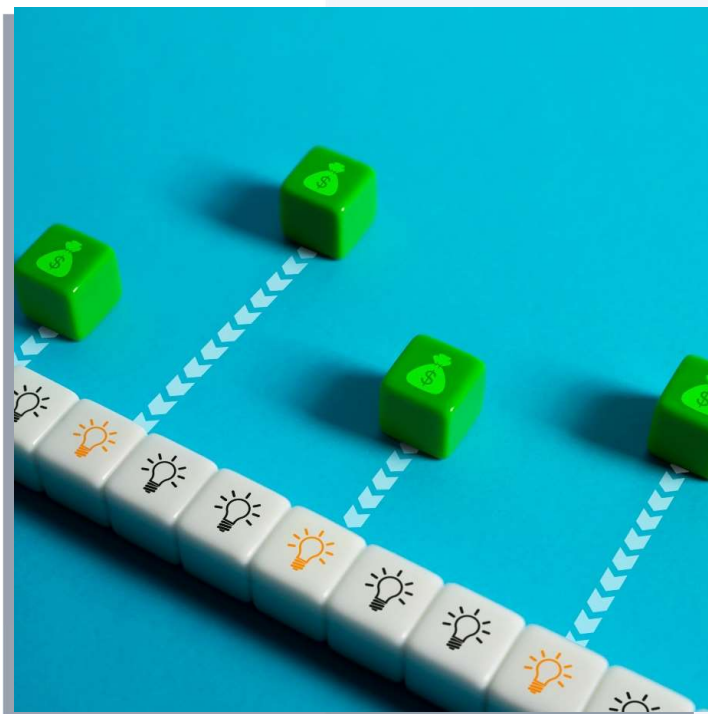




2025 investigator-led call: information session

Scope

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



KCE trials 2025 Investigator-led call

Who can submit?

Investigators conceive the research and develop the study proposal

- Sponsor in Belgium
 - Chief investigator
 - Support of a non-commercial sponsor
 - Support of Clinical trial centre (CTC)
- International trial
 - Investigator coordinating the Belgian part
 - Support of Belgian coordinating Centre (BCC) (+CTC)
 - Support of the international non-commercial sponsor



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 party offering support:

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



Scope KCE 2025 Investigator-led 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
 - Justification why not performed by marketing authorisation holder or manufacturer
 - High return on investment
- European state aid regulations
- No conflict of interest (investigator, sponsor, team)
- Carefully read Terms & Conditions in contract and call text



