BeNeFIT budget tool guidance notes

Introduction

The BeNeFIT call is a unique collaboration between ZonMw and KCE Trials to fund comparative effectiveness trials in Belgium and the Netherlands.

To facilitate the selection process and funding streams, candidates should submit the trial budget using the standardised budget tool designed for this call.

The budget tool integrates the ways of working of KCE Trials and ZonMw and is only to be used for BeNeFIT international calls. For national calls, the local organisational rules still apply.

For the BeNeFIT call, the tool differentiates between sponsor costs and site costs. All sponsor costs can be split between the Sponsor and the Coordinating Centre (either the Belgian Coordinating Centre or the Dutch Coordinating Centre). Each funding organisation will pay the costs allocated to the sponsor tasks in their respective country. Site costs will be paid by the funding agency of the respective country. Site costs can differ by country due to price differences and more importantly, due to the number of recruited patients per country. Therefore, a balanced number of recruited patients in the two countries is encouraged. Proposals with a balanced representation of Belgian and Dutch centres (and for Belgium, a good representation of Dutch and French speaking centres) will be prioritised.

There is no pre-set maximum budget per proposal other than the call budget limits. All necessary planned costs will be covered if justified in the completed budget tool.

The budget is constructed based on tasks that need to be performed rather than on an estimated FTE basis and contains automated formulae related to the study parameters.

We expect you to submit a draft completed budget tool excel along with the research outline (RO). Candidates who will be invited to submit a full research proposal (FRP) will receive initial comments on the draft budget, that need to be taken into account when submitting a revised budget with the FRP. The final budget should not deviate more than 15% from the original budget submitted at the RO stage (unless this is requested in the decision letter).

The budget tool and guidelines are developed by KCE Trials. If you wish to use this budget tool outside the KCE Trials Programme or the BeNeFit call, you should contact trials@kce.fgov.be.

Tell us how and why you wish to use the tool. Please include your contact details: name, institution/company, address, telephone number, and email.

Guidance to complete the BeNeFIT budget tool

These guidelines refer to version 3.0 date dd/mm/2020 of the BeNeFIT budget tool.

The budget template consists of different tabs detailing the study parameters, budget parameters, the sponsor costs, site costs and the overall costs. Extra tabs can be used if needed, for example to detail the costs of a contractor/collaborator. **The budget template is pre-filled with study related tasks but will need to be adapted according to each specific protocol.** Lines and tasks can be deleted or inserted as appropriate, however the general principles of the type of tasks allocated to a subheading should not be changed.

For general tasks a fixed price (FX) has been determined. Where relevant, formulas related to the study parameters have been inserted. Note that only in very rare cases for non-standard studies the fixed amount may be adapted after justification from the sponsor.

COLOR CODING

GREEN: DO NOT CHANGE

Cells in **green** contain formulas and are automatically calculated based on cells completed in other parts of the excel sheet. In general, **you should not change a figure in green**. By adding information elsewhere e.g. in the study parameters tab, this figure will be updated automatically. For some parameters, you might want to change the formula. In that case, please add a comment in the specific column

YELLOW: YOU NEED TO COMPLETE

Cells in yellow need to be completed to allow for automatic calculations throughout the worksheet.

This guideline document gives instructions on each of the tabs. Additional information is provided in the 'how to complete' tab of the budget tool excel file.

For questions related to the budget tool, please contact trials@kce.fgov.be.

STUDY PARAMETERS

In this tab, the general information about the trial and the trial timelines should be provided. Some of the information in the cells will be automatically transferred to the other worksheets. It is advised not to insert or delete lines in this tab as the links to the overall costs might no longer work. Should you wish to do so, please check corresponding formula in other tabs.

