Submission Template

For single Technology Assessment of Medical Devices

About this document

Single Technology Assessments (STA) are summaries of evidence focusing on effectiveness, safety, and cost-effectiveness of health technologies/medical products (including both medicines (MP), medical devices (MD) and in vitro diagnostic (IVD) medical devices). The Commissioning Forum may commission STAs when medical devices, diagnostic methods, procedures and pharmaceuticals are processed by [The National System for Managed Introduction of New Health Technologies within the Specialist Health Service](https://nyemetoder.no/). When commissioned, the health technology developer (HTD) or a representative agent provides relevant documentation and health economic analyses. This template is for the submission of the afore mentioned documentation for STAs of medical devices to the Norwegian Medical Products Agency (NoMA)[[1]](#footnote-2). This document will be updated when needed.

This template is not exhaustive and should be used together with the [guideline for single technology assessment of medical devices](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf) which provides more detailed descriptions and recommendations. NoMA encourages health technology developers/suppliers to ensure that documentation is presented systematically as instructed in this template. Deviations from the template must be justified by the submitter/HTD. NoMA accepts submissions in English or a Scandinavian language. Documentation should be submitted electronically, preferably in a format facilitating search functions and transposition to Microsoft Word. If a health economic model has been used to calculate cost-effectiveness, it should accompany the submission in either Microsoft Excel or TreeAge-format. NoMA does not accept web-based models or links to web-based models.

Please inform NoMA if your submission contains confidential information and highlight this in yellow in the text and tables (e.g. commercially sensitive information or data awaiting publication).

Questions about this template or other requests related to the submission may be addressed to: hta.medical.devices@noma.no

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

[Text highlighted in gray is meant to guide where the Submitter / HTD /hould add their information for the completion of this document and these grey sections should be deleted prior to submission.]

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# List of Tables

# List of Figures

1. Overview

## Glossary of terms

[Insert relevant key words and a definition or description of their meaning]

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

## General information (all fields should be completed)

|  |  |
| --- | --- |
| Company name | [Company name and postal address] |
| Contact person for this assessment, please provide alternate in addition | [Name, phone number and e-mail address] |
| Consultancy firm on behalf of Company commissioned to produce the submission | [Company name, Contact person name, phone number and e-mail address] |
| Letter of authorisation from Company | ☐ NO (to be provided within 7 days)☐ YES [please attach] |
| Brand / trade name of the device |  |
| Type of device, European Medical Device Nomenclature (EMDN) | Report the EMDN term description from (select the most granular level, as relevant) – if not clear please describe device type (from group W-in vitro diagnostic medical device) <https://webgate.ec.europa.eu/dyna2/emdn/> |
| CE marking in accordance with Medical Device Regulation (MDR (EU) 2017/745) or In Vitro Diagnostic Regulation (IVDR (EU) 2017/746) | CE marking: Conformity Certificates: [please attach]Unique Device Identification Device Identifier (UDI-DI):  |
| Declared Risk Class of the device (classification according to MDR Annex Annex VIII) - MD ONLY | ☐ Class III☐ Class IIb☐ Class IIa☐ Class Is, Ir, Im[please describe in detail which]☐ Class I |
| Declared Risk Class of the device IVD (classification according to IVDR Chapter 5, Art. 47) - IVD ONLY | ☐ Class A☐ Class B☐ Class C☐ Class D |
| “Nye metoder” Commission ID-number |  |
| Title of the commission  |  |
| Intended purpose (all) |  |
| Intended purpose for the scope of the STA |  |
| Does the submitted documentation differ from the commission? | [Yes – Provide a description of the differences / No] |
| Has the intervention been assessed previously by NoMA for this or another indication? | If yes, provide the commission ID number:  |
| Has the intervention been assessed by other HTA agencies? : | If yes, list the agency names and countries |
| Clinicians who have been consulted for this submission\* | Name, workplace |
| Has the intervention been reimbursed / publically financed / used in Norway before?  | [If yes, state the estimated number of patients annually and turnover in NOK] |

1. Patient population and intervention

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

[In what way might the introduction of the health technology impact clinical practice?]

