eHealth Governance - Country Report: Belgium

In collaboration with

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eHealth Governance- Country Report Belgium

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Version number – V.09 11.08.2021
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1 Introduction

1.1 Scope of the document

This report is one of the 6 reports on the eHealth Governance commissioned by EY Baltic to EHTEL in the context of a contract[1] aiming at proposing a new "Health ICT Governance Framework" to the Ministry of Social Affairs of Estonia (MoSA).

With these reports, EY and MoSA have access to a sample of international good practices on how to govern the deployment of digital health within a country or a region.

	Health system	Governance	EHR architecture
Belgium	Bismarck	Bottom-up/ Top-down	Decentralised
Catalonia	Centrally Managed	Top-down	Centralised
Denmark	Centrally Managed	Top-down	Decentralised
Israel	Bismarck	Bottom-up	Decentralised
Scotland	Centrally Managed	Top-down	Centralised
The Netherlands	Bismarck	Bottom-up	Decentralised

Figure 1: Profile of the countries and regions retained for their good practice in eHealth Governance

These reports have been prepared by EHTEL experts who either have an inside knowledge of the country or region subject to the report or worked in close collaboration with experts having such a knowledge.

They describe, for each country or region,

- The context, i.e. the health and care system and its enabling eHealth system, with its technical building blocks
- The organisation in place for involving stakeholder and
- The main governance processes

A short historical retrospective and a short analysis of successes and what could be done better helps to put these good practices in perspective.

This international experience is intended to be used as input for Deliverable 3 "To-Be model for eHealth system governance" defined in the above-mentioned contract.

This document was produced with the financial assistance of the European Union via the Technical Support Instrument. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

1.2 Methodology

The methodology for the developing these reports has been designed in two steps:

- Distinguishing IT governance from IT management
- Defining what should be included under the term eHealth governance framework.

[1] Contract reference: REFORM/SC2021/003, signed on 10.02.2021 between European Commission and EY.

The line between IT Governance and management has been drawn as follows:

- The governance function is responsible for determining strategic direction.
- The management function takes that strategic direction and translates it into actions to achieving the strategic goals.

To define what needs to be covered under the term eHealth Governance, a few models have been looked at and COBIT 5 has been retained as a relevant one to support health and care in systems in their digital transformation journey[2].

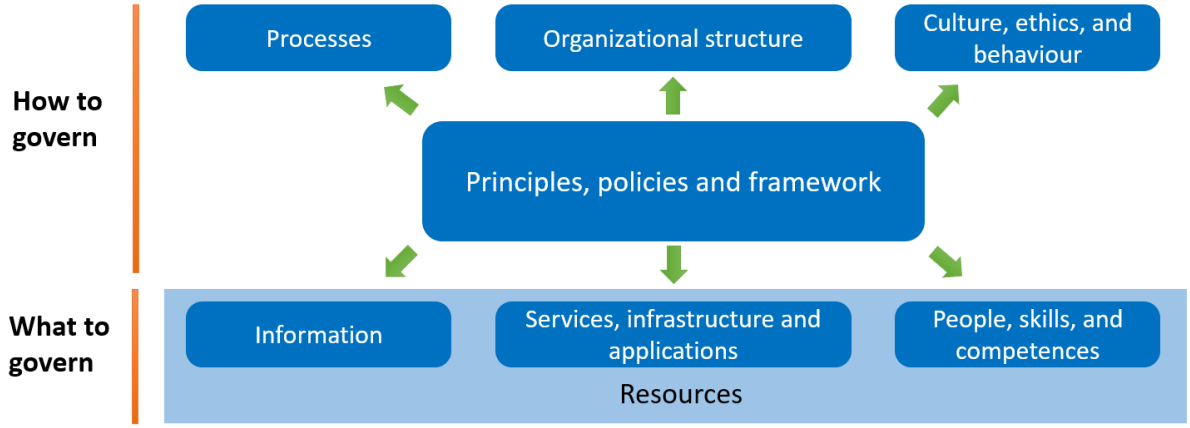


Figure 2: Governance Framework [MARCELO 2018]

2 Report on Belgium

2.1 Health and care System description

The Belgian healthcare system is an insurance - Bismarck type - health system with a number of peculiarities due - among other things - to the complexity of the federal institutional landscape and the multiple institutional reforms which have been taking place for 50 years. This has led to a particularly complex division of competence and responsibility between the different entities.

The 11.2 million inhabitants live in three regions (Flanders, Brussels and Wallonia) and speak three national languages (Dutch, French and German). However, in the case of Wallonia and Brussels the territory of the regions does not coincide with one specific language as in the Brussels region, both French and Dutch is spoken while the community who speaks German lives is also part of the Wallonia region.

[2] See "Transforming Health Systems Through Good Digital Health Governance", Alvin Marcelo, Donna Medeiros, Kirthi Ramesh, Susann Roth, and Pamela Wyatt (2018)

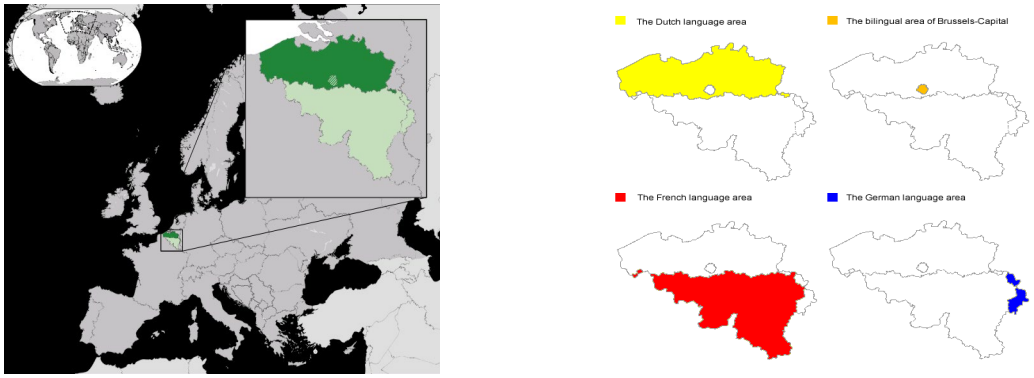
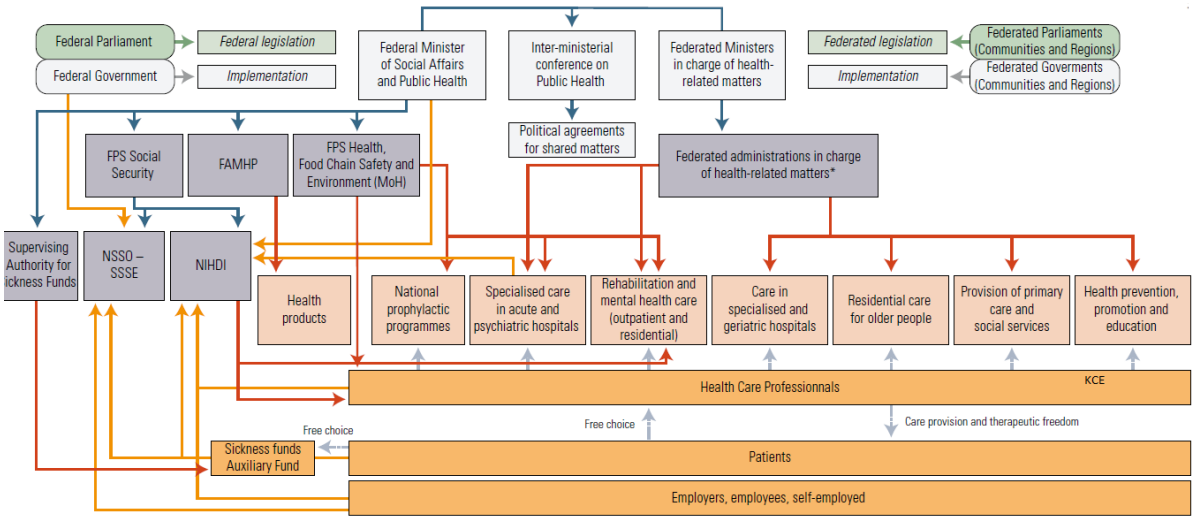


Figure 3: Belgium and its regions

As a consequence, aside from the federal level, 5 different federated entities (3 regions and 2 communities) are directly involved in different health matters. Hence, the 9 Ministers in charge need to coordinate their plans through an "inter-ministerial cell" which meets regularly. As the political majority which governs each of those entities is often different, alignment of objectives between them is challenging and is mostly the result of "arbitrage". While initially, the federal level was mainly in charge of healthcare organisation (including insurance), the federated levels were focusing on prevention. This has evolved over time and the federated levels are also increasingly involved in curative matters. This is summarized in the figure below.



