

ANNUAL REPORT

2025



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a year of self-reflexion,
updates and new
beginnings



FOREWORD

The Belgian healthcare system is constantly evolving, driven by changes in the national population, in the range of available medical services, and in infrastructure in general and digitalisation in particular. In this context, KCE's mission is to provide scientifically sound advice to policymakers, healthcare professionals and patients regarding the quality of care and the efficient use of resources.

One major evolution on which KCE is frequently asked for advice is the reform of the hospital landscape and funding. Our researchers have produced several reports on this topic in recent years. However, we have also worked on many other subjects such as the funding of home nursing, the organisation of palliative care, the cost-effectiveness of RSV prevention in babies, the development of care pathways for people with early-onset dementia, several NEED reports and various clinical practice guidelines.

"Classic" research reports aside, 2025 was also a particularly successful year for our KCE Trials programme. Joining the European consortium ERA4Health gives us the opportunity to take the clinical studies we fund to a European level, which should enable us to answer even more clinical questions. A special mention also goes to the ARON study, which demonstrated that applying a sound diagnostic strategy can lead to fewer antibiotic prescriptions in children – a fine example of how of non-commercial clinical studies contribute to better healthcare and better outcomes for patients, and for society in general.

For KCE itself, 2025 was also a year of change. We were requested to play a key role in reforming the Belgian Evidence-Based Practice landscape, with the aim of bringing the best possible evidence to all our healthcare providers. And so we have come full circle: from clinical trials, through cost-effectiveness analyses and clinical practice guidelines with accompanying implementation tools, to analyses of the financing and organisation of care, quality assessments through indicators, and finally the evaluation of the impact of new care models.

Ann Van den Bruel, General Manager

01

THIS WAS

2025



JAN

32 submissions received for
KCE Trials & ZonMw's 4th BeNeFIT call

Annual study programme updated
– 15 new studies

The layout of our reports gets an update!

FEB

MARCH

New pictures in our offices
following photo competition

APRIL

Board meeting:
3 reports approved



MAY

KCE's 400th report!

Individual and
group photos



Calls (2026 study
programme + Trials)

2026 programme:
73 proposals
received

Board meeting:
4 reports approved

JUNE

SOCIAL EVENT IN DINANT



JULY

2025 KCE Trials investigator-led call:
15 submissions received

Gender equality plan adopted

AUG

SEP

HOFSTADE TRIATHLON WITH
12 KCE TEAMS



Board meeting:
4 reports approved

OCT

NOV

First Trials4Health 2026 call through KCE Trials

NEED symposium



Board meeting:
6 reports approved

DEC



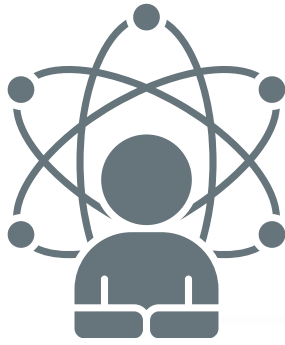
VISION



MISSION



VALUES



OUR CORE BUSINESS

Research on health care organisation, financing and reimbursement; health technology assessments; practice guidelines for health care professionals

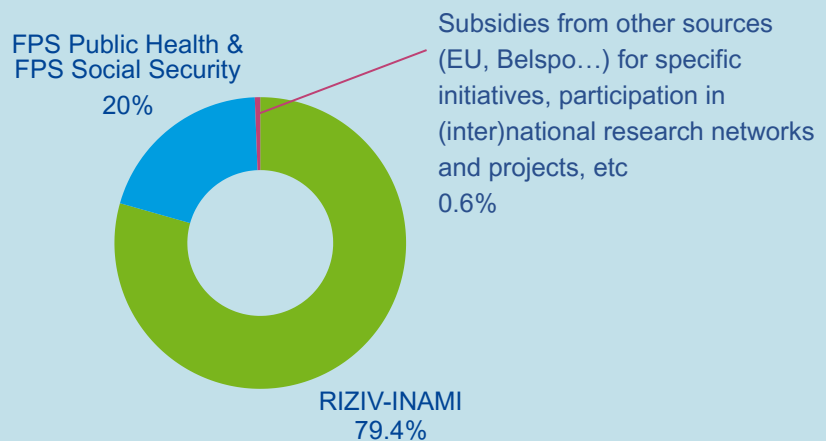
OUR ROLE

Provide scientific advice and insights to the relevant authorities and health care stakeholders (but we are not directly involved in decision-making or in the implementation of our policy recommendations).



BUDGET FOR KCE'S GENERAL PROGRAMME 2025: 12 778 971€

Total budget
25 040 411€



BUDGET 2025 FOR KCE TRIALS :
12 261 440€

**KCE'S STATUS AS A TYPE B PARASTATAL ORGANISATION
GUARANTEES ITS TOTAL INDEPENDENCE FROM THESE
FUNDING AUTHORITIES**

WE WANT TO BE



FOR OUR HEALTH CARE SYSTEM

03

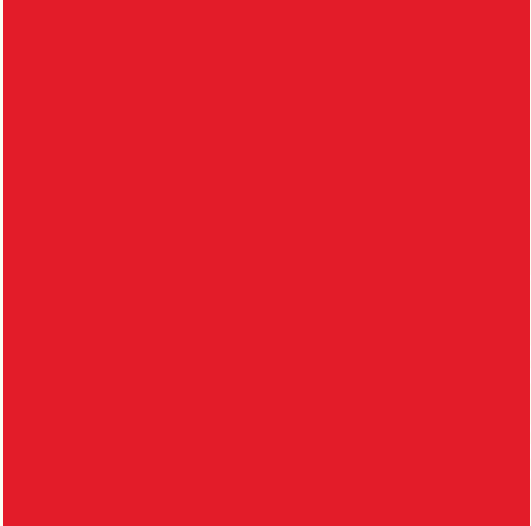
ABOUT US



Kennis

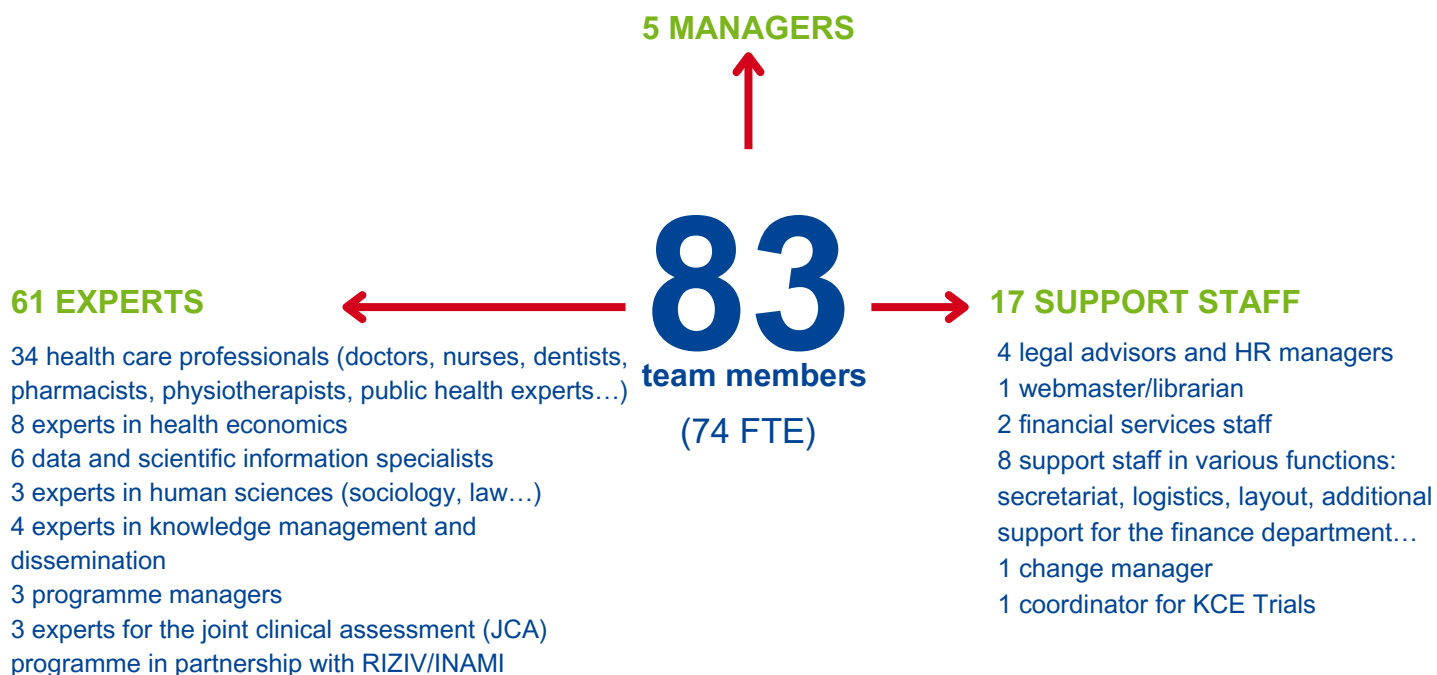
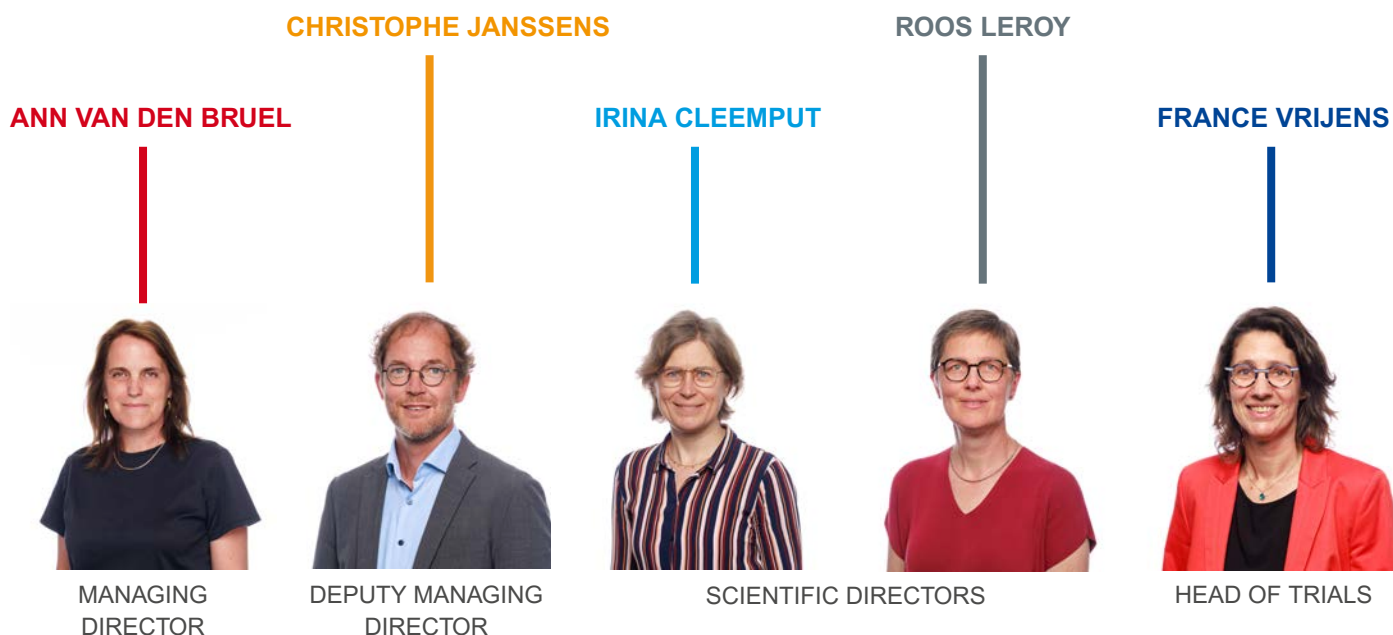


