

VIB and DNALytics team up to develop non-invasive Colorectal Cancer screening test

VIB and DNALytics are proud to announce their partnership to develop a data-driven, high-performance and non-invasive Colorectal Cancer screening test, the ColonoKit. Colorectal cancer is the third most common form of cancer globally and the second most common cause of cancer deaths. The chance of a cure is high if the cancer is detected early enough, but early detection is not a given. Based on a research program from VIB, KU Leuven and UZ Leuven, with the support of the Fournier Majoie Foundation, DNALytics will develop the ColonoKit which should make it possible to detect colorectal cancer in an early stage using a simple blood test.

Colorectal cancer: a growing medical problem

In 2012, a total of 1.4 million people worldwide were diagnosed with colorectal cancer, this figure is expected to increase to 2.4 million by 2035. This is a condition that affects a growing number of people each year. Colorectal cancer is very treatable if it is detected at an early stage, with approximately 95 % chance of a cure. If detected at a late stage, the chance of surviving 5 years after diagnosis is less than 10 %. Therefore, it is very important to be able to detect the disease in an early stage. And therein lies the rub.

Need for better tests

There are no global screening guidelines, but because early detection is so important, there are a number of national initiatives to screen the population. For example, in Belgium, the population group between the ages of 50 and 74 years is invited to undergo testing via the "immunological Fecal Occult Blood test" (iFOB), which detects blood in the stools. Even though the iFOB test is most widely used, diagnostic performance is suboptimal. In other words the available test detects only about two thirds of all colon cancers. More importantly, the test has about 90% false positive results, meaning that a lot of people are stressed unnecessarily.

Prof. Hans Prenen, UZ Leuven: "From my daily practice I experience the need for a test that offers greater certainty and that can detect bowel cancer at an early stage and at the same time reaches the whole population. It fills me with joy that via our research we can actually contribute to such a test."

A novel test by implementing scientific insights in a performant diagnostic platform

DNALytics will now develop ColonoKit making use of an online software platform derived from their currently marketed RheumaKit, for arthritis patients' management. The platform complements the transcriptomic inputs of the test with a Machine Learning approach, offering the perspective of a continuously-improving test, based on a routine feedback loop.

Thibault Helleputte, CEO of DNALytics: "We will develop the ColonoKit based on the research of Massimiliano Mazzone (VIB-KU Leuven) and Hans Prenen (UZ Leuven). With this test we strike several birds with one blow. It has a higher performance than the current available tests, and since it is a blood test it might lower the reluctance seen in patients towards the stool test."

Prof. Massimiliano Mazzone, VIB-KU Leuven: "I have been working on the role of the immune system in cancer for more than 10 years now. A puzzling field with a lot of potential towards clinical application. It is great that our works now forms the basis of a novel diagnostic kit with clear advantages for the patients."

This program was also supported by the Fournier Majoie foundation. Bernard Majoie PhD, President and Founder: "Back in 2010 the pioneering proposal of prof Massimiliano Mazzone about identifying cancer biomarkers out of monocytes was enthusiastically received by FFM's jury. 7 years later a "signature" has been confirmed and we are proud about our contribution to this achievement answering a real and urgent medical need. We consider our task is not at its end, there are still regulatory and late development issues to endeavor before the kit can be at practitioner's hands, the FFM will be happy to help the young company DNALytics to win this part of the course."

MORE INFO ON THE KIT

ColonoKit: diagnostics based on biomarkers

If we are affected by cancer, our immune system responds to this and tries to remove the cancer cells from our body. A specific role in this process is assigned to a specific type of white blood cell: the peripheral blood monocyte. From the moment that colorectal cancer cells are present in the body, the peripheral blood monocytes respond to the substances secreted by the cancer cells. The researchers from VIB, KU Leuven and UZ Leuven identified 23 genes with a specific role in this process that could be used as set of bio-markers. These bio-markers are incorporated in the test.

Clinical Evidence

In total, about 550 samples have been prospectively collected for this project so far. In a first step, the gene signature has been identified on about 100 individuals (healthy volunteers and CRC patients), followed by a second round including 200 samples (among which half from healthy volunteers and half from CRC patients). In a third step, about 150 samples have been used for the validation of the same approach in a technological setting fitting routine requirements.

