The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Forum on Drug Discovery, Development, and Translation
Roundtable on Genomics and Precision Health

The Role of Digital Health Technologies in Drug Development

A Workshop

March 24, 2020
10:00 a.m. – 4:15 p.m. (ET)

ZOOM WEBINAR REGISTRATION:
https://nasem.zoom.us/webinar/register/WN_8xfTtbfeQrGVh4Y1dAE38A

Agenda

Digital health technologies (e.g. smartphone apps, wearable sensors, and other remote, sensor-based tools that combine hardware and software) have become increasingly available to consumers, providers, and researchers. They offer new opportunities to address critical challenges or pain points, better connect patients and health care providers, and incorporate patient input throughout the drug research and development (R&D) life cycle. This workshop will provide a venue to discuss challenges and opportunities in using digital health technologies to improve the probability of success in drug development. Workshop participants may consider key components for an evidence-based framework for applying digital health technologies towards drug research and development.

WORKSHOP OBJECTIVES:

- Highlight critical barriers or "pain points" along the drug R&D lifecycle for which digital health technologies may be uniquely suited to address;
- Consider lessons learned from currently validated digital health technology applications that could be generalizable for newer digital health technologies;
- Consider opportunities to enable the practical application of digital health technologies for improving drug development (e.g. sharing best practices for the validation and use of digital health technologies, harmonizing guidelines across sectors).
- Consider strategies for evaluating and selecting digital health technologies that are fit-for-purpose in drug development (e.g. examining existing frameworks, establishing appropriate evidentiary criteria);
- Discuss privacy, ethical, and regulatory issues related to the use of digital health technologies.

10:00 a.m. ET **Welcome**

ROBERT CALIFF
Forum Co-Chair
Verily Life Sciences

GEOFFREY GINSBURG
Roundtable Co-Chair
Duke University School of Medicine

Opening Remarks

JENNIFER GOLDSACK, *Workshop Co-Chair*
Executive Director
Digital Medicine Society

JOSEPH MENETSKI, *Workshop Co-Chair*
Associate Vice President of Research Partnerships
Foundation for the National Institutes of Health

BRIEFING: ETHICAL CONSIDERATIONS

10:15 a.m. ET ***Ethicist Perspective***
CAMILLE NEBEKER
Director
Research Center for Optimal Digital Ethics
University of California San Diego

SESSION I DIGITAL TOOLS FOR CHARACTERIZING DISEASE

10:45 a.m. ET **Session Moderator**
EFFY VAYENA
Professor
Health Ethics and Policy Lab, ETH Zurich

Non-Profit Perspective/Platform Research Perspective
LARSSON OMBERG
Vice President, Systems Biology
Sage Bionetworks

NIH Perspective
CHRIS LUNT
Chief Technology Officer
All of Us Research Program
National Institutes of Health

Patient Engagement Perspective
ALICIA STALEY
Senior Director, Patient Engagement
Medidata Solutions

Developer Perspective
LUCA FOSCHINI
Chief Data Scientist & Co-founder
Evidation Health, Inc.

11:25 a.m. ET **Panel Discussion with Speakers and Workshop Participants**

11:45 a.m. ET **BREAK**

SESSION II DIGITAL TOOLS FOR RECRUITMENT AND SAFETY TRIALS

12:00 p.m. ET **Session Moderator**
DEVEN MCGRAW
Chief Regulatory Officer
Ciitizen Corporation

Regulatory Perspective
CHRISTOPHER LEPTAK
Director, Regulatory Science Program, Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Industry Perspective
YVONNE YU-FENG CHAN
Senior Director, Medical Affairs for Digital Medicine
Otsuka Pharmaceutical Companies

Developer Perspective
Chris Benko
Chief Executive Officer
Koneksa Health

Academic Perspective
ERIC PERAKSLIS
Rubenstein Fellow
Duke University

12:40 p.m. ET **Panel Discussion with Speakers Workshop Participants**

1:00 p.m. ET **BREAK**

FIRESIDE CHAT

1:30 p.m. ET **Session Moderator**
JENNIFER GOLDSACK, *Workshop Co-Chair*
Executive Director
Digital Medicine Society

Regulatory Perspective
AMY ABERNETHY
Principal Deputy Commissioner
U.S. Food and Drug Administration

SESSION III DIGITAL TOOLS FOR PIVOTAL TRIALS

2:00 p.m. ET **Session Moderator**
HUSSEINI MANJI
Global Therapeutic Head, Neuroscience
Janssen Research & Development

Industry Perspective
SEAN KHOZIN
Global Head of Data Strategy
Janssen Research & Development

Developer Perspective
RITU KAPUR
Head of Biomarkers
Verily Life Sciences

Regulatory Perspective
LEONARD SACKS
Associate Director of Clinical Methodology, Office of Medical Policy
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

2:30 p.m. ET **Panel Discussion with Speakers and Workshop Participants**

2:50 p.m. ET **BREAK**

SESSION IV DIGITAL TOOLS FOR POSTREGISTRATION SURVEILLANCE

3:00 p.m. ET **Session Moderator**
CHRISTINA SILCOX
Managing Associate
Duke-Margolis Center for Health Policy

Industry Perspective
MICHELLE CROUTHAMEL
Director, Digital Health & Innovation
AbbVie

Patient Engagement Perspective
SALLY OKUN
Policy and Ethics
UnitedHealth Group Research & Development

Clinician/Health System Perspective
EDMONDO ROBINSON
Chief Digital Innovation Officer
Moffitt Cancer Center

3:30 p.m. ET **Panel Discussion with Speakers and Workshop Participants**

KEY REFLECTIONS AND NEXT STEPS

3:45 p.m. ET **Key Reflections and Next Steps**

JENNIFER GOLDSACK, *Workshop Co-Chair*
Executive Director
Digital Medicine Society

JOSEPH MENETSKI, *Workshop Co-Chair*
Associate Vice President of Research Partnerships
Foundation for the National Institutes of Health

4:15 p.m. ET **Adjourn**