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Pharma's path to market for digital health solutions:

navigating the commercial, data, and regulatory challenges

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Introduction

Pharma's approach to digital health is maturing fast. Companies are now investing more in digital health solutions designed to deliver value at a clinical, patient, and commercial level. The era of early tactical experimentation with pilot solutions, which often had limited scope for deep commercial and clinical impact, is well and truly over.

Pharma is now more strategic with digital health solutions; requiring them to play a significant role in building, supporting, or improving on the core pharmacological business.

In contrast to digital wellness or digital marketing efforts, digital health solutions are intended to have an impact on clinical and healthcare outcomes and, as such, are more complex and held to more exacting regulatory, legal, and technical standards. Creating them and bringing them to market requires a clear understanding of the responsibilities, regulatory requirements, and the possible risks. While they require more investment, effort, and oversight, pharma stands to gain much more from digital health solutions.

Digital heath is an umbrella term that covers a range of digital solutions, including digital medicine, digital therapeutics (DTx), and digital therapy management.

Defining digital health solutions

We define digital health solutions here as solutions that deliver a health benefit directly to the patient or work directly to enhance the benefits of a pharmacological therapy, for example by gathering useful data and providing support that improves efficacy or adherence. They often have a health and/or economic value attributed to them, which could be reimbursed in certain circumstances and markets.

There are levels of reward and complexity within the various types of digital health solutions. Solutions that require the most clinical evidence, come with increased regulatory burden and workload during development, however, they have the greatest potential for impact and reward for the pharma company.

Digital heath is an umbrella term that covers a range of digital solutions, including digital medicine, digital therapeutics (DTx), and digital therapy management. Not all digital health products will meet the regulatory definition of a medical device or software as a medical device (SaMD), and so will not require the same regulatory rigor in that regard. Those that are classified as SaMD usually require more evidence than others.

A level of clinical evidence is required whenever clinical claims are made. These types of solutions can be defined as evidence-based software and/or hardware products that measure and/or intervene in the service of human health, for example digital diagnostics, digital biomarkers, or digital support software.

Digital therapeutics (DTx), for example, are often complex and require clinical evidence, proof of real-world outcomes, and varying degrees of regulatory oversight. These products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.

This paper does not concern itself with digital health marketing initiatives or general wellness products – such as consumer wellness apps on smartphones. Digital health solutions require a more nuanced and thorough approach than digital wellness and marketing efforts yet offer much greater value and potential return in exchange.

Good quality, useable data is the lifeblood of any digital health solution. Analyzed data, collected via a digital health solution, can be used to support claims for clinical effectiveness and impact; it is vital for reimbursement, market access negotiations, and tracking adoption and adherence to both the solution itself and, often, associated medication.

Data must be managed carefully, securely, and in compliance with regulations that often vary from country to country. For solutions launched globally or across geographically diverse regions, this point cannot be underestimated.

A solid strategy for regulatory approval is one of the key foundations for the commercialization of a viable digital health solution and requires a multi-disciplinary team from inside and outside the organization working closely together. Success also depends on understanding responsibilities that aren't always immediately apparent to companies more used to bringing pharmaceuticals to market rather than digital products.

Not least among these is the deep knowledge required of the extensive regulatory requirements that come with developing software as a medical device (SaMD).

Part of the challenge of a digital health solution versus a traditional pharmaceutical is their changeable nature; they have the potential to improve as their software evolves based on the data that they gather. Regulators and payors are still getting to grips with this as they adapt a process that was not designed to account for the rapid pace at which technology now moves.

On top of new challenges are the age-old, internal organizational and cultural hurdles that will slow the path to success if not tackled.

In response to these challenges, many companies are building the digital capabilities that they have previously lacked internally, are making acquisitions to bring experienced teams on board, or are partnering with specialist digital health firms to plug key gaps.

This white paper offers insights from several pioneers in the field of digital health and explores the challenges that they have overcome, the knowledge they have gained, and the approaches they now take as a result. They offer insights from how to approach legal and regulatory responsibility, to obtaining and managing the right type of data. We will explore how to gather the right internal support and build the right capabilities, partnerships, and commercial strategies to maximize the chances of success.

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