

Roadmap for bio-medical materials and regenerative medicine in the south of the Netherlands

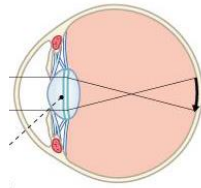


The south of the Netherlands has the power to realize step-changes for patients with biomedical materials and regenerative medicine ...

Examples of health solutions being developed in the region

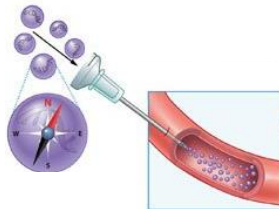
Restored vision

Accommodating intra-ocular lens from biomaterials with variable refractive indices that restores vision and releases drugs in a controlled way



Precision drug delivery

Active materials containing cancer drugs, programmed to deliver them only to the tumor and release them in exactly the right quantity at the right time



New cartilage

Biomaterial put on damaged cartilage (e.g. knee) that instructs the patient's own cells to regenerate native tissue



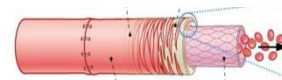
New heart valve

Artificial heart valve that replaces a damaged valve; it stimulates the patient's own cells to generate a real heart valve and dissolves when complete



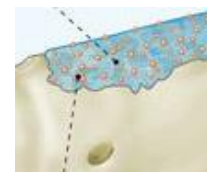
New vessel

Instructive stents and grafts for damaged vessels that use the patient's own cells to gradually transform themselves into living vessels



New bone

Biomaterial containing growth factors is put on the injury to accelerate the tissue repair process



... realize innovations in manufacturing, diagnostics and tooling that enable biomedical materials and regenerative medicine ...

Examples in the region

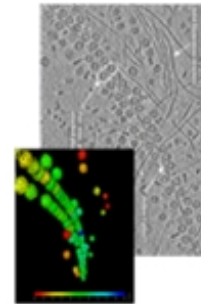
Additive manufacturing

New technologies for 3D printing – faster and with more types of materials and material combinations



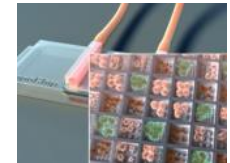
Molecular imaging

State-of-the-art cryo-electron microscopy to resolve the 3D structures of cells and materials at the nanometer scale



High-throughput technologies

Devices to study many materials for their effect on cells in parallel



Examples

iKnife

Intelligent surgical knife integrated in the OR that tests tissue as it contacts it during an operation



New materials with exceptional properties

Adhesives inspired by nature



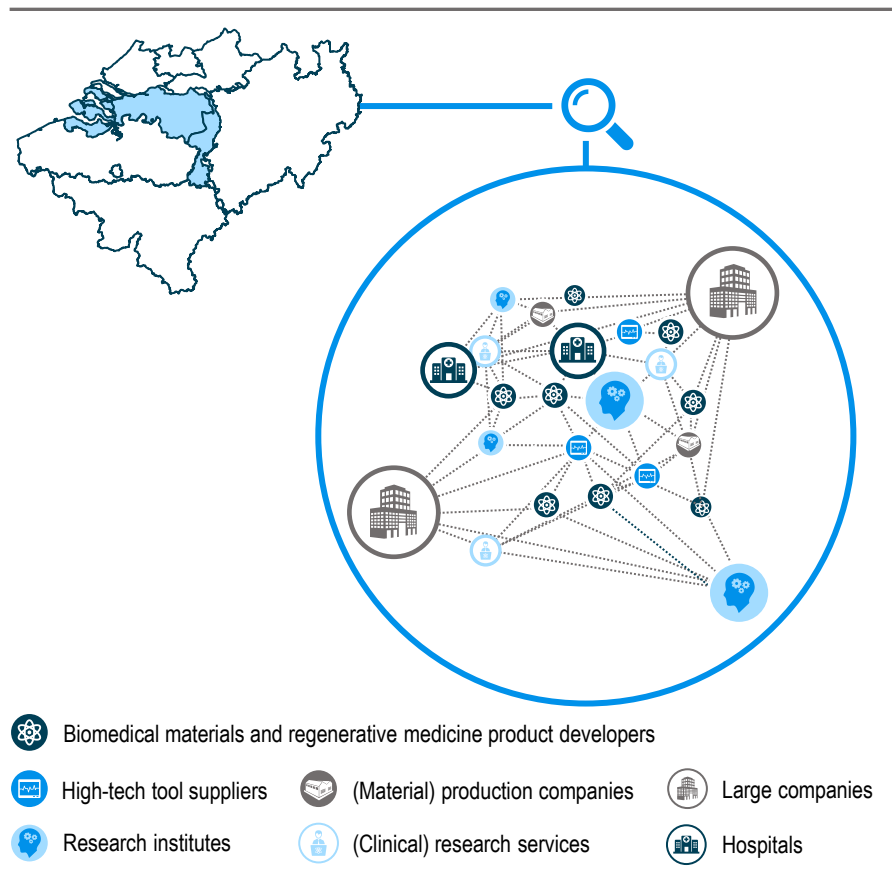
Cell production platforms

Bioreactor technologies and high-throughput cell culturing for large-scale, affordable production



... and create an ecosystem of innovators with international visibility that strengthens the regional economy ...

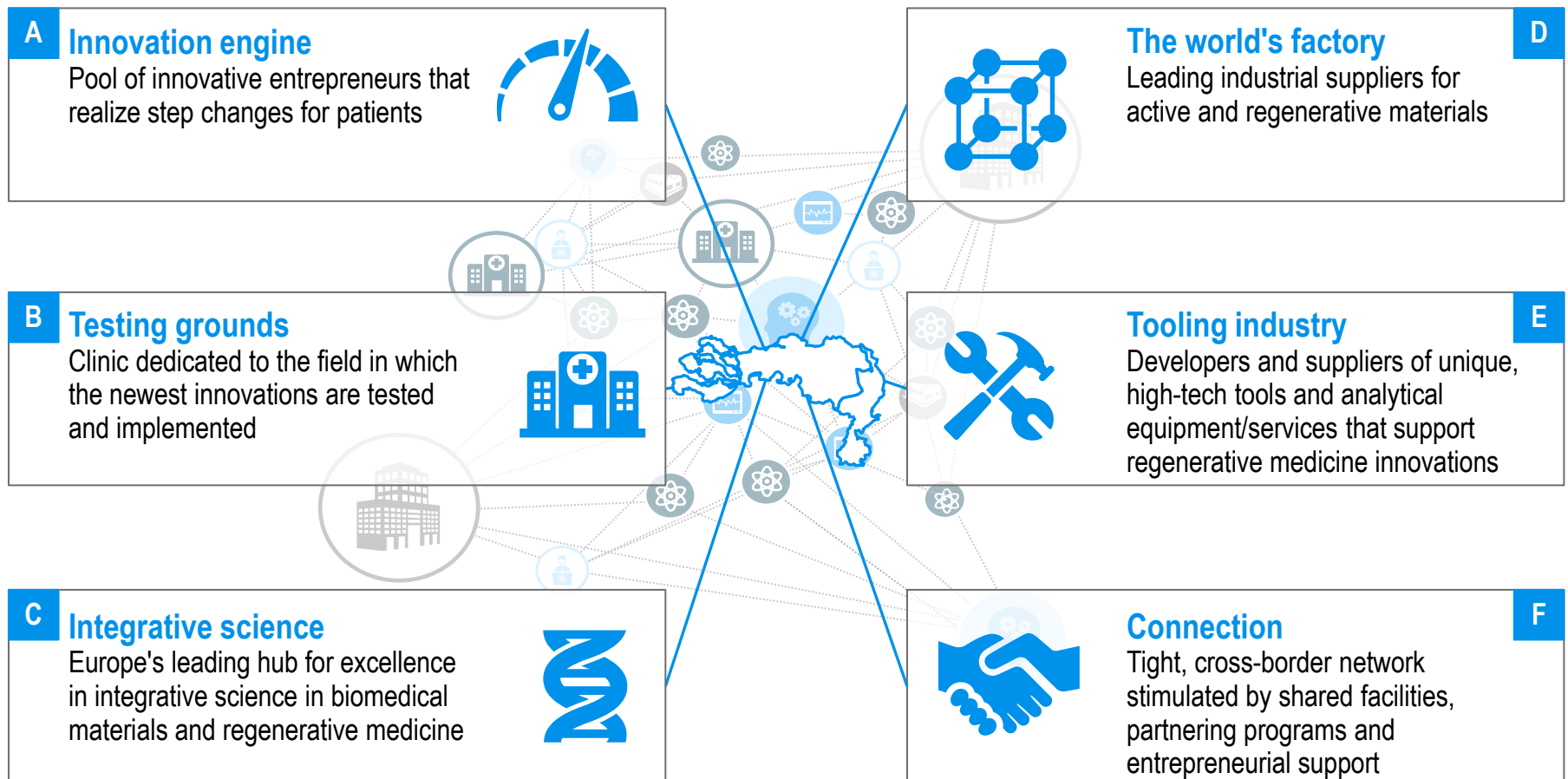
Ecosystem for biomedical materials and regenerative medicine



- > New concepts for biomedical material and regenerative medicine solutions, new materials and new tools start with frontier science at excellent research institutes and (associated) hospitals
- > Pools of (serial) entrepreneurs in and around these institutes pick up and transform concepts into spin-out companies that develop the concept into real solutions for patients, in close collaboration with the inventors
- > Large, globally-operating companies invest in these spin-outs and research institutes to accelerate product development, and give access to international markets; similarly, entrepreneurs can pick up concepts generated in large companies that are out of scope for the company
- > Production and (contract/clinical) research are outsourced to specialized companies and research institutes/hospitals, which are an integral part of the innovation process and host unique facilities in the region
- > Successful entrepreneurs remain in the ecosystem and re-invest energies and generated income in new spin-out companies, further boosting the regional ecosystem

... that consists of six pillars

Pillars of the ecosystem



To develop this ecosystem, a strategy has been proposed to strengthen the pillars of the ecosystem around priority areas

Strategy of the field going forward

> **Enhance all pillars of the ecosystem:**

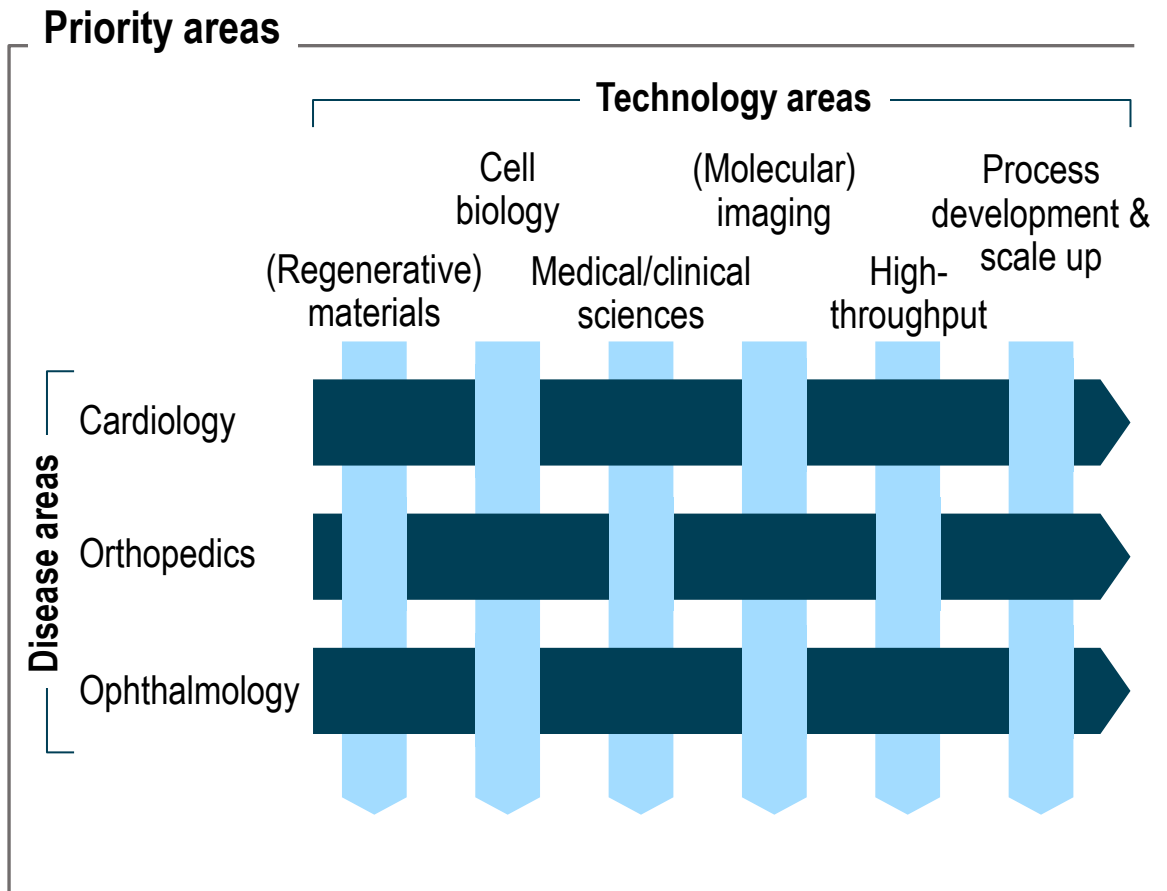
balance actions to build and strengthen the different pillars of the ecosystem in parallel, acknowledging that building an ecosystem requires continuous investments and a long-term perspective

> **Build on strengths:**







strengthen and connect existing initiatives/parties in the field in the south of the Netherlands, especially in disease and technology priority areas

> **Connect cross-regionally:**

align and cooperate with ecosystems/players outside the south of the Netherlands to fill knowledge/ infrastructure gaps, with special attention to Utrecht and Leuven

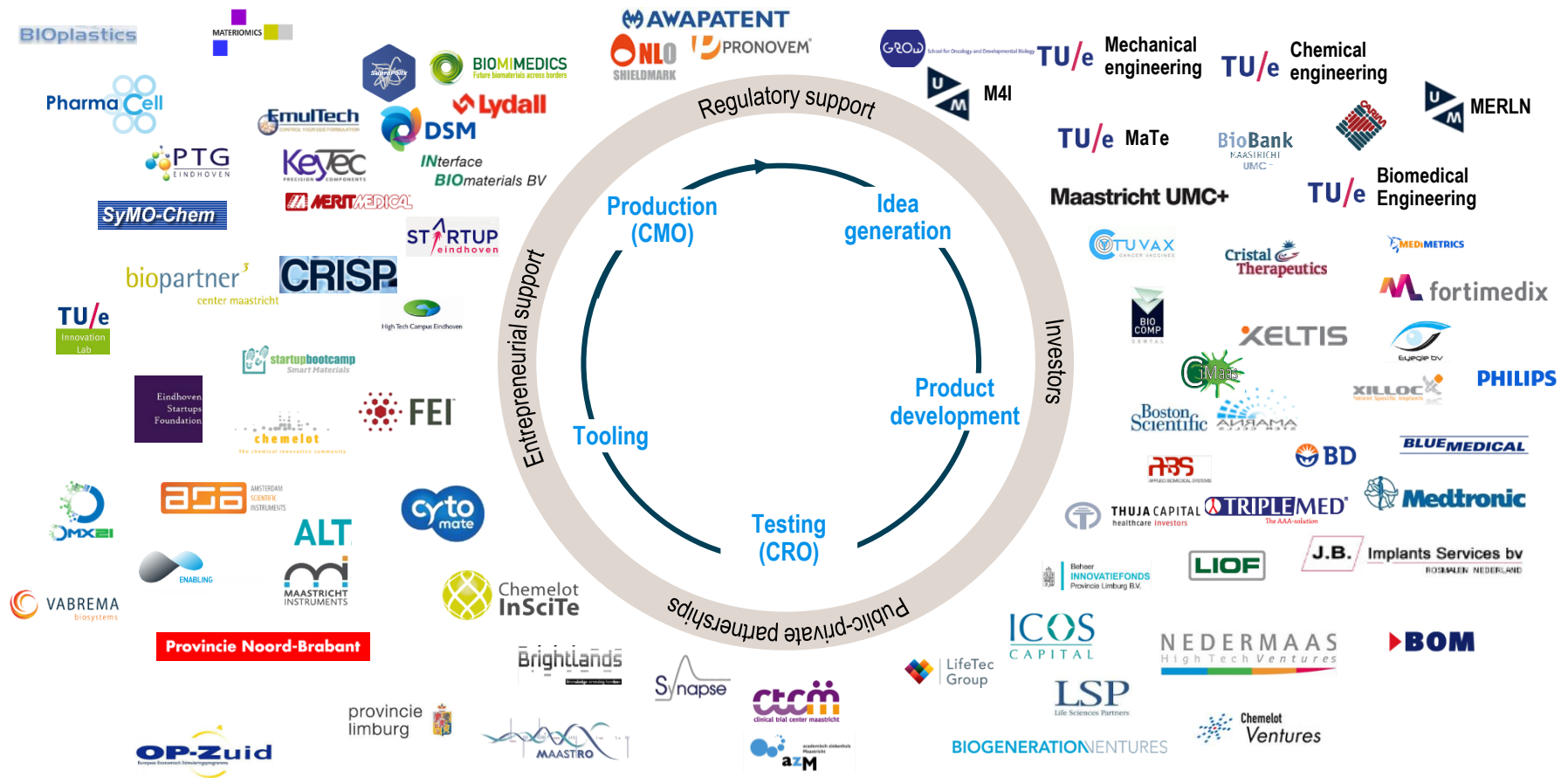


This strategy is translated into the "Brightlands RegMed" roadmap that consists of eight fields of action

	Innovation engine	RegMedAccelerator: Establish accelerator initiatives and facilities for biomedical materials and regenerative medicine companies		
	Testing grounds	RegMedClinic: Establish healthcare, clinical trial and pre-clinical infrastructure for translational research and adoption of regenerative medicine focusing on cardiology, orthopedics and ophthalmology ; including attraction of internationally-renowned doctors and the establishment of facilities that integrate molecular imaging in the clinic for inter-operative and pre-operative diagnostics and biobanking of stem cells		
	Integrative science	RegMedEducation: Integrate regenerative medicine in the curriculum of future surgeons and establish multidisciplinary educational programs to innovate at the intersection of fields		
	The world's factory	RegMedXB: Establish a world-renowned institute for excellent integrative science and top technology transfer together with neighboring regions		
	Tooling Industry	RegMedFacilities: Invest in unique facilities , especially for imaging, high throughput, (bio)chemical synthesis, process development, and pilot and scale up manufacturing facilities, and build service propositions around these facilities for companies, institutes and clinics	RegMedBranding: Make a strong claim on the subject of biomedical materials and regenerative medicine and brand it inside and outside the region	RegMedVentures: Set up a series of revolving funds to invest in entrepreneurs, in phase I/IIa trials and in unique facilities in the region
	Connection	RegMedPPP: Forge partnerships along the value chain to co-develop innovative solutions, including (large) material companies, research institutes, medical centers, (large) medical device/pharma companies and entrepreneurs		

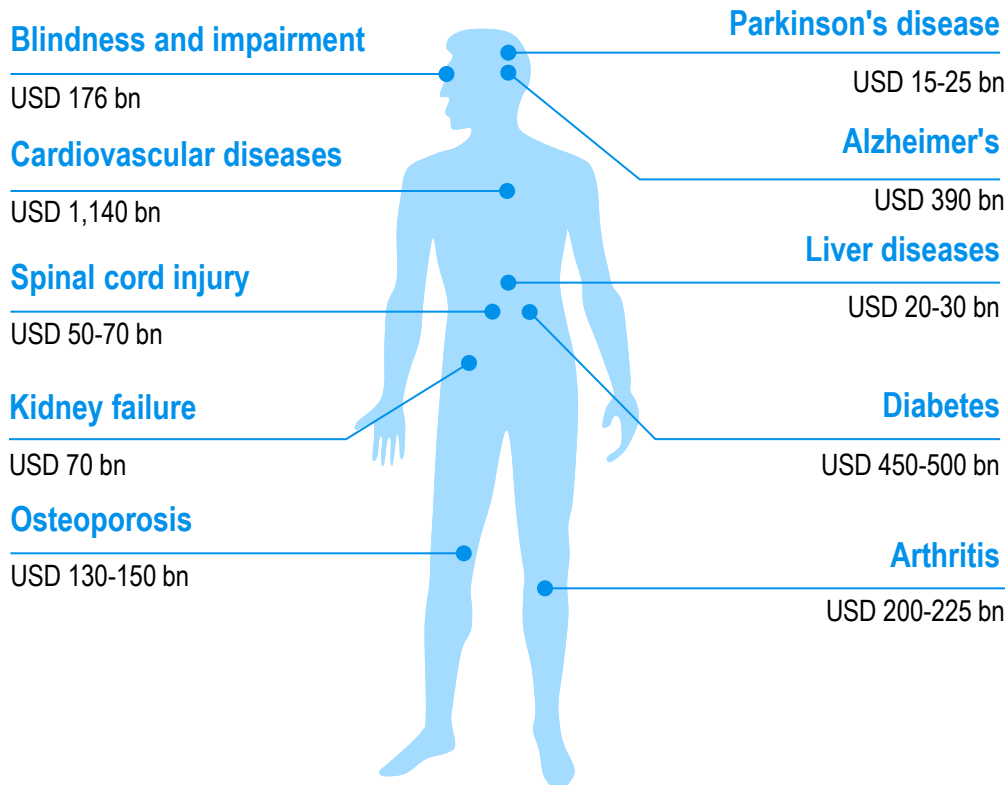
These actions will enable current and future innovative and leading organizations in the south of the Netherlands ...

Organizations in the field that are currently present in the south of the Netherlands



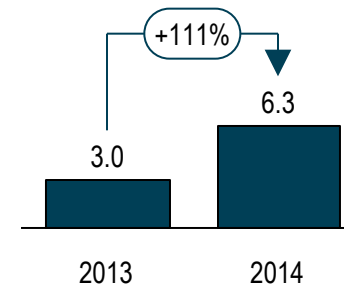
... to capitalize on one of the biggest economic opportunities of our time ...

Global healthcare market per disease area¹⁾

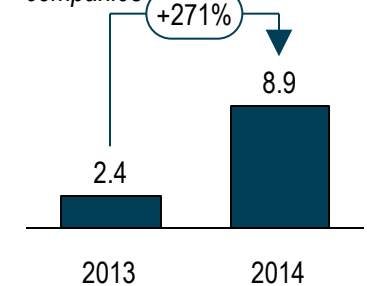


Investments [USD bn]

Investments in regenerative medicine companies

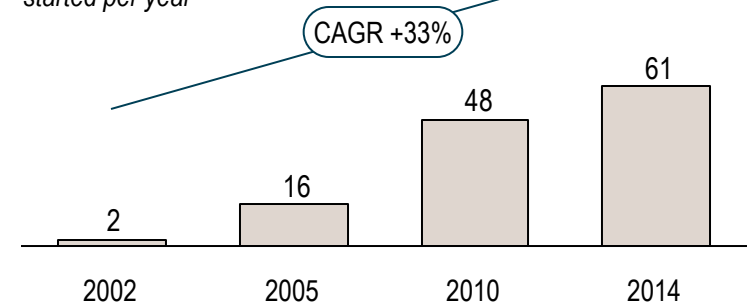


Partnership milestones for regenerative medicine companies



Clinical trials

Number of regenerative medicine²⁾ clinical trials started per year



1) Extrapolated based on available data from large countries

2) Key words: tissue engineering OR regenerative medicine OR regeneration, excluding observational studies, sorted by start year, including Cell Therapy and Gene Therapy trials

Source: Clinicaltrials.gov; Allied market research; Regenerative Medicine Annual Report 2014; WHO; World Data Bank



... to generate jobs, talent, companies, entrepreneurs, innovative treatments in the region and attract (inter)national investments ...

