myNEO Press File

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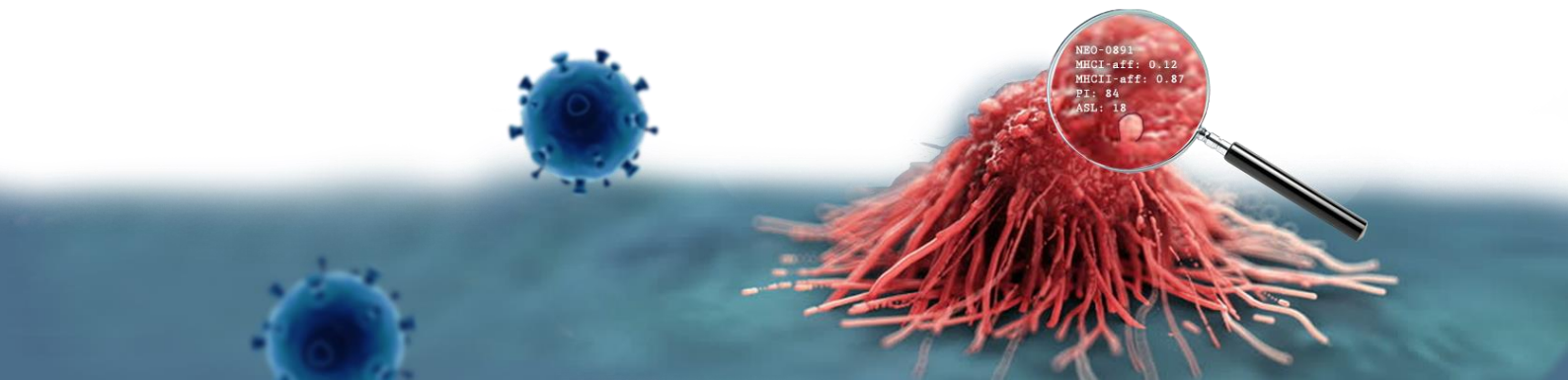

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1. myNEO – a personalised platform for cancer

"myNEO enables personalised immunotherapy for patients with difficult-to-treat tumours who do not benefit from standard therapies"

The myNEO technology specifically searches for the differences between tumour cells and healthy cells in the body for each patient. This is a critical first step in the development of a therapeutic vaccine, which uses the patient's immune system to eliminate specific tumour cells. The technology platform strives to assist the vast majority of cancer patients who do not benefit from existing general immunotherapies through **tailor-made immunotherapy** .

What is the added value of myNEO?

In the last 10 to 15 years, the treatment of cancer patients has changed dramatically and has been greatly improved through the discovery of immunotherapy that attempts to activate the patient's immune system against the tumour. The side effects of such therapies are much less serious since - unlike standard chemotherapy and radiotherapy - immunotherapy itself does not involve a harmful substance.

Despite the emergence of immune therapy, in addition to chemotherapy and radiotherapy, there is still a large proportion of cancer patients that do not benefit the existing treatments. This can be explained by the fact that some tumours are particularly similar to normal cells as they hardly mutate and therefore present few mutated proteins on their cell surface. These tumours are called 'cold' tumours because there is very little activity of the immune system since the tumour cells are not immediately recognised as foreign. The treatment of cold tumours is therefore very challenging, knowing that these tumours often also do not respond to chemotherapy and radiotherapy.

Detecting mutated proteins in cold tumours is a major challenge because only a limited number are formed. **myNEO offers a solution here** as myNEO is able to detect the few mutations that exist and predict which mutated proteins are most interesting to process in a vaccine. myNEO compares the DNA sequence of cancer cells (tumour tissue) with healthy, normal cells (blood sample) and has already developed algorithms that aim at a broad, but above all very thorough and deep analysis, which makes it possible to analyse cold tumours as well.

This allows the creation of a **personalised vaccine** , **tailored to the patient** , where the composition of the vaccine is determined by myNEO based on the information obtained from the complete genome of the individual patient. Consequently, this type of treatment is highly personalised and ensures that the patient's immune system is activated against the selected patient's mutated proteins and that the cancer cells are attacked (see **Figure 1**).

