



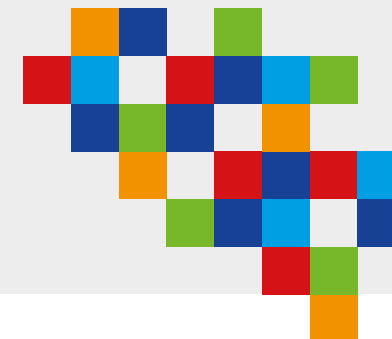
Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

ANNUAL REPORT

2023



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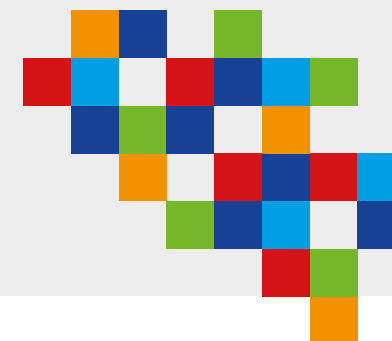
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FOREWORD



In 2023, KCE celebrated its 20th anniversary. When our institution was first created, the Rekenhof/Cour des Comptes voiced concerns that the work of the various federal research institutions involved in public health might end up overlapping. Today, efforts to co-construct a real public health research network have allowed KCE to reach full maturity.

It is with both pride and a great deal of humility that we celebrate this “20 years” milestone. Pride in the work accomplished since 2003, with almost 400 published reports and more than 50 funded clinical trials. Humility, because the breakthroughs to which we have contributed always depend not just on us, but also on the context, and on numerous other stakeholders and collaborations.

Twenty years after our first national recommendations on prenatal care, while the health insurance institute is helping the federated entities organise integrated care around perinatal monitoring (during the first 1000 days of life), we publish a detailed report on “referral

rules” between primary (GP/midwife) and secondary care (gynaecologist).

HSR (Health Service Research) topics account for 60% of our publications (excluding KCE Trials), probably because we are virtually the only organisation to publish scientific reports in this specific field. And these reports are often the talk of the town! This year’s study on breast cancer clinics, in particular, caused quite a stir among the federated entities and hospitals concerned.

In 2023, in collaboration with RIZIV/INAMI, Sciensano and the FOD/SPF, we also extended the scope of the conceptual framework for assessing the performance of the Belgian healthcare system. Two cross-cutting dimensions have been added to the model: resilience and governance. The results for the 142 indicators derived from this new model were published shortly after, in January 2024.

In the field of HTA, where are we now regarding the reimbursement of digital technologies in healthcare

– an absolutely crucial topic in a context defined, among other things, by a hitherto unknown boom of generative AI? Report 362 will hopefully serve as a useful basis for assessing these technologies.

With almost 30,000 patients enrolled, two-thirds of Belgian hospitals involved and 632 participating GPs, KCE Trials too can be proud of the work it has accomplished. I would particularly like to thank the intensive care teams in the 16 hospitals participating in the CONFIDENT study, which confirmed that passive immunotherapy (administration of convalescent plasma) has its place in the management of some infectious diseases (COVID-19 in this specific case).

You will find all this and much more about our 2023 achievements in the following pages, which I hope you will find an instructive and enjoyable read!

Pierre Gillet,
President of the KCE Board



WHAT IS KCE?

The Belgian Health Care Knowledge Centre (KCE) is an independent federal research centre which specialises in studying the organisation, financing and reimbursement of healthcare and the assessment of health technologies.

These studies are usually requested by public authorities, universities and professional associations, but all citizens, patients or patient organisations can submit a research proposal.

Each KCE study results in recommendations for the relevant authorities and healthcare stakeholders. However, KCE has no decision-making power, and the policy choices arising from the reports it publishes are not within its remit.

KCE also coordinates a non-commercial clinical trials programme (KCE Trials), has launched a separate study programme within the framework of the “Right to be Forgotten” law and participates in a number of projects in partnership with other federal and international stakeholders.

KCE is funded by the federal authorities (78% from the National Institute for Health and Disability Insurance/RIZIV-INAMI and 22% in total from the Federal Public Service for Public Health and the Federal Public Service for Social Security). In addition, some specific European subsidies cover KCE’s involvement in international research networks and projects. KCE’s status as a type B parastatal organisation guarantees its total independence from these funding authorities.

The acronym KCE
is a contraction
of the words

Kenniscentrum
and (Dutch)
Centre d’Expertise
(French)

OUR TEAM



The field of healthcare is very complex and there is no one scientific training that covers each and every aspect of it. This is why KCE has opted for a truly interdisciplinary approach. No research is conducted by a single researcher; instead, each research question can be examined from a medical, economic, social, legal and/or ethical perspective, depending on what is needed. This is greatly appreciated, both by the users of the study reports and by the researchers themselves.





THE EXPERTS

The KCE experts fall into five main categories:



Researchers with a **clinical or biomedical** background – physicians, nurses, physiotherapists, dentists, psychologists –, all of whom have acquired additional expertise (usually a PhD) in subjects such as public health, epidemiology, methodology for the development of guidelines, analysis and data management, clinical trials management, etc.



Researchers with a background in **health economics**. Thanks to their expertise, we are able to conduct very thorough economic assessments, including Health Technology Assessments (HTA). Their contribution is also essential for our studies on the organisation and financing of healthcare, an area in which KCE's expertise is increasingly in demand.



Researchers with a background in **human sciences**. Some of them conduct qualitative studies: they collect qualitative data (from field experts, patients, stakeholders, etc.) and ensure they are meticulously processed. Others enable us to address the possible legal or ethical aspects of the research questions submitted to us.



Data analysts, statisticians and specialists in scientific information. These researchers extract the information relevant to our research from international and Belgian data and figures. They also ensure that the data, which is sometimes very sensitive, is used in accordance with the privacy legislation, that all useful information is identified, and that the figures are interpreted correctly. This provides us with very accurate statistics to analyse.



Specialists in knowledge dissemination and management. The former adapt the language of our reports to the different target groups and ensure that the message reaches the appropriate audience. The latter help all our experts to maintain and develop their expertise and contribute to ensuring the quality of our work through the implementation of meticulous work procedures.

Some of these experts were or still are academically or clinically active, which ensures a better understanding of the field, while others have committed themselves to full-time research at KCE.





THE MANAGEMENT TEAM

KCE operates within a very horizontal, small-scale organisational structure in which working procedures are well organised and decisions are taken efficiently after deliberation.

The management team is composed of 3 people:

- Ann Van den Bruel as managing director since March 2024 (a post previously taken up ad interim by Marijke Eyssen);
- Christophe Janssens as deputy managing director;
- Irina Cleemput as scientific programme manager ad interim.



EFFECTIVE SUPPORT SERVICES

The researchers are supported by a range of talented, efficient support services (project management, ICT, webmaster, library, layout, secretariat, legal advice and human resources management, accountancy, etc.).

Together, they form an enthusiastic and united team of nearly 80 people, motivated by a common goal: to provide the studies needed to maintain and improve an effective, safe, accessible, sustainable and high-quality healthcare system.

