4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4187]

Coordinated Registry Network for Devices Used for Acute Ischemic Stroke Intervention; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Coordinated Registry Network (CRN) for Devices Used for Acute Ischemic Stroke Intervention (DAISI)." The purpose of the public workshop is to obtain stakeholders' input on the coordination of registries for DAISI.

DATES: The public workshop will be held on February 2, 2017, 8 a.m. to 5 p.m. EST. The deadline for submitting comments regarding this public workshop is March 2, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the Ruth L. Kirschstein Auditorium, Natcher Conference Center, Bldg. 45, National Institutes of Health Campus, 9000 Rockville Pike, Bethesda, MD 20892. Entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center located adjacent to the Medical Center Metro, where routine security check procedures will be performed. Please visit the following Web site for NIH campus location, parking, security, and travel information: http://www.nih.gov/about/visitor/index.htm. Please visit the following Web site for information on the Natcher Conference Center: http://www.genome.gov/11007522.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

In order to permit the widest possible opportunity for public comment, FDA is soliciting either electronic or written comments on all aspects of the workshop topics.

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-4187 for "Coordinated Registry Network (CRN) for Devices Used for Acute Ischemic Stroke Intervention (DAISI)." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2611, Silver Spring, MD 20993, 301-796-3063, email: Jamie.Waterhouse@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Stroke is the fifth leading cause of death in the United States and the number one preventable cause of disability (Ref. 1). Recent publication of five prospective randomized trials and revised practice guidelines in the treatment of stroke has suggested the potential therapeutic role of endovascular therapy in combination with pharmacotherapy (typically intravenous tissue plasminogen activator (IV t-PA)) for patients with proximal large vessel occlusion stroke in the anterior circulation (M1 Middle Cerebral Artery segment with or without concomitant Internal Carotid Artery occlusion) (Refs. 2-6). FDA believes that research and development in this field, including the collection of data through the use of registries, provides a potential data source for expanding indications for already cleared/approved devices. Development and leveraging support for data collected within appropriate registries; with the participation of professional

medical societies, industry, patient groups, healthcare facilities, and payers; can further drive innovation in this area and aid in the improvement of clinical care and patient outcomes. A coordinated registry network may also collect data reflective of clinical practice that is of sufficient quality and breadth to support scientific, clinical, and regulatory decision-making and aid in the design of future studies and performance testing requirements for new or existing devices.

II. Topics for Discussion at the Public Workshop

This workshop is aimed at addressing scientific, clinical, and regulatory considerations associated with medical devices used in the treatment of acute ischemic stroke medical devices and the development of coordinated registry networks to serve the following topic areas:

- Clinical Common Data Elements;
- Standardized Definitions and Case Report Forms;
- Informatics, Sustainability, and Data Quality; and
- Additional scientific, methodological, and clinical considerations for evaluating information obtained from registries.

III. Participating in the Public Workshop

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences (Medical Devices) calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. Persons interested in attending this public workshop must register online by January 26, 2017, at 4 p.m. EST. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by January 26, 2017, at 4 p.m. EST. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Peggy Roney, Center for Devices and Radiological Health, Office of Communication and Education, 301-796-5671, email: Peggy.Roney@fda.hhs.gov no later than January 19, 2017.

IV. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. American Stroke Association, "Impact of Stroke (Stroke statistics)" (http://www.strokeassociation.org/STROKEORG/AboutStroke/Impact-of-Stroke-Stroke-statistics_UCM_310728_Article.jsp#.VvFGChvruUk).

2. Berkhemer, O. A., et al. "A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke." New England Journal of Medicine. 372, 11-20 (2015).

3. Saver, J. L., et al. "Stent-Retriever Thrombectomy After Intravenous t-PA Versus t-PA Alone in Stroke." New England Journal of Medicine. 372, 2285-2295 (2015).

4. Goyal, M. et al. "Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke." New England Journal of Medicine. 372, 1019-1030 (2015).

5. Campbell, B. C., et al. "Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection." New England Journal of Medicine. 372, 1009-1018 (2015).

6. Jovin, T. G., et al. "Thrombectomy Within 8 Hours After Symptom Onset in Ischemic Stroke." New England Journal of Medicine. 372, 2296-2306 (2015).

Dated: December 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31143 Filed: 12/23/2016 8:45 am; Publication Date: 12/27/2016]