

FROM BEHIND THE CURVE TO BEYOND THE PILL

HARNESSING THE POTENTIAL OF DIGITAL TO DRIVE REAL PATIENT-CENTERED MODELS

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Moving beyond the pill implies a smarter, more connected approach to healthcare – one that places patients centre stage by capturing their preferences and data to inform developments and outcomes. While cynics might argue that such ideas are nothing new, the growing sophistication and ubiquity of smart devices and digital technologies is a game-changer.

Pharmaceutical companies may have traditionally been behind the curve when it came to adopting digital technologies, but they are increasingly embracing digital platforms as a means to connect with patients, devolve crucial evidence collection activities and enhance efficiencies. Likewise, patients seem willing to self-generate data through smart devices and applications where this drives beneficial outcomes, better disease management and enhanced therapies.

Of course, while more nuanced, data-driven understanding of patients and their promotion to active contributors is desirable, progress will depend on greater co-operation between stakeholders and overcoming many structural and commercial challenges. Accordingly, this paper draws on real world examples and case study evidence to highlight the developing relationship between digital technology and healthcare, while also addressing key issues and themes such as: how effectively can patient reported outcomes

(PROs) be digitised?; what is the nature of emergent partnerships between healthcare and technology companies?; how can payers' concerns be allayed?

Can Patient Reported Outcomes be Digitised?

The patient voice finds itself being accorded more weight in payer dialogue. In addition to the standard efficacy and safety dimensions, reimbursement decisions are gradually incorporating the impact of treatment on a patient's quality of life. For manufacturers, quantitatively characterising PROs using questionnaires has its limitations, notably the insensitivity of generic ones (e.g., EQ-5D and SF-36) to disease specific endpoints, the subjectivity of wellbeing, and the inability to continuously track patient progress. For patients, some might argue that the questionnaires do not accurately consider their daily experience if data collection is reserved for GP visits. These factors can negatively impact reimbursement decisions. Digital tools, such as smartphone applications, offer a novel way of measuring PROs and addressing both parties' concerns (box 1).

Although the use of electronic versions of traditional quality of life questionnaires has been accepted by payers, the widespread admissibility of complex, data-driven PROs remains uncertain as there remains validation issues. Responding to this problem, Mount Sinai Hospital conducted the Asthma Mobile Health Study, a remote,

smartphone-based study, and succeeded in verifying the consistency of PRO endpoints for asthma monitoring. Similar studies will be necessary across disease areas before we see active uptake by payers.

BOX 1

Launched in 2015, Apple's ResearchKit offers an ecosystem for conducting medical research through smartphone applications. Some pharmaceutical companies have already piloted software that allows for patients to self-generate PRO data:

- The PARADE study, launched by GSK, is a product-agnostic initiative looking to measure joint functionality in rheumatoid arthritis patients using a combination of daily questionnaires and exercises using the iPhone's built in sensors.
- VascTrac, developed by Stanford University, is a platform that augments disease management for patients living with peripheral artery disease. Collecting data on steps, stairs climbed, and a disease-specific endpoint (i.e., the maximum number of uninterrupted steps), it provides physicians with a more comprehensive perspective of patient activity between visits.

Wearables like Fitbits and Apple Watches could offer another way for patients to passively generate useful data—stress levels, for instance, could be inferred using sleep, blood pressure, and heart rate as proxies—but require more accurate sensors, improved software, and additional endpoints before they gain legitimacy as a PRO tool.

As it is not a matter of if digital PROs become an acceptable payer criteria, but rather when, pharmaceutical companies should be proactively developing and debuting digital applications in clinical trials that collect supplementary performance metrics tailored to the disease area.

Moving Towards Tailored Disease Management and Beyond the Pill Solutions

Moreover, self-generated data through medical devices can play a significant role in optimising the pharmaceutical management of patients living with chronic diseases. These high need patients require active monitoring and are susceptible to poor compliance over the long term, which ultimately increases health care costs to the payer. By continuously collecting information and training custom algorithms, digital drug delivery devices can help tailor care to individual patients' needs, boost adherence, and strengthen monitoring efforts. Connected devices are also a means for pharmaceutical companies to shift their business model to “beyond the pill” solutions (i.e., providing complementary services with their product) as a means of differentiation.

Remote monitoring has the potential to reduce the number of physician visits and consequently improve outcomes and quality of life in patients, free up short resources to providers, and deliver cost savings to payers. Partnerships have emerged between pharmaceutical and technology companies to develop ‘smart’ inhalers for asthma and COPD patient that delegate monitoring to an application:

- Novartis has partnered with Qualcomm Life to develop a next-generation Breezhaler™ inhaler that pushes usage data to the patient's device and to a cloud infrastructure for their physicians
- GSK in collaboration with Propeller Health have received FDA approval for a bolt-on sensor for the Ellipta inhaler that improves compliance and reduces asthma attacks by learning from treatment data and providing patients with personalised treatment recommendations

Digital tools do not necessarily need to be bundled with a product—treatment agnostic tools have demonstrated benefits in chronic disease patients. For instance, Proteus Discover, a platform linking ingestible sensors to mobile and physician portals, tackles subpar compliance. When used with conventional therapies for cardiovascular disease, the device improved blood pressure and LDL cholesterol levels compared to usual care. More efficient symptom management is another area of interest. A randomised study at the Memorial Sloan Kettering Cancer Center found that proactive symptom management in cancer patients using PRO insights collected through a web portal yielded a large, statistically significant increase in overall survival when compared to standard chemotherapy.

