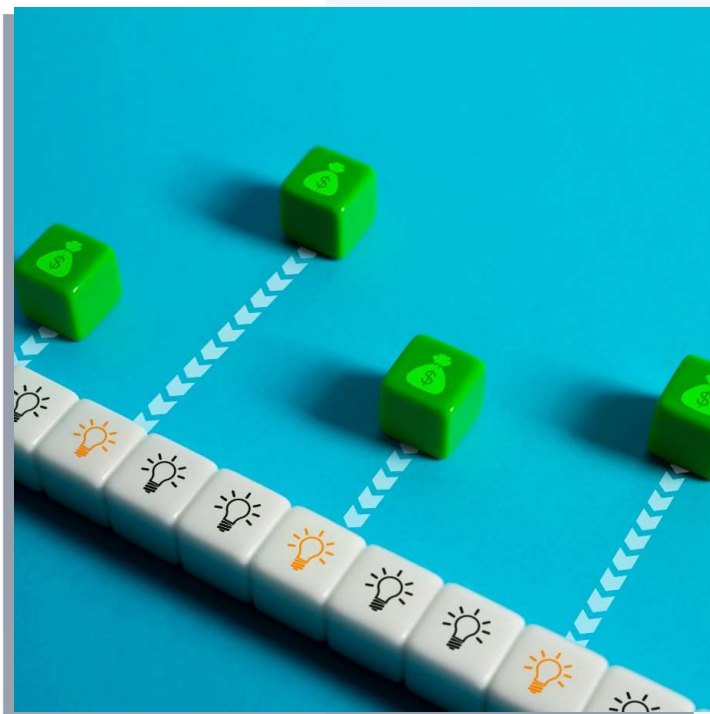


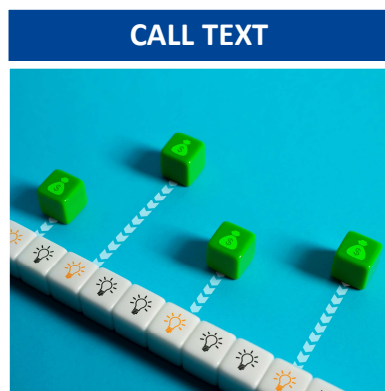


2025 investigator-led call: information session

Practical information on submission and
selection procedure

All documents and practical information are available on our website

<https://kce.fgov.be/en/kce-trials/calls/open-calls>: 2025 investigator-led call



OTHER CALL DOCUMENTS

ids

application form including guidance (Word) version 1.0 06, May 2025 [📄](#)
commitment letter party offering support (Word) version 2.0, 09 May 2025 [📄](#)
commitment plan (Word) version 3.0, 16 May 2025 [📄](#)
tips and tricks for a successful research outline (pdf) version 3.5, 12 May 2025 [📄](#)

for studies with sponsor in Belgium

if (Excel) version 7.0, 15 May 2025 [📄](#) + guidance (pdf) version 7.0, 15 May 2025 [📄](#)
support letter candidate sponsor (Word) version 1.6, 09 May 2025 [📄](#)
agreement template (Word) version 6.5, 12 May 2025 [📄](#)

for studies with international sponsor

if international trials (Excel) version 6.0, 15 May 2025 [📄](#) + guidance (pdf) version 6.0, 15 May 2025 [📄](#)
support letter Belgian coordinating centre (Word) version 1.5, 09 May 2025 [📄](#)
commitment letter international sponsor (Word) version 3.0, 09 May 2025 [📄](#)
agreement template BCC (Word) version 5.4, 12 May 2025 [📄](#)

<https://kce.fgov.be/en/kce-trials/resources/useful-links-resources-for-investigators>

