Executive summary

The biopharmaceutical industry is currently facing a number of macro-environmental factors, which underscore its need to think of itself not as a developer of singular products, but as a critical part of an interoperable system. This fundamental shift must include a strategic approach for engaging with an increasingly informed and connected patient population.

The amount of medical information now available to patients online is truly remarkable. Coupled with a decrease in the amount of time physicians can actually spend with their patients, today’s healthcare consumers are savvy, engaged and have a strong desire to learn as much as they can about their diseases.
Executive summary, continued

By not directly engaging with patients, biopharmaceutical companies are missing an enormous opportunity to reduce the time and cost of clinical development and maximize the return on their development investments. However, by earning patient trust and creating a two-way dialog, some companies have been able to engage patients to participate and remain in research; prove product value and safety by directly gathering personal outcomes, medical records, and diagnostic data from labs or devices; and accelerate product adoption and adherence.

This white paper discusses how biopharmaceutical companies can harness the power of the digital patient when it engages them in the appropriate manner. Quintiles’ Health Engagement & Communications was founded to continue to innovate around these areas of opportunity.
Introduction

Today's patients have a growing intellectual curiosity about their own health and a desire to gain the knowledge needed to empower them to advocate on their own behalf. Increasingly, patients are searching for health information online via a growing cadre of digital tools that enable self-education and greater personal control, even before consulting their physicians. Patients then use what they’ve learned online to enhance the dialog with their healthcare provider; they now enter the conversation about their healthcare needs far more informed than at any other time in history.

While dramatic advancements in communications have empowered the digital patient, eroding patient access to physicians has accelerated their plight. Physicians are now seeing nearly 17% fewer patients per day than they did in 2008.¹

Among other reasons, these dynamics are fueling the patient empowerment movement.

Patients, in fact, may be the most underutilized resource in the healthcare system, because many of the traditional approaches for interacting with patients were born in an unwired century. Understanding the digital patient and enabling them to become actively and appropriately involved in achieving better healthcare outcomes must become a new priority for the healthcare industry.

The key to success in the age of the digital patient is to think about the patient as being at the center of the healthcare and communication network and establish relationships to make it easier for them to participate in their own healthcare.

By properly engaging with digital patients, more effective healthcare products can be developed at significantly less cost and time compared to what the industry has spent in years past. Engaged patient relationships can also be leveraged to study product value and safety, and also to help biopharma companies maximize the return on their development investment through realization of time and cost efficiencies in product development and patient retention during product commercialization.

The changing dynamics of patient engagement

The 20th century, one-way communication model

In the controlled world of 20th century communications, biopharma companies had fewer ways to disseminate clinical research data, which facilitated a centralized approach to sharing this information. At the center of this model was the biopharma company with strategic communications targeted primarily to physicians. The physician received the message and then passed this information along to the patient as appropriate. This company-centric, cascading method was simple, understood by all parties and relied on the physician to be the conduit of all good patient information (see Figure 1).

The reality, however, is that patient care varies dramatically depending on physician knowledge and access. With limited interaction with their physicians, patients were often unaware of various treatment options. The chances of being informed about participation in the development of a clinical trial for a new therapy were purely serendipitous and virtually unheard of.
The evolution of direct-to-patient communication

Understanding the limitation of the traditional, one-way communications model, the biopharmaceutical industry lobbied to accelerate the awareness and education process with direct-to-consumer advertising (DTC), particularly in the United States.

This newer model biopharma still controlled the message development and delivery, but added general media to its communication mix. With greater awareness, patients can now be informed of new treatments and encouraged to speak with their physician to find out more (see Figure 2).

The age of the digital patient

We have now entered an era in which the digital world will dramatically shape healthcare, much as it has done to other industries. Today is the age of the digital patient – with the patient at the center of the networked environment – and patients are actively seeking information about their health without the constraint of geographical boundaries or physician intermediaries.

The impact of direct-to-consumer advertising

A 20-year communication strategy and investment in US direct-to-consumer (DTC) advertising proved effective for the industry. A 2003 study conducted by the Harvard School of Public Health – Demand Effects of Recent Changes in Prescription Drug Promotion – found that for every additional $1 the industry spent on DTC advertising in 2000, it earned an additional $4.20 in sales. Advertising via the internet comes with an even bigger payoff: Data show a 5:1 return on investment for online consumer advertising, which far outstrips earnings from either print or television ads.

Yet DTC’s impact on public perception is mixed. A number of studies conducted since the 1990s indicate that consumers’ feeling about pharmaceutical advertising is neutral, at best, and in some cases, they found the public to be skeptical of the messages.

