# Template for submission of documentation for single technology assessment of medical devices, diagnostic interventions and procedures to the Norwegian Institute of Public Health

# About this document

Single Technology Assessments (STA) is an evidence summary focusing on effectiveness, safety, and cost-effectiveness. The Commissioning Forum can commission STAs when medical devices, diagnostic methods, procedures and pharmaceuticals are processed within [The National System for Managed Introduction of New Health Technologies within the Specialist Health Service](https://nyemetoder.no/). When STAs are commissioned, the manufacturer/supplier or a representative agent provide analyses and submit the relevant documentation. This template applies to submission of documentation for STAs of medical devices, diagnostic methods and procedures to the Norwegian Institute of Public Health (NIPH)[[1]](#footnote-1). The template is a living document which will be updated when needed.

The current template is not exhaustive and should be used together with the [guideline](https://www.fhi.no/globalassets/guidelines-for-the-submission-of-documents-for-stas-2021.pdf) in which more detailed descriptions and recommendations are provided. NIPH encourages manufacturers/suppliers to ensure that the documentation is presented systematically as proposed in this template. Deviations from the template and elements that are considered by the manufacturer not to be relevant must be justified. Documentation may be submitted in English or in a Scandinavian language. The documentation should be submitted electronically, preferably in a format facilitating copy/paste into the final STA such as Word. If a health economic model has been used to calculate cost-effectiveness, it should accompany the submission in either Excel or TreeAge. Web-based models are not accepted.

If the documentation contains confidential information (commercially sensitive information or data awaiting publication), which cannot be published by NIPH, this should be discussed in advance. Questions concerning this template or other requests related to submission of documentation for an STA of medical devices, diagnostic methods and procedures to the NIPH can be submitted to: metodevurdering@fhi.no

[The text on this page should be deleted prior to submission.]

[Text highlighted in gray is ment to guide the completion, and is to be deleted after the template has been filled in.]

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1. Overview

## Glossary of terms

[Insert relevant key words]

|  |  |
| --- | --- |
| Abbreviation / term | Description  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

## Table of formalities

|  |  |
| --- | --- |
| Company Name | [Company name and postal address] |
| Contact person for this assessment | [Name, phone number and e-mail address] |
| Consulting firm commissioned |  |
| Brand / trade name |  |
| Commission ID-number |  |
| Title of the commission  |  |
| Indications (all) |  |
| Relevant indication(s) for this STA |  |
| Does the submitted documentation differ from the commission? | [Yes – How? / No] |
| Has the intervention been previously assessed by NIPH for this or another indication? | If yes, case number:  |
| Clinicians who have been contacted \* | Name, workplace |
| Has the intervention been reimbursed / publically financed / used in Norway before?  | [If yes, state estimated number of patients annually, turnover in NOK] |

\* Indicate as reference in the text and in the reference list where statements/assumptions from clinicians/KOL have been used.

1. Scope

[Briefly present the commission as outlined by the Commissioning Forum that this STA responds to. The scope section should include a brief description of intervention, the alternative interventions for comparison and the most important outcomes (Guidelines, Chapter 2).]

1. Description of the intervention and the disease/condition

[Describe and complete according to the guidelines, Chapters 3.1, 3.2, 3.3, 3.4]

## The target condition and the health technology’s position in clinical practice

[In what way can the introduction of the technology change clinical practice?]

Describe any Norwegian national clinical guidelines for the condition which could be affected by the health technology.

[Describe and illustrate expected patient flow in a diagram.]

Describe the prevalence and incidence of the disease / condition in Norway if possible.

Enter the developments for the past 5 years in the table below and future estimates of number of patients that might benefit from the health technology.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 20\_\_ | 20\_\_ | 20\_\_ | 20\_\_ | Current year |
| Incidence in Norway |  |  |  |  |  |
| Prevalence in Noway |  |  |  |  |  |
| Global prevalence \*  |  |  |  |  |  |

\*For particularly small patient groups, also describe the worldwide prevalence

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Current year | 20\_\_ | 20\_\_ | 20\_\_ | 20\_\_ |
| Patients currently in Norway who are expected to use the technology |  |  |  |  |  |

Provide the source(s) the information in the tables is based on.

## Description of patient population

[Describe according to chapter 3.2]

Describe as accurately as possible the patient population that is expected to use the intervention in Norway and estimate the number of patients relevant for this assessment. Describe relevant diagnostic tests and methods used to select patients.

