

FILTERS

Before executing a literature search, there is a number of decisions to make with respect to potential filters that may or may not be applied in order to ensure that State of the Art will be indeed reflected in the identified results.

❑ Date range

Depending on the novelty introduced by the device in scope and the maturity of the intended medical field, searching the 5-10 last years is usually sufficient to depict both standards of care and State of the Art.

TIP

Make a habit of running a search for historical articles (there is a dedicated checkbox for this in the new PubMed). This might retrieve useful information on the evolution of the medical field and the alternative treatment options that could explain why the device in scope remains State of the Art!

TIP

Want to search the new pubmed for a specific date range? Try this: "your search string" AND YYYY / MO / DAY:YYY / MO / DAY [dp]

❑ Language restrictions

New Medical Device Regulations allow **no excuses for exclusion of data due to language restrictions**. This often adds an extra financial load to Manufacturers but exclusion due to language might introduce bias and jeopardizes comprehensiveness of evidence with respect to safety and performance data.

TIP

Make an informed decision on inclusion of articles based on language criteria by taking into consideration the countries / geographical areas a device is marketed in as well as respective local clinical practice Guidelines because this might allow to draw conclusions on specific practices that introduce hazards and risks.

❑ Types of articles

To outline the State of the Art, a CER author will probably need to focus on published studies in peer-reviewed journals providing high level of evidence (see section **Appraisal Criteria**). Inclusion of unpublished studies may be considered to avoid publication bias however, the CER author will have to ensure that there is access to sufficient information for the assessment of methodology and/or outcomes. When possible, SoTA searches should be limited in **reviews, systematic reviews, meta-analyses and Clinical Practice Guidelines further delimited by data derived from studies in humans**. Nevertheless, depending on the special features of a medical device, the need to identify and discuss biomechanical, pre-clinical and/or other technical issues might emerge.

GUIDELINES

- ❑ Clinical Practice Guidelines are the core of a CER-related SotA section because they collect and revise all alternative treatment options for a given medical field from a clinical perspective. Therefore, their identification and critical presentation is mandatory. **Table 4** summarizes some sources for retrieval of Guidelines but a CER author should keep in mind that identification of clinical practice Guidelines usually requires hand searches based on the nature of the intended purpose of a medical device.

Table 4: Guideline sources and depositories

Source	Description
ECRI Guidelines Trust https://www.ecri.org/library/	<p>A publicly available online repository. One must create an account to search for guidelines and consult original documentation.</p> <p>Keep in mind that ECRI has inclusion criteria requirements for a clinical practice guideline to be included in the ECRI Guidelines Trust (e.g. to be available in English online for free or for a fee and published within the last 5 years).</p> <p>Check the process here: https://guidelines.ecri.org/inclusion-criteria</p>
Guideline Central https://www.guidelinecentral.com/summaries/	<p>>2600 free clinical practice guidelines. It requires a registration. It recently launched an android app with > 2,000 free guideline summaries, as well as 300 premium guideline titles.</p>
Guidelines International Network www.g-i-n.net/library/international-guidelines-library	<p>International guideline library from the Guidelines International Network (G-I-N) with > 6,500 documents from 96 organizations in 87 countries. The International Guideline Library has both a public section and a restricted section available only to members. Searches may be filtered per language and type of publication (e.g. guidelines, guideline clearing report, implementation tool etc.) and all documents are open access.</p>
Medscape Clinical Practice Guidelines https://reference.medscape.com/features/guidelines	<p>Clinical Practice Guidelines are published monthly after evaluation of recently published guidelines. Apart from a link to the actual document, Medscape, following systematic review, provides an abbreviated format of the guidelines focusing on workup, diagnosis, and treatment.</p>
EMA – European Medicines Agency Scientific Guidelines https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety-guidelines	<p>EMA prepares scientific guidelines in consultation with regulatory authorities in the European Union (EU) Member States, to help applicants prepare marketing-authorization applications for human medicines. Guidelines provide a basis for practical harmonization of how the EU Member States and the Agency interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy that are in the Community directives.</p>
PubMed https://pubmed.ncbi.nlm.nih.gov/	<p>In the new PubMed, go to “Additional filters” and under Article Type check the box “Guidelines”. Go back to the first page and select “Guideline” only under the “Article Type” feature.</p> <p>Tip: You will still need to screen the results due to the new algorithm used by PubMed.</p>
CINAHL Plus https://health.ebsco.com/products/cinahl-plus	<p>CINAHL is the online version of the Cumulative Index to Nursing and Allied Health Literature. Requires subscription to access it. Type the condition/ clinical procedure in the search box on the Advanced Search page. If you already know the name of the guideline, search by title. Select “Practice Guidelines” from the “Publication Type” menu in the Advanced Search or Limits section.</p>
NICE https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines#:~:text=NICE%20guidelines%20are%20evidence%2Dbased,prevent%20ill%20health	<p>NICE guidelines are evidence-based recommendations for health and care in England.</p>
NIH https://www.nih.gov/	<p>Includes guidelines within NIH's 27 Institutes and Centers:</p> <ol style="list-style-type: none"> Select the Institute that pertains to your topic, Search for practice guidelines by searching the websites of the Institutes within the National Institutes of Health network. <p>Tip: Try using each website's “Search” feature to look for “clinical practice guidelines”</p> <p>Check this as well: https://www.nccih.nih.gov/health/providers/clinicalpractice</p>

Before moving on to analysis of results, it is of utmost importance to run a control check and identify potential errors in the search strategy that could affect the integrity of information retrieved and therefore the **reproducibility** and **validity** of the systematic search approach.

A study by Sampson and McGowan¹⁰ identified that the commonest search errors in search strategies using MEDLINE were associated with missed MeSH terms (44.4%), whereas free text terms or irrelevant MeSH terms were also

noted (28.6%). A well-established source for search strategy optimization is the PRESS tool where the CER author may verify his/her work through the available checklist that addresses the research question, use of Boolean and proximity operators, subject headings, text word search, spelling, syntax, limits and filters.