

CLEAR TRIAL®

STUDY COSTING & OPTIMIZATION SERVICE

The world's leading biopharmaceutical, clinical research, and medical device organizations leverage ClearTrial's industry leading software each day to improve efficiency and performance in clinical operations. These organizations now are afforded greater visibility and control over clinical trial costs, resources, timelines, and project status. These same powerful capabilities are now available to smaller organizations through ClearTrial's turn-key, cost-effective Study Costing & Optimization Service (SCOS).

Key Clinical Development Challenges

Today, organizations large and small must ensure that their clinical trial dollars are being spent as effectively as possible. Many smaller companies lack the visibility to accurately forecast clinical trial costs, resources, and timelines. Even fewer have the resources to perform "what-if" analysis on multiple scenarios, which can lead to dramatic reductions in R&D costs and study timelines.

ClearTrial's SCOS: An Extension of Your Clinical Team

ClearTrial's Study Costing & Optimization Service leverages a powerful combination of ClearTrial's proven clinical trial operations (CTO) software and ClearTrial's Clinical Services personnel acting as an extension of your own team. As an expert in clinical development, outsourcing, and project management, your ClearTrial Clinical Services Manager will work with your team to deliver cost-effective and turn-key study costing and timeline forecasts.

ClearTrial SCOS Benefits

Dramatic Savings in Time and Cost from Better Operational Design

Unlike a "consultant with a spreadsheet," ClearTrial SCO service draws on industry intelligence and activity-based costing methodologies which enable the rapid creation of multiple cost, resource, and timeline scenarios. ClearTrial costing scenarios have been proven to deliver 1-5% accuracy when benchmarked against actual study costs. These scenarios can be tailored by your ClearTrial Clinical Services Manager to help you cut time, cost or both from clinical trials, without jeopardizing achievability of your plan.

Negotiation Leverage for Additional Cost Savings

ClearTrial costing scenarios also provide better negotiation leverage in sponsor/CRO negotiations. With a comprehensive inventory of clinical assumptions backing-up monthly budget estimates, and projections for unit costs, unit hours, timeline projections, cash flows and recommended resource staffing, the ClearTrial SCO service arms you with the data you need to ensure your project is getting the attention and the budget it requires.

Monthly Budget By Major Task

1_Annual Budget 2.5 for Clarity
Phase III / Protocol ID: CLR-001-1123
Indication: Circulatory System / Lipid Metabolism

Report generated on: 12-Oct-09

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 21-Aug-2008.
Note: Inflation has been added to the costs in this report.

		2009					
		Jan	Feb	Mar	Apr	May	Jun
Major CRO	Project Initiated	31,253	28,229	31,253	30,245	31,253	30,245
	Study Setup	6,301	5,692	6,301	6,098	6,301	6,098
	Study Setup Per-Location	14,447	13,049	14,447	13,981	14,447	13,981
	Unique CRF Page Developed	22,557	20,374	22,557	21,830	22,557	0
Sponsor Inc	Project Initiated	4,536	4,097	4,536	4,390	4,536	4,390
	Study Setup	2,385	2,155	2,385	2,309	2,385	2,309
	Sponsor Oversight	153,821	138,935	153,821	148,859	153,821	148,859
	Cost - Translation Services - 3rd Party	51	47	51	50	51	50

powered by CLEAR TRIAL

The ClearTrial SCO Service provides detailed monthly budget forecasts for outsourced as well as internal costs.

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ClearTrial SCOS Deliverables

ClearTrial's Study Costing & Optimization Service delivers a comprehensive array of timeline, cost and resource forecasts, supporting assumptions and responsibilities specifications, including:

Study Budget – ClearTrial's clinical operations experts will work with your team and develop an initial ballpark or detailed study budget.

Comprehensive Reports – The ClearTrial team will deliver a comprehensive set of reports which will provide a global view of your planned study. Reports provided include:

- Assumptions & Specifications
- Budget Summary
- Responsibilities Report (Sponsor and/or Outsourcing partner)
- Monthly Budget Report
- Milestone Report with Timeline

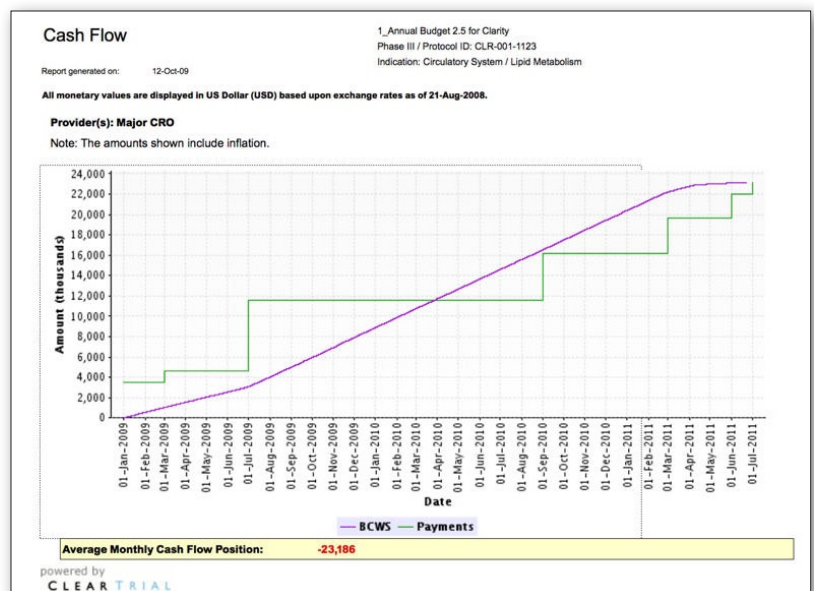
Scenario Testing and Study Optimization – Modeling of the study design (using ClearTrial software) to identify opportunities to save time and/or cost through more efficient operational design of your study. One SCO includes modeling of up to 3 scenarios for a single study.

Final Plan and Reports – After the final plan has been selected, the ClearTrial team will provide the following additional reports documenting your study:

- Resource Demand Summary
- Subject Enrollment Graph
- Site Approval Graph
- Summary of Unit Hours and Fees for Study Tasks (Fixed Unit Price Summary report)
- Side-by-side Comparison of Fees, Costs and Hours, at the task level, for up to 3 study scenarios
- Recommended **Milestone Payment Schedule** with corresponding **Monthly Cash Flow chart** to ensure optimal payment terms

Look to ClearTrial to Deliver Results – Quickly and Accurately

ClearTrial's Study Costing & Optimization Service provides the strategic guidance, accuracy, speed, and clinical operations expertise needed to accelerate the planning and execution of your clinical studies, while ensuring that you are maximizing your R&D budget.



ClearTrial software automatically generates a milestone payment schedule based on when work will be performed.