Deloitte.

Belgium as clinical trial location in Europe Key results for 2021 ^{18 January 2023}



Introduction

Objective of the study

Provide key statistics on clinical trials in Belgium and perform a benchmark of Belgium as clinical trial location in Europe for the year 2021.

Data sources

- Clinical trial authorisations (CTA) FAMHP
- Demographic statistics Eurostat
- Annual reports of country cohort's competent authorities
- Pharma.be member survey

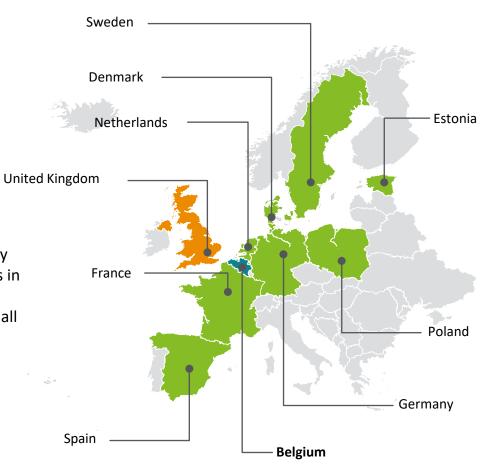
Data assumptions

A clinical trial is considered authorized if approved by the National Competent Authority (NCA). 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 NCAs to keep the European database up-to-date.

Disclaimer

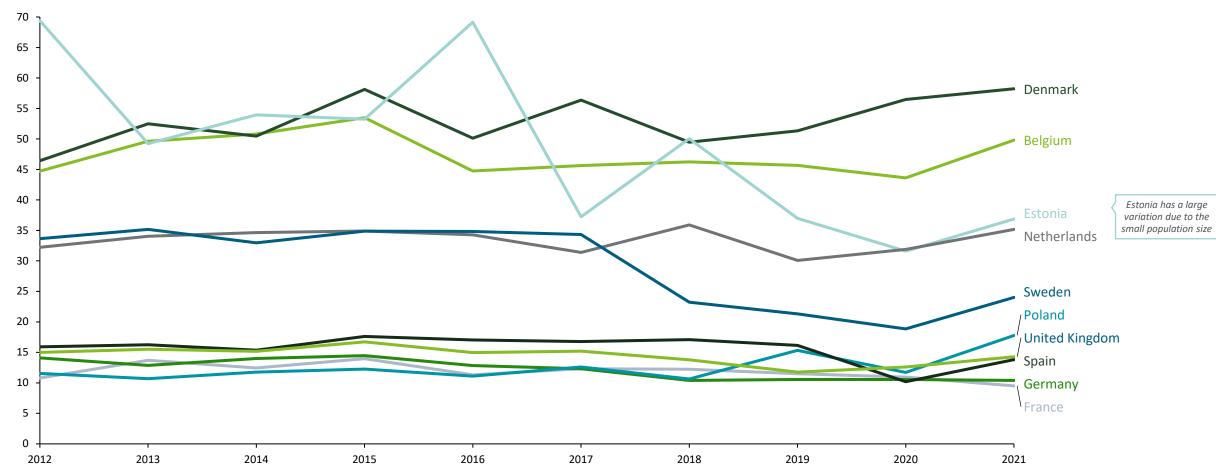
As of 31 January 2020, the United Kingdom does no longer provide data to the European database. The UK will be excluded from the EU cohort.





