



ZonMw



KCE
TRIALS

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

BeNeFIT

Belgium-Netherlands Funding of International Trials

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*Publicly Funded Clinical Studies and Trials on Infectious Diseases
during Future Pandemics, Brussels, 14-15 May 2024*



KCE, Belgian Health Care Knowledge Centre

www.kce.fgov.be



- Semi-governmental institution
- Operational 2004
- 50 researchers
 - medicine, economics
 - statistics, sociology, law
- Studies (n>300)
 - Clinical practice guidelines
 - Health services research (HSR)
 - **Health technology assessment (HTA)**
 - + KCE Trials**
 - started in 2016, € 9M per year
- Policy recommendations, no decisions



KCE Trials programme

Pragmatic &
practice-oriented

Comparative
effectiveness &
repurposing

Drugs, devices,
surgery, diet,
psychotherapy,...

Patients &
policy makers

National &
international

Commissioned
&
investigator-led

Clinical trials
Centres (CTC)

Non-
commercial
sponsor

Publication +
Data sharing

KCE Trials - Risk reduction efforts

Select high-quality trials, deliver in time and within budget

- **Symposia, sponsor workshops**
- **Trial selection and improvement process**
 - Multiple review cycles (panel, trials board)
- **Activity-based costing and payment**
 - Publicly available tool. *Trials*. 2019, 20(1):714
- **Feasibility by sponsor and funder**
 - Collaboration with CRO, advance payment
- **Microscopic monitoring of progress**
 - IT to monitor recruitment <https://trials.kce.be/dashboard/>

Working with knowledge to boost good health for all

All subsidy options

ZonMw programmes and funds research and innovation in health, healthcare and well-being, encourages the use of this knowledge and highlights knowledge needs.

Independent government body

ZorgOnderzoek Nederland (Care Research Netherlands, Dutch abbreviation: ZON) was established by law in 1998 ([ZON Act](#)). Since 2001, there has been a partnership between ZON and the Medical Sciences (Dutch abbreviation: MW) domain of the Dutch Research Council (NWO). This partnership is called ZonMw and constitutes an independent self-governing organisation.

Kenmerken

Status: In uitvoering

Budget: € 91.000.000

Looptijd: 93%



Kenmerken

Status: In uitvoering

Budget: € 48.700.000

Looptijd: 42%



Home > Financiering vinden > Programma's > Goed Gebruik Geneesmiddelen

Goed Gebruik Geneesmiddelen

Home > Financiering vinden > Programma's > DoelmatigheidsOnderzoek

DoelmatigheidsOnderzoek

Signed November 2017

Aims of the BeNeFIT programme



Christian Léonard (KCE) and Martijntje Bakker (ZonMw)

- 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.

Proposals in scope

- Comparative effectiveness trials with potential for return on investment.
- Interventions are already used in daily practice in both countries.
- Non-commercial aim.

Not in scope

- Implementation research
- Drugs without MA, devices without CE label
- Studies already started
- Interventions not eligible for reimbursement in both countries

- **A common management team**
 - Call Steering Committee (CSC): ZonMw + KCE

- **A common portal for applicants**
 - One secretariat (ZonMw)

- **A common team of investigators (BE + NL)**
 - Sponsor – Coordinating Centre in the other country

- **A common selection process**
 - Three (→ two) rounds

- **A common Scientific Evaluation Committee (SEC)**
 - 20 experts and 4 patients, 50% BE - 50% NL
 - 2 or 3 meetings, score for relevance and scientific quality
 - Chair NIHR

	ZonMw	KCE	BeNeFIT
Program/Call types	Rational Pharmacotherapy + Healthcare efficiency	Broad comparative effectiveness Repurposing	Rational Pharmacotherapy + Healthcare efficiency
Secretariat tool	In-house → AIMS	SmartSimple	In-house → AIMS (ZonMw)
Management	ZonMw Board	Prioritisation Group	Call Steering Committee
Selection	Scientific Evaluation Committee, 2 step	Panel + Trials Board, 2-5 steps	SEC BE+NL, 3 steps → 2 step, NIHR chair
Appeal procedure	Yes	Council of state	No common appeal
Budget calculation Advance payments	PhD FTEs No	Activity-based tool Protocol+feasibility	Activity-based tool Protocol+feasibility
Feasibility with CRO	No	Yes	Yes, in both countries
Payment schedule	6 Monthly, no border crossing	Milestone-based, can cross border	Milestone-based, no border crossing
Terms and conditions; funders rights on data and IP use and licensing (non-exclusive)	Grant letter referring to (BeNeFIT) terms and conditions	Agreement containing the (BeNeFIT) terms and conditions	Grant letter (NL) and Agreement (BE)

Challenges and Opportunities

- Discuss and agree on terms and conditions of funding contract or grant with legal experts of all university hospitals
- Grant management system
- Differences between healthcare in BE and NL, sometimes restricting pragmatic trials
- Differences in approach KCE and ZonMw
 - Meeting applicants, feasibility, appeal, budget, COI
 - Yearly budget at KCE, budget per call at ZonMw
 - Protocol improvement efforts
 - Intensity of follow-up during trial

Additional country-specific criteria

Belgium

- In Belgium, the sponsor or the national coordinating centre should qualify as non-commercial sponsor under the applicable laws, including the Belgian law related to experiments on human people (May 7th, 2004).
- Participating centres should include at least one centre from the Flemish and the French speaking part of the country.^{\$}
- The funding granted under the research agreement complies with the European state aid regulations.

The Netherlands

- In the Netherlands, the sponsor or the national coordinating centre must be a research organisation or care institution^P.
- At least one of the participating institutions in the Netherlands should be a non-academic hospital.^{\$}
- Studied interventions should be (or have the potential of being) reimbursed under the “Basic Health Care” Act and/or the “Long Term Care” Act packages (“basispakket Zorgverzekeringswet” and “Wet langdurige zorg”) in The Netherlands.
- Studies should fall within the scope of the “Efficiency Studies” (DoelmatigheidsOnderzoek) program or the “Rational Pharmacotherapy” (Goed Gebruik Geneesmiddelen) program of ZonMw For detailed information please consult the website of ZonMw

^P Definition (OOI kaderregeling): *Onderzoeksorganisatie en zorginstelling* (artikel 5, lid 1, [wet toelating zorginstellingen](#))

^{\$}*If not possible, please justify*

3 calls in 6 years (9€M/call)

