



# Change and the Growing Constellation of Asset Development Partnerships

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Senior Vice President

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Shortening the Drug Development Process  
from Lab to Life®.





**Alastair MacDonald**  
Senior Vice President  
Global Client Solutions

Alastair serves as Senior Vice President, Global Client Solutions at Syneos Health, where he is responsible for developing and nurturing relationships with Clients. Throughout his 30+ years in the industry running programs from IND to product approval he understands that this cannot be achieved without effective partnerships. Alastair has leveraged his experience to implement mutually beneficial partnership models and move from transactional outsourcing to partnership.

# Syneos Health in Summary: a Product Development Company



Syneos Health has helped to develop or commercialize 92% of Novel New Drugs approved by the FDA.



Syneos Health has helped to develop or commercialize 94% of products granted marketing authorization by the EMA.



## CLINICAL SOLUTIONS

- Early Stage
- Full Service
- FSP 360



## COMMERCIAL SOLUTIONS

- Deployment Solutions
- Communications
- Consulting



## MEDICAL AFFAIRS SOLUTIONS

- Bridging Clinical & Commercial
- Real World Evidence
- Medical Affairs Consulting

## PAST FIVE YEARS

**2,700+**  
Full-Service Studies

**90,000+**  
Sites

**743,000+**  
Trial Patients

**ILLINGWORTH.**  
RESEARCH GROUP  
a SYNEOS HEALTH company

**~28,000**  
Employees

Employees in  
**60+** Countries

Serving Customers in  
**110+** Countries

Industry-recognised  
excellence in site  
relationships



# Our End-to-End Model Enables Product Development Problem-Solving

Our breadth of capabilities spans the entire clinical development, medical affairs and commercial continuum, accelerating performance across the product development lifecycle.

Always-on insights lead to better, smarter problem-solving and more innovative solutions to reduce time to market and improve ROI.

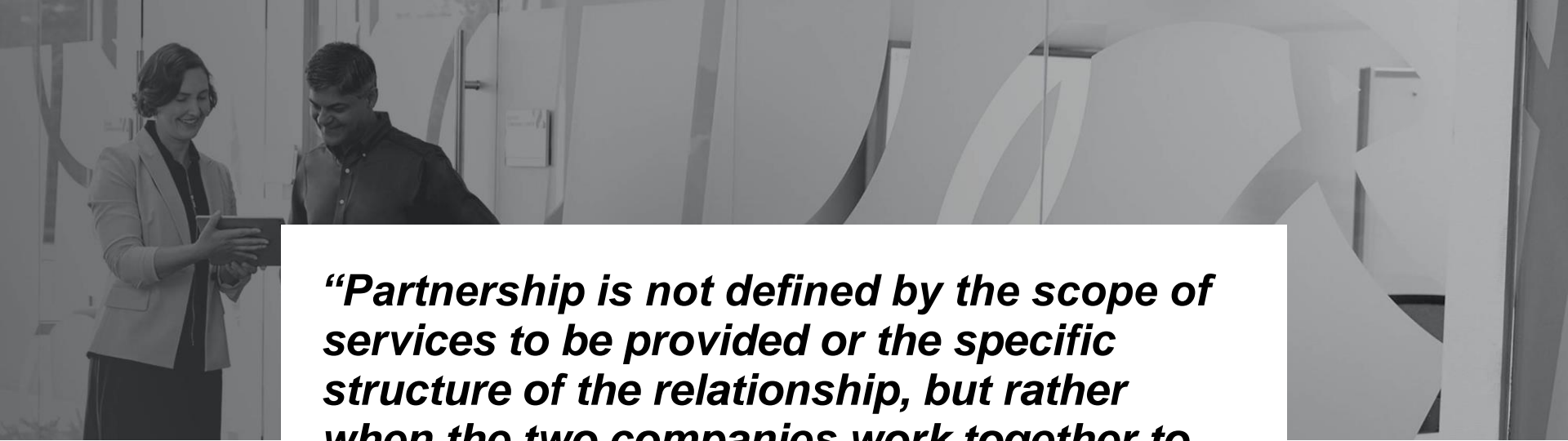


## AGENDA

### 1 Change and Behaviours

### 2 Partnerships Models

- Traditional Models
- The 5<sup>th</sup> Option



***“Partnership is not defined by the scope of services to be provided or the specific structure of the relationship, but rather when the two companies work together to achieve mutually beneficial objectives, and when each partner works actively to help the other party achieve their own objectives.”***



**Who am I dealing  
with?**



**With whom am I  
dealing?**







## PROMOTERS

are motivated by hopes.  
By aspirations.  
By the need to grow.



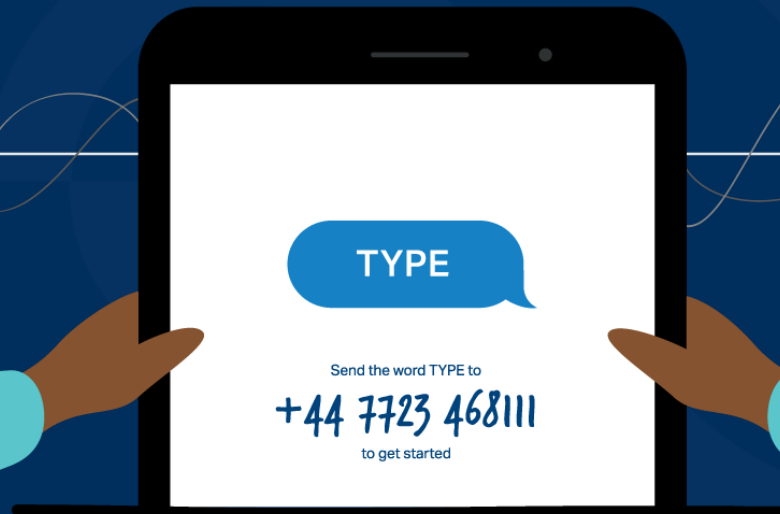
## PREVENTERS

are motivated by duties.  
By obligations.  
By the need to stay secure.

