

ClearTrial PLAN

ClearTrial PLAN software leverages embedded industry intelligence and clinical knowledge to optimize your clinical study planning. The software enables you to compress study planning cycle-times, reduce execution timelines, and reduce costs—while maintaining study feasibility.

Product Overview

ClearTrial PLAN is the core module of the integrated Clinical Trial Operations (CTO) software suite, which includes ClearTrial SOURCE and ClearTrial TRACK. ClearTrial PLAN encompasses the detailed tasks required to plan a clinical trial, enabling you to build study plans from the “bottom up” simply by entering your clinical assumptions.

Business Value

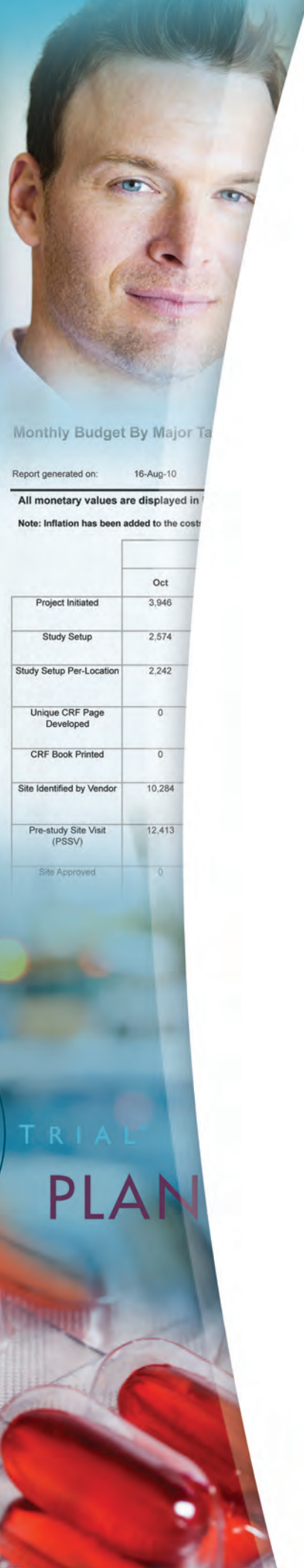
Effective study planning is becoming increasingly challenging for trial sponsors. Factors ranging from reduced financial and personnel resources and greater complexity of trial protocols, to the global nature of studies and shrinking tolerance for budget variances, are adding pressure throughout the planning process.

ClearTrial PLAN provides you with visibility to the operational and financial plan for a study, and the ability to quickly model new scenarios as your clinical assumptions or business requirements change. The result is more efficient and accurate clinical study planning, budgeting and execution.

“ClearTrial is a lifesaver in terms of making wise clinical investment decisions. It has made a significant difference in my ability to help our business. Thanks!”

Jan Troeger
Director, Clinical Planning and
Operations, Medication Delivery

Baxter



Monthly Budget By Major Task

Report generated on: 16-Aug-10

All monetary values are displayed in

Note: Inflation has been added to the costs

	Oct
Project Initiated	3,946
Study Setup	2,574
Study Setup Per-Location	2,242
Unique CRF Page Developed	0
CRF Book Printed	0
Site Identified by Vendor	10,284
Pre-study Site Visit (PSSV)	12,413
Site Approved	0

TRIAL
PLAN

Key Features

ClearTrial PLAN delivers a comprehensive set of features to help you meet your clinical study planning goals.

- **Embedded global clinical intelligence:** ClearTrial PLAN offers industry-proven algorithms for over 200 therapeutic indications and specific clinical development data from 80 countries, simplifying study planning.
- **Activity-based planning methodology:** By building study plans from the “bottom-up” from more than 140 documented study assumptions, you can ensure that study plans reflect your development goals and methodology.
- **Centralized repository for operational data:** With ClearTrial, your clinical plans are kept in a secure database, accessible via a secure web connection. Your institutional knowledge is thus highly secure, while the system is scalable to any number of users in any part of the globe.
- **Fast “what-if” scenario planning:** The software’s Rapid Scenario Planning™ capability lets you assess multiple clinical development strategies in minutes, and then select the one that best meets your business goals—whether driven by cost, timelines, resources, or a combination.
- **Rapid time to value:** Thanks to its Software-as-a-Service delivery model and easy-to-use interface designed by clinical operations professionals, ClearTrial software can be operational in less than a week, quickly delivering business value to your organization.

Key Benefits

ClearTrial PLAN provides you with:

- **Accuracy:** ClearTrial software has been benchmarked by leading biopharmaceutical and medical device companies to deliver 95-99% accuracy when compared with actual study costs.
- **Speed:** Using the software, you can create comprehensive clinical trial operational plans and detailed study budgets in minutes.
- **Efficiency:** ClearTrial PLAN allows you to optimize trials for maximum efficiency, shortening timelines and reducing costs while maintaining the achievability of the study.
- **Consistency:** The output of a set of clinical assumptions is the same no matter who builds the plan.
- **Flexibility:** The software supports all clinical development methodologies, such as adaptive studies, as well as your own business processes.

Why ClearTrial

ClearTrial provides Clinical Trial Operations (CTO) software that makes the planning, forecasting, and tracking of clinical project and financial performance faster and more accurate. The ClearTrial system creates dramatic internal and supplier efficiencies and cost savings for our biopharmaceutical and medical device customers by integrating their clinical operations from planning to payments.

Major CRO	Task	2010			
		Q3	Nov	Dec	2010 Total
	Project Initiation	3,945	5,577	5,790	17,319
	Study Setup	2,374	4,200	4,433	11,208
	Study Setup Per-Location	2,342	3,736	3,611	8,858
	Unique CRF Page Developed	0	15,963	29,108	45,071
	CRF Book Printed	0	0	0	0

ClearTrial PLAN provides a detailed monthly budget breakdown by service provider, location, and task, with costs reflected in the month they are actually incurred.

Milestone	Date
Project Activity Start Date	14-Oct-10
First Site Approved	27-Jan-11
Investigator Meeting	7-Feb-11
Drug Available to First Site	9-Feb-11
First Subject/Patient In (FSI/FPi)	14-Feb-11
Agreement on Statistical Analysis Plan	26-Mar-11
Last Site Approved	4-May-11
Last Subject/Patient In (LSI/LPI)	23-Oct-11
Last Subject/Patient Observation (LSO/LPO)	16-Jan-12
Last Data Query Resolved	25-Jan-12
Database Lock	30-Jan-12
Final Report	15-May-12
Study Duration (approx months)	19.0

ClearTrial PLAN gives you fast, accurate visibility into the key project milestones for your study.



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