

European Health Data Space

Data sharing is mandatory and supported – how can you, as a research institution, prepare for this?

Health-RI webinar for research institutes– 25 August 2026

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House rules



Microphone off



Questions may be asked in the chat



Presentation will be recorded and shared



Why is Health-RI organising this EHDS webinar?

Ruben Kok – board member Chief Strategic Alliances Health-RI

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Our mission

Better health(care) for citizens and patients

by

reusing health and life sciences data

with

an integrated infrastructure

for

data- & AI-driven research, innovation and policy



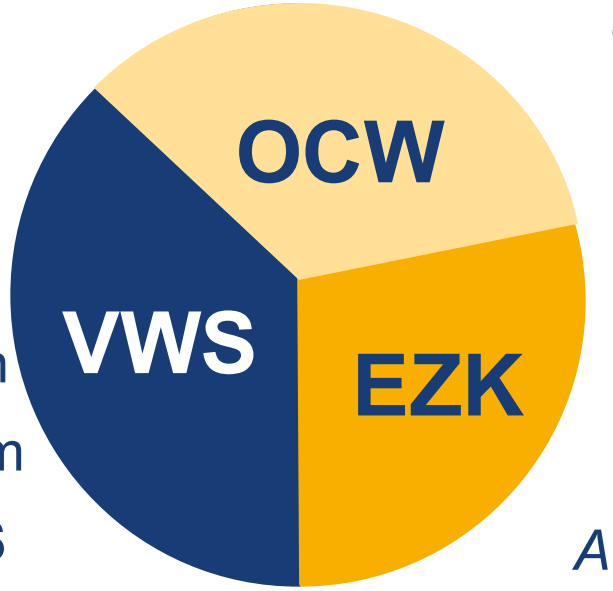
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Health-RI is aligned with national developments in areas covered by various ministries

Research infrastructures

digitalisation of research

Open Science



Health information system

EHDS

Secondary use

innovation sectors

key technologies

AI & Data

Ministerie van Volksgezondheid, Welzijn en Sport

Ministerie van Onderwijs, Cultuur en Wetenschap

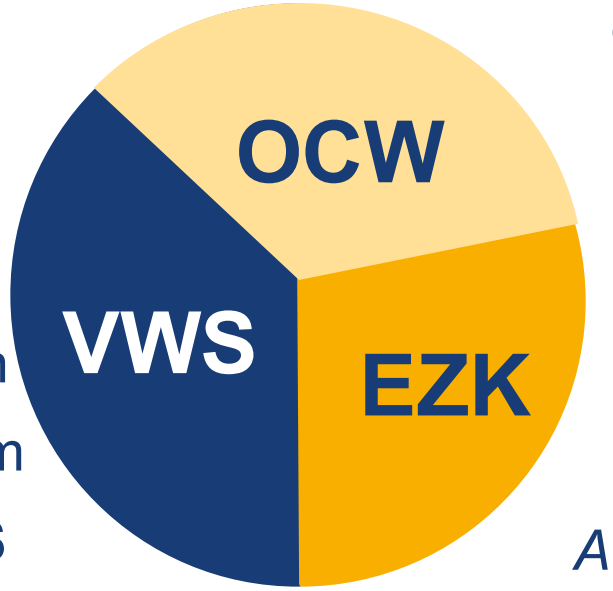
Ministerie van Economische Zaken en Klimaat

With support from NWO, we are linking up with (European) research infrastructures and organising the TDCC-LSH

Research infrastructures

digitalisation of research

Open Science



Health information system

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innovation sectors

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AI & Data

← News

Dutch Government has pledged 69 million euros investment to Health-RI

News | 9 April 2021

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~~The problem~~ The solution



National Steering Group for the Health-RI Obstacle Removal Programme

Ministries

- Health, Welfare, and Sport (VWS)
- Economic Affairs and Climate Policy (EZK)
- Education, Culture, and Science (OCW)

