

# **Medical Affairs 2.0: Innovating Medical Affairs for Digital Therapeutics**

**September 18, 2020**



## >> NOW SPEAKING: **Conor Schmitt**

Management Consulting Engagement Manager, SSI Strategy

# Disclaimer

1

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### Webinar Purpose



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## Speaker Profiles

### Conor Schmitt

Engagement Manager, SSI Strategy



Conor has 7+ years of experience as a management consultant across 8+ industries, he currently advises Chief Medical Officers and Medical Affairs executives from emerging to Fortune 500 organizations.

p / +1.630.699.5821  
e / conor.schmitt@ssistrategy.com

### Jennifer Shannon, MD

CEO, Digital Brain Consulting + Clinical Advisor, Cognoa



Jennifer is a Board-Certified Child and Adolescent Psychiatrist, Founder of Digital Brain consulting, and a member of the DTA Healthcare Advisory Board.

p / +1.425-577-9093  
e / jennifershannonmd@gmail.com



#### 1 Overview



#### 2 Relevant Sample Experience

- **\$2B Biotechnology Company** – engaged by the Head of Medical Affairs (US Oncology) to assess and prioritize medical gaps to guide recommendations for medical tactics to address community needs
- **\$1B Medical Device Company** – worked with the Chief Medical Officer (global) to design and implement a new function to support strategic planning needs of Medical functions
- **Emerging DTx Company** – led the development of a Medical Affairs Roadmap to guide tactics for the Chief Medical Officer ahead of the company’s first commercial launch

- **Subject Matter Expert** on Digital Mental Health and Digital Therapeutics
- **DTx Adoption Barrier Assessment**– analyzed impact of medical community unmet needs and patient impact to guide build of Medical Affairs strategy ahead of product launch
- **DTx Early Adopter Analysis**– defined medical characteristics Early Adopters supported by initial interviews with medical community to define impact of COVID and unmet needs of adopters
- **DTx KOL Engagement Strategy**– conducted KOL mapping for full US region and supporting engagement tactics





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# Presentation Objectives

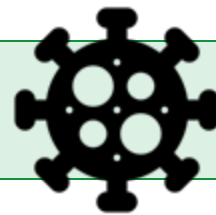
## 1 Overview & Landscape

Present an overview of the **current and near-term Digital Therapeutics landscape** with a focus on current stages of development.



## 2 Impact of COVID-19

Review the **impact of COVID-19 as an accelerator** for the development and use of Digital Therapeutics.



## 3 Real World Applications

Detail real **world applications of Digital Therapeutics** to illustrate the potential it holds in driving transformation of clinical practices to improve patient outcomes.



## 4 Role of Medical Affairs

Examine how **Medical Affairs can help act as a strategic partner** and shape the trajectory of the Digital Therapeutics pipeline and life-cycle.



**Digital Therapeutics** will be abbreviated as **DTx** throughout the presentation



## 1 Overview & Landscape

Present an overview of the **current and near-term DTx landscape** with a focus on current stages of development



