

A sculpture of a tightrope walker balancing a ladder on a globe. The tightrope walker is a stylized figure with a long, thin body, balancing on a thin wire. The ladder is leaning against the wire, and the globe is at the end of the wire. The sculpture is set against a dark background.

Striking a Balance

Operations Role at the Bidding Stage
of an Outsourced Project

TOPICS

- **Overview of Session:** Patricia Leuchten, The Avoca Group

- **Panel Response**
 - Patrick O'Connor – Ferring Pharmaceutical
 - Randy Marchbanks – PPD Development
 - Jim Powers – PRA International

- **Open Discussion and Q&A**



Overview of Session

Patricia Leuchten, President,
The Avoca Group, Inc.



Operations' Role at the Bidding Stage:

The Pharma and CRO Perspective



The Pharma Perspective

The Pharma Perspective

- Needs and expectations during the bidding process
- Consequences when Operations is not involved

Pharma's Perspective

- **Needs and expectations during the bidding process**
 - Presence of the actual team that will be involved in the project
 - Realistic bids
 - A cohesive team that works well together
 - Experienced people and input based on practical experience
 - Demonstration of thorough knowledge of the protocol and therapeutic area

Pharma's Perspective

- **Consequences if Operations is not involved**
 - Potential delays
 - Steeper learning curve
 - Potential change orders
 - Damage to the relationship if there is a perception of a "bait and switch"



The CRO Perspective

The CRO Perspective

- **Benefits of operational input**
- **Challenges**
- **Consequences when Operations is not involved**

The CRO Perspective

- **Benefits of operational input**
 - Buy-in and less resistance from operational teams
 - More realistic estimates
 - Better prepared for interactions with client
 - Knowledge of protocol and clinical issues
 - Smoother transition at project start

The CRO Perspective

- **Challenges to bringing Operations in early in the process**
 - Need to focus on billable hours
 - Operational staff do not see themselves as sales people
 - Significant time required to do feasibility and Pharma's reluctance to pay for feasibility
 - BD sometimes thinks Operations is too conservative
 - Classic tension between BD and Operations
 - Practicality of bringing Operations in early when sometimes timelines shift

The CRO Perspective

- **Consequences when Operations is not involved**
 - Unrealistic bids and assumptions
 - Ill-will and tension between BD and Operations
 - Operational team may not be as prepared at the client meeting
 - Lost opportunity



Striking a Balance



Panel Presentations



Patrick O'Connor
Senior VP, Clinical
Research
Ferring Pharmaceuticals

In this session, we're defining the "bidding stage" as all the interactions that take place between the sponsor and the CRO before a decision is made about which company will get the project

Topics

- **Ferring Outsourcing strategy**
- **CRO Selection Process**
- **Expectations of CRO's Operations**



Ferring Outsourcing Strategy

Ferring Clinical Outsourcing "Know your Company"

- **All phase I, II & III clinical studies are outsourced!**
 - What does this mean? – not what it might seem
 - All Phase II & III clinical studies use Web based EDC
 - External Vendor – Target Health
 - Some but not all Data management is outsourced
 - Seeking one external vendor for data management
 - All key studies are analyzed by Ferring Statisticians
 - Use external consultants for country specifics (Japan and US)
 - Medical Writing is sometimes outsourced
- **All project management and site monitoring is outsourced**

Clinical Outsourcing – Ferring's Clinical Research "Know your Company"

Outsourcing strategy- cont.

- **Most phase II & III studies are usually multinational**
 - North America
 - Japan
 - Rarely truly Global
- **Studies/Programs – We will try and use the same CRO for one development program**
- **Routinely use multiple suppliers for individual projects**
- **Operations are the drivers of the process – the CRO manager is the guardian to make sure that things are consistent**



CRO Selection Process

Ferring's CRO Selection Process

- **Ferring Clinical Research Therapeutic Group develops protocol synopsis**
- **Therapeutic Group collaborates with the CRO management group to:**
 - Select 3 to 4 CRO's to send RFP
 - Develop a bid spreadsheet (compare apples with apples)
- **Allow for CRO to develop efficiencies**

Ferring's CRO Selection Process

- **Often employ a bidders telephone conference to answer questions and provide for consistency in understanding – surprising how often it does not work**
- **When the proposals come in, they are reviewed by CRM and Medical Director within the Therapeutic Group and the CRO manager**
 - CRO selection primarily driven by Therapeutic Group
- **Selected CROs are asked to come in to present**

