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ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

Belgium as a Clinical Trial Location in Europe

Next-Gen Talent for Clinical Trials

Key results for 2023

22 January 2025

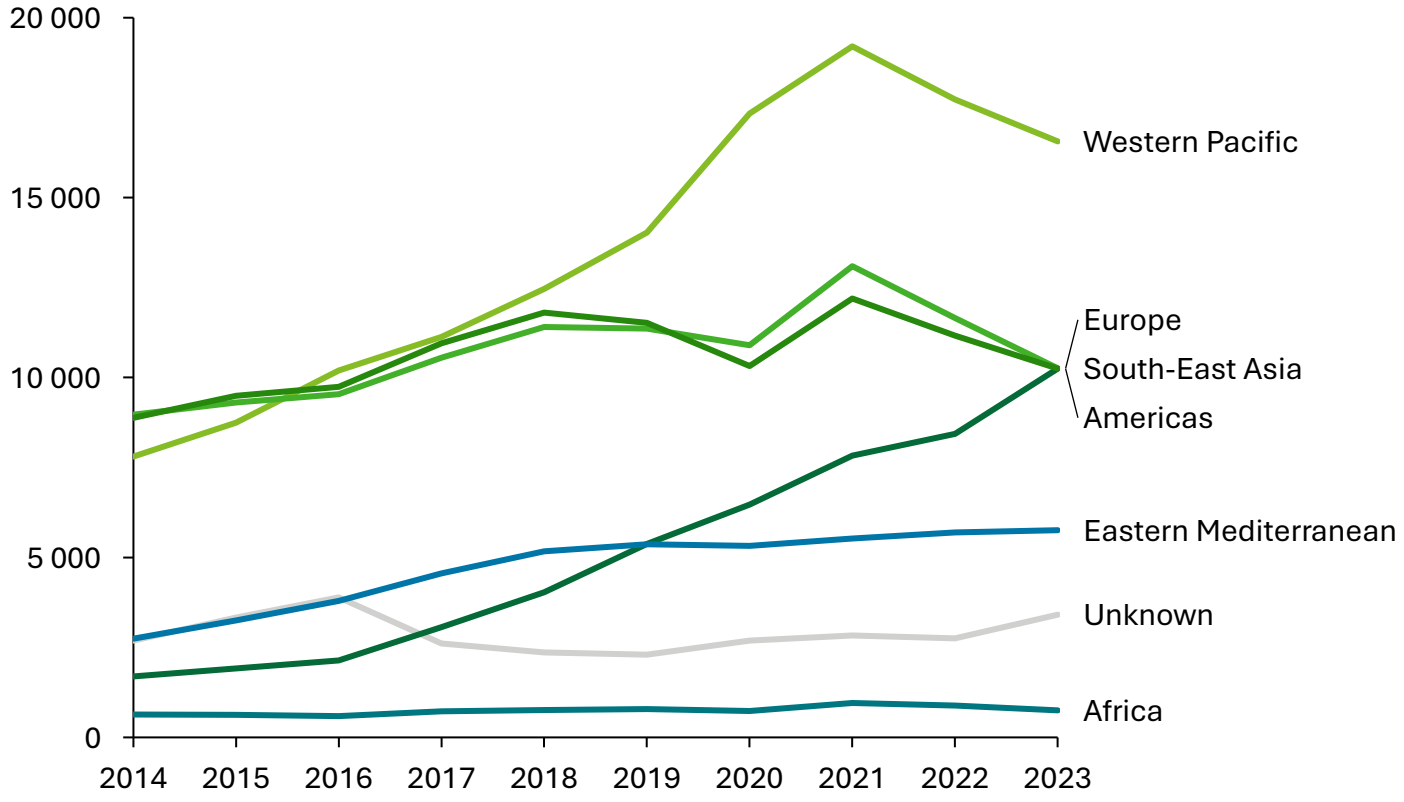
Executive summary

- 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, now having the same trial volume as 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. Only Spain and Poland demonstrate growth over the past decade
- 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 and first-in-human clinical trials
- 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
- A wide variety of therapeutic areas was covered in Belgium in 2023 with the largest proportion for oncology trials. 31% of all Belgian CTAs is conducted in the domain of cancer. However, the decrease in number CTAs for cancer (-18%) is higher than the total decrease in CTAs (-9%) for Belgium when comparing 2023 to 2022
- 21% of all CTAs in Belgium is conducted in the domain of rare diseases. The 5-year CAGR is showing a decreased volume of CTAs for rare diseases (-7%) in Belgium after a period of stable volume
- 3% of all CTAs that are conducted with a paediatric investigation plan. The 5-year CAGR is in decline due to a sharp decrease between 2022 and 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
- Trends and innovations transforming the pharma clinical trial landscape, requiring a gradual transition of today's talent pool towards future required skills and competencies such as real-time protocol adaptation, applying advanced genomics, and managing hybrid trial models
- Eight potential new roles are identified as clinical trial workforce of the future:

Global evolutions in clinical trials

South-East Asia continues its growth trajectory, now having the same trial volume as 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 (50% of total region), Japan (25% of total region) and Australia (16% of total region) taking on most of the trial volume. The decline that started in 2021 continues at the same pace over 2022 and 2023.

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 (83% of the region's total) and Thailand (15% 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.

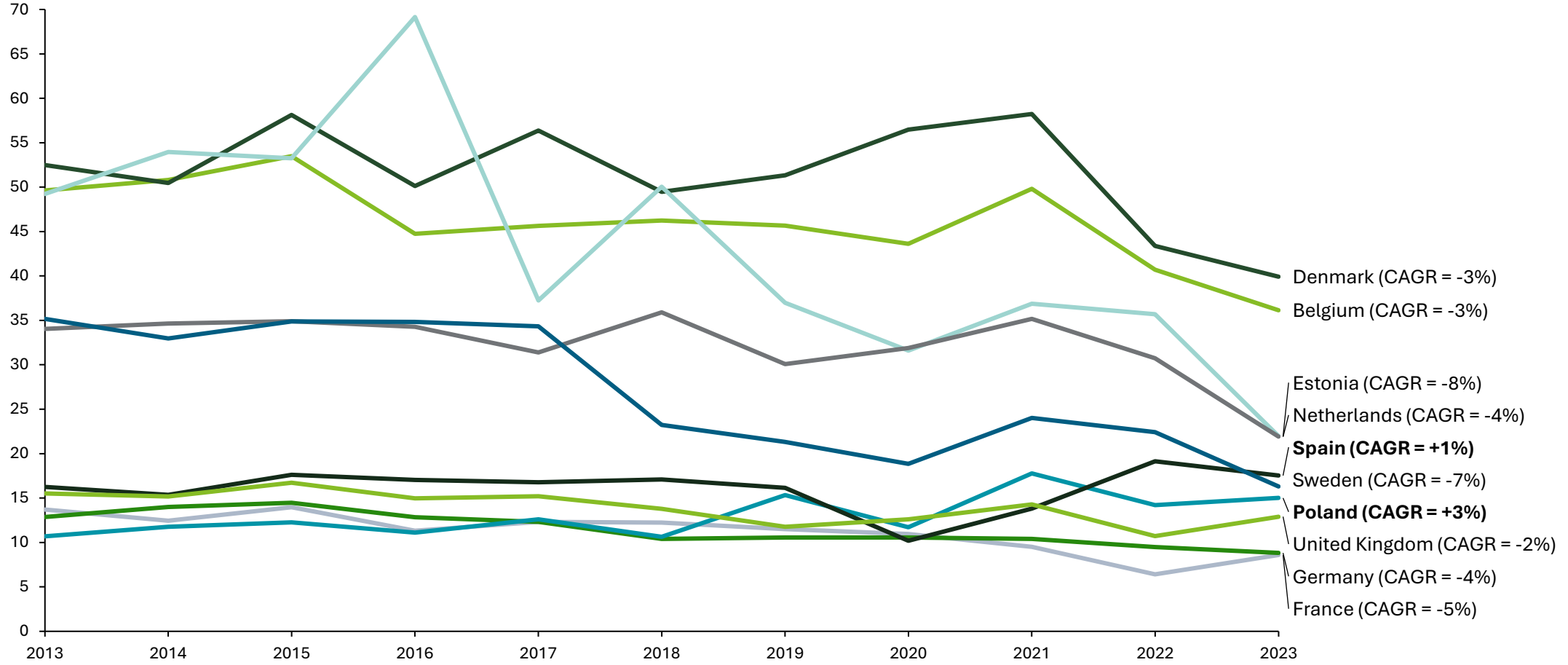
The rise of clinical trials in South-East Asia combined with the decline of trial volume in Europe and the Americas results in a now almost identical number of clinical trials conducted in these regions. Where clinical trial volume in the Americas is concentrated in a limited number of countries (United 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 (Germany,21%; France, 20%; Spain 19%; United Kingdom, 18%; and Italy, 16%).

