



# Increasing Planning Efficiency in Clinical Development

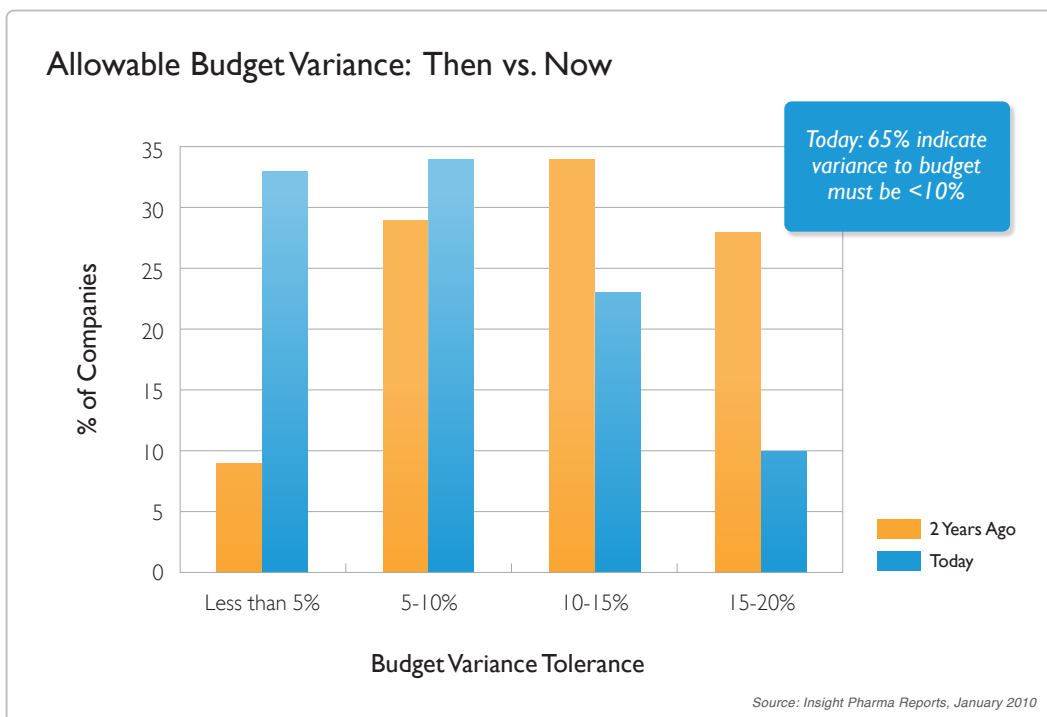
## Executive Summary

Under the current global operating environment, biopharmaceutical and medical device companies face far more limited financial resources, while time-to-market pressures are intensifying and worldwide clinical research activity is rising steadily. In response, companies are placing more demand on their planning and forecasting processes and capabilities and setting lower tolerances for variance between planned and actual performance. (See Figure 1)

Effective study planning, however, is becoming increasingly challenging for study sponsors. Factors ranging from greater complexity of study protocols to the increasingly global nature of studies are adding pressure throughout the planning process. In addition, the growing reliance on service providers such as Clinical Research Organizations (CROs) for planning, costing, and conducting clinical studies has reduced the planning visibility and control of study sponsors.

The incentive to be more efficient in study planning is increasing in parallel with the pressures described above. When companies can optimize their study planning, they achieve a higher return on R&D capital and are able to compress study planning cycle-times, reduce execution timelines, and reduce costs—while maintaining study feasibility.

This white paper explores the current landscape of planning trends and challenges in clinical development, and presents solutions and best practices that biopharmaceutical and medical devices companies are utilizing to increase planning efficiency.



**Figure 1: A survey by Insight Pharma Reports demonstrates that the industry's tolerance for budget variance is shrinking dramatically.**

## Planning Trends and Challenges Facing Clinical Development

Research<sup>1</sup> by the Tufts Center for the Study of Drug Development (Tufts CSDD) offers a first-hand look at how the industry is struggling with planning and forecasting in clinical development: “Most companies acknowledge that planning and forecasting techniques are neither sophisticated nor scientific. Many organizations report relying on institutional knowledge, politics, experience, and “gut feeling” in their planning decisions. Nearly all companies state that there is wide variability and inconsistency in planning and forecasting practices across various departments and areas within clinical development.”

