Digitalization of infectious disease surveillance in Europe

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18 March 2025

Rapid and efficient data collection is critical for early detection and effective response to infectious disease outbreaks

Vision for a modern surveillance system

1. **Standardised**: case definitions, reporting protocols, and laboratory standards to ensure data validity and comparability;
2. **Fit-for-purpose**: surveillance objectives and triggered PH actions are clear and determine system requirements;
3. **Electronic**: data transmission must be process fully digitalised:
4. **Efficient**: relevant data (e.g. from EHR) is processed and available to public health with no (added) effort from the healthcare provider;
5. **Automated**: manual steps in the notification process are gradually automated – from the provider to the different geographical levels of public health services;
6. **Integrated**: different data sources are linkable by public health services in a secure and GDPR compliant manner, whenever surveillance objectives cannot be achieved with data from one single source;
7. **Useful**: the system informs (timely) public health action and its performance can be continuously monitored;

Digitalised/automatic surveillance

Advantages:

- Decreasing effort on the provider's side
- Allowing comprehensive surveillance
- Improving timeliness
  - Continuous monitoring
  - Early detection of new or unexpected events
  - Prompt intervention
- Quickly design and implement epidemiological studies

Challenges:

- Data protection issues
- Data linkage between different sources
- Different surveillance systems in place in different countries and even regions
- Setting up and maintaining standard definitions for disease, exposures and outcomes

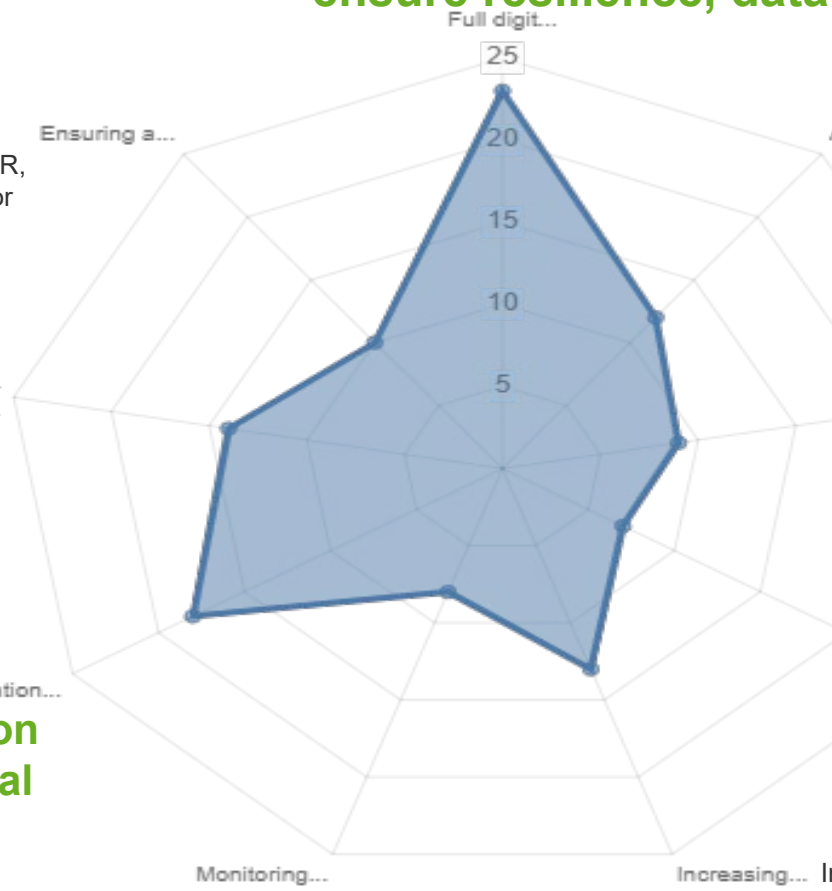
Developing surveillance systems: investment areas

Full digitalisation of surveillance process to ensure resilience, data quality, and comparability

