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Belgium as clinical trial location in Europe

Key results for 2020

11 January 2022

Introduction

Objective of the study

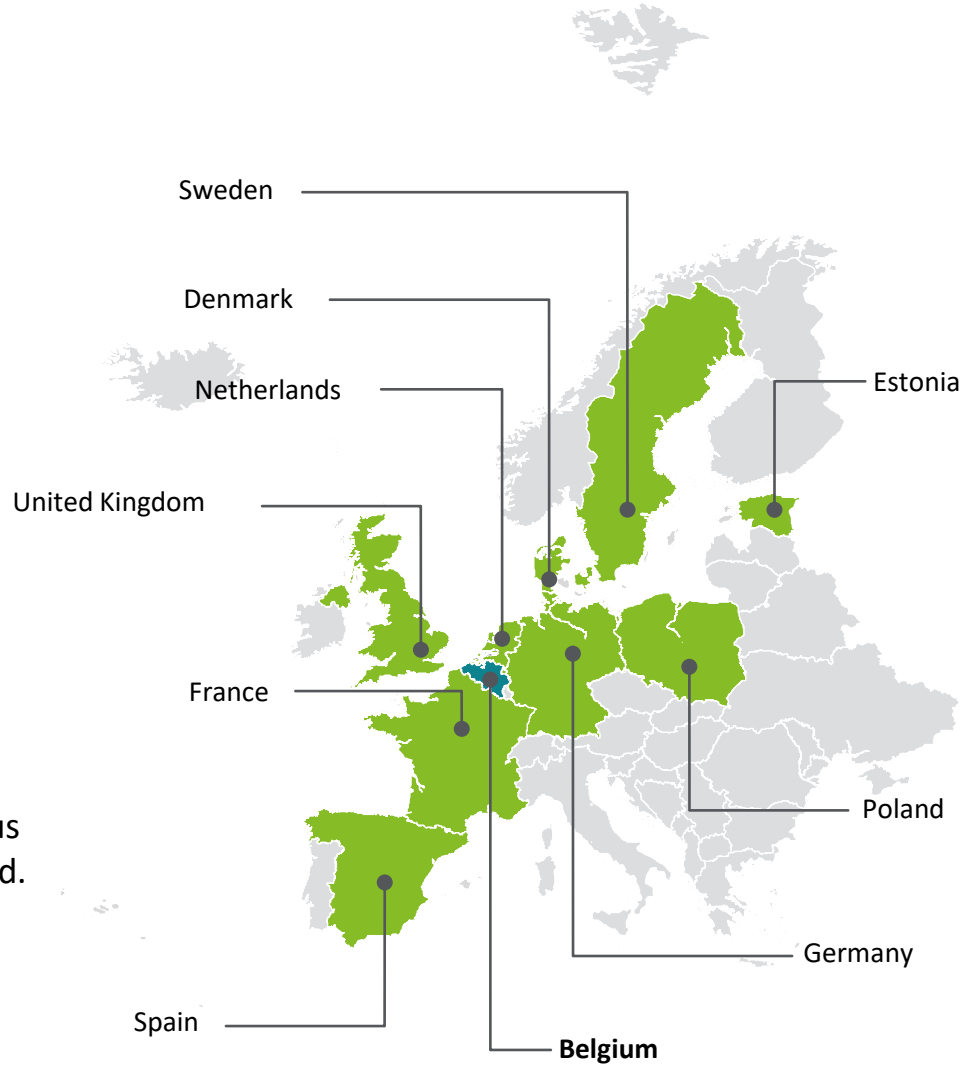
Provide key statistics on clinical trials in Belgium and perform a benchmark of Belgium as clinical trial location in Europe for the year 2020.

Data sources

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

Data assumptions

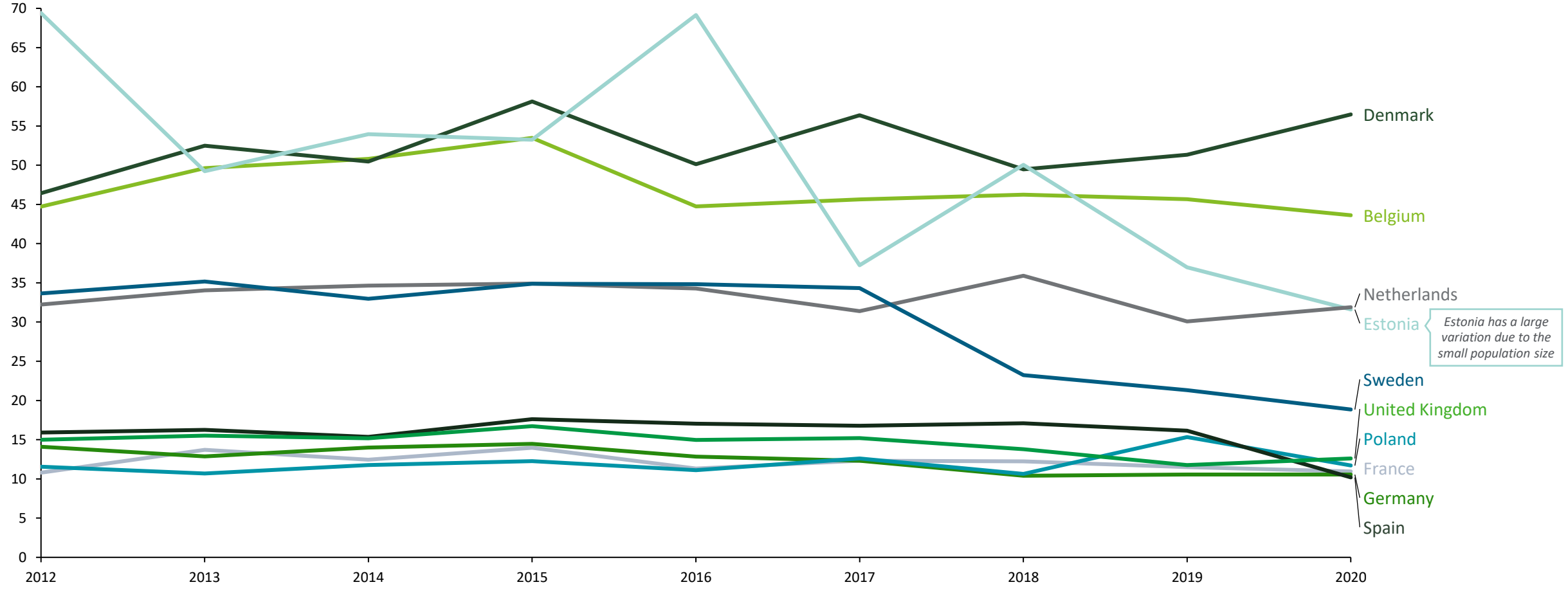
A clinical trial is considered authorized if approved by the National Competent Authority (NCA). For the information on the phase and the non-commercial status of clinical trials in Belgium, available data in the FAMHPs internal database is used. The correctness of all figures depends on the quality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



