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Expanding the European EHRxF to share and effectively use health data within the EHDS

Working paper: Public health data sets harmonized with EEHRxF HIDs

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Working paper description

Publishable summary	This working paper presents nine use cases that illustrate how a common data format and a direct link between data with collected for primary use can support public health purposes. These use cases vary in terms of citizen involvement and the use of tools like the Yellow Button. They aim to address objectives such as administrative simplification, improved data quality, real-time monitoring, patient identification, and knowledge generation. Three use cases—focused on antimicrobial resistance, healthcare-associated infections, and cancer—were selected for detailed analysis and harmonization with the EEHRxF and x-Bundles. The mapping of existing datasets to the EEHRxF standards is provided in the annexes. The working paper also includes public health feedback on the "IPS+R" dataset (from WP5) and outlines three planned public health dashboards (by Monasterio, Sciensano, and Charité), demonstrating the potential for real-time, cross-hospital data use without extensive data transformation.

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Statement of originality

This working paper contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Disclaimer

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Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

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1. List of abbreviations

Abbreviation	Term
AMC	Antimicrobial consumption
AMR	Antimicrobial resistance
AMS	Antimicrobial stewardship
ATC	Anatomical Therapeutic Chemical
CAUTIs	Catheter-Associated Urinary Tract Infections
CDA	Clinical Document Architecture
CDISC	Clinical Data Interchange Standards Consortium
CDM	Common Data Model
CLABSI	central line-associated bloodstream infections
CR	Cancer Registry
CSV	Comma Separated Values
DCAT-AP	Application profile for data portals in Europe
DDD	Defined daily dose
DSC	Data Structure Converter
EARS-Net	European Antimicrobial Resistance Surveillance Network
ECDC	European Centre for Disease Prevention and Control
ECIS	European Cancer Information System
EEA	European Economic Area
EEHRxF	European Electronic Health Record exchange Format
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EHR	Electronic Health Record
ENCR	European Network of Cancer Registries
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
ESCMID	European Society of Clinical Microbiology and Infectious Diseases
ESGAID	ESCMID study Group for Artificial intelligence and Digitalisation
ETL	Extraction Transformation Loading
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GP	General Practitioner
HAI	Healthcare-Associated Infection
HDAB	Health Data Access Bodies
HEALTHDCAT-AP	Health Data Catalog Vocabulary- Application Profile
HERA	European Commission's Health Emergency Preparedness and Response Authority
HL7	Health Level Seven
ICD	International Classification of Diseases
ICU	Intensive Care Unit
IPS	International Patient Summary
JRC	Joint Research Centre
LOINC	Logical Observation Identifiers Names and Codes (Regenstrief Institute, Inc.)

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MS	Member State
NCD	Non Communicable Disease
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
PH	Public Health
PHM	Population Health Management
PHR	Personal Health Record
PREMs	Patient Reported Experience Measures
PROMs	Patient Reported Outcome Measures
QCS	Quantitative Continuous Scoring
SNOMED CT	SNOMED Clinical Terms
SPC	Survivorship Care Plan
SSI	Surgical Site Infections
TESSy	European Surveillance System
TNM	Tumour, Nodes, and Metastasis
VAP	Ventilator-Associated Pneumonia
WHO	World Health Organization
XML	Extensible Markup Language

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2. List of tables

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3. Executive summary

This working paper builds on the findings of previous work, which explored the current landscape in Europe by analysing surveys, relevant initiatives, interviews, and literature to assess the needs for effectively linking data collected in primary care with the data needed to support public health.

The reuse of patient level data for public health use cases is unfortunately still lagging behind. Even in the countries and initiatives identified as best practice there are still substantial standardisation efforts that need to be undertaken to comply with the European EHRxF. In this working paper, we describe nine use cases which represent useful examples of needed seamless connection between primary and secondary use of data in Public Health.

The use cases differ depending on citizen involvement and the use of the Yellow Button. In some instances, the application supports existing workflows, while in others, it facilitates more innovative and forward-looking scenarios.; each use case is associated with one or several of the following high-level objectives: administrative simplification, data quality improvement, near real time monitoring, patient discovery, reverse data engineering (from secondary to primary use) or knowledge creation.

Three of these use cases were selected to be studied in further details to seek harmonisation with the available EEHRxF specifications and the x-Bundles. In particular, the three selected use cases refer to established European data sets already in use by the European Centre for Disease Prevention and Control (ECDC) and by the European Network of Cancer Registries (ENCR) to collect relevant data across countries concerning antimicrobial resistance, healthcare-associated infections and cancer. The specific mapping of the established datasets to the EEHRxF is provided in the Annexes I, II, III.

The prioritised datasets also enabled us to provide feedback from the Public Health perspective to the "IPS+R" dataset developed within WP5 in relationship to clinical research.

Additionally, this working paper includes the description of the three planned Public Health Dashboards by Monasterio, Sciensano and Charite. For each dashboard a description of the main statistics and variable involved is provided. The idea is to show that with the European EHRxF, such dashboards useful for public health, could be made available across-hospitals with near real time data without the need for time consuming data transformations.

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4. Use Cases for Public Health

The recent COVID-19 pandemic has highlighted the need for efficient data exchange and real-time monitoring of infection-related data. Merging and comparing infection data enables the creation of new knowledge, supports the monitoring of disease spread, and allows for the early detection of new outbreaks—thereby strengthening infection prevention and control efforts.

In addition to COVID-19, the last two decades have seen the emergence or re-emergence of several infectious diseases that pose significant threats to public health, such as Ebola, Zika, and Dengue. The so-called "silent pandemic" caused by antimicrobial resistance (AMR)[1] is also a major global concern, as it renders certain infectious diseases difficult or even impossible to treat. A key driver of rising AMR is the misuse and overuse of antimicrobials, particularly antibiotics. Immunisation has been one of the most effective tools for protecting public health, but vaccination rates still need to improve. According to the World Health Organization (WHO), coverage levels have not yet returned to pre-pandemic levels following the disruptions caused by COVID-19. Surveillance, based on the analysis of data within and across hospitals and countries is a crucial instrument for preventing and controlling infections[2]. Currently, data is collected across various systems in Europe using different formats and terminologies. This lack of standardisation makes knowledge generation inefficient, as it requires complex data transformation processes that inevitably delay the availability of critical information.

Six of the identified 9 use cases described in this working paper are addressing the need to improve infectious disease preparedness as well as reinforce prevention and control systems to support public health. Two use cases address the topic of Cancer which is one of the main priorities of the European Commission in the health domain[3]. Notably, 40% of cancers could be prevented through known strategies, yet only 3% of health spending is directed toward prevention and health promotion. Addressing cancer prevention also contributes to reducing other chronic conditions like obesity, heart disease, and diabetes, as they share similar risk factors. It is important to monitor and analyse cancer trends across Europe, support policy evaluation, guide research, and provide insights into cancer prevention, treatment, and control. It also serves as a resource for the public and helps forecast future cancer burden.

Not all the use cases involve the Yellow Button: four focus on the standardisation of established relevant data sets for public health, four uses cases represent possible innovative useful applications that the European EHRxF could enable.

Use case number 8 focuses on the possibility to cross-correlate datasets to gain new knowledge on possible impact of health conditions and undergoing treatment with traffic accidents to develop new knowledge on additional accident causes.

To ensure consistency with other WPs, we have used as much as possible the same template as in WP3 for describing the use cases. Despite the fact that the template was not created to fit the purposes of WP4, we were able to use it with only very minor adaptations. The description of the use cases mainly focusses on the data and does not always describe all the requirements necessary (mainly in relationship to security and privacy) to guarantee the feasibility of the use case.

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Use Case #	Topic	Type of service	Content
Use case 1	Antimicrobial resistance (AMR)	Administrative simplification, real time monitoring	ECDC dataset
Use case 2	Infection surveillance	Administrative simplification, real time monitoring	ECDC dataset
Use case 3	Cancer monitoring	Administrative simplification, real time monitoring	ECIS dataset
Use case 4	Vaccination support	Patient support, PROMs	Innovation
Use case 5	One Health surveillance data collection	Administrative simplification, real time monitoring	EFSA dataset
Use case 6	Patient reported outcome measures on Long COVID	Patient support, PROMS, patient discovery, knowledge creation	Innovation
Use case 7	Updating the survivorship passport	Patient Support, reverse data engineering	Innovation
Use Case 8	Traffic Data	Knowledge creation	Cross-correlation of databases
Use case 9	Use of antibiotics at home	Patient discovery, real-time monitoring, knowledge creation	Innovation

Table 1: *The list of identified public health use cases bridging the gap between primary and secondary use of data.*

The individual use cases are explained in detail in the following section.

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4.1 Use case 1: Antimicrobial resistance

Description	The ability of pathogens to change over time and no longer respond to medicines makes infections harder to treat, increasing the risk of disease spread, severe illness, and death. Prevention, appropriate antibiotic prescribing, and proper dispensation are key factors in combating this threat. Systematic collection of data on antimicrobial resistance (AMR) is essential for monitoring the incidence of specific bloodstream infections. Since the inappropriate use of antimicrobial drugs is a major contributor to AMR, the EU has set a target to reduce their use by 20% by 2030. At European level data on antimicrobial resistance are collected by the European Centre for Disease Prevention and Control (ECDC)[3] by means of a specific Network: the European Antimicrobial Resistance Surveillance Network (EARS-Net)[4]. The ESAC-Net[5], represents a network of national surveillance systems also coordinated by ECDC, that gathers reference data on antimicrobial consumption (AMC) across Europe. It collects and analyses data from EU and EEA countries, covering both community and hospital settings. This data is used to provide insights and feedback to EU and EEA countries on antimicrobial consumption indicators. These indicators help track progress toward the responsible use of antimicrobials. Data on antimicrobial resistance and consumption collected by EARS-Net and ESAC-Net represent an important instrument for antimicrobial surveillance and antimicrobial consumption monitoring in Europe. Data are submitted on a predefined schedule after being transformed to align with a specified metadata schema. With the EEHRxF data from laboratories as well as information on antimicrobial consumption could be made available in almost real-time both at national level and at international level for public health purposes without the need for error-prone data transformations. This enables data to be used for real-time monitoring and for anticipating critical issues thus allowing timely decision-making and prompt intervention.
Document Version:	V1.0
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As-Is Situation:	Little or no harmonisation exists in the field of microbiology across laboratories in Europe. Some organisations such as groups HL7 Europe[6] and ESCMID[7] are organising working groups to address this issue. Some countries have established their own national data models—such as the Danish MiBa[8] or the model included in the Austrian ELGA Laboratory Guidelines[9]. The former uses national standards, while the latter is based on HL7 CDA. Germany has recently published a data model[10] for microbiology that relies on international standards such as FHIR, SNOMED CT, and LOINC. An international approach is essential to ensure timely communication across systems in the field of AMR and AMC and real-time availability of data at cross-system level for critical decision making to control the spread of infections. EARS-Net and ESAC-Net represent an important instrument to collect comparable AMR and AMC data and to analyse their temporal and spatial trends in Europe. However, at the moment, each country collects data according to its own national procedures and then transforms it according to the metadata schema and its coding conventions before submitting it to the ECDC via TESSy[11] according to a pre-fixed schedule.
Currently available products/services and its vendors:	The European Surveillance System (TESSy) and the metadata schema by ECDC.
Which health-related standards or data formats are involved in this process:	To support data collection, the ECDC has developed a metadata schema aimed at harmonising AMR and AMC information across Europe. This is a valuable step toward European-level standardisation. However, many AMR-related concepts still rely on local or protocol-specific coding systems rather than international standards, particularly for epidemiological variables and answer value sets. In contrast, data on antimicrobial consumption follow the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC)/Defined Daily Dose (DDD) system to classify antimicrobial substances and measure consumption. Data can be submitted directly to the TESSy System or via CSV and XML files.

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<table>
<tr><td>Actors/Users and their Roles:</td><td>
<table>
<tr><td>Laboratories</td><td>Detect drug-resistant microorganisms</td></tr>
<tr><td>Patients</td><td>Take antibiotic medications.</td></tr>
<tr><td>Healthcare providers and laboratories</td><td>Prescribe /Administer antibiotic medications. Send EEHRxF compliant data to PH national agencies</td></tr>
<tr><td>Public Health regional/national agencies</td><td>Receive data from local healthcare providers in a common EEHRxF format and efficiently merge them for local real-time monitoring, decision making and for sending to ECDC</td></tr>
<tr><td>ECDC</td><td>Receives data from regional/national authorities and is enabled to do real-time monitoring</td></tr>
</table>
</td></tr>
<tr><td>User Perspective:</td><td>The same EEHRxF format is used in laboratories Healthcare providers systems, EHRs and public health systems for efficient data transmission.</td></tr>
<tr><td>System Perspective</td><td>EEHRxF-enabled systems can collect and exchange antimicrobial resistance and consumption data using the same format. Ideally also Tessy will be enabled to receive EEHRxF-compliant data.</td></tr>
<tr><td>Health Information Domain(s) - HIDs:</td><td>Laboratory, ePrescription/eDispensation, Patient Summary, Discharge Report.</td></tr>
<tr><td>National/regional strategy:</td><td>National and regional public health authorities are enabled to receive and send data according to the EEHRxF and establish near real-time monitoring programs and make informed decisions.</td></tr>
<tr><td>Strategy towards EHDS:</td><td>Exploit the EEHRxF to make antimicrobial data for resistance and consumption readily available for secondary use.</td></tr>
<tr><td>Business Goals/Benefits:</td><td>Administrative simplification by enabling “only once” strategies from laboratories and EHRs to public health authorities. Enable Public Health authorities to establish real-time dashboards for</td></tr>
</table>

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	antimicrobial resistance and consumption for critical decision-making.
KPIs:	Number laboratories adopting the format. Number of submissions of EEHRxF compliant data to ECDC. Number of operating real-time monitoring systems.
Application:	Import/Export functionalities for EEHRxF data.
Data Preconditions:	EEHRxF–Laboratory and Prescription data for antimicrobial resistance and consumption data.
User Preconditions:	Laboratories and healthcare providers are aware of the real time monitoring and can validate data in EEHRxF format. ECDC analysts are also familiar and trained to use the format.
System Preconditions:	Laboratory information systems, healthcare providers and ECDC systems need to import and export data according to the EEHRxF. Semi-automatic validation processes have been established.
Trigger:	AMR occurrence, antimicrobial consumption.
Challenges/Limitations:	The list of prioritised resistant organisms changes over time and it should be possible to quickly expand it. Current data collection process is well established and resistance to change is expected. More direct and agile communication protocols need to be established between ECDC (TESSy) and National contact points. Data format used in clinical setting are not sufficiently aligned with that used in secondary use. A large number of systems need to be adapted and become EEHRxF compliant.
Involved stakeholders in the BUC definition:	Charité, EHTEL, Sciensano.

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Application of pseudonymisation filters:	No
Basic Workflow:	ECDC needs to urgently collect information on how many cases of a specific resistant bacterium were detected in Europe, which resistance tests were performed and the results. Additionally, ECDC intends to run a near real-time survey on antimicrobial consumption and adherence. Thanks to the EEHRxF, ECDC can quickly collect laboratory and prescription data from national authorities because they all use the same format. National authorities and ECDC are enabled to monitor antimicrobial resistance and consumption in near real-time.