Ensuring adequate interpretation of public health mandate and GDPR, clearly differentiating public health use from other secondary uses for health data (such as research)

Making full use of electronic health records as primary source (i.e. no need to use discharge records or other delayed surrogates)

Automation of reporting and integration of different data sources, from the local to the European level



Addressing legal constrains to facilitate health data access, processing and dissemination in a timely manner

Enhancing surveillance of respiratory infections to tackle their burden and prepare for the next pandemic

Enable an operating sentinel healthcare network that ensures representativeness

Increasing capacity to perform Whole-Genome Sequencing or other highly specific laboratory tests

Monitoring healthcare capacity (human resources, infrastructure such as hospital beds, stock & flow such as admissions and discharge dynamics)

Investment areas identified by Surveillance NFP from 26 EU/EEA countries (EUSurvey, May 2023)

Serious Cross-Borders Threats to Health

Regulation EU 2022/2371

CHAPTER III: Epidemiological surveillance, EU Reference Labs and Ad Hoc Monitoring

- **Art 13**: **Network for epidemiological surveillance**
  - Detection and monitoring of trends and outbreaks, assess situation and facilitate appropriate response;
  - Strengthen the data collection and sharing capacity of MS;
  - IA – Commission: list of notifiable communicable diseases and case definitions.
- **Art 14**: **Digital Platform for Surveillance**
  - Continued development to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, to support communicable disease prevention and control.
  - Automated collection of surveillance and laboratory data, as well as relevant non-personal health data (electronic health records and health databases), media monitoring, and artificial intelligence

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Data protection exceptions

Article 27

Personal data protection

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 and Directive 2002/58/EC, and to the obligations of the Union institutions, bodies, offices and agencies relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.

2. The Commission and, where applicable, other Union institutions, bodies, offices and agencies shall not process personal data except in cases where it is necessary for the fulfilment of their mission. Where appropriate, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

GDPR – Art. 9

Protection of personal data – Art. 10

Processing of special categories of personal data

1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

2. Paragraph 1 shall not apply if one of the following applies:

(i) the processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices, on the basis of Union law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy; or

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Strengthened ECDC Mandate (2022)

Motivation examples:

(15) With a view to enhancing the effectiveness of epidemiological surveillance in the Union, the Centre should be tasked with the continuous development of secure and interoperable digital platforms and applications, supporting epidemiological surveillance at Union level, enabling the use of digital technologies, such as artificial intelligence and computer modelling and simulation, in the compilation and analysis of data, and with providing Member States with scientific and technical advice to establish integrated epidemiological surveillance systems.

(20) […] the Centre should ensure appropriate datasets as well as the procedures to facilitate consultation and secure data transmission and access, and the Centre should work towards enabling realtime sharing of data, carry out scientific and technical evaluation of prevention and control measures at Union level and work with the WHO, relevant Union agencies and other relevant bodies and organisations operating in the field of data collection.

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Surveillance via Electronic Health Records

ECDC eHealth programme – SUREHD project

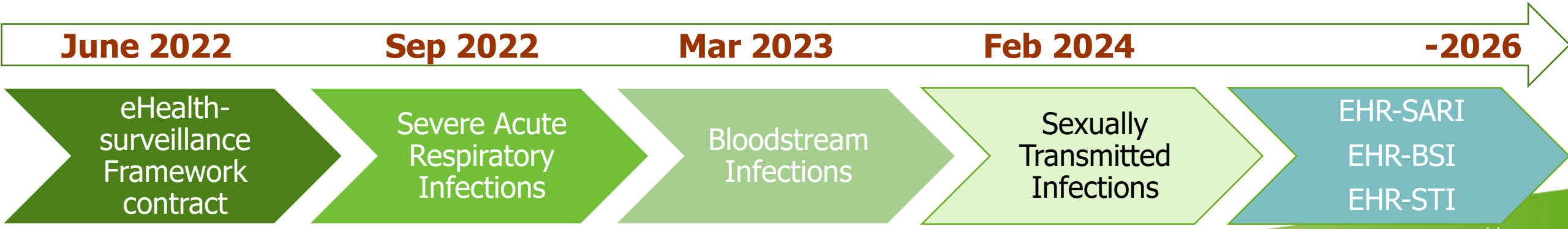
Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA

EHR-SARI 2022-2026 (16 countries)

EHR-BSI 2023-2026 (17 countries)

EHR-STI 2024-2026 (10 countries)

- Developing EHR-based **case definitions**/proxy case definitions
- Producing generic and country-specific **EHR-based surveillance protocols**
- Informing updates in surveillance **metadata and reporting protocols**
- Improving **sensitivity, timeliness, and representativeness** of the surveillance systems



Challenges and expectations

- Harmonise, **without being strict**
  - this applies to the case definitions and surveillance objectives!
- Provide **guidance**, **learning** with the experiences from MS
- Ensure there is a platform to **discuss common challenges**, while looking for tools that might help
- **Make some advances** in the use of electronic health records for surveillance

Surveillance of bloodstream infections from electronic health records (EHR-BSI)

ECDC eHealth tender – BSI/AMR

Support participating countries to establish **automated systems for electronic surveillance of BSI, including AMR** data.

Surveillance targets:

- **Surveillance of healthcare-associated BSI (HA-BSI incidence)**, including AMR profiles
- Surveillance/alert of possible pan-drug resistance in BSIs (PDR)
- Surveillance/alert of emerging pathogens in BSIs (e.g. *C. auris*)
- Automated surveillance of AMR according to EARS-Net protocol

Main Results (do not distribute)

Scope & Participation

- 17 EU/EEA countries sent reports; most collect hospital-level BSI data.
- Few countries have dedicated national HAI/BSI surveillance systems while most participate in ECDC surveillance programs for HAIs.

Objectives & Coverage

- Primary objective: Monitor HA-BSI incidence (77% implemented).
- 53% plan national systems; 35% start with selected hospitals or regions (12%).

Data Sources & Denominators

- Laboratory results (88%) & hospital records (82%); Patient days (88%) as denominator.

Main Results (do not distribute)

Capacity

- 100% mentioned capacity for automatic data extraction.
- 71% can perform data linkage across sources but only 53% can do so at the national level and 65% automatically.

Data extraction automatization

- Most patient characteristics and outcomes are in structured form while symptoms, infection origin and invasive device presence is in textual form.

