



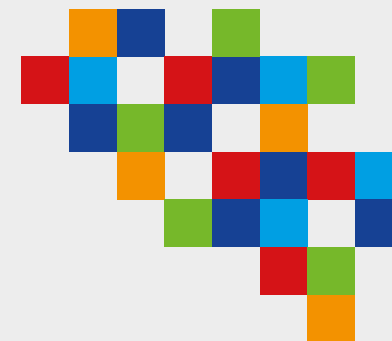
Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

ANNUAL REPORT

2022



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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 (the EBP network “Evikey”, EUnetHTA, etc.).

KCE is funded by the federal authorities (78% from the National Insurance for Health and Disability Insurance/NIHDI and 22% from the Federal Public Service “Public Health” and the Federal Public Service “Social Security” combined).

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

« **K**enniscentrum
– **C**entre
d’**E**xpertise »

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 cross-disciplinary 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 develop their expertise and contribute to maintaining 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 4 people:

- an interim managing director: Marijke Eyssen;
- an interim deputy managing director: Christophe Janssens;
- two interim scientific programme managers: Irina Cleemput and Sabine Stordeur (seconded to the COVID-19 Vaccination Task Force until September 2022).



EFFECTIVE SUPPORT SERVICES

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

Together, they form an enthusiastic and united team of 75 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, 2022

	In FTE
President	0.20
Management	3.90
General management	2.00
Programme management	1.90
Studies	50.30
Physicians, dentists, nurses, physiotherapists...	27.00
Health economists	8.20
Sociologists, legal experts	3.20
Data analysts, statisticians and scientific information specialists	7.30
Project facilitators	1.60
Dissemination and knowledge management experts	3.00
Support	12.50
Secretariat and layout	6.10
ICT, webmaster and library	1.00
Legal advice and human resources management	3.40
Budget and accountancy	2.00
TOTAL	66.90

OUR BOARD OF DIRECTORS



Our Board of Directors brings together representatives of the public authorities and the most important actors 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 obliged to publish all of its results within one month of their approval by the Board, which offers an additional guarantee of our independence and transparency.

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



VISIBILITY



Website traffic in 2022



301,489
visitors



646,632
page views



43,623
views of
our videos

Our followers

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



2,819
followers
on Twitter



6,182
subscribers
on LinkedIn



802
followers
on Facebook

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





The aim of the KCE studies is to guide the Belgian authorities as they prepare and implement new 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 Superior Health Council, NIHDI, the FPS Public Health, the Intermutualist Agency, the Federal Agency for Medicines and Health Products, 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)**
- **Health Technology Assessment (HTA)**
- **Good Clinical Practices (GCP)**
- **Methodological reports** (i.e. manuals intended mainly for KCE's own research, which are also made available to all researchers in the healthcare and public health sectors).

In 2022, we published no GCP studies or methodological reports.

HSR

HEALTH SERVICES RESEARCH (HSR) STUDIES

These studies focus on the best way of organising and financing health services in order to guarantee quality and accessibility of healthcare, while maintaining their economic viability for patients and society.

HSR studies are complex as they have to reconcile the organisational aspects of health policy with the human context, the opinions and interests of the various professions involved and budgetary factors. As a result, these research projects are always conducted by multidisciplinary teams. In general, HSR studies are based on an analysis of the scientific literature and grey literature, on qualitative methods (focus groups, surveys, etc.), and on a variety of examples from different countries. The various stakeholders are always closely involved in the main phases of the project. Through its HSR studies, KCE is able to suggest – sometimes radical – reforms for an entire sector.

HSR reports published in 2022:



Infant- and family-centred developmental care for preterm newborns in neonatal care (KCE Report 350)

The first few days of life are crucial for the creation of the bond between a newborn infant and its parents. Separation immediately after birth may interrupt the formation of this deep bond and have implications for the subsequent development of the child. However, it is not uncommon for a newborn – especially if premature – to have to stay in a hospital neonatal department for several days or weeks. Research into developmental psychology has resulted in “Developmental care for infants and their families”, which aims to minimise the separation between a newborn and its parents and promote interactions between them in all situations. Care of this type is already offered in many Belgian hospitals, but not all. In this report, KCE analyses the developmental care models described in the literature and the way in which they could be optimised in Belgium.



Health system performance assessment: care for people living with chronic conditions (KCE Report 352)

KCE periodically produces a general “dashboard” on the performance of the Belgian healthcare system. In this report, it offers a more detailed analysis of people living with a chronic disease. By analysing 27 quality indicators, it presents some observations, beginning with the fact that chronically ill patients are hard to identify in the Belgian databases and that they do not always have access to the benefits intended for them (e.g. a reference pharmacist or care trajectories). Some indicators are very good, such as the quality of the relationship with the physician, while others are more concerning, such as the risk of preventable hospitalisations for people with chronic pulmonary disease, the quality of monitoring for people with diabetes or the risk of having to delay treatment for financial reasons. Prevention remains the poor relation, as is so often the case.



