Deloitte Review

Complimentary article reprint



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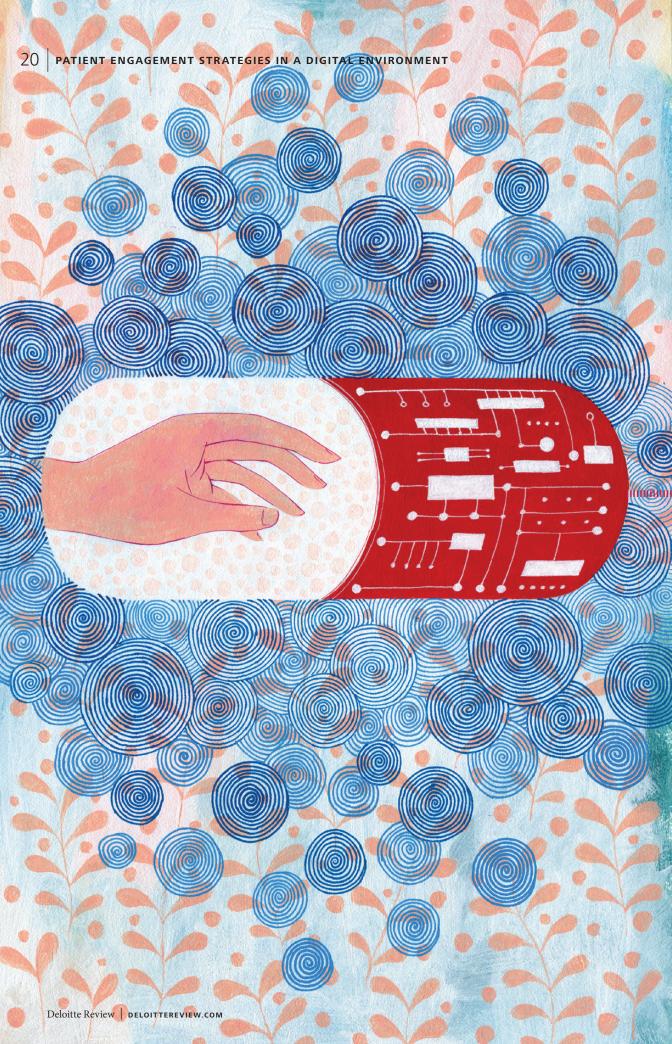
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Life sciences executives are responding to the pharmaceutical industry's changing focus toward holistic patient management and improved real-world outcomes. But are they moving swiftly enough, and in the right direction? New ecosystem participants outside of the traditional health care enterprise—wearable health monitors, mobile wellness apps, device companies, telecom companies, and more—are fast moving in order to cater to changing patient expectations.

Life sciences companies have a window of time to frame their patient engagement strategies for operating in the new, customer-centered, digital ecosystem—or risk the new players keeping them constrained within the traditional pharma model. Breaking out of that model does represent a new mindset for companies accustomed to communicating with patients somewhat impersonally through traditional indirect, mass media campaigns. But as new policies and technologies tilt the balance of power toward patients, health care companies must shift accordingly to take advantage of emerging opportunities for a more direct, personal relationship.

Imagine the following from a patient's point of view: You are diagnosed with a life-changing, chronic illness such as multiple sclerosis, diabetes, or chronic obstructive pulmonary disease. Your knowledge of the disease might range from complete unfamiliarity to basic awareness from pharmaceutical companies' TV commercials to a deeper understanding via a family member or friend enduring the disease. In any case, the news itself is overwhelming. While your doctor offers basic information, you feel lost and barely know what questions to ask. You are handed a pamphlet and connected with a community group, but you still have many questions left unanswered: *How will the disease affect my daily routine?* Which therapies are best for me? Will insurance cover the cost of my care, and for how long? Are there clinical programs I can consider?

Historically, the pharmaceutical companies that manufacture your prescribed tablets and formulas were not trusted go-to sources—for information or for support or counseling—compared to a physician, nurse, or community group, for example. But these companies are increasingly seeking to step in and answer these questions—and to help patients navigate the complexities involved in receiving the original diagnosis, deciding on treatment, securing financial assistance, connecting with other patients and community experts, and supplementing clinical education.

