



The **Investigator's Brochure** is a document that collects all important clinical and non-clinical data about the investigational product being studied. It helps investigators and others involved in the trial understand key details like the right dose, how often to give it, how to give it and how to monitor safety. Thus, the Investigator's Brochure helps investigators understand the risks, benefits and proper handling of the product to ensure safe and ethical conduct of the trial.

The Investigator's Brochure typically consists of the following brief table of contents:

- **Title Page** – Includes Sponsor's name, Investigational Product identity etc.
- **Confidentiality Statement** – Provides instructions to treat the Investigator's Brochure as a confidential document
- **Summary of key information** – Highlights key physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic and clinical information
- **Introduction** – Gives overview of product, rationale for research, anticipated uses etc.
- **Physical, Chemical and Pharmaceutical Properties and Formulation** – Provides description of Investigational Product, storage, handling, formulation details
- **Nonclinical Studies** – Provides summary results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies
- **Effects in Humans including pharmacokinetics and metabolism** – Elaborates the known effects of the investigational product in humans, including pharmacokinetics, metabolism, pharmacodynamics, dose response, safety, efficacy and other pharmacological activities
- **Summary of Data and Guidance for the Investigator** – Provides comprehensive overview of the nonclinical and clinical data and summarizes

the information from various sources on different aspects of the Investigational Product. The overall aim of this section is to provide the investigator with a clear understanding of the possible risks and adverse reactions and of the specific tests, observations, and precautions that may be needed for a clinical trial

- **Reference Safety Information** – Contains a cumulative list of Adverse Drug Reactions that are expected for the investigational product being administered to participants in a clinical trial

Key users of Investigator's Brochure:

The Investigator's Brochure is a critical document in clinical research that serves as a central reference for all parties involved in a clinical trial. It provides comprehensive information on the Investigational Product, including its preclinical and clinical data, potential risks and safety profile. The Investigator's Brochure is used by different stakeholders to ensure the safe, ethical and effective conduct of the study.

Below are the key users of the Investigator's Brochure:

Investigators: They use the Investigator's Brochure to understand the investigational product's safety, dosage and administration helping them manage trial participants properly

Monitors / Clinical Research Associates and Clinical Research Coordinators: They rely on the Investigator's Brochure for guidance on protocol compliance and safety monitoring

Medical and Safety Teams: They refer to the Investigator's Brochure for safety information to monitor and manage adverse events during the trial

Investigator's Brochure Amendment

An Investigator's Brochure is typically updated at least annually and whenever new, relevant safety or efficacy information becomes available during a clinical trial

Triggers for updates include:

- Identification of new safety data, increased risk or new adverse event
- Any update in dosing information
- If there are any new major efficacy results