



Owen McCarthy

Co-Founder & President



*Owen is the co-founder and President of MedRhythms Inc., a digital therapeutics company that builds evidence-based neurologic interventions for acute and chronic neurological populations using music, AI, and sensors.*

## What have been the biggest changes for the digital therapeutics industry over the last year?

The digital therapeutics industry has evolved rapidly over the past year. This is reflected in the magnitude and significance of the partnership and investment deals that DTx startups have made with established players, particularly pharmaceutical companies. Sanofi Ventures, for example, led Click Therapeutics' \$17M

fundraising round, and Novartis announced a partnership with Pear Therapeutics to commercialize its novel combination digital therapeutics for substance abuse disorder and co-development products.

Another important change for the industry has been the expansion of the Digital Therapeutics Alliance, which has taken input from DTx companies, including MedRhythms, to standardize the language and requirements within the DTx space and publish its whitepaper.

## What have been the startup challenges MedRhythms have learned that specifically relate to digital therapeutics?

As most DTx companies can probably attest to, a common theme of the industry's challenges thus far has been the absence of a blueprint for decisions related to key areas such as reimbursement and regulatory.

With regard to reimbursement, the difficulty for many DTx companies has been that there aren't obvious reimbursement pathways for DTx services and, moreover, insurance companies haven't established a precedent of reimbursing DTx products. In terms of regulatory pathways, this new asset class of products that use algorithms and software to treat, manage, and diagnose disease creates tension within existing regulatory frameworks.

Progress this year is encouraging, as the FDA has been working diligently to provide clarity and change the paradigms. Additionally, a related challenge is that prior to the DTA whitepaper, the distinction between a digital therapeutic and a digital health product was unclear. It is now becoming increasingly clear how DTx product fit as a subset



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within the larger digital health universe.

## What opportunities can digital therapeutics offer in the field of neurology?

Neurology is one of the best opportunities for digital therapeutics. This is an area where you can use an external stimulus to target specific circuits in the brain and drive the functional outcomes.

In our case at MedRhythms, the neuroscience supports the use of music and the components of music as the mechanism of action to drive motor recovery and lasting physiological change. Other examples are

using video games to change brain function to improve cognitive areas such as attention, or to use virtual reality to target brain circuits to lower perception of pain.

Neurology is also a really interesting frontier for digital therapeutics because there is a huge unmet need that singular treatment approaches have failed. The DTx products can be used in combination with other therapies and also be used to measure disease progression, since most products have measurement built into the intervention.

## Where do you see this industry in 5 years time?

I'm certainly not a fortune teller, so can't tell you exactly where it will be in 5 years, however, I can imagine that if companies focus on generating peer-reviewed evidence of the efficacy, build the products with clinical workflow and patient

experience in mind, and tell the value story that they will start to become pervasive. If that is the case, you will see more and more DTx products individualized to specific patients, you will see it common to be writing scripts of software as a therapeutic, and with a large amount of data generated we will start to understand and stratify sub-populations of disease more and more.

## What are you most looking forward to about attending DTx West 2019?

We are very excited about attending DTx West this year. It is an invaluable opportunity to get the entire industry in the same room, talk about the highlights since the last gathering, and discuss the blueprint for the future of the DTx industry.

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*Owen is delivering a presentation titled "Evidence-based Digital Interventions Using Music and Neuroscience" at 11:15 (PST) on Day 2 (February 28<sup>th</sup>) of DTx West 2019.*