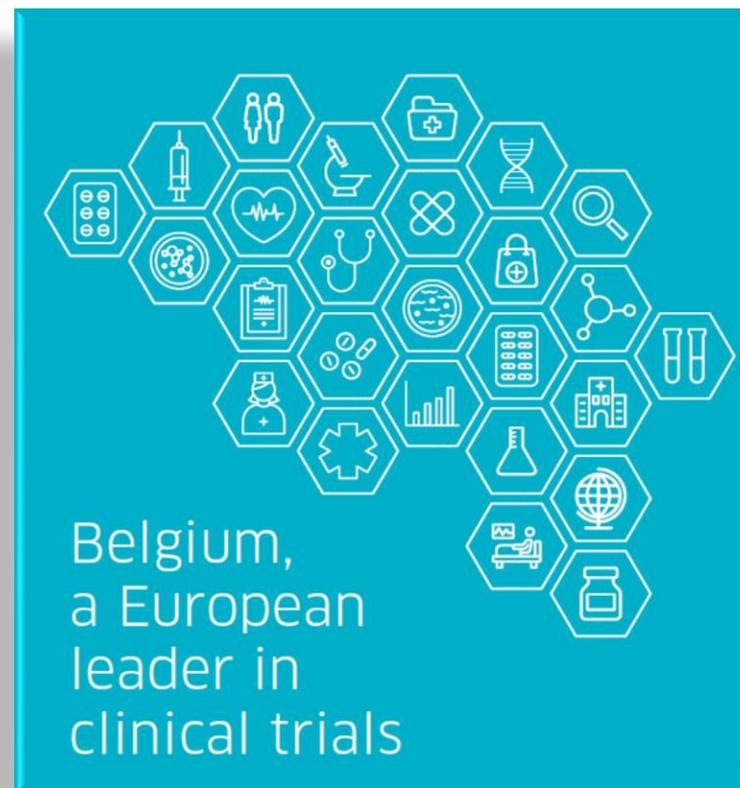


Belgium, a European leader in Clinical Trials (CTs)



Belgian facts & figures

- 507 new applications for CTs in 2016
- 1,399 CTs running in 2016
- 2nd position in Europe (per capita)



Optimal preparation for the new European framework in 2018



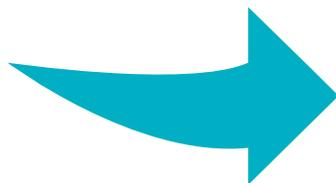
- **Pact of the future** in Belgium (2015-2019): fed gouvernement & pharma: “hold on to our **yellow jersey** in clinical trials within Europe”
- 20 april 2017: **new Belgian law** on clinical trials was voted to create a new framework for CTs in Belgium, in preparation for the new European Regulation (536/2014) that will come into force in 2019

Catherine Rutten, CEO at pharma.be: “The new Belgian law testifies the high level of commitment among all the stakeholders in health care to continue to attract clinical research. The intense cooperation between pharma companies, universities, hospitals, the agency for the evaluation of medicinal products and the ethics committees is a huge asset, meaning that clinical trials can be started up quickly and under the best possible conditions. That expertise and attractiveness also generates major benefits for patients in Belgium.”

Coordinated, simple and rapid clinical trial evaluations



The new Belgian law (20.04.2017): providing a new framework for clinical trials in Belgium.



- Keep our leadership in Europe for ultra-fast approval procedures for clinical trials, particularly for **Phase 1 trials (15 days)**
- National College to ensure the harmonised assessment of new study applications. The College will also monitor compliance with procedures to ensure high quality studies
- The evaluation of applications will be centrally coordinated in a simple and consistent way by the competent authorities and designated ethics committees.

Belgium is one of 'the best in Europe': why is this ?



