When Real-World Data Goes Public: Enabling Cutting-Edge Research

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EPICENTER
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Medical University of Innsbruck

March 4th, 2026

Agenda

Call for Action

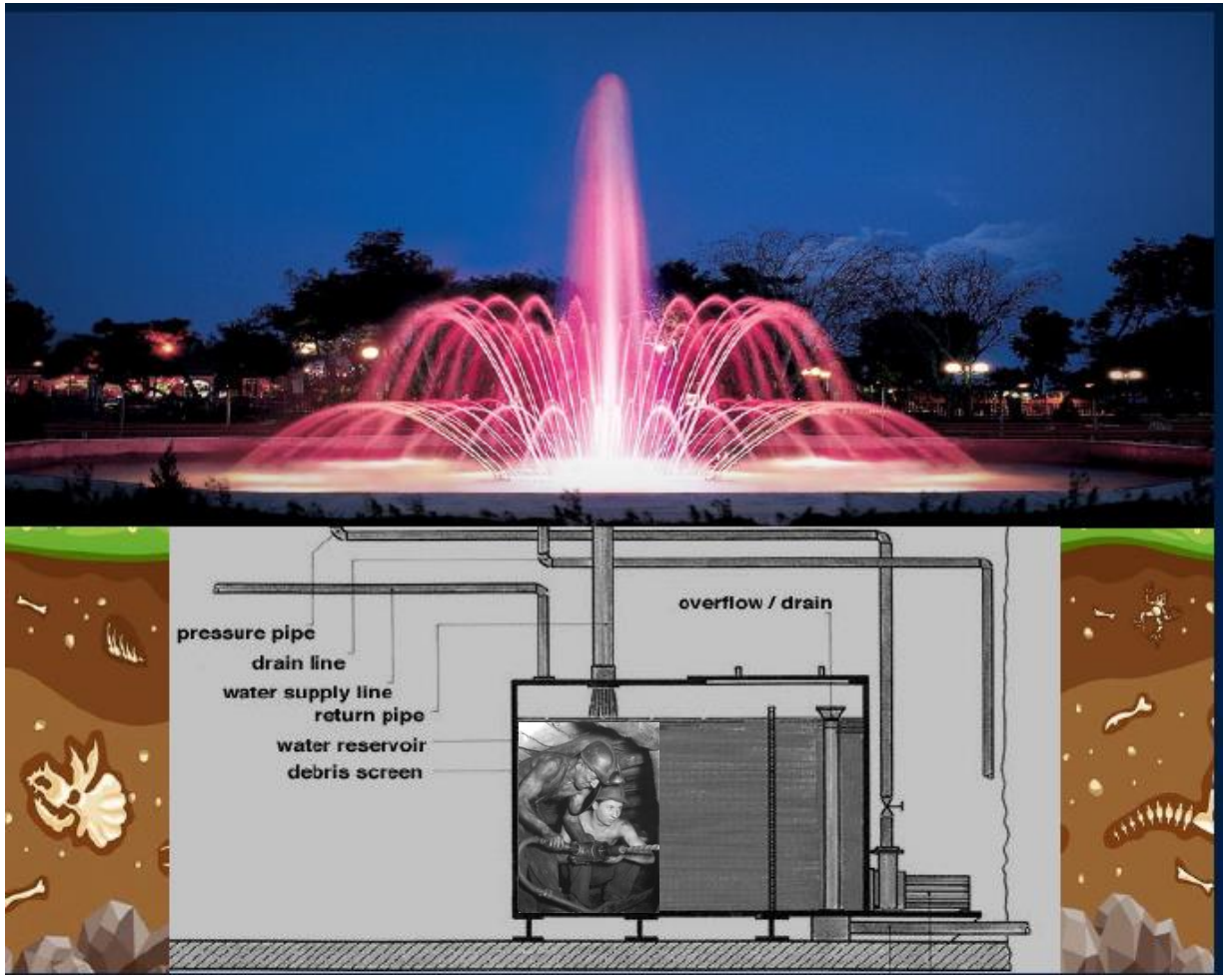
- The Good, the Bad …
- Real World Data – A Challenge for Real World Evidence?

Context

- EU Framework: EHDS and Dataspaces

What shall we do?

- Data Lifecycle & Steps towards an Austrian Network
- Fields of Action



Look at Sweden: recent HPV vaccination FU-study

(BMJ, Feb 2026)

Objective:
To evaluate the long term risk of invasive cervical cancer after receiving the quadrivalent human papillomavirus (HPV) vaccine

Data Source	Nationwide register based cohort study with up to 18 years of Follow-Up.
Observation Period:	2006 – 2023
Number of Patients:	926.362 female patients

Data:

All Data on patient level
Anthropometrics , educational level etc.
Household income
Origin of birth (also from parent/mother)
Family Medical Cervical Cancer History locations

Extended follow-up of invasive cervical cancer risk after quadrivalent HPV vaccination: nationwide, register based study

Shiqiang Wu,[1,2] Yunyang Deng,[1] Tiia Lepp,[3,4] Lina Schollin Ask,[3,5] Pär Sparen,[1] Mark Clements,[1] Joakim Dillner,[6] Jiayao Lei[1,6]

ABSTRACT

OBJECTIVES
To evaluate the long term risk of invasive cervical cancer after receiving the quadrivalent human papillomavirus (HPV) vaccine, how risk varies by time since vaccination, and to assess the population level impact of HPV vaccination programmes.

DESIGN
Nationwide register based cohort study with up to 18 years of follow-up.

SETTING
Sweden, from 1 January 2006 to 31 December 2023.

PARTICIPANTS
926 362 girls and women residing in Sweden between 2006 and 2023, born in 1985-88 (opportunistic cohort), 1989-92 (subsidised cohort), 1993-98 (catch-up cohort), or 1999-2001 (school based cohort), and with no previous HPV vaccination or diagnosis of invasive cervical cancer at the start of follow-up.

vaccine. 930 cases of invasive cervical cancer were identified, including 97 in vaccinated and 833 cases in unvaccinated individuals. Among participants vaccinated before 17 years, the overall fully adjusted incidence rate ratios compared with the unvaccinated group was 0.21 (95% confidence interval (CI) 0.13 to 0.32), with sustained protection for 13-15 years after vaccination (incidence rate ratio 0.23, 95% CI 0.11 to 0.46). For individuals vaccinated at 17 years or older, the overall fully adjusted incidence rate ratio was 0.63 (95% CI 0.49 to 0.81) compared with the unvaccinated group, with significant incidence reductions observed during years 10-12 (incidence rate ratio 0.54, 95% CI 0.33 to 0.86), and years 13-15 (incidence rate ratio 0.23, 95% CI 0.08 to 0.60) after vaccination. Compared with the opportunistic cohort, the school based cohort had a 72% (95% CI 11% to 91%) lower risk of cervical cancer after adjustment for covariates (incidence rate ratio 0.28, 95% CI 0.09 to 0.89).

PRESENT

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FINDATA
Social and Health Data Permit Authority

FFG
Promoting Innovation.

Objective:
Analysis of various types of time-series from industry & health service providers: predictive maintenance, clustering, visualization, data-modeling etc.