Active staff members as of December 31, 2023

	FTE
Chairperson	0,20

Management	2,90
General management	2,00
Study programme management	0,90

Research team	51,20
Physicians, dentists, nurses, physiotherapists...	28,90
Health economists	8,20
Sociologists, legal experts	3,20
Data analysts, statisticians and specialists in scientific information	6,30
Project facilitators	1,60
Experts in knowledge management and dissemination	3,00

Support services	14,20
Secretariat and layout	6,90
ICT, webmaster and librarian	1,00
Legal advice and HR management	3,40
Budget and accountancy	2,00
EU presidency	0,90

TOTAL	68,50
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At the end of 2004, just over a year into its existence, the KCE team consisted of 25 FTEs:

- Management: 2 FTE
- Experts: 15 FTE
 - Doctors: 6.25 FTE
 - Economists: 4.1 FTE
 - Sociologists: 1.6 FTE
 - Data analysts: 2 FTE
 - Knowledge manager: 1 FTE
- Support services: 8 FTE

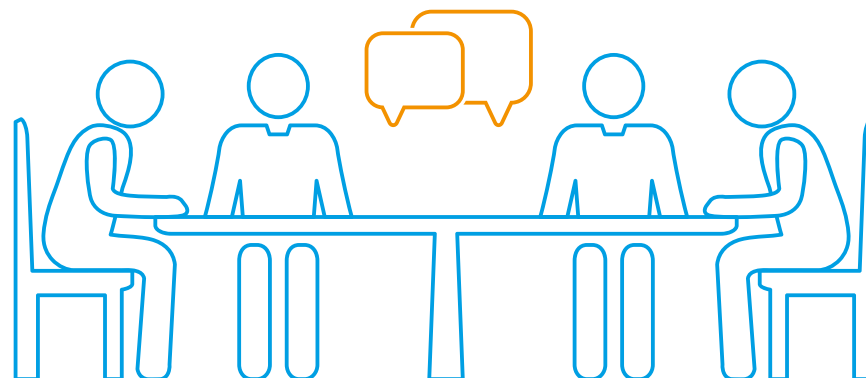
At the end of 2005, the team consisted of 35 people (31.5 FTE)... of which over half are still working at KCE!

OUR BOARD



Our Board brings together representatives of the public authorities and the most important stakeholders in healthcare, health insurance and patient associations, in a balanced distribution. It ensures our neutrality and guarantees our independence. Our latest reports are presented during Board meetings. The scientific content is normally not subject to modification, unless objective methodological arguments are put forward. The reports are approved by simple majority. KCE is legally obligated to publish all of its results within one month of their approval by the Board, which offers an additional guarantee of its independency and transparency.

The composition of our Board can be found [on our website](#) 



VISIBILITY



Website traffic in 2023



282,298
visitors



675,871
unique
page views



29,132
views of
our videos



2,887
followers
on X



7,123
subscribers
on LinkedIn



859
followers
on Facebook

We are also present on social media platforms [X](#), [LinkedIn](#) and [Facebook](#), which allows us to broaden our visibility and add immediate interactivity to our communication.

Our videos are available through our [YouTube channel](#).





2 THE 20TH ANNIVERSARY



KCE was officially founded in 2003, which means 2023 marked its 20th anniversary! To celebrate in style, a scientific symposium was organised in Brussels under the title **"Scientific recommendations in an evolving sector: what does the future hold?"** The day's programme included three high-profile presentations by international speakers, an interactive debate and, of course, a festive reception where some 550 current and former KCE staff, external partners and representatives of other government departments and organisations active in the healthcare sector came together to raise a glass to the health of the Knowledge Centre and to its next 20 years.

A brochure tracing KCE's footprint in the Belgian healthcare sector over its 20 years of existence (available in [French](#) or [Dutch](#)) was also produced for the occasion.



Yannis Natsis (European Social Insurance Platform) – ***The EU pharmaceutical revision and HTA: A revolution or much of the same?***

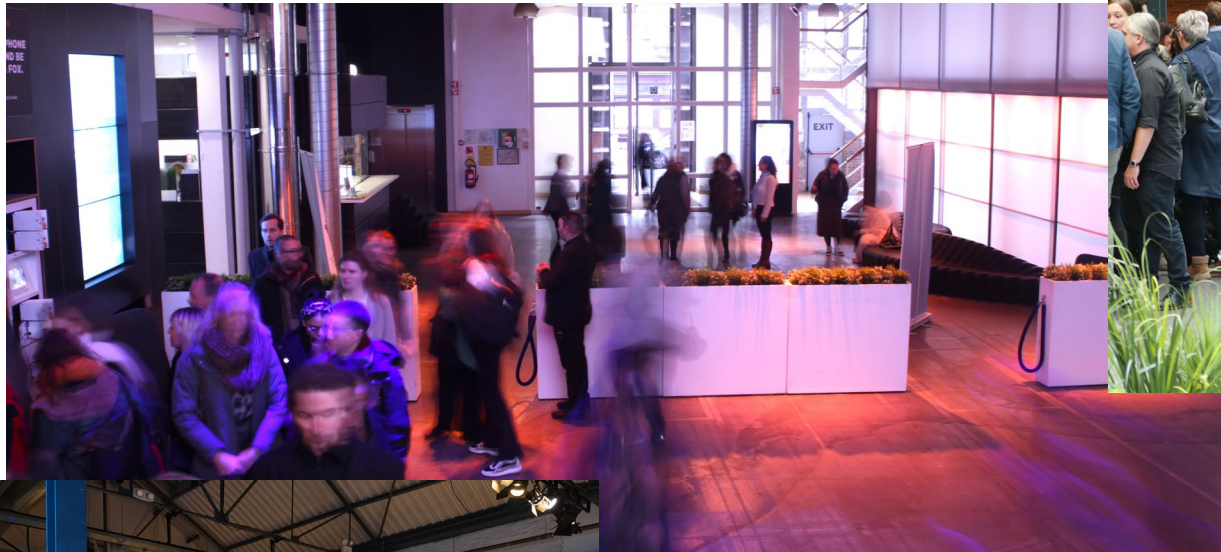


Interactive debate with Dirk Ramaekers (FPS Public Health), Marleen Finoulst (citizen/patient representative) and Benoît Collin (NIHDI), moderated by Bert Kruismans.

Reinhard Busse (Technische Universität Berlin & Co-Director, European Observatory on Health Systems and Policies) – ***Evidence-informed health policy-making: On everybody's agenda - but how far are we in reality?***



Tom Walley (University of Liverpool) – ***The importance of public funding for clinical trials: international perspectives***







3 WHAT DO WE DO?

The aim of the KCE studies is to guide the Belgian authorities as they prepare and implement health policies and make decisions on reimbursing new healthcare interventions. The studies provide a solid scientific basis for political decision-making, while ensuring that equitable, high quality healthcare remains accessible to all.

KCE researchers regularly collaborate with other key federal health and healthcare organisations, such as Sciensano, the *Hoge Gezondheidsraad/Conseil Supérieur de la Santé*, RIZIV/INAMI, the *FOD Volksgezondheid/SPF Santé publique*, the *Intermutualistisch Agentschap/Agence Intermutualiste*, the FAGG/AFMPS, the Belgian Cancer Registry, etc.

KCE is also involved in European and global expert networks and participates in numerous international projects.



The KCE research programmes

- Main research programme (HSR-HTA-GCP-Methods)
- KCE Trials programme
- “Right to be forgotten” programme
- Participation in the Belgian Evidence-Based Practice network (Evikey)
- Task force Therapeutics Viral Diseases
- International collaborations

MAIN RESEARCH PROGRAMME



Our main research programme encompasses 4 types of studies:

- **Health Services Research (HSR)** reports, which focus on the best way of organising and financing health services in order to guarantee quality and accessibility of healthcare, while maintaining their economic sustainability for patients and society.
- **Health Technology Assessment (HTA)** reports, which analyse the safety and efficacy of a medical technology (drug, implant, vaccine, surgical technique, etc.), usually along with a cost-effectiveness analysis if the technology is deemed safe and effective.
- **Good Clinical Practices (GCP)** reports (guidelines), which are tools designed to help clinicians treat their patients according to the best and most recent scientific knowledge, taking into account the local (Belgian) context and the daily reality of medical practice.
- **Methodological reports**, i.e. manuals intended mainly to support KCE's own research, which are also made available to all researchers in the healthcare and public health sectors.