Clinical trials

Evolution of clinical trial authorisations in selected European Countries: Belgium confirms its position in the top 3 for 10 consecutive years



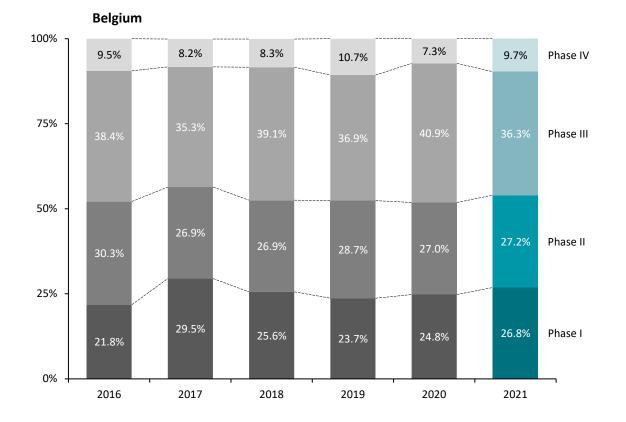
Evolution of CTAs per 1 million capita in cohort countries (2012-2021)

Source: Monitor Deloitte analyses based on National Medicines Agencies' reports, FAMHP data, and Eurostat; MHRA (2022). MHRA Update, March 2022 – Data out this report has been used to calculate the total amount of CTA of the UK during 2021 © 2023 Monitor Deloitte Belgium as a clinical trial location in Europe – Key results 2021

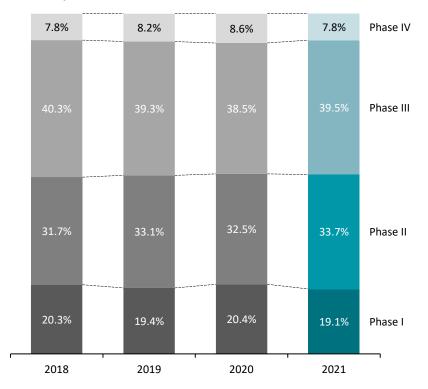
3

The Belgian proportion of phase 1 and 4 trials remains above the European cohort, sign of strong expertise in this field

Percentage of CTAs per phase in Belgium (2016-2021) compared to European cohort (2018-2021)



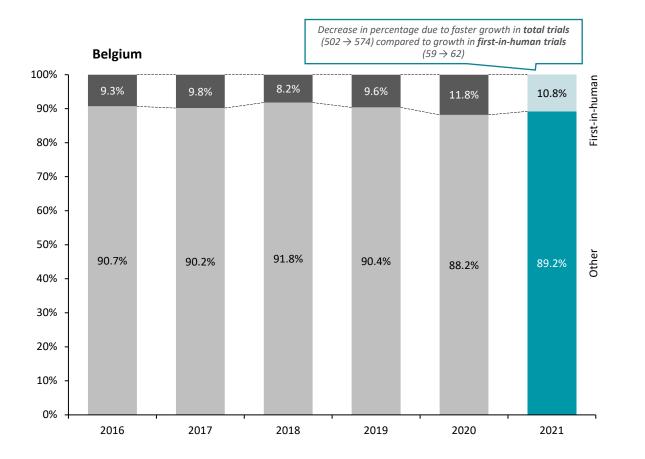
European Cohort

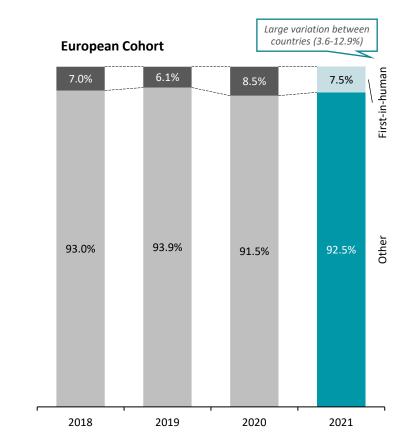


Source: Monitor Deloitte analyses based on FAMHP data. © 2023 Monitor Deloitte

The proportion of first-in-human CTAs in Belgium is stronger compared to the European cohort



