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

Update on KCE Trials and available sponsor capacity

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KCE, Belgian Health Care Knowledge Centre

www.kce.fgov.be

- Semi-governmental institution
- Operational 2004
- 50 researchers
  - medicine
  - economics
  - statistics, sociology, law
- Studies (n>250)
  - Health technology assessment (HTA)
  - Good clinical practice
  - Health services research

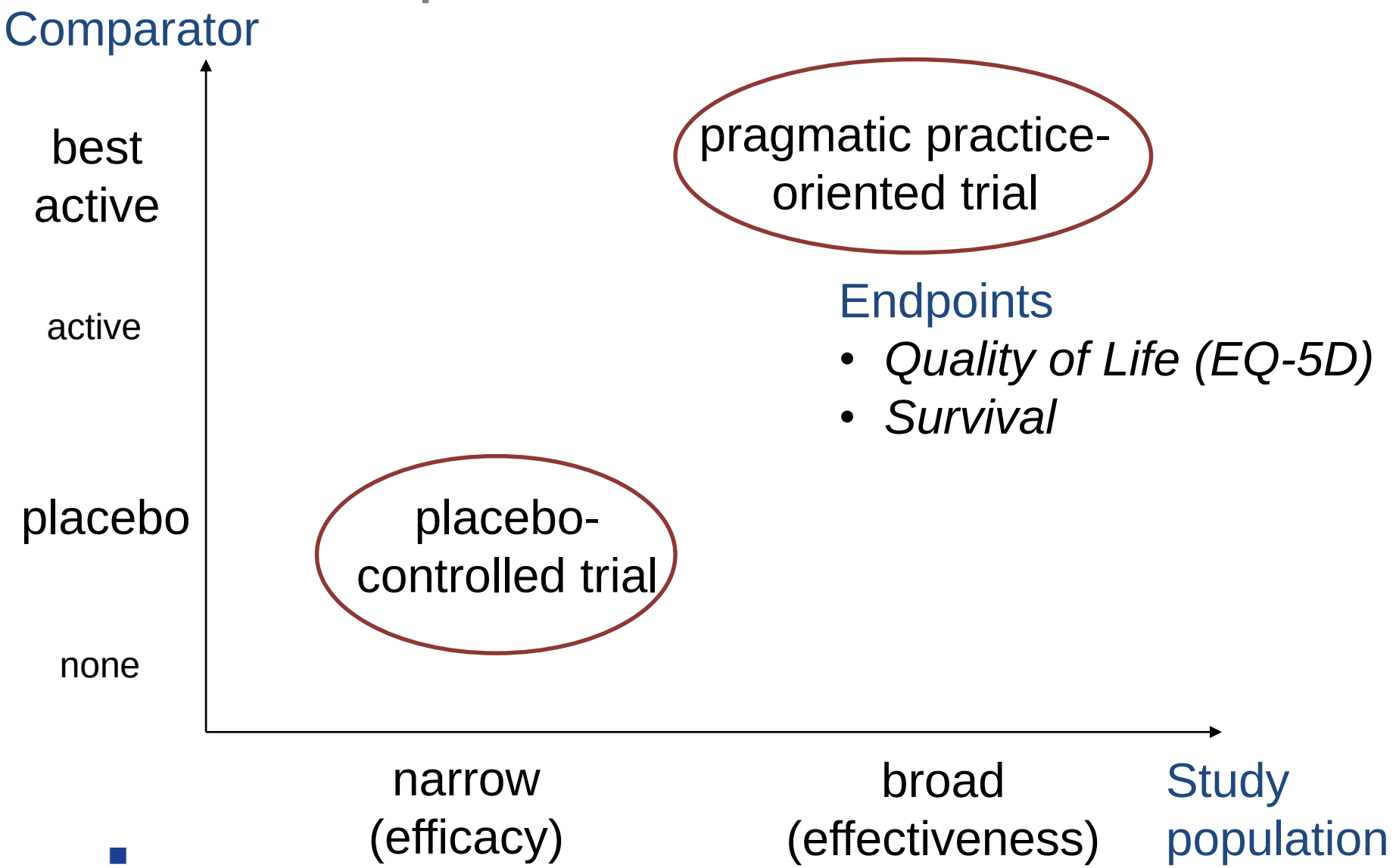
Need for non-commercial trials

- **Important research questions of interest to society that will never be answered by industry (no commercial interest)**
- **Examples**
  - **Pragmatic comparative effectiveness**
  - **Areas not owned by industry (surgical techniques, life style, diet, psychotherapy, ...)**
