The 2005 Avoca Group Report

The Current State of Clinical Outsourcing

August 23, 2005

Executive Overview

In June of 2005, The Avoca Group conducted an industry survey to study the current state of clinical outsourcing for the purposes of new drug and device development. The data collected from this survey constitutes the basis of this report, which looks at both sides of the contracted relationships – the sponsors' perspectives and opinions and trends held by and affecting clinical research service providers.

Methodology

Invitations to take this web-based survey were sent to approximately 350 pharmaceutical, biotechnology, medical device, and clinical services executives and managers. Respondents were offered the complete data report from this study as an incentive to participate. Forty-six respondents from 32 pharmaceutical, biotech, and device companies completed surveys. In addition, forty-six respondents from 26 clinical research service organizations such as CROs, imaging companies, and laboratories completed surveys as well. Two survey instruments were used – one for sponsor companies and a second for clinical services providers.

Respondents

The Avoca Group endeavored to gain representation from all of the largest companies (both sponsor and clinical research service) as well as a number of smaller companies, and was largely successful in doing so (see lists of companies represented on following two pages). No sampling scheme was employed to ensure equal or otherwise representative contribution to the data by different companies or different types of companies, and in some cases (as indicated on the lists), more than one respondent from an organization completed the survey.

All individual respondents' information is confidential and no answer may be linked to any particular company.

Pharmaceutical, Biotech, and Device Companies (Sponsor Companies)*

Abbott
Amgen
Allergy Therapeutics
AstraZeneca (3)
Biogen Idec
Bristol-Myers Squibb
Centocor R&D, Inc. (2)
CombinatoRx, Inc.
Cordis
Cylene Pharmaceuticals
Eli Lilly & Co., Ltd.
EPIX Pharmaceuticals
Ferring Pharmaceuticals (2)
GlaxoSmithKline
Johnson & Johnson
JJPRD (6)
LaJolla Pharmaceutical Company
McNeill Consumer & Specialty: Pharma
Merck & Co., Inc. (2)
Pain Therapeutics, Inc. (2)
Phenomix
Pfizer (3)
PharmAthene, Inc.
Purdue Pharma
Procter &Gamble Pharmaceuticals (2)
Regeneron
Roche
Santarus
Sepracor (2)
SuperGen, Inc.
Wyeth

*The number of respondents from each company is indicated in parentheses, if more than one.

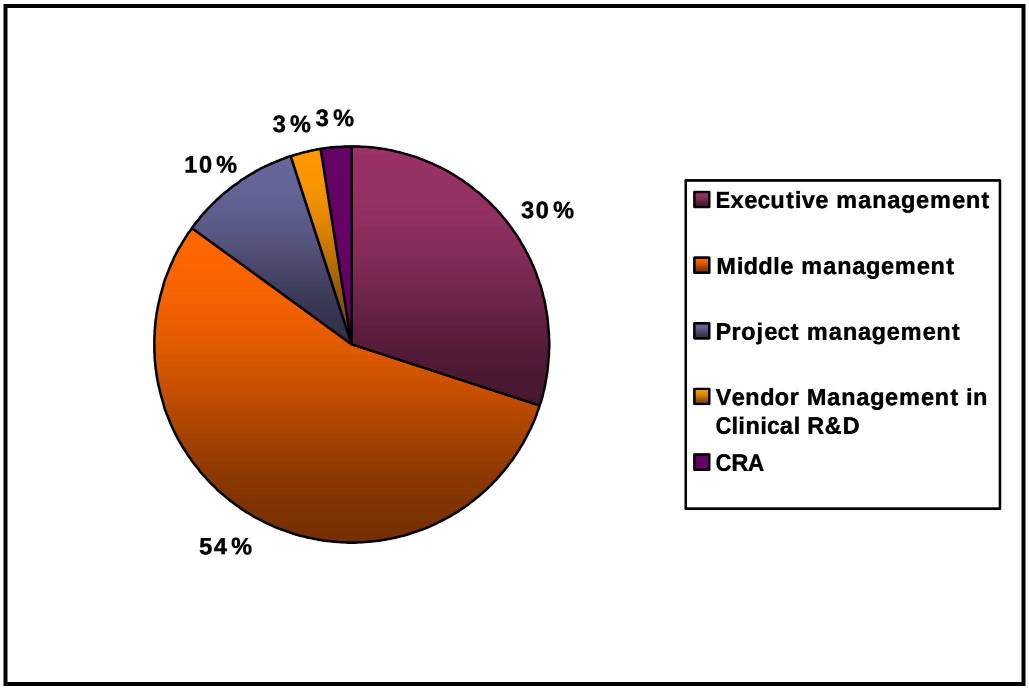
The functional areas in which the respondents from the sponsor side work and their positions within their organizations were as follows:

Functional areas:

- 53% Operations/Clinical
- 35% Contracts
- 12% Outsourcing

- 8% Finance

As shown below, 54% of respondents represented Middle Management and 29% represented Executive Management within the sponsor organizations.



N=41

Clinical Research Service Providers*

Beardsworth	PAREXEL
Bio-Imaging Technologies	PharmaNet (8)
Biomedical Systems	Pharmaceutical Performance Institute
Chiltern International	PRA International (6)
Covance (2)	PPD (3)
Endpoint Research	Quest Diagnostics Clinical Trials
E-trials	Quintiles (3)
i3 Research	ResearchPoint
ICON	RH Bouchard & Associates, Inc.
Inveresk	SCIREX Corporation (2)
Kendle International (2)	SRG Woolf Group
Metropolitan Research Associates	Synarc (2)
Omnicare Clinical Research (3)	TKL Research

*The number of respondents from each company is indicated in parentheses, if more than one.

