Chapter 10 Template: Clinical Evidence Strategy Decision Tree

Subtract to Ship: MDR Certification, Chapter 10: Clinical Evidence Strategy*

Instructions

Walk through this decision tree BEFORE committing budget to clinical evidence. The difference between the cheapest pathway (EUR 15,000) and the most expensive (EUR 500,000+) is a single strategic decision. Exhaust every alternative before defaulting to clinical investigations.

Part 1: Decision Tree

Question 1: What is your device classification?

- [ ] Class I, Literature review + bench testing typically sufficient. Clinical investigations rarely needed.
- [ ] Class IIa, Literature-based approach often sufficient. Equivalence can work.
- [ ] Class IIb, Evidence bar is higher. Equivalence harder. Clinical investigations may be needed.
- [ ] Class III or implantable, Clinical investigations required by default (Article 61(4)). Check exceptions.

Question 2: Does your device use well-established technology?

- [ ] Yes, Do recognised standards exist for this technology?
- [ ] Yes, Article 61(10) exception may apply. Document the justification.
- [ ] No, Move to Question 3.
- [ ] No (genuinely novel technology), Clinical investigations become much more likely.

Standards identified:

Question 3: Can you demonstrate equivalence to an existing device?

Check all three dimensions (Annex XIV Section 3):

Dimension	Your Device	Equivalent Device	Equivalent?
Technical (design, materials, specs)			Yes No
Biological (biocompatibility, tissue contact)			Yes No
Clinical (intended purpose, condition, population)			Yes No

Do you have sufficient access to the equivalent device's data? - Yes, own previous version or contractual access - No, equivalence to another manufacturer's device requires a contract (Article 61(5))

Equivalence viable? Yes No, If no, do not force it. Move to Question 4.

Question 4: Is the published literature sufficient?

Assessment	Answer
Conducted preliminary literature search?	Yes No
Number of relevant publications found	_
Do publications cover your intended purpose?	Yes Partially No
Do publications cover your patient population?	Yes Partially No
Is the data recent and of acceptable quality?	Yes No
Are there gaps that PMCF can address?	Yes No

Literature sufficient? Yes No, If no, you need primary data (clinical investigation).

Part 2: Your Evidence Pathway

Based on the decision tree, your pathway is:

Pathway	Est. Cost	Est. Timeline	Selected?
Literature-based CER + bench testing	EUR 15,000-50,000	2-4 months	
Equivalence-based CER	EUR 20,000-60,000	3-6 months	
Pre-market clinical investigation (small, 30-80 patients)	EUR 100,000-250,000	12-18 months	
Pre-market clinical investigation (large, 100+ patients)	EUR 250,000-500,000+	18-30 months	
PMCF as primary evidence builder (supplements any pathway)	EUR 10,000-30,000/year	Ongoing	

Your selected pathway:

____

Estimated cost: EUR

_

Estimated timeline:

_ months

Part 3: Clinical Evidence Claims Inventory

List every claim that flows from your intended purpose. Each claim requires evidence.

Claim #	Claim	Evidence Source	Evidence Document
1		Literature Standards Equivalence Investigation PMCF	
2		Literature Standards Equivalence Investigation PMCF	
3		Literature Standards Equivalence Investigation PMCF	
4		Literature Standards Equivalence Investigation PMCF	
5		Literature Standards Equivalence Investigation PMCF	

For each claim: can it be supported without a clinical investigation? If yes for all claims, you may not need one.

Part 4: NB Pre-Submission Preparation

Come prepared to the NB discussion with:

- [ ] Finalised intended purpose statement
- [ ] List of all clinical claims
- [ ] Proposed clinical evidence strategy (which sources and why)
- [ ] Preliminary literature search results
- [ ] Equivalence argument (if applicable, with 3-dimension comparison)
- [ ] Article 61(10) justification (if applicable)
- [ ] PMCF plan outline

Part 5: Clinical Expertise Gap Check

Question	Answer
Do you have a medical advisor with clinical domain expertise?	Yes No
Do you have someone with MDR clinical evaluation expertise?	Yes No
Are these the SAME person?	Yes No

If they are the same person: Verify they understand both clinical research AND MDR clinical evaluation frameworks. These are different competences.

If you only have the medical advisor: Your evidence strategy risks being over-scoped (academic research paradigm). Get MDR clinical evaluation input.

If you only have the regulatory expert: Your evidence strategy risks missing clinical nuances. Get medical domain input.

Both are needed. Neither replaces the other.

Part 6: Red Flag Check

- [ ] I have NOT already committed EUR 200,000+ to a clinical investigation without checking alternatives
- [ ] I have NOT let a medical doctor (without MDR expertise) define the clinical evidence scope alone
- [ ] I have NOT assumed clinical investigations are required without checking Article 61(10)
- [ ] I have NOT confused "best possible evidence" with "sufficient evidence"

Date completed:

_

Completed by:

_

Selected pathway:

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Estimated cost: EUR

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