

Economic evaluations linked to BeNeFIT trials

Frequently Asked Questions

1. Is there a budget foreseen to plan and perform an economic evaluation linked to a BeNeFIT trial?

Yes. Although the BeNeFIT budget tool* doesn't mention this budget separately, it is included in the fixed amounts, e.g.:

- section 1 (project design and set up)
- section 8 (statistics, report and publication).

It is not possible to predict an exact budget for economic evaluation before the start of the clinical trial because the need and the complexity of the economic evaluation depend on the results of the trial. The agreed total budget is a maximum and will be paid in proportion with the work performed.

*The aim of the BeNeFIT budget tool is twofold: first, to make sure the applicant considers all necessary trial activities for the budget; second, to facilitate a fair and similar compensation for comparable work across the trials funded.

2. Where can I find both national guidelines for performing economic evaluations?

In the Netherlands, Zorginstituut Nederland published a guideline that is applicable for all economic evaluations of interventions in health care [“Richtlijn voor het uitvoeren van economische evaluaties in de gezondheidszorg”](#).

The [Belgian guidelines for economic evaluations and budget impact analyses](#) were developed by KCE.

3. How do I cope with the differences between Belgium and the Netherlands when giving economic input at trial set-up and when performing the economic evaluation?

Usually the same input variables from the study can be used for both countries and the main difference is in the valuation of them, for which two scenarios (BE and NL) can be presented.

- The analysis of the effects can usually be based on the entire trial population (unless there is a good reason not to do this).
- To translate the EQ-5D-5L health states into utilities, there is a NL value set available as well as a [BE value set](#) (2 scenarios).
- Also the costs associated with the healthcare usage will probably be different in both countries.
- Although the base-case analysis should be performed from a healthcare payer perspective according to the Belgian guidelines, analyses from a broader perspective (e.g. societal perspective; reference case according to the Dutch guidelines), are allowed, especially when the broader consequences of a treatment are relevant and measured.

4. What important aspects do I need to keep in mind when designing my BeNeFIT trial and collecting the necessary variables to inform an economic evaluation?

Information on Quality of Life should be obtained using the generic [EQ-5D-5L](#) questionnaire in addition to disease-specific instruments¹.

Relevant (incremental) cost information should be gathered in the most reliable and efficient way:

- Some of the data collected could be obtained from routinely collected data or administrative data, which might be a very efficient way to collect the necessary data. If this is only possible in one country, it could still be useful in order to validate the data collected through the questionnaires and/or to have the exact costs per event in that country.
- For consistency, it is advisable to use the same questionnaires in both countries, e.g. iPCQ, iMCQ, WPAI, ...
- Comprehensibility and applicability of the language of the questionnaires should be checked in both countries. It is encouraged

¹ <https://tools.eunethta.be/files/Endpoints%20in%20REA%20-%20Health%20related%20quality%20of%20life%20and%20utility%20measures.pdf>

to involve physicians/specialists and patient representatives in this exercise.

- Too many and too lengthy questionnaires could lead to heavy, expensive trials and poor data quality. It is important to think upfront about relevant outcomes (those with the most important incremental impact) and only collect those that will be analysed. Some questionnaires can be adapted. It is important to focus on the “must-have” variables (and the “nice-to-have” variables that are easy to collect can be added).

5. What important aspects do I need to keep in mind if I want to perform data linkage in Belgium?

Data linkage with administrative databases is a very efficient and reliable way to collect information but:

- check if the specific information you want is available and can be extracted from an administrative database;
- the possibility to do this needs to be planned upfront in the informed consent and protocol*. Standard text for inclusion in informed consent and protocol is available upon request.
- it takes time to get the approvals and the data. Reach out for support early.

*Linking with IMA data will require the ability to provide the patient’s national number at some point to a trusted third party. The national number does not need to be included in the data collection itself, but participating health care providers or institutions need to be able to make the link between the national number and the study number (both of which are available at participating sites). The research protocol should specify how this link will be established at the level of the individual health care providers or institutions.