..... the practical approach

WHITEPAPER

How We Build an MDR-Proof CEP & CER Strategy

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Under MDR Article 61 and Annex XIV, every medical device must be supported by an ongoing clinical evaluation. Manufacturers are expected to plan, gather and continuously appraise clinical evidence demonstrating safety, performance and an acceptable benefit-risk profile.

A clinical evaluation therefore runs through five stages:

1. Scoping. Define the device, intended purpose, indications, target population, clinical claims and the GSPRs requiring clinical support.

2. Planning (CEP). Establish the clinical evaluation strategy, methodology, relevant data sources, outcome parameters, acceptance criteria and predefined appraisal methods in the Clinical Evaluation Plan (CEP).

3. Identification of clinical data. Systematically identify relevant literature and gather clinical investigation, pre-clinical, PMS, PMCF and other relevant clinical data.

4. Appraisal. Critically evaluate the relevance, quality and contribution of the available evidence using predefined criteria and standardized appraisal methods.

5. Analysis and reporting (CER). Bring the evidence together, evaluate the benefit-risk profile and document the conclusions of the clinical evaluation in the Clinical Evaluation Report (CER).

The important point is that these are not isolated regulatory tasks. Each stage needs to logically support the next.

Standardized Methodology Creates Consistency

A robust clinical evaluation should be based on predefined and consistently applied methods. These should cover, as applicable:

- Literature search and evidence identification;
- Inclusion and exclusion criteria;
- Data extraction;
- Relevance and quality assessment;
- Clinical evidence appraisal;
- Equivalence assessment, if applicable;
- Analysis of clinical benefits and risks;
- Documentation and traceability.

Using standardized methods reduces the risk that individual assessments are influenced by the availability or attractiveness of particular data, making the process more transparent and reproducible for independent reviewers.

AI-supported tools can be incorporated into selected activities within the clinical evaluation workflow, for example to assist with literature screening, document classification, information extraction and consistency checks. However, AI-generated outputs should be treated as supporting information requiring human verification, particularly where outputs influence clinical relevance, evidence quality, benefit-risk conclusions or regulatory interpretation.

The objective is not to use AI simply because it is available. The objective is to use appropriate technology within a controlled, standardized and scientifically defensible methodology to further optimize the clinical evaluation process.

Clinical Evidence Must Fit the Medical Device

One of the most important MDR expectations is that the clinical evidence actually supports the device's specific intended purpose and clinical claims. Thus, the evidence should be current, traceable, and directly applicable to what the manufacturer claims the device does.

The same principle applies throughout the technical documentation. Clinical claims in the CER should correspond with the intended purpose and labelling. Residual risks identified through risk management should be addressed through the clinical evaluation. Remaining clinical uncertainties should feed into PMCF.

This creates an evidence chain: Intended purpose and claims → clinical questions → standardized methodology → collection of clinical data → clinical data appraisal → analysis → benefit-risk determination → residual uncertainties → PMCF → new clinical data → appraisal → analysis → updated clinical evaluation

Where AI is used, it should be used as a controlled support mechanism, leaving the clinical conclusions to the human evaluator.

Common Gaps in CERs: Where Clinical Evaluations Break Down

A CER needs to function as a structured scientific argument. Several gaps can undermine that argument. We dedicated a blog from the CEP/CER series to what Notified Bodies expect to see during CER review and the common deficiencies that continue to appear. For now, we will describe them briefly.

Gap 1: Clinical evidence does not sufficiently support the intended purpose

The starting point should always be the device's intended purpose and the claims that require substantiation. A problem arises when the available clinical evidence is broader, older or materially different from the specific device, indication or patient population described in the technical documentation.

You should ask: *"Does the available clinical evidence adequately support this device, for this intended purpose, with these clinical claims?"* That answer should drive the entire clinical evaluation strategy.

Gap 2: Literature searches cannot be reproduced

A literature review should follow a systematic and transparent methodology. Notified Bodies need sufficient documentation to understand how the evidence base was identified, selected and assessed. A standardized search strategy should define, before execution:

- databases and information sources;
- keywords and search queries;
- search dates;
- inclusion and exclusion criteria;
- screening methodology;
- data extraction processes;
- methods for documenting decisions.

AI-assisted screening may improve efficiency, particularly for large evidence sets, but it should operate within the predefined methodology. AI-assisted decisions should remain traceable and

subject to appropriate human verification. The objective is not simply to perform a faster literature search. It is to establish a reproducible and defensible process for the identification of relevant clinical data.