- Trial Number: to be completed once a trial number has been assigned by the BeNeFIT call secretariat.
- Planned number of subjects (screened, randomised, completed)
  A screened patient means a patient that has signed informed consent and was formally asked to participate in the trial. As pragmatic trials have only a limited number of inclusion/exclusion criteria, the number of patients screened is not expected to differ much from the number of patients randomised.
  In exceptional circumstances, where a high drop-out rate during the study can be expected, the number of patients completed might have an impact on the budget. In that case this should be reflected in the tab site visit costs. E.g. if a high drop-out rate is expected, only a % of patients will perform all visits (less monitoring, medication,… required for the follow-up part).
- Number of protocol related visits per subject = the number of visits where data collection will be performed including the standard of care visits (therapy sessions that do not require data collection points are not to be included).
- Number of sites
- Trial with GPs: select “yes” or “no” from the dropdown list
- Trial with placebo/extensive training for participating sites: select “yes” from the dropdown list if one of the two conditions (or both) are met, otherwise select “no”
- Study timelines
  - FPI: First Patient In (first patient signed informed consent)
  - LPI: Last Patient In
  - LPLV: Last Patient Last Visit
  - DBL: Database Lock
  - CSR: Clinical Study Report
- Note that the time between LPLV and CSR should not exceed 6 months.
- The on-site and off-site monitoring frequency (if relevant) needs to be determined as well as the number of monitors (=Clinical Research Associate or CRAs) on the project. Take into account a back-up CRA, note that having 2 CRAs does not necessarily mean 2 FTEs. The monitoring frequency should be defined after a thorough risk-assessment of the trial and should be justified in a monitoring plan. The number of visits here does not include the initiation and close-out visits (mentioned on separate lines in the tab sponsor costs). More information can be found in section 3 Monitoring.
- It is expected that the monitoring is risk based …… as a minimum quality check, all Informed Consent forms and patient existence will be verified in all participating sites. Regarding the primary variable as far as not reported by the patients themselves, source data verification should be done according to the instructions in the monitoring plan.
- Planned number or monitoring visits abroad (fixed cost per visit abroad). Depending on the sponsor country this will be number of sites in BE or NL and will also depend on decision of outsourcing monitoring to a coordinating centre in the other country.
- Expected number of SUSARs

- Note that in a pragmatic trial, the expected number of SUSARs is expected to be low. Safety reporting should be based on the requirements in the protocol (which are in turn based on the risk assessment). Further details can be found in the section on Safety.
- Complexity of the trial: select “low” or “moderate” from the dropdown list. The distinction should be based on the number of data points, integration of electronic data from other sources and the required safety follow-up - pragmatic trials are by definition considered as low complexity trials.

The timelines for the study start at the milestone "first patient in". Time that is invested in tasks before that date are included in fixed prices. The sponsor can ask for an advance payment (€ 12 500) to help support the development of the protocol if a proposal is invited to submit a full research proposal (FRP). A second advance payment (€ 12 500) can be requested to support the required additional recruitment check, as stated in the call text. These upfront payments are part of the budget, however if the study would not be selected for funding, the advance payments do not need to be refunded by the applicant. In the total cost of the study, the advance payments are deducted to allow for milestone calculations.

Trial timelines should be estimated for the analysis and reporting of the primary endpoint. In cases where the data collection time points for secondary endpoints deviates considerably (e.g. > 6 months) from the primary endpoint, a separate budget should be developed and included as an additional excel sheet/tab in the file. It should reflect the less intense follow-up for the period and tasks involved in this long-term follow-up for secondary endpoints.

BUDGET PARAMETERS

In this tab the standard hourly rates/fees for the different roles involved in the study are mentioned, based on hourly rates used by KCE Trials and ZonMw.

We recommend that you use these rates to build your budget. In case an individual rate is higher because of seniority, we consider this will be counterbalanced by the margin as well as lower individual rates for other roles.

The aim is that the estimation of the number of hours per activity by the sponsor and the sites should be as accurately as possible (not underestimated nor overestimated). In addition, we added a margin of 10% to account for future indexation, unforeseen delays and extra costs or capacity needs during the study. Note that for items with a fixed cost no margin should be added.