Describe which age groups are principally affected by the disease, and indicate the mean age (median age if relevant) for the patient group that is currently eligible for treatment in Norway (not the age for potential study population(s)). This age should be supported by clinical experts, registry data or other relevant sources.

[Are there any subgroups of patients where the treatment/technology is expected to have a different efficacy and safety than anticipated for the entire population that the STA applies to? Please feel free to present this in your own section here. Provide a rationale for the group selection and indicate whether these subgroups were pre-defined (and how) in the clinical trials. Briefly describe any diagnostic tests and methods used for patient selection. Any subgroup analyses must be reported according to this template in a separate attachment.]

## Description of the intervention

[Describe according to chapter 3.3]

[What type of health technology is it? Medical device (if yes, outline category), diagnostic tool, procedure, other (please specify).]

[How does the health technology work? State the principle.]

[Is the health technology new or a further development of an existing health technology?]

[Is the health technology or procedure already in use for other patient groups or for other indications?]

[What is the status of the health technology concerning any certification, CE-marking, use or approval in a) Norway and b) other countries (internationally)?]

[Describe the development process for the health technology or procedure.]

[What advantages is the health technology intended to give compared with the current health technology?]

[Will the introduction of the new technology result in changes of the infrastructure (organisation of the health service, spatial requirements, training, monitoring, follow-up, administration or costs)?]

## Selection and description of comparators

[The selection of comparator(s) must be done in accordance with the guidelines, Chapter 3.4.]

[Describe and explain which treatment options that would primarily be replaced by the introduction of this intervention. Provide a reason if the chosen comparator is not currently in Norwegian clinical practice as described above.]

1. Literature search and selection of documentation

[Describe and complete according to the guidelines, Chapter 4]

## Study selection process

[Describe what has been done to identify relevant clinical data, both published and unpublished. ]

[State sources and databases searched]

[Fully describe search strategy in one of the databases used (can be done in an appendix) ]

[State the date when the search was performed]

## Study selection process

[State selection criteria used in the selection process]

[Describe the description of the selection process (screening strategy, whether one or more reviewer was involved etc.)]

[Provide a flow chart summarizing the selection process (Number of hits, number of hits excluded based on title and abstract screening, number of studies read in full-text, number of studies included). If appropriate, you can adapt the flow chart developed by PRISMA[[2]](#footnote-2).]

1. Documentation of clinical efficacy and safety

[Describe and complete according to the guidelines, Chapter 5]

## Relevant studies

[Prepare a complete list of all relevant studies.]

[If any of the identified studies will not be used further as part of the documentation basis, this must be stated and justified.]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study (acronym, ID no.)Type of design | Reference | Population | Intervention | Comparison |
| Study 1 |  |  |  |  |
| Study 2 |  |  |  |  |
| Etc. |  |  |  |  |

## Description of included studies

### Study characteristics

[Give a brief summary in text and describe details from each study in tables. Specify any important differences between the studies.]

|  |  |  |  |
| --- | --- | --- | --- |
| Study (acronym, ID no.) | Study 1 | Study 2 | Etc. |
| Location/place conducted/country |  |  |  |
| Design/study type |  |  |  |
| Duration of the study |  |  |  |
| Randomisation method |  |  |  |
| Blinding method (investigator, patient, outcomes assessor) |  |  |  |
| Intervention (n=) |  |  |  |
| Comparison/control (n=) |  |  |  |
| Primary outcome (including measurement tools and measurement times) |  |  |  |
| Primary outcome (including measurement tools and measurement times) |  |  |  |
| Follow-up time |  |  |  |

### Characteristics of the patients/participants in the studies

[Describe the patients/participants in each study]

[Describe details from each study in table form. Specify any important differences between the studies in text.]

|  |  |  |
| --- | --- | --- |
| Study (acronym, ID no.) | Inclusion criteria | Exclusion criteria |
| Study 1 | Important inclusion criteria such as age, gender, diagnosis, severity, etc. |  |
| Study 2 |  |  |
| Etc. |  |  |

[Present an overview table of important baseline characteristics of the patients in the studies included.]

|  |  |  |
| --- | --- | --- |
| Study (acronym, ID no.) | Intervention | Comparison |
| Study 1 (n=) | (n=) | (n=) |
| Age |  |  |
| Gender |  |  |
| etc. |  |  |
| Study 2 (n=) | (n=) | (n=) |

### Outcomes/endpoints

[Describe the endpoints in each study. Emphasis should be placed on clinically meaningful outcomes.]