Ferring's CRO Selection Process

- **Key criteria for selection**
 - Operational experience
 - Experience of proposed project team, especially PM
 - Price
 - 10% difference no discussion
 - 10 to 15% - discuss [not a deal breaker]
 - 15% plus – discuss [a deal breaker]
 - Team dynamics – personality matches
 - Past Experience
- **The therapeutic group head and the Ferring CRM are the key decision makers on CRO selection**
- **Selection approved by Head of Clinical Research**



Expectations of CRO Operations

Expectations of CRO Operations

- **In General:**
 - We expect CRO Operations to be able to deal with the unexpected
- **This means being problem-solvers, being proactive and communicating their level of expertise with the right questions and the right answers.**

Ferring's Expectations of CRO Operations

- **Proposals:**
- **If a generic proposal is provided**
 - The CRO will be eliminated
- **Proposals require CRO Operational input**
 - Need to demonstrate operational experience and expertise
 - Free feasibility not important
- **"You get what you pay for"**

Expectations from CRO Operations

- **Initial Meeting or Bid Defense meeting**
 - If we don't meet the key individuals from CRO operations who are going to be on the team – the CRO won't get the business
 - Project Manager
 - Lead CRA
- **Others – depending on tasks being outsourced**

Ferring's Expectations from CRO Operations

- **Initial Meeting or Bid Defense meeting (cont.)**
- **Much less Important**
 - Multiple CRO Senior Management
 - Consultants – rarely influential – Ferring has own
 - Representatives of services not requested
 - More than 4 CRO staff
 - Duplication of US & European Staff
 - Creates a perception that the CRO services are not seamless
 - Especially two BD Representatives

Ferring's Expectations of CRO Operations

Bid Defense – Advice for CROs:

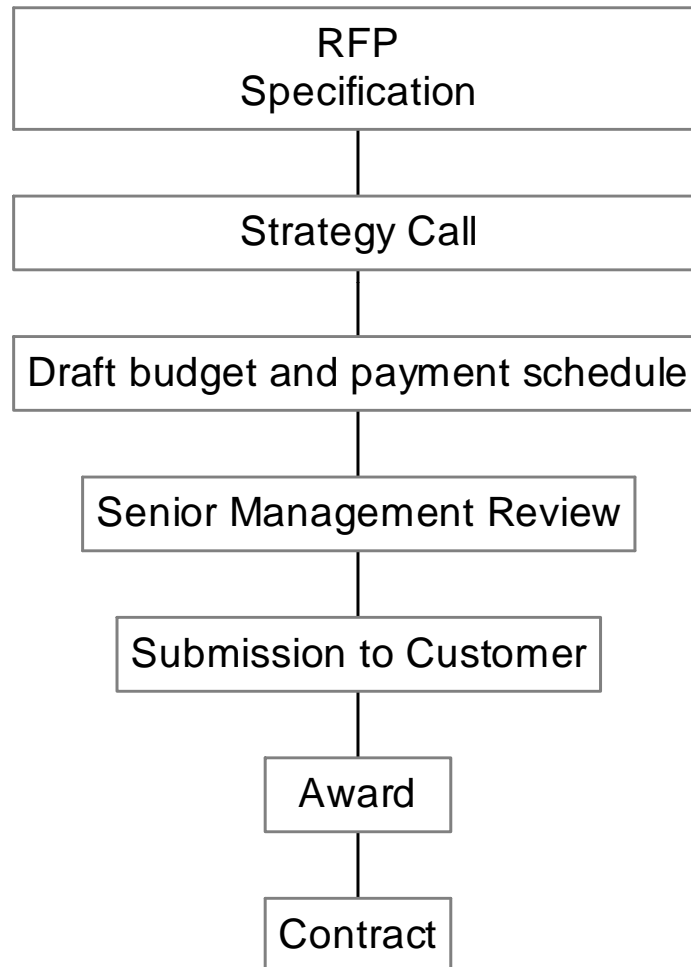
"Get the balance right."

The CROs that strike the right balance between bringing key operational staff and providing reassurance from senior staff stand a better chance at getting the business.



