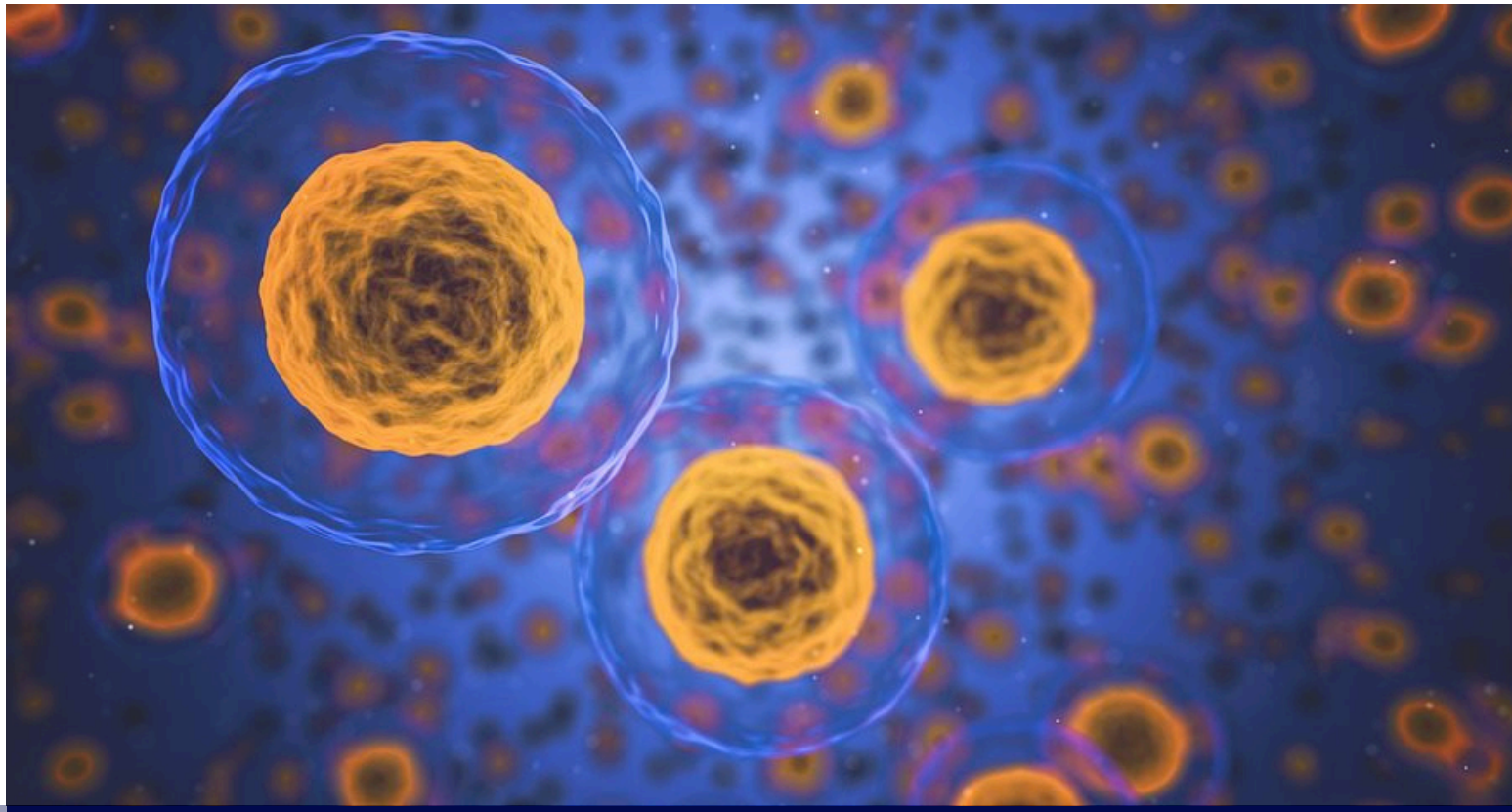
REGMEDXB
FROM CARE TO CURE

Highlights 2024



EXPLORE OUR HIGHLIGHTS FROM 2024

CEO's Foreword

Dear Reader,

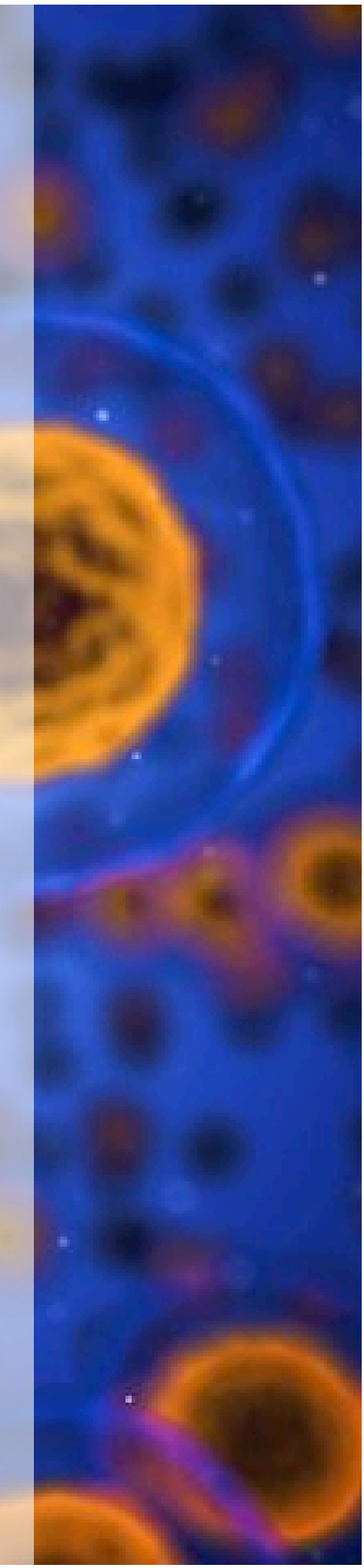
RegMed XB's 2024 was a year of significant progress. After years of effort, the realization of a €30 million subsidy for regenerative medicine projects became a reality. Additionally, new initiatives such as a Memorandum of Understanding (MoU) with Nakanoshima Qross in Osaka, Japan, were launched. The close collaborations between the Netherlands and Flanders also led to the introduction of the new Eye Moonshot initiative.

