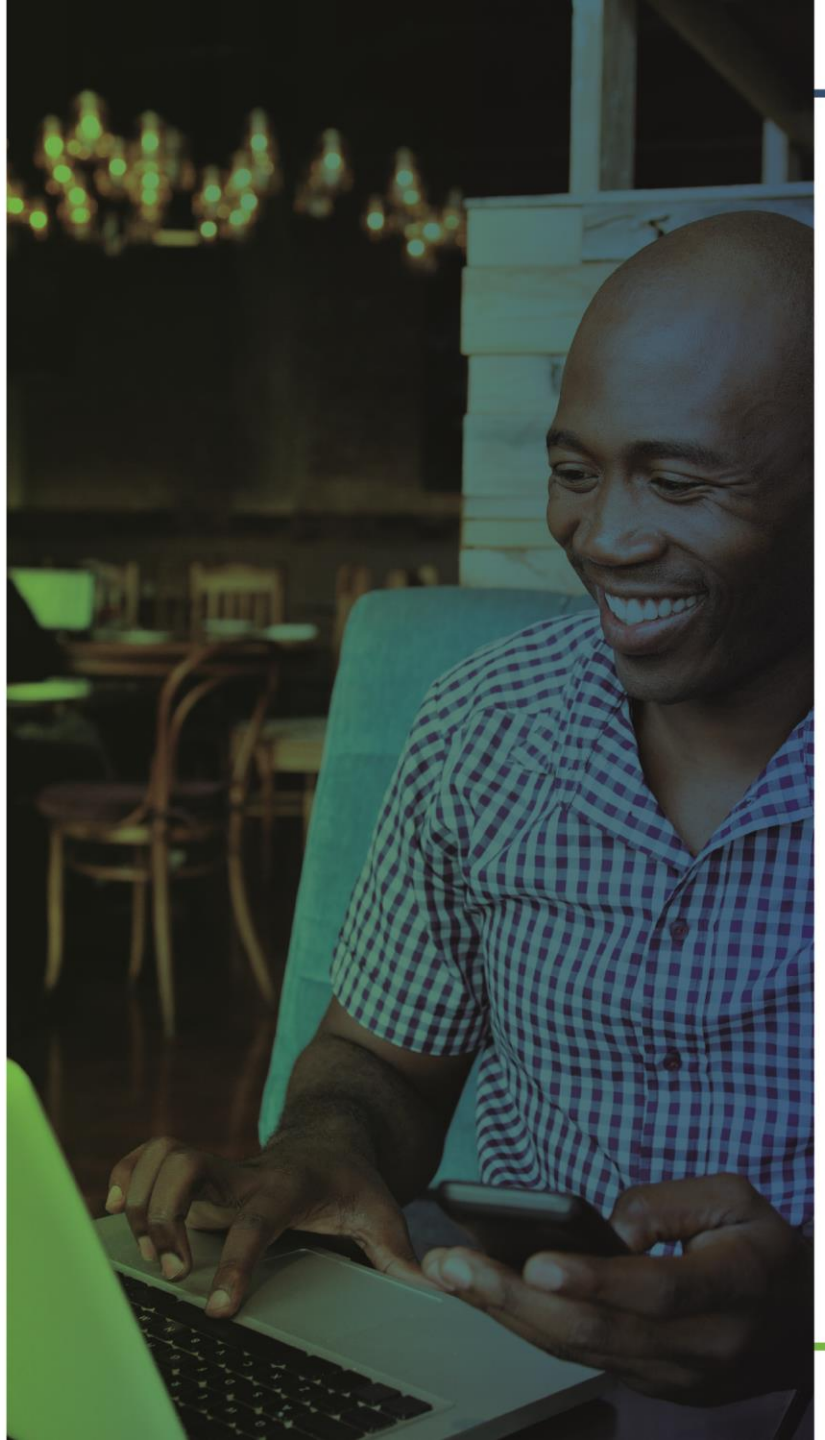


Sharing is (health)caring? A look into the European Health Data Space

Tuesday, 3 September
07:00–08:00 PDT
10:00-11:00 EDT
16:00–17:00 CEST

Welcomes and Introductions

Panelists

Isabelle Roccia, Managing Director Europe, IAPP

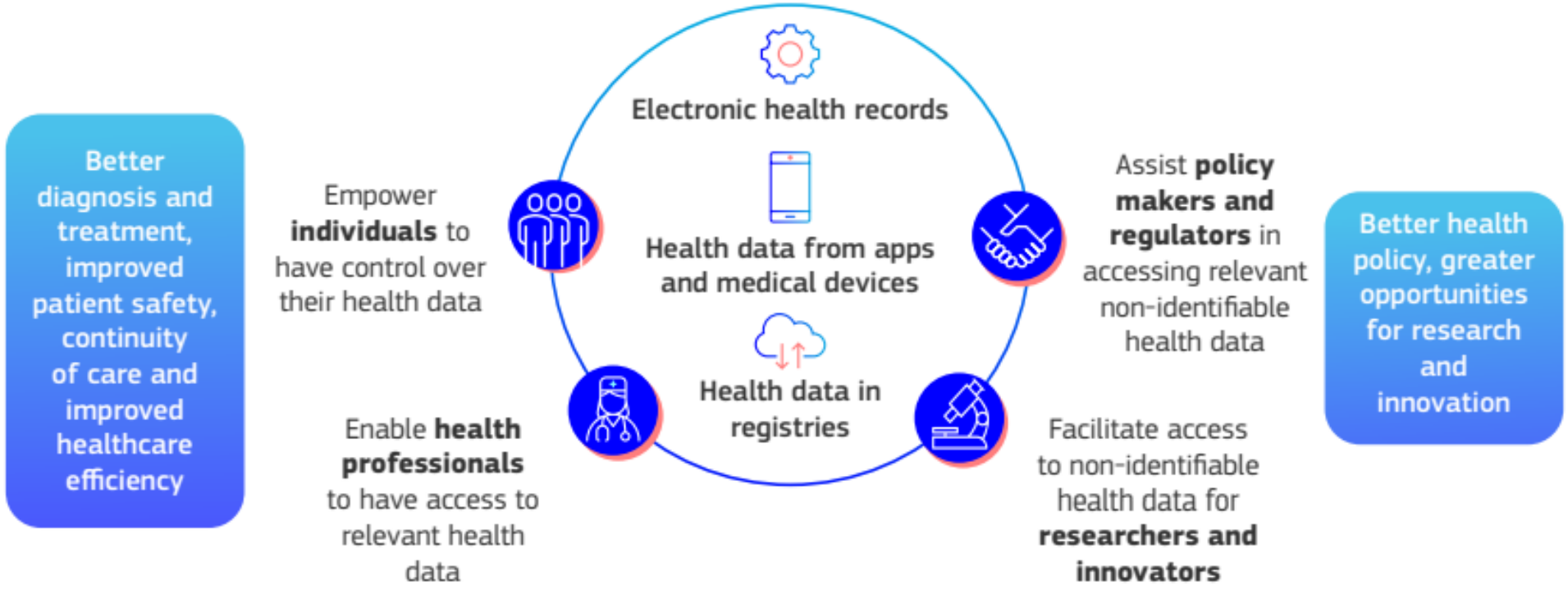
Alexandre Entraygues, Head Data Privacy Europe, Novartis & Co-Chair of EFPIA Data Governance Working Group

