European Data Health Space (EHDS) – Data Protection by Design and by Default

(… some bits & pieces …)

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Barcelona, 28 February 2024

Plattform Privatheit

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Overview

https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

The EHDS

"The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at

- empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide, and support to their free movement, as well as fostering a genuine single market for electronic health record systems, relevant medical devices and high risk AI systems (primary use of data)
- providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data)"

And what about the GDPR?

Overview

1. What is the EHDS?
2. The notion of risk
3. Data protection by design in data sharin
4. Summary
5. Links

https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

The EHDS

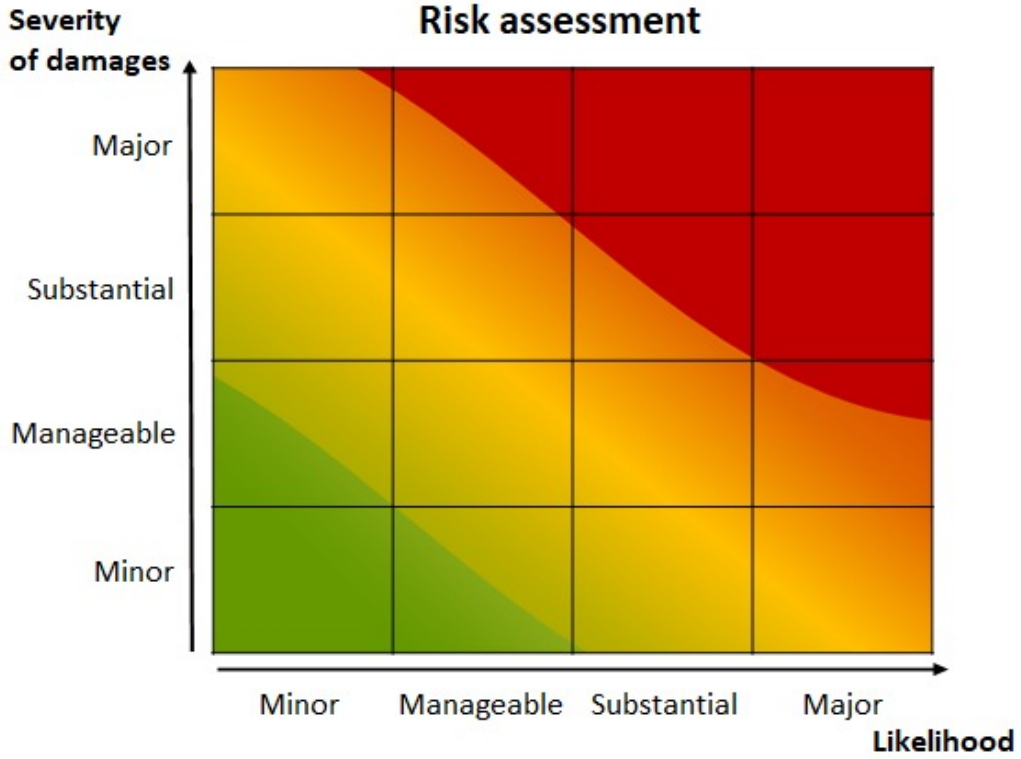
"The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at

> This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, […] [Data Governance Act COM/2020/767 final] and […] [Data Act COM/2022/68 final].
>
> This Regulation shall be without prejudice to Regulations (EU) 2017/745 and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.

↑ ***And what about the GDPR?*** ↑

Overview

Trustworthy? The GDPR's notion of risk



Risk for the rights and freedoms of natural persons – see Charter of Fundamental Rights

Source: 1) Internet Meme,
2) DSK on risk (Kurzpapier Nr. 18)

Overview

GDPR demands risk mitigation

High risk – not lawful without prior risk mitigation (design, technical and organisational measures)

Trustworthiness through appropriate built-in measures and checkability

Risks concerning health data

Examples in recital 75 of the GDPR:

- "physical, material or non-material damage"
- Personal data of vulnerable persons

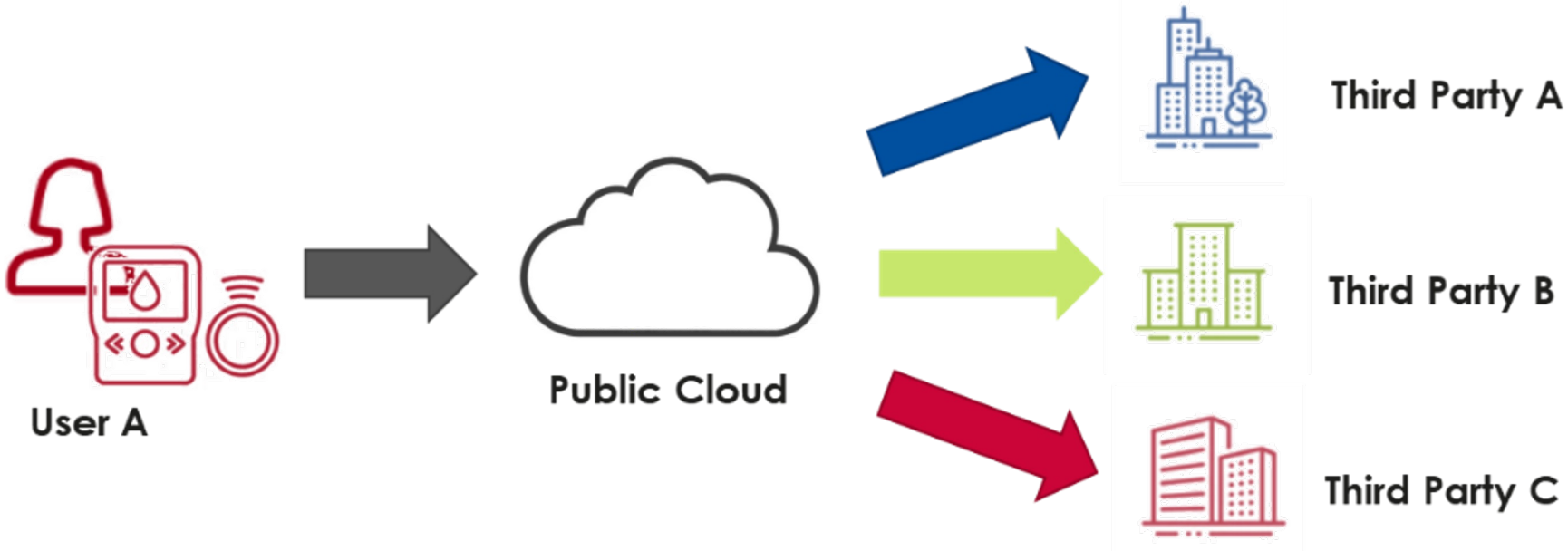
For health data:

- (Not only) security risks
- Wrong diagnosis
- Wrong treatment
- Loss of confidentialty
- Identification
- Economic or social disadvantage
- Discrimination
- Deprivation of rights and freedoms including data subject rights

Art. 25 GDPR:
Data protection by design and by default
i.e. through the entire lifecycle

Overview

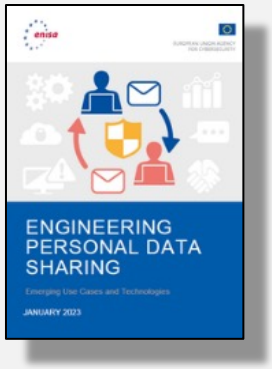
Data sharing scenarios
(same principle for public clouds and data spaces)



Generic model of user-controlled data sharing (Figure 1)

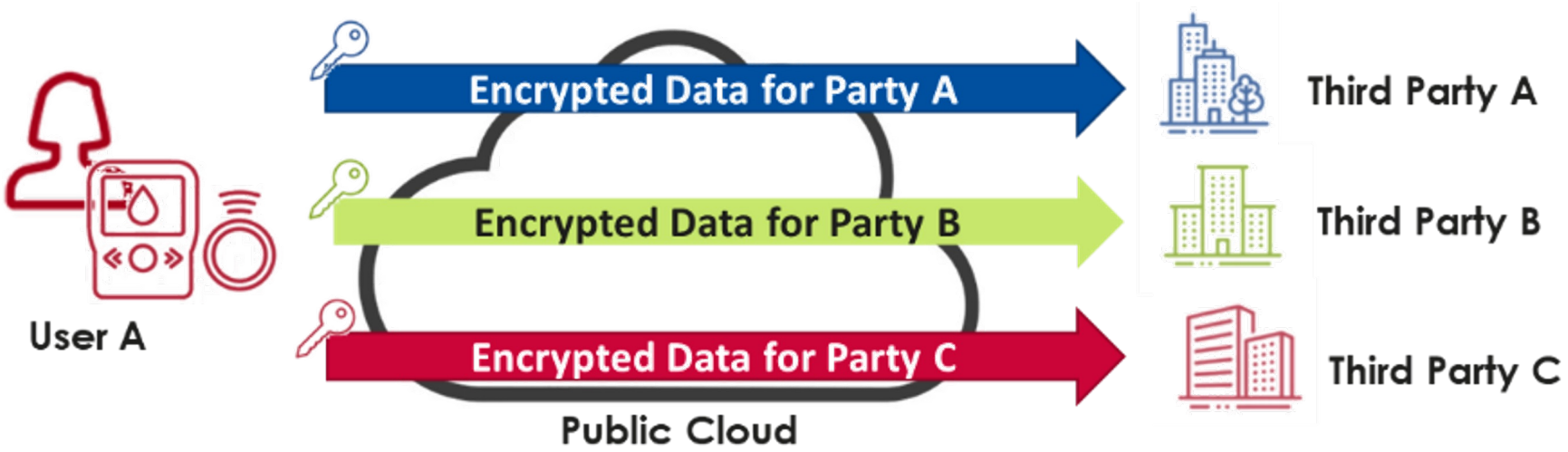
Source: ENISA Report 2023

Overview



Source: ENISA Report 2023

Data sharing with encryption: Asymmetric encryption [1.]

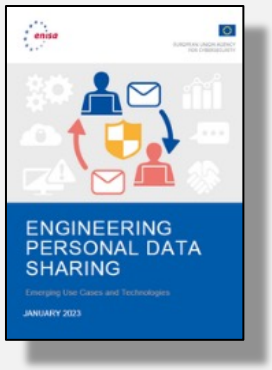


Encryption? – Sure thing.

Hmm, but we don't know all recipients beforehand.

