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Interconnecting Innovation Ecosystems for Common European Data Space in Health



**Funded by the
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D2.6 CASE STUDY: BELGIUM
AUTHORS: CEBR, BIOCAT, SCANBALT



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History of Versions

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Executive Summary

The present Deliverable 2.6 “Case Study Belgium” has been developed within the framework of WP2 “Analysis of ecosystems and innovation agendas” of **EDAH**.

EDAH (Interconnecting innovation ecosystems for common European data space in Health) is a 2-year preparatory action funded by Horizon Europe that aims to contribute to the development of the European Health Data Space. The 4-partners-consortium seeks to establish close collaborations with the EU presidencies during the project’s lifetime, to help prioritise EHDA in their successive agendas. EDAH also seeks to engage a wide range of quadruple helix stakeholders from diverse innovation ecosystems across Europe in identifying barriers and enablers to EHDS, channelling the different Member States’ inputs into EU policy processes. By bridging the current digital health divide in Europe, EDAH contributes to the New European Innovation Agenda with more inclusive, dynamic, diverse and interconnected European innovation ecosystems. **EDAH** aims to unlock the power of health data for innovative medicines and future healthcare by helping develop the European Health Data Space.

The project’s key milestones are:

1. Set an open dialogue to facilitate the agreement among Member States, Associated Countries and EU Regions about key aspects related to EHDS.
2. Advancing towards common legal, governance, data quality and interoperability framework to facilitate the advancement of EHDS.
3. Scaling up good practices and addressing important gaps in the regional and national innovation ecosystems, through a better understanding of the digital health innovation landscape.

This document is the sixth of a series of 7 case studies envisaged in this project (namely Portugal, Czech Republic, Sweden, Bulgaria, Spain, Belgium and Hungary). The studies are connected to the EU presidencies happening during the timespan of this preparatory action, from September 2022 to August 2024, corresponding to the end of Czech Republic’s, Swedish, Spanish, Belgian and the initial weeks of Hungarian Presidency. The following report is focused on Belgium and the readiness of the country with regards to the EHDS implementation. The, demarcated into three highly autonomous regions (the Flemish Region, Flanders; the Walloon Region, Wallonia; and the Brussels-Capital Region). The country is characterized by a highly advanced and high-income economy, providing high quality of life, prioritizing safety and boasting well-established social security and universal healthcare systems and social rights. Belgium's mandatory social health insurance covers approximately 99% of residents, ensuring non-discriminatory access to a wide array of healthcare services. Healthcare services (public or private) operate under a unified regulatory framework, with reimbursement available.

The e-Health sector in Belgium stands at the forefront of digital innovation in healthcare, driven by a robust infrastructure and a history of early adoption of electronic health technologies. Belgium was among the pioneers in implementing electronic health records. In the following pages we’ll see how a notable feature of Belgium's e-Health architecture is the hub-metahub system. With respect to EHDS readiness, multiple national acts are under revision in preparation for the HDA (Health Data Agency) and the implementation of the data space.

Despite these advancements, Belgium acknowledges the need for further progress in utilizing real-world data. The e-Health system primarily focuses on primary care, and challenges arise in using patient information for clinical trials or secondary use. Recent initiatives from various stakeholders, including the Belgian Health Data Agency aim to address these challenges and foster advancements in leveraging health data for improved patient care, healthcare outcomes and innovation in healthcare.

Introduction to this report

Specific objectives of EDAH

The partnership implementing EDAH has five specific objectives:

- O1 – Ensuring a coherent overview of the strategic developments related to the European Health Data Space (EU level policy processes, important initiatives, and projects) and developing a deeper understanding of seven important EU ecosystems (innovation agendas and ecosystem stakeholders) represented by clusters/networks from Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary, and Bulgaria.
- O2 – Setting up a coordination mechanism to connect important stakeholders from innovation ecosystems all around Europe and engage them in focused dialogue around key challenges and opportunities related to advancing the EHDS.
- O3 – Scaling up the dialogue at the EU level via developing further collaboration pathways with EU presidencies.
- O4 – All of the above will be used for, step-by-step, developing, validating, and finalising the Joint Action Plan (JAP) for synergetic work in the interconnected ecosystems of EU health-related clusters/ networks (facilitated by the dialogue mechanisms and collaboration frameworks developed in this project) to jointly advance the development of the EHDS.

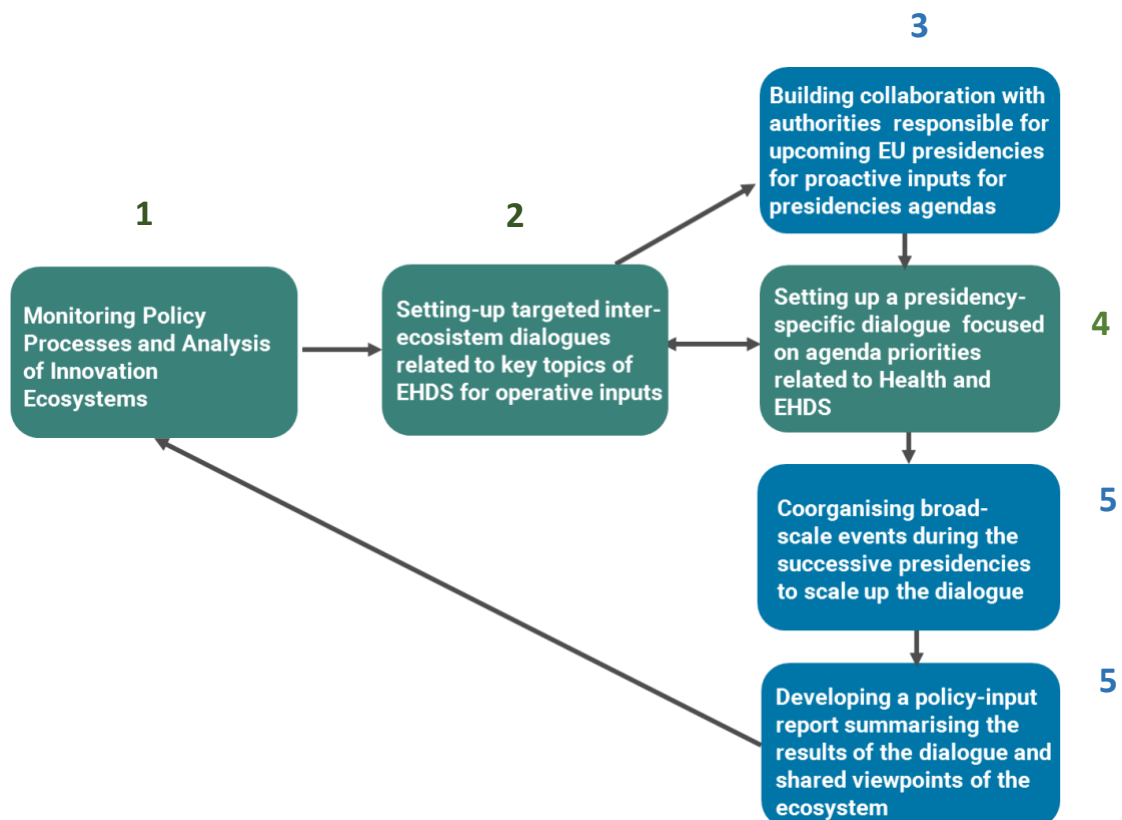


Figure n.1: Workflow of the EDAH project: step 1 is the analysis of Innovation Ecosystems

List of consortium partners and beneficiary numbers

| Beneficiary # | Name | Acronym | Country |
|---------------|--|----------|---------|
| 1 | BIOCAT LA FUNDACIO BIOREGIO DE CATALUNYA | Biocat | ES |
| 2 | HEALTH CLUSTER PORTUGAL | HCP | PT |
| 3 | SCANBALT | ScanBalt | EE |
| 4 | COUNCIL OF EUROPEAN BIOREGIONS | CEBR | BE |

Work Package 2 – Analysis of ecosystems and innovation agendas

Objectives

- Monitoring and analysing strategic EU-level processes related to the development of the European Health Data Space;
- Getting in-depth understanding of seven key innovation ecosystems, namely in Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria;
- Based on the above, identifying good practices, potential for synergies and complementarities in innovation agendas and with ongoing initiatives/processes to advance the development of EHDS as a joint effort of EU interconnected innovation ecosystems.

Task 2.1 Scanning strategic developments regarding European Health Data Space

The consortium continuously tracks advancements in various important EU-level policy processes, monitors progress related to initiatives such as TEHDAS and GAIA-X (e.g., key milestones achieved), relevant new studies and analyses, etc. This information is processed and analysed to identify potential synergies, needs for action and inputs by EDAH to support important developments in line with the idea of more dynamic, inclusive, gender diverse, and connected innovation ecosystems for the joint development of the European Health Data Space, fostering innovation in industry and the public sector.

The work under this task materialises into monthly Strategic Progress Updates (SPUs) prepared for the monthly EDAH Coordination Working Group meetings. The SPUs cover the key developments as well as suggestions for related response and actions in the context of the EDAH project.

Task 2.2 Carrying out case studies

Case studies on seven key EU clusters/networks/ecosystems are carried out in order to 1) facilitate learning from various good practices of strong EU clusters/networks in advancing digital health and related innovation in their regions/ countries as well as good practices related to quadruple helix collaboration; 2) reach a better understanding of the ecosystems and innovation agendas of these clusters/networks; 3) case studies additionally focus on the possibilities of advancing specific topics related to the EHDS in the context of the EU presidencies in the clusters'/networks' countries of origin. The clusters/networks selected for case studies represent Portugal, Czech Republic, Sweden, Spain, Belgium and Hungary (five countries holding the EU presidency during the life of the project), and Bulgaria (as an example of Emerging Innovator, to get insights about key needs for development in terms of digital health and related ecosystem in such context).



1 – Belgian Ecosystem Overview

Belgium, officially known as the Kingdom of Belgium, is a country located between France, Germany, the Netherlands, and Luxembourg. It covers an area of approximately 30.528 square kilometres and has a population of more than 11.6 million inhabitants.

Belgium functions as a sovereign nation and operates under a federal constitutional monarchy with a parliamentary system. Its institutional framework is intricate, characterized by divisions based on both regional and linguistic factors.

Belgium sits across the fault line that separates German and Latin cultures and has three official languages: Dutch, French and German. Belgium today has three communities¹: the Flemish Community, the French Community and the German-speaking Community. These communities therefore correspond with the population groups. Additionally, and mainly for economic reasons, the country is demarcated into three highly autonomous regions: the Flemish Region (Flanders) situated in the north, the Walloon Region (Wallonia) located in the south, and the Brussels-Capital Region. Among these, Brussels stands out as the smallest and most densely populated region while also boasting the highest GDP per capita. Additionally, Belgium is host to two primary linguistic communities: the Flemish Community, comprising approximately 60% of the population, and the French Community, representing roughly 40% of the population.

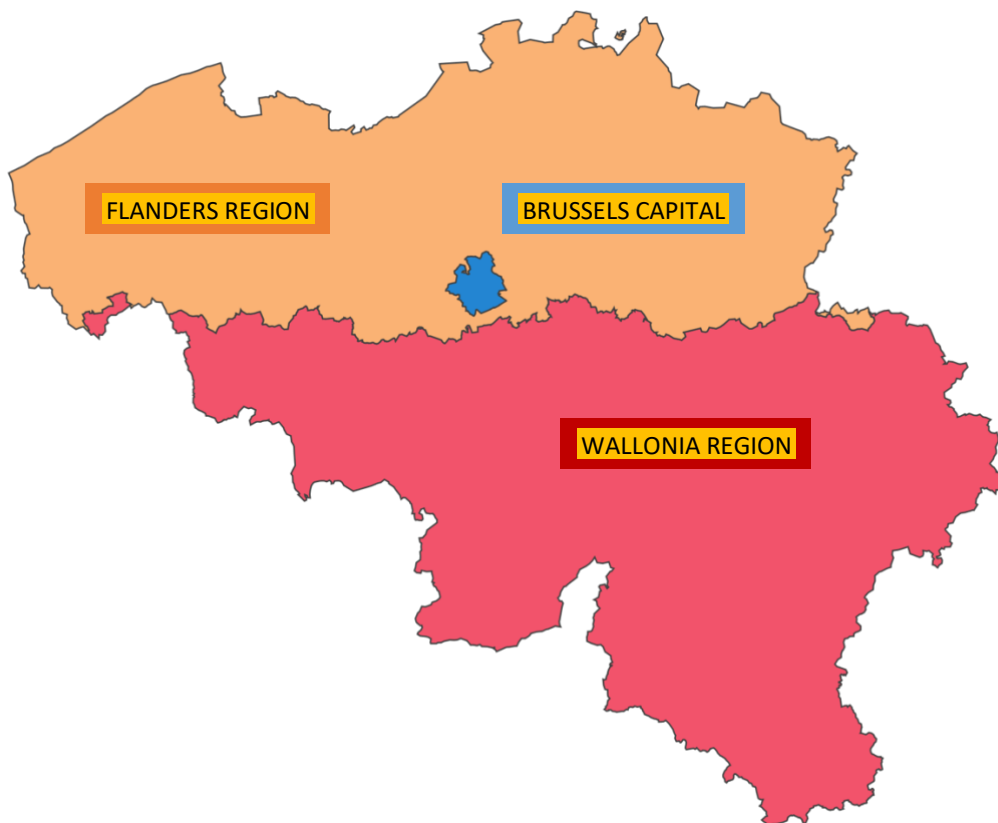


Fig 2. Map of Belgium and its three regions

¹ The concept refers to persons that make up a community and the bond that unites them, mostly their language and culture.

