

4BetterDevices Series on
Systematic Searches and Reviews

HOW TO CONDUCT

CLINICAL BACKGROUND REVIEWS

VERSION 2

How to conduct
medical background
SOTA ANALYSES

4BetterDevices GmbH

Version 2

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Version History

Version 1	First version released.
Version 2	Fixed condition-based SOTAs questions table. Fixed query section.

*To the memory of Gerold Labek—
your insights have made a lasting difference.*

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Acronyms

BfArM Bundesinstitut für Arzneimittel und Medizinprodukte

CDP Clinical Development Plan

CEP Clinical Evaluation Plan

CER Clinical Evaluation Report

DAEN Database of Adverse Event Notifications

HTA Health Technology Assessment

ICTRP International Clinical Trials Registry Platform

MAUDE Manufacturer and User Facility Device Experience

MHRA Medicines and Healthcare products Regulatory Agency

PICO Population/Patient/Problem, Intervention/Investigated condition, Comparison, Outcome

PMCF Post-Market Clinical Follow-up

PMS Post-Market Surveillance

PSUR Periodic Safety Update Report

QMS Quality Management System

SOTA State of the Art

Chapter 1

Introduction

State of the Art (SOTA) analyses are the backbone of any technical documentation. Don't believe it? Let's put it to the test.

Before developing your device, you likely assessed what the medical field needs—congratulations, that's a SOTA analysis. To market your device competitively, you probably researched what other manufacturers are doing—again, SOTA. Struggling to define acceptance criteria for your clinical evaluation? That's because you need a solid SOTA foundation. Determining the clinical benefit of your device compared to existing treatments? SOTA. Defining meaningful endpoints for clinical studies? SOTA. Identifying device harms, risks, and probabilities for risk management? You guessed it—SOTA. The same applies to Post-Market Surveillance (PMS): if you want to interpret incident data beyond just “3 incidents per 1,000 devices—sounds small,” you need SOTA insights at your fingertips. Which standards are relevant for your device or your company? SOTA analysis. And what about the applicable guidance? SOTA, SOTA, SOTA.

The above examples should make clear that SOTA is not just for clinical evaluation. It is essential for research and development, marketing, sales, risk management, post-market surveillance, and even QMS.

Yet, if SOTA is so important, why do so many companies get it wrong? Because, currently, there is

no proper guide on how to do it right. This document is here to change that.

While the identification of SOTA has gained particular relevance in Europe with the introduction of MDR, the information in this document applies to certification worldwide, not just in the EU. Let's start.

💡 BOX 1: Search, review, meta-analysis, umbrella review

The terms “systematic search” and “systematic review” are not synonymous.

A systematic review begins with a systematic search but also includes critical appraisal and a structured synthesis of the evidence, either qualitatively or quantitatively.

Systematic reviews that synthesize results quantitatively are called meta-analyses.

Finally, umbrella reviews synthesize multiple systematic reviews and meta-analyses.

1.1 Making clarity on SOTA

Let's begin our journey into SOTA analyses by addressing some of the most common misconceptions. The confusion often starts with the terminology itself. Many companies refer to SOTA analyses as *the* literature search, a phrasing that reflects two key misunderstandings.

First, most SOTA activities are not merely literature searches. Instead, they take the form of systematic reviews, meta-analyses, or umbrella reviews (see Box 1 for an explanation of these terms). This means that SOTA analyses go beyond simply retrieving literature—they involve a structured synthesis, either textual or numerical.

Second, a SOTA analysis is not a single, monolithic process. Figure 1.1 illustrates Typical list of systematic searches and reviews required to establish the state of the art for a medical device. The analysis begins with a systematic review to establish the medical background (the focus of this document). This review is the topic of this document.

The analysis then proceeds with meta-analyses to evaluate the performance and safety of medical alternatives (a dedicated guide on this will follow soon), which typically provides the criteria for the acceptance of benefit and performance in the clinical evaluation.

Additionally, SOTA analyses extend beyond clinical evidence, and include the identification of medical devices, applicable regulations, standards, and guidance. We will address these additional searches and reviews in the upcoming articles.

Another major misconception that affects the way companies conduct SOTA analyses—and ultimately their effectiveness—is the belief that SOTA analyses should be planned within the CEP. This is a common mistake, where searches are structured in the CEP and merely summarized in the CER. When done this way, the foundation for developing the CDP is missing.

For example, without a proper SOTA analysis, it is impossible to define *“an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device,”* as required by MDR Annex XIV for the CEP.

In reality, the SOTA analysis serves as underpinning of a wide range of regulatory processes, including state of the art analyses, research and development, risk management, and post-market surveillance. It should, therefore, be planned be-

fore these processes start.

