

New medicines entering clinical trials have <u>only a small chance of ever reaching the market</u>, but even after a therapeutic has been granted approval, ensuring that it can be accessed by all the patients whose quality of life it could improve remains challenging. More than <u>30% of drug launches miss expectations</u>, and even new treatments with innovative science behind them and strong efficacy profiles often fail to reach populations that could benefit.

Major barriers to drug access include medication costs, lack of insurance coverage, gaps in health literacy and provider attitudes and beliefs. Even when healthcare providers (HCPs) are able to offer the best-fit drugs to their patients, intentional and unintentional non-adherence is a prevalent problem with a significant impact on outcomes. It's estimated that <u>medication</u> non-adherence costs the U.S. health system as much as \$290 billion each year.

Amidst an increasingly competitive pharmaceutical landscape, it's essential — for the financial health of drug developers and the long-term well-being of patients — that new strategies be developed for pre- and post-launch support for new medicines. Gone are the days when a therapy, developed through clinical research and trials, could simply be commercialized, with success expected as a natural outcome.



Instead, pharmaceutical companies can address the greatest barriers to drug access head-on by developing digital tools, connected devices and companion apps that educate patients, verify insurance benefits, support providers, simplify medication administration and improve adherence. In today's world, medicines should no longer be thought of as standalone products, but instead as part of an interconnected care ecosystem whose effectiveness can be boosted by the appropriate use of technology.

"After the publication of new FDA guidance on prescribed digital health solutions, it will become increasingly common for physicians to prescribe clinically validated, insurance-reimbursable digital applications alongside a drug," says Marcus Bates, Vice President for Global Business Development and Global Head of Respiratory at Aptar Digital Health. "In the future, patients will often take the two treatments — the drug and the digital application — alongside one another, and they'll both be regulated as medical treatments."

In this playbook, we'll take a closer look at five ways digital health solutions can bolster the efficacy of promising new therapeutics, from helping patients receive and HCPs deliver high-quality care to expanding the reach and success of the therapeutic.

## **Companion App Benefits Across** the Therapeutic Lifecycle



Identify potential patients earlier



Improve therapeutic adherence and reduce patient leakage



Map treatment progress and symptoms



Make it easier for HCPs to provide high-quality care



Gather real-world data



## **Identifying Best-Match Treatments for Patients**

Many diseases aren't diagnosed immediately after the patient notices symptoms — in some cases it can be years until the patient receives an accurate diagnosis. In the interim, the patient may experience discomfort, stress and anxiety. Their disease may progress, leading to additional complications. They may have lower chances of successful treatment and recovery, especially if advanced disease states require the use of invasive procedures with higher complication rates. For life-threatening conditions like cancer, early diagnosis can greatly increase survival rates. Proactively anticipating disease progression can also better match patients with the appropriate treatments.

Pharmaceutical companies that help HCPs diagnose diseases earlier and more accurately can benefit from expanded market opportunities for their products. They can also improve patients' quality of life while increasing the treatment's potential effectiveness and lowering care costs.

Digital health solutions are now available that can accelerate time-to-diagnosis for a variety of conditions ranging from psoriasis to chronic obstructive pulmonary disease (COPD). Earlier diagnosis means patients gain access to effective treatments earlier, relieving them of discomfort or a sense of social stigma (in the case of atopic dermatitis or psoriasis, for example) or improving treatment efficacy to limit disease progression and increase life expectancy (for COPD).

Among other innovative uses, Software as a Medical Device (SaMD) solutions can leverage Al-powered image recognition to differentiate skin conditions such as psoriasis, atopic dermatitis (AD) and skin cancer from other conditions with high levels of specificity. These tools can also perform severity scoring, making it easier for HCPs to recommend medications or therapies suited for an individual patient's circumstance and condition and identifying if the patient might be a good clinical trial prospect.





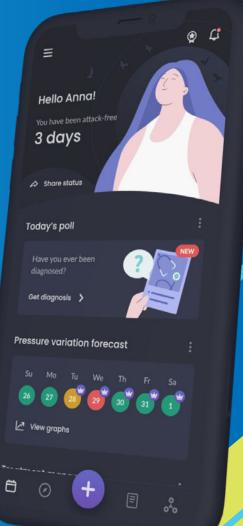
#### **Accelerating Migraine Diagnosis**

Migraine is the third most common illness worldwide, impacting an estimated 1.1 billion people. The underlying biological mechanisms that trigger migraines are not fully understood, but the disease has a major impact on patients' quality of life, leading to increased absenteeism from work or school and a greater risk of depression and anxiety.

