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# 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