When it comes to healthcare communication, 25 years of research has shown that people are mainly motivated in one of two ways: promoter or preventer.

Imagine how different the approach needs to be to motivate those two distinctly different styles? Sources of motivation and persistence are incredibly personal. And every word matters.

How are you motivated?



\* Note: no sign up required (or even requested)

*Take a 4-question text-message quiz to uncover your motivational style  
and learn more about how your style engages with healthcare information.*

# Motivation Segmentation

I used a simple motivational segmentation to quickly understand which triggers and nudges will motivate our group today. Normally, we use this approach to customize outreach, digital communications and follow-up to support each of the two commonly recognized motivational segments.

## VALUE TO SPONSOR

- More efficient recruiting
- Longer lasting participation and resilience
- New understanding about what engages and motivates people
- Relevance and customization across cultures

## VALUE TO SITES

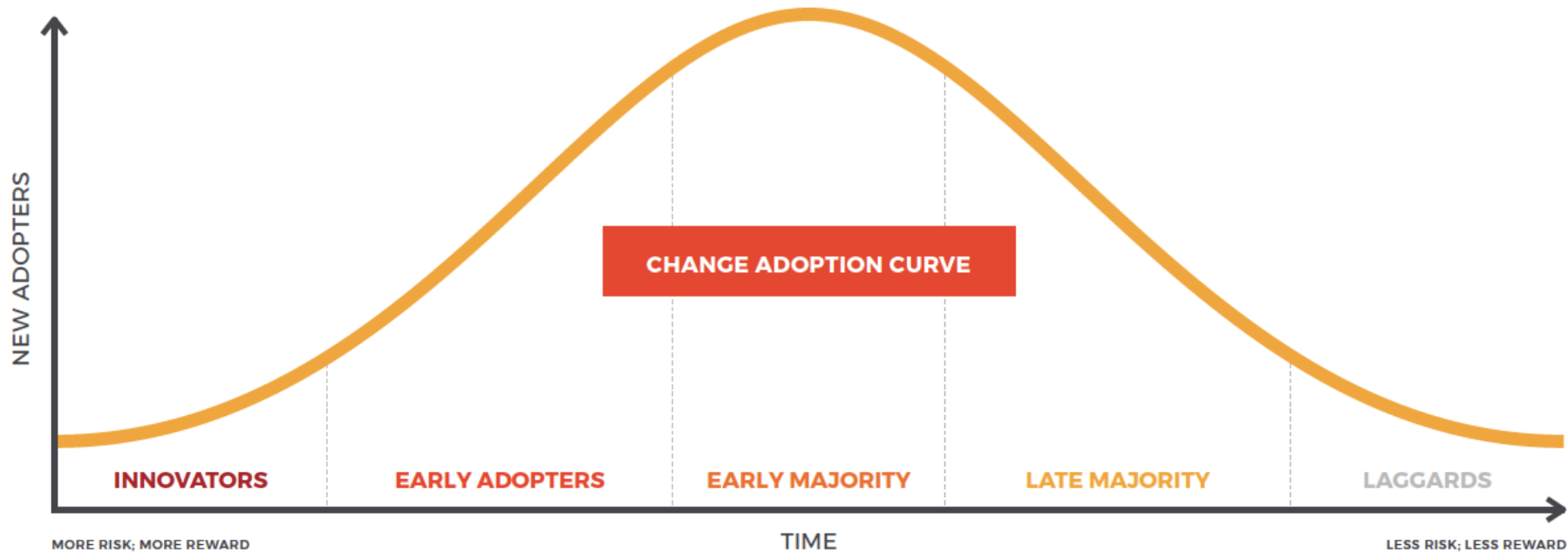
- Omnichannel recruiting support
- New insight into how to talk with patients about the value of their participation in clinical trials
- More motivated and committed participants

## VALUE TO PATIENTS

- Meaningful connections to what matters most to them
- Stronger sense of both commitment and fulfillment from their participation in the trial process

**Change can be  
difficult**







A photograph of a red hockey goal with a white net, positioned on an ice rink. The goal is centered in the frame, and the net is slightly sagging. The background shows the rink's boards and some arena lighting.