Health-RI

- Involving stakeholders in identifying potential solutions

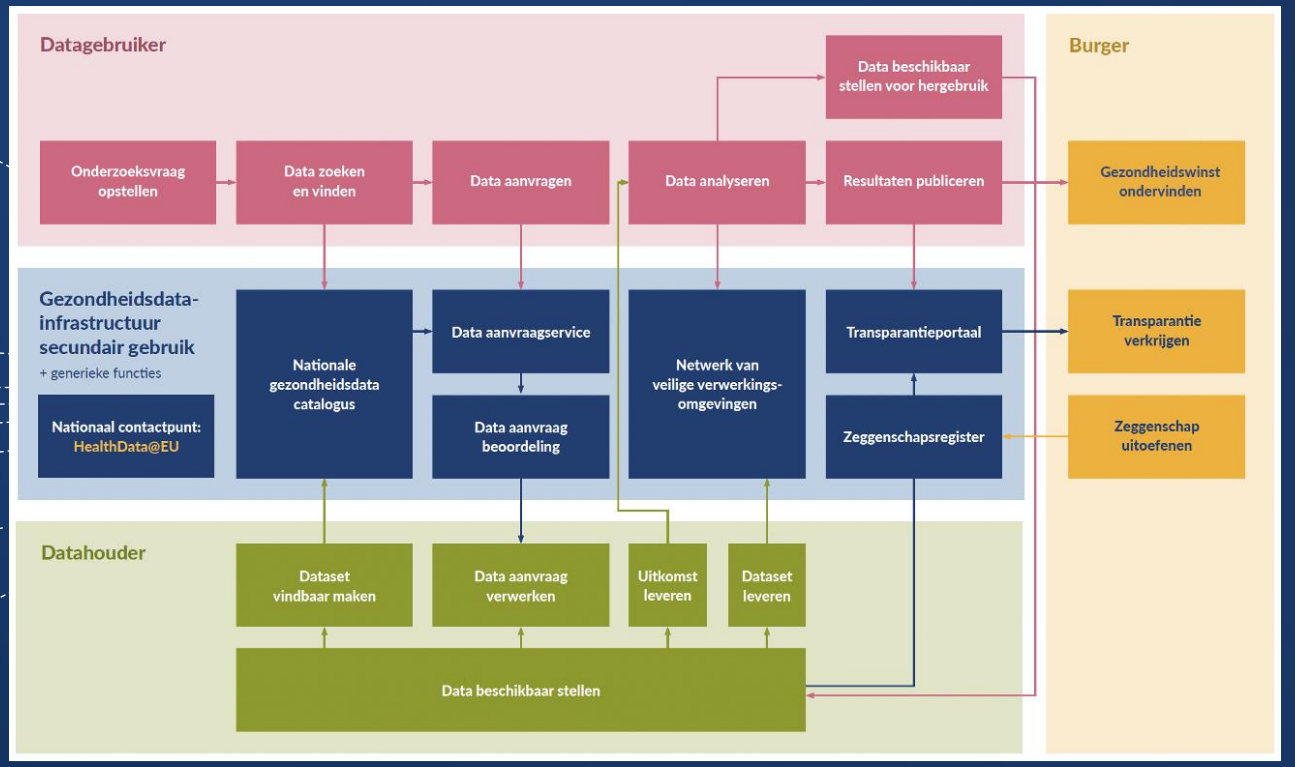
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Health data infrastructure is being set up in close consultation with the government and a wide range of stakeholders across the sector

8 regional Health-RI hubs

- Amsterdam
- Eindhoven
- Groningen
- Leiden
- Limburg
- Nijmegen
- Rotterdam
- Utrecht





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Health-RI is preparing the data infrastructure for the EHDS

- Health-RI is developing the national health data infrastructure for research, innovation and policy, in collaboration with national partners and in line with European standards
- Greater availability of data from a wide range of disciplines provides deeper insights into disease and health, leading to more innovation and better treatments
- The Health-RI approach: connecting existing infrastructures and engaging organisations and experts, such as researchers, healthcare professionals, policymakers, knowledge organisations, patient organisations and private sector bodies
- We ensure that the infrastructure is fully aligned, both technically and legally, with European research infrastructures and European data infrastructures, with a focus on the European Health Data Space

Why is the EHDS important for research organisations?



Health data is important for research and innovation



European regulations are changing the rules of the game



Research gets new possibilities



Research institutions are being given new responsibilities

Why is EHDS important for research organisations?

Opportunities

- Better access to (European) datasets
- Greater (international) collaboration
- Acceleration of research
- Greater reproducibility
- New opportunities for AI
- Better utilisation of existing data

Responsibilities

- Research organisations manage health data
- Research data often falls within the scope of the EHDS
- New role as data holder
- New role as data user

European Data Strategy

Common European data spaces form part of the European Data Strategy of February 2020.

