Determination of Whether an IND/IDE is Needed.'' This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in determining that the proposed research satisfies the criteria for approval contained in 21 CFR 56.111, that ''[r]isks to subjects are minimized . . . [and] reasonable in relation to anticipated benefits, if any, to subjects . . .'' In particular, the guidance addresses the IRB's role in reviewing: (1) The qualifications of clinical investigators, (2) the adequacy of the research site, and (3) the determination of whether an IND/IDE is required.

Many of the recommendations in this guidance have appeared in other FDA guidance documents. FDA has compiled the recommendations from these various sources into this guidance to ensure that all IRBs have access to it. The guidance also explains how IRBs may efficiently fulfill these important responsibilities.

To enhance protection of human subjects and reduce regulatory burden, the Department of Health and Human Services, Office for Human Research Protections (OHRP), and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts and in consultation with OHRP.

In the **Federal Register** of November 20, 2012 (77 FR 69631), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance, and considered them in preparing the final guidance. In the final guidance, FDA clarified that IRBs, sponsors, and clinical investigators all have responsibility for ensuring that the research complies with applicable laws and regulations and that risks to subjects are minimized. FDA also made changes to confirm that the recommendations in the guidance may be fulfilled by any IRB, whether independent or affiliated with an institution, and whether serving as a local IRB or as the central IRB, and made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2012, and replaces Question 56 in FDA's guidance entitled ''Institutional Review Boards Frequently Asked Questions—Information Sheet—Guidance for Institutional Review Boards and Clinical Investigators.'' [1]

[1] See *http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#GeneralQuestions.*

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). None of the collections of information referenced in this guidance are new or represent material modifications to previously approved collections of information. The collections of information under 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information under 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information under 21 CFR part 56 have been approved under OMB control number 0910–0130.

III. Comments

Interested persons may submit either electronic comments regarding this guidance 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov* or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm.*

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20822 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0972]

Strengthening the Operating Framework and Furthering the Objectives of Coalition for Accelerating Standards and Therapies Initiative (U24)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Drug Evaluation and Research (CDER) Data Standards Program. The goal of the CDER Data Standards Program is to strengthen and support the Coalition for Accelerating Standards and Therapies (CFAST) Initiative in its efforts to establish and maintain clinical data standards that will enable FDA reviewers to more efficiently perform efficacy analysis of potential new drugs in therapeutic areas that are important to public health.

DATES: Important dates are as follows:

1. The application due date is August 26, 2013.

2. The anticipated start date is September 15, 2013.

3. The expiration date is August 27, 2013.

ADDRESSES: Submit the paper application to: Kimberly Pendleton-Chew, Grants Management (HFA–500), 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, and a copy to Fatima Frye, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1195, Silver Spring, MD 20993. For more information, see section III of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Fatima Frye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1195, Silver Spring, MD 20993, 301–796–4863; or Kimberly Pendleton-Chew, Office of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, 301–827–9363, email: *Kimberly.Pendleton@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/*

FormsSubmissionRequirements/ElectronicSubmissions/ucm364432.htm.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–039
93.103

A. Background

CDER receives an enormous and growing amount of data in a variety of regulatory submissions from a multitude of sources and in a variety of formats. This wealth of data holds great potential to advance CDER's regulatory and scientific work, but the present lack of standardized data creates significant challenges to realizing that potential. The volume and complexity of drug-related information submitted to CDER for regulatory review is creating significant challenges to the Center's ability to efficiently and effectively perform its critical public health mission.

The lack of standardized data affects CDER's review processes by curtailing a reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage, and reporting of regulatory data. Improved data quality, accessibility, and predictability will give reviewers more time to carry out complex analyses, ask in-depth questions, and address late-emerging issues. Standardized data will allow reviewers to increase review consistency and perform evaluations across the drug lifecycle. This will enhance the Center's performance across key drug regulatory functions and ongoing business operations, including premarket review, post-market safety, oversight of drug quality, and oversight of drug promotion.

Standardized data elements that are common to all clinical trials, such as age and gender, have been established through Clinical Data Interchange Standards Consortium standards. However, data elements that are unique for a particular disease or therapeutic area still need to be developed so that the data are consistent and consistently understood for efficacy analysis, and that data from multiple trials can be more easily grouped for reporting and meta-analysis.

In short, establishing common standards for data reporting will provide new opportunities to transform the massive amount of data from drug studies on specific diseases into useful information to potentially speed the delivery of new therapies to patients.

B. Research Objectives

The CFAST Initiative aims to accelerate clinical research and medical product development by establishing and maintaining data standards, tools, and methods for conducting research in therapeutic areas that are important to public health. It is established as a public-private partnership (PPP) involving multiple stakeholders. The Grantee funded through this announcement would be expected to accomplish activities such as, but not limited to:

- Maintenance of the scientific and administrative infrastructure of the PPP to support a series of projects under the CFAST Initiative.
- Coordination and management of therapeutic area standards development projects with key experts in the specific therapeutic areas, including stakeholders from industry, professional organizations, academia, and Government agencies.
- Identification and engagement with key experts in the therapeutic areas, including stakeholders from industry, professional organizations, academia, and Government agencies.
- Development of therapeutic area data standards, initially proposed for diabetes, QT studies, lipid lowering/altering drugs, and hepatitis C. Additional or different areas can be considered as well.
- Identification and implementation of continuous quality improvements with respect to the data standards development process and product(s) to facilitate timely and sustainable standards.

C. Eligibility Information

The following organization is eligible to apply: The Critical Path Institute (C-Path).

Over the past 7 years, C-Path has become an international leader in forming and leading/managing collaborations globally. They currently lead 7 very active scientific consortia across multiple disease areas. C-Path consortia include more than 1,000 scientists from Government, academia, patient advocacy organizations, and 41 major pharmaceutical companies. C-Path has a proven process, capability, and institutional knowledge critical to successfully leading scientific consortia and rapid therapeutic area standards development projects through an open, transparent process as identified by the Prescription Drug User Fee Act V.

II. Award Information/Funds Available

A. Award Amount

Total amount of funding available is $2,000,000. Anticipate one award.

B. Length of Support

Scope of the proposed project should determine the project period. The maximum period is 3 years.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm364432.htm.* (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**.) Persons interested in applying for a grant may obtain an application at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm364432.htm.* For all the paper application submissions, 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: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to: Kimberly Pendleton-Chew, 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, 301–827–9363, email: *Kimberly.Pendleton@fda.hhs.gov.*

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20823 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for