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Belgium as clinical trial location in Europe

Research that reshapes care: clinical trials as a health system engine

Key results for 2024

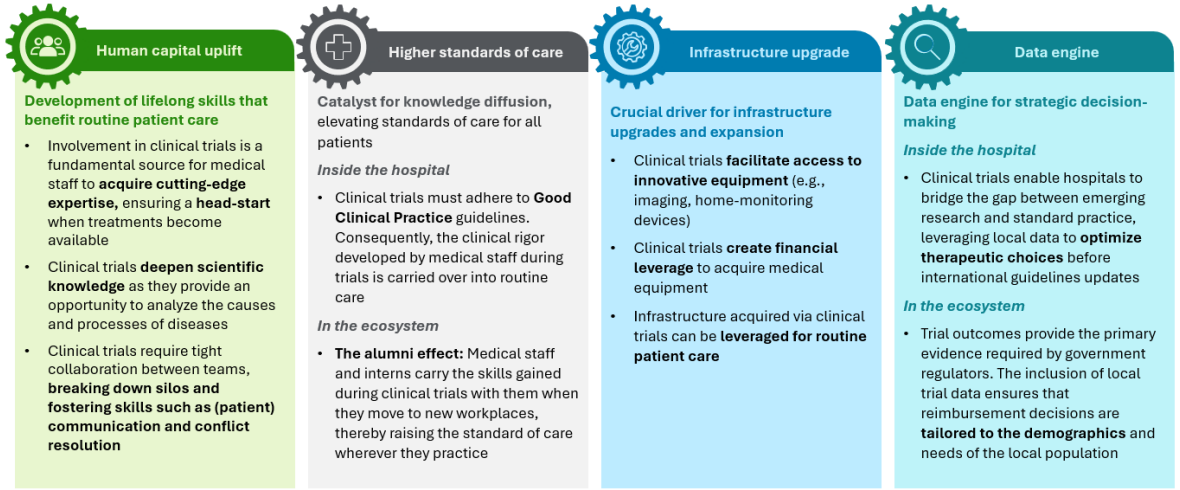
Table of content

Executive summary	3
Belgium as a clinical trial location in Europe	4
Research that reshapes care: clinical trials as a health system engine	16
Appendix	28

Executive summary

- A vibrant clinical trial environment is essential for advancing health, driving scientific progress, and sustaining a competitive position in the global healthcare landscape
- The implementation of the new EU regulation underscores the importance for Belgium to proactively monitor its historically robust clinical trials landscape and take actions accordingly
- South-East Asia continues its growth trajectory, and has surpassed the trial volume of Europe and the Americas
- Belgium has been ranked the 2nd country measured by clinical trial authorisations per inhabitant in the past 5 years, after Denmark. The Netherlands has entered the top 3
- While large variations between the selected countries are observed, Belgium holds its position as one of the leading European countries in terms of proportion of phase 1, despite a two-year decreasing trend
- An increasing decline in the overall number of CTAs is observed for Belgium, along with a decline in the absolute number of phase 1 trials and the absolute number of first-in-human studies
- Although the CTA volume in Belgium increased compared to last year, there is a small long-term decline in the overall number of CTAs, along with a decline in the number of phase 1 trials and stable number of first-in-human studies
- A wide variety of therapeutic areas was covered in Belgium in 2024 with the largest proportion for oncology trials. 32% of all Belgian CTAs is conducted in the domain of cancer. The increase in number CTAs for cancer (+13%) is higher than the total increase in CTAs (+12%) for Belgium when comparing 2024 to 2023
- Almost 24% of all CTAs in Belgium is conducted in the domain of rare diseases. The increase in number CTAs for rare diseases (+27%) is higher than the total increase in CTAs (+12%) for Belgium when comparing 2024 to 2023

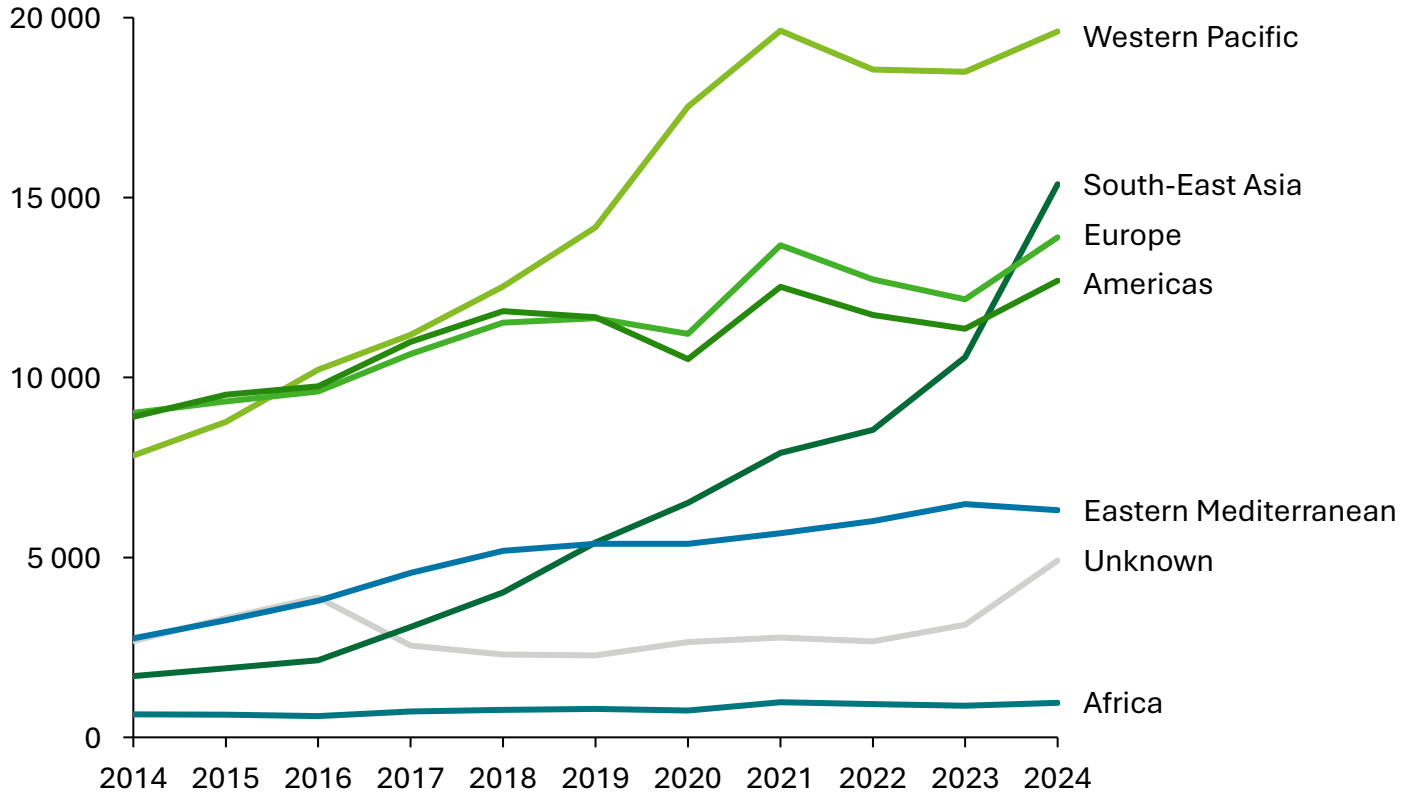
- Belgium holds a strong clinical trials footprint at European level with a relatively high percentage of clinical trials in Europe conducted in Belgium
- Strong regulatory, scientific expertise & quality of trials centres remain key drivers for the attractiveness of Belgium. Start-up timelines and the adoption of new technologies remain important attention points. Patient recruitment efficiency increases modestly
- The impact of clinical trials reaches much further than the patients directly participating. Clinical trials impact the regular healthcare system by upskilling the workforce, elevating standards of care, strengthening the hospital infrastructure and act as a data engine to facilitate decision-making



Global evolutions in clinical trials

South-East Asia continues its growth trajectory, surpassing the trial volume of Europe and the Americas

Number of interventional clinical trials by WHO region (2014-2023)



Dynamic shifts in clinical trials globally

The Western Pacific still stands out as the region with the highest number of trial registrations per year among WHO regions, with China taking a dominant position with more than 75% of trials in the region.

South-East Asia continues its growth trajectory. It is the only region able to consistently increase the number of clinical trials, mainly driven by India (+90% of the region's total). Multiple factors for this rise are identified including the ease of regulatory compliance, the low cost of conducting studies and a growing patient population.

