Successfully delivering on the Magic Triangle
How to ensure quality, speed, and value

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June 2019

The Presenter

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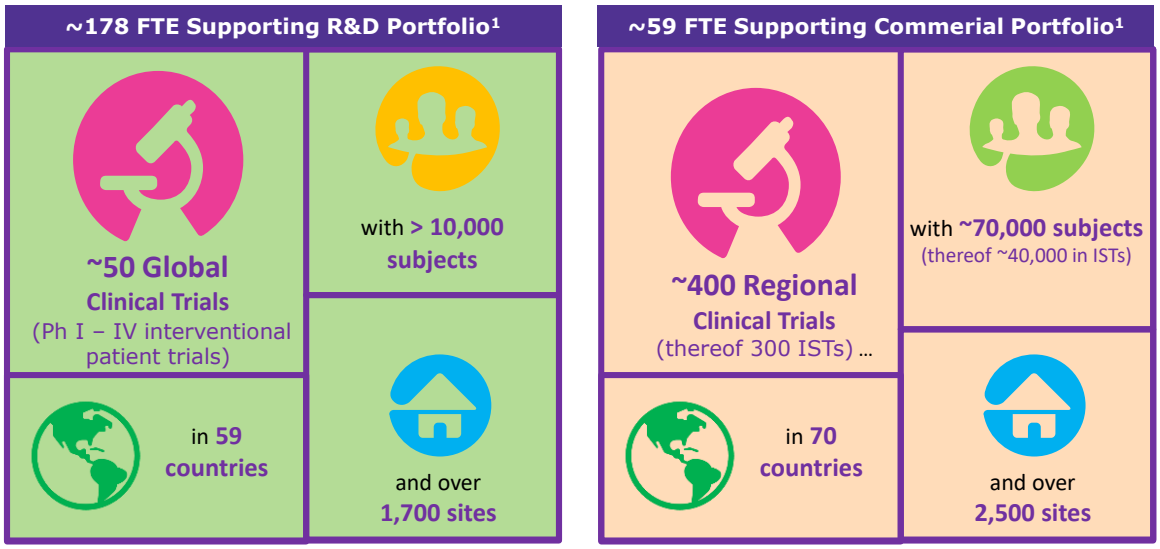
In the last 25 years Rich has worked for a number of large CROs in Business Development, Operations and Partnership Management roles. For the last 2 years he has moved over to the sponsor side, and now works for Merck KGaA, Darmstadt, Germany in the Alliance Management function of Global Clinical Operations

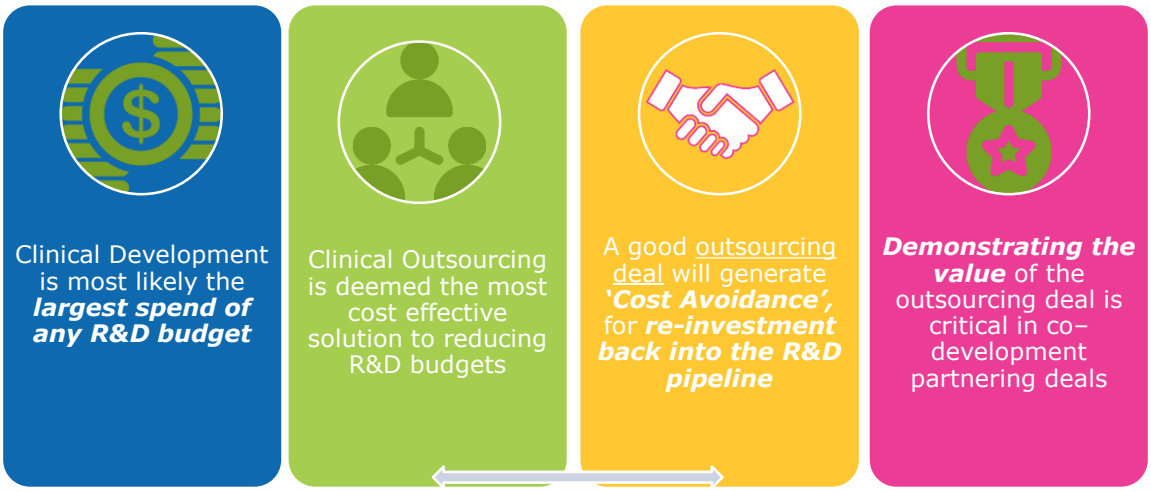
A Global Clinical Portfolio executed via an 'End to End' Outsourcing Model



[1]Representation of direct portfolio allocated FTE

MERCK

Why are 'Good' Clinical Outsourcing Deals Important for the Pharma Business?



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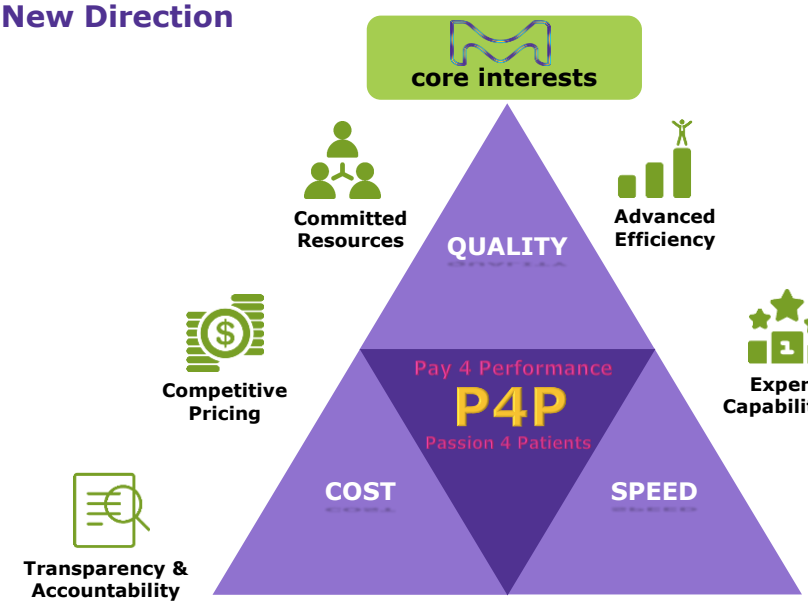
Successfully delivering on Quality, Speed and Value

