



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

KCE Trials

A Programme of Pragmatic Practice-oriented
Publicly-funded Clinical Trials

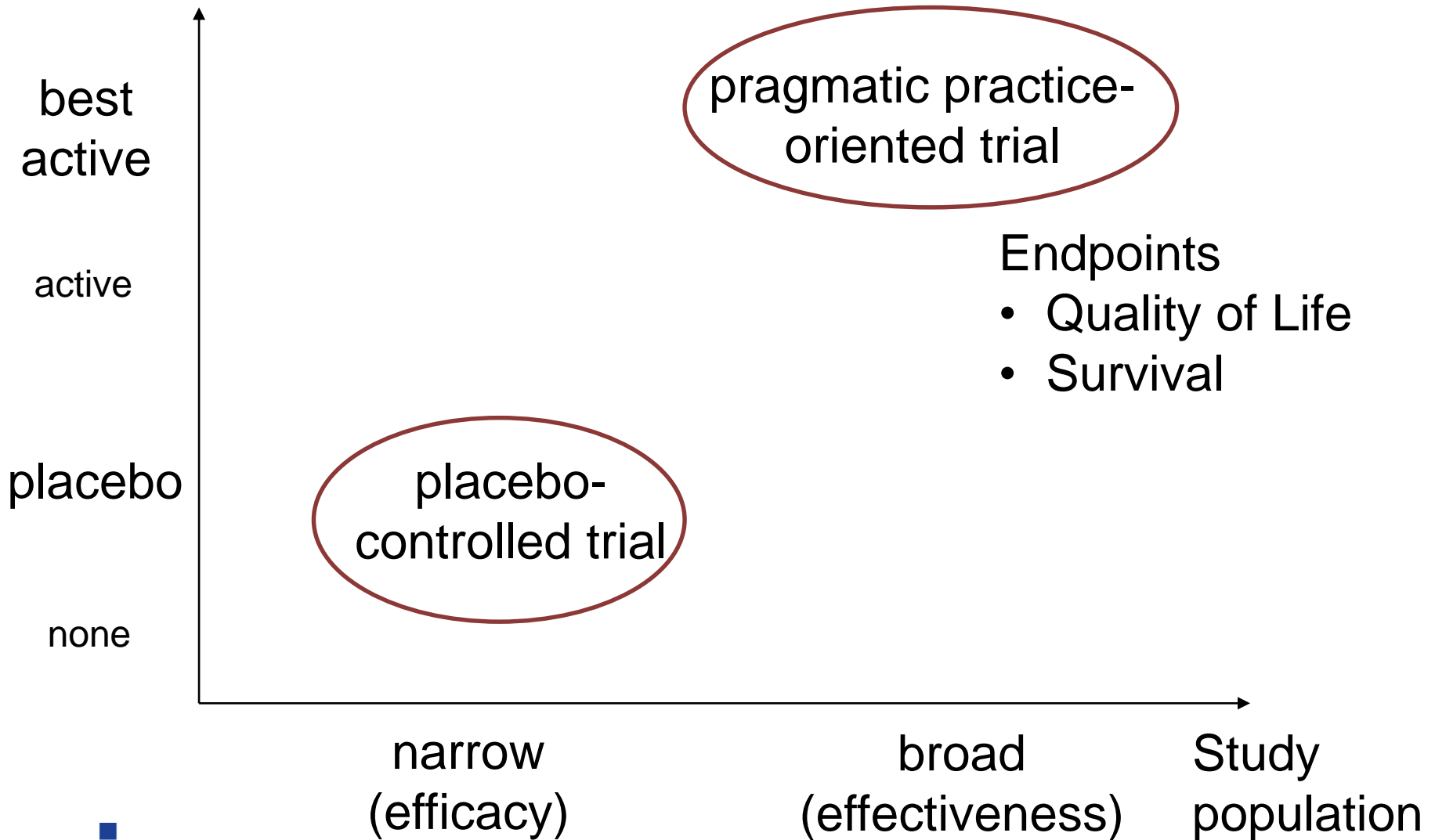
MAY 20, 2016 - FRANK HULSTAERT

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.**



Comparator



KCE Trials

- **Immediately useful to patients, clinical practice (effectiveness), and policy or decision makers (efficiency).**
- **Extension of KCE HTA programme as at NIHR.**
- **National and international trials.**
- **Commissioned and researcher-led.**
- **KCE is the funder, not the sponsor**

Team and collaborations

- **Christian Leonard**
- **PC: Nathalie Swartenbroekx**
- **Frank Hulstaert, Leen Verleye, France Vrijens, Jilly Harrison, Hilde Nevens + consultancy**
- **NIHR, ZonMw, EORTC, ECRIN, ERA-NET, FWO, Innoviris, ..**
- **Clinical trial units and experts**

KCE Trials WG - Prioritisation

Marc Bogaert, Roger Bouillon, Marc Debroe, Pierre Maquet, Jean-Marie Maloteaux, Françoise Meunier, Brigitte Velkeniers

Katelijne De Nys, Ellen De Wandeler, Cécile Dethier, Patrick Galloo, Pol Gerits, Pierre Gillet, Diane Kleineremans, Caroline Lebbe, Cathy Mathei, Greet Musch, Chris Van Hul, Thierry Velu, Ilse Weeghmans

Towards Belgian CTUs

- **KKS example: seed money in year 1, self-supportive thereafter**
- **Focus efforts based on gap analysis**
- **One day training seminar for sponsor-investigators and investigators**
 - **KCE Trials explained**
 - **Sponsor obligations : FAMHP**
 - **Reimbursement rules in trials : NIHDI**
 - **Experience at NIHR, ZonMw, ECRIN, EORTC**