Kristof Van Quathem, Of counsel, Covington & Burling

Policy Perspective

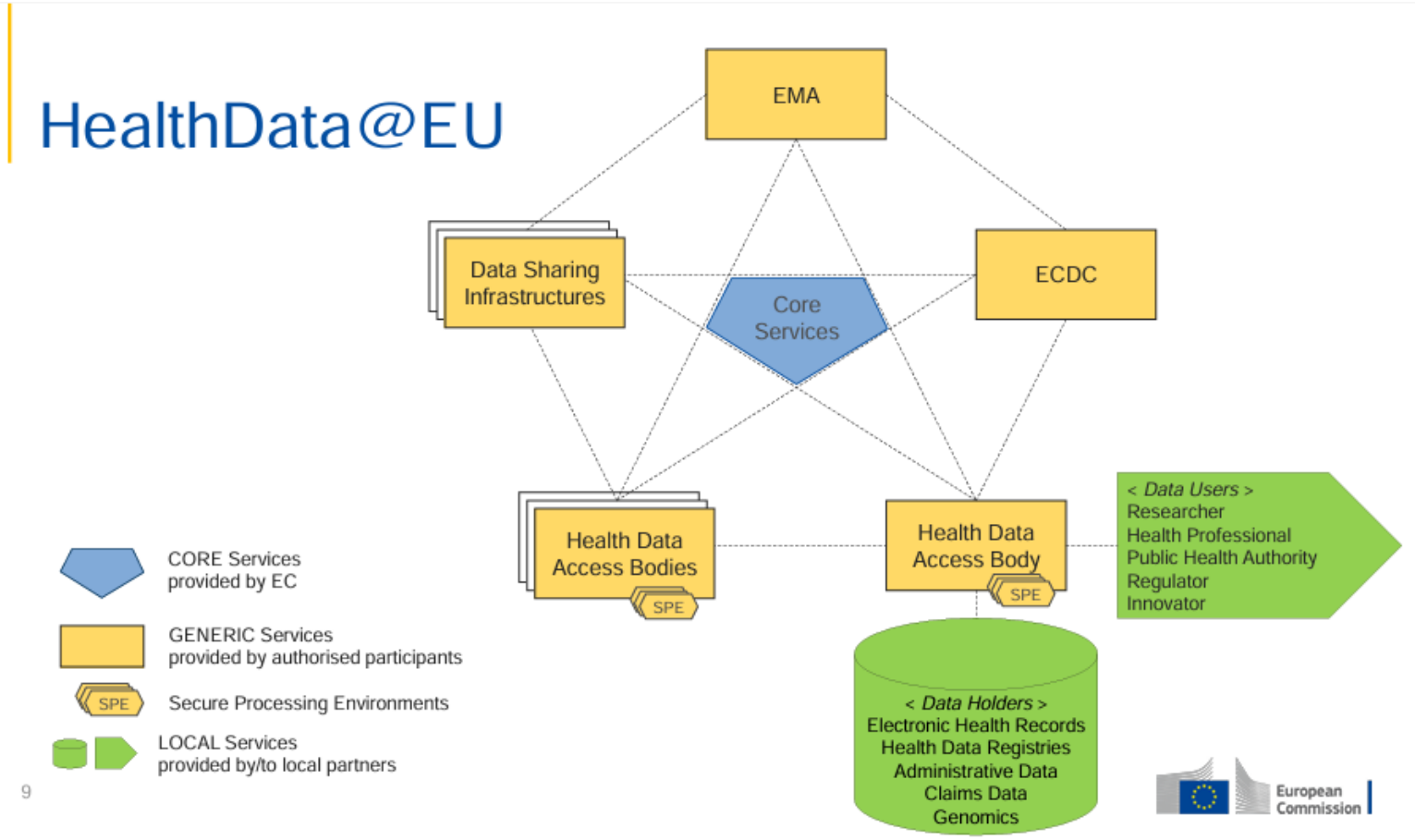
Source: European Commission

Policy Perspective



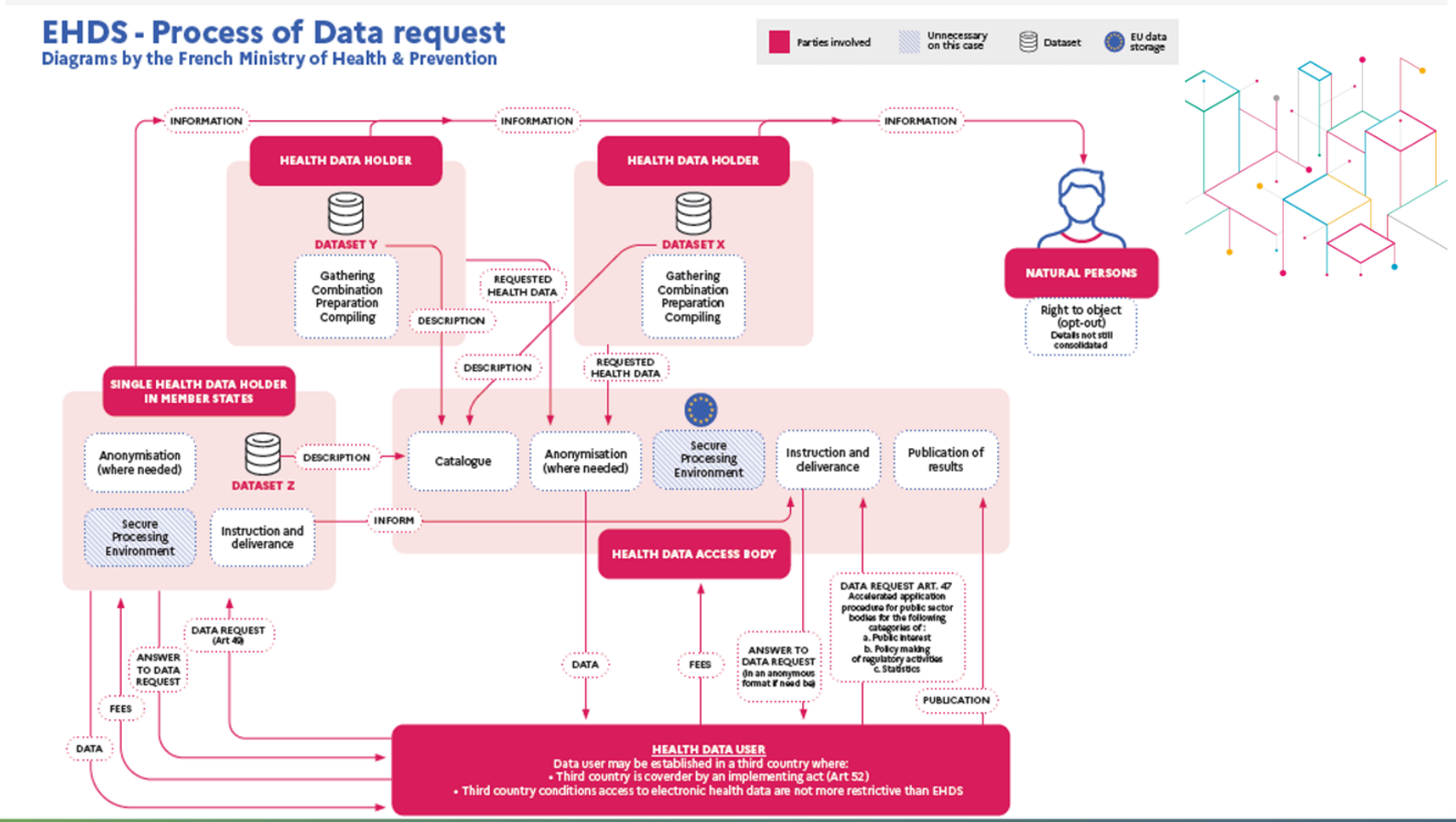
Source: European Commission

