With risk-sharing contracts already in place with payers, biopharmaceuticals companies must act quickly to digitize new collaborative frameworks that measure and influence patient outcomes.

Value-Based Care in Life Sciences: The Role of Digital Platforms
Executive Summary

Value-based care is the predominant model for enabling the healthcare industry to control spiralling costs and deliver better information to consumers. The basic idea is that reimbursements are based on the quality of the outcome of a procedure, episode of care, use of a device or therapy. Under this model, life sciences companies, from biopharma to medical device manufacturers, are rewarded for improving health outcomes and/or reducing the costs to achieve those outcomes - but they will also be paid less when their therapies are less efficacious than expected.

This model requires life sciences companies to rethink many of their processes, from R&D through the commercial phase. “Go/no-go” decisions must be made earlier in the development cycle, while evidence must be gathered for mature therapies to prove their value. New business development and contracting skills are required. Deeper engagement with patients is necessary to ensure medical adherence so therapies produce anticipated benefits.

Navigating these momentous shifts requires that life sciences companies embrace a range of digital technologies which will enable a holistic approach to value-based care. In particular, they will need powerful new systems of intelligence to gather data and distill meaning. These platforms will help companies collaborate effectively, anticipate outcomes of clinical trials and create better experiences by fully revealing the patient journey. The transformation enabled by these systems must begin quickly, as value-based care has already arrived.

This white paper will examine the drive for value-based care, its impact on life sciences companies and how technology platforms can address the challenges the industry is facing.

THE DRIVE FOR VALUE-BASED CARE

It’s no secret that market forces and government policy are driving a new era of value-based healthcare. This new standard of care is reshaping the entire delivery chain, as payers, providers, patients and life sciences companies adapt to a transformed environment in which shared financial accountability, shared risk, clinical value and patient outcomes are the primary pricing negotiation points. This new paradigm holds tremendous promise for ensuring patients receive appropriate treatment, driving overall adherence and optimizing clinical R&D investments. But it also presents many challenges.

The drive toward value-based care is not only happening in the U.S., but around the world. In fact, a recent study by The Economist noted that a key challenge across many healthcare systems internationally is finding information on the cost of care per patient and how that cost relates to health outcomes. Even in disease registries, “clinical care and outcomes of a particular patient population are often inaccessible, lack standardization and/or are not linked to each other, if they exist at all.”

The Rewards of Risk Sharing

According to research, the shift toward a value-based approach is being driven by pressure from commercial payers, varying by disease category. In a 2015 survey of 42 U.S. health plans representing 161 million covered lives, interest in outcomes-based contracts were especially strong
These risk-sharing arrangements can be a “win-win” for all stakeholders, providing patients with access to the most advanced new treatments, rewarding biopharmaceuticals companies for their R&D investments and yielding long-term savings to payers when new treatments provide the benefits documented in clinical trials.

Since then, multiple risk-sharing agreements have been signed and are making an impact on the commercial strategies of life sciences companies. Some of the more noteworthy deals of this type include Amgen and Harvard Pilgrim reaching an agreement for Repatha® (evolocumab) injections for lowering LDL cholesterol; Gilead and Cigna for Harvoni® (ledipasvir/sofosbuvir) tablets for hepatitis C; and Novartis and Aetna for Entresto® (sacubitril/valsartan) tablets for heart failure.

These risk-sharing arrangements can be a “win-win” for all stakeholders, providing patients with access to the most advanced new treatments, rewarding biopharmaceuticals companies for their R&D investments and yielding long-term savings to payers when new treatments provide the benefits documented in clinical trials. However, they require a dramatic change in business models, especially within life sciences companies. The data infrastructure and analytics must be in place to ensure that proposed deals are structured and negotiated profitably, to measure outcomes independently and to adjudicate payments fairly and transparently.