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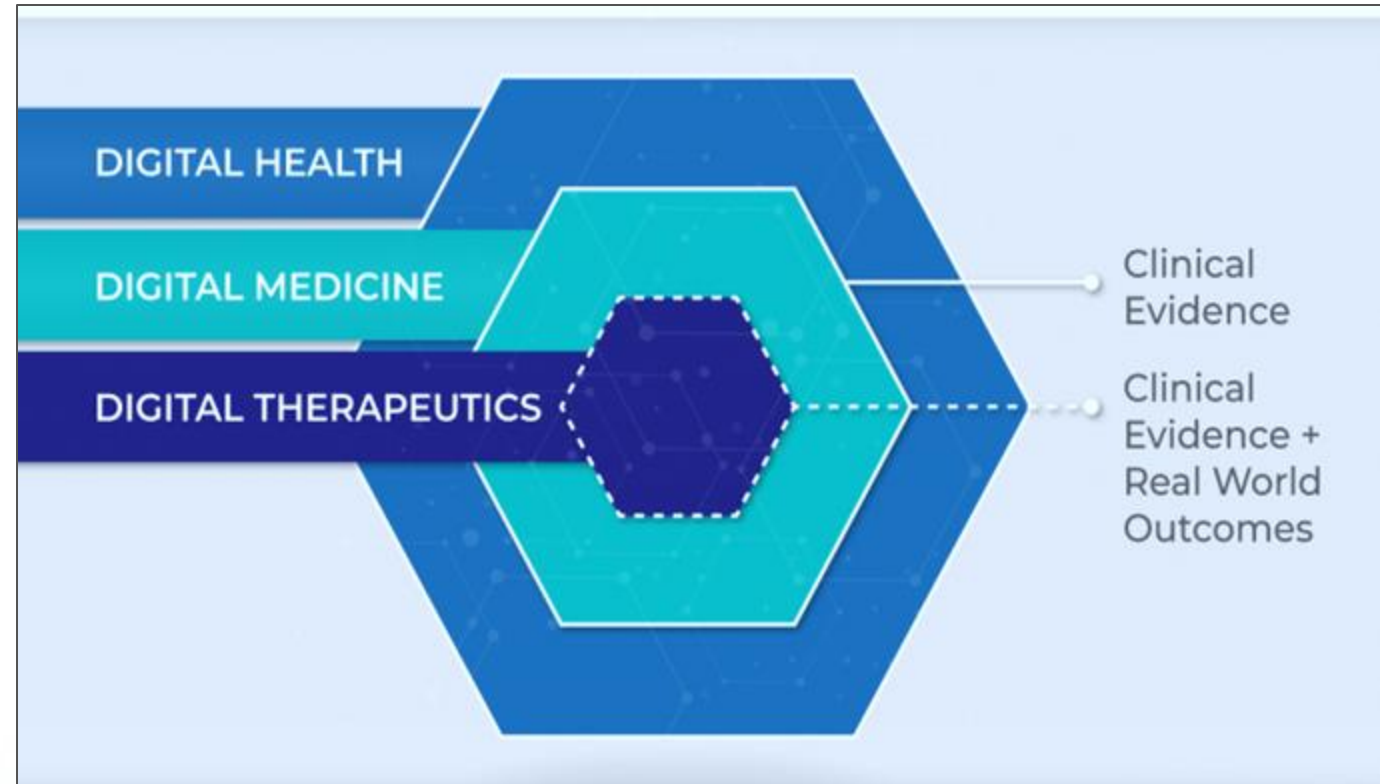
# Digital Health Landscape



**Digital Health** is a broad umbrella term that includes subsets of **Digital Medicine** and **DTx**

*“Digital Health connects and empowers people and populations to manage health and wellness, augmented by accessible and supportive provider teams working within flexible, integrated, interoperable, and digitally-enabled care environments that strategically leverage digital tools, technologies and services to transform care delivery”*

