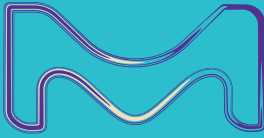


# Successfully delivering on the Magic Triangle

## How to ensure quality, speed, and value

Richard Butterworth  
June 2019



**MERCK**

## The Presenter



### Richard Butterworth

Senior Director Alliance Management, Service Provider Management, Merck KGaA, Darmstadt, Germany

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

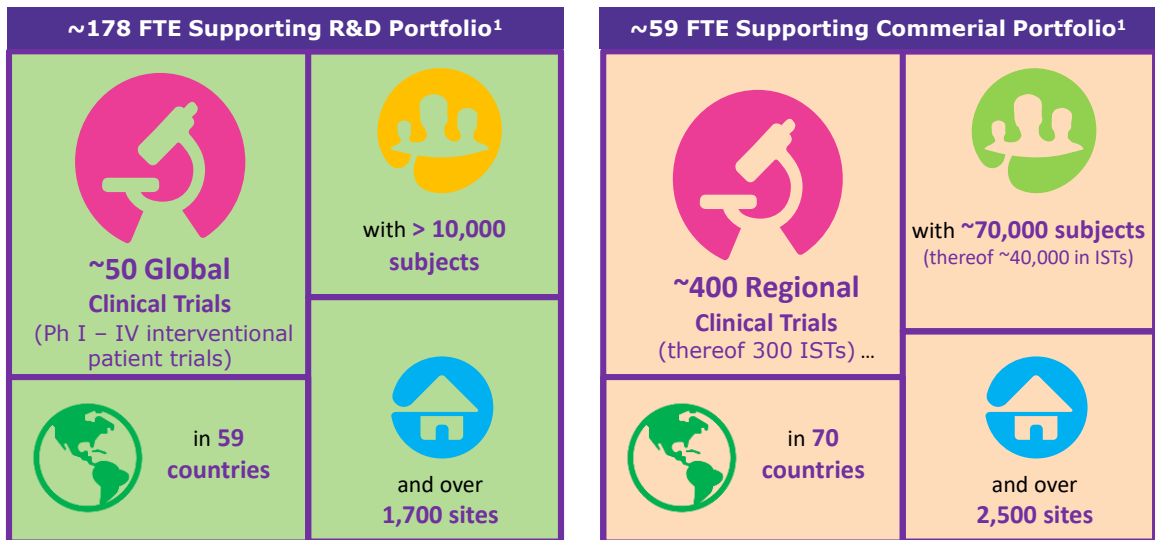
#### Cautionary Note Regarding Forward-Looking Statements and financial indicators

This communication may include "forward-looking statements." Statements that include words such as "anticipate," "expect," "should," "would," "intend," "plan," "project," "seek," "believe," "will," and other words of similar meaning in connection with future events or future operating or financial performance are often used to identify forward-looking statements. All statements in this communication, other than those relating to historical information or current conditions, are forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to a number of risks and uncertainties, many of which are beyond control of Merck KGaA, Darmstadt, Germany, which could cause actual results to differ materially from such statements.

Risks and uncertainties include, but are not limited to: the risks of more restrictive regulatory requirements regarding drug pricing, reimbursement and approval; the risk of stricter regulations for the manufacture, testing and marketing of products; the risk of destabilization of political systems and the establishment of trade barriers; the risk of a changing marketing environment for multiple sclerosis products in the European Union; the risk of greater competitive pressure due to biosimilars; the risks of research and development; the risks of discontinuing development projects and regulatory approval of developed medicines; the risk of a temporary ban on products/production facilities or of non-registration of products due to non-compliance with quality standards; the risk of an import ban on products to the United States due to an FDA warning letter; the risks of dependency on suppliers; risks due to product-related crime and espionage; risks in relation to the use of financial instruments; liquidity risks; counterparty risks; market risks; risks of impairment on balance sheet items; risks from pension obligations; risks from product-related and patent law disputes; risks from antitrust law proceedings; risks from drug pricing by the divested Generics Group; risks in human resources; risks from e-crime and cyber attacks; risks due to failure of business-critical information technology applications or to failure of data center capacity; environmental and safety risks; unanticipated contract or regulatory issues; a potential downgrade in the rating of the indebtedness of Merck KGaA, Darmstadt, Germany; downward pressure on the common stock price of Merck KGaA, Darmstadt, Germany and its impact on goodwill impairment evaluations as well as the impact of future regulatory or legislative actions.

