

DIGITAL THERAPEUTICS

SOFTWARE AS A DRUG THAT'S BENDING THE HEALTHCARE COST CURVE

What if a playlist on your iPhone could help forestall the effects of Alzheimer's?

That might sound far-fetched today. However, the team of tech entrepreneurs, musicians, and neurologists behind **The Sync Project** are actively working to create medicine from music.

The logic of The Sync Project's ambitions goes something like this: music has been used to affect moods for generations, so why not use the profusion of new sensor technologies to scientifically measure how songs change our behaviors?



Using those results, The Sync Project foresees being able to create highly personalized music playlists as a form of digital therapy with applications for pain, fatigue, anxiety, sleeplessness, and even the cognitive effects of Alzheimer's.

The Sync Project represents just one of part of an entirely new field in medicine: digital therapeutics.

“ Digital therapeutics isn't just something we have to wait for, it's increasingly operating today all around us.”

Digital therapeutics marries the latest in behavioral economics, smartphones, game-ification, biometric sensors, data analytics, and artificial intelligence. The digital therapeutics market, currently a nascent, sub-\$1 billion market, is poised to become a \$6 billion market in five to eight years, based on a research report by Goldman Sachs and supplementary Psilos research. Digital therapeutics will also become the biggest component of digital health. Helping to fuel growth are investments in digital therapeutics by major healthcare players such as Merck, Johnson & Johnson, and Amgen.

In the most recent tech boom, there has been an explosion in investments in digital health, a broad category that seeks to apply increasingly ubiquitous technological tools like wearables and smartphones toward healthcare.

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Digital therapeutics represents medicine that's more specific and ambitious than health tracking and telemedicine. It's marrying the latest in behavioral economics, smartphones, game-ification, biometric sensors, data analytics, and artificial intelligence. Digital therapeutics startups treat software as a drug capable of amplifying doctors' care, changing patient behavior, treating preventive costly chronic diseases, and most importantly, bending the healthcare cost curve.



Digital therapeutics isn't just something we have to wait for, it's increasingly operating today all around us. Here's what's happening.

Electrifying the Wellness Program

Wellness programs are everywhere these days. The problem, says Bryce Williams, is that only five percent of members actually use them.

Williams is president and CEO of **HealthMine**, a company whose own model and results provide a good illustration of digital therapeutics' evolving impact on healthcare. HealthMine is a Psilos portfolio company.

Working behind the scenes of several well-known health insurance plans, HealthMine seeks to make their wellness programs "the hub of, essentially, an electrified member experience," according to Williams.

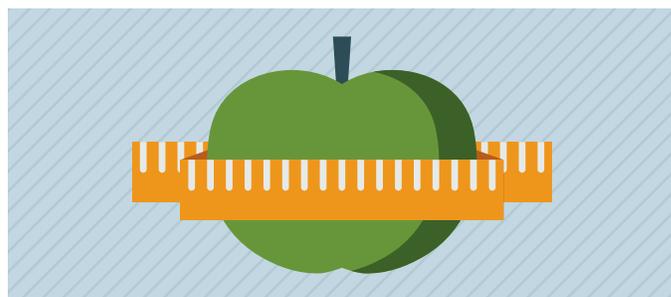
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To do that, HealthMine processes an unprecedented amount of data on its participants, using up to 200 different sources, including all their medical and pharmacy claims information and lab results. It can also track information from outside the clinic such as their Fitbit or Apple's HealthKit data. Each member's information is processed daily through HealthMine's system which looks for irregularities.

When it sees things that are out of range or informative about members' health—their BMI, heart rate, glucose—it sends one of 3,500 different and actionable personalized recommendations.

Creating an app that engages members is an ongoing challenge for digital therapeutics companies.

"You have to make it extremely enticing, and in some cases, we've actually had employers make it mandatory," Williams says.



Using the research of management consultant and executive coach Marshall Goldsmith, HealthMine has created something akin to a FICO score for personal health.

"In what universe are any of us able to get better if we're not measuring something?" asks Bryce. "You can't manage what you can't measure."

The score that HealthMine has created allows members to not only measure their progress, but gives them a game-like incentive to shoot for a higher one.

“ HealthMine has created something akin to a FICO score for personal health.”

For its part, HealthMine says its approach is already yielding results based on its three-year study of 120,000 employees enrolled in a wellness program.

