Together for tackling the biomanufacturing & breakthrough technologies challenges **in Europe**

A European Landscape analysis to guide decision making process to recover EU sovereignty in Bioproduction and Medical Technology Value Chain

October 2021

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Introduction

Biotech drugs and small molecules, called biomedicines, are a major issue for the future of the pharmaceutical industry. They account for at least 20% of a global pharmaceutical market of $ 1,000 billion, a share that could exceed 50% in a few years. Four out of ten drugs on the market today are derived from biotechnology. Monoclonal antibodies, gene therapy or cell therapy biologics, immunotherapy, all are very high technology drugs based on cellular and molecular biology, with very complex mechanisms of action and considerable added value.

One of the great challenges of biomedicines is to reduce production costs, through the improvement of manufacturing processes, to which is added the need to transfer disruptive medical technologies to the market to strengthen European competitiveness and sustainability.

It is in this context that EIT Health and EIT Manufacturing commissioned the Council of European BioRegions (CEBR) to carry out a pan-European study on the challenges of bioproduction and medical technologies. The request included identifying the assets of representative innovation ecosystems in European Regions, and the sector's development levers, tackling the opportunities to strengthen and connect these ecosystems to boost Europe’s competitiveness. The first conclusions of this analysis are presented below.

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EIT Preface

Martin Kern
EIT Director

The European Institute of Innovation and Technology (EIT) is an independent EU body. We increase Europe's ability to innovate by nurturing entrepreneurial talent and supporting new ideas. It is the EIT's mission to increase Europe's competitiveness, its sustainable economic growth and job creation by promoting and strengthening cooperation among leading business, education and research organisations. The EIT also seeks to power innovation and entrepreneurship in Europe by creating environments for creative and innovative thoughts to thrive.

When addressing the biomanufacturing challenges in Europe, revealed by the Covid-19 crisis, it is natural to leverage the joint networks and expertise of several EIT KICs' strengths in order to support the European effort to strengthen the biomanufacturing sector and supply chains and hence make European the healthcare systems stronger and more resilient.

I therefore welcome the realisation of this report in a cross-KIC approach with EIT Health and EIT manufacturing that will bring a clear understanding of the challenges in this field to European decision makers and investors. I would like to thank very much all the contributors that made this a reality."

Martin KERN, EIT DIRECTOR

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Why EIT Health, EIT Manufacturing partnering with the CEBR to produce this biomanufacturing European landscape ?

Jan-Philipp Beck
CEO EIT Health

*To execute this landscape, **EIT Health & EIT Manufacturing** thanks to their Community Members Complementary Assets have been partnering with the **European Council of Bioregions** which is a membership-driven network of life science clusters and regional ecosystems across Europe.*

Of course, this work has not the ambition to document every aspects of the biomanufacturing sector but to generate ideas, to identify opportunities of collaboration with other EU instruments and / or with member states we can leverage on and scale-up at European level. Finally, it aims at bringing collaboration opportunities to leverage the member states initiatives alongside the other EU Instruments synergies.

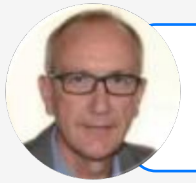
This important piece of work have been possible thanks to the strong commitment of EIT Health France that collaborated with the other Regional Innovation Hubs in Europe alongside the EIT Manufacturing Hubs.

The key findings are presented according to the Knowledge Triangle Framework which underline the upcoming opportunities for building innovation project consortia, the education route to tackle the Future of Skills and the levers to activate, to support the development and scale-up of innovative European based SMEs.

Jan-Philipp Beck, CEO EIT Health

Klaus Beetz
CEO EIT Manufacturing

Jean-Marc BOUREZ
EIT Health France Managing Director



Marc Dechamps
President of CEBR Board

Anaïs Le Corvec
Network Manager at Council of European BioRegions (CEBR)

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About CEBR

The European Council of Bioregions is a membership-driven network of life science clusters and regional ecosystems across Europe, representing over 40 subscription members and hundreds of cluster partners across the world. Together, we represent and support a critical mass of SMEs, and hundreds of universities and research centres.

Since 2020, involved together with the European Clusters Alliance in COVID task force leaded by DG Grow.

Currently working on a smart, dynamic map for detection of disruptions in Vaccines and therapeutics Value Chain for DG Grow, linked to the development of HERA.

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Council of European BioRegions Team

Marc Dechamps
President of CEBR Board

marc.dechamps@biowin.org

Marc Dechamps is a biologist with extensive experience of more than 30 years in the Pharmaceutical industry, with expertise in market development for new products including infectious diseases, immunological disorders, cancer, CNS diseases and vaccines.

Since 2016 Marc has supported biotechnological companies in the field of ATMP, Cell& Gene therapies with strategic advising and management leadership.

Marc served as Managing Director of Delphi Genetics, interim CEO of eTheRNA Immunotherapies and CXO of BioGenCell Europe.

Marc joined BioWin in 2018, the Health Cluster of Wallonia (Belgium) as Director International Affairs. In 2019, Marc was elected at the Board of CEBR, the Council of European BioRegions, and became President in 2020 while ensuring the international representation of BioWin."

Anaïs Le Corvec
Network Manager at Council of European BioRegions (CEBR),

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I am a specialist in international research management, and currently work as network manager in the Council of European Bioregions.

I am also the Co-founder of Cliclab Transformative Agent, a social innovation start up, with projects related to health, social transformation, and social impact measurement. I have worked in many different research fields such as Health, Information and Communication Technologies, International Cooperation, and Innovation.

I hold a Business Administration degree from the University of Montreal Business School HEC, with specialization in Marketing and International management. Established in Barcelona since 2001, I have been working as an International Research Advisor, andalso work as an expert reviewer for the European Commission in Research management related topics.

Biocat Support team

Montse Daban, PhD, MSc, MA
Scientific and Internatoinal Relations Director at Biocat, bioRegion of Catalonia.
Head of International Relations, Department of Research and Universities, Government of Catalonia.

Albert Guerrero
Degree in Biology in 2018, followed-up by a master's degree in Molecular Biotechnology, and is now a member of the International Relations Department at Biocat (Barcelona, Spain).

Maria Munujos
Degree in International Relations in 2020 followed by a master's degree in Global Health. Currently supporting European Projects and the development of strategic international partnerships and alliances.

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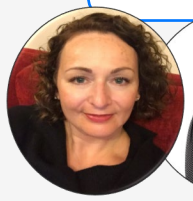
Project team

Jean-Marc BOUREZ
EIT Health France Managing Director

Jérôme FABIANO
Public Affairs & Stakeholder Relation Lead France

Martina CORTINI
Communication lead

Strategic Management Team
EIT Health Regional Innovation Hub Directors



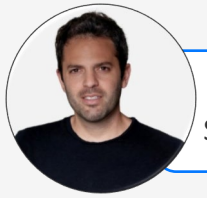
Christina Petris

Katharina Ludwig

Menno Kok

Balazs Furjes

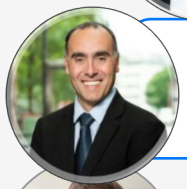
Cristina Bescos



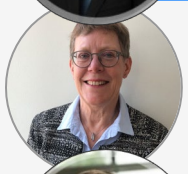
Rani AVISSAR
Senior Strategic Partnership EIT Manufacturing

Joel ROSENBERG
Business Development France

Jean-François DUROCH
Director of Innovation



Management Team
EIT Manufacturing Regional Innovation Hub Directors



- CLC West – Bilbao : Antoni Pijoan
- CLC North – Gothenburg : Anna Hultin Stigenberg
- CLC Central – Darmstadt : Christian Bölling
- CLC South – Milan : Gian Mario Maggio
- CLC East - Vienna : Johannes Hunschofsky

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EIT Health & EIT Manufacturing Complementary Assets

Ideation ***Development*** ***Production***

Life science needs & solutions

Life-science manufacturing supply chain

Strengthening healthcare systems in Europe

Promoting better health of citizens

Contributing to a sustainable health economy in Europe

Globally Competitive and Resilient Manufacturing

Competitive Manufacturing Skills and Social Sustainability

Manufacturing fit for the Digital Age

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Synopsis

The study was sponsored by EIT Health and EIT Manufacturing and delivered by the Council of European BioRegions (CEBR).

In this summarized report, you will find

Part I : Objectives and Scope of analysis

Part II : Main issues and executive summary

Part III : Country/Regions Landscape Summaries

Part IV: EIT Health Radar

Part V: Main Conclusions and Levers

EIT Health and EIT Manufacturing are working in partnership in order to suggest a cross-KIC activity across Europe on Bio Manufacturing and Medical Technologies

.

In order to build such a cross-KIC initiative, both KICs decided to carry a Consulting study about “How to deliver a European Landscape on Biomanufacturing breakthrough technologies & key technological challenges”.

This study will address multiple European areas across CLCs in 2 steps:
-1st step: Scandinavia, Belgium, Spain, The Netherlands, France, Germany
-2nd step: Switzerland Italy, Ireland, UK, and Central and Eastern European Region

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Part I

Objectives and **Scope of analysis**

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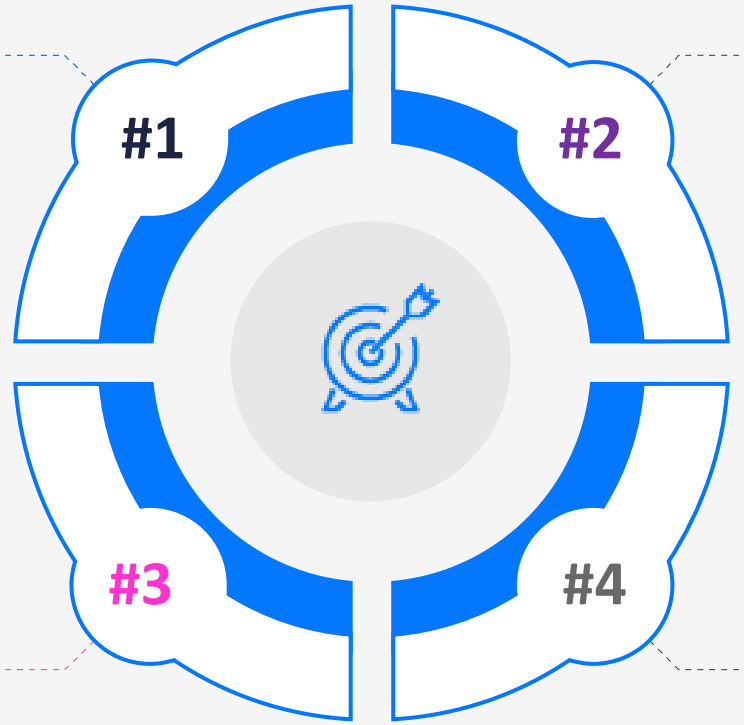
Objectives of the Landscaping Analysis:

1 **Validate the relevant barriers** (scientific, technologic, education & skills, environmental, production costs and processes) and enablers for the successful adoption of bioproduction and manufacturing value chain at the European level



2 **Identify opportunities** in Europe for disruptive technologies which could improve productivity of next generation bio-products, and medical technologies thus improving cost and affordable access to patients

3 **Outline the potential synergies with European initiatives** to accelerate and expedite integration of innovative technologies and therefore making EU more attractive and resilient for a production in the EU Member States.

