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

ROUNDTABLE AND FORUM CO-CHAIRS
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
10:35 a.m.   BREAK

SESSION II   DIGITAL TOOLS FOR RECRUITMENT AND SAFETY TRIALS

11:05 a.m.  Session Moderator
DEVEN MCGRAW
Chief Regulatory Officer
Ciitizen Corporation

Regulatory Perspective
BAKUL PATEL – INVITED
Director, Division of Digital Health
U.S. Food and Drug Administration

Industry Perspective
LAUREN BATAILLE – INVITED
Director
Digital Strategy Lead - Clinical Trial Innovation
Novartis

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)

KEYNOTE ADDRESS

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 R&D

**Developer Perspective**  
RITU KAPUR – INVITED  
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