Strong partnerships continue to be the driving force behind RegMed XB. By working together and contributing through everyone's efforts, we are strengthening the field of regenerative medicine. This is crucial for making a significant impact, as shared knowledge makes the difference.

At the end of 2024, we were conditionally awarded a three-year Public-Private Partnership (PPP) program from Health~Holland, called "Regenerative Medicine Translational Synergy." This program focuses on translational public-private partnership projects and offers many opportunities for our field. At the beginning of 2025, we will provide more detailed information about this subsidy for the period 2025-2027.

Thank you for your trust in RegMed XB and your commitment, especially the health foundations: Diabetes Fonds, DON, Hartstichting, Nierstichting, Oogfonds, and ReumaNederland. We also thank our academic partners: TU Eindhoven, KU Leuven, Leiden University Medical Center, Maastricht University, Maastricht UMC+, Universiteit Antwerpen, Universiteit Gent, UMC Utrecht, Utrecht University, Vrije Universiteit Brussel, and Vlaams Instituut voor Biotechnologie (VIB). And, of course, our industrial and governmental partners.

With kind regards, *Bernard Mulder*



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About RegMed XB

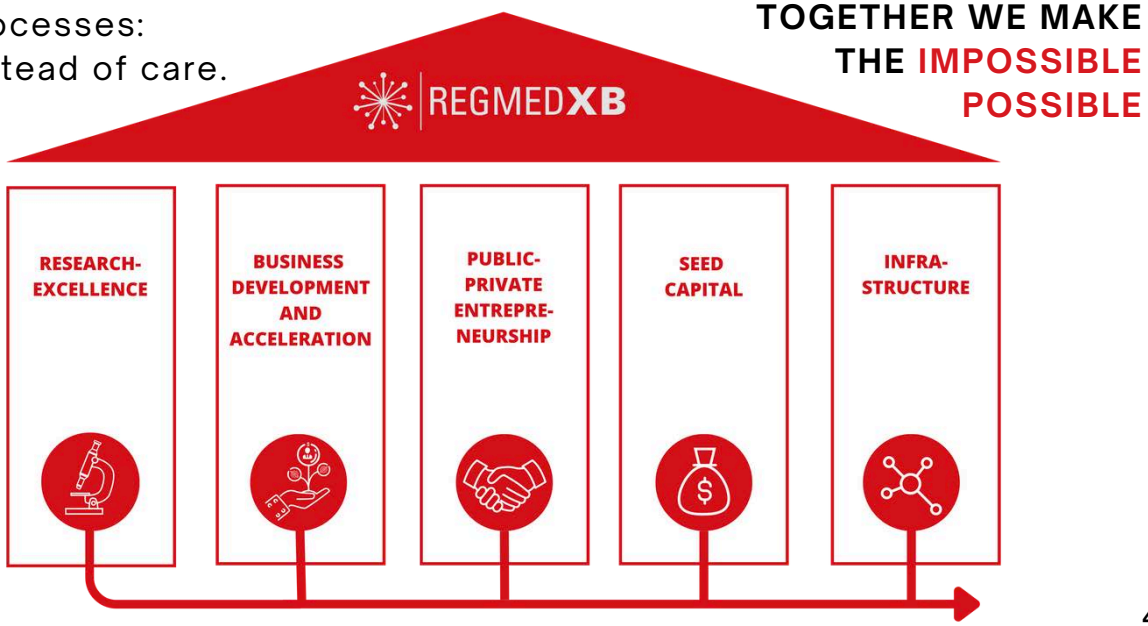
Our primary goal is ensuring regenerative research break-throughs have a meaningful impact on patients' lives.
All made possible through a strong ecosystem of researchers, industry experts, health foundations and governments.
Together we make the impossible possible.

The prevalence of chronic diseases worldwide is rapidly increasing. Regenerative Medicine (RM) aims to restore degenerated, diseased, or damaged tissues and organs, which contributes to increasing vital functioning of patients and reducing cost of healthcare.

RM holds the promise to cure many chronic conditions, restoring health rather than protracting decline, improving the lives of millions and at the same time preventing lifelong, expensive care processes:
cure instead of care.

We do this by bringing together leading scientists at Dutch and Flemish universities, university medical centres, institutes and a range of companies in so-called “Moonshots”: long-term visions of breakthroughs for patients.

