



# KCE Trials

France Vrijens, Head KCE Trials

28<sup>th</sup> November 2024

Symposium

### Specificities

- ✓ **Pragmatic & practice oriented**
- ✓ **Comparative effectiveness**  
(drugs, devices, surgery, physiotherapy, psychotherapy...)
- ✓ **Drug repurposing**  
(off-patent drugs)
- ✓ **Non-commercial**
- ✓ **Potential for return on investment**
- ✓ **Data sharing**

### Quality support

- Sponsor capacity assessed for all trials
- Trainings for Clinical Trials Centres
- Coaching of funded teams
- External audits of ongoing trials

### Calls for research proposals



### Funding budget

**10 million € annual budget**

- Median budget per trial 2 million €
- Milestone-based budget
- Use of template to budget non-commercial research

### Funded Trials

Ongoing

**41**

Completed

**15**

**+ 30 000**  
participants recruited



Hospitals



Primary care



Check the realtime recruitment in our dynamic dashboards

### Impact

**75**

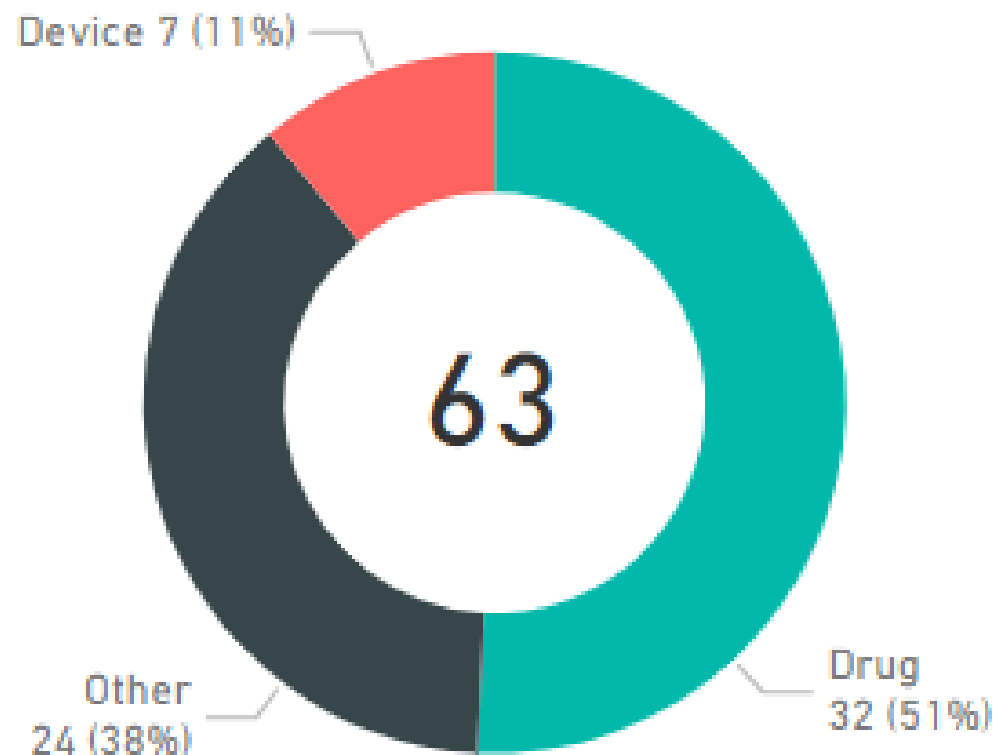
scientific peer reviewed publications

HTA & linkage with Real World Data

Changes to clinical guidelines



# Which type of trial ?



For patients with Irritable Bowel Syndrome, which option is better at controlling symptoms ?

