

# Value to outcomes 2.0 (V2O 2.0)

**John J. Doyle**, DrPH, MPH, Senior Vice President, Quintiles Advisory Services



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## Executive summary

As we enter a new era of value and outcomes-based healthcare, exercising “systems thinking” – accounting for political, economic, social and technological factors – will be critical to our collective success in improving population health.

As the former FDA chief, Dr. Andrew von Eschenbach, said of the biopharma industry, “We were trained to play golf. The game has switched to basketball.”<sup>1</sup> Now more than ever, industry players must team up with other healthcare stakeholders if they want to improve system performance and optimize patient outcomes. Biopharma companies who do will be amply rewarded for their innovation and contribution to healthcare system value and outcomes.

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### 1. Accelerating growth in healthcare spending growth drives demand for pricing transparency

After years of slow increases, growth in healthcare spending is accelerating. In December 2015, the CMS reported that U.S. healthcare spending had reached \$3 trillion in 2014, a 5.3% rise on 2013.<sup>2,3</sup> Forecasts suggest average spending growth of 5.8% per year between 2014 and 2024.<sup>4</sup> This growth reflects the Affordable Care Act’s coverage expansions, faster economic growth, and population aging. The health share of U.S. gross domestic product is projected to rise from 17.4 percent in 2013 to 19.6 percent in 2024.

Hospitals are feeling pressure as state policymakers, insurers and healthcare technology companies such as Castlight Health set up databases and mechanisms to allow employers and patients to compare prices. Although responsible for a smaller proportion of overall healthcare costs than hospitalization and physician services, prescription drug spending is a focus of attention<sup>5</sup> due to their relative pricing transparency. High-price, high-innovation specialty products will continue to garner special attention, such as the recent Congressional hearing on the pricing of Gilead’s Sovaldi.<sup>6</sup> A study suggests that cancer therapies are not as cost-effective as they used to be, but the question remains: how do we fairly evaluate the remarkable improvement in overall survival and benefit-risk profile of these new break-through agents?<sup>7,8</sup>

In primary care, the cholesterol-lowering PCSK9 inhibitors are already generating economic controversy; a draft Institute for Clinical and Economic Review analysis concluded that the products are not cost-effective.<sup>9</sup> Nonetheless, Express Scripts is covering both available PCSK9 inhibitors in contrast to setting an all-or-none formulary negotiation with hepatitis C drug manufacturers. Possibly as a result of that winner-take-all business case, when Merck entered the market with a new hepatitis C product earlier this year, the company hit headlines by pricing it substantially below competitors from Gilead and AbbVie.<sup>10</sup>

The 10 trends examined in this paper reflect the importance of interaction and cooperation among healthcare stakeholders to improve system performance and optimize patient outcomes.

Pharmacy benefit manager formulary exclusions are becoming more prevalent. Based only on pricing and the levels of discounts, these represent a crude approach to cost containment, tantamount to evaluating investment without return. Instead, the value of new and innovative products should be evaluated holistically, including clinical, humanistic, economic and healthcare system performance factors.

### What does this mean for biopharma?

Biopharma companies must embrace a health systems view when addressing this rising tide of costs. Reframing a cost problem as a value equation requires an evidence-based mechanism to measure return on investment. The onus will be on all manufacturers and service providers, including biopharma, to clearly delineate and communicate the ROI of their products and services. The patient journey – which is emerging as a unifying theme – is becoming more nuanced and complicated in 2016 as real-world data illuminates proximal and distal causal factors at each stage of the journey. Biopharma is uniquely positioned to perform system factor analysis and root-cause analysis to determine the key relationships and levers impacting the value chain. Biopharma can then target interventions to improve system performance, thereby enhancing their products' ROI and value proposition to the public.

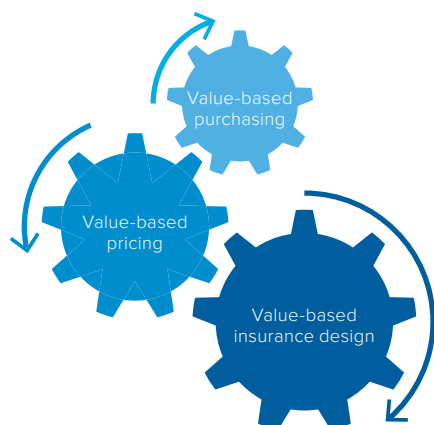
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## 2. The volume to value trifecta: purchasing, pricing, and premiums

Macroeconomic pressures and austerity measures continue to impact the global marketplace and the ongoing transition of reimbursement models “from volume to value” in U.S. healthcare is building momentum in 2016.<sup>11</sup> A survey of 2,300 physicians found physicians in leadership roles believe the shift from volume to value based payments will not compromise quality of care for patients, and is here to stay.<sup>12</sup> The value play is rolling out in three inter-related mechanisms, purchasing, pricing and premium/coverage setting in value-based insurance design (Figure 1).

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**Figure 1: Value-based purchasing, pricing and insurance design**



## Value-based purchasing

The Affordable Care Act-triggered shift to coordinated care and quality-based reimbursement continues to drive change in the marketplace.<sup>13</sup> By the end of 2016, the U.S. Department of Health and Human Services (HHS) aims to tie 30% of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models.<sup>14</sup> On March 11, 2016, the HHS issued a proposed rule<sup>15</sup> for a two-phase Part B drug payment model “that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. The first phase would involve changing the 6% add-on to Average Sales Price (ASP) that we use to make drug payments under Part B to 2.5% plus a flat fee (in a budget neutral manner). The second phase would implement value-based purchasing tools similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. We believe this model will further our goals of smarter, more efficient spending on quality care for Medicare beneficiaries.”

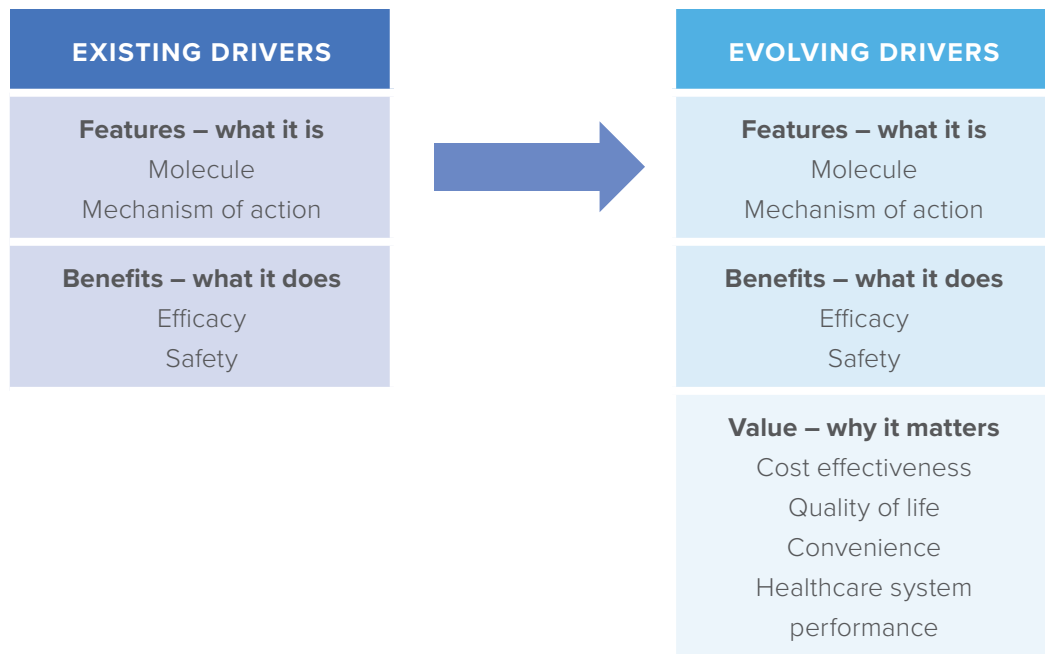
This government-led reimbursement reform will produce knock-on effects in the private sector as managed care organizations model similar approaches under their adopted “triple aim” mantra of improving population health, enhancing the quality of care and reducing costs. In January 2016, Lilly and Anthem produced a paper promoting value-based contracting arrangements, aiming to “accelerate the transition towards a value-based system with policy proposals that will help drive payment innovation.”<sup>16</sup> In February 2016, BIO issued principles on value,<sup>17</sup> supporting “novel value-based and outcomes-based contracting arrangements...alternative financing and payment mechanisms” or similar options.

