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# List of documents to add as appendices to clinical investigation applications under Article 62 and notifications under Article 74(1)

## Mandatory

* Cover letter
* Application form
* Investigators Brochure (IB)
* Clinical Investigation Plan (CIP)
* CIP Synopsis (in Finnish or in Swedish)
* Statement of conformity / Declaration of conformity
* Documents to obtain informed consent, informed consent procedure, all written information to participants, payments, and compensation of participants (in Finnish or in Swedish)
* Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/ personal information
* Proof of Clinical Investigation Insurance
* Statement from the Ethics Committee
* Invoicing information

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

* Clinical Evaluation Plan (CEP)
* Risk management documentation
* Test reports
* Suitability of investigational sites and investigation site team
* Suitability of the investigators
* Instructions for use for the investigational device
* Recruitment procedures and advertising materials
* Example of labels
* Notified Body Certificates
* Post Market Clinical Follow-up Plan (PMCF plan)
* Expert panel opinion (Article 61(2))