

KCE Trials

Practical information on submission and selection procedure

Information Session 7th June 2024
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Website

<https://kce.fgov.be/en/kce-trials/calls/open-calls>

CALL TEXT



2024 Investigator-led call

CALL TEXT



2024 Endometriosis care call

OTHER CALL DOCUMENTS

- Research application form inc
- Budget tool (Excel) version 6.
- Template support
- Template commitment
- Research agreement
- IMP/MD Protocol template for
- Non IMP/MD Protocol template
- Top ten tips and tricks for a
- Patient involvement plan (Wo

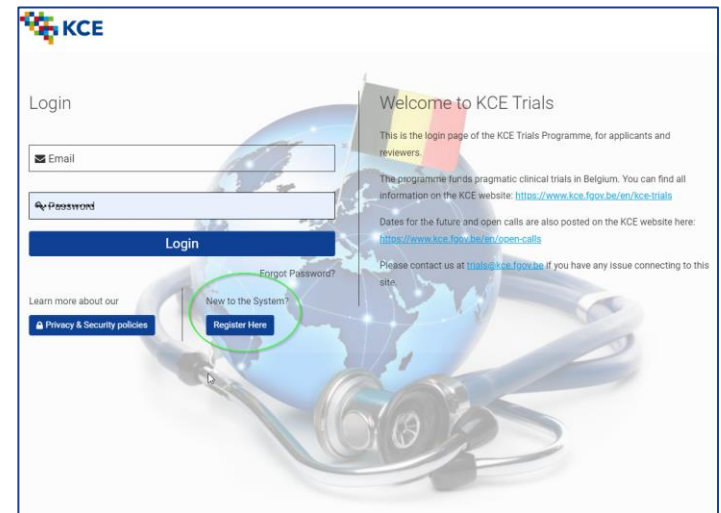
Documents in common
for both calls

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

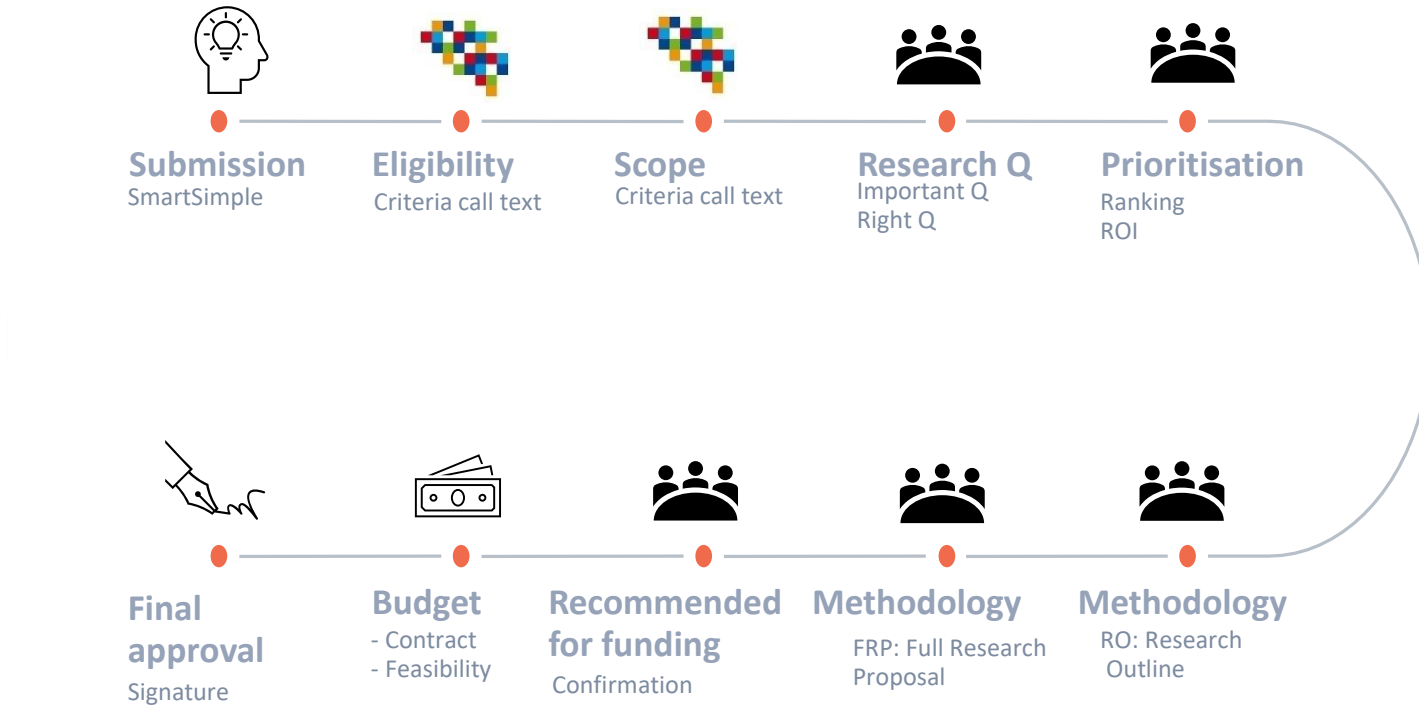
Submission portal

- All users should create a personal account
- CI 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 but all submissions in portal (eligibility)

