



Value-Based Contracting and Innovative Payer Engagement for Medical Affairs Professionals:

Where is the Market Moving?

Webinar
April 20th, 2018

Presenter Introduction



Moderator: Jamie L. Kistler, PhD

Sr. Director, Client and Strategic Services, ACC Global Medical Communications, ICON plc

Jamie has nearly 20 years of combined academic and medical communications industry experience. She has supported the development and implementation of US and global medical communications and publication plans, scientific communication platforms, educational symposia, advisory boards, and various analytics projects across a vast array of therapeutic areas. Jamie has a doctoral degree in Molecular and Cellular Pathobiology from Wake Forest University and completed a postdoctoral fellowship at Fox Chase Cancer Center.



Presenter: Michael Pace, MBA

Senior Principal, Pricing and Market Access, ICON plc

Mike has over 20 years of executive operating experience within global biopharmaceutical firms and digital health start-up ventures, leading commercialization and market access strategy, product development, payer account management, contracting and operations, business development, sales and leadership development functions. At EMD Serono, he conceived and led the value-based contracting effort that produced to the 1st outcomes agreement for a specialty medication with a health plan, followed by the 1st outcomes agreement with a pharmacy benefit manager in the US.

Today's discussion




- **Trends in value-based contracting: is traditional contracting enough?**
- **Optimizing commercial success: an approach to value-based contracting**
- **From theory to practice: insights on getting things right**
- **Q&A**

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Disruptive healthcare trends are forging a new payer environment and forcing manufacturers to adapt their operational models

Healthcare trends

-  Digitally enabled healthcare
-  Big data
-  Predictive analytics
-  Budgetary pressures
-  Real-world evidence

Evolving payer environment

-  Value based pricing
-  Payer partnerships
-  Health Economics
-  Evidence requirements
-  Health technology assessment

New pharma strategies

-  Patient pathway management
-  Digital solutions
-  Innovative pricing strategies
-  Companion diagnostics
-  RWE strategies

The major disruptive forces affecting the healthcare and life sciences industry are forging a new payer environment with value demonstration at its core; consequently, pharma and biotech companies are being forced to adapt and create new go-to-market strategies

Launching and managing the lifecycle of a drug involves compromise between payer and manufacturer objectives



Payer objectives

- Provide **access** to new, innovative therapies
- Comply with **public and political pressures** to make new drugs available
- Ensure **economic and rationale** use of new therapies
- Comply with ever increasing **budgetary constraints**
- Mitigate the **risk of uncertainty** over the drug's efficacy and real-world benefit



Manufacturer objectives

- Obtain **broad access** for a new, innovative therapy
- Achieve the **optimal price**, reflective of the products value
- Maximise **return on investment** and provide long-term stability
- Receive **reward for innovation** and ensure future investment
- Foster **positive relationships** with the various payer, physician and patient communities

