

### CONNECTING THE DIGITAL DOTS

*Digital health – patients’ use of mobile devices, wearables and connected virtual assistants to deliver health – is becoming integrated into virtually every aspect of healthcare. Innovative applications relevant to the pharmaceutical industry include identifying patients for therapy, enhancing the value and outcomes of treatment, engaging patients and tracking disease severity in clinical care and trial settings. Adoption of, and investment in, these technologies has now scaled to the point that pharmaceutical companies are developing and pursuing comprehensive digital health strategies. A foundational factor in drawing insights from the data derived through digital health channels is data connectivity. Linking data alone is not enough. By using real-world data methodologies, we can ensure that digital-health data produce reliable and unbiased evidence, and we can trigger changes in care management that ultimately enhance patient outcomes.*



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# Through connectivity, digital health is shaping the future of the pharmaceutical industry

Digital health is booming. According to the IQVIA Institute, there are currently more than 318,000 health apps to track, measure, access and connect healthcare stakeholders and over 340 consumer wearable devices available; with more than 200 new health apps added to app stores every day.<sup>1</sup>

While venture capitalists were once the primary investors in digital health, activity has spread to other sectors including insurance and pharmaceutical companies. In 2016, \$4.2 billion were invested in digital-health companies.<sup>2</sup> For their part, pharmaceutical companies are shifting their focus from simply providing drug-specific patient apps to developing digital biomarkers to track patient outcomes and gain a competitive advantage.<sup>3</sup>

Payers and providers are realizing the potential value that digital-health solutions have for addressing their needs. Anticipating the cost-savings potential of digital health, payers are starting to promote the use of digital-health interventions and to reimburse patients for them. For example, virtual office visits are gaining interest, since the charges are up to 40 percent less for primary care and 20 percent less for urgent care. Payers also recognize that digital health encourages the transition from a fee-for-service model to a value-based model by producing a variety of data on the quality of the patient-centered process and outcomes that can be gathered and analyzed quickly.

Physicians also see that remote monitoring gives them the opportunity to connect with their patients and better manage health outcomes; and patients are ready to implement this technology.

## CAPITALIZING ON DIGITAL HEALTH THROUGH DATA CONNECTIVITY

Since digital-health technologies, devices and applications are by definition electronic, one byproduct and underlying benefit of their use is the potential for data connectivity. Perhaps the greatest value of digital health is in collecting, analyzing and acting on data from multiple sources to better understand how medications, devices and services are used in the real world. For example, digital health gives us the ability to connect data from mobile devices with de-identified patient behavioral information and electronic medical records (EMRs) to arrive at a 360-degree view of patients and their needs.

Digital-health technologies generate so much data that the volume of data available, not to mention the variety of sources, can quickly become overwhelming. How can a pharmaceutical company devise a successful digital-health strategy, decide which technologies and sources are best suited to a given business need and sift through the incoming data to extract the relevant and reliable information? It's a daunting challenge that a few leading companies are beginning to tackle. Those that don't follow suit and are late in using digital health data may find that the world – or at least their competition – has passed them by in gaining real-world insights and engaging patients in ways that were never before possible.

Figure 1 on the next page shows a high-level view of various digital health sources and their accompanying insights and applications that are of interest to pharmaceutical companies.

