health RI

enabling data driven health

The European Health Data Space

Tom van den Heuvel,
Public Policy & Affairs Advisor

This round table

- Sharing health data in the Netherlands and it's obstacles
- National ambitions
- The European Health Data Space: what and why?
- The different chapters in the EHDS
  - Specific on chapter II
  - Specific on chapter IV
- Governance on secondary use of health data
- Control (zeggenschap) on health data
- Timeline (with reservations)
- How to stay updated and how to contribute
- Questions

Short introduction

Tom van den Heuvel

Background in Higher Education, public management and public policy

National infrastructure for secondary use of health data in the Netherlands

Actively involved in implementing the EHDS in the Netherlands
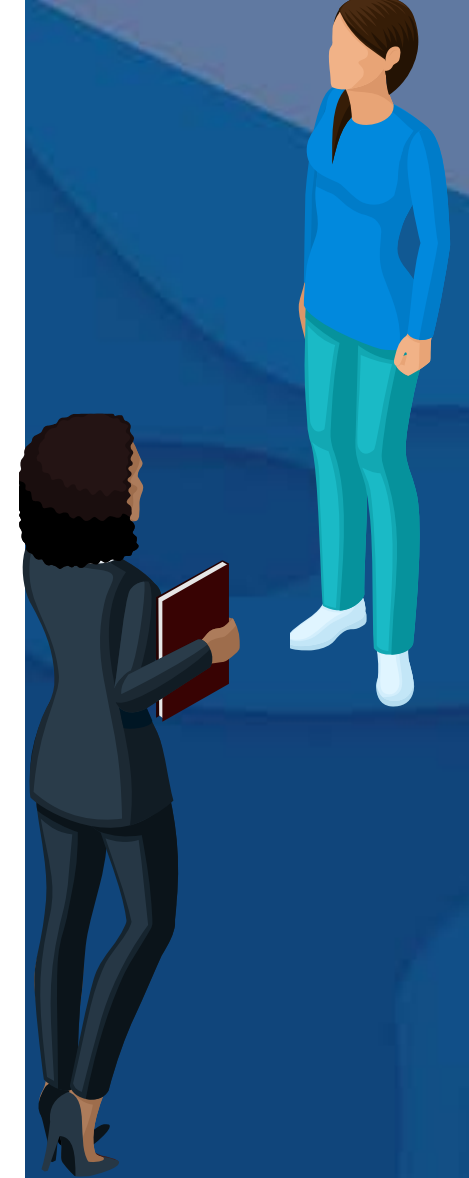
Sharing health data in the Netherlands

- Difference between sharing data for primary use and secondary use
  - Primary = sharing data for the purpose for which the data is collected (patient care, treatment planning etc)
  - Secondary = sharing data for research, innovation and policy development
- Examples of data: health record, medical data, imaging, omics etc etc.