## Pulling the Goalie: Hockey and Investment Implications

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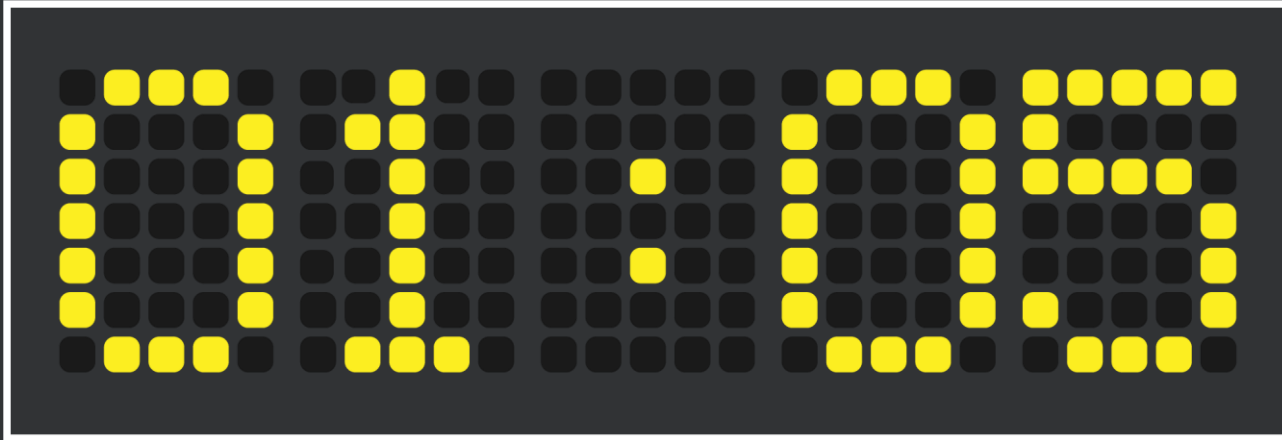
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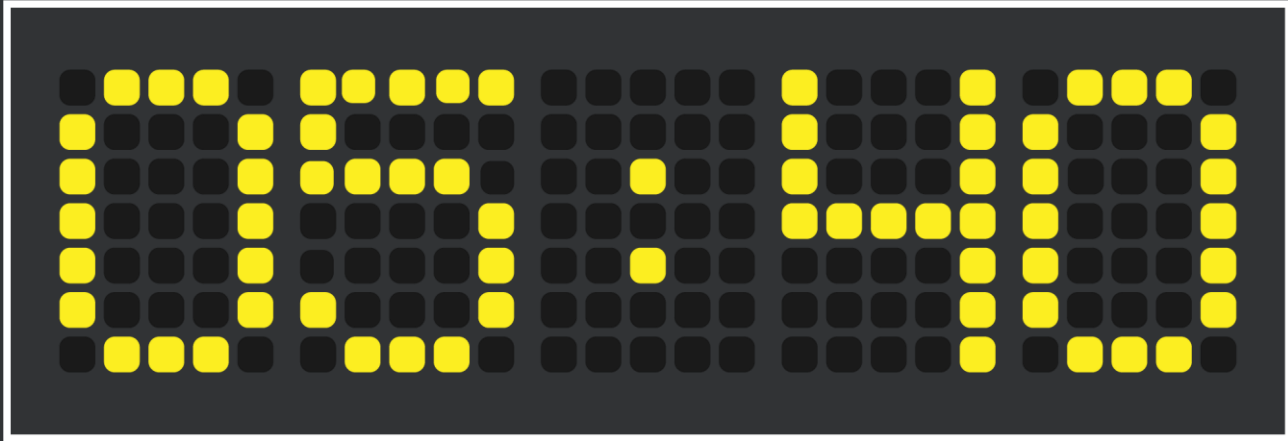
AQR Capital Management, LLC

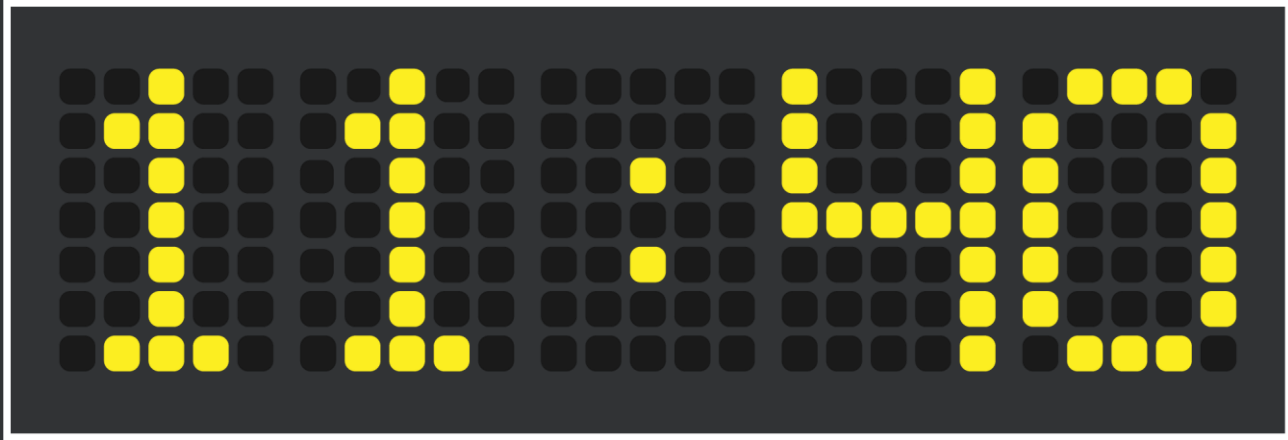
[Aaron Brown](#)

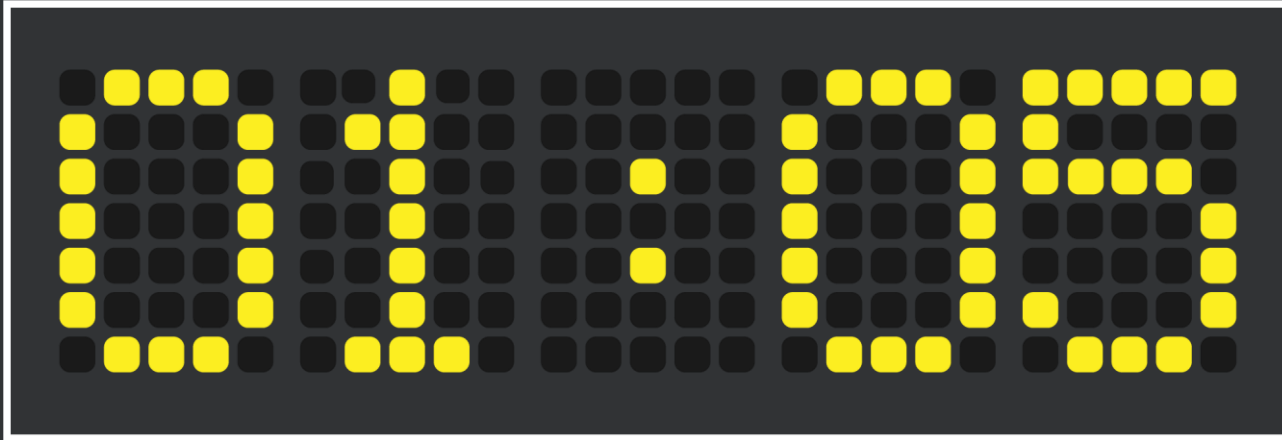
New York University (NYU) - Courant Institute of Mathematical Sciences; AQR Capital Management, LLC

