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WHITE PAPER

State of the Art (SOTA) Analysis for Medical Devices

A Strategic Framework for Clinical Evaluation, Regulatory Compliance, and Lifecycle Evidence Generation

01 Introduction

The Growing Importance of State of the Art (SOTA) in Medical Device Regulation

The concept of State of the Art (SOTA) has become a cornerstone of modern medical device regulation. Under EU MDR 2017/745, manufacturers must continuously substantiate a device's safety, clinical performance, and benefit-risk profile throughout its lifecycle — not just demonstrate it once at market entry.

This represents a fundamental shift from the previous Medical Device Directive (93/42/EEC), where conformity to harmonized standards was often sufficient. Under the MDR, Notified Bodies apply greater scrutiny, and manufacturers must show that devices remain aligned with current science, clinical practice, and patient expectations — the essence of SOTA.

SOTA is often mistaken for a one-time literature review supporting the Clinical Evaluation Report (CER). In reality, under MDR Annex XIV and MEDDEV 2.7/1 Rev.4, it is the ongoing benchmark against which safety, performance, and benefit-risk are assessed — underpinning Clinical Evaluation, PMCF, PMS, Risk Management, and regulatory decisions across the device lifecycle. This paper examines what a rigorous, lifecycle-ready SOTA process looks like in practice.

02 Evolution of SOTA: From Static Literature Review to Lifecycle Evidence Generation

Historically, many manufacturers treated SOTA as a one-time literature review conducted during initial CE marking activities. Current regulatory expectations recognize that SOTA evolves continuously, driven by:

New clinical evidence	**Technological advancements**	**Changes in standards of care**
Updated clinical guidelines	**Emerging safety concerns**	**Introduction of competing technologies**

As a result, SOTA must be treated as a living process that supports decision-making throughout the product lifecycle — the bridge between evolving scientific knowledge and evidence-based regulatory decisions.



Figure 1. Key drivers of SOTA evolution across the medical device lifecycle.

03 Common Gaps in SOTA Assessments – and How to Reframe the Approach

A common regulatory observation is that manufacturers compile extensive literature summaries but fail to establish how those findings influence clinical evaluation and benefit-risk conclusions. Other common findings identified during SOTA assessments include:

- Reliance on historical publications that do not reflect current clinical practice
- Failure to incorporate recent recommendations from professional societies and clinical organizations
- Insufficient evaluation of competing technologies and newly marketed products
- Lack of an ongoing monitoring process for periodic reassessment of SOTA throughout the product lifecycle

An effective SOTA analysis should therefore move beyond literature collection and focus on answering three fundamental questions that underpin evidence-based regulatory decision-making:

Q1 **What is the current state of the art for the intended medical condition?**

Assess the current standard of care, available therapeutic options, alternative technologies, and contemporary clinical practice based on the latest scientific and clinical evidence.

Q2 **How does the device compare with the current state of the art?**

Evaluate whether the device demonstrates comparable or superior performance, safety, clinical benefits, and an acceptable benefit-risk profile relative to existing treatment options and competing technologies.

Q3 **What additional evidence is required to demonstrate continued conformity?**

Identify remaining evidence gaps, uncertainties, or emerging risks that require further clinical investigation, PMCF activities, post-market surveillance, or updates to risk management documentation.

Answering these three questions consistently requires more than an ad hoc literature search — it calls for a structured methodology that organizes evidence across the full range of sources relevant to a device's clinical and technological context.

04 A Four-Domain Framework for SOTA Analysis

COD Research addresses this need through a Four-Domain SOTA Framework that integrates clinical, technological, scientific, and post-market evidence into a structured methodology. Rather than treating these evidence sources independently, the framework provides a structured approach for integrating diverse evidence sources into regulatory decision-making across the medical device lifecycle.