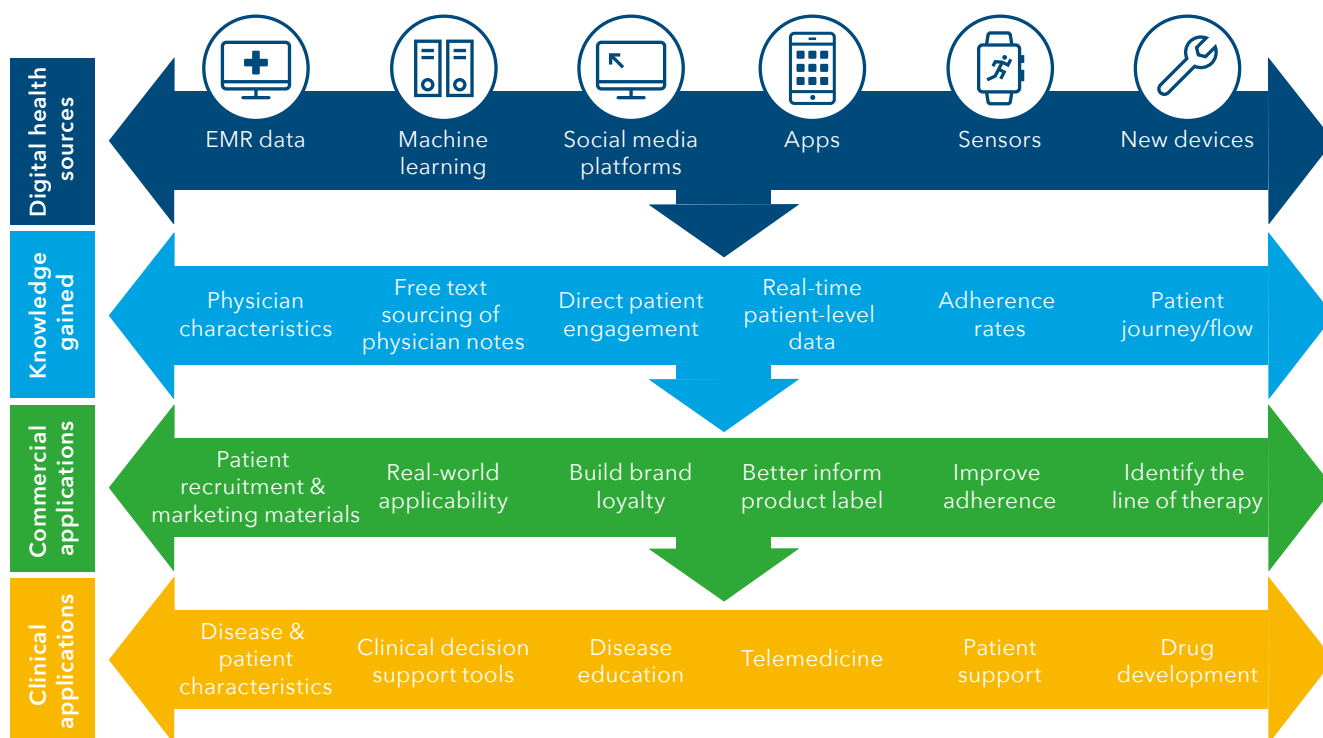
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***IQVIA has found that 40 to 42 percent of patients who are prescribed an app will engage with the healthcare professionals' digital health recommendation as delivered via IQVIA AppScript™***

# NEW APPLICATIONS OF HUMAN DATA

Figure 1: Clinical and Commercial Applications of Digital Health



## THE REGULATORY CLIMATE

Regulators are becoming more patient centric in their evaluation of treatments. The U.S. Food and Drug Administration (FDA) launched a patient-focused drug development initiative acknowledging, “the review process could benefit from a systematic approach to obtaining the patient’s perspective on disease severity and current available options in a therapeutic area.”<sup>4</sup> Indeed, there has been a shift away from traditional biomarkers as the primary endpoint for clinical outcomes with a simultaneous increase in patient-reported data.

More recently, the FDA has created a digital-health unit housed within the Centers of Devices and Radiological Health (CDRH). That unit has expressed excitement over “the convergence of medical devices with connectivity and consumer technology,” recognizing the power of digital health to gather the patient perspective.<sup>5</sup>

While not wanting to overregulate digital health, the FDA has been working to provide clarity using practical approaches that balance benefits and risks on a wide range of devices and technologies. The 21st Century Cures Act, enacted in December 2016, clarified that certain digital-health technologies, such as applications that encourage a healthy lifestyle, fall outside of FDA regulation. In addition, the FDA has launched a

pre-certification pilot program, through which the agency pre-certifies application developers that meet certain criteria. At this writing seven have already been approved.

