

Oracle Health Sciences ClearTrial Plan and Source Cloud Service Products



Oracle Health Sciences ClearTrial Plan and Source Cloud Service products leverage embedded industry intelligence and clinical knowledge to optimize clinical study planning and sourcing, as well as rationalize the deployment of R&D spending. The cloud-based software enables the compression of study timelines along with reduced costs, the accelerated delivery of accurate, defensible, achievable budgets, the reduction of outsourcing cycle times, and increased negotiation leverage.

QUICKLY AND ACCURATELY PLAN,
FORECAST, AND OUTSOURCE
CLINICAL PROJECTS

KEY FEATURES

- Embedded global clinical intelligence
- Activity-based planning methodology for Phase I-IV trials
- Support for complex study designs
- Capability to create RFPs, import vendor budgets, and compare competitive vendor bids
- Centralized, secure repository for operational and pricing data
- Fast “what-if” scenario planning
- Rapid time to value
- Precision bidding capabilities through the use of custom inputs, tasks and algorithms

Product Overview

The activity-based planning methodology in Oracle Health Sciences ClearTrial Plan and Source Cloud Service products encompasses the detailed tasks and costs required to plan a clinical study. This enables building study plans and Request for Proposal (RFP) documents from the bottom up simply by entering one’s clinical assumptions. Delivered as cloud-based, software as a service (SaaS) applications, Oracle Health Sciences ClearTrial Plan and Source Cloud Service products offer industry-proven algorithms for more than 200 therapeutic indications, specific, clinical development data and clinical research organization (CRO) labor rates for 90 countries, as well as detailed clinical, cost, and resource reports.

Monthly Budget By Major Task Ex3_Answer Key for Clarity
Phase II / Protocol ID: CLR-001-1123
Indication: Circulatory System / Lipid Metabolism
Report generated on: 29-Nov-16
All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 28-Sep-2016.
Note: Inflation has been added to the costs in this report.

Provider	Major Task/Cost	2016				2017			
		Oct	Nov	Dec	2016 Total	Jan	Feb	Mar	Apr
Major CRO	Project Initiated	4,218	18,078	18,680	40,976	19,054	17,210	19,054	6,146
	Study Setup	7,778	33,336	34,447	75,561	35,136	31,736	35,136	11,334
	Study Setup Per-Location	1,828	8,254	8,529	18,708	8,750	7,910	8,750	5,969
	A Written Protocol	13,606	44,705	0	58,311	0	0	0	0
	Protocol Amendment	0	0	0	0	0	0	0	0
	Protocol Amendment per Location	0	0	0	0	0	0	0	0
	Unique CRF Page Developed	0	0	12,323	12,323	17,711	16,997	6,285	0
	CRF Book Printed	0	0	0	0	0	0	0	0
	Meetings - Kickoff Meeting	0	25,714	0	25,714	0	0	0	0
	Meetings - Investigator Meeting - EU	0	0	0	0	0	0	0	111,679

Figure 1. Oracle Health Sciences ClearTrial Plan and Source Cloud Service products provide a detailed, monthly, budget breakdown by service provider, location, and task. Costs are reflected in the month they are projected to occur.

KEY BENEFITS

- Optimize deployment and management of R&D spending
- Increase study feasibility
- Gain 95 to 99 percent accuracy in study budgets from plan to actual costs
- Build detailed study budgets and operational plans in minutes
- Reduce outsourcing cycle times and costs
- Conduct activity-based, collaborative planning with clinical research organization (CRO) partners
- Implement program and portfolio-level planning and outsourcing
- Utilize any of 45+ pre-built reports for clinical, financial, and resource forecasting
- Gain access to seamless upgrades
- with cost model version controls

Business Value

Biopharmaceutical, medical device, and diagnostic companies are faced with the increasing complexity and cost of bringing new therapies to market. Traditional methods of using spreadsheets, generic planning software, and ad hoc planning processes have led to lengthy planning and contracting cycles, inaccurate budgets, and high variances between planned budgets and actual costs.