Nurse staffing in Belgian intensive care units: impact of two years of COVID-19 pandemic (KCE Report 353)

Nursing staff have been severely impacted by the COVID-19 crisis, particularly intensive care nurses. The situation was already worrying well before the pandemic; it has become critical today. This KCE study shows that many intensive care nurses are on the verge of burn-out and are considering leaving their jobs or even giving up the nursing profession altogether. A good working environment is essential to ensure that these professionals, who are highly trained and specialised and hard to replace, are retained in our hospitals. Establishing the Fonds Blouses blanches [White Coats Fund] was an historic first step to improve their situation (and that of the nursing profession in general) but it is now time to roll out a more effective and global plan to attract nurses into intensive care units and motivate them to stay there. This plan should focus, among other things, on better recognition, adequate remuneration, promotion of training, and maintaining staffing levels consistent with international standards.



Remote monitoring of patients with COVID-19 (KCE Report 354)

At the height of the health crisis, a number of remote monitoring initiatives for COVID-19 patients were set up in Belgium and around the world. Their aim was to alleviate the pressure on hospitals and reduce the workload for frontline care providers. Did they actually achieve their objectives? To answer this question, KCE researchers analysed 12 of the initiatives in detail. Their conclusion is that the concept of remote monitoring will play an important role in medicine in the future, but that many of its concrete aspects still need to be refined.



Use and organisation of ECMO in Belgium (KCE Report 355)

ECMO (Extra Corporeal Membrane Oxygenation) is a technique used in intensive care units, where blood is pumped outside of the body to a heart-lung machine that removes carbon dioxide and sends oxygen-filled blood back to tissues in the body. During the COVID-19 pandemic, many patients with severe respiratory failure benefited from this treatment. However, even though it can save lives, this technique is also very cumbersome and carries significant risks, so its use has to be well managed. KCE was asked to draw up a status report on the use of ECMO in Belgium and to identify the elements involved in optimising this practice. The literature describes several of these factors, such as the provision of ECMO in a limited number of hospitals, (continuous) training for the care team, setting up standardised protocols and recording data. KCE researchers conclude that, at present, the way ECMO is used in our hospitals is not understood clearly enough. They therefore recommend to start by setting up a process for systematically recording the data needed for a more objective review of a possible (re)organisation of ECMO provision at the national level.



Compulsory licensing for expensive medicines (KCE Report 356)

Throughout the world, the rising prices of innovative drugs are exerting considerable pressure on health systems. The future gives even more cause for concern, as medicine is moving in the direction of increasingly personalised treatments, and therefore increasingly complex – and expensive – drugs.

The issuing of mandatory licences by the public authorities is sometimes mentioned as a solution that would allow the manufacturing and marketing of cheaper versions of expensive drugs (generics). The Parliamentary Commission for Health and Equal Opportunities asked KCE to assess the extent to which this mechanism could be implemented in Belgium. It is clear from the study, which was carried out in close collaboration with teams coordinated by the University of Antwerp and KU Leuven, that mandatory licences are a mechanism for weighting the extended protection afforded by patents in cases where it seems unbalanced. However, they can only be used in exceptional circumstances, and as one of a number of tools for trying to keep drug prices affordable. Each situation must therefore be examined on a case-by-case basis. Coordinating efforts with other European countries is also deemed necessary.



Quality indicators for the management of epithelial ovarian cancer (KCE Report 357)

In this report, KCE proposes 15 quality indicators for the treatment of ovarian cancer. This approach is consistent with a continuous process for improving the quality of cancer care in Belgium and has already been applied successfully for other types of cancer. The results of the 15 indicators have been calculated at a national level, and all hospitals have received an individual assessment report sent by the Belgian Cancer Registry to allow them to identify their strengths and weaknesses and improve their practices if necessary. The second part of the study demonstrates that the odds of survival are significantly higher in hospitals which treat a large number of patients each year. KCE therefore argues in favour of offering ovarian cancer treatment in a limited number of reference centres. Recognition of these reference centres must not, however, be based solely on the number of patients treated.



Organisation of paediatric hospital care in Belgium: current situation and options for reform (KCE Report 358)

Is hospital really the right place for a sick child? Countries other than Belgium have set up “transmural” paediatric care facilities, which offer treatment at home for children who would normally be treated in hospital. This report analyses the way in which paediatrics is organised and financed in Belgian hospitals and examines how and to which extent transmural care could help to prevent or shorten hospital stays.



Towards integrated care in Belgium: stakeholders' view on maturity and avenues for further development (KCE Report 359)

Our current healthcare system is based primarily on a per-disease approach and is financed per service, which is not ideal for addressing the challenges of ageing and the proliferation of chronic diseases. For this reason, it seems advisable to move towards a system of "integrated care", in other words care that is better adapted to the multidimensional needs of chronically ill patients, throughout their lives and across the various care pathways. A range of initiatives are already underway in Belgium, at both the federal and the federated entity levels, however greater coordination is sought by certain stakeholders. The new Interfederal Plan for Integrated Care, expected in early 2024, should help to rectify this problem.