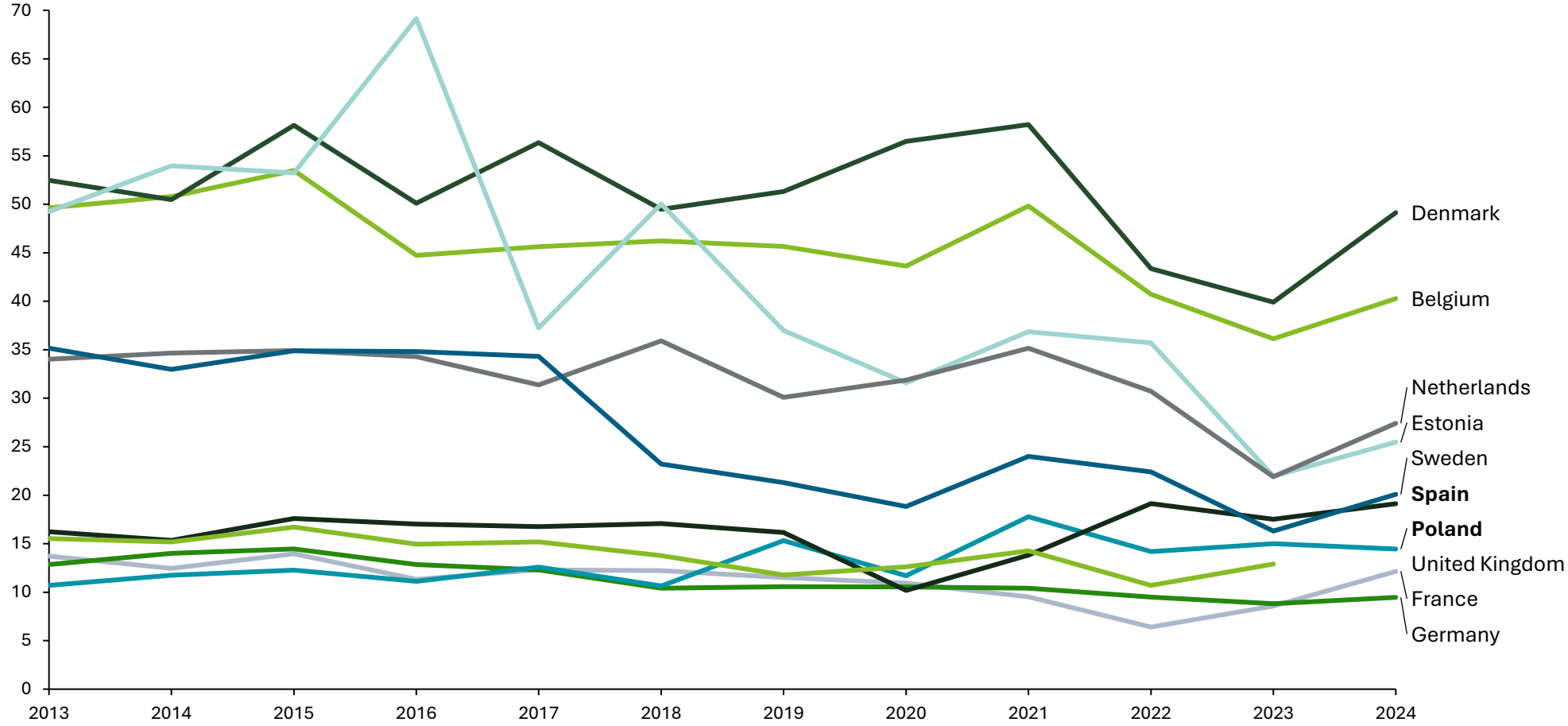
Americas and Europe, the two regions that had the highest trial volume in 2014, are now despite their growth compared to last year surpassed by Western Pacific and South-East Asia. Where clinical trial volume in the Americas is concentrated in a limited number of countries (United States, 82% of trials in the region; and Canada, 15% of trials in the region), clinical trials in Europe are more scattered across different countries (France, 19%; Germany, 18%; Spain 17%; Turkey, 16% United Kingdom, 15%; and Italy, 13%).

Source: : WHO (2026). Number of clinical trial registrations by location, disease, phase of development, age and sex of trial participants (1999-2024). Given that clinical trials are counted in the region (country) where they are conducted, multi-regional (multi-country) clinical trials are registered in multiple regions (countries) simultaneously.

Clinical trials

Evolution of clinical trial authorisations in selected European Countries: Belgium confirms its position in the top 2 for over a decade. The Netherlands enter the top-3

Evolution of CTAs per 1 million capita in cohort countries (2013-2024)

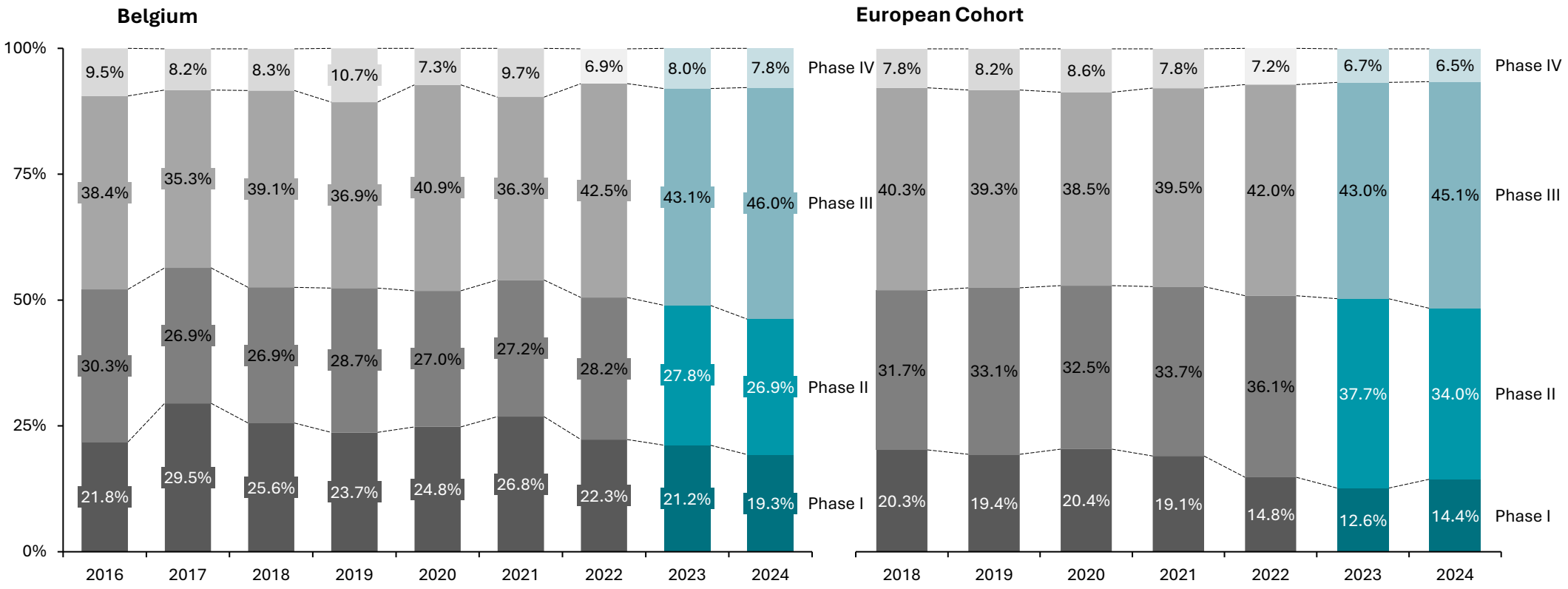


Source: Monitor Deloitte analyses based on FAMHP data and Eurostat; MHRA (2022). MHRA, Update October 2022 – Number of CTA assessed per month in UK (Jan-22 till Apr-22); MHRA (2023). Assessment of Clinical Trial Authorisation Applications and Substantial Amendments (Oct-22 till Sep-23); MHRA (2023). Assessment of Clinical Trial Authorisation Applications, Clinical Investigations and Amendments (Sep-23 till Oct-23); MHRA (2023). Assessment of Clinical Trial Authorisation Applications, Clinical Investigations and Amendments (Nov-23 till Dec-23)

Clinical trials in Belgium

The Belgian proportion of phase 1 is stronger compared to the European cohort, sign of remaining strong position in this field in Europe, despite a two-year decreasing trend

Percentage of CTAs per phase in Belgium (2016-2024) compared to European cohort (2018-2024)

