ERDERA
European Rare Diseases
Research Alliance

Who handles data: overview of different actors

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Feature	Data Controller	Data Processor
Determines purpose of data	✓✓ Yes	✗ No
Determines how data is used	✓✓ Yes	✗ No (follows controller's instructions)
Primary legal responsibility	✓✓ Yes	◈ Shared but secondary
Signs contracts with processors	✓✓ Yes	✓✓ Must comply
Data subject interaction	Direct (e.g., patients, users)	Indirect (e.g., service provider)

Examples in healthcare:

A **hospital** is the controller.

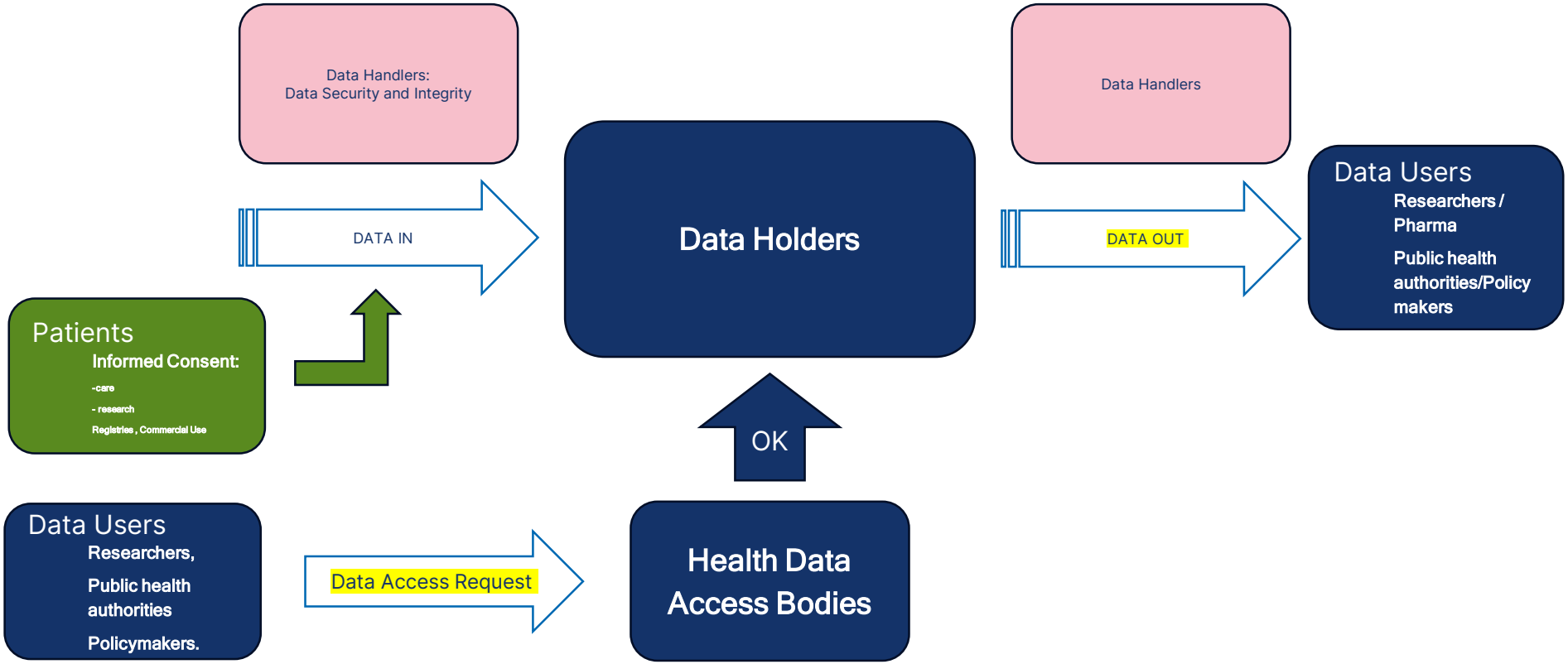
An **EHR vendor** like Epic or Cerner is a processor.

A **cloud platform** (e.g., AWS storing encrypted health data) is a **sub-processor**.

What is a data handler?

	Data Holder	Data Handler
Definition	An entity or institution that **owns or controls access** to health data (e.g., hospitals, national registries, research institutes).	A broader term referring to **any party involved in the collection, processing, storing, or transferring** health data.
Legal Standing	Legally responsible for **making data available** for primary or secondary use under GDPR and EHDS regulations.	Encompasses operational roles under GDPR as **data processors** or **data controllers** depending on function.
Typical Examples	- Hospitals with EHRs - National cancer registries - Biobanks - Laboratories - ERN registries	- IT system providers - Cloud storage services - Data processors (e.g., research institutions analyzing data) - Healthcare professionals inputting EHR data
Key Responsibilities	- Maintain data integrity - Ensure data security and compliance - Cooperate with Health Data Access Bodies (HDABs) for lawful secondary use	- Ensure secure handling of data throughout its lifecycle - Follow technical and security protocols - Support interoperability and data sharing infrastructure

Data Handlers Workflow



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Data Handlers duties:

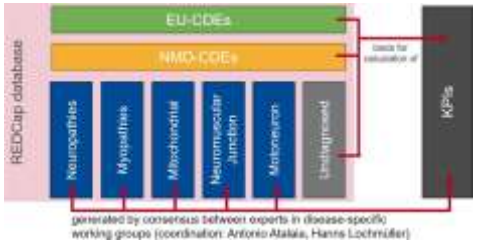
- Maintain data integrity
- Ensure data security and compliance
- Cooperate with Health Data Access Bodies (HDABs) for lawful secondary use

Use case: EURO-NMD Registry

Patient Portal

- Dynamic Consent Management
- PROMS app "PROMMY"
- Access own data

DATA IN



DATA OUT

Data Users

Researchers / Pharma

Public health authorities/Policymakers

Data Users

Researchers,

Public health authorities

Policymakers.

Data Access Request

Data Access Committee

Patient Reps

OK

Patient Consent

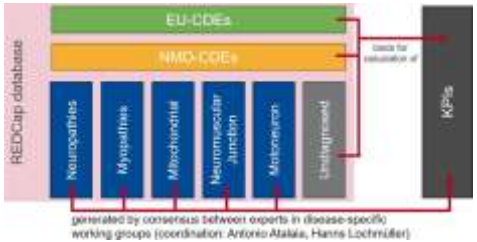
Ethical dispositions

Legal Dispositions

Use case: EHDS using EURO-NMD

Patients
Informed Consent

DATA IN



DATA OUT

Data Users
Researchers / Pharma
Public health authorities/Policymakers

Data Users
Researchers,
Public health authorities
Policymakers.

Data Access Request

Health Data Access Body (FR)

OK

Data Access Committee
Trusted data holder

Better than Consent
Ethical dispositions
Legal Dispositions

Use case: EHDS direct access to HCP data

Patients
OPT-OUT

DATA IN

Hospital Information System

DATA OUT

Data Users
Researchers / Pharma
Public health authorities/Policymakers

Data Users
Researchers,
Public health authorities
Policymakers.

Data Access Request

Health Data Access Bodies

OK

Better than Consent
Ethical dispositions
Legal Dispositions

EHDS regulation 11 Feb 2025

- Objectives of EHDS:
  - Enable easy access and control over electronic health data.
  - Facilitate secure secondary use of health data for research, policy, and innovation.
  - Establish a governance framework ensuring privacy and compliance.

EHDS regulation 11 Feb 2025

Health Data Access Bodies:

- Member States are required to designate health data access bodies responsible for granting access to electronic health data for secondary use.
- These bodies manage the access to data, ensuring it is used in compliance with the regulations, and act as intermediaries between data holders and users.

EHDS regulation 11 Feb 2025

Responsibilities of Data Holders:

- Data holders (entities in the health or research sector) must provide access to electronic health data for secondary use, which includes research, policy-making, and innovation.
- They must ensure proper documentation, contribute to dataset catalogs, and comply with security and data quality measures.

EHDS regulation 11 Feb 2025

Data Users and Permissions:

- Data users must apply for data permits, specifying the intended purpose, security measures, and expected outcomes of data usage.
- The health data access body decides on applications based on predefined legal and ethical guidelines.

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Security and Compliance:

- Electronic health data must be accessed within a secure processing environment, which includes measures to restrict unauthorized access, prevent data modification, and ensure data anonymity when necessary.
- Joint controllers, including data users and health data access bodies, share responsibility for data processing security.

EHDS regulation 11 Feb 2025

Cross-Border Data Access:

- The document outlines mechanisms for cross-border data access through the HealthData@EU initiative, ensuring data can be shared across Member States efficiently while maintaining legal compliance.

EHDS regulation 11 Feb 2025

Better-Than-Consent Mechanism and Opt-Out Model for Patient Data in EHDS

1. The "Better-Than-Consent" Mechanism for Data Access

The **"better-than-consent"** approach is proposed as an alternative to traditional **individual consent** for secondary use of electronic health data. Instead of relying solely on explicit patient consent, the **European Health Data Space (EHDS)** establishes a **trusted governance framework** that grants controlled access to quality health data for **researchers, policymakers, and innovators**.

EHDS regulation 11 Feb 2025

Better-Than-Consent Mechanism and Opt-Out Model for Patient Data in EHDS

Key Features:

- **Secure Data Access**: Researchers and policymakers can access anonymized or pseudonymized data via **secure processing environments** rather than relying on direct consent from each individual.
- **Lower Administrative Costs**: Reduces costs associated with obtaining and managing individual consents.
- **Standardized Access Framework**: Ensures uniform and transparent data-sharing mechanisms across **EU Member States**.
- **Data Permits**: Users must apply for **data access permits**, which are reviewed and granted based on **legal, ethical, and scientific justifications**.

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Rationale for Better-Than-Consent Mechanism:

- The current **fragmented consent-based system** limits **cross-border research**.
- The **opt-in model is inefficient**, as obtaining direct patient consent for every research project is time-consuming and may exclude important datasets.
- The governance model ensures **greater public trust** in health data use while **preserving privacy and security**.

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Thank you!

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