Source: : WHO (2025). 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 5 consecutive years

Evolution of CTAs per 1 million capita in cohort countries (2013-2023)

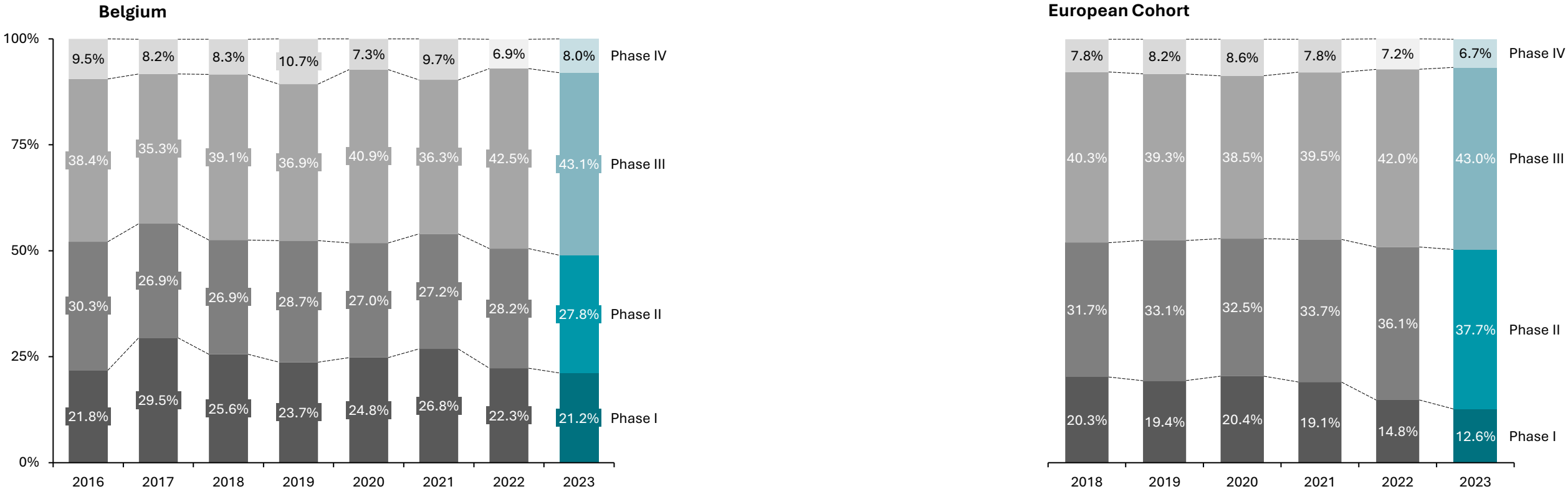


Source: Monitor Deloitte analyses based on FAMHP data and Eurostat; MHRA (2022). MHRA, Update October 2022 – Number of CTA assessed per month in UK (Jan-22 till Apr-22); MHRA (2023). Assessment of Clinical Trial Authorisation Applications and Substantial Amendments (Oct-22 till Sep-23); MHRA (2023).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

While large variations between the selected countries are observed, Belgium holds its position as one of the leading European countries for phase 1 clinical trials

Percentage of CTAs per phase in Belgium (2016-2023) compared to European cohort (2018-2023)

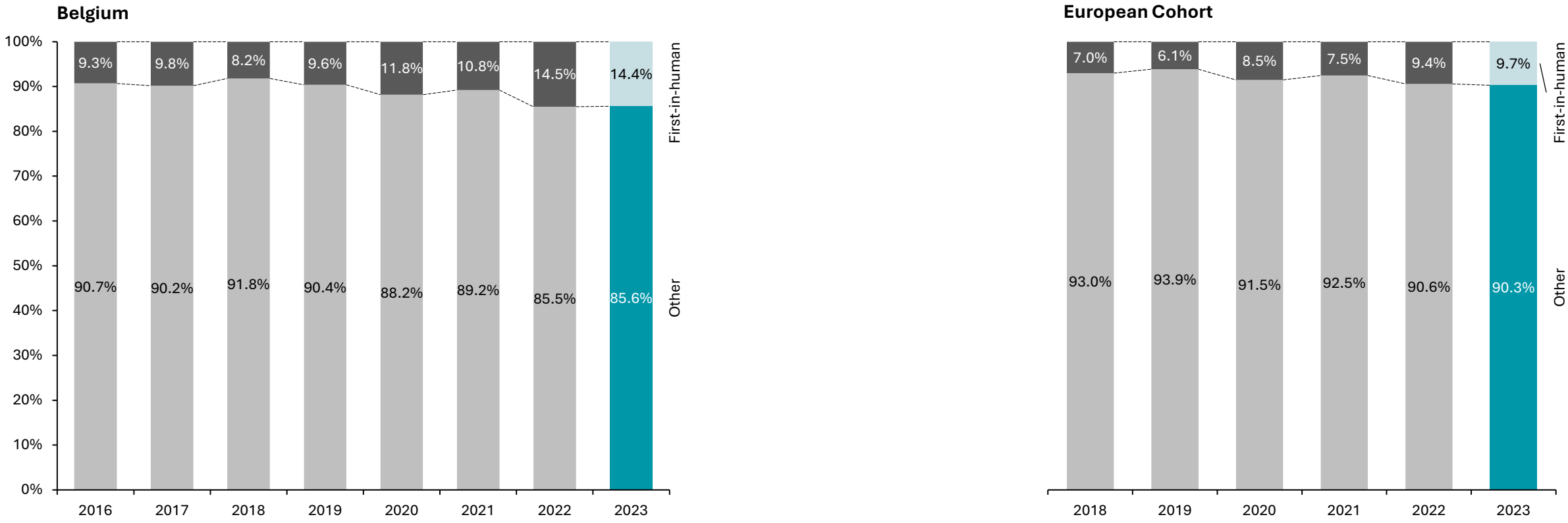


Source: Monitor Deloitte analyses based on FAMHP data

Clinical trials in Belgium

The proportion of first-in-human CTAs in Belgium is increasing over time and remains stronger compared to the European cohort

