External Assessment Centre report

The purpose of the External Assessment Centre (EAC) report is to review and critically evaluate the sponsor's clinical and economic evidence and may include additional analysis of the submitted evidence or new clinical and/or economic evidence.

The Assessment Report is an important component of the information available to the Medical Technologies Advisory Committee (MTAC) when developing its provisional and, following consultation, final recommendations on the technology.

The template should be completed with reference to the NICE 'Medical Technologies Evaluation Programme methods guide'. The headings and prompt questions in the template provide a consistent structure for the assessment of the sponsor's submission but the assessment, format and presentation may be adapted by the EAC to maximise the clarity of the report.

Any 'commercial in confidence' information in the submission document should be underlined and highlighted in turquoise.

Any 'academic in confidence' information in the submission document should be underlined and highlighted in yellow.

If either type of confidential information is quoted or described in the assessment report, it must be underlined and highlighted as in the original. This allows the automated removal of this information and makes subsequent editing far quicker and more reliable. It is very important to ensure removal of confidential information before public consultation. It is the assessment centre's responsibility to ensure all confidential information in the assessment report is underlined and highlighted in the appropriate colours.

All grey text in this template should be removed before submitting the final version to NICE.

Title: [Title]

The title should be taken from the NICE scoping document, unless it has been agreed with the Medical Technologies Evaluation Programme (MTEP) that an alternative should be used.

Produced by: [Name of External Assessment Centre]

Authors: [Name/s, job title, department/institution. The report should be referenced according to the contribution of each author]

Correspondence to: [Name and address]

Date completed: (dd/mm/yyyy)

Declared interests of the authors

Description of any pecuniary relationship with sponsors, both personal and of the EAC. Please refer to NICE's Code of Practice for declaring and dealing with conflicts of interests.
http://www.nice.org.uk/niceMedia/pdf/Guidanceondeclarationsofinterest.pdf

If there are none, please state 'none'.

Acknowledgements

Names, titles and organisational affiliations (for example, main employer) of individuals who provided advice.

Rider on responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Contents

The table of contents can be updated using the Reference tab in Microsoft Word

1 Summary

Scope of the sponsor's submission

Summary of clinical evidence submitted by the sponsor

Summary critique of clinical evidence submitted by the sponsor

All critiques in this report should be well balanced, reflecting both positive and negative aspects of the sponsor's submission as appropriate.

Summary of economic evidence submitted by the sponsor

Summary critique of economic evidence submitted by the sponsor

External Assessment Centre commentary on the robustness of evidence submitted by the sponsor

Summary of any additional work carried out by the External Assessment Centre

2 Background

2.1 Overview and critique of sponsor's description of clinical context

Include a review of the clinical pathway of care presented on the technology and comparator.

Does the EAC believe that the sponsor's description of the clinical context is appropriate and relevant to the decision problem under consideration?

2.2 Overview of sponsor's description of ongoing studies

Does the EAC believe the sponsor's description of ongoing studies is adequate? Are there any significant trials due to finish during or shortly after NICE's evaluation of the sponsor's technology?

2.3 Critique of sponsor's definition of the decision problem

Population

To what extent does the clinical evidence submitted by the sponsor match the patient population described in the final scope? If there is a mismatch, provide further details. It may be relevant to consider whether the clinical evidence submitted by the sponsor reflects the characteristics of the patient population in England eligible for treatment.

Intervention

Does the technology described in the sponsor's submission match the technology described in the final scope? Briefly describe the technology and state its relevant or proposed marketing authorisation/CE mark. Does the EAC believe that the sponsor has satisfied the regulatory requirements in the submission? Have all relevant documents been submitted?

Comparator(s)

Do the comparators described in the sponsor's submission match the comparators described in the final scope? If not, provide further details. If evidence is limited or not available for relevant comparators, has the sponsor asked an unbiased clinical expert, or carried out its own survey? Provide further details.

Outcomes

Do the outcomes in the sponsor's submission match the outcomes described in the final scope? If not, provide further details.

Cost analysis

Does the cost analysis in the sponsor's submission match the cost analysis specified in the final scope? If not, provide further details.

Subgroups

If any subgroups were specified in the final scope, have these been included in the sponsor's submission? If not, provide further details.

Special considerations, including issues related to equality

Have any special considerations identified in the scope been addressed in the sponsor's submission?

