

Future of CRO-Pharma Relationship: *Thriving with Collaborative Mindset*

Zoran M Pavlovic MD

CEO Heruka Lifescience & Health Innovations



***Euro Global Congress on Pharma & Clinical Trials
November 14th -15th, Rome, Italy***



- **MD degree and Board certified in Psychiatry.**
- **25 years of therapeutic expertise in psychiatry and neurology with a focus on Movement, Cerebrovascular disorders, Alzheimer's and Frontotemporal dementia, Neuropathic pain, schizophrenia, major depression, bipolar disorder, anxiety, ADHD, substance use and impulse control disorders.**
- **14 years in total of CNS clinical research experience as medical investigator, medical monitor, medical advisor and regulatory officer. More than 3 years of global CRO Medical monitoring Neuroscience expertise and more than 1 year of CNS/ Neurology and Psychiatry clinical assessments and psychometric data surveillance experience in conductance of multiple CNS/Neurology/Psychiatry phase III, II and I clinical trials.**
- **Extensive work experience with Regulatory Authorities including EMEA and FDA.**
- **National Advisor of European College of Neuropsychopharmacology (ECNP) and Member of Editorial Board of several CNS peer-reviewed journals.**
- **Experienced, goal-driven and strategically minded and enthusiastic professional with successful Line Management and Leadership experience.**



<https://www.linkedin.com/in/zoranmpavlovic>

AGENDA



- **PRINCIPLES OF COLLABORATIVE NETWORKS**
- **CURRENT STATUS OF CRO-PHARMA COLLABORATION**
- **CASE-STUDIES OF INNOVATIVE TYPES OF CRO-PHARMA COLLABORATIONS**
- **OPPORTUNITIES AND CHALLENGES IN CRO-PHARMA RELATIONSHIP**
- **HOW TO CREATE A SUCCESSFUL CRO-PHARMA PARTNERSHIP MODEL**
- **FUTURE DIRECTIONS IN CRO-PHARMA RELATIONSHIPS**
- **HOW CAN WE HELP YOU**

GENERAL PRINCIPLES OF ESTABLISHING EFFICIENT COLLABORATIVE NETWORKS





“COLLABORATIVE MINDSET” ELEMENTS

- **“We versus I”**
- **Sharing – information and outcome**
- **Trust and have faith**
- **Communicate frequently and openly**



BUILDING A PARTNERSHIP IS LIKE FARMING

**PHASE I:
PREPARING THE FIELD**

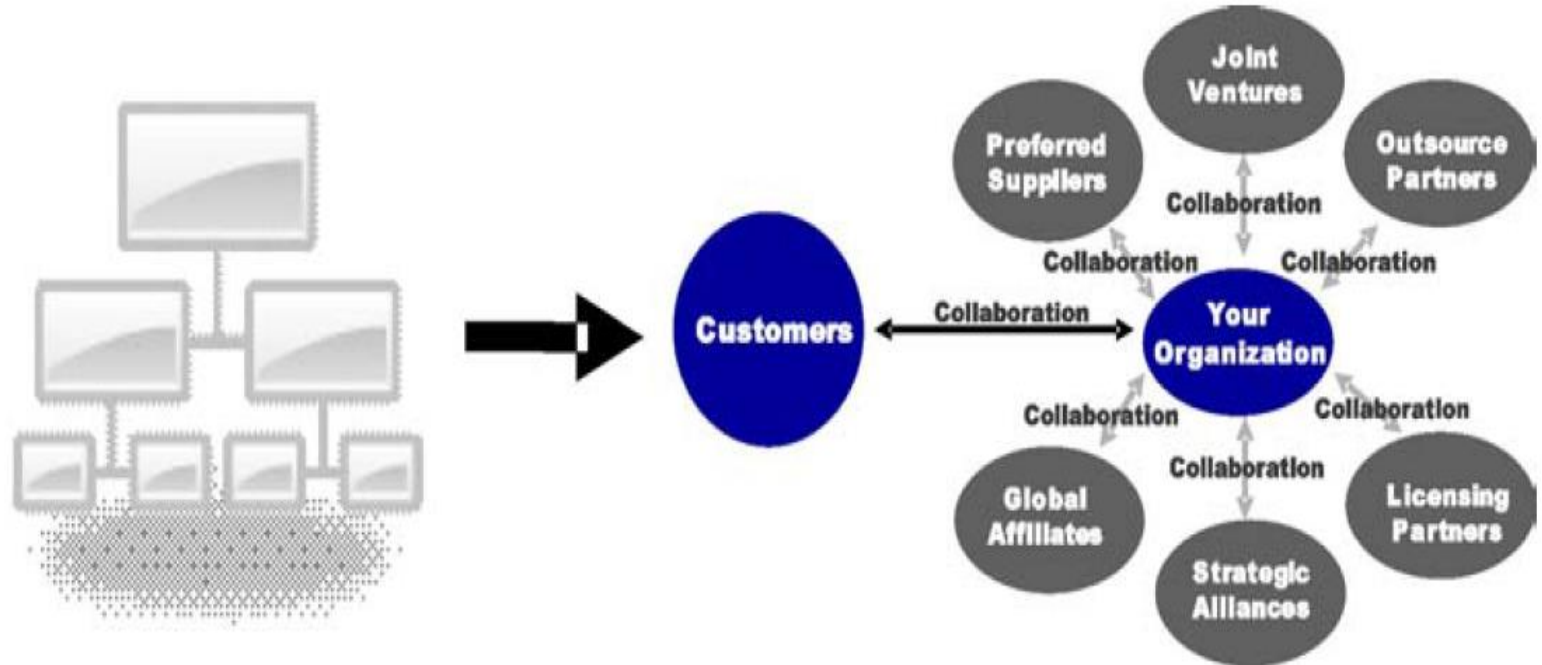
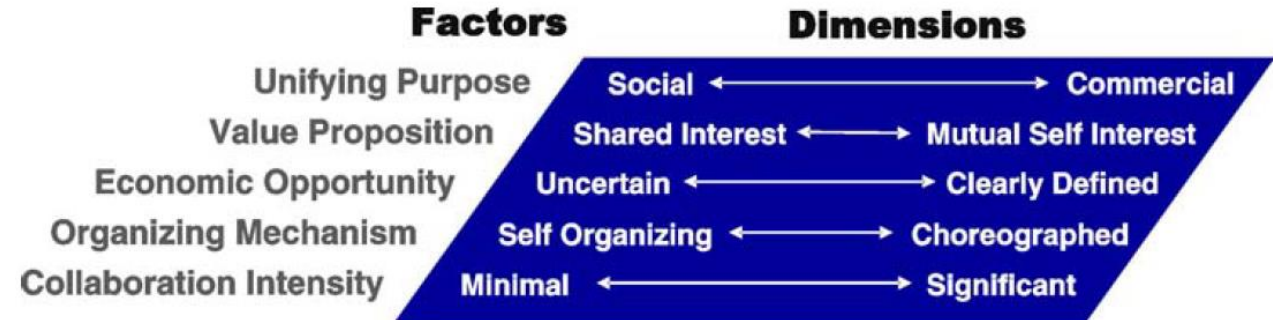
**PHASE II:
SOWING THE SEEDS**

**PHASE III:
WEEDING AND TENDING THE GROWING PLANTS**

**PHASE IV:
HARVESTING**

WHAT IS A COLLABORATIVE NETWORK

Figure 3: Network Design Model



KEY PRINCIPLES DRIVING COLLABORATIVE NETWORKS



Principle #1

Organizations and people only actively engage in collaboration when the benefit they derive is greater than the time and effort it takes to collaborate.

Principle #3

Every network has a choreographer, the individual or entity that organizes the network and is responsible for achieving the purpose of the network.

Principle #2

Collaborative networks are fit for purpose. The purpose determines how the network is structured.

Principle #4

Governance is the system for managing the joint and individual work of the collaboration. Governance principles have both structural and behavioural components.



Figure 4: Collaborative Network Governance Framework

Structural Elements

- ▶ Committee Composition
- ▶ Roles and Responsibilities
- ▶ Decision Making Authority
- ▶ Escalation
- ▶ Milestones
- ▶ IP Rights

Behavioural Elements

- ▶ Communication Protocols
- ▶ Meeting Management
- ▶ Decision Making Norms
- ▶ Conflict Resolution
- ▶ Evaluation
- ▶ Review Processes

CURRENT STATUS OF CRO-PHARMA COLLABORATION





5 TRENDS SHAPING CLINICAL TRIALS OUTSOURCING SDL (2018)

- 1) Expansion of technology enabled trials
- 2) Patient-centric approach to research
- 3) Globalization of clinical trials and focus on emerging markets
- 4) Strategic partnerships with CROs
- 5) Innovation is a priority that is driving change



Business

BROTHERS IN ARMS: BioPharma and CROs collaborating in early drug discovery

Align  Clinical CRO

FOR IMMEDIATE RELEASE

Leading CROs Form New Industry Standards Group to Improve Collaboration with Sponsors

*Align Clinical CRO to create open technology standards that make it easier
for life sciences companies and CROs to work together during clinical trials*

NEW YORK — March 27, 2018 — Six leading contract research organizations (CROs) and [Veeva Systems](#) (NYSE:VEEV) today introduced [Align Clinical CRO](#), a new industry standards group dedicated to making it easier for sponsors and CROs to work together during clinical trials. Founding members, with input across the industry, plan to help create open technology standards intended to improve trial execution and collaboration with life sciences companies.

For the first time, leading CROs, including [ICON plc](#), [Medpace](#), [Pharmaceutical Product Development, LLC \(PPD\)](#), [PRA Health Sciences](#), [Syneos Health](#), and [UBC](#) are coming together to develop open technology standards to transform clinical trial operations across the entire industry to speed product development.

"There is tremendous potential to enhance clinical trial execution with common technology standards that benefit the entire industry," said Henry Levy, president of Align Clinical CRO. "The assembly of Align Clinical CRO represents an important industry collaboration to improve the trial process and how the industry works together to accelerate drug development."

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Piazza Martiri della Libertà, 33 - 56127 Pisa, Italy
ph. +39 050 88.33.43
institute.economics@sssup.it

LEM WORKING PAPER SERIES

The increasing role of contract research organizations in the evolution of the biopharmaceutical industry

Margherita Balconi °
Valeria Lorenzi °

° Department of Economics and Management, University of Pavia, Italy

2017/10

March 2017

GETTING REAL

Partnering for clinical and real-world evidence studies

SELECTING A CRO AS A STRATEGIC PARTNER

Look for a service provider offering integrated development services, including all clinical phases and RWE studies. After initial due diligence and determining the best candidates, conduct an audit history and look for gaps in specific expertise. Acquire information on the prospect's quality record and project management expertise. A positive regulatory history is also important.