At the moment we have the following Moonshots: Cardiovascular, Diabetes, Eye-cornea, Kidney and Osteoarthritis. Health foundations and their related patient organizations champion each moonshot, putting patient impact at the heart.
At RegMed XB, we provide (translational) infrastructure through scientific, technological and business development.
Our approach, that links all phases from research to the production of therapies, makes RegMed XB unique. In the figure below, you can see the five pillars of RegMed XB.



Supervisory Board

Conny Helder, chair of our Supervisory Board. She is a Dutch healthcare manager, who served as the Minister for Long-term Care and Sport and, as Minister of Health, Welfare and Sport in the fourth Rutte cabinet in the Netherlands (2022–2024).

Koenraad Debackere is a professor of Technology and Innovation Management & Policy at KU Leuven since 1995. He is awarded the Prize for Scientific Excellence of the Belgian Entreprise Foundation and received an honorary professorship from the University of Sussex.

Maurice Horsten has a distinguished career in pharmaceuticals, medical devices, and biotechnology. He has worked for multinational companies like Eli Lilly & Company and Mediq NV in various countries and is also a successful entrepreneur.

Floris Italianer has worked in the healthcare and non-profit sectors over the last 20 years. Next to his role in our Supervisory Board, he is serving as the Chairman of the Supervisory Board at Pathan Laboratories, a pathology laboratory supporting Dutch hospitals and primary care centers.

Arno van Son has over 20 years of experience in the healthcare sector, contributing significantly to various organizations. He served as a member of the Board of Directors at CZ Groep from 2010 to 2022, one of the leading healthcare insurers in the Netherlands.

Flemish Investment

With an investment of fifteen million euro in the Flemish-Dutch collaboration RegMed XB, the Flemish government positioned Flanders alongside the Netherlands as a center for regenerative medicine. The funding, spread over a period of five years, will be used for the development of new regenerative therapies aimed at chronic diseases, including osteoarthritis and eye-cornea diseases.

The investment boost new therapies for osteoarthritis and eye diseases, developed by a consortium of knowledge institutions and companies from Flanders and the Netherlands.
Additionally, the funding strengthen the integration of RegMed XB and the Netherlands in Flanders, that supports this Flemish-Dutch network.

"Thanks to this investment, we can build two promising research programs together with many Flemish partners, leading to the development of new products for regenerative medicine. It also allows us to establish an integrated Flemish-Dutch management structure to scale these programs on both sides of the border."

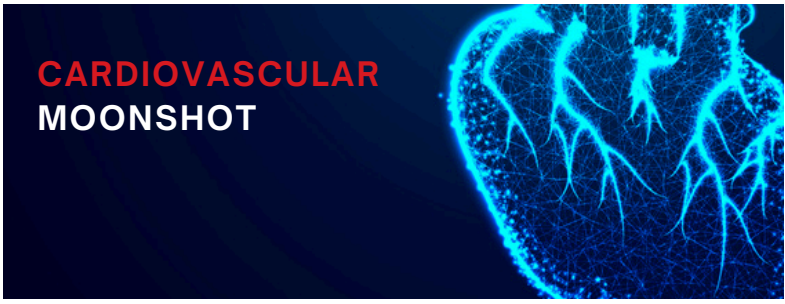
Bart Geers, Chair RegMed XB Flanders

“RegMed XB has paved the way for new projects focused on regenerative medicine with partners from Flanders and the Netherlands. With this new Flemish initiative, we can shift gears and take further steps to bring the first products to patients."

Bernard Mulder, CEO of RegMed XB the Netherlands

Collaboration together

Moonshot Updates



The Kidney Moonshot aims to create functional bioengineered kidneys using mini kidneys or organoids, grown from cells obtained from kidney tissue or urine.

Mimetas as well as the UMCU cooperate together with the Kidney Foundation, and RegMed XB. Within this Moonshot we are focused on developing an advanced tubuloid-on-a-chip model to study kidney physiology and pathophysiology. This model will be a crucial step in understanding kidney function and the interaction between the cells of the kidney tubule and the nearby blood vessels.

Using advanced cell culture technologies, the team has successfully grown donor-derived kidney tubuloids on a chip, that closely mimic human kidneys. This enables precise assessment of water and sodium transport and the response to drugs and toxic compounds, supporting drug discovery and toxicity studies.

This approach moves us closer to understanding kidney function at a cellular level, with potential to develop targeted regenerative medicine treatments.

The Cardiovascular Moonshot investigates the biology of the heart thoroughly, attempting to keep the heart alive for a longer period, by using a perfusion system. In doing so, we strive to develop regenerative therapies, including gene therapy and other approaches that might require a detached heart from the circulation.

In 2024, a follow-up project of the Cardiovascular Moonshot has been funded by the Dutch Heart Foundation and the Dutch Ministry of Economic Affairs by means of the public-private partnership allowance made available by the Top Sector Life Sciences & Health, focusing on the perfusion and keeping a heart in good condition for as long as possible. Coagulation Profile B.V. and Axion Biosystems are business partners for this project.

Publication 1: A novel cardioprotective perfusion protocol prevents functional decline during extended normothermic ex situ heart perfusion of marginal porcine hearts, PubMed, Oct 2024

Publication 2: A perspective on the added value of red blood cells during cardiac hypothermic oxygenated perfusion, PubMed, Oct 2024

Publication 3: A new Ex Vivo Model to study cardiac fibrosis in whole mouse hearts, PubMed, Oct 2024

The goal of the Diabetes Moonshot is to advance the cure for diabetes Type I by replacing damaged insulin-producing cells with new ones.

