



RWD4BE

Real world data for better healthcare

Policy recommendations for the implementation of the real-world data reuse framework and strategy in Belgium - A multi-stakeholder initiative

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Colophon

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Disclaimer

External experts have contributed via one-on-one meetings and participation in action meetings. Input from these meetings were analysed and discussed and resulted in this report. The external experts did not co-author this report and



VISION

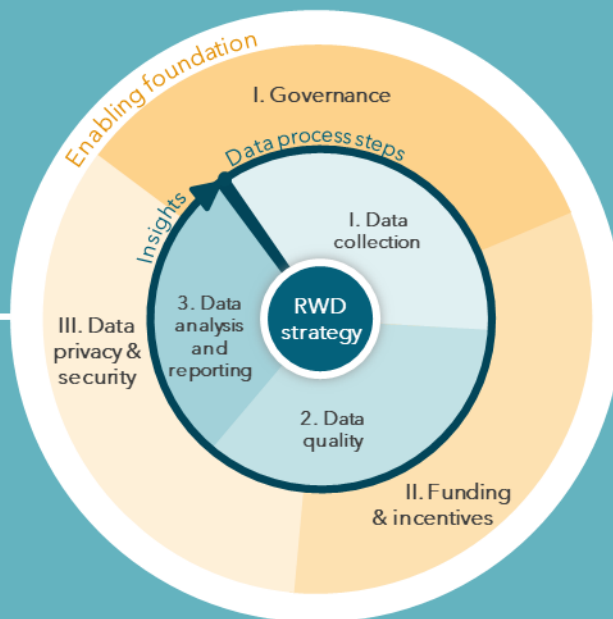
RWD4BE wants to establish a connected health data reuse environment to position Belgium as a breeding ground for transparent and patient-centric RWD projects
 With this multi-stakeholder initiative, we want to increase transmutal quality of care and promote value-based healthcare, optimise cost efficiency and enforce the Belgian position as a research and innovation epicentre

MISSION

The RWD4BE mission is to enable and implement the connected RWD reuse framework in Belgium by fostering education, integrating the medical and patient perspective, providing essential tools and well-informed policy recommendations
 The RWD4BE initiative supports an integrated action plan through multi-stakeholder collaborations to address the hurdles and challenges, raise awareness and educate the public

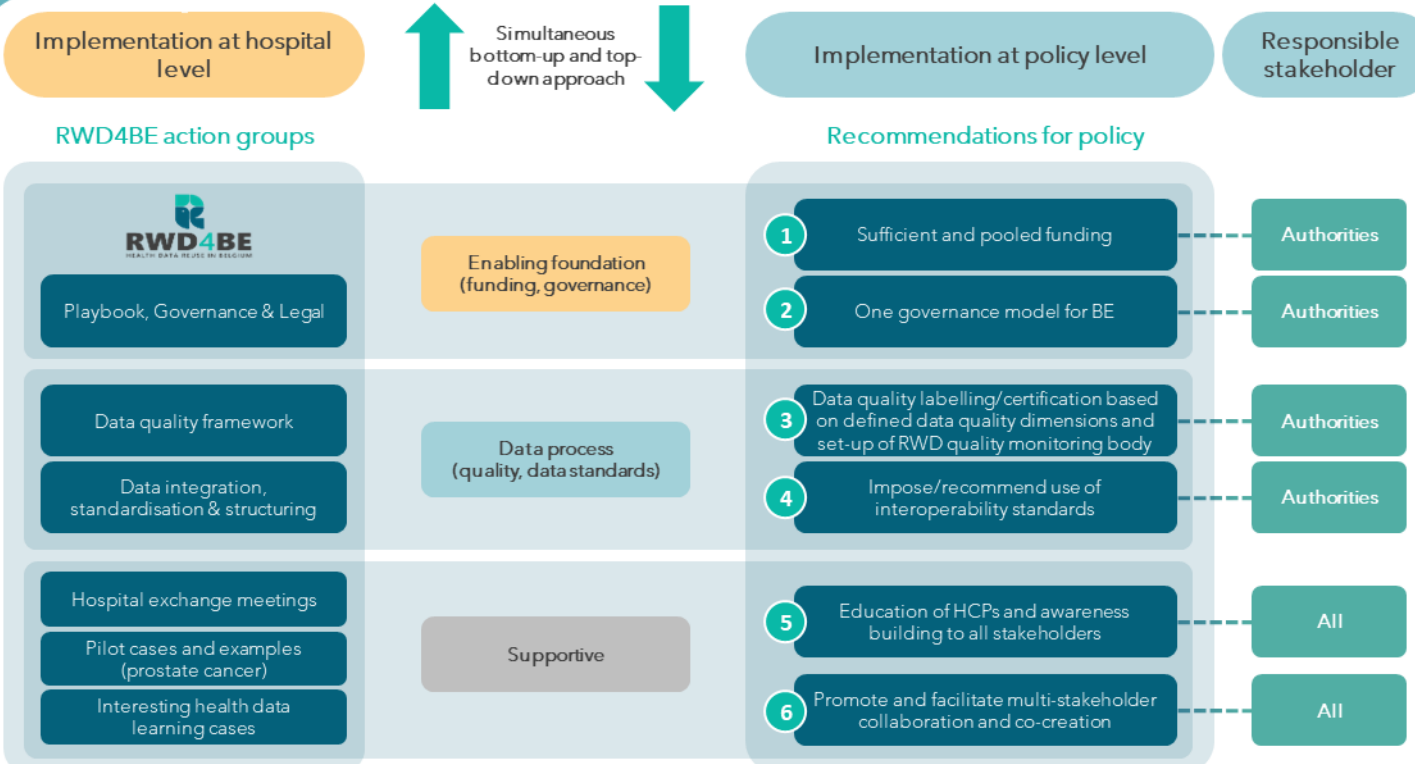
Objectives:

- Education & creating awareness
- Provide tools, methods, guidance to hospitals
- Provide policy recommendations



To bring the RWD reuse framework to live and implement it, action groups were set up and recommendations were made for implementation at both hospital and policy level

The RWD framework facilitates multi-stakeholder discussions and decision-making on the preferred RWD reuse solutions in Belgium. The RWD4BE initiative was set up to implement the framework



Preface – Jo De Cock

Two main lessons emerged from the recent COVID-crisis with regard to healthcare systems: the necessity to create preparedness and resilience on the one hand and the importance to develop policies for data ecosystems with the aim to improve population health on the other hand.

Data driven health care systems are investments in the future. Data can and should be mobilized for different purposes: to support patient-centred monitoring and evaluation of the quality of health care services, to adapt care supply to population unmet needs, to develop appropriate prevention policies and last but not least to inform and to nurture healthcare research. Data are valuable resources for health and life sciences research supporting the development of diagnostic tools, medicinal products and innovative treatments.

All the different objectives that were mentioned need approaches at a local, national and European level. The European Health Data Space is an opportunity to leverage information from EU-wide databases. The Health Data Agency, which was created last year in our country, is a necessary instrument to facilitate the secondary use of health data.

Data sharing will be an essential ingredient of well-functioning health systems. Top-down efforts by governments or international bodies are necessary but will not be sufficient. We will only be successful when aside bottom-up actions are undertaken with the involvement of different stakeholders such as health providers, hospitals, patients, sickness funds, public authorities, industry, universities.

The aim of the RWD4BE initiative is to bring all those stakeholders together in order to build a common project. This report is the result of the first phase of this multistakeholder initiative. During a number of meetings concrete policy recommendations for the implementation of a strategy and framework for the reuse of health data have been identified and formulated. Different working groups were created to find common ground, to analyse best practices and to align with other initiatives.

Managing data across different settings is challenging and needs a good governance model, data quality monitoring, interoperability standards, awareness building and education, financial resources and last but not least the further development of a data driven culture and of appropriate partnerships.

I'm convinced that the report has defined a clear pathway to make further progress and to achieve the outcomes of a data driven healthcare system.

Jo De Cock

Chairman of the multi-stakeholder initiative
Former Administrator General NIHDI
Chairman of the National Commission of Physicians and Health Insurance Funds
and the National Joint Commission of Physicians and Hospitals

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Executive Summary

Belgian RWD preparedness

Belgium has one of the best healthcare systems in Europe and is home to one of the world's strongest health and life science research clusters and has long been ranked as the best country in the EU for clinical trials. However, Belgium has been and is still losing ground. The OECD 'Health at a Glance 2023' report evaluates the preparedness for digital health of the European member states. According to this report, Belgium performs poorly, particularly in terms of health data availability for primary and secondary use, communication with the public, cybersecurity, and digital knowledge and skills. If Belgium wants to maintain its attractive research environment and its quality healthcare system with value-based healthcare and outcome-based reimbursement, the country needs to improve its position regarding the reuse of routine care data or also called real-world data (RWD).

RWD reuse framework for Belgium

In June 2022, the RWD Framework, created through a multi-stakeholder dialogue, was published to support the reuse of RWD in Belgium. The RWD Framework aimed at providing a structure to support multi-stakeholder discussions and decision-making on the preferred solutions allowing for RWD reuse in Belgium.

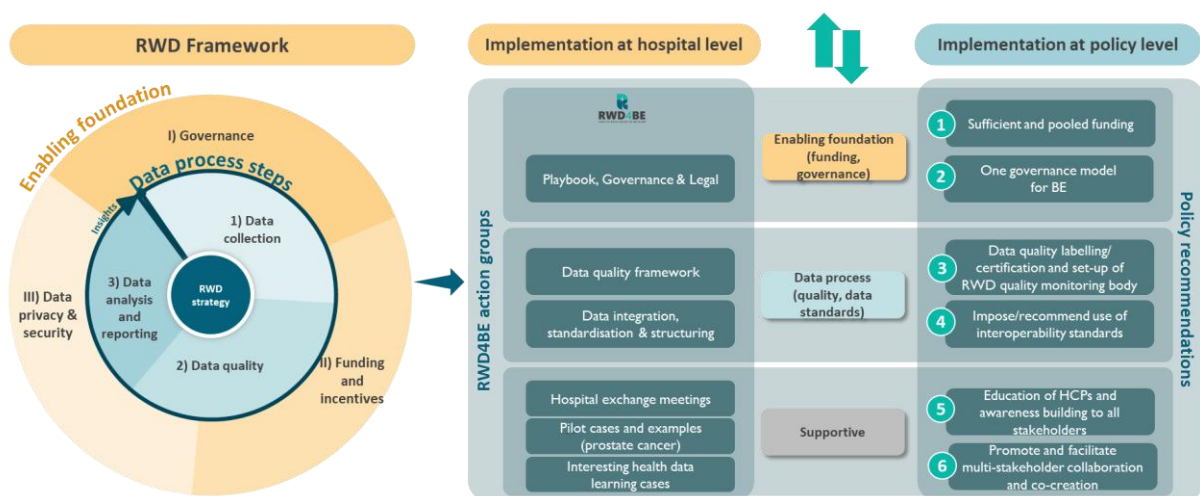
RWD4BE initiative

Building upon the foundations laid by the RWD Framework, the RWD4BE initiative has been launched in 2023 with the purpose of effectively integrating and **implementing this RWD reuse Framework**. The goal of the RWD4BE initiative is to provide tools, methods and guidance to hospitals, educate and create awareness about the need for RWD reuse and provide input to policymakers to create an overall better healthcare system and support personalised and data-enabled medicine. This initiative has been developed in multi-stakeholder agreement, supported by hospitals and clinicians, patient representatives, authorities, companies and the health clusters (MEDVIA and BioWin).



Top-down action is now required to complement bottom-up preparedness

To implement the RWD reuse framework, RWD4BE action groups have been created to address the key hurdles and challenges at hospital level, bottom-up. Government has now to put the top-down actions in place to complement and guide the hospital actions that are being executed within RWD4BE to be ready for RWD reuse. Top-down action on enabling foundation, data process related steps and supportive level is required to complement the bottom-up preparedness. Therefore, this policy report sets out the top-down policy recommendations derived from the insights and experiences gained through the RWD4BE initiative action groups, focusing on the implementation of RWD reuse in Belgian hospitals.