The New Direction



Defining the Negotiation Strategy:
A critical success factor to ensure a better outsourcing partnership

1. CREATE GOALS

- a ***Competitive Pricing***
- b ***Competitive Performance***
- c ***Value Generation***

2. BUILD TEAM KNOWLEDGE

- a ***Understand internal 'must haves' for a successful partnership***
- b ***Understand Terms and Conditions that favor both sides***
- c ***Know how your CRO (s) drive revenue***
- d ***BUNDLE all T/Cs together and present as a <u>total package</u>***

Defining the Negotiation Strategy:
A critical success factor to ensure a better outsourcing partnership

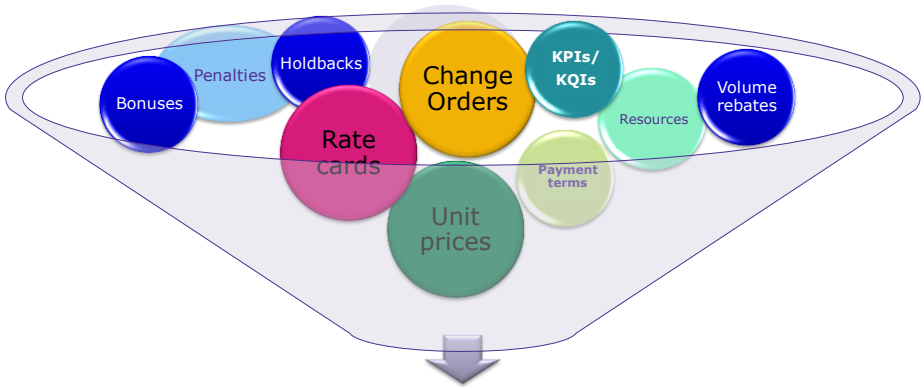
3. 'Negotiation Playbook'

Multiple Equivalent Simultaneous Offers	Offensive Approach	Defensive Approach
• Bring more than one CRO to the table • Be creative and provide multiple options that have the same value • Aim to get the best operational deal	• Concession associated with "replacement" • Come with new requests during the negotiations	• No or minimal concessions without "replacements" • React to new requests during the negotiations

Successfully delivering on Quality, Speed and Value
The Negotiation TEAM

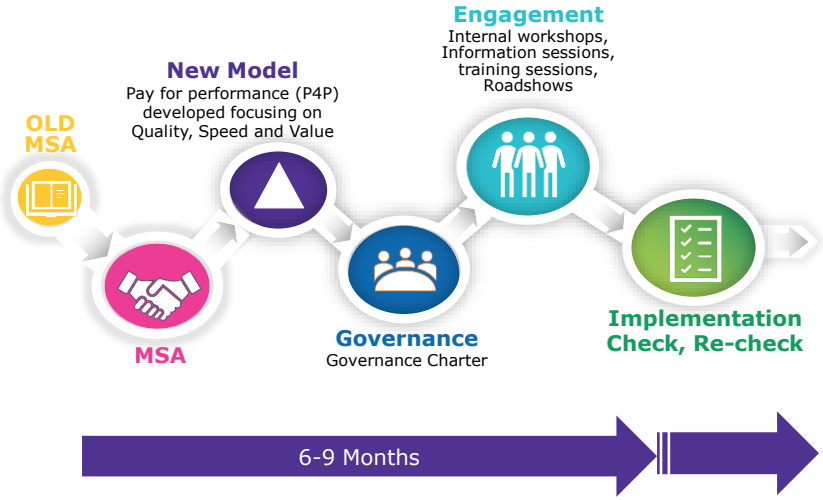
- Its important the function overseeing the CRO (s) is well represented to ensure appropriate balance in the deal
- Experts from different functions ensure clear understanding and correct focus
- Each member had a significant role to play during discussions
- Business (clinical) MUST be represented to understand what is being represented matches the intended outcome
- Share opinions on positions
- Consensus and voting within negotiation team

Successfully delivering on Quality, Speed and Value
Creating the Bundle



Successful Negotiated Master Service Agreement

Evolving Our Strategic Alliance



Key Process & Documentation
Communication
Change Management
Alliance Manuals
Legal Templates
Quality & Operational Agreements
Pricing Model
Technology Integration
Study Allocation Process
P4P Metrics & Goals

Successfully delivering on Quality, Speed and Value
Lessons learned

Committed Partnership

- Negotiate with strength: bring in the experts
- It isn't just an MSA: ensure the 'whole' package (performance on speed, quality and cost) are balanced appropriately
- Wording in the MSA is critically important: Describe how you are going to tackle the ambiguity before you get there

Competitive Performance

- Make sure the internal knowledge base is strong on how to price clinical operations appropriately
- Ensure you own the tools and the data…critical to maintain competitiveness
- Always use external sources (industry benchmarks) to ratify performance

Value-Add Focus

- Demonstrate value through improved and measurable efficiency
- Competition drives better outcome so keep the tension on the important elements of delivery
- Strive to evolve in the right direction!