How to improve access to health care for people with intellectual disabilities? (KCE Report 361)

In Belgium, as in other parts of the world, people with intellectual disabilities die earlier than the general population, notably as a result of failure to detect their health problems. KCE carried out a survey to identify the barriers these individuals face in obtaining routine healthcare. The study has led to 8 specific objectives, broken down into 25 areas for action. One of their common denominators is that carers need to be given more time when they are dealing with these patients. Another key observation is that most of the proposed solutions could be of benefit to a much larger proportion of the population than just people with intellectual disabilities.



An explorative survey to inform staffing policy in nursing homes: a study conducted during the COVID-19 pandemic

In hospitals, it has already been widely demonstrated that there is a relationship between, firstly, nurse staffing levels (number and mix of skills) and the quality of the working environment and, secondly, staff well-being and the quality of care. This study explores similar characteristics relating to staffing (ratio of residents to carers, working environment, care not provided, staff well-being, quality of care perceived by staff, etc.) in the context of care homes for the elderly (residential homes and nursing homes) during the COVID-19 pandemic.



HEALTH TECHNOLOGY ASSESSMENT STUDIES

Health Technology Assessments (HTA) analyse the safety and efficacy of a medical technology (drug, implant, vaccine, surgical technique, etc.).

When the results are positive, they will usually be followed by a cost-effectiveness analysis. The aim of this analysis is to establish the cost-benefit ratio for patients and for society in terms of increased life expectancy and quality of life. In addition to these clinical and economic aspects, a full HTA study also includes organisational, social, legal and ethical aspects. Most of those assessments are carried out on products presented as innovative, for which the industry negotiates prices with the public authorities that are often (extremely) high.

HTA report published in 2022.



Evaluation of the shingrix vaccine against herpes zoster (KCE Report 360)

Herpes zoster or shingles is a painful disease caused by a reactivation of the *varicella zoster virus* that also causes chickenpox. In the majority of cases, it heals spontaneously within 2 to 4 weeks. However, there can be complications, such as post-herpetic neuralgia (10 to 20% of shingles cases) or other issues that are rarer, but also more serious. Shingles usually affects the elderly and people with a weakened immune system. In 2021, a new vaccine (Shingrix®) became available on the Belgian market. The Superior Health Council has recommended that it be offered to the entire population from the age of 60, and to all immunosuppressed individuals from the age of 16. However, it also mentions that economic analyses need to be taken into consideration before a decision on reimbursement is made, as this vaccine is very expensive (€170 per dose, two doses being required for full vaccination). KCE has now given its opinion: this price is too high compared with the health benefits that can be expected from this vaccine. If reimbursement was granted, this vaccination would cost the healthcare budget around €602 million in the first year and nearly €23 million per year afterwards. This raises the question of whether such significant expenditure can be justified for a disease which remains relatively benign for most people, particularly in the current context of budgetary constraints.



THE KCE TRIALS PROGRAMME

KCE Trials is a publically-funded 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 importance, 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 **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>

