



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4562]

Safety Assessment for Investigational New Drug Safety Reporting; 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 public workshop entitled “Safety Assessment for IND Safety Reporting.” 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 “Safety Assessment for Investigational New Drug (IND) Safety Reporting.” This public workshop is organized in response to public comments received to Docket No. FDA-2015-D-4562 for the draft guidance “Safety Assessment for IND Safety Reporting” issued in December 2015 requesting a public meeting to discuss the draft guidance and its implications. The public workshop is intended to engage external stakeholders in discussions related to finalizing the draft guidance entitled “Safety Assessment for IND Safety Reporting.”

DATES: The public workshop will be held on January 11, 2018, from 9 a.m. to 4 p.m., Eastern Time. See the SUPPLEMENTARY INFORMATION section for registration date and information.

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 website: <https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting>. 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: Lauren Wedlake, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6362, Silver Spring, MD 20993, 301-796-2728, Lauren.Wedlake@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The IND safety reporting requirements for human drugs and biological products being studied under an IND are stated in § 312.32 (21 CFR 312.32). In 2012, FDA published final guidance for industry and investigators regarding implementation of these requirements entitled “Safety Reporting Requirements for INDs and BA/BE Studies¹.” During the evaluation of comments to the draft guidance for industry and investigators entitled “Safety Reporting Requirements for INDs and BA/BE Studies” (Docket No. FDA-2010-D-0482) and at meetings with stakeholders, FDA identified the need for additional guidance on IND safety reporting. The draft guidance for industry entitled “Safety Assessment for IND Safety Reporting” was issued in December 2015² as a follow-on to the guidance for industry and investigators entitled “Safety Reporting Requirements for INDs and BA/BE Studies” and provides recommendations for how sponsors of INDs can identify and evaluate important safety information that must be submitted to FDA and all participating investigators under the IND safety reporting regulations at § 312.32.

¹ Available at: <https://www.fda.gov/downloads/Drugs/Guidances/UCM227351.pdf>.

² <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM477584.pdf>

The focus of this draft guidance is on safety information that is only interpretable in the aggregate and therefore, this guidance is most applicable to late-stage studies and drug development programs that have multiple studies. This guidance contains recommendations on the following matters that are most relevant to sponsors' review of aggregate data for IND safety reporting: (1) the entity that reviews aggregate data, (2) methods for aggregate analyses of safety data, (3) maintaining trial integrity while reviewing unblinded data, and (4) reporting criteria. This guidance also contains recommendations regarding the development of a plan for safety surveillance, and includes considerations and recommendations.

Timely reporting of meaningful safety information allows FDA to consider whether any changes in study conduct should be made beyond those initiated by the sponsor and allows investigators to make any needed changes to protect subjects. Simply reporting all serious adverse events, however, including those where there is little reason to consider them suspected adverse reactions (suspected adverse reactions being those with a reasonable possibility of having been caused by the drug), does not serve this purpose because it may obscure safety information that is relevant to the investigational drug. Sponsors' effective processes for a systematic approach to safety surveillance, coupled with IND safety reporting of suspected adverse reactions to FDA and all participating investigators (and subsequent reporting to involved institutional review boards), allows all parties to focus on important safety issues and to take actions to minimize the risks of participation in a clinical trial. Sponsors are encouraged to have internal processes for governing the safety surveillance and safety reporting for their development programs. Such process may include documenting which adverse events are anticipated in the population under study and would not likely be reported as a single occurrence, but instead would be evaluated by assessing whether there are differences in the rate of

occurrence of such events between those receiving the intervention and the concurrent or historical control.

This public workshop is being held in response to public comments received to Docket No. FDA-2015-D-4562 for the draft guidance entitled “Safety Assessment for IND Safety Reporting” issued in December 2015 requesting a public meeting to discuss the draft guidance recommendations and their implications, including the new recommendations regarding the formation of a safety assessment committee and the submission of a portion of the safety surveillance plan to the IND before initiating phase 2 or 3 studies. The public workshop is intended to engage external stakeholders in discussions related to finalizing the draft guidance entitled “Safety Assessment for IND Safety Reporting.”

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will address a range of issues related to the draft guidance “Safety Assessment for IND Safety Reporting”, issued in December 2015. Items for discussion will include topics raised in public comments submitted to the draft guidance docket, including but not limited to: the entity that conducts aggregate analysis of safety data for IND safety reporting, concerns with unblinding of data and trial integrity, methods for determining the threshold for reporting, and developing and documenting a plan for safety surveillance. Furthermore, input will be sought on other factors that drive over-reporting of safety events that do not meet the definition of a suspected unexpected serious adverse reaction.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: <https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting> and register online by

January 8, 2018, midnight Eastern Time. There will be no onsite registration. 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 online by January 8, 2018, midnight 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. Duke-Margolis will post on its website if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy, 202-791-9561, sarah.supsiri@duke.edu, no later than January 4, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast; archived video footage will be available at the Duke-Margolis website (<https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting>) following the workshop. Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, we recommend that you review these technical system requirements in advance.

Transcripts: Please be advised that transcripts will not be available.

FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Meeting Materials: All event materials will be provided to registered attendees via email prior to the workshop and publicly available at the Duke-Margolis website:

<https://healthpolicy.duke.edu/events/fda-ind-safety-reporting-meeting>.

Dated: November 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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