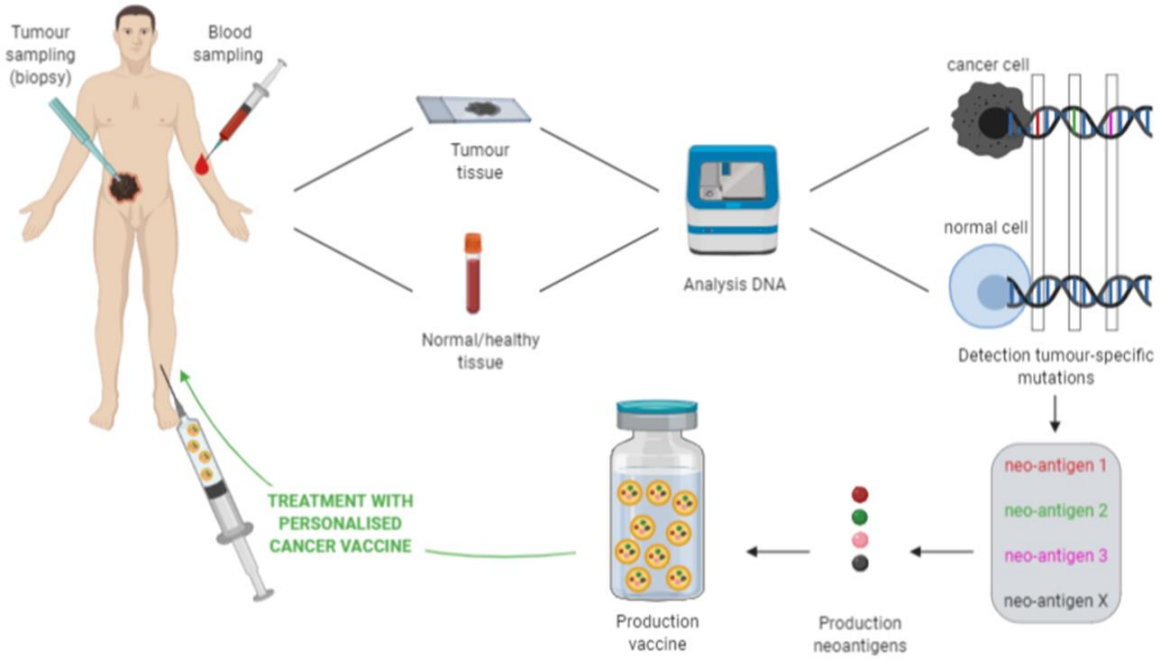

Figure 1 . Overview development of a personalised cancer vaccine

2. Situation – cancer and immunotherapy

Cancer and mortality

In Europe, cancer is still the **second leading cause of death** (see **Figure 2**), accounting for approximately 1.4 million deaths. Due to the aging and growth of the European population, this number is still increasing and it is expected to become the most common cause in Europe. This translates into the worrying fact that **40% of the total population** will be **diagnosed with cancer at some point in their lives** , and half of which will succumb, despite vastly improved techniques and the wide range of treatment options. It is obvious that this does not only have a personal impact. This also has economic consequences in society, as patients are sometimes treated with expensive therapies without benefit.

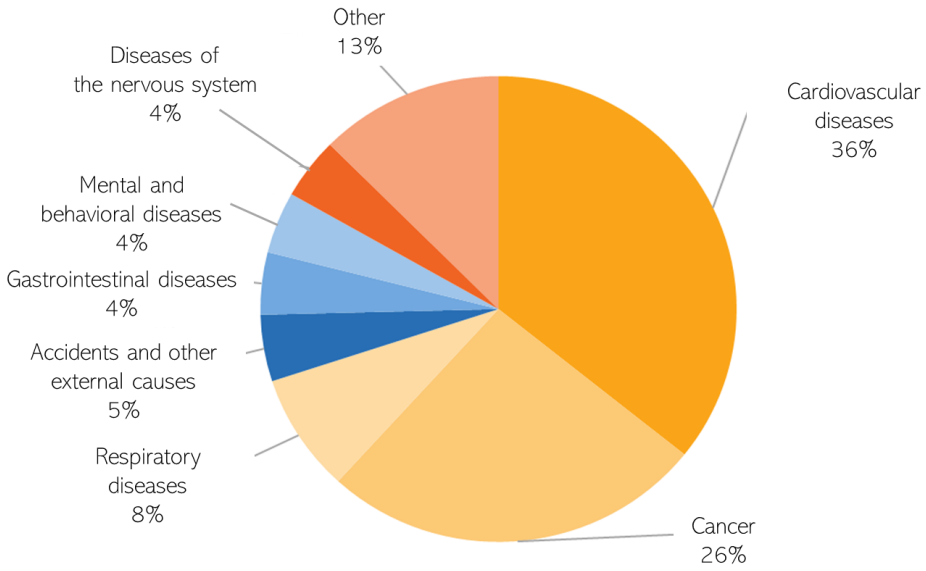

Figure 2 . Causes of death in Europe by type in 2016 (as% of all deaths)

It is important to know that, despite the fact that the number of cancer patients is increasing, the number of deaths from cancer is decreasing. This can be explained on the one hand because the diagnoses are more often made at an earlier stage due to the improved screening methods and the introduction of the known annual screenings for certain patient populations. On the other hand, because current treatment methods have been greatly improved and extended, allowing patients to be treated more specifically and efficiently.