4 **Outline the potential opportunities** for harnessing the capital risk co-investments in promising European SMEs on the sector, including CDMOs, therefore making EU Venture Capital Market more attractive, using as an eg. **the Venture Centre of Excellence** programme to support such a pathway.

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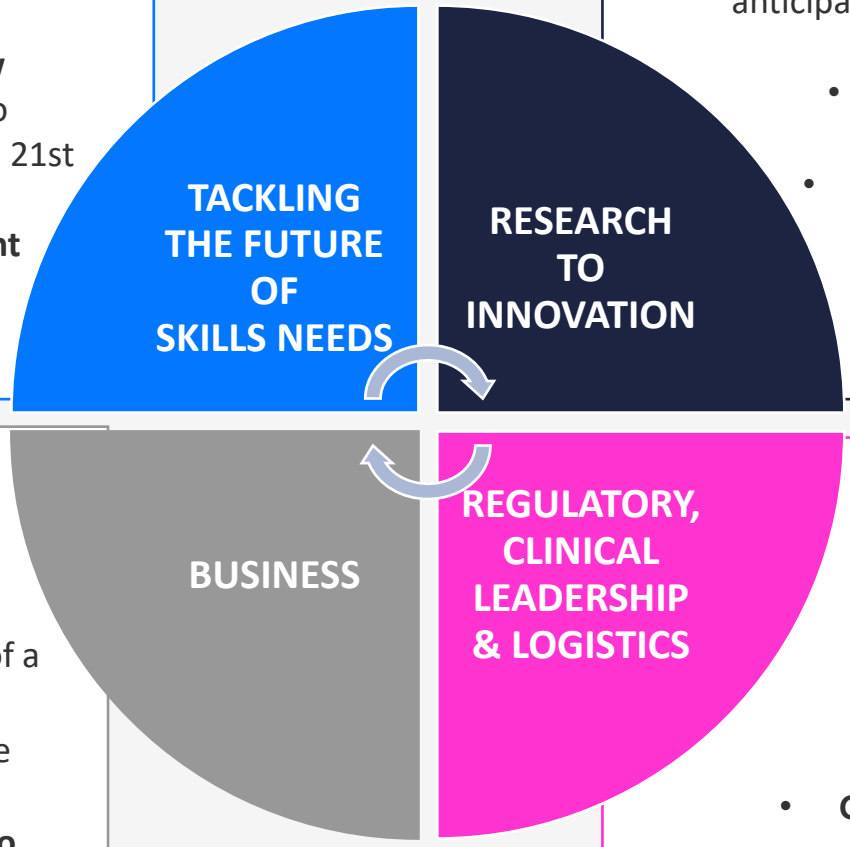
Scope of the study and key topics

- **Identifying the talent gap and the talent crunch** in that field, developing a Talent Market Place to tackle this challenge.
- **Developing new skills thanks to innovative new training modules** (academic and professional) to foster the employability of the workforce of the 21st century.
- Using the new digital technologies to **implement manufacturing digital twins** useful for these activities.



- **Developing simulation and artificial intelligence tools** to co-design the product and **its manufacturing process** to anticipate the challenges of the industrialization of an advanced therapies
- Developing new **production models** to meet the challenges of personalized medicine
- Reduce the **variability of the production steps** by on-line or **remote control** of bioproduction
- Improve intrinsic yields of expression and Purification of biological molecules or systems of interest

- **Creating a network of start-ups/SMEs and scale-up new access to finance tools.**
- Resulting from these breakthrough technologies (short and medium term), these technological breakthroughs will also enable the emergence of a **fabric of innovative new ventures** in dedicated incubators that will be located at the heart of the platforms that have integrated the consortium.
- **Breaking down the silos** to facilitate **the access to finance** needs, access to subsidies, to equity and to venture debt or guaranteed loan

- **Regulatory aspects**, tax and incentives for biopharmaceutical research and development
- **Business investment** in new vaccines and treatments
- **Growth in pharmaceutical air cargo,** network of rail and high ways

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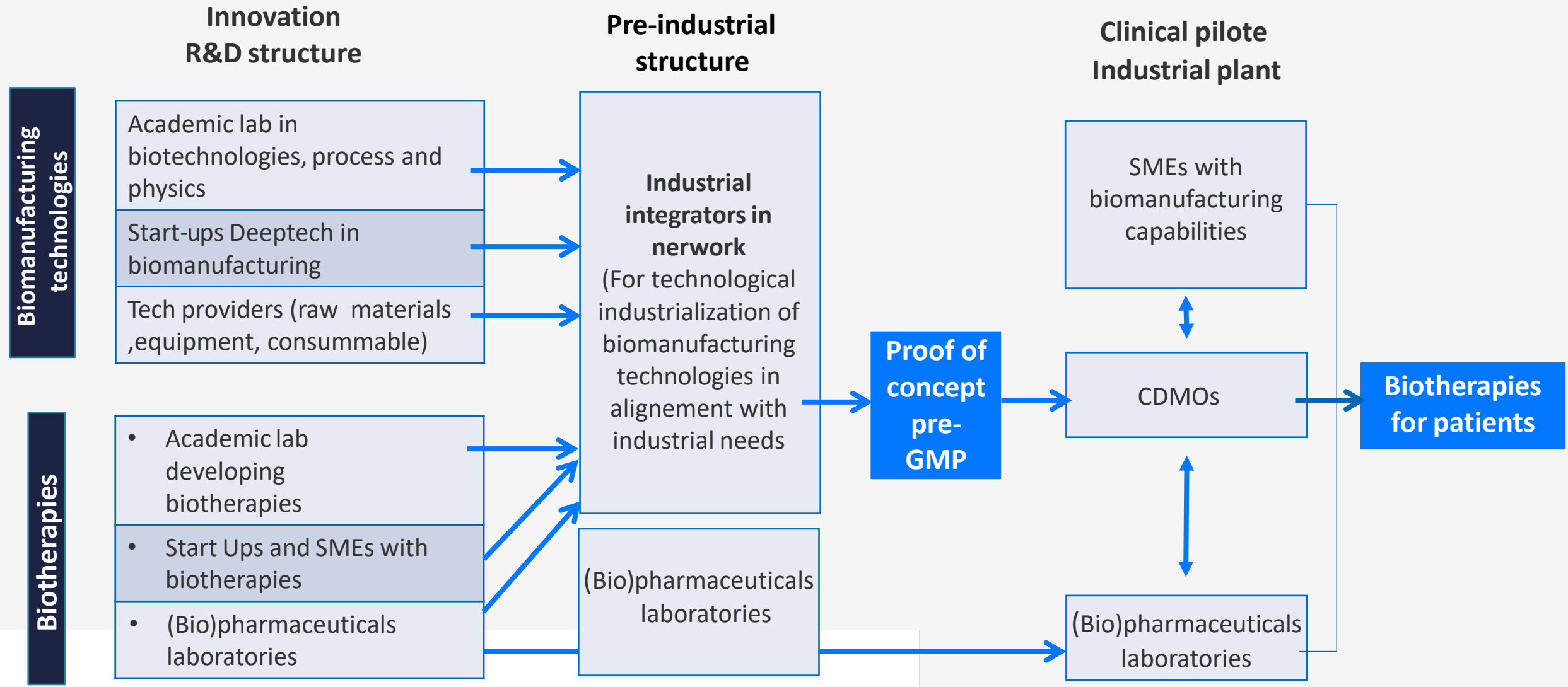
Biomanufacturing scope of the study



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Geographical scope of the report

This European study focuses on the conditions conducive to the emergence, development and industrialization of biomanufacturing breakthrough technologies - the production of advanced therapies and the key challenges to be addressed in this area.

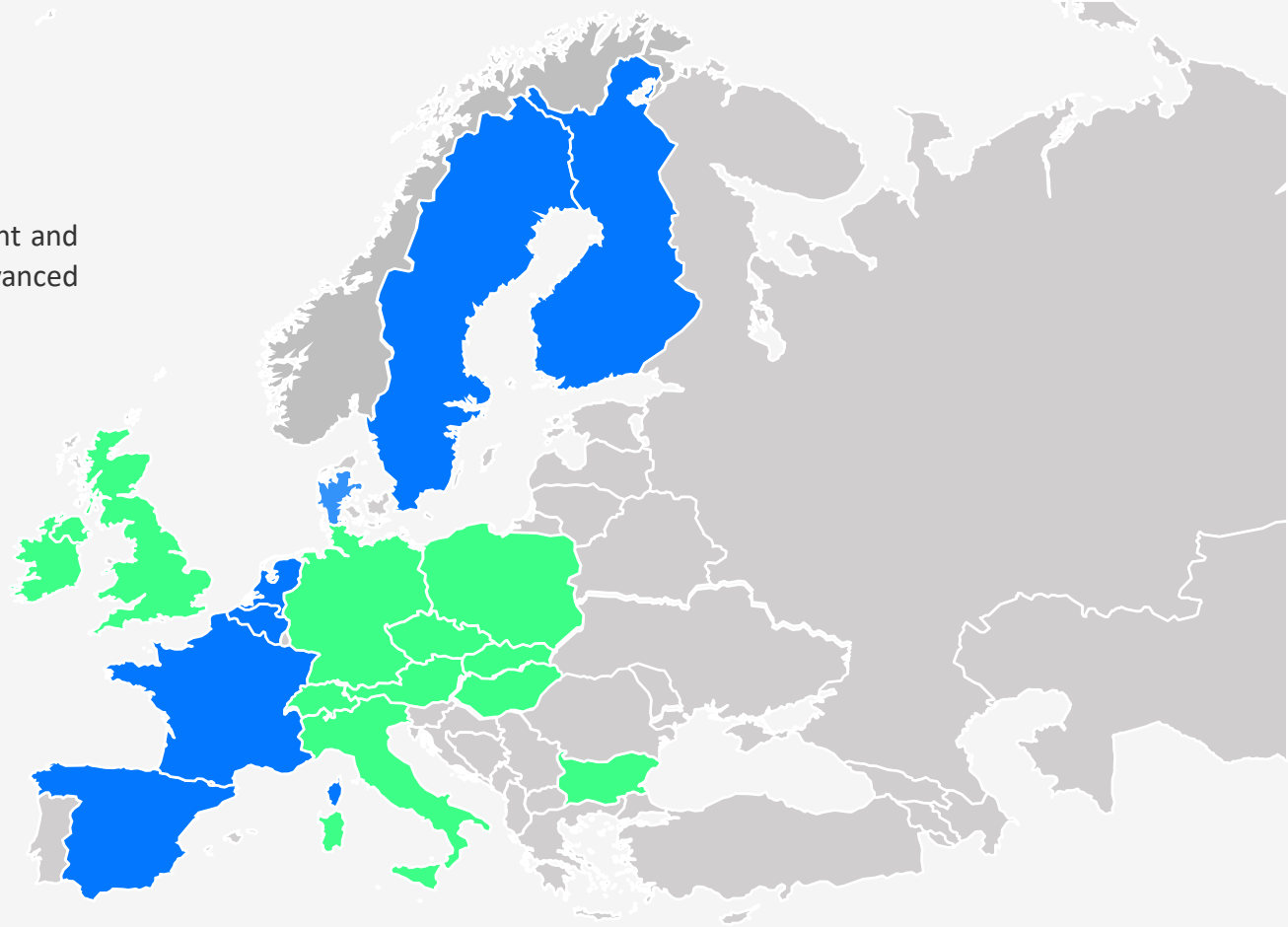
This study will focus on several European zones in two waves:

Wave 1:

- Belgium
- France
- Germany
- The Netherlands
  - Scandinavia
  - Finland
  - Denmark
- Sweden
- Spain

Wave 2:

- Central and Eastern Europe
  - Austria
  - Bulgaria
  - Czech Republic
  - Hungary
  - Poland
  - Slovakia
- Italy
- Ireland & UK
- Switzerland



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First wave of the Landscape Analysis on Biomanufacturing

Consulted Bodies

Scandinavia

TestaCenter · Stockholm Science City Foundation · STUNS · Turku Business Region · Stockholm The Capital of Scandinavia · Bio People

The Netherlands

BOM Enabling Growth · oost nl

Belgium

Univercells · BioWin The Health Cluster of Wallonia · flanders.bio · salamanderU

France

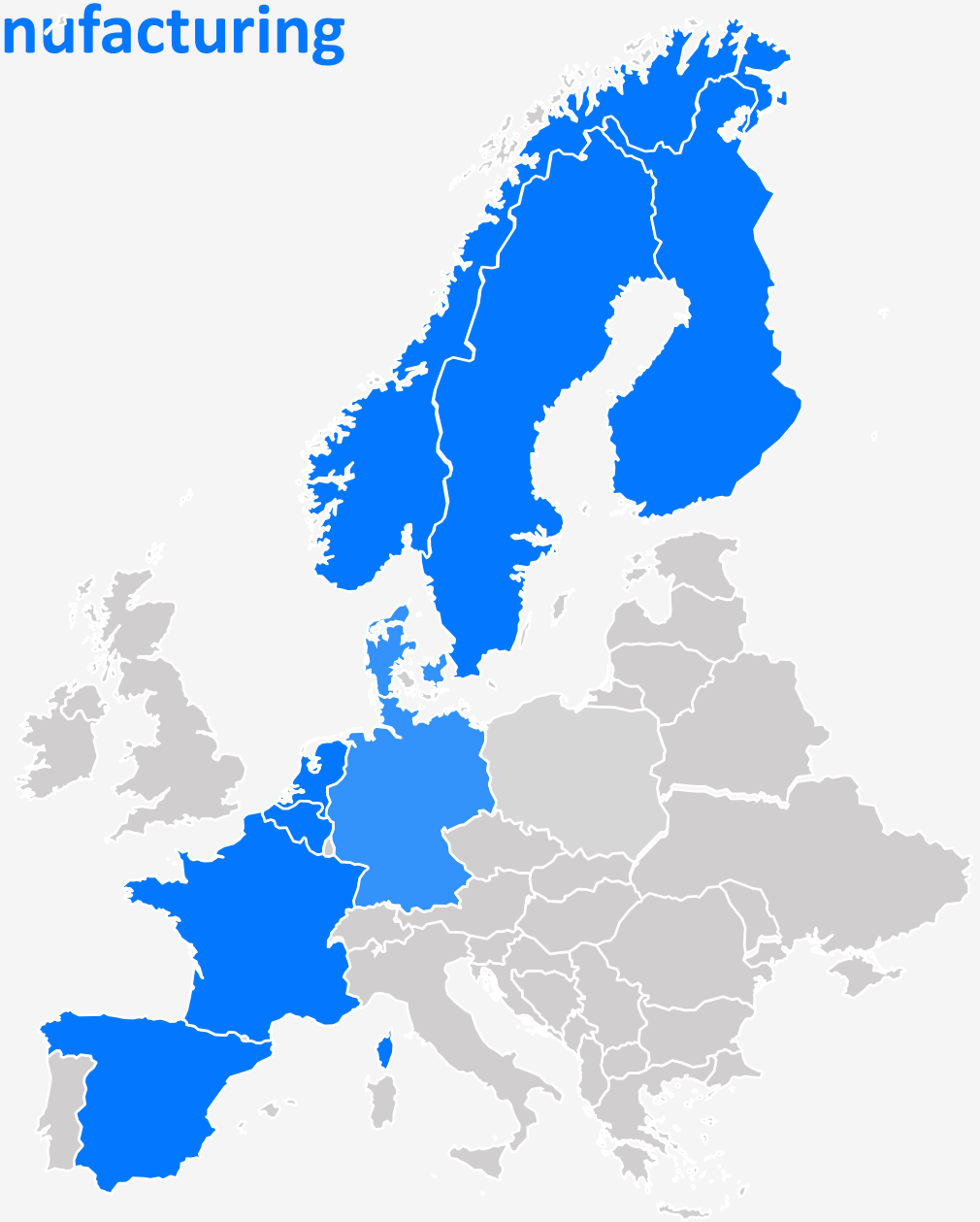
Premier ministre – Secrétariat général pour l'investissement · conseil national de l'industrie · D&C Consultants La performance pour l'innovation · Paris Region Source of Inspiration

Spain

biocat · BioBasque · Reig Jofre · fenin

Germany

HealthCapital Berlin Brandenburg · BioRegio STERN · BioRN · Bio M



EIT Health & EIT Manufacturing locations

EIT Manufacturing

Head Quarters
Paris

Five Regional innovation hubs
CLC West - Bilbao
CLC North - Gothenburg
CLC Central - Darmstadt
CLC South - Milan
CLC East - Vienna

EIT Health

Head Quarters
Munich

Six Regional innovation hubs
Paris
Rotterdam
Barcelona
Budapest
Stockholm
Dublin

13 Regional Innovation Scheme (RIS) (Pink pins)

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Council of European BioRegions (CEBR) locations

CEBR represents 40 Bio Regions across Europe, from 14 countries.

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Part II

Main Conclusions of the Landscape

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Summary

	Needs	Opportunities
Education	• Need for more specialized training education programmes • Talent development stretch vs future demand • Upskilling and re-skilling of labor forces from other industry sector • Talent chase, and high competition to attract digitally skilled workforce (digital twins, simulators, virtual & augmented reality) • Need for more entrepreneurship skills	• Co-develop training modules, especially related to upskilling and re-skilling (Cross-border Digital academia at EU level ?) • Distributed Education hub of Excellence in Europe • Active and dynamic communication to attract skills • Strong development of interdisciplinarity
Innovation	• Need to adapt the funding for the scaling up of innovation, and ensure to keep the talent • Need to explore new source of cells and differentiation process to create new cell therapies • Need to support the development & production capabilities of new therapeutic vaccines	• Create funding mechanisms, for every step of the innovation process, as well as reinforcing the Hubs that can take leadership in ATMPs (Advanced therapies & medicinal products) and Biomanufacturing • Create Synergies between co-funding instruments
Business	• Need to adapt the funding tools for the scaling up and growth of business • Need of larger investments from EU-based funds • Adaptation of regulatory constraints • No/few supplier of equipment, consumable and raw materials	• Reinforce Public-Private partnerships, develop cross-collaboration regional hubs to reinforce European sovereignty. • Supporting new generation of EU based private investments to take the lead in the co-investments made in growing of companies while keeping European sovereignty. • Diversify the access to finance solutions / interacting with other EU Institutions (EIB, EIF, Invest EU…)

Real dialogue between authorities and actors on the ground:

academic and industrial

Ex: Belgium - updated regulations facilitating the emergence of innovations

(e.g. regulatory framework for bioproduction)

Executive summary

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Part IV

Country/Regions Landscape Summary

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Belgium
Executive summary & main issues

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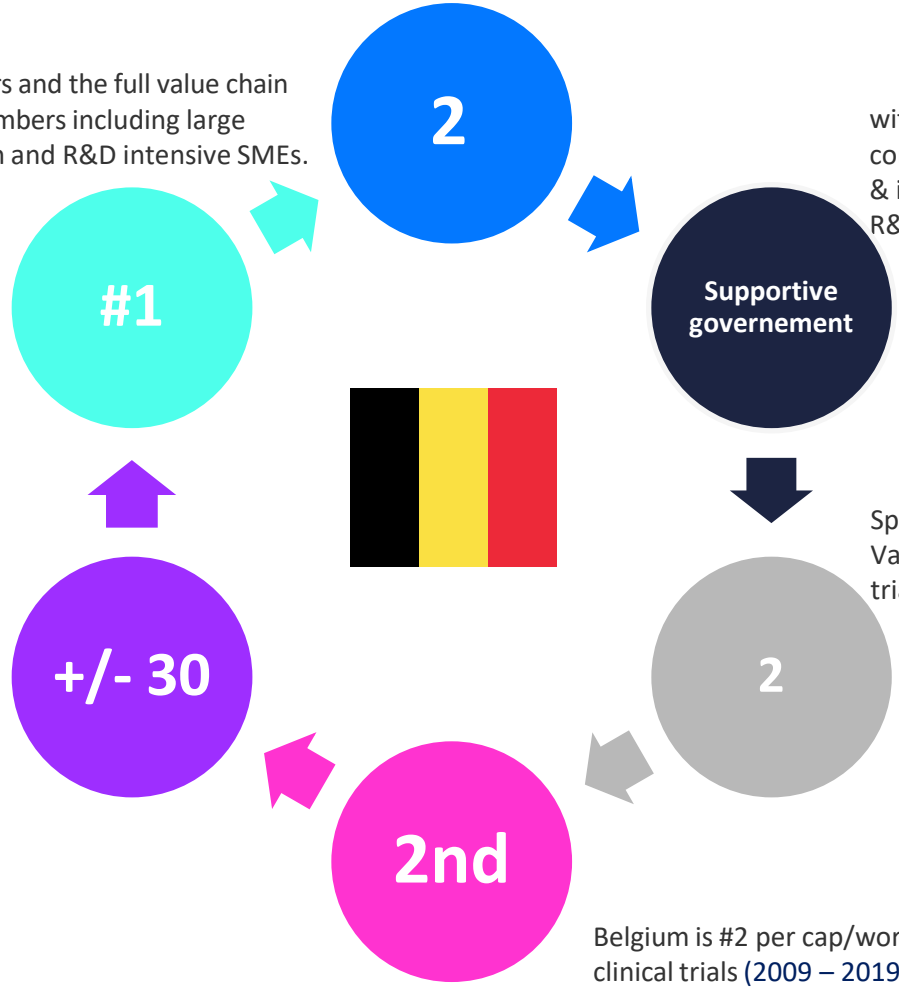
Belgium

«The Belgian R&D model is characterized by a strong integration of university-industry collaboration with a strong support of the government and regulatory authorities»

BIOCLUSTERS

- BioWin gathers 235 members and the full value chain
- flanders.bio gathers 340 members including large biopharma, scale-up biotech and R&D intensive SMEs.



with an interesting combination of tax measures & incentives for biopharma R&D

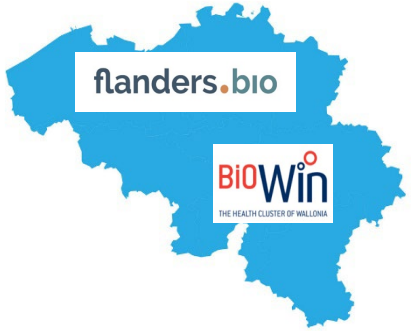
Specialized in ATMPs and Vaccines with phase 1 clinical trials approval 2 in weeks.