The research report goes on to note that “Most of the companies interviewed state that they are frequently unable to tie their forecasts to historical data. Many do not have systems in place to archive and track past projects and activities. Even when companies are able to refer to historical data, they often find the process resource intensive and the data comparisons difficult if not incompatible.”

In addition, clinical study planning as well as reforecasting is generally conducted in departmental as well as system silos, with data pulled from multiple sources. This information travels from department to department via email which, in addition to having inherent security problems, can’t guarantee that attachments represent the correct version of the data. There is no underlying explanation of the assumptions driving the forecast, and no audit trail of changes made along the way.

This lack of a centralized repository to store planning data leads to confusion and delays among clinical operations and project management, while executive management and finance are left with a deep distrust of the plans and budgets generated. Extremely problematic at the project level, this inaccuracy makes it virtually impossible to generate accurate long-range forecasts.

Research from Insight Pharma Reports<sup>2</sup> on portfolio management performance bears this out. In a survey of clinical development and corporate strategy executives at biopharmaceutical and medical device companies, 64% of respondents lacked confidence in their one-year horizon of project timelines at the portfolio level. Yet, meeting timelines was listed as the #1 measurement of portfolio management performance. In addition, 60% of respondents lacked confidence in their one-year portfolio budgets—yet budget accuracy was listed as the #2 measuring stick for portfolio management performance. (See Figure 2 on the following page)

When asked about their planning systems and methodologies, the answers—from senior managers in clinical development, operations, and outsourcing at biopharmaceutical companies—were revealing<sup>3</sup>:

***“Do not have good handle on it now. May be taken for a ride or not.”***

– Mid-Sized Pharma

***“The models are like putting a finger in the wind of applicability of benchmark. It’s not apples to apples, not 100% predictable.”***

– Large Pharma

***“No costing model, and no forecasting. Send out RFP to CROs with what they think costs may be.”***

– Large Pharma

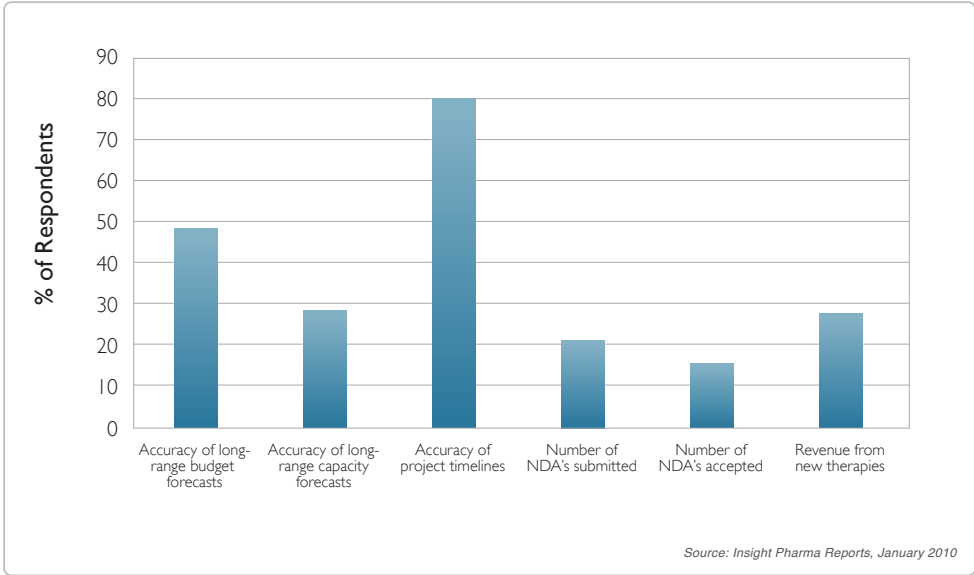
***“Wing it.”***

– Mid-Sized Pharma

<sup>1</sup>“Assessing Biopharmaceutical Company Practices in Measuring Capacity and Cost,” Tufts Center for the Study of Drug Development, September 2010

<sup>2</sup>“New Trends in Portfolio Management,” Insight Pharma Reports, January 2010

