

Clinical Evaluation under Medical Device Regulation

(EU) 2017/745

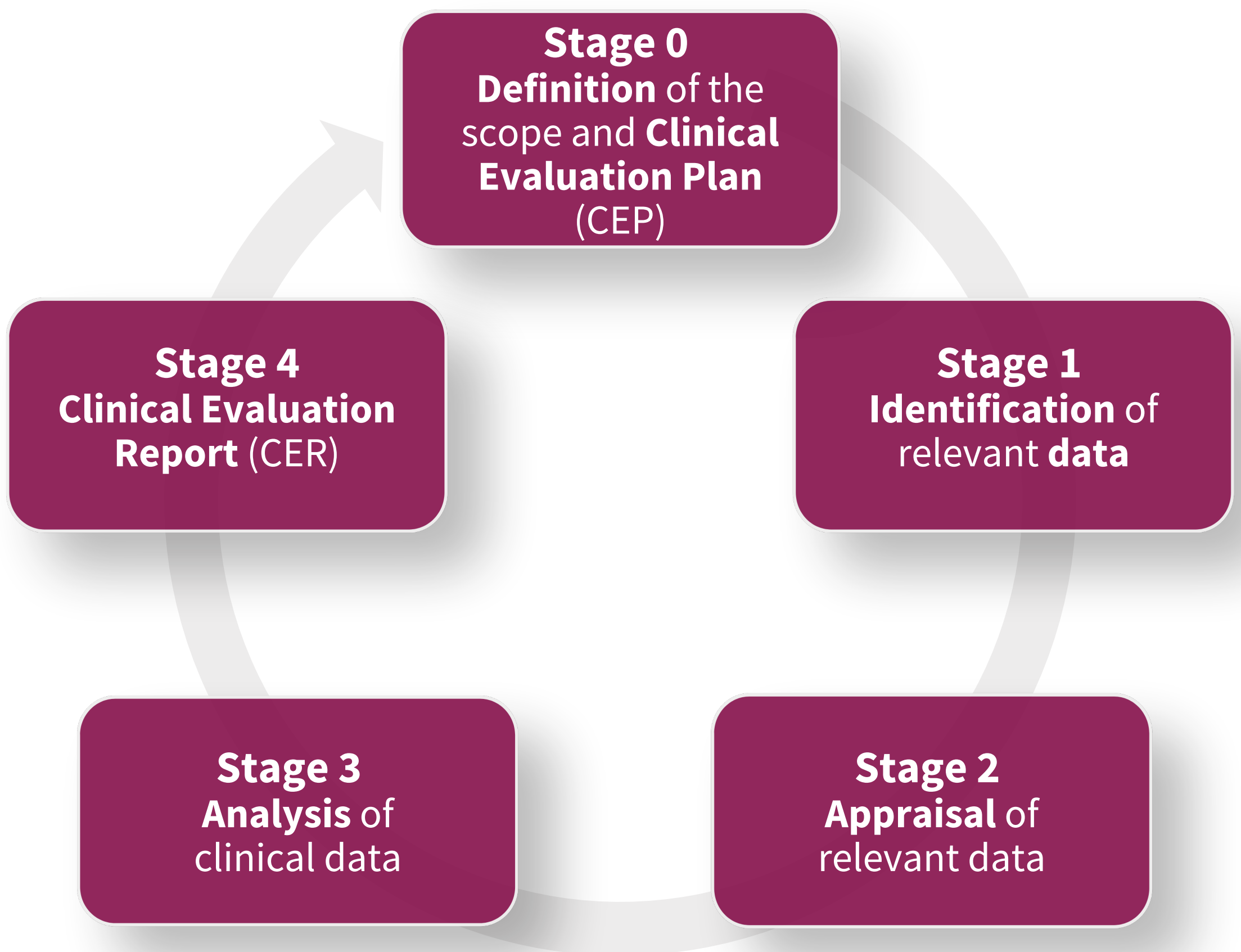
Regulatory basis: Regulation (EU) 2017/745 (MDR),
Article 61 and Annex XIV



Clinical Evaluation Objectives:

- Demonstrate compliance with relevant GSPRs
- Confirm clinical safety and performance
- Demonstrate clinical benefit
- Establish benefit-risk acceptability
- Support the intended purpose and clinical claims
- Identify residual risks and uncertainties
- Define the need for PMCF activities

Clinical Stages:



Key Documentation:

- 1** Clinical Evaluation Plan (CEP)
- 2** Clinical Evaluation Report (CER)
- 3** Literature Search Protocol and Report
- 4** PMCF Plan and PMCF Report
- 5** PMS plan and PMS Report/PSUR

Regulatory updates:



Clinical evaluations must be updated annually for class III or IIb implantable products.