### U.S. Health Plan Interest in Entering Into Outcomes-Based Contracts with Manufacturers

<table>
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<th>Condition</th>
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</table>

Source: Avalere Health

Figure 1
Thus, these deals will require significant investments in digital platforms and new skill sets – i.e., the ability to combine and analyze data from multiple sources to create actionable insights. In our report, “The Work Ahead: How Data and Digital Mastery Will Usher in an Era of Innovation and Collaboration,” 84% of life sciences executives cited analytical skills as most relevant and essential for the future; 74% cited strategic thinking and 68% decision-making. These are the precise skills needed to research, create, propose, negotiate, close and monitor value-based care deals.

**IMPACT OF VALUE-BASED CARE ACROSS LIFE SCIENCES FUNCTIONS**

Now that value-based deals are actually being enacted, life sciences companies must consider how to rapidly adapt their business models to support value-based care requirements at scale. We recommend the following:

- **Design clinical trials to not only demonstrate safety and efficacy to regulatory agencies but also to quantify the value** to payers and health technology assessment (HTA) vendors, defined by a reduction in total healthcare costs and/or improvements in quality of life.

- **Design and negotiate outcomes-based pricing contracts with individual payers.**

- **Implement new pricing and contracting administration processes to capture and measure patient outcomes.**

- **Influence providers and patients to ensure optimal therapy outcomes through the entire patient care journey.**

- **Adapt to changes in revenue recognition timelines as patient outcomes determine the final payout.**

In turn, these wide-ranging pressures on the life sciences business model are necessitating significant restructuring within life sciences organizations, driving changes that reach across R&D, medical and regulatory affairs, and commercial.
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Impact on R&D
As the value-based mindset takes hold, R&D is more accountable to design trials that include measuring cost-effectiveness. This includes assessing the burden of illness during preliminary stages of drug development and developing objective value propositions based on real-world outcomes such as quality of life, productivity, absenteeism and frequency of clinical events.

Moving further into the trial phase, companies are looking at valid comparators beyond just standard of care. They are designing trials with companion diagnostics and biomarkers to identify the right target population for the new treatment.

Impact on Medical & Regulatory Affairs
Medical affairs departments need to establish new communication channels with providers and payers to inform and monitor the care process more closely. They will embed post-launch monitoring and outcome measurement plans as a normal course of business in order to identify value. Regulatory affairs must now stay well-informed of developments not only in global regulations, but also in approval and reimbursement decisions for rival products and changes to recommended clinical pathways that may affect product value.

Impact on Commercial
Commercial teams are on the front lines of the shift to value-based care and will continue to lead the rest of the organization. In addition to developing well-publicized deals on new branded therapies, commercial departments are identifying potential risk-sharing and outcomes-based contracts with payers for non-innovator drugs. They routinely use health economics and outcomes research (HEOR) to gather real-world evidence and identify opportunities to gain a spot on the formulary lists or renegotiate reimbursement rates with payers. Offering guaranteed outcomes – such as reduced hospital admissions or lengths of stay – is an enticing way to maximize value in the eyes of payers.

Technology Platforms and Value-Based Care
We define a technology platform as layers of software that gather and connect multiple data sources and synthesize them with meaning to improve outcomes. As such, we believe the platform is set to be the organizing principle for innovation within and between companies as cocreation increases.

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In life sciences, these software layers gather data from a specific pharmaceutical process, a clinician need or a patient requirement. The platform then becomes an open data exchange, where scientists, regulators, doctors, patients and other life sciences stakeholders can index, experiment and collaborate to improve drugs, treatments and outcomes.

One example from the life sciences industry is the Shared Investigator Platform (SIP), built for members of TransCelerate BioPharma, a nonprofit organization with a mission to collaborate across the R&D community to implement solutions that drive efficient, effective and high-quality delivery of new medicines. The SIP was designed as a cross-industry solution to reduce the administrative burden on investigator sites and ultimately enhance efficiency during clinical trial planning and execution. TransCelerate member companies that choose to adopt the SIP can focus on high-value activities with investigative sites and eliminate the need to develop and maintain company-specific portals. (For more insights, read our white paper “Making Life Easier for Investigators: A Shared Solution for Smarter, Faster Clinical Trials.”)