EHDS secondary use structure

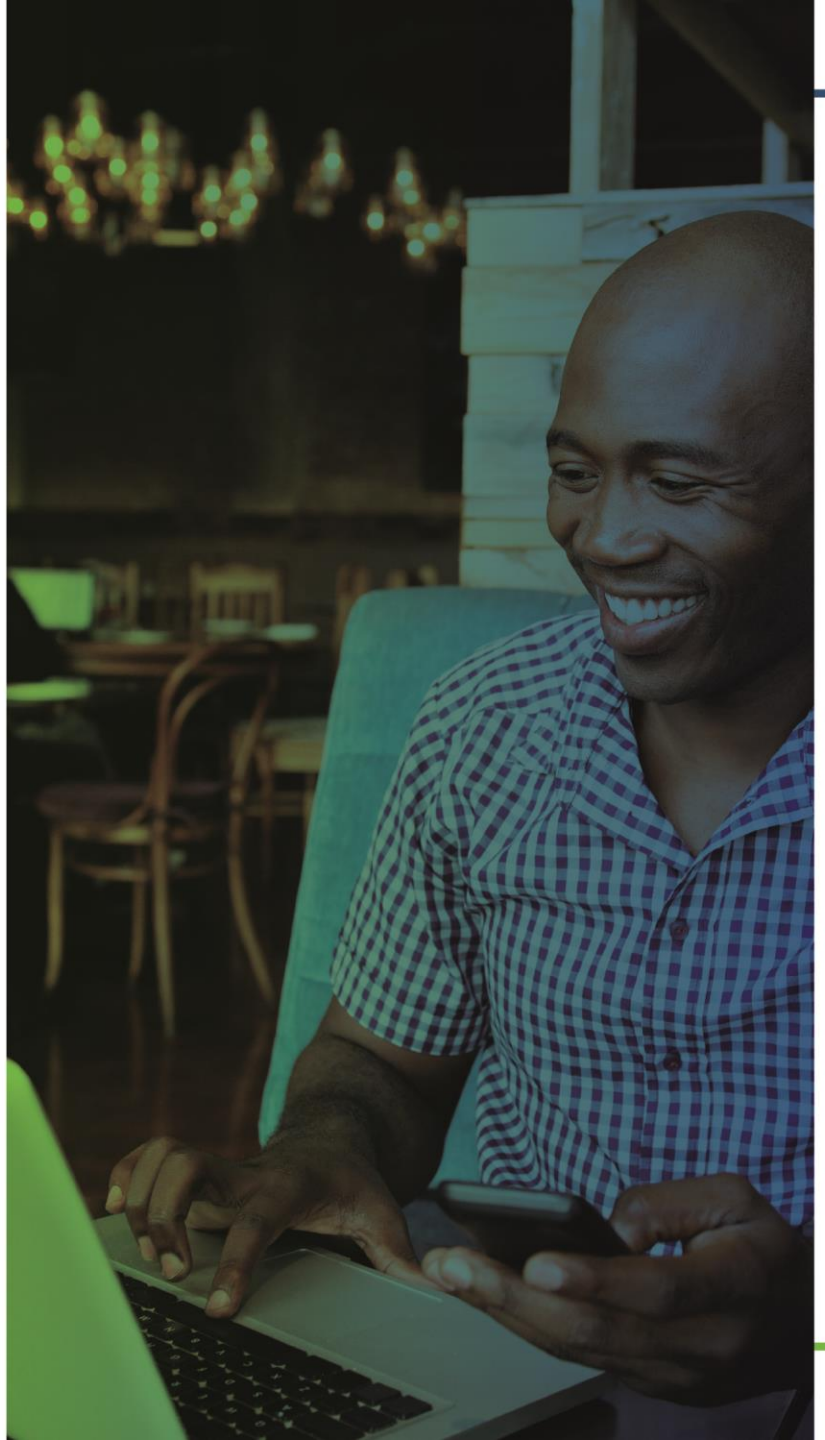


*illustrative

EHDS secondary use illustrative structure



*illustrative
Source: French Ministry of Health & Prevention



Primary Use of Health Data

Patient Rights and Access to Health Data

