

## Chapter 1

# *Introduction to Digital Therapeutics*

In 2017, a patient struggling with substance use disorder walked out of a clinic with a prescription that would have been unimaginable a decade earlier. It wasn't for methadone. It wasn't for an anti-craving pill. It was for an app.

The app, reSET®, guided the patient through cognitive behavioral therapy exercises, delivered reminders and reinforcement, and kept him engaged between appointments. Weeks later, he was still abstinent—something that traditional therapy alone often failed to achieve. For the first time, code had become cure.

That moment wasn't just a novelty. It was the birth of a new therapeutic category: digital therapeutics (DTx).

## **From Molecules to Code**

For centuries, medicine has been defined by the physical. Pills, syringes, scalpels—objects we could hold, measure, dispense. Digital therapeutics upend that assumption. They are evidence-based software interventions designed to treat, manage, or prevent disease.

Like drugs, they undergo clinical trials. Like medical devices, they require regulatory approval. Like both, they can be prescribed and reimbursed. But unlike anything before them, their raw material is software—algorithms, modules, and interactive designs that reshape behavior and outcomes.

## **Examples already exist across a spectrum of conditions:**

Somryst®, delivering digital CBT-I for insomnia, helps patients fall asleep faster and stay asleep longer.

EndeavorRx®, a prescription video game, improves attention in children with ADHD.

## 2 Code to Cure: Digital Therapeutics and the Future of Pharma

Omada Health, a program for diabetes prevention, reduces risk through coaching, feedback, and behavioral nudges.

Each is different in form, but they share a defining principle: clinical proof. They don't just inspire wellness—they deliver measurable outcomes.

### The Evolution: From Tracking to Therapy

To understand digital therapeutics, it is helpful to examine their origins.

The first wave of digital health was about tracking. Pedometers counted steps. Calorie apps logged meals. Sleep monitors measured restlessness. They offered visibility, but not therapy.

The second wave was about guidance. Apps like MyFitnessPal and Headspace coached users toward healthier habits. They changed behavior, but without clinical rigor or regulatory oversight.

Digital therapeutics represent the third wave. They take those same digital tools and hold them to the same standards as medicine—randomized controlled trials, peer-reviewed studies, and regulatory scrutiny. Where Fitbit tracks and Headspace guides, reSET and Somryst treat.

### Drawing the Line: Apps vs. Therapeutics

It's easy to confuse a wellness app with a digital therapeutic—they both live on your phone, both send reminders, and both encourage change. But the difference is as sharp as that between a self-help book and a prescription drug.

- Headspace calms millions with meditation, but it is not FDA-approved and cannot claim to treat anxiety.
- Somryst®, by contrast, is tested, regulated, and prescribed for insomnia.
- Fitbit gamifies activity, but no doctor prescribes it for obesity.
- reSET® has been proven in trials to improve abstinence rates in substance use disorder and gained FDA approval.

The difference comes down to three things: evidence, regulation, and reimbursement. Digital therapeutics prove themselves through trials, win approval from regulators, and gain legitimacy when insurers agree to pay for them. Wellness apps don't.

## Why they Matter: Filling the Gaps in Healthcare

The question then becomes: why do we need digital therapeutics at all? Isn't medicine already advanced enough?

The answer lies in the cracks medicine has never been able to fill.

- **Diabetes:** Drugs lower glucose, but they don't change diet. Omada Health addresses the behavioral gap by coaching patients daily.
- **Depression:** Medication helps, but therapy access is scarce. Deprexis offers digital CBT modules, closing the access gap.
- **Asthma and COPD:** Inhalers work—if patients use them. Propeller Health tracks usage, provides reminders, and improves adherence.

These aren't small problems. They're the everyday failures that turn effective medicine into ineffective outcomes. Digital therapeutics don't replace drugs. They reinforce, extend, and complete them.

## Closing Thought

When medicine is dispensed, it often stops at the pharmacy counter. Digital therapeutics pick up where prescription medicine ends—guiding patients through the complex realities of daily life. They don't exist to compete with pills, but to stand alongside them, filling in the blind spots where biology alone is not enough.