Oracle Health Sciences ClearTrial Plan and Source Cloud Service products provide visibility into the operational and financial study planning, as well as the ability to model new scenarios quickly, as clinical assumptions, business requirements, or outsourcing needs change. The result is more efficient and accurate clinical study planning, budgeting, outsourcing, and execution, reducing study cost and risk. It also optimizes R&D capital deployment.

Subject Enrollment By Location

1.0 ABC-9374 - Det Budget Planning v3.1 for 1.0 ABC-9374 Study
Phase II / Protocol ID: 111-0001
Indication: Oncology / Hodgkin's Disease

Report generated 22-Nov-2016

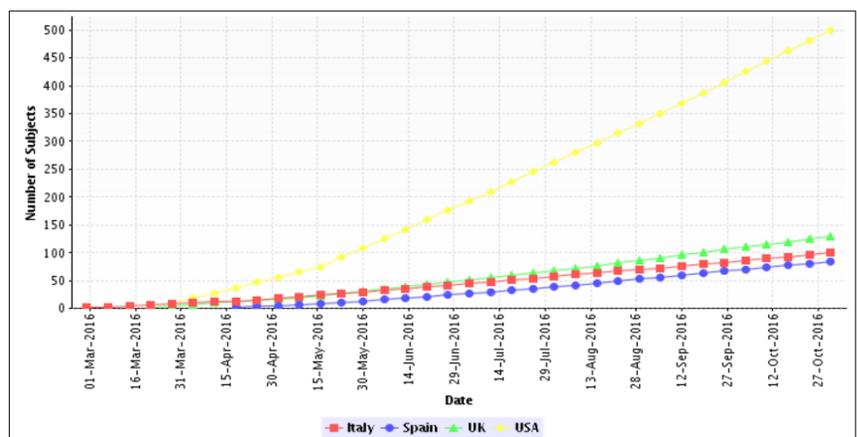


Figure 2. Oracle Health Sciences ClearTrial Plan and Source Cloud Service products offer fast, accurate visibility into the site approval curve, by week, for each location in the study.

Key Features

Oracle Health Sciences ClearTrial Plan and Source Cloud Service products leverage the following key features to deliver results:

- **Embedded global clinical intelligence.** Industry-proven algorithms are provided for more than 200 therapeutic indications with specific, clinical development data and CRO labor rates for 90 countries.
- **Activity-based planning methodology.** More than 140 documented study assumptions enable the creation of study plans from the bottom up, reflecting development goals and processes.
- **Capability to create RFPs, import vendor budgets, and compare competitive vendor bids.** RFP and Bid Management capabilities provide a mechanism to import and compare vendor budget data as submitted in response to an RFP.
- **Centralized, secure repository for operational and pricing data.** Clinical plans reside in a secure database, accessible, via a secure Web connection, to any number of users across the globe.

**ORACLE HEALTH SCIENCES
CLEARTRIAL CLOUD SERVICE
SOLUTIONS**

Oracle Health Sciences provides clinical trial operations software that makes the planning, forecasting, and tracking of clinical project and financial performance faster and more accurate. By integrating clinical operations from planning to payments, Oracle Health Sciences ClearTrial Cloud Service solutions enable dramatic internal and supplier efficiencies, as well as create cost savings for biopharmaceutical and medical device companies. Seamless software upgrades and cost model versioning eliminate the need for IT support.

RELATED PRODUCTS

- Oracle Health Sciences ClearTrial Plan and Source Standard Edition Cloud Service
- Oracle Health Sciences ClearTrial Plan and Source Enterprise Edition Cloud Service

- **Fast “what-if” scenario planning.** In just minutes, study team members can assess multiple clinical development strategies, including any combination of service providers and any outsourcing model.
- **Rapid time to value.** Delivered as a cloud-based application with an interface designed by clinical professionals, the software can deliver business value within less than one week.
- **Precision bidding capabilities through the use of custom inputs, tasks, and algorithms.** Custom input fields and tasks are created easily to reflect an organizations specific bidding requirements. These capabilities also enable the building of flexible algorithms based on an organization’s business processes.