Gap 3: Equivalence claims cannot withstand scrutiny

Where equivalence is used, manufacturers need to demonstrate it across the relevant clinical, technical and biological characteristics, with differences scientifically justified as not clinically significant.

Common weaknesses include insufficiently structured equivalence comparisons, unsupported conclusions and, where applicable, lack of access to the equivalent device's technical documentation. Standardized comparison frameworks can help ensure that the relevant characteristics are consistently assessed and documented.

AI may assist with organizing comparison data or identifying differences across large technical datasets, but equivalence conclusions require expert scientific and regulatory assessment. In the end, traceability is what turns separate documents into a coherent technical file.

Gap 4: The benefit-risk conclusion is disconnected from the evidence

A robust CER should connect the benefit-risk conclusion directly to the evidence presented. This means identifying and, where appropriate, quantifying clinical benefits, considering residual risks, acknowledging uncertainties and evaluating the findings in the context of the state of the art. Standardized analytical criteria can improve consistency in how evidence is considered across different updates and device versions.

AI may support data organization, trend identification or consistency checks, but the final interpretation and benefit-risk determination should remain under qualified human responsibility.

Gap 5: PMCF is generic rather than gap-driven

PMCF is closely connected to clinical evaluation because it should help address the uncertainties and evidence gaps that remain after the CER is completed. PMCF objectives should be linked to specific unanswered clinical questions, residual risks or uncertainties identified during the evaluation. The plan should define appropriate methods, timelines and objectives for generating the required evidence.

In other words, the CER should determine what you still need to know, and the PMCF strategy should explain how you are going to find out.

The Role of the CEP: Building the Clinical Evaluation Before Writing the CER

The CEP is the strategy. The CER is the evidence-based outcome of that strategy. Therefore, the CEP should always precede the CER.

A well-constructed CEP defines, before the evaluation begins:

- the intended purpose and indications for use;
- the clinical claims requiring substantiation;
- the clinical questions the evaluation must answer;
- criteria for appraisal of clinical data;
- inclusion and exclusion criteria;

- literature search methodology;
- the approach to equivalence, where applicable;
- relevant standards and regulatory guidance;
- outcome parameters and acceptance criteria;
- the relationship between clinical evaluation and risk management; and
- the standardized methodology to be applied throughout the evaluation.

Where AI-supported tools are intended to be used, the methodology should also establish their defined scope of use, verification requirements, documentation and human oversight. The CER then documents the evidence gathered and evaluated against that predefined methodology and presents conclusions on clinical safety, performance, benefit and residual risk.

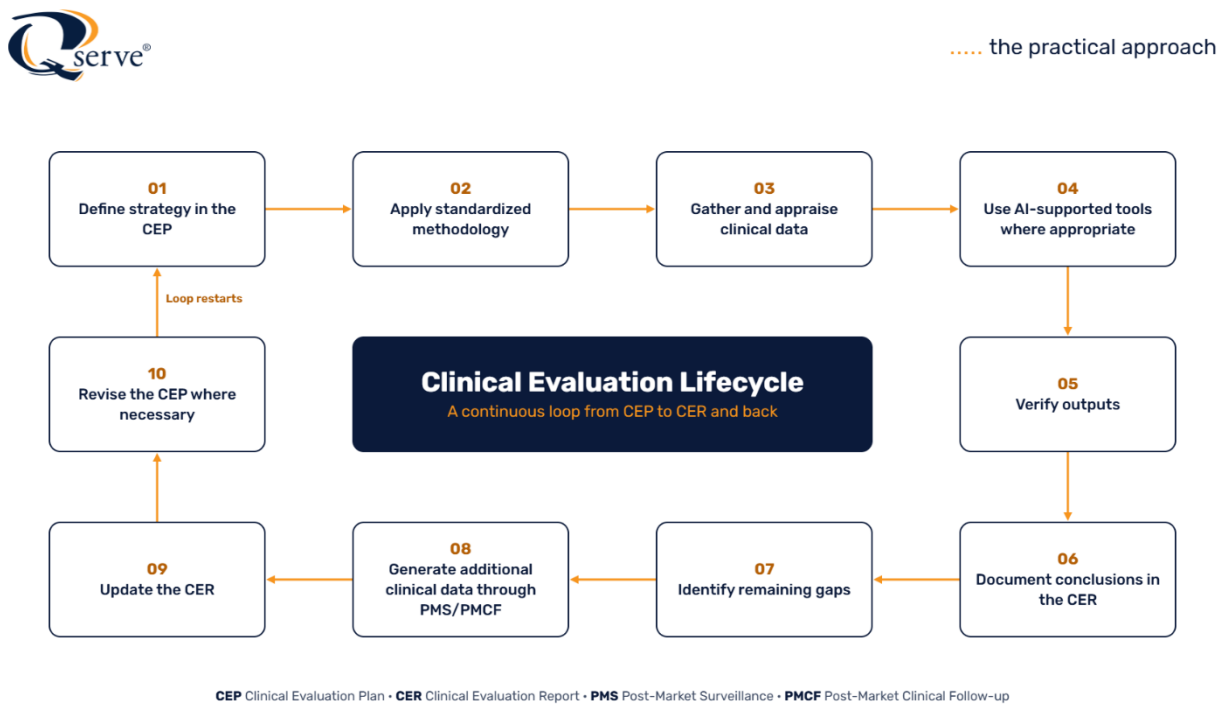
Writing the CEP retrospectively after reviewing the evidence creates a fundamental methodological problem: the evaluation criteria can unintentionally be shaped around the evidence already found. A predefined strategy reduces that risk. Without an established CEP, manufacturers may gradually change the scope of the clinical evaluation based on available literature rather than evaluating the evidence required by the device's actual claims.

