White Paper

Clinical Evaluation Report Basics from the Perspective of a Medical Writer

In light of the evolving regulatory environment in the European Union (EU), we reexamine the fundamental principles of the Clinical Evaluation Report (CER) as outlined by Regulation 2017/745 (EU MDR) in this white paper. This overview of CER basics is offered through the lens of an experienced regulatory writer focusing on medical device submissions.

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We Speak Science

Background

Since the introduction of Regulation (EU) 2017/745 (EU MDR) in 2017, medical device manufacturers have invested significant time and resources to ensure compliance with the updated regulations. As we transition into the phase of maintaining Conformité Européenne (CE) certification under EU MDR, efforts are focused on optimizing processes to efficiently manage clinical data and postmarket clinical follow-up (PMCF) activities. It is crucial to remain mindful of ongoing updates to regulatory interpretations by the Medical Device Coordination Group (MDCG) and the diverse feedback from evaluating Notified Bodies, as these factors can influence the strategy and approach of clinical evaluations.

To navigate this evolving landscape, it's valuable to revisit the fundamental requirements and objectives of the clinical evaluation: to assess the entirety of the clinical evidence supporting the safety and performance of the medical device(s) or device families. Various supporting documents authored by cross-functional teams aid in the continued development and innovation of the manufacturer's products, many of which are generated concurrently with the initial clinical evaluation to achieve CE marking. The iterative updating of documentation remains an ongoing process throughout the device's lifecycle.

With a deep understanding of the Clinical Evaluation Plan (CEP) and Clinical Evaluation Report (CER), it becomes clear how harmonization of various components helps ensure compliance. For a comprehensive review of clinical documentation interconnectivity, and recommendations to strengthen the "cross talk" between supporting documents, refer to the whitepaper titled "Why a Clinical Evaluation Needs a Medical Writer," accessible at www.whitsellinnovations.com/resources.

Figure 1 offers an overview of the clinical evaluation process, highlighting the key clinical and nonclinical evidence alongside other supporting documentation. This process begins with scoping in the CEP, progresses through clinical evaluation execution, and culminates in documentation within the CER. Ultimately, the goal is to demonstrate device safety and performance by confirming conformity with General Safety and Performance Requirements (GSPRs) 1 and 8. This white paper provides a regulatory writer's detailed perspective, offering insights into navigating the fundamental components of a clinical evaluation and the associated complexities.