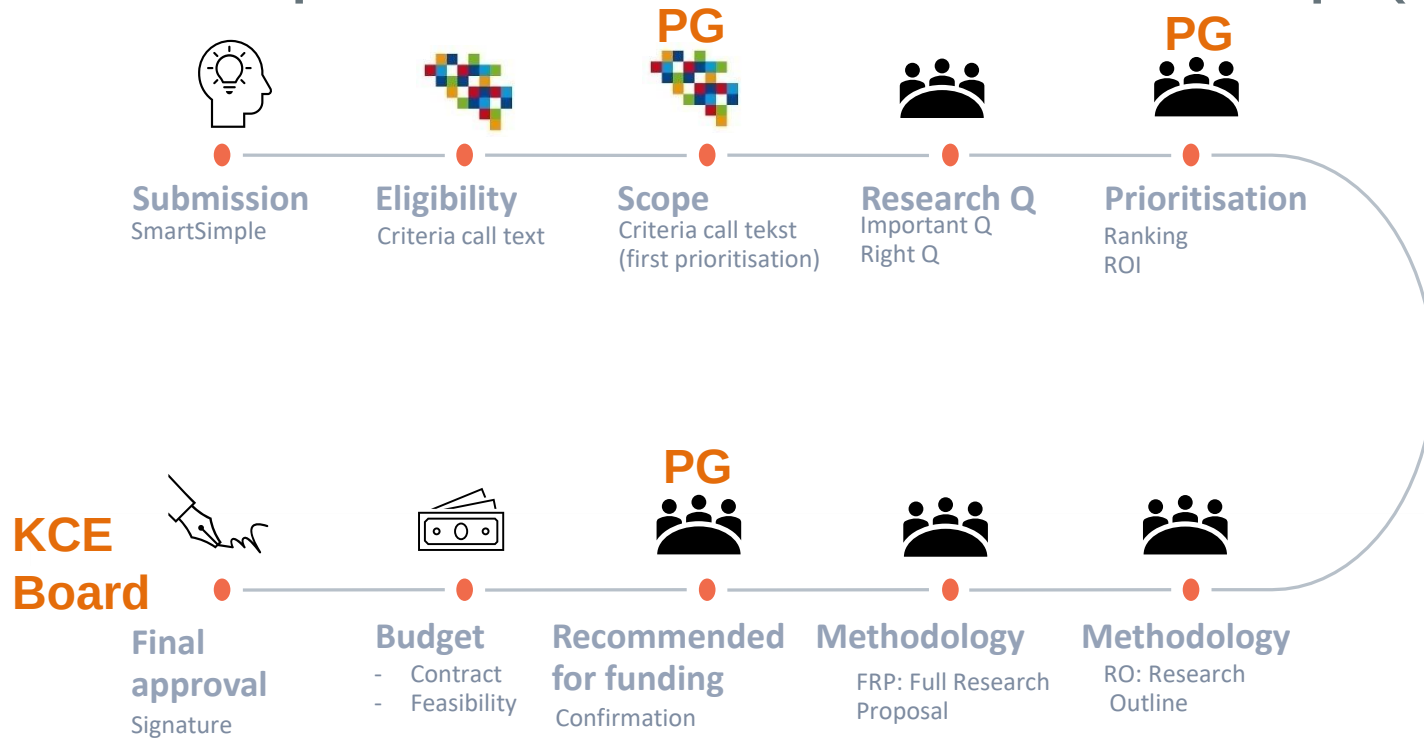
<https://kce.smartsimple.ie>



Selection process: advisory boards