In addition to operational, methodological and clinical experience, the CRO must have expertise in clinical and RWE studies. Also look for advanced technical capabilities, reliability, high quality of services/reputation, history of on-time delivery, strong quality record, etc. Work collaboratively with the sponsor to develop operating procedures, and have a dedicated project manager.

PPD[®]



“Big pharma will go towards preferred relationships, but mid-size and smaller pharma and biotechs will look towards working with partners that can do so in a cost-effective manner and provide individualised attention.”

*Ajit Nair, President Global Operations
SIRO Clinpharm*

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“CROs need to move away from a service-provider mindset, and the challenge for us is to move from a buyer mindset.”

*Karin Wingstrand,
Vice-president and head
of clinical development,
AstraZeneca*



WHY STRATEGIC PARTNERSHIPS

- Many trial sponsors are looking for strategic partners to handle the full gamut of clinical trial services from recruitment to reporting. Many also need specialist CROs with specific knowledge and experience in a particular therapeutic area. As sponsors look for development partners that bring breadth and depth of expertise to the trial, they are often considering how they might work with these partners more closely to increase efficiency and decrease costs.
- According to the Tufts Center for the Study of Drug Development, clinical trials conducted by CROs are completed on average 30 percent more quickly than those conducted in-house.
- This results in an average time savings of some four to five months, translating to \$120 million to \$150 million in increased revenue potential.
- CROs that offer greater value across the project will be well-positioned to attract and maintain longer-term partnership opportunities. Adjacent services that add value to sponsors current capabilities without requiring administration of additional contracts with multiple vendors will become strong differentiators.



2015 **OUTSOURCING** SURVEY



2016 **OUTSOURCING** SURVEY





FIGURE 3: What are the top three challenges that you face in working with operating pharmaceutical companies?

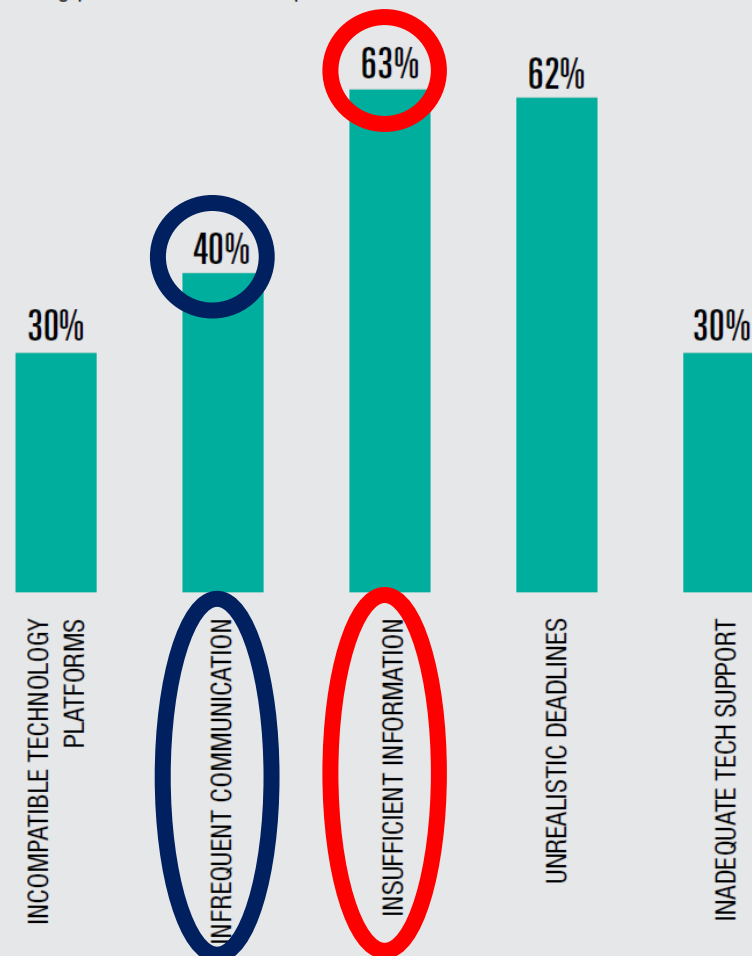
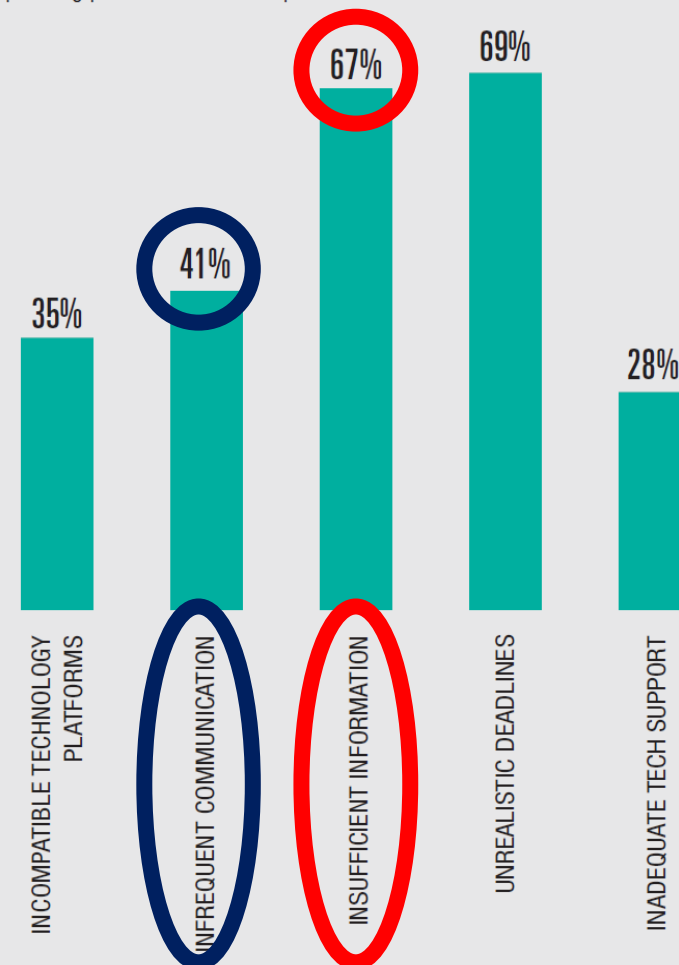


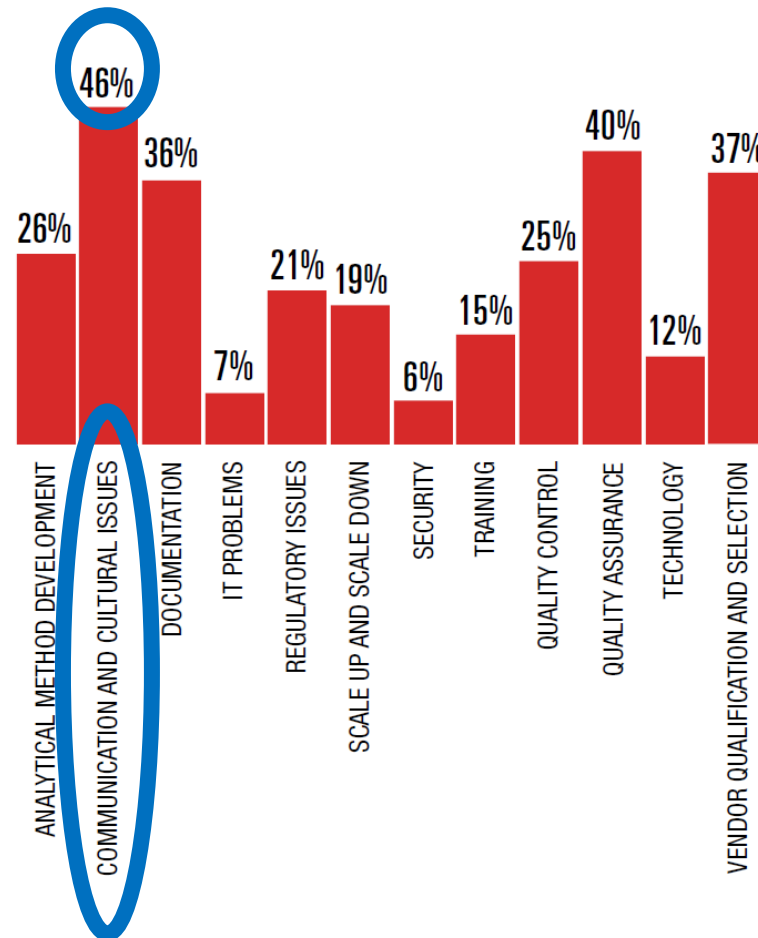
FIGURE 3: What are the top three challenges that you face in working with operating pharmaceutical companies?



Source: Contract Pharma (2016)

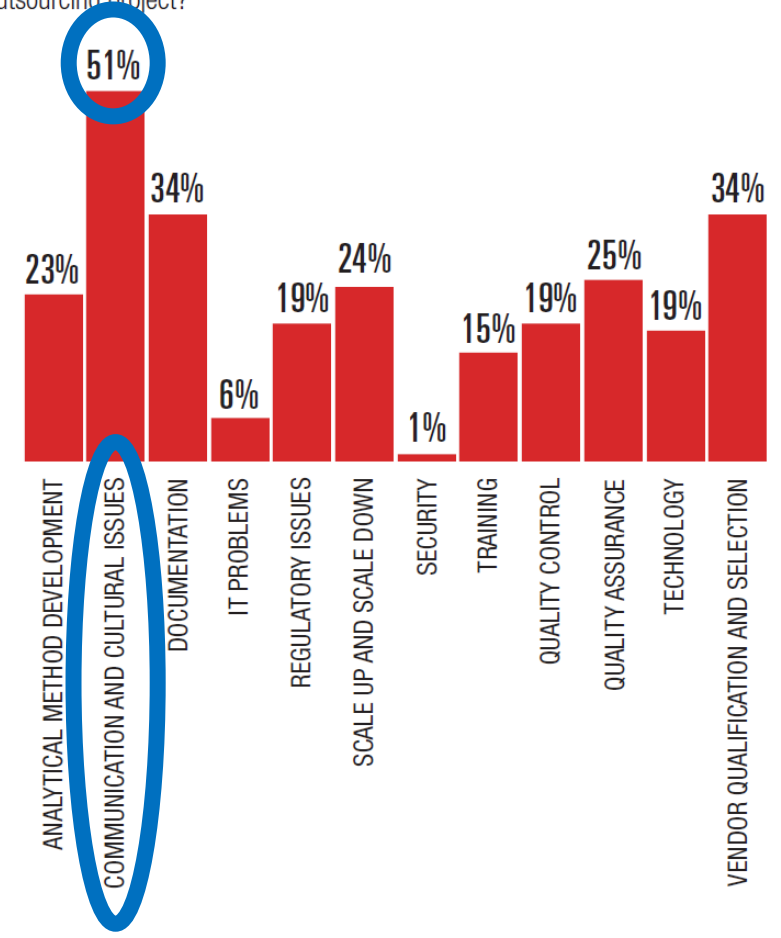


FIGURE 6: What do you find are the most challenging aspects of any outsourcing project?



