



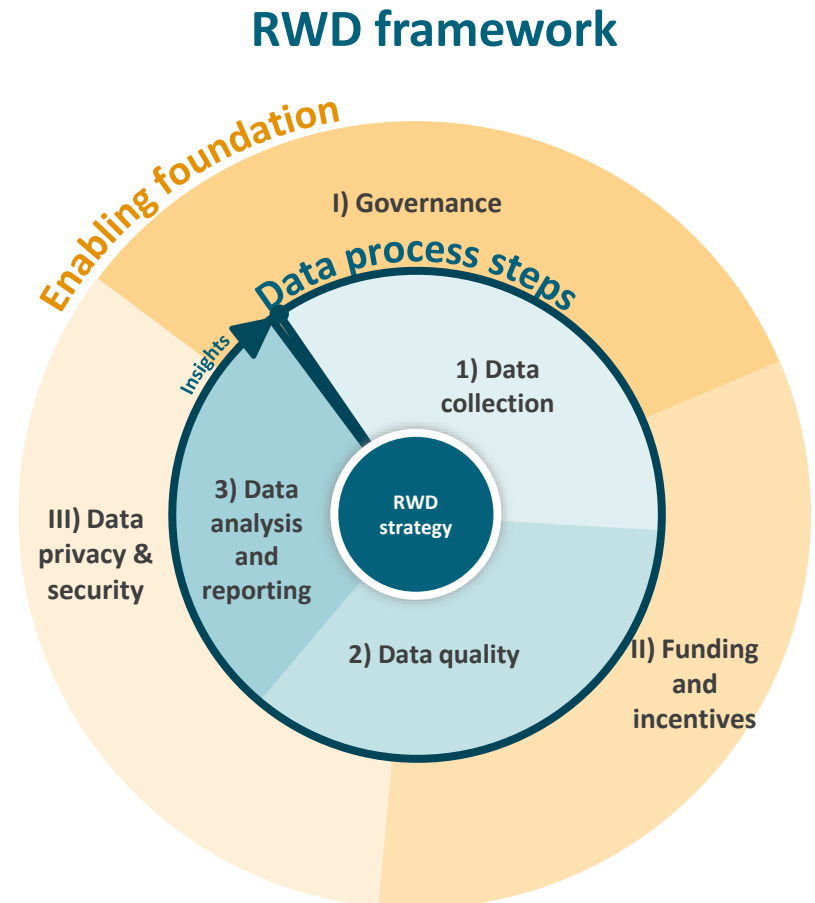
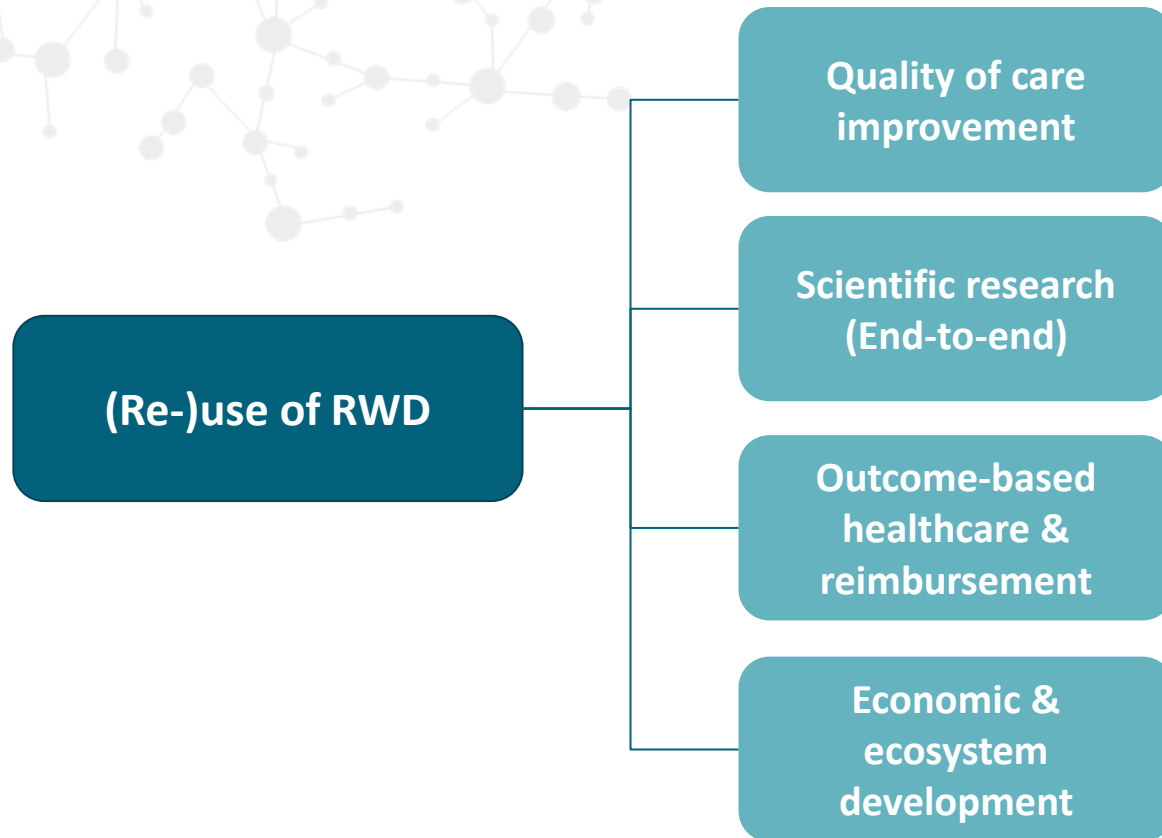
Session 2: Legal and ethical framework

