



# Belgium



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# Agenda



## 1. Main issues and executive summary Belgium

- a. Executive summary
- b. Key recommendations
- c. Belgium context specificity: **a strong country for Biopharma supply chain & logistics**

## 2. Tackling the talent gap and the talent crunch in biomanufacturing in Europe

- a. Academic Ecosystem: **strong academics & research centres**
- b. Talent policy: **one of the highest worldwide rate in Life Sciences Graduates**
- c. Success story: **ExeVir Bio**
- d. Opportunity: **European Biotechnology School Creation**

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- a. Innovation capabilities: **A strong Pharma Valley**
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- c. Success stories: **Vaccines Production Leaders**
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## Part II

# Main issues and **executive summary** Belgium





# 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

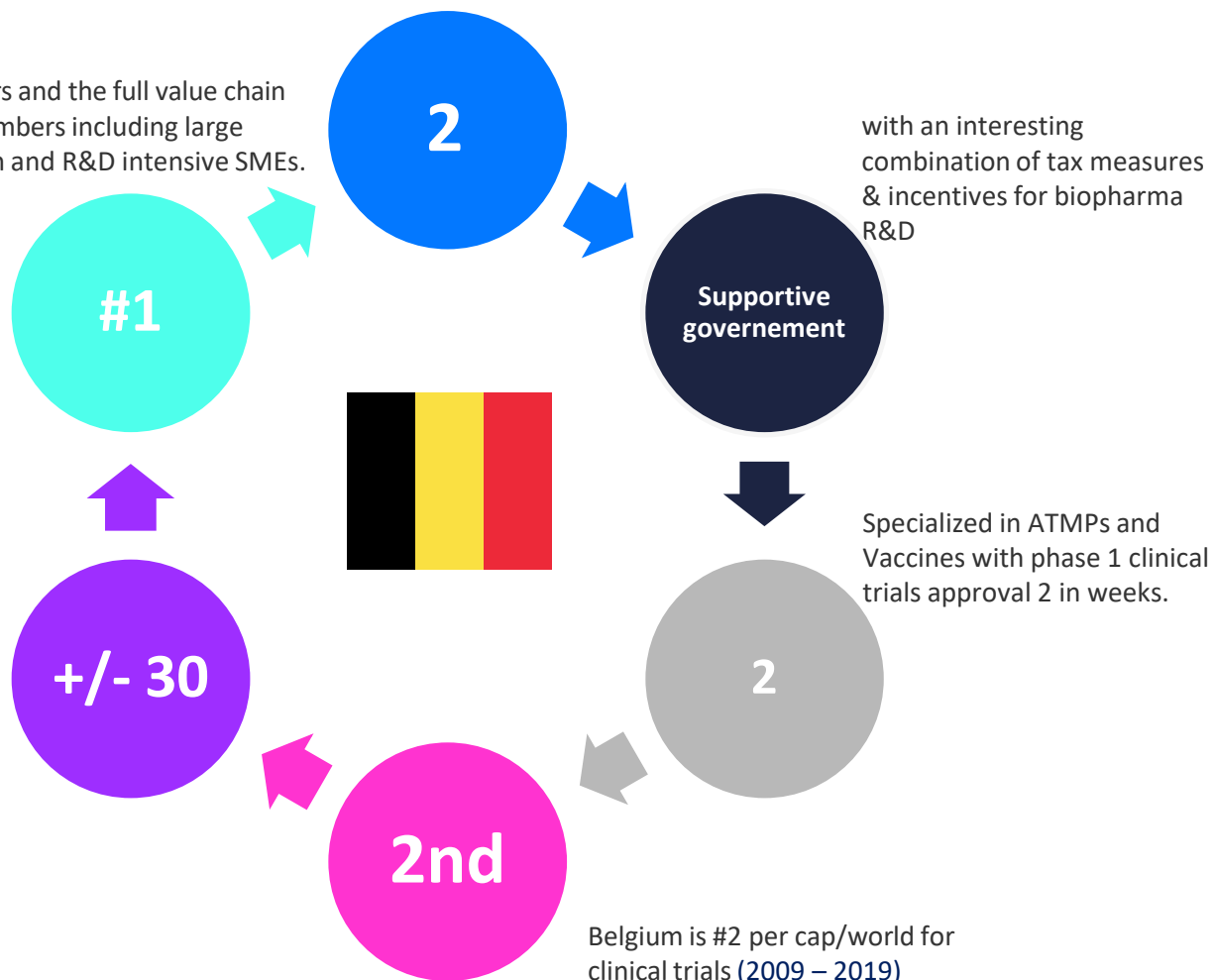
- BioWin gathers 235 members and the full value chain
- flanders.bio gathers 340 members including large biopharma, scale-up biotech and R&D intensive SMEs.

### 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

fundraisings in biotech/bioproduct in 2020



## BioClusters contributing to the 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

# Belgium



## 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

## Success stories

- **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)!

## Opportunities

- 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



# Contributors to this report



**Willem Dhodge,**  
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CLC Director at EIT Health Belgium &  
The Netherlands



**José Castillo**  
CSO & co-Founder Univercells



**Sylvie Ponchaut,**  
managing director Biowin



**Franck Toussaint**  
Managing Director  
BSMA Europe



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# Belgium

## Context specificity



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# Belgium a strong country for Biopharma supply chain & logistics

“Supply chain functions has become crucial over the last years. 2020 has shown us how this role was vital. From securing strategic supplies, avoiding disruptions, enabling manufacturing capacity and scale up and ensuring efficient distribution, cold chain and logistics, all biomanufacturers were under pressure. A performing environment is key to provide the world with medicines and therapies, should adapt permanently and integrate transformation such as digital supply chains.”