Does the EAC believe that equality issues identified in the scope have been addressed in the submission? Have any new equalities issues been raised by the sponsor? Has the EAC identified any further equalities issues?

3 Clinical evidence

If there is more than one study described in the sponsor's submission, it may be appropriate to discuss each study individually using the headings below.

The EAC should critique the methods used, and interpret the results in light of the methods used by the sponsor and generalisability to patients in England.

3.1 Critique of the sponsor's search strategy

Describe the search strategy submitted by the sponsor. List databases and other sources of information used by the sponsor (including unpublished sources) and describe any restrictions. Comment on whether the search strategy was appropriate.

3.2 Critique of the sponsor's study selection

Describe techniques used by the sponsor to select studies for inclusion in the clinical evidence section of the submission. State the inclusion and exclusion criteria used in the study selection. Comment on whether these criteria were appropriate.

3.3 Included and excluded studies

What studies were included by the sponsor in the clinical evidence review and what were excluded? Describe the studies. Where considered appropriate, provide a table of identified studies.

Provide details of any relevant studies not included in the sponsor's submission of clinical evidence. Why were these studies excluded and how were these studies identified by the EAC?

Provide details of any studies identified in the sponsor's submission of clinical evidence that were excluded by the EAC. Why were these studies excluded by the EAC?

Please provide a summary of the key points from the studies in a table (suggested column headings)

Study	Patient population	Country	Age	Study design	Sample size

Study	Patient population	Country	Age	Study design	Sample size

3.4 Overview of methodologies of all included studies

Summarise the methodologies of all included studies. Include statistical approaches and outcome selection for each study.

3.5 Overview and critique of the sponsor's critical appraisal

Summarise and discuss the critical appraisal submitted by the sponsor for all studies included in the clinical evidence section of the submission.

3.6 Results

State the total number of patients in each study and the number of patients in each treatment arm. Define each outcome (including outcome measures) and report absolute figures, levels of significance and follow-up. Please present the results of the technology first and then the comparator(s), even when the source material presents the results the other way round.

Please provide a summary of the key outcomes from the studies in a table (suggested column headings)

Study	Outcome 1	Outcome 2	Outcome 3	Outcome 4	Outcome 5

Does each relevant study include the patient population(s), intervention(s), comparator(s) and outcomes as defined in the final scope?

Discuss.

3.7 Description of the adverse events reported by the sponsor

Does the EAC believe that the adverse events reported by the sponsor raise any safety concerns for the technology being evaluated? What is the opinion of Expert Advisers to NICE?

3.8 Description and critique of evidence synthesis and meta-analysis carried out by the sponsor

If appropriate describe and critique any evidence synthesis and meta-analysis of the clinical evidence submitted by the sponsor.

3.9 Additional work carried out by the External Assessment Centre in relation to clinical evidence

Provide details of any additional work carried out by the EAC in relation to the clinical evidence. If the results of the additional work affect the direction of conclusions, refer the reader to the 'Impact on the cost difference between the technology and comparator of additional clinical and economic analyses undertaken by the EAC' section of this report.

3.10 Conclusions on the clinical evidence

Firm conclusions on the clinical evidence submitted by the sponsor should be made by the EAC to assist the Committee in its consideration of the clinical evidence and develop its recommendations.

Describe the completeness of the sponsor's submission with regard to relevant clinical studies and relevant data within those studies. Does the submission contain an unbiased estimate of the technology's (relative and absolute) treatment effects in relation to relevant populations, interventions, comparators and outcomes? Are there any remaining uncertainties about the reliability of the clinical evidence? Reference should also be made about the extent to which the submitted evidence reflects the decision problem defined in the final scope.

Comment on the sponsor's interpretation of clinical evidence. What does the EAC conclude from the clinical evidence submitted by the sponsor?

4 Economic evidence

4.1 Published economic evidence

Critique of the sponsor's search strategy

Describe the search strategy submitted by the sponsor. List databases and other sources of information used by the sponsor (including unpublished sources) and describe any restrictions. Comment on whether the search strategy was appropriate.

Critique of the sponsors study selection

Describe techniques used by the sponsor to select studies for inclusion in the economic evidence section of the submission. State the inclusion and exclusion criteria used in the study selection. Comment on whether these criteria were appropriate.