Sensitivity and specificity of the test were both above 90% in a validation cohort. Therefore, introducing ColonoKit in the screening campaign as a confirmatory step before colonoscopy could result in a decrease of up to 50% in the number of useless or non-urgent colonoscopies. ColonoKit is likely to be more expensive than stool tests, but will still represent only a fraction of the cost of a colonoscopy. Extra clinical validation is ongoing.

Prof. Mazzone has been recently awarded with a Proof of Concept grant from the European Research Council (ERC) to further develop the kit in close collaboration with Prof. Prenen. An important incentive and recognition. Apart from that this research was possible thanks to funding by FWO, Stichting Tegen Kanker, Kom op Tegen Kanker.

More info on www.colonokit.com

Questions from patients

A breakthrough in research is not the same as a breakthrough in medicine. The realizations of VIB researchers can form the basis of new therapies, but the development path still takes years. This can raise a lot of questions. That is why we ask you to please refer questions in your report or article to the email address that VIB makes available for this purpose: patienteninfo@vib.be. Everyone can submit questions concerning this and other medically-oriented research directly to VIB via this address.

BOILERPLATE PARTNERS

VIB-KU Leuven Center for Cancer Biology

Cancer has many causes. Often it is a combination of lifestyle, environmental factors and genetic variation. We need to fight cancer on many fronts, and this can only be done by using knowledge. VIB-KU Leuven Center for Cancer Biology researchers unravel new mechanisms in order to develop both specific diagnostic methods and treatments.

VIB

Basic research in life sciences is VIB's raison d'être. On the one hand, we are pushing the boundaries of what we know about molecular mechanisms and how they rule living organisms such as human beings, animals, plants and microorganisms. On the other, we are creating tangible results for the benefit of society. Based on a close partnership with five Flemish universities – Ghent University, KU Leuven, University of Antwerp, Vrije Universiteit Brussel and Hasselt University – and supported by a solid funding program, VIB unites the expertise of 75 research groups in a single institute. VIB's technology transfer activities translate research results into new economic ventures which, in time, lead to new products that can be used in medicine, agriculture and other applications. VIB also engages actively in the public debate on biotechnology by developing and disseminating a wide range of science-based information about all aspects of biotechnology. More information: www.vib.be.

KU Leuven

KU Leuven (University of Leuven) is a leading European research university dedicated to excellent research, education and service to society. It is a founding member of the League of European Research Universities and has a strong European and international orientation. Its sizeable academic staff conducts basic and applied research in a comprehensive range of disciplines. University Hospitals Leuven, its network of research hospitals, provides high-quality healthcare and develops new therapeutic and diagnostic insights with an emphasis on translational research. The university welcomes more than 57,000 students from over 140 countries. Its doctoral schools organise internationally oriented PhD programmes for over 4,500 doctoral students. More info: www.kuleuven.be/english/

UZ Leuven

www.uzleuven.be

DNALytics

DNALytics develops innovative data-driven precision medicine solutions (diagnosis, prognosis, treatment guidance) through partnerships with healthcare players such as pharmaceutical, biotechnological or In Vitro Diagnostic (IVD) companies. DNALytics wants its solutions to have a major impact on patients, healthcare practitioners and Society as a whole. DNALytics is a Belgian company founded in 2012 as a UCLouvain Spin-Off that bases its activities on a data mining technology platform. Aside from product (co)development in Rheumatology and Oncology, DNALytics also proposes its expertise in the form of a data mining consultancy service. DNALytics received various awards, namely from IBM, Microsoft, the European Commission or the MIT, both for its technology and its business model.

Foundation Fournier-Majoie

Created by Bernard Majoie and now managed by his son Jérôme Majoie, both with a solid experience in the pharma industry, the Foundation Fournier-Majoie (FFM) was created in December 1996. Since the start of its activities, FFM's has provided and still provides support both financial and operational to « researchers-discoverers-entrepreneurs » throughout the development course of their programs, most of them being focused on new diagnostic or prognostic cancer biomarkers.

In 10 years, 14 research teams in Belgium have been helped by FFM's team and its network of experts. Furthermore, FFM is actively involved in 2 Belgium biotech start up's, in oncology, endeavoring substantial steps toward growth. On December 31st, 2016, the total amount granted in those selected projects and start up's accounted for to 7, 2 million euros, of which 5, 9 million euros have already been paid out.

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