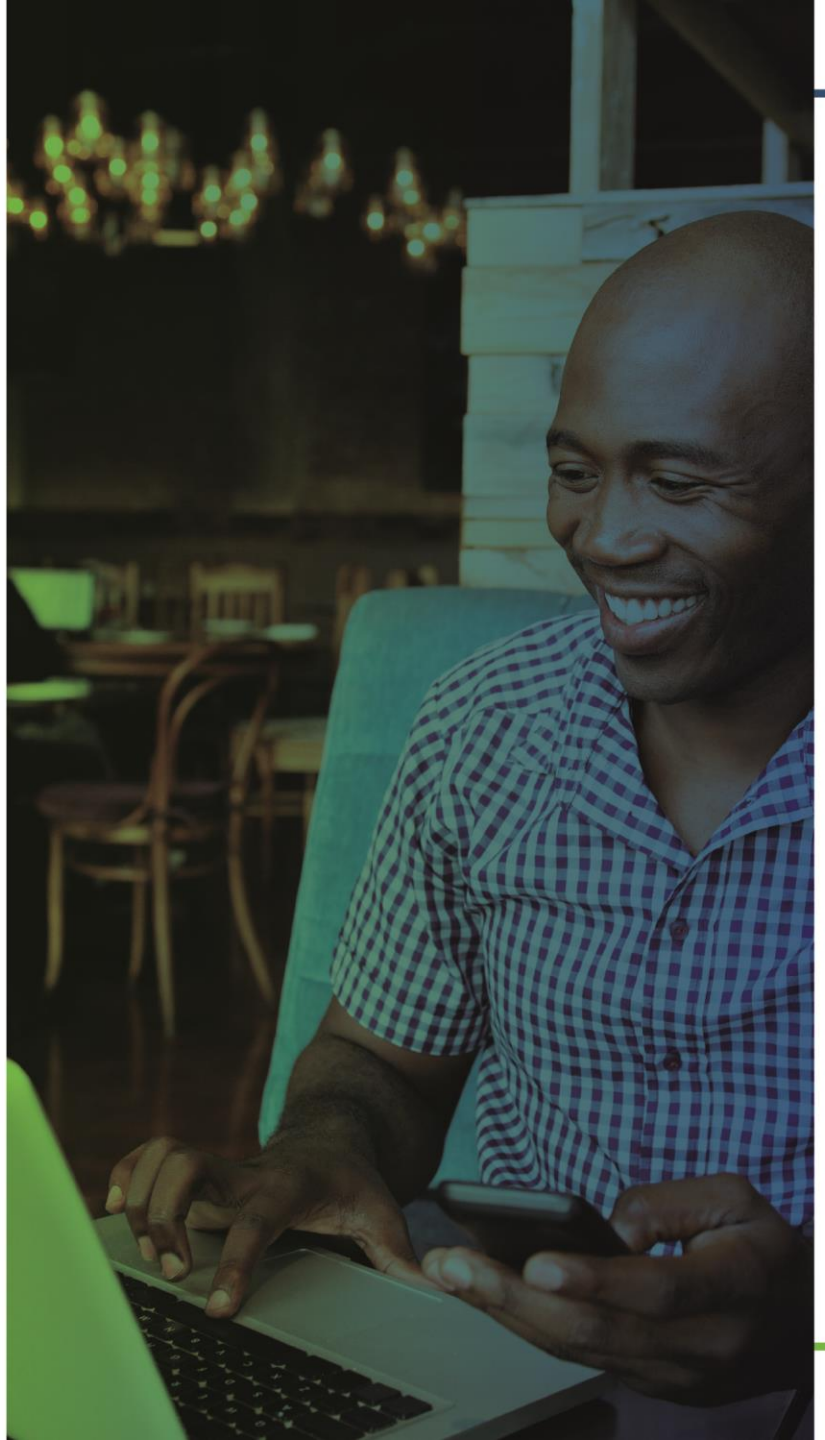
- Rules on rights for individuals in respect of their electronic health record
  - Right of access to electronic health data and right to restrict access
  - Right to rectification and portability, including across borders
  - Right to be informed of who accessed data
  - Right to insert data in Electronic Health Records (EHR)
- Rules on data access among health professionals for healthcare purposes
  - Enable cross-border healthcare