Access to high quality health data contributes to better healthcare and innovation
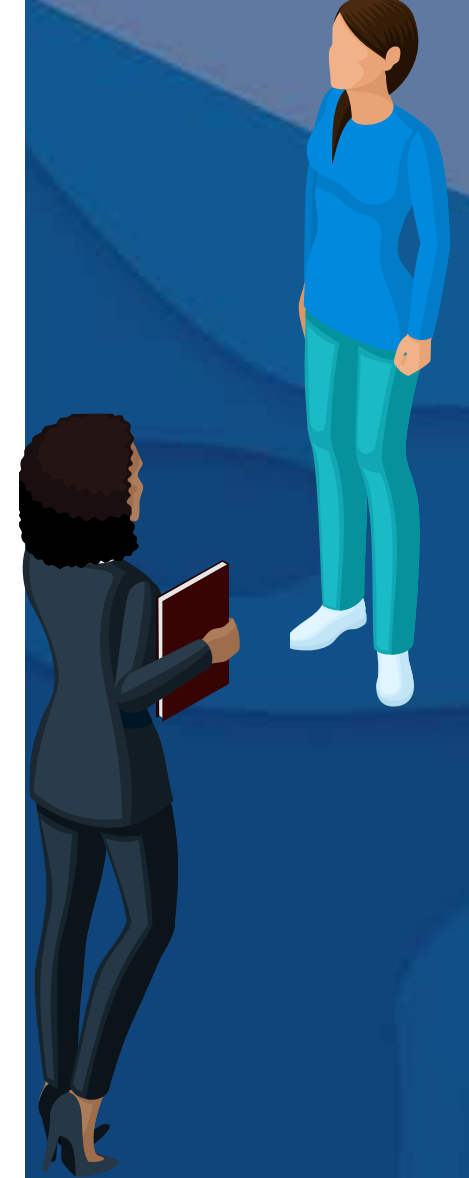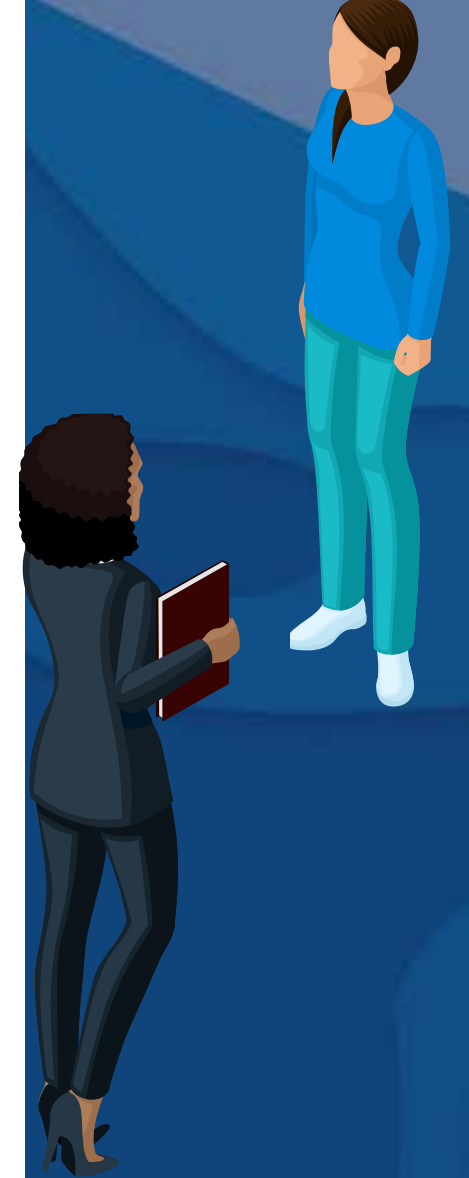
Sharing health data in the Netherlands

- New national legislation (july 2023) for primary use of health data: WEGIZ (Electronic Data Exchange in Health Care Act).

- No specific legislation for secondary use, but based on (interpretations of) the GDPR, Data Act, Data Governance Act, Medical Device Regulation and fragmented national laws (WGBO, WZL, WBO, WMO, WLZ, Wabvpz etc).