The aim of the data spaces is:

- To unlock the potential of data-driven innovation
- To enable data from across the EU to be made available and exchanged in a reliable and secure manner

The data spaces will form the basis for an interconnected and competitive European data economy.



https://digital-strategy.ec.europa.eu/nl/policies/strategy-data



European Health Data Space

Chantal Steegers, Manager Public Policy, Affairs & Communication

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What is the EHDS?

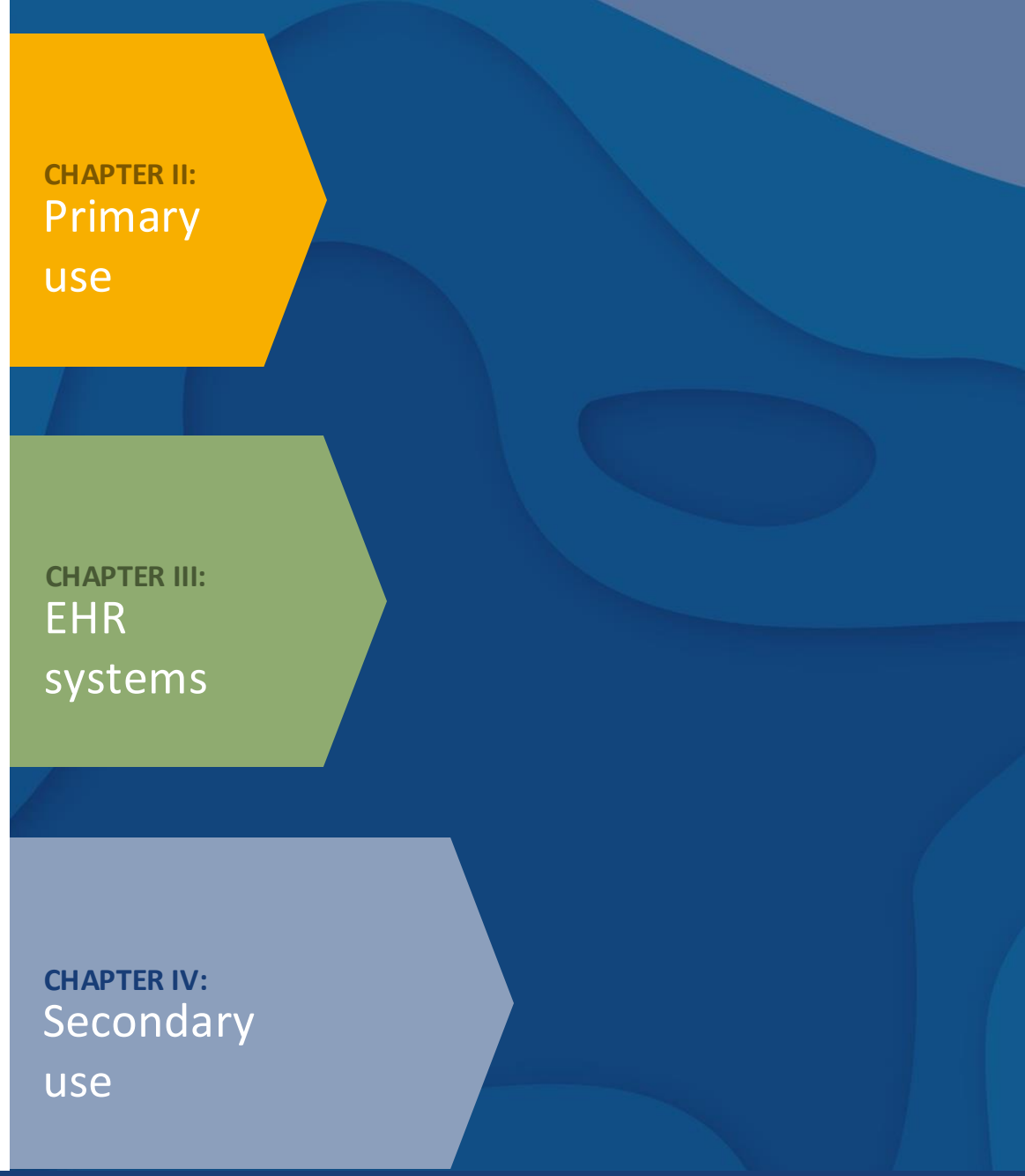
- In 2022, European Commission proposal for the European Health Data Space (EHDS) regulation.
  - Fisrt European Data Space
  - Entered into force in March 2025

- The European Health Data Space (EHDS) is a European regulation that will ensure better availability of electronic health data for primary (healthcare) use, secondary use, and better regulation of the market for health information systems (EHRs).