Percentage of CTAs that are first-in-human in Belgium (2016-2023) compared to European cohort (2018-2023)

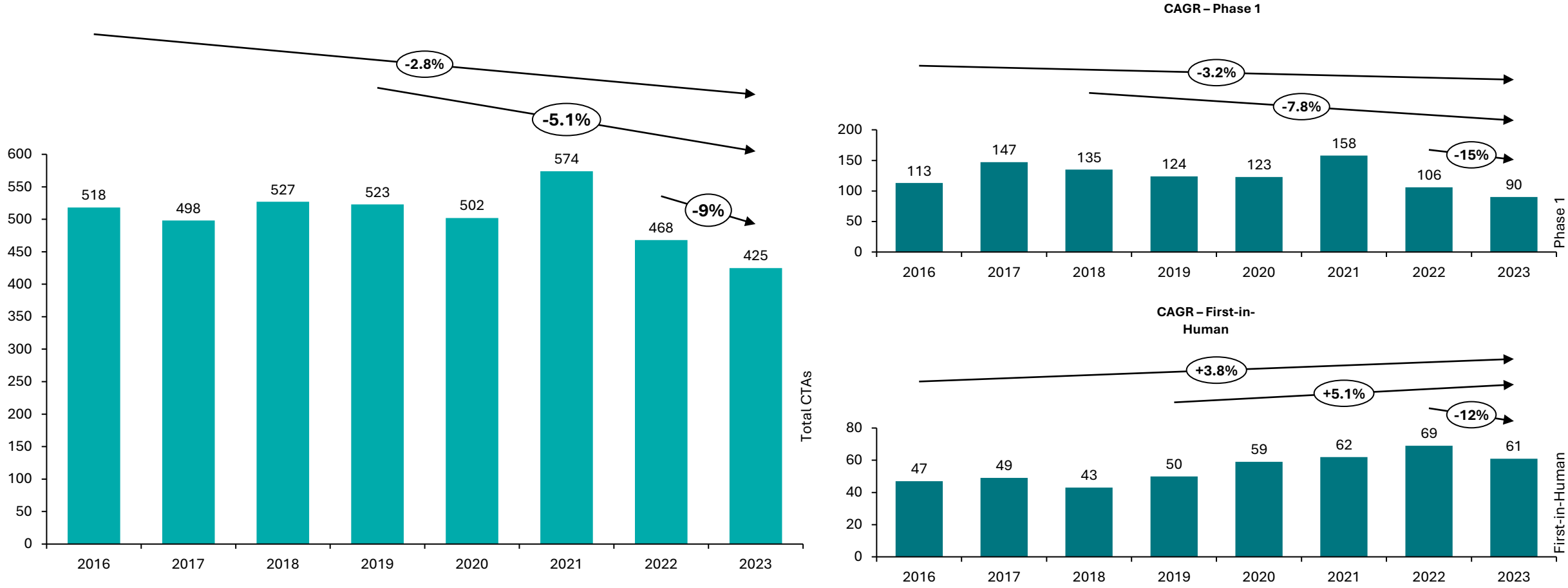


Source: Monitor Deloitte analyses based on FAMHP data

Clinical trials in Belgium

An increasing decline in the overall number of CTAs, along with a decline in the number of phase 1 trials and 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 (2016-2023)

