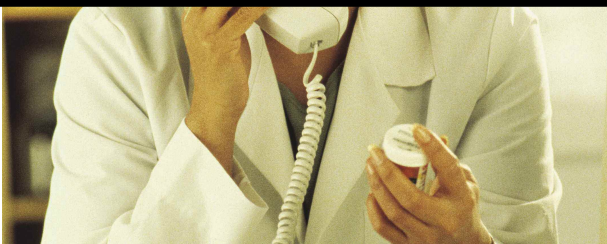


IBM COGNOS CLINICAL TRIAL RESOURCE PLANNING PERFORMANCE BLUEPRINT



A WEB-BASED
PERFORMANCE
MANAGEMENT
APPLICATION

IMPLEMENTATION GUIDE

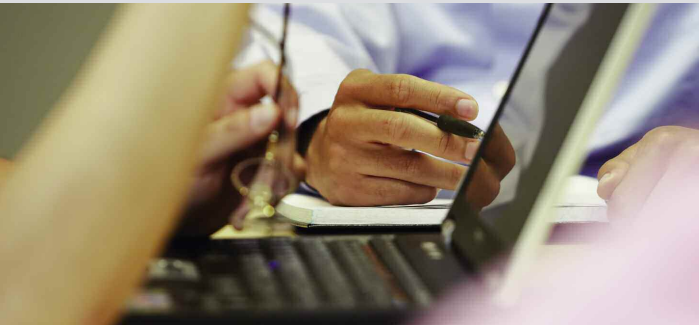
INTRODUCTION

This implementation guide demonstrates the design and functionality of the IBM Cognos Clinical Trial Resource Planning Performance Blueprint, a Web-based planning and reporting process model using IBM Cognos 8 Planning and IBM Cognos 8 Business Intelligence. It provides immediate insight into both the short- and long-term staffing requirements and costs for a successful clinical trial.

This Clinical Trial Resource Planning Blueprint can be used to manage the full-time, part-time and outsourced staff resources and costs of a company's clinical trial program. Utilizing the IBM Cognos 8 suite of performance management products, this Blueprint provides out-of-the box functionality including dashboards, analytical reports, and a pre-configured data model to facilitate rapid time-to-value.

Customers benefit from proven practices in model design that greatly reduce investment in implementation time and resources, and can focus on applying the technology to solve business problems, rather than fundamental process analysis and technical design.

Key aspects of the Blueprint model's operation are explained, followed by a section-by-section explanation of function, purpose, and operation. Users should have a basic understanding of the IBM Cognos 8 Planning Analyst and Contributor tools.



CLINICAL TRIAL RESOURCE PLANNING

Increasing budget pressures and growing study design complexity have heightened the need for robust budgeting and forecasting capabilities for clinical trial resource management.

Today resource planning models are often maintained in spreadsheet systems—an approach that is error-prone and inflexible for rapid, accurate clinical trial resource planning. 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.

Dedicated clinical trials management systems (CTMS) often lack robust forecasting functionality, since they are focused on transaction recording, rather than activity-based forecasting or scenario modeling—both essential for financial and resource management functions. Forecasting with CTMS presents a number of other challenges:

- Inability to link-in and update the plan based on actual spending.
- 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.

The *IBM Cognos Clinical Trial Resource Planning Performance Blueprint* addresses these concerns. It is one of a suite of IBM Cognos performance management solutions that help clinical trial project managers with the complex process of managing people, budgets and patients.

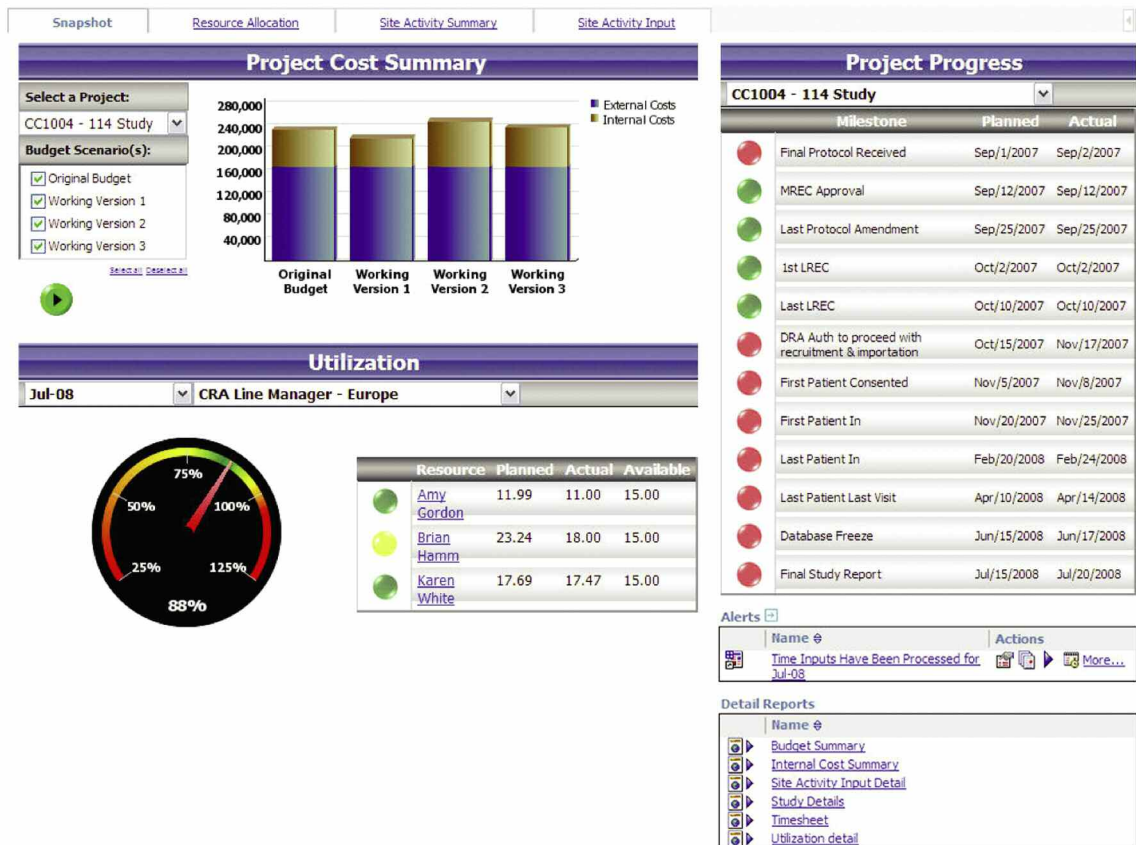
THE IBM COGNOS CLINICAL TRIAL RESOURCE PLANNING PERFORMANCE BLUEPRINT

This implementation guide demonstrates the design and functionality of the *IBM Cognos Clinical Trial Resource Planning Performance Blueprint*.

Key aspects of the *Blueprint* model's operation are explained, followed by a section-by-section explanation of function, purpose and operation. Users should have a basic understanding of the IBM Cognos 8 Planning Analyst and Contributor tools.

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




The dashboard, shown below, provides a snapshot view that serves as the starting point for a clinical trial project manager. The sections of this dashboard (clockwise from top left) are: 1) Project Cost Summary monitor; 2) a report on Project Progress; and 3) Utilization, in this case showing CRA Line Managers in Europe. A list of detailed reports, customized to the user, are available on the lower right portion of the screen.

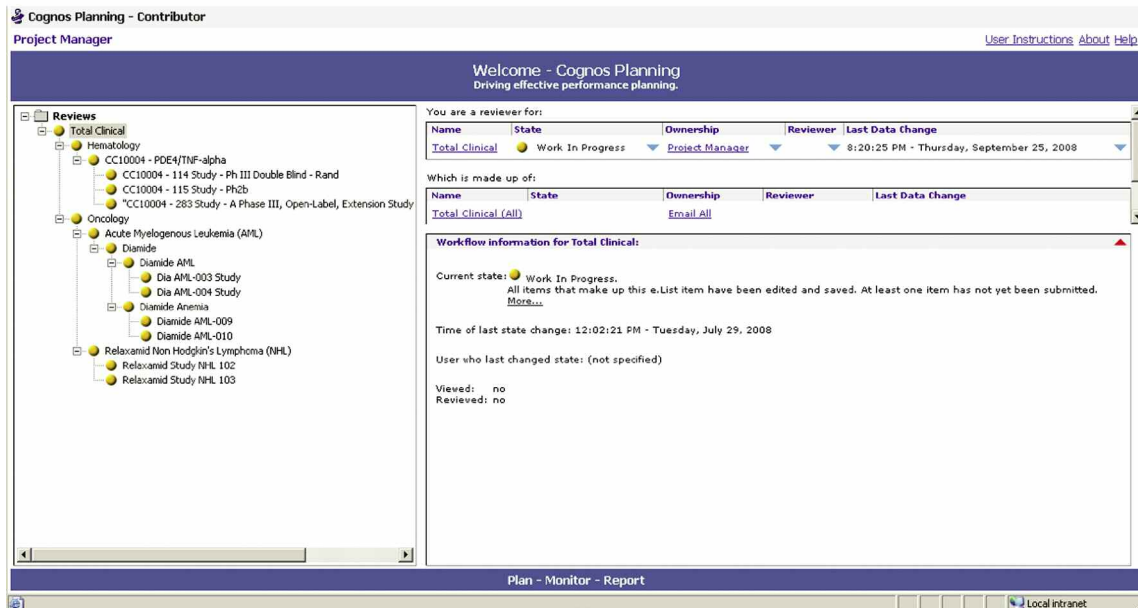


MODEL OVERVIEW

There are two components to the *Clinical Trials Resource Planning Blueprint*. They are the **Project Budgeting** module, where the forecast for the trial is created and resources are assigned to work on that trial; and the **Timesheet** module, where the resources are able to enter their Actual time worked and these Actuals are then compared to the forecast and target chargeable hours for that employee. The timesheet module can be bypassed and data loaded from existing time reporting systems, if desired.