A short and long-term roadmap was agreed upon, with the full support of the health foundations the Dutch Diabetes Research Foundation and Foundation DON. Major progress was achieved in 2024 both for the manufacturing of the insulin producing cells, and for the development of a delivery device, with outsourcing to industrial/private partners for e.g. QMS and safety studies.

Necstgen, a RegMed XB Pilot Factory line, supports the GMP transition of the cells, including scaling up the production of stem cell-derived insulin-producing cells.

In 2025, there is full focus with sense of urgency and close progress monitoring with the aim to initiate a first clinical trial as a sentinel device in the next year. To this end, scientific advice has been requested at the Dutch Medicines Evaluation Board (CBG-Meb).

Publication 1: Scaffolds for Encapsulation of Stem Cell-Derived β Cells, Maastricht University, Jan. 2024

Publication 2: Selecting Biocompatible Biomaterials for Stem Cell-Derived β-Cell, Springer, Feb. 2024

An Early Economic Evaluation of the RegMed XB Diabetes Moonshot:
K. Abraham, et al. *Islet Transplantation and Scaffolding Structures for Type 1 Diabetes Mellitus*, UMC Utrecht/Dutch Diabetes Research Foundation.

In the Osteoarthritis Moonshot we are working on a regenerative osteo-chondral implant for large and deep osteochondral defects in the 'young' patient (less than 60 years of age), together with ReumaNederland. Our broader vision aims to use this knowledge to create living joints for complete or partial joint replacement, for a larger patient population.

In this way, non-biological materials could be prevented, resulting in a reduction of the number of re-implants due to shelf life issues of the used materials

Facilities and personnel of RegMed XB's Pilot Factory are valuable contributors to this program. For instance, ICAT in Utrecht plans to take on the biofabrication of this implant.

In 2024, initial steps are taken to create a Quality Target Product Profile (QTPP), the first steps in the develop-ment of the dossier for marketing approval.

2025 is expected to bring an aligned focus by all Dutch and Flanders parties, resulting in a convincing Proof of Concept with the new implant towards the end of 2025, reaching Technology Readiness Level 3 and setting the first steps to final product freeze.

Eye-cornea team NL-Flanders

Professor Dr. Mor Dickman, **Head of department of Ophthalmology, Utrecht University Medical Center. Prof. Mor Dickman is an eye specialist with expertise in corneal transplantation. His translational research is focused on cell therapies for corneal diseases together with Vanessa LaPointe. He is affiliated with the MERLN Institute and the Regenerative Medicine Center Utrecht (RMCU).**

Associate Professor Vanessa LaPointe, **MERLN Institute, Maastricht University. Prof. Vanessa LaPointe is subject matter expert in cell therapy and the product development pathway, inclusive of regulatory dossier aspects and spin-offs.**

Dr. Heiko Locher, Ear Specialist, Leiden University Medical Center
Dr. Locher is not only an ear specialist, but also principal investigator in several regenerative medicine research projects.

Professor Dr. Sandra Van Vlierberghe, **Faculty of Sciences at Ghent University in the Department of Organic and Macromolecular Chemistry. Her expertise relates to the synthesis, modification, and processing of a variety of (bio)polymers, including thermoplastics and hydrogels, in the field of regenerative medicine.**

Professor Dr. Sorcha Ní Dhubhghaill, **Head of Department of Ophthalmology and Corneal and Cataract Specialist at VUB/UZ Brussels. Her main research focuses are anterior segment surgery, corneal biology and physiological optics. Driven by the commitment to improve currently available treatment options or develop new procedures for the benefit of our patients.**

Dr. Bert Van Den Bogerd, **Team leader of the Antwerp Research Group for Ocular Science (ARGOS). The Eye Moonshot continues the work he has done during his PhD, where he researched a new substrate for cultivating and transplanting corneal endothelial cells in collaboration with Ghent University.**

‘For all patients who need a corneal (biological) implant’, that is the ultimate regenerative therapy for this moonshot. In 2024, RegMed XB’s promising Eye Moonshot was launched together with the Dutch Oogfonds and researchers in the Netherlands and Flanders.

The Moonshot goal is to develop a combination product with iPSC-derived corneal endothelial cells seeded on a biomaterial membrane. Appropriate funding was obtained both in the Netherlands and Flanders for the cellular studies, the membrane development and the combination product.

Alignment between all participants, the route forward with well-defined work packages, responsibilities and close monitoring to make substantial progress is the focus in 2025. A Quality Target Product Profile exercise (to initially describe the final product) is ongoing together with a market analysis, with the support of outside consultants.

Strategic Advisory Board member

Meta Neeleman **has been the General Director of the Oogfonds since 2024. With extensive experience in leadership roles across various sectors, she brings insight to RegMed XB’s mission of preventing eye diseases and supporting people with visual impairments.**

Project Management Team

In 2024, RegMed XB's focus to drive research excellence was pushed to the next level by hiring a project management lead, Renate de Cler, and a new program manager for Flanders, Andromache Goethals. Clear roadmaps are one of the key outputs for each program and moonshot in 2025.