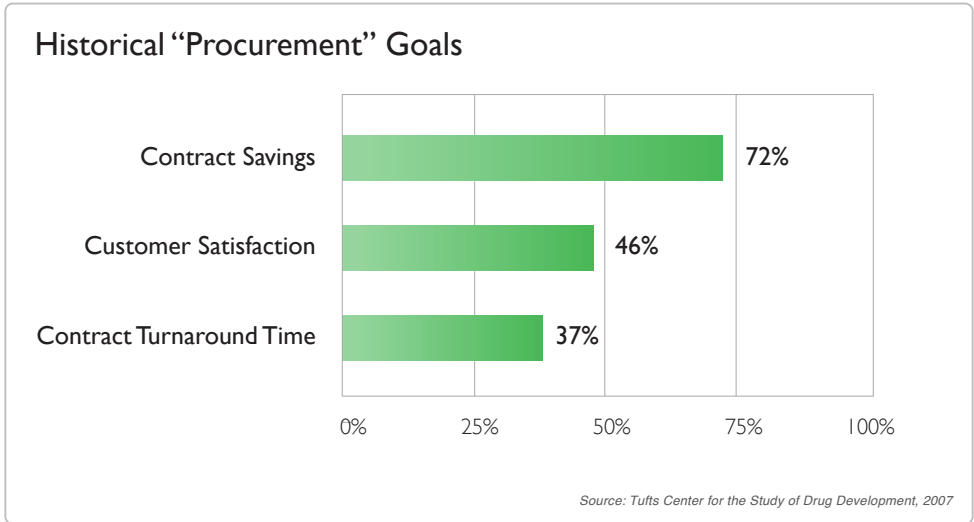
<sup>3</sup>Verbatim Responses for “Assessing Biopharmaceutical Company Practices in Measuring Capacity and Cost,” Tufts Center for the Study of Drug Development, September 2010



**Figure 2: Clinical development and corporate strategy executives at life sciences companies were asked how they measure the performance of their portfolio management function.**

Other research<sup>4</sup> by Tufts CSDD has revealed additional issues with traditional clinical planning methodologies. This research (see Figure 3) found historical practices of “fragmented and uncoordinated centers of ownership” as well as:

- Historically procurement-driven sourcing strategies.
- Limited inputs—lack of fundamental information on internal costs and capabilities.
- Planning influenced by operating dynamics.
- Limited vendor continuity and lack of trust in vendors.



**Figure 3: Historical “Procurement” Goals**

<sup>4</sup>Interviews with 31 biopharmaceutical companies by the Tufts Center for the Study of Drug Development, 2007

The result is that clinical study planning and budgeting is often:

- **Inaccurate:** 20% variance from plan to actual is often considered “acceptable,” while variances of 30% and even greater are not uncommon—amounting to millions of dollars over or under budget for a typical clinical study.
- **Time-consuming:** It can take weeks or even months to create a clinical study plan and budget.
- **Inefficient:** Traditional planning tools do not provide the ability to easily create “what-if” scenarios to optimize the operational design of a study.
- **Inconsistent:** Costs, timelines, and resource forecasts often vary depending on who creates the study plan and budget, even when the same input assumptions are used.
- **Not scalable:** Current company planning processes are highly dependent on the personal knowledge of a few individuals in an organization.
- **Not secure:** Valuable company data and intellectual property often reside in spreadsheets and in the minds of a few individuals.

### Industry Increasing Use of Software Systems That Incorporate Best Practice Methods

Historically, the life sciences industry has relied on a mix of spreadsheets, project and resource management software, databases of previously contracted prices, and ballpark estimates from CROs as study planning and budgeting tools—all of which have contributed to the planning challenges facing clinical development. New types of planning software have emerged, however, incorporating best practices from other industries and designed for the clinical study environment.

When evaluating clinical planning software, there are five important attributes that now should be on the “must-have” list of any organization, which directly contribute to greater planning efficiency:

- **Embedded global clinical intelligence:** Effective planning software should offer industry-proven algorithms for any therapeutic indication, specific clinical development data from countries where studies are being conducted, and labor rates for global, regional, and specialty CROs.
- **Activity-based planning methodology:** By building study plans from the “bottom-up” from study assumptions, new types of clinical planning software ensure that study plans reflect each organization’s unique development goals and methodology.
- **Centralized repository for operational data:** A centralized database for study plans enables institutional knowledge to be shared worldwide and across functional groups. It also allows for easy standardization of business rules and processes for planning studies, ensuring that all are following the same policies.