Centrum
entre



d'**E**xpertise

OUR TEAM



[More info?](#)

WE'LL NEVER WORK ALONE

Our studies are always conducted by **a team of researchers** combining different backgrounds, strengths and competences (clinical/biomedical knowledge, public health, statistics, health economics, data analysis, ethics, and more!).

If necessary, part or all of a study can be **outsourced** to e.g. universities, consultants or other public services through public tenders (under our supervision and final responsibility).

KCE studies are always conducted **in conjunction with the field** of study by inviting experts and stakeholders. For each project, specialists, clinicians, patients and other stakeholders are called upon to share their knowledge with the researchers, help them refine their research questions or methods, draw attention to important considerations our experts might have missed, etc.

All KCE reports are subject to **scientific validation** ("peer review") by three external experts, including at least one international expert.

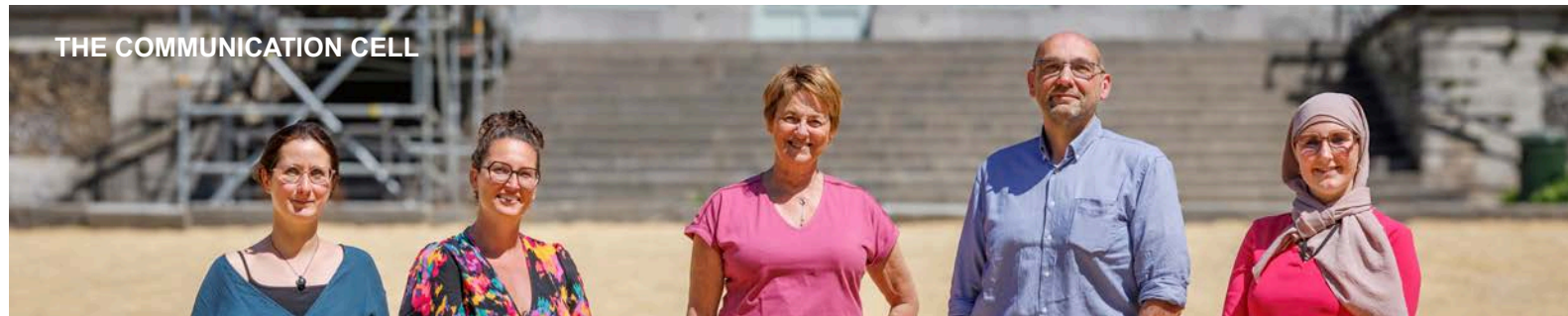
CONFLICT OF INTEREST POLICY

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

KCE TRIALS



THE COMMUNICATION CELL



THE PROGRAMME MANAGERS



THE NEED TEAM



THE SUPPORT STAFF



THE KCE TEAM



STUDY PROGRAMME

Our study programme is based on an annual call for topics. Anyone can submit a study proposal – policymakers, other health care authorities, health care professionals, institutions and citizens.

The collected proposals are carefully assessed following a well-defined procedure.

Our 2025 call yielded **73 study proposals** on a wide range of topics, from the organisation and financing of care to the assessment of existing care programmes over clinical practice guidelines.



33 from private organisations
or citizens



5 from universities or other
higher education institutions



9 from
hospitals



6 from RIZIV/INAMI



Volksgezondheid
Veiligheid van de Voedselketen
Leefmilieu

8 from the FOD/SPF for Public Health



3 from someone within KCE



4 from public institutions
not included in the other
categories



3 from other federal institutions



2 from the federated entities

**AFTER AN IN-DEPTH ASSESSMENT, 15 NEW STUDIES WERE
SELECTED FOR OUR STUDY PROGRAMME.**



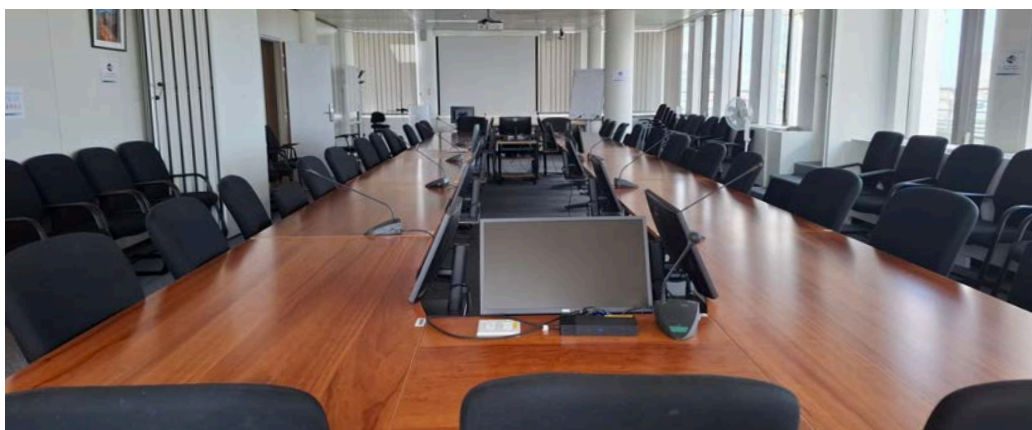
Register
on the '[Receive news](#)' section to be
informed of our next calls!

THE KCE BOARD AND BOARD MEETINGS

Our Board brings together representatives of the public authorities and the most important stakeholders in health care, health insurance and patient associations. Our latest reports are presented during board meetings, and approved by simple majority. This process mainly serves to ensure that we remain neutral and independent, and that our recommendations are well-balanced and acceptable to all parties. The scientific content is not subject to modification.

KCE is legally obligated to publish all of its results within one month of their approval by the Board, which further contributes to its independence and transparency: once a report is approved, its publication cannot be prevented or delayed by more than a few weeks.

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



25

MEMBERS

representing policymakers, other health care administrations, health care organisations, the main health care professions, health insurers, patient organisations, etc.

