



Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

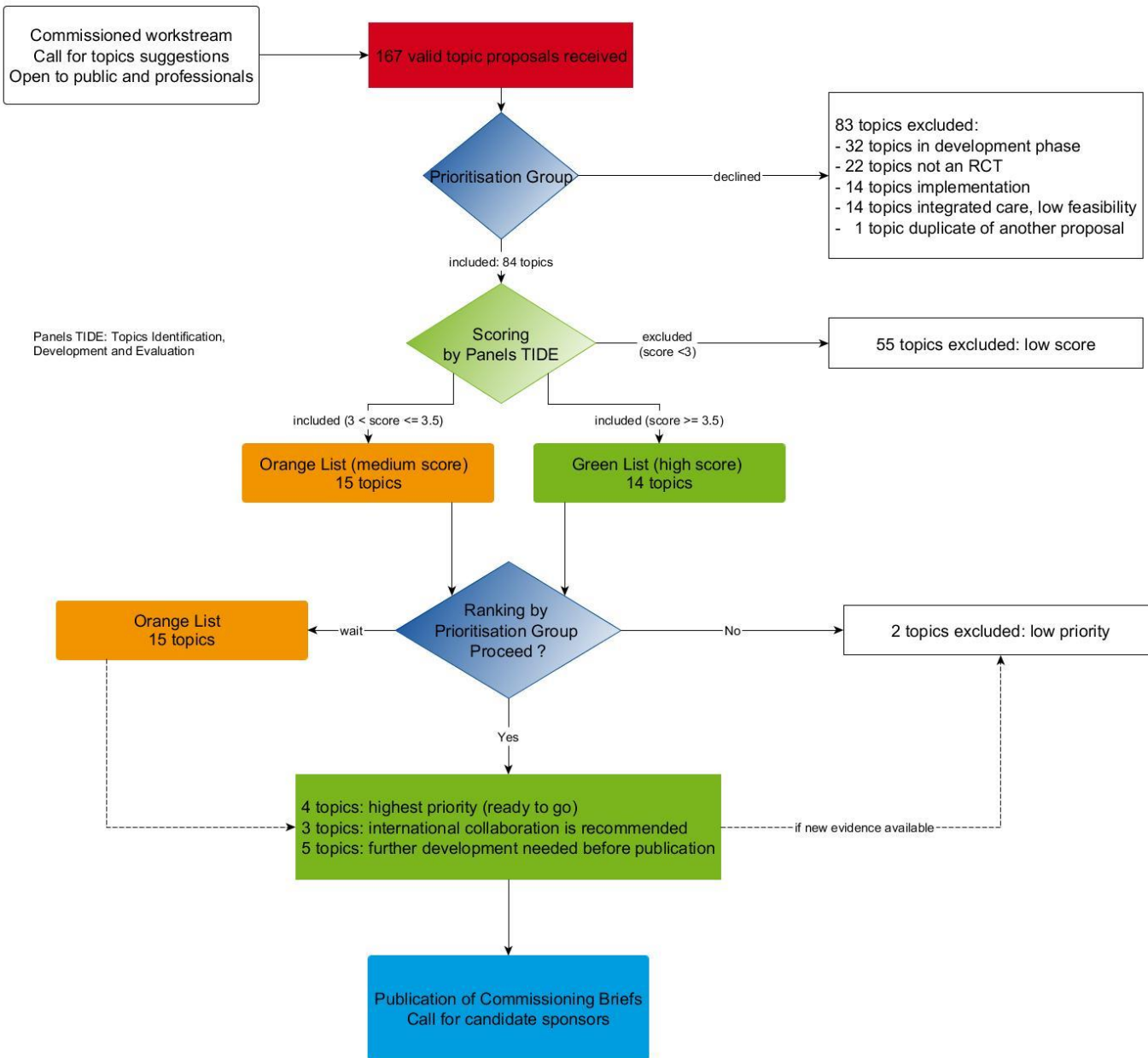
KCE Trials - Sponsors

Selection criteria & procedure



Overview

- **Procedure**
 - **Expression of interest (EOI)**
 - **Full proposal**
- **Assessment criteria**
- **Research budget**
- **Contract template (Quinz)**



Procedure

- **2-step process**
 - Expression of interest
 - Full proposal
- **Evaluation by KCE Trials Board based on assessment criteria**
- **Prioritisation by Working Group**
- **Approval by KCE Board**

Procedure

- **KCE shall remain entitled at all times to postpone, suspend and/or withdraw any pending research call upon its own discretion.**
- **Candidate sponsors can withdraw their submission at any time before signature of the research agreement.**