[Describe the selections for this research issue. When appropriate, state whether the tools used have been validated and are valid in Norway.]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study (acronym, ID no.) | Primary outcome  | Validity in current practice | Secondary outcome, including side effects  | Validity in current practice |
| Study 1 |  |  |  |  |
| Study 2 |  |  |  |  |
| etc. |  |  |  |  |

## Statistical analyses and definition of study groups

[Describe the research hypothesis that was investigated and the statistical analyses that were used.]

[Specify the strength calculation and sample size calculation, including the assumptions that have been made.]

[State clearly whether the analyses include patients that withdrew/had missing measurements and, if so, how this was handled.]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study (acronym, ID no.) | Hypothesis | Statistical analysis | Sample size, strength calculation | Handling of data (withdrawals, missing measurements, etc.) |
| Study 1 |  |  |  |  |
| Study 2 |  |  |  |  |
| etc. |  |  |  |  |

## Flow chart

[Present a flow chart of the patients’ progress through the study (randomised patients, withdrawal from the groups, replacement of groups, etc.). See for example [Consort’s chart](http://www.consort-statement.org/consort-statement/flow-diagram0/).]

## Quality assessment and/or risk of bias

[Give a detailed description of all included studies included.]

[A complete assessment of internal validity of included studies must be enclosed.]

[The evaluation will be checked by an employee of the NIPH.]

## Presentation of results

### Present results for all relevant endpoints.

[Where possible, data must be presented as “intention-to-treat” analyses (analyses where all the patients are analysed in the group in which they started). Depending on the study design and type of endpoint, other types of analyses may also be relevant (e.g. “on-treatment” and “safety-on treatment”).]

[Always define which patients are included in the analyses and, where applicable, the reasons why any patients were not included in the analyses.]

[State clearly whether the analyses include patients that withdrew/had missing measurements and, if so, how this was handled.]

[Data should be presented in the text, tables, and graphics where possible.]

### Meta-analyses

[If there is more than one study, consideration must be given to present meta-analyses. Clearly present the assessment behind the decision whether meta-analyses are suitable.]

[In cases where meta-analyses are included, provide at least the following: selection method (random or fixed effects model, choice of effect parameter, sensitivity analyses) and test for heterogeneity.]

### Indirect comparisons

[If there are no directly comparable studies (head-to-head studies), consideration must be given to the execution of indirect comparisons.]

[Present clearly the assessment behind choices made, how the studies for indirect comparison were identified, data extraction and methods adopted for analysis.]

## Summary of key findings

[Briefly summarise key findings of presently available clinical documentation, with a focus on effects and side effects of the new health technology (the device or procedure).]

[Provide a summary of the strengths and weaknesses inherent in the documentation available for the health technology (the device or the procedure).]

## Relevance to Norwegian conditions

[Discuss how and to what extent the provided documentation is relevant for the Norwegian context.]

[Identify factors with significance to external validity of the study results when applied in normal clinical practice.]

## Ongoing studies

[Provide a summary of any ongoing clinical studies identified and their expected publication dates/year.]

Example of table:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Title of the study and RCT (clinical-trials.gov) | Objective of the study(patient pop., etc.) | Intervention | Comparator | Outcome | Starting date | Expected end date |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. Relative efficacy/effectiveness and safety

[Describe and complete according to the guidelines, Chapter 6.]

[Specify which documentation the relative efficacy is based on and elaborate on whether direct comparisons, paired indirect comparisons, indirect treatment comparisons or other methods was used. Explain what the underlying studies are and why they have been selected.]

[Include the adverse reactions that are relevant to the assessment. This will usually be frequent, common and serious adverse reactions.]

## Direct comparisons

[When the relative efficacy documentation is based on a head-to-head study between the intervention and a comparator, it must be presented in this chapter. Tables may be used for clarification.]

[If intermediate outcomes (or surrogate endpoints) are used in the model, to what extent they are related to the primary endpoints must be described. Explain how the relationship has been estimated and what evidence it is based on.]

[Extrapolation of data should be described under the section below entitled "Extrapolation of relative efficacy."]

## Indirect comparisons

[When the relative efficacy documentation is based on an indirect comparison, the main results should be summarised in this chapter. Tables may be used if for clarification.]

[The complete methodology should be described in detail in the appendix or separate attachment.]

[If intermediate outcomes (or surrogate endpoints) are used in the model, to what extent they are related to the primary endpoints must be described. Explain how the relationship has been estimated and what evidence it is based on.]