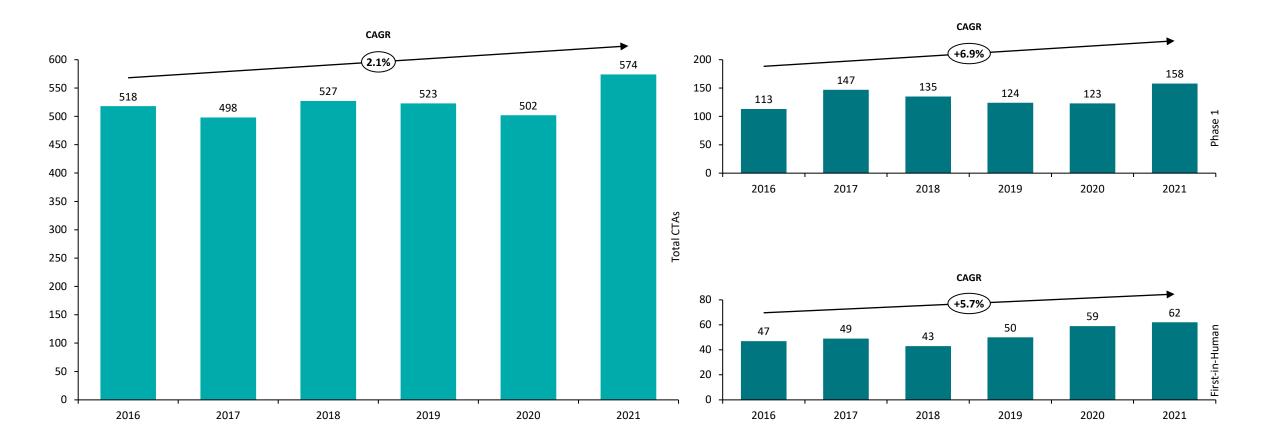




Source: Monitor Deloitte analyses based on FAMHP data. © 2023 Monitor Deloitte

Phase 1 and first-in-human clinical trials grow at a faster pace compared to the overall number of clinical trials in Belgium

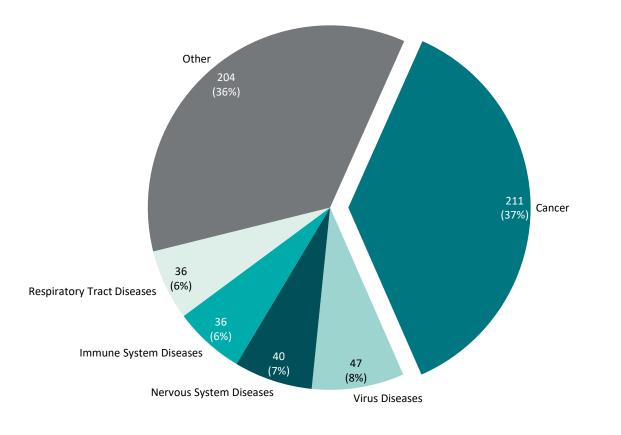
Comparison of growth in CTA volume in Belgium, absolute number of all CTAs vs. phase 1 CTAs vs. first-in-human (2016-2021)



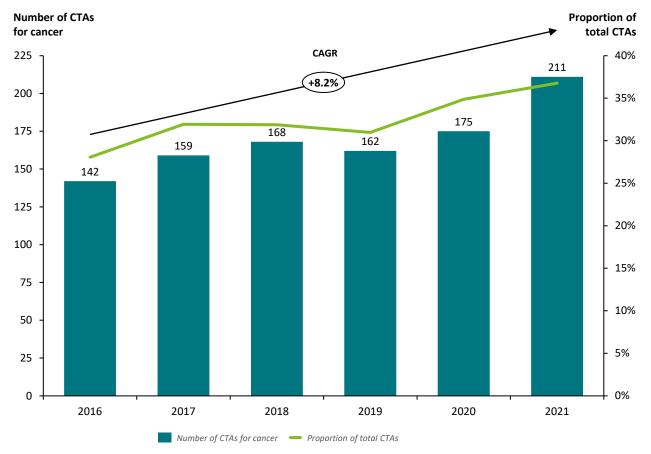
Source: Monitor Deloitte analyses based on FAMHP data $\ensuremath{\mathbb{O}}$ 2023 Monitor Deloitte

