

# Harmonization after the GDPR

Divergences in the rules for health data sharing

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Adult Immunization Board (AIB)

Technical meeting 2026:

Vaccine records and recall systems in Europe to strengthen adult vaccination

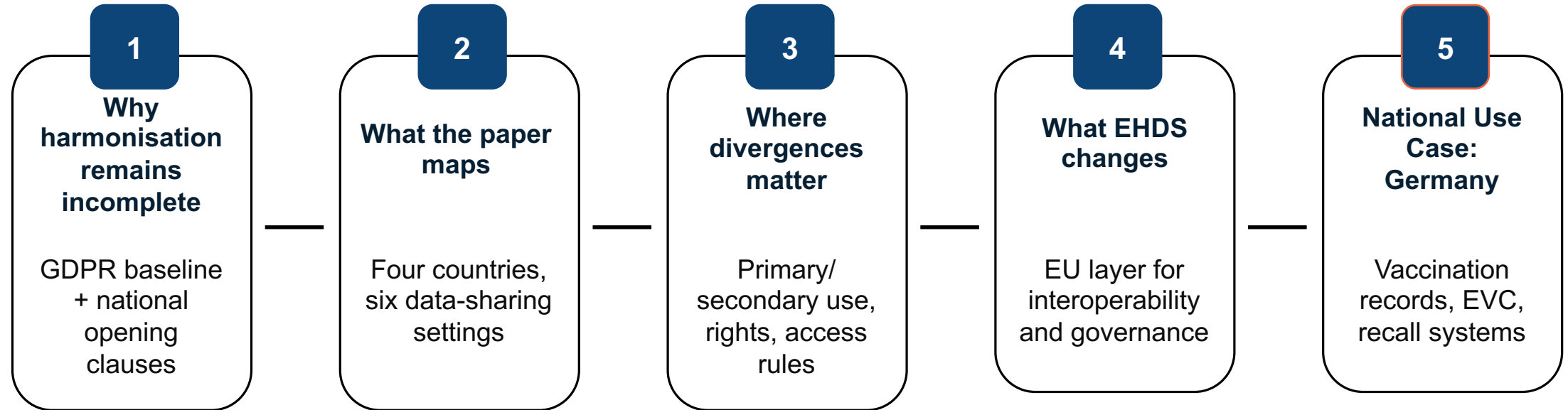
7-8 May 2026

Antwerp, Belgium

Speaker: Prof. Dr. iur. Fruzsina Molnár-Gábor,  
Heidelberg University

# Presentation structure

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Molnar-Gabor, F., Sellner, J., Pagil, S. ..., Nyström, K. (2022)

,Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden', Seminars in Cancer Biology, 84, pp. 271-283

# Why vaccination records are a GDPR issue

## 1 Vaccination record

- Contains personal health data
- Links identity, vaccine, dose, date, provider
- Often collected in care settings
- Completeness determines later value

## 2 GDPR governance layer

- Requires a legal basis for processing
- Health data trigger Article 9 safeguards
- Member-state opening clauses create variation
- Transparency, security and access control are central

## 3 Data use and sharing

- Primary use: care, documentation, recall
- Secondary use: policy, surveillance, research
- Cross-border use: EVC and European comparability
- Reuse must be purpose-bound and governed