The Belgian RWD (re)use framework

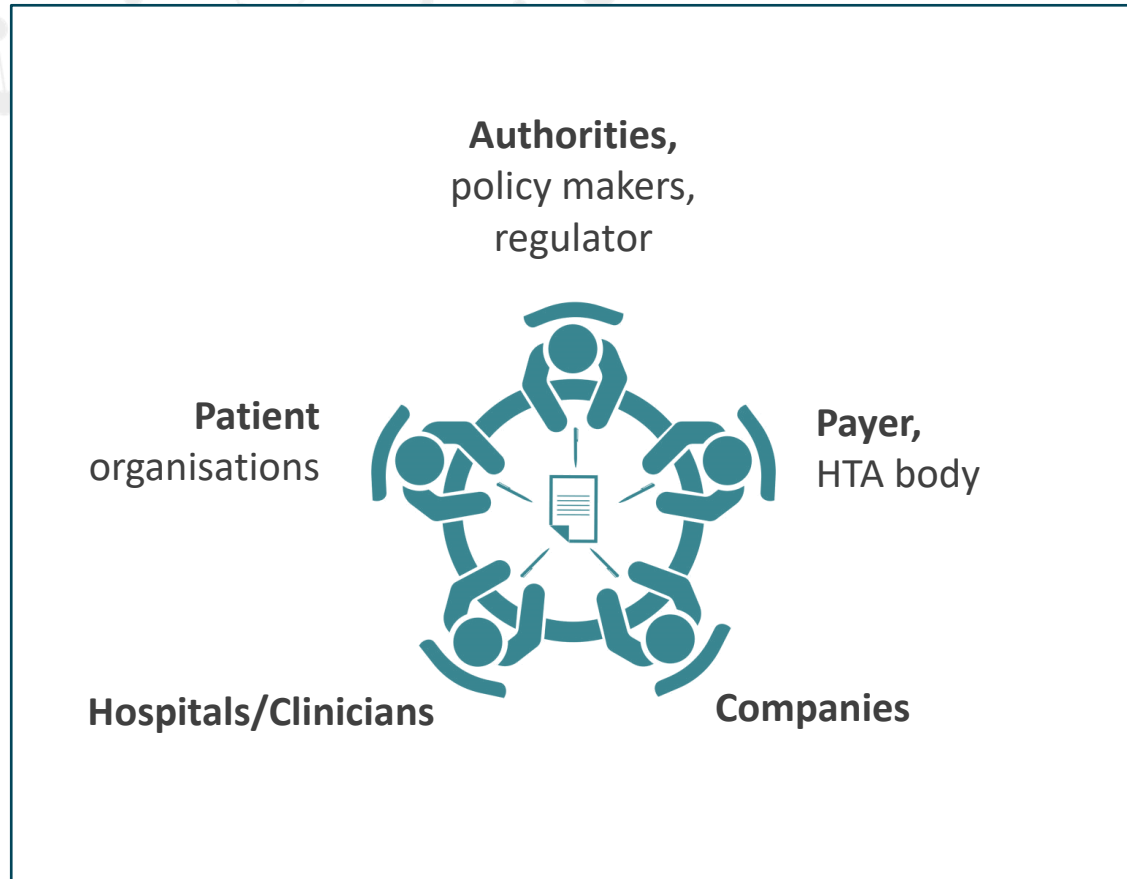
Governance, legal and ethical framework

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A proposal for a routine care data / RWD re-use framework for Belgium has been developed



Solutions have been developed in multi-stakeholder round tables



Data process steps

Enabling foundation

Roles and responsibilities

Proposed solutions per building block:

Solution:
<ul style="list-style-type: none"> Data sharing is a societal obligation and should be linked to medical practice, guidelines, NCPs and hospitals should be implemented and made responsible. A strong data strategy should be proposed at federal level and adopted by all hospitals. A national "Quality" program should be proposed describing what to do with data (which use), which data will be collected and how this data will be collected and handled.
RWD strategy & plan: <ul style="list-style-type: none"> Initiative should be taken by scientific community, expertise centers (based on research, clinical, operations), in early dialog. A broad set of outcomes data should be collected, incl. PROs, safety and side effects data Structured and up-to-date ERP systems and other data silos to support exchange of data Data exchange at hospital level, using OMOP or other interchangeable solution. Automated data harvesting from data sources, without major effort for NCPs. Data collected with harmonized definitions, common coding system (international codification standards) and common data entry procedures, in line with EMA RWD recommendations, subject to auditing.
