



# Increasing Clinical Trial Data Management Efficiencies by Utilizing a Satellite Office Model

*For pharmaceutical, biotechnology, and device companies (Sponsors) seeking increased efficiencies from their clinical trials, it is essential to create flexible/scalable solutions, contain costs, improve quality, streamline the work flow, and enhance productivity.*

Efficiently acquiring, reviewing, and processing study data that are critical to clinical studies are measurable ways to reduce costs, increase efficiencies, optimize labor, and improve process management. A data management model that is scalable, that integrates seamlessly into the Sponsor's operations, that provides economies of scale, and that improves time and cost savings allows Sponsors to: improve the control of clinical trials; provide better on-time delivery of programs; and markedly reduce the overall costs compared with other traditional outsourcing strategies.

RPS is the industry's first Pharmaceutical Resource Organization (PRO) built to offer unique, integrated global solutions to the Pharmaceutical, Biotechnology, and Medical Device industries. By combining an experienced clinical research operations infrastructure with the industry's largest resourcing engines, RPS is able to provide its customers with the highest quality services through innovative, cost effective, integrated functional clinical development solutions that speed the development of new life-changing therapeutics.

*A resource-based costing model absorbs the clinical trial variabilities without cost overruns.*

## **Outsourcing Challenges**

Clinical data are the most important, and often the most costly, part of a trial. A significant portion of trial costs result from inefficient use of labor required to move the data from the CRF to database for locking. By effectively controlling the data management process, costs can be curtailed, cleaner data can be mined, and time to

database lock can be improved. This involves an integrated process that moves the data to the right place at the right time. For clinical trials this means properly managing the processes required to capture, record, analyze, and store data.

*R&D remains a  
core Sponsor competency;  
resourcing is not.*

### **The Cost of Clinical Data Management**

In recent years, the debate has increased over whether clinical research is a core competency of Pharmaceutical, Biotechnology, and Device companies. Several experts and analysts have indicated that the future outlook for the clinical research sector may be based on more virtual alignment with Sponsor companies as they focus on sales, marketing, and manufacturing as core competencies. In line with this view, experts and analysts cite that outsourcing will continue to increase at a rapid pace and that the contract research organization (CRO) sector will flourish as principle experts in this arena.

Another view is that clinical research and development are absolute core competencies and that the true expertise lies within Sponsor companies. What is not a core competency of Sponsor companies is resourcing, and like other industries, this function has been delegated to outside vendors (Business Process Outsourcing structures). Resourcing management is defined as the ability to attract and manage clinical resources and to adapt to the strong ebbs and flows that exist in this industry.

A Pharmaceutical Resource Organization (PRO) model leverages internal systems and processes and allows for resourcing management to be overseen by another entity.

An efficient way to bridge this resource management gap, especially as it relates to clinical data management, is the ability to integrate a solution that would take advantage of economies of scale and existing IT and personnel infrastructures. Moreover, this combined solution — or Satellite Office — offers an integrated outsourced “crust and mantle” process that surrounds the Sponsor’s core capabilities and resources and allows for the development of best clinical practices through joint expertise collaboration. The result is a solution that is scalable, cost effective, and

flexible. The full implementation of this model has opportunities for both tangible (straight cost of personnel) and intangible (quality and trial completion) cost savings.

*By leveraging an experienced staff, the Satellite Office team builds relationships and collaborates with the Sponsor to develop solutions to operational and nonoperational issues.*