## GETTING CLOSER TO PATIENTS, ELECTRONICALLY

The pharmaceutical industry’s traditional business paradigm – manufacturers serving patients through other stakeholders (usually payers and providers) with little or no direct interface – has always put the industry at a disadvantage when it comes to understanding and relating to its customers. Consequently, pharmaceutical companies have struggled to move beyond product orientation to patient orientation. This gap is amplified by the growing tendency for patients to behave as consumers of healthcare products and services, bringing an increasing demand for real-time, transparent and personalized information to help them make decisions.

Thanks to digital health, it’s far easier for pharmaceutical manufacturers to understand, reach and support their consumers and enhance their user experience (see page 32 for an innovative example around patient care pathways). The IQVIA Institute predicts that within 10 years, the use of digital patient engagement tools related to specific conditions will be mainstream for healthcare companies.

## FOLLOWING THE PATIENT JOURNEY

The opportunities for using digital health span a patient's medical journey from pre-diagnosis to remission, as seen in Figure 2. It's possible to integrate data captured throughout the lifecycle to better understand patient and provider decisions, treatment choices, disease progression and experiences in the real world.

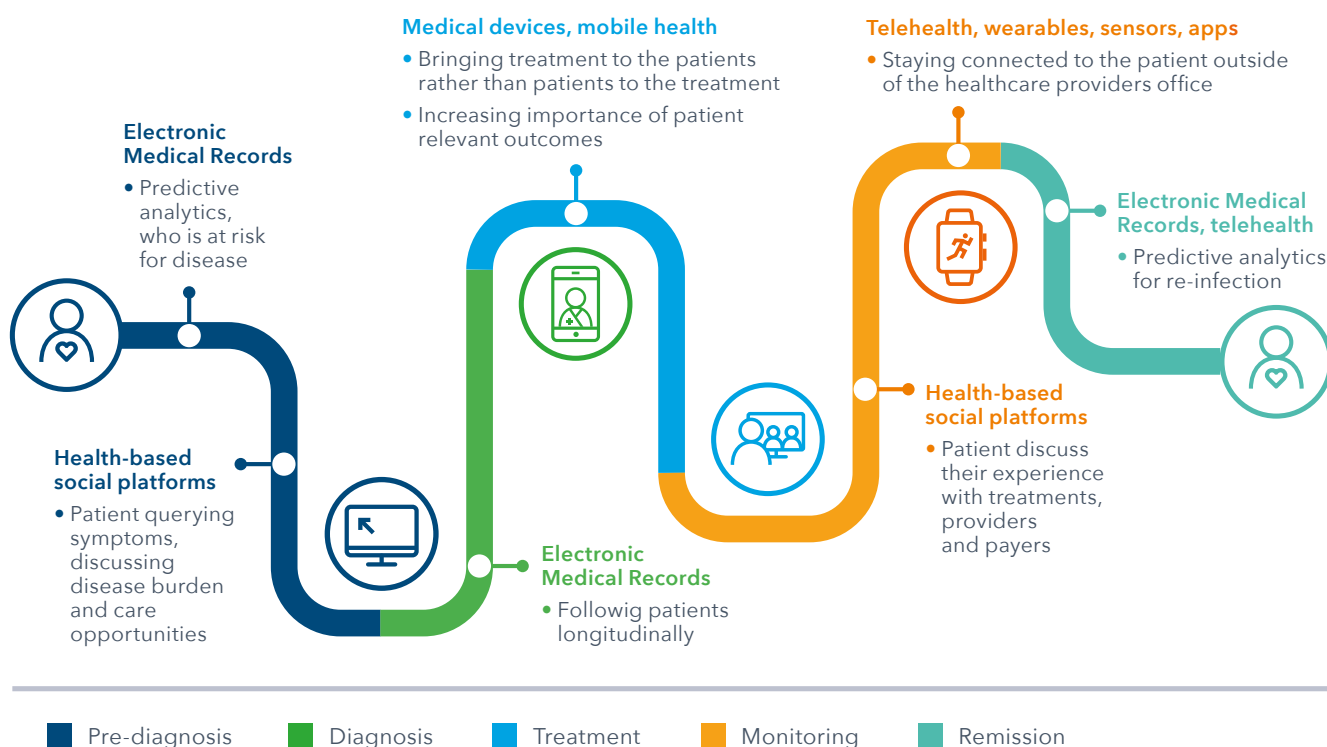
Integrating digital-health data with that derived from the broader health system is the way to unlock its full potential. By linking data from direct-to-patient digital solutions (such as electronic, patient-reported outcomes (ePRO), mobile apps and sensors, and social media communities) with disease registries, EMR, claims data and laboratory data, it is possible to associate patient behavior with clinical outcomes. Ultimately, this insight allows pharmaceutical manufacturers to maximize the commercial value of their products.