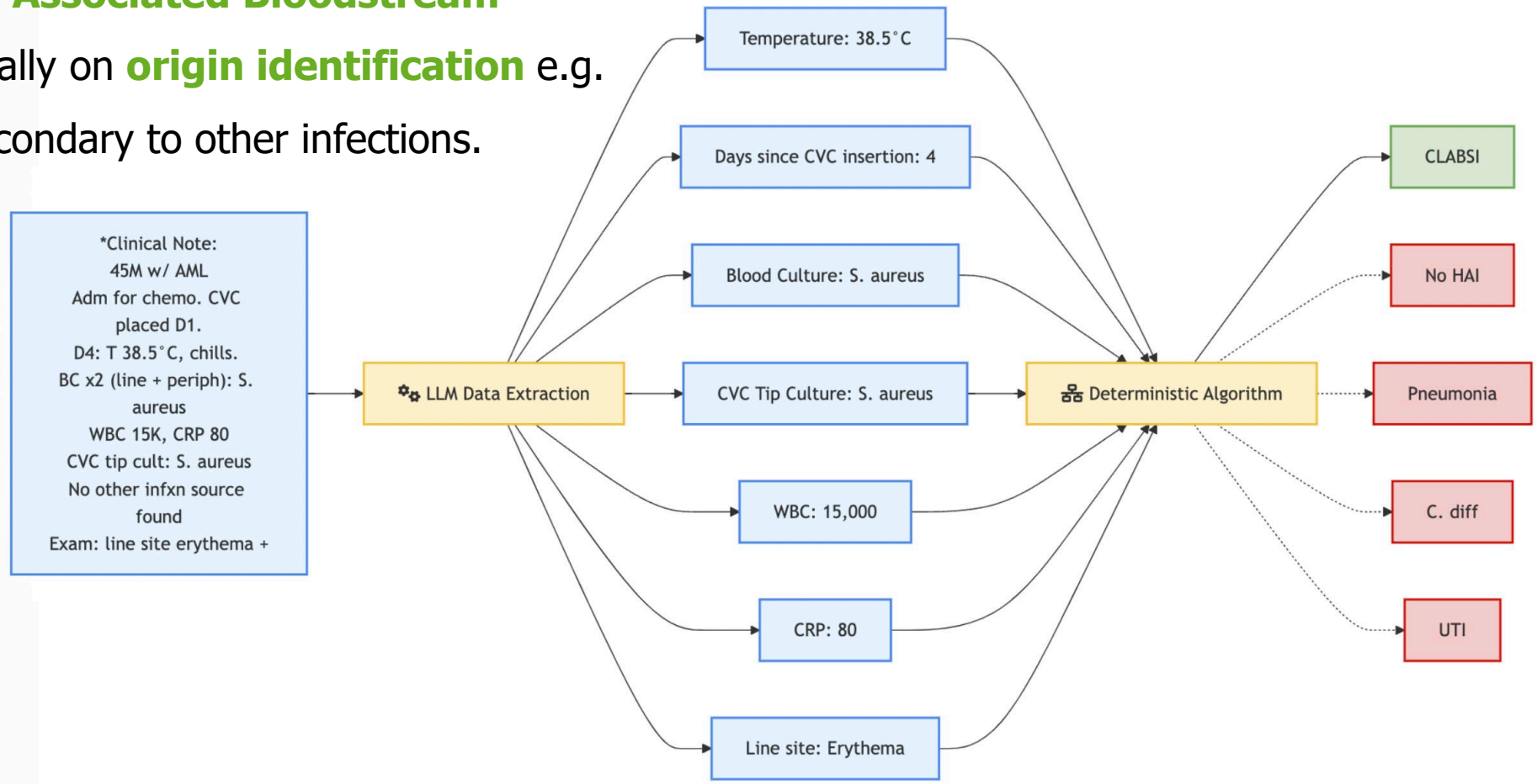
Challenges

- Data standardisation (76%), IT capacity (53%), Integration issues (47%).

AI supported HAI surveillance

AI supported HAI surveillance

- Use of **LLMs to extract clinical information** from unstructured clinical notes to be matched against ECDC HAI case definitions
- Focus on **Healthcare Associated Bloodstream Infection** and especially on **origin identification** e.g. catheter related or secondary to other infections.



AI supported HAI surveillance

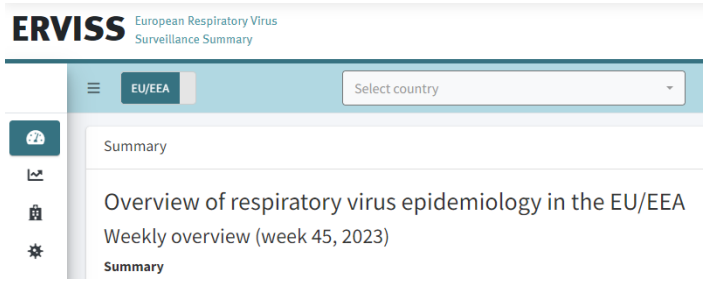
- **Small pilot project** to fund an exploration of the topic. Will be **followed by a larger multi-country effort**.
- Exploration of performance and of legal and infrastructural barriers.
- Tender will be launch by **April 2025** with awarding by **June 2025**.
- Details on the **EU tender platform**.