Date Written: March 1, 2018

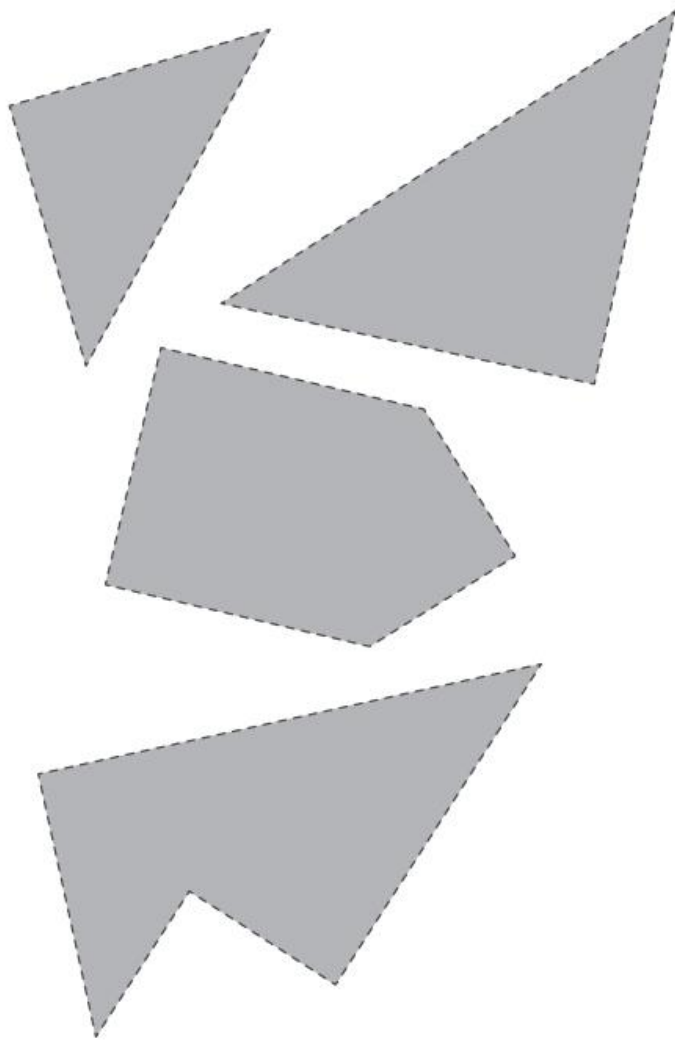




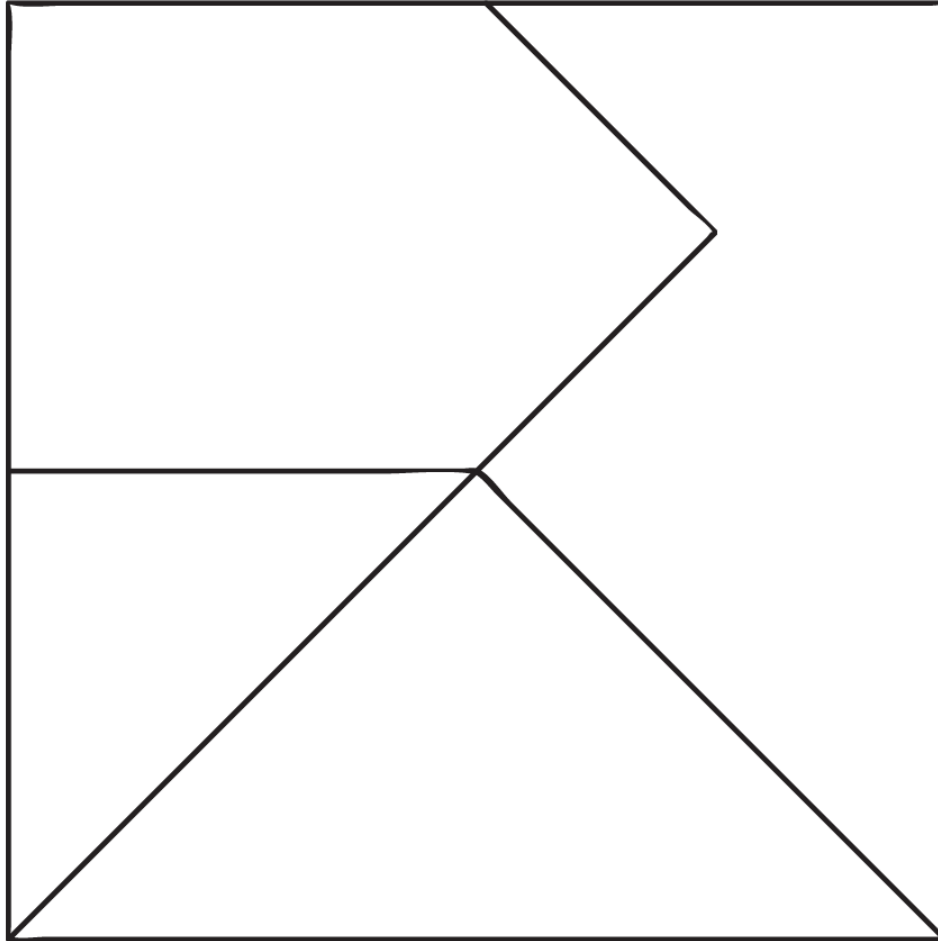