Let's start by going through the forecasting process for the Project Budgeting component. The Project Budgeting input is assigned by study, as can be seen in the contribution hierarchy below. A forecast reviewer can see the consolidated results of all clinical trials or drill down and look into specific detail for individual clinical trials. Reviewers can see the workflow status of each clinical trial. As co-owners of that information, they can also make edits, if required. All workflow status changes, data consolidations and aggregations occur in real time, allowing for frequent planning iterations.

Before a user enters data, the state of the plan is  **Not Started**. Once a user saves a plan, the state becomes  **Work in Progress** and remains accessible for further editing. When a user submits an item, the plan is  **Locked**, and permits no further changes. The Locked state indicates that the plan is ready for review. A reviewer can see a plan in any state, but can only reject a Locked item. When a reviewer rejects a Locked plan, the plan returns to a state of Work in Progress, which means it is again editable.



The screenshot displays the Cognos Planning - Contributor interface. The main window is titled "Project Manager" and "Welcome - Cognos Planning". The left pane shows a "Reviews" tree with a hierarchy: Total Clinical > Hematology > CC10004 - PDE4/TNF-alpha > CC10004 - 114 Study - Ph III Double Blind - Rand, CC10004 - 115 Study - Ph2b, CC10004 - 283 Study - A Phase III, Open-Label, Extension Study; Oncology > Acute Myelogenous Leukemia (AML) > Diamide > Diamide AML > Dia AML-003 Study, Dia AML-004 Study, Diamide Anemia, Diamide AML-009, Diamide AML-010; Relaxamid Non Hodgkin's Lymphoma (NHL) > Relaxamid Study NHL 102, Relaxamid Study NHL 103.


The right pane shows "You are a reviewer for:" with a table:

Name	State	Ownership	Reviewer	Last Data Change
Total Clinical	Work In Progress	Project Manager		9:20:25 PM - Thursday, September 25, 2008

Below this is a table "Which is made up of:":

Name	State	Ownership	Reviewer	Last Data Change
Total Clinical (All)		Email All		

The bottom section is "Workflow information for Total Clinical:":

Current state:  Work In Progress.
All items that make up this e.List item have been edited and saved. At least one item has not yet been submitted.
[More...](#)

Time of last state change: 12:02:21 PM - Tuesday, July 29, 2008
User who last changed state: (not specified)

Viewed: no
Reviewed: no

The bottom status bar shows "Plan - Monitor - Report" and "Local intranet".

Project Budgeting Module

The first tab in this module is the Study Details tab. It holds various information about the study, including Study Type (low, medium or high), which drives the number of predicted hours per task for the study. This tab also holds start and end dates for each phase of the trial, and these dates drive the allocation of cost and hours for each task across the appropriate months for that phase of the trial. The Study Details tab also includes inputs for percentages of expenses and hours that should be allocated to each region.

Study Details	Internal Cost Hours	Internal Costs Calc Type	Rate by Role	Budget Internal Costs	Budget External Costs	Budget Summary	Internal Cost Summary	External Cost Summary
CC1004 - 114 Study - Ph III								
	Original Budget			Working Version 1		Working Version 2		Working Version 3
Product	CC1004 - PDE4/TNF-alpha			CC1004 - PDE4/TNF-alpha		CC1004 - PDE4/TNF-alpha		CC1004 - PDE4/TNF-alpha
Study Code	PR_1001			PR_1001		PR_1001		PR_1001
Business Unit	BU 2			BU 2		BU 2		BU 2
Short Name	CC1004 - 114 Study			CC1004 - 114 Study		CC1004 - 114 Study		CC1004 - 114 Study
Medical Adviser	Dr. Horton			Dr. Horton		Dr. Horton		Dr. Horton
Safety Reporting Required	Yes			Yes		Yes		Yes
Comparator Drug 1	Diamide AML			Diamide AML		Diamide AML		Diamide AML
Comparator Drug 2								
Comparator Drug 3								
Comparator Drug 4								
Site Start Number for this Study								
Study Type	Medium			Low		High		Medium
Study Classification	Clinical Study Phase III			Clinical Study Phase III		Clinical Study Phase III		Clinical Study Phase III
Sponsor	Local			Local		Local		Local
CRD managed	Yes			Yes		Yes		Yes
Status	SET UJP			SET UJP		SET UJP		SET UJP
# of Sites	5			3		5		4
Frequency of Site Visits (per month)	2.0			3.0		2.0		3.0
Version Commentary	Original Study Budget			Original Budget adjusted based on Summer Study Reviews		Original Budget adjusted for most likely scenario based on newest data		Original Budget adjusted for probable unforeseen events
Primary Region	United States			United States		United States		United States
Primary Region Expense %	60.0%			75.0%		75.0%		75.0%
Secondary Region	Europe			Europe		Europe		Europe
Secondary Region Expense %	40.0%			25.0%		25.0%		25.0%
Startup Date	pre-Jan-08			pre-Jan-08		pre-Jan-08		pre-Jan-08
Startup Duration	0			0		0		0
Startup End Date	pre-Jan-08			pre-Jan-08		pre-Jan-08		pre-Jan-08
Active Duration	4			4		5		4
Active End Date	Apr-08			Apr-08		May-08		Apr-08
Close Out Duration	3			2		3		3
Close Out End Date	Jul-08			Jun-08		Aug-08		Jul-08

Current owner: Project Manager

Next is the Internal Cost Hours tab. This is an assumption tab and is pre-populated by the administrator; no input is required. This tab holds the assumptions for how many hours will be needed to complete each task for the three different study types—low, medium and high.

Study Details				
Internal Cost Hours				
Internal Costs Calc Type				
Rate by Role				
Budget Internal Costs				
	High	Medium	Low	
Setup				
1 Design Study / Protocol Input	40.00	36.00	32.00	
2 Write Protocol Outline & Club-Net Registration	20.00	16.00	12.00	
3 Protocol feasibility	30.00	24.00	15.00	
4 Write protocol (where applicable)	60.00	50.00	40.00	
5 Review protocol	15.00	15.00	8.00	
6 Prepare PI&C	20.00	15.00	10.00	
7 CDREC Application Form	16.00	12.00	8.00	
8 SSA Application (per site)	6.00	5.00	5.00	
9 R+D / PCT Application (per site)	8.00	7.00	6.00	
10 CTA Preparation (per site)	24.00	22.00	22.00	
11 Insurance	14.00	12.00	10.00	
12 TMF/ ISF preparation (per site)	8.00	8.00	8.00	
13 Prepare Monitoring Plan	20.00	16.00	12.00	
14 Prepare Study Manual	45.00	30.00	15.00	
15 Prepare CRF	72.00	64.00	56.00	
16 Tracking of Essential Docs (per site)	12.00	11.00	10.00	
17 Identification of study sites (per site)	4.00	4.00	4.00	
18 Site feasibility (per site)	4.00	4.00	4.00	
19 Set-up Project Management	40.00	32.00	24.00	
PSV				
20 Telephone PSV	16.00	14.00	12.00	
21 Travel to site	60.00	45.00	30.00	
22 On-site PSV time	60.00	45.00	30.00	
23 Report and follow-up letter writing	40.00	35.00	30.00	
Meetings - Internal				
24 CRA Kick-Off Meeting - Travel	9.00	6.00	4.50	
25 CRA Kick-Off Meeting - Preparation	30.00	25.00	20.00	
26 CRA Kick-Off Meeting - Attendance	45.00	30.00	15.00	
27 Investigator Meeting - Travel	3.00	3.00	3.00	
28 Investigator Meeting - Preparation/Presentation	80.00	70.00	60.00	
29 Investigator Meeting - Attendance	45.00	38.00	30.00	
30 TC with sites not at Investigator Meeting	24.00	18.00	12.00	
Initiation				
31 Initiation visit (per site)	4.00	4.00	4.00	
32 Travel to site (per site)	3.00	3.00	3.00	
33 Visit report and follow-up letter (per site)	6.00	6.00	6.00	
34 Telephone initiation (per site)	2.00	2.00	2.00	
Ongoing Study Conduct				
35 Ongoing updates into ClubNet/IMPACT	6.00	4.00	2.00	
36 Telephone off-site monitoring (per site/month)	6.00	6.00	6.00	
37 Monitoring Visit (per visit)	3.00	3.00	3.00	
38 Travel to Monitoring Visit (per visit)	2.00	2.00	2.00	
39 Visit report and follow-up letter (per visit)	2.00	2.00	2.00	
40 Ongoing File Management (per month/site)	16.00	15.00	14.00	
41 Ongoing Project Management (per visit)	8.00	7.00	6.00	
Close Out Activities				
42 Close out visit (time at site/follow up)	12.00	10.00	8.00	
43 Travel to site (per site)	6.00	6.00	6.00	
44 Report writing/follow-up letter(per site)	8.00	8.00	8.00	
Archiving Activities - Internal				
45 File Storage and Backup/Completion (per site)	0.00	0.00	0.00	

