4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4179]

# Cardiac Troponin Assays; 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, the Agency, or we) is announcing the following public workshop entitled "Cardiac Troponin Assays." The purpose of the workshop is to discuss the development of innovative troponin assays designed to aid in the diagnosis of myocardial infarction (MI) and additional clinical uses of these assays. The workshop is intended to enhance engagement with stakeholders to facilitate device development and to discuss scientific and regulatory challenges associated with the analytical and clinical validation methods for troponin assay devices. Public input and feedback gained through this workshop may aid in the development of science-based approaches to aid in the efficient development of innovative, safe and effective, troponin diagnostic assays, which may lead to better patient care.

DATES: The public workshop will be held on November 28, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by November 27, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (The Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer

to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 27, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of November 27, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: Go to 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

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2017-N-4179 for "Cardiac Troponin Assays." Received comments, those filed in a timely manner (see ADDRESSES) will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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." The Agency 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 Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

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 Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula Caposino, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 4644, Silver Spring, MD 20993, 301-796-6160, Paula.Caposino@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

Since first discovered, cardiac troponin has become increasingly valuable as a biomarker of MI. In 2007, the National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines and the Joint European Society of Cardiology, American College of Cardiology

Foundation, American Heart Association, and the World Heart Federation Task Force Guidelines recommended the use of cardiac troponin as a biomarker for the diagnosis of MI when used in conjunction with clinical evidence of myocardial ischemia (Refs. 1 and 2). Cardiac troponin has also been recommended in current clinical guidelines as a prognostic marker in patients with symptoms of acute coronary syndrome with respect to mortality, MI, or ischemic events. These recommendations solidified troponin's importance in MI diagnosis and triage; at the same time, they formalized an adjustment in the clinical cutoffs and changed the way troponin results were interpreted and used. There is a lot of interest in developing innovative troponin assays that aid in the diagnosis of MI and to support additional clinical uses of these assays. We are holding this public workshop to discuss several topics of interest that are important for the development of innovative cardiac troponin assays. The goal of the workshop is to enhance engagement with stakeholders concerning the development and validation of innovative troponin assay devices.

## II. Topics for Discussion at the Public Workshop

This public workshop will consist of brief presentations providing information to frame the discussion, followed by interactive panel discussions. Following the presentations, a moderated discussion is planned to ask speakers and additional panelists to provide their individual perspectives. Topics for discussion include:

- Clinical study design considerations and challenges
- Subgroup differences for troponin's clinical use (e.g., the need for sex-specific cutoffs)
- Reference range study design considerations and best practices for reference range study design and methods for calculating upper reference limits
- The use of deltas in the diagnosis of MI

- Point of care testing

In light of the changes to how troponin is used clinically, there is a need to explore and discuss troponin assay device development and evaluation. We are soliciting comments and feedback from stakeholders regarding additional topics for FDA to consider for discussion. These comments can be submitted to the docket prior to the meeting (see ADDRESSES). We anticipate that the comments and discussion at this public workshop will help facilitate the development of innovative troponin devices and lessen regulatory burden. The ultimate goal is to facilitate the availability of innovative, safe and effective troponin assay devices for patient care.

## III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) 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 November 17, 2017, by 4 p.m. Eastern Time. 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. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20993-0002, 301-796-5661, email: Susan.Monahan@fda.hhs.gov, no later than November 14, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by November 20, 2017. All requests to make oral presentations must be received by the close of registration on November 17, 2017 by 4 p.m. If selected for presentation, any presentation materials must be emailed to Paula Caposino (see FOR FURTHER INFORMATION CONTACT) no later than November 21, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the public workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web page after November 21, 2017. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview.

FDA has verified the Web site addresses in this document, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

## IV. References

The following references are on display in the Dockets Management Staff (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.

1. "National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Clinical Characteristics and Utilization of Biochemical Markers in Acute Coronary Syndromes." Circulation, 2007; 115, 356-375.

2. "Universal Definition of Myocardial Infarction." Circulation, 2007: 116, 2634-2653.

Dated: July 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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