[Extrapolation of data should be described under the section below entitled "Extrapolation of relative efficacy."]

## Extrapolation of relative efficacy

[If the extrapolation is not based on the time-to-event data (i.e. survival data), please explain and justify any assumptions made on how the effect differs beyond the study period. Does the effect remain the same, decrease, increase?]

## Time to event data

[If extrapolations from time-to-event data have been made, please present the full method used and results in Appendix C Parameterisation.]

[Specify which parametric function was selected for both intervention and comparator.]

[Graphical representation of the time to event data curves where both the Kaplan-Meier (KM) data and the parametric distributions are shown in the same figure must also be presented in this section (for both intervention and comparator). Specify whether corrections have been made for treatment switch / cross over (intervention and/or comparator).]

## Safety

[Follow Chapter 5.3. of the Guidelines.]

[Present harms/adverse events (including hospitalizations, all types of surgical and medical complications and unwanted effects) in a table (see example below) while using the intervention and comparator(s) in the studies described above. Include the adverse events that are relevant to the assessment. This will usually be frequent and/or serious complications.]

Example of table: Overview of adverse events

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Frequency of adverse reactions | Study 1 | Study 2 | Study 3 | Severity (grade) | Is the adverse event included in the model? Yes/no, if yes state duration in the model] |
| **Intervention** |  |  |  |  |  |
| Name of adverse event 1 |  |  |  |  |  |
| Name of adverse event 2 |  |  |  |  |  |
|  |  |  |  |  |  |
| **Comparator** |  |  |  |  |  |
| Name of adverse event 1 |  |  |  |  |  |
| Name of adverse event 2 |  |  |  |  |  |
|  |  |  |  |  |  |

[How the harms/adverse events are handled in clinical practice (monitoring, follow-up, resource use, etc.) should not be described here, but instead under the section "Resource use and costs."]

[Describe how the harms/adverse events affect the health-related quality of life. Give reasons for exclusion of any harms/adverse events from the health economic model.]

[Describe how the harms/adverse events have been accounted for in the model, for example with a reduced quality of life and/or as an additional a cost.

1. Health-related quality of life

[Describe and complete according to the guidelines, Chapter 8.]

[Quality-Adjusted Life Years (QALY) is the preferred objective for health. If QALY is not used in the analysis, this must be justified.]

[Describe how the disease affect the patients’ quality of life and how is the patients’ quality of life is expected to develop over time, with and without the currently established treatment.]

## Overview of health state utility values (HSUV)

 [Present in a table the HSUV (also called QALY weights) that have been used in the model. This may be from the literature search, clinical studies that underlie the relative efficacy in this assessment and/or from mapping.

[Specify and justify the quality of life weightings which were used in the health economic model in the following format:]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Health state/health situation | Quality of life weighting | CI (95 %) | Source | Reason for the selection |
| Health state 1 |  |  |  |  |
| Health state 2 |  |  |  |  |
| Etc. |  |  |  |  |
| Event 1 |  |  |  |  |
| Event 2 |  |  |  |  |
| Etc. |  |  |  |  |

[If the quality of life data was acquired in connection with the studies from which clinical data was obtained – describe in detail the method for valuing the patients’ quality of life and for acquiring this data. Include the time of measurement and the confidence intervals concerning the measurements.]

[Describe the strengths and weaknesses of the quality of life data used.]

1. Health economic analysis and modelling

## Previously published cost-effectiveness analyses

### Identification of other relevant published analyses

[If relevant health economic analyses are published, please enclose.]

Example of table

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study | Year | Country where the study was conducted | What type of model analysis? | Patient population (age, sex, state of health, etc.) | Incremental QALY\* benefit | Incremental costs | ICER\*\* | Comparison |
| Study 1 |  |  |  |  |  |  |  |  |
| Study 2 |  |  |  |  |  |  |  |  |
| Etc. |  |  |  |  |  |  |  |  |

\* QALY: Quality-Adjusted Life Years

\*\* ICER: Incremental Cost-Effectiveness Ratio

## Health economic analysis and model

### Health economic analysis method chosen for this STA

[Describe which type of health economic analysis has been used (cost utility analysis (CUA), cost-minimisation analysis, etc.). In the event that a cost-minimisation analysis was conducted, not all of the following items will be relevant.]

[If another type of analysis than CUA (cost per QALY) was conducted, state the reasons.]