Current owner: Project Manager

Likewise, the Internal Costs Calc Type is an assumption tab and requires no user input. This holds information for how each task should be calculated. Fields include Calculation Type (hourly, per site, or per visit), Task Performed By: (CPL, CPA, CRA, or IMP/Archivist), Project Phase (Start Up, Active or Close Out), Fixed/Spread Assumption and Month for Fixed Assumption.

Study Details	Internal Cost Hours	Internal Costs Calc Type	Rate by Role	Budget Internal Costs	Budget External Costs	Budget Summary
	Calculation Type	Task Performed By:	Project Phase	Fixed/Spread Assumption	Month for Fixed Assumption	
Setup						
1 Design Study / Protocol Input	hourly	CPL	Start Up	Spread		
2 Write Protocol Outline & Club-Net Registration	hourly	CPL	Start Up	Spread		
3 Protocol feasibility	hourly	CPL	Start Up	Spread		
4 Write protocol (where applicable)	hourly	CPL	Start Up	Spread		
5 Review protocol	hourly	CPL	Start Up	Spread		
6 Prepare PI&C	hourly	CPL	Start Up	Spread		
7 CDREC Application Form	hourly	CPL	Start Up	Spread		
8 SSA Application (per site)	per site	CRA	Start Up	Spread		
9 R+D / PCT Application (per site)	per site	CRA	Start Up	Spread		
10 CTA Preparation (per site)	per site	CPA	Start Up	Spread		
11 Insurance	hourly	CPA	Start Up	Spread		
12 TMF/ISF preparation (per site)	per site	CPA	Start Up	Spread		
13 Prepare Monitoring Plan	hourly	CPL	Start Up	Spread		
14 Prepare Study Manual	hourly	CPL	Start Up	Spread		
15 Prepare CRF	hourly	CPL	Start Up	Spread		
16 Tracking of Essential Docs (per site)	per site	CPA	Start Up	Spread		
17 Identification of study sites (per site)	per site	CPL	Start Up	Spread		
18 Site feasibility (per site)	per site	CPL	Start Up	Spread		
19 Set-up Project Management	hourly	CPL	Start Up	Spread		
PSV						
20 Telephone PSV	hourly	CRA	Start Up	Spread		
21 Travel to site	hourly	CRA	Start Up	Spread		
22 On-site PSV time	hourly	CRA	Start Up	Spread		
23 Report and follow-up letter writing	hourly	CRA	Start Up	Spread		
Meetings - Internal						
24 CRA Kick-Off Meeting - Travel	hourly	CRA	Active	Spread		
25 CRA Kick-Off Meeting - Preparation	hourly	CPL	Active	Spread		
26 CRA Kick-Off Meeting - Attendance	hourly	CRA	Active	Spread		
27 Investigator Meeting - Travel	hourly	CRA	Active	Spread		
28 Investigator Meeting - Preparation/Presentation	hourly	CPL	Active	Spread		
29 Investigator Meeting - Attendance	hourly	CRA	Active	Spread		
30 TC with sites not at Investigator Meeting	hourly	CRA	Active	Spread		
Initiation						
31 Initiation visit (per site)	per site	CRA	Active	Spread		
32 Travel to site (per site)	per site	CRA	Active	Spread		
33 Visit report and follow-up letter (per site)	per site	CRA	Active	Spread		
34 Telephone initiation (per site)	per site	CRA	Active	Spread		
Ongoing Study Conduct						
35 Ongoing updates into ClubNet/IMPACT	hourly	CRA	Active	Spread		
36 Telephone off-site monitoring (per site/month)	per site	CRA	Active	Spread		
37 Monitoring Visit (per visit)	per visit	CRA	Active	Spread		
38 Travel to Monitoring Visit (per visit)	per visit	CRA	Active	Spread		
39 Visit report and follow-up letter (per visit)	per visit	CRA	Active	Spread		
40 Ongoing File Management (per month/site)	per site	CPA	Active	Spread		
41 Ongoing Project Management (per visit)	per visit	CPL	Active	Spread		
Close Out Activities						
42 Close out visit (time at site/follow up)	hourly	CRA	Close Out	Spread		
43 Travel to site (per site)	per site	CRA	Close Out	Spread		
44 Report writing/follow-up letter(per site)	per site	CRA	Close Out	Spread		
Archiving Activities - Internal						
45 File Creation and Research Coordination (per site)	per site	CPL	Close Out	Spread		

Current owner: Project Manager

In the next tab, Rate by Role, the Project Manager begins to enter data on the hourly rate for each type of employee, which will be used to calculate the cost of performing each task. These rates can vary by geography and by currency as needed.

Internal Costs Calc Type			Rate by Role		Budget Internal Costs	
	United States	Europe				
	Hourly Rate					
CPL	50.00	45.00				
CRA	60.00	55.00				
CPA	55.00	50.00				
IMP/Archivist	45.00	40.00				

Current owner: Project Manager

After assigning internal rates and hours for the staff resources, we can start building the detailed budget in the Budget Internal Costs tab. All of the previous tabs' inputs are combined here to calculate the hours and costs by task. Overrides are available for the fixed/spread assumption, month for fixed, month to start spread, spread duration and hours.

Internal Costs Calc Type	Rate by Role	Budget Internal Costs	Budget External Costs	Budget Summary	Internal Cost Summary	External Cost Summary	Project Cost Summary
CC10004 - 114 Study - Ph III	United States	Original Budget					
Setup		1 Design Study / Protocol Input	2 Write Protocol Outline & Club-Net Registration	3 Protocol feasibility	4 Write protocol (where applicable)	5 Review protocol	6 Prepare PI&C
Calculation Type	hourly	hourly	hourly	hourly	hourly	hourly	hourly
Task Performed By:	CPL	CPL	CPL	CPL	CPL	CPL	CPL
Project Phase	Start Up	Start Up	Start Up	Start Up	Start Up	Start Up	Start Up
Fixed/Spread Assumption	Spread	Spread	Spread	Spread	Spread	Spread	Spread
Fixed/Spread Override							
Fixed/Spread	Spread	Spread	Spread	Spread	Spread	Spread	Spread
Phase Start Month	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08
Phase Duration							
Month for Fixed Assumption							
Month for Fixed Override							
Month for Fixed							
Month to Start Spread Override							
Spread Duration Override							
Final Spread Start Date	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08	pre-Jan-08
Final Spread Duration							
Hourly Rate	50.00	50.00	50.00	50.00	50.00	50.00	50.00
Total # of Sites	5	5	5	5	5	5	5
Frequency of Site Visits (per month)	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Study Type	Medium	Medium	Medium	Medium	Medium	Medium	Medium
Hours Assumption	36.00	16.00	24.00	24.00	50.00	15.00	15.00
Region Expense %	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%
Calculated Hours	21.60	9.60	14.40	14.40	30.00	9.00	9.00
Hours Adjustment	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total Hours	21.60	9.60	14.40	14.40	30.00	9.00	9.00
Cost/Task	1,080.00	480.00	720.00	720.00	1,500.00	450.00	450.00

Current owner: Project Manager

A similar process is applied in the Budget External Costs tab, where the user is asked to input a cost per unit and number of units for each type of external cost.