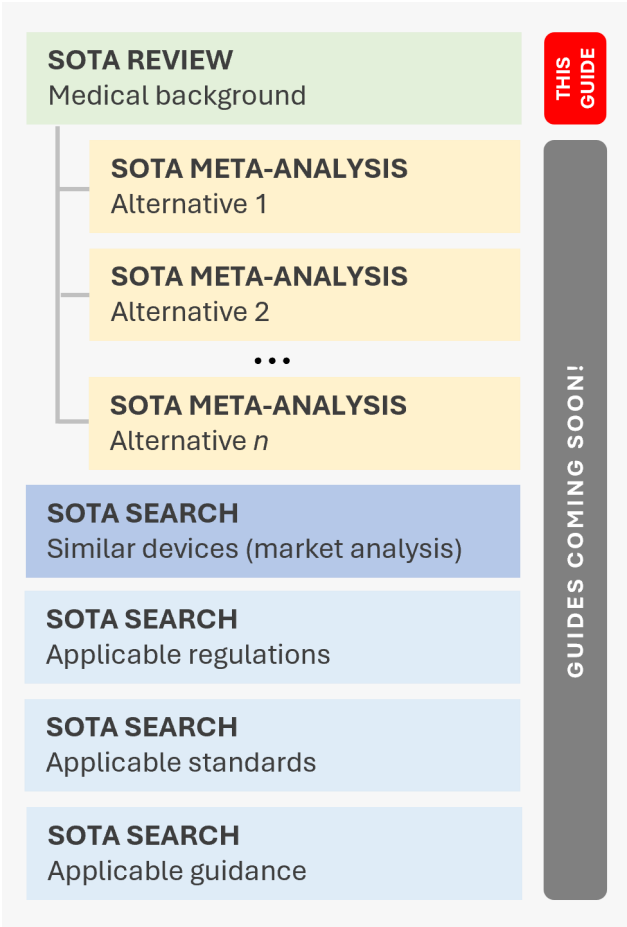


Figure 1.1: Typical list of systematic searches and reviews required to establish the state of the art for a medical device.

One notable—albeit very rare—exception is when the medical field cannot be identified through medical literature alone. In such cases, manufacturers would have to plan investigations to establish the clinical background within the CEP.

A final note: SOTA analyses are not the only systematic searches and reviews conducted in the pre-market phase (i.e., before receiving market access). Some systematic searches belong to PMCF and are carried out before certification, even though they are technically part of PMS. Figure 1.2 lists these searches.

Before continuing, we encourage you to read about post-market searches, which are detailed in our guidance POST-MARKET SEARCHES. Medical background SOTA analyses are, in many ways, mirror approaches to post-market searches. Comparing the two frameworks helps

understanding how to take decisions on planning, executing, documenting, and updating these searches. That is also the reason why at the end of chapter 2, we provide a side-by-side comparison of medical background SOTA analyses and post-market searches.



Figure 1.2: Typical list of post-market searches and reviews that should be conducted in pre-market.

You might ask: “How do I know whether a search or review belongs to SOTA or PMS?”. For example, consider a SOTA search on similar devices and a post-market search on the same subject—how do you differentiate between them? A simple rule applies: SOTA searches and reviews never include a specific device trade name in their queries. If your search is focused on a particular device, it is almost certainly a post-market search.

There is only one exception: when a specific device brand represents the state of the art in the medical field. That, however, is extremely rare.

1.2 Medical background

Now, let’s get to the core of the matter. This is where things become a bit more complex, but we can break it down step by step.

This guide covers the first type of analysis in Figure 1.1: the medical background analysis. This analysis helps clinical reviewers understand the broader medical context in which your device operates, including its role, alternatives, and clinical relevance.

There are two types of medical background anal-

yses:

- condition-focused and
- procedure-focused.

The first type—condition-focused—is aimed at device that are aimed at specific conditions. The term “condition” is not explicitly defined in regulatory guidance. However, it is widely used in medicine to describe a broad category of health issues, including diseases, injuries, disabilities, pathological processes.

The second option applies when your device is intended to assist, enable, or perform a medical procedure, regardless of the underlying condition.

Determining which type is needed for your device depends on whether its indication is condition-based or procedure-based. In version 3 of our guide on creating an intended purpose—see [INTENDED PURPOSE](#)—we cover this distinction in detail. We strongly encourage reading that guide before proceeding.

A condition-based medical background SOTA analysis systematically examines the current state of knowledge, clinical practices, and therapeutic approaches related to a specific medical condition. Instead of focusing on a single device or procedure, this analysis provides a comprehensive overview of all available alternatives for achieving the intended medical purpose. For example, if evaluating a device for diabetes diagnosis, the analysis would explore various diagnostic criteria and methods used for this condition.

A procedure-based medical background SOTA analysis, on the other hand, systematically examines the techniques and technologies used to perform a specific medical function. For instance, if the device under review is a thermometer, the analysis would cover all recognized methods of temperature measurement.

