INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER
<PRODUCT>, VERSION <XX.YY>
<DATE>
NONCLINICAL, CLINICAL, BENEFITS AND RISKS ASSESSMENT

AUTHORS

Explanatory text: Appendix 1 of Regulation (EU) No 536/2014 refers for the structure of the data to the following formats:

- *Module 4 of the ICH Common Technical Document for non-clinical pharmacology and toxicology data (Safety M4S);*
- *Module 5 of the ICH Common Technical Document for previous clinical trials and human experience (Efficacy M4E).*

Depending on the development stage of the product the amount of information required is more or less extensive. For early phase trials less information is expected than for later phase trials.

TABLE OF CONTENTS

Explanatory text: The table of contents for the pre-clinical medical parts is based on the assumption that the detailed information will be provided by the Investigational Brochure.

2.2 NON-CLINICAL PHARMACOLOGY, PHARMACOKINETICS AND TOXICOLOGY

For the summaries of non-clinical studies on <PRODUCT>, reference is made to the Investigators Brochure (provide version number and date).

2.2.1 Test Materials used in toxicity studies

Table 7: Impurities in <PRODUCT> drug substance

Impurities	***Batches used in Toxicity Studies***
No impurities >0.1% were found in the non-clinical toxicity studies	*K02; K1780005; K1780006; K1780107*

2.2.2 Integrated assessment of the data package

For this section reference is made to the Investigators Brochure (provide version number and date).

2.2.3 List of studies Conducted & References

A table of referenced non-clinical studies and references should be provided. They should be available on request.

Table 36: List of referenced non-clinical studies for <PRODUCT>

Study or Report Number	***Author(s)***	***Title of report***

**) Report in preparation*

2.2.4 GLP statement and bioanalytical methods

A GLP statement for the relevant non-clinical studies should be provided. Any relevant information on non-clinical studies not covered in the Investigator's Brochure should be provided here.

2.3 CLINICAL DATA

Referral should be made to the Investigator's Brochure for all clinical data.

2.3.1 Clinical pharmacology

A brief summary can be provided here, but a referral to the Investigator's Brochure should be sufficient.

2.3.2 Clinical pharmacokinetics

Details of the pharmacokinetic profile of <PRODUCT> in healthy subjects and hypertensive patients are presented in the Investigator Brochure.

2.3.3 Human exposure

Details of these studies are presented in the Investigator Brochure.

2.4 OVERALL BENEFITS AND RISK ASSESSMENT

This section should give a justification of the proposed study and discuss why the non-clinical and clinical data do allow this study to be performed in the given population. It is recommended to make this section part of the Investigator's Brochure and refer to it from the IMPD, if possible, as it is considered relevant information for an investigator.

References