Carbone F, Van den Houte K, Besard L DOMINO Study  
*Gut* 2022;**71**:2226-2232





50% RECRUITED

# TreatPaCS



**Treatment for Preschool age Children who Stutter - A randomised, multicentre, non-inferiority parallel group pragmatic trial with Mini-KIDS, social cognitive behaviour treatment and the Lidcombe Program**

- ✓ **Chief investigator: Sabine Van Eerdenbrugh (TMMA)**  
**Co-chief investigator: Anne-Lise Leclercq (ULiège)**  
**Co-chief investigator: Veerle Waelkens (Artevelde)**
- ✓ **Number of children: 249**
- ✓ **Budget: 1.77€ million €**
- ✓ **Collaboration of 30 speech language therapy practices**

**More information: <https://treatpacs.be/>**

First Patient In

# REPAIR



Rebuilding Parent young Adult Interpersonal Relationships

Targeting suicidality in young adults: a randomized controlled, pragmatic, multicentre trial evaluating Attachment Based Family Therapy compared to Treatment as Usual

- ✓ National Coordinator : Pr Bosmans (KU Leuven)
- ✓ 138 participants will be recruited in Belgium and in The Netherlands
- ✓ Budget: 1 million €
- ✓ Results expected in 2027

75% patients randomized

# PEPPER



Determining the optimal strategy for stopping chronic proton pump inhibitor (PPI) therapy in primary care patients: impact of on-demand use, adjunctive therapies and antacids

PEPPER: Primary carE PPi dEprescRibing trial

- ✓ Chief investigator: Pr Tack (UZ Leuven)
- ✓ 609 patients randomized by 75 GP practices
- ✓ Budget study: 1.96 million €
- ✓ Results in 2026



More information: [KCE website](#) > [KCE Trials](#) > [Funded Trials](#)

## HOW CAN WE IMPROVE ENDOMETRIOSIS CARE IN BELGIUM?





Budget : 3 Million €

Endometriosis care demands your expertise.

Let's bridge the gaps in knowledge and elevate patient outcomes.

# 2024 themed call for proposals on **endometriosis care**

- ✓ **Comparative effectiveness, non-commercial aim, Belgian sponsor or participation to international study**
- ✓ **Only multicentre pragmatic randomised clinical trials (RCTs)**
- ✓ **Online information session : June 7, 2024 (compulsory registration)**
- ✓ **Submission deadline: September 24, 2024**



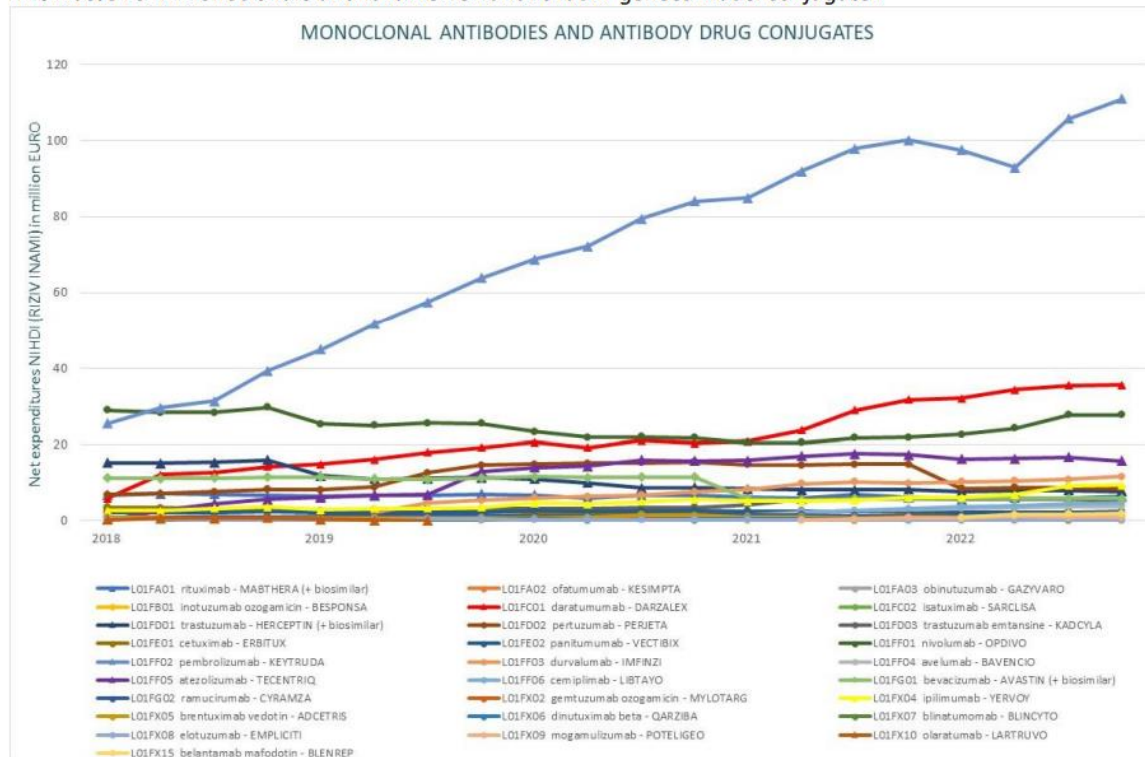
More information: <https://kce.fgov.be/en/kce-trials-2024-themed-call-for-proposals-on-endometriosis-care>