At this stage, the SOTA analysis remains technology-agnostic, concentrating on the procedural category rather than individual technical alternatives. This means you are not yet investigating specific implementations (e.g., capillary vs. infrared thermometers). Instead, the goal is to identify alternative methods, emerging innovations, and evidence-based best practices

within the field.

Similarly, analyzing the performance and safety characteristics of the identified alternatives is not yet required at this stage. This evaluation will be conducted in the next phase of the SOTA process, specifically during the meta-analysis of identified medical alternatives (see Figure 1.1).

Finally, remember that if your device has multi-

ple indications—such as both the diagnosis and prevention of diabetes—you are expected to provide a medical background for each indication (diagnosis of diabetes and prevention of diabetes).

Medical background analyses Post-market searches are systematic reviews. This means that they must be planned, conducted, reported, and updated according to best practices. Below, we outline these best practices.

Chapter 2

Planning the search

This chapter outlines the key elements to consider when planning medical background SOTA analyses. These include defining objectives, selecting sources, developing a search strategy, and establishing appraisal criteria. For additional guidance on planning systematic searches and reviews, you may refer to the [PRISMA 2020 statement](#).

We also encourage you to read about medical background SOTA analyses, which are detailed in our guidance **SOTA_BACKGROUND**. Post-market searches are, in many ways, mirror approaches to medical background SOTA analyses. Comparing the two frameworks helps understanding how to take decisions on planning, executing, documenting, and updating these searches. That is also the reason why at the end of this chapter we provide a side-by-side comparison of post-market searches and medical background SOTA analyses.

2.1 Evaluators

Specify who will perform the review. The definition of specific roles (such as author, reviewer, approver, etc.) typically depends on company-specific procedures.

The requirements of [MEDDEV 2.7/1](#) concerning the expertise of clinical evaluators also applies to post-market searches. These requirements include knowledge of:

- research methodology (including clinical investigation and biostatistics);
- information management;
- regulatory requirements;
- medical writing;
- the device technology and its applications,
- diagnosis and management of the conditions intended to be diagnosed or managed by the device, knowledge of medical alternatives, treatment standards and technology.

In addition, evaluators must possess a relevant degree from higher education in the respective field and 5 years of documented professional experience, or 10 years of documented professional experience if a degree is not a prerequisite for the given task.

2.2 Review questions

As mentioned earlier, the goal of medical background SOTA analyses is to provide an objective, unbiased overview of standard medical practice related to a specific condition or procedure.

Relevant medical literature is systematically retrieved, and information is extracted from each source to address the specific review questions. These questions, which guide data extraction, are defined in the objectives section of the review plan. Table 2.1 summarizes these questions

for a condition-based medical background SOTA analysis.

Questions for condition-focused SOTAs
<i>Definition:</i> What is the definition of the condition?
<i>Coding:</i> What are the specific codes for the condition in different medical coding systems (e.g., ICD-10, ICD-11, SNOMED)?
<i>Names:</i> Are there other medical or commonly used names for the condition?
<i>Etiology:</i> What is the cause or origin of the condition?
<i>Grading:</i> Are there standardized grading systems to classify or assess the severity of the condition?
<i>Epidemiology:</i> What is the distribution, prevalence, and incidence of the condition in different populations?
<i>Pathophysiology:</i> What are the functional and biological changes caused by the condition?
<i>Clinical presentation:</i> What are the signs, symptoms, and laboratory findings associated with the condition?
<i>Differential diagnosis:</i> What other conditions could present similarly to this condition?
<i>Risk factors:</i> What conditions, behaviors, or predisposing factors increase the likelihood of developing this condition?
<i>Natural course:</i> What is the expected progression of the condition, with and without treatment?
<i>Prognosis:</i> What is the anticipated outcome or long-term course of the condition?
<i>Complications:</i> What are the possible complications associated with the condition?
<i>Cultural and regional variations:</i> How do presentation, treatment, and outcomes vary across different populations and regions?
<i>Clinical outcomes and assessment tools:</i> What are the key clinical outcomes and validated assessment tools used to evaluate the condition?
<i>Medical alternatives:</i> What are the available medical alternatives available for (select based on your device purpose) preventing / predicting / prognosing / diagnosing / treating / etc. the condition? Which alternatives are considered outdated, standard of care, novel, first-in-line, second-in-line, supportive/adjuvant, gold-standard? Which alternatives can be combined?

Table 2.1: List of typical questions concerning a condition to be answered in a medical background SOTA analysis.

Table 2.2 summarizes the questions concerning a procedure to be answered in a procedure-focused medical background SOTA analysis.

2.3 Source selection

The objective of medical background reviews is to identify the highest-quality, evidence-based information from the most reliable and reputable sources—the “cream” of the literature.