Potential impact period 2015-2025

Jobs and talent

- > **2,000** new high-quality jobs in companies and institutes that attract and retain talent in the region
- > **~5-10** times more indirect jobs in the region

Companies and entrepreneurs

- > **100** new companies in the region: start-ups, spin-outs and existing companies attracted to the region

Innovative treatments

- > **50** innovative treatments and/or diagnostic solutions brought into the clinic
- > **Leading clinic** providing good access for people in the region to the most advanced regenerative medicine

Sustainable ecosystem

- > **Attracts** sufficient public investments from outside the region (national, international) to sustain the ecosystem

... and to transform healthcare, replacing palliative treatments for the chronically ill with cures and prevention

Today: palliative care

- > Diagnosis: Disease found during or after a critical episode
- > Treatment: Target symptoms and slow down disease progression



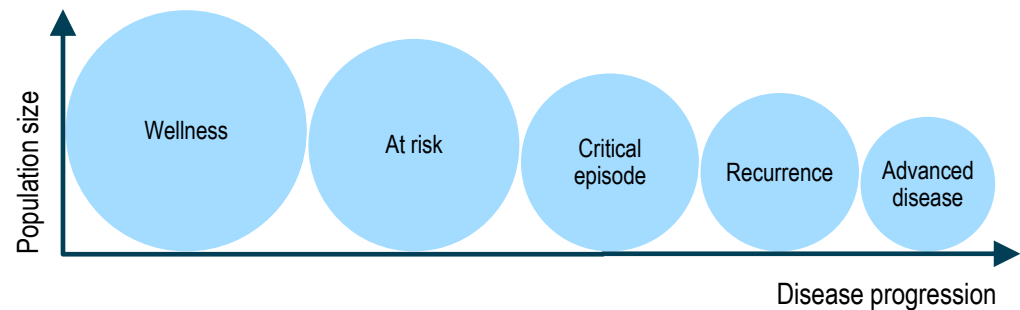
Tomorrow: from care to cure

- > Diagnosis: Disease sub-type and patient-specific considerations
- > Treatment: Use regenerative medicine to heal or replace damaged/diseased tissue in order to restore full functionality



Future: from cure to prevention

- > Diagnosis: Predictive, identifying people at risk
- > Treatment: Use regenerative medicine to prevent the degeneration from occurring in the first place



 Moment of intervention  Progression

The south of the Netherlands will become recognized as a global leader in biomedical materials and regenerative medicine

Possible quotes from people in 2030 – Illustrative

Susan, 60-year-old woman from Canada who received a new heart valve in Maastricht



"I chose the best doctor with the best treatment and came to Maastricht – now, I'm enjoying life again"

John, 40-year-old businessman, who established a company that develops new livers at Brightlands



"I love this place – the entrepreneurial spirit, excellent facilities, partnerships and talent"

Ling, 25-year-old PhD student in RegMedXB



"Learning from the best in an entrepreneurial environment is what brought me here"

Steve, 45-year-old investor



"We are doing our sixth investment in the region this year – two more than last year"

Karel, 50-year-old doctor in Maastricht



"Regenerative medicine is what patients from the region and from all over the world come for"

Marie, 30-year-old intrapreneur from Eindhoven



"We established our European scouting organization in Eindhoven to be close to the action"

This document has been developed by an expert group supported by Roland Berger

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> Emiel Staring	Chemelot InSciTe
> Jan Schrooten	Antleron

Interviews from which input was obtained

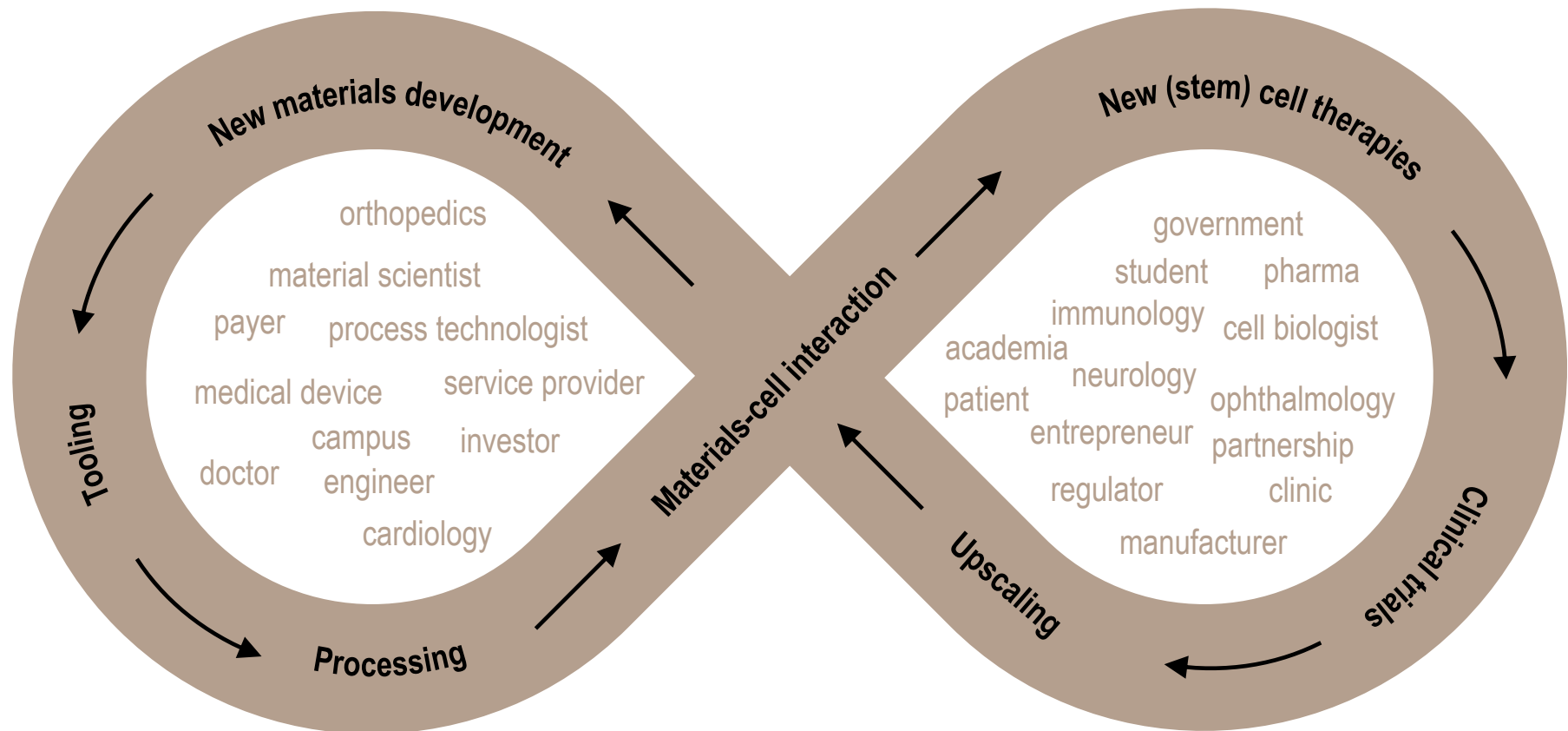
> Maikel Beerens	Xilloc
> Laurent Grandidier	Xeltis
> Alexander Vos	PharmaCell
> Marc Hendriks	DSM
> Frank de Jong	FEI
> Leo Kretzers	Medtronics
> Bert Meijer	TU/e
> Frank Baaijens	TU/e
> Martin Paul	Maastricht University
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> Albert Scherpbier	MUMC+
> Marianne van der Steen	UMC Utrecht
> Casper Bruens	Chemelot Ventures
> Maurice Lambriex	Brightlands
> Ed Rousseau	Brightlands
> Odile Steijger	Brightlands

This document describes the roadmap for the field of biomedical materials and regenerative medicine in the south of the Netherlands

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4	Roadmap to achieve the ambition and deliver on the promise	p.44
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Biomedical materials and regenerative medicine is a field in which many disciplines come together to develop new health solutions



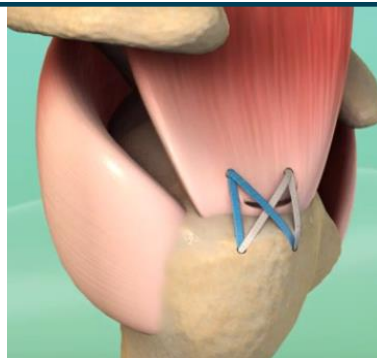
Materials are already used in many medical applications

Examples

Sutures



- > DSM's Dyneema® (a polyethylene fiber) is the strongest fiber in the world, very flexible and biocompatible
- > Dyneema wire is used to suture, fix bone fractures, and tie implants in the body



Endovascular stents



- > Fortimedix cuts a small tube from a metal alloy and treats it to get the right strength, flexibility and biocompatibility
- > The tube is used to strengthen narrow or weak arteries and restore blood flow



Implants



- > The material PEEK-OPTIMA® from Invibio is a strong and durable polymeric biomaterial
- > It is used by Xilloc to 3D print patient-specific implants



Drug delivery

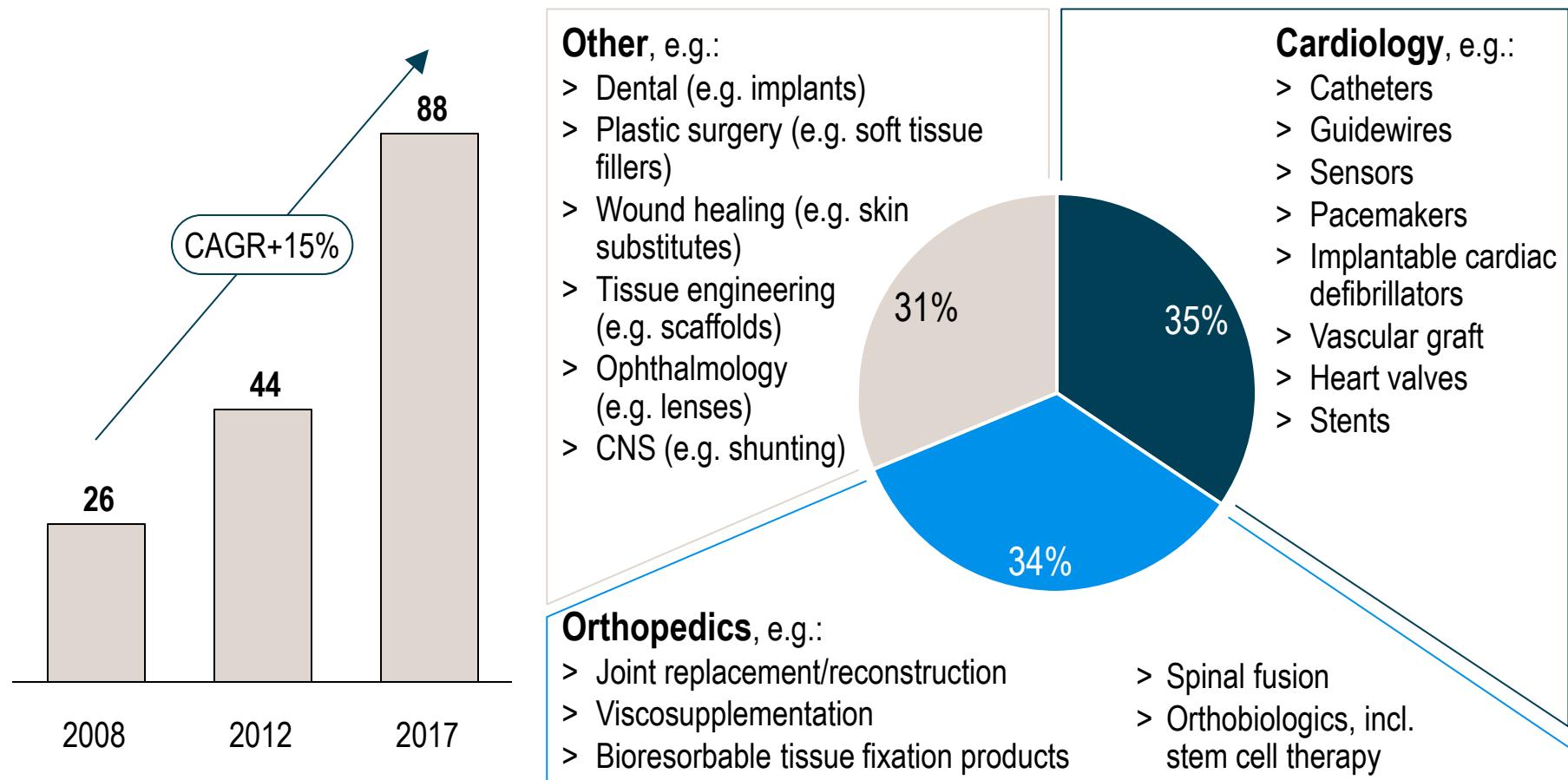


- > Solupor® membrane from Lydall, made from Dyneema, is engineered for high porosity, stability and flexibility
- > The membrane is used for controlled release of drugs in transdermal (skin) delivery systems



Material applications for health is a multi-billion dollar market, growing strongly by 15% per year

Global market estimates for biomaterials [USD bn] and market division in applications



The field is developing from passive to active and regenerative materials

Types of biomedical materials

Future promise

Regenerative medicine

The "Holy Grail" in healthcare: using materials to trigger and instruct the regenerative powers of our own bodies to restore diseased tissue and organs and/or prevent degeneration

Developing

Active

Biomedical materials that interact with biological tissue in the body and/or act as medical devices such as controlled release of drugs, disinfection and dissolving components

Established

Passive

Biomedical materials that do not interact with biological tissue and give medical devices characteristics like strength, flexibility, durability, biocompatibility and antifouling



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We are heading into the era of regenerative medicine, which will benefit our society, patients and economy

A **Society** – Tackling the rising challenge of chronic diseases

B **Patients** – Prevention and cures instead of palliative care

C **Economy** – Providing major economic opportunities

D **Science** – Booming scientific field

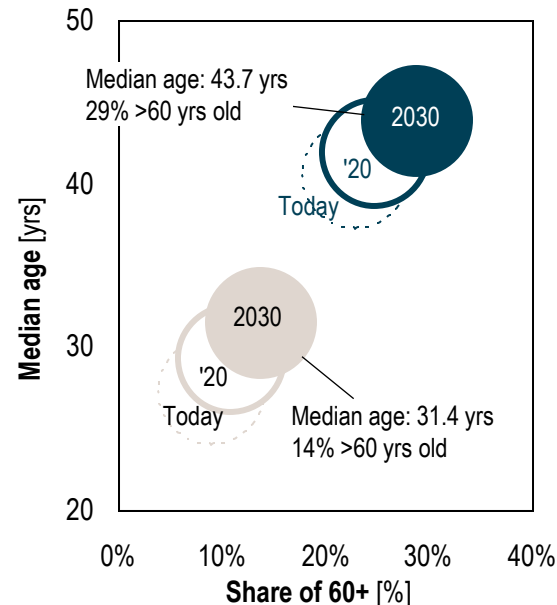
Regenerative medicine

- > Regenerate tissue outside the body as implants to replace diseased or damaged tissue
- > Induce and guide the regeneration of diseased or damaged tissue in the body (in situ)

The world is facing major health(care) challenges: rising chronic diseases resulting in escalating healthcare costs

Aging population ...

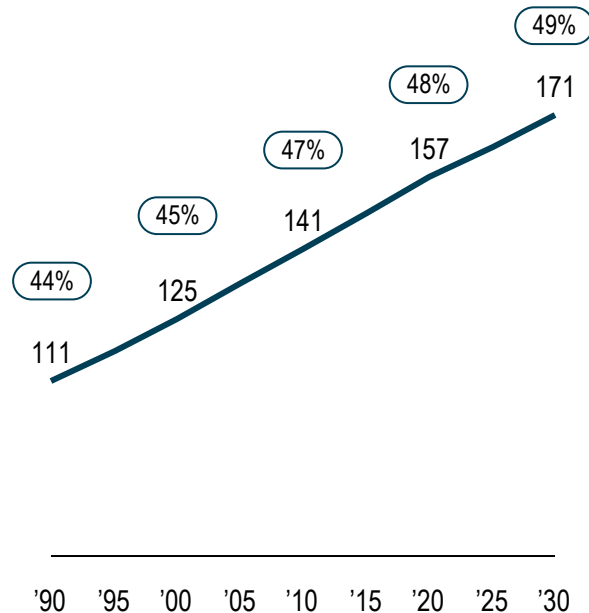
Median age and 60+ share of population



Developing countries (light brown circle) Developed countries (dark blue circle)

... increasing chronic illness ...

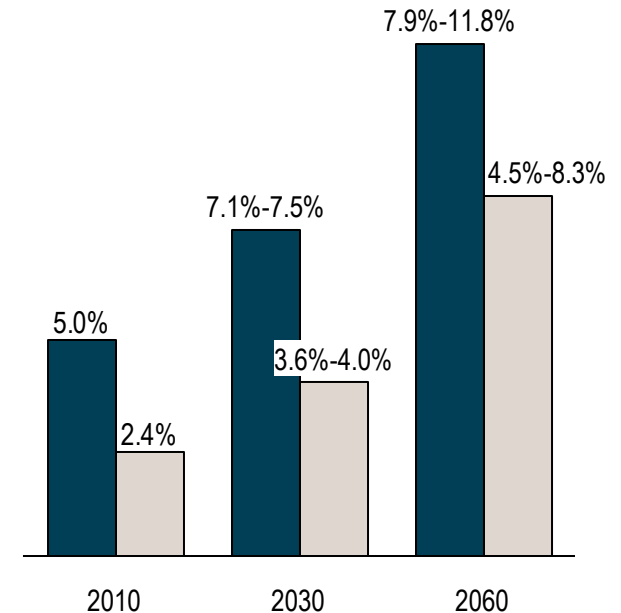
Chronic diseases in the US



— People with a chronic condition in the US [m]
 (x%) Percent of the US population with a chronic condition

... rising healthcare costs

Public healthcare expenditure as % of GDP (non-weighted average)



OECD (dark blue bar) Non-OECD (light brown bar)

Regenerative medicine promises to transform healthcare: cures and prevention will replace palliative treatments for the chronically ill

Today: palliative care

- > Diagnosis: Disease found during or after a critical episode
- > Treatment: Target symptoms and slow down disease progression



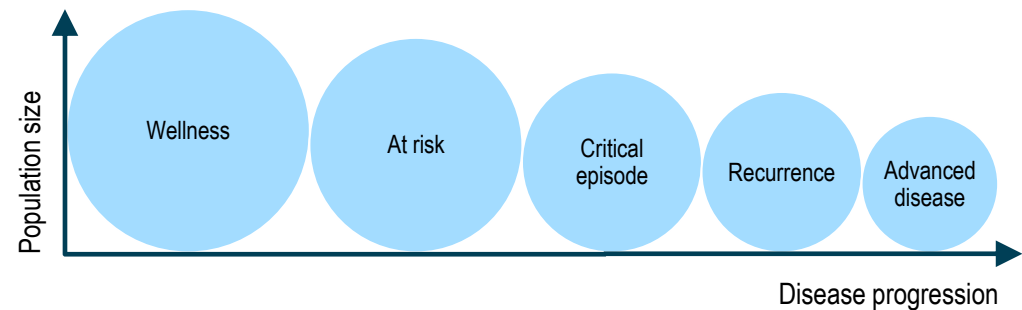
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Future: from cure to prevention

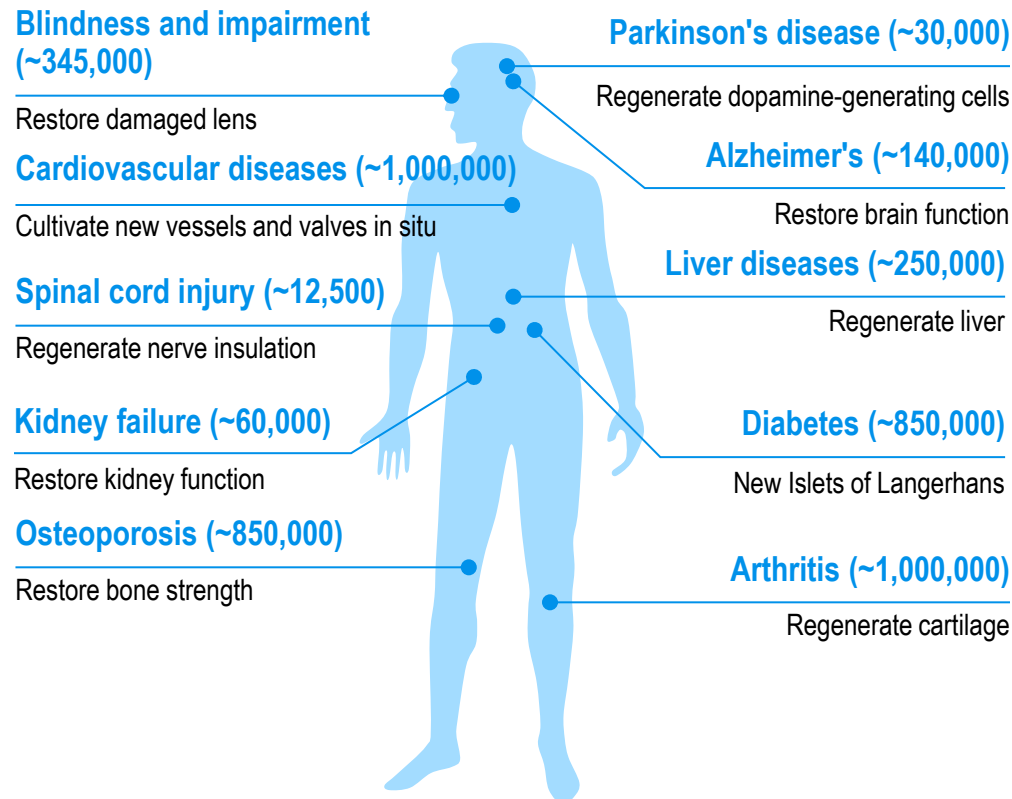
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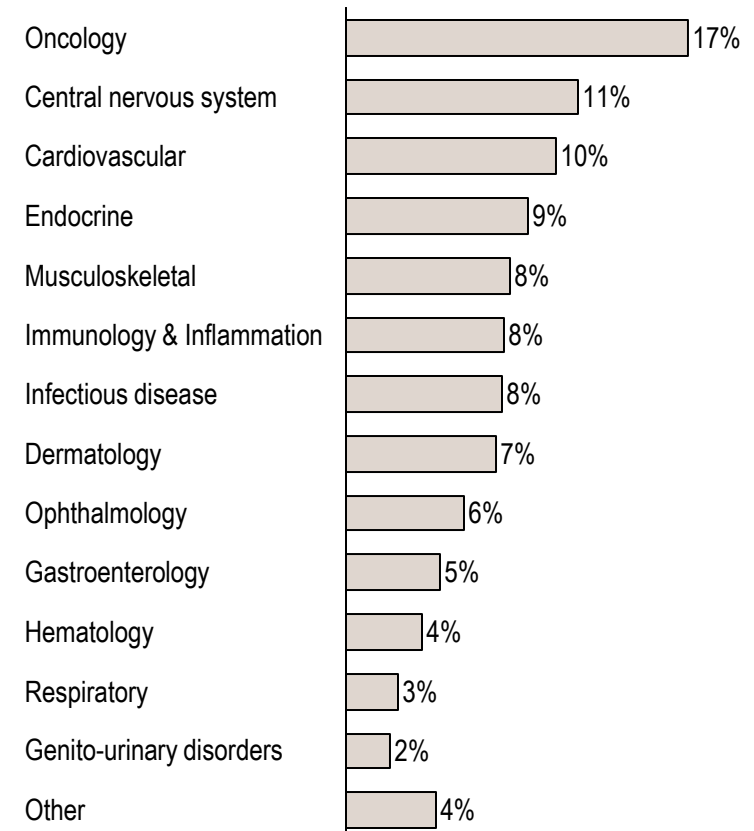
■ Moment of intervention → Progression