[In all models submitted (for example, in spreadsheets) the input data sources in the model must also be included in the attached spreadsheet.]

### The structure of the analyses

[Describe and explain the structure of the analyses.]

[Is the analysis based on modelling or based directly on costs and health effects collated as part of a comparative efficacy study (piggyback analysis)? Or a combination of these?]

[If the analysis is based directly on a comparative efficacy study, please describe the collation of costs and health effects in detail, such as choice of target group, determination of how the data (costs, quality of life data) is to be acquired and analysed, and choice of time interval/time frame for data acquisition.]

**Model**

[Describe the model (see Chapter 10 of the Guidelines) and depict the structure of the model clearly showing the different stages and the main features of how it works. State how the course of the disease with the current treatment is modelled and with the new treatment. Explain to what degree the model is appropriate for analysing the research question of the STA.]

[Describe and justify the choice of time horizon (see Chapter 10.5 of the Guidelines).

State the different discount rates for costs and benefits respectively (see Chaper 9.4 in the Guideline).]

[Describe how the model has been validated. Refer to the relevant publication(s) if external validation has been performed (see Chapter 10 of the Guidelines).]

[Describe and justify key assumptions in the model.]

[Describe the calculation of transition probabilities.]

**The patient group in the analysis**

[Describe the patient group at which the analysis is aimed. Does it differ from the target group (see defined in section 5), and if so, how?]

### Use of efficacy data in the model

[It is recommended that clinical efficacy data from the included studies, should be included in the model in the form of hazard ratios (or alternatively relative risks or odds ratios) for an event or condition applied to a background risk taken from Norwegian epidemiological data (see the section below).]

[Describe all the stages in the calculation of probability for different events in the model.]

[Clinical, hard endpoints (e.g. number of cases of relapse, infarction, death, etc.) are preferred in the modelling. If intermediate (surrogate) endpoints are to be used in the model instead of clinical endpoints, this must be justified (e.g. HbA1c, LDL-c, SBP, PSA, etc.). Please also give references and discuss the available evidence which supports the ratio between the chosen surrogates and the relevant clinical endpoints. See the [EUnetHTA guideline on the use of surrogate endpoints in health technology assessments](https://www.eunethta.eu/wp-content/uploads/2018/03/surrogate_endpoints.pdf) for details.]

[For how long time period was the efficacy data applied? If this extends beyond the period for which clinical documentation is available, this must be justified and assumptions must be described thoroughly. Show the results in diagram form, e.g. using the Kaplan-Meier curve.]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Value | 95% confidence interval | Probability distribution(type and parameters) | Reference |
| Outcome 1 |  |  |  |  |
| Outcome 2 |  |  |  |  |
| Etc. | … | … |  | … |

### Use of epidemiological data in models

[The analysis should preferably be based on Norwegian epidemiological data as the source for background risk. If Norwegian epidemiological data are not available, data from countries that are considered to be relatively similar to Norway in terms of the occurrence of diseases should be chosen. On occasions, a balance must be struck between study quality and transferability (internal vs. external validity). In such cases, advantages and disadvantages of the various choices should be discussed. The control arm from an RCT can be used as a last resort, if it is not possible to find other sources of epidemiological data.]

[Please complete the following summary table of the key epidemiological parameters used in the analysis:]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Value | 95% confidence interval | Probability distribution(type and parameters) | Reference |
| Probability of event X |  |  |  |  |
| Probability of event Y |  |  |  |  |
| Etc. | … | … |  |  |

### Resource use and costs

[In this section, present the various costs used in the model. The treatment of adverse events in clinical practice (monitoring, follow-up, resource use, etc.) should also be presented here. See Chapter 9.3 in the Guideline.]

Example of table: Costs used in the model

|  |  |
| --- | --- |
| Costs | NOK (per unit of measurement used in the model) |
| A- e.g. hospitalisation | NOK (per admission) |
| B- e.g. drug cost | NOK (per time period / patient) |
| C- e.g. blood glucose strips | NOK (per year) |
| G- e.g. patients' time spent in treatment | NOK (per hourly) |
| H- e.g. end of life costs | NOK (one time cost) |
|  |  |
|  |  |
|  |  |

[Describe each cost in its own section below, including resource use, unit costs[[3]](#footnote-3) and how it was included in the model. Describe the use of resources in clinical practice for each cost and inform if the resource use differ between health states. Show the calculations and cite the sources, and state what distribution that has been used, if applicable.]