Based on the multi-stakeholder discussions in the RWD4BE action groups, working on the main short-term actions to address the RWD reuse challenges, six key policy recommendations are listed in 3 levels:

- Enabling foundation -
 1. Sufficient and pooled funding
 2. One governance model for Belgium
- Data process steps -
 3. Data quality labelling/certification based on defined data quality dimensions and set-up of RWD quality monitoring body
 4. Impose/recommend use of interoperability standards
- Supportive layer -
 5. Education of HCPs and awareness building to all stakeholders
 6. Promote and facilitate multi-stakeholder collaboration and co-creation

Policy recommendations to support RWD implementation top-down				
The recommendations for policy	Enabling foundation	1 Sufficient and pooled funding	To support RWD reuse sufficient and pooled funding instruments and mechanisms are required for set-up, sustainability efforts and personnel, incl. incentives for high quality data collection, infrastructure, data curation, ...	Authorities
		2 One governance model for BE	Clarify and develop one uniform governance model for key RWD reuse applications. Set-up one-stop-shop to find and access all data, one contract model, privacy declaration, national GDPR interpretation, etc. Set-up of a sandbox as an initial step.	Authorities
	Data process	3 Data quality labelling/ certification and set-up of RWD quality monitoring body	Set up a data quality labelling / certification framework based on the defined data quality dimensions and, assessment and support a data life-cycle approach Appoint a body to monitor RWD maturity and efforts to inform policy	Authorities
		4 Impose/recommend use of interoperability standards	Recommend the use of standards (FHIR, OMOP) and put incentives in place to apply them. A minimal standard of interoperability should be imposed via EHR accreditation and via hospital (network) funding	Authorities
	Supportive	5 Education of HCPs and awareness building to all stakeholders	General public and patient education and awareness building by all stakeholders Inclusion of data science and RWD-enabled research in HCP curricula	All
		6 Promote and facilitate multi-stakeholder collaboration and co-creation	Provide a multi-stakeholder platform to facilitate collaboration on the key challenges to solve and implement them	All
				Responsible stakeholders for implementation

The 6 recommendations to support the implementation top-down, complement the outcomes of the bottom-up RWD4BE action groups.

Ultimate ambition

RWD4BE started with hospital data as the initial focus, but the ultimate ambition should be to cover all health care usage data from the entire patient journey, including first line data from primary care, in a staged approach.

The RWD4BE initiative wants through multi-stakeholder collaboration create the willingness to work towards a common vision of an ideal context of data capture and sharing the benefit of health outcomes and research (instead of only a technical/operational exercise to harmonise/integrate current data). Instead of capturing all data, we should select and prioritise the data needed to have optimal health and research inputs. The future system should be able to capture data by type of disease, so that we can improve outcomes by increasing the effectiveness and efficiency of our current healthcare system, which is a critical patient-relevant aspect in the use of secondary data.



1. Context and why the RWD4BE initiative has started

1.1 Unlocking the power of data in healthcare

Data is integral to the patient journey and data sharing across organisations enables personalised healthcare and research¹. Across the patient journey, the diverse stakeholders often operate in silos, thus there is a need for policies, frameworks and infrastructure to ensure that high quality data can be securely shared between stakeholders and across projects to enable personalised care.

The growing use of electronic health records (EHRs) in the Belgian healthcare system fuels the fast growth of clinical data available in electronic format. This growth offers tremendous potential for the use of routine care data beyond its primary intent (i.e., patient care and healthcare operations). Secondary use (or reuse) of clinical data is defined as “non-direct care use of personal health information including but not limited to analysis, research, benchmarking, quality and safety measurement”². The use of this data, also known as real-world data (RWD), supports hospitals and HCPs to improve their quality of care. For hospitals quality of care is not the only goal. Better use of the existing data will allow hospitals to work more efficiently and to provide patients the most optimal (non-care) services. Therefore, it allows for benefits on at least three of four ‘quadruple aim’ goals. Beside better quality of care, it also provides evidence on the long-term performance of new therapies in large and more diverse populations, necessary for evidence-based reimbursement. Furthermore, it enables research and increased insights into disease mechanisms, leading to new diagnostics and treatments. All these changes can streamline clinical decision making and improve outcomes at the individual patient level, resulting in improved population health conditions. Secondary use of health data makes it possible to analyse from a health policy perspective how patient populations within a specific disease area are performing, from early symptoms to end of treatment, to identify best practices based on key performance indicators and to identify areas for progress in patient outcomes.

Belgium is home to one of the world’s strongest health clusters and has long been ranked as the best country in the EU for clinical trials. However, Belgium has been and is still losing ground. According to the OECD ‘Health at a Glance 2023’ report, which evaluates the preparedness for digital health of the European member states, Belgium performs poorly, particularly in terms of data availability for primary and secondary use, communication with the public, cybersecurity, and digital knowledge and skills³. If Belgium is to maintain its high quality healthcare system and attractive clinical trial environment, the country needs to improve its position regarding the reuse of routine care data for quality of care, research, value-based healthcare and policy.

Availability and secure reuse of routine care data is high on the authorities’ agenda, for implementing value-based healthcare and outcomes-based market entry agreements (OB-MEA), for increasing efficiency and quality of care and for improving personalised care and care coordination⁴.

Reusing real-world health data is useful, but challenging

While health data reuse and sharing for research purposes is strongly supported in principle, it can be challenging to implement in practice. There are multiple challenges with the secure reuse of routine care or real-world health data. Most challenging is the lack of structured and high-quality data enabling robust research.

It is not the actual data transfer that is the bottleneck but rather the processes and systems around it, which were considered time-intensive and confusing. Also, logistics and data quality issues are practical bottlenecks in health data sharing. Areas of legal uncertainty include privacy laws when sharing data nationally and internationally, questions of “who owns the data”, inconsistencies on consent being implemented differently across different institutions, and definitions and operationalisation of anonymisation and pseudo-anonymisation. There must be a desire to create a “culture of data sharing” and

¹ Athena (2024), Using patient data to enable personalized healthdata, ATHENA shows us how!

² Safran A. *et al.* (2007), Toward a national framework for the secondary use of health data: an American Medical Informatics Association White Paper. JAMIA, 14(1), 1-9. <https://doi.org/10.1197/jamia.M2273>

³ OECD (2023), Health at a Glance 2023: OECD Indicators, OECD Publishing, Paris, <https://doi.org/10.1787/7a7afb35-en>

⁴ The evolution of healthcare in Belgium - Jan Bertels, Chief of Cabinet for public health and social affair

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to recognise that data sharing is a process with many steps, not an event, and that requires sustainability efforts and personnel. To be future prepared and benefit from health data reuse, we should move away from data sharing and the current privacy focus towards processes that facilitate data access. Facilitating such a data access culture in Belgium may require legal clarifications and templates to streamline the processes, further education about the process and resources to support data sharing, and further investment in sustainable infrastructure by funders and institutions.

1.2 The implementation of the RWD Framework for Belgium

Hospitals play an important role in health data generation and should be supported in leading the way in reusing their data to benefit themselves, the healthcare system, and more particularly patient care. To achieve this, a data culture must be established that harnesses the power of data to improve patient outcomes in all hospitals. Hospitals should be encouraged to work together and take action to collaborate at all levels, including with third parties, such as academic and industrial researchers.

The patient is at the core of this initiative. The aim of RWD4BE is to create an overall better healthcare system by leveraging patient health data to deliver better care for every individual. To realise this, active engagement with patients is required to clearly explain the objectives of their data use and reuse, ranging from prevention and population health to scientific research. These objectives should be documented in a pact between patient and healthcare provider, providing clarity and transparency on data use and reuse to build trust with patients and among the wider public.

For this purpose, the **RWD Framework** was developed and published in June 2022 through multi-stakeholder engagement and dialogue, to support the reuse of RWD in Belgium. The RWD framework aims to provide a structure to support multi-stakeholder discussions and decision-making on the preferred solutions allowing for RWD reuse. This framework is described in the “Recommendations on a Real-World Data Strategy for Belgium - Multi-stakeholder initiative on reuse of routine care health data” report (click [here](#) for the report or via the Inovigate website)⁵. The report discussed the necessary actions for Belgium to implement the RWD reuse framework from a bottom-up perspective, by the hospitals and also from a top-down perspective, by the government and from a policy perspective.

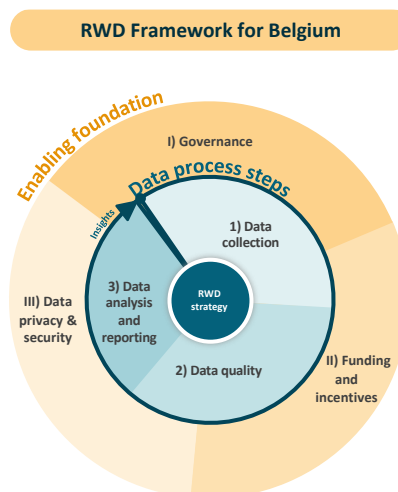


Figure 1: RWD framework

The bottom-up actions include:

- Implement a data strategy and take initiative to share data
- Set up well-structured, high quality data (via EHR) to extract for further analysis and reporting
- Restructure EHR and internal databases and systems to be compatible with different RWD infrastructures
- Establish a data culture in which outcomes are compared and benchmarked between hospitals
- Build a governance model at the hospital and hospital network level

The top-down actions include:

- Set up a governance and legal framework for RWD/one national health data charter and guidance on legal requirements for (re)use of RWD (e.g. possibility of opt-out system) , in line with the European Health Data Space (EHDS)
- Build excellent data infrastructure
- Impose data and interoperability standards for hospital EHRs
- Harmonise data infrastructures across diseases and international initiatives
- Update the HealthData.be infrastructure to support automated data harvesting and quality checks

⁴ Recommendations on Real-World Data Strategy for Belgium, a multi-stakeholder initiative on reuse of routine care health data (2022) Inovigate: <https://ap.lc/BKFWa>

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- Put incentives and funding in place for structured, high quality data collection and curation
- Reform conventions to ensure sustainable financing of data infrastructure, collection and analysis (in collaboration with the industry)

Top-down and bottom-up actions and initiatives are required:

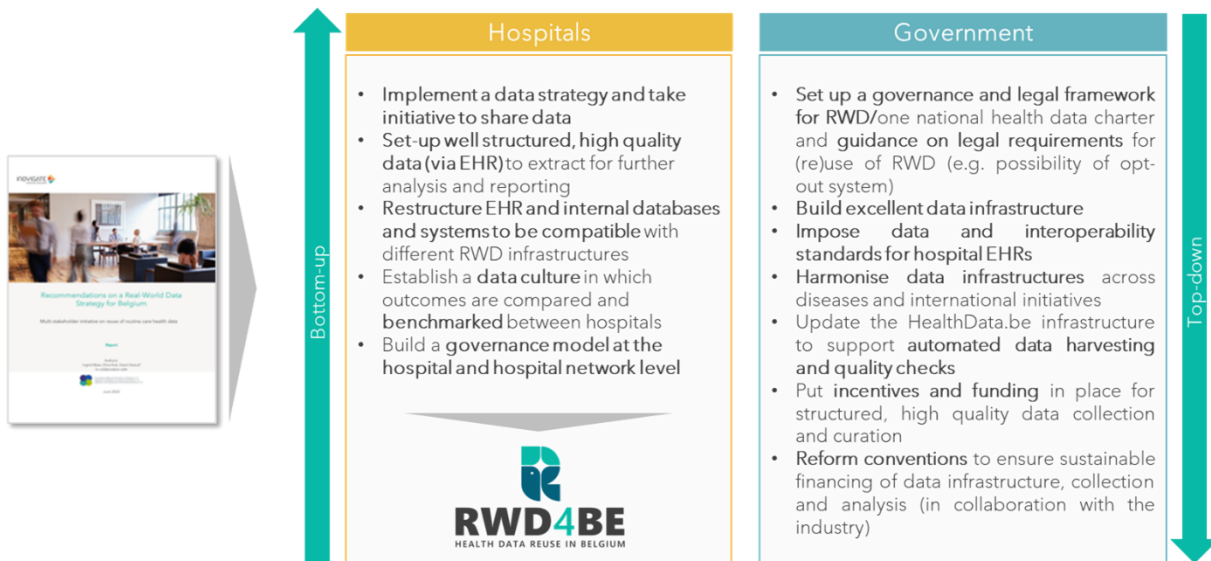


Figure 2: Top-down and bottom-up actions and initiatives

Building upon the foundations laid by the RWD Framework, the **RWD4BE initiative** has been started by the hospitals with the purpose of effectively integrating and implementing the RWD reuse Framework and the bottom-up actions.

This policy report wants to further build on the proposed top-down actions and initiatives and sets out the policy recommendations derived from the insights and experiences gained through the RWD4BE initiative.



1.3 The importance of the multi-stakeholder dialogue and co-creation

This RWD4BE initiative has been initiated by the by the hospitals in Belgium and the BAHM (Belgian Association of Hospital Managers), but meanwhile further extended with multi-stakeholder representatives, such as clinicians, patient representatives, authorities, the health and life science cluster organisations MEDVIA and BioWin and companies.

A list of the participating stakeholders can be found in the table below:

Hospitals	Authorities	Industry
BAHM	Cabinet	JNJ Innovative Medicine
AZ Maria Middelaes	NIHDI	CSL Behring
CHIREC	Health Data Agency	Tiro.health
UZ Gent	Universities	Pfizer
UZA	Ghent University	Novartis
AZ Monica	University of Hasselt	Roche
CHU Liège	University of Mons	Cascador Health
ZOL Genk	UCL Louvain	Move Up Care
AZ Groeninge	Sick funds	Patient organisations
CHU Brugmann	Onafhankelijk ziekenfonds	Patient Expert Center
OLV Aalst	Research institutes	RadiOrg
AZ Delta	VIB	Association Muco/ Mucovereniging
AZ St. Lucas, Gent	Sciensano	Huntington Liga
AZ Damiaan	Belgian cancer registry	LUSS
Institut Jules-Bordet	King Baudouin Foundation	Cluster organisations
UZ Leuven	Non-profit organisations	MEDVIA
CHU Charleroi	European Institute for Innovation through Health Data (i-HD)	BioWin

The initiative is primarily driven from the hospital perspective, as RWD originates from the hospitals, but is open to all parties and stakeholders interested in RWD and wanting to contribute to implementing the RWD reuse Framework in Belgium.

