



42nd
Annual Meeting



Philadelphia 2006

Outsourcing Strategy for Emerging Companies

Rikki Bouchard

President and CEO

RH Bouchard & Associates, Inc.

Learning objectives

At the conclusion of this session, participants should be able to:

1. State why and when an outsourcing strategy should be put in place
2. Understand the models and criteria for choosing between them
3. See how different strategies have worked in three companies



Introductions

Rikki Hansen Bouchard

President and CEO

RH Bouchard & Associates, Inc.

Kate Findlen

Senior Director, Clinical Compliance

CombinatoRx, Inc.

Karen Brennan

Senior Director, Clinical Operations

RenaMed Biologics, Inc.

Jennifer Goodfellow

Senior Director, Clinical Outsourcing

Sepracor, Inc.





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Outsourcing Strategy for Emerging Companies

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Outsourcing Strategy-Why, When and How?

- Why do you need a corporate strategy?
 - Maximize Resources/Minimize Risk
- When should you develop your strategy?
 - Dependent upon your pipeline/stage of development
 - Multiple projects at various stages
 - Single product in early development
 - Single product, single indication
 - Single product multiple indications
- How do you develop a strategy?



Development Models

- Internal Development
 - Evaluate internal resources
 - Short-term
 - Long-term
 - Capability to develop internal resources
 - Growth Plans
 - Funding
 - Set Priorities



Development Models

- Licensing
 - Early Phase Development
 - Proof of Concept
 - Phase II
- Partnerships/Co-Development
 - Shared resources
 - Joint development agreements
- Investment Model
 - VC/CRO Partnerships



Virtual vs. Traditional

- Skills and experience of staff
 - Early phase emphasis
 - Clinical development expertise
- Infrastructure and corporate support
 - Resources
 - Funding
 - Critical Mass
- Company Mission and Goals
 - Marketing products
 - Pure R&D



Outsourcing Strategies

- Geography-Global/International/Regional
- Preferred/Pre-Qualified Providers
- Project by Project—Tactical Outsourcing
- Full Programs/TA/Indications
- Core Competency



Outsourcing Models

- **Full Service**
 - Program
 - Project
- **Functional**
 - In-source staff
 - Outsource functional area
- **Niche**
 - Therapeutic Area
 - Geography
 - Technology
- **Multiple Providers—One Project**



Identifying the Best Provider

Requests for Information (RFI)

- **Establish and weight key decision-making criteria**
 - Therapeutic expertise
 - Team experience
 - Speed, responsiveness
 - Price
 - Cultural fit
- **Targeted RFI measured against criteria**
 - Prepare side-by-side RFI comparison
 - Score RFIs, discuss, and make decision



Best Practice Outsourcing

Quality of selection process has big payoff against future time spent resolving issues

- Selection of best team
- Commitment to your goals
- Effective communication of needs and expectations
- Understanding of project resourcing, contract terms and deliverables

Evaluation tools

- Targeted RFI, decision-making criteria, RFP, score cards, etc.



Small = Big Business

- **Drug Discovery**

- Biotech, not big pharma, are discovering most of the new drugs
- Biotech is approaching 50% share of outsourced clinical research market

- **Know your strengths**

- Early stage pipelines are viewed as entrée to later phase projects
- Small companies take partnering concept further
- Small to medium companies are growing CRO market segment

- **Sell yourself as a customer**

- Discuss development programs and strategies openly
- Provide context around planned development spending



Developing Partnerships

Implement structure around key Provider relationships

- Establish Senior Level Oversight Committee with regular (quarterly) meetings and point-to-point contact**
- Identify issue escalation and resolution path and process**
- Use metrics to measure performance against expectations**
- Develop consistent business processes for contracting, change orders, financial transparency, and discounting**
- Evaluate overall relationship progress at pre-defined time points**



What should you expect from a CRO?

- Experienced team
- Quality performance
- Responsiveness
- Open, honest, and frequent communications
- Problem solving
- Timely deliverables
- Reasonable cost



What do you need to do?

- Demonstrate trust and respect
- Set expectations and communicate them regularly
- Manage expectations-revising as needed
- Build in performance checks
- Establish clear communications pathways and escalation plans
- Recognize problems will occur-plan for them
- Mitigate risk on both sides
- Build a team
- Learn from your mistakes and your successes
- Share the glory





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Kate Findlen

Senior Director, Clinical Quality
Compliance

CombinatoRx, Incorporated

Philadelphia 2006

Who are we?

- Small biopharmaceutical company
- Develop Combination products in Immuno-Inflammatory disease, Oncology, Metabolic disease, Neurodegenerative Disease and Infectious disease
- Six products in Phase II



What goes around.....

The Background- 2003

- Small company, 2 single center US studies
- All monitoring and Project Management outsourced to one providers
- Data management in house
- Small clinical operations department in house



Comes around...