**Design implication: vaccination-record systems need interoperability and governance at the same time.**

legal basis

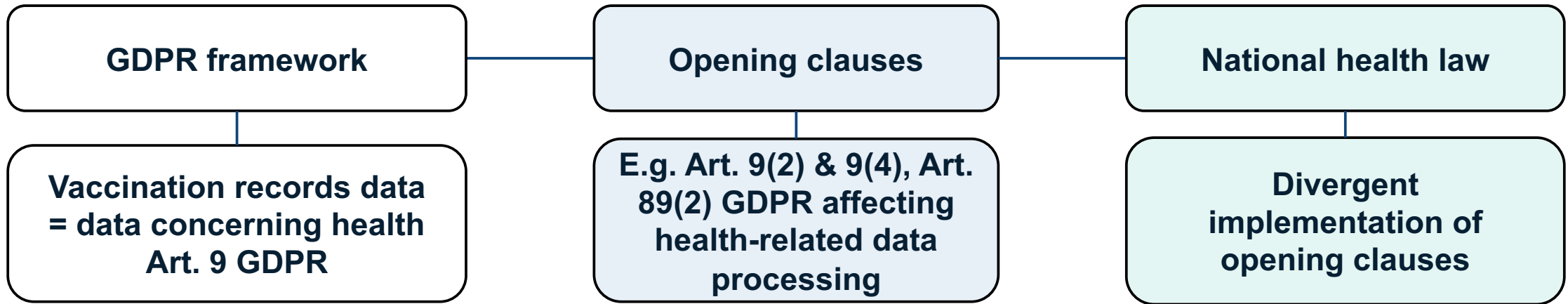
consent / opt-out


purpose limitation


data minimisation


secure access


# GDPR harmonises the baseline, not the sectoral reality



 **Legal bases**  
Art. 6 and 9 GDPR are paired differently across countries.

 **Consent models**  
Explicit consent, opt-out, public interest and ethics approvals differ.

 **Safeguards**  
Professional secrecy, pseudonymisation and access controls vary.

 **Rights**  
Access, objection and transparency are limited differently for research.

**Core finding: technical integration can advance faster than legal harmonisation, BUT ...**

# Opening clauses affect different aspects of health data processing

Germany

Greece

Latvia

Sweden

## Healthcare use



doctor–patient care; EHR access;  
professional secrecy

## Scientific research



consent or public-interest grounds;  
ethics review

## Data-subject rights



access/objection limits under  
research conditions

## Publication



consent, pseudonymisation or  
aggregation conditions

## Public authorities



public health, pharmacovigilance,  
statistics

## Secondary use

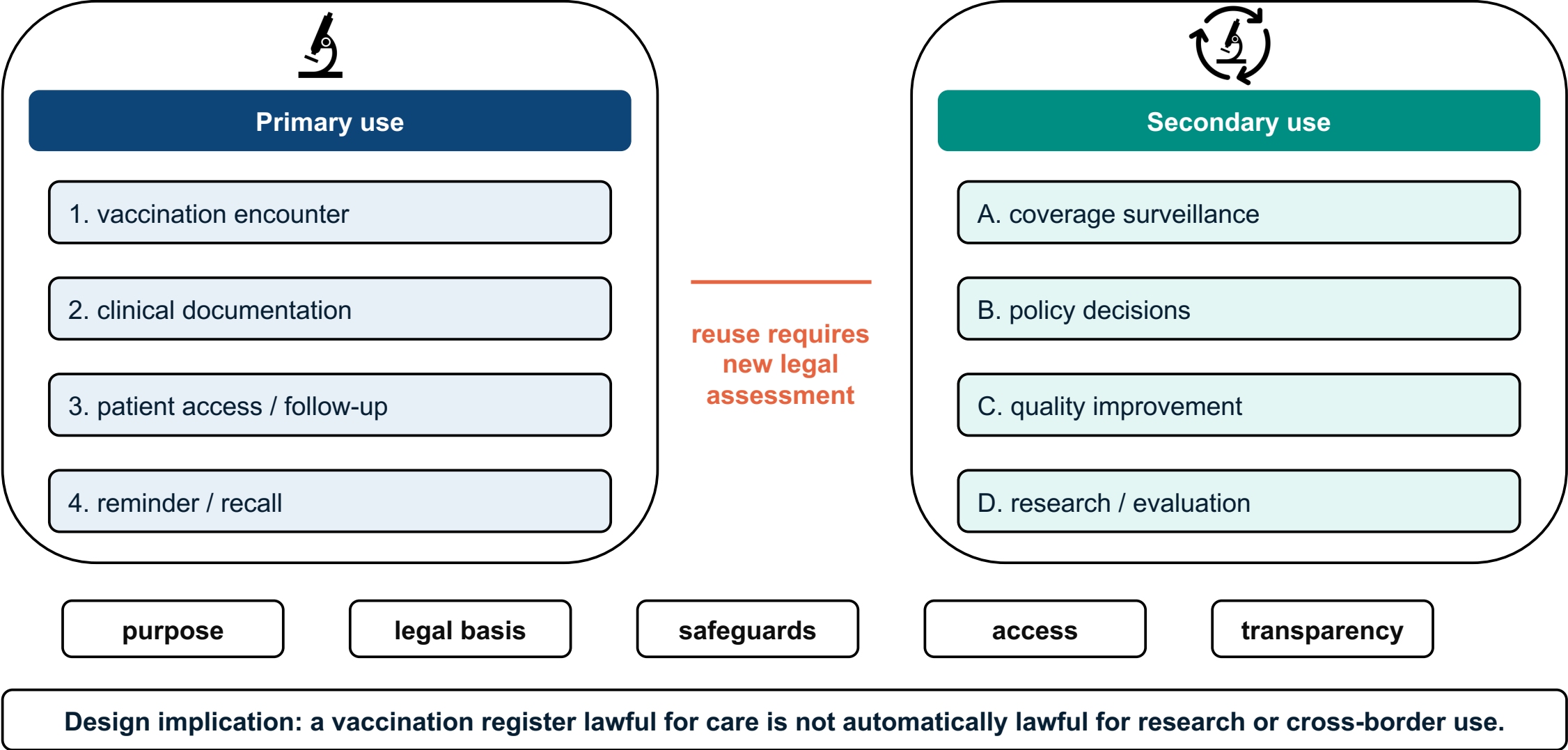


eHealth records, data trustees,  
access bodies

**Data sharing hurdles within the EU because of fragmentation**

**Interpretation for vaccination records: the same vaccination event moves through several legal contexts once it is reused for policy, recall or research.**

# Primary and secondary use are not just technical categories



# EHDS can standardise the layer, but not erase all national choices



National vaccine records including health related data fall within primary & secondary use regulation of EHDS

## EHDS transition timeline



**What can be harmonised: minimum dataset, interoperability, access routes, secure processing**

**What remains sensitive: consent, professional secrecy, research rights limits, national governance**

**Practical conclusion: Europe needs common functions and standards, while national laws still shape actual access and reuse.**

# National Use Case: Germany

## Current legal / data reality

ePA for all statutory-insured persons was created in 2025 unless the patient objects. Electronic vaccination record will be included.

Health Data Use Act expands the Health Data Lab and enables pseudonymised ePA data for research via opt-out.

Research secrecy, secure processing environments and simplified supervision are central safeguards.



## Policy strategy

Adult vaccination records remain partly paper/workflow-based; ePA can become the more structured carrier.

Policy direction: shift from consent-by-default to opt-out with transparent objection management.

Recall potential: insurer/provider data can support individual health-protection messages under legal limits.