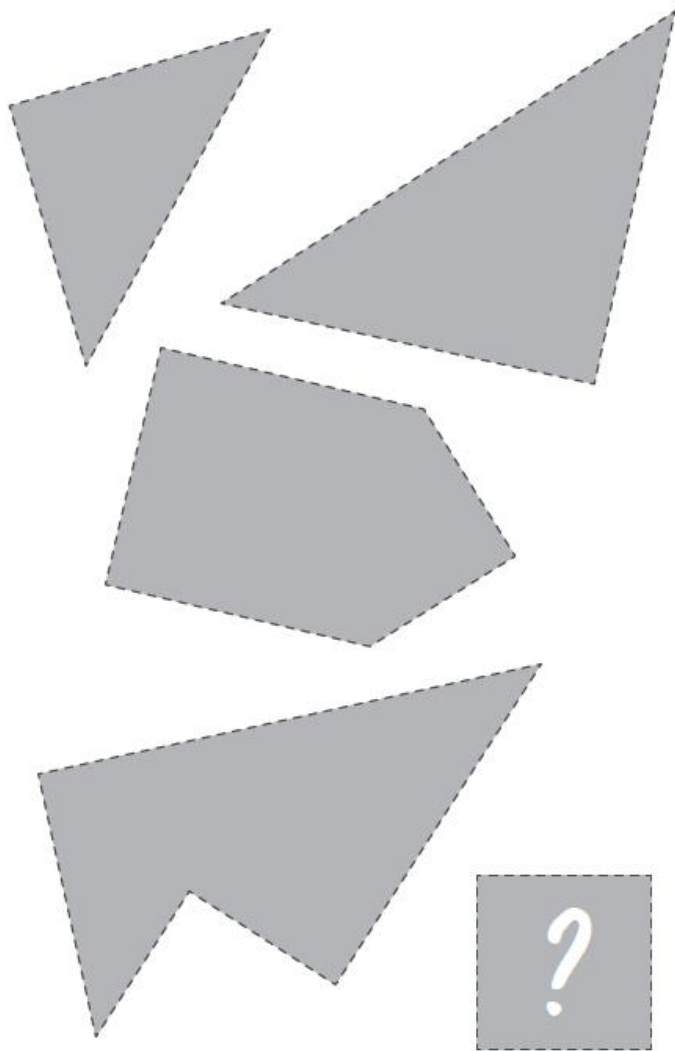




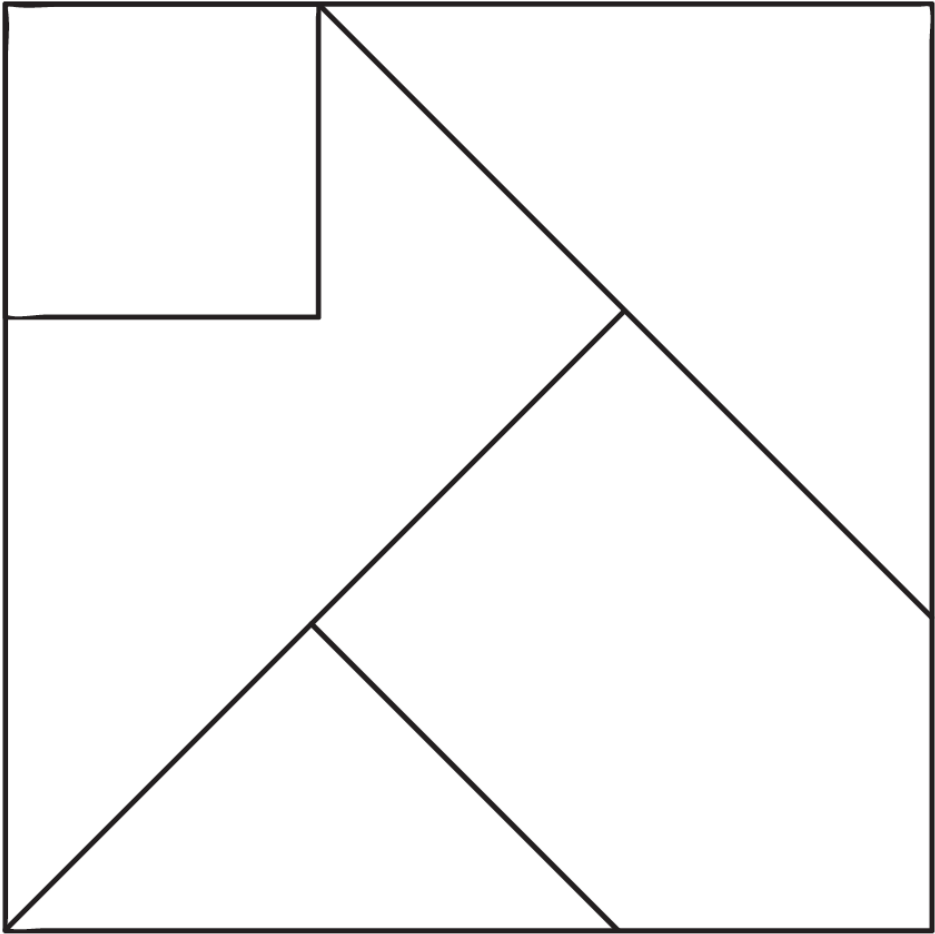


Solution 1.





Solution 2.



