

**UMANIQ**



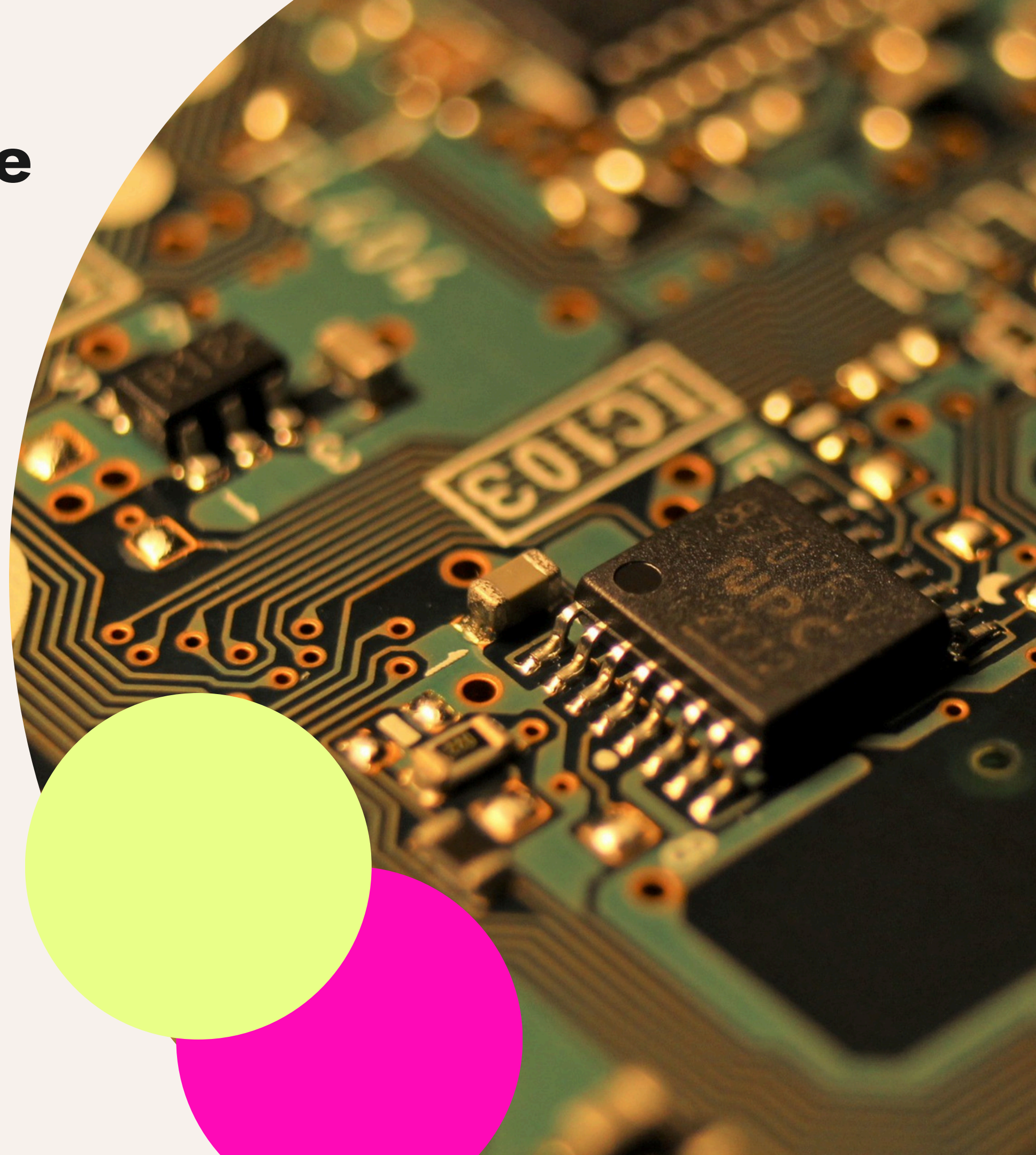


# Geoffrey Ceunen

- Managing Partner & Founder UMANIQ
- Lecturer PXL-Next: AI Compliance Officer Postgraduate
- 10+ years experience in Digital & Data Laws