  - **Drugs in paediatrics and orphan diseases**
  - **Medical devices including diagnostics**
  - **Repurposing of older drugs, including early clinical development**

The healthcare payers

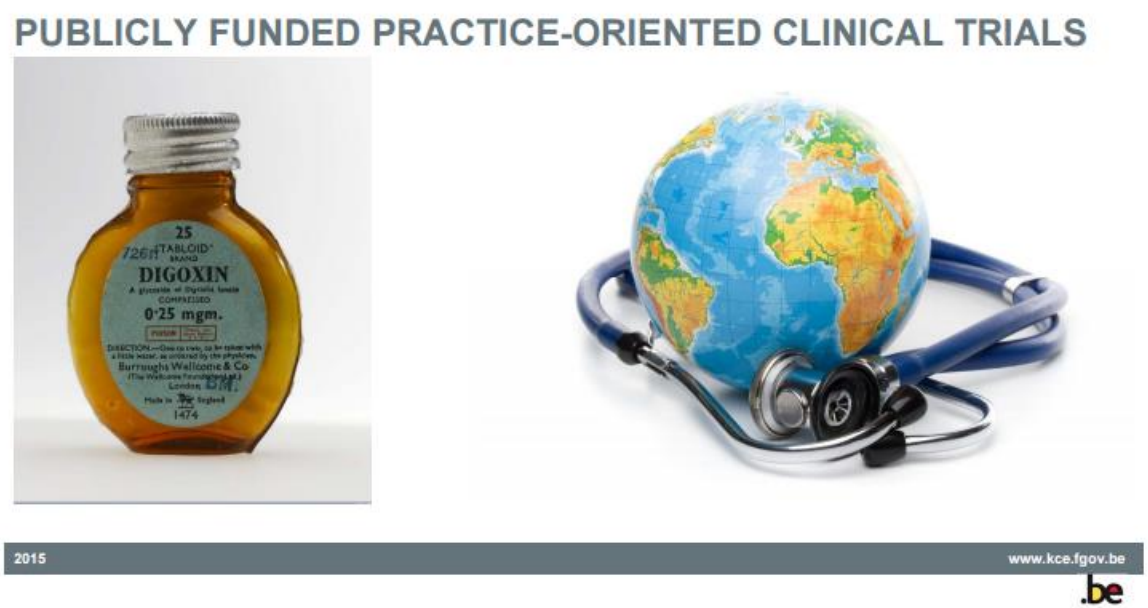
- **Aim to maximise health within the available budget**
- **HTA desktop research: often no answer, comparative trials missing**
- **Selecting and funding clinical trials should be part of the R&D of healthcare payers**
- **The trials should answer questions of relevance for the healthcare payer**

Comparative Effectiveness



KCE Report No. 246 June, 2015

www.kce.fgov.be



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

Publicly funded practice-oriented clinical trials: of importance for healthcare payers. Neyt M, Christiaens T, Demotes J, Walley T, Hulstaert F. *J Comp Eff Res.* 5:551-560; 2016