1) Data collection: <ul style="list-style-type: none"> Maximize the amount and quality of data to draw meaningful conclusions. Investment in data quality is key: data cleaning, data curation, filling missing data, control/validation, quality monitoring, auditing.
2) Data quality: <ul style="list-style-type: none"> Analysis by hospitals, mostly for primary use. Academia/Third parties/industry/Payers may have access if request is part of agreed purposes. Alternative: Science as Data Prevent Authority is main processor of data including gathering data, parallel processing, analyzing and reporting (but require more resources). Or separate organizations.
3) Data analysis and reporting:

Proposed solutions per building block:

Solution:
<ul style="list-style-type: none"> Organized in 2 chambers, Information Safety committee should decide, and establish platform (TTP) should operationalize. Governance by consortium of domain experts (clinicians), government/payer, companies (represented by pharma/bi), patient representative. Relevant Consent & approval model (see our model). (Most of the patients have NO opinion in sharing their data for secondary use if properly explained by NCP).
I) Governance:
II) Funding and incentives: <ul style="list-style-type: none"> Authorities and industry should create a joint fund for registers, TTP, data analysis and quality control Strong model for data quality efforts to be compensated. Mandatory to make data available in appropriate format (e.g. cancer registry and Turbid)
III) Data privacy and security: <ul style="list-style-type: none"> Light consent model and legal framework to be adapted for data re-use in a GDPR conform way. Real-time data model is preferred, in a privacy-preserving infrastructure. Access to raw data, aggregated, synthetic data depending on the request.

