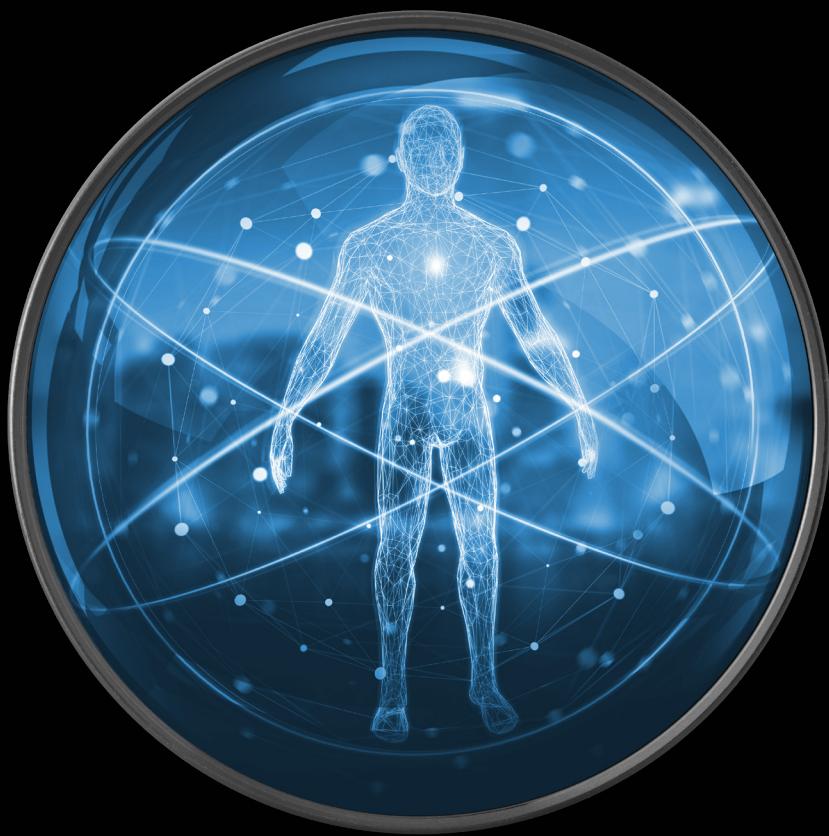


Deloitte.



Value-based contracts
Forging the way to impact patient outcomes



Propelling value-based contracts from experimentation to mainstream

Unsustainable health care costs and variable patient outcomes are accelerating the volume-to-value transformation of health care in the United States. Among pharmaceutical and medical device manufacturers, payers, and providers, interest in value-based contracts (VBCs) is increasing as a viable approach to assist in this transformation.¹

For the second time, Deloitte convened thought leaders from across the health care ecosystem to identify pathways to help overcome challenges in executing VBCs and drive meaningful change in US health care. Ideas from those who attended this Value Exchange Summit follow and ultimately address the core question: **How can organizations accelerate the future of value-based contracts to positively impact patient outcomes and help reduce the overall cost of health care?**

¹ Marylou Buyse, MD; Stephen Carter, BSc; Kyle Sarnataro, BSc. "Factors Influencing the Implementation of Value-Based Contracting Between Pharmaceutical Manufacturers and Payers." Journal of Clinical Pathways. May 2018. <https://www.journalofclinicalpathways.com/article/factors-influencing-implementation-value-based-contracting-between-pharmaceutical>



Why VBCs and why now?

As it exists currently, the US health care system tends to reward competition, not cooperation, and much of what's done today is motivated by what's profitable for the health care enterprise.² This legacy business model was built 60 to 80 years ago and it no longer works effectively—especially where high-dollar, life-changing, breakthrough innovations are concerned.

Many patients feel they are paying substantially more for prescriptions and treatments, and are demanding more transparency around costs and outcomes.

They also need access to the medicines that will make them well. As a result, the federal government is focusing on the issue of better patient outcomes and controlled costs. Many new health care industry business models are centering around value.

² Deloitte Analysis



Disrupting the system

The health care industry has awoken to the need to demonstrate value. Academia, special interest groups and technology heavyweights are all making moves to further not just short-term VBC implementation, but also widespread long-term initiatives. For example, not-for-profit Health Level Seven International (HL7) has developed FHIR, a proposed interoperability standard.³ The set standardization of electronic patient health care records is just one effort among many that are under development in an effort to better facilitate the flow of patient data.

