(i) Pharmacology and drug disposition. A section describing the pharmacological effects and mechanism(s) of action of the drug in animals, and information on the absorption, distribution, metabolism, and excretion of the drug, if known.

(ii) Toxicology. (a) An integrated summary of the toxicological effects of the drug in animals and in vitro. Depending on the nature of the drug and the phase of the investigation, the description is to include the results of acute, subacute, and chronic toxicity tests; tests of the drug's effects on reproduction and the developing fetus; any special toxicity test related to the drug's particular mode of administration or conditions of use (e.g., inhalation, dermal, or ocular toxicology); and any in vitro studies intended to evaluate drug toxicity.

The categories of information required for initiating clinical trials, as set forth in the IND, can also be found in documents submitted after completion of clinical trials, when the sponsor or investigator believes that the drug is worthy of regulatory approval. The document submitted for regulatory approval may be an NDA, BLA, or CTD, as reviewed below.

b. The Investigational New Drug and the Common Technical Document

To review the timeline of regulatory approval, the sponsor submits an IND in order to conduct Phase I, II, and III clinical trials. The IND is used for both traditional drugs, as well as for drugs that are biologicals. After submitting the IND, the sponsor is required, under 21 CFR 312.33, to submit an annual report. The annual report is a brief report of the progress of the investigation. It is submitted by way of an amendment to the IND (55).

Before submitting the IND to the Food and Drug Administration, the sponsor has the option of scheduling a pre-IND meeting. Pre-IND meetings are often held from 6 months to 1 year before filing the IND (56). As outlined by Poole (57) the sponsor submits a pre-IND Information Package prior to the pre-IND meeting. This package describes the chemical structure of the drug, the proposed dosages, the proposed indications and studies, and other information.

After conducting the Phase I, II, and III clinical trials, the sponsor submits an NDA, in the case of traditional drugs, and a BLA, in the case of biologicals.

The entire timeframe for conducting Phase I, II, and III clinical trials takes an average of 5 years, while the subsequent timeframe for FDA's review of the NDA takes an average of 2 years (58).

[55] Poole K. *The Sponsor's Guide to Regulatory Submissions for an Investigational New Drug. Biological Resources Branch, DCTD, NCI-Frederick, Biopharmaceutical Development Program*. SAIC-Frederick, Inc.; 2005.

[56] Poole K. *The Sponsor's Guide to Regulatory Submissions for an Investigational New Drug. Biological Resources Branch, DCTD, NCI-Frederick, Biopharmaceutical Development Program*. SAIC-Frederick, Inc.; 2005.

[57] Poole K. *The Sponsor's Guide to Regulatory Submissions for an Investigational New Drug. Biological Resources Branch, DCTD, NCI-Frederick, Biopharmaceutical Development Program*. SAIC-Frederick, Inc.; 2005.

[58] Poole K. *The Sponsor's Guide to Regulatory Submissions for an Investigational New Drug. Biological Resources Branch, DCTD, NCI-Frederick, Biopharmaceutical Development Program*. SAIC-Frederick, Inc.; 2005.