"Being able to work with highly motivated teams to create regenerative medicines (RM) solutions for chronic sick patients is very motivating. Accessible, affordable therapies for patients that is our vision, a goal that literally makes the world a bit better, step by step. We are not there yet, but with every milestone or every step, we are getting closer to that goal. I am grateful to be part of that road." ***>> Read more***

Renate de Cler, Project Management Lead

Why Andromache is passionate about our mission? Andromache is truly inspired by the cutting-edge world of regenerative medicine and how it can change lives. It's this blend of innovation and impact that makes her work so meaningful and exciting. Based in Leuven, she is the pioneering employee of the Flemish branch of RegMed XB.
>> Read more

Andromache Goethals, Senior Program Manager
Flemish Eye and OA Moonshots

What is Lena's drive to exceed in her role? She is dedicated to aligning research objectives for regenerative medicine solutions with the successful execution of projects. Helping people to create a notion on the benefits of collaboration and possible positive effects on public health are core to her motivation.
>> Read more

Lena Wijnen, Project Manager
Kidney and Cardiovascular Moonshots

Valorisation

RegMed XB collaborated with the Dutch CardioVascular Alliance (DCVA) and F!RST Fund (BGV) in a Thematic Tech Transfer (TTT) program to stimulate the clinical translation of promising projects within regenerative medicine and cardiovascular disease. The TTT-program is a subsidy tool that exists of two pillars, the first being a non-dilutive voucher of up to 25.000 euro for entrepreneurial researchers and the second is a pre-seed investment fund for promising spin-offs. Last year 2024, was the final year of this five year program.

40 VOUCHERS (2020-2024)

During the whole program, a total of 40 vouchers have been awarded.

These vouchers enabled researchers to take essential steps towards a viable and investable startup. So far, 11 spinoffs have been founded building on these voucher projects and we are excited to see what the future holds for all voucher laureates. F!RST Fund has invested in 7 promising startups, of which 3 investments were closed in 2024.

FIFTEEN VOUCHERS IN 2024

Over the past year, fifteen promising projects were awarded vouchers.

Out of these fifteen,

- Ten received full funding from RegMed XB
- Three were funded by DVCA
- Two were funded jointly by DVCA and RegMed XB

Without valorisation, scientific research does not reach the patient. We enable researchers to access the multidisciplinary expertise necessary to work towards an economically viable and scalable solution and ultimately translate their regenerative therapy from bench to bed.

DVCA & RegMed XB
Community Events

Like last year, we organized two community events this year, together with Dutch CardioVascular Alliance (DVCA).

We welcomed many professionals active or interested in the field of valorization including researchers, startup founders, Technology Transfer Offices (TTO) employees and investors.

May 21th, 2024
The event was filled with invaluable insights, within Industrial Partnerships for Life Sciences Ventures. Seasoned biotech entrepreneurs talked about their experience with strategic partnering in various stages of their company.

Thanks to Loyens and Loeff, Law & Tax for providing the venue and speakers who shared valuable insights on the legal considerations involved in forming partnerships, like the deeptech venture.

Dominique de Jong, Business Developer

October 23th, 2024
Special edition! We celebrated five years of collaboration between DCVA and RegMed XB. Focusing on: Venturing into New Waters - The transition from researcher to entrepreneur.

Two succesful academic founders joined us to talk about their personal journey as entrepreneur. Their reflections on the many challenges, highlights and learnings along the way lead to engaging discussions afterwards during the networking.

€30 Million Subsidy for Regenerative Medicine Projects

After years of significant effort and successful lobbying, we are excited with the realization of a €30 million euro subsidy for regenerative medicine projects.

The Government Gazette (Staatscourant van het Koninkrijk der Nederlanden) officially published this decision in the Publication of the regulation, Staatscourant, May 2024. Additionally, during our Annual Conference 2024 in Maastricht, the Netherlands Enterprise Agency (RVO) provided further explanation to participants.

Minister Micky Adriaansens released the official subsidy scheme on May 15, 2024, underscoring the critical importance of collaboration between science and Small- and Medium-sized Enterprises (SMEs) in advancing regenerative medicine.

A Public-Private funding opportunity for Regenerative Medicine Research
The Dutch government has committed €30 million to foster innovation in regenerative medicine through the Subsidy scheme for regenerative medicine Research Projects /Subsidieregeling Regeneratief Geneeskundige Onderzoeksprojecten (SRGO). This initiative is designed to promote collaboration between SMEs in the biomedical sector and research institutions, with the aim of accelerating the development of regenerative medicine solutions.

The SRGO is co-funded by the Ministry of Economic Affairs and Climate Policy and the Ministry of Health, Welfare, and Sport, and is managed by the Netherlands Enterprise Agency (RVO). The total €30 million will be allocated in stages through three separate tenders. The first tender was from July 1st until December 2nd, 2024.

>> Read more

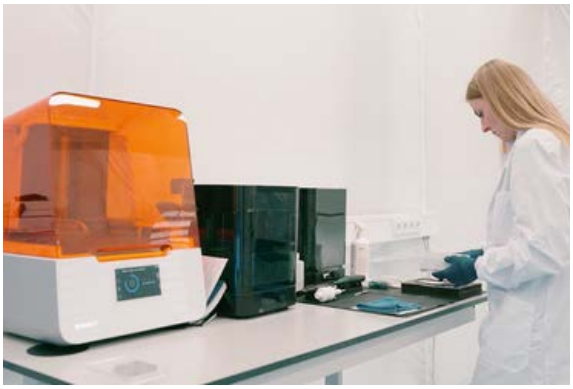

MEDXB
RE TO CURE
XB
ative

RegMed XB Pilot Factory

One of the largest international infrastructures for the production of regenerative products. Our mission is to accelerate the development of new solutions for chronic diseases and to bring affordable RM therapies to patients.

