**Overview of required information in Investigator’s Brochure and Clinical investigation plan according to Annex XV**

***Note:*** *The application shall contain information concerning all items in the MDR Annex XV. If in exceptional cases a required item is considered irrelevant for a specific clinical investigation, section 2 of this form (last page) must be filled in. We advise you to consult ISO14155:2020 for guidance.*

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| --- | --- | --- | --- | --- |
| SECTION 1. LIST / CROSS-REFERENCES BETWEEN REQUIREMENT IN ANNEX XV CHAPTER II AND SUBMISSION PACKAGE | | | | |
| Requirement | | Description of requirement | Location within submission package | |
| Annex XV Chapter II (2):  **Investigators Brochure** (information in IB or in *exceptional* cases enclosed as separate documents.  If enclosed as separate documents, a clear reference within the IB shall be made to the enclosed documents). | 2.1 | Identification and description of the device, including:  Information on the intended purpose | Document | Page |
| The risk classification and applicable classification rule pursuant to Annex VIII | Document | Page |
| Design and manufacturing of the device | Document | Page |
| Reference to previous and similar generations of the device. | Document | Page |
| 2.2 | Manufacturer's instructions:  For installation, maintenance, maintaining hygiene standards | Document | Page |
| For use, including storage and handling requirements | Document | Page |
| Information to be placed on the label | Document | Page |
| Instructions for use to be provided with the device. | Document | Page |
| Information relating to any relevant training required. | Document | Page |
| 2.3 | Pre-clinical evaluation based on pre-clinical testing and experimental data in particular as applicable:  in-design calculations, in-vitro test, ex-vivo test, animal test, mechanical test, electrical test, reliability test, sterilization validation, software verification and validation, performance test  evaluation of biocompatibility and biological safety.  Summary and evaluation of pre-clinical/ non-clincal data:  Have all relevant pre-clinical test been completed:  Yes  No  If no, provide justification for why the investigation can be initiated. | Document | Page |
| 2.4 | Existing clinical data, in particular:  from relevant scientific literature available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of the device and/or of equivalent or similar devices | Document | Page |
| other relevant clinical data available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance, clinical benefit and safety-related issues and any corrective actions taken. | Document | Page |
| 2.5 | Summary of the benefit risk analysis and risk management | Document | Page |
| Information regarding known or foreseeable risks, any undesirable side effects, contraindications and warnings | Document | Page |
| 2.6 | In case of devices that contains:  **medicinal substance**  Detailed information on the substance and on the compliance with the relevant general safety and performance requirements, and the specific risk management in relation to the substance, and evidence for the added value of incorporation of such constituents in relation to the clinicalbenefit and/or safety of the device. | Document | Page |
| In case of devices that contains:  **human blood / plasma or derivate**  Detailed information on the human blood / plasma or derivate and on the compliance with the relevant general safety and performance requirements, and the specific risk management in relation to the human blood / plasma or derivate, and evidence for the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device. | Document | Page |
| In case of devices that contains  **non-viable tissues or cells of human or animal origin, or their derivatives**  Detailed information on the tissues, cells or their derivatives and on the compliance with the relevant general safety and performance requirements, and the specific risk management in relation to the tissues, cells or their derivatives, and evidence for the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device. | Document | Page |
| 2.7 | List of fulfilment of the General Safety and Performance Requirements (GSPR).  A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and common specifications (CS) applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking. | Document | Page |
| 2.8 | A detailed description of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice. | Document | Page |
| Annex XV Chapter II (3):  **Clinical Investigation Plan**  (information in CIP or in exceptional cases enclosed as separate documents)  If enclosed as separate documents, a clear reference within the CIP shall be made to the enclosed documents) | 3.1.2 | Identification of sponsor, and sponsors contact person and/or legal representative, including name, address and contact details. | Document | Page |
| 3.1.3 | Information on the principal investigator at each investigational site, including emergency contact details. | Document | Page |
| Information on the coordinating investigator for the investigation | Document | Page |
| The address details for each investigational site | Document | Page |