The same principle applies to AI. AI tools should not be allowed to determine the methodology simply because a particular tool produces a convenient output. The methodology should be established first, and technology should then be used within that defined framework.

The CEP as a Lifecycle and Governance Tool

As PMCF generates new information, the device changes or new risks and clinical knowledge emerge, the CEP provides the methodological baseline against which the clinical evaluation can be updated.

The lifecycle can therefore be viewed as a continuous loop:



This approach makes clinical evaluation more manageable because updates become part of a defined process rather than repeated document-from-scratch exercises.

A Practical Framework for an MDR-Ready CEP & CER Strategy

To summarize, an MDR-ready clinical evaluation can be structured around six practical steps.

Step 1 – Start with the claims, not the literature. Key question**:** What exactly must the clinical evidence prove for this device?

Step 2 – Build the standardized methodology into the CEP. Key question: Could an independent reviewer understand exactly how we intend to identify, evaluate and interpret our clinical evidence?

Step 3 – Build a reproducible evidence base. Key question: Can we reproduce and defend how we arrived at this evidence set?

Step 4 – Create traceability across the technical documentation. Key question: Do our CEP, CER, risk management, PMS, PMCF and labelling all describe the same device and support the same conclusions?

Step 5 – Turn evidence gaps into a PMCF strategy. Key Question: Which clinical question or uncertainty must this PMCF activity answer?

Step 6 – Establish the lifecycle update loop. A mature process continually asks: What has changed? → Does it affect our evidence or conclusions? → Does the CER need updating? → Does the clinical strategy in the CEP need revising? → Does PMCF need to address a new question?

Standardized methods and appropriately governed AI-supported processes can help make this lifecycle more efficient and consistent, while maintaining human oversight over scientific and regulatory conclusions.

From Compliance Document to Defensible Clinical Strategy

Many deficiencies are strategy and process problems that become visible in the CER. A literature search cannot compensate for poorly defined clinical claims. A polished CER cannot repair an unsupported equivalence strategy. A generic PMCF plan cannot resolve clinical uncertainties that were never clearly identified. And AI cannot compensate for an inadequate clinical evaluation methodology.

The strongest clinical evaluations begin with a predefined CEP, a transparent and standardized methodology, and a clear understanding of what the clinical evidence must demonstrate. The CER then becomes the logical output of that process: a traceable scientific case connecting the device's intended purpose and clinical claims with evidence, risk management, benefit-risk conclusions and post-market activities.

Making stronger connections between strategy, standardized methodology, technology, evidence and lifecycle management is ultimately what makes a CEP and CER strategy more resilient under MDR scrutiny.

Is Your CEP & CER Ready for Notified Body Scrutiny?

Clinical evaluation weaknesses are often discovered when they are most expensive to fix, during Notified Body review. Qserve combines clinical and regulatory expertise with dedicated medical writing capabilities to help manufacturers identify those weaknesses earlier.

We can assess your current CEP and CER strategy, identify priority gaps and help define a practical route toward MDR-ready clinical documentation based on standardized methodologies, and robust evidence. Our teams support clinical evaluation across different device classes and therapeutic areas, from reviewing existing clinical data and conducting gap analyses to developing CEPs, systematic literature reviews, CERs and device-specific PMCF strategies. We also support manufacturers in establishing standardized clinical evaluation methodologies, helping ensure that technology is integrated into the clinical evaluation process without compromising traceability, scientific judgment or regulatory accountability.

Preparing a new clinical evaluation, updating an existing CER or responding to Notified Body findings? Talk to a Qserve clinical evaluation expert.