Rate by Role		Budget Internal Costs	Budget External Costs	Budget Summary	Internal Cost Summary		
CC10004 - 114 Study - Ph III		United States		Original Budget			
	Cost per Unit	Number of Units	Total Cost	Task Start Date	Task End Date		
Meetings - External							
CRA Training Venue	400.00	4.0	1,600.00	Jan-08	Jul-08		
CRA Training Materials	250.00	4.0	1,000.00	Jan-08	Jul-08		
Investigator Meeting Venue & Catering	15,000.00	1.0	15,000.00	Jan-08	Jul-08		
Investigator Meeting Materials	3,000.00	1.0	3,000.00	Jan-08	Jul-08		
Honoraria	2,000.00	1.0	2,000.00	Jan-08	Jul-08		
Archiving Activities - External							
Storage of Archived Documents(Iron Mountain costs)	2,000.00	1.0	2,000.00	Jan-08	Jul-08		
Courier of Documents (In-house to Storage)	1,000.00	1.0	1,000.00	Jan-08	Jul-08		
Courier of Documents (Site to Storage)	1,000.00	1.0	1,000.00	Jan-08	Jul-08		
Center Costs							
R&D Fee	2,500.00	1.0	2,500.00	Jan-08	Jul-08		
Pharmacy set-up, storage & close-down	2,800.00	1.0	2,800.00	Jan-08	Jul-08		
Supplies courier (site files etc)	1,500.00	1.0	1,500.00	Jan-08	Jul-08		
Patient Costs							
Pt travel	150.00	10.0	1,500.00	Jan-08	Jul-08		
Investigator Fee	500.00	1.0	500.00	Jan-08	Jul-08		
Screening Failure (Assume X%)	2,500.00	1.0	2,500.00	Jan-08	Jul-08		
Pharmacy dispensing costs	4,000.00	1.0	4,000.00	Jan-08	Jul-08		
Advertising	10,000.00	1.0	10,000.00	Jan-08	Jul-08		
Overheads @ X%	2,500.00	1.0	2,500.00	Jan-08	Jul-08		
Investigational Medicinal Product							
Number of pallets ambient storage	50.00	20.0	1,000.00	Jan-08	Jul-08		
Number of pallets Refrigerated	50.00	20.0	1,000.00	Jan-08	Jul-08		
Destruction costs	400.00	1.0	400.00	Jan-08	Jul-08		
Shipments to Site	50.00	10.0	500.00	Jan-08	Jul-08		
Central Laboratory Costs.							
Central Laboratory Costs	500.00	1.0	500.00	Jan-08	Jul-08		
CRD Monitoring Costs.							
CRD Monitoring Costs	2,500.00	4.0	10,000.00	Jan-08	Jul-08		
Data Management.							
CRF Design	3,000.00	1.0	3,000.00	Jan-08	Jul-08		
CRF Printing	4,000.00	1.0	4,000.00	Jan-08	Jul-08		
Data Management	3,000.00	1.0	3,000.00	Jan-08	Jul-08		
Statistics	3,500.00	1.0	3,500.00	Jan-08	Jul-08		
Medical Writing	3,500.00	1.0	3,500.00	Jan-08	Jul-08		

Current owner: Project Manager

The Budget Summary tab shows a summary-level view of internal and external costs for each of the forecast versions.

Budget External Costs				Budget Summary			Internal Cost Summary		
CC10004 - 114 Study - Ph III				Original Budget					
	United States	Europe	Total Regions						
Setup	19,821.00	11,960.00	31,781.00						
Meetings - Internal	6,270.00	3,800.00	10,070.00						
PSV	5,004.00	3,058.00	8,062.00						
Initiation	2,700.00	1,650.00	4,350.00						
Ongoing Study Conduct	22,179.00	13,448.00	35,627.00						
Close Out Activities	2,880.00	1,760.00	4,640.00						
Archiving Activities - Internal	6,420.00	3,860.00	10,280.00						
Total Internal Costs	65,274.00	39,536.00	104,810.00						
Meetings - External	22,600.00	22,600.00	45,200.00						
Archiving Activities - External	4,000.00	4,000.00	8,000.00						
Center Costs	6,800.00	6,800.00	13,600.00						
Patient Costs	19,500.00	19,500.00	39,000.00						
Patient Travel	1,500.00	1,500.00	3,000.00						
IMP	2,900.00	2,900.00	5,800.00						
Central Lab	500.00	500.00	1,000.00						
CRO Monitoring Costs	10,000.00	10,000.00	20,000.00						
Data Management	17,000.00	17,000.00	34,000.00						
Total External Costs	84,800.00	84,800.00	169,600.00						
Total Costs	150,074.00	124,336.00	274,410.00						

Current owner: Project Manager

The Internal Cost Summary calculates monthly cost and days for all internal costs by project phase, task, region and version.

Internal Cost Summary												
CC10004 - 114 Study - Ph III												
Original Budget												
Task Performed By	Fixed/Spread	Cost	Start Date	Duration	End Date	Date for Fixed	Period ID	Cost Calc	Fixed Flag	Days	Planned Days	
Meetings - Internal												
24 CRA Kick-Off Meeting - Travel	CRA	Spread	216.00	pre-Jan-08	4	Apr-08	0	2	54.00	2.00	0.45	0.11
25 CRA Kick-Off Meeting - Preparation	CPL	Spread	750.00	pre-Jan-08	4	Apr-08	0	2	187.50	2.00	1.88	0.47
26 CRA Kick-Off Meeting - Attendance	CRA	Spread	1,080.00	pre-Jan-08	4	Apr-08	0	2	270.00	2.00	2.25	0.56
27 Investigator Meeting - Travel	CRA	Spread	108.00	pre-Jan-08	4	Apr-08	0	2	27.00	2.00	0.23	0.06
28 Investigator Meeting - Preparation/Presentation	CPL	Spread	2,100.00	pre-Jan-08	4	Apr-08	0	2	525.00	2.00	5.25	1.31
29 Investigator Meeting - Attendance	CRA	Spread	1,368.00	pre-Jan-08	4	Apr-08	0	2	342.00	2.00	2.95	0.71
30 TC with sites not at Investigator Meeting	CRA	Spread	648.00	pre-Jan-08	4	Apr-08	0	2	162.00	2.00	1.35	0.34
Initiation												
31 Initiation visit (per site)	CRA	Spread	720.00	pre-Jan-08	4	Apr-08	0	2	180.00	2.00	1.50	0.38
32 Travel to site (per site)	CRA	Spread	540.00	pre-Jan-08	4	Apr-08	0	2	135.00	2.00	1.13	0.28
33 Visit report and follow-up letter (per site)	CRA	Spread	1,080.00	pre-Jan-08	4	Apr-08	0	2	270.00	2.00	2.25	0.56
34 Telephone initiation (per site)	CRA	Spread	360.00	pre-Jan-08	4	Apr-08	0	2	90.00	2.00	0.75	0.19
Ongoing Study Conduct												
35 Ongoing updates into ClubNet/IMPACT	CRA	Spread	144.00	pre-Jan-08	4	Apr-08	0	2	36.00	2.00	0.30	0.08
36 Telephone off-site monitoring (per site/month)	CRA	Spread	1,080.00	pre-Jan-08	4	Apr-08	0	2	270.00	2.00	2.25	0.56
37 Monitoring Visit (per visit)	CRA	Spread	4,320.00	pre-Jan-08	4	Apr-08	0	2	1,080.00	2.00	9.00	2.25
38 Travel to Monitoring Visit (per visit)	CRA	Spread	2,880.00	pre-Jan-08	4	Apr-08	0	2	720.00	2.00	6.00	1.50
39 Visit report and follow-up letter (per visit)	CRA	Spread	2,880.00	pre-Jan-08	4	Apr-08	0	2	720.00	2.00	6.00	1.50
40 Ongoing File Management (per month/site)	CRA	Spread	2,475.00	pre-Jan-08	4	Apr-08	0	2	618.75	2.00	5.63	1.41
41 Ongoing Project Management (per visit)	CPL	Spread	8,400.00	pre-Jan-08	4	Apr-08	0	2	2,100.00	2.00	21.00	5.25

Current owner: Project Manager

Similarly, the External Cost Summary calculates monthly costs and days for all external costs by project phase, task, region and version.