Today, many different RWD initiatives are ongoing in Belgium, all independent of each other. The RWD4BE initiative is a coalition that encourages all stakeholders to align and define a safe and secure data environment that makes Belgium a top region for RWD use and reuse, aiming to benefit Belgian patients, society and economy within a European context. The importance of the RWD4BE initiative lies in bringing all stakeholders together, focusing on the challenges that are not being addressed yet. RWD4BE does not want to duplicate initiatives that are already ongoing (e.g. ODHSI Belgian chapter, IMEC Healthdata panels, etc). By doing so, the whole sector puts forward united recommendations for policy towards the authorities regarding the reuse of RWD in Belgium in a bottom-up manner. Those recommendations have multi-stakeholder support, and their feasibility has already been validated by the authorities as they have been involved in this initiative from the start.



2. The ambition and objective of the RWD4BE initiative

The ambition of the RWD4BE initiative is to implement a connected health data reuse environment by addressing the key hurdles and challenges at hospital level, and laying the groundwork for findable, accessible, interoperable and reusable data (FAIR), based on recommendations from HDA and other institutions (a.o. European Health data space (EHDS))⁶.

It is important to mention that the RWD4BE initiative only focuses on the secondary use (or reuse) of RWD. It does not focus on the primary use of RWD, neither on the reuse of governmental data (as this is the role of the Belgian Health Data Agency). The RWD4BE initiative wants to speed up efforts, go beyond the conceptual modus and focus on practical cases, tools, processes, ... It also aims to defragment RWD initiatives in Belgium and consolidate and align the efforts. The RWD4BE initiative does not want to duplicate ongoing initiatives but wants to be complementary and focus on what is not yet being addressed. It **focuses on the hospital perspective and wants to support hospitals to prepare for RWD** collection (bottom-up), using the recommendations from the Belgian Health Data Agency (HDA) (top-down) to make their data ready for reuse. With this ambition, the RWD4BE initiative is perfectly complementary to the Belgian federal health data landscape.

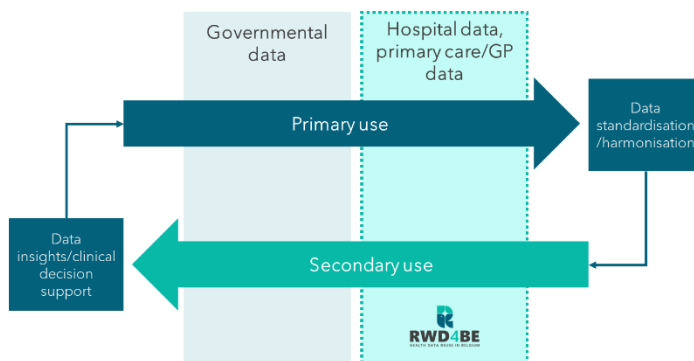


Figure 3: Focus of RWD4BE

The **vision** statement of the RWD4BE initiative clarifies this ambition.



Figure 4: Vision statement of the RWD4BE initiative

VISION

RWD4BE wants to establish a connected health data reuse environment to position Belgium as a breeding ground for transparent and patient-centric RWD projects

With this multi-stakeholder initiative, we want to increase transmutal quality of care and promote value-based healthcare, optimise cost efficiency and enforce the Belgian position as a research and innovation epicentre

With the term breeding ground, we refer to a place and set of circumstances suitable for or favourable to growth and development, based on RWD.

To realise this vision, the following **mission** statement has been formulated:

⁶ Geys L., Peeters L., (2024). Strategic Oversight Across Real-World Health Data Initiatives in a Complex Health Data Space: A Call for Collective Responsibility. 577-584. 10.5220/0012417700003657





Figure 5: Mission statement of the RWD4BE initiative

The **objective of the RWD4BE initiative** is three-fold, to support the reuse of RWD through:

- Providing tools, governance, and guidance to hospitals and health care providers (HCPs) to support them for RWD re-use:
 - Provide tools, methods, and guidance to hospitals
 - Develop the legal and governance framework
 - Create contract templates aligned with the legal and governance frameworks
 - Provide a data quality framework and guidelines, to support structured, high quality data collection at the source
- Educating and creating awareness at hospitals and other stakeholders:
 - Disseminate know-how on RWD reuse
 - Educate HCPs on the importance and value (also for their personal benefit to save time and perform better care) of RWD
 - Inform patients and the general public on the importance and value of RWD and stimulate their engagement for RWD
- Making policy proposals, bundled in this policy paper with recommendations for government and policymakers to support the implementation of the RWD Framework and also the tools and guidance developed by the hospitals, within the RWD4BE initiative:
 - Feed policy with recommendations to establish a clear legal and common governance framework for Belgium, supported by all stakeholders involved
 - Incentivise structured, high quality data collection at the source, based on the proposed data quality framework and guidelines to support this

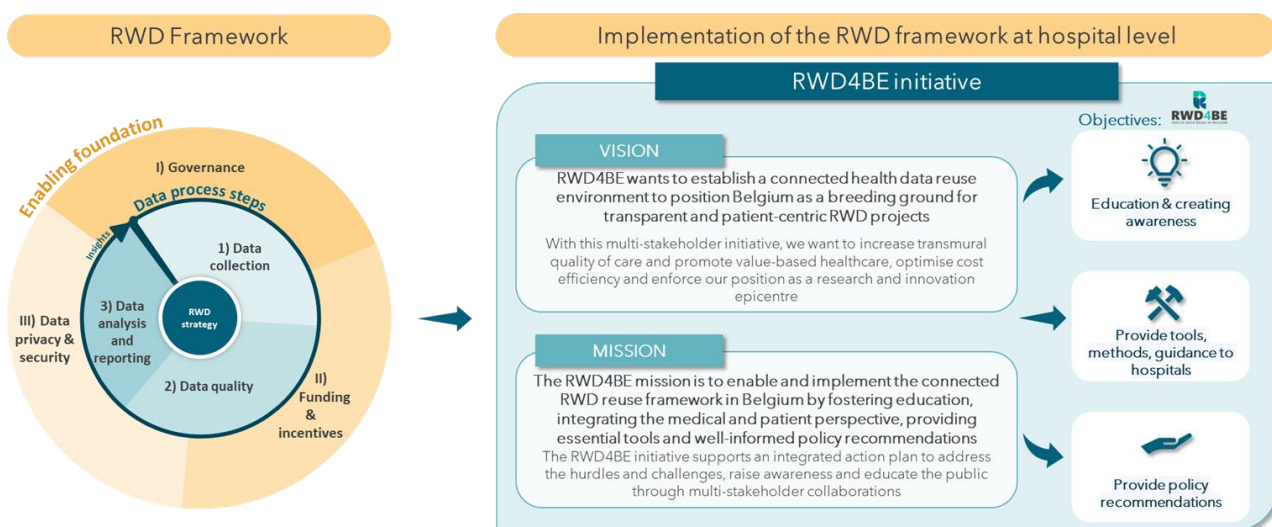


Figure 6: Objective of the RWD4BE initiative



3. The action portfolio

As multi-stakeholder engagement and dialogue is key for the implementation of the RWD Framework: multi-stakeholder round tables were organised to identify the biggest needs from a hospital perspective to implement the RWD framework and make it happen. The outcome of this dialogue was an **action portfolio addressing the key hurdles and challenges at hospital level**. Based on this action portfolio, several **action groups** (see the overview of the several action groups in figure 7) were launched beginning of 2023, tackling specific hurdles and challenges and providing the necessary tools, systems and guidance.

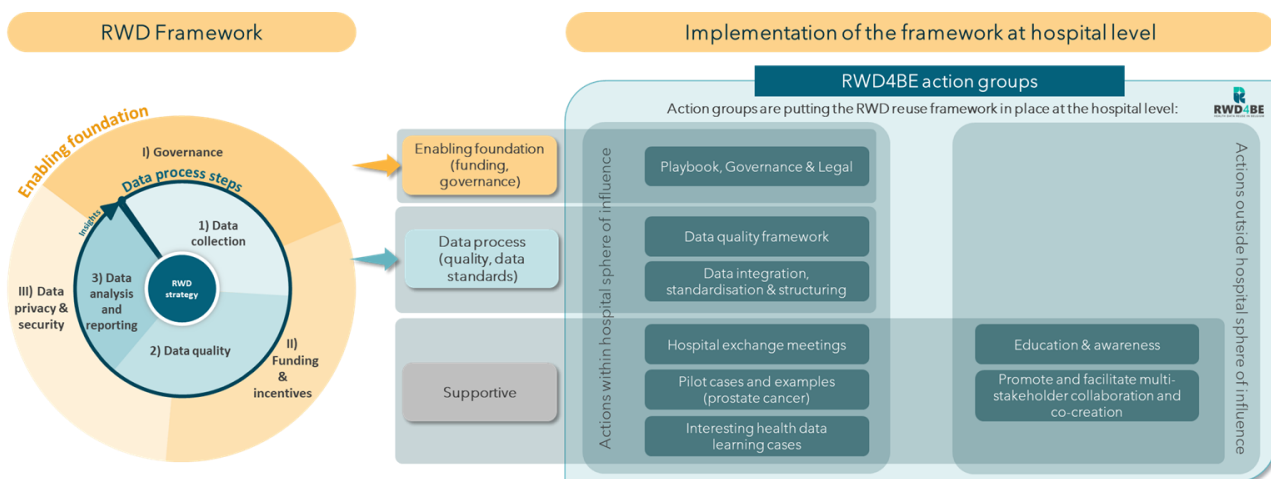


Figure 7: Overview of the RWD4BE action portfolio

3.1 The action groups working on the action portfolio

Eight action groups, each addressing specific challenges and hurdles have been set-up and form together the action portfolio to implement the RWD framework in Belgium. Each action group is led by an action lead and a team of multi-stakeholder contributors. The action groups are open for all parties willing to contribute. Each action group has defined their scope, objective and deliverables and key performance indicators (KPIs).

3.1.1 Playbook, governance and legal

Objective:

This action group aims at providing a playbook, a governance and legal framework, for hospitals that outlines the process steps and flows needed to implement secondary use of data. The group has the ambition to provide concrete implementation tools like one template/standard contract for collaboration between hospitals and/or with third parties, one privacy declaration and one interpretation of GDPR for all Belgian hospitals, ... to streamline the process.



Enabling foundation (funding, governance)

Playbook, Governance & Legal

RWD4BE action group

Scope:

- Develop and implement an implementation guideline/playbook: a scenario for hospitals to follow with common guidelines and on the interactions between parties/organisations
- Learn from other initiatives and organisations on all levels (hospitals, first line, industry, authorities, etc.) on governance and approvals (processes, tools, templates, etc.), rules and regulations
- Identify the biggest challenges and priorities: e-survey with questionnaire on key metrics and facts to communicate transparently
- Start small: at hospital level, and expand to other organisations later
- Transparency for all: citizens, patients, hospitals, government, etc. should be informed about how things work, who can see what, funding aspects, interface per user-group, etc.
- Build a centralized governance and create a legal framework with clarity and transparency for all (harmonised contracts within BE, etc.)


Critical interdependencies with other projects:
The work should not be done "on top off" other ongoing initiatives such as the Data Charter (RUZB/CHAB) or other (HDA). We need to focus on offering complementary insights, alignments and deliverables. This group could work as an alignment team between (academic and peripheral) hospitals and other data providers.

Project objectives and deliverables:

- Final purpose of this action is to provide input to policy makers (short-term goal) on governance, legal framework, ...
- A playbook for hospitals that outlines the process steps / process flow supported by all data providers
- Concrete tools (templates, example contracts) to request secondary use of data
- Addition to privacy declaration for hospitals - covering reuse of data by third parties

KPI's:

- E-Survey completed by multiple Belgian hospitals
- Playbook ready by the end of 2023
 - Alignment on approach across all relevant stakeholders
 - Process designed
 - Templates / deliverables ready
- Policy paper with recommendations for policy



Results and deliverables:

This action group has organised an e-survey amongst hospitals to list the needs and requirements of the Belgian hospitals and also assess the RWD reuse readiness and maturity. Based on the outcome of the survey, a playbook has been developed that addresses the main needs. The results from the e-survey can be found in chapter 4. The e-survey could preferably be repeated every year to monitor progress and maturity evolution on the implementation of RWD reuse at hospital level in Belgium and could also be a great input for policy.