Belgium is #2 per cap/world for clinical trials (2009 – 2019)

fundraisings in biotech/bioprod in 2020

in **pharma air cargo**
Liège airport chosen by WHO as EU Covid-19 logistics platform.
At least 7 companies currently involved in the production of Covid Vaccines

BioClusters contributing to this report



Collaborative example
Novadip Biosciences

NOVADIP
2015-2020: 36 patients implanted with the autologous 3D tissue engineering product of 1st and 2nd generation for the reconstruction of bone defects of critical size.
Collaboration with Saint-Luc clinics UCL for tech transfer

Executive summary

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Belgium

Key recommendations

	Pain points	Success stories	Opportunities
Education	• Concentration of many fast-growing companies looking for the same profiles • Generation of talents to support the fast development level of the CDMO and Biotech with biomanufacturing facilities	• **Active watch** driven by the Cluster BioWin to evaluate in real time the needs of companies in the biomanufacturing sector • **Virtual reality** makes trainings more real at GSK (VR/AR)!	• Consortium of local companies to centralise offers & opportunities – "One stop shop" • Development of a reconversion strategy • Supported by the regional, federal and... European authorities • Focus on innovative teaching methods
Innovation	• Need to ensure the continuity of the strong presence of public - private investors to support the development of innovative technologies	• **Univercells**: "affordability driven by re-invented bio-production technology" • Intensification and chaining leading to reduced footprint (7x), labor and materials usage • Reduced facility CAPEX (up to 10x) and operating costs (up to 5x)	• Collaborate with local and regional government, and private foundations to maintain and expand the support for innovation
Business	• Major fundings are coming from M&A and foreign investors, no clear European investors to support growth & development in this field	• **MaSTerCell** Initially created by the regional government and BioWin to develop a platform for cell therapy manufacturing. • **Anicells**, a similar initiative created by Provincial Innovation Centre of Antwerp (POM Antwerpen), the University of Antwerp and Antwerp University Hospital	• To develop a strategic & financial vision for biomanufacturing in Europe! Supporting tools are required not only to stimulate development of disruptive innovations in sector but also to actively fund the growth of the companies and keep the decision-making power in Europe for this very innovative industrial sector

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Conclusions & next steps

The success of the Belgian R&D model is characterized by a strong integration of university-industry collaboration with a strong support of the government and regulatory authorities

- Belgium has **more graduates** in Life Sciences & Health per capita than neighbouring countries
- Belgium has a **strong growth in Biotechnology** and Biopharma patent application
- Belgium has one of **highest density of Advanced Therapy Companies** in the world
- Belgium a strong country for **Biopharma Supply chain & Logistics**

Next steps are:

- **To develop a pro-active strategy for talents** generation to tackle the needs of many fast-growing companies looking for the same profiles. The "EU biotech School & Health Club" will be created by 2025 with 25 Mio€ investment.
- To support innovation in the pharmaceutical industry. The CESPE test centre for innovative (bio) pharmaceutical manufacturing in Ghent, operational in 2024 (approx. 20 million investment).
- **To get access to European and Private fundings** to not only stimulate development of disruptive innovations in sector but also to actively fund the growth of the companies in Europe for this very innovative industrial sector

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France
Executive summary & main issues

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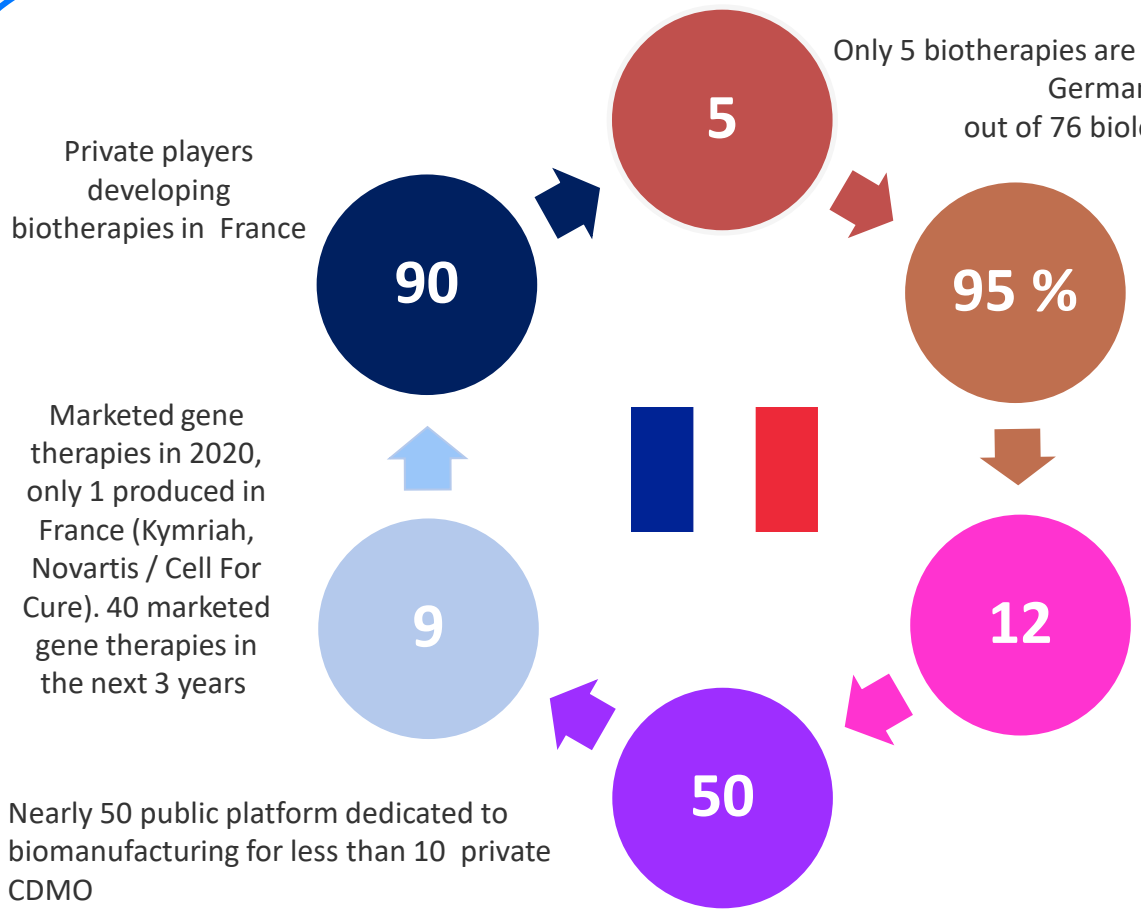
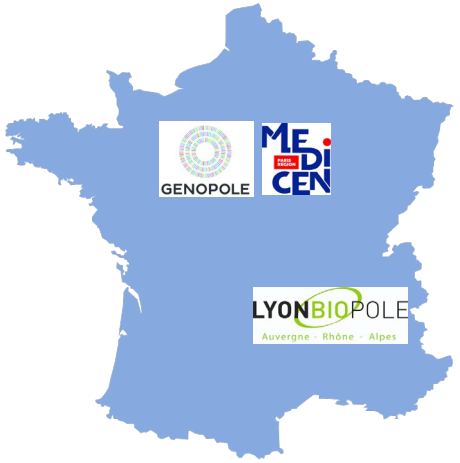
France *« France, a rich ecosystem for new biotherapies but with major lack on tech provider and ambitious CDMO for biomanufacturing. »*



Main BioClusters



Focus

- **Historical position as a leader for classic vaccines** with a cluster (Lyon Biopole) and leaders (Sanofi-Pasteur, Institut Pasteur)

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France

Key recommendations

	Pain points	Success stories	Opportunities
Education	• Nearly 50 public platform dedicated to biomanufacturing **but without national organization**, ambitious HR and internal innovation to develop new disruptive technologies	• A strong academic and clinic tissue in emerging therapies (**Cell and Gene therapies)** • **Strong competencies** in modelling, process engineering, sensors, synthetic biology/ genetic engineering and industrial biotechnologies on bacteria, yeast or micro-algae	**Campus Biotechnology and Digital Accelerator** (Sanofi, BioMerieux industrial partners, schools, start-ups).several spaces for **process design thinking** **Innovation digital training centre** (such as flight simulators) with digital twins, virtual & augmented reality, optimized control rooms with AI & robots
Innovation	• Need to explore **new source of cells and differentiation process** to create new cell therapies • Need to support the development of **new therapeutic vaccines**	**Aenitis Technologies is a French spin off ESPCI** ParisTech, a research engineer's school in Paris and The National Center for Scientific Research (CNRS). **Aenitis** Technologies is developing innovative separation, manipulation and filtration of biological elements solutions, based on acoustophoresis technologies.	• **A rich ecosystem** of private and academic actors developing biotherapies, especially for **therapeutic antibodies** • Strong growth of next generation Abs as ADCs and bispecific Abs in clinical development (some are marketed)
Business	• No/few supplier of equipment, consumable and raw materials • Only 10 private CDMO of small size • Not enough private investments in promising start-ups	**TreeFrog Therapeutics** has developed C-Stem™ : a proprietary technology platform that provides an end to end 3D scalable solution that will dramatically reduce treatment costs	• **creation of a national structure in charge of the French bioproduction strategy** with the aim of creating an aligned industrial sector and the marketing of disruptive technologies - industrialization. It may take the form of an **Alliance of industrial and academic players (Alliance France Bioproduction - AFB).**

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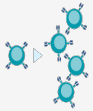
Conclusions: biotherapies, a major issue of sanitary independence

France is 95% dependent on imports for biotherapies

- In 2018, **3% of therapeutic antibodies used in France were produced in France**
- Strong growth of next generation Abs as ADCs and bispecific Abs in clinical development (some are marketed)

- **Historical position as a leader for classic vaccines** with a cluster (Lyonbiopôle) and leaders (Sanofi-Pasteur, Institut Pasteur)
- Need to support the development of new therapeutic vaccine

- **9 marketed gene therapies in May 2020**, only one produced in France (Kymriah, Novartis/Cell for Cure)
- Major role of French research in the development of 8 of these gene therapies
- 40 marketed gene therapies in the next 3 years



- **No real commercial success for cell therapy**
- Need to explore new source of cells and differentiation process to create new cells therapies

Recommendations from CSF-ITS – INITIATIVE TECHNOLOGIE DE RUPTURE POUR LA BIOPRODUCTION

With 2 priority areas, in the short term: the roadmap defined will aim to develop technological solutions to meet the challenges of bioproduction, namely **the deployment of industry 5.0 in factories with continuous monitoring for the prescriptive control of bioprocesses with priority axes on biosensors, microfluidics, simulation and hedge artificial intelligence and new high yeld and industrializable expression systems.**

Measure 1: ensure the visibility and attractiveness of the national bioproduction sector – establishment of the France Bioproduction Alliance
Measure 2: develop and industrialise major technological innovations through collaborations between stakeholders in accordance with the CSF roadmap
Measure 3: Facilitate the industrialization of disruptive technologies. In addition to this, you need to know more about it.
Measure 4: support the development of the bioproduction sector through the implementation of ambitious financing tools
Measure 5: ensure the development of skills in bioproduction.