## SOCIAL LISTENING AS A WINDOW INTO PATIENT BEHAVIOR

*To understand treatment switching patterns and the underlying drivers of switching decisions in multiple sclerosis, IQVIA combined "automated listening" and processing with manual analysis to gather data from social media websites, advocacy group forums and patient blogs. We captured language referring to switching between oral, injectable and IV therapies and extracted over 25,000 data points - more than 10,000 of which were relevant to the study objectives. The study revealed that treatment switching was most common for injectable therapy users, primarily due to side effects and lack of efficacy. Following our analysis, the company has invested in developing a command center to conduct further research via automated social listening combined with manual analysis.*

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**Figure 2: For Pharma, Opportunities to Leverage Digital Health Exist Throughout the Lifetime of a Patient's Condition**





# NEW APPLICATIONS OF HUMAN DATA

## GOING BEYOND THE PILL TO TRUSTED PARTNERS

With digital health, pharmaceutical companies can get much closer to patients, interacting with them through digital media. By creating a dialog and sharing data, they can foster a relationship and create brand loyalty. Many of the tools of relationship marketing, from creating a sense of belonging... to showing appreciation... to delivering a personalized customer experience are now available to companies. Ideally, their relationship with patients can evolve from being product suppliers to trusted resources that provide integrated patient solutions. Providing digital “wraparounds” to therapy is becoming a new area of competition for manufacturers.

### Improving adherence with personal proof points

Medication alone can only do so much to improve a patient’s health. This is especially true when patients are not adherent or persistent in taking those medications as prescribed. A recent review in the *Annals of Internal Medicine* reported that 50 percent of medications for chronic diseases are not taken as prescribed, regardless of the severity of disease.<sup>6</sup> This lack of adherence costs the U.S. healthcare system between \$100 and \$289 billion a year.<sup>7</sup> Digital health is helping to combat this, as evidenced by the IQVIA Institute, which shows that medication reminder apps now account for 11 percent of all digital health apps.<sup>8</sup>

An array of digital-health solutions are available to support patients in their wellness and health management regimens. For example, pharmaceutical companies are investing in digital-enabled smart devices such as asthma smart inhalers, connected pens for diabetes and smart blister packs. Both consumers and manufacturers are looking for ways to validate

these new digital health tools. By linking the data from mobile apps, for instance, to real-world clinical outcomes, the claims of the apps can be verified.

## SUPPORTING DRUG DISCOVERY AND DEVELOPMENT

Pharmaceutical companies are also beginning to use digital technologies in clinical research, increasingly making use of apps to collect PROs or to gather real-world data. They are looking to build in endpoints derived from digital health that can help to differentiate their products. At the moment, most experimentation is confined to the use of digital health in Phase IV trials, as there is some risk involved in using it in pivotal trials, at least until digital measures are validated.

