Investigator's Trial File

Study name

**Study Site Name:**

**Principal Investigator:**

**Sponsor:**

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| --- |
| 1. Contact information |
| 1. Study Protocol and amendments |
| 1. Examples of Patient Information Sheet and Informed Consent Form, Other written information provided to the subjects |
| 1. Ethics Committee approval and correspondence |
| 1. Fimea approval and correspondence |
| 1. Organisational approval for the study |
| 1. Contracts |
| 1. Insurance certificates |
| 1. Study Site Personnel   Signature and Delegation of Responsibilities log  Training log  CVs  GCP-certificates |
| 1. Study Subjects   Patient Identification and Enrollment Log  Screening Log  Signed Informed Consent Forms |
| 1. Monitoring   Site Visit Log  Monitoring Plan and Agreement  Signed Monitoring Reports |
| 1. CRF   Forms, instructions, manuals  Origin of Source Data document |
| 1. Safety Information   SAE/SUSAR Forms  SAE/SUSAR reports  Yearly safety report (DSUR)  Other safety reports |
| 1. Investigational Product   Investigator’s Brochure / Summary of the Product Characteristics  Instructions for handling investigational products and study materials  Shipping documentation of investigational products and study materials  Drug accountability and inventory logs  Destruction and return documentation |
| 1. Laboratory tests and technical methods   Reference values and certificates of laboratory tests and technical methods  Records of retained body fluids/tissue samples |
| 1. Correspondence |