Sharing health data in the Netherlands

- In addition to a fragmented legal framework regarding secondary use, data isn't FAIR by default
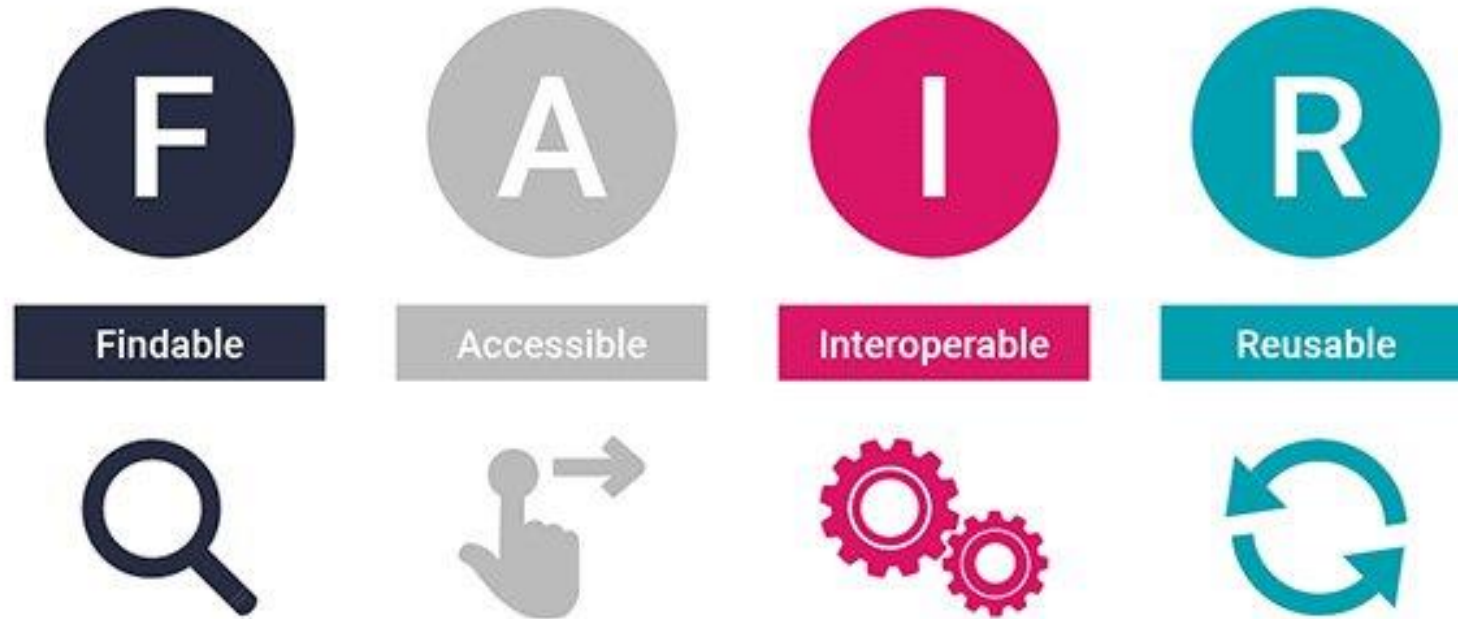
Re-use of health(care) data: integral approach of the obstacles to tackle

