

Literature

Guideline



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1. Introduction

This document describes how literature applied in submissions to the Danish Medicines Council must be identified, presented, and documented. It supplements the submission dossier and the methodological guideline and aims to ensure consistent and transparent reporting of the literature underpinning the assessments.

2. Literature used

The literature overview in the submission dossier must provide a full overview of the evidence base. It must include all references to internal documents (data on file) and published literature, including real-world evidence, used to assess the medicine's clinical effectiveness and safety, HRQoL, and other inputs to the health economic model.

It must be stated whether literature searches were conducted or whether data derive from a head-to-head study relevant to Danish clinical practice. Searches and selection processes must be documented in the appendix.

If parameters or literature from HTA bodies such as NICE are used, original references must be provided whenever possible. If data do not derive from a publication/reference, their source must be indicated.

Example: National Institute for Health and Care Excellence (NICE). Ibrutinib with venetoclax for untreated chronic lymphocytic leukaemia. Technology appraisal guidance [TA891]. London: NICE; 2023. Committee papers, p. 235. [4]

3. Literature search

3.1 Requirements for literature searches

3.1.1 Clinical effectiveness and safety

As a general principle, a systematic literature review (SLR) must be performed to identify relevant evidence for the assessment of clinical effectiveness and safety.

A de novo search may be carried out specifically for the Danish submission, or an existing global SLR may be used if it covers relevant comparators, populations, and treatments.

A systematic search may be omitted if a clinical study directly compares with Danish standard treatment and provides sufficient outcome and safety data.



No literature search is required if a Joint Clinical Assessment (JCA) is available and constitutes the sole source for the clinical assessment. In such cases, this must be stated as the justification for not conducting a systematic literature search.

3.1.2 Health-related quality of life (HRQoL) and other health economic inputs

If HRQoL data have not been collected in the clinical study or studies informing clinical effectiveness and safety, or if such data are insufficient, external literature must be identified and selected systematically. This also applies if, for some health states in the health economic model, instruments based on sources other than the clinical study or studies informing clinical effectiveness and safety are used, See *the Danish Medicines Council's guideline on health-related quality of life*.

In many cases, it will also be relevant for the health economic analysis to supplement inputs from the clinical study or studies with inputs from external sources, e.g. transition probabilities or treatment duration. Other external literature forming the basis for key inputs to the health economic analysis must likewise be identified through a systematic or focused literature search, depending on the importance of the input. The Danish Medicines Council may, where deemed necessary, request supplementary searches during the assessment process.

For detailed guidance on literature searches for utility values and model inputs, see NICE DSU Technical Support Document 9 [1].

3.2 Requirements for systematic literature searches

Systematic literature searches are characterised by a systematic and transparent approach and aim to identify all relevant evidence on a well-defined topic. They are based on international recognised methods and start from a clearly formulated, focused question. Searches are conducted across relevant information sources, and the selection process follows explicitly defined criteria set a priori. All steps must be documented in sufficient detail to allow critical appraisal and reproduction by others.

As a general rule, the literature search is not accepted if it is more than one year old. If this is the case, a new search (for example in PubMed) should be conducted to identify more recent literature.

3.2.1 Search process

The search process must be described and includes:

- Formulation of focused research questions (with an accompanying PICO when searching for evidence on clinical effectiveness and safety)
- Development of appropriate search concepts, translated into relevant index terms (MeSH and/or Emtree) and free-text terms, including relevant synonyms,



alternate spellings, and related concepts to ensure high recall/sensitivity

- When searching for effectiveness and safety data, search terms should be based on the population and relevant treatments. Outcomes should *not* be included as search terms, as doing so may increase the risk of missing relevant studies.

When searching for HRQoL data, a combination of search terms related to (broad) population and quality of life, instruments, utilities, etc. is typically used.

Searches for supplementary health economic inputs depend on the specific purpose.

- Selection of relevant databases. The Danish Medicines Council requires searches to include, at a minimum, PubMed/MEDLINE and Embase or CENTRAL. When identifying HRQoL data, it may be appropriate to search for relevant grey literature, such as published HTA assessments
- Appropriate use of filters, when necessary, with methodological justification (e.g., study design, population restrictions, publication type)
- Specification of search dates, including dates of any updates
- Documentation of search history, i.e., all search lines including the number of hits as executed for each database

3.2.2 Selection process

The selection of literature must be documented and includes:

- Predefined inclusion and exclusion criteria adapted to the purpose of the search (e.g. PICOs)
- A transparent screening process, including screening stages and the number of reviewers involved
- A list of all included studies/references, clearly indicating the evidence base for the assessment
- A list of studies excluded at full-text level with reasons for exclusion
- A PRISMA diagram showing the flow of references from identification to inclusion/exclusion

For detailed guidance on conducting systematic literature reviews and the associated documentation requirements, refer to the *Cochrane Handbook of Systematic Review, Chapter 4: Searching for and selecting studies* [2], *CRD's Guidance for undertaking reviews in healthcare* [3], and the [PRISMA guideline/checklist](#). For an introduction to planning systematic literature searches and their documentation requirements, see the Danish overview articles by Frandsen and Eriksen (2020) [4] and (2023) [5].