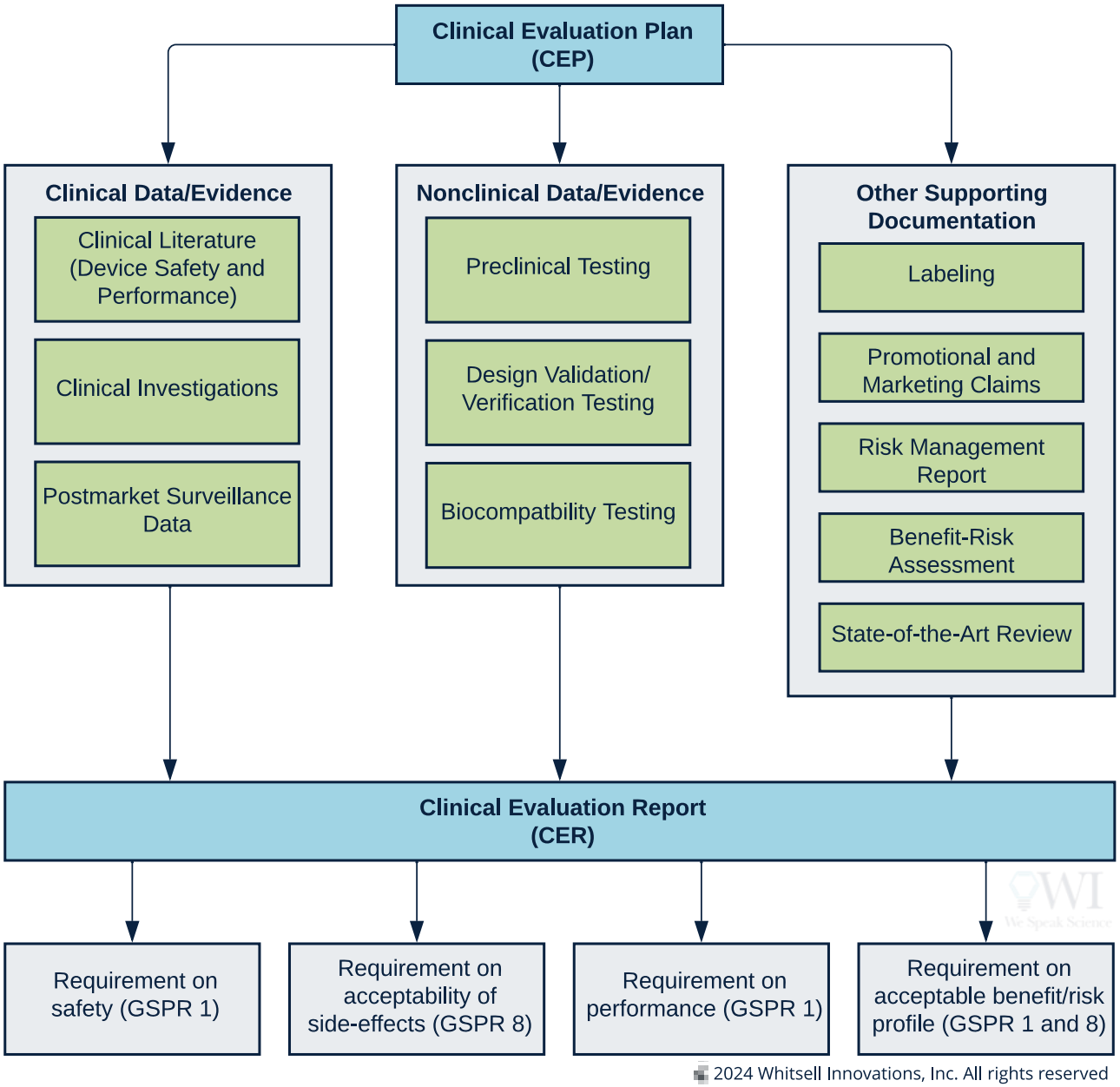
Complete the CEP – The First Step

The CEP defines the scope of the clinical evaluation. This should be based on the GSPRs that must be addressed from the clinical perspective, as well as the details of the specific device(s) of interest including the intended purpose, indications for use, intended target group, and contraindications. The CEP identifies the types of data that will be included in the evaluation to support the safety and performance of the device(s). Given the range of technologies and types of medical devices, the amount and types of clinical data necessary to support the safety and performance of the device(s) will vary greatly and will also largely depend on the lifecycle stage of the subject device(s). Nevertheless, the clinical data will usually include the 3 main pillars of clinical evidence: clinical investigations, clinical literature, and postmarket surveillance data. Sources of these data should be identified, along with any claims of equivalence to another device or compliance with harmonized standards for well-established technologies. The CEP should also consider a plan for evaluation of the state-of-the-art, risk management analysis, and identification of any clinically relevant changes or concerns. The manufacturer's clinical development plan, which documents the device's development from exploratory investigations to confirmatory investigations, as well as continued confirmation of safety and performance through PMCF studies should be included and evaluated. The clinical evaluation should be conducted anytime new information from postmarket surveillance activities indicate a potential change to the benefit/risk profile. If no new information is received, then the next evaluation should be conducted annually for high-risk device(s) or those that are not well established. For lower-risk device(s), the clinical evaluation can be carried out every 2 to 5 years, and a justification for the evaluation interval should be included (MEDDEV 2.7/1, Rev. 4, Section 6.2.3). A plan should be in place to keep the CEP up to date with each successive clinical evaluation.