In 2023, we published 10 HSR studies, 2 HTA studies, one GCP study and one methodological report.

In its first year of activity (2004), the KCE published 8 studies:

- Effectiveness and cost-effectiveness of treatments for smoking cessation (HTA)
- Potential cost of a modification of the legislation concerning medical liability (HSR)
- Antibiotics use in hospitals for acute pyelonephritis (GCP)
- Leukoreduction. A possible measure in the context of a national blood safety policy (HTA)
- Preoperative risk assessment (GCP)
- National recommendations for prenatal care. A base for a clinical pathway aimed at monitoring pregnancy (GCP)
- Validation of the Report of the Research Commission of Underfinancing of Hospitals (HSR)
- Financing of hospital drugs: a descriptive study of several European countries and Canada (HSR)

HSR reports published in 2023



Referral during low-risk pregnancy follow-up in primary care (KCE Report 363)

Uncomplicated pregnancies can be followed by a gynaecologist only, or by a primary care provider (midwife or GP) and a gynaecologist. In the latter case, it is important to set ground rules to identify situations where the gynaecologist's expertise is required to ensure the safety of mother and child. In consultation with professionals in the field, KCE has drawn up a document to support the development of such "referral rules" for 188 clinical or psychosocial situations which might entail a certain degree of risk. However, a prerequisite for the use of such rules is that gynaecologists and midwives can establish solid collaboration. Hence, KCE researchers also considered the conditions that need to be met for balanced partnerships between both professions.



Prevention of post-intensive care syndrome (PICS) (KCE Report 364)

Post-intensive care syndrome is a relatively recent entity that is attracting growing interest among physicians. It can manifest through intense and persistent muscle weakness, cognitive problems (memory, attention, etc.) or psychological problems (anxiety, depression, post-traumatic stress), affecting up to 40% of patients requiring a prolonged stay in an intensive care unit. The preventive measures described in the scientific literature sometimes involve a fundamental rethink of practices and habits within intensive care units, but also require additional staff. KCE has reviewed these measures to retain only those whose effectiveness has been proven.





Survival and Quality of care offered in Belgian hospitals with and without recognition for breast cancer (KCE Report 365)

In 2018, one in five women with breast cancer was treated in a hospital with no specific accreditation for the treatment of this type of tumour, and this is far from harmless. According to this new KCE study carried out in 50,000 breast cancer patients, these women have a significantly higher risk of dying from their disease than those treated in a “coordinating” breast clinic. Therefore, KCE called for a reorganisation of breast cancer care, with a healthy balance between quality on the one hand and regional availability and accessibility on the other. Accredited centres have to be clearly identifiable for patients, GPs and other healthcare providers, to ensure that the 10,000 patients diagnosed with breast cancer every year receive quality care from an experienced multidisciplinary team.



General practitioner remuneration: overview of selected countries with a mixed system of fee-for-service and lump-sum payments (KCE Report 366)

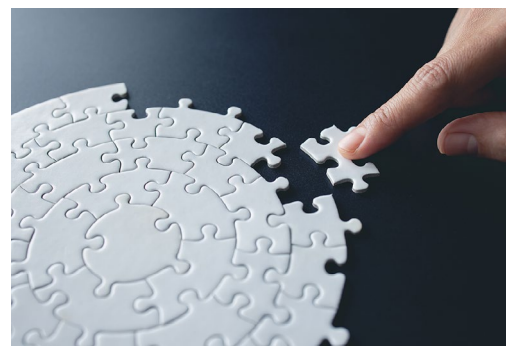
In June 2022, a “New Deal for the General Practitioner (Practice)” was launched, aiming to set up a new organisational and financing model which would allow for better support and organisation of GP practices, while also encouraging task sharing, cooperation and digitalisation. KCE was asked to identify countries that could serve as interesting examples for the development of a mixed fee-for-service and lump-sum payment system in Belgium, and to describe their remuneration system.





Palliative care - an exploratory study of categorisation tools based on patients' needs and their value for entitlement
(KCE Report 367)

The palliative phase of a serious illness - the more or less lengthy period preceding a foreseeable death - is often accompanied by significant assistance and care needs that are prone to rapid change. In hospitals and nursing homes, a significant share of the cost of end-of-life care and support is included in the establishment's normal funding. Patients who choose to die at home, on the other hand, will often have to cover substantial costs themselves. While financial support is available for palliative patients in our country, it is not always deemed sufficient, and can only be claimed at the terminal stage. KCE has been looking at ways of tailoring financial support to the individual needs of palliative patients... but has unfortunately not been able to identify an ideal solution.



Performance of the Belgian health system: Revision of the conceptual framework and indicators set
(KCE Report 370)

Since 2010, the performance of the Belgian healthcare system undergoes comprehensive check-ups on a regular basis. In preparation for the new assessment (2024), KCE researchers have carried out an in-depth review of the underlying conceptual framework. The new framework relies on six dimensions and four specific domains, with a total of 142 indicators providing a very comprehensive picture of the strengths and weaknesses of our healthcare system. It has also been enriched with a new dimension, resilience (the system's ability to bounce back after a disruption), which will be analysed in the light of the COVID-19 pandemic.





Developing a set of quality indicators to monitor the quality of care delivered by paediatric multidisciplinary obesity centres (PMOC) (KCE Report 372)

As part of the new measures put in place for the management of obesity in children and adolescents, (a maximum of) 25 paediatric multidisciplinary obesity centres are being set up in Belgium to offer these young patients specialised multidisciplinary care. At the request of RIZIV/INAMI, KCE has developed a series of indicators to measure the quality of care provided in these centres.



Nursing consultations for patients with complex health conditions (KCE Report 373)

Consultations are often spontaneously associated with doctors, but nurses too are increasingly called upon to provide certain types of consultation, particularly in complex situations where the patient needs closer monitoring or support. Is this a good idea? Based on the experience of other countries where this approach is already more developed and formalised, it certainly seems to work. KCE recommends pursuing the development of similar initiatives in Belgium but stresses those will require clear agreements between professionals, both nationally and at a local level. Legislative changes will probably be required to ensure that overly restrictive rules do not limit nurses in the activities that fall within the scope of their consultations, while ensuring that the right skills are available in the right place.



Organisation of medical care in CBRNE incidents: a guidance (KCE Report 374)

CBRNe incidents are emergency situations characterised by the release of chemical (C) or biological (B) substances or by radiological/nuclear (RN) contamination, sometimes caused by an explosion (e) (e.g. an accident in a chemical plant, a nuclear disaster, a terrorist attack, etc.). KCE was asked to suggest improvements for the organisation of medical aid in this type of situation. It recommends transferring all seriously injured victims to specialist hospitals with sufficient CBRNe expertise, while those with milder injuries can be cared for in other hospitals. At the scene of the incident, the priority is to decontaminate as quickly as possible and provide medical assistance. Achieving this will require reinforcing specialist medical expertise (and its rapid deployment) on-site.



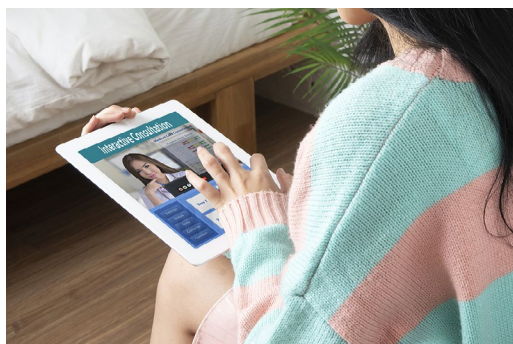
A quality standard and quality indicators for symptomatic knee osteoarthritis care (KCE Report 375)

To improve the quality of knee osteoarthritis care in Belgium, the KCE has developed a quality standard and a series of quality indicators - a first in the field of orthopaedics. However, this project is only the first step. In Belgium, healthcare policy and quality assessment are primarily the responsibility of the federated entities. This report is therefore primarily aimed at Belgian quality institutes and care providers involved in the management of knee osteoarthritis.





HTA reports published in 2023



Evaluation of Digital Medical Technologies (KCE Report 362)

Digital medical technologies have become an integral part of healthcare, which obviously raises the question of their reimbursement by the health insurance system. How can we identify those that are useful enough to warrant reimbursement? At the request of RIZIV/INAMI, KCE has analysed how these technologies are assessed in other European countries and interviewed Belgian stakeholders in order to outline a clear and transparent national assessment procedure. Assessment criteria and requirements vary widely between countries, but attempts to harmonise them are currently underway at EU-level. Finally, data protection must remain a key concern, for which efforts are still required in Belgium.



Silicone adhesive multilayer foam dressings to prevent hospital-acquired pressure ulcers: a Belgian RCT-based economic evaluation (KCE Report 368)

Multilayer silicone dressings have been used for some years to treat pressure sores, a frequent complication of prolonged bed rest or immobilisation. However, their effectiveness to prevent – and not just treat – these pressure sores has been established only recently, thanks to a clinical trial funded by the KCE Trials programme. The HTA report now shows that this preventive use is not only effective, but also cost-effective.



GCP reports published in 2023



Diagnosis and management of gonorrhoea and syphilis (KCE Reports 371)

In 2019, KCE published recommendations for the diagnosis and treatment of gonorrhoea and syphilis. Given the increasing resistance of gonococci to azithromycin, the antibiotic recommended at the time in combination with ceftriaxone for the management of this infection, an update had become necessary.

M methodological report published in 2023



Transversal Budget Impact Analysis (KCE Report 369)

For an implant or invasive medical device to be reimbursed by the health insurance, its producer must submit an application. As part of this procedure, they must estimate the impact reimbursement would have on the budget of all healthcare payers by means of a budget impact analysis. At the request of the RIZIV, KCE has examined how real-life data from Belgian national databases can be used in such analyses. It seems that these real-life data contain extremely valuable information, but they are also frequently incomplete or even completely lacking. They must therefore be treated with all due caution. In addition, other types of study are still required to determine the effect of treatment.



THE KCE TRIALS PROGRAMME



KCE Trials is a programme for non-commercial clinical trials funded by the Belgian federal authorities. These clinical trials address issues that are usually neglected by industry despite their high societal relevance, such as comparing treatment options (e.g. two surgical techniques) or studying the effect of existing drugs on populations that are rarely considered in commercial studies, such as children or the elderly. KCE Trials funds practice-oriented and multicentre comparative effectiveness studies.



The KCE clinical trials are

- **non-commercial**
- **practice-oriented and focused on current standards of care:** unlike commercial trials, these involve patients treated under real-life conditions (in hospitals, in the community, in nursing homes, etc.)
- **comparative:** they compare the efficacy of treatments which have previously been used but which have never been directly compared to one another
- potentially able to **improve patient care** and/or lead to **cost savings for health insurance**
- **not limited to drugs or medical devices:** they may also involve lifestyle changes, psychotherapies, diagnostic tests, surgical interventions, etc.
- guaranteed to generate **databases that are made available for public interest research**, e.g. to conduct detailed and independent cost-effectiveness studies



KCE Trials is responsible for the **selection** and **funding** of clinical trials, but it **does not conduct the trials itself**.

Hospitals, universities and non-commercial research institutions take on the sponsorship and coordination responsibilities.



More info
<https://kce.fgov.be/en/kce-trials>

2023 in numbers



2
calls for
studies



3
contracts
with Belgian
research
teams



35
studies
on-going

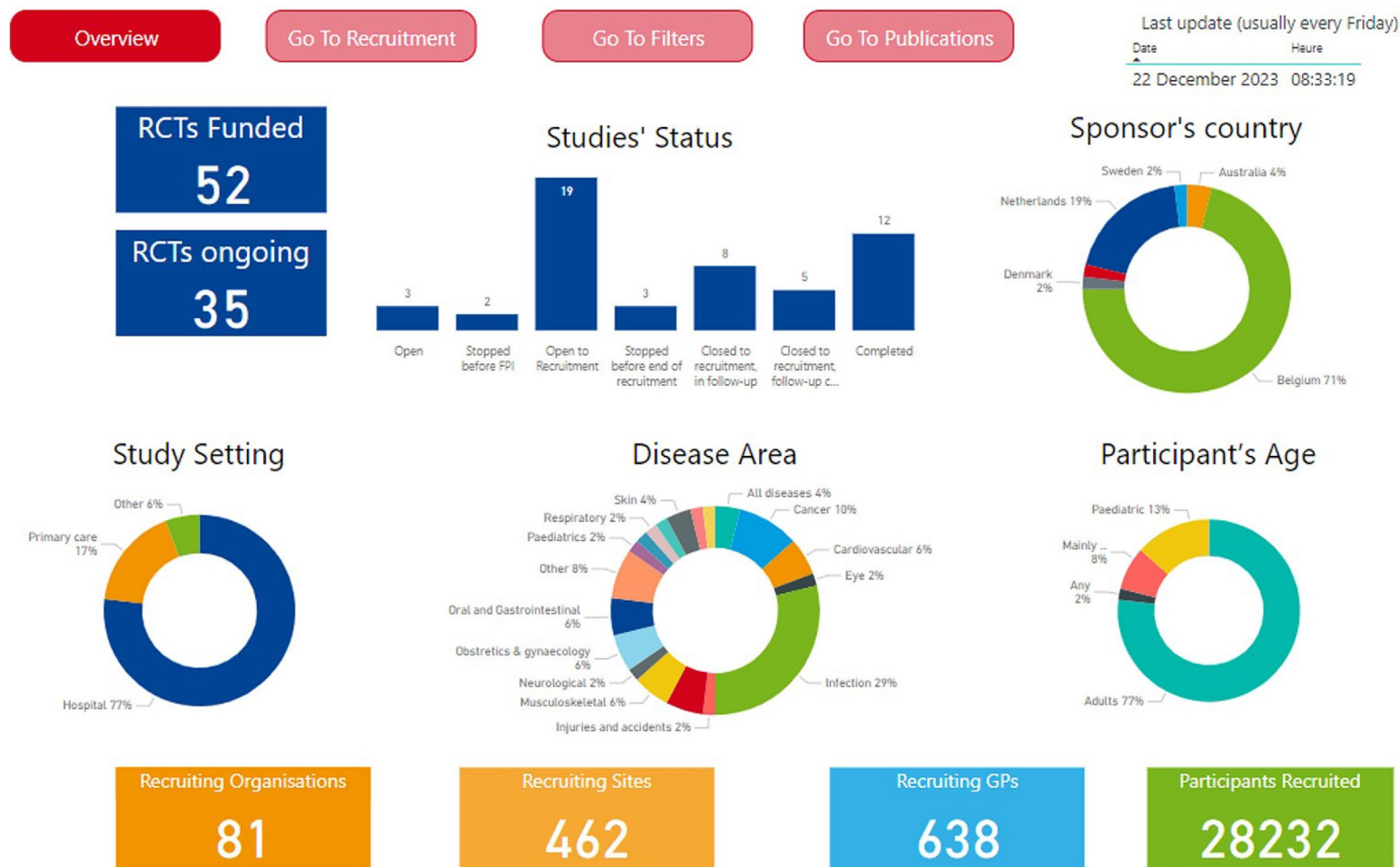


18
scientific
articles
published

The [KCE Trials dynamic dashboard](#) displays the recruitment status of the studies underway in Belgian hospitals and in other settings (general practice, mental health centres, etc.).