2004

- Add 3 small EU studies
- Add 2 additional CROs in EU
- Add Data Management provider
- Start building staff in clinical operations in-house



History...

- Providers originally chosen because of specialized services (therapeutic area, geographic location)
- No belief that services could translate to additional studies
- Changes in staff at sponsor and provider
- Budgets under tight scrutiny



Growth...

Internal Clinical Operations Department built

- In 6 months 14 new clinical studies started across EU and North America
- All monitoring and Project Management brought in house
- Five CRAs and one assistant added
- All relationships with outside monitoring and Project Management terminated



The best laid plans...

- Traveling staff also act as Lead CRAs for studies
- CRAs traveling 50 - 80%
- More than 50% of sites in EU
- All sites monitored by US staff



Full circle

Strategic outsourcing plan laid out

- Requirements
 - Personal service
 - Targeted monitoring capability with growth potential
 - True “team” members
- Niche North American monitoring group hired



The Future...

New (old) model of CRO / sponsor relationships

- Major CROs are partnering with venture capital firms to develop strategic partnering solutions in all phases of clinical development
- Portfolio approach to clinical development
- True shared risk for sponsor
- Little or no investment from sponsor unless significant milestones are reached
- Huge potential gains for the CRO if successful



The Lesson...

Learn from past mistakes

- Do not assume niche providers cannot be versatile if given the chance
- Understand your own weaknesses and strengths to best assess your true needs
- Look for innovative solutions across the organization
- Look for long term gains in partnering
- Build trust in the partnership





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Defining an outsourcing strategy in a small biotech company

Karen Brennan

Senior Director, Clinical Operations
RenaMed Biologics, Inc.



Who is RenaMed Biologics?

- Small biotech co. (~85 employees)
- Committed to the development of novel cell based therapies
 - treating life threatening illness
 - meeting unmet medical needs
- Single product in development – Renal Bio-replacement Therapy (RBT)
- Studies initiated for 2 indications (CKD and ARF)
- Privately held/venture funded
- Co-development partnership with large well established biotech co.



Product Profile

- Renal Bio-replacement Therapy (RBT)
 - Novel complex cell therapy product
 - Regulated by CBER with CDRH consult
 - Combination product (Human Renal Epithelial Cells contained within the hollow fibers of a standard hemofilter)
 - Therapy is provided using existing extracorporeal technology
 - Product received fast track designation from FDA April 2004
 - Aggressive development plan
 - Clinical trials being conducted US only



Clinical Development Plan

- Phase I
 - Conducted under 2 Investigator INDs
 - Completed in 2002
- Phase II
 - IIa study completed in December 05
 - *IIb study initiated in January 06*
- Phase III
 - To be initiated in Q207



The Challenge

- Small company with limited resources
- “new” (unplanned) study to be launched ASAP
 - Inpatient study (ICU patients with multi-organ failure; predicted mortality rates >60%)
 - 16 academic centers in the US
- Timing considerations
 - Decision to move forward with study: June 05
 - Draft protocol available: August 05
 - Final protocol available : December 05
 - Need First Patient In : Dec 05/Jan 06
 - Need to identify CRO partner : ASAP



Small Biotech seeks Development Partner

Small biotech company seeking long term relationship with full service CRO. Experience, flexibility and responsiveness are key to successful relationship. Must be proficient with EDC and willing to work with a milestone based contract. Travel within the US is required. Therapeutic expertise a plus.



CRO Selection Process and Timeline

- Evaluate internal capabilities
- Design RFP template
- Solicit bids from short list
- Review bids/revise with selected short list
- Proposal defense meetings
- Revised bids
- Final selection criteria
- Present to senior management for support/approval
- Present to BOD for approval
- Negotiate master services agreement and scope of work documents
- Execute final agreement
- August 05
- August-mid September 05
- September 05
- October 05
- October 05
- November 05
- November 05
- November 05
- November 05
- November 05
- November 05
- Dec 01, 2005



What help do we need?

- What can we do internally?
 - Provide *limited* services for study startup
 - Site identification and qualification
 - Regulatory document collection
 - Execution of Clinical Trial Agreements and study budgets
 - Select lab
- What do we need our CRO to provide?
 - Services
 - Monitoring
 - Data management
 - Biostatistics
 - Medical writing
 - Safety reporting
 - IVRS
 - DMC support
 - Experienced consultation



Developing the “short list”

Selected 4 CROs for consideration

- 1 large global CRO
- 1 niche provider
- 2 small general service providers (1 with prior history/experience with the company)



Evaluating options

- Have to haves
 - Full service capabilities
 - Experienced team
 - Flexible work processes
 - Cost efficiencies
 - EDC expertise
 - Experience with small virtual companies
 - Able to mobilize quickly
 - Team “fit”
- Nice to haves
 - Therapeutic expertise
 - Global reach (future development needs)
 - Fully dedicated team
 - No turnover issues