Conduct the Clinical Evaluation – The Second Step

Pursuant to the plan laid out in the CEP, the cross-functional team gathers all the relevant clinical and nonclinical evidence, risk management documents, labeling, promotional materials, postmarketing activity documentation, and technical changes for review (**Figure 1**). Each member of this cross-functional team maintains their respective documentation and provides their expertise to develop the clinical evaluation strategy. As appropriate, updates to supporting documentation should be made before the results of the clinical evaluation can be documented in the CER.

Figure 1: Clinical Evaluation Overview



Compile the CER – The Third Step

The CER is the culmination of the evaluation to collect, appraise, and analyze the clinical data pertaining to a medical device(s) and to evaluate whether there is sufficient clinical evidence to confirm compliance with the relevant GSPRs for safety and performance (Figure 1) when using the device(s) according to the manufacturer's Instructions for Use (MEDDEV 2.7/1, Rev. 4, Section 4). MEDDEV 2.7/1, Rev. 4 provides guidance on the development of a CER including an example table of contents (Table 1). The format and structure of the CER is tailored by the medical writer based on the quantity and type of data available on the subject device(s).

Following the plan laid out in the CEP, the medical writer pulls together all the documentation identified in the clinical evaluation process and begins to tell the story of the device(s).

Table 1: Example Clinical Evaluation Report Table of Contents

Clinical Evaluation Report Table of Contents
1. Summary
2. Scope of the clinical evaluation
3. Clinical background, current knowledge, state-of-the-art
4. Device under evaluation
4.1 Type of evaluation
4.2 Demonstration of equivalence (only when equivalence is claimed)
4.3 Clinical data generated and held by the manufacturer
4.3.1 Clinical investigations
4.3.2 Postmarket surveillance
4.3.3 Nonclinical data
4.4 Clinical data from literature
4.5 Summary and appraisal
4.6 Analysis of the clinical data
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4.6.4 Requirement on acceptable benefit/risk profile (GSPR 1 and 8)
5. Conclusions
6. Date of the next evaluation
7. Dates and signatures
8. Qualification of the responsible evaluators
9. References

Source: Adapted from MEDDEV 2.7/1, Rev. 4, Appendix A9

1. Summary

The summary section provides an overview and high-level analysis of the device(s), the regulatory status, scope of the evaluation, safety and performance objectives, and the clinical evidence included in the CER. The medical writer usually completes this section after the body of the CER is drafted.

2. Scope of the clinical evaluation

The scope of the clinical evaluation identifies the device(s) covered by the evaluation, regulatory history, physical and chemical description, technologies used including innovative aspects or incremental changes, device group, intended purpose, indications, contraindications, target population, any claims on clinical safety or performance, and changes since the last report which have an impact on the clinical evaluation. This information can be sourced from a variety of documents including the device labeling (directions for use, instructions for use, or operator's manual), technical documentation, regulatory records, marketing records, and biocompatibility reports. If not previously defined, the clinical evaluation team develops safety, performance, clinical performance, and clinical benefit objectives with associated endpoints to which the device(s) can be objectively compared (**Figure 2**).

3. Clinical background, current knowledge, state-of-the-art

For both initial CE marking and for updates to currently marketed devices, the state-of-the-art must be evaluated (MEDDEV 2.7/1, Rev. 4, Section 7). The current knowledge/state-of-the-art in the corresponding medical field can be identified by applicable standards and guidance documents, information relating to the medical condition managed with the device and its natural course, benchmark devices, other devices, and medical alternatives available to the target population.

Figure 2: Safety, Performance, and Clinical Benefit Definitions

Safety

The absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum[1]

Performance

The ability of a device to achieve its intended purpose[2]

Clinical Performance

The ability of a device to achieve its intended purpose, thereby leading to a clinical benefit[3]

Clinical Benefit

The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s)[4]

[1] World Health Organization
[2] Article 2(22) of EU MDR
[3] Article 2(52) of EU MDR
[4] Article 2(53) of EU MDR

