Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

KCE Sponsor budget tool guidelines

These guidelines refer to version 1.0 date 27/01/2017 of the KCE sponsor budget tool (in Excel)

The budget template consists of different tabs detailing the study parameters, budget parameters (hourly rates/ fees), the overall costs (sponsor costs plus site costs). An additional tab can be used to detail the site costs. Extra tabs can be used if needed, for example to detail the costs of a contractor. 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.

This guideline document gives instructions on each of the tabs.

STUDY PARAMETERS

Start completing the study parameters tab as some information here will be automatically transferred to the other worksheets. In this tab, the general information regarding the study should be captured:

- Study Title,
- Number of subjects
- Number of sites
- Study timelines (FPI, LPI, LPLV, DBL, CSR)

BUDGET PARAMETERS

In this tab the standard hourly rates/ fees for the different roles involved in the study are mentioned. These are largely based on KCE report 178 that analysed the cost of personnel working in hospitals. The number of worked hours per year is about 1600 taking into account vacation days, sickness leave, days for training, etc. The rates have been adjusted for indexation and include the 2017 indexation. The rate for the CRA has been adjusted to include transportation. KCE recommends that you use these rates to build your budget. Exceptions are possible, but should be justified. Roles other than those described in this tab can also be used, and should be mentioned here.

The aim is that the number of hours estimated per activity by the sponsor and the sites should be estimated as accurately as possible (not underestimated nor overestimated). In addition, KCE accepts during the first years of the KCE Trials programme a margin of 15% to account for future indexation, unforeseen delays and extra costs or capacity needs during the study. This is to support the learning curve in the first years of the KCE Trials programme. Note that for items with a fixed cost no margin should be added.

As the return on the investment of a trial depends on the time to results, KCE Trials is looking into possibilities to reward the sponsor and the sites for trials completed within the agreed timelines.

For overhead costs in KCE Trials, KCE accepts a maximum rate of 17%. Adding full overhead costs for expensive fixed cost items (>10.000 EURO) may not be appropriate and will require discussion on a case by case basis.

There is no overhead for the sponsor on the site costs, however overhead costs charged by sites with a maximum of 17%, can be included.

🗀 OVERALL COST

General Guidelines

The lines should be completed with the number of hours by role.

Eg. For protocol development a Chief Investigator, Project Manager, Statistician and Economist can be all be involved. Enter the details on a separate line for each team member.

	Units	No. of units	Team member	Unit cost	Cost (EURO)
Project Design and Set up					
Trial protocol incl. stats, econ input, any rework, meetings incl.	hours		**CI**	**€ 100,00**	
Trial protocol incl. stats, econ input, any rework, meetings incl.	hours		**PM**	**€ 50,00**	
Trial protocol incl. stats, econ input, any rework, meetings incl.	hours		**Stat**	**€ 55,00**	
Trial protocol incl. stats, econ input, any rework, meetings incl.	hours		**Econ**	**€ 55,00**	

KCE has already populated the grid with roles that are relevant to the performance of each defined task. This allocation is not mandatory to follow and can be changed according to the organizational structure or the type of trial.

However the tasks undertaken by a role should be appropriate for that role e.g. a Chief Investigator should delegate all activities that can reasonably be delegated.

The number of suggested hours for each task are real life estimates and should be sufficient to cover the task. In case of deviations, this should be motivated by the candidate sponsor.

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.

- Development of the protocol (including patient and public involvement, statistics, health economics, internal and external review, …)
- Development of patient related documents (e.g. Patient Information Sheet and Consent Form, specific questionnaires, …)
- Development of medicinal product/device related documentation including IMP label related activities (design, translation), if applicable and if needed for regulatory/ethics review
- Conducting a full feasibility of the study by the sponsor. In addition, KCE Trials will ask a contract research organisation to complete an additional check of recruitment feasibility. Where appropriate, the sponsor feasibility visit and the CRO visit to the site can be combined.
- Development of agreements with funder, sites, vendor/contractors. KCE has templates that can be used.

Costs for review of documents should be included here.
Costs for translation of documents and license fees for the use of questionnaires are to be included here.

2. Regulatory and Ethics Review

This section should include all costs that are related to

- Submission of the dossier to the Ethics Committee(s)
- Submission of the dossier to Competent Authorities, if applicable
- Provision of insurance, according to the legislation

3. Monitoring

This section should include all costs related to the implementation and follow-up of the study at the participating sites:

- Pre-study visit (if applicable e.g. in case not all questions were covered during the feasibility or the feasibility was done remotely)
- Training of CRAs
- Conduct of initiation visits
- Conduct of monitoring visits
- Conduct of study closure
- Any remote monitoring activities

4. Quality Assurance

- Should include any audits planned as part of the QA programme of the sponsor (Clinical Trials Unit).
- FU of any audit findings

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
- This section includes the administrative work involved in the set-up, execution and follow-up of invoices and payments by the sponsor.

6. Safety

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

- Set-up of safety database
- Follow-up of SAEs
- Writing of SUSARs (if IMP)
- Reporting to EudraVigilance Database (if IMP)
- Extra meetings on safety findings with DSMB (if IMP, can be Steering Committee otherwise)
- Reconciliation of the safety database

7. Data Management

This section includes all activities related to the data management activities 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.

- Design of eCRF
- Design of Clinical Trial Database
- Writing of the Data Management Plan
- Data Coding of adverse events
- 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

8. Statistics, report and publication

This section includes the activities related to the statistical analysis for this trial. Note that the statistical input at study set-up should be budgeted in section 1. Any meetings to discuss the statistical results should be included in this section.
There is a need for close collaboration between the writers of the clinical study report and the statistician. Therefore the reporting of the trial is also included in this section.

- Generation of randomisation scheme
- Generation of tables and listings
- Development of a Statistical Analysis Plan
- Statistical programming
- Statistical analysis and reports
- Generation of the Clinical Study Report, including meetings and review
- Writing and submission of the publication

This section includes any costs to assure open access of the publication. Note that any investigator meetings planned to present the trial results should be listed under Project Management.

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 time needed for the generation of study specific documents (monitoring plan, 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 above 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 above, need to be planned in this section.

- Project Management, other
- Project Status Reports (update KCE)
- Investigator Meeting(s)
- Steering Committee Meeting(s)

If meetings have to be held off-site costs for meeting room and any travel costs are to be listed.

10. 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, … need to be included here. As KCE 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
- Randomisation related activities (Codes, IXRS,…)
- Packaging, blinding, labelling
- Storage, distribution, maintenance
- IMP destruction & recovery unused products

11. Overview of Site Costs

It is advised to detail the site costs in a separate tab detailing the costs according to the activities required by the protocol. Start-up costs for sites (with motivation) should be detailed in this section.

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, …)

🗀 SITE COSTS (details)

In this tab an overview of protocol specific tasks should be generated. All activities that are considered as Standard of Care cannot be charged to the study budget. However study specific costs (Informed Consent discussion, investigations, pharmacy, …) and time spent for the administration and data entry need to be included here.