CRN-Based Clinical Trial Options: An FDA Perspective

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CDRH Strategic Priorities

- Excellent customer service
- Strengthen the clinical trial enterprise
- Strike the right balance between pre-market and post-market data collection
  - Increasing emphasis on “real-world” data

Peripheral Vascular Devices

- Pose unique challenges
  - Smaller patient population than coronary/cardiac disease
  - Enrollment in prospective studies can be slow
  - Multiple physician specialties involved
  - Single procedure often involves multiple devices
- Necessitate flexible approaches to collecting data
  - Traditional prospective studies
  - Registry-based clinical data collection and analysis
  - International data

Registry-Based Opportunities

- History of successful collaboration on data registries in peripheral vascular areas
  - VQI
  - NCDR

- Multiple possible uses
  - “Traditional” prospective pre-market studies
  - Use of retrospective post-market data for pre-market approval purposes
  - Establishing performance goals/patient-level control data
  - Broader range of data supporting regulatory decisions and actions

Regulatory Considerations

- Device-specific and class-effect registry data have multiple possible regulatory uses
- Pre-specified endpoints/goals important
  - Helps to build on past successes (e.g. PARC)
- Discuss proposals with FDA and other stakeholders early
  - More ambitious strategies will likely involve more complex and robust data collection/analysis plans

Potential Challenges

- Resources
- Impact of administrative issues
  - Informed consent
  - IRB approval
- Possible differences in data reliability/auditing compared to traditional studies

International Aspects

- Established history of international collaboration and data leveraging for vascular devices
- Involvement of non-US stakeholders can provide a unique aspect to RAPID
- Can clinical data be collected from/used in different geographies?

Summary

- Clinical registries represent a uniquely flexible mechanism for real-world data collection and analysis
- FDA is actively working to facilitate the establishment and use of registry-based collaborations among global stakeholders in the cardiovascular device space
- We hope that RAPID and other registry projects will improve the ability to collect and analyze global data, particularly for regulatory purposes

Thank You!