Cooperation between MUI & CanCom Austria AG: **how can data from Hospitals be used for these purposes**?

Data Sources:	Five Finnish University Hospitals (Helsinki, Tampere, Kuopio, Turku, Oulu)
Observation Period:	2019 – 2024 (more data available from > 1994, also from other hospitals)
Number of Patients:	**2.5 Mio patients / 28 Mio stays**
Data:	All Data at patient level: PatientID, lifestyle factors, anthropometrics, Primary / secondary diagnoses and comorbities, admission and discharge dates ICU admission and discharge timestamps Referring institution Longitudinal Medical History: link to previous treatment locations
Timespan:	**8 months**
FINDATA Costs:	**EUR 10.000 for data transfer, aggregation technical support, data access via SPE**

A local story about using Clinical Data

Lower major leg amputations in Innsbruck between 2006–2022 (N=623)
Local RWD academic study (J. Klocker / S. Kaser / B. Radinger):

DM-related:	270 Patients (43%) vs. non-DM related: 353 (57%)
Data Sources:	Local HIS & Registry of Amputations
	No other external registries included
	mostly manual data transfer of 100 clinical variables
First idea:	05 / 2023
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Data clearing	06 / 2024
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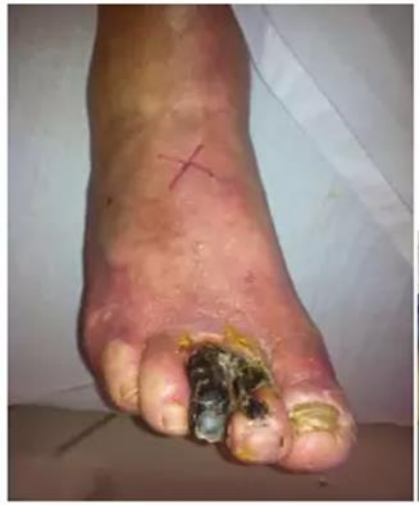
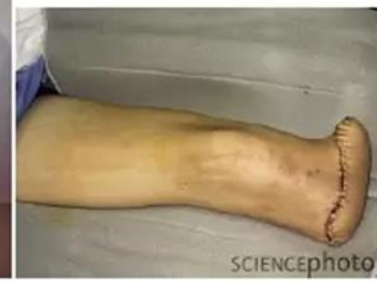
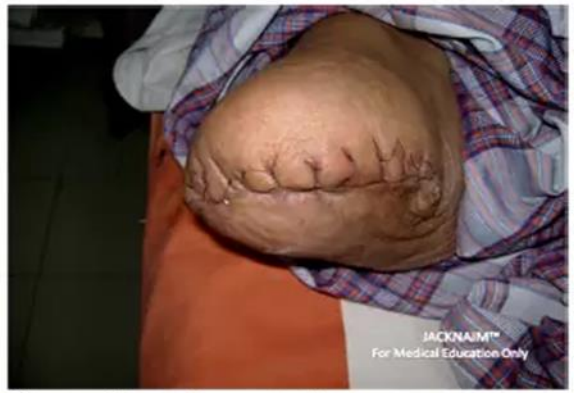
Accepted Publication	06 / 2025



2nd and 3rd toe gangrene



Below-Knee-Amputation



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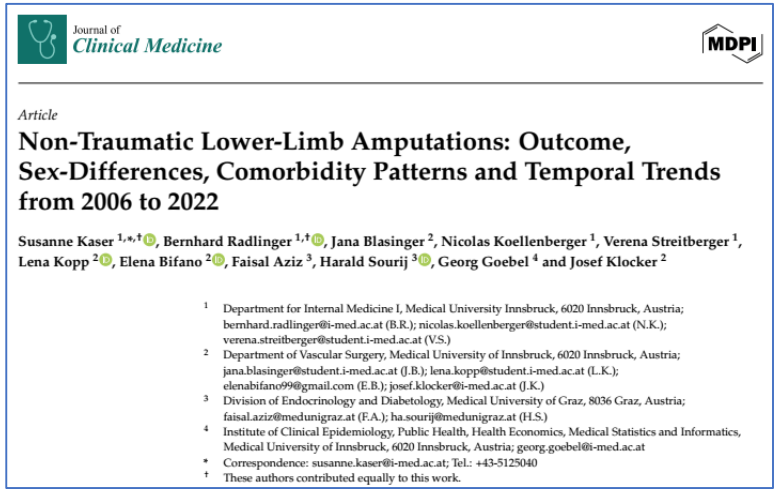

Journal of *Clinical Medicine* MDPI

Article

Non-Traumatic Lower-Limb Amputations: Outcome, Sex-Differences, Comorbidity Patterns and Temporal Trends from 2006 to 2022

Susanne Kaser [1,*,†], Bernhard Radlinger [1,†], Jana Blasinger [2], Nicolas Koellenberger [1], Verena Streitberger [1], Lena Kopp [2], Elena Bifano [2], Faisal Aziz [3], Harald Sourij [3], Georg Goebel [4] and Josef Klocker [2]

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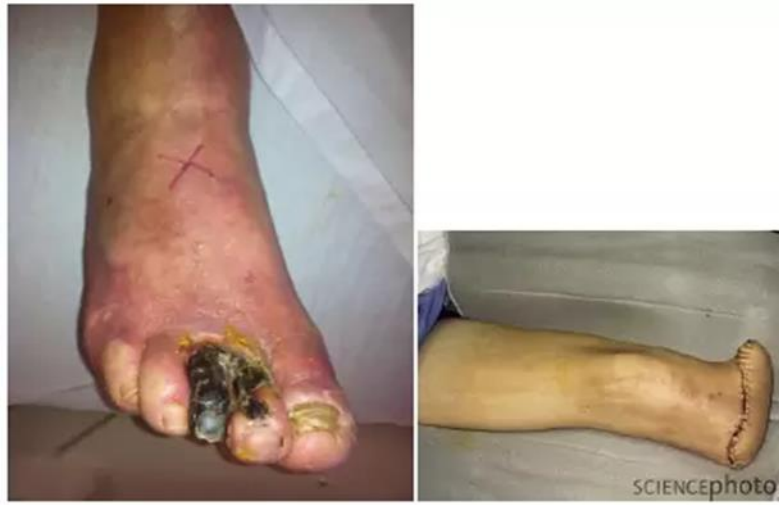
* Correspondence: susanne.kaser@i-med.ac.at; Tel.: +43-5125040
† These authors contributed equally to this work.



