

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

KCE Trials, a funder and facilitator of large pragmatic non-commercial clinical trials

France Vrijens, Head KCE Trials

KCE Trials Symposium, Brussels, 25th May 2023

KCE TRIALS

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Belgian Health Care Knowledge Centre

KCE Trials is a department of the **Belgian Health Care Knowledge Centre (KCE)**, an independent research centre that provides scientific advice on topics related to health care. KCE Trials was created in 2016.
KCE Trials **selects and funds non-commercial large multi-centre pragmatic randomised controlled clinical trials** (RCTs).

KCE TRIALS IN A NUTSHELL 2023

Specificities

- ✓ Pragmatic & practice oriented
- ✓ Comparative effectiveness
  (drugs, devices, surgery, physiotherapy, psychotherapy...)
- ✓ Drug repurposing
- ✓ Non-commercial
- ✓ Potential for return on investment
- ✓ Transparency and data sharing

Quality support

Sponsor capacity assessed for all trials

Training for Clinical Trials Centres

Coaching of funded teams

External audits of ongoing trials

Calls for research proposals

2 calls in 2023

14 calls since 2016

8th national call

3rd call **BeNeFIT** with ZonMw (NL)

Investigator-led calls & commissioned calls
Bottom up — Top down

Funding budget



9.4 million € annual budget

13.5 million € COVID-19 extra budget
(9 studies funded)

1.7M€ Median budget per trial (milestone-based)

Funded trials

Ongoing **35**

Completed **11**

+25 000 participants recruited

in +65 hospitals by +380 PIs

by +560 GP's

Check the realtime recruitment in our dynamic dashboards

+4 trials terminated before completion

Impact

41 scientific peer-reviewed publications

HTA & linkage with Real World Data

A tool for budgetting non-commercial trials

KCE Trials Dynamic Dashboard

Overview | Go To Recruitment | Go To Filters | Go To Publications

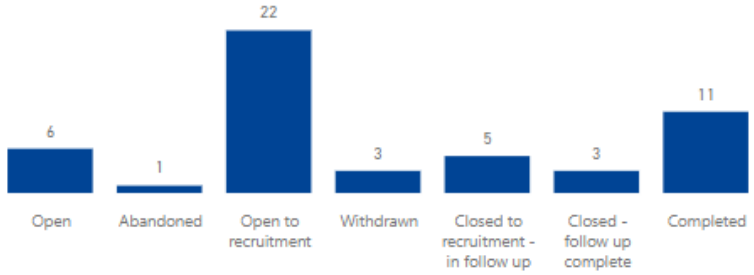
Last update (usually every Friday)

