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**

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**SESSION II  DIGITAL TOOLS FOR RECRUITMENT AND SAFETY TRIALS**

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*

**KIRSTEN TAYLOR – INVITED**
Biomarker and Experimental Medicine Leader
Roche

*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)

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**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  
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