Playing this role is hardly unprecedented: Companies focused on specialty treatments or orphan diseases (diseases afflicting fewer than 200,000 patients nationwide¹) have often been ahead of the curve when it comes to offering high-touch patient services and facilitating engagement, driven by smaller communities of patients and health care providers, more chronically ill patients, strict treatment regimens, and a complex reimbursement environment. For example, after the US Food and Drug administration swiftly approved Vertex Pharmaceutical's Kalydeco,² a breakthrough treatment for cystic fibrosis (CF), Vertex quickly mobilized a patient service program (dubbed GPS, for Guidance and Patient Support), since surviving CF demands not only adherence to pharmaceutical therapy but also physical interventions via airway-clearing techniques.³ The Vertex program,⁴

along with its rapid drug launch, offers support services to the tight network of CF patients and health care providers, contributing to health plan coverage despite the \$300,000 annual price tag.⁵

POWER TO THE PATIENT

hanges in technology and the health care ecosystem are increasing the patient's role in decision making and reshaping their expectations from health care companies. This is driven by several factors, including patients' ability to change their own outcomes based on behavior, financial scrutiny due to cost-sharing models that push more costs onto the patient, the industry's shift toward evaluating outcomes to determine value delivered to the patient, and the availability of technology solutions empowering patients with more information and the ability to play an active role in managing their well-being.

As such, patients are demanding care and solutions that are coordinated, convenient, customized, and accessible, and a number of nontraditional health companies are coming forward to address these emerging expectations, even as many large pharmaceutical companies focused on traditional markets have lagged behind. An example is the not-for-profit social network PatientsLikeMe, which allows

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patients to share health information and receive updates on research and community events related to their selected therapeutic areas; the network is also piloting a research platform on which researchers test new methods for measuring patient outcomes. We're also seeing a broad "consumerization" of health care products, expanding the ecosystem beyond the traditional players of providers, payers, big pharma, and health care data companies to include retail giants such as Nike, Apple Inc., and FitBit, as well as thousands of innovative mobile-application developers. As such, patients need to be thought of and engaged as traditional consumers when it comes to their use of health care products and services.

PHARMA'S UNIQUE POSITION

In the nonprofit sector, too, most players recognize the need to engage patients—to improve outcomes and patient experience and reduce costs. Sizable grants are helping establish patient engagement strategies. The Gordon and Betty Moore Foundation has an almost \$6 billion endowment⁷ focused on improving outcomes, and grants to the American Institute of Research⁸ in the last two years, totaling \$1 million, focus on patient and family engagement in health care, detailing a roadmap of key strategies such as patient preparation, clinician leadership preparation, system redesign, and measurement of key metrics.⁹

Despite this and other meaningful research on the benefits of patient engagement, private foundations, nonprofits, and government agencies are at a disadvantage compared to pharmaceutical companies (and other large, consumer-facing companies) in implementing these strategies in a timely fashion, due to familiar factors: lack of resources, both financial and human, and additional layers of oversight from board members and multiple partners. However, the explosion of research in the area of patient engagement further speaks to the need for timeliness on the part of pharmaceutical companies implementing and executing engagement strategies, and nonprofit and public sector organizations can play a key role in making this happen. There is no shortage of creative patient engagement ideas from respected health systems such as Cleveland Clinic and Mayo Clinic, from innovation consulting firms like IDEO, and from developers of applications such as the Kinsa Smart Thermometer and Health Tracker. The extent to which patients will benefit from these ideas will depend on which organization can stand up the required resources, teams, and partners to execute them effectively.

Along the lines of Vertex Pharmaceutical's branded GPS program, pharmaceutical companies have begun using their marketing competencies to brand their patient services offerings. Examples include Biogen's and Genzyme's Above MS¹⁰ and MS One to One¹¹ portfolio programs, respectively; AstraZeneca's AZ & Me clinical education and prescription savings programs; ¹² and Abbvie's MyHUMIRA support program for all of Humira's autoimmune indications. ¹³

It makes sense that pharmaceutical companies would look to establish their brand for patient engagement services. Being able to deliver consistent service to patients and health care providers alike is paramount in building trust and loyalty.

