

## Pharmaceutical Outsourcing: Effective Collaborations with CROs in Uncertain Times

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### Agenda

- The Pharmaceutical Industry
- Outsourcing to CROs
- Tracking Global CRO Usage
- Sponsor-CRO Relationships

## The Pharmaceutical Industry in 2009

- Economic downturn
- R&D spending has been down
  - Lay off R&D professionals - 7,000 R&D positions eliminated since June 2008
  - 7% of total R&D headcount employed by the top 30 pharmaceutical companies globally
  - Rising capacity constrains amidst a growing R&D workload
- Drop in early-stage research
- Focus on late stage assets
  - Face patent expiration
  - Higher probability of technical and regulatory success
  - Can be commercialized more quickly
- Move from preclinical pipeline development to molecules that were closest to the cash

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## The Pharmaceutical Industry – cnt'd

- Severe global market conditions
  - Smaller Pharma, Biotechs and startups were disproportionately affected
- Unforgiving investment community
- Slower growth in revenue
- Loss of \$\$ in patent-protected sales
- Seek further reduction in fixed costs
- Expansion to Asia Pacific region
  - cost effectiveness
  - recruitment efficiency

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## Pharmaceutical Outsourcing

- Demand to contract clinical research services continues to grow rapidly
- Usage of full-service and niche-service CROs is evolving
- Annual growth in CRO services **13.4%** since 2001
- Annual growth rate in total global drug development – **9.1%** during the same period
- CRO market is expected to grow 14% per year during the next three years, making contract service a \$35 billion industry by 2013

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## Pharmaceutical Outsourcing – cnt'd

- Sponsors require more specialized research services
- Increasing demand for bio-analytical services such as immunology and toxicology as well as pharmacology
- Strong growth across lab business
  - cGMP analytical testing labs for comparative clinical trials in Biosimilars
  - Immunogenicity testing services for vaccines and biologics
- Within the next three years, biologics are expected to account for more than 50% of newly approved medicines

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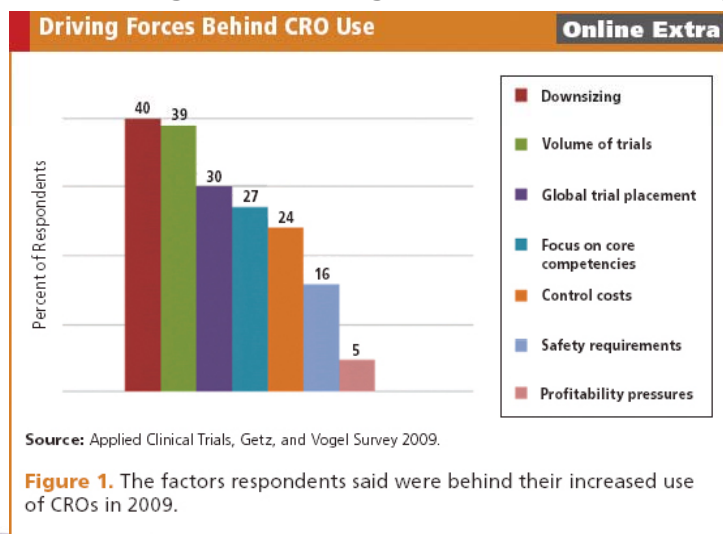
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## The Big Get Bigger

- Mega-mergers and acquisitions, driven by the need to streamline drug development will drive increased outsourcing; the acquiring company, with a reconstituted product pipeline:
  - seeks to achieve greater efficiencies
  - improved productivity
  - lowered costs that can be provided through outsourced partners
- Outcome of mergers is that big pharma companies will focus on drug discovery on the front end and marketing on the back end. Sponsors will need closer integration and strategic relationships with CROs

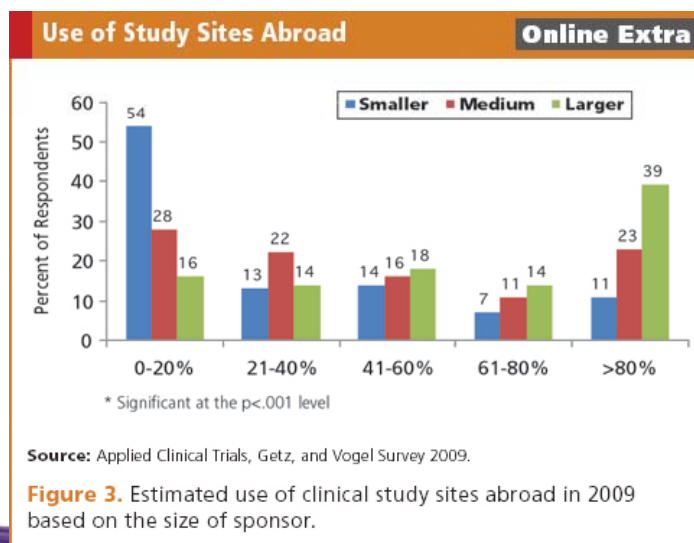
## Outsourcing: Tracking Global CRO Usage



## Tracking Global CRO Usage: Global Focus

- Larger sponsors are more likely to use sites abroad
- Smaller sponsors were less likely to use investigative sites in Eastern Europe, Asia, India, China, and Latin America
- 41% or more of studies planned for 2009 will be conducted among investigative sites in North America Western Europe was second most popular with 26% of respondents, followed by Eastern Europe with 18%
- Sponsors rely primarily on large global CROs to conduct studies abroad