Migraine Buddy, a digital health solution, was developed to enhance the quality of life for people living with migraine symptoms. The direct-to-consumer app facilitates the tracking, reporting and self-management of symptoms, and this information can be shared with clinicians to accelerate diagnosis and fine-tune treatment options.

Millions of patients across 132 countries have used Migraine Buddy to keep tabs on their condition, improving their access to more personalized and effective care.







# Improving Adherence and Reducing Patient Leakage After Prescription

Even after patients receive accurate diagnoses, many barriers remain that can prevent them from obtaining the appropriate treatment and continuing to take medications for the prescribed duration.

#### **Financial Concerns**

Financial issues are among the most significant of these barriers, especially in the U.S. Approximately <u>one in three Americans report foregoing necessary medical care due to costs</u>. Even for those with employer-sponsored health insurance, paying for treatment can be a hardship. As many as 38% of insured adults in the U.S. say that they sometimes delay care or skip necessary medications because of high out-of-pocket costs.

#### **Non-financial Barriers**

Non-financial barriers can also inhibit treatment access in ways that have a significant impact on patient outcomes and their quality of life. People may need help understanding their condition and the treatments they need, as well as with learning to administer their medications correctly and on the right schedule.

"Being diagnosed with a new condition can be overwhelming," says Bates. "You're in a doctor's office, you've been told that you have, for instance, a chronic immunological condition, and you're confronted with loads of new information that you're expected to remember. At the same time, you have to go on managing your everyday life, but with this new added stress."



Putting effective support in place can dramatically reduce the amount of patient leakage that occurs between the initial provider visit where the diagnosis is obtained and the start of treatment.

An automated prior authorization management solution can reduce the number of time-consuming tasks that HCPs, pharmacists and care managers have to perform. By helping patients understand their benefits and treatment options, this kind of solution can make it easier for them to get started on the best-possible treatment path.

**Digital training and onboarding kits** within a digital health tool can help patients understand how to take their medications correctly. This can be particularly helpful when patients have to master new and potentially difficult administration methods like self-injection.

#### **Empowering Patients, Reducing Anxiety, Improving Adherence**

Aptar Pharma partnered with a specialty pharmacy in the U.S. to conduct a study analyzing whether a <u>digital patient onboard</u> <u>training and engagement solution</u> could improve adherence for self-injected medications. The control group received support representing the standard of care, while the intervention group had access to a traditional patient education solution.

#### The results:

improvement in time to firs injection administration

40% improvement in achieving greater than 80% percentage of days covered

15% improvement in time to ordering first refill

29% improvement in medication adherence at six months

Patient-reported outcomes in the intervention group included greater confidence, feeling better prepared to take the medication and reduced anxiety.

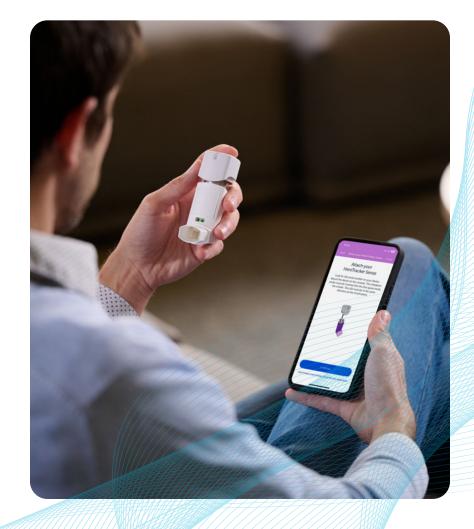


## **Advancing Treatment Management**

Digital health solutions can help patients better understand the progress of their treatment, whether they're administering drugs correctly and how best to manage symptoms and side effects. This boost to their health literacy can empower them to engage more effectively in their own care. Research has shown that this improves both outcomes and satisfaction with care experiences. Similar benefits are seen among pediatric patients, as well as for their families and caregivers.

For example, a mobile-enabled app for people with chronic skin conditions allows the patients to upload pictures of the affected areas for HCP review. The app also creates a repository of images, making it possible for patients to keep track of changes over time. This can help them understand which treatments are most effective, and what other circumstances may be correlated with improvements in their condition.