Source: .

Notes: Green arrows, legislative power; Grey arrow, executive power, Red arrows, regulation, organisation, evaluation, control; yellow arrows, representation; blue arrows, supervision; dashed grey arrows, service provision/contractual relationship.

Figure 4: Organisation of the healthcare system in Belgium (Source: KCE)

At federal level, the National Health and Disability Institute (NHDI) is a central player and manages the conditions and rules of reimbursement within the system. It is however not in direct contact with the patients: any Belgian resident must indeed be affiliated to a Mutuality. Aside from the basic insurance package, Mutualities compete and offer complementary insurance packages to which their affiliates may subscribe.

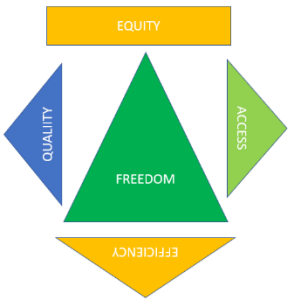


Figure 5: Values of the healthcare system

NHDI has its own governance structure with the social security system payers[3] being the decision makers at the strategic level and the mutualities and healthcare providers being equally represented at the tactical level (proposals submitted to the higher level).

The Belgian health system is characterised by a very high level of freedom (no compulsory gatekeeping), a wide access for all to all general and specialised services with relatively short waiting times and an overall good quality of services. Fee for service (FFS) remains the general rule for primary care while in secondary care, FFS is combined with Pay for Performance (PFP) and structural legally defined subsidies.

With a bit more 10% of the GDP, Belgium is in the top 10 OCDE countries in term of relative health spending, and the increased costs have been raising concerns about the sustainability and the efficiency of the system. The direct participation of the citizen (Out of pocket payment) remains limited but has been increasing over the last ten years with a clear tendency of health care practitioners not to abide to the NHDI voluntary conventions[4].

	INPATIENT CARE	OUTPATIENT CARE	LONG-TERM CARE A	ANCILLARY SERVICES	MEDICAL GOODS	PREVENTIVE CARE[1]	ADMINISTRATION	OTHER[1]	TOTAL
Governments	1.76	0.82	15.54	0.13	0.21	1.72	0.28	0.70	21.16
Compulsory health insurance	19.42	12.35	5.20	4.23	10.68	0.45	2.08	1.69	56.09
Household out-of-pocket payment	3.86	5.45	1.59	0.36	5.35	NA	–	1.02	17.64
Voluntary health insurance	2.72	0.23	0.66	0.14	0.01	<0.01	1.08	0.28	5.12
Total	**27.76**	**18.85**	**22.99**	**4.85**	**16.24**	**2.16**	**3.44**	**3.69**	**100.00**

Source: OECD (2019a).

Figure 6: Distribution of the contribution to healthcare expenses

2.2 eHealth System

2.2.1 National/Regional building blocks (infrastructure and services)

The Belgium eHealth system is the result of both centralized and decentralized initiatives in a complex federal institutional setting which started in 1998 and materialized with the creation of the eHealth platform (Belgian eHealth Competence Centre) in 2008. It relies on a **legal, regulatory and technical interoperability framework** wich has been developed in steps between 2001 and 2012. Although not mandatory by law, this framework has been widely implemented.The **operational global objectives** included in the Belgian eHealth action plan were first setup in 2012.

The basic eHealth infrastructure is based on **10 essential services** (e.g. data encryption, data anonymisation, secured email box) and relies on the use of a number of **Validated Authentic Data Sources (VAS)**. The basic services and the VAS are essential enablers of the interoperability framework and are embedded in the eHealth services with "added value" which are developed by both public and private organisations.

[3] Representatives of those who finance insurance, namely employers, employees, the self-employed and government officials hold 3/4 of the number of mandates. Insurance organizations (O.A.) have 1/4 of the mandates. Representatives of health care providers have only an advisory voice in this Council.

[4] Healthcare providers have some benefits if they accept in a convention the NIDHI negotiated fee.

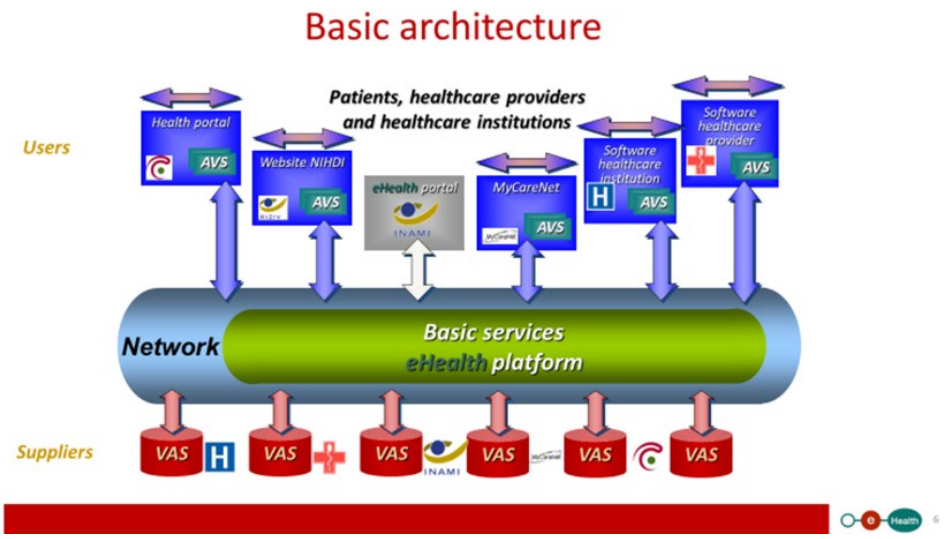


Figure 7: Architecture of the eHealth system

The validated data sources are under the control of Public Bodies but may also include data provided and managed by many other organisations. They are essential to manage a legal identification of all the actors in the system and to manage and orchestrate the many rules which need to be implemented. In some cases, such as in the case of the Authentic Data Source for Medicines, they can provide a critical contribution to semantic interoperability.

Initial investment has been shared by the several (mainly federal) public entities while buy-in from the industry has been ensured through an end-user incentivizing strategy. The Belgium eHealth strategy has also been built on the generic eGov infrastructure (e.g. e-ID) and on the experience of the digitalisation of the social security workflows[5] where Belgium has been pioneering.

The creation of building blocks fully respects the following principles:

- **No personal data is stored centrally**,
- **D**ata should remain under the control of the data producers and cannot be duplicated.

The « only once » policy is also a transversal principle which needs to be implemented as much as possible with the aim to reduce the burden of multiple data inputs by healthcare professionals. This has had a positive effect on the overall governance of the eHealth system as many initiatives used to be developed in silos without consideration for either user acceptance and compliance with existing standards.