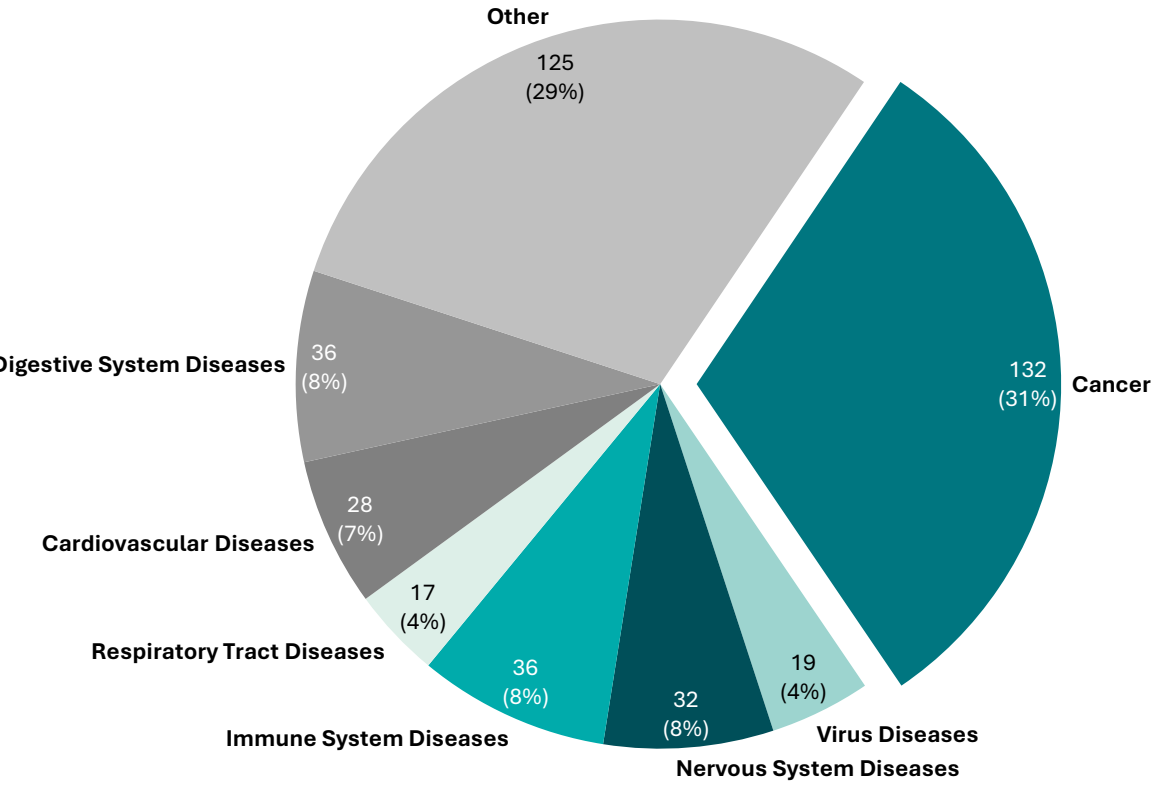


Source: Monitor Deloitte analyses based on FAMHP data

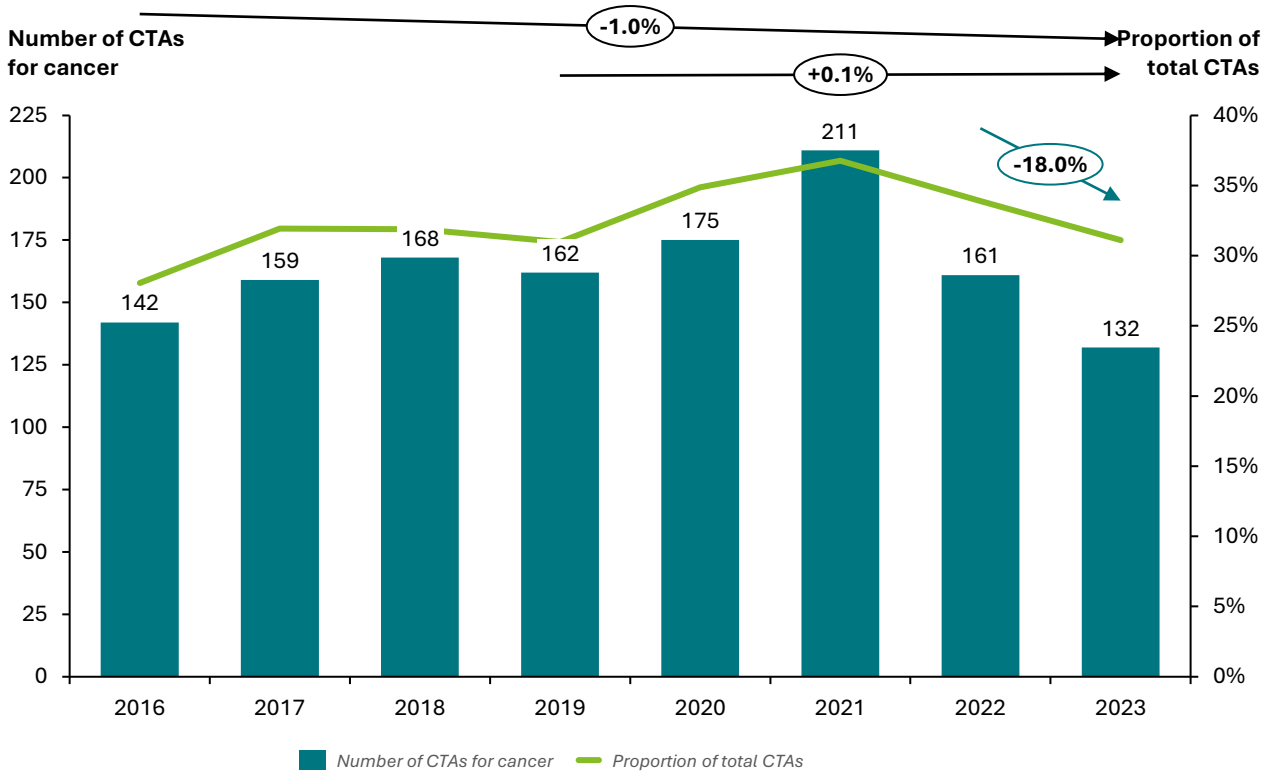
Clinical trials in Belgium

A wide variety of therapeutic areas is covered with a steady growth in cancer research over the past years. However, the decrease in number CTAs for cancer (-18%) is higher than the total decrease in CTAs (-9%) for Belgium when comparing 2023 to 2022

Proportion of CTAs for selected disease areas in Belgium (2023)



Evolution of CTAs for cancer in Belgium (2016-2023)

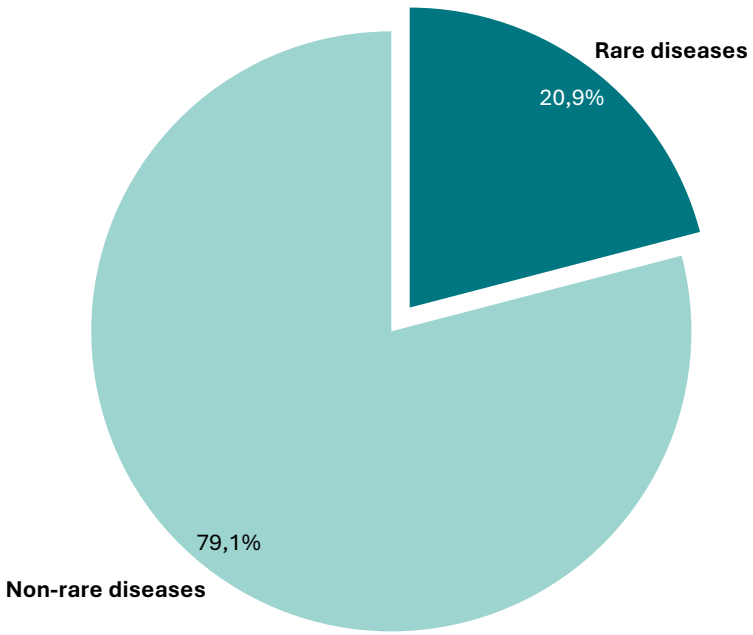


Source: Monitor Deloitte analyses based on FAMHP data

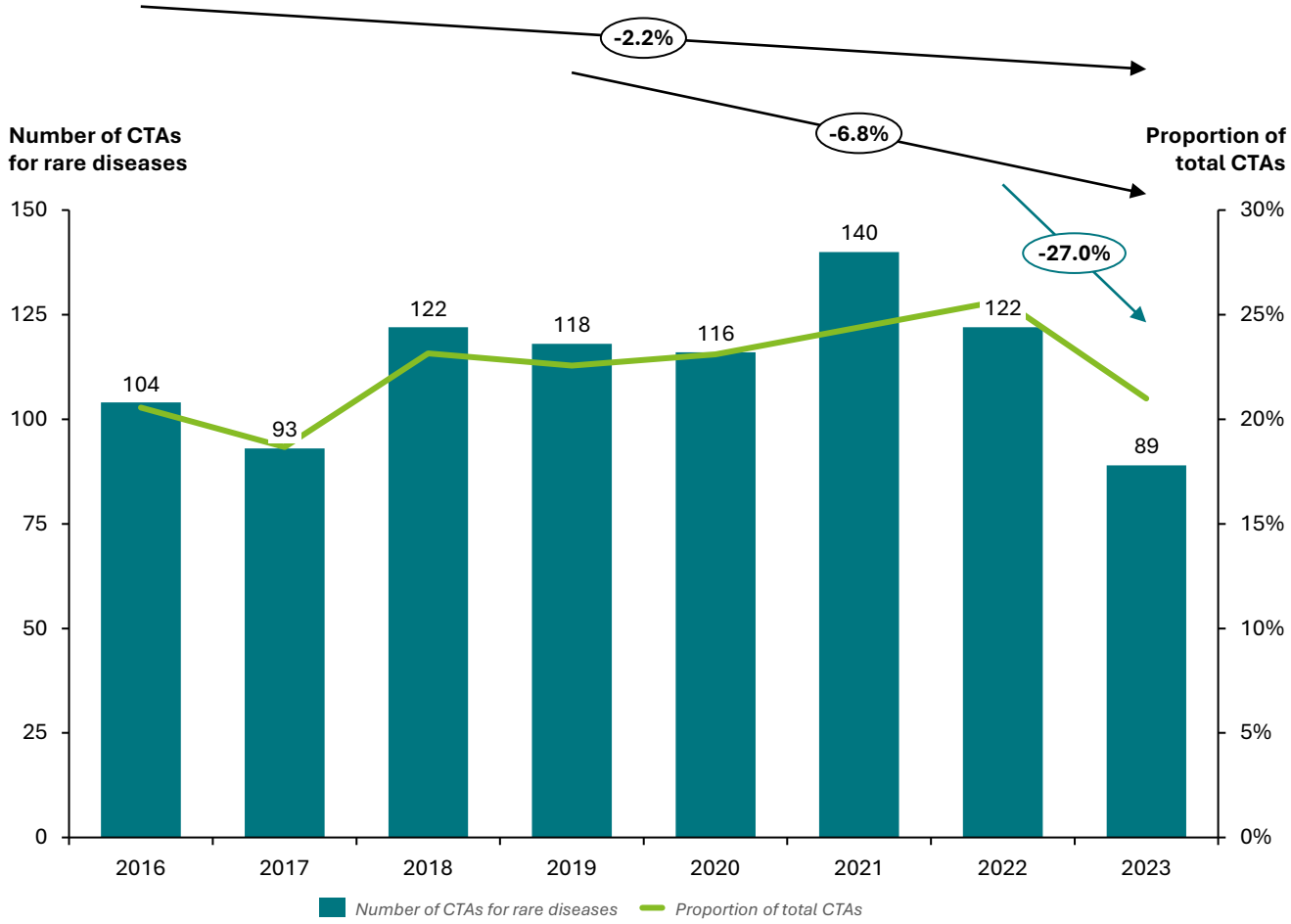
Clinical trials in Belgium

5-year CAGR is showing a decreased volume of CTAs (-7%) for rare diseases in Belgium after a period of stable volume

