Belgium, leading the way in Clinical Trials

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

7 REASONS
WHY TO CHOOSE BELGIUM FOR YOUR CLINICAL TRIALS

STRONG EXPERTISE

1,502 ongoing clinical trials in Belgium in 2017

PATIENT INVOLVEMENT

Nearly **13,000** patients/year are involved

BELGIUM AS AMBITIOUS FRONTRUNNER

Belgium ranks second in the EU in terms of CT's per inhabitant

WIDE RANGE OF THERAPEUTIC DOMAINS

19% of clinical studies conducted in EU in the area of cancer research are performed in Belgium

UNIQUE HEALTH ECOSYSTEM

7 academic hospitals, **12** universities, **52** member companies active in R&D

QUALITY OF RESEARCH

more than **70** hospitals with top quality clinical services and well trained staff

ADVANTAGE OF SPEED

15 day approval time for phase 1 trials

BELGIUM LEADING
THE WAY IN EUROPE

Belgium continues to be a **unique health ecosystem** in which clinical research can thrive. Thanks to a shared vision and common focus on solutions rather than problems between regulators, industry, researchers and government, Belgium has been able to put itself on the map as a particular location for conducting clinical trials, leading to milestone events such as the first clinical trial with CAR-T in Europe.

The Belgian competent authorities enjoy a strong reputation thanks to the **technical and scientific advice** they provide.

The **level of collaboration** in the Belgian Clinical Trial Regulation (CTR) pilot is high, which increases the learning opportunities for all stakeholders involved, reduces the risk of identifying potential issues late in the process and allows Belgium to take up a **leading role at the European level**.

With 498 new authorisations (commercial and non-commercial) for clinical trials in 2017 and a total of 1,502 trials ongoing that year, Belgium is one of the leaders in Europe. **Belgium is in 2nd place in Europe,** in terms of number of clinical trials per inhabitant.

The fact that Belgium is an attractive country for starting up clinical trials offers **benefits**. As well as providing **rapid access to innovative medications in development**, the trials can also generate valuable insights into treatments for other conditions. All actors involved in healthcare make every effort to keep Belgium's strong position as an attractive country for carrying out clinical trials.

Belgium is
2nd
in place in Europe

1,502
ongoing clinical trials in Belgium in 2017

498
new authorisations in 2017

80%
of the clinical trials are industry driven

Source: clinicaltrials.gov (trials started 2017) – FAMHP 2019, latest available data 2017 – Deloitte's report 2019 "Belgium as a clinical trial location in Europe" – results for 2017

1. STRONG **EXPERTISE**

BELGIUM HAS A LONG HISTORY OF EXCELLENT CLINICAL RESEARCH

Belgium has played a pivotal role in the development of new medicines, thanks to its leadership in clinical trials. In 2017, more than 1,500 trials were running in Belgium. The trials in Belgium are distributed evenly across the various phases in clinical research.

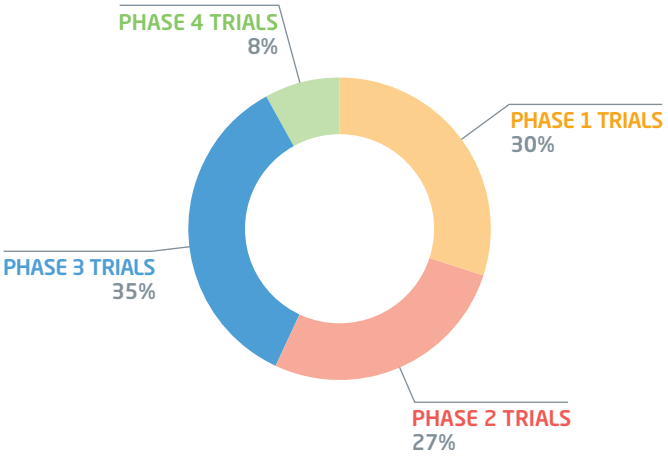
The "first in human" as part of **early clinical drug development** is one of the strategic focus areas of the competent authorities.