# Partnership Models

- Traditional Models
- The 5<sup>th</sup> Option





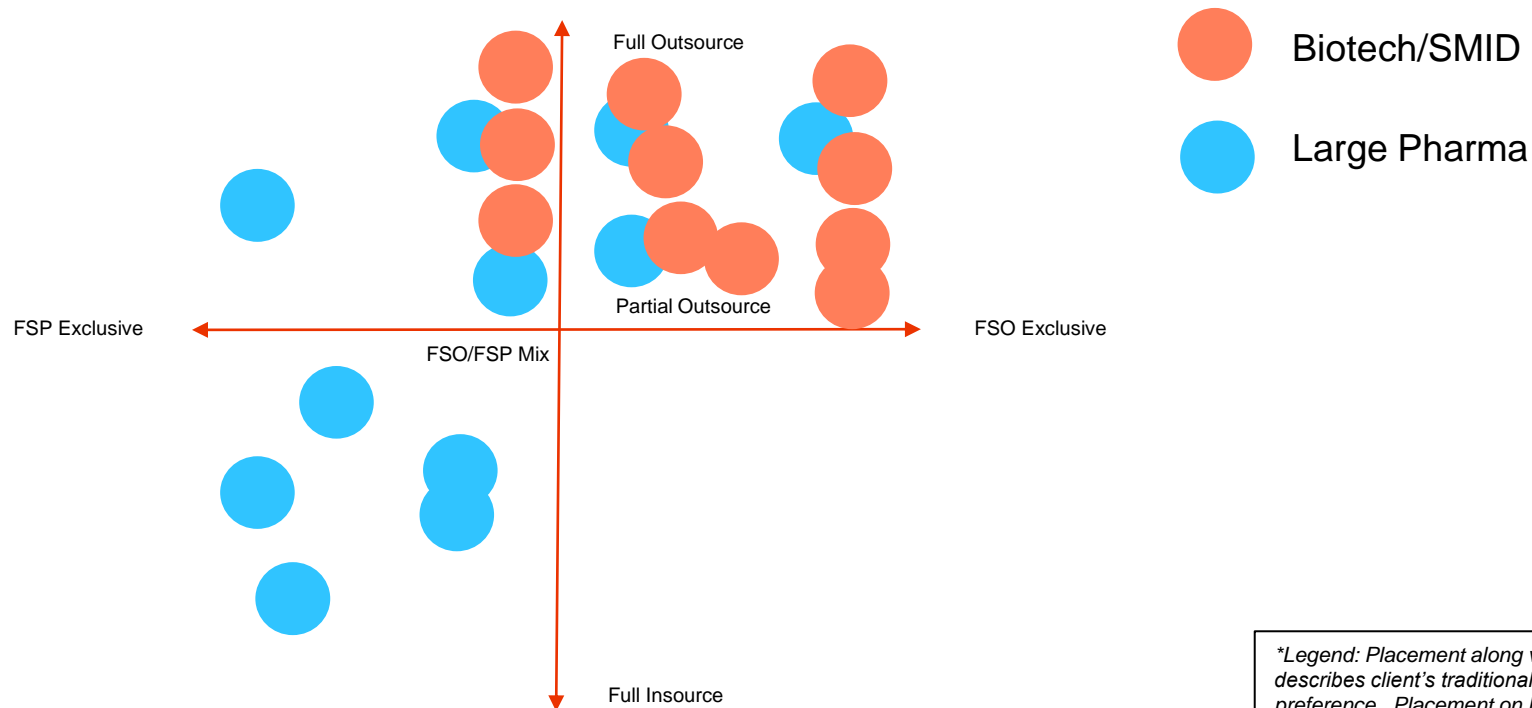
## Traditional Service Models

	Full Service	Stand-Alone Partial Service	FSP	Contingent Staffing
<b>Definition</b>	<ul style="list-style-type: none"> <li>CRO provides full suite of functions, including overall management</li> </ul>	<ul style="list-style-type: none"> <li>Provide single or several functions on 'by study' basis</li> </ul>	<ul style="list-style-type: none"> <li>Deliver select functional resources/services across client's portfolio</li> </ul>	<ul style="list-style-type: none"> <li>CRO provides contract labor; Pharma maintains management control</li> </ul>
<b>Advantages</b>	<ul style="list-style-type: none"> <li>Leverage CRO infrastructure &amp; delivery expertise</li> </ul>	<ul style="list-style-type: none"> <li>Flexibly utilize CRO services, fill internal gaps</li> </ul>	<ul style="list-style-type: none"> <li>Allows outsources whole functions</li> <li>Consistency and lower fixed costs</li> </ul>	<ul style="list-style-type: none"> <li>Avoid fixed cost investment</li> <li>Fast fill</li> <li>In-house or remote</li> </ul>
<b>Disadvantages</b>	<ul style="list-style-type: none"> <li>Operates best using CRO systems and SOPs</li> </ul>	<ul style="list-style-type: none"> <li>Requires more management by sponsor and FS CRO</li> </ul>	<ul style="list-style-type: none"> <li>Requires more sponsor oversight</li> <li>FS provider oversight may be higher</li> </ul>	<ul style="list-style-type: none"> <li>Designed to fill gaps only</li> <li>Not an efficient trial management strategy</li> </ul>
<b>Example</b>	<ul style="list-style-type: none"> <li>Full Ph I-IV Trial/Study</li> </ul>	<ul style="list-style-type: none"> <li>Programming, DM &amp; Statistical services on single Ph I-IV Trial/Study</li> </ul>	<ul style="list-style-type: none"> <li>Single contract for DM services across full customer portfolio</li> </ul>	<ul style="list-style-type: none"> <li>5 US biostatisticians for 6 months, managed by client</li> </ul>