Conversely, and unsurprisingly, poor execution can drive the optics of a company's brand in the wrong direction. As discussed, most specialty pharmaceutical companies are moving to offer at least baseline patient services such as start-up assistance, insurance/benefit coordination, and financial assistance. But the rapid launch of services to accompany new products has hardly been glitch-free, and in

such cases companies' field account teams have reported a backlash from providers. Of course, providers appreciate it when a pharma company's patient and provider services alleviate administrative burden for their practice and staff, but they are not shy about providing feedback to field sales representatives and liaisons when patient services operations don't run smoothly, be it too many lost insurer faxes, substandard third-party vendors contracted by the pharma company, or lack of coordination between different company representatives. With so many drugs on the market with similar safety and efficacy profiles, providers must take into account a dysfunctional patient services program when recommending which prescriptions their doctors should write. Even if a drug has a slightly less burdensome method or mode of administration (for example, weekly versus twice per week), many prescribing physicians see the added burden to their patients due to poor patient services as a larger trade-off.

WHAT DOES "GOOD" LOOK LIKE FOR PATIENT ENGAGEMENT?

With regard to patient engagement, there is emerging support for moving away from a reactive approach, in which coordination between stakeholders, therapy, and care is limited or ad hoc, to a proactive model in which engagement tools and support bolster both patients and health care providers. This benefits both the patient and the life sciences company: Patients get help with a range of both administrative tasks (securing financial assistance, filling prescriptions, receiving supplies) and emotional issues (dealing with a new diagnosis, understanding treatment options, providing basic educational and motivational support), while life sciences companies get assurance that their product is administered and delivered as intended, in a way that can optimize efficacy and outcomes. In an evolving reimbursement environment where payers increasingly demand proof of real-world outcomes, companies need to ensure that patients adhere to medication regimens and practices. Figure 1 depicts the five key needs that a comprehensive patient services suite should address.

- Therapy: Connecting with patients to provide access to and support with their care. Specific therapy-related solutions include access to care, specialty pharmacy triage, distribution solutions, site of care/infusion site match, lab/test results coordination, and nurse visits.
- Financial: Helping patients obtain the resources they require to stay on therapy. Specific financial solutions include insurance verification, benefits investigation, claims appeals and re-coding, prior authorization, co-pay assistance, and bridge therapy programs.
- Clinical: Providing patients with a point of contact during trials and

- assisting with transitioning from clinical to commercial drugs, specifically clinical trial support and risk evaluation and mitigation strategies.
- Engagement: Granting patients access to programs via traditional and
 emerging channels that will help support their unique treatment journeys
 and enable better long-term treatment outcomes. Specific engagement-related solutions include enrollment and consent, case management, patient
 adherence programs, portals, assistance with appointments and scheduling, mobile health monitoring, telehealth, and advocacy.
- Education: Delivering educational insights to inform patient decisionmaking and behaviors. Solutions include medical information and pharmacovigilance, nursing educational support, and between-visit care.

In order to evaluate their current patient engagement maturity levels, pharma companies should examine their current patient engagement strategy, service offerings, and enabling technology on the following parameters:

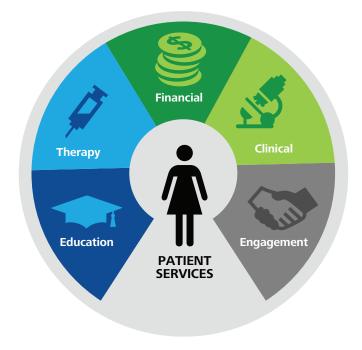


Figure 1. Five key needs to address with patient services offerings

Graphic: Deloitte University Press | DUPress.com

- Do you know, specifically, who your patients are?
- Are you meeting those patients' demands for support services?

- Do your services serve to optimize patient outcomes?
- Do your technology solutions allow you to leverage data as a strategic asset?

While these questions may seem simple, our experience working with pharmaceutical companies on products spanning primary care and specialty therapies suggests that some companies may struggle with the answers. In the case of two specialty biotechnology companies with analogous therapies, one could easily retrieve and view a report of all of their prescribing physicians and the active patients associated with each physician, while the other could obtain only the raw number of new patient referrals from their physicians, with no link to those patients' information.