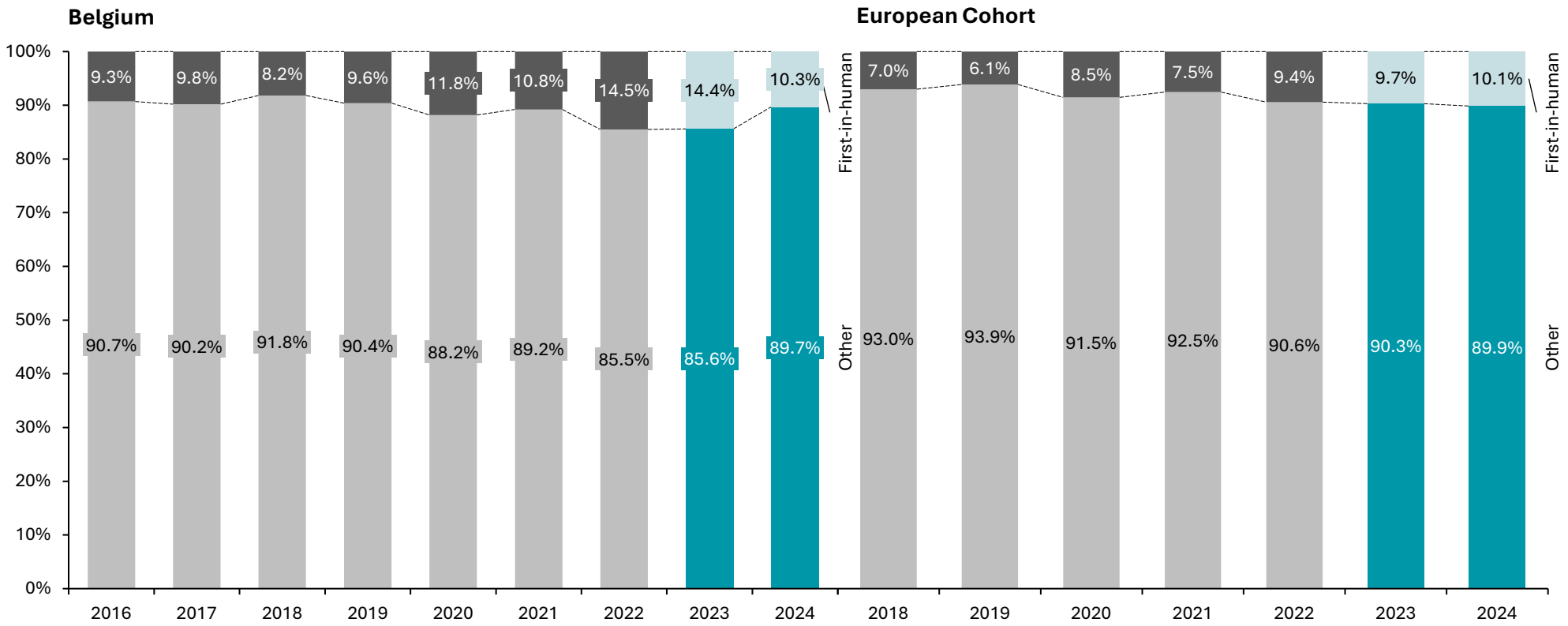


Source: Monitor Deloitte analyses based on FAMHP data; Since 2022 phase I/II clinical trials were taken into account as phase II trials, phase II/III trials as phase III trials and phase III/IV trials as phase IV trials.

Clinical trials in Belgium

The proportion of first-in-human CTAs in Belgium declined and is now at a similar rate as the European cohort

Percentage of CTAs that are first-in-human in Belgium (2016-2024) compared to European cohort (2018-2024)

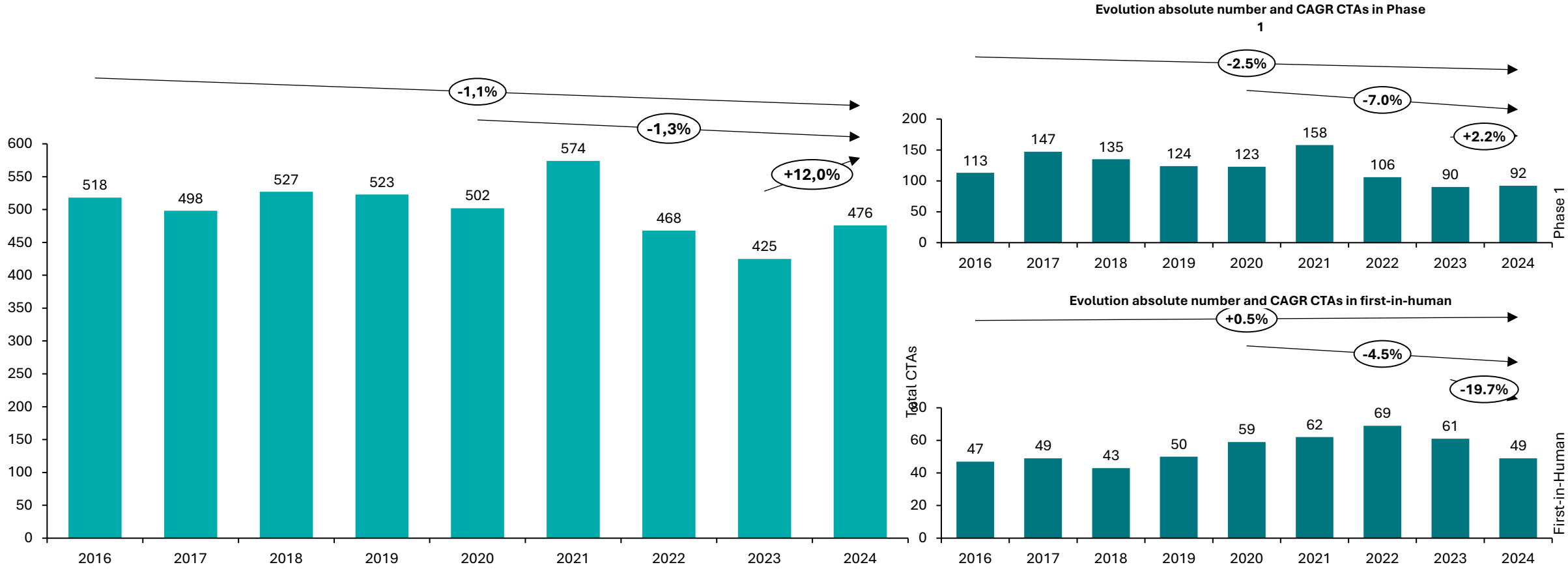


Source: Monitor Deloitte analyses based on FAMHP data and Eurostat; MHRA (2022). MHRA, Update October 2022 – Number of CTA assessed per month in UK (Jan-22 till Apr-22); MHRA (2023). Assessment of Clinical Trial Authorisation Applications and Substantial Amendments (Oct-22 till Sep-23); MHRA (2023). Assessment of Clinical Trial Authorisation Applications, Clinical Investigations and Amendments (Sep-23 till Oct-23); MHRA (2023). Assessment of Clinical Trial Authorisation Applications, Clinical Investigations and Amendments (Nov-23 till Dec-23);

Clinical trials in Belgium

A small decline in the overall number of CTAs, along with a decline in the number of phase 1 trials and stable number of first-in-human studies

Comparison of growth in CTA volume in Belgium, absolute number of all CTAs vs. phase 1 CTAs vs. first-in-human (2016-2024)