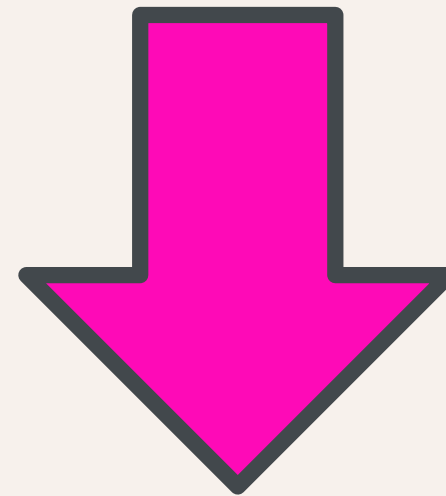


# **EHDS - A Legal Perspective**



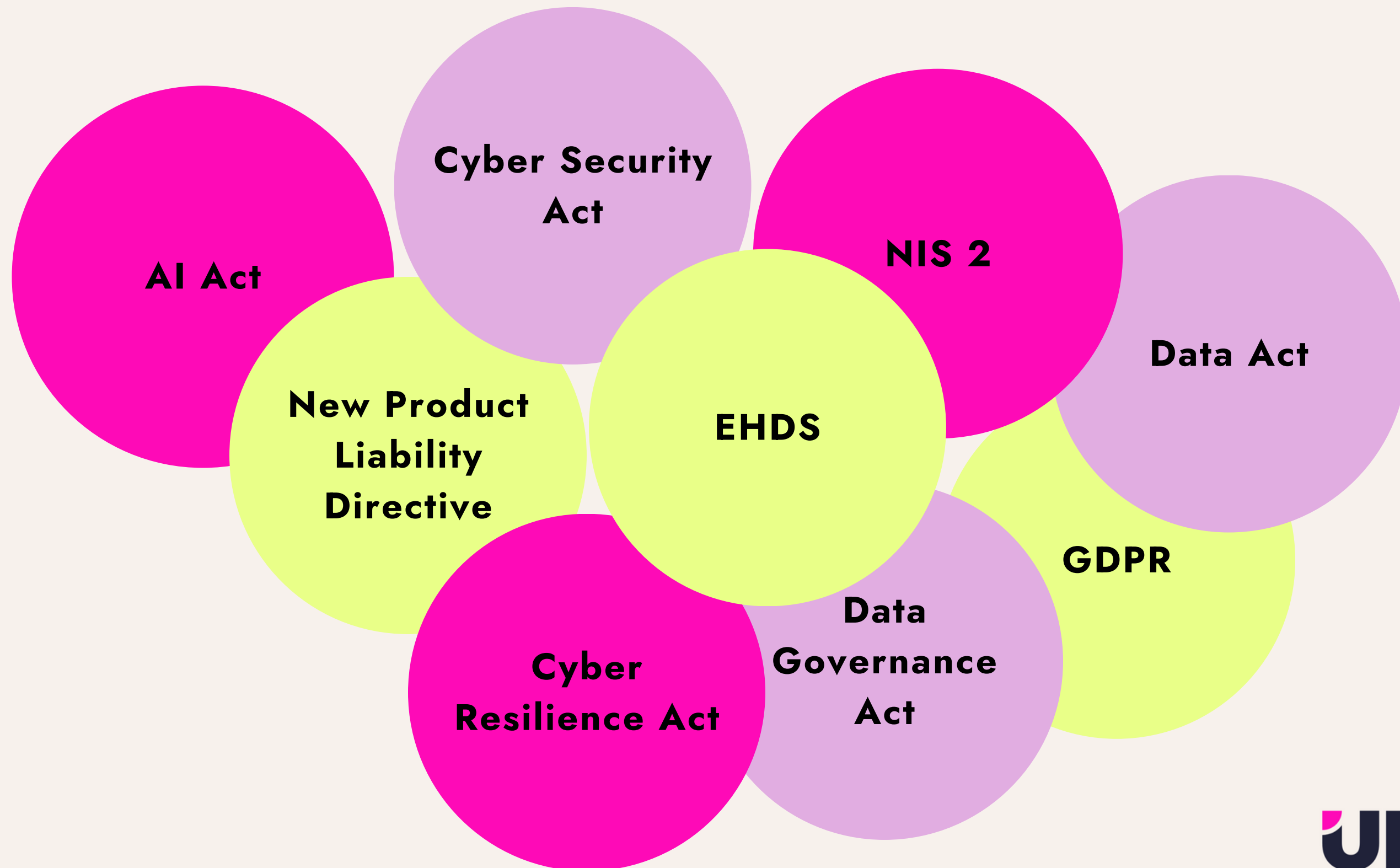
# EU Data Strategy

**Creating a single market for data**  
**Stimulate Europe's digital sovereignty**  
**Promoting data-driven innovation**  
**Protecting EU values and rights**

