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

Information for candidate sponsors including guidance notes for completing research outline application form

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KCE TRIALS PROGRAMME

PART 1: GENERAL INFORMATION

KCE Trials programme

Many research questions in healthcare are currently not sufficiently studied using clinical trials, despite their high societal importance. The KCE Trials programme (**Trials programme**) is a programme of pragmatic, practice-oriented clinical trials funded by KCE to support better patient care and to ensure a more efficient use of public resources (http://kce.fgov.be/content/what-is-the-kce-trials-programme).

These guidance notes set out the application process, selection criteria and review procedures for candidate investigators and sponsors who apply to the investigator-led call of the Trials programme (PART 2). These notes are intended to support candidate investigators and sponsors to provide the required information within the "Research Outline" application. (PART 3).

KCE sponsor visits

By submitting a research proposal under the Trials programme, each candidate sponsor acknowledges and accepts that KCE may at any time request a third party auditor to verify the candidate sponsor's overall capacity to perform the proposed research in accordance with the terms of its research proposal. These audit assessments may involve a site visit.

Data protection

By submitting research proposals under the Trials programme, each candidate sponsor acknowledges and accepts that all personal data provided by it in connection with the research proposals, including all personal data relating to any of its proposed research team members or research collaborators (for which, to the extent required, the candidate sponsor shall obtain their consent), can be processed by KCE and its employees, representatives, agents and consultants in accordance with the below. These personal data may include, but shall not be limited to, personal data such as name, gender and address. The purposes of this processing are for KCE (i) to be able to take informed decisions and actions under the Trials programme and (ii) to notify any candidate sponsor on upcoming research projects under the Trials programme.

By submitting research proposals under the Trials programme, each candidate sponsor acknowledges and accepts that said personal data can be transferred to third parties which KCE relies on for the provision of certain services related to the purposes mentioned above (including any third parties who may be performing quality audits of candidate sponsors and/or any of its research collaborators) and to any other funding organisations outside KCE, also outside the European Economic Area.

Subject to the data transparency principles set out below, KCE will not disclose said personal data to any other third parties, except if KCE has received the express written consent to do so or if KCE is otherwise legally authorised to do so.

KCE confirms that said personal data shall be processed proportionally within the purposes set out above and shall not be retained longer than necessary for the above mentioned use.

At all times, the relevant data subjects whose personal data are processed shall have the right to (i) object to any further processing of said personal data upon request and free of charge and (ii) to access said personal data which is processed by KCE and, where appropriate, to have any incorrect personal data corrected.

Data transparency

By submitting research proposals under the Trials programme, each candidate sponsor acknowledges and accepts that its name, the name of the key members of its research team and the name of its research collaborators may appear on KCE's website.

In addition, once a research contract is signed and funding is released to a candidate sponsor, the candidate sponsor acknowledges and agrees that the names set forth above may appear in other literature and that the content of the research contract and protocol may be shared with third parties and will be available on KCE's website.

Applications involving tissue collection and biobanks

If funds are requested for the creation of a tissue collection or biobank, the candidate sponsor should specify why it is necessary and is different from existing collections.

PART 2: SELECTION PROCEDURE

Relevant KCE bodies involved in the selection procedure

All members of the Trials Board (TB) and Prioritisation Group (PG) must agree to treat all information confidentially and declare any potential conflict of interest (COI). COIs are managed in line with KCE Trials COI procedure.

Trials Board

The TB is multidisciplinary, composed of experts in clinical trials and health economics, representatives of patients and members of the public, academics, subject experts, clinical staff, health and public health professionals. The TB is responsible for the review of the Research Outlines and Full Research Proposals (FRP) (as further defined below) based on the selection criteria set forth in Annex 1. Decisions will take into account all of the assessment criteria in an integrated way. For outlines, TB members will try to reach a consensus. If no consensus is reached there will be a vote. For FRPs, the decision will be taken based on a vote.

Prioritisation Group

The PG is responsible for prioritising pending proposals and ranking those research proposals recommended for funding under the Trials programme. The PG takes account of the available KCE budget, the overall portfolio of research, the care needs of patients and the most efficient use of public resources in making final recommendations to the KCE Board.