These mobile apps can also be connected to smart drug delivery devices to help track dose frequency, send reminders when it's time for the next dose and even ascertain that the medication is being administered correctly. Caregivers can also use these solutions to, for example, get alerts from the app telling them whether the prescribed treatment regimen is being followed by the patient.





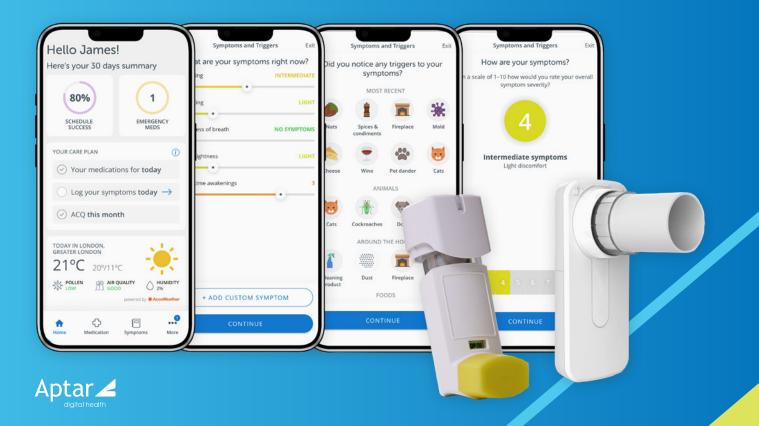


## **Enhancing Asthma Management**

Respiratory conditions like asthma and COPD can be debilitating, but patients who learn to treat themselves at home — consistently taking their medications the right way, at the right time — have improved outcomes.

<u>BreatheSmart</u> is an innovative mobile app that's part of the ADH Respiratory Disease Management Platform, which includes a connected metered dose inhaler (MDI) and a connected spirometer. These technologies make it possible to monitor the amounts and frequency with which doses of medication are taken by the patient, alongside a set of lung function markers. The information can be shared with HCPs and used to help patients understand trends in their health and disease progression.

The ADH Respiratory Disease Management Platform aims to enhance patient engagement, improve medication adherence and facilitate better communication between patients and their care teams by helping HCPs make decisions that improve their patients' quality of life.



## **Supporting and Engaging Healthcare Providers**

With burnout endemic among medical professionals, it's imperative for pharmaceutical companies and the entire healthcare ecosystem to help providers work smarter, partnering with them to achieve better outcomes for patients with less stress and administrative burden. Tools that lighten the load on HCPs while improving patient adherence and outcomes ultimately lower healthcare costs while giving providers better on-the-job experiences.

As mentioned earlier, automated solutions that help patients navigate the prior authorization process save time and administrative effort for provider organizations. They also make it easy for physicians to make better decisions about what to prescribe, since they can see at a glance whether a particular therapy will be covered by a patient's insurance.

Companion apps that share insights on patients' symptoms, disease state and medication adherence can also help HCPs make smarter decisions. Careful attention to user experience design is important, because HCPs are busy. They need the right amount of information — enough to provide visibility without causing overwhelm.

"Digital health solutions should not be designed so that HCPs are led to believe that they need to do more because huge volumes of data are being sent their way," says Bates. "It's important to be thoughtful and focus on simplicity. ... How much data should be shared in real time, and how much should be put into a concise report that's available at the time of the visit?"

"The goal is to deliver something that can be read and understood in less than a minute, so that most of the physician's time can be spent on what's most important — interacting with the patient."

- Marcus Bates

Vice President for Global Business Development and Global Head of Respiratory at Aptar Digital Health



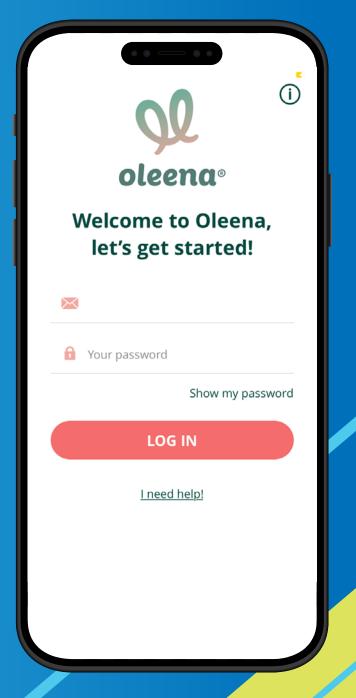


#### **Revolutionizing Cancer Treatment**

More than 18 million Americans alive today have had an invasive cancer diagnosis. More of these patients will experience remission, recovery and long-term survival than at any point in history, but 90% will also experience debilitating symptoms, and over 33% will visit an emergency room for chemotherapy-related side effects at least once during their first six months of treatment.