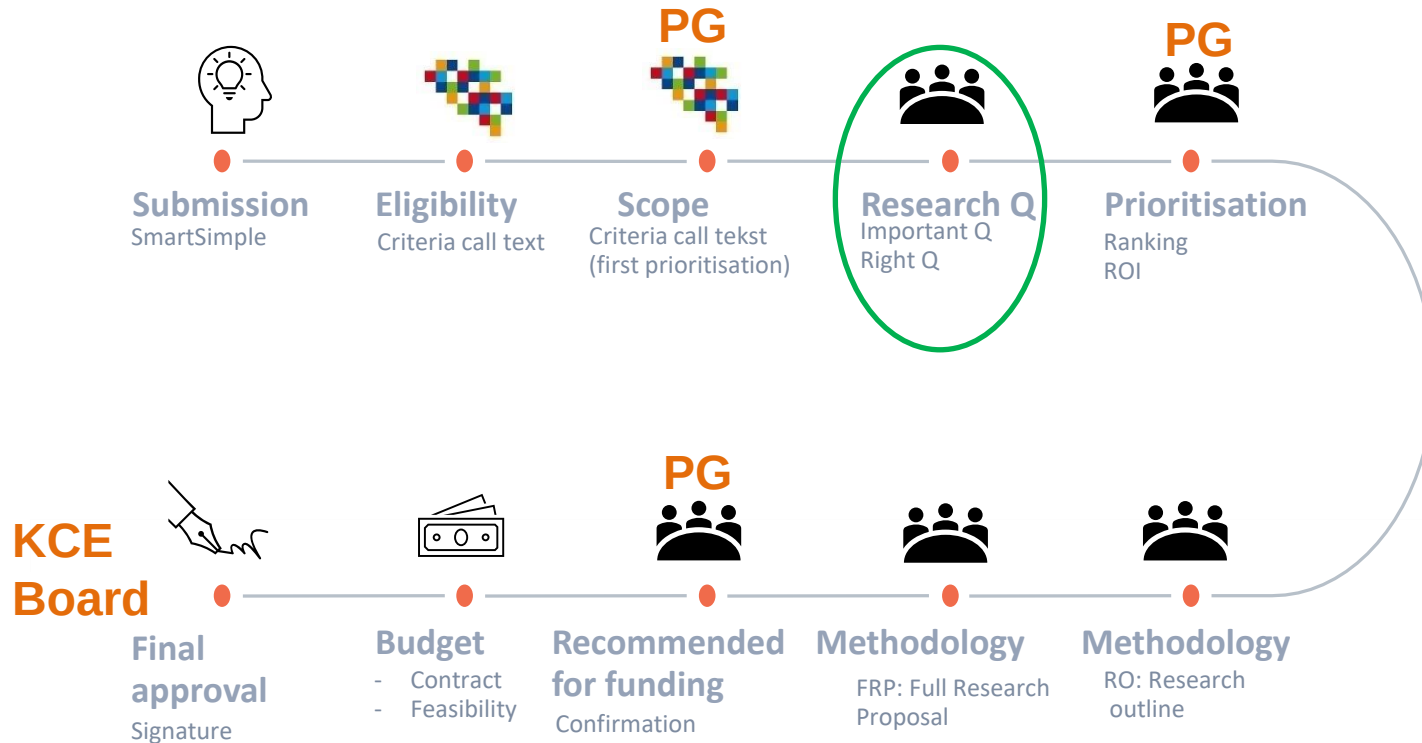
Selection process: Prioritisation Group (PG)



