



**The 2006 Avoca Report**

***The State of Clinical Outsourcing***

**The Avoca Group**

July 26, 2006

## **Introduction**

Each year, The Avoca Group polls key industry executives and managers to understand trends in the outsourcing of clinical research by pharmaceutical companies and other sponsors to clinical service providers. In 2006, Avoca again explored general trends in clinical outsourcing and also posed questions specifically about functional service provider (FSP)<sup>1</sup> outsourcing, a model that has gained a great deal of attention in the past year.

This year's web-based survey data were compiled and analyzed and were presented at the annual Drug Information Association Conference in June of 2006.

## **Methodology**

Two unique survey instruments were created: one was created specifically for pharmaceutical companies and other clinical research sponsors, and a second was created specifically for contract research organizations (CROs) and other providers of clinical research services. Therefore, the surveys addressed the perspectives from two opposite sides of the business relationship.

The survey instruments had yes/no questions, statement response/agreement level ratings, and free text response areas.

Avoca collected 39 sponsor surveys from 25 companies and 62 service provider surveys from 30 companies in a two month period of time. Participants were offered a copy of the survey results for their participation in the survey. No respondent names or company names were associated with any responses in the reports.

Data from the surveys were compiled and two data reports were created. Simple counts, means, and percentages were supplied from the initial reports. The data were further analyzed using other methods, and the comments that were written in were analyzed for information as well.

Key findings and Avoca's interpretations of these findings are presented below.

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<sup>1</sup> Functional Service Provider model is used when the sponsor company may elect to engage a service provider for just one or more elements of the clinical trial, as opposed to a full service model, where the service provider, or CRO, provides all or most of the services in the clinical trial. With the FSP model, more than one CRO (i.e. competitors) may be working on the same trial.

## Key Findings

In this paper, we review results from both the pharmaceutical and biotechnology companies that were represented by one survey and the clinical services providers who completed the second survey. We also explore the data collected specifically regarding functional services outsourcing and finally discuss the findings.

\*Note: See footnote for explanation of use of numerical answers in survey results and interpretations.<sup>2</sup>

### *Pharmaceutical and Biotechnology Companies (Pharma)*

Respondents from the following companies took the 2006 Industry Survey:

Pharmaceutical and Biotech	
AstraZeneca	Johnson & Johnson Pharmaceutical R&D
Bayer	Merck & Co., Inc.
BMS	Nippon Shinyaku Co., Ltd.
Celtic Pharmaceuticals	Novo Nordisk
Centocor	Ortho Biotech
CombinatoRX Inc.	Otsuka Pharmaceuticals
Cordis	Pain Therapeutics, Inc.
Cylene Pharmaceuticals, Inc.	Pfizer
Eisai	Procter & Gamble Pharmaceuticals
Eli Lilly & Company	Roche
Ferring Pharmaceuticals A/S	Sepracor Inc.
GlaxoSmithKline	Valeant Pharmaceuticals International
Johnson & Johnson	

Over 50% of respondents were middle management personnel, 31% were executives and 18% were project managers.

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<sup>2</sup> Throughout the presentation of findings and interpretation of these results, the author refers to answers to questions as certain numbers from one to five. This survey included statement ratings, where if a statement was made and a respondent “strongly agreed” with the statement, a “5” would be given. If a “4” was given, the respondent “generally agreed”; if a “3” was given, the respondent “neither agreed nor disagreed”; if a “2” was given, the respondent “generally disagreed” with the statement; and if a “1” was given, the respondent “strongly disagreed”. Therefore, the higher the number indicated in the discussion, the more in agreement the respondents were about the particular item.

