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ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

Belgium as clinical trial location in Europe

Presentation of results for 2016

4 May 2018

Methodology of the study

Objective of the study: to benchmark Belgium as a clinical trial location against other EU countries

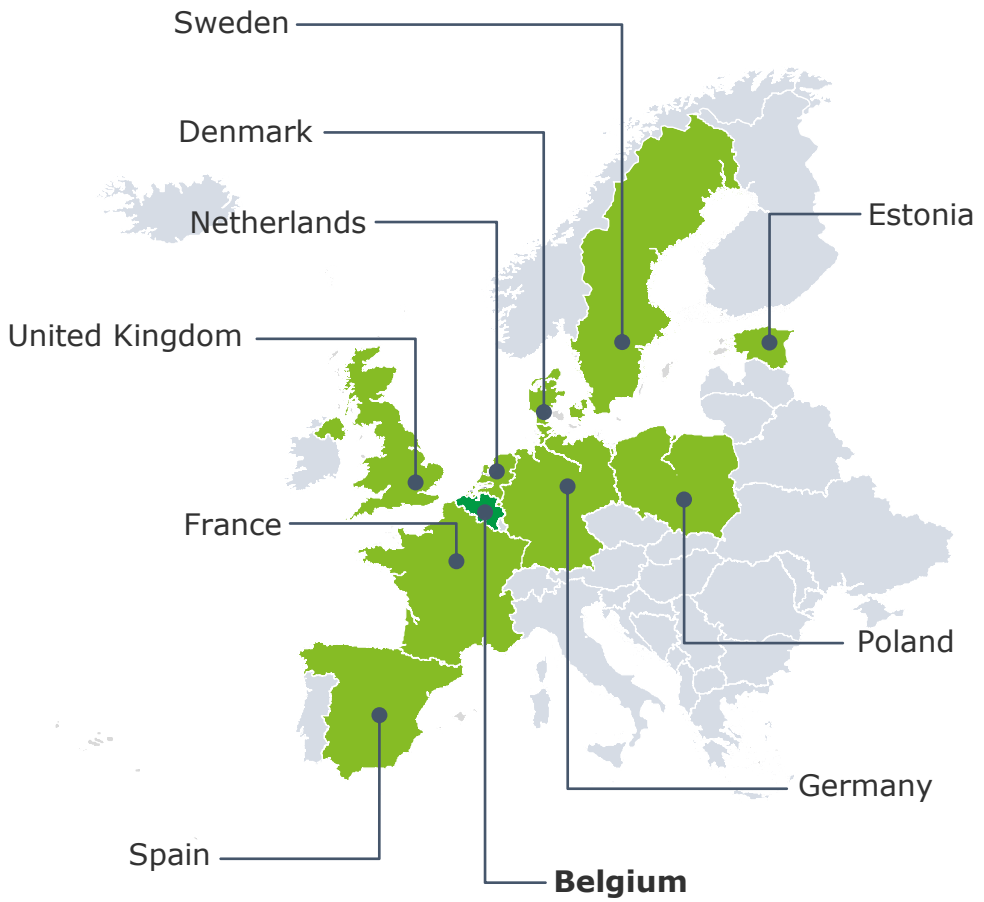
Ten EU Countries were included in the study: Belgium, Estonia, Denmark, France, Germany, the Netherlands, Poland, Spain, Sweden and the United Kingdom

Data sources:

- Data on clinical trial authorisations in Belgium for the year 2016, provided by the Federal Agency for Medicines and Health Products (FAMHP)
- Data from the EU Clinical Trials Register for clinical trial authorisations between 31/12/2014 and 1/8/2017
- Annual reports of the national medicines agencies
- Data on R&D expenditure and population data obtained from Eurostat
- Web survey conducted amongst the members of pharma.be
- In-depth interviews with industry experts, academics, and the FAMHP

Data validation: the results of the study were validated against annual reports of national authorities and data of the FAMHP. The results of the study were regularly discussed with the pharma.be project team and were also presented to the pharma.be clinical trial task force and clinical trial work group in order to obtain additional insights.

Limitations of the study: Comparison was based on data from the EU Clinical Trials Register: Country-specific reporting may vary considerably, impacting comparison of national medicines agency data across countries

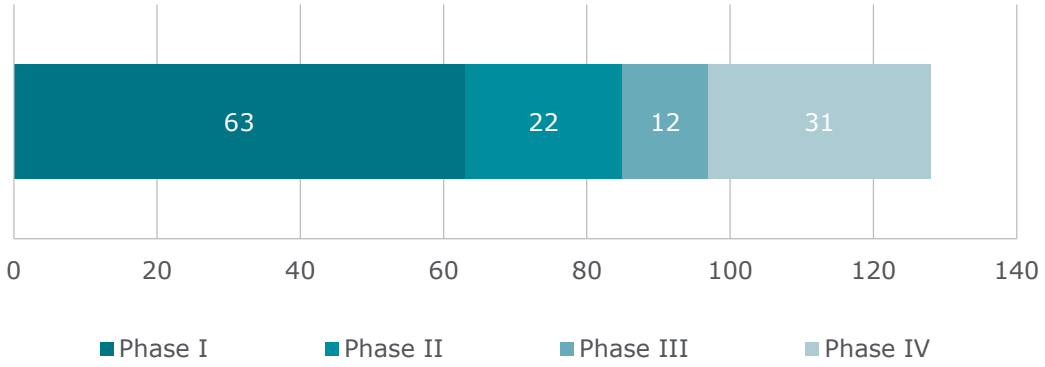


Descriptive statistics trial characteristics

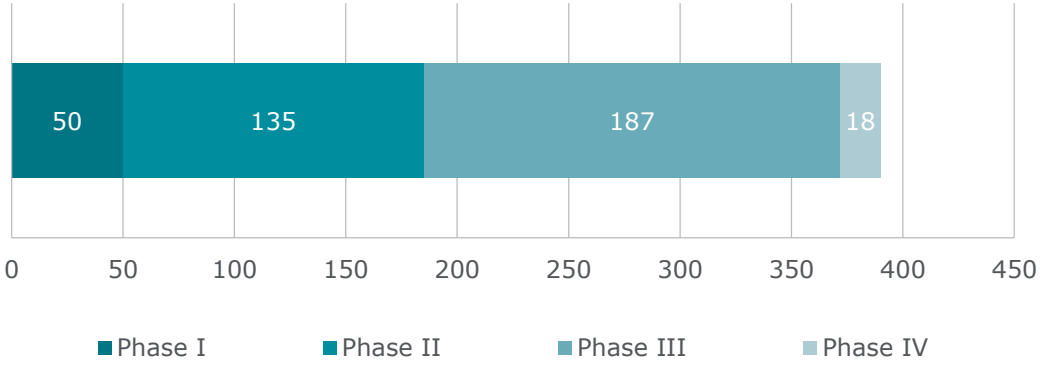
Clinical trials in Belgium

Strong expertise in Phase I studies thanks to a favourable regulatory framework of the FAMHP