The foregoing review of important factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included elsewhere, including the Report on Risks and Opportunities Section of the most recent annual report and quarterly report of Merck KGaA, Darmstadt, Germany. Any forward-looking statements made in this communication are qualified in their entirety by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us or our business or operations. Except to the extent required by applicable law, we undertake no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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



3

<sup>1</sup>Representation of direct portfolio allocated FTE  
 Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany



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



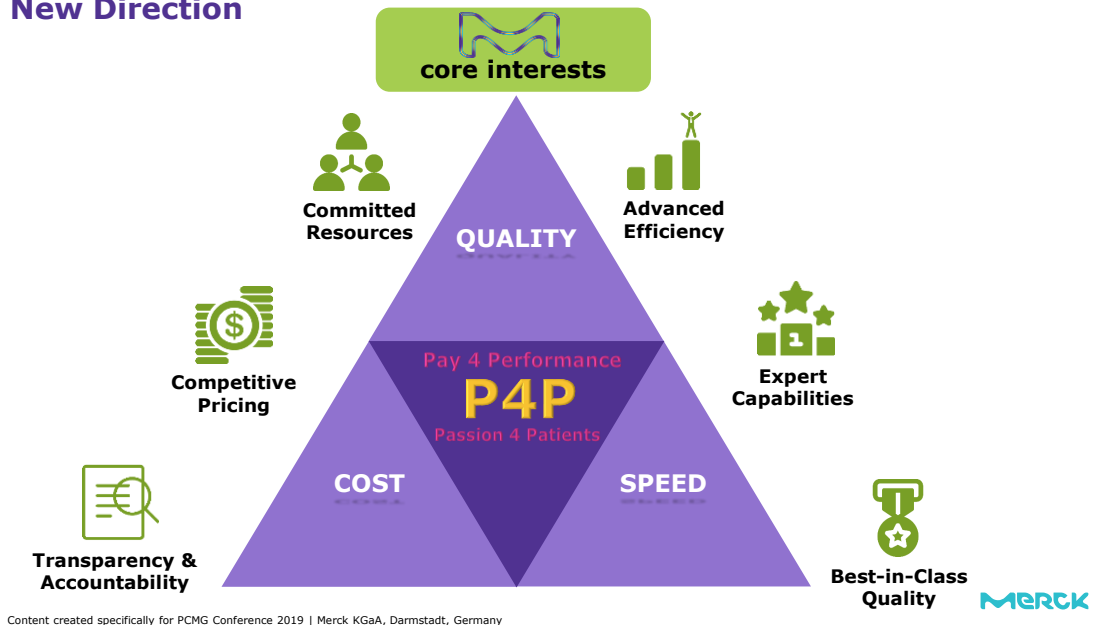
4

Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany



## 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 total package*

## Defining the Negotiation Strategy:

A critical success factor to ensure a better outsourcing partnership

### 3. 'Negotiation Playbook'

#### Multiple Equivalent Simultaneous Offers

- 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

#### Offensive Approach

- Concession associated with "replacement"
- Come with new requests during the negotiations

#### Defensive Approach

- No or minimal concessions without "replacements"
- React to new requests during the negotiations