Expression of interest

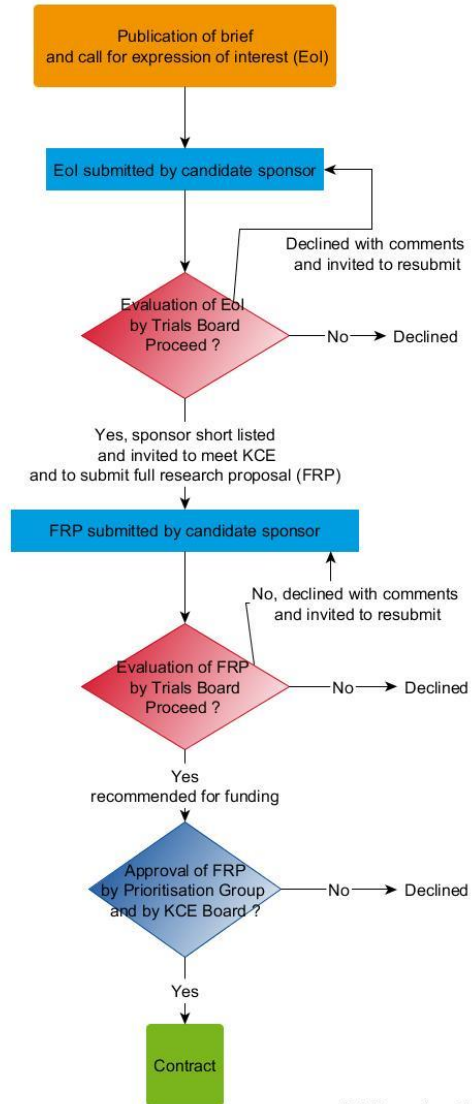
- **1st step**
- **Less extensive information than full proposal**
- **Publication of 1st briefs next week**
- **Deadline for submission: August 1st**
- **KCE Trials Board meeting:**
 - **Week of September 5th**
 - **November**

KCE Trials Board

- **Independent experts in trial methodology**
- **International reviewers**
- **Conflict of interest policy**
- **Voting system**
- **EOI decisions from KCE Trials Board**
 - **Declined**
 - **Declined + invited to resubmit**
 - **Shortlisted + invited to submit full proposal**

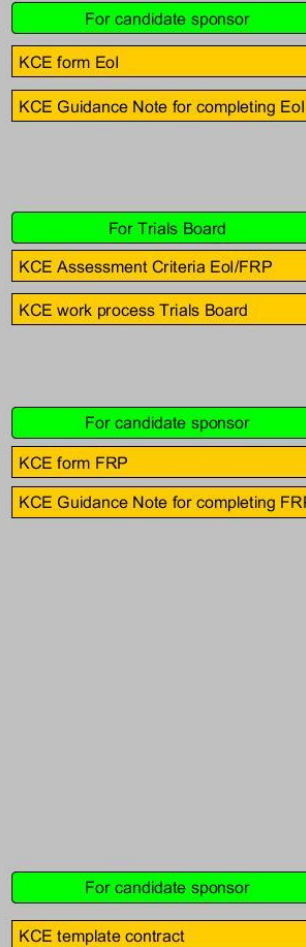
Commissioned Workstream, from call for Expression of Interest (Eol) to Contract

Flowchart



Eol: Expression of Interest
FRP: Full Research Proposal

Documents



Assessment criteria

- **Terms and conditions of template contract accepted (more info will follow)**
- **Collaboration between centres is encouraged**

Assessment criteria

- **Need for evidence**
 - **Burden of health or care problem in Belgium**
 - **Current standard practice in Belgium**
 - **Existing body of knowledge + ongoing trials**
 - **Documented search**

Assessment criteria

- **Value for money**
 - **Costs of the research are reasonable**
 - **Return on investment**
 - **Introduction of more cost-effective interventions**
 - **Net savings for the Belgian healthcare system**
 - **More information on research costs and reimbursement by RIZIV - INAMI will follow**

Assessment criteria

- **Scientific rigour**
 - **Study design relevant for the research question**
 - **Investigators have expertise in the disease and population studied**
 - **Sponsor team skilled for conducting non-commercial multicentre trials**
 - **Team accepts visit from KCE**

Assessment criteria

- **Design**
 - **Comparative effectiveness trials of interventions in use in Belgium**
 - **Randomised controlled trial designs**
 - **Centralised randomisation**
 - **e-CRF**

Assessment criteria

- **Patients**

- **Sufficiently high number of eligible patients in participating centres for short recruitment period**
- **Absence of competing trials**
- **Possibly KCE visit of study sites to assess recruitment potential**

Assessment criteria

- **Patient and public involvement**
 - **KCE strongly encourages patient-public involvement in research**

Assessment criteria

- **Timelines**
 - **First important outcomes should be available within a period of three years after the first patient first visit**
- **Implementation**
 - **Immediate impact on efficiency of the Belgian healthcare system without the need for an additional implementation project**

Next

- **Info on research costs and involvement of RIZIV/INAMI**
- **Info on contract template**

THANK YOU!



<http://ikce.yourict.net/?q=node/1957>



eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT



INAHTA