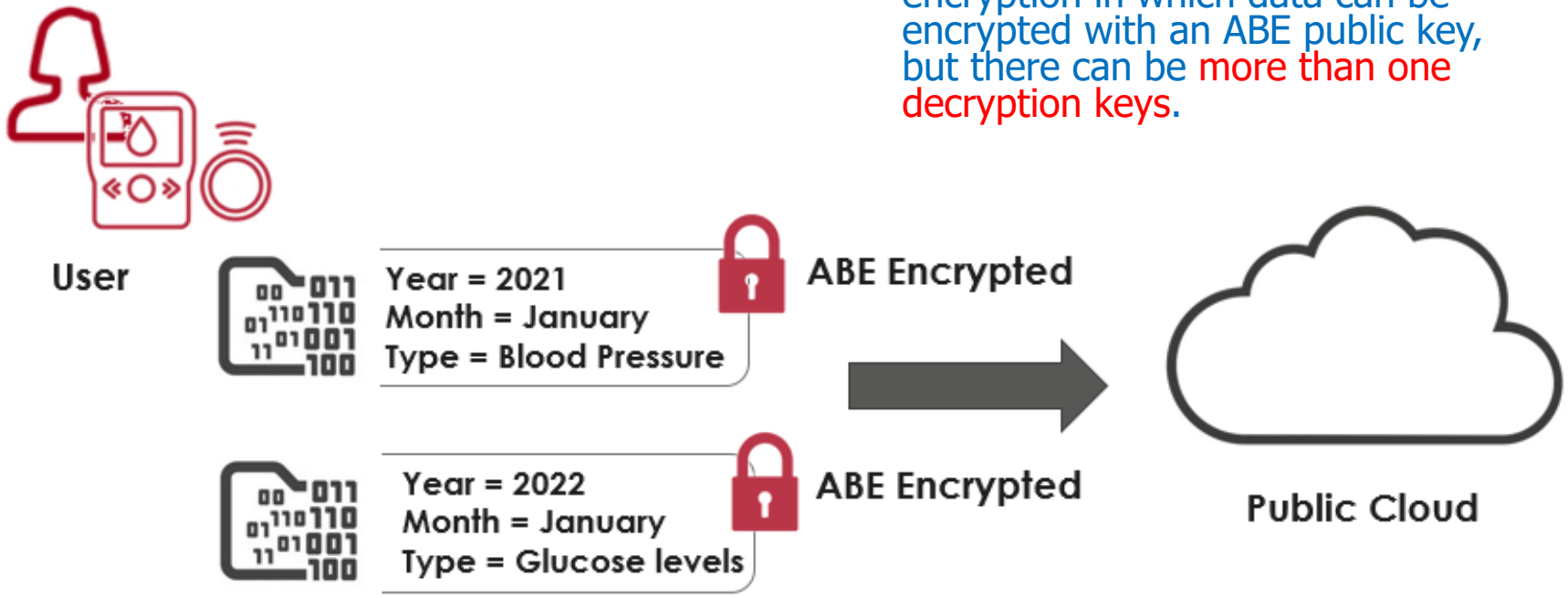
User-controlled data sharing through asymmetric encryption (Figure 2)

Overview



Data sharing with encryption: Attribute Based Encryption (ABE) [2.]

ABE: special type of asymmetric encryption in which data can be encrypted with an ABE public key, but there can be more than one decryption keys.