Electronic Health Records

- Rules on EHR and their interoperability
  - Essential requirements for EHR set out in Annex and common specifications to be adopted, including European electronic health record exchange format
  - Declaration of conformity and CE marking required
  - Specific documentation and transparency requirements
  - Public database of EHR that received declaration of conformity

Wellness apps

- If wellness app claims operability with EHR system, label required, issued by the app manufacturer
- Label contains information on the app and its validity period (not longer than 3 years)
- User must be informed of interoperability and its effect
- Interoperability does not mean automatic sharing
  - User in control of what is shared with EHR system



Secondary Use of Health Data

Policy Objective

- Recital 37b

  *The secondary use of electronic health data can bring **great societal benefits**. The uptake of real-world data and real-world evidence, including patient-reported outcomes, for evidence-based regulatory and policy purposes as well as for research, health technology assessment and clinical objectives should be encouraged. Real-world data and real-world evidence have the potential to complement health data currently made available. To achieve this goal, **it is important that data sets made available for secondary use by the present Regulation are as complete as possible.***

- Recital 38

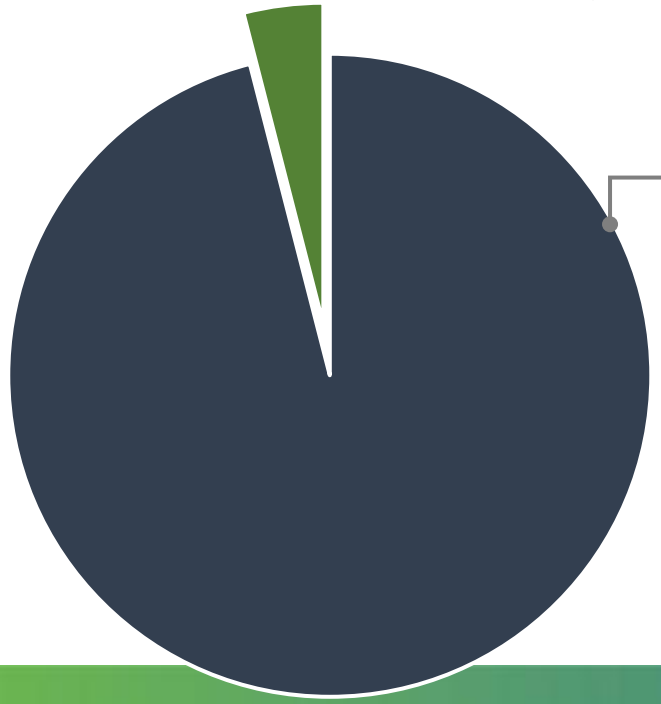
  [...] much of the existing health-related data is not made available for purposes other than that for which they were collected. This limits the ability of researchers, innovators, policy-makers, regulators and doctors to use those data for different purposes, including research, innovation, policy-making, regulatory purposes, patient safety or personalised medicine. **In order to fully unleash the benefits of the secondary use of electronic health data, all health data holders should contribute to this effort** in making different categories of electronic health data they are holding available for secondary use [...]

