CSRC Think Tank: ***Leveraging Remote Monitoring for Cardiac Safety in Clinical Trials***

Friday, March 1st, 2024 Pacific Time

8:00 **Welcome**

8:10 **Current Status of Remote Monitoring in Clinical Trials**
What is "real-time" monitoring—Mintu Turakhia(Stanford)
Issues in running decentralized trials—Vic Patel(Clario)
Safety Oversight of decentralized trials- Pamela Tanaerts (Medable)
Remote Arrhythmia Monitoring from an Academic Perspective - Krishna Pundi(UCSF)
Do Remote Heart-Monitoring Devices Work? Pros and cons—Polina Voloshko (ICON, formerly BioTel)

9:30 **Break**

9:45 **Current Status of Remote Monitoring in Clinical Trials**
Utility of continuous high-density data using wearable digital sensors in clinical research—Antoniu Fantana (EliLilly)
Wearable Ultrasound Technology-- Sheng Xu (UCSF)
Reducing Noise to Signal -- Waqaas Al-Siddiq (Biotricity)
AI based Diagnosis--- Atandra Burman (RCE.ai)
Discussion: Promise and Limitations of remote monitoring for cardiac safety in clinical trials—Discussant: Dave Albert (AliveCor)

11:00 **Regulatory issues related to validation of remote monitoring technologies-** Philip Sager (Moderator)
When does a device require CDRH approval? -- Rob Kazmierski (FDA)
Regulatory Issues regarding medical devices and drug development-- Rob Kazmierski (FDA)
A Center for Drug Perspective on Cardiac Safety—Rosilyn Adigun (FDA)
Consumer Wearables in pediatrics: Should there be standards?—Salim Idriss (Duke)
V3 Framework for Digital Clinical Endpoints – Candice Taguibao(Digital Medicine Society)
Data Standardization -- Jose Vicente (FDA)
Discussion: What are the primary regulatory concerns for implementing RPM in clinical trials— Discussant: Sanjeev Bhavnani (Scripps)

12:15 **Lunch**

1:00 **Are Remote Cardiac Monitors good enough for clinical trials—**How could / should RPM product design be optimized for trial subject use, adherence, and accessibility? What specific considerations (e.g., regulatory, data reporting, etc.) should be given around inter-subject variability of periods of RPM interruption (e.g., showering, device recharging, misplacement? **Rajesh Ghosh,** *Mark Mentzer, Todd Rudo, Krishna Pundi, Rosalyn Adigun, Rob Kazmierski*

Artificial Intelligence (AI) medical devices in clinical trials-- Do AI remote medical devices have a place in clinical trials? How would that differ from non-AI devices? How would regulatory authorities view use of AI devices in clinical trials? Do they require periodic validation? What regulatory considerations are there beyond algorithm validation for AI/ML medical devices? **John Rootenberg** *Sanjeev Bhavnani, Mintu Turakhia, Rosalyn Adigun, Rob Kazmerski, Atandra Burman*

Do we need new safety definitions when using RPM in clinical trials? — What should be the criteria for defining AE from the outliers/abnormalities identified by wearables from RPM? ? How do health authorities view RPM when assessing outcomes for clinical trials, and what are their key challenges? Can it be to support efficacy parameters? Is there a role for normative data? Do we need to define new endpoints to support remote monitoring? **Jonathan Seltzer,** *Antoniu Fantana, Rosalyn Adigun, Candice Taguibao, Waqaas Al-Saddiq*

3:30 **Wrap Up, Recommendations and Next Steps**