



**National Centre for
Pharmacoeconomics**
NCPE Ireland

NCPE Pre-submission Meeting Guidance for Applicants

Version 1.1. (updated 03 April 2020)

Introduction

The NCPE hosts pre-submission meetings with Applicants once the Corporate Pharmaceutical Unit has stated that a Health Technology Assessment (HTA) is required to inform a drug reimbursement decision.

What is the purpose of a pre-submission meeting?

The pre-submission meeting provides an opportunity for the Applicant to meet with the NCPE Review Team prior to finalising their HTA submission. The purpose is to outline the proposed approach to the clinical and cost-effectiveness modelling, and to obtain guidance from the NCPE on what may be the most appropriate approaches to adopt. The aim is to help the Applicant provide the best quality HTA submission possible, in order to avoid challenges later in the assessment process.

What information do I need to provide prior to the pre-submission meeting?

The parameters and methodology for the HTA submission will not be finalised until applicants have submitted a dossier and the NCPE has reviewed the submission in the context of the full dossier. The NCPE may ask Applicants to change some of the parameters/methods that have been provisionally discussed at the meeting. Discussions are non-binding on either the NCPE or the Applicant.

The NCPE prohibits the photographing, filming or recording of pre-submission meetings. Meetings may be webcast to facilitate remote access, but should not be recorded for replay.

Please provide the NCPE with the list of planned attendees prior to the meeting. Any PowerPoint slides to be used should be emailed to the NCPE three working days in advance of the meeting.

Who should attend a pre-submission meeting?

The local market access manager, someone to provide clinical insight into the intervention, and the model developers or those responsible for technical changes to the economic model, usually attend the meeting. Additionally employees of consultancy companies engaged to complete the HTA submission may attend meetings.

From the NCPE, it is likely meetings will be attended by the Deputy Head, a Senior Health Technology Assessor, a Health Technology Assessor, an Information Specialist and a Statistician.

What is the duration of a pre-submission meeting?

We allocate approximately one hour for the pre-submission meeting. If additional time is required, please notify the NCPE in advance to determine if it can be arranged.

What facilities are available for pre-submission meetings?

During the current COVID-19 pandemic the NCPE are facilitating video-conferencing for pre-submission meetings using Zoom. The NCPE will provide further instructions once the date for the pre-submission meeting is confirmed. The Applicant is requested to share the slides during the meeting.

What are the discussion points for a pre-submission meeting?

We recommend you consider the following points when preparing for the pre-submission meeting:

- Indication/patient population (including an sub-groups)
- Comparator(s)
- Efficacy data sources (which trials are used, and/or any other data)
- Main costs to be included and the source of costs
- Type and source of Quality of Life data
- Model outline/approach, including main assumptions and key drivers
- How treatment effects are modelled
- Approach to evidence synthesis, where required
- Long-term treatment effect assumptions
- Approach to sensitivity analysis
- Any limitation

Is there a charge for pre-submission meetings?

Pre-submission meetings are provided free of charge by the NCPE, in order to work with Applicants to ensure HTA submissions meet the quality standards required from the point of initial submission.