

IND Annual Report

A sponsor is required with 60 days of the anniversary date that the IND went into effect (i.e., the date the FDA permitted the study to begin) submit a brief report of the progress of the investigation. The report should include the following information:

Information on Individual Studies – A brief summary of the status of each study in progress and each study completed during the previous year. The individual study information should include the following:

- The title of the study, its purpose, patient population, and study status (ongoing or completed);
- The total enrollment goal, the number of subjects enrolled into the study to date, the number of subject who completed the study, the number of subjects who dropped out of the study and the reasons why;
- A brief description of any study results.

Summary Information – This section should include all additional product-related information collected during the previous year. The summary information should include the following:

- A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.
- A summary of all IND safety reports submitted during the past year.
- A list of all subjects who died during participation with the cause of death.
- A list of subjects who dropped out because of an adverse experience, whether or not thought to be drug related.
- A brief description of information that was learned regarding the drugs actions (e.g., dose response, bioavailability).
- (If applicable) A list of preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major findings.
- (If applicable) A summary of any significant manufacturing or microbiological changes made during the past year.

General Investigational Plan – A brief description of the general investigational plan for the coming year. It should include: rationale; indications; general approach in evaluating the drug; clinical trials to be conducted; estimated number of patients; and risks. If the plans are not yet formulated, the sponsor must indicate this fact in the report.

Investigational Brochure Revisions – When the investigator’s brochure has been revised, the sponsor must include a description of the revision and a copy of the new brochure. **If investigator sponsored, a statement that an investigator brochure is not required.**

Protocol Modifications - A description of any significant protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.

For Additional Information about IND Annual Reports please review, 21 CFR Part 312.33:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.33>