Healthcare Information and Management System Society





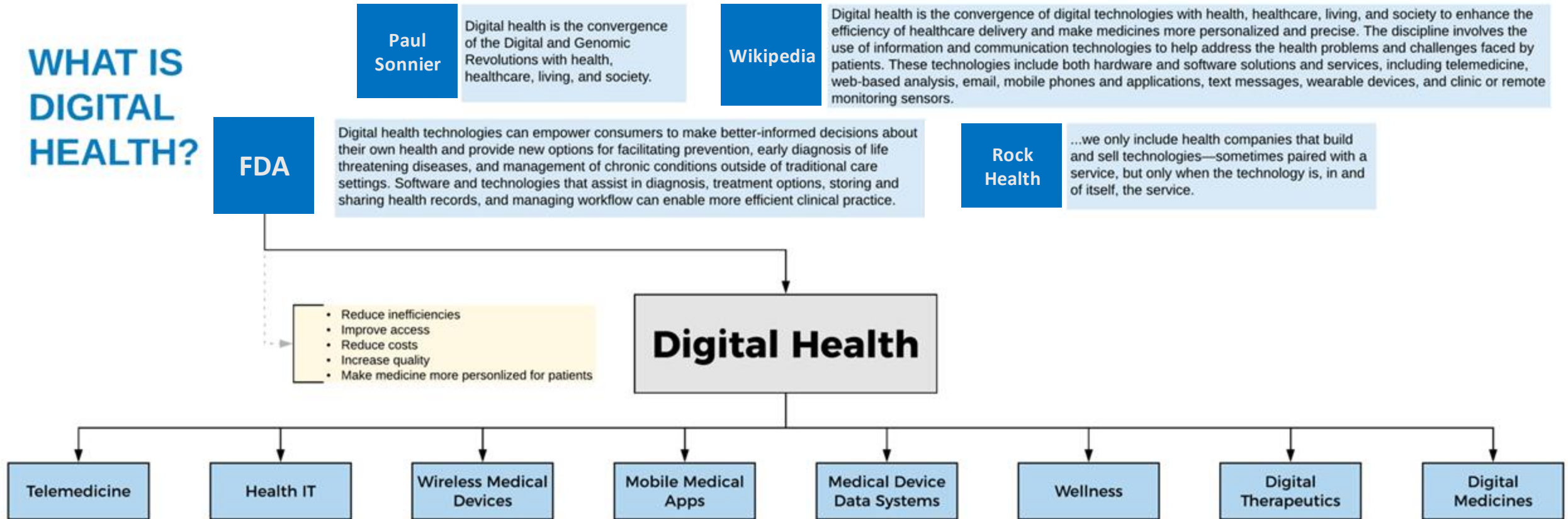


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## Overview of DTx

### WHAT IS DIGITAL HEALTH?



1. Source: Paul Sonnier, What is Digital Health



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## Defining DTx

### 1 What It's Not

DTx is not a drug, biologic, or wellness application – it's a new product category



### 2 Intervention Needs

DTx must deliver evidence based therapeutic interventions



### 3 Software + Device

Prevent, manage, or treat a medical disorder via software (as a medical device)



### 4 Standalone Use

Can be used as a standalone product or adjunct to a medication or device



### 5 Clinical Evidence

Requires robust clinical evidence and real-world outcomes



### 6 Regulatory Bodies

Subject to regulatory oversight to assess risk, efficacy, and intended use



### 7 Prescriptions

May require a prescription for use (PDT=prescription digital therapeutic)





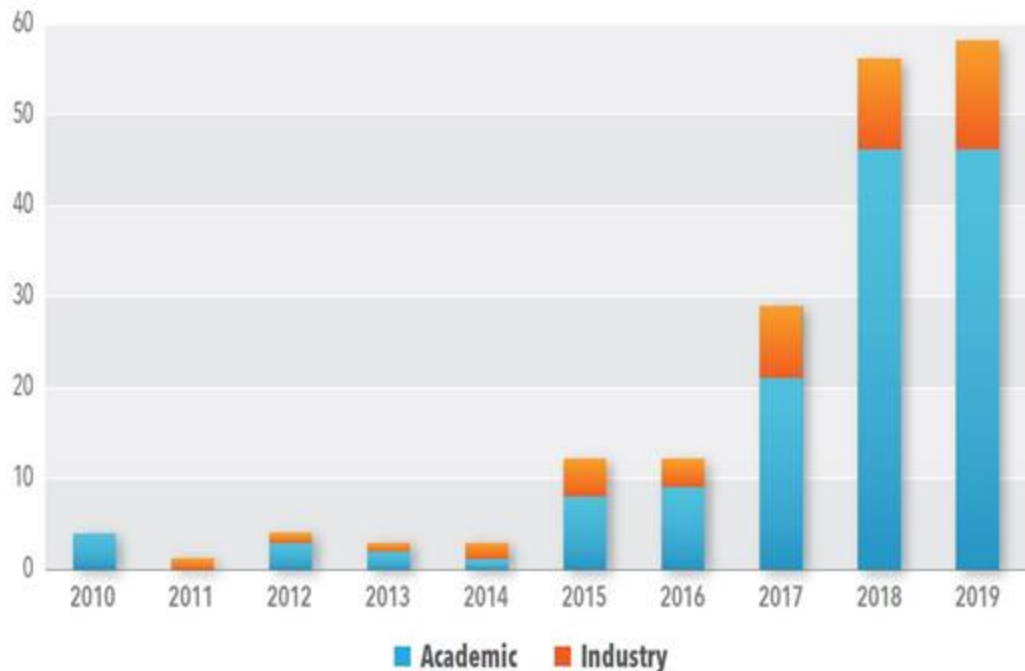


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# Current & Near-Term Landscape of DTx