Clinical trials in Europe

Evolution of the number of clinical trial authorisations per capita in selected European Countries
Belgium confirms its position in the top 3 over the years

Evolution of CTAs per 1 million capita in cohort countries, 2012-2020

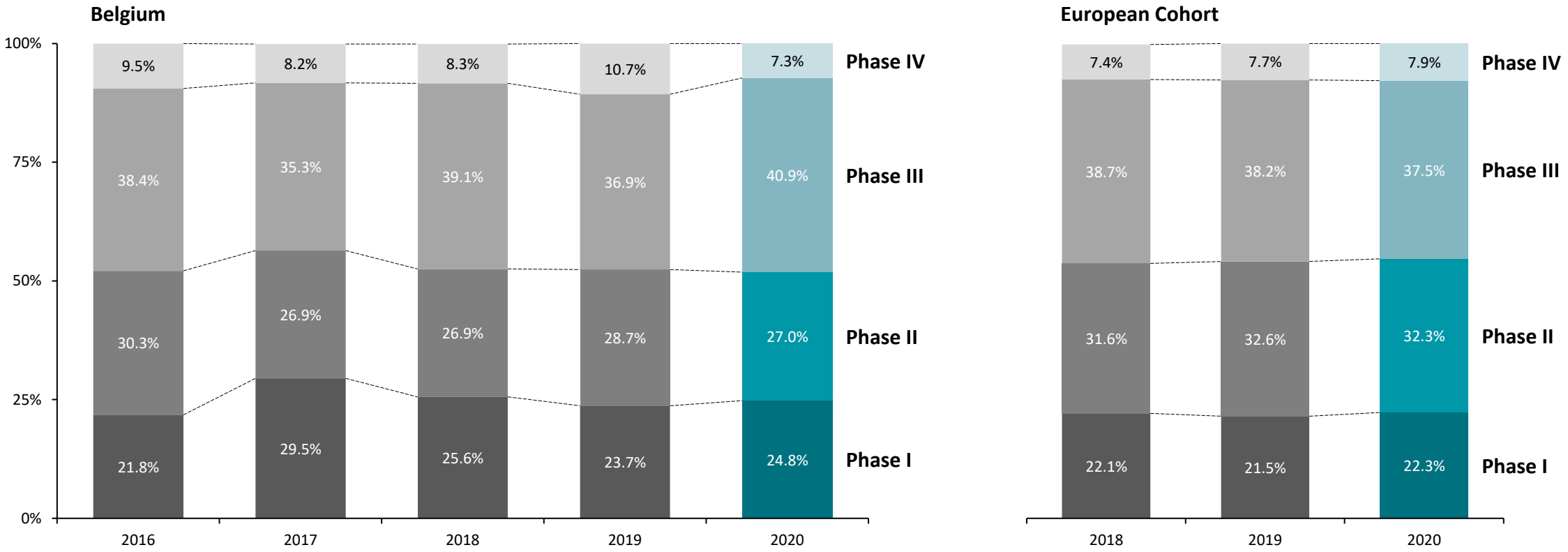


Source: Monitor Deloitte analyses based on National Medicines Agency's reports, FAMHP data, and Eurostat

Clinical trials in Belgium

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

Percentage of CTAs per phase in Belgium (2016-2020) compared to European cohort (2018-2020)