Questions for procedure-focused SOTAs
<i>Definition:</i> What is the definition of the type of procedure?
<i>Names:</i> Are there other medical or commonly used names for this type of procedure?
<i>Medical alternatives:</i> What are the available medical alternatives for performing the procedure? Which alternatives are considered outdated, standard of care, novel, first-in-line, second-in-line, supportive/adjuvant, or gold-standard? Which alternatives can be combined?

Table 2.2: List of typical questions concerning a procedure to be answered in a medical background SOTA analysis.

These criteria define the requirements for databases relevant to SOTA analyses.

1. The selected databases should be specialized in medical and life sciences literature.
2. Gray literature, preprints, and non-peer-reviewed sources are not of interest.
3. Full-text indexing is unnecessary. Since the focus is on high-level analyses related to the condition or procedure of interest, relevant publications should explicitly mention these terms in their title or abstract.
4. Reproducibility is crucial in medical background SOTA searches. Consequently, search engines like Google Scholar, which lack transparency and consistency in their search algorithms, are not recommended for this purpose.

It is important to highlight that these source requirements apply specifically to medical background SOTA analyses and do not necessarily extend to all searches conducted for technical documentation. For instance, post-market searches—outlined in our guide POST-MARKET SEARCHES—prioritize breadth over

reproducibility and therefore permit the use of sources such as Google Scholar.

Below is a minimum list of source types that post-market searches should rely on:

- Scholarly articles
- Systematic reviews and meta-analyses
- Medical associations websites

Below, we will consider each source type in detail.

2.3.1 Scholarly articles

The term “scholarly articles” refers to publications authored in academic settings. It is standard practice to begin with cross-publisher sources, as they streamline the search process by aggregating content from multiple publishers in one place. We recommend using two freely available aggregated sources that meet the four criteria outlined above: PubMed (US) and Livivo (EU).

Once you’ve completed your search in aggregated databases, you can turn to publisher-specific platforms. If you are aware that a specific journal or publisher is particularly likely to publish relevant data on the device you are researching, consider supplementing the aggregated database search with searches in the specific publisher’s databases.

2.3.2 Systematic reviews and meta-analyses databases

Systematic review and meta-analysis databases serve as repositories for research that follows structured methodologies to synthesize evidence on a given topic. These databases often include records of planned or ongoing systematic reviews rather than the full published studies themselves. Such records typically contain essential details about the review process, including objectives, inclusion criteria, data extraction methods, and planned analyses—elements collectively referred to as the protocol.

By registering systematic reviews in these databases, researchers enhance transparency, minimize duplication of efforts, and reduce the risk of publication bias. Importantly, these databases might not host the full systematic reviews or meta-analyses but instead provide

structured summaries that allow users to track ongoing research efforts and verify whether a particular review is already in progress.

PROSPERO is an international database specifically dedicated to prospectively registering systematic review protocols, primarily in health and social care. It ensures methodological transparency by requiring detailed information on the review plan before data extraction begins.

The **CDSR**, managed by the Cochrane Collaboration, is a key resource for high-quality, peer-reviewed systematic reviews in healthcare, often considered the gold standard due to its rigorous methodology and evidence synthesis approach. Access to CDSR articles may be geo-blocked in your country. If so, consider “traveling” to locations that allow access. A list of such locations can be found [here](#).

2.3.3 Websites

Medical associations Medical associations often publish clinical guidelines and position statements that reflect the current standard of care for specific conditions, procedures, or interventions. These guidelines are typically developed through expert consensus, systematic reviews, and evidence-based methodologies. Searching the websites of relevant national and international medical associations can provide access to high-quality recommendations that may not be fully indexed in standard databases. For example, organizations such as the American Heart Association (AHA), European Society of Cardiology (ESC), or the World Health Organization (WHO) regularly update their clinical practice guidelines. If a particular association has published a guideline relevant to your topic, it is worth reviewing their full list of documents and position statements, as well as monitoring updates or ongoing guideline development efforts.

2.3.4 Hand search

Hand searching originated in an era when researchers manually sifted through physical sources in libraries. Today, with searches conducted primarily online, it is essential to specify where each record was located to ensure transparency and reproducibility. In the context of medical background SOTA analyses, the use

of hand searching is deprecated because the goal is to identify the highest-quality, evidence-based information—the “cream” of the literature. If a source does not appear through systematic database searches, its relevance and reliability are questionable, making it inappropriate to introduce it arbitrarily.

2.3.5 Which sources you don't need

Medical background SOTA analyses generally benefit little from including clinical trial registries, such as [ICTRP](#) or [ClinicalTrials.gov](#). This is because, whenever possible, these analyses prioritize higher levels of evidence that synthesize and summarize findings from individual trials.

You do not need to search safety information databases (e.g., incident and adverse event databases such as [MAUDE](#) or [DAEN](#), or databases tracking actions by manufacturers or authorities, such as [MHRA](#) or [BfArM](#)). This is because SOTA analyses typically do not focus on specific devices.

