

Investigational new drug review process

[Health & Medicine](#), [Drugs](#)



INVESTIGATIONAL NEW DRUG REVIEW PROCESS Investigational New Drug Review Process Prashanth Kumar Ponugoti Northeastern University

INVESTIGATIONAL NEW DRUG REVIEW PROCESS Abstract Investigational New Drug (IND) review process begins from the time the sponsor files investigation new drug application and the purpose of the review is to confirm the safety and efficacy of the patient for the drug.

Moreover in the process of review if the review committee notifies any deficiencies by the new drug then there will be a clinical however if there are no deficiencies the drug will be approved for new drug application and will be under continuous review to make sure , that the drug does not cause any potential harm. This entire step wise process of review is explained in the following paper INVESTIGATIONAL NEW DRUG REVIEW PROCESS The following flow chart gives an overview of the IND review process Applicant (Drug Sponsor)

IND Review by CDER Statistical Pharmacology/ Toxicology Medical Chemistry Sponsor Submits New Data Safety Review Safety acceptable for study to proceed Clinical Hold Decision Notify Sponsor Complete reviews Reviews Complete and Acceptable? Sponsor Notified of Deficiencies No Deficiencies Study Ongoing INVESTIGATIONAL NEW DRUG REVIEW PROCESS I. Applicant (Drug sponsor): An applicant or the sponsor is a person or a group who takes responsibility and initiates for the investigation of new drug.

A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor. The sponsor may be an individual, partnership, government agency, private agency, or any other organization and moreover the sponsor does not <https://assignbuster.com/investigational-new-drug-review-process/>

conduct the investigation process unless the sponsor is a sponsor-investigator. The applications are submitted to Center for Drug Evaluation and Research (CDER) Food and Drug Administration Document and Records Section 5901-B Ammendale Rd. Beltsville, Md. 20705-1266 II.

Investigational New Drug Application: Sponsor thinks about new drug application when he has a successful results in preclinical studies (The studies conducted in animals to find the use of drug in human and ensure safety and efficacy) in other words it is the step taken after the successful preclinical studies to continue further studies that is clinical trial in humans. During the conduct of preclinical trial, step by step information of the process is recorded as data and stored. Thus stored information is helpful in filling an IND. The information is as follows A. Animal Pharmacology and toxicology studies

B. Manufacturing Information C. Clinical protocols and investigators information Animal Pharmacology and toxicology studies: The studies conducted in animals to ensure the use of the product is reasonably safe for initial testing in humans. Manufacturing Humans: This is the information obtained from manufacturing, storage, composition, storage and stability, for manufacturing of drug substance and product. Clinical protocols and investigators information: protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks.

Information on the qualifications of clinical investigators—professionals who oversee the administration of the experimental compound--to assess whether they are qualified to fulfill their clinical trial duties. The IND is not a marketing approval but The IND is the means through which the sponsor

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officially obtains this exemption from the FDA: however, its main intention is to detail the data that provide documentation that it is indeed reasonable to proceed with certain human trials with the drug. Types of INDs i. Investigator INDs ii. Emergency Use INDs and iii.

Treatment IND After the submission of the IND to the Center for Drug Evaluation and Research (CDER) committee it checks thoroughly the medical, chemistry, toxicological, and statistical data INVESTIGATIONAL NEW DRUG REVIEW PROCESS These terms are explained below in detail III. Medical Review: Medical also called as clinical review is conducted by medical officers or physicians to ensure the initial use of the drug in patients and are safe to use . This review is also conducted by the non medical officers based upon the data available from the re clinical studies.

Medical review plays a major role in new drug review process and is an initiating step for the test of the drug in humans: however it is an important step to be conducted and based upon the results obtained from the review it has a further scope to apply for next steps that is to file new drug application. During this review process the medical reviewers or physicians evaluate the clinical trial protocol for to determine A. If the participants will be protected from unnecessary risks; and B. If the study design will provide data relevant to the safety and effectiveness of the drug.

However the safety of the drug is taken by the sponsor during the phase I studies but during phase II, III, and IV Food and Drug Administration (FDA) must also ensure the safety of the medicament in humans for market approval. IV. Chemistry Review: Each review committee has an chemistry review department for reviewing the chemistry of the drug and the agenda <https://assignbuster.com/investigational-new-drug-review-process/>

of this chemistry department is to address issues related to drug identity, manufacturing control, and analysis. The reviewing committee ensures that the investigational new drug is adequately reproducible and stable.

If the drug is neither adequately reproducible nor stable then the chances of approval for IND are less because they are not sure about the drug's action in the body, and don't know what it does. So the major purpose of chemistry review is i. To ensure that the compound is adequately reproducible ii. To ensure that the compound is adequately stable In addition to this the sponsor should discuss any manufacturing and chemistry differences between the drug product proposed for the clinical use and drug product used in animal toxicology studies.

However these differences might affect the safety profile of the drug product and need to be stated if there are no differences. V. Pharmacology or Toxicology Review: This committee is a group of pharmacologists and toxicologists who evaluate the results of animal testing made during the clinical trial and compare it with the potential effects in humans. That is to ensure safety of the humans for the new drug. i. Pharmacology and Drug Distribution (21 CFR 312. 23(a)(8)(I)): This is nothing but absorption, distribution, metabolism and excretion of the drug in the animals.

These results should be obtained by conducting them in animals, so it should be recorded with an example. Moreover this should not be a reason for the clinical hold because these are the studies conducted in phase one of the IND and where FDA feels it as sponsor's great responsibility factor for the drug in achieving safety and efficacy to the humans. ii. Toxicology Data (21 CFR 312. 23(a)(8)(ii)(a)):

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Toxicology data is required from both vitro and vivo studies, because particular studies depend upon nature of the drug and phase of human investigation.

VI. Safety Review: After submission of the IND to the CDER then the committee takes about good 30 days to conduct review in every factor to achieve safety and efficacy and to avoid potential harm to the human. The review is an ongoing process however CDER notifies the sponsor immediately if there are any potential high risks associated with the drug upon usage in humans. If a notification is sent to sponsor then it is clear that the application is put on hold and the sponsor should conduct enough studies to clear the hold.

This hold will be removed and allows the sponsor for further studies only when changes made to the clinical hold achieve the safety and efficacy and does not case potential risks. If the sponsor is not notified with any information from CDER from the day of IND submission to the 30 th day then on the 31st- day further study can be proceeded as submitted. VII. Clinical Hold Decision: The Clinical hold is issued in during the thirty day review period and this is due to the following factors 1. The drug causes potential harm to the humans 2.

If drug is not having enough stability 3. The IND does not contain sufficient information required under 312. 23 to assess the risks to subjects of the proposed studies 4. The plan or protocol for the investigation is clearly deficient in design to meet its stated objectives. And CDER can hold the studies during the initial phases of the studies that is when filed for IND if observes potential risks on the data submitted initially. The Clinical hold will

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be removed if the sponsor addresses the issue based on the hold before the order is removed.

In addition the clinical holds are reviewed by higher authorities of CDER to assure scientific quality and consistency in the Center's clinical hold decisions. IX. Notify Sponsor: X. Sponsor Notified of Deficiencies XI. Study Ongoing Xii. Conclusion..... Page 17 and page 18 lo matter unnnadhi ... use gooogle search for material if required and provide the refrence where ever u grab the material..... Refrences: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.42> <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm082022.pdf>