In addition, advertising has not had a profound effect on clinical research participation. In fact, during this same time, any benefit of DTC advertising has not kept up with supply and demand. The number of patients per investigator has decreased significantly during this time period, and the number of patients indicating that they have been approached to participate has not substantially changed.

Finally, although this advertising theory effectively helps drive awareness and demand, it falls short in actively involving patients to help prove economic value and has amplified the safety issues inherent in any drug, with many more people actively medicating to modify their conditions.
The search for healthcare information is the third most common activity taking place online. Nearly six in ten patients (59 percent) turn to the internet first when researching a health concern – before talking to their friends, parents, spouse, or even their doctor. Additionally, 65 percent of internet users experiencing a medical crisis go online for health information. To be successful in the age of the digital patient, biopharma companies will need to be expert in their ability to interact with patients who are equipped with information and empowered to approach their healthcare providers based on this information obtained on the internet.

Harnessing the power of the digital patient

At the heart of engaging the digital patient is a relationship built on trust. As with any relationship, it starts with an introduction (awareness), which can happen at any number of digital destinations. By continuously providing content that has clear utility to that individual, the relationship can progress to familiarity and favorability. Providing content to patients on demand (as requested) begins to build a two-way dialog through which a trusting relationship can be forged.

With incentives aligned, the digital patient wants to participate in creating better health outcomes. In fact, patients will go “out of their way” to help. Quintiles published research across 206 feasibility and recruitment screening studies involving 8,599 patients indicate that 72 percent of patients are willing to be contacted to participate in clinical research, and 81 percent of patients are willing to provide personal health information to assist in observational research. More importantly, this participation is happening in practice. Quintiles’ Health Engagement & Communications is actively engaging more than three million patients, some of whom have already participated by providing direct, longitudinal data about their personal reported outcomes, medical records, lab samples and device data across a number of studies.

Engaging the digital patient in this manner makes it simple for the patient to participate, and far more cost-effective and expeditious for the biopharma company.

Harnessing the power of the digital patient will have a profound effect on:

- Streamlining product development
- Accelerating product adoption and adherence
- Demonstrating product value and safety
Figure 4

Streamlining product development

The ability to conduct clinical research efficiently is dependent upon enrollment into clinical research studies. Yet, more than 90% of industry-sponsored clinical trials experience delayed enrollment, and 37 percent of investigative sites fail to enroll a single patient. A lack of study participants creates delays in new drugs entering the market, which not only prolongs the time it takes to get new therapies to patients, but also adds to the overall development cost to the biopharma company. In addition, failure to enroll the necessary number of patients at each investigator site in a timely manner can compromise a trial’s statistical power and scientific validity. The use of digital tools and online communities offers a host of opportunities to improve upon the clinical research process from beginning to end. Specific uses include:

Informing the study protocol design

By connecting to and communicating with patients online, valuable information can be gleaned to inform the protocol for each study. What impact does each inclusion and exclusion criteria have on patient eligibility? Are patients motivated to participate in the clinical trial? What are the triggers that facilitate or prevent them from participating in a given design? How best to message to these patients?

Typical feasibility assessments are based, for example, on population, disease prevalence, investigator networks and historic recruitment rates for condition. Truly understanding and quantifying patient motives may have the largest impact on recruitment of them all.

Supplementing investigator recruitment

Referring patients to investigator sites has been done for decades with varying degrees of success. As noted previously, however, the mass advertising technique and old-school theories are over. Mass advertising is wildly inefficient, with the average cost of referral as much as 100 times the cost of digital referrals. The patient database theory (i.e., having a pre-existing list of patients with the noted condition) has also yet to be proven cost-effective for anything other than finding patients with very rare conditions. This low return on investment is often due to: 1) large costs in analyzing the data to find potential candidates, 2) time/cost associated with outreach to the potential candidate’s managing physician, and 3) the lack of motivation of the patient’s local physician who neither has the time nor the financial incentive to act on this request. In fact, in countries such as the United States where patients have a choice of physician and physicians are paid based on encounters, there is actually a disincentive for referral.

The new big database of patients today is the digital universe and the more than 2.4 billion internet users across the globe. It is always up-to-date and includes everyone who is actively seeking health information. Existing, active patient communities where large numbers of patients seek participation in clinical research provide a wealth of opportunity for engaging with patients. Outside of the active information seekers, there is an even broader database of passive observers who may choose to act on healthcare information obtained through day-to-day social interactions.