Source: Contract Pharma (2015)

FIGURE 6: What do you find are the most challenging aspects of any outsourcing project?



Source: Contract Pharma (2016)

Worldwide Clinical Trials' Annual Survey Reveals 2018 Trends in CRO/Sponsor Partnerships



- 1) There is a growing urgency for CRO expertise in early phase clinical research, i.e., first-in-human through proof of concept.***
- 2) There is stable growth in the overall demand for CROs.***
- 3) Data quality tops the list of CRO evaluation criteria.***
- 4) Sponsors are looking for CROs that provide innovative solutions.***
- 5) Sponsors continue to push for clinical trial efficiencies.***



WORLDWIDE
CLINICAL TRIALS

CASE-STUDIES OF INNOVATIVE TYPES OF CRO-PHARMA COLLABORATIONS



ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS



PRE

Case 1 – Progress Requires Partnerships: Collaborative Innovation Helps Fast Track Rare Condition Study

Location of Case: USA

Company Featured: Covance

Innovation Example: Collaborative Innovation

I

Case 2 - Innovation in Trial Recruitment Speeds the Clinical Trial Process

Location of Case: EU

Company Featured: PAREXEL

Innovation Example: Innovation in Trial Recruitment

II

Case 3 - Clinical Trial Costs Reduced Through Innovative Partnerships and a Revised Trial Design

Location of Case: Global

Company Featured: PPD

Innovation Example: Innovative Trial Design, Collaborative Innovation, Innovative Partnerships

II

III

Case 4 - Innovative Partnerships Put Cardiovascular Treatment Trial One Year Ahead of Schedule

Location of Case: USA

Company Featured: Covance

Innovation Example: Innovative Partnerships/Collaborative Innovation



II

III

Case 5 - CRO-Championed Innovation Leads to Early Completion for Global Study of Rare Pediatric Condition

Location of Case: Global

Company Featured: INC Research

Innovation Example: Collaborative Innovation/Innovative Partnerships/Logistics

II

III

Case 6 - Adaptive Trial Design Cuts Costs for Cancer Study by More Than \$1 Million

Location of Case: USA

Company Featured: PPD

Innovation Example: Innovative Trial Design (Adaptive), Optimizing Trial Design for Each Unique Trial and Set of Objectives

II

III

Case 7 - Innovative Partnerships Breed Success in Clinical Trials: Clinical Trial Educators Program

Location of Case: USA

Company Featured: inVentiv Health Clinical

Innovation Example: Innovative Partnerships, Innovation in Patient Recruitment, Collaborative Innovation

II

III

Case 8 - Innovations in Data Management and Strategic Partnerships Achieve Cost-Savings for Biopharmaceutical Trial Sponsor

Location of Case: Global

Company Featured: inVentiv Health Clinical

Innovation Example: Innovation in Data Management (data optimizing software), Innovative Partnerships



II

III

Case 9 - Clinical Trial Innovations Expedite Recruitment, Prioritize Communication, and Streamline Logistics for a Global COPD Trial

Location of Case: Global

Company Featured: PAREXEL

Innovation Example: – Innovation in Trial Recruitment, Innovation in Communication, Innovation in Streamlining Logistics

POST

Case 10 – Bringing Treatments to Market Through CRO-Supported Commercial Infrastructure

Location of Case: USA

Company Featured: Quintiles

Innovation Example: Innovative Partnerships, Innovation in Commercializing Treatments

POST

Case 11 - Making the Most of Data: Adopting eClinical Systems Allows CROs to Visually Track Safety Data in Real-Time

Location of Case: USA

Company Featured: ICON

Innovation Example: Innovation in Data Tracking and Management, Innovation in Trial Design, Adjudication

POST

Case 12 - Adaptive Trial Designs Maximize Trial Efficiency

Location of Case: EU, 9 countries

Company Featured: PPD

Innovation Example: Innovation in Trial Design (Adaptive), Collaborative Innovation (with EMA)

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Economist Intelligence Unit

The
Economist

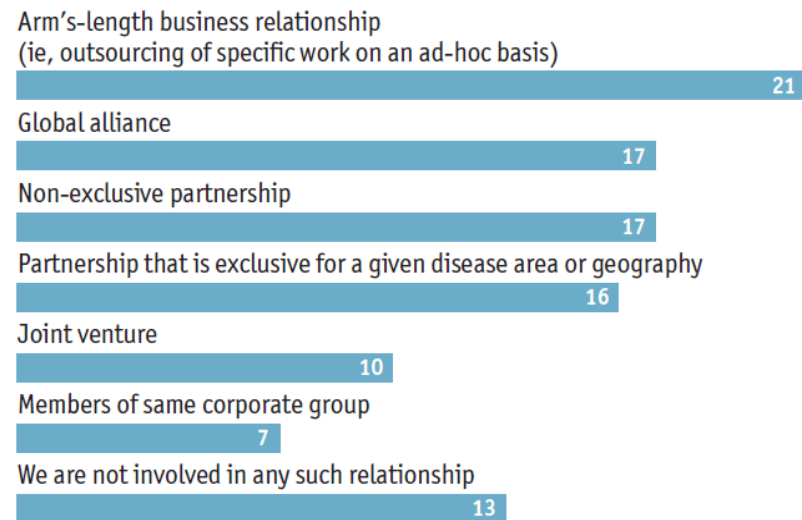
Finding Alignment

Opportunities and Obstacles in the Pharma/CRO Relationship



- **67% of respondents were or are still involved in some kind of CRO-Pharma partnership project.**
- **Majority of respondents favour Global Alliance as a partnership model.**

Considering the biggest relationships in which your company is involved between CROs and pharmaceutical or biotechnology companies, what form do these take in practice?
(% respondents)



Considering the biggest relationships in which your company is involved between CROs and pharmaceutical or biotechnology companies, what would be your preferred form?
(% respondents)





What are the most important attributes that you look for in selecting a CRO with which to do business?

Select up to three.

(% respondents)

Experienced, talented staff in general

49

Ability to deliver lower cost

44

Speed in completing studies/contracts

42

Global reach

35

Expertise in specific areas of drug development

34

Range of services provided

20

Provide access to specialised, cutting-edge technology

16

Willingness to engage in risk sharing

15

Provide access to high-quality data and advanced data-integration capacity

14

Ability to focus on target populations, conditions

7



Which of the following attributes does your company currently use to differentiate itself from competitors in attracting business from pharmaceutical and biotechnology companies?

Select up to three.

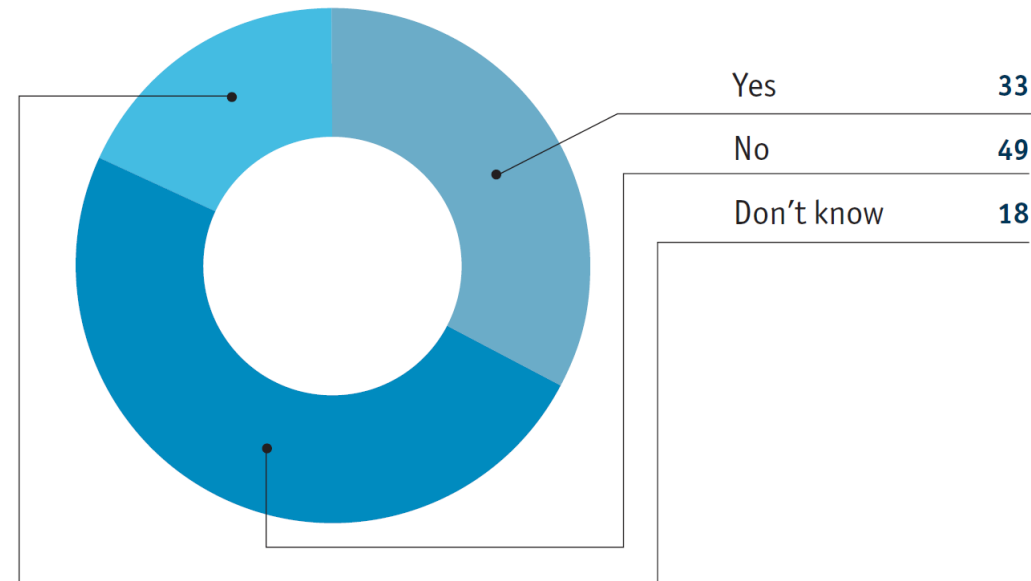
(% respondents)





Has your company been involved in an unsatisfactory relationship between pharmaceutical/biotechnology companies and CROs in the last three years?

(% respondents)



- **49% of respondents were not involved in some kind of CRO-Pharma unsatisfactory relationship.**
- **This means that there is lot of space for improvement especially when creating long-term strategical partnerships.**



What were the biggest challenges for successful relationships between pharmaceutical/ biotechnology firms and CROs?

Select up to three.

(% respondents)

Poor communication

46

Excessive expectations by one or both sides

29

The culture of one or both companies impeded necessary information sharing/co-operation

25

Lack of skills in maintaining partnership

22

Lack of technical ability by one or both sides

19

Incompatible technology

18

Lack of clarity in the terms of the agreement

13

One or both sides was unable to manage the internal changes necessary as a result of the partnership

10

We have not engaged in such a partnership

23



What were the biggest barriers to success in the unsatisfactory relationship?

Please select up to three.