What is immunotherapy?

Immunotherapy originated from the discovery that **the immune system - the human immune system against infections - is involved in the development of cancer** . Every person develops cancer cells every day due to errors in the DNA (mutations). These errors are presented on the cell surface as a mutated protein - also called neo-antigen - that is recognised by dendritic cells in most cases. These are immune cells that specialise in recognising foreign cells. Dendritic cells then activate T cells, which in turn specialise in recognising and selectively eliminating foreign cells such as bacteria and viruses, but also cancer cells. However, sometimes we do get sick and the cancer cells evade the attack because the immune system is not or not sufficiently active (see **Figure 3**).

Immunotherapy has been developed on the basis of this concept , which **attempts to reactivate the immune system** .

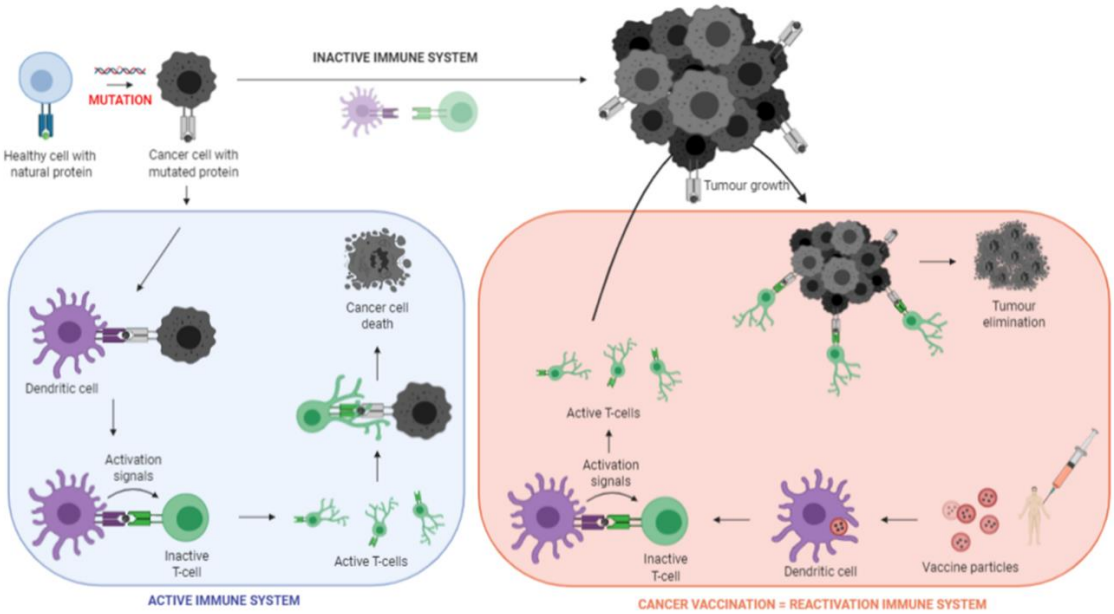

Figure 3 . The role of the immune system (blue) and the mechanism of cancer vaccination (orange) in the fight against cancer

A promising therapy here is **cancer vaccination** . Vaccination is now mainly known for its preventive protection against certain diseases, such as the annual preventive flu vaccination that ensures we do not get the flu. However, a cancer vaccine is only administered when the patient already has cancer and **tries to make sure that the immune system recognises the cancer cells again** so that they are attacked (see **Figure 3** - immune system reactivation).

Immunotherapy types

The standard treatments for cancer are well known, namely surgery, whether or not combined with chemotherapy or radiotherapy. Recently, immunotherapy has been added that aims to activate the patient's immune system so that it can recognise and remove the cancer cells.