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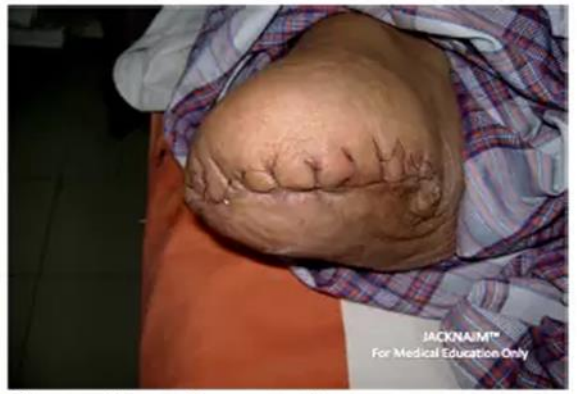

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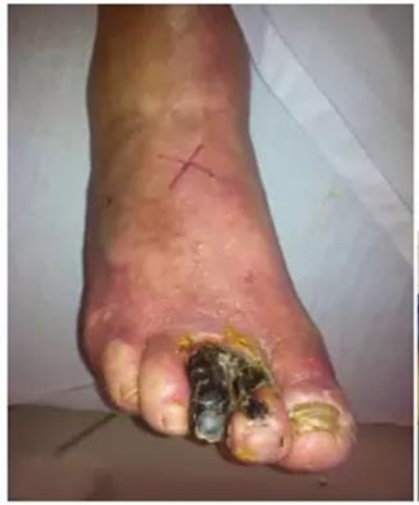
Further publications expected	? / 2026

KPIs

Data transfer	6 months ++
Data cleaning	6 weeks
Statistical analysis	3 weeks

We need 2 years from starting a project to the first publication!



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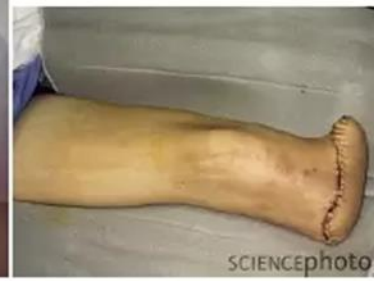

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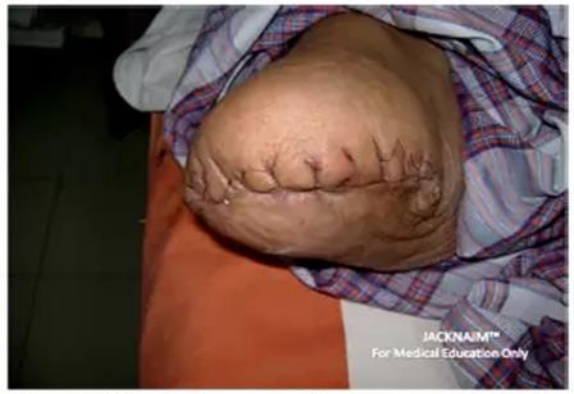

Above Knee Amputation

What are we talking about?

https://datasaveslives.eu/health-data-overview

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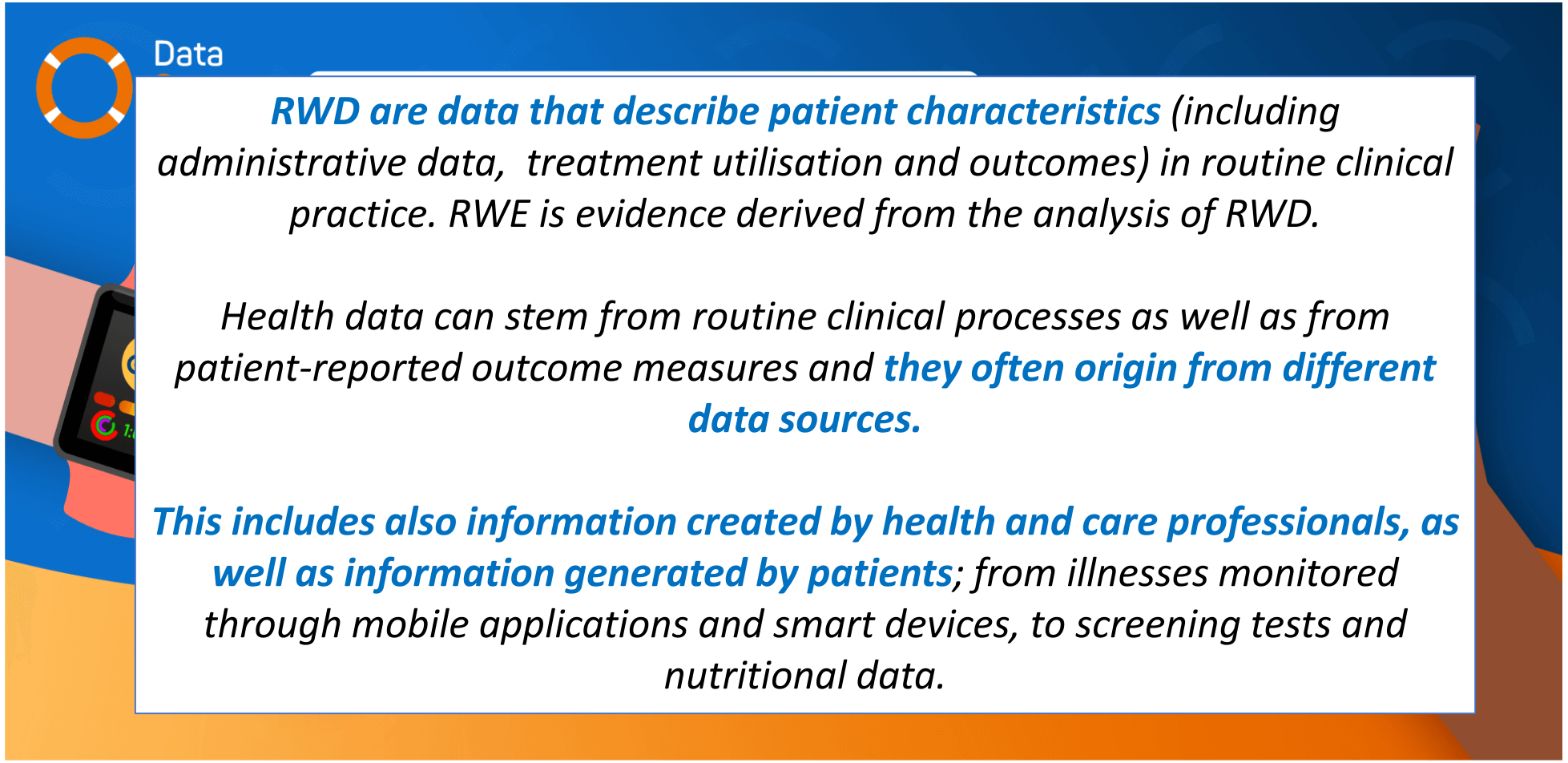


RWD are data that describe patient characteristics *(including administrative data, treatment utilisation and outcomes) in routine clinical practice. RWE is evidence derived from the analysis of RWD.*

Health data can stem from routine clinical processes as well as from patient-reported outcome measures and ***they often origin from different data sources.***

This includes also information created by health and care professionals, as well as information generated by patients*; from illnesses monitored through mobile applications and smart devices, to screening tests and nutritional data.*

https://datasaveslives.eu/health-data-overview
Reflection paper on use of real-world data, EMA/99865/2025

What are we talking about?