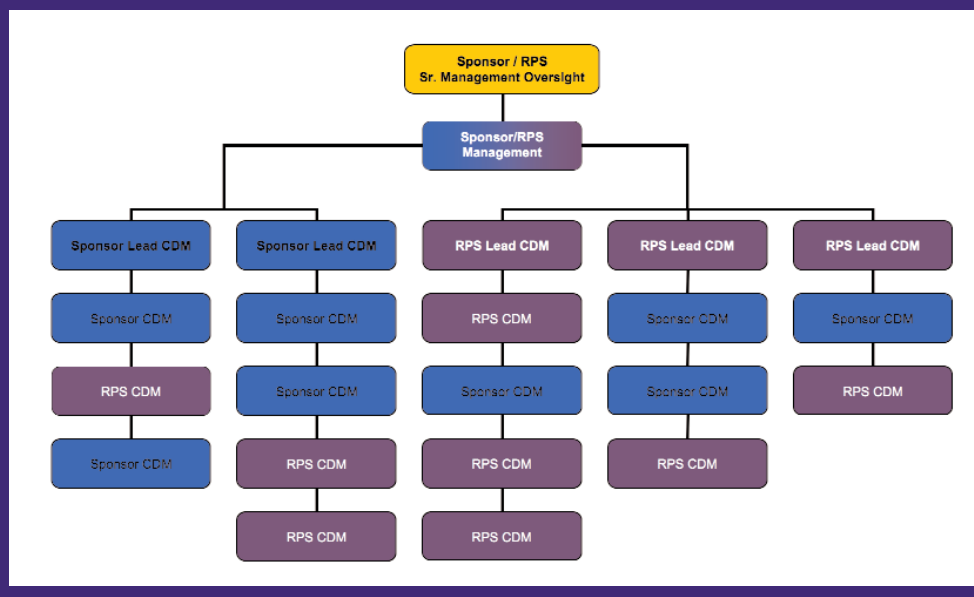
## The Satellite Office Solution

A Satellite Office can overcome the challenges of handling clinical data, resulting in a highly effective, integrated clinical data management process that returns greater efficiencies and cleaner data. This flexible solution can be customized to meet the unique needs of each Sponsor from a standalone integrated model to one protocol to an entire pipeline.

- **A Program Integrated Solution**

With a Program Integrated Satellite Office Solution, the project team members are comprised of both Sponsor and RPS industry professionals. This team functions cohesively under a joint management infrastructure thus allowing for geographic flexibility utilizing technology to streamline communication and efficient workflow.

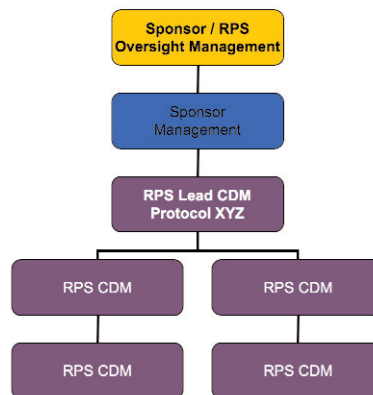
## Program Integrated Satellite Office Solution



- **A Protocol Specific Solution**

A Protocol Specific Satellite Office Solution is designed to integrate with Sponsor operations on a project level (single or multiple protocol scenarios) from specific tasks to the entire data management process.

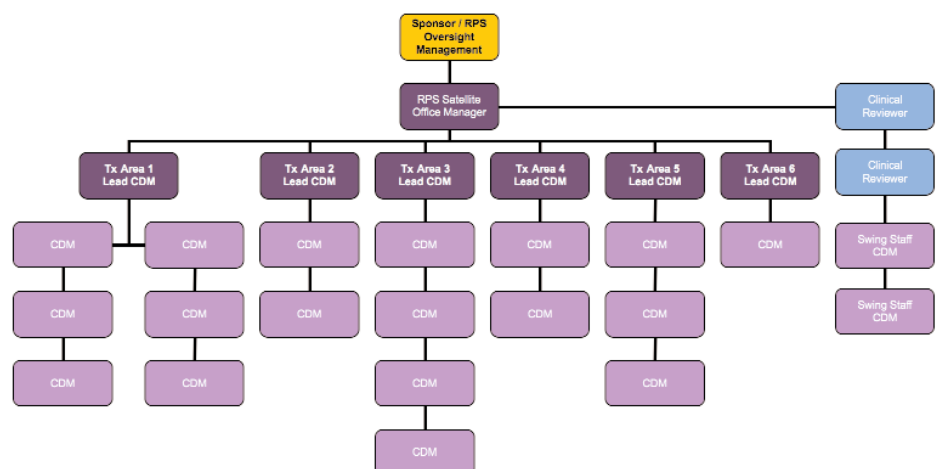
## Protocol Specific Satellite Office Solution



- **A Pipeline Down Solution**

The Pipeline Down Satellite Data Management Solution provides an encompassing partnership to handle all Sponsor data management programs across various therapeutic areas.

