

Value of Regulations

for Digital Health Products in the U.S.

WHERE DOES THE FIELD STAND?

The COVID-19 pandemic has accelerated broad interest and acceptance for digital health products – from the use of the digital endpoints in clinical trials for new drugs, devices, and combination products to the use of novel technologies for diagnosis, prevention, and treatment of medical conditions. Digital health solutions offer enormous promise to address some of the most pressing and persistent challenges in healthcare, but to fully realize the benefits of novel digital offerings, concomitant innovation in regulatory science and education for a new group of health technology leaders is necessary.

The [end users](#) are often confused as they seek to differentiate between the 300k+ health apps available for download and more sophisticated, evidence-based digital health solutions. Digital health innovators are simultaneously confused about how to commercialize and position their products.

There are **350,000+ digital health products in today's market**, with over 250 new products added on a daily basis. How can end users best differentiate among these product offerings?

A recent survey of the digital medicine community revealed that:



25% of digital health solution developers don't know if the product they're developing is regulated.



Of those respondents who knew their product was regulated,

3 out of 4

don't know the optimal regulatory pathway.

In a [recent survey of the digital medicine community](#), the Digital Medicine Society (DiMe) found that 25% of developers didn't know whether their digital health product should be regulated. Of those who knew their product should be regulated, 75% reported not knowing the optimal regulatory pathway. There are a number of vital accompanying questions around topics such as evidentiary needs for regulated products, inclusivity as part of development, capturing diverse patient community insights, and harmonization of best evidentiary practices to ensure effective translation in real-world settings.

FROM 1976 TO TODAY...

A LOT HAS CHANGED IN THE LAST 47 YEARS

In the rapidly changing landscape of digital health, innovation has often [outpaced regulations, especially for novel technologies and emerging industries](#). This scenario breeds uncertainty among individuals, teams, and companies about product regulations, leading to situations in which innovators deliberately avoid pursuing a formal regulatory pathway and instead opt to pursue a consumer health path, potentially '[skating the line](#)' between products that could be considered [general wellness products](#) and FDA-regulated products.

The proliferation of software-based medical products and advancing innovation has accelerated the clinical use of digital health technologies across a wide array of medical conditions. Such sophisticated modern-day digital solutions such as AI/ML algorithms for diagnosis and treatment, digital therapeutics, connected sensor products, etc., fall under the current U.S. regulatory framework that was developed for traditional hardware medical products such as orthopedic implants, coronary artery stents, and more.

Trust in emerging digital health products is essential to their adoption. Regulatory oversight offers a robust path for digital health product developers to demonstrate the safety and efficacy of their solutions. Regulatory oversight also opens the door to additional reimbursement pathways. However, there currently a large amount of uncertainty among digital health product developers, their clinical partners, and digital health investors regarding:

- The business implications of investment in regulated products with respect to the cost, time, and personpower, along with the long term return on investment.
- Fear of current regulatory frameworks being outdated and having overly burdensome requirements that are not tailored to today's technologies.
- Lack of awareness about regulatory categories and unclear evidentiary standards for clearance within modern day technological categories.
- Sustainability of investing in a regulatory path—especially for startups and research innovators.
- Insufficiently optimized regulatory pathways for innovative solutions, leading to concern in the field about stagnation in innovation due to long regulatory review timelines that may hamper the ability to innovate quickly.





A Digital Health Innovator's Decade-Long Regulatory Journey



Image Source: [Mobihealthnews](#)

Over a decade ago, a digital health company, AliveCor, went through the regulatory submission and review pathway for its first product, the **AliveCor mobile Heart Monitor**.

This product was an attachment (ECG monitor) to a smartphone (iPhone 4 and 4s) that could be used to detect atrial fibrillation, a type of irregular heartbeat that can increase the risk of stroke.

In order to bring their Heart Monitor product to market, [AliveCor](#) had to navigate the FDA's medical device regulatory clearance process. The company submitted a 510(k) premarket notification to the FDA and received [FDA 510\(k\) clearance in December 2012](#) as a Class II medical device. The product was cleared for use as an over-the-counter diagnostic tool for detecting atrial fibrillation. FDA clearance enabled AliveCor's Heart Monitor to be sold and marketed to licensed medical professionals to record, display, store, transfer, and evaluate single-channel electrocardiogram (ECG) rhythms.

The regulatory clearance process provided several benefits for AliveCor and the users of its product. First, its clearance provided assurance to consumers that the product had been evaluated and found to be safe and effective for its intended use. This evaluation helped to build trust and confidence in the product, which likely contributed to its commercial success.

Second, the clearance process helped to ensure that the product met certain standards for accuracy, reliability, and performance, which helped communicate that it would provide meaningful and accurate results for users.

Overall, the regulatory clearance process played a crucial role in bringing the AliveCor Heart Monitor to market and ensuring that it would be safe and effective for consumers to use.

