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RAPID:

An FDA View

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PASSION II Think Tank

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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)

To be decided - RAPID workshop on Wednesday, April 13, 2016



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

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