



# Passing fad or game-changer?

Outcomes-based contracting  
in life sciences

**EY**

Building a better  
working world

# Contents

<b>Prologue</b>	<b>2</b>
<b>Section 1: The growing inevitability of outcomes-based contracting</b>	<b>4</b>
The rationale for the health care system is very compelling	5
Life sciences also has a lot to gain	5
The current state of outcomes-based contracts	5
<b>Section 2: Overcoming historic barriers</b>	<b>8</b>
Barrier #1: "We can't agree on the right outcomes let alone influence them"	8
Barrier #2: "We can't capture the data to measure outcomes robustly"	10
Barrier #3: "It's just too risky for us"	11
<b>Section 3: How to progress while managing risk</b>	<b>12</b>
A framework for delivering outcomes-based contracting	12
Building the critical capabilities	20
Getting started	22
Time to change the game	23

# Purpose of this paper

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This paper has three main aims, and is therefore divided into three sections. Section 1 aims to provide a comprehensive overview of the compelling rationale for outcomes-based contracting (OBC) and the benefits for all stakeholders of adopting this innovative way of commissioning and paying for health care. In section 2, we outline the valid historical barriers and why, this time, we believe it is different, before finally setting out in section 3 a practical action plan for how to progress in a way that manages the risk.

For those who are already convinced of the rationale and familiar with the challenges, we recommend jumping to section 3, which sets out a framework for delivering outcomes-based contracts, the new capabilities required to deliver and some practical tips on how to get started.

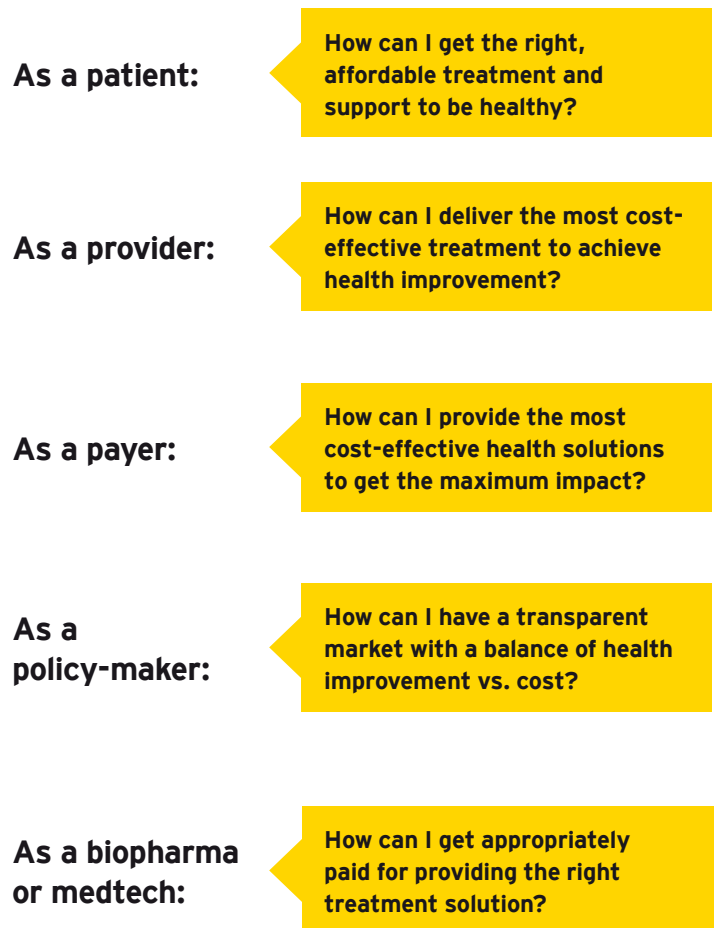
## Food for thought

- ▶ How can life sciences companies extract their “fair share” of the value they create in health care?
- ▶ When you are judged on outcomes, how confident are you in making the grade?
- ▶ How do we build trust between multiple parties so they can work together in a frictionless way?

# Prologue

The pressures facing health care systems are well understood. Many health care systems around the world are fast reaching, or already at, a breaking point and struggling to balance the multitude of demands on their limited resources. While health care stakeholders often have related but slightly differing priorities and define value differently (see Figure 1), three things will continue to be some of the most critical challenges we face as societies today: managing escalating health care costs, maximizing access to innovative medicines and treatments, and improving the quality and outcomes of care.

**Figure 1: Balancing related but different stakeholder needs**

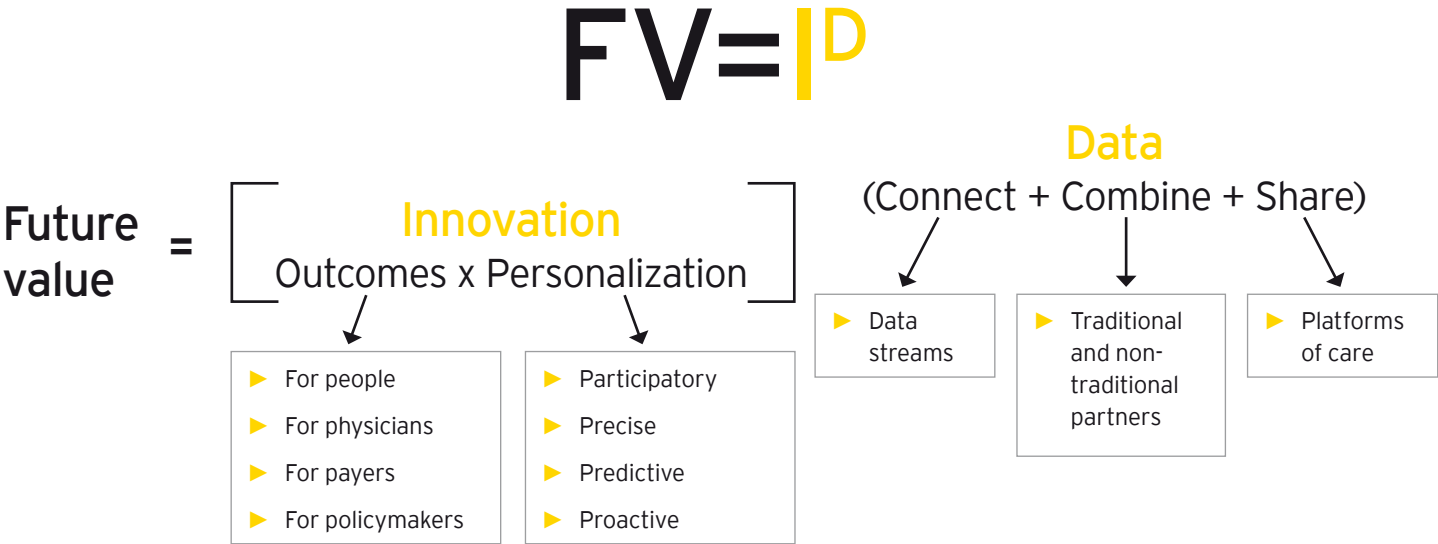


Operating within this context, life sciences companies need a fundamentally different approach to creating value in the future. Existing business models and ways of both commissioning and delivering medicines, medical products and services need to change. The ability to deliver better outcomes, which are enabled by greater personalization, and amplified by connecting, combining and sharing data will determine the amount of value life sciences companies are able to create in the future (see Figure 2). Clearly, companies who are able to develop innovative products with a high unmet need will continue to be rewarded, but even these companies will not be exempt from the pressure to deliver better outcomes and ensure their products are only being given to patients that will respond. For other companies that don't have products that are first or best in class, the ability to demonstrate better outcomes through a combination of products and services will be critical to their success.

The equation in Figure 2 outlines the drivers of future value (FV). At the heart of the model is innovation (I), which is about delivering the outcomes that matter for people, physicians, payers and policymakers. In order to maximise the outcomes, a degree of personalization is required. Personalization has a number of dimensions – engaging and empowering people to ensure they participate in the management of their health, being more precise with interventions and where possible predict things before they become issues to be more proactive. The ability to innovate through outcomes and personalization is significantly influenced and amplified by data (D). This is enabled by connecting diverse and disparate data streams, combining the resources and expertise of all players in the ecosystem – both traditional and non-traditional, and then facilitating the secure and real-time sharing of these resources and assets through platforms.

Figure 2: The new equation for delivering value

Building Life Sciences 4.0



This paper builds on EY's latest paper – *Life Sciences 4.0: Securing value through data-driven platforms* and outlines how life sciences companies can set out a clear outcomes and service strategy, underpinned by a data platform (EY's Health Outcomes Exchange) and supporting capabilities to transform how value is created and rewarded in the industry and create "win-wins" for all. Outcomes-based contracting is at the heart of *Life Sciences 4.0* and is both

an urgent need globally and an opportunity. If companies create a clear outcomes and service strategy, while leveraging technology to create platform interfaces that helps combine their proprietary data with those from other health stakeholders to enable better interventions, they can position themselves as powerful leaders and capture sustainable future value.