What do we offer?

- Strong public-private partnerships.
- State-of-the-art technologies and production facilities.
- Research and development services and expertise.
- Adherence to golden standards and regulatory guidelines.



PARTNERSHIP DEMCON AND REGEN BIOMEDICAL

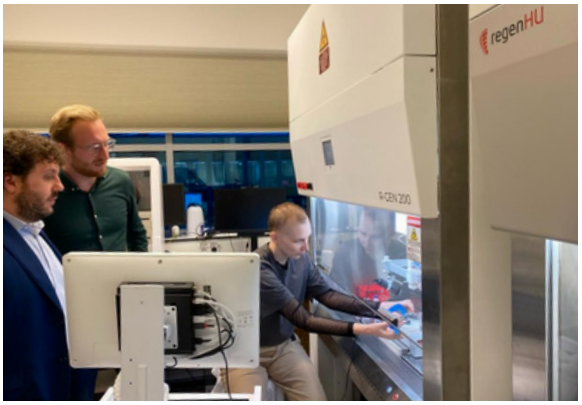
Maastricht University and Demcon joined forces for ReGEN Biomedical. Demcon has become a technology partner and co-shareholder of ReGEN Biomedical, which emerged from Maastricht University. >> Read more

EMBASSY OF THE KINGDOM OF THE NETHERLANDS IN THE UNITED KINGDOM

Representatives from our pilot lines attended an event at the Embassy of the Kingdom of the Netherlands in the United Kingdom. It was a opportunity to share best practices, and explore collaboration with potential UK partners. >> Read more

INNOVATION MISSION SWITZERLAND: INNOVATIVE THERAPIES DEVELOPMENT

A delegation of academic institutions, RegMed XB, representatives from the Ministry of Economic Affairs, Health~Holland, and the Netherlands Enterprise Agency, were on a mission to Switzerland to strengthen ties between Swiss and Dutch life sciences sectors and to optimize the ecosystem. >> Read more

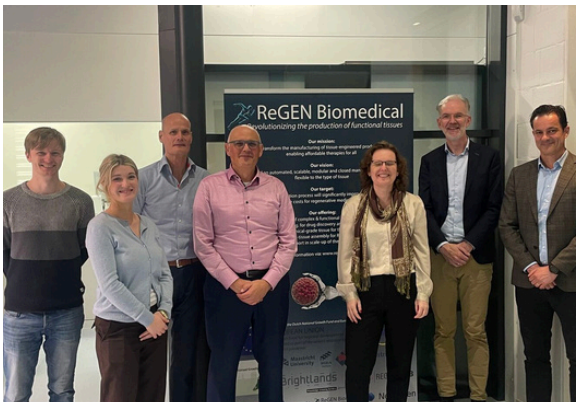


OPENING ICAT'S NEW LAB FACILITY

We proudly announced the opening of the Innovation Center for Advanced Therapies (ICAT) in Zeist. The pilot line of the RegMed XB Pilot Factory specifically focused on microtissues.
>> watch movie

INNOVATION MISSION TO GERMANY

RegMed XB and partners went on a innovation mission to Germany, organized by the Consulate General of the Kingdom of the Netherlands Munich, Innovatie Attaché Netwerk, the Netherlands Enterprise Agency (RVO), International Innovation department, and Health~Holland.
>> Read more



PARLIAMENT MEMBER FEMKE ZEEDIJK-RAEVEN VISITED REGEN BIOMEDCIAL

During a working visit to RegMed XB and ReGEN Biomedical, Femke Zeedijk-Raeven (former member of the Dutch House of Representatives for NSC) discovered one of the initiatives of Health~Holland. >> Read more

BIO-EUROPE IN STOCKHOLM, SWEDEN

November 2024, colleagues from the Pilot Factory attended the BIO-Europe conference to represent the Pilot Factory.
>> Read more