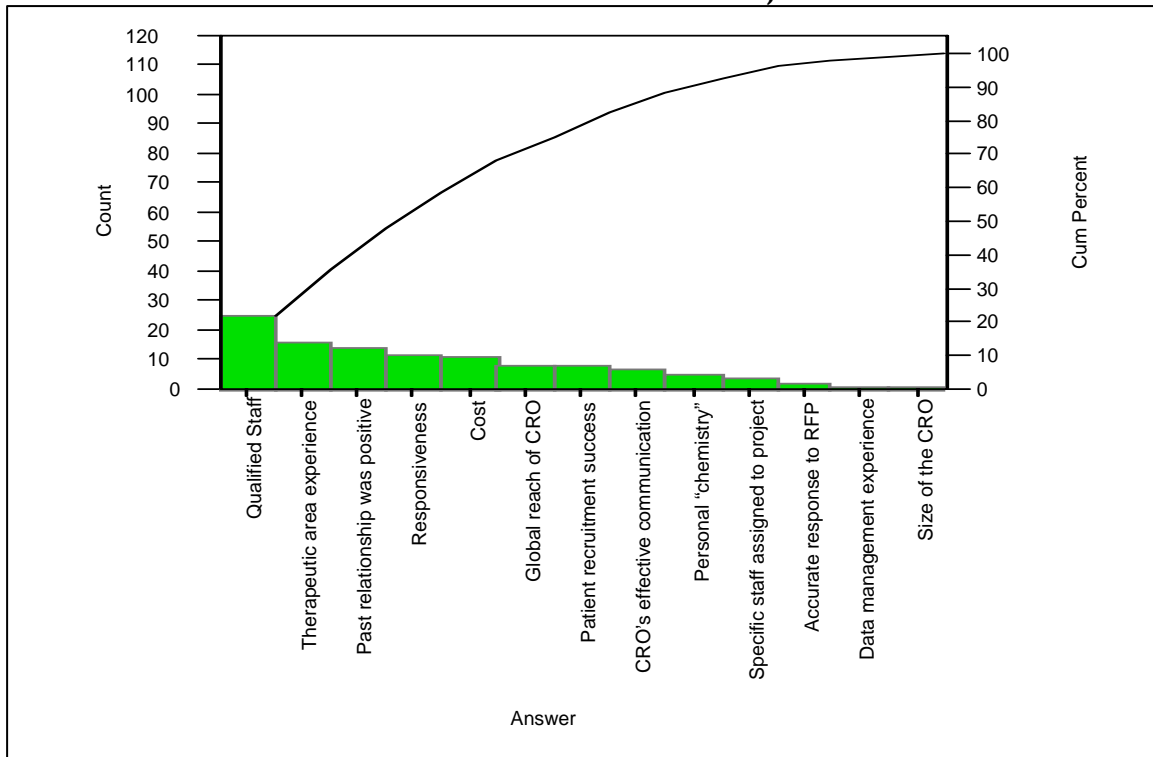
## Opinions about Relationships with Clinical Service Providers

Sponsor company representatives were asked for their opinions regarding their business relationships with their clinical service providers.

- 80% of sponsor representatives provided favorable ratings (scores of 4 or 5 on a scale of 1 to 5) when asked about their satisfaction with CROs
- Respondents commented that the factors that most contributed to the success of sponsor-CRO relationships are:
  - Qualified staff at the CRO
  - Therapeutic experience of the CRO
  - Past relationship between the CRO and sponsor
  - Responsiveness of the CRO

When sponsors were asked what characteristics were most important to them when working with a clinical service provider, they answered as depicted below.

**Top Factors Important to Sponsors when Working with a CRO on an Outsourced Project**



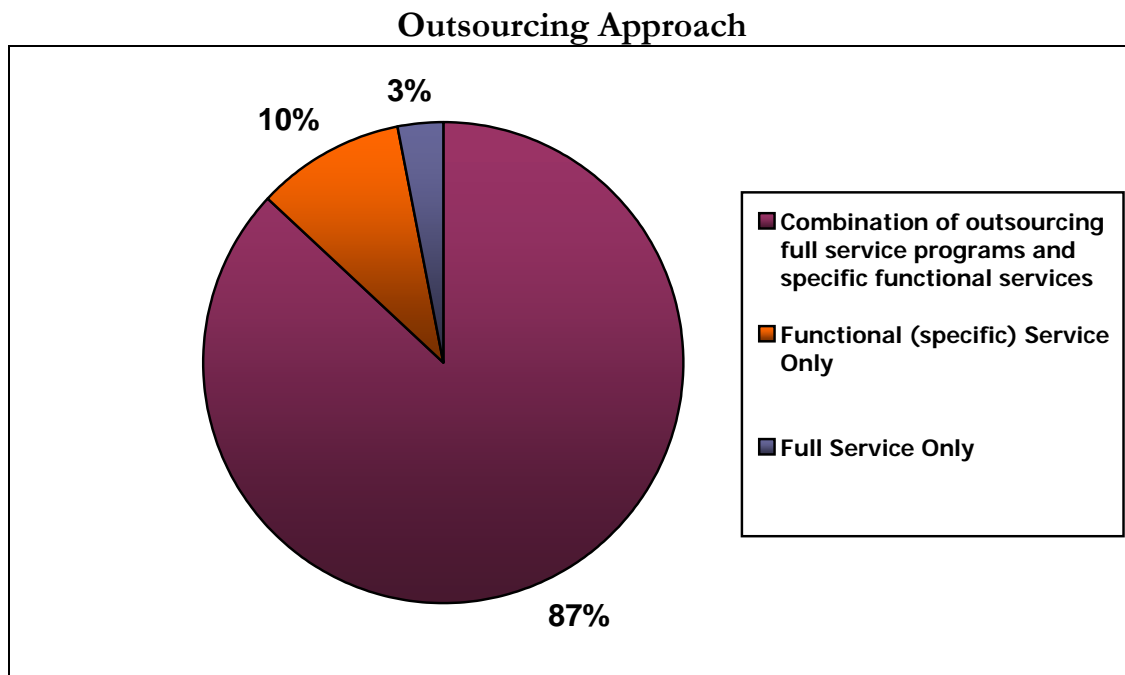
When asked about sources of conflict with CROs, of the sponsor company respondents surveyed, 39% strongly agreed (rating of 5) and 92% agreed (rating of 4 or 5) that mismatched expectations at the beginning of a project were a significant problem. Most of the other strongly endorsed statements were also about the setting of expectations. Issues of communication, “bait and switch” of personnel, and CRO size were problems for some sponsor companies, but received lower agreement ratings on average than did issues surrounding mismatched or changing expectations.