It reports that:

- There was a measurable increase in preventive visits with members taking actions to control unhealthy conditions.
- Members used the hospital less. Hospital utilization showed a decreased trend, averaging 10–20% fewer hospital admissions, bed days, and ER visits over the first year. Hospital readmission rates saw a 50% reduction by the third year, and the average length of stay slightly decreased, reflecting that the right care was provided in the right setting.
- During the three-year period, 70% of the participants had an annual wellness visit/preventive exam.

In addition to that study, Williams reports that HealthMine’s system discovered 7,100 diabetics not identified by one of its health insurance clients.

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HealthMine is one of many companies competing to rethink the wellness program.

Similar to HealthMine, **Canary Health** runs a behavior-focused engagement platform that works behind the scenes of healthcare providers, and it reports that it has already achieved measurable results.

“Financial incentives and tracking aren’t enough,” said Canary Health CEO Adam Kaufman.

Among its findings, Canary—which has partnered with Stanford University and the University of Pittsburgh to build digital health self-management tools—reports that it has demonstrated positive outcomes in terms of weight loss, pain reduction, lower stress levels, depression management, chronic disease prevention, hospital utilization rates, and quality of life.

Another engagement platform that stands out is **Telcare**. The Concord, Massachusetts-based firm has created the first cellular-connected blood glucose meter to win FDA approval. Interestingly, it’s not your typical blood glucose meter. After diabetes patients test themselves with it, Telcare sends them individualized messages based on their unique results. Furthermore, Telcare’s product allows their doctors or care providers to send them messages based on those results. Like other digital therapeutics, their product goes beyond tracking: Telcare is interested in changing diabetes patients’ behavior.

“ Digital therapeutics go beyond tracking: they’re interested in changing patients’ behavior. ”



Digital Rx

It might sound like science fiction, but several digital therapeutics startups are actually developing FDA-approved apps, apps that your doctor could prescribe to be used in conjunction with, or completely in place of, a drug or other traditional treatment options.

Underlying this trend is the increasing reliance on behavioral modification therapy to treat unhealthy, repetitive patterns like smoking, drinking, lack of exercise, as well as drug and other addictions.

The logic goes as follows: address the behavior, prevent or help abate the problem, and save big on future health costs from health perils like substance abuse addictions, obesity, and diabetes.

One company seeking FDA approval for apps that could treat a wide range of behavioral health disorders is **Pear Therapeutics**, which secured a \$20 million investment in February 2016.

In a recent interview, Pear President and CEO Corey McCann explained why digital therapeutics offers to radically disrupt traditional chronic disease management, ultimately cutting healthcare costs.



“We’re not talking about telemedicine,” said McCann. “This is not an interface between a patient and a physician. To us, very simply, [digital therapeutics] means software as a drug, or—taking it a step further from a regulatory perspective—software as a medical device.”

McCann added, “We don’t sit in the health and wellness space. We aim to treat disease, and for us, the more severe the disease, the more interesting.”

According to Pear, it has already achieved statistically significant results in the treatment of substance abuse disorders over traditional therapy-based approaches.

“These products have demonstrated clinical data supporting enhanced abstinence, enhanced retention in treatment, enhanced quality measures like Addiction Severity Index (ASI), and significantly reduced clinician intervention time,” said Tim Petersen, Managing Director at Arboretum Ventures, a Pear investor.

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Beyond its focus on substance abuse, the Boston-based company is also developing a suite of products to treat schizophrenia as well as enhancing medications for treating chronic pain, post-traumatic stress disorder, general anxiety disorder, major depressive disorder, and insomnia.

Neurotrack is another digital therapeutics company seeking FDA approval. Using a webcam, Neurotrack reports that it can detect early signs of cognitive decline like Alzheimer’s years before typical symptoms arise. In January 2016, it raised \$6.5 million in funding to achieve scientific validation for its cognitive assessment tool.

Propeller Health is also seeking a regulatory green light for its artificial-intelligence-powered inhaler for asthma and COPD patients. Used in conjunction with a smartphone app, its sensor records why, where, and when patients have symptoms. Then, using AI, it promises to help patients prevent attacks. The company reports that its users experience fewer attacks and more symptom-free days.



In July, **Big Health**, another digital therapeutics startup, raised \$12 million to create Sleepio, a digital sleep improvement program. Sleepio, according to Big Health, is already being used by Comcast, LinkedIn, Boston Medical Center, and other employers, which have made the application available to their combined 750,000 employees. The company provides a good example of the scientific rigor many digital therapeutics startups are applying to the emerging field. It's already published fourteen peer-reviewed papers, and the company reports that Sleepio has an efficacy rivaling in-person cognitive behavioral therapy treatment. The company seeks to expand into mental health.