Common interest
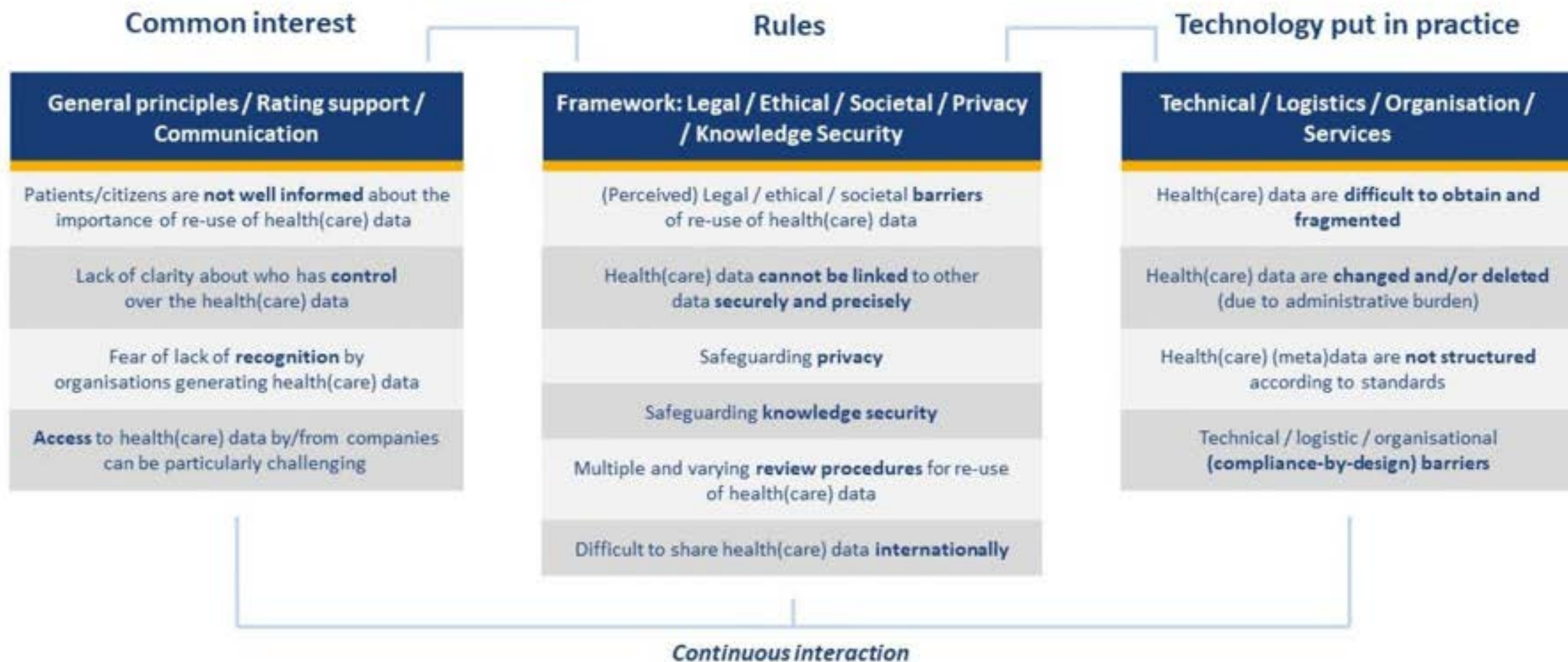
Rules

Technology put in practice

General principles / Rating support / Communication

Patients/citizens are **not well informed** about the importance of re-use of health(care) data

Lack of clarity about who has **control** over the health(care) data

Fear of lack of **recognition** by organisations generating health(care) data

Access to health(care) data by/from companies can be particularly challenging

Framework: Legal / Ethical / Societal / Privacy / Knowledge Security

(Perceived) Legal / ethical / societal **barriers** of re-use of health(care) data

Health(care) data **cannot be linked** to other data **securely and precisely**

Safeguarding **privacy**

Safeguarding **knowledge security**

Multiple and varying **review procedures** for re-use of health(care) data

Difficult to share health(care) data **internationally**

Technical / Logistics / Organisation / Services

Health(care) data are **difficult to obtain and fragmented**

Health(care) data are **changed and/or deleted** (due to administrative burden)

Health(care) (meta)data are **not structured** according to standards

Technical / logistic / organisational **(compliance-by-design) barriers**

Continuous interaction

health **RI**

National ambitions

- National vision and strategy on the healthcare information system[1]
  - Long term vision and strategy (2035) to cope with challenges in health care

- National vision and strategy on secondary use[2]
  - Short term vision and strategy (2028) to facilitate the use of anonymised or pseudonymised data for secondary purposes

1. https://open.overheid.nl/documenten/ronl-36667024db962a4962d0815e7cf2d3c9596d7255/pdf

2. https://open.overheid.nl/documenten/ronl-3f08b9fdcb894267976f5b7da1c90d450c7f5e60/pdf

European Health Data Space

European Data Strategy

- EU wants to be a leader in a data driven society

- Creating a single market for data will allow it to flow freely within the EU and across sectors (EC, 2023).

- Developing several European Data Spaces

- Health is the first data space
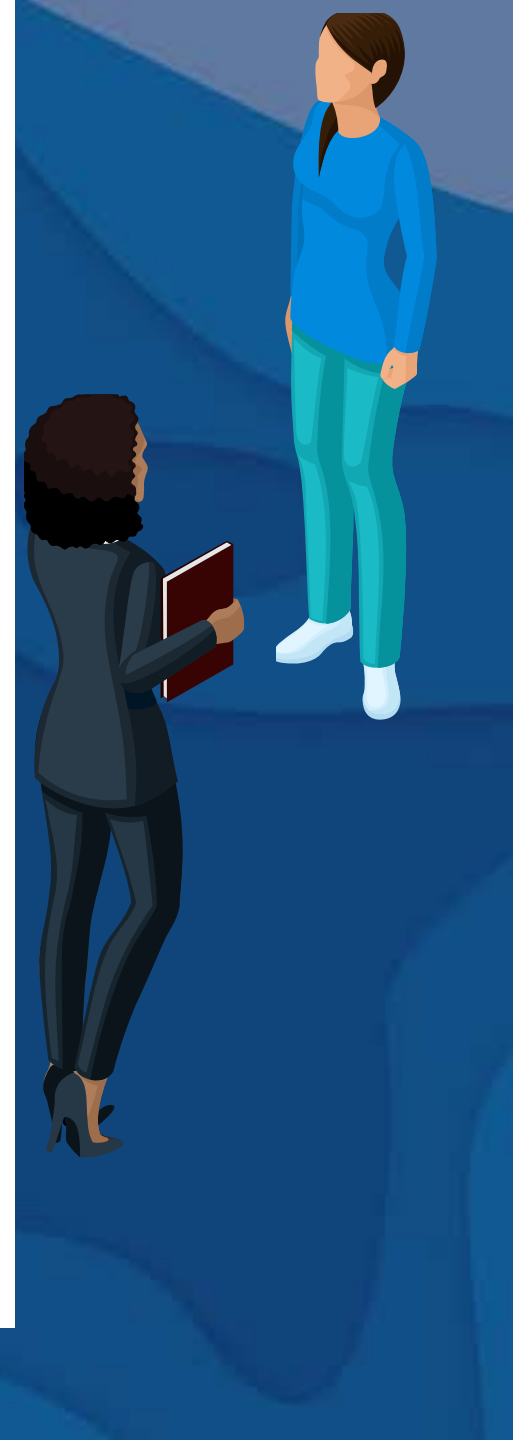
Common European data spaces