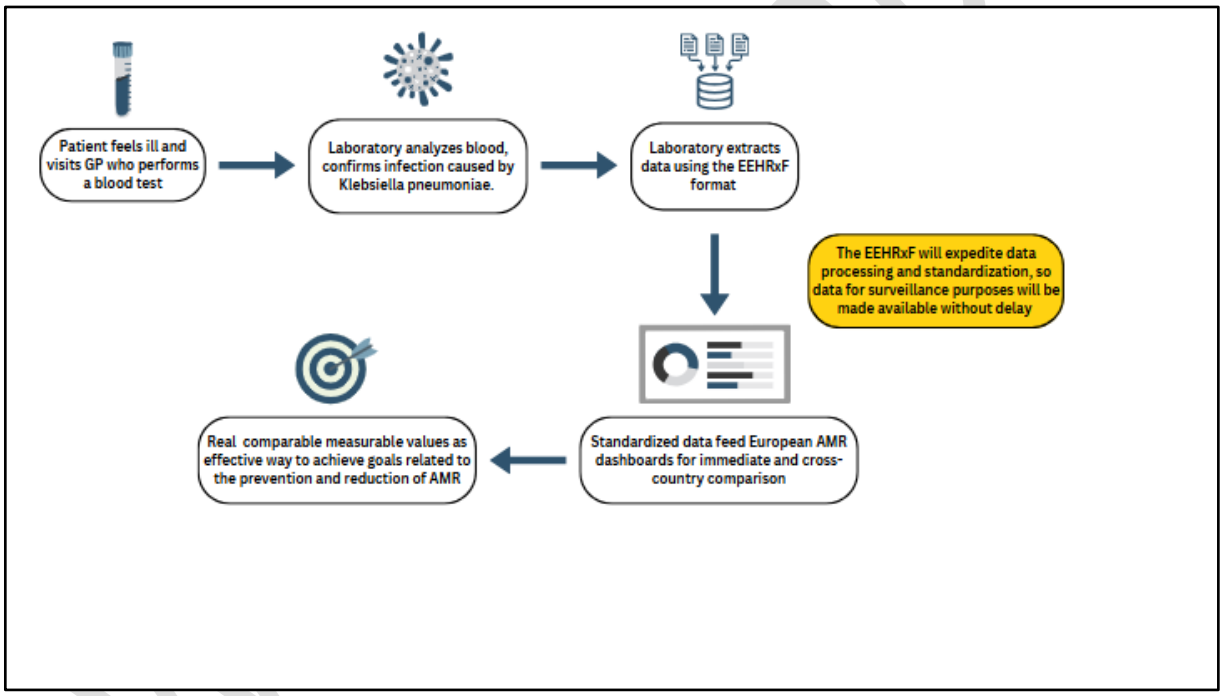

Fig.1: Use Case 1 Workflow example.

4.2 Use case 2: Infection surveillance

Description	Over the past two decades, we have seen outbreaks of emerging, re-emerging, and endemic pathogens that have spread rapidly, driven by factors such as global connectivity, an aging population, population growth, and climate change. In order to improve prevention and control of the diseases caused by these pathogens it is essential to establish surveillance systems that efficiently and effectively detect outbreaks and notify them to competent authorities. The timely exchange of data across

	institutions and countries is crucial to contain the spread of the infection. The term Healthcare Associated Infections (HAI) in particular refers to infections that patients get in a healthcare facility while receiving medical care. HAIs among infections, deserve particular attention for the complications that they might cause in patients and also because HAIs can largely be avoided by applying correct infection prevention and control measures. The data on HAI at European level is collected by the ECDC through the TESSy surveillance system. This use case aims to support the efficient exchange and monitoring of HAI data by mapping the data collected by ECDC[12] to international interoperability standards. The goal is to establish a direct connection between data captured in clinical setting and the information needed for HAI monitoring at both national and European levels. This will be achieved by proposing a standard data model that is consistent across systems collecting data for primary use and systems created for secondary use, enabling seamless mapping to international standards.
Document Version:	V1.0
Responsible party:	WP4
Source:	xShare
As-Is Situation:	HAI data are collected by European countries following local procedures and are then transformed to align with the TESSy metadata schema for integration at the international level. The data collection follows a predefined schedule, with national public health authorities submitting their data in accordance with the specified metadata schema. Submissions can be made directly through the TESSy platform or by uploading XML or CSV files.
Currently available products/services and its vendors:	Data is submitted to ECDC via the TESSy system. HelicsWin.Net is a Free software tool for local data collection.
Which health-related standards or data formats are involved in this process	To support data collection, the ECDC has developed a metadata schema aimed at harmonising HAI information across Europe. This is a valuable step toward European-level standardisation. However, many HAI-related concepts still rely on local or protocol-specific coding systems rather than international standards, particularly for epidemiological variables and answer value sets. Data can be submitted directly to the TESSy System or via CSV and XML files.

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<table>
<tr><td>Actors/Users and their Roles:</td><td><table>
<tr><td>Healthcare facilities</td><td>Collect HAI data according to the EEHRxF format and send them to national authorities</td></tr>
<tr><td>National authorities</td><td>Send the data from the different healthcare facilities to the TESSy system and are enabled to create real-time monitoring systems at different levels</td></tr>
<tr><td>ECDC</td><td>Tessy imports EEHRxF-compliant data. ECDC is enabled to create real-time monitoring systems</td></tr>
</table></td></tr>
<tr><td>User Perspective:</td><td>The same EEHRxF format is used by laboratories, healthcare providers, EHRs and public health authorities to reduce delay between data collection and data transmission to competent authorities while also preserving data quality.</td></tr>
<tr><td>System Perspective</td><td>EEHRxF-enabled systems will be able to collect and exchange HAI data using the same format. Ideally also TESSy will be enabled to receive EEHRxF-compliant data.</td></tr>
<tr><td>Health Information Domain(s) - HIDs:</td><td>Laboratory report, Discharge Report.</td></tr>
<tr><td>National/regional strategy:</td><td>National public health authorities are enabled to receive and send data according to the EEHRxF</td></tr>
<tr><td>Strategy towards EHDS:</td><td>Exploit the EEHRxF to make HAI data readily available, reduce data delay and maintain data quality in the transmission of data from laboratories to public health authorities</td></tr>
<tr><td>Business Goals/Benefits:</td><td>Administrative simplification by enabling “only once” strategies from laboratories to national and international public health authorities.

Enable real-time monitoring.</td></tr>
<tr><td>KPIs:</td><td>• Number of laboratories and healthcare facilities adopting the EEHRxF for HAI data</td></tr>
</table>

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	• Number of submissions of EEHRxF compliant data to ECDC • Number of real-time monitoring systems
Application:	Import/Export functionalities for EEHRxF data.
Data Preconditions:	EEHRxF –compliant data model for HAI data.
User Preconditions:	Capability of sending data in EEHRxF format.
System Preconditions:	Healthcare facilities information systems should be enabled to manage HAI data according to the EEHRxF. ECDC should be enabled to import EEHRxF-compliant data.
Trigger:	HAI infection occurring in ICU.
Challenges/Limitations:	Enable all laboratories and healthcare providers to produce data according to the EEHRxF. Enable TESSy to receive data in a EEHRxF –compliant format.
Involved stakeholders in the BUC definition:	Charité, EHTEL, Sciensano
Application of pseudonymisation filters:	No
Basic Workflow:	A nosocomial infection occurs while patient is in ICU. HAI information compliant to Laboratory and Discharge Report EEHRxF is stored at the hospital and also sent to the regional and national authorities. Same surveillance detection algorithms can be shared across different hospitals because they all use the EEHRxF.

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	National authorities are enabled to immediately receive and use the data for real-time monitoring of HAIs. National authorities send EEHRxF data to the European HAI Surveillance Network. Thanks to the EHDS and the standardisation of data no transformation is needed to send the data from ICU to the European Network Surveillance.

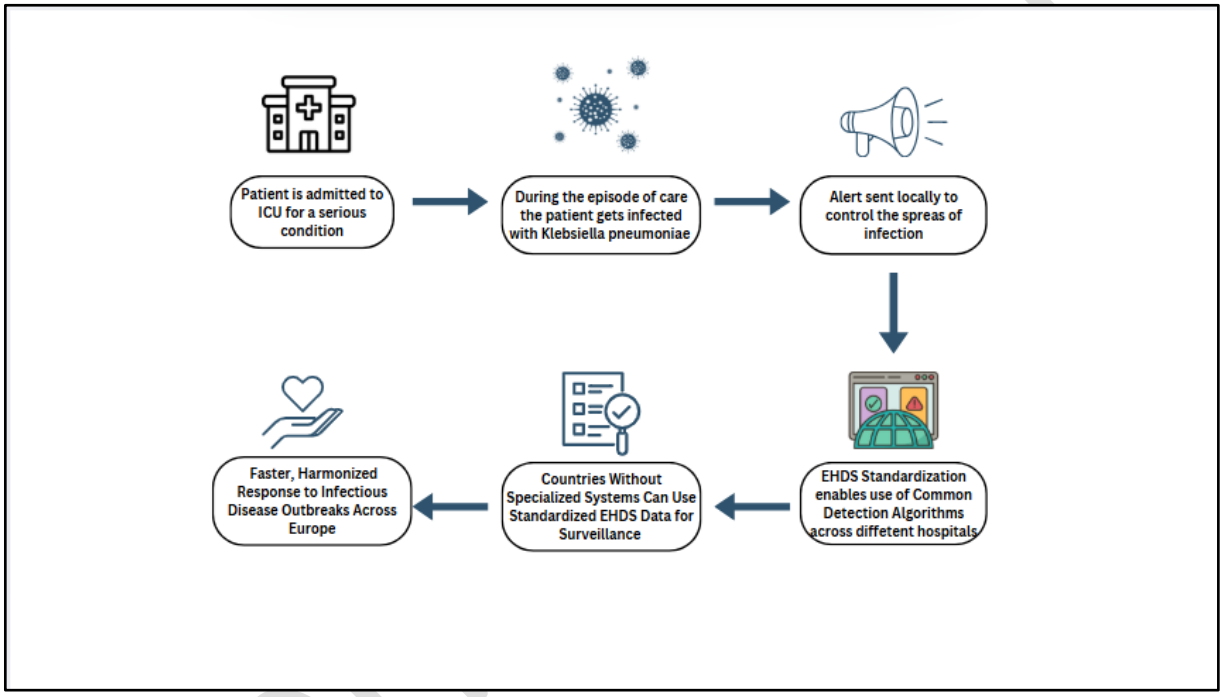

Fig.2: Use Case 2 workflow example

4.3 Use case 3: Cancer monitoring

Description	The European Cancer Information System (ECIS)[13] monitors cancer trends and burden, providing advanced tools for in-depth regional data analysis. It relies on national datasets, though there is a significant time lag before historical data becomes accessible. The range of data collected includes Patient Summary and Discharge Reports with detailed cancer-specific information. Data are collected according to the Call for Data Protocol for European Population-Based Cancer Registries[14]
Document Version:	V1.0

<table>
<tr><td>Responsible party:</td><td>WP4</td></tr>
<tr><td>Source:</td><td>xShare</td></tr>
<tr><td>As-Is Situation:</td><td>No European standard-based data model is available for these data. On the semantic level, there have been however efforts to provide adapted vocabularies such as WHO ICD-O, ICD-10 and the TNM Classification of Malignant Tumours which are used by most registers and the US NCI Meta thesaurus as possible meta-integrator; Those resources are often completed by national resources (for pathological anatomy for example). All countries collect data according to local procedures. ENCR has established a Call for Data Protocol for European Population-Based Cancer Registries through ECIS.

There here have been limited attempts to better connect the cancer registries with data available in EHR systems.</td></tr>
<tr><td>Currently available products/services and its vendors:</td><td>All participating countries submit data according to the ECIS protocol. Data quality is checked using the cancer data quality check list included in the Joint Research Centre (JRC) technical report[15]

The data collection process follows thus a two steps approach: First at national level and then at European level with the responsibility of eventual mapping falling under the responsibility of the registry owner.</td></tr>
<tr><td>Which health-related standard are currently being used:</td><td>Data is currently submitted under CSV format containing 40 variables via a secured webportal. “The file should be a text file (.csv or .txt) with semi colon (;) separators and should include a header, with variables’ names and order as specified in the text below.

PAT; MoB; YoB; Age; Sex; Geo_Code; Geo_Label; TUM; MoI; YoI; BoD; Topo; Morpho; Beh; Grade;Autopsy; Vit_stat; MoF; YoF; Surv_time; ICD; CoD; TNM_ed; cT; cN; cM; pT; pN; pM; ToS; Stage;Surgery; Rt; Cht ; Tt; It; Ht; Ot; SCT

Two tools have been developed to support users: A Data Structure Converter (DSC) software is available, as a protocol data adapter as well as a Quality Check Software (QCS), both available via this link: https://encr.eu/tools-for-registries.</td></tr>
<tr><td>Actors/Users and their Roles:</td><td><table><tr><td>Healthcare Providers</td><td>Collect data in EEHRxF Format</td></tr></table></td></tr>
</table>

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	<table><tr><td>Local Public health authorities</td><td>Receive and share cancer data for the registries with EEHRxF-compliant information</td></tr><tr><td>ECIS</td><td>Receives data in the EEHRxF format</td></tr></table>
User Perspective:	Healthcare providers and oncology units in particular have been made aware of the need to provide essential data as quick as possible in the EEHRxF.
System Perspective	Systems are enabled to send and receive data according to the EEHRxF. The EEHRxF formats used in EHR is used to populate national and European cancer registries. The specific variables not currently included in the EEHRxF are provided through a dedicated pop-up with adapted user constraints. Local systems and Registers are synchronised through adapted connectors.
Health Information Domain(s) - HIDs:	Patient Summary. Discharge Report. (Imaging report)
National/regional strategy:	National public health authorities can send EEHRxF- compliant cancer data to ECIS limiting to the minimum the need of transformation.
Strategy towards EHDS:	Use EEHRxF-compliant data collected right from the source to have quality data readily available to support research as well as public-health monitoring and decision-making in the field of cancer at National and European level.
Business Goals/Benefits:	Both administrative simplification and real time monitoring Exploit the EEHRxF to enable real- time monitoring of key variables related to cancer burden across Europe and preserve data quality by removing data transformations.
KPIs:	• Number of national cancer registries compatible with the format • Number of submission to national portal/ECIS using the EEHRxF
Application:	Import/export functionalities for EHR and cancer registries using the EEHRxF

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Data Preconditions:	EEHRxF compliance and adherence to specific semantic constraints
User Preconditions:	Roles have been allocated within the organisation related to the responsibility of data production and the specific constraints attached (semantics, time).
System Preconditions**:**	Local system can identify relevant data (cancer diagnosis) and trigger a Patient Summary including the key variables agreed upon. The local system can manage related terminology bindings and mappings. A (HL7 FHIR) connector is existing to transfer and validate the data to the national register. The national Cancer register has provided a digital script to local systems which allows to provide the data not covered by the EEHRxF. A synchronisation process is established between national register and ECIS concerning the priority variables. Security and Privacy Policies should already be in place.
Trigger:	Confirmation of a Cancer diagnostics.
Challenges/Limitations:	Compliance to EEHRxF to format for priority variables by all cancer registries Development needed by all actors (local EHR systems, Connector provider, Cancer Register and ECIS.
Involved stakeholders in the BUC definition:	Charité, EHTEL, Sciensano.
Application of pseudonymisation filters:	Yes
Basic Workflow:	A hospital is legally obliged to feed the national Cancer Register. This is however a time- consuming process which is performed by dedicated staff. A new data collection process is established: Essential data such as diagnostics is provided on (near) real time while other data are

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	provided at a later stage. The national Registers and the European Cancer Information System are now fed with near real time data while complete data collection follows later. The Hospital collects initial cancer information according to the EEHRxF format. Because of the EHDS the format and terminology of cancer data and EEHRxF are aligned, and the complete data collection is facilitated without duplication of data.