OVERHEAD

No overhead is to be included in the budget of BeNeFIT studies for sponsor costs.

VALUE ADDED TAX (VAT)

The VAT that is applicable to research activities should be checked in this tab. It is indicated at 21% at the time of publication of this guideline. The costs for medication might be subject to another VAT regimen. Check your local requirements and update the total amount in the tab overall costs if required.

'Deductible VAT' means VAT that is recoverable under the national 'VAT system' (i.e. the system of collection and deduction under the national VAT legislation). Such VAT is not a genuine and definitive cost and, according to accounting standards, should not be recorded as such. Therefore, it is not actually incurred by the beneficiary and should not be added to the study budget.

In Belgium, the Federal Public Service Finances has issued a decision E.T.131.445/2 that clarifies that the payments from KCE to the Sponsor or CC fall outside the scope of the VAT legislation.

The services provided by the collaborators to the Sponsor (e.g. participating sites and/or subcontractors) or to the CC however, will be subject to VAT. As far as the VAT is not deductible by the Sponsor or CC, KCE will assume this as an eligible cost that can be added to the site costs.

In summary:

- What KCE pays to Sponsor/CC is outside the scope of the VAT legislation
- What collaborators invoice to Sponsor/CC is inside the scope of the VAT legislation

The start-up costs for the site are set at €1.000. It should cover the costs for the site involved in the preparation for the initiation of the study (contracts, training, site set-up). This amount will be lower if working with GP sites (suggested fee of €200) and can be higher if working in a very complex setting involving several departments, pharmacy, lab etc. Any adjustment to the start-up costs should be justified.
There is a fixed amount set, to cover the travel costs for the monitoring visits, a margin is included, overhead does not apply.
A formula is introduced to calculate the time allocated to project management keeping in mind that some project management time is also budgeted in the fixed amounts of specific sections in the budget tool.
To calculate the costs for the site, fees are provided for the activities performed by the hospital pharmacy or the hospital lab if this is applicable for your study.

🗀 SPONSOR COST

General Guidelines

The number of suggested hours for each task are real life estimates and should be sufficient to cover the task. Several factors such as the complexity of the trial, the location and organisation of the participating sites (e.g. GPs, hospitals, presence of trial nurse,…) will drive the costs. **A 'reality check' of the total amount of each section is part of the budget building exercise**.

It is not the intention that the maximum suggested number of hours is used as a general rule. Sponsor teams will have to justify the time they think is needed.

We have populated the grid with roles (team member column) that are relevant to the performance of each defined task. This allocation is not mandatory to follow and can be changed according to the organisational structure or the type of trial. However, the tasks undertaken by a role should be appropriate for that role; all activities that can reasonably be delegated should be delegated to people with the necessary profile, experience and qualifications e.g. a junior PhD student should not be given the role of Project Manager for a multicentre RCT and, vice versa, a senior Project Manager should not be doing tasks that can be done by an administrative assistant.

FIXED AMOUNTS

For several tasks, a fixed amount (FX) has been calculated that represents the total of the time invested by the different roles. E.g. project design and set-up include protocol development where the Investigators, Project Manager, Statistician and Health Economist are all involved. The total estimate of the time and costs related to this have been integrated into a fixed amount. (FX in the team member columns).

EXTERNAL COSTS

For some tasks it can be necessary to look for external providers, these costs are labelled as EXT in the budget tool. Note that public tendering might be required in case you outsource activities above a legally defined threshold.

Depending on the study setting (e.g. hospital based, GP practices, specialist centres) the time needed may vary. The grid has been developed for a low/medium complexity (based on data points and safety) trial in a hospital setting.

There are 2 columns (K and L) to indicate what % of the costs will go to the Sponsor and to the Coordinating Centre. Column M and N have been added to have an automatic calculation of the amounts, thus allowing the funding agencies to get an overview of the budget distribution across the countries.