Example: Novel Sources of Healthcare Data outside of Clinical Trials can be used to Support Medicines Development and Approval

- Most sources are underutilized, including imaging data

Clinical trial data are available in only ~3% of all patients[1,a]

- Clinical signs and symptoms
- Imaging (radiology and pathology)
- Laboratory tests



Deeper insights can be gained from RWD sources

- Registries (product or patient/disease)
- Health insurance claims and billing
- Prescription drug databases
- Paper healthcare records
- Health surveys (patient reported outcomes)
- Imaging (routine assessments)
- Electronic healthcare records

Scope

- EHDS provides a mechanism for the re-use of health data for specific purposes
- Broad and diverse set of data (personal and non-personal), including:
  - EHR
  - Genetic data
  - Clinical trial data, registries and biobanks
  - Pathogen data
- Data held by a "data holder"
  - Territorial scope is unclear

Purposes

- List of allowed purposes, for example:
  - Public health and serious cross-border threats
  - Policy making
  - Scientific research (e.g., development and innovation, training algorithms such as in AI)
- List of prohibited purposes, for example:
  - Taking decisions detrimental to a natural person or group of natural persons
  - Advertising
  - Developing products harmful to health (e.g., illegal drugs, alcohol, weaponry)
- EHDS does not prevent data sharing outside the context of EHDS

Main Stakeholders

- Health Data Access Body (HDAB)
  - Public body to be set up by Member States
  - Publishes catalogue of available data sets
  - Grants permits to data users and makes data available to data users
  - Enforces EHDS
- Data holder
  - Entity having control over electronic health data
  - Provide a catalogue of data sets to HDAB
  - Make available data to HDAB upon request of HDAB
  - May request a fee

Main Stakeholders

- Data user
  - Individual or organization seeking access to data for an allowed purpose
  - Must obtain a permit
  - Only access to anonymous or pseudonymous data
  - May not attempt to re-identify individuals
  - Only in the EU, unless Commission adopts implementing act
- Individuals
  - Have a right to opt-out from having their personal health data re-used (exceptions for public bodies)

Process

- Data user makes access request to HDAB
- HDAB provides permit to data user
- HDAB contacts relevant data holders to provide data
- HDAB makes data available to data user on its secure platform
- Data user can access data on secure platform and download anonymous data
- Data user publishes results

Process - Concerns

- IP/trade secret protection
  - Vague language in the text
  - Data holder can provide an indication in the data catalogue
  - Only the HDAB decides what is IP/trade secret protected or not
  - Specific procedure in case of disagreement with data holder
- Anonymization
  - Core concept of EHDS, but standard is notoriously unclear and context-specific
  - Who will decide on standard of anonymization, who will anonymize and when?
- Personal data – GDPR legal basis
  - Data holder – legal obligation to share
  - Data user – if access to pseudonymous data, EHDS offers legal basis for Art. 9 derogation

International Transfer Restrictions

- Personal health data = GDPR
- Non-personal health data
  - All EHDS data is qualified as highly sensitive in accordance with Data Governance Act
  - Restrictions on transfers to third countries
    - Only apply to data held by HDAB (not the data holders)
  - Restrictions on Government access to data
    - Only applies to data held by HDAB and data obtained by data users
  - Restrictions can only be overcome by Commission Implementing Act (*cfr*. adequacy decision under GDPR)

Timelines Secondary Use

- EHDS informally adopted in April 2024
  - Final sign-off expected in Autumn 2024

- Secondary use provisions of EHDS start applying **four years** after its entry into force
  - Except for some data categories, such as clinical trial data and human genetic data, it is six years
  - Other timelines in specific cases