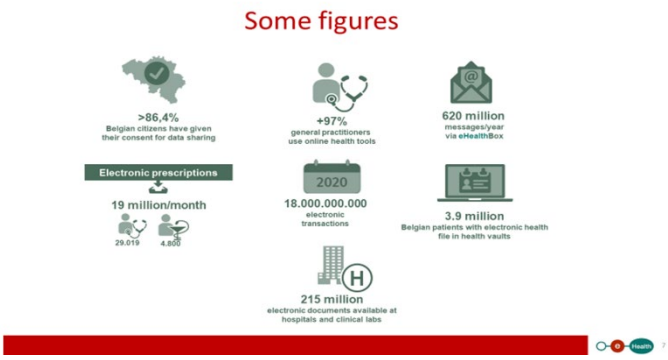


Figure 8: State of deployment of ePrescription

The e-Prescription service is a separate service with its own governance and storing infrastructure, governed and managed by users' representatives and supported financially by NIHDI. It is fully operational and deployed country-wide.

A national medication schema is currently (in 2021) being implemented.

Apart from some critical clinical exceptions (e.g. the shared EHR, the

[5] https://www.ksz-bcss.fgov.be/en

medication scheme, the e-prescription services), the majority of the developed services are pursuing public health/regulatory objectives such as achieving an administrative simplification, improving the policy and decision-making processes or guaranteeing a full traceability.

The services are usually developed as system-to-system communication protocols although for a number of them, complementary web solutions have also been developed.

2.2.2 Data sharing and access

The "Hubs/meta-hub" service is the backbone of the data sharing infrastructure in Belgium. The different Hubs (nodes) only notifies the meta-hub when they have information concerning one specific person identified with his/her national number. The requesting Hub will then directly communicate with the hubs which have data for a specific patient and will be able to retrieve (i.e. visualize) them.

Data sharing is actually performed thanks to the global implementation of normalised web-services which also includes the orchestration of a number of sub-services.

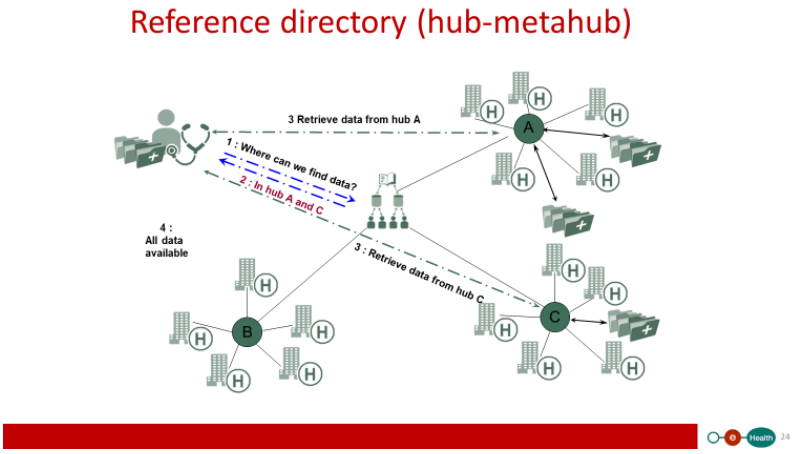


Figure 9: Data sharing and access architecture

Each Hub has its own governance but needs to abide to the general rules established for the global service and make an explicit reference to those rules in their own internal governing documents. The control of the compliance to those rules by each individual organisation part of a particular Hub is under the responsibility of this Hub. By doing so, a global "circle of trust" has been developed.

The Hubs can be different, both in term of scope and services, but have often a regional dimension:

- The Wallonia and Brussels Hubs include all Healthcare organisations (including laboratories) of their region and provide a safe storage capacity (InterMed, Brusafe) for the information to be provided by primary care actors who do not have a permanent connected ICT infrastructure;
- In Flanders, three different Hubs have been created; one includes a wide number of healthcare providers, another one focuses only on a number of hospitals which usually share the same IT system developed by the Hub coordinator and finally the Flemish Government has supported the creation a separate Hub (Vitalink) for the storage of the information of the primary care sector.
- The Pharmacists have also developed their own hub, called the Pharmaceutical Care Data Hub, which makes use of the meta-Hub; this Hub is also the authentic data source for the "dispensed medicines".

All the hubs are strictly governed and managed by representatives of the users and are financially supported with public money.

Within this Hub/Meta-hub system, access to data by healthcare professionals is conditioned to:

- A preliminary Patient overall consent (Opt-In)
- A Proven therapeutic link with the patient (with defined rules for the duration of this link)
- Their right to access data which is differentiated by healthcare profession
- The availability of data in primary care containers.

Patients have the possibility to control access to their data in a very granular way (exclusion of specific data, of a specific healthcare professional, of specific data for a specific healthcare professional etc..) and may also contribute with personal notes.

A federal Portal for Citizens has been created but access to data by the patients remains limited: Patient Summary and lab results are always accessible but access to other type of data and reports (e.g. Hospital report.. require prior authorisation of the data producer.. An increasing number of hospitals are however now deciding to liberate the data by default. Different rules may also be applied by in the different Hubs reflecting specific regional sensitivity.

Beyond the Hub-metahub service, the system-to-system communication with other services thus require specific work on the developer's side. However, when addressing the same need, webservices have been reused by the different services.

In the **clinical domain**, a number of transactions have been fully standardized in KMEHR, the current HL7 based official standard for data exchange: One of the most commonly used transaction is the Sumehr (Summarized Electronic Health Record). This Belgian Patient Summary is validated by the general practitioner (evolving towards a multi-fed patient summary coordinated by the GP) and is deployed since more than a decade.

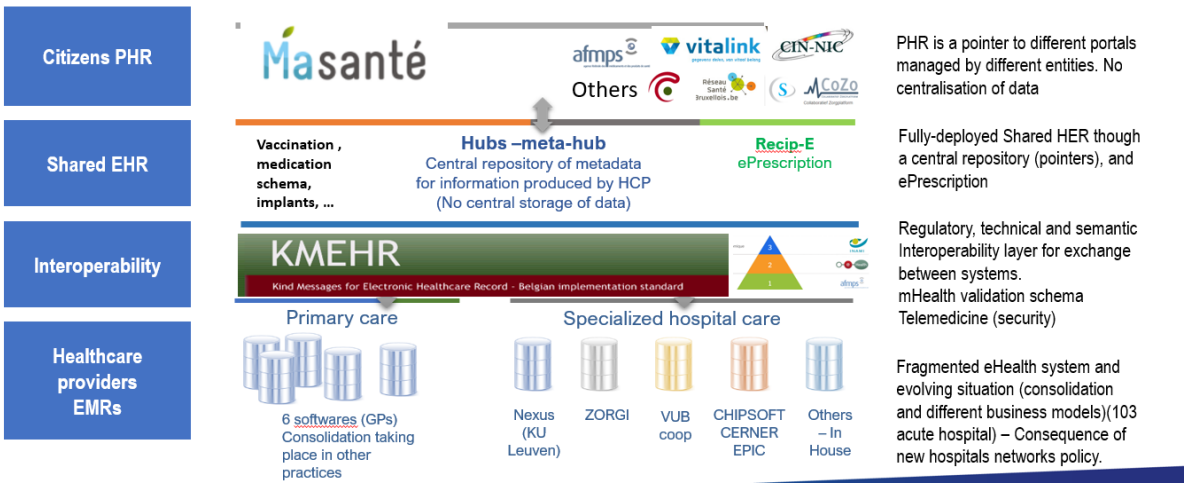


Figure 10: Belgium eHealth landscape in a nutshell

Multiple entry points to the PHR exist, either though the Hubs portals or though the federal portal (also called "Personal Health Viewer") which acts as a pointer towards all the different services offered to citizens/patients and managed by different public and private organisations. Some Regional Hubs have also developed dedicated Mobile Apps.