- **Fast “what-if” planning:** Today’s clinical planning software provides fast and accurate scenario planning at the study or portfolio level, letting companies assess multiple clinical development strategies and select the one that best meets their business goals—whether driven by cost, timelines, resources, or a combination.
- **Rapid time to value:** New models of software delivery such as Software-as-a-Service, combined with graphical user interfaces designed by clinical operations professionals, mean clinical planning software should be operational and delivering business value within 48 hours.

## In the Search for Efficiency, Outsourcing Begins to Mature in the Life Sciences

It is not news that outsourcing studies to Clinical Research Organizations (CROs) has become a key tool in the search for greater clinical development efficiencies. What is noteworthy is that, in line with other industries, life sciences is finding ways to collaborate more effectively with its vendor partners.

Tufts CSDD research has noted a rising level of integrated vendor relationships driving program-level and portfolio-level planning and forecasting: “At the same time, a growing proportion of pharmaceutical companies are entering into more extensive relationships with CROs in order to integrate systems and processes and achieve higher levels of efficiency. As such, pharmaceutical companies are transferring more operating risk to contract service providers.”<sup>5</sup>

Most of the respondents in this research also marked the importance of achieving greater transparency and deeper sharing of development cost and time data in order to exploit the efficiencies offered by more integrated relationships. They noted some important drawbacks limiting their ability to do this, however, among them the lack of standardized “bid grids” or work performance assignments. Respondents believe that a more standardized approach would go far in establishing more predictable fee-for-service costs that can be compared more easily between contract service providers.

In addition, respondents pointed to limitations they have found in traditional planning tools preventing closer collaboration, especially “an inability to account for unique project characteristics, out-of-scope and unplanned activities due to unforeseen events, and cross-functional and sponsor-CRO synergistic effects.”

These limitations are surpassed, however, with newer planning systems utilizing the best practices noted previously. For example, because an activity-based planning methodology builds study plans from the “bottom up” based on the specific tasks required to conduct the study, it is able to account for the unique characteristics of each study. In addition, activity-based planning provides the flexibility to easily and accurately reforecast studies due to out-of-scope and unplanned activities, simply by entering new clinical assumptions based on the new business requirements.

## Benefits of Implementing Clinical Planning Software Incorporating New Principles

*“The biotech compressed the CRO contracting cycle time from over three months to two weeks, and saved \$600,000 on a single Phase II contract. An unforeseen but positive consequence was a shift toward a more constructive and collaborative working relationship between the biotech and the CRO.”*

*“Biotech’s Long Road to Savvy,” Applied Clinical Trials, January 2012*

*“The software offers capabilities that are crucial to achieving more cost-effective clinical studies and a more open cost dialogue with contract research organization (CRO) partners. It enables the creation of more-comprehensive and accurate clinical study plans and budgets that are so elusive to life science companies, which are seeking to reduce costs and increase accountability.”*

*“Cool Vendors in Life Sciences,” Gartner, April 2011*

*“What we’ve found is that activity-based costing (ABC) software supports planning best practices. We find we’re consistently within 5% variance from plan to actual—and being within 1% to 3% is well within our expectations.”*

*“An Assessment of 5 Clinical Study Costing Methods,” Life Science Leader, January 2011*

*“The experience of Abbott Vascular suggests software can be a key enabler of otherwise elusive efficiency gains. Last year, the software helped the device maker keep clinical trial spending within a mere 1% of target.”*

*“Efficiency vs. Operation Readiness,” Bio-IT World, March 2010*

*“We performed comparisons of completed trials to what the system would have predicted as the total budgets. In all of these tests, the estimate came within 5% of our actual costs.”*

*“Better Quantifying Clinical Trial Costs,” Life Science Leader, November 2009*

<sup>5</sup>“Assessing Biopharmaceutical Company Practices in Measuring Capacity and Cost,” Tufts Center for the Study of Drug Development, September 2010

Leading biopharmaceutical and medical devices companies are also utilizing new types of planning software to link different functional areas, from clinical operations and outsourcing to project management and finance, into an efficient and centralized planning function. The software acts as the “backbone” integrating the different organizational functions, anchored by a single repository that holds industry standards, business rules, and plans and forecasts accessible by any authorized person, from anywhere in the world, at any time—ensuring that all functions are speaking the same language for consistent and highly efficient study planning.

