

# Remote Digital Monitoring for Medical Product Development Workshop

*The Bethesda Hotel  
Bethesda, MD  
February 18 - 19, 2020*

## AGENDA

**Day 1 -- Tuesday, February 18, 2020**    **Bethesdan Ballroom, Level 2**

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

<b>11:40 AM – 12:10 PM</b>	<b>Case Study 1: Panel Discussion</b> <i>Moderator: Jen Goldsack (DiME)</i> <i>Panelists: Diane Stephenson (Critical Path Institute), Dan Karlin (HealthMode), Abhi Pratap (SageBionetworks), Ninad Amondikar (MJFF), Xuemei Cai (Pfizer)</i>
<b>12:10 PM – 12:50 PM</b>	<b>Presentation: Regulatory Guidance and Evidentiary Principles for Digital Health Technology Development</b> <i>Bakul Patel (FDA/CDRH)</i>
<b>12:50 PM – 1:50 PM</b>	<b>Lunch</b> <i>Leo &amp; Liv Restaurant – Lobby Level</i>
<b>1:50 PM – 2:30 PM</b>	<b>Case Study 2: Cardiac Monitoring in Phase 1 Clinical Trials</b> <i>John Wagner (Foresite Capital), Elena Izmailova (Koneksa Health), Vadim Zipunnikov (Johns Hopkins Univ.)</i>
<b>2:30 PM – 3:00 PM</b>	<b>Case Study 2: Panel Discussion</b> <i>Moderator: Elena Izmailova (Koneksa Health)</i> <i>Panelists: Qi Liu (FDA/CDER), Vadim Zipunnikov (Johns Hopkins Univ.), John Wagner (Foresite Capital), Dan Bloomfield (Anthos Therapeutics)</i>
<b>3:00 PM – 3:40 PM</b>	<b>Case Study 3: Continuous Glucose Monitoring &amp; Remote Digital Monitoring (VERKKO Study)</b> <i>Roberto Calle (Pfizer), Nadir Ammour (Sanofi)</i>
<b>3:40 PM – 4:00 PM</b>	<b>Break</b> <i>Ballroom Foyer</i>
<b>4:00 PM – 4:30 PM</b>	<b>Case Study 3: Panel Discussion</b> <i>Moderator: Roberto Calle (Pfizer)</i> <i>Panelists: Nadir Ammour (Sanofi), Andrea Bell-Vlasov (FDA/CDRH), Joe Mather (Pfizer), Denyse Niemerov (Abbott); Jagdeep Podichetty (Critical Path Institute)</i>
<b>4:30 PM – 5:00 PM</b>	<b>Summary of Day 1</b> <i>Joe Menetski (FNIH)</i>
<b>5:00 PM – 6:30 PM</b>	<b>Networking Exchange and Reception</b> <i>Ballroom Foyer</i>  <i>Dinner on your own</i>

**Day 2 -- Wednesday, February 19, 2020**    **Bethesdan Ballroom, Level 2**

<b>7:00 AM – 8:00 AM</b>	<b>Registration and Continental Breakfast</b> <i>Ballroom Foyer</i>
<b>8:00 AM – 8:15 AM</b>	<b>Welcome to The Workshop - Day 2</b> <i>Steve Hoffmann (FNIH)</i>
<b>8:15 AM – 8:55 AM</b>	<b>Case Study 4: Stride Velocity 95<sup>th</sup> Centile 2<sup>o</sup> Endpoint in Duchenne’s Muscular Dystrophy</b> <i>Pat Furlong (PPMD), Laurent Servais (Univ. of Oxford), Francesca Cerreta (EMA)</i>
<b>8:55 AM – 9:25 AM</b>	<b>Case Study 4: Panel Discussion</b> <i>Moderator: Luca Foschini (Evidation)</i> <i>Panelists: Ieuan Clay (Evidation), Pat Furlong (PPMD), Laurent Servais (Univ. of Oxford), Francesca Cerreta (EMA), Michelle Campbell (FDA)</i>
<b>9:25 AM – 10:05 AM</b>	<b>Case Study 5: Remote Assessment of Disease and Relapse in Major Depressive Disorder (RADAR – MDD)</b> <i>Matthew Hotopf (King’s College), Vaibhav Narayan, Linda Brady (NIH/NIMH)</i>
<b>10:05 AM – 10:35 AM</b>	<b>Case Study 5: Panel Discussion</b> <i>Moderator: Linda Brady (NIH/NIMH)</i> <i>Panelists: Amos Folarin (Kings College), Francesca Cerreta (EMA), Matthew Hotopf (King’s College), Vaibhav Narayan (Janssen), Hussein Manji (J&amp;J)</i>
<b>10:35 AM – 10:55 AM</b>	<b>Break</b> <i>Ballroom Foyer</i>
<b>10:55 AM – 11:40 AM</b>	<b>Presentation: NIH Pipeline in Digital Technologies</b> <i>Jill Heemskerk (NIH/NIBIB)</i>
<b>11:40 AM – 12:10 PM</b>	<b>Open Mic and General Feedback</b> <i>Moderators: Joe Menetski (FNIH) and Steve Hoffmann (FNIH)</i>
<b>12:10 PM – 12:30 PM</b>	<b>Next Steps and Workshop Deliverables</b> <i>Joe Menetski (FNIH)</i>
<b>12:30 PM</b>	<b>Meeting Adjourns</b>