## Value-based pricing

Pressure for drug prices to reflect value to the patient continues to mount. In October 2015, Reuters<sup>18</sup> quoted Steven Pearson, president of the Institute for Clinical and Economic Review, as saying, “Americans at the same time are getting tremendously ripped off with drugs and also getting tremendous value and we almost never know when we’re getting ripped off and when we’re getting real value, and that has to change.”

Value-based medicine is not about cutting costs. It is about optimizing the cost effectiveness of therapy. Clinical proof – once sufficient foundation for product success this therapeutic area – must today be complemented with compelling demonstration of treatment value<sup>19</sup> (Figure 2).

**Figure 2: The evolving drivers for assessing the “value” of a drug<sup>20</sup>**



*Biopharma has a clear mandate to price products based on value, and link pricing to metrics that already govern payment contracting. If they do not proactively define the pricing mechanism, others will do it for them.*

### Value-based insurance design

In February 2015, the CMS’s Center for Medicare and Medicaid Innovation launched an approach to payment and practice reform, the oncology care model (OCM).<sup>21</sup> Value-based formularies are also increasingly taking hold among private payers in the U.S.,<sup>22</sup> including Premier Blue Cross,<sup>23</sup> CVS Caremark<sup>24</sup> and Anthem.<sup>25</sup> Payers are applying value-based decision-making to their insurance product design, shifting economic risk to consumers as shown by the remarkable uptick in high deductible health plans.<sup>26</sup> With some 50 million patients purchasing insurance from either private or public exchanges by 2018, healthcare consumerism will firmly take root. Since 2010, deductibles for all workers have increased roughly three times as rapidly as premiums, and seven times as fast as wages and inflation.<sup>27</sup>

### What does this mean for biopharma?

Biopharma has a clear mandate to price products based on value, and link pricing to metrics that already govern payment contracting. If they do not proactively define the pricing mechanism, others will do it for them. Indeed, many healthcare stakeholders have pioneered pharma valuation schemes, most evident in oncology, with proposals from the American Society of Clinical Oncology (ASCO) and others. On February 10, 2016, HHS Secretary Sylvia Burwell told the House Ways and Means Committee that her department “is considering issuing guidelines on an executive action known as ‘march-in rights’ as a way to fight high drug prices.”<sup>28</sup> This applies where federally funded research was used to create a new drug, allowing HHS “to break a drug patent when the price is too high and not ‘available to the public on reasonable terms,’” reports *The Hill*. The HHS later rejected the proposal.<sup>29</sup>



Biopharma clearly stands to benefit by being more proactive in establishing an objective scorecard for products. A recent publication describes a systematic and evidence-based approach to appraising a drug's relative performance.<sup>30</sup> Quintiles' multi-attribute valuation methodology – which takes into account efficacy, safety and economic factors to synthesize relative value created by pharmaceutical interventions – was applied to a cohort of 10 oncologic therapies. Five key value attributes were considered: Overall Survival (OS), Progression Free Survival (PFS), population size, trial comparator and adverse events. The results indicated that the evidence-based appraisal framework allows simplification of comparison of relative performance of oncology treatments. By including cost, the framework can provide a simplified mechanism to compare relative value of these treatments. Regardless of the framework utilized, a tailored valuation must embrace each stakeholder's unique perspective. Yesterday's direct-to-consumer (DTC) was geared to educating with the purpose of starting the conversation between patient and provider. Tomorrow's DTC needs to personalize the value proposition to patients who are making critical decisions about their healthcare not only based on risk and benefit, but also price. Biopharma should prepare for patients participating in value-based purchasing decisions in healthcare much as they do in finance, real estate, and other major investments in their lives.

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### 3. Lean healthcare: matching promise with reality

Lean healthcare – minimizing waste so that all work adds value and serves patients' needs – is increasingly being employed by health systems, hospitals, physician practices, and government departments. At the Centers for Medicare and Medicaid Services (CMS), contract modification cycle time is being cut by over 50%, yielding a 95% reduction in post implementation IT change requests in quality programs, and saving staff time.<sup>31</sup>

Writing in the *New England Journal of Medicine*, Robert C. Young, M.D., notes that “the momentum behind increased attention to costs by physician organizations is attributable in part to the Choosing Wisely campaign, an initiative... that involves identifying each specialty's ‘Top Five’ opportunities for eliminating overuse and misuse of tests and procedures and highlighting therapies that confer little or no patient benefit.” The American Society of Clinical Oncology has published two such lists.<sup>32</sup>

There is much to improve on the journey to Lean healthcare. For instance, a study of 1.3 million Medicare beneficiaries found that 25-42% received low-value services, which accounted for 0.6-2.7% of overall spending.<sup>33</sup> Medicare's Pioneer ACOs recorded a 1.9% drop in “low-value” services their first year, leading to a 4.5% drop in spending on such services.<sup>34,35</sup> Over five years, Intel's pilot Healthcare Marketplace Collaborative in Portland, Oregon used new clinical processes for treating and screening patients, reducing direct costs of treating three conditions by 24-49%.<sup>36</sup>

Tomorrow's DTC needs to personalize the value proposition to patients who are making critical decisions about their healthcare not only based on risk and benefit, but also price.

Cost, quality and outcomes metrics are integral to lean process management. Pressures are mounting for providers to use outcomes-based evidence to drive decisions on service offering.<sup>37</sup> Contracts hinging on these metrics quickly are becoming more popular and robust. In January 2015, several major U.S. health systems and insurers<sup>38</sup> set up the Health Care Transformation Task Force aimed at shifting 75% of their business to contracts with incentives for quality and lower-cost healthcare by January 2020.<sup>39</sup> Reconfiguration is being seen in the U.S. health insurance industry's top ranks with Anthem's agreement to purchase Cigna<sup>40</sup> following Aetna's agreement to buy Humana,<sup>41</sup> set to reduce the five major players to three; only the largest, UnitedHealth Group, is bucking the merger trend.

Controversy remains around the potential for Lean approaches, with a Health Policy paper concluding that "even though Lean results appear to be promising, findings so far do not allow [us] to draw a final word on its positive impacts or challenges when introduced in the healthcare sector."<sup>42</sup>

### What does this mean for biopharma?

Some pharma companies have started to transform their business model from a transactional to an integrated, outcomes-based approach. For example, Novartis CEO Joe Jimenez recently said, "in the future, companies like Novartis are going to be paid on patient outcomes as opposed to selling the pill."<sup>43</sup> There is a complementary push for increased operational efficiency based on the systems view governing the market.

Signals from regulators such as progressing adaptive clinical trial design, and payers fostering coverage with evidence development, are precipitating new linkages inside pharma. If a payer requires a pay-for-performance contract based on real-world outcomes, then brand strategy, managed markets, HEOR, medical affairs and other functional teams must work in concert.

Measuring and translating value in Lean healthcare systems is necessitating a shift in commercial strategy from promotion of product features to differentiation of product value based on market-validated benefits.