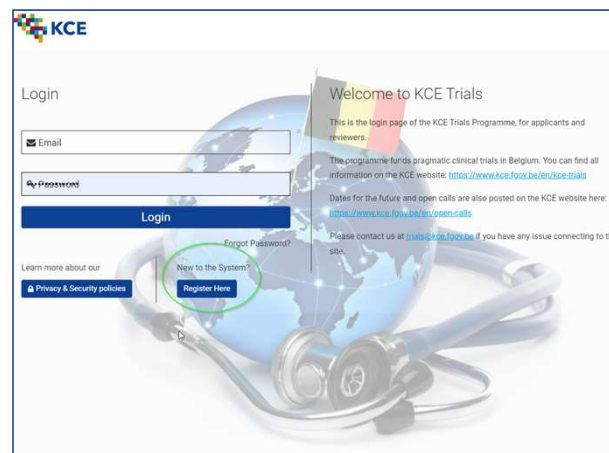
<https://www.kce.fgov.be/en/frequently-asked-questions-faq>



Your submission is only eligible through the portal

- All users should create a personal account
- CI (= main applicant) creates and submits application
- Collaborators can be invited to work on it in the system (CTC)
- Save and continue later
- Word version of application form (with guidance notes) available for developing proposal

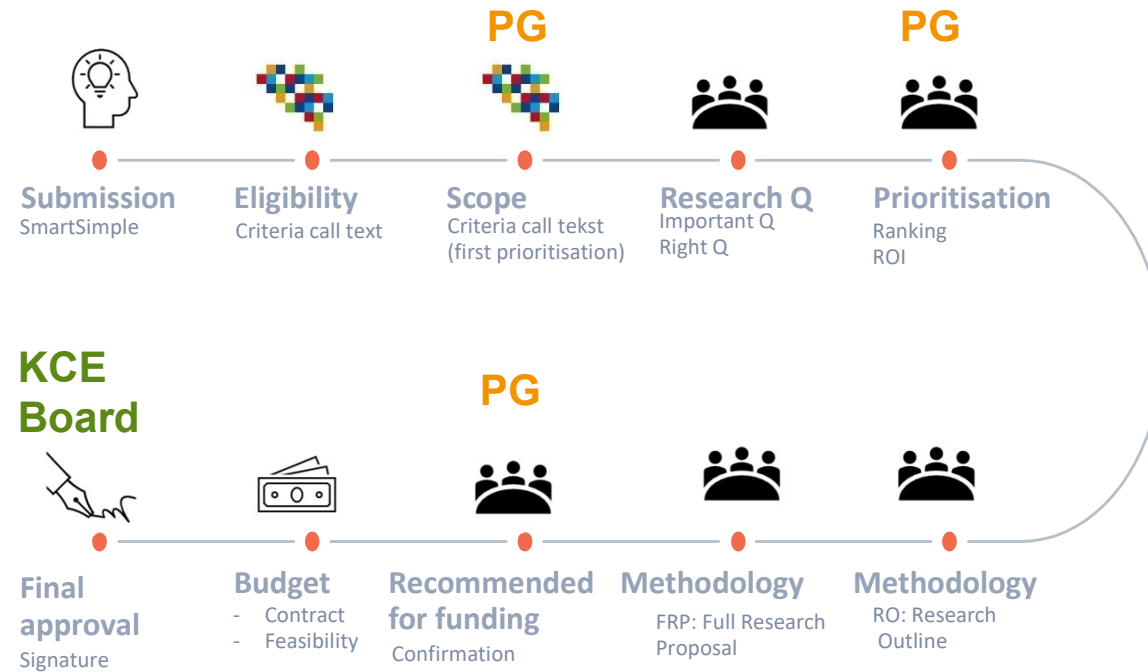
<https://kce.smartsimple.ie>



Several external advisory boards are involved in the selection process



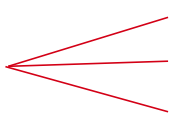
The Prioritisation Group (PG) oversees the selection proces