	Real-world data	Data from controlled clinical trials and studies
Aims	Effectiveness/response	Efficacy
Setting	Real-world clinical practice	Controlled research
Patient inclusion criteria	No strict criteria for patient inclusion	Strict criteria for patient inclusion
Drivers of data	Patient-centered	Investigator-centered
Medication interactions and comorbidities	Real-world clinical practice	Only included according to the study protocol
Role of the physician	Multiple physicians, as decided by the patient	Designated investigator
Comparator	Patient need, real-world and variable treatments, as determined by the market and physician	Placebo or standard care
Treatment	Variable treatments, as determined by the market and physician	Fixed, according to the study protocol
Response monitoring	Variable	Continuous through the study
Patient follow-up	Determined by real-world clinical practice	Variable, according to the study protocol

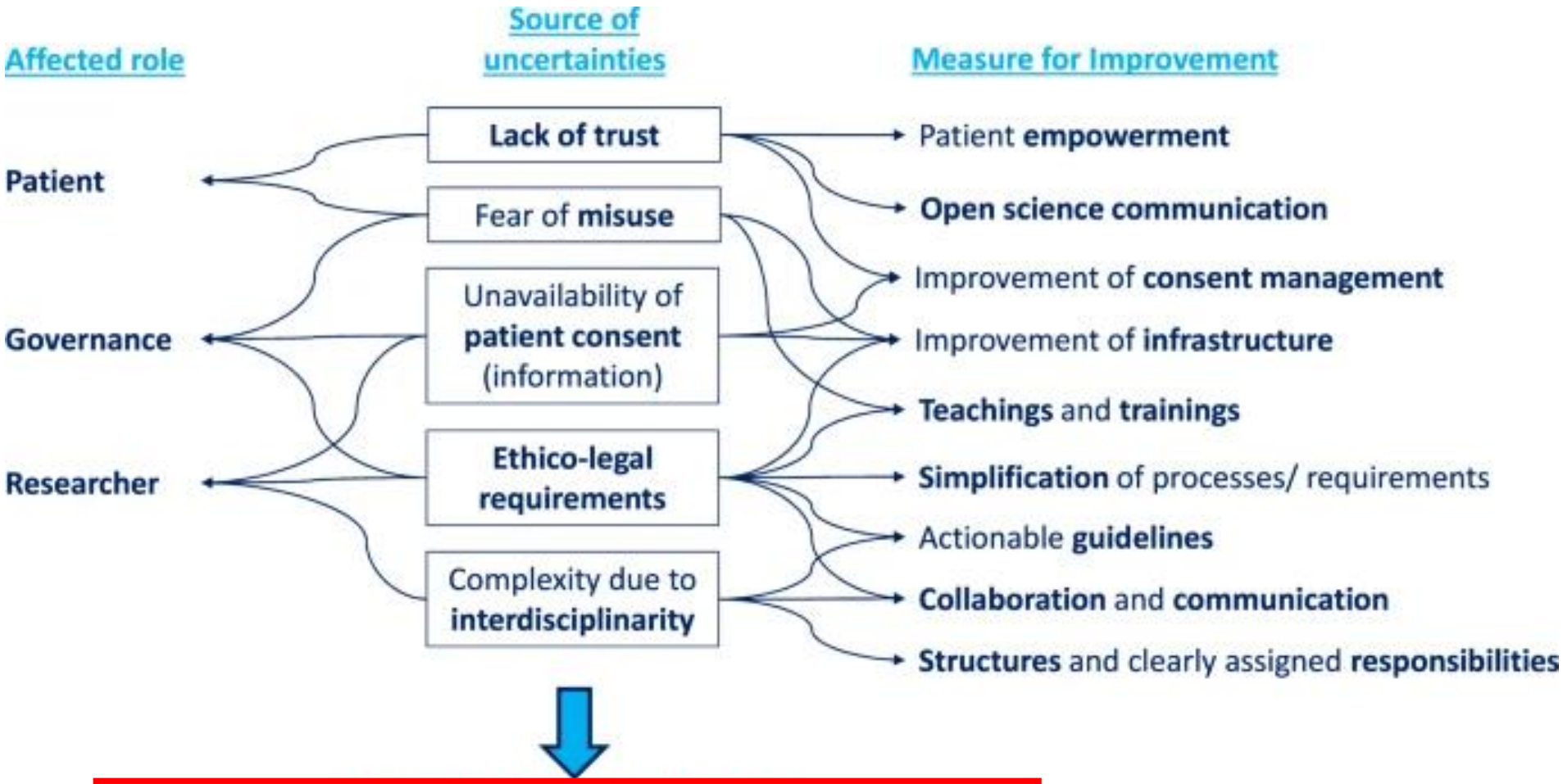
Med Sci Monit. 2025 Aug 27;31:e951118.

Way out?

“Medical real-world data stored in clinical systems represents a valuable knowledge source for medical research, but its usage is still challenged by various technical and cultural aspects.”

Gehrmann, J., Herczog, E., Decker, S. *et al.* What prevents us from reusing medical real-world data in research. *Sci Data* **10**, 459 (2023). https://doi.org/10.1038/s41597-023-02361-2

Challenges for Secondary Usage of Health Data



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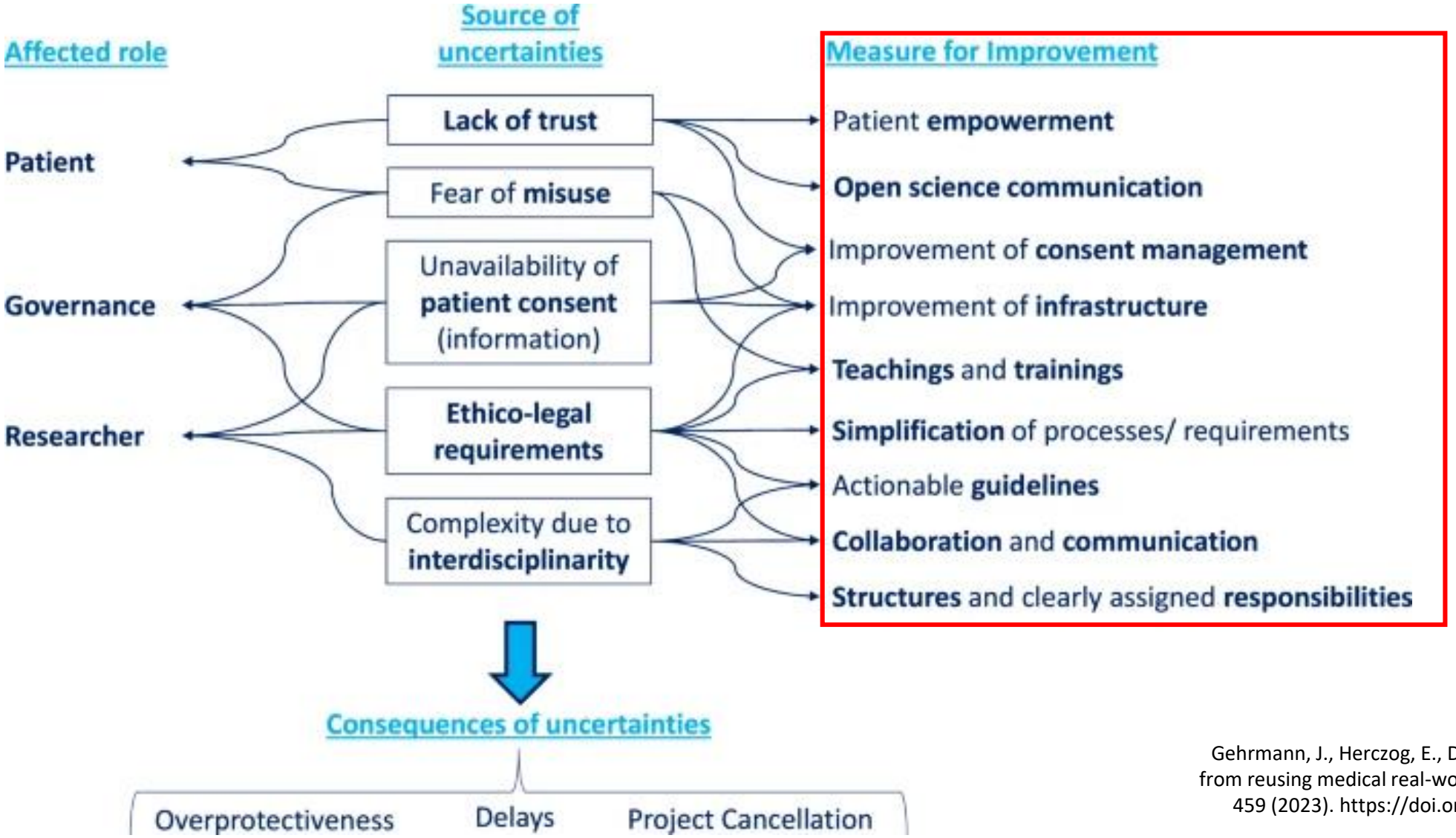

