Aptar digital health

Why Develop Digital Therapeutics in Oncology?

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Today, cancer remains a worldwide leading cause of morbidity and mortality. According to the report "Global Cancer Observatory" published by the International Agency for Research on Cancer (IARC), 2020 saw nearly 20 million new cancer cases globally and close to 10 million deaths . The five-year prevalence of cancer worldwide totals more than 50 million cases. By 2040, the same organization expects 30.2 new million cancer cases per year, which represents a 57% increase compared to 2020. Cancer care and treatment remains a specialty medicine that requires attention, monitoring and personalization of care due to various unmet medical needs:

- Lack of effective approaches to control cancer. For most advanced cancers, existing treatment options are not sufficient to offer a path to recovery, and many patients face no other option than palliative care.
- Treatment toxicity, management of side effects and impact on quality of life. Side effects related to treatment (including diarrhea, nausea, fatigue, pain, and vomiting) are common in cancer treatments. As they can appear early in the patient journey, side effects often lead to lower treatment adherence and poorer health outcomes.
- Insufficient access to affordable cancer care. In the United States, the annual cost of cancer treatment was an estimated $170Bn in 2020. This is an increase of 40% compared to 10 years earlier . One major factor in this increase is avoidable spending, such as costs related to unplanned hospitalizations or ER visits.

According to IQVIA Institute, oncology is the leading therapeutic area within the pharmaceutical market, representing around $273Bn and close to 20% of the total market share across all therapeutic areas. Oncology is also the leading area of R&D investment.

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Consequently, the next four years should see an increase in spending of more than $100Bn and the approval of close to 100 new oncology drugs.Thirty-three pharmaceutical companies with annual revenue above $10bn are active in oncology. With so many new therapies in development, finding strategies to bring innovative oncology drugs to market is, and will remain, a top priority.

Unfortunately, four significant challenges in the real-world setting can stand in the way of bringing innovative cancer therapies to market and putting them in the hands of patients who need them.

- Innovative therapies are inherently complex to administer, either because of technical requirements or their schedule of administration. This can lead to issues with dosage and adherence, and to poorer health outcomes.
- Driven by the need to decrease overall healthcare costs and facilitate care delivery outside the hospital setting, more innovative drugs are administered under limited supervision by trained, professional care teams. This trend is only expected to grow in the future.
- Side effects are very common in cancer therapies. Close to 90% of patients undergoing chemotherapy suffer from side effects. It impacts their quality of life and has a potential dose-limiting effect detrimental to clinical outcomes. While immunotherapy and other recent advances in medical oncology carry hope for improved efficacy, their toxicity profile is still not ideal.
- Novel cancer treatments emerging from precision medicines require greater personalization at the time of diagnosis and across the treatment journey. The "one-size-fits-all" drug development model is progressively disappearing in favor of a patient-centric approach where the type of therapy and its dosing schedule is calibrated differently for each homogenous group of patients or each patient. This profile can be derived from baseline characteristics, and from iterative feedback loops. After several months of therapy, three metrics can be used to make informed decisions on treatment strategies and adjustments:

» Data related to the patient's response,
» Reported adverse events, and,
» Overall impact on quality of life

Providing continuous personalized support and recommendations to patients facing these new challenges is key to reaching appropriate levels of adherence and better outcomes. Digital innovations can provide solutions to these challenges. For this reason, Aptar Digital Health has chosen to develop Digital Therapeutics (DTx) for the management of cancer symptoms with the clear objective to augment innovative drugs in the oncology space.

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The Value for End-Users

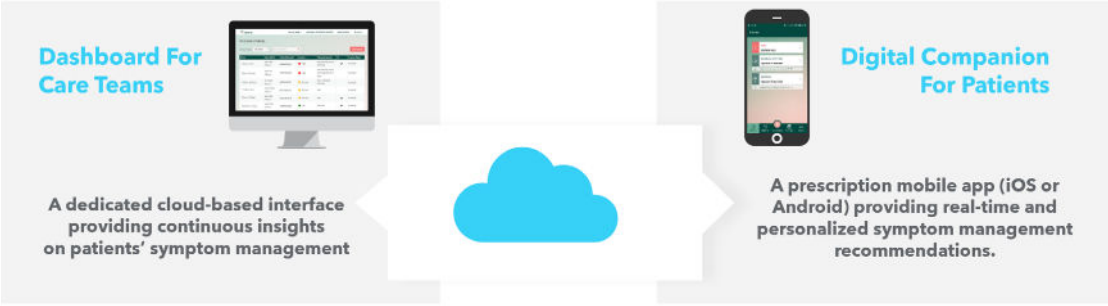
Digital therapeutics offer a unique opportunity to provide support tailored to the individual needs of cancer patients. According to the Digital Therapeutics Alliance, DTx delivers medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage and prevent a broad spectrum of diseases and disorders. DTx simplifies the decision-making process for patients while providing them and their care team with safe and actionable support, as needed over time.