**Interventional DTx Clinical Studies by Year<sup>1</sup>**



## Impactful Trends & Events

Advances in mobile technology, data, AI in everyday lives, and now COVID-19 have increased role for DTx



## Digital Health Funding

US digital health companies raised \$5.4B first six months of 2020. The industry is on track to have its largest funding year<sup>2</sup>



## DTx Application Trials

The number of DTx application trials has increased more than 5x in over the last 5-years

1. Source: EVIDERA, analysis of clinicaltrials.gov in last 10 years

2. Source: Rock Health, analysis of private funding



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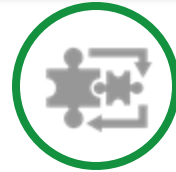
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# Recent Developments in DTx Landscape



1

FDA approvals of Pear's reSET and reSET-O for SUD and OUD (2017), Akili's Endeavor Rx for ADHD (2020)



2

Large scale acquisitions of DTx companies, e.g. Propeller acquired by ResMed for \$225 million (2019)



3

Increasing Pharma and DTx partnerships (e.g. Otsuka and Proteus, Lilly and Livongo)



4

Digital Medicine Society (DiMe), Digital Therapeutics Alliance (DTA), HealthXL, and NODE.Health helping to establish guidelines and framework for DTx



5

Express Scripts named Livongo, Propeller Health, SilverCloud Health and other companies to its digital health formulary, starting in 2020



6

FDA Digital Health Innovation Action Plan, International Medical Device Regulatory Forum (IMDRF), NICE's evidence standards framework, eHSG Guidance

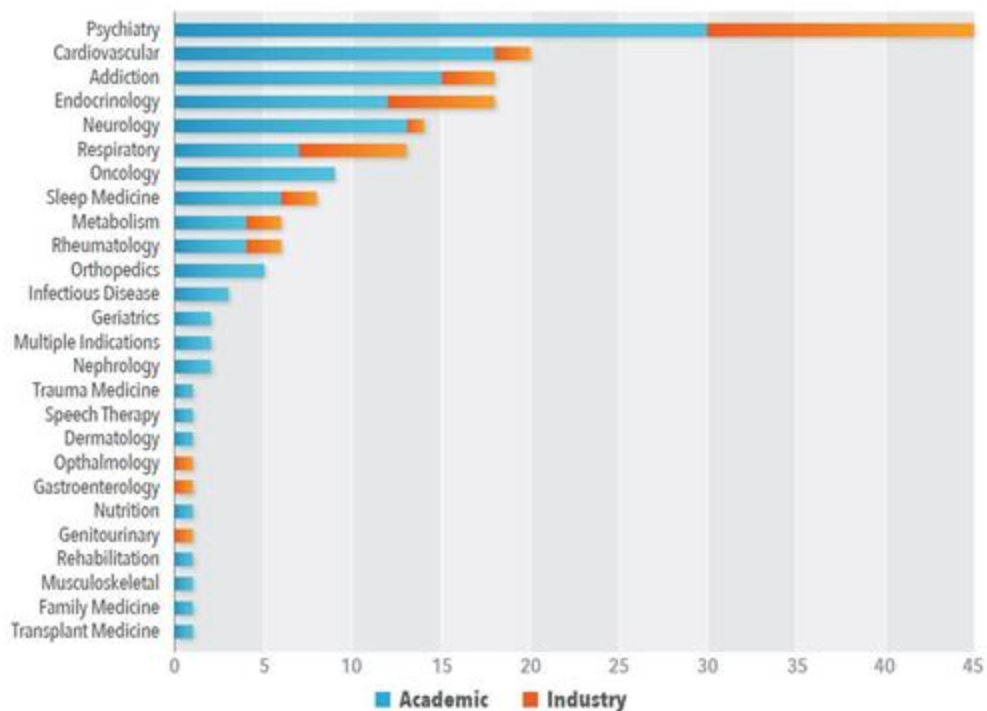


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# DTx Products & Disease States