1. Strong expertise

- 1,399 CTs took place in Belgium in 2016
- 507 new CT applications were submitted in Belgium in 2016
= 12% of the 4,000 new CTs started up each year in Europe (EMA)

Applications for clinical trials in Belgium



Source: famhp
(2016)

Distribution Industry-sponsored clinical trials vs. Academic clinical trials



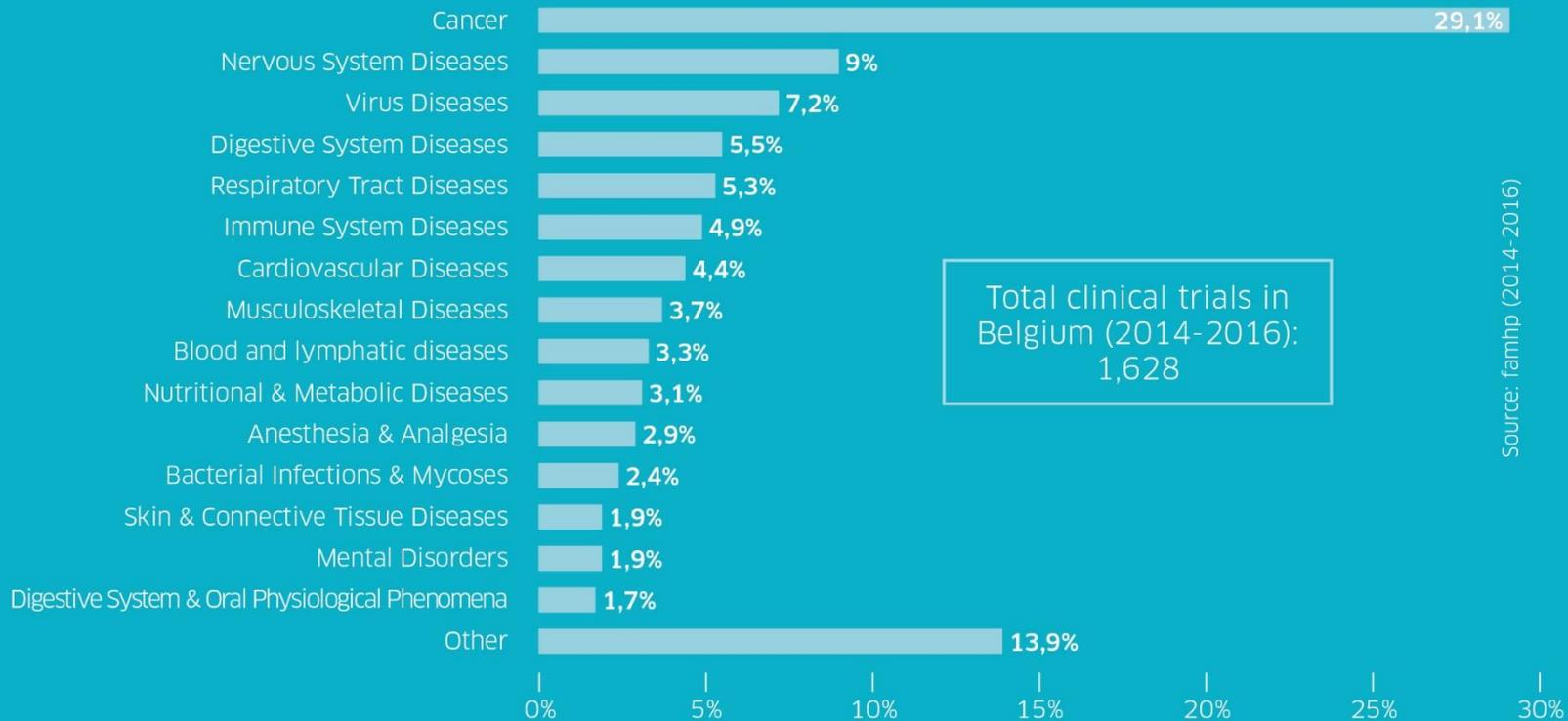
Source: famhp
(2016)

Belgium is one of 'the best in Europe': why is this ?



2. Wide range of therapeutic domains

Clinical trials in Belgium address a broad range of therapeutic areas - top 15 (2014-2016)



Belgium is one of 'the best in Europe': why is this ?



3. Advantage of speed

Thanks to the new law, Belgium will continue to be a champion in the rapid evaluation of CT applications: **15 day approval time for phase 1**



4. State-of-the-art infrastructure

Companies in Belgium have access to an extensive infrastructure: more than **70 hospitals** with top quality clinical services and a well trained staff.