At Aptar Digital Health, we developed Oleena®, a digital therapeutic for patients and their care team for the management of cancer-related treatments. Oleena consists of a mobile app for patients and a web portal for Healthcare Professionals (HCPs). It provides patients with personalized insights to self-manage the symptoms they experience over the course of their disease. Patients are guided with real-time personalized recommendations, such as initiation or dosage of supportive therapies based on their care plan and treatment profile, which are intended to support them in their treatment journey. For example, when patients experience moderate diarrhea, they may be encouraged to take symptomatic medication (such as loperamide) initially prescribed by their care team, and to start a BRAT (Bananas, Rice, Applesauce, Toast) diet.

Cancer patients express specific needs regarding their treatment experience. They are looking for ways to control their disease and treatment journey and take an active role in the self-management of their disease. Answering these needs leads to positive outcomes. Research in chronic diseases has shown several benefits associated with patient self-management:

- Increased satisfaction and trust,
- Higher quality of life,
- Reduced stress,
- Better understanding of personal responsibilities,
- More positive, direct communication with care professionals,
- Planning and decision-making improvements,
- An increased sense of empowerment.

DTx not only benefits patients. By supporting remote monitoring, they can also improve communication and collaboration between patients and their care team. Acting as coordinator of care delivery, practices see in digital therapeutics a way to enhance the quality of delivered care through better outcomes and reduced costs. DTx can also improve workflow efficiency, focus efforts where they should be, and ultimately increase staff well-being at work.



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According to Michael Seiden, MD, President of the US Oncology Network:

> «Digital technologies offer significant opportunities to provide higher value cancer care and are an important step in bringing practical medical interventions to patients in a timely and highly efficient manner»

In line with the Quadruple Aim of Healthcare (improve patient experience, clinical care, and patient outcomes while reducing care costs), improving symptom management in oncology can help reduce the overall cost of cancer, as demonstrated by Barkley et al , DTx supporting the management of symptoms can therefore be an important factor to achieve value-based care objectives in oncology, both from the patients and providers' perspectives.

Augmenting drugs with the power of digital

Certain drug families or mechanisms of action are known to present specific preventable and or reversible side effects. For example, checkpoint inhibitors can commonly lead to dermatologic manifestations; they can also lead to less common but potentially severe pneumonitis. Furthermore, drugs of the same family can sometimes present with unique toxicity challenges. This is the case of Cyclin-Dependent Kinase (CDK) 4/6 inhibitors. These drugs have shown very positive results for patients with certain types of advanced breast cancer. However, while one CDK 4/6 demonstrates a higher rate of gastrointestinal adverse effects than other drugs in the same family, another drug of this same class is known to pose a risk of QTc prolongation, a marker for the potential development of certain cardiac complications such as atrial fibrillation. Together with each drug, it is possible to provide a companion digital solution that will help patients and care teams manage these unique challenges. This can be achieved by leveraging a technology platform able to support algorithms adapted to each drug and each patient profile. Such Rx/ DTx combinations require close collaboration between pharmaceutical leaders and digital therapeutics pioneers like Voluntis to deliver on the promise of a better treatment experience individualized for each patient.

DTx, an opportunity to address unmet medical needs

Using the same approach in areas of medicine beyond oncology, digital therapeutics in the form of Rx/ DTx combinations could be valuable in any clinical situation where improved patient engagement, education and decision support can deliver better treatment experiences and outcomes. Solutions like Oleena® could present a new opportunity to address unmet clinical needs related to efficacy, safety, and accessibility of drug assets for patients and care teams in many areas of specialty medicine.

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.

oleena®

Oleena is a prescription mobile app intended for use by healthcare professionals and their adult patients with cancer as an aid for the management of symptoms experienced during the oncology treatment phase. Before use, please carefully read product instructions available in the "More" tab of the app. Oleena is not to be used during pregnancy and by patient under 18 years old. Oleena is a registered trademark of Aptar Inc. For distribution in the US only.
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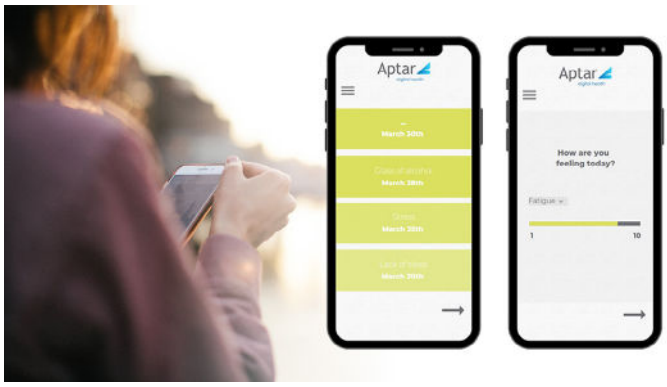

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