# Section 1:

## The growing inevitability of outcomes-based contracting

Historically, the way health care has been paid for has not been aligned to value. This is down to many reasons from the difficulties in getting multiple stakeholders to agree what “value” is, to actually measuring it. The result is that health care continues to reimburse via mechanisms that are utilization, not value based.

Added to this, the nature of health care systems, and the inherent market frictions within them, create barriers to effectiveness and efficiency (see Figure 3), which, coupled with a misalignment of priorities and incentives, make it incredibly difficult for the various stakeholders to work together for the benefit of all.

**Figure 3: Barriers to health care system efficiency and effectiveness**

### Underlying market frictions ...

- ▶ Fragmented health care system
- ▶ Difficulty capturing and integrating data
- ▶ Data privacy considerations
- ▶ Information asymmetry
- ▶ Non-transferable nature of physical care
- ▶ Lack of transparency around cost
- ▶ Differing priorities and definitions of value
- ▶ Gap between decision-making and payment
- ▶ Annual budgets

### ... Creating barriers

- ▶ Episodic nature of care
- ▶ Variability of demand
- ▶ Lack of trust
- ▶ Poor information flow
- ▶ Inefficient resource allocation
- ▶ Delayed actions and interventions
- ▶ Resource constraints
- ▶ Short-term focus

But this doesn't need to be the case. OBC is increasingly seen as a viable, and perhaps the only sustainable way of aligning payment to value, and in turn incentivizes and enables greater efficiency and effectiveness in the system.

## The rationale for the health care system is very compelling

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While many have found outcomes-based contracts a challenge to execute or deploy at scale, there is a growing belief that OBC can ultimately be a sustainable model for the health care industry. Contracting on outcomes not only drives better results for patients, which alone is sufficient reason for adoption, but it also delivers three additional benefits to health care systems:

- ▶ **Delivers a better patient experience:** a prerequisite for delivering better outcomes is being more patient-centric, which translates to understanding and engaging with patients in a more meaningful and targeted way, resulting in a better experience for them. The right outcomes can also focus attention on improving patient pathways, which greatly impacts not only the patient experience but also overall efficiency through improving services (for example, reducing waiting times or getting people out of hospital sooner), simplifying patient access to care (for example, more virtual and home-based care), and supporting self-management.
- ▶ **Provides a clear link between price and treatment effectiveness:** this will ultimately drive increased cost effectiveness by ensuring that the health care system does not have to pay for treatments that are less effective or do not have the desired effect in the real world. Linking payments to treatment effectiveness also focuses innovation on solutions with a tangible impact.
- ▶ **Incentivizes manufacturers to play a broader role in health care:** if manufacturers sign up to deliver outcomes, there will be a greater incentive for them to engage in patient pathways to enhance (or de-risk) target outcomes.

## Life sciences also has a lot to gain

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If the case for patients, providers and payers is clear, what about life sciences companies? Is this just a route to lower prices and value erosion? It doesn't have to be and indeed, if executed correctly creates win-wins for all. We believe there are five reasons why OBC needs to be a strategic imperative for life sciences companies and why they need to start moving to this model now.

- 1. OBC fundamentally changes the relationship companies have with their customers:** better alignment of incentives and taking greater ownership of outcomes can help companies become true partners of the health care ecosystem. Selling a product without being involved in its use in real life, and its impact, is increasingly no longer sufficient.
- 2. OBC helps shift the conversation from price to value:** pricing by products and "inputs" will always create ongoing downward price pressure. Focusing on value can help differentiate and shift the focus away from the price of a product to the impact it is having for different stakeholders.
- 3. There are first-mover advantages:** those that take the lead can help establish and set the agenda for how value will be measured for different therapy areas. It is better to be part of the conversations from the start and to have more of an influence rather than be forced to react to an agenda that has been set by others.
- 4. OBC will help future-proof businesses:** whether life sciences companies like it or not, the direction of travel is clear. It won't be long before certain outcomes are the standard way of assessing value and contracting in the industry and manufacturers need to be ready to respond accordingly. To do this effectively requires new skills and capabilities that can't easily be switched on overnight and take time to develop, perfect and embed.
- 5. OBC creates opportunities for new revenue streams:** by offering solutions and effective treatments that lower the cost of care that payers are prepared to pay for, or are contract based on "gain share" agreements.

Overall, OBC has the potential to be game changing for all involved by creating a greater focus on the interventions that matter to drive efficiency, innovation and a better patient experience. However, doing this has to start with stakeholders working together to agree on the outcomes that are right for all.

## The current state of outcomes-based contracts

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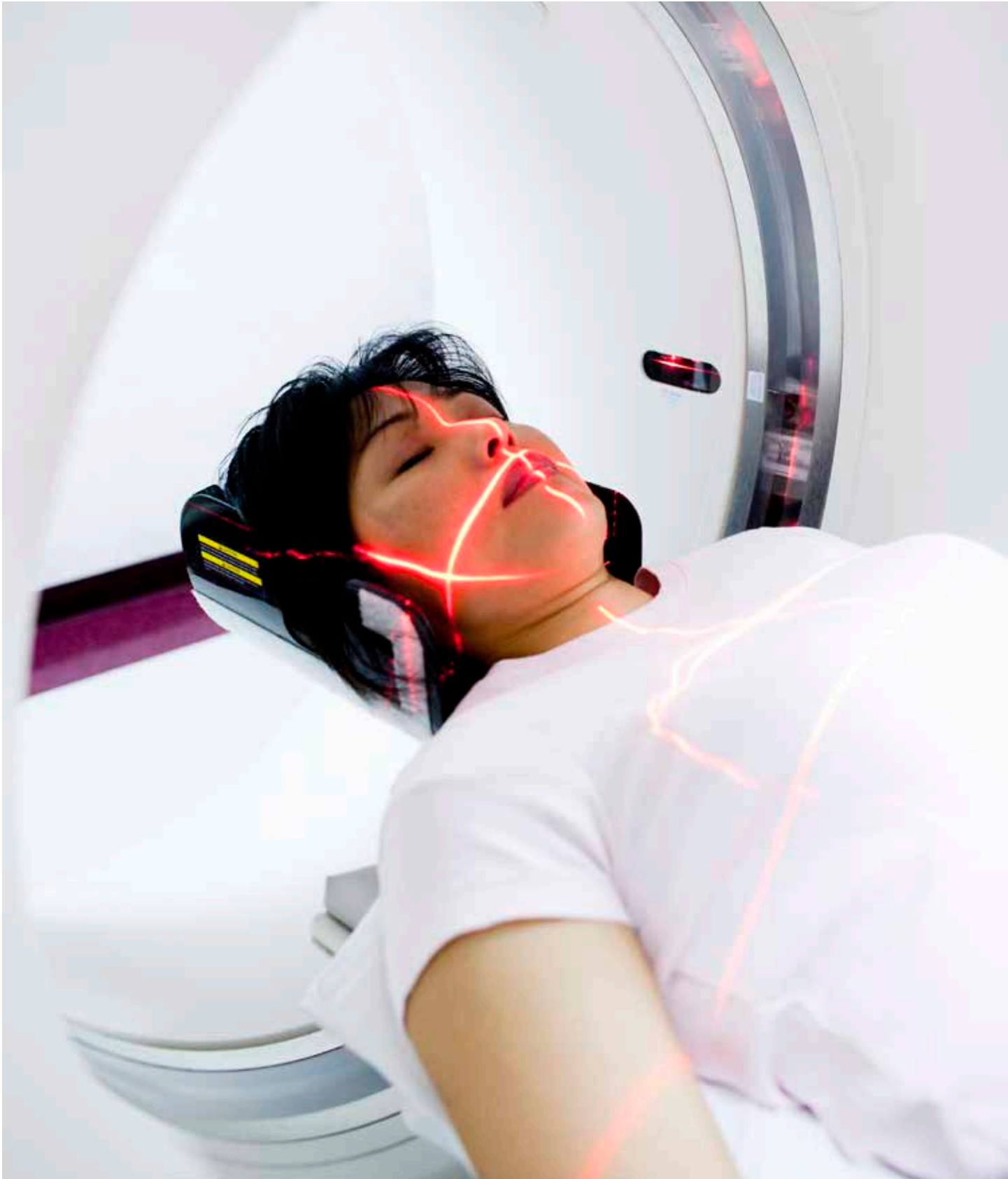
At present, the vast majority of outcomes-based contracts focus on using clinical measures (for example, response to treatment), with these being increasingly common in Italy and the US. Currently, only a few contracts are based on other types of outcomes such as performance or cost savings. However, therein lies the opportunity as these and other types of outcomes often align better to your customers' agendas and can help differentiate.