1. Project Design and Set up

This section includes all activities that are performed to enable the set-up of the project and that are required before the project undergoes regulatory/ethics review. There are two parts in this section: one fixed and one variable, based on number of sites to be visited.

Section 1a FIXED AMOUNT:

This fixed amount includes the following:

- Development of the protocol (including patient and public involvement, statistics, health economics, internal and external review, …); in case experts are consulted, the cost for travel, etc. should be covered by this amount
- Development of a Risk Assessment and Risk Management Plan
- Development of patient related documents (e.g. Patient Information Sheet and Consent Form, specific questionnaires, …) including any translations
- Development of agreements with funder, vendor/contractors (including public tender if applicable)
- Costs for review of documents related to this section
- Initial selection of participating sites/GPs

The feasibility of the study depends on the number of sites and their experience in setting up and running randomised clinical trials. In the current pre-populated grid, 50% of the sites are scheduled to have an on-site feasibility visit and 50% of sites are scheduled to have a remote feasibility visit. For large scale trials (e.g. more than 30 sites), this will not be possible and this line should be adapted. E.g. a full site feasibility visit in 10% of the sites and remote feasibility check in other 90% of the sites (€250/site).
The conduct of the feasibility and site selection visits is the responsibility of the sponsor. In addition, KCE/ZonMW will ask a contract research organisation (CRO) to complete an additional check of recruitment feasibility (see call text). Where appropriate, the sponsor feasibility visit and the CRO visit to the site can be combined.

The set-up, negotiation and finalisation of agreements with sites will depend on the number of sites involved. In case GPs are involved or in situations where there is no negotiation with hospital management required, the fixed amount for the contract development and negotiation needs to be reduced. The set-up, negotiation and finalisation of agreements with external collaborators can be added here (you will need to adapt the formula as it only takes into account the number of sites). The fee for contracts with external collaborators is to be reduced to 500€ per contract in case no public tender is needed.

License fees for the use of questionnaires are to be included in this section. However if an app, IT platform or another tool is developed, the costs for this should be detailed in section 12a, study specific equipment unless they are integrated in the eCRF platform.

2. Regulatory and Ethics Review

This section should include all costs that are related to:

- The development of medicinal product/device related documentation including IMP label related activities (design, translation), if applicable and if needed for regulatory/ethics review

- The logistic activities for the submission of the dossier to the Ethics Committee(s)
- The logistic activities for the submission of the dossier to Competent Authorities, if applicable
- The cost for uploading the study results to the EudraCT database, if applicable
- The provision of insurance, according to the legislation. Check with your insurance department if your institution already has undertaken an insurance policy that covers this.
- The formulas related to Competent Authorities will need to be manually updated if this is applicable to your study.

3. Monitoring

The purpose of trial monitoring is to verify that

- The rights and well-being of human subjects are protected
- The reported trial data are accurate, complete, and verifiable from source documents
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirements
  Source: ICH-GCP E6 (R2) 5.18

This section should include the cost for the monitoring of the trial as specified above and should take into account a risk based approach. The monitoring of a low-risk, pragmatic trial will require less frequent on-site monitoring visits and can even be done completely centralised. It is important to develop a monitoring plan as soon as possible to determine the monitoring requirements and frequencies for the specific trial.

The development of a monitoring plan (fixed amount) and all costs related to the implementation and follow-up of the study at the participating sites are to be covered in this section:

- **Training of CRAs**: this is the time needed for the CRAs to study the protocol and to get familiar with the disease area. It is not the training that is delivered to the sites (this is included in initiation visit and investigator meeting)
- **Conduct of initiation visits**. The suggested time (16 hours) needs to be adapted in case of remote initiation, investigator meetings counting as initiation visit or blended formula. Also the complexity of the trial and the involvement of different departments will need to be taken into account; e.g. time needed for an initiation visited at a GP practice will be considerably lower than a trial which involves different hospital departments, pharmacy, lab etc. The suggested standard time for studies with GPs is 8 hours. The formula can be adapted as such and a comment should be added in the comments field (column O). The suggested time includes the time to prepare, conduct and follow-up the visit and also includes the travel time to the site
- **Conduct of on-site monitoring visits**: The suggested time (16 hours) needs to be adapted for studies with GPs (suggested time for studies with GPs is 8 hours). The suggested time includes the time to prepare, conduct and follow-up the visit and also includes the travel time to the site.
- **Conduct of study closure**: The suggested time (16 hours) needs to be adapted for studies with GP's (suggested time for studies with GP's is 8 hours). The suggested time includes the time to prepare, conduct and follow-up the visit and also includes the travel time to the site.
- **Any remote monitoring activities**: for this activity, the formula contains 4 hours per contact per site but the time will highly depend on risk assessment, number of patients, number of data points. The formula should be adapted depending on monitoring plan and a comment should be added in the comments field to justify the change.– This activity can be split between data manager and CRA.
- **Travel costs for monitoring visits** (fixed cost per visit).
- **Travel costs for monitoring visits abroad** performed by sponsor or CC not in their respective country (fixed cost per visit to cover extra costs like transport/hotel costs). It is expected that the monitoring visits are performed by the sponsor or the CC in their respective country. The travel costs for visits abroad should be kept to a minimum and need to be justified.

The time allocated to each activity in this section is for a study of medium complexity. It should be adapted for studies of low complexity and should be justified in a monitoring plan.

4. Quality Assurance

Section 4 FIXED AMOUNT:

This fixed amount has been calculated to cover the costs of 4 days of QA activities (sponsor audit, site audit, systems audit, TMF audit, …) and includes time for preparation, reporting and travel.
This activity should be taken care of by an independent quality department. It can be the quality department of the hospital or can be outsourced.

5. TMF Handling & Administration

- This section includes all administrative activities related to the documentation, collection and archiving of essential documents: set-up and maintenance of a (e)TMF, (e)ISF, set-up and maintenance of a study portal.
- A fixed amount has been calculated for the general set-up.
- All activities that are dependent on the number sites involved, are mentioned on separate lines.
- If extra budget is needed for shipments of study material (e.g. in case of a fully remote study initiation) this should be included on a line 5c “Shipment and Distribution Services”.
- This section includes the administrative work involved in the set-up, execution and follow-up of invoices and payments by the sponsor. This needs to be adapted according to the agreed number of payments and depending on the trial setting (could be once yearly).
- Archiving costs for the Trial Master File at the sponsor: fixed amount of €250 per large box, assuming 2 boxes for the whole trial and 1 box for every 4 sites for 25 years archiving.

6. Safety

This section includes all activities related to the evaluation of the safety of the intervention studied (IMP, device, procedure, …).

The number of expected SUSARs should be estimated in the tab study parameters. Note that this should cover the SUSARs and/or SAEs requiring expedited reporting, as defined in the protocol. As the majority of trials within the BeNeFIT programme are pragmatic trials with registered medications used within the label, the expected number of SUSARs will be low.

For studies not involving IMP or devices, the safety evaluation and follow-up will be based on the risk assessment as documented in the protocol. This section might be not applicable in certain study settings.

Note that if working with a registered drug in an approved indication, safety reporting will follow the routine reporting for drugs with marketing authorisation.

Adjudication of endpoints will need to be evaluated on a case by case basis

Section 6 FIXED AMOUNT:

This fixed amount includes:

- Follow-up of SUSARs
- Writing of CIOMS (if IMP)
- Reporting to EudraVigilance Database if IMP or materiovigilance reporting if device
- Meetings on safety findings with DSMB if applicable (if IMP, can be Steering Committee otherwise)

7. Data Management

This section includes all activities related to the data management for the clinical trial. Keep in mind that the number of data items collected should be kept to a strict minimum and should only address the research questions in the protocol. All data collected should be analysed.