Figure 2 describes a maturity model for patient engagement capabilities based on our experience with life sciences companies. As discussed, maturity levels across companies are highly variable; maturity in patient engagement has not been correlated to the overall maturity of the organization.

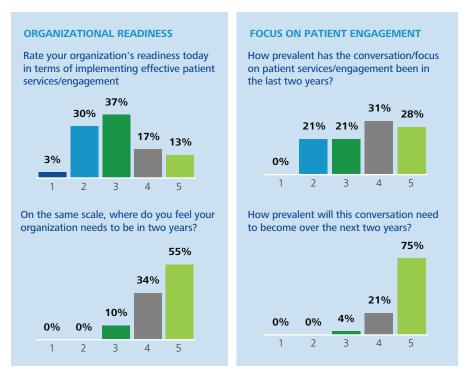
Figure 2. Illustrative patient engagement maturity levels



Figure 3a. Patient engagement maturity and readiness

Pulse on patient engagement: Survey responses (1/2)

Workshop participants completed a short survey on patient engagement topics; there were 30 respondents.



Most respondents (70%) indicated that their organizations were moderately/somewhat ready to implement effective patient engagement strategies.

However, **more than half (55%)** felt they needed to be "extremely ready" in the next two years.

The focus on patient services over the last two years varied across organizations, but **75% agreed** that it needs to become "extremely prevalent" in the next two years.

Graphic: Deloitte University Press | DUPress.com

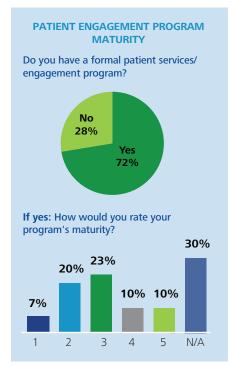
WHERE IN THE ORGANIZATION IS PATIENT SERVICES?

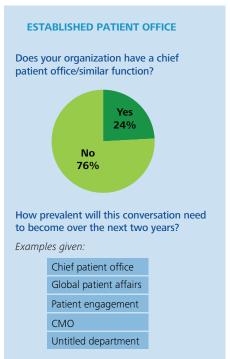
ariability of maturity levels also stems from the variability in organizational structure within pharmaceutical companies. Patient services groups may be structured as part of the market access and reimbursement center, as a separate group within the commercial unit, or as a standalone center of excellence. One company's patient services group resides within the market access organization; at another, the market access group was completely unaware that the company even had a patient services group. Some companies maintain an operational firewall between marketing and patient services, while at others the two work together. Some companies rely on marketing to define the patient engagement strategy and use

Figure 3b. Patient engagement maturity and readiness

Pulse on patient engagement: Survey responses (2/2)

Workshop participants completed a short survey on patient engagement topics; there were 30 respondents.





Most companies (72%) have established formal patient services programs, but half of them rated their program's maturity as moderately mature or not at all mature.

Some companies have established an office dedicated to patients (i.e., chief patient office); the names/titles/roles vary across organizations.

Graphic: Deloitte University Press | DUPress.com

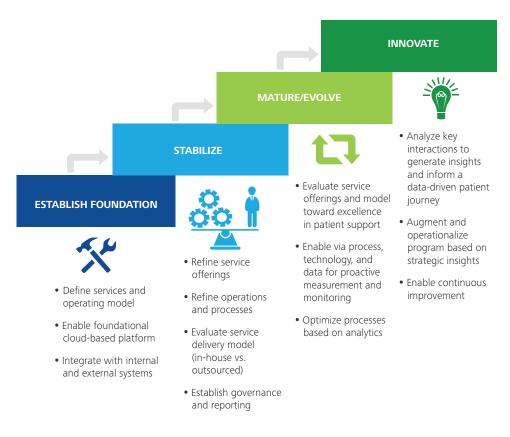
patient services only as a means to execute that strategy; elsewhere, companies empower other patient services groups to define and implement adherence strategies and interventions, within marketing and legal guidelines. The bottom line is that there are any number of ways to structure patient services within an organization; so if the current structure isn't effectively supporting and executing the patient engagement strategy and therapeutic outcomes, alternatives and precedents should be considered.