122 mononational clinical trials authorised by the FAMHP



360 multinational clinical trials authorised by the FAMHP



98 single site

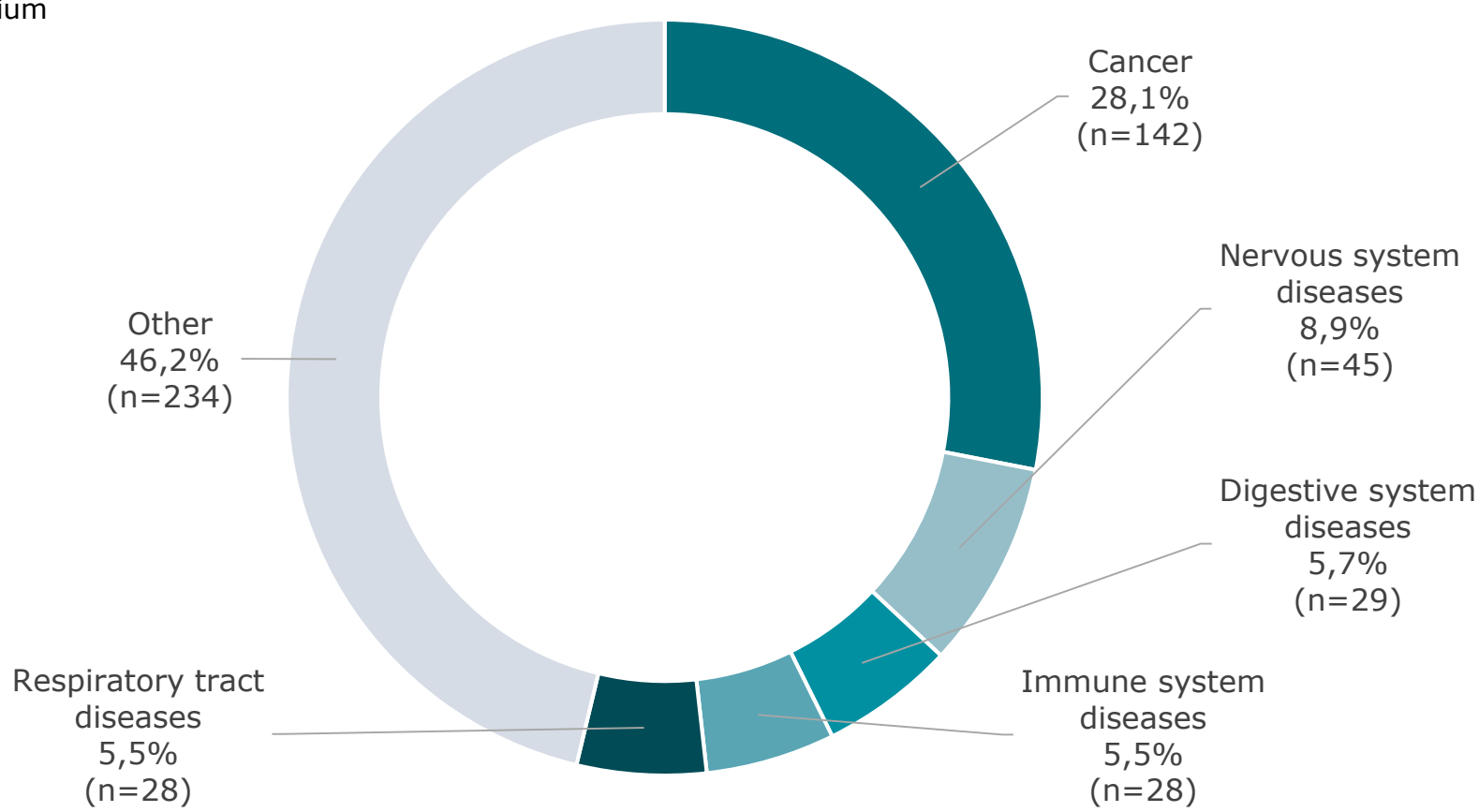
24 multiple sites

Source: FAMHP

Clinical trials in Belgium

A wide variety of therapeutic areas, with strong expertise in cancer research

Top 5 therapeutic areas in Belgium

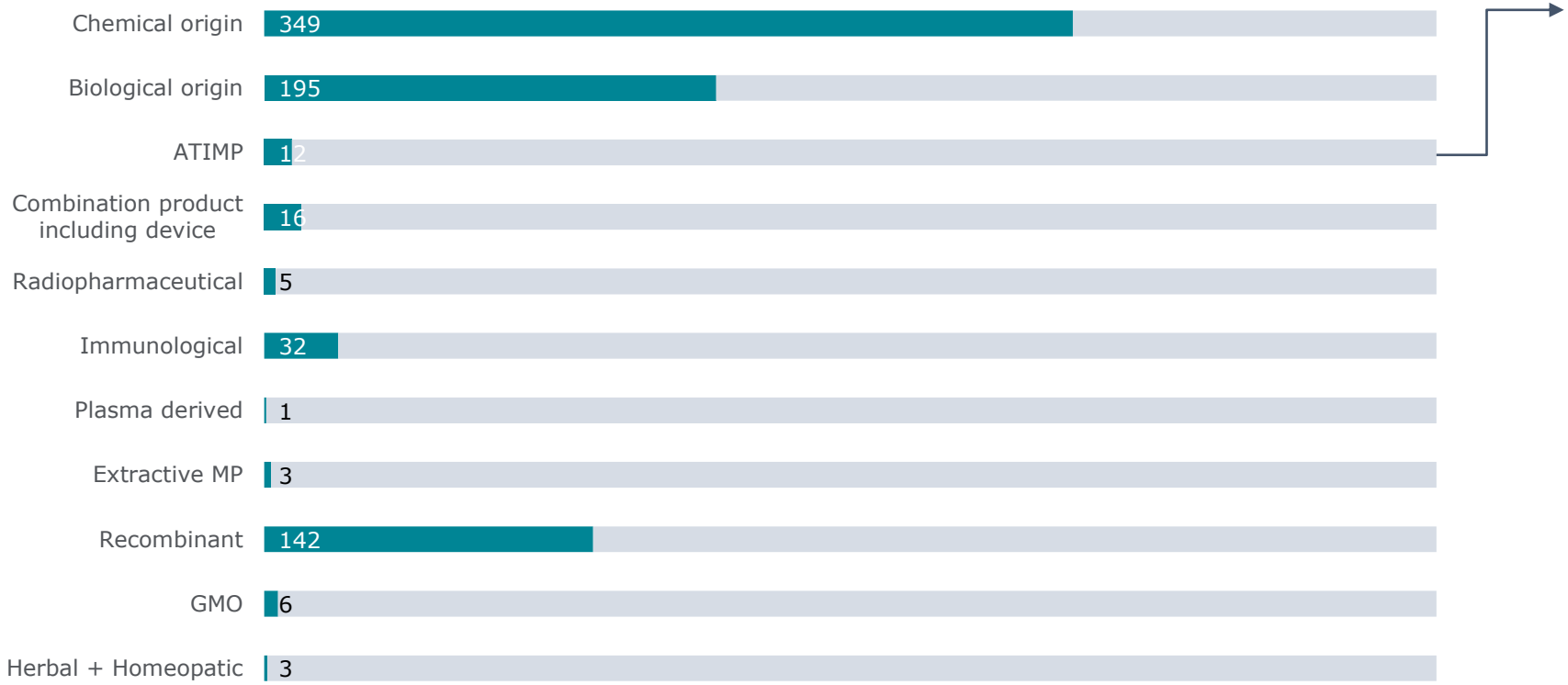


Source: FAMHP. The therapeutic areas are mutually exclusive. Cancer [C04]; Nervous system [C10]; Digestive system [C06]; Immune system [C20]; Respiratory tract [C08].