(% respondents)

Poor communication

40

The culture of one or both companies impeded necessary information sharing/co-operation

35

Lack of technical ability by one or both sides

32

Lack of skills in maintaining partnership

28

Lack of clarity in the terms of the agreement

24

One or both sides was unable to manage the internal changes necessary as a result of the partnership

22

Incompatible technology

18

Excessive expectations by one or both sides

17



STRATEGIC PARTNERSHIPS 2013

Strategic Partnerships

Collaboration Talent Alignment

Improved Cycle Times

Global Reach Emerging Markets

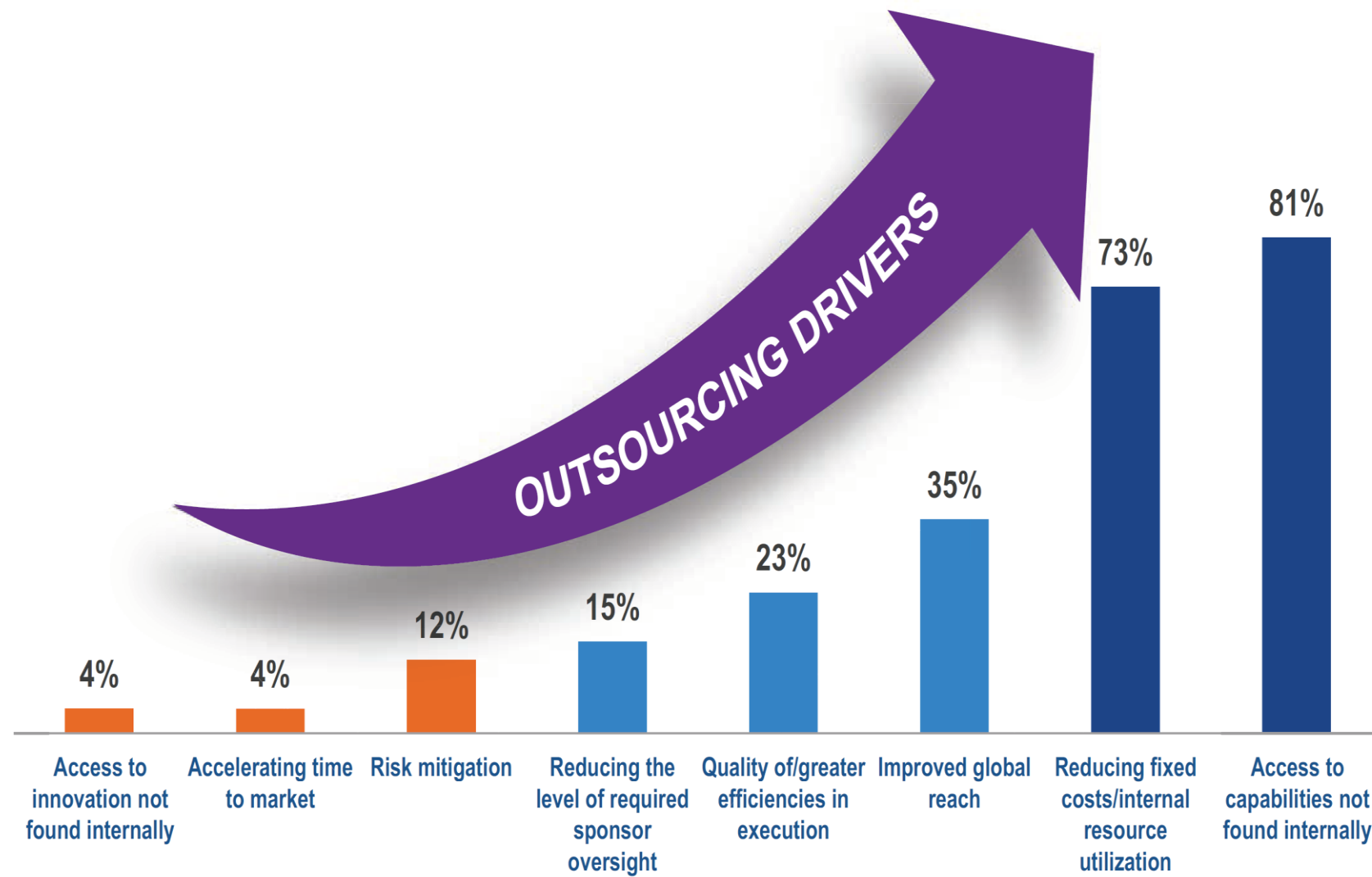
Quality Technology

Cost Reduction

Transforming and Unlocking Value in
Biopharmaceutical Development



PAREXEL



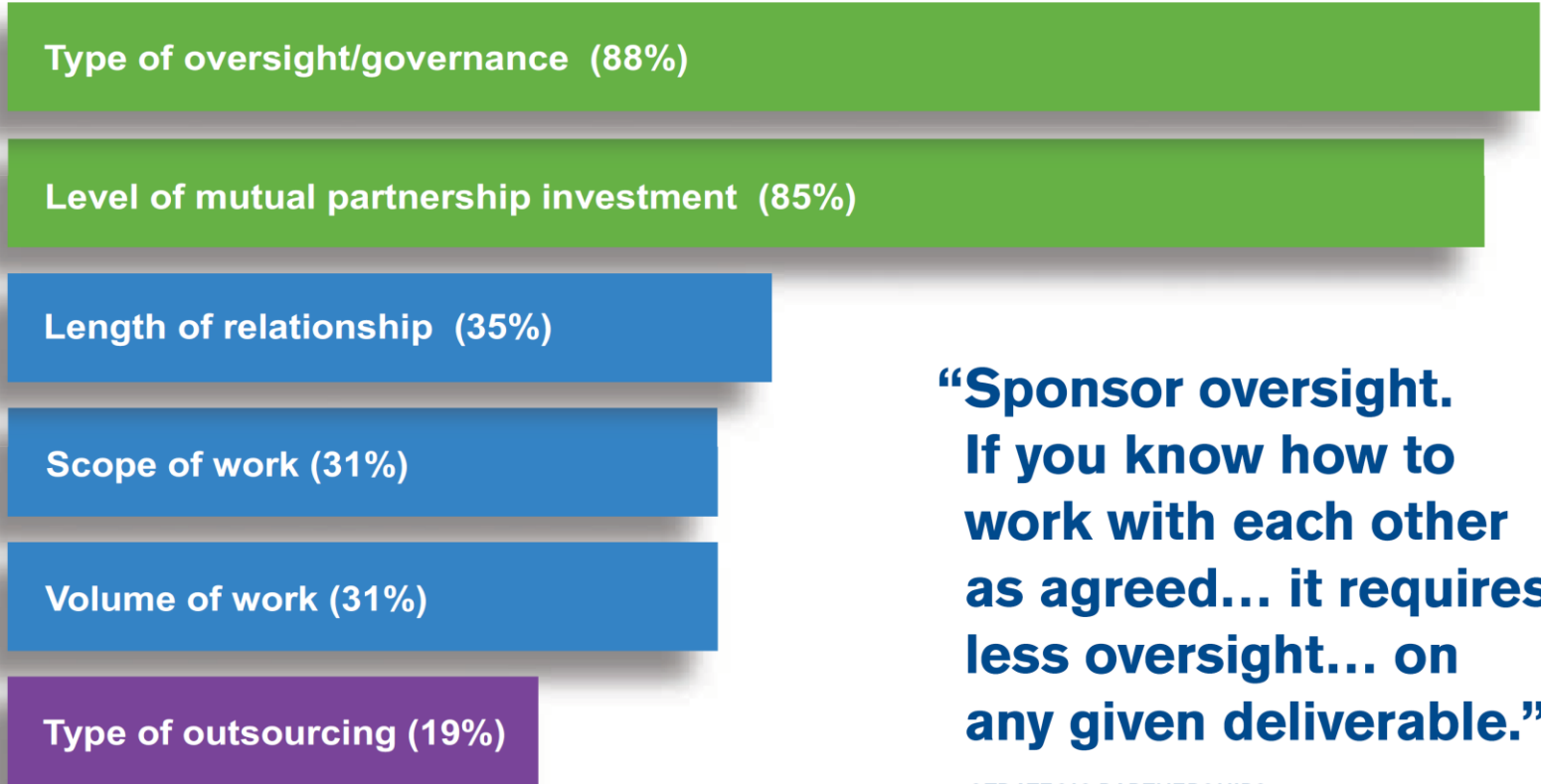


85%

**...of executives believe
Strategic Partnerships
have had a positive
impact on the CRO-
sponsor relationship**

Impact of Strategic Partnerships on CRO-Sponsor Relationship





**“Sponsor oversight.
If you know how to
work with each other
as agreed... it requires
less oversight... on
any given deliverable.”**

STRATEGIC PARTNERSHIPS 2013
PARTICIPANT

FIGURE 4

Q. How would you define a Strategic Partnership with a CRO today? Please select your top three choices.
Some respondents provided less than or more than three choices.

STRATEGIC PARTNERSHIP KEY DRIVERS

1. **Dedication**, where the CRO team is committed to the client's results and success, and aligned with the company's specific needs.
2. **Risk-Sharing***, where the CRO is operationally or financially vested in shared success.
3. **Value**, in which the relationship is expected to yield cost and operational efficiencies without sacrificing quality.
4. **Transparency**, which the executives define as better communication between the two organizations, and greater sharing of information and expertise.



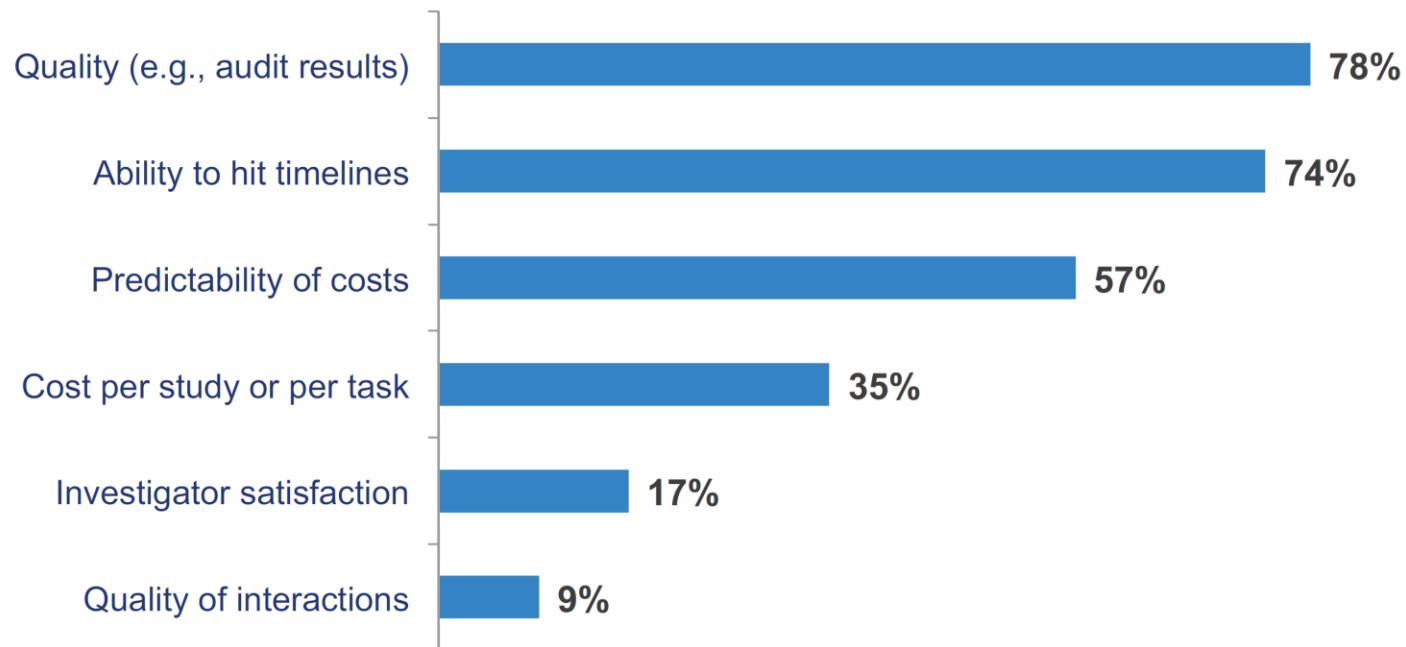


FIGURE 7

Q. In what ways do you measure success of outsourcing versus internal development?

Respondents were allowed to give multiple responses.



