

FDA Public Workshop on a Coordinated Registry Network for Devices Used for Acute Ischemic Stroke Interventions

Thursday, February 2, 2017
National Institutes of Health Campus
Ruth L. Kirschstein Auditorium
Natcher Conference Center, Bldg. 45
9000 Rockville Pike
Bethesda, MD 20892

Workshop Objectives

- Provide brief background on the development of the Devices Used for Acute Ischemic Stroke Interventions (DAISI) Coordinated Registry Network (CRN)
- Obtain stakeholders' input on the data needs and other value propositions to be captured in the CRN for acute ischemic stroke medical devices
- Establish working groups to address considerations in the following areas:
 - Clinical Common Data Elements, Standardized Definitions and Case Report Forms
 - Informatics and Methodology
 - Sustainability and Value
- Develop overall project work plan and estimated timelines to establish this CRN to begin capturing data for all stakeholders' needs, including for United States (U.S.) Food and Drug Administration (FDA) regulatory use

Proposed Deliverables from Working Groups:

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 Working Group:

- Determine appropriate infrastructure model for DAISI CRN
 - Distributed vs. Central model (examples will be described from prior experiences)
- 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

Coordinated Registry Network (CRN) for Devices Used for Acute Ischemic Stroke Intervention (DAISI) Workshop

Sustainability and Value Working 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
 - Collects 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
- 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 appropriate value for all stakeholders and report to the Coordinating Group.
- Formulate funding structure (long and short term) and report to the Coordinating Group
- Outline plan for data use agreements

Breakout Session Chairs:

Clinical Working Group:

Sameer Ansari, MD, PhD	SNIS, Northwestern University Feinberg School of Medicine
Kuo Chao, MD	FDA, Kaiser Permanente
Manish Gupta	Medtronic Neurovascular
Scott Janis, PhD	National Institute of Neurological Disorders and Stroke, NIH

Informatics and Methodology Working Group:

Matthew Fusco, MD	FDA, Vanderbilt University Medical Center
Yosef Khan, MD, MPH, PhD	American Heart Association
Terrie Reed	FDA
Ryan Shields	Stryker Neurovascular

Sustainability and Value Working Group:

Jack Cronenwett, MD	Dartmouth-Hitchcock Medical Center
Daniel Davis	Penumbra Inc.
Benjamin Eloff, PhD	FDA
Adnan Siddiqui, MD, PhD	University at Buffalo, The Jacobs Institute