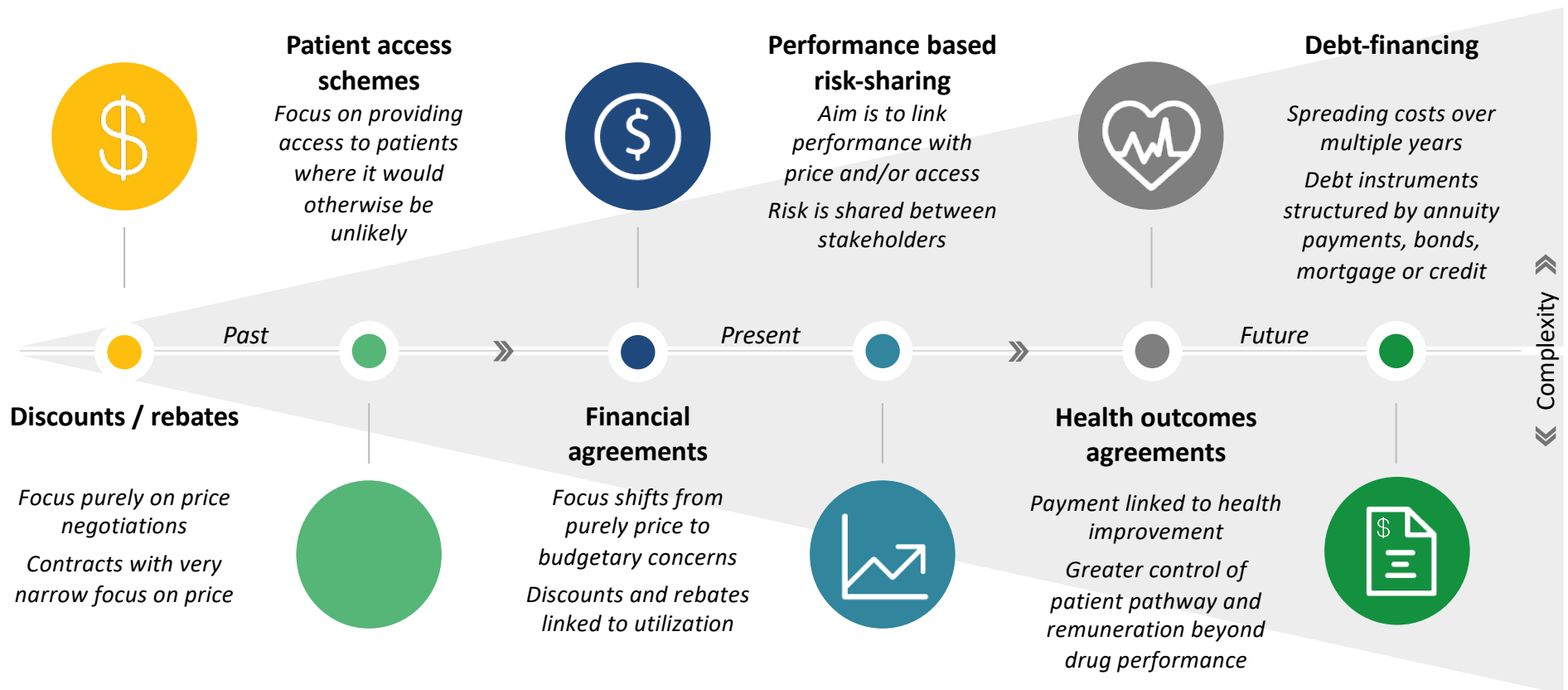
While some objectives will align and others conflict, ultimately we are striving for a win-win agreement to satisfy both parties

Where the perceived risk to a payer outweighs the benefit of providing access to a drug, reaching an agreement is unlikely










Value-based contracting is a tool which can be individually designed to address uncertainty, mitigate / share risk and facilitate access to drugs where an agreement could not otherwise be reached

Consequently, contracting to obtain market access is evolving to include innovative ways of reaching mutually beneficial agreement

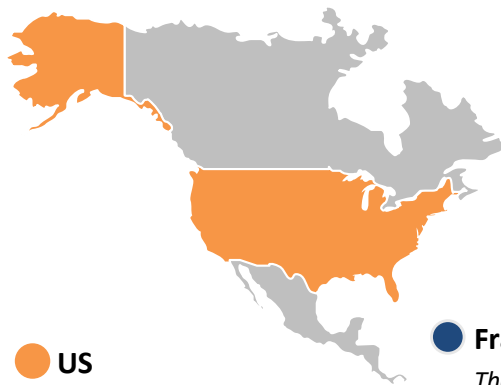


In the US, value-based contracts are becoming more common due to improvement in EMR and access challenges

