

**Investigator Brochure (IB) Template**

**The IB may cover multiple research projects sponsored by the same research sponsor and using the same Medicinal Product (MP) in the same formulation**

**An IB should only be written when no Summary of Product Characteristics (SmPC/SPC) is in existence.**

**The IB should be reviewed annually and updated if required.**

**The CI should consider whether a confidentiality statement is included in the IB. This may 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 what to include in each section of the IB please refer to ICH-Good Clinical Practice 1996 section 7.**

*(Insert version number, date and page number)*

**Investigator Brochure (IB) Template**

**Co-Sponsors:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Trial(s) name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**EudraCT number(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Treatment(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Version:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Insert version number, date and page number)*

**Table of Contents**

1. **Summary**
2. **Introduction**
3. **Physical, chemical and pharmaceutical properties and formulation**
4. **Non-clinical studies**
	1. Non-clinical pharmacology
	2. Pharmacokinetics and product metabolism
	3. Toxicology
5. **Effects in human use**
	1. Pharmacokinetics and product metabolism
	2. Safety and efficacy
	3. Marketing experience
6. **Summary of data and guidance for the investigator**
7. **References**
8. **Appendices**

*(Insert version number, date and page number)*

1. **Summary**

*This should include a brief synopsis incorporating all sections in the document.*

1. **Introduction**

*This should include the chemical name, active ingredients, the pharmacological class, rationale for research, anticipated indications and the approach to be used (eg randomised controlled trial etc).*

1. **Physical, chemical and pharmaceutical properties and formulation**

*This should include chemical and/or structural formula, a brief summary of properties, description of the formulation (including excipients) and instructions for storage and handling.*

1. **Non-clinical studies**
	1. ***Non-clinical clinical pharmacology***

*This should include all relevant non-clinical (animal) pharmacology and information should be tabulated using headings such as species tested, unit dose, dose interval etc.*

* 1. ***Pharmacokinetics and product metabolism***

*This should include all relevant pharmacokinetic and metabolism data from animal studies and information should be tabulated using headings such as absorption, bioavailability, metabolites etc.*

* 1. ***Toxicology***

*This should include all relevant toxicology data from animal studies and information should be tabulated using headings such as single dose, repeated dose, carcinogenicity etc.*

1. **Effects in human use**
	1. ***Pharmacokinetics and product metabolism***

*This should include all known effects in humans and information should be tabulated using headings such as pharmacokinetics, metabolism, pharmacodynamics, dose response etc.*

* 1. ***Safety and efficacy***

*This should include a summary of available data on safety (including tabulations of adverse drug reactions), pharmacodynamics, efficacy, dose response etc.*

* 1. ***Marketing experience***

*If the MP in any formulation has ever been marketed (or removed from marketing) in any country this should be described, together with a summary of any significant information eg formulations, doses, reactions etc.*

*(Insert version number, date and page number)*

1. **Summary of data and guidance for the investigator**

*The overall aim of this section is to provide the research team 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 research project*

1. **References**

*All studies and publications referred to in previous sections should be fully referenced.*

1. **Appendices**

*If there are relevant documents or other information these can be included as an appendix.*

*(Insert version number, date and page number)*