GENDER EQUALITY PLAN



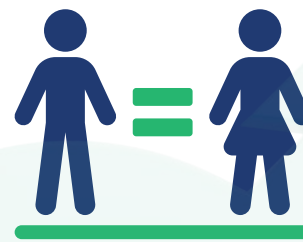
GENDER EQUALITY PLAN

In August 2025, KCE adopted a gender equality plan outlining its current and future actions to strive for a research and working environment in which gender equality is recognized as a source of innovation, creativity and social relevance.

This new plan materialises KCE's commitment to increase attention to gender questions across all aspects of its work through targeted actions, training, inclusive communication, and continuous monitoring. It targets both organisational aspects and attention to gender in research performed and funded by KCE, covering areas like:



Attention to work-life balance
and an inclusive organisational culture



Sufficient (and ideally balanced)
representation of both genders
in internal leadership and decision-making
bodies like boards, panels, etc.



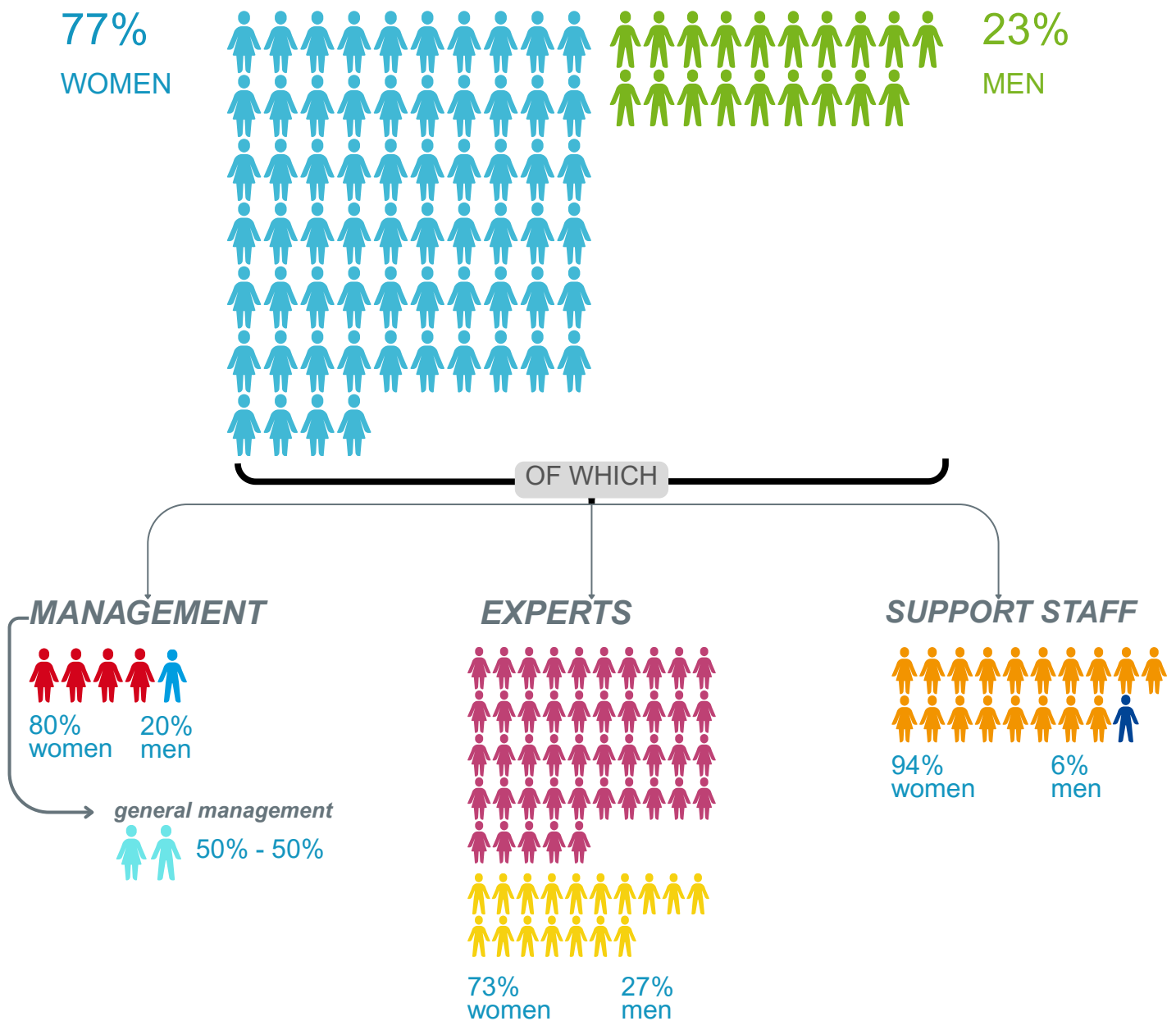
Equal opportunities
in recruitment and career progression



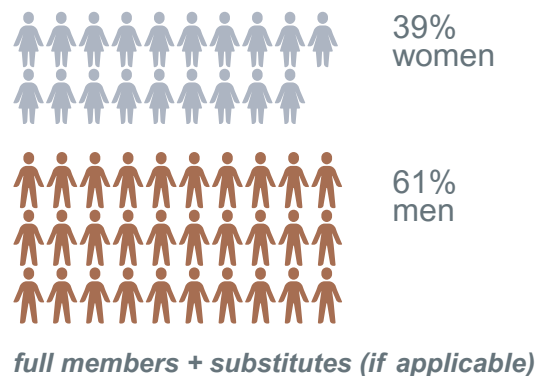
Integration of the gender dimension
in research and clinical trials to contribute to
more relevant, fair, and impactful healthcare
research and policy

KCE TEAM

SITUATION ON 31 DECEMBER 2025



KCE BOARD



05

VISIBILITY



PRESS

206 articles

18 TV interviews

22 radio interviews

11 press releases

REPORTS WITH THE HIGHEST VISIBILITY IN THE PRESS

1

- Hospital reform
- Organisation of ICU



2

- Palliative care
- screening for PFAS



3

Young-onset dementia



SOCIAL MEDIA



LINKEDIN
10 740 FOLLOWERS



FACEBOOK
965 FOLLOWERS



YOUTUBE
2001 FOLLOWERS



STUDIES: DOMAINS & PUBLICATIONS

Health Services Research (HSR)

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



Health Technology Assessment (HTA)

HTA studies 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 Practice (GCP)

These studies aim to develop guidelines for Good Clinical Practice (GCP) – 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.

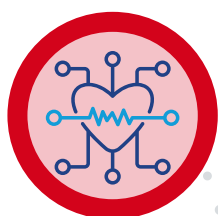


Methodological reports

Methodological reports are intended mainly to support KCE's own research, but they are also made available to all researchers in the health care and public health sectors (see [page 33](#)).

PUBLICATIONS IN 2025

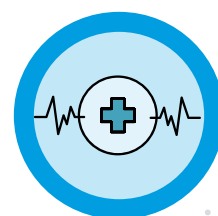
18 REPORTS



HTA



HSR



GCP



Method



Collaboration



**Patient
Involvement**

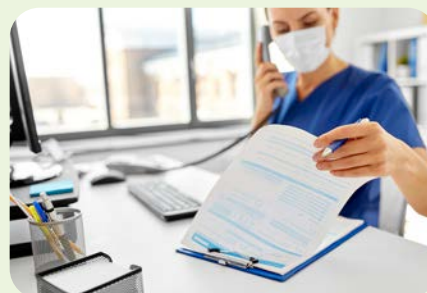
1 RAPID DATA COLLECTION AND ANALYSIS AT THE START OF A NEW OUTBREAK



[KCE Report 393](#)



In the event of an outbreak involving an as yet unknown infectious disease (like COVID-19 at the time), it is crucial to report, analyse and communicate the characteristics of the first 100 patients, the course of the infection and the effect of the measures taken to treat it as quickly as possible. This is the only way to ensure that decision-making is based as much as possible on factual data, and that clinical trials can be set up in a targeted manner. Belgian infectious disease specialists have asked KCE to examine how this process could be organised in a faster, more flexible and more transparent manner in the event of a future pandemic, with rapid feedback to professionals in the field. KCE recommends that the existing risk management platforms (the Risk Assessment Group and the Risk Management Group) should develop a procedure for rapid and standardised data collection across all federal entities, in order to enable faster analysis at federal and European level.