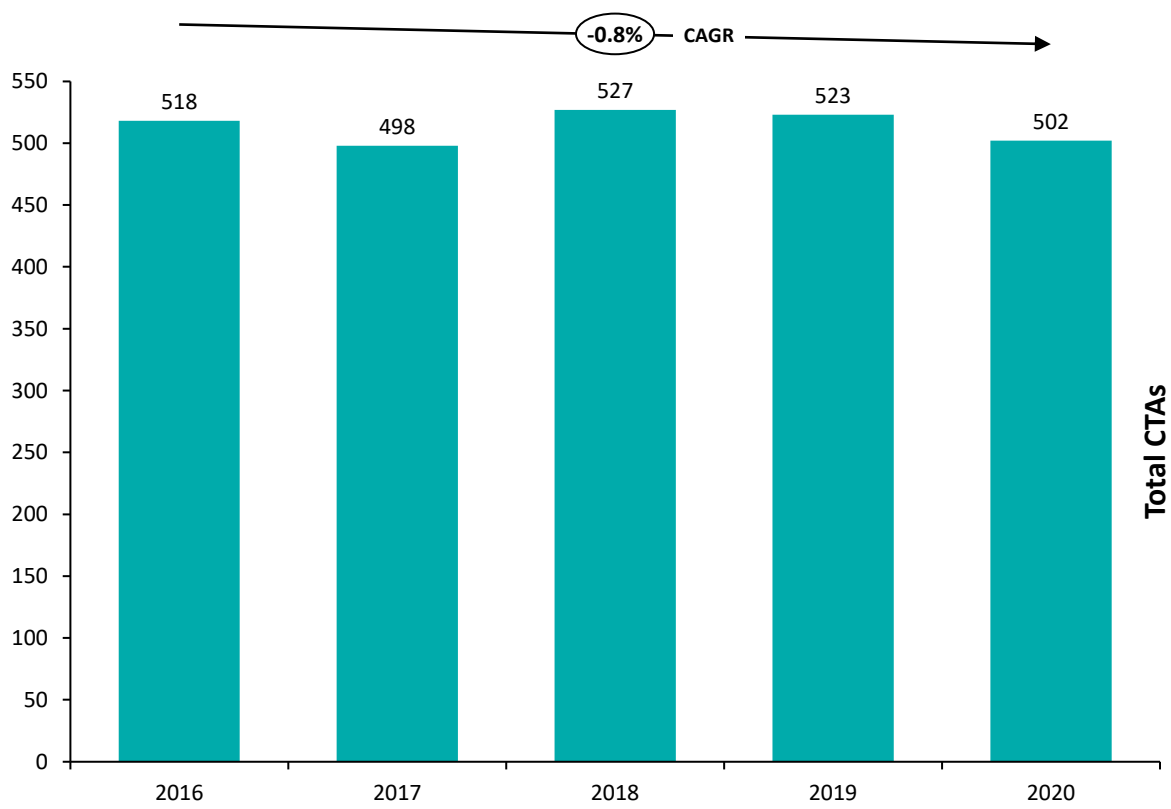


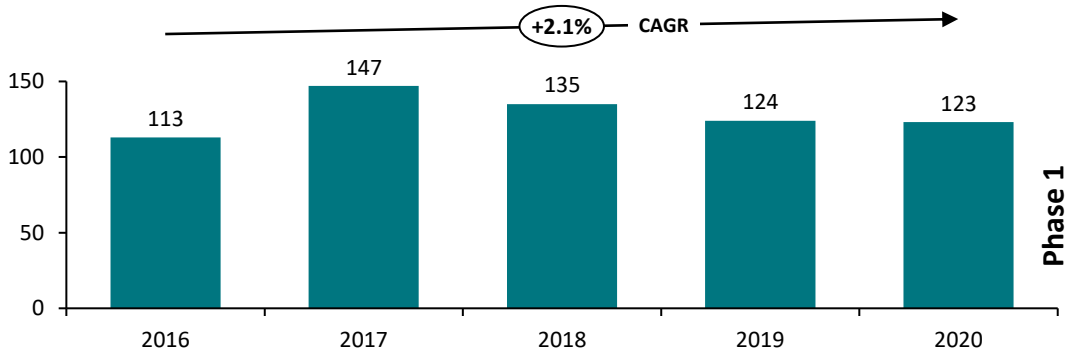
Source: Monitor Deloitte analyses based on FAMHP data

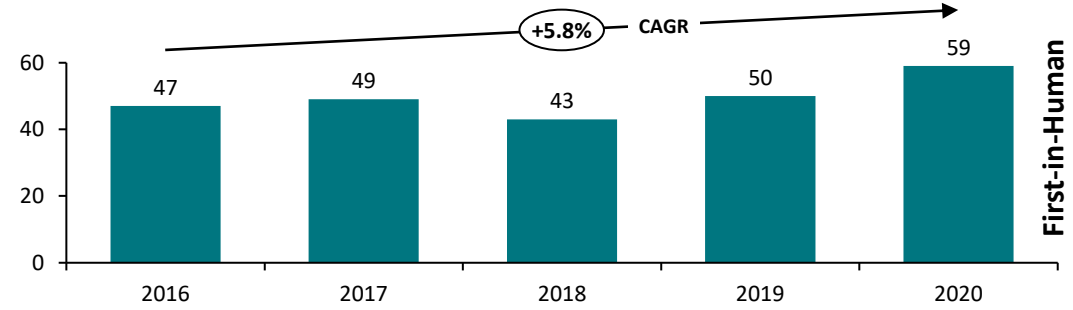
Clinical trials in Belgium

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 (2016-2020)