Many firms are now focusing on the patient as the nexus of research and commercial activity. Partnering with providers to optimize the benefit-risk profile of their agents will link biopharma to the Lean healthcare train as it leaves the station. Ultimately, the healthcare system will reward companies for value and "goodness of fit" in the system. Value is modulated by stakeholder demands for favorable cost-benefit along the patient's journey. Macro-economic pressure and pricing scrutiny will only sharpen this already intense focus on efficiency and effectiveness. By integrating clinical and commercial functions to ensure biopharma assets are value-priced and supported with the appropriate customer service, biopharma companies can improve the return on their innovation.



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## 4. Streamlined regulatory and reimbursement pathways to optimize patient access

State right-to-try (RTT) laws, aimed at giving terminally ill patients access to unapproved, experimental therapies are sweeping the country. The first state RTT law was passed by Colorado in May 2014.<sup>44</sup> Since then, some 20 states have enacted RTT laws<sup>45</sup> and a federal RTT bill, HR 3012,<sup>46</sup> was introduced in the House in July 2015. Such laws remain controversial, with a *Health Affairs* op-ed saying, “although these laws have created an expectation that terminally ill patients will be able to quickly access potentially lifesaving treatments by being exempted from the rules of the U.S. Food and Drug Administration (FDA), this expectation is, quite simply, false.”<sup>47</sup>

In response to these laws, in February 2015, FDA accelerated its process for reviewing requests under its expanded access or compassionate use program.<sup>48</sup> This is also arousing controversy, with an *NEJM* article saying, “debate will need to take into account the simple concept...that it may well not be in the interest of patients, however sick they may be, to have easier access to products that are ineffective and may actually worsen their clinical status.”<sup>49</sup>

### Alternative development pathways

Discussions around the proposed 21st Century Cures legislation<sup>50</sup> have included alternative development pathways. These could potentially replace the traditional three-phase clinical trial paradigm, since today’s technologies and science have potential to keep patients safe while accelerating access in ways not envisioned with the Gold Standard three-phase randomized clinical trial program.

Adaptive trial designs and Master Protocols allow multiple drugs to be evaluated in the same trial, identify effected and non-effected populations faster, reducing duplicative start up and patient recruitment processes, and positively impacting time and cost. Adaptive trial designs use Bayesian methodology to characterize drug efficacy more precisely and efficiently in selected populations, based upon cumulative experience. A Master Protocol allows multiple drugs to be evaluated in the same trial. An example of an adaptive trial using a Master Protocol is the I-SPY 2 trial (Investigation of Serial Studies to Predict Your Therapeutic Response With Imaging and Molecular Analysis), from a consortium involving industry and academia, with FDA collaboration. The trial is for women with newly diagnosed locally advanced breast cancer segregated into treatment arms based upon biomarkers and other criteria.

Quintiles’ research suggests patients are willing to use therapies developed under an accelerated pathway. This is based in part on a 2012 survey of patients living with chronic disease, which found that patients want access to new medicines sooner, and that those in greatest need are willing to accept more uncertainty about a new therapy if it offers potential to improve their health.<sup>51</sup>

### What does this mean for biopharma?

Looking ahead, pressure to get new therapies to appropriate populations, where the risk-benefit profile is acceptable at the earliest possible stage of development, will increase. As regulators accelerate the experimental stage of development, observational data will be essential in complementing the RCTs in evaluating real-world risks and benefits. A collaborative and networked approach will be needed, such as that used in MIT's NEW Drug Development ParadIGmS (NEWDIGS) program, a "think and do" tank that takes a systems approach to advancements aimed at enhancing capacity to deliver new, better, affordable therapeutics to the right patients, faster. Members include Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer and Sanofi.<sup>52</sup>

As regulators explore adaptive pathways, biopharma companies can shape statistical design of clinical trials and evidence generation as a whole, broadening the view of regulators to consider observational designs. Regulators are exploring data sharing and even parallel pathways with health technology assessment (HTA) agencies to gain a better-informed view of product effectiveness.

Biopharma companies can seize this chance to harmonize core elements of their evidence package such as benefit-risk profile, while tailoring other clinical, economic, and humanistic proof points to specific decision-makers.

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## 5. Real-world evidence underpinning value-based healthcare: "just prove it"

The biopharma industry is increasingly harnessing the power of data collected outside of a controlled clinical environment to generate valuable insights to support products throughout their lifecycle.<sup>53</sup> This real-world evidence (RWE) is based on outcomes in heterogeneous patients in real world practice settings.<sup>54</sup> Relevant data come in multiple healthcare process and outcomes, types and forms, such as:

- Claims data from insurance reimbursements
- Electronic Health Record (EHR) data
- Pharmacy data on prescription orders and fulfillments
- Patient registries
- Patient-reported outcomes
- Safety surveillance/risk evaluation and mitigation strategy (REMS)
- Effectiveness/comparative effectiveness research (CER)
- Health Economics and Outcomes Research (HEOR)
- Epidemiological studies and other observational research.

**Figure 3: Types and sources of RWE55**

Real-world evidence is now generated from multiple types of data, collected from multiple sources, aggregated, shared and often reaggregated in multiple sectors of the healthcare system.

	 Claims	 Clinical trials	 Clinical setting	 Pharmacy	 Patient powered
Types of data	Medical claims	Clinical trial data	EHR Data	Point of sale data	Patient reported outcomes
			Genomic data		
			Lab tests		Social media
	Prescription drug claims		Specimen/ tissue pathology data	Prescription fill data	“Patient utility” data
Primary aggregators/users	State Medicaid	NIH	Providers	Pharmacies	Patients
	Insurance companies	FDA	Clinical labs		Patient communities/ social networks
	CMS	Pharma and device companies	Private genetic test companies	Prescription benefit managers	
Secondary aggregators/users	Insurance company analytics subsidiaries	Third party analysts	Genomic databases	Private sector pharmacy data aggregators	Patient advocacy organizations
	FDA sentinel	Patient advocacy organizations	Professional society clinical registries		Patient powered networks
	All payer claims databases		PCORnet		

Multiple real-world evidence data elements can provide a comprehensive and longitudinal picture, including:<sup>56</sup>

- Activity (patient encounter, clinical document)
- Laboratory and observation (numeric clinical lab and text values)
- Insurance (commercial, Medicare, Medicaid, self)
- Location (partial zip code)
- Medication (medicine, drugs, supplies)
- Patient (demographic – age, gender, race/ethnicity, profile, allergies, etc.)
- Problems and diagnosis (health concerns, personal/ family history, reason for visit)
- Pathology (full spectrum of studies)
- Radiology (conventional, ultrasound, MRI)
- Notes (discharge, procedure, consultation, visit)
- Other (ongoing enrichment).

These data provide information on practice patterns, treatment safety and effectiveness, cost of treatment or illness, benefit/risk, diagnosis and care plans, and disease prevalence.<sup>57</sup>

### RWE in value-based healthcare

RWE will be the currency of trade for the value-based healthcare system in the near future. Biopharma companies and payers will increasingly partner to generate RWE, with respondents to an IMS survey indicating that in the future, they expect to use RWE more broadly.<sup>58</sup> Experience from existing partnerships, such as that between AstraZeneca and HealthCore, suggests that RWE analysis is of highest value in examining health outcomes and the costs of chronic disease care.<sup>59</sup>

### FDA: Efficacy to effectiveness

Regulators are increasingly looking for evidence of both efficacy and effectiveness. Efficacy, based on the results of phase 1-3 clinical trials, is “the extent to which a drug has the ability to bring about its intended effect under ideal circumstances.”<sup>60</sup> Effectiveness, demonstrated once a product is approved, refers to “the extent to which a drug achieves its intended effect in the usual clinical setting.”<sup>61</sup> This reflects the holistic patient journey and outcomes in a broader population.<sup>62</sup> Both approaches are necessary and complementary in appraising a product’s performance.