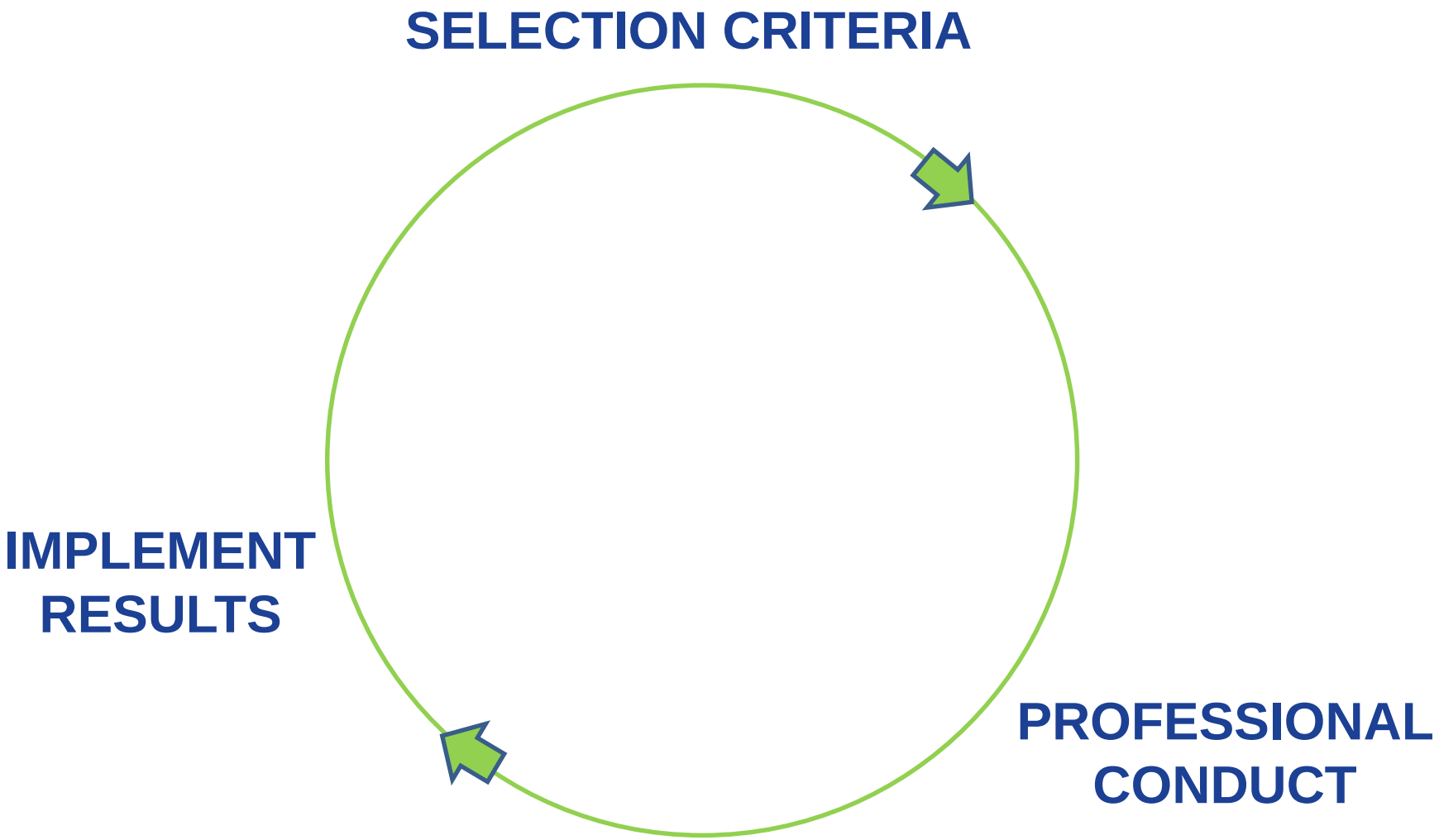
Impact of KCE Report June 2015

- **Decision October 2015**
  - **KCE to set up a programme of practice-oriented clinical trials: "KCE Trials"**
- **Budget**
  - **2016 and 2017: €5 million per year**
  - **From 2018 onwards: €10 million per year**
- **Return on investment is expected**
- **Challenge 2016: first patient in a trial**