“ Using a webcam, Neurotrack reports that it can detect early signs of cognitive decline like Alzheimer's years before typical symptoms arise.”

Then there's **Akili Interactive Labs**. The Boston-based startup has raised more than \$42 million to apply a very digital solution to diagnosing and treating cognitive disorders using video game-like software.

Akili's main product “is designed to monitor and improve the brain's executive function, which is impacted in a number of disorders such as attention deficit hyperactivity disorder, autism, Alzheimer's disease, and traumatic brain injury,” according to the company.

Today, Akili is in the midst of a study that it hopes will win it FDA approval, said Daphne Zohar, Cofounder and CEO of PureTech, an investor in Akili.

“The idea behind Akili is that a doctor would prescribe this treatment,” Zohar said in a recent interview. “You would get a prescription code, download it, and play the game for a certain amount of time.”

“It is really a treatment we believe with drug-like efficacy but without the drug. That is actually a theme across a number of things we are doing.”

Not surprisingly, Big Pharma has also shown interest in the evolving trend, placing bets on digital therapeutics startups, according to CB Insights.

Akili's investors include the venture arm of Amgen. Roche is an investor in a diabetes management app called **mySugr**, which uses “a charming, sometimes outspoken” digital coach to encourage patients to better watch their blood sugar levels.

Merck's venture fund is another active investor in digital therapeutics. Among its investments is **WellDoc**, whose BlueStar product is a “mobile prescription therapy” aimed at adults with type 2 diabetes. WellDoc also received an investment from Johnson & Johnson Innovation as part of its \$29.5 million Series B round in March.

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Wearables' Next Step

Fitbit might have started out as an activity tracker, but its ambitions go well beyond that, pointing toward a role for wearables in digital therapeutics.

During an investor conference call in May 2016, CEO James Park discussed a role for his company's wearables in healthcare, and he specifically addressed engagement as one of Fitbit's key strengths:

"We are learning that lack of consumer engagement is a critical missing element in many broad healthcare efforts, such as population health and disease management," said Park. "Since our devices and services are already engaging, Fitbit has an incredible opportunity to serve as the consumer healthcare engagement engine. I could argue that, better than anyone else, we can help people engage with their health, engage with their family's health, engage with their insurer and employer, and engage with the healthcare system."

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—FitBit CEO James Park

Moves by much larger, established tech giants also increasingly signal an interest in an expanded health and medical role for wearables.

Samsung, the South Korean electronics giant, sees big potential in wearables with medical device capabilities. The firm projects there will be 183 million wearables by 2017, up from 116 million in 2015. It sees health monitoring capabilities adding value to wearables, according to a June 2016 Samsung presentation to the Institute of Electrical and Electronics Engineers (IEEE).

Not to be outdone by Samsung, **Apple** has been making similar moves in health tech.

One year after Samsung unveiled its own activity tracking app, Apple launched its Health app in partnership with the Mayo Clinic.

Then this year, the Cupertino, California-based company unveiled an even more ambitious product, CareKit. Apple's current Health app allows iPhone users to easily track things like how many steps they've taken per day, their weight, and their body mass index. However, CareKit, which is still very much in development, goes much further.

“ There's recent evidence that Google might be getting in on the trend as well.”

CareKit is a software framework that Apple is now encouraging digital health developers to use to “make it easier for individuals to keep track of care plans and monitor symptoms and medication, providing insights that help people better understand their own health. With the ability to share information with doctors, nurses or family members, CareKit apps help people take a more active role in their health,” according to Apple.

And there's recent evidence that **Google** might be getting in on the trend as well.

In June 2016, CNBC reported that Eric Schmidt, Executive Chair of Google parent Alphabet, said, “The application of digital technology in mental health, in heart disease, and in many cancers will revolutionize the industry.”



Six Factors Increasing Traction of Digital Therapeutics Products

Entrepreneurs deeply invested in digital therapeutics report the wind is at their backs, pointing to a confluence of six main factors increasing the current and future traction for their innovative products.

