Unpacking State-of-the-Art for Clinical Evaluation Reports

State-of-the-Art

Overview

This white paper will provide an overview of the state-of-the-art (SOTA) section for clinical evaluation reports and offer guidance and suggestions for the literature review process during the development of SOTA.

Goal

To assist medical writers writers in the development and organization of the state-of-the-art section and literature review process for clinical evaluation reports (CER).

What is State-of-the-Art?

The term state-of-the-art has not been explicitly defined, however the Medical Device Coordination Group (MDCG) refers to it as "currently and generally accepted good practices in medicine and technology." While 'generally accepted good practices' may include recent advances, "it does not necessarily imply the most technologically advanced solutions" according to MDCG.

The SOTA literature review for device under evaluation should include:

- Generic background on disease or medical condition
- Alternative and current treatments available to the target population
- Comparisons of current practices
- Applicable standards and guidance documents

Why is this important? SOTA is a critical section because it outlines current practices in the medical field for a medical condition and provides the "pros" and "cons" of multiple treatment options, risks vs. benefits, and allows for a justified comparison of a medical device to reported current practices based on an intensive literature search and analysis of available clinical evidence.

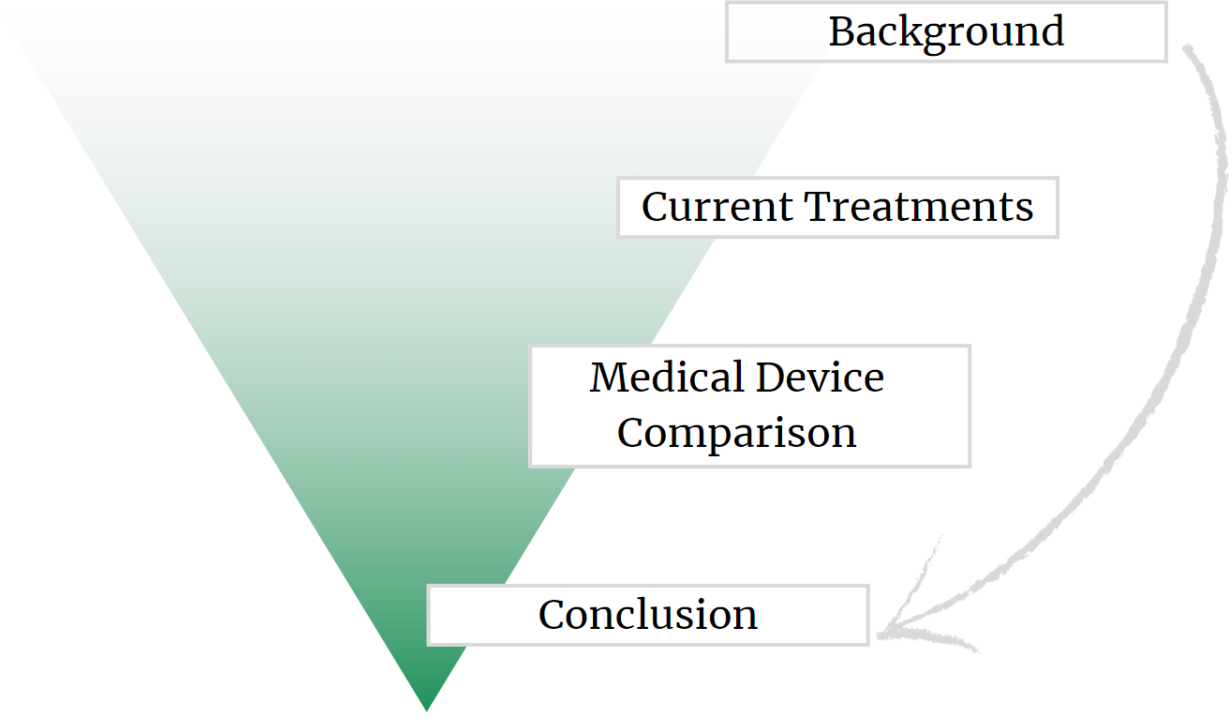
The entire development process of a state-of-the-art is important, from the literature search and identification of studies to the summary of these studies.

Here we will discuss sections to be included in the SOTA, as well as suggestions for literature search methods, to simplify the development process of this valuable resource.

SOTA Sections:

In general, the following sections should be included in a state-of-the-art, framed as a story in which the information starts out broader and gradually becomes more specific and detailed.

- Background on the specified medical condition/disease
- Current treatments and/or interventions for the target population
- Clinical Safety & performance outcomes
- Acceptance Criteria (with specific and measurable outcome parameters)
- Conclusion



Background:

The 'background' section allows for a general introduction into the medical condition(s) and/or disease(s) for which the medical device is currently used. If there are multiple medical conditions, the writer should consider spending time to review all of them equally.

General things to include in this section are:

- [ ] Information on the medical condition
- [ ] Diagnosis and disease prognosis
- [ ] Frequency of disease

Current Treatment Options and/or Interventions:

The purpose of this section is to outline standard treatment options for all relevant medical conditions, often starting with the least invasive method (ex. supplements, prescription medicine) and advancing to more invasive treatment methods (ex. device implantation). These treatments can be indirectly compared to the medical device, since they are different methods of treatment.

Once these treatment options are covered, the writer should move on to discuss medical devices that can be similarly compared to the device under evaluation . These comparable medical devices are often from competitors that are currently in practice in the medical field that offer the best direct comparison.

In both the indirect and direct treatment comparisons, it is best to include...