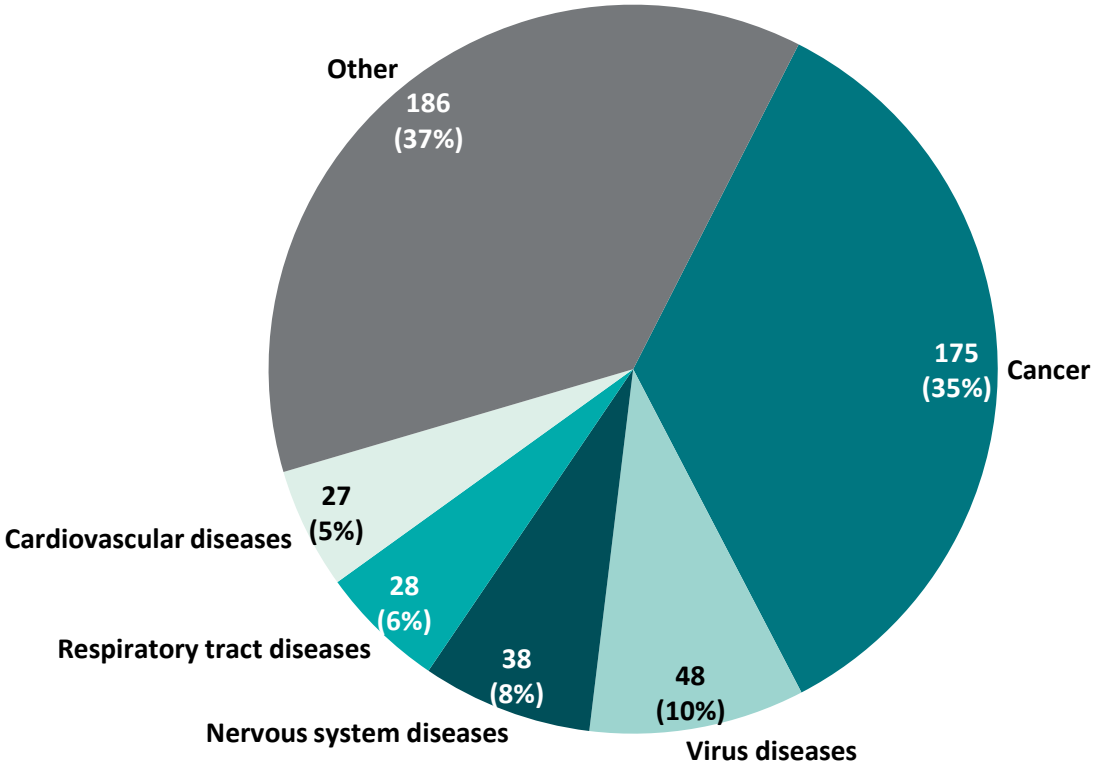


Source: Monitor Deloitte analyses based on FAMHP data

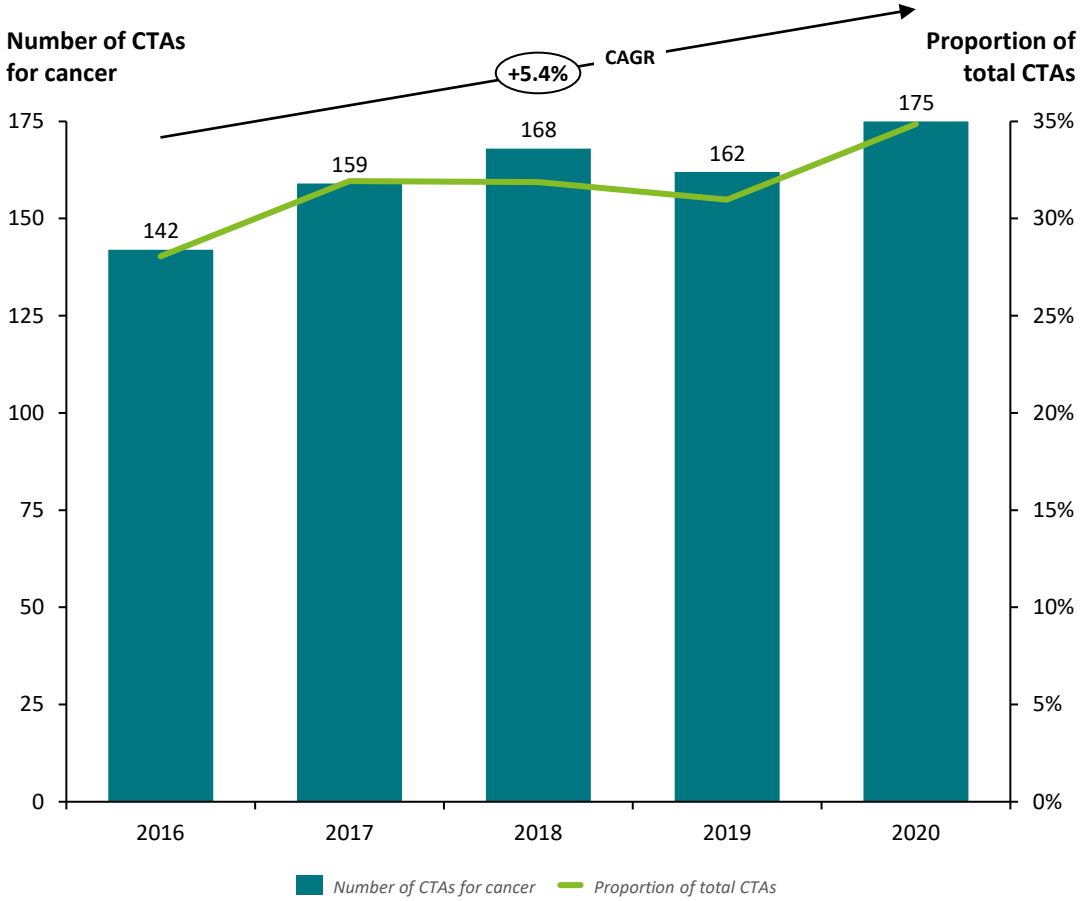
Clinical trials in Belgium

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

Proportion of CTAs for selected disease areas in Belgium (2020)