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Way out?

Technical Challenge	Measure for Improvement
Lack of **interoperability**	**Standardization** and **harmonization** of frameworks, data models, formats, terminologies and interfaces.
Lack of **accessible interfaces**	**Re-designing data systems/ creating data warehouses** aiming for increased accessibility, support data protection
Department-specific **data silos**	
Patient- and transaction orientation of clinical data systems	
Lack of **structured data**	(Automated) **data structuring**

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European Health Data Space is an enabler!

All „Producers & Holders“ of Health Data will be affected!

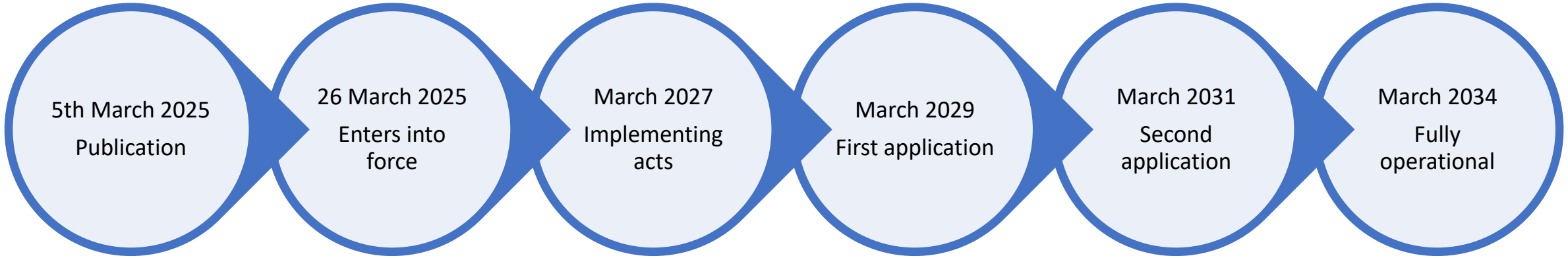
EHDS Ch 4: Secondary Usage of Health Data

The EHDS will ensure the comprehensive, trustworthy, and efficient reuse of anonymized health data for research, innovation, policymaking, and regulatory activities (secondary use of data).

- Electronic Health Records
- Human Molecular and -omic Data
- Research Cohorts, Questionnaires and Surveys
- Healthcare-related Administrative Data
- (Data from) Medical Devices
- Registries: Population-based, Medical, Mortality
- Human Genetic, Epigenomic and Genomic Data
- Data from Clinical Trials, Clinical Studies and Clinical Investigations

Art. 51

EHDS TIMELINE



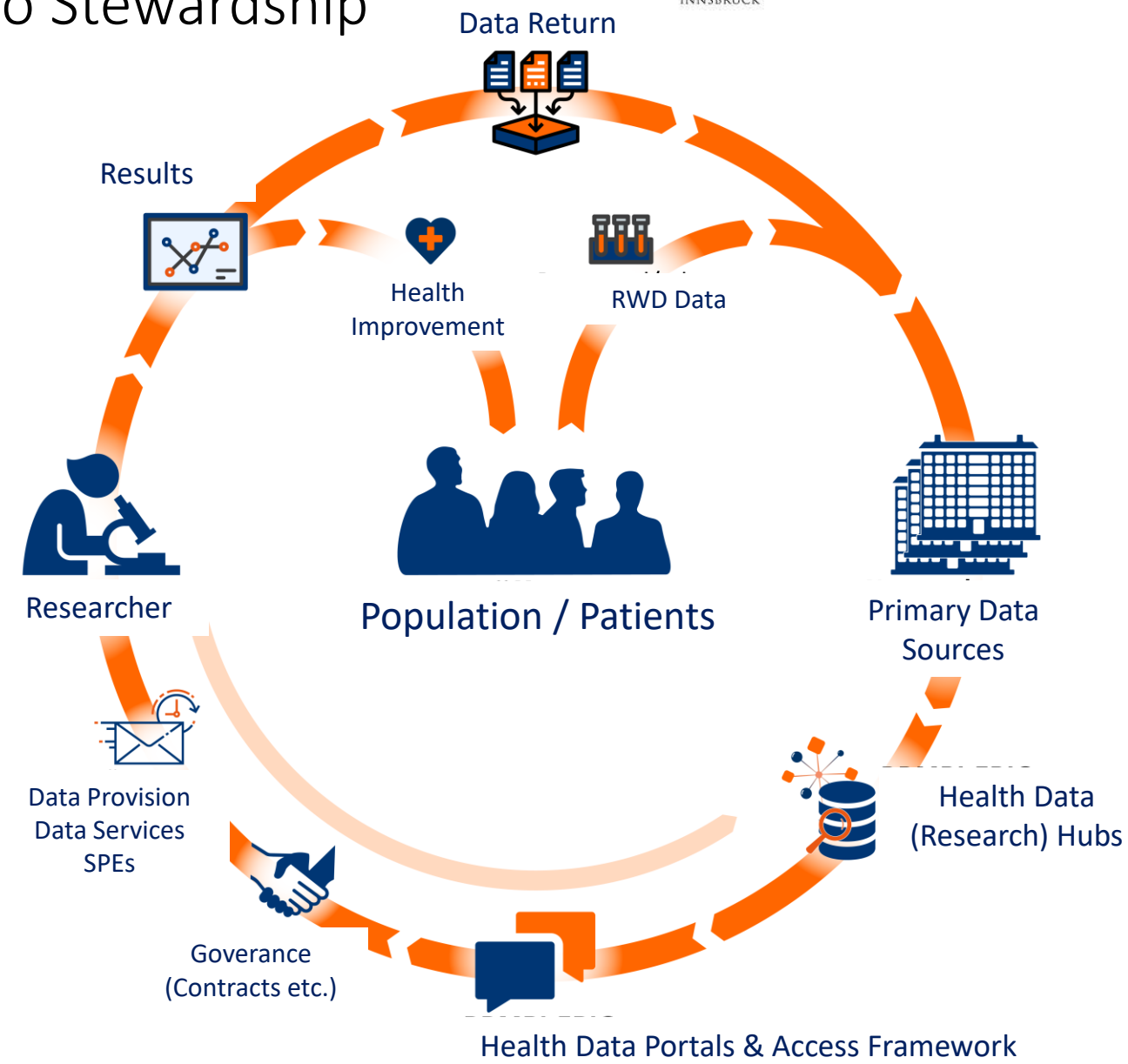
- Published in the Official Journal of the European Union.
- Beginning of the transition phase towards application.
- Commission to adopt several key implementing acts, providing detailed rules for the regulation operationalization.
- Exchange of the first group of priority categories of health data (Patient Summaries, ePrescriptions/eDispensations) in all EU Member States.
- **Rules on secondary use will also start to apply for most data categories (e.g. data from electronic health records).**
- The exchange of the second group of priority categories of health data (medical images, lab results, and hospital discharge reports) should be operational in all EU Member States.
- **Rules on secondary use will also start to apply for the remaining data categories (e.g. genomic data).**
- Third countries and international organisations will be able to apply to join HealthData@EU.

