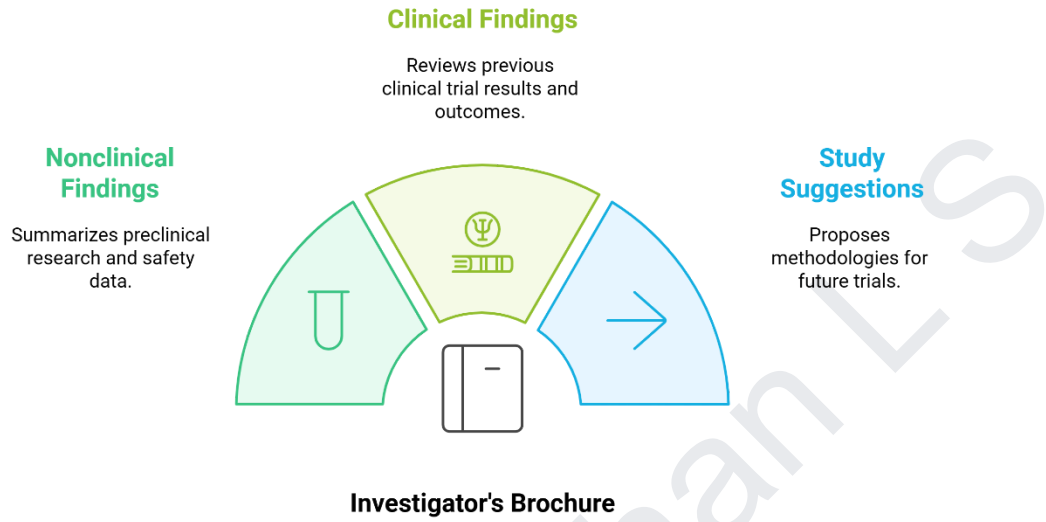
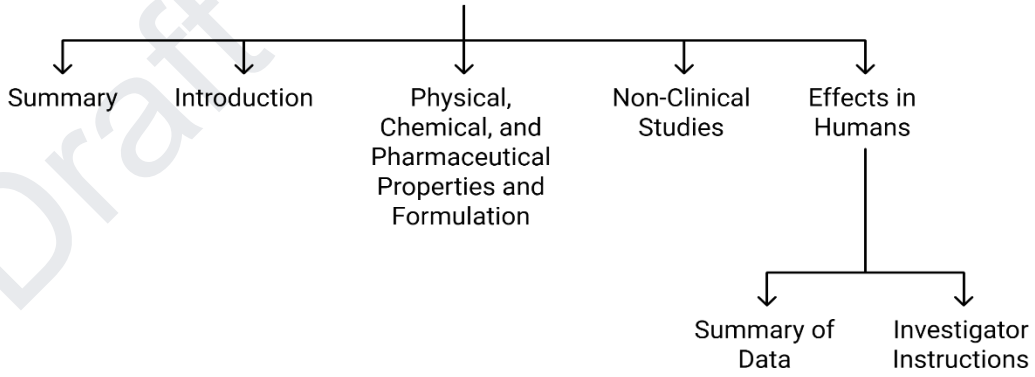
The Investigator's Brochure (IB) is a resource for clinical trial investigators. It highlights the key components of a product's development to date, reviews nonclinical and clinical findings, and suggests ways to study the new product's benefits and dangers.



Regulatory Guidance on Structure and Content

Section 7 of ICH E6 lists the highest-level sections as follows:

- Summary
- Introduction
- Physical, chemical, and pharmaceutical properties and formulation
- Non-clinical studies
- Effects in humans
- Summary of data and investigator instructions.