KCE Board

The KCE Board, as set forth in article 270 of the Programme Act (I) of 24 December 2002, is responsible for making the final selection and funding decision on the candidate sponsor's research proposals which were recommended for funding by PG.

Questions and any possible complaints regarding decisions of the TB, PG and KCE Board can be sent to trials"at"kce.fgov.be. Decision are final however and there is no organised administrative appeal procedure for candidate sponsors to appeal the decisions.

Overview of selection procedure

(A schematic flow chart summarising the applicable selection procedure is attached below).

Research proposals submitted by candidate sponsors to the Trials programme will undergo a stepped selection procedure:

1. The submission of an initial research outline by candidate investigators and sponsors outlining the key information on the research proposal: review of outline by a panel of clinicians and health economists, by KCE's TB and notification of the outcome to the candidate sponsor.
2. Invitation to submit full research proposals by candidate sponsors shortlisted by KCE's TB: submission of a full research proposal (FRP) by the shortlisted candidate sponsors for consideration by KCE's TB.

This stepped approach facilitates a proportionate and timely assessment of the eligibility, feasibility and value for money of the research proposals which can progress to the second stage. Only shortlisted candidates will be invited and required to develop an FRP for further consideration and review by KCE's TB.

Step 1: Submission of Research Outline

A call for research proposals for the investigator-led workstream is published on the KCE website. A call is usually open for approximately 6 to 8 weeks. Research outlines must be submitted before the deadline, as specified for each call on the KCE website).

Candidate investigators and sponsors must submit an outline by using the outline template form associated with this call (which can be found on KCE Trials website) and by following the research outline guidance notes for candidate research teams (PART 3). The research outline must include a short description of the planned research, the candidate sponsor's trials capacity, draft budget and provide any initial feasibility data.

Please read the '**Top ten tips and tricks for a successful research outline'** document to help you with your submission.

KCE Trials encourages collaborations between research centres. Models where a candidate sponsor delegates some sponsor or research tasks to other centres (including monitoring the performance of multicentre trials) are possible. Any proposed collaborations with other centres should preferably already be identified and addressed by the candidate sponsor in the outline. KCE is willing to advise candidate sponsors how such collaborations can best be organized.

KCE Trials encourages candidate sponsors to use trial interventions that reflect Belgian current clinical practice as close as possible (i.e. pragmatic trial).
This UK report on risk adaptive approaches to the management of clinical trials of investigational medicinal products may provide practical ideas as to how pragmatic approaches can be implemented in studies. It complements existing waivers that exist for non-commercial trials.
MRC/DH/MHRA Joint Project - Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products

An option to consider, if of interest for the design of the pragmatic trial or economic analysis, could be the use by the candidate sponsor of study subjects' Belgian national number (rijksregisternummer/ numéro national) to acquire data, for examples RIZIV-INAMI billing data. This needs upfront discussion with KCE Trials on trusted third party involvement and protection of privacy.

After selection by a panel of clinicians and health economists and prioritisation by the PG, selected research outlines will be assessed by the TB using the criteria set out in Annex 1. The TB assessment for each outline will result in one of the following 3 decisions:

1. Outline not selected for further review (***declined***).
2. Outline not shortlisted but the relevant candidate sponsor is invited to submit a revised outline, taking account of the TB's recommendations (***declined and invited to resubmit***).
3. Outline shortlisted and candidate sponsor invited to submit an FRP (***shortlisted and invited to submit full proposal***).

Any candidate sponsor shall be individually informed of the relevant decision by the TB. Where the TB's decision as set out in option 1 above is to decline a specific outline, this shall be duly motivated and then there shall be no further assessment process.

Step 2: Submission of Full Research Proposal

Candidate sponsors whose outlines were shortlisted by the TB are invited to submit an FRP within the deadlines set out in KCE's invitation to submit an FRP (approximately 6 to 8 weeks after the invitation) for further evaluation by KCE Trials. In well justified cases, KCE may make a limited (non-reimbursable) advance payment to contribute to the candidate sponsor's costs of developing the FRP. The FRP must include the full protocol, a final budget and a more mature feasibility assessment and where applicable commitments from collaborating sites.