At this stage of the SOTA process, you do not need to include Health Technology Assessments (HTAs). Even if your SOTA is procedure-based, you are analyzing a medical procedure itself, not a specific technology used to implement that procedure. We will consider HTAs when discussing SOTA analysis concerning the performance and safety of specific alternatives.

In the market, you'll find plenty of paywalled databases claiming to deliver more relevant results for device searches. However, in our experience, these sources often fall short compared to the freely available ones we highlighted in the search strategy above. A CE mark can be achieved successfully without relying on these paywalled options.

2.4 Search strategy

Post-market searches aim to identify any written information concerning a specific device. For this reason, the search strategy should be as broad as possible, while remaining manageable. Below are the key steps.

2.4.1 Inclusion criteria

Medical background SOTA analyses reviews apply a version of the [PICO](#) framework that addresses clinical questions related to interventions, exposure, and risk/prognostic factors: (P)atient, (I)nvestigated condition or procedure, (C)omparison, and (O)utcomes.

For medical background SOTA analyses, the *P* typically represents one of the target populations relevant to the device under evaluation. In condition-based SOTA, the *I* (Investigated condition) refers to the condition under analysis. In procedure-based SOTA, the *I* (Intervention) represents the medical procedure being evaluated.

At this stage of the SOTA process, *C* (Comparison) and *O* (Outcomes) are often not strictly defined and can remain broad or unspecified.

2.4.2 Queries

For condition-based SOTAs, use the condition's name, including alternative terms or synonyms. For procedure-based SOTAs, use the name of the procedure. You can also tailor the query to restrict the level of evidence (see Section 2.4.3). Indeed, that database filters are not always reliable—some records may be misclassified or incorrectly included. For example, in PubMed, studies are sometimes tagged with the wrong evidence level.

2.4.3 Limits and filters

Targeted level of evidence

Medical background SOTA analyses aim to retrieve the highest level of evidence available in the medical field for the specific condition or procedure under review. The following represents the typical hierarchy of evidence considered in systematic reviews, from which the most relevant and highest-quality sources should be selected:

1. Evidence-based guidelines
2. Systematic reviews / meta-anal.
3. Randomized controlled trials
4. Observational / cohort studies
5. Case studies, mechanistic reasoning, low-

quality evidence.

Time Period

The search timeframe is typically set to the last 5, 10, or 20 years, depending on the update frequency within the field:

- 5 years – Suitable for fast-evolving fields with frequent advancements (e.g., emerging medical technologies, novel drug therapies).
- 10 years – Used when significant advancements occur, but older studies may still be relevant (e.g., surgical techniques, chronic disease management).
- 20 years – Appropriate for slow-changing or rarely updated fields where foundational knowledge remains largely unchanged (e.g., basic physiology, rare diseases).

2.4.4 Exclusion criteria

For medical background SOTA analyses we recommend using a two-steps screening process: 1) Title and abstract screening to filter out clearly irrelevant records, followed by 2) Full-text screening to assess the relevance of the remaining records.

2.5 Synthesis

The synthesis step in a medical background SOTA analyses is primarily textual, focusing on summarizing and interpreting findings rather than conducting a meta-analysis unless the data allows for quantitative pooling.

2.6 Appraisal

For medical background SOTA analyses, appraisal occurs at two levels.

First, the appraisal of included records assesses their quality, risk of bias, and overall reliability. The choice of appraisal method depends on the study type of the retrieved records, which, in turn, is determined by the targeted level of evidence, as follows:

1. Evidence-based guidelines — Assessed using AGREE II (Appraisal of Guidelines for Research & Evaluation).
2. Systematic reviews / meta-analyses — Evaluated with AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews).
3. Randomized controlled trials — Appraised using the Cochrane Risk of Bias tool (RoB 2) or GRADE (Grading of Recommendations, Assessment, Development, and Evaluations).
4. Observational / cohort studies — Assessed with the Newcastle-Ottawa Scale (NOS) or the ROBINS-I tool (Risk of Bias in Non-Randomized Studies of Interventions). The GRADE framework is also applied to adjust for potential confounding and bias.
5. Case studies, mechanistic reasoning, low-quality evidence — Evaluated using the Joanna Briggs Institute (JBI) checklist.

Second, once the evidence has been synthesized, it is further classified according to the Oxford Centre for Evidence-Based Medicine (OCEBM) levels of evidence. Alternatively, other methods can be used, such as GRADE (Grading of Recommendations, Assessment, Development, and Evaluations), USPSTF (U.S. Preventive Services Task Force) grading system, NHMRC (National Health and Medical Research Council) evidence hierarchy, or SIGN (Scottish Intercollegiate Guidelines Network) levels of evidence, depending on the context and purpose of the review.

Table 2.3: Comparison of the plan characteristics between medical background SOTA analyses and post-market searches.