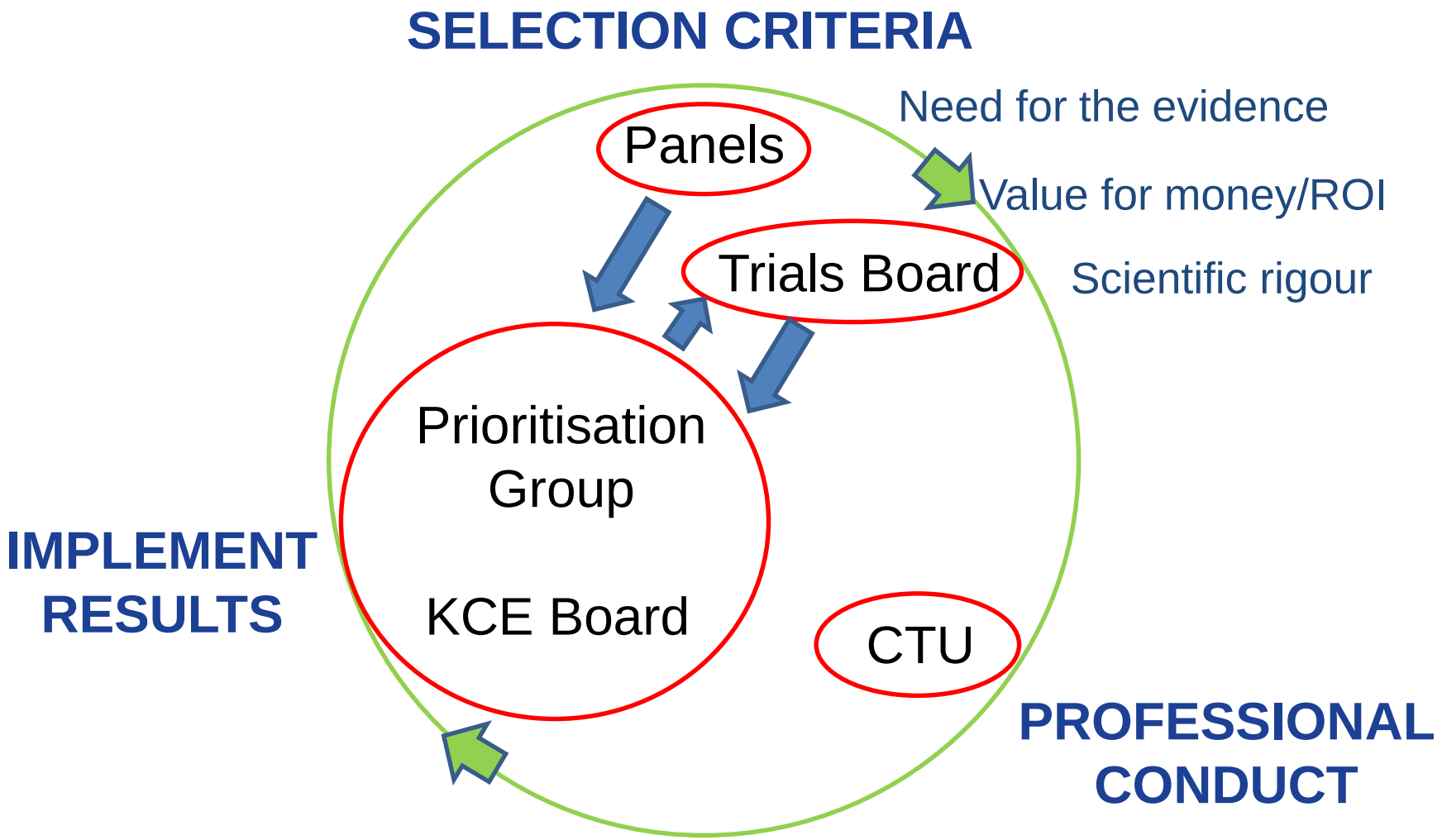
KCE Trials programme

- **Immediately useful**
  - **to patients, clinical practice (effectiveness)**
  - **to policy or decision makers (efficiency)**
- **Extension of HTA programme, as at NIHR**
- **National and international trials**
- **Commissioned and investigator-led**
- **KCE is the funder**
- **Non-commercial sponsor**
- **Need for clinical trial units (CTU)**

