Top Digital Therapeutic Highlights of 2019 So Far

Updated
Dear Colleagues,

With an influx of exciting partnership, reimbursement contracts and regulatory breakthroughs, it is clear **2019 has been a ground-breaking year for the digital therapeutics industry.**

In order to celebrate the industry’s collective achievements, here at the DTx Team, we’ve **collated our top 20 favourite pieces of DTx highlights and industry news of 2019** so far into one handy document for you.

Digital therapeutics are accelerating towards the healthcare mainstream and this year has already been crucial to this.

Happy reading!

Jason

---

Jason Green  
*Head of the DTx Series*
January started with a bang as it was announced Otsuka and Click Therapeutics signed a collaboration agreement to develop and commercialise Digital Therapeutics for Patients with Major Depressive Disorder.

This approach has combined Click’s proven ability to discover and deploy new software applications with Otsuka’s expertise in developing and commercialising mental health treatments.

You can view the press release here.
Early January saw Pear Therapeutics successfully close a $64 million Series C financing.

This cross-disciplinary financing will allow Pear to globally commercialise their prescription digital therapeutics and advance their clinical-stage pipeline.

View the announcement here.
January: Kaia Health Secures $10m in Series A Funding

January saw more exciting DTx funding news!

Kaia Health raised $10 million in Series A funding, led by Balderton Capital.

This funding will be used to fund further clinical studies and to scale its app-based, chronic pain therapy to the U.S.

Read more here
February got off to a great start, particularly for Cognoa! The company announced that the FDA had granted Breakthrough Device designations for its lead products, the first digital therapeutic and digital diagnostic devices for autism.

Read the press release here
In February Big Health launched its new product, Daylight™.

Daylight™ is a CBT-based app focused on combating and reducing feelings of worry and anxiety.

Following the success of their first product, Sleepio™ (a sleep improvement app), Big Health’s newest product has the potential to help many more people back to good mental health.

Check out the press release here
Propeller Health and Orion Corporation announced a partnership in February to bring new digital medicines for people with COPD and asthma.

This partnership will connect Orion’s existing Easyhaler® line of inhalers with Propeller’s digital medicine platform via a small sensor.

Orion serves patients across many European countries, so this partnership will expand Propeller’s European presence.

View the announcement here.
In early March, Akili and Shionogi announced they were teaming up, in an exciting partnership worth $125 million.

In exchange for $20 million upfront Shionogi will have the rights to the marketing, clinical development and regulatory filings for AKL-T01 and AKL-T02 (Akili’s two leading DTx products) in Taiwan and Japan, while Akili will be eligible to receive royalties of up to $105 million.

This strategic collaboration will help bring the first prescription digital therapeutics to Asian markets.
In a landmark study, Kaia Health announced the results of its first randomized controlled trial of its app-based therapy for patients with non-specific low back pain. The study, published in NPJ Digital Medicine reported significantly lower pain levels compared to the control group receiving physiotherapy and online education.

View the press release here
Happify and Sanofi hit the headlines in May with the announcement of their partnership to explore digital therapies for patients with depression and multiple sclerosis.

This collaboration advances the trend of large pharma and digital therapeutic companies working together to improve the lives of patients with difficult to treat conditions.

View the announcement here
In a significant country-wide step forward, the German Ministry of Health (BMG) announced its draft bill for legislation that will cover reimbursement of digital therapy software.

In a process that is set to be similar to drug reimbursement, evidence will be paramount and all payers in Germany will be obliged to reimburse after the decision by the BfArM (Federal Institute for Drugs and Medical Devices).

View the announcement in German here
Yet more huge news as Express Scripts announces the launch of their Digital Health Formulary.

Set to be available in 2020, the formulary will be similar to a drug formulary and will feature a curated list of tech-and software-enabled applications and devices.

This is also set to help streamline the number of digital health tools for payers and providers.

Find out more information here
May was clearly the month for announcements, as NightWare’s Apple Watch based digital therapeutic for PTSD patients affected by nightmares receives FDA Breakthrough Designation.

It addition to this, NightWare opened enrollment for two randomized controlled trials to drive their product through the pipeline.

Find out more information here
In the first of three significant announcements on the same day (June 11th), MedRhythms partners with Health Catalyst to provide stroke survivors with access to their digital therapeutic.

The partnership aims to select patients who could benefit from the “rhythmic auditory stimulation”-based digital therapeutic, accurately measure their clinical outcomes and integrate the treatment into provider clinical workflow.

Take a look at the press release here
CVS unveiled its Vendor Benefit Management with the announcement that Big Health’s Sleepio would be the first product offered on this service. In a huge step forward for potential broader adoption and reimbursement of digital therapeutics, CVS Health will provide Pharmacy Benefit Management (PBM) clients access to digital and non-digital solutions. This will enable Sleepio to reach hundreds of thousands of Americans who may need help battling sleeplessness.

Find out more information here
The final piece of news on June 11th was that Neurotrack raised $21M in Series C funding.

This round of funding will help Neurotrack commercialize its Memory Health Program and expansion into global markets.

Take a look at the press release here

June 11th is up there with the most important days in the history of digital therapeutics!
Off the back of the launch of AppScript One Click Studies in 2018, IQVIA partnered with EMIS Health to support Physicians in England electronically prescribe digital health apps to patients.

IQVIA will populate the EMIS App Library by evaluating apps against the NHS’ evidence standards guidelines.

View more details here
In July, the FDA announced the validation of their streamlined review process of Software as a Medical Device (SaMD) under its PreCert Program.

Pear swiftly followed this by announcing the submission of their digital therapeutic (Somryst) for chronic insomnia and depression, which is the first product to be submitted through the updated PreCert program.

Read the FDA Announcement here
Read Pear Therapeutics Announcement here
Digital therapeutics are going global and this is evident by the announcement in July that Korea’s Ministry of Food and Drug Safety approved Nunaps’ clinical trial of Nunap Vision.

This digital therapeutic is targeting patients with visual disorders after brain injury.

Find out more information here
The good news continued rolling in July as Walgreen’s announced that its Find Care Platform would also now include Propeller Health’s Digital Therapeutic for patients COPD.

The goal of this platform is to allow users to learn about and enroll for treatments such as Propellers.

Find out more information here
Closing out July, Voluntis announced that it has successfully completed an FDA review of Oleena™, its software for oncology-related symptom management and remote patient monitoring.

Oleen™ is determined as a Class II medical device that will support patients across a wide range of cancer diagnoses and anticancer treatments.

Take a look at the press release here
Have your say by leaving us a comment on the blog.