77	0.00	70.27	0.00	0.00	0%
Data Coordinator	1	2	129.23	258.47	76.73	153.46	105.01	41%
Administrator			117.12	0.00	64.62	0.00	0.00	0%
Project Manager			173.65	0.00	121.15	0.00	0.00	0%
Projects Director			234.23	0.00	181.73	0.00	0.00	0%
Medical Director			254.43	0.00	201.92	0.00	0.00	0%
Marketing Assistant			125.19	0.00	72.69	0.00	0.00	0%
Head of Administration			153.46	0.00	100.96	0.00	0.00	0%

Advance Cash

The Advance Cash tab is used to capture data on expected cash receipts. Required inputs include Advance Cash Type (which is a drop-down list showing available cash advance categories), Month and Amount. The Advance Cash detail then feeds forward to the P&L and Cash Flow tab.

Advance Cash Type	Month	Amount
1 Setup	Jun-2009	40,000
2 Recruitment	Sep-2009	100,000
3 Investigator Fees	Dec-2009	200,000
4		0
5		0
6		0
7		0
8		0
9		0
10		0

Contract Summary

The Contract Summary tab consolidates all previously collected data to show an overall total contract value. Additional Costs, Other Costs and Other Upfront Payments can be manually entered as needed.

Visit/Cost/Payment Description	Day	Estimated. #	Fee	Total
Number of Countries		1		0
Number of Centres		1		0
Number of Chats		65		0
Number of Screens		39		0
Number of Rands (total)		31		0
1 VisitPreScreen	(14)	40	24.29	971
2 Visit1	0	39	53.17	2,077
3 Visit2	90	25	11.64	291
4 Visit3	180	25	41.52	1,038
5 Visit4	225	25	41.52	1,038
6 Visit5	270	25	41.52	1,038
7 Visit6	365	25	11.64	291
8 Visit7	455	25	46.80	1,170
9 Visit8	545	25	13.23	331
10 Visit9	590	25	20.65	516
11 Visit10	635	25	26.70	667
12 Visit11	730	25	20.65	516
Total Estimated Investigator Fee		329	353.33	9,945
Patient Expenses		64	80.49	5,156
Recruitment Budget		1	160,000.00	160,000
Call Centre - Protocol Calls		50	1.00	50
Call Centre - Attempted Protocol Calls		25	1.00	25

Visit/Cost/Payment Description	Day	Estimated. #	Fee	Total
11 Visit10	635	25	26.70	667
12 Visit11	730	25	20.65	516
Total Estimated Investigator Fee		329	353.33	9,945
Patient Expenses		64	80.49	5,156
Recruitment Budget		1	160,000.00	160,000
Call Centre - Protocol Calls		50	1.00	50
Call Centre - Attempted Protocol Calls		25	1.00	25
Call Centre - Call Centre Setup		1	2,400.00	2,400
Call Centre - Telescreen		500	1.00	500
Call Centre - Appointment		500	1.00	500
Call Centre - DNA Calls		50	1.00	50
Call Centre - Retention Calls		100	1.00	100
Procedures		25	350.00	8,750
Study Archive Costs		25	100.00	2,500
Startup Payments (Non-refundable)		1	2,000.00	2,000
Project Management Fees		140	0.00	0
Reporting - CI		1	4,200.00	4,200
Reporting - Endpoints		5	200.00	1,000
Reporting - Ad Hoc		25	100.00	2,500
Investigator Meeting		4	135.29	541
Overall Estimated Contract Value		1,846	!#####	200,218
Start-up Payment		1	2,000.00	2,000
Total Up Front Payments		1	2,000.00	2,000

Summary Forecast

The Summary Forecast consolidates and breaks out the entered data by month based on these assumptions for spreading the different costs:

- Set-up Fees - month prior to FPFV
- Visits - from visit start to visit end dates
- Recruitment Budget - from Start Recruitment for length of recruitment
- Call Centre - month prior to FPFV
- Archive - month after LPLV
- Project Management - from Stop Recruitment date for length of Study Duration
- Reporting - from Stop Recruitment date for length of Study Duration
- Investigator Meeting - month prior to FPFV
- Procedures - from corresponding visit start to visit end dates
- Patient Payments - from Stop Recruitment date for length of Study Duration
- Patient Expenses - from Stop Recruitment date for length of Study Duration
- GP SDVs - from Start Screens date to Start Run Ins date
- Other Costs - from Stop Recruitment date for length of Study Duration

Procedures Reporting Investigator Meeting Advance Cash Contract Summary **Summary Forecast** Summary Forecast - Visits

Rows: [Summary Forecast] Columns: [Summary Forecast Calc] Context: CC10004 - 114 Study - Ph III Double Blind - Rand [Elist] Contracted [Version] UK [Country]

	Description	Visit Type	Begin Date	Duration	End Date	Total Amount	This Period Amount
	Set-up Fees Income		16-09-2009	1	17-09-2009	2,000	
	Set-up Fees Costs		16-09-2009	1	17-09-2009	947	
1	VisitPreScreen	Pre Screen	18-08-2009	45	02-10-2009	971	
2	Visit1	Screen	01-09-2009	45	16-10-2009	2,077	
3	Visit2	Randomization	30-11-2009	45	14-01-2010	291	
4	Visit3	Randomization	28-02-2010	45	14-04-2010	1,038	
5	Visit4	Randomization	14-04-2010	45	29-05-2010	1,038	
6	Visit5	Randomization	29-05-2010	45	13-07-2010	1,038	
7	Visit6	Randomization	01-09-2010	45	16-10-2010	291	
8	Visit7	Randomization	30-11-2010	45	14-01-2011	1,170	
9	Visit8	Randomization	28-02-2011	45	14-04-2011	331	
10	Visit9	Randomization	14-04-2011	45	29-05-2011	516	
11	Visit10	Randomization	29-05-2011	45	13-07-2011	667	
12	Visit11	Randomization	01-09-2011	45	16-10-2011	516	
13			01-09-2009	45	16-10-2009		
14			01-09-2009	45	16-10-2009		
15			01-09-2009	45	16-10-2009		
16			01-09-2009	45	16-10-2009		
17			01-09-2009	45	16-10-2009		
18			01-09-2009	45	16-10-2009		
19			01-09-2009	45	16-10-2009		
20			01-09-2009	45	16-10-2009		

Current Owner: rvanlier

Procedures Reporting Investigator Meeting Advance Cash Contract Summary **Summary Forecast** Summary Forecast - Visits

Rows: [Summary Forecast] Columns: [Summary Forecast Calc] Context: CC10004 - 114 Study - Ph III Double Blind - Rand [Elist] Contracted [Version] UK [Country]

	Description	Visit Type	Begin Date	Duration	End Date	Total Amount	This Period Amount
1	VisitPreScreen	Pre Screen	18-08-2009	45	02-10-2009	688	
2	Visit1	Screen	01-09-2009	45	16-10-2009	1,361	
3	Visit2	Randomization	30-11-2009	45	14-01-2010	173	
4	Visit3	Randomization	28-02-2010	45	14-04-2010	669	
5	Visit4	Randomization	14-04-2010	45	29-05-2010	669	
6	Visit5	Randomization	29-05-2010	45	13-07-2010	669	
7	Visit6	Randomization	01-09-2010	45	16-10-2010	173	
8	Visit7	Randomization	30-11-2010	45	14-01-2011	771	
9	Visit8	Randomization	28-02-2011	45	14-04-2011	198	
10	Visit9	Randomization	14-04-2011	45	29-05-2011	309	
11	Visit10	Randomization	29-05-2011	45	13-07-2011	416	
12	Visit11	Randomization	01-09-2011	45	16-10-2011	309	
13			01-09-2009	45	16-10-2009		
14			01-09-2009	45	16-10-2009		
15			01-09-2009	45	16-10-2009		
16			01-09-2009	45	16-10-2009		
17			01-09-2009	45	16-10-2009		
18			01-09-2009	45	16-10-2009		
19			01-09-2009	45	16-10-2009		
20			01-09-2009	45	16-10-2009		
21			01-09-2009	45	16-10-2009		
22			01-09-2009	45	16-10-2009		
23			01-09-2009	45	16-10-2009		

Summary Forecast – Visits

This tab allocates the total number of visits over the months based on the same proportion as the visits income to the months on the Summary Forecast tab.