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Germany
Executive summary & main issues

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Germany

«The German R&D model is characterized by a strong support system and cooperation between industry and science and for innovative business start-ups.»

Executive summary

Sales of biopharmaceuticals (in the pharmacy and hospital market) in 2020 increased by 14 percent from 2019, amounting to €14.6 billion

€14.6 billion

35 %

of biopharmaceutical agents in the clinical pipeline are for cancer treatments

350+

companies active in medical biotechnology

120K

Germany has the largest European labor pool in Health sector

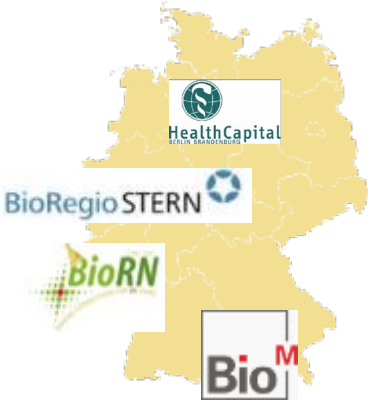
5.4 %

In 2020, companies active in medical biotechnology continue to hire. With expansion of 5.4%, the workforce grew considerably, to over 44,600—a new record

82

on recombinant antibodies. By the end of 2020, 82 molecules in this class of active substances had been approved in Germany, twice as many as five years before.

BioClusters Contributors



Focus

The German pharmaceutical sector shows the highest research intensity across all major German industries- – about 12.5% of revenues were reinvested in R&D in 2018.

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COUNTRY

Key recommendations

	Pain points	Success stories	Opportunities
Education	• For manufacturers to embrace the opportunity of Industry 4.0 successfully, investing in technology alone is not sufficient. • This must be accompanied with significant investment in talent, skills and training to help the workforce adapt to this.	• 2 German universities in Europe's top 15 in life sciences and medicine. • OECD #3 in number of new PhD graduates in biological and related sciences.	• In 2020, companies active in medical biotechnology continue to hire. • With expansion of 5.4%, the workforce grew considerably, to over 44,600—a new record.
Innovation	• A report published by vfa bio and Boston Consulting Group assessing the state of biotech in Germany revealed the country is falling behind in production capacity when compared globally to other countries.	• Disposable fermenters, significantly increase flexibility with rapid switching between different products in multi-purpose plants and faster ramp-up of capacities. • Translational approach to innovation, brining all stakeholders together (Leipzig, Stuttgart or Berlin)	• Securing and expanding production in Germany, • Using the opportunities of digitalization, • Removing administrative hurdles in clinical trials.
Business	• In terms of European production capacities (based on the volume of fermenters), the country is falling two places since 2018. • One reason for this is the tax framework which is not competitive compared to other countries with more investments in biopharmaceutical production.	• Only from Ludwig-Maximilians-Universität München, 75 spin-offs have been founded over the past 10 years. • Pharmaceutical industry (being 90% of drug manufacturers SMEs) is one of the main suppliers of novel biopharmaceuticals	• Improving framework conditions for the supply of venture and innovation capital, and • Strengthening the networking and cooperation of all stakeholders.

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Conclusions & next steps

The success of the COUNTRY R&D model is characterized by a strong integration of university-industry collaboration with a strong support of the government and regulatory authorities

Recommendations for medical biotechnology in Germany (From VFA & BCG report on Biomanufacturing in Germany, 2020)

The Covid-19 pandemic poses major challenges for Germany, Europe and the world. Rather than a return to the status quo ante, **the pandemic should be used as an opportunity to reduce bureaucracy and specifically strengthen promising and innovative industries and technologies** such as drug research, development and production, including medical biotechnology in Germany. More precisely, this means:

- securing and expanding production in Germany,
- using the opportunities of digitalization,
- removing administrative hurdles in clinical trials,
- improving framework conditions for the supply of venture and innovation capital, and
- strengthening the networking and cooperation of all stakeholders of the healthcare system.

If all involved players work together to implement these points, Germany's chances of standing its ground in international competition will be good—to the benefit of patients, society and the country as a whole.

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The Netherlands
Executive summary & main issues

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European Union

The Netherlands

«The Dutch R&D model is characterized by a strong innovation system, unique mix of businesses working alongside world-class knowledge institutes from agriculture to transportation, with a highly skilled workforce and attractive R&D incentives»

Covid-19 vaccines

home of Janssen, and current producer of COVID-19 Vaccines

9th

of 119 nations in The Global Talent Competitiveness Index by INSEAD Business School

9th

out of 40 countries for student skills in the OECD Better Life Index

60%

Exports of medicines and vaccines increased by 60% since 2015

65.400

2019: Jobs n Life sciences

EMA

Important European Agencies located in NL, such as the European Medicines Agency

Main BioClusters

Focus

Many Bioclusters coïncide with academic centers: Leiden-Delft-Rotterdam; Amsterdam; Utrecht; Maastricht-Geleen; Enschede, Groningen. Oss Pivot Park is a dedicated Biopharma Campus, once occupied by Organon.

Executive summary

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The Netherlands

	Pain points	Success stories	Opportunities
Education	• Stretch in development of talents vs current and future demand • Need for more entrepreneurship skills • Digitalization	• Strong partnerships with Industry at Educational level (collaborative campus schemes) • Collaborative model for the Dutch Centres for Entrepreneurship	• Collaborative models • National Strategy for innovation and talent • Attractiveness of the Dutch university and education system
Innovation	• Fragmented • High competition between hubs and regions within the country • Does not house the HQ of large Pharma or Biotech companies	• Centre for BioScience and Diagnostics – Training facility for GMP • Brightlands Campus	• Strong digital infrastructure, 14 universities • R&D incentives
Business	• Regulatory constraints • Complex and fragment funding landscape • Limited presence of large Pharma or Biotech	• Brabant biopharmaceutical research campus Pivot Park • Netherlands Center for the Clinical advancement of Stem Cell and Gene Therapies (NECSTGEN)	• Cross-sectorial collaboration (i.e AgroFood) • Transport hub • Digital hub • One of Europe's largest start-up ecosystems • High level of public-private partnerships

Key recommendations

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Conclusions & next steps

The success of the Dutch R&D model is characterized by

- **Strong partnerships** with Industry at Educational level (collaborative campus schemes)
- **Collaborative model** for the Dutch Centres for Entrepreneurship
- **National Strategy** for innovation and talent
- **Attractiveness** of the Dutch university and education system
- **Cross-sectorial collaboration** (i.e AgroFood)
- **Digital hub** and Digital Innovation Hubs
- One of Europe's largest **start-up ecosystems**
- High level of **public-private partnerships**

Next steps are:

- **To work on solutions** to overcome the highly fragmented and competitive own LifeScience environment
- **To get access to European and Private fundings** to not only stimulate development of disruptive innovations in sector but also to actively fund the growth and scale up of the companies in Europe for this very innovative industrial sector

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Spain
Executive summary & main issues

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Spain

«The Spanish R&D model is characterized by a talented research and innovation ecosystem, with strong regional ecosystems, in biomanufacturing especially located in Catalonia, the Basque country and Madrid area.»

177 k — Employees, 10,000 activities exclusively dedicated to R&D.

#3 — Spain is 3rd in the EU in Clinical Trials, with Catalonia accounting for 75% (119) and ranking 5th in Europe. Same positions for COVID-19 CT, with 130 in Catalonia (data 2021). Top 15 global pharma companies by revenue have clinical trials undergone in Catalonia.

5th — In Europe in terms of scientific output and 12th country in the world

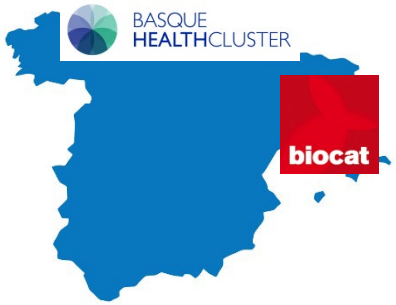
2,800 — Companies involved in biotech activities and more than 713 strictly biotech.

425 — Pharma companies set up in Spain, 60% of them are foreign. Pharma exports represent 23% of the total of high technology products in Spain.

80 — Science and technology parks, research centers, technology institutes and universities with state-of-the-art technology for research

€ +225M — Raised by biotech and Life Sciences startups in 2020.

BioClusters Contributors to this report



Focus

with an interesting combination of tax measures & incentives for biopharma R&D. Biocat is a public-private organization supported by local and regional governments and key public and private players.

Executive summary

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Spain

Key recommendations

	Pain points	Success stories	Opportunities
Education	• To meet demand for capacities in light of the changes in the life sciences and healthcare System • Attracting and retaining talent • To boost the critical mass of executive talent to scale up the life sciences and healthcare ecosystem	• **Centro Tknika** is a centre promoted by the Deputy Ministry of Vocational Education and Training of the Education Department of the Basque Government.	• Scale-up of the success story (Centro Tknika, Basque Region) • Co-development of new training and educationl modules for Biomanufacturing
Innovation	• Attracting and retaining talent • Funding for Companies to suport scale-up in research	• **Catalan Advanced Therapies Hub**: Emerging therapies and personalized medicine HUB, currently being developed with the support of Biocat.	• Re-industrialisation strategy • Territorial balance policies for competitive industries • NextGen EU funds • Regional Hubs
Business	• Fragmented funding • High competition to reach funds for smaller companies • Lack of large investments / equity investors (early stage)	• **Viralgen** is a CDMO JV between Askbio and Columbus, Venture Partners with service offerings to the gene therapy market. • Institutional CAR-T development in the Andalusian network for the Research and Transfer of Advanced Therapies.	• Policy support to keep the decision power in Spain/Europe (i.e Viralgen) • New initiatives such as the Catalan Advanced Biotherapies Hub • Spanish government offers funding, low interest loans during the startup and growth phases, along with incentives and tax deductions that drive growth in the industry.

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Conclusions and Next steps

«The Spanish R&D model is characterized by a talented research and innovation ecosystem, with strong regional ecosystems, in biomanufacturing especially located in Catalonia, the Basque country and Madrid area.»

- Supportive regional governments with an interesting combination of tax measures & incentives for biopharma R&D. Biocat is a public-private organization supported by local and regional governments and key public and private players.
- Supportive Regulatory agency Catalonia is #2 in clinical trials per capita(2017) and #5 in Europe for Covid-19 clinical trials (116). All world top 15 pharma by revenue have clinical trials underway in Catalonia.

Next steps are:

- To develop further and scale up specific profesional/vocational training to feed the demand
- To support the interaction between industry and technology suppliers
- To Tackle possible barriers to competitiveness in attracting innovative and executive talent
- To push for more governmental support for mid to large CDMOs and related, to ensure expansion, not only at the Company's risks

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Scandinavia
Executive summary & main issues

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Scandinavia

"The Scandinavian R&D model is characterized by supportive governments, high level of integration between academia and industry"

#2 & #3 & #4

Sweden, Denmark and Finland are respectively ranked 2nd, 3r and 4th on tertiary education and R&D occupation.