### Outsourcing Models – Including Functional Service Providers

The approach to outsourcing is mixed, with the largest percentage of sponsor respondents using a combination of FSP and full service outsourcing models.

**Question: What approach or model do you currently use when outsourcing clinical projects?**

Response	Response Count	Percentage
Combination of outsourcing full service programs and specific functional services	34	87%
Functional service outsourcing only	4	10%
Full service outsourcing only	1	3%
<b>Number of Responses</b>	<b>39</b>	



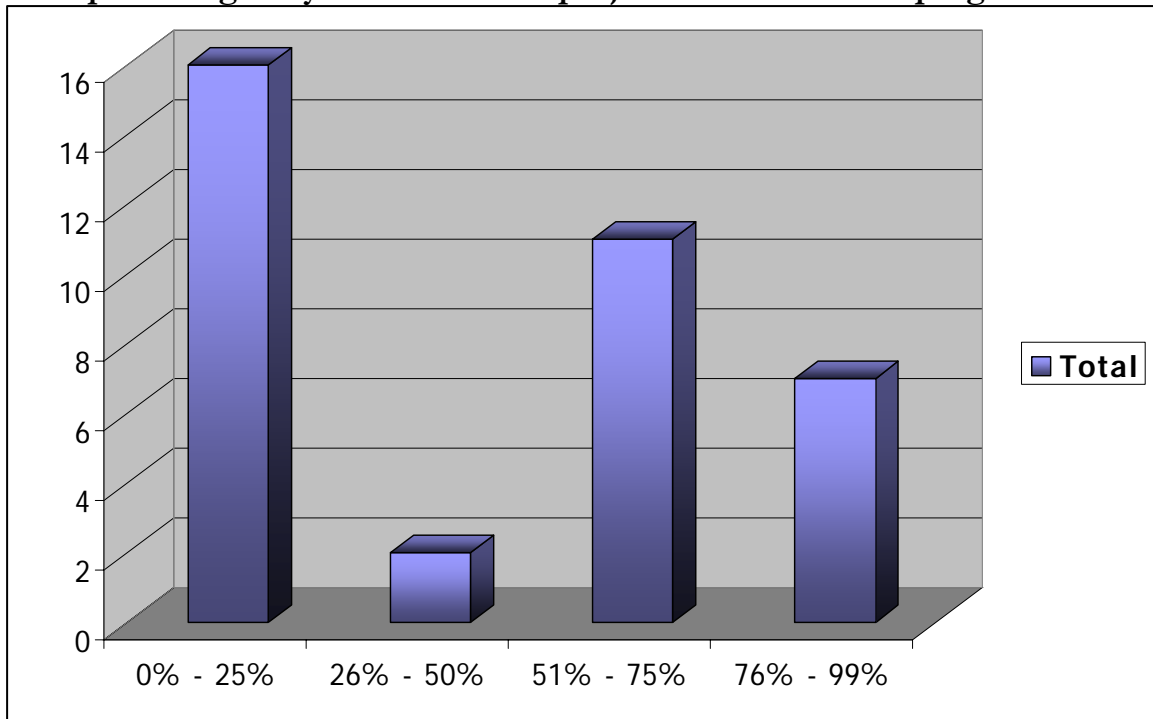
n=39

Respondents who answered that a combination of outsourcing models was used reported that the breakdown was as follows:

**Question: If a combination of outsourcing approaches, what approximate percentage of your outsourced projects are full service programs?**

Response	Response Count	Percentage
0% - 25%	16	44%
51% - 75%	11	31%
76% - 99%	7	19%
26% - 50%	2	6%
<b>Number of Responses</b>		<b>36</b>

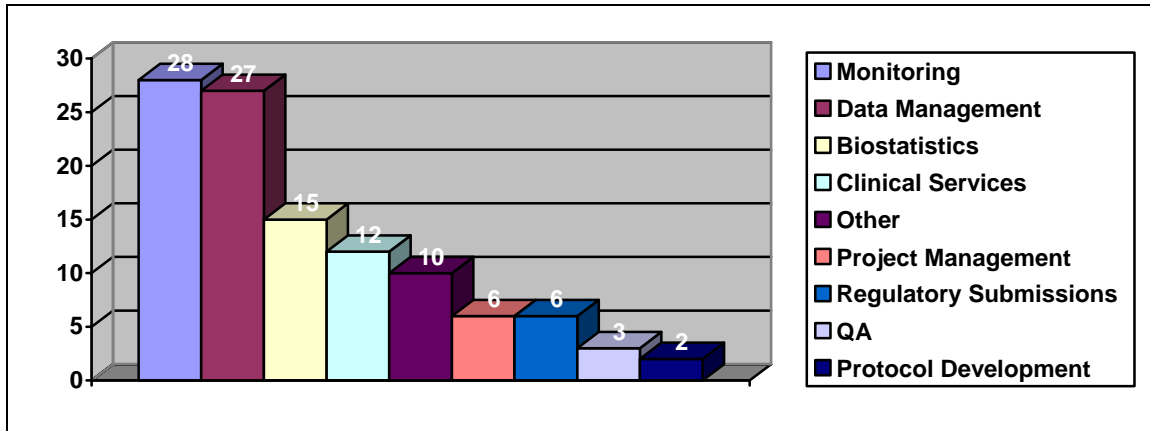
**If a combination of outsourcing approaches is used, what approximate percentage of your outsourced projects are full service programs?**



Services that are outsourced to functional service providers are largely data management and monitoring, although other services are outsourced as well.

**Question: If you engage in Functional Service outsourcing, what individual services do you outsource?**

Response	Response Count	Percentage
Monitoring	28	74%
Data Management	27	71%
Biostatistics	15	39%
Clinical Services	12	32%
Other	10	26%
Project Management	6	16%
Regulatory Submissions	6	16%
QA	3	8%
Protocol Development	2	5%
<b>Number of Responses</b>		<b>61</b>



Companies were asked if their use of FSP was likely to increase over the next 2 - 5 years. Their answers varied according to the size of their company.

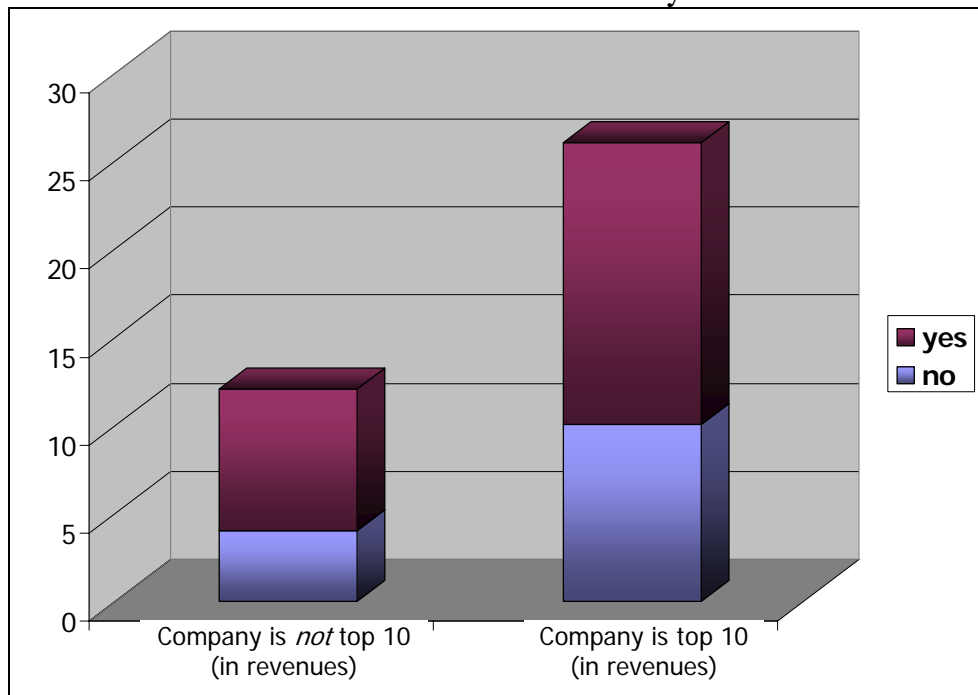
**Question: If your company engages in both full service and functional service outsourcing, do you anticipate that your functional service outsourcing will increase or decrease in 2006, as compared to 2005?**