RWE can support regulatory approval by augmenting RCT data on the safety and efficacy of new drugs and medical devices. RWE also plays a part in FDA’s accelerated approval program, which mandates that sponsors carry out post-approval RWE studies.<sup>63</sup>



*Biopharma companies are migrating from a focus on achieving product approval based on safety and efficacy to one based on benefit-risk and real-world outcomes. This shift is driving changes in the role of pharmacoepidemiology throughout the drug development and commercialization cycle.*

A paper by two Massachusetts Institute of Technology authors<sup>64</sup> criticizes FDA's judging of clinical trial requirements by a uniform statistical standard.<sup>65</sup> The study suggests that for devastating diseases, current standards are too risk-averse, "erring on the side of keeping drugs off the market even when patients, facing a dire prognosis, would accept higher risks that the drug doesn't work or comes with toxic side effects."<sup>66</sup>

### What does this mean for biopharma?

Biopharma companies are migrating from a focus on achieving product approval based on safety and efficacy to one based on benefit-risk and real-world outcomes. This shift is driving changes in the role of pharmacoepidemiology – the study of the utilization and effects of drugs in populations – throughout the drug development and commercialization cycle. This discipline applies methods of clinical epidemiology to understanding beneficial and adverse drug effects, impacts of genetic variation on drug effect, duration response relationships, and the effects of medication non-adherence.<sup>67</sup>

The pharmacoepidemiology function is a key element in gathering real-world evidence, transitioning from a reactive, technical specialization to a forward-looking strategic role focused on demonstrating value to external stakeholders. A focus on value requires better internal integration of clinical and commercial functions. Companies that achieve this and respond to the "evidence-based marketplace" – solving provider, payer and patient needs with medicines that deliver broad population outcomes – will thrive.

Historically, the pharmacoepidemiology function "played defense" for biopharma companies by studying potential adverse drug reactions. As regulators accelerate approval pathways, these studies will also provide information on product benefits, which have traditionally been handled by the clinical development team (i.e. efficacy measurement), as well as the health economic and outcomes research (HEOR) department (i.e. value measurement). However, regulators, payers,

integrated providers, patients and other stakeholders want effectiveness data to better understand "real-world" performance. Due to the lack of randomization and control in most RWE studies, pharmacoepidemiologists must take into account the influence of chance, bias, confounders, and effect modifiers when inferring causality in observational designs. Complementing their traditional risk equation with benefit assessment will enable them to "play offense" and help pharma capture more real-world value for their patients.

We are entering a new era of healthcare catalyzed by real-world research. Demonstration of value will increasingly determine market access for a new product. Efficacy will give way to effectiveness, which includes cost as a key variable. Effectiveness and efficiency evidence generation will be paramount to support value demonstration.

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## 6. The dichotomy of big data: reconciling individualized intervention with population health goals

“Big data” is translated and applied as real-world evidence (RWE) in healthcare. RWE, in turn, potentiates the “triple aim” of improving the experience of patient care and health of populations, while reducing per capita costs of care. “The interest of manufacturers in communicating RWE now appears to be converging with the interest of many payers in using RWE to make coverage and reimbursement decisions,” notes a September 2015 brief from the Network for Excellence in Health Innovation.<sup>68</sup> The brief notes that RWE “is not just ‘big data,’ it’s the integration of multiple sources of data.”

The future is not about a siloed dialogue around one drug, one physician, and one patient. The dialogue will be driven by clinically relevant information aimed at reconciling individualized interventions with system-wide efficiency and cost savings. Reconciling population health goals with individual patient needs is proving to be a formidable challenge for all stakeholders across the system. Data integration and sharing across systems enables system players to “zoom in” on patient-level decision-making and “zoom out” on population-level policy-making.

As discussed at Pharmaceutical Executive’s roundtable,<sup>69</sup> “Epidemiology Arising” (August 11, 2015), a major transition is underway in healthcare financing and delivery. To define value, a clear perspective is needed on what proof points stakeholders are seeking. The patient is at the center: all the key players have endorsed patient centricity as their goal. The challenge is that stakeholders differ in their progress towards adopting the patient-driven value mandate. There remain gaps in adoption, and geographic variations in readiness. To address these, a stronger commitment to integration of service and information is required. A common vision of population health linked to better value and outcomes is also needed.

### What does this mean for biopharma?

Biopharma firms face continuing scrutiny over drug costs, and they have little choice but to demonstrate the benefits, risks, and outcomes of their products. Harnessing the power of “big data,” biopharma companies should upgrade and accelerate the way they collect, analyze, and apply real-world data to attain a premium position in patient centricity. Other healthcare system players are advancing rapidly on this front, with integrated hospital systems such as Kaiser<sup>70</sup> and Geisinger<sup>71</sup> applying “big data” to develop guidelines and manage formularies. In parallel, managed care organizations, major retail pharmacies and drug distributors are increasingly leveraging claims data to understand better what motivates the patient.<sup>72</sup>

Analysis of retrospective data can help elucidate a drug’s impact on value and outcomes as well as the effect of payers’ utilization controls such as tiered co-pays on these outcomes. As technological advances facilitate real-time data collection and advanced



*Looking ahead, demonstration of real-world value and outcomes will increasingly determine initial and sustained market access for a new product, as efficacy and safety will give way to effectiveness and benefit-risk profiling.*

analytics, these retrospective evaluations are increasingly potentiating prospective observational studies. Given that these studies are generally not randomized, special attention must be paid to potential bias and confounding when conducting real-world research. Pharmacoepidemiologic methods to address potential sources of bias and confounding should be deployed in the study design and analytic phases of research, and should set the standard for observational research, regardless of stakeholder or setting. Approaches such as the Good ReseArch for Comparative Effectiveness (GRACE) checklist, which aims to recognize non-interventional studies that are good enough for decision support, are helpful here.<sup>73</sup>

It will be incumbent on pharmaceutical companies to link the various data-driven, go-to-market functions, including health economics and outcomes research (HEOR), market access, commercial operations and medical affairs in a way that mirrors the integrated market they seek to serve. As this market continues to drive toward evidence-based decision-making, pharmacoepidemiology will play a crucial role in designing and vetting value and outcomes demonstration projects. The validity and reliability of this new order, real-world data hinges on sound research methodology and biopharma is uniquely positioned to provide this scientific oversight and patient insight.

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## **7. “Globalization” of market access: a ground game to optimize patient access**

To support local market access, biopharma companies must supplement real-world, large-scale demographic and pharmacoepidemiological information with data reflecting local nuances. The United States and Europe have seen transformative changes in their healthcare systems in recent years. The shockwave of national laws and policies are reverberating in local communities in the major markets.

In the U.S., the 2010 Affordable Care Act (ACA) has had major implications for the cost structure of the healthcare market, providing coverage for the uninsured, creating Accountable Care Organizations (ACOs) and Patient-centered Medical Homes (PCMHs), and reforming payment by linking reimbursements to quality metrics and reductions in total cost of care.

In addition to the newly established health insurance exchanges, the ACA's Medicaid expansion resulted in record increases in Medicaid enrollment and spending nationally in fiscal year 2015, with both increasing an average of almost 14%.<sup>74,75</sup> The 29 states that expanded Medicaid in fiscal 2015 reported enrollment and total Medicaid spending growth nearly three times the rate recorded in non-expansion states.