Clinical trials in Belgium

More than two out of five clinical trial authorisations include biological products

Clinical trial authorisations by type of investigational medical product, as proportion of total



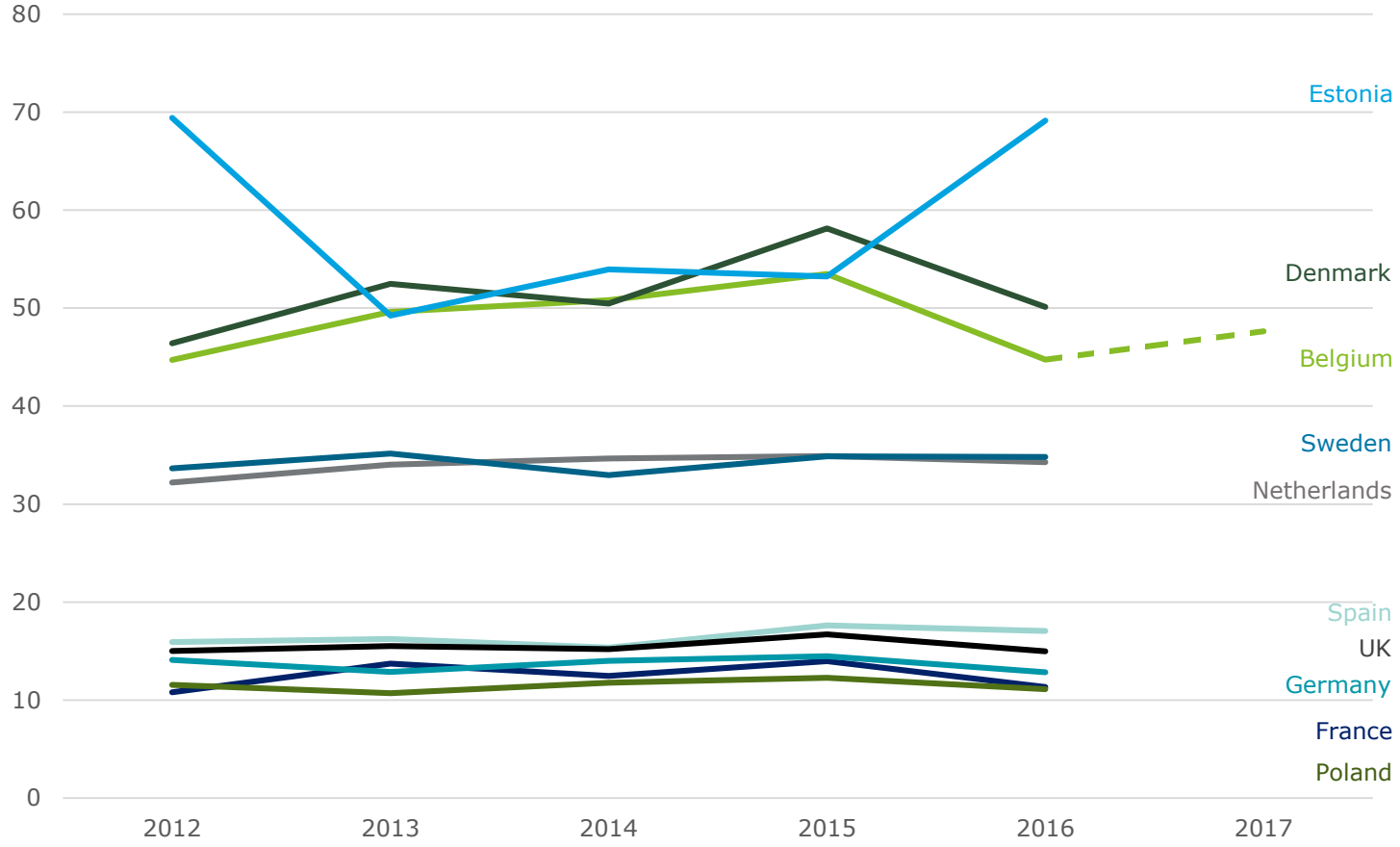
- **6** gene therapy medical product
- **4** somatic cell therapy medical product
- **1** tissue engineered

Extractive MP = a medicinal product derived from human tissue such as blood or plasma.
Source: FAMHP. Categories are not mutually exclusive.