All of these variations contribute to a wide range of maturity levels in patient services offerings. A recent Deloitte Consulting LLP survey also suggested that life sciences commercial leaders recognize a gap between current patient engagement capability maturity and where they would like their companies to be¹⁴ (figures 3a and 3b).

No matter where patient services resides, a common platform across the organization and its vendors is becoming increasingly important, and is an effective way to leverage data as a strategic asset. Indeed, ownership of data has shifted to the forefront of patient engagement strategies. Whether engagement services are delivered in-house or by an external partner, life sciences companies are taking back control of their data by building a common, integrated platform for all of their vendors to use. Over the last three to five years, we have observed life sciences companies beginning to implement cloud-based platforms on which internal and external users can access the same platform, allowing the company to centrally control data access, ensure data quality, easily generate real-time reports, and quickly distribute system updates to all users.

Depending on a company's maturity level, its need for patient engagement enablers will be different. Figure 4 depicts four phases of operationalizing patient engagement services. For example, a company at the "aware" or "practicing" maturity level would likely need to start at the beginning and establish a foundational, common platform to enable its patient engagement and services strategy.

Figure 4. Stages of operationalizing the patient engagement strategy



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Establishing the foundational strategy, service offerings, and enabling technology is the first step, and either the pharmaceutical company or a vendor can put it in place. Hybrid models—employing a combination of in-house resources and outsourced partners to execute different services—are the most common and recommended based on a company's core competencies. We have observed a trend toward bringing more services in-house to improve service quality, consistency, and adherence to the overall patient service strategy. As such, services that are good candidates to be delivered in-house may require a *high level of control*, help to demonstrate a differentiated level of service, quickly effect change, directly impact the company's brand, or support strategic customer relationships. In addition, these services are usually *less transactional in nature*, requiring strategic thinking and case-by-case handling.

The 2x2 matrix in figure 5 shows one way that services can be evaluated based on these two domains (level of control and transactional nature); services in the lower right quadrant are in the sweet spot for in-house delivery and a high level of control. Services falling in this quadrant include differentiating patient interactions such as case management and, also, the common data platform—as companies value control and ownership over their patient and provider data.

HIGH Potential to insource or Outsource with defined processes and SLAs outsource with strict process Level of transactional activity controls MEDIUM **Outsource/shared** Sweet spot for insourcing service LOW MEDIUM HIGH. **Desired level of control**

Figure 5. Illustrative assessment criteria for service delivery decisions

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Once a strategy is in place, companies can engage with patients throughout the product life cycle

Pharmaceutical companies can also consider patient engagement across the product lifecycle, from clinical development through product launch. Critical and meaningful opportunities exist to engage patients and use their insights to drive the company's strategy (figure 6).

Strategy **Exploratory clinical Full clinical** Production & Life cycle Launch development development distribution development management Manufacturing Sales and marketing Strategy R&D Post LOE Market access Logistics Patient engagement examples Capture patient Personalization Patient Personalization Adherence Research oriented by insights during managed of packaging to of messages programs patient insights patient needs services Education Affordability RWE-driven • Recruitment Protocol design through remote • Distribution programs development adherence and & management technologies through (apps, sensors, social media) follow-up tools Patient outcome partnerships Formulation Personalized for clinical trial and experience decisions based reimbursement programs monitoring Direct patient Patient on patient supply (rare preference Patient-centric Chief patient reference Social listening disease models) protocol design officers groups Homecare **RWE-driven** pathway collaboration complaint primary analysis outcomes analytics

Figure 6. Illustrative patient engagement examples across the patient life cycle

Graphic: Deloitte University Press | DUPress.com

For example, enrolling patients into clinical trials represents considerable time and cost, as companies work with clinical sites to find patients who meet inclusion/exclusion criteria and manage their treatment through multiple study visits. (Patient recruitment contributes to 32 percent of clinical trial costs.¹⁵) Enrollment and keeping patients enrolled throughout the trial can account for significant delays in study timelines, representing between a third and half of the total study duration.¹⁶ This points to the need for a patient-centric model for clinical trials to improve the operational efficiency of patient recruitment and increase patient retention and to introduce innovative solutions to enhance patient recruitment and retention processes and procedures.