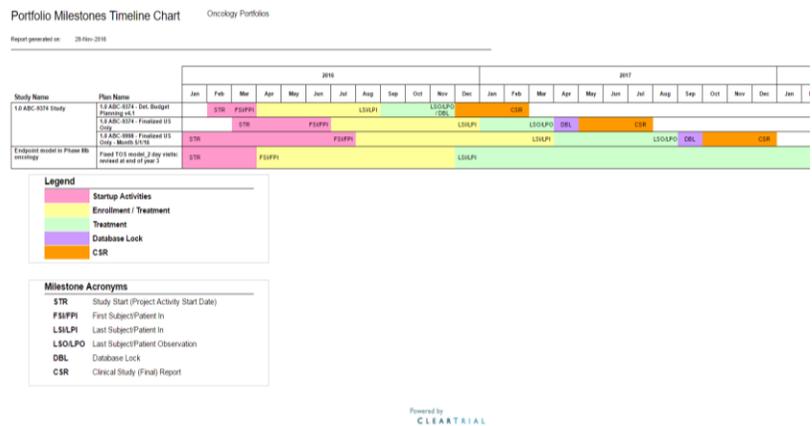


Figure 3. A graphical overview of key milestones in a portfolio.

Key Benefits

Oracle Health Sciences ClearTrial Plan and Source Cloud Service products deliver the following benefits:

- **Accuracy.** Oracle Health Sciences ClearTrial Plan and Source Cloud Service products have been benchmarked by leading biopharmaceutical and medical device companies to deliver 95 to 99 percent accuracy, when compared with actual study costs.
- **Speed.** In minutes study team members can create comprehensive, clinical project, operational plans, and detailed study budgets and RFP documents, all directly driven from clinical assumptions. Outsourcing contract closure time, also, can be accelerated by up to 75 percent while maintaining study objectives.
- **Efficiency.** Oracle Health Sciences ClearTrial Plan and Source Cloud Service products allow studies to be optimized for maximum efficiency. This shortens timelines and reduces costs, while maintaining study achievability.
- **Consistency.** The output of a set of clinical assumptions is the same no matter who builds the plan. The audit trail makes it easy to identify the most up-to-date version of the operational plan and budget, as well as any modifications.
- **Flexibility.** The software supports all clinical development methodologies and outsourcing strategies, as well as a company’s business processes. Oracle Health Sciences ClearTrial Plan and Source Cloud Service products also provide a common platform for sponsors and CROs to conduct more-collaborative development. This puts the focus on study feasibility and business value.

Provider: Sponsor Demo							
Project Initiated	(Project Initiation)	Start:	01-Feb-2016	End:	16-Mar-2016	Duration:	45ed
Task	UOM: Study	Unit	Unit Cost	#Unit	Ext Hours	Ext Cost	
Develop scope of work, timeline, work assignments		50.667	8,007.50	1	50.667	8,008	
Finalize contract (post award)		8.000	1,141.52	1	8.000	1,142	
Develop and agree with client/vendor on study metrics		0.000	0.00	1	0.000	0	
Involve senior management		0.000	0.00	1	0.000	0	
Develop project team		12.000	1,526.48	1	12.000	1,526	
Develop study operating guidelines		30.667	2,915.82	1	30.667	2,916	
Prepare project timeline (not included in develop scope of work)		20.000	4,148.88	1	20.000	4,149	
Develop resource plan (not included in develop scope of work)		8.000	1,174.24	1	8.000	1,174	
Develop detailed project budget (not included in develop scope of work)		0.000	0.00	1	0.000	0	
Develop operation plan, database tracking and project report formats		7.200	868.91	1	7.200	869	
Total		136.534	19,783.35	1	136.534	19,783	

