Collaborative C2SHIP/SHIC/FDA workshop on:

Improving the Quality of Home Health Care with Interoperable Medical Devices: Clinical Opportunities and Regulatory Science Gaps

Oct. 27, 2023, Venue: University of Southern California, Capital Campus, 1771 N Street NW, Washington DC

8:45 - 9:00 Opening and welcoming Remarks: David Armstrong & Dorn Carranza

9:00- 10:00 Session 1: Overview of home monitoring use cases and medical device needs to accelerate care

Session Chairs: Drs. Marjorie Skubic & David Armstrong (Marge will be lead on writing)

9:00- 9:15 Facilitating transition from hospital to home (**Michael Johnson, RN, President at Aspire Clinical Intelligence**)

9:15- 9:30 Home monitoring for the aging population (**Tony Hyk, TheraTech CEO**)

9:30- 9:45 Introduction to CDRH's OSEL and the role of regulatory science tools to advance medical device (**Chris Scully, Assistant Director in the Division of Biomedical Physics at FDA**)

9:45- 10:00 Q&A

10:30 - 11:30 Session 2: Engineering Interoperable Device Systems for Home Care

Session Chairs: Chris Scully & Bijan Najafi (Bijan will be the lead on writing)

10:30 – 10:45 Why is interoperability critical to improve care quality? Lessons from the artificial pancreas development (**Lane Desborough, CEO of Nudge BG**)

10:45 – 11:00 Regulatory science design/testing gaps for interoperable devices (**Sandy Weininger, Senior Electrical/Biomedical Engineer at US FDA, CDRH/OSEL/DBP**)

11:00- 11:15 Wearable Sensors and digital health technologies for tracking neurological and neuromuscular disorders (**Ashkan Vaziri, PhD, CEO and Co-founder of BioSensics LLC**)

11:15 – 11:30 Q&A

11:30 - 12:30 Session 3: Making Use of All the Data

Session Chairs: Janet Roveda & David Armstrong

11:30- 11:45 The Most Data, or the Right Data? Generating tech-specific algorithms (**Naomi Hachen, Senior Scientist & Manager, Applied Research at Best Buy Health**)

11:45- 12:00 Streaming data analyses and interfaces to provide actionable insights (**Ed Ramos, PhD - Director, Digital Clinical Trials, Scripps Research**)

12:00- 12:15 Interchangeability of data: Sensor validation and understanding factors impacting accuracy and precision (**Kimberly Kontson, Biomedical Engineer at FDA, CDRH/OSEL/DBP**)

12:15 – 12:30 Q&A

Lunch break - 12:30 - 1:45

1:30 – 2:45 Session 4: Navigating the Regulatory Pathways

Session Chairs: Drs. Kouhyar Tavakolian and Dorn Carranza *(Kouhyar will be the lead writing).*

1:45 - 2:00 Overview of FDA regulatory pathways (**Shawn Forrest, Digital Health Specialist at FDA, Digital Health Center of Excellence**)

2:00 - 2:15 Overview of reimbursement framework and evidential requirements (**Susan Xu, Principal WyDus, Healthcare Reimbursement Strategic Advisor**)

2:15 - 2:30 Driving Adoption by Healthcare Systems, Providers, Patients, and Caregivers (**Maureen Shaffer, Chief Marketing Officer, CorVent Medical, CEO**)

2:30 -2:45 Q&A

2:45 – 3:00 Short break and networking

3:00 - 4:00 Session 5: Data Security and Sharing

Session Chairs: Drs. Janet Roveda and David Armstrong

3:00 – 3:15 Securing Healthcare Environments involving Protected Data and Instrument Resource Sharing (**Prasad Calyam, PhD, Professor and Cyber Education, Research and Infrastructure Center Director; Mauro Lemus, PhD student, University of Missouri**)

3:15- 3:30 Safe at Home: Ensuring Medical Device and Data Security and Privacy Beyond the Hospital Setting (**Ryan Vega, MD, Chief Health Officer, Vantiq**)

3:30-3:45 Data Gaps in AI/ML Device Development, Testing and Monitoring(**Nicholas Petrick, PhD, Deputy Director CDRH/OSEL/DIDSR at the FDA, OSEL / Division of Imaging, Diagnostics, and Software Reliability**)

3:45-4:00 Q&A

4:00 – 4:15 Closing remark - Dorn Carranza & Bijan Najafi