This dashboard is updated every Friday, based on the data entered into SmartSimpleBelgium by the study's project managers. It also includes the results of previously published studies.

KCE TRIALS DYNAMIC DASHBOARD



As of December 2023, the KCE Trials programme included...



68
participating
hospitals



638
participating
GPs



28,232
recruited
patients



2
million €
average budget
per trial



In 2023...



3 new contracts were signed

PEPPER - Primary carE PPI dEprescRibing

Proton pump inhibitors (PPIs) are very effective to relieve symptoms of acid reflux for a well-identified group of diseases and conditions by reducing excessive acid secretion. However, their use has increased considerably over the years, fuelling concerns regarding adverse effects and costs associated with improper use. Guidelines recommend reducing chronic use of PPIs, but with little success so far, partly because acid secretion increases and symptoms tend to flare up for a couple of weeks after the treatment is stopped (rebound effect).

This open-label randomized trial will assess two different strategies (a period of on-demand use before stopping, and the use of other medications) to overcome this period of increased secretion when trying to interrupt chronic PPI therapy, and compare them to the current standard approach of stopping after gradually decreasing intake. It will be conducted in 609 patients from primary care practices with chronic PPI intake outside of the established disease indications.



Total budget is €1.96 Mio.



COL BE PCI - Colchicine after PCI

Coronary artery disease (CAD) clinically presents as myocardial infarction or stable angina, both of which are typically treated with percutaneous coronary interventions (PCI) on top of optimal medical therapy. Even with the best standards of care, the rate of recurrent cardiovascular events after a PCI remains high. Colchicine is a well-known, safe and well tolerated anti-inflammatory medication, which has recently yielded promising results for the prevention of such recurrent cardiovascular problems in patients with CAD. It is also off-patent and very cheap

COL BE PCI is a randomized, double-blind, placebo-controlled multicentre trial in Belgium comparing low doses of oral colchicine versus placebo in 2770 patients with CAD treated with PCI. It aims to show a 25% reduction in new heart problems after PCI. If this hypothesis is confirmed, colchicine might bring substantial benefits both for patients and for the healthcare system.



Total budget is €5.37 Mio.

SHAPERS - Short-course radiotherapy vs total neoadjuvant therapy in older patients with locally advanced rectal cancer

The management of locally advanced rectal cancer has improved over time, but a significant number of patients still succumb to the disease. To enhance survival rates, intensive preoperative treatments combining radiotherapy and chemotherapy have become common practice. However, the trade-off between efficacy and potential side effects remains a concern, especially for older patients who are more sensitive to toxicities and, due to their shorter life expectancy, less likely to benefit from the relatively small survival advantage.

The SHAPERS trial aims to demonstrate that less intensive strategies like radiotherapy alone offer a better trade-off between efficacy and toxicity than total neoadjuvant therapy in rectal cancer patients aged ≥ 70 . It has the potential to establish optimal care in this setting and to provide comprehensive evidence to inform decision-making, ultimately improving overall patient experience during treatment as well as survivorship.

SHAPERS aims to recruit 230 older patients (≥ 70 years old) with high-risk stage II-III rectal cancer, who will be randomized in 20 participating centres.



Total budget is €2.26 Mio.



Results were published for 2 clinical trials



CONFIDENT - CONvalescent plasma therapy in patients with invasive COVID-19 and acute respiratory failure treated with mechanical ventilation

The CONFIDENT trial aimed to determine whether it would be worthwhile administering plasma from blood donors who were recovering from COVID-19 to patients suffering from the most severe form of the disease. The hypothesis was that this might reduce the symptoms, viral load and high mortality of ventilated patients suffering from respiratory distress due to COVID-19.

A total of 475 patients were recruited in 16 Belgian hospitals and randomly assigned to receive either convalescent plasma or usual care. The primary outcome was a mortality rate of 35.4% in patients treated with convalescent plasma vs 45.0% in the control group receiving a conventional treatment 28 days after study inclusion. This effect was observed mainly in patients who were included early (less than 48 hours) after the start of mechanical ventilation. Convalescent plasma caused no adverse effects. These results confirm that passive immunotherapy has its place in the management of certain infectious diseases.



[Link](#) to published results

SAFEBOOSC III - Treatment based on near-infrared spectroscopy monitoring versus treatment as usual in premature infants (international study)

The care of extremely preterm infants (EPI) increasingly involves monitoring of oxygen levels in the brain through cerebral oximetry, as time spent outside normal cerebral oxygenation ranges is associated with poor neurological outcome. However, there is currently no evidence that this approach improves clinical outcomes. The objective of SafeBoosC-III was to investigate the benefits and harms of measuring oxygen levels in the brain based on near-infrared spectroscopy (NIRS) monitoring for the first 72 hours after birth, compared with treatment as usual.

A total of 108 infants (out of 1601 internationally) were recruited in 6 Belgian hospitals. At 36 weeks postmenstrual age, there was no difference in death or severe brain injury rates between both groups, which amounted to 35.2% in the cerebral oximetry group and 34.0% in the usual-care group. The incidence of serious adverse events did not differ between both groups.



[Link](#) to published results



Two other studies had to be terminated before completion and published results of their qualitative analysis



DAWN antivirals - Antivirals for ambulatory COVID-19 patients

The DAWN antivirals study investigated the effectiveness of the antiviral drugs camostat and molnupiravir for treating symptomatic COVID-19 patients aged 40 or older in a primary care setting.

The trial was stopped prematurely after failing to reach the target sample size of 474 (ultimately, only 44 patients were recruited), but a process evaluation was performed to capture lessons learnt and improve future national trial set-ups in general practice. Most difficulties were found to be related to the pandemic itself (disruption to routine clinical services, multiple changes to the service model for COVID-19 patients, overwhelmed clinical staff, delays of trial medication, and staff shortages). However, other hurdles such as a small and inexperienced sponsor and clinical teams, delays in regulatory processes, and research capacity in routine settings could be overcome by established research infrastructure and standardisation of processes.



[Link](#) to published results

PELICAN - Topical treatment versus systemic treatment in localised neuropathic pain

Neuropathic pain, caused by lesions within the somatosensory nervous system, has a considerable impact on patients' quality of life and is associated with a high economic burden. The PELICAN trial aimed to compare the effectiveness of topical interventions to that of the current oral standard of care in patients with localised neuropathic pain (LNP), recruited in multidisciplinary pain centres.

The comparative trial was stopped due to lasting recruitment problems (recruitment in 16 centres yielded a total of 32 patients, while the initial target sample was 591), and qualitative research (survey and in-depth interviews) was performed subsequently to identify and assess reasons for recruitment failure. These include issues with referral, a lack of specific expertise on LNP in some centres, scarcity of staff, limited reimbursement to administer complex analgesic schemes, overestimation of the patient population, and the reluctance of patients to participate in pain research. Some shortcomings in the study design and a need for more logistical investments were also identified.