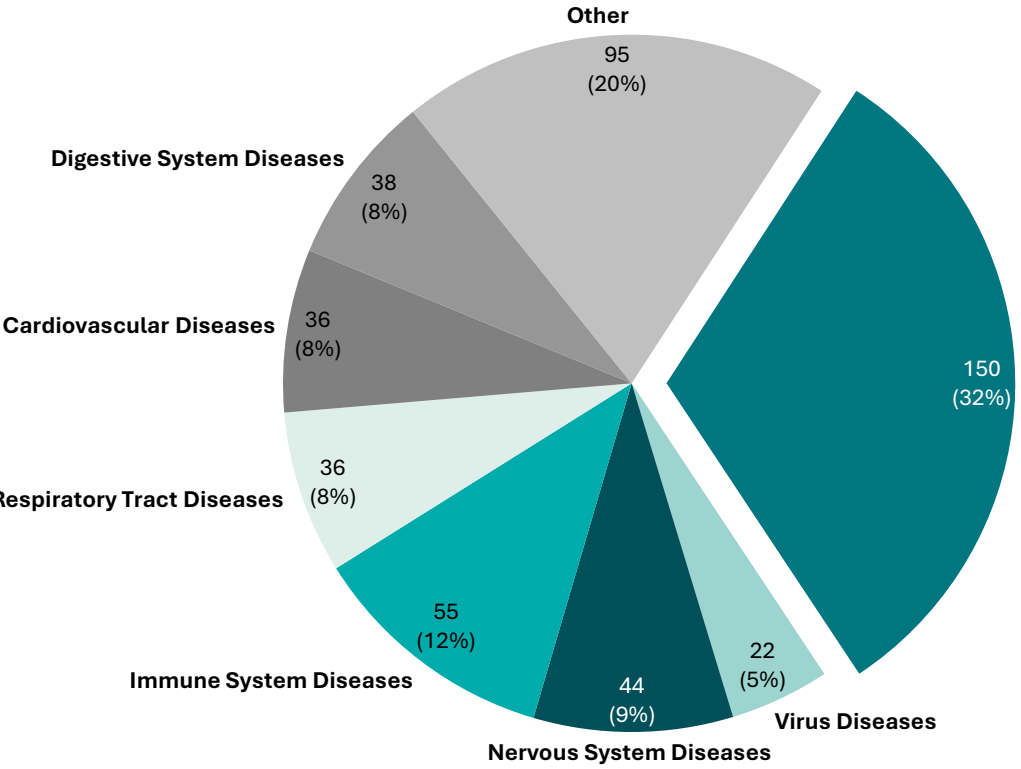


Source: Monitor Deloitte analyses based on FAMHP data

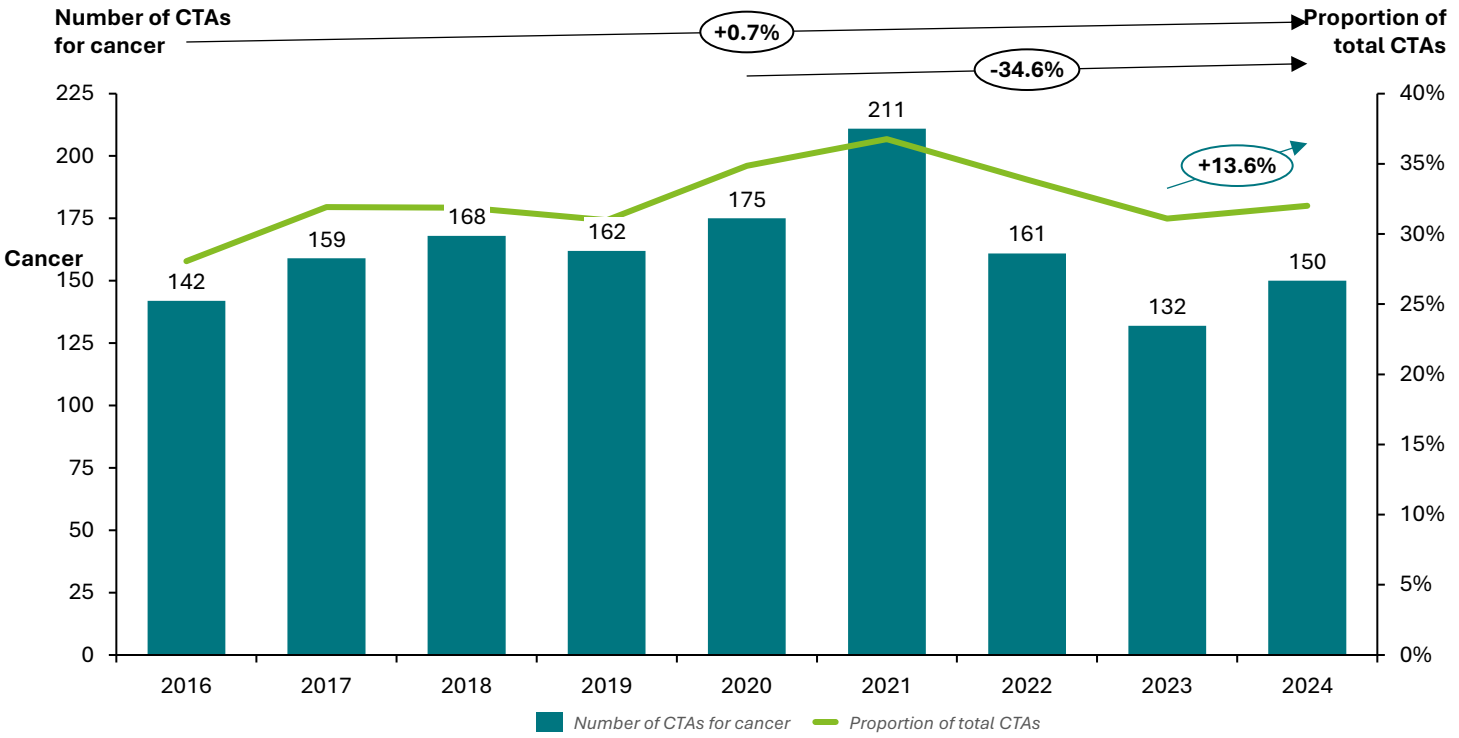
Clinical trials in Belgium

A wide variety of therapeutic areas is covered with stable long-term volume in oncology and an increase over the past year that is slightly higher than the increase in CTAs overall (13.6% vs 12%)

Proportion of CTAs for selected disease areas in Belgium (2024)



Evolution of CTAs for cancer in Belgium (2016-2024)

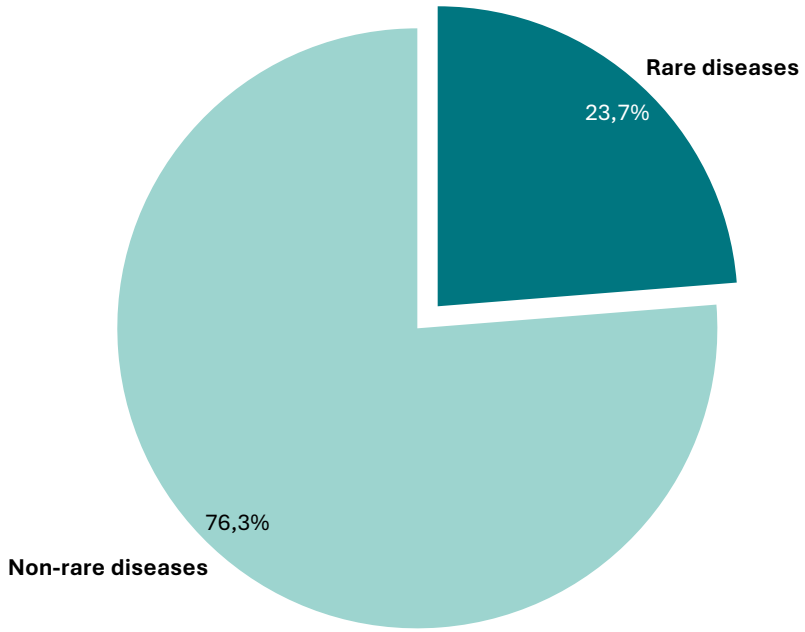


Source: Monitor Deloitte analyses based on FAMHP data

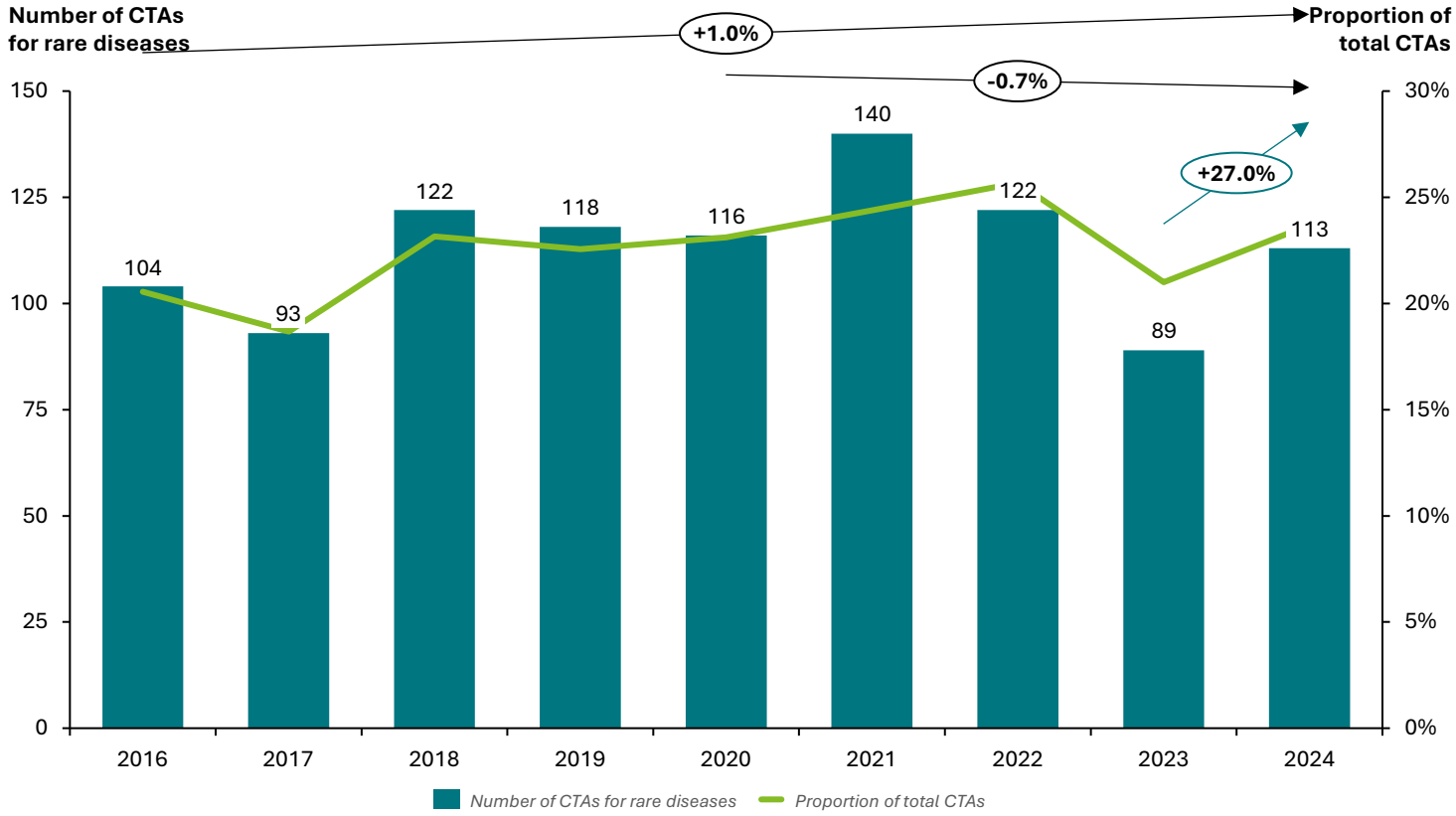
Clinical trials in Belgium

The long-term volume of CTAs in rare diseases is stable, with an increase over the past year that is higher than the overall increase in CTAs