- Representatives KCE board and universities
- Confirms decisions other groups



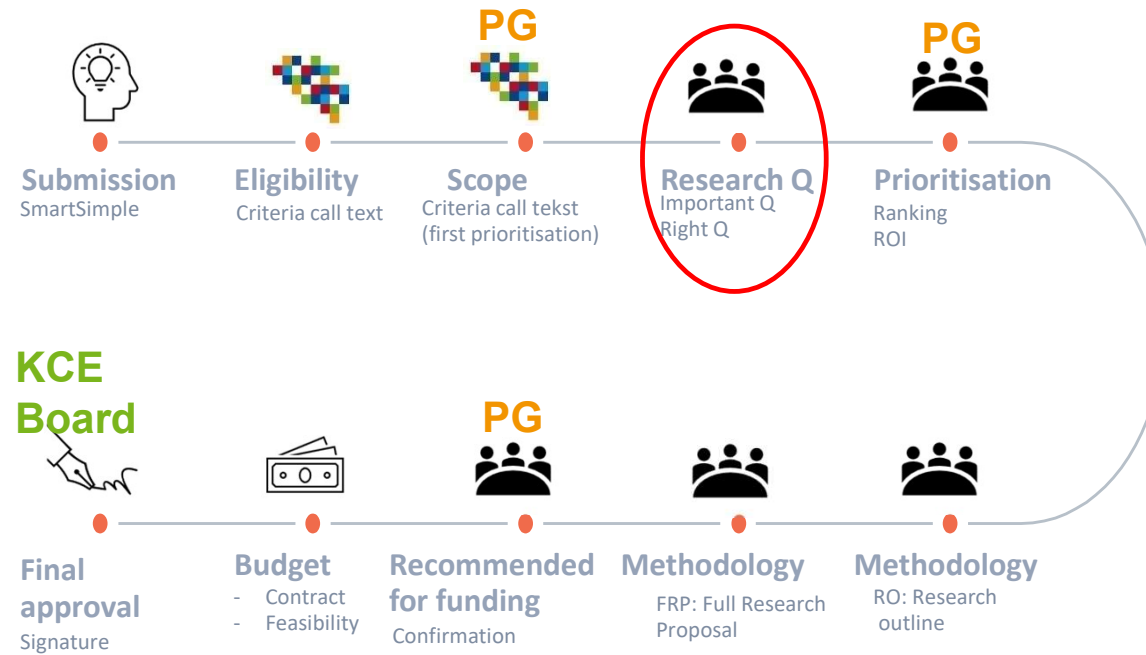
The **panel** ranks the clinical questions

Clinical experts and patient representatives  important for clinical practice in Be?
right research question?
need for evidence

