



CLEAR TRIAL[®] SOURCE

ClearTrial SOURCE

ClearTrial SOURCE software streamlines the outsourcing process by providing visibility to industry-standard study hours, costs, and resources. The software allows you to accelerate outsourcing cycle-times, increase negotiation leverage, and improve sponsor/CRO relationships—whether outsourcing all or part of your clinical trials.

Product Overview

ClearTrial SOURCE is a module of the integrated Clinical Trial Operations (CTO) software suite, which includes the core module ClearTrial PLAN, and ClearTrial TRACK. The software lets you quickly assess different clinical outsourcing scenarios to select the one that best meets your business goals. ClearTrial SOURCE supports all outsourcing models including Functional Service Provider (FSP), full-service, staff augmentation, hybrid, and more.

Business Value

New practices and greater complexity in outsourcing, increased scrutiny on contracts, and tighter financial controls are straining the resources of clinical outsourcing professionals. In addition, the growing reliance on Clinical Research Organizations (CROs) for planning, costing, and conducting clinical studies has reduced the visibility and control of sponsors over virtually every aspect of a study.

ClearTrial SOURCE provides detailed clinical, cost, and resource reports—including comprehensive unit price schedules—letting you accurately assess CRO bids, rapidly pinpoint discrepancies, and reduce the disruptive nature and impact of change orders. The result is greater efficiency in your outsourcing operations.

“ClearTrial software has enhanced our ability to quickly assess the costs associated with multiple development strategies. It has proven to be an effective tool that we can rely on to rapidly estimate project costs and establish guidelines for negotiating contracts with our service providers.”

Brian Birchler
Vice President, Development Operations,
Isis Pharmaceuticals, Inc.



Key Features

ClearTrial SOURCE delivers a comprehensive set of features to help you meet your clinical outsourcing goals.

- **Embedded global clinical intelligence:** ClearTrial SOURCE offers industry-proven algorithms for over 200 therapeutic indications, CRO billing rates, and specific clinical development data from 80 countries.
- **Activity-based planning methodology:** By building outsourced study plans from the “bottom-up” from more than 140 documented study assumptions, you ensure that study plans reflect your outsourcing goals and methodology.
- **Rapid “What-if” Scenario Planning:** ClearTrial SOURCE lets you quickly and easily create multiple outsourcing scenarios, using any combination of service providers and any outsourcing model. You can then assess the impact of each scenario on the study’s timeline, cost, and internal resource demand.
- **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 SOURCE 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 generate RFP documents and outsourcing schedules in minutes, directly driven from your clinical assumptions. And when your assumptions change, your RFP documents are updated automatically.
- **Efficiency:** ClearTrial SOURCE allows you to accelerate contract closure time by up to 75% while maintaining study objectives. The software ensures that your requirements and key milestones are reflected in bids, lets you compare vendor proposals without re-keying data, and delivers greater consistency in bids from different providers.
- **Flexibility:** ClearTrial SOURCE provides a common platform for sponsors and CROs to execute cost and risk-sharing strategies, while 3rd-party industry intelligence for costs and resource demand provides “neutral ground”—putting the focus on value and relationships.

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.

Fixed Unit Prices

Clarity baseline v0 for Clarity study
Phase II / Protocol ID: PT08889
Indication: Oncology / Lung

Provider: Major CRO

Major Task Name		Unit Hours	Unit Cost	# Units
Project Initiated	(Project Initiation)	175.4	30,964.83	1
Study Setup	(Study Setup - Centralized tasks)	133.2	22,808.71	1
Study Setup Per Location	(Study Setup - De-centralized tasks)	189.3	22,282.66	2
A Written Protocol	(Protocol Preparation)	153.0	26,779.76	1
Unique CRF Page Development	(CRF Development)	23.4	4,851.35	12
CRF Book Printed	(CRF Printing)	0.2	26.26	379
Site Identified by Vendor	(Site Identification - by Vendor)	4.1	572.55	40
Pre-study Site Visit (PSSV)	(Pre-Study Site Visits)	15.8	2,239.28	44
Site Approved	(Site Approval)	21.6	2,828.53	40
Site Initiation Visit	(Site Initiation Visits)	17.5	2,499.10	40
Study Drug Shipment Tracked	(Drug Shipment Tracking)	0.0	0.00	0

The comprehensive Fixed Unit Price report allows you to quickly identify proposal items that are outside of standard ranges and pinpoint overbid and underbid tasks.

Responsibilities

Clarity baseline v0 for Clarity study
Phase II / Protocol ID: PT08889
Indication: Oncology / Lung

Task and Additional Specifications	Locations	
	Argentina	Belgium
Study Setup Per Location		
Develop distribute and collect investigator meeting materials	Major CRO	Major CRO
Produce and critique country specific ICFs	Major CRO	Medium CRO
Print Investigator Brochure	Sponsor Company	Sponsor Company
Distribute Investigator Brochure	Sponsor Company	Sponsor Company
Develop distribute and collect training materials	Major CRO	Medium CRO
Obtain clinical trial application and exemptions	Major CRO	Medium CRO
Negotiate central IRB/EC	Major CRO	Medium CRO
Site Identified by Vendor	Argentina	Belgium
Identify and screen investigators	Major CRO	Medium CRO

Detailed task assignments ensure that service providers clearly understand the project scope and their responsibilities for more accurate bids and reduced change orders.



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