Clinical trials in Belgium

Belgium demonstrates continued leadership in the number of clinical trials per capita in the EU

Evolution of clinical trial applications per 1 million capita between 2012-2016 in cohort countries



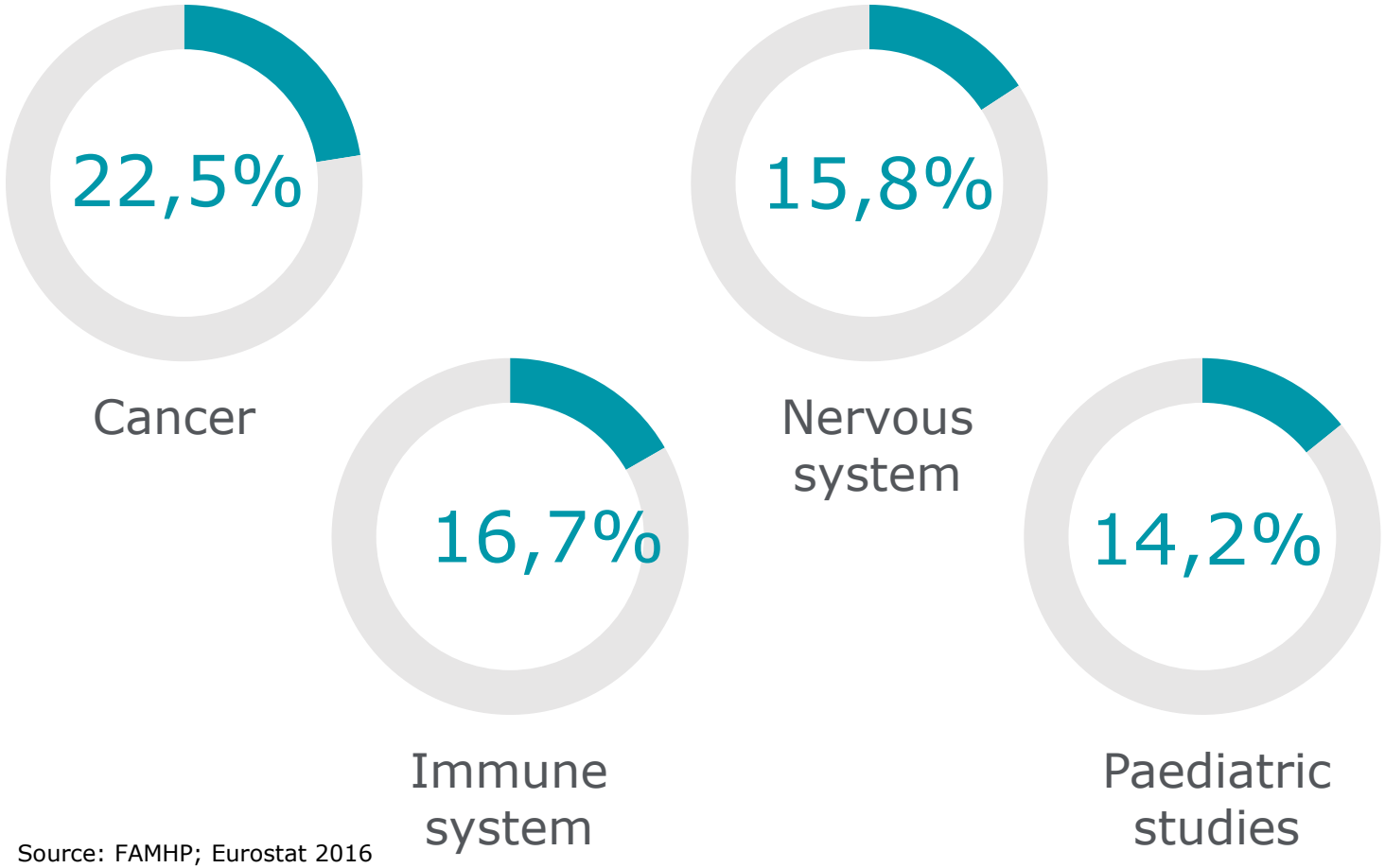
Source: Eurostat (2017); Annual report NMAs; FAMHP

- Belgium, together with Estonia and Denmark, is consistently part of the top 3 countries in terms of number of clinical trial applications per 1 million capita.
- Although it has the lowest absolute number of clinical trial applications, Estonia has the highest number of clinical trial applications per capita due to its very small population of 1.3 million people.
- Based on this chart, 3 main groups can be distinguished:
  - Countries with a high number of clinical trial applications per capita: Estonia, Denmark, Belgium
  - Countries with a medium number of clinical trial applications per capita: Sweden, Netherlands
  - Countries with a low number of clinical trial applications per capita: Spain, the United Kingdom, France, and Poland
- In 2017, clinical trial applications per 1 million capita in Belgium was 47,63

Clinical trials in Belgium

A relatively high percentage of clinical trials in Europe are conducted in Belgium