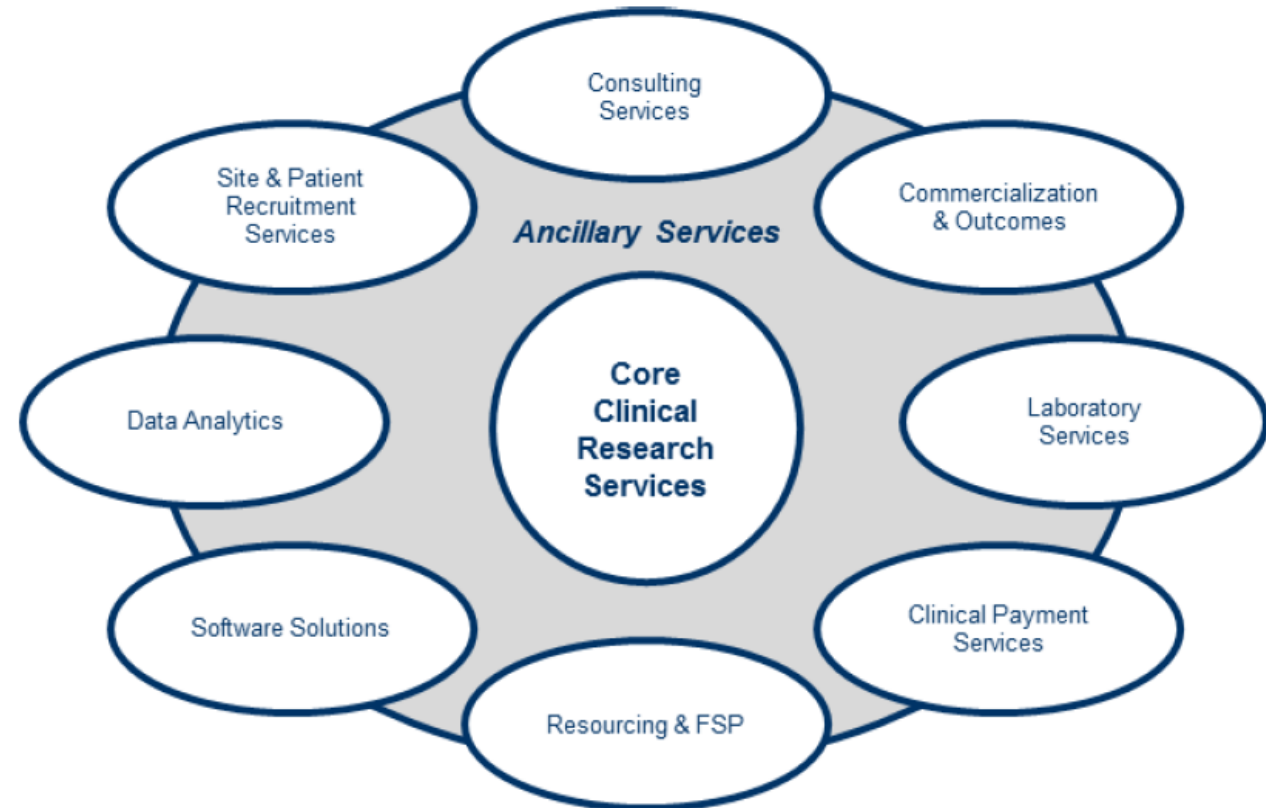
THE EVOLVING CRO MODEL:

A SHORTCUT TO STRATEGIC CRO-PHARMA ALLIANCES



Expansion of CRO Service Offering

The traditional model has evolved beyond core research to include a variety of ancillary services as large CROs seek to increase their strategic partnerships and “share of wallet” with pharmaceutical companies



Quintiles Case Study: Building a Multi-Function CRO Platform Through M&A



October 2011: Quintiles acquires Outcome Sciences for \$177 million

- Market leader in registries, post-approval research and quality-improvement initiatives for biopharma, medical device and government
- Strengthened Quintiles' late-phase offerings

August 2012: Quintiles acquires Expression Analytics

- Provider of genomic sequencing
- Expands Quintiles' personalized medicine capabilities

May 2013: Quintiles raises \$947 million as part of Initial Public Offering

August 2013: Quintiles acquires Novella Clinical

- Provider of preclinical to post-approval clinical trial management services
- Additionally, provider of resourcing solutions including FSP and contracting staffing

May 2014: Quintiles acquires Encore Health Resources

- Provider of IT consulting services to healthcare market as well as clinical, strategy and physician advisory services

May 2015: Quintiles acquires Clio Science

- Full service CRO in Japan

November 2016: Quintiles merges with IMS Health. Rationale for the merger includes:

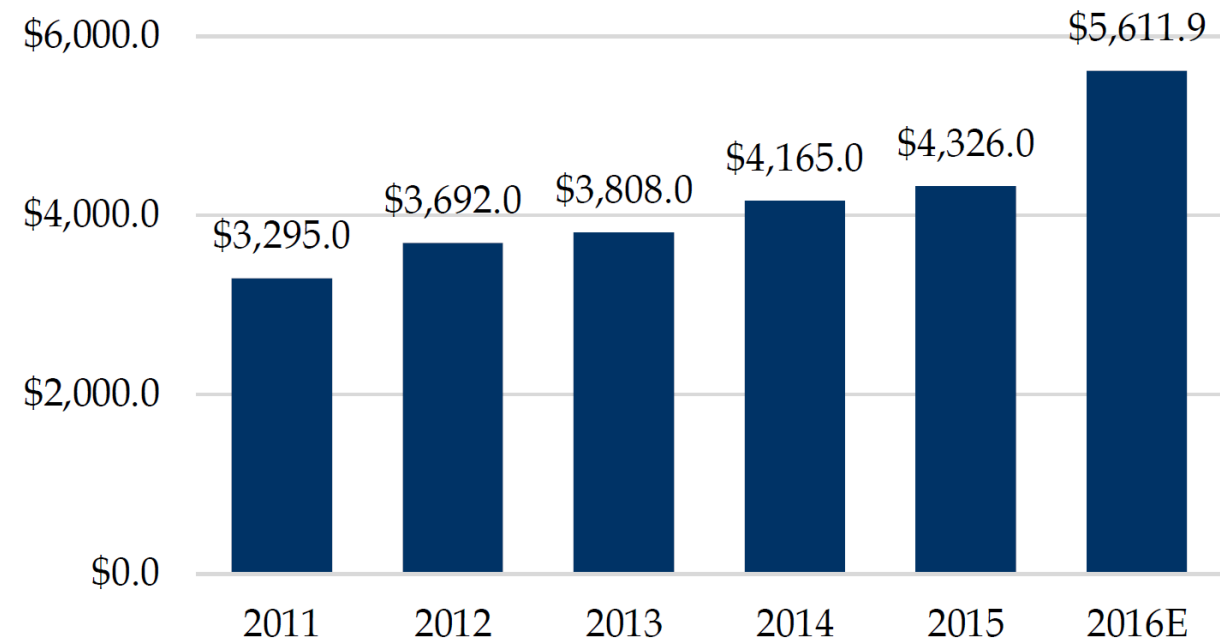
- Integration of IMS Health's Real World Evidence (RWE) analytics, consulting, outsourcing and technology services to make Quintiles IMS an end-to-end service provider for pharmaceutical clients
- Creation of the world's largest portfolio of healthcare information, therapeutic & regulatory expertise, and proprietary technologies with presence in 100+ countries
- Strengthening of client strategic partnerships through deep integration of data services

Source: Delancey-Street Partners (2016)

Quintiles Case Study: Revenue Growth Through M&A

Quintiles Revenue Growth

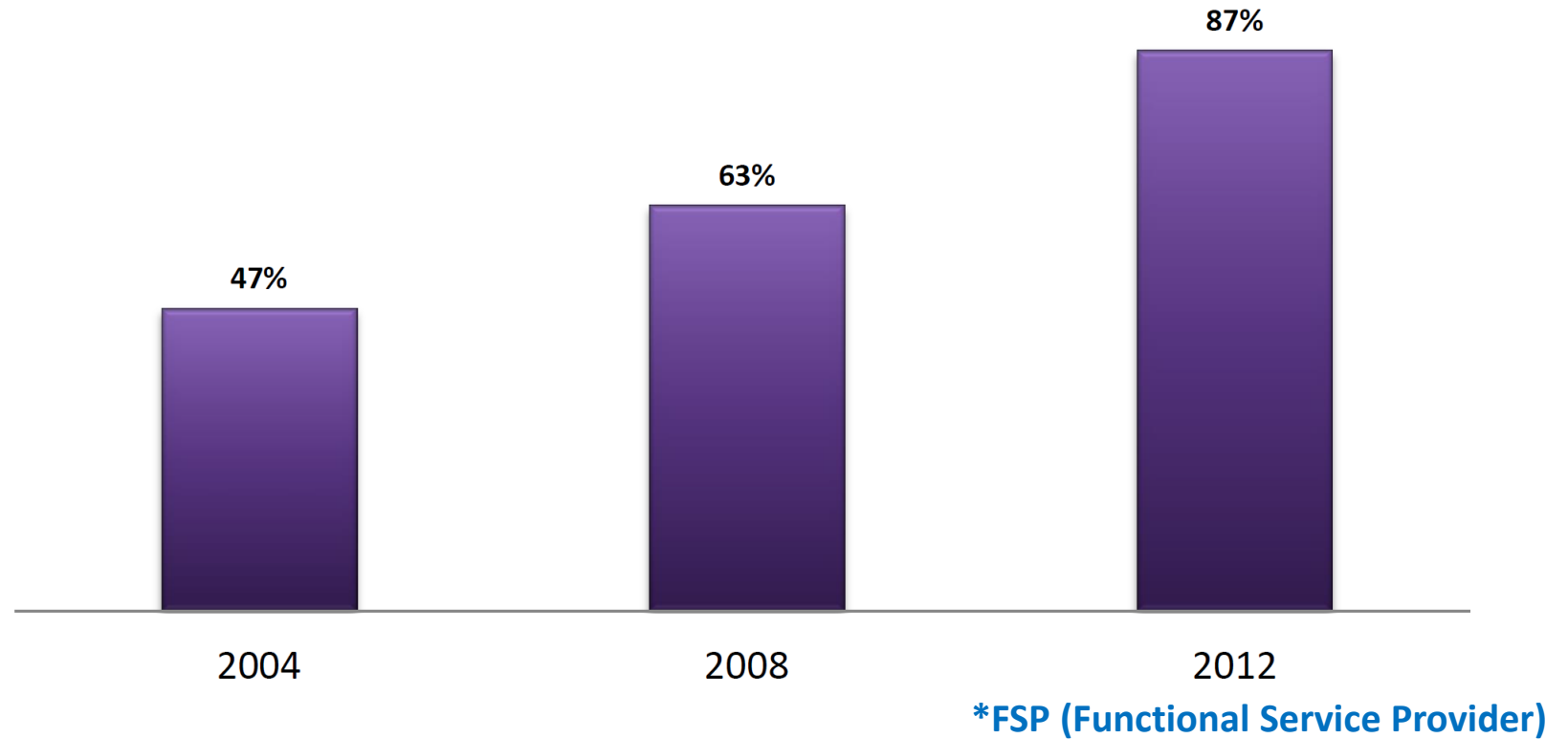
(\$ in billions)



Source: CapitalIQ.



