**Overview of required information in Investigator’s Brochure and Performance Study Plan according to IVDR Annex XIV**

***Note:*** *The application shall contain information concerning all items in the IVDR Annex XIV. If in exceptional cases a required item is considered irrelevant for a specific performance study, section 3 of this form (last page) must be filled in. We advise you to consult ISO 20916:2019 when preparing the application.*

**SECTION 1: INVESTIGATOR’S BROCHURE**

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| **SECTION 1. LIST / CROSS-REFERENCES BETWEEN REQUIREMENT IN ANNEX XIV CHAPTER I AND SUBMISSION PACKAGE** | | | | |
| **Requirement** | | **Description of requirement** | **Location within submission package** | |
| Annex XIV Chapter I, Section 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 and 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 | Analytical performance | Document | Page |
| 2.4 | Existing clinical data | Document | Page |
| 2.5 | Summary of the benefit-risk analysis and risk management, including information regarding known or foreseeable risks and warnings. | Document | Page |
| 2.6 | In the case of devices that include:  **tissues, cells and substances of human, animal or microbial origins**  Detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to those tissues, cells and substances | 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 performance study and in particular information on any deviation from normal clinical practice. | Document | Page |

**SECTION 2: PERFORMANCE STUDY PLAN**

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| **SECTION 2. LIST / CROSS-REFERENCES BETWEEN REQUIREMENT IN ANNEX XIII SECTION 2 AND SUBMISSION PACKAGE**  *Annex XIV Chapter I, Section 3 refers to Sections 2 and 3 of Annex XIII for the requirements to the performance study plan.* | | | | |
| **Requirement** | | **Description of requirement** | **Location within submission package** | |
| Section 2 of Annex XIII.  **Performance Study Plan**  (information in PSP or in exceptional cases enclosed as separate documents.  If enclosed as separate documents, a clear reference within the PSP shall be made to the enclosed documents) | 2.3.2 (b) | Identification of sponsor, and, if applicable, sponsor’s contact person and/or legal representative | Document | Page |
| 2.3.2 (c) | Information on the investigator(s) – principal, coordinating or other – and investigation site(s) | Document | Page |
| In the case of devices for self-testing, the location and number of lay persons involved | Document | Page |
| 2.3.2 (d) | The starting date and scheduled duration for the clinical performance study | Document | Page |
| 2.3.2 (e) | Identification and description of the device, its intended purpose, the analyte or analytes or marker or markers, the metrological traceability, and the manufacturer | Document | Page |
| 2.3.2 (f) | Information about the type of specimens under investigation | Document | Page |
| 2.3.2 (g) | Overall synopsis of the clinical performance study, its design type, such as observational, interventional, together with the objectives and hypotheses of the study, reference to the current state of the art in diagnosis and/or medicine | Document | Page |
| 2.3.2 (h) | A description of the expected risks and benefits of the device and of the clinical performance study in the context of the state of the art in clinical practice, and with the exception of studies using left-over samples, the medical procedures involved and patient management; | Document | Page |
| 2.3.2 (i) | The instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other devices, medical devices, medicinal product or other articles to be included or excluded and the specifications on any comparator or comparative method used as reference | Document | Page |
| 2.3.2 (j) | Description of and justification for the design of the clinical performance study, its scientific robustness and validity, including the statistical design, and details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors | Document | Page |
| 2.3.2 (k) | The analytical performance in accordance with point (a) of Section 9.1 of Chapter I of Annex I with justification for any omission | Document | Page |
| 2.3.2 (l) | Parameters of clinical performance in accordance with point (b) of Section 9.1 of Annex I to be determined, with justification for any omission; and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions | Document | Page |
| 2.3.2 (m) | Information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity of target population and, if applicable, information on vulnerable subjects involved, such as children, pregnant women, immuno-compromised or elderly subjects | Document | Page |
| 2.3.2 (n) | Information on use of data out of left over specimens banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens | Document | Page |
| 2.3.2 (o) | Monitoring plan | Document | Page |
| 2.3.2 (p) | Data management | Document | Page |
| 2.3.2 (q) | Decision algorithms; | Document | Page |
| 2.3.2 (r) | Policy regarding any amendments, including those in accordance with Article 71, to or deviations from the CPSP, with a clear prohibition of use of waivers from the CPSP. | Document | Page |
| 2.3.2 (s) | Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical performance study and the return of unused, expired or malfunctioning devices | Document | Page |
| 2.3.2 (t) | Statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical performance studies as well as with the applicable regulatory requirements | Document | Page |
| 2.3.2 (u) | Description of the informed consent process, including a copy of the patient information sheet and consent forms | Document | Page |
| 2.3.2 (v) | Procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting; | Document | Page |
| 2.3.2 (w) | Criteria and procedures for suspension or early termination of the clinical performance study | Document | Page |
| 2.3.2 (x) | Criteria and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up | Document | Page |
| 2.3.2 (y) | Procedures for communication of test results outside the study, including communication of test results to the performance study subjects | Document | Page |
| 2.3.2 (z) | Policy as regards the establishment of the clinical performance study report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 2.2 of Annex XIII; | Document | Page |
| 2.3.2 (aa) | List of the technical and functional features of the device indicating those that are covered by the performance study | Document | Page |
| 2.3.2 (ab) | Bibliography | Document | Page |

**SECTION 3. OMISSIONS FROM ANNEX XIV (if relevant)**

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

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