3.3 Requirements for focused searches (targeted searches)

Focused searches are used when a full systematic literature search is not considered necessary or appropriate. This may be because the data need is narrower and well-defined, or because it is difficult or inappropriate to address with a systematic search. Focused searches are used particularly for supplementary inputs to the health economic analysis, but also as a supplementary approach when a systematic search has not yielded usable results.

The approach for a focused search must still be transparent and, to the greatest extent possible, reproducible. Any deviations from this requirement must be justified. It is not sufficient to indicate “hand searching” as a search technique without further qualification.

3.3.1 Search process

A focused search typically:

- Is limited to a specific information need and not aimed at covering entire evidence fields
- Is conducted in fewer or more specialised information sources. PubMed/MEDLINE and Embase remain important sources, but grey literature and specialised collections are also relevant
- Is pragmatic in its approach, for example by:
 - Using narrower or fewer search terms, more limits/filters, or more AND-combinations of concepts
 - Limiting to specific fields (e.g., title) in bibliographic databases to reduce noise, or restricting to certain publication types such as systematic reviews

3.3.2 Selection and documentation

The documentation should include:

- A statement of purpose clearly describing the specific data need covered by the search
- Identification of sources used (internal and external) and the search date.
- The search terms used and how they were combined, with an explanation of any filters.
- Documentation of the search. If it cannot be documented by download, copy-pasting the search history, or by screenshots, a brief description of the procedure must be provided
- Identified results
- Description of criteria for relevance assessment



For detailed guidance on identification and documentation of inputs for model parameters, see NICE DSU Technical Support Document 13 [6]. Further inspiration for documentation methods can be found in Frandsen and Eriksen (2023) [5].

4. Documentation

To improve readability and minimize technical issues when copying/pasting or entering large amounts of text, documentation for literature searches may be split between the appendix of the submission dossier and supplementary material. This is particularly relevant when starting from an existing SLR. The submission dossier also provides guidance in the form of headings and brief instructions.

4.1 Content to be included in the appendix to the submission dossier

- Description of the literature search, including purpose, search strategy, and choice of concepts and any filters. When using an existing SLR, describe the adaptation to the Danish context
- Overview of databases and other information sources
- Description of the selection process and a table of inclusion and exclusion criteria. When using a global SLR, the “Change, local adaptation” section must be filled in where relevant. For focused searches, describe the process as comprehensively as possible
- PRISMA diagram (for systematic searches). When using an existing SLR, indicate how many studies/publications are transferred and excluded in the Danish assessment by completing the “Local adaptation” level
- Overview of included studies and references relevant to the Danish context

4.2 Content that may be placed in the appendix or supplementary material

- Search history/search strings for individual sources. The format may be as exported from the database, as screenshots, or copy-pasted into a table. If the search comes from an existing SLR, these may be attached in the original report format (e.g., extracts or screenshots of relevant pages as PDF or Word) or copy-pasted into a table
- Overview of excluded (full-text) references with reasons for exclusion. The format may be PDF, Excel, or Word. When using an existing SLR, this overview must consist of the references included in the SLR but not considered relevant for the Danish assessment. An existing table from the SLR listing included studies/references may be used as a starting point and adapted, for example, by adding a column for exclusion reasons



- Original PRISMA diagrams from the global SLR, if relevant, e.g. in the case of updates
- Any supplementary documentation from the global SLR not included directly in the application form

4.3 Examples of local adaptation of SLR

Example of description of a literature search

"A comprehensive global systematic literature review (SLR) was used as the evidence base for this application, followed by a local adaptation to fit the scope of the assessment. The global SLR had a broader scope and thus included all studies potentially relevant in a Danish context.

Search strategies and concepts were developed informed by the PICO framework (population and interventions only) by an experienced information specialist, and systematic searches were performed in Embase, PubMed and CENTRAL using a combination of controlled vocabulary and natural language adapted to each database. Validated filters for RCTs were applied. Search histories from each database are presented in the supplemental appendix SLR search strings.PDF.

