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ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

ONE PAGER

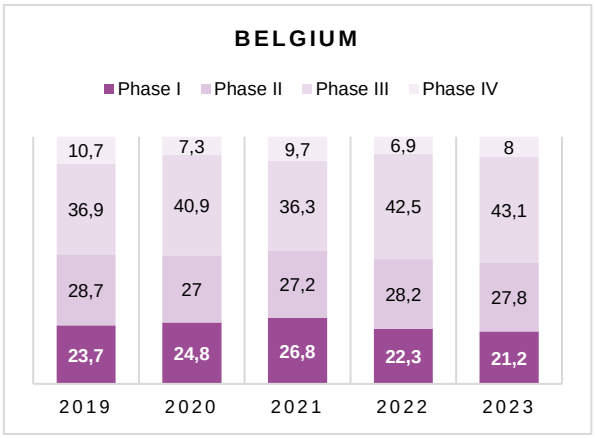
Phase I Clinical Research in Belgium

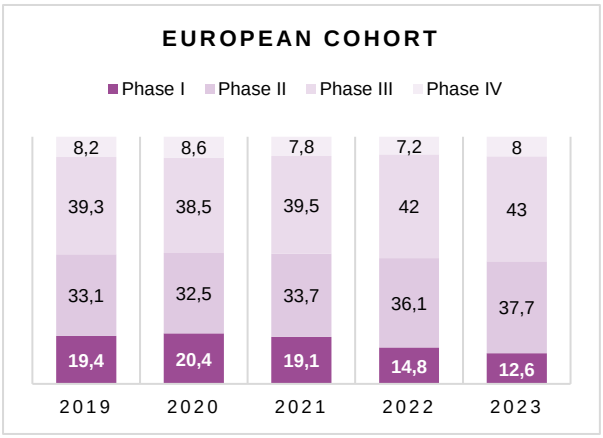
Belgium has long been an innovative pioneer in the field of phase I clinical trials. This is reflected in 3 essential pillars:

- **Its extensive, high-quality ecosystem**
- **A favourable regulatory environment**
- **Openness towards innovation**

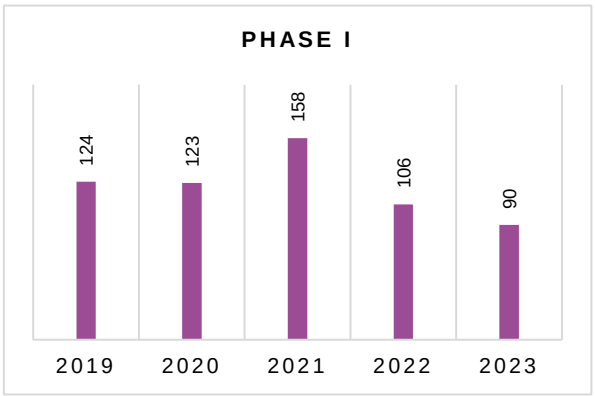
This positive climate for phase I clinical research is being created through a culture of an open dialogue between the different stakeholders to reflect on solutions for shared challenges and a strong collaborative national network.

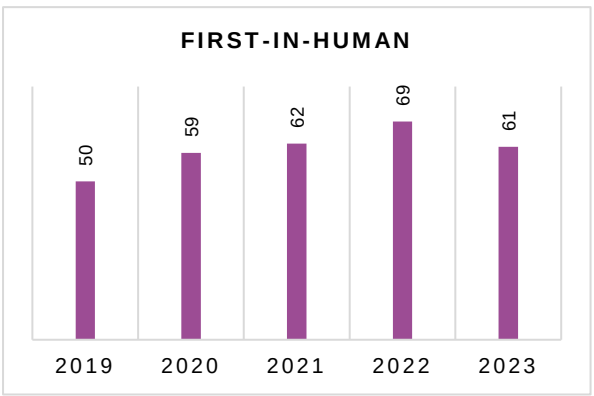
Percentage of CTAs per phase in Belgium compared to European cohort (2019-2023)





Comparison of growth in phase I CTAs vs First-in-Human in Belgium (2019-2023)





Source: ***Belgium as a Clinical Trial Location in Europe*** **(Deloitte / pharma.be)**

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OPERATIONAL EXCELLENCE

Belgium has established a strong footprint in early-phase clinical trials over the years. The operational capabilities have **evolved alongside the latest scientific advancements**, enabling diverse methodologies across various disease domains such as infectious diseases and oncology. Other key aspects include:

- Site with steady expertise in **healthy volunteers studies** and **First-in-human clinical trials**.
- An increase in sites capable of performing **First-in-patients clinical trials**, accommodating more complex molecules and more invasive administration routes.
- Recent investments in sites to facilitate **Controlled Human Infection Model (CHIM) trials**

Belgium boasts **a high number of specialized phase I clinical units** with longstanding and dedicated expertise:

COMMERCIAL PHASE I UNIT

COMPANY-ONWED PHASE I UNIT

HOSPITAL PHASE I UNIT WITH A DEDICATED PATIENT FOCUS

VACCINES-FOCUSED UNIT

Belgian academic sites feature **expert doctors and researchers** who have **access to (niche) patient population** and maintain an open attitude **towards collaboration with pharmaceutical companies.**

High quality clinical trial unit workforce, labs and hospital pharmacies, **consistently meeting the necessary GxP-requirements and showcasing necessary trial capabilities,** even in complex trials. Sites undergo **frequent, thorough inspections (by the competent authorities)** to maintain high-quality standards.

FAVOURABLE REGULATORY ENVIRONMENT

Belgium's regulators (FAMHP) **have a longstanding focus on phase I clinical trials.** They possess **extensive knowledge and expertise** in early clinical development, **ensuring a smooth and efficient regulatory approval process** while continuously following scientific trends. The regulators are **professional and open to scientific dialogue**.

BELGIUM OFFERS RELIABLE AND UNIQUE FAST-TRACK REGULATORY TIMELINES FOR PHASE I TRIALS, WITH A LEGALLY SET MAXIMUM REVIEW PERIOD OF 66 DAYS.

The FAMHP is actively taking part in **national and European initiatives** to boost clinical research, such as:

- National innovation office
- Competitive National STA (free of charge if study is conducted in Belgium)
- Specific focus on vaccines and ATMP
- Lead in a pilot-project to harmonise combined CTR/IVDR applications
- Europe is also making efforts through revised CTIS transparency rules for phase I

ECOSYSTEM OPEN TO INNOVATION AND NEW METHODOLOGIES

Belgium boasts a well-equipped ecosystem that has steadily evolved alongside scientific advancements, thanks to the **central role of stakeholder collaboration** in promoting innovation in clinical research.

Belgium is open towards **more novel, digital approaches:**

- Belgium was a pioneer country in approving clinical trials with CAR-T therapies, leading to optimized timelines for CTA with GMOs
- All stakeholders recognize the benefits of incorporating decentralised elements in a clinical trial protocol (such as wearables or micro sampling)
- Several national start-ups are using digital tools to facilitate clinical trial conduct