Additional resources

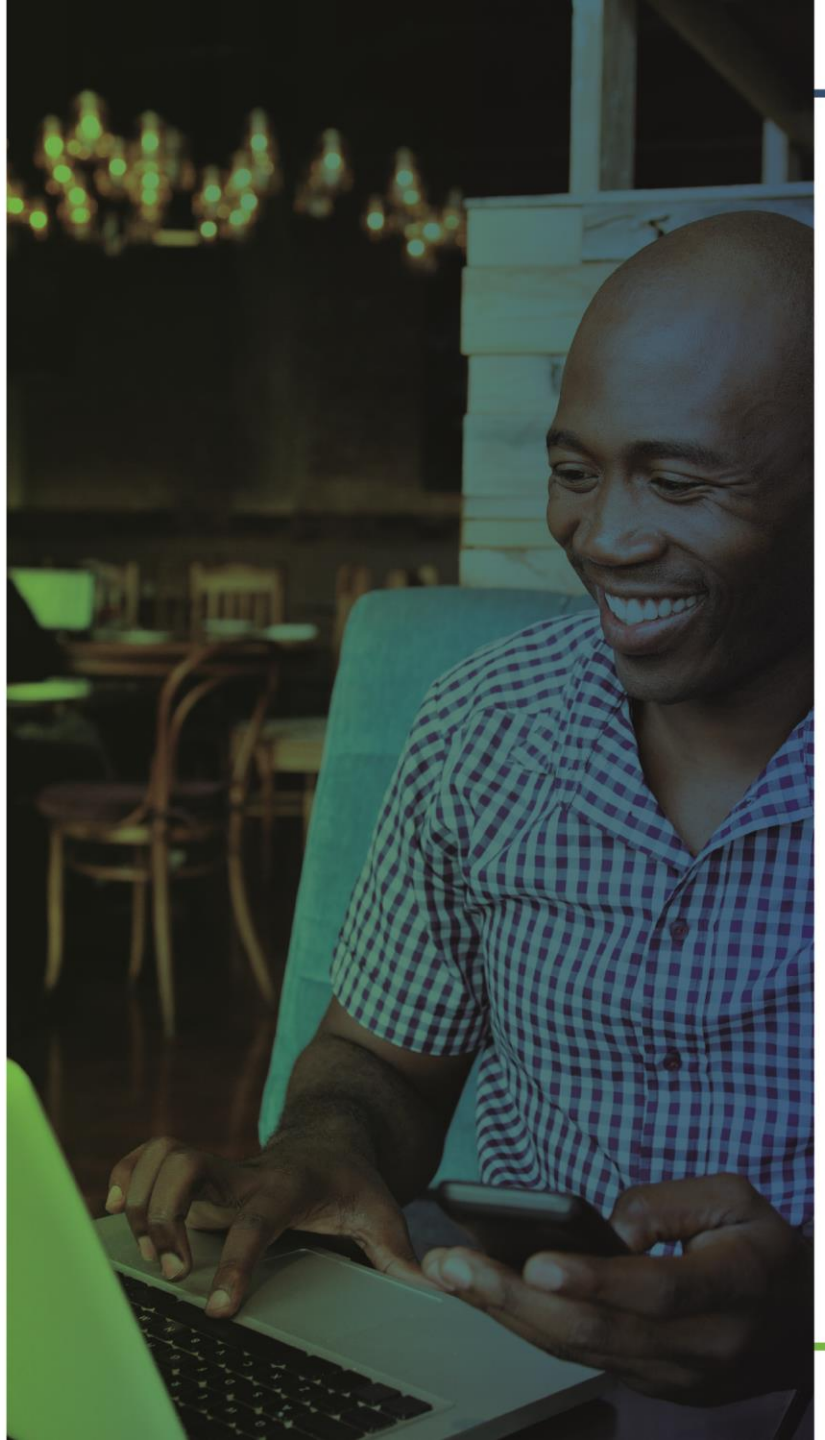
- Final compromise text with a view to agreement (18 March 2024): https://www.consilium.europa.eu/media/70909/st07553-en24.pdf

European Commission

- EHDS webpage: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
- FAQ: https://ec.europa.eu/commission/presscorner/detail/en/QANDA_24_2251
- Factsheet: https://ec.europa.eu/commission/presscorner/detail/en/FS_24_1347
- Proposal on the European Health Data Space (3 May 2022)
- https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF

IAPP resources

- EU Data Governance Act: 101: https://iapp.org/resources/article/eu-data-governance-act-101/
- EU Data Act 101: https://iapp.org/resources/article/eu-data-act-101/
- EU NIS2 Directive 101: https://iapp.org/resources/article/eu-nis2-directive-101/
- IAPP article: "European Health Data Space: Revolutionizing health care, scientific research in the EU," Kristof Van Quathem (23 May 2024): https://iapp.org/news/a/european-health-data-space-revolutionizing-health-care-scientific-research-in-the-eu



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