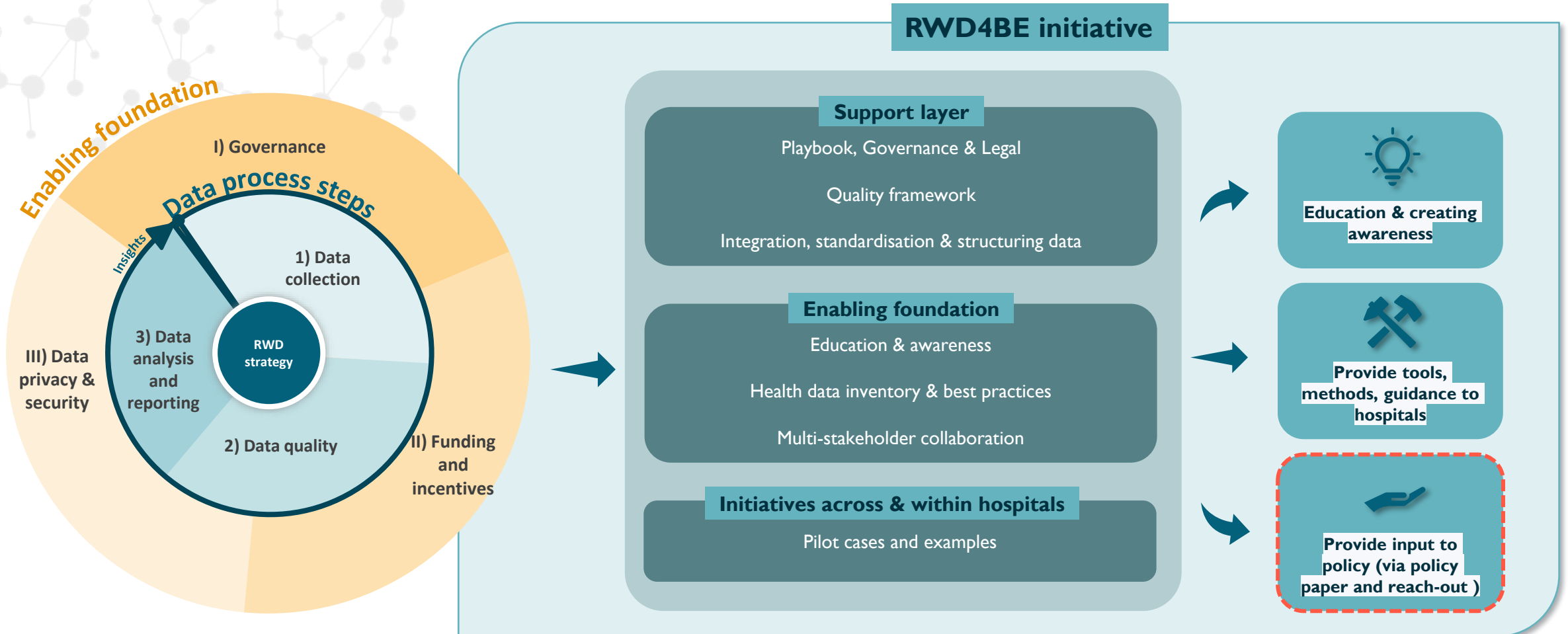
Proposed solutions per building block:

Roles:
RWD strategy & plan: <ul style="list-style-type: none"> Scientific community, authorities and industry should decide in early dialogue which data will be collected.
1) Data collection: <ul style="list-style-type: none"> Clinicians are obliged to collect data, and utilization of the patient to donate data Patients are obliged to donate data. Others (occupational health, social security, e-prescription, payer and sick funds, population information systems, ...)
2) Data quality: <ul style="list-style-type: none"> NCPs have a key role in data quality Patients can also ensure data quality for certain types of data. Authorities have to impose data quality standards and requirements.
3) Data analysis and reporting: <ul style="list-style-type: none"> Scenario: data aggregation and analysis (but more resources and expertise are allocated to this group) NCPs & Academia: data analysis to update guidelines and patient pathways. Companies: to provide RWE for products in conditional reimbursement.
I) Governance: <ul style="list-style-type: none"> Federal Authorities should organize governance. Multi-stakeholder consortium should operationalize.
II) Funding and incentives: <ul style="list-style-type: none"> A joint fund with government and industry for registers, to pay NCPs and the independent TTP for quality control. Federal authorities should impose the obligation to share quality data and make link to hospital financing.
III) Data privacy and security: <ul style="list-style-type: none"> Authorities: guarantee data privacy and security of data (via Data Protection Authority) And all other stakeholders are made responsible.

RWD4BE wants to implement the RWD re-use framework

RWD Framework for Belgium

Implementation in Belgium





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