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

AGENDA

Friday, March 1st, 2024

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)
Digital Health and the Patient Experience—Ethan Fricklas (Duke)

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 – Jen Goldsack(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, 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, Jen Goldsack, Waqaas Al-Saddiq*

3:30 Wrap Up, Recommendations and Next Steps