In case the study runs over a long time (>4 years), additional budget might be required for data management activities.

Section 7 FIXED AMOUNT

This fixed amount includes the following:

- Design of eCRF including all necessary development steps and UAT (user acceptance testing)
- License for eCRF software
- Design of Clinical Trial Database (including ePROs and eQoL)
- Design of the Safety Database if applicable
- Writing of the Data Management Plan
- Data Coding of adverse events (if applicable)
- Data Coding of medication (if applicable)
- Programming of queries (and sending in batches)
- Running query batches and distribution to sites
- Follow-up on query resolution
- Import of data (ECG, lab, images, … if applicable)
- Database lock
- Hosting of database on a server
- Archiving of the database

The fixed amount proposed makes a distinction between a trial of low complexity and a trial with moderate complexity. The distinction between low and moderate complexity should be based on the number of data points and the required safety follow-up.

8. Statistics, report and publication

This section includes the activities related to the statistical analysis for this trial, from statistical programming to collaboration between statisticians and clinical team to write the clinical study report.
Statistical input at the study set-up (including activities related to the randomisation process) is already budgeted under section 1.

Section 8 FIXED AMOUNT

This fixed amount includes the following:

- Statistical programming
- Generation of tables and listings
- Development of a Statistical Analysis Plan

- Statistical analysis and reports
- Generation of the Clinical Study Report, including meetings and review
- Writing and submission of the publication
- Any costs to ensure open access to the main publication of the study

Note that:

- Any subsequent analyses and publications are also included in this budget
- Any investigator meetings planned to present the trial results should be included under section 9, Project Management
- Costs for data linkage to existing administrative databases should be discussed on a case by case basis.
- Regarding the health economic analysis, the study budget will include the costs of collecting any data required to perform the health economics analysis (e.g. EQ5D) however the costs of performing the actual analysis will not be budgeted. Depending on the study results a health economic analysis may be justified. This will be a separate project and the options can be consulted in the call text. Involvement of a health economist in the development of the protocol, is covered in section 1.

9. Project Management

This section consists of the project management activities that are not mentioned in any of the above sections. It takes into account the time needed for the generation of study specific documents (communication plan, development of newsletters,…), the day to day follow-up of the trial (contact with key stakeholders, planning of meetings, follow-up of recruitment, follow-up of budget …). Costs related to activities detailed in the other sections need to be included in their respective sections rather than attributing them to the role of PM in this section (e.g. development of regulatory documents need to be included in section 1 or section 2).
Time for meetings that are not linked to any of the activities in the other sections, need to be planned in this section.

- Project Management: The formula in this line takes into account the calculations documented in the tab budget parameters.
  In case a study involves a long term follow-up, a separate line should be inserted to cover this part of the study at a lower FTE rate if still applicable (e.g. 50% of the active study period).
- Project Status Reports (reporting to the funders); during the recruitment phase of the study, regular updates are required. In a 2nd line, the less frequent reporting after the recruitment period is captured.
- Investigator Meeting(s): typical 2 meetings at the start and 2 result meetings are planned in the budget. For some type of trials(e.g. large trials or trials with a long duration) an additional meeting may be planned; this should be motivated in the column 'comments'
- Steering Committee Meeting(s): time and travel for external attendees should be covered by the fixed amount
- Study team meetings are budgeted with a fixed amount per meeting taking into account the presence of the majority of the Study Team/Trial Management Group. The frequency is estimated to be 2-weekly during the recruitment phase, followed by monthly meetings during the follow-up phase of the study

10. Patient and Public Involvement

This section includes the costs related to the involvement of patients or patient representatives in the trial. It is expected that patients will be involved before the endpoints are defined and the study outline is

submitted under the BeNeFIT Trials programme. In addition to their input on the choice of patient important outcomes, patients should evaluate the burden for the patient of participating to the trial, review patient information and consent form, and discuss the dissemination of the results.