Response	Response Count	Percentage
Increase	15	43%
Remain the Same	13	37%
Decrease	7	20%
Number of Responses		35

**Question: Do you believe that your utilization of functional service outsourcing will increase within the next 2 – 5 years?**

Response	Response Count	Percentage
Yes	26	68%
No	12	32%
Number of Responses		38

**Do you believe that your utilization of Functional Service outsourcing will increase within the next 2-5 years?**



Reasons provided for use of a full service outsourcing model included:

- An expectation of improved communication and efficiency
- An expectation of cost efficiency
- An expectation of better control of project with fewer resources required from the sponsor

Reasons provided for use of a functional service provider model included:

- Requirement of simple staff augmentation
- A perception of better expertise and higher quality staff
- If the same vendor is always used for the same functions, sponsors cite familiarity with the sponsor and cost effectiveness as the main benefits

Please see Appendix I for further details regarding rationale provided for use of the different outsourcing models.

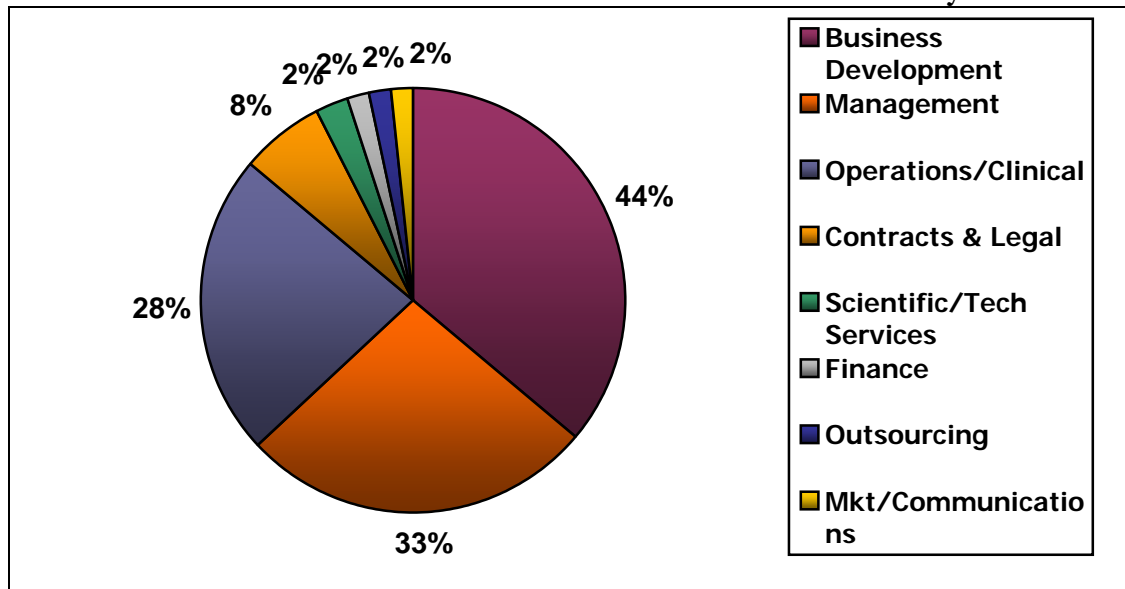
### *Clinical Service Providers (CROs)*

Respondents from the following companies took the 2006 Industry Survey.

Pharmaceutical and Biotech	
ARS, Inc.	PPD
Beardsworth Consulting	PRA International
Bio-Imaging Technologies Inc.	Quest Diagnostics Clinical Trials
Biomedical Systems	Quintiles
Chiltern International	ReSearch Pharmaceutical Services, Inc. (RPS)
Clinsys, Inc.	RH Bouchard & Associates, Inc.
Endpoint Research	ResearchPoint
Everest Group	SCIREX Corporation
ICON	SBFC International/PharmaNet
INC Research	Spectra Clinical Research
Metropolitan Research Associates	SRG Woolf Group
Omnicare Clinical Research	The Clinical Resource Network
PharmaLink FHI	TKL Research
PharmaNet	Uniform Data System
PhaseForward	West Pharmaceutical Services

Clinical service providers surveyed were largely company executives, with 64% in executive management roles and 36% in middle management roles. Their functional areas varied, however.