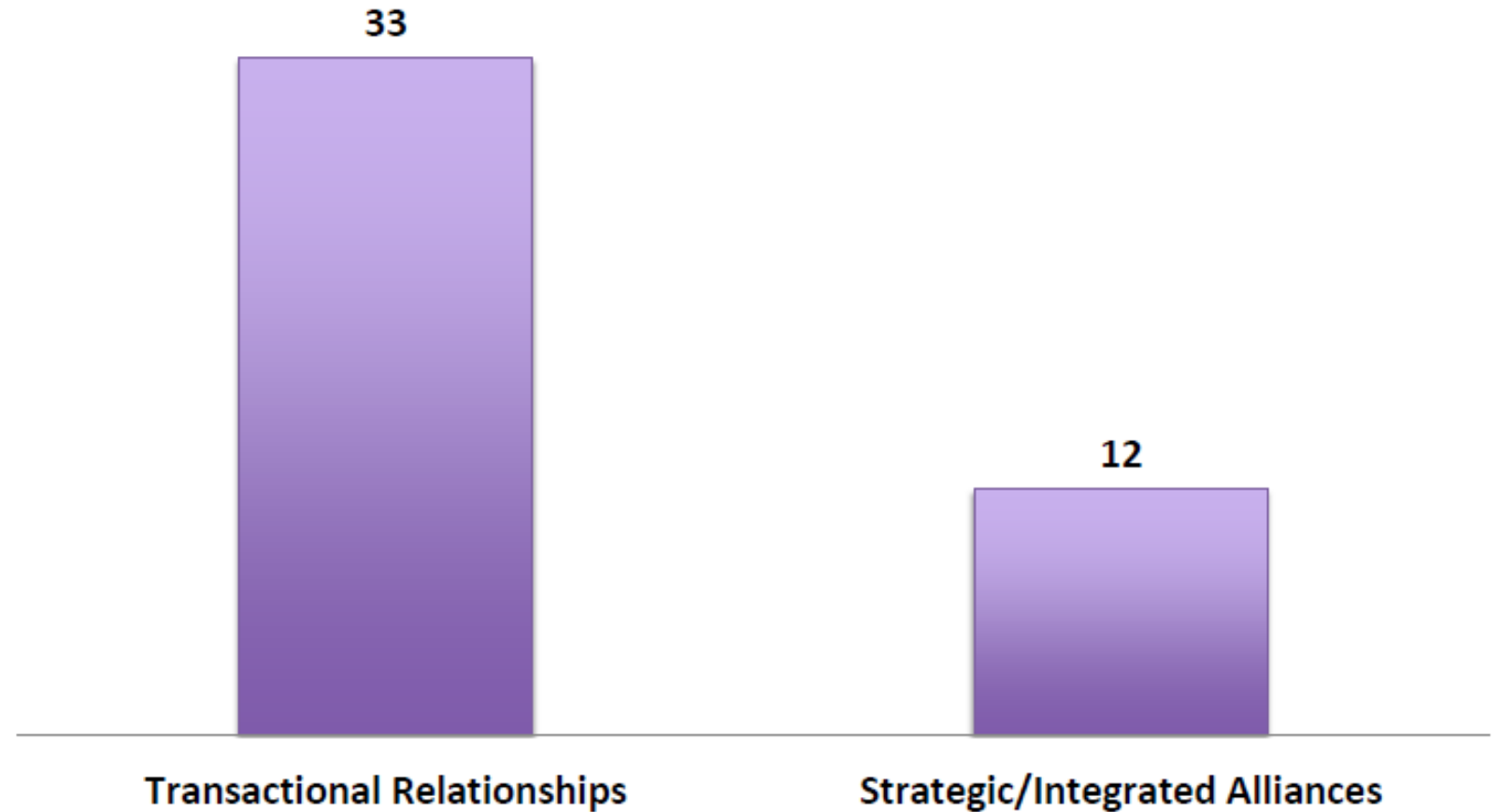
Proportion of Top 30 Pharma Companies in at least One FSP/Multi-FSP/Integrated Alliance



Source: CenterWatch (2013)



Average Number of Sponsor FTEs Assigned per Project

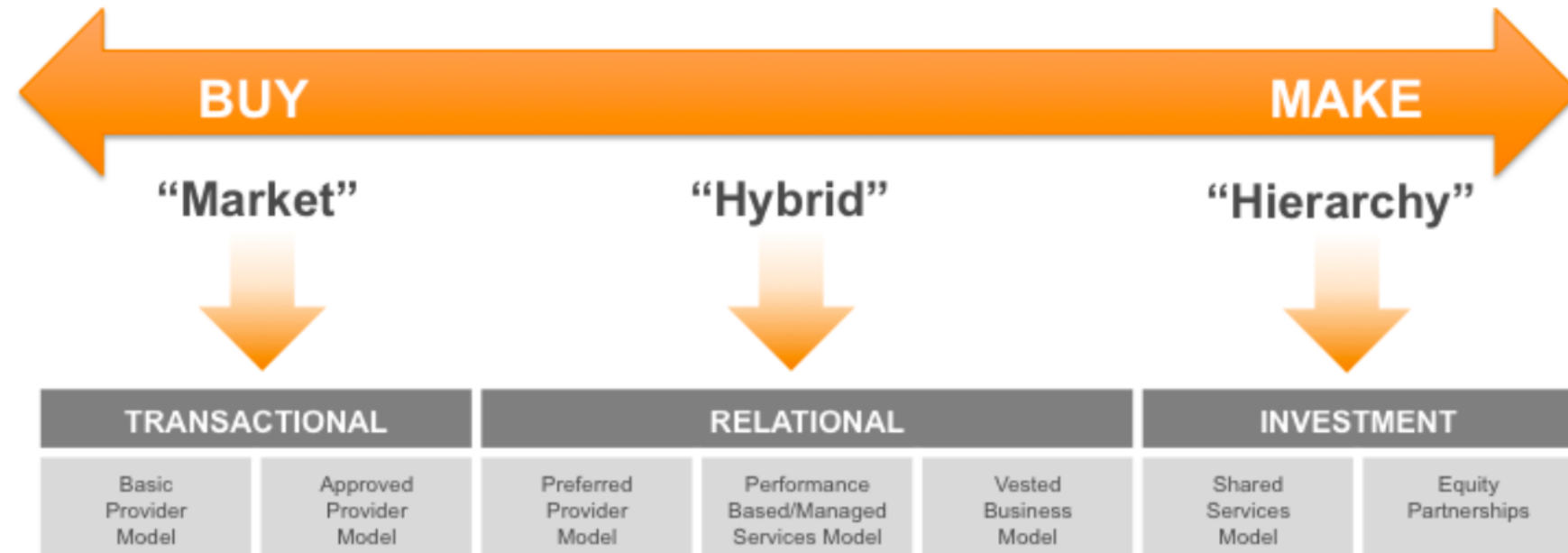


*FTE (Full Time Employee)

Source: Parexel (2011)

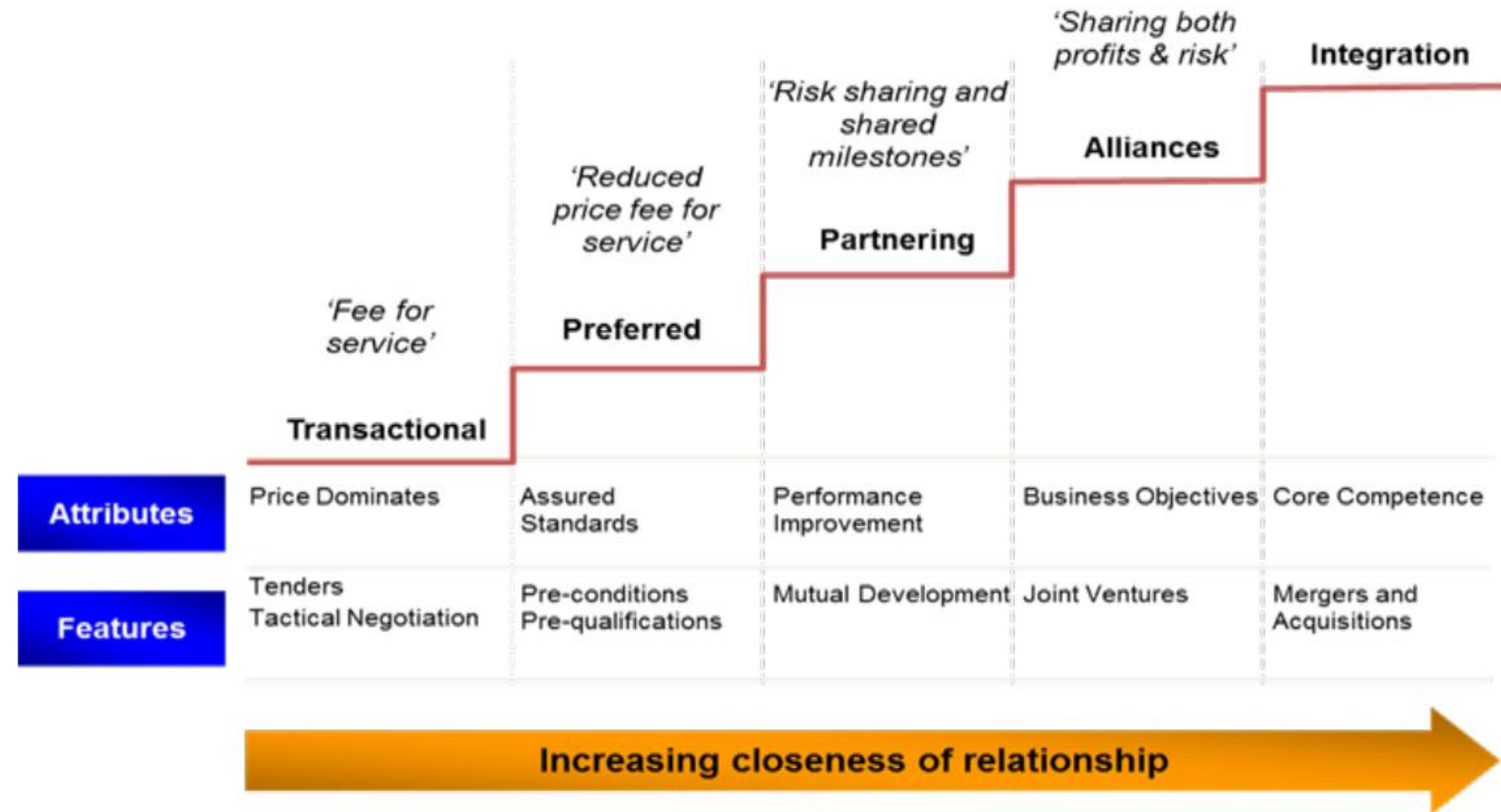
SEVEN SOURCING BUSINESS MODELS

Figure 2: The Continuum of 7 Sourcing Business Models



KEY TRENDS IN CRO OUTSOURCING: THE RISE OF PARTNERING AND ALLIANCE RELATIONSHIPS

Exhibit 3: The Trend Toward Partnering





From Transactional Relationships to Alliances



Transactional Relationships

- Ad-Hoc
- Capacity-based
- Reactive, project task outsourcing
- Shadow headcount, sponsor SOPs
- Mid-management governance committee
- Lowest-bid/Many Providers
- High out-of-scope costs/ Fee for service