EHDS consists of 3 parts:

- European regulation for better healthcare through improved availability of health data
- Strengthens patient care
- Gives citizens more control over their stored health data
- Gives healthcare providers more time for patient care
- Promotes scientific research, innovation, and policy development in Europe through data (re)use



Timeline

- EHDS entered into force on 26 March 2025 but is being applied in a phased manner (2027, 2029, 2031)
- 2029:
  - 1st application of EHDS components regarding first categories of data for primary and secondary use
  - Entry of civil rights (including opt-out)
  - Health Data Authority operational (primary and secondary)



Maart 2025

Maart 2027

Maart 2029

Maart 2031

Secondary use

- Rules for the use of electronic health data for purposes other than direct patient care.
- Ensures data availability for scientific research, policy, and innovation throughout the European Union.
- Right of opt-out regarding availability (= the ability to object)
- Stricter requirements possible for the availability of genome data, wellness data, and biobanks
- Strict review framework for access through a licensing system
- Establishment of a Health Data Access Body (HDAB)
- Making data available always in a secure processing environment under the supervision of a Health Data Access Body
- Principle: anonymous, unless
- Data also available and requestable in the EU via HealthData@EU

Categories of health data under the EHDS

Office on the web Frame

om EHRs

Genetic, epigenomic and genomic data

Data from **clinical studies, research cohorts and questionnaires**

Data from **biobanks and associated databases**

Data on factors **impacting health, including socioeconomic factors**

Data from **wellness applications**

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Purposes for processing health data for **secondary use**

Article 53 EHDS



- Policymaking
- Statistics
- Education
- Scientific research
- Innovation, including the development of AI

Prohibited **secondary use**

Article 54 EHDS



- *Decisions detrimental to health*
- *Discrimination*
- *Advertising or marketing activities*
- *Developing harmful products*
- *Activities in conflict with ethical provisions laid down in national law*

Stakeholders secondary use



Data holder

If you process health data, you likely have obligations regarding certain categories.

If fewer than 10 people work in your organization, then in principle not.



Citizen

If health data about you is processed, you will be given insight into its secondary use and an opt-out right.



Data user

If you have a valid reason to use health data for secondary purposes, you can obtain a permit for:

- Policy
- Statistics
- Education
- Scientific research/innovation
- Improving healthcare

Data user

- A natural or legal person, including institutions, bodies or agencies of the Union to which lawful access to electronic health data for secondary use has been granted pursuant to a data licence, approval of a request for health data or an access authorisation of an authorised participant in HealthData@EU.