Regenerative medicine has the potential to cure many patients

Promise of regenerative medicine solutions for patients (# of patients in NL)

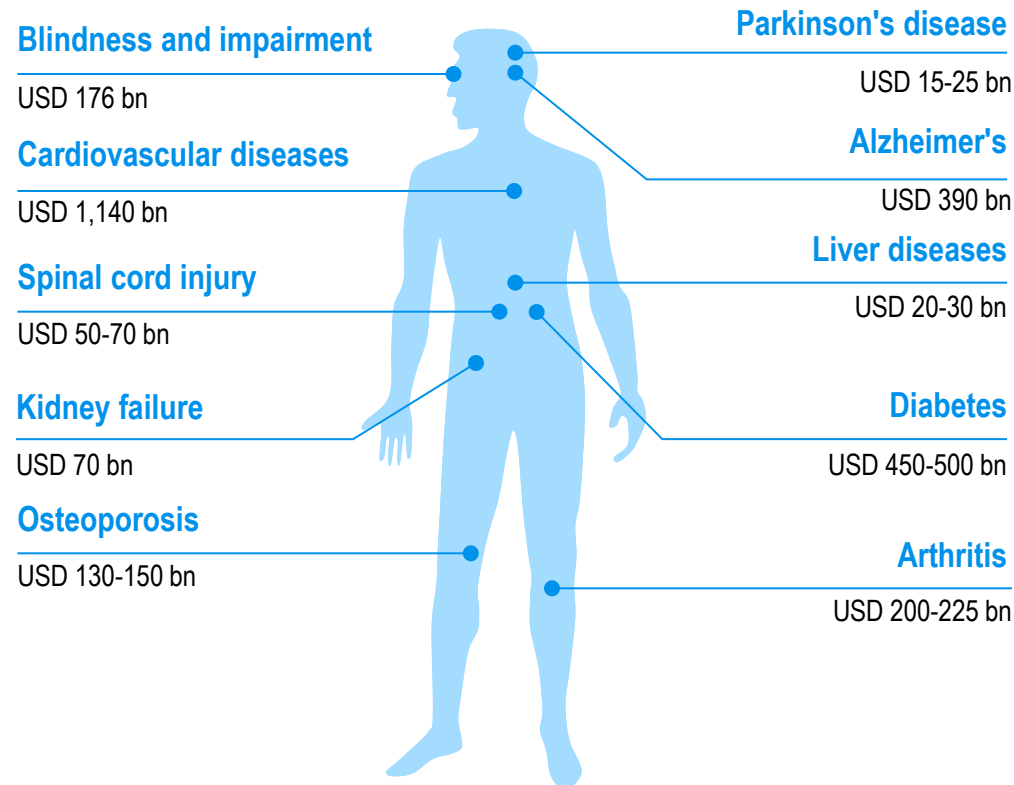


Application area of regenerative medicine companies [% of total, world]



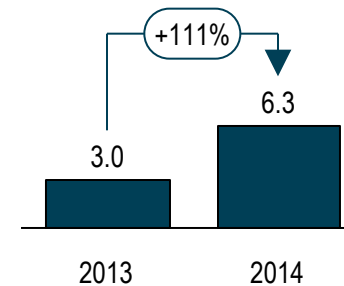
Regenerative medicine is a major international economic opportunity

Global healthcare market per disease area¹⁾

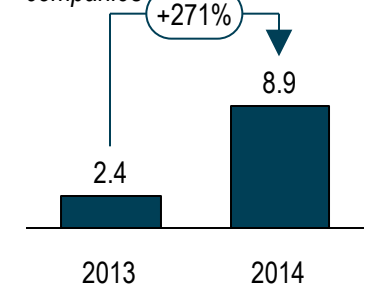


Investments [USD bn]

Investments in regenerative medicine companies

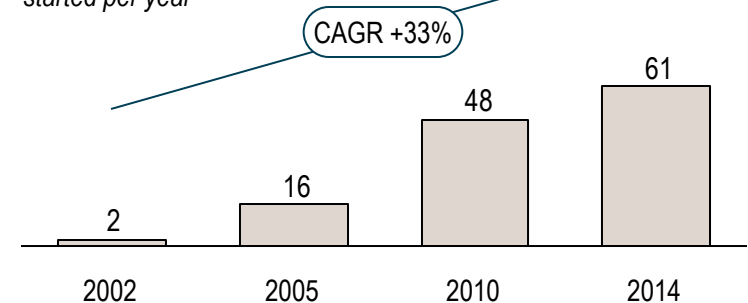


Partnership milestones for regenerative medicine companies



Clinical trials

Number of regenerative medicine²⁾ clinical trials started per year



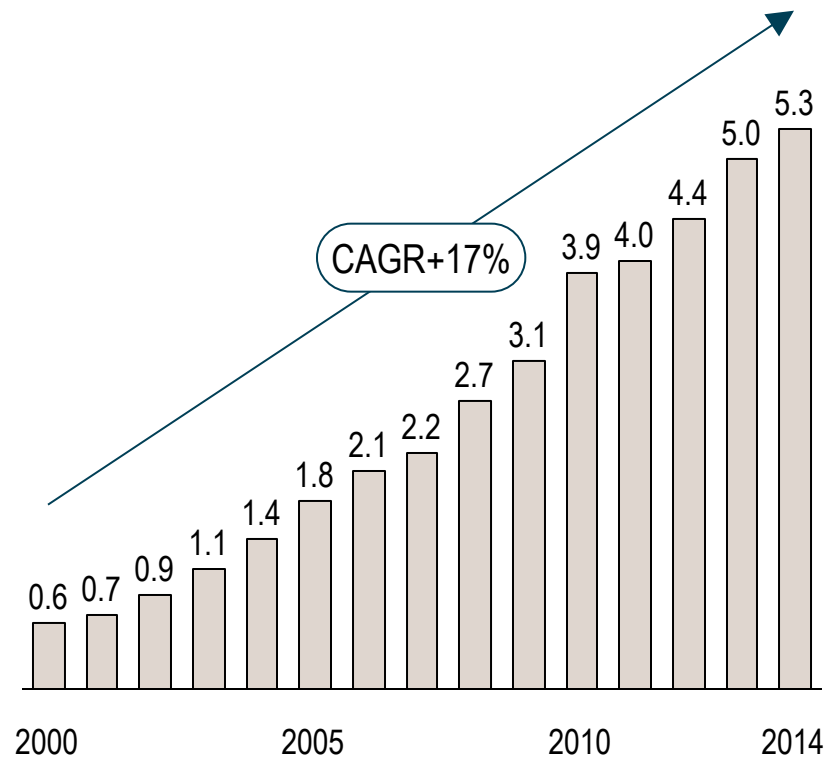
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2) Key words: tissue engineering OR regenerative medicine OR regeneration, excluding observational studies, sorted by start year, including Cell Therapy and Gene Therapy trials

Source: Clinicaltrials.gov; Allied market research; Regenerative Medicine Annual Report 2014; WHO; World Data Bank

Regenerative medicine is a booming scientific field

Number of regenerative medicine publications worldwide ['000]



Stem Cell Scientists Awarded Nobel Prize in Physiology and Medicine

In what researchers view as validation of the field, the Nobel committee on Monday recognized pioneering contributions to stem cell science by John Gurdon and Shinya Yamanaka



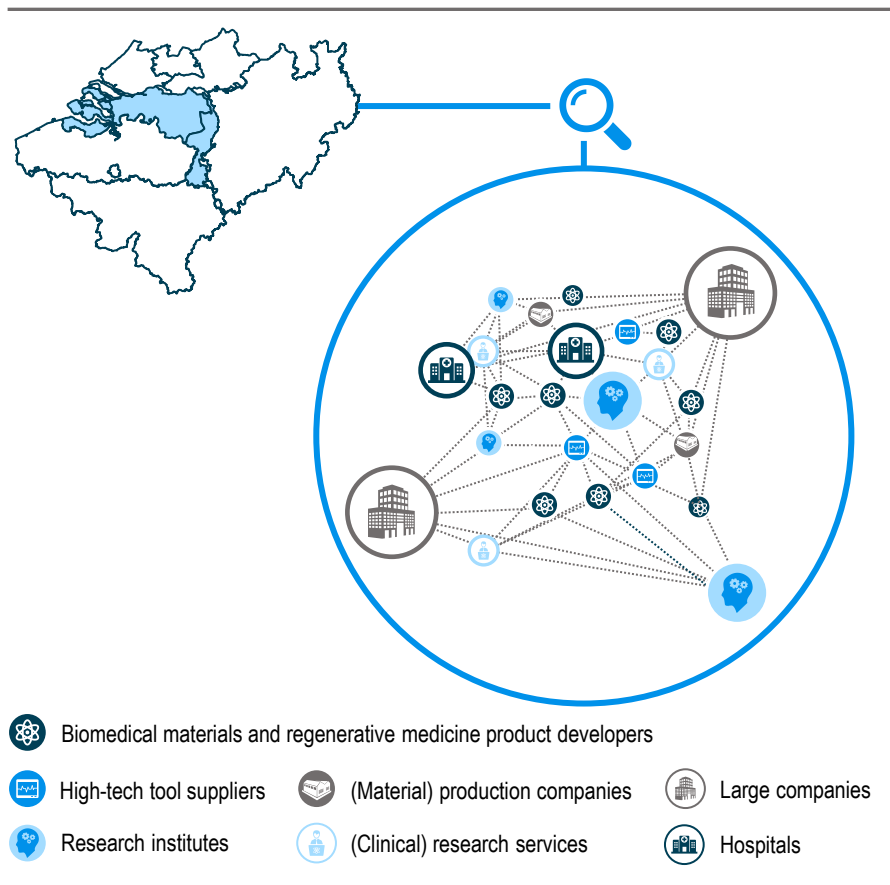
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The south of the Netherlands aims to develop into an ecosystem of innovators for biomedical materials and regenerative medicine

Ecosystem



- > New concepts for biomedical material and regenerative medicine solutions, new materials and new tools start with frontier science at excellent research institutes and (associated) hospitals
- > Pools of (serial) entrepreneurs in and around these institutes pick up and transform concepts into spin-out companies that develop the concept into real solutions for patients, in close collaboration with the inventors
- > Large, globally-operating companies invest in these spin-outs and research institutes to accelerate product development, and give access to international markets; similarly, entrepreneurs can pick up concepts generated in large companies that are out of scope for the company
- > Production and (contract/clinical) research are outsourced to specialized companies and research institutes/hospitals, which are an integral part of the innovation process and host unique facilities in the region
- > Successful entrepreneurs remain in the ecosystem and re-invest energies and generated income in new spin-out companies, further boosting the regional ecosystem

The ecosystem will generate jobs, attract talent, create and attract companies, deliver innovative treatments and attract investments

Potential impact period 2015-2025

Jobs and talent

- > **2,000** new high-quality jobs in companies and institutes that attract and retain talent in the region
- > **~5-10** times more indirect jobs in the region

Companies and entrepreneurs

- > **100** new companies in the region: start-ups, spin-outs and existing companies attracted to the region

Innovative treatments

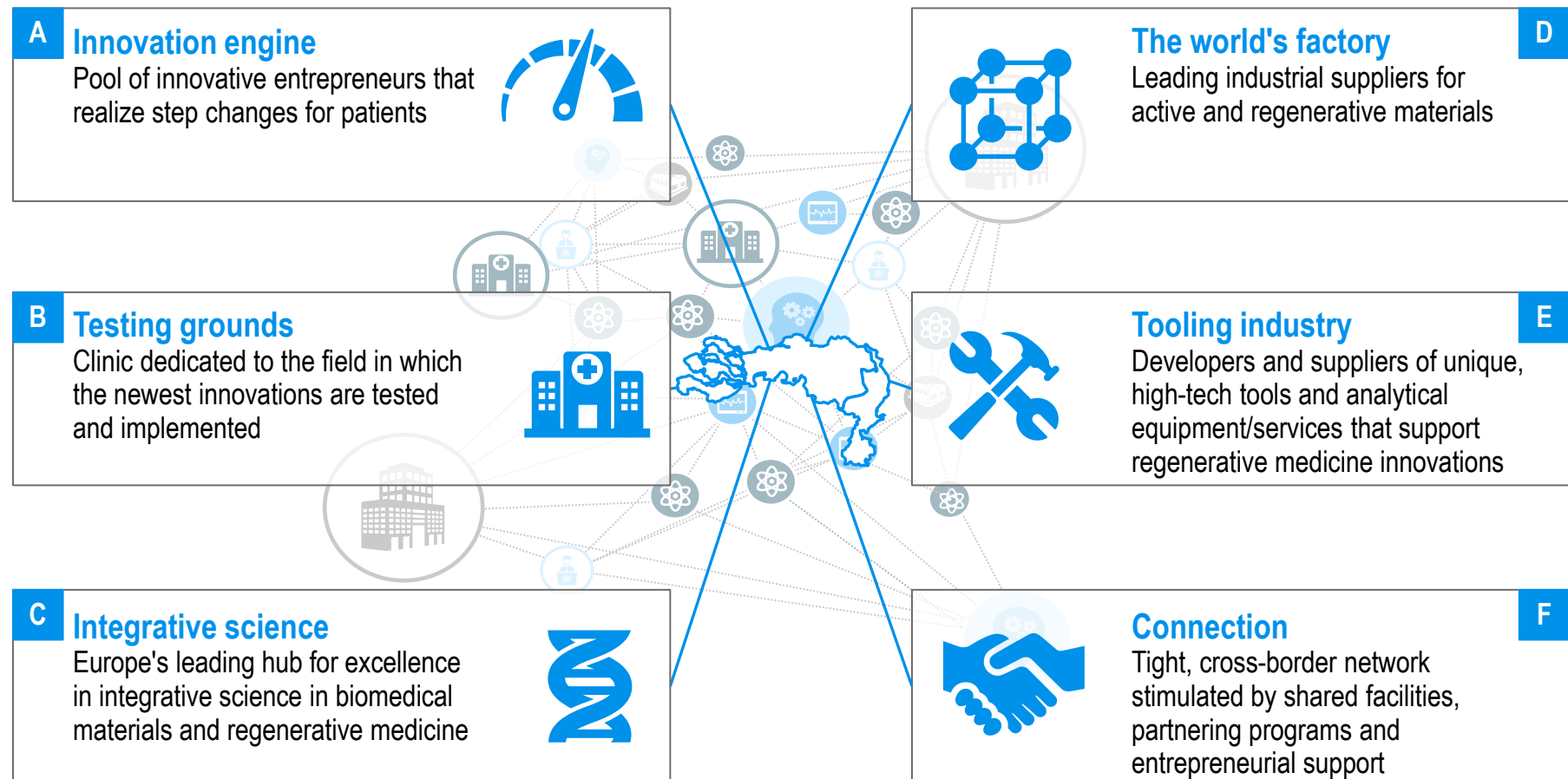
- > **50** innovative treatments and/or diagnostic solutions brought into the clinic
- > **Leading clinic** providing good access for people in the region to the most advanced regenerative medicine

Sustainable ecosystem

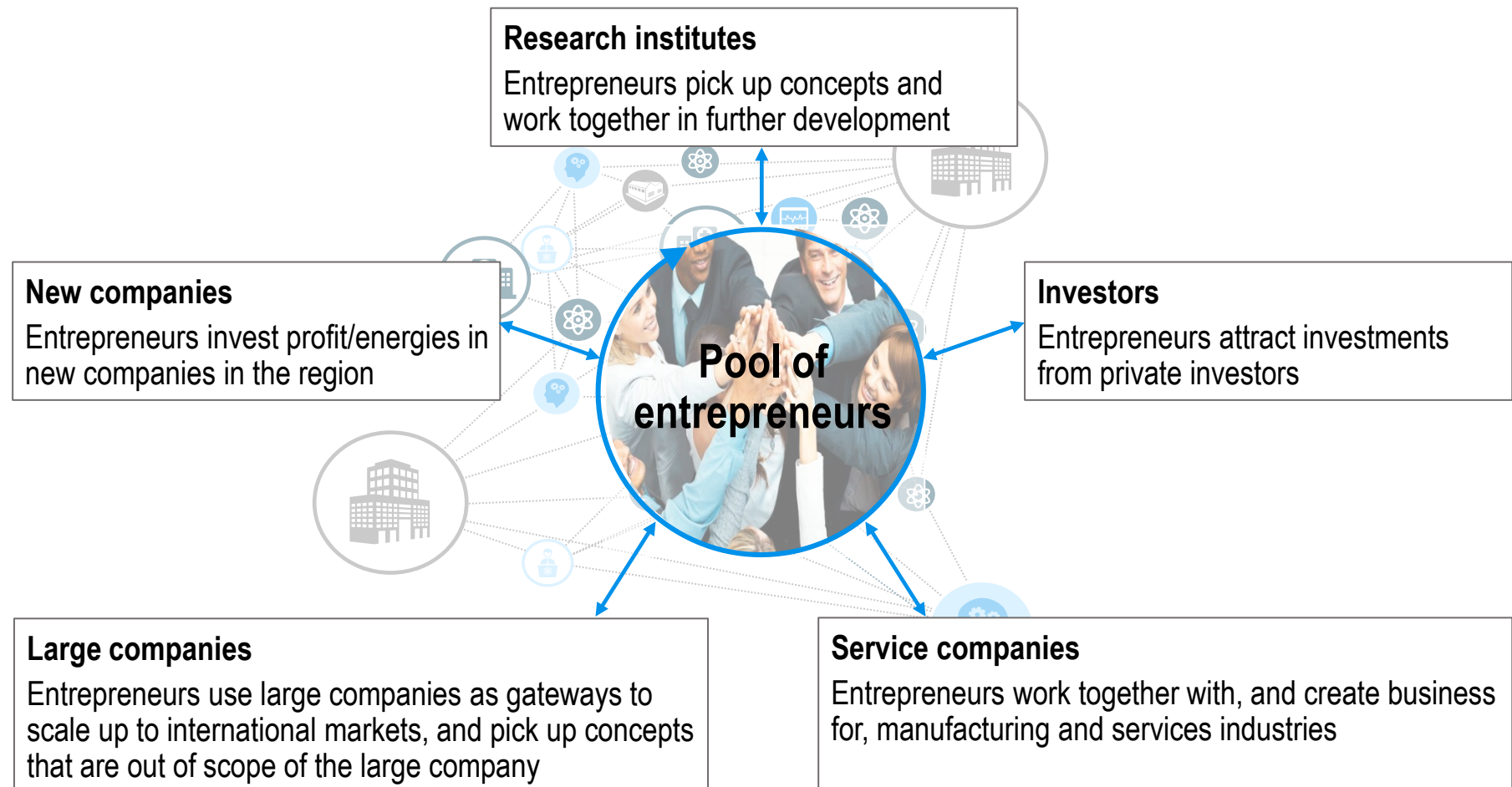
- > **Attracts** sufficient public investments from outside the region (national, international) to sustain the ecosystem

The ecosystem will be built on six pillars

Pillars



At the heart of the ecosystem will be a pool of entrepreneurs in the south of the Netherlands who develop new solutions for patients

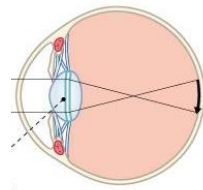


The innovation engine in the south of the Netherlands will realize step changes for patients

Examples of health solutions being developed in the region¹⁾

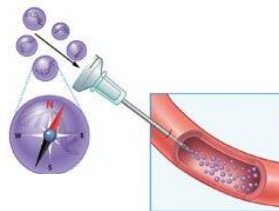
Restored vision

Accommodating intra-ocular lens from biomaterials with variable refractive indices that restores vision and releases drugs in a controlled way



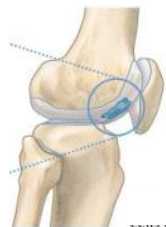
Precision drug delivery

Active materials containing cancer drugs, programmed to deliver them only to the tumor and release them in exactly the right quantity at the right time



New cartilage

Biomaterial put on damaged cartilage (e.g. knee) that instructs the patient's own cells to regenerate native tissue



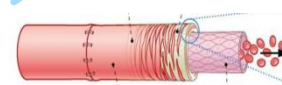
New heart valve

Artificial heart valve that replaces a damaged valve; it stimulates the patient's own cells to generate a real heart valve and dissolves when complete



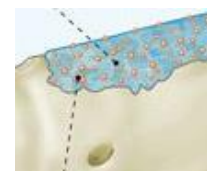
New vessel

Instructive stents and grafts for damaged vessels that use the patient's own cells to gradually transform themselves into living vessels



New bone

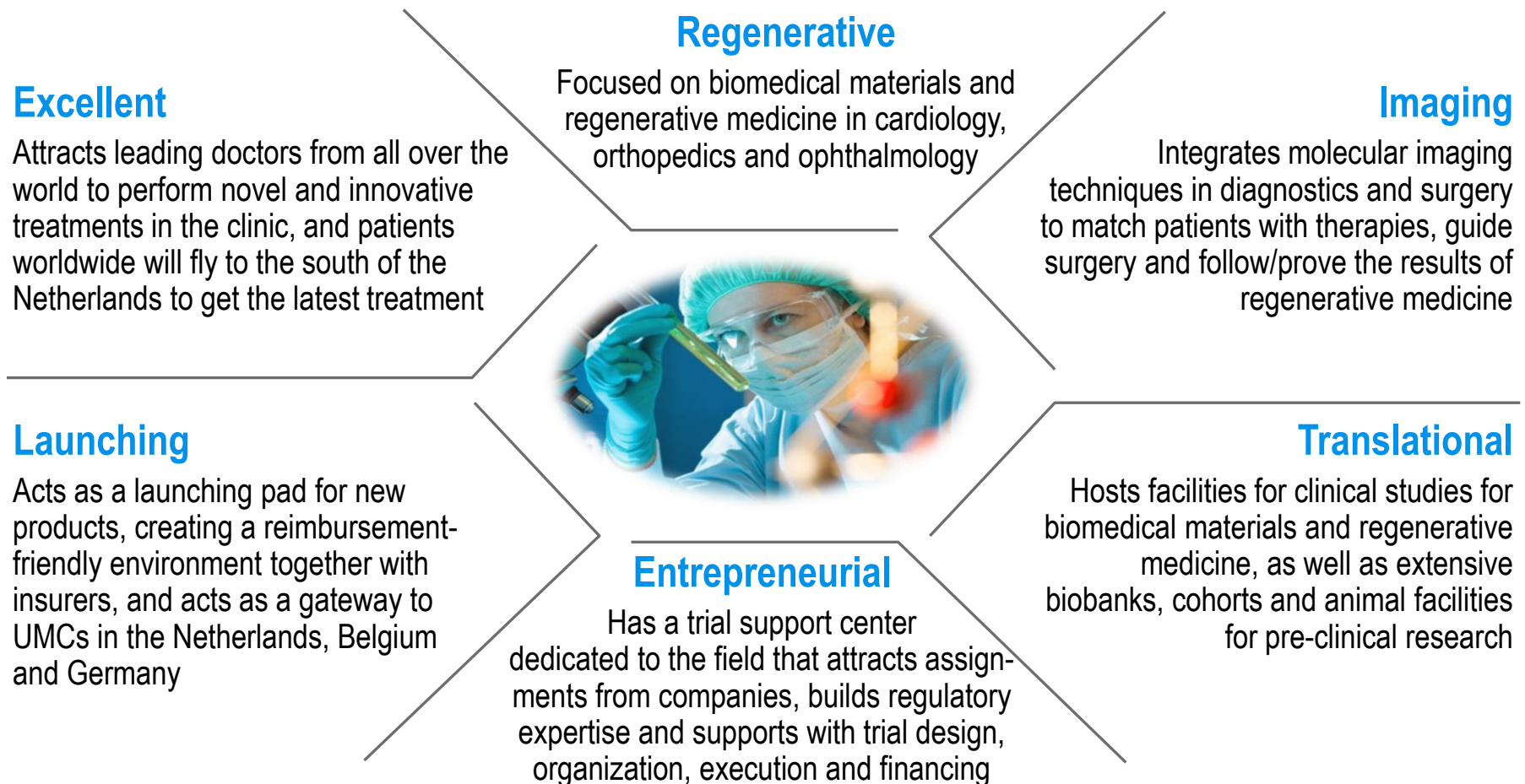
Biomaterial containing growth factors is put on the injury to accelerate the tissue repair process