Shortlisted candidate sponsors must submit their FRP using the FRP template form and take account of the FRP guidance notes for candidate sponsors (which will be made available on the KCE website in due course).

FRP's will be assessed by the TB based on the criteria set forth in Annex 1 within approximately 4 weeks following their submission. Further to this assessment, the TB will set forth which FRP is recommended for funding (if any), with or without changes. Possible decisions by the TB are:

1. FRP not selected for further review (***declined***).
2. FRP not selected and the relevant candidate sponsor invited to resubmit a revised FRP addressing the TB's recommendations (***declined and invited to resubmit***).
3. FRP selected pending detailed changes (***recommended for funding with changes***).
4. FRP selected (***recommended for funding***).

If the TB recommends an FRP for funding (decisions 3 or 4 above), the PG will consider whether recommendations can be supported based on the final prioritisation and ranking of all the recommendations and consideration of the available budget for the Trials programme. The PG will submit its recommendations for funding to the KCE Board for approval.

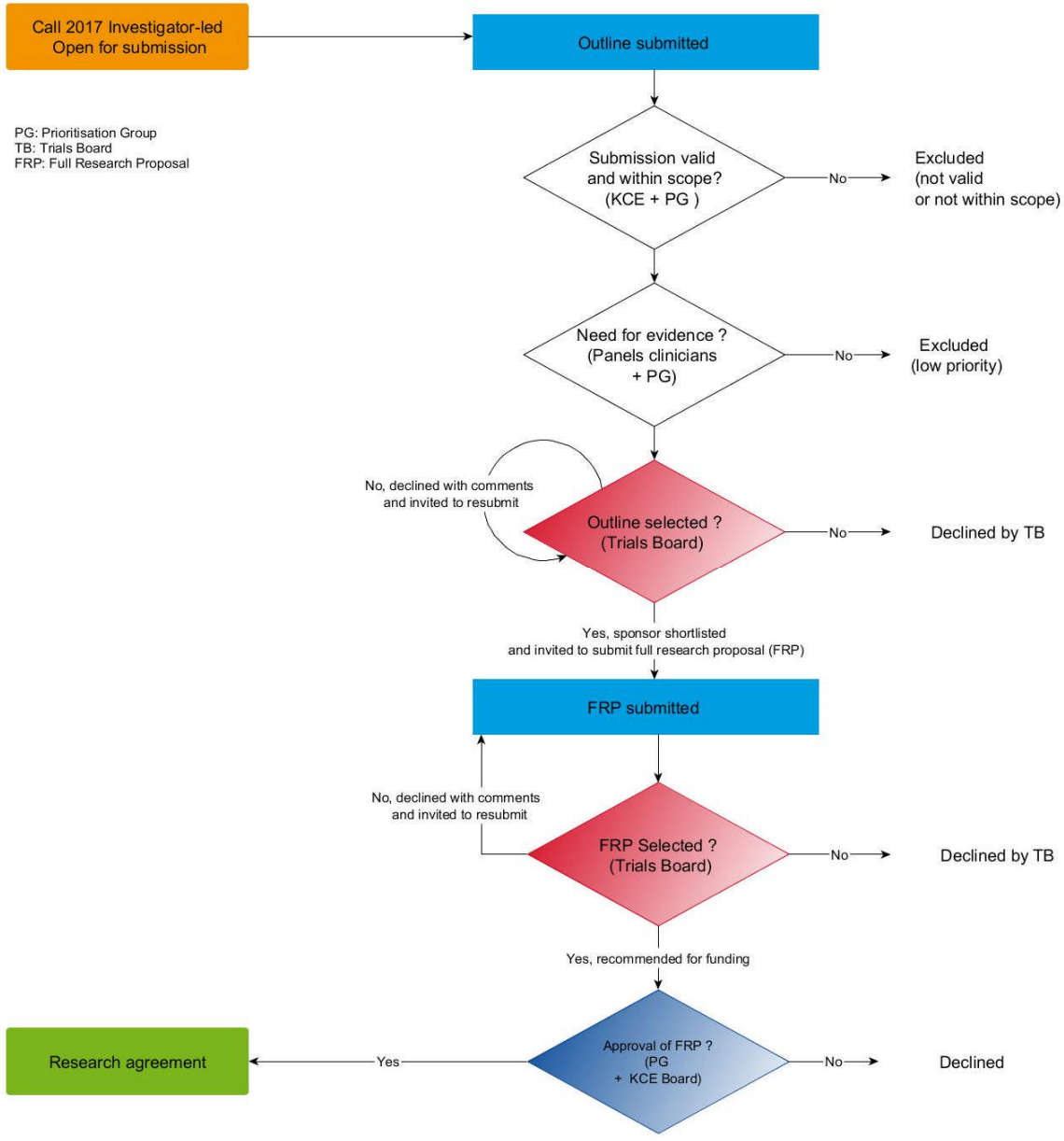
Negotiation of research agreement

Following the selection and approval of an FRP as set out above and before entering into a research agreement, KCE and the selected candidate sponsor will finalize the trial feasibility checks, review in detail the proposed trial budget and adjust it where deemed appropriate. The research agreement is to be signed before the initiation of the study. An advance payment is possible to finalize a protocol when an outline is shortlisted for FRP. Similarly, and advance payment is possible for the sponsor to conduct the trial feasibility checks.

Please note that KCE shall remain entitled at all times to postpone, suspend and/or withdraw any pending research call (even during the negotiation of the research agreement) at its own discretion; KCE shall under no circumstances be obliged to select any pending FRP or enter into a research agreement after FRP selection. Candidate sponsors can withdraw their submission at any time before signature of the research agreement.

Questions and any possible complaints regarding decisions of the TB, PG and KCE Board can be sent to trials"at"kce.fgov.be. Decisions are final however and there is no organised administrative appeal procedure for candidate sponsors to appeal the decisions.

Schematic overview of the investigator-led workstream under the Trials programme



PART 3: GUIDANCE FOR COMPLETING YOUR OUTLINE APPLICATION FORM

[The following headers refer to sections of the Outline application form]

