
Guidance for Industry Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Theresa Toigo, Office of Special Health Issues (OSHI) 301-827-4460.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**June 2001
Procedural**

Guidance for Industry

Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan

*Additional copies are available from:
Office of Training and Communication
Division of Drug Information, HFD-240
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573*

<http://www.fda.gov/cder/guidance/index.htm>

or

*Office of Communication, Training and
Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Rockville, MD 20852-1448
<http://www.fda.gov/cber/guidelines.htm>
Fax: 1-888-CBERFAX or 301-827-3844*

(Tel) Voice Information System at 800-835-4709 or 301-827-1800

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**June 2001
Procedural**

TABLE OF CONTENTS

I. INTRODUCTION..... 1

II. BACKGROUND 1

III. IMPLEMENTATION PLAN..... 2

A. What Information Do I Submit to the Clinical Trials Data Bank?.....2

B. How do I Submit Information to the Clinical Trials Data Bank ?.....3

C. What Happens to the Information Submitted to the Clinical Trials Data Bank?.....4

D. Can I Submit Other Information Voluntarily to the Clinical Trials Data Bank?.....4

E. Are There Exemptions for Submitting Clinical Trials Information?.....4

F. When Does This Requirement Go into Effect?.....4

Guidance for Industry¹

Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan

This draft guidance represents the Food and Drug Administration's (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.

I. INTRODUCTION

This is the second draft guidance document intended to assist you when submitting information to the Clinical Trials Data Bank required by Section 113 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). The first draft guidance document was published on March 29, 2000.² It addressed statutory requirements for submission of protocol information. This guidance document discusses procedural issues that were not included in the first document. A final combined guidance will be issued after consideration of any comments received. Until the final guidance document is available, sponsors submitting clinical trial information for inclusion in the AIDS Clinical Trials Information Service (ACTIS) data bank should continue to follow procedures currently in place.

II. BACKGROUND

Section 113 of the Modernization Act provides for the public availability of specified information on studies of drugs for serious or life-threatening diseases conducted under FDA's IND regulations (21 CFR part 312).

The Modernization Act, enacted November 21, 1997, amends section 402 of the Public Health Service Act (42 U.S.C. 282) and directs the Secretary of Health and Human Services, acting through the Director of NIH, to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions.

The Clinical Trials Data Bank is intended to be a central resource, providing current information

¹This guidance has been prepared by the Office of Special Health Issues in the Office of the Commissioner in cooperation with the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research at the Food and Drug Administration, in consultation with the National Library of Medicine at the National Institutes of Health.

² The first draft guidance is available at <http://www.fda.gov/cder/guidance/3585dft.htm>

Draft — Not for Implementation

on clinical trials to individuals with serious or life-threatening diseases, to other members of the public, and to health care providers and researchers. Specifically, the Clinical Trials Data Bank will contain (1) information about clinical trials, both federally and privately funded, of experimental treatments (drugs, including biological products) for patients with serious or life-threatening diseases; (2) a description of the purpose of the experimental drug; (3) patient eligibility criteria; (4) the location of clinical trials sites; and (5) a point of contact for patients wanting to enroll in the trial. Section 113 of the Modernization Act specifies that information for the Clinical Trials Data Bank must be in a form that can be readily understood by the public.

The National Institutes of Health (NIH), through its National Library of Medicine (NLM) and with input from the FDA and others, developed the Clinical Trials Data Bank and is implementing it in a phased approach. The first version of the Clinical Trials Data Bank was made available to the public on February 29, 2000, on the Internet at <http://clinicaltrials.gov>. It included primarily NIH-sponsored trials.

FDA published a draft guidance entitled *Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank* in the *Federal Register* on March 29, 2000 (65 FR 16620). A November 9, 2000, *Federal Register* notice announced that the proposed collection of information was submitted to the Office of Management and Budget (OMB) for review (65 FR 67385). A March 23, 2001, *Federal Register* notice announced OMB approval of Agency information collection activities for the program (66 FR 16251).

The March 29, 2000, draft guidance provided recommendations for industry on the submission of protocol information to the Clinical Trials Data Bank. It included information on the types of clinical trials for which submissions will be required under Section 113 of the Modernization Act, as well as the types of information to be submitted. The draft guidance stated that an implementation plan, addressing procedures, would be available later and would include information on how to submit protocols to the Clinical Trials Data Bank and how to provide certification to the Secretary that disclosure of information for a particular protocol would substantially interfere with the timely enrollment of subjects in the clinical investigation. The guidance stated that the implementation plan would discuss issues related to the voluntary submission of information not required by Section 113 of the Modernization Act (e.g., study results, trials for nonserious or non-life-threatening diseases) and establish a time frame for submitting the information.

