

absolutely essential element for ICH success.

#### B. Research Objectives

The program's grant funds will support the ICH to develop a series of international guidelines for implementation according to each region's requirements aimed at achieving the following: (1) Develop and register safe, effective, and high quality medicines in the most efficient and cost effective manner; (2) prevent unnecessary duplication of clinical trials and minimize the use of animal testing without compromising safety and effectiveness, and (3) provide public assurance that the rights, safety, and well-being of subjects are protected during clinical trials.

The ICH aims to make information readily available on ICH, ICH activities, and ICH guidelines to any country or company that requests the information. Additionally, the organization promotes a mutual understanding of regional initiatives in order to facilitate harmonization processes related to ICH guidelines regionally and globally, and to strengthen the capacity of drug regulatory authorities and industry to utilize the guidelines. These objectives will be accomplished by bringing together representatives from both regulatory agencies and pharmaceutical industries from the three founding regions to establish guidelines.

#### C. Eligibility Information

The following organization is eligible to apply: ICH. Within the ICH, the mission is to make recommendations towards achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines. Leveraging its status as a neutral nonprofit entity focused on technical standards harmonization, the ICH aims to promote international harmonization of drug regulatory standards by bringing together representatives from both regulatory agencies and pharmaceutical industry to discuss and establish common guidelines.

## II. Award Information/Funds Available

#### A. Award Amount

FDA intends to fund one award, corresponding to a total of up to \$500,000, for fiscal year (FY) 2016. Future year amounts will depend on annual appropriations, availability of funding, and awardee performance.

CDER anticipates providing four additional years of support up to the following amounts:

FY 2017: \$500,000

FY 2018: \$500,000

FY 2019: \$500,000

FY 2020: \$500,000

#### B. Length of Support

The support will be 1 year with the possibility of an additional 4 years of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a noncompeting continuation application and available Federal FY appropriations.

## III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at <http://www.grants.gov>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Search by Funding Opportunity Number: RFA-FD-15-014.

For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: May 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-1377]

#### Electronic Study Data Submission; Data Standards; Study Data Standardization Plan Recommendations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft recommendations for preparing a Study Data Standardization Plan (Standardization Plan). The Standardization Plan is referenced in the Study Data Technical Conformance Guide (Guide). The Guide supplements the guidance for industry "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" and provides specifications, recommendations, and general considerations on submitting standardized study data using FDA-supported data standards. The Guide recommends that, for clinical and nonclinical studies, sponsors include a plan that describes the submission of standardized study data to FDA. The proposed recommendations describe the information that should be included in the Standardization Plan. The proposed recommendations for creating a Standardization Plan are posted on FDA's Study Data Standards Resources Web page at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>.

**DATES:** Although you can comment on these recommendations at any time, to ensure that the Agency considers your comments, please submit either electronic or written comments by July 2, 2015.

**ADDRESSES:** Submit written requests for single copies of the recommendations to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Hillendale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to <http://www.regulations.gov>. Submit

written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft recommendations for preparing the Standardization Plan.

**FOR FURTHER INFORMATION CONTACT:** Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993-002, 301-796-5333, email: [ronald.fitzmartin@fda.hhs.gov](mailto:ronald.fitzmartin@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of draft recommendations for preparing the Standardization Plan. The Standardization Plan is referenced in the Guide. The Guide supplements the guidance for industry "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" and provides specifications, recommendations, and general considerations on submitting standardized study data using FDA-supported data standards; it is posted on FDA's Study Data Standards Resources Web page at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>.

The Guide recommends that, for clinical and nonclinical studies, sponsors include a plan that describes the submission of standardized study data to FDA. The Standardization Plan will assist FDA in identifying potential data standardization issues early in the development program (e.g., pre-investigational new drug application stage). The draft recommendations describe the information that should be included in the Standardization Plan. The recommendations include, but are not limited to, the following: (1) General sponsor information, (2) product information, (3) list of completed studies and standards, and (4) list of planned studies and standards.

##### **II. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and

will be posted to the docket at <http://www.regulations.gov>.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the proposed recommendations at either <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm> or <http://www.regulations.gov>.

Dated: May 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-2015-D-1439]

##### **Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff." This guidance provides sponsors and FDA staff with guidance on how to plan and implement adaptive designs for clinical studies when used in medical device development programs. An adaptive design for a medical device clinical study is defined as a clinical trial design that allows for prospectively planned modifications based on accumulating study data without undermining the trial's integrity and validity. Adaptive designs, when properly implemented, can reduce resource requirements and/or increase the chance of study success. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 17, 2015.

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the

**SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Greg Campbell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2110, Silver Spring, MD 20993-0002, 301-796-5750.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This guidance provides sponsors and FDA staff with guidance on how to plan and implement adaptive designs for clinical studies when used in medical device development programs. This document addresses adaptive designs for medical device clinical trials and is applicable to premarket medical device submissions including premarket approval applications, premarket notification (510(k)) submissions, de novo submissions (evaluation of automatic class III designation), humanitarian device exemption applications, and investigational device exemption submissions. This guidance can be applied throughout the clinical development program of a medical device, from feasibility studies to pivotal clinical trials. This guidance does not apply to clinical studies of combination products or codevelopment of a pharmaceutical product with an unapproved diagnostic test.

##### **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the adaptive design of clinical