Percentage of CTAs in rare diseases authorised by the FAMHP in Belgium (2023)



Evolution of CTAs for rare diseases in Belgium (2016-2023)

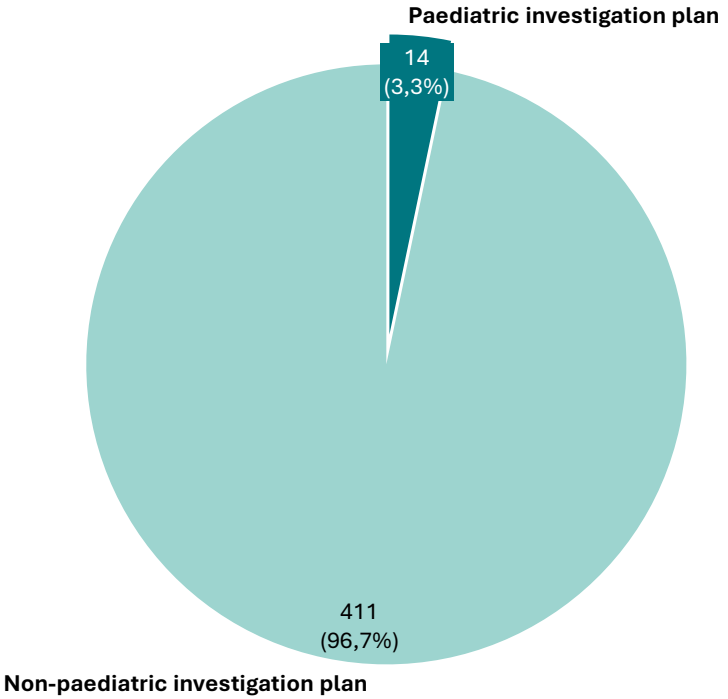


Source: Monitor Deloitte analyses based on FAMHP data

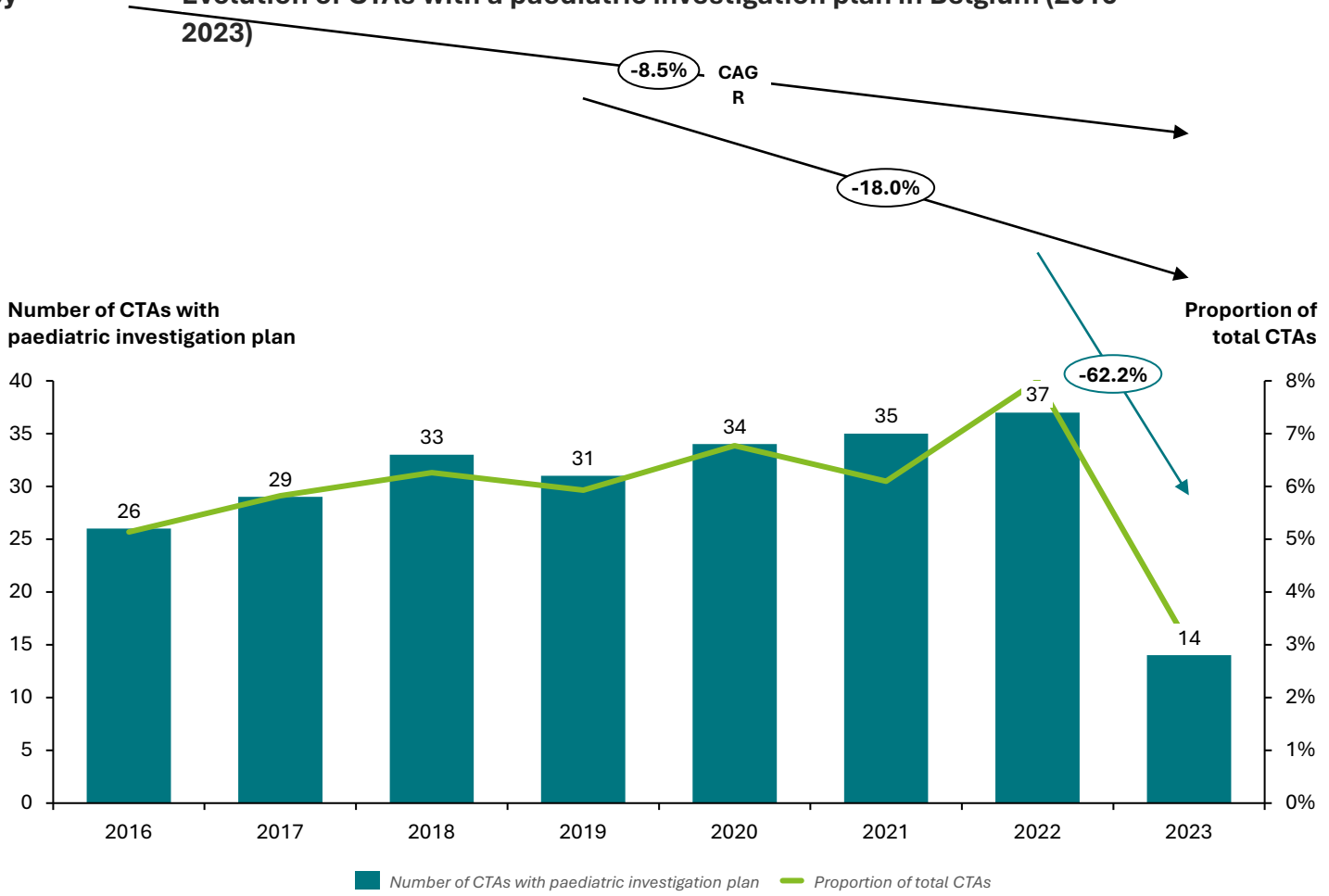
Clinical trials in Belgium

The 5-year CAGR is showing a sharp decline for CTAs with paediatric investigation plan

Percentage of CTAs with a paediatric investigation plan authorised by the FAMHP in Belgium (2023)



Evolution of CTAs with a paediatric investigation plan in Belgium (2016-2023)

