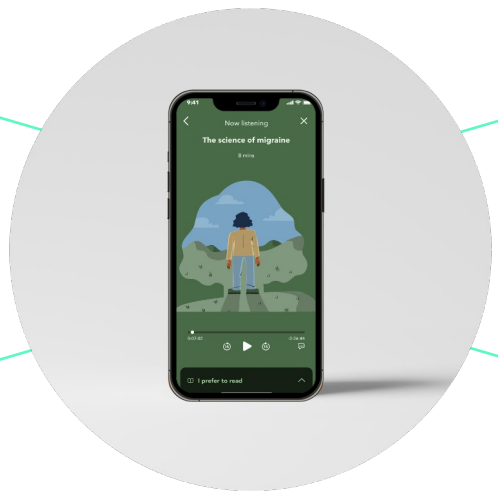
Prescription Digital Therapeutics

Evidence-based software as prescription medical treatment that can offer new therapeutic options to improve the current standard of care.

Prescription Digital Therapeutics (PDTs) are software-based interventions that are regulated by the FDA, validated by clinical trials, and prescribed by a licensed healthcare professional (HCP) to treat a disease. While drugs are “approved” by the FDA, PDTs are “authorized” or cleared as a software as a medical device (SaMD). All of them are required to have clinical trials as part of the FDA authorization. They fill unmet needs where pharmaceutical therapy alone is not sufficient and help address the gap between what providers can offer in person and the challenges patients with health conditions face day to day.



Standalone or adjunct to pharmacotherapy

Prescribed by a physician

Clinically validated and FDA-regulated

Delivered via smartphone app

What are Prescription Digital Therapeutics?

They deliver **evidence-based treat**ments directly to a patient via their smartphone in the form of a mobile app.

They comply with existing **Software-as-a-Medical Device** regulations to ensure rigor and compliance during development and commercialization.

PDTs meet **higher clinical and regulatory benchmarks** than health and wellness apps. They are rigorously studied and validated for safety and effectiveness in randomized clinical trials.

Can be **standalone or an adjunct to pharmacotherapy**, but do not enable drug label expansion.

What benefits can Prescription Digital Therapeutics offer?

Can help address the gaps between what providers can offer in person and the challenges the patient faces face day to day by making treatment **accessible anywhere at any time**.

Because PDTs are delivered digitally, people treated with them are **less likely to experience adverse events or drug interactions**.

Can be used in combination with both pharmacological and non-pharmacological interventions by **supporting self-management of conditions** and related health factors.

Partners of Choice For A Digital Future

Extensive clinical trial experience with **2,300 sponsors**, **35,000 studies**, **11 million patients**

Powers clinical validation

Develops the digital intervention

Deep **scientific and regulatory expertise** in developing **software-based treatments** across multiple therapeutic areas

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