	Medical background SOTA (This document)	Post-market searches (see reference POST-MARKET SEARCHES)
Type	Systematic review	Systematic search
Objectives	The objective of medical background SOTA analyses is to provide an objective, unbiased overview about standard medical praxis concerning a specific condition or procedure.	Gather <i>any</i> written record that provides information about the performance and safety of a particular medical device.
Source Selection		
Scholarly article databases	• PubMed • Livivo	• PubMed • PMC • EU PMC • OpenAlex • Google Scholar
Publisher specific	Ad hoc	Ad hoc
Clinical trials	Rarely required	ICTRP
Health technology assessments		Rarely required
Incidents and adverse events	Rarely required	• MAUDE • DAEN • MDID
Actions by manufacturers and authorities	Rarely required	Database of any authority in countries in which the devices is sold
Patient registries	Rarely required	Ad hoc
Websites	• Medical associations	• Author websites • Manufacturer websites • App stores
Use of handsearch	Not acceptable	May be acceptable: reporting evidence has priority over how evidence is found.
Systematic reviews	• Cochrane CDRS • PROSPERO	Rarely required
Paywalled databases (e.g., Embase, Scopus, Web of Science)		Not required
Search Strategy		
Inclusion criteria	PICO strategy	Any record that reports information concerning the performance or safety of the device (in humans)
Queries	Condition or procedure name(s)	• Device name • Device name + manufacturer name (if device name too generic)
Time limits	Last 5, 10, or 20 years, depending on field update frequency.	From date device was brought onto the market to search date
Peer review	Records must be peer-reviewed	Records do not need to be peer-reviewed
Continues on the next page ...		

(Continued from previous page) Table 2.3: Comparison of the plan characteristics between medical background SOTA analyses and post-market searches.

	Medical background SOTA (This document)	Post-market searches (see reference POST-MARKET SEARCHES)
Search Strategy (continued from previous page ...)		
Level of evidence	The highest level among: 1. Evidence-based guidelines 2. Systematic reviews / meta-anal. 3. Randomized controlled trials 4. Observational / cohort studies 5. Case studies, mechanistic reasoning, low-quality evidence.	Any
Exclusion criteria	The record does not provide information concerning the performance and safety of the device (on humans)	• Non relevant patient population • Non relevant intervention • Non relevant comparator • Non relevant outcome
Synthesis	Textual synthesis	None
Appraisal	• Single study appraisal • Synthesis appraisal	Not required: appraisal will be conducted in the processes where data from the search are used.



Create successful medical background SOTA analyses even *with no regulatory expertise*. Follow the “review wizard”, answer the questions. **evidence** will *automatically* generate the full review plan, including objectives, search questions, inclusion and exclusion criteria, and appraisal plan. But that’s not all—**evidence** goes a step further by *automatically* conducting proposed searches across relevant scholarly, systematic review, and health technology assessment databases. Simply review the plan, lock it, and shift your focus to the science. No matter your level of regulatory expertise, **evidence** ensures you’ll get it right.

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Chapter 3

Conducting the search

This chapter outlines the key elements to consider when conducting a medical background SOTA analyses. These include collecting all database information such as search details and search results, retrieving missing information, screening and data extraction. Below we review each element in detail.

If you are familiar with our guide [POST-MARKET SEARCHES SOTA](#), you may skip this section, as it closely mirrors the content of that guide.

3.1 Search details

For each query in each source, provide as much relevant information as possible. This should include:

- The source name and link
- The original search query
- The actual search conducted by the database (including any automatic modifications or expansions to the terms)
- Any filters applied (e.g., publication type)
- Any limits or restrictions (e.g., date range)
- The name of the person who performed the search
- The date and time the search was conducted

💡 BOX 2: Searches with no results

The fact that a search returns no hits is an information on its own. You should document it to show to reviewers why a search strategy didn't provide results.

3.2 Search results

Document all records identified during database searches. Make sure the metadata are complete for all retrieved records, even for those you already plan to exclude. These should include:

- Full citation details (e.g., title, authors, journal, volume, issue, page numbers, year, report number, study number)
- Any further information required to uniquely identify the record (e.g., incident number or trial identifier)
- The abstract of scholarly articles (some scholarly articles does not provide an abstract, you should note this information in the documentation)
- The text of all records that you scan on full text.

You can retrieve missing metadata by cross-verifying with other databases or the publisher's website.

3.3 Deduplication

Before processing the records you must identify duplicates. While this may seem straightforward, there are several common misconceptions about the process (see also Box 3). Finding duplicates involves identifying instances where the same record appears across different searches within the same source or from multiple sources. However, this task is more complex than it seems, as the same record may be represented with different metadata in different sources. It's important to note that for one record to be considered a duplicate of another, it must represent the exact same full text. For instance, a preprint is *not* a duplicate of the corresponding journal-published article, as editorial changes may have occurred during final publication.