¹⁾ See appendix for more details

In a world-renowned regenerative medicine clinic, leading doctors will apply these innovations and supply them to patients

Testing grounds



The testing grounds will deliver new healthcare facilities to people in the south of the Netherlands and research facilities for scientists

Examples of new healthcare and research facilities being developed in the region

Mosae Vita

Institute for the development of innovative products and services in prevention, together with residents and practitioners, that will help people in the south of the Netherlands live a healthy and conscious life



Human Performance Lab



The Computer-Assisted Rehabilitation Environment will provide exercises and monitor the movements of patients, supporting more rapid recovery

An intelligent surgical knife integrated in the OR that tests tissue as it contacts it during an operation, guiding a surgical procedure to save healthy tissue and improve surgical outcomes

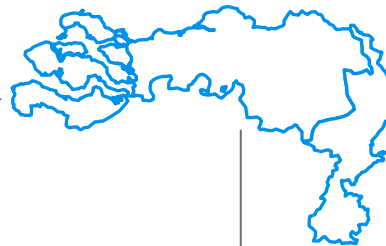


iKnife

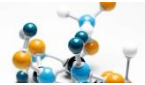
Expansion and rebuilding of the animal facilities at the MUMC+ to support the development of medical breakthroughs



Central animal facilities



The region will be considered Europe's leading hub for integrative science in biomedical materials and regenerative medicine



Material science:

understanding composition, shape, mechanics and kinetics of current materials and discovering new ones



Tooling:

creating tools for characterization and manipulation of materials and material-cell interaction, high-throughput screening and data analysis



Biology:

understanding (stem) cell and tissue development and growth



Medicine & clinical research:

understanding health and disease progression, and testing medical innovations



Processing:

development of new production processes

Integrative science:

integrating research areas into biomedical materials and regenerative medicine concepts and connecting basic and applied/clinical research

Integrative science in the region will be rooted in excellence, focus, connection, education and first-class technology transfer

Research excellence	Shared focus	Basic and clinical research connected	First-class technology transfer	Dedicated education
<ul style="list-style-type: none"> > World-renowned scientists in the region perform excellent research > Partners from all over the world come to the region to work with top scientists > Talent from all over the world is drawn to the region to learn from industry leaders 	<ul style="list-style-type: none"> > Leading scientists in the region work together on major step changes for patients > These topics of focus are ambitious and high-risk 	<ul style="list-style-type: none"> > Scientists in basic and clinical sciences are well connected and work together on an ongoing basis > Basic and clinical scientists are housed so they can regularly physically interact 	<ul style="list-style-type: none"> > Research results are easily picked up by entrepreneurs and taken to the next level in cooperation with the inventors > Technology transfer is supported by excellent and pragmatic professionals 	<ul style="list-style-type: none"> > Curriculum for regenerative medicine attracts & educates talent > Digital education (incl. MOOCs) allows people worldwide to learn from and about the ecosystem in the south of the Netherlands

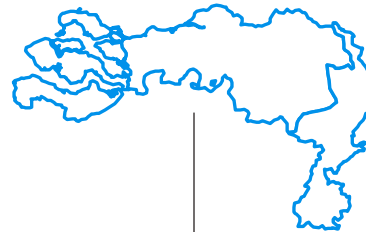


Integrative science will attract excellent scientists and talent to the region

Examples of initiatives being developed in the region

Establishment of MERLN and M4I

- > UM/MUMC+ established two new institutes in 2014, M4I (molecular imaging) and MERLN (regenerative medicine)
- > Through the institutes, UM/MUMC+ attracted three top scientists to the region: Prof. dr. C.A. van Blitterswijk, Prof. dr. R.M.A. Heeren and Prof. dr. P.J. Peters
- > With the advent of MERLN, three out of the five top scientists of the Netherlands, Belgium and North Rhine-Westphalia in the field of regenerative materials, in terms of publications, now are settled in the south of the Netherlands



MSc of Regenerative Medicine

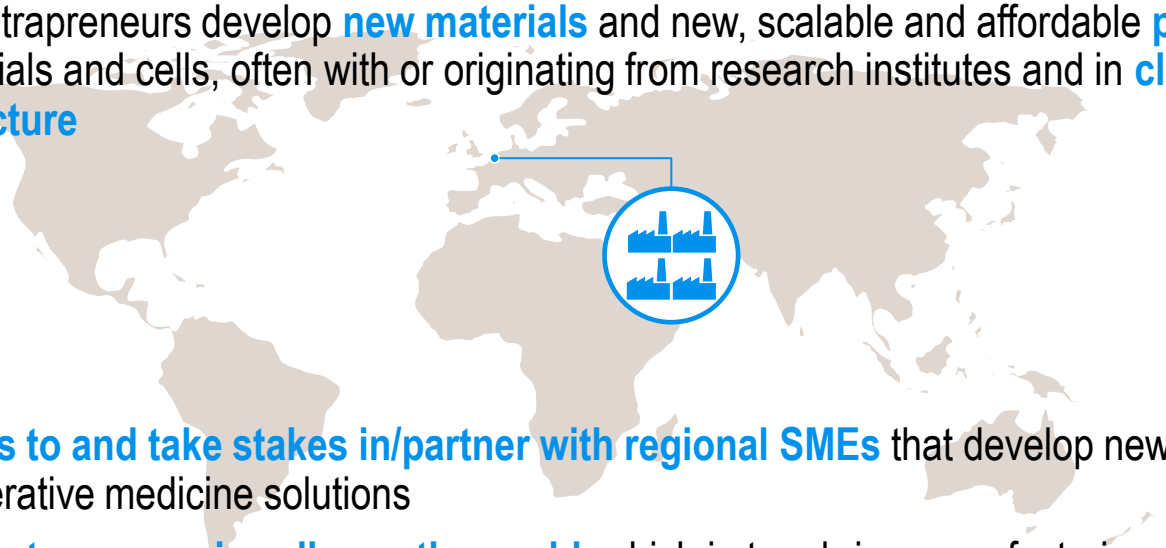
- > In 2012, Utrecht University and TU Eindhoven started a special two-year Master's track Regenerative Medicine and Technology (RMT)
- > In 2014, 12 students enrolled to become multidisciplinary researchers at the intersection of biomedical science, technology and clinical applications
- > The MSc track combines the expertise of both universities and allows the students to use the state-of-the-art laboratories of both universities



Universiteit Utrecht

Innovative manufacturers in the south of the Netherlands will form one of the pillars of the ecosystem, creating business and jobs

The world's factory

- > Large and small contract **manufacturing companies** for materials, cells and medical solutions thrive in the south of the Netherlands
 - > Entrepreneurs and intrapreneurs develop **new materials** and new, scalable and affordable **production processes** for materials and cells, often with or originating from research institutes and in **close proximity to clinical infrastructure**
- 
- > They deliver **services to and take stakes in/partner with regional SMEs** that develop new biomedical materials and regenerative medicine solutions
 - > They deliver **services to companies all over the world**, which in turn bring manufacturing questions and associated business to the south of the Netherlands
 - > They provide a **stable platform of jobs and business** in the biomedical materials and regenerative medicine ecosystem in the south of the Netherlands

These manufacturers will supply the world with new materials and innovative production processes for materials, cells and devices

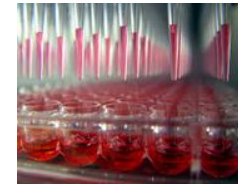
Examples of material and manufacturing innovation in the region

Additive manufacturing

New technologies for 3D printing – faster and with more types of materials and material combinations

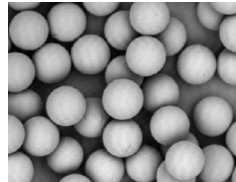


Innovative cell production platforms



Innovative bioreactor technologies and high-throughput cell culturing for large-scale, affordable industrial production of human cells

New emulsion technology for microencapsulation, forming droplets in microchannels that can then be solidified, revolutionizing controlled release of drugs



New formulation technologies



For example adhesives for medical devices inspired by gecko-type nanostructures, with the chemical approach to underwater adhesion used by mussels

New materials with exceptional properties

A cluster of entrepreneurial, innovative high-tech tool suppliers in the south of the Netherlands will facilitate the ecosystem

High-tech tool suppliers



Cluster of **innovative companies** – often university spin-outs – that work together with institutes, clinics and other companies to develop and deploy new, **high-tech tools** that support biomedical material and regenerative medicine innovation and application

Imaging

New tools to image materials and material-cell interaction at the molecular level, stratify patients, guide biomedical materials application in real-time, and monitor results

High-throughput analysis

New tools for high-throughput screening of biomaterials to rapidly test the interaction between cells and many materials to find promising leads

Analytical tools

New tools for analyzing material and cell properties and composition

Biochemical synthesis

New chemical approaches that allow manipulation of cells for cell-based therapies in vitro and for the development of conventional chemical and biological therapeutics to stimulate endogenous cells regeneration in vivo.

Data handling/analysis

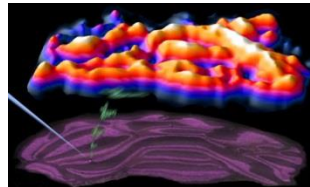
Databanks and techniques to manage large amounts of data that imaging technologies generate, with real-time processing

These entrepreneurs will "fuel" the ecosystem with innovative new tools

Examples of tooling innovation in the region

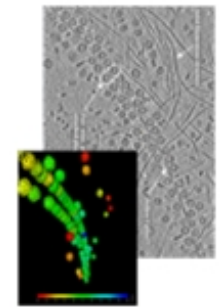
Imaging mass-spectrometry

State-of-the-art mass spectrometry-based molecular imaging approaches for molecular imaging of biological surfaces

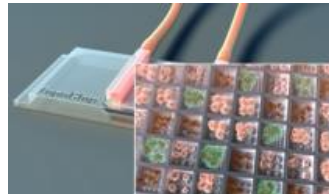


Electron microscopy

State-of-the-art cryo-electron microscopy to resolve the 3D structures of cells and materials at the nanometer scale

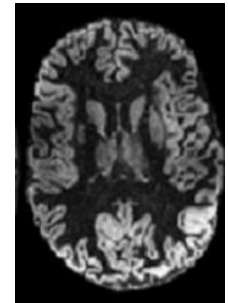


Microfluidic devices that make it possible to study many materials for their effect on cells in parallel, using fluorescence to identify promising interactions



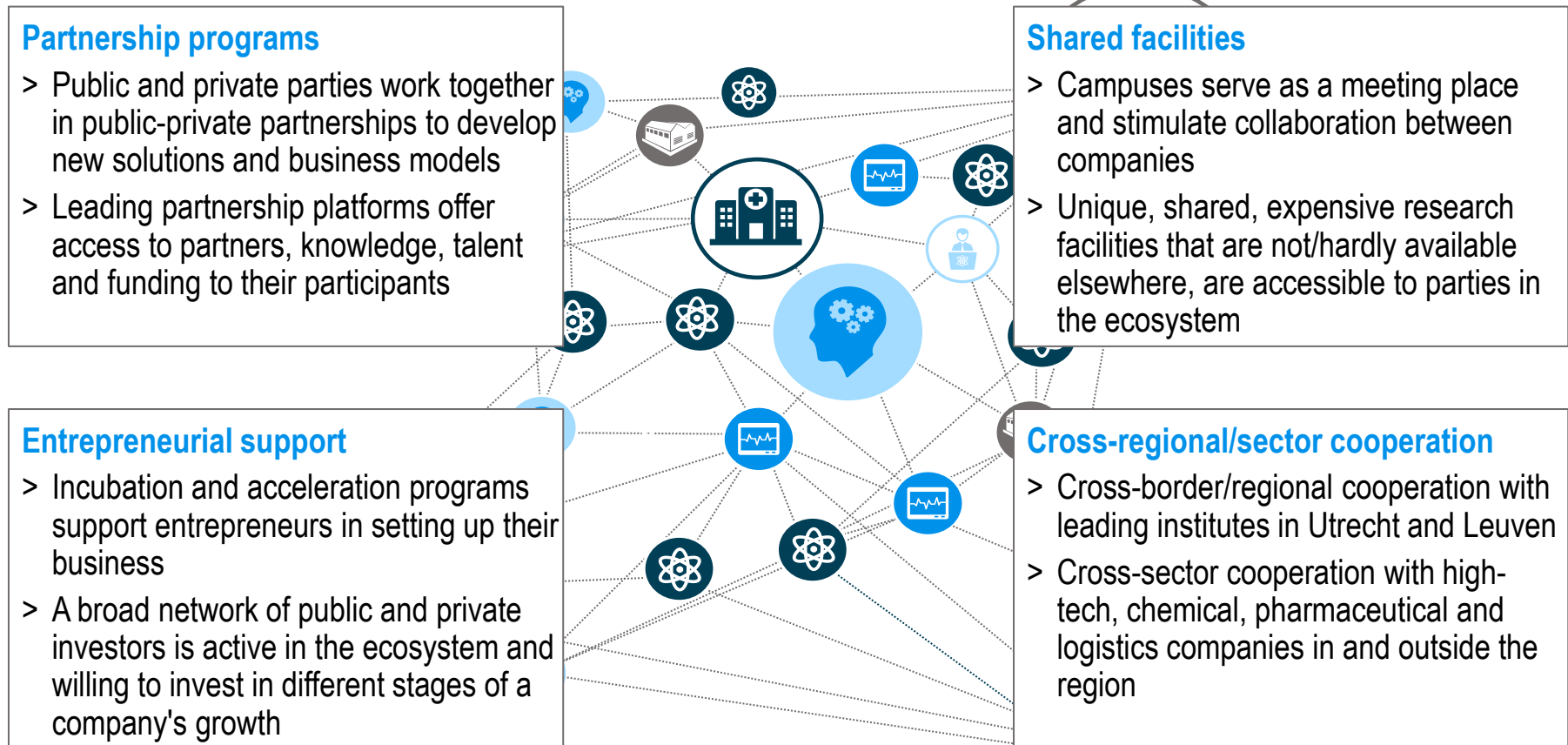
High-throughput material screening

A 9.4T Magnetom ultra-high field MRI – one of the world's strongest – allows looking into the body for health problems and results of health solutions in extreme resolution



Ultra-high field MRI

Shared facilities, partnering programs and entrepreneurial support will strengthen the connection between players in the ecosystem



These initiatives will enable participants in the ecosystem to develop new health solutions

Examples of regional developments

Partnership programs

In the InSciTe program, for example, TU/e, UM and Eyegle BV collaborate to develop an implant that is placed under the eyelid and comprises a unique biomaterial that can deliver a drug over a period of weeks to months



Shared facilities

At Brightlands, a brand new biomedical research and production facility has been realized by InSciTe, comprising 600 m² of equipped state-of-the-art open laboratories and class B (ISO 5) cleanroom suites



In 2015, the first startupbootcamp smart materials was launched at Brightlands, supporting e.g. a new company developing injectable hydrogels for the treatment of osteoarthritis



In 2014, public and private partners in the south of the Netherlands launched a EUR 40 m investment fund, participating e.g. in Cristal Therapeutics that develops nanomedicine based on polymeric technologies



Accelerators

Venture capital

The ecosystem will provide room for new business models needed to make biomedical materials and regenerative medicine successful

New business models

Personalized health products

Developing business models and supply chains for global scale-up and control of personalized products at acceptable costs

Many small volumes of materials

Developing business models for contract manufacturing for many different materials in very small volumes

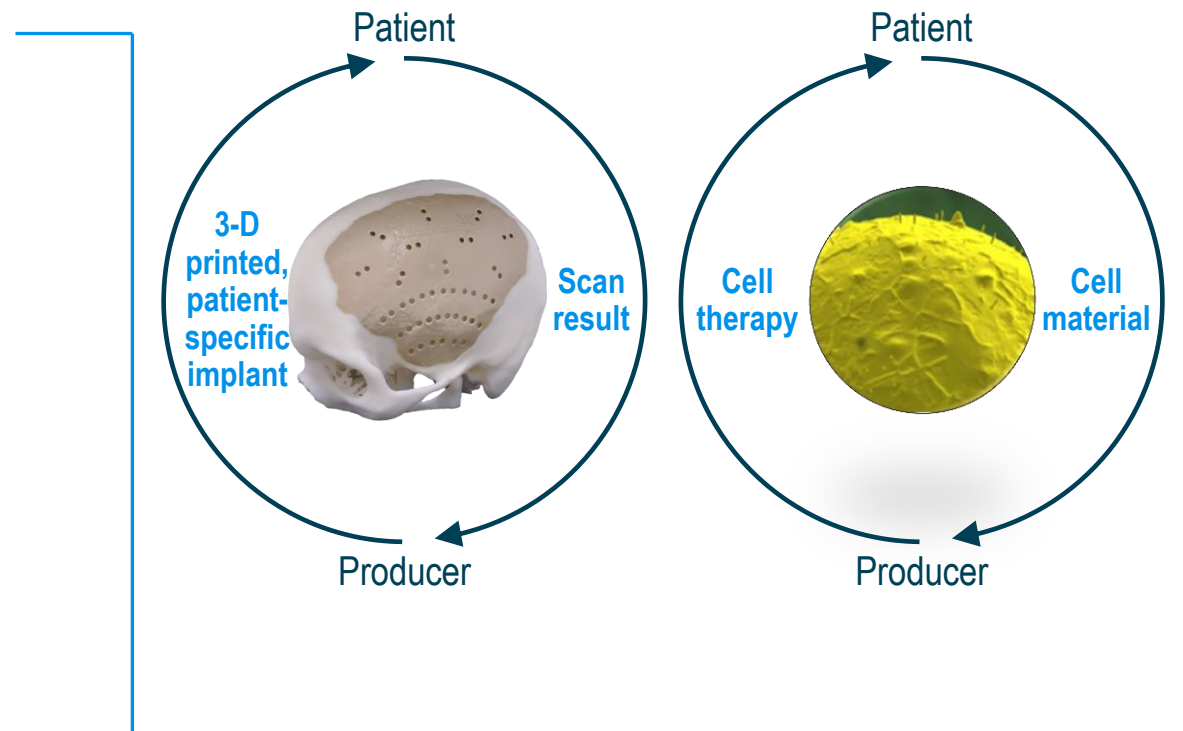
Prevention

Developing business models for preventive biomedical material products and regenerative medicine for healthy/at-risk individuals

Early availability

Developing business models for early availability of health products for patients, integrated in, or by speeding up, the development process

Examples from the region



This document describes the roadmap for the field of biomedical materials and regenerative medicine in the south of the Netherlands

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1	Introduction to the field of biomedical materials and regenerative medicine	p.14
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To achieve the ambition, all elements of the ecosystem will be strengthened around priority areas

Strategy of the field going forward

> Enhance all pillars of the ecosystem:

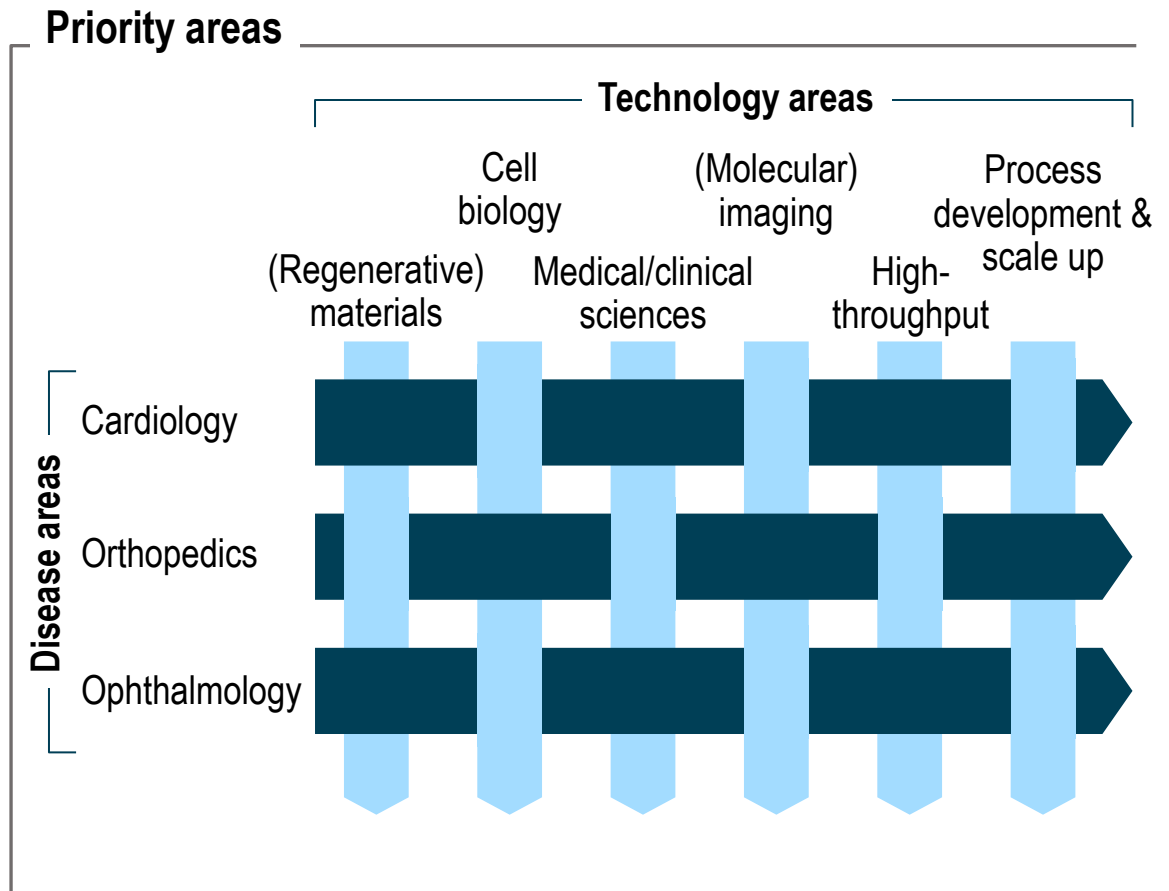
balance actions to build and strengthen the different pillars of the ecosystem in parallel, acknowledging that building an ecosystem requires continuous investments and a long-term perspective

> Build on strengths:

strengthen and connect existing initiatives/parties in the field in the south of the Netherlands, especially in disease and technology priority areas

> Connect cross-regionally:

align and cooperate with ecosystems/players outside the south of the Netherlands to fill knowledge/ infrastructure gaps, with special attention to Utrecht and Leuven



