



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

KCE Trials Update

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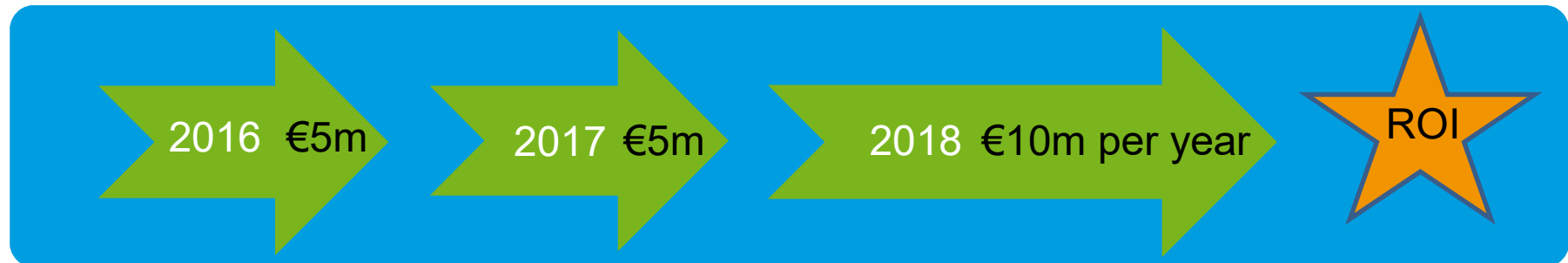
Brussels, November 28, 2017



Impact of KCE Report no 246

June 2015

“In addition to patient benefit, publicly funded trials can provide a positive return on investment”



PUBLICLY FUNDED PRACTICE-ORIENTED CLINICAL TRIALS



2015

www.kce.fgov.be
be

2016 challenge: first patient in trial

End 2016 first patient in VINCA trial



KCE Trials programme

Pragmatic &
practice-
oriented

Comparative
effectiveness

Commissioned
&
investigator-led

Patients &
policy makers

National &
international

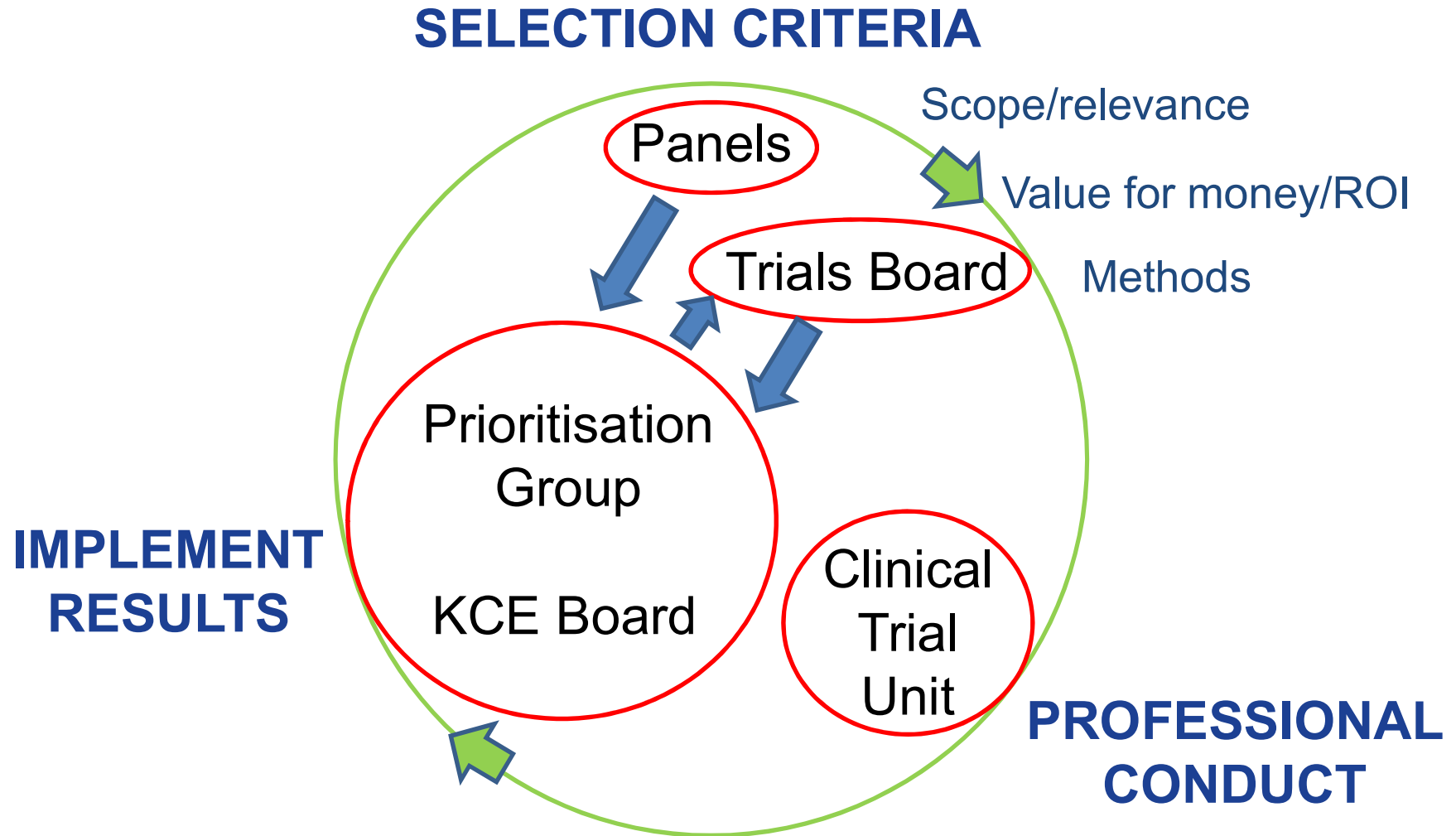
Clinical trials
units (CTU)