Clinical evaluations must be updated every 2-5 years for low-risk class products.

Top 5 non-conformities:

1

Clinical benefits are not clearly defined



Key takeaway:

Define each clinical benefit in precise, specific terms aligned with the device's intended purpose, and avoid vague claims such as “good outcomes”, “effective” or “safe”. Link each claimed benefit to a measurable and clinically relevant outcome parameter.



‘Clinical benefit’ means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.



2

Clinical outcome parameters to be used to determine, based on the state-of-the-art in medicine, the **acceptability of the benefit-risk ratio** for all indications are not defined.

**Key takeaway:**

Define the clinical performance and safety outcome parameters used to assess clinical benefit, performance and safety, together with their acceptance criteria based on the state-of-the-art literature for similar and benchmark devices. Justify why these outcome parameters are clinically relevant.

2

Clinical outcome parameters to be used to determine, based on the state-of-the-art in medicine, the **acceptability of the benefit-risk ratio** for all indications are not defined.

Clinical benefit	Outcome parameter	Acceptance criteria	Clinical relevance
Reduction of pain	Pain score (Visual Analogue Scale 0 – 100)	≤ 15	Direct patient-relevant outcome and reflects post-operative tolerability and recovery.
Good short-term dental implant survival	Implant survival rate at 1-year follow-up (%)	$\leq 95\%$	Key indicator of procedural success and functional short-term treatment outcome.
Low risk of infection	Surgical Site Infection rate (%)	$\leq 7.5\%$	Clinically significant safety outcome that may impair healing and require additional treatment.

3

Lack of a robust literature search methodology



Key takeaway:

Generate a Literature Search Protocol and establish a literature search strategy, including search terms, databases searched, search filters, and time interval, as well as screening strategy with defined inclusion/exclusion criteria and an appraisal plan (e.g., Appendix D of GHTF SG5/N2R8:2007). Ensure that the searches are repeatable.

4

No specific PMCF activities are defined, or the study/survey design is inadequate, when such activities are necessary.



Key takeaway:

Define a robust, device-specific Post-Market Clinical Follow-up (PMCF) activity that includes, as a minimum, the research questions, objectives, study design, study location(s), inclusion and exclusion criteria, endpoints, target population, indications covered, statistical justification for the sample size, statistical analysis plan, and potential sources of bias, together with the corresponding mitigation measures. The activity description must provide sufficient detail and realistic timelines.

5**Inconsistencies across technical documentation****Key takeaway:**

The content of the Clinical Evaluation Report (CER), including the intended purpose, indications, target population, intended users, contraindications, warnings and precautions, and use environment, must be consistent with the Instructions for Use (IFU), Risk Management File, Post-Market Surveillance (PMS) Plan, Post-Market Clinical Follow-up (PMCF) Plan, Summary of Safety and Clinical Performance (SSCP), and product labelling.

Standard and Guidelines Overview

- **MEDDEV 2.7/1** rev.4 Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC. June 2016.
- **MDCG 2020-5** Clinical Evaluation – Equivalence: A guide for manufacturers and notified bodies. April 2020.
- **MDCG 2020-7** Post-market clinical follow-up (PMCF) Plan Template: A guide for manufacturers and notified bodies. April 2020.
- **MDCG 2020-8** Guidance on PMCF evaluation report template. April 2020.
- **MDCG 2020-6** Guidance on sufficient clinical evidence for legacy devices. April 2020.
- **MDCG 2020-13** Clinical evaluation assessment report template. July 2020.
- **MDCG 2019-9** Rev.1 Summary of safety and clinical performance. March 2022.
- **MDCG 2022-21** Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745. December 2022.
- **ISO 14155:2020** Clinical investigation of medical devices for human subjects - Good clinical practices.

Why work with us?



Multidisciplinary team:
clinical & regulatory affairs
and quality assurance



Pragmatic approach to
guide medtech
developers



Experience with a wide
variety of medical
technologies



Flexible collaboration
model for start-ups, SMEs
and large companies



Optimization of
Time to Market

Do you need **support with**
your Clinical Evaluation?

Contact us:
info@asphalion.com