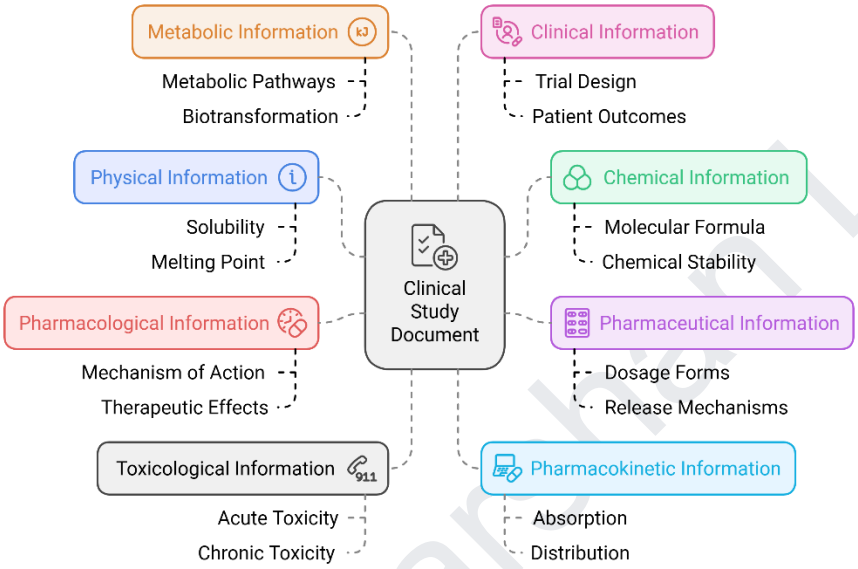


When researchers conduct the first human clinical trial, they require an IB. According to ICH E6, a team should review an IB at least once a year and revise it when necessary. However, the team may increase the frequency of revisions based on the development stage and new relevant information.

The Six Main Sections of an IB

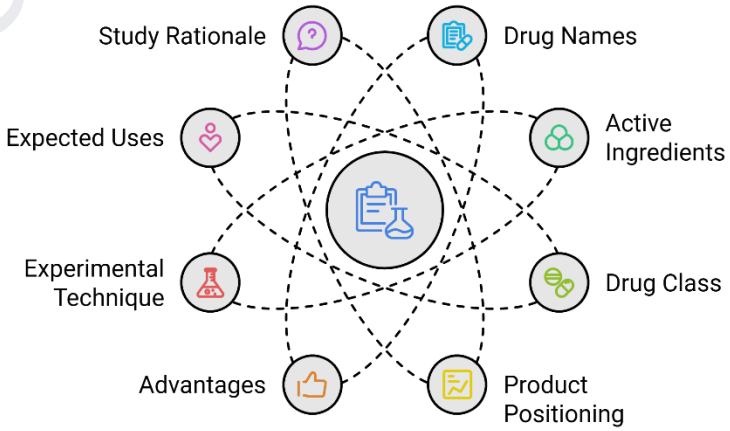
Summary

This part summarizes the next sections. It profiles physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic, and clinical information. According to ICH E6, the document's length should remain within two pages.



Introduction

The introduction should give a summary of the investigational product and its context. It should include the drug's generic and trade names, its active ingredient(s), and its class. It must also detail the product's position within this class and highlight any advantages over other products. It also includes a summary of the experimental technique. Someone has undertaken it or plans to undertake it. It identifies expected preventive, therapeutic, or diagnostic uses. It highlights the reason for studying the investigational product.



Physical, Chemical, and Pharmaceutical Properties and Formulation

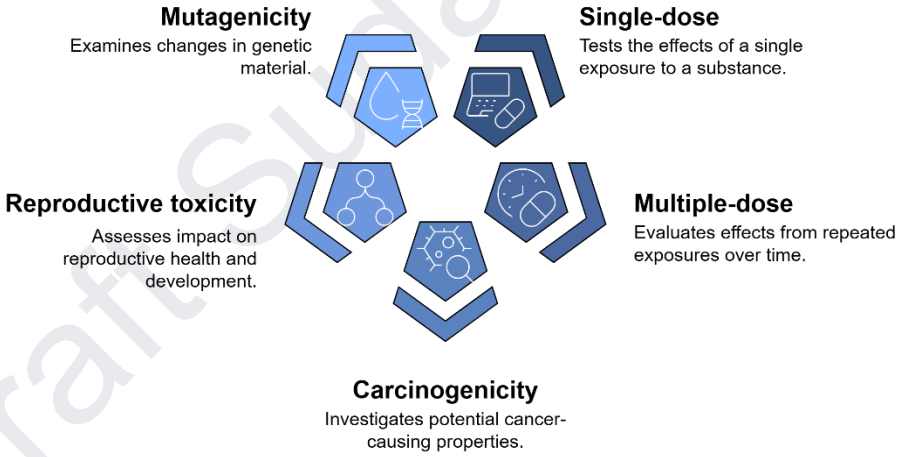
This section explains the investigational product's pharmacological, physical, and chemical traits. It covers the drug product and, if relevant, the drug substance. Also, it should include instructions on handling and storage. It must cover any pre-administration preparations, such as reconstitution or dilution.