Belgium stands as a developed country, characterized by a highly advanced high-income economy. It provides high quality of life, prioritizing safety and boasting well-established social security and universal healthcare systems and social rights. As one of the six founding members of the European Union, Belgium holds a pivotal role in the EU's structure. Its capital city, Brussels, also serves as the *de facto* capital of the European Union itself. Brussels hosts the official headquarters of critical EU institutions, including the European Commission, the Council of the European Union, and the European Council. Furthermore, it is one of the two primary seats of the European Parliament, the other being in Strasbourg. Belgium's international affiliations are extensive, as it is also a founding member of the Eurozone, NATO, OECD, and WTO. Within Europe, Belgium is an integral part of both the trilateral Benelux Union and the Schengen Area. Additionally, Brussels plays host to the headquarters of numerous significant international organizations, including NATO, further underlining the country's global significance.

1.1 National health system

Belgium's mandatory social health insurance covers approximately 99% of residents, ensuring non-discriminatory access to a wide array of healthcare services. Residents must join a sickness fund or opt for the public auxiliary fund, emphasizing autonomy in medical practice, direct patient access, and fee-for-service payments. Healthcare services, whether public or private, operate under a unified regulatory framework, with reimbursement available, where administration is shared between the federal government and federated entities.

The Ministry of Health handles overall healthcare system organization, while federated entities are responsible for primary care, elderly care, mental health services, rehabilitation, health promotion, and disease prevention. Inter-ministerial conferences facilitate collaboration. Despite the quality of care, the complex distribution of health-related competences among various Ministries may lead to some fragmentation and inefficiency in the system.

Belgium's healthcare financing relies mainly on mandatory health insurance, where social contributions are income-dependent. Since 1995, a cap on real growth has set the overall budget target for compulsory health insurance expenditure. As of 2022, the budgeting process emphasizes resource allocation based on defined health objectives, with a focus on long-term vision and a multi-year financial plan.

The National Institute for Health and Disability Insurance (NIHDI) oversees compulsory health insurance management, allocating a forward-looking budget to sickness funds. These non-profit entities manage reimbursement for healthcare services, serving their members and providing replacement income during extended illness. Budget negotiations involve government representatives, patients (via sickness funds), employers, salaried employees, and self-employed workers, fostering collaborative financial planning and decision-making in the healthcare sector.

Healthcare expenditure has risen over the last two decades and has remained stable at approximately 10% of the gross domestic product (GDP) since 2009, reaching 11.6% in 2020.



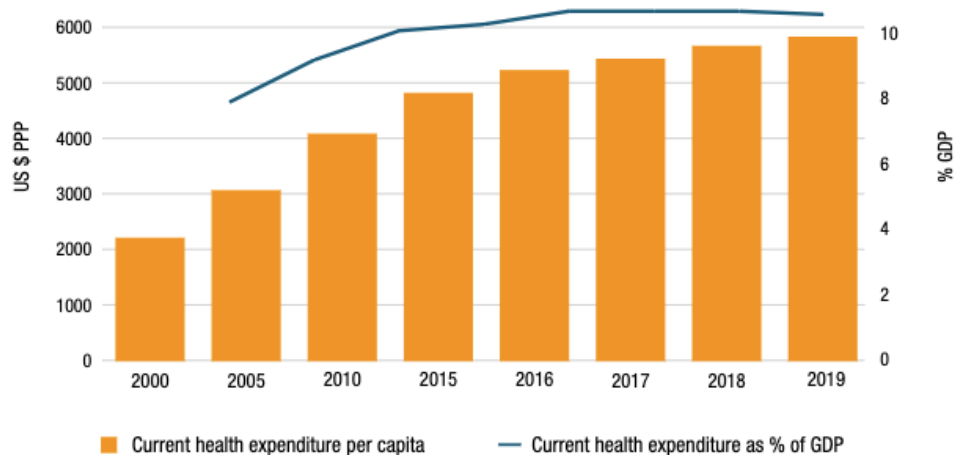


Fig 3: Belgium: Trends in health expenditures 2000-2019 (source: WHO Global Health Expenditure Database, Dec 2021)

In the realm of healthcare infrastructure, a notable trend in Belgium involves hospital mergers, leading to the creation of larger facilities, often spanning multiple sites. These hospitals are primarily classified into acute care (104 hospitals) and psychiatric (60 hospitals across 274 sites as of January 2020). Specialized and geriatric hospitals are now under the jurisdiction of Federated entities.

Over the years, there has been a gradual reduction in the density of curative care beds, decreasing from 620 to 500 per 100,000 population between 2000 and 2019. Belgium's bed density is second only to Germany among neighbouring countries. A prospective study for 2025 anticipates a decreased need for conventional hospital beds (-5.4%), particularly in maternity and surgical categories. However, there is an increased demand for day hospitalization, geriatric beds, and chronic care beds. Belgium, like neighbouring nations, has observed a decline in the average length of hospital stays. The country has also embraced national planning strategies concerning the allocation of significant medical equipment and specialized services, aligning with care program developments.

At present Belgium is actively engaged in enhancing healthcare transparency and performance assessment through the HSPA framework. Future initiatives focus on substantial measures to improve healthcare quality and efficiency: these include ongoing hospital reforms, advancements in mental health, integrated care projects, the establishment of a national health research system, restructuring fee schedules, and potential integration of vulnerable populations. Post-COVID-19, discussions persist on strategies to bolster the healthcare system's resilience, promoting multidisciplinary care, patient empowerment, evidence-based medicine, and digital enhancements.

1.2 E-Health and health data landscape

The e-Health sector in Belgium stands at the forefront of digital innovation in healthcare, driven by a robust infrastructure and a history of early adoption of electronic health technologies. Belgium was among the pioneers in implementing electronic health records and was the first European country to introduce electronic ID cards for its entire population.

Central to Belgium's e-Health landscape is the e-Health platform, established by law on August 21, 2008. This platform plays a pivotal role in securing the exchange of health data for various applications, including healthcare delivery, streamlining administrative processes, and contributing to health policy development.

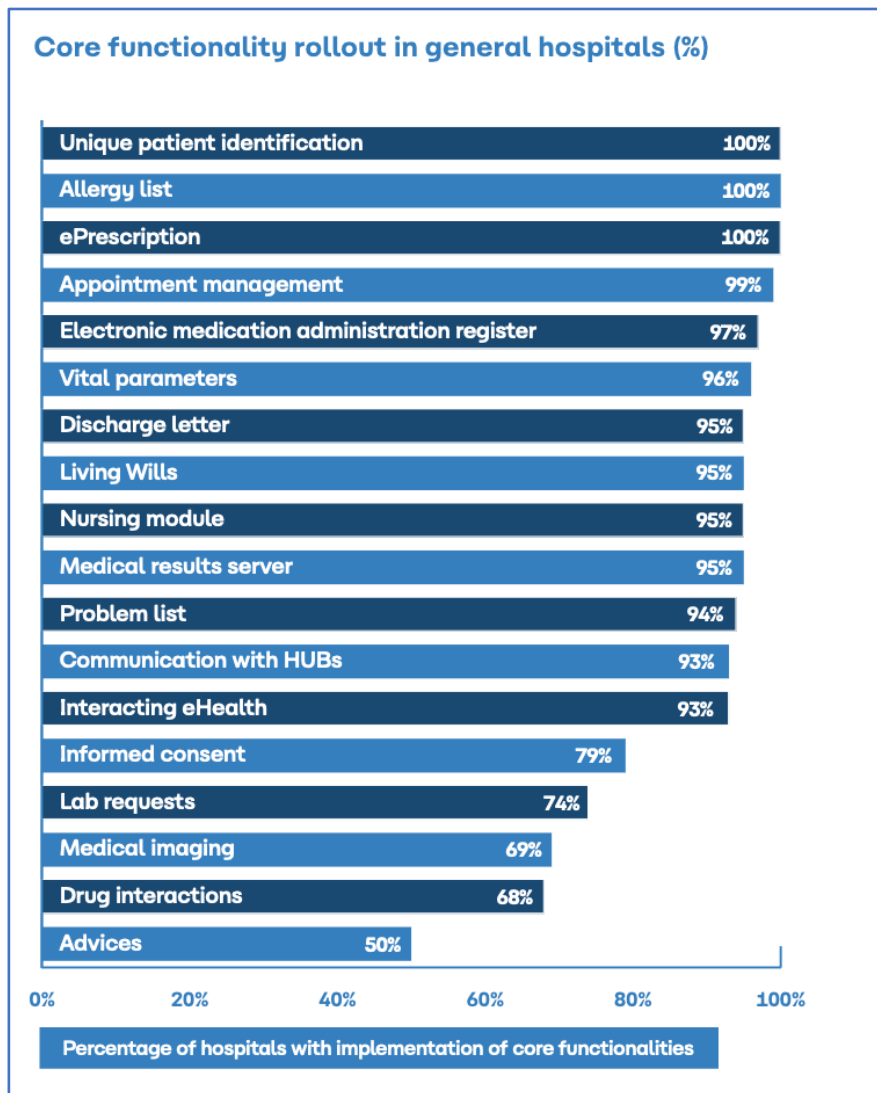


Fig. 4: Main e-Health functionalities activated in Belgian general hospitals (source: Inovigate 2022)

A notable feature of Belgium's e-Health architecture is the hub-metahub system (see Fig. 5), which facilitates the exchange of health data without centralizing information. This system is designed to empower healthcare providers, allowing them to retrieve and access electronic health and well-being documents for a specific patient, regardless of the documents' storage location. This decentralized approach ensures data accessibility while respecting patient privacy.

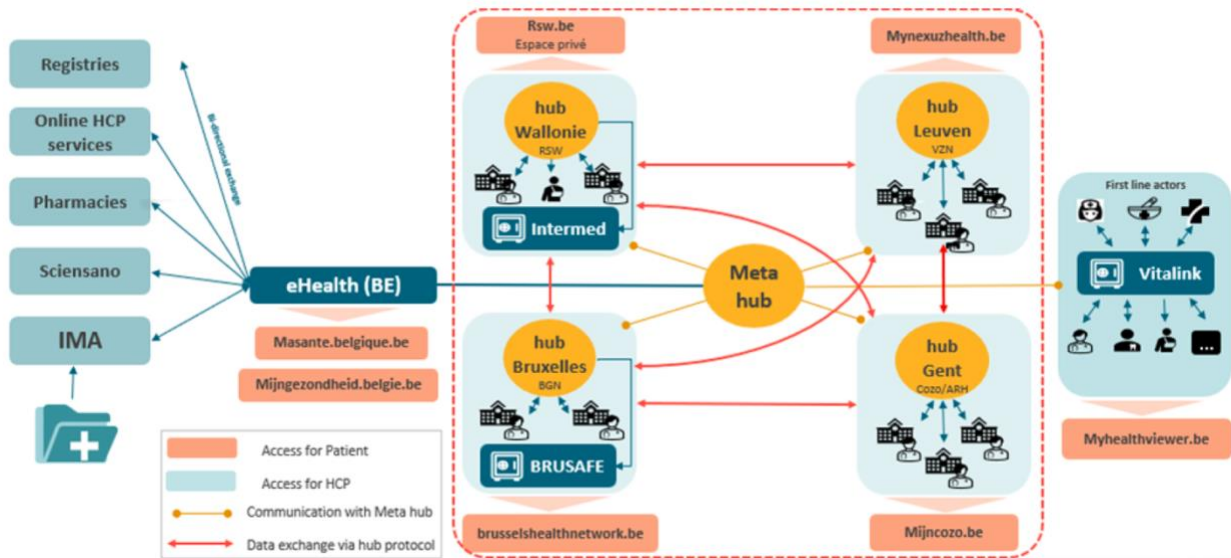


Fig. 5: Present situation in Belgium: the hub/meta-hub approach (source: Inovigate 2022)

Despite these advancements, Belgium acknowledges the need for further progress in utilizing real-world data. The e-Health system primarily focuses on primary care, and challenges arise in using patient information for clinical trials. Recent initiatives from various stakeholders, including the Belgian Health Data Agency, the Agoria Health Data Charter, ICURO's exploration of "Big data in healthcare," and the RWE4Decision project, aim to address these challenges and foster advancements in leveraging health data for improved patient care and healthcare outcomes.

As Belgium continues to navigate the dynamic landscape of e-Health, collaboration among stakeholders, ongoing technological advancements, and a commitment to privacy and security remain crucial elements in shaping the future of digital health in the country.²

² <https://www.e-Health.fgov.be/fr/page/roadmap-4.0>



Fig. 6: Belgian main public partners in the e-Health domain

1.3 Life sciences and healthcare ecosystem

Belgium boasts a thriving MedTech industry, employing a workforce of 20,000 individuals dedicated to advancing medical technologies. These professionals, with their expertise and commitment, contribute significantly to the nation's healthcare landscape and global medical advancements.

The economic impact of Belgium's MedTech industry is substantial, with a turnover of more than €3.5 billion: this figure underscores the industry's robustness and its ability to generate value for both the national economy and the global healthcare sector.

Belgium's pharmaceutical industry is equally noteworthy, employing a substantial workforce of almost 30,000 individuals and playing a pivotal role in the country's economy, with a combined turnover of €65.5 billion, including the chemistry subsector.