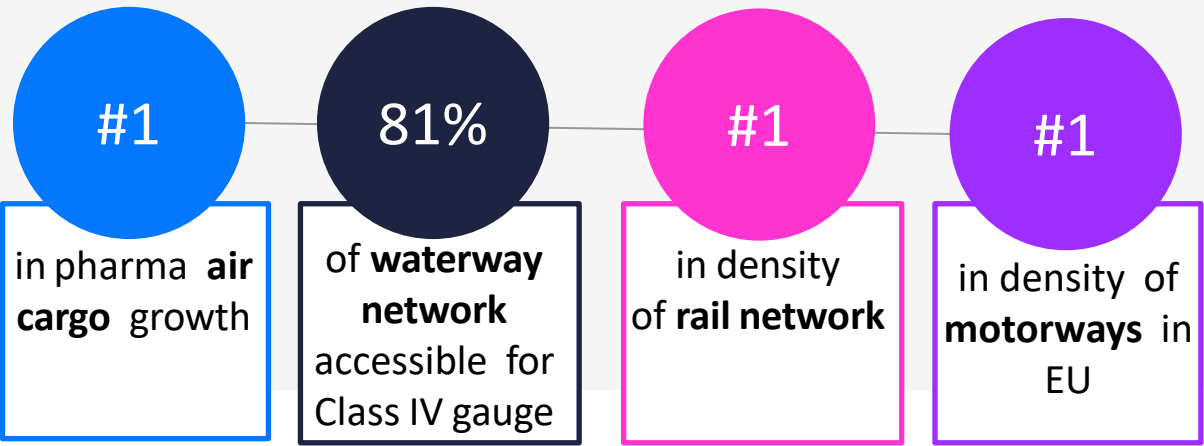


Franck Toussaint  
Managing Director  
BSMA Europe



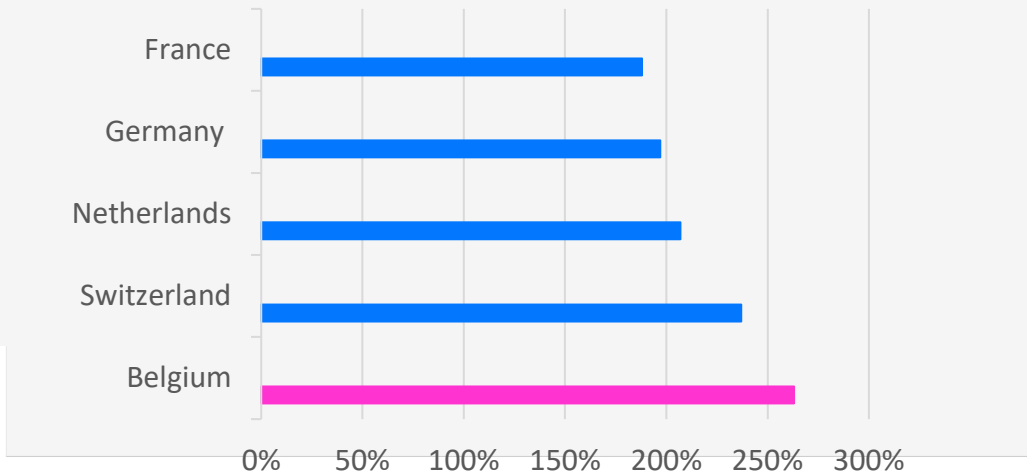
**Liège airport in Wallonia  
chosen by WHO as  
European Covid-19 logistics platform**

## Growth in pharmaceutical air freight, density of motorway and rail networks:



## Belgium exhibited the strongest of pharmaceutical air cargo between 2000 and 2017

Pharma air cargo volume growth %, 2000-2017





Part II.A

# Tackling the talent gap and the talent crunch in biomanufacturing in Europe 🎓 🇧🇪



# Belgium has strong academics & research centres



## KU LEUVEN

The university has invested nearly 15 million euros in spin-offs over the past 10 years. This is nothing compared to the amount invested by external investors attracted to the ecosystem over the same period: 1.1 billion euros.

## KU LEUVEN ecosystem & key figures



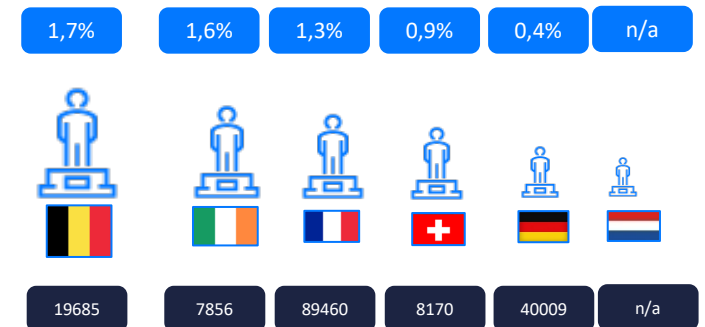
180.580

Students from universities and high school (2016-2017)

2.500/  
year

People following a lifelong training

Belgium has more graduates in Life Sciences & Health per capita than neighbouring countries...



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# Belgium has a proactive talent development policy

More graduates in Life Sciences & Health per capita than neighboring countries...



