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# Digital Therapeutics Commercialization Tips and Challenges

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Digital therapeutics, telemedicine, and asynchronous medicine are changing the way patients and healthcare providers interact.

For many years, the healthcare industry has combined Star Wars-level technology with Flintstones-level delivery. For example, even while the rest of the world moves to full digitization, fax machines remain a staple of physician offices. But digital solutions are starting to change the paradigm. Pharmaceutical manufacturers, and now digital therapeutic distributors, must evaluate their commercialization planning in the new digital era of healthcare.

## The Digital Demand and Evolution of Healthcare

The digital era has changed expectations within healthcare. With the wide entrenchment of online shopping for everything from coffee to cars—often with next day delivery—and digital streaming of video content, people now have expectations of immediate gratification. This translates into an expectation for immediate access to health information and therapeutic solutions. Patients expect immediate access to expert advice and their own health information with the click of a mouse. Healthcare providers also expect timely access to clinical information and analytics in an easily digestible manner to help with clinical decision-making and management.

The healthcare industry is evolving to meet these demands. The digital health evolution has created solutions across healthcare development and distribution that offer patients and healthcare providers faster access to information, improved analytics, and new ways to interact. Online patient portals now offer immediate access to medical records, email capabilities with providers, and online appointment making. Patients can request an appointment and communicate with a physician on the phone, video, or text within minutes.



The digital health evolution has also brought providers into patients' pockets through apps that enable telemedicine and asynchronous medicine. Today's digital technology gives providers the ability to consult with patients through HIPAA compliant telemedicine-conferencing tools. Asynchronous medicine enables providers to leave descriptive videos of diagnosis and treatment recommendations that patients can view at their convenience and review multiple times for clarity. Providers can send prescriptions to local pharmacies through e-prescribing, and patients can even have the pharmacy deliver to their door. In some cases, patients literally never have to leave their homes to get healthcare.

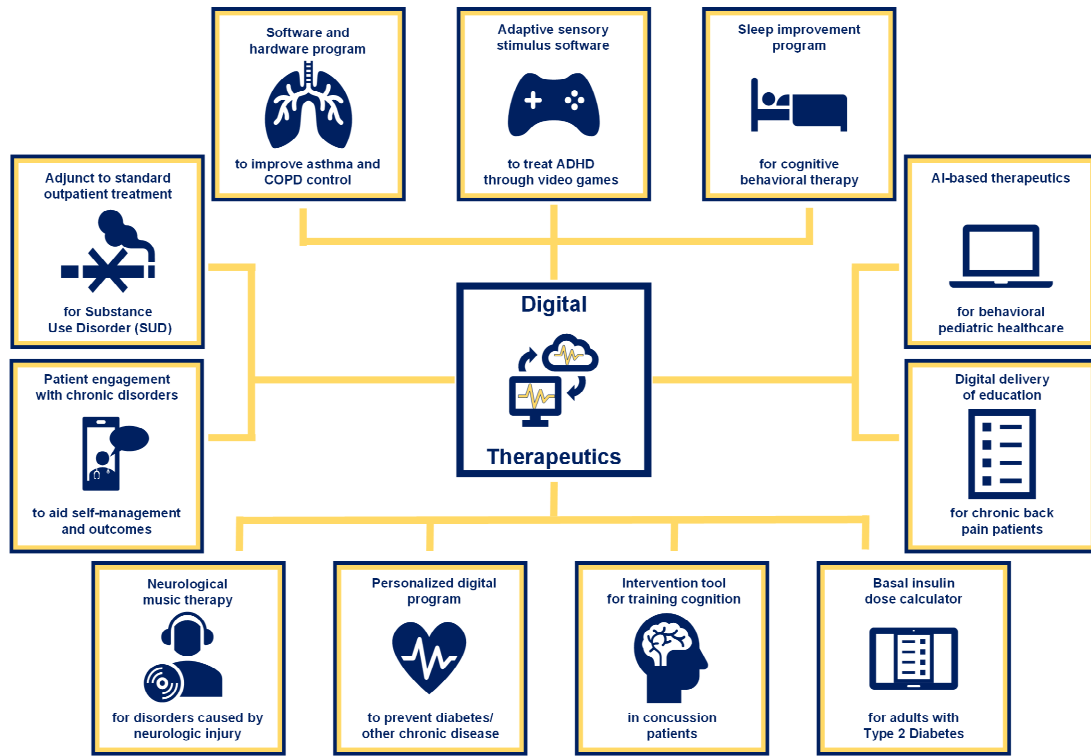
For providers, improved analytics and dashboards enable access to clinical decision-making tools and longitudinal patient information from wearable devices and apps that provide real-time feedback. Hospitals are using software to better mine their real-world data. Even diagnostics and patient adherence are evolving to include more portable and smartphone connected devices.