[Describe any Norwegian national clinical guideline for the target condition that could be affected by the health technology.]

[Describe the prevalence and incidence of the target condition in Norway if possible.]

[Enter the trends 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 Norway |  |  |  |  |  |
| Global prevalence \*  |  |  |  |  |  |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 20\_\_ | 20\_\_ | 20\_\_ | 20\_\_ | Current year |
| Patients in Norway who are expected to use the technology at present and in the future |  |  |  |  |  |

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

## Description of the target patient population

[Describe as accurately as possible the target patient population for the intervention in Norway and estimate the number of patients relevant for this assessment. If relevant, describe diagnostic tests and methods used to select patients who will receive the intervention.]

[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 or IVD test in Norway. This age should be supported by the opinion of 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 to which the STA applies? Provide a rationale for the subgroup 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 enclosed.]

## Description of the intervention

[Describe according to Section 2.3 in the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf)]

|  |  |
| --- | --- |
| Brand / trade name of the device | Relevant device /equipment, diagnostic test, software version, and an overview of models approved for the European market, if applicable |
| Type of device, European Medical Device Nomenclature (EMDN) and according to the Medical Device Regulation (MDR (EU) 2017/745) or In Vitro Diagnostic Regulation (IVDR (EU) 2017/746).  | Report the EMDN term description from (select the most granular level, as relevant) – if not clear please describe device type (from group W-in vitro diagnostic medical device) <https://webgate.ec.europa.eu/dyna2/emdn/> |
| CE marking in accordance with Medical Device Regulation (MDR (EU) 2017/745) or In Vitro Diagnostic Regulation (IVDR (EU) 2017/746) | CE marking: Conformity Certificates: [please attach]Unique Device Identification Device Identifier (UDI-DI):  |
| Notified Body Date of first approval of the device/equipment for commercial use in the EU (CE marking) and the expiry date of current certificate. (Copy of the CE certificate must be attached). | Name and number:Date of 1st approval: [DD/MM/YYYY]Expiry date of current certificate: [DD/MM/YYYY]☐ Certificate Attached |
| Declared Risk Class of the device (classification according to MDR Annex Annex VIII) MD ONLY | ☐ Class III☐ Class IIb☐ Class IIa☐ Class Is, Ir, Im[please describe in detail which]☐ Class I |
| Declared Risk Class of the device IVD (classification according to IVDR Chapter 5, Art. 47) - IVD ONLY | ☐ Class A☐ Class B☐ Class C☐ Class D |
| Intended purpose and target population(s) |  |
| Contraindication(s), residual risks, and any undesirable side-effects |  |
| Additional documentation to be submitted:* Summary of Safety and Clinical Performance (SSCP),
* Instructions for Use (IFU) in English and Norwegian,
* Clinical Evaluation Report (CER) for MD or Performance Evaluation Report (PER) for IVD
* Clinical Evaluation Assessment Report (CEAR), and
* Expert Panel Opinion or View, if available.
 | ☐ SSCP☐ IFU in English☐ IFU in Norwegian☐ CER for MD☐ PER for IVD☐ CEAR☐ Expert Panel Opinion / View, if available |

[Describe the intervention composition, technical characteristics and technologies involved.]

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

[What is the context of use (in what sort of environment will it be implemented)?]

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

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

[What is the regulatory status of the health technology, specifically CE-marking, and use in a) Norway and b) the EU, c) US, d) Canada, e) Australia and f) New Zealand?]

[Specify the expected lifetime of the device and how disposal will be handled.]

[Describe any required installation and maintenance services, including frequency and who potentially is responsible.]

[Specify any other equipment and/or consumables that will be used alongside the device, and whether these need to be procured separately or if they are part of the device.]

[For active implantable devices, specify the compatibility with MR imaging.]

[Are there any conditions of sale/rent/lease? If so, specify.]

[What advantages does the health technology offer compared with the current standard of care?]

[Approved intended purpose or application area, and any disease/condition relevant for the use of the method.]

[Expected application area if the intervention is introduced into Norwegian clinical practice.]

[If the intervention is already in use in clinical practice, this should be described (population, extent and time of introduction).]