**Figure 4: Examples of Outcomes-based contracts**

Year	Company	Payer (country)	Product (therapeutic area)	Summary	Type of outcome
2011	AstraZeneca	AMNOG (Germany)	Brilique (acute coronary syndrome)	In one of the first early-benefit assessments now conducted as standard in Germany, Brilique was shown to have considerable benefit vs. alternatives in non-ST-elevation myocardial infarction or unstable angina patients.	Clinical
2014	Gilead	TLV (Sweden)	Sovaldi (hepatitis C)	Sweden's TLV, which has overseen pricing and reimbursement since 2002, established a risk-sharing agreement for Sovaldi, with refunds paid to local councils.	Health effect
2015	Celgene	CEPS (France)	Imnovid (oncology)	Celgene agreed one of the first outcomes-based pricing agreements in France, undertaking to repay the cost of the initial 21-day treatment period if ineffective.	Clinical
2016	GSK	AIFA (Italy)	Strimvelis (ADA-SCID)	AIFA pay for the Strimvelis gene therapy, indicated for pediatric ADA-SCID only if it successfully demonstrates cure.	Health effect
2016	Eli Lilly & Co.	Harvard Pilgrim (US)	Trulicity (diabetes)	Deal mandates enlarged rebate to payer if fewer Trulicity patients reach A1C target compared with other GLP-1 drugs.	Clinical
2016	Novartis	Aetna (US)	Entresto (heart failure)	Payment for Entresto is linked to the number of hospitalizations due to heart failure occurring in the treated population.	Performance and efficiency
2017	Merck KGaA	NHS England (UK)	Mavenclad (multiple sclerosis)	A first-of-its-kind outcomes-based deal for the NHS allowed patients early access to the drug, with a NICE appraisal to be conducted concurrently.	Clinical
2017	Medtronic	Aetna (US)	Insulin pumps, including MiniMed 670G system (diabetes)	Value-based agreement partially ties Medtronic's reimbursement to successfully meeting clinical improvement thresholds.	Clinical
2017	Myriad Genetics	Large US Health Insurer	Various	Collaboration establishes pricing for diagnostic tests in multiple therapeutic areas including breast cancer, prostate cancer, rheumatoid arthritis and neuropsychiatry.	Performance and efficiency
2017	Novartis	Centers for Medicare and Medicaid Services (US)	Kymriah (oncology)	CMS will only pay for Kymriah if patients respond within one month of initiating treatment.	Clinical

Source: EY and company reports.





## Section 2: Overcoming historic barriers

Historically, efforts to implement outcomes-based contracts have been fraught with valid difficulties but we are fast reaching the tipping point and seeing signs that it could be different now.

Below are the top three “historic barriers” to OBC and why we believe these challenges can now be overcome. As Vasant Narasimhan, CEO of Novartis, recently quoted at the 2018 World Economic Forum when commenting on digital disruption and three things that will change in medicine in 2018, “the companies that will prove most successful in the future are those that see this transformation as an opportunity, rather than as an insurmountable challenge.” We believe the same applies for OBC, which is greatly enabled by the three digital disrupters Narasimhan calls out: the Internet of Things (IoT), artificial intelligence (AI) and machine learning and emerging data platforms.

### **Barrier #1: “We can’t agree on the right outcomes, let alone influence them.”**

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- ▶ We can’t agree on the right set of outcomes that are appropriate for all stakeholders.
- ▶ We can’t agree on the contractual mechanism in terms of time period and level of measurement and the contractual conditions for the different parties.
- ▶ We do not have a relationship with the patient or control over the patient pathway so we cannot influence outcomes in the real world.
- ▶ We are not (and do not want to be) a service provider.

### What's different this time?

Three things will help overcome these challenges:

- ▶ **Target the more innovative, forward-thinking customers:** willingness to engage is a key factor. Not all customers will be interested so it is important to seek out and work with those who are more progressive. Looking at where health care systems are consolidating or devolving budgets and creating more accountable care organizations (a growing trend), or where there is a significant private insurance market, are good places to start. A “bottom up” approach, starting with an individual hospital, group of hospitals or area can also help to prove the case with a willing customer, and this can be used as a template and a basis for scaling up.
- ▶ **Build trusted relationships based on a shared vision, openness and collaboration:** agreeing on the right outcomes, ways of contracting and the part each participant has to play in delivering the agreed outcomes is not easy but certainly isn't rocket science. It requires strong and early collaboration between stakeholders with the right intent. Most health care providers are now far more open to such arrangements and actively encourage them.
- ▶ **Have a clear service strategy and adopt a “not built here” mentality:** developing services that influence outcomes does not always have to involve companies making huge investments in building and delivering the services themselves. Life sciences companies need to identify and work with digital start-ups and leverage solutions that are emerging or already exist (and are often far more advanced). Making a conscious decision about where to play in the health care value chain and how far the company is prepared to go into care delivery is a key decision. Does the company just stick to today's model of focusing on empowering stakeholders through awareness and education, or take a more active role in enhancing care pathways and supporting patients throughout their care journeys, or is it worth moving into full delivery of care? What is certain is that in a world where better outcomes are being demanded, it is in companies' best interests to try to influence these as best they can.



## Barrier #2: “We can’t capture the data to measure outcomes robustly.”

- ▶ Providers are unable or reluctant to give us access to the necessary data due to data privacy and security issues.
- ▶ It is too complicated to collect and measure the right data and creates a large administrative burden for providers.
- ▶ We don’t have the ability to capture good economic or humanistic data.
- ▶ Even if we can capture the data we don’t have the capability and capacity to analyze and model the data.

### What’s different this time?

With the increasing maturity of new technologies, it has never been easier to safely and securely connect, combine and share large amounts of data and automate the data collection process, overcoming many of the historic barriers (see Figure 5).

More specifically, a number of investments, technologies and changes in policies are helping to overcome these challenges:

- ▶ Many health care systems across the world are making big investments in digitizing and integrating data such as medical records.
- ▶ Technologies such as cloud computing, machine learning, artificial intelligence (AI), analytics, visualization and blockchain are making it easier to capture, safely store, share and analyze huge data sets.

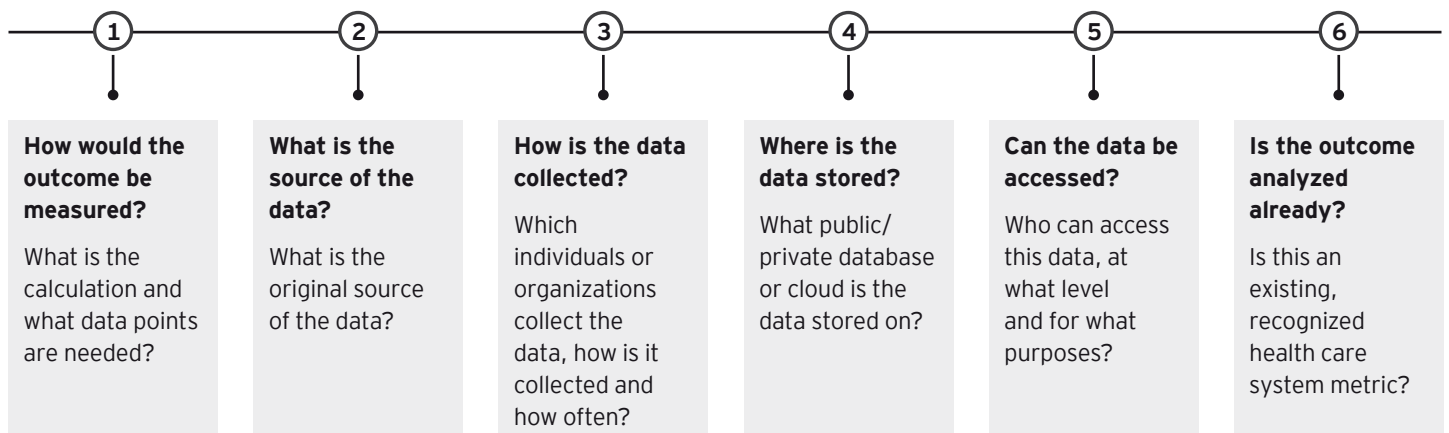
- ▶ Health care integrators: There are many companies that now specialize in health care data integration and platforms such as Orion Health and ConnectHealth.
- ▶ Tech start-ups are capturing new sources of data – for example patient reported outcome platforms such as uMotif can capture how a patient is feeling in real-time. Wearables and sensors are also generating new sources of data that can be extremely valuable, such as measuring mobility for MS patients using a smartphone’s GPS.
- ▶ Changes in policy at the global, national and local levels, such as the General Data Protection Regulation (GDPR) and open source – or data sharing agreements (for example the NHS DataWell project), are paving the way to allow key stakeholders to utilize data in ways that add value.

Platforms are beginning to transform health care as they have in other sectors. We define a platform as:

**A mechanism to connect different stakeholders in order to combine and share data easily and securely to deliver a shared goal: improved health outcomes.**

As platforms mature, these interfaces enable new business models built on the collaborative design and delivery of health solutions.