Percentage of CTAs in rare diseases authorised by the FAMHP in Belgium (2024)



Evolution of CTAs for rare diseases in Belgium (2016-2024)

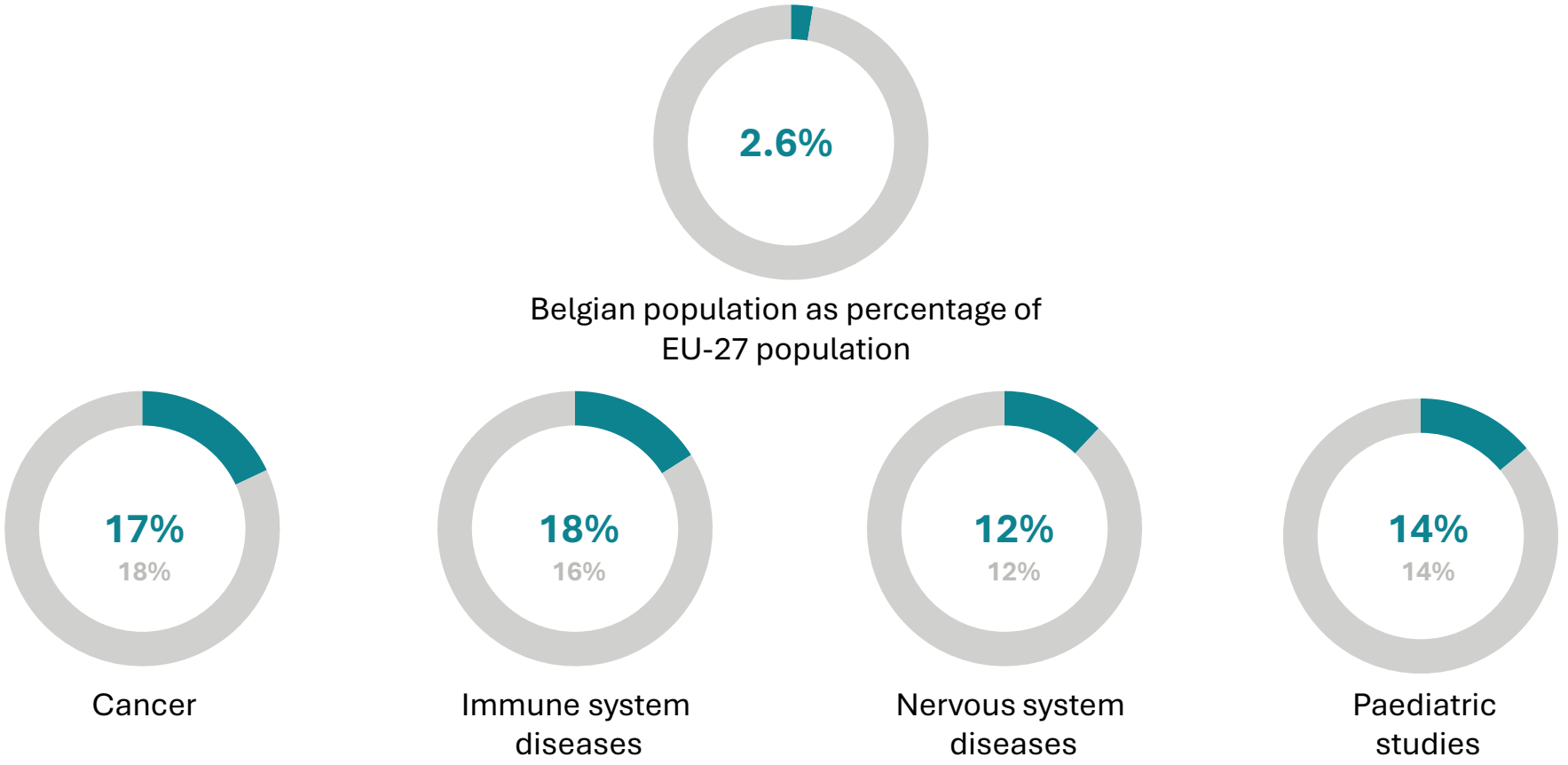


Source: Monitor Deloitte analyses based on FAMHP data

Clinical trials in Belgium

A strong clinical trials footprint of Belgium at European level with a relatively high percentage of clinical trials in Europe conducted in Belgium

Proportion of European clinical trials conducted in Belgium for selected type of studies compared to the proportion of the Belgian population in Europe (2024 vs 2023)

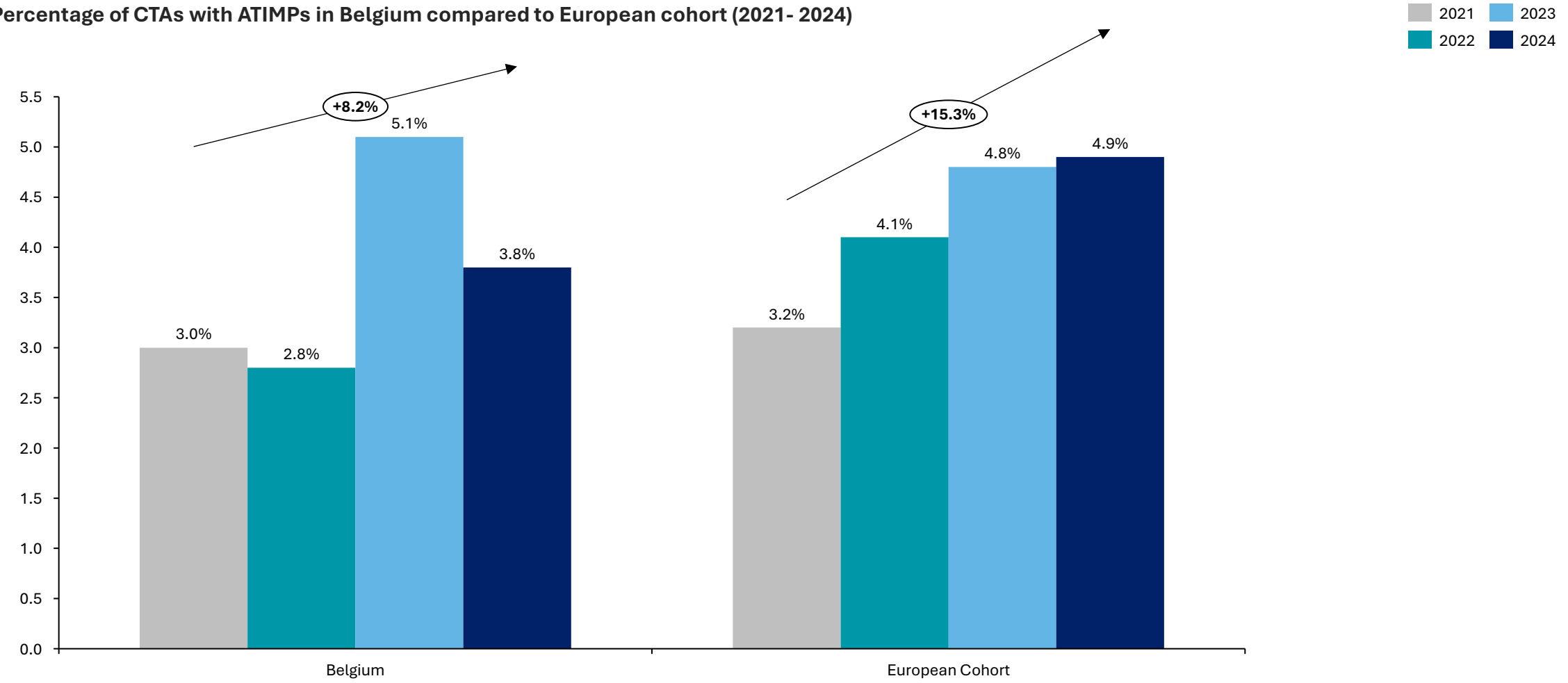


Source: Monitor Deloitte analyses based on FAMHP data

Clinical trials in Belgium

The annual growth of CTAs with ATMPs is higher in the European cohort compared to Belgium

Percentage of CTAs with ATIMPs in Belgium compared to European cohort (2021- 2024)



