Five Steps for Success:
Developing Digital Medicines and Digital Therapeutics

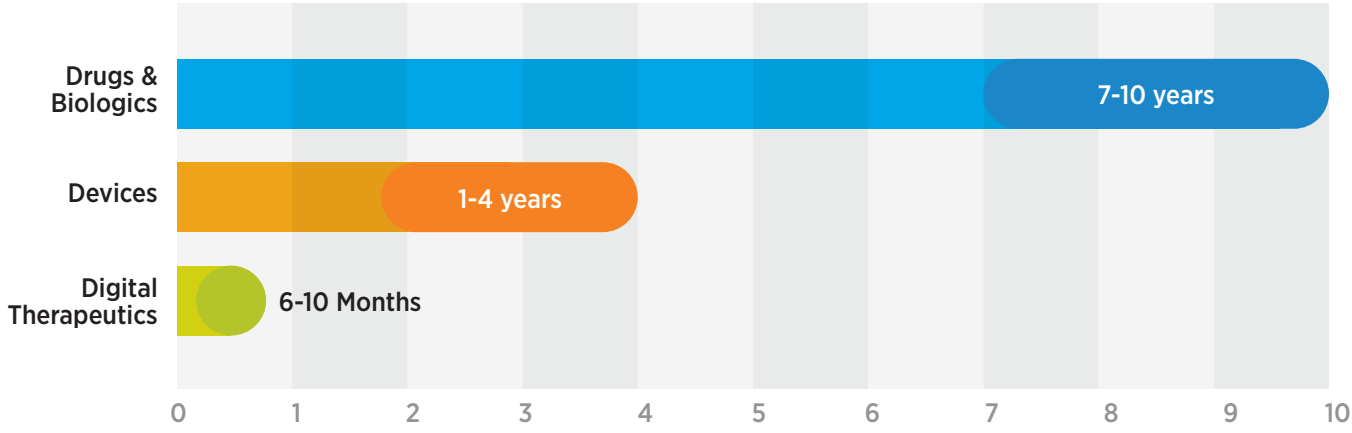
Digital medicines and digital therapeutics (DTx) are changing the future of healthcare by empowering patients to participate in—and influence—their treatment, health, and well-being. These technologies can support various stages of the healthcare journey, addressing unmet needs and bridging gaps in the market for traditional medicine. This convergence of software and healthcare creates opportunities, but the task of developing digital medicines and DTx comes with unique challenges arising from an evolving regulatory and reimbursement landscape.

Successfully developing and commercializing digital medicines and DTx require careful planning. Regulatory requirements and commercial goals should be integrated into a cohesive go-to-market strategy that addresses barriers to uptake and drives adoption. This planning should include five key steps:

1. Clarify regulatory expectations

A key finding of the Software Precertification Pilot Program, which was launched by the U.S. Food and Drug Administration (FDA) in 2017 and concluded in 2021, was that the current device regulatory framework is not optimized for regulating digital medicines and DTx. The FDA found that rapidly evolving technologies in today's medical device landscape could benefit from a new regulatory paradigm, which will likely require legislative change. While it takes an average of 7-10 years to develop drugs and biologics and 1-4 years to develop devices, digital medicines and DTx have an average development time of 6-10 months (*see Figure 1*). To keep pace with technology that is continuously changing, review timelines need to be accelerated, and regulators may have to adjust both the expectations for submission and the requirements for approval and post-marketing data collection.

Figure 1. Development time (years)



While the regulatory pathways for traditional drugs, biologics, and devices are well-known, the path to market for digital medicines and DTx is less clear and may depend on whether the product has a predicate and whether it requires a prescription. In some cases, digital health product developers may opt to submit a product for clearance and approval and continue to iterate and evolve that product while it is on the market. Initiating and maintaining dialogue with regulators can help developers identify the most appropriate roadmap for development and approval. To prepare for this regulatory discussion, developers should identify the clinical need, interact with clinicians who are likely to drive usage of the proposed product, and in many cases generate data to present to the agency.