The growing need for technology platforms to deliver and measure value-based care at multiple touchpoints of the patient journey is a common denominator across R&D, regulatory and commercial functions. Data feeds from wearables, biosensors, ingestibles, pharmacovigilance and medical information systems, patient support programs (PSPs), digital health apps and a range of other data sources will supercharge the growth of platforms and provide a catalyst for collaboration and innovation inside and between companies.

Agile life sciences ventures will emerge, pivoting around data mastery, innovation and value. An example is the partnership between Verily, formerly known as Google Life Sciences, and Ethicon Endo-Surgery, Inc., part of the Johnson & Johnson Medical Devices Companies. Verb Surgical, Inc. was founded in 2015 to develop a digital surgery platform built with technology from Verily and Ethicon, its goal being to “democratize surgery” by making technology and information available to more patients globally, improving outcomes and reducing overall cost of care.

Verb’s platform will include robotics, visualization, advanced instrumentation, data analytics and connectivity; it is already demonstrating a digital surgery prototype.

Of course, there will be many challenges along the way, and some transformative partnerships will fail to achieve their goals in the timeframes desired, if at all. At the March 2017 annual meeting of shareholders, Novartis Chairman Joerg Reinhardt talked down the prospects of its smart contact lens project (which it began with Google in 2014) yielding anything incredible in the next four years. The collaboration was once seen yielding a commercial product in 2019, with the goal being to continuously monitor a wearer’s glucose levels and potentially provide a data feed for platforms that measure outcomes from diabetes treatments.

We have identified three areas where we believe technology platforms will drive success in value-based care for life science companies in the short term:

- **Incorporating real-world evidence into R&D investment decisions and studies:**
  As profit margins are squeezed across the life sciences industry, R&D investments and clinical study designs must take into consideration economic and competitive factors affecting therapeutic areas and the cost of care. Real-world evidence (RWE) must become part of the equation in go/no-go decisions as well as in developing study protocols that measure outcomes and value.
The three-year GetReal project, part of the European Union’s public-private collaboration known as the Innovative Medicines Initiative (IMI), is an example of where a future platform could aid collaboration. GetReal brings together large pharmaceutical companies, SMEs, academics, HTA agencies, regulators and patient organizations to assess existing RWE methodologies and explore new ones. Chris Chinn, head of Real World Investigations for Sanofi, a member of GetReal, told the publication Eye For Pharma that the ultimate goal is to produce better-quality evidence for HTAs. He advises RWE, R&D, HEOR and market access colleagues to discuss strategies before starting a development process in a new disease area. GetReal is providing a framework to guide key conversations between different teams within pharmaceutical companies.

Frameworks such as those being developed by GetReal and other collaborations can be transformed into systems of learning and collaboration when they are digitized into technology platforms.

- **Designing and administering outcomes-based pricing contracts:** The Health Care Transformation Task Force is an industry consortium that assembles provider networks, payers, purchasers and patient groups with the “triple aim” of better health, better care and lower costs. With a commitment from its payer and provider members to put 75% of their respective businesses under value-based payment arrangements by January 2020, the task force has an intense focus on value-based care that is permeating its negotiations with life sciences companies for new drug therapies. If current models hold, these contracts will be extremely granular, as these examples attest:

- **Payment dependent on desired outcome:** Entresto® (sacubitril/valsartan) tablets; Novartis negotiated payment with Aetna, Cigna and Harvard Pilgrim based on reduction in hospitalizations for heart failure.

- **Larger rebate in absence of outcome:** Repatha® (evolocumab) injection; Amgen agreed to a higher rebate to Cigna if it missed LDL and utilization goals in people with plaque-related heart or blood vessel problems.