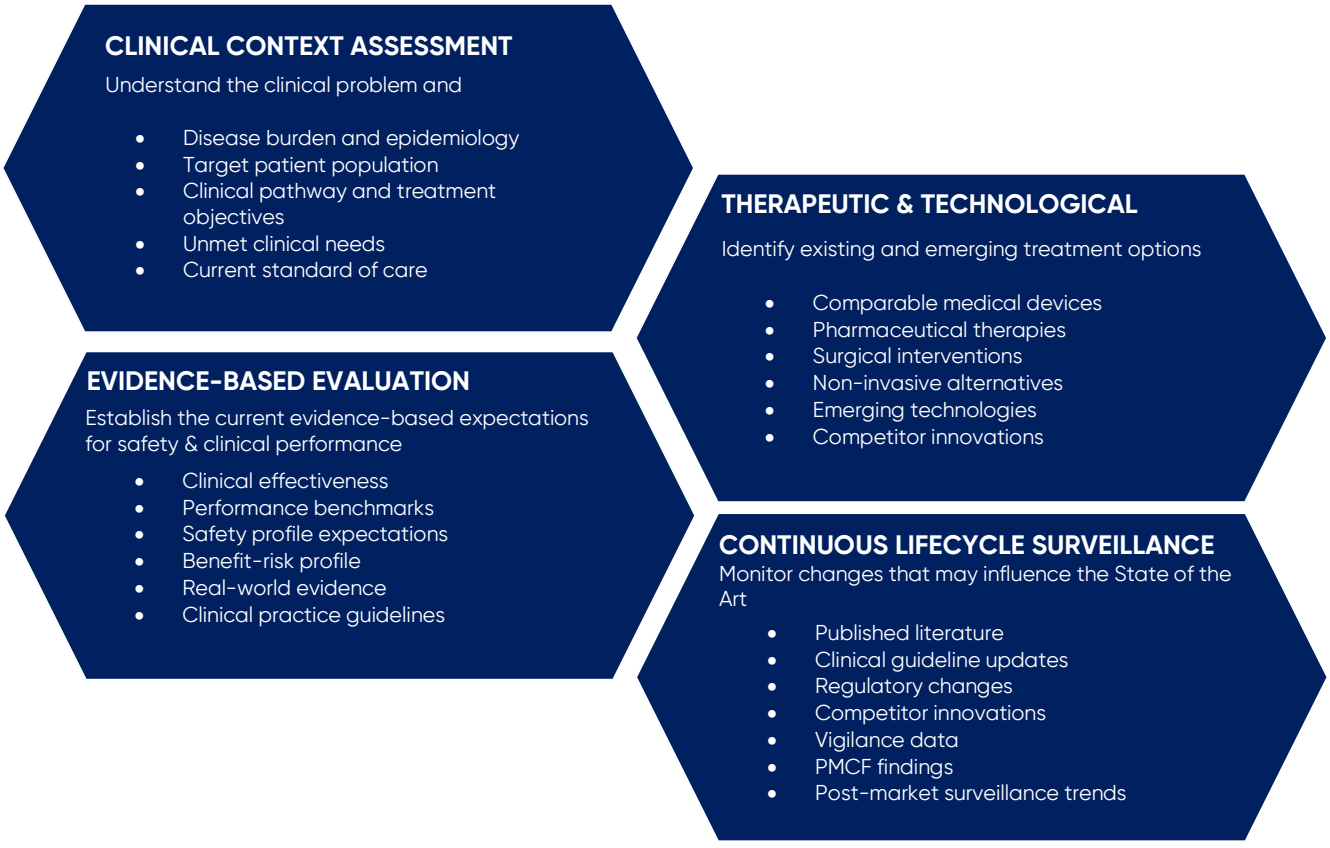


Figure 2. The Four-Domain Framework for SOTA analysis.

05 Application of the Four-Domain SOTA Assessment Framework Across Medical Device Activities

The Four-Domain SOTA Assessment Framework integrates clinical, technological, scientific, and post-market evidence into a structured methodology that supports evidence-based decision-making across development, regulatory approval, and post-market surveillance. By continuously evaluating evolving medical knowledge, manufacturers can ensure that their devices remain aligned with contemporary clinical practice, regulatory expectations, and patient safety requirements.

