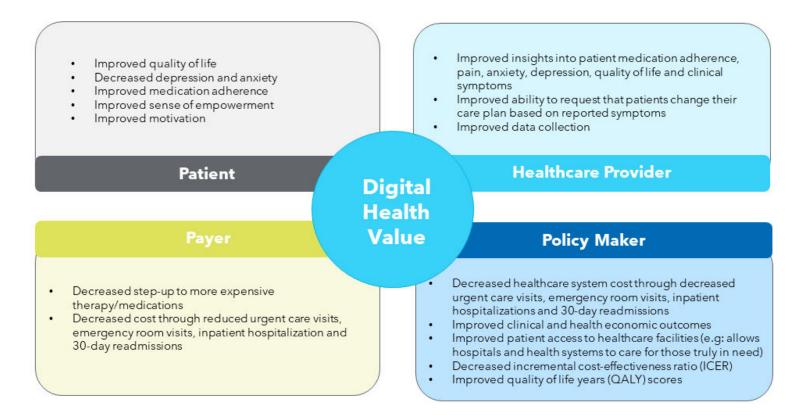


The methodology for existing health technology assessments (HTAs) is focused on pharmaceutical and medical device products, which are not well-suited to digital health solutions. In addition, healthcare systems globally are slow to adopt new technology or a therapy, while digital innovations evolve rapidly. Digital health solutions have shown tremendous value for patients, providers, policy makers and payers.



This white paper serves as a high-level overview on how to successfully achieve global market access for digital health technologies. Understanding the challenges and opportunities in the healthcare space, pharmaceutical companies can leverage key strategies to successfully market their digital health products. Akash Bijlani, Aptar Digital Health's Global Market Access Director, presents six key steps and best practices that can assist your organization to unlock the clinical and health economic value of combining pharmaceutical products with digital health solutions.

1. Understand the Potential Value at the Earliest Design Stage

Any market access team first needs to understand the "why, what, how and for whom" of any product before embarking, to ensure their pitch is strong enough to promote the product's value in front of market access entities. Key questions to ask the project team include:

- Why will the patients use the solution?
- What issue(s) does it solve?
- What is the value proposition of the product?
- What is the targeted population? In which countries?
- How can we generate evidence?

With all these answers in mind, the Market Access team can start designing the best pathway to ensure the product is deployed. This first step aims to accelerate the market time and derisk all chances of refusal with the competent authorities. Setting up the framework is key for the next steps.

2. Create an Integrated Marketing Strategy

Developing an integrated marketing strategy is crucial to effectively promote your digital health product and reach your target audience. This step involves aligning your marketing goals and objectives with the overall business strategy, ensuring consistency and synergy across all activities. Integration also involves

coordinating the market access efforts with other departments, such as Medical Affairs and the Project Team, to leverage their expertise and create a unified approach, especially with the rigorous process for clinical evidence evaluation and cost-benefit analysis.

3. Navigate Regulatory and Compliance Considerations

Aligning the marketing strategy with regulatory requirements and compliance standards is a mandatory step for several reasons:

- Ensuring patient safety: Regulatory agencies set standards and guidelines to ensure the safety and effectiveness of healthcare products, including medical devices and software-as-a-medical devices (SaMD). Complying with regulations helps protect patients from potential risks associated with improperly marketed or unproven products.
- **Enhancing** trust credibility: and Compliance with regulations enhances trust and credibility among technology assessment bodies. healthcare notified bodies professionals, patients. It demonstrates that the product has undergone rigorous evaluation and meets the required standards, increasing confidence in its safety and efficacy.
- Data Privacy and Security: Digital health products involve the collection and processing of sensitive patient data. Compliance with privacy and security regulations ensures that patient data is appropriately protected, maintaining

confidentiality and building trust with users.

