Session 2:
Legal and ethical framework

Ingrid Maes, Inovigate

AGENTSCHAP INNOVEREN & ONDERNEMEN
Vlaanderen is ondernemen

The Belgian RWD (re)use framework

Governance, legal and ethical framework

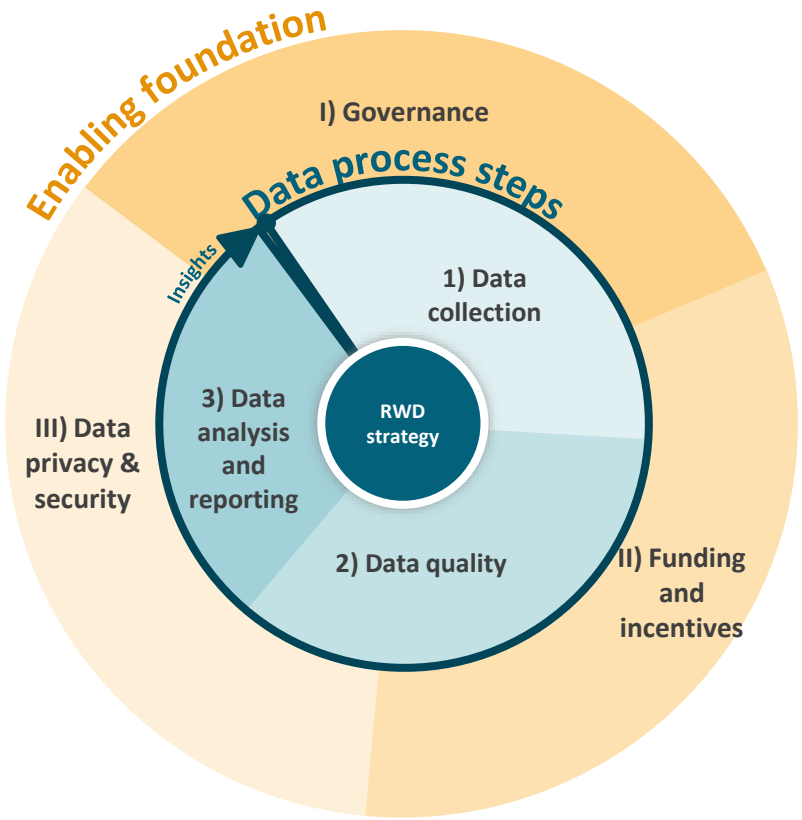
Ingrid Maes, Inovigate

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

(Re-)use of RWD

- Quality of care improvement
- Scientific research (End-to-end)
- Outcome-based healthcare & reimbursement
- Economic & ecosystem development