Funder

Non-
commercial
sponsor

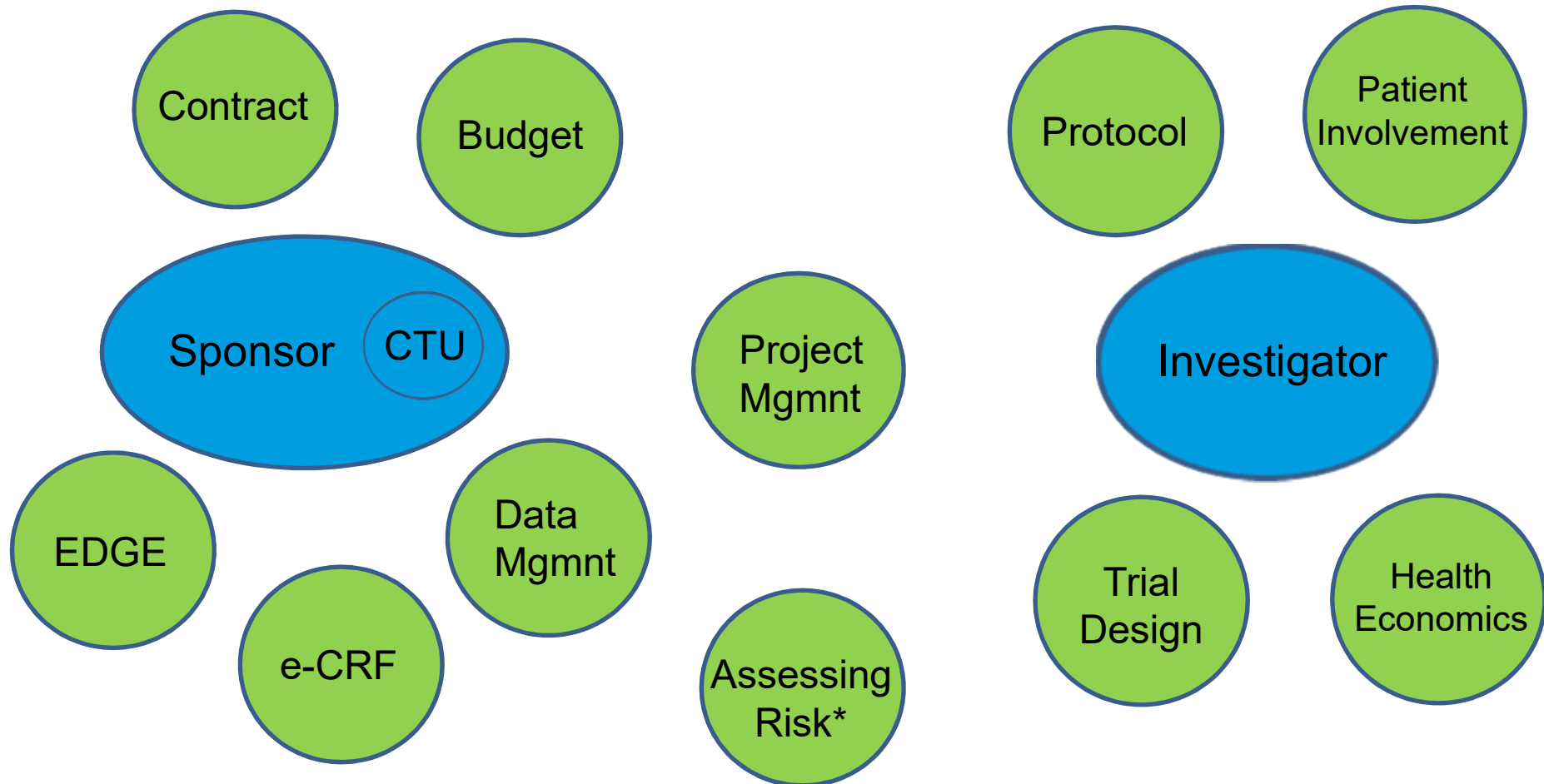
Data sharing

Key success factors for publicly funded trials



HOSPITAL SPONSOR CAPACITY REVIEWED	U	U	U	U	U	U	U	NU	NU	NU	NU
SPONSOR ORGANISATION AND MANAGEMENT											
1. Organisation	Yellow	Green	Yellow	Yellow	Yellow	Red	Yellow	Green	Yellow	Green	Green
2. Management Oversight	Green	Green	Yellow	Green	Green	Yellow	Yellow	Green	Green	Green	Green
3. Quality Management System	Red	Red	Red	Yellow	Red	Red	Red	Yellow	Red	Yellow	Red
4. Document Management Process	Yellow	Yellow	Red	Yellow	Yellow	Red	Yellow	Red	Red	Red	Red
5. Staff and training	Yellow	Yellow	Red	Red	Yellow	Yellow	Yellow	Green	Red	Yellow	Red
6. Regulatory knowledge	Yellow	Green	Green	Green	Green	Red	Green	Green	Yellow	Green	Yellow
7. Quality Assurance and auditing processes	Red	Yellow	Yellow	Yellow	Yellow	Red	Red	Yellow	Yellow	Yellow	Yellow
8. Non compliance and CAPA management	Red	Red	Red	Red	Red	Red	Red	Yellow	Red	Yellow	Yellow
INFRASTRUCTURE FOR CLINICAL RESEARCH											
1. Multicenter Clinical Trials	Yellow	Yellow	Yellow	Yellow	Yellow	Red	Red	Green	Yellow	Green	Red
2. Protocol development	Yellow	Yellow	Yellow	Yellow	Red	Yellow	Yellow	Green	Red	Green	Yellow