ERVISS for respiratory virus surveillance

Evolving surveillance and reporting of respiratory viruses in the EU/EEA

Today

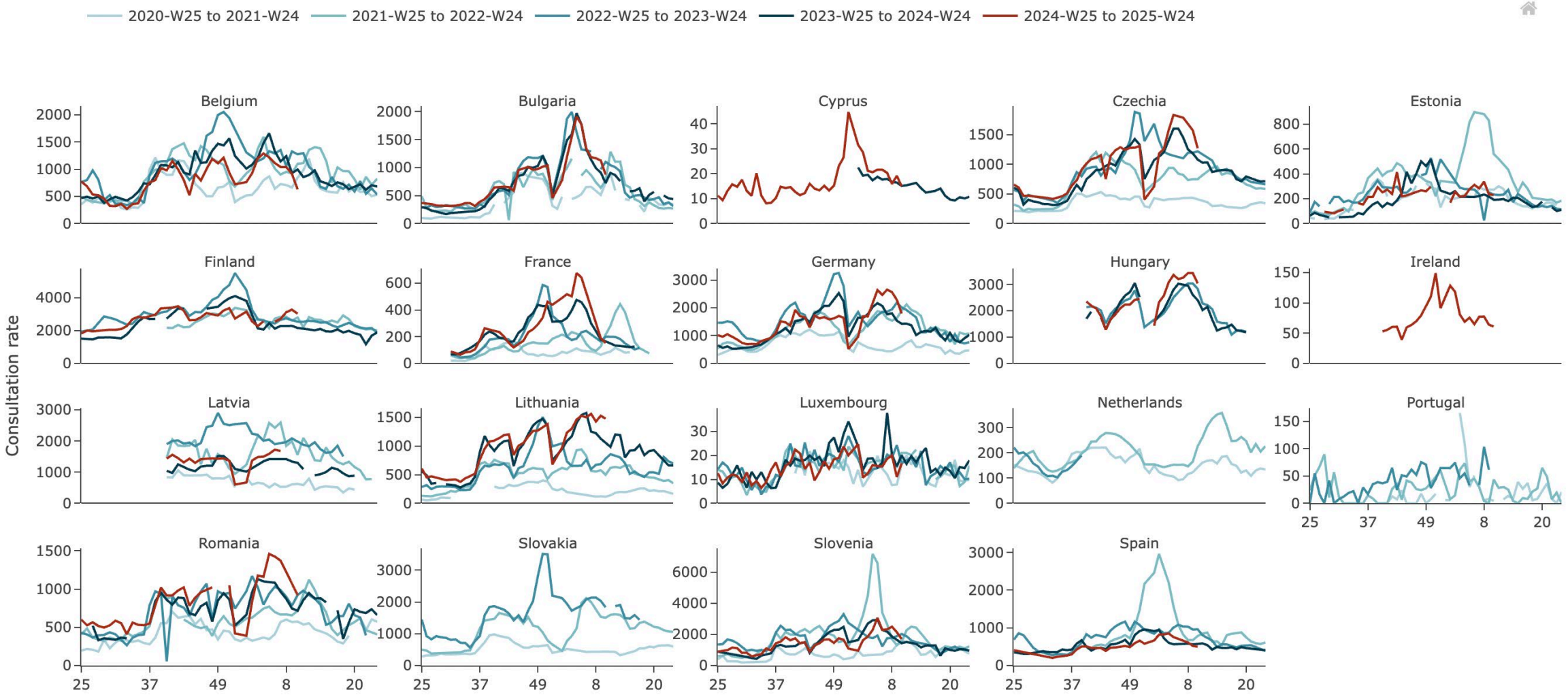
- Integrated surveillance of influenza, SARS-CoV-2, and respiratory syncytial virus (RSV)
- ERVISS replaces Flu News Europe and COVID-19 country overview



European Respiratory Virus Surveillance Summary (ERVISS)