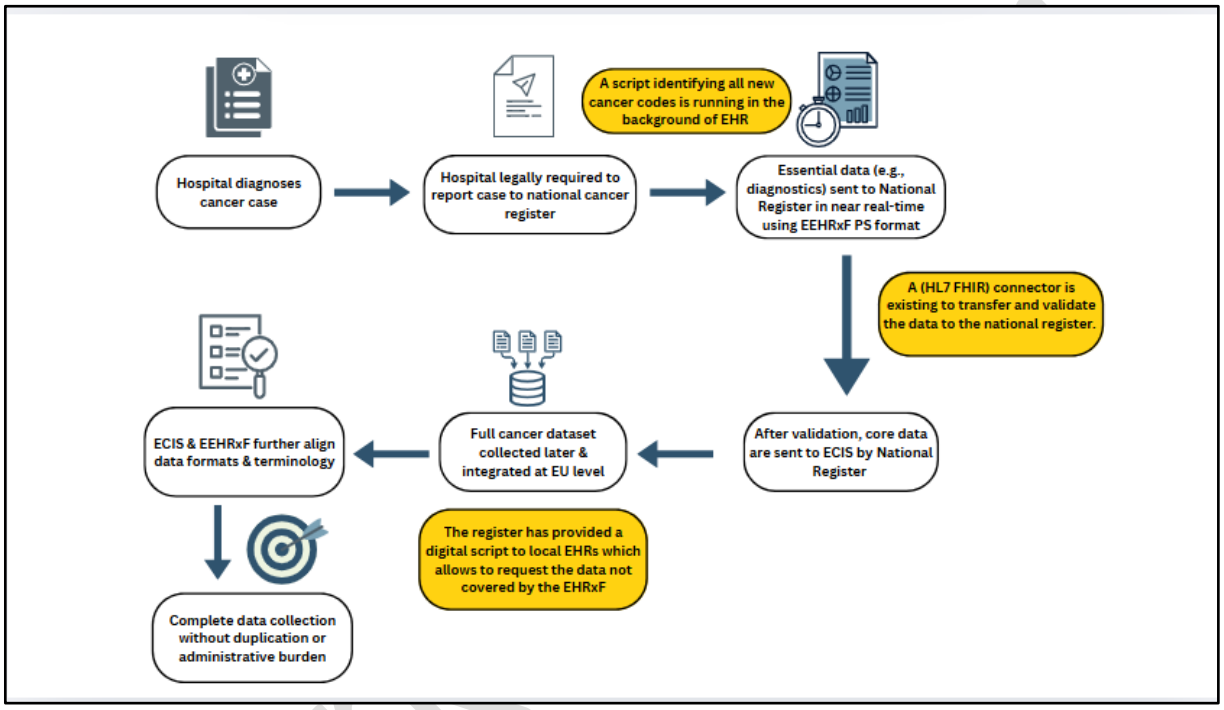

Fig.3: Use Case 3 workflow example

4.4 Use case 4: Vaccination support

Description	As vaccination rates continue to decline and infectious diseases become an increasing threat to global health, it is important to engage with citizens to build trust in vaccination. Providing citizens with a means of communicating with competent authorities about their motivation, doubts and questions could help invert this trend. Through the Yellow Button, citizens could, if they wished, express their vaccination hesitancy by completing specific questionnaires, provided by the competent regional or national authorities via EHR portals and PHR apps, to share with them their hesitancy motivations. Additionally, through the same platforms they could receive selected scientifically evidence-based information about the risks and benefits of the specific

<table>
<tr><td></td><td>vaccine, or even further details about how they are developed and how they work.

On one hand, this would help public health authorities better understand the causes of vaccine hesitancy and plan interventions; on the other, it would support informed decision-making on immunisation by citizens, reducing the chances of decisions being influenced by non-scientific information easily available on the internet.

Through the Yellow Button citizens could also have the chance to add vaccination information to their EHR as self-reported information if not already included.</td></tr>
<tr><td>Document Version:</td><td>V1.0</td></tr>
<tr><td>Responsible party:</td><td>WP4</td></tr>
<tr><td>Source:</td><td>xShare</td></tr>
<tr><td>As-Is Situation:</td><td>While vaccination information is included in the patient summary, patients cannot usually add EEHRxF data on vaccination themselves. Even in countries where a global vaccination registration system exists which connects with EHRs, it often does not succeed to collect information coming from a number of systems. Additionally, if citizens receive a vaccine in a different country this is not directly visible on their EHRs.

Furthermore, citizens are often exposed to multiple sources of information about the benefits and risks of vaccination, making it challenging to identify reliable, evidence-based content on which to base informed decisions.</td></tr>
<tr><td>Currently available products/services and its vendors:</td><td>EHR systems and regional/national vaccination registers.</td></tr>
<tr><td>Which health-related standards or data formats are involved in this process</td><td>Patient summary, ad hoc questionnaires.</td></tr>
<tr><td>Actors/Users and their Roles:</td><td><table><tr><td>Citizens</td><td>Receive selected scientific information about benefits and risks of specific vaccinations. They are also able to send EEHRxF-Patient Summary compliant additional vaccine information to their EHRs. Citizens can also be enabled to provide vaccine hesitancy</td></tr></table></td></tr>
</table>

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		information through specific questionnaires provided on their health portals/web by public health authorities
	Local Public health authorities	Provide information about risks and benefits of vaccination when requested. Receive EEHRxF-compliant additional data from patient about vaccination and in case, approve its inclusion in the EHR. Authorities can decide to collect information on vaccine hesitancy through standardised questionnaires distributed through the health portals/apps.
User Perspective:	Citizens can obtain selected information by relevant authorities on benefits and risks of vaccination if they are not aligned with the recommended vaccination schema. Additionally, they can add vaccination information, if missing, to their EHR/PHR. The user interface needs to be adapted to non clinicians and make sure data are collected according to the format. Citizens can also be invited to provide vaccine hesitancy information to public health authorities via standard questionnaires through their health portal/apps.	
System Perspective	EHR systems should be enabled to accept data on immunisation status directly from citizens if not already included. The Yellow Button can be used to trigger download of vaccine safety and efficacy information. The Yellow Button could be used to upload vaccine hesitancy information.	
Health Information Domain(s) - HIDs:	Patient Summary	
xShare Yellow Button:	The Yellow Button can be used to download selected vaccination-specific information on the patient personal space of the health portal or app. The Yellow Button can be used to upload additional vaccination-specific information to the (shared) EHR. The Yellow Button can be used to upload also vaccine hesitancy information from citizens which is shared with Public Health authorities	

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National/regional strategy:	National and regional public health authorities could base interventions on more complete vaccination data also addressing hesitancy issues with targeted actions. Vaccination rates increase.
Strategy towards EHDS:	Empower patients to make active informed decisions and share their data.
Business Goals/Benefits:	• Provide patients with selected scientific information about the risks and benefits of vaccination to help increase vaccination rates. • Ensure that all vaccination records, including those obtained in other European countries can be included. • Understand the causes of vaccination hesitancy • Increase vaccination rates
KPIs:	• Number of downloads of vaccine information • Number of uploads of additional vaccine information • Numbers of vaccine hesitancy questionnaires submitted • Vaccination rates
Application:	Yellow button, EHR, PHR.
Data Preconditions:	EEHRxF compliance (also for the vaccine hesitancy questionnaire).
User Preconditions:	Citizens are willing to receive and provide information on vaccinations.
System Preconditions:	Yellow Button-enabled EHRs.
Trigger:	Need for trustworthy information/Possibility to add data to HER.
Challenges/Limitations:	Set up of the download and upload functionalities for vaccine-related data
Involved stakeholders in the BUC definition:	Charité, EHTEL, Sciensano.

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Application of pseudonymisation filters:	No
Basic Workflow:	• Citizen is hesitant to receive vaccination because he/she is not sure about positive/negative effects of the substance. They fill out a standardised questionnaire created by the competent authorities through the patient app/portal and click the Yellow Button to upload their answers and share with them the reasons for their hesitancy. • Through the Yellow Button citizens can also request and receive specific scientific evidence- based information on the safety and efficacy of vaccination • Citizen read the scientific material and decides to get vaccination • Through the Yellow Button updates his/her EHR if the information is not up to date • Public health authorities identify possible causes of vaccine hesitancy and plan targeted communication campaigns

Paper

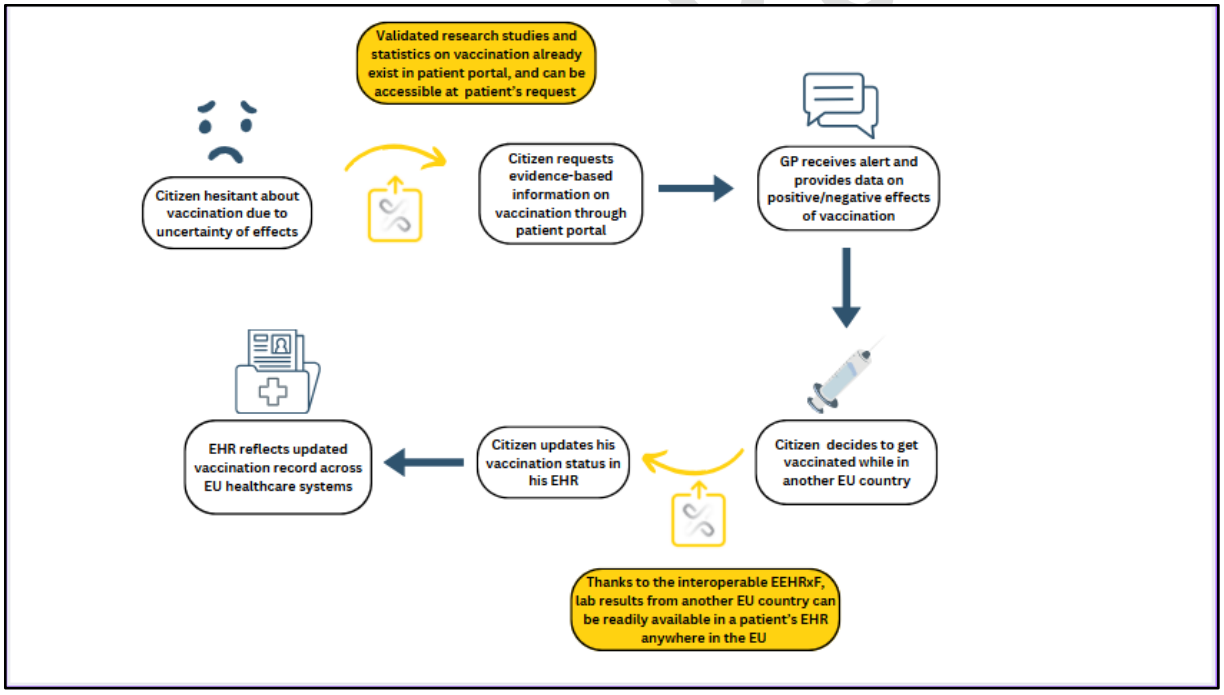

Fig.4: Use Case 4 workflow example

4.5 Use case 5: One Health surveillance data collection

Description	With the increasing threat of zoonoses—infectious diseases originating from animals, also due to environmental factors—it is

	particularly important that data be comparable and shareable across human, animal and environmental disciplines. The European Food Safety Authority (EFSA) has been tasked by the European Commission to collect, analyse and visualise the results from the surveillance activities concerning cross-border pathogens that threaten Europe carried out within the 2022 EU4Health using the One Health approach[16]. Thanks to the EHDS and the standardisation of data, the same format for zoonosis-related microbiology data can be used across veterinary and human laboratories and public health authorities. Additionally, using the same data format, infection detection algorithms can be shared across different organisations.
Document Version:	V1.0
Responsible party:	WP4
Source:	xShare
As-Is Situation:	All countries collect data according to local procedures. No common format for laboratory data across human and veterinary laboratories exists. EFSA has established a European Reporting guidance for the One Health surveillance data collection using the Standard Sample Description (SSD2) data model
Currently available products/services and its vendors:	For countries reporting to EFSA, data is submitted according to the One Health surveillance data collection protocol by EFSA. Laboratory data for One Health surveillance are reported using the SSD2 data model, and submitted via XML through the Data Collection Framework (DCF) in line with EFSA's Data Exchange Guidance (GDE2). The SIGMA EST mapping tool helps mapping data to the SSD2 format.
Which health-related standards or data formats are involved in this process	EEHRxF laboratory data, microbiology specific terminology, SSD2 format for describing food and feed samples and analytical results that is used by EFSA's data providers.

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<table>
<tr><td>Actors/Users and their Roles:</td><td><table>
<tr><td>Veterinary and human laboratories</td><td>Detect infections and send data to relevant local public health authorities using EEHRxF</td></tr>
<tr><td>Local/National Public health authorities</td><td>Receive data in EEHRxF from all laboratories and can merge them and send them to national or international authorities (e.g. EFSA)</td></tr>
<tr><td>EFSA</td><td>Receives high quality data in EEHRxF compliant format ready to be merged and analysed</td></tr>
</table></td></tr>
<tr><td>User Perspective:</td><td>Veterinary laboratories can collect data in a standard EEHRxF compliant format and share them with national and international competent authorities without further data transformation.</td></tr>
<tr><td>System Perspective</td><td>The same EEHRxF format is used across veterinary and human laboratories and relevant public health systems to improve real-time availability of data. The same format allows for data to be immediately available for integration and comparison.</td></tr>
<tr><td>Health Information Domain(s) - HIDs:</td><td>Laboratory</td></tr>
<tr><td>National/regional strategy:</td><td>National public health authorities are enabled to receive and send data according to the EEHRxF without performing data transformation before submitting data to the European One Health surveillance networks, Real-time monitoring and comparison of infection outbreaks with human microbiology laboratories is possible because they all share the same format.</td></tr>
<tr><td>Strategy towards EHDS:</td><td>Support the secondary use of data. Exploit the EEHRxF to apply “only once” strategies to reduce data delay and maintain data quality in the transmission of data across laboratories and to public health authorities.</td></tr>
<tr><td>Business Goals/Benefits:</td><td>Create one EEHRxF-compliant data model for information on zoonotic infections for the data defined by the data used in EFSA's One Health surveillance data to
Enable “only once” strategies across laboratories and to public health authorities
Obtain faster outbreak detection
Enable efficient joint analysis of data for real-time monitoring</td></tr>
</table>

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KPIs:	• Number of veterinary laboratories adopting the format • Number of submissions of EEHRxF compliant data to the One Health surveillance system by EFSA
Application:	Import/Export functionalities for EEHRxF data for laboratory data.
Data Preconditions:	A common EEHRxF-compliant data model concerning microbiology data is available.
User Preconditions:	Capability to receive and send laboratory data in EEHRxF format
System Preconditions:	Systems should be enabled to receive and send data in EEHRxF format
Trigger:	Detection of pathogens in animals that pose a cross-border public health threat.
Challenges/Limitations:	Enable EFSA systems to receive EEHRxF laboratory data
Involved stakeholders in the BUC definition:	Charité, EHTEL, Sciensano
Application of pseudonymisation filters:	No
Basic Workflow:	• Zoonoses data are collected in veterinary and human laboratories using the EEHRxF • Data are sent to local/national health authorities • Possible outbreaks are detected, and the responsible livestock reservoir is identified immediately. • National authorities laboratory data can share data in One Health European Networks • Real-time monitoring of zoonotic infections is possible at national/regional and international level