[Link](#) to published results





BeNeFIT

KCE co-finances certain trials with its Dutch counterpart [ZonMw](#) as part of a joint call called **BeNeFIT (Belgium-Netherlands Funding of International Trials)**.

As numerous issues relating to healthcare are relevant for both countries; developing joint selection processes and exchanging best practices between researchers helps to strengthen the expertise of both teams and obtain results more quickly. BeNeFIT currently includes 15 studies resulting from an initial call launched in 2018 and subsequent calls launched in 2020 (BeNeFIT-2) and late 2022 (BeNeFIT-3).

"RIGHT TO BE FORGOTTEN" PROGRAMME



People who have had cancer in the past or who are suffering from a chronic condition are viewed as having an "increased health risk". As a result, they might be faced with serious challenges to obtain outstanding balance insurance and mortgage loans, which makes it harder for them to become property owners. The same holds true for guaranteed income policies.

In 2019, Belgium introduced a "right to be forgotten" for this type of insurance. People who have been declared free of cancer for at least 8 years can now take out an outstanding balance insurance with no additional premium due to their medical history. The new law also reduces this 8-year waiting period for certain types of cancer, limits the possibility of a refusal and lowers the additional premium ceiling for other cancers or chronic diseases. KCE is responsible for reassessing the list of these conditions every other year in accordance with the medical advances in these areas and the relevant scientific data available at that point in time.

Early in 2022, KCE published a first report within this new programme, with new suggestions for some types of breast cancer. A second study, on diabetes type 1, was published in 2024.



More information on our [website](#).



PARTICIPATION IN THE BELGIAN EVIDENCE-BASED PRACTICE (EBP) NETWORK



The **Belgian EBP network** (known as **Evikey** since 2022) coordinates various partners involved in EBP at the federal level in Belgium, makes all primary care guidelines and other evidence-based materials available to care providers via a single online portal (www.evikey.be) and provides access to a digital library (CDLH).



KCE is responsible for coordinating the Belgian EBP network's prioritisation unit. The role of this unit is to define and implement the selection procedure for prioritising the activities to be undertaken.

A comprehensive call for project proposals was launched in the spring of 2023. Twenty-two projects were submitted, of which the following four were ultimately retained:

- Implementation of the Belgian guideline "Depression in adults" in general practice, with a specific focus on phasing out antidepressants;
- Development of a multidisciplinary guideline & implementation plan regarding the treatment of irritable bowel syndrome;
- Implementation of the guideline "Asthma in adults", with a focus on the proper use of asthma medication;
- Implementation of the guideline "Occupational therapy for maintaining functionality and social participation of physically frail older persons living at home".



TASK FORCE THERAPEUTICS VIRAL DISEASES



Since December 2021, KCE has coordinated the federal Task Force **Therapeutics Viral Diseases**. Initially dedicated to the scientific analysis of drugs for treating COVID-19 (hence its original name of COVID Therapeutics Task Force), the Task Force has gradually expanded its scope to include treatments against other viral diseases that may constitute an epidemic threat, such as mpox, influenza, or haemorrhagic fevers (e.g. Lassa fever or Ebola viral disease).

The Task Force's missions include assessing the safety, efficacy and cost-effectiveness of these treatments, but also determining whether it is appropriate to stockpile them. For treatments which are not yet in the usual distribution circuit, the Task Force has also developed procedures for issuing them out of the Federal Strategic Stock through hospital or community pharmacies.

The Task Force includes roughly fifteen Belgian experts – academics, clinicians and experts from federal agencies – and half a dozen KCE experts (you will find the current composition of the Task Force [here](#)).

Since its creation, the Task Force has published 20 scientific advices : 13 on [new drugs used for treating COVID-19](#), two on tecovirimat against [mpox](#), and five on treatments against [other viral epidemic threats](#).

In addition, the Task Force coordinated the work around the development of a guidance document [to inform general practitioners](#) on the drugs available to treat COVID-19 and their use. The Task Force was also involved in drafting and updating a [similar document aimed at hospital doctors](#).



TASK FORCE THERAPEUTICS VIRAL DISEASES





INTERNATIONAL COLLABORATIONS

KCE is involved in European and global expert networks. With its reputation for scientific rigour, it receives numerous collaboration requests from international working groups.



International networks

KCE is an active member of several international networks, such as:

- The **European Health Technology Assessment Coordination Group** (HTACG) was established by the European HTA Regulation 2021/2282 ([EU HTA Regulation](#)). It coordinates and adopts the joint work carried out by its subgroups and adopts methodological and procedural guidance documents for joint work. There are four subgroups: the subgroup for joint clinical assessments, the subgroup for joint scientific consultations, the subgroup for the identification of emerging health technologies and the subgroup for the development of methodological and procedural guidance. KCE is member of the latter subgroup, NIHDI of all the others, as the work falls within their specific remit. KCE and NIHDI both represent Belgium in the HTACG.





- **INAHTA** (*International Network for Health Technology Assessment*) offers its members a forum to identify common interests in the field of health technology assessment. INAHTA publishes the international [HTA database](#) of projects and reports and collaborates on the [HTA Glossary](#) project.



- **IHSI** (International Horizon Scanning Initiative) is an international organisation that gathers information on treatments which will reach the market in the next two years and could have a significant impact, both clinically and financially. This data allows political leaders to anticipate the arrival of these new products and prepare their policies accordingly. This information can also be useful during price negotiations with the pharmaceutical industry. KCE is represented in its *Steering Group* (and, in 2024, also in its *Quality Management Group*).



- **Beneluxa Initiative on Pharmaceutical Policy** is an association of HTA agencies in Benelux, Austria and Ireland. Its aim is to facilitate access to quality pharmaceutical treatments at reasonable prices for patients in those countries. To that end, its members share information, expertise and best practices, and jointly negotiate the prices of new products entering their respective markets (resulting in greater price transparency).



- **GIN (Guidelines International Network)** is an international network of organisations and experts involved in the development of clinical practice guidelines. The aim of GIN is to contribute to improving the quality of care by promoting the systematic development of guidelines and their implementation on an international scale.



- **HTAi** is the global scientific and professional organisation for health technology assessment. It is a neutral forum which brings together researchers, research agencies, policy makers, industry representatives, academics, healthcare providers, patient and consumer representatives and other stakeholders from 65 countries and 5 continents. HTAi organises an annual international scientific conference and collaborates on the HTA Glossary project. KCE staff members participate in working groups (e.g. the Patient and Citizen Involvement Group) and training courses.





Current European projects



- KCE takes part in various projects relating to the **EU clinical research response to pandemic threats**:
 - A KCE expert participates as HTA expert in the **EU Joint Access Advisory Mechanism (JAAM)**, which provides an independent scientific assessment of new intervention arms of EU platform trials. It also provides coordination between the various EU platform trials regarding the uptake of new interventions, together with the extended Trial Coordination Board (TCB), which was initially established to facilitate coordination of Adaptive Platform Trials for COVID 19 therapies in Europe. Both are now integrated in the **EU CoMeCT** (*Coordination Mechanism of Cohorts and Trials*), which continues to review possible candidate treatments for use in the EU platform trials and currently advises the newly formed Subgroup of the HERA Board on such matters.
 - In the aftermath of the COVID-19 pandemic, the European Commission created a new General Direction for enhancing the Health Emergency Preparedness and Response (**HERA**). A KCE expert is member of the HERA Advisory Forum. This forum discusses a broad range of subjects relating to the assessment of health threat priorities and the identification of relevant Medical Counter Measures (MCM), from ongoing preparedness initiatives by Member States to epidemiological intelligence and challenges in supply chains. Its opinions, recommendations and reports are adopted by consensus and presented to the HERA Board.
 - A KCE expert was appointed as one of the two representatives for Belgium in the **Subgroup of the HERA Board that coordinates the clinical research response to future pandemic threats at EU level**. This subgroup has three roles: the prioritization of medicinal products for use in clinical trials, the set-up and maintenance of warm-based clinical trials and cohorts and the funding of these trials and cohorts (EU in collaboration with member states).