## Interventional Dx Clinical Studies by Disease State<sup>1</sup>



### 1 Chronic Disease

- Omada Health
- Noom
- Canary Health
- Propeller
- WellDoc
- Voluntis
- Blue Mesa

### 2 Mental Health

- SingFit
- Akili
- Ginger.io
- Neurotrack
- alzHUP
- Dthera Sciences

### 3 Rehab & PT

- Kaia Health
- Salaso

### 4 Addiction Medicine

- PEAR Therapeutics
- Rja Health
- CureApp
- Click Therapeutics

1. Source: EVIDERA, analysis of clinicaltrials.gov in last 10 years





## 2 Impact of COVID-19

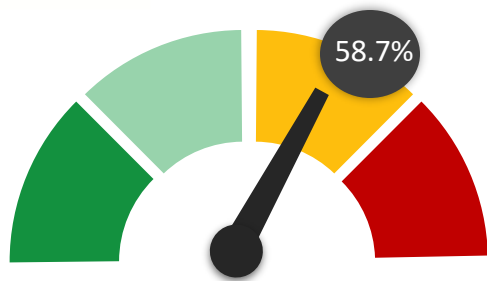
Review the impact of COVID-19 as an accelerator for the development and use of DTx.



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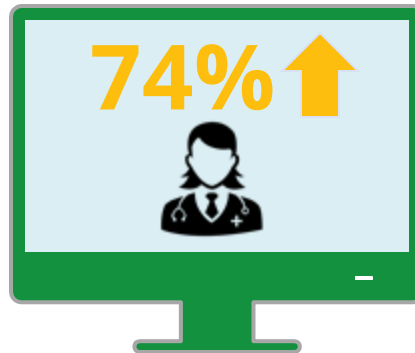
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# Impact of COVID-19 on the Medical Community



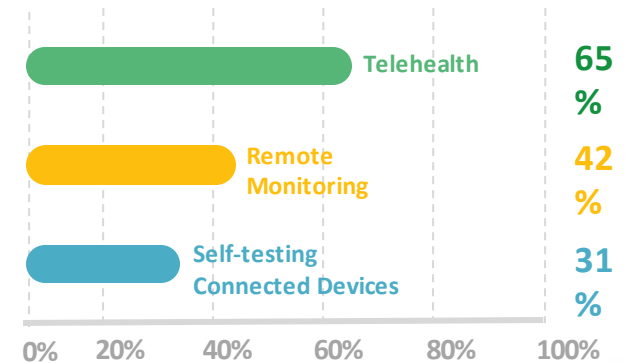
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**58.7%** of Patients cited a change in access to care due to COVID-19 – provider cancellation, patient cancellation, or postponed<sup>1</sup>



2

**74%** of Healthcare Experts believe COVID-19 will drive telehealth to become the norm for access of care<sup>2</sup>



3

Healthcare Experts believe the areas most accelerated by COVID-19 will be **Telehealth (65%)**, **Remote Monitoring (42%)**, and **Self-testing Devices (31%)**<sup>2</sup>

1. Source: SHADAC Analysis of Coronavirus Patient Survey – Apr 8 to Apr 13, n = 1,001

2. Source: R2G Global Survey of Healthcare Experts, n = 513 (Europe (49%), North America (26%), Asia (8%) and the rest of the world (17%))