The **strong technical expertise of the Federal Agency of Medicines and Health Products (FAMHP)** and the scientific advice they provide is highly appreciated and it enables to deal with critical questions early on in the evaluation process.

Members of the FAMHP are also well represented in the different working groups at the European Medicines Agency (EMA) which benefits Belgium in terms of knowledge generation, steering strategic choices, and leadership opportunities.

Amongst others, the head of FAMHP is part of the EMA management board and EU Clinical Trials Facilitation Group.

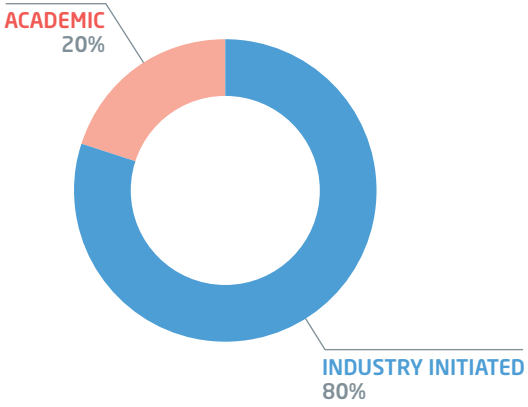
FIG. 1: **AUTHORISATIONS FOR CLINICAL TRIALS IN BELGIUM (N=498)**



Source: FAMHP 2019, latest available data 2017

One third of the phase I clinical trials are 'first in human' trials.

FIG. 2: **DISTRIBUTION INDUSTRY-INITIATED CLINICAL TRIALS VS. ACADEMIC CLINICAL TRIALS**



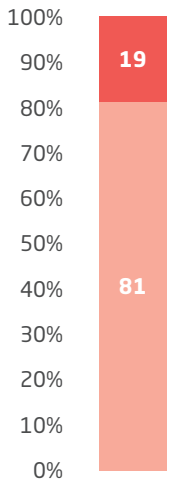
Source: Deloitte's report 2019 "Belgium as a clinical trial location in Europe" – results for 2017

The majority, or **80%**, of clinical trials in Belgium are initiated by the pharmaceutical industry. The remaining **20%** are clinical trials initiated by universities or academic centres.

FOCUS ON RARE DISEASES AND PAEDIATRIC CLINICAL TRIALS

Nearly one fifth of the clinical trial authorisations (CTA's) is dedicated to rare diseases.

FIG. 3: **PERCENTAGE OF CTA'S FOR RARE DISEASES IN BELGIUM (N=498)**



Source: FAMHP 2019, latest available data 2017

Rare diseases are rare, but rare disease patients are numerous

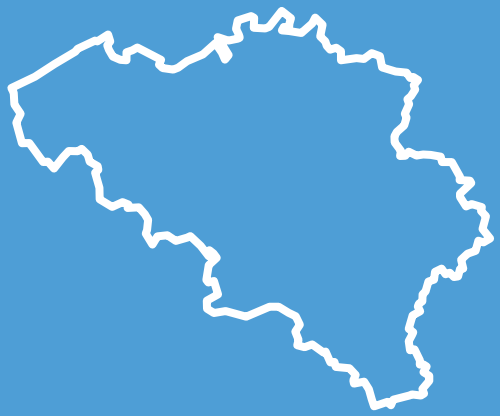
A disease is considered rare if fewer than five in 10,000 people are affected by it. Around 30 million people in the European Union (EU) suffer from a debilitating rare disease, which means one in 17 people. Finding effective treatment for these rare diseases is a huge challenge.

