



European
Commission

EUROPEAN HEALTH DATA SPACE

#EUDigitalHealth

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- **Q1-** *You travel to another country, and you get sick. Doctors need to access your clinical data from your home country... would you feel comfortable with this access?*
- **Q2-** *What if such data was recycled by....*
- University researchers - for developing a new medicine?
- Companies - for profit?
- **Q3-** *Would it be the same if your data could not be linked to you?*



WHAT IS THE “EHDS”?

PRIMARY USE

- Processing health data for health services (e.g. prescription of medicines) = Q1

SECONDARY USE (data recycling)

- Processing health data for purposes different to healthcare delivery.
- E.g. scientific research related to health, health statistics, developing medicines and medical devices...(R&D) = Q2
- Training of algorithms, AI and digital health apps.

WHY A REGULATION? - CHALLENGES

- + **Superabundance of legislation** } GDPR, e-Privacy Dir., Clinical Trials Reg., Medical Devices Reg., NIS Directive, AI Act, Data Governance Act, Data Act....
- + **National level.** 1/2 MS do not have specific legislation on secondary use of electronic health data.
- + **Uneven implementation and interpretation of the GDPR.** E.g. art. 9: MS may introduce further conditions to the processing of health data.
= *Chaos*

PATIENTS' EMPOWERMENT

HOW? DATA PROTECTION. But...

- GDPR did consider many risks of AI.
- GDPR leaves much room for barriers to secondary use.
- GDPR requires data minimization, but how do we know exactly what data we need?
- GDPR provides many legal bases. It would be desirable to enhance OPT-OUT options + legal bases of public interest and the necessity for scientific research (over consent).



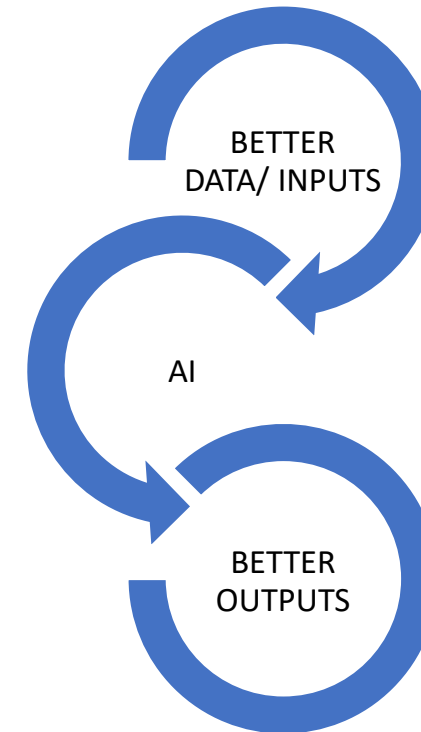
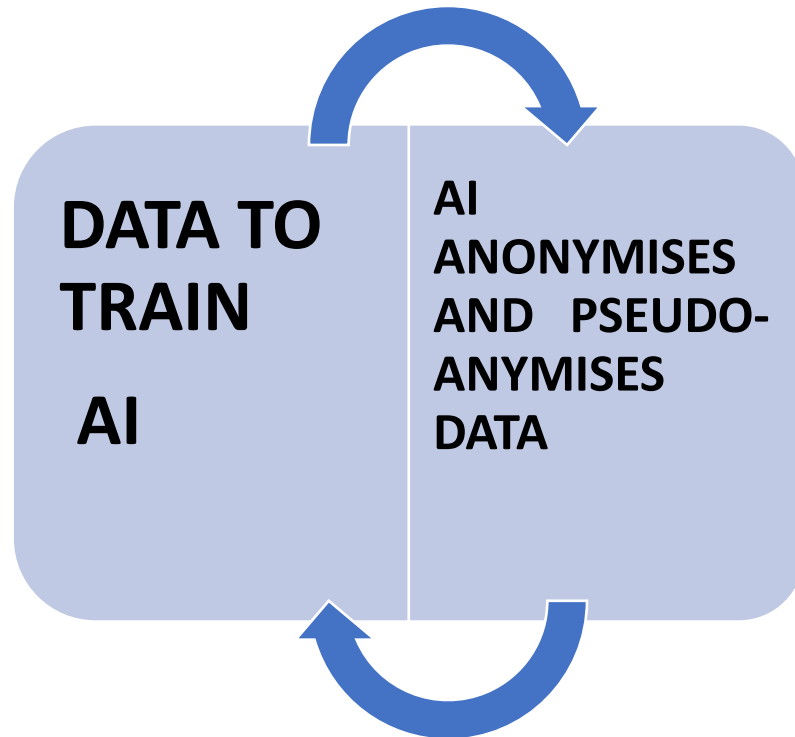
PATIENTS' EMPOWERMENT

HOW? AI - ANONIMISATION AND PSEUDOANONIMISATION

- =Q3
- When purpose not possible with anonymised data: pseudoanonymised
- **Prohibition:** data users shall not reidentify pseudoanonymised data
- *But...*
- No legal consequences? Paper tiger
- What about anonymised data?

PATIENTS' EMPOWERMENT

HOW? AI - SINERGY





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