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

San Diego, California
Friday, October 6th, 2023
8:00 - 16:00 Pacific Time

Overview: State of the Art Talk

Part 1: Current Status of Remote Monitoring in Clinical Trials

- Issues in running decentralized trials
- Endpoint Definitions for remote monitoring
- Data Standardization for remote devices
- Case Studies: Arrhythmia/ QT , Blood Pressure, CHF, Pediatrics

Discussion: Promise and Limitations of remote monitoring for cardiac safety in clinical trials

Part 2: Regulatory issues related to validation of remote monitoring technologies

- Does device require CDRH approval?
  - What can a device be cleared for and its appropriate use in clinical trials? Can you use a non-cleared device for a drug approval? 510K vs PMA pathway
- Regulatory Issues
  - Review of Guidance
  - When safe use of a drug requires a device
  - Medical Device and Drug Development Tools
  - Relationship between approval and patient specificity
  - Determination of risk in device utilization
- Study Case Study (REACT)

Discussion: What are the primary regulatory concerns for implementing RPM in clinical trials

Part 3: Panel Discussion: Hot Topics

- **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?
- **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? What regulatory considerations are there beyond algorithm validation for AI/ML medical devices. Is there a role for normative data?
- **Do we need new safety definitions when using RPM in clinical trials?**--Do we have a true measure of false positives and false negative AEs 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?

Part 4: Wrap Up: Recommendations and Next Steps

Confirmed Speakers

LeAnn Madre (Medable)
Robert Kleiman (Clario)
Christopher Longhurst (UC San Diego Health)
Shen Xu (UCSD)
Robert Califf (FDA)(Pending)
Rob Kazmierski (FDA)(Pending)
Rosalyn Adigun (FDA)
Jose Vicente (FDA)
Sanjeev Bhavnani (FDA)(Pending)
Gregory Marcus (UCSF)
Waqaas Al-Siddiq Biotricity)
Polina Voloshko (BioTel Research)
Salim Idriss (Duke)
Philip Sager (Stanford)
Euan Ashley (Stanford)
Mintu Turakhia (Stanford)
Jonathan Seltzer (CSRC)