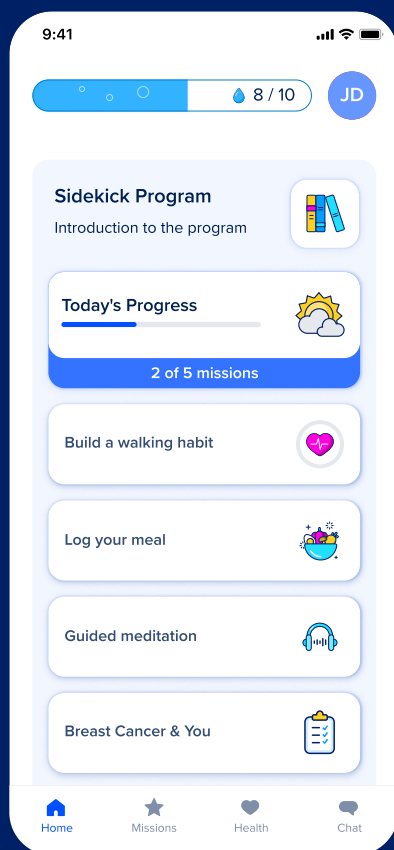




New FDA guidance on PDURS ushers in a new era for digital innovation in Life Sciences

Tech savvy pharma companies to leverage new FDA guidance as patients demand more digital tools





Introduction

In a world where patient engagement and adherence are pivotal to successful healthcare outcomes, pharmaceutical and life sciences companies face mounting pressure to innovate beyond traditional therapies.

The FDA's new draft guidance on Prescription Drug Use-Related Software (PDURS*) represents a transformative opportunity for pharmaceutical companies to harness the power of digital health solutions to improve both patient outcomes and product success. With this new draft guidance, pharmaceutical companies have a clearer path for incorporating digital solutions designed to enhance the safe and effective use of medications into their product offerings.

The FDA's new draft guidance on PDURS is more than just a regulatory update—it will enable a strategic turning point for pharmaceutical companies seeking to enhance their competitive edge. By integrating digital solutions into their product offerings and label claims, pharmaceutical companies have a new opportunity to differentiate their drugs in a crowded market.

As the landscape of healthcare rapidly evolves, and patients demand more personalized, tech-enabled care, the FDA's new guidance on PDURS couldn't come at a more opportune time. Companies that embrace this innovation now will be well-positioned to lead in a new era of healthcare.

With over 10 years of experience partnering with Life Sciences companies to support their digital innovation needs, Sidekick Health has been at the forefront of designing and delivering software that enhances medication adherence and patient engagement. With the new FDA guidelines on PDURS, companies like Sidekick are uniquely positioned to help pharmaceutical companies seize this opportunity for innovation.

In this white paper, we will explore the implications of the FDA's draft PDURS guidance, examine how digital health solutions are transforming patient care, and provide insights into how pharmaceutical companies can leverage this opportunity to drive both commercial success and improved patient outcomes.

*Note - This draft guidance is not yet in effect.



PDURS Draft Guidance: Key Features of a Prescription Drug Use-Related Software

Prescription Drug Use-Related Software (PDURS) refers to a wide range of applications that can help to optimize the use of prescription drugs, through drug- or disease-specific education, tracking of medication adherence, assistance with dosing, or to guide lifestyle and behavioral aspects of care. The PDURS draft guidance is focused on applying drug labeling rules to software that is disseminated by or on behalf of a drug sponsor (pharmaceutical company) for use with a prescription drug. PDURS software applications and experiences produce an end-user output (text, images, and other multimedia content) that is designed to supplement, explain, or that is otherwise textually related to one or more of the sponsor's drug products.

PDURS FDA-Required Labeling for Software with Claims of Clinical Benefit

Pharmaceutical companies can leverage PDURS labeling to demonstrate the clinical benefits of software experiences that (a) provide a function that is critical to the safe and effective use of the drug product, (b) provide a clinically meaningful benefit when the software is used, or (c) utilize data from the device constituent part of a combination product.

In support of such label claims, the FDA will require “adequate and well controlled” evidence demonstrating the clinical impact of the software. This data will be submitted via a new drug application (NDA), abbreviated new drug application (ANDA), biologics license application (BLA), or as a supplement to any of those. The FDA will take a risk-based approach in evaluating these claims; end user outputs with lower risks to patients, will have a lower evidentiary burden as well. Most PDURS software experiences are likely to be low-risk, and could potentially utilize high-quality Phase 4 or real-world evidence data in support of claims.

Table 1: PDURS Draft Guidance Categories

	Promotional/marketing labeling	FDA required labeling
Software Impact	No claims of clinical effect nor potential for harm	Claims of meaningful clinical benefit to the drug
Regulation	Sponsor completes Form 2253 (FDA notification)	Sponsor to generate evidence for a claim and submit as NDA supplement
Software Examples	Disease self-management, dosing and injection support	Side effect management, behavioral therapy, flare prediction, dose optimization, etc

PDURS Promotional Labeling

For drug-related software experiences which will not have any associated claims of clinical benefit, the software outputs will be considered as promotional content. Pharmaceutical companies will notify the FDA about the relevant software outputs for these experiences via Form 2253. This use-case will apply to many current companion health applications and patient support tools.