## Digital Therapeutics: The Next Healthcare Evolution

The latest digital evolution supporting greater access to care is focused on digital therapeutics. Prescription or non-prescription digital therapeutics (PDT or DT) offer treatments to support, or even possibly replace, prescription drugs to improve patient outcomes. They can be used independently or in tandem with a prescription medication or device. According to the Digital Therapeutics Alliance, a global non-profit trade association with the mission of broadening the understanding, adoption, and integration of clinically validated digital therapeutics.

As this new category of medicine continues to be integrated across the healthcare ecosystem, digital therapeutics will increasingly influence the way healthcare is delivered and consumed across the world. Digital therapeutics deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a broad spectrum of behavioral, mental, and physical diseases.

Digital therapeutics are available to help improve patient outcomes in a variety of therapeutic areas (shown on the following page).



Areas of Digital Therapeutics

## Traditional Marketing for an Innovative Delivery

A key digital therapeutics evolution in recent years is the transition from apps to clinically validated tools. This typically means completion of one or more clinical studies, including an adequately powered randomized control trial in the target patient population, and publication of trial results inclusive of clinically meaningful outcomes on the stated primary outcome in peer-reviewed journals. This is meaningful for commercial teams as they seek to educate healthcare providers through marketing and scientific communication.

While the advent of digital therapeutics implies a significant evolution of the healthcare environment, traditional marketing goals still apply. These include:



**Market-Shaping:** Market-shaping ensures healthcare providers understand the value of a therapeutic and how to use it in practice. Right now, this can be a particular challenge for marketers as awareness remains low and clinical guidelines are lacking.



**Publications of Clinical Validation:** Publications that validate the efficacy, health economics to show improved outcomes, and recommendations on use patterns are necessary to influence guideline development.



**Promotional Efforts:** Promotional efforts that increase awareness of the attributes of a new product and encourage trial are critical to the marketing funnel.

## FDA Pre-Cert

The FDA's Software Precertification (Pre-Cert) Program is intended to help inform future regulatory models that will provide effective and efficient regulatory oversight of digital therapeutics.

In September 2017, the FDA selected the following nine companies from over 100 applicants to participate in the development of the Software Pre-Cert pilot program:

1. Apple
2. Fitbit
3. Johnson & Johnson
4. Pear Therapeutics
5. Phosphorus
6. Roche
7. Samsung
8. Tidepool
9. Verily

Only a few solutions from among these companies are available to date. Expect new prescription and non-prescription solutions across therapeutic categories to become available in coming years.

## Key Considerations for a New Approach

Targeting has traditionally been based on prescribing behavior and sometimes on attitudinal research studies. With today's completely new paradigm of digital therapeutics, there is no past behavior on which to predict use. With such limited awareness and a lack of clinical guidelines, even attitudinal studies might be insufficient for true targeting. Early adopter studies based on uptake of new medications might be predictive but are just as likely to be insufficient. A new approach to targeting that incorporates personal digital behaviors may be valuable.



Reaching providers through digital, non-personal methods and engaging for demonstrations might be most predictive of prescribing potential. Non-personal, omni-channel marketing is important when we consider the volume of physicians meeting patients through telemedicine. While many of the physicians in telemedicine situations are doing it part-time or after hours, more and more are working for telemedicine companies as employees in an office or even working from their homes. This fragmentation of care location makes it even more challenging to reach physician through traditional sales force models. Just as

telemedicine and digital therapeutics are intended to increase access to care, marketers need to also increase their ability to reach physicians across all locations. An omni-channel method may be the best approach for both promotional and scientific education communication.

Integration of patient data from digital therapeutics into the provider workflow is a critical element for viable use. To satisfy both patients' and physicians' security concerns around sensitive healthcare data, digital therapeutic providers will have to work in the commercial readiness stage to ensure integration into medical record platforms across health systems and doctors' offices.