- [ ] Risks & Benefits
- [ ] Side effects
- [ ] 'Pros' & 'Cons' of each treatment option
- [ ] Relevant performance & safety outcomes
- [ ] Acceptance Criteria

What are Performance & Safety Outcomes?

Performance and safety outcomes are specific and measurable parameters that are used to determine the acceptability of the benefit/risk profile for the various indications and for the intended purpose of the device under evaluation, based on the state of the art in medicine.

For example, a **performance outcome** could be a specific and measurable 'technical success' of a medical device when it achieves its intended purpose.

Meanwhile, a **safety outcome** could be a relevant side effect such as rate of infection, hypoglycemia, bleeding, or a generic term of 'adverse effects' that is specific and measured in response to a treatment or medical device.

The performance and safety outcomes selected based on your SOTA will be entirely dependent on the medical condition that is being treated and the commonly occurring side effects, or outcomes, as a result of the treatment. Specific performance and safety outcomes selected must be justified. The results of the literature review and data analysis will help inform what performance and safety outcomes are most relevant to the specific medical condition treated by your medical device.

What is Acceptance Criteria?

Acceptance criteria is directly informed from the data collected during the literature review and analysis process. Acceptance criteria often have an upper and lower limit (ex. 2.0-7.3%) to demonstrate a range for acceptance of device performance and safety. An acceptance criterion must be set and justified for all performance and safety outcomes.

Acceptance criteria can be defined as the threshold on which the determination of acceptability of risks and benefits for a medical device is based in relation to the state of the art on the current treatment landscape.

How to Determine Acceptance Criteria?

Acceptance criteria can be determined through current literature, through clinical trial data or through data provided from the medical device manufacturer.

Guidelines for Literature Search:

When preparing a state-of-the-art, one of the most crucial and daunting steps is the literature review. From the literature review, it is important to gather background information on the disease or medical condition, alternative treatments, and current practices. Based on recent updates and requirements, it is critical to have a documented literature review process that supports full transparency in not only data collection, but also in the search process so it is clear how data was obtained and what studies may have been excluded. To facilitate this process, we offer the following tips.

Choosing a database

- It is important to conduct a literature search from a proper database that will allow a systematic approach to your search strategy and provide you with the necessary clinical evidence to minimize bias. According to recent recommendations by MEDDEV 2.7/1 rev 4, Embase and MEDLINE databases are excellent resources.

Conducting a search

- As one of the first steps in a literature review, it is essential to cover all databases. It is important to properly document all search terms used when performing the literature search, as well as to include a wide variety of relevant search terms to ensure you gather a variety of studies.
- Make sure to record all studies/literature that are to be included in the results of the search.
- It should also be noted that the selection of clinical data that characterizes the state of the art should be objective and writers should refrain from selecting data on the basis of being favorable for the device under evaluation.

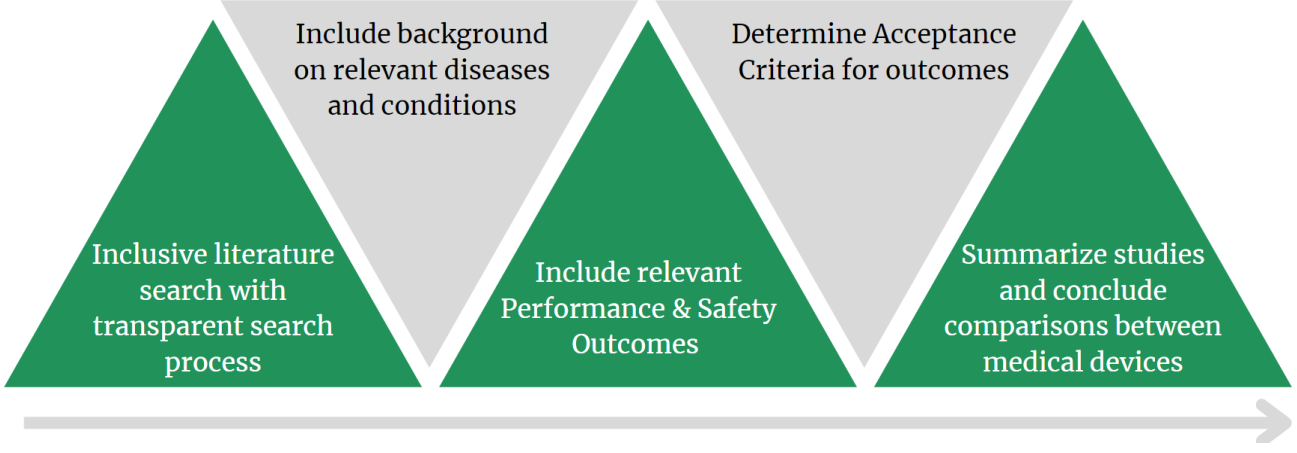
Inclusion and/or Exclusion of Studies

- While performing a literature search, you may deem it necessary to exclude certain studies. However, reasons for exclusion of studies must be properly documented with appropriate justification.

Summary of Included Studies

- All relevant and included studies collected from the literature search are summarized in a data extraction table. Some information to include in your summary can be study type (ex. Phase 3 trial), number of patients/individuals in the study, and conclusion of the study.
- Based on your search you may find it necessary to include additional information in your table, which can easily be added with more rows or columns in a clear and concise manner.

Key Points


Include background on relevant diseases and conditions
Determine Acceptance Criteria for outcomes
Inclusive literature search with transparent search process
Include relevant Performance & Safety Outcomes
Summarize studies and conclude comparisons between medical devices