Evolution of CTAs for cancer in Belgium (2016-2020)

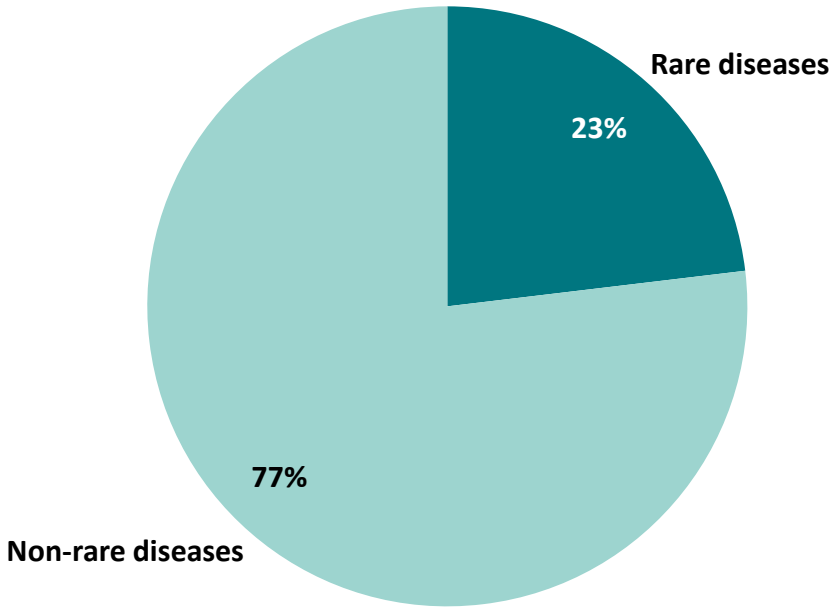


Source: Monitor Deloitte analyses based on FAMHP data

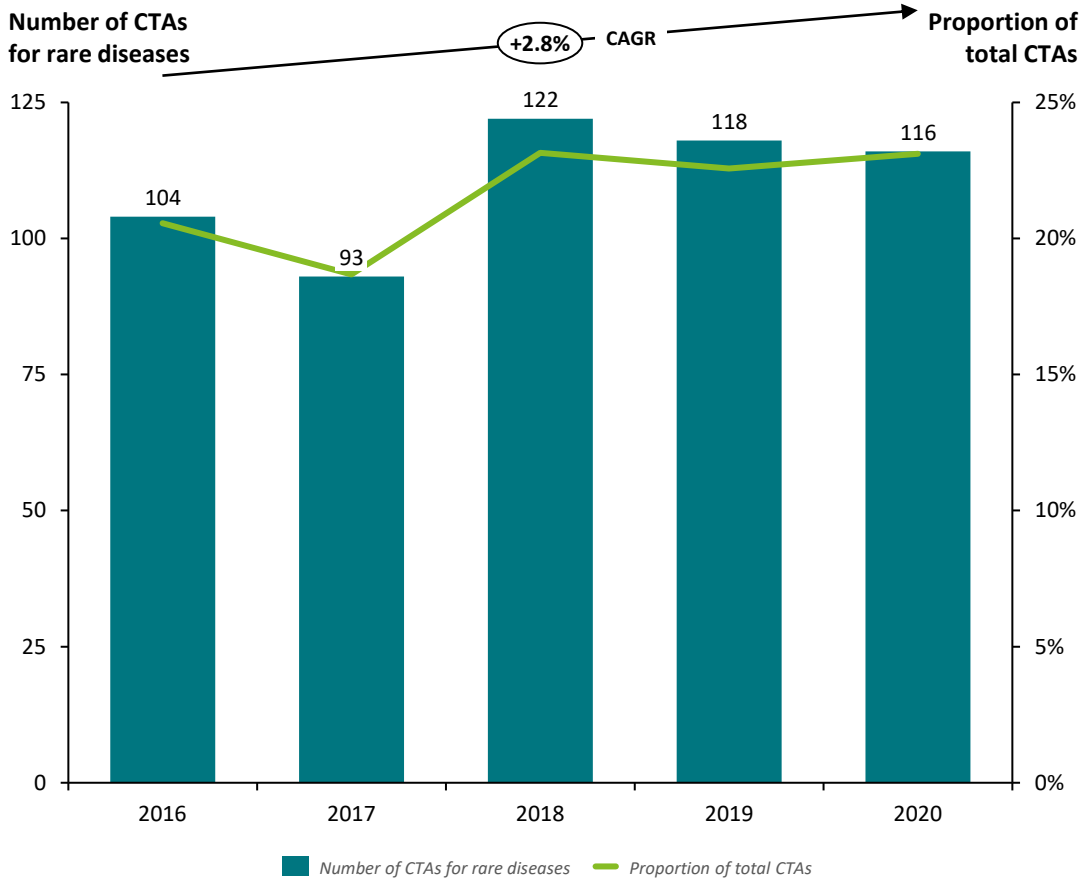
Clinical trials in Belgium

Despite its population size, more than 1 out of 5 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 (2020)



Evolution of CTAs for rare diseases in Belgium (2016-2020)