## Business Constructs & Incentives



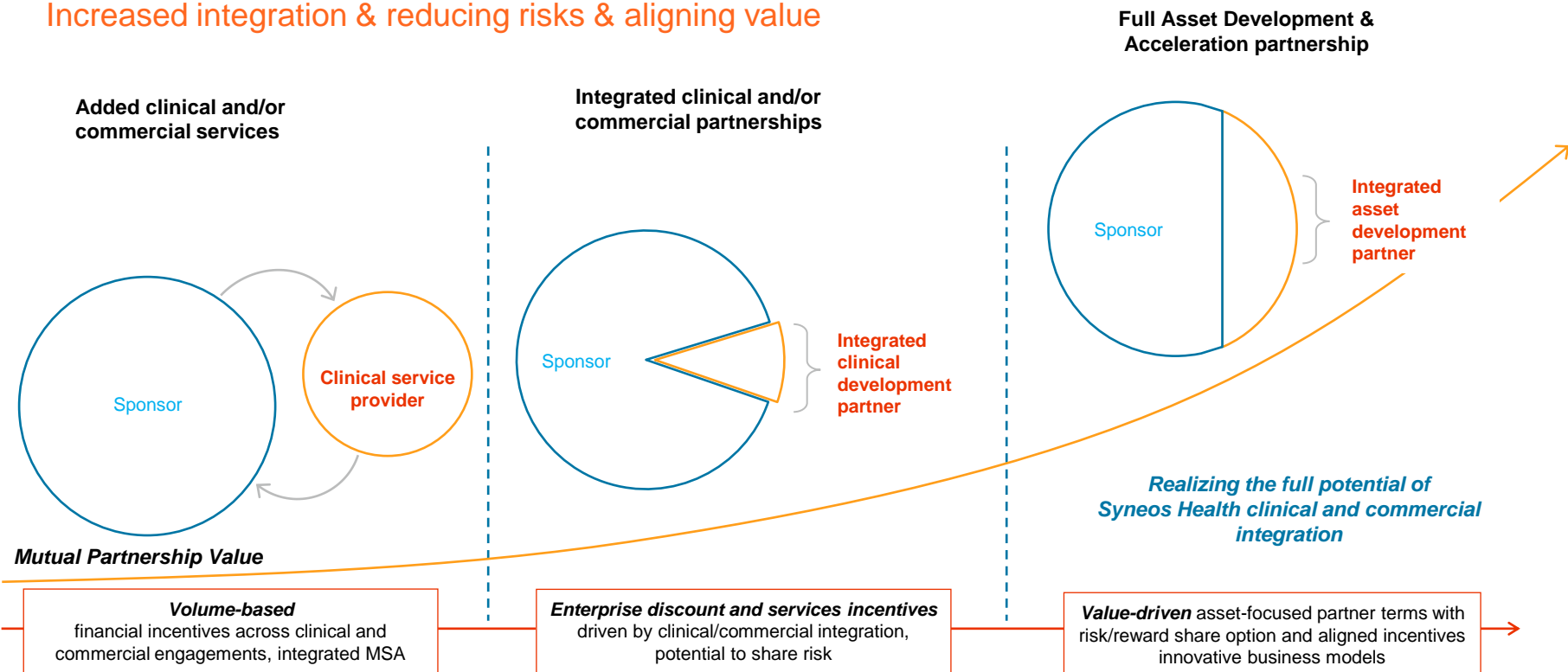
## Large Pharma & Biotech Outsourcing Strategy Mix



*\*Legend: Placement along vertical axis describes client's traditional in/outourcing preference. Placement on horizontal axis details which CRO service offering they tend to prefer when outsourcing.*

# Evolution of Sponsor-CRO Partnerships - The 5<sup>th</sup> Option

Increased integration & reducing risks & aligning value



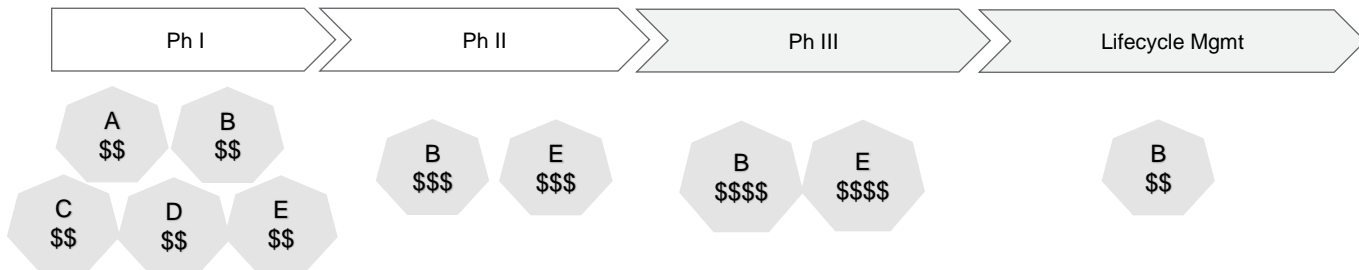
# Next Step on the Partnership Continuum