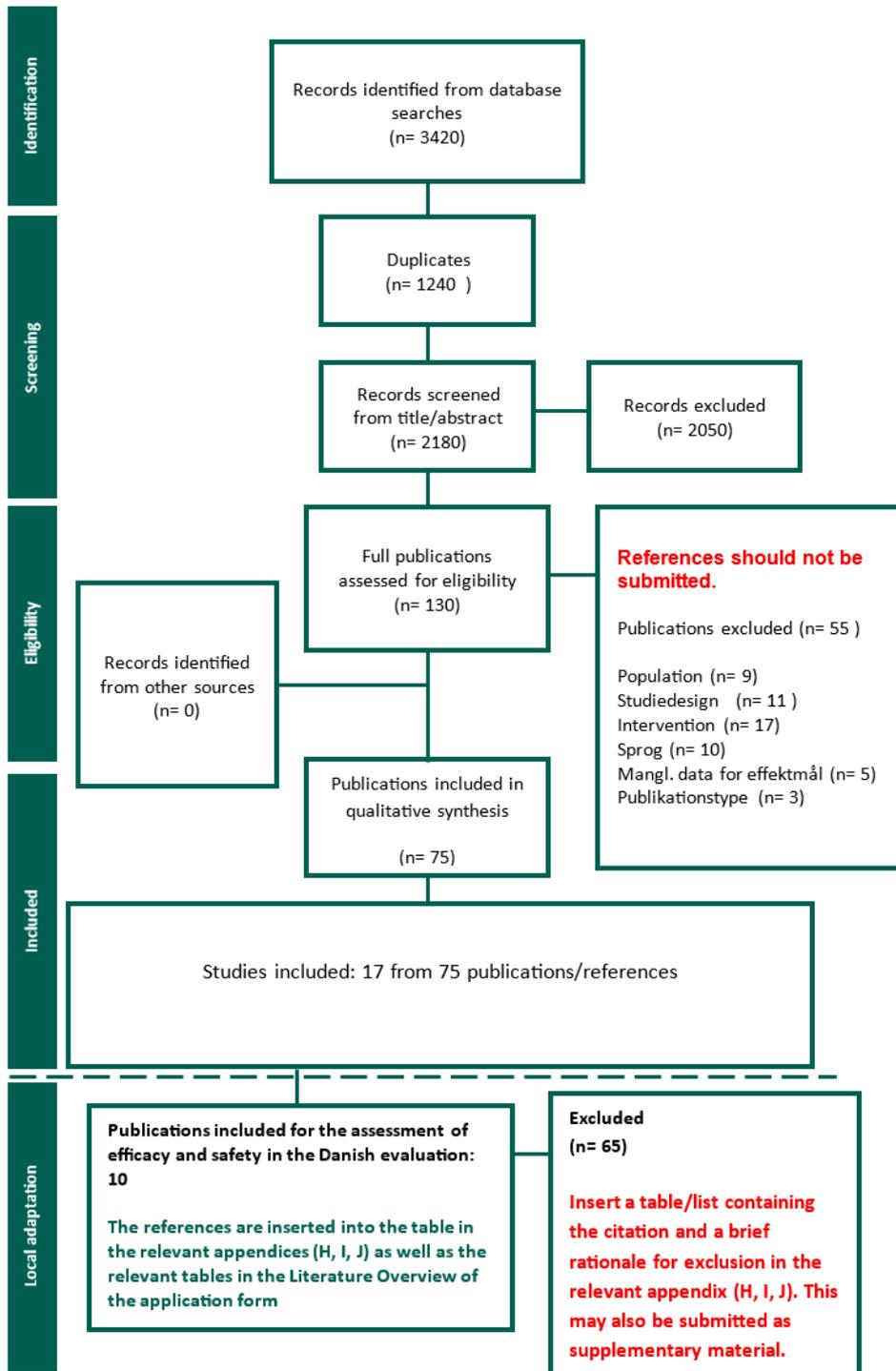
The global SLR included more interventions and study types than were relevant for this assessment. A total of 47 publications for efficacy and safety were included for data extraction in the global SLR. Based on the full-text reports included in the global SLR, a local adaptation was conducted using the modified inclusion and exclusion criteria (PICO) described in Table 42 below. This resulted in the inclusion of 10 references from 7 studies, providing evidence relevant only to intervention and comparators reflecting the Danish patient population and current clinical practice.

A combined PRISMA diagram illustrating the screening and selection processes for both the global SLR and the local adaptation is provided below. Full-text references originally included in the global SLR but not deemed relevant for the Danish submission are listed, together with reasons for exclusion, in the supplemental appendix Excluded full-text references.xlsx.

The studies/references included for this submission are presented in Table 10 in the Literature Overview and Table 44 below."



Example of PRISMA including local adaptation





5. References

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6. Version log

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