## Flanders



- **Lecture programme by biotech professionals** to young graduates at Flemish universities & university colleges (OPINNO)
- Centralised job & vacancy database at [flanders.bio](https://flanders.bio)
- Dedicated training programme on BD, GMP and clinica

## Wallonia



### Creation of a public – private "Biotech School" based on:

- **Active watch driven by the Cluster BioWin** to evaluate in real time the needs of companies in the biomanufacturing sector
- **Creation of a consortium** of companies to centralize job and training offers (one stop shop)
- **Focus on innovative teaching methods** (VR/AR) & digital twins
- **Supported by the regional & federal governments and EU**

*(more details on slide 13)*

## Workforces in the biopharma industry in Belgium



**TOTAL JOBS**  
2019

**121.000+**

**EMPLOYMENT  
GROWTH RATE**  
Since 2015 **+13%**

38.489 **DIRECT JOBS**  
49.035 **INDIRECT JOBS**  
33.639 **INDUCED JOBS**





# Success Story - Education

## Transfer of technology policy in Belgium



### Success story

#### 63% per capita

- Growth of Biotechnology and pharma patent applications to EPO by Belgium since 2012.

#### 4 times higher than EU28

- the increase of biopharmaceutical patent applications in Belgium between 2015-2019

#### 15%

- of submitted patent applications become patents



**VIB (Vlaams Instituut voor Biotechnologie) is a world-leading life sciences research institute with:**

- Strong ability to translate scientific results into pharmaceutical and industrial applications and
- Breakthrough research increasing economic growth



The Belgian biotech ExeVir Bio, which is currently developing an anti-Covid-19 drug candidate, will raise 19 million euros in addition to the 23 million already raised in 2020, in order **to finance the production of the 1st European antibody against Covid-19.**

This additional financing is led by Fund + with VIB, UCB Ventures and SFPI-FPIM, and new investors including VIVES IUF, SRIW, Noshag, SambrInvest, as well as several Belgian family offices.

**ExeVir Bio is a spin-off of the VIB of the UGent created on the basis of the discoveries of two professors.**



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# Opportunity - Education Pillar

European biotechnology school and a health hub at the heart of the Biopark ecosystem in Gosselies

As part of the Belgium recovery plan, Wallonia with 25 Mio € investment will create by 2025 a **European biotechnology school and a health hub** at the heart of the Biopark ecosystem in Gosselies.

- “One stop shop” interdisciplinary platform available for start-up, scale-up or international actors
- Focus on Biotechnology & Biopharmacy and new generation Bioproduction
- Digitalisation, machine learning and artificial intelligence
- Soft skills & Mini MBA to support young companies to acquire commercial and management skills
- Strategy for attracting talents from Belgium and abroad

Today, the sector assesses the needs of businesses at :

**2,400**

jobs creation for the next three years, in Wallonia alone.

**700 - 800**

positions are said to be currently vacant

**2,150**

new positions were opened in this sector

**700**

more new positions opened in comparison with 2019



**This shortage of manpower concerns "almost all types of functions,** as well the laboratory assistants as the engineers in development or the scientific profiles, at the level production processes. The local pool is exhausted, so we must attract foreign profiles, or train existing profiles."



**Hughes Bultot, CEO of Univercells**



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Part II.B

Research to

**Innovation**  



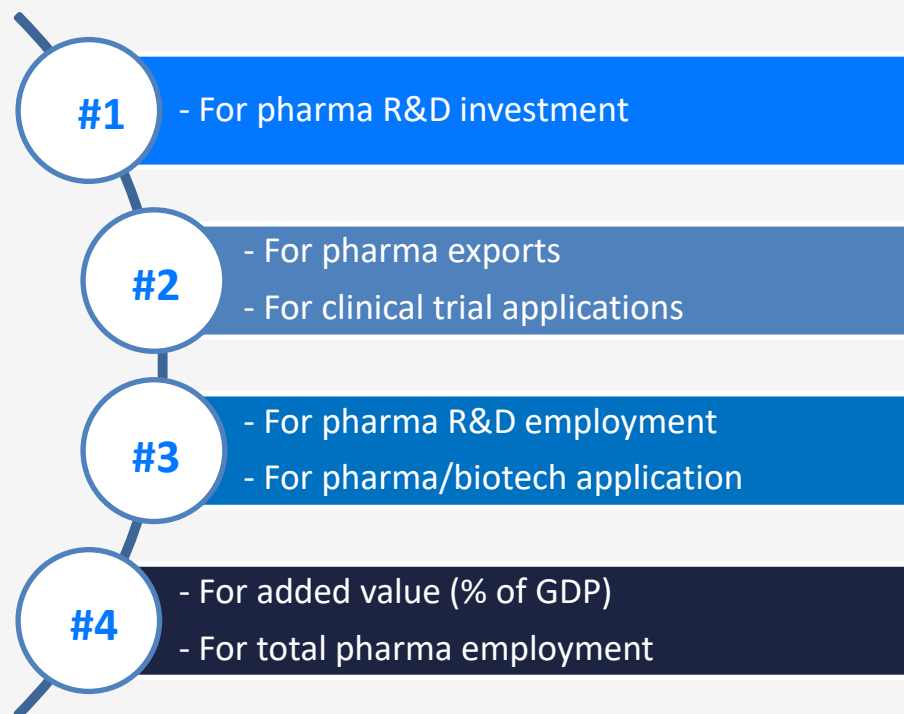
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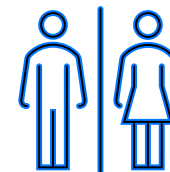
# Innovation capabilities in Belgium