The playbook is a step-by-step plan for hospitals to prepare and set up the required RWD reuse strategy, governance systems and processes, technology, organisation and teams. Templates and examples have been added to the playbook to support the practical implementation and avoid re-inventing the wheel at each hospital wanting to set up for RWD reuse. It will be further substantiated in the coming months and best practices from other hospitals will be added. This tool is also a great way to align and harmonise amongst hospitals.

3.1.2 Data quality framework

Objective:

This action group want to define data quality and set up a data quality framework and roadmap on data quality requirements, measurements, labelling, governance, ... for the secondary use of healthdata

Data process (quality, data standards)

Quality framework

RWD4BE action group

Scope:

- Define data quality and set up a data quality framework
- Determine how to measure data quality (dimensions, methodologies, etc.)
- Quality labelling/certification
- Define governance requirements
- Draft a data quality roadmap for secondary use of health data


Critical interdependencies with other projects:
Work together with other action groups

Project objectives and deliverables:

- Conduct a data quality analysis in Belgian hospitals on a common patient dataset
- Give a workshop on data quality
- Build a Data Quality Framework for secondary use of health data
- Provide input to policymakers on requirements for structured, high quality data

KPI's:

- Published results of the data quality analysis, together with the Data Quality Framework




Results and deliverables:

This working group is currently assessing the quality of data within hospitals across a large network of Belgian hospitals, through pilot projects.

3.1.3 Data integration, standardisation & structuring

Objective:

The final purpose of this action group is to provide input with recommendations and a roadmap to policymakers (short-term goal) on data integration, standardisation and structuring. Data is power, so at some point it needs to be decided what minimal standards/ practices will be imposed on everyone (to assure an equal level-playing field) to make sure the market remains fair and just.

Data process (quality, data standards)

Data integration, standardisation & structuring

Scope:

- Propose data standardisation for clinical decision-making.
- Clarification and standardisation of terminology and definitions
- Information on and comparison of the different data models (a.o. FHIR, OMOP-CDM (OHDSI), openEHR, IPS, BIHR, etc.)
- Process harmonisation to create data standardisation: clinical content standards based on patient flow (ICHOM) , including synchronisation of data points
- Define what is required as standards and how to enforce them
- Build a roadmap that explains how to define a minimum dataset per disease area: establish the fundamental data layer for routine care data and determine a quality label for the hospitals using the same minimum data set


Project objectives and deliverables:

- Comparison of the different data models
- Create a roadmap to define a minimum dataset per disease area
- Provide input with recommendations and a roadmap to policy makers (short-term goal) on data standardisation, structuring and integration

KPI's:

- Recommendations on data standards
- Roadmap to define a minimum dataset per disease area

RWD4BE action group



Results and deliverables:

This action group has been put on hold as the activities are taken over by The Belgium Chapter of the international OHDSI initiative.

3.1.4 Hospital exchange meetings

Objective:

On-site meetings at hospitals take place to stimulate exchange and best practice sharing between hospitals. Each hospital is hosting the meeting and presents their efforts and methods.



Supportive
Hospital exchange meetings

Scope:

- Organising several hospital visits to exchange information
- Providing the opportunity to ask questions to other hospitals
- Informing each other about the approach in his/her hospital

Critical interdependencies with other projects:

Part of the education and awareness action group because of communicating tools and methodologies with each other. In addition, it can also give input to the playbook.


Project objectives and deliverables:

- Sharing learnings, tools and methodologies with each other
- Identifying good examples to complement the playbook
- Creating openness and trust between hospitals

KPI's:

- Several hospital visits across the country

RWD4BE action group



Results and deliverables:

In 2023, three meetings took place at OLV Aalst, AZ Maria Middelaes in Gent, and AZ Groeninge in Kortrijk. More hospital visits are planned at UZA, CHU Liège, UZ Gent and other hospitals during 2024. The hospital visits have also provided input (good examples for others) to the playbook action group.

3.1.5 Pilot cases and examples

Objective:

The pilot cases will serve as practical cases to collaborate between hospitals and also to develop blueprints for data-driven solutions for effective application and organisation of real-world health data.

Supportive
Pilot cases and examples (prostate cancer)

Scope:

- Generate a patient journey from a clinical point of view from screening till therapy follow-up
- Identify at what point in the patient journey data-driven solutions can be rolled out focusing on screening/diagnosis, therapy and long-term (post-treatment) follow-up
- Identify the missing data
- Identify existing data sources and who can get access to them
- Explore how the RWD can be translated into RWE and which data deliver the best insights

Critical interdependencies with other projects:

Build further upon the insights from other action groups


Project objectives and deliverables:

- Develop the project concept: blueprint for data-driven solution for effective application and organisation of real-world health data linked to prostate cancer
- Establish a consortia for the project group
- Identify potential funding streams for the project

KPI's:

- An outline of the optimal clinical landscape
- A recommended wish list of data sources at the different stages of the patient journey
- A high-level proposal of a technical data solution
- A list of potential funding streams

RWD4BE action group



Results and deliverables:

A project group has been put together on the prostate cancer pilot case, and the demand for funding for this project has been submitted.



3.1.6 Interesting health data learning cases

Objective:

This action group has created an inventory of existing health data initiatives in Belgium and abroad, with the aim to extract best practices from those initiatives to be used as source of inspiration for the implementation of RWD reuse solutions and proposals. When building the inventory, it became clear that the health data landscape is a mess. Multiple initiatives exist and more are continuously arising, the strategic oversight across these initiatives is lacking, which leads to a fragmented ecosystem.

An overview of which initiatives work on unlocking real-world health data, making this data accessible for research and/or innovation and/or policy and getting an idea about which aspects of the ecosystem the initiatives are working on, is very helpful. It could support alignment and building synergies, avoids to reinvent the wheel, demonstrates gaps, supports building useful consortia and inform newcomers.

Supportive Interesting health data learning cases (inventory)

RWD4BE action group

Scope:


- Create an inventory of existing (open source, non-commercial) initiatives in Belgium and abroad: List relevant local, national and international initiatives.
 - Relevant means accessible, open for cooperation, based on FAIR
 - Relevant also means inspiring/best practices, helping to weigh on policy making
- Map characteristics of listed data projects, cluster them and assess them on various parameters (governance, underlying technology, funding,...)
- Extract best practices from those initiatives (as source of inspiration for the other action groups)

Critical interdependencies with other projects:
This project might provide input and an intelligence source to the other working groups (as source of inspiration, example cases, etc.)

Project objectives and deliverables:

- Inventory of interesting health projects and initiatives, that can serve as learning cases
- Identify best practices
- Final purpose of this action is to provide input to policy makers (short-term goal)

KPI's:
Initial "inventory" before end of 2023



Results and deliverables:

The overview has been created, resulting in a static list, that can be updated at regular intervals. It serves as a valuable resource for stakeholders in the field. The list is however not the primary objective, but the list has been used to define best practices and learnings from these initiatives. A selection has been made of the most interesting initiatives in Belgium and abroad. Based on these initiatives, nine best practices and key learnings have been identified. They are covered in Chapter 5, as inspiration for the policy recommendations and to support the feasibility of the proposed policy recommendations.

This action group has been closed for now as it reached its goal and realised its deliverables:

3.1.7 Education and building awareness

Objectives:

This action group works on education and build awareness among all relevant stakeholders (patients, HCPs and hospitals, government, general public, companies, health insurance funds, doctors' and medical associations, etc.) on the importance of (structured and high quality) data collection.



Supportive
Education and building awareness

RWD4BE action group

Scope:

- Educate about what exists: to not reinvent the wheel, we should educate on what is there already and what is not.
- Maturity on education/awareness
- Education of patients, HCPs and hospitals, government, general public, industry, health insurance funds, doctors' associations, etc.
- Educate citizens: they should be made aware and educated on how data is collected, what the value of their (anonymous) data is for the community (cfr. giving blood, organ donorships) and for themselves
- RWE inspires awareness in hospitals: communicate about RWE successful pilot cases, not from the technical point of view, but on the value/insights for society
- Create awareness towards software providers - their responsibility is key: EHR software vendors should be encouraged to build a good and solid foundation in their EHR, so you can leverage data-driven healthcare from the EHR by-design. Via open discussions, on customer request or even enforced by law.


Critical interdependencies with other projects:
Action group on Playbook/e-survey: e-survey to be used to check how hospitals communicate on this topic

Project objectives and deliverables:

- Explain ultimate importance (what's in it for me) for all stakeholders
- Promote more openness to (privacy conserving) sharing of data
- Educate all involved stakeholders: (patients, HCPs and hospitals, government, general public, industry, health insurance funds, doctors' associations, etc.)
- Obtain a comprehensive view of initiatives/organisations involved in the communication towards each stakeholder in BE
- Communication action plan with multi-stakeholder focus

KPI's:

- Have an inventory
- List of stakeholders to be targeted
- Education & awareness building plan (to whom, what, how)
- Measuring efforts (e.g. available information, dissemination strategies, levels of co-creation, ...)



Results and objectives:

An overview has been made of all organisations and initiatives in Belgium that are involved in the education and communication towards the different stakeholders. An education and awareness plan is being built based on the identified missing gaps. In the course of 2024, a series will be developed together with the TV channel Kanaal Z / Canal Z, on the importance of health data from the perspective of each stakeholder. A parallel press release will be developed to maximise the impact of the series.

3.1.8 Multi-stakeholder collaboration

Objective:

This action group worked on setting up a coalition-of-the-willing by reaching out to stakeholders to coordinate and align, communicate progress and successes, etc. This is an action group that will continue to liaise with all relevant stakeholders and with key contacts at existing and new data initiatives in Belgium.

Supportive
Multi-stakeholder collaboration

RWD4BE action group

Scope:


- Set up a coalition of the willing
- Reach out to key contacts per stakeholder or initiative to communicate and coordinate on the initiatives, progress, successes, etc.
- Interaction with federal and regional levels (primary care vs prevention)
- Include patient representatives, the industry, MedTech, etc.
- As a sounding board (incl. leads, alignment and communication)

Project objectives and deliverables:

- Define which stakeholders should be involved
- Representatives of different stakeholder groups are invited to the steering group and meetings and systematically report back to their stakeholder group.
- Set-up multi-stakeholder sounding board that can be used for multiple purposes

KPI's:

- 1-2 representatives of different stakeholder groups who have direct reporting link with their stakeholder group.
- Multi-stakeholder sounding board that can be used for multiple purposes



Results and objectives:

Since the start of RWD4BE, many stakeholders have joined the initiative. This action group will continue to invite and engage with the various stakeholders to make sure all stakeholder groups and initiatives are aligned.



3.2 Governance and leadership of RWD4BE

From the start the RWD4BE initiative wanted to apply good project management practices and project governance to ensure progress and have balanced perspectives and decisions. To support a balanced approach, a core steering committee (steerco), under the leadership of Jo De Cock (NIHDI), consisting of representatives of the various stakeholder groups, has been put in place. The role of the core steerco is to keep oversight on the objectives and direction of the initiative, and also to monitor progress.

The composition of the core steering committee is as follows:

Name	Representing affiliation
Jo De Cock	NIHDI (Chairman)
Pedro Facon/Guillaume d'Ansembourg	NIHDI
Pascal Verdonck (UGent)/Frank Staelens (OLV Aalst)	BAHM
Nick Marly/Isabelle Huys (KUL)	Cabinet Min. of Health
Stefan Gijssels/Stefan Joris	Patient representatives
Sofie De Broe/Wannes Van Hoof	HDA/Sciensano
Stef Heylen	UZA, AZ Turnhout, ex-industry
Ann Van Gysel/Isabelle François	MEDVIA
Sylvie Ponchaut	BioWin

Next to the core steerco, an operational steering committee, consisting of the leads of each of the action groups, is put in place that meets monthly to keep oversight on the execution of the actions and align between the various action groups. The composition of the operational steerco can be found in the table below.

Name	Affiliation	Action group
Geert Smits	AZ Monica, BAHM	Education & awareness
Pascal Verdonck	UGent	Education & awareness
Bart Vannieuwenhuysse	JNJ Innovative Medicine	Interesting health data learning cases
Ingrid Maes / Geert Dewulf	Inovigate	Interesting health data learning cases; Data integration, standardisation & structuring; Promote multi-stakeholder collaboration
Frank Staelens / Mona Bové	OLV Aalst	Playbook, Governance & Legal
Pascal Coorevits	UGent	Data quality framework
Marc Van de Craen/Liz Renzaglia	MEDVIA	Pilot cases and examples (Prostate cancer)



4. Results from the e-survey

To explore the needs in the hospitals, an e-survey was launched. This e-survey was sent to all Belgian hospitals in the second half of 2023 (June to November). The e-survey was completed by 16 data managers from 13 different hospitals across Flanders and Wallonia. Several pain points were examined. The first questions covered the topic of communication around reuse of data in hospitals. Three questions were asked:

- Does the hospital communicate about data reuse to its stakeholders (such as doctors, patients, etc.)?
- Is communication done by hospital or at broader level (e.g. on a hospital network level)?
- What is missing to do the communication?