Integrated Clinical Research Alliances

- Formalized
- Virtual/Competency-based
- Planned, portfolio outsourcing
- Lean operation, integrated/coordinated
- Multi-level shared governance & SOPs
- Few Partner-Providers
- Shared operating risk/Fixed pricing

- Lower transaction costs**
- More transparency**
- Greater risk sharing**
- More motivated staff**
- Faster start-up**
- More senior level commitment**

SATISFACTION GUARANTEED

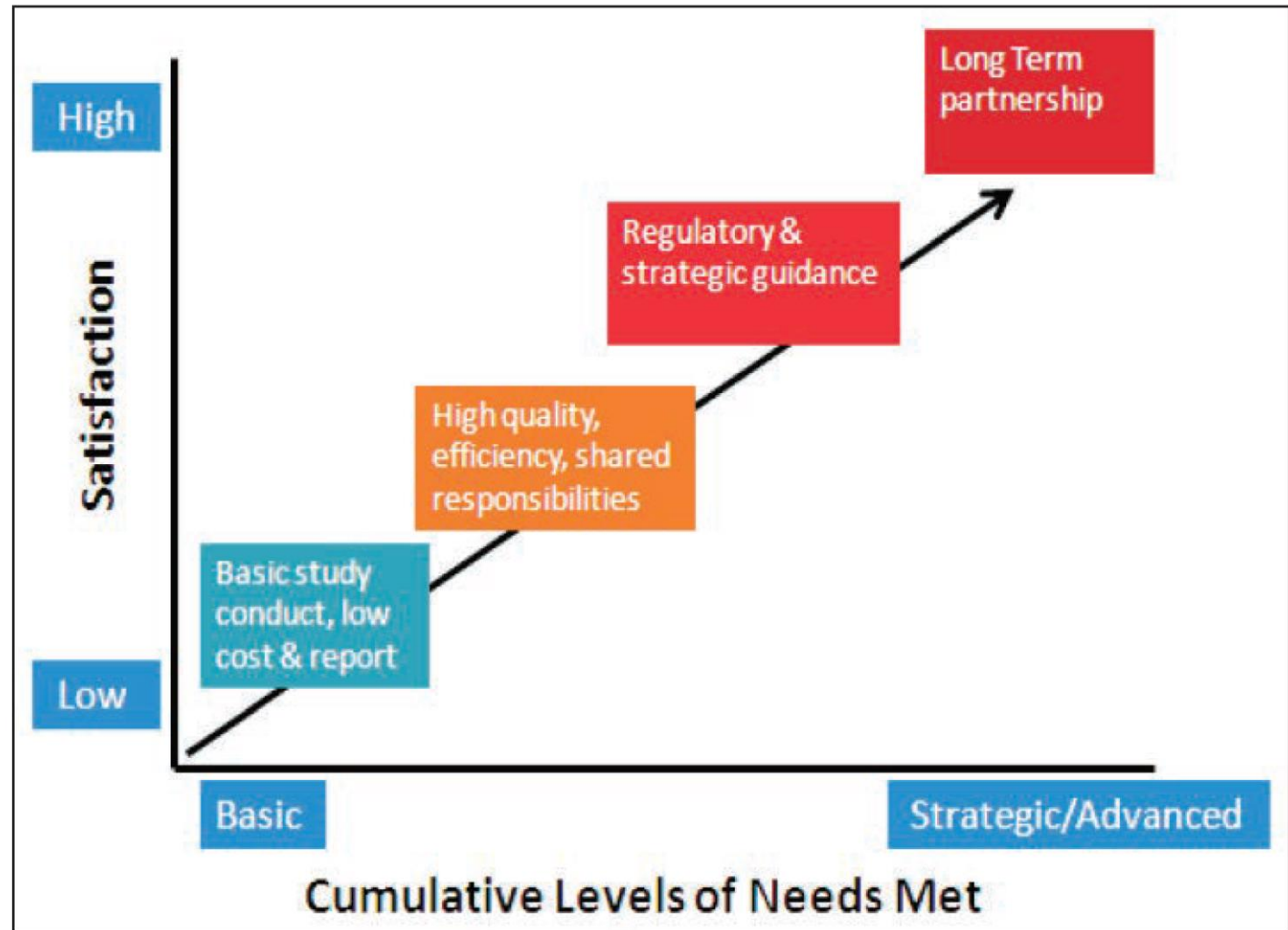


Figure 1: Schematic representation of the satisfaction gained by the sponsors when their needs are met at different levels and cumulatively.

Source: Chakraborty BS (2013)

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HOW TO CREATE A SUCCESSFUL CRO-PHARMA PARTNERSHIP MODEL

Kinapse (2016)



SUCCESSFUL PARTNERSHIP MODEL: *PARTNER SELECTION PROCESS*

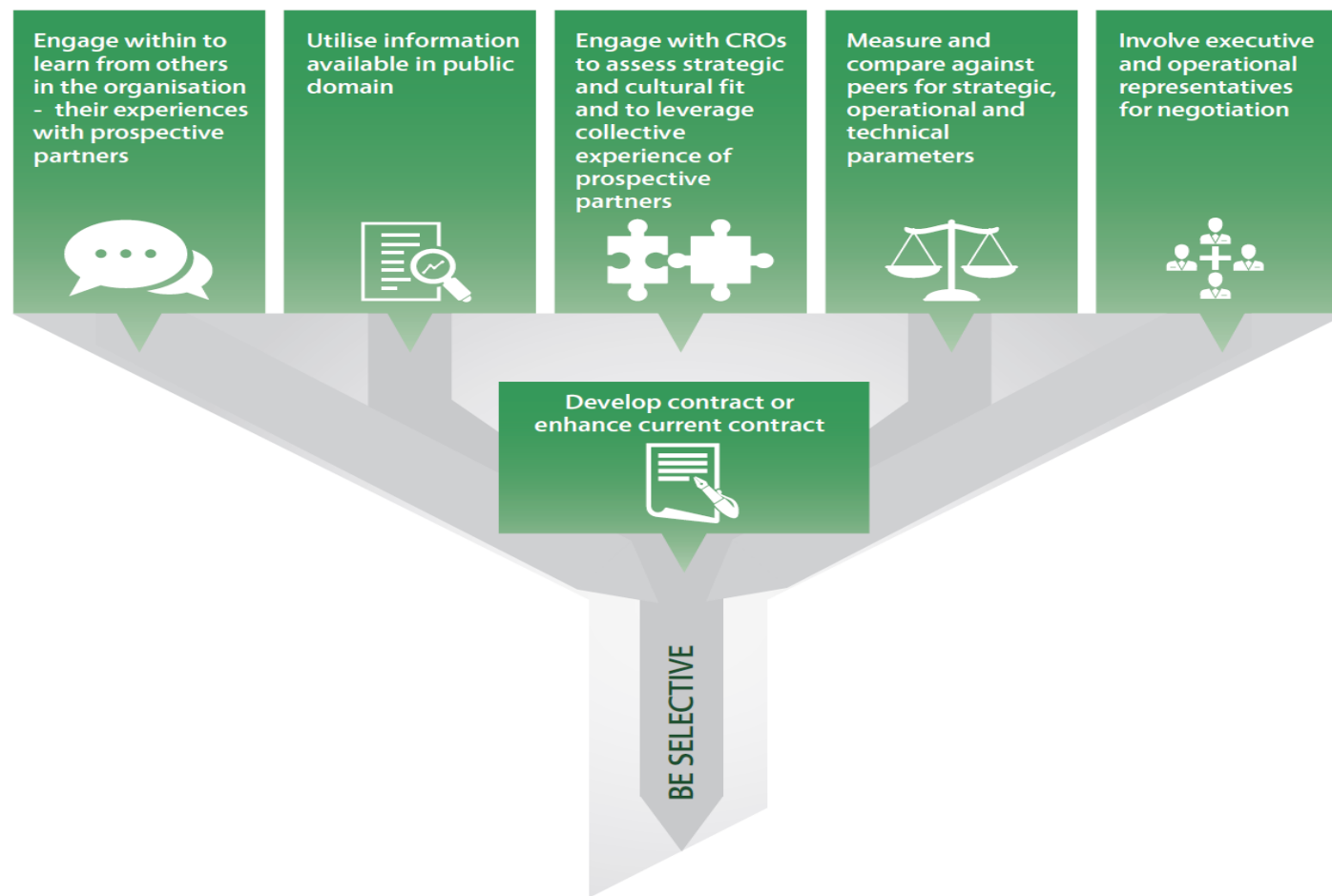


Figure 1: Steps for partner selection



SUCCESSFUL PARTNERSHIP MODEL: *PREPARING THE CONTRACT*

Key principle of the financial contract should be to create a win-win situation for both parties and to ensure clarity

The contract should therefore clearly define the operational framework



Figure 2: Operational enablers of the sourcing partnership should be defined in the contract