2 PROPOSITIONS FOR REINFORCING AND EXPANDING THE BELGIAN PALLIATIVE CARE OFFER: THE RIGHT CARE AT THE RIGHT MOMENT AT THE RIGHT PLACE

[KCE Report 394](#)

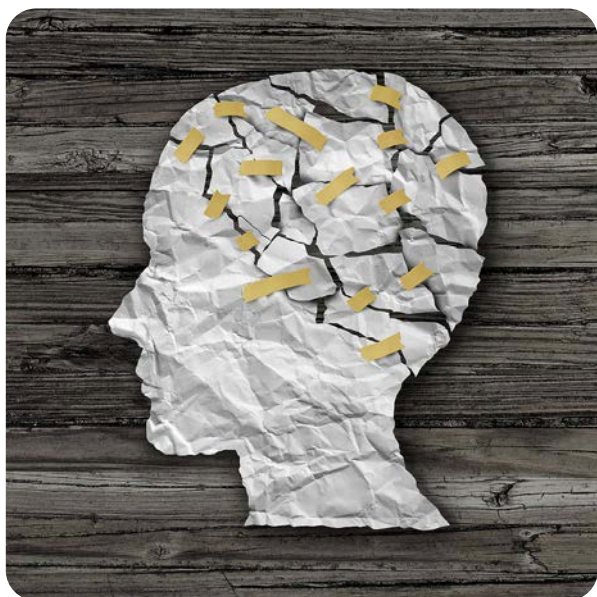


The number of patients that might benefit from palliative care has been steadily increasing in recent years, and this type of care also covers an increasingly wide range of situations. Although Belgian palliative care professionals already perform remarkable work on a daily basis, the palliative care offer undeniably needs to be both expanded in terms of capacity and diversified, to ensure all patients receive palliative care that meets their needs and preferences. KCE performed two studies on this topic.

The first, published in early 2023, aimed to identify a tool for assessing the needs of palliative care patients in order to better match funding to the assistance required (KCE report 367). This second report sets out proposals to strengthen and supplement the existing offer.

3 YOUNG-ONSET DEMENTIA: PAVING THE WAY FOR AN INTEGRATED CARE PATHWAY IN BELGIUM

[*KCE Report 395*](#)



Early-onset dementia is much less common than later-onset dementia, but it also comes with specific challenges. For example, atypical symptoms make the diagnostic process more challenging, the disease has a more profound impact on patients' professional, social and family life, and there is often a mismatch between (health)care services largely designed for an older population and the needs of these younger dementia sufferers. People affected by early-onset dementia need to have access to a coherent and integrated care pathway.

In this study, KCE formulates recommendations for the practical implementation of such a pathway. Rather than creating multiple pathways, it advises adapting resources that already exist for later-onset dementia to this specific population.

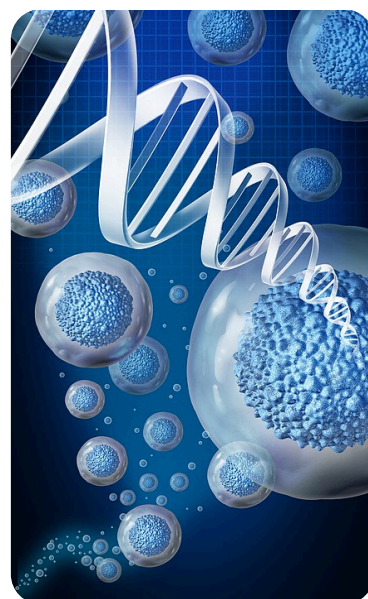
4 ACADEMIC DEVELOPMENT OF ATMPs IN BELGIUM – AN EXPLORATORY STUDY OF THE LEGAL AND STRATEGIC OPTIONS

[*KCE Report 396*](#)



Advanced therapy medicinal products (ATMPs) are complex therapies based on cells, genes or tissues; so far, they mainly target certain types of cancer or genetic diseases. Only a few ATMPs are currently marketed by commercial players, and they are often expensive, with a cost of up to several million euros per treatment. At the request of several Belgian cancer organisations, KCE examined how to optimise the role of Belgian universities in this field, with the aim of improving patient access to ATMPs.

To achieve this goal, it will be essential for both academic stakeholders and authorities to have cutting-edge expertise and to collaborate more closely. Furthermore, given that the development of such products can take many years, funding should cover a sufficiently long period and be less fragmented.



5 SPEECH/LANGUAGE THERAPY FOR CHILDREN WITH NEURODEVELOPMENTAL DISORDERS

[*KCE Report 399*](#)



Speech therapy sessions provided by individual speech therapists are currently not reimbursed for children with certain neurodevelopmental disorders: according to the federal health authorities, it is preferable to treat this specific population in multidisciplinary centres. However, parents and other stakeholders disagree with this arrangement, not least because there are considerable delays in accessing multidisciplinary centres and because these facilities are not well-distributed across Belgium.

KCE has examined which form of speech therapy is most suitable for these children and concludes that a multidisciplinary approach is clearly preferable for young patients with intellectual development disorders or autism spectrum disorders. It is therefore essential that the federal entities work to remedy the shortcomings in the provision of multidisciplinary outpatient centres and speech therapy in schools. In the meantime, the reimbursement of monodisciplinary speech therapy can be temporarily extended.

6 BELGIAN GUIDELINES FOR ECONOMIC EVALUATIONS AND BUDGET IMPACT ANALYSES: THIRD EDITION

[*KCE Report 400*](#)



In Belgium, cost-effectiveness is one of the criteria used by public authorities to assess applications for reimbursement of medicines and Class 1 medical devices, i.e. products for which the applicant claims added therapeutic value and for which a higher price may be charged. For other interventions as well (surgical procedures, vaccines, disease prevention strategies, screening programmes, etc.), economic evaluations and budget impact analyses provide valuable support for the efficient use of limited resources.

This guideline is the result of the second update of the KCE guideline on economic evaluations in health and budget impact analyses. The aim is to improve the relevance, methodological quality, transparency and consistency of these economic evaluations of health interventions in Belgium.



The goal of the NEED initiative is to assess patients' and society's unmet health-related needs in a scientific and structured way. This information, collected in a dedicated database, can then be used to inform innovation and healthcare policies to help them target the areas of highest need. Three new reports were published within this research programme in 2025.

7 NEED ASSESSMENT FRAMEWORK 2025: EU EXPERT CONSENSUS AND CORE VERSION

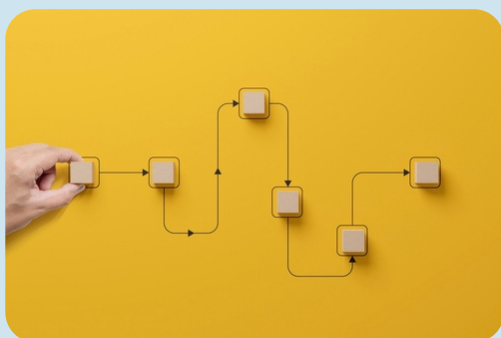
[KCE Report 401](#)



This new report presents the latest version of the framework used for the assessment of unmet needs, following a European consensus and an internal team discussion. It also introduces a core version of the framework containing the minimally required criteria for a meaningful assessment of unmet health-related needs.



8 PROTOCOL FOR NEED RESEARCH PROJECTS



[KCE Report 406](#)



9 NEED RESEARCH TOOLBOX



[KCE Report 407](#)



10 COST-EFFECTIVENESS OF NEW PREVENTIVE OPTIONS AGAINST RSV INFECTIONS IN BELGIAN INFANTS

[*KCE Report 402*](#)



Two new products have recently become available in Belgium to prevent respiratory infections caused by RSV in infants under one year of age: a vaccine administered to expectant mothers during pregnancy and an antibody administered directly to the baby. Their safety and efficacy had already been established, but their financial impact remained to be clarified. KCE and Antwerp University have carried out an analysis of the expected health benefits of both products, as well as an economic evaluation. They conclude the clinical impact of prevention strategies involving these products can be substantial, particularly for those using the injectable antibody. In addition, cost-saving prevention strategies or strategies with reasonable overall costs are possible with both products, provided that lower prices can be negotiated with the manufacturer.



The two prevention options discussed in this study were also the subject of two distinct KCE reports, intended to inform a Superior Health Council report:



11

Evaluation of Abrysvo® maternal vaccine against RSV infection in infants

[*KCE Report 397*](#)



12

Evaluation of nirsevimab against RSV infection in infants

[*KCE Report 398*](#)



13 SCREENING FOR PFAS EXPOSURE IN HUMANS

[*KCE Report 403*](#)



Hardly a week goes by without a news report about PFAS, pollutants that are widely present in our environment and to which we are all potentially exposed. Faced with growing public concern, policymakers and healthcare professionals feel a clear need to take action. However, to avoid doing more harm than good, it is important to know which measures or recommendations make sense. To help healthcare professionals provide the best possible support to people thought to have high blood levels of PFAS, the Interministerial Conference on Public Health has asked KCE to formulate national recommendations on the relevance of individual screening.

Based on current knowledge, KCE experts conclude that this screening is not appropriate unless it is part of scientific research. Advancing our knowledge of PFAS is, however, absolutely essential.



14 ORGANISATION AND FINANCING OF INTENSIVE CARE SERVICES IN BELGIUM

[*KCE Report 404*](#)



The COVID-19 pandemic has clearly demonstrated that intensive care is absolutely crucial... but it is also vitally important outside of a crisis context, for example after a transplant or a serious accident. However, capacity in this area is under pressure due to staff shortages and an ageing population. Belgium has a large number of intensive care beds, but care is fragmented, unevenly distributed and not always well aligned with care needs. KCE is calling for a two-tier structure covering general intensive care on the one hand and specialised intensive care on the other, with clear accreditation criteria.