PDURS Solutions Can Drive Value Across the Healthcare Continuum

Key Market Dynamics and Challenges

Digital companion solutions deployed via the PDURS framework will be well suited to help pharmaceutical companies address many of the key challenges they currently face in the market.

Patients aren't experiencing the full benefit of their medications and are interested in solutions – including digital – to address this. In fact, 57% of patients emphasized the need for ongoing support to manage their medications appropriately and to take the correct dose.

Furthermore, 75% of patients feel that pharmaceutical companies have a responsibility to provide tools and services that complement their drug products¹, and 76% of patients reported a belief that technology has the potential to improve their care².

This reinforces the notion that patients are increasingly becoming critical decision-makers around their care and are exhibiting more digital-first expectations, supporting the myriad opportunities for PDURS solutions in the market. Doctors and care providers agree, with 90% of HCPs saying that biotech and pharmaceutical companies should support improving patient health outcomes in ways beyond high-quality drugs³.

Software Experiences Can Create Positive Outcomes and Market Differentiation

Over time, the medication brands that bring solutions directly to patients, that improve outcomes and relieve HCP burden, will have a competitive edge over those that do not. As healthcare delivery in the US becomes increasingly value-based, doctors and payers are looking for the most effective and patient-centric solutions overall. In fact, 50% of doctors say they are more likely to prescribe medications from companies that are more patient-centric⁴.

Digital tools and software experiences are a key way that pharmaceutical companies can deliver more effectively to these key stakeholders within the care continuum, and create positive impacts for the patients that use their medications and the doctors that prescribe them.

For example, patients using Sidekick Health's mobile oncology program alongside cancer therapy showed improved quality of life, energy and activity levels⁵ while their self-reported pain levels showed a decrease⁶. In cardiometabolic indications, Sidekick Health programs have been shown to improve key physiological biomarkers during treatment, including: HbA1c, weight and liver fat⁷.

Crucially, many of these improvements were sustained over time, illustrating the ability for digital solutions to create positive behavior and lifestyle changes with lasting effects that are often out of reach of traditional therapies.

¹ Turcotte J (2020). *Salesforce Research: 4 Ways Pharmaceutical Companies Can Drive Patient Engagement*.

² Chatham L (2016). *Kareo: ROI of Patient Engagement*

³ WE Brands in Motion (2023). *Healthy Reputations: More Than Medicine Report*

⁴ Lubkeman M et al (2020). *BCG Report: What Do Patients Want, and Is Pharma Delivering?*

⁵ Bjarnadottir OK et al (2024). ASCO https://doi.org/10.1200/JCO.2024.42.16_suppl.1570

⁶ Gudmundsdóttir SL et al (2022). <https://doi.org/10.1007/s13555-022-00821-y>

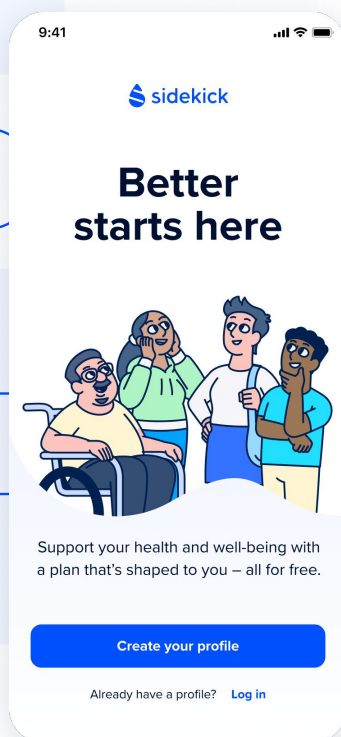
⁷ Byornsdottir S et al (2023). <https://doi.org/10.2337/db23-646-P>



SUPPORT AND INSTRUCTIONS

IMPROVING PATIENT ENGAGEMENT
WITH TREATMENT PLAN

PATIENT EDUCATION



- ↑ Quality of life
- ↑ Energy and activity levels
- ↓ Self-reported pain levels showed a decrease
- ↑ Improved key physiological biomarkers during treatment

Developing a PDURS with Sidekick Health

The PDURS framework offers pharmaceutical companies the opportunity to increase the overall impact they can have in caring for patients and improving health outcomes. Sidekick Health, a leading digital health and DTx company, works with partners to digitize and fundamentally improve how patients engage with their care in order to make healthcare more impactful, equitable, and efficient.

Sidekick has developed a single, multi-chronic indication platform that is flexible and scalable across our twenty therapeutic areas, including cardiometabolic, oncology, inflammation/immunology as well as women's health indications. It can be adapted to serve as a foundation for PDURS development across these indications, specialty medications, and chronic care.



