

KCE TRIALS PROGRAMME

KCE Trials 2025 Investigator-led call

Deadline for submission: 23 September 2025; 13h

Call text

Key Dates

20 May 2025	The call opens on the KCE Trials research management platform (https://kce.smartsimple.ie/)
5 Jun 2025; 10h	Information session on scope and Q&A (online)
23 Sept 2025; 13h	Deadline for submission of Research Outline (call closes on KCE Trials research management platform)
End Nov 2025	Decision on prioritisation of proposal (by Prioritisation Group)

1. AIM

KCE Trials is a national funding programme of clinical research managed by KCE. It funds pragmatic clinical studies that are of high societal importance in Belgium and have no direct commercial purpose. The studies should contribute to better patient care, show clear value for money and should have the potential for return on investment. Accepted study interventions for treatment or prevention include a wide range of healthcare interventions, such as drugs, medical devices, surgery, physiotherapy, psychotherapy, lifestyle changes, diagnostic tests or complex interventions with several components. Study settings can vary from highly specialized hospital care to primary care. All trials are randomised and require a multicentric setting.

Two types of studies are funded:

- **Comparative effectiveness studies** comparing two treatment options that are already used in clinical practice for a given indication, but have not yet been sufficiently directly compared (i.e. which of the two treatment options works best in daily practice and is the most cost-effective).
- **Drug repurposing studies** investigating a new indication for an off-patent drug.

Information on the trials that are being funded by KCE Trials Programme can be found on [our website \(Funded Trials\)](#) and on [our dynamic dashboards](#).

Calls for proposals are organised every year. This document describes the criteria for participation and selection for the 2025 investigator-led call. The budget available for this call is € 8.0 million with the aim of funding 4-6 studies.

2. SCOPE

2.1 Who can submit to the 2025 investigator-led call?

This call is investigator-led, meaning that investigators conceive the research and develop the study proposal.

Sponsor in Belgium (Belgian studies)

The investigator should have the support of a Belgian non-profit organisation or institution (usually a hospital or a university) that is willing to act as the sponsor of the trial and has the ability to comply with all sponsor related obligations. It is strongly recommended that studies are developed and conducted with the support of a clinical trial centre (CTC) or equivalent.

In general, participants must be recruited primarily in Belgium. If funding is requested for a minority of participants recruited abroad, justification should be provided and will need to be approved by KCE. For trials with a large number of participants recruited abroad, participation of other funders will be required to cover site costs for those participants and to contribute to the sponsor costs.

Sponsor abroad (International studies)

The participation of Belgian centres to an international non-commercial trial within the scope of this call is also eligible for funding. KCE Trials will provide funding for the participation of Belgian centres through a Belgian Coordinating Centre (BCC). The sponsor abroad and the BCC should both be non-profit organisations or institutions.

2.2 Scoping criteria

Inclusion criteria

The primary aim of the study is non-commercial, this means:

- The candidate sponsor (and the BCC, if applicable) should be a non-profit organisation or institution that can function as sponsor of non-commercial multicentre trials and has the ability to comply with all sponsor related obligations.
- They are not the holders of existing intellectual property rights (e.g. patent on a medicinal product or registered trade mark for a medical device) on the products or invention to which the experiment relates.

- The candidate sponsor and the research team have [no conflict of interest](#)¹ with regard to the conduct and possible results of the trial.
- The sponsor exercises the intellectual property rights to the concept of the trial, its implementation and the scientific data resulting from it.
- If there is a potential commercial interest in the trial (e.g. the trial requires the use of drugs, apps or medical devices), an exclusivity criterion comes into play. In general, the results of the trial cannot bring an exclusive benefit to a single company only².
- Studies on the effect of medical devices, tools (including software and apps) or on-patent drugs are only in scope, provided that there is a strong justification why the study would not be performed by the marketing authorisation holder or manufacturer. In this situation an expected high return on investment is required.
- The funding granted under the research agreement complies with the European state aid regulations.

Design

- The trial is randomised (at individual level or in clusters) and multicentric (with at least one recruiting centre in each region, unless there is a good justification not to do so).
- There is substantial underlying peer-reviewed evidence that supports moving to a large-scale confirmatory randomised trial.

Additional inclusion criteria for comparative effectiveness studies

- The trial compares two therapeutic or diagnostic interventions (no treatment/no test can also be an option) that are already in use in daily practice in Belgium in the studied indication.
- Medication used off-label in daily practice is considered in scope.
- Studying an intervention that is already in use in a patient group (e.g. adults) in another patient group, (e.g.; children, elderly, oldest old) can be considered in scope. A change of timing, e.g. first line versus second line, or change in dosing or duration of the treatment can also be considered in scope.