To be more specific, in Flanders region biopharmaceutical firms have a large footprint in terms of employment and research, with more than 5,000 active industry scientists and €3.9 billion in R&D investments in 2019. Wallonia, on the other hand, stands out in terms of aggregated market capitalization in biopharma, where it ranks within the top 3 in the European Union. The Gross Added Value in Life Sciences is a striking four times higher than that of surrounding EU countries, underscoring the economic significance of the sector to the region. Foreign companies have recognized Wallonia as a prime destination for investment, with a staggering over €16 billion invested in the region between 2000 and 2020 and now biopharmaceuticals constitute an impressive 33% of the total Walloon export, also thanks to two CEIV Pharma airports. Worth to

mention are also the 20,000 hospital beds and the 11,000 researchers in life sciences, spread among 12 world leading companies, 5 universities (with over 400 research units), 6 private R&D centres and over 250 innovative SMEs.

Brussels capital region sports a notable concentration of expertise in clinical trials, e-Health, and MedTech: the region has the highest rate for clinical trial authorizations in the European Union (47 authorizations per 1 million capita), a remarkable 50% of Brussels citizens have given their consent for Electronic Medical Records (EMR) and all 18 hospitals in Brussels, along with a network of 9,000 healthcare professionals, have integrated EMR into their practices. The city is also home to 69,000 healthcare and social care professionals.

Patient's Associations

The Belgian ecosystem is very rich in terms of patient's associations and organisations, on one side because the healthcare sector represents a preeminent industry at national level, on the other side because being Brussels the place of main European institutions, many European organization – with branches and representatives located in different countries - tend to concentrate their physical main presence there. In general, all the main medical conditions are represented; here we mention just a few examples of patient organisations active in Belgium (Flanders, Wallonia or in the Brussels Capital area)

- [Belgian Cancer Foundation \(Stichting tegen Kanker\)](#): focuses on supporting cancer patients and promoting cancer research.
- [Alzheimer Liga](#): is an organization dedicated to supporting individuals with Alzheimer's disease and their families.
- [Diabetes Liga](#): is a patient organization for people with diabetes, providing support and information.
- [European Patients' Forum \(EPF\)](#): is a pan-European organization that represents the interests of patients.
- [Multiple Sclerosis Liga](#): offers support and information to individuals living with multiple sclerosis.
- [Association against mucoviscidosis \(cystic fibrosis\)](#): provides information, scientific knowledge and support to the patients and is particularly sensitive towards a better use of health data.

Cluster organisations and networks

Belgium has been actively involved in the life sciences sector, and several cluster organizations and initiatives have been established to support collaboration and innovation in this field. Here are some examples of life sciences-related cluster organizations in Belgium:

- [BioWin](#) is the health cluster of Wallonia. It focuses on promoting collaborative research and development in the life sciences sector, including biotechnology and healthcare.
- [FlandersBio](#) is a networking organization that supports and promotes the life sciences sector in Flanders region. It brings together biotech companies, research institutes, and other stakeholders to foster collaboration and innovation.
- [MedVia](#) is a public-private partnership with the Flemish government, is an industry-driven network uniting healthtech companies, research institutions, universities, hospitals, and patient groups at the intersection of biotechnology and digital technology to foster healthcare innovations. It has been founded in 2021.

- [Lifetech.brussels](#) is the cluster for innovative healthtech companies located in Brussels capital area. It aims to facilitate and stimulate the attractiveness and success of high-potential HealthTech solutions, with a focus on social and environmental impact.
- [Medtech Wallonia](#) is the entry point for medical device and Digital Health projects in Wallonia.
- [BioVox](#) is not a cluster but a platform that provides information and news related to the life sciences sector in Belgium; it serves as a hub for the Belgian biotech and life sciences community.

Academia

The university system in Belgium is characterized by its diversity and autonomy. Each of the country language community —Dutch, French, and German— has its own set of universities. The Flemish Community is served by universities such as KU Leuven and Ghent University, where instruction is primarily in Dutch. The French Community has institutions like the Université Libre de Bruxelles and the Université Catholique de Louvain, where instruction is in French. The German-speaking Community has a smaller university, Universität Verviers, offering programs in German. Additionally, there are several international and English-taught programs to accommodate a growing number of international students. The Belgian university system is known for its high academic standards, research output, and commitment to fostering a multilingual and multicultural learning environment.

[KU Leuven \(Katholieke Universiteit Leuven\)](#)

Founded in 1425, KU Leuven is Belgium's oldest (will celebrate its 600th anniversary in 2025) and largest university, consistently ranked among the top universities globally. The Faculty of Medicine at KU Leuven is renowned for its cutting-edge research in life sciences, encompassing areas such as biomedical sciences, pharmaceutical sciences, and molecular medicine. The university's commitment to interdisciplinary collaboration (counting on more than 65,000 students) and state-of-the-art facilities makes it a focal point for advancements in medical and biological research. Associated to KU Leuven is the UZ Leuven university hospital.

[Université Catholique de Louvain \(UCLouvain\)](#)

UCLouvain, established in 1425, is another prominent institution that has significantly contributed to the field of life sciences. The Faculty of Medicine and Dentistry at UCLouvain is at the forefront of research in areas such as genetics, neuroscience, and bioinformatics. The university's emphasis on international collaboration and its strategic location in Louvain-la-Neuve contribute to a vibrant academic community engaged in pushing the boundaries of scientific knowledge. UCLouvain welcomes nearly 40,000 students and is involved in 2 science parks with more than 300 companies and 2 incubators, one of which fully dedicated to life sciences.

[Vrije Universiteit Brussel \(VUB\)](#)

Situated in the heart of Brussels, VUB is a dynamic and research-oriented university known for its commitment to innovation. The Faculty of Medicine and Pharmacy at VUB excels in various life science disciplines, including biotechnology, bioengineering, and medical imaging. The university's strong ties with governmental institutions and international organizations provide its 21,000 students from 145 countries and its researchers with valuable opportunities for real-world applications of their work. The university was founded in 1834 as a free university.



[Université libre de Bruxelles \(ULB\)](#)

ULB, established in 1834, is a French-speaking university located in Brussels. The Faculty of Medicine at ULB conducts groundbreaking research in areas such as molecular biology, epidemiology, and medical imaging. The university's commitment to promoting diversity and its international outlook make it an attractive destination for students and researchers seeking a multicultural and intellectually stimulating environment. It hosts more than 31,000 students and 2,000 researchers.

[Ghent University \(UGent\)](#)

Ghent University, founded in 1817, is a leading research institution with a strong focus on life sciences. The Faculty of Medicine and Health Sciences at UGent is recognized for its contributions to fields such as immunology, microbiology, and biomedical engineering. The university's collaborative approach, often engaging with industry partners (1356 patents filed, 84 spin-offs created), fosters an environment where academic research translates into practical solutions with societal impact. UGent hosts 50,000 students, 7,300 of which are international.

[Hasselt University](#)

Founded in 1971, Hasselt University is a relatively young but rapidly growing institution. The Faculty of Medicine and Life Sciences at Hasselt University is known for its innovative approach to medical education and research, with a focus on personalized medicine, environmental health, and biostatistics. The university's close collaboration with research institutes and hospitals enhances the practical relevance of its life sciences programs. The University hosts over 7,000 students, in two campuses.

Worth to be mentioned are also Université de Namur (UNamur), University of Liège (ULiège), University of Antwerp, Universität Verviers and University of Mons (UMons): the latter is home of the [Institute for Health Sciences and Technology](#), a multidisciplinary institute of biologists, clinicians, pharmacists, chemists, physicists, engineers, psychologists and sociologists whose research activities concern the health sector and, more specifically, focus on improving individual and public health.

Research centres

[Sciensano](#)

Established in 2018 through the merger of ISP and CERVA, Sciensano is a crucial entity in Belgium's public health sector. It focuses on research areas such as animal health, vaccine and medicine quality, and medical laboratories. Sciensano also addresses food safety, healthy diets, and conducts nationwide health surveys. The institute integrates health and environment, monitoring ecosystems for potential public health threats, and evaluates healthcare system performance. With an annual budget of nearly €82 million in 2020, Sciensano employs over 700 professionals, including 46% in scientific roles and 26% as lab technicians. It provides scientific advice to public authorities, collaborates with regional agencies, and coordinates international public health issues, maintaining relationships with organizations like WHO and the European Medicines Agency.

[The Flanders Institute for Biotechnology, VIB](#)

VIB is an independent research institute where some 1,700 top scientists from Belgium and abroad conduct pioneering basic research. Based on a virtually integrated partnership with five Flemish universities – Ghent



University, KU Leuven, University of Antwerp, Vrije Universiteit Brussel and Hasselt University – and supported by a solid model-based funding programme, VIB unites the expertise of all its research collaborators and research groups in a single institute.

While research forms the basis of VIB model, transferring research results to the market is of equal importance to VIB. The Innovation & Business team ensures that research results are translated into tangible products and services that find their way to patients and consumers. Financial return from tech transfer activities is reinvested in VIB's basic research programmes.

The Flemish Institute for Technical Research, VITO

VITO stands as an autonomous research center specializing in cleantech and sustainable development within Flanders. Operating as a forward-thinking, client-focused research entity, VITO expedites the shift toward a sustainable global environment by delivering expertise and technological breakthroughs that ease the transition to a more sustainable society. By de-risking innovation for businesses and implementing interdisciplinary research and extensive pilot installations, VITO reinforces both the economic and societal foundation of Flanders. The center's initiatives span the domains of energy, chemistry, materials, health technology, and land use.

The Institute for Tropical Medicine, ITM

ITM is a global leader in tropical medicine and healthcare in developing countries. In 2020, ITM excelled in training, research, and support, training over 400 students, publishing 387 scientific articles, and engaging in 40,000+ patient contacts. ITM houses high-security laboratories, specializing in HIV, and played an active role in responding to the COVID-19 pandemic, focusing on diagnostics, biomedical research, clinical trials, and societal impact studies. With a dedicated team of over 160 professionals, ITM particularly addresses pandemics in low- and middle-income countries, prioritizing vulnerable populations.

The Digital Agency – Agence du Numerique Wallonia region

The Digital Agency (AdN) is a public limited company, not a traditional research center, mandated with implementing the Digital Wallonia strategy (2019-2024). As a key player in the region's digital transformation, AdN operates as a digital expertise hub with crucial missions:

- Offering guidance to the Walloon Government
- Monitoring technological advancements
- Promoting Wallonia's digital strategy & ecosystems
- Contributing to digital transformation programs and projects.

AdN manages the Digital Wallonia platform, featuring over 4,000 profiles of active digital stakeholders, including 2,000 businesses. Additionally, it oversees digital ecosystems and an e-health platform, playing a pivotal role in driving the region's digital initiatives forward.

WELBIO Walloon Excellence in Life Sciences and BIOTEchnology

Founded in 2009, WELBIO is an inter-university life sciences research institute aimed at promoting scientific excellence and translating research outcomes into medical, pharmaceutical, and veterinary applications. With total funding of over €60 million, the institute operates through biennial project calls and supports researchers through various grant instruments. Recognized for industrial valorization, WELBIO collaborates closely with business-university interfaces to protect intellectual property and promote the development of inventions.



In addition, in Wallonia Region, the government oversees funding for four academic hospitals: Erasmus Hospital (ULB), Saint-Luc, and Mont-Godinne clinics (both UCLouvain), and the University Hospital Centre of Liège (ULiège). It finances construction, renovation, and investment in crucial medical equipment, including Nuclear Magnetic Resonance (NMR), radiotherapy, and PET scan.

IMEC – Interuniversity Microelectronics Centre

IMEC is a world-renowned independent research and innovation hub located in Leuven, Belgium. Established in 1984, IMEC has played a pivotal role in advancing microelectronics and nanotechnology.

IMEC stands apart through its collaborative ethos, engaging in partnerships with industry entities, universities, and research institutions on a global scale. Housing state-of-the-art cleanroom facilities, IMEC is at the forefront of semiconductor research, encompassing diverse realms such as the IoT, AI, and other pioneering technologies. The center actively participates in European research initiatives, underscoring its commitment to global collaborative endeavors. Beyond its research pursuits, IMEC plays a pivotal role in Belgium's innovation ecosystem. By fostering technological advancements, the center propels the growth of both emerging startups and established corporations within the high-tech sector.

A special initiative of IMEC is the Belgian Data Spaces Alliance which gathers 8 organisations (Agoria, KU Leuven, Digitaal Vlaanderen, Paradigm Brussels, Agence du Numérique, Vlaams Datanutsbedrijf now called Athumi and SolidLab) to stimulate and support data space activities in Belgium, including healthcare with a dedicated working group . The group aims to guide a network of stakeholders through the essential stages required to link an ecosystem to a data space. The emphasis will be on establishing a shared comprehension of data spaces and this involves creating practical examples, executing pilot projects based on these examples, and pinpointing potential sources of funding for the initiatives.

It is also important to mention that IMEC also has one of the strongest start-up incubator and accelerator. IMEC's accelerator program, imec.istart, is ranked number 1 in the 'World Top Business Accelerator - Linked to University' category compiled by UBI Global.