- Confirms decisions other advisory groups
- Closely follows selection process
- Representatives KCE board and universities



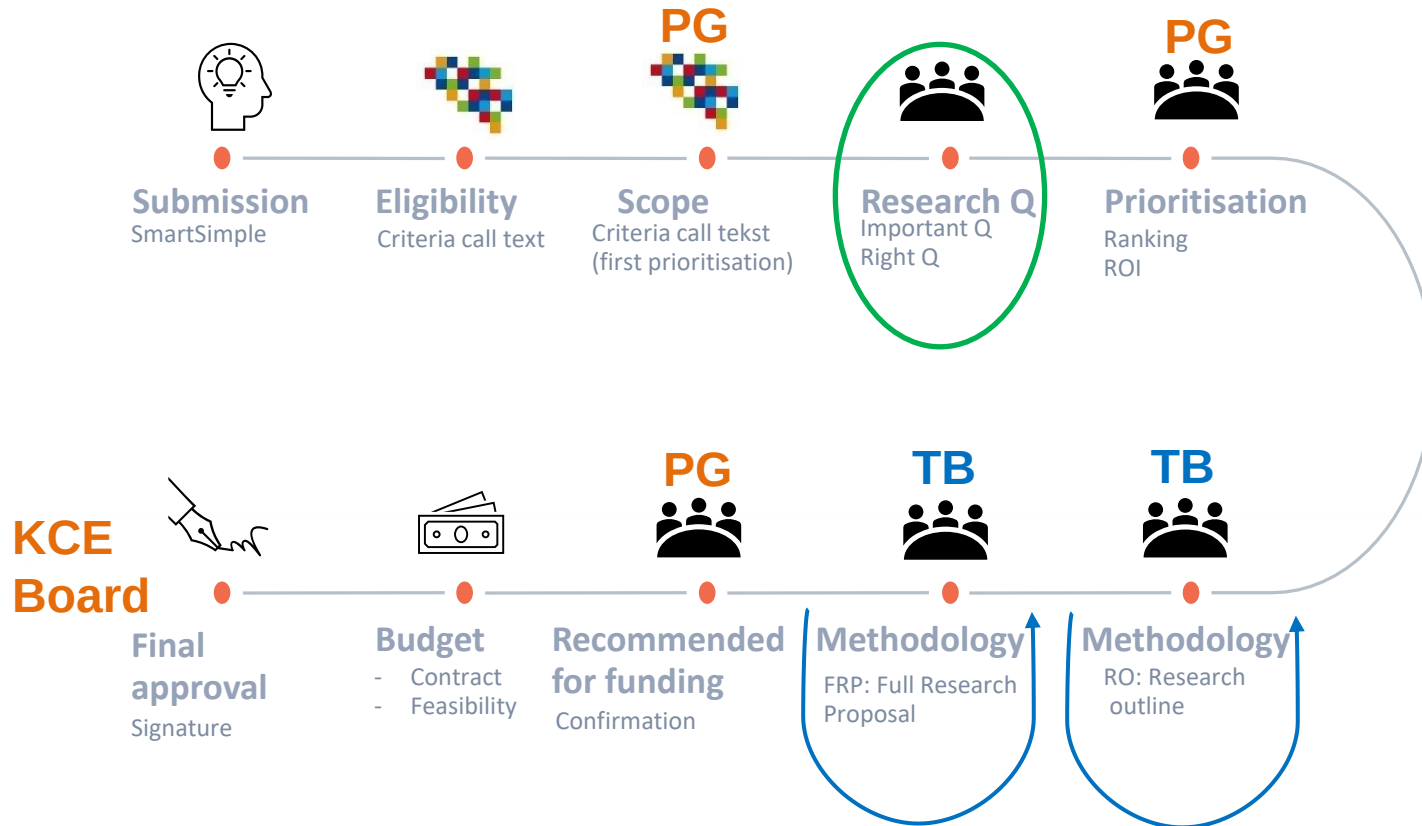
Right and important clinical question



- Clinical experts and patient representatives (panel)
 - important for clinical practice in Be?
 - right research question?
- Need for evidence
- Health economists (potential value for money)