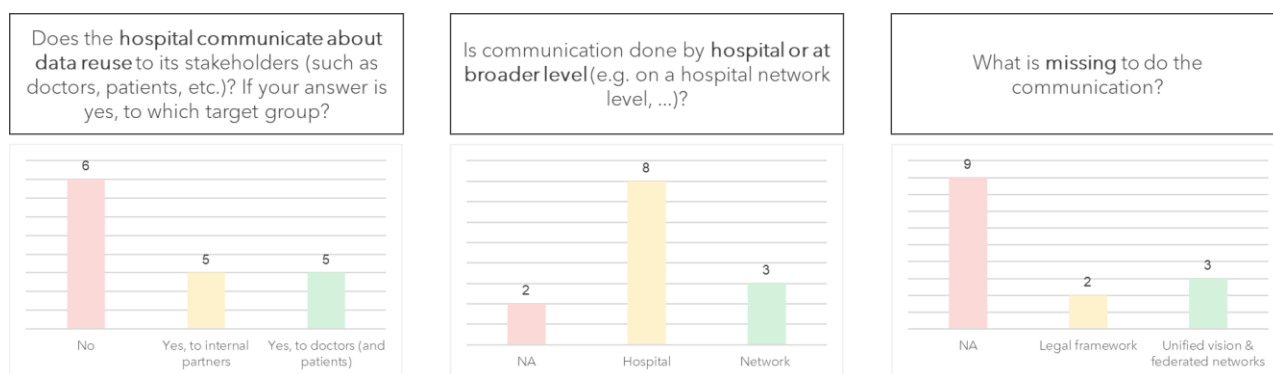


Figure 8: Outcome e-survey questions on communication (total of 16 respondents)

According to the e-survey results, the majority (10 out of 16 respondents) indicated that their hospital communicates around data reuse. This communication is done to both internal partners and doctors (and indirectly to the patients). The communication around data reuse is mainly done at hospital level. Going deeper into what is still missing in the communication, many respondents indicated that a clear vision and legal framework is often missing.

In addition to the questions on communication, the pain points on data reuse within hospitals were also assessed. The survey focused on locating the pain points within the following four different reuse applications and use cases:

- RWD reuse for benchmarking
- RWD reuse for prospective clinical studies
- RWD reuse for a commercial objective
- RWD request by government

Within each of these use cases, the hospitals were asked to evaluate themselves on five criteria linked to data reuse: data access and availability, data quality, governance structure, duration data response (turn-over time) and availability of qualified staff. There were three evaluation possibilities: is that data reuse criteria in that specific use case a major pain point (**high**), a point with still room for improvement (**medium**) or no pain point (**low**)? The results are shown in Figure 9.

Data access and availability is about having access to the right (structured and high quality) data to draw conclusions or to use it for other purposes. According to the 16 responders, this is a major pain point in hospitals when it comes to data for benchmarking and prospective clinical studies. Access to data for commercial objectives could be improved in some hospitals.

According to the hospitals, data quality (and thus the usability of data) is low when it comes to benchmarking or implementing clinical studies. For commercial purposes, data quality is acceptable, but has the potential to be further improved in the future.

When asked whether there is clear governance in place on the use of data, the majority of hospitals surveyed said they have a governance in place (such as an ethics committee, data access committee, ...etc.).

Hospitals indicated that the time (turn-over time) taken to get the right data from their systems is very long. They also indicated that this is a problem for all applications and needs to be addressed in the near future.



The lack of qualified staff (such as data managers) was already pointed out through various sources, and this also came up in the e-survey. Many hospitals mentioned that they have good people on board but that these people are overloaded and that the teams need reinforcement.

		Criteria				
		Data access & availability	Data quality	Governance	Duration data response (turn-over time)	Qualified staff available
Use cases	RWD reuse for benchmarking	High	High	Low	High	Medium
	RWD reuse for prospective clinical studies	High	High	Low	High	Medium
	RWD reuse for a commercial objective	Medium	Medium	Medium	High	Medium
	RWD request by government	Low	Low	Low	Medium	Medium

Figure 9: Outcome e-survey

The different action groups have performed a deeper analysis of these results. According to the hospitals, the biggest pain points are connected to each other. For instance, it takes a long time to acquire quality data from the hospital internal systems. The hospitals identify the data quality at the data entry point as the root cause of this long turn-over time. Low quality and unstructured data complicate and slow down the process of retrieving the data to reuse it for other applications. Addressing this issue requires data expertise (staff), which is often not present/limited today due to understaffing.

The hospitals score well on governance within the hospitals, presumably because most hospitals have an ethics and data access committee in place. This does, however, not mean that there are clear governance mechanisms present to promote interoperability and facilitate data reuse.



5. Best practices from other data initiatives

With the goal to leverage existing data initiatives and best practices both in Belgium and abroad, the action group ‘Interesting health data learning cases’ has been set up to provide a comprehensive overview of relevant initiatives related to health data (reuse). The listed data projects and initiatives have been systematically categorised into various segments such as registries, data spaces, federated networks, governmental initiatives, ... Subsequently, the initiatives were all assessed based on several parameters such as subject (governance, technology, roles and responsibilities), (multi)stakeholder involvement and funding model. The findings of this in-depth analysis are summarised in six key learnings that capture the relevant take-aways. These learnings play an important role for the development and implementation of an RWD ecosystem and have served as building blocks to shape the input towards the policy recommendations, listed in the next chapter.

- **Encourage patient engagement, based on transparency and education**

Many initiatives focus on the education of patients and the broader public such as the European Data Saves Lives, Understanding patient data project (UK)⁷, Sundhedsdata styrelsen (Danish)⁸, GO FAIR projects and the Belgian King Baudouin Foundation. These initiatives promote patient engagement, improve transparency, and encourage a mindset change. Projects like the 101 Genomes Foundation which was started by patient representatives, educate, and encourage patients to take part in RWD collection⁹. Also, the Patient Expert Center has a project on the use of RWD/RWE for patient organisations in collaboration with hospitals and companies. They co-design the best interactive models for data capture and use by type of disease, including the definition of what are patient relevant KPIs.

- **Involve health care professionals (HCPs) and incentivise structured and high-quality data collection**

Data of high quality is still missing in many cases today. Without high quality data, no conclusions can be made without requiring a large administrative burden and/or investment to improve the data quality. It all starts with the data input from HCPs. Therefore, HCPs should be involved in the design of a data infrastructure and be encouraged to deliver data of high quality. VIKZ (Flemish Institute for Quality of Care) stimulates quality of care and high-quality data collection and transparency on quality of care in Flanders. Projects such as the Actionable RWE Networks aim to lower the data burden of HCPs and hospitals by facilitating real-world data collection and the translation of real-world data to real-world evidence.

- **Develop governmental, multi-stakeholder and public-private partnerships to support high-impact changes**

Multi-stakeholder collaborations and support are essential for project scalability and sustainability. Governmental involvement and public-private partnerships are also crucial to realise high-impact changes. The Multiple Sclerosis Data Alliance is a world-wide data catalogue for Multiple Sclerosis that was the perfect example for setting up a valuable registry through multi-stakeholder engagement. Another source of inspiration is OSCAR, the Swedish clinical research ‘Virtual Public Register’, a successful public-private one-stop-shop RWD platform.

- **Promote FAIR data networks**

The principles of FAIR (findable, accessible, interoperable, reusable) data was defined by a consortium of scientists and organisations in 2016¹⁰. The Joint Action Towards the European Health Data Space

⁷ Understanding patient data, <https://understandingpatientdata.org.uk/>

⁸ Sundhedsdata - styrelsen, Borger, <https://sundhedsdatastyrelsen.dk/da/borger>

⁹ Patient expert center. *Toolkit*. <https://patientexpertcenter.be/toolkit/>

¹⁰ Wilkinson, M., Dumontier, M., Aalbersberg, I. *et al.* The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data* 3, 160018 (2016). <https://doi.org/10.1038/sdata.2016.18>

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(TEHDAS)¹¹, the European Health Data Space (EHDS)¹² and the French Health Data Hub¹³ are examples of data initiatives striving towards a FAIR data sharing framework by introducing common standards, rules, a governance model, ...

- **Create sustainable and scalable data platforms in hospital networks**

Hospital network organisations are key to share knowledge and best practices and to harmonise data sources to create sustainable and scalable data platforms and technologies. The Swiss Personalised Health Network (SPHN), a consortium of university hospitals open to all other Swiss hospitals and supported by Swiss government, is a good example of a strong network organisation building a data reuse infrastructure with common data models, federated networks and knowledge sharing¹⁴. Another good example is the effort that has been done in the Tuscany region in Italy, organised by the National Health Service. Data were collected and shared by disease by all hospitals to track progress on patient outcomes by becoming more transparent and systematic. This effort was done initially in the context of COVID19 on performance assessments, focussing on population health to define needs and inform healthcare system re-organisations¹⁵.

- **Develop a national legal framework on secondary use of health data**

Clear rules and a legal framework are needed to further implement the Belgian RWD framework. The European Union is creating guidelines, regulations and/or recommendations on data collection and reuse e.g. the EHDS, Acts on Data Governance, AI, GDPR, ... Finland is one of the first European countries that implemented a national legislation on secondary use of health data, facilitating the effective and safe processing of and access to health data.

- **Develop and harmonise technological infrastructures based on the 'enter data only once' principle**

Hospital data infrastructure should be adapted to realise the 'enter data only once' principle. This will lower the administrative burden of HCPs, reduce error probability and guarantee FAIR data collection. This hospital patient database of structured and high-quality data will allow a flawless data exchange with national and international registries. The Digital Europe program lists existing digital health solutions to identify which technological solutions are still missing, an initiative similar to the Belgian KCE NEED program.

¹¹ TEHDAS, <https://tehdas.eu/>

¹² European Health data space, <https://www.european-health-data-space.com/>

¹³ Health data hub, <https://www.health-data-hub.fr/>

¹⁴ Ormond K., Bavamian S., Becherer C., et al. (2024). What are the bottlenecks to health data sharing in Switzerland? An interview study. *Swiss Medical Weekly*. 154. 3538. 10.57187/s.3538.

¹⁵ Vainieri M., Ferrè F., D'Orio G., et al. (2022). il sistema di valutazione della performance dei sistemi sanitari regionali.

https://www.santannapisa.it/sites/default/files/inline-files/Report_Network_2022.pdf

RWD4BE- Real world data for better healthcare - Policy recommendations for the implementation of the RWD framework and strategy in Belgium - Multi-stakeholder initiative



6. Policy recommendations

The hospitals are progressing and preparing themselves through the work performed within the RWD4BE action groups. This is, however, not enough to make Belgium a top RWD reuse region. Complementary top-down actions and guidance are now needed to build a connected and sustainable ecosystem.

The policy recommendations are based on solutions to hurdles and challenges addressed within each action group. They represent conditions, which must be approved by policy, to enable further implementation of the RWD framework and get RWD reuse integrated in Belgium through a parallel top-down by government and policy, and bottom-up approach by hospitals, as illustrated in Figure 10.

