Investigational New Drug Application (IND) Annual Reports

08FEB2022

Summary

- Brief reports on clinical trial status
- FDA Form 1571 (required with report)
- Frequency: Annual
- Responsible: IND Sponsor
- Due: 60 days from IND anniversary date

Contents of Annual Report

Section	Description
Individual study information	A brief summary of the status of each study in progress and each study completed during the previous year. The summary is expected to include the following information for each study: 1.The title of the study (with any appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient population, and a statement as to whether the study is completed. 2.The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; the number of participants who completed the study; and the number who dropped out of the study for any reason. 3.A brief description of any available study results.
Summary information	Information obtained during the previous year's clinical and nonclinical investigations conducted under the IND application, including: 1.A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system. 2.A summary of all IND safety reports submitted during the past year. 3.A list of subjects who died during participation in the investigation, with the cause of death for each subject. 4.A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related. 5.A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for example, information about dose response, bioavailability, or relevant information from controlled trials. 6.A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings. 7.A summary of any significant manufacturing or microbiological changes made during the past year.

https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-reporting-annual-reports

Contents of Annual Report (continued)

Section	Description
Update to the General Investigational Plan	A description of the general investigational plan for the coming year to replace that submitted 1 year earlier.
Update to Investigator's Brochure	If the Investigator's Brochure has been revised, a description of the revision and a copy of the new brochure.
Significant protocol updates	A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.
Update on foreign marketing developments	A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.
A log of outstanding business	If desired by the sponsor, a log of any outstanding business with FDA with respect to the IND application for which the sponsor requests or expects a reply, comment, or meeting.

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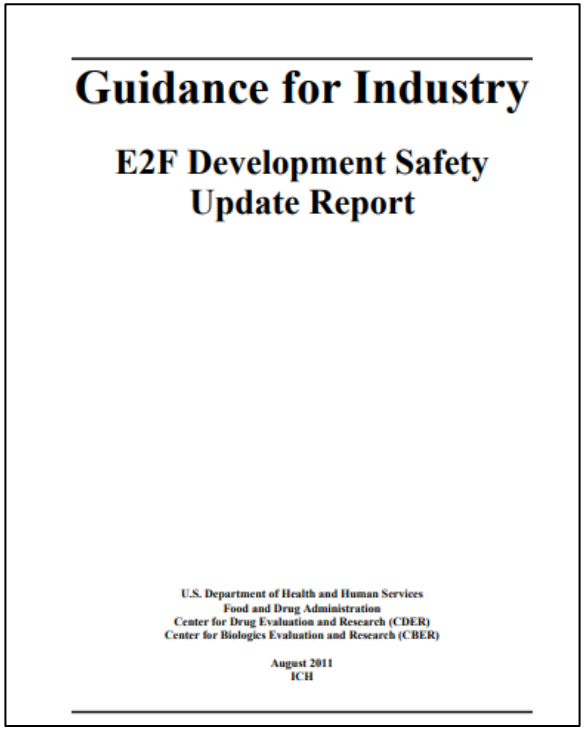
Guidance Document

"To promote global harmonization, FDA will accept the DSUR to meet an IND application annual report requirements."



Guidance for Industry

E2F Development Safety Update Report

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)

August 2011
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