The medical writer works closely with the subject matter expert(s) to develop a clinical literature search protocol with a systematic search strategy that is thorough, objective, and unbiased. Careful consideration should be given when identifying the appropriate benchmark devices (ie, similar devices marketed by other manufacturers) and medical alternatives available for the indicated condition. In addition to searching scientific literature databases, expert documents issued by professional medical associations and clinical practice guidelines can provide a basis for the development of a comprehensive review of the state-of-the-art. An example of a typical systematic literature search and review method is the PICO (population, intervention, control, and outcome) model, which establishes a strong foundation for the literature search. In addition to the literature search strategy, the state-of-the-art clinical literature search protocol should define the inclusion/exclusion criteria for the documents retrieved (**Table 2**), along with the appraisal criteria (**Table 3**) that are used to weigh the evidence collected from the literature (MEDDEV 2.7/1, Rev. 4, Section A5).

After the systematic literature search is conducted by a qualified librarian, the output from the databases is delivered to the medical writer who systematically screens the literature according to the inclusion and exclusion criteria in the approved protocol. Of note, exclusion of any article based on the favorable or unfavorable nature of the results at any point in the search or screening process is not allowed. The set of included clinical literature is then appraised according to the approved criteria.

The current state-of-the-art in the corresponding medical field and any associated limitations on patient populations and/or medical conditions should be considered. The state-of-the-art should accurately characterize the clinical performance and clinical safety profile of the medical alternatives and benchmark devices in the medical landscape. A systematic presentation of the data, including the benefits and drawbacks of alternative therapies and benchmark devices, should be discussed. While the state-of-the-art literature search report should objectively discuss the current and alternative approaches to the medical landscape, the discussion within the CER compares the clinical performance and clinical safety of the

device(s) of interest with those in the state-of-the-art review. The literature review may identify gaps in treatment where the device(s) of interest may fill a need. Alternatively, such gaps may not exist. In this case, the discussion within the CER should demonstrate an improved benefit/risk profile (or an equivalent profile, at a minimum) compared to the state-of-the-art review (MEDDEV 2.7/1, Rev. 4, Section A7.2.e).

Table 2: Example Inclusion and Exclusion Criteria for State-of-the-Art and Device Safety and Performance Literature Searches

State-of-the-Art	Device Safety and Performance
Inclusion Criteria	
High-quality systematic review, meta-analysis, clinical practice guideline, or guidance document presenting clinical safety and performance outcomes of subject device(s), benchmark device(s), and/or medical alternatives.	Human clinical study presenting safety or performance data on the subject device(s) when used as intended.
	Article presenting a previously unknown complication related to the subject device(s).
Exclusion Criteria	
Article unrelated to the indicated use	No clinical performance or safety results on subject device(s)
Article that did not provide state-of-the-art	Study contains insufficient information to assess methodological quality
Controlled clinical study (unless systematic reviews, meta-analyses, or any other evidence-based state-of-the-art reports are unavailable)	Study where clinical data are unextractable
Uncontrolled study	Study where the subject device(s) was not the main focus of the study
Nonclinical study without a clinical application	Nonclinical study, such as animal, biomechanical, or cadaveric
Non peer reviewed article	Non peer reviewed article
Duplicate article between or within a given search or between publications	Duplicate article between or within a given search or between publications
Article with date of publication outside the reporting period	Article with date of publication outside the reporting period
Narrative review	Review article
Isolated case report	
Abstract or conference proceeding	

4. Device under evaluation

4.1 Type of evaluation

This section introduces the types of clinical evidence that are presented in the subsequent sections. These include clinical literature, clinical investigations, and postmarket surveillance data, or a justification if demonstration of conformity with GSPRs based on clinical data is not appropriate.

4.2 Demonstration of equivalence

The clinical evaluation may be based on the clinical data of an equivalent device. Three main aspects of both devices should be compared to demonstrate equivalence of the subject device(s) with the equivalent device(s). These criteria include the following:

- Technical equivalence
- Biological equivalence
- Clinical equivalence

The manufacturer must have sufficient access to the data relating to the equivalent device(s) to justify all 3 criteria for equivalence (MDCG 2023-7). There should be no clinically significant difference in the safety and performance of the subject device(s) and the equivalent device(s) in these categories. If equivalence can be demonstrated, then the clinical data collected on the equivalent device(s) may be leveraged to demonstrate conformity of the subject device(s) with the relevant GSPRs.