News

**EORTC/EMA workshop suggests an international way forward for treatment optimisation studies**

**Figuur 99 : evolutie van de uitgaven van het RIZIV per kwartaal (ziekenhuizen (alle patiënten ( 2018 – 2022)) voor ATC klasse L01F Monoclonale antilichamen en antilichaam-geneesmiddel conjugaten**



## Rapport MORSE

Chaque année, nous analysons les dépenses pour les médicaments remboursables. Il s'agit du « Rapport MORSE ». Ces rapports sont disponibles depuis 2008.

**Tabel 11 : evolutie van de jaarlijkse uitgaven RIZIV (zonder rekening te houden met ontvangsten) voor geneesmiddelen - top 80 % (ziekenhuizen)**

| Ranking |      |      | Forfait | ATC3 |                                                        | Groei (%) |           | Totaal in mio EUR <sup>2</sup> |
|---------|------|------|---------|------|--------------------------------------------------------|-----------|-----------|--------------------------------|
| 2020    | 2021 | 2022 |         |      |                                                        | 2021-2020 | 2022-2021 |                                |
| 1       | 1    | 1    | No      | L01F | MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES (T) | 12,9%     | 9,7%      | 998,3                          |

STARTING SOON

# Opt-Pembro



OPTimizing adjuvant prescription of PEMBROLizumab in patients with **early-stage triple-negative breast cancer** achieving pathologic complete response after standard neoadjuvant chemotherapy and pembrolizumab

- ✓ Chief investigator: Dr. Joana Mourato Ribeiro (Unicancer, France)
- ✓ Belgian Coordinating Center: Prof. Duhoux (UCL St Luc)
- ✓ Start of study: End 2024
- ✓ Budget: 1.5 million €
- ✓ Number of participants: 200 in Belgium (2454 in total)

**More information: [KCE Trials > Funded Trials](#)**

CONTRACT SIGNED

# PULSE



**Maintenance Pembrolizumab at Usual or Low doSE  
in non-squamous lung cancer: a non-inferiority  
study**

- ✓ **National Coordinating investigator: Prof. Frank Aboubakar Nana (Cliniques Universitaire St Luc)**
- ✓ **Start of study: Q3-4 2024**
- ✓ **Budget: 1.48 € million**
- ✓ **number of participants, sites: BE 200 participants, 12 sites (Study 1166 participants randomized)**