A wide variety of therapeutic areas is covered with a growing expertise in cancer research over the past six years

Proportion of CTAs for selected disease areas in Belgium (2021)



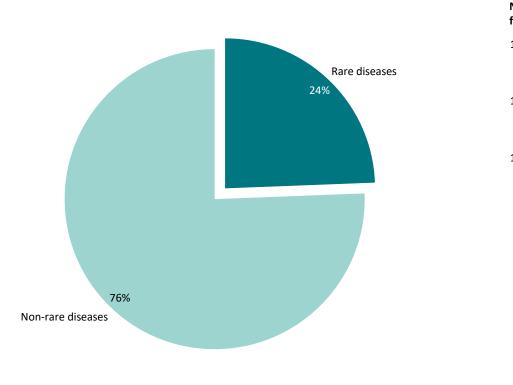
Evolution of CTAs for cancer in Belgium (2016-2021)

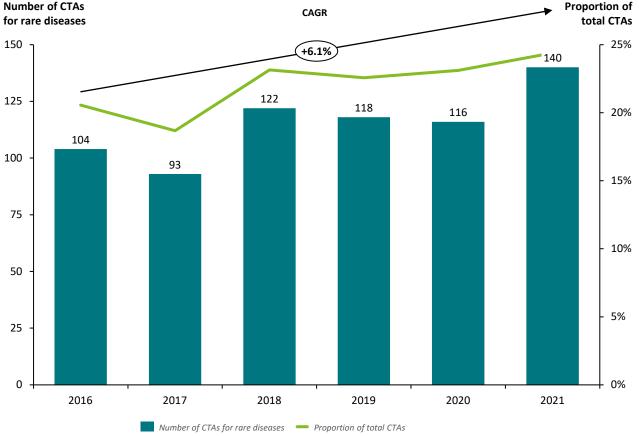


Despite its population size, more than 1 out of 4 clinical trials authorised in Belgium is conducted in the domain of rare diseases

Percentage of CTAs in rare diseases authorised by the FAMHP in Belgium (2021)

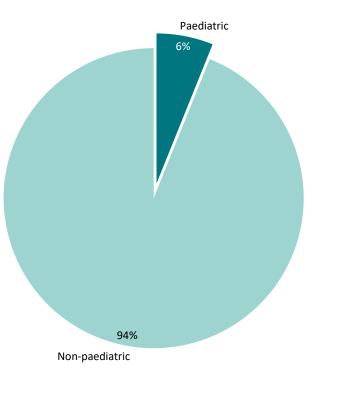
Evolution of CTAs for rare diseases in Belgium (2016-2021)



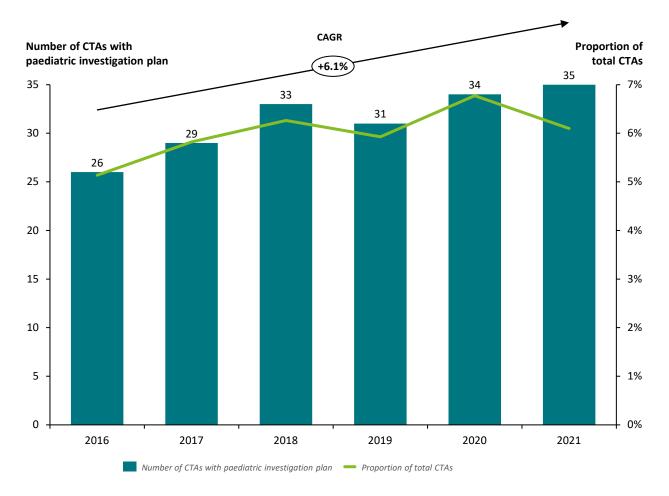


The overall number of clinical trials in Belgium grows at a faster pace compared to the continuous growth of paediatric trials