**Belgium, and its regions Flanders & Wallonia, form an innovative biopharma valley in Europe**



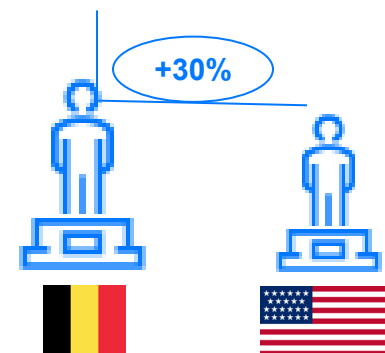
The chemical and pharmaceutical sector has **more than 11,000 employees active in R&D**



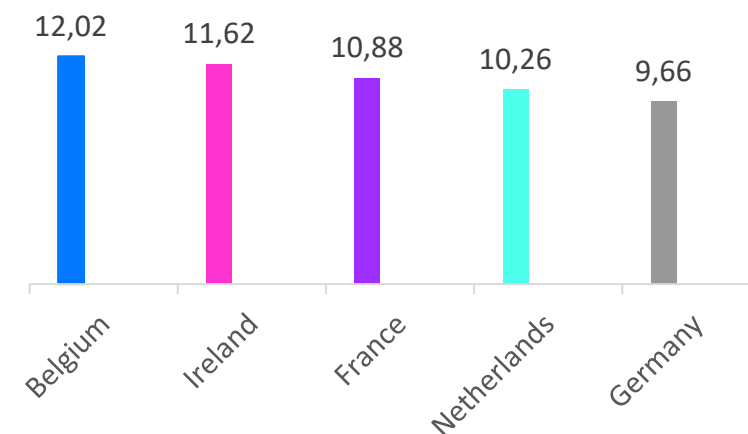
**One in two researchers is a woman in Belgium.**

**More researchers per 1,000 employees**

in Belgium than in the US



**Number of researchers  
# per 1,000 employees, 2018**





# Belgium innovation policy

Access to Finance: Strong presence of public investors sector to support the development of innovative technologies in Biomanufacturing



## INVESTMENTS 2019

Companies' investment  
in R&D of new vaccines  
and treatments in  
Belgium



3.8 B €

+50% in 5  
years

In addition to these private actors, regional governments also release funds for Belgian biotech start-ups through entities such as the Participation Company Flanders (PMV) and the Regional Investment Company of Wallonia (SRIW). According to BNP Paribas, **these local investments from both private and public actors create a "snowball effect" attracting foreign investors.**



	EU Countries	R&D Intensity	Intramural R&D Expenses (mEuros)
1	Belgium	17,7 %	2.904
2	Slovenia	17,7 %	228
3	Germany	17,5 %	9.987
4	Sweden	16,5 %	1.237
5	France	15,4 %	5.041
6	Danemark	15,4 %	1.776
7	Croatia	14,4 %	65
8	Austria	10,3 %	627
9	Portugal	8,7 %	138
10	Finlandia	8,1 %	309
	EU 27	11,1 %	26.348

**But the Belgian authorities are not only helping with funds.** The Belgian government approves human clinical trials within 15 to 20 days, while in neighboring France, the fast-track procedure takes 40 days. **Thanks to this favorable environment, more than 1,500 clinical trials are currently underway in Belgium.**



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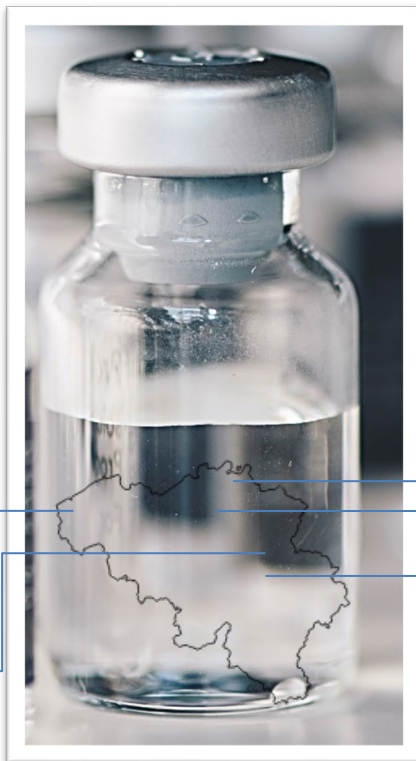


# VACCINES: Belgium at the center of the Covid-19 Vaccines Bioproduction




R&D and Bioproduction of Covid-19 vaccines in Belgium as of December 2020

## R&D



## Bioproduction



 now supporting the CureVac Covid-19 Vaccine production



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# Factories of the Future by Digital Wallonia and Made Different

Reaching the Level of Excellence in Industry 4.0

Digital Wallonia is the Digital strategy of Wallonia. Its Regional program

« Industrie du Futur 2020-2024 » aims to:

- Support the competitive advantage, economic resilience and adaptability of the wallonian industry by using **digital transformation**
- Develop decision-making aid tools for the manufacturing companies
- Organise events and workshops to make companies aware of the 4.0 opportunities
- Highlight manufacturing companies which have performed in the digital transformation by giving a label of excellence « Factory of the Future »

Launched in 2017, the « Factory of the Future Awards » has honoured 6 enterprises in Wallonia :