Percentage of clinical trials in Europe conducted in Belgium



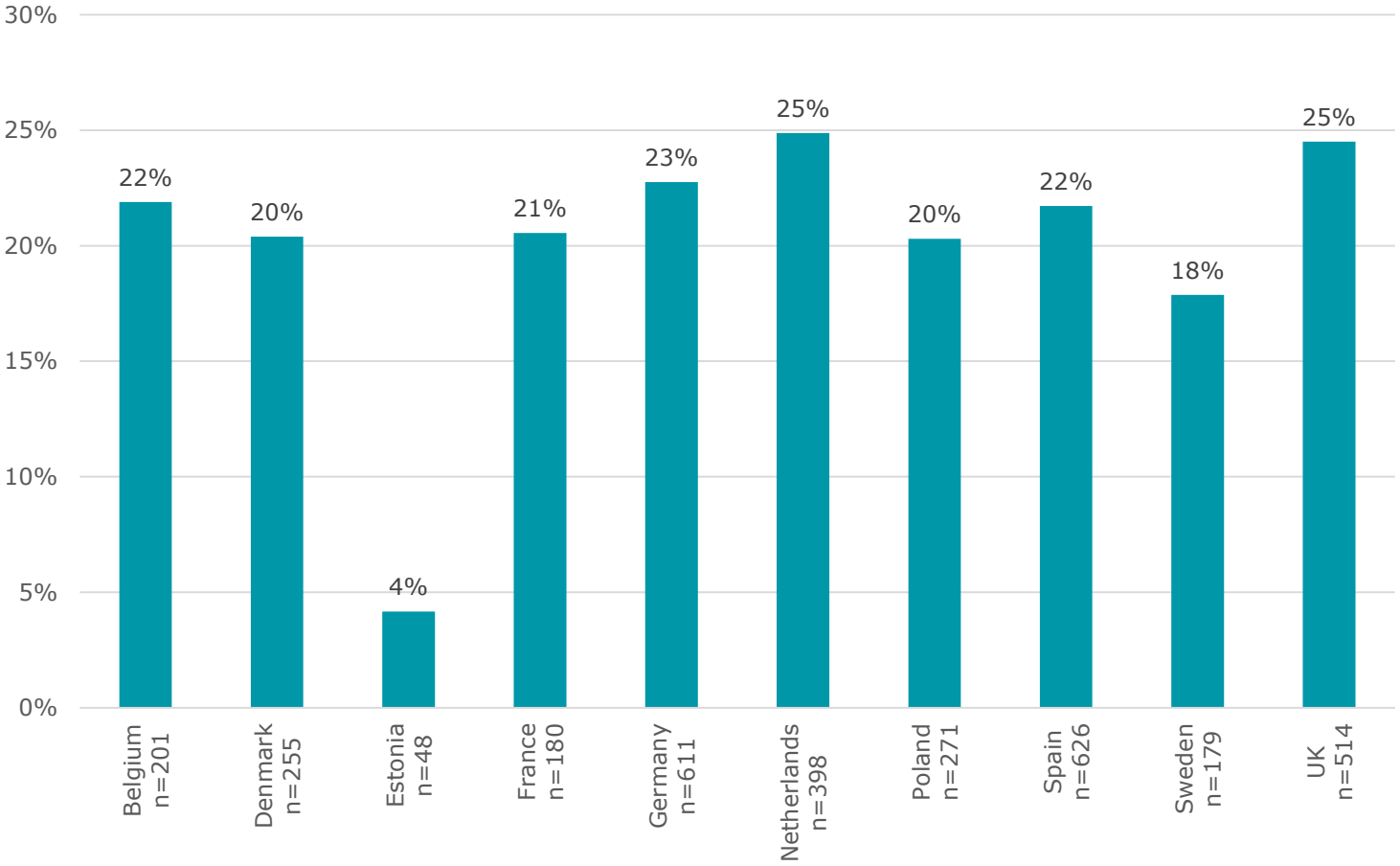
Source: FAMHP; Eurostat 2016

Total population of Belgium relative to the total population of the European Union in 2016

Clinical trial characteristics

The proportion of clinical trials for rare disease in Belgium is comparable to other countries in scope

Percentage of clinical trial applications aggregated over all phases (I-IV) for rare diseases per country



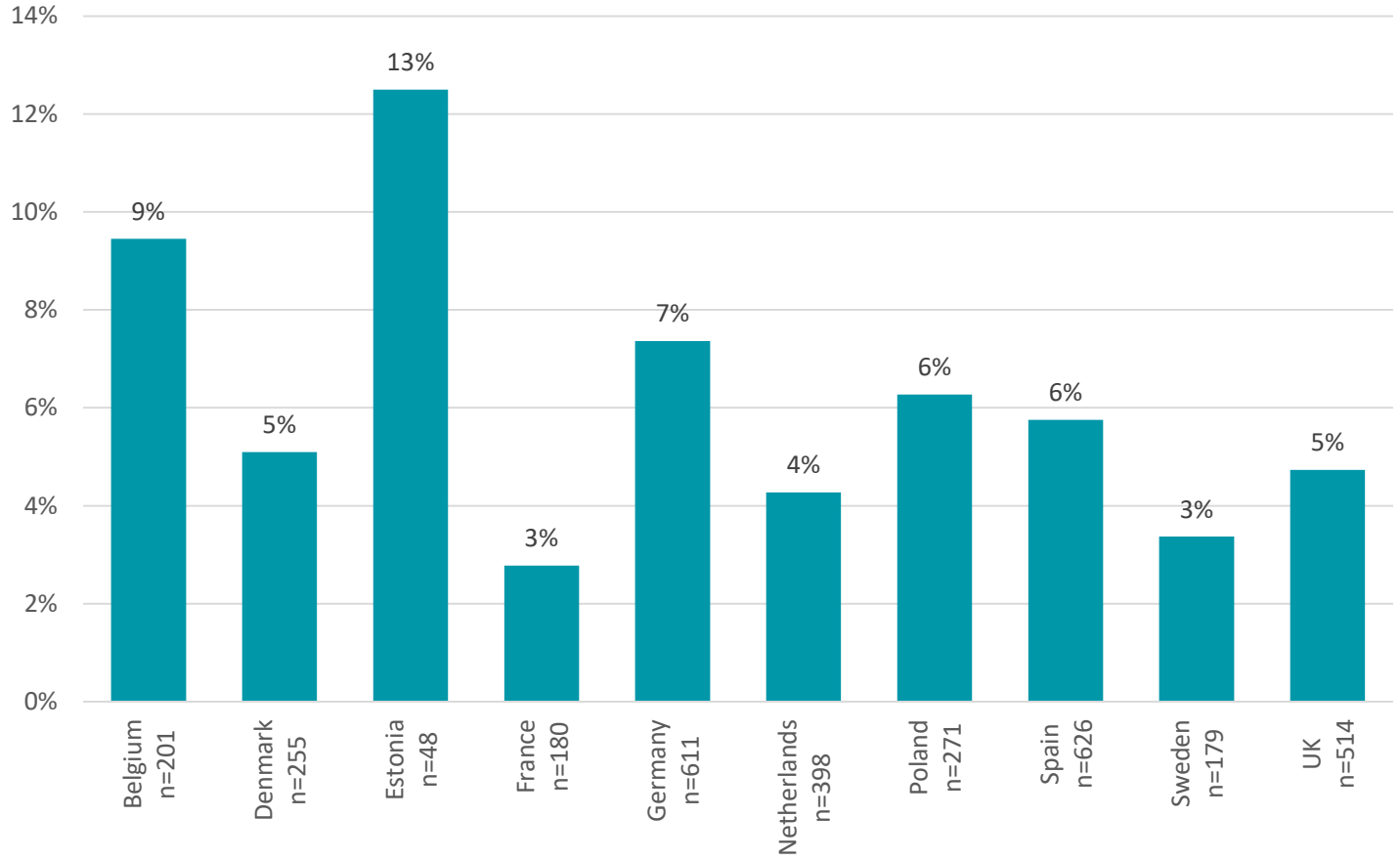
Source: Monitor Deloitte analyses based on EU Clinical Trials Register data

- The United Kingdom and the Netherlands have the highest proportion of clinical trial applications for rare diseases.
- The number of clinical trial applications for rare diseases is stable across the cohort countries apart from Estonia, a country with a very small population.
- The number of clinical trial applications for rare diseases is not higher in countries with a large population such as Germany, France or Spain.

Clinical trial characteristics

Belgium, together with Estonia, are leaders in conducting paediatric clinical trials

Percentage of clinical trial applications aggregated over all phases (I-IV) for clinical trials that are part of a paediatric investigation plan



- Estonia and Belgium have a larger proportion of clinical trial applications that are part of a paediatric investigation plan compared to the other cohort countries.
- This may be linked to the fact that paediatric oncology is one of the strategic focus areas of the FAHMP.