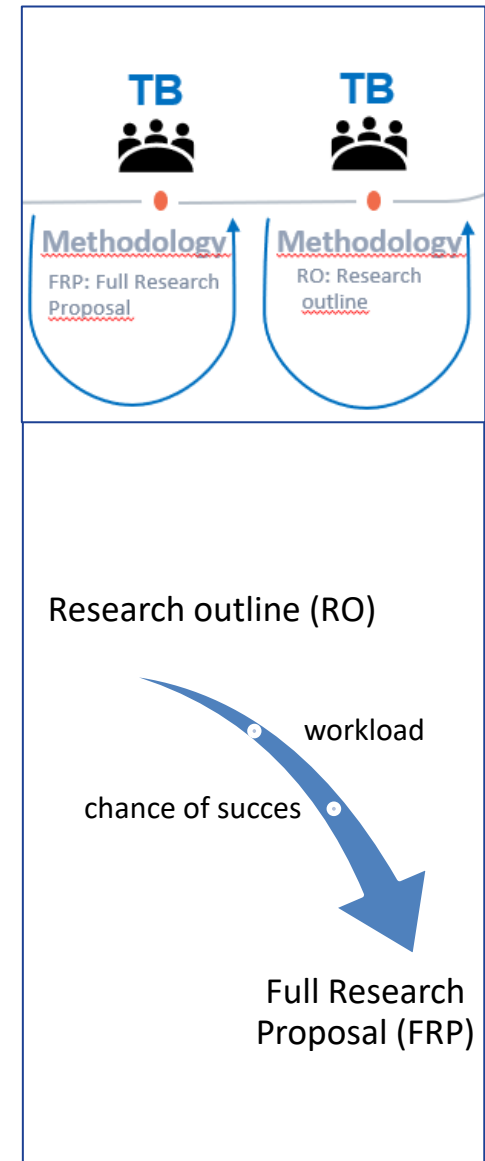
Selection Process: Trials Board (TB)



- 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

Methodology review

- **2-step process (RO → FRP)**
- **several cycles (max. 5)**
- **RO:**
 - RO declined
 - invited to submit an updated RO
 - Shortlisted & invited to submit a FRP
- **FRP:**
 - Protocol template (optional)
 - FRP advance up to 12,500 euro
- **Evaluation criteria**

