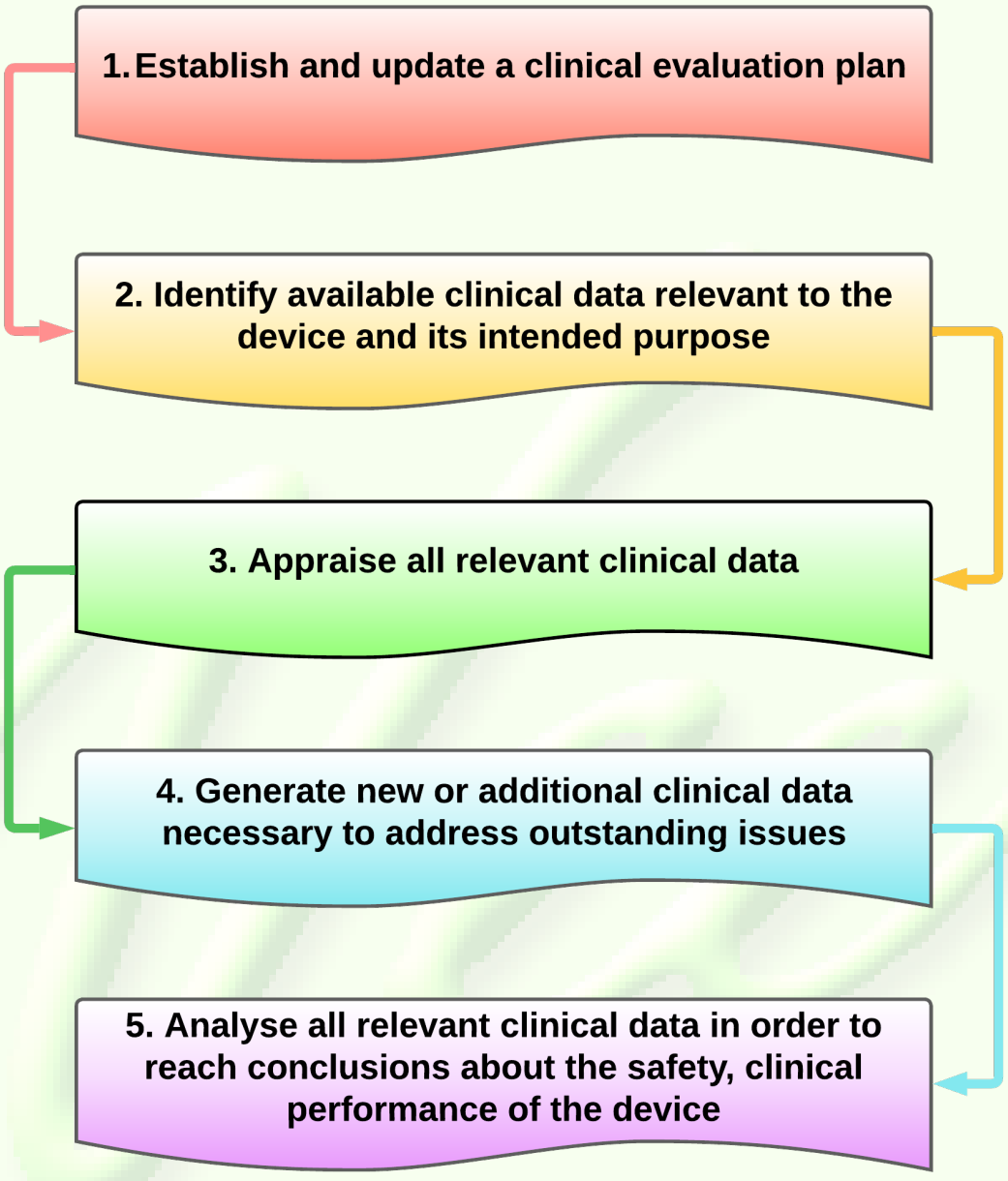
CLINICAL EVALUATION PROCESS



CLINICAL EVALUATION PLAN

1. Scope of Clinical Plan
2. Subject Device Descriptions
3. Conducting and Documenting the Clinical Evaluation
- 3.1. Relevant GSPRs
- 3.2. Intended Clinical Benefits and Outcome Parameters
- 3.3. Applicable Standards and Common Specifications
- 3.4. Clinical Development Plan
- 3.5. Assessment of Equivalent Device (if applicable)
- 3.6. Evaluation Method

4. Identifying Pertinent Data
- 4.1. Clinical Data Generated and Held by manufacturer
- 4.2. Clinical Data from Literature

5. Appraising Pertinent Data
- 5.1. Inclusion/Exclusion Criteria
- 5.2. Appraisal in relation to Device Safety and Performance
- 5.3. Appraisal in relation to State of Art
- 5.4. Level of Evidence

6. Analyzing Pertinent Data
- 6.1. Safety and Performance Assessment
- 6.2. Clinical Benefits/Risk Analysis

7. Clinical Evaluation Report
8. Ongoing and Planned Evaluation Activities
9. Qualification of Responsible Evaluators

CLINICAL EVALUATION REPORT

1. Executive Summary
2. Scope of Clinical Evaluation Report
3. Subject under Descriptions
4. Clinical Background, Current Knowledge, and State of Art
5. Device under Evaluation
- 5.1. Type of Evaluation
- 5.2. Demonstration of Equivalence
- 5.3. Clinical generated and held by Manufacturer
- 5.4. Clinical data from Literature
- 5.5. Appraisal of Clinical Data
- 5.6. Critical Analysis of Clinical Data

6. Conclusion of the Clinical Evaluation
7. Continuous Clinical Evaluation Process Activities
- 7.1. Risk Management
- 7.2. Post Market Surveillance Plan
- 7.3. Post Market Clinical Follow-Up Plan
- 7.4. Labelling and Promotion Materials
- 7.5. Updating the Clinical Evaluation Report

8. Qualification of the Responsible Evaluators