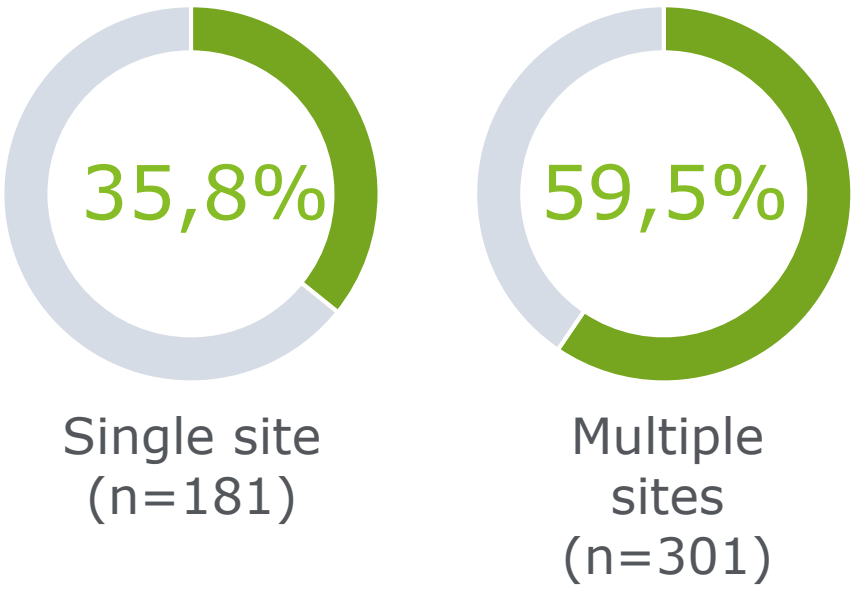
Source: Monitor Deloitte analyses based on EU Clinical Trials Register data

Patient involvement

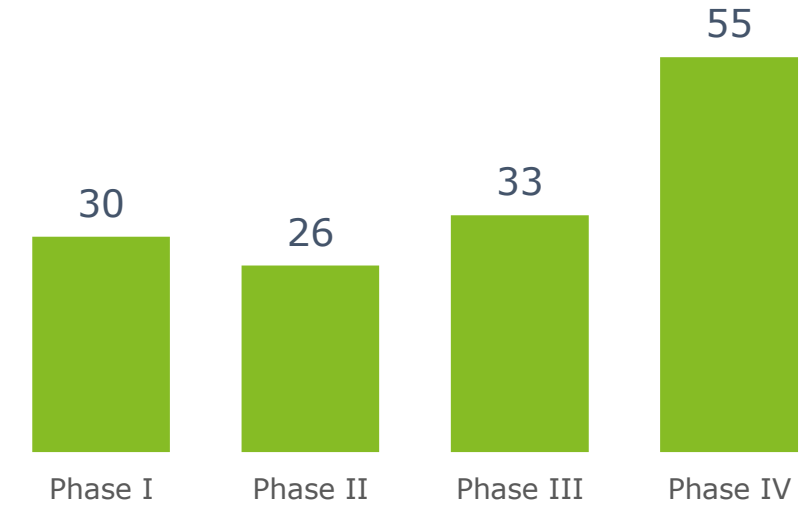
Patient involvement in Belgium

A larger proportion of multiple sites facilitates patient access to clinical trials

Clinical trial authorisations on single vs multiple sites



Average planned number of patients and healthy volunteers recruited per phase (I-IV) across all sites

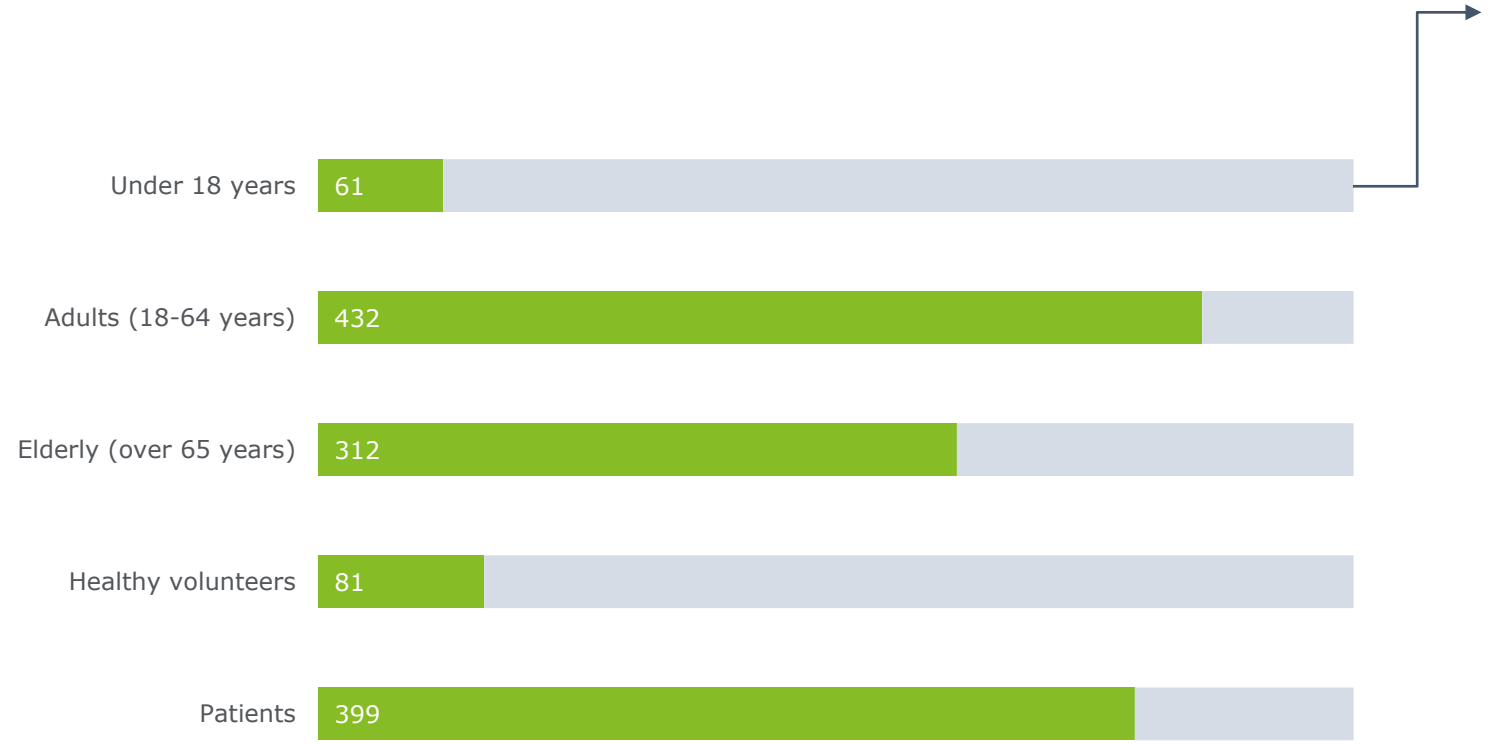


Source: Monitor Deloitte analysis based on FAMHP data

Patient involvement in Belgium

A large diversity in recruited patients and healthy volunteers

Number of clinical trial authorisations in 2016 planning recruitment of specific population groups



