## AGENDA

### Day 1 -- Tuesday, February 18, 2020

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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| 8:00 AM – 8:30 AM | Registration and Continental Breakfast  
Ballroom Foyer                                                          |
| 8:30 AM – 8:40 AM | Welcome and Opening Remarks  
Joe Menetski (FNIH)                                                        |
| 8:40 AM – 9:10 AM | Keynote and Charge: Challenges for the Implementation of Digital Monitoring Technologies in Drug Development  
Jennifer Goldsack (DiME)                                                  |
Chris Leptak (FDA/CDER)                                                    |
| 9:50 AM – 10:20 AM | Panel Discussion and Audience Q&A  
**Moderators:** Jennifer Goldsack (DiME) and Chris Leptak (FDA)  
**Panelists:** Francesca Cerreta (EMA), Pam Tenaerts (CTTI), Steve Berman (FDA), Elektra Papadopoulos (FDA) |
| 10:20 AM – 10:40 AM | Break  
Ballroom Foyer                                                          |
| 10:40 AM – 11:00 AM | Presentation: Review of the General Framework and Case Study Set Up: Issues and Considerations  
John Wagner (Foresite Capital)                                              |
| 11:00 AM – 11:40 AM | Case Study 1: Mobile Parkinson Observatory for Worldwide, Evidence-based Research (mPower) and Parkinson’s Disease  
Diane Stephenson (Critical Path Institute), Dan Karlin (HealthMode), Abhi Pratap (SageBionetworks), Ninad Amondikar (MJFF), Xuemei Cai (Pfizer) |
11:40 AM – 12:10 PM  Case Study 1: Panel Discussion  
**Moderator:** Jen Goldsack (DiME)  
**Panelists:** Diane Stephenson (Critical Path Institute), Dan Karlin (HealthMode), Abhi Pratap (SageBionetworks), Ninad Amondikar (MJFF), Xuemei Cai (Pfizer)

12:10 PM – 12:50 PM  Presentation: Regulatory Guidance and Evidentiary Principles for Digital Health Technology Development  
_Bakul Patel (FDA/CDRH)_

12:50 PM – 1:50 PM  Lunch  
_Leo & Liv Restaurant – Lobby Level_

1:50 PM – 2:30 PM  Case Study 2: Cardiac Monitoring in Phase 1 Clinical Trials  
_John Wagner (Foresite Capital), Elena Izmailova (Koneksa Health), Vadim Zipunnikov (Johns Hopkins Univ.)_

2:30 PM – 3:00 PM  Case Study 2: Panel Discussion  
**Moderator:** Elena Izmailova (Koneksa Health)  
**Panelists:** Qi Liu (FDA/CDER), Vadim Zipunnikov (Johns Hopkins Univ.), John Wagner (Foresite Capital), Dan Bloomfield (Anthos Therapeutics)

3:00 PM – 3:40 PM  Case Study 3: Continuous Glucose Monitoring & Remote Digital Monitoring (VERKKO Study)  
_Roberto Calle (Pfizer), Nadir Ammour (Sanofi)_

3:40 PM – 4:00 PM  Break  
_Ballroom Foyer_

4:00 PM – 4:30 PM  Case Study 3: Panel Discussion  
**Moderator:** Roberto Calle (Pfizer)  
**Panelists:** Nadir Ammour (Sanofi), Andrea Bell-Vlasov (FDA/CDRH), Joe Mather (Pfizer), Denyse Niemerov (Abbott); Jagdeep Podichetty (Critical Path Institute)

4:30 PM – 5:00 PM  Summary of Day 1  
_Joe Menetski (FNIH)_

5:00 PM – 6:30 PM  Networking Exchange and Reception  
_Ballroom Foyer_

_Dinner on your own_
Day 2 -- Wednesday, February 19, 2020  Bethesda Ballroom, Level 2

7:00 AM – 8:00 AM  Registration and Continental Breakfast
Ballroom Foyer

8:00 AM – 8:15 AM  Welcome to The Workshop - Day 2
Steve Hoffmann (FNIH)

8:15 AM – 8:55 AM  Case Study 4: Stride Velocity 95th Centile 2° Endpoint in Duchenne’s Muscular Dystrophy
Pat Furlong (PPMD), Laurent Servais (Univ. of Oxford), Francesca Cerreta (EMA)

8:55 AM – 9:25 AM  Case Study 4: Panel Discussion
Moderator: Luca Foschini (Evidation)
Panelists: Ieuan Clay (Evidation), Pat Furlong (PPMD), Laurent Servais (Univ. of Oxford), Francesca Cerreta (EMA), Michelle Campbell (FDA)

9:25 AM – 10:05 AM  Case Study 5: Remote Assessment of Disease and Relapse in Major Depressive Disorder (RADAR – MDD)
Matthew Hotopf (King’s College), Vaibhav Narayan, Linda Brady (NIH/NIMH)

10:05 AM – 10:35 AM  Case Study 5: Panel Discussion
Moderator: Linda Brady (NIH/NIMH)
Panelists: Amos Folarin (Kings College), Francesca Cerreta (EMA), Matthew Hotopf (King’s College), Vaibhav Narayan (Janssen), Husseini Manji (J&J)

10:35 AM – 10:55 AM  Break
Ballroom Foyer

10:55 PM – 11:40 AM  Presentation: NIH Pipeline in Digital Technologies
Jill Heemskerk (NIH/NIBIB)

11:40 AM – 12:10 PM  Open Mic and General Feedback
Moderators: Joe Menetski (FNIH) and Steve Hoffmann (FNIH)

12:10 PM – 12:30 PM  Next Steps and Workshop Deliverables
Joe Menetski (FNIH)

12:30 PM  Meeting Adjourns