Evaluating selection criteria

	A	B	C
Full service	✓	✓	✓
Experienced team	✓	✓	✓
EDC expertise		✓	
Costs	✓	✓	✓
Efficient processes	✓	✓	
Flexibility		✓	
Team fit	✓	✓	
Therapeutic experience	✓		✓
Global capabilities	✓		
Fully dedicated team	✓		



The Decision

- Selected niche provider (“B”)
 - Experience of the project team
 - Quality of their proposal (including costs)
 - Internal processes in place to meet our needs
 - Expertise with EDC
 - Ability/commitment to meet our timelines
 - Experience of the organization
 - Strength of the reference checks



Managing expectations

- Establish performance expectations up front
- Establish metrics to evaluate performance
- Monitor performance and address issues in a timely fashion
- Establish schedule to discuss performance (operationally and against budget)
- Establish problem escalation policy up front



Six months later.....

- ✓ Experienced team
- ✓ EDC expertise
- ✓ Cost and process efficiencies
- ✓ Committed to meeting timelines
- ✓ Flexibility and willingness to work with us to solve complex problems
- ✓ Low turnover
- ✓ Open communication
- ✓ Established performance reviews





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Jennifer Goodfellow

Sr. Director, Clinical Outsourcing
Sepracor Inc.



Who Are We?

- Medium-sized pharma company specializing in CNS and Respiratory
- ~2215 employees (of which 1600 are in sales and ~200 are in R&D)
- Three marketed drugs including Lunesta®
- Profitable for 1st time in 4Q05



Who Are We?

- Outsourcing Strategy
 - Pre-qualified providers
 - Full service
 - Program based
- Approx. 95% of clinical studies outsourced (some DM and biostat in-house)
- Dollars contracted by Outsourcing in 2004 and 2005: Approx. \$80M each year
- Outsourcing group consists of 3 people



Many years ago...

- Project Coordination, not Outsourcing
- No corporate outsourcing strategy
- Used CROs that were most recently used
- Study-by-study outsourcing
- No set CRO selection criteria
- Contracts took months to finalize
- CROs not audited by QA



Many Years Ago...

- Okay RFP, but not stellar
- Used CRO's Work Order or a recent one we liked
- Subjective rather than objective selection
- Little effort put into relationship building at multiple levels
- Easy to point the finger: Always the CRO's fault



Where We Are Now

- Small pool of pre-qualified providers
 - Structured selection process
 - Detailed RFI
 - Multi-function selection team
 - Corporate support to only use pre-qualified providers
 - MSAs executed
 - Audit performed by Corporate QA and functional group
 - Negotiating Business Term Agreements (preferred rates, inflation, exchange rates, governance)



Where We Are Now

- Standard internal contracting timelines and agreement about contracting starting point
- Excellent RFP
 - Heavy functional involvement RFP specs
 - Detailed Responsibility Matrix
 - Study Specifications
 - Monitoring Summary
 - Study Timeline
 - Unitized Budget Grid linked to specs, timeline, and monitoring summary



Where We Are Now

- Standard Work Order template allows CRO to focus proposal on:
 - Strategy
 - Team
 - Budget
 - Differentiating factors
- Standard WO template requires no review by functional team before execution (saves time!)
- Interactive/Proactive Change Order process



Where We Are Now

- Proposal summary template
- CRO selection score cards
 - Proposal review scoring
 - Defense scoring
- Corporate Governance
 - Executive Steering Committees
 - Joint Oversight Committees



Where We Are Now

- Goal of full-service outsourcing to one CRO per study/program but some functional splits
- Goal of full-program outsourcing (need Program Development Plans) but some study-by-study contracts
- Most studies within a drug development program outsourced to 1 - 2 CROs



Where We Are Now

- Outsourcing Manager member of study teams
- Outsourcing Director sits on or chairs joint oversight committees
- Priorities discussed/set monthly with all program directors at one meeting
- Weekly contracts telecons with CROs
- Central repository for CRO information, performance, capabilities
- Outsourcing group members are strategic experts regarding CROs and contracts
- Outsourcing: the Go-To People for solving issues with CROs



Where We Want To Be

- Automated RFI process
- Tighter timelines
- Improved tracking and metrics
- CRO-specific Budget and WO Templates based on Sepracor standard templates



Where We Want to Be

- All full-service outsourcing (no functional-splits)
- All full-program outsourcing (no study-by-study contracting)
- Relationship surveys completed and implemented
- Executed Business Term Agreements with all pre-qualified providers



Summary

- Strategies evolve as companies grow
- Don't be afraid to change course
- Build in periodic reviews of strategy
- Develop tools and processes that promote efficiency
- Plan and plan some more



Q&A

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