**Evidence Dossier**

**Expert elicitation exercise for xxx**

*General advice is presented in italics throughout this template, this should be removed prior to distribution of the dossier. We encourage, where possible, to use bullet point format to ensure readability. More detailed, relevant information should be presented within the corresponding appendix.*

*Experts should be given the chance to review this document to highlight any potentially missing literature. If deemed relevant, the dossier should then be updated prior to final distribution for the workshop.*

**Notes for experts**

*Example: This dossier has been compiled to support the upcoming elicitation workshop you have kindly agreed to participate in. This document should contain all relevant and supplementary information that may help you and other workshop participants to formulate their judgements on the quantities of interest (defined in full in Section 2). We ask you to review this document, as subject experts, in order to ensure we have included all relevant information that may influence participants when making their judgements. The provision of this dossier aims to minimise potential availability bias within the exercise by ensuring all participants have the same evidence base to support their judgement making.*

*To help guide you when reviewing the dossier, we ask you to consider the key review points below.*

|  |  |  |
| --- | --- | --- |
| **Review point** | **Please tick when item reviewed** | **Additional comments or content to be included** |
| Are the elements in Section 1 clear?  *Please consider the description of the disease background, population of interest, overview of the pivotal trial and rationale of the workshop.* |  |  |
| Are the quantities of interest clearly defined? |  |  |
| Is the evidence base, presented in Sections 4 and 5,   1. clearly presented and easy to understand; 2. complete (i.e., are any key studies missing); 3. or missing any key information points? |  |  |
| Would any modification to the format, make the dossier more accessible to you? |  |  |
| Please provide any additional comments or clarification points you would like addressed prior to the elicitation workshop. |  |  |

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# Abbreviations

*List all abbreviations at the top of the document for easy referral during the workshop.*

# Overview

## Background

* *Use this space to provide the background of the project.*

## Target population

* *Use this space to clearly define the eligible population of interest.*
* *Highlight any differences between the target population and the population within the pivotal trial(s) for which data are being used to inform the elicitation workshop.*

## Intervention(s) overview

* *Outline key information regarding the intervention(s) including its placement within the clinical pathway (for the relevant market).*
* *Information relating to the mechanisms of action can be covered briefly in this section but refer to the appendices for more detailed information.*

## Pivotal trial(s)

* *Describe the key information from the pivotal trial(s) being used to inform the elicitation exercise.*
* *Highlight whether patients were permitted to crossover and how this was handled. Refer to more detailed information in the appendices where necessary.*
* *Refer readers to the appendices for detailed baseline characteristics and treatment administration regimes.*
* *Highlight any other defining features of the pivotal trial(s).*

## Rationale for the elicitation workshop

* *In the context of an HTA, this space can be used to outline how the elicited judgements will be used, e.g. within the context of a submission to an HTA body.*
* *Outline how the judgements will be used within the context of the above, e.g. to aid model selection for survival extrapolation.*

# Quantities of interest

*Define the quantities of interest that will be elicited during the workshop. Add as many QoIs as necessary.*

|  |  |
| --- | --- |
| QoI X |  |
| … | *…* |
|  |  |

# Evidence summary

*Use this section to summarise the evidence that is included within the dossier. This will include a summary of data presented in the following section, but also the evidence presented in the appendices.*

# Survival data: XXXXX trial

*This section should be used to present the* ***main*** *evidence bases for the workshop which should include:*

# Supporting evidence

*This section should highlight key studies and trials which provide information that will help experts formulate their judgements which support the main evidence. Study publications should be provided to experts separately via an appropriate platform.*

## Trial evidence for the intervention(s)

*In the table template below, list and summarise all relevant trials for the intervention(s) of interest. Add a row for each study. Include brief summaries of the trials along with key figures of survival data from the trials.*

|  |  |
| --- | --- |
| ***Trial name (with data cut-off/study duration)*** | |
| Resource | Description |
| *Study author and year with bibliographic reference*  *e.g.  Smith et al. 20241* | *Title of publication*   * *Bullet points describing key information from the trial including trial design, population of interest, key results* * *Limit to 5 bullet points per trial* |
| *If appropriate, figure from publication.* | |
| ***Trial name (with data cut-off/study duration)*** | |
| Resource | Description |
| ... | ... |
| … | |

## External evidence

*This section should include a list of publications whereby evidence for the intervention(s) is reported outside of the key trials but deemed relevant, for example long-term non-randomised controlled trial (RCT) evidence, trial evidence in a different indication. Include brief summaries of the analyses, with key information and figures where applicable.*

|  |  |
| --- | --- |
| ***Source of evidence*** | |
| Resource | Description |
| *Study author and year with bibliographic reference* | *Title of publication*   * *Bullet points describing key information including methods used and key findings.* |
| *If appropriate, figure from publication.* | |
| … | … |
| … | |

# Appendix

# Appendix A: XXXXX pivotal trial supplementary information

*Use this appendix to supplement information provided in Sections 1 and 4, refer to this appendix in Section 3. The sub-sections below are examples of suggested relevant information that may be useful to experts when formulating their judgements. Additional sections can be added where appropriate.*

## Eligibility criteria

## Exclusion criteria

## Population baseline characteristics

## Treatment administration

## Crossover

## Progression-free survival

## Time to treatment discontinuation

# Appendix B: General background and mechanism of action of XXXXX

*This section can be used to list review articles or other publications surrounding the new intervention(s). These articles should provide context for the intervention and additional details regarding the mechanism of action.*

|  |  |
| --- | --- |
| Resource | Description |
| *Study author and year with bibliographic reference* | *Title of publication*   * *Summary of the article and the information it contains.* |
| … | … |

# Reference list