2. Define a target product profile before developing a prototype

In the nascent digital medicine and DTx space, there is not yet a standard go-to-market approach, but it is critical to have a clear commercial strategy and target product profile (TPP) at the earliest stages of development. Even prior to developing a prototype, there are several questions that should be asked and answered with stage-appropriate rigor to drive the development program:

- What **disease or condition** will the product treat or help patients manage?
- What is the **journey** taken by the target patients who are seeking treatment for their disease? Where will this new therapy fit into their journey?
- Who are the **target customers** for the proposed product?
- What **benefits** will the product provide for the target customers? How will these benefits be differentiated from existing and/or new competitors?
- What **evidence** must be generated to demonstrate the product's value, and what claims will motivate target customers to purchase the product?
- How will target customers **access** and purchase the product? How will the product be priced to maximize uptake and revenue?

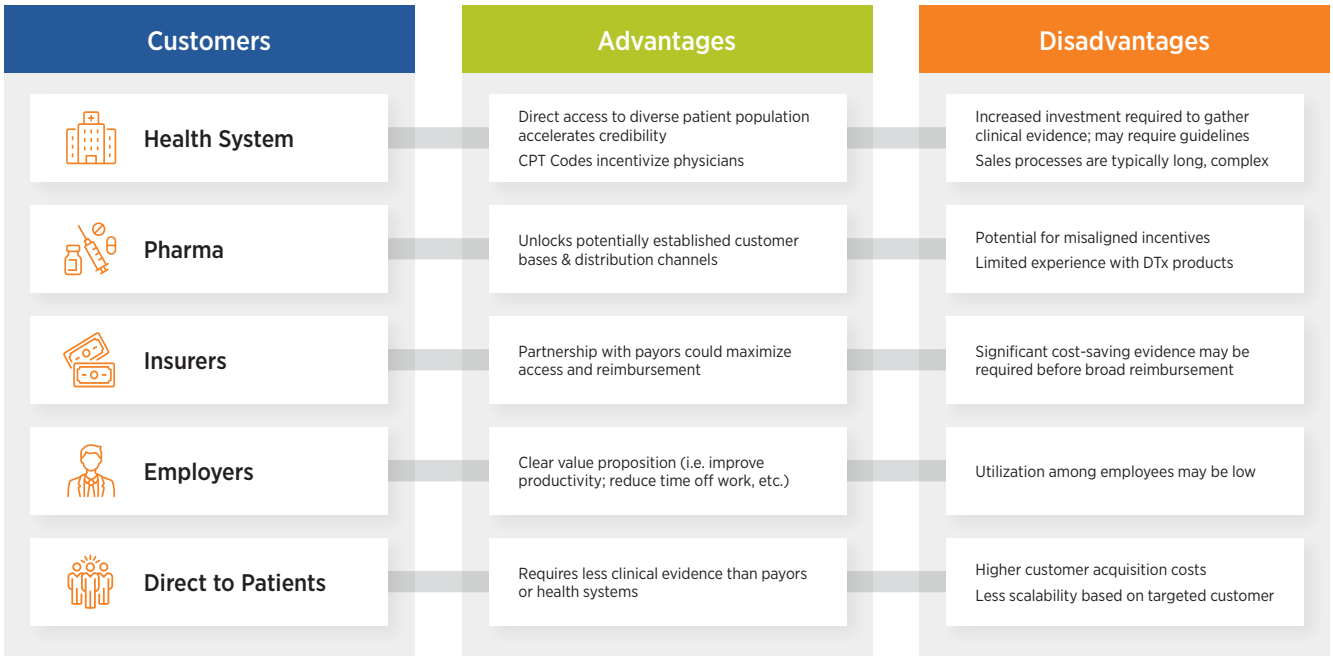
Understanding the target customer is critically important. With traditional pharmaceuticals and medical devices, the target customer is either the patient or the treating physician, since most of these products are provided by prescriptions. With digital health and digital medicine products, the target customer base is broader and may include not only patients and physicians but also pharmaceutical companies, health systems, insurers, and employers. For example:

- **MyFitnessPal**, a weight loss and fitness app, is marketed using a direct-to-patient model and has 19 million users.
- **Theraxium** is a disease-agnostic platform for tracking side effects and adverse experiences and for improving patient engagement with medication and treatment. The company has signed multiple agreements with pharmaceutical companies to develop companion digital medicine devices.
- **Omada** is a diet and exercise app that leverages Diabetes Prevention Program (DPP) study data to help prevent diabetes, improve cardiovascular outcomes, and enhance overall wellness. The company has successfully targeted health systems and insurers.
- **Hinge Health**, which offers DTx for musculoskeletal conditions, is focused on employers as its target market.