The infrastructure for data sharing is described under section 2.2.2. Dedicated infrastructure have been created for e-prescription, e-dispensation, vaccination, implants etc…

Interoperability is a shared public responsibility: the Authentic data sources are important interoperability contributors. The standardisation and integrated management of the webservices which support system to system communication and the use of the KMEHR standard for the transactions have provided a solid foundation for the exchange of data . Testing environments and connectathons together with compliance certification (EHRs and mHealth solutions), training offer and incentivisation policy have led to a successful implementation of the agreed standards and services. Important changes to support the integration of new standards such as FIHR and new semantic requirements will require further road mapping and fine-tuning to be supported by all the actors.

Over the last 15 years, the eHealth EHR market has been consolidating with a drastic reduction of the number of EHR solutions providers in the primary care sector which followed the need to add new functionalities and services and the incentivisation strategy. This consolidation process is still very much ongoing in the secondary care sector.

2.2.3 People, skills, and competences

Till the creation of the eHealth platform, eHealth technical competencies used to be concentrated mainly within (University) research centres, standards development organisations and a few people with a medical background but a strong ICT interest.

Technical eHealth related ICT expertise within the public administrations such as NHIDI or the Ministry of Health, used to be (and is still) a rare resource. Hence, most of the ICT developments are used to be delegated to a public not for profit organisation, called SMALS[6]; this organisation does not have the same administrative constraints than public administrations and is therefore able to recruit the needed profiles and develop synergies between domains. The eHealth platform is also largely supported in its work by SMALS although it hold its own resources for tasks related to business analysis and support to existing services.

The responsibility of the management of added value services remains with the organisations which have the ownership of those services: they had thus to recruit and/or train the adapted profiles. This is also true for the non-profit organisations set up to govern the different hubs.

All major healthcare organisations are represented in clinical projects and global governance levels, hence they have now developed specific expertise. One needs however to differentiate between the official umbrella organisations supporting the interests of each healthcare segment (medical syndicates) and the ones more invested in the promotion of scientific and evidence medicine such as ebmpracticenet.be[7], the “Société scientifique de médecine générale » (SSMG)[8] or Domus medica[9] While (para)medical syndicates are usually more involved in strategic governance fora, the scientific medical associations play a more active role at project level.

[6] https://www.smals.be/fr
[7] https://www.ebmpracticenet.be/fr
[8] http://www.ssmg.be/
[9] https://www.domusmedica.be/

Each Region also supports and funds an « eHealth » training centre targeting mainly primary care professionals: e-santewallonie[10] (Wallonia), ehealth.brussels[11] (Brussels) and Eenlijn.be[12] (Flanders). The different EHR Users Clubs developed by the main EHR providers play also an important role to improve usability and use of services.

Healthcare professionals need to comply with a continuous training programme in order to be allowed to contract with the insurance system: eHealth education modules are integrated and can be accounted for.

Finally **Patients organisations** (established at regional levels) are also involved both at project and strategic levels and play an active role in developing eHealth awareness among the numerous specific (disease or problem oriented) associations present in Belgium. The four main platforms are LUSS[13] (French speaking) , VPP[14] (Dutch speaking), PRT[15] (German speaking) and Radiorg[16] (Rare diseases)

2.3 eHealth system organisational structure - overview

2.3.1 Stakeholders of the national/regional layer

Federal level:

The **Inter-Ministerial conference** (IMC) brings together the many Ministers with health competencies at federal and regional levels: It validates the strategic choices and establishes formal cooperation mechanisms. It approves the federal eHealth action plan which is supported and monitored by a de dedicated **Programme Director** who reports directly to the IMC.

The eHealth platform is the Belgium eHealth competence centre. It provides the generic operational eHealth services and is driving the overall Belgium interoperability roadmap. It is therefore directly involved in all major projects. It is supported by two committees: The management committee and the concertation committee.

The management committee of the eHealth Platform includes representatives of healthcare providers and organisations, the industry (Agoria), the health insurance funds and the public health services from all authority levels the Federal Minister of Public Health. The concertation committee has an advisory body and assists the Management Committee carrying out its tasks. It has permanent and thematic working groups which can include very different types of profiles. The members of this committee are individuals who play an active role in major eHealth initiatives. Official representatives have here only an consultative role.

The eHealth platform is also responsible for the registration of the primary care sector EHR systems but the compliance testing in itself is delegated to a sub-contractor.

NIHDI: National Institute for Health and Disability Insurance provides Authentic Data Sources, develops and/or supports eHealth projects, provides financial incentives to primary care users for the meaningful use of eHealth services and organize the accreditation of healthcare professionals (continuous education).

[10] http://www.e-santewallonie.be/
[11] http://ehealth.brussels/
[12] http://www.eenlijn.be/
[13] https://www.luss.be/
[14] https://www.luss.be/
entenplatform.be/
[15] https://www.patientenrat.be/
[16] https://www.radiorg.be/fr/

Mutualities: develops eHealth projects (Mainly related to reimbursement and authorisation rules).

The Federal Public Service Public Health (PFS-PH) provides Authentic Data Sources, develops eHealth projects for policy support and provides financial incentives to secondary care organisations for the meaningful use of eHealth services. It also shelters the Belgium Terminology Centre which manages the Terminology resources used in Belgium.

Sciensano (ISP:WIV), the **National Public Health Institute** develops eHealth projects for policy evaluation and support and is leading the work around secondary use of data.

The **National Agency for Drugs and medicinal products (AFMPS)** provides Authentic Data Sources and develops eHealth projects for policy support and traceability

The **Public Federal Service Social Security: Social care, handicap, Health access** develops eHealth projects mainly related to authorisation rules.

The **Public Federal Service Strategy and support (BOSA)** develops and maintains e-Government building blocks

The **Data Protection Authority** issues legally binding authorisations for the exchange of health data and sets the rules for information security and privacy protection when processing health data

AGORIA, the non-profit organisation representing the Industry: is active in standardisation working groups and operationalizes the mHealth strategy.

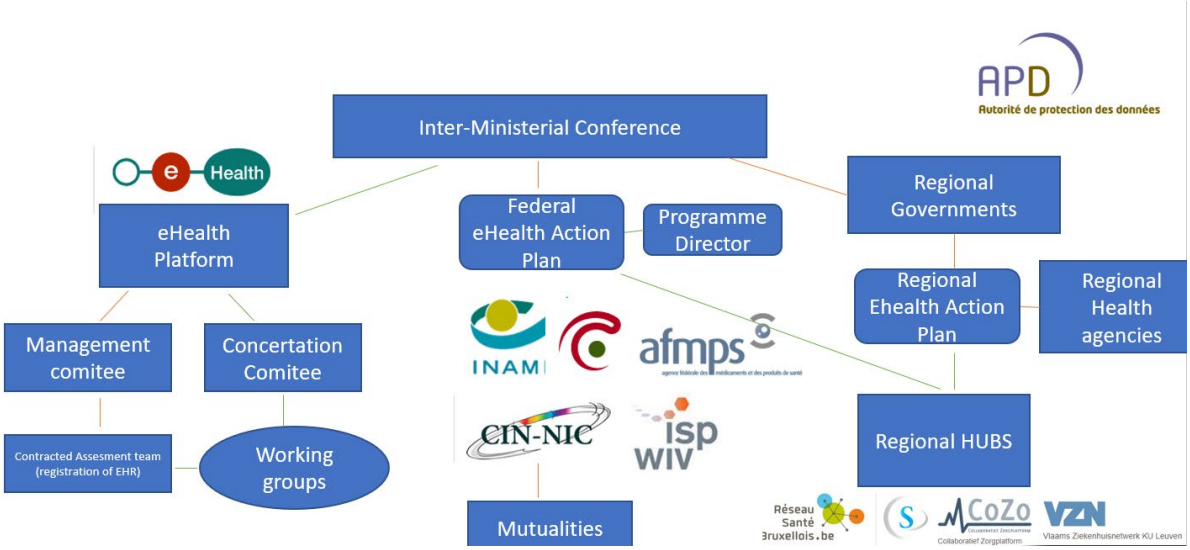


Figure 11: Main official public stakeholders at the national/regional levels

At regional level:

Regional Health Agencies and administrations

- The Flemish Agency for Health and Care develops and maintains eHealth services for the Flanders (Vitalink[17], vaccinet[18], medication schema ...) and supports financially eHealth projects
- The Wallonia Agency for Health, Family and Handicap (AVIQ) and Wallonia and Brussels public service administration support financially the relevant eHealth projects in their region.

