

Volume 18 • Number 2

PUBLISHER Lisa Barket

EDITOR Taren Grom

CREATIVE DIRECTOR Marah Walsh

MANAGING EDITOR

Denise Myshko

SENIOR EDITOR

Robin Robinson

FEATURES EDITOR

Kim Ribbink

DESIGN ASSOCIATE

Ariel Medel

DIRECTOR OF SALES

Cathy Tracy

NATIONAL ACCOUNT MANAGER

Suzanne Besse

WEBCAST NETWORK PRODUCER

Daniel Limbach

CIRCULATION ASSISTANT

Kathy Deiliulis

Copyright 2018

by PharmaLinX LLC, Titusville, NJ

Printed in the U.S.A.

Volume Eighteen, Number Two

PharmaVOICE (ISSN: 1932961X) is published monthly except joint issues in July/Aug. and Nov./Dec., by PharmaLinX LLC, P.O. Box 327, Titusville, NJ 08560. **Periodicals postage paid** at Titusville, NJ 08560 and additional mailing offices.

Postmaster: Send address changes to PharmaVOICE, P.O. Box 292345, Kettering, OH 45429-0345.

PharmaVoice Coverage and Distribution:

Domestic subscriptions are available at \$190 for one year (10 issues). Foreign subscriptions: 10 issues US\$360. Contact PharmaVoice at P.O. Box 327, Titusville, NJ 08560. Call us at 609.730.0196 or FAX your order to 609.730.0197.

Contributions: PharmaVOICE is not responsible for unsolicited contributions of any type. Unless otherwise agreed in writing, PharmaVoice retains all rights on material published in PharmaVoice for a period of six months after publication and reprint rights after that period expires. E-mail: tgrom@pharmavoicel.com.

Change of address: Please allow six weeks for a change of address. Send your new address along with your subscription label to PharmaVoice, P.O. Box 292345, Kettering, OH 45429-0345. Call us at 800.607.4410 or FAX your change to 937.890.0221. E-mail: mwalsh@pharmavoicel.com.

IMPORTANT NOTICE: The post office will not forward copies of this magazine. PharmaVoice is not responsible for replacing undelivered copies due to lack of or late notification of address change.

Advertising in PharmaVOICE: To advertise in PharmaVOICE please contact our Advertising Department at P.O. Box 327, Titusville, NJ 08560, or telephone us at 609.730.0196. E-mail: lbarket@pharmavoicel.com.

Letters...

Send your letters to feedback@pharmavoicel.com. Please include your name, title, company, and business phone number. Letters chosen for publication may be edited for length and clarity. All submissions become the property of PharmaLinX LLC.

Weird Science

Digital therapeutics are a hot commodity. As reported in this month's cover story, software programs are part of a new class of therapeutics — digital medicines — that can lead to changes in behavior and provide clinical benefit. But digital therapeutics go beyond behavior modification programs; they are digital tools that have been tested in clinical trials to assess safety and efficacy. These software-enabled therapeutics represent a new generation of healthcare that uses innovative, clinically validated disease management, and treatment technologies to enhance, and in some cases replace, current medical practices and treatments.

Currently, there are about three dozen companies operating in this emerging space, with significant growth expected in the future. One analyst predicts that the digital therapeutics market will be valued at \$457.9 million in 2021, and another report from Grand View Research states the digital therapeutics market will be worth more than \$9 billion in 2025. Grand View believes the market is being catapulted by increasing incidences of chronic diseases, increasing emphasis on preventive healthcare, the need to curb healthcare expenditures, and added benefits offered by digital therapeutics. Additionally, the increasing number of venture capitalists investing in the market is another factor that is accelerating its growth. Digital therapeutics, which also encompass software-for drugs, offer a number of benefits, such as continuous monitoring of patient's vital stats and the ability to ensure adherence to medications.



Last fall, a group of health startups in the digital therapeutics space joined together to create a new industry association, the Digital Therapeutics Alliance (DTA). Founding members include a number of digital health innovators: Propeller Health, WellDoc, Akili Interactive, Omada Health, and Voluntas. Their goal is to work together to promote real-world evidence studies and pilot programs, create industry standards and frameworks, and develop shared data repositories.

According to Akili Interactive CEO Eddie Martucci, Ph.D., digital therapeutics are re-writing our definition of medicine, further noting that it's critical that industry, academia, government, and the medical community work together in the next phase of medical adoption.

"We're excited to drive this effort alongside other leaders who share our dedication to rigorous clinical validation and organizational excellence in product development; it is truly a new class of medicine," he said in a statement.

He believes that five years from now we will see digital medicine being used in mainstream medical care, meaning alongside or even in combination with standard pharmacological treatment.

In October 2017, digital therapeutics received a big boost when Pear Therapeutics received an Expedited Access Pathway-O (EAP) designation from the FDA for its reSET Prescription Digital Therapeutic, a first of its kind treatment designed for treating opioid use disorder. reSET is the first FDA-cleared prescription digital therapeutic to treat any disease.

As we move forward, it's clear that software has come a long way since those two teenagers in the John Hughes' 80s classic engaged in weird science to create Kelly LeBrock's super human character.

Taren Grom
Editor

Their word...

DENISE MYSHKO

Managing Editor



Digital medicines aim to go beyond games to provide clinically tested therapeutics to

enhance treatments for many diseases.

ROBIN ROBINSON

Senior Editor



Within the next two years, the pharma industry will be piloting other uses for blockchain

technology, such as EHRs and smart contracts, beyond supply chain track and trace.

KIM RIBBINK

Features Editor



The move to more uniform regulations is slow, but companies should take advantage of greater efforts to harmonize.

March 2018

- Moving Beyond the "Beyond the Pill" Conversation
- Data Analytics
- Diversity in Clinical Trials
- Compassionate Use
- RNAi Technologies
- Women & Health: Women Leaders
- Showcase Features:
 - Brand Building
 - Market Research