Distinct from drug delivery, a digital therapeutic may undergo updates based on real-world evidence or data privacy. This may require additional training of users and updates to better integrate with medical records platforms. While traditional pharma marketers have to frequently manage the implications of product label updates, digital therapeutic providers will need to consider the approach to updates as they roll out first commercialization.

## Payer Reimbursement Concerns and Coverages

Digital therapeutics, and payer reimbursement of such, are in their infancy. The many benefits of the category that should drive payer coverage include:



- Improved clinical and health economic outcomes at the patient and population levels for a large range of physical, behavioral, and mental disorders and diseases
- Increased patient population exposure to effective and engaging treatments, without requiring an equivalent workforce expansion
- Increased ability to gather and analyze individual and population health outcomes
- Decreased economic burden of medical conditions via a reduction of overall healthcare costs

The Academy of Managed Care Pharmacy (AMCP) recently brought together a forum of healthcare leaders to discuss digital therapeutic coverage. As the landscape is in its infancy, many possible approaches were discussed, including the creation of a unique digital therapeutic coverage class.

Slowly, DTs are being covered by payers and through partnerships:

- Omada's Type 2 Diabetes Digital Care program is available as a covered benefit for the Blue Cross and Blue Shield of Minnesota commercial plans and Cigna
- WellDyneRx, a full-service, independent pharmacy benefit manager (PBM), incorporated Voluntas' Insulia® into the WellManaged-Diabetes program. Insulia® is an FDA-cleared, prescription-only digital therapeutic for people and their care teams using basal insulin to treat type-2 diabetes
- Welldoc's BlueStar program for type 2 diabetes is offered at a discounted rate to employers in the Business Health Care Group Coalition
- Freespira, an in-home digital therapeutic device for panic disorder and panic attacks occurring with other anxiety conditions, was added to Highmark's medical policy
- Propeller Health and Express Scripts provide Propeller's FDA-cleared digital solution to Express Scripts members using inhaler sensors and a mobile app to manage asthma or COPD.

## To Partner or Not to Partner?

Pharmaceutical companies are both engaging with technology developers in partnership to build new digital health solutions and conducting their own internal development. Much like traditional approaches to clinical development, it's important for pharma to place multiple bets on multiple approaches to ensure a route to success.

A key question for technology start-up digital therapeutic developers: *what's the best way to commercialize?* The options include to do it alone; seek partnerships with payers like many telemedicine companies did; or leverage larger pharmaceutical partners to commercialize. Independent commercialization requires careful planning to achieve adequate distribution, trial, and broad payer access. This includes end-to-end prescription and procurement process, distribution, medical affairs, technical support, and patient data management.

## Engaging Commercialization Expertise

Engaging a partner with deep pharmaceutical and device commercialization expertise, along with digital health implementation experience, is the best approach to ensure success. Experienced partners with the ability to connect the dots along development, customer experience, distribution, and payer coverage will help reduce risk and achieve timelines.



## Contact Us

For more information or to discuss how Herspiegel Consulting can help with digital therapeutics commercialization, please contact Beth Schurman at [Beth@Herspiegel.com](mailto:Beth@Herspiegel.com) or 267-759-2132.

## Herspiegel Consulting<sup>LLC</sup>

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References: [1] [https://dtxalliance.org/wp-content/uploads/2018/09/DTA-Report\\_DTx-Industry-Foundations.pdf](https://dtxalliance.org/wp-content/uploads/2018/09/DTA-Report_DTx-Industry-Foundations.pdf) [2] <https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program#who> [3] <https://www.nytimes.com/2018/03/18/technology/take-this-app-and-call-me-in-the-morning.html> [4] <https://www.triple-tree.com/strategic-insights/2019/august/digital-therapeutics-emerging-as-a-future-key-area/> [5] [https://www.amcp.org/sites/default/files/2019-10/PF-SEPT2019\\_execsummary%20%28oct15%29.pdf](https://www.amcp.org/sites/default/files/2019-10/PF-SEPT2019_execsummary%20%28oct15%29.pdf) [6] <https://www.mobihealthnews.com/content/north-america/cvs-health-kicks-digital-health-friendly-service-pbm-clients-big-health-s> [7] <https://freespira.com/highmark-inc-adds-coverage-for-medical-innovations-in-treatment-of-panic-attacks/> [8] <https://drugstorenews.com/retail-news/walgreens-find-care-platform-to-support-diabetes-asthma-patients> [9] <https://dtxalliance.org/industry-resources/>