SUCCESSFUL PARTNERSHIP MODEL: OPPORTUNITIES FOR CRO TO ADD VALUE

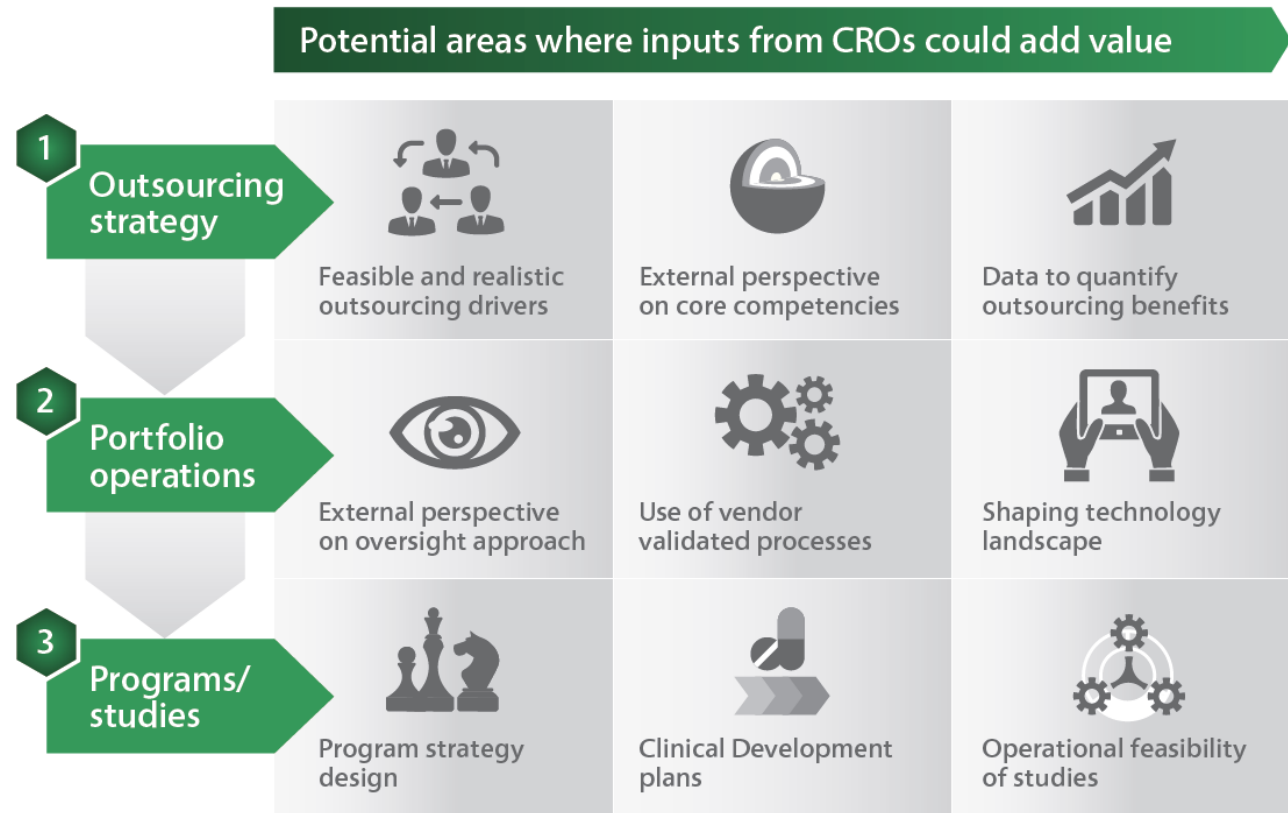


Figure 3: Potential areas where inputs from CROs could add value



WHAT'S NEXT:

**FUTURE DIRECTIONS IN
CRO-PHARMA PARTNERSHIPS**



Key Attributes of Future Strategic Partnerships

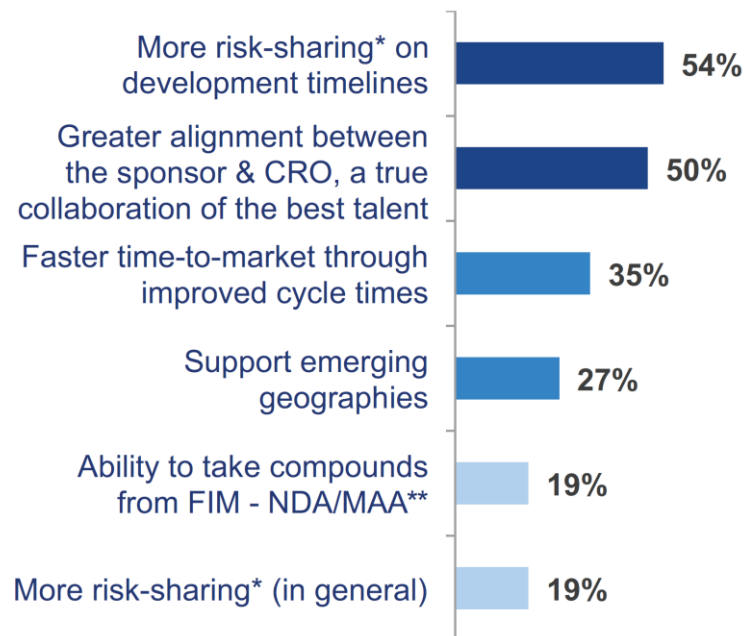


FIGURE 8

Q. What would strategic partnering 2.0 look like to you? In which of the followi will it differ from strategic partnerships today? Please tell me your top three

Some respondents provided less than or more than three choices.

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Cycle time improvements



Reduction in sponsor oversight



Professional fees



Executing in emerging markets



Service provider throughout life cycle



Overall quality

FIGURE 9

Q. Please tell me which two of the following will define the value of Strategic Partnerships with CROs in the next three to five years?

Source: Parexel (2013)



CROs Today

- To Share
- To Align
- To Collaborate
- To Improve
- To Expand
- To Minimize
- To Reduce

PROMISE

CROs Tomorrow

- Shared risk* on development timelines
- Achieved greater alignment
- Became a true collaborator
- Improved cycle times
- Expanded into emerging markets
- Minimized level of sponsor oversight
- Reduced professional fees per unit

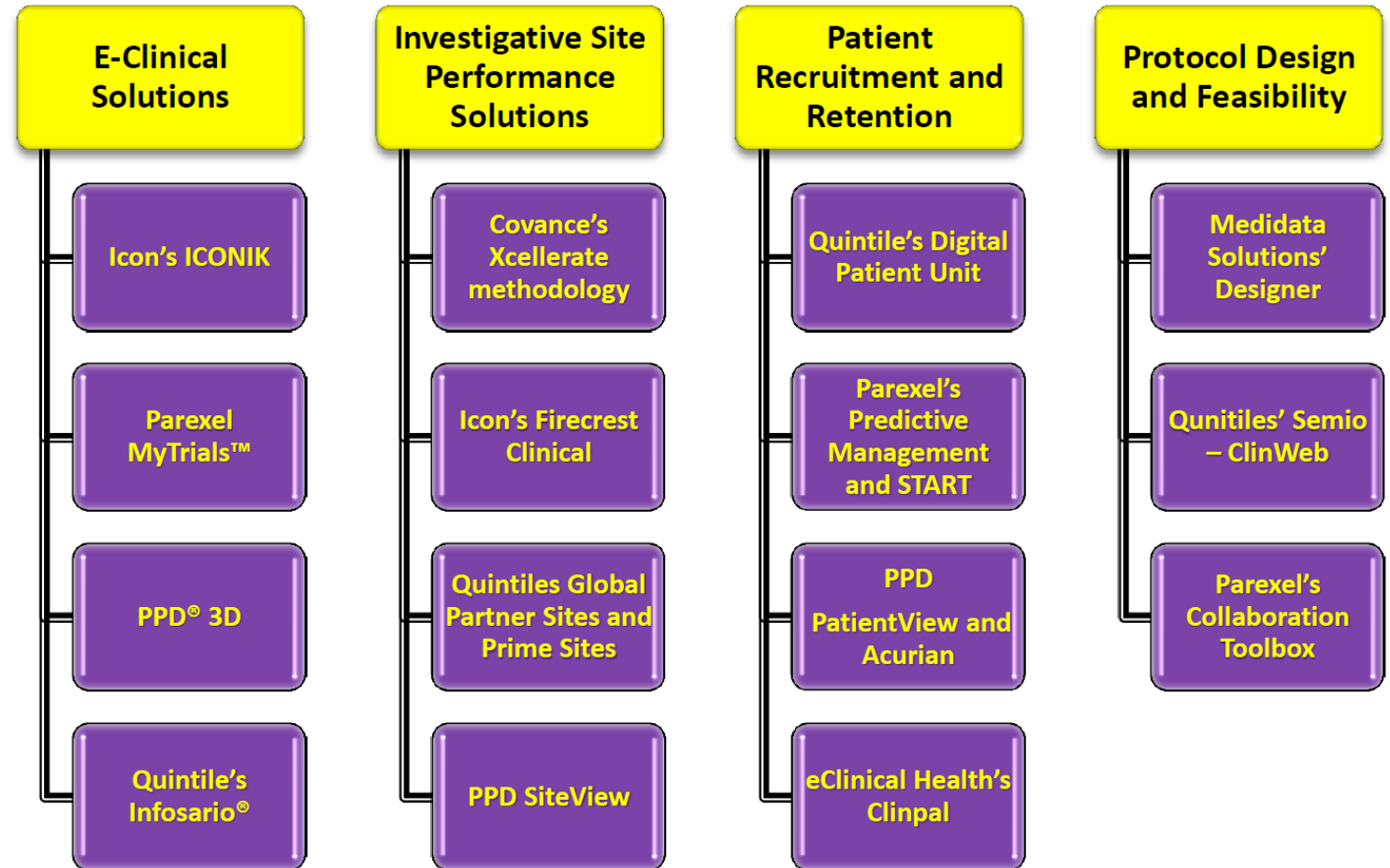
DELIVERY

**“I want CROs saying.
‘How do I enable a
pharma company to
get medicines to
market faster, more
cost effectively, with
high quality?’”**

STRATEGIC PARTNERSHIPS 2013
PARTICIPANT



Innovate to Add Value and Advantage



HOW CAN WE HELP

We can help you to:

- **Create a Partnering Culture based on Openness, Creativity, Agility and Resiliency**
- **Increase your people's Partnership skills**
- **Enhance your Mindfulness Communication skills**
- **Increase your comfort with change, your ability to trust, your comfort with interdependence, and your comfort with self-disclosure and feedback**
- **Increase your win/win orientation, conflict management and problem-solving skills**
- **Strengthen the leadership skills of your key people**





WHAT IS *PC² FIT*® PROGRAM

- **PARTNERSHIP SKILLS FIT**
- **COMMUNICATION SKILLS FIT**
- **CORPORATE CULTURE FIT**

STAGES OF *PC² FIT*® PROGRAM

- **Evaluation**
- **Training**
- **Monitoring**
- **Reporting**
- **Follow-Up**



DELIVERY FORMATS OF *PC² FIT*® PROGRAM



- **F2F ON & OFF-SITE WORKSHOPS**
- **COACHING RETREATS (2-5 DAYS)**
- **INDIVIDUAL BOOSTER ONLINE SESSIONS (VIA SKYPE)**



Let's keep
in touch!

Contact Us@
heruka.innovations@gmail.com

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