



# Partnering Strategies for Emerging Sponsors and Niche Providers

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# Introductions

- Donna Berk, Clinsys--Full Service CRO, 200 staff, Therapeutic Specialization, US/EUR/India
- Karen Brennan, RenaMed Biologics--Critical Inflammatory Diseases, 1<sup>st</sup> product in Phase II
- Kathryn Steide, Praecis Pharmaceuticals—Oncology and Autoimmune Disorders, 2 products in Phase I
- Kate Findlen, CombinatoRx—Combination Products in Immuno-Inflammatory, Oncology, Endocrine, multiple products in Phase II



# Opening Remarks

## Qualities of a Successful Partnership

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



# What Sponsors Want

- Expectations fulfilled
- Quality, experienced CRO staff
- Milestones completed on time or early
- Proactive communication
- Team member compatibility
- Highly responsive team
- Reasonable Cost



# What Niche CRO's Provide

- Specialized Teams
- High Quality
- Management Oversight
- Personalized Service
- Value Added
- Cost Competitive



# Does Size Matter?

Yes, No, Maybe—A Discussion



# Biotech and Niche CROs

Donna Berk  
Chief Operating Officer  
Clinsys, Inc.



# Biotech Growth

## ■ Market capitalization

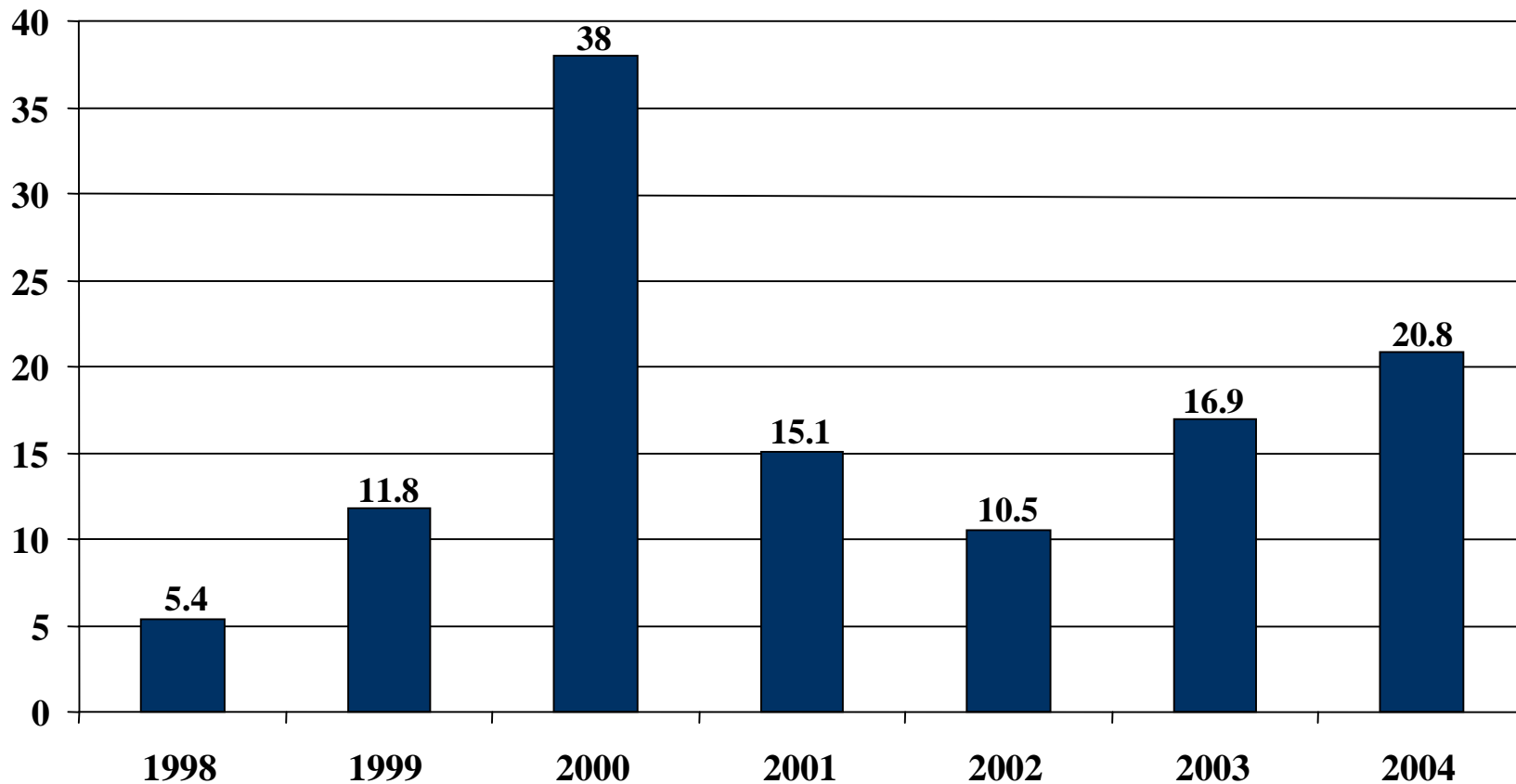
- Total value of publicly traded biotech companies (U.S.) at market prices, was \$311 billion as of early April 2005.