Budget Summary Internal Cost Summary External Cost Summary Project Cost Summary Internal Costs by Role						
CC10004 - 114 Study - Ph III United States Jan-08						
	Cost	Start Date	Duration	End Date	Period IID	Cost Calc
Meetings - External						
CRA Training Venue	1,600.00	Jan-08	6	Jul-08	2	228.57
CRA Training Materials	1,000.00	Jan-08	6	Jul-08	2	142.86
Investigator Meeting Venue & Catering	15,000.00	Jan-08	6	Jul-08	2	2,142.86
Investigator Meeting Materials	3,000.00	Jan-08	6	Jul-08	2	428.57
Honoraria	2,000.00	Jan-08	6	Jul-08	2	285.71
Archiving Activities - External						
Storage of Archived Documents(Iron Mountain costs)	2,000.00	Jan-08	6	Jul-08	2	285.71
Courier of Documents (In-house to Storage)	1,000.00	Jan-08	6	Jul-08	2	142.86
Courier of Documents (Site to Storage)	1,000.00	Jan-08	6	Jul-08	2	142.86
Center Costs						
R&D Fee	2,500.00	Jan-08	6	Jul-08	2	357.14
Pharmacy set-up, storage & close-down	2,800.00	Jan-08	6	Jul-08	2	400.00
Supplies courier (site files etc)	1,500.00	Jan-08	6	Jul-08	2	214.29
Patient Costs						
Pt travel	1,500.00	Jan-08	6	Jul-08	2	214.29
Investigator Fee	500.00	Jan-08	6	Jul-08	2	71.43
Screening Failure (Assume X%)	2,500.00	Jan-08	6	Jul-08	2	357.14
Pharmacy dispensing costs	4,000.00	Jan-08	6	Jul-08	2	571.43
Advertising	10,000.00	Jan-08	6	Jul-08	2	1,428.57
Overheads @XXX%	2,500.00	Jan-08	6	Jul-08	2	357.14
Investigational Medicinal Product						
Number of pallets ambient storage	1,000.00	Jan-08	6	Jul-08	2	142.86
Number of pallets Refrigerated	1,000.00	Jan-08	6	Jul-08	2	142.86
Destruction costs	400.00	Jan-08	6	Jul-08	2	57.14
Shipments to Site	500.00	Jan-08	6	Jul-08	2	71.43
Central Laboratory Costs.						
Central Laboratory Costs	500.00	Jan-08	6	Jul-08	2	71.43
CRO Monitoring Costs.						
CRO Monitoring Costs	10,000.00	Jan-08	6	Jul-08	2	1,428.57
Data Management.						
CRF Design	3,000.00	Jan-08	6	Jul-08	2	428.57
CRF Printing	4,000.00	Jan-08	6	Jul-08	2	571.43
Data Management	3,000.00	Jan-08	6	Jul-08	2	428.57
Statistics	3,500.00	Jan-08	6	Jul-08	2	500.00
Medical Writing	3,500.00	Jan-08	6	Jul-08	2	500.00

Current owner: Project Manager

The Project Cost Summary provides a view of the monthly projected costs by task and region.

Internal Cost Summary		External Cost Summary		Project Cost Summary		Internal Costs by Role			
CC10004 - 114 Study - Ph III		United States		Original Budget					
	pre-Jan-08	Jan-08	Feb-08	Mar-08	Apr-08	May-08	Jun-08	Jul-08	
Setup									
1 Design Study / Protocol Input	0	0	0	0	0	0	0	0	
2 Write Protocol Outline & Club-Net Registration	0	0	0	0	0	0	0	0	
3 Protocol feasibility	0	0	0	0	0	0	0	0	
4 Write protocol (where applicable)	0	0	0	0	0	0	0	0	
5 Review protocol	0	0	0	0	0	0	0	0	
6 Prepare PI&C	0	0	0	0	0	0	0	0	
7 COREC Application Form	0	0	0	0	0	0	0	0	
8 SSA Application (per site)	0	0	0	0	0	0	0	0	
9 R+D / PCT Application (per site)	0	0	0	0	0	0	0	0	
10 CTA Preparation (per site)	0	0	0	0	0	0	0	0	
11 Insurance	0	0	0	0	0	0	0	0	
12 TMF/ ISF preparation (per site)	0	0	0	0	0	0	0	0	
13 Prepare Monitoring Plan	0	0	0	0	0	0	0	0	
14 Prepare Study Manual	0	0	0	0	0	0	0	0	
15 Prepare CRF	0	0	0	0	0	0	0	0	
16 Tracking of Essential Docs (per site)	0	0	0	0	0	0	0	0	
17 Identification of study sites (per site)	0	0	0	0	0	0	0	0	
18 Site feasibility (per site)	0	0	0	0	0	0	0	0	
19 Set-up Project Management	0	0	0	0	0	0	0	0	
PSV									
20 Telephone PSV	0	0	0	0	0	0	0	0	
21 Travel to site	0	0	0	0	0	0	0	0	
22 On-site PSV time	0	0	0	0	0	0	0	0	
23 Report and follow-up letter writing	0	0	0	0	0	0	0	0	
Meetings - Internal									
24 CRA Kick-Off Meeting - Travel	0	54	54	54	54	0	0	0	
25 CRA Kick-Off Meeting - Preparation	0	188	188	188	188	0	0	0	
26 CRA Kick-Off Meeting - Attendance	0	270	270	270	270	0	0	0	
27 Investigator Meeting - Travel	0	27	27	27	27	0	0	0	
28 Investigator Meeting - Preparation/Presentation	0	525	525	525	525	0	0	0	
29 Investigator Meeting - Attendance	0	342	342	342	342	0	0	0	
30 TC with sites not at Investigator Meeting	0	162	162	162	162	0	0	0	
Initiation									
31 Initiation visit (per site)	0	180	180	180	180	0	0	0	
32 Travel to site (per site)	0	135	135	135	135	0	0	0	
33 Visit report and follow-up letter (per site)	0	270	270	270	270	0	0	0	
34 Telephone initiation (per site)	0	90	90	90	90	0	0	0	
Ongoing Study Conduct									
35 Ongoing updates into ClubNet/IMPACT	0	36	36	36	36	0	0	0	
36 Telephone off-site monitoring (per site/month)	0	270	270	270	270	0	0	0	
37 Monitoring Visit (per visit)	0	1,080	1,080	1,080	1,080	0	0	0	
38 Travel to Monitoring Visit (per visit)	0	720	720	720	720	0	0	0	
39 Visit report and follow-up letter (per visit)	0	720	720	720	720	0	0	0	
40 Ongoing File Management (per month/site)	0	619	619	619	619	0	0	0	
41 Ongoing Project Management (per visit)	0	2,100	2,100	2,100	2,100	0	0	0	
Close Out Activities									
42 Close out visit (time at site/follow up)	0	0	0	0	90	90	90	90	
43 Travel to site (per site)	0	0	0	0	270	270	270	270	
44									

Current owner: Project Manager

The Internal Cost by Role tab shows a view by resource type of the activities that are predicted for each month.

External Cost Summary		Project Cost Summary		Internal Costs by Role												Resource Assignment excl CRAs												Resource Allocation excl CRAs												Site Assignment												Resource Assignment - CRAs														
CC10004 - 114 Study - Ph III		United States		Active												Cost												Original Budget																																						
		Jan-08	Feb-08	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09																																																
CPL	Project Management	2,100.00	2,100.00	2,100.00	2,100.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																
	Project Administration	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																
	Study Start-Up	187.50	187.50	187.50	187.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																
	Travel Time	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																
	Monitoring	525.00	525.00	525.00	525.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																
	Site Coordination	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																
	Total Tasks	2,812.50	2,812.50	2,812.50	2,812.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																
CRA	Project Management	36.00	36.00	36.00	36.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Project Administration	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Study Start-Up	270.00	270.00	270.00	270.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Travel Time	936.00	936.00	936.00	936.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Monitoring	2,124.00	2,124.00	2,124.00	2,124.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Site Coordination	990.00	990.00	990.00	990.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Total Tasks	4,356.00	4,356.00	4,356.00	4,356.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
CPA	Project Management	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Project Administration	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Study Start-Up	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Travel Time	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Monitoring	618.75	618.75	618.75	618.75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Site Coordination	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Total Tasks	618.75	618.75	618.75	618.75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
IMP/Archivist	Project Management	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Project Administration	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Study Start-Up	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Travel Time	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Monitoring	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Site Coordination	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
	Total Tasks	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																	
Total Roles	Project Management	2,136.00	2,136.00	2,136.00	2,136.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																		
	Project Administration	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																		
	Study Start-Up	457.50	457.50	457.50	457.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																		
	Travel Time	936.00	936.00	936.00	936.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																		
	Monitoring	3,267.75	3,267.75	3,267.75	3,267.75	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																		
	Site Coordination	990.00	990.00	990.00	990.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																		
	Total Tasks	7,787.25	7,787.25	7,787.25	7,787.25	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																		

The Resource Assignment excl CRAs tab lets the user define which employees are assigned to the different project roles by month and region. Up to two people may be assigned to each role for a given month and region. CRAs are the only employee type that does not show up here, since the CRAs are assigned later in the model to the specific sites they will be responsible for.

External Cost Summary		Project Cost Summary		Internal Costs by Role												Resource Assignment excl CRAs												Resource Allocation excl CRAs												Site Assignment												Resource Assignment - CRAs											
CC10004 - 114 Study - Ph III		United States		Active												Role Assignments																																															
		Jan-08	Feb-08	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08																																																			
CPL1	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson	Jenna Thompson																																																			
CPL2																																																															
CPA1	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts	Haley Roberts																																																			
CPA2	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells	Maggie Wells																																																			
IMP/Archivist1	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones	Molly Jones																																																			
IMP/Archivist2																																																															

Next, the Resource Allocation excl CRAs tab allocates cost and hours to individual employees based on the roles they were assigned and the activities that are predicted that month for that particular role. By default, if two employees are assigned to a given role, each will be allocated 50% of the cost and hours for the role. The user can override that 50% split and, for example, assign one employee 75% and the other 25% of the cost and hours related to their role.