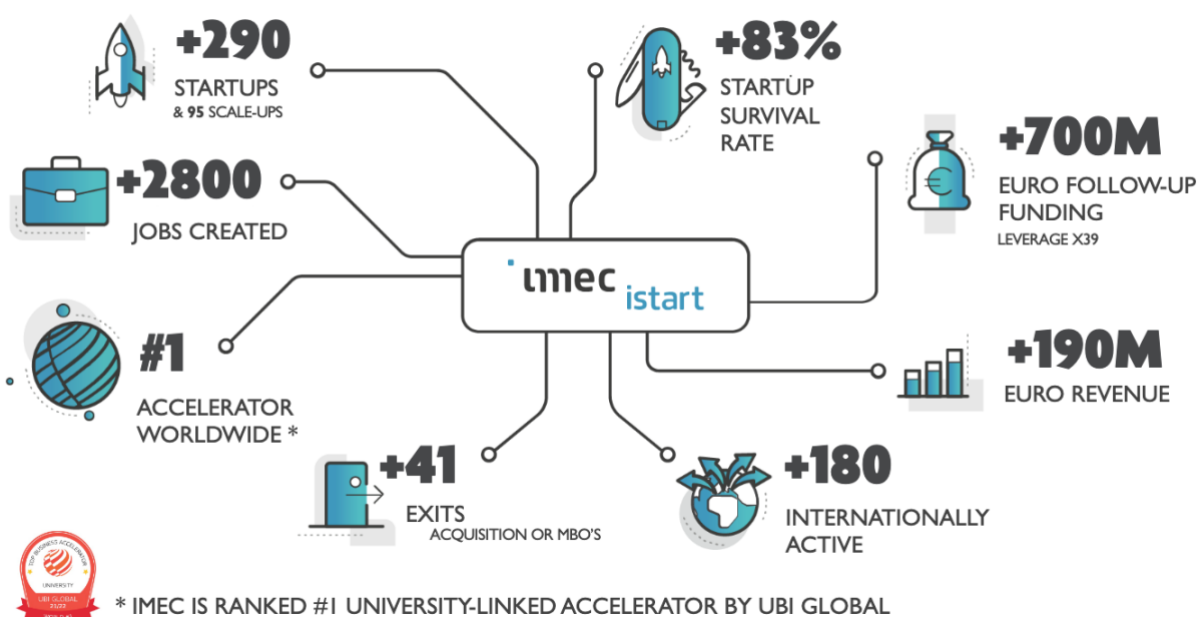


Fig. 7: imec.istart accelerator programme in figures

2 – Existing legal framework

The main strategic documents and legislation that define the e-Health system in the country offering guidelines, development, and coordination activities for the implementation of state policy are:

- Act on the Performance of the Healthcare Professions of 10 May 2015;
- Act on Hospitals and Other Care Facilities of 10 July 2008;
- Health Care Quality of Practice Act of 22 April 2019;
- Patients' Rights Act of 22 August 2002;
- Law on Medicines of 25 March 1964;
- EU Regulation 2017/745 on Medical Devices (MDR); Medical Devices Act of 22 December 2020; EU Regulation 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDMDR) of 5 April 2017; *In Vitro* Diagnostic Medical Devices Act of 15 June 2022;
- Law on Experiments with Humans of 7 May 2004; EU Regulation 536/2014 on clinical trials on medicinal products for human use of 16 April 2014; and
- Several legislative initiatives and already adopted instruments considering the EU's digital strategy, such as the Digital Services Act (EU Regulation 2022/2065) and the EU proposal for an artificial intelligence (AI) act.

Multiple national acts are under revision in preparation for the HDA (Health Data Agency) and EHDS: Patients' Rights Act, The Health Care Quality of Practice Act, and The Belgian Privacy Act.

2.1 E-Health Action Plan 2022-2024

A first thread running through the e-Health 2022-2024 action plan is the concept of the "Belgian Integrated Health Record" (BIHR), developed by a group of healthcare experts and seen as the reference framework for the evolution of e-Health in the years to come, in support of integrated, multidisciplinary care.

Health and the continuity of high-quality care are at the heart of this approach, which is driven by citizens/patients (and those around them) who wish to actively contribute to their good health. The second thread is the secondary use of data, which will be facilitated by the Health Data Authority (HDA). Secondary use should enable data to be used for innovation, research and development, as well as population management and decision support based on aggregated data. This can be achieved by making IBRD's "real-world data" available as "regularly collected data", and by improving data documentation, retrievability, accessibility, quality and reusability. The HDA program is set out in a specific action plan.

The COVID-19 pandemic has given a major boost to e-Health. This is an opportunity to continue introducing the public to e-Health services and the positive experience they have had with applications as part of vaccination campaigns and with the COVID-19 certificate application to facilitate travel, and to stimulate the evolution of these services, considering the needs of care teams and active patients.

This action plan takes account of lessons learned from the previous action plan: for example, the number of projects has been reduced by combining existing and new projects and integrating them into a single project,

with the individual parts (previous projects) defined as "work packages". The aim is to facilitate the harmonization of previous projects, which were often long and tedious. The aim is no longer to set up a governance structure (including a steering committee) for each work package but to do so solely at the "project" level.

Finally, with this action plan, Belgium is preparing for the future introduction of regulation on the European health data space. This regulation, better known as the European Health Data Space (EHDS), follows on from the RGPD, the proposed Data Governance Act, the proposed Data Regulation and the CRS Directive. It complements these initiatives and provides rules more suited to the digital health sector. This European Health Data Space will be based on three pillars:

- an efficient system of data management and rules for data exchange
- data quality
- good infrastructure and interoperability

The Belgian National Institute for Health and Disability Insurance (NIHDI) is responsible for establishing reimbursement schemes for healthcare services, health products and medicines. Further, the Federal Agency for Medicines and Health Products (FAMHP) supervises the quality, safety and efficacy of medicines and health products. The Institute for Public Health (Sciensano) monitors public health and diseases and evaluates the effectiveness and safety of vaccines, medicines and health products and was therefore of paramount importance during the COVID-19 pandemic. Additionally, professional associations such as the Order of Physicians and the Order of Pharmacists regulate the deontological aspects of healthcare professions, while the self-regulatory organisations Pharma.be and BeMedTech provide industry guidance. Lastly, the Belgian Data Protection Authority (DPA) enforces compliance with data protection and a Health Data Protection Authority (yet to be established) should oversee the sharing and use of healthcare data. Belgium faces unique challenges in collecting and using data due to its federal structure, whereby the data landscape remains fragmented across multiple stakeholders. The data in Belgium is distributed across various dimensions, creating a fragmented landscape that poses challenges in terms of making the data easily discoverable and accessible.³

2.2 Primary and secondary use of data for the provision of health and social care by health and care providers to the patient)

The European Health Data Space (EHDS) aims to make the primary use of health data for healthcare provision more continuous, effective, and (cost) efficient. Moreover, it pursues to facilitate the secondary use of health data for purposes such as research, innovation, and policy making. In the context of secondary use, the EHDS legislative proposal (published on 3 May 2022) argues that Member States should develop Health Data Access Bodies (HDABs) whose responsibilities include facilitating the secondary use of health data, issuing data permits, and implementing high levels of accountability and security. In Belgium, the setup in 2023 of a federal Health Data Agency (HDA) that is developing and implementing a policy strategy and framework for the secondary use of health data, aligns well with the responsibilities set out for HDABs⁴.

³ <https://iclg.com/practice-areas/digital-health-laws-and-regulations/belgium>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10496332/>



In March 2023, a new Health Data Agency (HDA) was established in Belgium with a primary mission of ensuring the collection, standardisation, and responsible use of health data for the benefit of Belgian citizens and the broader European community. The agency will facilitate the secondary use of health data, a practice that involves reusing data initially collected for healthcare purposes for research and innovation in healthcare, as well as ensuring privacy, data security and transparency. The goal is to ensure open communication with patients and citizens⁵.

2.3 The secondary use of data

Belgium faces unique challenges in collecting and using data due to its federal structure, whereby the data landscape remains fragmented across multiple stakeholders. Following the COVID-19 pandemic, the Belgian government recognised the urgent need for improved access and availability of health data, including steps to facilitate the secondary use of health data.

Secondary use (for scientific or historical research by both public and private sector organisations)

Belgium has a rich health data landscape. However, these data are often fragmented and not sufficiently compliant with the FAIR (Findable, Accessible, Interoperable, Reusable) principles. Requests for secondary use are not harmonised and they require considerable investments, both in terms of time and effort. To counter these obstacles, the legislative proposal concerning the establishment and organisation of a federal Health Data Agency (HDA) has been voted on March 9th 2023 and signed on March 14th 2023. The Belgian HDA pursues the central objectives of facilitating the availability of health (related) data, developing and implementing a policy strategy concerning health (related) data, and stimulating innovation as well as scientific and policy-supporting research. To facilitate the secondary use of health data, the HDA aims, among other things, to function as a preferred point of contact regarding secondary use, develop a governance model, provide a data catalogue, facilitate health data access requests, and support the communication between data holders and data users. The intentions of the Belgian HDA align well with some of the responsibilities set out for HDABs in the EHDS proposal. Especially their facilitating tasks such as providing a national data catalogue, expanding the availability of health data, promoting the development of common data standards and AI in health, and harmonising data request procedures, seem to align well.

However, there are also some differences between the ambitions of European HDABs and the Belgian HDA. Firstly, HDABs should take on the role of Trusted Third Party (TTP), as they are the only ones who should hold the encryption keys of pseudonymised data. HDABs will also process electronic health data (including data from other data holders) for various purposes such as collecting, preparing, linking or disclosing these data for secondary use as foreseen in the corresponding data permit.

Legal or regulatory mechanism which addresses the use of health data for research purposes.

Research projects that require access to data generally need ethical approval and approval from the Information Security Committee. In addition to the Belgian privacy law, by the law of September 5, 2018, the Information Security Committee was established. It consists of two chambers: the Social Security and Health Chamber, located at the KSZ and the e-Health Platform, and the Federal Government Chamber, located at

⁵<https://www.euractiv.com/section/health-consumers/news/belgium-new-agency-to-tackle-fragmented-health-data-collection/>



the FPS BOSA. It has specific missions in the field of information security - including the granting of deliberations for certain types of communications of personal data.

2.4. Patients' rights

Patients' rights are generally regulated by the Patient Act, the Belgian Privacy Act, the Belgian Law on the Protection of Natural Persons regarding the Processing of Personal Data and the GDPR, which includes nearly any action or operation related to personal data.

In the physician–patient relationship, patients have the right to consult their medical record, which should be updated and stored carefully (art. 10 of the Act on Patients' Rights, arts 22–24 of the Code of Medical Ethics of the NCOP, arts 33–40 of the Health Care Quality of Practice Act of 22 April 2019). Since 2008, a national e-Health platform has been established, where healthcare providers upload electronic health records of a patient after having obtained the patient's consent (art. 5.4(b) of the Law Establishing and Organising the e-Health Platform). Only healthcare providers having a therapeutic relation with the patient may access the electronic health records of a patient, excluding, for example, medical advisors from insurance companies. In the broader context of (e-)health services, one must take account of the GDPR and the Belgian Law on the Protection of Natural Persons regarding the Processing of Personal Data⁶.

2.5 Electronic Health Records

In 2016, the Belgian government implemented an EHR system called the e-Health Platform, which allows for the sharing of patient data between healthcare providers and hospitals.⁷ The system is mandatory for general practitioners and hospital doctors, and it is expected to improve the continuity of care for patients.

An electronic health record (EHR) is a longitudinal record of a patient's health information that is completed following contact with healthcare actors. The record ideally includes data from all clinicians involved in a patient's care.

For many years, the Belgian government has recognised the need for the widespread deployment of EHRs so that information can be easily shared between healthcare providers and organisations. A Belgian e-Health action plan was launched several years ago. One of the action items relates to the roll-out of EHRs in hospitals. The goal is to have EHR in which:

- messages are exchanged between systems
- different functions are implemented within one integrated system.

In any case, core functionalities should be integrated, and data should be captured and managed according to the Original Source Principle. This means that the information is not duplicated and is retrieved from the original source.

A programme of financial incentives was established to promote the roll-out of EHRs. To that end, several Belgian Meaningful Use Criteria were defined in consultation with hospitals. In July 2022, €57 million was

⁶ <https://iclg.com/practice-areas/digital-health-laws-and-regulations/belgium>

⁷ <https://www.healthybelgium.be/en/key-data-in-healthcare/general-hospitals/quality-and-innovation/electronic-health-record>

distributed amongst the country's general hospitals. The budget was distributed according to the level of use of the various functionalities in the EHR.

In most areas, retrieving, aggregating, and converting information into valuable insights is still a lengthy and manual process. This is due to various obstacles related to data exchange between information systems of different providers. Interoperability is important, partly because, in practice, patients often consult multiple healthcare providers during a care pathway and because information exchange between healthcare providers is crucial for optimal treatment.

Data collections/sources

- Primary health care providers use multiple electronic health records (EHR) systems. The EHRs are mostly digitalised using a unique national identifier that is also used by general practitioners (GP).
- Secure exchange of EHRs between health care providers and patients is possible through the national e-Health platform.
- Citizens can access most of their data through the online platform www.mijngezondheid.be/ www.masante.belgique.be.
- Belgium has over 150 clinical registries containing health data.
- The Belgian Cancer Registry (BCR), a national, population-based registry collecting data on cancer incidence since 2004.
- The Belgian institute for health (Sciensano) manages surveillance systems, part of the clinical registries (e.g. Central Rare Disease Registry), and health surveys (e.g. the Health Interview Survey).
- The Belgian statistical office (Statbel) mainly collects sociodemographic data.
- The Common Sickness Funds Agency (AIM-IMA) collects data on reimbursed healthcare services and prescription medication from the 7 Belgian sickness funds.
- The INTEGO project is based on an automated data collection of EHRs of patients from Flemish GP practices⁸.