| Specification of roles, responsibilities and qualifications of the different kinds of investigators (coordinating investigator, principal investigator, sub-investigator) at each site. | Document | Page |
| 3.1.4 | A brief description on how the clinical investigation is financed | Document | Page |
| A brief description of the agreement between sponsor and the site | Document | Page |
| 3.1.5 | Synopsis of the clinical investigation in Norwegian language | Document | Page |
| Synopsis of the clinical investigation in English language | Document | Page |
| 3.2 | Identification and description of the device, including:  Its intended purpose and the target population, | Document | Page |
| Identification of manufacturer | Document | Page |
| Identification and description of the device’s traceability | Document | Page |
| Identification and description of materials coming into contact with the human body | Document | Page |
| Identification and description of the medical or surgical procedures involved in its use | Document | Page |
| Identification and description of and the necessary training and experience for its use | Document | Page |
| Identification and description of background literature review | Document | Page |
| Identification and description of the current state of the art in clinical care in the relevant field of application and the proposed benefits of the new device | Document | Page |
| 3.3 | Risks and clinical benefits of the device to be examined, with justification of the corresponding expected clinical outcomes in the clinical investigation plan | Document | Page |
| 3.4 | Description of the relevance of the clinical investigation in the context of the state of the art of clinical practice | Document | Page |
| 3.5 | Objectives and hypotheses of the clinical investigation. | Document | Page |
| 3.6.1 | General information such as type of investigation with rationale for choosing it, for its endpoints and for its variables as set out in the clinical evaluation plan | Document | Page |
| 3.6.2 | Information on the investigational device, on any comparator and on any other device or medication to be used in the clinical investigation. | Document | Page |
| 3.6.3 | Information on subjects, selection criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved such as children, pregnant women, immuno-compromised or, elderly subjects. | Document | Page |
| 3.6.4 | Details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors. | Document | Page |
| 3.6.5 | Description of the clinical procedures and diagnostic methods relating to the clinical investigation and in particular highlighting any deviation from normal clinical practice. | Document | Page |
| 3.6.6 | Monitoring plan.  (The *general* outline of the monitoring plan.) | Document | Page |
| 3.7 | Statistical considerations, with justification, including a power calculation for the sample size, if applicable | Document | Page |
| 3.8 | Data management. | Document | Page |
| 3.9 | Information about any amendments to the CIP. | Document | Page |
| 3.10 | Policy regarding follow-up and management of any deviations from the CIP at the investigational site and clear prohibition of use of waivers from the CIP | Document | Page |
| 3.11 | Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices | Document | Page |
| 3.12 | Statement of compliance with the recognised ethical principles for medical research involving humans (i.e. declaration of Helsinki), and the principles of good clinical practice in the field of clinical investigations of devices (ISO 14155), as well as with the applicable regulatory requirements (MDR). | Document | Page |
| 3.13 | Description of the Informed consent process. | Document | Page |
| 3.14 | Safety reporting, including definitions of adverse events and serious adverse events, device deficiencies, procedures and timelines for reporting. Please refer to [MDCG 2020-10/1 Rev 1](https://health.ec.europa.eu/system/files/2022-11/md_mdcg_2020-10-1_guidance_safety_reporting_en.pdf) for guidance. | Document | Page |
| 3.15 | Criteria and procedures for follow-up of subjects following the end, temporary halt or early termination of an investigation, for follow-up of subjects who have withdrawn their consent and procedures for subjects lost to follow-up. Such procedures shall for implantable devices, cover as a minimum traceability. | Document | Page |
| 3.16 | A description of the arrangements for taking care of the subjects after their participation in the clinical investigation has ended, where such additional care is necessary because of the subjects' participation in the clinical investigation and where it differs from that normally expected for the medical condition in question | Document | Page |
| 3.17 | Policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I. | Document | Page |
| 3.18 | List of the technical and functional features of the device, with specific mention of those covered by the investigation. | Document | Page |
| 3.19 | Bibliography | Document | Page |

**SECTION 2. OMISSIONS FROM ANNEX XV (if relevant)**

If in exceptional cases, requirement of MDR Annex XV is omitted from the application, please list requirements below including a justification for the omission.

|  |  |
| --- | --- |
| **Requirement** | **Justification for omission** |
| fill in text | fill in text |
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