The Role of Digital Health Technologies in Drug Development

A Workshop

March 24, 2020

Keck Center of the National Academies, Room 100
500 Fifth Street NW, Washington, DC 20001

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;

Agenda

8:00 a.m. Breakfast available outside Keck 100

8:30 a.m. Welcome

ROBERT CALIFF
Forum Co-Chair
Verily Life Sciences

GEOFFREY GINSBURG
Roundtable Co-Chair
Duke University School of Medicine

GREGORY SIMON
Forum Co-Chair
Kaiser Permanente Washington

MICHELLE PENNY
Roundtable Co-Chair
Goldfinch Bio
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

8:45 a.m.  
Ethicist Perspective  
CAMILLE NEBEKER  
Director  
Research Center for Optimal Digital Ethics  
University of California San Diego

SESSION I  DIGITAL TOOLS FOR CHARACTERIZING DISEASE

9:15 a.m.  
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

10:05 a.m.  
Panel Discussion with Speakers and Workshop Participants
11:05 a.m. **Session Moderator**  
DEVEN MCGRAW  
Chief Regulatory Officer  
Ciitizen Corporation

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

**Industry Perspective**  
MICHELLE CROUTHAMEL  
Director, Digital Health & Innovation  
AbbVie

**Developer Perspective**  
Chris Benko  
Chief Executive Officer  
Konesksa Health

**Academic Perspective**  
ERIC PERAKSLIS  
Rubenstein Fellow  
Duke University

11:55 p.m. **Panel Discussion with Speakers Workshop Participants**

12:30 p.m. **LUNCH** (Available Outside Keck 100)

**FIRESIDE CHAT**

1:30 p.m. **Regulatory Perspective**  
AMY ABERNETHY  
Principal Deputy Commissioner  
U.S. Food and Drug Administration
SESSION III  DIGITAL TOOLS FOR PIVOTAL TRIALS

2:10 p.m.  Session Moderator
HUSSEINI MANJI
Global Therapeutic Head, Neuroscience
Janssen Research & Development

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

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

Developer Perspective
RITU KAPUR
Head of Biomarkers
Verily Life Sciences

Payer Perspective
TBD

3:00 p.m.  Panel Discussion with Speakers and Workshop Participants

3:30 p.m.  BREAK

SESSION IV  DIGITAL TOOLS FOR POSTREGISTRATION SURVEILLANCE

4:00 p.m.  Session Moderator
CHRISTINA SILCOX
Managing Associate
Duke Margolis Center for Health Policy

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

Patient Engagement Perspective
SALLY OKUN
Vice President, Policy and Ethics
PatientsLikeMe
Clinician/Health System Perspective
EDMONDO ROBINSON
Chief Digital Innovation Officer
Moffitt Cancer Center

Payer Perspective
TBD

4:50 p.m.  Panel Discussion with Speakers and Workshop Participants

WRAP UP

5:15 p.m.  Wrap Up Discussion and Closing 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

5:30 p.m.  Adjourn