[The intervention’s placement in the treatment or diagnostic sequence.]

[Describe the current patient flow in the application area.]

[Expected patient flow if the intervention is introduced (preferably in a flow diagram).]

[Proposed user competence and training of users, described in accordance with the Instructions for use (IFU) and Summary of Safety and Clinical Performance (SSCP).]

1. Description of comparator(s)

## Selection and description of comparators

[The selection of comparator(s) must be done in accordance with the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Chapter 3.]

[Describe and explain which treatment options would primarily be replaced by the introduction of this intervention. If the chosen comparator is not currently in Norwegian clinical practice, provide a reason for the choice of comparator.]

1. Outcomes

## Intermediate outcomes

[If intermediate outcomes (or surrogate endpoints) are used in the health economic model, describe the extent of their relation to the primary endpoints . Explain how the relationship has been estimated and on what evidence it is based.]

## Learning curve

[Is the intervention associated with a learning curve? If yes, briefly describe the training process involved and how this has been addressed in the clinical studies and/or the health economic model.]

## Incremental innovation

[If documentation supporting previous versions of the device has been submitted previously to NoMA, describe the changes since that previous submission with respect to the current device and discuss the significance of those changes.]

## Safety

[Briefly state the most important risks/residual risks/harms/adverse events associated with use of the intervention, both for the patient and the operator. More detailed information should be given in Chapter 6 in this template.]

[If the device involves radiation, describe the accumulated risk and how it has been addressed in the health economic model.]

## Organisational implications

[Will the introduction of the new technology result in changes to the health care infrastructure (organisation of the health service, spatial requirements, staff and/or patient training, monitoring, follow-up or administrative routines)?]

[Are there any potential consequences for (personnel) capacity?]

1. Information retrieval

**Selection criteria**

[State selection criteria used in the selection process, including limits by study design and publication year in table format. With justifications.]

**Search process**

[Describe what has been done to identify relevant published and unpublished clinical data. Describe and justify the choice of PICO (Population – Intervention – Comparison – Outcome) components in the literature search strategy. Provide examples of search terms for each of the PICO components used.]

[State the sources searched (databases, trials registries, web sites etc.) and date of last search.]

[Describe any supplementary search methods used – citation searching, contacting authors, browsing tables of contents, web sites.]

[Indicate whether published search filters or search strategies from prior works have been re-used or adapted.]

[Describe any peer review process.]

[Search strategies for ALL databases and study registries must be provided in an appendix, copied and pasted exactly as run, including number of hits per search line. Provide information on platform (Ovid, EBSCO, ProQuest, etc.) and user interface (basic or advanced search.)]

**Study selection process**

[Describe the study selection process (screening strategy, number of reviewers involved, conflict resolution process, use of tools or artificial intelligence/machine learning.)]

[Provide a flow chart summarizing the selection process (number of records retrieved, (also specify these per database) number of records excluded based on title and abstract screening, number of studies read in full-text, number of studies included). If appropriate, adapt the flow chart developed by PRISMA[[2]](#footnote-3).]

[Provide a list of excluded studies following selection of full-text articles with a justification for each exclusion.]

1. Documentation of clinical efficacy and safety

[Describe and complete according to the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Chapter 6. If the intervention is diagnostic, refer to the questions regarding diagnostic accuracy in chapter ‎8 in this template before returning to this chapter to adapt the tables accordingly.]

## Relevant studies

[Provide a 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.]

|  |  |  |  |
| --- | --- | --- | --- |
| Title of the study  | Population | Intervention | Comparator |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Ongoing studies

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

Example of ongoing studies table:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Title of the study and study identifier e.g. NCT number | Objective of the study | Study design | Intervention | Comparator | Outcome Primary and Secondary | Starting date | Expected end date |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

## Description of included studies

### Study characteristics

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

|  |  |  |  |
| --- | --- | --- | --- |
| Study (acronym, ID no.) | Study 1 | Study 2 | etc. |
| Location/place conducted/country/year |  |  |  |
| Design/study type |  |  |  |
| Duration of the study (or NA if cross-sectional study) |  |  |  |
| Randomisation method (for RCTs) or method for selection of participants into study arms |  |  |  |
| Blinding method (investigator, patient, outcomes assessor) |  |  |  |
| Intervention (n=) |  |  |  |
| Comparison/control (n=) |  |  |  |
| Primary outcome (including measurement tools and measurement times) |  |  |  |
| Secondary outcome (including measurement tools and measurement times) |  |  |  |
| Follow-up time (please include rational) |  |  |  |

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

[Describe the patients/participants in each study.]