Examples of Value-Based Contracts in the US

Product	Manufacturer / Payer / Year	Agreement Details
	Amgen / Harvard Pilgrim (2017)	<ul style="list-style-type: none"> Amgen will pay rebates to Harvard Pilgrim if patients taking Enbrel score below certain levels based on six criteria measured via an effectiveness algorithm (measurements include patient compliance, switching or adding drugs, dose escalation and steroid interventions)
	Merck / Aetna (2016)	<ul style="list-style-type: none"> Merck's rebates on Januvia and Janumet are based in part on those products' contributions to helping Aetna's commercial T2DM population achieve or maintain treatment objectives
	Novartis / Cigna (2016)	<ul style="list-style-type: none"> Payments by Novartis are linked to how well Entresto improves the relative health of Cigna patients, based on a reduction in the proportion of patients who are admitted to hospital for heart failure
	Genentech / Priority Health (2015)	<ul style="list-style-type: none"> Genentech was not required to pay Priority Health a rebate if a patient remained progression-free for longer than six months. But if a patient had to change treatments, either because of toxicity or disease progression, Genentech would then provide a rebate to Priority Health
	Amgen / Harvard Pilgrim (2015)	<ul style="list-style-type: none"> Amgen provides a pre-negotiated discount if the patient's cholesterol levels are not lowered enough to meet a pre-specified benchmark from clinical trials
	EMD Serono / Prime Therapeutics (2012)	<ul style="list-style-type: none"> EMD Serono pays rebates to Prime if patients taking Rebif have a higher overall total cost to their plans than patients on a different MS drug, or if the medication adherence rate remains above a specified level
	P&G/Sanofi-Aventis (2009)	<ul style="list-style-type: none"> P&G/Sanofi-Aventis reimbursed HAMP for the costs of treating non-spinal fractures suffered by patients who were taking Actonel

Within the evolving payer environment, receptiveness to more complex value-based contracts is increasing, but hurdles remain



US

Recent examples illustrate the growing trend for plans and insurers to enter into value-based contracts; this is expected to increase exponentially within the new political environment

UK

Financial agreements are predominant; payers are increasingly receptive of value-based contracts, however, technical and administrative issues remain major barriers

Germany

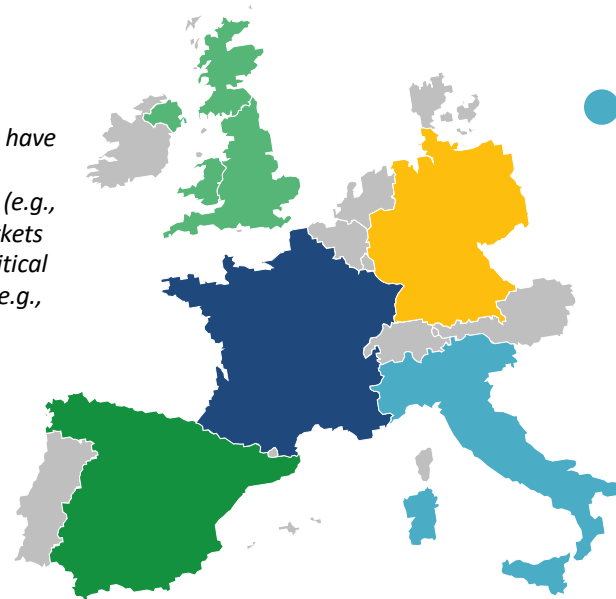
Historically unreceptive to anything other than simple financial agreements, although recent contracting at the regional / local level indicates an increasing appetite for value-based contracts; technical hurdles and infrastructure barriers will need to be overcome

France

The majority of agreements have been financial, with some exceptions in rarer diseases (e.g., Imnovid in r/rMM) and markets where there are intense political and competitive pressures (e.g., Sovaldi in HCV)

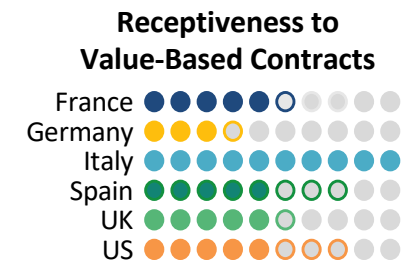
Italy

Fully mature market in terms of value-based contracts with a combination of financial, payment-by-results and conditional treatment continuation based agreements to offset risk and manage affordability



Spain

Simple financial agreements remain pre-dominant at the national level, however, within more progressive authorities at the regional level there is both experience and increasing appetite for value-based contracts to manage risk and budget