## ■ Clinical Trial Impact

- There are more than **300 biotech drug products and vaccines currently in clinical trials** targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis.



# Total Financing, 1998-2004 (in billions of U.S. dollars)



Source: *BioWorld*



# Biotech Growth

- Drug Discovery

- Biotechs, not big pharma, are discovering most of the new drugs

- Biotech and specialty pharma emergence

- Biotechs are approaching 50% share of outsourced clinical research market

- Biotech ≠ Small



# Partnership Challenges

- High stakes – a lot at stake for company/sponsor contact
- Funding sufficient to cover study/ development program
- Could be stops/starts/delays – risk is a bigger factor in working with these clients; earlier stage development
- High expectation/stress for meeting deliverables



# Meeting Smaller Company Needs

- What do they need help with?
  - Pay and play, “Do as I say”?
  - Systems
  - Critical thinking
  - Collaborative/consultative
- What is important?
  - Timelines, quality, price, individual attention, sense of priority, competencies

# One Size Fits All? Are All CRO's the Same?



- Consider how smaller CROs market themselves:
  - A “boutique” approach
    - Unique and special products
    - Narrower focus
    - Individual attention to customer needs
    - “Custom” service
- With:
  - Department store prices



# Outsourcing Strategies-A Case Study

Karen Brennan

Sr. Director Clinical Operations

RenaMed Biologics, Inc.



# 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.



# The Challenge

- Small company with limited resources
- “New” study to be launched ASAP
  - Single product in phase II (complex cell therapy/device combination product)
  - Inpatient study (ICU patients with multi-organ failure; high mortality rates)
  - 15 academic centers in the US
- Time constraints!
  - Decision to move forward with study: June 05
  - Data results needed: Q3 06





# The Strategy

- Select 4 CROs for consideration
  - 1 large global CRO
  - 1 niche provider
  - 2 small general service providers (1 with prior history with the company)
- Solicit bids: be specific with RFP information
- Evaluate written proposals
- Evaluate proposal defense strategy
- Evaluate references
- Compare and contrast capabilities
- Develop priority list (have to have it!)
- Determine best “fit”



# 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/turn on a dime
- Team “fit”

## ■ Nice to haves

- Therapeutic expertise
- Global reach (futuristic)
- Fully dedicated team
- No turnover
- Creativity



# The Decision

- Selected niche provider
  - Full service capabilities
  - Expertise with EDC
  - Experienced team
  - Flexible processes
  - Able to meet cost considerations
  - Team “fit”