Section 10 FIXED AMOUNT The fixed amount in the budget tool takes into account the financial support for 2 patients/patient representatives including transport, preparation and attendance to meetings.

A separate line has been included to cover the costs for attendance to TSC. If specific activities for patients will be organised, this can be included on a separate line.

11. IMP/Intervention Handling

In case the study requires a specific Investigational Medicinal Product, a device or a special intervention, all costs for purchasing, labelling, developing, tracking, etc. need to be included here. As comparative effectiveness trials are pragmatic trials, efforts should be made to prescribe and invoice medication or other interventions as in routine practice.

- Sourcing of IMP, comparator/placebo, device, … (including import license if applicable)
- IMP or intervention accountability, will vary for pragmatic trials: this includes the time needed by the pharmacist to perform all IMP related tasks
- Storage, distribution, maintenance
- Packaging, blinding, labelling
- Randomisation related activities (Codes, IXRS,…) if not taken care of by the eCRF system
- IMP destruction & recovery of unused products

This section is not pre-filled as it will highly depend on the type of IMP/device/intervention.
In case IMP handling is totally outsourced, it should still be captured in this section. Provide quotes regarding the costs for outsourcing to document the costs in this section.

Add VAT if not deductible to your organisation; if VAT is deductible the line should be deleted.

12. External vendors/contractors and central review

All costs related to the outsourcing of activities that do not relate to any of the above (e.g. central review, …) should be included in this section.
This section should also include costs for any specific equipment that needs to be purchased for the study. It should not include material needed for the day to day business of the personnel working on this study (e.g. PC, printing, paper, …)
It is highly recommended to provide supporting information such as quotes (preferably from different providers) to support the amounts in this section. Candidate sponsors should check institutional procedures and regulatory requirements related to the need for (public) tendering.

In general, no margin can be applied on these costs.

Any costs that are related to qualitative research or a SWAT (Study within a Trial) need to be included here. You can add your own estimation of the costs; however, the cost should be proportionate to the total cost of the trial.

Add VAT if not deductible to your organisation; if VAT is deductible the line should be deleted.

SITE COSTS

In this tabs an overview of protocol specific tasks should be generated. A specific tab has been created for each country.

Consideration should be given to the standard of care in each country. The sponsor team should determine the standard of care related to the frequency of follow-up visits, reimbursement criteria for the intervention and for any protocol related investigations. Activities that are considered as standard of care cannot be charged to the study budget. Tests and procedures charged to the study budget cannot be charged to the patient or health care system.

As comparative effectiveness trials are pragmatic trials, the data collected should come from routine medical data. However study specific costs (Informed Consent discussion, investigations, pharmacy, …) and time spent for the administration and data entry can be included here.

As a standard, the non-procedure section takes into account an average estimated time required by the study nurse and local investigator for the administration and follow-up of a pragmatic clinical trial which should be limited to data entry tasks, questionnaires and time needed for monitoring. In case safety follow-up is needed in addition to the normal pharmacovigilance for marketed products, this should also be added.
In general, there is a time allocation of 2 hours per study visit for the study coordinator covering the study procedures that are not considered standard of care (e.g. questionnaire) and the time needed to complete the eCRF. Ten minutes per visit of physician time are calculated on top of the routine consultation.

For costs related to pharmacy and lab, standard fees are applied that can be found in the tab budget parameters.

An example has been added in the budget tool template. This needs to be adapted to the study specific setting. Carefully check the formulas and delete or add columns and lines as appropriate

Start-up costs for sites are taken from the budget parameters tab.

Concluding remarks

When preparing for the initial application for the BeNeFIT call, it may be difficult to have the budget exercise fully completed. When the project is selected, the budget will be refined and further developed together with the funder's team. If the final budget would deviate more than 15% from the initially requested budget, this should be well motivated.

If you have any questions please don't hesitate to contact Trials@kce.fgov.be