General comment: Candidate sponsors should ensure that their research outline application form provides sufficient information for KCE Trials to evaluate the application against the selection criteria outlined in Annex 1. To facilitate international review, submissions should be in English.

History of application, sponsor, chief investigator and collaborators

If you are applying to the investigator-led workstream under the Trials programme, please ensure that you read the applicable selection criteria thoroughly before starting your application. If you are unsure about any item addressed, please contact the KCE team at trials"at"kce.fgov.be.

History of application to KCE Trials and other funders

KCE Trials: If this application is a resubmission of a research proposal, please indicate how your current research proposal differs from previously submitted outlines, if applicable. If this resubmission is within the same call, please provide a detailed reply to each individual comment of the TB in attachment.

Other funders: Where a similar proposal has been submitted to another funding organisation, please detail *to which* funding organisation it was submitted, *when* such proposal was submitted, and the *outcome* of the submission or date of expected outcome.

Research proposals that are part of an international initiative for non-commercial pragmatic trials are eligible for the investigator-led call.* Please provide sufficiently detailed information regarding the candidate-sponsor and collaborators and possible funding sources in other countries in order to allow KCE Trials to evaluate whether the proposal falls within the scope and the non-commercial set-up of the KCE Trials programme. Co-funding of the sponsor is expected if a significant proportion of patients will be recruited abroad.

*Please note that ongoing international trials (recruitment started) are excluded from this call. For possible participation of Belgian centres to already ongoing international trials, please contact trials"at"kce.fgov.be.

Note: Financing by multiple funders is not allowed, unless explicitly agreed otherwise by KCE Trials.

Sponsor Organisation

Please give details of the organisation that will act as the sponsor if the trial is funded, as well as the main contact person. If this proposal is part of an international initiative with a sponsor not located in Belgium, please provide in addition the contact details of the candidate Belgian coordinating centre and its main contact person. All correspondence by KCE with the organisation will be addressed to this contact person.

Chief Investigator

Please give contact details of the chief investigator. Please provide a mobile telephone number where the CI can be reached after the Trials Board meetings.

Collaborators

Please list the planned participating sites (or if international, countries with planned number of sites per country). More information should be provided below in the feasibility section.