The MDCG has issued guidance documents to clarify under what circumstances equivalence may be claimed. The scope and definition of equivalence continues to be discussed and clarified and has evolved from MEDDEV 2.7/1, Rev. 4 to EU MDR.
MDCG 2020-5 was issued with the purpose of highlighting the differences between EU MDR and MEDDEV 2.7/1, Rev. 4 and offers additional guidance on the demonstration of equivalence.

4.3 Clinical data held by the manufacturer

4.3.1 Clinical investigations

A clinical investigation is defined by MDR as any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device (Article 2[45] of EU MDR). There is extensive guidance within EU MDR and additional guidance documents issued by MDCG regarding the planning, conduct, and reporting of clinical investigations for various types of devices.

At the time of the clinical evaluation, the medical writer appraises the available clinical investigation reports per the defined appraisal criteria (**Table 3**). The study details should be reported including objectives, patient population, length of follow-up, relevance to the EU population, and statements regarding conduct in accordance with applicable regulations and ethical standards. Key demographic information and a summary of results should be detailed. Specific attention to the performance and clinical benefit objectives should be included. Comparison with the safety acceptance criteria should be discussed along with a full tabulation of all reported adverse events both expected and unexpected.

4.3.2 Postmarket surveillance

The manufacturer is required to maintain a postmarket surveillance system that actively and systematically gathers, records, and analyzes relevant data on the device(s) throughout the entire lifetime. This plan is

documented in the postmarket surveillance plan and summarized in the CER. The data collected from the postmarket surveillance activities should be tabulated to support the safety profile of the device(s). Trend analysis on the market experience data is presented along with a discussion of any preventive and corrective actions that have been implemented. While the clinical evaluation requires postmarket surveillance data, the evaluation may generate new information that may, in turn, require updates to the postmarket surveillance plan and risk management processes.

4.3.3 Nonclinical studies

Nonclinical studies relevant to the clinical evaluation should be summarized and included in the CER. These studies can include biocompatibility reports, device verification and validation data, and usability studies. These data can support safety as well as performance of the device and should be interpreted in coordination with the clinical data.

Table 3: Example Appraisal Criteria

Criteria	Description	Grading System	
Suitability			
Appropriate device	Were the data generated from the device in question?	D1 D2 D3	Actual device Comparable device Other medical device
Appropriate device application	Was the device used for the same intended use (eg, methods of deployment, application, etc.)?	A1 A2 A3	Same use Minor deviation Major deviation
Appropriate patient group	Were the data generated from a patient group that is representative of the intended treatment population (eg, age, sex, etc.) and clinical condition (ie, disease, including state and severity)	P1 P2 P3	Applicable Limited Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1 R2 R3	High quality Minor deficiencies Insufficient information
Data Contribution			
Data source type	Was the design of the study appropriate?	T1 T2	Yes No
Outcome measures	Do the outcome measures reported reflect the intended performance of the medical device?	O1 O2	Yes No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1 F2	Yes No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1 S2	Yes No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1 C2	Yes No

Source: IMDRF MDCE WG/N56FINAL:2019

4.4 Clinical data from literature

As differentiated from the clinical data types held by the manufacturer, ie, manufacturer-sponsored clinical investigations and postmarket surveillance data, clinical data collected and published in the scientific literature is not owned by the manufacturer. The clinical data from the published literature should cover the lifetime of the device and be analyzed without bias.