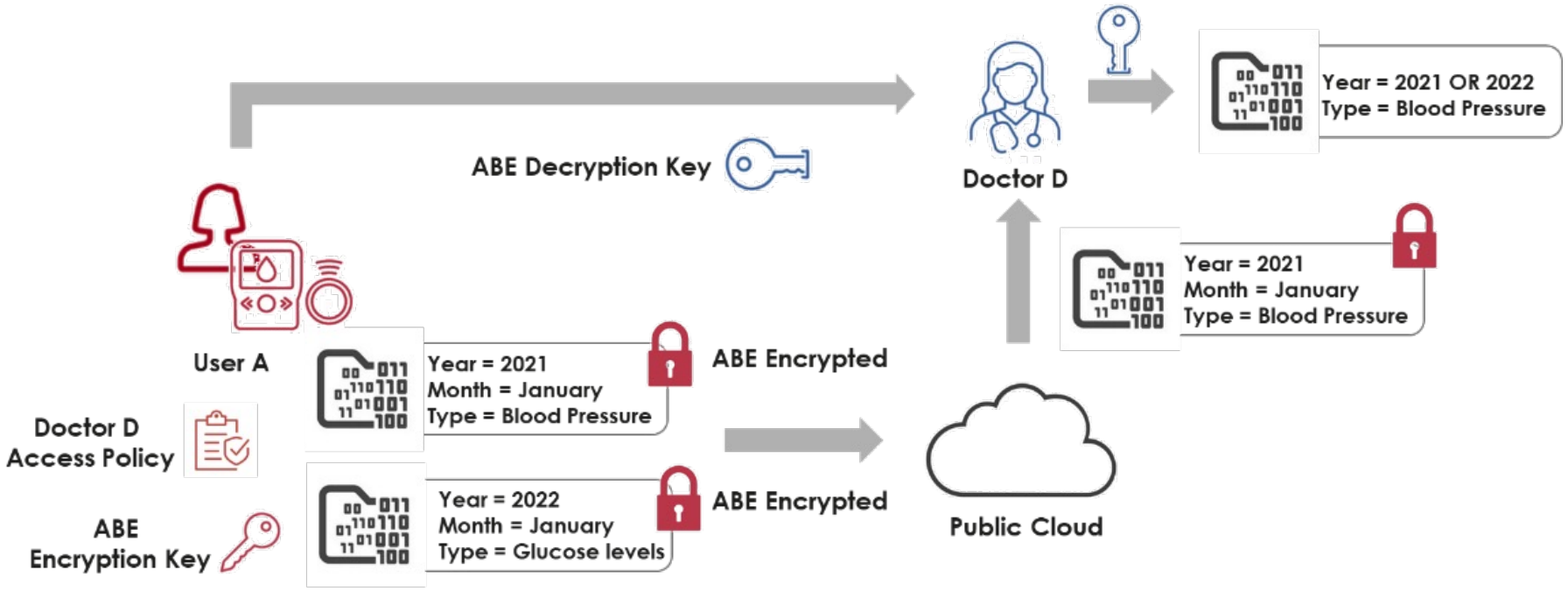


Storing encrypted objects to the cloud (Figure 3)

Source: ENISA Report 2023

Overview

Data sharing with encryption: Attribute Based Encryption (ABE) [2.]

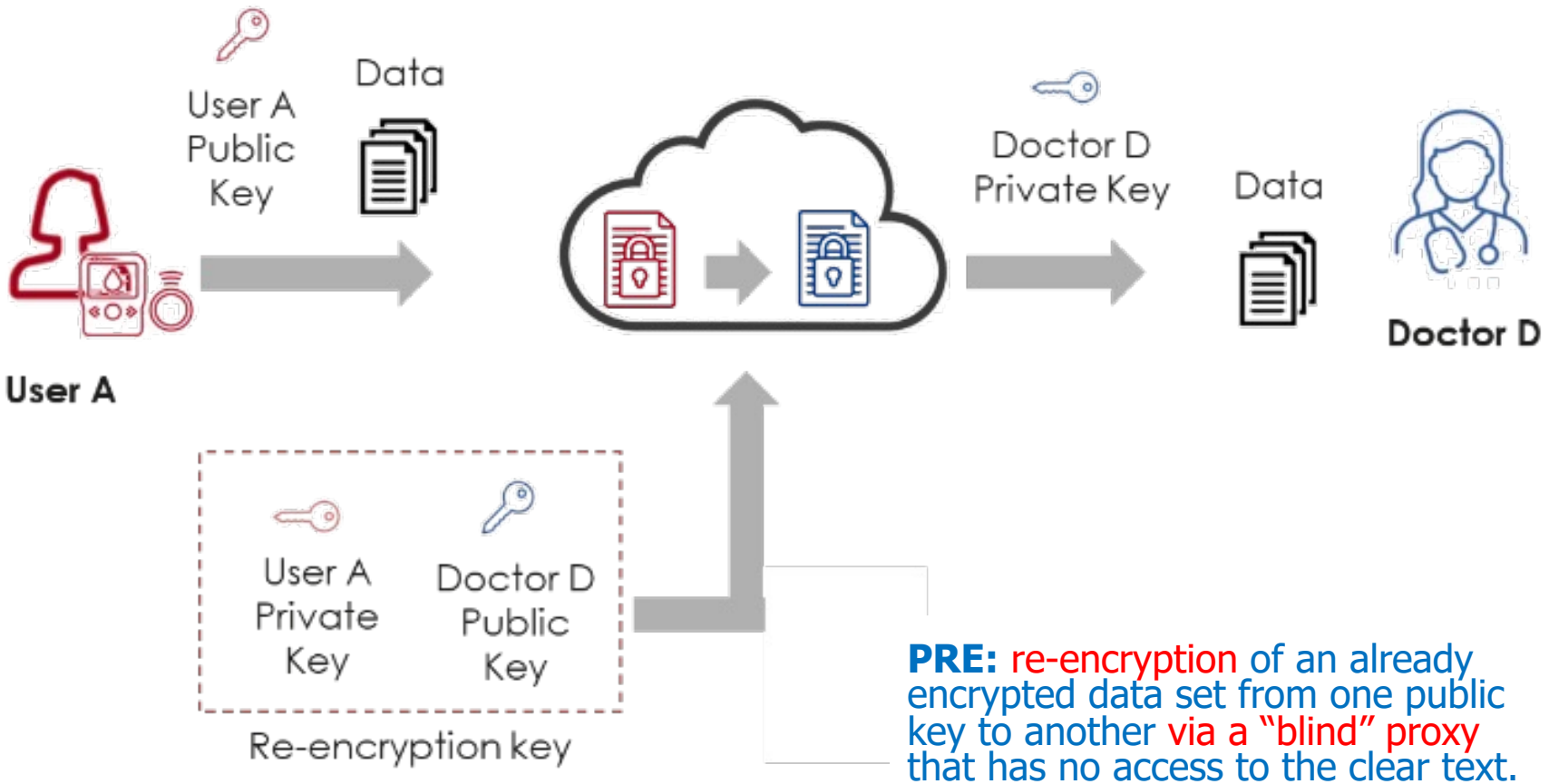


Sharing the ABE decryption key and encrypted data (Figure 4)

 Source: ENISA Report 2023

Overview

Data sharing with encryption: Proxy Re-Encryption (PRE) [3.]