Additional inclusion criteria for drug repurposing studies

- The available evidence suggests that there is a potential for high return on investment.
- The drug is authorised and effectively commercialised in Belgium (or in use in daily practice in Belgium).
- The drug is off-patent. The applicant will have to demonstrate at a later stage in the selection process that there is no intellectual property issue (e.g. secondary patents).

Exclusion criteria

Started studies

- Studies for which recruitment has already started in Belgium, or which have already been submitted to a Belgian ethics committee and/or to the FAMHP (Federal Agency for Medicines and Health products) are out of scope. International studies that have already started abroad (but not in Belgium) are eligible if all other criteria are met.

Implementation studies and quality improvement studies

- If the primary aim of the studied intervention is to promote the uptake of research findings, the study is considered implementation research, which is out of scope. Interventions that aim to improve implementation of existing guidelines, health policies, programmes and practices are also out of scope, as are studies that aim to improve quality of care.

Development and innovation studies

¹ <https://kce.fgov.be/nl/kce-trials/resources/kce-trials-policies-and-procedures>

² For instance, studies including drugs that are available in generic form or studies in medical devices that are produced by several companies would be considered as having an aim which will not bring commercial benefit to exclusively one company. Studies aiming to extend the indication of drugs still on patents or studies using unique medical devices would be considered as having a commercial aim (and should therefore be funded by the company itself).

- Drugs without marketing authorisation in Belgium are out of scope except if already widely used in Belgium.
- Medical devices without a CE label are out of scope.
- All types of interventions, including interventions related to organisation of care, should already be in use in daily practice. Interventions that have been used only within the framework of clinical research or pilot testing are out of scope.
- Proof of concept studies are out of scope.

Mobile health studies (apps)

- Software and apps used as part of the intervention that are not fully developed, piloted and that do not meet all regulatory requirements on data protection are out of scope. Apps that are not used in daily practice in Belgium are also out of scope.
- Study proposals on software and apps should also include an implementation plan which is in agreement with the non-commercial aim of the KCE Trials programme. Proposals without this implementation plan will be considered out of scope.

Studies that have already been submitted twice to the KCE Trials programme

- An application that has been declined can be resubmitted once in a KCE Trials investigator-led call. In this case, the applicant should clearly state which changes were made and how the concerns of the previous review were addressed. If the application is declined again, a similar project will no longer be eligible for KCE Trials funding.

2.3 Duration of study and maximum budget

The study should be able to generate results **within 60 months** after the start of the study. Exceptions to this rule are possible but will need to be justified and accepted.

A long term follow-up after collection of the primary outcome period can be included if appropriate.

The **maximum budget** of a study cannot exceed half of the total available call budget.

2.4 Patient and public involvement

KCE strongly encourages patient involvement in research, ideally individuals with lived experience. The involvement of patients and/or the public in the development of the project (e.g. the choice of the research question, the selection of patient-relevant trial endpoints, the feasibility of trial assessments) and their continued involvement through the lifecycle of the research project is required for submissions to the call. Therefore, KCE Trials has prepared a patient involvement document to be completed and added to the application (see links and downloads).

3. HOW TO SUBMIT ?

- The call will be open for submission during the dates indicated on the first page of this call text.
- As a first step, candidates are invited to submit a Research Outline (RO). Shortlisted candidates will be invited to submit a Full Research Proposal (FRP) (including the study protocol) later in the process.
- All submissions must be made through the KCE Trials [online submission platform](#). Once you have created an account, you will find information to start your submission under the “funding opportunities” tab.
- You may prefer to prepare your application using the application form in Word format, which is available on the [KCE Trials website](#) for your convenience (applications submitted using the Word template will **not** be accepted). This document also provides guidance on how to complete your application.
- Only the chief investigator can initiate an application and complete the submission. However, other members of the research team can assist in completing the application form if they are added to the “contacts” list. **You are encouraged to contact your statistician, legal advisor, health**

economist, clinical trial centre or equivalent early in the process and give them access to your application to complete their parts.

- A detailed budget should be submitted using the dedicated budget tool, **for which separate guidance notes are available**. It is recommended to complete the budget tool in collaboration with the clinical trial centre.
- All documents required for the submission are listed below in section 7.