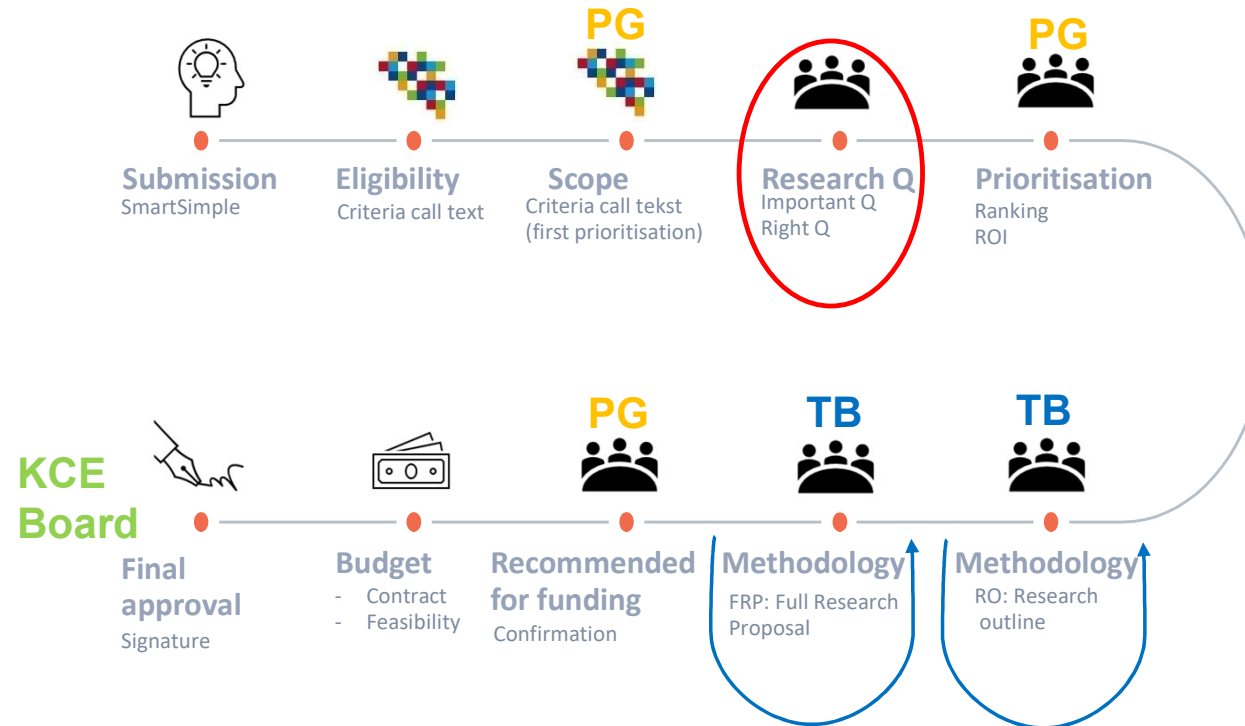
Health economists  potential value for money



The **panel** ranks the clinical questions



The Trials Board (TB) checks (and improves) methodology

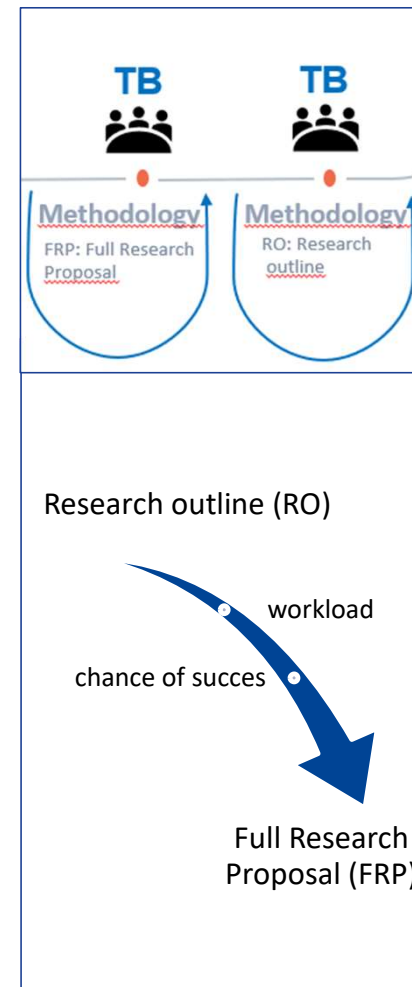


- Experts in all aspects of trial methodology
- Ensure a study design that will give a robust answer in a timely manner
- Review and feedback
- Team to justify decisions and how they impact the proposal



The methodology review is a 2-step process (RO → FRP)

- Several cycles (max. 5)
- Research Outline - RO
 - RO declined
 - invited to submit an updated RO
 - Shortlisted & invited to submit a FRP
- Full Research Proposal - FRP:
 - Protocol template (optional)
 - FRP advance up to 12,500 euro
- Evaluation criteria



