RAPID:

An FDA View

Jose Pablo Morales, MD
FDA Division of Cardiovascular Devices
RAPID working group meeting
April 13, 2016

Center for Devices and Radiological Health
CDRH

Basic Principles for Registries

- Developing uniform definitions and CRFs for a particular area
- Defining relevant questions
- Establishing quality by design principles to ensure data quality and ability of registry to withstand audit
- Successfully addressing any relevant informed consent issues
- Developing incentives for sustainability of the registry

Potential Uses for Registries

- Meeting post-approval requirements for new devices
- Leveraging the registry infrastructure to nest IDE studies
- More broadly contribute to a learning health model

If all the above are met: Developed National Medical Device Evaluation System

Nesting Clinical Studies?

- Once the RAPID core data set are selected, defined and finalized, we plan to blend them into the existing registries with peripheral intervention modules
- Since by then the these registries will be capable to collect and pull data side-to-side, a testing exercise collecting data from real devices will be performed
- If we succeed, the next step will be to conduct a clinical study using the platform designed and hopefully such study will allow us to make some source of regulatory decision

Potential Scenarios of Clinical Studies to be Nested

- Randomized Clinical Trial – (e.g., Does direct thrombin inhibitor improve patency of SFA interventions)
- Expansion of indications for an approved device
- Comparison of two existing treatment modalities (e.g. atherectomy vs angioplasty in popliteal or any comparison of new device type with historical treatment.)
- Developing objective performance goals (e.g. for tibial artery treatment in diabetic patients based on current real world practice)
- Manufacturers ideas

To be decided today

Deliverables

- RAPID should allow for Standardization and Homogeneity
- Global CRF with respective definitions should lower the reviewer regulatory burden as well as decrease cost to sponsors
- Facilitate International Device Evaluation
- GUDID / NLM should allow:
  - for device specific outcomes searches
  - lessen the cost for device data entry
  - optimize accuracy of device data

Take home message

- We have built up the foundation to assess medical devices being used for peripheral artery interventions
  - National and International
- Multi-stakeholder collaboration is essential to move in the right direction
- Registries are here to stay and if we develop them together they can work on our behalf

Contact Information

Jose Pablo Morales, MD

Medical Officer

FDA Division of Cardiovascular Devices

(301) 776-8936

Jose.Morales@fda.hhs.gov