Source: European Medicines Agency

Special care for children

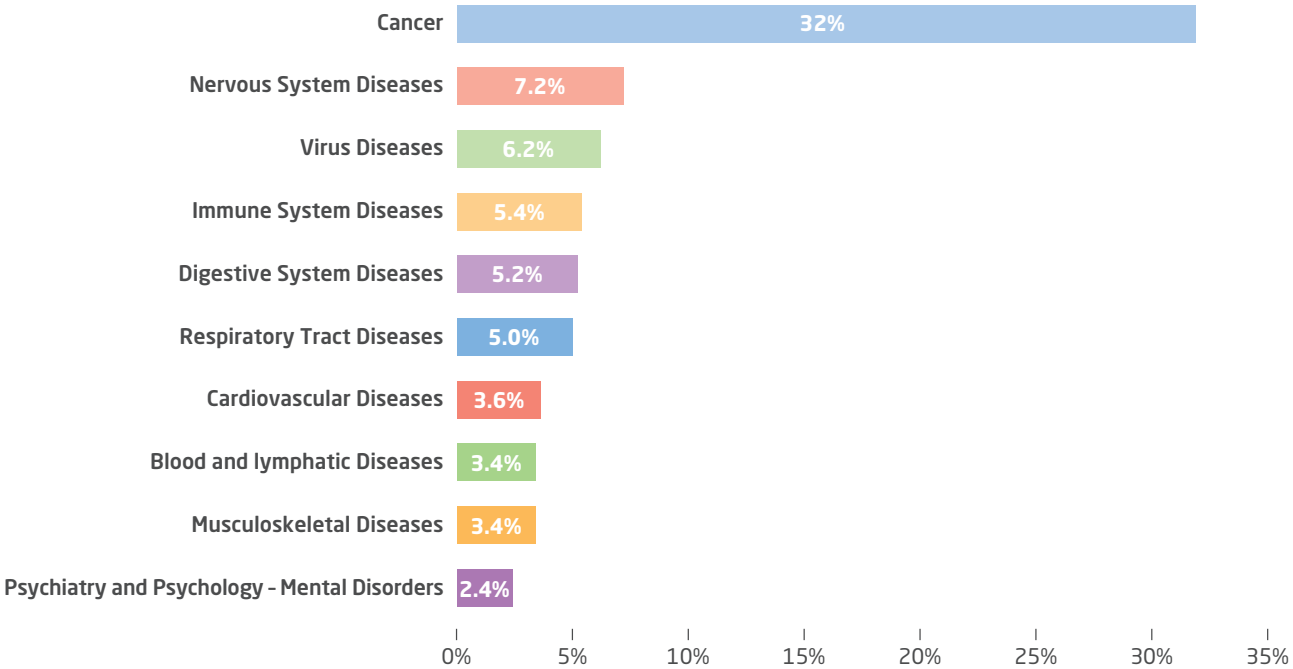
Children are a unique population with distinct developmental and physiological differences from adults. Clinical trials in children are essential to develop age-specific, empirically-verified therapies and interventions to determine and improve the best medical treatment available. In 2017, 29 clinical trials for children were approved in Belgium.

2. WIDE RANGE OF **THERAPEUTIC DOMAINS**



The clinical trials carried out in Belgium cover nearly all therapeutic areas. Belgium's specific expertise in oncology is notable: over **30 percent of the authorised applications for clinical trials are intended to test new cancer treatments**. Other trials address central nervous system disorders, digestive diseases, cardiovascular conditions etc.

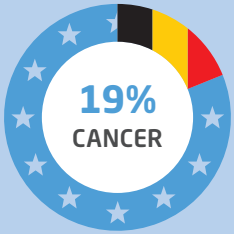
FIG. 4: **CLINICAL TRIALS IN BELGIUM ADDRESS A BROAD RANGE OF THERAPEUTIC AREAS – TOP 10 (2017)**



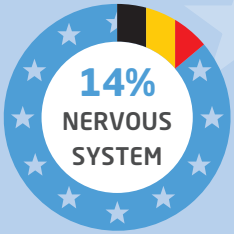
Source: FAMHP 2019, latest available data 2017

