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

Top ten tips and tricks for a successful research outline

1. **Read the guidance notes before you start completing the Application form**.
The guidance notes for completing the 2018 Application form can be found here.
If you have any questions please contact KCE on Trials[at]kce.fgov.be.

2. **Contact a clinical trial unit early in the process.**
Contact a clinical trial unit of a non-commercial sponsor to ask if they are willing to support your research proposal. It is important to contact the clinical trial unit as soon as possible in the process as you will need to develop and write your research proposal together to ensure all scientific, organisational and regulatory requirements are met.

3. **Make sure the proposed research question is relevant for current Belgian practice**.
The KCE Trials programme focuses on practice-oriented comparative effectiveness trials. Comparative effectiveness trials compare the benefits and harms of different treatment options that are already in use in the health care system but which have never been adequately compared directly (i.e. which of two treatments work better in a real-life situation). Accepted study interventions include a broad range of interventions for example psychotherapy, diet, life-style interventions, diagnostic tests, surgery, drugs, medical devises or ways to deliver health care. Trials focussed on innovation and development or implementation trials are not eligible for funding by KCE Trials.

4. **Explain why more randomised research is needed**.
Make sure to clearly explain the rationale for the trial, the current evidence and situation in Belgium. Trials methodology reviewers may not necessarily be experts in your field. The need for evidence can, for example, be demonstrated by a systematic review of existing evidence that shows inconclusive results or the lack of high-quality randomised trials that directly compare several existing treatment options. It is also important to check if no similar randomised trials are currently ongoing or are about to be published. It should be clear what your proposed study will add and how it will help health care funders in their decision making.

5. **Use a pragmatic approach in your trial design**.
A pragmatic trial is designed to test interventions in the full spectrum of everyday clinical practice in order to maximise applicability and generalisability. The research question under investigation is whether an intervention actually works in real life. To ensure generalisability, pragmatic trials should, as far as possible, represent the patients to whom the treatment will be applied. Furthermore, the setting and the way the studied interventions are applied should copy routine practice as closely as possible. Pragmatic trials usually measure a wide spectrum of patient-centred outcomes. Only data that are essential for analysis of important outcomes should be collected.

In making your trials as pragmatic as possible, please take into account existing waivers that exist for non-commercial trials and the following document that may provide practical ideas as to how pragmatic approaches can be implemented in studies: MRC/DH/MHRA Joint Project document on Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products.

6. **Clearly define the primary endpoint of the trial.**
Make sure that the primary endpoint of your study is defined and described clearly enough: what is the primary outcome, how will it be measured and when will it be measured. This is key for understanding your proposal. The lack of a precisely defined primary endpoint is a frequent criticism of proposals. The primary endpoint should be the outcome that is used to calculate the sample size.

7**. Describe the sample size calculation so that it can be replicated.**
Your proposal will be reviewed by a Trials Board composed of trials methodology experts. They should be able to understand and reproduce the sample size calculation for your proposed study using the information you provide.

8. **Involve patient representatives in the design and the entire lifecycle of your study**
Clinical trials should be designed in such a way that the question and results are really important to patients. The outcomes of a trial should be patient-centred and important to patients, therefore it is important to involve patients right from the start. Furthermore, including the voice and experience of patients when designing your study is helpful to ensure eligibility and feasibility of your trial, avoiding problems later on during the study. More information on patient involvement can be found here: http://www.invo.org.uk/ and http://www.eu-patient.eu.

9. **Consider a possible health economic analysis when designing your study**
Improving the efficiency of the Belgian health care system is an important objective of the KCE Trials Programme. Depending on the effectiveness results, the clinical trial may be followed by a separate economic analysis. Therefore, it is important to already collect the variables that are essential for a later economic analysis during the trial. Health economists at your institute or at KCE can advise you in this. Please do not hesitate to contact trials”at”kce.fgov.be to discuss health economic considerations in your research design.

10. **Provide an implementation plan already at the start of your study**
Think upfront how the results of the trial might have impact on the health care system. How will these results change the current practice and how can this be implemented?