This strategy is translated into the "Brightlands RegMed" roadmap that consists of eight fields of action

	Innovation engine	RegMedAccelerator: Establish accelerator initiatives and facilities for biomedical materials and regenerative medicine companies		
	Testing grounds	RegMedClinic: Establish healthcare, clinical trial and pre-clinical infrastructure for translational research and adoption of regenerative medicine focusing on cardiology, orthopedics and ophthalmology ; including attraction of internationally-renowned doctors and the establishment of facilities that integrate molecular imaging in the clinic for inter-operative and pre-operative diagnostics and biobanking of stem cells		
	Integrative science	RegMedEducation: Integrate regenerative medicine in the curriculum of future surgeons and establish multidisciplinary educational programs to innovate at the intersection of fields		
	The world's factory	RegMedXB: Establish a world-renowned institute for excellent integrative science and top technology transfer together with neighboring regions		
	Tooling Industry	RegMedFacilities: Invest in unique facilities , especially for imaging, high throughput, (bio)chemical synthesis, process development, and pilot and scale up manufacturing facilities, and build service propositions around these facilities for companies, institutes and clinics	RegMedBranding: Make a strong claim on the subject of biomedical materials and regenerative medicine and brand it inside and outside the region	RegMedVentures: Set up a series of revolving funds to invest in entrepreneurs, in phase I/IIa trials and in unique facilities in the region
	Connection	RegMedPPP: Forge partnerships along the value chain to co-develop innovative solutions, including (large) material companies, research institutes, medical centers, (large) medical device/pharma companies and entrepreneurs		

Action: Establish RegMedXB to become a leading research institute for excellent integrative science and top technology transfer

RegMedXB

Rationale

- > The region has a **strong scientific basis** in biomedical materials and regenerative medicine with the UM/MUMC+ and TU/e to build upon
- > The south of the Netherlands is flanked by **other regions with complementary strengths**
- > Integrative science in biomedical materials and regenerative medicine is the basis of new health solutions – the **best science creates the most impact** for patients and the economy
- > **Valorizing** scientific results and translating results into health solutions remains a **major challenge** in the field

Action

Set up **RegMedXB** (cross borders):

- > A **world-renowned research institute** in regenerative medicine that injects the ecosystem with new concepts for health solutions and is a magnet to scientists, talent, companies and entrepreneurs
- > The institute **bundles excellent, entrepreneurial scientists** in the Netherlands and Flanders, with the south of the Netherlands as one of the strongholds for research
- > The scientists build a **multidisciplinary** research program that **connects basic and translational research**, to the **highest level of scientific excellence**
- > The institute **invests in this research**, therewith also creating new positions for **talent and several leading, established researchers from abroad**
- > The institute bundles results and IP and establishes **dedicated technology transfer support** to biomedical materials and regenerative medicine
- > The technology transfer team consists of **professionals in the field** that **generate and invest** in promising **spin-out companies**, and make **license deals** with existing companies
- > Institute and scientists are evaluated on **scientific and valorization results**, creating an atmosphere where **valorization is as valued as publications**

Action: Lay the foundation for a clinic in biomedical materials and regenerative medicine, integrated with molecular imaging

RegMedClinic

Rationale

- > With the MUMC+, the region hosts a **strong clinical (research) infrastructure**
- > Biomedical materials and regenerative medicine connects well to **focal areas of MUMC+**, especially cardiology, motion and eye diseases
- > The **regulatory environment is complicated** for regenerative medicine and few applications have yet been realized in clinics
- > Picking the **right therapy for the right patient and following/proving the results** of regenerative medicine is a major challenge

Action

Take first steps towards a regenerative medicine clinic:

- > Attract **world-renowned doctors** in regenerative medicine by financing temporary positions (~1 month) in the MUMC+ in cardiology, orthopedics and ophthalmology
- > Establish a fund to **co-finance phase I/IIa trials** for regenerative medicine at the MUMC+ (see also RegMedVentures)
- > Establish **biobanking facilities** and associated services
- > Involve **insurers and regulators** in establishing the testing grounds
- > Establish a **molecular OR** at the MUMC+: a facility that integrates state-of-the-art **molecular imaging** techniques in the clinic for inter-operative and pre-operative diagnostics

Establish **research cooperation** between regenerative medicine and molecular imaging scientists

Action: Invest in unique facilities, connect these with leading scientists and build a service proposition for companies/institutes/clinics

RegMedFacilities

Rationale

- > In manufacturing and tooling, new, **capital and knowledge intensive facilities** are required for regenerative medicine
- > The south of the Netherlands is building unique public-private facilities, e.g. at Brightlands industrial **3D-printing**, **GMP**, **clean room**, **imaging mass spectrometry** and **nanoscopy** facilities
- > When accessible to companies, entrepreneurs, researchers and clinics as a service proposition, such facilities form a **unique proposition** of the ecosystem in the south of the Netherlands

Action

Realize a **facilities fund/commitment** to co-invest in and establish facilities:

- > That are relevant for biomedical materials and regenerative medicine and are **unique/competitive on a European scale**, especially in the areas of imaging, high throughput, (bio)chemical synthesis, process development, and pilot and scale up of manufacturing facilities
- > That are **too sophisticated/expensive for many companies/institutes to build for themselves**
- > That **connect to knowledge from people/organizations in the region**, or the required knowledge to build and operate the facility is acquired
- > That offer a **service proposition** to companies/institutes to make them accessible
- > That are **flexibly designed** such that they can also serve as **research infrastructures** to improve the tool/factory

Action: Forge partnerships along the value chain to co-develop innovative solutions

RegMedPPP

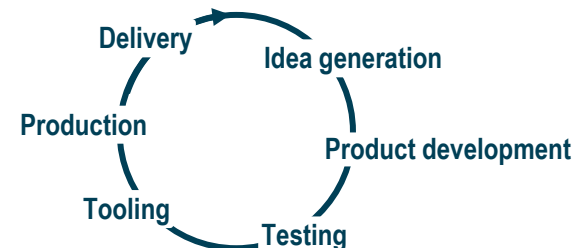
Rationale

- > The region has a **strong base** in (large) materials companies, universities and a UMC, but has a limited medical device/pharma industry – all are needed to develop, produce and deliver biomedical material products and regenerative medicine
- > Large materials companies typically sell their products in high quantities, while for biomedical applications often **low quantities of materials** are needed
- > With **Chemelot InSciTe**, the south of the Netherlands hosts a **platform** to support the forging of public-private partnerships

Action

Forge new **partnerships along the value chain**:

- > Bring together **universities, medical centers, materials companies, tooling companies, medical device/pharma companies and entrepreneurs** to pool competencies and resources in developing, manufacturing and delivering biomedical material products and regenerative medicine
- > Develop partnership **models for all to benefit** from, including stimulating materials companies to forward-integrate into co-developing a health application instead of just being a supplier of low quantities of materials, to achieve a viable business proposition
- > Involve relevant parties **outside the region**, including connecting to large medical device/pharma companies to integrate product development expertise and act as gateways to international markets



Action: Establish accelerator initiatives and facilities for biomedical materials and regenerative medicine companies

RegMedAccelerator

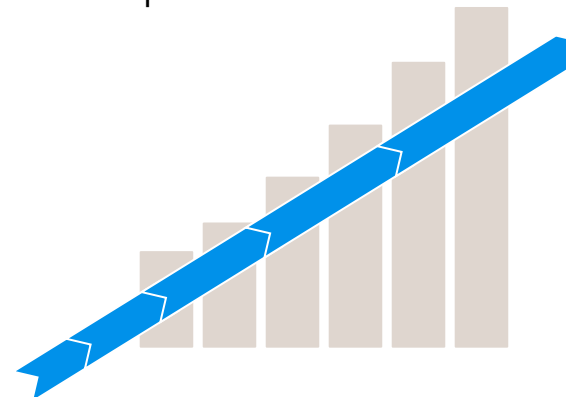
Rationale

- > A **growing and promising company base** has been created/is establishing itself in the region
- > For start-ups the **first steps of company development are challenging**, and can be sped up by accelerator initiatives
- > Startupbootcamp has performed a **smart materials accelerator** initiative in the south of the Netherlands that has generated much interest from entrepreneurs in the biomedical materials and regenerative medicine field

Action

Establish **accelerator initiatives and facilities** for biomedical materials and regenerative medicine companies:

- > **Build** a physical accelerator (building) close to the UM/MUMC+ for regenerative medicine companies
- > **Attract** promising accelerator programs and other entrepreneurial support initiatives to the region
- > **Support** such initiatives to create focus on biomedical materials and regenerative medicine entrepreneurs



Action: Integrate regenerative medicine in the curriculum of future surgeons and establish multidisciplinary educational programs

RegMedEducation

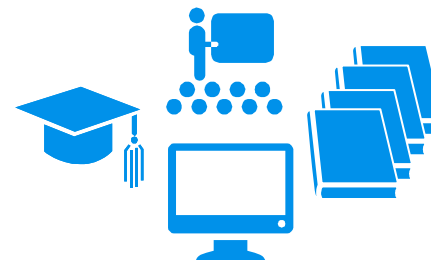
Rationale

- > Biomedical materials and regenerative medicine innovation requires **integration of traditional disciplines**
- > Application of regenerative medicine in healthcare requires **innovative and informed healthcare providers** to co-develop and adopt the solutions
- > TU/e and Utrecht University/UMCU have established a **multidisciplinary MSc** in regenerative medicine to prepare talent for this multidisciplinary field

Action

Educate the next generation of talent for regenerative medicine:

- > Integrate regenerative medicine in the **curriculum of future healthcare professionals** at the MUMC+
- > Connect the entire region to the **MSc program** Regenerative Medicine and Technology from the TU/e and Utrecht University
- > Develop **post graduate courses and training** to attract professionals from all over the world and teach them about the latest developments in regenerative medicine
- > Develop a **Massive Open Online Course** to teach people everywhere about biomedical materials and regenerative medicine, and showcase the strengths and opportunities in the south of the Netherlands
- > Set up a **marketplace for internships** at companies in the south of the Netherlands



Action: Set up a series of revolving funds to invest in the region

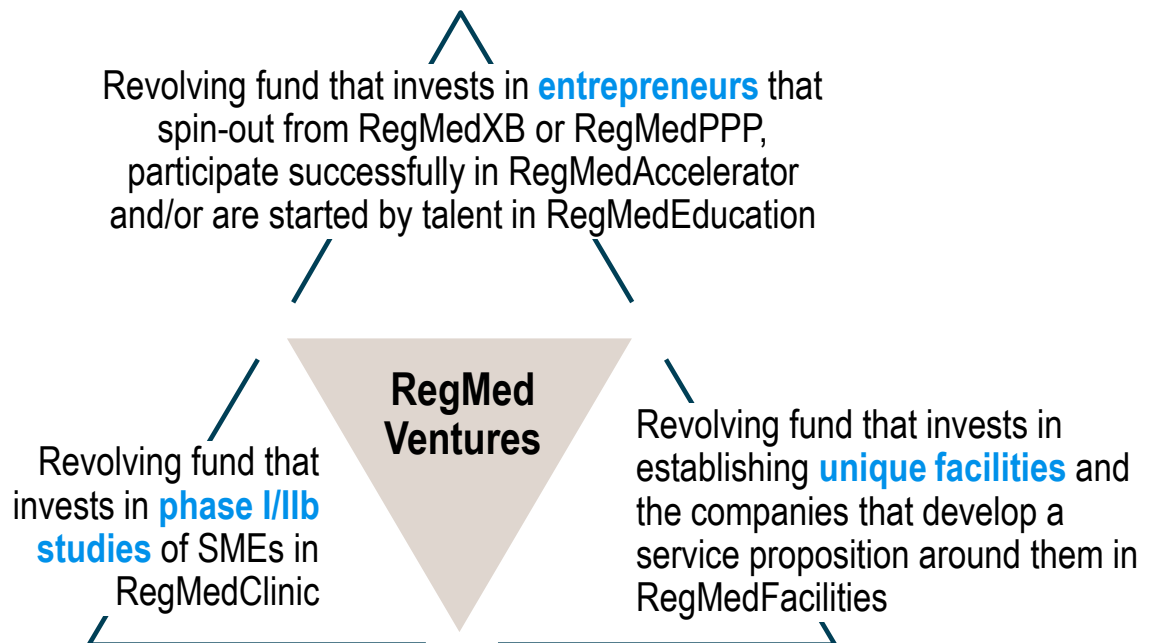
RegMedVentures

Rationale

- > Biomedical materials and regenerative medicine is a **capital-intensive** field, where investments are done years before products reach the healthcare market
- > **Access to capital** is important for creating and attracting companies, and have them flourish
- > **Chemelot ventures** recently launched a new public-private fund to invest in entrepreneurs, and several other public and private funds are present in the region – yet a sizeable investment community is lacking

Action

Set up a series of **revolving funds** to invest in the region, connected to other RegMed initiatives



Action: Make a strong claim on the subject and market it inside and outside the region

RegMedBranding

Rationale

- > The south of the Netherlands has **many strengths** in the field of biomedical materials and regenerative medicine, and **many parties** are already present

Action



- > **Claim** the subject – always and everywhere possible
- > **Measure and share successes** with the public – inside and outside the region
- > **Design and open showcase labs** for the public – design open architectures for all new facilities
- > **Start a marketing campaign** about the sector in the south of the Netherlands, including a digital platform for discussions and sharing information

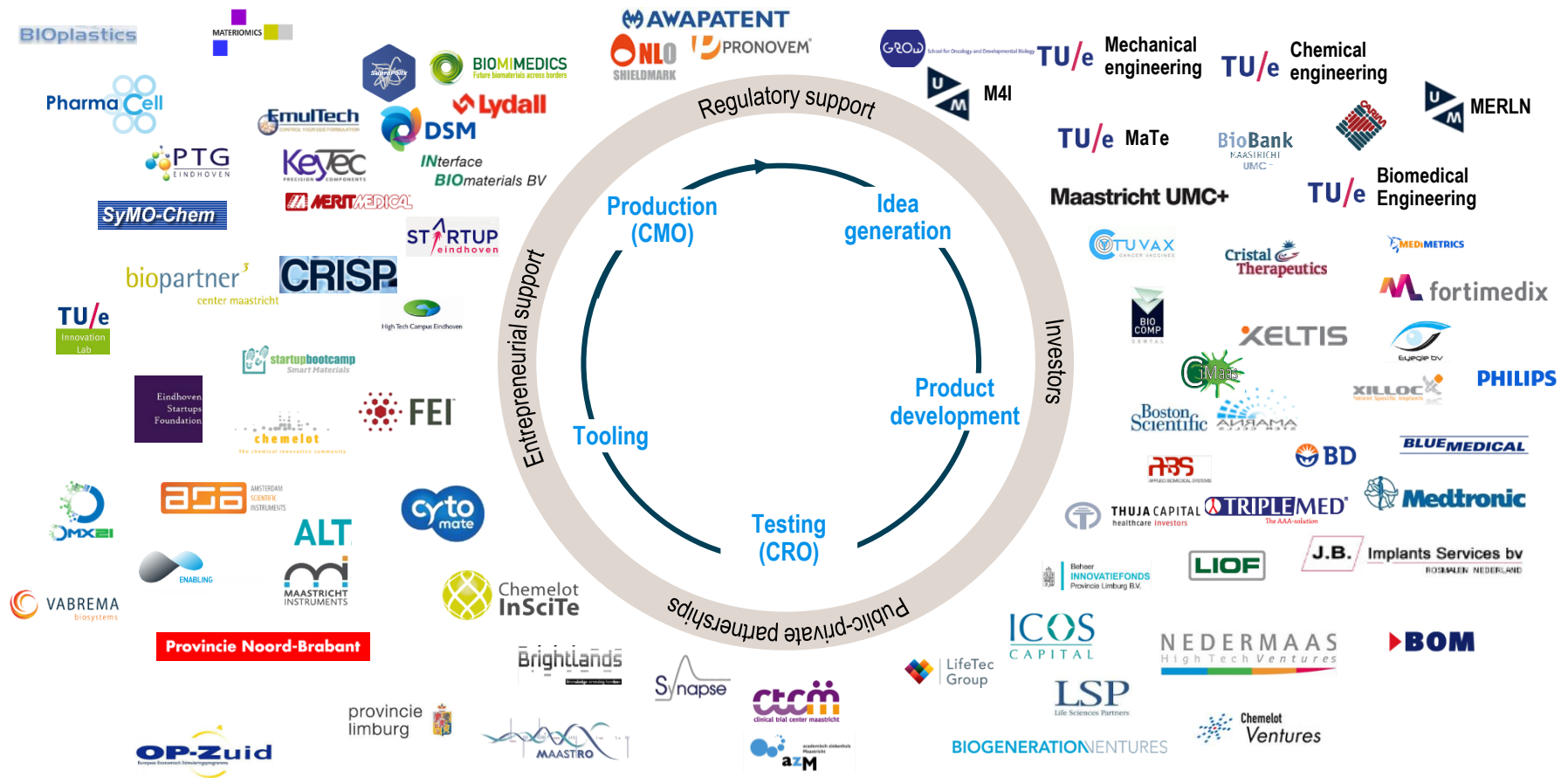
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The south of the Netherlands already has the capacity to form the ecosystem

Organizations present in the south of the Netherlands



The biomedical materials and regenerative medicine field in the south of the Netherlands has many public and private strengths

Strengths

A cademic excellence	<ul style="list-style-type: none">> Combining scientific disciplines to engineer biomedical material innovations> Promising applications in cardiology and orthopedics> Presence of all scientific building blocks: materials, biology, medicine, tooling
B usiness cluster	<ul style="list-style-type: none">> Growing base of innovative biomedical materials companies in the region> Presence of leading companies in the field that create a stable business climate> Focus on cardiovascular and orthopedic solutions
C ooperative mindset	<ul style="list-style-type: none">> Unique infrastructure for public-private cooperation> Visionary government that participates in and stimulates cooperation
D aring mentality	<ul style="list-style-type: none">> Entrepreneurial mindset and activities of leading academics> Entrepreneurial support activities
E nvironment of opportunities	<ul style="list-style-type: none">> Presence of complementary sectors in terms of knowledge and attraction of talent> Part of a robust, larger cross-border biomedical materials cluster

The region hosts a technical university and a university medical center with activities in all disciplines of biomedical materials

Academic groups/departments

Material science

TU/e MaTe

TU/e Mechanical engineering

Tooling



Biology



Medicine & clinical



Processing

TU/e Chemical engineering

Integrative science



TU/e Biomedical Engineering

The TU/e and UM host leading groups that integrate disciplines into new biomedical materials and regenerative medicine concepts...



Orthopedic Biomechanics

Prof.dr. K. (Keita) Ito

The disciplines of engineering and biology are combined to expand the understanding of the biomechanical function of musculoskeletal tissues as well as their adaptive developmental and physiological nature in order to develop regenerative treatment strategies for bone, articular cartilage and the intervertebral disc

Soft Tissue Biomechanics & Tissue Engineering

Prof. dr. C.V.C. (Carlijn) Bouten, Prof.dr.ir. F.P.T. (Frank) Baaijens

Multi-disciplinary research on the biomechanics and mechanobiology of soft biological tissues and the engineering of living cardiovascular tissues

Cardiovascular Biomechanics

Prof.dr.ir. F. (Frans) van de Vosse

Research in the field of computational and experimental biomechanical analysis of the cardiovascular system with the aim to develop both computational models and medical devices



Maastricht University Maastricht UMC+

MERLN

Prof.dr. C.A. (Clemens) van Blitterswijk, Prof.dr. J. (Jan) de Boer, Prof.dr. P. (Pamela) Habibović

Developing novel technologies to advance the field of repair and regeneration of both tissues and functional organs by, among others, the development of “smart” biomaterials which can trigger intrinsic tissue repair mechanisms mediated by the patient’s own cells

CARIM – Physiology

Prof.dr. M.J. (Mark) Post

The department conducts cardiovascular research, focusing on six research themes, one of which is vascular regeneration

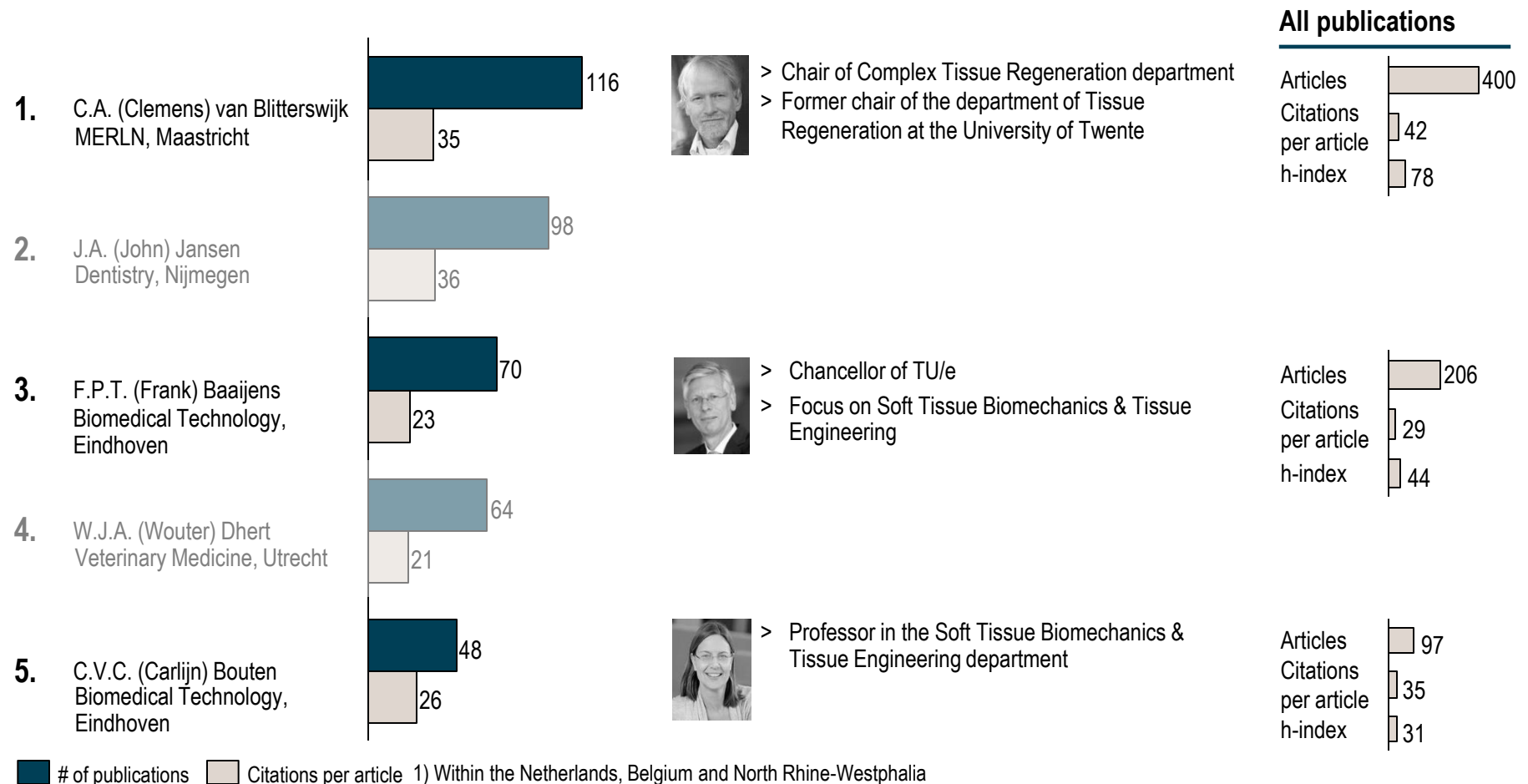
CARIM – Biomedical Engineering

Prof.dr. T. (Tammo) Delhaas

Physiologic description of biological processes, including the fundamental study of phenomena only occurring in living organisms and implementations of known physical principles in medical science