**Figure 5: The data collection process and challenges**





### Barrier #3: "It's just too risky for us."

- ▶ We don't know how we will perform in the real world and we prefer our existing, predictable revenue streams.
- ▶ Payers value budget certainty more and aren't willing to take the risk.
- ▶ Payers believe they won't get a good deal.
- ▶ We haven't got enough insight into how different patient populations respond to model our risk appropriately.
- ▶ Our competitors may benefit more than us.

### What's different this time?

All of these challenges will continue to remain valid but can be overcome by working in collaboration with customers and putting strong risk management in place for both sides. Budget certainty can be addressed in many ways, such as being completely transparent on expected budget impact and ongoing contract performance with certain safeguards (such as spending caps or rebates) in place to minimize the risk for payers. This will also help tackle the perception that the payers won't get a good deal.

It is always risky jumping into the unknown but risk can be managed once it is understood. Adopting a more gradual, pragmatic approach can help generate the necessary data for both sides to understand their risk exposure and get comfortable. This also gives life sciences companies time to develop services and interventions that work. In reality, the best way to overcome this challenge is to start experimenting and learning in a controlled way. Only then will all parties be able to move forward with confidence.



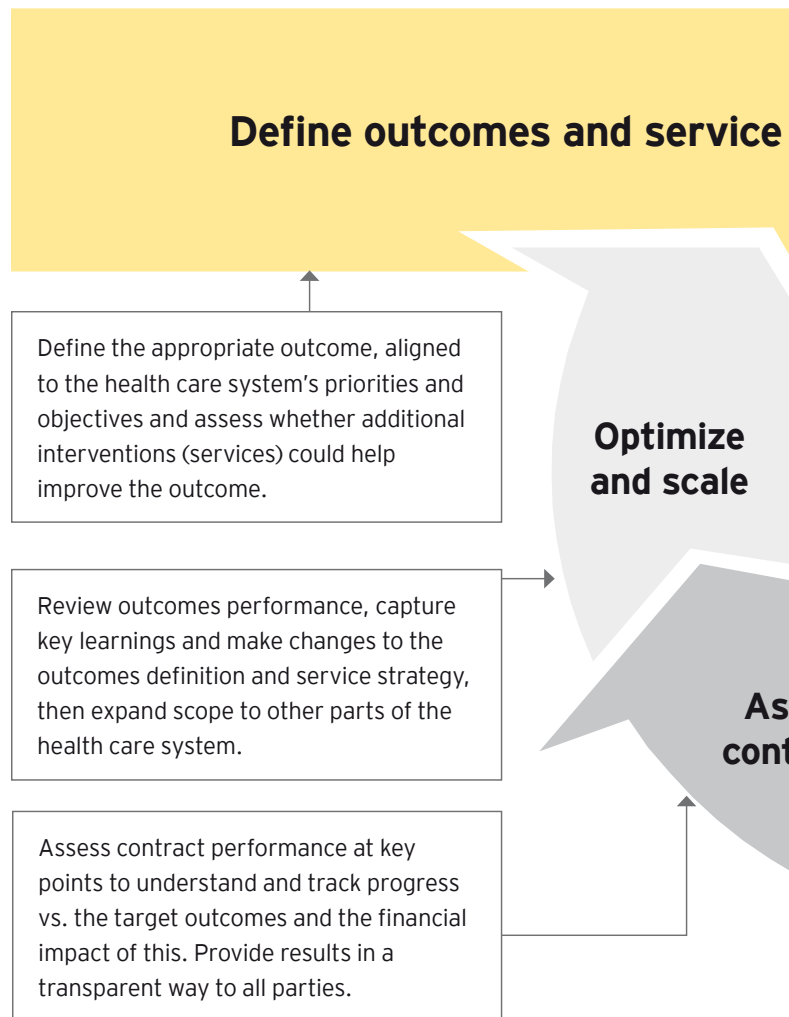
# Section 3: How to progress while managing risk

So, the question is where to start and how to progress in a way that doesn't require unacceptable levels of risk, huge investments and "big bets"? In this next section, we outline the framework required to set up and deliver outcomes-based contracts, the underlying capabilities that need to be built to enable this and some practical next steps to get moving.

## A framework for delivering outcomes-based contracts

To successfully deliver outcomes-based contracts requires a robust and agile methodology with six recommended steps.

Figure 6: EY's OBC methodology



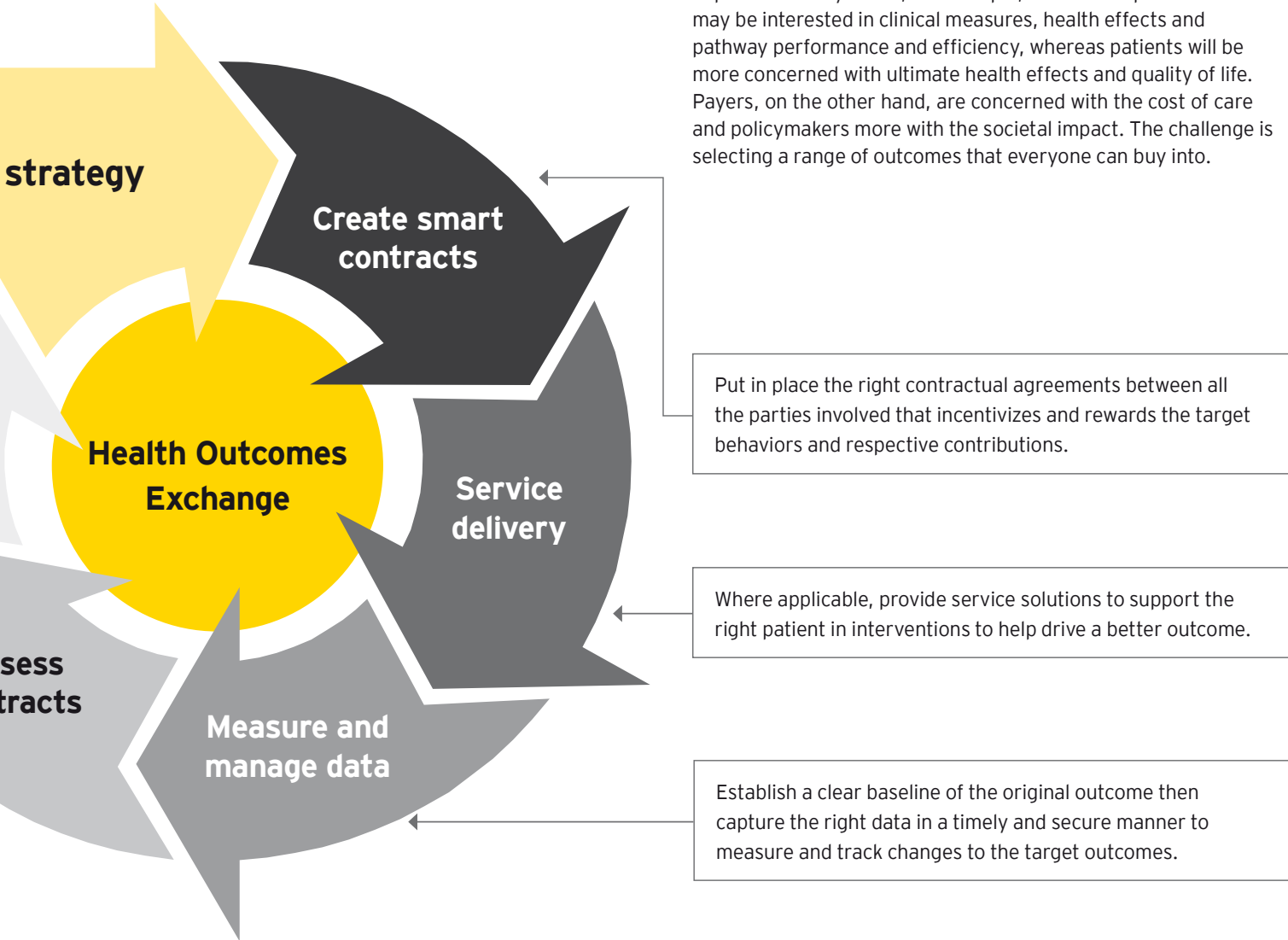
**Step 1: Define outcomes and service strategy**

The first step is to define the appropriate outcomes for both the manufacturer and the key health care stakeholders. Customers' priorities and objectives need to be assessed to select the right outcome that best aligns to all stakeholders' needs. From the manufacturer's perspective, the best outcome needs to be assessed in the context of a thorough understanding of product performance, Real World Evidence (RWE) and its' brand strategy. The challenge here is facilitating a process that helps different stakeholders agree on a common definition of value and deciding if certain customers deserve more priority than others, for example, if patients are focused on their overall experience, should quality of life be the primary measure? Often, a number of outcomes will need to be selected with different weightings to get a better balance.