Each intensive care unit should have at least 12 beds. Less complex and more appropriate funding and a single national database should improve collaboration, quality and efficiency. This reform is part of a broader overhaul of the hospital landscape.

15 PILOT STUDY ON A NEW PAYMENT SYSTEM FOR HOME NURSING

[KCE Report 405](#)



RIZIV/INAMI has developed a new model for financing home nursing care, in collaboration with the sector itself and with the mutualities. The new model aims to ensure a financing that is better aligned with the actual care needs of patients, while reducing the workload of nurses and promoting collaboration with other healthcare professionals. Initially, it will be tested in a pilot project, which will be evaluated by KCE. This report sets out the research protocol developed for this evaluation.

16 KCE PROCESS NOTE: QUALITATIVE RESEARCH METHODS

[KCE Report 408](#)

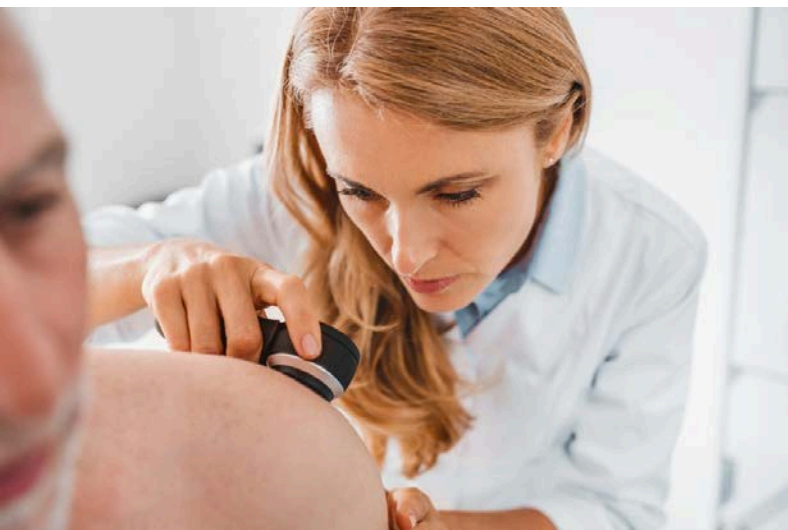


In the context of KCE research, qualitative methods can provide a deeper, more concrete understanding of the topic under investigation than purely quantitative data, as well as valuable insights regarding its wider context. Their aim is not just to describe, but also to obtain more meaningful explanations of a phenomenon. They can also be useful in generating hypotheses.

The first KCE process note on qualitative research methods (QRM) was issued in 2012, as part of a collection of methodological guidance documents. Thirteen years later, the time had come to revise, improve and develop the original process note to include recent evolutions and new experiences, and provide KCE researchers with up-to-date methodological guidance on qualitative research methods.

17 GUIDELINE FOR THE DIAGNOSIS, TREATMENT, AND FOLLOW-UP OF CUTANEOUS MELANOMA IN SECONDARY CARE

[*KCE Report 409*](#)



The incidence of cutaneous melanoma has been increasing for several decades, both in Belgium and worldwide. Fortunately, mortality rates have been falling in recent years, largely thanks to the progress of medical treatments. In some areas, however, clinical practice remains relatively variable, and greater harmonisation seems desirable in order to further improve survival rates. This is why KCE formulated a series of recommendations for medical specialists, covering seven areas identified as priorities by relevant stakeholders.

18 USING THE SCENARIO APPROACH IN KCE STUDIES

[*KCE Report 410*](#)



In order to inform decision-makers' choices, KCE is increasingly being asked to consider different possible developments in the field of healthcare. The uncertainties associated with these developments can be analysed using the scenario approach, i.e. coherent descriptions of plausible futures and the path(s) leading to these futures.

In this context, KCE has developed a step-by-step guide providing practical advice on the use of the scenario approach in KCE studies.

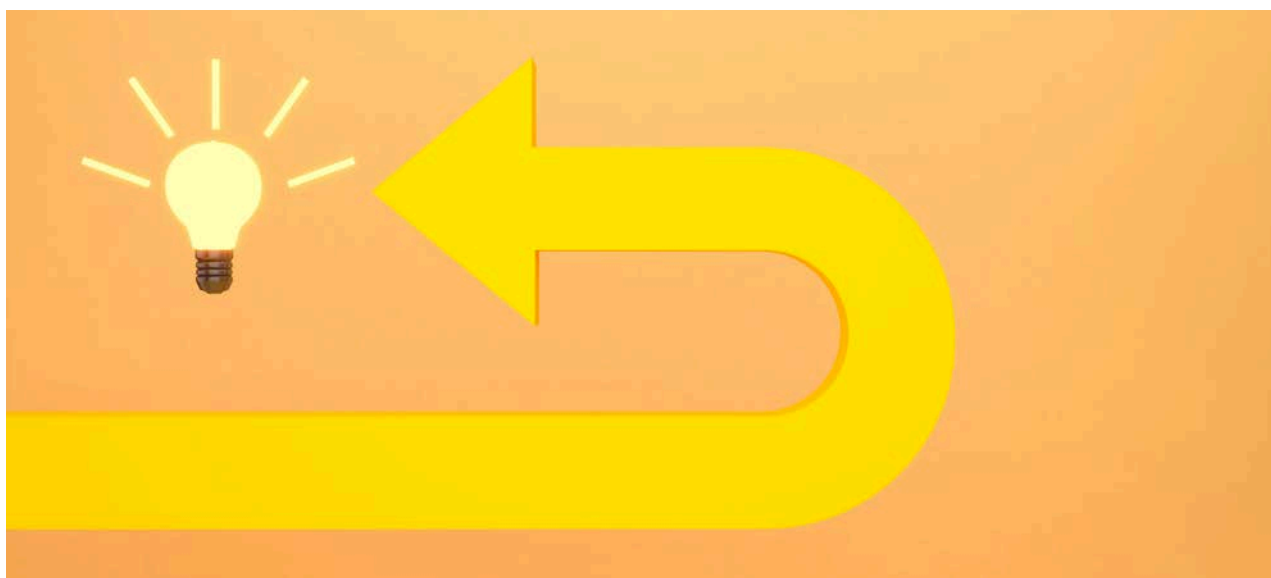


FOCUS ON METHOD REPORTS

Most KCE research projects relate directly to healthcare topics. However, it is also important for our experts to reflect on the way they work and to develop **methodological handholds** for future studies. This will ensure, for instance, that our economic evaluations follow certain common principles, or that qualitative data is collected in a similar way in all studies. The resulting reports, guidelines, manuals or process notes are made publicly available to all researchers in the healthcare and public health sectors... and they are much-used and much appreciated well beyond our own team!

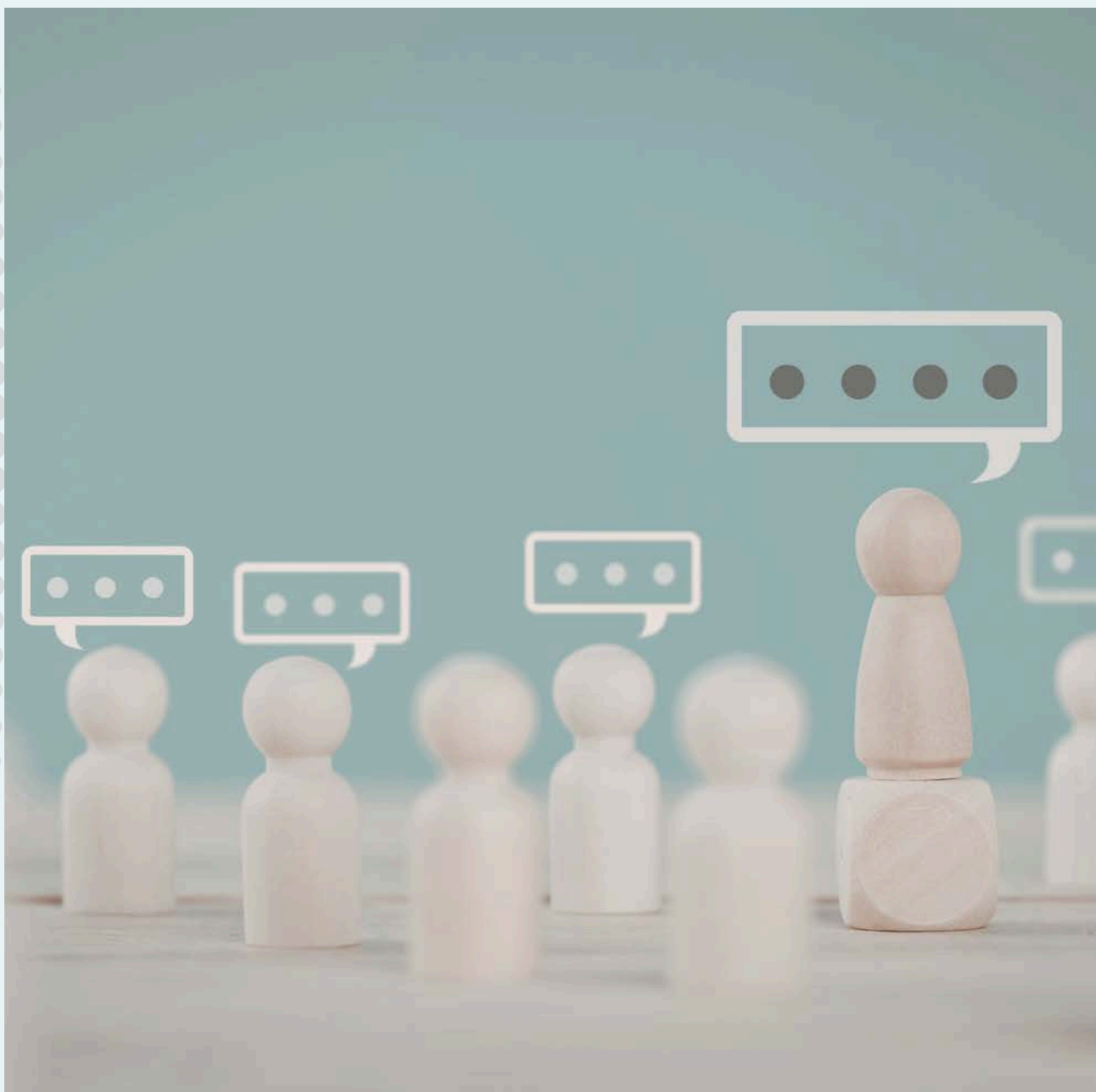
Many such manuals have been produced over the years about a wide range of topics, from stakeholder involvement to budget impact analyses over accelerated research methods. However, nothing is ever written in stone and these documents are often **revised and updated over time to ensure they remain useful and relevant**. 2025 was a particularly productive year in this respect.