...including three of the top-5 researchers in regenerative materials in the Netherlands, Belgium and North Rhine-Westphalia

Ranking¹⁾ of scientists in # publications (2005-2015)



TU/e and UM have many strengths in cardiovascular and orthopedic biomedical materials and regenerative medicine

Main scientists per focus area

		MERLN Maastricht	CARIM Maastricht	Biomedical Engineering Eindhoven
Cardiology	Vessels		Prof. dr. M.J. (Mark) Post	Prof.dr.ir. F.N. (Frans) van de Vosse
	Valves			Prof.dr. C.V.C. (Carlijn) Bouten
Orthopedics	Bone	Prof.dr. J. (Jan) de Boer Prof.dr. P. (Pamela) Habibović		Dr.ir. B. (Bert) van Rietbergen
	Cartilage	Prof.dr. C.A. (Clemens) van Blitterswijk		Dr. C.C. (René) van Donkelaar
	Disk			Prof.dr. K. (Keita) Ito
	Muscle		Prof. dr. M.J. (Mark) Post	

MUMC+ provides an excellent basis for medical/clinical research

MUMC+

Facts & Figures (2014)

- > 715 beds
- > 7,170 employees
- > 27,207 hospitalizations
- > 433,489 outpatient consults
- > 26 operating rooms
- > 2,085 publications
- > 4,647 students

Excellent infrastructure for clinical research

- > Clinical trials are critical to test and enhance medical innovations, but at the same time are very challenging in terms of required infrastructure, access to patients and stringent regulation
- > With the MUMC+, the region hosts excellent facilities for clinical research – in 2014, 128 clinical trials were performed at the MUMC+ for which MUMC+ was the primary sponsor
- > With the Clinical Trial Center Maastricht (CTCM), the knowledge to organize, design and control clinical trials is at hand

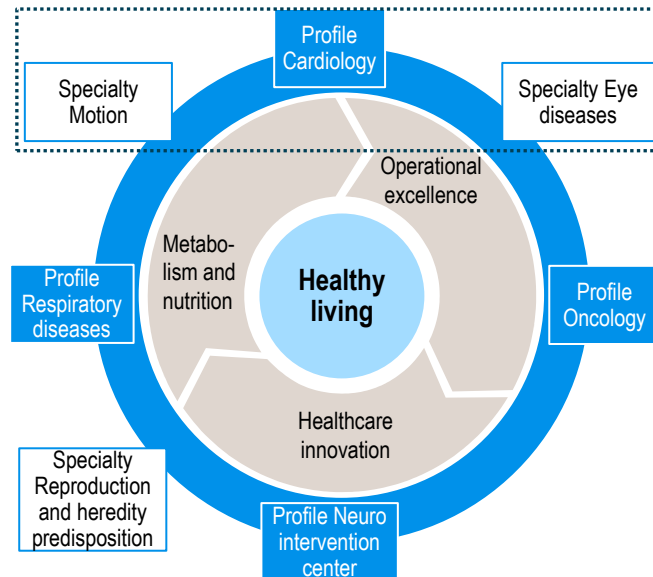


Internationally recognized

- > **Ranked #6** in the 2015 *Times Higher Education* 100 under 50 Rankings, the ranking of the **top 100 universities under 50 years old**
- > **Ranked #44** in the 2015-2016 *Times Higher Education* World University Rankings in **clinical, preclinical and health subjects**

Biomedical materials and regenerative medicine is at the heart of several of the focal areas of the MUMC+

Focal areas of the MUMC+



Cardiology

- > CARIM, School for Cardiovascular Diseases, leads European universities in translational cardiovascular research
- > The Maastricht Study tracks 10,000 people aged 40 to 75 years for the causes and consequences of chronic diseases, including cardiovascular diseases

University ranking¹⁾ in specialization

Maastricht University	9.2%
Leiden University	6.4%
University of Amsterdam	5.6%
University of Groningen	5.3%
University of Duisburg-Essen	5.1%

Orthopedics

- > Research of the Laboratory of Experimental Orthopedics focuses on understanding cartilage development, how it remains healthy or degenerates
- > Part of the Orthopedics department is the "Trialbureau", specialized in conducting clinical trials on the effects of medication on orthopedic diseases

University ranking¹⁾ in specialization

University of Munster	1.8%
VU Amsterdam	1.5%
University of Groningen	1.1%
University of Cologne	1.1%
Maastricht University	1.1%

Ophthalmology

- > The University Clinic for Ophthalmology performs excellent clinical research in e.g. glaucoma, refractive (cataract) surgery, corneal transplants and early detection/prevention of macular degeneration
- > It is a partner in the Maastricht Study and InSciTe

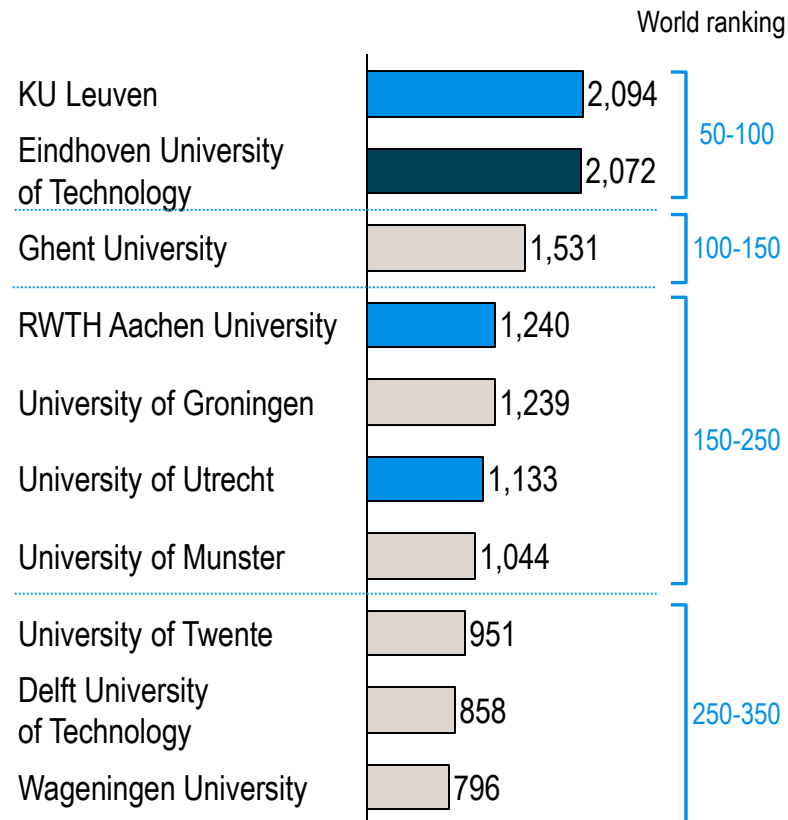
University ranking¹⁾ in specialization

University of Cologne	1.7%
University of Bonn	1.3%
Maastricht University	1.2%
University of Duisburg-Essen	1.0%
University of Münster	0.8%

1) Top-5 within the Netherlands, Belgium and North Rhine-Westphalia in terms of number of publications as % of total articles per institute between 2005 and 2015

TU Eindhoven has a strong base in material science, with a leading position in the area of polymers

Ranking of universities in polymer science¹⁾



Material research groups at the TU/e

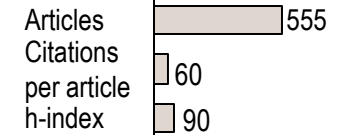
Meijer Research Group – Complex molecular systems

Prof.dr. E.W. (Bert) Meijer

The group focuses on supramolecular systems and how individual molecules can influence the properties of the assembly of multi-component systems



Prof.dr. E.W. Meijer is an internationally recognized Spinoza laureate who is among the most cited scientists in the Netherlands



Mechanics of Materials – Mechanical Engineering

Prof.dr. V.S. (Vikram) Deshpande, Prof.dr.ir. M.G.D. (Marc) Geers

The research activities concentrate on the fundamental understanding of various macroscopic problems in materials processing and forming

Polymer Technology – Mechanical Engineering

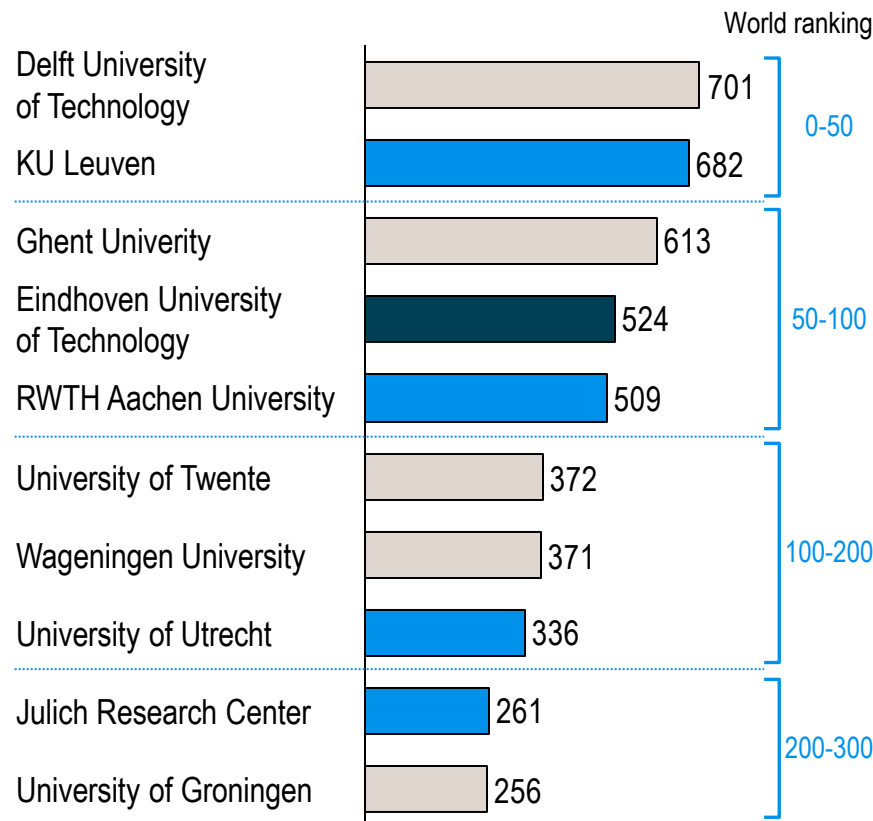
Prof.dr.ir. P.D. (Patrick) Anderson

The research is aimed at bridging the gap between science and technology in the area of polymer processing and design, through the use of experimental and computational tools

1) Universities in the Netherlands, Belgium and North Rhine-Westphalia are explicitly ranked; ranking in terms of number of publications in polymer science (2005-2015)

TU Eindhoven has a strong base in processing technology

Ranking¹⁾ of universities in processing technology



Department of Chemical Engineering at the TU/e

The research within the Chemical and Process Technology cluster covers a broad spectrum in the field of the chemical engineering sciences. The major research areas in this cluster are reactor and separation technology, process intensification and molecular heterogeneous catalysis. Combining these research areas often leads to novel or improved reactor, separation and process technologies and concepts

1) Universities in the Netherlands, Belgium and North Rhine-Westphalia are explicitly ranked; ranking in terms of number of publications in processing technology (2005-2015)

Maastricht is building a unique molecular imaging infrastructure and is making its facilities commercially available

Imaging groups in Maastricht

Nanoscopy

The M4I Division of Nanoscopy aims to gain greater insight into the **3D form of cell proteins**, thus paving the way for the development of more effective treatments

Chair: Prof.dr. P.J. (Peter) Peters



Articles	121
Citations per article	113
h-index	54

Imaging Mass Spectrometry

The M4I Division of Imaging Mass Spectrometry is a world leader in high resolution **molecular imaging of biological surfaces**. It targets the development and application of mass spectrometry-based molecular imaging approaches

Chair: Prof.dr. R.M.A. (Ron) Heeren



Articles	170
Citations per article	21
h-index	33

Brains Unlimited

Within Brains Unlimited, researchers from the Faculty of Psychology and Neuroscience perform **cognitive brain research** for the development of new analysis methods for MRI data, using **whole-body MRI scanners**, including the "9.4T" system, one of five in the world

Enabling Technologies

Enabling Technologies is a **joint venture** between DSM Resolve, the Maastricht University/ MUMC+ and the Province of Limburg. Enabling Technologies **provides access to high-end analytical tools** by hiring out these facilities in the open Joint Facility Centre, a unique R&D platform. The goal is to **maximize the use of facilities** and **stimulate innovation** by providing access to analytical tools for SMEs and start-ups.

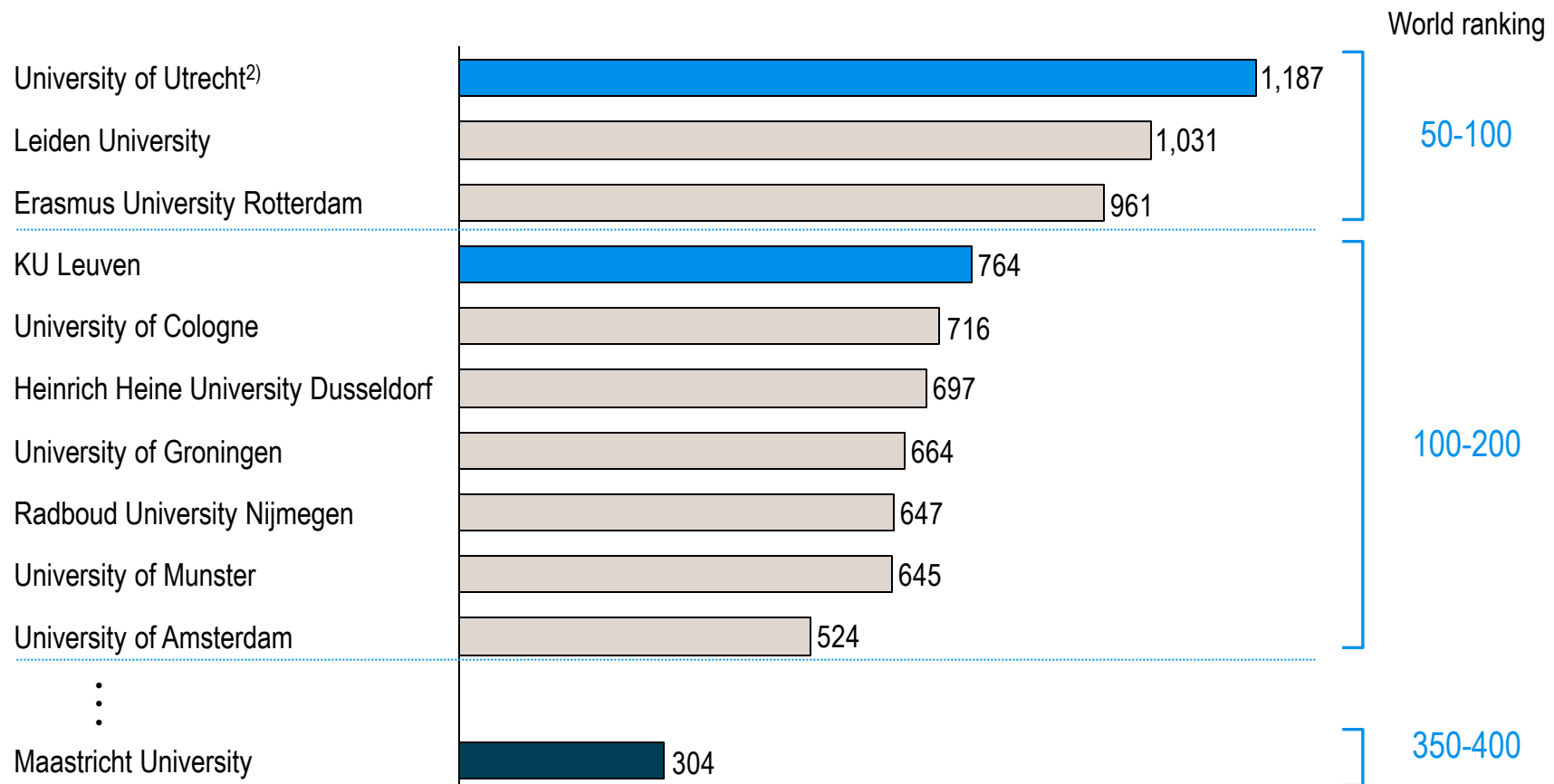
Maastricht MultiModal Molecular Imaging Institute (M4I)

M4I is a molecular imaging institute bringing together high-end, innovative imaging technologies. It is the **largest molecular imaging center in Europe**, and is embedded in the Faculty of Health, Medicine and Life Sciences



The south of the Netherlands has a limited footprint in the area of cell biology

World ranking¹⁾ in terms of number of publications in biology (2005-2015)



1) Within the Netherlands, Belgium and North Rhine-Westphalia; 2) Including the Hubrecht Institute

TU/e together with Utrecht University hosts an MSc track Regenerative Medicine and Technology

MSc Regenerative Medicine and Technology

- > Joint program from TU/e and Utrecht University
- > Started in 2012
- > 12 students enrolled in the year 2014/2015
- > Two-year track, of which 70% are minor and major research projects

> Focus on collaborations among different disciplines

Examples of courses/electives in the MSc track

- > Introduction to regenerative medicine and technology
- > Introduction into stem cells
- > Biomaterials
- > Protein engineering
- > Molecular imaging
- > Bone mechanics
- > Cartilage mechanics
- > Entrepreneurship and innovation in life sciences & health seminar
- > Laboratory animal sciences
- > History of medicine

The biomedical materials and regenerative medicine field in the south of the Netherlands has many public and private strengths

Strengths

Academic excellence

- > Combining scientific disciplines to engineer biomedical material innovations
- > Promising applications in cardiology and orthopedics
- > Presence of all scientific building blocks: materials, biology, medicine, tooling

Business cluster

- > Growing base of innovative biomedical materials companies in the region
- > Presence of leading companies in the field that create a stable business climate
- > Focus on cardiovascular and orthopedic solutions

Cooperative mindset

- > Unique infrastructure for public-private cooperation
- > Visionary government that participates in and stimulates cooperation

Daring mentality

- > Entrepreneurial mindset and activities of leading academics
- > Entrepreneurial support activities

Environment of opportunities

- > Presence of complementary sectors in terms of knowledge and attraction of talent
- > Part of a robust, larger cross-border biomedical materials cluster

The south of the Netherlands already hosts many businesses in the biomedical materials field

Organizations present in the south of the Netherlands (examples)

Production



Product development



Businesses



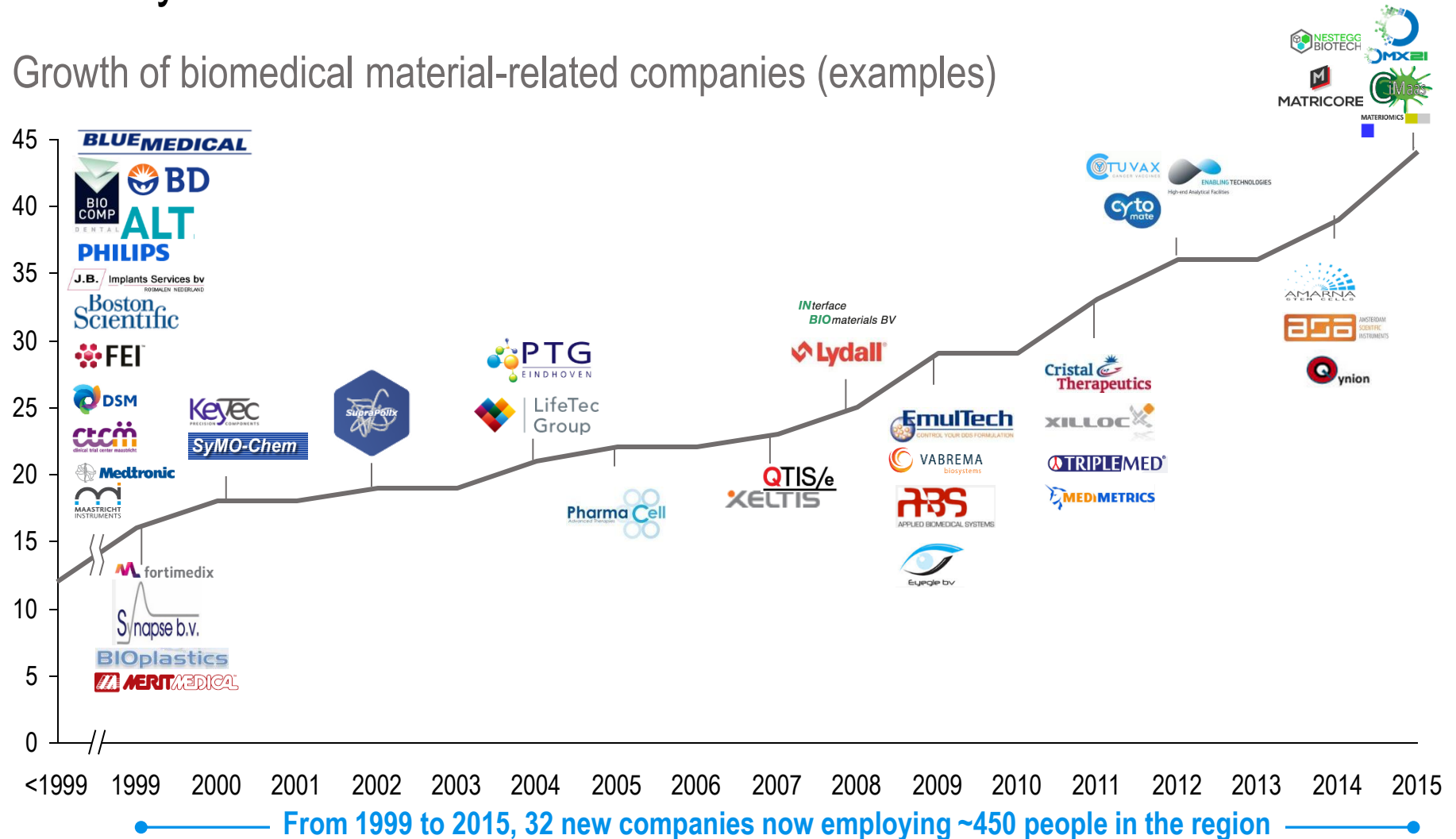
Testing



Tools

The business cluster in the south of the Netherlands has grown in recent years

Growth of biomedical material-related companies (examples)



Promising new companies emerge and grow in the region ...