3. Sponsor Insurance	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
4. Site selection and oversight	Red	Yellow	Yellow	Yellow	Red	Red	Red	Green	Yellow	Green	Yellow
5. Vendor Management	Red	Red	Red	Red	Red	Red	Red	Green	Red	Green	Yellow
6. Recruitment Strategy, tracker, status reports and oversight	Red	Yellow	Yellow	Yellow	Red	Red	Red	Green	Red	Green	Yellow
7. Trial Master File process, documentation and archiving	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Yellow
8. Data management processes	Yellow	Yellow	Red	Red	Yellow	Red	Red	Green	Red	Green	Red
9 Pharmacovigilance processes	Red	Red	Red	Red	Yellow	Red	Red	Green	Red	Yellow	Yellow
10. Biostatistics and reporting processes	Yellow	Yellow	Red	Red	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Yellow
11. Regulatory submission processes	Green	Green	Green	Yellow	Green	Yellow	Yellow	Green	Green	Green	Green
12. Clinical Supplies processes	Green	Green	Green	Red	Green	Green	Green	Yellow	Yellow	Green	Yellow
13. Central laboratory processes	Green	Green	Green	Green	Green	Green	Green	Yellow	Green	Green	Green
INFRASTRUCTURE AND IT SUPPORT											
1. Information Systems	Green	Green	Green	Green	Green	Yellow	Yellow	Green	Green	Green	Green