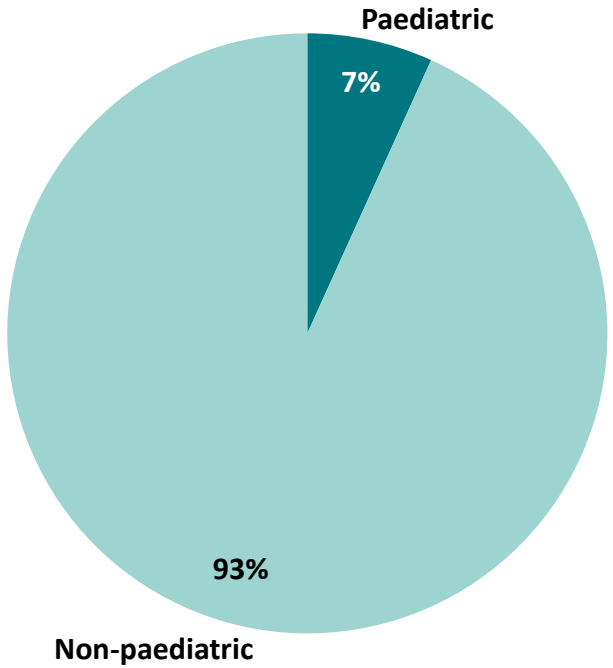


Source: Monitor Deloitte analyses based on FAMHP data

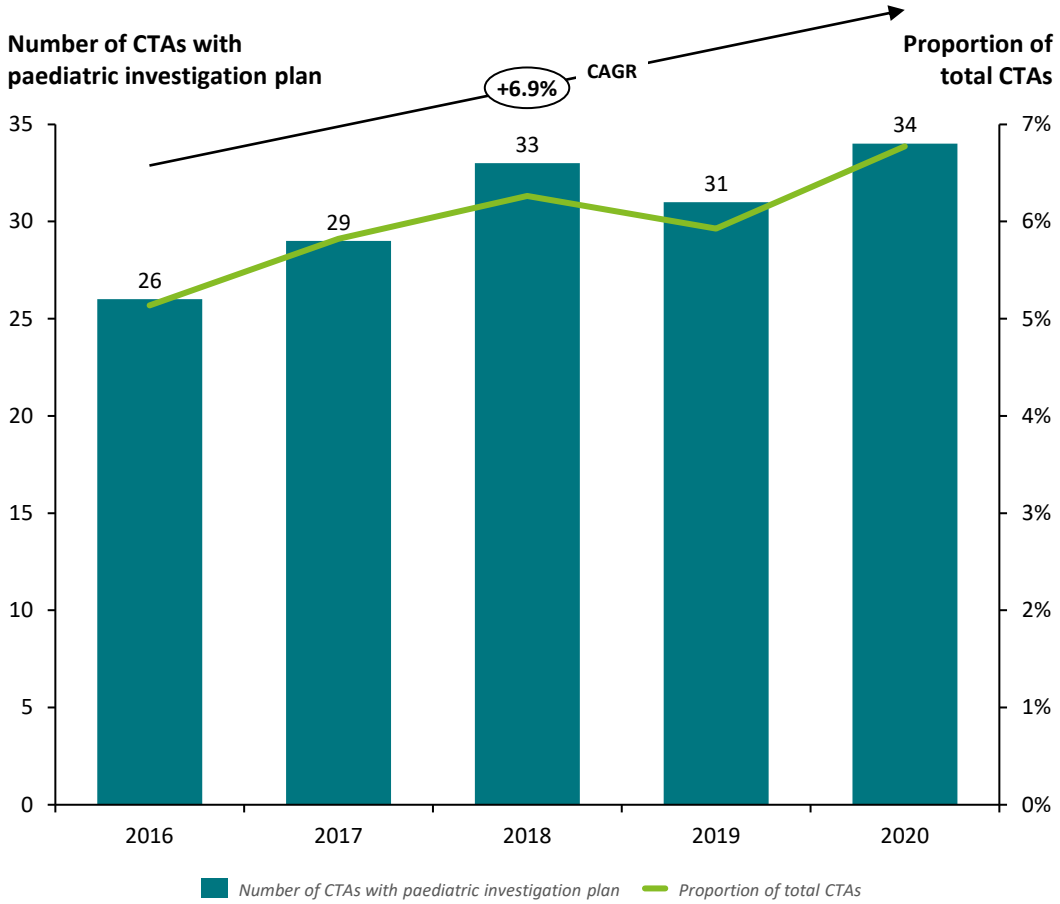
Clinical trials in Belgium

An upwards trend in paediatric trials can be observed over the past 4 years

Percentage of CTAs with a paediatric investigation plan authorised by the FAMHP in Belgium (2020)



Evolution of CTAs with a paediatric investigation plan in Belgium (2016-2020)

