

# PLANVIEW APPROACH TO SERVICES RESOURCE PLANNING FOR CLINICAL RESEARCH ORGANIZATIONS



A single pharmaceutical clinical trial can cost up to USD \$100 million. No one has to underscore the dramatic nature of the risk-reward ratio of what you're managing.

No matter the offering: in the pharmaceutical arena, the stakes are high. Be it a medical device or drug, the competition is sharp, regulations are convoluted (and ever changing!), and your resources — the one area nominally within your control — are working harder than ever as unpredictable fluctuations in demand limit your abilities to create workable, strategic allocation plans.

## The Rising Costs

Costs keep rising: what's driving the increase? In a word, resources.

In the U.S., recent research shows that, from 1999 to 2005, the average length of a clinical trial rose by 70%; the average number of routine procedures per trial rose by 65%; and the average clinical trial staff work burden rose by 67%.<sup>1</sup> And with FDA regulations growing in complexity, these percentages (and their attendant costs) are only going up.

CHANGES IN CLINICAL TRIALS			
Function	1999	2005	Percent Change
Median procedures per trial protocol (e.g., blood work, routine exams, x-rays, etc.)	96	158	65%
Average clinical staff work burden, work effort units	21	35	67%
Average length of clinical trial, days	460	780	70%

In Europe, the impact of the well-intentioned but overly strict 2004 EU Clinical Trials Directive has been such that clinical research organizations (CROs) are seeing their manpower costs essentially doubled.<sup>2</sup> As a result, the number of new trials in Europe between 2007 and 2011 dropped by a quarter<sup>3</sup>, and companies are fearing for their ability to remain competitive.

## Services Resource Planning: Your Key to Balancing the Cost of Capacity

To prove the safety and efficacy of new products, your organization creates complex studies, which require substantial staffing for both strategic and operational support. As we have seen, this staffing contributes not insignificantly to the overall costs of the studies themselves; optimizing these resources can drive costs out of your studies while enabling your organization to ensure:

- More effective use of resources, such as clinical monitors, investigators, and research partners
- Better communication and alignment across study sponsors, partners, and investigators
- Improved resource budgeting and financial visibility between study sponsors and partners
- Rapid response to changing circumstances that would otherwise consume resource time

Effective resource planning comes down to having the right people in the right place at the right time — to strategically plan your capacity holistically for the entire portfolio of compounds or device ideas, allocate your staff and partners to studies, and respond to change as circumstances demand.

## Close the Gap: From Fragments to Whole

Many CROs use software tools that provide project and resource managers with just a snapshot of how resources are allocated and utilized against any given study segment or phase. Few CROs have the ability to holistically view all resource pools against both the totality of a study and the complete portfolio of all studies, so that resource managers can take informed operational action while process and service executives can make intelligent strategic decisions.

For CROs to shorten bench-to-market time and create more efficient study performance processes, they must close this gap between all the snapshots of resource views to form a complete, accurate, and real-time picture that will enable:

- Faster trials at a lower cost by linking strategic and operational resource activities
- Fewer problems with the ability to respond to changing conditions
- Enhanced relationships with partners

<sup>1</sup> *Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials*, Manhattan Institute for Policy Research, April 5, 2012

<sup>2</sup> *EU red tape making drugs trials 'impossible'*, The Telegraph Media Group, February 13, 2012

<sup>3</sup> *Ibid.*

Services Resource Planning (SRP) solutions deliver this holistic view, taking the clinical research organization from a place of managing demand all the way through performance analysis. Let's examine the capabilities these solutions encompass in some depth.



**Take Control of Demand**

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You must accurately assess committed and forecasted studies and trials to avoid costly resource fire drills that can threaten your performance, efficiency, and margin. Look for a solution that gives you the tools to accurately identify study requirements and assess scope, with features like:

- A user-friendly, centralized location to do things like request work, delegate requests, review lifecycles and check status
- Automated user alerts and easy-to-read dashboards to quickly remediate resource utilization issues
- Easily accessible reports to analyze demand trends, simplify workflow, and improve overall performance

**Maintain Optimal Capacity Levels**

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Only by accurately monitoring your organization's capacity at any given moment can you effectively balance your resources against portfolio demand. Look for a solution that gives you the ability to:

- Understand how capacity and demand align across various resource pools
- Highlight where capacity gaps and excess exist
- Dynamically plan and deploy resources where the need is greatest or the margins are highest

**Commit Resources with Confidence**

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This is the core of an SRP solution. The #1 capability to look for is an interactive view of supply and demand. This dynamic approach means that when you need to move resources, you know exactly how other existing studies are affected, to optimize backfill resource choices. Also look for robust scenario-planning support in what-if analysis, that will enable you to evaluate and prioritize many different contingency plans to find the one that best meets your organization's needs, both as you develop your plans and you adapt plans to evolving conditions. Other important features are the ability to:

- Optimize resources by both financial axes (like cost, revenue, and margin) and people axes (like skills and geography)
- Create resource pools based on attributes like expertise, role, or location
- Speed deployment by developing custom resource templates that address common study scenarios
- Build teams using resources from multiple pools

**Analyze and Optimize Study Performance**

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Not all SRP solutions provide adequate analytics; as resources represent a prodigious share of study and trial costs, it is vital that an SRP application provide the kind of analytics and reporting that will help you drive stronger performance, optimize processes, and achieve better margins.