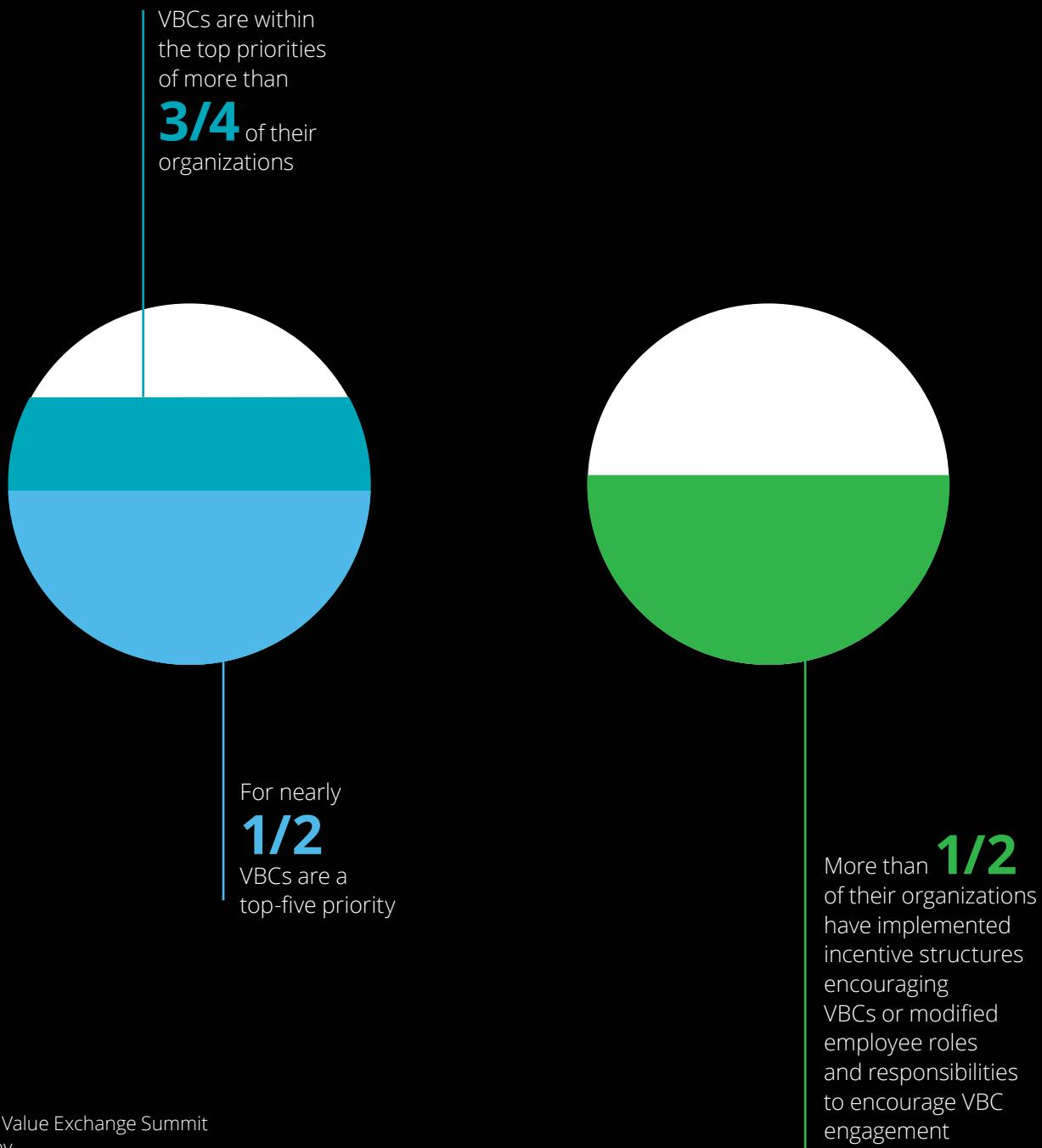
By putting data and patients at the center of the US health care transformation, VBCs can provide a foundation for the much-needed changes. All stakeholders—payers, including employers, providers, patients and life sciences companies—can work to disrupt the current system and find ways to collaborate without undermining competition.

The set standardization of electronic patient health care records enables better flow of patient data.