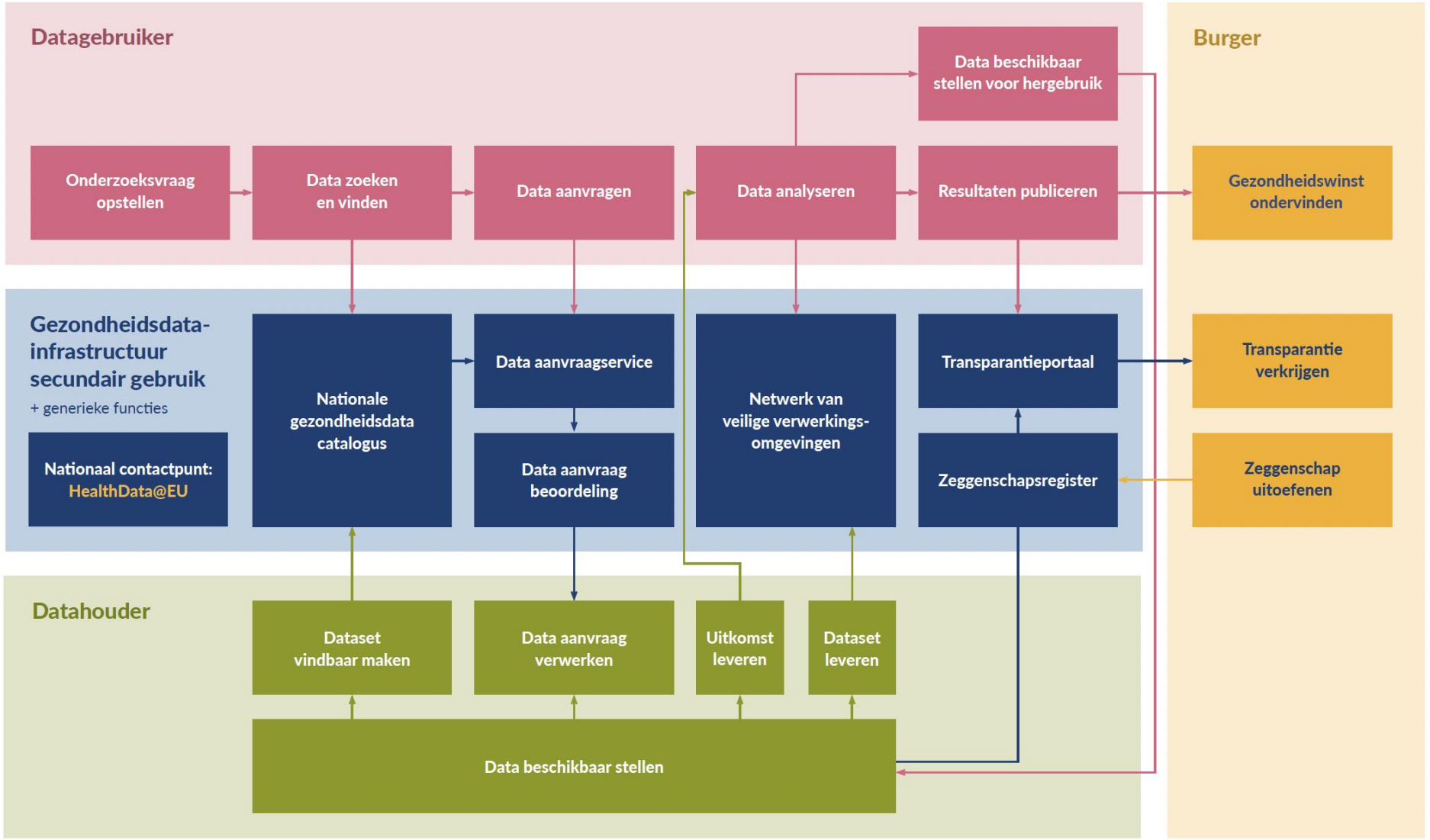
Data holder (1)

- A natural or legal person, public authority, agency or other body in the health or care sector
- Any natural or legal person that
  - Develops products or services intended for the health, health care or care sector
  - Develops or manufactures wellness apps
  - Conducts scientific research in connection with the health or care sector
  - Acts as a mortality register
- …

Datahouder (2)

- Union bodies or agencies
  - Have the right or obligation, in accordance with applicable Union or national law and in their capacity as controllers or co-controllers, to process personal electronic health data for the provision of healthcare or care or for purposes of public health, reimbursement, research, innovation, policy-making, official statistics or patient safety or for regulatory purposes; or
  - Able to make non-personal electronic health data available by controlling the technical design of a product and related services, including recording, providing, restricting or exchanging the data

Health data infrastructure secondary data usage under EHDS



Health Data Access Body (HDAB)

Each country establishes an HDAB to enable the exchange of data for secondary use and ensures structural funding.

HDAB increases the findability of data and ensures that data is handled in a coordinated manner in a secure processing environment.

The national HDAB connects to HDABs of other countries via HealthData@EU, the European infrastructure for the secondary use of health data.

Dutch HDAB must be notified and incorporated into national legislation 2 years after the EHDS legislation enters into force (26 March 2027).

There will be one Health Data Access Body in the Netherlands

There will be a single organization housing both the Digital Health Authority (primary use) and the Health Data Access Body (secondary use).

Work is underway towards a new Independent Administrative Body: the Health Data Authority.

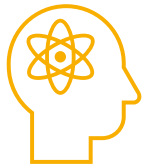


Importance for research institutions

Ruben Kok, board member - Chief Strategic Alliances Health-RI

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Data request and issuance process



Data user



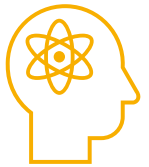
HDAB



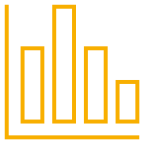
Data holder

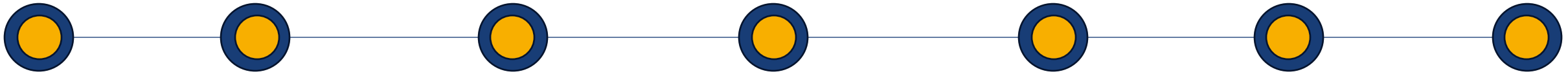


HDAB



Data user





Finding data
Which data can I request?