BOX 3: Duplicated records vs. duplicated data

It is not uncommon that researchers publish the results of a single study across multiple publications. In the terminology of the PRISMA 2020 flow diagram, this is described as multiple reports corresponding to the same study (see also box 4). Some may refer to this situation as “duplicated data,” but it is important to clarify that two distinct publications based on the same dataset are not considered duplicate records.

3.4 Translation

Translate relevant non-English documents for inclusion in the analysis. Ideally, translations should be performed by a field expert proficient in both languages. However, in practice, notified bodies in Europe currently accept automated translations.

3.5 Screening

For each identified record, clearly indicate whether the record is included or excluded based on the exclusion criteria outlined in Section 2.4.4. For each excluded record, document the specific exclusion criterion applied.

3.6 Full text

You are expected to retrieve the full text of all records that you include during the screening. For two-step screening (first screening on title and abstract, followed by screening on full text) you should also make available the full text of the records that were excluded during the second (full-text) screening step.

3.7 Contact the authors

Some information may be missing from the retrieved record. For example, articles often fail to clearly specify the model or variant of a device family or device, and details about the reported data may sometimes be unclear. In such cases, consider reaching out to the author of the article, field safety notice, or incident report. While responses are not guaranteed and may be rare, it is worth attempting to obtain clarification.

3.8 Citation search

The process of including records in the search does not end with the imports from the sources. For each record included during screening, you are expected to review the references cited within those articles (see MEDDEV 2.7/1, Section A4). This is because *literature found to be relevant is likely to cite other literature that is of direct interest to the manufacturer*. Indeed, even the PRISMA 2020 flow diagram (see also Section 4.1.3) provides a dedicated space for documenting records retrieved through citation search.

3.9 Data extraction

For each question defined in the objectives of your literature search plan (see Section 2.2), extract the information pertaining to that question from each record included in the screening. Document when a record does not provide information for a specific question.

If the record is a study report (see Box 4) it is best practice to extract basic study information for future retrieval. These include study characteristics such as country, number of sites, study direction, type (interventional or observational), design, inclusion and inclusion criteria, primary and secondary outcomes, follow-up and main results.



Save hundreds of hours of tedious work. **evidence** automatically captures queries, search date, search details, filters, and limits from your searches in PubMed, Google Scholar, PubMed Central, Europe PubMed Central, OpenAlex, Cochrane, Prospero, ICTRP, MAUDE, DAEN, MDID. It also automatically imports the search results and works in the background to retrieve missing metadata, including titles, authors, abstracts, journals, etc. **evidence** then automatically identifies duplicates and downloads the full text of open-access articles. But it doesn't end here **evidence** provides suggestion for the screening, automatically extracting study characteristics and answering the questions of your search objectives using the information from the full texts, and automatically synthesizing the extracted evidence for you.

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Chapter 4

Reporting the search

Reporting the search can be one of the most tedious and time-consuming tasks in systematic searches and reviews, especially when it comes to managing screening details and summaries. Below, we briefly outline the key principles for documenting medical background [SOTA](#) analyses.

If you are familiar with our guide [POST-MARKET SEARCHES](#) on [SOTA](#), you may skip this section. Apart from the reporting of synthesis results, the reporting of medical background [SOTA](#) analyses closely follows that of post-market searches.

4.1 Reporting the screening

To ensure total clarity, in the search report, you should include three types of screening summaries, each presented at a different level of granularity:

1. screening summary for each query in each source;
2. screening details for each item retrieved in the search;
3. a flow diagram overview of the screening for the totality of the records imported in the systematic search (see Section 4.1.3).

below we analyze each report in detail.

4.1.1 Screening report

Begin the screening summary by providing the reviewer with an overview of the different queries across the various sources. For each query in each source, include the following details:

1. The total number of records retrieved from the query.
2. The number of records that were ultimately included after screening.
3. The total number of records excluded during the screening process.
4. A detailed count of records excluded under each specific exclusion criterion.

4.1.2 Screening detail for each item

Provide detailed screening information for each item retrieved in the search, including the specific exclusion criteria applied. To streamline the review process, display the screening details alongside basic record information, such as the title, authors, and abstract/summary. This approach allows reviewers to quickly sample and verify your screening without needing to search for the information separately.

4.1.3 Flow diagram

The [PRISMA 2020](#) flow diagram—see [PRISMA 2020 statement](#)—is a standardized tool designed to summarize the retrieval and screening

process of studies (see Box 4). It is expected that you use this diagram to document each stage of the search process, including the number of records identified, screened, assessed for eligibility, and included in the final synthesis.

BOX 4: Record, report, study

The PRISMA 2020 guidance^a clarifies the difference between record, report and study.

Record—The title or abstract (or both) of a report indexed in a database or website (such as a title or abstract for an article indexed in Medline).