Against this backdrop, some 32 million people in the U.S. remained uninsured as of early 2015,<sup>76</sup> with about half eligible for Medicaid or subsidies under the Affordable Care Act (ACA). Around half of the remaining uninsured, 16 million, are in states that have expanded Medicaid. The rest are in states that have not expanded Medicaid and where there is strong anti-ACA sentiment.<sup>77</sup>

The number of ACOs has risen from fewer than 100 to more than 700 in the past five years, now providing care for over 23 million people across all 50 states.<sup>78</sup> However, analysis by both the Brookings Institution and Leavitt Partners indicate that while most ACOs realize quality improvements, reducing costs is proving more difficult.<sup>79,80</sup>

### Quality metrics between payer and provider

With the aim of improving outcomes, the CMS is linking quality metrics to hospital reimbursement under the In-patient Prospective Payment System (IPPS), with penalties for non-participation in quality measures. Since implementing a financial penalty, participation among hospitals paid under IPPS has increased to over 99%. In addition, the Medicare Shared Savings Program for ACOs involves 33 quality measures for the 2015 quality-reporting year.<sup>81</sup>

Commercial payers are also beginning to influence quality of care through risk sharing contracts with providers. The Alternative Quality Contract (AQC) is the largest commercial payment reform in the U.S.

This is used in some 75% of contracts within the BCBS of MA physician network; under the contract, providers have a fixed budget for their patient population. The AQC has improved quality of care, with providers achieving a 10% savings on medical spending in the fourth year of the program.<sup>82</sup>

### European trends

Fragmentation of the payer landscape is a Europe-wide trend, with market access teams facing multiple local, regional and national decision-makers (see Figure 4).

**Figure 4: Payers are diverse and have different needs**

National		Regional		Local	
P&R	HTA	Budgets	Access	Budgets	Healthcare delivery
CEPS/CT, AIFA	G-BA, NICE, HAS, SMC	Sick funds, regional authorities	Guidelines and protocols	CCGs, formulary committees	TA networks or specialists
Different decision makers have different needs					

The redesign of the English National Health Service in 2013 created 211 local purchasers of products and services, the Clinical Commissioning Groups (CCGs). Each covers a geographic area, and focuses on long-term conditions and common diseases. The new NHS also has Commissioning Support Units to advise CCGs, and networks to inform clinicians and payers on best practices. Negotiations can continue to the level of pharmacists, and more fragmentation is possible.

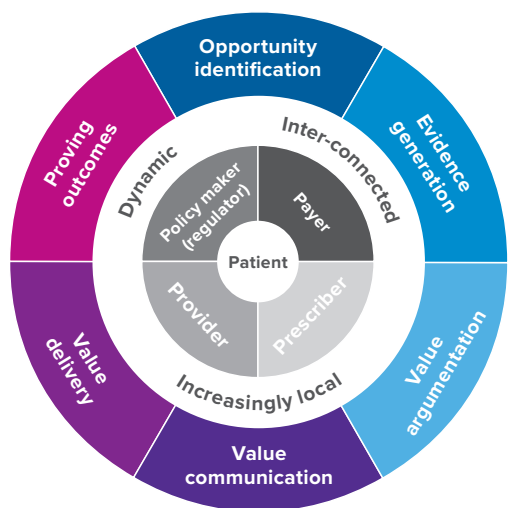
Germany's statutory health insurance (SHI) system has 131 competing SHI insurers ("sickness funds" in a national exchange). The Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011 created a scoring system for incremental benefit associated with newly approved drugs. Companies have one year to prove value over existing drugs to sustain price premium and stave off discounting. This has altered the paradigm for market access in Germany, reducing the government's pharmaceutical spending.

The rapid growth of health technology assessments (HTA) by some 100 worldwide HTA bodies is also impacting value positioning and amplifying the needs to define value locally.

### What does this mean for biopharma?

Securing and sustaining optimal market access hinges on successfully engineering a value and outcomes "evidence generation cycle" (see Figure 5).

**Figure 5: The "evidence-value-outcomes" cycle**



Two-way information exchange between local market segments and global headquarters is paramount in order to provide nimble and adaptive evidence-based approaches to markets.

Traditional approaches such as crafting an international value message campaign, developing a global value dossier, and creating multinational registries<sup>83</sup> can inform pivotal discussion with national and sub-national payer bodies.<sup>84</sup> This macro view is necessary but insufficient for achieving market access in an increasingly fragmented global marketplace. Locally sourced real-world data should also be obtained through a value and outcomes audit,<sup>85</sup> including a range of patient-centric data illustrating the patient journey and various healthcare system stakeholder influence patterns impacting that journey.

Global teams who are developing the overarching value and outcomes strategies need to consider commonalities and differences across the world. Archotyping markets based on healthcare system designs, supply considerations, demand drivers, regulatory climate and other macro factors is a useful technique to segment the markets for strategic pathways. These pathways need to be further customized, however, to address the local system dynamics, such as payer and provider contracting in order to ensure relevance on the ground. Accordingly, two-way information exchange between local market segments and global headquarters is paramount in order to provide nimble and adaptive evidence-based approaches to markets.

Health system navigator teams represent one approach for ensuring a collaborative and evidence-based “sense-and-respond” mechanism in the market (see Figure 6).

**Figure 6: Health system navigators**

I. Healthcare system diagnostic responsibilities			
a. Frame the system			
i. Players	ii. Geography	iii. Local system attributes 1. Pre-specified market archetypes 2. ACO adoption 3. Medicaid reform adoption 4. Level of integration	
b. Identify the players			
i. Stakeholder mapping 1. Relationship mapping 2. Influence mapping	ii. Decision-making mapping 1. Stakeholder needs a. Problem tree analysis 2. Stakeholder incentives 3. Evidence requirements	iii. Experience diagramming 1. Patient journey 2. Customer buying experience	iv. Communication channel preference 1. Traditional 2. Technology-enabled
c. Map relevant system processes			
i. Patient flow	ii. Information flow	iii. Service flow	iv. Economic flow
d. Specify system outcomes of interest			
i. Clinical	ii. Humanistic	iii. Economic	iv. Social
e. Delineate system dynamics			
i. Players relationships 1. Interactions 2. Influence Patterns	ii. System performance 1. Efficiency 2. Effectiveness 3. Equity (e.g. universal access to patients)	iii. System Levers 1. Drivers 2. Barriers a. Friction points (causing inefficiency of process) b. Leakage points (causing loss of patients from the system)	

II. Healthcare system solution design responsibilities		
a. Identify requisite players for design team		
i. Internal	ii. External	
b. Design integrated solutions		
i. Institute “design thinking” 1. Storyboarding 2. Schematic diagramming 3. Solution prototyping	ii. Define system success 1. Reverse-engineer to optimize the system 2. Solve for component part performance (i.e. products)	iii. Prioritize solutions 1. Bulls-eye diagramming 2. Importance vs. difficulty matrix
c. Partner for success		
i. Customers	ii. Competitors	iii. Other players
d. Apply balanced score card		
i. Align and link incentives	ii. Monitor, measure and communicate across system	

III. Healthcare system solution scaling responsibilities		
a. Practice “discovery-driven planning”		
i. Milestone-based approach / series of “little bets”	ii. “OODA” loop philosophy – observe, orient, decide and act	
b. Institute system learning		
i. Optimize solution design based on system feedback	ii. Create checkpoints	iii. Create feedback channels
c. Create “capabilities exchange” with other navigators		
i. Identify commonalities between systems	ii. Specify “best practices” 1. Internal 2. External	

IV. Biopharma strategy input responsibilities	
a. Communicate call to action back to headquarters	
i. Hub-and-spoke model	ii. Triangulate local ground-level insights with macro market information (i.e. policy and trends)
b. Clinical development	
c. Commercialization	
d. Life cycle management	

## 8. Patient centricity: a unifying theme for all stakeholders

All major stakeholders – including biopharma companies, payers, providers and regulators – are implementing patient centric initiatives. Patient advocacy groups are accelerating and amplifying these initiatives.