External Cost Summary		Project Cost Summary		Internal Costs by Role		Resource Assignment excl CRAs		Resource Allocation excl CRAs		Site Assignment		Resource Assignment - CRAs	
CC10004 - 114 Study - Ph III		United States		Jan-08									
	Role Assignments	Days Allocated Calculated	Override Calculated Allocation?	Allocation % Override	Allocation % Override Calc	Days Allocated Override	Final Days Allocated						
CPL1	Project Management	Jenna Thompson	5.25	0.0%	0.0%	0.00	5.25						
	Project Administration	Jenna Thompson	0.00	0.0%	0.0%	0.00	0.00						
	Study Start-Up	Jenna Thompson	0.47	0.0%	0.0%	0.00	0.47						
	Travel Time	Jenna Thompson	0.00	0.0%	0.0%	0.00	0.00						
	Monitoring	Jenna Thompson	1.31	0.0%	0.0%	0.00	1.31						
	Site Coordination	Jenna Thompson	0.00	0.0%	0.0%	0.00	0.00						
	Total Tasks		7.03	0.0%	0.0%	0.0%	0.00	7.03					
CPL2	Project Management		0.00	0.0%	0.0%	0.00	0.00						
	Project Administration		0.00	0.0%	0.0%	0.00	0.00						
	Study Start-Up		0.00	0.0%	0.0%	0.00	0.00						
	Travel Time		0.00	0.0%	0.0%	0.00	0.00						
	Monitoring		0.00	0.0%	0.0%	0.00	0.00						
	Site Coordination		0.00	0.0%	0.0%	0.00	0.00						
	Total Tasks		0.00	0.0%	0.0%	0.0%	0.00	0.00					
Total CPLs	Project Management		5.25	0.0%	0.0%	0.00	5.25						
	Project Administration		0.00	0.0%	0.0%	0.00	0.00						
	Study Start-Up		0.47	0.0%	0.0%	0.00	0.47						
	Travel Time		0.00	0.0%	0.0%	0.00	0.00						
	Monitoring		1.31	0.0%	0.0%	0.00	1.31						
	Site Coordination		0.00	0.0%	0.0%	0.00	0.00						
	Total Tasks		7.03	0.0%	0.0%	0.0%	0.00	7.03					
CPA1	Project Management	Haley Roberts	0.00	0.0%	0.0%	0.00	0.00						
	Project Administration	Haley Roberts	0.00	0.0%	0.0%	0.00	0.00						
	Study Start-Up	Haley Roberts	0.00	0.0%	0.0%	0.00	0.00						
	Travel Time	Haley Roberts	0.00	0.0%	0.0%	0.00	0.00						
	Monitoring	Haley Roberts	0.70	0.0%	0.0%	0.00	0.70						
	Site Coordination	Haley Roberts	0.00	0.0%	0.0%	0.00	0.00						
	Total Tasks		0.70	0.0%	0.0%	0.0%	0.00	0.70					
CPA2	Project Management	Maggie Wells	0.00	0.0%	0.0%	0.00	0.00						
	Project Administration	Maggie Wells	0.00	0.0%	0.0%	0.00	0.00						
	Study Start-Up	Maggie Wells	0.00	0.0%	0.0%	0.00	0.00						
	Travel Time	Maggie Wells	0.00	0.0%	0.0%	0.00	0.00						
	Monitoring	Maggie Wells	0.70	0.0%	0.0%	0.00	0.70						
	Site Coordination	Maggie Wells	0.00	0.0%	0.0%	0.00	0.00						
	Total Tasks		0.70	0.0%	0.0%	0.0%	0.00	0.70					
Total CPAs	Project Management		0.00	0.0%	0.0%	0.00	0.00						
	Project Administration		0.00	0.0%	0.0%	0.00	0.00						
	Study Start-Up		0.00	0.0%	0.0%	0.00	0.00						
	Travel Time		0.00	0.0%	0.0%	0.00	0.00						
	Monitoring		1.41	0.0%	0.0%	0.00	1.41						
	Site Coordination		0.00	0.0%	0.0%	0.00	0.00						
	Total Tasks		1.41	0.0%	0.0%	0.0%	0.00	1.41					
IMP/Archivist1	Project Management	Molly Jones	0.00	0.0%	0.0%	0.00	0.00						
	Project Administration	Molly Jones	0.00	0.0%	0.0%	0.00	0.00						

Current owner: Project Manager

In the Site Assignment tab, the user has to populate the investigator and town for each site that will be used for the study.

Resource Allocation excl CRAs | **Site Assignment** | Resource Assignment - CRAs | Resource Allocation - CRAs

CC10004 - 114 Study - Ph III

	Study Code	Short Name	Investigator	Town
1	PR_1001	CC1004 - 114 Study	H. Thompson	Princeton
2	PR_1001	CC1004 - 114 Study	B. Robinson	Springfield
3	PR_1001	CC1004 - 114 Study	W. Harrington	Syracuse
4	PR_1001	CC1004 - 114 Study	G. Winters	Chester
5	PR_1001	CC1004 - 114 Study	W. Harrington	Bath
6	PR_1001	CC1004 - 114 Study		
7	PR_1001	CC1004 - 114 Study		
8	PR_1001	CC1004 - 114 Study		
9	PR_1001	CC1004 - 114 Study		
10	PR_1001	CC1004 - 114 Study		
11	PR_1001	CC1004 - 114 Study		
12	PR_1001	CC1004 - 114 Study		
13	PR_1001	CC1004 - 114 Study		
14	PR_1001	CC1004 - 114 Study		
15	PR_1001	CC1004 - 114 Study		
16	PR_1001	CC1004 - 114 Study		
17	PR_1001	CC1004 - 114 Study		
18	PR_1001	CC1004 - 114 Study		
19	PR_1001	CC1004 - 114 Study		
20	PR_1001	CC1004 - 114 Study		
21	PR_1001	CC1004 - 114 Study		
22	PR_1001	CC1004 - 114 Study		

Current owner: Project Manager

Now we come to the Resource Assignment – CRAs tab, where the user has to populate the center status and the CRA assigned to that site for each month of the study.

Site Assignment | **Resource Assignment - CRAs** | Resource Allocation - CRAs | Milestones | Assumptions

CC10004 - 114 Study - Ph III | Jan-08

	Study Code	Short Name	Investigator	Town	Region	Centre Status	CRA
1	PR_1001	CC1004 - 114 Study	H. Thompson	Princeton	United States	Active	Randy Holmes
2	PR_1001	CC1004 - 114 Study	B. Robinson	Springfield	United States	Active	Carrie Woods
3	PR_1001	CC1004 - 114 Study	W. Harrington	Syracuse	United States	Active	Steve Clark
4	PR_1001	CC1004 - 114 Study	G. Winters	Chester	Europe	Active	Karen White
5	PR_1001	CC1004 - 114 Study	W. Harrington	Bath	Europe	Active	Amy Gordon
6	PR_1001	CC1004 - 114 Study					
7	PR_1001	CC1004 - 114 Study					
8	PR_1001	CC1004 - 114 Study					
9	PR_1001	CC1004 - 114 Study					
10	PR_1001	CC1004 - 114 Study					
11	PR_1001	CC1004 - 114 Study					
12	PR_1001	CC1004 - 114 Study					
13	PR_1001	CC1004 - 114 Study					
14	PR_1001	CC1004 - 114 Study					
15	PR_1001	CC1004 - 114 Study					
16	PR_1001	CC1004 - 114 Study					
17	PR_1001	CC1004 - 114 Study					
18	PR_1001	CC1004 - 114 Study					
19	PR_1001	CC1004 - 114 Study					
20	PR_1001	CC1004 - 114 Study					
21	PR_1001	CC1004 - 114 Study					
22	PR_1001	CC1004 - 114 Study					

Current owner: Project Manager

In the next tab, Resource Allocation – CRAs, the predicted days required of each CRA are calculated by month, site and region. This data will then feed into the Timesheet module, if that module is used, in order to calculate predicted vs. actual days and target chargeable time for each CRA.

	Role Assignments	Region	Final Days Allocated
1	Randy Holmes	United States	0.03
2	Carrie Woods	United States	0.03
3	Steve Clark	United States	0.03
4			0.00
5			0.00
6			0.00
7			0.00
8			0.00
9			0.00
10			0.00
11			0.00
12			0.00
13			0.00
14			0.00
15			0.00
16			0.00
17			0.00
18			0.00
19			0.00
20			0.00
21			0.00
22			0.00
23			0.00
24			0.00
25			0.00
26			0.00

The next tab is Milestones, where the user is able to enter date information on the various milestones that occur during a study.