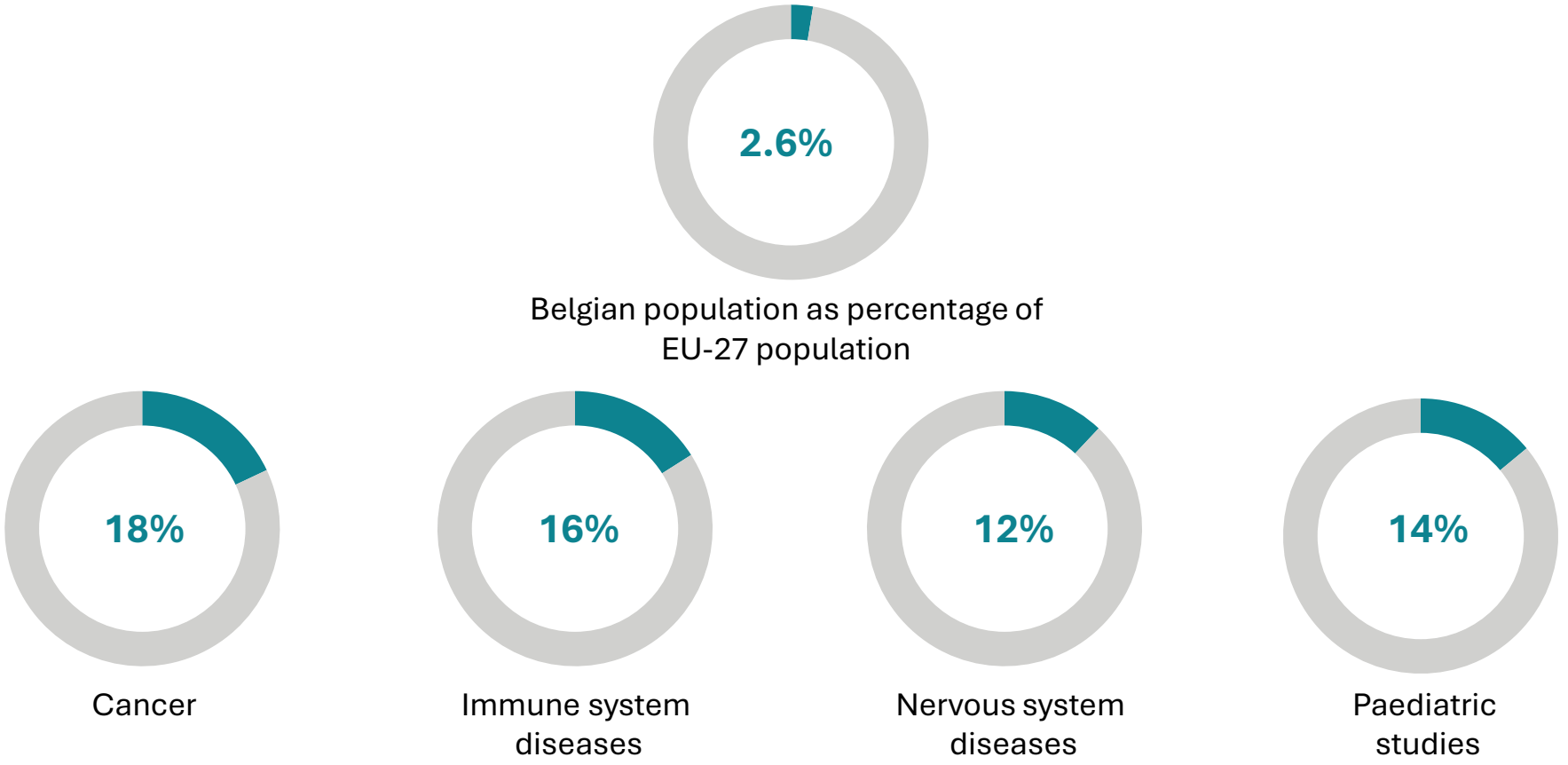


Source: Monitor Deloitte analyses based on FAMHP data

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 (2023)

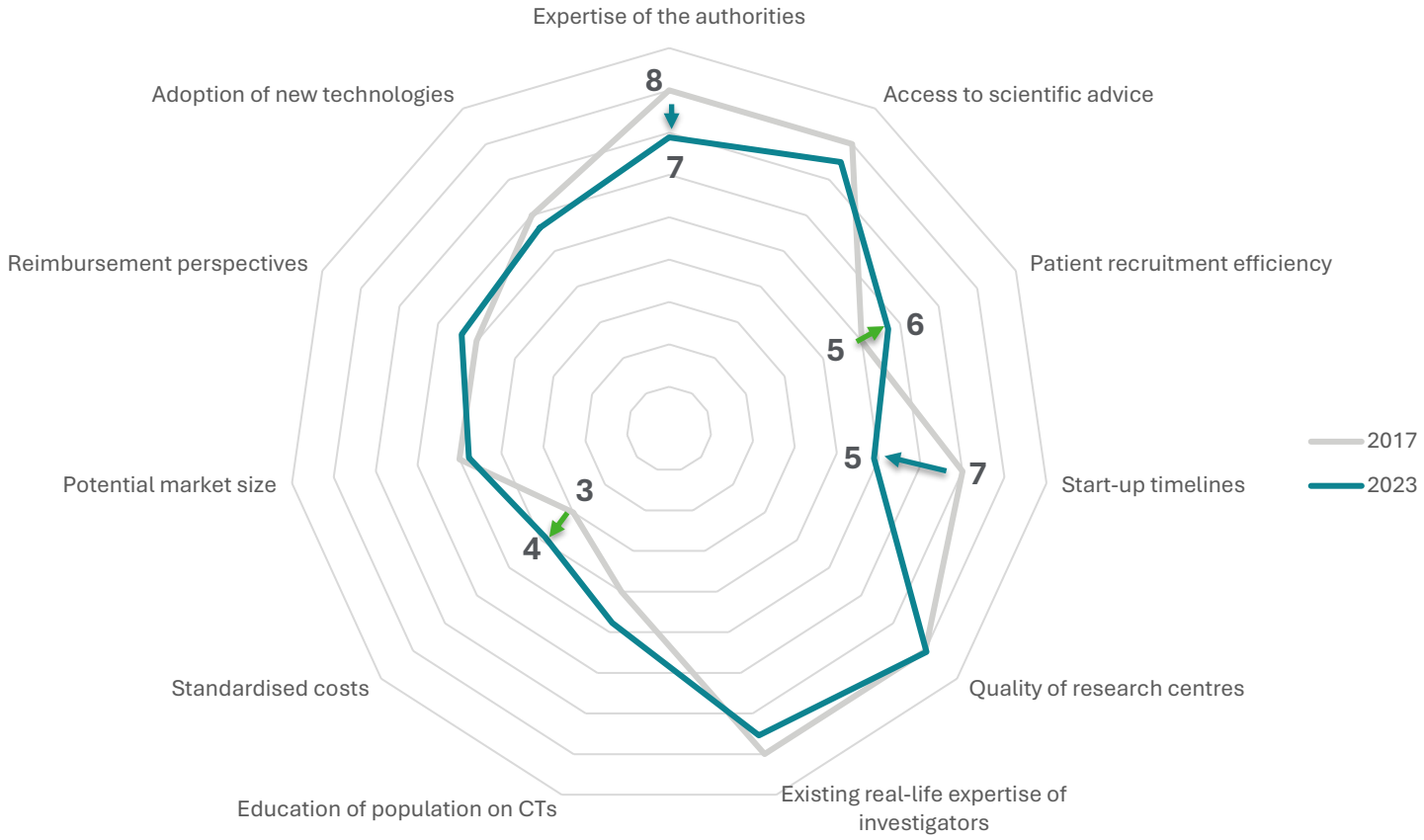


Source: Monitor Deloitte analyses based on FAMHP data

Attractiveness of Belgium

There is a decline in self-reported attractiveness for start-up timelines, expertise of authorities and access to scientific advice compared to 2017, yet patient recruitment efficiency has gone up

Average rate of Belgium on the following drivers for clinical trial location selection on a total score of 10 (2017-2023)



n=13

Source: pharma.be member survey 2017, 2023

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Belgium as a Clinical Trial Location in Europe

Next-Gen Talent for Clinical Trials

Imagine the future together...