3.1%

Sweden spends 3.1% of its GDP on R&D, the sixth highest level of any country

3th

Denmark has the third highest rate of life science employees per capita in Europe

50%

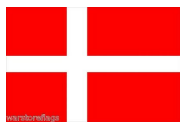
Exports account for 50% of GDP and foreign-owned companies are responsible for around half of Swedish exports.

74

For the European biotechnology sector in 2020, there were 74 listings for Nasdaq Nordic, compared to 43 for London and 12 for Switzerland.

SDGs

Strong compliance towards SDGs



Main BioClusters

Focus

Above average investment in Research and Development

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Scandinavia

	Pain points	Success stories	Opportunities
Education	• Talent development stretch vs future demand • Upskilling and re-skilling of labor force • Digitalization in Lifesciences • Talent chase, and high competition to attract	• Fermentation Based Biomanufacturing initiative • Competence Centre for Advanced BioProduction by Continuous Processing, AdBIOPRO	• Strong academic- business connection • International scope • Attract talent policies • Strong vocational training programmes through integrated approaches
Innovation	• Scalability • Fragmented system • Gender gap • Need for more upskilling programmes • Academic Culture vs entrepreneur culture (i.e scientific excellence vs business results)	• Testa Center • Kuopio Center for Gene and Cell Therapy (KCT)	• Green Manufacturing leadership • University and business codevelopment policies • Education rankings towards start-up developments • Facilities
Business	• Each country has specific issues: • Denmark depending too much on the large corporations • Sweden with high level of start up funding, but issues to keep up on larger funding • Finland has issues on the early phase funding	• Aztrazeneca • NovoNordisk • Cambrex • Cytiva And their interactions with the smaller actors and Education partners	• Dynamic ecosystem • International attractiveness • Stability • High involvement of public sector • High level of public-private partnerships

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Conclusions & next steps

The success of the Scandinavian R&D model is characterized by a strong integration of university-industry collaboration with heavy participation and support of the governments

- Scandinavian countries are **very attractive towards external and international VCs**
- The three countries in study in the report, Sweden, Denmark and Finland **lead the innovation** in Europe
- They are leader in the **Green transition** of their industries and are showing integration of the **Sustainable Development Goals** in own entrepreneurial and research culture.

Next steps are:

- **To develop a pro-active strategy for talents** generation to tackle the needs of many fast-growing companies looking for the same profiles
- To **improve and adapt the funding schemes**' available according to each's country's needs the access to finance for the companies.
- To promote **the digitalization of the sector**, in particular working on industry 4.0 and automation processes

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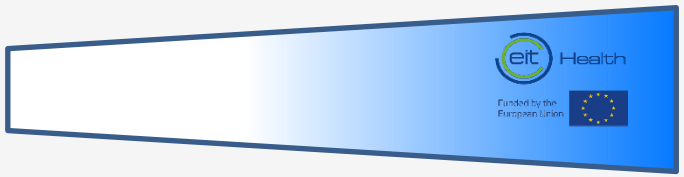
Radar
EIT Health Footprint

EIT Health network Footprint in Belgium

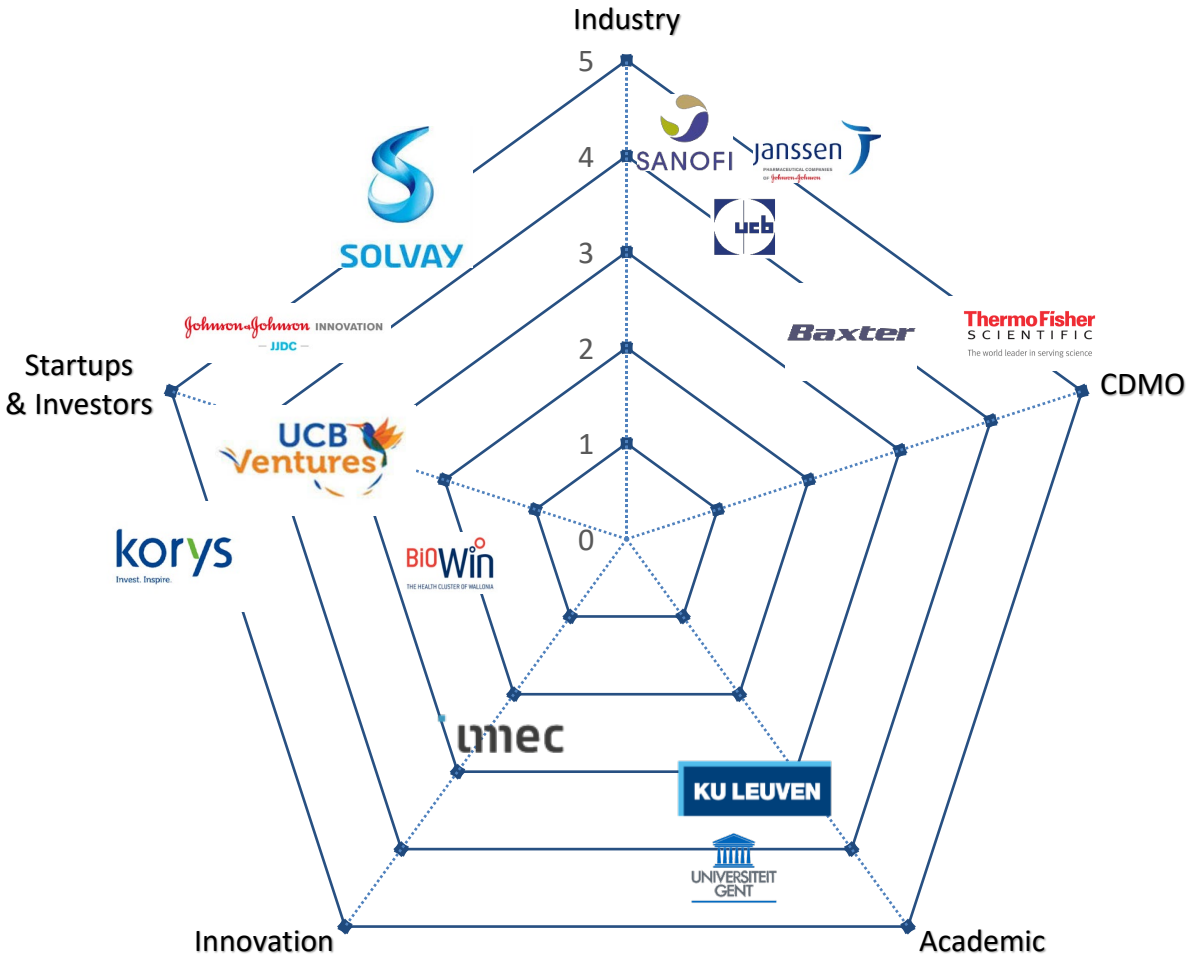
1. Industry
2. CDMO
3. Academic
4. Innovation
5. Start-ups & Investors

Scoring - Partners engagement with EIT Health

Neutral — High



Belgium EIT partners position radar



EIT Health footprint radar

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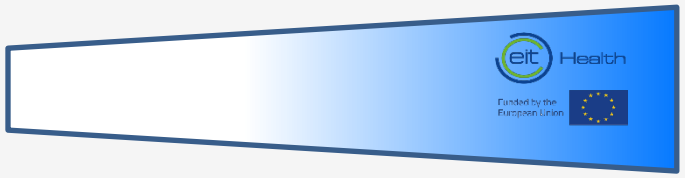
EIT Health Network Footprint in France

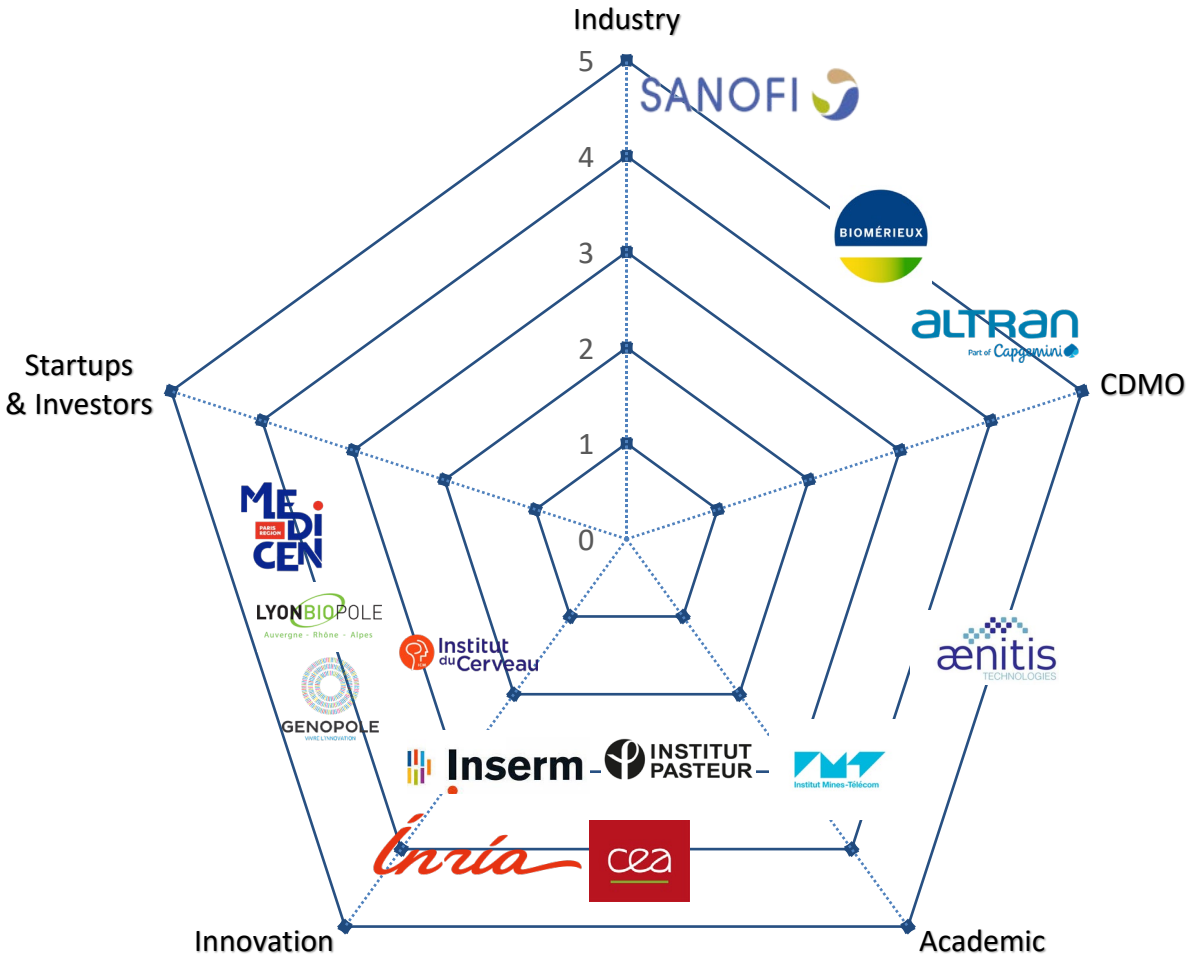
1. Industry
2. CDMO
3. Academic
4. Innovation
5. Start-ups & Investors

