Oracle Health Sciences ClearTrial Plan and Source Cloud Service Products

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HEALTH SCIENCES

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.

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.

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- 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.
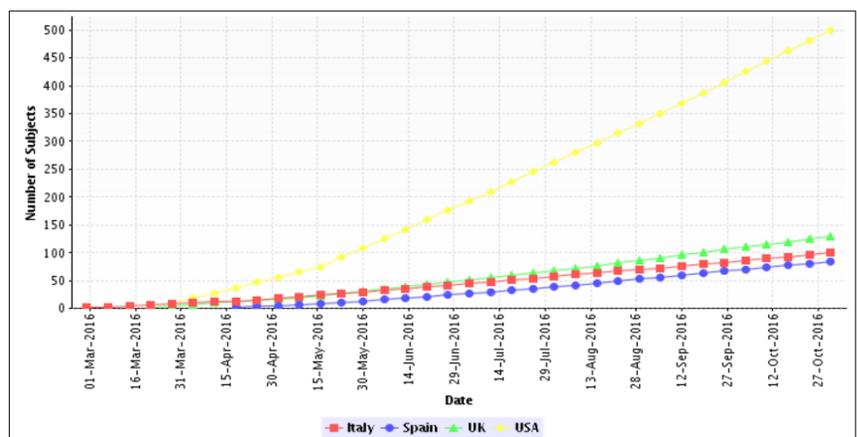

Figure 2. Oracle Health Sciences ClearTrial Plan and Source Cloud Service products offer fast, accurate visibility into the site approval curve, by week, for each location in the study.

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 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.
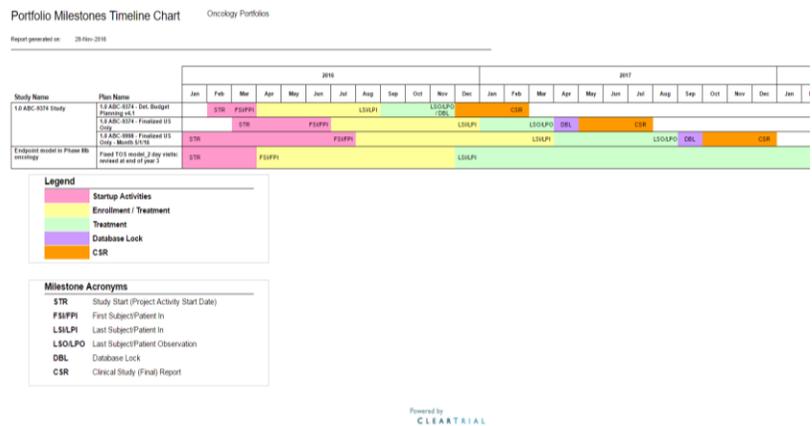

Figure 3. A graphical overview of key milestones in a portfolio.

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
		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
		363.998	**42,667.96**	**1**	**363.998**	**42,668**

Study Setup Per-Location	(Study Setup - De-centralized 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
		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

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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.

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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