The Regional Hubs already mentioned earlier play a critical role which is detailed in the next section.

2.3.2 Stakeholders of the health service provider layer

EHRs providers:

A huge majority of primary care health providers work with a **certified EHR**. As a result of certification and higher requirements, the number of solutions used has drastically been reduced. Three health containers (under the control of Healthcare Providers organisations but supported with Public funding) have been setup to store the data to be shared in the primary care sector.

Hospital EHRs remain diversified (with 5 dominant products and quite a few local developments) and important market evolutions will still take place in the near future.

Regional Hubs:

The Regional Hubs are supported financially by Regional Administrations but are managed in a collaborative manner by their members. They are critical enablers as they act as trusted intermediaries between individual healthcare providers (individuals and organisations) and central bodies such as the eHealth platform for data exchange related to continuity of care. Each Hub has its own governance and specificity but usually represent correctly the interests and objectives of its users/members.

The main Hubs are the following ones

- Brussels health network[19]: Hospitals, Other HC Institutions and Primary care Container in Brussels region
- Wallonia health network[20]: Hospitals, Other HC Institutions and Primary care Container in Wallonia region
- Vitalink[21]: Primary care Container for Flanders region
- VZNKUL[22]: Network of hospitals managed by KULeuven
- COZO[23]: Network of hospitals and other healthcare institutions in Flanders

One may also mention two other initiatives managed by the users:

- **Recip-e** is a non-Profit Organisation which gathers all professional organisations representing prescribers (Doctors, dentists, pharmacists)
- The **Pharmaceutical Care Data Hub** (PCDH) is another non-profit organisation managed by the representatives of the Pharmacists which organizes the sharing of information related to the dispensation of medicines and the pharmaceutical care record.

[17] https://www.vitalink.be/
[18] https://www.vaccinnet.be/Vaccinnet/welkom.do
[19] https://brusselshealthnetwork.be/
[20] https://www.reseausantewallon.be/
[21] https://www.vitalink.be/
[22] https://www.vznkul.be/
[23] https://www.cozo.be/

As mentioned earlier, **end-users organisations** are included in the different governance structures (both at strategic, tactical and project (operational) taking into consideration their actual role and (official) representativity.

2.3.3 Stakeholders of the innovation layer (including businesses)

Most of the initiatives taken to support innovation have been set up with the support of **regional governments**. Some of those initiatives are cross domains while others have specifically been designed to support eHealth innovation or a specific segment of the industry (SMEs/Start-ups). The list provided below is not exhaustive.

- ***Flanders:***
  - VLAIO: The Flanders Agency for Innovation and Enterprise has mainly a funding function.
  - Flanders health: is a membership network which gathers Universities, Industry and payers in Flanders and focus on crossover domains of biotech, medical and digital technologies
  - Medtech Flanders is a membership industry network focusing on Medical Device Development in Flanders
- ***Brussels:***
  - Innoviris: The Brussels Agency for Innovation has mainly a funding function.
  - Lifetech Brussels is a multi-stakeholders membership based cluster which aims at facilitating and stimulating the attractivity and success of high potential HealthTech solutions with a focus on social and environmental impact.
  - eHealthventure is a network of experts to support new start-ups investing in eHealth.
- ***Wallonia***
  - MED-TECH Wallonia is supported by the Wallonia regional administration and aims at supporting and funding **MedTech** innovative initiatives in Wallonia.
  - well-livinglab.be aims at supporting new technologies or new uses of existing technologies while putting the **end-users at the center** of the development process.
  - Digital attraxion is a digital **start-up accelerator** supported by Digital Wallonia, a collaborative project involving many public and private partners.
  - CETIC is a competence centre in ICT technologies working cross domains but focusing mainly on software industry.

Public research centres, (University) hospitals and **scientific medical associations** are also important stakeholders with the existence of several initiatives and networks to support knowledge discovery and provide a fertile soil for innovation testing. Most of them are active members of the initiatives mentioned above.

As already mentioned, Sciensano (**National Institute of Public Health**) also plays a critical facilitator and operational role in creating a dedicated infrastructure for research, called healthdata.be. Sciensano has brought two main innovations:

- bring all the data that stored in multiple health registers into a single Internet-based platform and contribute to the progressive alignment and mapping of all existing registers
- Provide APIs which implement the “only once” policy and reduce at the minimum the burden associated with the encoding of data requested by the different registries.

The Industry is represented in many of the initiatives listed above but have also developed specific – mainly membership based – ***Innovation support Organisations:***

- **AGORIA (HealthTech.Belgium) :** The national representation of Industry (including SMEs) in Belgium
- Bemedtech: the Belgian Medical devices Industry association
- In4care: A networking organisation which brings together 350 care actors, start-ups, companies and other innovation partners
- BlueHealth Innovation Center : This innovation Centre supported by Microsoft stimulates innovation and entrepreneurship at the intersection of technology and healthcare in Flanders bringing together local governments, companies, research centres and healthcare institutions

2.4 Approach to main governance aspects:

Belgium is a recent independent country (less than 200 years of existence) but the country sub-regions and cities have a very long and rooted history of local independence and of negotiation of freedoms with the occupying state, whoever it was. The relationship of citizens to the State remains thus ambivalent for a number of reasons: people expect that the State will protect them and guarantee their well-being but in the same time remain very cautious and have a limited trust in the official institutions. This is of course also the result of the complex political landscape and the difficulty to provide the citizens with a clear and transparent picture of the strategies and choices operated, often the result of many compromises. This background has also important consequences on eHealth governance where people and organisations want to avoid to leave to the State the overall control of the system and want to protect their vested interests. The Belgium eHealth strategy – and the governance attached to it – is thus also the result of multiple compromises.

2.4.1 Planning and strategizing

The Belgium eHealth roadmap which summarizes the strategy and plan the key smart actions to be implemented is the result of a large but structured and evolving consultation process.

The first roadmapping exercice took place in 2012 and involved a large number of organisations and people. While, aside from public bodies, representative organisations of end-users, industry, SDOs and payers were proactively approached, individuals had also the possibility to be involved, at their request. The exercise was entirely organized by an independent third party.

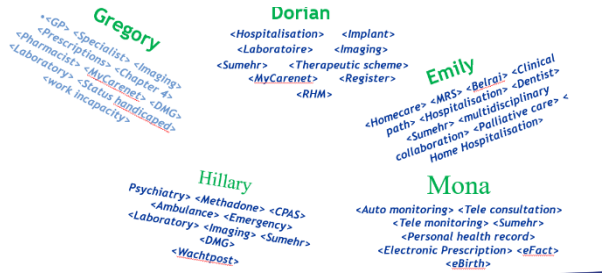


Figure 12: xxx

To facilitate the discussion and increase ownership, this first exercise focused on the first immediate perceived priorities with a clear emphasis on administrative simplification and quick added value. A number of situations have been described with As Is/To Be Scenarios: concrete actions and responsibilities have then been described.

As a result, 20 priority actions to be implemented in the 5 years have been identified. Each action was requiring a more detailed action plan in order to achieve the expected results and mobilize the needed resources. Once formalised, this action plan has been submitted for approval to the Inter-Ministerial Conference, providing thus a formal legal basis for its implementation.