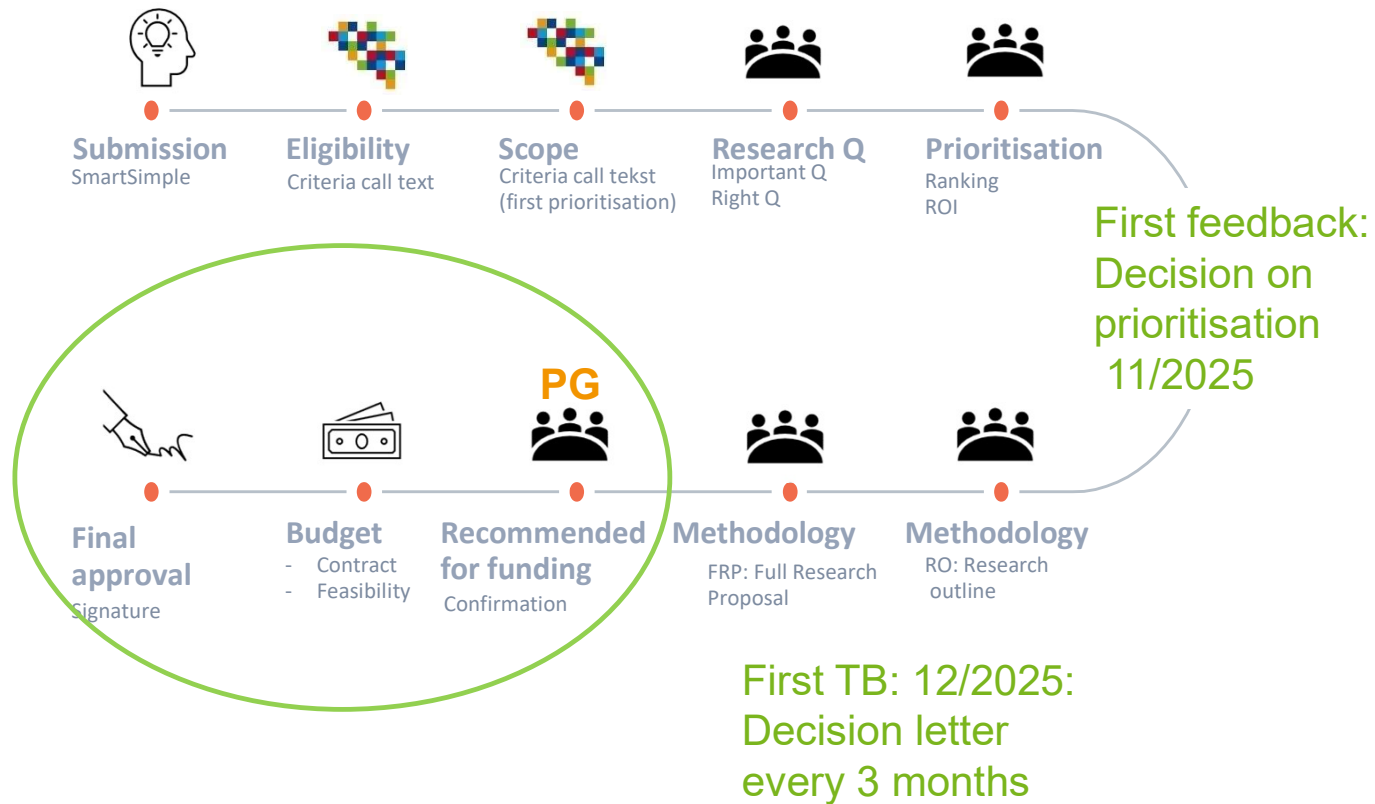
International studies follow a modified selection procedure

- International trials are eligible for the 2025 investigator-led call
- Belgian led:
 - normal review process
 - participation other funders
- Belgian participation
 - usually, limited support and in line with participation
 - usually, 1 methodology review round (take-it or leave-it)



When will I receive feedback?