2022 in numbers



2
calls for
studies



10
new
contracts
with Belgian
research
teams



6
studies in
analysis
phase

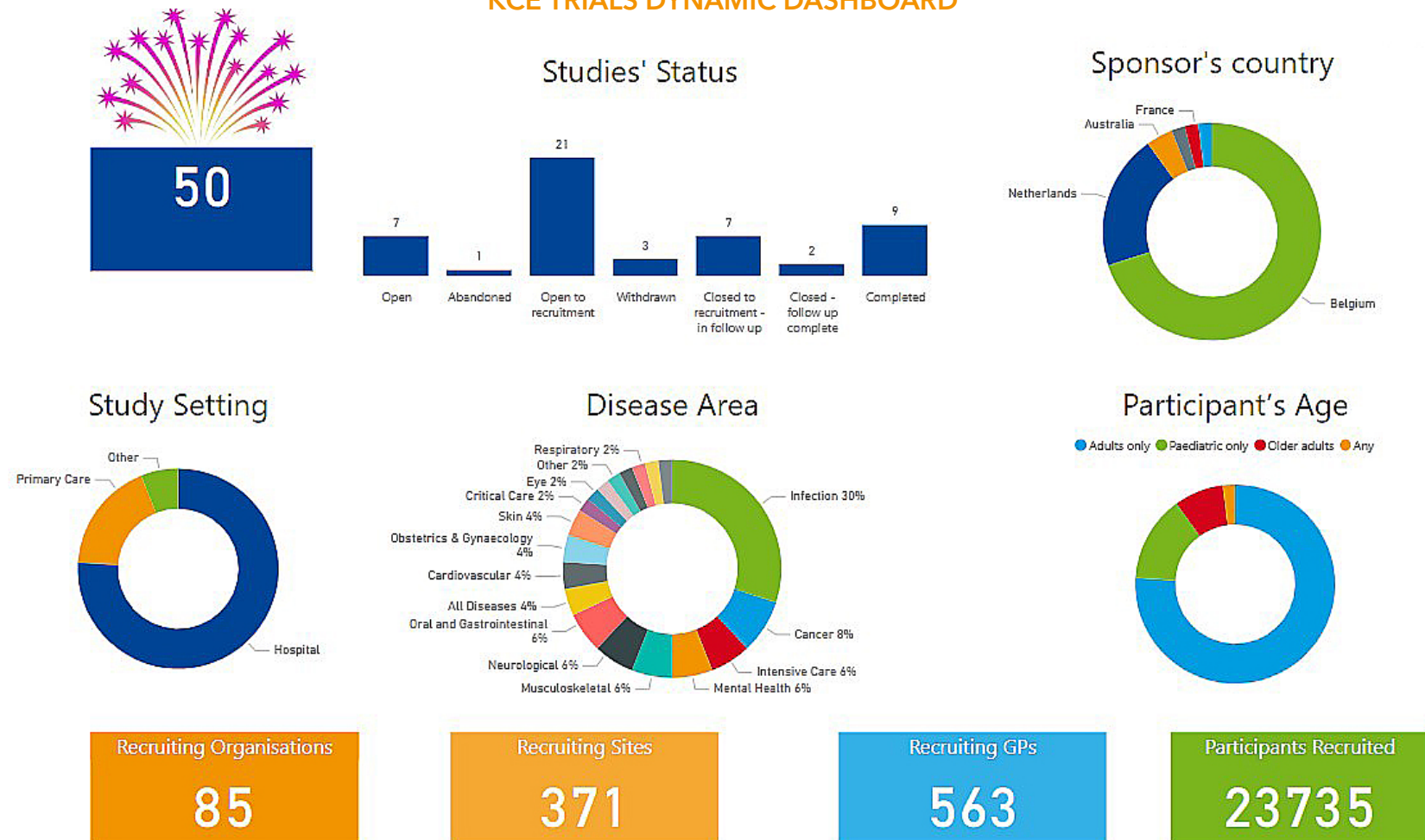


11
scientific
articles
published

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 EDGE Belgium by the recruitment sites. It also includes the results of previously published studies.

KCE TRIALS DYNAMIC DASHBOARD



A few figures for the KCE Trials programme (as of December 2022)



73
participating
hospitals



563
participating
GPs



23,735
recruited
patients



1.7
million €
average budget
per trial

In 2022

7 clinical trials were completed and their results published



ADVOR: Diuretic effects of Acetazolamide (Diamox®) in patients with Decompensated heart failure and Volume Overload.



BeNeDuctus*: Non-inferiority trial of early treatment versus expectative management of patent ductus arteriosus in preterm infants.



Big Bird: Effectiveness of a blended care program for the discontinuation of benzodiazepines use for sleeping problems in primary care.



COV-AID: Safety and efficacy of anakinra, tocilizumab et siltuximab in COVID-19 patients with acute hypoxic respiratory failure and systemic cytokine release syndrome (342 patients in 16 Belgian hospitals). The results have been published ([JAMA](#)).



DAWN-Plasma: Donated antibodies working against nCoV in hospital in-patients. This study enrolled 489 patients treated in 21 Belgian hospitals. The results have been published ([European Respiratory Journal](#)).



DisCoVeRy: Multi-centre trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults, coordinated by INSERM (France). Three Belgian hospitals participated with a total of 53 patients. The results have been published ([Lancet](#)).



DOMINO: Diet Or Medication in Irritable bowel syndrome. The first results are available, publication pending.

6 clinical trials have entered the analysis phase



BLING III*: Comparison of continuous beta-lactam infusion and intermittent beta-lactam dosing in critically ill patients.



GonoScreen: Efficacy of screening sexually transmitted infections (STI) in men who have sex with men (MSM).



IODA-pilot: Feasibility of conducting a pragmatic, randomized trial that compares Immediate versus Optional Delayed surgical repair for treatment of acute anterior cruciate ligament injury.

* Studies marked with an asterisk are carried out as part of international multicentre collaborations. A number of these studies are being carried out as part of the BeNeFIT project (see p.28).



CareRA 2020: COBRA-Slim with or without fast access to TNF blockade for remission induction in early rheumatoid arthritis (RA). The results are expected in 2023.



CONFIDENT: Assessment of the efficacy of CONvalescent plasma therapy in patients with Invasive COVID-19 and acute respiratory failure treated with mechanical ventilation. The protocol has been published and the results are expected in 2023.



IMCOVAS: Assessment of the immunogenicity and safety of the Pfizer, Moderna et Astra-Zeneca vaccines for COVID-19 after regular schedule and adapted vaccine schedules and routes. 840 patients were enrolled in this trials. The results are expected in 2023.

2 clinical trials have completed their recruitment



RenoMet: Evaluation of metformin as RenoProtector in Non-Diabetic Patients with Progressive Chronic Kidney Disease.