BELGIUM'S REMARKABLE POSITION **IN EUROPE**

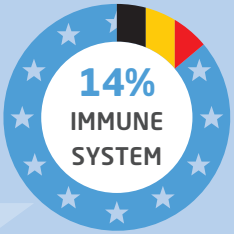
A LARGE PERCENTAGE OF THE CLINICAL TRIALS CONDUCTED IN EUROPE, IS CONDUCTED IN BELGIUM



of clinical studies in the area of cancer research



of clinical studies to investigate diseases affecting the nervous system

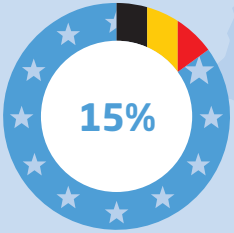


of clinical studies conducted to research diseases affecting the immune system

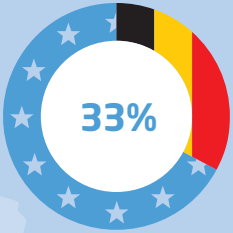
of clinical studies in paediatric diseases

Source: Deloitte's report 2019 "Belgium as a clinical trial location in Europe" – results for 2017

BELGIUM AT THE FOREFRONT OF NOVEL MEDICAL TECHNIQUES



of all clinical trials in the EU to explore biological phenomena



of all clinical trials in the EU to explore genetic phenomena

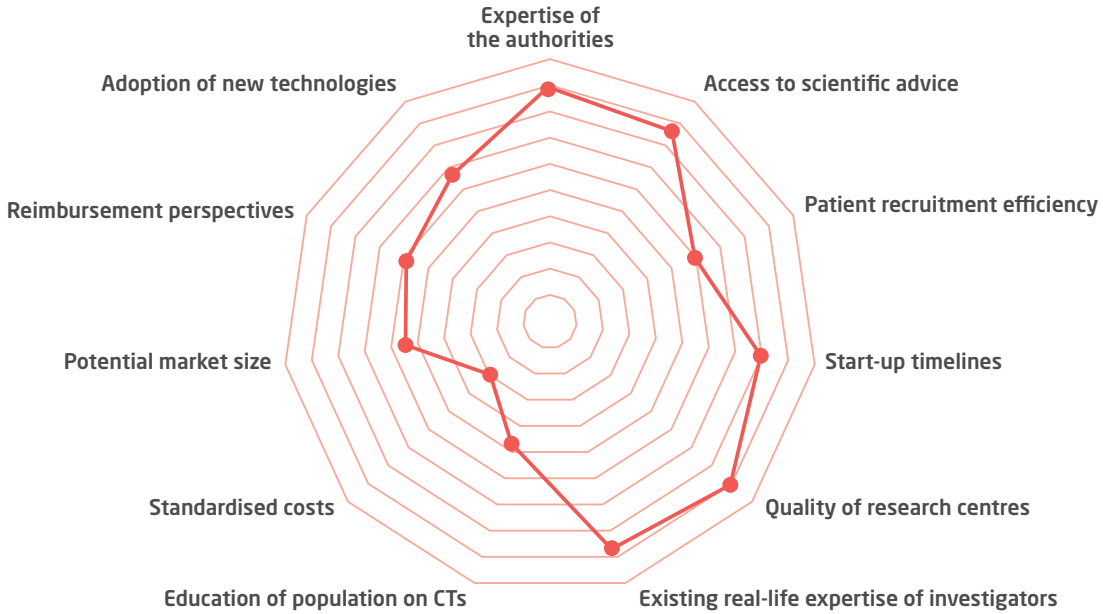
Source: FAMHP (2014-2016)

3. ADVANTAGE **OF SPEED**

Thanks to a new law, Belgium will continue to be a champion in the rapid evaluation of applications to set up clinical trials. The **15 day approval time for phase 1 trials** remains in place. This rapid evaluation process is very important for pharmaceutical companies, as was shown by a recent survey of pharmaceutical companies carrying out clinical research in Belgium.

New legislation approved in April 2017 is intended to create a more coordinated, **simple and rapid procedure** for clinical trials, while also opening the door to pilot projects. Even more recently, the federal government decided to make the clinical trials application procedure **free of charge**.