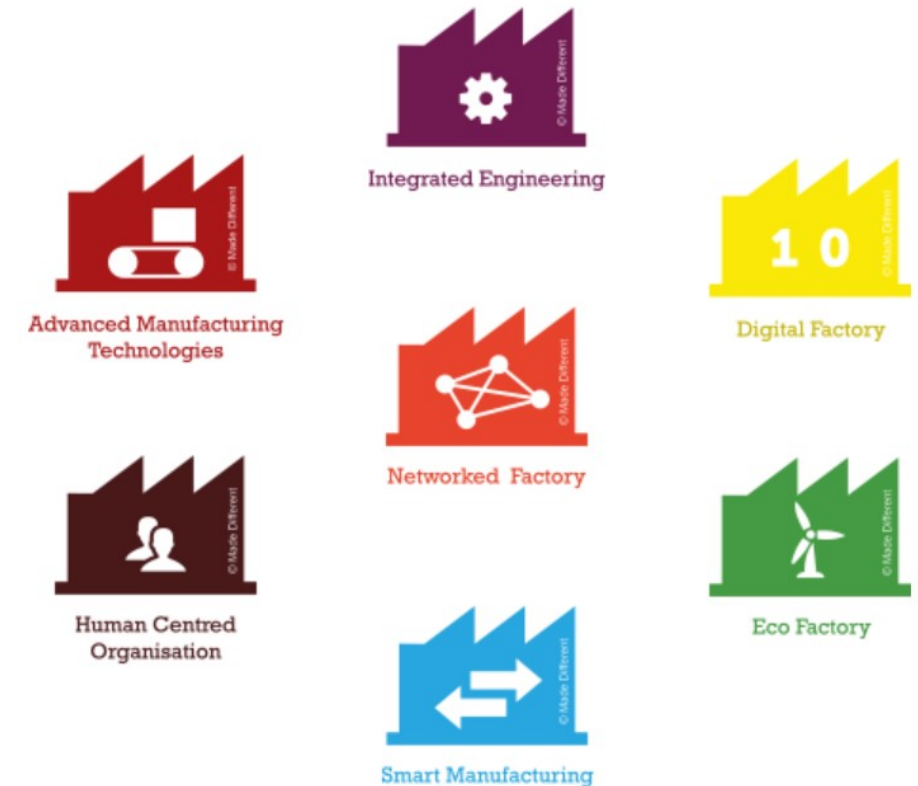
- Jumo Automation, Alstom Belgium, Valeo, AW Europe, Stas, Jtekt
- Yet no biomanufacturing companies at this stage, ongoing!

Made Different action plan is designed to give the manufacturing industry in Flanders a future in the industrial landscape of the 21st century.

In total >40 companies have been awarded with the Factory of the future award (since 2015). Some are in the life sciences sector (health, medtech and food), such as Janssen, Dentsply, Rousselot, Nuscience, Cargill.



digital  
wallonia  
.be







Part II.C

# Business

# Innovation



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# Belgium industrial capacity