Over the coming years, we expect that chronic disease patients will become more autonomous in their care as they will be continuously connected to their service providers by a stream of self-generated data that pre-empts and actively manages their conditions. Pharmaceutical companies should be investing in this space to ensure the full benefit of their therapies are realised not only in real world use, but possible also in clinical trials to promote successful commercialisation.

Answering to Payers' Real World Evidence Concerns

The absence of real-world evidence (RWE) at the time of launch is an intrinsic limitation. Payers increasingly require a guarantee that new assets, especially very costly ones, perform equally well when taken out of the tightly controlled environment of clinical trials. In the absence of suitable evidence, performance-based managed entry agreements, potentially linking reimbursement to individual patient performance targets or the collection of confirmatory population level evidence, are sometimes used as contractual instruments to bridge the gap.

As health care infrastructure modernises and becomes digitally integrated, manufacturers can instead pre-empt payer challenges on RWE by collaborating with patients and providers to capture performance data. Electronic medical records especially have the greatest potential in this capacity due to the breadth of longitudinal information. Collecting RWE in this manner could revolutionise both clinical trial design and post-launch evidence collection commitments. In fact, the EMA has recently established a taskforce whose mandate is to evaluate how best to incorporate 'big data', such as EMR data, in clinical trials and marketing authorisation applications.

The Salford Lung Study, sponsored by GSK, provides an apt proof of concept for a "digitally enhanced" RCT. Published results from the pioneering study, conducted in situ in Manchester, England, revealed that Revlar Ellipta met its primary endpoint in COPD patients compared to usual care using only RWE data collected from EMR. Bespoke software integrated data from GPs, pharmacists, and hospitals in the NHS network, allowing investigators to monitor patients almost in real time as they interacted naturally with the health care system. The study generated a wealth of data that will continue to be analysed for additional patient outcomes over the coming years. The study coordinators noted, however, that it was logistically challenging, and was only made possible due to the extensive, existing EMR infrastructure not common to many health networks.

This is changing though, with healthcare providers seeing not just the internal efficiencies that such integrated networks can bring but also the opportunities for external collaboration. In late 2017, three NHS trusts in Dorset, England, announced a project, with the aim of producing a single care record. Amongst the many stated benefits for this project was the impact it could have on medical research and how attractive this could be for pharma, opening several interesting opportunities with regards a RWE.

The Salford study marked the first departure from the purist approach of conventional randomised controlled trials (RCTs), and we anticipate that additional studies will embrace the novel design due to the advantage of RWE in reimbursement decisions. Given their comparatively basic needs, post-launch observational studies could be early adopters of the integrated EMR approach. With sufficient centre coverage it could ultimately remove the need to establish drug-specific registries. From the patient perspective, the new design shifts their role in clinical development from being a subject to an active contributor. While data privacy concerns still dominate, analogues in other regulated and sensitive industries like finance suggests that patients are interested in engaging and sharing sensitive information so long as they ultimately benefit from the exchange. Pharmaceutical companies will consequently need to engage directly with patients, as opposed to having an indirect relationship through healthcare providers.

Why Invest in Digital Solutions

With expectations set by the digitisation of other aspects of their lives, patients serve as the impetus for the uptake of digital tools in health care. There is a rising willingness of patients to self-generate data through devices and applications so long as it can improve their outcomes, disease management, or even advance the ongoing development of therapies for their condition. Digital solutions are well-placed to help address current commercialisation issues related to the generation of reliable PRO data, lagging compliance, the collection of RWE, and to increase the quality of care through personalised insights. Bundling products with digital services could grant a competitive advantage to manufacturers and represents a welcome shift towards a business model focused on comprehensive patient care.

As payers are still discovering the appropriate reimbursement model, manufacturers should look to develop an innovative framework in collaboration with the authorities and internally, strive to:

- Incorporate digital solutions as an additional dimension to commercialisation decisions, preferably early in the drug development process
- Develop new internal processes that stimulate innovation in digital services
- Gain early alignment on payer data needs to feedback into the clinical development process
- Collaborate with payer and other stakeholders to validate self-generated patient insights
- Collaborate with health care providers to generate longitudinal data and RWE using integrated care records
- Understand the implications of a data-centric business model on the roles of traditional market access and commercial business units

Manufacturers should consider the intensified focus by payers on real world evidence and value “beyond the pill” as an opportunity to co-develop a portfolio of digital services that engage directly with patients to improve outcomes, drive efficiencies, and reduce health care costs.



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