



## IND Annual Report Overview

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

**Individual Studies under the IND** – 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 (tabulated by age group, gender, race), the number of subjects 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 (interim or final data analysis).

**Summary Information** – This section should include all additional product-related information (clinical and non-clinical) 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 during the past year.
- 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 drug's actions (e.g., dose response, bioavailability, information from controlled trials).
- (If applicable) A list of preclinical studies (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 to replace what was submitted one year earlier. 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.

**Investigator Brochure (IB) 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.

**Protocol Modifications** - 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

**Foreign Marketing** – A brief summary of significant foreign marketing developments with the drug during the past year, such as approval or marketing in any country or withdrawal or suspension from marketing in any country.

**Outstanding Business** – If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

What to include in the submission:

- Cover Letter ('Annual Report' in bold letters at the top)
- Annual Report
- Form FDA 1571 (needed for *all correspondence* to the FDA)--Check box "Annual Report"; include a new serial number: e.g. 0004
- Form FDA 1572 (*if* there are investigator changes)
- Form FDA 3674 (*if* this was not previously sent in—this form refers to ClinicalTrials.gov postings)
- DSMB reports, *if* applicable
- Approval letters, protocols and approved consents
- Approval letters and approved consents from external sites, if applicable. Be sure that the external site approvals designate the correct protocol version)
- Investigator CVs of any new investigator listed on the 1572 & updates on CVs older than 2 years

Include any document pertaining to the IND that was collected during the past approval period

21 CFR Part 312.33:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.33>