



2026 KCE Trials calls: information session

Scope and criteria

KCE Trials programme

started 2016, set up in collaboration with NIHR, ZonMW

Pragmatic &
practice-oriented

Comparative
effectiveness &
repurposing

Drugs, devices,
surgery, diet,
psychotherapy,...

Patients &
policy makers

National &
international

Investigator-led
(open or themed)
& commissioned

Clinical Trial
Centers (CTCs)

Non-commercial
sponsor

Publication + data
sharing policy



2026 KCE Trials calls

Who can submit?

Investigator led = investigators conceive the research and develop the study proposal

- National trial
 - Chief investigator
 - Support of a non-commercial Belgian sponsor
 - Support of clinical trial centre (CTC)
- International trial
 - Investigator coordinating the Belgian part
 - Support of the international non-commercial sponsor
 - Support of Belgian coordinating centre (BCC) and CTC



Letter of support (KCE Trials template)

From Belgian sponsor or BCC:

- Acceptance of trial sponsor/BCC obligations
- Acceptance of terms and conditions including KCE-sponsor/BCC research agreement

From international sponsor:

- Acceptance KCE trials terms and conditions regarding non-commercial nature of the trial
- Right of KCE to obtain a copy of the Belgian study data (pseudonymized) to use for public health purposes

From third party offering support:

- Acceptance all the principles set forth in the KCE Trials research agreement





2026 COMPARATIVE EFFECTIVENESS CALL

- ✓ Large noncommercial multicentre randomised trials
- ✓ Online information session: June 4, 2026
- ✓ Submission Deadline: September 22, 2026



More information on the KCE Trials website: Calls/KCE Trials 2026 comparative effectiveness call

Scope KCE 2026 comparative effectiveness call

Compare 2 diagnostic or treatment options (no treatment or test is possible comparator) not sufficiently directly compared

Broad range of interventions e.g. physiotherapy, psychotherapy, diet, diagnostic test, surgery,...

treatments that are (or have the potential of being) reimbursed by health care payers in Belgium

in use in **daily practice** in Belgium in the studied indication

substantial underlying peer-reviewed evidence that supports moving to a large-scale confirmatory randomised trial

Considered in scope are:

Medication used off-label in daily practice

Intervention in another patient group e.g. children

Change in timing, dosing or duration of treatment



Scope KCE 2026 comparative effectiveness call

Primary aim is non-commercial:

- Non-commercial entities as sponsor (and BCC)
- Studies on drugs, apps/ software or medical devices: no potential benefit to a single company
- European state aid regulations
- No conflict of interest (investigator, sponsor, team)

Carefully read Terms & Conditions in contract and call text!



Scope KCE 2026 comparative effectiveness call

- **Design:**
 - Multicentre: Good representation of all three regions, at least one recruiting centre from each region
 - Randomised: Individual or cluster



KCE 2026 comparative effectiveness call: out of scope

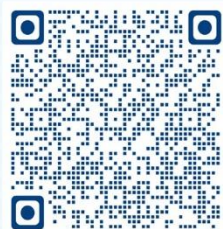
- Trials already started/ submitted in Belgium
- Implementation & quality improvement research
 - Promotion of uptake of research findings
 - Improvement of implementation of guidelines or quality of care
- Development or innovation studies
 - Proof of concept studies
 - Interventions used only in clinical research
 - Drugs without MA (unless widely used in daily practice) or medical devices without CE label
- Mobile health studies
 - Apps/ software not fully developed and piloted, not meeting requirements on data protection, not used in daily practice
 - Proposals without implementation plan (in agreement with non-commercial aim)
- Studies that have already been submitted twice to the KCE Trials programme





2026 DRUG REPURPOSING CALL

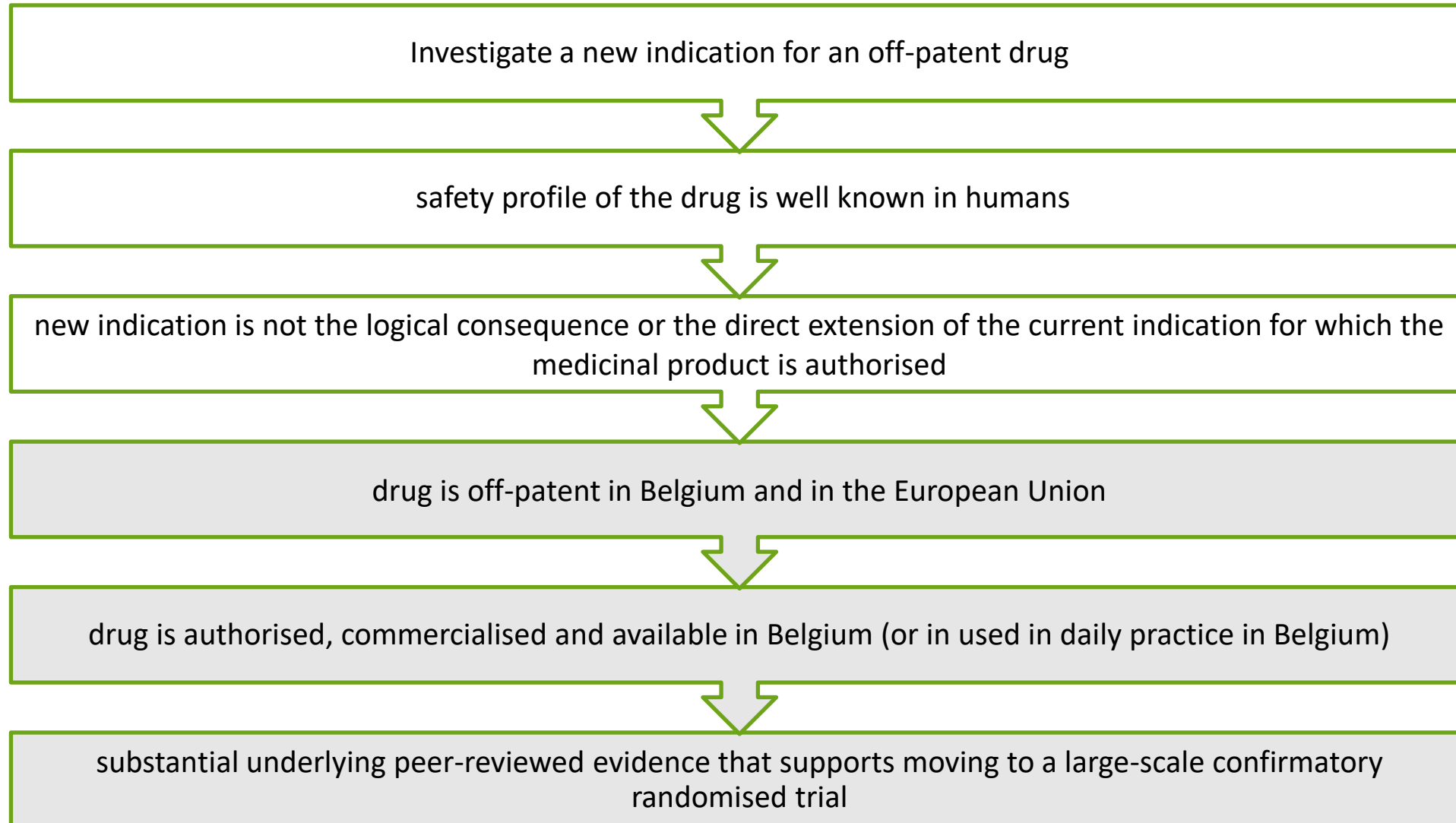
- ✓ Large noncommercial multicentre randomised trials
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More information on the KCE Trials website: [Calls/KCE Trials 2026 comparative effectiveness call](#)



Scope KCE 2026 drug repurposing call



Scope KCE 2026 drug repurposing call

- **Primary aim is non-commercial (see before)**
- **Design**
 - **Multicentre**
 - **Randomised**



KCE 2026 drug repurposing call: out of scope

- Trials already started/ submitted in Belgium
- Development or innovation studies
 - Proof of concept studies
 - Studies primarily focused on reformulating a medicinal product are out of scope.
- Studies that have already been submitted twice to the KCE Trials programme
- Out of scope but could be submitted to the comparative effectiveness call:
 - Studies about the use of medicines in the same indication but in groups not covered by the existing MA (e.g. children, the elderly and pregnant women).
 - Studies about the use of medicines that is already widely established in practice and has been incorporated into the guidelines.



