

# Small Changes, Big Results



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# Outsourcing Case Study

- Medium sized Pharma company
- Potential blockbuster pending approval
- First Phase IV study
- Limited in-house Phase IV experience
- Lead Time: 9 months to Investigator Meeting

# Study Specifications

- 10,000 Patients
- 2,500 Sites
- 3 month enrollment
- 2 visits per patient
- 10 page CRF
- 15 months from study start date to final report
- Services:
  - Monitoring, DM, stats, final report
  - Study tools, CRF, Web site
  - Investigator selection/regulatory document collection
  - Satellite investigator meetings (12)
  - Study Supply Management
  - AE management

# The Sponsor Team

- Makeup of the Team
  - Head of newly formed Phase IV group
  - Functional representatives from each discipline
  - Program Director for the drug
  - Head of Outsourcing

# Providers

- Multiple Providers planned in order to maximize expertise
  - CRO with Phase IV Unit
  - Satellite Meeting
  - Pharmacy Vendor
  - Marketing/Investigator Recruitment
  - Meeting Planner
  - CRO Safety Provider (AE Management)

# Process-Phase I

- Team invited Providers to present capabilities for all service areas
  - Prior experience with Sponsor
  - Phase IV reputation
  - General information provided
  - Providers to present Phase IV capabilities

## Now What?

- Team had a great deal of generic information about Providers
- Team recognized they needed help in collecting and analyzing specific information
- Phase IV selection criteria was needed
- An outsourcing consultant was added to the Team

# Outsourcing Strategy

- Team defined the goals of the project
- Finalized specifications with information gained in the Provider interviews
- Team was committed to a multiple Provider strategy; acknowledged the pitfalls
- Team agreed to consider a Primary Provider to “manage” the other Providers
- Team agreed to selection criteria in advance



# Multiple Provider Strategy

- Most experienced Provider selected for each aspect of the project
- Opportunity for exceptional quality
- Increased creativity and “best practice”
- Sponsor receives Phase IV training from highly qualified specialists

# Challenges

- Stresses internal Sponsor resources
- Overlap of duties, duplication of effort
- Scope for each Provider must be crystal clear and understood by all
- Greater opportunity for conflict
- Duplicate quality control steps
- Lines of communication can be blurred
- Decision-making slowed and difficult
- Primary Provider has limited responsibility for the other Providers—shared accountability

# RFP

- List of Providers narrowed using agreed criteria
- RFP required a specific project plan and methodology for achieving the project goals, creative solutions were requested
- Proposals were evaluated on creativity, understanding project goals, project plan, and experience; not cost

# Proposal Process

- Two-stage process
  - Stage One
    - The top 3 Providers were asked to present their project plans
    - Other Providers were narrowed to two and final selection was postponed until the Primary Provider was identified
  - Stage Two
    - Final candidates were expected to attend a Pre-project Launch Meeting to define the final scope by Provider

# Pre-Project Launch

- Providers came prepared to work together to define best practice
- Services, primarily start-up, would be allocated to the Provider demonstrating the greater expertise
- Goal of the Meeting: the final scope for each Provider and handoffs would be finalized
- Final budgets submitted 3 days after the meeting

# What Happened?

- Providers were prepared to work together
- Sponsor required two primary Providers
  - Niche CRO for Investigator Selection, Investigator/Patient Kit preparation, Regulatory Document collection, Meeting Planning, Satellite Investigator Meetings (with technology partner), Marketing Materials.
  - Full Service CRO for all other study start-up, CRF design, clinical, data management , stat analysis and report writing.
  - One of these would manage the other Providers; pharmacy, safety, meeting planer, technology provider.

## Best Laid Plans...

- Sponsor walked through the project plan and services
- Providers discussed expertise and methodology
- Results:
  - Cultures did not mesh
  - SOPs were not compatible
  - Ownership issues--accountability
  - Lack of Trust between the Providers
  - Team was dysfunctional from the outset

# Changing Horses...

- The Sponsor Team met to discuss the Pre-project launch
  - All members felt the project would suffer if the multiple Provider strategy was implemented
  - The Team wanted to explore options



# Final Answer

- Full Service CRO had demonstrated expertise in all areas of the project, even those being targeted for the other Provider
- Sponsor Team felt they could work with this CRO-good cultural fit, demonstrated flexibility
- CRO was creative in their approach; demonstrated time (and cost) savings
- CRO was willing to manage other specialty Providers

# Small Changes

- Criteria for selection agreed in advance and applied consistently
- Did not focus on cost
- Adequate time was available for the selection process
- Pre-project meeting was held prior to final selection

# BIG Result

- Project currently running
- Project Team working well together
- Sponsor pleased with results
- Project on time
- CRO actuals are below the original projected budget

# Why did this work?

- Adequate time for planning, selection, and review
- The process was managed and selection criteria determined in advance
- Sponsor supplemented their selection team-knew their limitations
- Providers were willing to attend Pre-Project Meeting prior to award and have open discussions
- Sponsor was open-minded and willing to admit their original plan was flawed
- Sponsor did not focus on cost but on the right selection for the project's success

# Thank You

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