UK ECONOMIC MISSION

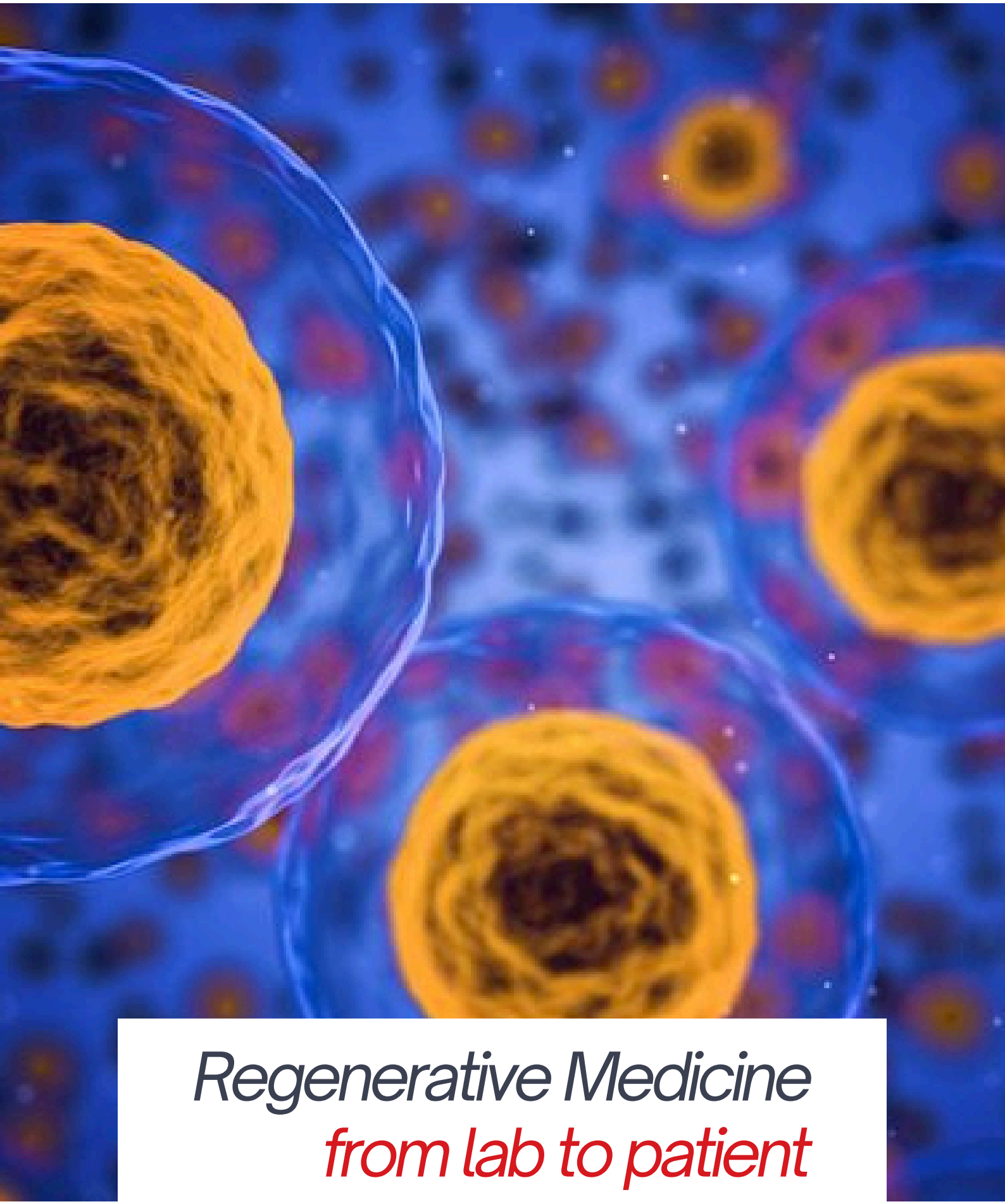
Bernard Mulder, CEO from RegMed XB and all our Pilot Factory pilot lines participated in the Life Science & Health - Economic Mission in London.
>> Read more

NECSTGEN HAS STARTED GMP IPSC BANKING PROJECTS

To support the group of Prof. Dr. Eelco de Koning and Associate Prof. Françoise Carlotti at LUMC, they started this project. Additionally, a multi-party Top consortium for Knowledge and Innovation (TKI) grant was awarded which included the development of bioreactor processes for the scale up of iPSC derived beta-islet cells to potentially treat diabetes. >> Read more

NECSTGEN COLLABORATE WITH UMC UTRECHT FOR BONE REGENERATION THERAPY

NecstGen and UMC Utrecht partner to advance bone regeneration therapy using MSC-derived spheroids, marking a significant step forward in regenerative medicine. This collaborative activity has been sponsored by a RegMed XB and the Dutch CardioVascular Alliance Thematic Tech Transfer (TTT) Voucher Program.
>> Read more



Regenerative Medicine
from lab to patient

National Collaborations

Following the joint statement, we and two other National Growth Fund-supported initiatives: Biotech Booster and Oncode Accelerator signed a cooperation agreement.

- The collaboration is rooted in a shared vision of fostering innovation and improving human health.
- Focused on - but certainly not limited to - driving the development of advanced therapy medicinal products (ATMP's) and biopharmaceuticals.
- In order to provide novel treatments for a spectrum of diseases ranging from cancer to autoimmune diseases.

Our joint office space at the HI-FIVE (fifth floor) in the Beatrix Building, Utrecht

International Collaborations

Our XB, for Crossing Borders. It signifies international, multidisciplinary collaboration to achieve groundbreaking results within the field of Regenerative Medicine. This year we actively engaged in various international initiatives.

We signed a memorandum of understanding (MoU) with Nakanoshima Qross (International Hub for Future Medicine) in Osaka, Japan - to promote cooperation in the field of regenerative medicine.

The signing ceremony was co-hosted by the Japan Medical Advancement Organization and the Consulate General of the Kingdom of the Netherlands in Osaka, and took place at Tekijuku, which has historical ties to Dutch studies.

オランダ団体と
再生医療で覚書
中之島クロス

再生医療や最先端医療の
産業化を進める国際拠点
「中之島クロス」（大阪市
北区）は8日、オランダで
再生医療を推進する団体
「RegMed XB」と
覚書を締結した。今後、両
者は再生医療の実用化や人
材育成に向けて協力する。

Japanese newspaper, following the signing of the Memorandum of Understanding

Read more >>

RegMed XB 2nd Annual Conference

June, 12th and 13th 2024 at Maastricht University

Our Annual Conference 2024 was the network and knowledge-sharing event of the year. The engaging program was designed to push the boundaries of what is possible in regenerative medicine. Whether you are expert or just starting out in the Regenerative Medicine (RM) field.