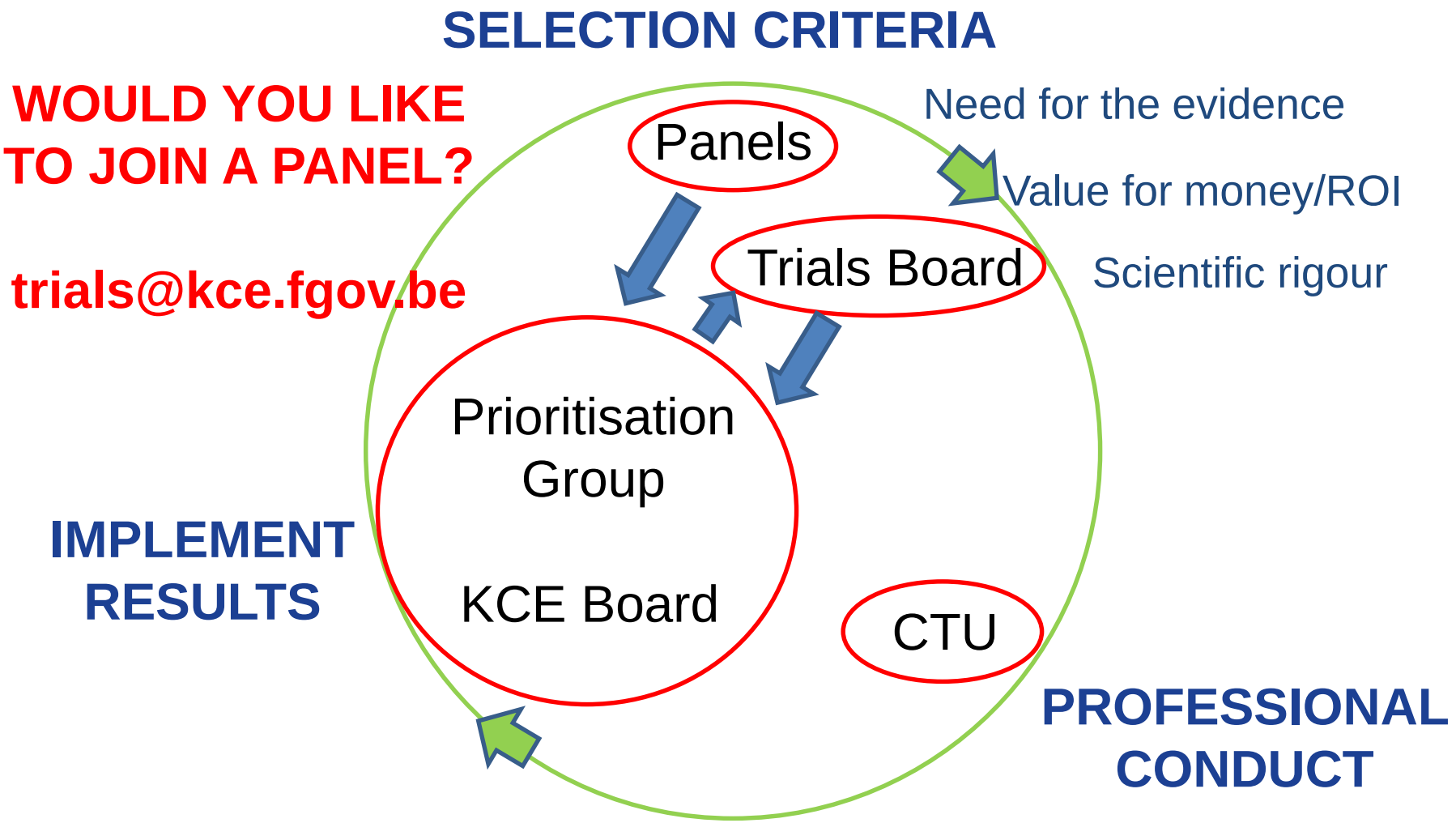
Key success factors for publicly funded trials