SAFEBOOSC III*: Evaluation of a treatment based on near-infrared spectroscopy monitoring versus treatment as usual in premature infants.

20 clinical trials are still recruiting participants



AGNOHSTIC: Effect of HYALOBARRIER® GEL ENDO following operative hysteroscopy for improving reproductive outcome in women with intrauterine pathology wishing to become pregnant.









ALLTogether1*: Evaluation of various treatment protocols in recently diagnosed children and young adults with acute lymphoblastic leukaemia (ALL).



ARON: Impact of clinical guidance & point-of-care CRP in children on the antibiotics of GPs.

* Studies marked with an asterisk are carried out as part of international multicentre collaborations. A number of these studies are being carried out as part of the BeNeFIT project (see p.28).

-  **BeNeBio (BeNeFIT)*:** Dose reduction of the new generation biologics (IL17 and IL23 inhibitors) in psoriasis.
-  **BENEFICIAL:** Impact Of Bedside Model-Informed Precision Dosing Of Vancomycin In Critically Ill Children.
-  **BEST CORNEA:** Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) versus Descemet Membrane Endothelial Keratoplasty (DMEK) in corneal endothelial decompensation.
-  **BLENDED:** Blended Care Psychodynamic Therapy or Cognitive Behavioral Therapy versus Face-to-Face Psychotherapy for Depression: A pragmatic multicentre randomized controlled non-inferiority trial.
-  **C-EASIE:** Early administration of Vitamin C in patients with sepsis or septic shock in emergency departments.
-  **COGENIUS:** Comparison of conventional and cooled radiofrequency treatment of the genicular nerves versus sham procedure for patients with chronic knee pain.
-  **CovCOG:** Immediate and long term cognitive and quality of life improvement after cognitive versus emotion management psychoeducation programs in long covid patients
-  **DUET (BeNeFIT)*:** Azole-echinocandin combination therapy for invasive aspergillosis.
-  **Foot Drop:** Comparison of conservative versus surgical treatment of foot drop in peroneal nerve entrapment.
-  **HYFOIL:** Impact on fertility after additional tubal flushing with oil-based contrast versus no additional flushing (randomised, multicentre, pragmatic trial in infertile women with at least one patent tube at HyFoSy).
-  **PRECISE (BeNeFIT)*:** Impact of high vs standard enteral protein provision on functional recovery following Intensive Care admission in mechanically ventilated, critically ill patients.
-  **PRIMALung:** PRophylactic cerebral Irradiation or active MAgnetic resonance imaging surveillance in small-cell Lung cancer patients.
-  **PuRe-COVID:** Pulmonary rehabilitation for Long COVID.
-  **SOPRANO:** Prevention of postoperative endoscopic disease recurrence in Crohn's disease.
-  **SurLym:** Comparison of reconstructive surgery versus no surgery, additional to decongestive lymphatic therapy (usual care), for the treatment of lymphoedema.
-  **TreatPaCS:** Treatment for preschool age children who stutter: comparison of three treatment options (Mini-KIDS, social cognitive behaviour treatment and Lidcombe programme).
-  **UNLOCK:** Nutrition and Locomotor rehabilitation in Long Covid. Pilot study for a randomised trial of locomotor and nutritional revalidation modalities in patients with long COVID.

* Studies marked with an asterisk are carried out as part of international multicentre collaborations. A number of these studies are being carried out as part of the BeNeFIT project (see p.28).

7 clinical trials are currently in the start-up phase



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



PRIORI: Evaluation of synbiotics in Patients at Risk for preterm birth.



PERSuaDER (BeNeFIT)*: PERi-operative Selective Decontamination of the Digestive tract to prevent severe infectious complications after Esophagectomy.



SAUNA (BeNeFIT)*: Continuing Somatostatin Analogues Upon progression in Neuroendocrine tumour patients.



ALIVE (BeNeFIT)*: (Cost)-effectiveness of Attachment Based Family Therapy for suicidal youth.



BONANZA: Evaluation of a management strategy guided by early brain tissue oxygen monitoring in patients with severe traumatic brain injury to improve long term neurological and functional outcomes.



CASES (BeNeFIT)*: Carotid Artery Stenting during Endovascular treatment of acute ischemic Stroke versus deferred treatment of carotid artery stenosis.



* Studies marked with an asterisk are carried out as part of international multicentre collaborations. A number of these studies are being carried out as part of the BeNeFIT project (see p.28).



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)**.

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 nine studies (of which two were subsequently abandoned) resulting from an initial call launched in 2018 and a second call launched in 2020.

A third call was launched in late 2022. The proposals are currently being evaluated.



"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 ten years can now take out an outstanding balance insurance with no additional premium due to their medical history. The new law also reduces this ten-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.

Another study was started to investigate the possibility of including diabetes type 1 (chronic disease) in the current reference grids and, if so, under which conditions (the results are expected in 2024).

