

Clinical Evaluation Plan (chapter structure)

Approval

- 1 Meta information
 - 1.1 Objective of this document
 - 1.2 General safety and performance requirements
 - 1.3 Procedure for clinical evaluation
- 2 Device
 - 2.1 Intended purpose of the device
 - 2.1.1 Intended medical purpose
 - 2.1.2 Other normal use (optional)
 - 2.2 Target groups
 - 2.2.1 Characterization of users
 - 2.2.2 Characterization of the patients
 - 2.3 Indications
 - 2.4 Contraindications
 - 2.5 Claims
- 3 State of the art, clinical background, scientific validity
 - 3.1 Identification of similar devices
 - 3.2 State of the art – technology
 - 3.3 State of the art – medicine
 - 3.4 Standalone software: Proof of scientific validity
 - 3.5 Summary of the state of the art
 - 3.5.1 Patient population, indication and contraindication
 - 3.5.2 Benefit
 - 3.5.3 Clinically relevant parameters
 - 3.5.4 Risks
- 4 Clinical benefit
- 5 Equivalence analysis
 - 5.1 Identification of the equivalent device
 - 5.2 Summary of the equivalence analysis

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- 6 Specification of methods for the investigation of qualitative and quantitative aspects of clinical safety and performance
 - 6.1 Pre-clinical data¹
 - 6.2 Clinical data²
 - 6.2.1 Data from the usability assessment
 - 6.2.2 Clinical studies prior to market launch
 - 6.2.3 Post-Market Surveillance
 - 6.2.3.1 PMS data from the manufacturer
 - 6.2.3.2 PMS data from safety databases
 - 6.2.3.3 PMCF measures
 - 6.2.3.4 Clinical data from registers
 - 6.2.3.5 Scientific literature
- 7 Clinically relevant parameters for the justifiability of the benefit-risk ratio
 - 7.1 Performance parameters
 - 7.2 Safety parameters
- 8 Benefit-risk ratio for certain components
- 9 Clinical development plan
 - 9.1 Selected data route
 - 9.2 Determination of clinical evidence
 - 9.3 Description of the clinical investigation and timetable (optional)
- 10 Annexes
 - 10.1 Version history of the plan
 - 10.2 References
 - 10.3 List of references
 - 10.4 Directories
 - 10.4.1 List of abbreviations
 - 10.4.2 List of illustrations
 - 10.4.3 List of tables
 - 10.5 Literature search protocol - State of the art
 - 10.6 Literature research report - State of the art
 - 10.7 Equivalence analysis
 - 10.7 Appraisal Plan

¹ For standalone software: verification of technical performance

² For standalone software: clinical validation

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