# EU BIG DATA Stakeholder Forum
# European Health Data Space

*Andrzej RYS, Director*

*Directorate B - Health systems, medical products and innovation*

*Directorate-General for Health and Food Safety*

# Big Data and the EHDS

- The European Health Data Space aims to bring European digital health to the 21st Century
- Key challenges include the fragmentation of data reuse frameworks across the EU and conditions for access / means to control data use and reuse.
- EHDS aims to bring real value from health data to patients, through improvement of primary care, easier exchange of health data and promoting reuse of health data for research, innovation and public oversight
- Patients should have an actionable right to data control and understand how their health data is processed by whom for which purposes

European Commission

# European Health Data Space

## Use of data for healthcare (primary)

### Sharing of health data for healthcare

**Problems**

- Limited control of patients over their health data
- Limited interoperability between health care providers

**Areas of work**

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

### Single market for digital health products and services

**Problems**

- Uneven national legislative frameworks
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

**Areas of work**

- Eliminate barriers to free movement
  - Labelling
  - Interoperability
  - Reimbursement
  - Liability

## Re-use of health data (secondary)

### Access to health data for research, innovation, public health policy making

**Problems**

- Low re-use of health data
- Cumbersome cross-border access to health data
- Fragmented digital infrastructures

**Areas of work**

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

### AI

**Problems**

- Limited provision of data for training of AI
- Difficulties for regulators to evaluate AI algorythms
- Uncertainty on AI liability in health

**Areas of work**

- Support for development and rollout of AI
- Data for AI
- Support for regulators

# EHDS: articulation with EU regulatory framework

Cross-border healthcare Directive

GDPR

Data Governance Act

AI Act

Data Act

European Digital Identity (eIDAS)

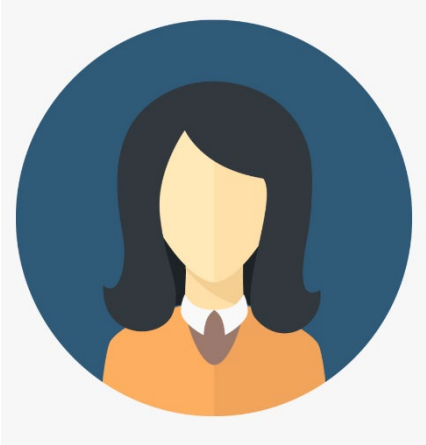
**European Health Data Space, specific rules for**

- Primary use of health data
- Secondary use of health data

**Ensuring compliance with**

- Cybersecurity regulatory framework
- Medical Devices regulation
- Pharmaceutical regulatory framework
- Cross-border health threats reg. framework


# Use of health data for healthcare, access to health data by citizens and healthcare professionals



## Access to health data in digital format

Today, a large number of EU citizens and healthcare professionals cannot access health data in a **digital format**. Data are often available in paper, or only a limited set of data categories are available in digital format.

## Interoperable health data

Health data is collected in such a way, that **the format is different** everywhere. This makes it impossible to understand the meaning of health data in different contexts. Therefore, interoperability standards are required to **promote wider use and understanding**.

## Tools and infrastructure

Member States organise health data access through different means. Some member states have patient or professional **portals** at the level of healthcare provider, region or nation, while others have apps or **personal data space** solutions. Also, registries of who should have **access** are also local, regional or national solutions.

The Commission set up **MyHealth@EU infrastructure** to facilitate cross-border exchange of health data (7 MS currently participate).

# Primary use of health data

The legislative proposal will focus on a number of areas:

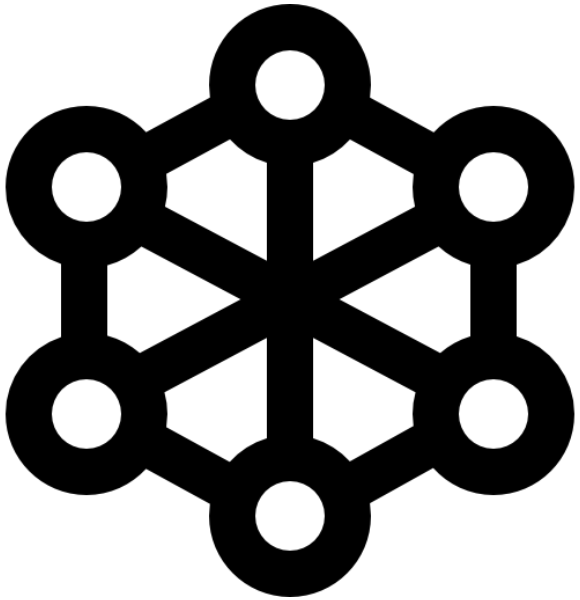
- Expanding the rights of citizens to **control** their health data
- Strengthening the position of the **eHealth Network**
- Expanding the **MyHealth@EU** services
- Promoting **interoperability** of health software solutions (including EHR, apps, medical devices)