What began with a pedometer on a waistband and a meditation app on a phone has now become something larger: software that doesn't just track or guide, but treats.

As reSET showed in 2017, the most powerful prescription may not come in a bottle—but in a download.



## 1.1 What are Digital Therapeutics?

In 2017, a 28-year-old patient struggling with substance use disorder left his clinic with an unusual prescription. It wasn't for methadone or naltrexone. It wasn't even for a pill. Instead, it was for a mobile app. The patient downloaded reSET®, a program built on cognitive behavioral therapy modules, and began working through exercises each day. Within weeks, he reported fewer cravings and stronger adherence to his recovery plan.

For centuries, medicine has been defined by the physical—pills in blister packs, syringes in refrigerators, devices strapped to the body. Digital therapeutics (DTx) challenge that definition. They are software-based interventions that treat, manage, or prevent diseases with the same clinical rigor as drugs or devices.

### The Core Idea

At their heart, digital therapeutics are evidence-based software programs. They're not health-tracking apps or step counters. They must demonstrate efficacy in clinical trials, often undergo regulatory review, and may be prescribed and reimbursed in the same manner as traditional therapies.

Think of them as the next therapeutic modality—joining drugs, biologics, and devices. But instead of chemistry or hardware, their raw material is code.

### Examples in Action

- Insomnia (Somryst®)

Cognitive Behavioral Therapy for Insomnia (CBT-I) is effective but hard to access. Somryst digitized CBT-I, delivering structured sleep therapy through an app. In clinical trials, patients fell asleep more quickly, stayed asleep longer, and maintained their improvements months later. What once required a specialist is now accessible on a smartphone.

- ADHD (EndeavorRx®)

When Akili Interactive launched EndeavorRx, parents were astonished. The therapy resembled a video game—complete with bright visuals, obstacles, and challenges. But behind the gameplay were algorithms designed to target attention pathways in the brain. Following trials that

demonstrated measurable improvements in focus, the FDA approved it as the first prescription video game for children with ADHD.

- **Diabetes (Omada Health)**

Managing diabetes isn't just about glucose—it's about daily behaviors. Omada Health's digital therapeutic combines coaching, data tracking, and behavioral nudges to prevent and manage Type 2 diabetes. Studies have shown that participants reduced their weight, improved glycemic control, and lowered long-term healthcare costs.

## **Why they Matter?**

Traditional drugs address the biochemical side of disease. Digital therapeutics address the behavioral, psychological, and access gaps that drugs alone cannot fix. They deliver therapy in the spaces where patients live their lives—in kitchens, bedrooms, offices, and commutes—rather than only in clinics.

The power of DTx is not that it replaces medicine. It's that they expand it. They make therapy continuous, personalized, and responsive in ways that pills never could.

## **Closing Thought**

When a doctor prescribes software instead of a pill, it feels almost counterintuitive. However, that is precisely the point: digital therapeutics challenge our assumptions about what therapy entails. They ask us to accept that a well-designed algorithm, grounded in science and validated by evidence, can be just as therapeutic as a drug.

And if the patient who once relied on a prescription bottle now finds healing through a prescription download, it may be time to redefine what we mean by medicine.



## 1.2 The Evolution of Digital Health Solutions

In 2009, a Silicon Valley engineer strapped a pedometer to his waistband, not because his doctor told him to, but because he was curious. Every beep, every count of his steps, gave him a small surge of motivation. That curiosity soon gave rise to Fitbit, one of the first devices to make health data personal, portable, and engaging.

It was a small leap at the time—counting steps is hardly therapy—but it planted a seed. If measuring behavior could influence it, could software one day treat behavior-driven disease?

That question set digital health on an evolutionary path that would eventually lead to digital therapeutics.

### From Tracking to Guiding

The first wave of digital health was about measurement. Step counters, calorie trackers, sleep monitors—they gave people visibility into habits they often ignored. But measurement alone rarely changed outcomes.