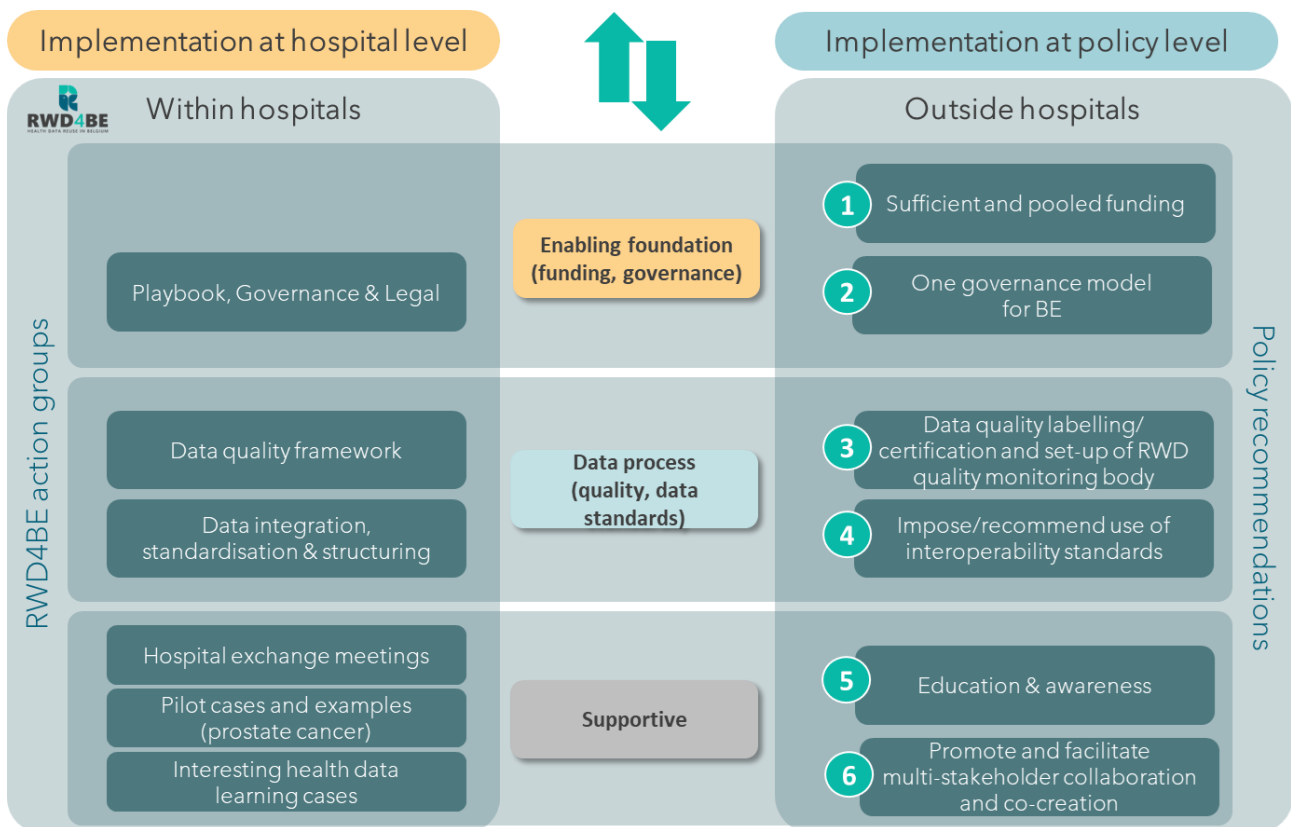


Figure 10: The top-down and bottom-up actions structured according to 3 levels: the enabling foundation, the data process steps and the supportive layer

Based on the insights and outcomes from the action groups, we identified the **necessary top-down actions** and translated them into **six policy recommendations**. These recommendations are structured across three layers: the enabling foundation, the data process steps and the supportive layer. These layers will collectively contribute to the creation of a Belgian health data reuse ecosystem, adhering to FAIR principles and answering the needs of the different Belgian stakeholders to implement the RWD reuse framework. The six recommendations to support the top-down implementation are:

- Enabling foundation -
 1. Sufficient and pooled funding
 2. One governance model for Belgium
- Data process steps -
 3. Data quality labelling/certification based on defined data quality dimensions and set-up of RWD quality monitoring body
 4. Impose/recommend use of interoperability standards
- Supportive layer -
 5. Education of HCPs and awareness building to all stakeholders
 6. Promote and facilitate multi-stakeholder collaboration and co-creation



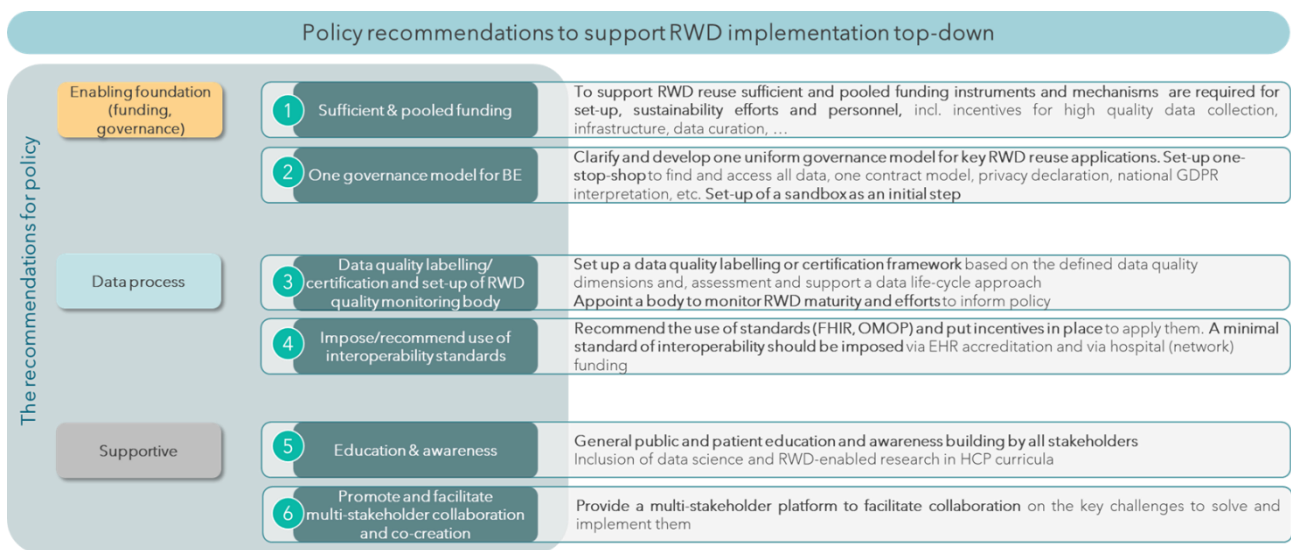


Figure 11: Policy recommendations

In the sections that follow, each recommendation is elaborated in more detail.

To illustrate the feasibility of the implementation of the proposed recommendations, they are complemented with reference cases from Belgium and abroad to learn from their best practices and provide guidance for the implementation. These best practices will save time and support quick implementation of the proposed recommendations.

For each recommendation, also the responsible stakeholder that needs to take action for implementation is mentioned.

6.1 Enabling foundation

Data reuse of real-world data in the context of better care and outcome-based agreements is high on the authorities' agenda. This is the reason the government is funding multiple data projects (a.o. FOD's Data capabilities)¹⁶. Stakeholders, however, raised major concerns due to the fact that many initiatives are overlapping, not all projects are considered highest priority nor are they aiming for generalised or generalisable and scalable solutions. Additionally, the total budget and governmental investment in RWD reuse is low compared to our neighbouring countries and funding for sustainability efforts and personnel is missing. Moreover, the current funding principles do not incentivise data quality, creating large differences between hospitals in the quality of collected data.

In the context of these considerations, the following two recommendations are proposed.

¹⁶ Federale overheidsdienst volksgezondheid veiligheid van de voedselketen en leefmilieu. *Oproep projecten « Data Capabilities »*. Health Belgium: <https://www.health.belgium.be/nl/oproep-projecten-data-capabilities>
RWD4BE- Real world data for better healthcare - Policy recommendations for the implementation of the RWD framework and strategy in Belgium - Multi-stakeholder initiative



Recommendation 1

1

Sufficient & pooled funding

Enabling foundation
(funding, governance)

Sufficient and pooled funding instruments and mechanisms for set-up and sustainability (to avoid fragmentation), incl. incentives for structured and high quality data collection, infrastructure, data curation, ... to support RWD reuse.



There are several funding needs that need to be included in the budget such as training for skilled data professionals (data managers and scientists for data curation, processing and analysis), hospital infrastructures (to collect, store and analyse data in a structured and interoperable manner), governance bodies (with clear assigned roles and responsibilities for governance, security and privacy) and harmonised, scalable and innovative projects to stimulate collaboration and innovation and to ensure interoperability and FAIR data.

The funding should cover needs on several levels:

- **Skilled professionals**
To ensure interoperability and FAIR data processing and analysis we need more skilled data professionals. There is a shortage of data managers and scientists responsible for data curation. Within the hospitals clear roles and responsibilities should be defined for these positions as well as for professionals responsible for data governance, security and privacy. Policy should provide clear guidance on what the standard for data skilled professionals should be.
- **Hospital data infrastructure**
Hospital data reuse will only be possible if hospitals invest in appropriate data infrastructure and analytical tools. This infrastructure is needed to collect (EHR) and store (data warehouses or lakes) data in a structured and interoperable manner. Funding should be structured as a positive incentive (reward mechanism) and allocated to hospitals that perform structured and high quality data collection, have control and validation procedures in place and perform monitoring and auditing of data quality. This includes completing missing data and making the data available in the appropriate formats for R&D, reimbursement, improvement of quality of care, among other purposes.
- **Data projects (e.g. FOD data capabilities project funding)**
As a clear first step before any project is funded, a clear data strategy and vision should be formulated. Every project that is started should fit into this strategy in order to work most efficiently, purposefully and effectively towards the predefined vision, ensuring that the available budget is used optimally. Inter-hospital project harmonisation and scaling should be encouraged to promote collaborations and innovations and avoid duplication.
Project funding decisions should depend on the scalability, roll-out and generalisation potential of the solution on a national level. Only projects with the main focus on contributing to developing a nationwide data-sharing infrastructure, should be funded. It should also depend on the accessibility of the resulting structured and high-quality data to both hospitals and researchers. Finally, it should have a measurable positive impact (baseline measurement and return on investment) on the Belgian healthcare system. These three criteria create a decision framework to decide which innovative data projects to fund and to prioritise and align them. An independent decision committee should be created to decide on the allocation of the budget, guaranteeing the best use of the available public project funding based on the decision framework developed.
Ideally, data projects are organised amongst hospitals and industrial partners, creating a multi-stakeholder supported data strategy. These projects should drive research to develop solutions to the main challenges associated with the implementation of data reuse programs, thereby demonstrating the full added value of data reuse.

Funding could come from the cost and time savings realised by the implementation of this framework, increasing care quality and efficiency by having data readily available. The implementation of the framework eliminates substantial hidden costs associated with a shortage of (structured and high quality) data, thereby realising a positive economic impact including lower burden of chronic illnesses, reduction of mortality rates due to inefficient and ineffective care, cost reduction related to non-suitable reimbursement strategies and overall improvement of quality of life. Also significant added value will be created, for example by enabling AI applications. It will be important to consider how these resources are (re)distributed in society (e.g. a correct valuation of data).






Responsible stakeholders for implementation: [authorities](#)



Reference cases on the amount of governmental funding needed

Governmental funding of data projects abroad

Health data initiatives in surrounding countries are mainly funded by the government. As illustrated in the table below, European countries are actively investing important amounts in initiatives that aim at facilitating and coordinating the secondary use of RWD.

Country	Project	Funding period	Amount
Germany 	Medical Informatics Initiative	2016-22	€ 180M
	Hospital Future Act (KHZG)	2020-23	€ 4.3Bn
Switzerland 	Swiss Personalised Health Network	2017-20	CHF 68M
		2021-24	CHF 66.9m
France 	Health Data Hub	2020-23	€ 36M € 40M
UK 	Health Data Research	2017-22	€ 50M
NL 	Health-Research Initiative PHT (Personal Health Train)	2021-26	€ 69M

Governmental funding of data projects in Belgium

Belgium	Data Capabilities	2023	€ 20M
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The objective of the FOD Data Capabilities call and funding is to foster collaborations among hospitals by funding inter-hospital health data reuse projects. In 2023, a budget of € 20M was allocated to further develop hospital 'data capabilities'. This budget was distributed among 15 hospitals. The funded projects, however, showed a lot of duplication and overlapping, thereby missing valuable opportunities for maximising the further development of 'data capabilities' in the respective hospital networks.



Recommendation 2

2

One governance model for Belgium

Enabling foundation
(funding, governance)

Clarify and develop one uniform governance model for key RWD reuse applications. Set-up one-stop-shop to find and access all data, one contract model, privacy declaration, national GDPR interpretation, etc. Set-up of a sandbox as an initial step.

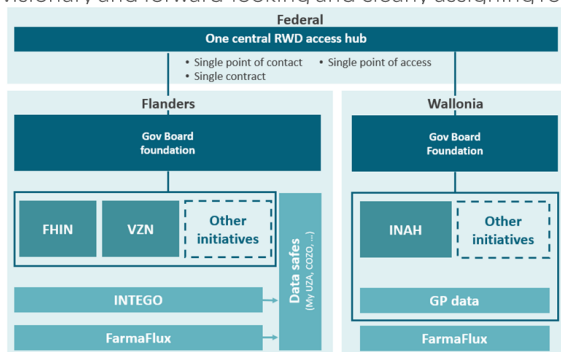


RWD reuse serves different reuse applications and purposes. For instance, the use of RWD to evaluate therapeutic treatments differs from its use for evidence generation for reimbursement or scientific research. It is crucial to align these priorities and provide clear top-down guidance to clarify, update and monitor them effectively. The development of one clear and uniform legal and governance model (nation wide) for prioritised RWD reuse applications is a key success factor. A one-stop-shop, at hospital network level, should be created with a single point of contact for data access, uniform contract templates and a clear privacy declaration for all. To freely test the success of this one-stop-shop approach, the set-up of a sandbox could be a good initial step.

There is a lot of confusion today around data ownership (patient, doctor, government). This should be clarified in an interpretation guideline for RWD use cases. This guideline is especially important in light of the coming EHDS regulation implementation.

The uniform governance template for RWD reuse could be adjusted every 5 years, based on input from a multi-stakeholder composed panel, comparable to the Sciensano multi-stakeholder panel.

A first 'to be' governance model for the secondary use of data is proposed in the figure below. It should be noted, however, that this model mostly focuses on existing initiatives and entities. The 'to be' governance model should be visionary and forward-looking and clearly assigning roles and responsibilities.



