

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0545]

Submission Date 12-29-04
Publication Date 12-30-04
Director R. TEDESMA

Nonclinical and Clinical Datasets; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is seeking volunteers to participate in a pilot project involving the evaluation of various analysis tools to facilitate the use of electronic datasets for analysis of animal and human data submitted to FDA by applicants of biologics license applications (BLAs). These analysis tools will allow a reviewer to more efficiently capture and evaluate nonclinical and clinical datasets submitted in electronic format.

DATES: Submit written requests to participate in the pilot project by *[insert date 60 days after date of publication in the **Federal Register**]*. Comments on this pilot project may be submitted at any time.

ADDRESSES: Submit written requests to participate and comments regarding the pilot project to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *<http://www.fda.gov/dockets/ecomments>*.

FOR FURTHER INFORMATION CONTACT: Richard Diamond, Center for Biologics Evaluation and Research (HFM-6), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0372.

SUPPLEMENTARY INFORMATION:

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I. Background

Under current FDA regulations (21 CFR 601.2), applicants must provide nonclinical and clinical data in BLAs. CBER provided recommendations for the electronic submission of BLAs, as well as new drug applications (NDAs), in the “Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications” dated November 1999. A joint CBER and Center for Drug Evaluation and Research (CDER) document entitled “Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations” dated January 1999 provided recommendations for the file formats for nonclinical and clinical datasets.

FDA announced on July 21, 2004, a standard format, called the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium (CDISC), that sponsors of human drug clinical trials can use to submit data to the agency. It is expected that this step will lead to greater efficiencies in clinical research and FDA reviews of NDAs and BLAs. CDISC is an open, multidisciplinary, nonprofit organization including members from pharmaceutical companies, biotechnology companies, contract research organizations, and software vendors. CDISC committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. CDISC is currently facilitating the work on similar standards for nonclinical and clinical datasets. Where possible, the standards developed for clinical datasets and metadata should be used in the development of standardized presentations of the datasets for routine toxicology studies (e.g., chronic toxicology and carcinogenicity

studies). Version 3.1 (V3.1) of the CDISC Submission Data Domain Standards was officially released on June 25, 2004. These standards and the accompanying Implementation Guide can be viewed on the CDISC Web site at www.cdisc.org.¹

FDA has performed some initial pilot testing of nonclinical and clinical data applicable to drugs. The purpose of this pilot project is to evaluate the Version 3.1 of the CDISC SDTM and the Implementation Guide to determine applicability to clinical and nonclinical data required for submission of CBER regulated BLAs, to help in the refinement of analysis tools designed to facilitate the review and evaluation of electronic nonclinical and clinical datasets, and to obtain feedback from reviewers and pharmaceutical companies on the creation and use of standardized nonclinical and clinical data and metadata in a format that is applicable to BLA submissions.

II. Pilot Project Description

This pilot project is part of an effort to improve the process for submitting nonclinical and clinical data. Eventually, FDA expects to recommend detailed data standards for the submission of nonclinical and clinical data. Participants in this pilot project will have the opportunity not only to assist the agency in testing the use of various analysis tools and standardized nonclinical and clinical data and metadata, but would also be able to familiarize themselves with the process at an early stage of development. Only a few participants are needed for this pilot.

A. Initial Approach

Because a limited group of voluntary participants are needed, the agency will use its discretion in choosing volunteers, based on their having previously

¹FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

submitted nonclinical and clinical datasets to FDA and having demonstrated familiarity with our recommendations for creating nonclinical and clinical datasets as presented in the “Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications.” During the pilot project, specific technical instructions for providing the nonclinical and clinical data for testing will be made available to pilot participants.

Participants in the pilot project will be asked to provide nonclinical and clinical datasets as described in the technical instructions and to provide technical feedback.

B. Scope

Existing requirements for the submission of CBER nonclinical and clinical data will not be waived, suspended, or modified for purposes of this pilot project. The pilot project will test the preparation and use of the submitted nonclinical and clinical electronic datasets.

C. How to Participate

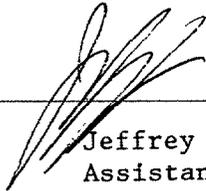
Written requests to volunteer should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. We will consider all received comments in making a

determination on electronic filing and when drafting a guidance document for submitting CBER nonclinical and clinical study data as electronic datasets. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 12/16/04
December 16, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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