Included and excluded studies

What studies were included by the sponsor in the economic evidence review and what were excluded? Describe the studies. Where considered appropriate, provide a table of identified studies.

Provide details of any relevant studies not included in the sponsor's submission of economic evidence. Why were these studies excluded and how were these studies identified by the EAC?

Provide details of any studies identified in the sponsor's submission of economic evidence that were excluded by the EAC. Why were these studies excluded by the EAC?

Overview of methodologies of all included economic studies

Summarise the methodologies of all included studies.

Overview and critique of the sponsor's critical appraisal for each study

Summarise and discuss the critical appraisal submitted by the sponsor for all studies included in the economic evidence section of the submission. Please present the results of the technology first and then the comparator(s), even when the source material presents the results the other way round.

Does the sponsor's review of economic evidence draw conclusions from the data available?

Discuss.

4.2 De novo cost analysis

The headings in this section are suggested headings. The EAC may prefer to include additional headings.

Include a description and critique of the key assumptions related to the model structure.

Patients

Technology

Comparator(s)

Model structure

Comment on chosen model structure in line with clinical pathway of care, list of assumptions and health states. Consider including a diagrammatical representation of the model structure.

Clinical parameters and variables

Include description and critique of data sources. How were clinical data used in the cost analysis? What time horizon was used in the cost analysis and does the EAC believe the assumptions to be valid? Comment on outcome measures used and the input of sponsor's Expert Advisers. Comment on the variables applied in the cost model.

Resource identification, measurement and valuation

Using the headings in the sponsor's submission as a guide, report and comment on resource identification, measurement and valuation by the sponsor.

Technology and comparators' costs

Using the headings in the sponsor's submission as a guide, report technology and comparators' costs.

Sensitivity analysis

Using the headings in the sponsor's submission as a guide, describe and critique the sensitivity analysis carried out by the sponsor.

4.3 Results of de novo cost analysis

Include the cost difference between technology and comparator(s) stated in the sponsor's submission. Include results and interpretation of the results of the sensitivity analysis.

Base-case analysis results

Sensitivity analysis results

Subgroup analysis

Model validation

4.4 Interpretation of economic evidence

Describe and critique the sponsor's interpretation of economic evidence.

4.5 Additional work undertaken by the External Assessment Centre in relation to economic evidence

Provide details of any additional work conducted by the EAC in relation to cost analysis. For example, if the EAC does not agree with some of the assumptions in the sponsor's cost model, or the structure of the model, or the scenarios presented by the sponsor, please present the results of alternative outputs. It may be necessary for an EAC to build its own model but please check with the technical team at NICE before proceeding with this work. It is acceptable for an EAC to disagree with some or all of the sponsor's model, but if this is the case, an EAC must provide alternative parameters or an alternative model to help inform the Committee's decision. If the results of any of the additional work affect the cost difference between technology and comparator(s), refer the reader to the summary table in the 'Impact on the

cost difference between the technology and comparator of additional clinical and economic analyses undertaken by the EAC' section.

4.6 Conclusions on the economic evidence

Firm conclusions on the economic evidence submitted by the sponsor should be made by the EAC to assist the Committee in its consideration of the economic evidence and develop its recommendations.

Describe the completeness of the sponsor's submission with regard to relevant economic studies and data described in any de novo cost analyses. Consider including discussion on any major limitations and/or remaining uncertainties about the reliability of the cost evidence. Make reference to the extent to which the submitted evidence reflects the decision problem defined in the final scope.

Impact on the cost difference between the technology and comparator of additional clinical and economic analyses undertaken by the External Assessment Centre

If appropriate, this section should include a table that shows (i) the effect of any major clinical or cost parameter change or structural change on the size of the base-case cost difference and (ii) the effect of making all changes simultaneously on the size of the base-case cost difference.

5 Conclusions

Focus on discussing information that will be useful to the Committee. This should include commentary on the robustness of the evidence submitted by the sponsor, relevant to the decision problem, including strengths, weaknesses and remaining uncertainties. The section should also consider any difference(s) of opinion between the sponsor and the EAC that might influence the clinical effectiveness and cost difference between the technology and comparator(s). Further summary of evidence is not needed in this section.

6 Implications for research

Describe research that may address weaknesses and uncertainties in the evidence base to support the guidance.

References

Appendix