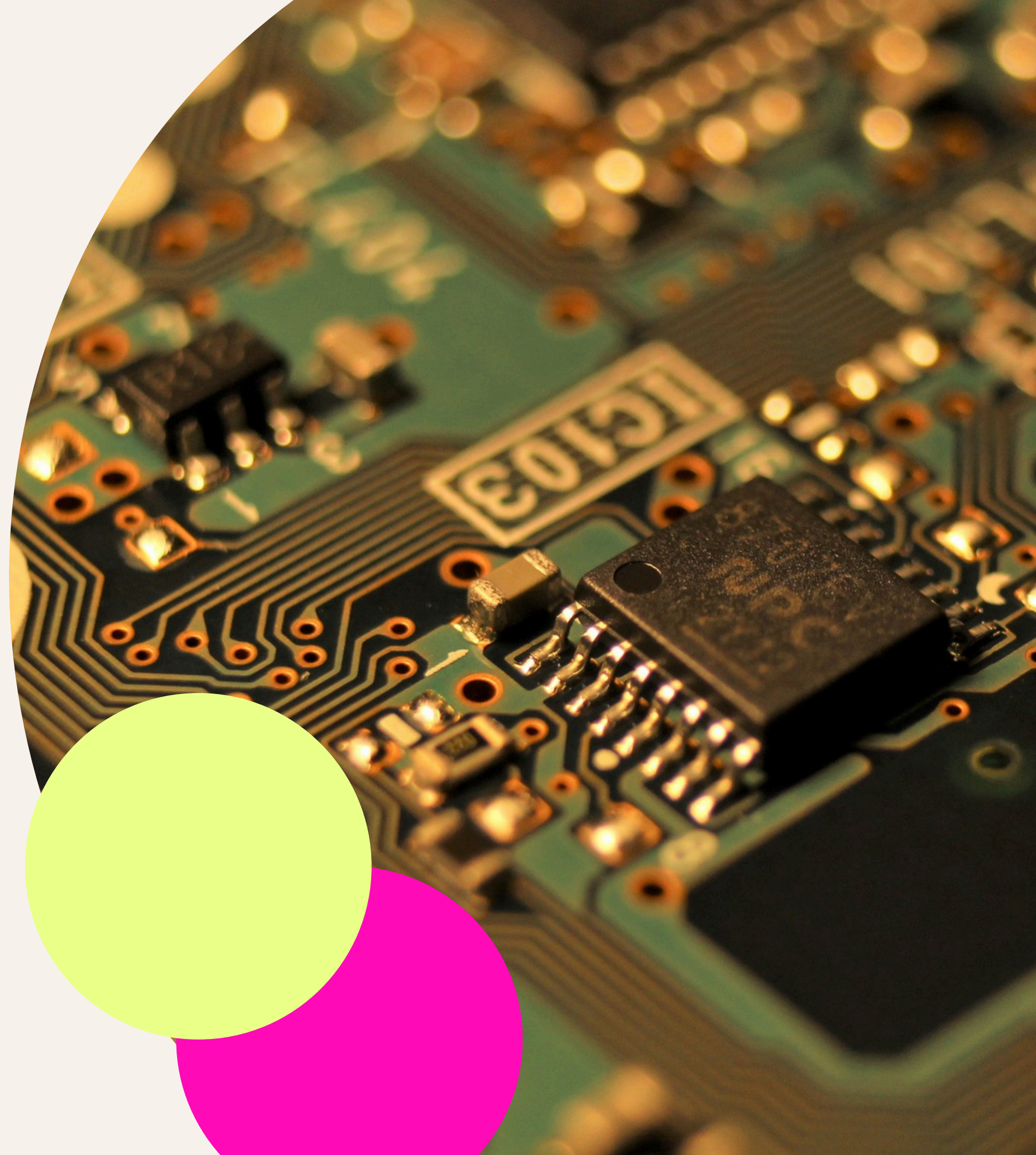


**EHDS as a first "Data Space"**

# Interconnection with other regulations



# GDPR & Health Data



# Territorial scope of the GDPR

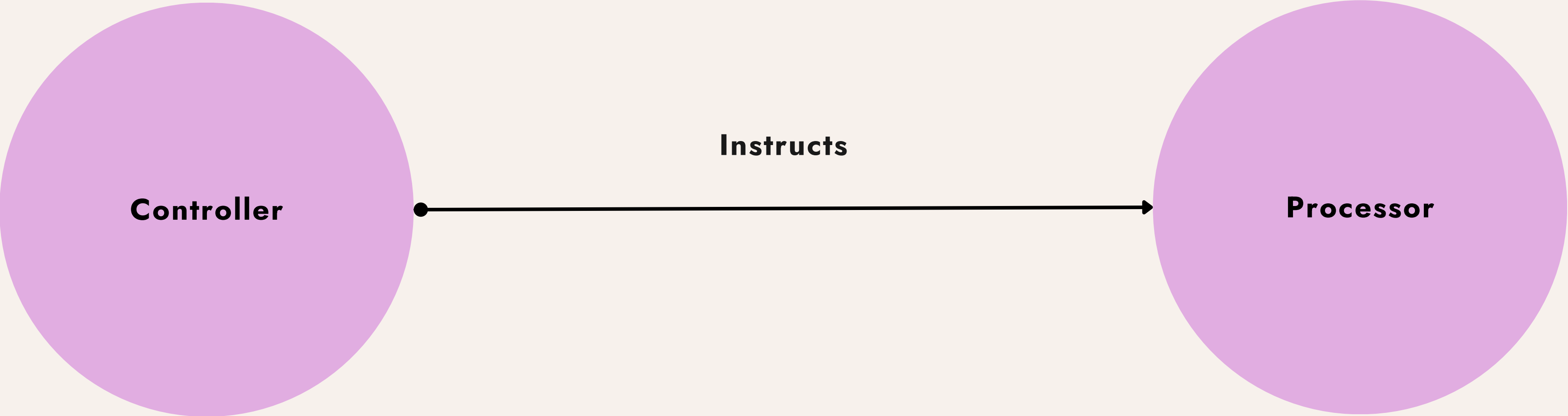
## Territorial scope:

- Organisations within the EU: Applicable to all organisations processing personal data within the EU.
- Organisations outside the EU: Applicable for all organisations that:
  - Offer goods/services to individuals in the EU.
  - Monitor behavior of individuals in the EU

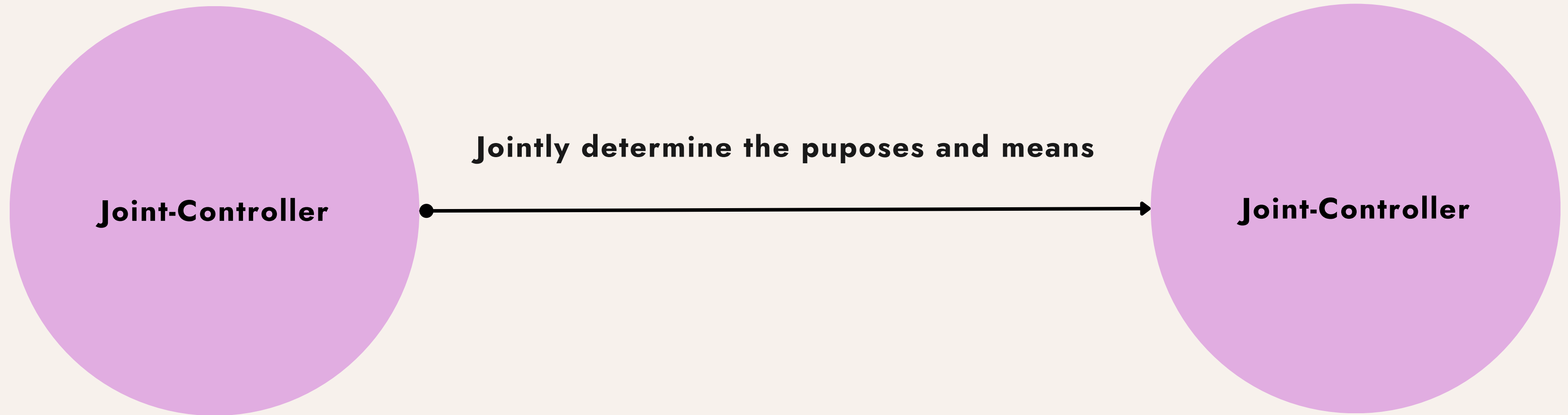
## Material Scope:

- Applies to:
  - Personal data: Identifiable data such as names, IP addresses, medical and biometric data.
  - Processing activities: Collection, storage, sharing, and deletion of data.
  - Automated and non-automated processing.

# Actors



# Actors



# GDPR Principles

- Lawfulness, fairness, and transparency
- Purpose limitation
- Data minimisation
- Accuracy
- Storage limitation (Time)
- Integrity and confidentiality
- Accountability

# Rights of Data Subjects

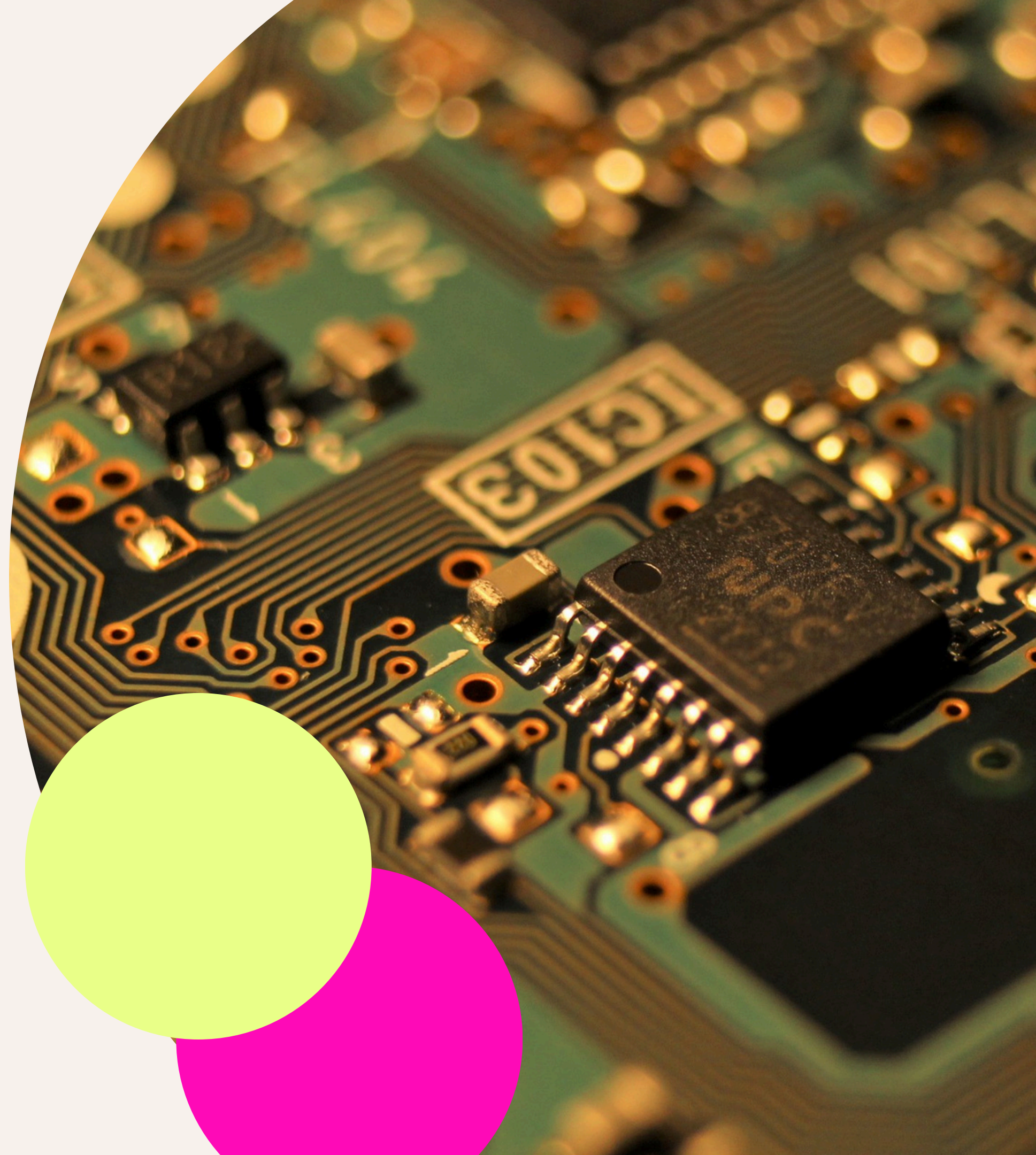
- Right to information
- Right of access
- Right to rectification
- Right to erasure
- Right to restriction of processing
- Right to data portability
- Right to object
- Right not to be subject to solely automated decision-making

# Processing Health Data under GDPR

The GDPR prohibits the processing of health and genetic data unless covered by exceptions under Article 9:

- Explicit Consent: Must be given explicitly for a specific purpose.
- Vital Interests: Applied if a person cannot provide consent and processing is necessary to protect life.
- Public Interest: Must serve a clear purpose, such as monitoring epidemics or policy development.
- Scientific Research: Strict conditions apply, such as anonymisation or pseudonymisation, to protect rights.