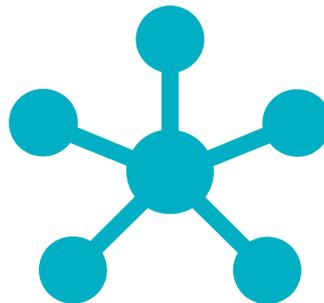


Belgium is one of 'the best in Europe': why is this ?



5. Pilot projects, a multistakeholder initiative

- The new Belgian law = starting signal for pilot projects in April 2017 (2nd wave foreseen in Sept 2017, with a call for new candidates), to prepare for the implementation of the European Regulation in 2019.
- Belgium is **one of the first countries in Europe** to initiate pilot projects.



Belgium is one of 'the best in Europe': why is this ?



6. National Innovation Office within famhp (late 2017)

- Simple, central access point for scientific and technical/regulatory questions
- Support to companies and universities to set up early-phase trials
- Support to SMEs in their R&D activities
- Strong role within the European network of Innovation offices



Belgium's position in the EU



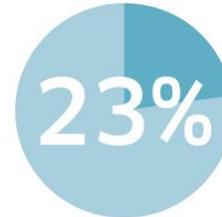
Belgium holds a **remarkable position in the EU**, with:



of all clinical trials in the EU for cancer



of all clinical trials in the EU for the digestive system



of all clinical trials in the EU for virus diseases

Belgium is at the forefront of **novel medical techniques**, with:



of all clinical trials in the EU to explore genetic phenomena



of all clinical trials in the EU to explore biological phenomena

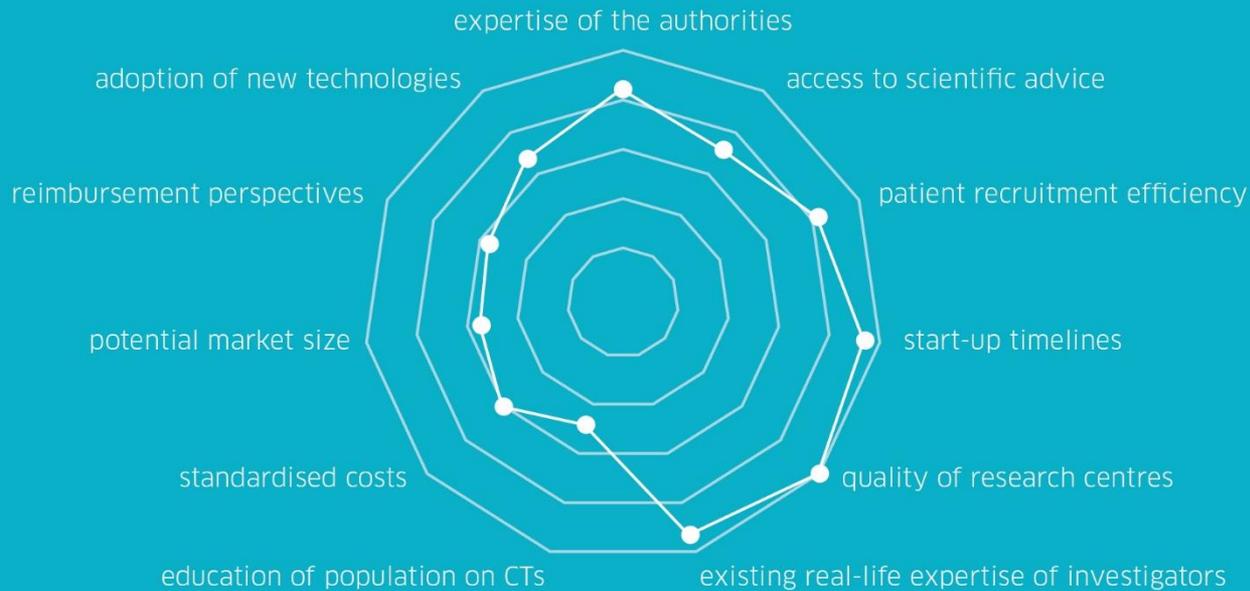
pharma.be 2017 survey (i)



* relative score of each indicator. N = 45 (participation N = 31), April 2017

What are the decisive drivers to choose a country to conduct a clinical trial ?

pharma.be 2017 survey (ii)



* relative score of each indicator. N = 45 (participation N = 31), April 2017

How does Belgium perform for the defined key drivers ?