In a biopharma company example, Pfizer has used patient centric approaches to recruit for a sickle cell disease clinical trial, partnering with a healthcare ethnography firm to “shadow” sickle cell patients to gather real-life insights.<sup>86</sup> Among payers, UnitedHealthcare announced in February 2015 that more than 11 million people were being cared for by providers paid based on quality and health outcomes.<sup>87</sup> Humana plans to launch a real-time prescription drug benefit service giving physicians access to patients’ drug coverage during an office visit.<sup>88</sup>

Providers are increasingly operating their practices as patient-centered medical homes.<sup>89</sup> A recent study found that providing cash incentives to both doctors and patients to lower patients’ cholesterol levels led to modest improvements.<sup>90</sup> The study involved primary care providers (PCPs) working in a Pioneer Accountable Care Organization with a compensation model in which a large percentage of PCP salary is based on quality performance. The authors concluded that “most PCPs saw patient behavior as a major obstacle to improving quality and many were frustrated that patient behaviors affected their compensation.” There is also a trend for hospitals to set up patient advisory councils to work on projects and policies along with hospital staff.<sup>91</sup>

In the regulatory space, the FDA’s device arm, the Center for Devices and Radiological Health (CDRH), announced in September 2015 that it was launching a Patient Engagement Advisory Committee to provide perspective on topics such as patient preferences, risk-benefit determinations and device labeling.<sup>92</sup> Meanwhile the ACA-formed Patient-Centered Outcomes Research Institute (PCORI) has recently formed a network of researchers, PCORnet, to incorporate the patient perspective. PCORI has also funded 468 studies, and in October 2015 launched phase two of a program to create research networks covering specific diseases and involving millions of patients.<sup>93</sup>

The art and science of “listening to the patient” will become paramount as regulators call for more patient-centric risk-benefit assessment, payers require more member-centric values, and patients demand more consumer-centric messaging.

Patient advocacy groups are moving beyond helping with recruitment for clinical trials, and are increasingly providing input into trial design.<sup>94</sup> A conference focused on “the trials we want” was held in 2014 in Brussels, bringing together melanoma patients from 11 EU countries to discuss with clinicians, industry, regulators and the Centre for the Advancement of Sustainable Medical Innovation (CASMI) “how to explore innovative trial concepts such as adaptive licensing to ensure that clinical trials fulfill patients’ needs.”<sup>95</sup> On December 4, the *Boston Globe*<sup>96</sup> reported that hundreds of parents with children who have spinal muscular atrophy have created a “new grass-roots organization called Families for Acceleration of SMA Treatments” to “press drug makers... and the Food and Drug Administration, to get treatments to patients more rapidly.”



*The art and science of “listening to the patient” will become paramount as regulators call for more patient-centric risk-benefit assessment, payers require more member-centric values, and patients demand more consumer-centric messaging.*

Outside of the immediate healthcare arena, in April 2015, John Hancock Life Insurance Company<sup>97</sup> launched a program for U.S. consumers offering policy discounts in return for sharing of health data.<sup>98</sup> Customers receive a Fitbit monitor and can earn a discount of up to 15%, plus other perks.

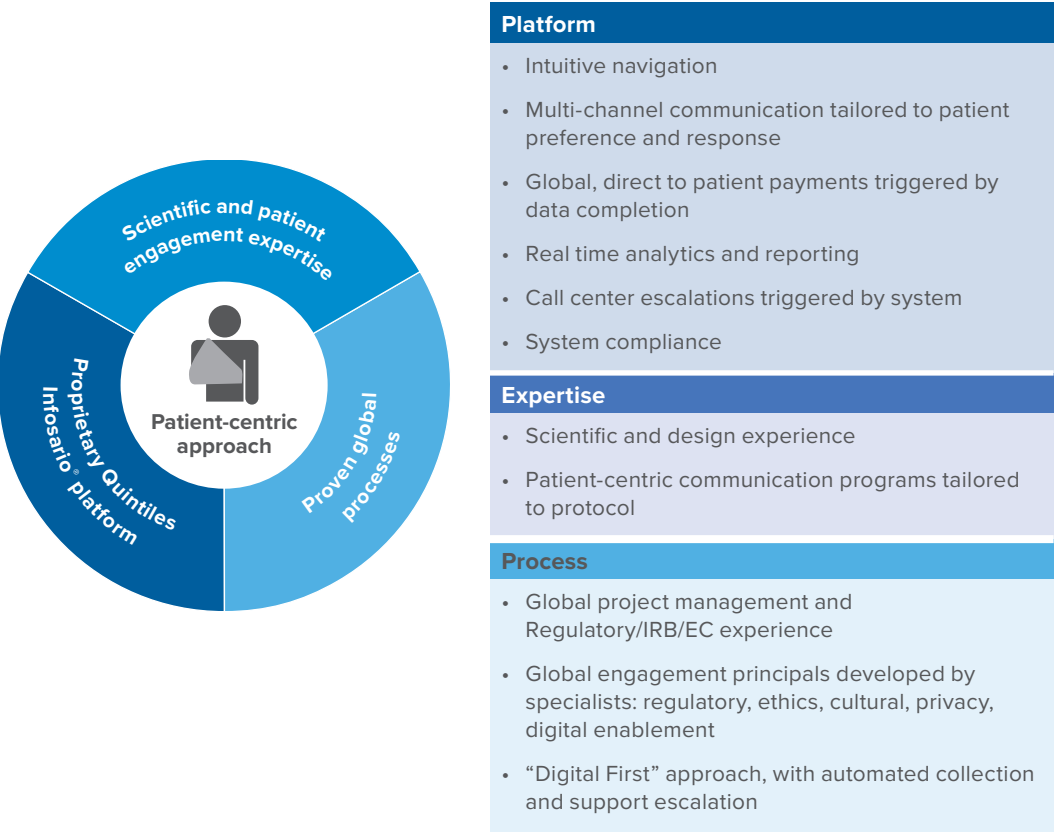
Walgreens also offered new incentives to customers willing to share healthcare data through a loyalty card channel.<sup>99</sup>

Employers such as IBM, PepsiCo and J&J are weighing how to report and measure the health of their workforce.<sup>100</sup> Dr. Kyu Rhee, chief health officer for IBM, says his company has long been committed to a “data-driven, evidence-based approach to employee wellness.” Such ratings would give insight into a company’s success in improving employee health.

In March 2016, the *Wall Street Journal* reported that employees at a several companies would soon be able to get an Apple Watch for \$25, “but there is a catch – they must meet monthly fitness goals over two years or pay the full price.”<sup>101</sup> The deal is offered through the Vitality Group and will roll out in 2016 to employees of Amgen Inc., medical group DaVita HealthCare Partners Inc. and Lockton Cos., an insurance brokerage firm.

New technologies are facilitating the trend towards increased patient centricity (Figure 7).

Figure 7: Technology within a patient-centric approach

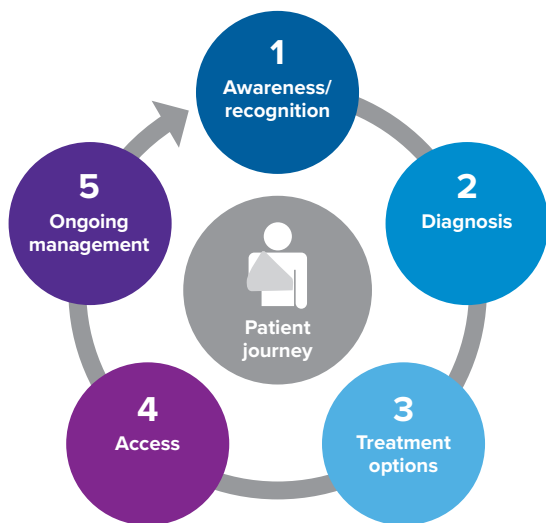


What does this mean for biopharma?

