

RH Bouchard & Associates

- ◆ BioPharma/Clinical
Research Consulting

Contracting and Negotiating Clinical Trials

Workshop E: **Sponsor/CRO Contracts and Relationships**

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Introductions

- ◆ Rikki Bouchard
 - President
 - RH Bouchard & Associates, Inc.

- ◆ Lynn McGovern
 - Director of Outsourcing
 - SYNTA Pharmaceuticals

- ◆ Karen Wall
 - General Counsel, Director Contracts Management
 - INC Research, Inc.

- ◆ Martha Hayes-Burkhead
 - Counsel for Clinical Trials
 - GTx, Inc.



Workshop Topics

- ◆ Business Terms and Contract Terms
 - Key Business Terms
 - Critical Contract Terms
- ◆ Goal of the Workshop: Creating strong relationships through good contract management



Business Terms and Contract Terms—Equally Important?

- ◆ Business Terms
 - Relationship/Culture
 - Communications/Escalation Pathways
 - Expectations
 - Business Process
 - Success Measures
 - Financial Considerations



Contract Terms

- ◆ Risk management and mitigation
- ◆ Ownership
- ◆ Non-use/allowed use
- ◆ Confidential and proprietary information
- ◆ Regulatory compliance
- ◆ Applicable laws



Framework of Contract: Interests, Options and Alternatives

- ◆ Financial
- ◆ Legal
- ◆ Relationship/Operational



Business Terms and Contract Terms

Both are critical to success!



The Environment--CROs

- Sponsors hold us to a higher standard
- Negotiations are often “one-sided”
- There is an inability to focus on the “big picture”
- Sponsors “micromanage”
- Trust and sharing of information is an issue
- Lack of understanding of “the CRO world” – business issues, experience of the teams
- We are not treated like professionals, not respected
- CROs want to be “part of the team”



Challenges of Sponsor/CRO Relationships—The CRO

- Sponsor expectations are not clear
- Disconnect between expectations of outsourcing group and the clinical teams
- Helping Sponsors understand that the lowest bid may not be the best value
- Functional outsourcing makes building a team and successful project management difficult
- Tremendous timeline pressure
- Ineffective internal communication at Sponsor
- Sponsor does not take advantage of the value CROs provide



Challenges Sponsor/CRO Relationships – The Sponsor

- CROs underbidding and then not having sufficient capabilities to deliver services
- Getting a high quality deliverable with minimal Sponsor input
- Limited number of ‘A’ level people at each CRO
- Little variation between CROs - no differentiation
- Lack of transparency in budgeting
- CRO becomes less responsive once project has been awarded
- Finding a CRO that truly “has it all”



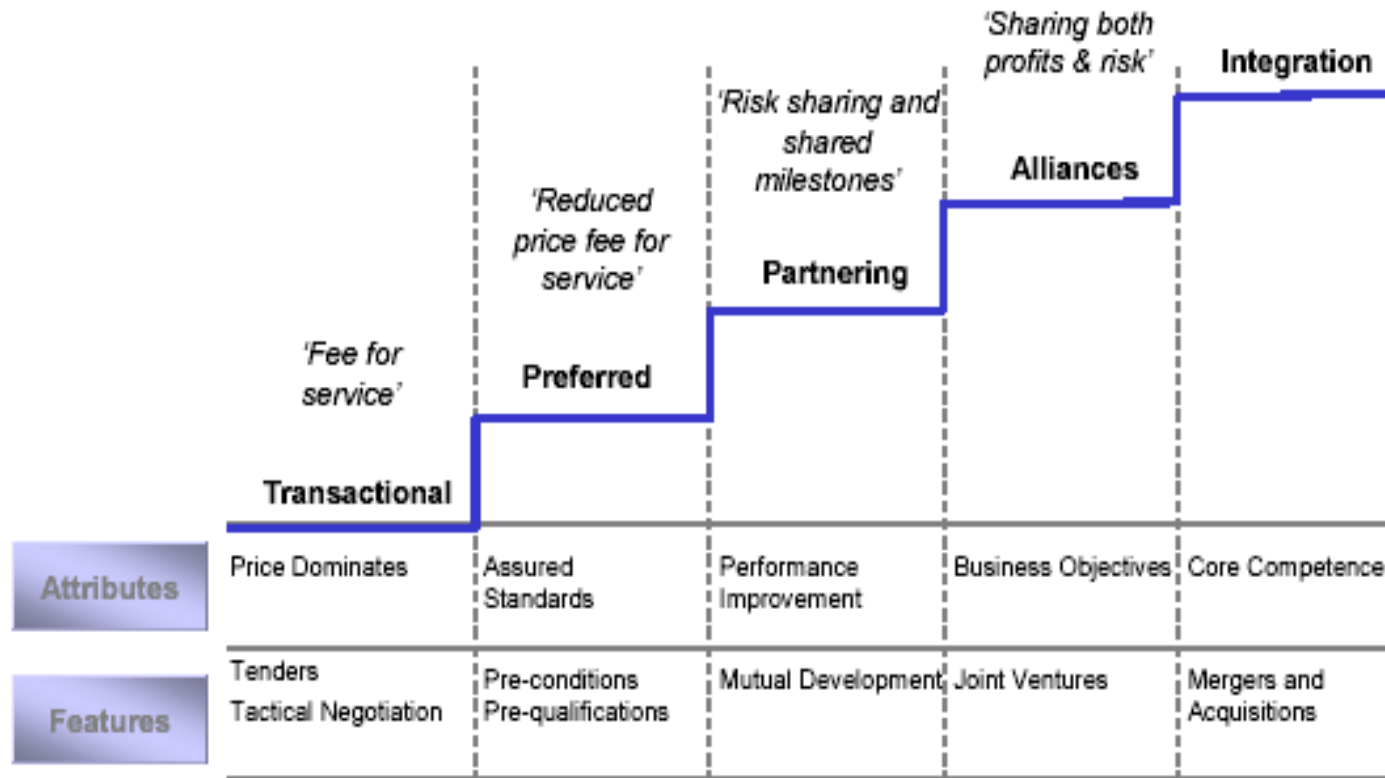
Common Sponsor mistakes....