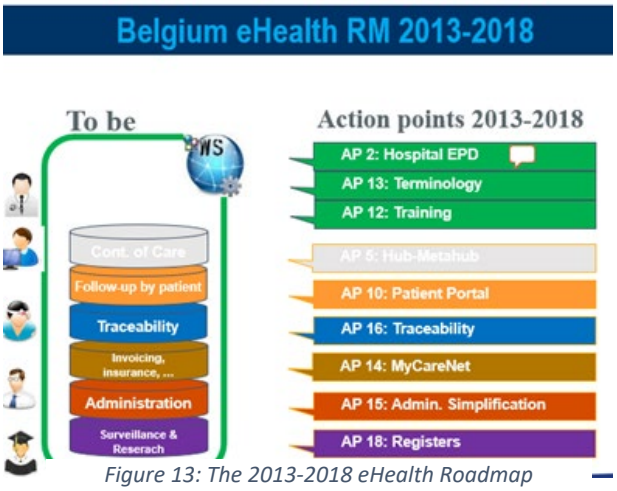


Figure 13: The 2013-2018 eHealth Roadmap

After 2 years and following a change of political majority, an update of this plan has been requested. Instead of a new large consultation, the update exercise relied only on experts group with a tighter control of the health cabinet. Some adaptations were made and some new action points added. In order to have a better overview of the roadmap planning and implementation, an independent programme director – reporting directly – to the IMC has been appointed.

Version 3 of the roadmap is organising its objectives under 6 different clusters considered as sufficiently generic to support a long term vision. The duration of this new action plan is limited to 2 years (2019-2021) with annual update from 2021 on. These updates remain subject to validation by the Inter-Ministerial Conference.

Figure 14: 2019-2020 eHealth Roadmap

2.4.2 Financing of eHealth investments

Financing of eHealth requires the mobilisation of resources originating from multiple sources. A part of this financing needs to be structural when it relates to fundamental building blocks and services since, after an investment phase, they need to be maintained and constantly updated.

Being responsible for the availability of basic services, the eHealth Platform receives an annual **structural dotation** (15,2 Mo € in 2021) from BOSA (Public Federal Service Strategy and support) to support its activities augmented by a contract signed with SMALS of 5 Mo € to support the maintenance of the core services.

Each public body to be involved in a project is responsible for including the needed resources in its own budget (e.g. validated authentic sources, specific service related to is mandate...) and has to do so with a pluri-annual perspective. Given the administrative rules applicable to public administrations, new projects have usually a 2-3 years take-off period. The backing-up of the plan by the Inter-Ministerial Conference is usually a guarantee that the needed resources will be made available.

A significant part of the national eHealth budget is dedicated to the provision of financial incentives to users in order to make sure that the interoperability framework is implemented and that deployed services are actually used. Together with the EHR registration (compliant testing), those incentives are also instrumental to guarantee that industry developers have sufficient means to adapt their products as the price of those products have been partially adapted to reflect the new services and functionalities.
Hospitals are mainly funded via the reimbursement of acts (NIHDI and patients) and the hospital budget (PFS Public health) which represent roughly 50% of income. They decide freely the amount of resources to invest in ICT. There is no yet a well identified ICT "envelope". In parallel to the meaningful use policy, discussion is ongoing concerning the possibility to address ICT costs for hospitals in a closed envelope. While social security funds through NIHDI are used to incentivize the primary care users**,** the hospital budget managed by the PFS Public Health includes also a meaningful use incentivisation package**.**

With respect to mHealth, Belgium is also one of the very few EU countries which have developed a framework based on a three levels validation pyramid for prescribing and reimbursing the use of mHealth solutions. Seed money has been provided by NIHDI but the framework is operated by AGORIA while three public bodies are involved in the validation process. If approved at level 3, the solution will be reimbursed by NIHDI.

Figure 15: mHealth validation pyramid

The regional Hubs (networks) have benefited from a (limited) financial support from the PFS Public Health till 2015 but since then, these hubs are mainly funded by their members with, in Wallonia and Brussels, a structural funding from the Regional Administration. Regional Governments also fund specific projects related to their competences and geographical coverage.

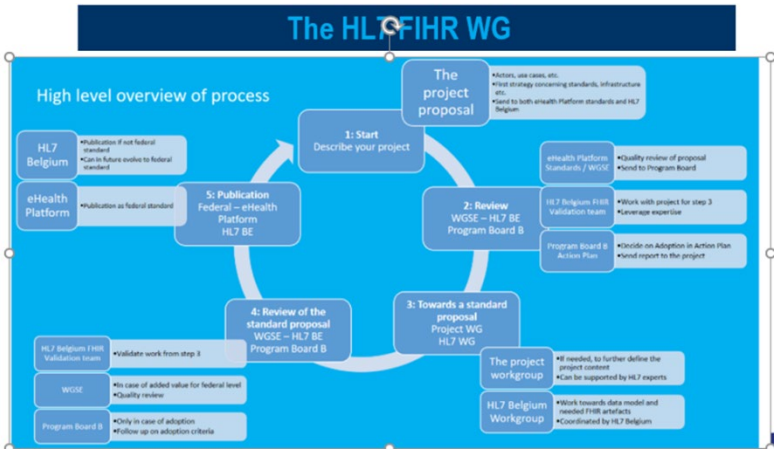
Projects which support use cases which mainly benefit one specific type of users are usually only funded by their members e.g. the shared pharmaceutical record.

Regional Administrations in the three regions are the main funders and supporters of the initiatives developed to support innovation.

2.4.3 Defining and enforcing an interoperability framework

Most of the critical elements of the technical interoperability framework have been discussed and documented by the Telematics Commission as early as 2003. The **eHealth platform** and the **different working groups** established in its concertation committee are now the central player for the maintenance and the evolution of this framework. The eHealth platform is also responsible for the

registration (certification) of the EHR systems for primary care. If new needs arise, new ad hoc groups can be created but the WGs "architecture" and " structuring of elements" act as gatekeepers to make sure that choices remain coherent.



The creation of the Belgian HL7 FIHR working group is very exemplative of how new standards are defined and implemented. HL7 Belgium is the main enabler of this group but the eHealth Platform initiates and closes the process. The working group 'structuring of elements' intervenes to review the quality of the initial proposal which is then discussed with the project team. Once the standard is formalized, it is then again assessed by the working group "structuring of elements.

As already mentioned before, the members of the different working groups are usually the existing main users/developers complemented by people with a recognised expertise. Attendance to those working groups takes place however on a voluntary (and unpaid) basis.

Semantic integration remains limited although coding systems are already embedded in all EHRs and semantic aspects are already included in the documentation of the transactions. The creation and distribution of the adapted semantic resources is a responsibility of **the PFS Public Health** which also require a specific governance process and engagement of stakeholders. The creation of the Belgian SNOMED-CT sub-set (including the translation in French and Dutch) has mobilized **some 50 clinicians** in many different specialities who have defined together the needed rules of validation, guaranteeing thus an initial buy-in from the clinicians. R**equirements for a national efficient** terminology server still need to be defined and more work is needed to ensure a sustainable governance process.

The eHealth Platform, the different Hubs and individual projects have each organized their own their own testing and certification processes. In the case of Hubs, it concerns IT systems and organisations organized at loco-regional level such as general and specialized hospital EHR, Labs, long term care facilities and systems used by primary care users. The projects managed by the association of Mutuality's test and certify IT systems and organisations for the data workflow related to reimbursement.

The eHealth Platform organizes the registration of IT systems used by primary care providers (GPs, nurses, dentists and physiotherapists as they need to comply with both functional and not functional criteria and demonstrate the correct use of standards and services. Those systems usually leave the end-user choose the Hub they prefer to work with.

One also needs to mention a cross-domain initiative implemented by **SMALS** which aims at a maximum reuse of existing components with a constantly updated catalogue of all the existing validated components.