Belgium has one of highest density of Advanced Therapy Companies in the world



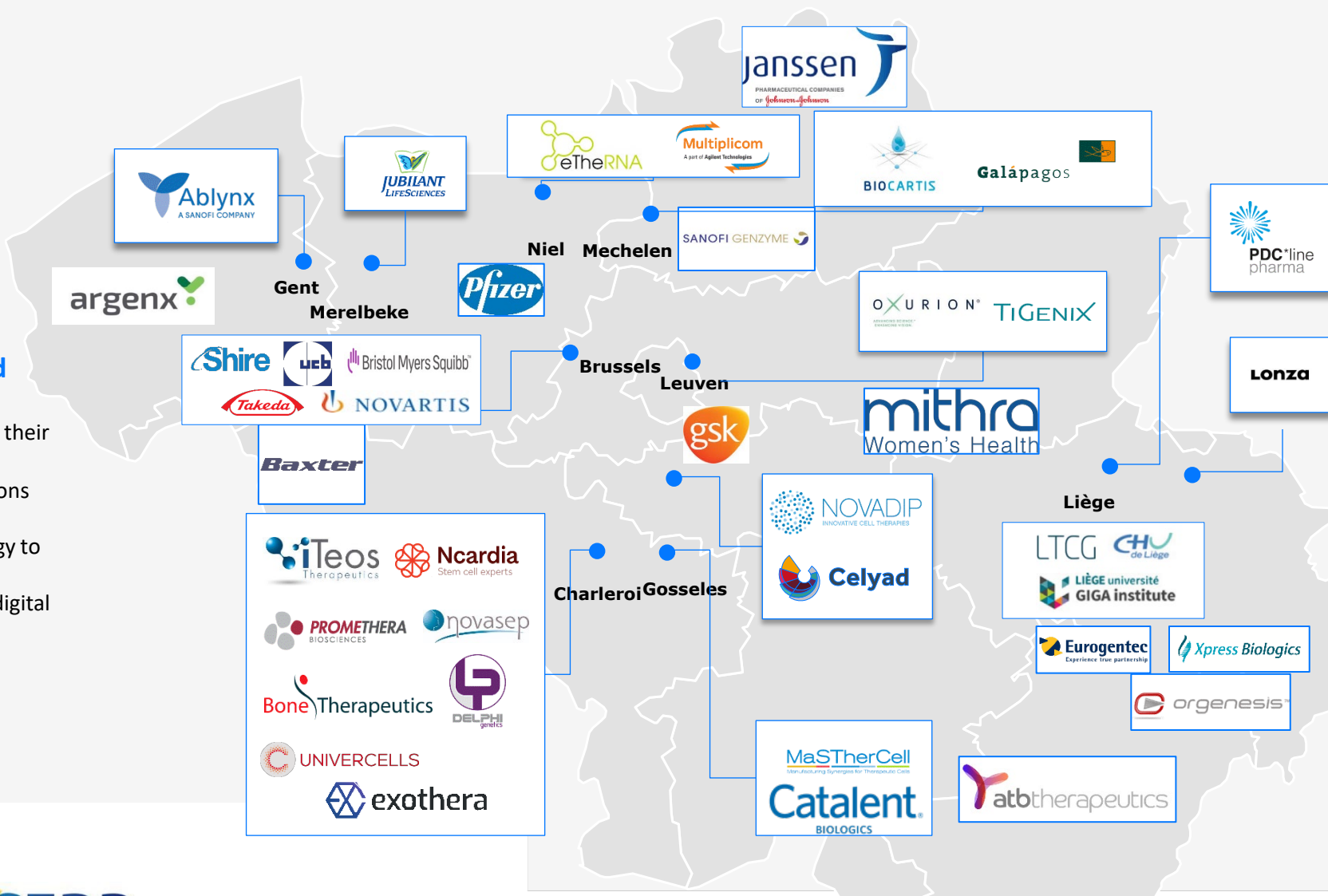
## EXPORTATIONS 2019 ✈️

Exports of medicines and vaccines increased by 16,3%

49,8 B €

Belgium has a diverse ecosystem of industries and research centers active in the Biomanufacturing field

- Pharmaceutical industries (majors, SMEs) developing their own innovative biopharmaceuticals
- Contract development and manufacturing organizations (CDMO)
- Products and services in molecular and cellular biology to optimize bioproduction
- Products and services companies in engineering and digital technologies to design the bioprocesses and plan
- General support companies



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# Access to Finance



**Access to Finance:** Strong presence of public investors sector to support the development of innovative technologies in Biomanufacturing

- **Federal investor:** SFPI - FPIM
- **Regional investors:**
  - SRIW & Sowalfin, PMV
  - Government: DGO6, Vlaio
  - Local investors : Noshag, Sambrinvest, NamurInvest, NivellInvest, Investsud (FSOL) Luxembourg développement ...
- **Banks:** BNP, Belfius, ING, ...
- **Europe:** loan from BEI, FEI, ...
- **Large Private Investors:** GIMV, Fund+, VBio Ventures, Bioqube Ventures, Capricorn

**Issue:** No clear European investors' presence for supporting companies' growth & development in that field

- **M&A drives investment in the field of biomanufacturing:**
  - 2020: Catalent (US) acquires MaSTherCell for \$325 Mio
  - 2021: ThermoFisher (US) acquires Novasep biologics for €725 Mio
  - Previously Eurogentec was acquired by Kaneka (JPN)
- **2019- 2020:** Univercells +/- \$250 Mio fund raising by foreign foundations and funds. They received a loan from EIB
- **Pfizer invests approx. 80 million** per year in the production site in Puurs (+ new recent investments for production of Covid-19 vaccines)





1

## The problems faced by biopharmaceutical manufacturing

- Too many paper documents that generate human errors
- Problem of data integrity
- Huge workload and long lead time documentation and release process
- Failure to use the power of available data

3

## Our demonstrated results:

- Significant decrease of head count
- No more human error on document
- Shorten release lead time
- No more scribe people in operations
- Release by exception
- Availability of data for data mining

2

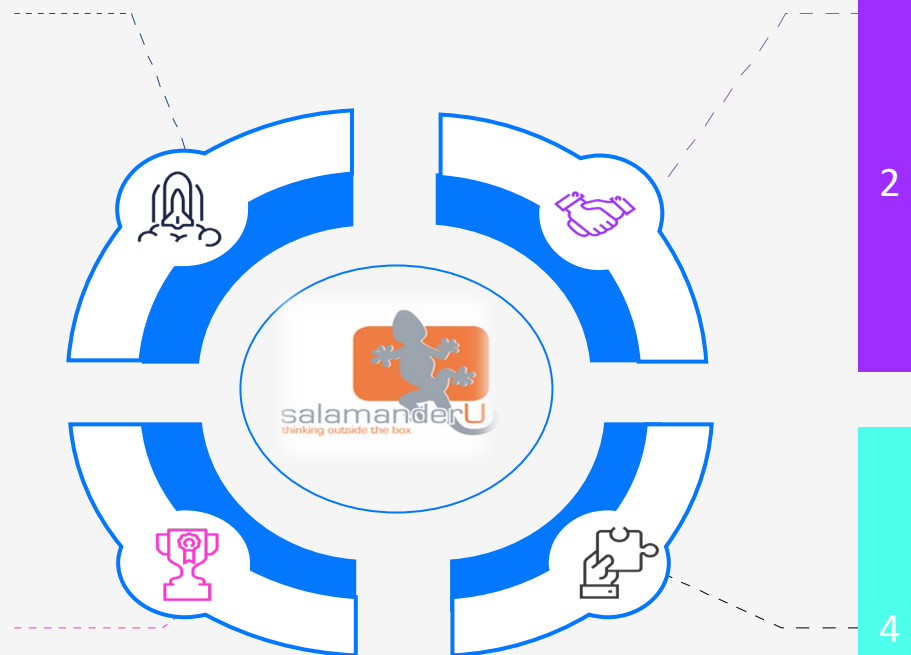
## Our digital solution SmartReg: e-BR+MES