Deadline:
23/9/2025

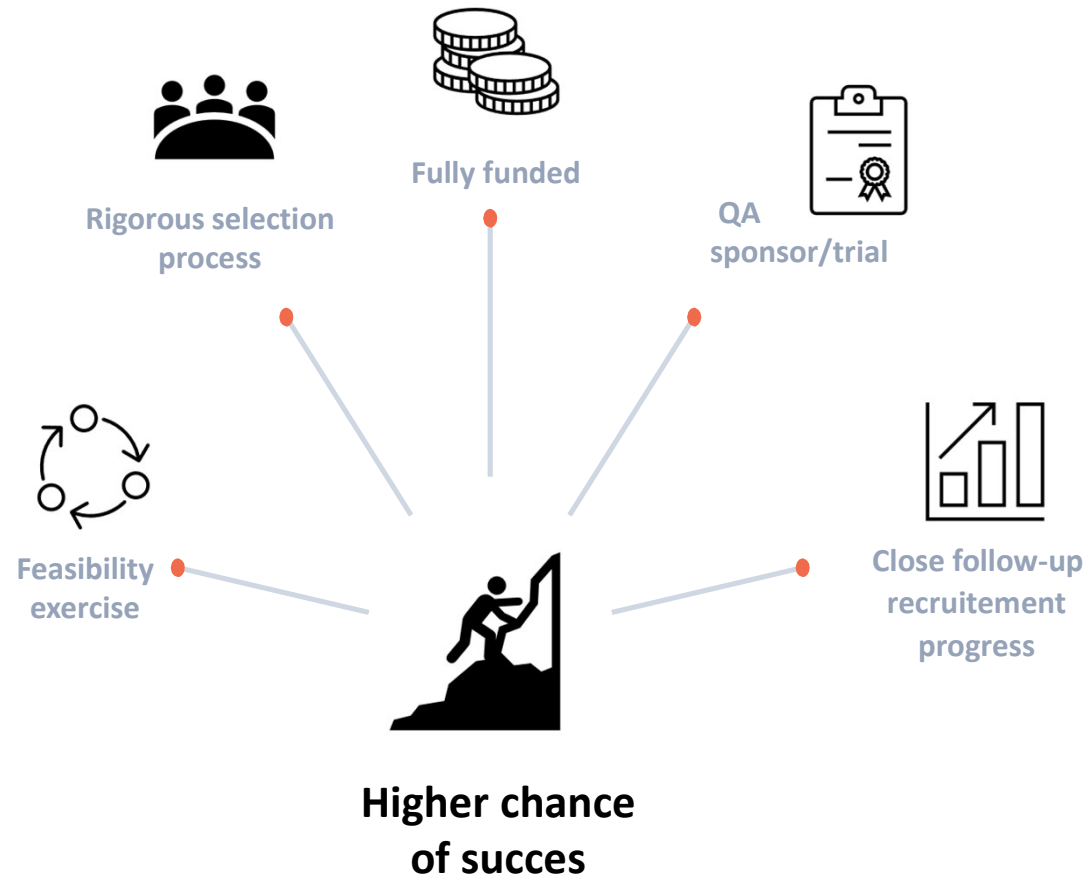


What happens after my proposal has been recommended for funding?

- KCE study Lead (and back-up)
- TB recommendation to fund ($\pm$ changes)
 1. Protocol changes requested by TB
 2. Feasibility check (feasibility advance up to 12.500€)
 3. Budget & payment schedule negotiations
 4. Contract
- KCE Board approves funding (funding isn't awarded until KCE Board approval)



We would like a robust answer in timely manner



- “Top ten tips and tricks for a successful research outline”
- Get input from collaborators well before the submission deadline
 - CTC
 - Legal/stat/HE
 - Patients!

OTHER CALL DOCUMENTS

- Research application form inclu
- Budget tool (Excel) version 6.3
- Template support letter candid
- Template commitment letter pa
- Research agreement template
- IMP/MD Protocol template for
- Non IMP/MD Protocol template
- Top ten tips and tricks for a s
- Patient involvement plan (Worc

