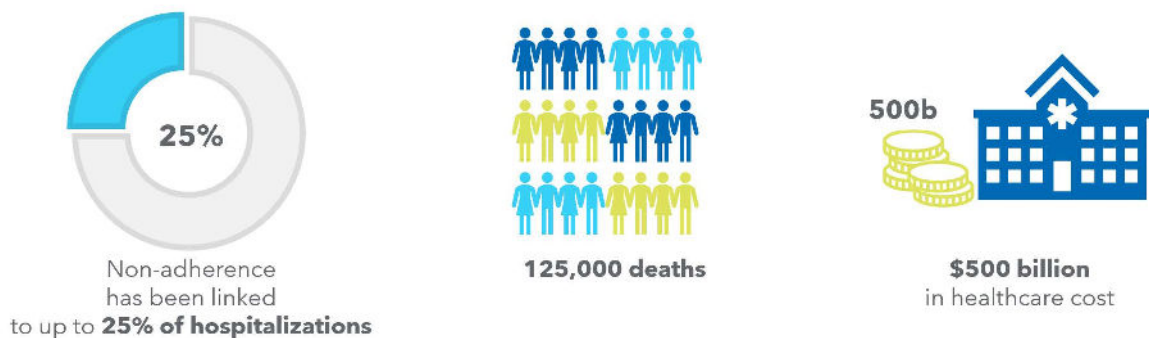


Reimagining Healthcare with Drug, Device and Digital Offerings

Simply prescribing a medication to a patient is not enough to guarantee that patients will take their pills and improve their outcomes. Non-adherence rates for medications that manage chronic conditions can be as high as 50%, and non-adherence has been linked to up to 25% of hospitalizations, 125,000 deaths, and more than \$500 billion in healthcare costs each year in the United States.

Impact of medication non-adherence per year in the U.S:



It is clear from these sobering statistics that healthcare needs to build a broad set of services around chronic condition management; a pill alone is not enough. This requires a holistic approach to care that uses digital therapeutics and medical devices alongside prescription drugs. Through this combination of drug, device, and digital offerings, physicians are better positioned to monitor patient progress, close care gaps, and address other unmet medical needs – and in the process, patients improve their physical and mental health while building valuable self-management skills.

At Aptar Digital Health, we partner with the pharmaceutical industry to bring to market a device and digital combined with their drug. We focus on chronic conditions that impact millions of patients in the United States and around the world – patients who often struggle to take their medications due to a range of factors largely outside their control. Our goal is to help these patients self-manage their medications and their conditions and achieve the clinical outcomes and quality of life they deserve.



The Benefits of the Drug, Device and Digital Approach

There are many reasons why patients may not take their medications as prescribed. They may be afraid of side effects or interactions with other medications they already take. They may face physical or mental health barriers to taking a drug, such as memory impairment or difficulty self-injecting due to arthritis. They may not be able to afford a medication, or they may lack transportation to the pharmacy where the prescription has been sent. They may not be motivated to take a pill, either because they have not been educated on its importance or because they view taking medications as a sign of weakness.

It is not enough for pharma companies to just manufacture medication and assume that it will end up in the hands of patients who need it. Likewise, it is not enough that healthcare providers just prescribe medication and assume that the patient will take it as directed. This approach looks at the medication in isolation when, in fact, patients face additional clinical and non-clinical burdens to taking the medication in their everyday lives. Failing to address these issues only makes healthcare services and therapeutics more inaccessible to certain patient populations, further increasing gaps in health equity, quality of life and mortality rates.

That is why providers and pharma companies need to work together and create a comprehensive set of holistic services that go “beyond the pill,” giving patients the guidance and support they need to take their medications and giving providers insight into whether a medication is working as it should. Increasingly, these services consist of a drug, a digital therapeutics (DTx) application that guides patients through their treatment journey and a medical or remote monitoring device that tracks vital signs, symptoms and other metrics that give providers insight into how a patient is progressing.

By enabling a more personalized treatment, drug, device and digital offerings benefit both patients and providers. Patients receive significantly more support and engagement in between in-person episodes of care; this helps them self-manage their condition, strengthens their self-esteem and reduces their anxiety. Providers can keep a closer eye on patients, which helps to prevent disease progression and reduce unnecessary hospitalizations – both of which lower overall healthcare costs.