Prescription DTx generally follow the traditional pharmaceutical model, where the end user is the patient and the target customer is the prescribing physician.

There are advantages and disadvantages to targeting each customer segment (*see Figure 2*). A deep understanding of the target customer forms the basis for developing the digital medicine or DTx, designing clinical studies, and determining go-to-market tactics.

Figure 2. Advantages and disadvantages of different target customers



3. Identify potential barriers to uptake

To achieve commercial success for a digital medicine or DTx, a developer must understand how targeted the product is and whether it is scalable. The expectations of—and potential uptake barriers for—each stakeholder group are key considerations:

- **Patients** expect a quality digital experience.
- **Employers** want digital tools to lower healthcare costs and to improve employee satisfaction.
- **Regulators** have established guidelines and frameworks for controlling these products.
- **Insurers** are skeptical of the benefit, value, and cost savings associated with these products but have started to reimburse.
- **Providers** have a high level of skepticism of the clinical benefit of these products and are unsure how digital tools fit into their existing workflow. They are also concerned about reimbursement.

Between 2015 and 2022, use of digital medicines and DTx increased by only 1.6%, reflecting low uptake among providers. They point to lack of integration into their clinical workflow and electronic health records, as well as a lack of awareness, training, and evidence-based outcomes as challenges to adoption.

4. Understand reimbursement models

Reimbursement for DTx is evolving. Currently, reimbursement is equally split between medical benefits and pharmacy benefits:

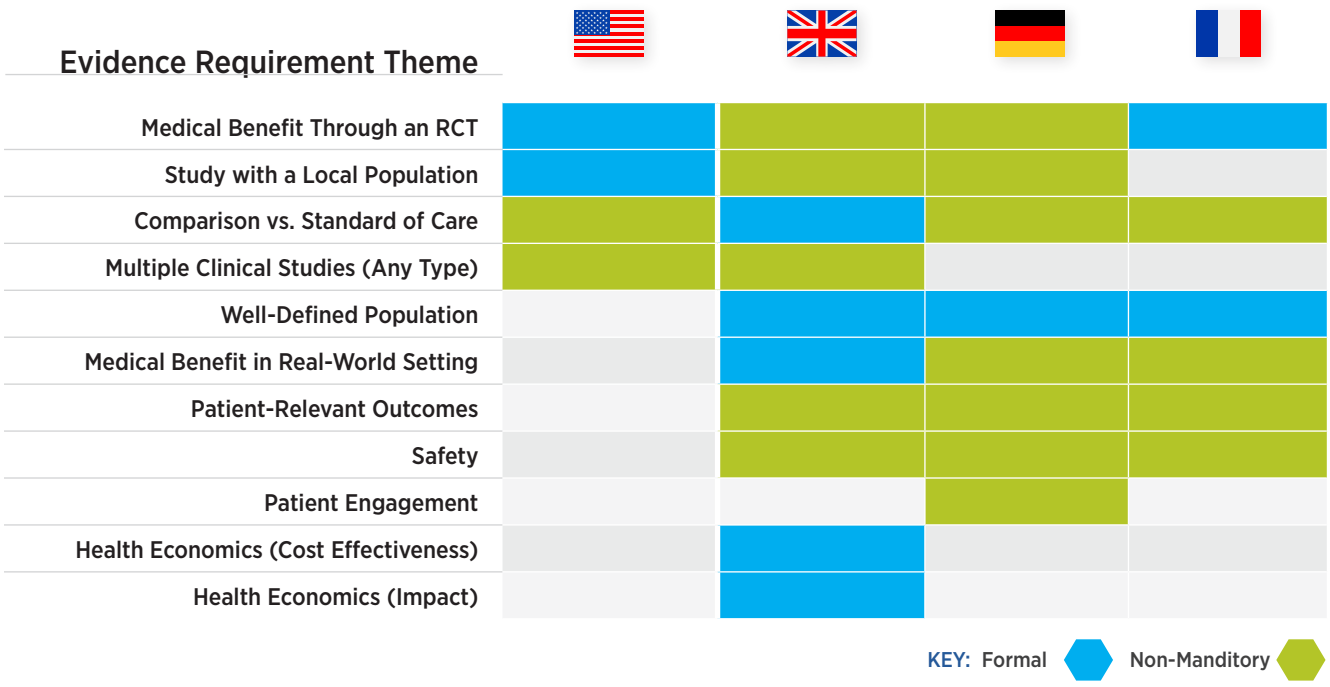
- **Medical benefit.** Providers prescribe the DTx and bill insurers based on existing Current Procedural Terminology (CPT) codes such as "remote monitoring" or "prescription behavioral therapy." The patient may have to pay co-insurance.
- **Pharmacy benefit.** Providers prescribe the DTx, and the patient pays a co-pay based on formulary status.