VALUE OF DIGITAL HEALTH REGULATIONS



Bring to market safe, effective, ethical, and equitable digital health products that deliver high-value care to consumers by improving their health, wellness, and care experience.



Ensure evidence-based digital medical products reach consumers.



Increase trust in digital tools by ensuring medical benefit, security, privacy, and compliance.



Create baseline gold-standards of measurement for the use of digital medical products.



Ensure harmonization of best practices by multi-stakeholder communities (innovators, regulators, clinicians, payers, developers, health systems, etc.).



Reduce misleading and misaligned claims or claims that lack sufficient evidence for digital health solutions.



Increase transparency by requiring manufacturers to provide detailed information about the design, performance, and safety of their products.



Foster innovation in digital health by providing a clear framework for product development, which helps encourage investment in the field and support the development of new and improved products.



Ensure fair competition in the digital health market by providing a level playing field for all companies and products.





Strong Regulatory Strategy Can Influence Commercial Business

A well-planned regulatory strategy, like the one employed by Pear Therapeutics, can help digital health companies demonstrate the safety and efficacy of their products, which can increase credibility, acceptance, and adoption of the product among healthcare providers and payers, leading to improved patient outcomes, increased revenue, and business success.

Pear Therapeutics' reSET and reSET-O digital therapeutic apps are examples of digital therapeutic products for which a regulatory strategy improved business/commercial success. These apps are designed to treat substance use disorder (SUD) and opioid use disorder (OUD) respectively and received FDA classification ([reSET via the De Novo Pathway](#) in 2017) and FDA clearance ([reSET-O via the 510\(k\) pathway](#) in 2018).

The regulatory strategy employed by Pear Therapeutics was to demonstrate the safety and efficacy of its apps through clinical trials and then seek clearance from the FDA on the basis of clinical evidence. This strategy allowed the company to market the apps as medical devices and to prescribe them to patients with SUD and OUD.

Experience suggests that the regulatory clearance has had a significant impact on the business success of Pear Therapeutics. After receiving FDA clearance, the company received [\\$80 million in additional funding](#), the company's net financing cash flow [grew by over 600%](#), and the company saw [expanded market access](#) with 30+ organizations expanding access to company products to more than 31.7M covered lives.

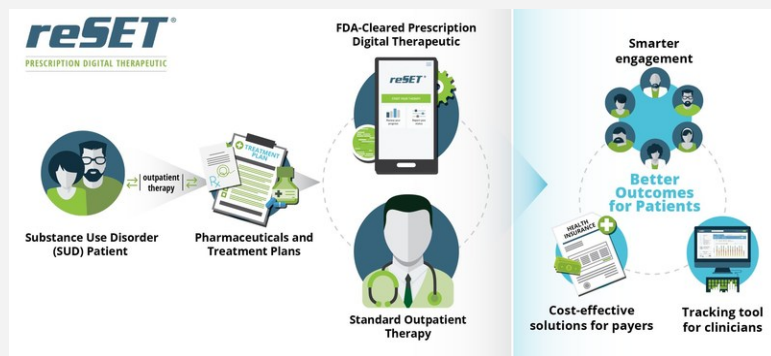


Image Source: [Pear Therapeutics](#)

Additionally, a 12-week [reSET study](#) demonstrated that patients who used the reSET app “doubled” their rate of abstinence from substance use, as compared to the rate of substance use in the control group. An over 13% improvement in the retention rate also demonstrated the improved acceptance of the products.

FLIPPING THE SCRIPT

Regulatory Strategy as a Differentiator

Current regulatory processes may seem overwhelming and tedious, and at times may feel either undesirable or unnecessary for digital health innovators. Engaging with regulators early on in the product development process may also seem unnecessary or overly burdensome without immediate payoffs. But crafting a good regulatory strategy for a digital health product can help short- and long-term commercial planning and success.

There are clear benefits to gaining regulatory clearance or approval for digital health products, including credibility and market access. However, there are also occasions where a digital health product is not the focus of FDA oversight based on the product, its risk, and its limited claims. Such products can be marketed without FDA clearance or approval. Therefore, based on the business objectives, problems addressed by the product, and its claims, a good regulatory strategy will inform the level of regulatory rigor and its path to market with or without FDA oversight.

The FDA works to assure patient safety and medical device effectiveness. Working with regulators throughout the development of a product can lead to positive health and economic outcomes. Early demonstration of regulatory compliance also provides significant advantages in regards to product and business differentiation.

Digital health innovators who take the time to work with the FDA to demonstrate product safety and effectiveness are likely to be seen as more marketable and reliable by investors and payers, leading to more capital investment and a higher likelihood of payers' willingness to reimburse for such tools.

“We need to flip the script and see regulatory strategy become a differentiator for digital health solution providers.”