Percentage of CTAs with a paediatric investigation plan authorised by the FAMHP in Belgium (2021)

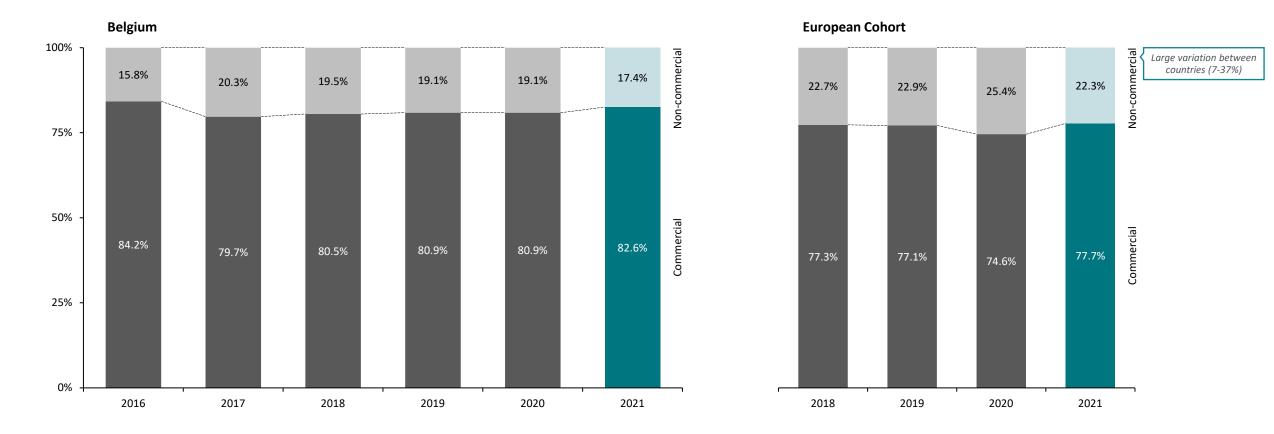


Evolution of CTAs with a paediatric investigation plan in Belgium (2016-2021)



Commercial trials show a faster growth than non-commercial trials in Belgium and the European cohort

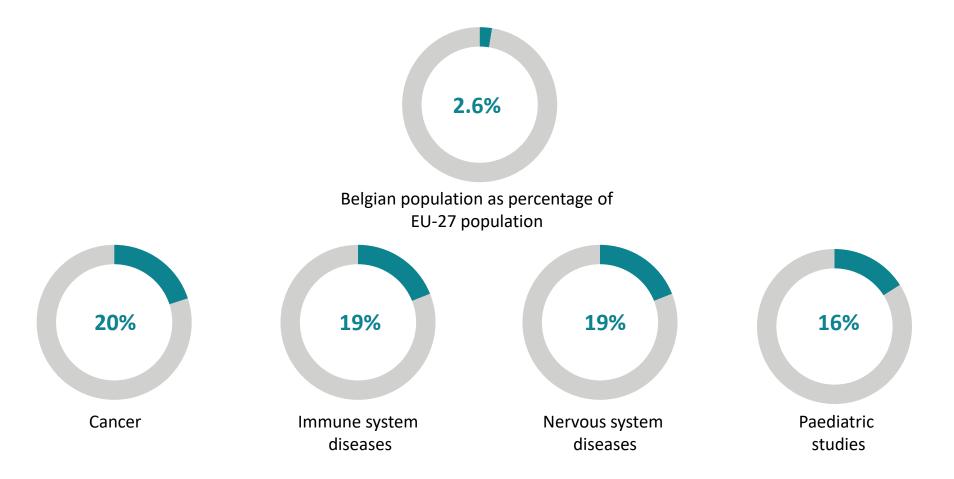
Percentage of CTAs per status of the sponsor in Belgium (2016-2021) compared to European cohort (2018-2021)