Conflicts or potential conflicts of interest

Please declare any conflicts or potential conflicts of interest that the sponsor, its study team members and, where applicable, its collaborators may have in undertaking this research, including any relevant, non-personal and commercial interest that could be perceived as a conflict of interest. Please be sufficiently specific, e.g. names of companies are to be mentioned.

Summary of the research proposal

Research title

The project title should clearly and concisely state the proposed research in a structured way. Please spell out any abbreviations (max of 300 characters)

Example:

Outcome X after intervention A versus B: a randomized, multicentre, parallel group pragmatic trial in Y patients with disease Z.

Short title

The short title (max of 50 characters) will be used in administrative documents.

Rationale for research

- What is the problem being addressed? Why is this research important in terms of improving the health of the public and/or to patients and the Belgian Healthcare system? Provide as much information as possible that is relevant to the Belgian healthcare system: number of patients, current practice, current reimbursement situation etc. (maximum 2000 words).
- How does the existing literature support this proposal? What would the proposed study add to the existing body of evidence and ongoing trials? Applicants are invited to add in annex the search performed to find the completed as well as the ongoing trials.
- How does the research proposal meet the selection criteria with special attention for the specific criteria of the 2017 call on value for money and possible return on investment? Please note that research outlines that contain insufficient information to judge the value for money and expected return on investment will receive a low score in the evaluation procedure.

Patient and public involvement

The KCE Trials programme strongly recommends to have patients and public actively involved in the design of the study. Please briefly describe how patient and public involvement has informed and/or influenced the development of the application and how they will contribute during the lifecycle of the project (*250 words max*). This can include, for example, involvement in the choice of the research topic, choice of the outcomes, assisting in the design, advising on the feasibility of the research project etc. Further information and resources can be found on the INVOLVE website http://www.invo.org.uk/.

Please note that this section does not refer to the recruitment of patients or members of the public as participants in the research.

PICO

What is the research question? You should include a clear explanation of the main (single) research question phrased in PICO terms. Please be concise when completing the table. A well-defined PICO research question is a prerequisite to have a valid outline submission.

Population: target population i.e. real patients; provide main eligibility criteria
Intervention: A technology that is or could be used now in Belgium; also indicate the health service setting(s) in which the study will occur
Comparator: Usually next best treatment or usual care, but could be placebo
Outcome: Patient centred, leading to effectiveness and cost-effectiveness

- Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established.

Design

Design: Give a brief statement on the type of study design to be used. Explain how random treatment allocation and allocation concealment will be assured.

Sample size: State the required sample size, giving details of the estimated effect size, power and/or precision employed in the calculation (provide details under section statistical considerations)

Visit schedule: specify which visits are standard treatment and which additional/study specific. Please add a flowchart and/or visit schedule in attachment.

Outcomes: describe the way and time points that outcomes will be measured (PRO, questionnaires, EQ-5D etc.…). Details should include justification of the choice of outcome measures where a legitimate choice exists between alternatives. If the study includes a health economic component, state from what perspective costs and benefits will be considered, and (briefly) how these will be collected.

Follow-up: discuss and specify any long term follow-up plans after the main analysis.

Statistical considerations:

Provide sufficient details of the sample size calculation so it can be reproduced (superiority vs non-inferiority, alpha, beta, clinically relevant difference). Detail the population(s) for the analyses planned (intention to treat, per protocol, safety), primary analysis (define the time point, variable, test that will be used, details of any adjustments), secondary analyses.

You may find useful information in the following guidance from the NHS Health Research Authority: http://www.hra.nhs.uk/documents/2014/05/guidance-questions-considerations-clinical-trials.pdf

Health economic considerations

Describe health economic considerations by stipulating the expected impact (if any) on mortality, quality of life and cost items. For cost items, please include at least current costs for all interventions, both for RIZIV-INAMI and patients. Also consider the impact on adverse events and related costs (e.g. hospitalisations) and describe the possible impact on other important variables. The focus should be on items that are different (i.e. incremental elements) between the alternative treatment arms in the trial, both in the short and long term. Think for example about possible differences in follow-up, productivity, etc. As such, you can generate the hypothesis whether the results of the research could lead to net saving for the Belgian healthcare system budget or to the introduction of more cost-effective interventions.

To be able to have an idea of the possible budget impact, please also provide an estimate of e.g. yearly number of patients in Belgium and/or frequency of use.