## Pipeline Down Satellite Office Solution



A highly efficient Satellite Office model can:

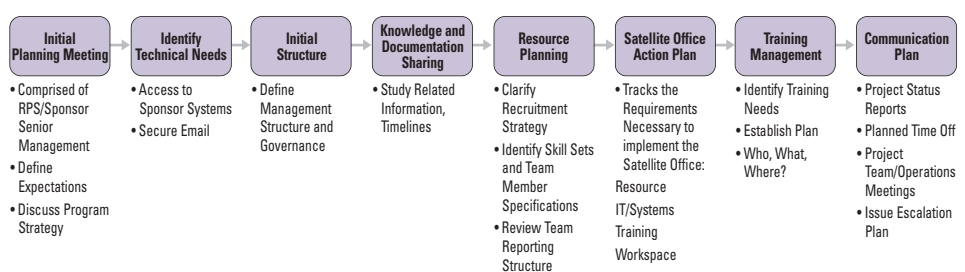
- **Maintain strategic control** — Because the Satellite Office team utilizes the Sponsor's SOPs and systems, the data-management plan is designed to meet the needs of the individual Sponsor. In this way, the Sponsor maintains control over its studies and the way that the data are managed.
- **Enhance flexibility** — The Satellite Office team works seamlessly in conjunction with all functional areas of the Sponsor company. The Satellite Office model retains the ability to expand or contract with the ebs and flows of clinical development providing the Sponsor with greater flexibility. Team members also serve as ambassadors of the Sponsor company and they work directly with all third-party vendors.
- **Increase cost efficiencies** — A resource-based costing model absorbs the clinical trial variabilities without cost overruns. Historically, the resources average well beyond the required agreed upon hours per week.
- **Promote team unification** — The Satellite Office team becomes part of the Sponsor's internal team. The team has a true understanding of the Satellite model and a knowledge of the Sponsor's vision, goals, and values.
- **Capitalize on the experience of seasoned Data Management Professionals** — This allows the staff to hit the ground running for any project. RPS brings a team of highly experienced data management professionals, with an average experience of eight years, to the project.
- **Alleviate geographic and facility constraints**
- **Improve oversight** — A Satellite Model includes oversight management at multiple levels. This high-level support is responsible for providing integration, guidance, and governance of the project.

*To ensure the success of a data-management project utilizing a Satellite Office model, the partner should understand the requirements and pain points of the Sponsor.*

## Satellite Office — Partner Selection Considerations

- **Integration**
  - Utilization of Sponsor infrastructure, systems, and SOPs
  - Collaborative IT support
- **Experience**
  - Hand-selection of experienced resources based on Sponsor’s specifications
  - Less oversight required
- **Consistency**
  - Higher level of team commitment and quality
  - No loss of time and costs associated with re-training
- **Cost Efficiencies**
  - Resource-based costing model resulting in less variability and changes in scope
- **Scalability**
  - Ability to ramp up/ramp down quickly
  - Ability to shift resources based on project demands
  - Dedicated resources that serve as an extension of existing Sponsor team
  - Resource planning and forecasting through joint planning and operations

## Process of Integration and Becoming a Seamless Operation



To ensure the success of a data-management project utilizing a Satellite Office model, the team should understand the needs of the Sponsor and provide:

- **A Communication Plan** — It's vital to establish and continually re-evaluate a communication plan. The team needs to maintain an open, honest, daily, and transparent relationship; provide immediate notification of potential/actual issues; and evaluate what works well and what does not and apply learnings for future growth.
- **A Collaborative and Cooperative Management Approach** — This includes monitoring team productivity, reviewing metrics, and recognizing milestones.
- **A Level of Trust** — Establishing trust through the collaborative selection of team members and providing examples of proven team commitment and productivity.