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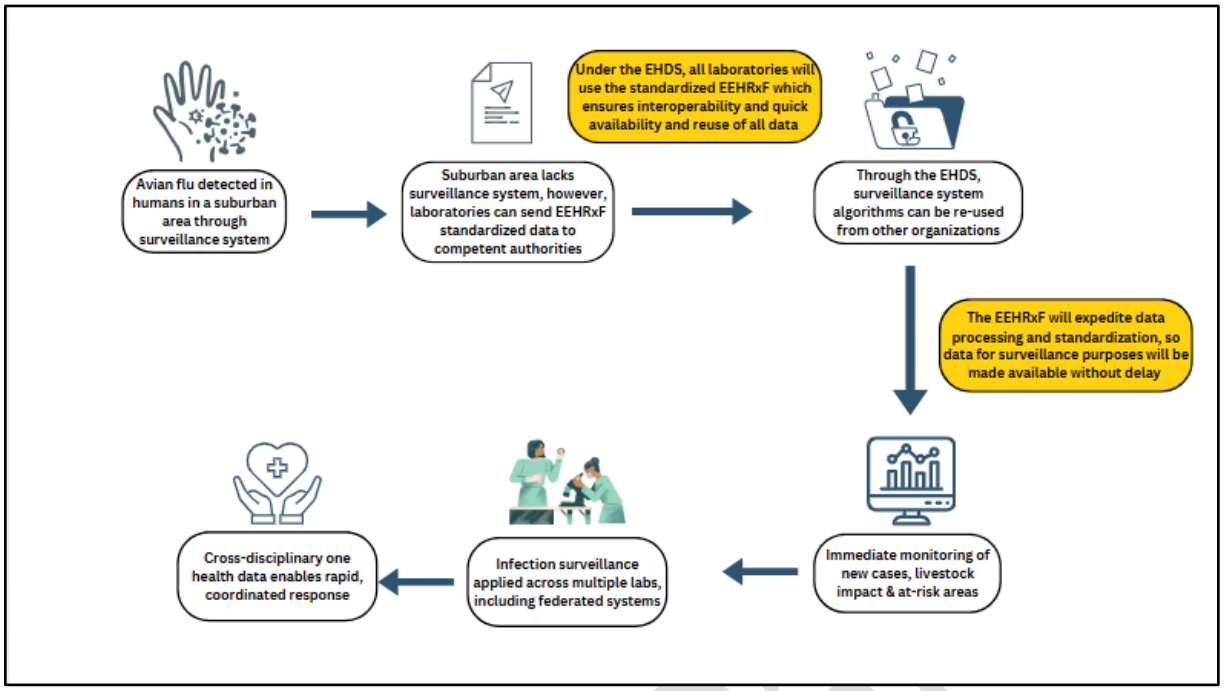

Fig.6: Use Case 6 workflow example

4.6 Use case 6: long COVID

Description	This use case proposes a visionary application of the Yellow Button, allowing citizens to choose to share data directly with public health authorities to support specific public health initiatives. Long COVID, for example, is a condition that may be caused by a combination of different factors, and extensive research is still needed to better understand what determines its onset and severity. The disease refers to a wide range of symptoms and conditions that some people experience four or more weeks after an initial infection with the SARS-CoV-2 virus. Due to its broad and evolving definition, it is often undiagnosed. As a result, many patients suffer from symptoms but do not receive adequate support for managing or identifying the condition. These patients not only need proper care but could also serve as valuable sources of information to help generate new knowledge about the disease. Thanks to the European EHRxF, existing national and international guidelines on Long COVID could be used to automatically identify potential cases based on data available in their electronic health records. These individuals could then be informed about the opportunity to participate in public health programs that investigate various aspects of Long COVID, with the aim of improving understanding of the condition. Patients who choose to participate could be enabled to directly provide the necessary information to public health authorities through the Yellow Button.

Working Pa

<table>
<tr><td>Document Version:</td><td>V1.0</td></tr>
<tr><td>Responsible party:</td><td>WP4</td></tr>
<tr><td>Source:</td><td>xShare</td></tr>
<tr><td>As-Is Situation:</td><td>Long COVID research is ongoing, with studies exploring various aspects of the condition, including symptom profiles, potential causes, and treatment options. Many cases of Long COVID are not diagnosed due to the vast range of symptoms and conditions that it involves.</td></tr>
<tr><td>Currently available products/services and its vendors:</td><td>EHR</td></tr>
<tr><td>Which health-related standards or data formats are involved in this process</td><td>EEHRxF</td></tr>
<tr><td>Actors/Users and their Roles:</td><td><table>
<tr><td>Patient</td><td>Patients may receive an invitation to join Long COVID study programs based on their symptoms. If they choose to participate, they can use the Yellow Button to share their data with public health authorities.</td></tr>
<tr><td>Health Professional treating the patient</td><td>Receive notification about their patients being possible long COVID cases based on their EHR data</td></tr>
<tr><td>Public Health authority</td><td>Identify potential and existing Long COVID patients to improve the knowledge around the disease</td></tr>
</table></td></tr>
<tr><td>User Perspective:</td><td>Patients matching specific criteria receive an invitation to join a study group to develop new knowledge around Long COVID by sharing their health information.

Patients who decide to participate can use the Yellow Button to share their data.</td></tr>
</table>

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System Perspective	The system identifies eligible patients based on the EHR information and the available national and international guidelines.
Health Information Domain(s) - HIDs:	Patient summary – Laboratory report
xShare Yellow Button:	Sharing of data with public health authorities conducting specific studies.
National/regional strategy:	Collect information directly from patients for Public Health purposes.
Strategy towards EHDS:	Empower patients to be an active part of the ecosystem of health data
Business Goals/Benefits:	Identify patients possibly affected by Long Covid not yet diagnosed. Provide useful information on Long COVID for Public Health programs focusing on creating new knowledge around the disease and improving national clinical guidelines. Support physicians in the diagnosis and management of long COVID.
KPIs:	• Number of persons that have pressed the xShare Yellow Button to share their data • Number of persons that join the initiative • Number of new diagnoses of Long COVID
Application:	Yellow button and EHR/PHR systems
Data Preconditions:	Data collected according to the EEHRxF
System Preconditions:	Compliance to EEHRxF, use of an algorithm for detecting Long COVID based on EHR data
User Preconditions	Patients have their EEHRxF Patient Summary and lab reports in their Personal health record or Patient has authorised access to their EEHRxF through the health portal/application. Patients are sufficiently digitally literate to support the development of new knowledge around Long COVID.

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	Treating physicians are open to be supported in the identification of long COVID cases.
Trigger:	Users with a long COVID symptoms, patients with a diagnosis of long COVID.
Challenges/Limitations:	•Mental health data which would be relevant for the study of Long COVID are not yet included in EEHRxF • GDPR issues • Ethics approval issues
Involved stakeholders in the BUC definition:	Charité, EHTEL, Sciensano
Application of pseudonymisation filters:	Yes – Secondary data use.
Basic Workflow:	• A patient suffering fatigue, headaches, brain fog and tremor without a specific diagnosis is identified as being possibly a Long Covid patient. Depending on the level of maturity of data sharing infrastructure, this pre-identification takes place directly surveying shared EEHRxF records or through a specific communication campaign where patients are proposed to share their EEHRxF in a trusted secure processing environment handled by a trusted partner. • The patient receives an invitation to take part to a Long COVID study program and provides his consent to participate and share data. • The treating physician also receives a notification that, based on the national and international guidelines his/her patient is a possible Long COVID case and that he/she has accepted to be part of a longitudinal study. • The physician, after further studying the case and having access to last findings possibly decides to diagnose it as Long COVID and treats the patient in accordance with the last version of the clinical guidelines. • The patient contributes to the development of new knowledge around the disease by sharing his/her data with the public health authority via the Yellow Button.

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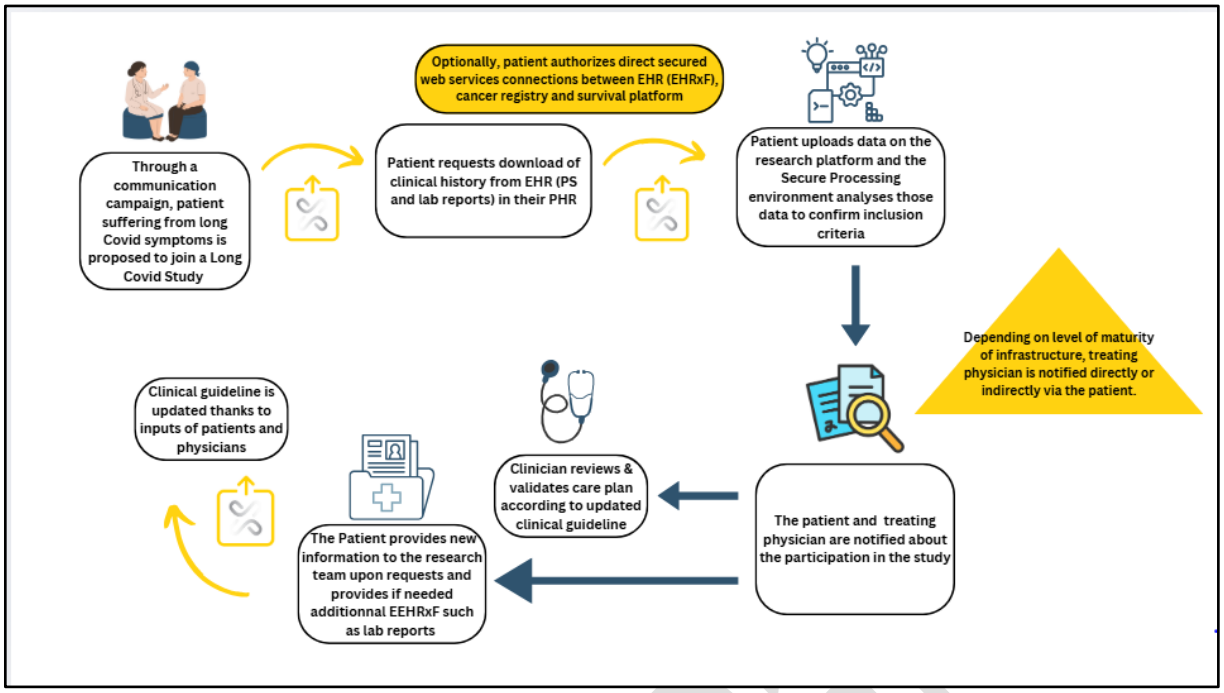

Fig.6 Use case 6 workflow example

4.7 Use case 7: Updating the survivorship passport

Description	The cancer survivor authorizes the transfer of their clinical history from the hospital's Electronic Health Record and treatment information from cancer registries. This data is integrated to form the Survivorship Passport[17], which then undergoes clinician validation. A care plan is generated within the Survivorship Passport (SurPass) [18] based on the treatments and returned to the patient.
Document Version:	V1.0
Responsible party:	WP4
Source:	xShare
As-Is Situation:	The Survivorship Passport is a web-tool that provides instant access to the medical history of patients who ended a cancer therapy, making survivors and healthcare professionals aware of the potential risks or late effects stemming from the previous disease and treatment received. Currently supported by a number of University Hospitals in six European countries: Austria, Belgium, Germany, Italy, Lithuania and Spain.

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	Although the web-based platform already exists, the currently running PanCareSurpass project is instrumental in defining further the specifications of the passport. See: https://www.pancaresurpass.eu/
Currently available products/services and its vendors:	The Survivorship Passport is a tool to provide all European childhood cancer survivors with optimal long-term care. The SurPass encompasses all relevant treatment data and evidence-based care tailored on individual risk factors. To achieve this, the SurPass platform currently uses a common template and internationally confirmed coding systems (e.g. ICD-O-3, ATC codes) for the Treatment summary and EU-wide and international recommendations for the SCP. The PanCareSurPass project will also develop recommendations for surveillance from the end of treatment until 5 years after diagnosis based on adaptation of existing IGHG (International Guideline Harmonization Group) and PanCare FollowUp recommendations In February 2025, a new HL7 Europe track was started to use the experience achieved in a European project, such as PanCareSurPass and national initiatives, to define a minimal, extensible, non-exhaustive European cancer data model that is agnostic to the type of cancer, usable across different use cases. The model leverages the experiences of the European projects working with primary and secondary usage, takes into account the availability and usability of reliable data in electronic health record (EHR) systems, and allows its HL7 FHIR representation in the form of an HL7 FHIR Implementation Guide. Next step is the creation of the European Common Cancer Logical Model and on the HL7 Europe Cancer Common FHIR Implementation Guide. The possible connexion with EEHRxF has however not yet been considered. SurPass generates thus a survivor-specific treatment summary and Survivorship Care Plan (SCP) using algorithms that link treatment data with available follow-up recommendations. The SurPass has been implemented throughout 3 European health system scenarios (national European Health Information Systems (EHISs), regional EHISs, and cancer registries or hospital-based EHISs). The third scenario is the least favourable in terms of semi-automated data input, interoperability, and data protection. Unlike the scenarios with nationally or regionally organised health data, this scenario requires the integration of data from a multitude of sources to generate a SurPass. Epidemiological data will need to be obtained from cancer or bone marrow transplant registries such as the German Childhood Cancer Registry, while disease and treatment-specific clinical data will need to be retrieved from hospital database.

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<table>
<tr><td>Which health-related standards or data formats are involved in this process</td><td>HL7’s international patient summary (IPS) standard specifies an EHR extract containing essential health information intended for use in cross-border care scenarios [18].</td></tr>
<tr><td>Actors/Users and their Roles:</td><td><table>
<tr><td>Patients</td><td>Receive information in an easily understandable way about recommendations for follow-up, depending on individual risk factors.</td></tr>
<tr><td>Healthcare providers</td><td>Provide updated data in the EHR. Validate the information of the Survivorship passport</td></tr>
<tr><td>Public Health National agencies</td><td>Send treatment data to the Survivorship Passport</td></tr>
</table></td></tr>
<tr><td>User Perspective:</td><td>Patients can trigger the creation of a Survivorship Passport</td></tr>
<tr><td>System Perspective</td><td>The Survivorship passport can receive data from data EHR complemented by data provided to cancer registry according to the EEHRxF

An HL7 Europe Cancer Common FHIR Implementation Guide will be instrumental in facilitating the reuse of the cancer registry data.

Efficient security and privacy core services need to be in place.</td></tr>
<tr><td>Health Information Domain(s) - HIDs:</td><td>Patient Summary, Discharge Report</td></tr>
<tr><td>xShare Yellow Button:</td><td>The Yellow Button triggers the creation of a Survivorship passport by combining data from the EHR and the cancer registry.</td></tr>
<tr><td>National/regional strategy:</td><td>The scenario depends on the existence or not of National/Regional dedicated information systems related to cancer.