The underlying theme of the conference was: **Connect. Innovate and Accelerate.** Including various topics, like valorisation, ethics, business development, regulatory and much more. With interesting keynotes from Lucien Engelen, Pamela Habibovic and Maurilio Sampaolesi.

SAVE THE DATE
June 18th and 19th 2025
RegMed XB | 3rd | ANNUAL CONFERENCE | LEUVEN

Stay connected by following us on LinkedIn.

RegMed XB 2nd Annual Conference 2024

Thanks to all Partners

Academic partners

Ghent University
KU Leuven
LUMC Leids Universitair Medisch Centrum
Maastricht University
Maastricht UMC+
TU/e Eindhoven University of Technology
University of Antwerp
UMC Utrecht
Utrecht University
VUB Vrije Universiteit Brussel
VIB

Health Foundations

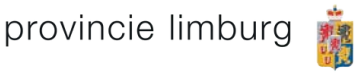
Diabetes Fonds
don We just care for cure
Hartstichting
Nierstichting Je nieren zijn je leven.
Oogfonds
ReumaNederland

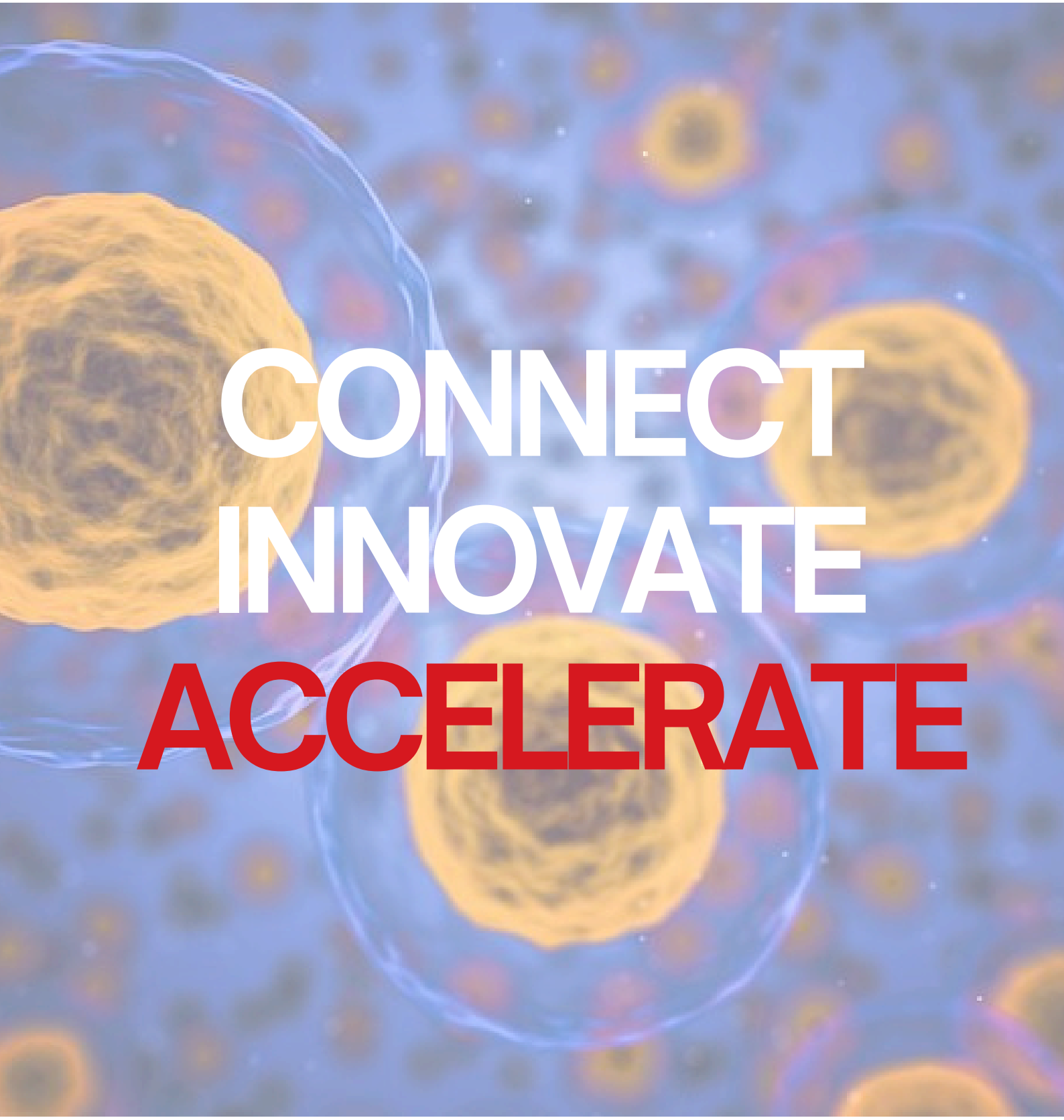
Pilot lines

ICAT Innovation Center for Advanced Therapies
LUMC Leids Universitair Medisch Centrum
NecstGen
ReGEN Biomedical
SBMC Smart BioMaterials Consortium

Industrial and valorisation partners

Governmental partners





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