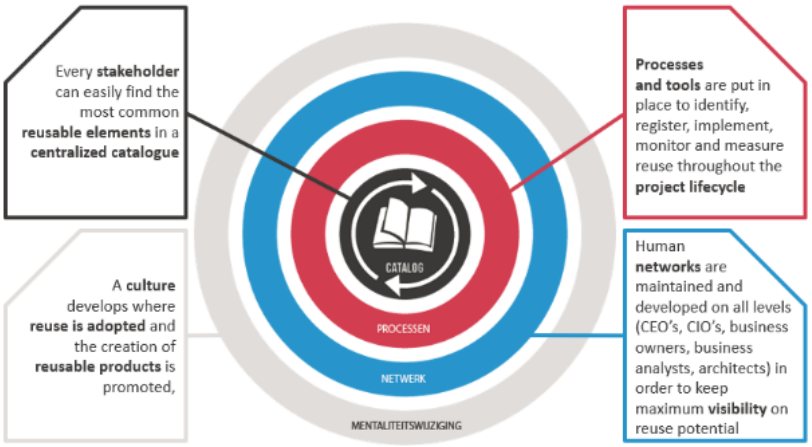


Figure 16: Components reuse strategy

2.4.4 Developing new eHealth building blocks

The core building blocks (basic services) are developed and funded by the eHealth Platform upon approval of its management committee and provided that the building block is part of the overall updated eHealth action plan. The core building blocks have been stable over the last 8 years.

The actual use of these core services is not straightforward and no formal agreement has been reached on the best strategy to use those services. A market has thus de facto been created which allowed intermediaries to **propose "connectors"** which facilitate the use of those services by EHR developers and end-users. Some important actors have considered that the connector itself should have been part of the public infrastructure. As a consequence, both private and cooperatively developed connectors are available.

The creation and update of authentic validated sources to support eHealth transactions are under the responsibility of all involved (Public) bodies, often with a technical support from SMALS. The development of those sources often requires a close collaboration and orchestration between different entities. For example, Cobrha – the Common Base Registry for HealthCare Actor – integrates data controlled by NIHDI, the Medicinal Products Agency, the regional administrations and PFS Public Health, the Cross-Road bank for enterprises.

A testing environment (mini-labs) has been established at central, project and regional network levels in order for all concerned systems to test new eHealth building blocks

New major eHealth services related building blocks are first either proposed by public federal or regional administrations or by other actors. The working groups installed under the concertation committee of the eHealth platform play an important role in the preparation phase.

New versions of eHealth services or new projects are submitted to political validation via the IMC.

2.4.5 Maintaining and improving eHealth building blocks

The core services developed by the eHealth platform are subject to SLAs and the services are continuously monitored. The services are updated, based on the analysis of incidents and the feed-back-received from the users.

Support services have been created to assist end-users and collect feed-back.

The eHealth platform reports regularly via its management committee on all incidents and on the measures taken to solve them and improve the services.

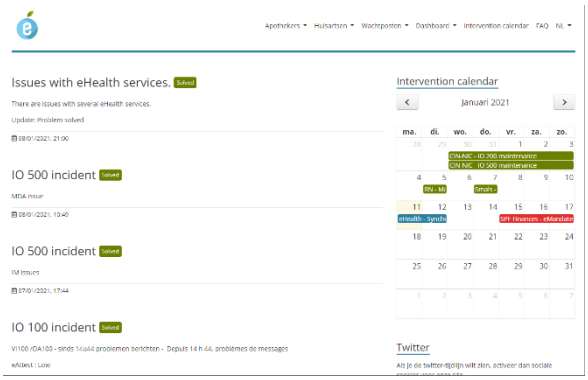


Figure 17: Example of incident reports

The different projects may introduce « change requests » via the different Working Groups established within the concertation committee of the eHealth platform.

Substantial versioning of an existing building block with subsequent impact on actors needs to be included in the updated action plan and approved by the IMC. The programme director plays an important role in identifying and documenting those updates and analysing their impacts.

As already mentioned, many public bodies have de facto delegated a substantial part of the work related to development and maintenance of the building block they are responsible for to SMALS.

This entity is thus best placed to establish synergies and make the best use of existing components as demonstrated by the initiative ICT reuse.

2.4.6 Monitoring and evaluating eHealth service delivery

All the projects and action points part of the eHealth Roadmap are requested to provide regular and structured feedback to the Programme Director who oversees all the clusters of the eHealth action plan.

The Programme Director ensures the daily coordination and management, in terms of consistency and general operation, of the portfolio of projects of the eHealth plan within the framework of defined strategies and objectives and project tolerances (budget, high-level milestones, scope, etc.) approved by the Inter-Ministerial Conference. This involves direct monitoring and operational/tactical steering of execution projects, with a maximum deviation of 20% depending on what has been agreed.

He addresses any difficulties/problems to the appropriate decision-making bodies. He is assisted in his task by a board which ensures the monitoring and adjustments of the programme and projects in accordance with the decisions taken. He reports/transmits information on the progress of the action plan to the federal steering group of the Inter-Ministerial Conference and the eHealth platform management committee.

Each project sets up its own monitoring process (and governance structure) but once defined, the KPIs are shared with the programme director

Key central indicators are collected by the eHealth platform (number of consents, number of exchanged documents, number of active HCPs, number of patient summaries produced, number of consultation of documents (per type) etc..).

The implementation of the meaningful use policy relies on the objectivization of effective use of eHealth services. The proof of the use of the services by individuals and organisations is either

provided directly by the EHR solutions and/or by third parties on the base of the effective use of a digital certificate.

2.4.7 Stimulating innovation in eHealth

Stimulating innovation is mainly a regional competence and there is for now no specific action and governance process to align objectives between the different regions, which are therefore free to define their own priorities.

The industry, and in particular its main representative organisation Agoria, plays however an important role to liaise between the different initiatives and – when relevant – propose the inclusion of innovation related action points. This has been the case for example for the inclusion of the mHealth action point already described under section 2.4.2.

Another example of this federating role is the launch in 2019 of a new cross-sector initiative: AI 4 Belgium[24]. It is a grassroot community that enable Belgian people and organizations to capture the opportunities of AI while facilitating the ongoing transition responsibly. This coalition brings together AI key-players from public sector (such as BOSA - Public Federal Service Strategy and support), private sector, academia and civil society. AI 4 Belgium has the ambition to position Belgium, including its regions, in the European AI landscape. Agoria is present in all essential governance structures and working groups.

Most of the Innovation Hubs active in the different regions of the country (see section 2.3.3) are supported financially by the regional administrations. Many of these initiatives try to establish an eco-system which creates the necessary conditions for innovation development and testing, i.e. gathering developers and care providers and, beyond providing general support services, launch regular thematic calls. At the central level, the PFS Public Health and NIDHI may also support pilot projects although the focus is usually more on healthcare providers than solutions developers.

As mentioned under section 2.3.3, Sciensano (Institute of Public Health) is the main player to support research in the field of population data. It has been instrumental in the implementation of the « only once policy » in order to simplify and harmonize registers and offer a one shop entry to health data for innovators and researchers. Together with the eHealth platform, Sciensano has played an important role to create a « circle of Trust » strategy which has been tested and validated in the framework of the COVID-19 pandemic. It is also the main link with other strategic European initiatives with a leading role in the TEHDAS joint action (with a focus on the European Health Data Space) and the PIHRI project (Population Health Information Research Infrastructure).