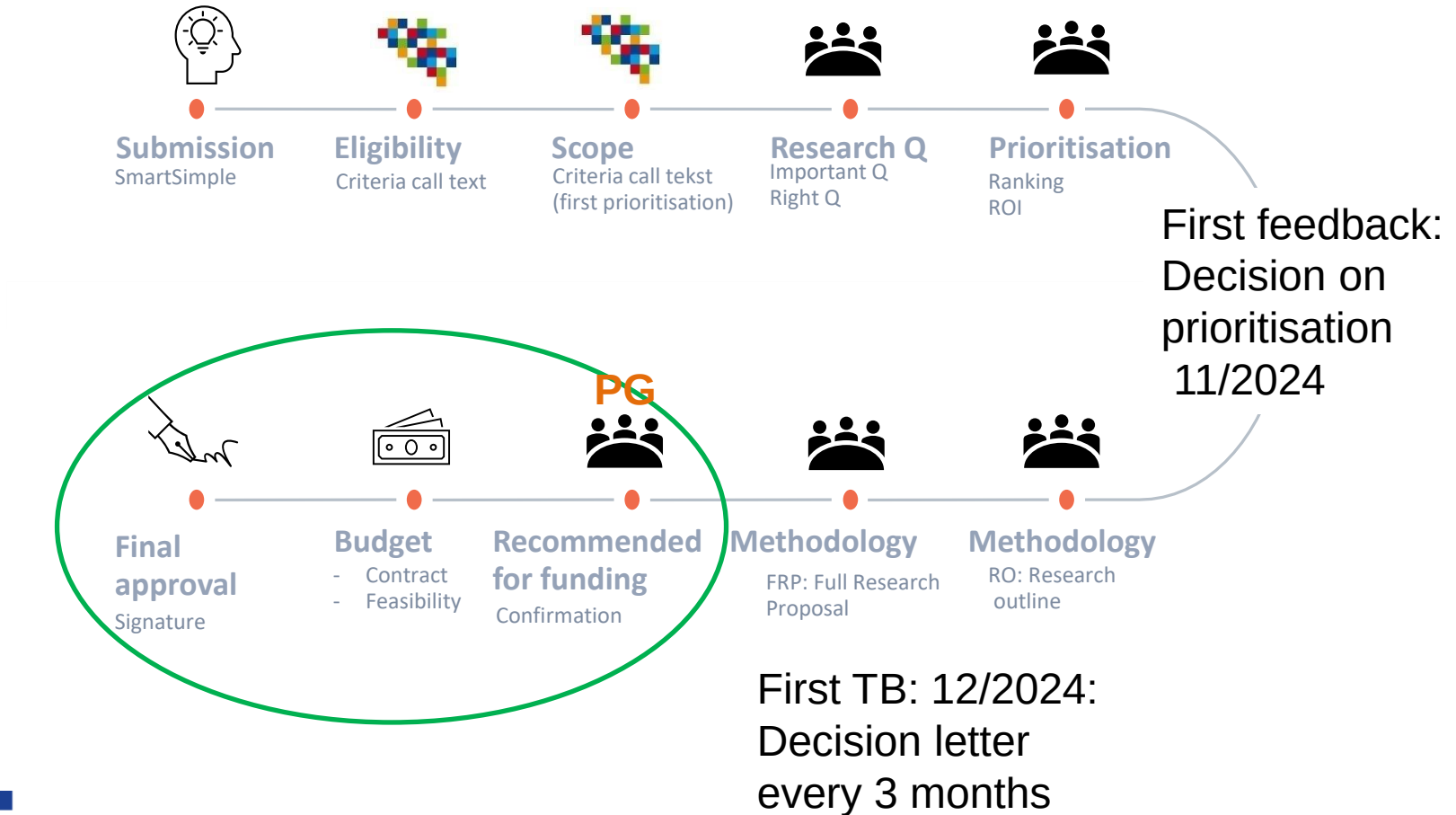


International studies

- International trials are eligible for the 2024 investigator-led call and endometriosis care 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)