Biopharma companies are uniquely suited to provide the healthcare marketplace with patient-centric intelligence. The journey of drug development affords biopharma companies an extended, long-term view of disease epidemiology, etiology, treatments and outcomes. The patient is at the center of these wide-angle views. Now, pharma needs to zoom in on the patient experience, leveraging the multiple touchpoints in the R&D process. Measuring the patient perception of their end-to-end “customer experience” can enable an evidence generation cycle where patient perceptions of healthcare states is captured systematically and quantitatively.

This approach departs from the linear model of the patient journey where patient insights were captured only qualitatively. Notwithstanding the value of anecdotal patient stories in understanding patient decision-making and perceptions, demand for metrics in an increasingly data-driven healthcare system warrants measurement of patient factors with concrete data in a valid and reliable manner. Biopharma has the scientific acumen to design these metrics, and the biostatistical/ epidemiological firepower to crunch the patient data for a “Moneyball” perspective on patients. The quantitative view will hinge on technology to enable the appropriate level of integration to aggregate data from disparate data sets and fuel the necessary advanced analytics. Complementing this technology platform and analytics expertise is a set of core processes that facilitate patient-centric decision-making at every touchpoint in R&D, through to commercialization and life cycle management. Patient and product statistics should intertwine and correlate for the life of an asset, and in a quality-based healthcare system, those assets that optimize patient statistics are rewarded.

Looking ahead, biopharma companies should aggregate data into one patient-centric system, enabling them to tell a holistic story of the value and outcomes conferred by their products.





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## 9. Technology enabling the democratization of research

Mobile, cloud, sensors and social media technologies and analytics offer vast opportunities for patient care and connectivity. The convergence between patient-centric approaches and digital technology is fundamentally changing the way patients collect and share their healthcare data. This builds on the 2015 trend for patients beginning to behave as proactive healthcare consumers, seeking to manage their own outcomes.

Makers of monitoring devices are taking this consumer-driven healthcare to the next level. Much of today's digital, patient-centric research targets chronic conditions that are costly to treat. Used in partnership with patient advocacy groups, this technology promises to democratize research by enabling extensive data collection and sharing.

This sharing of data offers a “huge crowdsourcing opportunity,” according to Steven Keating, a graduate student at the MIT Media Lab and a brain cancer survivor.<sup>102</sup> Historically, patient data has been used for research in pooled databases. The launch of Apple's ResearchKit may allow researchers to recruit subjects and collect their data from iPhones or iPhone-linked fitness monitors such as Fitbit or Apple Watch. The NYT quotes Dr. Stephen Friend, president of Sage Bionetworks, a nonprofit organization that advocates open-data policies, as saying, “The patient, doctor and researcher – each is a different kind of expert.” The promise is to “democratize medical discovery.”

In October 2015, Johns Hopkins announced that its epilepsy study, EpiWatch, was the first ResearchKit App to use Apple Watch to collect patient data.<sup>103</sup> Johns Hopkins' EpiWatch modules enable participants to complete informed consent; track their seizures in real time; and answer research surveys. Users can review their data and compare their symptoms to others in their demographic with similar seizures.

In January 2016, The Michael J. Fox Foundation said it was working with Cynapsus Therapeutics and Intel Corporation on a pilot incorporating wearable devices and “big data” into a phase 3 clinical trial of a potential Parkinson's disease drug. The trial involves Cynapsus' thin-film, under-the-tongue strip of apomorphine.

Reuters reported in June 2015 that Amazon.com was in a race against Google to store data on human DNA, a market that may be worth \$1 billion a year by 2018.<sup>104</sup> Academic institutions and healthcare companies are reportedly picking sides between the two companies' cloud computing offerings, Google Genomics and Amazon Web Services. Microsoft Corp and IBM are also competing for market share.

Google is developing various apps and projects involving health data, using Google Fit<sup>105</sup> to track fitness data and integrate information from third-party health apps.<sup>106</sup> Google is also investing in health research through Google Genomics,<sup>107</sup> a cloud storage service for DNA data, and has backed 23andMe,<sup>108</sup> a DNA analysis service.

Mobile, cloud, sensors and social media technologies and analytics offer vast opportunities for patient care and connectivity. The convergence between patient-centric approaches and digital technology is fundamentally changing the way patients collect and share their healthcare data.

Telcare has launched an FDA-cleared diabetes monitor,<sup>109</sup> said to be “the first cellular-enabled solution that connects everyone who can help you manage your condition: healthcare professionals, clinical services, educational resources, and your network of family and friends.”

### What does this mean for biopharma?

Wearables are increasingly being used in clinical trials, with close to 300 trials currently underway using such technology, according to the National Institutes of Health (NIH).<sup>110</sup> The NIH itself is considering using smartphones and wearables for data collection as part of the White House’s Precision Medicine Initiative.<sup>111,112</sup> In addition to collecting data during a trial, such devices have potential to reduce screen failure rates by qualifying participants in advance.<sup>113</sup> Biopharma should continue down this path of exploring and piloting technology-based solutions in their clinical trials but not stop there. The same technology used to improve efficiency of the trial process and enhance interactions with clinical trial patients can be deployed to enhance the customer experience in the market.

Companion devices – non-invasive health devices that accompany drugs – can provide information on the effect and delivery of drugs. Using mobile health (mHealth) capabilities, these devices remotely monitor health data, providing an opportunity for more frequent personalized. The challenge with such devices is making them financially viable and obtaining reimbursement. Examples include Mobile Prescription Therapy (MPT), such as WellDoc’s BlueStar,<sup>114</sup> the first mobile app approved by the FDA for management of type 2 diabetes; disease centered devices used in the clinic; and drug-device combinations such as inhalers, transdermal patches, and nebulizers.

Notwithstanding the tremendous promise of these technological advancements, limitations exist. Generalizability is a concern. For instance, some evidence suggests that uptake of wearables is greater among men than among women.<sup>115</sup> Also, wearable users may behave differently when being monitored – a phenomenon known as the Hawthorne Effect.<sup>116</sup> Concerns around data privacy remain. If we can overcome these limitations and truly democratize research, patient research will transform to population research in the near future.

*The same technology used to improve efficiency of the trial process and enhance interactions with clinical trial patients can be deployed to enhance the customer experience in the market.*

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## 10. Public health innovation: biopharmaceuticals lost in translation?

A Global Burden of Disease Study published in 2015 in *The Lancet*,<sup>117</sup> covering 188 countries between 1990 and 2013, found that low back pain and major depressive disorder were among the top ten causes of years lived with disability (YLDs) in every country. The main drivers of increases in YLDs were musculoskeletal, mental, and substance use disorders, neurological disorders, and chronic respiratory diseases.

A 2013 *Lancet* article<sup>118</sup> set out an ambitious investment framework for achieving what the authors called a “grand convergence in global health” by 2035. As highlighted in a March 2016 PLoS paper,<sup>119</sup> this “prospect of achieving a grand convergence in global health within a generation, averting about 10 million deaths annually from 2035 onward, represents an unprecedented opportunity to boost human development worldwide. This opportunity can only be realized through a serious, renewed effort to step up investments in R&D to tackle the health conditions of poverty.”