Rich pool of data (varying degree of accessibility)

Free flow of data across sectors and countries

Full respect of GDPR

Horizontal framework for data governance and data access

| Health | Industrial & Manufacturing | Agriculture | Finance | Mobility | Green Deal | Energy | Public Administration | Skills |

—Technical tools for data pooling and sharing
—Standards & interoperability (technical, semantic)

— Sectoral Data Governance (contracts, licenses, access rights, usage rights)
— IT capacity, including cloud storage, processing and services

https://ec.europa.eu/digital-single-market/en/policies/building-european-data-economy
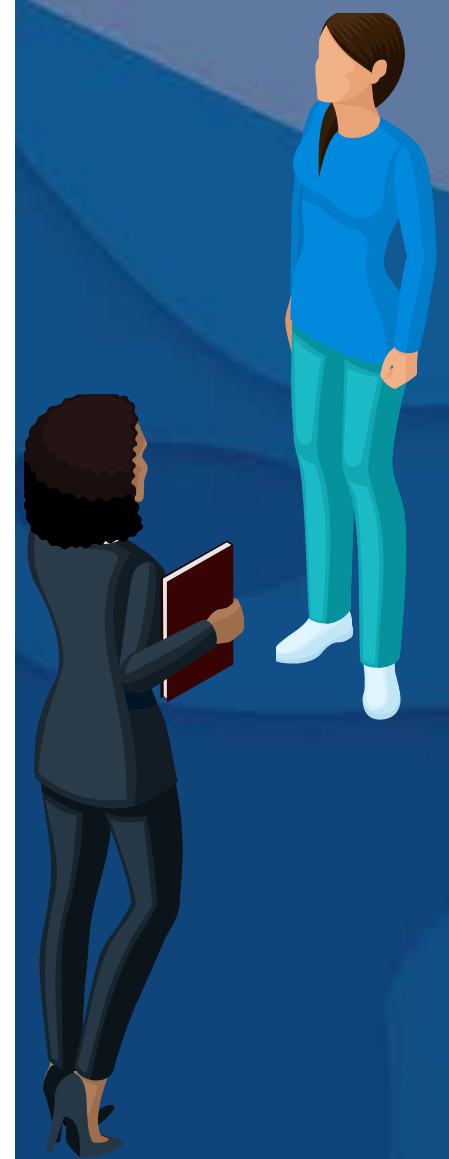
What is the European Health Data Space

- Proposal for a regulation for a European Health Data Space

- Additional to the GDPR, Data Act etc.

- Legal basis for cross-border access and exchange of electronic health data for primary and secondary purposes

Why a European Health Data Space

- Citizens will have more controle over health data recorded about them

- Increasing the quality of healthcare, both in the primary care and research and innovation

- Strengthen the European knowledge economy

- Regulating EHR's and wellness apps in the European Market

The topics in the EHDS

- Chapter I: Scope of application and definitions

- Chapter II: Primary use

- Chapter III: EHR'r and wellness apps

- Chapter IV: Secondary use

- Chapter V: International access to non-personal data

- Chapter VI: Collaboration in the EHDS council

- Chapter VII: Delegated acts

The topics in the EHDS

- Chapter I: Scope of application and definitions

- **Chapter II: Primary use**

- Chapter III: EHR'r and wellness apps

- Chapter IV: Secondary use

- Chapter V: International access to non-personal data

- Chapter VI: Collaboration in the EHDS council

- Chapter VII: Delegated acts

Chapter II: Primary use

Scope:

- Only for providing healthcare

- Only electronic health data

- National ánd cross border exchange (EU)

- The following determines whether a care provider falls within the scope:
  - Do you fully or partially own data components that fall under the categories from article 5

Chapter II: Primary use

Prioritized categories (Article 5):

- Patient summary

- Electronic recipes

- Electronic dispensing (medication)

- Medical images and related image reports

- Lab results and related lab reports

- Hospital discharge letters

The topics in the EHDS

- Chapter I: Scope of application and definitions

- Chapter II: Primary use

- Chapter III: EHR'r and wellness apps

- **Chapter IV: Secondary use**

- Chapter V: International access to non-personal data

- Chapter VI: Collaboration in the EHDS council

- Chapter VII: Delegated acts

Chapter IV: Secondary use

1. Scope of data types (minimum categories art. 33)

2. Prohibited purposes

3. Governance on secondary use of health data

4. Application of data-altruïsm

5. Fees for access to data for secondary use

6. Conditions for access to data

7. Cross-border access

8. Data sets and their quality

Important principle: data stays at the source.

Chapter IV: Secondary use

1. Scope of data types (minimum categories art. 33)

2. Prohibited purposes

3. Governance on secondary use of health data

4. Application of data-altruïsm

5. Fees for access to data for secondary use

6. Conditions for access to data

7. Cross-border access

8. Data sets and their quality

Important principle: data stays at the source.

Minimum categories (paraphrased)

1. EHR in structured format
2. Social, environmental and behavioral determinants of health
3. Aggregated data about healthcare needs and resources
4. Pathogen data impacting human health
5. Healthcare-related administrative data in structured format
6. Human genomics and other molecular data (omics)
7. Generated by people via digital resources
8. About the professional status of a practitioner
9. Public health registries
10. Medical records including mortality
11. Clinical trials that have ended
12. Data from medical devices
13. Data from registers for medical devices and medicines
14. Completed research related to health
15. Biobanks and associated databases
16. Data related to insurance, professional and educational status, lifestyle, well-being and behavior

Chapter IV: Secondary use

1. Scope of data types (minimum categories art. 33)
2. Prohibited purposes
3. **Governance on secondary use of health data**
4. Application of data-altruïsm
5. Fees for access to data for secondary use
6. Conditions for access to data
7. Cross-border access
8. Data sets and their quality

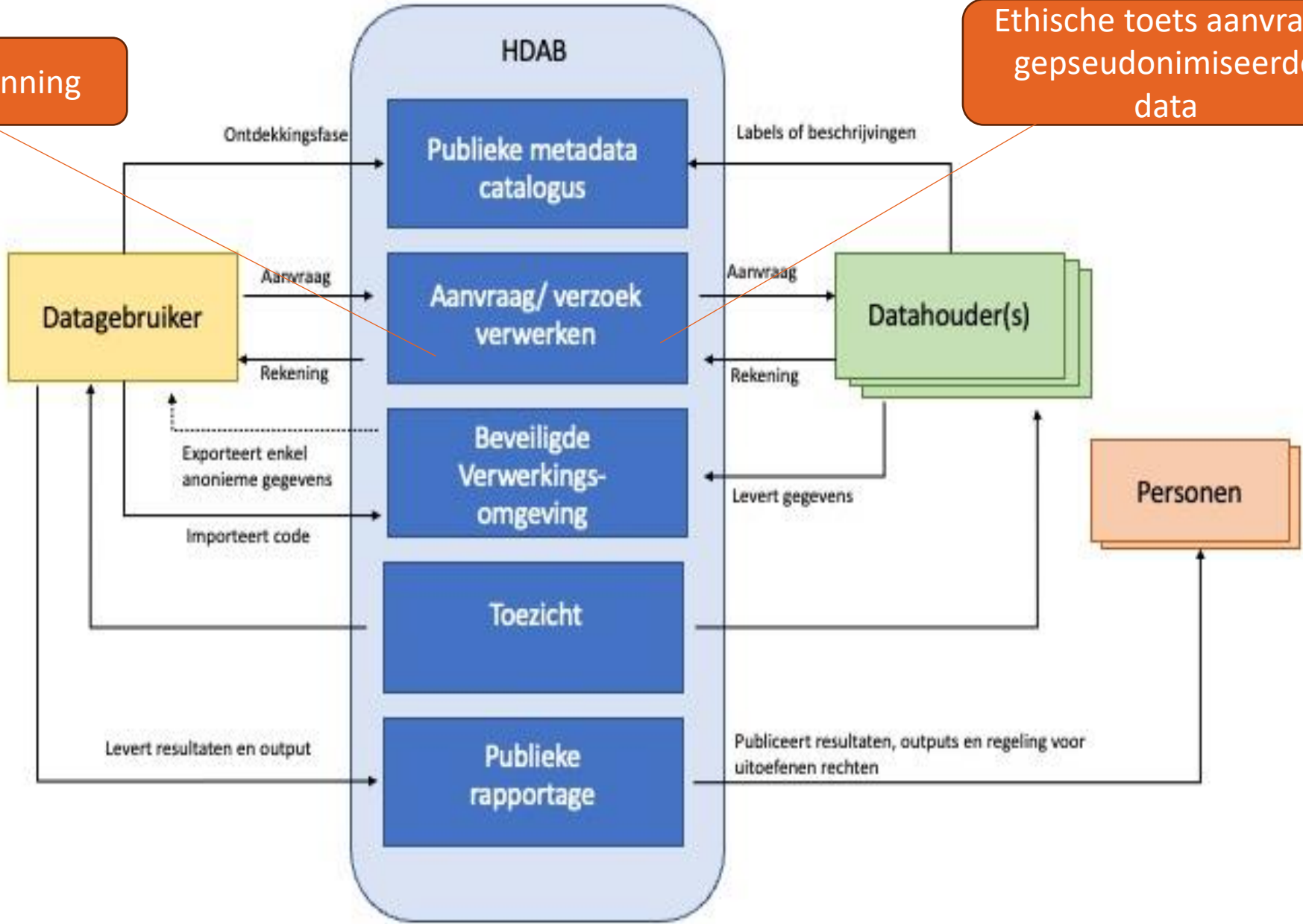Important principle: data stays at the source.