Scoring - Partners engagement with EIT Health

Neutral High



French radar



EIT Health footprint radar

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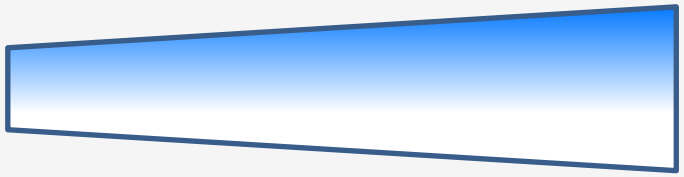
EIT Health Network Footprint in Germany

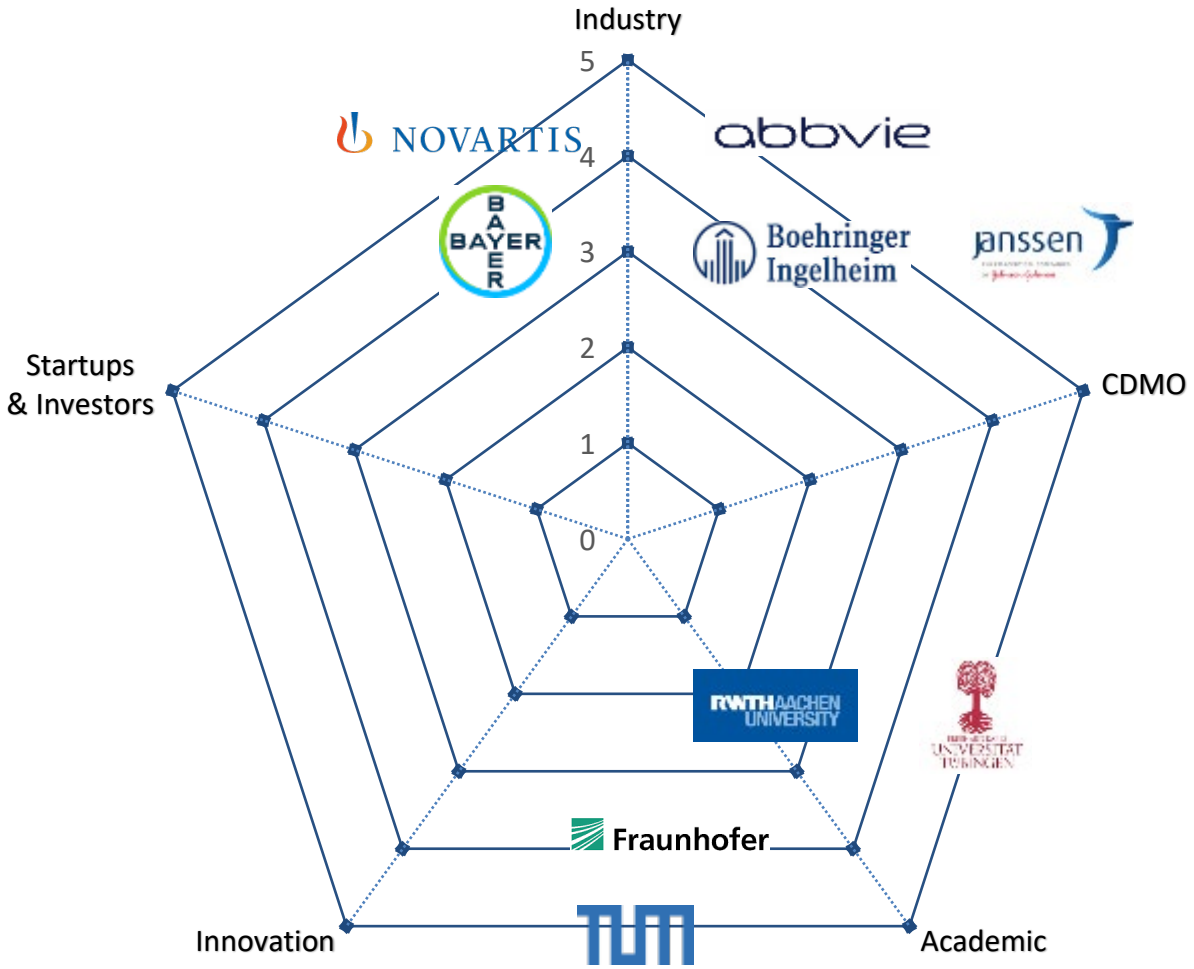
1. Industry
2. CDMO
3. Academic
4. Innovation
5. Start-ups & Investors

Scoring - Partners engagement with EIT Health

Neutral — High



Germany EIT partners position radar



EIT Health footprint radar

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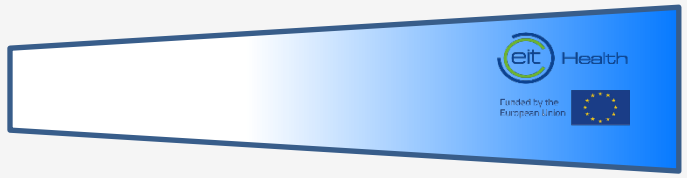
EIT Health network Footprint in the Netherlands

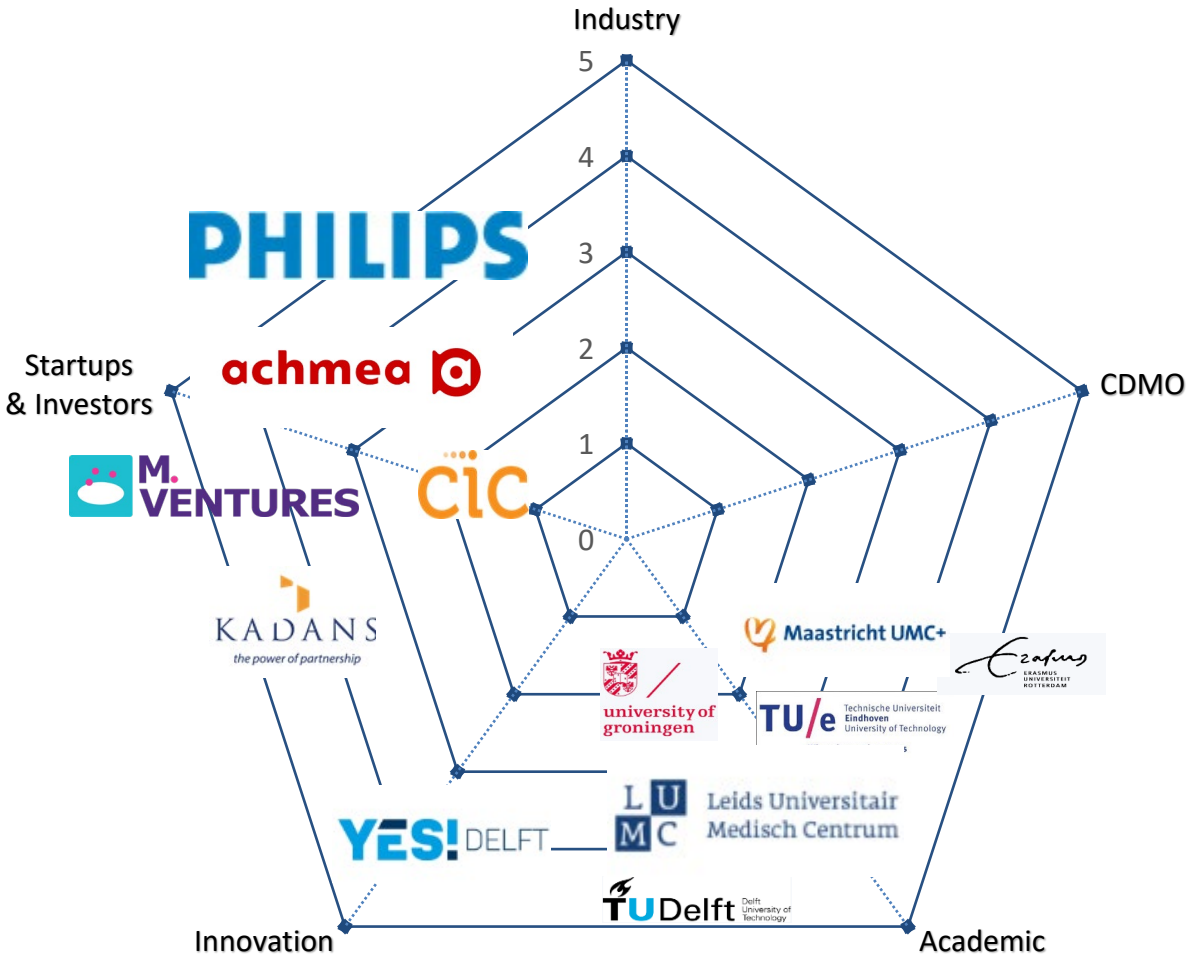
1. Industry
2. CDMO
3. Academic
4. Innovation
5. Start-ups & Investors

Scoring - Partners engagement with EIT Health

Neutral High



Netherlands radar



EIT Health footprint radar

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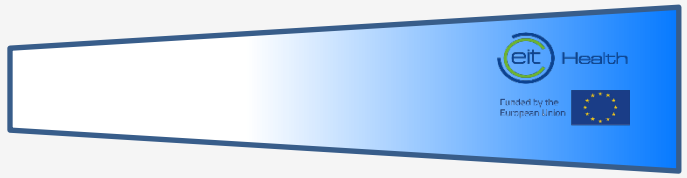
EIT Health Network Footprint in Spain