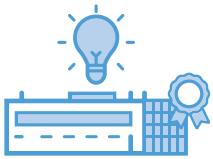
FIG. 5: **AVERAGE RATE OF BELGIUM ON THE FOLLOWING DRIVERS FOR CLINICAL TRIAL LOCATION SELECTION (N=19)**
PHARMA.BE SURVEY (2018)



Source: Deloitte's report 2019 "Belgium as a clinical trial location in Europe"

ASSETS
FOR BELGIUM

The results of the survey show that **Belgium has excellent assets in**:



I. **Quality of research centres** and dense medical infrastructure

II. **Rapid start-up timelines of clinical trials:** the study approval by the authorities and the ethics committee, as well as the study initiation timelines.

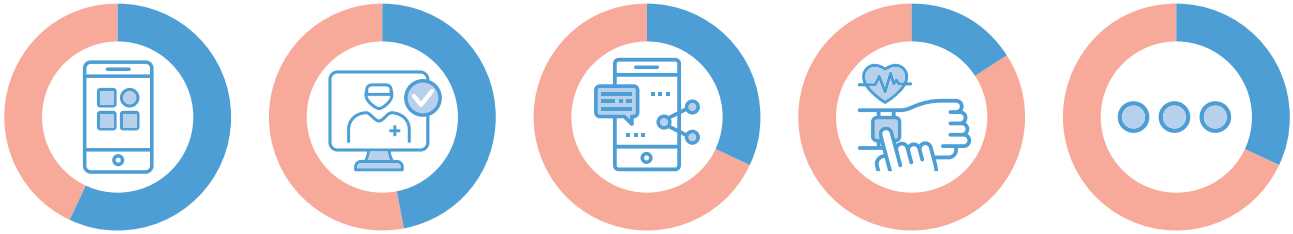
III. **Existing real-life expertise of investigators** with innovative medicines and access to state-of-the-art medical infrastructure in the investigated medical domain.

4. QUALITY OF **RESEARCH**

Pharmaceutical companies in Belgium have access to an extensive infrastructure comprising more than 70 hospitals with top quality clinical services and well trained staff. The quality of the research centres, the 'real life' expertise of scientists and a strong willingness to collaborate are all highly valued. Through intensive collaboration, the pharmaceutical sector, hospitals, universities and research centres are continuing to build Belgium's strong reputation as a destination for clinical research.

THE USE OF **DIGITAL TECHNOLOGY**

PERCENTAGE OF PHARMA.BE MEMBERS THAT HAS EVER USED ANY FORM OF DIGITAL TECHNOLOGY WHILE CONDUCTING CLINICAL TRIALS IN BELGIUM (N=19)



57% Mobile apps

47% Medical-grade devices

32% Social media

16% Wearables

32% Other

Source: Deloitte's report 2019 "Belgium as a clinical trial location in Europe" – results for 2017

5. UNIQUE HEALTH **ECOSYSTEM**

Belgium constitutes a unique health ecosystem in which clinical research can thrive. Thanks to a shared vision and common focus on solutions between the regulators, the industry, the researchers and the government, Belgium has been able to put itself on the map as one of the preferred locations for conducting trials in Europe (and even in the world).

BELGIUM IS A CLUSTER OF EXCELLENCE AT THE HEART OF EUROPE

With 7 academic hospitals, 12 universities with internationally-renowned life sciences departments and research teams, 14 bio-incubators and 52 member companies active in clinical R&D, Belgium is a cluster of excellence at the heart of Europe.

Belgium boasts several trendsetting companies and excellent, world-class centres of research, in such domains as oncology, vaccination and gene and cell therapies. The country's many biopharma clusters are a key driver of the Belgian economy and competitiveness, with over 37,000 people and about 5,300 researchers active in biopharmaceutical companies.

