

Briefing Book Guidance for Company

General Points for Preparing a Briefing Book:

- Use the provided [template](#) to submit a Briefing Book (BB) to NICE Scientific Advice (SA) in **Microsoft Word format**.
- The company may insert its logo on the title page.
- Replace information in brackets [] with relevant information on your product/company
- The length of the briefing book should not exceed 50 pages (excluding list of references) or 10Mb in size.
- Any annexes or essential self-standing documents such as study protocols, reports, etc., should be submitted as separate documents in Word or PDF format. Please do not embed these documents directly into your briefing book.
- The template should be used as a guide and judgement exercised as to which sections are relevant to the product for which advice is being sought.
- Additional sections may be inserted into the BB when required. Where relevant data are missing, this should be explained and an indication given as to when they may become available.
- Questions to NICE SA should be followed by company's explanation of its position. The wording of the questions should be clear and concise.
- It is not necessary to reference all statements in the BB; however, references should be provided if they relate to the methodology being proposed or the questions asked.
- Do not include preclinical data, pharmacodynamics or pharmacokinetic data unless specifically relevant to questions for SA
- Results of Phase II trials are not required if these are not available by the time of BB submission.

Selected section-specific points:**3.2 Treatment Options and Relevant Guidelines:**

- Current clinical care pathway and variations across the NHS
- NICE or relevant UK guidance
- Current clinical outcomes
- Include any products in established use regardless of the licence status
- Include non-drug treatment/procedure options if appropriate
- Include new treatments on the horizon in advanced stages of development if known

3.4 Regulatory Scientific Advice:

Indicate if regulatory scientific advice has been/will be obtained on the product. While the minutes of regulatory advice might be of interest, the Company is not required to submit these as part of this briefing book.

3.5 HTA Scientific Advice:

Indicate if HTA scientific advice has been/will be sought on the product.

4.3 Indication and Target Population:

- Specify clearly the intended indication(s).
- Specify product positioning in the treatment pathway (e.g. first line, second line, third line, screening pre-treatment, monitoring during treatment, etc.).
- State if it is combination therapy or monotherapy.
- Aim of treatment (preventative, curative, palliative, symptomatic, disease modifying).
- Target population.

4.5 Summary of Patient Engagement Information:

Briefly describe if you have engaged with patients and/or patient organisations as part of your product development programme, and the nature of that engagement

- if so, what issues/questions have you explored with patients/patient organisation groups e.g. real world applicability, limitations of the trials, outcomes of importance to patients, mode of administration, clarity of definitions etc.

4.6 Clinical Data Available to Date:

Describe clinical trials performed to date and provide results if available.

If the administration of the product is associated with the use of a diagnostic test, a medical device or a medical procedure, provide relevant information, e.g. describe if:

- additional monitoring is required for the product
- additional resources and training required
- adverse effects and management.

5. Product Value Proposition (s):

This section of the BB is mandatory. Describe value propositions for the product and how the trial evidence will be used to support these.

6. Proposed Clinical Development Programme:

For each trial, describe the objective, design (randomisation, blinding, etc.), location(s), doses and duration of treatment, comparator(s), number of subjects and description of studied population and end point(s). Provide a trial diagram if available. Specifically describe:

- **Patient population** (inclusion and exclusion criteria, patient characteristics). Discuss any differences between the licensed population and the population for the analysis.
- **Subgroups** identified (provide justification).
- Selected **comparators** (provide justification).

- **End points** (primary, secondary, other). All scales and scores that will be used for end point measurement should be presented and their validity should be reported.
- Study duration and follow-up.
- Crossover design (if applicable).
- Relevant methodologies and analyses of trial data.
- Data gaps expected in the evidence at the time of the initial appraisal.
- Provide plans to address these data gaps at the current time and following licensing.

You may include trial diagrams.

7. Proposed Economic Analysis:

This section is optional if no questions on economic evaluation are submitted to NICE Scientific Advice.

If plans for the economic evaluation are provided, these should include to the extent possible:

- Description of the proposed model (diagram, modelling approach, time horizon, perspective).
- Data collection plans to inform the model:
 - Evidence synthesis/meta-analysis – sources of evidence
 - Comparators – mixed treatment comparisons and indirect comparisons and evidence available
 - Trial end points used to derive health outcomes in the model
 - Quality of life – source and methods, tools used to measure QoL
 - Incorporation of adverse effects

- Resource use – sources and methods, tools used to measure resource utilisation
- Methodological Approaches:
 - Extrapolation – assumptions and data sources
 - Continuation rules
 - Use of surrogate outcomes
 - Planned sensitivity analyses

Evidence gaps and model assumptions should be described.

If you have further questions about the content of the briefing book, please contact NICE Scientific Advice for an informal telephone discussion (0161 870 3241) prior to your briefing book submission.