INVESTIGATOR'S BROCHURE

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Introduction

- The Investigator’s Brochure(IB) is a compilation of the clinical and non-clinical data on the investigational products that are relevant to the study of the products in human subjects.
- IB is a comprehensive document summarising the information about the Investigational product obtained during a clinical trial.
- The information should be presented in short,simple,objective,and non-promotional form that enables a clinical or potential investigator to understand it.
- IB is prepared by sponsor and having up to date information about IMP.

Purpose of IB

- Provide the information to investigators and others involved in the trial such as the dose, dose frequency/interval, methods of administration and safety monitoring procedures.
- The IB also provides insight to support the study, subjects to clinical management during the course of the clinical trial.
- For assessment of appropriate proposed clinical trial a medically qualified person should be participate in editing of IB.

General Considerations

The IB should include:

1. Title Page

This should provide the

- Sponsor’s name
- Product
- Research number
- Names: Chemical, Generic(if approved) & Trade names
- Edition number
- Release date
- Replaces Previous Edition number

2.Confidential Statement

- The spnosor may wish to include a statement instructing the investigator/recipient to treat the IB as a confidential document for the sole information and use of the Investigator's team and the IRB/IEC.
- **Contents of the Investigator's Brochure—**

The IB sholud contain the following sections—

- Confidentiality statement (optional).
- Signature page (optional).

3. Table of Contents

- **Summary**– A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetics, metabolic, and clinical information.

- **Introduction–** Contains the chemical name (generic and trade name when approved), all APIs, pharmacological class, the rationale for performing research of the Investigational product, and the anticipated prophylactic, therapeutic, or diagnostic indications.
- **Physical, Chemical, and Pharmaceutical Properties and Formulation–** A description including the chemical and structural formula, relevant physical, chemical, and pharmaceutical properties, description of the formulation, including excipients, instructions for the storage and handling of the dosage form.
- **Non-clinical Studies–** The information provided may include the following—

1. Species tested
2. Number and sex of animals in each group

3. Unit dose (e.g., mg/kg)
4. Dose interval
5. Route of administration
6. Duration of dosing
7. Information on systemic distribution
8. Duration of post-exposure follow-up
9. **Results, including the following aspects:**

- Nature and frequency of pharmacological or toxic effects
- Severity or intensity of pharmacological or toxic effects
- Time to onset of effects
- Reversibility of effects
- Duration of effectsl

- Dose response

A) Non-clinical Pharmacology– Efficacy models, receptor binding, and specificity other than the intended therapeutic effect.

B) Pharmacokinetics and Product Metabolism in Animals– Absorption and the local and systemic bioavailability of the Investigational product and it's metabolites, and their relationship to the pharmacological and toxicological effect in animal species.

C) Toxicological– Described under the following heading where appropriate—

- Single dose
- Repeated dose

- Carcinogenicity
- Special studies (e.g. irritancy and sensitiation)
- Reproductive toxicity
- Genotoxicity (mutagenicity)
- **Effects in Humans—**

A) Pharmacokinetics and Product Metabolism in Humans–

- Pharmacokinetics (including metabolism, absorption, plasma protein binding, distribution, and elimination).
- Bioavailability
- Population subgroups (e.g., gender, age, and impaired organ function).
- Interactions (e.g., product-product interaction and effect of food).

B) Safety and Efficacy–

- Safety, pharmacodynamics, efficacy, and dose response that were obtained from preceding trails in humans (healthy volunteers and /or patients).
- **Summary of Data and Guidance for the Investigator—**
- Provide an overall discussion of the non-clinical and clinical data.
- The published reports on related products should be discussed.This could help the investigator to anticipate adverse drug reactions or other problems in clinical trial.
- **References on—**
- Publications
- Reports

References

- Guidance for industry E6 Good Clinical Practice: Consolidated Guidance by ICH.
- Handbook for Clinical Trial by European Union.
- http://www.europeanmedicalagency.com