- Little or no preparation prior to outsourcing a project
- Assuming that the CRO understands your expectations
- Ignoring potential issues that could derail project success
- Not customizing the approach to your project
- Engaging in non-value added work
- Lack of focus on the hand-offs and transitions between companies and within the CRO
- Minimizing the importance of *energizing the team*



Outsourcing Models-Structure the Relationship

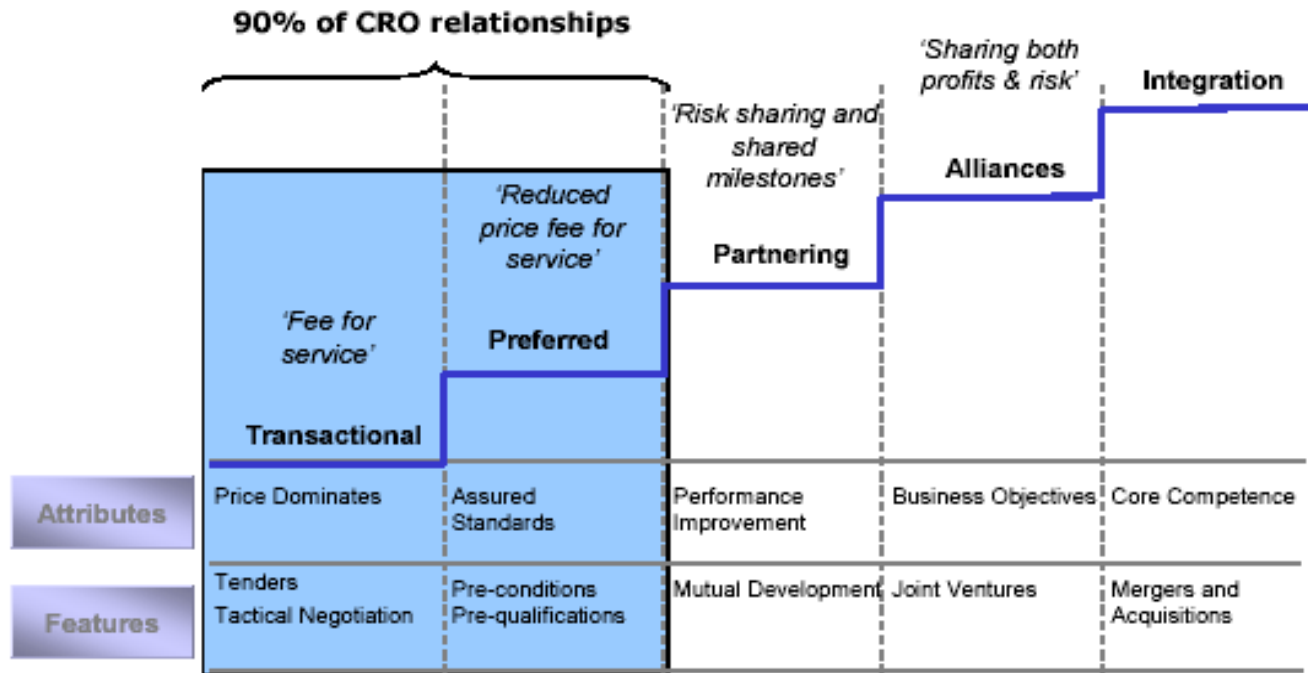
There are different levels of supplier relationship, any of which are valid under the right circumstances





Outsourcing Models

Where do most supplier - sponsor relationships stand





What Defines a Successful Sponsor/CRO Relationship?