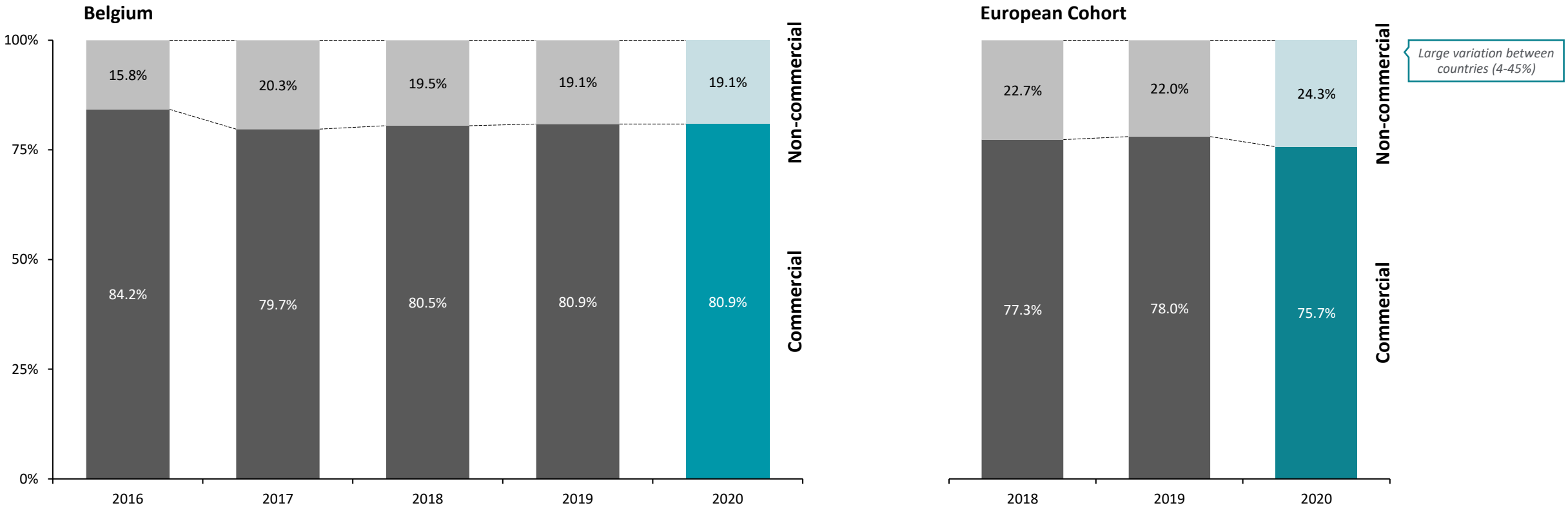


Source: Monitor Deloitte analyses based on FAMHP data

Clinical trials in Belgium

Commercial trials have a higher footprint in Belgium compared to the European cohort

Percentage of CTAs per status of the sponsor in Belgium (2016-2020) compared to European cohort (2018-2020)

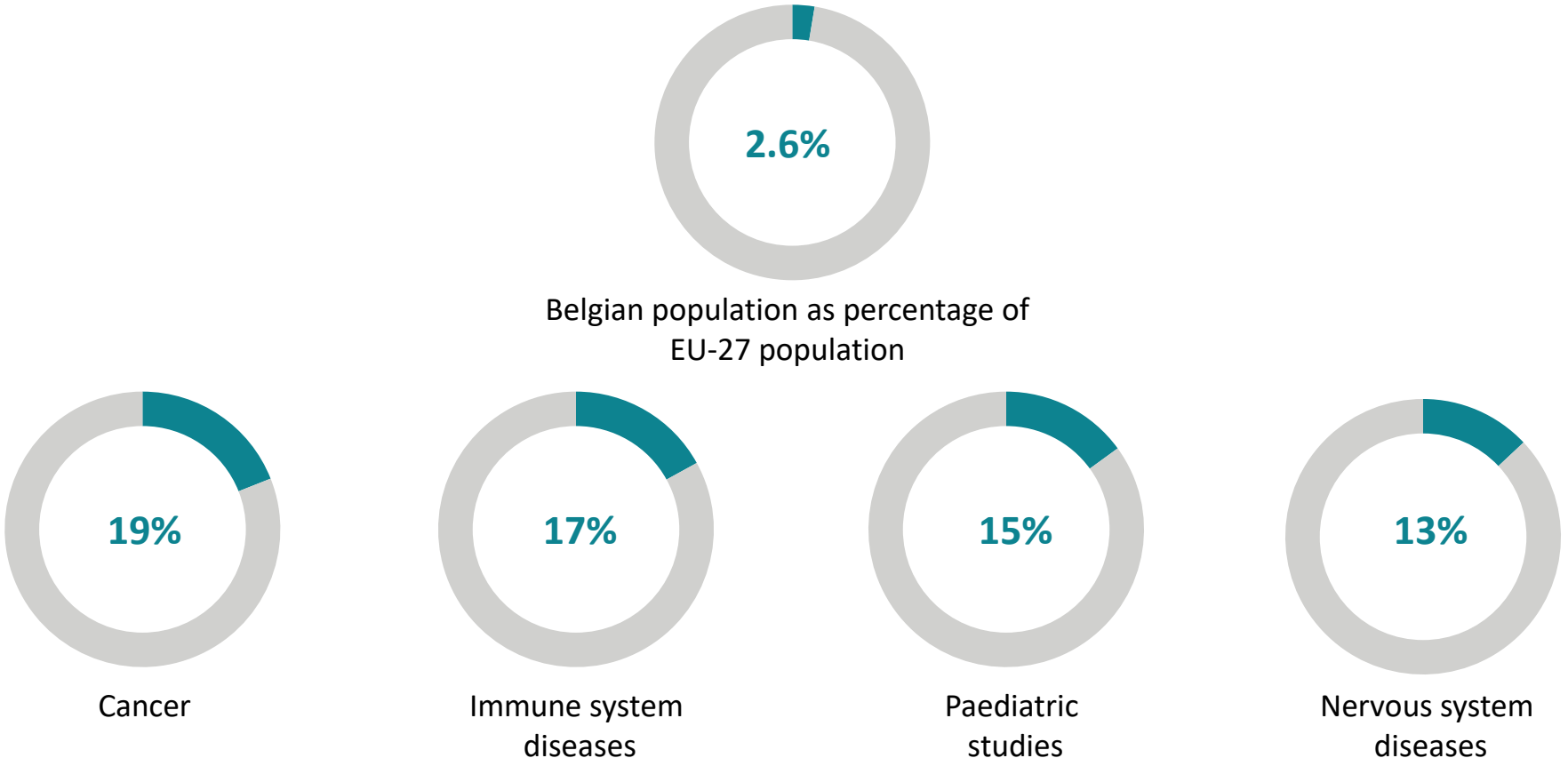


Source: Monitor Deloitte analyses based on FAMHP data

Clinical trials in Belgium and in Europe

A high percentage of clinical trials in Europe is 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 (2020)

