INVESTIGATOR'S BROCHURE (IB)

CONTENT

B.1 General

B.1.1 Introduction

If the required information of the IB is provided in other documentation (e.g. the CIP or instructions for use); such documents shall be referenced in the IB and shall be made available upon request. The content of the IB shall contain, as a minimum, all topics listed in this document.

NOTE Not all requirement elements might be relevant for post-market clinical investigations or information can be described in other product documentation

The information shall be presented in a concise, simple, objective, balanced, and non-promotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased benefit-risk analysis of the appropriateness of the proposed clinical investigation.

B.1.2 Identification of the IB

a) Name of the investigational device.
b) Document reference number, if any.
c) Version or date of the IB.
d) Confidentiality statement, if appropriate.
e) Summary of the revision history in the case of amendments, if appropriate.
f) Version/issue number and reference number, if any, with the page number and the total number of pages on each page of the IB.
g) Table of contents.

B.1.3 Sponsor/manufacturer

Name and address of the sponsor of the clinical investigation and manufacturer of the investigational device, if different from the sponsor.

B.2 Investigational device information

a) Summary of the literature and evaluation supporting the rationale for the design and intended use of the investigational device.
b) Statement concerning the regulatory classification of the investigational device, if relevant.
c) General description of the investigational device and its components, including any materials used, and details on those that will be in contact with tissues or body fluids. This shall include details of any medicinal substances, human, or animal tissues or their derivatives, or other biologically active substances and reference to compliance with applicable national regulations.
d) Summary of relevant manufacturing processes and related validation processes, to demonstrate that the investigational devices are manufactured and verified under a controlled process according to the applicable regulations.
e) Description of the mechanism of action of the investigational device, along with supporting scientific literature.
f) Manufacturer's instructions for installation, maintenance of hygienic conditions and use of the investigational device, including any necessary storage and handling requirements, preparation for use and any intended re-use (e.g. sterilization), any pre-use safety or performance checks and any precautions to be taken after use (e.g. disposal), if relevant.
g) Sample of the label, for example sticker or copy, and instructions for use or reference to, and information on any training required.

h) Description of the intended clinical performance.

B.3 Preclinical testing

Summary of the preclinical testing that has been performed on the investigational device, together with an evaluation of the results of such testing, justifying its use in human subjects.
The summary shall include or, where applicable, refer to the results of

a) design calculations,
b) in vitro tests,
c) mechanical and electrical safety tests,
d) reliability tests,
e) validation of software relating to the function of the device,
f) any performance tests,
g) ex vivo tests,
h) in vivo animal test,
i) evaluation of biological safety,
j) validation of procedures for cleaning, disinfection, or sterilization.

B.4 Existing clinical data

a) Summary of relevant previous clinical experience with the investigational device and with medical devices that have similar characteristics, including such characteristics that relate to other indications for use of the investigational device.
b) Analysis of adverse device effects and any history of modification or recall.

B.5 Risk management of the investigational device

a) Summary of the benefit-risk analysis including identification of residual risks.
b) Contra-indications and warnings for the investigational device.

B.6 Regulatory and other references

a) a) List of international standards, if any, complied with in full or in part.
b) Statement of conformity with national regulations, where appropriate.
c) List of references, if relevant.

B.1 General

B.1.1 Introduction

If the required information of the IB is provided in other documentation (e.g. the Clinical Performance Study Protocol or instructions for use); such documents shall be referenced in the IB and shall be made available upon request.

The content of the IB shall contain, as a minimum, all topics listed in this document.

B.1.2 Identification of the IB

a) Name of the IVD device under investigation.
b) Document reference number, if any.
c) Version or date of the IB.
d) Confidentiality statement, when applicable.
e) Summary of the revision history in the case of amendments, when applicable.
f) A version/issue number and reference number, when any, with the page number and the total number of pages on each page of the investigator brochure.

B.1.3 Sponsor/manufacturer

a) Name and address of the sponsor of the IVD medical device under investigation.
b) Name and address of the legal representative or contact person, as applicable.

B.2 Information on IVD medical device under investigation

a) Summary of the literature and evaluation supporting the rationale for the design and intended use of the IVD medical device under investigation.
b) Statement concerning the regulatory classification of the IVD medical device under investigation, when relevant.
c) General description of the IVD medical device under investigation and its components.
d) Description of the intended use of the IVD medical device under investigation, along with supporting scientific literature.
e) Manufacturer's instructions for installation and use of the IVD medical device under investigation, including any necessary storage and handling requirements, preparation for use, any pre-use safety or performance checks and any precautions to be taken after use (e.g. disposal, decontamination), when relevant.
f) Description of the intended clinical performance characteristics, when applicable.

B.3 Analytical testing

Summary of the analytical testing that has been performed on the IVD medical device under investigation, together with an evaluation of the results of such testing, justifying its use in the clinical performance study.

B.4 Existing clinical performance data

a) Summary of relevant previous clinical experience with the IVD medical device under investigation and with IVD medical devices that have similar characteristics, including such characteristics that relate to other intended uses of the IVD medical device under investigation.
b) Analysis of adverse device effects and any history of modification or recall.

B.5 Risk management

a) Summary of the risk analysis for the IVD medical device, including identification of residual risks.
b) Result of the risk assessment (risk chart).
c) Anticipated risks, warnings, hazards, etc., for the IVD medical device under investigation.
d) A plan for reporting results to clinicians or public health institutions in cases for which a result might have an immediate public health effect (e.g. emerging infectious disease).

B.6 Regulatory and other references

a) List of international standards, if any, complied with in full or in part.
b) Statement of conformity with national regulations, where appropriate.
c) List of references, if relevant.