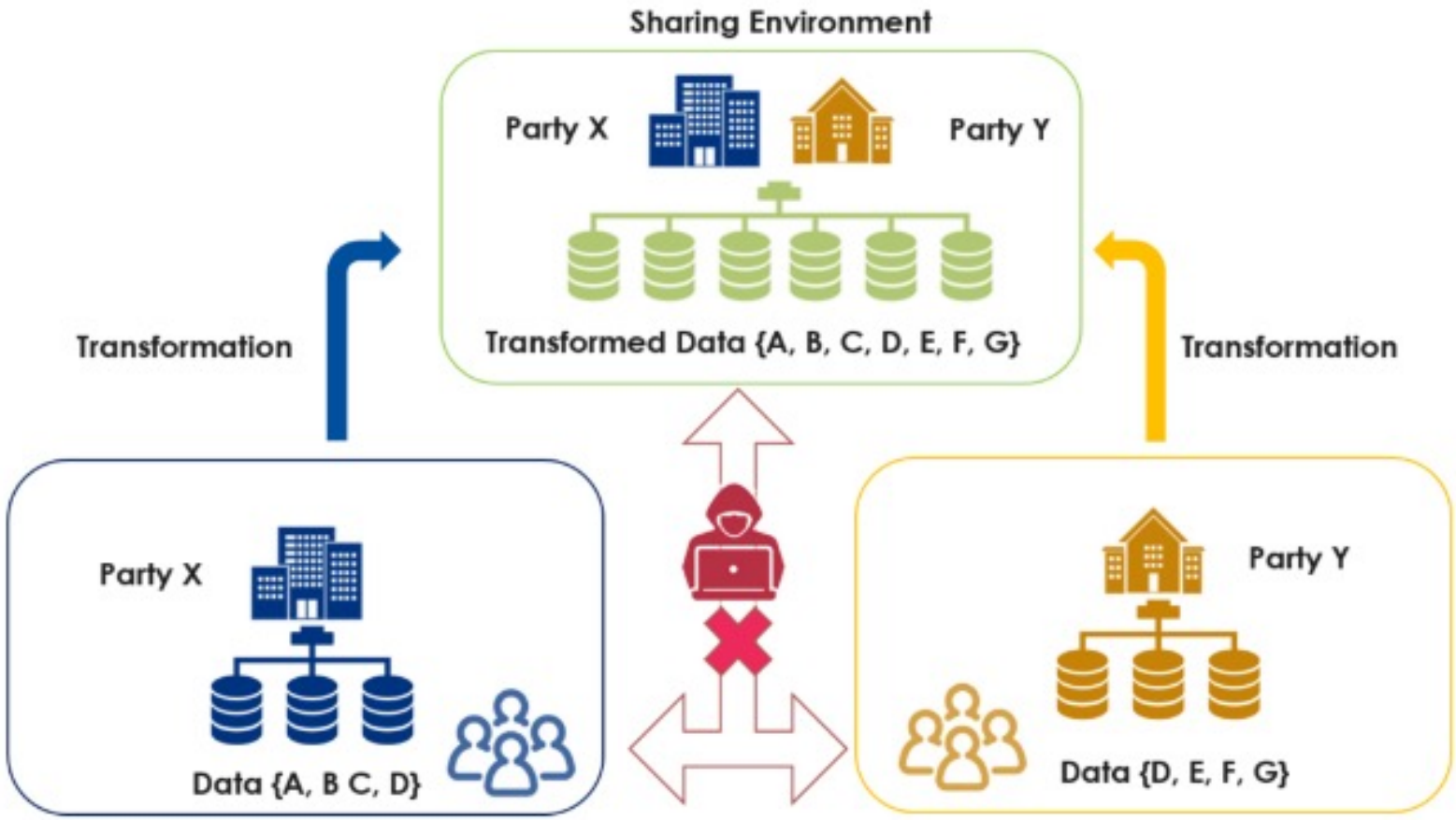
PRE: re-encryption of an already encrypted data set from one public key to another via a "blind" proxy that has no access to the clear text.

Proxy Re-Encryption process (Figure 5)