The right to be forgotten in breast cancer: new propositions (Report 351)



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 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.

In the spring of 2022, a call for project proposals was issued for the 2023 programme. Twelve proposals were submitted. After scientific assessment and taking into account the available budget, the following projects were selected:

- Cox- & Gonarthrosis (implementation of a guideline)
- Malnutrition in the elderly (development of a new guideline)
- Good Practice Logo for midwives (implementation of a guideline)

A call was also issued for COVID-related projects. Four proposals were submitted, of which one was ultimately selected : Follow-up and revalidation of long-term COVID complaints in a primary care setting (implementation of a guideline).

In 2022, the prioritisation cell was also involved in developing and supporting the running of Evikey and in launching the translation of the Joanna Briggs Institute (JBI) guidelines. In addition, the prioritisation cell allows KCE to take part in the federal steering committee and task force for the development of primary care guidelines (WOREL).

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 other viral diseases that may constitute a threat to our health system, such as monkeypox or a flu epidemic.

The duties of the Task Force involve assessing the safety and efficacy of the drugs used for treating such viral infections, determining the volumes to be purchased and analysing their cost effectiveness in terms of therapeutic value (HTA), their positioning in the therapeutic arsenal and their distribution.

The Task Force is composed of around twenty Belgian experts – academics and people from federal agencies and administrations – and around ten experts from KCE (for the composition of the Task Force, [see here](#)).

Since its creation, the Task Force has published [10 opinions](#) on new drugs used for treating COVID-19 (Lagevrio, Veklury, Paxlovid, Xevudy, Evusheld, Bebtelovimab), one opinion on Tecovirimat, which is used for treating [monkeypox](#), and one opinion on the clinical effectiveness of the antiviral oseltamivir (Tamiflu) in treating [flu, at the request of the Belgian Strategic Pharmaceutical Stock Platform](#).

Whenever these drugs have become available on the Belgian market, the Task Force has developed procedures for issuing them in hospital or community pharmacies (as they are provided not through the usual commercial channel but through the federal strategic stock).

In addition, the Task Force coordinates the development work for a [guidance document](#) to inform general practitioners on the drugs available to treat COVID-19 and their use. This document is constantly updated.

The Task Force is 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 :



EUnetHTA, the European network for Health Technology Assessment, with over 30 participating countries. Its overall objective is to create an effective and sustainable HTA network across Europe and to help develop reliable, timely, transparent and transferable information to support HTA in European countries. To do this, EUnetHTA produces a repository of methods and processes, and organises the collaborative production of Joint Clinical Assessments which can be used by member states. EUnetHTA also works on Joint Scientific Consultations with the pharmaceutical industry to enable manufacturers to gather the evidence needed by pharmaceutical authorities and HTA agencies to make decisions on marketing authorisation and reimbursement of medicines. In September 2021, EUnetHTA launched the **EUnetHTA21** project, which aims to develop the procedures for future work within the EU's sustainable HTA network, as specified in the new European HTA Regulation (**EU HTA Regulation**). Both KCE and NIHDi collaborate on all work packages of EUnetHTA21 within their own competences and mandates.



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 both in its *Steering Group* and 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).



ECRIN is an international non-profit organisation that brings together European scientists involved in clinical research. Its objective is to facilitate transnational multicentre research by providing investigators with support and tools to manage the difficulties associated with the multinational nature of research. Belgium is not a member of ECRIN, but the KCE Trials programme has regular contact with this structure and its members in the course of international collaborations.



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



EUnetHTA21: the EUnetHTA21 project was launched in September 2021. It follows on from the joint actions undertaken by EUnetHTA and will be based on the lessons learnt from that initiative. Its work is intended to support the future European HTA system as part of the new European HTA regulation. The EUnetHTA21 consortium is managed by ZIN (Netherlands) and includes the following HTA agencies: AEMPS (Spain), AIFA (Italy), AIHTA (Austria), GBA (Germany), HAS (France), INFARMED (Portugal), IQWiG (Germany), KCE (Belgium), NCPE (Ireland), NIPN (Hungary), NOMA (Norway) and TLV (Sweden).



EU-RESPONSE is a research and preparedness network for pandemics and emerging infectious diseases. It is a 5-year multinational project, coordinated by INSERM (France) and funded by the European Research and Innovation Programme Horizon 2020, to design an adaptive European platform for clinical trials on COVID-19 and other emerging infectious diseases (SolidAct Trial). As a result, hospitals from all over Europe may be involved. A KCE researcher is a member of the independent scientific and ethical advisory board set up to advise on the structure of the "EU-SolidAct" platform and which treatments should be studied first.



PERMIT (PERsonalised Medicine Trials) is a project that aims to establish methodological standards for clinical trials in personalised medicine. It was launched in January 2020 under the European research and innovation programme H2020. The consortium includes pan-European research structures (ECRIN, EATRIS, ELIXIR-LU/UNILU), research funders (DLR), HTA agencies (KCE, ISCIII), patient representatives (ETH), competent authorities (ISS), and data protection researchers (TMF).