Description	Visit Type	This Period Amount
1 VisitPreScreen	Pre Screen	0
2 Visit1	Screen	0
3 Visit2	Randomization	0
4 Visit3	Randomization	0
5 Visit4	Randomization	0
6 Visit5	Randomization	0
7 Visit6	Randomization	0
8 Visit7	Randomization	0
9 Visit8	Randomization	0
10 Visit9	Randomization	0
11 Visit10	Randomization	0
12 Visit11	Randomization	0

Resource Requirements

The Resource Requirements tab calculates the number of hours each type of staff is required to handle the forecasted visits. This tab is monthly and by clinic. The country data is allocated to clinics based on the percent allocation to each clinic that is entered in the Site Allocation tab.

	Jan-2009	Feb-2009	Mar-2009	Apr-2009	May-2009	Jun-2009	Jul-2009	Aug-2009	Sep-2009	Oct-2009	Nov-2009	Dec-2009	Total 2009	Jan-2010	Feb-2010	Mar-2010
Total								19	80	21	1	26	147	11	1	26
Research Physician								3	13	3		4	24	2		4
Site Director																
Senior Nurse																
Research Nurse								5	23	6		7	42	3		7
Radiographer																
Clinical Trials Technician																
Data Coordinator								7	29	8		9	53	4		9
Administrator								4	15	4		5	28	2		5
Project Manager																
Projects Director																
Medical Director																
Marketing Assistant																
Head of Administration																
Operations Director																
Call Centre Charges																
Call Centre 2																
Locum Dr																
Locum RN																
Locum DC																
Locum Admin																

Site Allocation

The Site Allocation tab is used to allocate the forecast that was created by country to the appropriate clinics that will be participating in the study. This is accomplished by entering either the number of expected rands by clinic or by entering the percentage of the total country's rands for each clinic. Two checks are built into this tab to ensure that the correct number of sites and the correct number of rands have been allocated to the sites. The first check makes sure that the Sites Allocated Field for each country total equals the Total Sites to Allocate field for that country. The second check makes sure that the number of rands for each country total equals the Total Rands to Allocate for that country.

	Total Sites to Allocate	Sites Allocated	Total Rands to Allocate	# of Rands	% of Country Allocation
Total Clinics		4		100	300%
Total UK Clinics	1	1	25	25	100%
Lancashire		1		25	100%
Manchester					
Midlands					
Total US Clinics	2	2	50	50	100%
Chicago		1		25	50%
Orlando		1		25	50%
Total France Clinics	1	1	25	25	100%
Paris		1		25	100%
Lyon					
Total Germany Clinics					
Berlin					
Frankfurt					

Recruitment Allocation

The Recruitment Allocation tab is used to allocate recruitment over the recruitment period. If the week falls in the recruitment period, the Ongoing field will be set to **Yes** and a number of rands can be entered in that week. By scrolling all the way to the right, a Total to Allocate column is available and can be compared to the Total Years column to ensure that the forecast number of rands was appropriately allocated to each clinic. If the number of rands entered does not match the Total to Allocate, the model will use the proportion allocated to each week and will allocate the correct number of rands by calculating each week's proportion to total entered.

