DID YOU KNOW?

- Although Clinical Trials Database (e.g. Clinicaltrial.gov) is NOT peer-reviewed, it represents a potential useful source of clinical data especially in situations where data is limited and publication bias might emerge. The clinical trials database may be searched for both similar / benchmark / equivalent device(s) and the device in scope. However, its use in SotA section might not be necessary if a thorough systemic search is executed (searches in Chochrane library will retrieve results from clinicaltrials.gov).
- PubMed was rebuilt in May 2020 into a cloud-based service aiming to allow greater scalability. These changes have resulted in increased number of returned hits compared with the legacy version, likely due to:
    - automatic term mapping,
    - removal of the previous limit to 600 iterations when using a wildcard (*) search, and
    - default search now ignores Boolean operations (AND, OR, etc.), and defers to PubMed's own "best match" algorithm.

  This has a major regulatory implication: replication of searches by Auditors and/or Competent Authorities will eventualy not be possible although legacy PubMed will remain (inactively) available in this link: https://pmlegacy.ncbi.nlm.nih.gov/
- Embase has featured a dedicated Section for medical devices with comprehensive content and search strategies indexing trade names linked to Manufacturer names https://www.embase.com/search/medicalDevice
- If you are looking to manage Google Scholar hits, consider using Publish or Perish, a software program that retrieves and analyzes academic citations form a variety of data sources including Google Scholar. Get it here: https://harzing.com/resources/publish-or-perish. Keep in mind it might require a few pilot searches before finalizing the features that match your search
- Scopus database, developed by Elsevier, includes Cited References and incorporates searches of scientific web pages through Scirus. It indexes Medline. Although it covers a very wide range of disciplines that may result in increased noise, it is particularly useful when searching for proceedings of abstracts

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.