Timetable

Provide an overview of the timelines of your research proposal if your research proposal would be recommended for funding by the Trials Board. Consider the Trials Board decision as month zero and indicate the estimated timelines in months after the TB decision for each listed event.

Please be realistic about your possible start date *inter alia* taking into account the necessary time to enter into the applicable research contract, and any approvals by governmental bodies and/or ethics committees that you may need prior to starting your project. Please take into account that the necessary capacity in term of manpower to assure continuity needs to be in place.

Research costs and feasibility

Estimated research costs

The initial research outline requires a 'financial estimate' of the research costs. Successful outlines will be invited to submit FRP's including development of full study cost assessments with financial approvals. All costs need to be fully justified by the candidate sponsors to demonstrate that the study offers good value for money for the Belgian healthcare system and tax payer.

Please enter estimated values for the research costs and add the current reimbursement practice for any investigations under study.

The Trials programme accepts that some variance in costs is likely to occur between outline and FRP and will carefully scrutinise all full application costs and any variance from the outline.

Research costs (with a split between sponsor and collaborating site costs)

Research costs include (amongst others and as applicable): protocol development including statistics, database design, set-up and data management, management of contracts and finances, regulatory submissions, site selection, training and management, quality assurance and monitoring, pharmacovigilance, drug and sample management, analysis and reporting. All planned analyses should be justified. Data that will not be analysed should not be collected. A breakdown and justification of the budget should be provided as an attachment using the excel budget template provided with the call.

Visits or tests that are additional to standard care will form part of the research costs rather than standard care costs.

Costs for the trial interventions (medication, devices, other) are part of the research costs unless the approval is obtained to use the RIZIV-INAMI (or any of its counterparts) reimbursement for the interventions.

VAT: Any VAT should be mentioned and included in the estimates provided.

Overheads: Any overhead costs should be justified and mentioned in the estimates provided.

Interventions under study that are reimbursed

Please provide details of price and current reimbursement status of the interventions used in the trial.

Sponsor and collaborators' capacity

Please provide details of the sponsor and collaborators experience and track-record to act as a sponsor of multicentre randomized trials.

The team (sponsor and collaborators) should be multidisciplinary and include relevant expertise in the clinical area concerned, in health economics, in performing systematic reviews, and (where appropriate) other areas. The Trials programme encourages the sponsor to work with, and delegate some sponsor responsibilities to, other centres where this results in a stronger submission.

Recruitment considerations

Please provide information on the planned recruitment rate (a calendar with the estimated number of patients per month from the start to the end of recruitment). Provide evidence that the number of participating sites is sufficiently high and that the investigators have access to a sufficient number of eligible patients to keep the planned recruitment period as short as possible, while fully respecting the scientific rigour of the trial. Provide details of the number of patients seen in each of the participating sites last year and what percentage may be eligible for the proposed research.

In addition, indicate the measures that are in place to maximally reduce the risk for a delay in recruitment including the absence of competing trials that may hamper patient recruitment. Highlight any potential issues that may hamper accrual.

General comments

Use this box to add any information you would like to provide to KCE Trials and the Trials Board.

Proposed terms of the research agreement

Following the selection and approval of an FRP, KCE and the selected candidate sponsor will enter into a research agreement prior to the initiation of the study.

A template research agreement has been drafted by KCE in consultation with representatives from the Belgian university hospitals. Please highlight your main comments/reservations (if any) in respect of the proposed terms of **the template research agreement**. You can add the draft template research agreement with your comments in tracked changes as an attachment to the outline form. There is no need to scrutinize and address in depth all the terms of the template research agreement at this stage, but KCE will expect to receive your potential main comments/reservations on the template research agreement. If you do not have any major comments, please indicate this in the form.