- **0** in utero
- **0** preterm new-born infants
- **2** newborns (0 – 27 days)
- **18** infants and toddlers (28 days – 23 months)
- **46** children (2 – 11 years)
- **48** adolescents (12 – 17 years)

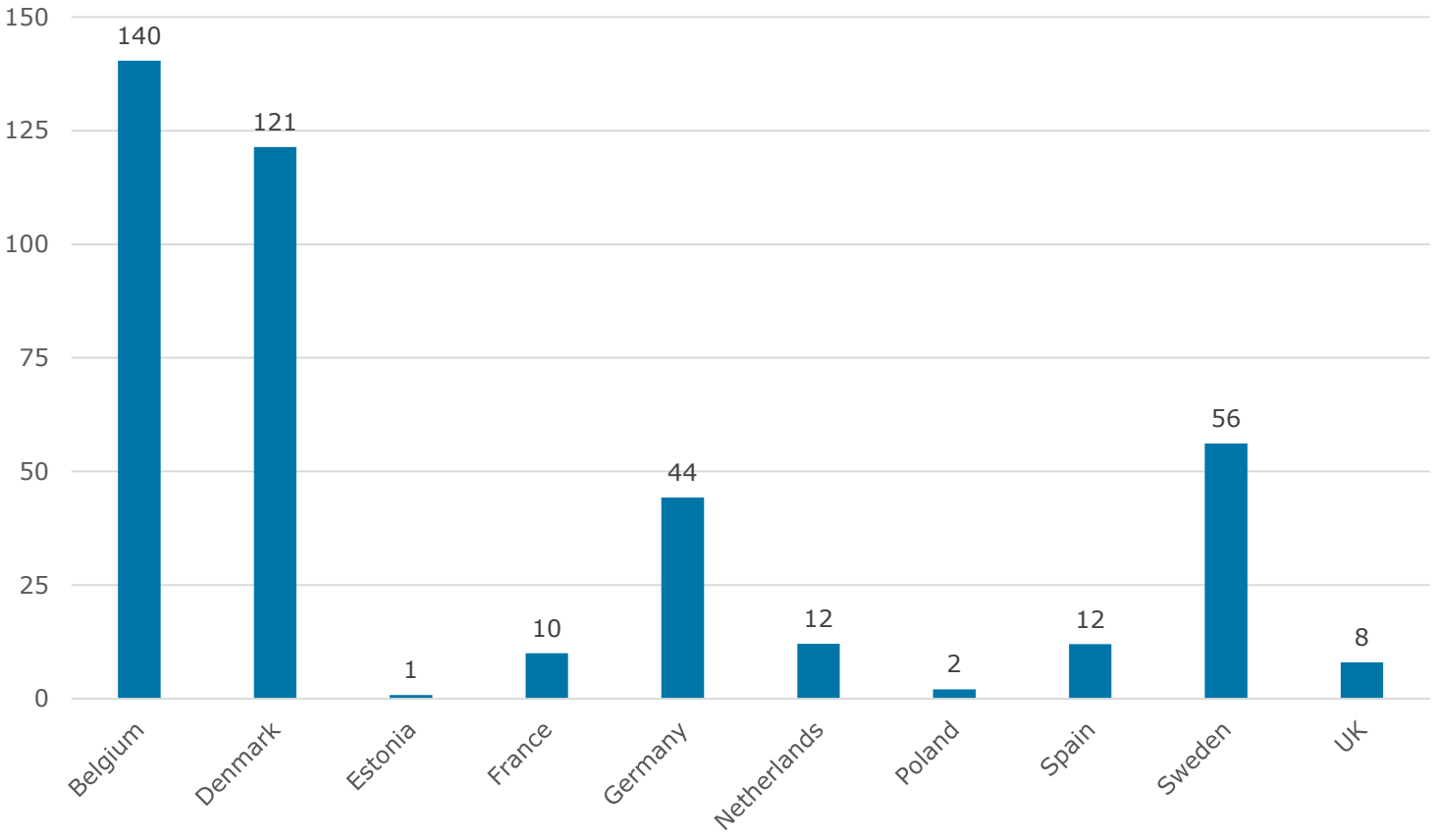
Source: Monitor Deloitte analysis based on FAMHP data

Economic impact

Economic impact

Business enterprises in Belgium invest most in pharmaceutical R&D per capita within the country cohort

Business R&D expenditure for manufacture of basic pharmaceutical products and pharmaceutical preparations by country in 2013, expressed in purchasing power standard per inhabitant at constant 2005 prices



- Belgium has the highest business R&D expenditure expressed in purchasing power standard per inhabitant at constant 2005 prices, closely followed by Denmark.
- Other countries follow at a large distance.

"The purchasing power standard is an artificial currency unit. One purchasing power standard can buy the same amount of goods and services in each country. However, price differences across borders mean that different amounts of national currency units are needed for the same goods and services depending on the country. Purchasing power standards are derived by dividing any economic aggregate of a country in national currency by its respective purchasing power parity.

