

Regulatory Strategy for Digital Health Products in the U.S.



A fit-for-purpose regulatory strategy for digital health product(s) is good for business and commercial decision-making.

BUILDING THE RIGHT STRATEGY TO OPTIMIZE MARKET ACCESS

Regulatory strategy for digital health products is an important factor in their development and commercialization. One of the primary steps is to first determine whether the product will be regulated by the FDA. There are some occasions where a product may not be the focus of FDA oversight based on a few factors such as product functionalities, risks, claims, environment of use, and more. Crafting an appropriate regulatory strategy around how the product will be regulated by the FDA is a key first step.

A well-thought-out regulatory strategy can help ensure that the product meets the necessary regulatory requirements, is authorized for marketing, and can be successfully and legally launched. In addition to commercial decision criteria (like market share, revenue, etc.), regulatory requirements are also critically important. Individuals or organizations who fail to take regulatory aspects of new product development seriously often risk wasting capital, time, and personpower in product development. A product may not reach the market at scale (or reach the market at all). And, if it does, they risk failing to comply with applicable regulations. A robust regulatory strategy also serves to ensure that the product under development is safe, effective, and meets the necessary quality standards – thereby helping to minimize potential risks and challenges that may arise during the regulatory review process.

Developing a regulatory strategy for digital health products can be complex, as it involves [navigating the regulatory landscape](#) and requirements in various regions and markets, the myriad specific characteristics of the digital health product itself, alongside anticipating future changes in regulations. It may also seem unnecessary or overly burdensome without immediate payoffs to invest in a regulatory strategy early. However, a well-designed regulatory strategy can help ensure that a product is able to be brought to market in a timely manner, and that it is safe and effective for use by patients and healthcare providers.

“The digital health industry is a heterogeneous, innovative, and dynamic sector. More importantly, it is continuously changing. Regulatory processes aren't the limiting factor for digital innovation. Rather an optimal regulatory strategy is a critical part of successful product and business strategy.”

- **Smit Patel**, Assoc. Director,
Digital Medicine Society

A Digital Health Product's Early Regulatory Strategy Lead to Optimized Market Access and Commercial Success



Image source: [Propeller health](#)

The Propeller Health sensor is a digital health product that has demonstrated that the right regulatory strategy can drive commercial and economic value. It is a product that attaches to inhalers used to treat **asthma and chronic obstructive pulmonary disease (COPD)** and tracks use data.

The sensor sends the data to an app on the patient's smartphone, which can be accessed by the patient and their healthcare provider.

Propeller Health is a digital health company that develops and markets connected inhaler devices and software solutions to improve the management of chronic respiratory conditions such as asthma and chronic obstructive pulmonary disease (COPD).

Since 2014, they have adopted a proactive regulatory strategy, [working closely with FDA](#) to ensure their products meet regulatory requirements from early engagement, submission of premarket notifications, to conducting [clinical studies](#) to support the safety and efficacy of its products. Their strategy supports claims regarding the products' ability to gather data and provide insights on patient behavior, and help predict exacerbations in patients with asthma and COPD.

Over the years, this regulatory strategy has allowed the company to bring products to market in diversified channels (i.e. via prescription and the over-the-counter route) faster and at lower cost. Their products' journey has been successful in:

- Providing insights on asthma patients' behavior that lead to [high medication adherence](#).
- Providing [population level health management](#) using the propeller health asthma platform.
- Leading to a [reduction in healthcare resource utilization](#).
- Bettering [outcomes for vulnerable and underserved populations](#) such as in southwest Detroit.
- Pushing [toward value-based care](#) with potential [cost savings up to \\$4,000/patient](#).
- Building trust among patients who have a [84% high satisfaction score](#) with their inhaler sensor devices and monitoring.

In conclusion, a well-crafted regulatory strategy can be crucial for products like the Propeller Health product(s). Such a regulatory strategy can help to identify the best way to classify the product, how to articulate the claims it makes, reduce time and cost of getting to the market, and ensure the product is safe and effective. It can also allow the product to provide insights on patient behavior and adherence to medication which can lead to better outcomes and reduced healthcare costs.