Source: ENISA Report 2023

Overview

For Data Spaces: prevention of identification for all unauthorised stakeholders

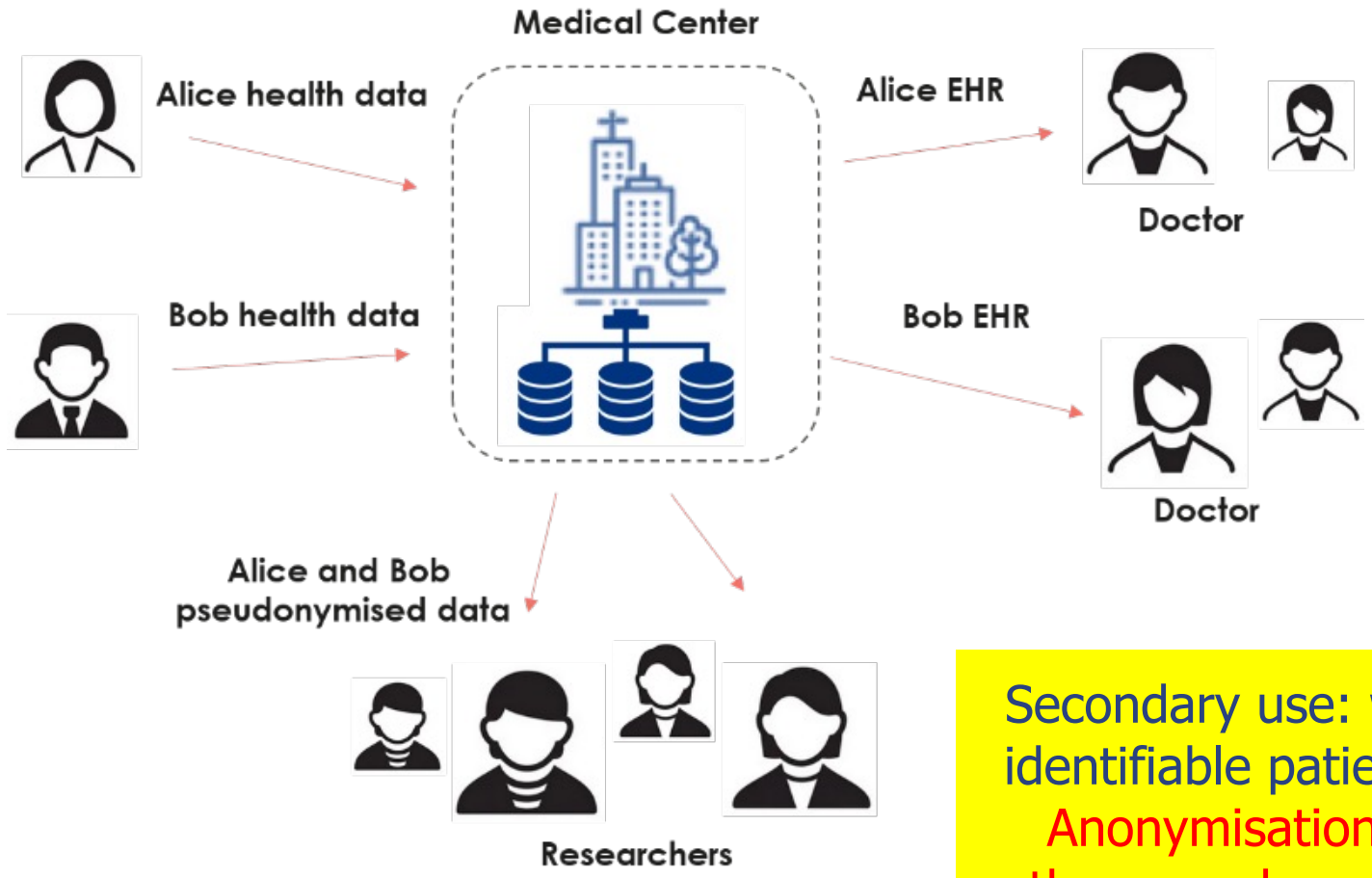


(Input +) Output Privacy Problem (Figure 3)

Source: ENISA Report 2024

Overview

Data sharing with pseudonymisation [4.]

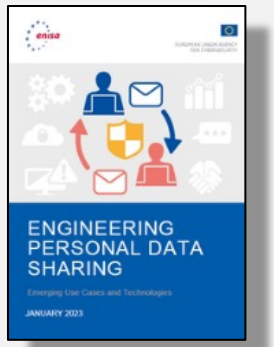


Large scale data gathering example (Figure 6)

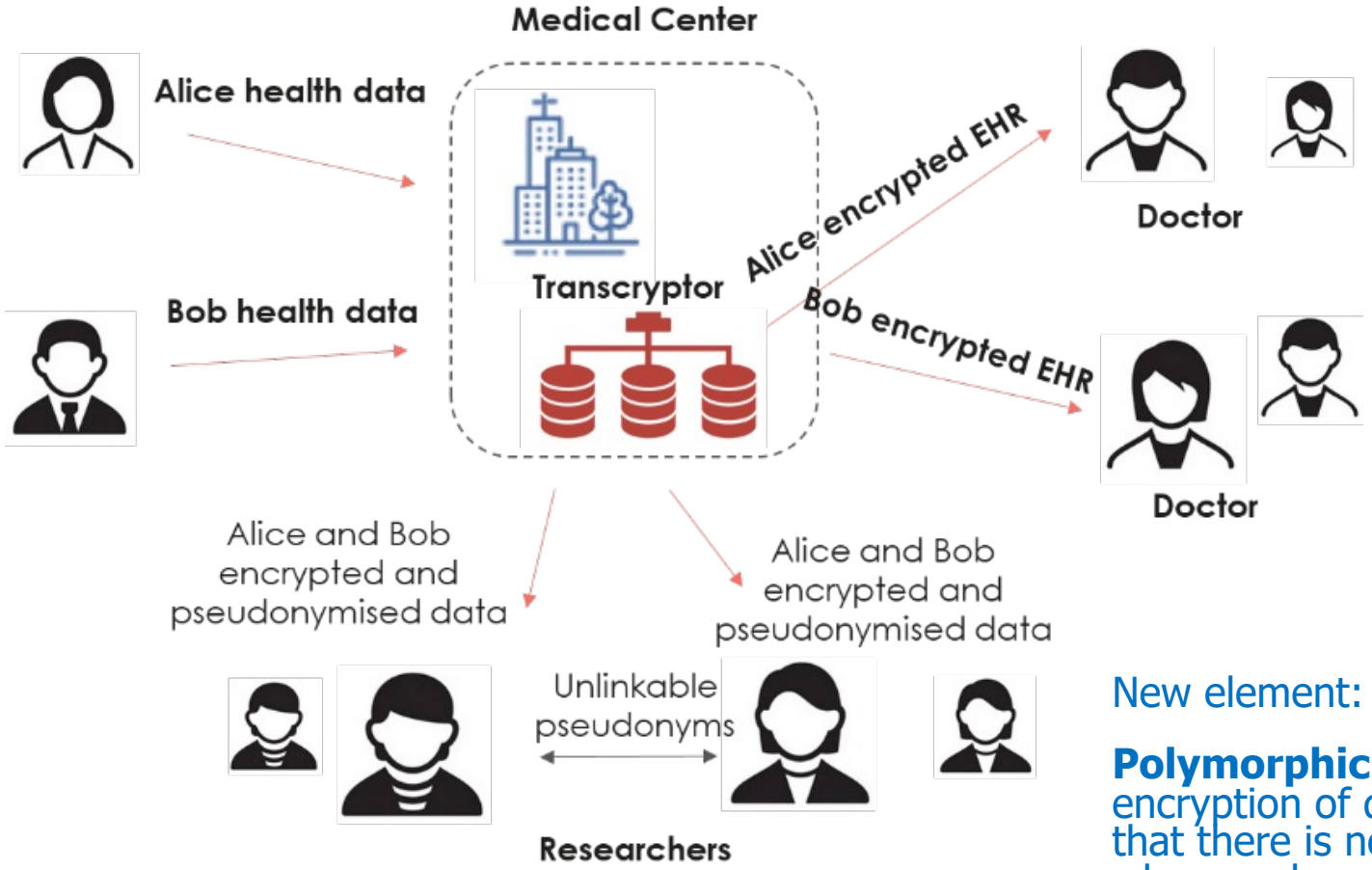
Secondary use: without identifiable patient data
Anonymisation? No, rather pseudonymisation!