For this use case, we consider the scenario where data are provided by EHR systems but also considers the requirements of both the national/regional cancer registry and the patient survival passport.</td></tr>
</table>

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Strategy towards EHDS:	Use the same EEHRxF as input across EHR, cancer registry and Survivorship Passport. Patients take a more active role by accessing their data and triggering the creation of the passport.
Business Goals/Benefits:	Enable cancer Survivors to use the Yellow Button to access and activate all available structured information to obtain updated information on guidelines and care Plan.
KPIs:	Number of Passports created
Application:	Import/export functionalities for EHR and cancer registries using the EEHRxF to the Passport.
Data Preconditions:	Data available from EHR and cancer registry have been mapped and are interoperable. The data model used by the cancer register is used as reference by the survivor platform.
User Preconditions:	Users need updated Survivorship Passports
System Preconditions:	EHR systems are EEHRxF compatible. The passport system embeds the Yellow Button and can establish a trusted and secured connection with the patient allowing the upload of data. The cancer register provides access to the patient data and allows its download in a standardised HL7 FHIR format. The passport platform must support: • Secure user authentication (for patient access) • Upload and parsing of data from both EHR and cancer registry • Data mapping to SurPass data model (e.g. ICD-O-3, ATC codes) • Generation of SCP (Survivorship Care Plan) based on integrated data • Trusted and encrypted communication channels (e.g., HTTPS, OAuth2, FHIR APIs) must be in place between the EHR, cancer registry, and the SurPass platform.

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Trigger:	Possibility of submitting data without further transformation and automatically obtain an updated passport.
Challenges/Limitations:	• Compliance to EEHRxF to format by all cancer registries • Even with EEHRxF, there may be differences in how clinical data are recorded, requiring mapping or transformation.
Involved stakeholders in the BUC definition:	Cineca, Charité, EHTEL, Sciensano
Application of pseudonymisation filters:	Yes, an integrated management of identifiers is necessary for the whole process.
Basic Workflow:	• A cancer survivor wants to obtain their Survivorship Passport with the recommendations for long-term follow-up by sharing their medical data • The patient requests the creation of the passport. Both PS and discharge report are downloaded. The data available in the EEHRxF are reused to populate the appropriate data fields of the passport and uploaded on the passport secured website. Optionally the data available in the last available discharge report provides additional inputs for data fields not available in the patient summary. The complementary data provided previously to the cancer register are accessed by the patient, downloaded and also uploaded to the passport. The integrated data form the treatment summary that reflects the patient's cancer journey • The Survivorship Passport platform generates the personalised care plan/recommendations that can be reviewed by the clinician and accessed and downloaded by the survivor for ongoing health management. • In the best-case scenario, a direct communication through webservices is established between the EHR system, the Passport server and the cancer register thanks to a governed management of identifiers. In this case, the Yellow Button is only used to download the passport. In other cases, the actions need to be performed by the patient himself/herself (with some orchestration process by the passport server).

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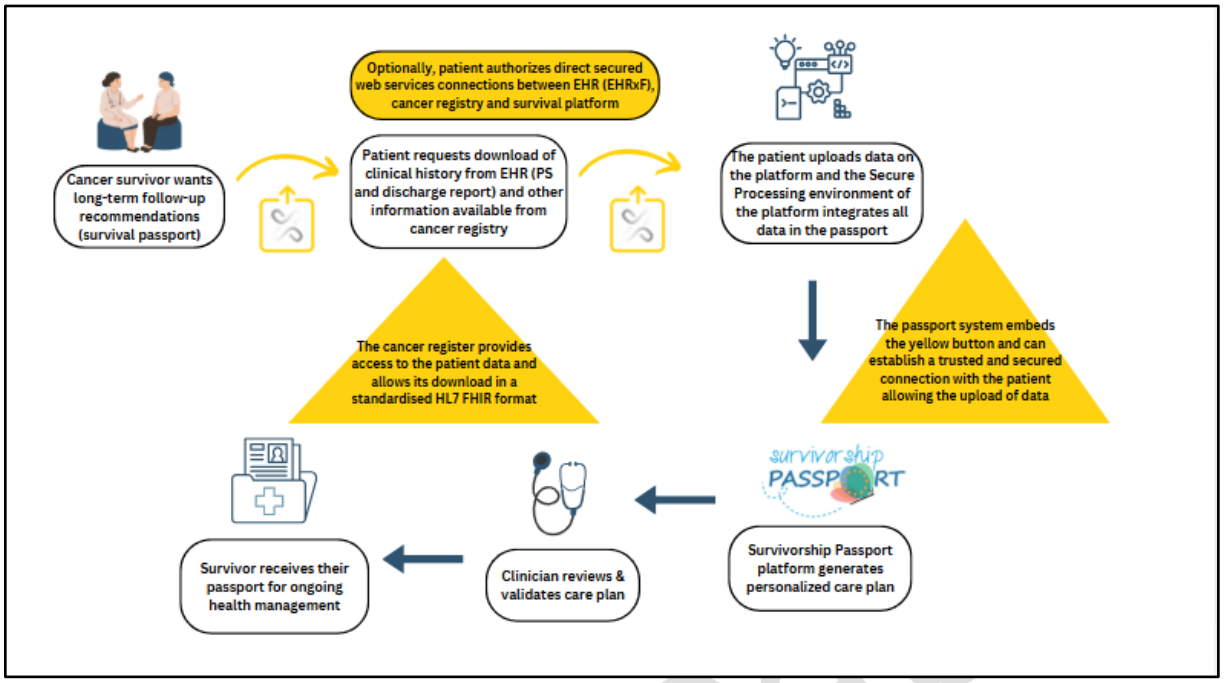

Fig.7 : Use Case 7 workflow example

4.8 Use case 8: Traffic Data

Description	The Traffic administrations collect this data from different sources but does not have information when the injured are foreigners and are transferred to their country. In addition, health competences in some countries are assumed by the autonomous communities or regions and information is not always obtained for all the injured. Also, effective practice recognizes that no accident database will provide sufficient information to provide a complete view of traffic accident victims to fully understand the causes of injuries. Accident data are a valuable source of information on accident risk, the value of which can be significantly increased when combined with other data sources such as health sector data. Linking traffic incident reports to individual health profiles using anonymised identifiers and semantic data standards will allow identifying how chronic conditions or medication use contribute to accidents and fatalities. Data fusion techniques would be applied for correlation analysis, using data mining, machine learning, and semantic interoperability frameworks. Special attention is given to the legal and ethical implications of data access and sharing.
Document Version:	V1.0

Working Par

<table>
<tr><td>Responsible party:</td><td>WP4</td></tr>
<tr><td>Source:</td><td>xShare</td></tr>
<tr><td>As-Is Situation:</td><td>The national traffic accident victims' registers collect information from several sources related to accidents, vehicles, police officer, passengers, drivers, pedestrians, etc. Usually, the information is collected through web services to access to databases as drivers, towns and municipalities and roads catalogues. In addition, the traffic administrations collect this data from different sources but does not have information when the injured are foreigners and are transferred to their country. Nowadays, there is no correlation between health and road traffic data.</td></tr>
<tr><td>Currently available products/services and its vendors:</td><td>The public road traffic authorities collect Traffic Data to create the National Traffic Accident Registries, which include detailed information about accidents, such as location, time, road conditions, and characteristics of vehicles and drivers. But usually, there is no correlation with Health Data: medical records, hospitalisation histories, diagnoses, and treatments of accident victims. These data can be obtained from EHRs and PHRs.</td></tr>
<tr><td>Which health-related standard are currently being used:</td><td>Web services must collect data EHRF-compliant from EHDS.</td></tr>
<tr><td>Actors/Users and their Roles:</td><td><table>
<tr><td>Healthcare Providers</td><td>Collect data in EEHRxF Format to to be able to exchange data properly</td></tr>
<tr><td>Public road Traffic authorities</td><td>Ask and receive heath data (in origin EEHRxF) to integrate them in national traffic accident victims’ registries</td></tr>
</table></td></tr>
<tr><td>User Perspective:</td><td>The public road traffic authority needs to be able to ask and receive EEHRxF compliant data.</td></tr>
<tr><td>System Perspective</td><td>The national traffic accidents system will be enabled to combine data from EHDS in EEHRxF and traffic data.</td></tr>
</table>

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Health Information Domain(s) - HIDs:	Patient Summary. Electronic Prescription.
National/regional strategy:	National public health and road traffic authorities can share / combine EEHRxF- compliant data so it can be exchanged between different systems and regions.
Strategy towards EHDS:	Obtain EEHRxF-compliant data collected right from the source EHDS to have data readily available to support the correlation of traffic accident data with health data. Secondary use of the health data.
Business Goals/Benefits:	Combining traffic accident data with health records to understand additional accident causes, such as chronic diseases or medication effects (e.g., psychotropics). Obtain information from EHDS when the injured are foreigners and are transferred to their country.
KPIs:	Number of cases (accidents) detected caused by chronic diseases or medication effects.
Application:	Integrate / combine functionalities for EHR / Electronic Prescriptions and Road traffic registries using the EEHRxF
Data Preconditions:	EEHRxF compliance and adherence to specific semantic constraints in order to integrate the health with the road traffic data.
User Preconditions:	Capability of asking/receiving data in EEHRxF format.
System Preconditions:	National system can identify relevant data and trigger a Patient Summary or Electronic Prescription to find out the necessary health data related to the involved people in an accident. The system must adapt the information coming from EHDS to its registers. Security and Privacy Policies should already be in place.

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Trigger:	Need information about a driver or passenger involved in current accident.
Challenges/Limitations:	Development needed by all actors in order to properly integrate health and traffic data. The correlation of traffic accident data with health data might be done by cross-referencing information from the databases. This includes hospital data, public health records, and traffic statistics. By analysing this data together, additional patterns and risk factors can be identified, such as medical conditions that could have contributed to the accidents. This comprehensive approach allows for a better understanding of the underlying causes and the implementation of more effective preventive measures
Involved stakeholders in the BUC definition:	UVEG
Application of pseudonymisation filters:	Yes- secondary use.
Basic Workflow:	• The national police are usually the first to arrive at the scene of the accident and collect detailed information about the incident, including the location, time, those involved, and the severity of the injuries. • The initial information is included in the national traffic accident victims • This data is supplemented with information from hospitals to get a more complete picture of serious injuries (EHDS). • The anonymised data is stored in national databases and analysed to identify patterns and causes of accidents, which helps to develop prevention strategies.

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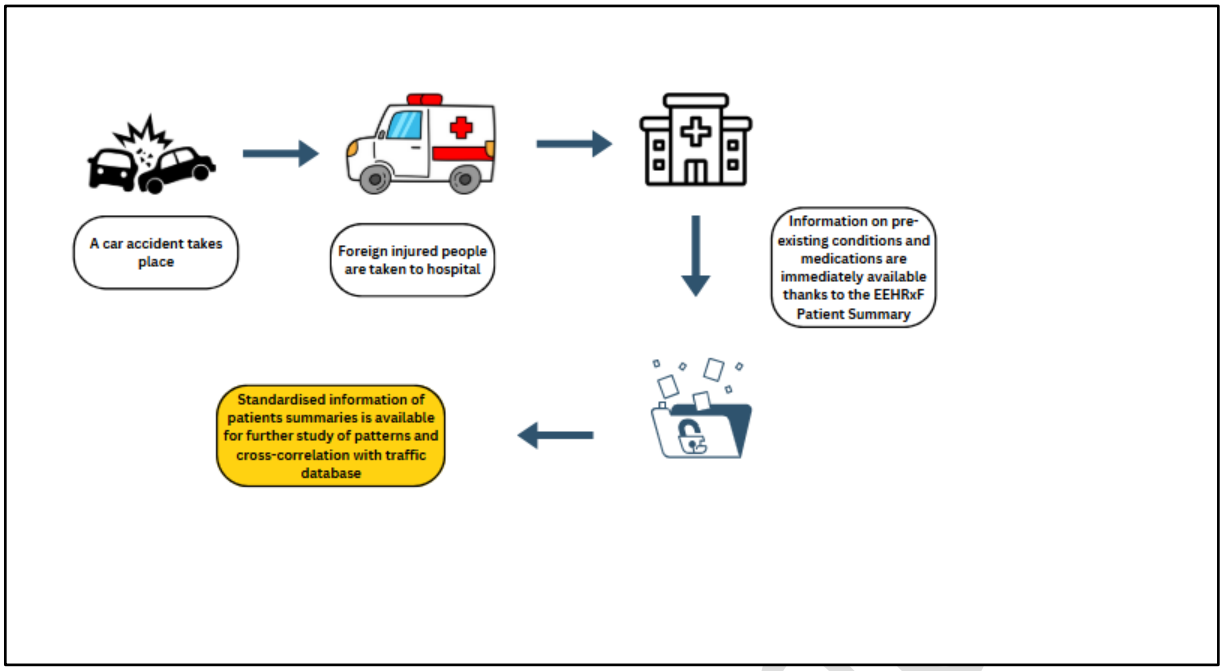

Fig.8: Use Case 8 workflow example

4.9 Use case 9: Monitoring of second/third line antibiotics and Use of antibiotics at home

Description	Gather detailed data on prescription of Antibiotics of second or third line and collect information on patient adherence to antibiotic prescriptions, including the handling of leftover medication and the role of laboratory reports in prescribing antibiotics. Citizens may dynamically interact with researchers, ensuring efficient, accurate, and secure data gathering while maintaining privacy through anonymisation. This approach promises to enhance public health research by offering valuable insights into antibiotic use and fostering deeper patient-researcher interactions, ultimately informing better public health recommendations and practices. The European EHRxF laboratory report is used to analyse if prescription of certain antibiotics has been done after a lab check has been performed. The use of EEHRxF will allow comparison between EU countries. Furthermore, patients matching possible inclusion criteria based on the patient's health records, such as recent antibiotic dispensation and lab reports are asked to answer a specific survey, which includes data not usually available in the European EHRxF, such as the handling of leftover pills and quantity of antibiotics stored at home.
Document Version:	V1.0
Responsible party:	WP4
Source:	xShare

Working Par

<table>
<tr><td>As-Is Situation:</td><td>Antimicrobial consumption is currently usually monitored following national and international protocols through longitudinal or cross-sectional studies. Longitudinal studies rely on existing administrative data with few details that are continuously collected, whereas cross-sectional studies collect details on the applied preventive or curative regimen at a given point in time (point prevalence study). The data currently used are those collected for reimbursement purpose and data collected locally through a network of volunteer hospital and long-term facilities network. The report on antibiotics consumption and AMR is thus often the result of a consolidation of different reports and is often delayed by a few years.</td></tr>
<tr><td>Currently available products/services and its vendors:</td><td>PHR systems are only emerging with countries having focused first on patient portals. Current AMR data collection processes are either indirect or ad hoc.</td></tr>
<tr><td>Which health-related standard which health-related standards or data formats are involved in this process?</td><td>Antimicrobial agents are classified using the Anatomical Therapeutic Chemical (ATC) classification of the World Health Organization (WHO) Collaborating Centre for Drugs Statistics and Methodology.

Most of PHR systems have readily been relying on HL7 FHIR.