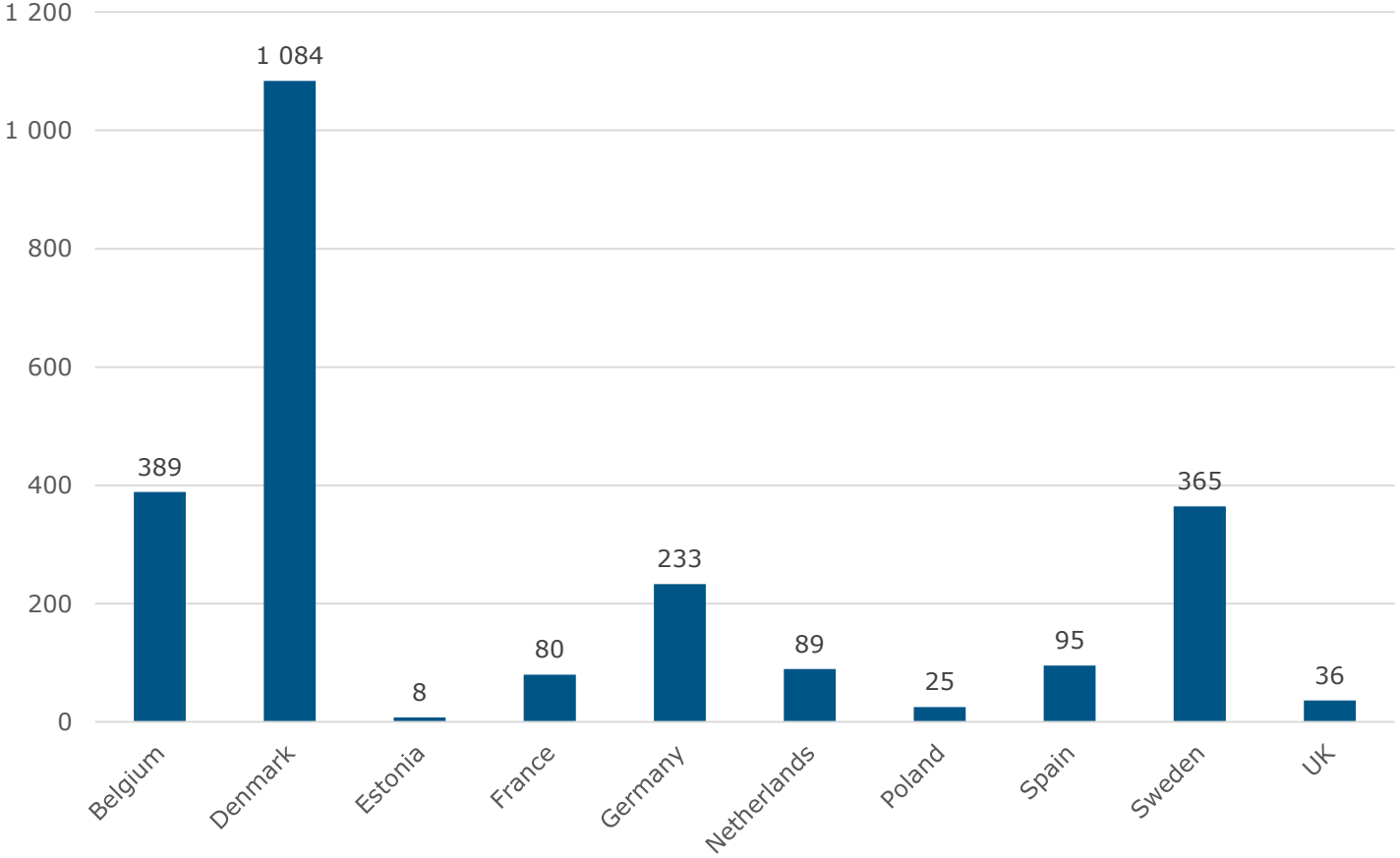
The purchasing power standard is the technical term used by Eurostat for the common currency in which national accounts aggregates are expressed when adjusted for price level differences using purchasing power parities. Thus, purchasing power parities can be interpreted as the exchange rate of the purchasing power parities against the euro."

Source: Eurostat (2017). R&D expenditure: business R&D expenditure (BERD) by economic activity (NACE Rev. 2 Manufacture of basic pharmaceutical products and pharmaceutical preparations); Eurostat (2017). Statistics explained: glossary.

Economic impact

Belgium has the second highest R&D employment per capita in the pharmaceutical industry within the country cohort

R&D employment in business enterprise: Manufacture of basic pharmaceutical products and pharmaceutical preparations in FTE per capita, per million, by country in 2013



- Total R&D employment expressed in FTEs in Belgium in the biopharmaceutical industry is 4330, of which an estimated 60% is related to clinical trials. The Belgian R&D employment per 1M capita in the biopharmaceutical industry is 389.
- Belgium has the second highest R&D employment when expressed as FTE per 1M capita and the 5th highest R&D employment expressed in FTE of the cohort countries, ranked after Germany (18767 FTEs), Denmark (6071 FTEs), France (5261 FTEs) and Spain (4449 FTEs).
- At the FAMHP, 17.6 FTEs were directly employed in the area of clinical trials in 2016.

Source: Eurostat (2017). Total R&D personnel and researchers, in business enterprise sector by economic activity and sex (NACE Rev. 2); web survey pharma.be members; FAMHP

Attractiveness of Belgium

SWOT analysis by Deloitte

Overview of the strengths, weaknesses, opportunities and threats for Belgium as a clinical trial location in Europe

Strengths

- Accessibility of clinical expertise
- Pragmatic and flexible medicines agency with pronounced expertise in strategic areas
- Research-minded environment
- Post-trial access through Early Temporary Authorisation (ETA)

Weaknesses

- Patient recruitment and retention
- Policy making needs to keep pace with scientific developments and technological trends

Opportunities

- Healthcare reform and hospital networks
- Momentum of European Clinical Trial Regulation
- Recruitment of European Medicines Agency experts by the FAHMP after Brexit
- Digitalisation

Threats

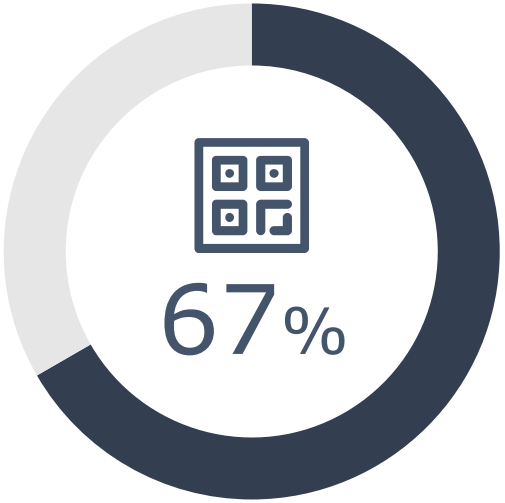
- Competitors on the horizon
- Readiness for the new European regulation
- Uncertainty around potential impact of Brexit

Source: Monitor Deloitte analysis based on primary research

The use of digital technology to support clinical trials

Belgium has employed various technologies to increase the efficiency of clinical trial recruitment and management

Biopharmaceutical companies that have used any type of digital technology to support clinical trials in Belgium



Type of technologies used

- Medical-grade devices (67%)
- Mobile apps (33%)
- Social media (33%)
- Tablet for PRO questionnaire (33%)
- Wearables (33%)
- Bar code scanner (8%)

Objectives

- Increase accuracy of data collection
- Increase speed of accessibility to source data
- Increase regulatory compliance (e.g. use of adequate informed consent forms
- Increase patient recruitment
- Provide easily accessible information to investigators and site personnel
- Improve patient adherence and persistence

Source: Monitor Deloitte analysis based on primary research

Deloitte.