Table 2: Potential Examples of PDURS

	Example Use-Case in Oncology	Example Use-Case in Cardiometabolic (Obesity)	Example Use-Case in Immunology
	PDURS with a breast cancer therapy	PDURS with a new Obesity medication, eg a GLP-1 based mono, dual or triple agonist	PDURS with a biologic drug (psoriasis) that is approaching loss of exclusivity
Real-world problem(s) to solve	Patients experience anxiety, depression, and a sense of isolation after diagnosis and throughout treatment, which affects their mental health and overall well-being⁸ Patients experience significant side effects, eg: nausea, fatigue, hair loss, and hormonal changes that severely impact their quality of life	Patients experience high discontinuation rates after initiating on therapy¹⁰ Patients struggle with side effects experienced during periods of therapy titration (nausea, discomfort, etc)	Patients require personalized dermatology regimes as well as education around flare mitigation, symptom control, and the psychological aspects of their condition¹¹ Patients experience uncertainty around a medication's effectiveness and may be inclined to switch amongst competing brands during this time
Digital intervention	Digital experience using a cognitive and behavioral approach to address patient mental health, nutrition, and side effect management during their treatment journey ⁹	Digital experience designed to enhance persistence mechanistically through a holistic lifestyle intervention that emphasizes disease self-care, dose management and side effect management	Digital experience designed with disease and injection-specific education alongside personalization that can drive lasting habits around therapy and topical regimes Include holistic content designed to address the psychological and physiological aspects of the condition and treatment
Supplemental Label Claim	Improved quality of life, work function, daily activities	Improved quality of life, patient satisfaction on therapy	Improved quality of life (reduced injection anxiety), improved symptom management
Business Impact	Innovation and market differentiation: Pharmaceutical companies can promote the evidence of digital solutions via label claims New opportunities to engage patients and HCPs around the novel hybrid drug plus digital solutions that better care for patients and improve outcomes overall		

⁸ American Cancer Society: Chemotherapy for Breast Cancer

⁹ Wolff J et al (2023). *Breast Care*. 18 (5): 354–365. <https://doi.org/10.1159/000531495>

¹⁰ Terhune C (2024). Reuters report on discontinuation of GLP-1 medicines for weight loss.

¹¹ Ujjie H et al (2022). *Front Med (Lausanne)* 9: 875492. DOI 10.3389/fmed.2022.875492



Summary

The central advance within the new PDURS draft guidance is it clarifies the pathway for pharmaceutical companies to demonstrate the clinical evidence of software-based claims, and how to incorporate such claims within drug labels. Until now, the evidence burden was higher for certain claims, which potentially limited how pharmaceutical companies could discuss digital solutions alongside their drugs going to market.

The longitudinal digital experiences offered through the Sidekick platform can serve a synergistic role alongside treatments to demonstrate such impact. Together, we can co-develop these innovative new products in order to deliver an even more impactful solution that is designed and demonstrated to produce even greater outcomes in the real-world, all aligned to the most current FDA guidelines and best practices.

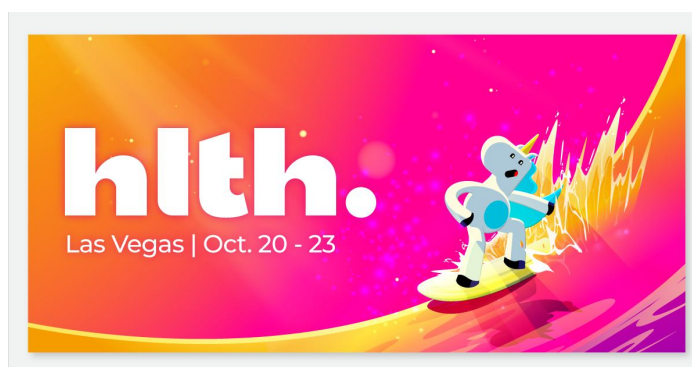
As the healthcare landscape continues to evolve, the integration of digital health tools like PDURS will be crucial to unlocking the full potential of modern treatments and staying ahead of market expectations. Pharmaceutical companies that embrace these innovations today will be the leaders of tomorrow, delivering life-changing outcomes to patients worldwide.

We'll be at the HLTH Conference in Las Vegas NV, October 20-23, and would welcome your feedback and thoughts around the future of PDURS. Schedule a meeting with us below.

[Schedule a meeting with us](#)



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About Sidekick Health

Sidekick Health is a global healthcare company that works with partners to fundamentally improve how care is managed and delivered, making healthcare more impactful, equitable, and efficient. We work with a quarter of the global top-20 healthcare companies across insurers, life sciences, and prescription digital therapeutics industries to deploy single and multi-condition care journeys for more than 20 therapeutic areas.

Learn more about our work and our innovative partnerships at sidekickhealth.com/research and sidekickhealth.com/media.

Get in touch

Find us at sidekickhealth.com/contact
or email us at info@sidekickhealth.com

Coronary Artery Disease

Colorectal Cancer

Rheumatoid Arthritis

High-Risk Maternity

Obesity

Crohn's Disease

Behavioral Health

Sidekick programs cover

Obesity Trial Support

Psoriatic Arthritis

Lung Cancer

Ulcerative Colitis

Maternity Basics

+20
conditions

Prostate Cancer

Atopic Dermatitis

Pediatric Obesity

Breast Cancer

Heart Failure

Whole Person Health

Oncology Navigator

Type 2 Diabetes

Post-Hospital Discharge Management

Oncology Treatment Support