III. IMPLEMENTATION PLAN

A. What Information Do I Submit to the Clinical Trials Data Bank?

Section 113 of the Modernization Act requires you to submit information for a clinical trial for a serious or life-threatening disease if it is a trial to test effectiveness. You can also provide information for a clinical trial for a condition that is not serious or life threatening or not a trial to test effectiveness.

The specific data elements required in Section 113 of the Modernization Act were described in

Draft — Not for Implementation

March 29, 2000, draft guidance. The data fields and their definitions can be viewed in the preview of the Protocol Registration System (PRS) at <http://prsinfo.clinicaltrials.gov/>.

These elements fall into several areas: descriptive information, recruitment information, location and contact information, and administrative data.

1. **Descriptive Information**
 - Brief Title (in lay language)
 - Official Title and Detailed Description (if desired)
 - Brief Summary (in lay language)
 - Study Design/Study Phase/Study Type
 - Condition or Disease
 - Intervention
2. **Recruitment Information**
 - Study Status Information including start date and verification date.
 - Completion date (if desired).
 - Eligibility Criteria/Gender/Age
3. **Location and Contact Information**
 - Location of Trial/Site Status information
 - Contact information (includes an option to list a central contact person for all trial sites)
4. **Administrative Data**
 - Unique Protocol ID Number and Any Secondary Numbers
 - Study Sponsor
 - Study Collaborators (if desired)

You should also include the IND number and designate whether the IND is located in the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This information is important for administrative purposes and will not be made public in *ClinicalTrials.gov*.

B. How do I Submit Information to the Clinical Trials Data Bank ?

You should submit information to *ClinicalTrials.gov* through the Web-based PRS. For a publicly available preview of the PRS system see <http://prsinfo.clinicaltrials.gov/>.

The system allows for entry of required and voluntary information about clinical trials. You or your designee should initiate submission of clinical trial information to *ClinicalTrials.gov* by registering with the official PRS system. Sponsors should complete the registration form at <http://prsinfo.clinicaltrials.gov/>.

After you have entered and validated the data, the PRS generates a receipt for use by sponsors. An electronic copy of the receipt will be sent to FDA.

C. What Happens to the Information Submitted to the Clinical Trials Data Bank?

Except for the IND number, all information submitted through the PRS is made available to the public at <http://clinicaltrials.gov>.

D. Can I Submit Other Information Voluntarily to the Clinical Trials Data Bank?

You can submit more detailed information about the protocol. Data fields (e.g., projected enrollment) are included in the PRS.

You can submit information about results of the trial. This information, which would come from the published literature, would be linked by including the unique MEDLINE PMID for citations of publications.

A *link* section is also provided to allow pointers to Web pages directly relevant to the protocol.

If you link to other Web pages from your entries, you should ensure the links do not misbrand your products, for example, by promoting the products either preapproval or off-label. See 21 U.S.C. §§ 321(n), 331(a)(b)(c)(d), 352(a), <http://www.fda.gov/opacom/laws/fdcact/fdcact1.htm>.

E. Are There Exemptions for Submitting Clinical Trials Information?

Section 113 of the Modernization Act requires you to provide information on trials for serious or life-threatening diseases that are trials to test effectiveness. However, section 113 also allows you to provide a certification to the Secretary of Health and Human Services if you believe that disclosure of information for a specific protocol would substantially interfere with timely enrollment of subjects in the clinical trial.

FDA has not identified specific instances when disclosure of information would substantially interfere with enrollment of subjects in a clinical investigation. We are soliciting comments on this topic and may include a listing of acceptable reasons for certification in the final guidance.

F. When Should I Begin Submitting Clinical Trials Information?

Section 113 requires you to provide information on trials for serious or life-threatening diseases. This requirement is in effect. We have established the PRS to facilitate collection of this information. We encourage you to meet your requirements under Section 113 by submitting information through the PRS for inclusion in the data bank as soon as possible. Once this guidance is final, sponsors should meet these requirements by submitting information through the PRS no later than 21 days after the trial is first open for enrollment.

Until the final guidance document is available, sponsors submitting clinical trial information for inclusion in the AIDS Clinical Trials Information Service (ACTIS) data bank should continue to follow procedures currently in place.