- Interactive surveillance dashboard for influenza, RSV, and SARS-CoV-2 and includes epidemiological summary
- Updated weekly
- Joint publication of ECDC and the WHO Regional Office for Europe
- Serves as a tool for the early detection and communication of signals of respiratory virus circulation in the EU/EEA and WHO European Region
- Free access via https://erviss.org/

European Respiratory Virus Surveillance Summary (ERVISS)



Other initiatives

- **EpiPulse**: Integrated platform for MS public health authorities and global partners to collaboratively collect, analyse, share, and discuss infectious disease data.
- **EWRS**: Rapid alert system for the notification of serious cross-border health threats at the EU level.
- **ERVISS**: A WHO/ECDC managed interactive dashboard offering a weekly integrated epidemiological overview of influenza, Respiratory Syncytial Virus (RSV), and SARS-CoV-2.
- **RespiCast**: European Respiratory Diseases Forecasting Hub, a platform to upload and compare modelling results and forecasts on respiratory diseases.
- **ECDC Crowd**: Platform for public engagement in contributing to health science initiatives.

Secondary uses of health data via the EHDS

EHDS in a Nutshell – what is it about?

EHDS establishes a **legally and technically harmonized framework** to ensure that electronic health data from all Member States is interoperable.

Data from different countries can "**speak the same language**" making cross-border health data exchange seamless and efficient.

EHDS sets out **specific requirements for EHR systems**, mandating harmonised components (like interoperability and logging) so that any certified EHR system can be used across the EU without compatibility issues

EHDS in a Nutshell – what is it about?

1. **Primary use**: use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. **Secondary use**: use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

EHDS in a Nutshell – what is it about?

Roles and requirements

- Member States are required to set up **Digital Health Authorities** (for primary use) and **Health Data Access Bodies** (for secondary use)
- the European Commission provides central infrastructures like **MyHealth@EU** (primary use) and **HealthData@EU** (secondary use).

Type of data

electronic health data from **EHRs**;

healthcare-related **administrative data**, including dispensation, claims and **reimbursement** data

human **genetic, epigenomic and genomic** data;

other **human molecular** data such as proteomic transcriptomic, metabolomic, lipidomic and other -omic data;

automatically generated personal electronic health data, through **medical devices**;

data from **wellness applications**;

other health data from medical devices.

Data on factors impacting health, including **socio-economic, environmental and behavioural determinants** of health;

Aggregated data on **healthcare needs**, **resources** allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;

Pathogen data, impacting on human health

population-based health data **registries** (public health registries);

data from medical registries and **mortality registries**;

