4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1291]

# Stakeholder Engagement on ICH E6: Guideline for Good Clinical Practice; Public Web Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public web conference.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a free public web conference for discussion of the International Council for Harmonisation's (ICH's) good clinical practice guidelines, ICH E6. This public web conference, "Stakeholder Engagement on ICH E6: Guideline for Good Clinical Practice," is being convened and supported by a cooperative agreement between the Clinical Trials Transformation Initiative (CTTI) and FDA. The purpose of the web conference is to capture stakeholder experiences with current ICH E6 guidelines for good clinical practice (GCP) and to gather stakeholder input to further inform the development of an updated guideline, ICH E6(R3).

DATES: The public web conference will be held on Thursday and Friday, June 4 and 5, 2020, from 10 a.m. to 1 p.m. Eastern Time. Further details on the web conference (including times) are available at the website provided under ADDRESSES. See the SUPPLEMENTARY INFORMATION section for details.

ADDRESSES: The web conference will be held online. Meeting details and background materials, including the web conference link, are available at the following website:

https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement.

FOR FURTHER INFORMATION CONTACT: Suzanne Pattee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3328, Silver Spring, MD 20993, 301-796-1706, Suzanne.Pattee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

To support GCP renovation, FDA and ICH are seeking stakeholder input to develop a new ICH guideline, "ICH E6(R3): Guideline for Good Clinical Practice," to enable flexible application of those guidelines to interventional clinical trials, including innovative clinical trial designs and data sources. ICH E6(R3) materials, including the ICH Reflection Paper on "GCP Renovation," concept paper, business plan, work plan, and an expert list, as well as the current guideline, "ICH E6(R2): Guideline for Good Clinical Practice," are available on the ICH website: https://www.ich.org/page/efficacy-guidelines.

The purpose of the public web conference announced in this notice is to obtain input on stakeholder experiences with the current GCP guideline (ICH E6(R2)) and suggested changes to improve the guideline's applicability to the changing clinical trial landscape.

## II. Topics for Discussion at the Public Web Conference

During the public web conference, speakers and participants will cover a range of GCP issues to inform revisions to the current GCP guidelines. Topics for discussion will include and are not limited to: (1) issues with application of current guidelines to traditional interventional clinical trials, (2) ways to modify the guideline to address innovative trial designs, (3) use of digital technology tools, (4) new data sources, and (5) other topics relating to GCPs.

## III. Participating in the Public Web Conference

*Registration*: To register for the free public web conference, complete the registration form at https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

*Streaming Public Web Conference*: This live web conference will be recorded and archived and will be available after the event at the event website. Persons interested in participating in the live web conference are encouraged to register in advance (see *Registration*). The live web conference will also be available at the website above on the day of the event without preregistration. Detailed information is available at the following website: https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement.

Registered web conference participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming web conference of the public event.

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 web conference and will be publicly available at the https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-stakeholder-engagement.

*Transcripts*: Please be advised that transcripts of the public web conference will not be available.

Dated: May 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-10975 Filed: 5/20/2020 8:45 am; Publication Date: 5/21/2020]