- **Performance against competitors:** Trulicity® (dulaglutide) injection; Lilly negotiated rebates with Harvard Pilgrim and Cigna based on success in meeting A1C targets vs. other GLP-1 therapies in adults with type 2 diabetes mellitus.

- **Indication-specific pricing:** Tarceva® (erlotinib) tablets; Genentech/Astellas negotiated with Express Scripts for higher pricing in metastatic non-small-cell lung cancer indication than in advanced-stage pancreatic cancer, based on better survival rates.

Success under these types of contracts will require life sciences companies to collect and analyze data that provides evidence of goals met, positioning them well for future negotiations. To date, pharmaceutical companies have been reluctant to handle any data that includes patient identifiers, but these pay-for-performance contracts may require changes to these policies. Platforms that aggregate real-world data from electronic medical records (EMR), electronic health records (EHR) and claims systems and then present them in a de-identified manner until patient identification is needed can help to minimize the informed consent process that has proven to hamper patient recruitment in clinical trials.

- **Measuring and influencing patient outcomes:** With revenue and profits riding on patient outcomes, perhaps the best investment in technology are platforms that help patients get the best results possible and pro-
Platforms that aggregate real-world data from electronic medical records, electronic health records and claims systems and then present them in a de-identified manner until patient identification is needed can help to minimize the informed consent process that has proven to hamper patient recruitment in clinical trials.
vide evidence of these results. Life sciences companies have developed a plethora of PSPs that have been effective in tightening the relationship with patients and can contribute to the body of RWE to demonstrate success to payers. Platforms can ingest these data points as well as those from mobile apps, wearables and home-based monitoring devices. Ideally, a single platform across brands will improve the user experience for the growing number of patients that are managing multiple chronic conditions.

Platforms will enable life sciences companies to gain a deeper understanding of patient journeys for particular conditions. These insights may aid in designing solutions to modify patient behaviors and support greater medical adherence. For example, developers using APIs could write apps enabling voice-driven interfaces such as Apple's Siri, Amazon's Alexa and other tools to offer coaching and reminders to influence patient behavior and long-term compliance.

At the same time, we need a deeper understanding of the patient journey and the patient's willingness to interact with technology in order to design and deploy these solutions. New techniques in anthropology, digital ethnography and evidence-based research are being applied to develop the most appropriate strategies for meeting patients' needs. In research conducted with partner ReD Associates, we found that patient desire for greater empathy, personalization and autonomy in their healing journeys is often at odds with a healthcare system that focuses on measurable outcomes.

**LOOKING FORWARD: PREPARING FOR THE FUTURE**

Value-based care offers the potential to bring together life sciences companies, providers, payers and patients to improve both financial and health outcomes. At the same time, it requires robust platforms to measure, benchmark, report and optimize those outcomes. Success in this new environment requires all stakeholders to collaborate and develop frameworks that can be digitized into agile technology platforms and systems of learning.

We recommend beginning by developing a cross-functional team that includes commercial, R&D, medical and regulatory affairs, and technology members, and running workshops to define upcoming plans for value-based contracts, the data available and needed to measure outcomes, and the external collaborating stakeholders.

Adopting platforms as systems of learning will help insulate life sciences companies from cultural and demographic shifts. The underlying data will always be available as will the intelligence required to make meaning from it. How that data is used may change depending on advances in technology, shifting regulatory requirements, marketplace developments and the demands from new generations of healthcare consumers. APIs to open platforms enable the flexibility developers need to tap into data and create apps that deliver the experiences health consumers want, however those desires evolve.

Thus, with platforms underpinning value-based care strategies, life sciences companies can be confident they will have the agility to adapt to changes we cannot yet imagine in the healthcare industry. In the meantime, platforms will enable life sciences companies to gather and analyze data throughout their product lifecycles and patient journeys to succeed under value-based care reimbursement models.
FOOTNOTES

3. Ibid
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