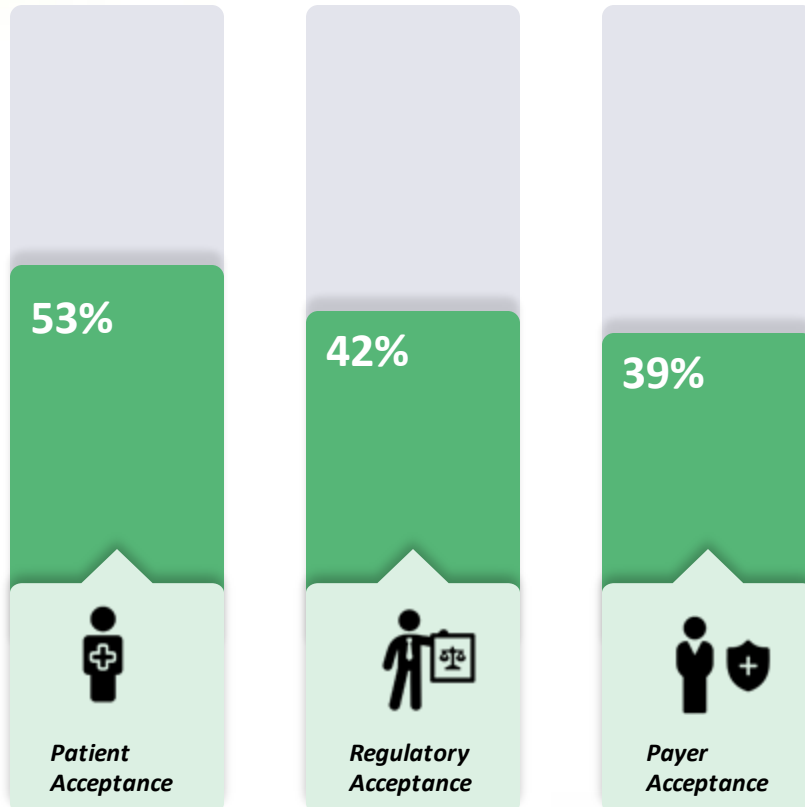
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CEO, Digital Brain Consulting + Clinical Advisor, Cognito

# COVID-19 & Digital Therapeutics



*How COVID-19 will drive positive changes in the digital health industry, based on a survey of 513 Healthcare Experts<sup>1</sup>*



## What does this mean for the industry?

- 1 Adoption of digital solutions will increase, stakeholders across segments are expecting increased utilization.
- 2 The pandemic will highlight new areas of need for the medical community, driving needed attention to develop new solutions.
- 3 With a rapidly increasing landscape, in both size and scope, there will be a critical need to drive the medical education of the broader community.

1. Source: R2G Global Survey of Healthcare Experts, n = 513 (Europe (49%), North America (26%), Asia (8%) and the rest of the world (17%))





### 3 Real World Applications

Detail real world applications of DTx to illustrate the potential it holds in driving transformation of clinical practices to improve patient outcomes.



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## Barriers for DTx

### 1 / Clinical Validation



*Defining a “digital clinical endpoint”*  
*Does input data = accurate, reliable output data?*  
*Does output data = improved clinical outcomes in target patient?*  
*What is the “standard of care” comparison?*  
*Efficacy vs. Effectiveness of a DTx?*  
*Measures of Physician and Patient Engagement*

### 2 / Regulatory



*How do you approve a product that will change continuously?*  
*What would a DTx generic be?*  
*How do you use RWE to expand label over time?*

### 3 / Reimbursement



*Are you filling an unmet need?*  
*Who is going to pay for your product?*  
*What are key stakeholder concerns?*  
*What is the value proposition?*

### 4 / Physician & Patient Adoption



*Extensive education and training necessary, “digital natives”, adoption curve and identifying early adopters, physician and patient engagement*



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# Barriers for DTx

1



Pt. and Physician Usability

2



Device Accuracy

3



Device Efficacy

4



Device Safety

5



Data Privacy

6



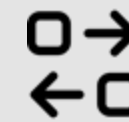
Risk

7



Financial Incentives

8



Integration into Workflow





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# Real World DTx Case Study | Propeller Health

## 1 / Overview



FDA cleared, Class II Medical Device (Software as a Medical Device). Focused on treatment plans management for Asthma or COPD.



## 2 / Device Detail



Digital sensor attaches to inhaler and communicates through smartphone app for pts with persistent asthma and Stage 11-IV COPD. Digital platform helps patients record and monitor data, physician uses portal to review data.