Successful biomedical material spin-offs in the region (examples)



- > Located in Maastricht and Geleen
- > Established in 2005
- > Spin-off from Maastricht University
- > 70 employees
- > Leading contract manufacturing organization (CMO) for cellular therapies and regenerative medicine in Europe, supporting Phase I to Phase III clinical trials
- > Cell therapy CMO services include: transfer of technologies, QP release of products for the EU market, controlled temperature transportation and process development, including cell culture scale-up know-how and manufacturing of advanced therapeutic medicinal products



- > Located in Eindhoven
- > Established in 2004 (originally HemoLab)
- > Spin-off from TU/e
- > ~15 employees
- > CRO for performing compliance and efficacy studies of innovative healthcare products, interventions and therapies in the field of cardiology and orthopedics
- > Has a number of in-house developed technology platforms and facilities



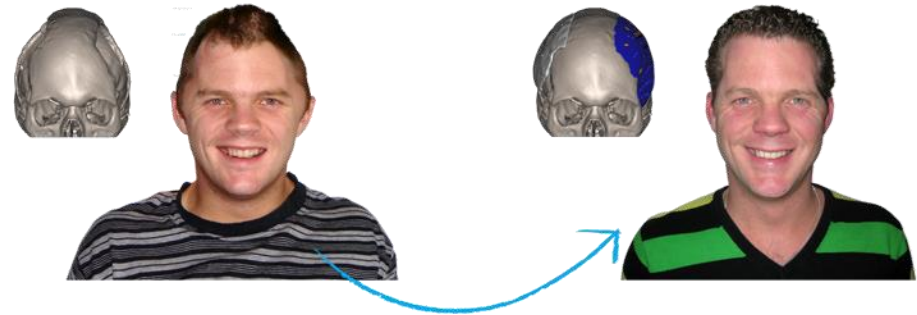
- > Located in Eindhoven (R&D and production) and Zurich (headquarters)
- > Established in 2007
- > Original technology from QTIS/e, a spin-off from TU Eindhoven, QTIS/e merged with Xeltis in 2012
- > ~15 employees
- > A medical device company dedicated to developing bio-absorbable synthetic heart valves and vessels, i.e. the matrices can be absorbed by the body as the new valves and vessels grow
- > Two first in-human studies have been completed successfully
- > Xeltis has been elected as one of the 15 most promising medtech companies in the world in 2015 by FierceMedicalDevices



- > Located in Geleen
- > Established in 2011
- > Spin-off from the MUMC+
- > ~10 employees
- > Provides 3D printed patient-specific implants to reconstruct parts of the human skeleton, for example, titanium jaw and skull implants
- > Offers 3D printing services in prototyping, production, consultancy and training

... and are already improving patients' lives

Story of a patient from Xilloc



August 2004

Marc, a healthy 21-year-old, got involved in a bicycle accident which caused traumatic brain injury. During his hospitalization, two parts of his skull were removed to give his brain space and prevent brain herniation and consequently death

November 2004

The neurosurgeons reimplanted the original bone parts removed during the first surgery

April 2006

One of the reimplanted bone parts failed and was completely resorbed leading to major deformations on the right side of his face and skull. The right side of his skull had to be reconstructed using bone cement

April 2008

The second bone part resorbed as well, leaving the left side of his face and skull deformed

April 2010

Marc received a patient-specific implant to correct the deformation. He can now live his life again as we all do

Large companies in the region with a stake in biomedical materials and regenerative medicine provide a stable business climate

Biomedical material-related large/leading companies in the region (examples)



- > Located in Geleen
- > ~6,000 employees in NL
- > DSM Medical is a medical device materials development and manufacturing company
- > DSM has created a wide variety of standard, high-quality biomedical materials and has partnered with medical device companies, large and small, to offer customized solutions that meet their individual needs and exact specifications in order to increase the performance of each medical device



- > Located in Maastricht
- > ~1,500 employees in NL
- > Multinational in medical technology with a diverse portfolio of medical applications, e.g. pacemakers, stents, monitoring systems
- > The Bakken Research Center in Maastricht – clinical research and innovation in cardiac rhythm & heart failure and cardiovascular trials
- > Distribution center and production facility in Heerlen and Kerkrade; R&D center in Eindhoven



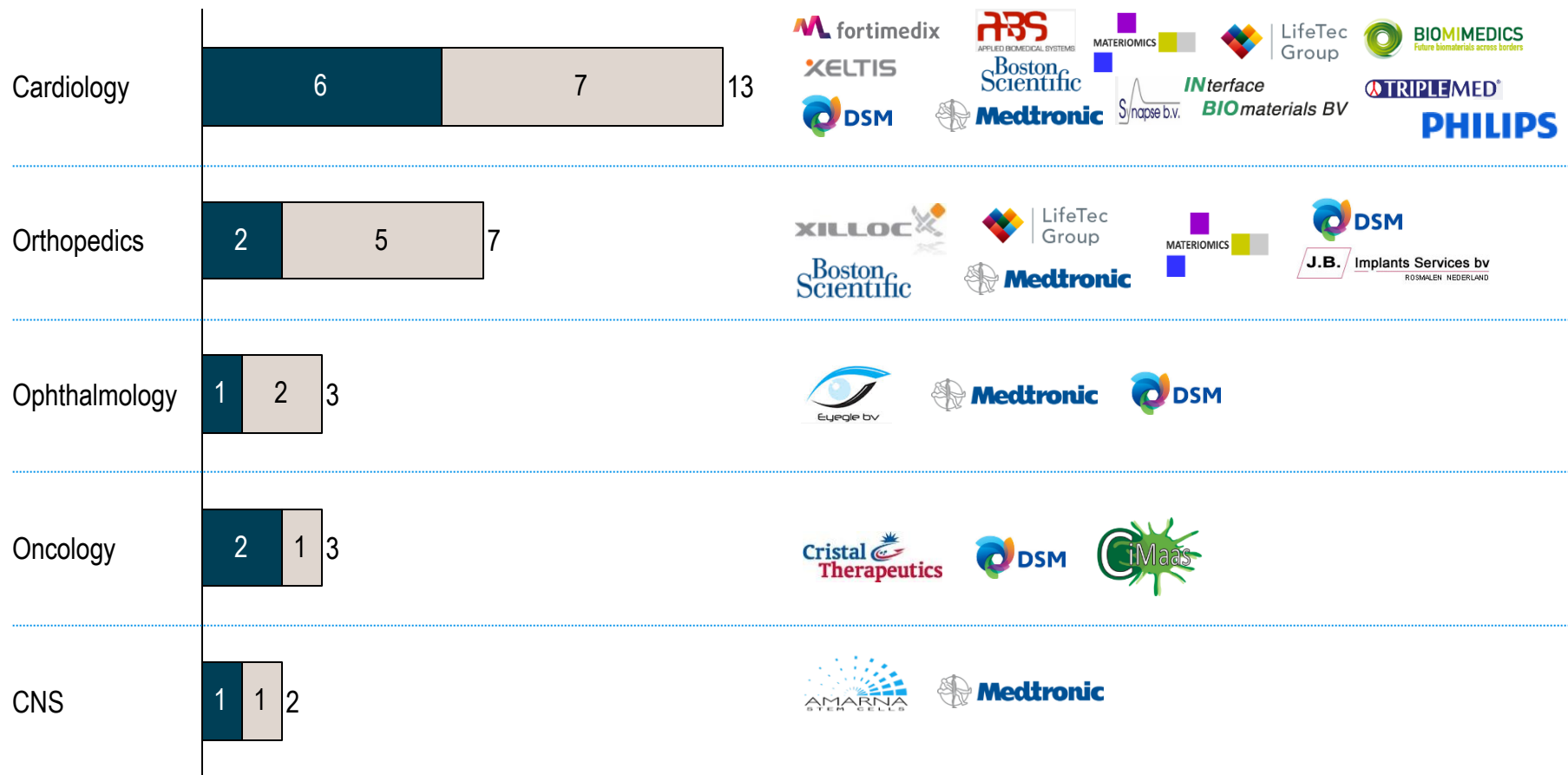
- > Located in Eindhoven
- > ~600 employees in NL in R&D and manufacturing
- > FEI designs, manufactures and supports a broad range of high-performance microscopy workflow solutions that provide images and answers at micro-, nano- and picometer scales



- > Located in Eindhoven
- > ~13,000 employees in NL
- > The healthcare division of Philips is a leading medical device company specializing in imaging for diagnosis and treatment, and mobile, distance and ICT technologies for healthcare and health management

Companies in the region focus on cardiology and orthopedics

Disease focus area¹⁾ (number of companies), not exhaustive



1) Multiple focus areas per company possible; excluding companies that are not disease-related

Focused
 Multiple disease areas

The biomedical materials and regenerative medicine field in the south of the Netherlands has many public and private strengths

Strengths

Academic excellence

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Business cluster

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Cooperative mindset

- > Unique infrastructure for public-private cooperation
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Daring mentality

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- > Entrepreneurial support activities

Environment of opportunities

- > Presence of complementary sectors in terms of knowledge and attraction of talent
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The government in the south of the Netherlands is committed to the field and proven an important investor

Innovation focus

Focus areas of the south of the Netherlands

- > With the **Smart Specialization Strategy (RIS3)**, the economic development of the south of the Netherlands has been mapped out and put into perspective
- > Seven focus areas for the region have been defined: **high tech systems & materials (HTSM), Chemistry, Agro & Food, Life Sciences & Health, Logistics, Bio-based and Maintenance**
- > **Biomedical materials and regenerative medicine** are an integral part of the focus area Life Sciences & Health, with important cross-links to High Tech Systems & Materials and Chemistry

Recent investment examples

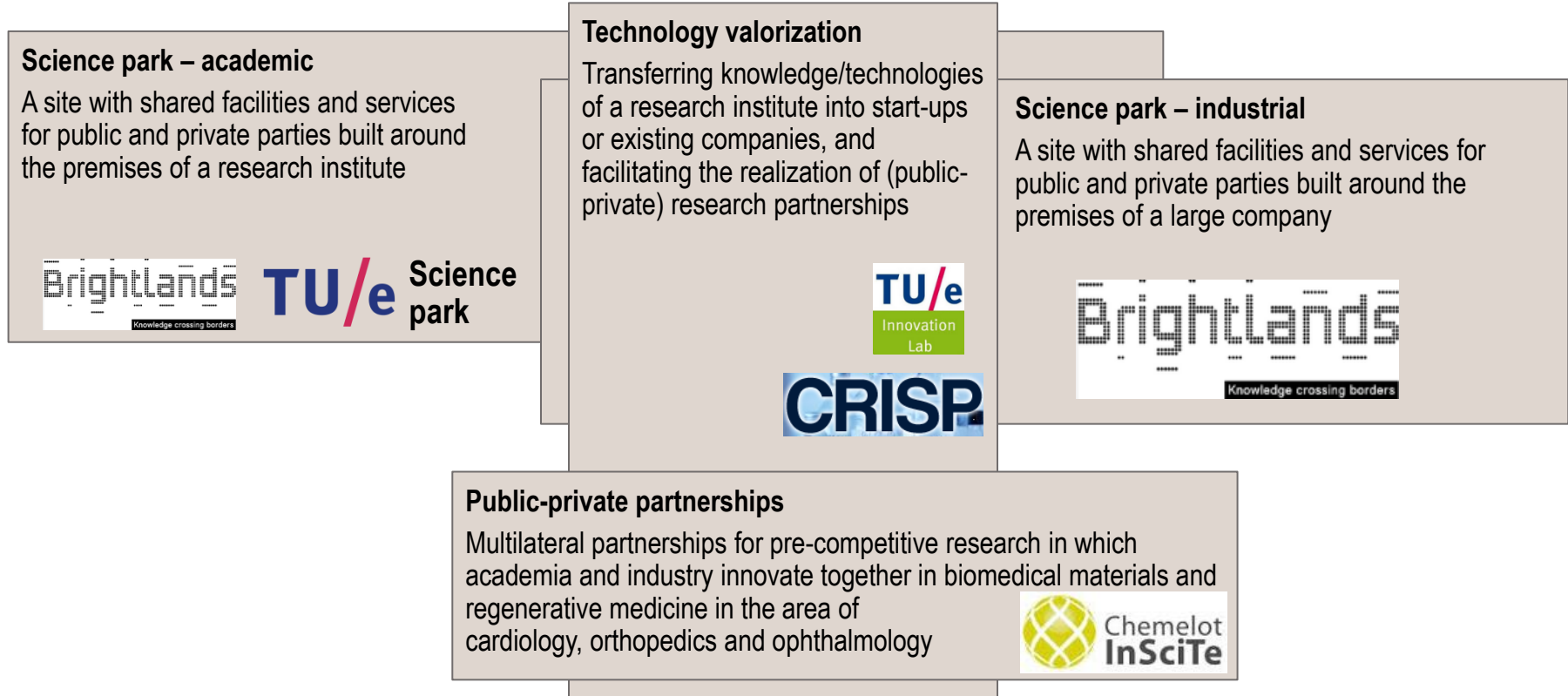
- > EUR 125 m of the Province of North Brabant in the **Brabant Innovation Fund** for innovative SMEs active in one of the top sectors in North Brabant
- > EUR 50 m of the Province of Limburg in **Chemelot InSciTe**, for R&D activities and research/production facilities in the area of biomedical materials and bio-based materials
- > EUR 15 m of the Province of Limburg in the **Brightlands Materials Center**, for research and development of (polymer) materials
- > EUR 14 m of the Province of Limburg for establishing **MERLN and M4I** at the Brightlands Maastricht Health Campus

Campuses and public-private partnerships foster cooperation

Infrastructure for collaboration

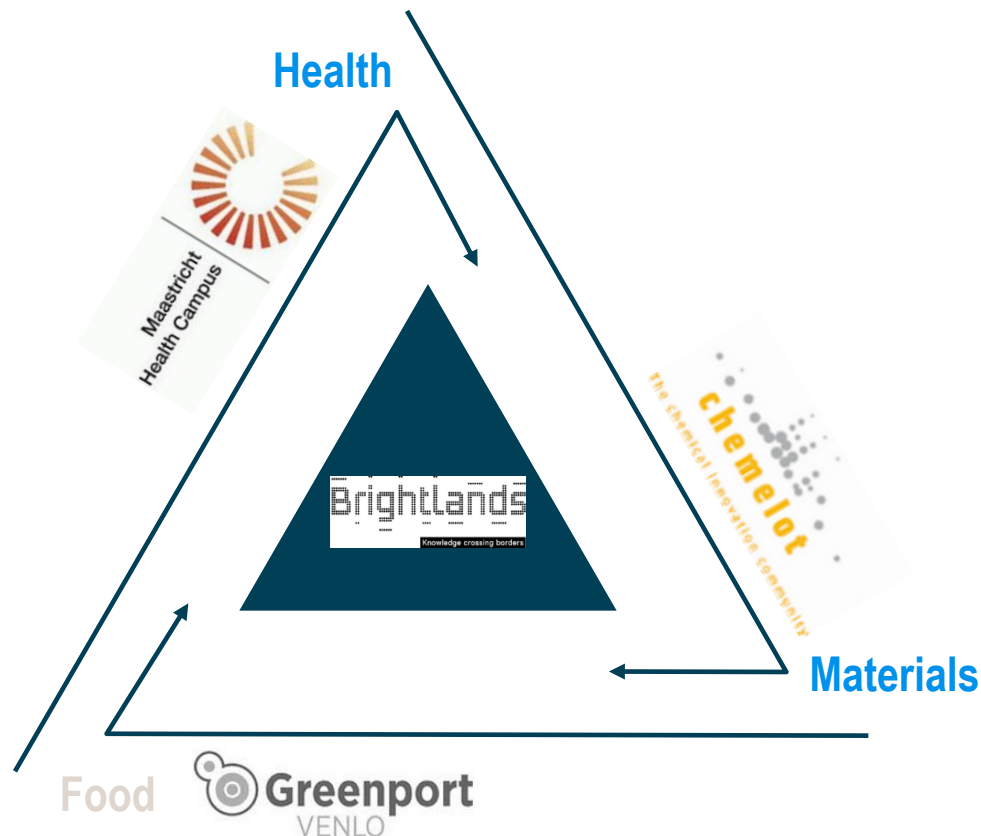
Research

Development & delivery



Brightlands is home to professionals, students and companies that work across and between the health and materials sector

Brightlands



Brightlands Maastricht Health Campus and Brightlands Chemelot Campus

~10,000 people work in the area

~6,500 people study there

~90 companies

~5 medical and healthcare-related spin-offs per year, on average

~110 nationalities

InSciTe offers a home to entrepreneurs, pioneering R&D, R&D facilities and a breeding ground for talent

InSciTe

Entrepreneurs

Home to entrepreneurs, helping them to start, settle and grow by creating an ecosystem in which entrepreneurship is facilitated for both large and small companies: from, for example, DSM through knowledge-intensive SMEs to start-up and spin-out companies



Research

Public-private research programs for biomedical materials to establish proof of concept in first patients in the areas of cardiology, orthopedics and ophthalmology



provincie limburg



Founding Fathers



Maastricht UMC+
Maastricht University

State of the art R&D facilities for the development and scale up of new biomedical materials and devices – 600 m² open R&D laboratories and class B cleanroom suites to allow a wide range of testing



A breeding ground for talent

includes the development of shared education and training programs for scientists and entrepreneurs – establishing the mindset and networks for open innovation

Facilities

Education

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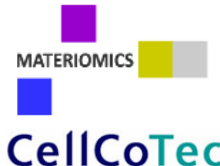


Daring mentality

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Environment of opportunities

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Entrepreneurial professors translate research into businesses

Professor	Company
 <p>Prof.dr.ir. F.P.T. (Frank) Baaijens Soft Tissue Biomechanics and Tissue Engineering, TU/e</p>	 <ul style="list-style-type: none"> > QTIS/e was acquired by Xeltis in 2014 > Xeltis is a medical device company developing fully bioabsorbable synthetic heart valves and vascular grafts intended to enable for the first time the spontaneous growth of natural, healthy valves and vessels. The products are synthetic matrices designed to harness the body's natural healing response from the inside
 <p>Prof.dr. E.W. (Bert) Meijer Biomedical Chemistry, TU/e</p>	 <ul style="list-style-type: none"> > SupraPolix develops innovative polymeric materials for applications ranging from adhesives and specialty coatings, to biomedical materials and cosmetics. SupraB™-materials deliver unique processing and rheological benefits together with tunable material performance
 <p>Prof.dr. C.A. (Clemens) van Blitterswijk Complex Tissue Regeneration, MERLN Working for private equity firm LSP</p>	 <ul style="list-style-type: none"> > Materiomics is a company specialized in improving the biological performance of the surface of a device. Materiomics provides research in order to optimize the functionality of medical devices, cell culture products and the biological properties of polymer-, metal-, or ceramic surfaces > CellCoTec is an orthopedic medical device company using cellular regeneration technology to provide a single-surgery solution for damaged articular cartilage in the knee
 <p>Prof.dr. R.M.A. (Ronald) Heeren Division of Imaging Mass Spectrometry, M4I</p>	 <ul style="list-style-type: none"> > Omics2Image (O2I) is a biotechnology start-up, founded in 2012. O2I brought a pixelated mass spectrometry detector, the IonPix camera, to the market in 2012. The detector is employable for a wide range of applications, including mass spectrometry, neutron imaging and electron microscopy

The region hosts opportunities from entrepreneurial support and access to public and private investors

Entrepreneurial support – selection

Investors – selection



Startupbootcamp supports entrepreneurs in getting their new biomedical materials companies up and running

Selection of start-ups from Startupbootcamp Smart Materials 2015¹⁾



Injectable hydrogels for the treatment of osteoarthritis, and in particular repair of focal cartilage defects in the knee



MATRICORE

Hybrid 3D scaffold manufacturing system, providing standardized and tested scaffolds to enable 3D tissue constructs

Medical Device Works
Organ Isolation Technologies

Instructive stents and grafts for damaged vessels that recruit the patient's own cells, and gradually transform into living vessels

Start-ups in the biomedical materials field in the south of the Netherlands

Technology to integrate all of the tasks associated with cell culturing while adding automated live cell imaging via a computer-controlled profile, which allows for more complex experiments while maintaining ease of reproducibility



1) Program is ongoing

Simplification of hip surgery with a perfect-fit 3D printed hip implant to preserve patients' bone and autonomy for life



Method for creating 3D printing materials in order to create better-than-industrial grade materials, for example, by incorporating biopolymers



The biomedical materials and regenerative medicine field in the south of the Netherlands has many public and private strengths

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Daring mentality

- > Entrepreneurial mindset and activities of leading academics
- > Entrepreneurial support activities

Environment of opportunities

- > Presence of complementary sectors in terms of knowledge and attraction of talent
- > Part of a robust, larger cross-border biomedical materials cluster

The south of the Netherlands hosts other clusters that are complementary in knowledge and attraction of talent

Complementary clusters

High-tech

- > The high-tech industry contributes to imaging technology and diagnostics, improving biomedical material testing, as well as material development
- > On the High Tech Campus in Eindhoven, more than 135 companies and ~10,000 people are working on the design and development of high-tech equipment



High Tech Campus Eindhoven



Chemistry

- > The chemical industry has expertise in materials science and characterization and processing of materials
- > Chemelot campus in Geleen hosts 63 chemical and material companies focusing on chemical engineering, advanced (bio) organic chemistry and (bio-based) performance materials



Pharma

- > The pharma industry has a strong knowledge of drug delivery, modeling, clinical development and disease understanding
- > Pivot Park is a campus facilitating open innovation in life sciences with a strong focus on drug development as a result from partnerships between small and large companies and research institutes

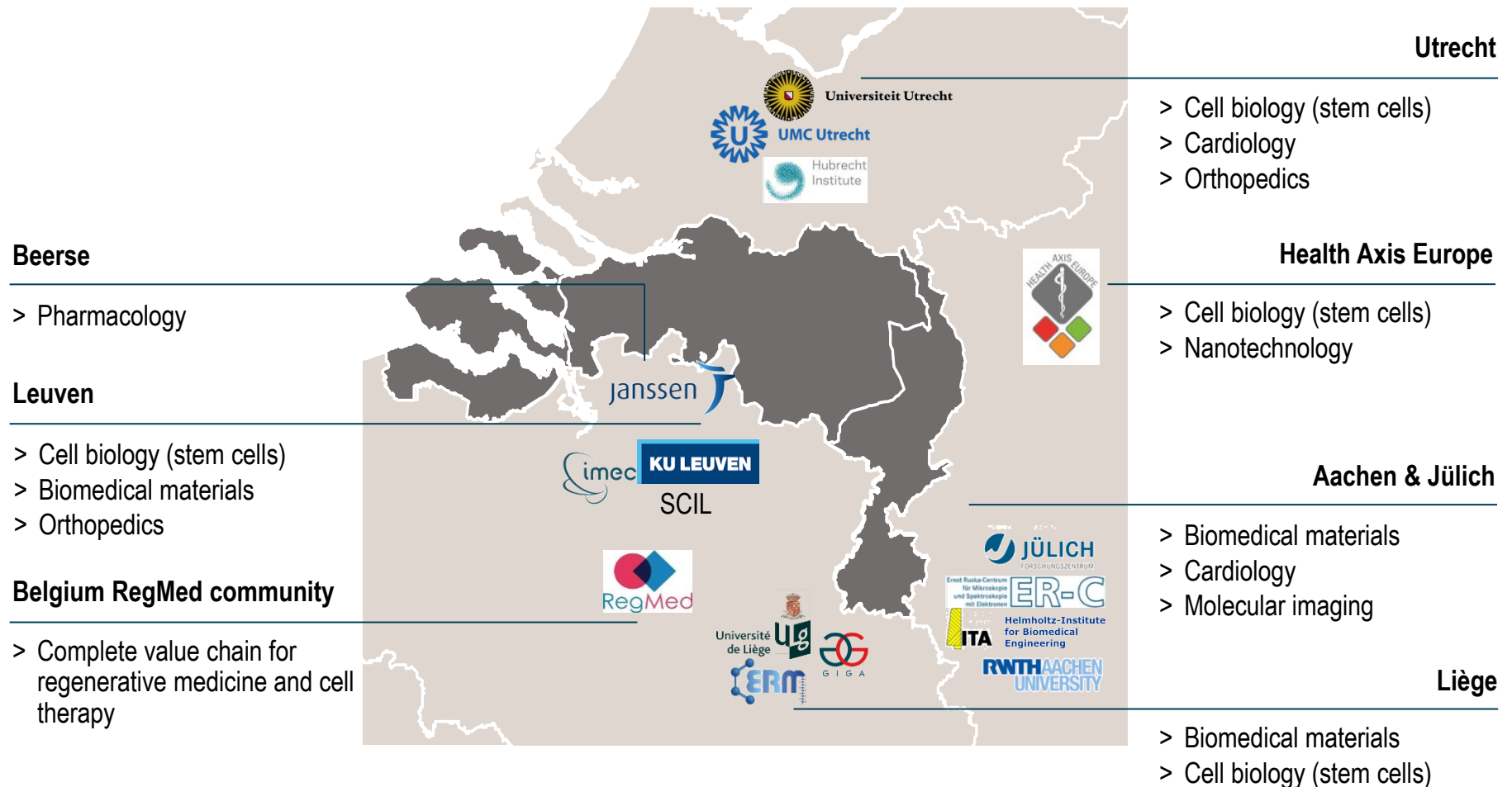


Logistics

- > The logistics industry is key in supply chain management – and an innovation partner in new models to get personalized therapies to patients
- > At the SMART Logistics Centre Venlo business, government and research institutes interact in order to further develop the north of Limburg into a top European region for logistics