Cost A (e.g. hospitalisation)

Resource use for cost A: [Text] [Clinical practice, what monitoring is required, resource use.]

Unit cost(s) for cost A: [Text]

Value used in the model for cost A: [Text] [Must be given as cost per unit, e.g. per admission, per cycle, for any projection, see Chapter 9.3.3 in the Guidelines).]

## Results

### Base case cost-effectiveness results

[Overview of all treatments assessed in the analysis in ascending order with regard to total costs in the tables below. State the incremental cost effectiveness ratio (ICER) for each of the treatments in relation to the relevant comparator.]

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **Total costs (NOK)** | **Total number of life years** | **Total number of QALYs** | **Incremental costs** | **Life years gained** | **QALY gained** | **ICER vs. relevant comparator (QALYs)** | **NHB****(Net Health Benefit)** |
| Treatment alternative 1 |  |  |  |  |  |  |  |  |
| Treatment alternative 2 |  |  |  |  |  |  |  |  |
| Treatment alternative 3 |  |  |  |  |  |  |  |  |
| Etc. |  |  |  |  |  |  |  |  |

### Uncertainty

[Chapter 12 of the Guidelines must be followed.]

[The uncertainty concerning the results of the analysis must be investigated, described and discussed via one-way and probabilistic sensitivity analyses, as well as scenario analyses.]

**Sub-group analyses**

[Is data available which indicates that the efficacy and/or costs associated with the health technology under consideration differ between sub-groups? If so and the measure has indication/CE marking for the treatment of these sub-groups, state whether the sub-groups were identified before the clinical study was conducted (a priori) or after the results of the study became available (a posteriori); describe the sub-groups’ characteristics; and finally report the model’s results for these sub-groups.]

### Interpretation of the analysis results

[What does the submitter consider to be the key strengths of the analysis? And the key weaknesses?]

[Are the results of the submitter analysis in accordance with the results of previously published analyses? If not, state the possible reasons behind the differences.]

1. Calculation of severity

[Follow Chapter 11 of the Guidelines.]

[Enter the sources used to estimate the mean age of the patient group.]

[The example below is a general table for reporting severity calculation. It is made in particular for the calculation of the absolute shortfall (AS) of the treatment alternatives evaluated in a model using a lifelong perspective. If other considerations need to be taken into account (for example, that the model cannot estimate the lifelong prognosis, that the prevention of one or more diseases is concerned, comorbidities, etc.), the table below will likely not suffice and it will often be necessary to present this in another way. The table below only serves as an example.]

|  |  |  |
| --- | --- | --- |
| Average age at the start of treatment | A | XX |
| Expected remaining QALYs (undiscounted) for the general population without the disease  | QALYsA | XX |
| Expected remaining QALYs (undiscounted) for those with the disease and without the new treatment (that is, prognosis of patients treated with current standard treatment)) | PA | XX |
| *If adjustments are made:* Expected remaining QALYs (undiscounted) for those with the disease without the new treatment (prognosis) - adjusted.*If adjustments are not made, this line in the table can be deleted*  | P\*A | XX |
| Number of QALYs lost due to disease (absolute shortfall) | AS | XX |

Calculation of severity based on current treatment predict an absolute shortfall of approx. XX QALY.

1. Budget impact of the new technology

[The manufacturers/submitters must provide/present an analysis of their technology’s budgetary consequences. The NIPH evaluates and carries out own calculations if necessary.]

[See Chapter 13 in the Guideline for table examples and guidance.]

1. Discussion of the submitted documentation

[Describe the strengths and weaknesses of the documentation submitted (max 2 pages). The focus must be placed in particular on the uncertainty related to the clinical documentation used and other key input data, the health economic model structure, and the relevance for the Norwegian context. See Chapter 12.2 of the Guidelines.]

1. References

[Insert the reference list]

1. Other templates and guidelines apply to single technology assessments of pharmaceuticals. See the [Norwegian Medicines Agency](https://legemiddelverket.no/english/public-funding-and-pricing/documentation-for-sta/template-for-submission-of-documentation-for-the-single-technology-assessment-of-pharmaceuticals) webpages for more information. [↑](#footnote-ref-1)
2. <http://prisma-statement.org/prismastatement/flowdiagram.aspx> [↑](#footnote-ref-2)
3. You may consult the Norwegian Medicines Agency’s [unit cost database](https://legemiddelverket.no/english/public-funding-and-pricing/documentation-for-sta/unit-cost-database) for relevant unit costs. [↑](#footnote-ref-3)