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-Medical Devices is a project which began within the international **IHSI** Horizon scanning network for pharmaceutical products. This initiative aims to develop a similar system for medical devices. KCE is a member of the working group and was specifically invited to share its expertise in prospective analysis (cf. **Report 283 from KCE**) with the working group.



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 selection procedure is transparent and 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 for its clinical trial topics. But, in contrast to KCE's annual study programme, the KCE Trials programme has no fixed schedule for its calls however it generally opens at least one call each year.

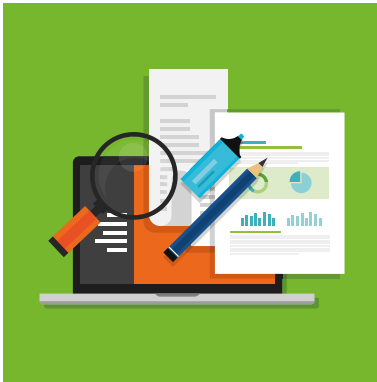
You can request to be informed of calls and other information from KCE Trials by subscribing to KCE's Trials mailing list via the following [link](#).

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

Calls for the “Right to be forgotten” programme

KCE has also launched a call for research topics as part of its new “Right to be forgotten” mission and review of the medical conditions mentioned in the relevant law with regard to outstanding balance insurance. The aim of this call was to identify the medical conditions to be analysed by KCE as a priority over the coming years. Several patient associations took part in the process.

For further information on this type of call, please register on the website via the [‘Receive news’](#) section.

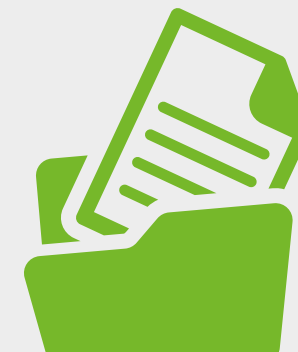


Calls for the EPB-network - Evikey

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 FPS “Public Health”.

For further information on this type of call, please register on the website via the [‘Receive news’](#) section.

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 each report.

Subcontractors

Despite the many skills of its in-house team, KCE does not always have the necessary internal expertise – or, indeed, the time – to carry out all its studies itself. For this reason, some studies are fully or partially outsourced through [public tenders](#) to e.g. university teams, specialist consultants or other public services. 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 always works 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 elements that need to be taken into account to ensure the acceptance of the results in the field and their translation into the day-to-day practice of health professionals.

Similarly, in each of its studies, KCE also invites interested stakeholders for consultations to gather their opinions. Stakeholder opinions are always taken into consideration, but are clearly identified as such and distinguished from the research results.

Every external participant is asked to sign a declaration of 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 of their personal and possibly collective experience of the health issues addressed gives them a complementary view to that of the researchers on how the study should be conducted and on the relevance of the results. They may also be invited, 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.

For the **external validation**, KCE requests the contribution of three external experts, of whom at least one is international. In this way, KCE benefits from critical, constructive, external views 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.

As a result, its policy on conflicts of interest is clear and transparent:

- 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 who are 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 colophon of the corresponding report.



BALANCE 2022

ASSETS		
	31/12/2021	31/12/2022
FIXED ASSETS	154,957.39	139,865.71
I. Formation expenses		
II. Intangible fixed assets	17,995.12	9,553.48
III. Tangible fixed assets	119,756.47	113,106.43
A. Land and buildings	53,342.49	43,994.53
B. Plant, machinery and equipment	44,610.99	54,090.33
C. Furniture and vehicles	21,802.99	15,021.57
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	18,901,830.60	16,445,507.69
V. Amounts receivable after more than one year	510.87	1,827.54
A. Trade debtors		
B. Other amounts receivable	510.87	1,827.54
VI. Stocks		
VII. Amounts receivable within one year	1,524,340.71	297,233.76
A. Trade debtors		
B. Other amounts receivable	1,524,340.71	297,233.76
VIII. Current investments		
IX. Cash at bank and in hand	17,258,193.62	15,983,882.14
X. Deferred charges and accrued income	118,785.40	162,564.25
TOTAL ASSETS	19,056,787.99	16,585,373.40



BALANCE 2022

LIABILITIES		
	31/12/2021	31/12/2022
EQUITY	6,369,431.65	6,355,656.64
I. Capital		
III. Revaluation surpluses		
V. Accumulated profits (losses)	6,369,431.65	6,369,431.65
result before reimbursement Bonus		3,162,225.66
reimbursement Bonus		-3,176,000.67
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	12,687,356.34	10,229,716.76
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		

	31/12/2021	31/12/2022
IX. Amounts payable within one year	12,687,356.34	10,229,716.76
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	2,133,742.50	2,750,433.12
D. Advanced received on contracts in progress	4,342,748.85	3,247,651.02
E. Taxes, remunerations and social security		
1. Taxes		
2. Remunerations and social security	1,054,853.38	1,055,631.95
F. Other amounts payable	5,156,011.61	3,176,000.67
X. Deferred charges and accrued income		
TOTAL LIABILITIES	19,056,787.99	16,585,373.40