Source: Monitor Deloitte analyses based on FAMHP data

Attractiveness of Belgium as CT location

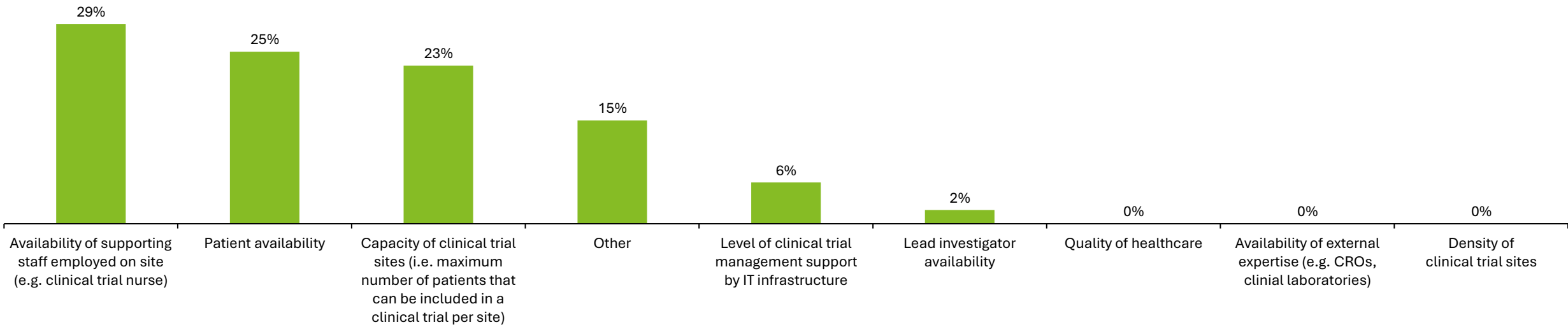
Pharma.be members report that more available supporting staff and patients could increase the Belgian clinical trial capacity

Self-reported average use of maximum operational clinical trial capacity in Belgium in 2024 (n=13)

66%

Last year: 67%

Self-reported ways Belgium could increase its overall clinical trial capacity (n=14)

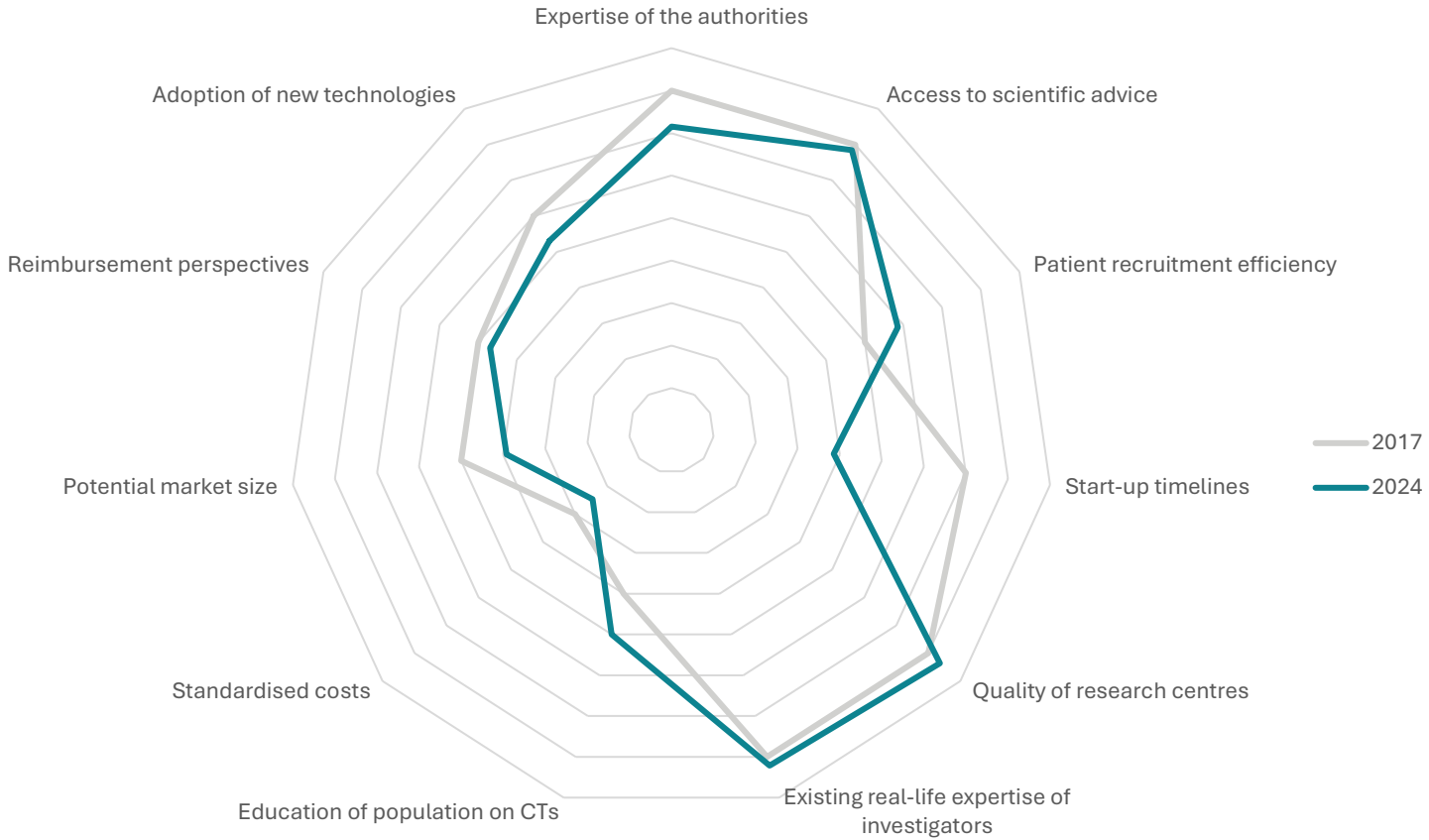


Source: pharma.be member survey 2024

Attractiveness of Belgium

The self-reported attractiveness for start-up timelines continues to decline while patient recruitment efficiency modestly increases

Average rate of Belgium on the following drivers for clinical trial location selection on a total score of 10 (2017-2024)



n=14

Source: pharma.be member survey 2017, 2024

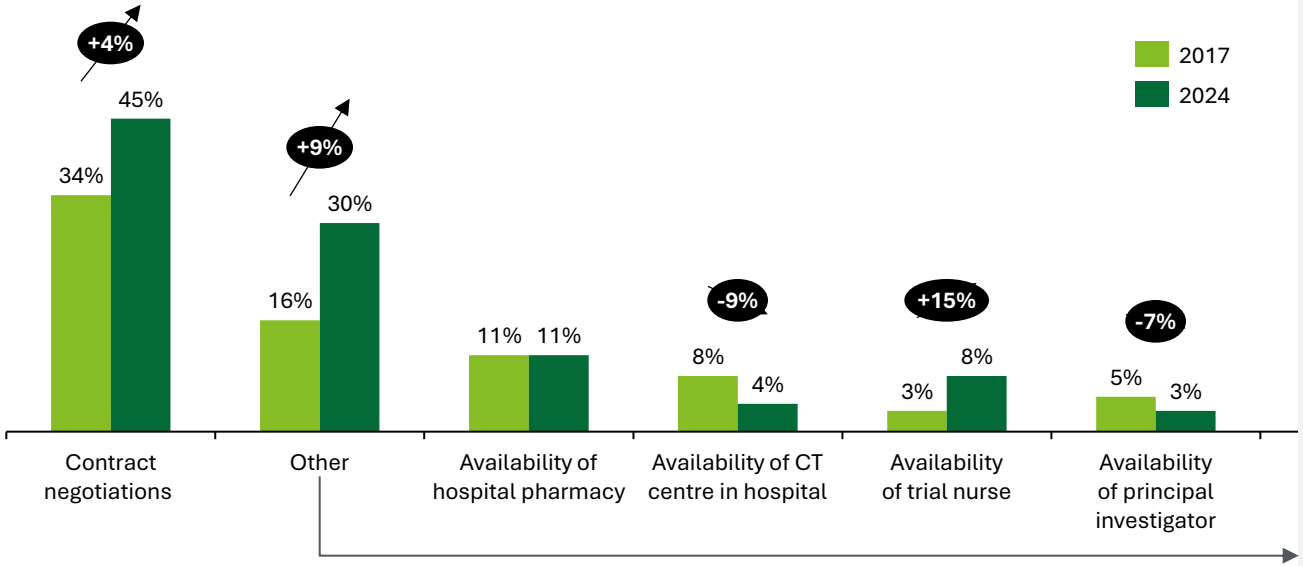
Delays in clinical trials in Belgium

Pharma.be members report that delays in clinical trials are primarily driven by complex contract negotiations and extensive patient recruitment (first patient, first visit)

What were the average timelines (in days) between the CTIS submission and the CTR approval (full regulatory approval, condition fulfilled) in 2024? (n=12)

126 days

Self-reported main reasons for delays in clinical trials in Belgium in 2024 (n=12)



Source: pharma.be member survey from 2017 and 2024

EU CTR
- Part II conditional approval
- RFIs

Administrative and Contractual Challenges:
- Differences between hospitals and departments causing difficulties for sponsors to be proactive
- High non-negotiable fees communicated late
- Time-consuming contract negotiations and legal reviews
- Receiving only conditional approval having consequences on study start-up

Training and Staffing Issues:
- Lengthy training of site staff
- Delays in site start-up due to incomplete trainings or delayed tests for certain procedures

Regulatory and Approval Process:
- Loss of the advantage of fast approval compared to the rest of the world
- Challenges with aligning EC comments and making them more predictable for sponsors
- Challenges with the Pharma.be contract template and legal wording alterations