Governance on secondary use

- Each Member state establishes on or more Health Data Access Body /ies (HDAB's)

- The HDAB will become a central facility for processing data requests and making health data available

- The HDAB hands out data permits for access to health data

- The HDAB reports publicly and is accountable on an European level

HDAB

Vergunning

Ethische toets aanvraag gepseudonimiseerde data

Datagebruiker

Publieke metadata catalogus

Aanvraag/ verzoek verwerken

Beveiligde Verwerkings-omgeving

Toezicht

Publieke rapportage

Datahouder(s)

Personen

Ontdekkingsfase

Labels of beschrijvingen

Aanvraag

Aanvraag

Rekening

Rekening

Exporteert enkel anonieme gegevens

Levert gegevens

Importeert code

Levert resultaten en output

Publiceert resultaten, outputs en regeling voor uitoefenen rechten

HDAB's in the Netherlands

- Currently investigating whether we want 1 or more HDAB('s)

- The must always be 1 coördinating HDAB

- Consortium of CBS, RIVM, VWS and Health-RI for developing the necessary business capabilities for a HDAB in the Netherlands
  - Application for the European Commission (sept '22 – febr '23)
  - Project plans (juli - dec '23)
  - Ontwerpfase, ontwikkelfase en
    Implementatie (dec '23-'27)

HDAB consortium

10 work packages

1) Management and coordination

2) Dissemination, training and support

3) Evaluation

4) Sustainability

5) Data Access Application Management Solution

6) Dataset catalogue

7) Secure processing environments

8) Infrastructural solutions

9) Data quality enhancement

10) Establishment of a coordinating HDAB

Forms of consent on secondary use

- General approach Council: opt-out

- General approach Parliament: opt-out, with exception of human genomics and biobanks (opt-in)

- In the national parliament: shift from opt-in to opt-out

Timeline

With reservations, but:

- The Council has finished it's General Approach: november 2023

- The Parliament has finished it's General Approach: november 2023

- Start trilogue: december 2023

- Completion trilogue: end of March 2024 (BE presidency)

- Consent Council and EP april/may 2024

- National implementation 5 to 7 years

Stay up to date

www.platform.informatieberaadzorg.nl

www.gegevensuitwisselingindezorg.nl

www.health-ri.nl

- Upcoming years: consultations, working groups etc

Thank you very much