RWD framework



Solutions have been developed in multi-stakeholder round tables

Authorities,
policy makers,
regulator

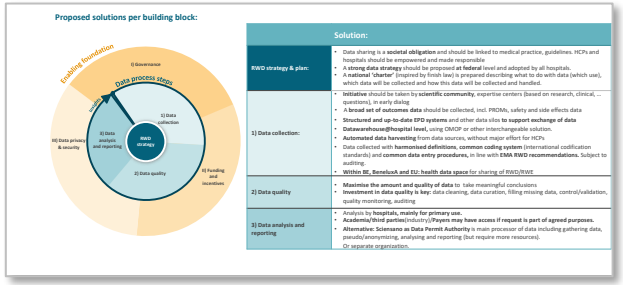
Patient
organisations

Payer,
HTA body

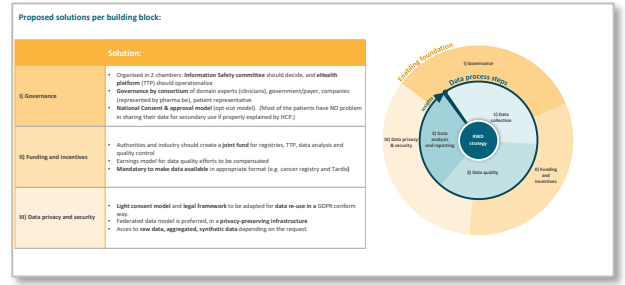
Hospitals/Clinicians

Companies

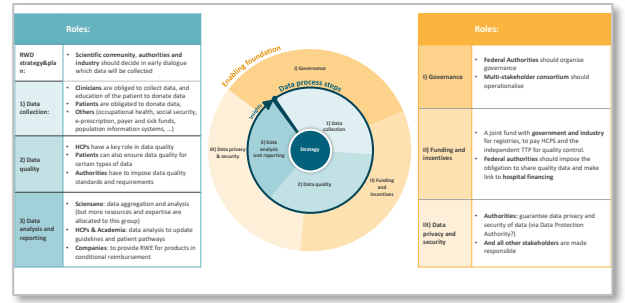
Data process steps



Enabling foundation

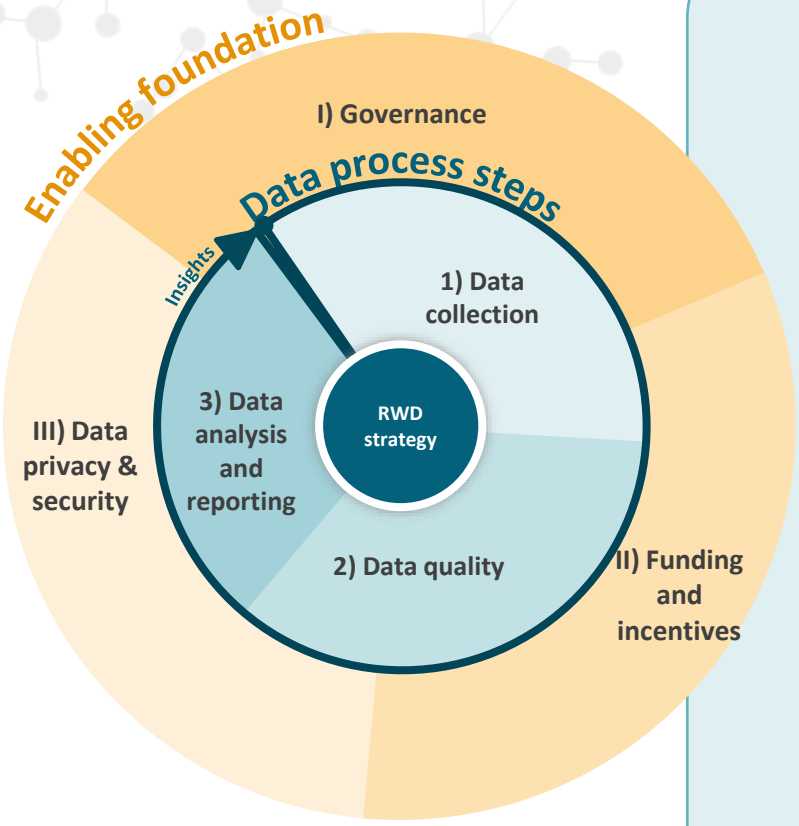


Roles and responsibilities



RWD4BE wants to implement the RWD re-use framework

RWD Framework for Belgium



Implementation in Belgium

RWD4BE initiative

Support layer

Playbook, Governance & Legal

Quality framework

Integration, standardisation & structuring data

Enabling foundation

Education & awareness

Health data inventory & best practices

Multi-stakeholder collaboration

Initiatives across & within hospitals

Pilot cases and examples

→ Education & creating awareness

→ Provide tools, methods, guidance to hospitals

→ Provide input to policy (via policy paper and reach-out)

Griet Verhenneman, PhD

Data Protection Officer UZ Leuven (resigning)

Professor Privacy Law University Ghent

Magali Feys

IP, IT and Data Protection Lawyer at AContrario.Law

Chief Strategist Ethical Data Use at Anonos