**More information:** See KCE Trials website, funded studies

# Impact KCE Trials ? (work in progress)



**Scientific publications**



**Changes in guidelines**



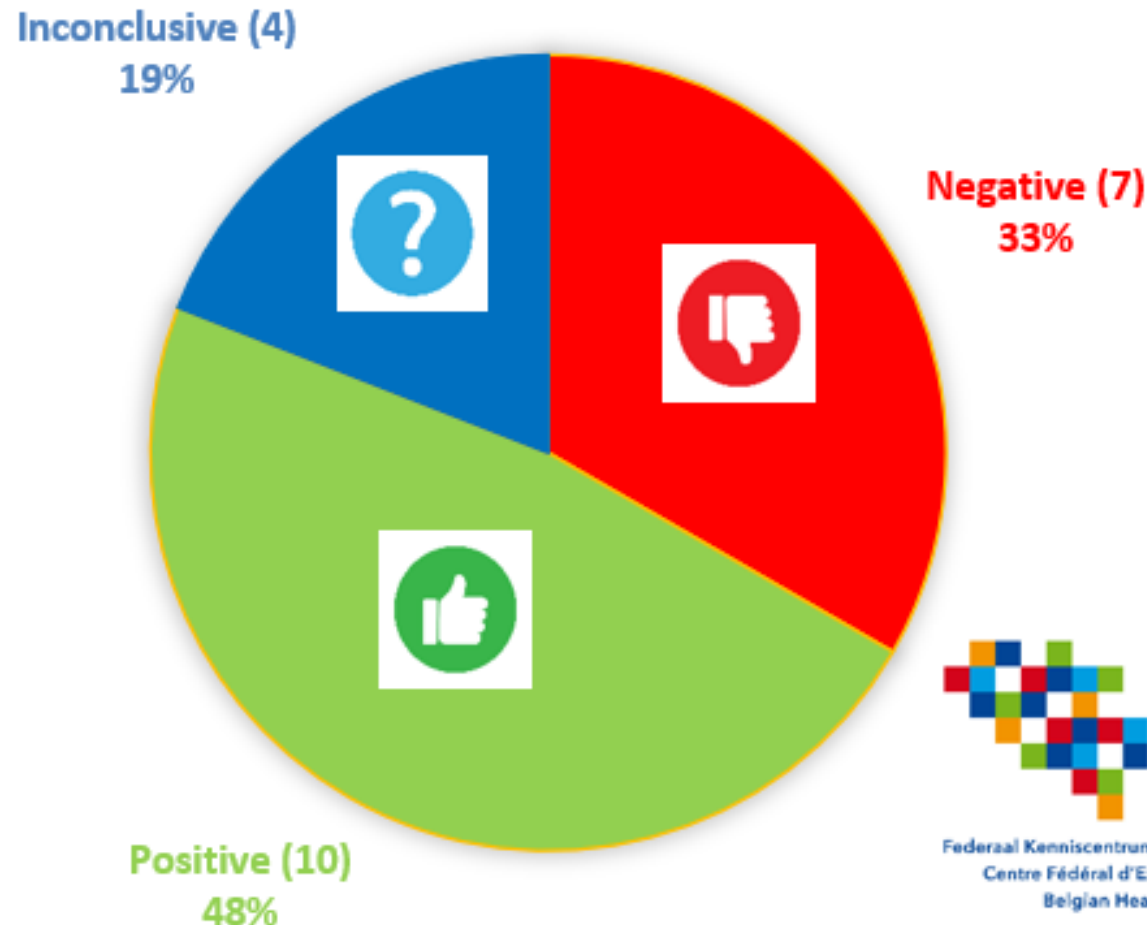
**Health economics  
considerations (HTA)**



