Coordinated Registry Network for Acute Ischemic Stroke intervention: Partnering with Stakeholders for Success

The Beginning, February 2, 2017

Goals for a CRN

- *Consistently and systematically collect data on outcomes following use of neurothrombectomy devices and make this data available as a shared resource*
  - *Postmarket safety*
  - *Expansion of indications*
  - *Precision medicine*
  - *Nesting of clinical studies within the CRN*
  - *Support marketing submissions*
  - *Data for hospitals*
  - *Data for scientific research*

Goals for Today

- *Identify the general scope of the effort that would be of value to all stakeholders*

- *Identify potential specific uses of a coordinated registry network*

- *Discuss as much about the details of standing up a coordinated registry network as is practical in the time available*

- *Develop a plan going forward and infrastructure to complete this effort*

Working Groups

- *Clinical*
- *Informatics and Methodology*
- *Sustainability and Value*

Clinical Working Group

- *Establish draft list of core data elements and definitions for each*
- *Formulate plan, complete with timelines, for finalizing the list of core data elements and definitions*
- *Create a volunteer working group composed of industry, FDA, patients, registry owners, physicians (professional society representative), and other stakeholders to finalize the minimum clinical core data elements and standard definitions and report back to the Coordinating Group*

Informatics and Methodology

- *Determine appropriate infrastructure model for DAISI CRN*
- *Determine methodology for data collection*
- *Create a volunteer working group composed of stakeholders with expertise in registry/data management, epidemiology and information technology (IT) to finalize and implement the plans*
- *Determine data sharing structure (interoperability)*
- *Propose the use of Quality Systems tools for the CRN to monitor data accuracy and validity*

Sustainability and Value

- *Formulate funding structure (long and short term)*

- *Outline plan for data use agreements*

- *Create a volunteer working group composed of multi-stakeholders with expertise in registry creation and sustainability to implement the use of the CRN. In addition, this volunteer working group will create a plan that ensures that appropriate value will be applied to all stakeholders and report to the Coordinating Group*

- *Establish a plan for the Governance structure of the CRN including a Coordinating Group. The Coordinating Group should be composed of representatives from all stakeholders and charged with:*
  - *Ensuring that each working group completes its tasks in a timely manner*
  - *Collecting the deliverables from each working group*
  - *Distributing the working group's deliverables to the combined stakeholder group*
  - *Reconvening the combined stakeholder group to finalize the plans developed and to coordinate implementation and use of the CRN by all stakeholders*

Logistics

- *Each working group will have co-chairs from different stakeholder groups including industry, govt., societies, and academia*

- *Each working group has 2 note takers to assist in documenting the discussion; others with notes and post meeting comments should communicate with the co-chairs*

- *Co-chairs of the working groups have a list of questions to help frame the discussion*

- *Breakout groups and rooms will remain the same for all 3 sessions*

- *Workshop attendee list will be distributed*

Logistics

- First Breakout - 90 minutes
  - Clinical- Room E1/E2
  - Informatics and Methodology- Room A
  - Sustainability and Value – Room F1/F2
- Lunch (*on your own*)
- Second Breakout (working groups reconvene) - 90 minutes
- Breakout summaries for the full group and feedback- 70 minutes
- Third Breakout - 30 minutes for feedback integration
- Final report back to full group
- Closing remarks

After the Workshop/Moving Forward
- Anticipate continued efforts from all working groups
- FDA to continue to support efforts in this area

Questions before we begin?