# Data Act



# Data Act: Objective

- Enhancing innovation by improving access to data.
- Connected devices play a central role, such as medical and health-related devices.
- Making data accessible: IoT devices and digital services must provide access to data.
- Data includes:
  - Personal data (e.g., user information)
  - Non-personal data (e.g., environmental information)

# Actors

## User:

- A natural or legal person who owns, rents, or otherwise lawfully uses a connected product or receives a related service.
- Not necessarily a data subject, as the data generated by the connected product may not always relate to an identifiable individual.
- Examples:
  - **A patient** wearing a smart pacemaker.
  - **A healthcare provider using connected medical equipment** such as a portable ECG monitor.

## Data Holder:

- A natural or legal person who has the right, obligation, or ability to make data available under the Data Act.
- This includes manufacturers, service providers, and any entity controlling access to data generated by connected products or related services.
- Examples:
  - **A manufacturer** of a smart pacemaker or ECG monitor.
  - **A platform provider** managing the data storage for medical devices.

# Actors

## Data Recipient:

- A natural or legal person who receives data from a Data Holder, under the conditions defined in the Data Act.
- Data recipients must comply with fair, reasonable, and non-discriminatory (FRAND) access conditions and ensure compliance with GDPR if the data contains personal information.
- Examples:
  - **A hospital accessing** pacemaker data to monitor a patient's health and provide improved treatments.
  - **A research institution** using anonymized health data to study heart diseases or develop new treatment methods.

# Key Provisions

## **Access to data for users:**

- Users of connected devices (e.g., IoT products) have the right to access data generated by them.
- Users can share these data with third parties under fair, reasonable, and non-discriminatory conditions.

## **Data sharing between businesses (B2B):**

- Data holders must share data upon request with data recipients.
- Conditions:
  - Fair and transparent contractual terms.
  - Reasonable compensation may be requested.

## **Access by public sector in emergencies:**

- Government bodies can request access to private data in emergencies, such as:
  - Disaster response or public health crises.

# Key Provisions

## **Protection against unfair contract terms:**

- SMEs are protected from unfair terms imposed by larger companies in data-sharing agreements.