**Implementation**

# Impact KCE Trials ? (work in progress)

## OVERVIEW RESULTS FROM 21 FUNDED CLINICAL TRIALS

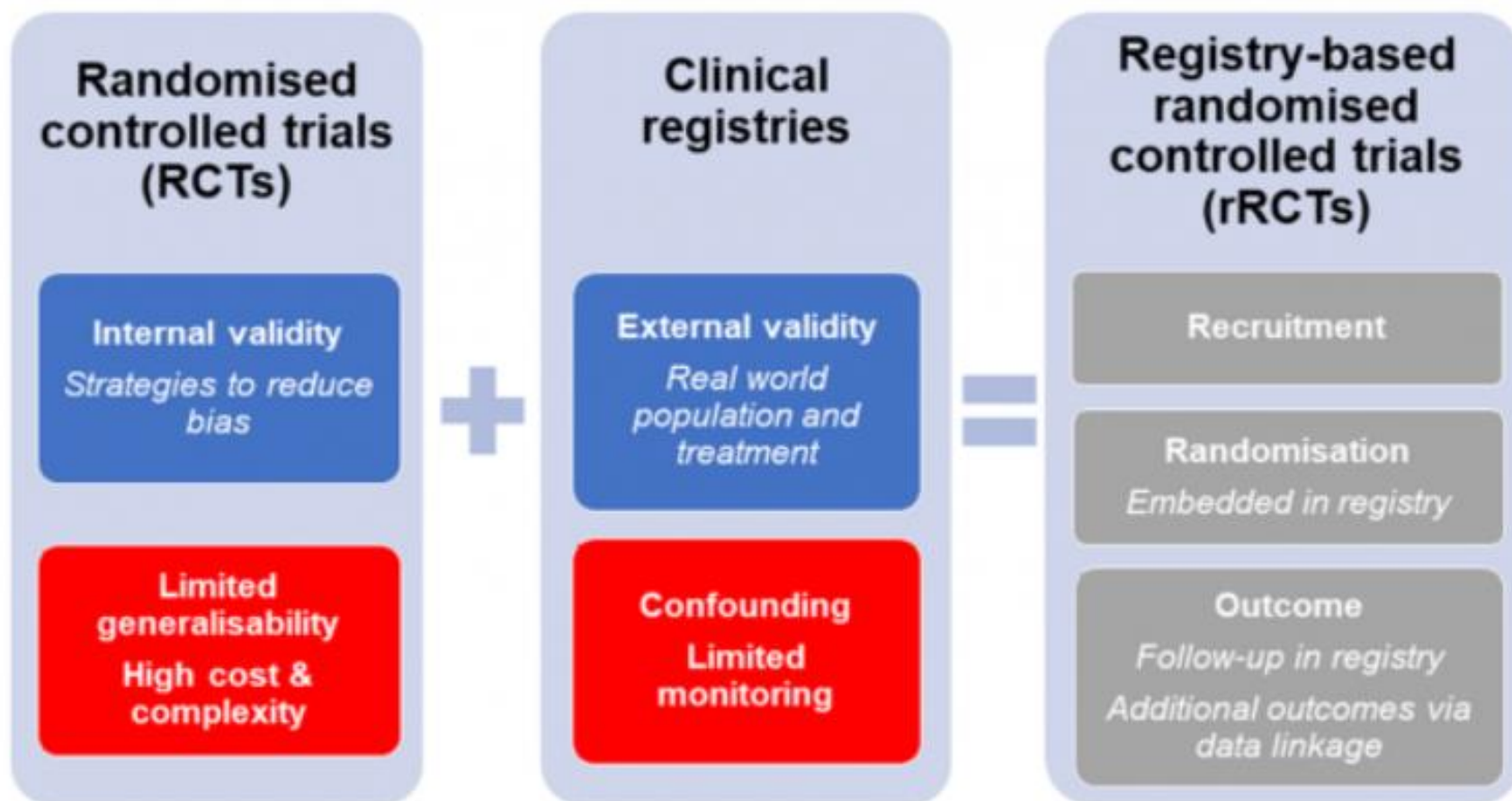


# R - RCT

## The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.

Related article, p. 1587



Slide from VCC Alliance (Australia Comprehensive Cancer Centre)

## Interested in participate in an exploratory phase on R-RCTs ?

More info will be published soon.

If the exploratory phase is positive, there will be a specific call for funding for R-RCTs.



**Disease-specific or condition-specific clinical registry**  
(clinical patient data, regular follow-up, robust clinical outcome data)



**Good geographic coverage**  
(in three regions Belgium)



**Data quality validation**



*The KCE Trials team  
(say cheese...)*