Data request
Can I use this data for my research?

Assessment of request
Granting of the permit?

Data preparation
Preparing data for use

Making data available
Access to SPE

Data use
Data analysis

Publishing results

Why is EHDS important for research organisations?

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Responsibilities

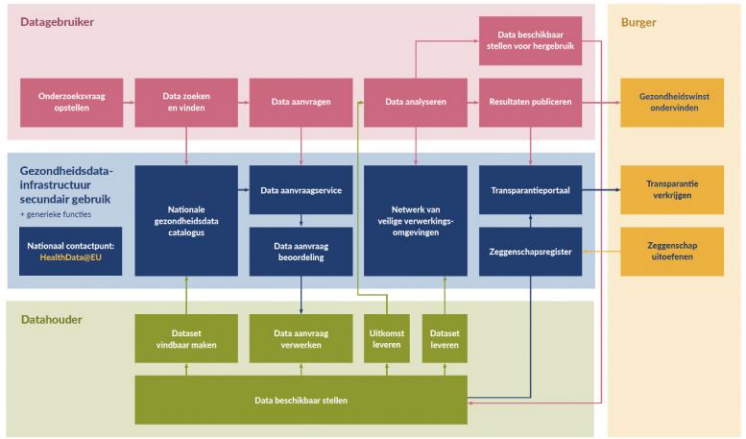
- Research organisations manage health data
- Research data often falls within the scope of the EHDS
- New role as data holder
- New role as data user

EHDS obligations for research institutions as data users

- Use of data exclusively based on a valid data permit or approved data request
- Processing only within the secure processing environment; no access for unauthorized persons
- Re-identification of persons is prohibited
- Publish results (anonymized only) within 18 months and inform the HDAB thereof
- Citation: acknowledge the origin of the data and its use within the EHDS
- Report relevant health findings to the HDAB and cooperate with its activities

Health data infrastructure supports research institutions as data users

- Be able to select and request relevant data
- Combining data through standards and linking
- Support for (federated) analysis
- Can train, validate, and apply algorithms



EHDS obligations for research institutions as data holders

- Providing health data to the Health Data Access Body (HDAB) based on an approved data license or an approved data request.
- Submission within 3 months (extension by a maximum of 3 months in exceptional cases).
- Registering datasets in the national dataset catalogue and checking and updating the description at least annually.
- Substantiating quality labels with the necessary documentation.
- Making non-personal health data available via reliable open databases.

Health data infrastructure supports research institutions as data holders

Being able to make data available securely and securely (control) for multiple uses

Making data available for analysis and machine learning 'at the source'

Meet the requirements of the EHDS, provide data for secondary use



What can you do now to prepare for 2029?

Chantal Steegers, Manager Public Policy, Affairs & Communication

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Preparation for the EHDS as a data holder