PHARMA

130+
pharma.be member companies

23
Headquarters

52
Member companies active in R&D

37
Production sites

ECOSYSTEM

12
Universities & research centres

7
Academic hospitals

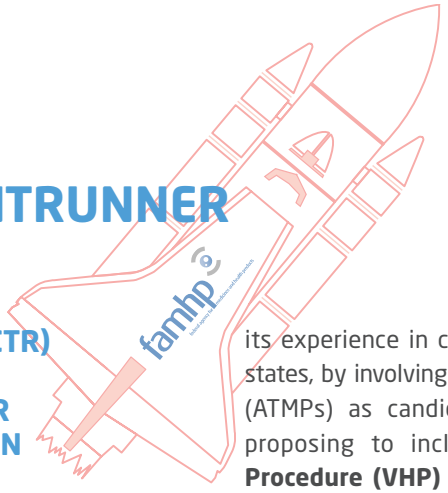
14
Bio-incubators

2
Airports with CEIV* certification: Brussels & Liège

famhp
federal agency for medicines and health products

* CEIV Pharma addresses industry's need for more safety, security, compliance and efficiency, by the creation of a globally consistent and recognized pharmaceutical product handling certification

6. BELGIUM AS AMBITIOUS FRONTRUNNER



CLINICAL TRIALS REGULATION (CTR) PILOT PROJECTS IN BELGIUM: AN OPTIMUM PREPARATION FOR THE EUROPEAN HARMONIZATION

- A new Belgian law on clinical trial has given the starting signal for pilot projects in April 2017 in preparation for the implementation of the European regulation on clinical trials. **Belgium has been one of the first countries** in Europe to initiate such a pilot engaging different stake-holders, and testing the new way of working established by the new regulation.

- A national **CT-College** has been set-up via the new legal framework for clinical trials to prepare the application of the new European regulation on clinical trials. One of its missions is to ensure an harmonized and **high quality assessmen**t of clinical trial applications in Belgium.

- As a first initiative, the CT-College has prepared, together with all stakeholders (including patient associations), a template for the informed consent form for the Belgian participants in a clinical trial. A dedicated brochure explaining the rights of the participants will be worked out.

- In 2019, the Federal Agency of Medicines and Health Products (FAMHP) has confirmed the willingness to move one step forward in the preparation of Belgium to the new regulation on clinical trials and consolidate its experience in collaborating with the other member states, by involving advanced therapy medicinal products (ATMPs) as candidate for the pilot project and by proposing to include the **Voluntary Harmonized Procedure (VHP)** for clinical trials in the pilot project (the so-called "**VHP+**").

- In many clinical trials human body material samples are being collected. At Belgian level, the Law on human body material lays down rules on the collection of human body material for scientific purposes (« **biobanking** »). Amongst others, the rules on biobanking require that human body material used for scientific research needs to pass through a biobank, where a medical doctor or pharmacist is responsible for the traceability of the material and to check the consent from the donor. The Belgian lawmaker considered that within clinical trials, there are sufficient guarantees through the Good Clinical Practices framework to be sure that material collected within clinical trials adheres to the same principles. The law on human body material was therefore changed in December 2018 to clarify that material collected within the scope of an authorised clinical trial does not need to pass through a biobank. The rules on biobanking start reapplying when material collected in clinical trials is used for other goals or objectives than described in the authorised clinical trial. This approach **avoids unnecessary administration at the Belgian level** but also guarantees the rights of the donor.

NATIONAL INNOVATION OFFICE WITHIN FEDERAL AGENCY OF MEDICINES (FAMHP)

The FAMHP aims at a stronger role for the Belgian National Innovation office within the European network of Innovation offices, to ensure that the responses that are provided can also be placed within a European context. Furthermore, a more iterative advisory process will be developed, to accelerate the procedures for early-phase applications. This is one of the spearheads of the **FAMHP**.