Randy Marchbanks
VP Clinical Operations
PPD Development

PPD Bidding Process



PPD Bidding Process (cont')

- **Automated Bid Template**
 - US Clinical- FTE-based
 - ROW Clinical- Task-based
 - Almost always produces same labor allocations
- **Operations Drives the Bid**
 - Therapeutic leads
 - Franchise leads
 - Functional leads
- **Recently Introduced Dedicated Operations Bidders**

Problems (Opportunities!) with Current Process

- **Little dialogue between parties**
- **Study design- process often in a vacuum from CRO expertise...too late to have real input**
- **Objective is to derive “apples to apples” comparison, not to identify innovative delivery options to enhance chance for success**
- **Original Customer specification materially overestimates enrollment**
 - 70% of all studies enroll less than 100% of specified enrollment rate (mean = 60%)
 - 30% of all studies enroll at 100% of specified enrollment rate

Case Study - Model of Inefficiency

- **Received RFP for Global Schizophrenia Trial**
- **Variables specified in RFP included**
 - Country selection
 - Number of sites per country
 - Study start up timelines
 - Enrollment rate
- **RFP requirements**
 - Full text description of services
 - CV's of key staff
 - Eight page detailed budget grid

Case Study - Model of Inefficiency (cont')

- **RFP allocated to Operations**
- **Bidder's combined experience - 27 Schizophrenia trials**
 - 12 conducted by PPD
 - 15 conducted in prior life (client or CRO)
- **Problems noted with RFP**
 - Country selection not optimal (placebo-control)
 - High quality/High enrolling countries omitted
 - Start-up timelines totally unachievable
 - Enrollment rate 2x higher than historical experience
 - No open-label extension proposed

Case Study - Model of Inefficiency (cont')

- **PPD was awarded the trial**
- **However. . .Required 7 iterations of the bid!**
 - Multiple country/site distribution scenarios
 - With and without patient recruitment campaign
 - With and without open-label extension protocol
- **Estimated resources consumed - 625 Man-Hours**

Observations of Bidding Process

- **Clients are missing opportunities to harness CRO expertise and experience**
- **Multiple iterations cost time (= \$)**
- **Frustration on both sides**
- **Sacrificing way too many trees**

Conclusions and Recommendations

- **Bring CRO's in before RFP is finalized**
 - Problematic inclusion/exclusion criteria
 - Optimal country selection
 - Realistic start-up timeline and enrollment rate
- **Conduct or contract good feasibility studies**
 - Scientific validity
 - Global/local standard-of-care
 - Competitive landscape

Conclusion and Recommendations (cont')

- **Apples-to-Apples Comparison - Alternative Approach**
 - Rates for key positions
 - Unit prices for common tasks
 - Simple "mock bid" comparison
- **Strike the Balance between....**
 - Client corporate objectives
 - CRO experience and innovation
 - Price/Value



Jim Powers
Executive VP
PRA International

Traditional CRO Bidding Approaches

- **Centralized**
 - One location bids for all
- **Decentralized**
 - Bid by location that will perform the work

PRA Historical

- **Automated bid model**
 - Evolved to multi-phase
- **Decentralized (bid on location)**
- **Avoid "over the wall" mentality (BD vs. Operations)**
- **Operations managers review and approve hours**
- **Rules of engagement**
 - Operations has final say
- **Instituted daily RFP call to assign "home" location**
 - Resource availability
 - Experience

The Challenge

- **Global expansion**
- **Increased complexity**
- **New functional managers**
- **Bids require 25% of functional manager time**
 - Distraction from Operations!
- **Operations resistance**
 - Time
 - Interest

The Solution

- **Moved to centralized bidding in mid-2003**
- **Proposal Coordinators at 2 locations (NA and EU)**
 - Bidding tool
 - Proposal production
- **Proposal Directors**
 - Located regionally
 - Top Operations managers and PMs
 - Necessary growth step to VP (know the business)
 - Bid parameters and implementation strategy
 - Direct contact with client during RFP cycle

The Result

- **Operations' acceptance**
- **"Buy-in" meeting with Operations**
 - Involvement in rebids post start-up
- **Higher quality of Proposals – we think**
 - Improved linkage implementation strategy and costing
 - Consistency in bidding throughout all locations
 - Client surveys
- **Faster turnaround of proposals**
 - Improved review process
 - Greater productivity

Ongoing Challenges

- **Proposal Director training**
- **Burn-out**
- **Shortened turnaround requirements by clients**
- **Accessibility to client during RFP cycle**

Open Discussion/Q&A





For More Information

www.theavocagroup.com



Thank You