Components of Building a Regulatory Strategy for Digital Health Product

- **Identify the target market:** Determine the appropriate geographical market region/country that will be best suited for your product. There may be more than one.
- **Define the product claim:** Determine who will be the user of the product, what does the [product claim to do for those users](#), how will the product achieve the intended results for that user population, in what settings will the product be used, and more. Early distinctions between marketing claims (promotional language) and the product's claims (intended use) could be deemed helpful.
- **Conduct a benefit-risk profile:** Evaluate the [potential risks and benefits of the product](#) that may impact, and identify any potential challenges that may arise during the regulatory review process.
- **Determine product class:** The U.S. FDA and the E.U. regulatory authorities [classify digital health products](#) that meet their respective definitions of medical devices based on the level of risk they pose to patients. This will help determine the level of regulatory oversight and testing required for a product.
- **Design non-clinical (e.g. bench testing) and clinical testing plan:** Based on the intended use and risk profile of the product, clinical trials may be needed to demonstrate safety and effectiveness. It is important to carefully plan a clinical development strategy and ensure that there are the necessary resources and expertise to carry it out.
- **Communicate with regulators:** Companies should establish [effective communication with regulatory agencies](#) and keep them informed of their product development efforts and any changes to the product. This can help to ensure that the regulatory process goes smoothly and that the product receives appropriate clearance, approval, or marketing authorization in a timely manner.



There is a balance between leveraging precedent to your advantage and creating a digital health product that is novel and innovative. You only have “one hill to die on” so pick it wisely. A “robust” strategy is a result of thoughtful diligence and ongoing collaboration with FDA – it’s an iterative process.

A holistic regulatory strategy is an iterative, cross-functional process that requires expert input and review from multiple disciplines within an organization. The key to business success is identifying viable commercial and regulatory strategies before organizations have committed large amounts of time, capital, and resources to product development.



Components of Implementing a Regulatory Strategy for Digital Health Product

- **Navigate the regulatory pathway:** Based on the claims and additional factors, digital health products may require different rigor of regulatory oversight. It is important for companies to [identify the appropriate regulatory pathway](#) for their product and to understand the requirements for approval.
- **Manage the regulatory review process and timeline:** It is helpful to work closely with the regulatory agency to address questions or concerns that may arise during the review process, as well as to ensure that the product meets all necessary regulatory requirements. Ensuring the timing of the regulatory review process is aligned with the business timeline for product commercialization is key.
- **Establish quality management systems:** Establishing and maintaining robust quality management systems is important for ensuring the safety and effectiveness of digital health products. This may involve implementing processes for design, development, production, and distribution, as well as establishing policies and procedures for managing recalls and other issues that may arise.
- **Execute product testing with robust evidence:** Digital health products should be developed and deployed with high evidentiary standards in order to ensure their safety and effectiveness. This may involve conducting clinical trials or other types of studies (e.g., those using real-world data to generate real-world evidence) to demonstrate the product's safety and effectiveness.
- **Manage data privacy and security:** Digital products often involve the collection and storage of sensitive personal and medical data. Companies must ensure that they have robust data privacy and security measures in place to protect this information.
- **Ensure compliance with regulatory requirements:** A regulatory strategy helps ensure that a product meets the necessary standards for safety, efficacy, and quality. This can help prevent delays in the product development process and reduce the risk of regulatory issues or recalls once the product is on the market.
- **Develop a plan for post-market surveillance.** Even after a product has been cleared or approved, it is important to continue monitoring its safety and effectiveness and to report any adverse events or other issues to the regulatory agency. This may involve conducting additional clinical studies or implementing other monitoring measures.
- **Stay up to date with changing regulations:** Regulatory requirements for digital health products are constantly evolving; it is important to stay up to date with changes that may affect your product. This may involve subscribing to relevant industry publications, attending conferences and workshops, and keeping in touch with regulatory agencies.



Overall, a comprehensive regulatory strategy is critical for the success of digital health products and should be carefully planned and implemented in order to minimize risk and ensure a smooth and successful regulatory review process. It helps to ensure that the products meet the necessary quality standards and are approved for use by the appropriate regulatory agencies.

Access DiMe's Digital Health Regulatory Pathway Resources



Identify your regulatory pathway



Build your regulatory strategy



Interact with regulators