Digital-health technology improves the efficiency of clinical trials in a number of ways. Solutions for identifying sites, targeting and recruiting the right patients, collecting PROs, gaining digital consent, screening patients remotely and conducting virtual trials all have proven themselves. They reduce resources, optimize site selection, speed enrollment and support rapid decision-making through immediate access to data.

Complementing this, biosensors, predictive analytics and novel patient assessment media lead to new discoveries, reduced time to insight, optimal patient identification and commercial effectiveness.

## BRIDGING THE GAP BETWEEN CLINICAL AND COMMERCIAL

Digital-health technologies also help bridge the gap between a product’s performance in clinical trials and in the real world. Clinical trials typically have specific

## CASE STUDY #2

### VALIDATING A PATIENT SUPPORT APP

*To evaluate the effectiveness of a mobile app in improving patient persistence in staying on cholesterol-lowering therapy, IQVIA undertook a retrospective, matched cohort study. We de-identified the list of the app users and linked it to our prescription database, creating a corresponding control group based on therapy type and key demographics. We then calculated therapy persistence using drug refill status for six months following the first treatment. The investigation showed that patients using the digital health app had a 15 percent higher persistence rate than those without it. The company used these insights to design a randomized study to build an even stronger base of evidence.*

inclusion criteria, strict protocols and close patient supervision, while the real world is made up of a diverse patient population, multiple treatment alternatives and limited patient follow-up. Several digital-health tools can be used to enhance the breadth, depth and follow-up data collection efforts enabling patient centric data collection in various healthcare settings from the hospital to the home. Such tools include those used to improve compliance, identify target patients, educate patients and allow physicians to monitor their patients remotely. Digital health tools can help, along with traditional biomarkers, to stratify patients by their symptoms and self-reported assessments of benefits and risks (as identified by sensors). This insight can be used to identify the right patient for treatment at the right time, as well as to track disease severity.

Using digital-health solutions in this way has the potential to lead to better outcomes, increases the drug's value to the healthcare system, reduces uncertainty for payers and providers, and mitigate the overall risk to pharmaceutical companies in outcomes-based contracting.

## **FIVE STRATEGIES TO COMPETING IN A DIGITAL WORLD**

As is the case with adopting so many innovations, pharmaceutical companies that integrate digital health technologies into their clinical and commercial business strategies will need to make organizational changes in staffing, processes and technology. In particular, companies will need to

### **1. Connect digital devices with clinical data.**

In order to validate the use of new and existing digital devices, it is important to validate them with clinical endpoints. Connecting information obtained from digital technology with clinical information provides deeper insights and understanding of patient behavior. When linking data across sources, it is extremely important to ensure the data cannot be decrypted and individual patients identified.

**2. Develop a digital health strategy.** Companies should begin with a comprehensive strategy that lays out how to draw upon the best solutions to further their business goals. Having everyone informed of the goals helps in implementing any new strategy. If employees know why something is being done and are briefed on the end objective, they are much more likely to be onboard.

**3. Be proficient in mining Big Data.** Data from digital health applications is the very definition of Big Data. Not all of it will be good, and not all of it will be applicable. Finding the right data and proper analytics is key to a successful digital health implementation. The appropriate real-world research methods must be deployed when mining digital health data to ensure valid, reliable and unbiased results are realized.

### **4. Optimize adoption of apps and devices.**

Digital-health technologies should be selected based on an objective rating of the investment made in them, development profile, strategic objectives and performance. Then, they need to be validated to ensure that they do what they claim to do before they can be applied with any confidence. This is also key for regulatory approval or implementing digital-health technologies as outcomes in trials.

**5. Continuously monitor digital health market updates.** Innovations in digital health are proliferating almost daily, and companies must commit to staying abreast of the almost continuous advances and to having an open mind about experimentation.

## **CONCLUSION**

Benefitting from digital-health data is all about taking advantage of the connectivity possible with electronic data sources. Companies that make connections across digital data sources and integrate into a common data model enjoy a more holistic view of the patient journey. These connected data will reveal new drivers and barriers that need to be addressed in order to improve the consumer experience.

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