Quintiles has sought to harness the power of the digital patient with two online communities. Launched in 2007, MediGuard provides free medication safety monitoring to more than 2.6 million registered users. ClinicalResearch.com provides social networking opportunities and information about clinical trials to 250,000 patients. Users who register on these sites are sent notifications about local clinical trials. Additionally, at the end of 2012 Quintiles launched “I Am More than Lupus,” a Facebook page with more than 35,000 fans that provides a place where people dealing with lupus, and those who support them, can get information, make connections and find ways to improve their lives.
Driving study retention and alumni communities

Although patient adherence is a widely publicized issue in the product commercialization phase, it is often overlooked in the product development phase. Building patient communities for a specific research drug not only improves the recruitment process, it also transforms the communication model between biopharmaceutical companies and patients.

Cultivating long-term patient relationships during clinical trial recruitment can build on itself by making it easier to recruit patients for future trials well in advance. Historically, patients deemed inappropriate for participation in a particular trial were released and ultimately lost. At the beginning of each trial, therefore, researchers started from scratch. By using digital tools to obtain and retain the information gathered pre-trial, an available pool of patients interested in participating in research, along with their clinical information, is readily available.

Perhaps most important, however, is how building communities better serves the patients who contribute valuable time, energy, and in some cases obtain a sense of hope from the clinical research trials in which they participate. At the conclusion of a trial today, study results are often poorly communicated to patients. Yet, the industry has an ethical obligation to inform patients of a trial’s outcome, and the use of digital tools makes it possible to live up to that obligation and create an alumni community out of the patients who participated in a clinical trial.

Accelerating product adoption and adherence

The opportunity to engage patients in their own healthcare does not stop at regulatory approval. Upon product launch, the objective is clear for biopharma and patients alike: to enable as many patients to benefit from the product as possible. This takes on two forms: product adoption and product adherence. Driving both ensures the greatest marginal return along the product lifecycle for biopharma companies and the best patient outcomes for the greatest number of people.

With an embedded universe of engaged patients made possible by the clinical trial alumni community, there is ample opportunity to help accelerate the product adoption process. Typically, there are hundreds of clinical trial alumni, and, as a result of product approval, most of them have already experienced the benefits of the product. The engaged patient relationship enables the biopharma company to immediately contact these patients and notify them that the product is commercially available.

Extending the solution further is the opportunity to engage these early adopters to become advocates for any number of patient education campaigns. These trial alumni can provide the first testimonials, ready-made, even before the first script is written. Their stories can be integrated into physician detail aides, on the product website, and if carefully directed, on social networks consistent with appropriate regulatory guidelines.

In addition, data from these patients on their patient-reported outcomes – quality of life, work productivity, etc. – can be extremely helpful in supporting market access by integrating this data into formulary dossiers and budget impact and other health economic models. Finally, the information from these patients can be a supplement to the observational and market research being conducted to better understand patient attitudes, behaviors, and treatment patterns as they change over time with introduction of other new products and services.

The challenge is greater than simply getting patients onto the therapy – it’s maintaining therapy. With an engaged patient relationship, this is made possible. The key to success is three-fold: understanding patient motivation, providing value-added services to drive that motivation and enabling contact via the appropriate communication vehicle.

Increased retention

A recent study undertaken by Quintiles and a large biopharma company sought to understand drivers for patient participation in research. With a single informed consent document on file for the 1,255 people in the women’s health study, a customized communication plan with patient preferences for contact was created for each individual. With the ability to notify patients who might otherwise be lost to follow-up or drop out of the study entirely, the customized communications program kept patient interest high and resulted in a 59% increase in retention for the duration of the study.
Again, it starts with appropriate understanding of the patient needs, achievable only if you have a direct line to patients and have sought their advice and input. Ongoing contact methodologies are fully dependent on patient needs and capabilities of that audience. Value-added services will range dramatically, but at the heart are educational content and a point of escalation to a nurse advisor.

**Demonstrating product value and safety**

Increasingly, healthcare payers and provider organizations are looking for proof of economic value when making decisions about which therapies they will and won’t reimburse. At the same time, regulators are increasingly insistent upon measuring ongoing product safety. Biopharmaceutical companies face the pressure of doing both and typically use a combination of physician-constructed patient registries and long-term investigator follow-up.