To be deemed valid and to enter the selection process, a submission must:

- Be written in English.
- Be submitted via the [online submission platform](https://kce.smartsimple.ie) (kce.smartsimple.ie) before the deadline.
- Include details of the chief investigator and candidate sponsor.
- For Belgian trials, include a signed sponsor support letter using the KCE Trials template or, for international trials with a non-Belgian sponsor, a support letter from the Belgian Coordinating Centre (BCC) and a commitment letter signed by the international sponsor, using the applicable KCE Trials templates. The letters must be signed by the legal representative of the sponsor/BCC (usually the CEO), or an official delegate.
- Include a study budget in the appropriate template.
- If there is any collaboration with a commercial partner (e.g. supply of free/discounted medication, apps, medical devices etc.), a signed commitment letter from the commercial partner accepting the KCE Trials terms and conditions using the applicable KCE template should be included in the initial submission. This will be used in order to assess the non-commercial nature of the trial and additional information may be requested. Standard purchasing under normal market conditions does not require a signed commitment letter.

4. SELECTION PROCESS AND SELECTION CRITERIA

4.1 Selection process

In general, throughout the selection process, proposals will be evaluated on the basis of the information available in the submission. Applicants should ensure that there is sufficient clear information available in the proposal to evaluate the submission according to the listed criteria.

The evaluation and selection of research proposals for trials with Belgian sponsors involves several steps:

1. All valid research outlines received will be assessed by the KCE Trials Prioritisation Group (PG) as to whether or not they fall within the scope of the call as defined in this call text.
2. The 'in scope' Research Outlines (ROs) will then be evaluated and scored by a Panel of clinical experts, health economists and representatives of patients for their relevance and importance for the Belgian health care system. A maximum of 15 proposals will be discussed by the Panel. If a larger number of ROs are received and in scope, the ROs with a low score on the prioritisation criteria may be excluded at the previous stage by the PG or by a pre-ranking by the Panel.
3. Based on the prioritisation criteria and the available budget, the PG will prioritise the most relevant research proposals for further evaluation.
4. Candidates will be informed of the results of the first steps of the selection process in December 2025.
5. The shortlisted ROs considered to be of highest priority will be evaluated for their methodological quality and scientific value by the Trials Board (TB) (see Annex I). The first TB meeting for the 2025 call will be scheduled at the end of 2025.
6. The TB can either decline the RO, invite you to resubmit the RO (once maximum) or shortlist the RO to continue to the Full Research Proposal (FRP) stage. The sponsor team will have at least six weeks to develop and submit the FRP (including a draft trial protocol) or the revised RO.
7. The evaluation of your proposal by the TB may involve several review cycles, with a maximum of five times in total.
8. Once a proposal is recommended for funding by TB, and in collaboration with you, KCE or a Contract Research Organisation (CRO) may visit participating sites to check accrual commitments and predictions. This feasibility phase is part of the selection process.

For international trials with a sponsor abroad, the first 4 steps are the same. If selected, the ROs will not be forwarded to the TB as protocols for international trials are usually written in consensus with the international partners. The final draft protocol and budget for Belgium participation has to be submitted to the TB within the timelines of the call. Protocols for international trials will be reviewed by the TB once, in a 'take it or leave it' fashion. Exceptionally, a second review by the TB can be done, if requested changes can still be implemented by the international sponsor or additional information needs to be provided.

More information on the selection process can be found [here](#) on the KCE website.

4.2 Selection and prioritisation criteria

The detailed evaluation criteria for this call are listed in Annex I. The prioritisation criteria are listed below.

Prioritisation criteria

Study proposals will be prioritised based on:

- The need for generating new evidence in clinical practice.
- The potential efficiency gain for the Belgian health care system (see "potential value for money" in Annex I).

In addition, the following criteria will be taken into account during the prioritisation process:

- The **number of people** potentially impacted by the intervention is large. For rare indications, international trials are preferred.
- The **expected effect of the intervention/improvement** is large (mandatory if the previous criterion is not met).
- Funding of the trial by commercial stakeholders is unlikely and/or not warranted.
- The **geographical distribution of the participating centres** is well balanced across the different regions.
- The research question has been put forward as a **priority by patient groups** or is ranked high on a research agenda developed in collaboration with patients.
- The **overall portfolio of the KCE Trials programme** remains well balanced in terms of disease areas, types of interventions and settings.
- The **trial budget** is justifiable and commensurate with the work involved and is acceptable within the overall KCE Trials budget. A good return on investment (see Annex I) is expected.

Finally:

- Proposals aimed at improving mental health and proposals investigating treatments specifically supporting older people (as they are generally underrepresented in trials) would be welcomed. However, this should not be considered as a limitation of the accepted trial populations or the scope of the call.