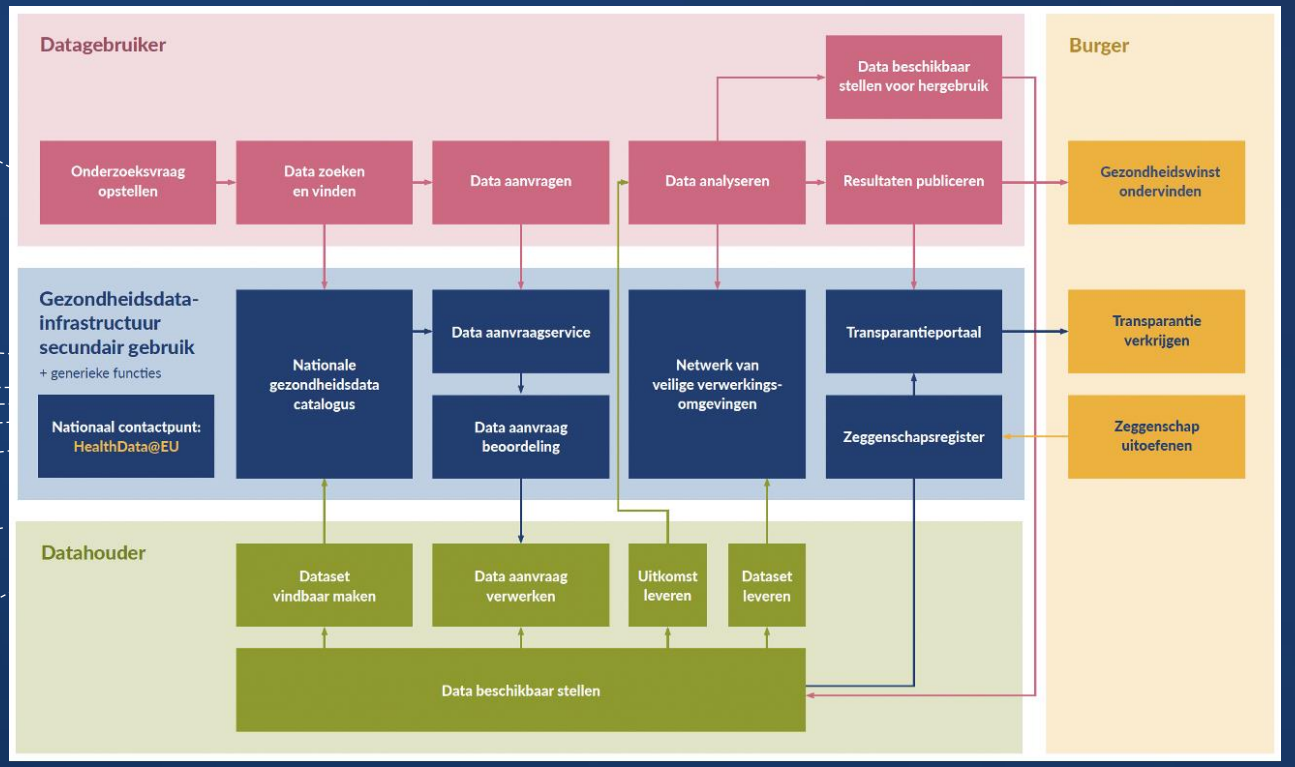
1. Read the EHDS Regulation and explore the impact on the current infrastructure and work processes within your organization together with colleagues.
2. Create an overview of the data sources and datasets within your organization that fall under Article 51 of the EHDS.
3. Inventory the data request and issuance processes currently in place within your organization.
4. Create a ‘single point of contact’ for submitting metadata regarding your data(sets) and for issuing data(sets) following an approved request.
5. Start metadata mapping on a dataset using Health DCAT-AP (European standard for describing/exchanging datasets) and onboarding into the Health-RI catalog.

Connect to Health-RI and the Health-RI nodes

8 regional Health-RI hubs

- Amsterdam
- Eindhoven
- Groningen
- Leiden
- Limburg
- Nijmegen
- Rotterdam
- Utrecht





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Contact regional hubs

- **Health-RI:** ehds@health-ri.nl

- **Amsterdam**: Ronald van Schijndel - info@healthdataspaceamsterdam.nl
- **Groningen**: Alexandra Chuprova-Beun - a.p.chuprova-beun@umcg.nl
- **Leiden**: Sonja Meeuwsen - s.meeuwsen@lumc.nl
- **Limburg**: Pascal Suppers – datahub@maastrichtuniversity.nl
- **Nijmegen**: Peter-Bram 't Hoen of Sander Bervoets – research@radboudumc.nl
- **Rotterdam**: Anne-Lotte Masson – rso@erasmusmc.nl
- **Utrecht**: Charlotte Onland-Moret & Sarita Hartgring - health-ri@umcutrecht.nl



Take aways and more information

Ruben Kok, board member – Chief Strategic Alliances Health-RI

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Key takeaways webinar:

The EHDS changes the way health data is shared

Knowledge institutions receive both new rights and obligations.

Preparation requires collaboration within the institution between research teams, IT and (T)DCCs, legal affairs, and management.

Starting early prevents falling behind and creates opportunities

Work with us and the regional hubs on the implementation of the national health data infrastructure.

More information?

Health-RI website: https://www.health-ri.nl/european-health-data-space-ehds

Data for health: https://www.datavoorgezondheid.nl/

HDAB-NL event 21 september: https://hdab-event.yellenge.nl/

TDCC-LSH: https://tdcc.nl/lsh/

Health-RI conference 29 oktober: https://www.aanmelder.nl/healthriconferentie2026/home