Non-Clinical Studies

Before testing the substance in humans, we must do nonclinical trials. They are the only way to find its benefits and dangers. ICH E6 lists key subsections. They are nonclinical pharmacology, pharmacokinetics, and toxicity.

Researchers classify toxicological studies into five types:

1. Single-dose
2. Multiple-dose
3. Carcinogenicity
4. Reproductive toxicity
5. Mutagenicity



The summaries should include the kind, frequency, and intensity of any drug or toxic effects. Also, they should include the time to onset, duration, and reversibility of these effects.

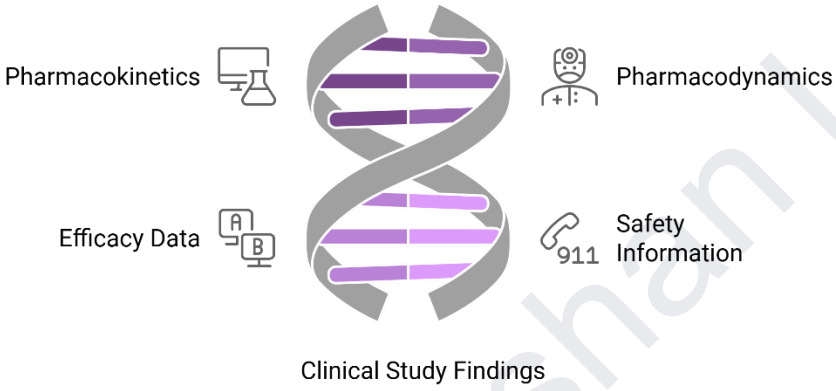
Clinical Studies (Effects in Humans)

This section summarizes the findings from all clinical studies of the investigational product to date. According to ICH E6, researchers should summarize information for pharmacokinetics, metabolism, pharmacodynamics, dose-response, safety, efficacy, and other pharmacological

activities. Pharmacokinetics, pharmacodynamics, and product metabolism are the primary emphases of phase 1 investigations, which researchers usually conduct on healthy subjects.

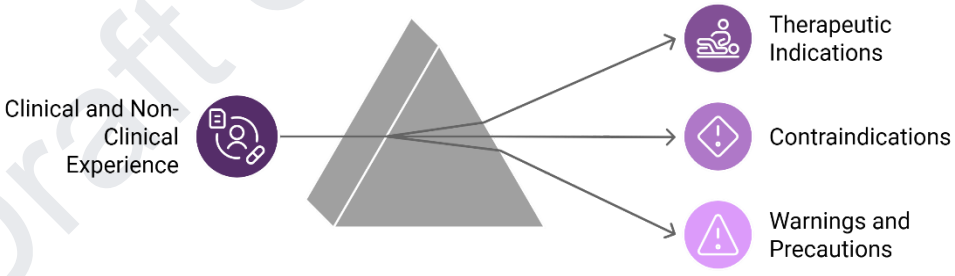
Phases 2 and 3 gather efficacy data from the intended patient population. ICH E6 states that researchers should provide a summary of each completed clinical trial.

If the investigational product has already been sold at any point during the preparation of the IB, the sponsor's post-marketing safety information must also be summarized. Typically, this information is provided by the sponsor's pharmacovigilance team.



Summary of Data and Guidance for Investigators

The non-clinical and clinical experience is summarized. It is interpreted to conclude the usage of the investigational product in future studies. This section also helps manage people treated with the experimental product. It includes subheadings from the prescribing info. They are therapeutic indications, contraindications, and warnings and precautions for use. So, this part may be seen as a prelude to the prescribing info prepared when seeking marketing permission.



Reference

European Medical Writers Association

ClinicalTrials.gov