

Join us in shaping the future of healthcare

Joint statement NXTGEN Hightech Biomedical domain, Oncode Accelerator Cell & Gene Therapy workstream, RegMed XB pilot factory and Biotech Booster

Utrecht, 17 September 2024

"Cellular-based therapeutical products and approaches, such as those employed in regenerative medicine and immunotherapy, represent a promising frontier for addressing a broad spectrum of complex diseases, including malignancies such as cancer and autoimmune diseases.

These therapeutical approaches require high quality cellular products, for which manufacturing is underpinned by technological development. The distinct yet complementary goals and expertise embedded in our three consortia, provides a nurturing environment to develop and test new approaches to effectively treat patients.

Our three pioneering consortia—NXTGEN Hightech, RegMed XB, and Oncode Accelerator are pushing the boundaries of regenerative medicine, scalable production technologies, and cancer drug development. Together, we're building the foundation for life-changing treatments and positioning the Netherlands as a European hub for advanced therapeutic innovation and development. In order to bring innovations from this joint venture faster into the market we will collaborate closely with Biotech Booster, another National Growth Fund program established to support the commercialization of biotechnology findings in The Netherlands.

By bringing together these multiyear large scale research public-private partnerships, we seek to enhance the competitive edge of the Dutch R&D&I ecosystem; position the Netherlands market as a European hub for the development of Advanced Therapeutical Medicinal Products; and attract international stakeholders.

Now is the time to get involved. Whether you're an investor, industry leader, or skilled professional, we invite you to be part of this groundbreaking movement. Let's accelerate the development of life-saving therapies and make a lasting impact on global health."

Partner with us today to drive the future of medicine."

Contact Dr. Emma Martinez Sanchez Program Manager Cell and Gene Therapy Department Hematology University Medical Centre Utrecht <u>e.martinezsanchez-5@umcutrecht.nl</u>

NXTGEN Hightech Biomed05 Visit to UMC Utrecht-ICAT Viral Vector Facilities

Tuesday 17 September, 10:00-16:30 Innovation Center for Advanced Therapies (ICAT) Utrecht Science Park Zeist, Utrechtseweg 48 (Zeist)

Meeting objectives

- 1. Show biomed05 partners UMCU-ICAT viral vector development facilities & bioreactor
- 2. Introduction to UMCU-ICAT viral vector production & facilities
- 3. Facilitate discussion among Biomed05 partners & other relevant parties regarding Biomed05 viral vector demonstrator project
- 4. Open session (14.30-17.00): Build bridges between National Growth Fund initiatives

Program	
09.45	Arrival, coffe/tea
10.15	Ruud Das, Scinus Cell Expansion, NXTGEN Hightech Biomed05 coordinator
	'NXTGEN Hightech Cell Production Technology demonstrator project'
10.30	Joost van Duijn, Innovation Centre for Advanced Therapies (ICAT), UMC Utrecht
	'Building bridges between research and clinical practice for Regenerative Medicine'
10.45	Wout Weuring, Viral Vector Specialist, ICAT, UMC Utrecht
	'Setting up UMCU Viral Vector Facility: Rationale, Current status & Future Outlook'
11.00	Birgit Romberg, Cell Therapy Facilities, UMC Utrecht
	& Anil Deshantri, CGT Specialist, ICAT
	'Bridging the gap between research and clinical practice: From GMPsim to GMP at UMCU'
11.20	ICAT site tour with short talks:
	1. Viral vector development, Ganesh Ramesh, doctoral candidate, ICAT&UMCU
	2. ATMP Quality Control, Aiko Ballardini, Quality Control Specialist, ICAT&UMCU
	3. Users' needs: Preliminary findings Biomed05 survey, Emma Martinez, Cell & Gene
	Therapy Program Manager, UMC Utrecht
12.20	Lunch
13.00	Biomed05 consortium brainstorming discussion
	'Viral vector demonstrator project'
14.00	Facilities tour Scinus Cell Expansion
14.30	Break
14.45	Jürgen Kuball, Center for Translational Immunology, Department Hematology, UMC
	Utrecht
	'UMC Utrecht cell and gene therapy cross-cutting research initiatives'
15.00	Bernard Mulder, Chief Executive Officer, RegMed XB
	'RegMed XB and National Pilot Factory for Regenerative Medicine'
15.15	Ingrid Relou, Program Manager Biomedical Production Technologies, NXTGEN Hightech
	'NXTGEN Hightech Biomedical domain'
15.30	Karlijn Wilschut, Project Manager Pharma, Oncode Accelerator
	'Oncode Accelerator Program & Demonstrator Projects'
15.45	Closing statement
16.00	Networking reception