- High quality deliverables
- Adherence to timelines/milestones
- Adherence to methodological specifications
- Adherence to regulatory and other quality standards
- Minimization of management required by Sponsor
- Containment of costs
- Positive interpersonal interactions
- Clarity in communication
- Compatible Corporate Cultures



Qualities of a Successful Relationship

- ◆ Trust
- ◆ Excellent Communication
- ◆ Quality
- ◆ Integrated Team
- ◆ Efficient (Time/Cost)



CRO performance is most strongly correlated with:

- ◆ CRO's understanding of Sponsor's expectations
- ◆ Quality of CRO staff
- ◆ Meeting Timelines
- ◆ Communication
- ◆ Personal compatibility between teams
- ◆ Cost
- ◆ CRO responsiveness
- ◆ Seamless work process



#1 Reason for Dissatisfaction with CRO

Failure to meet Sponsor Expectations



Who is at fault?

- ◆ Sponsors need to better define their expectations
- ◆ CROs need to ask for clarification and direction—don't assume
- ◆ Business terms need to be clearly laid out in the contract



Have you heard (or said) this?

- "They're charging us enough money; they should be able to figure it out."
- "The CRO should just know."
- "We just didn't have time to think about these things with everything else that was going on."
- "We have internal organizational problems and couldn't get everyone to come together and agree."
- "We didn't realize what we were going to need to be thinking about."
- "It's confidential information"

Communication is Key!



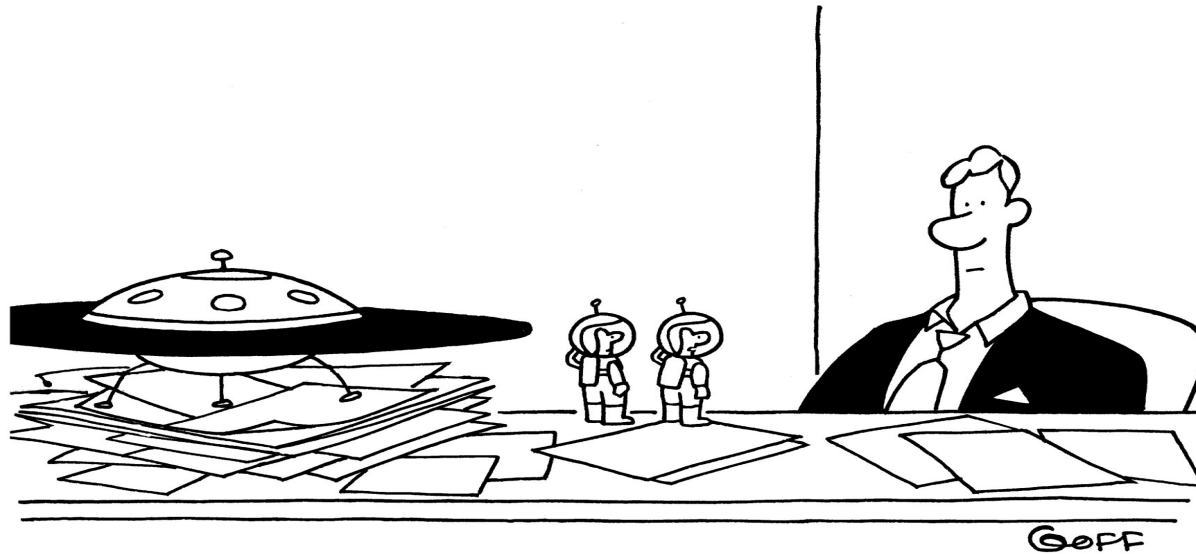
Biggest Pitfalls for Sponsors

- ◆ **Failure to specify:**
 - Details
 - Methods/means
 - Timing
 - Contingency plan requirements
 - Priorities
 - Formats
 - Commitments
 - Responsibilities/initiative
 - Review procedures and expectations
- ◆ **Failure to align expectations with contract**
- ◆ **Failure to provide detail in the contract**



“It’s in the contract”

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**“We told you we were coming.
Didn't you read our memo?”**



Know Your Contract

- ◆ Include detailed business terms in the contract or work order
- ◆ Manage to the terms
- ◆ Communicate often and well
- ◆ Measure your success
- ◆ Make revisions when needed



Key Business Terms

- ◆ Governance
- ◆ Relationship Management
- ◆ Financial
- ◆ Process Improvement
- ◆ Measures of Success: Key Performance Indicators