Developing an Integrated Drug, Digital and Device Solution

Creating a solution that can deliver the right therapy with the right intervention for the right patient at the right time is no small task. That is why the most successful drug, digital and device solutions are developed from the very beginning as comprehensive wrap-around offerings. The earlier that these three elements are considered as part of a single solution, the greater the likelihood that the solution will align with a company's broader commercial strategy. This approach also ensures that the drug, digital and device elements will come to market as a single, integrated solution and not as a set of standalone products that require custom interactions.

In building a solution that will add value for a pharmaceutical company, **there are five important considerations.**

One is **linking a new solution with an existing brand.** Since both providers and patients are quite familiar with already existing brands on the market, this approach removes a common barrier to new product adoption. As a result, pharma companies can focus the conversation on key benefits of the new solution and spend less time providing general education about the brand itself.

The second is **emphasizing a demonstrable and measurable impact.** Providers and patients have more options for managing chronic conditions than ever before. They are most likely to choose a solution that addresses an existing unmet medical need. Does the product reduce their disease burden, increase the accessibility of treatment, provide new treatment options, and/or strengthen patients' abilities to manage their medications and their conditions? Keeping these questions in mind will help to ensure that a combined drug, digital, and device solution addresses a market need while providing value to the company.

The third is **integrating the governance and evaluation of digital health technology** in the same manner that companies are used to integrating the development of drugs and their accompanying medical devices. This may require involving the digital health team – whether it is internal or external – with those who are already working on drug and device development. While this may present operational challenges and upset the organizational chart, it will help to ensure that the digital health's teams innovative work is not done in a vacuum and bolted onto the drug and device combination once it is finished.

The fourth is **ensuring that a solution aligns with broader healthcare delivery trends.** A pharma company may have a grand vision for how physicians and patients will interact with solution. But several obstacles can hinder adoption: Fee-for-service reimbursement models, fragmented care delivery networks, limited incentives to improve patient engagement, electronic medical record systems that struggle to integrate with third-party solutions, operational models that do not support digital health tools, and so on. Companies should strive to minimize the potential for these barriers to prevent large-scale adoption while recognizing that not all provider organizations may be ready to take on a drug, digital, and device solution at this time.

The fifth is **understanding the complex regulatory landscape**. The U.S. Food and Drug Administration (FDA) applies different regulatory requirements to drugs, digital therapeutics, and medical devices. As a company designs and develops a combined solution, it will be imperative to manage each of these regulatory processes in tandem, as a delay or a lack of approval for one component will prevent the fully integrated solution from coming to market on time.

As the leaders of drug, digital, and device development initiatives push their products through design, development, testing and clinical trial, they must be prepared to encounter resistance. It is no secret that change comes slowly to the healthcare and life science industries, with new developments making their way into clinical practice 15 years or more after they were initially conceived. In fact, this cultural change is likely to be more difficult to overcome than the tactical, technical, and regulatory requirements of solution development, as these are well-documented and easily managed.



That said, the industry is beginning to recognize that digital health is really centered around health. Forward-thinking healthcare leaders increasingly recognize that the benefits of creating or adopting drug, digital and device combinations outweigh the risks and are repositioning their organizations for this future state. That is why it is critical to emphasize how the solution will improve clinical and financial outcomes and address unmet needs in the market – this will help to convince resistant leaders that a solution is worth pursuing.

Successfully Bringing a Drug, Digital and Device Solution to Market

Once a pharma company has completed its drug, digital and device solution, the next step is to bring the product to market. Here, companies need to be cautious as the commercialization strategy for a combined solution is different from that of a pharmaceutical product. Emphasis needs to be placed on how the integrated solution functions as a whole. It is more than a medication with proven benefits and potential side effects or a medical device that collects data on a specific vital sign.

Medication



Digital + Device Solution



Pharma companies should strive for an approach similar to how they begin conversations about targeted therapies. It is important to emphasize how the drug, digital and device solution:

- Integrates with their existing care model while minimizing the need for additional administrative work or adoption of intrusive technology;
- Addresses specific unmet medical needs for the targeted patient population in a way that other care pathways or treatment options cannot;
- Places patients at the center of their care and treatment journey, empowering their self-management and decision-making.