Consultancy - CRO

- **Harmony CR (+KCE: Hilde Nevens)**
- **Aim: risk reduction (compliance, recruitment), align with FAMHP GCP check**
- **Tasks:**
 - 1. On-site evaluation of sponsor capacity at universities and hospitals (May-September)**
 - 2. Pre-contract on-site evaluation of recruitment capacity**
 - 3. Ad hoc in-house support**

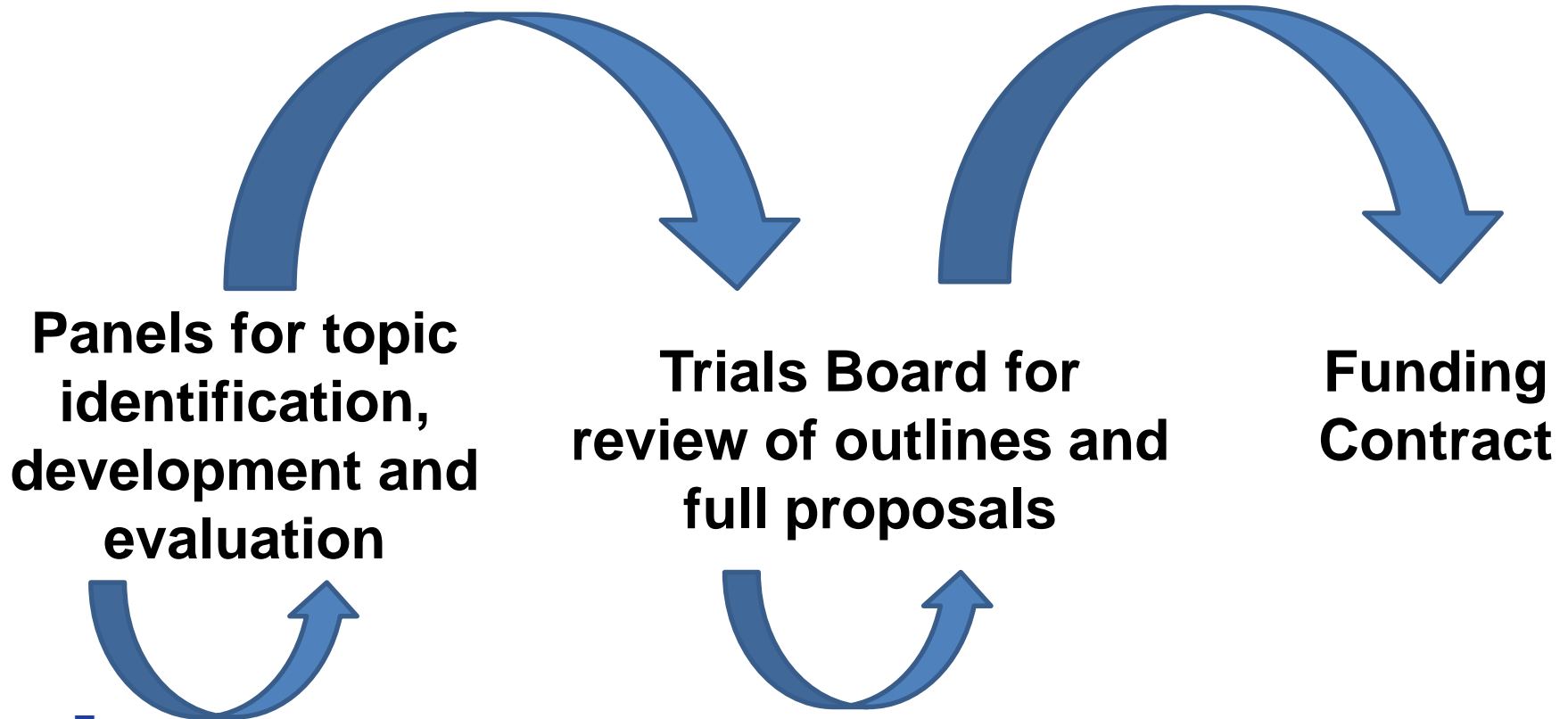
Consultancy - legal

- **Quinz (+KCE: Elisabeth Petit, Irm Vinck)**
- **Adapt NIHR template contract(s) to Belgian situation**
- **General legal questions concerning KCE Trials**
- **Ad hoc support for trial contracts with sponsor and third parties**
- **Ad hoc legal support for KCE Trials**

KCE Board



KCE Trials Working Group
(Prioritisation WGp: only experts without COI)



Timeline Topics Selection

FEB 8

165 topic suggestions received

Board MAR 15

KCE Trials and WG/WGp role

WGp MAR 15

out of scope deliberation, 85 topics remaining

All panels MAR 21

briefing panel members

Panel APR 11

neurology, pediatric neurology, urology, obstetrics and gynecology

Panel APR 12

psychiatry, primary care, dermatology, clinical pharmacology, intensive care, nephrology, endocrinology, rheumatology, physiotherapy, nutrition, pain treatment, and various forms of integrated care

Panel APR 14

oncology, hemato-oncology, hematology, pneumology, cardiology, neonatology and paediatrics

WGp APR 19

prioritisation meeting, 14 (+15) topics

Board MAY 3

approval of call for up to 10 proposals



KCE Trials – general criteria

both for topic selection and review of proposals

- **Need for the Evidence**
 - Importance, impact
- **Value for Money**
 - Possible Return on Investment
- **Scientific Rigour**
 - Will answer the question
 - Feasible and deliverable

Specific criteria for 2016 commissioned workstream

- **Comparative effectiveness trial.**
- **Randomised.**
- **eCRF.**
- **Patients available in Belgian centres.**
- **Max three year period.**
- **Low risk of recruitment delay.**
- **Implementation after trial is feasible.**