## Innovative Proof-of-Concept Model

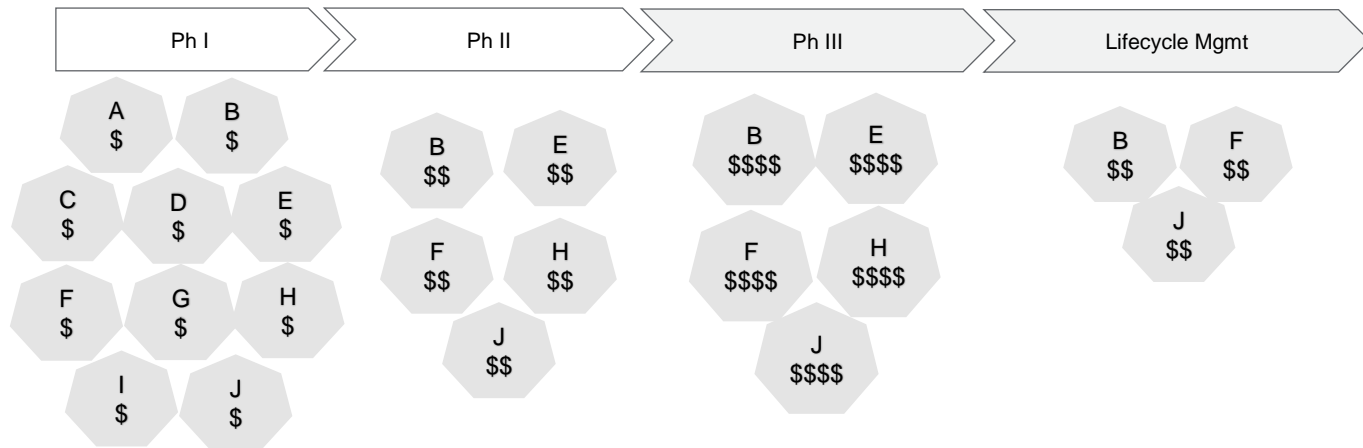
### Benefits of Proof-of-Concept Model

- Exchange of delivering Phase I at cost for guarantee of later-phase conduct
- Provides for further increased 'shots on goal'
- As assets bring value, CRO is further incentivized
- Requires singular-provider relationship given risk of asset development

### Traditional



### Proof of Principle Model





# Integrated Global Asset Development Partnership Across Multiple Assets

**13** Studies launched in



**1 YEAR**

>1,100 employees on boarded  
and trained in the ways of working

## UNIQUE LEVEL OF SERVICE INTEGRATION FULL ENTERPRISE MSA

- Clinical Development ➤ Oncology BU ➤ PM ➤ DM ➤ Biostats
- Medical Writing ➤ Safety/PV ➤ SSU ➤ Regulatory ➤ Medical Affairs ➤ Training ➤ Commercial Consulting ➤ Communications
- Rare Diseases Consortium ➤ Clinical Supply Operations
- Vendor Management

**Strong cross-functional governance**  
for solid KPI achievement consistently  
meeting client expectations

**CLINICAL MONITORING**



**TRIP REPORT TURNAROUND**



**AGGREGATE SAFETY  
REPORTING**



**PROTOCOL DEVIATIONS**



**ACTION ITEM AGING**



**QUALITY IMPACT ON STUDY  
DATA**



**RELATIONSHIP/TEAM  
STABILITY**



## Integrated engagement across **CLINICAL AND COMMERCIAL** divisions

**CLINICAL  
DEVELOPMENT**

**ONCOLOGY  
BUSINESS UNIT**

**REGULATORY  
CONSULTING**

**COMMERCIAL  
CONSULTING**

**DEPLOYMENT  
SOLUTIONS**



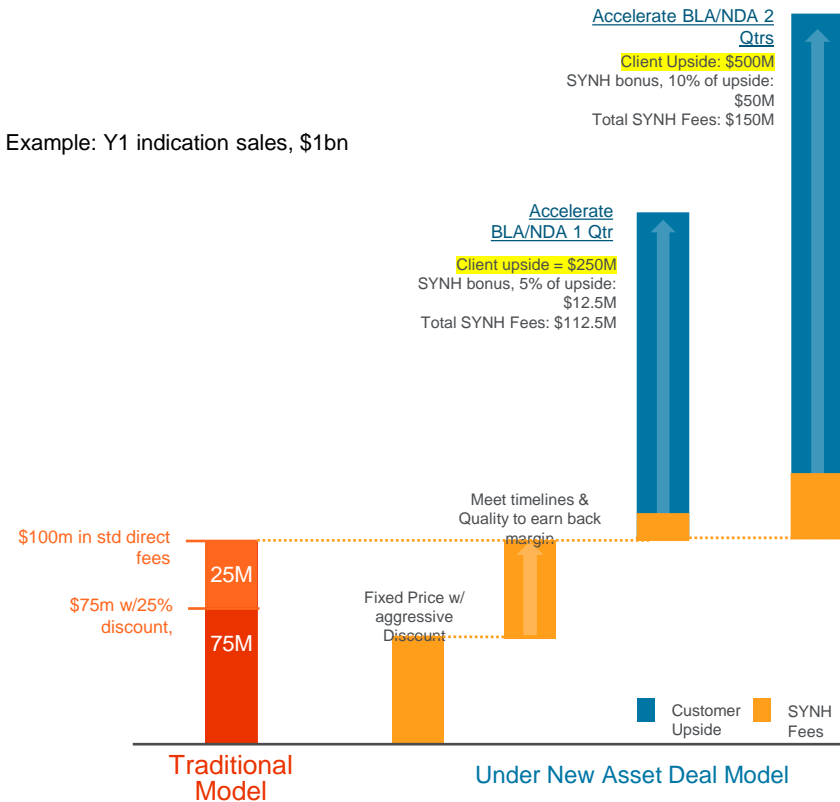
**Teams united by a  
JOINT GLOBAL VISION**  
**One Team. Delivering for Patients**

**Innovative  
ASSET DEVELOPMENT PARTNERSHIP**  
driving **CONSISTENCY**, **ACCELERATION**,  
operational and cost **EFFICIENCIES**

**Multi-level governance, KPI and KQI** framework established to drive overall  
performance and timeline acceleration

# Asset Development Program

➤ Example: Y1 indication sales, \$1bn



## Key Benefits of Product Development Model – The 5<sup>th</sup> Option

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- Customer retains full ownership of assets
- Small & Mid-size customers can benefit from large pharma expertise without additional fixed costs
- Early engagement enables PDO to take more risks
- Better aligns outcomes for both Biotech and PDO

## — Ideal Customer for the Product Development Model

- Small- to mid-sized companies
- Assets in early development
- Desire to keep a small fixed-cost footprint
- Priority to fully align incentives with partner