Recruitment Allocation													
Rows:	Columns:												
[Clinic for Recr Allo]	[Week]												
	1/2/2009	1/9/2009	1/16/2009	1/23/2009	1/30/2009	2/6/2009	2/13/2009	2/20/2009	2/27/2009	3/6/2009	3/13/2009	3/20/2009	3/27/2009
Start Visits	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09	01-Sep-09
Duration	45	45	45	45	45	45	45	45	45	45	45	45	45
Stop Visits	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09	16-Oct-09
Ongoing?	No	No	No	No	No	No	No	No	No	No	No	No	No
Lancashire	0	0	0	0	0	0	0	0	0	0	0	0	0
Manchester	0	0	0	0	0	0	0	0	0	0	0	0	0
Midlands	0	0	0	0	0	0	0	0	0	0	0	0	0
Total UK Clinics	0	0	0	0	0	0	0	0	0	0	0	0	0
Chicago	0	0	0	0	0	0	0	0	0	0	0	0	0
Orlando	0	0	0	0	0	0	0	0	0	0	0	0	0
Total US Clinics	0	0	0	0	0	0	0	0	0	0	0	0	0
Paris	0	0	0	0	0	0	0	0	0	0	0	0	0
Lyon	0	0	0	0	0	0	0	0	0	0	0	0	0
Total France Clinics	0	0	0	0	0	0	0	0	0	0	0	0	0
Berlin	0	0	0	0	0	0	0	0	0	0	0	0	0
Frankfurt	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Germany Clinics	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Clinics	0	0	0	0	0	0	0	0	0	0	0	0	0

Recruitment Cumulation (*hidden*)

The Recruitment Cumulation tab is used to allocate the correct proportion of study participants to the correct clinics and periods. In the Recruitment Allocation tab, we spread rands across the weeks. Because Pre Screens, Screens and Run Ins must also be allocated, the Recruitment Cumulation is necessary as an interim step to pull out the rands by ongoing week number. Then, another link feeds the proportions by week back into the Recruitment Allocation tab for Pre Screens, Screens and Run Ins.

Weekly Enrollment

The Weekly Enrollment tab shows a view of new Pre Screens, Screens, Run Ins and Rands by week and can be used to adjust the enrollment by entering an Adjustment or by keying over the Final (adjust if necessary) field.

Weekly Enrollment											
Rows:		Columns:		Context:							
[Clinic]	[Week]	[Visit Type no Total]	[Enrollment Calc]	CC10004 - 114 Study - Ph III Double Blind - Rand [Elist]		Contracted [Version w Actuals]					
Pre Screen				Screen				Run In Period			
	Calculated	Adjustment	Final (adjust if necessary)	Cumulative Final	Calculated	Adjustment	Final (adjust if necessary)	Cumulative Final	Calculated	Adjus	
7/17/2009	28	0	28	28	0	0	0	0	0	0	
7/24/2009	41	0	41	69	0	0	0	0	0	0	
7/31/2009	81	0	81	150	17	0	17	17	0	0	
8/7/2009	41	0	41	191	25	0	25	41	0	0	
8/14/2009	28	0	28	219	48	0	48	90	0	0	
8/21/2009	25	0	25	243	25	0	25	115	13	0	
8/28/2009	17	0	17	260	17	0	17	131	20	0	
9/4/2009	0	0	0	260	15	0	15	146	39	0	
9/11/2009	0	0	0	260	10	0	10	156	20	0	
9/18/2009	0	0	0	260	0	0	0	156	13	0	
9/25/2009	0	0	0	260	0	0	0	156	12	0	
Total Clinics											
10/2/2009	0	0	0	260	0	0	0	156	8	0	
10/9/2009	0	0	0	260	0	0	0	156	0	0	
10/16/2009	0	0	0	260	0	0	0	156	0	0	
10/23/2009	0	0	0	260	0	0	0	156	0	0	
10/30/2009	0	0	0	260	0	0	0	156	0	0	
11/6/2009	0	0	0	260	0	0	0	156	0	0	
11/13/2009	0	0	0	260	0	0	0	156	0	0	
11/20/2009	0	0	0	260	0	0	0	156	0	0	
11/27/2009	0	0	0	260	0	0	0	156	0	0	
12/4/2009	0	0	0	260	0	0	0	156	0	0	

Outreach Performance

The Outreach Performance tab shows the cost of additional recruitment for each recruiting method. It helps users analyze increasing recruitment if Actual recruitment falls below forecast recruitment.