Date	Heure
Monday, May 22, 2023	8:25:26 AM

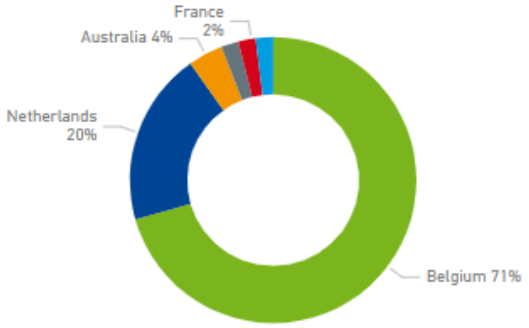
RCTs Funded

51

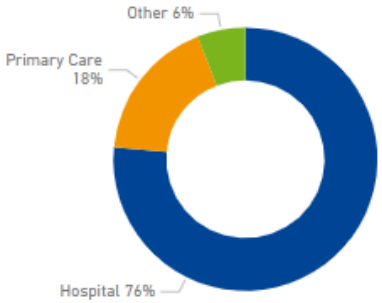
Studies' Status



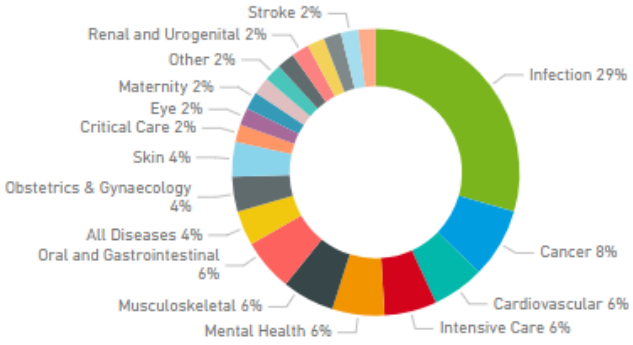
Sponsor's country



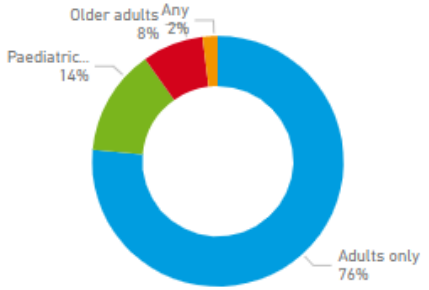
Study Setting



Disease Area



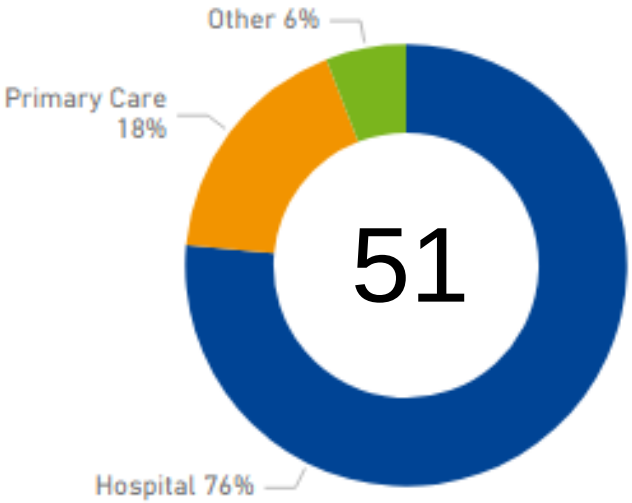
Participant's Age



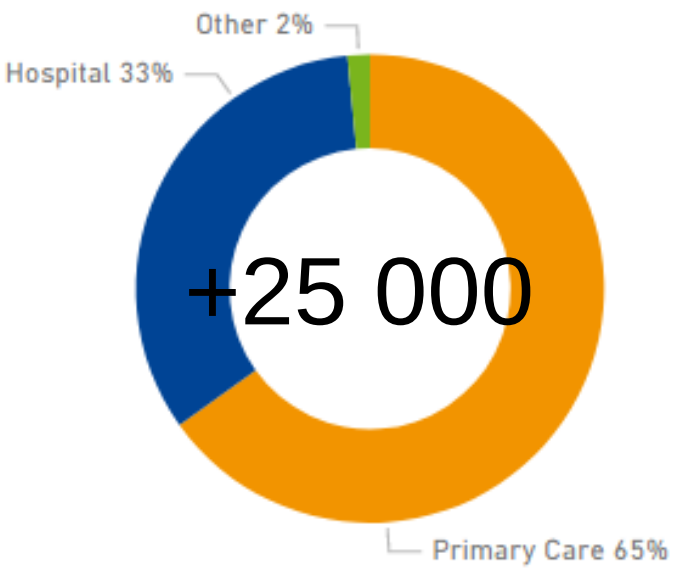
Recruiting Organisations	Recruiting Sites	Recruiting GPs	Participants Recruited
88	400	563	25749

Portfolio: by *Setting*

studies



participants recruited



Portfolio: by *Intervention*





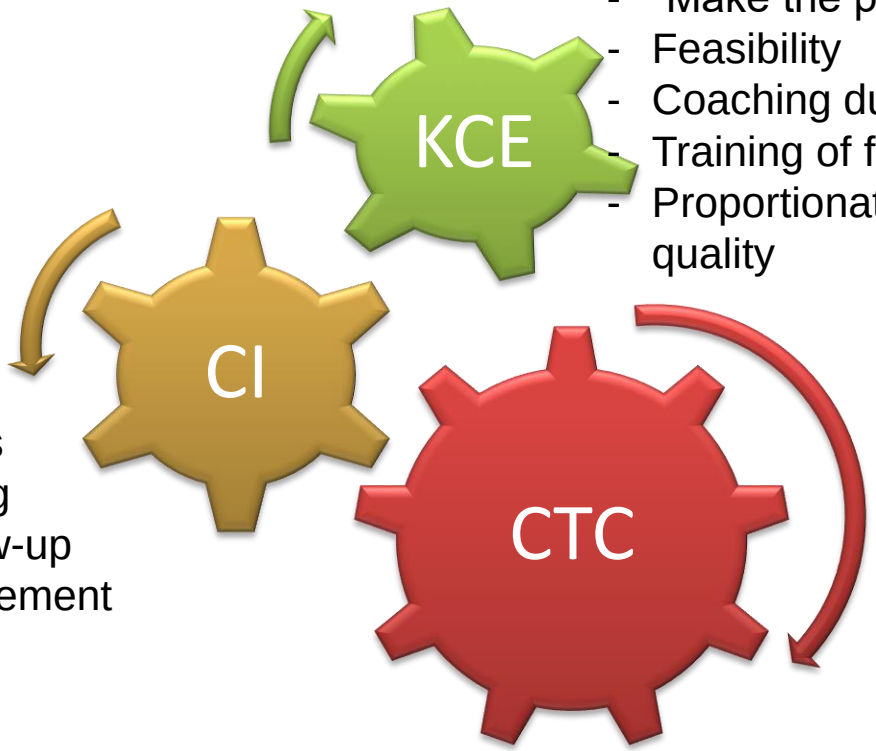


KCE Trials Advisory Boards

- Prioritisation Group (PG) members
- Trial Board (TB) members
- Panel members
- All groups include patient representatives

High quality pragmatic trials – practice changing

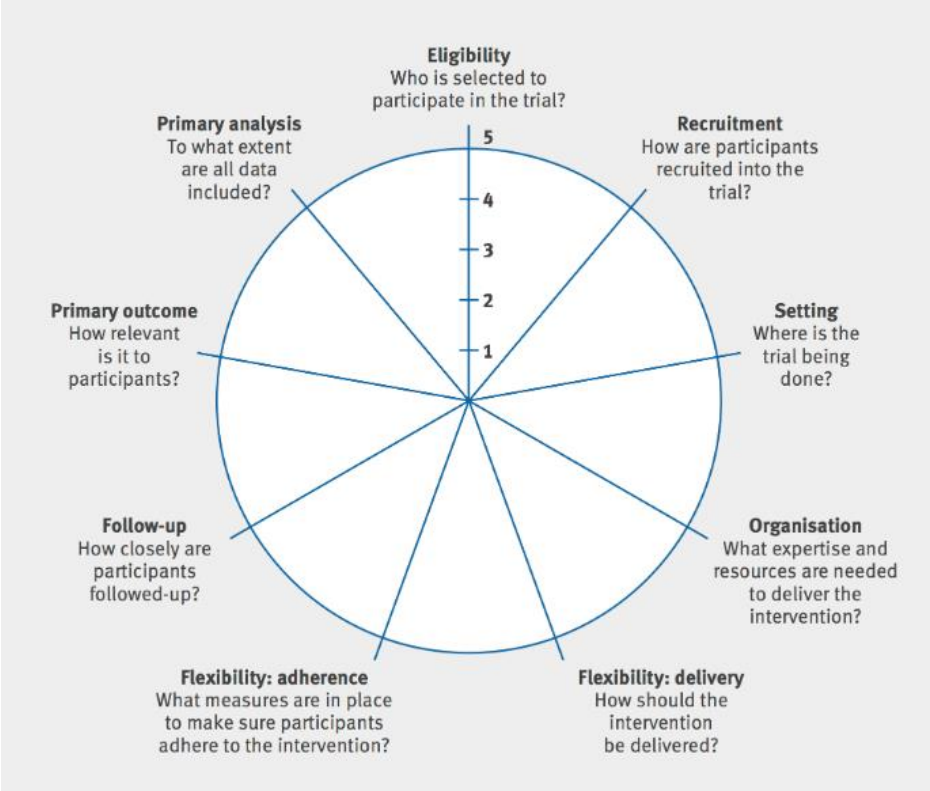
- **Funding**
- CTC capacity building
- Methodological review/support
- “Make the protocol pragmatic”
- Feasibility
- Coaching during studies
- Training of funded teams and CTCs
- Proportionate approach to ensure quality