# Justification (Sr. Mgmt. and BOD)

- RFP sent to 4 CROs
- 3 CROs brought in for proposal defense meetings
- All CROs evaluated on the following:
  - Quality of their proposal (including costs)
  - Experience of the project team
  - Internal processes in place to meet our needs
  - Ability/commitment to meet timelines
  - Experience of the organization
  - Strength of the reference checks



# CRO Selected

- Identified an appropriate team
- Exhibited a good understanding of program
- Ability to efficiently and expertly manage EDC
- Provided senior management support
- Committed to aggressive timelines
- Displayed a willingness to negotiate
- Provided excellent references



# Conclusions.....

- This will be one of your most important decisions
  - Spend the time to accurately assess your needs and your requirements
  - Know what is most important and focus your search accordingly
  - Find the time to get it right!
  - And finally...
    - Deciding which CRO is right for you is only the beginning
    - The relationship needs to be nurtured and re-evaluated on an ongoing basis



# Small Sponsor Considerations

Kathryn Stiede

Sr. Director Clinical Operations

Praecis Pharmaceuticals, Inc.



# Niche Provider Benefits

- Strong knowledge base of niche indication
  - Provides sponsor with meaningful feedback
    - Protocol and CRF design
    - Site recruitment
    - Subject recruitment and retention
- Staff experience in niche indication
  - Project Management
  - Monitoring
  - Data Management
  - Biostatistics





# Niche Provider Benefits

- Flexibility

- Willingness to work outside the box

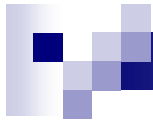
- SOP's

- Work to sponsor needs

- Sharing of responsibilities

- Decreased start up time

- Cost – Competitive (usually lower)



# Managing the Relationship

- Establish a relationship with all members of the niche provider team
- Work towards a project team that is a single unit
- Expect change during the project



# Managing the Relationship

## ■ Communication

- Establish a detailed communication plan
  - Communication flow
  - Expectations
  - Assigned responsibilities
- Include all appropriate team members in your communications
  - Teleconferences
  - Emails
  - Letters
  - Document review
- Elicit feedback and opinions



# Managing the Relationship

## ■ Communication (cont.)

### □ Don't hold back

#### ■ Be open about problems or issues

- Protocol

- Sites

- Recruitment

- Staffing

#### ■ Communicate successes

### □ Respond to all communications in a timely manner



# Disadvantages of Niche Providers

Kate Findlen

Sr. Director Clinical Operations

CombinatoRx, Inc.



# Why Relationships Fail

- Niche provider has narrow focus
  - Experience cannot be transferred to new products (Ex. Oncology vs. cardio)
  - Staff not interested in transferring to different focus
  - Lack of flexibility for team due to specialization



# Why Relationships Fail

- Project takes too long
  - Small studies with specialized population = accrual nightmare
  - Use of high profile investigator = too many competing studies = slow accrual
  - Sponsor inexperienced and learning on the job = many protocol changes



# Why Relationships Fail

- Changes in staff at sponsor and provider
  - Slow start and progress = promotions, changes, transfers
  - Change in focus of sponsor to new projects
  - Change in focus of CRO to more lucrative contract opportunity





# Why Relationships Fail

- Scope changes not well documented
  - Under developed tracking and metrics management systems in place
  - Budgets under tight scrutiny
  - Payment to CRO slow



# Overcoming Resistance to Outsourcing

- Talk to real peer references
- Do plenty of homework
  - Good RFP
  - Comparison chart
- Spread the wealth
  - Do not be afraid to use multiple niche providers
  - Ask CRO for more input to cost comparison of outsource vs. in-source



# Summary

- Outsourcing Strategy must fit the goals, needs, and culture of your organization
- Pick your partners carefully—invest the time to get it right
- Support the long-term relationship
- No one element (size, cost, or even experience) should be the determining factor



Q & A

Thanks for your participation  
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