Study Setup							
(Study Setup - Centralized tasks)	Start:	01-Feb-2016	End:	16-Mar-2016	Duration:	45ed	
Task	UOM: Study	Unit	Unit Cost	#Unit	Ext Hours	Ext Cost	
Negotiate central laboratory		21.334	2,583.34	1	21.334	2,583	
Establish committees or management structure		2.667	234.86	1	2.667	235	
Design study documents		86.000	8,493.20	1	86.000	8,493	
Review protocol		0.000	0.00	1	0.000	0	
Write Investigator Brochure		189.582	26,113.01	1	189.582	26,113	
Edit Investigator Brochure		27.082	3,730.26	1	27.082	3,730	
Develop SAE Management Plan		37.333	1,513.29	1	37.333	1,513	
Total		363.998	42,667.96	1	363.998	42,668	

Study Setup Per-Location							
(Study Setup - Decentralized tasks)	Start:	01-Feb-2016	End:	13-Jul-2016	Duration:	164ed	
Task	UOM: Location(s)	Unit	Unit Cost	#Unit	Ext Hours	Ext Cost	
Print Investigator Brochure		27.082	4,304.19	6	162.492	25,825	
Distribute Investigator Brochure		12.000	1,312.77	6	71.997	7,877	
Obtain clinical trial application and exemptions		26.667	4,162.37	6	160.002	24,974	
Total		65.748	9,779.33	6	394.491	58,676	

A Written Protocol							
(Protocol Preparation)	Start:	01-Feb-2016	End:	02-Mar-2016	Duration:	31ed	
Task	UOM: Location(s)	Unit	Unit Cost	#Unit	Ext Hours	Ext Cost	
Develop protocol		31.000	3,100.00	1	31.000	3,100	
Total		31.000	3,100.00	1	31.000	3,100	

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Figure 4. The comprehensive Fixed Unit Price report allows quick identification of the proposal items that are outside of standard ranges. It also enables Pinpoint Overbid and Pinpoint Underbid tasks.

Clinical, Medical, and Bios Services for Protoc

Bid Grid

LAM-SDP_Demo Plan for CT Product Review

Phase III

Indication: Acute

Location: Centralized

(Please enter the location name here)

All monetary values should be entered in US Dollars (USD)

Cost Type	Location	Major Task / Cost	Task	Resource	Mapping Exp	Unit of Measure	# Units	Resource Location	Base Billing Rate
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Clinical Research Associate	000-0002-0001	Study		Research, Clinical, Biostatistics/Research	15.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Senior Clinical Research Associate	000-0002-0002	Study		Research, Clinical, Biostatistics/Research	95.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Senior Vice President Clinical	000-0002-0004	Study		Research, Clinical, Biostatistics/Research	120.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Senior Director, Clinical Therapeutics	000-0002-0005	Study		Research, Clinical, Biostatistics/Research	150.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Project Admin Assistant	000-0002-0007	Study		Research, Clinical, Biostatistics/Research	199.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Data Manager	000-0002-0017	Study		Research, Clinical, Biostatistics/Research	19.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Research Manager	000-0002-0031	Study		Research, Clinical, Biostatistics/Research	150.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Medical Writer	000-0002-0034	Study		Research, Clinical, Biostatistics/Research	170.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Director Regulatory Affairs	000-0002-0024	Study		Research, Clinical, Biostatistics/Research	190.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Senior Biostatistician	000-0002-0015	Study		Research, Clinical, Biostatistics/Research	199.00
Labor	Centralized	Project Initiated	Develop scope of work, timeline, work assignments	Director Biostatistics/Data Management	000-0002-0023	Study		Research, Clinical, Biostatistics/Research	19.00

Figure 5. The software generates a scenario-specific Bid Grid report that can be used to import fees, costs, and units for the study scenario, enhancing collaborative planning and negotiation with CROs.



CONTACT US

For more information about Oracle Health Sciences ClearTrial Plan and Source Cloud Service solutions, visit oracle.com/healthsciences, email healthsciences_ww_grp@oracle.com or call +1.800.633.0643 to speak to an Oracle representative.

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Integrated Cloud Applications & Platform Services

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