4.3 Submitting to multiple funding agencies

If a study has already been submitted to another funder, or if the application is simultaneously in the selection process with another funder, this must be stated transparently on the application form. Also, if the applicant subsequently submits the study to another funder while it is still in the selection process, KCE Trials should be informed as soon as possible. Once the decision of the other funder is known, the applicant will immediately inform KCE Trials. If the other funder reaches a positive decision accepted by the applicant, the proposal will be removed from the KCE Trials selection process.

4.4 Important information on decision-making during the selection process

Please note that KCE reserves the right to postpone, suspend and/or withdraw the review of or support for any research proposal at any time at its sole discretion and that KCE is under no obligation to select any pending proposal or enter into a research agreement after FRP selection.

Applicants may withdraw their proposals at any time prior to signing a research agreement with KCE.

Questions and any possible complaints regarding the decisions of the Trials Board, Prioritisation Group and KCE Board can be sent to trials@kce.fgov.be. However, the decisions are final and there is no organised administrative appeal procedure for candidate sponsors.

5. STUDY BUDGET

5.1 Budget tool

The budget for the proposal should be submitted using the budget tool designed for this call. By submitting an application, the candidate sponsor agrees to the principles of the budget tool and guidance notes. **You are advised to carefully read the guidance notes related to the budget tool template or the budget tool BCC template for international trials**, as they contain useful information that will help you to better understand the different tasks and the rationale for the formulas used when preparing the budget for your trial. You are encouraged to contact your clinical trial centre early in the process of developing your budget.

- For Belgian studies the budget covers the sponsor costs and site costs.
- For international studies, the budget will depend, among other things, on the Belgian contribution to the study.

Payments will be milestone based and are dependent on recruitment.

5.2 Contributions and donations from third parties

Co-funding or collaboration with a commercial entity (including provision of drug or non-standard preferential discounts) is only allowed if accepted by KCE in writing. The party offering support should accept all the principles set forth in the KCE Trials research agreement template prior to submission. If selected and funded, the contracts with parties offering support need to be reviewed and approved by KCE Trials.

6 LEGAL ISSUES

6.1 Terms and conditions

By submitting a research proposal to the 2025 investigator-led call, the candidate sponsor/BCC and research team accept the terms and conditions of the KCE Trials programme, as stipulated in the research agreement templates (last version available at the publication of the call text) that can be found on the website.

In particular, applicants should carefully read the terms and conditions on ownership of the results, data sharing, intellectual property and the non-commercial primary aim of the trial.

If candidate research teams have comments on the research agreement template, this should be discussed with the KCE Trials team before submitting a proposal. In that case and if a prior written agreement is given by KCE Trials, the template with these comments in tracked changes must be attached to the submission.

If your proposal involves medicinal products or medical devices, you should consult with your legal advisors or technology transfer office (TTO) early in the process to check that your freedom-to-operate is not limited by intellectual property rights (e.g. primary or secondary patents) and that you are able to comply with the KCE requirements regarding intellectual property and data sharing. If you are, at a later stage, invited to submit a FRP, a report containing details of a full-scale search may be requested together with your implementation plan.

6.2 Data protection

By submitting a research proposal under the KCE Trials programme, each candidate investigator and sponsor team acknowledges and accepts that any personal data provided by it in connection with the research proposals, including any 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. Such personal data may include, but is not limited to, personal data such as name and address.

The purposes of this processing are for KCE to:

- (i) be able to take informed decisions and actions under the KCE Trials programme
- (ii) notify any candidate investigator and sponsor on upcoming activities under the Trials programme
- (iii) use your data anonymously to perform statistics

By submitting a research proposal under the Trials programme, each candidate investigator and 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 (e.g. members of KCE Trials panel and Trials Board, external reviewers, any third parties who may be performing quality audits of candidate sponsors and/or any of its research collaborators) and to any other non-commercial funding organisations outside KCE, including outside the European Economic Area (EEA).

Subject to the data transparency principles set out below, KCE will not disclose, share or sell said personal data to any other third party, 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 will be processed proportionally within the purposes set out above and will not be kept longer than necessary for the above mentioned use.

By sending an e-mail request to trials@kce.fgov.be, you can obtain from KCE free of charge the written communication of your personal data and, where appropriate, the correction of any inaccurate, incomplete or irrelevant data, or exercise any other legal right concerning your personal data.