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10496332/>



3 – Innovation agenda in the field

In the last years the topic of e-Health, health data and related aspects has been covered in two main strategic Belgian national documents: the e-Health action plan and the Recovery and Resilience Plan (RRP).

3.1. The e-Health action plan (2022 – 2024)

The rapid evolution of digital innovation not only introduces groundbreaking solutions but also necessitates swift adaptation from institutions and business, fostering a culture of continuous learning and agility. Considering this situation – in the field of e-Health – Belgium relies since 2013 on a 3-years plan, called e-Health action plan: now in its fourth iteration, covering the period 2022-2024, the plan builds upon its predecessors of 2013-2015, 2016-2018, and 2019-2021.

A key focal point of the e-Health action plan for 2022-2024 revolves around the concept of the "**Belgian Integrated Health Record**" (BIHR). Crafted by a panel of healthcare experts, this framework is positioned to shape the trajectory of e-Health, emphasizing the importance of high quality, integrated and multidisciplinary care. This is propelled by the active involvement of citizens/patients and their support networks, all eager to contribute to their own well-being.

The second major emphasis is on the secondary use of data, a facet that will be facilitated by the **Health Data Agency** (see box below). This approach is designed to enable the innovative use of data for purposes such as research, development, population management, and data-driven decision support, in line with the EHDS. The achievement of this goal involves making the "real-world data" from BIHR available as "regularly collected data," concurrently enhancing documentation, data retrieval, accessibility, quality, and the reusability of data.

BOX: THE HEALTH DATA AGENCY

The Belgian Health Data Agency (HDA) has been established with a law of March 14th, 2023.

The mission of the ADS is to contribute to making health, healthcare, and well-being data more easily accessible in a secure, uniform, and transparent environment.

This agency, established in the form of an administrative service within the SPF Public Health, Food Chain Safety, and Environment, has two main objectives:

1. Ensure better availability of healthcare data and data related to health and healthcare
2. Facilitate reliable and simplified access to those data

The agency's missions include serving as the primary point of contact for GDPR-compliant reuse of healthcare data to support scientific research and policy development. It aims to document, facilitate, and optimize processes for data reuse requests, establish transparent governance, implement a data management system, provide opinions on standardization and FAIR principles, offer support and regulatory guidance, ensure transparency, share knowledge through a Health Data Academy, organize consultations between data holders and users, and build and maintain citizen trust in the proper use of their healthcare data.



It has to be noted that distinctions exist between the aspirations of European Health Data Aggregators (HDABs) and the Belgian Health Data Agency. Primarily, HDABs are envisioned to serve as the Trusted Third Party (TTP), uniquely holding encryption keys for pseudonymized data. HDABs are tasked with processing electronic health data, including data from various sources, for purposes like collection, preparation, linking, or disclosure for secondary use, as outlined in the relevant data permit. In contrast, the current structure of the Belgian HDA does not designate it as a TTP. This is due to the existing authorization of other institutions, such as the e-Health-platform, the Crossroads Bank for Social Security, and Statbel, which already function as TTPs. The HDA aims to avoid overlapping with the legal competences of these established federal bodies.

The current action plan capitalizes on the increased use of online health services during the COVID-19 pandemic to raise public awareness of their benefits. Drawing from previous experiences, it consolidates and integrates multiple projects into a unified initiative, with these components now identified as "work packages," and establishes governance at the project level. Furthermore, the plan anticipates the implementation of the **European Health Data Space (EHDS) regulation**, which builds upon existing frameworks and provides tailored regulations for the digital health sector. The action plan is positioned as a foundational step for projects aligned with EHDS pillars.

Main objectives of the e-Health action plan

The present e-Health action plan consists of 44 interconnected projects with 6 main objectives.

1 – To shift towards demand-driven, person- and population-centered care, placing emphasis on well-being and quality of life. The goal is to enhance the quality, continuity, and safety of care through efficient and secure patient data exchange across all healthcare levels and sectors. Administrative simplification is a key focus. The plan includes integrating essential tools like BelRAI, with special attention to improving mental healthcare. The approach underscores multidisciplinary collaboration, interpreting "integration" as the involvement of healthcare professionals in both intra and extramural care settings.

2 – To optimally supporting individual health and healthcare goals, emphasizing empowerment, self-management, and active participation in the care process. This includes joint management of health data with consent mechanisms, allowing individuals to input and communicate information, maintain journals, access data, and make necessary adjustments. Creating a strong digital culture, user-friendly services, and support from the immediate environment and community, including volunteer caregivers and health workers, is crucial to ensuring universal access to these opportunities.

3 – To support healthcare professionals within multidisciplinary teams, ensuring seamless continuity of care, especially in cases of multiple chronic conditions. The cornerstone for this is an integrated electronic medical record (EMR) outlined in the DSIB (Disease Specific Imaging Burden) concept. The EMR, based on interoperable and multidisciplinary distributed systems, is envisioned for use in hospitals and care providers' homes, providing a comprehensive overview of patients' relevant health status through tailored dashboards accessible via primary data vaults or other data-sharing networks.

4 – To emphasize the importance of standardizing data sets and individual data for effective data exchange and interoperability, both at the primary and secondary levels, including internationally. A crucial role will be played by unique data sources and the harmonization of data models and descriptions.



5 – To orient towards innovation, particularly in personalized medicine and augmented intelligence decision systems. Attention is drawn to the integration of digital medical technologies, such as wearables and mobile applications, into the electronic medical record (EMR), focusing on principles like uniqueness, interoperability, standardization, security, and privacy protection.

6 – To support secondary use facilities to leverage aggregated data for healthcare quality development, innovation in health technologies, and population management and policy support. The quality and timeliness of data are emphasized as paramount.

A governance strategy envisioning the integration of the political-strategic, tactical, and operational levels is anticipated and the projects that compose the action plan are categorized into “clusters”, coherent with the core goals of the Action Plan.



Fig. 8: The six “clusters” that compose the 2022-2024 Action plan

Establishing robust governance is considered crucial, be it for project results related to the structuring of exchanged data ('care-sets') or the evolution of codes (Snomed CT, LOINC, FHIR etc.). Governance is also imperative for orchestrating collaboration, decision-making, and evolution among all stakeholders (healthcare actors, industry, government). In contrast to the previous action plan, there is a significant reduction in the number of individual projects, since they are now consolidated into a set of bigger comprehensive projects with sub-projects or work packages, an approach that minimizes administrative overhead and allows to concentrate more effectively on both tactical and strategic oversight.

A more detailed view of the content of each cluster is provided here below:

Cluster 1: Quality, continuity, and safety of care

The focus is on developing dedicated systems and applications intended for use by healthcare stakeholders, including patients, with the aim of ensuring and augmenting the quality of care, preserving care continuity, and concurrently managing the costs associated with care. Projects within this cluster include:

- Electronic Referrals
- VIDIS: Integrated Virtual Medical Record
- Decision Support Platform
- Integrated Care

- DZOP
- Development of a digital care and support plan by Flanders.
- Citizen Platform for Wallonia

Cluster 2: Empowerment of citizens and access to health data and services

This cluster focuses on establishing and standardizing rules and guidelines for systems within the online health ecosystem accessing a citizen/patient's health information. These guidelines encompass elements like informed consent, therapeutic and care relationships, access matrix, and powers of attorney. Additionally, the cluster aims to empower citizens/patients by enhancing digital and health literacy, offering increased access to personal data. An integral part of this initiative involves evolving the current "Personal Health Viewer" into a more comprehensive "Personal Health Record," allowing citizens/patients to actively record their data, integrated with a personal vault.

Cluster 3: Empowerment of healthcare professionals and care professionals and access to health data and services

This cluster involves implementing a local Electronic Medical Record (EMR) tailored for healthcare providers and institutions. Financial support is extended to hospitals to adopt an integrated electronic patient record, a requirement for realizing the BIHR concept. Furthermore, efforts include facilitating software development for primary care providers facing limited software options. Support is provided to healthcare professionals to ensure compliance with regulations and guidelines for data and service access. Investments are made in education, literacy programs, and awareness-building for all available digital healthcare services. Specific incentives are introduced to promote qualitative and timely data sharing, fostering care continuity and multidisciplinary collaboration, and supporting secondary data use. The development of a dedicated portal for healthcare providers, serving administrative purposes and linking to COBRHA, is also part of this initiative.

Cluster 4: Facilitating the exchange of data on care and health

This cluster aims to establish functional and IT frameworks to streamline the exchange of standardized, structured, and encrypted data across all healthcare entities. Key components include transitioning from textual DSEO to more granular and structured "care-sets," implementing an API economy for data access, defining and implementing data standards, and ensuring the quality of databases like SAM and COBRHA. The project consolidates efforts from the previous action plan, focusing on structuring communications among diverse stakeholders in healthcare. The primary objective is to automate the generation and processing of messages related to a citizen/patient's health, converting raw "data" into actionable "information." The approach involves adhering to international standards with minimal Belgian-specific extensions, including FHIR, LOINC, and Snomed CT. Data exchange occurs through "care sets," structured to meet Belgian providers' logical model needs, standardized based on international FHIR standards, and coded using SNOMED CT Value Sets, with flexibility for alternative codifications like LOINC. These care sets facilitate data exchange across intra and extramural care stakeholders, promoting collaboration around coherent clinical meanings. The metahub/hub/health vault system orchestrates this exchange, with the consolidation of these projects expected to enhance efficiency and speed of delivery.

Cluster 5: Innovation and promotion of research and development

This cluster focuses on ensuring the seamless integration of new technologies, including artificial intelligence, telemedicine, and expanded home care, into the current online health ecosystem. Additionally, the project aims to organize and enhance access to anonymized or pseudo-anonymized health data, encompassing open

data, big data, AI, and the Health Data Authority (HDA). Another objective is to advance the evaluation of health technologies.

Cluster 6: Digitization and optimization of administrative processes

This cluster aims to accelerate the transition from inefficient and error-prone manual processes, mainly paper-based, to rapid and secure electronic exchanges among healthcare entities. The projects include:

- Mult-eMediatt: Implementation of Electronic Disability Certificates
- MyCareNet: digitization of forms and contracts
- Vocational Rehabilitation: Formulation and implementation of a communication platform among stakeholders (general practitioners, consultants, and workers) for vocational rehabilitation.

3.2 E-Health support by the National Recovery and Resilience Plan (2021 – 2025)

The National Recovery and Resilience Plan (NRRP), introduced in 2021 alongside the e-Health action plan, aligns closely with e-Health priorities. In the framework of Axis 2 “Digital Transformation”, component 2.2 “Public Administration”, there is one project fully dedicated to e-Health and healthcare digitalization, with an approximate value of 40 Meuro.

Within the project the emphasis is on providing healthcare providers with more user-friendly digital tools and a comprehensive overview of health data for seamless integration into medical records, aiming to enhance patient profiles and optimize care delivery. Recognizing current challenges of disparate initiatives and conflicting priorities, the document calls for a focus on reducing costs, improving prescription quality through decision support tools, and ensuring structured information sharing among healthcare professionals. Harmonized and transparent governance is deemed crucial, along with addressing issues like double encoding of medical information.

Three main goals are set for the NRRP, in the field of e-Health, here detailed:

- 1. The empowerment of citizens, both in their role as an active contributor to their health or their healing process.**
 - *Empowerment of the citizen/patient by making access to health data as user-friendly as possible, and by providing for a more active role with attention to those who are less digitally savvy.*
 - *Enable data sharing by promoting and developing interoperability and multidisciplinary in all applications made available, with the healthcare user as an active participant*
 - *Work on citizen trust in health applications and safe use of data with absolute respect for the privacy of all health care users.*
- 2. Provide efficient digital tools to healthcare providers and healthcare institutions to further optimize care and innovate the healthcare experience**
 - *Ensure knowledge, user support, training of caregivers and support in the use of e-Health services.*
 - *Digitalization of clinical biology and medical imaging requests and results and Tools allowing or facilitating teleconsultation*
 - *Visualization of patients' integrated medication regimen, i.e. a complete and global view of the entire medication regimen (medication regimen, prescription, advice, dispensing, dosage, diary, reimbursement, etc.)*



- *Support for home hospitalization and integrated care through digital systems which are being developed for this purpose to enable effective care and communication within multidisciplinary care teams.*
 - *Support and promotion for innovation in the digitalization of healthcare*
- 3. Developing the secondary use of health data for policy support, population health management, research and innovation.**
- *Definition of a health data governance framework and organization, common objectives and priorities, common standards and methodologies emphasizing communication and dissemination of knowledge.*
 - *Ensure data availability in accordance with FAIR principles*
 - *Develop technical information capabilities for health data and define a framework for privacy and security policy.*
 - *Creation of indicators and collection of data related to healthcare, allowing better financial management, reducing waste and improving general health by being able to make political choices based on qualitative data and analyses.*

The **implementation** is going to be different depending on the proposed actions. Part of the actions aims to support the industrial market for the successful implementation of strategic and high added value projects in e-Health for patients, providers, society and public policies and to ensure integration with the European Data Space about health. The “decalogue” for the implementation phase is the following:

1. Support multidisciplinary care by providing Care Sets.
2. Expand electronic prescribing capabilities.
3. Improve the quality of prescriptions and reduce costs using clinical decision support systems.
4. Create an integrated view of dispensed medicine information and activate care user.
5. Operationalization of tele-consultation.
6. Establish a health data ecosystem aligned with healthcare market objectives open data from the European Commission.
7. Activate and empower citizens in managing their own health and well-being
8. Stimulating innovation in digitalization in healthcare.
9. Support and stimulation of integrated care teams thanks to specific reusable software components.
10. Assembling existing online health applications into a user-friendly information flow (care pathway), simple and easily usable with clear added value for 1st and 2nd line care providers.