The south of the Netherlands is part of a broader network of innovators in biomedical materials and regenerative medicine



Utrecht has strong research focus on cell biology and tissue engineering in the cardiovascular and musculoskeletal fields

Strengths in Utrecht

Academic position

- > Utrecht University has a strong position in all disciplines in the field of biomedical materials
- > The regenerative medicine and stem cells research program is dedicated to three fields: musculoskeletal tissue regeneration, cardiovascular tissue regeneration and stem cell-based therapies

World ranking ¹⁾	NL	World
Tissue engineering	3	50-100
Cell biology	1	50-100
Cardiology	2	0-50
Orthopedics	3	50-100
Polymers	3	200-250

1) Ranking in terms of number of publications

Relevant research programs

Hubrecht Institute

Research focus is on developmental biology and stem cells at the organismal, cellular, genetic, genomic and proteomic level to gain insights into the development of (human) diseases

Regenerative Medicine & Stem Cells research program

Musculoskeletal tissue regeneration

Focus is on the development of novel technologies within several areas: cartilaginous tissues, bone regeneration, joint and tissue homeostasis and complex tissues

Cardiovascular tissue regeneration

Focus is on vascularization with available stem cells, stem cell regeneration and the potential use of induced pluripotent stem cells (iPSCs) for cardiac, vascular and renal regeneration

Excellent researchers (selection)



Prof.dr. D.B.F. (Daniël) Saris
Reconstructive medicine



Prof.dr. J.C. (Hans) Clevers
Molecular Genetics

In Belgium, KU Leuven is the leading university in the biomedical materials field

Strengths in Leuven

Academic position

- > KU Leuven is the number one university in Belgium within the field of biomedical materials
- > There is a strong focus on creating synergy between medical expertise and engineering technologies to approach scientific and medical potential – within the Skeletal Tissue Engineering division there is a strong focus on bone development
- > Another focus is advanced research on innovative materials and biomaterials

World ranking ¹⁾	BE	World
Tissue engineering	1	100-150
Cell biology	1	100-150
Cardiology	1	50-100
Orthopedics	1	50-100
Polymers	1	50-100

1) Ranking in terms of number of publications

Relevant research programs

Stamcelinstituut Leuven (SCIL)

The aim is to develop an understanding of stem cell biology in health and disease and to translate this knowledge into innovative stem cell-based or derived therapies

Imec

Imec is a CRO which performs research in nanoelectronics and delivers technology solutions within healthcare, ICT and energy

Department of Development and Regeneration

Skeletal Biology and Engineering Research Center

Research focus is on the understanding of the cellular and molecular basis of skeletal tissue formation, remodeling and repair, with the aim of developing regenerative treatments for skeletal disorders (cartilage, bone and joint)

Excellent researchers (selection)



Prof.dr. F. (Frank) Luyten

Regenerative medicine, osteoporosis and osteoarthritis

The University of Liège has GIGA and CERM as relevant parties in the biomedical materials field

Strengths in Liège

Academic position

- > The University of Liège does not have a leading academic position within the field of biomedical materials in terms of numbers of publications

World ranking ¹⁾	BE	World
Tissue engineering	3	>500
Cell biology	4	450-500
Cardiology	5	450-500
Orthopedics	7	>500
Polymers	3	300-350

1) Ranking in terms of number of publications

Relevant research programs

Groupe Interdisciplinaire de Génoprotéomique Appliquée (GIGA)

GIGA encompasses clinicians and clinicians-researchers covering cancer, immunity and inflammation, neurosciences and cardiovascular sciences. It has eight research themes, one of which is Development, Stem Cells and Regenerative Medicine, where researchers are interested in the molecular mechanisms underlying the formation of various organs.

Center for Education and Research on Macromolecules (CERM)

Expertise is found in macromolecular engineering and in engineering of interfaces and surfaces. Research is centered around six themes, one being Biomaterials Engineering. This group focuses on polymer implants (intra-ocular lens), drug delivery and scaffolds for tissue engineering

Excellent researchers (selection)



Yves Beguin

GIGA-Inflammation, Infection & Immunity; Laboratory of Hematology

Research at Aachen University is focused on cardiovascular de- and regeneration and polymers, the latter in collaboration with Jülich

Strengths in Aachen (region)

Academic position

- > Together with the Charite Medical University of Berlin and the Dresden University of Technology, RWTH Aachen University has a leading position in biomedical materials
- > With the Jülich Research Center, the university established the Jülich Aachen Research Alliance (JARA) focusing on six key research areas, in which the shared goal is to harness synergies and interlink knowledge in order to achieve insights for the future

World ranking ¹⁾	GE ²⁾	World
Tissue engineering	1	50-100
Cell biology	6	250-300
Cardiology	3	150-200
Orthopedics	2	150-200
Polymers	1	150-200

Relevant research programs

JARA-SOFT

Explores the properties of soft matter (polymers, colloidal and amphiphilic structures)

RWHT faculty of Medicine – Cardio-vascular Degeneration and Regeneration³⁾

Addresses the understanding of degenerative processes caused by diseases and new strategies for regeneration in the vascular system and heart

Helmholtz Institute for Biomedical Engineering Aachen

Focus on interdisciplinary basic and applied research in biomedical engineering

Jülich Institute of Complex Systems

Investigates the structure and dynamics of soft matter using neutron scattering, and develops neutron scattering instruments

Ernst Ruska-Centre

Facility for microscopy and spectroscopy with electrons

Excellent researchers (selection)



Prof.dr. Dieter Willbold
Structural Biology (Jülich)

1) Ranking in terms of number of publications; 2) Only universities located in North Rhine-Westphalia included; 3) Collaboration with CARIM

With Janssen, Belgium houses the main R&D center of one of the largest global pharmaceutical companies

Strengths of Janssen in Belgium

Strong research departments

- > The 4,600 employees, of which 1,800 are in R&D, focus on five disease areas:
 - Cardiovascular and metabolic diseases
 - Oncology
 - Infectious diseases and vaccines
 - Immunology
 - Neuroscience
- > In 2014 Janssen Belgium invested EUR 1,009 m in R&D, making Janssen the largest private investor in R&D in the country



Pioneering in production

- > Janssen has two production plants in Belgium: a chemical plant in Geel and a pharmaceutical plant in Beerse
- > In 2014, a EUR 34 m investment was made in a new continuous manufacturing production line in Beerse, eliminating the time-consuming intermediate and control steps in the production process
- > In 2014 a EUR 56.5 m renovation project of the chemical production plant started in order to improve the infrastructure and production equipment and to further standardize installations and processes



Boosting innovation

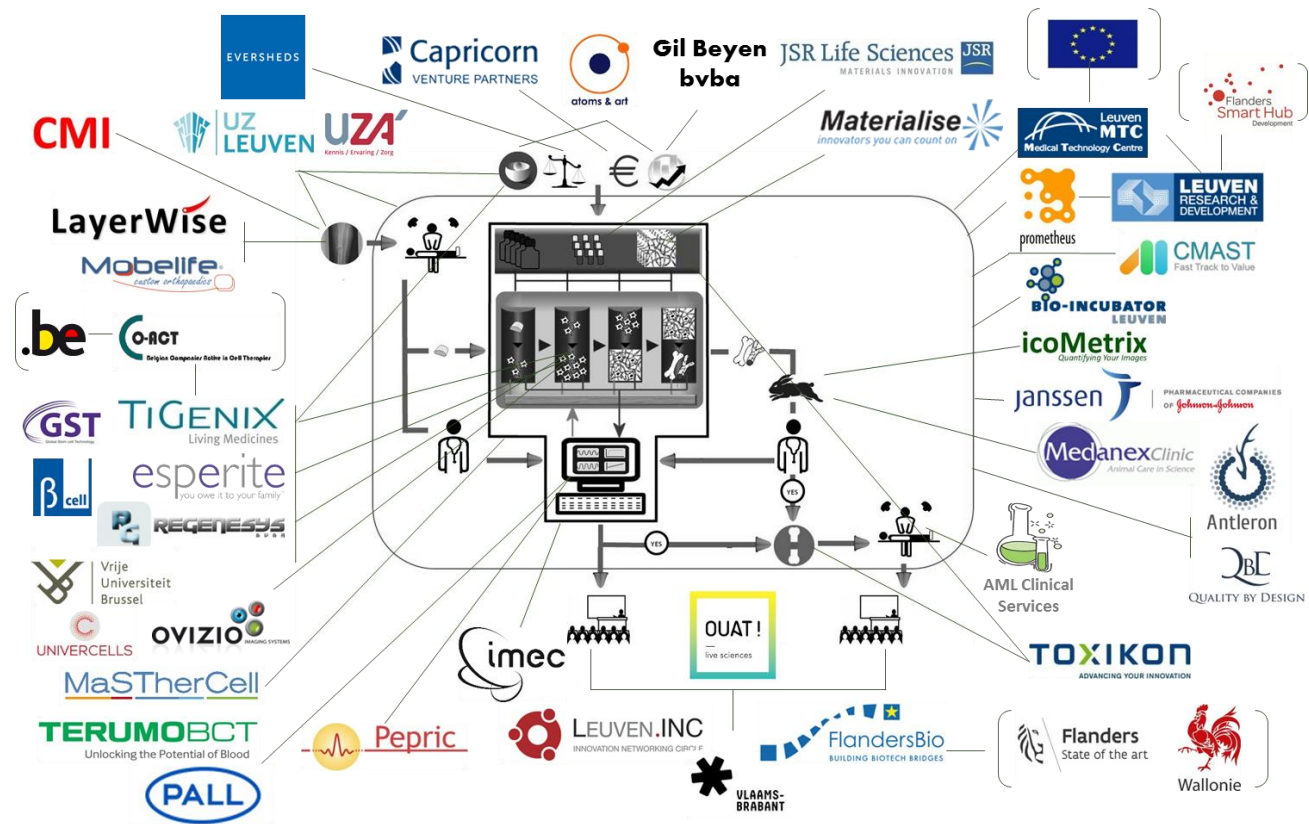
- > Janssen is building an ecosystem: a closely-related cluster of research institutes and large and small companies with government support to increase and commercialize their knowledge
- > Janssen announced an incubation center for 20 start-ups, opening in 2015
- > Promising healthcare projects are stimulated by the Entrepreneurial Innovation Bootcamps, held around the world and with a total investment of USD 46.6 m over five years



Belgium has a strong and evolving regenerative medicine community organized in the Belgium RegMed platform

RegMed platform

- > Belgium hosts a **critical mass** of experienced and complementary actors **along the value chain**
- > The goal of the Regenerative Medicine Innovation Platform is to create a **leading public-private community** that, by building on its regional actors, can **drive regenerative medicine towards a real industry** with clinical applications and a socio-economical return



Through Health Axis Europe the region has a strategic alliance with biomedical clusters in five countries

Health Axis Europe

Renowned institutes

University of Cambridge



KU Leuven



University of Heidelberg



Maastricht University



University of Copenhagen



Objectives

- > Establish international competitiveness and thus accelerate innovation and economic growth
- > Facilitate and coordinate EU-funded collaborative R&D projects
- > Support of cross-border cooperation in the training and further education of talented persons
- > Facilitate cross-border investments and cooperation between established venture capital (VC) funds
 - With the HAE Accelerator, innovative start-up teams are identified, trained and put in touch with international VC investors

Innovation culture

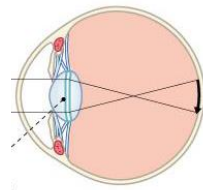
- > All biomedical clusters are internationally outstanding universities and share a common innovation culture
- > All clusters have a substantial health industry base and are driven by strong key individuals that are personally committed to foster economic growth and entrepreneurship
- > The clusters are focused on complementary health technology areas:
 - Cell biology (stem cells)
 - Nanotechnology
 - Personalized medicine
 - Cardiology
 - Pathology

This appendix provides additional details of six examples of biomedical materials solutions being developed

Examples of biomedical materials solutions being developed

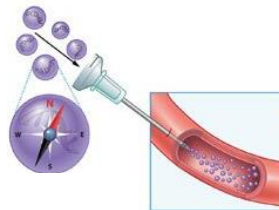
Restored vision

Accommodating intra-ocular lens from biomaterials with variable refractive indices that restores vision and releases drugs in a controlled way



Precision drug delivery

Active materials containing cancer drugs, programmed to deliver them only to the tumor and release them in exactly the right quantity at the right time



New cartilage

Biomaterial put on damaged cartilage (e.g. knee) that instructs the patient's own cells to regenerate native tissue



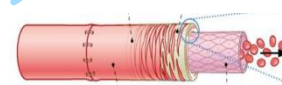
New heart valve

Artificial heart valve that replaces a damaged valve; it stimulates the patient's own cells to generate a real heart valve and dissolves when complete



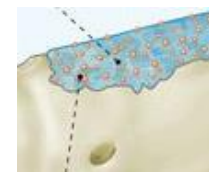
New vessel

Instructive stents and grafts for damaged vessels that use the patient's own cells to gradually transform themselves into living vessels



New bone

Biomaterial containing growth factors is put on the injury to accelerate the tissue repair process



The south of the Netherlands aims to restore vision

Restored vision

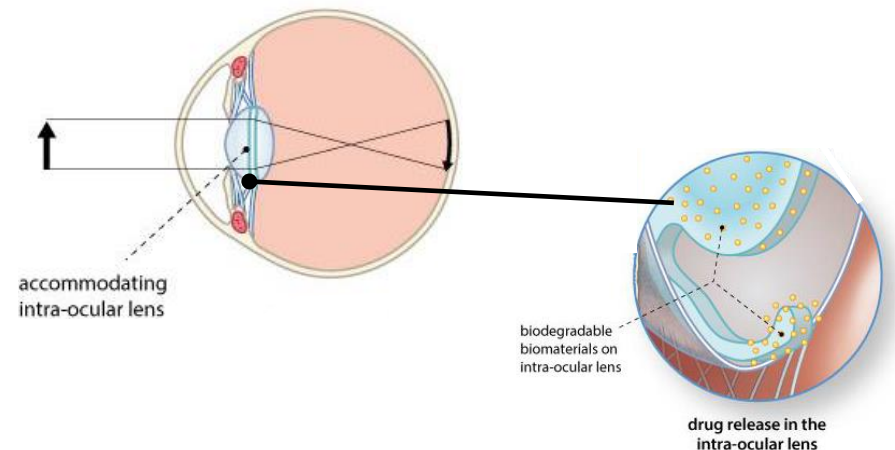
Problem

- > ~500,000 Dutch people suffer from a severe eye-related disease
- > The costs of visual impairment to Dutch society exceed EUR 1.8 bn per year
- > Expensive and uncomfortable glasses and lenses are needed to restore vision, and (often ineffective) eye drops are necessary to deliver drugs



Solution

- > The biomedical materials community in the south of the Netherlands aims to use biomaterials to develop:
 - An accommodating intra-ocular lens by using biomaterials with variable refractive indices
 - Coils for customized drug release by an intra-ocular lens



The south of the Netherlands aims to deliver drugs exactly where they are needed

Precision drug delivery

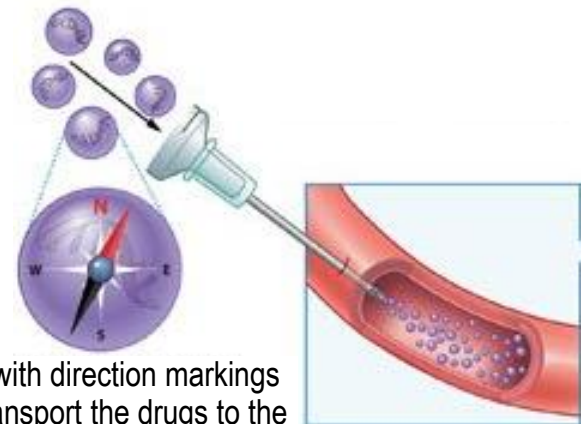
Problem

- > Life saving drugs against cancers are administered throughout the body, and do not only kill cancer cells, but also healthy tissue
- > This limits the dosage – and thus the effect of the drugs – and creates many side-effects for patients



Solution

- > The biomedical materials community in the south of the Netherlands aims to develop active materials that package cancer drugs to:
 - Deliver them exactly to the tumor
 - Release them in the concentration and speed with the most effect



Nanostructures with direction markings on the surface transport the drugs to the right place and dissolve at the right pace

The south of the Netherlands aims to develop new cartilage

New cartilage

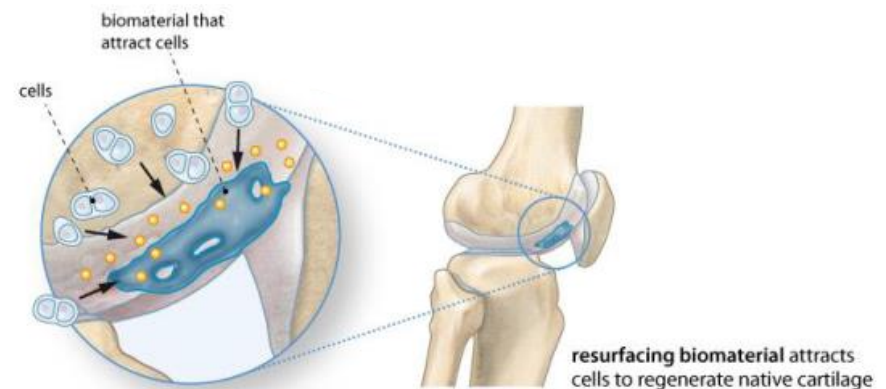
Problem

- > 600,000 people in the Netherlands suffer from osteoarthritis, which is a breakdown of joint cartilage (e.g. knee), leading to pain and physical disability
- > There is no satisfactory therapy for osteoarthritis – a joint replacement (e.g. a knee prosthesis) is possible, but used as an end stage therapy as it is not a long-term solution and is very difficult to replace
- > Joint replacements cost Dutch society EUR ~700 m per year



Solution

- > The biomedical materials community in the south of the Netherlands aims to develop a regenerative implant to stop osteoarthritis at an early stage
- > The cartilage-resurfacing biomaterial instructs the patient's own cells to regenerate native tissue



The south of the Netherlands aims to develop new bone

New bone

Problem

- > Per year, more than 83,500 people over the age of 55 break a bone, often due to osteoporosis which is a disorder in which the bones become increasingly porous, brittle and subject to fracture, owing to a loss of calcium and other mineral components
- > Over 800,000 people in the Netherlands suffer from osteoporosis
- > Osteoporosis treatment costs Dutch society over EUR 300 m per year and will increase due to an aging population



Solution

- > The biomedical materials community in the south of the Netherlands aims to develop new bone, using synthetic and biological materials such as calcium phosphates, combined with cell-signaling materials such as growth factors, to support and stimulate new bone formation in-vivo

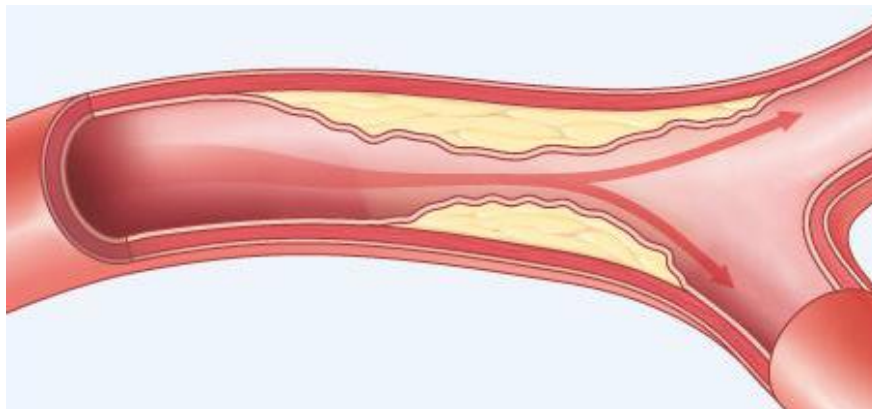


The south of the Netherlands aims to develop new blood vessels

New blood vessel

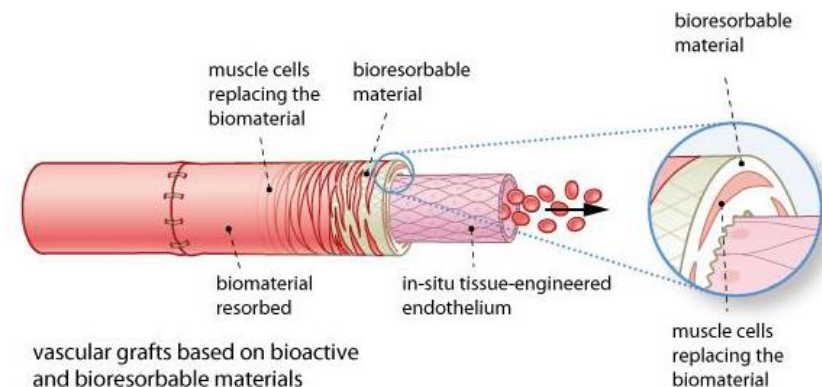
Problem

- > Over 1 m Dutch people suffer from vascular diseases like a narrowing of an artery or weak arterial wall
- > Vascular diseases cost Dutch society EUR ~800 m p.a.
- > Currently, stents are placed in arteries to strengthen/open them, or synthetic grafts are placed to bypass the damaged artery
- > These remain weak spots and can induce thrombosis



Solution

- > The biomedical materials community in the south of the Netherlands aims to develop stents and grafts that:
 - Recruit the patient's own cells, and gradually transform into living vessels
 - Do not activate blood clotting, reducing the chance of thrombosis



The south of the Netherlands aims to develop new heart valves

New heart valve

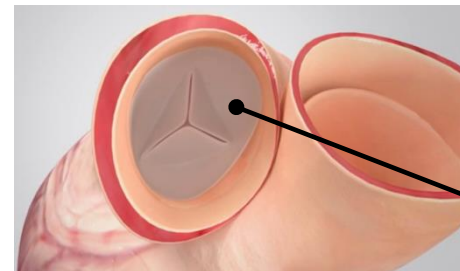
Problem

- > If a patient's heart valve malfunctions and does not fully open or close, the heart has to pump harder to circulate the blood, making it eventually collapse
- > About 5,000 Dutch people get a replacement for a malfunctioning heart valve each year, saving their lives but at the cost of heavy surgery, repeated operations, life-long medication and reduced life expectancy



Solution

- > The biomedical materials community in the south of the Netherlands aims to develop a material, molded into the form of a patient's heart valve that:
 - Replaces the function of the damaged heart valve
 - Recruits the patient's own cells to stimulate the growth of a new heart valve
 - Dissolves over time, leaving a real heart valve behind



Biodegradable scaffold replaces heart valve

Scaffold instructs cells to form a real heart valve