European Commission

# Re-use of health data for research, innovation, policy making and regulatory decision

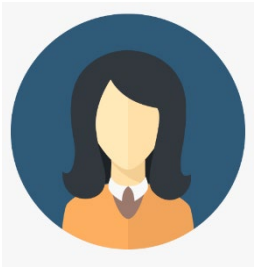
# Secondary use in the EHDS

Reuse of health data by researchers, policy-makers and industry



Rules, protocols and governance

Health data from patients and healthcare professionals



**Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format**

European Commission

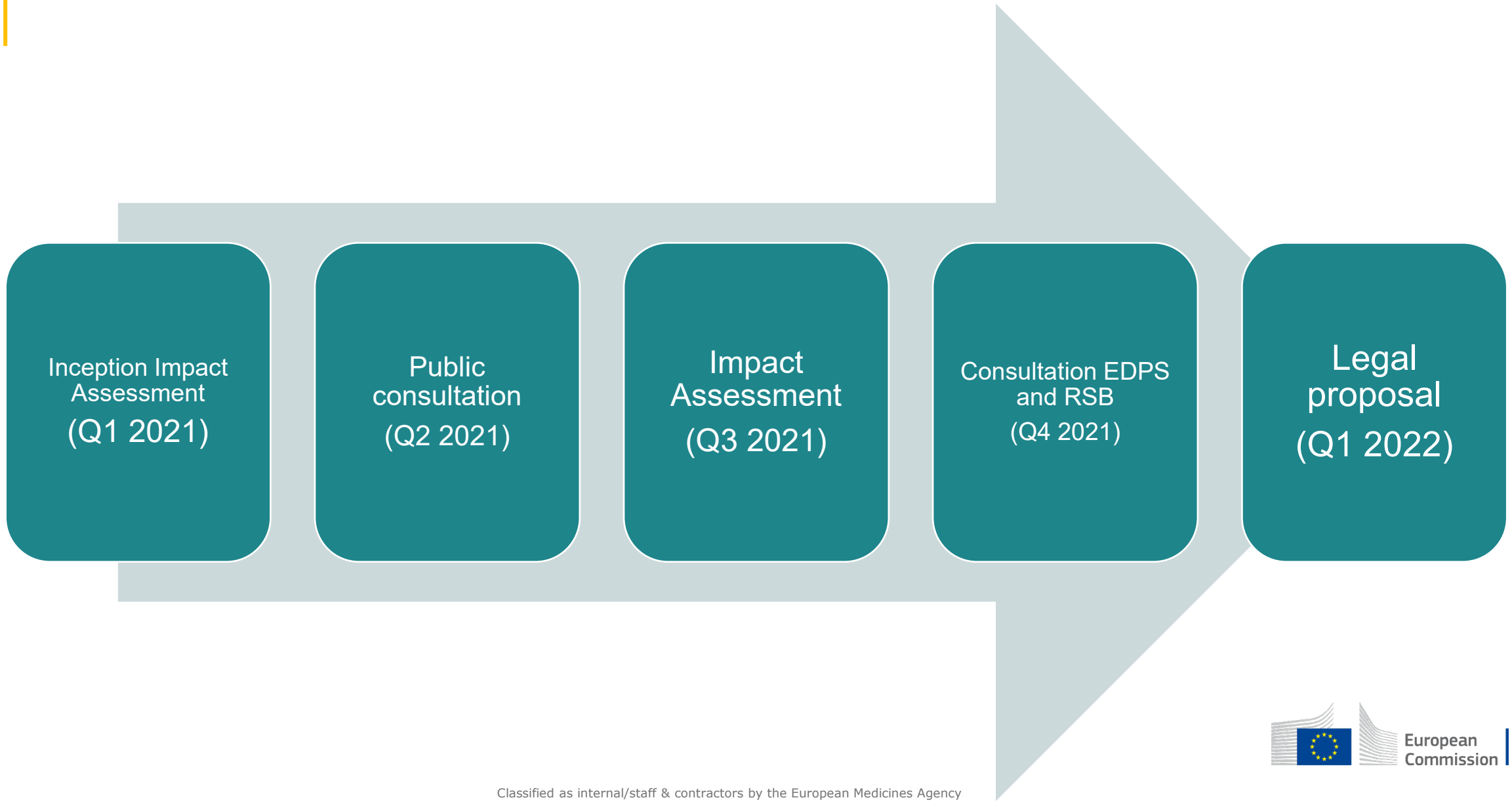
# Secondary use of health data

The legislative proposal will focus on a number of areas:

- Expanding on the existing **infrastructure** in Member States (Data Permit Authorities)
- Introduce a European **network** with common rules
- Promoting **interoperability** and **data quality** transparency
- Strengthening the **legal base** for the re-use of health data

European Commission

# EHDS legal proposal : next steps




# EC Pharmaceutical strategy

# EC Pharmaceutical strategy

- The strategy foresees the revision of the pharmaceutical legislation, to adapt to cutting-edge products, scientific developments and technological transformation
- The **revision of the general pharma legislation** due for adoption end of 2022 aiming to:
  - make the legislation future-proof, benefiting from digitalisation; and
  - reducing regulatory burden while ensuring that medicines are available to patients

European Commission

# EC Pharmaceutical strategy

- The use of **real world data (RWD)** holds great potential in several contexts to support healthcare decision-making, pharmacovigilance, drug discovery, etc
- The Commission will propose to **revise the pharmaceutical legislation to consider how to make best use of digital transformation.** This includes:
  - new methods of evidence generation and assessment, such as analysis of big and real world data to support the development, authorisation and use of medicines
- This is especially important in the field of medicines for rare diseases where collection of relevant data happens still after the marketing authorisation.
- The EMA will be a node in the EHDS infrastructure for secondary use of health data.

European Commission

# Thank you



European Commission