**Functional Areas of Clinical Services Providers Surveyed**



n=61

## Opinions about Relationships with Pharma Companies

The clinical service providers' perceptions of their relationships with their customers differed slightly from the perceptions of their customers.

- 67% of CRO respondents provided favorable ratings when asked about their satisfaction with sponsors.
  - Among the top 10 CROs, 83% rated this a 4 or better
  - Among the smaller CROs, 53% rated this a 4 or better; most were neutral
- The leading factors related to the success of relationships were felt to be as follows:
  - Clear expectations expressed by sponsor at the beginning of project
  - Sponsor's treatment of CRO as part of the team
  - Clear communication

When asked about sources of conflict with sponsors, 48% of service provider respondents strongly agreed (rating of 5) and 79% agreed (rating of 4 or 5) that mismatched expectations were a significant problem. Most of the other strongly endorsed statements were also about expectations, and put the burden on the sponsor for changing demands and a lack of definition of needs up front. Lack of respect and trust were also cited by CRO respondents as issues, but these complaints were far less common than mismatched expectations.

## Outsourcing Models – Including Functional Service Providers

81% reported that they provide a combination of both functional service and full service projects, but none reported providing full service programs only.

**Question: What primary approach or outsourcing model to you currently supply to customers?**

Response	Response Count	Percentage
Combination of outsourcing full service programs and specific functional services	50	81%
Functional service outsourcing only	12	19%
<b>Number of Responses</b>	<b>62</b>	

For companies that offer full service, the following percentages of their programs were reported to be full service:

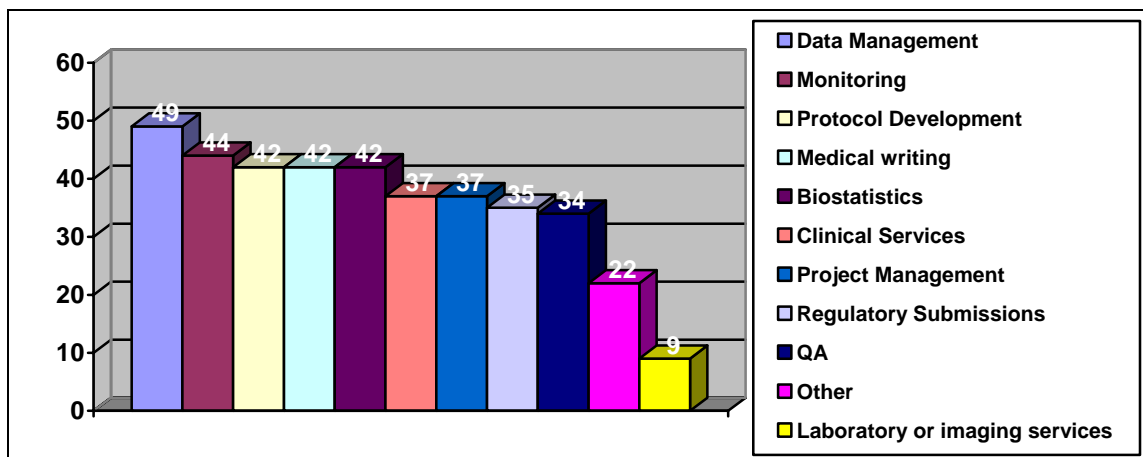
**Question: If a combination of outsourcing approaches, what approximate percentage of your outsourced projects are full service programs?**

Response	Response Count	Percentage
51% - 75%	25	47%
76% - 99%	12	23%
26% - 50%	10	19%
0 - 25%	6	11%
<b>Number of Responses</b>	<b>53</b>	

Companies that provided functional services reported providing the following:

**Question: If applicable, what individual services do you provide as a functional service provider?**

Response	Response Count	Percentage
Data Management	49	80%
Monitoring	44	72%
Protocol Development	42	69%
Medical Writing	42	69%
Biostatistics	42	69%
Clinical Services	37	61%
Project Management	37	61%
Regulatory Submissions	35	57%
QA	34	56%
Other	22	36%
Laboratory or Imaging Services	9	15%
<b>Number of Responses</b>	<b>61</b>	



CROs see many challenges arising from the FSP model:

- Multiple lines of communication
- More effort required for project management
- Resourcing complications
- Business concerns: decreased ability to make a profit or to remain competitive with smaller FSP companies
- Lack of control of overall study success and milestones
- Differences in company cultures of CROs vs. vendors
- Dependency on other providers to work efficiently.