- Real time data recording and acquisition
- Patented voice interfaces – Text to speech & Voice Recognition
- Manage operation, automatization & process equipment integration
- Regulatory Compliance

4

## The challenges we managed:

- Culture of change “digital transformation”
- Pilot the re-engineering of processes and related paper documentation
- We are innovative, expertise of content and solutions oriented







# Univercells – Biologics for all!

*"We dream of a world where people can equally live up to their full potential and are free to take their destiny into their hands."*



José Castillo  
CSO & co-Founder

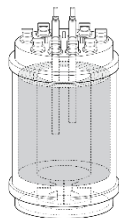


At the base of **UNIVERCELLS**:

- **Affordability driven by** re-invented bio-production technology

**INTENSIFICATION** through **scale-X™**

Very **high cell-density** bioreactor technology



**CHAINING** through **NevoLine™**

Fully integrated and automated process

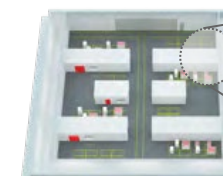


**Standard**

**NevoLine™**



5x750 L bioreactors  
**50M doses/y**



**4x NevoLine**  
(600 m² bioreactors)  
**50M doses/y**



CAPEX (USD M)	NevoLine	<div></div>	<b>~20</b>
	Standard	<div></div>	~ 200
Footprint (m²)	NevoLine	<div></div>	<b>1,500m²</b>
	Standard	<div></div>	~ 10,000m²
CoGs (/dose)	NevoLine	<div></div>	<b>&lt;\$ 0.30</b>
	Standard	<div></div>	\$ 1.2-1.5

**Impact**

- > Intensification and chaining leading to reduced footprint (7x), labor and materials usage
- > Lower footprint enabling reduced facility CAPEX (up to 10x) and operating costs (up to 5x)
- > Enabling technology transfer for local production in an **AFFORDABLE** manner



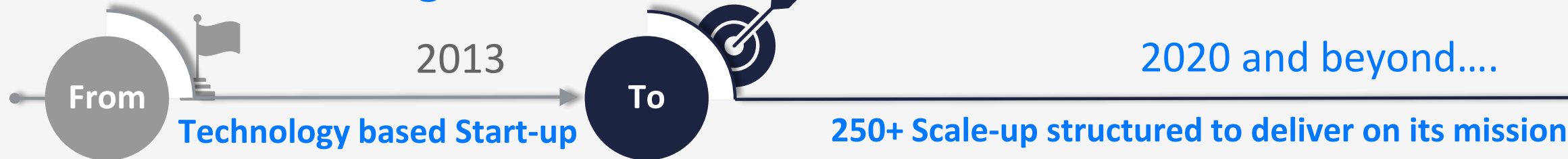
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# Univercells – Biologics for all !



## Key investors and partners

BILL & MELINDA  
GATES foundation



World Health  
Organization

NIH National Institutes of Health

CEPI

Takeda  
TAKEDA VENTURES, INC.

GLOBAL HEALTH  
INVESTMENT FUND

European  
Investment  
Bank

KKR

inventures I  
Impact venture capital fund

true friend Korea Investment  
Partners Co., Ltd.

INNOVATION  
FUND

## Technology-centric

### Re-invented viral manufacturing technologies

- Next generation bioprocessing and manufacturing technologies;
- Intensification and chaining of bioproduction.

UNIVERCELLS  
Technologies

## Process-centric

### Best-in-class development and manufacturing expertise

- Innovative bioproduction platforms to deliver optimized processes
- Bridge the clinical gap and rapidly reach commercial scale production

exothera

## Product-centric

### The vaccine manufacturer for Global Health

- Supplying affordable finished products to market; and
- Tech transfer of manufacturing facilities for specific products, including processes and protocols.

UNIVERCELLS  
Vaccines

## Patient-centric

### Make technology transfer a REALITY !

- Creating the health systems to diagnose and treat patients; with
- Local bioproduction capacity.

unizima

eit Health

eit Manufacturing

CEBR  
Council of European BioRegions

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# 2021: Acquisitions and developments



## ThermoFisher (US) acquires Novasep biologics for €725 Mio

This transaction illustrates the major interest in the production of viral vectors, reinforced by the coronavirus crisis.

Repurchases and investments have thus multiplied in recent months, to the point of making these production capacities strategic elements for CDMOs.

For Novasep, this transaction could initiate a refocusing on the **production of active ingredients via its Synthesis Solution business unit.**



The transaction includes the two production sites of Novasep, based in Seneffe and Gosselies

## Ghent site of Legend



### Legend Biotech Announces Advancement of Global Manufacturing Infrastructure

New Cell Therapy Facility in Belgium Establishes Manufacturing Presence in the European Union

New facility builds upon Legend Biotech's collaboration with Janssen to advance the manufacturing of investigational CAR-T therapy ciltacabtagene autoleucel (cilta-cel), being developed for the treatment of multiple myeloma

SOMERSET, N.J.— June 22, 2021 — Legend Biotech Corporation (Legend Biotech, NASDAQ: LEGN), a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications, announced the establishment of a state-of-the-art manufacturing facility in Belgium, as part of a joint investment with Janssen Pharmaceutica NV (Janssen), to expand global manufacturing capacity of innovative cellular therapies.