A second and related challenge stems from the nature of the business case for the drug, digital and device solution. Pharma companies in the United States have spent decades creating sales forecasts based on how they engage with physicians or market to patients, but forecasts for drug, digital, and device combinations depend on successfully and simultaneously selling to both physicians and patients. It is quite difficult to predict whether patients will engage with the combined solution as the pharma company or physician may have anticipated.

In this scenario, it is critical for companies to find ways to earn patients' trust. After all, many are unlikely to be accustomed to using either a medical device or a digital health tool to help them take their medications or manage their conditions. In addition, they may be accustomed to contacting their physicians directly when they have questions and receiving updated treatment plans or dosing recommendations during in-person medical appointments. Companies can position the combined solution to patients as a "doctor in their pocket," but only if they are able

to demonstrate that their solution provides an otherwise unavailable benefit to the patient's well-being and quality of life that is otherwise unavailable.

Successfully Bringing a Drug, Digital and Device Solution to Market

Pharmaceutical companies face a variety of challenges in developing and bringing to market combined drug, digital and device solutions. They must ensure that each product complements the other to form a cohesive solution, achieves distinctive and measurable outcomes while meeting complex regulatory requirements, and that physicians and patients alike are willing to adopt the solution for long-term chronic condition and medication management.



Given these complexities, it comes as no surprise that pharma companies have achieved the greatest success by partnering with leading digital therapeutics companies as part of these efforts. This positions the pharma company to lean on the expertise of its partners in designing, commercializing and obtaining regulatory approval for digital health platforms. With these partnerships in place, the pharma company can focus on its core competencies of developing and commercializing pharmaceuticals and medical devices, without the need to stand up a brand-new business unit.

However, pharma companies must choose their partners carefully. Digital health expertise on its own is not enough; pharma needs partners that have successfully created platforms that integrate with and support existing product offerings. Otherwise, the pharma company runs the risk of bringing to market yet another siloed solution that can only be integrated with existing offerings through complex and costly custom development projects.

At Aptar Digital Health, our drug, device and digital approach is materialized in several therapeutic areas:

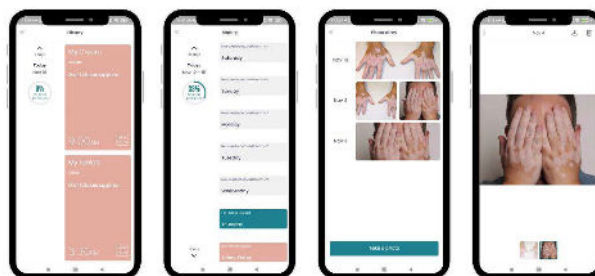
- For respiratory conditions, we developed multiple connected devices such as [HeroTracker Sense](#), a digital health solution that transforms a metered dose inhaler (pMDI) into a connected healthcare device helping patients to track and monitor their asthma or COPD.
- For immunology, we have partnered with [Stallergenes Greer](#) for the development of a new connected drug delivery device combined with a mobile app, the first of its kind, for patients undergoing allergen immunotherapy treatments with sublingual solutions.
- For oncology, we are developing a digital therapeutic to guide patients in the self-administration of their cancer treatment at home.

With our technology platforms, Aptar Digital Health has successfully built approved digital therapeutics in the US, European Union and Canada. Our successful track record of pharma partnerships with companies such as AbbVie, Bristol Myers Squibb, Novartis, Sanofi and Chiesi also positions us as a key leader in the industry. Aptar Digital Health is committed to creating device and digital solutions that meet the needs of patients, physicians and our customers.

About Aptar Digital Health

Aptar Pharma's Digital Health division is part of AptarGroup, Inc., a global leader in the design and manufacturing of a broad range of drug delivery, consumer product dispensing and active material science solutions and services. Aptar Digital Health creates end-to-end solutions to enhance patient experiences every day, leveraging a holistic ecosystem of digital interventions. Amplified by an industry-leading portfolio of products and solutions, Aptar Digital Health's offerings combine mobile and web apps, connected drug delivery systems, onboarding, training and advanced data analytics services to actively empower patients and create a positive treatment journey.

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1. Medication Adherence Is Not a Zero-Sum Game. American Journal of Managed Care. April 5, 2022.
2. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. July 5, 2018.