Patient recruitment
- Delays in patient recruitment

Manufacturing
- Challenges related to manufacturing process

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Belgium as clinical trial location in Europe

Research that reshapes care: clinical trials as a health system engine

Key results for 2024

The impact of clinical trials on the regular healthcare system

Clinical trials impact the regular healthcare system by upskilling the workforce, elevating standards of care, strengthening the hospital infrastructure and act as a data engine to facilitate decision-making

Human capital uplift

Development of lifelong skills that benefit routine patient care

- Involvement in clinical trials is a fundamental source for medical staff to **acquire cutting-edge expertise,** ensuring a **head-start** when treatments become available
- Clinical trials **deepen scientific knowledge** as they provide an opportunity to analyze the causes and processes of diseases
- Clinical trials require tight collaboration between teams, **breaking down silos and fostering skills such as (patient) communication and conflict resolution**

Higher standards of care

Catalyst for knowledge diffusion, elevating standards of care for all patients

Inside the hospital

- Clinical trials must adhere to **Good Clinical Practice** guidelines. Consequently, the clinical rigor developed by medical staff during trials is carried over into routine care

In the ecosystem

- **The alumni effect:** Medical staff and interns carry the skills gained during clinical trials with them when they move to new workplaces, thereby raising the standard of care wherever they practice

Infrastructure upgrade

Crucial driver for infrastructure upgrades and expansion

- Clinical trials **facilitate access to innovative equipment** (e.g., imaging, home-monitoring devices)
- Clinical trials **create financial leverage** to acquire medical equipment
- Infrastructure acquired via clinical trials can be **leveraged for routine patient care**

Data engine

Data engine for strategic decision-making

Inside the hospital

- Clinical trials enable hospitals to bridge the gap between emerging research and standard practice, leveraging local data to **optimize therapeutic choices** before international guidelines updates

In the ecosystem

- Trial outcomes provide the primary evidence required by government regulators. The inclusion of local trial data ensures that reimbursement decisions are **tailored to the demographics** and needs of the local population

Understanding the impact of clinical trials on the regular healthcare system

Clinical trials are an engine for organizational development and systemic quality improvement within the healthcare system

Clinical trials represent far more than a mechanism for testing new therapeutic interventions. They are an **engine for organizational development and systemic quality improvement within the healthcare landscape**.

Research protocols, ethical standards, and regulatory requirements set high expectations for participating institutions, requiring them to maintain a gold standard of operational excellence.

This report examines the various ways clinical trials contribute to strengthening the healthcare system, organized around four key pillars:

1. **Clinical trials as human capital uplift**

   Refers to how specialized medical skills, multidisciplinary collaboration, enhanced communication, and critical-thinking acquired during trials benefit the broader non-trial patient population.

2. **Clinical trials for higher standards of care**

   Refers to how adherence to stringent standards, such as Good Clinical Practice, fundamentally raise the quality and rigor of patient care in the whole healthcare system.

3. **Clinical trials for infrastructure upgrade**

   Refers to how cutting-edge infrastructure mandated by clinical trials upgrades the overall capabilities of the hospital.

4. **Clinical trials as data engine**

   Refers to the systemic benefit derived from robust data produced in clinical trials and its influence on broader decision-making, treatment guidelines and policy.

sources: (1) medical doctor, Belgian hospital, (2) international pharma companies, (3) literature review (details).

Human capital uplift

Involvement in clinical trials is a fundamental source for medical staff to acquire cutting-edge expertise, ensuring a head start when treatments are authorized

Acquisition of cutting-edge technical knowledge

Involvement in clinical trials is a fundamental source for medical staff to acquire cutting-edge expertise. By working directly with innovative therapies and exploring new approaches to disease management, healthcare professionals expand their knowledge and clinical skills. This experience helps them develop competencies and familiarity with emerging treatment options[2].

Institutions involved in clinical research tend to adopt innovations more rapidly than those without a research focus[6]. This faster uptake is often attributed to the advantage gained by staff during trials, who acquire detailed product knowledge (including managing side effects and patient responses) before treatments receive formal approval.

Moreover, clinical trials in precision medicine require clinicians to use advanced technologies, such as intratumoural devices and microfluidic platforms, to monitor individual patient responses. This hands-on experience prepares staff for integrating these technologies into standard care practices.

Real-world examples

"Looking at CAR-T, its clinical trials did more than generate data. They trained our entire clinical system. Pharmacists and other specialists were fluent in its complexities long before launch because the trial network actively disseminated that critical knowledge" – *Professor at Belgian University Hospital*

"Staff who perform robotic procedures or use specific new biologics for example in inflammatory bowel disease have a significant starting advantage over those in non-research centers." – *Professor at Belgian University Hospital*

Human capital uplift

Clinical trials deepen scientific knowledge as they provide an opportunity to analyze the causes and processes of diseases

Deepening scientific knowledge

Clinical trials provide a valuable opportunity to enhance understanding of the fundamental causes and mechanisms of diseases. As researchers evaluate new treatments, they closely observe how these therapies interact with the body and the disease itself. This process yields deeper insights into the underlying biology of the condition.[3]

Real-world example

The scientific knowledge acquired during clinical trials frequently leads to unexpected scientific breakthroughs. For instance, studies conducted during clinical trials have been key to identifying the specific genetic mutations that drive certain types of cancer[3].

"Clinical trials are far more than just a testing ground for new drugs; they are the birthplace of tomorrow's medical standards. The objective scoring systems we were forced to develop for Crohn's disease during research have now become the gold standard for every single patient. Without these trials, we would have spent years struggling to implement these innovations manually; instead, research instantly elevates the level of care across our entire hospital community" – Professor at Belgian University Hospital

Human capital uplift

Clinical trials require tight collaboration between teams, breaking down silos and fostering skills such as (patient) communication and conflict resolution

Working with multidisciplinary teams

Clinical trials require close coordination among multiple teams and key stakeholders (such as sponsors, nurses, pharmacists, and data specialists) helping to break down traditional silos. This collaborative environment encourages medical staff to develop essential teamwork skills, including timely communication, conflict resolution, relationship-building, and navigating complex team structures.[12]

The structured collaboration in clinical trials fosters lasting multidisciplinary teamwork habits among medical staff. These skills enable more efficient implementation of coordinated care pathways, support shared decision-making, and help overcome the silos that often impede collaboration across the healthcare system.[1]

Real-world example

The need for collaboration is clearly demonstrated by essential role of the Clinical Research Coordinator, who serves as the primary liaison connecting all stakeholders involved in the trial[4].

"Within clinical trials , multidisciplinary meeting teams are frequently used for discussing trial protocol and patient care. This practice offers the advantage of promoting collaboration across different clinical and research departments, which is important for both trial execution and patient safety." – *Professor at Belgian University Hospital*

Enhancing interpersonal dynamics

Clinical trials enhance (patient) communication, relationship-building and presentation skills.

- Participation in clinical trials enhances medical staff's skills in patient communication. The informed consent process requires them to clearly and respectfully explain the potential risks and benefits of a study, ensuring participants' rights are fully respected[9, 12, 14].
- Presenting research findings publicly offers another professional development opportunity. This experience strengthens the ability to critically appraise evidence and organize it into clear, comprehensive presentations[12]. It enables medical staff to communicate medical information effectively and reliably across the healthcare system. Additionally, practicing these presentation skills can boost professional confidence and overall communication abilities.

Higher standards of care

Clinical trials is a catalyst for knowledge diffusion, elevating standards of care for (non-) trial patients

Knowledge diffusion across the entire hospital

The involvement of medical staff in clinical trials serves as a powerful catalyst for knowledge sharing, raising the overall standard of care across the hospital and benefiting both trial and non-trial patients:

- Participation in trials equips professionals with essential research skills and confidence, enabling them to become key sources of knowledge. They actively support colleagues and promote evidence-based practice[5], fostering a stronger, research-informed professional culture that enhances care standards hospital-wide.
- Clinical trials require complex collaboration across diverse medical specialties (such as oncology, neurology, radiology, and pharmacology) leading to the development of advanced scientific expertise. This knowledge strengthens clinical capabilities across multiple departments, directly improving the quality of care for non-trial patients.
- Knowledge diffusion extends beyond medical staff. Patients undergoing screenings receive information that improves their health literacy. Additionally, strategic partnerships with patient advocacy groups amplify these efforts, serving as a force multiplier for education and awareness around chronic diseases.

Real-world examples

"There is benefit in the initial trial screening process, even if a patient is not eligible. […] It increases patient knowledge about their condition."
– Pharmaceutical Professional

"Many immunosuppressive products required a strong, detailed vaccination schedule as an eligibility criterion for the study. This high-standard requirement has been adopted into the later standard of care for general practice" – Professor at Belgian University Hospital

Higher standards of care

Clinical trials must adhere to Good Clinical Practice guidelines. Consequently, the clinical rigor developed by medical staff during trials is carried over into routine care

Elevation of clinical rigor

Participation in clinical research demands a level of training rarely required in routine clinical practice, and this specialized rigor acts as a key driver of quality.