The second wave was about guidance. Apps like MyFitnessPal or Headspace didn't just measure—they coached, encouraged, and built habits. Yet, while they improved wellness, they didn't undergo the gauntlet of clinical trials or regulatory scrutiny. They were tools, not therapies.

The leap to digital therapeutics occurred when innovators asked: What if we apply the behavioral science behind these tools to the same standards as medicine?

### The First Digital Prescriptions

That leap became real in 2017 with Pear Therapeutics' reSET®, the first FDA-approved prescription digital therapeutic. Unlike a wellness app, it had randomized controlled trial data proving its efficacy in substance use disorder. It wasn't just guidance. It was therapy.

Germany accelerated this shift with its DiGA Fast-Track program, which allowed certain digital health apps to be prescribed and reimbursed. Solutions like HelloBetter (for depression and anxiety) and Kaia Health (for chronic pain)

proved that digital health could move beyond lifestyle and into mainstream medicine.

## **Paving the Way: The Role of Consumer Tech**

Ironically, it was consumer tech that made this leap possible. The smartphone ensured constant access. Wearables like the Apple Watch and Dexcom's continuous glucose monitors made real-time data collection seamless. Cloud computing enabled storage and analytics at scale.

Without these foundations, digital therapeutics would have remained theory. With them, they became practice.

## **The Lesson**

The evolution of digital health is a story of progressive ambition:

- First, measure (pedometers, calorie counters).
- Then, motivate (wellness apps, guided meditation).
- Finally, medicate (digital therapeutics validated by trials and regulators).

Each step built trust. Each step pushed the boundary of what “health through technology” could mean.

## **Closing Thought**

The pedometer didn't cure the disease. But it nudged millions to walk more. The wellness app didn't require FDA approval. But it made mindfulness mainstream. These early tools were not the destination, but the bridge.

They set the stage for a more radical idea—that software itself could be therapy. And in that sense, digital therapeutics are not a rupture with digital health. They are its inevitable next chapter.



## 1.3 Differentiating Digital Therapeutics from Digital Health and Wellness Apps

On the surface, a wellness app and a digital therapeutic can look strikingly similar. Both live on your phone. Both offer daily reminders, interactive modules, and even soothing visuals. But the difference between them is the difference between a cookbook and a prescription—one inspires healthier living, the other is designed to treat disease.

### Headspace vs. Somryst

Take Headspace, one of the world’s most popular meditation apps. Millions of users swear by its calming voices and guided sessions. Studies suggest it reduces stress and improves focus. However, Headspace is not regulated, not prescribed, and not reimbursed by insurance providers. It is a wellness tool, valuable but optional.

Now contrast that with Somryst, a prescription digital therapeutic for insomnia. Built on Cognitive Behavioral Therapy for Insomnia (CBT-I), it underwent randomized controlled trials, submitted clinical data to the FDA, and earned approval as a bona fide treatment. Physicians prescribe it. Insurers reimburse it. Patients don’t just use it for “better sleep”—they use it to treat a clinical disorder.

This is the dividing line: apps promise; therapeutics prove.

### Fitbit vs. reSET®

Consider Fitbit. It transformed how millions engage with fitness by counting steps, logging sleep, and gamifying activity. But no regulator oversees its claims. It’s designed for motivation, not for managing chronic disease.

Now consider reSET®, the first FDA-approved digital therapeutic for substance use disorder. Its clinical trials showed significantly higher abstinence rates compared to standard care. Like a drug, it had to prove efficacy and safety before it reached patients. Unlike Fitbit, it is prescribed by physicians and often reimbursed by payers.

Both are digital, both are health-related—but one focuses on lifestyle, while the other is medicine.

## The Three Distinctions

Digital therapeutics differ from digital health and wellness apps in three crucial ways:

1. Evidence: DTx must demonstrate clinical efficacy through rigorous studies. Wellness apps may cite user satisfaction, but not randomized trials.
2. Regulation: DTx undergoes approval by authorities like the FDA or EMA. Wellness apps launch directly in app stores.
3. Reimbursement: DTx can be prescribed and reimbursed like drugs. Wellness apps rely on consumers paying out of pocket.