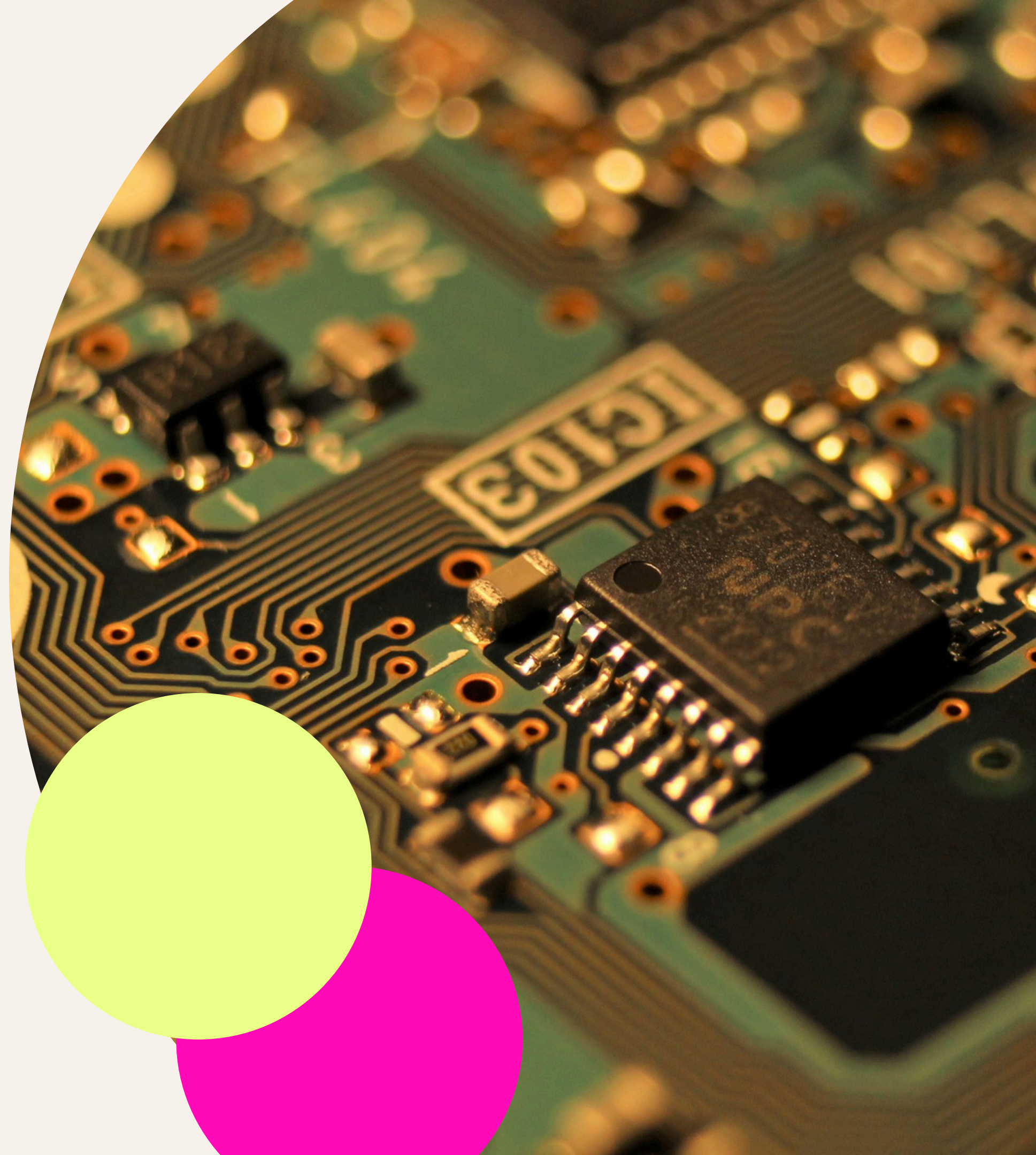
## **Interoperability standards:**

- The law establishes technical standards to ensure seamless data exchange.

## **Protection against international access:**

- Non-EU countries cannot access non-personal EU data in violation of EU laws.

# Data Governance Act



# DGA: Objectives

- Enhancing **data availability** while ensuring strong governance and security.
- Establishing a framework for **secure data sharing** between **public and private entities**.
- Facilitating **data altruism**, allowing individuals to **voluntarily donate health data** for societal benefits.

# Data Intermediation Entities

- **Independent, neutral entities** that facilitate **voluntary data sharing**.
- **Ensure compliance with security and privacy regulations** (aligned with GDPR).
- **Different from EHDS Health Data Access Bodies (HDABs):**
  - DGA: Voluntary data intermediation for any sector (not just health).
  - EHDS: Mandatory health data sharing framework for secondary use.

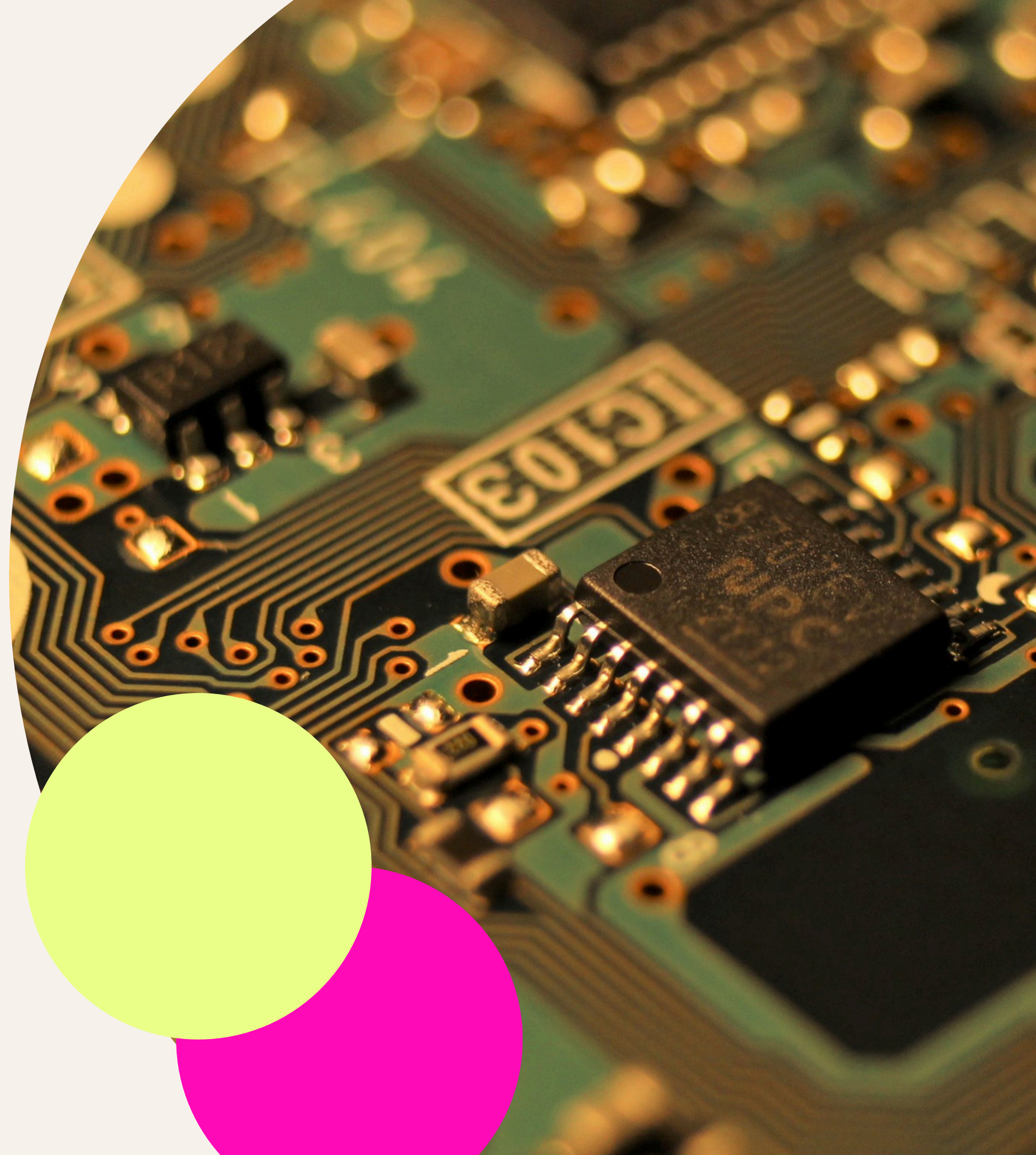
# Data Altruism

- Allows individuals to **voluntarily donate their health data** for research, policymaking, or innovation.
- Requires **registration & transparency mechanisms** for **data altruism organizations**.
- **Supports EHDS objectives** by increasing **public participation in secondary use**.

