Clinical investigation supporting documents

Appendix of documents to attach

Version 1.0

Document	Version/Date [DD-MM-YY] At time of NCA application	Version / Date [DD-MM-YY] At time of NCA authorisation / refusal	Summary of changes made	Amended as a result of NCA / REC assessment
Mandatory				
Cover letter				☐
Application form				
Investigator's Brochure (including any annexes) (if applicable)				☐
Clinical investigation plan				☐
Clinical evaluation plan				☐
CIP synopsis				☐
Statement of conformity				☐
Example of labels				☐
Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/ personal information				☐
List of General Safety and Performance Requirements				☐
As applicable				
Description of the arrangements to comply with the applicable rules on the protection and				☐

confidentiality of personal data/ personal information				
Risk management documentation				☐
Test reports				☐
Proof of Clinical Investigation Insurance				☐
Suitability of investigational sites and investigation site team				☐
Manufacturer's Instructions for Use				☐
Suitability of the investigators				☐
Recruitment procedures and advertising materials				☐
Documents to obtain informed consent, informed consent procedure, all written information to participants, payments and compensation of participants				☐
Notified Body Certificates				☐
Decisions form other countries				☐
PMCF plan				☐
Expert panel opinion				☐
Other documents				☐

Notes

This template has been prepare by the Clinical Investigation and Evaluation Working Group of the European Commission to support document traceability in the absence of EUDAMED.

This template should be used in conjunction with the document ‘Clinical investigation – application form under Medical Device Regulation’. The use of this template is not mandatory, and it is advisable to check with the relevant NCA regarding expectations for the use and completion of the template.

Fields marked as ‘mandatory’ are required to support a submission with respect to Regulation 745/2017, ‘optional’ fields may or may not be required, depending on the clinical investigation.

With respect to the ‘summary of changes made’ please include a short description of the sections amended and the type of change.

Acronyms

NCA	National Competent Authority
REC	Research ethics committee
PMCF	Post-market clinical follow-up