**Time to think more broadly**

Outcomes come in many shapes and sizes and vary by their focus, time period in which they are measured and ease of measurement. To date, most outcomes have focused on shorter-term clinical results, but for manufacturers, this misses an opportunity to truly align to your customers' agendas and change the relationship companies have with them. It is important to select outcomes (or a range of outcomes) that customers are trying to achieve, in order to create long-term, win-win relationships. These could be broader than just clinical outcomes and include economic-based outcomes (for example, driving patient pathway performance or reducing the cost of care) or more humanistic ones (for example, delivering a great patient experience or driving societal benefits such as reduced incidence of disease) (see Figure 7 on outcomes measurement framework).

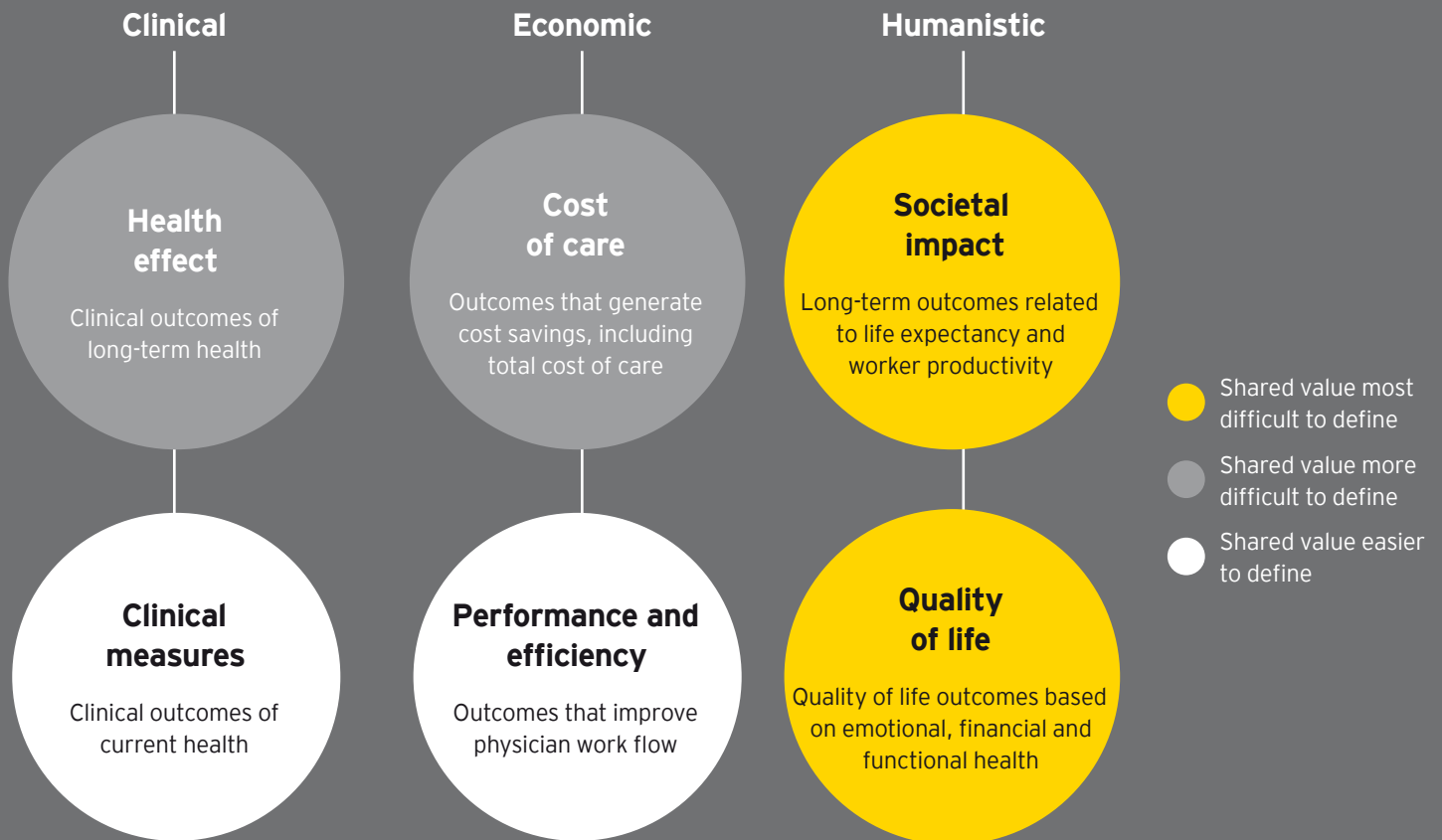
Naturally, the outcomes that are most important to you will depend on who you are, for example, health care providers may be interested in clinical measures, health effects and pathway performance and efficiency, whereas patients will be more concerned with ultimate health effects and quality of life. Payers, on the other hand, are concerned with the cost of care and policymakers more with the societal impact. The challenge is selecting a range of outcomes that everyone can buy into.



## Outcomes definition framework

Outcomes can vary by type and ease of measurement that create six types of outcomes (Figure 7)

Figure 7: Outcome measurement framework



- ▶ **Clinical measures:** shorter-term measures of health, for example, vital signs, whether a patient is within target International Normalized Ratio (INR) range for atrial fibrillation (AF), hemoglobin A1c for diabetics.
- ▶ **Health effects:** clinical measures typically measured over a longer-term, better for chronic conditions, for example, survival rates, stroke incidence, relapses, etc.
- ▶ **Performance and efficiency:** measures focused on driving process and patient pathway efficiency, for example, reduced hospital re-admissions, waiting times, referral to treatment (RTT) rate.

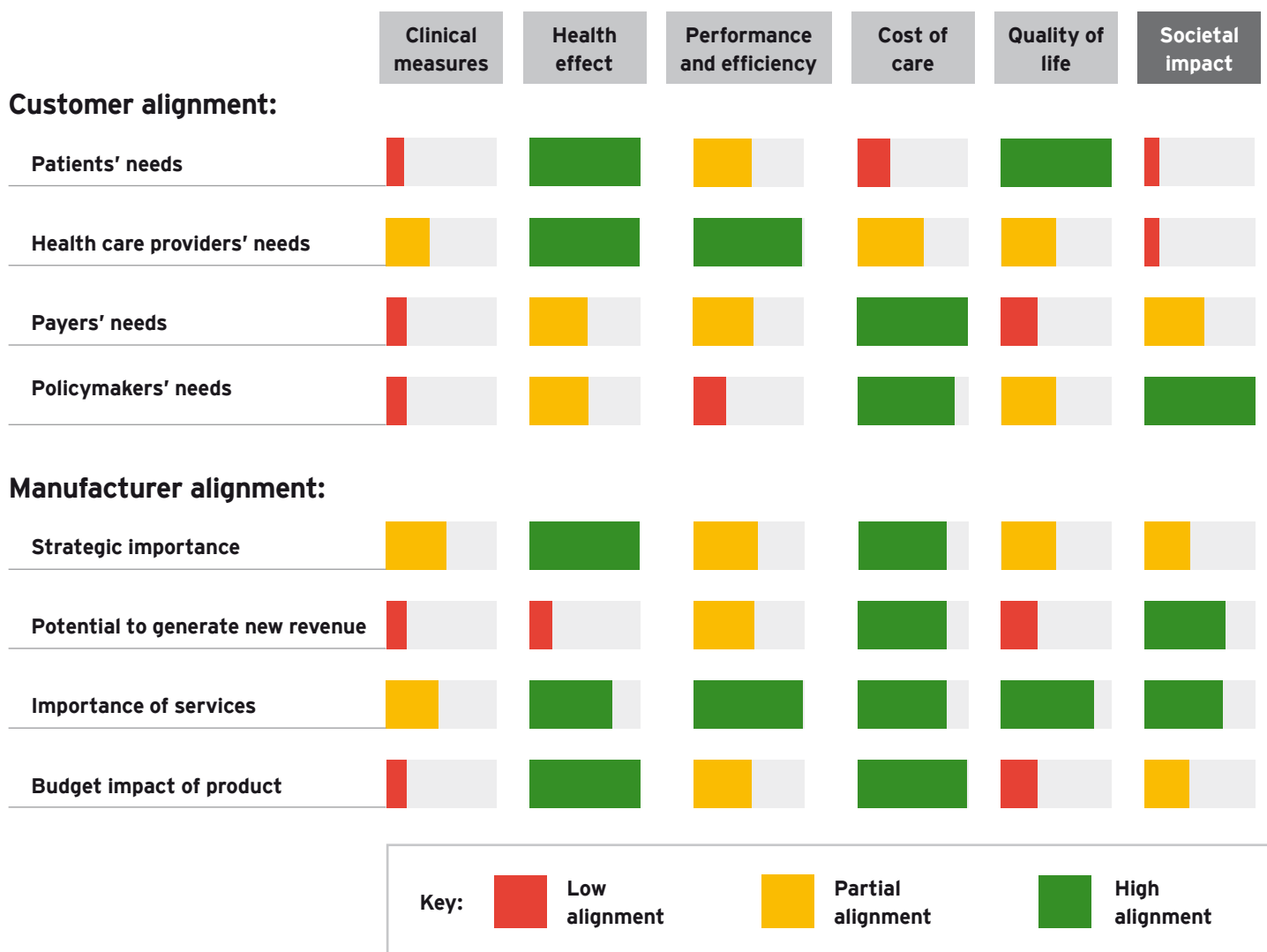
- ▶ **Cost of care:** focused on realizing longer-term cost savings across the health care system, e.g., freeing up hospital beds to ease capacity constraints, helping reduce overtime spend on nurses or expensive social care, or reducing out-of-pocket costs for patients or consumers.
- ▶ **Quality of life:** focused on measuring the quality of the patients life including emotional and functional wellbeing, for example, anxiety, ability to work, pain, nausea or mobility.
- ▶ **Societal impact:** focused on the broader population and societal impact, for example, disease incidence rates, lost days of work, life expectancy or reduced tax.