Leverage reporting and analytics during and after a study to shed light on the variance between planned results and actuals in terms of trial costs, margins, and profits. This helps you determine accurate baselines, accurately quote new trials, and promote a healthy bottom line. And you can mitigate negative impacts on study margins by continually monitoring the replanning it requires through the lens afforded you through the right reporting tools.

Plus, you can improve partner relationships by communicating better on financial resource transparency and performance expectations. Strong SRP analytics and reporting will help you:

- Better understand resource and study costs, margins, and profits, and communicate their impact
- Track and report time worked and expenses
- Mitigate risks and issues such as delays
- Analyze trends on work, resources, and milestones



### Interface with and Get More from Your Existing Systems

CROs everywhere already rely on extensive — and expensive — software suites to support everything from designing new study protocols to reimbursing partners. Your SRP solution should easily interface with your extant infrastructure to help you get the most complete picture possible, what some call “one source of truth,” and share insights across the continuum of your clinical study management software.

Look for vendors who have developed APIs, integration platforms, or other prebuilt interoperability mechanisms that offer a seamless interface between their SRP solution and your existing systems. Avoid systems that require that you develop custom hooks between the SRP tool and your CTBBT, CTMS, CTSM, and other tools, as these can be complex and often fail when a new version of one system is released.

Another system to look for: Project and portfolio management (PPM). According to leading analysts, PPM can help you with integrated support for planning cycles and milestones, study financials, and schedules, as well as the resource management tools you need to bring for studies and trials to completion on time and budget.

### Get Visibility into your Resources

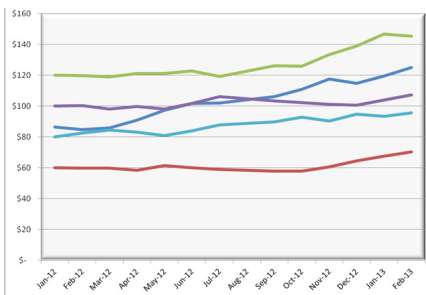
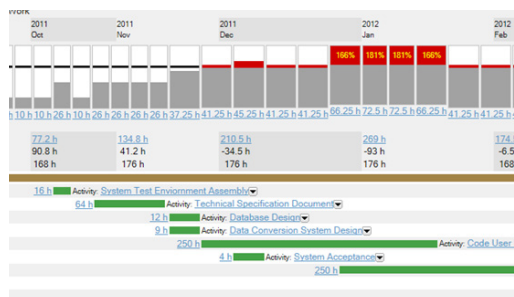
Analytics and reports are your key to understanding and communicating upwards and to your partners the status of your studies. Not all SRP solutions are created equal when it comes to this vital capability: be sure to look for analytics and reporting that are powerful yet easy to use, both out of the box and configured to your custom needs.

Some solutions also offer extra accessibility features, such as availability via mobile devices, intranets, or email. This can be useful not only if you’re on the go, but also if you’re looking for a way to offer views to executives or other stakeholders who don’t necessarily need a resource manager’s detailed view.

Some of the things that the right analytics can help you do include:

#### Conduct Resource Capacity Planning:

A graphical representation of scheduled resource capacity across projects can consolidate the view of your resource pool and show you which resources will be available when.

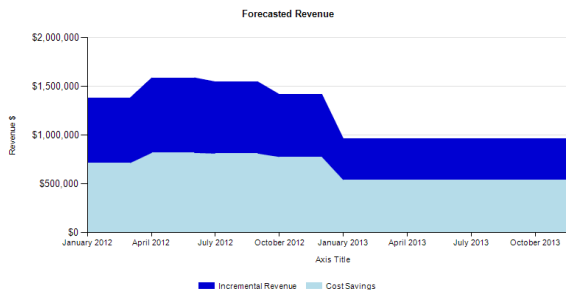


#### Compare Roles by Rate:

Track roles by rate and see how they have trended over time to optimize study resource cost decisions.

#### Forecast Revenue:

For service-focused organizations, the ability to forecast revenue is a key driver in the planning process and vital in driving the business in the right direction.



There's no one-size-fits-all solution when it comes to planning your resources. The smart approach is to find the right vendor with the right solution for you, one that will help you close the gap and create the comprehensive view you need.



Once you know what to look for, you'll be empowered to seek out a vendor partner with proven technology to help you:

- Deliver studies on time, within budget, and at target margins
- Improve the productivity of your resources and satisfaction of partners
- Increase accuracy of forecasts and simplify planning

Planview has been building this kind of technology for more than 20 years, so we know what it takes to understand, optimize, and plan for resource consumption across roles, skill sets, studies, and geographies. We can help you see around the corners when it comes to deploying a flexible, large-scale solution, be it SaaS or on-premise. And our solutions grow with you and easily interface with your existing systems: use what you need, build on early wins, and leverage more of our end-to-end approach as your requirements evolve.

Ready to learn more?

See how other CROs are getting the most from their studies, see special videos and demos, and more at [Planview.com/CRO](http://Planview.com/CRO).