Alex, a 67-year-old woman living with Amyotrophic Lateral Sclerosis (ALS), embarks on a revolutionary journey through a clinical trial that may significantly change her life course

1

Alex had been managing her ALS with the latest therapies, but one promising new treatment catches her eye. Scanning a health app on her wearable device, she receives a notification about a new clinical trial tailored for her specific genetic markers and medical history. Leveraging artificial intelligence, blockchain technology, and patient registries, the app identifies her as a perfect match and **seamlessly connects her with the trial coordinators**.

2

Within minutes, Alex' profile details and medical history are securely shared with the research team. Virtual reality consultation portals allow her to **discuss the trial's potential benefits and risks with the clinical staff from the comfort of her home**. Throughout this process, Alex feels well-informed and empowered, thanks to transparent communication facilitated by AI-powered virtual assistants.

3

Trial enrolment no longer entails tedious paperwork or frequent visits to medical facilities. Instead, **Alex' enrolment is confirmed digitally through her e-consent via a secure, blockchain-powered platform**. She signs the digital documents, and the same day, an autonomous delivery drone drops off a package containing her necessary trial materials right at her doorstep. Included in the package is an augmented reality headset, a set of smart devices to monitor her vitals, and detailed instructions delivered through interactive video guides. Alex is also assigned a personalised avatar that represents her in virtual meetings with the research team, ensuring continuous support and engagement.

4

Alex' journey is highly decentralised, with the trial taking place predominantly within her home environment. Her **smart devices continuously stream real-time data related to her health metrics**—such as blood pressure, heart rate, and motor function—directly to the clinical trial database. Machine learning algorithms analyse the data in real-time, detecting anomalies and alerting the clinical team if intervention is needed. Alex engages in weekly virtual check-ins with a team of clinicians, augmented by AI-powered chatbots for daily queries. This **continuous virtual support fosters a deeper connection between Alex and the clinical team**, mitigating any feelings of isolation.

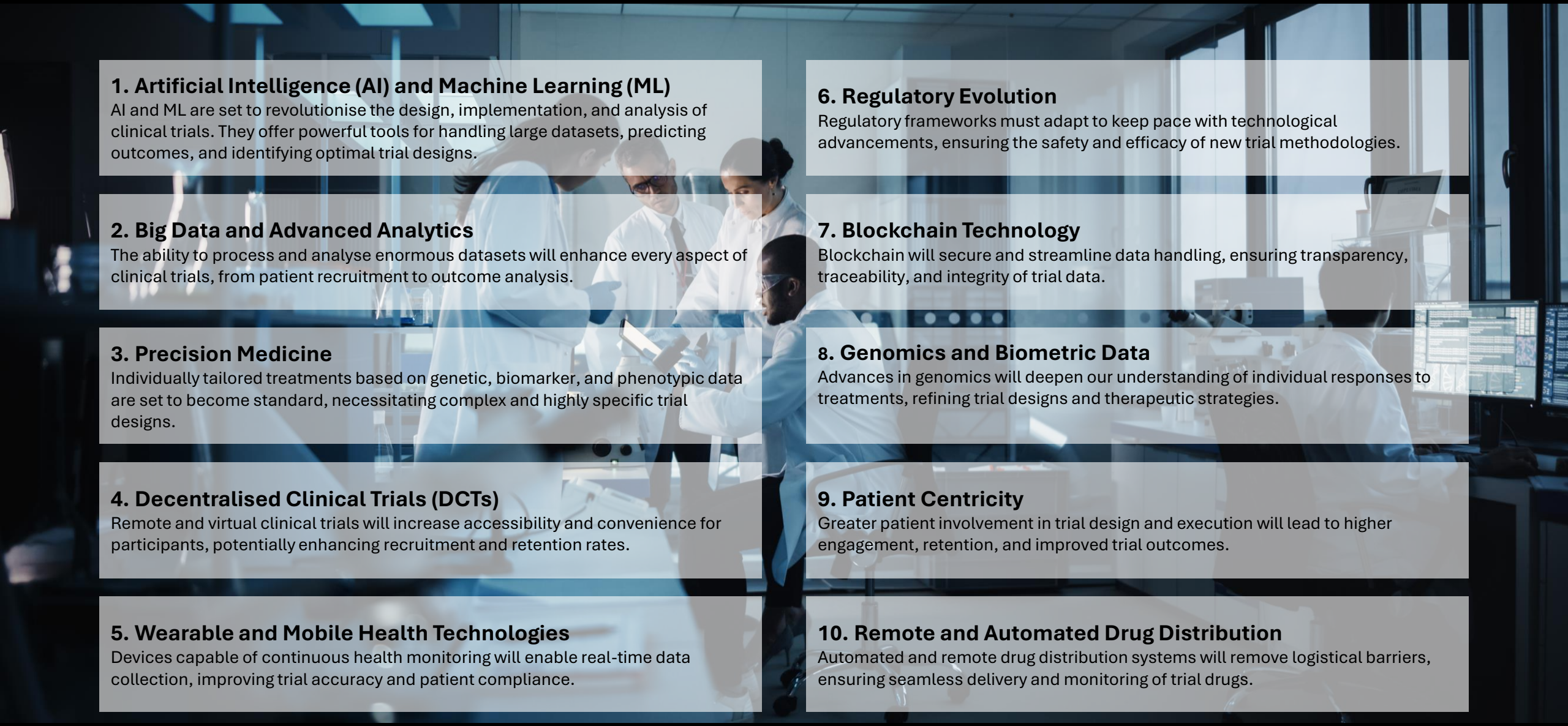
5

To maintain high engagement levels, Alex' progress and adherence are gamified in an ethical way. She earns virtual rewards and recognitions for compliance, making the experience more enjoyable. **Social platforms dedicated to trial participants allow Alex to share her experiences**, fostering a community of support and motivation.

6

Upon the trial's conclusion, Alex transitions into the post-trial phase seamlessly. **The clinical team continues to monitor her remotely for any long-term effects** of the treatment through her smart devices. Blockchain ensures the security and immutability of her medical records, allowing health professionals to track her progress without requiring physical records. She also **participates in a follow-up virtual reality event** where she connects with other participants, sharing insights and experiences while receiving updates about the trial outcomes from the researchers.

Trends and innovations transforming the pharma clinical trial landscape



1. Artificial Intelligence (AI) and Machine Learning (ML)
AI and ML are set to revolutionise the design, implementation, and analysis of clinical trials. They offer powerful tools for handling large datasets, predicting outcomes, and identifying optimal trial designs.

2. Big Data and Advanced Analytics
The ability to process and analyse enormous datasets will enhance every aspect of clinical trials, from patient recruitment to outcome analysis.

3. Precision Medicine
Individually tailored treatments based on genetic, biomarker, and phenotypic data are set to become standard, necessitating complex and highly specific trial designs.

4. Decentralised Clinical Trials (DCTs)
Remote and virtual clinical trials will increase accessibility and convenience for participants, potentially enhancing recruitment and retention rates.

5. Wearable and Mobile Health Technologies
Devices capable of continuous health monitoring will enable real-time data collection, improving trial accuracy and patient compliance.

6. Regulatory Evolution
Regulatory frameworks must adapt to keep pace with technological advancements, ensuring the safety and efficacy of new trial methodologies.

7. Blockchain Technology
Blockchain will secure and streamline data handling, ensuring transparency, traceability, and integrity of trial data.

8. Genomics and Biometric Data
Advances in genomics will deepen our understanding of individual responses to treatments, refining trial designs and therapeutic strategies.

9. Patient Centricity
Greater patient involvement in trial design and execution will lead to higher engagement, retention, and improved trial outcomes.