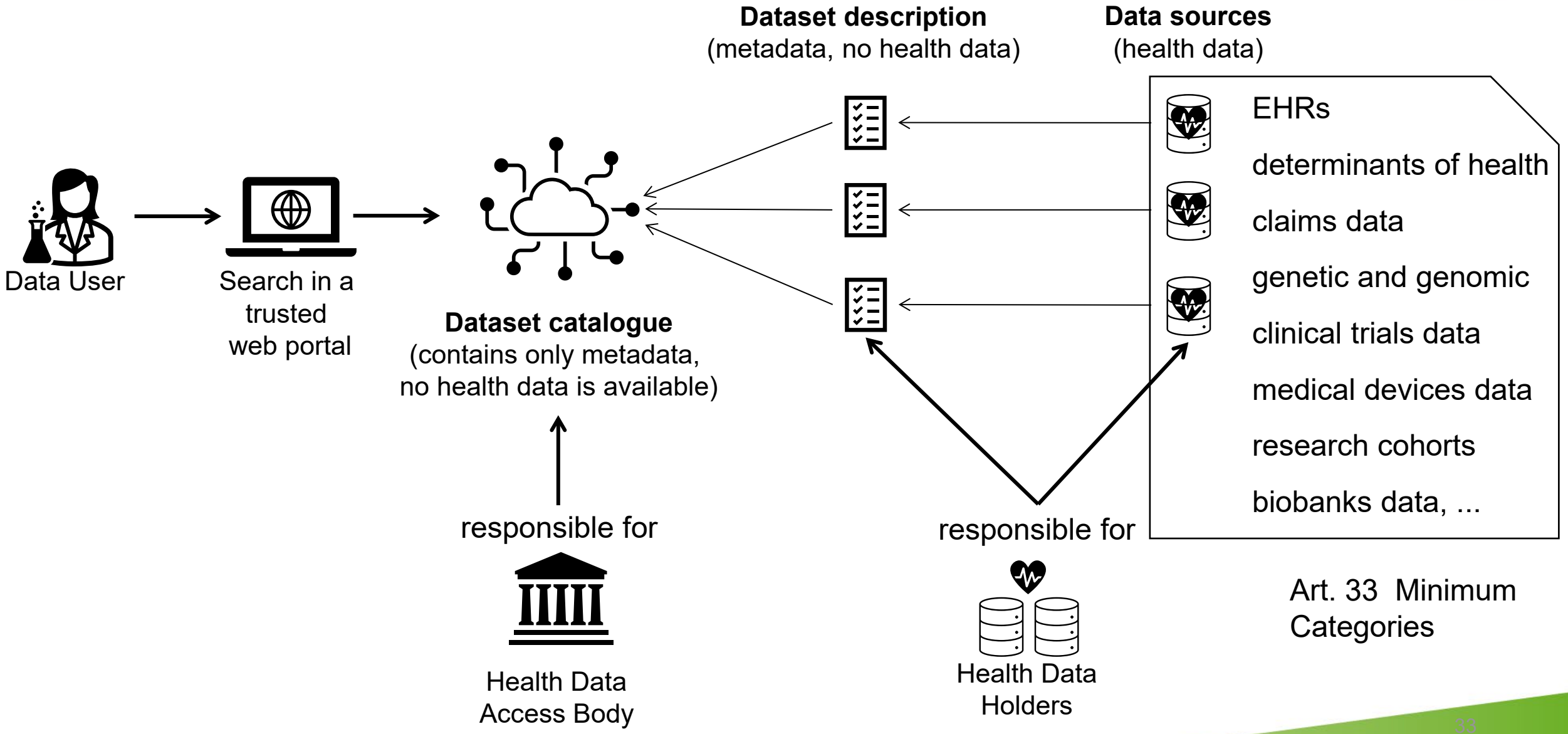
data from registries for medicinal products and medical devices;

health data from **biobanks** and associated databases.

data from **clinical trials**, **clinical studies** and **clinical investigations** subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively;

data from **research cohorts, questionnaires** and surveys related to health, after the first publication of results

Request process



Allowed uses

- Public interest in the area of public and occupational health;
- Policy making and regulatory activities to support public sector;
- Statistics;
- Education or teaching activities in health or care sectors;
- Scientific research;
- Improving delivery of care, treatment optimization and providing healthcare.

Forbidden uses

- Taking decisions detrimental to individuals or groups;
- Employment-related decisions based on health data;
- Advertising or marketing;
- Developing products or services that could harm individuals;
- Activities that conflict with ethical standards set by national law.

Benefits of EHDS2

For regulators and policymakers

- Easier access to health data for purposes of public health, patient safety, general functioning of healthcare systems...
- Better evidence basis for regulatory activities and policy-making.

