BELGIUM: WORLD LEADER IN CLINICAL TRIALS

Clinical Trials are an important asset that should be preserved and consolidated

Today, notwithstanding medical progress, there still is no cure for many diseases. Every day pharmaceutical companies and academic researchers from all over the world join forces to develop new medicines and therapies, that bring relief, hope and cure to patients who need innovative treatments. The development of new medicines runs through different stages, of which the various stages of 'clinical trials' are crucial ones. For many companies, Belgium plays a pivotal role in the development of new medicines, thanks to its world leadership in clinical trials. It is an asset that we need to preserve and to consolidate, as it is beneficial to the Belgian patients, to their treating physicians, and to the Belgian scientific community.

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1. BELGIUM: WORLD LEADER IN CLINICAL TRIALS

- Every year >170.000 Belgian patients participate in phase 2 and 3 trials[1]
- Over the last 6 years >228.000 Belgian cancer patients participated to a clinical trial
- In 2014 >1.500 clinical trials ran in Belgium[2], of which 270 with specific focus on children
- >400 clinical trials applications are submitted by the biopharmaceutical industry in Belgium each year[3]
- Top 4 domains of research:
  - 21.0 % on cancer
  - 13.0 % on cardiovascular diseases
  - 8.3 % on central nervous system diseases
  - 7.6 % on respiratory disease

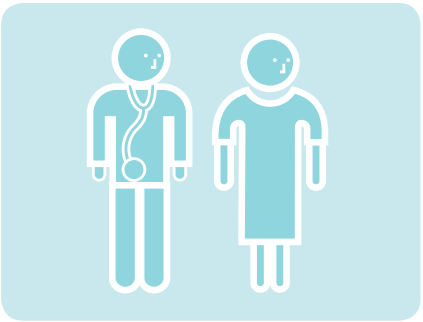
2. WHY IS BELGIUM THE PREFERRED COUNTRY TO CONDUCT CLINICAL TRIALS?

Belgium excels because of its:

- Short approval timelines, that are respected
- Highly qualified clinical researchers & research centers
- Highly qualified competent authorities & ethics committees
- Biopharmaceutical ecosystem: i.e. a positive environment in which biopharmaceutical companies can work closely together with universities and other companies to do research to fight the diseases of tomorrow.

3. WHY ARE CLINICAL TRIALS IMPORTANT FOR BELGIUM?

For the Belgian patients & their treating physicians



- Patients get early and free access to promising new medicines that are not otherwise available
- Often a clinical trial is the treatment of last resort, increasing the patient's quality of life or even saving his/her life
- Clinical trials bring new valuable insights for research, that will also be beneficial to future patients

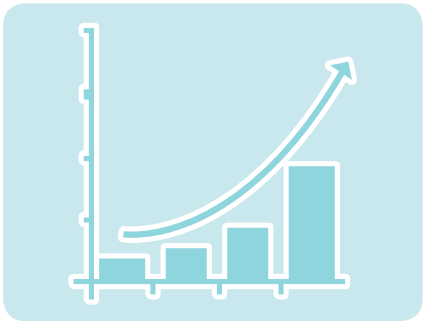
1. Based on data from the clinical trials registry in 2012, clinicaltrials.gov
2. Based on data from the clinical trials registry, clinicaltrials.gov
3. Based on data from the Federal Agency for Medicines & Health Products (famhp), 2006-2013
4. Ranking in number of clinical trials per capita, based on data from the clinical trials registry, clinicaltrials.gov. Global leader: USA.

For the Belgian research community

» Clinical trials strongly contribute to the scientific knowledge creation and innovation in Belgium

» They allow for Belgian clinical researchers and research centers to be at the cutting edge of research in some of the major health challenges of our time, such as cancer, cardiovascular diseases and central nervous system diseases

For the Belgian economy



» The Belgian biopharmaceutical industry is one of the most R&D intensive industries in Belgium

» Despite the recession, the Belgian biopharmaceutical industry has continuously invested in R&D[5]

» Clinical trials create employment in research organizations, universities and hospitals

» >5800 researchers are active in the pharmaceutical industry[6]

4. THE NEW EUROPEAN REGULATION ON CLINICAL TRIALS

» In July 2016 the new European regulation on clinical trials -EC 536/2014- will enter into force

» EU regulation 536/2014 introduces the submission of a single application for a clinical trial via a European portal to the European Medicines Agency (EMA), which will be evaluated in consultation by all member states concerned by the trial

» The timelines for evaluation & approval will be harmonized throughout Europe

» This regulation is an important step in the stimulation of clinical research in Europe, allowing for administrative simplification and harmonization while ensuring high quality standards for patient safety and clinical data

A CALL FOR ACTION

Today, Belgium is a world leader in clinical trials.

In order to maintain and even strengthen our competitive advantage, we need to

» implement the new European regulation as soon and efficiently as possible

» join forces (industry, authorities and academic centers alike) to continue to leverage and communicate about our strengths, such as the speed with which a clinical trial
can be initiated in our country. The simplification of patient recruitment for clinical trials is another priority.

So that Belgian patients, treating physicians, and the scientific community continue to have fast and free access to the new therapies of tomorrow.

5. In 2014, the Belgian biopharmaceutical industry has spent almost 2,36 billion euro on R&D. Sources : "pharmafigures 2014" (April 2015)
6. Based on figures from 2012 from the Belgian Science Policy Office (Belspo)

WHAT ARE CLINICAL TRIALS?

» In order to find one molecule that has the potential of bringing new health benefits to patients, thousands of potential molecules need to be screened

» When a promising molecule is identified, it can be accepted for a clinical trial program

» Clinical trials can only be conducted in recognized clinical centers and follow a well-defined protocol in which all data is rigorously analyzed and documented

» Clinical trials are needed to test a new potential medicine on

- » Efficacy and safety, including possible interactions with other medicine and potential adverse effects
- » The most effective way of delivery to the patient and its optimal dosing
- » The type of patients for which it brings the strongest therapeutic benefit

» A clinical trial typically consists of the following consecutive phases:

PHASE 0 screening	**PHASE 1 Volunteers** (tens of persons)	**PHASE 2 Patients** (hundreds of persons)	**PHASE 3 Large population** (thousands of persons)	**PHASE 4 Use in real life**
» Tests of the chemical and pharmaceutical characteristics of the molecule (including preclinical tests on cells and animals) to verify its efficacy and tolerance » Exploratory micro-dosing tests in humans to analyze whether the molecule behaves in the human body as was to be expected based on the preclinical tests	» Tests on humans (mostly volunteers) to study the behavior of the new molecule in the body and identify potential adverse effects	» Tests on patients to determine the optimal dosing of the medicine	» Confirmation of previous test results in a larger population » Comparison of the new medicine with existing treatment and/or placebo in a blind and randomized test *After a successful phase 3, the results will be evaluated by the European Agency of Medicines (EMA), that will deliver a license to bring the new medicine to market*	» After market introduction, phase 4 tests are performed on a very large number of patients to gain insight on the use of the new medicine in real life conditions (long term effectiveness)

THIS CAN TAKE UP TO 12 YEARS

Responsible editor: Catherine Rutten for pharma.be, General Association of the Pharmaceutical Industry. pharma.be vzw - asbl I Terhulpsesteenweg 166 Chaussée de La Hulpe I 1170 Brussels I D/2015/4021/3

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