Organiser: Emma Martinez-Sanchez (+31-619507272), Cell & Gene Therapy Program Manager, UMC Utrecht

About NXTGEN Hightech and Biomed05

NXTGEN Hightech officially launched in May 2023. The goal of the program is to boost economic growth in the Netherlands and make the Dutch high-tech sector the leading cluster in Europe. To achieve this, the NXTGEN Hightech program will invest approximately €1 billion euros by 2030 and will involve 330 partners. The National Growth Fund supports this program with €450 million euros.

In the period 2023-2030, intensive work will be done in six technological domains to develop smart solutions. One of these domains is Biomedical Production: for instance, cell production technology for new chips that mimic organs and accelerate the search for new drugs without animal testing. The NXTGEN Hightech program provides a determined approach to transform state-of-the-art academic knowledge into groundbreaking products to address societal challenges. This comprehensive approach comprises five projects: One-stop-shop; Lab-on-a-chip; Organ-on-a-chip; Artificial Organs; and **Cell production technology (Biomed05).**

Cell culture plays a central role in various next-generation technologies. From advancements in cell and gene therapy, to the production of vaccines, replacing animal models, discovering novel drugs, and enabling the creation of cultivated meat and leather. The cell production technology project and consortium seeks to develop the next-generation bioreactor technology to meet the demand for high numbers of high-quality cells. Bioreactors are the manufacturing system that provides the ideal environment for biological processes wherein crucial factors like oxygen, temperature and pH are accurately controlled. However, other important factors play a role in successful cell cultivation, like nutrients and growth factors.

The Biomed05 consortium includes end-users (Scinus Cell Expansion, Batavia, Ncardia, UMC Utrecht) to pioneer novel technologies aimed at next-generation bioreactors for further automation and precise control over cell cultivation processes. This involves the development of innovative sensor technology to continuously monitor cell death (Helia Biomonitoring, TU Eindhoven) and biomarker concentration (ChiralVision, and University of Twente); animal-component-free cell cultivation media (TCNBio); and the seamless integration of the different components into the next-generation bioreactors via microfluidics (Bronkhorst, Demcon). This way, far-reaching control over the cell culture process will be realized, leading to high-quality cells and cell-derived products.

NXTGEN Hightech Biomed05 consortium partners: <u>Scinus</u>; <u>Demcon</u>; <u>Helia Biomonitoring</u>; <u>Batavia Biosciences</u>; <u>Ncardia</u>; <u>Lionix International</u>; <u>ChiralVision</u>; <u>Bronkhorst</u>; <u>TNCBio</u>; <u>TU</u> <u>Eindhoven</u>; <u>University Twente</u>; <u>UMC Utrecht</u>.

About RegMed XB

RegMed XB stands for Regenerative Medicine Crossing Borders. RegMed XB is a public-private partnership dedicated to bringing regenerative medicine solutions to patients and creating a new industrial sector in the participating regions.

RegMed XB brings together leading scientists at Dutch and Belgian universities and institutes and a range of companies in so-called "Moonshots": long-term visions of breakthroughs for patients, translated into research roadmaps with specific short-term milestones. Each is championed by a Health Foundation and their related patient organizations, putting patient impact at the heart of RegMed XB. The RegMed XB Pilot Factory is one of the largest international infrastructures for regenerative medicine. It brings together all the expertise and infrastructure needed to bring regenerative medicine to the market. Our mission is to accelerate the development of new solutions for chronic diseases and to bring affordable regenerative medicine therapies to patients.

The Pilot Factory consists of an ecosystem of specialized pilot lines that support universities, research institutes, start-ups and industry with developing, testing, upscaling and producing their new regenerative medicine therapies. The Pilot Factory can be divided over several pilot lines including: Smart Biomaterials Consortium (SBMC), focused on biomaterials; NecstGen, focused on stem cells; LUMC, focused on iPSC and Organ-on-Chip; ReGEN Biomedical, focused on microtissue; and the Innovation Center for Advanced Therapies (ICAT), focused on microtissue.

About the Innovation Centre for Advanced Therapies (ICAT)

In 2021, a National Growth Fund application (total €56 million) was awarded to RegMedXB, with Utrecht receiving €12.7 million. This fund will help overcome the challenge of regenerative medicine, as it will be used to make a pilot plant concerning regenerative medicine therapies. In Utrecht and Zeist, we will establish one part of that: the Innovation Center for Advanced Therapies (ICAT).