There are several types of immunotherapy, the most common of which are listed in **Table 1. The most promising immunotherapy** at present involves **Immune Checkpoint Inhibitors (ICI)** . There are currently several ICIs on the market for a wide range of cancer indications. These have led to a drastic change in the treatment strategy of cancer patients because they obtained very good results, even in cancer patients for which no (longer) a solution could be offered. This class of drugs removes a specific blockade that is very often used by tumours and prevents the immune system from working. When ICI is administered, this blockage is removed and the immune system can do its work again.

Table 1. Overview of the main types of immunotherapy

Monoclonal antibodies	makes sure that the immune system can recognise the cancer cells
Immune checkpoint inhibitors	removes immune system blockade
Cancer vaccines	activates and strengthens the immune respons
Adoptive cell transfer	injection of activated immune cells that can recognise the cancer cells

The pros and cons of immunotherapy

The emergence of immunotherapy has drastically changed the field as it offers **a solution** for a large number of patients , including **patients who have already received and / or completed many different treatments** . This is illustrated in **Figure 4,** which shows how many patients with advanced skin cancer have no disease worsening from the start of treatment. With chemotherapy (red line), everyone does not benefit from the treatment after 2 years. The yellow line represents treatment with an older generation immune checkpoint inhibitor while the blue line corresponds to a more recent ICI.

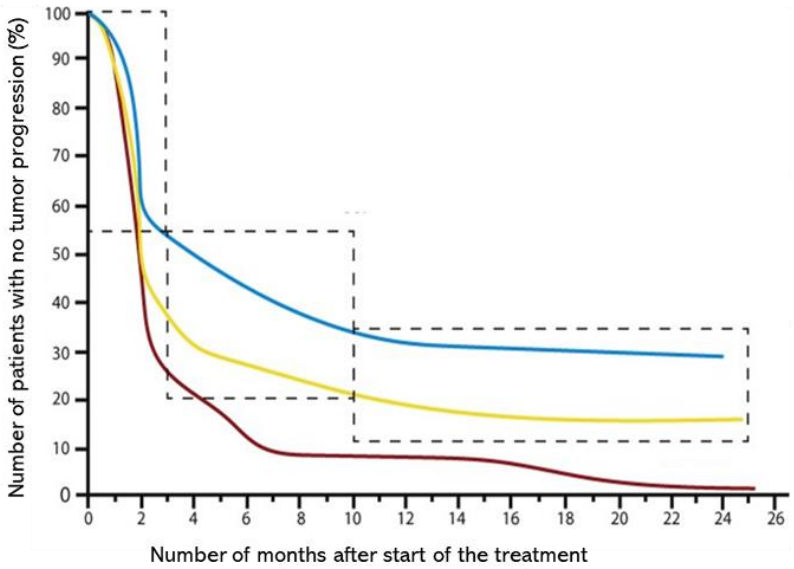

Figure 4. The percentage of patients with advanced skin cancer who remain stable during treatment with chemotherapy (red), old generation (yellow) and newer generation (blue) ICI

Although these patients have advanced cancer, these checkpoint inhibitors have a markedly positive effect, demonstrating the potency of these new immunotherapies. In addition, these therapies lead **to less severe side effects,** which greatly improves the comfort and quality of life of the patient. But there are **still many patients who do not benefit** from the standard chemotherapy and radiotherapy or the new immunotherapies. Namely, half of cancer patients do not survive. So there is still a lot of room for improvement.

In addition, there are also the **high costs** that are currently associated with the existing medication. Knowing that many patients are being treated with medication that they are not affected by, it is clear that this has a major impact on the economy. The average cost for a full treatment in 2017 was $ 150,000 ($ 79,000 in 2013), according to a report by IQVIA Institute for Human Data Science . It also describes that this cost is expected to double by 2022.

The new therapies, including immunotherapy, are therefore much more expensive than the standard methods, namely chemotherapy and radiotherapy. The high costs are explained by the pharmaceutical industry to be a consequence of the development of these medicines, which requires very large investments for innovation and researching new treatments.
The high percentage of patients that is not served by current treatments, along with the high cost of the new drugs show very clearly that there is a **need for a more personal approach that examines the best strategy for each patient** to avoid unnecessary costs, but especially to increase the chance of a cure.

myNEO strategy

It is myNEO's strategy to offer a solution. myNEO looks at the tumour per patient, so that the therapy is tailor-made, i.e. **tailored to the patient** , which increases the chance of success. By thoroughly analysing the DNA sequence of the tumour cells per patient, myNEO is able to determine the correct targets for cancer vaccination. In addition, the myNEO technology also makes it possible to treat cold tumours, which usually do not respond to chemotherapy or radiotherapy nor to standard immunotherapies such as checkpoint inhibitors.