KCE published a much-anticipated update to its “Belgian guidelines for economic evaluations and budget impact analyses” (KCE report 400), reviewed its process notes on qualitative research (KCE report 408) and clinical guideline development (KCE report 411, published early 2026) and devoted a new report to the use of future scenarios in research (KCE report 410). A toolbox and a common protocol were also developed specifically for NEED research projects (KCE reports 406 and 407).



We don't just think, we think about how we think

PATIENT INVOLVEMENT



PATIENTS AS PARTNERS IN THEIR OWN RIGHT

A clear divide between researchers and patients? That's not how we envision research at KCE. Directly or indirectly, the goal of our scientific work is always to improve the Belgian healthcare system for the benefit of the patients who need and use it... and to achieve this goal, we also need their contribution.

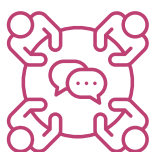


Patients can help our experts to refine their research questions or their data collection tools, share their insider's perspective on their disease, help them understand what really matters or identify game-changing interventions, support them in interpreting results, disseminate findings, etc. They bring a perspective that is both different and complementary to that of other stakeholders (healthcare professionals or institutions, mutualities, administrations...), which substantially enriches our projects and **strengthens their scientific quality, their relevance and their impact.**

Important note : in this context, patient involvement specifically refers to a direct participation in the research project, not to contributions like filling in a survey or taking part in an interview.

INVOLVED IN OUR STUDIES FROM PREPARATION TO BOARD APPROVAL

Three measures contribute to implement and reinforce patient involvement in our research activities:



Once a year, representatives of Belgian patient associations' umbrella organisations and mutualities come together to examine our **study programme for the following year** and assess the relevance of patient involvement for each study.

Our **Executive board**, which approves the recommendations of our reports before they are published, includes two representatives of patient organisations who are both entitled to vote (see page 15).



In 2024, KCE launched a **patient involvement cell** (see below), which is responsible for proposing new actions and improvements to reinforce our partnerships with patients.

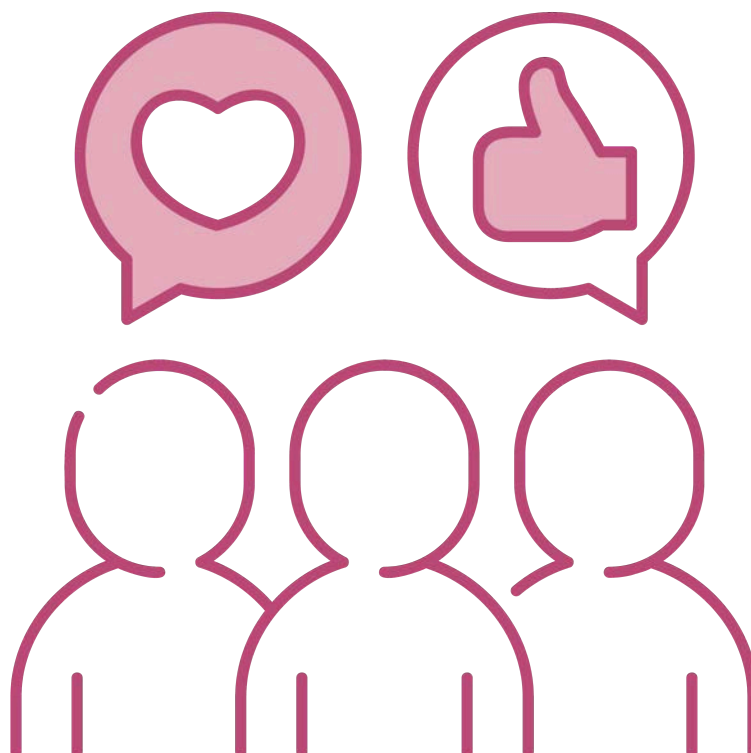
HOW DOES THIS WORK IN PRACTICE?

Depending on the specific needs of the study, patients can be consulted at a specific stage (this is known as targeted involvement, e.g. around the acceptability of our recommendations), or at multiple points during the study (this “integrated” involvement can include aspects like defining research questions together with our experts, refining tools or questionnaires, and much more).

The process always starts with a kick-off meeting, during which the team will present the project to the patients, clarify what KCE expects of them and discuss practical arrangements with them. This sometimes involves making adjustments to accommodate the needs and practical circumstances related to their disease; if required, a member of the patient involvement cell can act as a facilitator. A debriefing meeting is also organised at the end of the study.



Interested in taking part in a KCE study?
More information [here](#) (in French) or [here](#) (in Dutch)



IN 2025...

Patients were involved in a targeted way in:

- 3 HSR studies (report 394 on palliative care, report 395 on early-onset dementia, report 399 on speech therapy in neurodevelopmental disorders)
- 1 GCP study (report 409 on the clinical management of melanoma)
- **Study proposals stemming from patients or patient associations:**
- Out of 73 study proposals following our 2025 call (for the 2026 study programme), 7 were submitted by patient associations or their umbrella organisations, and 9 by patients or citizens (22%).
- Out of 15 study proposals selected and endorsed by our Board, 2 were submitted by patient associations or their umbrella organisations (13%).



THE PATIENT INVOLVEMENT CELL

STRUCTURED SUPPORT FOR MORE INCLUSIVE RESEARCH

Patients have been contributing to KCE research for over ten years already. Over time, our experts have refined and structured this approach through position papers, methodological guides and strengthened collaborations with the patient associations' umbrella organisations. Today, patient involvement is no longer an ad-hoc tool, but an integral part of our organisational culture.

In late 2024, an internal working group – the Patient Involvement cell – was created to answer a pressing need among our experts: **support and guidance for the concrete, consistent and methodologically sound implementation of patient (or patient representative) involvement in research projects.**

The cell includes researchers with **diverse educational backgrounds and expertise**, but also **programme managers** with an in-depth knowledge of KCE's research processes. Their combined skills ensure a transversal approach of patient involvement, taking into account methodological requirements, organisational constraints, the challenges of working with people who might be living with a disease or disability and KCE's primary mission of producing recommendations to support decision-making.

A DIVERSE AND EXPERIENCED TEAM



METHODOLOGICAL SUPPORT THROUGHOUT THE PROJECT

The main goal of the cell is to provide a **methodological support that meets the needs of the research teams** at every stage of the project. For example, it can help the researchers with :

- **Thinking things through before the project starts** : is patient involvement going to be relevant to this specific research? What would be its goals?
- Deciding on the most relevant **mode of involvement** (targeted or integrated).
- Clarifying the **roles and expectations** of both parties (researchers and patients).
- Identifying means of making patient participation truly **accessible and meaningful**.

This approach is in line with the KCE's long-standing conviction that **there is no single model for patient involvement**, but rather a variety of options to be adapted to suit the research questions, the available resources and the profiles of the patients involved.

The creation of the Patient Involvement Cell thus marks a new stage in KCE's commitment to more inclusive research, building on the initiatives implemented in recent years.