KCE Trials workshops & trainings



* Planned Q1 2018

KCE Trials - 2016

Commissioned workstream

- 165 Topic suggestions
- 11 Clinical questions
- 5 Trials being funded

International collaboration (ZonMw)

- VINCA: recruiting
- BeNeDuctus:
agreement signed

1. The effect of **evidence-based order sets** within a computerised physician order entry system on the quantity and quality of laboratory test ordering

- **Cluster randomised trial**
- **300 general practitioners**
- **12 000 to 15 000 patients**
- **Data from labs, GPs and patients combined via Healthdata.be**

2. Multilayer dressings in pressure ulcer prevention

- **Nursing trial in 8 hospitals**
- **Two brands of multilayer dressings**
- **(1:1):1 randomised**
- **1662 ICU and non-ICU at risk patients**

3. Early anti-TNF in rheumatoid arthritis

4. Diet or medication for IBS

5. Blended psychotherapy for depression



KCE Trials 2017/2018

Investigator-led
workstream
2017

- 16 Applications
- 10 Proposals under review

International
collaboration (ZonMw)
2018

- BeNeFIT call
- Open Jan to May 2018

Investigator-led
workstream
2018

- National call
- Open Jun to Sep 2018



BeNeFIT



AIM

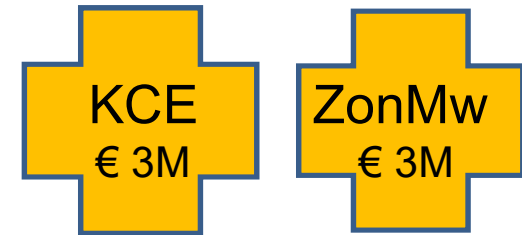
To pilot international collaboration between national public trial funding agencies to perform non-commercial comparative effectiveness trials that are relevant for patients, health care professionals and healthcare decision makers in Belgium and The Netherlands.

Comparative effectiveness

Reimbursable interventions

Medicines and other interventions

Recruitment matching budget contributions



Call opens
16 Jan 2018

Outlines by
8 May 2018

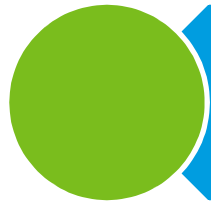
Full
proposals by
2 Oct 2018

Revised full
proposals by
30 Apr 2019

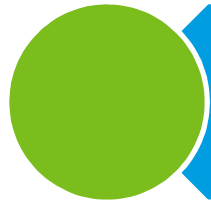
Tips for applicants



Consult a trial statistician



Build a multi-site team in time (FR/NL)



Collect input from patients on endpoints and feasibility



Identify other expertise needed and work with a CTU



KCE Trials for you?

- Interested to receive KCE Trials News?
 - Subscribe to Trials News on KCE website
- Patients, members of the public and healthcare workers interested to review and discuss clinical trial proposals, please contact us at trials@kce.fgov.be

www.kce.fgov.be

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