### The RPS Satellite Office Model

As the industry's first PRO, RPS offers a multitude of solutions, including satellite office models, to create a highly efficient data management process.

Designed to meet all of the requirements outlined in this paper, in addition the RPS Satellite Office model employs several best practices to ensure the success of a data management project, including:

- Listening to Sponsors' needs and understanding Sponsors' goals
- Developing a Bipartisan Charter
- Ensuring that Information Technology from both the Sponsor and RPS are on the same page with Operations
- Ascertaining that the right people (integrity, industry knowledge, soft skills) are on the project and allowing the Sponsor to take part in the interviewing process
- Delivering a high-quality product on time and on budget — consistently
- Eliminating the “us-vs.-them mentality” and focusing on a “team approach” to conducting data management
- Developing metrics to facilitate performance measurement and to identify opportunities for continual improvement
- Shifting resources based on project demands

The Satellite Office solution is just one of many offerings RPS has for tactical or full-service partnerships. The Satellite Office solution, except for the database hosting, can become a full-spectrum solution for all clinical trial functions — from database build (IQ, OQ, and PQ) using CDISC Standards 3.1 to data entry, data management, and coding of all trials from Phase I to IV using traditional, to Electronic Data Capture (EDC) standards.

*Schering-Plough  
Research Institute*

*Because RPS's Satellite  
Office staff works within  
SPRI's systems, the  
economies of scale and  
benefits are significant.*

*The total cost for two  
very similar studies was  
about one-third when using  
the RPS Satellite Office model  
vs. a traditional CRO model.*

### **Benefits of a Satellite Office Model: Case Study**

The leadership mission of RPS is to improve clinical data management through integrated solutions, including its core expertise in developing a Satellite Office model, as well as through its various other integrated solutions, is complemented by year-long participation and sponsorships of associated conferences.

In October 2006, RPS was a Sponsor of the Fall Society for Clinical Data Management conference held in Buena Vista Palace, Lake Buena Vista, Florida.

At this meeting, RPS thought leaders presented case studies featuring Client/Sponsors that are utilizing the integrated clinical data management Satellite Office model.

According to Carolina Cubillos, Associate Director, Clinical Data Management, at Schering-Plough Research Institute, the advantage of the RPS Satellite Office solution in terms of scalability compared with traditional CRO models, is first and foremost a very efficient way to quickly ramp up with experienced resources.

“With the traditional CRO model we need to specify the detailed tasks to be performed for each specific protocol,” Ms. Cubillos says. “The Satellite Office model provides an established business relationship that helps both RPS and SPRI meet their business goals. This allows more flexibility to shift resources to support any protocol or CDM task based on workload demands.”

The benefits that the RPS model brings to SPRI's own in-house infrastructure, in terms of economies of scale, are significant because the Satellite Office staff works within its systems.

“Using our processes and technology eliminates the effort necessary to customize the way we conduct our business,” Ms. Cubillos says. “This has not been our experience when working with a CRO. The fact that we resource a study through the Satellite Office is seamless to the SPRI study team members. Additionally, the Satellite Office staff is strictly dedicated to our projects. This is a significant benefit because proficiency and loyalty to our projects are demonstrated very early on in the process — this of course translates into quality and efficiency.”

Ms. Cubillos provided the following examples of how the RPS Satellite Office model helped improve SPRI’s processes:

- Using the RPS Satellite Office model, RPS was able to respond to a request for 11 experienced CDCs in a two-week timeframe, which included the onboarding process. For SPRI, this was a record.
- Knowing SPRI’s business needs, RPS pre-screened interview candidates for the company. This saves time and has proven to facilitate successful matches.
- The total cost for two very similar studies was about one-third when using the RPS Satellite Office model vs. a traditional CRO model.

### **About Research Pharmaceutical Services, Inc. (RPS)**

RPS is a Pharmaceutical Resource Organization (PRO) providing services to the pharmaceutical and biotechnology industries for clinical trials. The company is privately held.