	Contracted	Budget	Forecast	Revised Plan	Scenario 1	Actuals	Var. Actuals to Contracted	Var. Actuals to Budget	Var. Actuals to Forecast
Number of Sites	1	1	1	1	1	1	0	0	0
Recruitment Method Split %									
Database Mailshots	30.0%	30.0%	30.0%	30.0%	30.0%	29.3%	0.7%	0.7%	0.7%
GP Mailshots	25.0%	25.0%	25.0%	25.0%	25.0%	25.5%	(0.5%)	(0.5%)	(0.5%)
Press / Radio	45.0%	45.0%	45.0%	45.0%	45.0%	45.2%	(0.2%)	(0.2%)	(0.2%)
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total Recruitment Methods	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%	0.0%
Recruitment Methods									
Database Mailshots (per site)	1,953	1,953	1,953	1,953	1,953	1,973	(20)	(20)	(20)
Database response rate %	2.00%	2.00%	2.00%	2.00%	2.00%	1.94%	0.06%	0.06%	0.06%
Database Mailshots (total)	1,953	1,953	1,953	1,953	1,953	1,973	(20)	(20)	(20)
Database Mailshots (total cost)	1,425	0	0	0	0	9,863	(8,439)	(9,863)	(9,863)
Database Mailshots (cost per unit)	0.73	0.00	0.00	0.00	0.00	5.00	(4.27)	(5.00)	(5.00)
GP Mailshots (per site)	1,302	1,302	1,302	1,302	1,302	1,276	26	26	26
GP Mailshot response rate %	2.50%	2.50%	2.50%	2.50%	2.50%	2.53%	(0.02%)	(0.02%)	(0.02%)
GP Mailshots (total)	1,302	1,302	1,302	1,302	1,302	1,276	26	26	26
GP Mailshots (total cost)	771	0	0	0	0	3,828	(3,057)	(3,828)	(3,828)
GP Mailshots (cost per unit)	0.59	0.00	0.00	0.00	0.00	3.00	(2.41)	(3.00)	(3.00)
Press / Radio (per site)	59	59	59	59	59	60	(2)	(2)	(2)
Press / Radio response rate %	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%	0.00%	0.00%
Press / Radio (total)	59	59	59	59	59	60	(2)	(2)	(2)
Press / Radio (total cost)	7,000	7,000	7,000	7,000	7,000	9,100	(2,100)	(2,100)	(2,100)

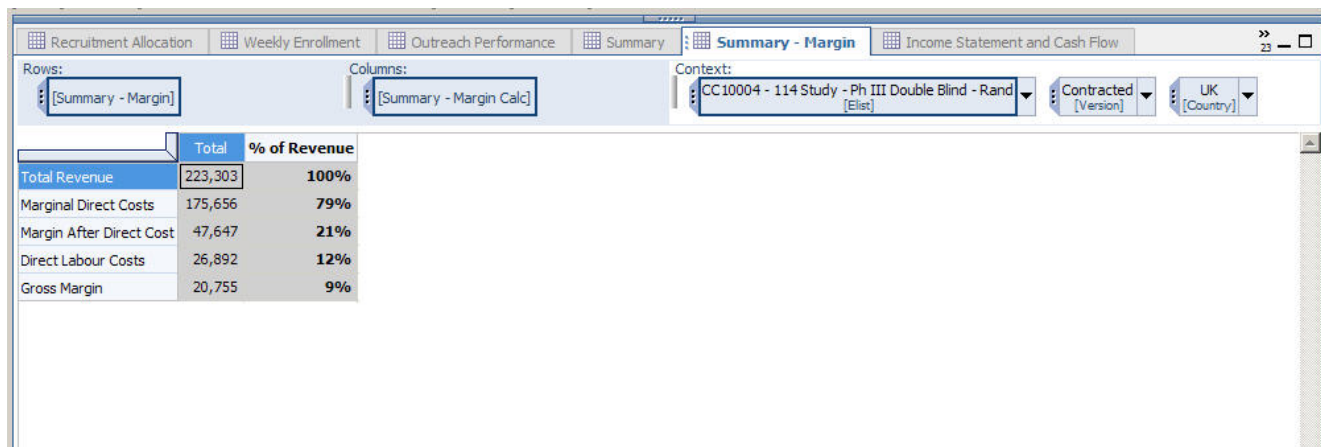
Summary

The Summary tab displays a summarized view of the forecast Income, Costs and Margin.