When evaluating and selecting outcomes there are some key things that need to be carefully considered:

- ▶ Which products or indications merit an OBC approach given the current market state (access challenges, competition, relative product performance in the real world, etc.) consideration also needs to be given to whether you believe certain outcomes may benefit your competitors and the impact this could have.
- ▶ The degree to which the outcome aligns to stakeholder needs and if there is an appetite from them (see Figure 8).
- ▶ Time horizon for measurement – longer-term measures are often more difficult to track over time and hence riskier for all.
- ▶ Whether you are measuring at a population or individual level (or somewhere in between, with a sensible sample size).
- ▶ The ease of capture based on current level of data availability and maturity.

**Figure 8: Customer and manufacturing alignment by type of outcome**



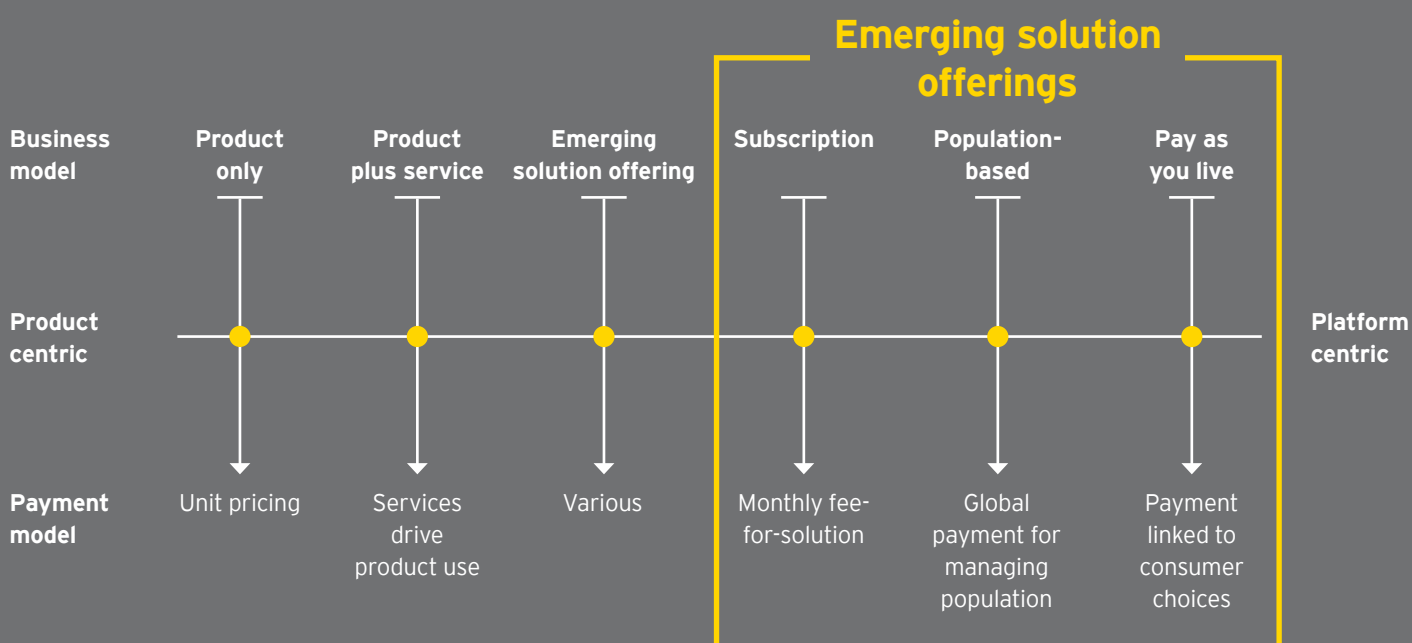
Once the target outcomes are defined, a detailed assessment of the patient pathway is required to identify all the points where potential “failures” could exist that need to be addressed. Failures are points in the pathway that could negatively impact the outcome if something doesn’t go as planned. They can include everything from the patient being unaware of their symptoms so not seeking advice, to not taking medicines as prescribed, missing hospital appointments or failing to adapt their life style accordingly. Based on this gap assessment, it will be possible to design services that focus on high impact points of “value leakage” to deliver the best outcome.

Finally, establishing and agreeing on a clear baseline is critical to any OBC. This will be the basis for which any change or improvement in outcomes IS measured and will need to be agreed upon by all parties.

## Step 2: Create smart contracts

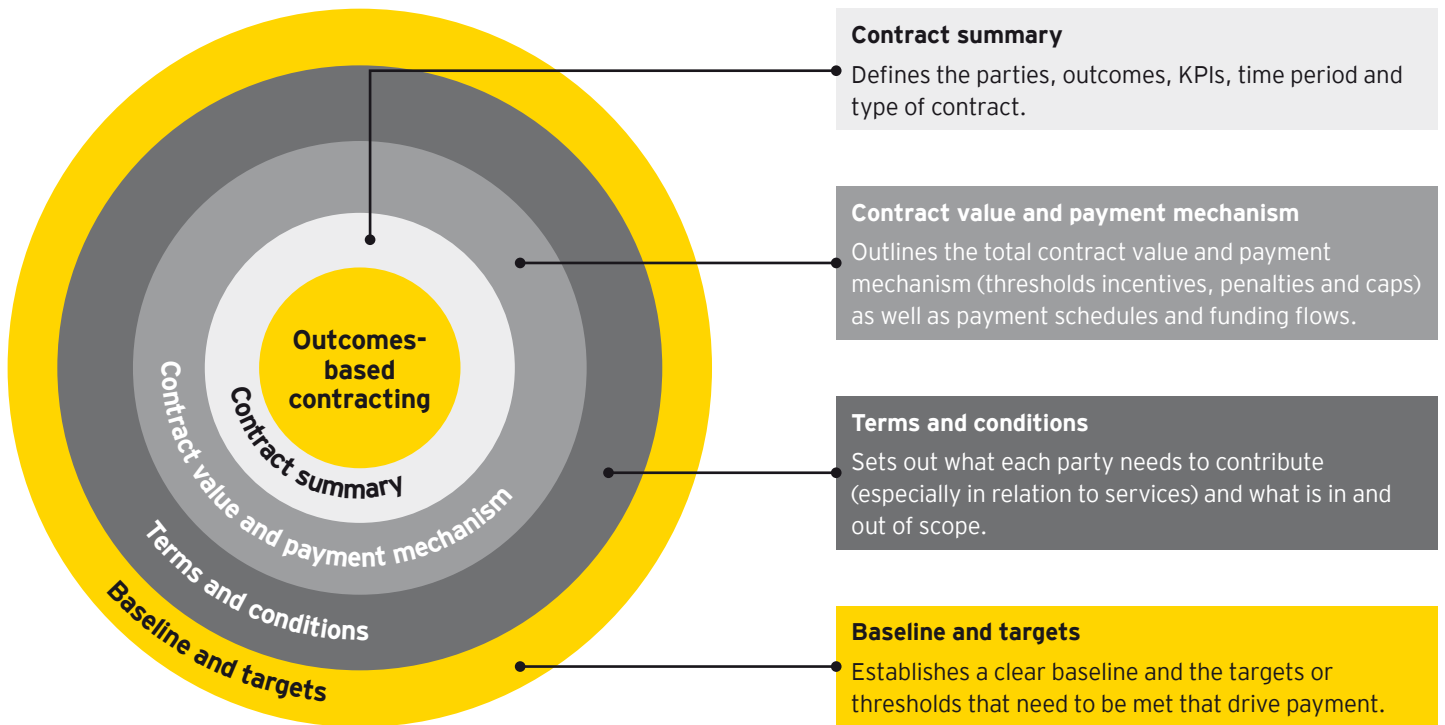
Step 2 involves taking the target outcome and service strategy and turning it into a contractual agreement. The beauty of outcomes-based contracts is that they open the door to new business models and ways of capturing value (see Figure 9), moving forward away from unit-based pricing toward more service-, performance- or even population-based models.