Selection process: timelines

Deadline:
24/9/2024

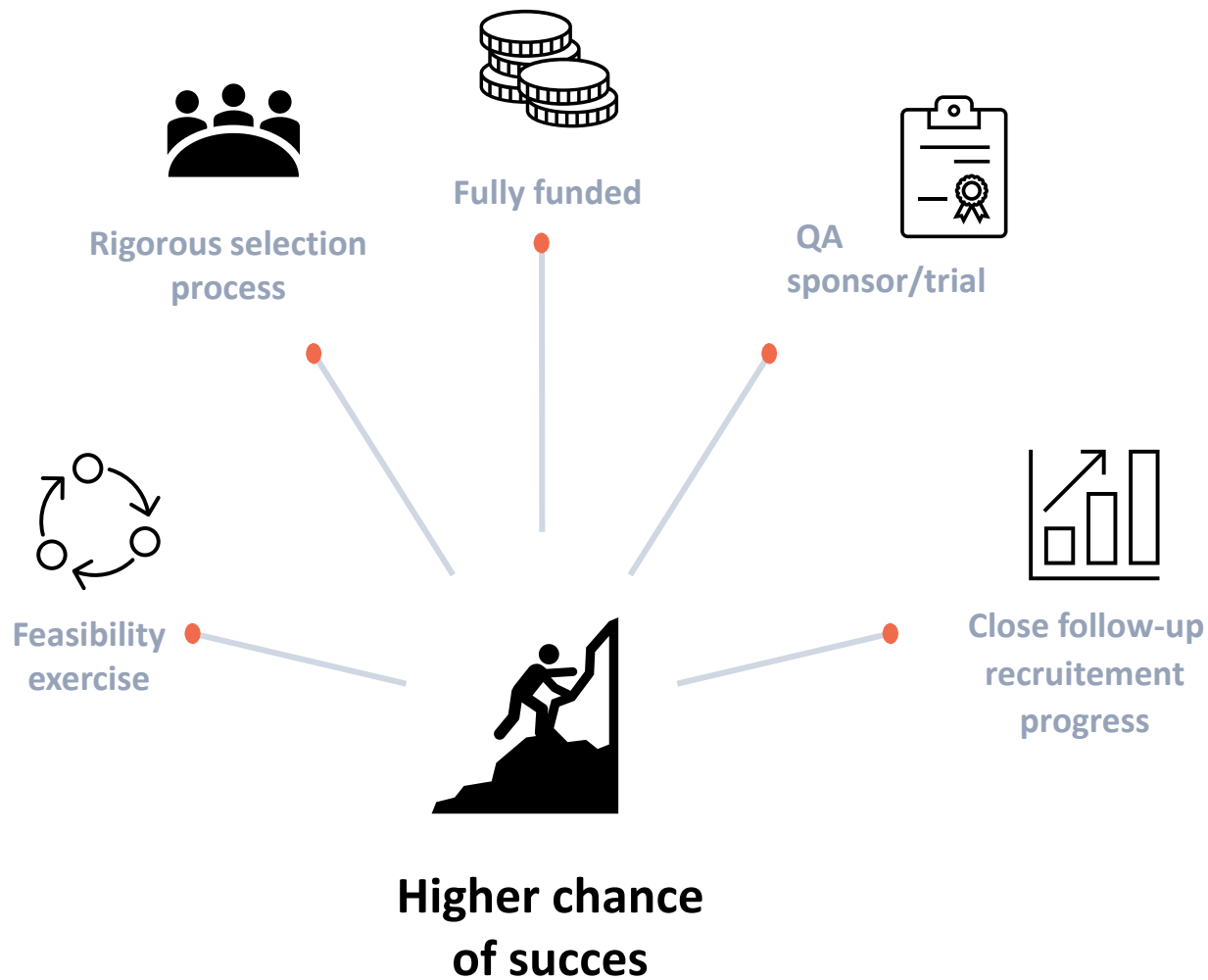


After recommendation to fund

- **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 negotiations (minimal)
- **KCE Board approves funding (funding isn't awarded until KCE Board approval)**



Robust answer in timely manner

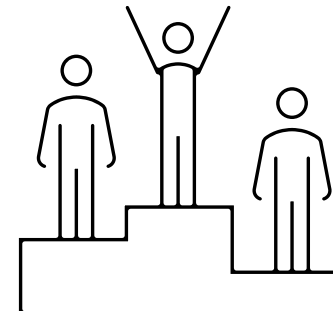


Tips and tricks

- **“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

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- Budget tool (Excel) version 6.3
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- 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 (Word**





Any questions?

Contact: kce_trials@kce.fgov.be