With the founding of RPS, Inc. in 1998 by Daniel Perlman, Chairman and CEO, RPS began a five-year business plan to build the industry’s first PRO model in anticipation of evolving clinical strategies within Sponsor companies, consolidation within the industry, and cost-containment pressures. This plan was dedicated to achieving the goal of giving the pharmaceutical/biotechnology industry a modern model that offers customized integrated solutions that solve the predicted problems of increased clinical trial spend, decreased quality, and the need for Sponsor control and speed. The end goal, therefore, was to achieve a structure that was scalable and

provided Sponsor companies with greater integrated control of their clinical trials while improving on-time delivery of programs and reducing the overall lifecycle costs compared with traditional outsourcing strategies.

RPS can provide services to our Sponsors ranging from stand alone functions to the management of your entire clinical trial program. Service areas are inclusive of:

- Project Management
- Clinical Monitoring
- Investigator Recruitment
- Contract and Grant Negotiation and Administration
- Data Management
- Database Programming
- SAS Programming
- Biostatistics
- Medical Writing
- Regulatory Affairs
- Pharmacovigilance
- Medical Monitoring
- Stand Alone Clinical Trial Management System (TrakWare™)
- Technical and Operational Strategy
- Health Outcomes, Pharmacoeconomics and Scientific Affairs
- Quality Assurance

To advance expertise and promote thought-leader development in important areas of clinical trial data management, RPS sponsors and exhibits at several prestigious industry conferences and events throughout the year.

- Exhibitor — **22nd Annual DIA Clinical Data Management Symposium and Exhibition**, March 18 - 20, 2007, Hilton in the Walt Disney World Resort, Lake Buena Vista, Fla.

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- Exhibitor/Sponsor — **18th Annual Partnerships with CROS**,  
April 10 - 12, 2007, Rosen Shingle Creek, Orlando, Fla.
- Exhibitor/Sponsor — **ACRP 2007 Global Conference & Exhibition**,  
April 20 - 24, 2007, Washington State Convention Center, Seattle, Wash.
- Sponsor — **Waife & Associates Inc., Tenth Annual Executive Retreat on  
Clinical Operations**, May 21 - 23, 2007, Ritz-Carlton Amelia Island, Amelia  
Island, Fla.
- Exhibitor/Sponsor — **The Pharmaceutical Industry SAS Users Group  
(PharmaSUG) Annual Meeting**, June 3 - 6, 2007, Hyatt Regency Denver at  
Colorado Convention Center, Denver, Colo.
- Exhibitor — **DIA 43rd Annual Meeting**, June 18 - 21, 2007, Georgia World  
Congress Center, Atlanta, Ga.
- Exhibitor — **Society of Clinical Data Management (SCDM) Fall  
Conference**, Sept. 16 - 19, 2007, Hyatt Regency Chicago on the Riverwalk,  
Chicago, Ill.
- Exhibitor — **Regulatory Affairs Professional Society (RAPS) 2007 Annual  
Conference and Exhibition**, Sept. 23 - 26, 2007, Hynes Convention Center,  
Boston, Mass.
- Exhibitor — **2007 Society of Clinical Research Associates (SoCRA) Annual  
Meeting**, Sept. 28 - 30, 2007, Adam's Mark Denver Hotel, Denver, Colo.
- Exhibitor/Sponsor — **American Medical Writers Association (AMWA)  
67th Annual Conference**, Oct. 11 - 13, 2007, Marriott Marquis, Atlanta, Ga.
- Exhibitor/Sponsor — **Partnerships Europe**, Nov. 6 - 7, 2007, Amsterdam,  
Netherlands

RPS currently has nine Satellite Office configurations that partner with Clients in the areas of data management, statistics, programming, medical writing, and drug safety. To learn more about the RPS Satellite Office, as well as our other integrated solutions, contact our Strategic Development Team at 866-RPS-1151, or visit [www.rpsweb.com](http://www.rpsweb.com).



610 West Germantown Pike  
Suite 200  
Plymouth Meeting, PA 19462  
Tel: 215-540-0700  
Fax: 215-540-0770

[www.rpsweb.com](http://www.rpsweb.com)