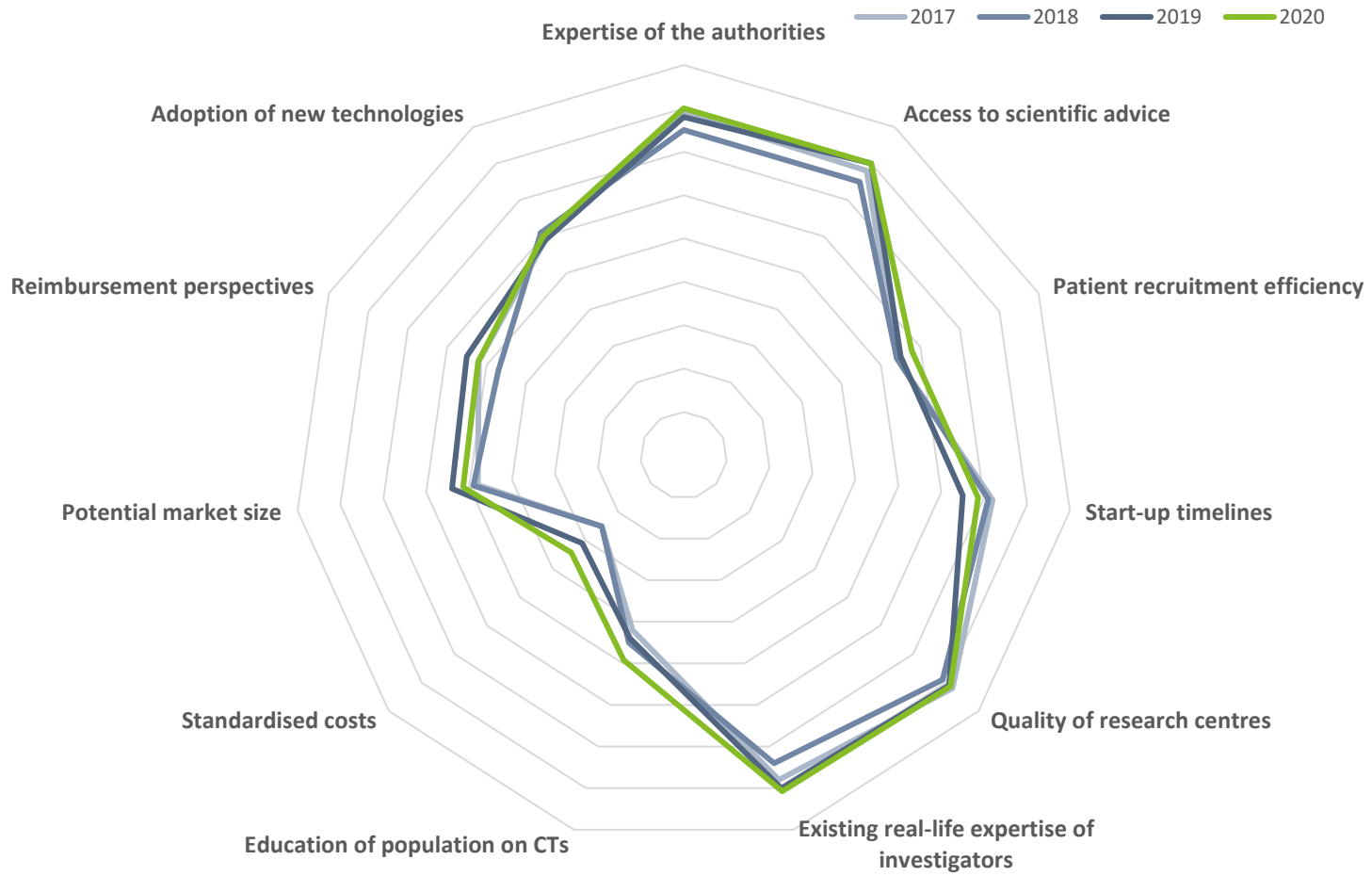


Source: Monitor Deloitte analyses based on FAMHP data

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



Source: pharma.be member survey 2017, 2018, 2019, and 2020

Attractiveness of Belgium

Belgium is rated quite well in terms of flexibility in case of emergencies such as the COVID-19 pandemic but there is room for improvement

Average rating out of 10 (range) of flexibility in case of emergencies such as the COVID-19 pandemic (2020)

Overall flexibility compared to other European countries	7.2 (5-10)
Time needed by the **regulator** to adapt to the COVID-19 pandemic	6.5 (3-9)
Time needed by the **hospitals** to adapt to the COVID-19 pandemic	7.5 (6-9)

✓ *Remote source document verification made possible in some countries when hospital access was restricted due to COVID-19*
↔ FAGG does not allow this

✓ *Faster and more clear instructions are key for proper continuation and start-up of clinical trials during a crisis*

Source: pharma.be member survey 2020

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