

- Building and leveraging existing community infrastructures for information, counseling, and assistance.

- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including preventive services, envisioned under the Affordable Care Act.

The current members of the Panel are: Kellan Baker, Associate Director, Center for American Progress; Robert Blancato, President, Matz, Blancato & Associates; Dale Blasier, Professor of Orthopaedic Surgery, Department of Orthopaedics, Arkansas Children's Hospital; Deborah Britt, Executive Director of Community & Public Relations, Piedmont Fayette Hospital; Deena Chisolm, Associate Professor of Pediatrics & Public Health, The Ohio State University, Nationwide Children's Hospital; Josephine DeLeon, Director, Anti-Poverty Initiatives, Catholic Charities of California; Robert Espinoza, Vice President of Policy, Paraprofessional Healthcare Institute; Louise Scherer Knight, Director, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; Roanne Osborne-Gaskin, M.D., Senior Medical Director, MDWise, Inc.; Cathy Phan, Outreach and Education Coordinator, Asian American Health Coalition DBA HOPE Clinic; Kamilah Pickett, Litigation Support, Independent Contractor; Brendan Riley, Outreach and Enrollment Coordinator, NC Community Health Center Association; Alvia Siddiqi, Medicaid Managed Care Community Network (MCCN) Medical Director, Advocate Physician Partners, Carla Smith, Executive Vice President, Healthcare Information and Management Systems Society (HIMSS); Tobin Van Ostern, Vice President and Co-Founder, Young Invincibles Advisors; and Paula Villescaz, Senior Consultant, Assembly Health Committee, California State Legislature.

III. Copies of the Charter

The Secretary's Charter for the APOE is available on the CMS Web site at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/APOECharter2017.pdf> or you may obtain a copy of the charter by submitting a request to: Thomas Dudley, Designated Federal Official (DFO), Office of Communications, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1 05-06, Baltimore, MD 21244 1850 or via email at Thomas.Dudley@cms.hhs.gov.

Dated: July 21, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017-15960 Filed 7-28-17; 8:45 am]

BILLING CODE 4120-01-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.

[FR Doc. 2017–16007 Filed 7–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Developing a Framework for Regulatory Use of Real-World Evidence; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Developing a Framework for Regulatory Use of Real-World Evidence." Convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA, the purpose of the public workshop is to bring the stakeholder community together to discuss a variety of topics related to the use of real-world data (RWD) and real-world evidence (RWE) in drug development and regulatory decision making. Topics will include an update on FDA's activities to address the use of RWE in regulatory decisions and the development of a framework for tackling challenges related to RWE's regulatory acceptability. In addition, panelists will discuss opportunities to improve data development activities, study designs, and analytical methods used to create robust RWE.

DATES: The public workshop will be held on September 13, 2017, from 9 a.m. to 4:30 p.m., Eastern Time.

ADDRESSES: The public workshop will be held at the Conference Center at 1777 F Street NW., Washington, DC 20006. For additional travel and hotel information, please refer to the following Web site: <https://healthpolicy.duke.edu/events/public-workshop-developing-framework-regulatory-use-real-world-evidence>. There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of Public Workshop*).

FOR FURTHER INFORMATION CONTACT: Kayla Garvin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, Rm. 6314, Silver Spring, MD 20993, (301) 796–7578, Kayla.Garvin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

RWD (data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources) and RWE (clinical evidence regarding the usage and potential benefits or risks of a drug derived from analysis of RWD) are increasingly being used by multiple stakeholders within the health care system. Payers may rely on RWD and RWE to refine formularies or assist in coverage decisions. Physicians and professional societies can utilize RWE to further tailor clinical practice guidelines and decision-support tools. Medical product developers can use RWE to further develop a product's benefit-risk profile, monitor postmarket safety and adverse events, or generate additional hypotheses for continued clinical development.

The 21st Century Cures Act, section 3022 (Pub. L. 114–255), enacted on December 13, 2016, directed FDA to establish a program to evaluate the potential use of RWE. The framework of the program was to include information describing the sources of RWE, the gaps in data collection, standards and methods for collection and analysis, and the priority areas and challenges.

To date, RWD and RWE have been used in very specific regulatory contexts. Some treatments for rare diseases, for example, have utilized RWE as part of the historical controls used for clinical study and, ultimately, regulatory submission. Postmarket safety surveillance has also relied heavily on RWD-generating networks. As part of exploring the opportunities for enhanced use of these types of data and evidence in additional regulatory decision-making contexts, FDA is seeking input on the opportunities and challenges in using RWE to support the approval of a new indication for an already approved drug, and to help support or satisfy postapproval study requirements.

This public workshop is being held to engage external stakeholders in discussions around the current state of RWE development and potential challenge areas for using RWE in regulatory decisions beyond postmarket safety surveillance.

II. Topics for Discussion at the Public Workshop

During the course of the public workshop, speakers and participants will cover a range of issues related to