Chapter 12 Worksheet: Two-Phase Approach, Phase Assessment & Transition

Subtract to Ship: MDR Certification, Chapter 12: The Two-Phase Approach

Instructions

Determine whether you are in Phase 1 (R&D, "Does this work?") or Phase 2 (Medical Device Development, "Can we certify this?"). Starting Phase 2 too early wastes years on premature documentation. Starting Phase 2 too late creates regulatory risk. This worksheet helps you draw the line.

Part 1: Which Phase Are You In?

Question	Answer	Phase Indicator
Has your core technology been validated with bench tests or simulated data?	☐ Yes ☐ No	No = Phase 1
Has your prototype been used on or near a patient?	☐ Yes ☐ No	Yes = potential Article 62 territory
Is your intended purpose locked (not shifting)?	☐ Yes ☐ No	No = Phase 1
Do you have a written EN 62304 software development plan (if software)?	☐ Yes ☐ No ☐ N/A	No = Phase 1 code
Has market demand been validated with real evidence (LOIs, conversations)?	☐ Yes ☐ No	No = Phase 1
Is your Phase 2 budget secured?	☐ Yes ☐ No	No = stay in Phase 1

Assessment:

☐ **I am in Phase 1.** Stay here until Phase 1 is done. Do not let investor pressure push you into Phase 2 prematurely.

☐ **I am in Phase 2.** Verify you completed Phase 1 properly.

☐ **I am unclear.** This ambiguity is your highest-risk item. Clarify this week.

Part 2: Phase 1 Checklist, "Does This Work?"

Activity	Status	Notes
Prototype development (rapid, iterative)	☐ Done ☐ In progress ☐ Not started	

Activity	Status	Notes
Feasibility testing (bench tests, simulated conditions)	☐ Done ☐ In progress ☐ Not started	
Customer feedback on concept (NOT clinical use)	☐ Done ☐ In progress ☐ Not started	
Retrospective data analysis (if software)	☐ Done ☐ In progress ☐ Not started	
Market validation (Chapter 2 PMF work)	☐ Done ☐ In progress ☐ Not started	
State of the art / competitive analysis	☐ Done ☐ In progress ☐ Not started	

Phase 1 Red Line Check

- ☐ No prototype has been tested on patients
- ☐ No prototype has been used in clinical settings without ethics approval
- ☐ No informal "let me try this on a volunteer" testing has occurred
- ☐ All testing has been in lab, on simulated data, or on bench models

If any box is unchecked: you may have crossed into Article 62 territory. Address immediately.

Phase 1 Record-Keeping (not MDR-compliant, but retained)

- ☐ Lab notebooks maintained
- ☐ Test results recorded
- ☐ Design decisions documented with rationale
- ☐ Customer feedback notes captured

Part 3: Phase 1 to Phase 2 Transition Criteria

All five must be met before entering Phase 2:

Criterion	Met?	Evidence
Technology feasibility confirmed	☐ Yes ☐ No	
Market demand validated	☐ Yes ☐ No	
Intended purpose locked	☐ Yes ☐ No	
Phase 2 budget secured	☐ Yes ☐ No	
Feature scope subtracted to essentials	☐ Yes ☐ No	

If any criterion is "No": you are not ready for Phase 2.

Part 4: Feature Subtraction Audit

Before entering Phase 2, list every feature. For each, apply the subtraction test:

Feature	Serves intended purpose?	Affects risk profile?	User would pay for it specifically?	Can be added post-certification?	Keep / Cut / Defer
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	

Target: 3-5 essential features for Phase 2. Every additional feature adds weeks of documentation, testing, and NB review.

Essential features for Phase 2: _____

Features deferred to post-certification: _____

Part 5: Phase 2 Checklist, "Can We Certify This?"

Activity	Status	Notes
QMS operational (Chapter 8)	☐ Done ☐ In progress	
EN 62304 software development plan written (if applicable)	☐ Done ☐ N/A	
Risk management plan and initial analysis (EN ISO 14971)	☐ Done ☐ In progress	
Design inputs documented formally	☐ Done ☐ In progress	
Design and development procedure followed	☐ Done ☐ In progress	
Technical documentation structure established (Annex II)	☐ Done ☐ In progress	
Verification protocols written before testing	☐ Done ☐ In progress	
All design changes going through formal change control	☐ Done ☐ In progress	

Part 6: What Carries Over (and What Does Not)

From Phase 1	Carries to Phase 2 as...
Technology knowledge	Design inputs, risk analysis inputs
Feasibility data	State-of-the-art analysis, clinical evidence inputs

From Phase 1	Carries to Phase 2 as…
Design rationale	Design history file content
User feedback	Usability engineering inputs (EN 62366-1)

From Phase 1	Does NOT carry over
Code (for software devices)	Phase 2 code starts clean within EN 62304 plan
Prototype hardware	Phase 2 hardware uses design-controlled materials
Informal test results	Phase 2 testing follows formal protocols

Current phase: ☐ Phase 1 ☐ Phase 2 ☐ Transitioning

Transition date (actual or planned): _____

Completed by: _____

This worksheet is part of the Subtract to Ship: MDR Certification playbook by Felix Lenhard and Tibor Zechmeister. It does not replace professional regulatory advice.