# Safeguards for International Data Access

- **Restricts non-EU access** to sensitive European health data.
- Ensures compliance with **EU privacy laws** when **transferring data internationally**.
- Aligns with **EHDS rules on secure processing environments** and **data protection**.

**EHDS**



# Who benefits from the EHDS?

## **Citizens**

- Full control over health data
- Easy access and sharing within EU

## **Healthcare Professionals**

- Cross-border patient records access
- Reduced costs through prevention of duplicate testing

## **Researchers**

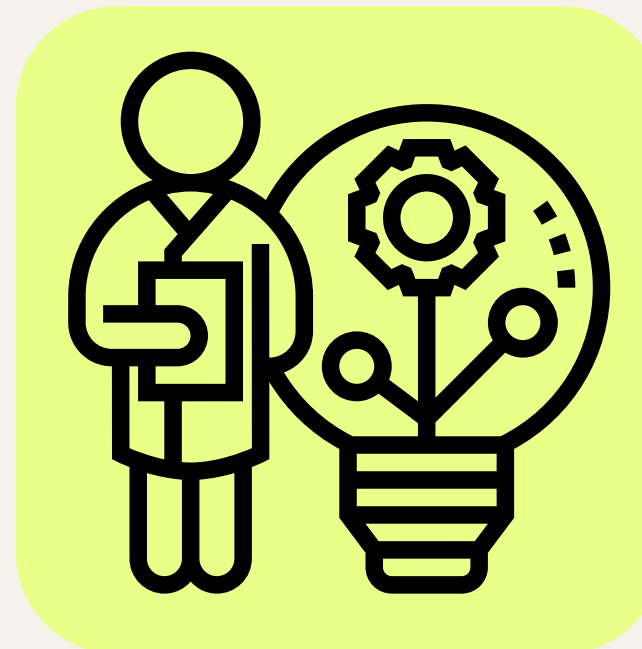
- Access to high-quality anonymised data
- Innovation at lower costs

## **Policymakers**

- Data-driven healthcare improvements
- Enhanced public health systems

## **Industry**

- Standardised EU health records market
- AI-driven and personalised solutions

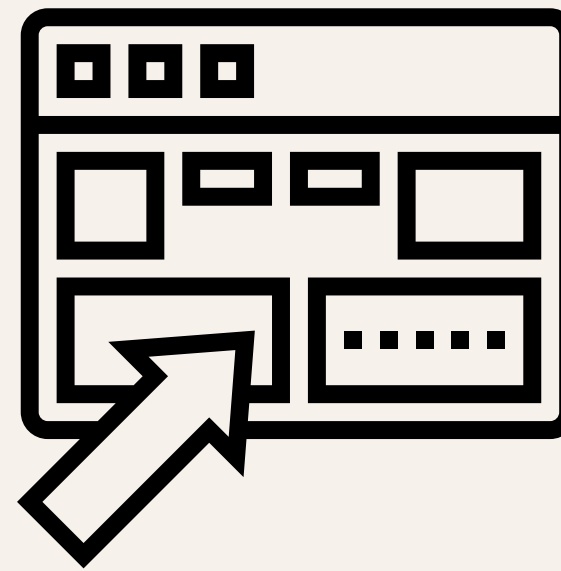


# EHDS: Objectives



## Primary Use

Empowering citizens with control over their health data and its sharing.



## Secondary use

Enhancing the use of health data for research, innovation, and policymaking.



## Main goal

Improving the exchange and reuse of health data within the EU.

# Primary Use

- Empowers citizens with control and ownership over their electronic health data.
- Doctors and hospitals share patient data securely across EU borders.
- Applies to both personal and non-personal data.

**Patient Records**

**Electronic  
Prescriptions**

**Medical Imaging**

**Lab results**

# Secondary Use

- **Obligation for data holders to make certain categories of health data available (Data Act and DGA).**
- **Data must be anonymised or pseudonymised.**
- **Use is limited to specific purposes.**

**Scientific  
Research**

**Education in the  
healthcare sector**

**Public interest in  
relation to public  
health**

**Training and  
testing AI for  
public health**

# Secondary Use - Approval process

- Application submitted to Health Data Access Body - Belgian Health Data Body (BHDA)
- Review of compliance with EHDS guidelines.
- Secure data access granted under anonymisation requirements.

# Prohibited with secondary use

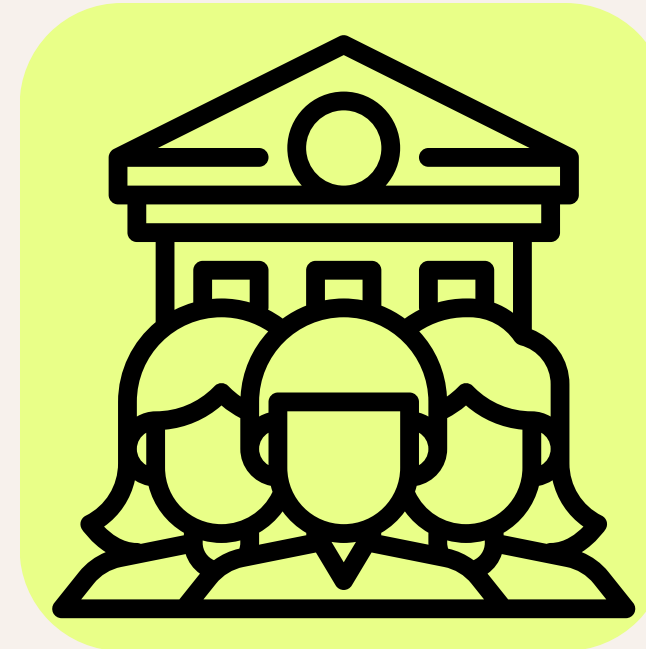
**Decisions that  
negatively impact  
an individual**