### Measuring success in improving public health

One of the greatest challenges in efforts to improve public health lies in how to measure success,<sup>120</sup> writes Sandro Galea, MD, dean of the Boston University School of Public Health. “If we simply measure overall population health, we can almost certainly improve it by...improving the health of groups that are easily accessible and most amenable to changing their behavior...But these efforts will inevitably widen health gaps, improving the health of some while leaving marginalized communities behind.” Galea notes that “health is a public good that forms part of the social fabric...health inequities fray that fabric, contributing to broader resentments of social inequities.” Galea concludes that “payers and providers could broaden their expectations about outcomes to include equity, which ultimately benefits everyone.”

### Global health risk framework

The West African Ebola outbreak illustrated the need for a unifying global health system framework.<sup>121</sup> A Commission on a Global Health Risk Framework for the Future has been set up to recommend a more effective global architecture to mitigate infectious disease threats. Writing in the *New England Journal of Medicine*, Bill Gates asserts, “Of all the things that could kill more than 10 million people...the most likely is an epidemic stemming from either natural causes or bioterrorism.”<sup>122</sup> The world needs a global warning and response system for outbreaks, writes Gates. The World Bank projects that a worldwide influenza epidemic, for example, would reduce global wealth by an estimated \$3 trillion. Gates advocates for investment disease-surveillance and laboratory-testing capacity.

### What does this mean for biopharma?

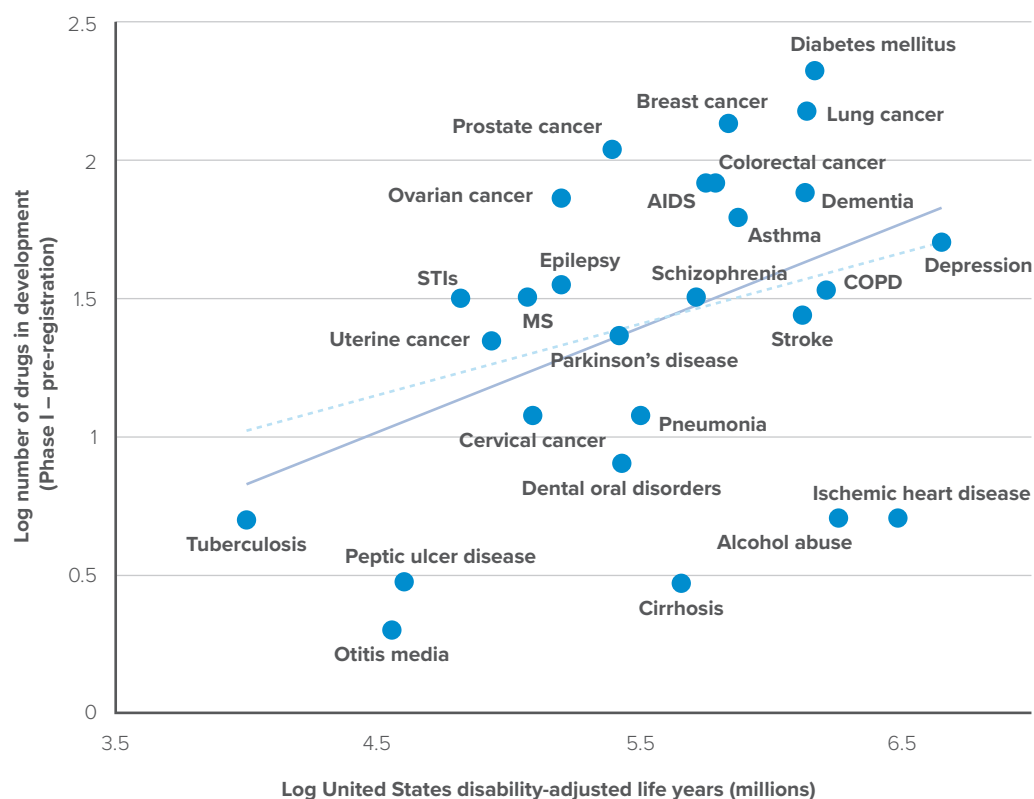
Taking treatments from bench to bedside requires a viable pathway connecting molecular science to global need. Halim and Doyle<sup>123</sup> present a systematic analysis of the effectiveness of translating basic science into reduced global burden of disease as a proxy for systemic public health impact. They pose a compound research question: Is the current drug development pipeline aligned with current and future global burden of disease, and, if not, where do the disconnections occur?

The authors posit that drug development may not be optimally poised to reduce the global burden of disease. For breakthroughs to reach patients, stakeholders must collaborate for greater innovation and reengineer their approach to meeting public health needs. While the globe becomes more connected the challenge to collaborate across and within increasingly complex and localized healthcare systems can be immense.

There is an opportunity for a “Public Health Index” to guide efficient and effective healthcare resource allocation. Such an index should incorporate not only burden of disease metrics and new drugs in development, but also variables such as the number of available interventions, economic impact, medication adherences, education and prevention. The index can determine unmet medical need from various stakeholder perspectives, build evidence to support adoption, and score and prioritize target disease areas (Figure 8).

**Figure 8: Drugs in development vs. U.S. disease burden**

**Number of drugs in development in the U.S. (Phase I – pre-registration) and U.S. Disease Burden in disability-adjusted life years (DALYs) in 2004 for 27 Common Medical Conditions.** The solid line illustrates the results of a regression analysis, showing the relationship between U.S. disease-specific DALYs and the number of drugs in development in (Q4 2011). The dashed line projects drugs in development in a regression model that requires that a disease with no burden has no drugs in development (constrained model). Disease states that fall above the line have an increased number of drugs in development than would be predicted by DALYs while disease states that fall below the line have fewer than expected drugs in development than would be predicted by DALYs.



*By solving for population health goals that include quality of care, efficiency of care and outcomes of care, biopharma can optimize their value contribution in the global healthcare system.*

In valuing research and setting funding priorities, the operating assumption is often that conditions representing the highest burden receive higher research priority, positing that burden of disease rankings are roughly translated into a demand for research. However, pharmaceutical R&D “gaps” remain. To address these, there is a need for greater collaboration between stakeholders. Biopharma R&D should be viewed from a public health perspective, incorporating new epidemiological, population and health system variables, in order to take translational medicine from clinic to the community.

With healthcare spending continuing to rise, and a focus of attention on prescription drug prices, pressure will continue for biopharma companies to prove the value of their products in addressing unmet medical needs within the healthcare system. By solving for population health goals that include quality of care, efficiency of care and outcomes of care, biopharma can optimize their value contribution in the global healthcare system. When these system goals are focused on the most pressing burden of disease, considering the advantaged and disadvantaged communities equitably, public health can be optimized. System reform needs to enable adequate return on biopharma innovation to fuel this population health optimization to ensure it can be sustained in the face of political and economic pressures.

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## About the Author



### **John J. Doyle, Dr.P.H., M.P.H.**

#### *Senior Vice President, Quintiles Advisory Services*

Dr. Doyle leads the Values & Outcomes Center of Excellence – working with Life Science companies to navigate the transformational changes in the healthcare marketplace from a population health perspective. As the global healthcare system migrates from volume to value and outcomes-based medicine, Dr. Doyle's team of strategists partners with clients to diagnose, strategize and illuminate a product's benefit-risk and economic profile tailored to a myriad of market stakeholders to drive healthcare system performance in an increasingly evidence-based environment. Functional areas of expertise include pricing and reimbursement, health economic and outcomes research (HEOR), and policy analysis.

Over the last two decades, Dr. Doyle has authored over 100 abstracts and original research articles in a variety of therapeutic areas, with special concentration in oncology. He has lectured for academic and commercial audiences in the U.S., Canada, Europe, Latin America and Asia.

Dr. Doyle received a Bachelor of Science degree in Applied Economics with a concentration in the Life Sciences from Cornell University. He received a Master of Public Health degree and a Doctor of Public Health degree in Epidemiology from the Mailman School of Public Health at Columbia University, where he maintains an adjunct faculty position.