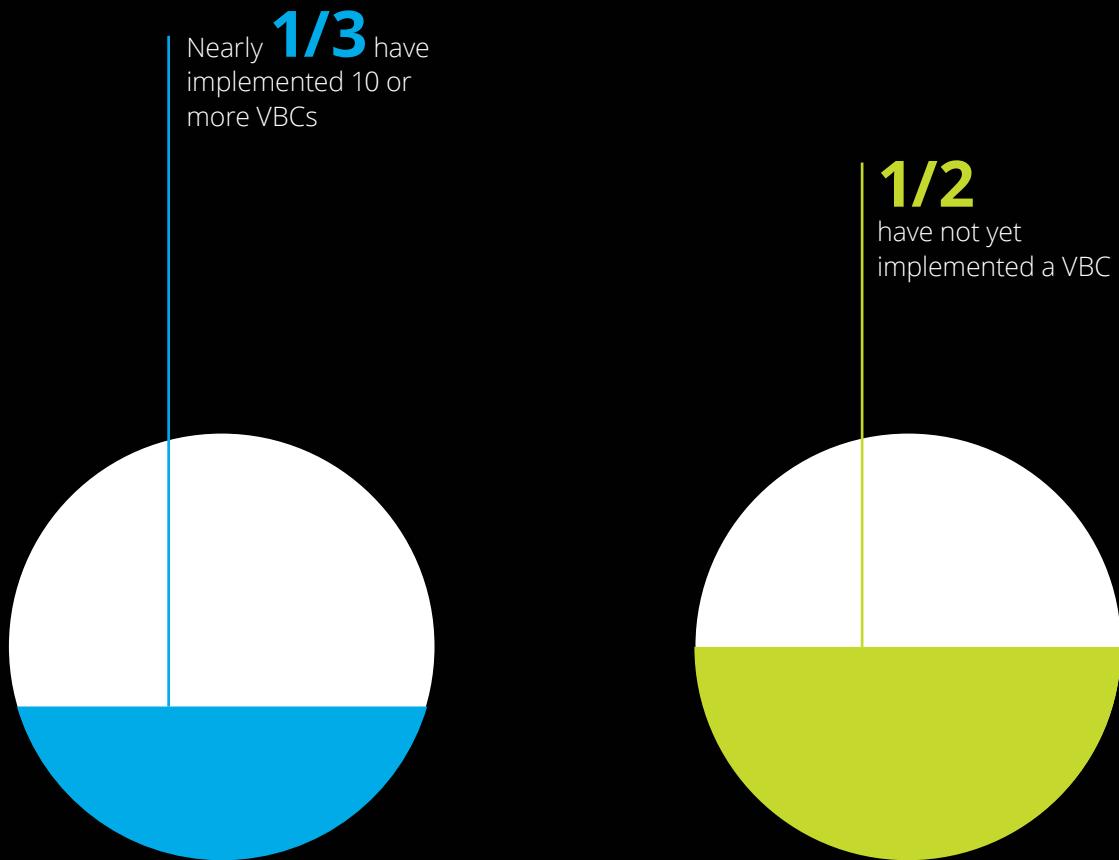
³ HealthIT.gov. "Health IT Standards." June 4, 2019. <https://www.healthit.gov/topic/standards-technology/health-it-standards>

Adoption of VBCs is gaining momentum

Participants at the second Value Exchange Summit indicated:



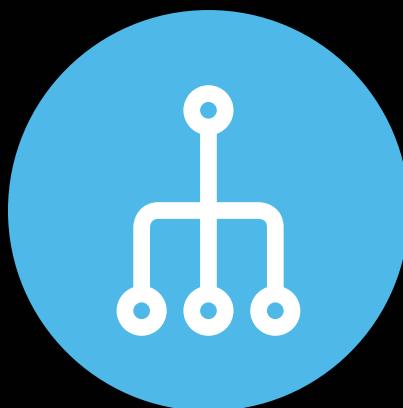
Source: Deloitte Value Exchange Summit Participant Survey.
n=14



Choosing the right treatments for VBCs is important to Summit participants. They listed chronic conditions such as diabetes and heart failure the most frequently referenced disease states that are well-positioned for VBCs. Inflammatory conditions are a close third. They felt gene therapies and immuno-oncology agents represented the classes of treatments likely to make the most meaningful impact on VBCs in the next one to three years.

Shared technology

Improved technology including a shared platform to collect and analyze patient data are needed.



Level of maturity

Organizational capabilities need to reach a level of maturity to support scaling VBCs in an efficient and sustainable manner.



Streamlined approach

Developing a streamlined approach to operational aspects of VBCs and sharing leading practices are needed.



Better collaboration

Better collaboration and communication are needed to promote more widespread adoption of VBCs.