08

KCE TRIALS



KCE Trials is a programme for **non-commercial** clinical trials funded by the Belgian federal authorities. It supports comparative multicentre pragmatic effectiveness studies about aspects of health care that are usually neglected by the industry despite their high societal importance (e.g. comparing a change in lifestyle to a medication, comparing two types of surgeries, finding a new indication for a drug which is off patent), with a focus on potential return on investment. KCE Trials is responsible for the selection and funding of the included trials, but it does not conduct the trials itself. The sponsorship and coordination responsibilities fall to hospitals, universities and non-commercial research institutions.

2025 IN NUMBERS

3

CALLS FOR STUDIES

50

STUDIES ONGOING

9

CONTRACTS WITH BELGIAN RESEARCH TEAMS

4

**STUDIES PUBLISHED
THEIR RESULTS**



WANT TO KNOW MORE?

To be notified of calls for proposals and other news, subscribe to KCE's Trials [mailing list](#) or follow [KCE Trials on LinkedIn](#)

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

The [KCE Trials 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.

THE CLINICAL TRIALS FUNDED BY KCE ARE

NON-COMMERCIAL

they involve patients treated under real-life conditions (in hospitals, in the community, in nursing homes, etc.)

PRACTICE-ORIENTED AND FOCUSED ON CURRENT STANDARDS OF CARE

COMPARATIVE

they compare the efficacy of treatments which have previously been used but 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.

their data are made available for public interest research, e.g. to conduct detailed and independent cost-effectiveness studies.

A SOURCE OF DATA FOR OTHERS

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 health care 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), late 2022 (BeNeFIT-3) and late 2024 (BeNeFIT-4). The studies from the last call are still under selection.



ERA4HEALTH: NEW EUROPEAN FUNDING OPPORTUNITIES

KCE Trials has joined forces with 16 other EU funders to support multinational clinical studies in Europe. The scope is the same as KCE Trials', focusing on comparative effectiveness or the repurposing of old medication, but specifically for cardiovascular, metabolic or autoimmune diseases.

A new funding opportunity for Belgian researchers who want to take part in ambitious clinical studies!

Trials4Health 2026 Pre-announcement



"Multi-country Investigator-Initiated Clinical Trials in Cardiovascular, Autoimmune and Metabolic diseases"

#Trials4Health_E4H



ERA4Health
Partnership



Co-funded by
the European Union

DOING RESEARCH IS GOOD, SHARING IT IS BETTER!

While KCE trials' funding activities are essential because they allow clinical trials to happen, it is important to remember that the ultimate goal of these studies is to **generate scientific evidence** to help clinicians make the right decisions for their patients, to inform policymakers and regulation authorities, to feed further research, etc. This implies that results must be made public, no matter whether they show what the researchers were hoping to see or not: either way, this information can be relevant and important for others. If for example a treatment is not effective, not safe, or not cost-efficient, this is something we need to know!

Unfortunately, **a significant proportion of clinical trials will never be published**, often because their results are negative. As a result, the available evidence base is incomplete and potentially biased. In July 2025, KCE Trials officially joined the WHO initiative on clinical trials transparency, which aims to address this very issue: all signatory organisations (the list currently includes 24 medical research funders, including KCE Trials and its Dutch counterpart ZonMw) **commit to require all clinical trials they fund or support to be registered, and to disclose their results**.



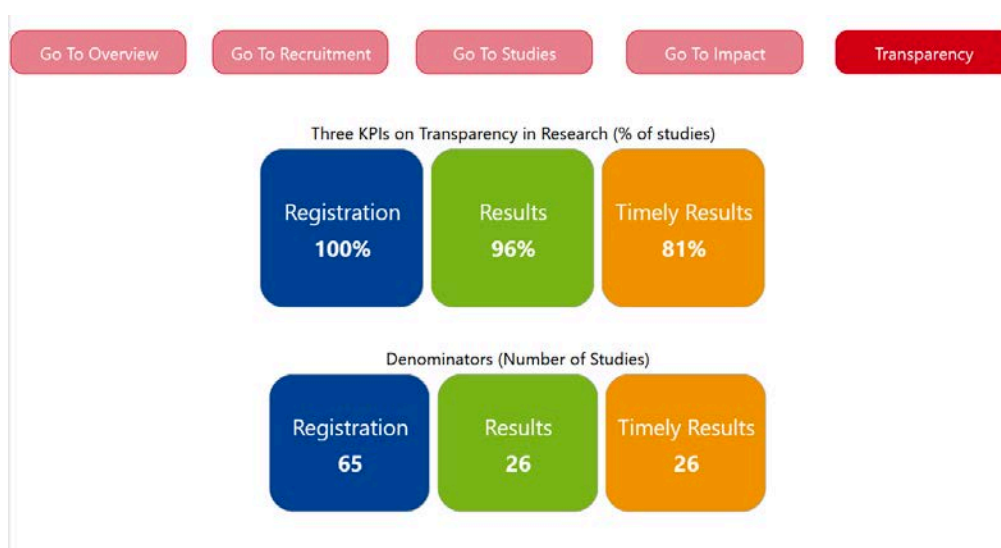
KCE TRIALS' COMMITMENT TO TRANSPARENCY

A first step towards joining the WHO initiative was taken in 2023, when KCE Trials published its first policy on clinical research transparency. This policy introduces a number of principles, which apply to all KCE Trials funding agreements signed from May 2023 onwards (though they can, of course, be followed by any study team on a voluntary basis). Particularly,

- All trials must be registered in a **publicly accessible database** before they start recruiting patients, and their study protocol must be added within six months. This information must be kept **up to date**, and a **summary of the results** must be made available on the same platform within 12 months of the end of the study.
- Results must be published in a **peer-reviewed, open-access journal or platform** as early as possible. As this is not wholly within the study team's control, the indicative timeframe is 24 months after the end of the study (in line with the WHO guidelines). KCE Trials' funding also covers costs for open-access publication. Published results should be actively **communicated to the parties involved in the study**, including participants..
- A detailed **clinical study report** including all study results must be made public on the KCE website within 24 months of the end of the study.
- The funding contract also includes arrangements for the **sharing and reuse of data** by KCE and by non-commercial third parties.

KCE Trials commits to **monitoring and reporting** on compliance with these obligations, and to taking previous instances of non-publication of results into account when selecting clinical trials for funding. It also provides a description of the trial, a lay summary and links to available documents on the **KCE website**.

A new section on transparency has also been added to the **KCE Trials dashboard**. It presents three key indicators relating to our transparency policy: the percentage of trials registered, of trials with results published and of trials with results published within 2 years after completion.



The KCE Trials Transparency Policy can be found on this page:
<https://kce.fgov.be/en/kce-trials/resources/kce-trials-policies-and-procedures>

COLLABORATIONS





IN BELGIUM

EVIDENCE-BASED PRACTICE

For the past several years, federal activities aiming to **promote evidence-based practice in Belgium** have been coordinated by the Belgian EBP network Evikey. Thanks to the joint efforts of Evikey and its partners, many healthcare providers have been trained in EBP, information tools have been developed, long-term effects have been evaluated, and strategies have been developed to facilitate the integration of scientific knowledge into practice.

In particular, the network provided healthcare providers with **validated practice guidelines**, available at the point of care through a single online portal (ebpracticenet), and with an access to a digital library (CDLH).

KCE was responsible for the coordination of Evikey's **prioritisation unit**, i.e. for organising and monitoring the selection of priority topics for the development or implementation of (clinical) practice guidelines.

Every year, KCE issued a call for proposals, assessed submitted topics based on scientific criteria, and discussed them with the key partners, the Advisory Committee and the Federal Steering Committee of the network. The topics with the highest scores were selected by consensus, taking into account the available budget. A public call for tenders was then launched for each topic by the Federal Public Service for Public Health.

MAJOR CHANGES IN 2026!



In June 2025, following an analysis, RIZIV/INAMI and the Federal Public Service for Public Health decided to significantly modify the organisation of EBP in Belgium. **As of 2026, all evidence-based practice activities that were previously coordinated by the Evikey network will be centralised within KCE.**

WHY CENTRALISE EBP ACTIVITIES AT KCE?

- To **strengthen the integration of EBP activities** within a single federal structure
- To ensure **optimal linguistic balance** in implementation
- To **harmonise coordination** between primary and secondary care
- To improve the **visibility, efficiency and impact** of EBP activities in the field

In 2025, KCE has drawn up a transition plan in consultation with its network partners to prepare for this change. The transition will take place gradually throughout 2026, with full implementation in 2027.

AN EVEN CLOSER COLLABORATION WITH RIZIV/INAMI AS OF 2025



RIZIV-INAMI

The National Institute for Health and Disability Insurance (RIZIV/INAMI) is not only KCE's main funder, but also one of its closest partners. Over the years, KCE has regularly carried out studies to support RIZIV/INAMI's work both upstream (e.g. to help define the best approach for a change of course or a new initiative) and downstream (e.g. to assess whether projects have achieved their goals or how they could be improved).