Source: Monitor Deloitte analyses based on FAMHP data $\ensuremath{\mathbb{O}}$ 2023 Monitor Deloitte

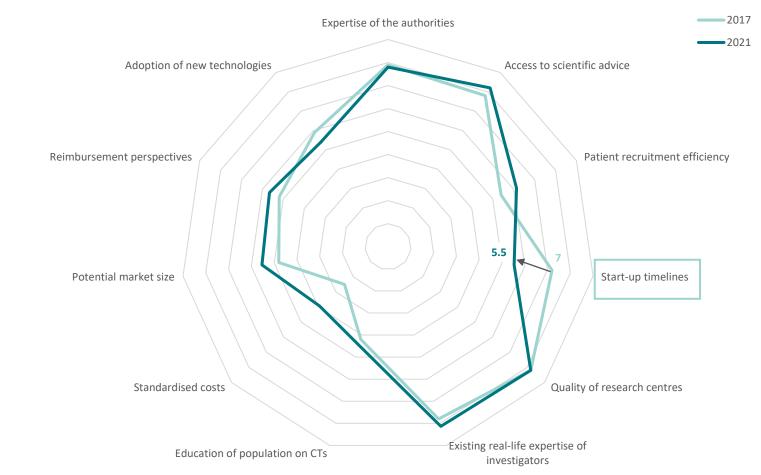
A strong clinical trials footprint of Belgium at European level with a relatively high percentage of clinical trials in Europe conducted in Belgium

Proportion of European clinical trials conducted in Belgium for selected type of studies compared to the proportion of the Belgian population in Europe (2021)



Attractiveness of Belgium

Strong regulatory and scientific expertise remain key drivers for the attractiveness of Belgium as a clinical trial location

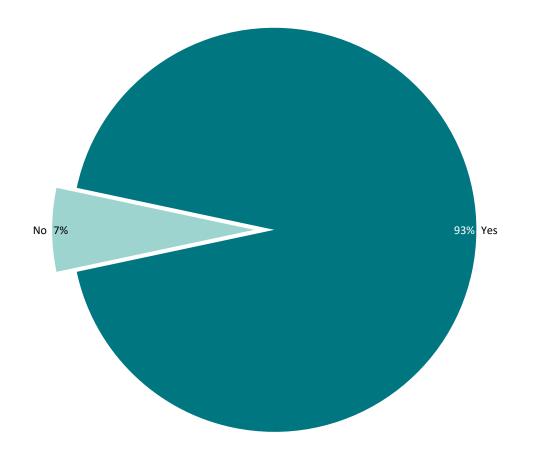


Average rate of Belgium on the following drivers for clinical trial location selection (2017 vs 2021)

Attractiveness of Belgium

Pharma.be members show high adoption of digital technology in clinical trials

Percentage of pharma.be members that has ever used any form of digital technology while conducting clinical trials in Belgium (2021)



Deloitte.

This communication contains general information only, and none of Deloitte Touche Tohmatsu Limited ("DTTL"), its global network of member firms or their related entities (collectively, the "Deloitte organization") is, by means of this communication, rendering professional advice or services. Before making any decision or taking any action that may affect your finances or your business, you should consult a qualified professional adviser.

No representations, warranties or undertakings (express or implied) are given as to the accuracy or completeness of the information in this communication, and none of DTTL, its member firms, related entities, employees or agents shall be liable or responsible for any loss or damage whatsoever arising directly or indirectly in connection with any person relying on this communication. DTTL and each of its member firms, and their related entities, are legally separate and independent entities.

Deloitte is a leading global provider of audit and assurance, consulting, financial advisory, risk advisory, tax and related services. Our global network of member firms and related entities in more than 150 countries and territories (collectively, the "Deloitte organization") serves four out of five Fortune Global 500[®] companies. Learn how Deloitte's approximately 330,000 people make an impact that matters at www.deloitte.com.

© 2023 Deloitte Belgium. All rights reserved.