Call for Action – Austria needs …

Health Data Excellence	Sustainable and legally compliant digital access to health and biomedical data is crucial to overcome challenges in scientific data use and to enable future top-level research, innovative treatment methods, and the development of AI/ML tools and methodologies.
Distributed Health Data Plattforms	We need a distributed digital architecture and standardized interfaces to avoid centralization of data while still ensuring efficient and secure access to a comprehensive data pool.
Health Data Privacy & Security	We need effective protection mechanisms to safeguard infrastructure, along with anonymization, pseudonymization, and secure data encryption to achieve a high level of protection against cyberattacks and data breaches, thereby strengthening the trust of citizens and researchers.
Collaborative approach	A common governance framework and harmonized processes are needed to ensure that data for statistical and bioinformatic analyses, or for machine learning (ML)-based methods, can be used in a quality-assured, legally and ethically compliant manner, following a unified nomenclature and shared standards.

Shifting from Data Ownership to Stewardship

- Move away from hoarding & emphasize „data dignity“
- Accept Non-Randomized Evidence & Embrace hybrid approaches
- Recognise & reward
- Move from "No" to "How“ & build consensus
- Breake the silos & activate patient engagement



Hulsen T. Sharing Is Caring-Data Sharing Initiatives in Healthcare. Int J Environ Res Public Health. 2020 Apr 27;17(9):3046.
Figure provided by BBMRI-ERIC (adapted)

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→ Institutions, particularly academic hospitals, must stop viewing patient data as a proprietary asset and instead view themselves as custodians who should share data to accelerate scientific discovery.
A focus on treating patient data with respect, using it for the common good, and fostering trust through transparency.

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The traditional hierarchy of evidence, which places Randomized Controlled Trials (RCTs) at the top, must be updated to accept high-quality Real-World Evidence (RWE).

Cultivating comfort with "pragmatic trials" that combine the rigor of randomization with the practical, diverse data of real-world settings.

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→ Shifting academic culture to reward data sharing in hiring, tenure, and promotion decisions, similar to how publications are currently treated.

Encouraging researchers to follow FAIR principles (Findable, Accessible, Interoperable, and Reusable) and to share data regardless of the outcome to avoid publication bias.

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→ Shifting the mindset of data protection officers and ethics committees from overprotecting data to finding secure ways to make it accessible (e.g., using SPEs).
Overcoming mistrust between clinicians, researchers, and industry by clearly defining the benefits of RWD, such as improved patient safety and better treatment insights

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→ Cultivating a culture where clinicians, data scientists, and regulatory experts collaborate early in the process.

Including patients in decisions about their data (e.g., through dynamic consent models) to build trust, as patients are more likely to support data use if it serves the common good.

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Fields of Action for an Austrian Health Data Space

Quo vadis, Austria?

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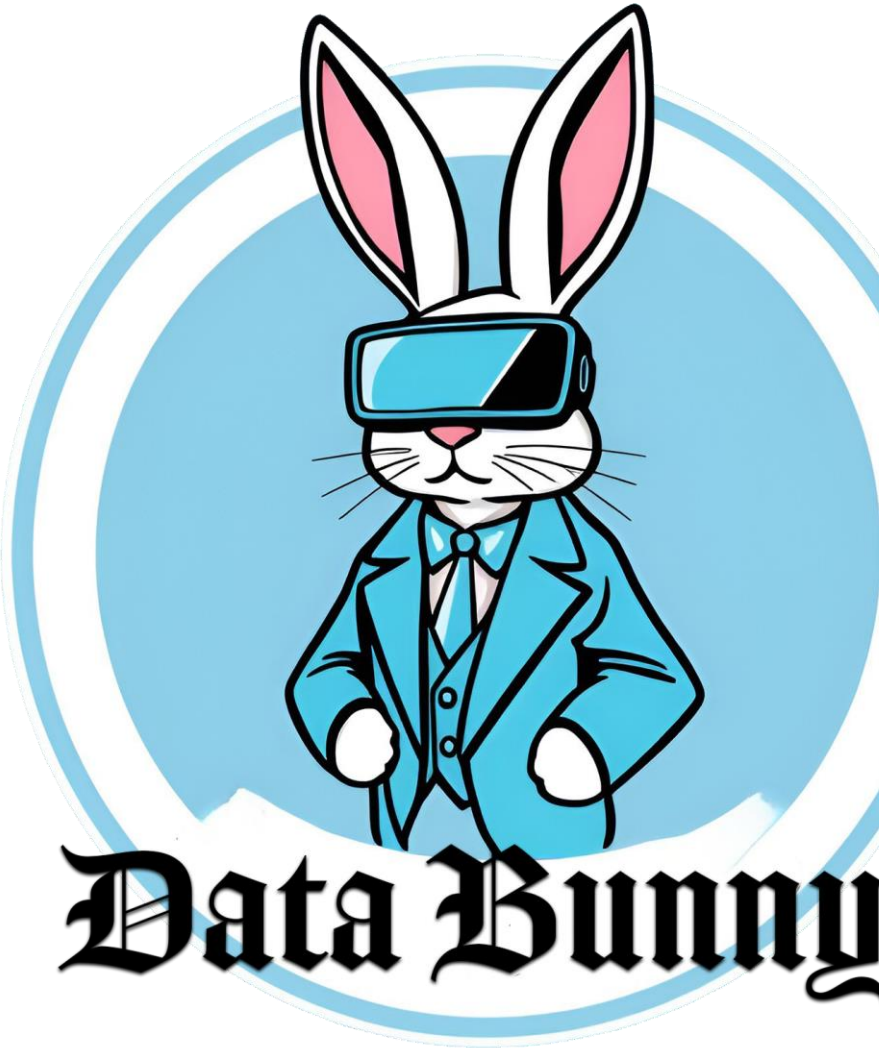
“The availability of quality-assured health data for research is a matter of survival for our scientific location in the fields of health sciences and clinical research.”

