

March 2, 2017

Carlos Pena, Ph.D, MS, Director
Division of Neurological and Physical Medicine Devices
Food and Drug Administration
Office of Device Evaluation, Center for Devices and
Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Docket: FDA-2016-N-4187 Coordinated Registry Network (CRN) for Devices
Used for Acute Ischemic Stroke Intervention (DAISI)**

Dear Dr. Pena:

The undersigned members of the Cerebrovascular Coalition (CVC), a multispecialty alliance of specialty societies comprising the majority of physicians who perform acute, endovascular stroke interventions in the United States, would like to follow up on the Food and Drug Administration (FDA) workshop held on February 2, 2017, regarding the development of a coordinated registry network for Devices Used for Acute Ischemic Stroke Intervention (DAISI). We believe that this is a critically important initiative to assure the safety and improve the quality of care for patients being treated with these devices for acute ischemic stroke.

At present, the AANS/CNS Cerebrovascular Section (CVS) and the SNIS each have an established registry for acute stroke interventions. The CVS registry is part of the Quality Outcomes Database project of the NeuroPoint Alliance (NPA). The SNIS registry is part of their NeuroVascular Quality Initiative (NVQI) governed under the SNIS Patient Safety Organization (SNIS PSO).

The SNIS, CVS, NVQI and NPA have committed to combining their well-established database efforts into a single registry. They have already made great progress in regard to a standard data dictionary, standard data elements, the data collection platform and a business plan.

The professional societies represented in the Cerebrovascular Coalition strongly support the use of this NVQI/NPA registry for the coordinated registry network for Devices Used for Acute Ischemic Stroke Intervention (DAISI). We are convinced that this registry will help us achieve the goals that were proposed and discussed at the FDA symposium.

Thank you for your time and consideration. Please let us know if there is other information we can supply.

Sincerely,

American Academy of Neurology
American Association of Neurological Surgeons
American Society of Neuroradiology
Congress of Neurological Surgeons
Society of NeuroInterventional Surgery