- The KCE is the Belgian representative for the WHO's [European Observatory on Health Systems and Policies](#). This body supports evidence-based health policies by producing extensive and rigorous analyses of the dynamics of healthcare systems in Europe, such as the [HiT \(Health systems in Transition\)](#) country reports which are detailed descriptions of each health system. KCE has been responsible for updating the report on the health system in Belgium via [The health systems and policy monitor: Belgium](#) since 2010 and the platform summarising the measures taken by Belgium to deal with the COVID-19 crisis via the [COVID-19 Health System Response Monitor: Belgium](#) since 2020.



- **IHSI - unmet health-related needs assessment** is a project which emerged from the need of the International Horizon Scanning Initiative to improve the assessment of unmet health-related needs in the data-base of emerging health technologies. KCE was invited to share knowledge and expertise from the NEED project and collaborate to develop a feasible and appropriate needs-assessment framework for IHSI.

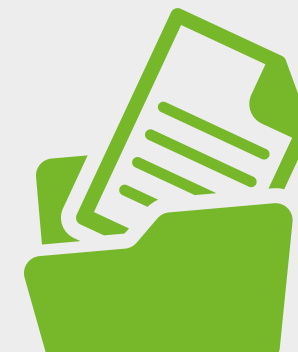


- A KCE expert is a member of the policy board of the EU project **REMEDI4ALL**, discussing funding, regulatory, and reimbursement issues on drug repurposing.



4 HOW DO WE WORK?

SETTING UP OUR STUDY PROGRAMMES



KCE establishes its study programmes on the basis of widely publicised calls for topics. The collected proposals are then subjected to strictly codified selection procedures.



Call for the KCE annual study programme

Every year before summer, KCE launches a call for study proposals for the work programme of the following year. Any citizen, organisation, institution or policymaker can submit a study proposal.

The transparent selection procedure is [explained in detail on the KCE website](#).

If you would like to be informed of our next calls for projects, please register on the website via the '[Receive news](#)' section.



Call for the KCE Trials programme

The KCE Trials programme also requests input from clinicians, patients and others. There is no fixed schedule for these calls, though there is typically one every year.

To be notified of calls and other news from KCE Trials, subscribe to KCE's Trials [mailing list](#).

You can find more information on the calls for clinical trials [here](#).

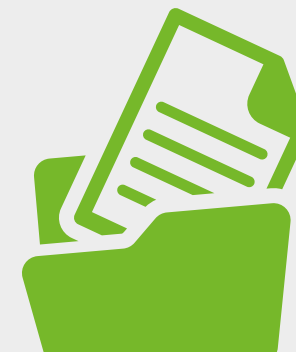


Calls for the EPB-network - Evikey

As coordinator of the EBP network prioritisation unit, KCE launches an annual call for project proposals (development, adaptation, updating or implementation of guidelines). This call is widely publicised to allow all interested parties (professional groups, specialised units, academic centres, etc.) to respond. All proposals are examined and rated by KCE based on scientific criteria. They are then discussed with the EBP network partners and those that receive the best score are selected through a consensus process, taking into account the available budget. For the selected projects, a public call for tenders is launched via the FOD Volksgezondheid/SPF Santé publique.

For updates about the next call, keep an eye on the www.evikey.be website or on Evikey's LinkedIn page.

OUR EXTERNAL COLLABORATIONS



We regularly seek external expertise – including that of patients – to support us in the design and execution of certain parts of our studies. We also call on external experts for the validation of every report.

Subcontractors

Despite the many skills of its in-house team, KCE does not always have the necessary expertise – or, indeed, the time – to carry out all its studies itself. For this reason, some studies are fully or partially outsourced to e.g. universities, consultants or other public services through **public tenders**. However, even in those cases, KCE always remains responsible for coordinating and supervising the projects and for the final results.

External experts and stakeholders

KCE studies are always conducted in connection with the field. For each project, specialists, clinicians and others are called upon to share their knowledge with the researchers and help them e.g. to refine their research questions or refine their methods. They may also draw their attention to important factors that need to be taken into account to ensure that the results are accepted and adopted by healthcare professionals in their daily practice.

For each of its studies, KCE also organises consultations with interested stakeholders to gather their opinions. These stakeholder opinions are always taken into consideration, but are clearly identified as such and distinct from the research results.

All external participants are asked to declare any potential conflict of interest.

Through these external collaborations, the communication between researchers and caregivers, patients and decision-makers in healthcare can be improved and professionalised.



PATIENT INVOLVEMENT ON THE RISE

KCE has committed to involve patients as partners in its research in a more systematic way. Patients can be involved as 'experts by experience' because their personal - and possibly collective - experience of a health issue offers a valuable complement to the researchers' regarding, for instance, the way the study should be conducted or the relevance of the results. They may also be asked, as stakeholders, to represent their interests as patients and users of health services.



Validators

All KCE reports are subject to internal and external scientific validation.

Internal validation is carried out by two KCE experts who were not involved in the research and by the management team.

For the **external validation**, KCE requests the contribution of three external experts, including at least one international expert. This provides KCE with a critical, constructive, external opinion on its work, which contributes to the relevance and scientific rigour of its reports.

Over the years, these external validations have enabled KCE to develop a very diverse network, with highly specialised national and international experts in a wide range of fields.



CONFLICT OF INTEREST POLICY

KCE is deeply committed to its independence and neutrality and has a clear and transparent policy regarding conflicts of interest:

- KCE researchers are not permitted to engage in other professional activities that may give rise to a conflict of interest;
- All external experts, subcontractors or validators involved in a KCE study must complete and sign a declaration detailing any potential conflict of interests. If applicable, those interests are then mentioned in the report.