 Source: ENISA Report 2023

Overview



Data sharing with Polymorphic Encryption and Pseudonymisation (PEP) [5.]



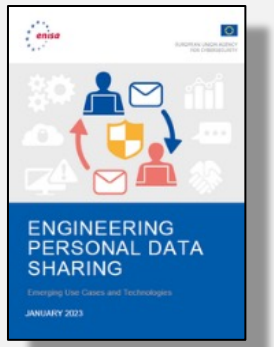
New element: Transcryptor.

Polymorphic encryption: enables encryption of data in such a way that there is no need to fix a priori who can decrypt the data.

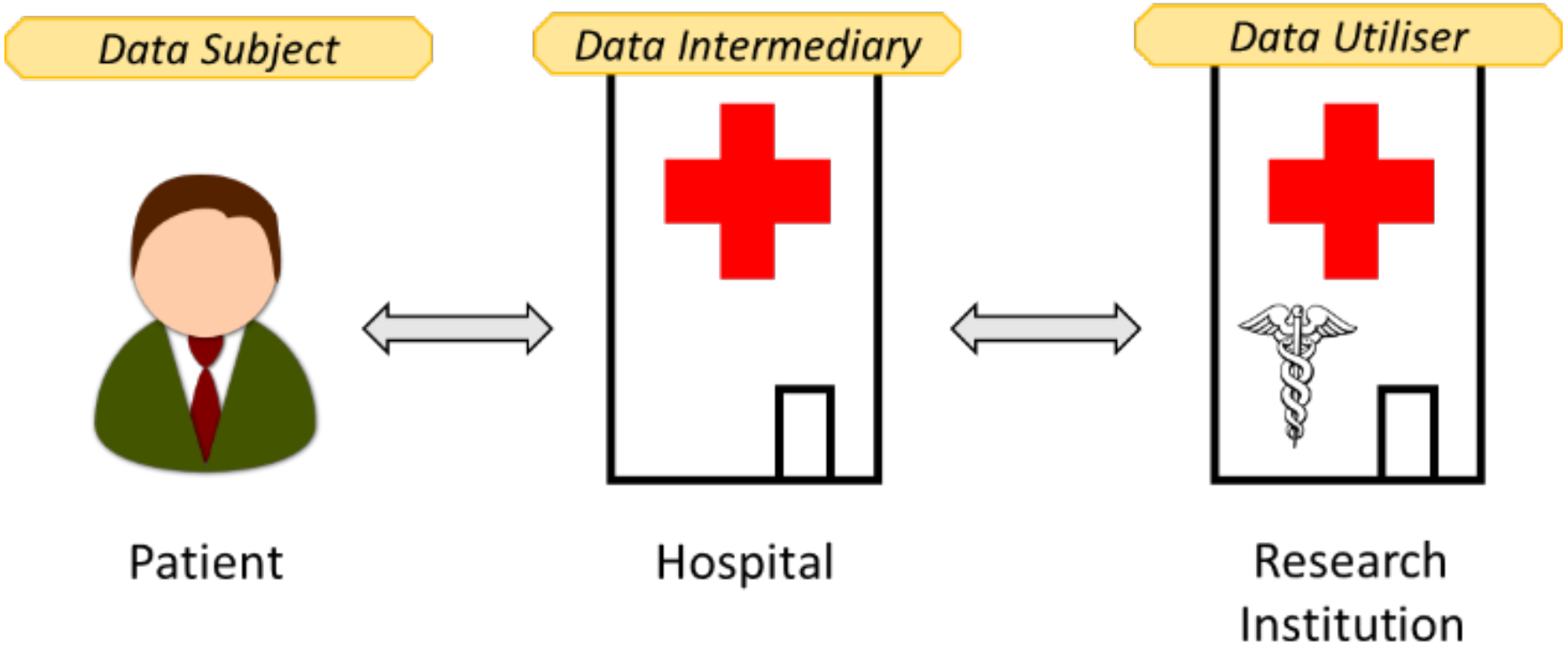
Using PEP in large scale data gathering (Figure 7)

Source: ENISA Report 2023

Overview



Data sharing with intermediaries enforcing conditions [6.]