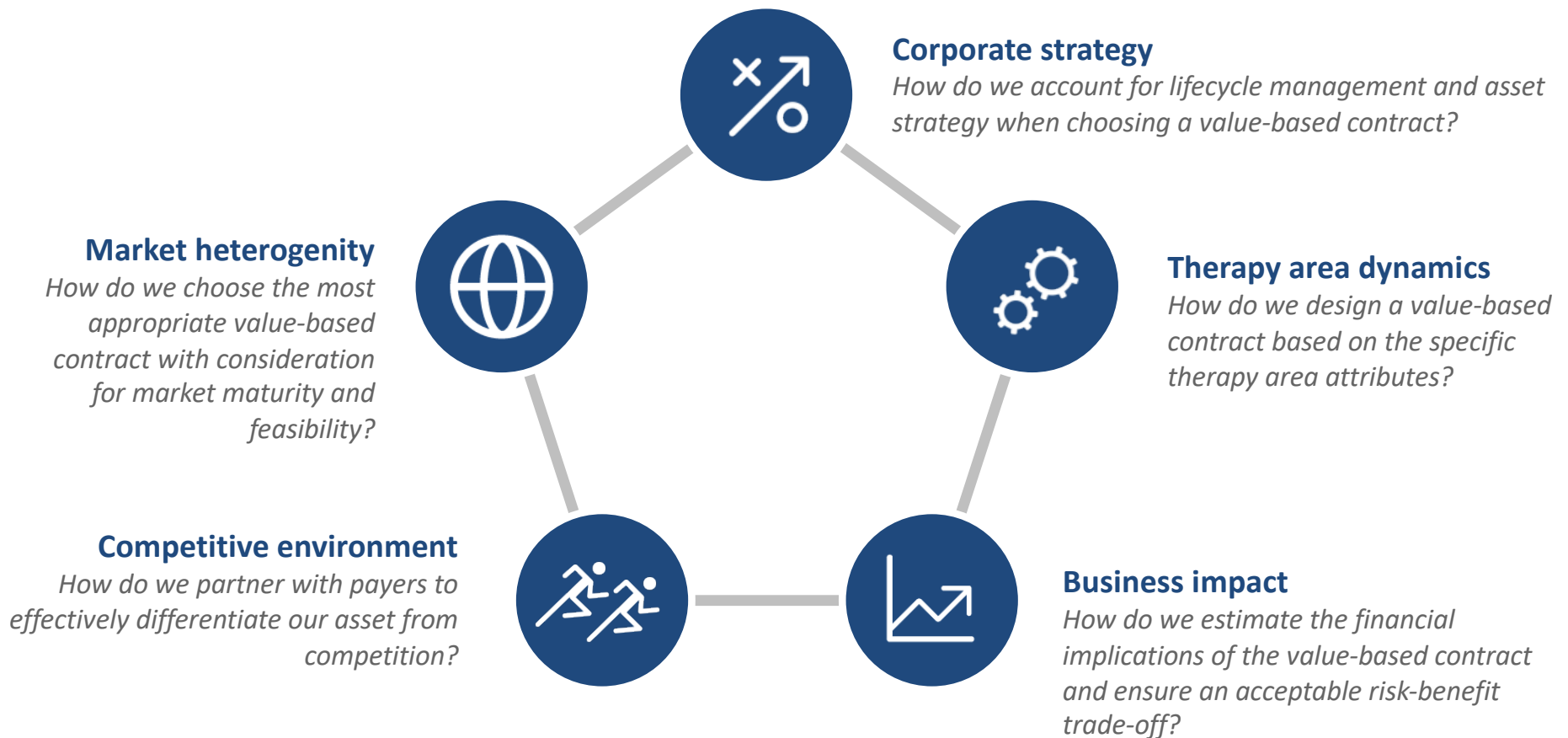
The digital revolution is reducing implementation hurdles that have held back wide adoption of value-based contracts

Data analytics		<i>Large scale computational power is becoming increasingly affordable and accessible to stakeholders providing greater opportunities for real-world insights into patient behaviors, treatment costs and efficacy</i>
Patient data		<i>Social media, health sensors, electronic medical records and genomics generate huge amounts of patient information that can be fed into modern data analytics</i>
Mobile health		<i>Pervasive adoption of smartphones and mobile apps creates new models for patient engagement and changes care of chronic conditions with patients actively monitoring their own health status</i>
HCP digital workflow		<i>Integration of electronic medical records and telemedicine platforms enable digital workflows to improve real world quality of care and reduction of medical errors</i>

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With so many considerations and complexities, selecting and implementing an appropriate value-based contract is challenging



Evaluation of the market environment and strategic objectives is crucial when assessing the need for a value-based contract

MARKET

Payer concerns

- Evaluate whether payer concerns are either data, financial or performance related
- Identify issues related to affordability and / or price-value mismatch

Market readiness

- Evaluate the market maturity and receptiveness to value-based contracts
- Assess confidentiality or cross-market risks

COMPETITION

Competitive intensity

- Assess the volume of competitor products, direct substitutes and generic competitors within the context of the present and future landscape

Competitive differentiation

- Assess whether products compete on value or price and how this affects potential value-based contract selection
- Benchmark known value-based contracts of competitors