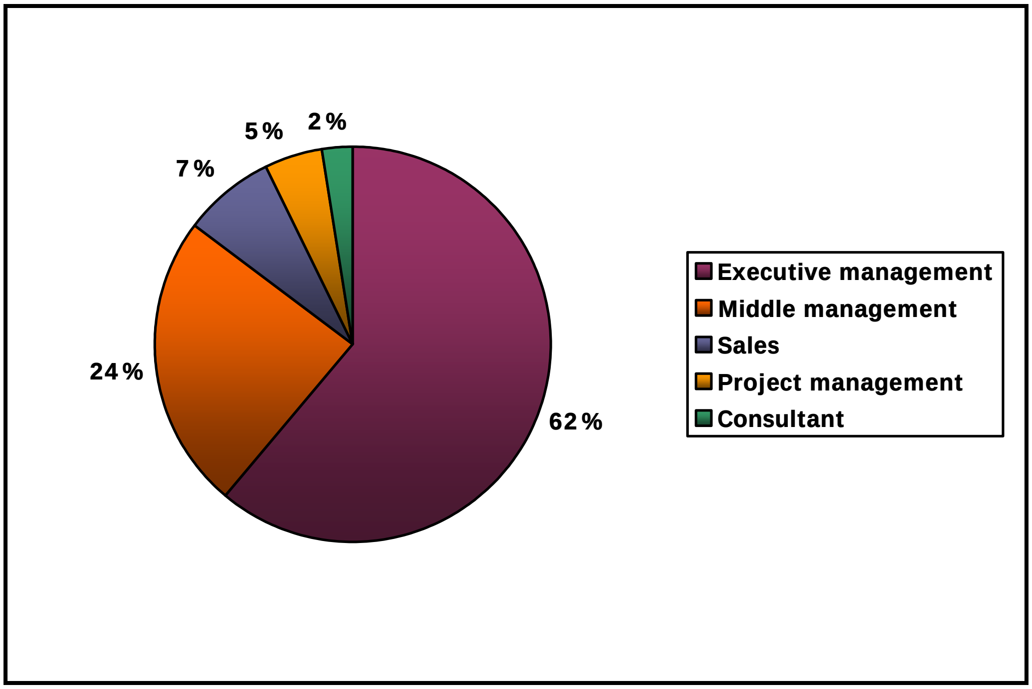
Of the clinical research service provider respondents interviewed, 79% were employed at CROs, 7% were from imaging companies, 5% were from consulting companies, 2% were from ECG Core Labs, 2% were from Clinical Research Staffing Companies, and 2% were from central labs.

The functional areas in which the respondents from the service provider side work and their positions within their organizations were as follows.

Functional areas:

- 55% business development
- 33% operations/clinical
- 10% contracts
- All other functional areas had 2% (or one) respondent only

As shown below, 62% of respondents represented Executive Management and 24% represented Middle Management within the service organizations.



N=42

Key Findings

Some of the key findings of the research are as follows. The complete set of data is provided in the accompanying data report.

Sponsor Company Highlights

- 43% of sponsor company respondents indicate that their company's approach to clinical outsourcing is changing in 2005.
- Approximately 76% of respondents reported that they were either "generally satisfied" or "very satisfied" with their relationships.
- For sponsor representatives, the most important features in selecting clinical research service providers were:
    - Qualified staff (56%),
    - Therapeutic area experience (40%),
    - A positive past experience (37%),
    - Cost (30%), and

- Responsiveness (26%).

(Respondents were allowed to endorse more than one item.)

- An emerging and controversial trend in clinical research service outsourcing is Reverse Auction. In this industry survey, 36% of Pharma, biotech, and device company respondents reported that they will utilize Reverse Auction in 2005. 19% of respondents from sponsor companies report that there has been a shift toward utilization of Reverse Auction in their companies from 2004.

- Sponsor company respondents reported on their most important reasons for using Reverse Auction. Of those who reported, 44% indicated that shortened cycle time was a key reason and 31% noted that Reverse Auction helps establish expected costs for similar services in the future.

- Respondents from sponsor companies who stated that they would not use Reverse Auction provided the following reasons: 74% cited the high probability for mismatched expectations and assumptions, 70% noted that Reverse Auction underestimates the complicated nature/factors involved in clinical research, and 63% noted that savings realized at the end of the auction might not always represent savings at the end of the project. Similarly, 59% noted that there would be a high probability for low bids resulting in subsequent change orders. Other reasons cited can be found in the data report.

- Only 23% of sponsor company respondents believe that Reverse Auction is an effective way to outsource. 43% disagree that it is an effective way to outsource, and the remainder are neutral.

Service Provider Company Highlights

- 95% of clinical research service providers reported having at least one Master Services Agreement in place, 88% reported having at least one preferred provider agreement in place, and 63% reported having participated in Reverse Auctions.

- Service providers reported on the structure of their outsourcing agreements. The majority of respondents indicated that most of their outsourcing agreements were full service (64%).

- The majority of clinical research services companies provide services for Phase II-III trials (96%). 91% also provide services for Phase IV trials.

- Respondents reported on the types of functional services they provide. 77% of respondents reported providing project management, 74% protocol development, 74% monitoring, 71% data management, 69% biostatistics, 66% regulatory submissions and 66% Quality Assurance.

- 77% of respondents from clinical research services organizations reported being “generally satisfied” with their relationships with sponsors and another 5% report being “very satisfied” with their relationships with their sponsor clients.

- 84% of the respondents from service providers have participated in Reverse Auctions.

- 91% of clinical research service provider respondents disagree that Reverse Auction is an effective method for procuring services and 98% believe that the advantages do not outweigh the disadvantages.