Similar to the state-of-the-art literature review, a systematic review of the current clinical literature on the subject device(s)'s safety and performance is conducted for both initial CE-marking evaluations and for updates to the CER. The scope and strategy of the subject device(s) literature search are focused more on the safety and performance of the specific device of interest as opposed to the broader medical field. For some devices, the clinical evidence retrieved from the literature constitutes the majority of clinical data available on the subject device(s). This literature search protocol should specify the databases being searched, publication date range of interest, and search terms related to the device(s). Gathering literature on high-quality clinical trials (eg, randomized controlled trials) conducted with the subject device(s) used as intended is the ultimate goal of this type of search, as these data provide the most objective analyses of safety and performance of the subject device(s). Off-label use and articles presenting previously unknown complications should also be identified through this search. The protocol should be detailed enough that the search could be reproduced from the protocol and yield the same results.

Additionally, this literature search protocol should also define the inclusion/exclusion criteria for the documents retrieved (**Table 2**), along with the appraisal criteria (**Table 3**) used to weigh the evidence collected from the literature (MEDDEV 2.7/1, Rev. 4, Section A5).

After the device safety and performance literature search is conducted according to the approved protocol, the medical writer assesses the set of acquired articles. This includes a systematic process of appraising and weighting the articles in addition to sorting and tabulating the studies by study design. Each article is analyzed, and the data that pertain to the safety and performance of the device are extracted and organized. These data are often tabulated according to the specific safety and performance objectives identified for the clinical evaluation of the device(s). Additional points of discussion include the device(s)'s use in various patient populations, off-label use, unknown complications, and clinical benefits. The literature search protocol(s), literature search report(s), and full text copies of the relevant articles become a part of the clinical evidence included in the CER. They should also be included in the technical documentation for the device (MEDDEV 2.7/1, Rev. 4, Section 8.2).

4.5 Summary and appraisal

This brief section summarizes the types of clinical and nonclinical data that are available for analysis along with the appraisals of each set of data. The appraisal criteria should have been previously defined in the CEP, and the weighting of the clinical data is included here.

4.6 Analysis of the clinical data

In the following sections, all the clinical, nonclinical, risk management, and other applicable data are analyzed to demonstrate compliance with the GSPRs for safety, performance, and the acceptability of the benefit/risk profile (**Figure 1**). The safety and performance of the device(s) in the clinical literature should be compared across datasets and to the safety and performance acceptance criteria. The medical writer ensures that the presentation of the 3 types of clinical data (clinical investigations, postmarket surveillance, clinical literature) is consistent, which allows for a conclusive discussion on conformity with the GSPRs.

4.6.1 Requirement on safety (GSPR 1)

GSPR 1 is defined in Annex I, Chapter 1 of EU MDR (**Figure 3**). Conformity with the safety aspect of GSPR 1 is demonstrated in this section. The entirety of the clinical and nonclinical data collected on the safety of the device(s) is collated and compared against the previously identified safety objectives and the safety outcomes identified across the medical landscape in the state-of-the-art review. Throughout the main body of the CER, the intended conditions or on-label use is defined, labeling is discussed, and data are presented. The medical writer combines all these aspects together to demonstrate safety. Additional aspects considered in this analysis include the appropriate documentation of risk management activities, appropriate documentation of safety in the labeling, and a usability assessment.

4.6.2 Requirement on acceptability of side-effects (GSPR 8)

GSPR 8 is defined in Annex I, Chapter 1 of EU MDR (**Figure 3**). In addition to the identified safety objectives, all adverse events identified in the clinical data and through risk management activities should be considered and minimized as possible. While consideration to systematic off-label use should be addressed by the manufacturer, conformity with GSPR 8 is restricted to on-label use of the device.

4.6.3 Requirement on performance (GSPR 1)

In addition to the requirement on safety, GSPR 1 requires that the manufacturer demonstrates the performance and suitability of the device(s) for the intended purpose. The clinical and nonclinical data collected in the body of the CER are compared against the identified performance objectives and against the performance endpoints identified in the state-of-the-art literature.

4.6.4 Requirement on acceptable benefit/risk profile (GSPR 1 and 8)

The clinical benefit of a device is the "positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s)." (Article 2[53] of EU MDR). These clinical benefits must outweigh the known and foreseeable risks of the device when used as intended. Consideration for special features such as pharmaceutical components and animal or human tissue inclusion needs to be addressed in this analysis. Additionally, the benefit/risk profile should be placed in context of the available

treatment or diagnostic modalities available to the end user.