Newer approaches to patient recruitment and retention will be needed to address today's challenges. For emerging technology-based innovations to drive clinical trial efficiency, they need to be patient-centric, data-driven, and flexible. For example, pharmaceutical companies can support global and remote recruitment, enrollment, and retention through similar patient service strategies used post product launch. These strategies can aim to reach patients located far from typical clinical trial centers, maintain the commitment and interest levels of patients who are recruited prior to study start-up, provide support between visits, and help bridge medication gaps following study completion.

In addition to clinical trial success and recruitment by pharma companies, patient engagement is set to become prominent in regulatory decision making. In September 2015, the FDA launched the Patient Engagement Advisory Committee for medical devices, intended to advise companies on how to engage patients during the development and assessment process, including taking patient preference into account by understanding which risk-benefit trade-offs are most important for patients and the relative importance of different device attributes.¹⁷

While the FDA's Center for Drug Evaluation and Research has not yet announced a similar patient engagement body, pharma companies are looking to the FDA for further guidance about its stance on patient engagement as it relates to the drug development process, including when it is appropriate for companies to engage with patients. Without FDA guidance, companies may hesitate to engage patients during clinical trials and prior to product launch, despite the benefits.

UNDERSTAND THE OPPORTUNITIES

iven the new patient-centered health care ecosystem, the cloud-based technology platforms that can enable leading patient engagement strategies, and the growing competitive environment for pharma companies as previously consumer-focused firms enter the patient engagement market, pharma companies need to ask key questions about their current strategy, products, capabilities, and offerings:

Do you fully understand the patient market you are addressing—and its key pitfalls? If the answer is no, life sciences companies can leverage patients and providers early to provide insights into key elements for designing a patient engagement strategy, such as patient motivators, most bothersome symptoms, and the nuances of the patient-provider relationship in that therapeutic area. For example, patients with hypertension—a large group of patients who often intentionally don't adhere to their oral medication regimens because they don't like taking pills—require different engagement strategies to motivate them to stay on therapy than hemophiliacs, a smaller and tight-knit community of patients who tend to interact via community groups on a regular basis and know their providers personally, but may struggle with injection of medication at home.¹⁹

Are you providing leadership for your patients and health care providers when it comes to clinical education and therapy administration? Some pharma

companies are stepping in to supplement clinical education for patients or office staff, as an added-value service to health care providers. As providers may not have the time to spend an hour per week with a patient to discuss the causes of a new chronic obstructive pulmonary disease diagnosis, offer smoking cessation support, and train in the proper technique for using an inhaler, pharma companies are training their own nurse educators, or the provider's site staff, to provide this ongoing support and additional education to patients.

Are you optimizing patient pull-through and adherence to your product(s)? If the answer is no, companies need to explore how they can move the needle on patient start-up and adherence activities in the short term (for example, implementing a program to provide patients with starter doses while waiting for reimbursement or offering medication reminder programs via email, text, or phone calls) and further standardize those support efforts in the long term through established programs (for example, appointing case managers or specialists to help patients work through reimbursement issues preventing them from beginning recommended therapy or developing a companion app to track patient adherence to doses and customize reminders).

Are you supporting health care providers' efforts to improve patient outcomes? If not, consider how your providers are equipped to measure patient outcomes and collect real-world evidence, as payers continue to shift their focus toward proof of outcome. Pharma companies are building tools and platforms to collect and analyze data, shouldering some of the burden of evidence for their providers. Furthermore, patient engagement programs that demonstrate a link to improved outcomes will build brand loyalty and trust for the pharma company among patients, providers, and payers alike.

If a company cannot answer yes to these questions, it should take steps to rectify this before new players replace it. In the new digital age where patients behave like active consumers, they will expect to be engaged accordingly. Pharmaceutical companies should ensure they are central to the conversation, or they will be left out as others in the health care ecosystem engage patients with information and support. DR

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The authors would also like to acknowledge support and development assistance from **John Choi**, **Candy Lurken**, and **Ryan Myers**.

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