As we anticipate a tightening of funding for digital innovators, the importance of selecting optimal regulatory pathways for individual products and product portfolios becomes critically important to ensure market access, trust, and adoption.”

- **Jennifer Goldsack**, CEO,
Digital Medicine Society



A Digital Health Product's Expedited Journey via FDA's Enforcement Discretion

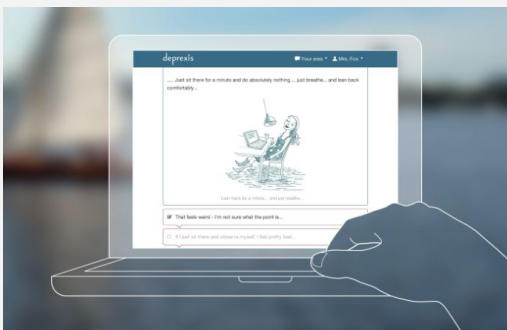


Image source: [pharmaphorum](#)

FDA's "Enforcement Policy" allowed for **accelerated commercialization** of scientifically proven digital therapies like Orexo's deprexis®, a product for the treatment of psychiatric disorders.

One example of a digital health product whose regulatory path to market was accelerated is GAIA's (now Orexo's) [deprexis](#), a tailored cognitive behavioral therapy for the treatment of symptoms of depression during a period of 12-weeks.

In the wake of the COVID-19 pandemic and recognizing the need for additional treatment solutions for rising mental health conditions, the FDA introduced an "[Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders](#)" with the aim of increasing access to digital therapies within the area of psychiatric disorders.

On July 1, 2020, Orexo launched deprexis® in the market, abiding with FDA's Enforcement Policy. The policy provided an accelerated route to Orexo's product based on patient need for access to low-risk clinically-validated digital health products. This approval allowed Orexo to not only bring deprexis® to market, but, with a [Veterans Affairs Federal Supply Schedule contract](#), expand product access to ~15 million U.S. citizens receiving healthcare through the federal government.

In conclusion, engaging with regulators and considering all relevant factors can inform developers if a product falls within FDA oversight and/or if it can be marketed without FDA clearance or approval. Such a process can help devise a strategy for launching an initial product that may not require clearance or approval. In the future, with new features additions, one can reassess the regulatory process based on the new product, intended claims, and more.

PLAYING THE LONG GAME

Proven Value for Long-Term Reward

Developing a regulatory strategy for digital health products requires companies to consider a number of factors, including the intended use of the product, the population it is intended to serve, and the potential risks and benefits of the product. Companies must also consider the regulatory requirements and standards that apply to their products, which can vary depending on the country or region in which they are sold. This document focuses on the United States, but in other geographies, other considerations and regulatory processes will need to be considered.

Leading medical product developers have always embraced regulatory strategy as fundamental to their business plans and portfolio strategies. This should be no different in the digital era. Recognizing the full breadth of regulatory pathways that exist for digital health solutions – and the value they can bring digital product manufacturers, clinicians, and most importantly, patients – is critical to a thriving healthcare ecosystem in the digital era.

In addition to regulatory requirements, companies may also need to consider other aspects of their regulatory strategy, such as how to communicate the risks and benefits of their products to consumers, how to handle adverse events or product recalls, and how to maintain compliance with relevant laws and regulations.

A proactively articulated regulatory strategy for digital health is an important consideration for companies that develop and sell these products, as it helps to ensure the safety and effectiveness of new tools, and helps to build trust with consumers and regulatory authorities.

A solid, differential regulatory strategy for a product is also an important aspect of the development and marketing of these products. Such a strategy involves identifying the relevant regulatory requirements and developing a plan to ensure that the product meets these requirements. This process can include obtaining necessary approvals, such as clearance, approval, or authorization from regulatory bodies, and ensuring that the product is designed and manufactured in compliance with relevant standards and guidelines.

Developing a regulatory strategy can be a complex process, as it involves understanding the regulatory landscape for digital health products in various countries and regions, as well as anticipating future changes in regulations. 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. It can also help to protect the product from post-market regulatory challenges or enforcement actions, which can be costly and time-consuming.

Overall, the value of a regulatory strategy for a digital health product is that such a strategy helps to ensure that the product meets all necessary requirements and can be successfully introduced to the market, while also protecting its manufacturer from potential regulatory risks.





References & Resources

- [The Playbook: Digital Healthcare Edition | DiMe](#)
- [Digital health apps balloon to more than 350,000 available on the market, according to IQVIA report | MobiHealthNews](#)
- [Digital health innovators should engage early with regulators | STAT](#)
- [Regulatory considerations to keep pace with innovation in digital health products | Nature Digital Medicine](#)
- [Skating the line between general wellness products and regulated devices: strategies and implications | J Law Biosci](#)

Access DiMe's Digital Health Regulatory Pathway Resources



Identify your regulatory pathway



Build your regulatory strategy



Interact with regulators