There are also new modalities, including payment based on outcomes, value, or therapy adherence and digital formularies.

Requirements for reimbursement are also starting to emerge. These evidence standards may be either formalized as part of medical policies or non-standard. In the U.S., it is becoming imperative for developers to demonstrate medical benefit through a randomized clinical trial and to study the product with a local population to gain reimbursement. Comparison against standard of care and multiple clinical studies are becoming more common but are not required.

Developers of DTx with global applications should be aware that evidence standards for reimbursement vary throughout the world (*see Figure 3*). Thus, planning ahead to meet those standards in countries where the product is expected to be commercialized is critical.

Figure 3. Emerging DTx evidence standards for access and reimbursement in select countries



CHALLENGE	OPPORTUNITY
Roughly 75% of medical devices are rejected by the FDA for insufficient evidence. Even when clinical evidence is provided, providers need to know how to integrate DTx into their treatment plans.	Use well-designed studies not only to generate clinical evidence for FDA approval but also to demonstrate use of DTx in clinical treatment to remove barriers to uptake.
Reimbursement models are still evolving, and only 10% of DTx are supported by published economic studies demonstrating cost savings.	Consider cost savings outcomes alongside clinical outcomes to support reimbursement.
Reaching providers is a significant hurdle. Developers of DTx have explored partnering with pharmaceutical companies or pharmacy benefit managers or even creating their own provider networks to support commercialization.	Understand the patient and provider journeys, and where unmet needs exist, to identify the most appropriate commercialization pathway for a particular product.

Figure 4. Challenges and opportunities in the digital medicines and DTx landscape

5. Turn challenges into opportunities with early strategic planning

Current challenges in the digital medicines and DTx landscape can be turned into future opportunities (*see Figure 4*). Early strategic planning that begins well before prototypes have been developed is essential for ensuring the product is the right innovation. Below are three examples of existing challenges and potential opportunities.

1. **Challenge:** Roughly 75% of medical devices are rejected by the FDA for insufficient evidence.[1] Even when clinical evidence is provided, providers need to know how to integrate DTx into their treatment plans.

   Opportunity: Use well-designed studies not only to generate clinical evidence for FDA approval but also to demonstrate use of DTx in clinical treatment to remove barriers to uptake.

2. **Challenge:** Reimbursement models are still evolving, and only 10% of DTx are supported by published economic studies demonstrating cost savings.

   Opportunity: Consider cost savings outcomes alongside clinical outcomes to support reimbursement.

3. **Challenge:** Reaching providers is a significant hurdle. Developers of DTx have explored partnering with pharmaceutical companies or pharmacy benefit managers or even creating their own provider networks to support commercialization.

   Opportunity: Understand the patient and provider journeys, and where unmet needs exist, to identify the most appropriate commercialization pathway for a particular product.

Conclusion

There is no one-size-fits-all approach to successfully developing and commercializing digital medicines or DTx. Early strategic planning that focuses on the needs and expectations of target customers helps developers tailor their product and go-to-market approach. At Premier Consulting, we help digital developers formulate development plans that balance regulatory and commercial considerations to optimize the likelihood of success. As a strategic product development and global regulatory consulting company dedicated to helping biotech innovators transform their life-changing ideas and breakthrough science into new medical treatments, we stay current on the shifting landscape to provide up-to-date guidance and solutions. To learn more about how Premier Consulting can help you with digital medicine and DTx development, contact us.

[1] *Greenlight Guru. The 510k and Substantial Equivalence: Why do so many get it wrong? Available at greenlight.guru/webinar/510k-substantial-equivalence.*

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