Challenges to VBCs

There are a number of common challenges that are preventing widespread adoption of VBCs. These include lack of technology to efficiently administer and adjudicate agreements, which was listed by Summit participants as the No. 1 need. Part of this technology challenge is the necessity for a shared platform to effectively collect and analyze patient data.

To help promote more widespread adoption of VBCs, industry can work to improve collaboration and communication, specifically around defining value and understanding incentives. Furthermore, developing a streamlined approach to operational aspects of VBCs and sharing leading practices are crucial. At a majority of companies, organizational capabilities have not reached a level of maturity to support scaling VBCs in an efficient and sustainable manner.

Other major challenges to adoption of VBCs revolve around data needs. These often include data standardization, the availability of data to measure outcomes and identification of the appropriate metrics to measure. In addition, data ownership and privacy concerns around data are important considerations.



Trust, regulatory and risk issues

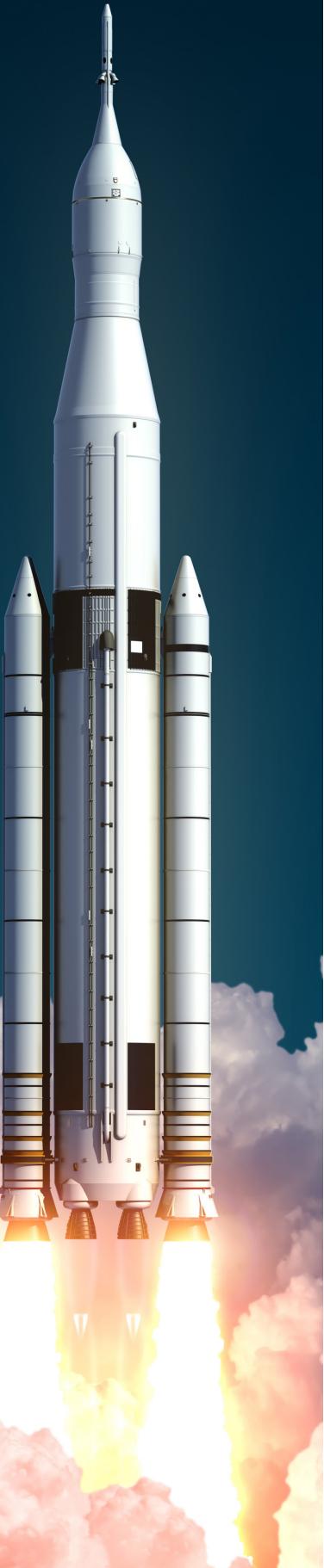
Trust among all parties and alignment of incentives is key to promoting increased adoption of VBCs, according to Summit participants, although they felt trust among organizations has improved recently. To address trust issues and streamline the VBC process, many indicated that the involvement of a neutral (3rd) party is becoming an increasingly attractive option. This neutral party can bring an objective and reasonable viewpoint to coordinating stakeholders.

Government and compliance or regulatory issues remain a concern, especially privacy regulations and those dealing with Safe Harbor, off-label drug use, anti-kickback legalities and government-instituted pricing.

Equally challenging are finding the right drug, product profile and population for effective VBCs, specifically in the case where outcomes differ, and a drug's effectiveness is unclear. The question is: Will different populations using the same medication require different metrics and contracts?

Finally, financial risk, inadequate resources devoted to exploring VBCs, organizational inertia and short-term thinking are additional barriers to address. One organization has been successful in their adoption of VBCs because articulating the value of early contracts did not include financial return. The value of real-world effectiveness is what resonated most with the company's executives.

To address trust issues and streamline the VBC process, involvement of a neutral (3rd) party is becoming an increasingly attractive option.



Overcoming barriers

The initial step in addressing challenges to VBC adoption is defining value—which differs across stakeholders—and aligning the value definition among stakeholders who care, such as employers, patient advocacy groups and HR benefits managers.

Bold leadership and buy-in all the way to the top are needed to build relationships and trust over the cycle of the contract and encourage collaboration and transparency among all parties. But the collaboration must be nimble and agile, not fettered by time-consuming consensus building. Solutions can be co-developed with a neutral outside party to confirm effectiveness before industry adopts them. A regulatory push may be necessary to accomplish this.

The development of technology-enabled data collection can not only support a product's cost effectiveness, but can lead to a better understanding of patients' health. However, currently each stakeholder has one piece of the data puzzle. Having complete data sets for patient populations will require investment. Building a data platform utility, that could be shared by multiple stakeholders, would alleviate the financial burden of development on any one stakeholder group or company. Initially the data could be used just for the sake of learning—opening up the possibilities of VBC design scenarios with real-world evidence.

