



List of documents to add as appendices to clinical investigation applications under Article 82

Mandatory

- Cover letter
- Application form
- Investigators Brochure (IB, when the sponsor is the manufacturer of the investigational device)
- Clinical Investigation Plan (CIP)
- CIP Synopsis (in Finnish or in Swedish)
- Declaration of conformity (when the investigational device is CE-marked medical device / Statement of conformity (when the investigational device is not CE-marked)
- Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/ personal information
- Statement from the Ethics Committee
- Risk management documentation
- Suitability of investigational sites and investigation site team
- Investigator CVs
- Documents to obtain informed consent, informed consent procedure, all written information to participants, payments, and compensation of participants (in Finnish or in Swedish)
- Decisions from other countries involved (if applicable)
- Description of the procedure in emergency situations to ensure that devices used in the study can be immediately identified and, if necessary, returned.
- Invoicing information

Documents that Fimea may request to be presented during the application processing stage as applicable

- Test reports
- Instructions for use for the investigational device
- Notified Body Certificates