Please see Appendix 2 for further details regarding perceived challenges.

These companies predict an increase in full service work in 2006.

**Question: If yours is a company that has the capability of providing full service, do you anticipate that the proportion of your projects that are full service will increase or decrease in 2006, as compared to 2005?**

<b>Response</b>	<b>Response Count</b>	<b>Percentage</b>
Increase	30	<b>56%</b>
Remain the Same	16	<b>30%</b>
Decrease	8	<b>15%</b>
<b>Number of Responses</b>	<b>54</b>	

## Conclusions

### *Overall Relationships*

Overall satisfaction with relationships in the industry is largely very good, though somewhat better from the sponsor side than from the CRO/clinical service provider side.

- Within the pharma/biotech sector, 80% of respondents gave a rating of 4 or better for overall satisfaction with their outsourcing relationships; only 10% rated the relationships as 2 or less.
- Within service providers, 67% gave a rating of 4 or better, and only 8% were 2 or less.

It is interesting to note that among the top ten CROs, 83% rated their relationships at a 4 or better, while only 53% of respondents from smaller service providers rated their relationships at the same level.

The leading contributors to good sponsor/service provider relationships are seen somewhat differently, depending on which side of the relationship the respondent is on.

<b>Sponsor “Top 4” important factors from a service provider</b>	<b>Service Provider “Top 3” important factors from a sponsor company</b>
Qualified Staff	Clear expectations at the beginning of a project
Therapeutic area expertise	Treating the CRO as part of the team
Past experience with the provider	Communication
Responsiveness	

Interestingly, both sides agreed that the top sources of conflict were related to mismatched expectations, and both sides agreed that sponsors don’t do a good enough job of setting expectations. Sponsors actually feel more strongly about this than do CROs.

### *Functional Service Provider Model*

Most sponsor companies use a combination of full service and functional service outsourcing, with approximately half of projects being full service. 59% of top ten sponsors do half or less of their outsourcing using a full service model while smaller companies use a full service approach more frequently.

Among service providers, for most companies, the majority of their projects are still full service.

Interestingly, it was more common for sponsor respondents to say that FSP would increase this year than it was to say that it would stay the same or decrease. Sponsor respondents were also most likely to expect an increase over 2-5 years. In contrast, most service provider respondents said that they expected more of their projects to become full service over the same time horizons.

The functional service approach is perceived by CROs as challenging, because of communication, accountability sharing, and other similar factors.

## **Appendix I:**

### **Select Verbatim: Industry Survey: Pharma/Biotech**

**What do you consider to be the main advantages of *Full Service Outsourcing*?**

#### **Top Responses:**

- Easier communication
- Lower cost
- Fewer resources needed from sponsor for management
- Benefits of using a CRO (experience, expertise, additional resources)

#### **Select Verbatim:**

- Better communication, less chance of playing the blame game if something goes wrong.
- Simplified communication and fewer sponsor resources invested in buffering the various resources.
- More efficient for the CRO which can translate into cost savings. Lower internal cost for Pharma Company because fewer resources needed.
- There are more efficiencies when tasks transition from one function to another.
- Established relationship and goals at onset carried through differing services versus re-establishing for every company for every service.
- More operational integration and control at the CRO. Also, potential for synergies that couldn't be as easily captured with separate functional providers.
- Fewer hand-offs between companies. Increased accountability at provider.
- Ability of CRO to work within their own company teams/processes.
- Allowing the CRO to do the work within their own processes, which is, in theory, more efficient.
- Fewer resources for oversight and simpler logistics such as invoice processing, negotiation, etc.

## What do you consider to be the main advantages of *Functional Service Provider* outsourcing?

### Top Responses:

- Specialized expertise in functional area
- Lower cost
- Better qualified CRO Personnel

### Select Verbatim:

- Level of functional detail and expertise appears to be stronger within functional service providers.
- Focused expertise and ownership by the internal sponsor function.
- Expertise in that particular function. This is particularly common for newer functions and capabilities; eDiaries, etc.
- High focus on specific deliverables.
- For tasks like data management and IVRS it is much more cost effective for a sponsor to outsource with the same group.
- Cost savings to sponsor company when you factor in fully-loaded cost of an internal resource.
- Easily defined and negotiated rates.
- You are able to get better qualified people on your program i.e., CRAs and program managers.
- Working with a vendor on a specific area will make the vendor familiar with my company and thereby a better partner over time.
- If done appropriately and the functional staff are truly aligned with the sponsor company this model allows sponsor to maintain flexibility with resources.
- Long term relationships with one vendor can significantly streamline processes.
- Can tailor the services needed based on the core competencies of both the sponsor and CRO.