Data sharing scenario with data intermediaries (Figure 14)

 Source: ENISA Report 2023

Overview

Machine-Readable User's Data Processing Preferences / Conditions [6a.]

User A Data Processing Preferences
I want my data to be processed only by Utiliser X, Y & Z
I want my data to be processed only within the EU
I want my data to be processed only for 2 years
I want my data to be processed only for medical research purposes

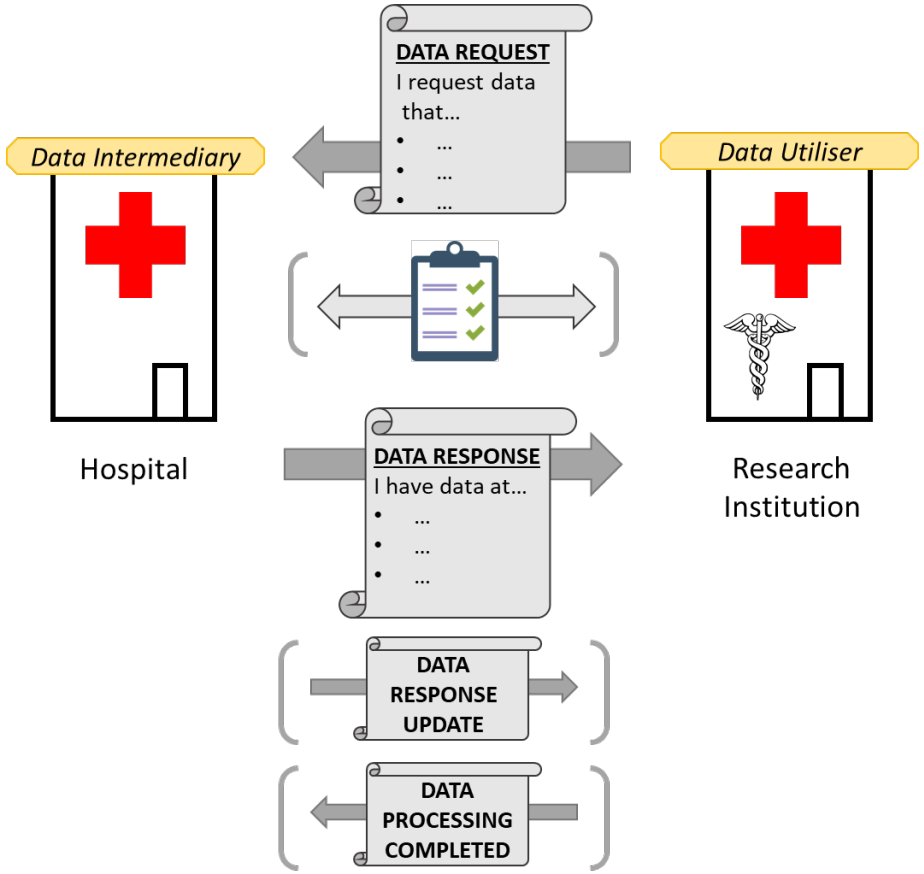
Should it be more than "consent" or "opt-out"?

Data Processing Preferences Example (Figure 15)

Source: ENISA Report 2023

Overview

Data sharing protocols for interacting with data intermediaries [6b.]



Goals:

- accountability (Art. 5 (2), Art. 24 GDPR)
- enabling data subjects to exercise their rights

Interaction between Data Intermediary and Data Utiliser (Figure 16)

Source: ENISA Report 2023

Overview

Summary & outlook

- Processing of health data = high risk
- GDPR demands
  - Above all: risk mitigation
  - Art. 25: Data protection by design and by default
  - Encryption & pseudonymisation
  - Data subject rights
  - Data protection management

- Note: anonymisation in the health context is often not possible. Or not helpful.
- EHDS = infrastructure – we need proper standards & defaults, not one centralised huge database without user control

Overview

Links

- DSK: The Standard Data Protection Model Version 3.0a (English version), 2022, https://www.datenschutz-mv.de/static/DS/Dateien/Datenschutzmodell/SDM_V3_en.pdf
- EDPB: EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 2022, https://edpb.europa.eu/our-work-tools/our-documents/edpbedps-joint-opinion/edpb-edps-joint-opinion-032022-proposal_en
- ENISA: Data Protection Engineering, January 2022, https://www.enisa.europa.eu/publications/data-protection-engineering
- ENISA: Deploying Pseudonymisation Techniques, March 2022, https://www.enisa.europa.eu/publications/deploying-pseudonymisation-techniques
- ENISA: Engineering Personal Data Sharing, January 2023, https://www.enisa.europa.eu/publications/engineering-personal-data-sharing
- ENISA: Engineering Personal Data Protection in EU Data Spaces, January 2024, https://www.enisa.europa.eu/publications/engineering-personal-data-protection-in-eu-data-spaces