7

Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany



## Successfully delivering on Quality, Speed and Value

### The Negotiation TEAM



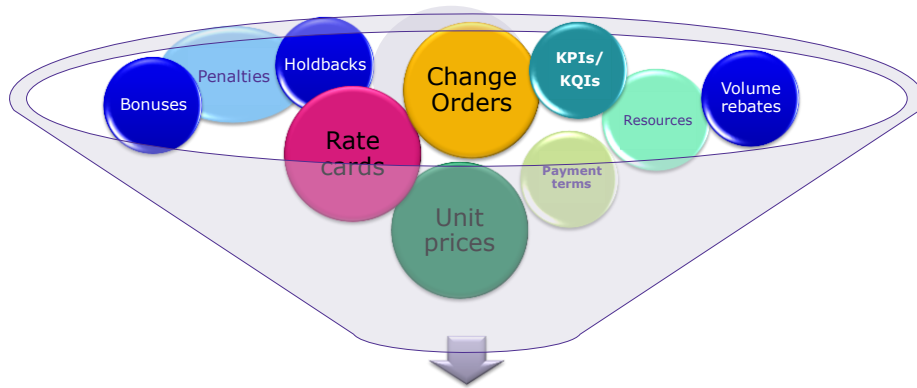
- Its important the function overseeing the CRO (s) is well represented to ensure appropriate balance in the deal
- Experts from different functions ensure clear understanding and correct focus
- Each member had a significant role to play during discussions
- Business (clinical) MUST be represented to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

8

Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany



## Successfully delivering on Quality, Speed and Value Creating the Bundle



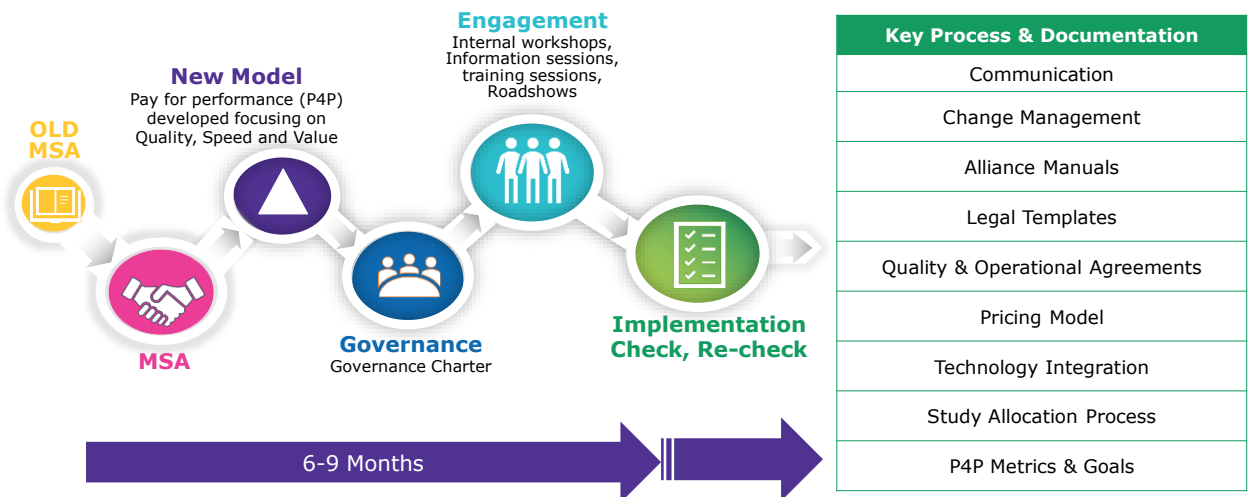
### **Successful Negotiated Master Service Agreement**

9

Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany

MERCK

## Evolving Our Strategic Alliance



10

Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany

MERCK

## Successfully delivering on Quality, Speed and Value

### Lessons learned



- 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



- 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



- 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!

11

Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany



**Thank  
You!**

12

Content created specifically for PCMG Conference 2019 | Merck KGaA, Darmstadt, Germany