3.3 Use of data for a Europe that “cares, prepares and protect” – Belgian EU Council Presidency – 1st semester 2024

Some insights about the envisaged use of data for a Europe that 'cares, prepares, and protects' have been provided by the Belgian Prime Minister Vandenberghe on October 11th, 2023 on the occasion of the first governance board of the HDA. Here following an extract from its speech.

“A crucial period is approaching, during which the Health Data Agency plays a significant role: the start of Belgium's European presidency on January 1st in H1 2024 where Belgium aims to focus on a Europe that 'cares, prepares, and protects.' To achieve these three ambitions, data is essential.

Under the banner of CARE

In order to provide the appropriate multidisciplinary care that Belgium envisions, it is crucial to ensure that their healthcare providers are well-trained and develop the necessary skills – continuously evolving and acquiring new insights. For this, data is essential. To transition to a needs-driven system and effectively reform, it is important to identify unmet needs in the healthcare system and establish priorities in an empirically supported manner. Again, data is necessary. To engage in population management and implement preventive measures that truly contribute to achieving optimal health, or to ensure that everyone can make choices for their health... data is essential in those scenarios as well.

Under the banner of PREPARES

COVID-19 has clearly demonstrated that data are essential for the effective management of a pandemic. Proactive knowledge, rapid availability, and utilization of data are crucial for this purpose. Groups such as the Risk Assessment Group, Risk Management Group, and operational and political policies can only function when relying on real-time information that shows us how the pandemic is evolving on a daily or faster basis, indicating where priorities need to be set. Data are also indispensable in the study of Antimicrobial Resistance (AMR), research for better antibiotics, or the development of new ones.

Under the banner of PROTECTS

The minister of health took the initiative in Europe to ensure the availability of medication in the future by establishing a solidarity mechanism between countries. If a shortage threatens in one country, another can help. However, for this to happen, you need to know where shortages are imminent and to what extent. The same applies to the Critical Medicines Act that Belgium has proposed. The Critical Medicines Act aims to ensure production capacity in Europe as well. For both the solidarity mechanism and the Act, data are indispensable."

European partners have also recognized that the amount of data in one EU member state is often insufficient. The establishment of the European Health Data Space (EHDS) is a significant step forward in this regard. Belgium immediately embraced this initiative, but also has to be strict regarding the GDPR regulation. And rightfully so. If Belgium expects to use health data from their citizens, they want to demonstrate responsibility and earn that trust from the outset. The availability of high-quality data is also the key ingredient for developing AI systems. These AI systems offer opportunities to share knowledge and provide support to policymakers, healthcare providers, and even individuals. However, the necessary data must be available to scrutinize the AI models and contextualize them.

On this European aspect: in terms of competencies, Belgium is not the simplest country in Europe. They also need to involve the regions. Therefore, they are currently exploring how to give the Health Data Agency an inter-federal role, with the regions having, for example, voting rights in the management committee.

The Health Data Agency will and must play a crucial role in future healthcare policies. In its country and by collaborating closely in Europe."



4 – SWOT Analysis on digital health innovation

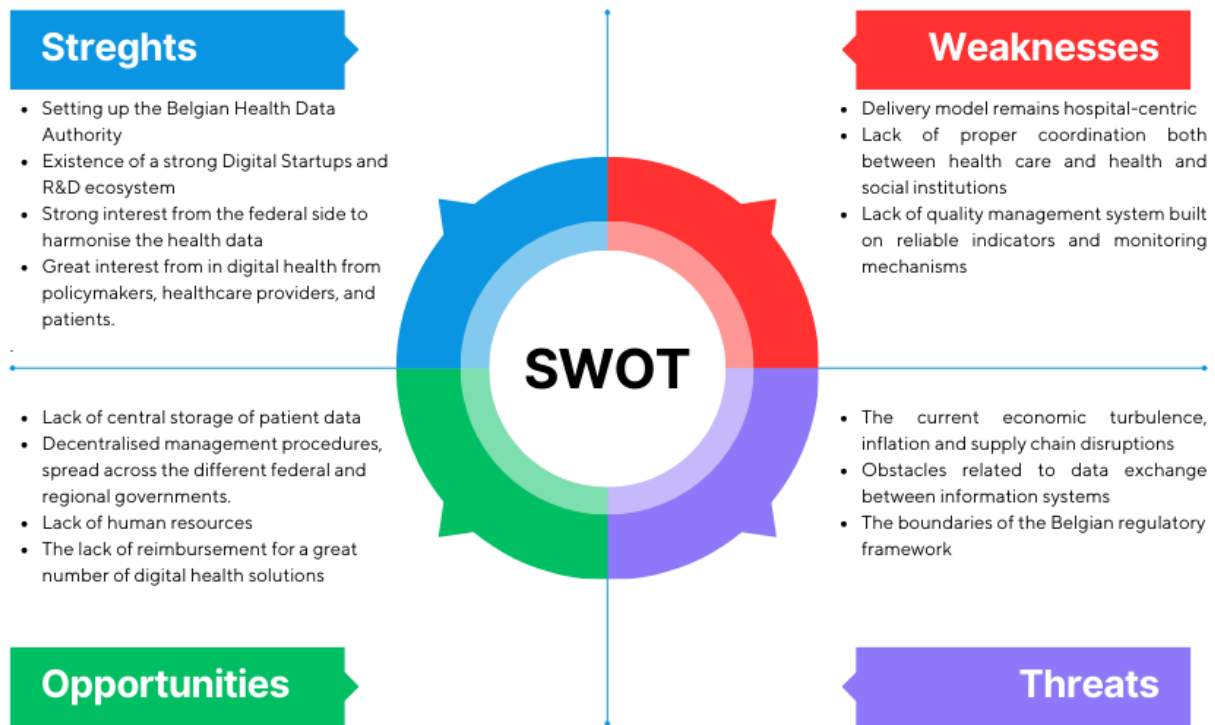


Fig. 9: SWOT Analysis of the Belgium landscape of digital health innovation

4.1. Strengths

- **Establishing the Belgian Health Data Authority** provides a centralised and coordinated approach to data governance, access, and standardisation, fostering improved interoperability, data security, and strategic planning for the benefit of healthcare delivery and public health outcomes.
- Over the last few years **concrete steps have been taken on the federal level to harmonise health data** contribute to improved interoperability, data standards, access, quality, collaboration, public health planning, trust, research, and compliance with regulations. These factors collectively enhance the overall efficiency and effectiveness of the healthcare system.
- **Existence of a vibrant digital health community, composed by strong digital start-ups and R&D ecosystem and multidisciplinary opportunities for collaboration between the sectors** fosters innovation, encourages entrepreneurial culture, provides diverse solutions, facilitates collaboration, attracts talent, offers funding opportunities, enhances global competitiveness, and ensures adaptability to emerging trends — all of which can contribute to the continuous improvement and advancement of e-Health practices in Belgium.
- Great interest in **digital health innovation from healthcare providers, patients, and policymakers** signifies a commitment to patient-centric care, improved healthcare delivery, enhanced patient engagement, data-driven decision-making, efficient communication, tele-Health expansion, policy support, efficient resource allocation, global competitiveness, and increased public awareness and adoption of digital health solutions.

4.2. Weaknesses

- **No central storage of patient data** distributing patient information across various healthcare providers and institutions. The absence of a central storage system can lead to interoperability challenges. Different healthcare providers may use varied systems, standards, and formats for storing and managing patient data. Without a centralized oversight mechanism, maintaining consistent data quality becomes a challenge.
- **Decentralised management procedures**, spread across the different federal and regional governments raises several challenges related to standards fragmentation, data integration inconsistencies, coordination difficulties, interoperability barriers, resource inefficiencies, limited scalability, policy variability, implementation challenges, and data governance complexities. Addressing these challenges is crucial for creating a more cohesive and effective e-Health ecosystem.
- **Shortage of qualified human resources** represents a substantial obstacle in the development of e-Health field, affecting expertise, innovation, governance, system deployment, user support, cybersecurity, research, and strategic planning. Especially for the public sector, it seems difficult to be attractive for talents in data science, mainly due to the competition of the private sector. Addressing this challenge is crucial to ensuring the successful and sustainable evolution of digital healthcare initiatives.
- **The lack of reimbursement for a great number of digital health solutions** is one of the major deficiencies in the Belgian (regulatory) landscape.
- **A certain “conservative” attitude of Belgian corporates, hospitals, and institutions to work with start-ups**: this implies some reluctance to embrace new and unconventional methods, technologies, or partnerships, while preferring stability and established practices over taking risks associated with engaging with start-ups.

4.3. Opportunities

- **The COVID-19 crisis has brought the digitalization of public health to the forefront**, increasing the pace of the application of digital healthcare products (e.g., the increased use of medical, fitness and well-being apps). Radical social distancing measures and the need to reduce pressure on hospital units resulted in clusters of emergency tele-Health measures being adopted.
- **Political commitment to reform and re-organisation of the clinical departments** are success factors for effective development and implementation of e-Health.
- **Active use of EU funds** to support setting up the new framework for data sharing across stakeholders.

4.4. Threats

- **The current economic turbulence, inflation and supply chain disruptions** will undoubtedly continue to have an impact on the digital health landscape. Payers will have to find new and inventive ways of funding health solutions to accommodate constrained healthcare budgets and fragmented reimbursement schemes, for example by exploring value-based payment schemes.
- **Obstacles related to data exchange between information systems** of different providers. Interoperability is important, partly because, in practice, patients often consult multiple healthcare providers during a care pathway and because information exchange between healthcare providers is crucial for optimal treatment.
- Novel health technologies (e.g., AI, the IoMT, 5G networks and Bluetooth) are challenging **the boundaries of the Belgian regulatory framework**, which is often ill-adapted to address the legal concerns such technologies entail. Existing laws and regulations scarcely accommodate the questions



raised because of a continuously developing digital healthcare industry and a strict application of the GDPR regulation, sometimes represents a hurdle for the development of innovative projects.

- In such a quickly challenging environment, requiring actions and pragmatic approaches, the **times of regulatory bodies are sometimes perceived to be too slow or not fast enough to cope with the speed of change in the field.**

5 – Transferable Good practices

5.1 Good practice n.1: Belgian Health Data Agency

Belgian Health Data Agency (HDA) serves as a framework dedicated to enhancing the discoverability of data collections. It achieves this by establishing a metadata catalogue and facilitating the simplification, and standardisation of procedures for accessing data, while also harmonising governance. The main objective of the Belgian HDA is to guarantee the collection, standardisation, and ethical utilisation of health data, ultimately benefiting the citizens of Belgium and the wider European community.

To summarise its goals and relevance we take advantage of the words pronounced by the Belgian Prime Minister Vandebrucke on October 11th, 2023 on the occasion of the first governance board of the HDA:

“Although Belgium has a tradition of collecting many types of data on health at the population level - which is indispensable for the management and proper functioning of our health and social security services, among other things – Belgium has long come to the conclusion that these data are too fragmented across different organizations and systems. In the past ten years progress has been made in standardizing health data and making it searchable, accessible and reusable, but an integrated federal initiative was really needed. Belgium needed (1) a vision and a long-term health care policy, based on scientific evidence; (2) to organize a policy for sustainable changes in the way we organize our care; and (3) to arrive at a policy for investments in care that - in both the short and long term - contribute most to health gains, accessibility, quality and efficiency. That’s why the HDA has been founded. Not just as a unique focal point for sharing and providing access to health data in a GDPR-compliant manner, but also as the foundation for ensuring a high-quality and, above all, efficient healthcare system. To fulfil this ambitious vision, unlocking, decoupling, and interconnecting health data, including demographic and socio-economic information, is imperative. These data need to be (re)used, especially for research and innovation in healthcare. The newly established Health Data Agency is set to play a pivotal role in such a data-driven healthcare system.

The mission of the HDA is both substantial and indispensable: it involves establishing a data catalog, making data FAIR (Findable, Accessible, Interoperable & Reusable), harmonizing and expediting procedures for accessing this information and building knowledge and expertise through training. The HDA will also ensure that all this occurs in a secure manner and with full respect for the privacy of citizens and patients. However, it doesn't end there: only through transparent communication, providing information, and explaining to citizens and patients why this is crucial – for instance, in the development of new therapies – can a relationship of trust be established.

The Health Data Agency inherently supports academic research, as well as research in the pharmaceutical industry. Belgium has a top position in organizing Clinical Trials which faces new challenges. Belgium wants



to reinforce their pioneering role by ensuring smooth and accurate data availability for product development, especially in times of advancing genetic research and artificial intelligence.

To illustrate, innovative drugs demonstrate their ability to cure diseases that were previously untreatable during clinical trials, though uncertainty remains about long-term effects. Therefore, Belgium wants to aggregate this data, gather expertise to monitor qualitative and quantitative evidence over time, additionally, to measure the effectiveness and economic impact of innovative therapies and systems. This is also why the minister proposes a reform in the reimbursement system for pharmaceutical products in Belgium, ensuring early and rapid access to innovative therapies, also wanting to establish a 'real-world evidence platform' to collect and analyze scientific evidence."

The official (public) launch of the Agency will be on January 17th, 2024.⁹

5.2 Good practice n. 2: DPO Connect

DPO Connect is an initiative that brings together national data protection officers (DPOs), both from the public and private sector, to discuss challenges and exchange experiences.

