# 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))