**Decisions related  
tot insurance**

**Advertising or  
marketing  
activities**

# Belgian Health Data Agency (Authority)

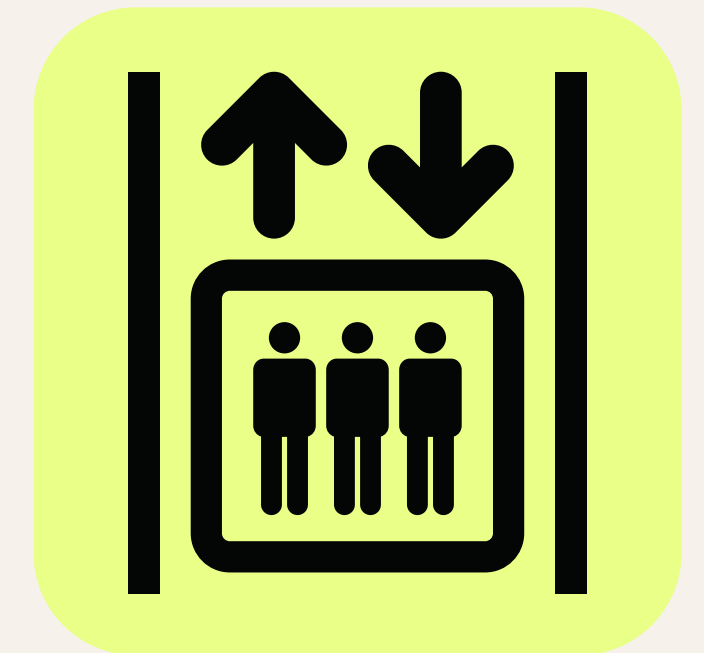
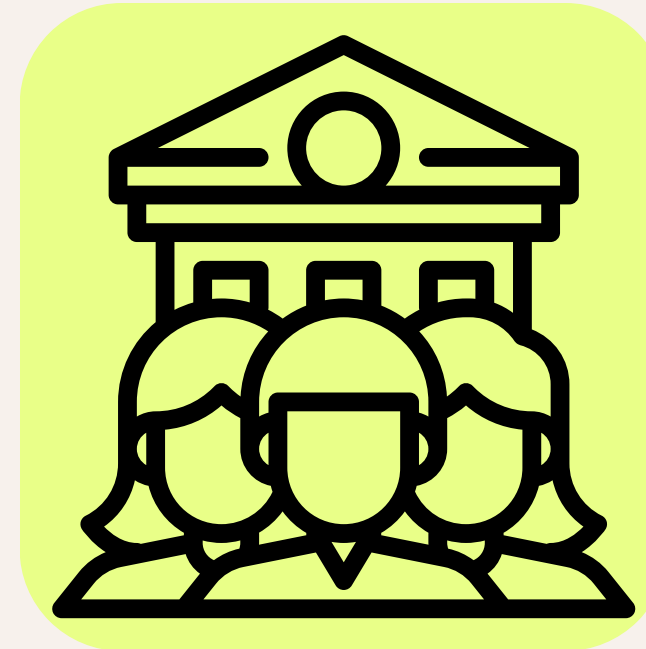
- ✓ Established by law on: **March 14, 2023**
- ✓ Officially launched on: **January 17, 2024**
- ✓ Autonomous agency within: **FPS Health, Food Chain Safety & Environment**
- ✓ Purpose: **Facilitating the secondary use of health data for research, innovation, and policymaking.**



# Belgian Health Data Agency (Authority)

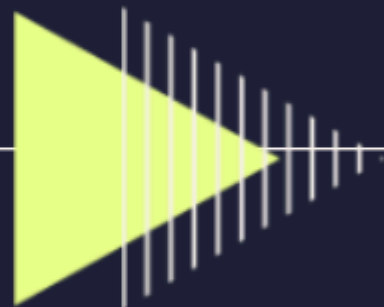
## Responsibilities:

- **Approves** requests for **access** to anonymised and pseudonymised **health data**.
- **Ensures compliance** with GDPR, EHDS, and Belgian national law.
- **Oversees the ethical and legal framework** for secondary data use.
- **Coordinates** with **HealthData@EU** to enable cross-border health data exchange.
- **Reviews applications** from researchers, AI developers, and policymakers to ensure lawful use.



# EHDS Regulation timeline

- **March 5, 2025 – EHDS Regulation published** in the **Official Journal of the EU**.
- **March 26, 2025 – EHDS Regulation enters into force** (start of the transition period).
- **March 2027** – Deadline for implementing acts, ensuring the operationalisation of **Digital Health Authorities** and **Health Data Access Bodies (HDABs)**.
- **March 2029**
  - **Primary use** application begins, enabling the exchange of priority health data categories (Patient Summaries, ePrescriptions) in all EU Member States.
  - **Secondary use** rules apply to most data categories for research and policymaking.
- **March 2031**
  - **Expansion of primary use**, including additional health data categories (medical imaging, lab results, discharge reports).
  - **Secondary use rules** apply to remaining data categories, including genomic data.



# Thank you

**UMANIQ**

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