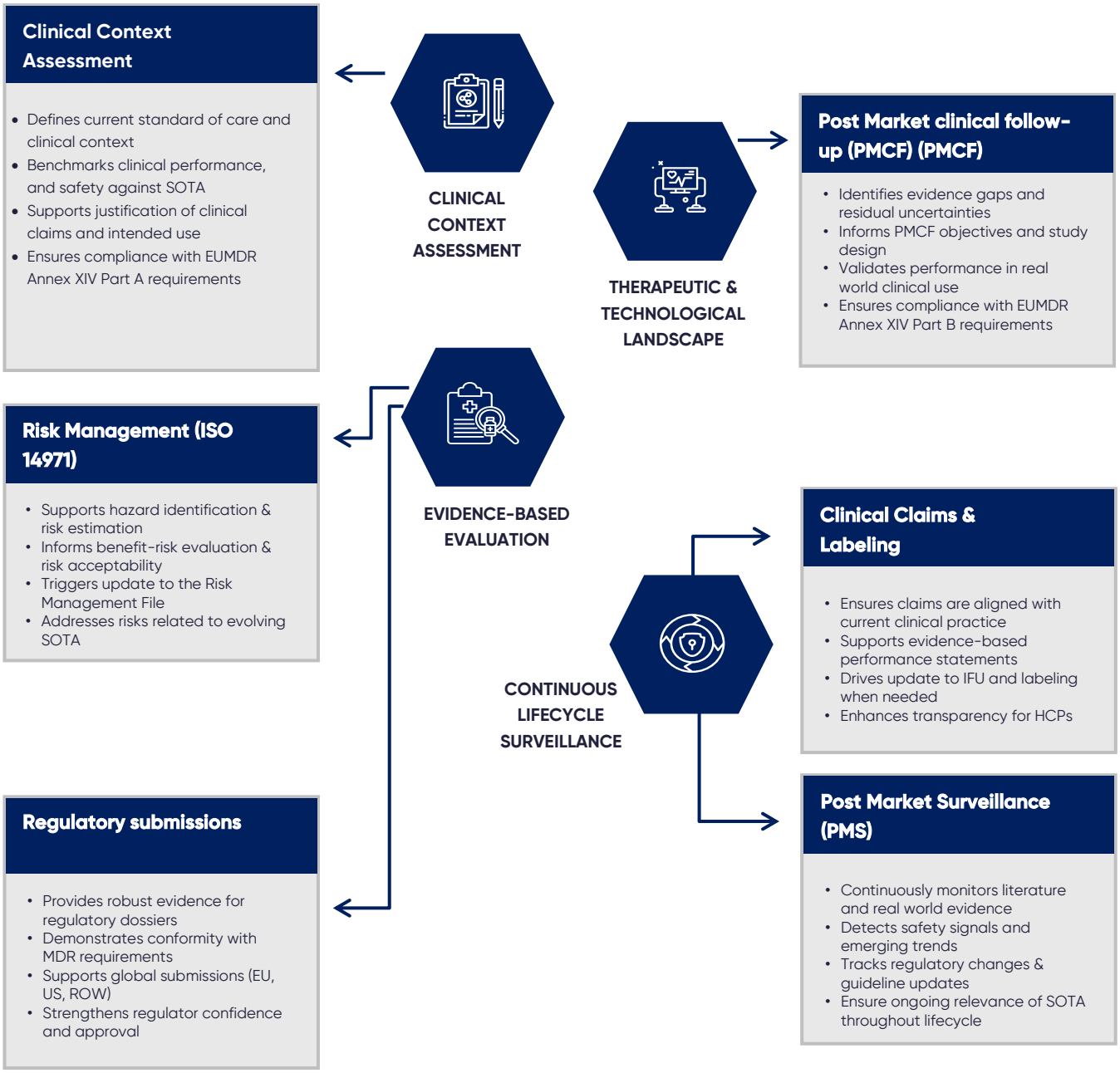


Figure 3. Mapping the Four-Domain Framework to clinical evaluation, PMCF, PMS, risk management, clinical claims, and regulatory submissions.

The value of a structured SOTA assessment lies in its ability to transform diverse evidence sources into regulatory decisions that support the entire product lifecycle. Rather than generating independent evidence for each regulatory activity, manufacturers can leverage a single, continuously updated SOTA assessment to inform multiple interconnected processes. This integrated approach improves consistency, reduces duplication of effort, and strengthens the scientific justification supporting regulatory documentation.

Clinical Evaluation (CER)

Clinical evaluation represents one of the primary applications of SOTA analysis. The framework establishes the current standard of care, identifies relevant comparator devices and alternative therapies, and benchmarks expected safety, clinical performance, and clinical benefit. These assessments provide the scientific context required to demonstrate conformity with the General Safety and Performance Requirements (GSPRs) and to justify clinical claims throughout the Clinical Evaluation Report (CER).