European and Belgian legislation require that clinical trials comply with Good Clinical Practice (GCP) standards. Additionally, trials must be conducted by a competent and qualified workforce[11, 17].

In Belgium, GCP knowledge is standardized through unified training programs, which are provided by the clinical trial centers of the seven Belgian university hospitals[10].

GCP (Good Clinical Practice) *sets the international ethical and scientific standard for research conduct and data integrity, establishing a non-negotiable floor of quality assurance in all research activities.*

Standards such as GCP support the development of specialized operational expertise. Research personnel acquire specific skills through applying these standards, which directly enhance clinical rigor.

Illustrative examples:

- The principal investigator is responsible for ensuring that all data reported to the sponsor is accurate, complete, legible, and timely. This requirement reinforces the ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, and Complete) as ingrained habits among medical staff[17]. These practices naturally extend to routine charting and documentation across the hospital, resulting in fewer errors and clearer, more comprehensive patient records.
- The management of investigational products demands strict accountability, including precise tracking of each study dose throughout its lifecycle, covering dispensing, storage conditions, patient use, returns, and resolution of discrepancies. This process reduces medication errors through increased vigilance. While the full rigor of a clinical study cannot be maintained in routine care, it fosters a critical mindset, particularly in relation to safety monitoring[17].

"The rigorous demands of the oncology study necessitate that our specialists, including neurologists and radiologists, adopt and perfect advanced techniques. This research-driven refinement raises our operational quality, a benefit that translates directly into improved standards of care for all our patients." – *Professor at Belgian University Hospital*

Higher standards of care

Medical staff and interns carry the skills gained during clinical trials with them when they move to new workplaces, thereby raising the standard of care wherever they practice

The “alumni effect”

The advanced skills medical staff gain through participation in clinical trials extend beyond research hospitals. Staff mobility acts as a powerful channel for spreading best practices throughout the healthcare system.

- Medical residents and interns who train in research-heavy environments absorb the culture of evidence-based rigor. When they rotate to other hospitals, they carry these habits with them, challenging (old) clinical practices and introducing higher standards of documentation and care.
- Many medical staffs operate in both public research hospitals and private clinics. A dermatologist running a trial on a new biologic agent in a hospital will often apply the same strict diagnostic criteria and monitoring protocols to their patients in private practice. This effectively raises the standard of care in the private sector, even if those patients are not enrolled in the trial.
- When nurses or study coordinators leave research to work in general care or other institutions, they take their GCP mindset (meticulous record-keeping, safety reporting, and protocol adherence) with them. This slowly cultures the broader healthcare workforce toward higher operational standards.

Real-world examples

“In oncology, a residents that treats 50% of their patients within a study context know the products/drugs when they leave the service. This knowledge translates into superior drug management and patient safety in future roles.” – Professor at Belgian University Hospital

“I've seen many residents leave who later send me letters where they've included all those [standardized reporting] scores. While not every practitioner always maintains this level of detail, on average, you raise the level of documentation across the system.” – Professor at Belgian University Hospital

“In gastroenterology, residents become perfectly capable of recognizing immune-correlated colitis, which allows them to diagnose and manage this complex condition swiftly in future patients that are not participating to a study” – Professor at Belgian University Hospital

Infrastructure upgrade

Clinical trials are crucial to acquire and facilitate access to innovative equipment, e.g., imaging and home-monitoring devices

Infrastructure upgrade and expansion

Clinical trials are a key driver of investment in advanced physical and diagnostic infrastructure. They require and enable access to specialized equipment, such as scanners or advanced home-monitoring devices. For instance, certain innovative therapies demand specific imaging capabilities. Some Alzheimer's therapies require PET scans for patient selection and MRI scans throughout the course of treatment[8]. While this equipment is primarily acquired to support clinical trials, it can also be used in routine patient care. This results in a lasting enhancement of the hospital's capabilities, ultimately benefiting the wider public[16].

Clinical studies also provide financial leverage that can be used for strengthening the hospital infrastructure, which ultimately benefits all patients.

Finally, ongoing collaboration with industry sponsors, such as medical device manufacturers, positions hospitals and the country to gain faster access to new technologies, an important advantage for current and future patients.

"If studies decrease, then people won't know Belgium anymore as a research center. This close relationship ensures faster access to innovation. This collaborative process is evident [...] in developing new techniques. Engineers sometimes stand behind me [observing], and a month later, we receive a new prototype."

– Professor at Belgian University Hospital

Data engine

Clinical trials enable hospitals to bridge the gap between emerging research and standard practice, leveraging local data to optimize therapeutic choices before international guidelines updates

Data system enhancement

The growth of decentralized trials and the use of AI tools are driving hospitals to modernize their Electronic Health Records (EHR) systems with standardized fields and automated workflows. While these improvements meet the rigorous demands of external clinical research, they also primarily benefit hospitals and routine care by providing medical staff with cleaner, more reliable data for everyday use. By reducing data fragmentation, these enhanced systems enable real-time internal audits and quality improvement initiatives, allowing patient outcomes to be monitored across departments with unprecedented accuracy.

> *"Easy access to IT tools and implementing a robust push to EHR eliminates data silos. This accessibility underscores the importance of having data readily available, allowing us to share critical insights across the healthcare ecosystem to improve patient outcomes."*
> *– Pharmaceutical Professional*

Local data informing medical practices and clinical guidelines

This digital maturity allows the hospital to move beyond generic protocols. When data systems are standardized, hospitals involved in research can quickly analyze their own patient outcomes to update medical practices and clinical guidelines, often ahead of standard international recommendations[6].

Clinical trial data provides the robust evidence necessary for hospital committees to make informed decisions about whether to adopt or exclude a therapy, ensuring care consistency across all departments. Complementary Real-World Evidence then helps contextualize these outcomes within routine clinical practice, providing a solid foundation for all decisions based on current evidence-based medicine[7].

Data engine

Hospitals engaged in clinical trials can refine clinical guidelines in real-time ahead of standard international updates

Shaping national policy and reimbursement

During drug development, clinical trials play a vital role in gathering robust data on a new treatment's effectiveness and safety. This evidence forms the cornerstone of the documentation required for regulatory marketing approval[13].

Locally conducted trials provide aggregated data that directly inform national healthcare decisions. The results serve as key evidence for organizations such as NIHDI when assessing reimbursement eligibility and allocating resources. Data collected from public hospitals offers valuable, real-world insights into how treatments perform across the broader national population.

Even when a drug has received international approval, public health authorities often require Belgian-specific real-world evidence. This makes trial-participating centers indispensable in generating the critical data needed to secure national reimbursement.

Real-world examples

"Clinical trials drive the creation and validation of objective scoring systems for disease activity, establishing global standards that leave a lasting legacy. For example, novel scoring methods for Crohn's disease and advanced radiographic assessments (developed out of necessity during trials) are now adopted worldwide." – *Professor at Belgian University Hospital*

"Our extensive experience in conducting a high volume of clinical trials is what empowers local experts to shape international guidelines. In fields such as immunology and oncology, Belgian specialists consistently 'punch above their weight' in setting global standards (an achievement rooted in this sustained trial activity). Yet, maintaining this influence depends entirely on our ongoing commitment; should our centers or country reduce trial participation, this hard-earned credibility will inevitably wane." – *Professor at Belgian University Hospital*

"The Sciensano rare disease registry has exceeded its initial aim of attracting clinical trials, evolving into a cornerstone not only for policymaking but also as a vital repository of expertise for symptom tracking, identifying diagnostic gaps, and disease awareness." – *Pharmaceutical Professional*

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Methodology

Data collection

Quantitative data used to assess Belgium as a clinical trial location in Europe was obtained from following data sources:

- Federal Agency for Medicines and Health Products (clinical trial authorisations)
- Eurostat (demographic statistics)
- pharma.be member survey

Regarding the impact of clinical trials on the regular healthcare system, information was gathered from different stakeholders: industry sponsors, academic researchers, hospital executives. This was done through semi-structured interviews as well as written communication and served as input to substantiate and nuance the observations described in the report. In turn, this allowed to explore concrete pathways to how clinical trials serve as an engine for organizational development and systemic quality improvement within the healthcare system.

Information verification

As it is crucial to ensure that observations and recommendation put forth in this report are accurate and correctly depict the situation in Belgium, PubMed database and grey literature were consulted to complement the information communicated in interviews.

Assumptions

A clinical trial is considered authorized if approved by the National Competent Authority. For the information on the phase and the non-commercial status of clinical trials in Belgium, available data in the FAMHP's internal database is used. The correctness of all figures depends on the quality of the data provided by the sponsors and the actions of all Competent Authorities to keep the European database up-to-date.

Disclaimer

As of 31 January, 2020, the United Kingdom no longer provides data to the European database. Consequently, the UK is excluded from the EU cohort.

As of 31 January, 2022, the EU Clinical Trials Regulation 536/2014 has replaced the EU Clinical Trials Directive 2001/20/EC. During the ongoing transition from the Clinical Trials Directive to the EU Clinical Trials Regulation, there may be some inconsistencies in the reporting of Clinical Trial Applications that have inadvertently occurred in the reported data.

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