 Accelerating reimbursement and increasing access: Many healthcare systems work with a reimbursement system.
 Demonstrating regulatory compliance and providing the right evidence can facilitate the reimbursement process, allowing wider access to the product and increasing its market potential. related quality of life or user engagement metrics specific to the digital health solution. You can also supplement traditional research with real-world evidence (RWE) obtained from user data, wearables or electronic health records. RWE can provide valuable insights into the effectiveness and impact of the digital health solution in real-world settings. Once you have collected enough valuable data and can



4. Generate and Measure Evidence & Success

All datapoints generated are key to defending your product in front of market access or reimbursement institutions. Data can come from observational studies, clinical trials, user experience evaluations, surveys, and feedback or real-world studies. The outcome you will measure must align with the objectives of your studies. These measures could include clinical endpoints, patient-reported outcomes, health-

demonstrate that your product has a positive impact on the life of the patients or on the healthcare system (economic health), you can submit your study for peer review to reputable journals, which will strengthen the credibility of the evidence.

5. Engage Key Stakeholders

Engaging with stakeholders and Key Opinion Leaders (KOLs) is crucial for marketing a digital health solution:

- Influencing Policy Decisions: KOLs and stakeholders, such as healthcare providers, payers and policymakers, have significant influence in shaping healthcare policies and reimbursement decisions. Engaging with them allows you to present the value proposition, clinical evidence and realworld data supporting your digital health solution.
- **Expert Validation**: KOLs and stakeholders lend credibility to your digital health solution through their expertise and reputation.



Their endorsement and support can help build trust among decision-makers and increase the likelihood of reimbursement.

• **Clinical Advocacy**: KOLs can advocate for the clinical benefits and patient outcomes

- associated with your digital health solution. Their endorsement and advocacy can influence payers or governmental systems to consider reimbursement based on the demonstrated value to patients and the healthcare system.
- Addressing Adoption Barriers and Concerns: Engaging with stakeholders and KOLs allows you to address any barriers or concerns they may have regarding the adoption and reimbursement of your digital health solution. This engagement provides an opportunity to address questions, clarify misconceptions and demonstrate how your solution aligns with their priorities.
- Evidence Generation: KOL involvement in clinical studies, scientific publication, evidence collection and data analysis enhances the validity and relevance of the evidence, strengthening the case for reimbursement.

KOLs and stakeholders have insights into local healthcare systems, reimbursement mechanisms and decision-making processes. Engaging with them allows you to understand the specific requirements and navigate the complexities of reimbursement pathways, increasing the chances of successful market access.

6. Launch

Your solution has generated evidence and demonstrated impact. It is now cleared and ready to hit the market and be used. However, having all the green lights to market your product does not mean that people will use it.

To maximize engagement, your marketing, content creation and distribution strategies play a vital role in educating and engaging the target audience. The evidence-based information and cost-benefit messaging that you demonstrated earlier can now be shared broadly to convince your end-users of the benefits of the product. By following these six steps, pharmaceutical companies can effectively market their digital health products to drive awareness, adoption and success. With the right partner, pharmaceutical companies can maximize the potential of their digital health offerings and make a meaningful impact on patient care and outcomes.

Product Development Regulatory Approval Clinical Evid	
Inderstand the Integrate Your Align with Regulatory Requirements Generate Evide Product Value Marketing & Compliance Standard to Support Market Strategy	

About Aptar Digital Health

At Aptar Digital Health, we are on a mission to elevate patient experiences at every stage of their treatment journey. Our suite of end-to-end, patient-centric digital solutions leverages our unmatched expertise and diverse, industry-leading product portfolio to deliver differentiating experiences and more positive outcomes. Our Market Access and Global Health Economics Services include evidence-generation studies, clinical and health economics trials, and clinical and health economic publication strategy.

Aptar Digital Health is a division of <u>Aptar Pharma</u>, which 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.

To learn more about Aptar Digital Health's services ir Global Health Economic and Market Access visit: www.aptardigitalhealth.com

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