Functioning as a professional digital social network, DPO Connect provides a collaborative platform whose primary aim is to facilitate the definition, execution, and implementation of projects among its members, thereby creating a network effect that extends to various business project engineering communities.

This collaborative space is the outcome (2021) of a partnership subsidized by the European Commission, comprising three key members: the Data Protection Authority, the Vrije Universiteit Brussel, and DPO-pro, the professional association of Belgian data protection officers (DPO).

Key to the effective use of DPO Connect is the establishment of common rules and the articulation of the "rights and duties" along with the conditions of use. These foundational elements must be accepted by individuals seeking to register as members, ensuring a framework conducive to positive and productive interactions within the DPO Connect community.

Each member registered on the DPO Connect platform has the opportunity to engage in exchanges within established public groups, adhering to general operating rules. Additionally, members can take the initiative to create their own groups, assuming the role of the "Found" member and administrator.

The essence of DPO Connect lies in the active participation of its members, emphasizing that the value is derived from user engagement. Creating a collaborative group involves not only establishing it but also nurturing its vitality by engaging and animating its members. The primary responsibility of founders and administrators is to breathe life into these groups.

The DPO connect platform and its content are not directly accessible by Internet users via search engines but require a registration.¹⁰

5.3 Good practice n.3: FAQIR Foundation

FAQIR advocates for the implementation of a data-driven healthcare system, emphasizing the potential benefits of personal health data records for enhancing data usage by both individuals and machines,

⁹ www.hda.be

¹⁰ www.dpoconnect.be



contributing to the overarching goal of saving lives (#DataSavesLives). FAQIR envisions a scenario where health data serves as a catalyst for positive change, empowering citizens and stakeholders through more intelligent and meaningful data utilization. FAQIR aims to establish itself as a trusted entity in the healthcare landscape, with the philosophy and utilization of SOLID at the core of its rapidly scaling operations.

To foster trust within the healthcare ecosystem, FAQIR is establishing a robust governance framework. This structure ensures the trustworthy, secure, and ethically sound handling of health data. SOLID, a fundamental specification embraced by FAQIR, plays a pivotal role in secure data storage. In the decentralized realm of Pods, FAQIR grants individuals control over their health data, whether it's structured data or regular files. This empowering feature allows individuals to grant or revoke access to their data as needed.

FAQIR is committed to fully interoperable standards, facilitating seamless data accessibility and sharing. The use of standard, open, and interoperable data formats and protocols within the SOLID framework encourages collaborative work with the same dataset across different applications, fostering interoperability and innovative healthcare applications.

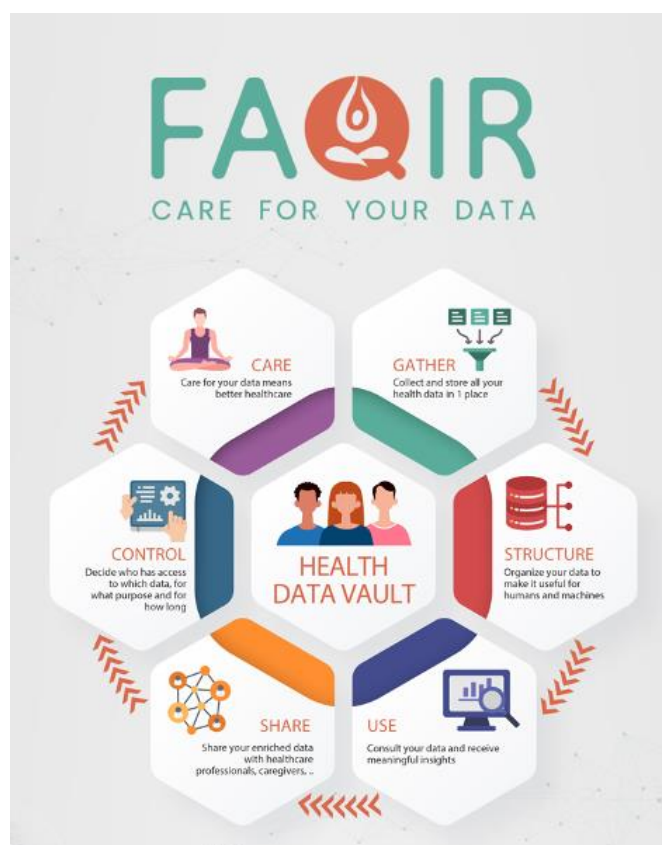


Fig. 10: Main building blocks of FAQIR for data storage and sharing. Source: www.faqir.org

5.4 Good practice n.4 - Open Data Platforms

Belgium hosts various **open data platforms**, such as the HISIA platform housing survey data at Sciensano, and the IMA-AIM Atlas dedicated to socio-demographic indicators and healthcare utilization. These platforms offer interactive tools facilitating the analysis of publicly accessible, anonymized datasets.

The Belgian Health Interview Survey Interactive Analysis (HISIA), now accessible through Sciensano features an online application which allows people to conduct analyses on Health Interview Survey (HIS) data.

Equipped by a user-friendly interface, featuring pre-defined procedures accessible through menus, it ensures ease of use without requiring prior knowledge of the SAS® statistical package.

HISIA functions as an interface between health survey data on the one hand and the Internet module of the statistical software package SAS® (Stored Process on SAS BI) on the other hand. The user can select the necessary parameters on the interactive web page which will be analysed with the SAS system. The application's results can be used for free, with the only condition of mentioning the source.

The statistics of the Health Interview Survey (HIS) are classified in 6 main chapters: Health and quality of life, Lifestyle, Prevention, Mental health, Health and social services, Health and society and each of these chapters are subdivided in modules.

Data are collected through a large-scale Health Interview Survey (HIS) among the Belgian population, launched for the first time in 1997 and then repeated every 4 to 5 years since. The present survey data collection started in January 2023 and will be completed in June 2024.

All HIS results are available online in extensive reports and via the interactive tool HISIA.

Webpage: <https://www.sciensano.be/en/projects/health-interview-survey>

IMA-AIM Atlas (<https://ima-aim.be/>) is a permanent resource curated by the InterMutualistic Agency, featuring statistics divided into six themes: demography, socio-economics, prevention, health status, healthcare consumption, and organization of healthcare.

Data come from the national insurance funds that, in order to fulfill their responsibilities, contribute with invoicing data (e.g., date, place, and cost of services) and administrative member information (e.g., gender, age); data are coded and medical specifics are never being transferred.

On these data IMA conducts comprehensive studies and offers governmental recommendations. Data analysis is undertaken proactively by the IMA or upon request from legal partners, including the National Institute for Health and Disability Insurance (Riziv), the Federal Public Service (FPS) Public Health, FPS Social Security, and the Federal Knowledge Center for Healthcare. Additionally, the IMA collaborates on research with various federal government bodies, regions, communities, and universities. Finally, through the Atlas, individual users can access and download global figures for Belgium, regions, and provinces, as well as detailed figures for districts and municipalities; specific indicators are available per hospital.

The table here following showcases an example of data available from the IMA-AIM databases, highlighting in this case the number of patients undergone through surgery for lung cancer in the period 2006-2014 in Flanders region.



Chirurgie utilisée en cas de cancer de poumons [nombre de patients] Flandre 2006-2014

| | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|--|------|------|------|------|------|------|------|------|------|
| UZ Leuven | 275 | 289 | 280 | 297 | 267 | 297 | 302 | 316 | 303 |
| AZ Sint-Jan Brugge-Oostende [Brugge] | 68 | 79 | 68 | 80 | 82 | 88 | 103 | 122 | 141 |
| UZ Gent | 64 | 71 | 108 | 87 | 93 | 115 | 117 | 114 | 118 |
| UZ Antwerpen | 81 | 88 | 88 | 100 | 104 | 96 | 129 | 96 | 112 |
| Ziekenhuis Oost - Limburg [Genk] | 65 | 56 | 69 | 73 | 59 | 75 | 67 | 72 | 96 |
| Jessaziekenhuis [Hasselt] | 58 | 49 | 57 | 55 | 60 | 53 | 67 | 54 | 71 |
| AZ Groeninge [Kortrijk] | 37 | 41 | 30 | 33 | 49 | 39 | 58 | 54 | 68 |
| GZA- Ziekenhuizen [Wilrijk] | 67 | 64 | 70 | 54 | 66 | 57 | 61 | 65 | 60 |
| Ziekenhuisnetwerk Antwerpen | 49 | 49 | 43 | 50 | 42 | 54 | 57 | 65 | 55 |
| Onze Lieve Vrouwziekenhuis Aalst | 45 | 44 | 42 | 40 | 52 | 40 | 39 | 59 | 53 |
| AZ Nikolaas [Sint-Niklaas] | 25 | 14 | 21 | 33 | 30 | 25 | 45 | 38 | 45 |
| Imelda Ziekenhuis [Bonheiden] | 18 | 20 | 19 | 21 | 18 | 13 | 10 | 23 | 30 |
| AZ Turnhout | 16 | 16 | 20 | 26 | 35 | 47 | 30 | 22 | 30 |
| AZ Monica [Deurne] | 9 | 10 | 8 | 8 | 19 | 21 | 11 | 13 | 29 |
| AZ Sint-Lucas [Gent] | 34 | 25 | 26 | 30 | 25 | 36 | 32 | 32 | 27 |
| AZ Maria Middelaars [Gent] | 19 | 30 | 18 | 25 | 19 | 25 | 36 | 31 | 26 |
| RZ Sint-Trudo [Sint-Truiden] | 8 | 16 | 18 | 21 | 19 | 16 | 12 | 14 | 25 |
| Algemeen Stedelijk Ziekenhuis [Aalst] | 19 | 20 | 22 | 23 | 17 | 19 | 19 | 14 | 25 |
| AZ Sint-Maarten [Mechelen] | 13 | 15 | 18 | 12 | 9 | 11 | 8 | 23 | 25 |
| Mariaziekenhuis Noord-Limburg [Overpelt] | 10 | 12 | 13 | 10 | 15 | 18 | 21 | 24 | 22 |
| AZ Sint-Lucas [Brugge] | 15 | 10 | 5 | 11 | 10 | 16 | 22 | 24 | 21 |
| H.-Hartziekenhuis Roeselare - Menen | 16 | 24 | 28 | 27 | 23 | 22 | 24 | 36 | 19 |
| AZ Sint-Dimpna [Geel] | 7 | 7 | 9 | 11 | 7 | 14 | 14 | 15 | 16 |
| AZ Damiaan [Oostende] | 7 | 14 | 13 | 9 | 15 | 18 | 23 | 33 | 15 |
| Jan Yperman Ziekenhuis [leper] | 7 | 6 | 8 | 14 | 21 | 21 | 19 | 7 | 15 |
| AZ Jan Palfijn [Gent] | 11 | 5 | 11 | 8 | 7 | 7 | 4 | 5 | 14 |
| AZ Sint-Blasius [Dendermonde] | 15 | 16 | 17 | 11 | 12 | 14 | 14 | 19 | 14 |
| Stedelijk Ziekenhuis [Roeselare] | 3 | 10 | 6 | 6 | 6 | 4 | 5 | 5 | 14 |

Communiqué de presse IMA-AIM 24/04/2016

www.ima-aim.be atlas.ima-aim.be

Fig. 11: Example of data available from the IMA-AIM databases



6 - Good practices related to gender diversity and inclusiveness

As of 2023, Belgium has been recognized for its significant strides in gender equality, placing it in the upper echelons among EU countries (see Figure X) below, with considerable advancements in reducing the gender pay gap and in implementing policies to combat workplace discrimination. However, it continues to face challenges in achieving balanced representation in top leadership positions, like other EU nations and strives to align its policies with the European Union's overarching goal of fostering greater gender equality across member states.



Fig. 12: With 71.4 out of 100 points, Belgium ranks 9th in the EU on the Gender Equality Index. Belgium's score is 3.5 points above the EU's score. Source: <https://eige.europa.eu/gender-equality-index/2023/BE>

In recent years, Belgian policymakers have shown escalating concern regarding gender-specific health issues, prompting a need for gender-sensitive health reporting beyond mere sex-based comparisons. Addressing this gap, a Belgium women's health report aimed to identify gender-specific health concerns and knowledge gaps. Findings revealed multiple data gaps, including the prevalence of conditions like endometriosis and polycystic ovary syndrome, alongside underutilized data on fertility treatments, abortions, and contraception. Particularly concerning was the stark difference in the health status of girls (11-18 years) compared to boys, with girls exhibiting higher rates of psychosomatic symptoms, negative health perceptions (22% vs. 15% in boys), and depressive symptoms (47% vs. 31% in boys). Conversely, boys were more likely to meet WHO physical activity recommendations. This inaugural report underscored the necessity for improved data collection on women-specific issues and advocated for targeted interventions, especially for teenage girls.¹¹

6.1 Good practices within healthcare and data ecosystems

Belgium has been at the forefront of implementing various initiatives and policies to promote gender diversity and inclusiveness within its healthcare and data ecosystems. Here are some notable good practices in this regard:

¹¹ Original data and findings from the Women's Health Report for Belgium, 2023.