	Planned	Updated Plan	Actual	DRA/CDM Informed within 21 Days of Actual Date
Final Protocol Received	09/01/07	09/01/07	09/02/07	Yes
MREC Approval	09/12/07	09/12/07	09/12/07	
Last Protocol Amendment	09/25/07	09/25/07	09/25/07	
1st LREC	10/02/07	10/02/07	10/02/07	
Last LREC	10/10/07	10/10/07	10/10/07	
DRA Auth to proceed with recruitment & importation	10/15/07	10/15/07	11/17/07	
First Patient Consented	11/05/07	11/10/07	11/08/07	
First Patient In	11/20/07	11/20/07	11/25/07	
Last Patient In	02/20/08	02/20/08	02/24/08	
Last Patient Last Visit	04/10/08	04/10/08	04/14/08	
Database Freeze	06/15/08	06/15/08	06/17/08	
Final Study Report	07/15/08	07/15/08	07/20/08	

Enter dates as DD/MM/YY format

Current owner: Project Manager

The final tab in the Project Budgeting application is Assumptions, which holds the assumed number of working hours per day for each region and the forecast version that is being used for the resource allocation calculations. The administrator is able to adjust these assumptions as necessary.

	Factor	Current Forecast Version
United States	8.00	Original Budget
Europe	7.50	Original Budget

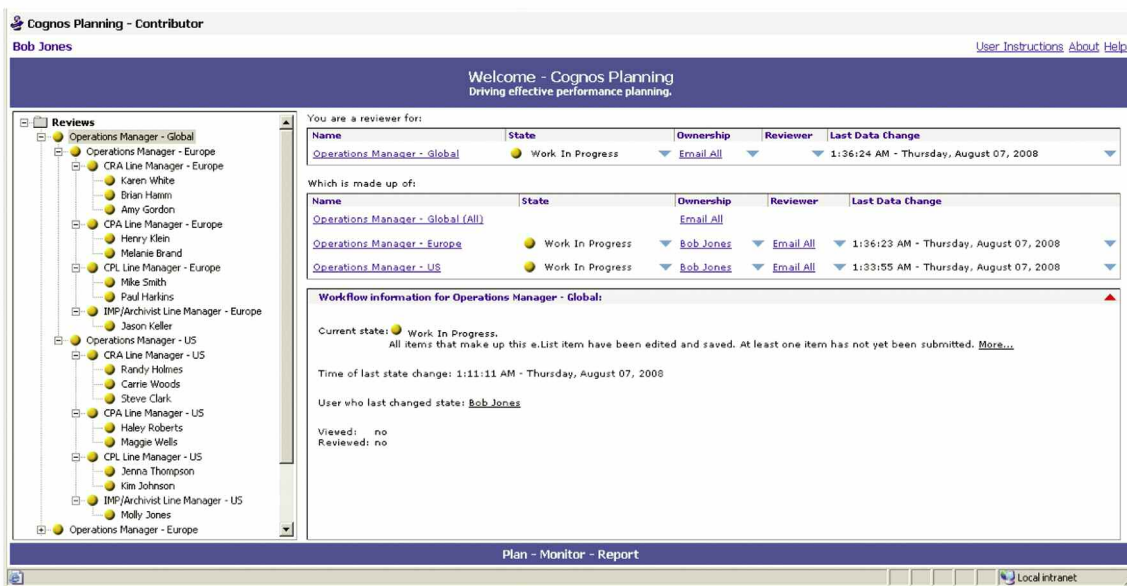
Current owner: Project Manager

This concludes the description of the tabs in the Project Budgeting module. There are several links that populate the Timesheet module, if used, with the appropriate data from the Project Budgeting module. They are described in detail in the Setup document provided with the data model download.

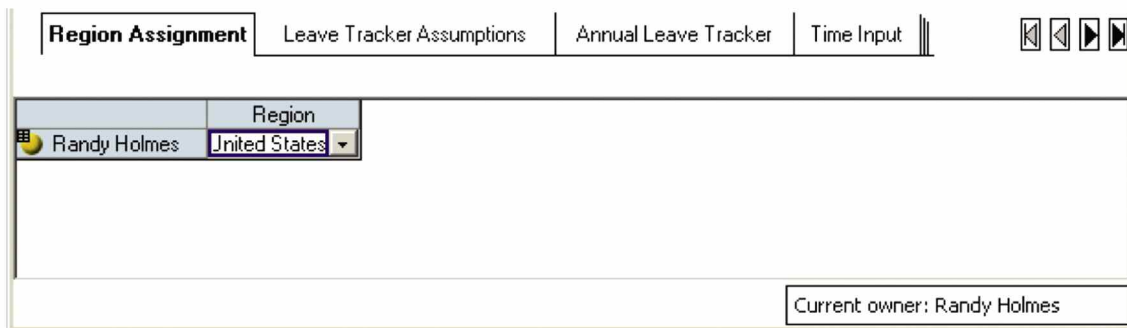
Now let's turn to the Timesheet module. As noted, the timesheet module can be bypassed and data loaded from existing time reporting systems. In addition, the *Blueprint* enables additional scenario modeling capabilities where necessary.

Timesheet Module

Access to the Timesheet module is assigned by employee. Each employee is responsible for populating a timesheet with actual time worked against projects and tasks on a regular basis. This input is then compared against calculated projections that are fed in from the Project Budgeting module. The employee submissions roll up to line manager and then operations manager reviews by region.



The first tab in the Timesheet module is the Region Assignment tab. Each employee is assigned to work in a single region.



The Administrator populates the Leave Tracker Assumptions tab with data about which days are weekends and public holidays for the employee's region.

Region Assignment	Leave Tracker Assumptions	Annual Leave Tracker	Time Input	Time Summary	Site Activity Input	Site Activity Summary	Days Available																										
Leave Assumption		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Jan-08	ph					w	w						w	w						w	w						w	w					
Feb-08		w	w							w	w						w	w						w	w							n/a	n/a
Mar-08		w	w							w	w						w	w					ph	w	w	ph					w	w	
Apr-08					w	w						w	w							w	w							w	w			n/a	n/a
May-08			w	w	ph						w	w							w	w						w	w	ph			w	w	
Jun-08		w						w	w						w	w							w	w					w	w		n/a	
Jul-08					w	w							w	w							w	w					w	w					
Aug-08			w	w						w	w						w	w							w	w	ph				w	w	
Sep-08							w	w						w	w							w	w						w	w		n/a	
Oct-08				w	w							w	w							w	w							w	w				
Nov-08		w	w						w	w						w	w								w	w				w	w	n/a	
Dec-08							w	w						w	w										ph	ph		w	w				
Jan-09	ph		w	w							w	w							w	w											w	w	
Feb-09		w						w	w						w	w							w	w					w	w	n/a	n/a	
Mar-09						w	w							w	w							w	w						w	w			
Apr-09			w	w							w	w							w	w							w	w				n/a	
May-09		w	w					w	w						w	w									w	w				w	w		
Jun-09					w	w							w	w							w	w							w	w		n/a	
Jul-09			w	w						w	w										w	w							w	w		w	
Aug-09		w						w	w						w	w							w	w						w	w		
Sep-09				w	w																										w	w	
Oct-09		w	w						w	w						w	w														w	w	
Nov-09					w	w																									w	w	
Dec-09			w	w							w	w															w	w				w	

Current owner: Randy Holmes

In the next tab, Annual Leave Tracker, the employee has the ability to enter information on additional non-chargeable days. The categories available through the drop-down menu for each day are holiday, 1/2 day holiday, training, 1/2 day training, sick, 1/2 day sick, public holiday, not working, weekend, not applicable, absence with permission and 1/2 day absence with permission.

Region Assignment	Leave Tracker Assumptions	Annual Leave Tracker	Time Input	Time Summary	Site Activity Input	Site Activity Summary	Days Available	Mandays	Mandays Summary																														
Randy Holmes		Final Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31						
Jan-08	ph				w	w	h	h	h					w	w							w	w														3.00	0.00	0
Feb-08		w	w							w	w					w	w																				0.00	0.00	0
Mar-08		w	w							w	w											ph	w	w	ph					w	w					0.00	0.00	0	
Apr-08					w	w								w	w																						1.00	1.00	0
May-08			w	w	ph								w	w												w	w	ph								0.00	0.00	0	
Jun-08		w						w	w							w	w																			0.00	0.00	0	
Jul-08					w	w																														0.00	0.00	0	
Aug-08			w	w						w	w															w	w	ph								0.00	0.00	0	
Sep-08							w	w																												0.00	0.00	0	
Oct-08				w	w																															0.00	0.00	0	
Nov-08		w	w							w	w																									0.00	0.00	0	
Dec-08							w	w																												0.00	0.00	0	
Jan-09	ph		w	w																																0.00	0.00	0	
Feb-09		w																																		0.00	0.00	0	
Mar-09						w	w																													0.00	0.00	0	
Apr-09			w	w																																0.00	0.00	0	
May-09		w	w																																	0.00	0.00	0	
Jun-09					w	w																														0.00	0.00	0	
Jul-09			w	w																																0.00	0.00	0	
Aug-09		w																																		0.00	0.00	0	
Sep-09					w	w																														0.00	0.00	0	
Oct-09		w	w							w	w																									0.00	0.00	0	
Nov-09																																				0.00	0.00	0	
Dec-09				w	w																															0.00	0.00	0	

Enter any adjustments into the Final Days dimension. Enter Annual Holiday Allowed for each month.