Initiating VBC demonstration projects with government agencies, such as the CMS and the Centers for Medicare and Medicaid Innovation, could yield promising results. With government involved, regulatory and legal concerns could be addressed both in the short and long term.

Three key solutions

**Industry alignment
on value definitions**
and the metrics that
would support them



**Data and analytics
technology platform**
that would be "utility-
like" by nature



Scenarios and pilots
that use real-world
data in support of
proving the value that
VBCs can afford to all
stakeholders, most
importantly, the patient

Solutions

Three key solutions that can help the industry push VBCs forward and into widespread use are: 1) industry alignment on value definitions and the metrics that would support them 2) a “utility-like” data and analytics technology platform 3) scenarios and pilots that use real-world data in support of proving the value that VBCs can afford to all stakeholders, most importantly, the patient.

1) Aligning on value definitions

Value and standards should be defined initially in order for a VBC to become a viable solution able to improve outcomes at reduced costs. When the definition of value that supports the interest of all stakeholders is agreed upon, arriving at consensus around measurement is easier.

One suggestion of a value equation is quality outcomes divided by cost. If the ultimate goal of VBCs is patient well-being, the price put upon value is dependent on the system implemented around that value. VBC stakeholders must agree on clinical improvements and the measures that demonstrate these improvements when a drug or therapy is utilized.

Value can mean different things to each organization, from cost to quality, to affordability, to performance. At the end of the day, value is determined by the combination of patient well-being, patient access, and patient choice—with transparency on the implications of that choice. Stakeholders should agree on strategies to fully engage providers and patients. In order to develop strategies, those involved must arrive at consensus on therapeutic areas where value metrics can be standardized.

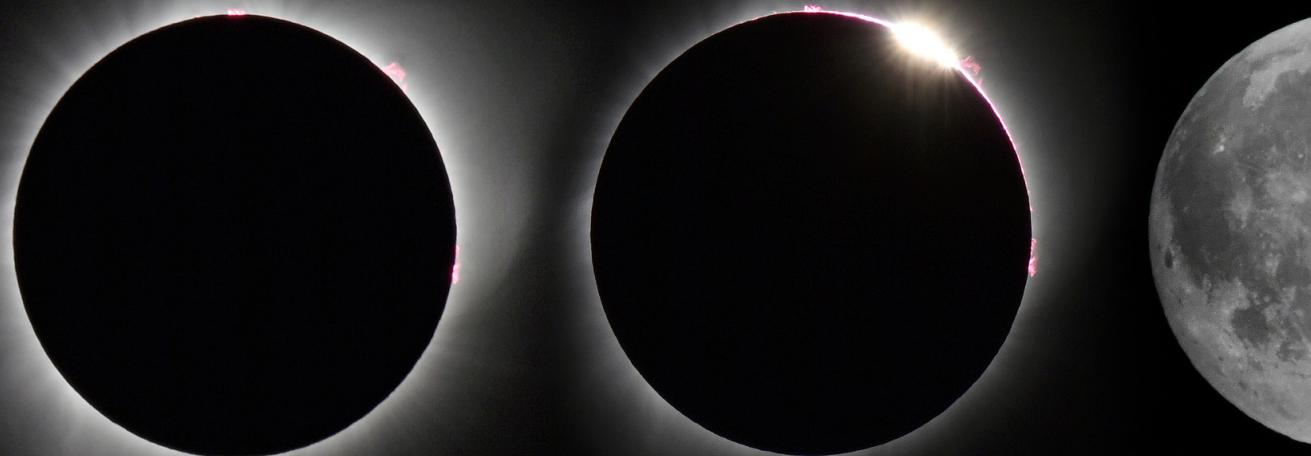
At the end of the day, value is determined by the combination of patient well-being, patient access, and patient choice.



2) Building data collection and analytics technology

VBC solutions are driven by data, and the amount of data that must be collected and analyzed is enormous. It must be able to show which patient benefits from which treatment and which patient is not positively affected by the same treatment. Data should demonstrate what medication is best for a certain sub-population and help explain variability. Insights from analytics of this data help stakeholders understand the real-world experiences of treatment approaches, costs and outcomes with the goal of refining evidence-based protocols. These insights will only be available through deployment of appropriate technology, such as a utility platform to ingest and analyze data, which can be used to design, pilot and operationalize VBCs.