BELGIUM IS CONSOLIDATING ITS FUTURE WITH A UNIQUE TOOL AT THE EUROPEAN LEVEL: THE (BIO)PHARMACEUTICAL INDUSTRY OBSERVATORY

In 2018, Belgium created the (bio)pharmaceutical industry Observatory. The Observatory, set up within the Department of Economic Affairs, is composed of 16 members with representatives of the Federal Agency for Medicines and Health Products (FAMHP), the National Institute for Health and Disability Insurance (INAMI-RIZIV), the Federal Public Service of Public Health, the Federal Planning Bureau, the National Bank of Belgium and the innovation sector of the (bio) pharmaceutical industry. This **unique tool** will be able to formulate policy recommendations based on an international comparison and **aims to strengthen the competitive position of Belgium**.

Since 2018, the submission of clinical trial applications in the pilot project is **free of charge** for all sponsors thanks to the support and investment of the Belgian government.

FAMHP and the CT-College are currently reinforcing their human resources with the **recruitment of new experts** dedicated to the CTR pilot projects.

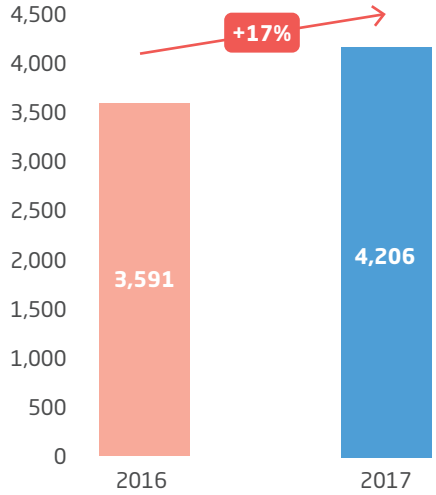
The **average timeline** for the evaluation of the application is **shorter** than the maximum allowed timeline, and is decreasing while experience is gained.

7. PATIENT INVOLVEMENT

Aggregated number of patients and the newly included patients in all active Belgian clinical trials has increased in 2017 compared to 2016. The number of new patients included rose with 17 percent to 4,200 in 2017.

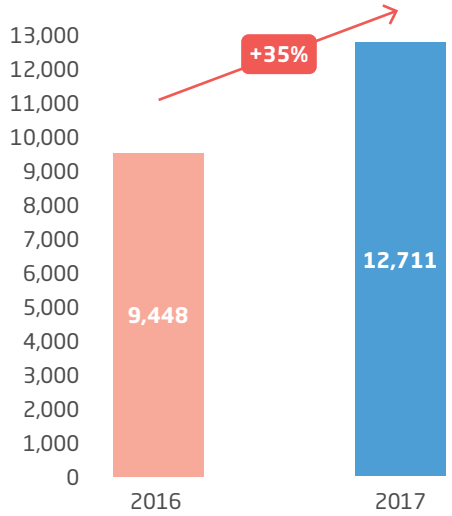
In total, nearly 13,000 patients are involved on a yearly basis in all CTs running in the country. This is a rise with 35 percent compared to 2016.

FIG. 6: **TOTAL NEWLY INCLUDED PATIENTS AGGREGATED OVER ALL BELGIAN RESEARCH FACILITIES ACROSS ALL ACTIVE CLINICAL TRIALS, 2016 AND 2017**



Source: pharma.be member survey

FIG. 7: **TOTAL NUMBER OF PATIENTS INCLUDED AGGREGATED OVER ALL BELGIAN RESEARCH FACILITIES ACROSS ALL ACTIVE CLINICAL TRIALS, 2016 AND 2017**



IN DECEMBER 2017, THE **FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)** LAUNCHED A CAMPAIGN TO ENCOURAGE PATIENT PARTICIPATION IN CLINICAL TRIALS

Through posters at the doctor's office, a brochure, a radio spot and an internet site, the FAMHP emphasized the importance of clinical trials and explained the rights, obligations, benefits and risks of participating in clinical trials.

On the internet site (**www.klinischeproeven.be (NL)** – **www.essaiscliniques.be (FR)**) there is a link to a user-friendly database containing information about all clinical trials in Belgium which have been approved by the FAMHP.

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famhp
federal agency for medicines and health products

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