Finally, a very few forward-thinking biopharmaceutical organizations are extending this “backbone” to include their CRO partners for more efficient collaboration. They are leveraging global clinical intelligence, a single repository of data, and activity-based planning methodology to build common unit pricing and resource rules—allowing both the sponsor and the CRO to build study plans and budgets together. The result is a focus back on the study’s clinical assumptions and study feasibility; complete understanding by both parties of their responsibilities; and the elimination of a prolonged RFP-bidding-contracting cycle time, thus shortening the timeline of the study itself.

## New Software Approaches Offer Important Benefits for Clinical Development Efficiency

The features of newer planning software enables study sponsors to conduct more effective study planning, gaining significant benefits.

### Clinical Development

With visibility to the operational and financial plan for a study, and the ability to quickly and easily create “what-if” scenarios based on clinical assumptions, clinical development groups at biopharmaceutical and medical device are compressing clinical study planning cycle-times from months to weeks while reducing study costs by millions. (See Figure 4)

Fee and Cost Comparison				
Report generated on: 24-Aug-2010				
All monetary values are displayed in US Dollar (USD) based upon individual plan exchange rates.				
Note: The first line of each cell contains the cost, the second line contains the effort in hours (not applicable for pass through costs).				
Cost Name	Clarity baseline v0	Clarity v1.1	Difference	% Difference
Project Initiated	96,653	81,275	-15,378	-15.9 %
	541.8	527.4	-14.5	-2.7 %
Study Setup	42,291	35,023	-7,268	-17.2 %
	229.2	229.2	0.0	0.0 %
Study Setup Per-Location	61,154	49,967	-11,186	-18.3 %
	436.5	429.4	-7.1	-1.6 %
A Written Protocol	26,377	21,074	-5,303	-20.1 %
	153.0	153.0	0.0	0.0 %
Unique CRF Page Developed	58,216	45,147	-13,069	-22.4 %
	280.8	280.8	0.0	0.0 %
CRF Book Printed	9,954	13,627	3,673	36.9 %
	67.4	91.5	24.1	35.6 %
Site Identified by Sponsor	0	0	0	
	0.0	0.0	0.0	

Figure 4: New planning software enables quick and accurate “what-if” planning to determine the best approach based on the business requirements—whether driven by cost, timeline, resources, or a combination.

## Case Study: “What-if” Planning at a West Coast Biotech

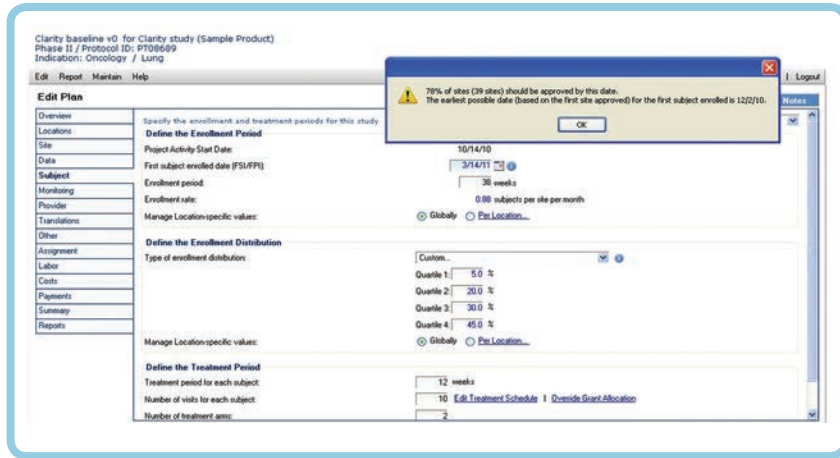
A West coast biotech was planning a Phase II study while switching to an Electronic Data Capture process. They chose to discard their existing spreadsheet-based process and utilize software incorporating activity-based planning and other key principles of newer approaches in clinical planning software.