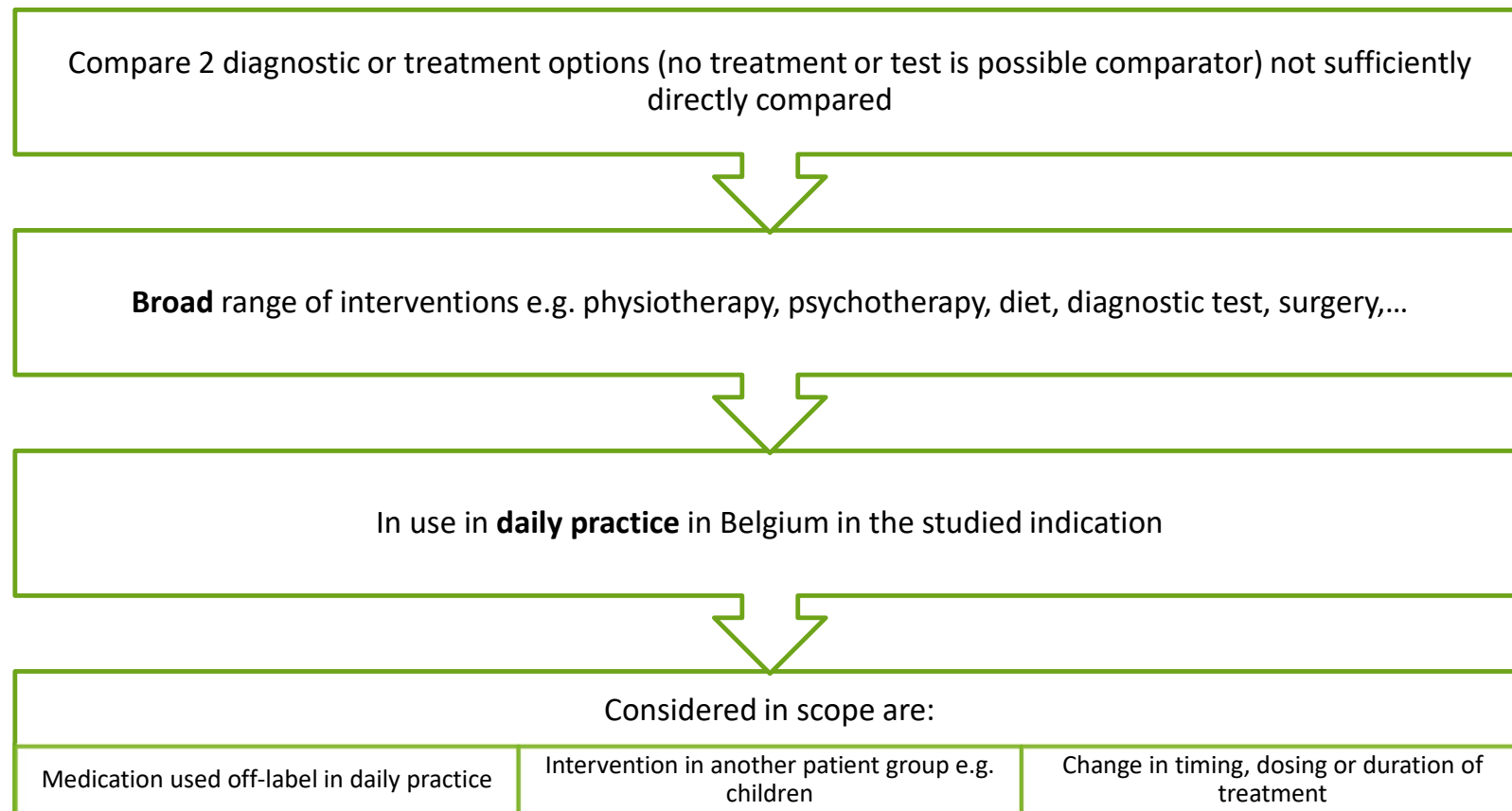
Scope KCE 2025 Investigator-led call

- Multicentre design
 - Good representation of all three regions, at least one recruiting centre from each region
 - Additional centres abroad if needed (other funder required to cover costs for participants recruited abroad and contribute to sponsor costs or provide justification for funding)
- Randomised design
 - Individual or cluster
- Substantial underlying peer-reviewed evidence that supports moving to a large-scale confirmatory randomised trial



Scope KCE 2025 Investigator-led call

Comparative effectiveness trials:



Scope KCE 2025 Investigator-led call

Drug repurposing trials:

- Off-patent drug
- Evidence for high return on investment
- Drug is authorised and commercialised in Belgium (or in use in daily practice)



2025 Investigator-led 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 marketing authorisation 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



Prioritisation based on:

**Need for generating
new evidence in
clinical practice is
large**

**Potential efficiency
gain for the Belgian
health care system
Value for money**



Additional prioritisation criteria:

- 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
- Overall KCE trials portfolio balanced (encourage studies on underrepresented populations like older people)
- Acceptable study budget



Criteria

Return on

Reasonable and proportionate to work involved

Investment

Budget tool and guidance to calculate budget

No maximum (but $< \frac{1}{2}$ total call budget)

Value for money

Increase efficiency of the health care system (saving for healthcare payers) with at least the same patient benefit

Increase patient benefit/ QOL at a reasonable cost

PICO

Trial intervention(s) reflect current clinical practice

Inclusion and exclusion criteria are well defined and reflect the real-world population

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, select more sites if possible

Results preferably within 5 years (relevance results)

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