[Provide details for each study in a table. 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 included studies.]

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

### Outcomes/endpoints

[Describe the endpoints for 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  | Secondary outcome  |
| Study 1 |  |  |
| Study 2 |  |  |
| etc. |  |  |

### Safety

[Present harms/adverse events (including hospitalizations, all types of surgical and medical complications and unwanted effects) in a table (see example below) that are device-related or procedure-related , for the intervention and comparator(s) in the studies described above. Include the adverse events that are relevant to the assessment and which are incorporated into the health economic model. This will usually be frequent and/or serious complications.]

Example of table: Overview of adverse events (AEs)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Study 1(number of patients with AE, and Proportion of patients with AE) | Study 2(number of patients with AE, and Proportion of patients with AE) | Study 3(number of patients with AE, and Proportion of patients with AE) | Severity (grade) | Is the adverse event included in the health economic 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.]

## Statistical analyses and definition of study groups

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

[Specify the power calculation and sample size calculation, including the assumptions that were made.]

[State 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, power 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 chart](http://www.consort-statement.org/consort-statement/flow-diagram0/).]

## Quality assessment and/or risk of bias

[Give a detailed description of the quality/risk of bias of all included studies. State the tools used for quality assessment/risk of bias, how they were used, and how many people did the assessment.]

[Include a complete assessment of the internal validity of each included study. The type of assessment will vary by study design.]

[The assessments will be checked by NoMA employees.]

## 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 presented if relevant (e.g. per protocol analysis, “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 summarised and presented in the text, with details provided in tables, and graphics.]

## Summary of key findings

[Provide a summary of the key findings of the available included studies and analyses, with a focus on effects and adverse effects of the new intervention (the device).]

[Provide a summary of the strengths and weaknesses inherent in the included studies for the health technology (the device).]

## Relevance to the Norwegian context

[Discuss how, and to what extent, the included studies are relevant for the Norwegian context.]

[Identify factors with relevance to the external validity of the submission when applied in normal clinical practice.]

1. Evidence synthesis
* Complete this section if evidence synthesis methods were used to combine multiple sources of evidence to estimate comparative effectiveness and/or safety, e.g. a pairwise meta-analysis, indirect comparison or network meta-analysis.

[Describe the objective of the analysis by defining each of the PICO components (Population, Intervention, Comparator, Outcome) and study design.]

[Specify the documentation on which the relative efficacy is based and elaborate on whether direct or indirect comparisons were used. List the underlying studies and why they have been selected.]

Present a table of the individual studies in the synthesis, including:

[Study design (phase, randomisation, blinding, condition)]

[Definition of endpoints

Statistical analysis (including estimand and how intercurrent events and missing data were addressed).]

[Dates of the study recruitment period]

[Duration of follow-up]

[Treatment duration]

[Reasons for and proportion of censored observations]

[Countries covered by the studies]

[Types and distributions of any subsequent treatment received in the studies]

[Any other factors that might differ between the studies and that can affect the treatment effect]

[Risk of bias assessment using validated tools]

## Assumption of exchangeability

[Provide a discussion as to whether the assumption of exchangeability is fulfilled in accordance with the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Section 7.3.]

## Statistical methods for evidence synthesis

[Describe the software used, as well as codes and scripts (this may be done in an appendix).]

## Direct comparisons

[Describe and justify the chosen statistical model (frequentist or Bayesian) and method for the meta-analysis and heterogeneity parameter.]

[Present a table of individual study results, including the number of patients per study.]

[Include Forest plots with point estimates and confidence intervals. If a Bayesian analysis has been performed, report credible and predictive intervals.]