**What expectations do you have of a CRO when working in Functional Service Provider models that are different from when your CRO is providing a full service program?**

**Top expectations that differ:**

- Increased emphasis on communication
- Expertise
- Cost efficiencies

**Select Verbatim:**

- Better communication between CRO and sponsor and especially CRO to CRO.
- We expect them to follow the study specifications, do their job, communicate well and give us a “heads up” on potential problems.
- Range of expertise and experience is required from full service versus specialty from functional service providers.
- Demonstrated expertise and capability in the area, since we will only outsource very specialized functions in the Functional Service Provider Model.
- Detail and depth or knowledge.
- More experienced personnel.
- Improved familiarization with my company and the way of working.
- Cost efficiencies.

## **Appendix II:**

### **Select Verbatim: Industry Survey: Clinical Service Provider**

**What do you consider to be the main advantages of *Full Service Program Outsourcing*?**

#### **Top Reasons:**

- Flexibility
- Ease of communication
- Process efficiencies
- Cost efficiencies
- Control

#### **Select Verbatim:**

- Flexibility in managing the projects. More control over the processes and quality.
- Communication between the involved departments is easier and knowledge of internal systems results in fewer errors or miscommunication.
- Efficiency of cross-functional coordination with respect to project timing, budget, and communications.
- It is much more efficient for us and the sponsor to complete all the tasks of a project. If the sponsor or another vendor is responsible for some of tasks, this requires another level of communication plus significant efforts to coordinate processes and systems.
- Efficiencies which derive from close collaboration and communications among internal functional groups resulting in 1) high-quality clinical research and 2) the shortest possible timelines.
- It is more cost effective for the sponsor due to less overlap of work and smoother transitions from department to department.
- Control over all aspects by the CRO; having control over all tasks and complete timeline responsibility.
- Clear accountability.

## What do you consider to be the main advantages of *Functional Service Provider* outsourcing?

### Top Reasons:

- Expertise
- Efficiency resulting from repeat engagement with same FS provider
- Lower cost
- Specialization/Expertise

### Select Verbatim:

- More flexibility in choosing the team that works best with each functional group; chemistry and expertise.
- Allows expertise in each operational area to be provided by multiple vendors so you get the best from each CRO.
- Efficiency resulting from repetitive engagement.
- Cost and resource efficiency.
- There may be some cost savings for the sponsor if they have an efficient process for managing multiple vendors.
- Focus on vendor's core competency rather than expecting consistent excellence among different functional areas. Often greater capabilities in that area than a full service provider.
- The department responsible for that functional service becomes very knowledgeable of the sponsor's expectations.
- Provides specific resources to meet immediate needs; highly specialized resource allocation.

## **What are the challenges for CROs in working in a Functional Service Provider type model?**

### **Top Responses:**

- Barriers to communication
- Resourcing
- Working with Other Vendors/Sponsors
- Lower profit potential
- Lack of Control

### **Select Verbatim:**

- Interfacing with other suppliers to develop an open line of communication to maintain quality and ensure on-time delivery of all objectives.
- Multiple lines of communication create more work for Project Manager.
- Need to maintain a dedicated team with the ability to flex resourcing on demand.
- Adequate resourcing without having any control over the overall study progress.
- Matching the staffing resources to the work requirements is both facilitated by providing services on a functional basis and the biggest challenge of providing services on a functional basis.
- Often you are having to work with other vendors as you are handed off the work from one vendor and then pass the work off to another vendor as you complete your functional service.
- Working with providers from other CROs/vendors - communication, systems integration, culture differences.
- Coordinating activities of companies providing different functional services, accountability for final deliverable.
- Dependency on other providers to work as efficiently. Dependency on sponsor to communicate equally with all providers so we all have the information we require to get the job done. Challenge working with some other providers who may not communicate effectively with us.
- Lack of clear guidance from Sponsor and other CRO involved (depending on the type of service outsourced to our CRO. Inability to move quickly in decision making when too many parties are involved.
- Cost is a big issue for larger global CROs.
- Competing with lower priced, lower quality staffing companies.
- Ability to make a profit.
- You have the accountability for the deliverables but do not have full control over the processes.