STRATEGY

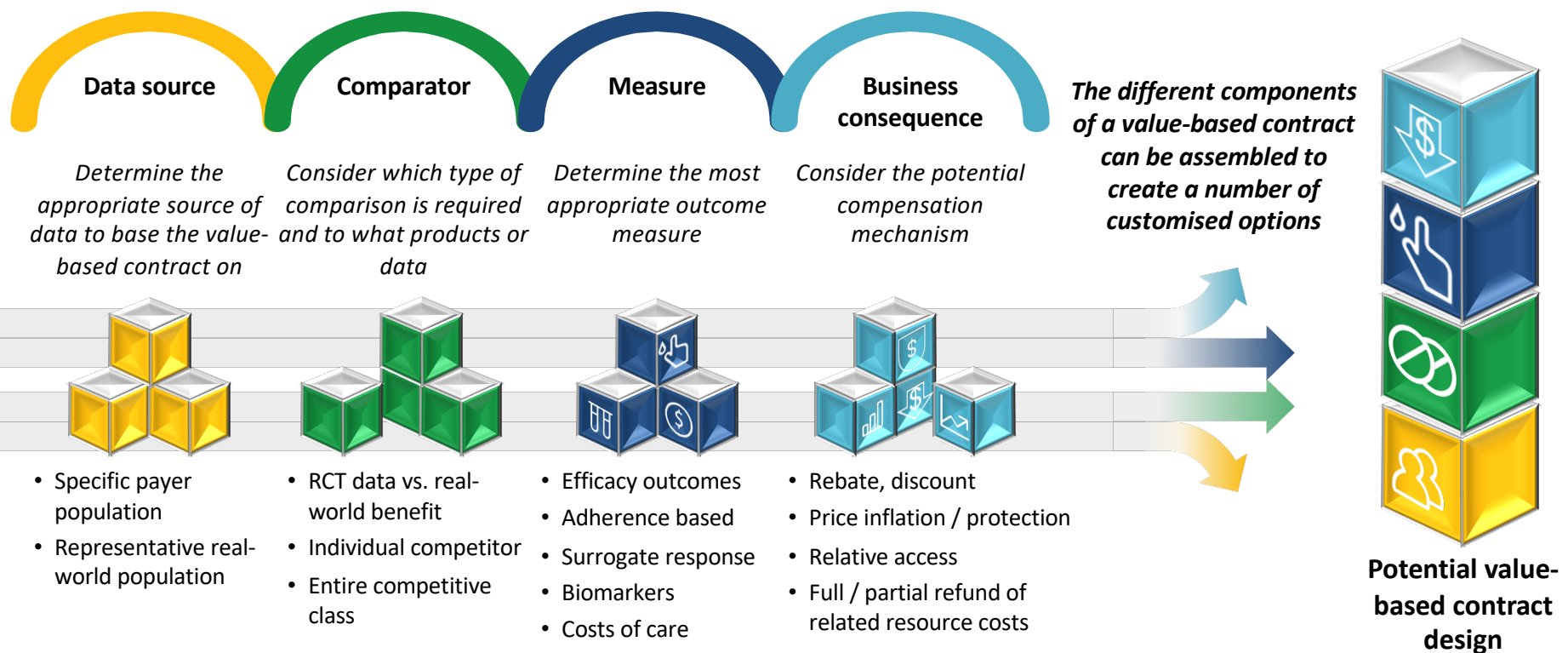
Global vs. regional / local

- Consider and align on differences between global, regional and local strategy
- Identify potential conflicts and develop solutions

Product or portfolio

- Consider objectives and strategy for both the brand and portfolio and implications for price, access and time to market of both current and future products

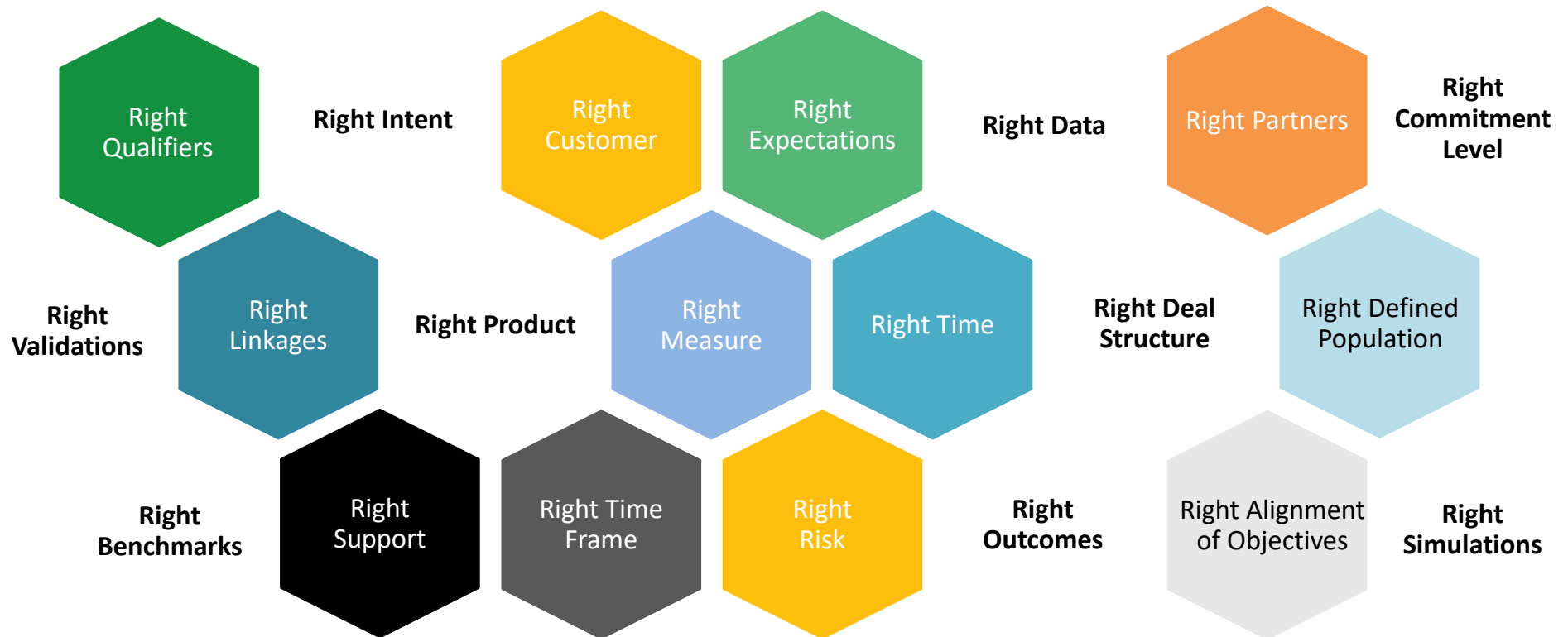
Next, we consider the different components of a value-based contract before combining them into multiple customised options