[In the case of Bayesian analysis, report information on the nature of the prior distribution for all relevant parameters and evaluation of the impact of the prior distribution on the results of the analyses.]

## Indirect comparisons

Provided that the assessment of exchangeability is deemed to be fulfilled (Section ‎7.3 in the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf)):

[Provide a full statistical description of the chosen model.]

[Describe the appropriateness of the chosen method according to the evidence base].

[Provide graphical and tabular presentations of the evidence network with number of studies per comparison.]

[Provide a Tabular presentation of number of patients and individual study results for the endpoints included in the evidence base.]

[Also include Forest plots and tabular presentation of the relative effect estimates with measure of uncertainty for the intervention versus all comparators included.]

[Present and assess the results from both direct and indirect evidence if present in the network.]

[In the case of Bayesian analysis, present the number of iterations for burn-in and estimation, the number and convergence of Markov chains, and information and justification for the choice of prior distributions for all relevant parameters.]

[In the case of inconsistency models within the Bayesian framework, plots of posterior mean deviance for both the model and the inconsistency model present plots of posterior mean deviance for both the model and the inconsistency model.]

## 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, or increase?]

## Population-adjusted methods

* In cases of anchored comparisons (connected evidence provide a justification that bias in the analyses will be reduced by using population-adjustment methods.

Include the following:

[Complete description of the method and model for population adjustment and treatment effect estimation.]

[Evidence that one or more of the observed patient characteristics are effect modifiers, and that the distribution of those effect modifiers is imbalanced enough to result in bias in the relative treatment effect].

[Method for identification and selection of effect-modifying covariates which are adjusted for, and the potential for un-measured effect modifiers.]

[Potential for residual bias in the results and the size and direction of the bias.]

* In cases of regression-based methods (STC, ML-NMR) fit an outcome regression model of the available individual patient data.

Include the following:

[Model fit and justification of the appropriateness of the chosen model.]

[Description of the degree of covariate overlap between the studies included.]

• For STC:

[the method used to estimate outcome and the treatment effect that is targeted by the chosen approach.]

• For ML-NMR:

[whether the data are sufficient to handle treatment-covariate interactions, if the shared effect modifier assumption is required, and whether any other assumptions have been made for model estimation.]

* In case of a MAIC:

[Distribution of effect modifiers before and after weighting in the intervention population versus the comparator population and description of the impact of any residual imbalance.]

[Distribution of weights and effective sample size after matching.]

[Method for confidence interval estimation; the robust or bootstrapping methods are preferred.]

* In case of unanchored MAICs and STC: The points described above also apply for unanchored analyses. In addition, include:

[Method for identification of all relevant prognostic variables.]

[Description of whether the unanchored indirect comparison is appropriate with regards to which data are available for adjustment, outcome definition, and comparability of study characteristics.]

[The extent of missing prognostic variables and the direction and size of bias from the lack of adjustment for prognostic factors.]

## Non-randomised evidence

* If non-randomised evidence forms part of the synthesis, include:

[Comparison of the inclusion and exclusion criteria.]

[Comparison of baseline patient characteristics.]

[Method used to identify prognostic and effect modifying factors and method used to adjust for confounding (see [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Section 7.4).]

[Risk-of-bias assessment using an appropriate tool.]

[Present results for crude and adjusted analyses with appropriate sensitivity analyses for evaluation of robustness.]

## Extrapolation of data

* For non-TTE (time-to-event) data

[justify the assumptions made and sources used to model long-term efficacy beyond the study period and the transitions between health states in the health economic model.]

* For time to event data

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

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

[Graphical presentation 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 be presented in this section for both the intervention and the comparator.]

## Treatment switching

[In accordance with the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Section 7.5, specify whether corrections have been made for treatment switch / cross over (for the intervention and/or comparator).]

1. Diagnostic interventions
* NOTE: This section should be left blank if the intervention covered by the STA is not diagnostic

[Specify the scope of the diagnostic test (diagnostic, prognostic, monitoring etc. (If the test has several objectives, state the one relevant for the indication covered by the STA).]

[Are end-to-end studies that follow the patient from testing to treatment outcomes available? If yes , list the publication details (author, year and title). If such studies are ongoing, they should be listed in accordance with the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Chapter 5.]

