**Investigator Brochure (IB) Template**

* **The IB may cover multiple research projects authorised by the same research sponsor, using the same Medicinal Product (MP) and the same formulation.**
* **An IB need only be written when no Summary of Product Characteristics (SmPC) exists.**
* **The IB must be reviewed annually and updated earlier if required.**
* **The Chief Investigator (CI) should consider whether to include a confidentiality statement in the IB.**
* **NB: This would be appropriate for MP where the CI or Sponsor holds or has applied for the patent or for other commercially sensitive situations.**
* **For further guidance on IB content please refer to ICH-Good Clinical Practice.**

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**Investigator Brochure (IB)**

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| --- | --- |
| **Sponsor(s):** |  |
|  |  |
| **Project(s) name:** |  |
|  |  |
| **EudraCT number(s):** |  |
|  |  |
| **Medicinal Product(s):** |  |
|  |  |
| **Version number:** |  |
|  |  |
| **Date:** |  |
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| **CI signature:** |  | **Date:** |  |
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| **Sponsor(s) signature:** |  | **Date:** |  |

**<<Amend or Remove as required>>**

**Confidentiality Statement:** This document contains proprietary and confidential information belonging to the Sponsor <<insert details>>. The contents of this document are for the information and use of the sponsors, applicable research teams and regulatory representatives and may not be disclosed or used without the permission of the Sponsor.

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1. **Summary**

A brief synopsis of the project incorporating all sections in the document –preferably not exceeding two pages.

1. **Introduction**

Brief introductory information on MP to include chemical name, active ingredients, pharmacological class, rationale for performing the research, anticipated prophylactic, therapeutic or diagnostic indications and the approach to be used e.g. randomised controlled trial etc.

1. **Physical, Chemical and Pharmaceutical Properties and Formulation**

Description of the MP including chemical and/or structural formula, brief summary of physical, chemical and pharmaceutical properties, description of the formulation(s) (including excipients), storage and handling instructions.

1. **Non-clinical Projects**

4.1 Good Laboratory Practice

Description of which studies were conducted to GLP and justification for those conducted in the principles of GLP like conditions.

***Non-clinical Pharmacology***

To include details of all relevant non-clinical pharmacology. Information should be tabulated using headings such as species tested, unit does, dose interval etc.

* 1. ***Pharmacokinetics and Product Metabolism***

To include details of all relevant pharmacokinetic and metabolism data. Information should be tabulated using headings such as absorption, bioavailability, metabolites etc.

* 1. **Toxicology**

To include all relevant toxicology data. Information should be tabulated using headings such as pharmacokinetics, metabolism, pharmacodynamics, dose response etc.

1. **Clinical Experience**
	1. ***Pharmacokinetics and Product Metabolism***

To include details of all relevant pharmacokinetic and metabolism data in humans. Information should be tabulated using headings such as pharmacokinetics, metabolism, pharmacodynamics, dose response etc.

* 1. ***Safety and Efficacy***

To include a summary of available safety data. Adverse Drug Reactions (ADRs) should be tabulated with efficacy, dose response etc.

* 1. ***Marketing experience***

To include details of any MP(s) that have been marketed, or withdrawn in any country. Information should include a summary of all significant information e.g. formulations, doses, ADRs experienced, administration routes, country etc.

5.4 Other Clinical Studies

To include data from all other clinical studies using the MP (including different formulations)

1. **Summary of Data and Guidance for the Investigator**

An overall discussion of the available non-clinical and clinical data to provide the research team with a clear understanding of the possible risks and ADRs expected to inform the specific tests, observations and precautions that will need to be considered for the research project including the recognition and treatment and treatment of possible overdose.

6.1 Summary of pre-clinical and clinical data

6.2 Dosage and Method of Administration

6.3 Warnings and Precautions for use

6.4 Contraindications

6.5 Interactions

6.6 Pregnancy and Lactation

6.7 Overdose, Abuse and Dependency

6.8 Reference Safety Information (RSI) for assessment of expectedness of Serious Adverse Reactions

To include a list/table of expected SARs indicating severity and frequency of each.

1. **References**

All studies, reports and publications referred to in each section must be fully referenced.

1. **Appendices**

To include all relevant documents or other information described in any section.