ICAT integrates 3 facilities; a biofabrication pilot facility, a GMP simulation facility, and a GMP production facility, enabling the development, optimization and standardization of complex manufacturing processes of engineered immune cells and (patient specific) microtissues. From May 2024, ICAT opened its new facility in Zeist where innovation and simulation activites will take place.

The Innovation Center for Advanced Therapies (ICAT) aims to improve and accelerate the translation of research into healthcare solutions by bringing together all relevant expertise and infrastructure for the development of regenerative treatments, Advanced Therapy Medicinal Products (ATMPs) including Tissue Engineered Products, Cell & Gene Therapies, and disease models. ICAT facilitates and stimulates the cooperation between academic and commercial partners. By integrating state-of-the-art equipment and dedicated staff, they can swiftly bring radical medical innovations and complex technologies from the bench to the bedside.

The services of ICAT includes feasibility studies, validation of therapies, GMP production, Codevelopment, scale-up and standardization GMP and Training, consultancy, coaching the goto market.

About Biotech Booster

Biotech Booster is a national program funded by the Dutch National Growth Fund that supports the commercialization of biotechnology findings in The Netherlands. Biotech Booster offers financial support, mentorship and networking opportunities to guide scientists and entrepreneurs from the idea stage to an investable or commercial proposition. The goal is to make sure that the benefits of biotechnology will have more and faster impact on society. Moreover, Biotech Booster facilitates close collaborations between public and private partners in the biotechnology sector and established five Thematic Clusters following biotechnological focus areas: White: Industrial Biotechnology & Production (TC 1); Green: AgroFood biotechnology (TC 2); Red: human health, diagnostics, therapeutics (TC 3, 4 & 5).

About Oncode Accelerator and Cell and Gene Therapy workstream

Oncode Accelerator is a public-private partnership funded by the Dutch National Growth Fund, dedicated to innovating and accelerating the preclinical development of new cancer therapies with a patient-centric approach. This collaboration brings together six key coordinating partners: Leiden University, Leiden University Medical Center, the Netherlands Cancer Institute, Princess Máxima Center, UMC Utrecht, and the Oncode Accelerator Foundation.

Oncode Accelerator partners believe that preclinical drug discovery and therapy development can be significantly accelerated and de-risked by leveraging an innovative combination of well-defined patient cohorts, organoid models, and artificial intelligence platforms. Oncode Accelerator preclinical drug discovery pipelines, known as workstreams, focus on the four most prominent types of cancer therapies: small molecules; biologics; **cell and gene therapy**; and therapeutic vaccines. The intersection of these workstreams and platforms is designed to create a synergistic effect, leading to the development of more effective therapies tailored to individual patients or specific patient populations.

The Cell & Gene Therapy Workstream, a consortium between UMC Utrecht (Prof. Kuball), the Netherlands Cancer Institute, Radboud UMC, Groningen UMC, and the European Bone Marrow Transplantation Society, focusses on advancing the promising research areas of CAR T-cell and Tumor-Infiltrating Lymphocyte (TIL) therapies. The overarching goal of Oncode Accelerator is to develop, validate, and provide the infrastructure and expertise required for patient-centric therapeutic innovations.

The first Oncode Accelerator call for <u>Demonstrator Projects</u> opened in April. Academics, biopharma, and start-ups are invited to propose projects for different stages of the program development pipelines to receive up to 50% in project co-funding, gain access to cutting-edge equipment, facilities, technologies, and expertise, and support testing and validation of the innovative Oncode Accelerator infrastructure.

About Biotech Booster

Biotech Booster is funded by the National Growth Fund with the aim to speed up the commercialization of Dutch biotech innovations and to increase the focus of researchers on valorization. Biotech Booster uses several instruments to reach these goals:

- Project funding for proof-of-principle projects (max €200k/project; 50/year)
- Project funding for proof-of-concept projects (max € 1.9M/project; 5/year)
- Business and Impact developers (in total 39), who are employed at Universities, UMC's and Universities of Applied Science; their job is to scout for relevant projects in their thematic clusters.
- Biotech Booster has divided the biotechnology in 5 clusters including one on 'ATMP's and biopharmaceuticals'
- Biotech Booster linked > 130 biotechnology entrepreneurs to the program to ensure market and business focus from the early onset on.

Overall, this will generate more and faster impact of biotechnology on society.