[Specify the target condition and its prevalence in Norway. Unless already specified, also state the Number of people in the test population.]

[Describe the test, in terms of the technology involved and how it is carried out, unless this has already been completed in Chapter ‎2.]

[State whether the test will replace another test. State if it is a stand-alone or complementary test.]

[Describe the position of the test in an integrated diagnostic process and in the clinical pathway. Explain how the test is performed in clinical practice, and provide information on turnaround time, amount of biological material needed (if applicable), ease of interpretation of the test, if the test is qualitative or quantitative, and the training and equipment needed to perform the test.]

[Describe characteristics that may be important to the patient or operator but are not captured by the test outcomes (e.g. feasibility, risk of adverse events, comfort).]

[If artificial intelligence is used as part of the diagnostics please provide information on the decision rule/algorithms and whether these are in the public domain.]

[Present the results of diagnostic accuracy studies using the tables shown in Chapter 6 of this template. Specify parameters such as the reference standard, disease prevalence, and test results in terms of sensitivity and specificity for each study.]

[The internal validity and applicability of the included diagnostic accuracy studies should be critically appraised using an appropriate instrument such as QUADAS-2, and the choice of tool justified.]

1. Real-world evidence
* NOTE: This section should be left blank if the STA does not include real-world evidence

[If real-world evidence has been included, describe the studies following the recommendations in the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Chapter 9. Describe the study characteristics, and how risk of bias has been handled.]

1. Artificial intelligence
* NOTE: This section should be left blank if the intervention covered by the STA does not include machine learning algorithms and/or artificial intelligence

[If the device involves an artificial intelligence component, answer the relevant questions in the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Chapter 10.]

1. Health-related quality of life

[Describe and complete according to the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Chapter 11.]

[Quality-Adjusted Life Years (QALY) are recommended by NICE as its preferred measure of health outcome for use in technology appraisals. If QALY are not used in the analysis, provide a justification.]

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

## Overview of health state utility values (HSUV)

 [Present in a table the HSUV (QALY weights) that have been used in the model. The HSUV may have been identified from the literature search, from clinical studies that inform the relative efficacy in this assessment and/or from mapping procedures.

[Specify and justify the quality-of-life weightings which were used in the health economic model with and without age-adjustment (see Section 11.5 in the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf) for details).]

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Health state/health situation | Quality of life weighting | Confidence Interval (95 %) | Probability distribution(type and parameters) | Source | Instrument  | Reason for the selection |
| Health state 1 |  |  |  |  |  |  |
| Health state 2 |  |  |  |  |  |  |
| etc. |  |  |  |  |  |  |
| Event 1 |  |  |  |  |  |  |
| Event 2 |  |  |  |  |  |  |
| etc. |  |  |  |  |  |  |

[If quality of life data were acquired as part of the studies from which clinical data were obtained, describe in detail the method used to value the patients’ quality of life and to acquire these 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

## 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, some of the following items will not be relevant.]

[If CUA (cost per QALY) was not conducted, state the reasons for the choice of the alternative analysis.]

[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.]

[Describe whether the analysis is based on modelling or based directly on costs and health effects collated as part of a comparative efficacy study (piggyback analysis), or is a combination of these approaches?]

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

**Model**

[Describe the model 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 is modelled, with the current treatment 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.

State the discount rates for costs and benefits .]

[Describe how the model has been validated. Refer to the relevant publication(s) if external validation has been performed (see Section 12.1 of the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf)).]

[Describe and justify the 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, including the mean/median age used in the model. If it differs from the target group (see defined in Chapter 5) describe how it differs.

### 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 **Use of epidemiological data in models** 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.). Also provide 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.]

[State the time period for the application of the efficacy data. If this extends beyond the period for which clinical data from this submission is available, provide a justification, and describe the assumptions in detail. Show the results in a diagram, e.g. using the Kaplan-Meier curve.]

Table title

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 occasion, a balance must be struck between study quality and transferability (internal vs. external validity). In such cases, justify the sources chosen. 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.]

Table title

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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. Present the treatment of adverse events in clinical practice (monitoring, follow-up, resource use, etc) ]

Example of table: Costs used in the model

|  |  |
| --- | --- |
| Costs item | 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) |
| D- e.g. patients' time spent in treatment | NOK (per hourl) |
| E- e.g. end of life costs | NOK (one time cost) |
| etc. |  |

[Describe each cost in its own section below, including resource use, unit costs[[3]](#footnote-4) and how they were included in the model. Describe the use of resources in clinical practice for each cost and specify whether the resource use differs between health states. Provide the calculations and cite the data sources. State what distribution has been used, if applicable.]

[If the intervention includes capital costs, specify these as described in the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf), Section 12.8]

The format that is expected for Cost Tables are shown below:

[Cost A (e.g. hospitalisation)

Resource use for cost A: [Text] [Clinical practice, what kind of 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.)]

## Results of the cost-effectiveness analysis

### Base case cost-effectiveness results

[Provide an overview of all health technologies assessed in the analysis in ascending order with regard to total costs, as shown in the table below. State the incremental cost effectiveness ratio (ICER) for each of the treatments in relation to the relevant comparator.]

Table title

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

Key: ICER: incremental cost-effectiveness ration; QALYs: quality adjusted life years.

1. Calculation of severity

[Follow Chapter 13 of the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf). The [Excel files on the NOMA website](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.dmp.no%2Fglobalassets%2Fdocuments%2Foffentlig-finansiering-og-pris%2Fdokumentasjon-til-metodevurdering%2Ftools-for-severity-calculation-and-age-adjustment-apr-24.xlsx&wdOrigin=BROWSELINK) can be used to calculate severity.]

[Specify 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 used , 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. In that case, it will often be necessary to present the information in another way.]

Table title

|  |  |  |
| --- | --- | --- |
| Average age at the start of treatment | Age | 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 |

Key: QALYs: quality adjusted life years.

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

1. Uncertainty about the results

[Chapter 14 of the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf) 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**

[Are data available which indicate that the efficacy and/or costs associated with the health technology under consideration differ between sub-groups? If yes, 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 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? Also describe the key weaknesses.]

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

1. Budget impact of the new technology

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

[See Chapter 15 in the [Guideline](https://www.dmp.no/globalassets/documents/offentlig-finansiering-og-pris/dokumentasjon-til-metodevurdering/noma-submission-guideline-241218.pdf) for guidance. Use the Excel templates for [single](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.dmp.no%2Fglobalassets%2Fdocuments%2Foffentlig-finansiering-og-pris%2Fdokumentasjon-til-metodevurdering%2Fbia-template-device-single-user.xlsx&wdOrigin=BROWSELINK) and [multi](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.dmp.no%2Fglobalassets%2Fdocuments%2Foffentlig-finansiering-og-pris%2Fdokumentasjon-til-metodevurdering%2Fbia-template-device-multi-user.xlsx&wdOrigin=BROWSELINK) user devices.]

[Describe the sources and assumptions on which the budget impact analysis is based.]

1. Discussion of the submitted documentation

[Describe the strengths and weaknesses of the documentation submitted (maximum 2 pages). Focus on the uncertainty related to the efficacy and safety data used and other key input data, the health economic model structure, and the relevance for the Norwegian context.]

1. References

[Insert the reference list. Please use a citation style that includes the digital object identifier (doi) for journal articles, for example APA, NLM, or Sage Vancouver.]

1. Appendices

**Search strategies for all databases and study registries**

**List of excluded studies with reasons for exclusion**

**Time-to- event data: Results and description of extrapolation methods**

Statistical software and methods description

1. Other templates and guideline apply to single technology assessments of pharmaceuticals. [↑](#footnote-ref-2)
2. <http://prisma-statement.org/prismastatement/flowdiagram.aspx> [↑](#footnote-ref-3)
3. You may consult the [unit cost database](https://www.dmp.no/en/public-funding-and-pricing-of-medicines/single-technology-assessments/submission-of-documentation-for-single-technology-assessment-of-pharmaceuticals/unit-cost-database) for relevant unit costs. [↑](#footnote-ref-4)