# Evaluation proposal to the Danish Health Technology Council regarding <technology> for <treatment/ use/ diagnosis of/ in patient population>

**Instructions for applicant**

This template is used to submit evaluation proposals to the Danish Health Technology Council for evaluation of a new or existing health technology. The evaluation proposal should be completed by the applicant and aim to provide the Council with a background for initiating evaluations. It is recommended that applicants engage in dialogue with the Danish Health Technology Council secretariat for guidance on completion.

The template is relevant for the overall themes:

* background information
* clinical outcome and safety
* patient perspective
* organisation
* budget and finances
* other relevant information

The scope of the response to each of the themes will depend on the individual health technology. If the applicant considers that a question is not relevant, the applicant should state 'not relevant' with brief supporting arguments. Explanatory text for the questions is in grey and is not exhaustive. It may contain definitions, more detailed descriptions, etc. The applicant may delete the explanatory text when the field has been completed. Under relevant enclosures' it is possible to list and enclose relevant publications and other documents, e.g. certificates, etc.

If there is confidential information in the evaluation proposal, this should be clearly marked by applying following to your answer: //CONFIDENTIAL//

The evaluation proposal must contain a reference list, should be kept as short and as precise as possible, possible (<20 pages, excl. Reference list), contain literature citations (Vancouver reference style), and written in either Danish or English.

Should any questions arise in preparation of an evaluation proposal or outline of costs, applicants can contact the Danish Health Technology Council secretariat for assistance or clarification.

In addition to the actual evaluation proposal, companies should enclose an outline of costs explaining the total costs associated with use of the health technology. The outline of costs is used to confirm that the health technology is likely to be cost-neutral or cost-reducing. The Danish Health Technology Council secretariat provides an [outline of costs](https://behandlingsraadet.dk/wp-content/uploads/2021/06/Omkostningsskitse.xlsx) form for use by companies. Regions and hospital administrators may also apply this outline, but this is not a requirement.

The completed evaluation proposal is the applicant’s material.

# Background

## State the type of health technology

Medical device: apparatus, software, in-vitro diagnostic devices/materials, used, for example, for treatment, prevention, diagnosis or to alleviate illness. State also the risk class of the device.

Procedures: Procedures in connection with diagnosis, treatment, rehabilitation and/or preventive procedures.

Organisation or type of collaboration: Organisational structure, organisation of procedures, collaboration between specialist groups and/or patients.

## Briefly describe the technology and the current Danish clinical context in which the technology will be used.

Description of the mode of action of the technology, its *intended use/purpose*, expected users of the technology, single/multiple use including lifetime, contra-indications, etc.

Indicate the expected annual use of the product/procedure assuming a specified, estimated market take-up in Denmark (e.g. number of units in a market take-up of 50%).

## Describe the expected patient population

If the technology is aimed at one or more specific patient group(s), describe these, including current and expected changes in prevalence and incidence, as well as long-term and short-term consequences of the disease and severity.

## Describe the current status for use in Denmark and abroad

Include whether the health technology has been put into service, if yes, for which groups or indications?

If it is a new technology, it will be relevant to state whether it has already been put into service in Denmark, either fully or partly, for example in selected regions or hospitals.

## State completed or ongoing health technology evaluations performed by health technology assessment (HTA) organisations.

The health technology evaluation(s) must be available in Danish or English.

## State Danish or international clinical guidelines on use of the technology.

The clinical guidelines should be available in Danish or English and they should be relevant for use in a Danish clinical context.

## Describe the best existing, widely implemented alternative(s) to the technology.

Description of alternative(s) (possible standard-of-care), including mode of action, users, single/multiple use, etc.

If possible, the alternative(s) should be the best solution already implemented in Denmark that the technology proposed is to replace.

The alternative(s) may be similar devices or medicine, or possibly a more general alternative such as 'conventional surgical intervention'. If there is no real existing alternative to the proposed technology, the alternative will be ' no active treatment'.