Attachments

Please attach (in PDF format):

1) Signed and dated short English CV of chief investigator (max 1 page)
2) A signed letter of support from the candidate sponsor clinical trial unit (CTU)
3) A one page flowchart and/or visit schedule
4) Description of the literature search performed to find completed as well as ongoing trials summarising and referencing relevant and existing systematic reviews of the available evidence, including reference to any more recently published literature that is relevant. Where no reviews exist, an appropriate review of the current available and relevant evidence should be performed in a systematic way, with a summary of the methods and findings
5) A breakdown and justification of the requested budget (in the excel template provided, do not convert to PDF)
6) Template research agreement (see KCE website) with comments in tracked changes. If you have no comments, please indicate in the attachment that you have no major comments on the template research agreement.
7) If the trial includes an international collaboration, add a description of how it is organised, including information on collaborators and delegated tasks
8) If this is a resubmitted outline, please attach an overview with responses to the TB comments.

Please mark in the table in the outline form which attachments are added to the application and name the files as advised.

ANNEX 1 - ASSESSMENT CRITERIA

Specific criteria investigator-led call 2017

Expected return on investment (ROI)	Highest score: substantial cost savings are expected. Either substantial savings per patient for small populations as well as savings for large populations that are substantial because of the size of the population fall within this category. Interventions with an equivalent effectiveness that result in relevant cost savings compared with existing alternatives also fall within this category. High score: Increased patient benefit comes at acceptable extra expense for society. Low score: It is very questionable whether the increased patient benefit comes at an acceptable extra expense for society. Research outlines that contain insufficient information to judge the expected ROI will receive a low score.

General criteria

Need for Evidence	• The importance or burden of the health or care problem to those who would use the evidence generated by the proposed study. In particular, whether the trial would likely lead to improved health and care in Belgium and contribute to change in practice. • What the proposed study would add to the existing body of knowledge based on a well-documented search for completed and ongoing research.
Value for Money	• The proposed costs of the research are reasonable and commensurate with the work involved. • The costs of the trial are reasonable in relation to the likely benefit of the research to decision-makers, patients and the public. In particular, in addition to the health benefits, the results of the research could lead to net saving for the Belgian healthcare system budget or the introduction of more cost-effective interventions (return on investment). • The trial results can have an immediate and important impact on the efficiency (decrease of the costs and/or improvement of the results) of the Belgian healthcare system, preferably without the need for an additional implementation project. (see specific criteria 2017)
Sponsor	• The sponsor's team has the necessary skills, procedures and experience in conducting non-commercial multicentre trials and has the ability to comply with all sponsor related obligations under the applicable laws, including the law of May 7, 2004. The candidate sponsor allows KCE to verify these requirements during a visit. If the sponsor is not located in Belgium, said sponsor must demonstrate that it benefits from advantages that are similar to the advantages that apply to non-commercial multicentre trials in Belgium (the law of May 7, 2004). • The investigators in all study sites demonstrate an expertise in the disease and patient population that will be studied.

Design	• The study design would answer the research question proposed. • The trial is a comparative effectiveness trial of interventions in use in Belgium, without limitation in terms of therapeutic domain or type of intervention or comparator. Trials evaluating new interventions in development would be excluded. • The trial interventions should reflect Belgian current clinical practice as close as possible. • A randomised, multicentre design is highly preferred. • The use of centralised randomisation and e-CRFs are recommended. • A pragmatic design is to be selected if this would be most informative. Only a limited set of variables, needed for the pre-planned analyses, are to be collected. All variables collected need to be well justified.
Patients	• The number of participating sites is sufficiently high and the investigators have access to a sufficient number of eligible patients such that the planned recruitment period is kept as short as possible while fully respecting the scientific rigour of the trial. In addition, measures are in place to maximally reduce the risk of a delay in recruitment including the absence of competing trials that may hamper patient recruitment. The investigators allow KCE to verify these requirements during a study site visit.
Timelines	• The risk of recruitment delay is considered low. • The relevance of the trial results at the time of publication should be justified.
Implementation	• The trial results can have an immediate and important impact on the efficiency of the Belgian healthcare system, preferably without the need for an additional implementation project.
Patient and public involvement	• KCE strongly encourages patient involvement in research. The involvement of patients and public in the development of the project and their continued involvement through the lifecycle of the research project.
Terms and conditions of the research agreement	• The terms and conditions of the proposed collaboration between sponsor and KCE should be acceptable (**see collaboration agreement version 1.2**).

In case of a resubmission, KCE will include the reply of the candidate sponsor to the TB recommendations as an additional criterion in the assessment.