Investigator's Trial File

Study name

**Study Site Name:**

**Principal Investigator:**

**Sponsor:**

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| 1. Contact information
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| 1. Study Protocol and amendments
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| 1. Examples of Patient Information Sheet and Informed Consent Form, Other written information provided to the subjects
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| 1. Ethics Committee approval and correspondence
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| 1. Fimea approval and correspondence
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| 1. Organisational approval for the study
 |
| 1. Contracts
 |
| 1. Insurance certificates
 |
| 1. Study Site Personnel

Signature and Delegation of Responsibilities logTraining logCVsGCP-certificates |
| 1. Study Subjects

Patient Identification and Enrollment LogScreening LogSigned Informed Consent Forms |
| 1. Monitoring

Site Visit LogMonitoring Plan and AgreementSigned Monitoring Reports |
| 1. CRF

Forms, instructions, manualsOrigin of Source Data document |
| 1. Safety Information

SAE/SUSAR FormsSAE/SUSAR reportsYearly safety report (DSUR)Other safety reports |
| 1. Investigational Product

Investigator’s Brochure / Summary of the Product CharacteristicsInstructions for handling investigational products and study materialsShipping documentation of investigational products and study materialsDrug accountability and inventory logsDestruction and return documentation |
| 1. Laboratory tests and technical methods

Reference values and certificates of laboratory tests and technical methodsRecords of retained body fluids/tissue samples |
| 1. Correspondence
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