Figure 9: Health outcome commercial models



There are a number of elements to a fair and robust contract that need to be worked through (see Figure 10)

**Figure 10: The components of an outcomes-based contract**



A good outcomes-based contract is made up of four critical components:

- ▶ **The contract summary:** outlines the names of the parties to the contract, the duration of the contract (including start and end dates), what the target outcomes are that are being contracting on (and their weightings), the underlying KPIs that help monitor progress and data requirements and sources. It also includes the target patient population, what type of contract this is (i.e., pay for performance, share of cost saving, pay for service) as well as what triggers the payments.
- ▶ **Contract value and payment mechanism:** the next part is to work out the total contract value, which is typically a subset of a certain budget calculated by working out the cost of delivering health care for the area in scope. Once this is defined any incentives for over performance (including caps) and penalties for under performance (including floor prices) can be defined along with payment schedules and who pays.

- ▶ **Terms and conditions:** they must clearly state what is expected from each party and ensure each stakeholder plays their part. It is important here to ensure that the contracting parties have sufficient control and ability to influence the outcome. Where they do not, terms and conditions will be essential to manage the risk.
- ▶ **Baseline and targets:** the contract needs to be assessed within the context of today's performance (the baseline). Ultimately, the outcomes-based contract needs to include a measurement regarding the uplift in performance versus today and payment to this. Targets will need to be set that trigger payments once they have been reached.

## What is a smart contract?

A smart contract is an automated way of measuring, managing and executing contracts, and is most commonly described in relation to blockchain. The aim is to create a digital contract to help companies exchange money, property, shares, or anything of value, in a transparent and highly secure way, cutting out the need for third parties and middlemen. Ultimately, blockchain can be used to create outcomes-based contracts that become self-executing and self-enforcing, and that:

- ▶ Use pre-written logic or algorithm
- ▶ Use transaction data stored and replicated on a distributed storage platform (also known as a blockchain)
- ▶ Are executed/run by a network of computers (usually the same ones running the blockchain)
- ▶ Can result in ledger updates (for example payments)

Put simply, smart contracts are small computer programs that analyze transaction data against the predefined terms of a contract to check “if this happens then do that” and all of this is run and verified by many computers to ensure trustworthiness.

## Step 3: Service delivery

This is where the “rubber hits the road.” Once a contract is agreed to and signed, it goes “live” and patients start getting diagnosed, treated and managed. As they do there is a window of opportunity to make positive interventions to influence the outcome, which closes when the contract period expires and the contract is settled.

As discussed under Barrier #1, life sciences companies do not have to build and deliver every service themselves. The good

news is that those that don't can partner with start-ups to offer well-designed services without having to invest time and money in building them. However, from a value capture standpoint, if a company feels it can deliver the service itself, it is worth doing so since it can then capture 100% of the value delivered.

For those that choose to build and own their own services, a note of caution. To date, the industry has been notoriously unsuccessful at bringing services to market, and scaling and extracting value from them. Just look at the thousands of health care apps available that are rarely used by patients. Building an agile innovation and service design capability is critical. These capabilities will be explored further in the next section.

## Step 4: Measure and manage data

The challenges of data capture and management are well known. To address these, it is essential to make data capture as seamless, easy and secure as possible, particularly given the sensitivity of the data (patient records from health providers or insurers). To do this, a data platform, such as the **Health Outcomes Exchange** (see side box on EY's Health Outcomes Exchange), is recommended to allow the easy capture and/or input of data. To minimize complexity, a standard industry platform is the best approach. Without a standard solution, each manufacturer will have a different system and way of collecting, which makes it too complicated and difficult for health care systems to manage.

The data platform will not only access, and where permissible store, the data but also provide the analytics engine and necessary visualizations for all parties to the contract to understand contract performance, expected outlook and financial impact. As sophistication grows, patient populations (based on anonymized data) that are at risk or not responding in the right way can be identified to support further interventions to maximize the outcome.

### EY's Health Outcomes Exchange

Trillions of dollars are spent globally on health care, but few systems exist to ensure resources are spent on selecting the best health care interventions and optimizing patient access. In response to this, EY has developed the world's first Health Outcomes Exchange that will allow transparent, end-to-end, seamless contracting between life sciences companies, providers and payers, to deliver improved patient outcomes while reducing total health care costs. The exchange brings together one of the best of breed in assurance, legal, digital and infrastructure capabilities to solve the complex and fundamental challenge companies are facing today in delivering sustainable health outcomes.

The Health Outcomes Exchange is a global industry platform to facilitate a fundamental change in the way in which health care spending occurs. It brings stakeholders together to understand what health interventions work best in the real world and rewards those products or solutions with access and reimbursement for results. Payers will be able to safely, securely and confidently contract for health outcomes at a fair price, while biopharmaceutical and health care providers will be able to provide services and products to payers and gain transparency on health outcome performance – all working together to deliver better patient outcomes.

With our proven heritage of assurance to capital markets, EY brings a trusted third-party review of contract performance, and alongside our legal and financial capabilities, we will deliver an end-to-end service. The Health Outcomes Exchange, which is supported by Microsoft, is a transparent, scalable and secure cloud-based industry solution that will fundamentally change the way outcomes-based contracts are set-up, managed, monitored and optimized. This data platform leverages the EY Synapse platform – a highly secure and compliant public cloud platform, with open source data standards for both medical and non-medical events (e.g., Fast Healthcare Interoperability Resources (FHIR)), blockchain and data integration tools.

### Step 5: Assess contracts

The assessment of contract performance will happen throughout the life of the contract (in order to identify outcome optimization opportunities) and at the contract expiry date. To build trust in the system, an independent third party is best placed to provide contract assurance. If one party takes on the responsibility, there will always be a perceived bias to the analysis. Once the technology matures, blockchain is expected to play a critical role here – enabling smart contracts that are automatically verified and settled. For transparency purposes, both parties should have access to the same contract performance data and analysis in real-time. As soon as one party controls the data or has early access, this creates information asymmetry, which creates market friction and breeds mistrust.

This stage ends with contract adjudication and payment to the necessary parties according to the contract and their respective contributions.

### Step 6: Optimize and scale

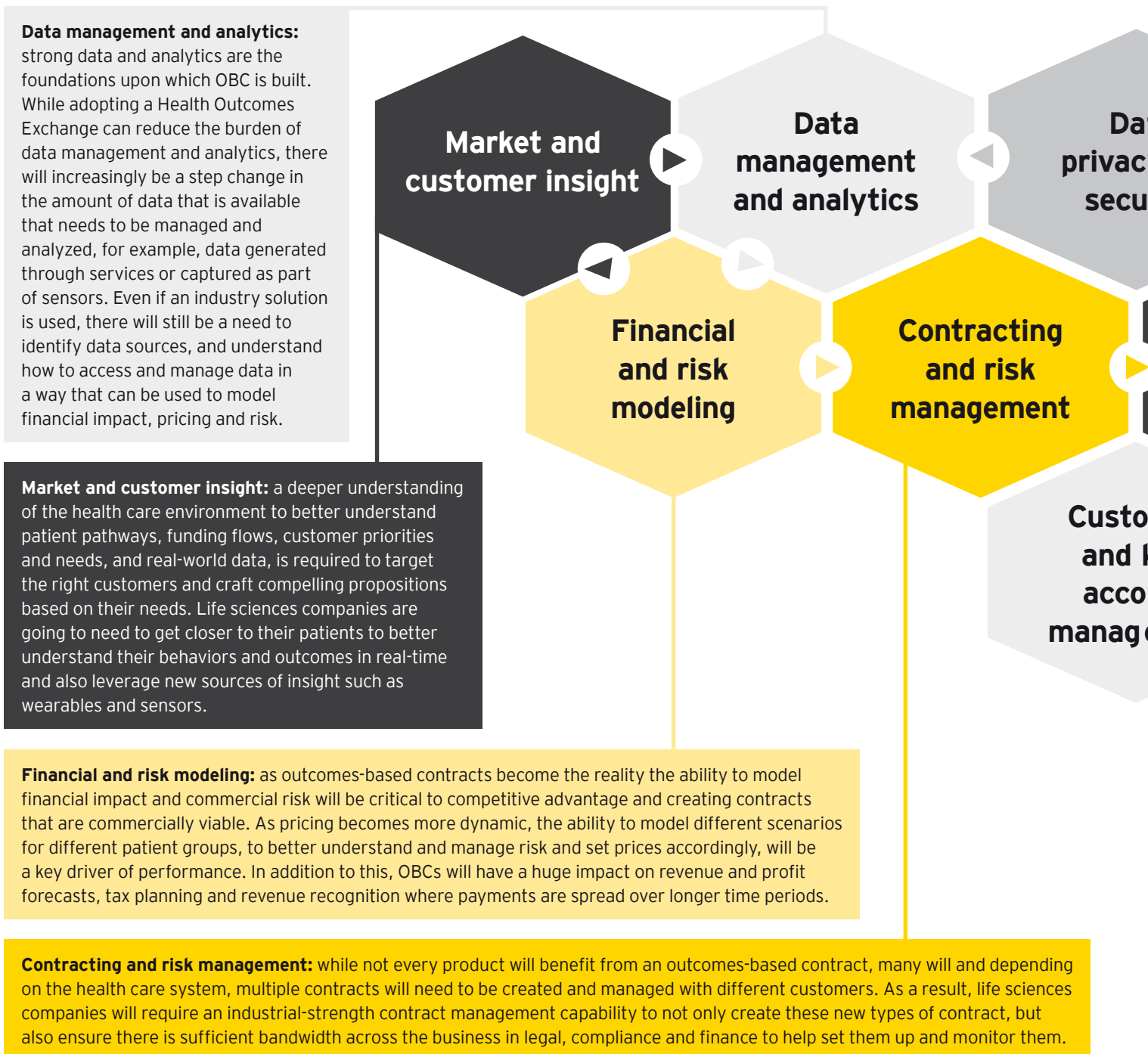
Once contracts have been settled, a robust feedback and review process is critical to optimizing future contracts. Manufacturers and their customers need to adopt a similar mentality to insurance companies in how they understand risk and price accordingly. Services should also be assessed on an ongoing basis to ensure they are having the desired effect and they are not being delivered at too high a cost for too little value.

