

Volume 16 • Number 9

**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 DeIulius

Copyright 2016

by PharmaLinX LLC, Titusville, NJ

Printed in the U.S.A.

Volume Sixteen, Number Nine

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@pharmavoices.com](mailto:tgrom@pharmavoices.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@pharmavoices.com](mailto:mwalsh@pharmavoices.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@pharmavoices.com](mailto:lbarket@pharmavoices.com).

## Letters...

Send your letters to [feedback@pharmavoices.com](mailto:feedback@pharmavoices.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.

## Clinical Data in Real Time

The number of clinical trials using mobile apps more than doubled, rising from 135 in 2014 to 300 in 2015, according to the IMS Health Study Patient Options Expand as Mobile Healthcare Apps Address Wellness and Chronic Disease Treatment Needs. No doubt when 2016 numbers are crunched, we will see another significant increase in the number of trials that are incorporating some type of mHealth technology as part of the protocol. In fact, as of Aug. 29, 2016, a search of [clinicaltrials.gov](http://clinicaltrials.gov) showed 272 studies that mention use of mHealth and 186 studies mention a wearable. These studies range from a study of cancer care coordination in chemotherapy patients to the impact of mHealth in transplant management to a wearable to promote teenagers' physical activity.



This month's cover story — mHealth and Clinical Data — explores the potential that sensors, wearable devices, and mobile apps will offer pharmaceutical sponsors in respect to patient data that complement existing data and provide a more complete view of safety and efficacy. In a recent SCORR Marketing report, 50% of industry experts surveyed say they use mHealth technology in their clinical trials and protocols, and of those, 60% consider mHealth very or extremely important to their research.

One advantage of using a wearable technology as a research tool is the ability to do continuous monitoring without the subject needing to keep a daily diary. This is particularly effective for chronic diseases, such as diabetes, where glucose monitoring can be done continuously.

Medidata, just little more than a year ago, completed its MOVE-2014 behavioral study to test whether mHealth devices and tools could be used to drive better health outcomes in overweight adults with type 2 diabetes. MOVE-2014 study participants exhibited high compliance with charging and using the mobile devices, which included wearable activity trackers and smartphones. The study also showed that quantifiable, objective data — i.e., movement levels and sleep patterns — from the activity trackers and subjective, patient-reported diary data collected via smartphones could be securely pulled into the Medidata Clinical Cloud platform and seamlessly integrated with other clinical trial information in a regulatory-compliant manner. Additionally, in assessing the feasibility of using a consumer-grade wearable device to monitor activity among people with type 2 diabetes in a real-world setting, MOVE-2014 demonstrated that continuous feedback on exercise and diet regimens could impact patient behavior and, ultimately, health outcomes; more than half of the study participants lost weight.

One of the challenges that the industry faces is on a regulatory front. As UBC reported, the FDA will most likely be overwhelmed with all the wearables data to review. It is important that developers and the life-science companies that they partner with for pilots develop tools that will truly impact clinical judgment.

As our experts note, the opportunities are great and mHealth technologies will transform the future of the industry.

Taren Grom  
Editor

## Their word...

**DENISE MYSHKO**  
Managing Editor



*The use of smartphones and wearables in the general population will drive use in clinical research.*

**ROBIN ROBINSON**  
Senior Editor



*TV still reigns as the ad spending king of DTC, but numerous digital channels are being used to personalize consumer messaging.*

**KIM RIBBINK**  
Features Editor



*Attention in the French pharma market is turning to generics, M&A, and the search for breakthrough R&D.*

## Coming in NOV/DEC 2016 YEAR IN PREVIEW

- ▶ Cancer MoonShot
- ▶ Combination Therapies
- ▶ Gene Editing
- ▶ Health Bots
- ▶ The Industrial Internet
- ▶ Precision Medicine
- ▶ Smart Technology
- ▶ Talent War
- ▶ Triple Aim
- ▶ Virtual Reality
- ▶ Showcase: e-Solutions