Using the software, they quickly created several scenarios evaluating the schedule implications and regulatory considerations of adding more global locations, as well as the cost and schedule efficiencies gained by using EDC. The software generated detailed monthly budget, site approval and patient enrollment graphs based on a baseline each “what-if” scenario, enabling them to easily compare scenarios to choose the operational design that best fit their business goals.

The results:

- Gained cost savings of ~\$2M due to EDC implementation
- Avoided cost of \$450K based on a review of statistical requirements for patients randomized/completed
- Weighed tradeoffs of cost vs. schedule considerations of adding China sites and decided to incur 3-month timeline increase to gain cost savings of \$967K
- Avoided cost of \$47K through optimization of required resources in support of critical milestones
- Overall savings: \$3.3M

They are also compressing study execution timelines by optimizing the operational design of the study. And with the embedded clinical intelligence providing guidance based on the clinical assumptions entered and industry standards, study sponsors are reducing their study risks at the same time. (See Figure 5)



**Figure 5:** With embedded global clinical intelligence and activity-based planning, new types of planning software allow clinical professionals to optimize a study for cost, timeline, and resource utilization, while maintaining study feasibility.

### Clinical Operations

By providing fast and accurate forecasts of costs, FTE demand, milestone dates and more, new planning software is allowing clinical operations groups at study sponsors to accelerate delivery of accurate, defensible, and achievable study budgets. They are able to create ballpark study budget plans in less than 30 minutes, and reduce the end-to-end study budgeting process from weeks to hours. In addition, comprehensive clinical, resource, and cost reports allow them to justify budget and headcount requests, validated against 3rd-party industry intelligence. (See Figure 6)

Monthly Budget By Major Task

Clarity baseline v1 for Clarity  
Phase II / Protocol ID: PT086  
Indication: Oncology / Lung

Report generated on: 16-Aug-10

All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 15-Apr-2010  
Note: Inflation has been added to the costs in this report.

		2010			2010 To
		Oct	Nov	Dec	
Major CRO	Project Initiated	3,946	6,577	6,796	17,319
	Study Setup	2,574	4,290	4,433	11,297
	Study Setup Per-Location	2,242	3,736	3,861	9,839
	Unique CRF Page Developed	0	15,963	29,108	45,071

**Figure 6:** Activity-based planning and embedded global clinical intelligence allows for detailed and accurate cost breakdowns by service provider, location, and task, with costs reflected in the month they are actually incurred.

### Case Study: A Global Search for Planning Efficiency

A Top 20 biopharmaceutical company recently launched an exhaustive and global search for a new system to meet their needs for greater efficiency in planning and forecasting. Business drivers for the search included an inaccurate and inconsistent study plans and budgets, as well as a time-consuming planning process. Historical planning methods in use included an internal cost modeling tool built in Excel; requesting ballpark budgets from CROs, regardless of whether the study would be out-sourced; and guesswork based on gut feel or previous study experience.

The company established strict criteria for the new solution. It would have to be:

- consistently accurate to within 95% of actual costs
- easy to use for clinical people
- support fast development of different study scenarios
- provide extensive supporting data (e.g., therapeutic indication, phase, country-specific information)

Conducting a global search for a new planning solution, the company looked at internally developed tools, at solutions offered by CROs, and solutions offered by the industry at large. The company quickly ruled out internally developed systems as they were all based on spreadsheets and had the same limitations as current solutions. It ruled out CRO systems due to concerns about maintaining sufficient control and oversight, the large amounts of proprietary data, and a sample size limited to the CRO that provided the system.

Industry solutions held more promise. However, the company ruled out cost benchmarking tools as these could not accommodate the unique characteristics of a study, had limited scenario planning capability, and required the company to provide data back to the vendor system, which was deemed impractical and burdensome.

Ultimately, the Top 20 sponsor found that new planning software incorporating an activity-based planning methodology and embedded global clinical intelligence exceeded all key search criteria:

- 97% accurate compared with actual costs
- Easy for clinical people to use by building study plans from the “bottom up” simply by entering clinical assumptions
- Took only 90 minutes to create a highly detailed study plan with multiple scenarios
- Came with an extensive and regularly updated repository of clinical data (e.g., 160 different therapeutic indications, 80 countries with local labor rates)

The result? The sponsor selected the new software system and mandated its use as the global planning and budgeting system.