Patient data can be both governmental and medical. It should be clearly stated which connected governance bodies are for all data streams. Medical data originates from various sources, including first (GPs and pharmacy) and second line (HCPs) care and from the patients themselves through patient surveys or digital biomarkers. Data sourced from first line care can be governed through organisation bodies as FarmaFlux and INTEGO. Hospital-supported initiatives, such as the Walloon INAH and the Flemish FHIN and VZN, could be responsible for the governance of hospital data.

A central coordination and governance board should unify these governance structures and ensure that a common strategy is developed. On a federal level, we should have a single point of contact, a contract and a single point of access for all data requests coming from both public or private players. We need to collaborate and build one "federal central RWD access hub" to build a strong RWD reuse governance model for Belgium. In the next phase, additional data points could be added such as databases from wearables, implants, government, etc.

We should start small with a pilot use case and from there start to build a broader set of use cases, developing the governance model for each of these use cases. Clear top-down guidance is required to set use case priorities. The strategic goals must be defined and put on a timeline to prioritise our needs accordingly.

Hospitals should focus on RWD that supports the needs, experiences and outcomes from the patient perspective, rather than prioritising performance-based parameters.

Responsible stakeholders for implementation: authorities



Reference cases on collaborative data projects:

Swiss Personalised Health Network (SPHN)

The SPHN is an initiative from the Swiss government aiming to enable and facilitate health data reuse. A single budget has been allocated to the SPHN initiative (instead of budgets per project or per hospital) to build infrastructures within and between the hospitals for data reuse. The Swiss university hospitals are responsible for the implementation of this data reuse ecosystem in a collaborative and harmonised way. Some of the key achievements:

- The hospitals have agreed on international data standards and on including the semantic meaning of the data to facilitate collaborations and multi-modal data usage
- Implementation, education and trust building is being driven by use cases at different levels
- Development of a federated network for secure data sharing: the SPHN Semantic Interoperability Framework
- Defragmentation of health software within each hospital by gathering all tools on one platform for smoother governance and a 'self-service' for researchers

INAH 2.0

This project aims at developing a federated network for data reuse, allowing secure and ethical access to health data for scientific and statistical research. Currently the network spans across three hospitals. Through the help of use cases in different domains they are striving towards the industrialisation of the platform.

6.2 Data process steps

Effective data reuse is based on accessible and high-quality data. Hospitals and HCPs should be incentivised to develop an appropriate data strategy and infrastructure to collect and give controlled access to high quality, structured, interoperable and future-proof data. Efficiency in data collection and curation can be increased by applying the 'enter only once' principle and maximising automated data harvesting using structured fields and quality checks at data entry.

Based on this aim, the following two recommendations are made.



Recommendation 3

3

Data quality labelling/certification and set-up of RWD quality monitoring body

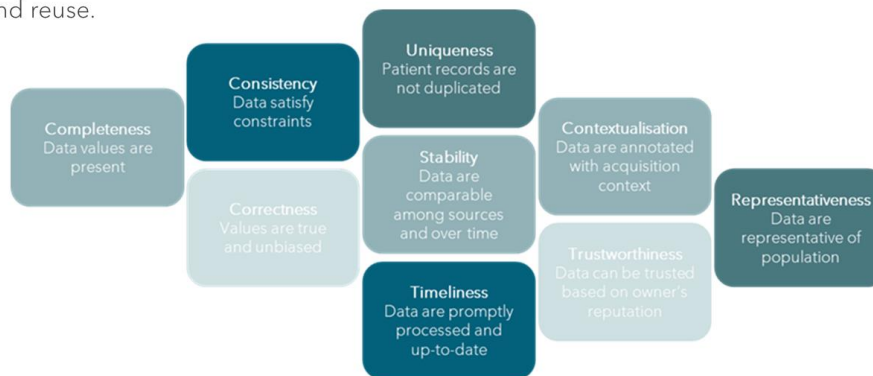
Data process
(quality, data
standards)

Set up a data quality labelling / certification framework based on the defined data quality dimensions and, assessment and support a data life-cycle approach.

Appoint a body to monitor RWD maturity and efforts to inform policy



The set-up of a data quality labelling or certification framework is needed based on data quality dimensions (completeness, consistency, correctness, uniqueness, stability, timeliness, contextualisation, trustworthiness and representativeness) and data quality assessment. To support a data life-cycle approach, data quality should be monitored along the entire data flow, starting from data collection, submission, processing and analysing till data dissemination. Data quality assessments should be ensured by a multi-disciplinary team of clinicians and data scientists, which are currently not sufficiently available in hospitals due to a lack of funding, health care providers and IT-staff. If appropriate funding is provided, high quality data, on all quality dimensions, should be available for collection and reuse.



Responsible stakeholders for implementation: authorities, hospitals and HCPs

A body should be appointed to monitor RWD maturity and efforts to inform policy. Continuous assessments and improvements will be needed to create and maintain an integrated RWD ecosystem that is both innovative and sustainable. An RWD implementation maturity assessment could measure the RWD maturity and its evolution within Belgian hospitals. This knowledge can be applied to draw and update health data policy and measures for Belgium.

Within the RWD4BE initiative an e-survey has been organised to probe the current RWD maturity at hospitals. The results have been used to fuel the development of the playbook to support hospitals in local RWD implementation. This effort could be repeated every year to monitor progress and take specific actions to remediate and/or further evolve.

Responsible stakeholders for implementation: authorities

Reference case on (data) maturity within organisations:

Data maturity assessment tool

A data maturity assessment tool indicates the typical stages organisations go through to achieve a 'data-driven culture' and provides a method to measure the data maturity within an organisation. It assesses factors like quality, governance, architecture, analytics and security to identify the strengths and weaknesses.



Recommendation 4

4

Impose/recommend use of interoperability standards

Data process
(quality, data
standards)

Recommend the use of standards (FHIR, OMOP) and put incentives in place to apply them. A minimal standard of interoperability should be imposed via EHR accreditation and via hospital (network) funding



Interoperable and harmonised data are essential to ensure data comparability and exchange. A minimal standard of interoperability should be imposed via EPD accreditation and via hospital (network) funding. To create this data harmonisation, authorities should decide which data standards have to be used (in line with EU and the EU TEHDAS) for which purpose. To ensure one national data standard, top-down guidance is needed to prevent multiple data initiatives creating a range of different data standards and models.

Currently, three standards are commonly used: OpenEHR, FHIR and OMOP. OpenEHR is meant to store data in a standardised way in EHR's (primary use). FHIR is an exchange standard for primary use. OMOP is a "data storage" standard that facilitates analyses across different data sets, hospitals and even countries. Both FHIR and OMOP can be positioned as complementary standards.

There is a difference if we look at first line data. In Belgium we have no first line data in OMOP, which limits participation in international research, DARWIN and other international initiatives. Interoperable and harmonised data are essential to ensure data comparability and enable exchange with other countries. These first line data are crucial for public health management. In the neighbouring countries large first line data sets are available for example: IPCI in The Netherlands, SIDIAP in Catalonia, CPRD and THIN in the UK, etc. The Intego data set could be a good starting point for Belgium.

Responsible stakeholders for implementation: authorities

Reference case using the OpenEHR standard:

The universal Catalan healthcare model

In Catalonia, the SISCAT (Integrated Public Healthcare System of Catalonia) is building the local Clinical Data Repository (CDR) based on the OpenEHR international standard, setting a new benchmark in healthcare data standardisation and accessibility. They will start testing the technology by uploading over 146 million vaccination records, previously in CDA format, now archetyped in OpenEHR. SISCAT integrates all healthcare networks, consisting of over 600 health organisations, into one single system. € 40M will be invested to develop a new model of information systems.

6.3 Supportive layer

Effective communication and collaboration are key for building trust among the public, empowering stakeholders to work together and harmonising the needs of all parties involved. These elements are crucial for facilitating high quality data collection and promoting a sustainable RWD reuse framework.



Recommendation 5

5

Education of HCPs and awareness building to all stakeholders

Supportive

General public and patient education and awareness building by all stakeholders
Inclusion of data science and RWD-enabled research in HCP curricula



Communication strategies should be developed to reach out to and inform all parties about the importance of use and reuse of medical data and to build trust between all involved stakeholders. Patients should be informed about what is happening with their data and the importance of medical data reuse. They should be made aware of the importance of medical data reuse for society, for advancing science, for improving care, and for supporting other patients, ultimately leading to the improvement of the Belgian healthcare system as a whole. Engaging with patients and building trust is crucial, not only for patients but for all other relevant stakeholders. We need to demonstrate that the data are used responsibly, solely with the purpose to enhance the healthcare system and provide better care for patients.

Responsible stakeholders for implementation: authorities, patient representatives organisations, hospitals and HCPs, researchers and industry

Data science, RWD-enabled research and care quality assessment should be included in HCP curricula. Digital health awareness of HCPs should start early on in the education to ensure an appropriate level of digital data literacy. The importance of structured and high quality data and its reuse should already be made clear during the HCP training. Likewise, education needs to be in place to train data managers and data scientists with the expertise required to ensure and oversee the collection and analysis of structured and high quality data within hospitals to solve the current shortage in the market.

Responsible stakeholders for implementation of RWD in HCP curricula and data manager/scientist education: academia

Reference cases on educating the public:

Data Saves Lives

Data Saves Lives is a multi-stakeholder initiative led by the European Patients' Forum (EPF) and the European Institute for Innovation through Health Data (iHD). Through a web portal, they share information and best practice examples to broaden awareness among patients and the public about the significance and use of health data, fostering multi-stakeholder dialogue on responsible use across Europe. All content is reviewed by an independent editorial board and user group. The initiative is funded by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and EIT Health as an 'unrestricted educational grant' (they have no control over the content).

Education Charter Sciensano

Sciensano created an "Education Charter" on health data in Belgium¹⁷. In particular, this document specifies which data are health data, where it is used and by whom, how its safety is managed and how citizens can be involved in the reuse of health data. This information is accompanied with 2 use cases to give a better idea on the importance of data reuse and what this would mean in practice.

¹⁷ Sciensano, Healthy Data, 2023, <https://www.sciensano.be/en/biblio/tehdas-healthy-data>
RWD4BE- Real world data for better healthcare - Policy recommendations for the implementation of the RWD framework and strategy in Belgium - Multi-stakeholder initiative



King Baudouin Foundation

The King Baudouin Foundation aims to contribute to the sustainable use of health data by promoting digital literacy, health competences and participation of citizens. In response to a survey on citizens' knowledge and confidence about the use and reuse of their health data, the foundation has published a paper: "Zorg voor je data/Prenez soin de vos données"¹⁸. This publication addresses the questions of the public regarding health data, its utilisation, associated risks, and the measures taken to safeguard its privacy.

Z - healthcare series

The Z-healthcare series, a collaboration between channel Z and RWD4BE, is being developed on the importance of health data from the perspective of each stakeholder. The episodes will cover diverse topics on the challenges and opportunities of secondary use of health data across the health continuum and its potential for innovations in the health sector. In parallel, a press release will be issued to reach a broader community and stimulate the social debate on this issue. The aim is to paint a positive and forward-looking picture on the secondary use of health data, to create a broad support base and to educate the public. The content of the 10 episodes is supported by all stakeholders in the integrated care sector (government, patients, hospitals and industry).

NEED (Needs Examination Evaluation & Dissemination)

This KCE project developed a 'NEED framework' to identify and measure unmet health-related needs in order to align healthcare innovation with these needs and communicate the insights to the various stakeholders (HCPs, policymakers, health insurance funds, industry, researchers, hospitals).

Reference case on digital health education:

A course on AI and digital health at the Faculty of Medicine at the UMONS and ULiège

Medical doctor Giovanni Briganti teaches a lecture on Artificial Intelligence (AI) and digital health in the 3rd bachelor year of Medicine at the University of Mons (UMONS) since 2022. This initiative is one of the efforts to integrate AI education in the curricula of HCPs and was initiated with the help of RMN (Reflexion Medical Network). Since 2023, this course is also given at the Faculty of Medicine of the University of Liège (ULiège).

¹⁸ King Baudouin foundation paper: "Zorg voor je data"; https://media.kbs-frb.be/nl/media/8912/2022_PUB_3832_Zorg%20voor%20je%20data
RWD4BE- Real world data for better healthcare - Policy recommendations for the implementation of the RWD framework and strategy in Belgium - Multi-stakeholder initiative




Recommendation 6

6
Promote multi-stakeholder collaboration and co-creation
Supportive

Provide a multi-stakeholder platform to facilitate collaboration on the key challenges to solve and implement them

Multi-stakeholder collaboration is needed at all levels, it is a joint responsibility to take action and to make it happen and work.
All stakeholder groups should be included to collaborate on solving the key challenges and implementing the solutions. Multi-stakeholder dialogue and engagement encourage exchange and the co-creation of solutions. By actively participating in joint action groups, stakeholders can collaborate in real-time, leveraging their collective expertise and resources to drive meaningful progress.