## Why the Difference Matters

The distinction is not academic—it determines trust. A physician may recommend a wellness app as a complement to care, but they prescribe a digital therapeutic as treatment. A payer may cover a DTx because it lowers hospitalizations or relapse rates. A regulator ensures that a product is safe and effective before it reaches patients.

Wellness apps can inspire. Digital therapeutics must deliver.

## Closing Thought

It is tempting to blur the lines between digital health and digital therapeutics—after all, both leverage technology to improve well-being. But the difference lies in the stakes. If a wellness app fails, the user shrugs and deletes it. If a digital therapeutic fails, a patient suffers.

That's why one is marketed as a lifestyle and the other is regulated as a medicine. And it's why digital therapeutics represent not just a new category of apps, but a new category of therapy altogether.



## 1.4 The Rationale behind Digital Therapeutics: Addressing Unmet Needs in Healthcare

In 2015, a man in rural Montana was diagnosed with depression. His doctor prescribed medication but also recommended therapy. The problem? The nearest psychiatrist was a three-hour drive away, and the wait time for an appointment was four months. For him, therapy wasn't just expensive—it was inaccessible.

This story isn't unusual. Across chronic and mental health conditions, medicine often delivers the drug but fails to deliver the supporting care. That gap—between what medicine prescribes and what patients actually experience—is where digital therapeutics step in.

### The Behavior Gap: Diabetes and Daily Choices

Take Type 2 diabetes. Physicians can prescribe metformin or insulin, but medication alone cannot undo years of dietary habits or sedentary lifestyles. The real challenge lies in the “last mile” of care—helping patients make healthier decisions each day.

This is what Omada Health recognized. Their digital therapeutic combines connected devices, coaching, and behavioral nudges. Patients receive real-time feedback on their food, activity, and glucose levels, along with a personalized plan that adapts as they progress. Clinical studies show it reduces the risk of progression to full-blown diabetes.

The unmet need wasn't a lack of drugs—it was a lack of behavioral reinforcement. Omada filled that gap.

### The Access Gap: Depression and Geography

Mental health offers another example. Access to therapy is uneven at best and impossible at worst. In some regions, patients face months-long waits for therapists; in others, stigma prevents people from seeking help at all.

Deprexis, a digital therapeutic for depression used in Europe, bridges this gap. Delivered entirely online, it provides structured cognitive behavioral therapy modules. Patients log in when needed, regardless of their location or the availability of specialists. Trials show significant symptom reduction compared to control groups.

The unmet need wasn't a lack of treatments—it was a lack of reach. Deprexis solved for access.

## The Adherence Gap: COPD and Asthma

Even when drugs are available, patients often don't take them as prescribed. For conditions like COPD or asthma, adherence to inhalers can be inconsistent, leading to flare-ups and hospitalizations.

Propeller Health addressed this problem with a simple yet powerful solution: a digital sensor that attaches to inhalers, tracking usage and linking it to environmental triggers. Patients get reminders, and doctors get adherence data. The result? Fewer hospital visits, better self-management, and measurable cost savings.

The unmet need wasn't a lack of drugs—it was a lack of adherence. Propeller closed that gap.

## The Lesson

Digital therapeutics are not trying to replace medicine. They are trying to repair its blind spots.

- Where drugs can't fix behavior, DTx can.
- Where geography blocks access, DTx can.
- Where adherence falters, DTx can.

They target the invisible moments in a patient's life—the choices, lapses, and barriers that often decide whether treatment succeeds or fails.

## Closing Thought

The rationale behind digital therapeutics is deceptively simple: healthcare is more than prescribing. It is about living with a condition, day in and day out. And in those daily moments, pills often fall short.

Digital therapeutics meet patients where they are—on their phones, in their homes, in their habits—and offer what medicine alone cannot: constant, personalized, behavioral reinforcement.

That is why they exist. And that is why, increasingly, they matter.