## 3 / Points of Interest



15 peer reviewed articles with good randomized controlled trials, strong RWE looking at acute care utilization and shown increased medication adherence by 58%, reducing rescue inhaler use by 78% and decreasing ED visits and hospitalizations = decreased costs.



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CEO, Digital Brain Consulting + Clinical Advisor, Cognoa

# Real World DTx Case Study | PEAR Therapeutics

## 1 / Overview



Reset and Reset-O, had 510K FDA clearance and approval for treatment of substance use disorder and opioid use disorder respectively in 2017, and Somryst for insomnia in 2020.



## 2 / Device Detail



Cognitive Behavioral Therapy (modeled after community reinforcement approach) is delivered via software on patient's smartphone. Available via prescription by physician for a 90-day treatment program. Physician monitors data through provider dashboard.



## 3 / Points of Interest



Launched first prescription digital therapeutic on the market, creating a completely new class (PDT), pivotal clinical trial for Reset showed 2x increase in abstinence rates with treatment vs. control and increased retention rates in treatment.



#### 4 Role of Medical Affairs

Examine how Medical Affairs can help serve as a strategic partner and shape the trajectory of the DTx pipeline and life-cycle.





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# Medical Affairs & DTx Challenges



*There's no existing standard, we are creating a new landscape! What is the role of Medical Affairs within DTx and how can it be tailored to the unique needs of DTx?*



## 1 / Evidence Generation

- Identifying evidentiary needs
- Efficacy vs. Effectiveness in DTx
- What is considered a good “digital endpoint?”
- Digital trial considerations
- How does RWE with DTx translate to value?



## 2 / Scientific Comms.

- Physicians may not have baseline knowledge of DTx
- There is no existing clinical workflow/pathway for DTx
- Many physicians do not know what DTx is and some questions may not have answers



## 3 / Stakeholder Mgmt.

- The 4Ps: Physician, Patient, Payer, Policy
- Unmet needs and adoption barriers
- Engaging clinicians and product at earliest stage of development
- Early Adopters, KOLs, and Digital Opinion Leaders (DOL)



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# How Medical Affairs Can Shape DTx



## Key Question to Solve For (Real World Example):

What are the **unmet needs** of the physicians that will use DTx and how do we **segment them**?

### 1 Sample Solution A: Adoption Barriers & Unmet Needs



**Step One:** assessed adoption barriers derived from discussions with the Medical Community (eg: physician not comfortable performing certain step)



**Step Two:** analyzed barriers to translate to unmet needs (eg: training needed on certain step physician is not comfortable with) conduct prioritization assessment



**Step Three:** developed Key Medical Objectives, driven by prioritized unmet needs to derive strategic imperatives for Medical Affairs



**Step Four:** aligned cross functional engagement on Key Medical Objectives, reinforced with field insights – ensure integration with product development, clinical adoption, and launch strategy

### 2 Sample Solution B: Early Adopter Engagement



**Step One:** defined medical characteristics of early adopters of products, with light alignment across functions on additional characteristics to consider



**Step Two:** identified quality improvement programs that were already addressing unmet needs to serve as a source of identifying and engaging early adopters at scale



**Step Three:** engaged cross functional stakeholders to educate on importance of quality improvement, made case to integrate with programs versus start from scratch



**Step Four:** on-going partnership and engagement with programs to define mutually beneficial areas of partnership (eg: integration with studies or education areas)



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CEO, Digital Brain Consulting + Clinical Advisor, Cognoa

# Conclusions



### 1. Overview of DTx

Digital Therapeutics are a subset of digital health that provide evidence-based treatments to prevent, manage, or treat a medical disorder via software that are subject to review by regulatory bodies



### 2. Current Landscape & Recent Developments

Many recent developments in the DTx landscape reflect increased interest and opportunities



### 3. Barriers to Adoption

There are potential barriers to adoption that are unique to DTx in the areas of clinical validation, regulatory, reimbursement, physician and patient adoption



### 4. Role of Medical Affairs in DTx

Medical affairs plays a crucial role in DTx and requires an innovative and tailored approach to effectively address these issues