# Clinical outcome and safety

## Briefly describe the most significant clinical outcomes from the health technology compared with the alternative.

Briefly describe important clinical outcomes that have been examined in development, testing or post-marketing studies of the technology. State the relevant outcome estimates compared with the alternative (see #7).

In certain cases it may be relevant to use other outcomes than clinical outcomes to describe the *effect* of a technology, such as 'performance' etc.

## Briefly describe the most important risks associated with use of the health technology compared with the alternative.

Include a description of undesirable incidents that may occur in use of the health technology, as well any adverse effects that may occur using the health technology.

## State ongoing and/or completed clinical studies of the technology in the table.

State for each ongoing and/ or completed clinical study:

* Study-ID (for example PMID, DOI, NCT number or the EudraCT number) of completed and ongoing studies
* Study design (RCT, observational study, single arm and so on)
* Number of participants
* Did the study include a comparator?
* Vancouver citation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study ID** | **Study design** | **Participants** | **Comparator?** | **Citation** |
| DOI: 10.1234/5.678910 | Observational study | 100 | Yes | [1] |
|  |  |  |  |  |
|  |  |  |  |  |

## State and describe any important data on clinical outcome and safety which has not yet been published.[[1]](#footnote-2)

State whether there is important data that has not been published and/or made publicly available or which may be confidential. If this is the case, briefly outline the study design(s) and methodology and present the relevant results.

The above may, for example, be extracts from a data-on-file in the form of relevant sub-group analyses or data with longer follow-up times than exist in the published material.

# Patient perspective

## State and describe data concerning patient experience as regards the choice between the technology and comparator(s).

List and briefly outline methodology and relevant results.

Data concerning the patient perspective could be qualitative studies, statements, questionnaire surveys, interviews or similar material.

## State and describe any issues regarding accessibility and inequality for specific patient groups in use of the health technology.

Description of whether the technology leads to increased or reduced availability or inequality, for example in treatment and/or diagnostics for specific patient groups.

Description of any ethical implications in using or not using the health technology.

# Organisation

## State and describe the organisational conditions in the health care sectors which are likely to be changed or influenced if the Danish Health Technology Council recommends use\* of the health technology.

Description of whether use of the technology may give rise to task shifting or function creep between sectors, for example, compatibility issues (IT, hardware, etc.), increased or changed needs for training, physical frameworks, engagement of specific specialist and staff groups, etc.

\*Unless the evaluation proposal has been prepared in order to phase out the health technology under examination. In this case, the question will concern a recommendation to phase out the technology.

## Describe current experience with the health technology and its use.

Description of experience in connection with testing in practice within the Danish healthcare system, clinical trials, user groups, etc.

If possible, the applicant should account for experienced or expected indirect risks in connection with using the health technology. For example, risk of confusion, incorrect use, lack of maintenance or other factors which may influence patient safety.

# Budget and finances

## State and describe a list of published, peer-reviewed economic analyses of the technology

List these and state method designs (eg cost-effectiveness analyses, cost-consequence analysis, cost) and effect measures (eg QALY, number of bed days, survival).

Furthermore, state which comparator was used in any existing economic analyses.

## Describe the overall results from the completed outline of costs\*.

Description of the total results of the outline of costs, including the overall conclusion (cost-reducing, cost-neutral or cost-driving), sectors with significant costs, etc.

\*If public-sector applicants do not use the outline of costs, there should be a summary of significant costs associated with the health technology.

# Other relevant enclosures

*Relevant publications and documents will go to the Danish Health Technology Council secretariat, but they will not be forwarded to the Council for their decision. However, applicants may choose to insert references to publications, for example hyperlinks, so the Council can search them itself.*

## State and attach relevant publications on the health technology.

Applicants should consider any issues concerning copyright or similar.

## State and attach relevant documents on the health technology.

Including, for example CE certificates from notified bodies.

1. The Danish Health Technology Council may include unpublished and possibly confidential data concerning clinical outcome and safety in its evaluations, provided that a number of criteria have been met. See the principles from the Danish Health Technology Council for use of unpublished data (LINK). [↑](#footnote-ref-2)