Extra work for DR applications

TTO/Legal must confirm

- **Freedom to conduct** → nothing blocking the study
- **Patents fully expired** → including:
 - administration mode
 - dosage regimen
 - formulation/device
- **Freedom to implement** → drug can be used as proposed

Use the KCE template → TTO must complete specific form



KCE Funding – What clinicians must know (all calls not only repurposing)

Public-health mission is central → evidence needed for patients, clinicians & payers

KCE pays per milestone : not the classic academic grant freedom

- **Contractual deliverables** → KCE pays what is done
- **Funding can stop early** → poor recruitment, infeasible timelines, study not started on time, evolving evidence

KCE can use the data and results

- **Results reused by authorities** → guidelines, policy, system improvement
- **No IP restrictions** → data and results must be reusable by anyone
- **No exclusive access** → you cannot negotiate exclusive rights for companies

Before you start

TTO/legal → ensure your institution accepts KCE conditions

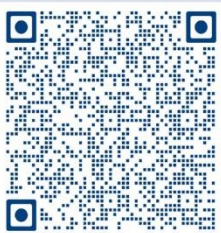


Will be back in 2027 &
2028



2026 THEMED CALL ON CARE FOR ADDICTION

- ✓ Large noncommercial multicentre randomised trials
- ✓ Online information session: June 4, 2026
- ✓ Submission Deadline: September 22, 2026



More information on the KCE Trials website: [Calls/KCE Trials 2026 themed call on care for addiction](#)

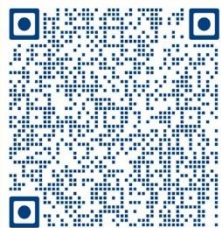


Will be back in 2027
& 2028



2026 THEMED CALL ON PALLIATIVE CARE

- ✓ Large noncommercial multicentre randomised trials
- ✓ Online information session: June 4, 2026
- ✓ Submission Deadline: September 22, 2026



More information on the KCE Trials website: [Calls/KCE Trials 2026 themed call on palliative care](#)



Prioritisation (all calls) based on:

Need for generating new evidence in clinical practice is large

Potential efficiency gain for the Belgian health care system and expected return on investment

Proposal is submitted within an open **themed call**



Additional prioritisation criteria (all calls):

- Number of people impacted
- Expected effect of intervention
- Funding by commercial stakeholder unlikely an/or not warranted
- Balanced geographical spread
- Research question is a priority for patients
- Research question is a priority for FPS Health (see call text)
- Overall KCE trials portfolio balanced (encourage studies on underrepresented populations like older people)
- Acceptable study budget



Criteria

Return on Investment	Costs are reasonable in relation to the likely benefit of the research and proportionate to work involved
	Budget tool and guidance to calculate budget
	No maximum (but < ½ total call budget)
Value for money	Substantial cost savings with at least the same patient benefit
	Increase patient benefit/ QOL at a reasonable cost
PICO	Inclusion and exclusion criteria are well defined and reflect the real-world population
	Trial intervention(s) reflect current clinical practice
	Outcomes are patient centred and include the core outcome set



Criteria

Patient and public involvement	From design onwards
	Patient-relevant research question and outcomes
	Feasibility of trial assessments
	Language of lay summary and patient information
Duration	Realistic duration, preferably results within 5 years (results still relevant)
	Sufficient participating sites, access to sufficient eligible participants, absence of competing trials
	Long term follow-up study after primary outcome if appropriate
Implementation	Results can have an immediate and important impact on the efficiency of the Belgian healthcare system