In 2025, this collaboration resulted in the launch of a dedicated study programme within KCE, the Evaluation Programme. It focuses on the evaluation of healthcare interventions introduced by RIZIV/INAMI, like e.g. new care programmes or care trajectories. It will not only assess whether an intervention was effective (i.e. effect evaluation), but also why the expected result was achieved or not, in which (sub)groups and in which context (i.e. process evaluation).

Report 405 – Pilot study on a new payment system for home nursing is a good example of this narrow collaboration: KCE has set up a protocol for a pilot study which assesses whether a new payment system for home nursing improves the focus on patients' care needs and whether the professional expertise of healthcare providers is better utilised.

HOSPITAL REFORM COMMISSION

The Belgian hospital sector faces major challenges, which are only set to grow: persistent staff shortages, an ageing population with increasingly complex care needs, rising costs and a historical fragmentation in the provision of services.

The Interministerial Conference (IMC) on Public Health commissioned an expert working group to examine how Belgian hospitals can continue to provide high-quality, affordable and accessible care within a ten-year timeframe. This group included a KCE expert.

In December 2025, the experts formulated a number of recommendations, for which a simulation tool developed by KCE provides a backbone. The tool maps the current healthcare provision and the accessibility of hospitals, and simulates how that landscape would evolve during the transition to the new model.





INTERNATIONALLY

KCE is involved in European and global expert networks. With its reputation for scientific rigour, it receives numerous collaboration requests from international consortia or working groups. KCE is an active member of the EU HTA Coordination Group and the Heads of HTA Agencies group, and takes part in various European initiatives around guideline development, pandemic preparedness, health system performance assessment, etc.

KCE is also 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 thorough analyses of the dynamics of health care 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.



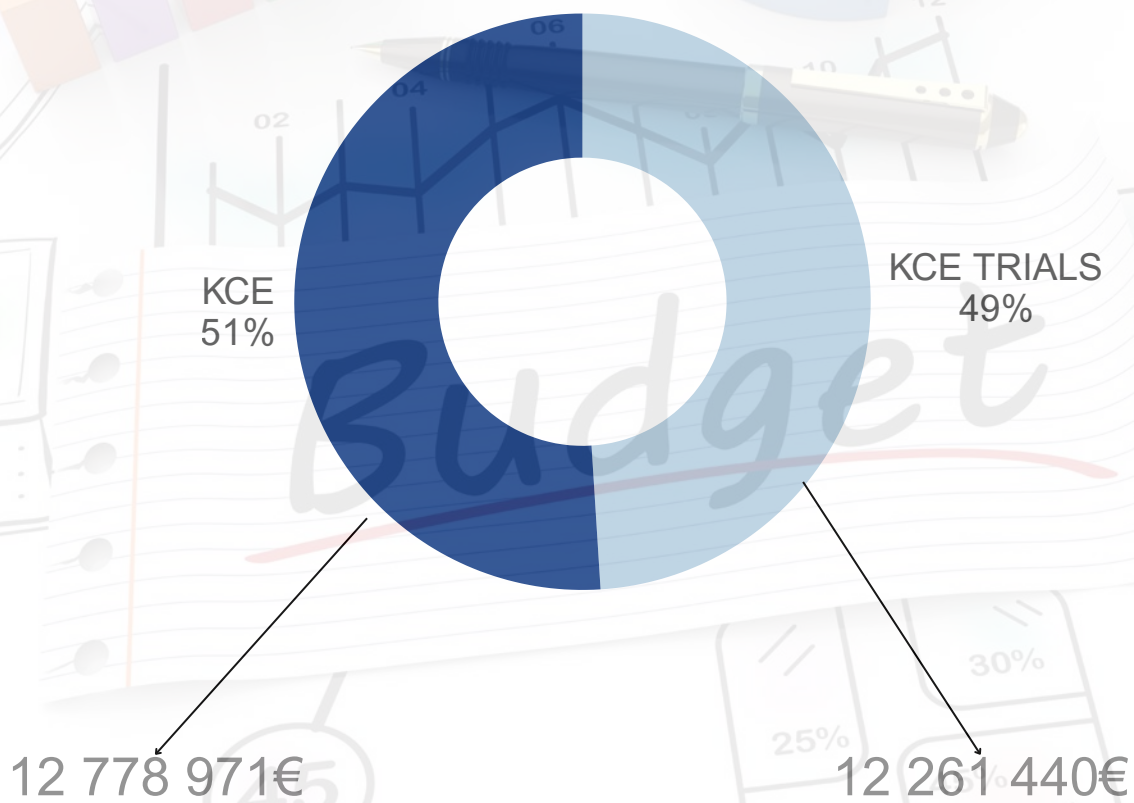
More about our international collaborations? Have a look on [our website!](#)

FINANCIAL STATEMENTS

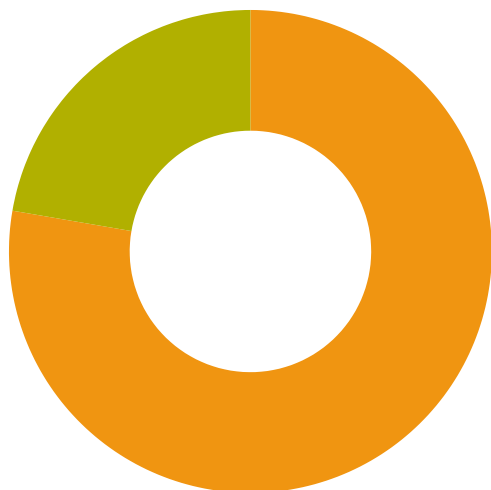


ANNUAL BUDGET

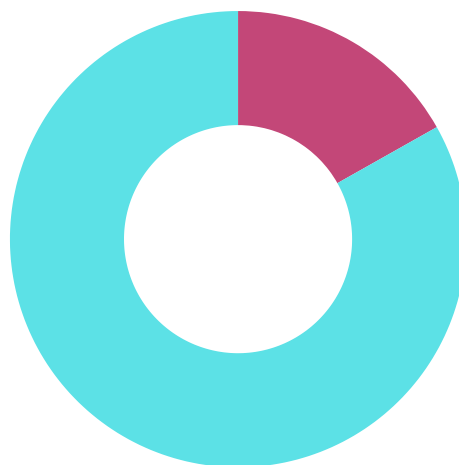
25 040 411€



- personnel
- studies & overall functioning



- personnel
- studies & overall functioning



BALANCE

	31/12/2024	31/12/2025
ASSETS		
TANGIBLE ASSETS	110 487	110 136
I. Formation costs		
II. Intangible assets	547	11 585
III. Physical Fixed Assets	92 734	81 345
A. Real estate and structures	37 355	21 287
B. Installations, machinery, and equipment	46 499	39 132
C. Furnishings and rolling stock	8 880	20 926
IV. Financial Fixed Assets	17 206	17 206
CURRENT ASSETS	21 308 519	18 972 638
V. Long-term receivables	1 943	0
B. Additional claims	1 943	0
VI. Equities		
VII. Claims payable within one year	139 418	237 234
B. Additional claims	139 418	237 234
VIII. Investments		
IX. Liquid Assets	21 009 122	18 411 891
X. Current Accounts	158 036	323 513
TOTAL ASSETS	21 419 006	19 082 774

	31/12/2024	31/12/2025
LIABILITIES		
EQUITY	6 326 394	6 324 099
I. Capital		
III. Revaluation surpluses		
V. Accumulated profits (losses)	6 322 341	6 326 394
VI. Investment grants		
PROVISIONS AND DEFERRED TAXES		
VII. Provisions for liabilities and charges		
AMOUNTS PAYABLE	15 092 612	12 758 675
VIII. Amounts payable after more than one year	0	0
IX. Amounts payable within one year	15 092 612	12 758 675
C. Trade debts	2 749 180	3 175 269
D. Advanced received on contracts in progress	3 453 901	866 478
E. Taxes, remunerations and social security		
1. Taxes		
2. Remunerations and social security	1 167 806	1 143 427
F. Other amounts payable	7 721 726	7 573 501
X. Deferred charges and accrued income		
TOTAL LIABILITIES	21 419 006	19 082 774

RESULTS

Income

Expense

		31/12/2024	31/12/2025
I. Operating income and generated fixed assets		24 859 594	25 151 674
E. Additional income		24 859 594	25 151 674
II. Operational Expenses		20 961 393	21 531 399
B. Services, diverse deliveries, and internal billing		10 224 769	10 014 379
C. Compensation, social security contributions, and retirement benefits		10 660 755	11 452 538
D. Depreciation and write-downs of fixed assets		75 869	64 482
III. Outcome of the operation		3 898 201	3 620 275
IV. Financial Returns		572	56 545
B. Opbrengsten uit vlottende activa			55 923
C. Additional financial income		572	623
V. Financial Expenditures		0	0
C. Additional financial expenses			
VI. Outcome of routine activities		3 898 773	3 676 820
VII. Extraordinary income		0	0
VIII. Extraordinary charges		3 894 720	3 679 115
E. Additional extraordinary expenses		3 894 720	3 679 115
IX. Financial Year Results		4 053	-2 295

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