3. Team

An overview of the management team is shown below in **Figure 5** . myNEO was founded in 2018 by Prof. Wim Van Criekinge, Jan Van den Berghe and Cedric Bogaert. In addition, Prof. Kris Thielemans is active as scientific advisor.

Figure 5. The myNEO management team

Cedric Bogaert graduated as a bio-engineer from the University of Ghent with a master's degree in medical genetics. After his studies, Cedric continued his research in epigenetics and precision diagnostics. In 2018 he founded myNEO together with Jan and Wim, where Cedric currently takes on the role of manager.

Wim Van Criekinge is a professor of computational genomics and bioinformatics at the University of Ghent. He founded several innovative start-ups including Devgen and Genohm , and is active on the board of several other biotech companies in the US (MdxHealth , Doc.ai, etc.).

Jan Van Den Berghe is a serial entrepreneur in the biotech and food industry and is a co-founder of Genohm and Lipa Holding and is a partner in Victus Participations . Jan obtained an MBA from INSEAD and a master's degree in general management from the Vlerick management school.

Kris Thielemans focuses on translational research within immunotherapy and has developed with his team the mRNA-based TriMix technology for which several phase I and II clinical studies have been initiated and which led to the founding of eTheRNA NV.

Also **Bert Coessens,** a well-known name within the Flemish biotech -Landscape his success Cartagenia , is heavily involved in myNEO.

Due to several large partnerships with leading biotech / pharma players (see section 6), myNEO experienced strong growth in the past year, with 11-12 experts and employees actively contributing to the growth of myNEO. The management team is assisted in this by a team of bio-informatics specialists, clinicians, entrepreneurs and experts with leading expertise within the immunotherapy domain. Names such as Bruno Fant (PhD, Sr Bioinformatician), Lien Lybaert (PhD, Project manager) and Christophe Van Huffel (PhD, Business Development Manager) stand out.

4. History

The myNEO technology has been in development since 2017 and in 2018 the platform was incorporated into myNEO as a company by the Novalis Biotech Incubation . This incubator fund, founded by Prof. Wim Van Criekinge and Jan Van Den Berghe, continuously invests in innovative technologies within the biotech industry with potential to have a lasting impact in the long term.

myNEO is located in Ghent and its mission is to provide every cancer patient with an optimised personalised therapy. That is why academics, clinicians and private companies alike are showing interest in the personalised platform. For example, myNEO is currently involved in several projects, including with Persomed, in which myNEO will participate in a clinical study (www.persomed.be).

5. Technology & focus

The myNEO platform focuses on identifying, investigating and validating tumour-specific mutations and their impact on the immune system . In a personalised way genomic data from tumour cells (biopsy) and healthy cells (blood) are compared. For example, tumour-specific mutations are detected that lead to tumour-specific peptides (neo- antigens) that are presented on the surface of the tumour cells. These peptides are absent in healthy cells and are ideal targets for cancer vaccination as this will activate an immune response solely against the tumour cells. This avoids serious side effects such as chemotherapy and radiotherapy. The biological passport of each individual tumour is determined and the patient can be treated with focus.

The platform - called the ImmunoEngine - is continuously optimised and expanded, which means that it can also treat cold tumours that were previously unsuitable for immunotherapy. For this reason, the myNEO ImmunoEngine is the most sensitive platform for detecting neo-antigens . The ImmunoEngine is trained on more than 2.5 million data points and replaces the need for extensive lab tests that are not only expensive but also require a lot of time, and are therefore not possible to perform individually for each patient. A machine learning layer ensures that the platform technology strengthens itself with every patient it analyses, which emphasises the importance of the current partnerships.

In addition, the platform is also highly integrated in an End- to- End solution that provides the entire chain that is necessary for the development of a personalised vaccine: from sampling and processing to analysing the DNA of the tumour and developing the vaccine (see **Figure 6**). myNEO has several collaborations that can guarantee rapid analysis and production so that the therapy can be brought quickly to the patient.