	Income	Costs	Margin	Margin %
Additional Call Centre Requirements	1,225	919	306	25%
Total	223,303	53,221	170,082	76%
Set Up Fees	2,000	947	1,053	53%
Investigator Fees	9,945	6,403	3,542	36%
Recruitment Budget	160,000	10,673	149,327	93%
Call Centre Setup	2,400	2,000	400	17%
Patient Expenses	5,156	4,906	250	5%
Patient Payments	0	0	0	0%
GP SDV's	0	0	0	0%
Archiving	2,500	2,500	0	0%
Project Management Fees	24,311	16,962	7,349	30%
Procedures	8,750	6,250	2,500	29%
Reporting	7,700	2,250	5,450	71%
Investigator Meeting	541	331	210	39%

Summary – Margin

The Summary Margin tab shows a summarized view of the forecast, displaying Revenue, Costs and Margin as a % of revenue.



	Total	% of Revenue
Total Revenue	223,303	100%
Marginal Direct Costs	175,656	79%
Margin After Direct Cost	47,647	21%
Direct Labour Costs	26,892	12%
Gross Margin	20,755	9%

P&L and Cash Flow

The P&L and Cash Flow tab displays Income, Costs and Cash Flow by month and also calculates expected cash position for each month.

	Apr-2010	May-2010	Jun-2010	Jul-2010	Aug-2010	Sep-2010	Oct-2010	Nov-2010	Dec-2010	Total 2010	Jan-2011	Feb-2011	Mar-2011	Apr-2011	May-2011	Jun-2011
Miscellaneous Income	1,475	1,524	1,475	1,524	1,524	1,475	492	10,000	0	23,914	0	0	0	0	0	0
Prescreen Income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Screen Income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rand Income	2,768	2,860	2,768	1,107	0	776	388	104	3,224	17,285	1,352	29	912	1,162	1,463	
Set Up Fee Income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Project Management Income	8,104	8,374	8,104	8,374	8,374	8,104	2,701	0	0	76,444	0	0	0	0	0	0
Total Direct Income	12,347	12,758	12,347	11,005	9,898	10,355	3,581	10,104	3,224	117,644	1,352	29	912	1,162	1,463	
Prescreen Staff Cost	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Screen Staff Cost	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rand Staff Cost	1,783	1,842	1,783	713	0	461	230	69	2,124	11,106	891	18	545	696	881	
Miscellaneous Cost	6,362	6,574	6,362	6,574	6,574	6,362	2,121	10,000	0	70,017	0	0	0	0	0	0
Set up Fee Cost	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Direct Costs	8,145	8,416	8,145	7,287	6,574	6,823	2,351	10,069	2,124	81,123	891	18	545	696	881	
Screen Patient Travel Income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rand Patient Travel Income	502	518	502	201	0	141	70	19	584	3,133	245	5	165	211	265	
Rand Procedure Income	0	2,000	20,000	8,000	0	0	0	0	0	30,000	0	0	0	0	0	0
Advertising Income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Pass Through Income	502	2,518	20,502	8,201	0	141	70	19	584	33,133	245	5	165	211	265	
Screen Patient Travel Cost	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rand Patient Travel Cost	448	463	448	179	0	116	58	17	534	2,790	224	4	137	175	221	
Rand Procedure Cost	0	2,000	20,000	8,000	0	0	0	0	0	30,000	0	0	0	0	0	0
Advertising Cost	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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 *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.

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