5 FINANCIAL STATEMENTS 2023

BALANCE 2023

ASSETS		
	31/12/2022	31/12/2023
FIXED ASSETS	139,865.71	106,550.36
I. Formation expenses		
II. Intangible fixed assets	9,553.48	5,349.46
III. Tangible fixed assets	113,106.43	83,995.10
A. Land and buildings	43,994.53	32,175.75
B. Plant, machinery and equipment	54,090.33	38,261.68
C. Furniture and vehicles	15,021.57	13,557.67
D. Leasing and similar rights		
E. Other tangible fixed assets		
F. Assets under construction and advance payments		
IV. Financial fixed assets	17,205.80	17,205.80
CURRENT ASSETS	16,445,507.69	18,150,078.37
V. Amounts receivable after more than one year	1,827.54	1,827.54
A. Trade debtors		
B. Other amounts receivable	1,827.54	1,827.54
VI. Stocks		
VII. Amounts receivable within one year	297,233.76	215,355.97
A. Trade debtors		
B. Other amounts receivable	297,233.76	215,355.97
VIII. Current investments		
IX. Cash at bank and in hand	15,983,882.14	17,779,168.51
X. Deferred charges and accrued income	162,564.25	153,726.35
TOTAL ASSETS	16,585,373.40	18,256,628.73



BALANCE 2023

LIABILITIES		
	31/12/2022	31/12/2023
EQUITY	6,355,656.64	6,322,341.13
I. Capital		
III. Revaluation surpluses		
V. Accumulated profits (losses)	6,369,431.65	6,355,656.64
result before reimbursement Bonus	3,162,225.66	3,793,689.71
reimbursement Bonus	-3,176,000.67	-3,827,005.22
VI. Investment grants		
PROVISIONS AND DEFERRED TAXES		
VII. Provisions for liabilities and charges		
A. Pensions and similar obligations		
B. Taxes		
C. Major repairs and maintenance		
D. Other liabilities and charges		
AMOUNTS PAYABLE	10,229,716.76	11,934,287.60
VIII. Amounts payable after more than one year	0.00	0.00
A. Financial debts		
1. Credit institutions, leasing and other similar obligations		
2. Other loans		
B. Trade debt		
C. Advanced received on contracts in progress		
D. Other amounts payable		

	31/12/2022	31/12/2023
IX. Amounts payable within one year	10,229,716.76	11,934,287.60
A. Current portion of amounts payable after more than one year falling due within one year		
B. Financial debts		
1. Credit institutions		
2. Other loans		
C. Trade debts	2,750,433.12	3,503,919.26
D. Advanced received on contracts in progress	3,247,651.02	3,445,980.98
E. Taxes, remunerations and social security		
1. Taxes		
2. Remunerations and social security	1,055,631.95	1,157,381.47
F. Other amounts payable	3,176,000.67	3,827,005.89
X. Deferred charges and accrued income		
TOTAL LIABILITIES	16,585,373.40	18,256,628.73



RESULTS 2023

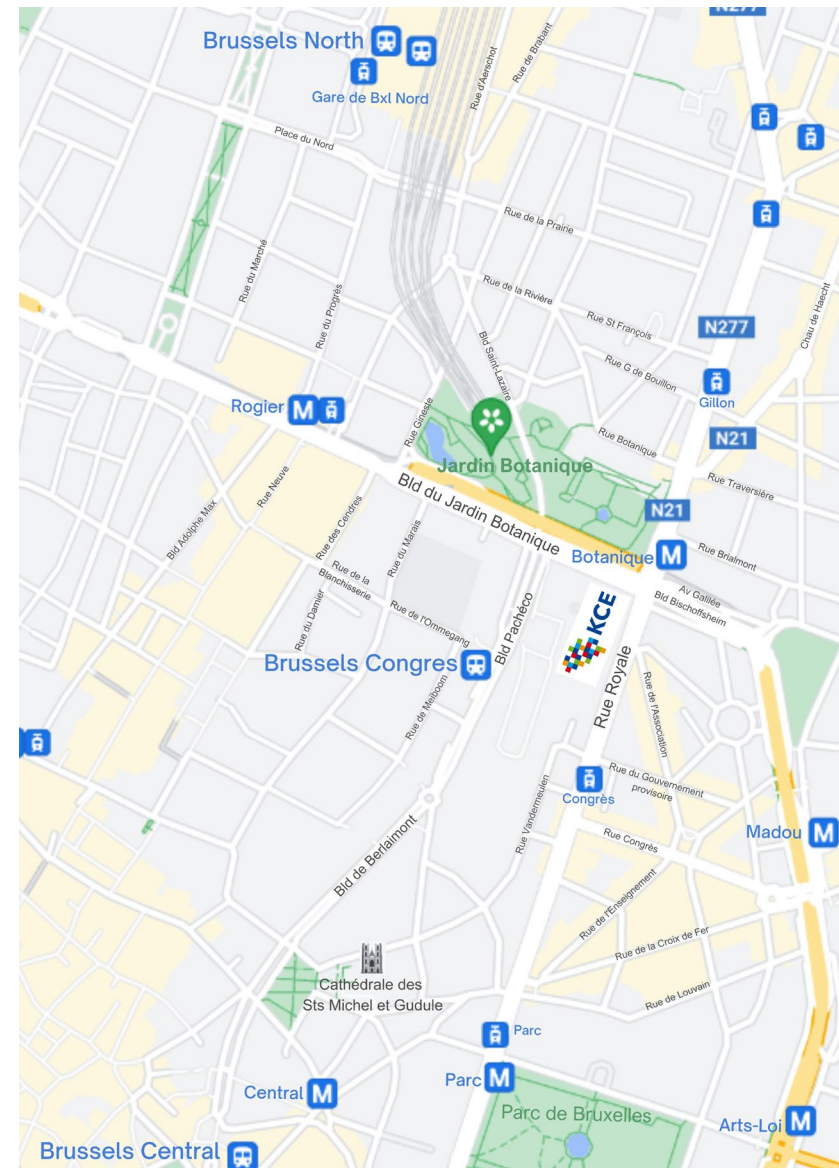
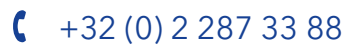
	31/12/2022	31/12/2023
I. Operating income	25,553,485.79	24,865,806.08
A. Turnover		
B. Stocks: increase (decrease)		
C. Own construction capitalized		
D. Facturation Interne		
E. Other operating income	25,553,485.79	24,865,806.08
II. Operating charges	23,190,954.95	21,067,755.37
A. Purchases and stocks		
B. Services and other goods	13,623,959.39	10,442,254.94
C. Remunerations, social security costs and pension	9,474,390.59	10,553,040.71
D. Depreciation of and other amounts written down formation expenses, intangible and tangible fixed assets	92,604.97	72,459.72
E. Amounts written down stocks, contracts in progress and trade		
F. Provisions for risks and charges		
G. Other operating charges		
H. Operating charges carried to assets as restructuring costs		
III. Operating profit (loss)	2,362,530.84	3,798,050.71
IV. Financial income	0.00	520.00
A. Income from financial fixed assets		
B. Income from current assets		
C. Other financial income		520.00
V. Financial charges	305.18	4,881.00
A. Debt charges		
B. Amounts written down on current assets except stocks, contracts in progress and trade debtors		
C. Other financial products	305.18	4,881.00

	31/12/2022	31/12/2023
VI. Profit (losses) on ordinary activities before taxes	2,362,225.66	3,793,689.71
VII. Extraordinary income	800,000.00	0.00
A. Write-back of depreciation and of amounts written down intangible and tangible fixed assets		
B. Write-back of amounts written down financial fixed assets		
C. Write-back of provisions for extraordinary liabilities and charges		
D. Gains and disposal of fixed assets		
E. Other extraordinary income	800,000.00	
VIII. Extraordinary charges	3,176,000.67	3,827,005.22
A. Extraordinary depreciation of and extraordinary amounts written down formation expenses, intangible and tangible fixed assets		
B. Amounts written down financial fixed assets		
C. Provisions for extraordinary liabilities and charges		
D. Losses on disposal of fixed assets		
E. Other extraordinary charges	3,176,000.67	3,827,005.22
F. Extraordinary charges carried to assets as restructuring costs		
IX. Gain (loss) of the period	-13,775.01	-33,315.51





5 CONTACT AND LEGAL NOTICE





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

KCE is a public institution with legal personality, classified in category B as referred to in the Act of 16 March 1954 on the supervision of certain entities of public interest (Parastatal B). Founded under the Programme Law (1) of 24 December 2002, published in the Staatsblad-Moniteur belge of 31 December 2002.

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