The workflow proposed rely on e-prescription, e-dispensation and laboratory reports on one side and ad hoc patient generated data on the other side.</td></tr>
<tr><td>Actors/Users and their Roles:</td><td><table>
<tr><td>Patients</td><td>Receive notification of their eligibility for the study and provide specific information to the Public Health Agency if matching selection criteria</td></tr>
<tr><td>Healthcare providers</td><td>Provide prescription report</td></tr>
<tr><td>Public Health National agencies</td><td>Monitors if second and third generation antibiotics are prescribed after laboratory check
Design study protocol and define selection criteria
Analyse Patient generated data</td></tr>
<tr><td>Laboratory providers</td><td>Provide laboratory report</td></tr>
<tr><td>Pharmacies</td><td>Provide dispensation report</td></tr>
</table></td></tr>
<tr><td>User Perspective:</td><td>Pending the availability of the three mentioned reports, no specific action other than producing the reports is expected from healthcare providers. Eligible patients receive a notification to ask consent to participate in the study and fill the questionnaire.
The Research unit is allowed to interact with patients.</td></tr>
<tr><td>System Perspective</td><td>The system used by the Research unit is integrated to the national data sharing infrastructure. Patients can be easily and securely notified.</td></tr>
</table>

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Health Information Domain(s) - HIDs:	E-Prescription, E-dispensation, Lab report and Patient Reported Outcome Report.
xShare Yellow Button:	The Yellow Button is used to transfer information generated by the patient to the Research Unit in the agreed format.
National/regional strategy:	The scenario requires a mature and integrated regional/data sharing infrastructure.
Strategy towards EHDS:	Use of the same EEHRxF allows comparison between EU countries with the possibility of EU near real time monitoring of essential indicators. Patient generated data will possibly lead to the creation of new HID for Patient Reported outcomes.
Business Goals/Benefits:	The availability of real time information on prescription behaviours should allow quicker adaptations in term of prescription authorisation processes and directly impact progression of resistance. Patient generated data will also allow to adapt communication messages and collect new evidence.
KPIs:	• % of prescriptions emitted without prior lab check • Number of Patients matching selection criteria • Number of Patients accepting to participate in the study
Application:	DATA needs to be analysed in a secured processed environment using core privacy and security validated services.
Data Preconditions:	Data available from EHR and other systems have been mapped and are interoperable (See also use case 1). Ideally Unique Reference validated data source for Medicines are being used by all systems and EEHRxF specifications compliant.
User Preconditions:	Patients provide specific consent to be included in the study.
System Preconditions:	EHR, pharmacy and Laboratory systems are EEHRxF compatible. The system used by the Research Unit has been integrated in the National Data Sharing Infrastructure and is also EEHRxF compliant. The system can make use of a Secure Process Environment which relies on core trusted privacy and security services.
Trigger:	No specific action is needed by the clinical users as the monitoring relies entirely on data available in the EEHRxF.
Challenges/Limitations:	• Internal Processes at Hospital/Long term facilities level might not be monitored and require additional specifications. • PHR needs to be widely used, and an efficient notification system needs to be operational. Specific data analysis tools connected to the Secure Processing Environment are available.

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Involved stakeholders in the BUC definition:	Charité, EHTEL, Sciensano.
Application of pseudonymisation filters:	Yes, for all sequences
Basic Workflow:	• The research unit is registered in the official national directory as a trusted third party which has access to the (primary use) data sharing infrastructure. The unit has identified the molecules which need to be monitored specifically. • Through the validated secure processing environment, the unit requests access to all prescriptions including the selected molecules. It checks then if for the selected patients first line antibiotics had been prescribed previously. If yes, and for the patients concerned, it checks if a laboratory exam (antibiogram) has been performed before the prescription. • The results are returned and integrated in a dashboard which shows the evolution of the number of second- and third-line antibiotics prescribed and the % of prescriptions which was made based on results of lab reports. • The patients who had met the selection criteria receive a notification through their PHR or secured messaging system connected to a patient web portal asking their consent to be approached in the context of a study related to the fight against AMR. Their positive response triggers the sending of a structured form by the research unit to collect specific PROMs. The patient fills in the form which is fully encrypted using trusted core encryption services by the PHR (or the secured webportal) which feeds the study registry.

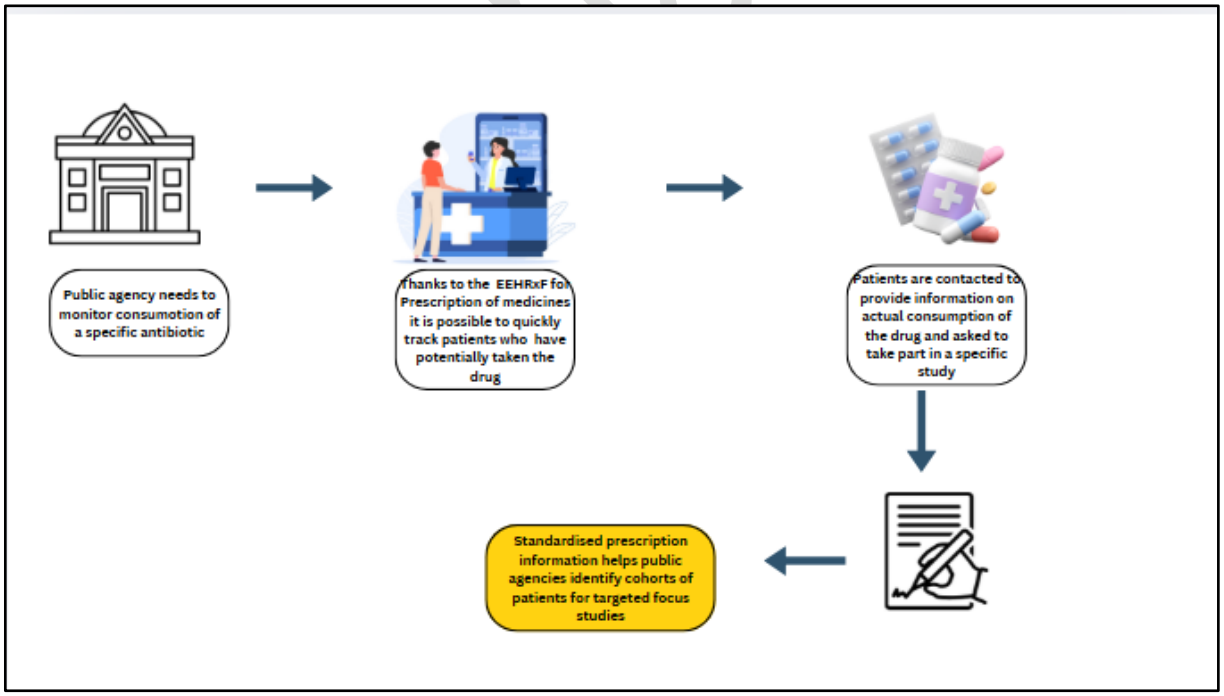

Fig.9: Use Case 9 workflow example

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5. Standardisation of data

5.1 Selection of data sets

During the Partnership Council in Madeira in February 2025 the use cases have been presented to the xShare project partners to select together the three most relevant use cases for Public Health to prioritise for harmonisation with the EEHRxF and the x-Bundles.

A few questions were submitted to the participants to allow them to provide comments on the use cases. Based on their answers we decided to select Antimicrobial Resistance, Infection Surveillance and Cancer Monitoring. Fig.10 shows a screenshot of one of the questions and the distribution of answers.

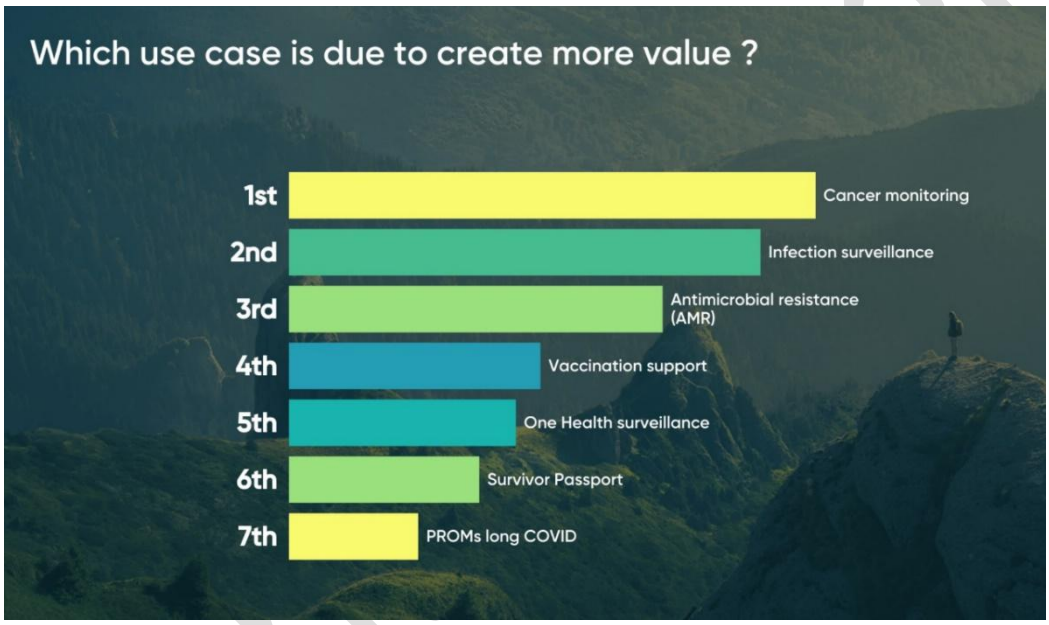

Fig. 10: Outcome of the vote on the use cases during the Partnership Council in Madeira

This choice aligns perfectly with the priorities of the EU4Health programme 2021-2027 which among its objective's lists:

- Health promotion and disease prevention, in particular cancer
- Prevention, preparedness and response to cross-border health threats

All three prioritised use cases which correspond to Use Case 1,2,3 involve the concrete standardisation of an established value set rather than innovative applications of the Yellow Button, Patient discovery applications or direct interaction between public health authorities. The next two paragraphs provide some additional information on the datasets involved in the prioritised use cases.

5.2 ECDC datasets

The ECDC represents the point of reference concerning infectious diseases in Europe. Since 2005, it has monitored over 50 health threats, including COVID-19 and antibiotic resistance, providing expert guidance to support prevention and outbreak response. It coordinates several networks where data is

collected across member states such as the European Antimicrobial Resistance Surveillance Network (EARS-Net) and the Healthcare-associated Infections Surveillance Network (HAI-Net).

The data protocols for the two Networks can be found on the ECDC website along with a metadata schema showing the data collected across Europe.

Within xShare contact was established with ECDC for the standardisation of the datasets.

As mentioned in Working paper 4.1, we also started a collaboration with the European initiative UNITED4Surveillance which is supporting ECDC's strategic goals and aims to learn from the gaps revealed by the COVID-19 crisis. The initiative organised surveys to document the availability of surveillance system across several European countries. The working papers were shared with xShare, and they clearly outlined the need for more availability of digitalised well-structured data to support automated surveillance across the different countries to improve outbreak detection systems and enhance prevention.

5.3 ECIS Dataset

The European Cancer Information System (ECIS) is a comprehensive cancer-information resource for hosting and processing the European cancer data. Monitoring cancer data is one of the priorities of the collaboration between the European Network of Cancer Registries (ENCR), established in the framework of the Europe Against Cancer Programme of the European Commission and the Joint Research Centre (JRC), a Directorate-General of the European Commission.

The ENCR is a professional, non-profit organisation committed to fostering collaboration among Cancer Registries (CRs), establishing data collection standards, and offering training to CR staff. Its goal is to enhance the foundation for tracking the cancer burden in the EU and across Europe by delivering consistent and timely data from European CRs. JRC conducts scientific research to deliver independent advice and support for EU policy-making. In this capacity, the JRC collaborates closely with the ENCR Steering Committee to define priorities for improving the value and use of cancer registry data across Europe.

5.4 Harmonisation of the EU Datasets

The three prioritised use cases refer to established European datasets already in use to collect information across the European countries by ECDC and ENCR.

In particular, the datasets examined include:

- Protocol for the surveillance of healthcare-associated infections and prevention indicators in European intensive care units
- Antimicrobial resistance (AMR) reporting protocol 2023 European Antimicrobial Resistance Surveillance Network (EARS-Net) surveillance
- European Cancer Information System Protocol

They all represent existing efforts to harmonize and monitor specific data across Europe. However, they do not conform to the European EHRxF format and often use local codes for example for microorganisms and tests.

Within WP4, standardisation activities were performed to analyse the variables and the value sets included in the identified datasets and map them to the international standards defined by the EHDS.

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The EHDS offers the opportunity to define the structure and terminology of data to be used from primary care to research and public health. The main advantages of sharing a common format are:

- Enable “only once” strategy avoiding re-entering the same data
- Maintain data quality by reducing or removing data transformation
- Real-time availability of data for monitoring and prompt intervention
- Application of the same analysis and AI algorithms to data
- Support of data protection by enabling distributed analysis

5.5 Antimicrobial resistance

The European Antimicrobial Resistance Surveillance Network (EARS-Net) is the largest publicly funded system in Europe for monitoring antimicrobial resistance (AMR). Coordinated by the ECDC, it collects reliable data to track AMR trends, support policy decisions, and strengthen national surveillance systems. The network also helps improve diagnostic quality through annual external assessments. Data is shared with the public via the ECDC Surveillance Atlas and detailed in reports and scientific publications. EARS-Net involves national health institutions across Europe, with coordination guided by a committee of expert representatives.

The data collected by EARS-Net is based on the data reporting Protocol which provides data collection guidelines for the countries’ data managers. The protocol includes also the list of variables and value sets to be collected. The protocol offers a harmonised way to collect data across the different countries and a represents a core data set of AMR relevant data that should be harmonised with EEHRxF across Europe.

As the Annex I shows, the 28 epidemiological variables were mapped to FHIR and the value sets to SNOMED and LOINC.

The mapping was based on the HL7 Europe Laboratory Report FHIR IG which uses the HL7 FHIR Observation resource to model information about laboratory test.

Table 2 is a simplified version of the Observation structure used in the standardisation of the variables included in Annex I, showing the main FHIR elements for a susceptibility test:

HL7 FHIR element	Description	Coding system	Example
Observation.code	Type of test performed	LOINC	18919-1 Erythromycin [Susceptibility]
Observation.value	Result	Numerical	0,03 µg/ml
Observation.interpretation	Interpretation of result	SNOMED	131196009 Susceptible (qualifier value)
Observation.method	Methodology used	SNOMED	708073008 |Minimum inhibitory concentration susceptibility test technique (qualifier value)|

***Table 2**: FHIR Observation elements relevant for describing susceptibility tests.*

It is important to mention that there is an ongoing collaboration between LOINC and SNOMED with the purpose to minimize duplication of codes. A primary aim of the agreement is to create an extension of SNOMED for the LOINC terminology. Within this agreement for example, the LOINC codes for the

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susceptibility tests can also be identified with SNOMED codes. However, in compliance with the HL7 Europe Laboratory Report we used the LOINC codes.

A lot of standardisation work is still in progress at national and international levels in member states and detailed European specifications for microbiology data are still to be published. Here we propose a model which uses a general LOINC code (which as we have mentioned also has a SNOMED match) to define the susceptibility test whereas the specific methodology used is specified in *Observation.method*.

S I R Values

SIR refers to the Susceptible-Intermediate-Resistant classification system used in antimicrobial susceptibility testing to determine how effectively an antibiotic will work against a specific bacteria. To be noted is that the two most used guidelines for reporting susceptibility testing are the European EUCAST[19] and the American CLSI[20].