Both of these tried and true methods are important, and can be enhanced or in some cases offset by direct-to-patient methodologies. Executing direct-to-patient engagement strategies requires a unique combination of patient engagement and analysis made possible by collecting patient reported outcomes (PRO), medical records and in many cases lab data. By working directly through the patient, we can now conduct some types of observational research by obtaining consent for medical record access, generating a laboratory prescription for sample collection, and/or delivering a DNA collection kit directly to the patient’s home. Similarly, we can collect data from a growing universe of biosensor devices. In addition to validating patient condition, this linkage between PRO, electronic medical records (EMR), laboratory information (Labs), and device data (Device) begins to closely approximate the type of information that can be generated through longitudinal, physician-based, observational registries (i.e., PRO+EMR+Labs+Device).

Further, directly engaging with patients in this manner enables remote follow-up of clinical trial participants. Instead of asking a patient to return to their physician for assessment, outcomes data can be gleaned from the patient him or herself, thereby reducing study attrition as well the considerable time and cost of traditional physician-based follow-up.

While engaging patients directly has demonstrable benefits in terms of accelerating research, designing clinical studies that more robustly address the needs of patients, and facilitating patient access to new therapies more rapidly, it is essential that such interactions respect the integrity of patients. The means by which these interactions occur are as important as the benefits that they provide to patients, families and society. Commonly accepted medical ethics such as respect for privacy, beneficence, transparency and informed consent are important components of interactions with patients.

**The digital patient’s impact on future research**

The digital patient is pushing the biopharmaceutical industry to make fundamental changes, many of which present solutions to a number of the industry’s biggest challenges. Harnessing the digital universe can not only help to save money from the healthcare system, but also improve patient outcomes. Online patient communities represent new opportunities for the industry, and help to raise patient awareness about clinical research, how to manage and cope with illnesses and available treatments.

Investing in patient-driven services and online communities that help to build a networked model of communication among patients, their healthcare providers and other stakeholders will be critical for the biopharmaceutical industry going forward. Companies that embrace the idea of digital patients and learn to successfully engage with them will distinguish themselves.

**Involvement related to outcomes**

To determine disease involvement relative to patient outcomes, Quintiles recruited 425 patients with chronic obstructive pulmonary disease (COPD) from its online patient community. As a further sign of patient willingness to participate in research, the first digital patient in was enrolled in six minutes and the last digital patient in was confirmed in a mere nine calendar days. Using traditional recruitment methods, a study this size would normally take several months at significant cost to complete enrollment.

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References


5. Ibid; page 6.

6. Ibid; page 8.


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David Coman is the Senior Vice President of Communications and global head of Quintiles’ Health Engagement & Communications. David formed Quintiles’ Health Engagement & Communications to provide digitally-connected patients with information to better manage their personal health and to offer them opportunities to participate in clinical research, observational studies and programs to better manage their conditions. At the core of Quintiles’ Health Engagement & Communications is its ability to develop, maintain and interact with patient communities, including its flagship websites: www.MediGuard.org (with 2.6 million subscribers) and www.ClinicalResearch.com (with 250,000 subscribers).

As head of Quintiles Communication, David also leads the company’s corporate digital strategy, thought leadership, media relations, internal communications, corporate citizenship, crisis management and messaging.

Prior to joining Quintiles in May 2008, David served as Chief Marketing Officer at Dendrite (now Cegedim). David has held executive leadership positions in high-growth telecommunications companies, including AOL Local & Long Distance (Talk America), Excel Communications and Aerial (now T-Mobile), where he initiated groundbreaking direct-to-consumer strategies. He began his career with Young & Rubicam, a world-renowned advertising agency, for clients such as AT&T, Miller Brewing Company and Xerox among others.

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Jeffrey A. Spaeder, M.D., is Chief Medical and Scientific Officer for Quintiles. In this role, Dr. Spaeder serves as Quintiles’ lead medical expert, representing the company’s position on a wide variety of governance, ethical and scientific issues. He chairs Quintiles’ Drug Safety Committee, serves as vice-chair of Quintiles’ Council on Research Ethics, and provides guidance on strategic scientific initiatives.

Prior to joining Quintiles, Dr. Spaeder served in increasingly senior roles within the biopharmaceutical industry at Takeda and Abbott Laboratories and was previously a cardiologist at Johns Hopkins Hospital. He has performed research in personalized medicine and novel uses of telemedicine, and holds U.S. patents for medical applications of advanced technologies, telemedicine and information systems.

Dr. Spaeder is a graduate of the Pennsylvania State University and the Johns Hopkins University School of Medicine. He also holds a Master of Business Administration (MBA) degree from Northwestern University with a concentration in finance. He is a Fellow of the American College of Cardiology and a Diplomate in cardiovascular disease with the American Board of Internal Medicine.