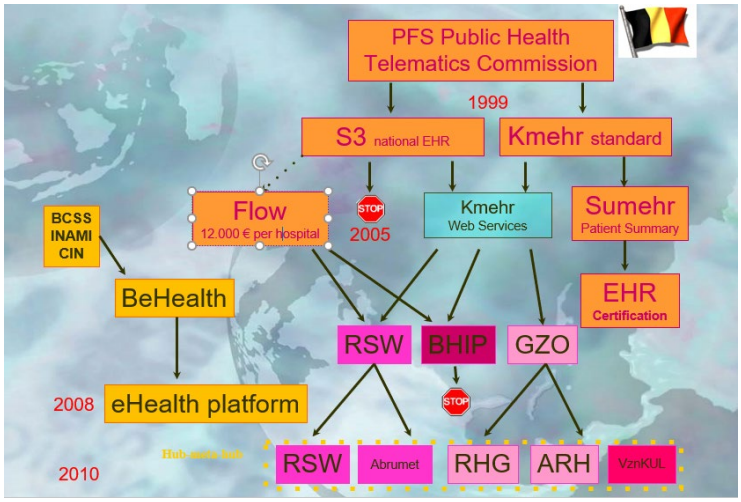
Many Belgian University Hospitals are also part of large scale Innovative European eHealth projects.

2.5 Some historical retrospective - how the current state has been achieved / if doable?

As in many other countries, the history of eHealth is Belgium has experienced different phases of development. While a bottom-up approach was the main initial driver and a key condition to create trust, it had to compose with more top-down strategies privileged by some key institutional actors.

The initial steps of the eHealth development strategy are summarized in the figure below.

[24] https://www.ai4belgium.be/



The Telematics Commission was created in 1999 with the aim of providing the Ministers of Public Health and Social Affairs with opinions on issues linked to the electronic exchange of data relating to patients. It produced a number of concrete results: it created the first working groups (users and industry) for the structuration of EHR in the primary care sector and established the basis of the certification system and the incentivisation policy. It also defined the Kmehr standard and documented the first transactions such as the Patient Summary (Sumehr). In parallel it funded a proof of concept called "S3" which has set the foundation of the national infrastructure for data sharing through the creation of generic web-services. The initiative Flow provided in parallel a symbolic financial support to Hospitals in order to provide seed money for ICT collaborative protocols between healthcare actors.

Those first initiatives have been developed in a context where the digitalisation of the Health system was not yet very high in the political agenda. They have thus benefited from a lack of interference and have been instrumental in developing a eHealth culture at the level of organisations and create the basis for a eHealth multi-stakeholders taskforce which had materialized in the creation of this "Telematics Commission". The commission wanted to build on the existing cooperation networks with different situations in the three regions of the country: while in the South, public hospitals had a long tradition of cooperation and had established voluntary loco-regionals associations, in the North, competition between private hospitals was more the rule with however one notable exception in the region of Gent

In 2005, the Federal Government prepared a bill, called the "behealth bill", in order to provide a structural sustainability and governance to the proposed data sharing infrastructure. This bill was strongly attacked by the main representative associations of clinicians who refused the principle of a unique centralized infrastructure, even in the absence of centralization of data. Consequently, the Minister decided to drop the bill.

The PFS Public Health has then decided to support the creation of regional networks, under the total control of healthcare organisations, but on the basis of the legacy of the S3 proof of concept. Three operational sharing platforms have thus been created in the three regions of the country.

Following the failure of the "ehealth bill", a new federal initiative was launched; it was limited to the creation of a new central body, with a dedicated governance: the eHealth platform. The platform took over most of the missions entrusted to the Telematics Commission and, in order to have the buy-in from all parties, described in some details its perimeter of action and the main limitations.

The key fundamental principles were:

- ✔ *No central storage of personal healthcare data: System to system communication is the main rule.*
- ✔ *The only component to be centralized is the location service (with an Opt-In patient consent).*
- ✔ *The platform will make a maximum reuse of existing e-Gov components*

- ✔ *Respect for and support of* existing local or regional initiatives but also of private initiatives regarding electronic service to healthcare actors
- ✔ *Use of the services of the eHealth platform services was not mandatory*
- ✔ *The Platform is managed by the representatives of the various healthcare actors*
- ✔ *Unrestricted application of law (privacy, secrecy, patient's rights and free choice) with special attention to information security and privacy protection*
- ✔ *Trust is created through federating governance rules (Consent, exclusions, therapeutic relationship…)*

The government was thus aware of the need to give some time to the time in order to create trust before addressing more sensitive and complex processes, directly in connexion with the organisation of the health system**.** For this reason, the accent has first been put on quick wins, such as administrative simplification.

Regional initiatives had the capacity to further extend their development process but entered in a new phase of active collaboration within the new established governnace structures. Only two technical platforms [25]remained serving each two (sub)regional networks. A third- purely hospital based network- was created in Flanders. Those networks are still today the key backbone of the clinical data sharing infrastructure in Belgium.

In parrallel, the Flemish government has decided in 2011 to launch its own datasharing platform called "Vitalink", adressing mainly specific needs of the primay care sector. The initiative brought an additionnal level of complexity for the Flemish organisations as its technical governance was not aligned with the federal level.

The decision in 2012 of the Federal Minister of Health to launch a large consultation and establish a common roadmap was thus an answer to establish a global governance at political level. Following the official approval of the first roadmap, all actors have from then on working within the approved governance structures.

More details on the recent period can be found under section 2.4.1

2.6 Successes and what could be done better?

Key successes:

- Belgium has developed a mature, scalable and trusted data sharing infrastructure which is rooted in a direct involvement of end-users both at strategic and operational levels.

- The costs of development of this infrastructure have been significatively lower than in most EU countries; this is explained by:
    - The maximum reuse of existing mature e-Gov components
    - The high commitment of local actors who own the system
    - The generic and agile nature of the federated infrastructure
    - The long existence of formal and informal collaboration mechanisms between healthcare organisation which led to very significant economies of scale
    - The initial limited investment at central level before any consensus could be reached.

[25] The Cozo platform in Gent (Flanders) and the RSW platform in Wallonia

- Major investment costs are been progressive and shared between a number of institutions, making budgetary structural adjustments easier to absorb.

- The correct implementation of the standards and the priority eHealth services and their actual effective use has been enforced through:
    - A long-established working mechanism with both solutions developers and end-users.
    - A certification strategy completed by an increasingly use oriented incentivisation strategy
    - A large and adapted training offer both at service and product level

- The successful implementation of a number of Public-Private partnerships

- The "only once" strategy has largely contributed to reduce the administrative burden on end-users.
- A natural market consolidation (still ongoing) in all segments of the system which has led to a serious improvement in the quality of the products deployed and in their capacity to comply to continuously evolving requirements.

Could do better

- The lack of initial political alignment (vision) has led to the development of a number (although limited) of competitive initiatives (both at standards and projects levels) which are still creating unnecessary silos and brakes in the overall system.

- The complexity of the political governance process has as consequence a rather long decision-making process which however can suffer exceptions as demonstrated by the response to the recent Covid-19 crisis.

- Public administrations have first been reluctant to align with the proposed technical governance as it required a real change of culture and a perceived loss of independence in the choices they could make. It led in some instances to major drawbacks such as for example the major delay in the development of a truly and correctly governed operational terminology centre.

- The current roadmap remains based on the principles agreed upon at the creation of the eHealth platform. A number of actors however consider that the centralisation of data is a necessary requirement for the creation of more added value in the system. A recent legal proposal to establish a central database of prescriptions managed by public administrations together with a proposed centralisation of data in the context of integrated care has however been again attacked by representatives of the end-users as this would deeply affect the current governance process. In absence of a global strategic response to these open questions, Belgium might not be in the best position to answer upcoming challenges, such as the data reuse strategy.

- The secondary care sector is in full transition with the compulsory creation of new entities aiming at increasing synergies and efficiency. The financing of the sector remains very complex and require a substantial simplification. It does not provide sufficient visibility to the ICT related costs which are now of strategic importance.

- The overall system actually excessively relies on a number of (multi-cards) individuals: this situation raises numerous questions concerning the transparent functioning of the overall governance process even if it has contributed to achieve important results.

- Impact (quality assessment) monitoring is still to very rudimentary and only rely on ad hoc studies and processes.