10. Remote and Automated Drug Distribution
Automated and remote drug distribution systems will remove logistical barriers, ensuring seamless delivery and monitoring of trial drugs.

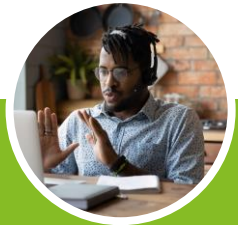
Bridging technology and talent: future skills for clinical success

Gradually evolving today's talent pool towards future required skills and competencies

Area of operations	Current skills and competencies	Future skills and competencies
Data management	Proficiency with electronic data capture systems and databases	**Expertise in advanced analytics and visualisation** such as AI/ML, real-world evidence and blockchain data integrity
Study design	Creating mostly static, one-size-fits-all clinical trial protocols	**Adapting protocols in real-time** using adaptive trial models and digital twin simulations
Patient recruitment	Relying on site-based strategies for enrolment	Leveraging digital platforms, wearables, and community-engagement for **inclusive recruitment**
Regulatory compliance	Understanding and applying local and international regulatory frameworks	**Anticipating regulatory changes**, navigating balancing global and local standards, and managing AI and genomics-related ethics
Clinical monitoring	On-site monitoring of trial sites and data collection	Utilizing remote tools and real-time monitoring systems for **decentralized hybrid trials**
Biostatistics	Analysing data using standard statistical models	Incorporating predictive modelling and bioinformatics for **genomic-driven precision medicine**
Interpersonal communication	Collaborating with teams and patients in person	**Navigating hybrid communication platforms** for global teams and patient engagement
Ethical considerations	Addressing patient privacy and manage traditional informed consent process	Focus on **patient convenience** while ensuring AI and genetic data usage **aligns with evolving ethical guidelines**
Site management	Coordinating physical trial sites effectively	**Managing hybrid trial models** across multiple virtual and physical locations
Clinical knowledge	Understanding disease area and current treatment strategies	**Applying advanced genomics**, biomarkers and personalised approaches to treatment

8 potential new roles required to conduct future clinical trials

Health Data Scientist



Digital Health Coordinator

Patient Engagement Manager

Regulatory Innovation Officer

Genomic Data Analyst

Remote Trial Coordinator

AI Ethics and Compliance Officer

Cyber Security Specialist

Future clinical trials require adapted or even new roles with specific competencies and capabilities

8 potential new roles required to conduct future clinical trials

As a **Health Data Scientist** in clinical trials, you will leverage advanced AI and quantum computing to delve into vast, complex datasets, uncovering patterns and insights that drive the next frontier of personalised medicine. Your role will be crucial in developing predictive models that transform raw data into breakthrough therapies, accelerating drug development towards the future of healthcare.

As a **Digital Health Coordinator**, you will be at the epicentre of integrating state-of-the-art wearable technologies and AI-driven health applications into clinical trials. Your efforts will enable continuous, real-time monitoring of participants, collecting invaluable data that enhances trial accuracy and brings futuristic healthcare solutions to life.

As a **Patient Engagement Manager**, you will utilise immersive virtual reality (VR) and AI-powered communication platforms to enhance the participant experience in clinical trials. Your innovative approaches will ensure that participants remain informed, motivated, and deeply engaged, building new paths in patient-centric research environments.

As a **Regulatory Innovation Officer**, you will pioneer the regulatory frameworks necessary to integrate next-gen technologies like AI, blockchain, and personalised genomics into clinical trials. Your strategic vision and regulatory acumen will facilitate the seamless approval of groundbreaking trials, steering in a new era of compliant and rapid medical research advancements.

As a **Genomic Data Analyst**, you will explore the cutting edge of genomic science, combining AI with genomic sequencing to uncover biomarkers and genetic patterns. Your work will be pivotal in crafting hyper-personalised treatment protocols, leading the march towards a future where therapies are tailored to the unique genetic makeup of each person.

As a **Remote Trial Coordinator**, you will orchestrate the complex logistics of decentralised clinical trials using advanced AI-driven management systems. Your role will ensure the seamless coordination of trials across a global network of participants, enabling unprecedented inclusivity and efficiency in futuristic clinical research.

As an **AI Ethics and Compliance Officer**, you will oversee the ethical deployment of AI and machine learning in clinical trials, crafting policies that balance innovation with integrity. Your forward-thinking leadership will safeguard the ethical standards of the future, ensuring that cutting-edge technologies are used responsibly and transparently.

As a **Cybersecurity Specialist**, you will join advanced encryption and AI-driven threat detection to protect sensitive clinical trial data. Your expertise will secure the digital landscape of clinical trials, ensuring the integrity and confidentiality of patient data, and maintaining trust in a world where data security is vital.

How to prepare the clinical trial workforce of the future, today?

All stakeholders play a critical role in preparing the clinical trial workforce for the future

BIOPHARMA COMPANIES

- **Professional Development**: Implement ongoing training in emerging technologies
- **Innovation Labs**: Establish labs for hands-on tech experience
- **Education Collaboration**: Partner with universities for specialised courses

GOVERNMENT

- **Education Investment**: Fund programs in AI, ML, digital health, genomics, cybersecurity
- **Adaptive Regulations**: Develop flexible, robust regulatory frameworks
- **Public-Private Partnerships**: Create internships, apprenticeships, and continuous learning opportunities

REGULATOR

- **Specialised Training**: Train staff on the latest methodologies, AI, and digital health technologies
- **Advanced Technology**: Invest in analytical tools to streamline trial approvals
- **Collaborative Dialogue**: Engage with industry and academia to keep regulatory frameworks relevant

HOSPITALS

- **Clinical Training**: Conduct workshops on digital health tools, wearables, and AI-driven analysis
- **Research Partnerships**: Collaborate with pharma, regulators, and academia to stay on the cutting edge
- **Patient-Centric Training**: Train staff in AI-enhanced patient engagement techniques

HIGHER EDUCATION INSTITUTIONS

- **Curriculum Modernisation**: Include courses on AI, digital health, genomics, and cybersecurity
- **Industry Collaboration**: Develop joint programs and internships with pharma, regulators, and hospitals
- **Interdisciplinary Programs**: Create courses integrating life sciences, engineering, data science, and bioethics

How to prepare the clinical trial workforce of the future, today?

Multi-stakeholder roadmap towards 2040 to facilitate a gentle transition towards the Next Gen Clinical Trial Workforce

1

2025-2030

Foundations for the Future

- Conduct an ecosystem-wide skills audit and empower current clinical trial workforce
- Strengthen partnerships with academia and technology providers
- Develop and implement a talent attraction strategy and policy roadmap
- Pilot programmes

2

2031-2035

Scaling Next Gen Talent

- Integrate pilot learnings in regular operations
- Create centers of excellence for clinical research workforce development
- Build strategic academia-industry pipelines
- Create specialized roles and career pathways

3

2036-2040

Leading the Future

- Establish continuous learning platforms and national certification programmes
- Install recognition programmes for clinical trial workforce excellence
- Leverage Belgium's expertise and success on the international forum
- Monitor, evaluate, and implement new trends and technologies to stay at the forefront of clinical trial innovation

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 need and call to action for more diversity, equity, and inclusion in clinical trials, information was gathered from different stakeholders: industry sponsors, FAMHP and ethics committees. 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 enhance diversity, equity, and inclusion in clinical trials.

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. The number of CTAs assessed per month in 2021 and 2022, which is publicly available on the MHRA website, was utilized as a key indicator for CTA characteristics in the UK in this report.

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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