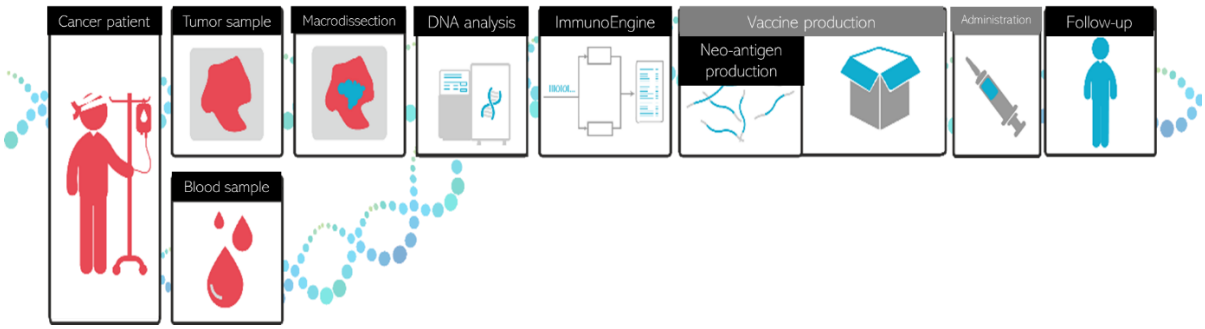

Figure 6. Overview of the End-to-End flow of myNEO

Due to the success of the platform, **myNEO is currently further expanding its portfolio to infectious diseases, including COVID-19** . Because viruses, like cancer cells, give rise to mutated epitopes (neo-antigens), the myNEO platform can also be used for virus vaccines, provided some adjustments. While all companies developing a COVID vaccine focus only on the S protein of the virus, myNEO has also analysed other proteins important for the survival of the virus. In addition, the vaccine will fight all current Covid-19 forms and other viruses from the corona group such as SARS and MERS. This increases the chance of obtaining **a vaccine that protects against the current coronavirus as well as all other (future) forms of the same virus family**. Currently, the selected targets are being tested preclinical in collaboration with a European biotech company with a cancer vaccine technology.

6. Projects & partners

myNEO focuses on innovation and therefore has several internal and external research projects with a view to continuously improving its technology and thus always offering the patient the highest chance of success.

The myNEO pipeline includes several preclinical and clinical studies, all leveraging the added value of the myNEO platform in discovering and selecting neo-antigens. An overview of current collaborations and partnerships is given in **Figure 7.**

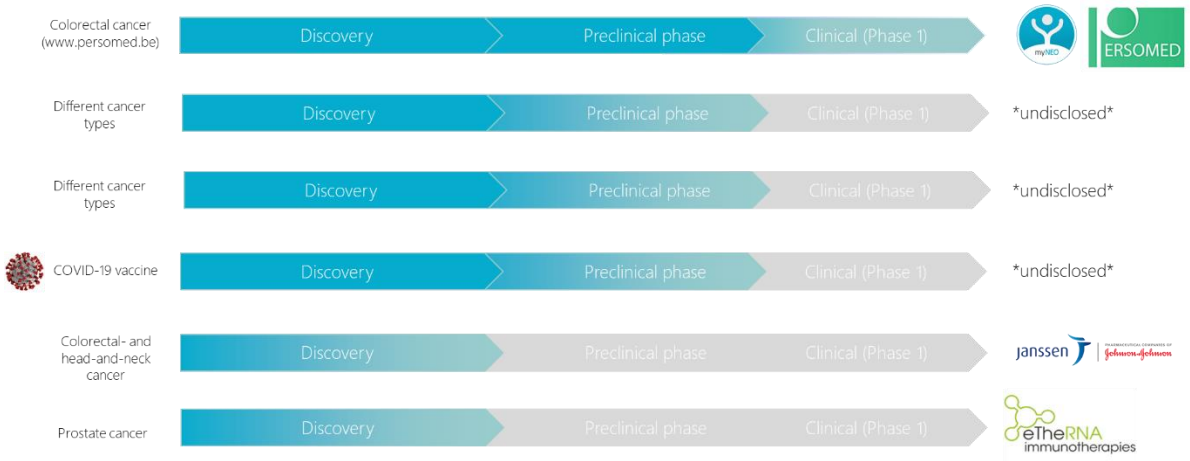

Figure 7. The current myNEO pipeline with the ongoing collaborations

myNEO collaborates with **various partners,** whereby myNEO always predicts the most interesting neo-antigens and the respective partners convert these targets into a vaccine. For example, myNEO has collaborations with large pharmaceutical giants such as Janssen, but also with biotech companies such as eTheRNA and the University of Brussels, who trust the myNEO technology in the development of personalised vaccines.

The young company has also received the necessary recognition from the Flemish Government, which has generated **more than € 1M in subsidies** in recent months . myNEO is also currently preparing for a first clinical trial in which myNEO will participate together with partners QbD , Antleron and the Free University of Brussels (www.persomed.be).

7. Contact details

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