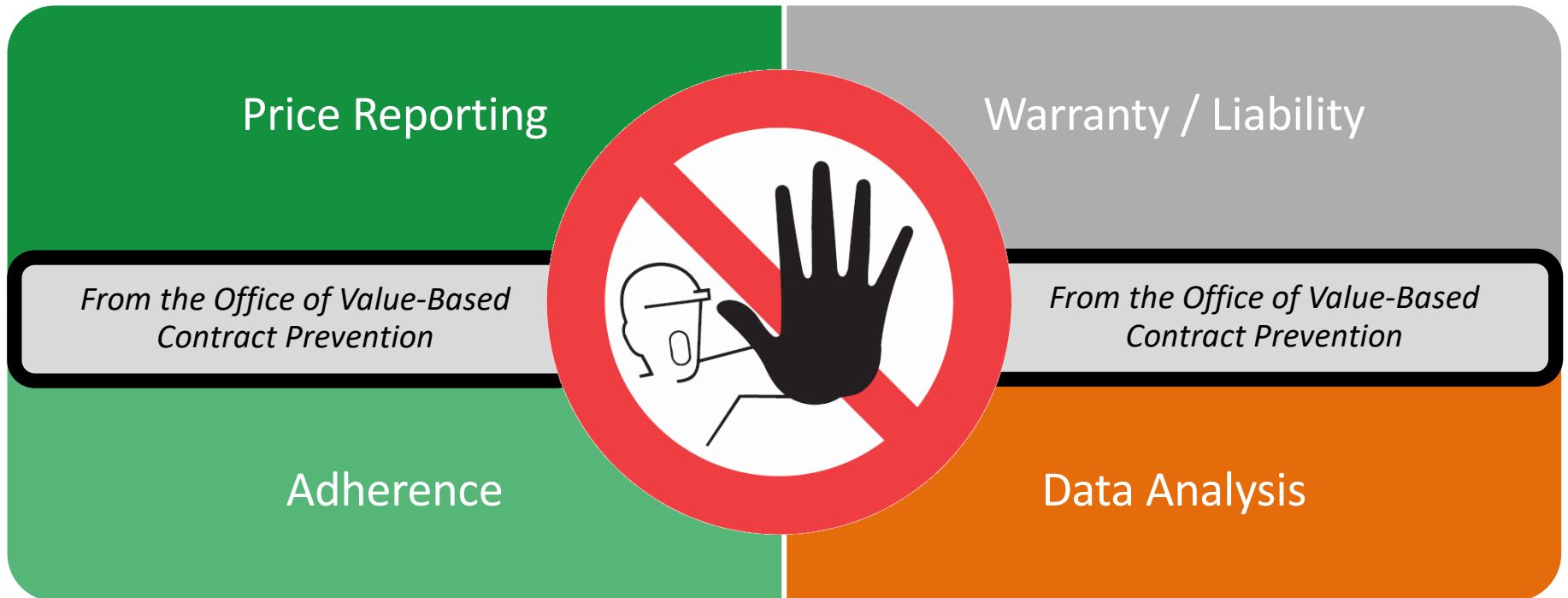
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Good partners, with “the right stuff,” will accelerate value-based arrangements regardless of inertia



However, clarity and safe harbors will foster a more fertile environment for novel contract constructs



Key Takeaways: Role of Medical Affairs in an Evolving Market



- **Understand** evolving payer evidence requirements (e.g., US trend towards value-based contracting)
- **Foster** positive relationships with various payer, provider, and patient communities
- **Build** a strong scientific evidence base for your product that will support value-based pricing agreements
- **Drive** cross-functional collaboration internally
 - Medical Affairs, Clinical / R&D, Health Economics and Outcomes Research, Market Access
- **Integrate** clinical, economic, and outcomes data dissemination plans into a single, cohesive strategic vision
- **Master** emerging digital and data technologies to analyze vast volumes of real-world evidence data

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