



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

Budget estimation and provision of study treatments/ interventions

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KCE Trials programme information session for candidate sponsors

20th May 2016



Overview

- **Budget estimation for EOI**
- **Research costs:**
 - **Sponsor costs**
 - **Site costs**
- **Costs of study treatments/ interventions**
 - **Non-reimbursed trial interventions**
 - **Reimbursed trial interventions (standard trts)**
- **Budget for full project proposal**

Budget versus Payments

- **Budget**
 - **As complete as possible**
 - **Sponsor costs**
 - **Site costs**
- **Payments to sponsor:**
 - **10-20% at start**
 - **70-80% by visit completed according to plan**
 - **10-15% for study report and manuscript**

Possible sponsor costs I

- **Protocol development including statistics**
- **Database and eCRF design, set-up and data management**
- **Management of contracts* and finances**
- **Regulatory submissions (CA/EC)**
- **Site selection**, training and management**

***KCE can provide template**

****KCE will visit sites to assess recruitment capacity before contract signed**



Possible sponsor costs II

- **Quality assurance and monitoring**
- **Safety reporting (drugs, devices)**
- **Drug and sample management**
- **Any centralized testing + logistics**
- **Analysis and reporting**
- **Management and coordination**
 - **reporting on trial progress to KCE**
 - **Steering Committee meetings**

Possible site costs I

- **Local study set-up**
- **Training (initiation visit, meetings, ...)**
- **Start-up fee**
- **Visit fee**
 - **study specific evaluations**
 - **CRF completion**
 - **(S)AE reporting**

Possible site costs II

- **Depending on the protocol**
 - fees for supporting departments (laboratory, pharmacy, radiology, ...)
 - patient travel cost
- **Archiving of site study documents**

Study drugs / interventions I

- **For non-standard of care treatments or treatments used in designs randomised against placebo:**
 - **Study drugs will be provided, labelled and financed in the usual way for clinical trials**
 - **Study drug (provision, packaging, blinding, labelling, storage & distribution, re-supply, destruction or recovery of unused drug) should be costed in the research costs**

Study drugs / interventions II

- **For standard treatments which are reimbursed interventions:**
 - **RIZIV / INAMI will reimburse standard treatments in the usual way even if they are prescribed following randomised allocation**
 - **Reimbursed study drug should not be costed in the research costs but they should be listed as ‘reimbursed study interventions’ in the EOI form**

Budget for full proposal

- **For those EOIs invited to submit a full proposal we encourage to have a meeting and discussion with the KCE trials team regarding the development of the final budget**
- **More information will be provided at the time of invitation to submit a full proposal**

THANK YOU!



<http://ikce.yourict.net/?q=node/1957>



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