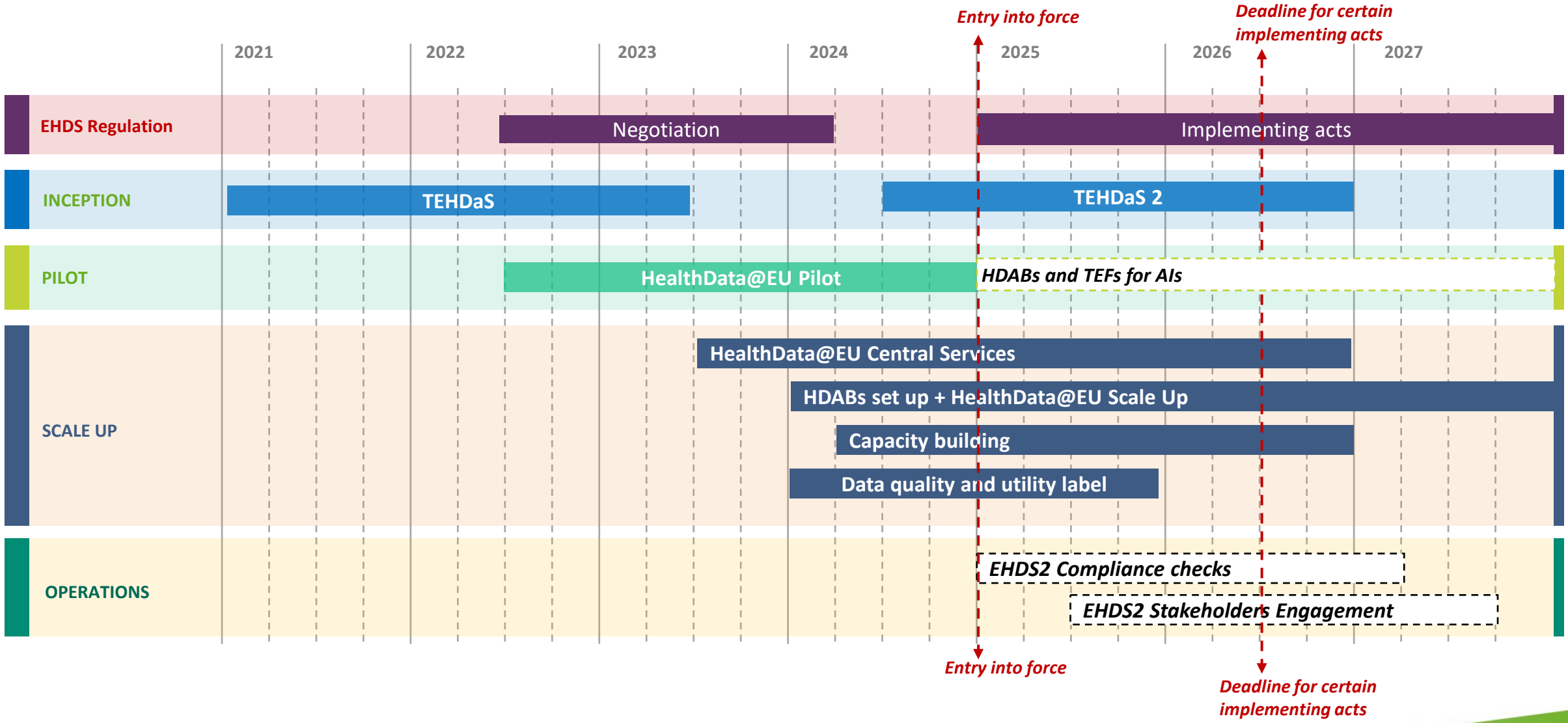
For patients

- In the long run: research leading to new and better treatments
- Transparency of data use

For researchers, including in industry

- Easier access to data for research and development;
- Knowing which health data of which quality are available where;
- Easier and more cost-efficient access to data;
- Easier merging of data, including cross-border .

Roadmap


Entry into force
Deadline for certain implementing acts
2021
2022
2023
2024
2025
2026
2027
EHDS Regulation
Negotiation
Implementing acts
INCEPTION
TEHDaS
TEHDaS 2
PILOT
HealthData@EU Pilot
HDABs and TEFs for AIs
SCALE UP
HealthData@EU Central Services
HDABs set up + HealthData@EU Scale Up
Capacity building
Data quality and utility label
OPERATIONS
EHDS2 Compliance checks
EHDS2 Stakeholders Engagement
Entry into force
Deadline for certain implementing acts

Thank you

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