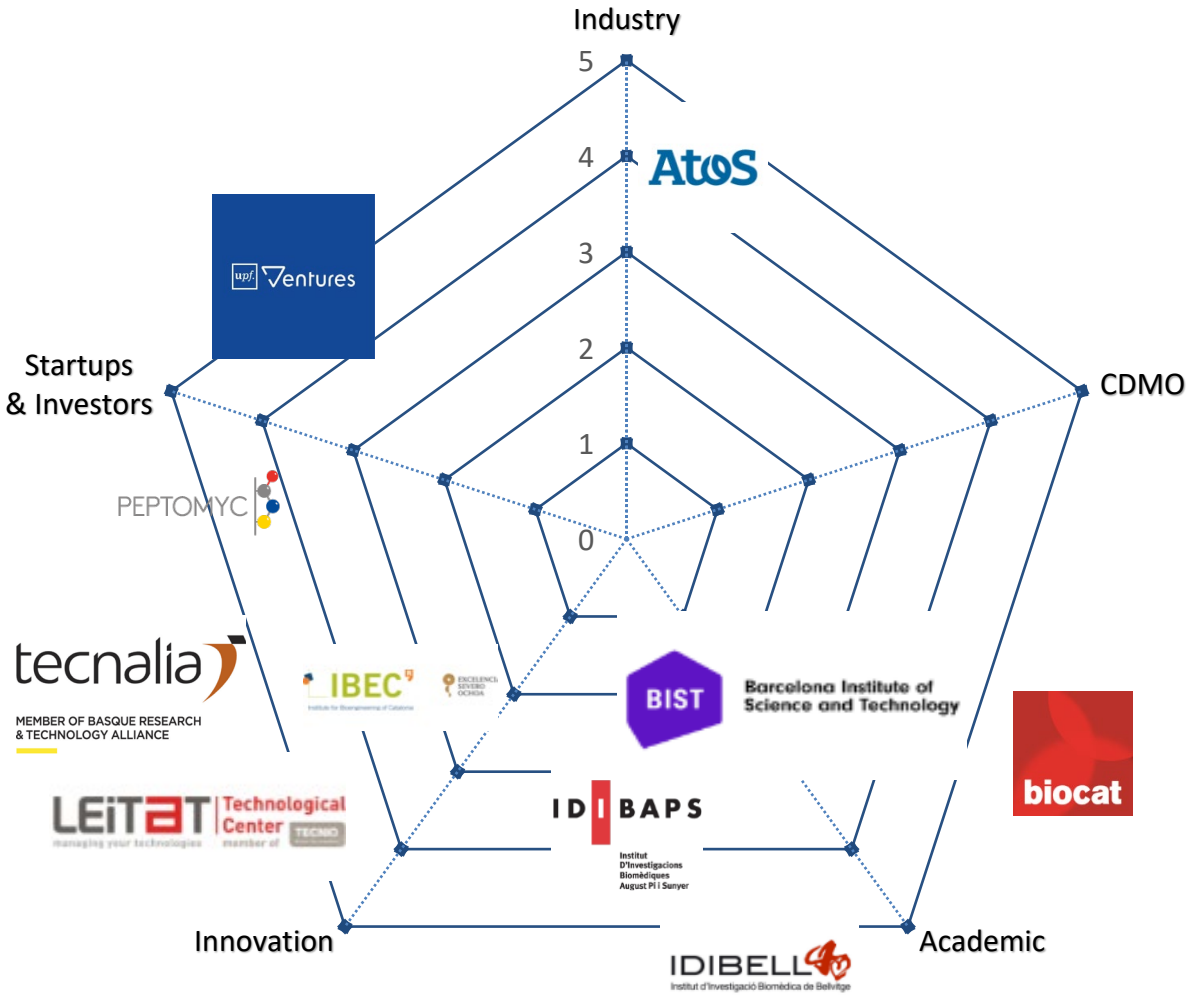
1. Industry
2. CDMO
3. Academic
4. Innovation
5. Start-ups & Investors

Scoring - Partners engagement with EIT Health

Neutral High



Spain radar



EIT Health footprint radar

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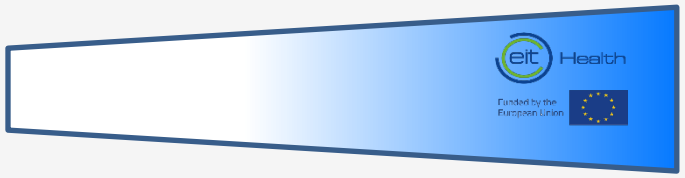
EIT Health Network Footprint in Scandinavia

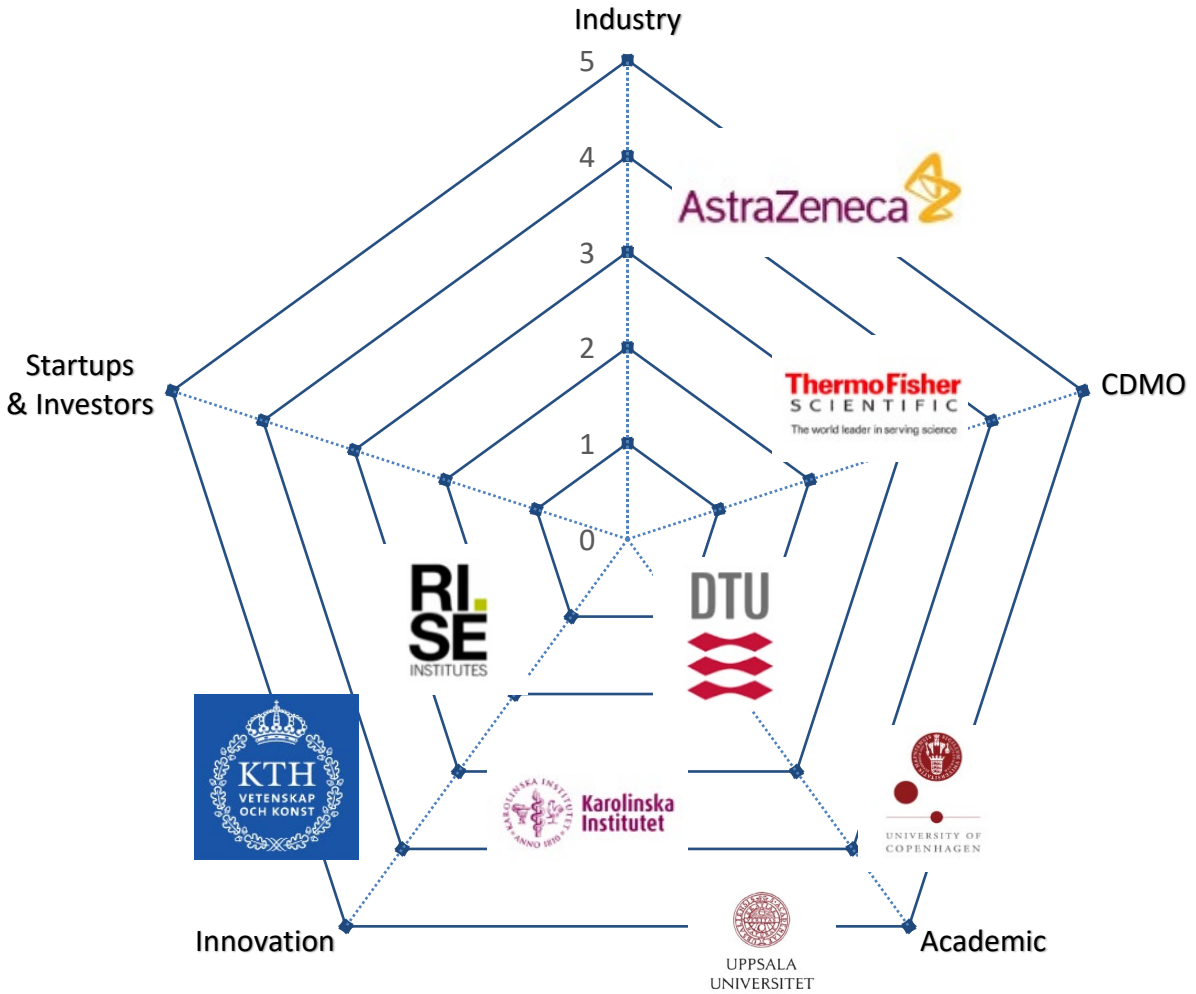
1. Industry
2. CDMO
3. Academic
4. Innovation
5. Start-ups & Investors

Scoring - Partners engagement with EIT Health

High



Scandinavia EIT partners position radar



EIT Health footprint radar

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Part V

Main Conclusions and Levers

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Education - Main conclusions

The development of a biomanufacturing capacity in Europe will necessarily require the training of a new type of professionals both seasoned in the challenges of bioproduction 4.0 but also experts in regulatory issues and specific production standards related to biologics. In this regard, the report shows that the number of professionals trained in these subjects does not meet the current needs of the sector (needs that are expected to increase in the years to come).

On the other hand, several regions in Europe have announced the creation of academic initiatives to meet this challenge. We believe it is important to stress that a concerted effort is necessary to foster collaboration and strengthen European capacities, leveraging and connecting existing educational program at national /regional level. The collaboration efforts between these initiatives and programs should be facilitated through dedicated funding programs, and can be connected through both the cluster community and EIT Health and EIT Manufacturing

We add that the creation of an Erasmus + -type “pan-EU alliance for Education and Innovation” dedicated to bioproduction issues would be desirable to coordinate a comprehensive European School and training offer. EIT Health and EIT Manufacturing, together with CEBR propose to act at this level by developing and financing programs between European establishments and initiatives, for example the Campus Biotech Digital and the European School of Bioproduction recently created in Belgium.

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Innovation - Main conclusions

One of the major challenges of bioproduction activities in Europe, in addition to market opportunities, lies both in reducing production costs and improving the yields of processes , while working on increasing its sustainability. A massive investment is needed to meet this challenge as many of the existing innovations require scaling up and are driven by start-ups or CDMOs that are struggling to raise funds in Europe.

This is also the reason why France and several other Member States have proposed the launch of a Programme of Common European Important Interest (PIIEC) which will make it possible to release substantial budgets to finance infrastructure projects of scope dedicated to health and in particular production capacities or medical technologies. This PIIEC will also finance the industrialization of innovative bioproduction processes, but only manufacturers and SMEs will be eligible. Academics and clinical research centres wishing to join forces will have to find additional funding to participate. In addition, it will probably be difficult for the leaders of these consortia, especially for SMEs, to coordinate such European projects.

Our recommendation is to use the CEBR and EIT Health and EIT Manufacturing networks as a platform for setting up and monitoring PIIEC projects. In addition, the KICs could devote part of their innovation budgets to financing academic and clinical players. Finally, it is essential to seek further for complementarities with other funds such as the FEDER (for regional and cross border initiatives) or Horizon Europe, Next Generation, HERA, and more.

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Business - Main conclusions

The report shows the rich fabric of start-ups and SMEs active in the field of bioproduction and medical technologies, but it also shows that most of the large investments made in recent years come from non-European players, particularly in CDMOs. **On this issue, our recommendation is to offer start-ups and / or CDMOS granted through the PIIEC to benefit from privileged access to the co-investment programme developed by the European Investment Fund (EIF) in partnership with EIT Health, the Venture Centre of Excellence.**

Indeed, this program launched in October 2020 brings together investment and industrial funds in the sector, a program financially supported by the European Commission, by the EIF and by EIT Health, it has at this stage a total capacity of co-investments of 1.7 billion euros, a capacity which should grow in the coming months by recruiting other manufacturers and venture capital funds to cover all member states. This program enables European start-ups or SMEs in the healthcare sector to raise significant funds for their scale-up through venture capital companies based in Europe. In addition, these start-ups or SMEs will be able to benefit from EIT Health or EIT Manufacturing acceleration programs in their internationalization trajectory.

Our report also stresses the role of clusters to promote joint initiatives to strengthen the sector and address value chain disruptions at EU level. The role of cluster organisations in these innovative ecosystems to accelerate business and scale up the industry is revealed as key.

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Levers

Topics	Levers	Link with other EU prog / tools
Education	• Potential Cross-KIC EIT Health & EIT Manufacturing • European Innovation ecosystems	• European skills Chart • Erasmus+ Alliance for Innovation and Education • **European Health Emergency Preparedness and Response Authority (HERA)**
Innovation	• Potential Cross-KIC EIT Health & EIT Manufacturing • European Innovation ecosystems	• Important Project of Common European Interest (IPCEI) • **European Health Emergency Preparedness and Response Authority (HERA)** • Regional Development Fund for Innovation
Business	• Venture Centre of Excellence (EIF /EIB) • European Investment Bank guaranteed loans	• Invest EU Programme • **European Health Emergency Preparedness and Response Authority (HERA)**

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More information

www.cebr.net

https://eithealth.eu

https://eitmanufacturing.eu/

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