Finally, the ability to quickly replicate and scale is essential. Successful contracts can quickly be replicated with other customers and markets. A robust methodology and platform in place can help accelerate this but also, we expect “standards” of care to form, where all products within a certain therapy area or for a certain condition are forced to adopt the dominant outcomes that emerge. This will also simplify things for customers and underlines the importance of engaging early to benefit from first-mover advantages.

## Building the critical capabilities

Having a clear methodology and process is important, but success will also require the development of some fundamental new capabilities. In this section, we outline the nine critical capabilities. All have an important role to play. Failing to invest in any one will have big implications on the ability to execute and the subsequent success of any OBC efforts.

**Figure 11: The nine critical capabilities for OBC**

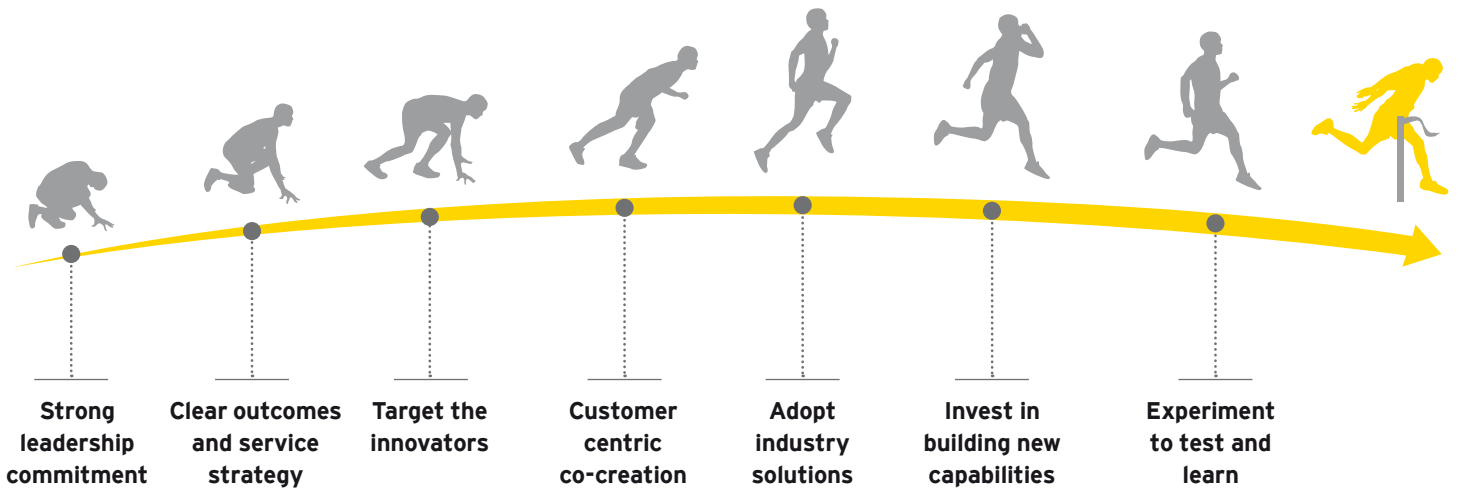




## Getting started

If this paper has convinced you of the need to get started or given you added impetus to push forward with current efforts, there are some critical things to keep in mind when moving forward (see Figure 12)

**Figure 12: Key steps to mobilize**



- ▶ As with any change that is bold, new and challenging, OBC will not happen without **strong leadership commitment**. Part of the challenge for leaders is understanding the rate of change and direction of travel and then having the conviction to invest time, effort and money to build and prepare for tomorrow while balancing a myriad of other shorter-term priorities.
- ▶ Defining a **clear outcomes and service strategy** by product, in line with your customers' needs and objectives, is a good place to start. Engaging customers and realizing there is appetite for OBC helps build the case for change and momentum, and setting a clear outcomes and service strategy will help convince the organization that this is a sensible and valuable strategy to adopt.
- ▶ For the best chance of success, you need to **target the innovators** and work with like-minded customers who are

equally committed to making this work. It will be important to have an understanding of your local health care system and which providers have a focus on outcomes, or are investing in key enablers such as consolidating and/or devolving health care budgets and creating accountable health care systems. Prioritize working with those who are most willing in order to prove the value. This doesn't have to be a top down "national" approach but could be with an individual provider. What is important in the early stages is to get some "runs on the board" and scale from successes.

- ▶ **Customer centric co-creation** is the only way to design a strategy and solution that aligns to all your customers' needs. Avoid the temptation of second guessing what your customers want and need and thinking too narrowly or in a product-focused way. The more you can align to your customers' needs, the higher the chance of success and, most likely, the only way



you can do that is to involve customers often and early. Walk in your customers' shoes and make sure any solution is easy for them to implement and operate. Complexity increases the probability of failure. Underpinning this are transparency and trust. Lack of trust creates market frictions that will in turn create blockers for any OBC scheme. Being customer-centric also means being open on both what it will take to deliver (not pretending it will be an easy ride), and on the contract performance. Information asymmetry destroys trust.

- ▶ **Adopting industry solutions** may initially feel counter intuitive. If you design a great strategy or solution, wouldn't you want to protect it and make it exclusive to your company? Historically, this would have been a sensible strategy but not in today's world. Ease of implementation for health care providers is a critical success factor. As such, trying to design and "own" a bespoke solution that only your company can use is doomed to failure. The aim of a health outcomes exchange is to simplify things for your customers, which can only be a good thing. Life sciences companies need to accept the fact that the success of platform-based business models depends on openness, collaboration and scale. An industry health outcomes exchange that all players can use to create, monitor and manage these contracts will ultimately emerge, which will expedite the removal of the biggest market frictions.
- ▶ As outlined in the last section, this new world and new ways of defining, measuring and capturing value require **investing in building new capabilities**. Given the challenges to implementation, the ability to execute will be a bigger driver and influencer of success than coming up with a fantastic strategy. Building capabilities takes time, so life sciences companies need to start now. As players in other sectors have experienced, new standards and ways of operating can emerge very quickly and not having the capability to respond could prove fatal for your organization.
- ▶ This leads to the final call to action of **experimenting to test and learn**. Moving to OBC is important, new and can be difficult and risky if not managed in the right way. Life sciences companies can't keep making excuses for not doing this but need to get some practice in this environment because it is coming, even if we don't know exactly when. Experimenting in a controlled way reduces risk. We believe it is best for both sides to test the water before jumping into a full-fledged

contractual agreement that both parties may perceive as risky. Creating a shadow contract will allow all stakeholders to not only test the process but also better understand the financial implications to give themselves more comfort. Unless it is win-win, OBC won't work.

## Time to change the game

In closing, this paper has outlined the case for OBC, presented why this time it is different and recommended a practical way forward for those who are convinced that OBC will play a significant role in how life sciences companies are reimbursed in the future. There has never been a better time to pursue OBC. Doing so will allow the health care system to work together for the greater good while helping to ensure all parties capture a fair share of the value they create. The time is now for life sciences companies to truly change the game for the industry and to prepare to be judged on the outcomes they deliver.

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As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of nearly 17,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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