### Clinical Outsourcing

With visibility into industry-standard study hours, costs, and resources—combined with intelligence on CRO labor rates—clinical outsourcing professionals are reducing outsourcing cycle-times while increasing their negotiating leverage. They are doing this by quickly generating study RFP specifications based on a minimal number of clinical assumptions, automatically updating RFP’s when assumptions change; easily assessing CRO bids and rapidly pinpointing discrepancies; and reducing the disruptive nature and impact of change orders with clear, comprehensive unit price schedules. (See Figure 7)

Fixed Unit Prices		Clarity baseline v0 for Clarity study Phase II / Protocol ID: PT08689 Indication: Oncology / Lung				
Report generated on: 31-Aug-2010						
All monetary values are displayed in US Dollar (USD) based upon exchange rates as of 15-Apr-2009.						
Note that for display purposes, all extended costs are rounded to the nearest whole US Dollar, and all times are rounded to the nearest tenth of an hour.						
Provider: Major CRO						
Major Task Name		Unit Hours	Unit Cost	# Units	Ext Hours	Ext Cost
Project Initiated	(Project Initiation)	175.4	30,994.83	1	175.4	30,995
Study Setup	(Study Setup - Centralized tasks)	133.2	22,808.71	1	133.2	22,809
Study Setup Per Location	(Study Setup - De-centralized tasks)	169.3	22,282.66	2	338.5	44,565
A Written Protocol	(Protocol Preparation)	153.0	26,376.76	1	153.0	26,377
Unique CRF Page Developed	(CRF Development)	23.4	4,851.35	12	280.8	58,216
CRF Book Printed	(CRF Printing)	0.2	26.26	379	67.4	9,954
Site Identified by Vendor	(Site Identification - by Vendor)	4.1	572.55	40	163.0	22,902
Pre-study Site Visit (PSSV)	(Pre-Study Site Visits)	15.8	2,239.28	44	695.2	98,528
Site Approved	(Site Approval)	21.6	2,828.53	40	864.6	113,141
Site Initiation Visit	(Site Initiation Visits)	17.5	2,499.10	40	700.0	99,964
Study Drug Shipment Tracked	(Drug Shipment Tracking)	0.0	0.00	0	0.0	0
Meetings (Investigator)	(Investigator Meetings)	237.0	43,487.22	2	474.0	86,974
Meetings (Non-Investigator)	(Meetings - other)	34.5	4,972.90	1	34.5	4,973
Completed Statistics & Analysis Plan (SAP)	(Statistical Analysis Plan)	108.3	21,186.90	1	108.3	21,187
Subject/Volunteer Randomized	(Subject Randomization)	0.1	22.93	270	36.5	6,192

Figure 7: Software incorporating an activity-based planning methodology and with embedded global clinical intelligence enables sponsors and their CRO partners to negotiate contracts from clear, comprehensive unit price schedules.

### Conclusion

Leading biopharmaceutical and medical device companies are demonstrating that it is possible to achieve higher returns on their R&D capital by optimizing study planning. These companies have gained the capability to conduct quick and accurate “what-if” scenario planning, as well as greater visibility to the operational and financial plan for a study. They are seeing the benefits in dramatically compressed study planning cycle-times, reduced execution timelines, and reduced costs—while maintaining study feasibility.

### 5 key characteristics to look for in study planning software

When evaluating clinical study planning software, there are some important attributes that should be on the “must-have” list of any organization. With today’s industry pressures and the advances in software development, there is no reason to settle for less.

#### Accuracy

Forecasted study costs should be 95-99% accurate when compared with actual study costs.

#### Speed

Creating comprehensive clinical trial operational plans and detailed study budgets should take minutes rather than days or weeks.

#### Flexibility

The software should support, out of the box, an organization’s unique business processes and goals, as well as new development methodologies.

#### Consistency

The same input assumptions should result in the same output every time, from person to person and across functional areas.

#### Ease of use

Clinical people should be able to easily build study plans and budgets simply by applying their clinical knowledge and expertise, without being technology, financial, or project management experts.