Still-rising Healthcare Costs

Although US healthcare spending has moderated in recent years, it's still rising, and rising faster than the GDP. As a result, the government's own estimates assume the share of national income spent on healthcare will rise by 2.5 percentage points between 2014 and 2025 to more than 20% of the economy. That trajectory, fueled by an aging and increasingly sick population, has created an imperative among government and private payers to embrace technological solutions, according to digital health entrepreneurs.

The Shift Toward Value-based Payments

In large part due to still-rising costs, the healthcare industry has experienced a paradigmatic shift in pay that bodes well for digital therapeutics. Today, it's increasingly the rule, not the exception, for private healthcare giants—everyone from Anthem BCBS to UnitedHealthcare to Aetna—to tout their focus on paying for value over volume. For example, Deloitte reported in 2016 that more than 80% of US health providers have at least one value-based care contract with commercial health plans.

Employers Encouraging Health Management

Looking for ways to trim their own costs on insurance premiums and improve worker productivity, American employers have embraced wellness programs that, in theory, are designed to encourage employees to better manage their own health.

The most extensive study of its kind, research by the Rand Corporation found that approximately half of American companies with at least fifty employees offered wellness programs, though results have been underwhelming. A new generation of digital therapeutics-based solutions are beginning to deliver on their promise.

Consumerism Comes to Healthcare

Another significant factor increasing pressure on the healthcare system to curb costs is the cost shift to individuals through higher deductibles and premium contributions, along with an influx of consumers onto the private insurance market. Private insurance was once long-dominated by employers, who shopped for plans that covered their employees.

However, as a result of the Affordable Care Act's insurance premium subsidies, along with access to public and private health exchanges, individuals are increasingly shopping for plans themselves—and they want value for their dollar.

Ubiquity of Smart Phones and the "Quantified Self" Movement

We are experiencing a seismic shift in the way consumers are accessing and interacting with the healthcare system via mobile devices, often in real time. The near ubiquity of smartphones, along with increasing cultural acceptance around measuring and sharing our personal health information, provides the platform for delivering a range of digital therapy solutions.

Venture Funding Increasing at Record Rates

Investment data from CB Insights underscore venture capitalists' confidence in digital health, a term encompassing a wide range of health-focused technology startups. With \$5.7 billion invested, last year saw the highest amount ever in overall venture funding to digital health startups. We are likely to see a new high watermark again this year.

To Bend the Curve, it's Time to Adapt

With healthcare costs projected to grow faster than general inflation and consume an even greater share of domestic wealth, digital therapeutics offers the potential to do what well-intentioned policy changes, including the Affordable Care Act, have not: shrink healthcare costs relative to GDP.



All players in America's healthcare system have a role. Patients can get more engaged with their own health and start using software tools to manage, treat, and prevent disease. Providers can shed old practices that have done little to treat long-term behavioral problems that underlie costly chronic conditions.

However, payers are in a powerful position to effect the most change.



Employers

Employers, who have watched their health insurance premiums continue to rise, have already begun embracing wellness programs. That's not enough, and success so far has been limited. Now, they have to make sure employees are actually using them. The combination of clinically effective digital therapeutics programs and employee incentives will demonstrate value and will be an essential part of employer-sponsored health and wellness programs.



Insurance Companies

Insurance companies that provide these programs must evaluate the most effective programs and begin to integrate them into their plan administration and benefit designs.



Government

With the government playing an increasingly larger part of healthcare, it has a uniquely potent role. The Department of Health and Human Services has already helped to expedite the important shift toward value-based care. Now, the federal government can continue the momentum. The NIH can allocate more resources to the research and development of software as a scientifically validated therapy. This year, the FDA will consider green-lighting software as a prescription drug. The agency has a tendency to drag its feet. In light of the huge cost savings and outcomes improvement potential, it should give this new field the scientific consideration it deserves. And the HHS, through Medicaid and Medicare, can start making digital therapeutics an increasingly important part of its thus far largely ineffective approach to the treatment of costly, chronic, and preventable disease.

The potential benefits are enormous. The costs of not doing more to embrace this technology are too. The bottom line: beyond big data and telemedicine, digital therapeutics will deliver a revolution in care.



Psilos Group Managers is a New York City-based digital healthcare venture capital and growth equity investor that has been disrupting the status quo since 1998. Psilos has invested in companies such as ActiveHealth, Definity Health, Extend Health, HealthEdge, PatientSafe Solutions, and HealthMine, which have played, and continue to play, key roles in the transformation of the US healthcare economy. Its investments in the healthcare economy have created more than \$2.5 billion worth of value.

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