Report—A document (paper or electronic) supplying information about a particular study.

Study—An investigation, such as a clinical trial, that includes a defined group of participants and one or more interventions and outcomes. A “study” might have multiple reports.

^aBMJ 2021;372:n160

Results from search engines such as Google Scholar (see Section 2.3.1), from citation searches (see Section 3.8), and from websites (see Section 2.3.3) should be documented under the “*Identification of studies via other methods*”

part of the diagram.

4.2 Reporting the data

Ensure full transparency. Report every aspect of the data extraction for each included record. This includes the information extracted for each question outlined in the search objectives, study characteristics, and—if applying appraisal—the appraisal details for each record.

4.3 Synthesis

Medical background SOTA analyses are systematic reviews that include a synthesis step: summarizing the bits of information that were extracted from each relevant record. For this review, the synthesis is primarily textual, focusing on integrating findings from multiple sources into a coherent narrative.

To ensure transparency and traceability, each synthesized statement must be directly linked to the original sources from which the information was derived. This is done by placing references next to each synthesis, allowing readers to verify the supporting evidence. The synthesis should aim for clarity and conciseness while accurately reflecting the scope, quality, and limitations of the available literature.



Generate a submission-ready literature search protocol with just one click. Once screening and data extraction are complete, your work is done. Why waste time with clunky Excel tables or corrupted Word files? Simply download the protocol, sign it, and send it to your notified body. And don't worry—**evidence** organizes all full texts seamlessly, ensuring reviewers can easily follow every step.

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Chapter 5

Updating the search

The work of conducting medical background SOTA analyses does not stop with market approval. These searches must be continuously updated through regular intervals as part of post-market surveillance activities. Below we explain when, how, and how long you should be updating your medical background SOTA analyses.

5.1 When to update

At a minimum, updates are required to align with the updates to the clinical evaluation and PSUR, which should ideally be synchronized. According to the MDR, Article 86, and IVDR, Article 81, these updates must occur at least annually for high-risk devices. For other devices, updates may be less frequent but should still adhere to a periodic schedule defined by the manufacturer based on the risk classification and intended use of the device.

5.2 How to update

A common misconception about search updates is that using the “delta” approach is sufficient. This method involves updating a search by retrieving only the results published after the date of the last search. However, this approach is flawed because it overlooks how databases operate. Records are often added to databases with significant delays, meaning that older records can be added after the last search was com-

pleted. If your search update starts from the last date of your search, you will miss these results, as illustrated in Figure 5.1.

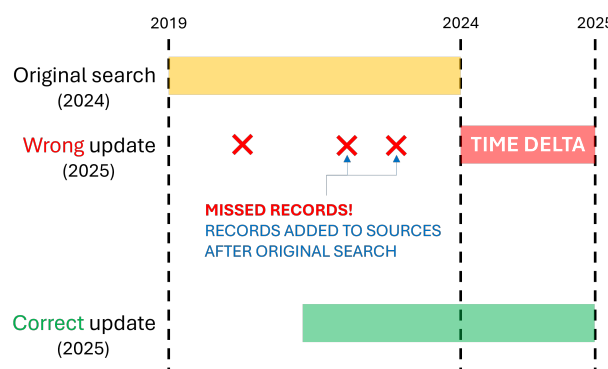


Figure 5.1: The “delta” approach for updating searches misses records that have been added to the sources after the last update. The correct way to update searches is to repeat the search across the full planned time frame.

The correct way to update searches—whether for state-of-the-art reviews or medical background SOTA analyses—is to repeat the search across the full planned time frame.

If you follow our recommendation to perform post-market searches without restrictive time filters (see Section 2.4.3), this means that each search update should cover the entire period from date the device was first placed on the market (anywhere in the world) onward. This does not mean, however, that you need to re-screen old records or extract again their data. You can

simply retain the results (screening and data extraction) from the previous search for any records that reappear in the updated results.

5.3 How long to update

You are expected to update medical background SOTA analyses throughout the lifetime of the de-

vice (see MDR Article 86, and IVDR, Article 81). For example, if a device has a lifetime of 6 years and you place the last device on the market in 2024, you are expected to keep your PMCF up-to-date until 2030.



Keep your searches up-to-date with minimum effort. **evidence** is the only literature software that allows you to update searches in a methodologically correct way while minimizing effort. How does it work? Simply inform **evidence** that you're updating a search. Import the new results. **evidence** will ensure that all your previous screening and data extraction work for earlier articles is preserved.

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Meet Cesare



Hi, I am Cesare! I specialize in clinical and regulatory affairs and have been part of the medical device industry for over a decade. During this time, I have contributed to the certification of hundreds of medical devices. Currently, I am the CEO of 4BetterDevices GmbH, where I consult for medical device manufacturers and develop crazy software to automatize regulatory processes. You can contact me via email at cesare.magri@4betterdevices.com.

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