Key success factors for publicly funded trials



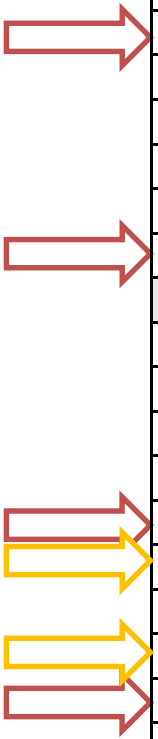
Key success factors for publicly funded trials



Sponsor capacity - CTU

- **Industry: dedicated department**
- **Hospital clinical trial unit:**
  - **Currently mainly legal, budget, ethics**
  - **Also needed for data management, monitoring, vigilance etc.**
  - **Out of scope of hospital accreditation**
- **Two day visits to all 7 university hospitals**
  - **Period May – September 2016**
  - **Including clinical departments conducting trials**
  - **Win-win situation**

Sponsor capacity - results



	I	II	III	IV	V	VI	VII
1.SPONSOR ORGANISATION AND MANAGEMENT							
1.1.Organisation							
1.2. Management Oversight							
1.3 Quality Management System							
1.4. Document Management Process							
1.5. Staff and training							
1.6. Regulatory knowledge							
1.7. Quality Assurance and auditing processes							
1.8. Non compliance and CAPA management							
2.INFRASTRUCTURE FOR CLINICAL RESEARCH							
2.1. Multicenter Clinical Trials							
2.2. Protocol development							
2.3. Sponsor Insurance							
2.4. Site selection and oversight							
2.5. Vendor Management							
2.6. Recruitment Strategy, tracker, status reports and oversight							
2.7. Trial Master File process, documentation and archiving							
2.8. Data management processes							
2.9 Pharmacovigilance processes							
2.10. Biostatistics and reporting processes							
2.11. Regulatory submission processes							
2.12. Clinical Supplies processes							
2.13. Central laboratory processes							
3. INFRASTRUCTURE AND IT SUPPORT							
3.1. Information Systems							

Sponsor capacity - conclusions

- **Few multicentre RCTs**
- **Expertise scattered, not shared**
  - **No central management of sponsored trials, procedures, quality management, recruitment, vigilance, vendors etc.**
  - **Trial data management**
    - **Limited eCRF expertise**
    - **Study data in excel, not in a database**
- **KCE support (IT tools, training,…)**

Status KCE Trials

- **Commissioned workstream 2016**
  - **165 Topic suggestions**
    - **proposed by clinicians, patients, payers etc.**
  - **11 Clinical questions published**
    - **GP topics to high cost specialized care**
  - **Two step review process ongoing**

- **International collaboration**
  - **3 trials funded by ZonMw (Netherlands)**

Frequently asked questions I

- **Why a pragmatic trial approach?**
  - **Most informative for payers**
- **Why non-commercial sponsors only?**
  - **Regulatory exemptions**
- **What about industry involvement?**
  - **Free product is possible, if no strings attached**
- **Why multicenter trials only?**
  - **Speed of recruitment**
  - **Broad support for implementation**

Frequently asked questions II

- **When are international trials indicated?**
  - **Speed of recruitment**
  - **Co-funding may be needed**
- **Why strict data management, data access?**
  - **Solid basis for public health decision making**
- **Why detailed budget with all activities specified?**
  - **Fairness, reassurance all activities are planned**
  - **Microscopic monitoring**
- **Why involve patients from the start?**
  - **Input on acceptance, feasibility, endpoints**

Status – What is next

- **Investigator-led workstream 2017**
  - **Focus on return on investment**
  - **Announcement Q1 2017**
  - **Any questions? trials@kce.fgov.be**