## Use of Study Sites Abroad



## Tracking Global CRO Usage: Usage Mix

- Low outsourcers (less than 40% of their development budgets) tend to favor managing a broad mix of full- and niche-service providers
- High outsourcers (greater than 60% of their overall development budgets) clearly favor working with full-service providers
- A majority of sponsors (61%) report that they use less than five CROs
  - inefficiencies inherent in managing a fragmented number of service providers
  - delegating more responsibility to fewer providers offers an opportunity to reduce operating inefficiency and cost

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## Transactional Sponsor-CRO Relationship

- Outsourcing on an ad hoc, per project basis to perform a given task or function
- Sponsors solicit multiple bids and select the lowest bid-provider
- Sponsors have relationships with large number of contract clinical service providers annually
- Frequently, CROs must perform out-of-scope activity, resulting in cost overruns
- Sponsors usually resort to micro-managing the relationship with CRO in order to ensure communication and coordination with the project team
- Sponsors most often turn to transactional outsourcing relationships once the development plan and protocol are completed

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## Partnership-Based Sponsor-CRO Relationships

- Partnership-based relationships lies in an in-depth assessment of, and commitment to the sponsor's core competencies
- Sponsors retain senior-level expertise, but reduce the number of internal staff involved in those functions deemed most suitable for outsourcing
- Once a sponsor has selected a partner, the companies together create a senior-level committee. Executives on the committee come from the sponsor and CRO companies
- Governance in partnership-based relationships is a shared responsibility. The sponsor and the CRO rely on a set of Coordination Operating Procedures (COPs) to ensure that each party's own respective SOPs are consistent, integrated and compatible

## Partnership-Based Sponsor-CRO Relationships – cnt'd

- On the CRO side, these partnership-based relationships:
  - Afford an opportunity to anticipate and plan for upcoming activity
  - Affords the CRO greater autonomy to leverage its expertise, operating practices and efficiencies
  - Reduces the likelihood of out-of-scope costs and allows the CRO to be more proactive
- Sponsors tend to work with only a few full-service CROs, and the responsibility of managing niche service CROs is transferred to the partner provider

## Partnership-Based Sponsor-CRO Relationships – cnt'd

- The sponsor's time is optimized and can be focused on the overall performance of the partner provider and its managed network of contractors
- Nearly all functional tasks can be outsourced to CRO, including:
  - protocol development
  - data management
  - medical writing
  - quality assurance
- Sponsor focuses on:
  - preparing the development plan
  - handling interactions with regulatory agencies

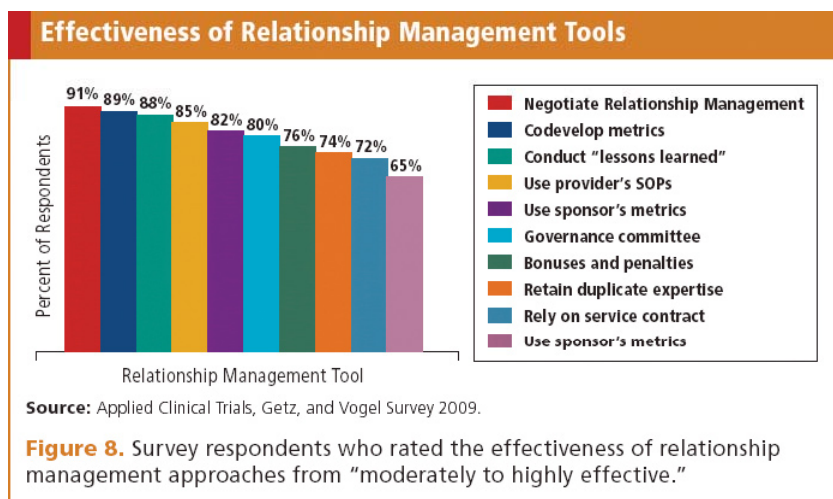
## Relationship Structures

- Drug developers anticipate using a mix of outsourcing relationship approaches depending on a number of factors:
  - priority status of projects in the portfolio
  - competitor landscape
  - competencies chosen to remain in-house
- Large drug development companies are shifting to partnership-based outsourcing relationships
- Small and mid-size pharmaceutical and biotechnology companies have chosen to maintain more transactional relationships and develop fewer partnership-based arrangements with CROs

## Budgets and oversight

- Utilization of CROs is highest among the largest, globally positioned sponsors
  - one-third of sponsors spent less than 20% of their development budgets on outsourcing
  - 40% of sponsors spent between 21% and 60% of their development budgets on outsourcing
  - approximately one-fourth of sponsors spend the majority of their budget (61%+) on outsourcing
- The majority of sponsors do not expect to enter into risk-sharing relationships with their CRO partners

## Effectiveness of various relationship management approaches



## Conclusions

- Although CROs have forecast more conservative growth expectations for 2009, it's only a matter of time until biotech funding and overall R&D spending picks up
- Innovation is vital for successful drug development
- Outsourcing will remain a key solution to efficient drug development
  - Wide variety of activities and functions outsourced on a global level
  - Recession help drive increased focus to the Asia Pacific region
  - Rising capacity demands
  - Growing prevalence of partnership-based outsourcing relationships holds the promise of delivering decreased operating expenses, decreased cycle times, and increased operating flexibility