Dear Easter Bunny ....*(rather than a Take Home Messages)*

- **Holders of Health Data** ("Data Holders") – in the context of clinical-university research – **are jointly the Medical Universities and (corresponding) Hospital Operators.**
- **Research-oriented data storage of health data** at individual organizational units/clinics and by external "contractors" **will**, due to the requirements, increasingly **be viewed critically** in the future and will also reduce the role of centralized registries.
- **Early and detailed coordination of processes** for data collection, data storage as well as the sustainable availability and FAIR use (including results) internally and at consortium-level is as a crucial success factor for data projects especially in the ML/AI context.
- The **EHDS will enable improved RWD-usage and registry research** and it will also foster the use of large European cohorts, offering new opportunities for providers of "high-quality" datasets.



QUESTIONS & IDEAS?

Assoz.-Prof. Dr. Georg Göbel
HDRH @ EPICENTER
Medical University of Innsbruck, BBMRI.AT
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EHDS FOR SECONDARY USE

MAIN ENTITIES

- **National Contact Points** – implementing national interfaces
- Health **Data Access Bodies (HDABs)**
  - deciding on health data access applications
  - processing electronic health data

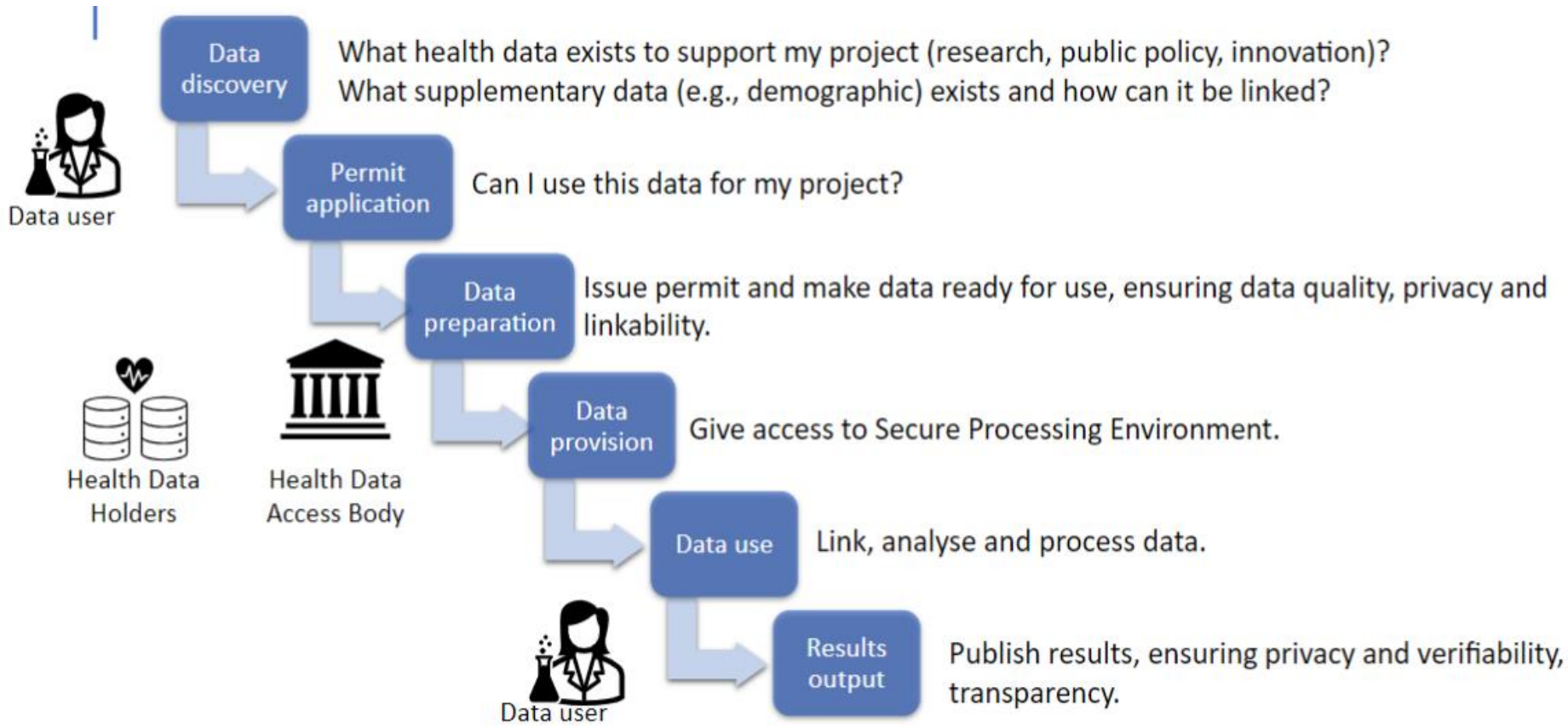
- **Health Data Holders** – include hospitals, clinics, and other organisations (except individual researchers, natural persons, and micro-enterprises) that have either:
  - the right or obligation to process personal electronic health data
  - the ability to make available non-personal electronic health data
- **Trusted Health Data Holders**
  - able to provide access to health data through a SPE
  - has the necessary expertise to assess health data access applications and health data requests

- **Intermediation Entities** – can take over some duties of DHs
- **Authorised participants** – Data sharing infrastructures e.g., ERICs and EDICs:
  - Metadata catalogue
  - Handle data access applications

Art. 75
Art. 55
Art. 57
Art. 2
Art. 50
Art. 60
Art. 72
Art. 50
Rec. 80

EHDS FOR SECONDARY DATA USE

USER JOURNEY FROM RESEARCHER'S PERSPECTIVE



Key terminology for researchers

Health data Access Application – process to ask for access to health data.
Data Permit – authorization to process data (inside an SPE).
Data Request – a query which can be responded to by summary statistical information.
Secure Processing Environmnets (SPEs): where the data is securely processed, based on Data Governance Act.

Art. 73
Art. 67
Art. 68
Art. 69

Is the European Health Data Space (EHDS) a solution?