Gender Diversity Initiatives:

1. **Women in STEM Programs:** Belgium has actively promoted women's participation in Science, Technology, Engineering, and Mathematics (STEM) fields. Institutions like the Brussels Women in Technology (BWIT) organization have been instrumental in organizing workshops, mentorship programs, and networking events to encourage and support women in pursuing careers in STEM. These efforts have contributed to reducing gender gaps in the technology and healthcare sectors.¹²
2. **Diversity Policies in Healthcare Institutions:** Several healthcare institutions in Belgium, such as the University Hospitals Leuven, have implemented inclusive policies that prioritize gender diversity in their workforce. They have established comprehensive recruitment strategies that ensure equal opportunities for all genders. Through these measures, they have successfully created a more inclusive and diverse healthcare environment.¹³

These practices underscore Belgium's commitment to fostering an inclusive and participatory healthcare ecosystem. By prioritizing gender diversity Belgium has advanced towards ensuring equitable access to healthcare services and promoting a patient-centered approach to data governance.

6.2 Relevant organizations

BEWISE mentoring programme

BEWISE was established as an independent non-profit organisation cutting across the linguistic borders in Belgium. It currently involves around 300 volunteers who offer mentoring to women STEM researchers, as well as skill-building workshops. Mentees are matched with experienced mentors (at least 10 years' experience) from other fields and institutions, reflecting their needs, career choices, strategies, work-life balance and mobility.

Observatory for Research on Scientific Careers

The independent Observatory for Research on Scientific Careers was created following the joint decision of representatives of the different French-speaking universities, the FWB and FNRS. It aims to create and follow up (missing and random) data on researchers in order to create a comprehensive, objective data collection. Its main goals are to monitor and use the expertise of different universities and partners to carry out analytical evaluations and statistics on researchers in the FWB.

6.3 Initiatives for gender equality by research performing organisations

In response to the 2012 decrees, the five Flemish universities came together in the VLIR and formed a High-Level Task Force on Gender to develop gender policy at universities from the ground-up. The Task Force developed the Action Plan for Gender Higher Education, which was approved by the Ministries of Higher Education and Research, and Equal Opportunities. Under the Action Plan, universities committed to setting

¹² <https://www.bwit.be/>

¹³ (Source: University Hospitals Leuven Website - <https://www.uzleuven.be/en/diversity>)



up a tailored GAP in each university, as well as an Inter-University Charter on Gender Equality by early 2014 (renewed for 2019). The VLIR is to carry out a biennial evaluation of the Inter-University Charter.

Using grants received from the FWB, all universities in the French-speaking Community appointed a Gender Contact Person. Their mission is to:

- Compile an annual report on gender balance, including a list of gender policies within the university;
- Facilitate networking between all people involved in gender issues at the university;
- Ensure better visibility for gender matters;
- Propose an action plan to foster gender balance in the university, in collaboration with academic authorities.

All universities seem to have complied with the above requirements. Most French-speaking universities initiated the drafting process of the GAPs for 2020, in this examples are: University of St. Louis, Liège, Catholic University of Louvain, KU Leuven, University of Antwerp's, Hasselt University among others.¹⁴

7 - Potential synergies with other EU regions

7.1 - Cross-border cooperation in healthcare

Belgium, due to its geographical localization, has been a pioneer in fostering cross-border cooperation in healthcare and synergies with other European countries and regions.

The country recognizes the importance of collaborative efforts to address health challenges that transcend national borders and is very active in initiatives with neighboring countries, such as France, Germany, Luxembourg, and the Netherlands, to enhance the efficiency and effectiveness of healthcare delivery in border regions.

A key aspect of Belgium's cross-border healthcare cooperation is the promotion of seamless access to medical services for residents living near the national boundaries. Agreements and partnerships with neighboring countries - historically with France but also in the framework of the BeNeLux – Belgium, Netherlands, Luxembourg cooperation - facilitate the exchange of patient information, harmonization of medical standards, and coordination of healthcare services.

The commitment to cross-border healthcare cooperation is also evident in Belgium's involvement in cross-border health networks and initiatives. Collaborative platforms and partnerships bring together healthcare professionals, policymakers, and stakeholders from different countries to address common challenges, share best practices, and facilitate continuous learning. This exchange of experiences enhances the adaptability of healthcare systems to diverse needs and promotes a more holistic understanding of health on a regional level.

Here following we present some examples of initiatives, networks, and projects where Belgian stakeholders are involved.

Belgium-France Cooperation

Since the 1990s, Franco-Belgian cooperation in health has significantly developed through the signing of framework agreements, the elaboration of cooperation conventions, and the formalization of joint projects

¹⁴ <https://eige.europa.eu/gender-equality-index/2023/BE>



(thanks to INTERREG). These collaborations primarily focus on the fields of healthcare, medico-social services, and emergency medical assistance.

The action is particularly relevant at the cross-border space France-Wallonia-Flanders, which is composed of territories with diverse geographical, demographic, cultural, socio-economic, and health-related characteristics, where the question of access to healthcare inevitably refers to the distribution and organization of healthcare services. The long term cooperation has resulted into the creation of a series of organised zones for cross-border access to healthcare (ZOAST). These zones facilitate cross-border patient mobility, pool resources and techniques and coordinate social security systems for cross-border healthcare districts.



Fig: 13: The cross-border space France-Wallonia-Flanders (in dark blue)¹⁵

For a detailed history of the French-Belgian cooperation in healthcare, since the first inter-hospital agreement in 1993, it is possible to visit [this link](#).

The cross-border cooperation between Belgium and France is a case study but similar agreements exist with the Netherlands and Germany at the respective cross-border areas with Belgium¹⁶.

Belgium-Luxembourg cooperation

Much more recently, in March 2023, Luxembourg and Belgium have signed their framework agreement on cross-border healthcare cooperation: in concrete terms, it establishes a legal basis that will facilitate cooperation between the two healthcare systems. This agreement is intended to improve access to healthcare for residents in border areas and promote exchanges, similarly to the existing agreement with

¹⁵ <https://www.google.com/url?sa=i&url=http%3A%2F%2Fwww.espaces-transfrontaliers.org%2Fen%2Fresources%2Fterritoires%2Fterritory-factsheets%2Fterritoires%2Fterritory%2Fshow%2Fgrande-region%2F&psig=AOvVaw2yNabQbQKa-RakBNtdHVLY&ust=1702340247197000&source=images&cd=vfe&opi=89978449&ved=2ahUKewiT6YTfjYaDaxU-5bsIHZSHBMMQr4kDegQIARB>

¹⁶ [https://www.europarl.europa.eu/RegData/etudes/STUD/2021/690904/IPOL_STU\(2021\)690904_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2021/690904/IPOL_STU(2021)690904_EN.pdf)



France. It also allows for the expedited handling of emergencies and is also intended to assist in the context of a shortage of doctors by facilitating cross-border consultations and their coverage by health insurance.

7.2 – Examples of Innovation networks

EIT-Health Belgium-Netherlands

EIT Health, established in 2015 as part of the European Institute of Innovation and Technology (EIT), operates as a knowledge and innovation community (KIC) specializing in health and aging. Within the EIT framework, various KICs concentrate on distinct innovation sectors. The underlying principle, known as the 'knowledge triangle,' emphasizes that optimal innovation occurs when experts from business, research, and education collaborate, creating an environment conducive to innovation.



At EU level EIT-Health is organized around seven Co-Location Centres (hubs) and InnoStars. One of the co-location centres covers Belgium, Luxembourg and Netherlands; it consists of 23 partners from key areas of healthcare such as imaging, biotech, MedTech, health policy and economics, as well as from some of the world's leading academic and research organisations & healthcare providers.

Vanguard Initiative – Pilot action Smart Health/ Personalised Medicine

The Vanguard Initiative is an alliance that gathers 38 of the most advanced industrial regions in Europe, focused on stimulating industrial innovation and building European value-chains based on complementarities in regional smart specialisation strategies.



The primary focus of the Vanguard Initiative lies in executing its Pilot Projects, conceived through the active involvement of clusters, science parks, research institutes, and universities within the member regions. Through the collaboration of regions and their stakeholders, the Pilot Projects strive to expedite the adoption of innovations in eight thematic areas: one of those is dedicated to Smart Health and Personalised Medicine and is co- led by 2 Dutch regions and 1 Belgian Region (Flanders).

7.3 - Selected European Projects in the field of Health data with partners from Belgium

Following a dedicated analysis on CORDIS project repository, it has been possible to identify a series of projects related to the topic of “Health Data” where one or more partners come from Belgium. Here is a selection of some of them: for each we report a short summary, the total budget and the names of the Belgian partners involved. Data are extracted from CORDIS database, IMI and other EC official sources. It is important to note that Belgium hosts a wide variety of organisations and associations with a European scope, representing partners located all over the continent and not only based in the Belgian regions.

GDI - Genomic Data Infrastructure (2022 – 2026)

The Genomic Data Infrastructure (GDI) project aims to create a secure and sustainable infrastructure for accessing genomic, phenotypic, and clinical data held in databases across Europe. This project builds upon the Beyond 1 Million Genomes (B1MG) project and supports the ambition of the 1+Million Genomes (1+MG) initiative by establishing a federated network of national reference genome collections. The GDI project involves experts from various fields and organizations to ensure ethical and legal compliance while allowing access to secure datasets. The project will use "real" synthetic data for validation before making the data accessible through the infrastructure.¹⁷

Total budget: 40 Meuro

Belgian partners: Interuniversity Microelectronics Centre (IMEC), Sciensano, VIB, Interuniversitair Micro-electronica Centrum.

IMI BIGPICTURE (2021 – 2027)

The BIGPICTURE project, funded under IMI – Innovative medicine Initiative – aims to create a repository of digital copies of around 3 million slides covering a range of disease areas. This repository will then be used to develop artificial intelligence tools that could aid in the analysis of slides. The project will first create the infrastructure needed to store, share and process millions of image files; secondly, legal and ethical issues to ensure patient privacy and data confidentiality will be addressed. Finally, the project aims to develop functionalities to facilitate the use of the database as well as the processing of images for diagnostic and research purposes.

Total budget: 70 Meuro

Belgian partners: University of Liege, Janssen Pharmaceutica NV, UCB Biopharma SRL, Cytomine SCRLFS, European Institute for Innovation through Health Data, European Society of Pathology, Timelex.

Joint Action TEHDAS – Towards the European Health Data Space (2021 – 2023)

The TEHDAS project developed joint European principles for the secondary use of health data, thanks to a consortium composed by members from 25 countries. The project's main objectives are as follows:

- Initiate a conversation with European projects and policymakers regarding the EHDS.

¹⁷ <https://gdi.onemilliongenomes.eu/>



- Ensure the durability of health data's secondary use in Europe.
- Formulate a governance structure for cross-border co-operation among European countries for the secondary use of health data.
- Boost the consistency, compatibility, and accessibility of health data for secondary use.
- Clarify the position of individuals in the secondary use of health data and incorporate them in discussions about health data usage for policymaking and research.

The outcomes of the TEHDAS project are providing key inputs for the European Commission's legislative proposal on the European Health Data Space and contribute to the broader pan-European discussion that follows the conclusion of the project.

Total budget: 4.16 Meuro

Belgian partner: Sciensano

European Health Data and Evidence Network

The EHDEN Consortium in Europe harnesses extensive patient-level data found in Electronic Health Record (EHR) systems and other health databases, comprising both structured data like diagnoses and medications, and unstructured data in clinical narratives. This initiative seeks to enhance clinical practices and individual patient outcomes by enhancing the understanding of disease and treatment pathways through transparent and reproducible analytics. EHDEN uses a common data model (OMOP-CDM), standardized outcome assessment (ICHOM), and open-source analytics (OHDSI) to facilitate large-scale, real-world evidence research.

Total budget: 30 Meuro

Belgian partners: Forum des patients Europeens, Janssen Pharmaceutica NV, UCB Biopharma

PHIRI - Population Health Information Research Infrastructure (2020-2023)

The PHIRI project aims to facilitate open and data-driven research on the broader impacts of COVID-19 on the health of populations in Europe by sharing cross-country COVID-19 population health information and best practices related to data collection and processing. It seeks to provide a Health Information portal for COVID-19 with FAIR catalogues on health and health care data, structured exchange between countries on COVID-19 best practices and expertise, and to promote interoperability and tackle health information inequalities.

Total budget: 5 Meuro

Belgian partner: Sciensano

B1MG – Beyond 1 Million Genomes (2020 – 2023)

The B1MG project aims to establish a support and coordination structure for the European 1+ Million Genomes initiative, which involves 20 EU states and Norway committing to the sequencing of at least 1

million genomes in the EU by 2022. The project helps to create a pan-European genome-based health data infrastructure that includes data quality and exchange standards, access protocols, and legal guidance. B1MG will collaborate with international initiatives and consult with various stakeholders to provide concrete guidance on implementing personalized medicine at the local, regional, and national level.

Total budget: 4 Meuro

Belgian partner: University of Leuven

[X-e-Health \(2020 – 2022\)](#)

The X-e-Health initiative, funded by the EU, set the groundwork for a practical, secure, and cross-border Electronic Health Record exchange format to promote the growth of the e-Health sector. With the backing of over 40 entities, the project targeted a faster and more sustainable digital transformation of the EU, consisting of eight work packages, four of which focused on technical and functional activities. The goal was to develop a standardized data-sharing format structure, building on the existing Patient Summary service and establishing a common foundation for medical imaging, discharge letters, laboratory results, and rare diseases.

Total budget: 3 Meuro

Belgian partners: MedTech Europe, COCIR, EHTEL

NOTE ON REFERENCES AND SOURCES

This report has been elaborated with inputs from available public sources published on the Internet. All the main sources used for information or assessment are mentioned in the text, linked to the text or listed as foot notes or as links to the text. The authors thank all the contributors and reviewers for their valuable insights.

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