The value set provided by the HL7 terminology specifically refers to the CLSI[21][20][19] system[21]. In SNOMED we can find EUCAST specific values such as:

SNOMED CODE	SNOMED FULLY SPECIFIED NAME
1306577009	|European Committee on Antimicrobial Susceptibility Testing category 2019 Susceptible, standard dosing regimen (qualifier value)|
1306583007	|European Committee on Antimicrobial Susceptibility Testing category 2019 Susceptible, increased exposure (qualifier value)|
1306581009	|European Committee on Antimicrobial Susceptibility Testing category 2019 Resistant (qualifier value)|

***Table 3**: SNOMED CT concepts to describe results of microbiology susceptibility tests*

However, also general, not guidelines-specific concepts are possible, such as:

SNOMED CODE	SNOMED FULLY SPECIFIED NAME
131196009	Susceptible (qualifier value)
1255965005	Susceptible with increased exposure (qualifier value) (inactive!)
264841006	Intermediately susceptible (qualifier value)
30714006	Resistant (qualifier value)

***Table 4**: SNOMED CT concepts to describe results of microbiology susceptibility tests without referring to a specific norm.*

The definition of the values “S”, “I” and “R” was updated by EUCAST in 2019. In particular, the category “I” after 2019 refers to “Susceptible with increased exposure”. The code *1255965005 Susceptible with increased exposure (qualifier value)* was deactivated by SNOMED to replace it with *1306583007*

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|European Committee on Antimicrobial Susceptibility Testing category 2019 Susceptible, increased exposure (qualifier value)|

The specific European Microbiology data model is under development and will provide guidance on which are the most appropriate SNOMED codes to use.

5.6 Healthcare associated infections

The Healthcare-Associated Infections Surveillance Network (HAI-Net) is a European initiative focused on monitoring healthcare-associated infections (HAIs), coordinated by the European Centre for Disease Prevention and Control (ECDC). Its core activities include organising the European point prevalence survey on HAIs and antimicrobial usage in acute care hospitals, as well as overseeing surveillance efforts related to surgical site infections, infections occurring in intensive care units, and Clostridioides difficile infections. In addition, HAI-Net conducts repeated prevalence surveys on HAIs and antimicrobial use within long-term care facilities across Europe, aiming to improve infection control practices and antimicrobial stewardship.

Considering the high incidence of intensive care units infections, the standardisation of the protocol for the surveillance of healthcare-associated infections and prevention indicators in European intensive care units seems of particular importance. The general laboratory data model for the laboratory information is the same as for the AMR Protocol. The HAI protocol additionally includes 4 lists of value sets to be used for reporting purposes:

- Microorganisms code list
- Extended antimicrobial resistance data for ICU-acquired infections
- Healthcare-associated infections code list
- Antimicrobial ATC codes

Besides using ATC codes to identify antimicrobial substances, the other lists, use local codes to identify the different values.

The values included in the list of HAIs include, besides the infection, information about the specimen and the methodology or the site of infection. In order to map this information to FHIR a proposal to separate this information into separate information elements is presented in Annex II.

Additionally, for the test we assume to use a generic code for the detection of a microorganism via antimicrobial culture such as the one represented by the LOINC code *11475-1 Microorganism identified in Specimen by Culture*.

New European guidelines for microbiology are under development, currently the HL7 Europe Laboratory Report (v.0.2.0-ci - ci-build 150)[6] shows two possible ways of building information concerning the detection of a microorganism, one using the *Observation.component* element.

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HL7 FHIR element	Description	Coding system	Example
Observation.code	Type of test performed	LOINC	11475-1 Microorganism identified in Specimen by Culture
Observation.value	Name of identified microorganism	SNOMED	56415008 Klebsiella pneumoniae (organism)
Observation.interpretation	Interpretation of result	SNOMED	260373001 Detected (qualifier value)
Observation.method	Methdology used	SNOMED	703751005 Anaerobic culture technique (qualifier value)

Table 5: *FHIR Observation elements that describe a microbiology procedure for detecting microorganisms via culture.*

HL7 FHIR element	Description	Coding system	Example
Observation.code	Type of test performed	LOINC	11475-1 Microorganism identified in Specimen by Culture
Observation.value	Result	SNOMED	260373001 Detected (qualifier value)
Observation.method	Methodology used	SNOMED	703751005 Anaerobic culture technique (qualifier value)
Observation.component	Name of identified microorganism	SNOMED	56415008 Klebsiella pneumoniae (organism)

Table 6*: FHIR Observation elements that describe a microbiology procedure for detecting microorganisms via culture using also the element Observation.component to report the name of the microorganism.*

The mapping provided in Annex II shows the mapping of the HAI value sets to SNOMED and LOINC as well as a proposal of the FHIR modelling. It is important to note that HAI values contain concepts that include information about condition, test results specimen and devices. To make information more EEHRxF compliant it has been de-constructed into separate pieces of information matching different FHIR resources: Condition, Observation, Specimen, Device.

5.7 European Cancer Information System

The data collection protocol outlined to feed the ECIS web application, launched in February 2018 and populated with indicators computed from data submitted by the ENCR-affiliated registries. ECIS has been drafted in alignment with the requirements of CI5 and EUROCARE projects.

Some FHIR-based specifications for cancer data have been defined by projects such as Idea4RC[22] oder PanCareSurvivalPass[23], however, a complete European common cancer data model is presently under development thanks to the work of **PHOENIX** Cancer Initiative and HL7 Europe. For this reason, the mapping of ECIS to FHIR elements did not seem appropriate at the moment. Although the choice

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of the terminology codes is dependent on the final data model, we provide in Annex III a provisional mapping of ECIS value sets to SNOMED which should be reviewed when the European common cancer data model is published. The proposed mapping in Annex III is also summarised in Table 7.

SNOMED Semantic Tag	Valueset Description
Procedure	Treatment, Chemotherapy, Surgery, Radiotherapy
Finding	Stage, Evidence
Morphologic abnormity	Behaviour
Qualifier value	Grade
Tumour staging, observable entity	Tumour staging system

***Table 7**: SNOMED semantic tags for cancer-specific data elements.*

5.8 HealthDCAT-AP

HealthDCAT-AP (Data Catalogue Application Profile) is a metadata schema designed to standardize the description of health datasets within the EHDS. It builds upon the European DCAT-AP standard but is tailored for the specific needs of health data sharing and interoperability.

The following tables represent the mandatory elements[24] of the HealthDCAT-AP for sharing information about Datasets customised for the three selected datasets based on the published Editor[25].

HealthDCAT-AP category	Element	Value
Data Discovery	Title	EARS-Net
	Description	European Antimicrobial Resistance Surveillance Network (EARS-Net) dataset
Data Access	Distribution Title	Antimicrobial resistance (AMR) reporting protocol 2023
	Distribution URL	https://www.ecdc.europa.eu/en/publications-data/ears-net-reporting-protocol-2023
Technical Metadata	Dataset Identifier	https://www.ecdc.europa.eu/sites/default/files/documents/EARS-Net-reporting-protocol-2023_1.pdf
	Metadata Revision Date	13.05.2025

***Table 8**: HealthDCAT-AP mandatory metadata for the European Antimicrobial Resistance Surveillance Network (EARS-Net) dataset.*

HealthDCAT-AP category	Element	Value
Data Discovery	Title	ECIS dataset
	Description	Data Protocol for European Population-Based Cancer Registries
Data Access	Distribution Title	Call for Data Protocol for European Population-Based Cancer Registries
	Distribution URL	https://www.encr.eu/
Technical Metadata	Dataset Identifier	https://www.encr.eu/sites/default/files/JRC113106_ecis_wa_guide_11_sept_2018_print-.pdf

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	Metadata Revision Date	13.05.2025

Table 9: HealthDCAT-AP mandatory metadata for the Data Protocol for European Population-Based Cancer Registries.

HealthDCAT-AP category	Element	Value
Data Discovery	Title	HAI-Net ICU dataset
	Description	Protocol for the surveillance of healthcare-associated infections and prevention indicators in European intensive care units HAI-Net ICU protocol, version 2.3 2024
Data Access	Distribution Title	HAI-Net ICU Protocol Version 2.3
	Distribution URL	https://www.ecdc.europa.eu/en/publications-data/protocol-surveillance-healthcare-associated-infections-and-prevention-indicators
Technical Metadata	Dataset Identifier	https://www.ecdc.europa.eu/sites/default/files/documents/protocol-surveillance-healthcare-associated-infections-intensive-care.pdf
	Metadata Revision Date	13.05.2025

Table 10: HealthDCAT-AP mandatory metadata for Protocol for the surveillance of healthcare-associated infections and prevention indicators in European intensive care units HAI-Net ICU protocol, version 2.3 2024.

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6. IPS+R Data set

Based on the three prioritised datasets we would like to offer an insight on what are the relevant value sets and variables that might contribute to the IPS+R dataset developed within WP 5 as part of the information collected at European level for public health purposes.

The following represents the list of microorganisms whose detection is collected and monitored at European level by ECDC.

SNOMED ID	FSN
91288006	|Acinetobacter baumannii (organism)|
82550008	|Acinetobacter calcoaceticus (organism)|
77045006	|Acinetobacter haemolyticus (organism)|
83088009	|Acinetobacter lwoffii (organism)|
59343002	|Anaerobic bacteria (organism)|
32684000	|Aspergillus fumigatus (organism)|
89354002	|Aspergillus niger (organism)|
55247009	|Bacteroides fragilis (organism)|
53490009	|Beta-hemolytic Streptococcus (organism)|
113669008	|Burkholderia cepacia (organism)|
53326005	|Candida albicans (organism)|
3,491E+12	|Candida auris (organism)|
61302002	|Candida parapsilosis (organism)|
47885008	|Candida tropicalis (organism)|
6265002	|Citrobacter freundii (organism)|
114264004	|Citrobacter koseri (organism)|
5933001	|Clostridioides difficile (organism)|
445562004	|Cronobacter sakazakii (organism)|
409822003	|Domain Bacteria (organism)|
14385002	|Enterobacter cloacae (organism)|
78065002	|Enterococcus faecalis (organism)|
90272000	|Enterococcus faecium (organism)|

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112283007	|Escherichia coli (organism)|
106544002	|Family Enterobacteriaceae (organism)|
417513008	|Family Enterococcaceae (organism)|
427501004	|Family Moraxellaceae (organism)|
115072003	|Family Neisseriaceae (organism)|
115070006	|Family Pseudomonadaceae (organism)|
414225004	|Family Staphylococcaceae (organism)|
264408003	|Filamentous fungus (organism)|
91620006	|Genus Achromobacter (organism)|
7757008	|Genus Acinetobacter (organism)|
40560008	|Genus Actinomyces (organism)|
88529008	|Genus Aeromonas (organism)|
33436009	|Genus Agrobacterium (organism)|
68571003	|Genus Alcaligenes (organism)|
2429008	|Genus Aspergillus (organism)|
44762009	|Genus Bacillus (organism)|
57522007	|Genus Bacteroides (organism)|
35408001	|Genus Campylobacter (organism)|
3265006	|Genus Candida (organism)|
16241000	|Genus Chlamydia (organism)|
75972000	|Genus Citrobacter (organism)|
8191000	|Genus Clostridium (organism)|
77086004	|Genus Corynebacterium (organism)|
407444007	|Genus Cytomegalovirus (organism)|
243633006	|Genus Enterovirus (organism)|
18986002	|Genus Flavobacterium (organism)|
69256005	|Genus Gardnerella (organism)|
71268004	|Genus Haemophilus (organism)|

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20523001	|Genus Hafnia (organism)|
43690008	|Genus Lactobacillus (organism)|
7527002	|Genus Legionella (organism)|
50713005	|Genus Morganella (organism)|
78981005	|Genus Mycoplasma (organism)|
59674005	|Genus Nocardia (organism)|
407359000	|Genus Norovirus (organism)|
87579009	|Genus Pasteurella (organism)|
114129000	|Genus Prevotella (organism)|
34844008	|Genus Propionibacterium (organism)|
50517009	|Genus Proteus (organism)|
112284001	|Genus Providencia (organism)|
417542000	|Genus Rotavirus (organism)|
27268008	|Genus Salmonella (organism)|
42025004	|Genus Serratia (organism)|
77352002	|Genus Shigella (organism)|
65119002	|Genus Staphylococcus (organism)|
4668009	|Genus Yersinia (organism)|
87172008	|Gram-negative bacillus (organism)|
18383003	|Gram-negative coccus (organism)|
83514008	|Gram-positive bacillus (organism)|
59206002	|Gram-positive coccus (organism)
44470000	|Haemophilus influenzae (organism)|
51593004	|Haemophilus parainfluenzae (organism)|
80774000	|Helicobacter pylori (organism)|
32452004	|Hepatitis A virus (organism)|
81665004	|Hepatitis B virus (organism)|
62944002	|Hepatitis C virus (organism)|

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74871001	|Human adenovirus (organism)|
19965007	|Human herpes simplex virus (organism)|
19030005	|Human immunodeficiency virus (organism)|
407498006	|Human parainfluenza viruses (organism)|
6415009	|Human respiratory syncytial virus (organism)|
1838001	|Human rhinovirus (organism)|
407479009	|Influenza A virus (organism)|
407480007	|Influenza B virus (organism)|
407482004	|Influenza C virus (organism)|
414561005	|Kingdom Fungi (organism)|
62592009	|Klebsiella aerogenes (organism)|
40886007	|Klebsiella oxytoca (organism)|
56415008	|Klebsiella pneumoniae (organism)|
36094007	|Listeria monocytogenes (organism)|
24226003	|Moraxella catarrhalis (organism)|
113858008	|Mycobacterium tuberculosis complex (organism)|
110379001	|Mycobacterium, non-tuberculosis (organism)|
444877006	|Nakaseomyces glabratus (organism)|
17872004	|Neisseria meningitidis (organism)|
417937002	|Order Enterobacterales (organism)|
115015008	|Pantoea agglomerans (organism)|
16452009	|Pichia kudriavzevii (organism)|
716346000	|Pluralibacter gergoviae (organism)|
73457008	|Proteus mirabilis (organism)|
45834001	|Proteus vulgaris (organism)|
52499004	|Pseudomonas aeruginosa (organism)|
5595000	|Salmonella enterica subspecies enterica serovar Typhi (organism)|

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73525009	|Salmonella Enteritidis (organism)|
50136005	|Salmonella Typhimurium (organism)|
23787004	|Serratia liquefaciens (organism)|
33522002	|Serratia marcescens (organism)|
1263733001	|Severe acute respiratory syndrome coronavirus (organism)|
840533007	|Severe acute respiratory syndrome coronavirus 2 (organism)|
3092008	|Staphylococcus aureus (organism)|
60875001	|Staphylococcus epidermidis (organism)|
83452006	|Staphylococcus haemolyticus (organism)|
116197008	|Staphylococcus, coagulase negative (organism)|
113697002	|Stenotrophomonas maltophilia (organism)|
43492007	|Streptococcus agalactiae (organism)|
9861002	|Streptococcus pneumoniae (organism)|
80166006	|Streptococcus pyogenes (organism)|
19551004	|Varicellovirus humanalpha3 (organism)|
49872002	|Virus (organism)|
62093005	|Yeast (organism)|

Table 11: *List of microorganisms whose detection is submitted to ECDC*

In the case of Streptococcus Pneumoniae also the serotype as shown in Table 12 is to be transmitted.