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- The EHDS, or European Health Data Space, is an EU initiative to create a secure and interoperable framework for health data across member states.
- It enables individuals to control and share their electronic health data for better care (primary use)
- The EHDS also facilitates the secure, anonymized reuse of health data for research, innovation, and policymaking (secondary use)

https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

Health Data governance

Health Data protection

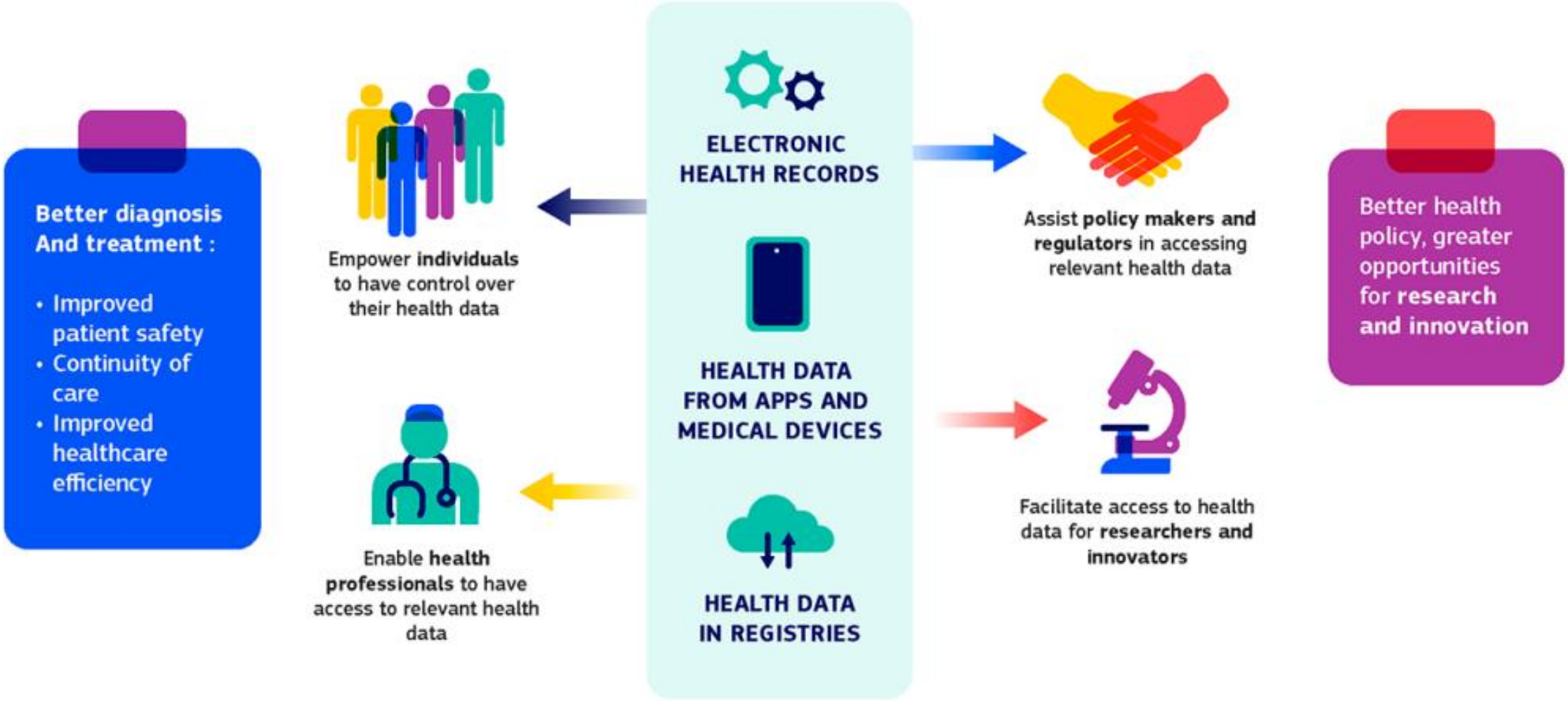
Patient control

Interoperability

Primary & Secondary Use of Health Data

Art. 51

What's the European Health Data Space (EHDS)?



https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

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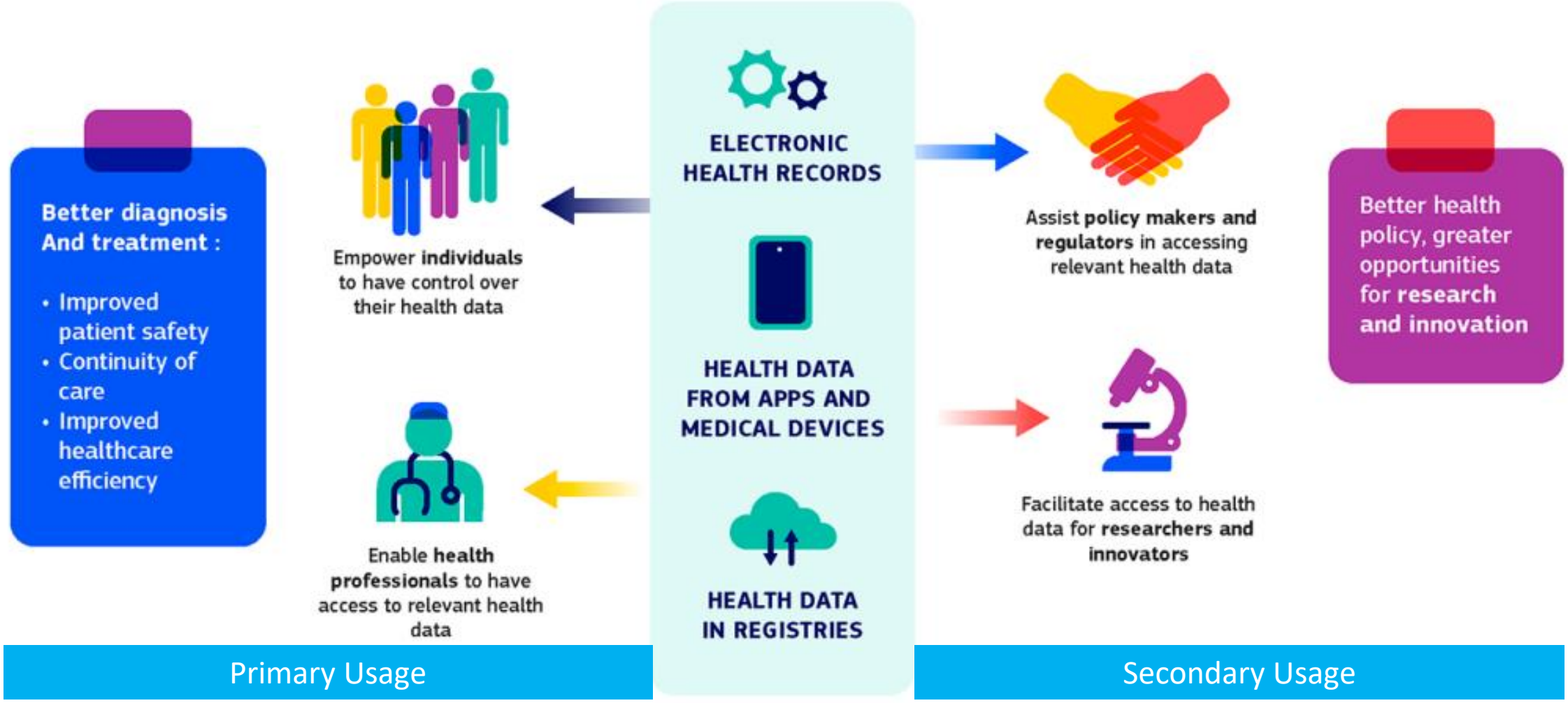

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