6.3 Data transparency

By submitting a research proposal under the Trials programme, each candidate investigator and sponsor acknowledges and accepts that its name, the name of the key members of the research team and collaborators may appear on KCE's website, if their proposal is selected for funding.

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 contents of the research contract, protocol and clinical study report may be shared with third parties and made available on the KCE website.

Prior to submitting a new application, a candidate Sponsor/BCC should have made publicly available the results of all previous KCE-funded trials that are past 12 months from primary study completion (the last visit of the last subject for collection of data on the primary outcome). If this condition is not met, KCE Trials will notify the investigator and the Sponsor/BCC who will have three months from then to comply.

7. CALL DOCUMENTS AND TEMPLATES

- 2025 Call text (pdf) version
- Research application form including guidance (Word) version 1.0, 06 May 2025
- Template commitment letter party offering support (Word) version 2.0, 09 May 2025
- Patient involvement plan (Word) version 3.0, 16 May 2025
- Top ten tips and tricks for a successful research outline (pdf) version 3.5, 12 May 2025

Documents for studies with sponsor in Belgium:

- Budget tool (Excel) version 7.0, 15 May 2025 + guidance (pdf) version 7.0, 15 May 2025
- Template support letter candidate sponsor (Word) version 1.6, 09 May 2025
- Research agreement template (Word) version 6.5, 12 May 2025

Documents for studies with international sponsor:

- Budget tool international trials (Excel) version 6.0, 15 May 2025 + guidance (pdf) version 6.0, 15 May 2025
- Template support letter Belgian coordinating centre (Word) version 1.5, 09 May 2025
- Template commitment letter international sponsor (Word) version 3.0, 09 May 2025
- Research agreement template BCC (Word) version 5.4, 12 May 2025

Protocol templates for second stage submission (Full Research Proposal):

- Templates published on the [KCE Trials website](#)

Useful links and documents on our website:

- [Answers to frequently asked questions](#)
- [Resources for investigators](#)

8. CONTACT AND FURTHER INFORMATION

Applicants have the opportunity to ask questions about this call and on their specific research project during the online information session (see date on first page).

Applicants have also the opportunity to discuss their specific questions with KCE Trials members during a short online meeting before the submission deadline. KCE Trials members can only provide their informed opinion, but do not have final decision-making power in the selection process.

For any questions, contact us at trials@kce.fgov.be.

Annex I

Evaluation criteria investigator-led call 2025

Sponsor and research team	• There is a representative distribution of recruiting sites. Minimally participating centres include one centre from each region (Flanders, Brussels, Wallonia), unless there is a good justification not to do so, as explained in the submission. • The sponsor and the CI have no conflict of interest in regards with the performance and the possible results of the trial and ensure that their team and collaborators do not either. • The sponsor's team has the necessary skills, capacity, procedures and experience in conducting non-commercial multicentre trials and has the ability to comply with all sponsor related obligations. There is sufficient support from a clinical trial centre or equivalent. • 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 design is pragmatic. • Trial design should allow for sufficiently long follow-up. • A randomised, multicentre design is mandatory. • Sample size should be correct and well justified. • The use of centralised randomisation and e-CRFs are mandatory. • Only a limited set of variables, needed for the pre-planned analyses, are to be collected. All variables collected need to be well justified. • The design and data collected allow for possible health-economic analysis.
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 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.
Potential value for money for the Belgian health care system	• 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 value for money will receive a low score.
PICO	• The trial intervention(s) should reflect current clinical practice as close as possible. • The inclusion and exclusion criteria are well defined and reflect the real-world population for which the intervention is intended. • Outcomes are patient centred and include the core outcome set, if available.
Return on investment	• The proposed costs of the research are justifiable 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. • The trial results can have an immediate and important impact on the efficiency (decrease of the costs and/or improvement of the outcomes) of the Belgian healthcare system, preferably without the need for an additional implementation project (see potential value for money).

Patient and public involvement	• KCE strongly encourages patient involvement in research. The involvement of patients, preferable individuals with lived experience, and/or the public in the development of the project (selection of patient-relevant study endpoints, feasibility of trial assessments) and their continued involvement through the lifecycle of the research project is required for submissions to the Call (see patient involvement document). • A lay summary of the study in English should be included.
Timelines and feasibility	• The duration of the study is realistic and will preferably generate results within five (5) years. An extension of the follow-up period after the primary outcome is included if needed. • The risk of recruitment delay is considered low. The number of participating sites is sufficiently high and the investigators have access to a sufficient number of eligible participants 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 participant recruitment. The investigators allow KCE to verify these requirements during a study site visit. • 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, without the need for an additional implementation project.