Available only by prescription, <u>Oleena</u> is the first digital therapeutic for oncology patients in the U.S. When patients use the app to report their symptoms, they receive guided recommendations and support to help them manage their symptoms. The app also shares automated, adaptive insights with providers, highlighting the patient population with the greatest symptom severity so that providers know where to focus their attention. If symptom severity becomes too high for self-management, Oleena connects the patient to their care team.

Improving adherence by empowering patients to selfmanage their symptoms, this solution also enables HCP intervention when it's needed. This evidence-based approach is aiming to enhance the quality of life and improving treatment outcomes while increasing survival rates.

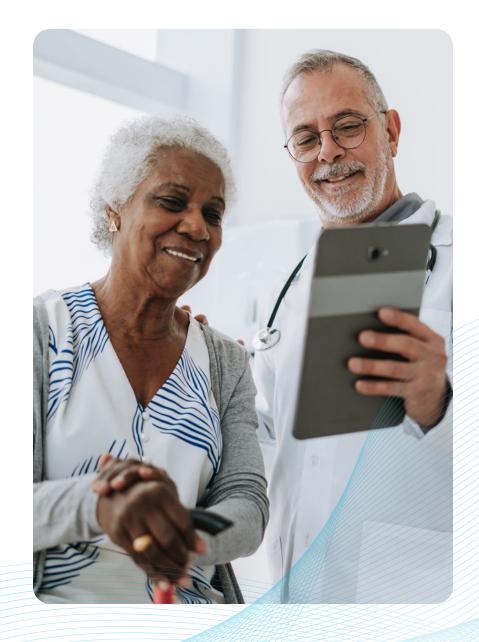




# Gathering Efficacy Data for Post-Market Research

Once a drug has been commercialized, post-market research remains critical for ensuring patient safety, product performance and regulatory compliance. By monitoring how the product works in real-world settings, pharmaceutical companies can identify adverse effects that may not have been apparent during clinical trials. They can also gain insights into how the product performs across various demographics, using these insights to optimize future formulations and improve patient outcomes.

Companion apps can provide drug developers with an indepth understanding of their product's performance via real-world data on the administration, side effects and efficacy profile of their medicine. It can also help them better target patient populations, both at launch and after the drug is established on the market. The potential for submitting companion app data to regulators is growing as these technologies come into more widespread use.







### **Conclusion**

Today's pharmaceutical companies can no longer rely on yesterday's strategies to support the launch and commercialization of their products if they are to ensure equitable care access and best-possible patient outcomes in a complex care landscape. Instead, they should be ready to think of drugs not as standalone products, but as part of a care delivery ecosystem that also includes companion apps, Software as a Medical Device and other technology solutions.

Aptar Digital Health helps pharmaceutical companies create digital assets that will maximize their products' ability to improve the lives of patients. With expertise in building both regulated and unregulated digital health solutions, Aptar Digital Health supports drug developers as they navigate the approval process and helps

them stay abreast of ever-changing compliance requirements. With a diversity of offerings and extensive in-house expertise, Aptar Digital Health is an ideal partner to help you engineer and build solutions that will improve user experiences for patients and HCPs alike. Aptar Digital Health's expertise extends across the entire process of conceiving, designing, delivering and operating a new digital health asset. Having developed one of the best-inclass platforms available in the industry today, Aptar Digital Health currently serves more than 4 million patients around the world. Aptar Digital Health's solutions provide a diverse set of features and industry-leading user interfaces.

**Learn more** 





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 offering combines mobile and web apps, Software-as-Medical-Device, connected drug delivery systems, advanced data analysis services and patient onboarding and training solutions to actively empower patients and create a positive treatment journey.

Aptar Pharma's Digital Health division is part of AptarGroup, Inc., a global leader in drug and consumer product dosing, dispensing and protection technologies. Aptar is headquartered in Crystal Lake, Illinois and has more than 13,000 dedicated employees in 20 countries.

For more information, visit aptardigitalhealth.com

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