Responsible stakeholders: all



These recommendations are requested by the hospital sector and must be implemented by government and policymakers to put Belgium at the forefront of RWD reuse. Complementary actions within hospitals are required to make BE a top RWD reuse region:

- A governance model at the hospital network level must be established
- Hospitals are also accountable for supporting outcomes-based or value-based healthcare (instead of today's disease-centered care). Key to this is the establishment of a rewarding mechanism that supports output-driven behavior
- Set up well-structured data (via EPD) in the hospitals to extract for further analysis and reporting
- Hospitals are also accountable for establishing and supporting a data culture and mindset in which outcomes are compared and benchmarked between hospitals.

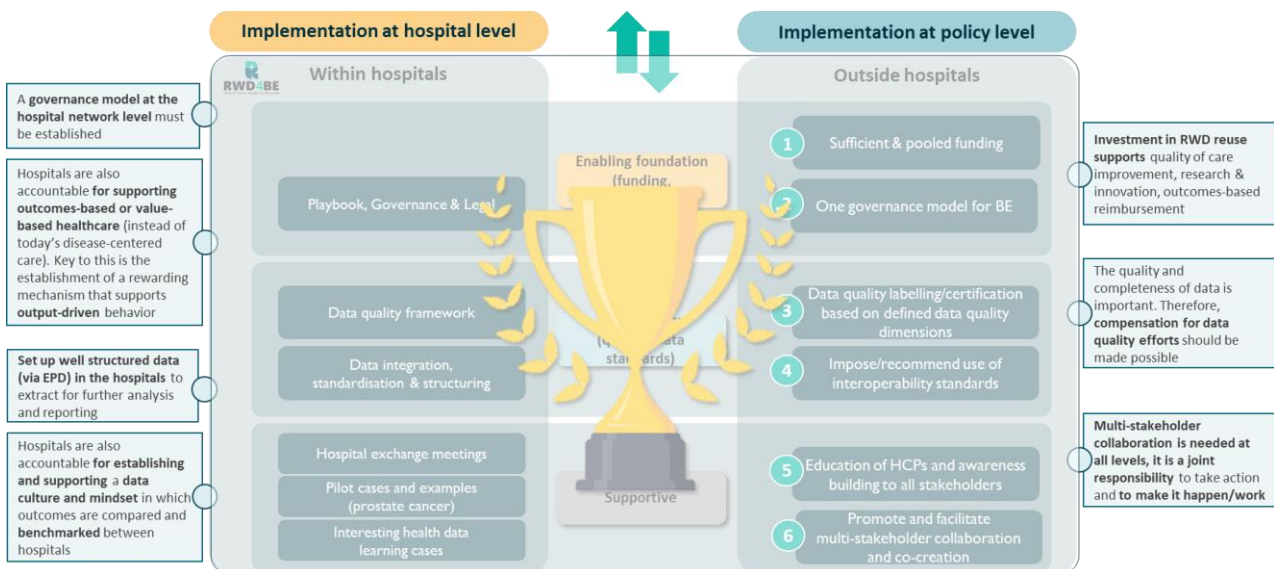


Figure 12: Complementary actions in- and outside hospitals to make Belgium a top RWD reuse region



6.4 Benefits for all stakeholders

The recommendations are developed in multi-stakeholder collaboration to establish a connected RWD ecosystem that benefits all stakeholders and takes interests and objectives of all into consideration.

But also, for each stakeholder group important benefits of RWD reuse could be realised. Below the benefits per stakeholder group are outlined.

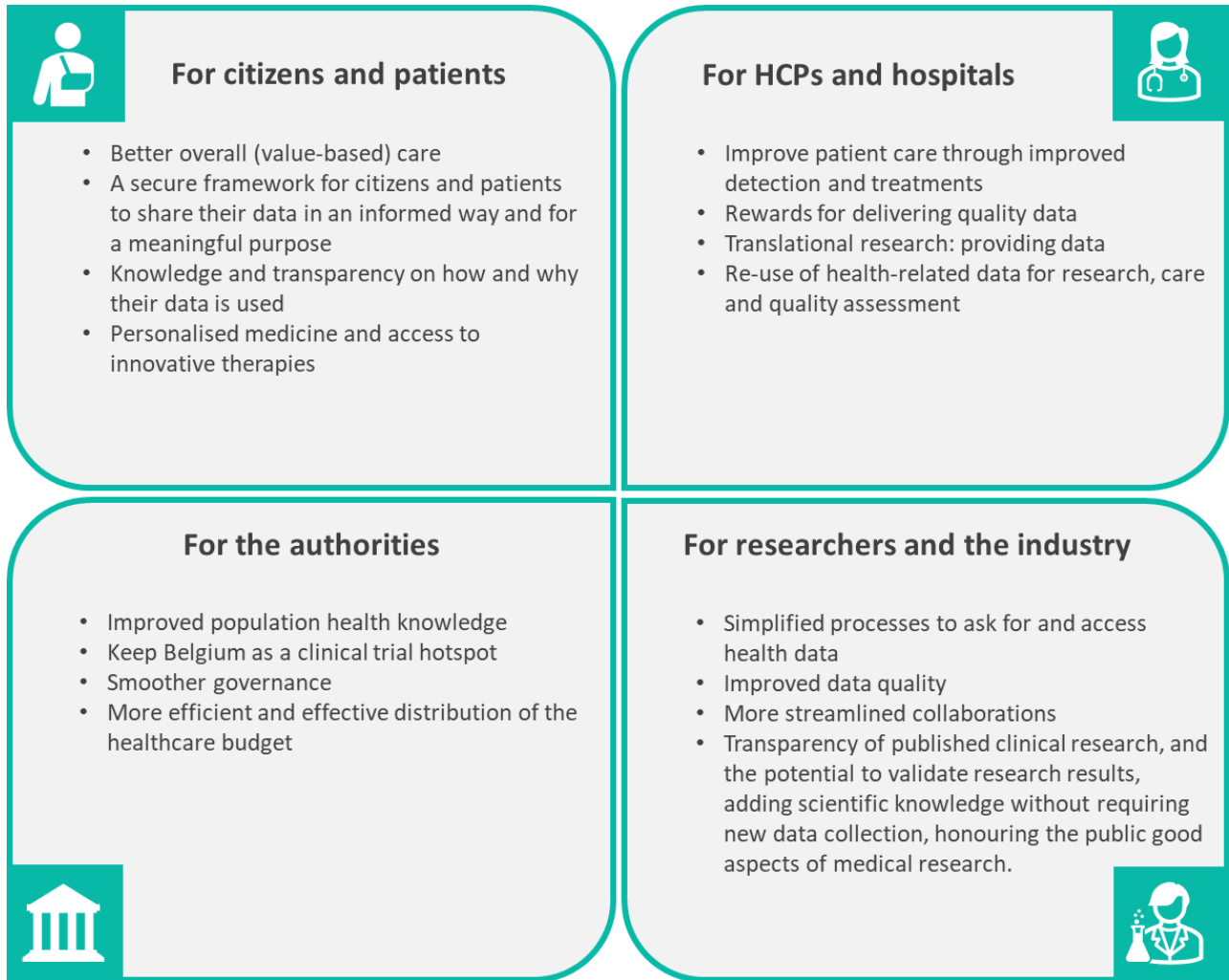


Figure 13: An overview of the benefits for all stakeholders involved



7. Conclusion

The RWD4BE initiative provides an answer to the implementation challenges of the RWD reuse framework. It aims to provide tools and methodologies and to share best practices and guidance for hospitals, to educate and raise awareness about RWD reuse to patients, general public and other stakeholders, and finally also to provide policy recommendations to policymakers.

To get RWD reuse integrated in BE, a parallel top-down and bottom-up approach is required. Government has to put the top-down actions in place now to complement the hospital bottom-up actions developed within the RWD4BE action groups, to be ready for RWD reuse.

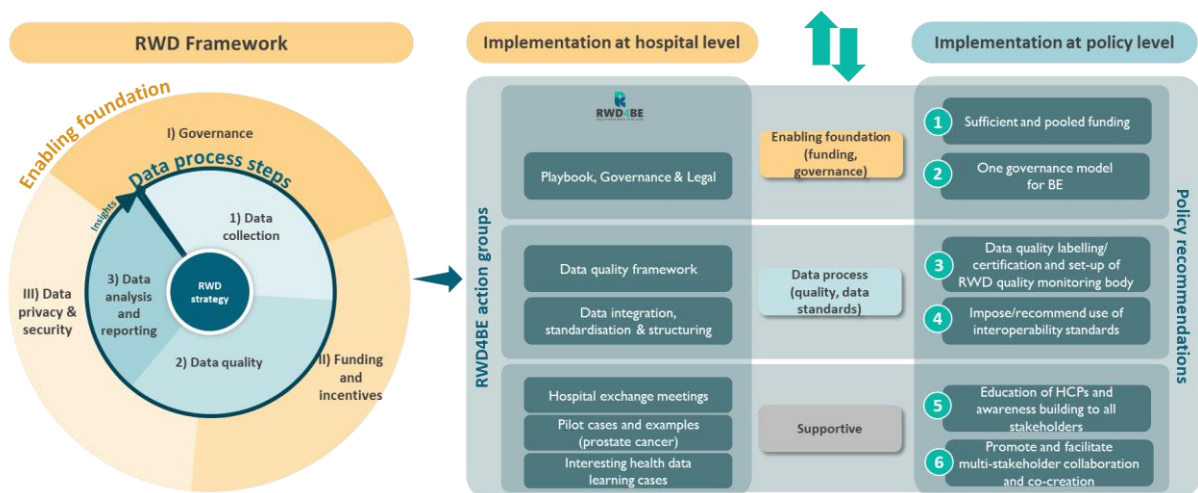


Figure 14: Overview RWD4BE - RWD framework, action portfolio, recommendations

From the RWD4BE initiative, six policy recommendations emerged to stimulate top-down actions. These policy recommendations were formulated based on the outcome of the RWD4BE action groups, research and interviews with various stakeholders. The six policy recommendations are structured across 3 layers, and have been put forward as the biggest demand from the sector towards policy:

Enabling foundation -

1. Sufficient and pooled funding
2. One governance model for Belgium

Data process steps -

3. Data quality labelling/ certification and set-up of RWD quality monitoring body
4. Impose/recommend use of interoperability standards

Supportive layer -

5. Education of HCPs and awareness building to all stakeholders
6. Promote and facilitate multi-stakeholder collaboration and co-creation

Implementing the recommendations will ensure that all stakeholders benefit from optimising RWD collection and data reuse, bringing Belgium one step closer to a learning healthcare system, prepared and sustainable for the future.



Outlook

Looking ahead a few key steps are crucial to make further progress. Firstly, top-down guidance from the EU will be needed. We are awaiting the upcoming core discussions at the EHDS and translation to the Belgian context.

Secondly, education efforts need to be further expanded to reach also the healthy individuals and not only the patients.

Third, hospitals should shift their focus towards the needs, experience, and outcomes from the patient perspective, rather than prioritising performance-based metrics.

Fourth, hospital data should be complemented with data from the first line. The RWD framework must broaden to include other datatypes, such as GP and pharmacy data. And finally on the longer term also environmental data, data on healthy individuals, long-term data, socio-psychological data, treatment regret information, etc. should be added for a more comprehensive view.



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List of abbreviations

Abbreviation	Definition
BAHM	Belgian Association of Hospital Managers
EHDS	European Health Data Space
EHR	Electronic Health Record
EU TEHDAS	Joint Action Towards the European Health Data Space
FAIR	Findable, Accessible, Interoperable, Reusable
HCP	Health care professional
HDA	Health Data Agency
IMA-AIM	Intermutualistisch Agentschap - l'Agence Intermutualiste
NIHDI	National Institute for Health and Disability Insurance
OB-MEA	Outcomes-based market entry agreements
RWD	Real-world data
RWE	Real-world evidence
SPHN	Swiss Personalised Health Network



About Inovigate

Healthcare is complex and constantly evolving. A successful business strategy means understanding and controlling numerous factors and stakeholders. Being able to see "the bigger picture" is crucial for this. Inovigate helps to look at the life science sector with a helicopter view. We combine research data and knowledge through years of experience in such a way that the missing pieces of the puzzle can be put together, ultimately creating the bigger picture.

Inovigate is a neutral, leading and reliable knowledge partner within the life science and healthcare sector. With over a decade of experience, we provide impartial guidance and expertise to stakeholders across the sector. From innovation to seamless implementation, we offer comprehensive solutions tailored to each client's needs. Our mission is to help clients bring life science innovations to market and navigate the complexities of the healthcare ecosystem with clarity and confidence. We make the difference through customised advice based on our profound management experience, sector expertise and network.

About the RWD4BE Consortium

The RWD4BE consortium consists of all participants that are present in the various action groups. They give input, create deliverables or share insights during the action group meetings. The RWD4BE consortium participants are:

