

BEYOND THE PILL STRATEGIES:

Biopharma Partnering's Next Frontier

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Buffeted by the Winds of Digital Transformation

Biopharma's customer – the healthcare delivery industry – is being buffeted by the winds of digital transformation. Patients want control over their healthcare – and have the mobile devices that connect them to and analyze their data. Payers (and patients) need prices to reflect true value delivered. Smart biopharma companies are responding by evolving their business models and embracing a holistic, “beyond the pill” approach to the future. Biopharma partnering and alliance professionals should dive in, head first.

Beyond the pill strategies are a subset of the digital transformation initiatives that biopharma companies are pursuing. Related initiatives include accelerating and improving drug discovery, development, and manufacturing, as well as omnichannel communications with patients, providers, and payers. Beyond the pill strategies wrap services and data in a bundle with the drug to drive patient adherence and outcomes, as well as to collect real world evidence (RWE) to determine efficacy. For most biopharma companies, beyond the pill is largely a defensive strategy aimed at justifying or preserving pricing or perhaps gaining reimbursement in any amount. If prognosticators are correct, this bundle of product, services, and data (typically referred to as a solution) will be required for receiving regulatory approval in the not-too-distant future. The bundle may even be part of a single label.

Many early efforts are in chronic disease areas – primarily in disease management – as a way to improve patient outcomes, and to collect RWE on the efficacy of both drugs and overall treatment regimens. Most require partnering to gain access to data, capabilities, or relationships that biopharma doesn't have. For example:

- **Biogen** has partnered with wearables developer **Fitbit** to monitor and measure MS patients' walking activity, yielding data and encouraging patients to make lifestyle changes as part of an overall strategy of driving better patient outcomes
- **Daiichi Sankyo** works with **Partners Healthcare** to create a coaching platform that supports behavioral change in patients with atrial fibrillation

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- **Sanofi** has partnered with **Verily Life Sciences** (an Alphabet company) to work on a variety of device and disease management projects to shore up its diabetes franchise
- **Novartis** and **Proteus** developed a “chip on a pill” that can gather specific data once ingested by a patient

Some companies are experimenting with service offerings directly aligned with a patient’s experience of a chronic disease. A good example is **Bayer’s MS Gateway** that wraps a suite of services around the “patient pathway” to help optimize patient outcomes while subtly demonstrating the company’s commitment to patients.

There are also opportunities to generate net new revenues that currently are largely the domain of digital health startups, often focusing on wellness and prevention, such as **Livongo Health**¹, a venture-funded startup that is using a combination of a device, data, messaging, and a trained coach to help diabetes patients live healthier lives, sometimes even free of medication. More than half the companies in the *Fortune* 100 are working with Livongo.

Three Trends Necessitating New Business Models

Biopharma companies have been talking about beyond the pill for nearly a decade. Only in recent years has it emerged as a must do – as is typical, because of the convergence of three trends (See *Figure 1 – Converging Trends*):

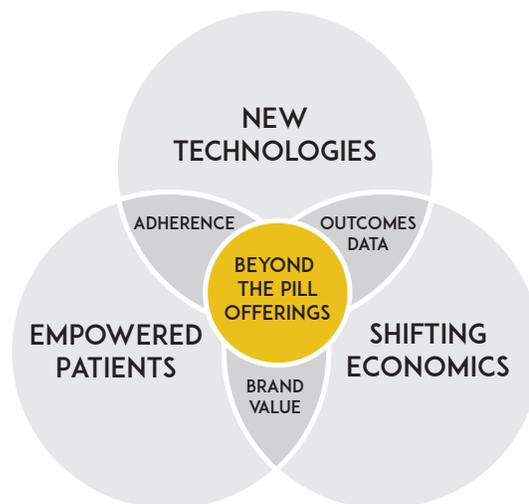


Figure 1 – Converging Trends

¹Neville, S., Digital disrupters take big pharma ‘beyond the pill’, *Financial Times*, April 24, 2017.



- **New technologies**, including therapeutic technologies such as gene therapy and immunotherapy; data and analytics technologies including deep learning, artificial intelligence, and intuitive display, as well as Internet of Things (IoT) technologies that enable remote and intelligent sensing.
- **Shifting economics**, including a desire by payers to move to outcomes- or value-based reimbursement models that require the real world evidence (not just clinical trial evidence) enabled by data, analytics, and Internet of Things (IoT), as well as overall pressure on the cost of healthcare generally and prescription drugs, specifically. There is also a shift from focusing on treatment of chronic, lifestyle, and environmental diseases (which include many cancers) to prevention through behavior modification enabled by data and services and nontraditional cures made possible by new therapeutic technologies.
- **Empowered patients** who, because of our omnipresent use of mobile communication and information technologies, expect to control their experience in every venue, including healthcare. Patients – especially those who work outside of the life sciences and healthcare industries – have a fairly negative perception of biopharma, something that beyond the pill strategies can counter by focusing on service and health outcomes.

Each of these trends powerfully disrupts biopharma's traditional business model. As with most disruptions, change creates gold to be mined if companies can develop a focused and phased strategy, build required capabilities, and carefully place bets intended to produce specific results across multiple time horizons. Outcomes consisting of data, adherence, and improved brand value are essential to evolving the biopharma business model.

Partnering Opportunities

Opportunities to create, deliver, and capture value abound across the value chain. All require partnering – frequently with unfamiliar partners and in partnering models that are a cross between service provider and joint asset development and commercialization models that are most familiar to biopharma partnering professionals.

Also unfamiliar territory – with implications for partnering models – is increasing pressure to move to economic models based on patient outcomes. For example, an initiative in New York State has the aggressive objective

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of moving 80 to 90 percent of managed care payments to value-based methodologies, which will have an impact on biopharmaceutical companies². It means that companies' ultimate compensation isn't determined until patients achieve certain "endpoints," which could mean that more of a service provider partner's compensation is at risk than in typical fee for service and milestone models. Outcome-based models can be very challenging to implement because the more risk that is shared, the more decision making should be shared, requiring a deep partnering capability throughout the company. Governance is needed and, from the top down, leaders must model appropriate collaborative behavior.

A few of the ways companies are partnering to create value can be summarized in broad categories that include:

- **Data** – Building the means of collecting RWE of patient outcomes to demonstrate the value of drugs and enhance treatment. This can involve partnering with payers – several of which have set up data and analytic subsidiaries, such as **Anthem's Healthcore**. Companies are also engaging with startups focusing on wellness to build services through which data is collected, such as the previously mentioned Livongo.
- **Devices** – Advances in drug delivery mechanisms are giving patients greater autonomy in managing their disease, improving adherence, and reducing system costs. Biopharma companies are partnering with medical device companies in creating combination products, such as syringes made to the specifications of a particular drug and infusion sets coupled with measurement and data collection devices.
- **Diagnostics** – Biomarkers and related tests that point to specific treatments – the backbone of personalized medicine – are usually created by specialized firms, such as **Nanostring** or **Ventana**, a subsidiary of Roche. These companies specialize in the very specific development and regulatory pathways required to advance a companion or complementary diagnostic that may be required for regulatory approval of certain drugs, especially oncology treatments. Most biopharma companies are partnering to develop these, rather than building the capability themselves.
- **Disease Management** – Value-adding solutions that personalize and tailor patients' treatments, drive adherence, and also provide data and other benefits for providers and payers. Significantly more than traditional patient support, you can see the essence of beyond the pill in this form of complex co-development and, in some instances, co-commercialization partnering.

²KPMG Global Strategy Group, *Pharma Outlook 2030, From Evolution to Revolution*, 2017.



Success Factors

Beyond the pill is uncharted territory for most biopharmaceutical firms. By most accounts, **Novartis** is seen as the leading company, having partnered with **Google** to create a smart contact lens (now on hold) and forming a joint venture with a Swiss health insurer to provide coaching and remote monitoring of certain patients in support of Entresto, a promising heart disease drug, to name but a few of the company's many initiatives. However, it is still early days and too early to judge success or failure.

Nonetheless, biopharma companies – and their technology and service partners – have sufficient experience to start to define success factors and challenges. A few success factors that are emerging include:

- **Support the Core Business** – Offerings should align with corporate strategy and therapeutic focus. Remember that one of the goals of beyond the pill strategies is to differentiate and demonstrate the value of a drug, gaining or maintaining suitable pricing and reimbursement. Some of the most promising patient-facing initiatives are in support of late-stage pipeline assets, wrapping services and data “around the pill.” However, companies should not overlook the potential for developing multiple revenue streams including device sales, subscriptions for coaching, or sales of aggregated data. These revenue streams likely will be shared with a partner – but developed much more quickly, improving the odds of capturing more market share.
- **Focus on Outcomes** – Beyond the pill offerings should result in measurably improving patient outcomes – with measurably being a key word. Successful offerings will use predictive algorithms to create and deliver “advice” back to patients to detect when they may have missed a medication or a key measurement indicates an acute or worsening disease condition.
- **Partner** – Beyond the pill offerings require a range of capabilities that most biopharma companies don't have, thus partnering is key. For example, very few have the experience in mobile applications, sensor technologies, or the deep learning required to develop algorithms that learn and provide diagnostic guidance. As a result biopharma companies are partnering with pure play technology companies such as **Qualcomm** and **Intel**, sometimes developing specialized solutions and at other times leveraging the technology company's expertise to invest in digital health startups.

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- **Multi-Stakeholder Value** – Beyond the pill strategies and offerings must be holistic, considering the needs of the overall healthcare ecosystem and creating value for patients, providers, and payers, alike – in addition to shareholder value. For example, while patients are better able to manage their chronic disease, providers and payers get data about how patients actually experience treatment and what prompts adherence to treatment plans – or not. In addition to any monetary value, this creates value derived from data that can inform everything from marketing and messaging to clinical studies and product design.
- **Adopt an Entrepreneurial Mindset** – There is no doubt about it. Biopharma companies must evolve their business models – and beyond the pill is the tip of the spear. *So it can't be business as usual.* Establish a safe environment to nurture a “start-up,” learning, iterating, and scaling what works. An end-to-end, ideation-to-monetization engine *outside* the normal drug development process is essential (See Figure 2 - *Ideation-to-Monetization Engine*). Resources – in every meaning of the word – need to be dedicated to this transformation effort. Staff can't be expected to add it on to an already overloaded day job and produce good outcomes. Investment is required. Experiments that fail must be viewed as learning experiences and a necessary component of the journey.

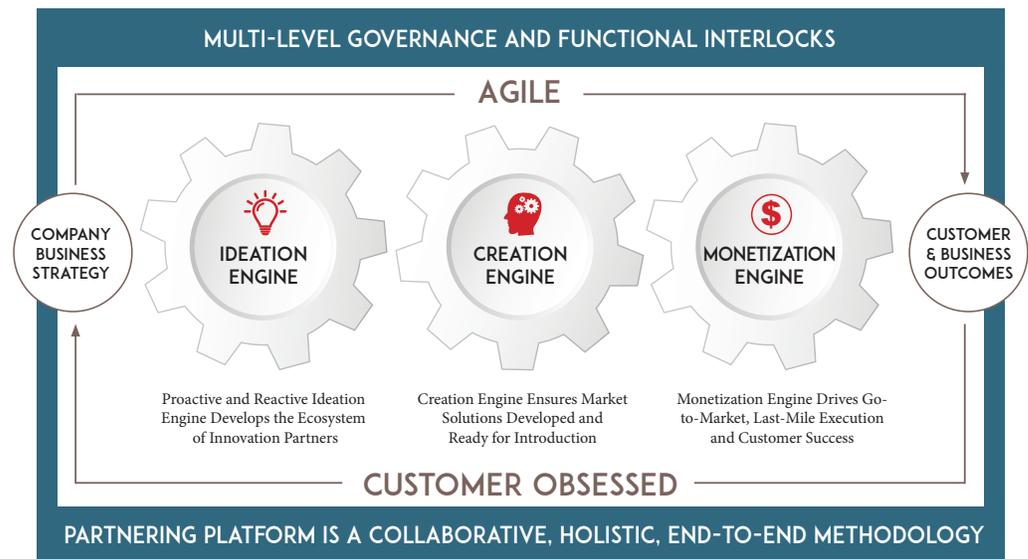


Figure 2 – Ideation-to-Monetization Engine
Source: Alliancesphere and The Rhythm of Business Joint Venture

Challenges and Risks

Early efforts have highlighted many of the challenges these initiatives face. The risks are significant and multi-faceted. But the biggest risk is not doing anything at all. The business is changing and companies must transform. Of course, biopharma companies are not without an ability to innovate and create value for patients, build substantial businesses, and attract smart, talented people. A non-exhaustive review of some of the major challenges and risks – and ways in which biopharma companies can use their strengths to counter – include:

- **Non-pharma competitors** – There are many nimble startups trying to capture a piece of this space. Venture funding of digital health startups hit \$6.9B in 2016 and is projected to reach \$10B in 2017³. Well-funded companies in the space, such as IBM, Alphabet, Intel, Apple, Samsung, Qualcomm, and more, don't have the regulatory hurdles biopharma companies do. All of these companies are potential partners, and are actively engaged in partnering with biopharma companies. However, these companies do not have a link to payers and providers and lack experience working in the healthcare regulatory environment. But make no mistake – they have strong, trusted relationships with consumers, possess valuable brands, and are not afraid to tackle new businesses.
- **Untested business models and regulatory paths** – Exactly because these are transformative business models, there is no clear path to follow, either to create and deliver value or to gain regulatory approval and inclusion on pricing and reimbursement formularies. Different components of a solution have different regulatory paths. For some, especially service offerings, there aren't regulations in place or clarity about what approvals are required. Additionally, some regulations, such as anti-kickback regulations, restrict what biopharma companies must charge for services. At this point in time, health and wellness startups and legacy companies in other industries have no such restrictions. However, we must assume that biopharma companies have an advantage in their existing relationships with regulators.
- **Lower margins and/or indirect revenues** – Biopharma companies should not be planning for lucrative new revenue streams, although there may be ancillary revenues produced. What is more important to biopharma revenues is the value that comes from the ability to gain market share or maintain pricing and reimbursement on the

³CB Insights, *Healthy & Wealthy: Digital Health Deals and Funding Hit Record Highs*, August 7, 2017.

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drugs at the center of the solution offering. Measuring ROI will be exceedingly complex and require acceptance of value models that take into account revenue maintenance and cost avoidance. This will require the extensive data analytics capability – which is required to best understand patient outcomes – to also collect and analyze the data that support sophisticated financial models. The biopharma alliance professional's understanding of the value of access, capability, validation, and other intangibles (also known as non-cash or relationship currencies) will be critical to arriving at fair and financially profitable agreements with partners.

- **Resource allocation** – As stated previously, dedicated resources are needed for a beyond the pill initiative. It can't become the shiny object that initially gets capital and people, then is quickly reprioritized when promising traditional drug development opportunities come along. Forward-looking biopharma companies understand that maximizing the value of that promising molecule requires a beyond the pill strategy combining some of the elements we've discussed, and always including a data and service component. The complex solution integrates its individual parts to create a greater whole.
- **Lack of digital acumen** – Digital talent is hard to come by – and the best typically don't see biopharma as a desirable industry. Biopharma needs to work on this through every conceivable avenue. The good news is that talent of all disciplines wants to be part of something new and breakthrough. Companies must craft – and live – the right values. Provide opportunities for personal and professional growth. Offer compensation commensurate with the value created. These items are all within the control of biopharma companies. Adopting these policies and objectives creates advantage in the fight for talent. However, no matter what any single company does or offers, all the smart people won't work for it, so embrace the liberal use of partnering to gain access to other smart folks not working inside your business.



Action Plan for Biopharma Alliance Professionals

Traditional alliance management is mature within most biopharmaceutical companies. Its focus needs to shift to how the business is evolving and the role of partnering in that evolution. There is no greater opportunity to deliver value in the next generation of biopharma business models than beyond the pill. Here are a few steps that biopharma alliance management should take to ensure partnering leaders are a critical component of this business model transformation:

1. Understand your company's current strategies and initiatives around beyond the pill strategies. Assume you have significant value to add relative to the partnering required to implement the strategies. Acknowledge to yourself that this partnering will require expanding your horizons and working to create new partnering models. A deep understanding of the underlying economics will be essential.
2. Work with key stakeholders who have developed or are developing a strategy for beyond the pill initiatives to build a specific partnering strategy to deliver on objectives.
3. Build an end-to-end, ideation-to-monetization framework to move solutions from conception to customers.
4. Create champions within functional stakeholders and business owners to invest in change, and work with these champions to secure the required resources.

Beyond the pill strategies are the next frontier in biopharma partnering. Successfully executing these strategies will take new models, but the core behaviors and processes of partnering are completely applicable. Smart biopharma professionals will seize upon this opportunity to create new value for patients, their companies, and their partners – many of whom will be unfamiliar bedfellows.

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About Authors and The Rhythm of Business

Jan Twombly, CSAP and **Jeff Shuman CSAP, PhD**, are the principals of **The Rhythm of Business**. Since 1999 they have developed thought leadership, consulted globally, and offered education and training to life sciences companies and beyond, focusing on driving successful business outcomes through partnering and alliances. Built on a foundation of entrepreneurship and new business development, the firm's end-to-end frameworks embed the primacy of the customer, a rich understanding of value, and a focus on quickly learning and implementing what matters for success.

Shuman is also professor of management at Bentley University in Waltham, Massachusetts where he is educating the next generation of business leaders in entrepreneurial thinking coupled with managing strategic alliances and partnering initiatives.

In 2013 The Rhythm of Business joined forces with Alliancesphere, a leader in collaborative execution. Together, they are delivering executive suite-sponsored, enterprise-wide solutions to build the next generation partnering everywhere capability required to realize the value of digital business transformation.



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