- Scientific ideas
- Protocol writing
- Scientific follow-up
- Project management

- **Sponsor**
- Protocol writing
- Data Management
- Monitoring
- Safety
- Contracts
- Approvals
- Insurance
- Finance
- Logistics
- …

How to know if your trial is pragmatic enough ?



PRECIS-2

. PRECIS – PRagmatic Explanatory Continuum Indicator Summary ·

Supplementing RCT data

RCT + RWD

Randomised Clinical Trial

Unbiased effects
QOL
Short-term follow-up
Expensive

Real World Data

Reliable administrative databases
Cheap
Long term follow-up
Real utilisation of health care services (costs)

Linkage at individual level
Requires prior authorisation

RCT + RWD

CLINICAL TRIAL

BJD
British Journal of Dermatology

Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic noncommercial multicentre randomized open-label parallel-group medical device trial

D. Beeckman[1,2,3] A. Fourie[1] C. Raepsaet,[1] N. Van Damme,[1] B. Manderlier,[1] D. De Meyer,[1] H. Beele,[4] S. Smet,[4] L. Demarré,[5] R. Vossaert,[5] A. de Graaf,[6] L. Verhaeghe,[7] N. Vandergheynst,[7] B. Hendrickx,[8] V. Hanssens,[8] H. Keymeulen,[9] K. Vanderwee,[10] J. Van De Woestijne,[11] S. Verhaeghe,[1] A. Van Hecke,[1] I. Savoye,[12] J. Harrison,[12] F. Vrijens[12] and F. Hulstaert[12]

1633 patients in 7 belgian hospitals
Follow-up 14 days
Outcome : incidence of PU cat 2, 3, 4

Hospital administrative data
Full length of stay for each patient

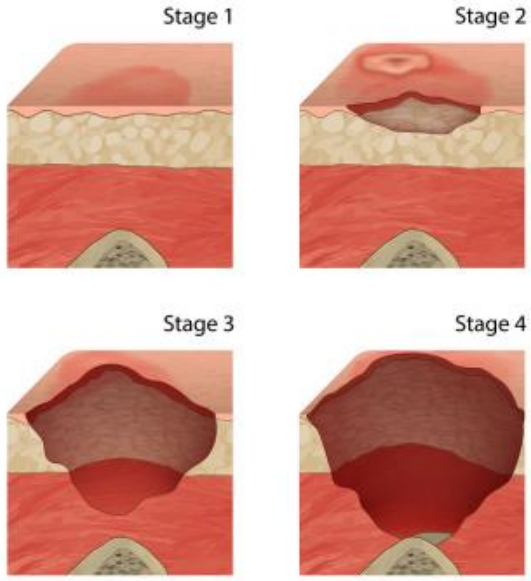
Linkage at patient level

KCE REPORT 368

Federaal Kenniscentrum voor de Gezondheidszorg
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SILICONE ADHESIVE MULTILAYER FOAM DRESSINGS TO PREVENT HOSPITAL-ACQUIRED PRESSURE ULCERS: A BELGIAN RCT-BASED ECONOMIC EVALUATION





World Health Organization

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Joint statement on public disclosure of results from clinical trials

The World Health Organisation's Joint Statement sets out 11 safeguards that all medical research funders worldwide should adopt to prevent research waste and maximise the value of funds invested in medical research:

TRIAL REGISTRIES	1. Prospective trial registration
	2. Registry records kept up to date
	3. Results posted onto registry within 12 months
	4. Protocol posted onto registry within 12 months
JOURNAL PUBLICATION	5. Results made public in journal
	6. Trial ID included in all publications
	7. Open access publication
MONITORING COMPLIANCE	8. Funder monitors trial registration
	9. Funder monitors results reporting
	10. Funder publishes monitoring reports
SANCTIONS	11. Funder considers PI's past reporting record when deciding on new grants

JAMA Network Open

Original Investigation | Health Policy

Adoption of World Health Organization Best Practices in Clinical Trial Transparency Among European Medical Research Funder Policies

Till Bruckner, PhD; Florence Rodgers, MD; Lea Styrmisdóttir, MD; Sarai Keestra, MSc

FEATURE

Check for updates

Paris

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http://dx.doi.org/10.1136/bmj.p840

Published: 19 April 2023

Funders crack down on unpublished clinical trials—but is it enough?

Failure to report clinical trial results is a longstanding problem in medical research, but funders are starting to take action against laggard investigators, new research finds. **Barbara Casassus** reports

TranspariMED

NEWS TOOLS REPORTS

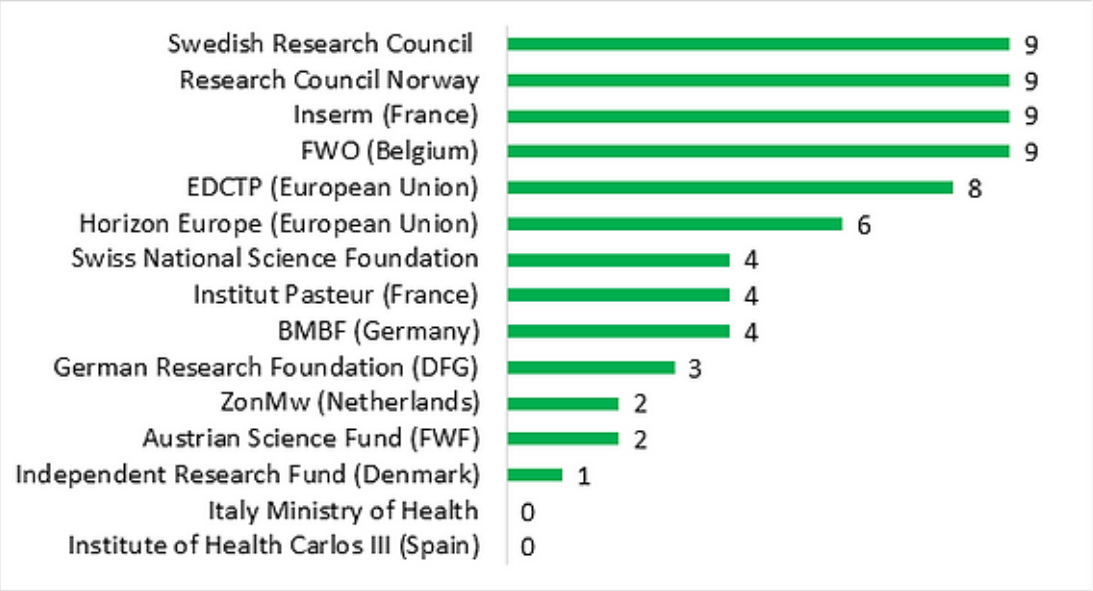
Till Bruckner · Apr 18

Which of the world's top 39 research funders ensure that clinical trial results are made public?

Europe

In mainland Europe, the picture is also very mixed.

While no European funder has adopted all WHO-recommended safeguards, several European funders now have strong policies in place, including public funders in ***Sweden***, ***Norway***, and ***Belgium***. However, public funders in Austria, Denmark, Germany, Italy, the Netherlands and Spain continue to disappoint.



Note: Several of the funders listed above significantly strengthened their policies during 2021-2022. For funder-by-funder data on improvements, please see this preprint.

KCE TRIALS

Aiming at 100% compliance in 2023

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