



The Future of Secondary Use

Promises and Pitfalls of Health Data Unleashed

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Secondary Use of Health Data

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the European Health Data Space

Article 2, Definitions:

“secondary use of electronic health data’ means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. [...]”

Affected data categories (Article 33)

- EHR
- health-related administrative data (claims, reimbursement)
- medical devices, wellness applications, ...
- clinical trials
- human and pathogen genetic data
- data impacting on health, including social, environmental behavioural determinants of health
- ...

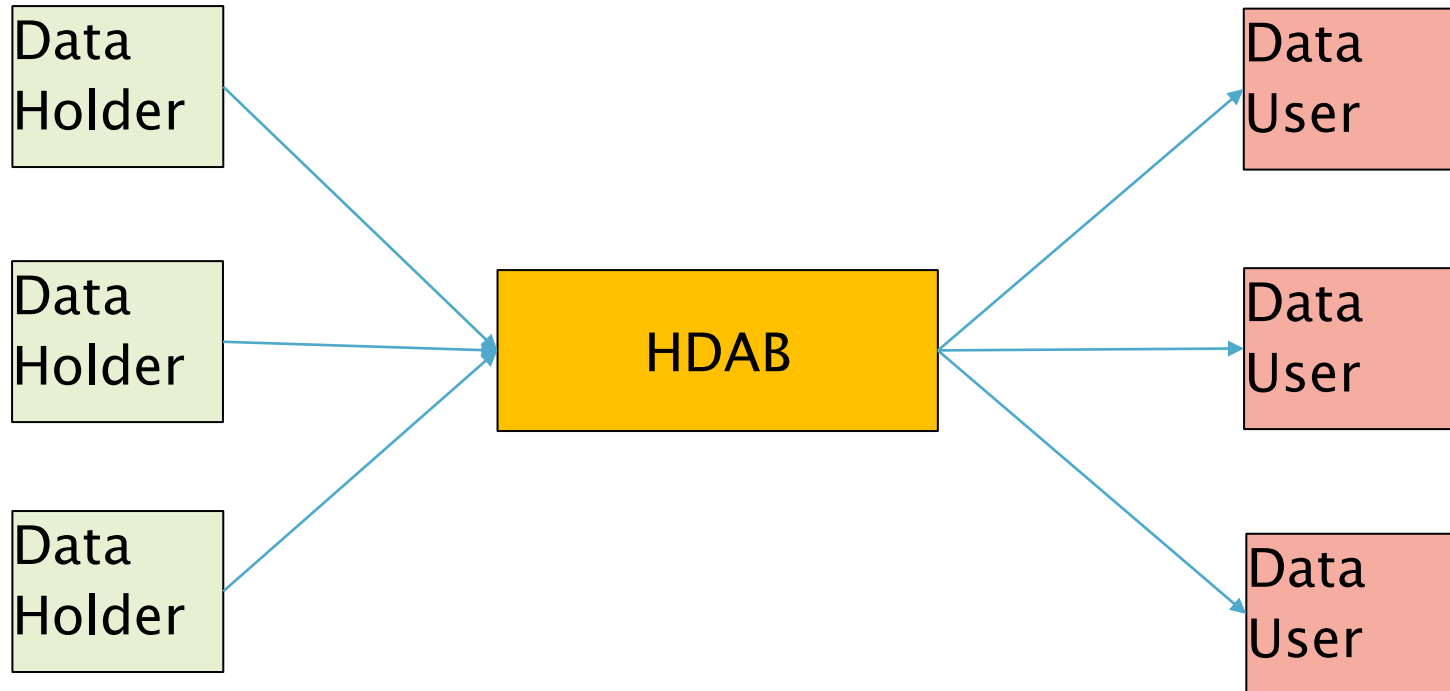
Purposes (Article 34) – The Promises!!!

- public interest (surveillance, quality, safety, ...)
- scientific research related to health or care sectors
- training, testing and evaluating of algorithms [...] contributing to the public health or social security, or ensuring high levels of quality and safety [...]

Prohibited (Article 35):

- decisions detrimental to a natural person
- insurance, advertising
- may harm individuals and societies

Health Data Access Body (Art. 36 – 39)



Looks simple, what's the fuss?

Health Data Access Body (Art. 36 – 39)

Establishment (when regulation in force):

- all the necessary national regulations,
- the infrastructure,
- the processes,
- requirements
 - standards and interfaces
 - IDs of records and of patients
 - ...
- ...

Preparation (now)!!!

Promise or Pitfall?

- scientific independency
- objectivity, neutrality
- ultima ratio: public benefit, common good
- open, honest, transparent discussions
- public discourse
- transparency
- trust

The Unavoidable Pitfall?

- data sharing vs. privacy
- society vs. individual
- public benefit vs. infringement of privacy
- Is the difference constant?
- Maximise benefit + minimise infringement?
- 2ndary use: aggregated information
 - aggregated analysis result = ideal anonymization
 - “anonymized” individual level data, in an SPE
 - pseudonymized individual level data, in an SPE

The Occasional Mini-Pitfall

- requirement: national dataset catalogue
- no requirement: hold all linked data centrally

- occasion: successful application
- minimisation:
 - only minimum necessary subsets of data
 - only from relevant data holders
- risk = provision:
 - most aggregated level possible
 - “most anonymised” level possible
 - SPE

Buzzwords!

- privacy by design
 - governance
 - processes
 - technical implementation
- data access application management
- case to case evaluation
 - scientific
 - ethical
 - risk-benefit
 - public interest
- ID management, data linkage
- ...

The not facing the pitfalls „Pitfall“

- pitfall = risk when we move
 - not to move = a risk, too
 - Can we afford to stay where we are?
 - The time is now. Let's move together.
-
- data = dog
 - No: Unleash the beast.
 - No: Tie each other up in leashes, like 10 dogs in the park.
 - Yes: Untie, but keep good leashes!

Untie, but keep good leashes!