Post-Market Clinical Follow-up (PMCF)

SOTA assessment also guides PMCF planning by identifying evidence gaps, residual uncertainties, and evolving technologies that may require additional clinical data. Findings from the Clinical Context, Therapeutic Landscape, and Evidence-Based Evaluation domains help define PMCF objectives, study endpoints, and target populations while ensuring continued demonstration of clinical benefit during routine clinical use.

Post-Market Surveillance (PMS)

Within the PMS system, SOTA serves as a dynamic surveillance process rather than a one-time literature review. Continuous monitoring of published literature, clinical practice guidelines, vigilance databases, regulatory communications, and competitor innovations enables manufacturers to identify emerging trends that may influence device safety, performance, or benefit-risk balance. These activities support periodic updates to the Clinical Evaluation Report, PMS Report, or Periodic Safety Update Report (PSUR), as appropriate.

Risk Management

Risk management under ISO 14971 requires manufacturers to continuously collect and evaluate production and post-production information. The Four-Domain Framework complements this requirement by incorporating newly published evidence, safety signals, post-market experience, and evolving standards into ongoing benefit-risk evaluation. Consequently, SOTA findings directly support hazard identification, risk estimation, risk acceptability, and updates to the Risk Management File throughout the device lifecycle.

Clinical Claims and Labelling

Clinical claims must remain scientifically valid throughout the commercial life of a medical device. By comparing the device against current therapeutic alternatives and evolving standards of care, SOTA assessment ensures that claims relating to safety, performance, intended purpose, and clinical benefit remain supported by contemporary evidence. Where necessary, SOTA findings may trigger revisions to Instructions for Use (IFU), labelling, or promotional materials to maintain regulatory compliance.

Regulatory Submissions

The Four-Domain Framework also supports multiple regulatory submissions, including Clinical Evaluation Reports, Technical Documentation, PMCF Evaluation Reports, Design Dossiers, and global regulatory applications. Because the framework integrates clinical evidence with post-market experience and evolving regulatory expectations, it provides a robust scientific basis for demonstrating continued conformity throughout the product lifecycle.

06 Operationalizing the Four-Domain SOTA Framework with COD Research

The Four-Domain Framework delivers the most value when it runs as a continuous service rather than a series of standalone deliverables. At COD Research, we're structured to deliver this integrated approach in practice — something manufacturers often intend but struggle to execute consistently once surveillance, CER updates, and PMS reporting are handled by different teams or timelines.

Our methodology emphasizes continuity of evidence across the product lifecycle, enabling multiple regulatory activities to draw from a consistent scientific foundation while maintaining traceability and alignment with current regulatory expectations.

The framework is designed to support both initial evidence generation and ongoing lifecycle maintenance, allowing organizations to adapt the depth and frequency of assessment according to product maturity, regulatory requirements, and post-market experience.

Information generated through SOTA assessment can support multiple regulatory activities, promoting consistency while reducing unnecessary duplication of effort.

Because the same evidence base underpins every deliverable, cross-functional alignment of evidence facilitates consistency across lifecycle documentation and supports regulatory traceability.

This integrated methodology enables manufacturers to maintain documentation that reflects current State of the Art throughout the product lifecycle, facilitating regulatory inspections, Notified Body assessments, and ongoing compliance with EU MDR expectations.

07 Conclusion

- State of the Art analysis has evolved from a regulatory documentation exercise into a strategic process that supports clinical evaluation, risk management, post-market surveillance, and regulatory decision-making throughout the medical device lifecycle.
- A robust SOTA framework enables manufacturers to demonstrate alignment with current scientific knowledge, clinical practice, and technological innovation while maintaining compliance with evolving global regulatory expectations.
- Manufacturers that embed SOTA as a structured evidence integration approach — not merely a regulatory requirement — will be better positioned to maintain compliance, respond to evolving clinical practice, and demonstrate sustained clinical value throughout the product lifecycle.

References

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COD Research helps medical device manufacturers build and maintain defensible, lifecycle-ready SOTA assessments. To discuss how the Four-Domain Framework can be applied to your clinical evaluation, PMCF, PMS, or risk management program, contact our team.

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