Current owner: Randy Holmes

h
0.5 h
t
0.5 t
s
0.5 s
ph
n/w
w
n/a
a/p
0.5 a/p

The next tab, Time Input, is pre-populated with the activities that an individual had been assigned in the Project Budgeting module by study and month. At the bottom of the tab there are also categories for non-chargeable activities. The user is required to enter actual time worked against each study (or non-chargeable category) by day and activity type.

Region Assignment		Leave Tracker Assumptions		Annual Leave Tracker		Time Input		Time Summary		Site Activity Input		Site Activity Summary		Days Available		Mandays		Mandays Summary				
Randy Holmes		Apr 08																				
Role	Activity	1	2	3	4	7	8	9	10	11	14	15	16	17	18	21	22	23	24	25	28	
CC1004 - 114 Study	CRA - Project Management	0.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	CRA - Study Start-Up	0.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	CRA - Travel Time	0.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	CRA - Monitoring	0.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	CRA - Site Coordination	0.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Total		0.00	8.00	8.00	8.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CC1004 - 115 Study		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Total		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CC1004 - 283 Study		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Total		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Dia AML-003 Study		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Total		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Dia AML-004 Study	CRA - Project Management	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	CRA - Travel Time	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	0.00	1.00	0.00	0.00	
	CRA - Monitoring	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	3.00	3.00	0.00	3.00	3.00	3.00	3.00	0.00	3.00	0.00	0.00	
	CRA - Site Coordination	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00	0.00	1.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Total		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8.00	8.00	0.00	8.00	8.00	8.00	8.00	0.00	8.00	0.00	0.00
Diamide AML-009		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	

*** - indicates lower than expected hours for the day

Current owner: Randy Holmes

The Time Summary tab summarizes the data from the time input tab by activity, month and study, and it can be viewed by days or hours worked.

Region Assignment Leave Tracker Assumptions Annual Leave Tracker Time Input Time Summary Site Activity Input Site Activity Summary									
Randy Holmes Apr-08 Days									
	Total	CC1004 - 114 Study	Dia AML-004 Study	Diamide AML-010	Total Non chargeable	NC to CO	NC by CO		
Total Clinical Ops Activity	22.00	3.00	7.00	5.00	7.00	2.00	5.00		
% Chargeable Time	68.2%	100.0%	100.0%	100.0%	0.0%	0.0%	0.0%		
Total Chargeable	15.00	3.00	7.00	5.00					
Project Management	4.63	0.75	2.63	1.25					
Project Administration									
Project Handover									
Study Start-Up	0.69	0.38		0.31					
Travel Time	1.88	0.38	0.88	0.63					
Monitoring	4.63	0.75	2.63	1.25					
Site Coordination	3.19	0.75	0.88	1.56					
Total Nonchargeable	7.00				7.00	2.00	5.00		
Business Unit Advisory									
IST Management									
General Admin	5.00				5.00		5.00		
General Management									
General Training									
Training Delivery									
Holiday	1.00				1.00	1.00			
Sick	1.00				1.00	1.00			
IS Issues									
Supplier Training									
Public Holiday									

Current owner: Randy Holmes

On the Site Activity Input tab, the CRA enters information about the activities performed at each site during the month. If an employee is not a CRA, any site-specific (CRA-only) tabs would be hidden from that employee.

Region Assignment Leave Tracker Assumptions Annual Leave Tracker Time Input Time Summary Site Activity Input Site Activity Summary Days Available Mandays Mandays Summary										
Randy Holmes Jul-08										
	1	2	3	4	5	6	7	8	9	10
Study Code	PR_1001	PR_1005	PR_1005	PR_1005	PR_1005	PR_1012	PR_1012	PR_1009		
Short Name	CC1004 - 114 Study	Dia AML-004 Study	Dia AML-004 Study	Dia AML-004 Study	Dia AML-004 Study	Diamide AML-010	Diamide AML-010	Relaxamid Study NHL 103		
Investigator	H. Thompson	W. Harrington	G. Winters	H. Thompson	R. Emerson	R. Emerson	N. Russell	R. Emerson		
Town	Princeton	Syracuse	Columbus	Danbury	Greenwich	Olatando	Kansas City	Olatando		
Centre Status	Close Out	Initiated	Initiated	Initiated	Initiated	Active	Active	Non-active		
Initiation Date	Jan-08	Jun-08	Jun-08	Jun-08	Jun-08	Apr-08	Apr-08	Feb-08		
Recruitment End Date	Mar-08	Oct-08	Oct-08	Oct-08	Oct-08	Sep-08	Sep-08	Mar-09		
Patient Target	0	35	35	35	35	40	40	0	0	0
Patient Target Cumulated	125	70	70	70	70	160	160	0	0	0
# of patients screened	0	46	43	44	46	53	51	0	0	0
# of patients screened cumulated	150	90	89	88	91	214	206	0	0	0
# of patients entered	0	34	35	38	36	39	40	0	0	0
# of patients entered cumulated	125	70	69	71	70	161	160	0	0	0
# of patients in follow-up	0	0	0	0	0	5	5	0	0	0
# of patients completed or withdrawn	0	0	0	0	0	56	52	0	0	0
# of patients completed or withdrawn cumulated	125	0	0	0	0	56	52	0	0	0
# of CRF segments to DM this month	0	0	0	0	0	0	0	0	0	0
# of CRF segments on site req CRA SDV/verification	0	0	0	0	0	0	0	0	0	0
# of visits conducted this month	0	185	174	163	173	316	326	0	0	0
# of visits reports outstanding	0	0	0	0	0	0	0	0	0	0
# of Recorded Telephone Contacts this month	0	0	2	2	1	5	2	0	0	0
Check						WARNING	WARNING			
Site Count	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	0.0

Current owner: Randy Holmes

The Site Activity Summary tab summarizes actual vs. predicted hours and site counts by study and month.

		Jan-08			Feb-08			Mar-08			Apr-08			May-08			Jun-08	
		Predicted	Actual	Variance	Predicted	Actual	Variance	Predicted	Actual	Variance	Predicted	Actual	Variance	Predicted	Actual	Variance	Predicted	Actual
Total	# of sites	3.00	3.00	0.00	3.00	3.00	0.00	3.00	3.00	0.00	7.00	7.00	0.00	7.00	7.00	0.00	7.00	7.00
	Hours	41.34	41.00	(0.34)	41.34	41.00	(0.34)	41.34	41.00	(0.34)	145.22	120.00	(25.22)	109.11	108.00	(1.11)	182.01	124.00
CC1004 - 114 Study	# of sites	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00	0.00	1.00	1.00
	Hours	24.20	24.00	(0.20)	24.20	24.00	(0.20)	24.20	24.00	(0.20)	31.70	24.00	(7.70)	7.50	12.00	4.50	7.50	12.00
CC1004 - 115 Study	# of sites	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Hours	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CC1004 - 283 Study	# of sites	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Hours	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Dia AML-003 Study	# of sites	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Hours	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Dia AML-004 Study	# of sites	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	4.00	4.00	0.00	4.00	4.00	0.00	4.00
	Hours	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	59.72	56.00	(3.72)	59.72	56.00	(3.72)	132.62	72.00
Diamide AML-009	# of sites	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Hours	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Diamide AML-010	# of sites	2.00	2.00	0.00	2.00	2.00	0.00	2.00	2.00	0.00	2.00	2.00	0.00	2.00	2.00	0.00	2.00	2.00
	Hours	17.14	17.00	(0.14)	17.14	17.00	(0.14)	17.14	17.00	(0.14)	53.90	40.00	(13.90)	41.89	40.00	(1.89)	41.89	40.00
Relaxamid Study NHL 102	# of sites	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Hours	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Relaxamid Study NHL 103	# of sites	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Hours	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Shows CRA Activity only for both Predicted and Actual Current owner: Randy Holmes

The Days Available tab shows target chargeable days by month for each role.

		Jan-08	Feb-08	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09	Jun-09	Jul-09	Aug-09	Sep-09	
CPL	Days Available	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Comment																						
CRA	Days Available	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	
	Comment																						
CPA	Days Available	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Comment																						
IMP/Archivist	Days Available	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Comment																						
Total Roles	Days Available	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	

Current owner: Randy Holmes

The final tab in the Timesheet module is the Hours per Day Assumption tab, which holds the assumption for number of working hours per day by region.

	Hours per Day
United States	8.00
Europe	7.50

SUMMARY

Performance management systems allow clinical trial managers to forecast staffing resources and provide a measurement process so that performance against the goals can be tracked and updated. Manual spreadsheet-based systems are error-prone and consume valuable staff time to reconcile and rekey information. The *IBM Cognos Clinical Trial Resource Planning Performance Blueprint* addresses these inefficiencies and allows clinical trial managers to effectively forecast, manage and track staffing costs. It provides a flexible template that can be easily adapted and modified to meet the needs of the individual clinical trial manager.

To learn more about the *IBM Cognos Clinical Resource Planning Performance Blueprint* or other Blueprints, please visit <http://www.cognos.com/innovationcenter>.

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