RESULTS 2022

	31/12/2021	31/12/2022
I. Operating income	25,311,226.77	25,553,485.79
A. Turnover		
B. Stocks: increase (decrease)		
C. Own construction capitalized		
D. Facturation Interne		
E. Other operating income	25,311,226.77	25,553,485.79
II. Operating charges	20,156,786.39	23,190,954.95
A. Purchases and stocks		
B. Services and other goods	11,979,546.22	13,623,959.39
C. Remunerations, social security costs and pension	8,089,612.38	9,474,390.59
D. Depreciation of and other amounts written down formation expenses, intangible and tangible fixed assets	87,627.79	92,604.97
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)	5,154,440.38	2,362,530.84
IV. Financial income	0.00	0.00
A. Income from financial fixed assets		
B. Income from current assets		
C. Other financial income		
V. Financial charges	0.00	305.18
A. Debt charges		
B. Amounts written down on current assets except stocks, contracts in progress and trade debtors		
C. Other financial products		305.18

	31/12/2021	31/12/2022
VI. Profit (losses) on ordinary activities before taxes	5,154,440.38	2,362,225.66
VII. Extraordinary income	0.00	800,000.00
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	5,156,061.61	3,176,000.67
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	5,156,061.61	3,176,000.67
F. Extraordinary charges carried to assets as restructuring costs		
IX. Gain (loss) of the period	-1,621.23	-13,775.01





5 CONTACT AND LEGAL NOTICE

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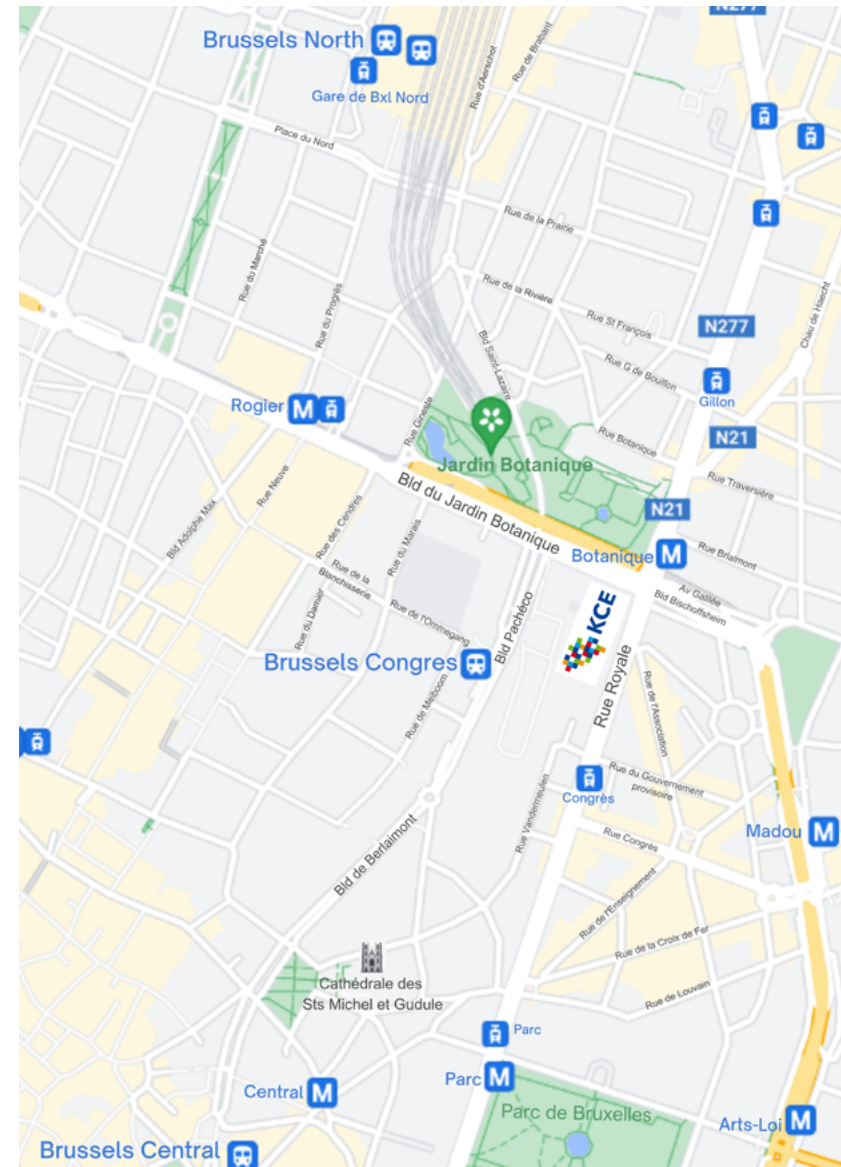
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Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

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