If VBCs are adopted efficiently and become mainstream, there may not be a need for them in the future. It will become clearer as to what therapies and medicines work for what sub-populations with broadly shared information. In the meantime, data could benefit all stakeholders in a VBC arrangement, so some form of universal data set or exchange available for industry use that did not have to be reinvented every time would be useful and aid in transparency and collaboration.



3) Operationalizing pilots

Pilot projects that address value definitions for appropriate drugs or therapies and third-party adjudication of the VBC are the generally accepted approach. Such studies should be conducted in the environment of reduced or no regulations to see what's most effective and how current regulation might need to evolve to help make VBCs mainstream. The pilots should also ensure patient access is supported versus hindered and that positive patient outcomes result. This type of successful demonstration project will enable stakeholders to learn about the solution so it can be applied across the industry in widespread fashion.

Furthermore, pilots implemented without risk or financial reward offer a high-level roadmap that can later be refined to address payment models and financial benefit. A focus on quality first can lead to a path of shared savings and eventually a move toward risk-sharing among stakeholders.



Success factors

In order for VBC solutions to be able to succeed, they should be:

- Frictionless
- Flexible
- Transparent and trackable across stakeholder organizations
- Able to quantify benefits
- Scalable and repeatable
- Trusted by stakeholders
- Engaging for patients and providers
- Developed with a neutral third party

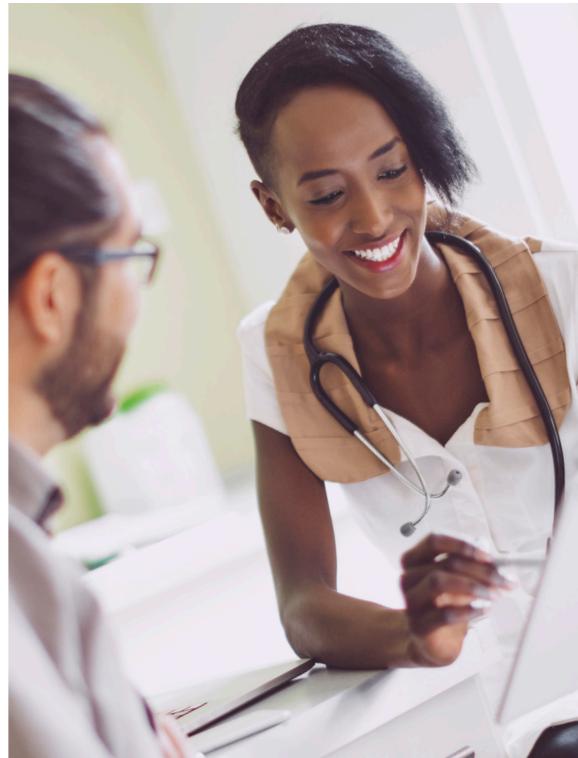
A focus on quality first can lead to a path of shared savings and eventually a move toward risk-sharing among stakeholders.

Moving forward

At the end of this Value Exchange Summit, participants were asked how their organizations may further the development of VBCs as viable solutions to escalating health care costs and variable patient outcomes. Among the actions expressed were to:

- Work collaboratively to share data
- Continue to work to develop ideas and to operationalize VBCs
- Partner on innovative VBCs and share findings and lessons learned
- Support the data analytics and technology required for VBCs, patient centricity and precision medicine
- Help to shape a multi-stakeholder solution that will drive positive outcomes

Linking value to life sciences treatments via patient outcomes is on the horizon. However, drug pricing continues to be a top priority for the US and regulation that imposes requirements for VBCs is a very real possibility. Companies that pre-empt these mandates and begin the transition now can be a competitive step ahead of those that lag.



Authors

To learn more, visit www.deloitte.com/us/vbc-solutions

Joseph M. Coppola

Managing Director
Deloitte Consulting LLP
jcoppola@deloitte.com

Andy Davis

Principal
Deloitte Consulting LLP
andavis@deloitte.com

Jeff Morgan

Managing Director
Deloitte Consulting LLP
jefmorgan@deloitte.com

Marcy Imada

Principal
Deloitte and Touche LLP
mimada@deloitte.com

Deloitte.

As used in this document, "Deloitte" means Deloitte Consulting LLP, a subsidiary of Deloitte LLP. Please see www.deloitte.com/us/about for a detailed description of our legal structure. Certain services may not be available to attest clients under the rules and regulations of public accounting.

This publication contains general information only and Deloitte is not, by means of this publication, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services. This publication is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor. Deloitte shall not be responsible for any loss sustained by any person who relies on this publication.

Copyright © 2019 Deloitte Development LLC. All rights reserved.