4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1214]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), is announcing a 3-day training course for clinical investigators on the scientific, ethical, and regulatory aspects of clinical trials for medical products. This training course is intended to provide clinical investigators, such as clinicians, nurses, pharmacists, and other health care providers involved in conducting clinical trials, with expertise in the design, conduct, and analysis of clinical trials; to improve the quality of clinical trials; and to enhance the safety of trial participants. Senior FDA staff, along with other experts, will present on issues critical for successful conduct of clinical research.

DATES: The training course will be held on November 7, 2016, from 8:20 a.m. to 5:30 p.m. (registration begins at 7:30 a.m.); on November 8, 2016, from 8:30 a.m. to 4:45 p.m.; and on November 9, 2016, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The course will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Place, Silver Spring, MD 20910. GPS device address: 8525 Fenton St., Silver Spring, MD 20910. For additional information, please refer to http://www.silverspringdowntown.com/go/silver-spring-civic-building-and-veterans-plaza.

(FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.)

FOR FURTHER INFORMATION CONTACT: Nicole Silva, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6323, Silver Spring, MD 20993, 301-796-3419, Nicole.Silva@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This course is intended to train clinical investigators in all elements of clinical trials, including the preclinical and clinical information needed to support the investigational use of medical products; the statistical design of trials; and scientific, regulatory, and ethical considerations related to conduct of clinical trials. The course lecturers will include a diverse representation of senior FDA staff and other experts, enabling communication on issues critical for successful conduct of clinical research.

II. Description of the Training Course

A. Purpose

The training course is designed to provide clinical investigators with an overview of the following information:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
- Fundamental issues in the design and conduct of clinical trials;
- Statistical and analytic considerations in the interpretation of trial data;

• Appropriate safety evaluation during studies; and

• The ethical considerations and regulatory requirements for clinical trials.

In addition, the course aims to:

• Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;

• Promote communication between clinical investigators and FDA;

• Enhance investigators' understanding of FDA's role in experimental medicine;

• Improve the quality of clinical trial data; and

• Enhance protection of subjects in clinical trials.

B. Agenda

The course will be conducted over 3 days and will be presented mainly by senior FDA staff with other lecturers presenting on selected topics. The agenda is available at http://www.fda.gov/Training/ClinicalInvestigatorTrainingCourse/default.htm.

C. Target Audience

The course is targeted toward clinicians, nurses, pharmacists and other health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Registration: There is no registration fee to attend this in-person training course; however, seats are limited and registration will be on a first-come, first-served basis. To register, you need to complete the registration online by October 28, 2016, at http://www.fda.gov/Training/ClinicalInvestigatorTrainingCourse/default.htm. Upon completion of registration, you will receive an email that confirms your registration. There will be no onsite registration or remote access for this training.

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Nicole Silva (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

Dated: September 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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