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# With strategic service providers such as CDMO

**Contract Development and Manufacturing Organizations** proposing biomanufacturing services and facilities

- The research stage of a molecule (process development)
- At time of the bio-production and pre-marketing certification processes (manufacturing).

**Catalent**  
BIOLOGICS

**MaSTerCell** was created by the regional government and the cluster BioWin to develop a platform for cell therapy manufacturing. Then it became a private company expanding to the US and South Korea before being acquired by Catalent to create **Catalent Biologics**



**MaSTherCell**  
Manufacturing Synergies for Therapeutic Cells



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Part VI

# Conclusions and **next steps** **Belgium**



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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



# EIT Health Belgium members engagement

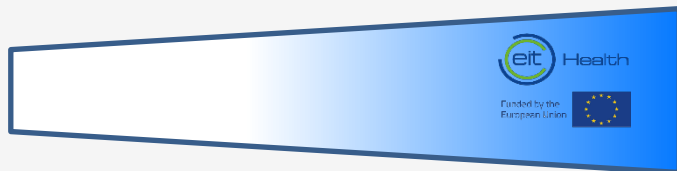


1. Industry
2. CDMO
3. Academic
4. Innovation
5. Start-ups & Investors

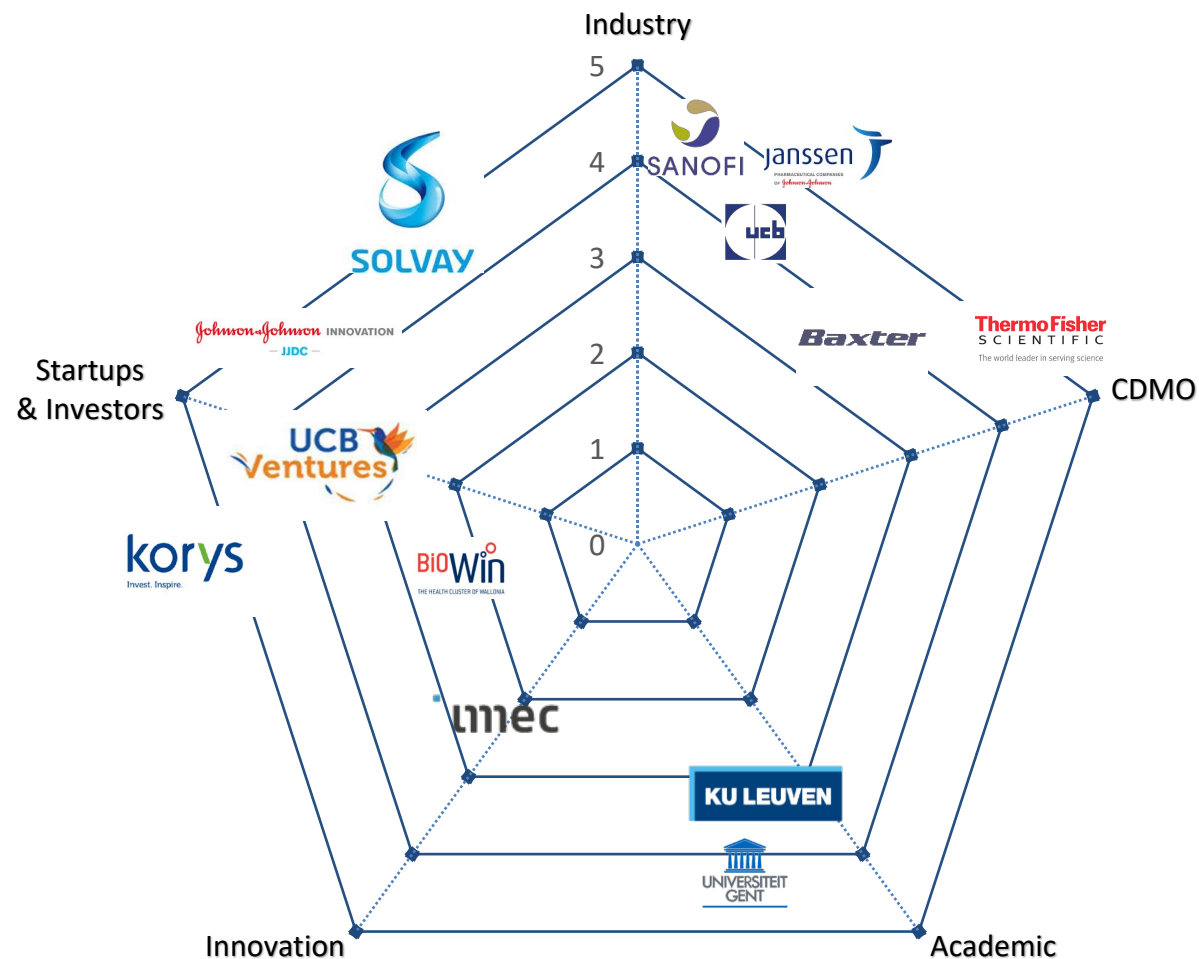
## Scoring - Partners engagement with EIT Health

Neutral

High



## Belgium EIT partners position radar



# References

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- **Eurostat** – Structural Business Statistics & Global Business Activities database
- **CRISP** – L'actionnariat des Entreprises Wallonnes
- **Statbel**
- **Innovationdata.be**
- **Bioinformant database; Biopharmguy**
- **Company websites**
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- **World Intellectual Property Organization**, Economic Research Working Paper No.46, October 2018
- **Wallonia.be**