5. Conclusions

Finally, the medical writer provides a valid conclusion on the achievement of the intended performances and on the acceptability of risks and side-effects when weighed against the intended benefits of the device(s) based on the body of clinical evidence reviewed while taking into account the state-of-the-art. Any gaps in clinical evidence identified during the clinical evaluation are discussed and plans to address those gaps are defined through PMCF activities.

Figure 3: General Safety and Performance Requirements Relevant to the CER

Devices shall achieve the **performance** intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are **suitable for their intended purpose**. They shall be **safe and effective** and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute **acceptable risks when weighed against the benefits to the patient** and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.[1]

All known and foreseeable risks, and any **undesirable side-effects**, shall be minimised and be acceptable when **weighed against the evaluated benefits** to the patient and/or user arising from the achieved performance of the device during normal conditions of use.[1]

[1] Annex I, Chapter 1 of EU MDR

6. Date of the next evaluation

The manufacturer must define and justify the intervals at which the clinical evaluation should be conducted on the device(s) (MEDDEV 2.7/1, Rev. 4, Section 6.2.3). The clinical evaluation should be conducted anytime new information from postmarket surveillance activities indicate a potential change to the benefit/risk profile. If no new information is received, then the next evaluation should be annually for high-risk device(s) (ie, Class IIb or Class III) or those that are not well established. For lower-risk device(s) (ie, Class I or Class IIa), the clinical evaluation can be carried out every 2 to 5 years, and a justification for the evaluation interval should be included.

7. Dates and signatures

The date of final release of the CER along with signed and dated statements from the evaluators indicating their agreement with the contents of the CER is included in this section.

8. Qualification of the responsible evaluators

MEDDEV 2.7/1, Rev. 4 defines the qualifications expected from the clinical

evaluators (Table 4). These qualifications can be fulfilled by an individual or team of evaluators. Each evaluator should provide documentation of their qualifications and experience and a declaration of interest.

9. References

All references included in the CER should be listed, including published clinical literature, internal reports, and guidance documents. A reference manager should be used to cross-link in-text references with the full bibliography in this section.

Table 4: Qualifications of the Evaluators

Consideration
Areas of Expertise
Research methodology (including clinical investigation design and biostatistics)
Information management (scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline)
Regulatory requirements
Medical writing (post-graduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review, and clinical data appraisal)
Device-specific Experience
Knowledge of the device technology and its application
Knowledge of the diagnosis and management of the conditions intended to be diagnosed or managed by the device
Training and Experience Qualifications
A degree from higher education in the respective field and 5 years professional experience
10 years of professional experience if a degree is not a prerequisite for a given task

Source: Adapted from MEDDEV 2.7/1, Rev. 4, Section 6.4

Conclusion

Since the introduction of EU MDR, medical device manufacturers have dedicated significant efforts to compliance. As these efforts transition to maintaining certification, the focus is shifting toward efficiently managing clinical data.

Fundamentally, the objective of the clinical evaluation is to assess the entirety of the clinical evidence supporting the safety and performance of medical device(s). This process involves the development and maintenance of various supporting documents authored by cross-functional teams, ensuring compliance with CE marking requirements.

Understanding the intricacies of the CEP and CER is crucial. The CEP defines the clinical evaluation scope, data types, risk analysis, and updates. The clinical evaluation itself involves cross-functional teams reviewing relevant data, updating documentation, and compiling results in the CER. Ultimately, the CER serves as the culmination of the evaluation process: collecting, appraising, and analyzing clinical data to confirm compliance with relevant GSPRs. The format and structure of the CER are tailored based on the quantity and type of data available on the subject device(s).

Insights from regulatory writers provide valuable perspectives when navigating the complexities of clinical evaluations. As the industry continues to adapt to regulatory changes and evolving best practices, maintaining a thorough understanding of clinical evaluation processes remains paramount for ensuring the safety and performance of medical devices in the European market.

References

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