SNOMED CODE	**FSN**
415607008	|Streptococcus pneumoniae Danish serotype 1 (organism)|
415621005	|Streptococcus pneumoniae serogroup 10 (organism)|
415608003	|Streptococcus pneumoniae Danish serotype 10A (organism)|
428124003	|Streptococcus pneumoniae Danish serotype 10B (organism)|
698103009	|Streptococcus pneumoniae Danish serotype 10C (organism)|
441602004	|Streptococcus pneumoniae Danish serotype 10F (organism)|
363768008	|Streptococcus pneumoniae serogroup 11 (organism)|

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419071000	|Streptococcus pneumoniae Danish serotype 11A (organism)|
698104003	|Streptococcus pneumoniae Danish serotype 11B (organism)|
698105002	|Streptococcus pneumoniae Danish serotype 11C (organism)|
698106001	|Streptococcus pneumoniae Danish serotype 11D (organism)|
763392007	|Streptococcus pneumoniae Danish serotype 11E (organism)|
698107005	|Streptococcus pneumoniae Danish serotype 11F (organism)|
116500005	|Streptococcus pneumoniae serogroup 12 (organism)|
698108000	|Streptococcus pneumoniae Danish serotype 12A (organism)|
698109008	|Streptococcus pneumoniae Danish serotype 12B (organism)|
419305002	|Streptococcus pneumoniae Danish serotype 12F (organism)|
428366009	|Streptococcus pneumoniae Danish serotype 13 (organism)|
103498008	|Streptococcus pneumoniae Danish serotype 14 (organism)|
415609006	|Streptococcus pneumoniae serogroup 15 (organism)|
443239003	|Streptococcus pneumoniae Danish serotype 15A (organism)|
415610001	|Streptococcus pneumoniae Danish serotype 15B (organism)|
1339010008	|Streptococcus pneumoniae Danish serotype 15B or Streptococcus pneumoniae Danish serotype 15C (finding)|
443240001	|Streptococcus pneumoniae Danish serotype 15C (organism)|
698110003	|Streptococcus pneumoniae Danish serotype 15F (organism)|
131362008	|Streptococcus pneumoniae serogroup 16 (organism)|
698111004	|Streptococcus pneumoniae Danish serotype 16A (organism)|
698112006	|Streptococcus pneumoniae Danish serotype 16F (organism)|
131361001	|Streptococcus pneumoniae serogroup 17 (organism)|
698113001	|Streptococcus pneumoniae Danish serotype 17A (organism)|
420138009	|Streptococcus pneumoniae Danish serotype 17F (organism)|
418147001	|Streptococcus pneumoniae serogroup 18 (organism)|
698114007	|Streptococcus pneumoniae Danish serotype 18A (organism)|
698115008	|Streptococcus pneumoniae Danish serotype 18B (organism)|

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418451009	|Streptococcus pneumoniae Danish serotype 18C (organism)|
698116009	|Streptococcus pneumoniae Danish serotype 18F (organism)|
127541006	|Streptococcus pneumoniae serogroup 19 (organism)|
415611002	|Streptococcus pneumoniae Danish serotype 19A (organism)|
698117000	|Streptococcus pneumoniae Danish serotype 19B (organism)|
698118005	|Streptococcus pneumoniae Danish serotype 19C (organism)|
419915004	|Streptococcus pneumoniae Danish serotype 19F (organism)|
419527005	|Streptococcus pneumoniae Danish serotype 2 (organism)|
767202000	|Streptococcus pneumoniae serogroup 20 (organism)|
698097002	|Streptococcus pneumoniae Danish serotype 21 (organism)|
363767003	|Streptococcus pneumoniae serogroup 22 (organism)|
441566007	|Streptococcus pneumoniae Danish serotype 22A (organism)|
420216004	|Streptococcus pneumoniae Danish serotype 22F (organism)|
415613004	|Streptococcus pneumoniae serogroup 23 (organism)|
698098007	|Streptococcus pneumoniae Danish serotype 23A (organism)|
427741005	|Streptococcus pneumoniae Danish serotype 23B (organism)|
418217008	|Streptococcus pneumoniae Danish serotype 23F (organism)|
698099004	|Streptococcus pneumoniae serogroup 24 (organism)|
698119002	|Streptococcus pneumoniae Danish serotype 24A (organism)|
698120008	|Streptococcus pneumoniae Danish serotype 24B (organism)|
698121007	|Streptococcus pneumoniae Danish serotype 24F (organism)|
698122000	|Streptococcus pneumoniae serogroup 25 (organism)|
698123005	|Streptococcus pneumoniae Danish serotype 25A (organism)|
698124004	|Streptococcus pneumoniae Danish serotype 25F (organism)|
698125003	|Streptococcus pneumoniae Danish serotype 27 (organism)|
443155000	|Streptococcus pneumoniae serogroup 28 (organism)|
444352000	|Streptococcus pneumoniae Danish serotype 28A (organism)|
444353005	|Streptococcus pneumoniae Danish serotype 28F (organism)|

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131363003	|Streptococcus pneumoniae Danish serotype 29 (organism)|
103497003	|Streptococcus pneumoniae Danish serotype 3 (organism)|
443670000	Streptococcus pneumoniae Danish serotype 31 (organism)
698126002	|Streptococcus pneumoniae serogroup 32 (organism)|
698127006	|Streptococcus pneumoniae Danish serotype 32A (organism)|
698128001	|Streptococcus pneumoniae Danish serotype 32F (organism)|
415614005	|Streptococcus pneumoniae serogroup 33 (organism)|
442049002	|Streptococcus pneumoniae Danish serotype 33A (organism)|
698129009	|Streptococcus pneumoniae Danish serotype 33B (organism)|
698130004	|Streptococcus pneumoniae Danish serotype 33C (organism)|
698131000	|Streptococcus pneumoniae Danish serotype 33D (organism)|
420148006	|Streptococcus pneumoniae Danish serotype 33F (organism)|
767201007	|Streptococcus pneumoniae Danish serotype 34 (organism)|
429569005	|Streptococcus pneumoniae serogroup 35 (organism)|
698132007	|Streptococcus pneumoniae Danish serotype 35A (organism)|
698133002	|Streptococcus pneumoniae Danish serotype 35B (organism)|
698134008	|Streptococcus pneumoniae Danish serotype 35C (organism)|
698135009	|Streptococcus pneumoniae Danish serotype 35F (organism)|
698136005	|Streptococcus pneumoniae Danish serotype 36 (organism)|
698137001	|Streptococcus pneumoniae Danish serotype 37 (organism)|
767204004	|Streptococcus pneumoniae Danish serotype 38 (organism)|
767208001	|Streptococcus pneumoniae Danish serotype 39 (organism)|
415616007	|Streptococcus pneumoniae Danish serotype 4 (organism)|
767274003	|Streptococcus pneumoniae Danish serotype 40 (organism)|
698138006	Streptococcus pneumoniae serogroup 41 (organism)
698139003	|Streptococcus pneumoniae Danish serotype 41A (organism)|
698140001	|Streptococcus pneumoniae Danish serotype 41F (organism)|
767285001	|Streptococcus pneumoniae Danish serotype 42 (organism)|

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767284002	|Streptococcus pneumoniae Danish serotype 43 (organism)|
767283008	|Streptococcus pneumoniae Danish serotype 44 (organism)|
767282003	|Streptococcus pneumoniae Danish serotype 45 (organism)|
767281005	|Streptococcus pneumoniae Danish serotype 46 (organism)|
698146007	|Streptococcus pneumoniae serogroup 47 (organism)|
698147003	|Streptococcus pneumoniae Danish serotype 47A (organism)|
698148008	|Streptococcus pneumoniae Danish serotype 47F (organism)|
767275002	|Streptococcus pneumoniae Danish serotype 48 (organism)|
419871001	|Streptococcus pneumoniae Danish serotype 5 (organism)|
415618008	|Streptococcus pneumoniae serogroup 6 (organism)|
443156004	|Streptococcus pneumoniae Danish serotype 6A (organism)|
418902003	|Streptococcus pneumoniae Danish serotype 6B (organism)|
698095005	|Streptococcus pneumoniae Danish serotype 6C (organism)|
719028004	|Streptococcus pneumoniae Danish serotype 6D (organism)|
441523000	|Streptococcus pneumoniae serogroup 7 (organism)|
415619000	|Streptococcus pneumoniae Danish serotype 7A (organism)|
698102004	|Streptococcus pneumoniae Danish serotype 7B (organism)|
698096006	|Streptococcus pneumoniae Danish serotype 7C (organism)|
103499000	|Streptococcus pneumoniae Danish serotype 7F (organism)|
418759005	|Streptococcus pneumoniae Danish serotype 8 (organism)|
417270004	|Streptococcus pneumoniae serogroup 9 (organism)|
419167001	|Streptococcus pneumoniae Danish serotype 9A (organism)|
418883007	|Streptococcus pneumoniae Danish serotype 9L (organism)|
103500009	|Streptococcus pneumoniae Danish serotype 9N (organism)|
418322006	|Streptococcus pneumoniae Danish serotype 9V (organism)|

***Table 12**: SNOMED codes and fully specified names for the Streptococcus pneumonia serotypes collected by ECDC.*

Among the laboratory tests, the microbiology procedures such as those shown in Table 13 allow for coding the type of investigation performed, while also providing the option to further specify the methodology used via the FHIR Observation.method element:

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LOINC ID	Fully Specified Name
41852-5	Microorganism or agent identified in Specimen
11475-1	Microorganism identified in Specimen by Culture

***Table 13**: LOINC codes to describe the procedure for the detection of a microorganism without specifying a method and via culture.*

LOINC offers additional codes that include specific methodologies, such as PCR. However, discussions are still ongoing among experts regarding the appropriate level of detail to include when describing the test performed.

Considering the increasing global health threat caused by antimicrobial resistance the value sets concerning susceptibility tests are also very important. In particular, we highlight those whose results are collected by ECDC as illustrated in Table 14. In the same table also tests detecting presence of resistant agents are included at the bottom.

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LOINC	Fully specified name
18863-1	5-Fluorocytosine [Susceptibility]
18862-3	Amikacin [Susceptibility]
18878-9	Amoxicillin [Susceptibility]
51724-3	Amoxicillin+Clavulanate [Susceptibility]
32378-2	Amoxicillin+Clavulanate [Susceptibility]
18908-4	Amphotericin B [Susceptibility]
18910-0	Ampicillin [Susceptibility]
73603-3	Azithromycin [Susceptibility]
73602-5	Beta lactamase.extended spectrum [Susceptibility]
18916-7	Caspofungin [Susceptibility]
100049-6	Cefamandole [Susceptibility]
6984-9	ceFAZolin [Susceptibility]
99280-0	Cefepime [Susceptibility]
18855-7	Cefiderocol [Susceptibility]
18923-3	Cefotaxime [Susceptibility]
18924-1	cefOXitin [Susceptibility]
25596-8	Cefpirome [Susceptibility]
18927-4	cefTAZidime [Susceptibility]
18937-3	cefTAZidime+Avibactam [Susceptibility]
18945-6	Ceftolozane+Tazobactam [Susceptibility]
88892-5	cefTRIAXone [Susceptibility]
18952-2	Cefuroxime [Susceptibility]
18954-8	Cephalothin [Susceptibility]
18994-4	Ciprofloxacin [Susceptibility]
73592-8	Clarithromycin [Susceptibility]

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18972-0	Clindamycin [Susceptibility]
23640-6	Cloxacillin [Susceptibility]
41739-4	Colistin [Susceptibility]
18998-5	DAPTOmycin [Susceptibility]
18993-6	Dicloxacillin [Susceptibility]
18991-0	Doripenem [Susceptibility]
18900-1	Eravacycline [Susceptibility]
18876-3	Ertapenem [Susceptibility]
18889-6	Erythromycin [Susceptibility]
60535-2	Floxacillin [Susceptibility]
18964-7	Fluconazole [Susceptibility]
18907-6	Fosfomycin [Susceptibility]
18919-1	Fusidate [Susceptibility]
18866-4	Gentamicin [Susceptibility]
20629-2	Gentamicin.high potency [Susceptibility]
31039-1	Imipenem [Susceptibility]
18888-8	Ketoconazole [Susceptibility]
18961-3	levoFLOXacin [Susceptibility]
18906-8	Linezolid [Susceptibility]
18974-6	Meropenem [Susceptibility]
29258-1	Meropenem+Vaborbactam [Susceptibility]
35789-7	Methicillin [Susceptibility]
18864-9	Moxifloxacin [Susceptibility]
18861-5	Nalidixate [Susceptibility]
18929-0	Netilmicin [Susceptibility]
19000-9	Norfloxacin [Susceptibility]
18989-4	Ofloxacin [Susceptibility]
18862-3	Oxacillin [Susceptibility]

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18886-2	Penicillin [Susceptibility]
18893-8	Piperacillin [Susceptibility]
18895-3	Piperacillin+Tazobactam [Susceptibility]
18879-7	Plazomicin [Susceptibility]
18928-2	Polymyxin B [Susceptibility]
18996-9	Quinupristin+Dalfopristin [Susceptibility]
18860-7	rifAMPin [Susceptibility]
18959-7	Sulbactam [Susceptibility]
18956-3	Teicoplanin [Susceptibility]
18932-4	Temocillin [Susceptibility]
18943-1	Tetracycline [Susceptibility]
35802-8	Ticarcillin [Susceptibility]
42357-4	Tigecycline [Susceptibility]
18912-6	Tobramycin [Susceptibility]
18970-4	Trimethoprim+Sulfamethoxazole [Susceptibility]
18969-6	Vancomycin [Susceptibility]
48813-0	Methicillin resistance mecA gene [Presence] by Molecular method
104864-4	Beta lactamase.extended spectrum [Presence]
86930-5	Carbapenemase [Presence] in Isolate

***Table 14**: List of microbiology tests concerning resistance submitted to ECDC.*

The following Information shown in Table 15 on the type of encounter between patient and healthcare provider is relevant to monitor, control and find root causes of infections and are reported to the ECDC.

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Variable	FHIR	Values
Department type	Encounter.serviceType	702877000|Internal medicine clinic (environment)| 309945009|Pediatric department (environment)| 309910001|Pediatric intensive care unit (environment)| 418433008|Surgical intensive care unit (environment)| 309902002|Clinical oncology department (environment)| 309942007|Obstetrics and gynecology department (environment) | 309904001|Intensive care unit (environment)| 225728007|Accident and Emergency department (environment)| 309932005|Genitourinary medicine department (environment)| 309934006|Infectious diseases department (environment)| 74964007|Other (qualifier value)| 261665006|Unknown (qualifier value)|
Patient type	Encounter.class	416800000|Inpatient (person)| 373864002|Outpatient (person)| 74964007|Other (qualifier value)| 261665006|Unknown (qualifier value)|

***Table 15**: List of data elements relevant for the ECDC data collections.*

Tumour-specific information is not explicitly addressed in the IPS+R dataset, but it is partly covered by the problem ad medication list. The following cancer-specific information are collected by ENCR through ECIS and are relevant for cancer monitoring. The specific value sets can be found in Annex III.

Basis of diagnosis	This variable indicates the degree of certainty with which the diagnosis of cancer has been established.
Topography	This variable indicates the anatomic site of the primary tumours.
Morphology	This variable records the type of cell that has become neoplastic, the specific histological term.

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Behaviour	This variable indicates whether a tumour is malignant, benign, in situ, or of uncertain behaviour.
Grade of differentiation / immunophenotype	This variable describes how much a tumour resembles the normal tissues from which it arose and is also used to denote cell lineage for leukaemias and lymphomas.
Tumour Stage	This variable describes the stage of the tumour

***Table 16**: List of cancer-related elements from the ECIS protocol to be considered for IPS+R.*

Table 16 shows cancer-related elements that could be added to the IPS+R. As the European Cancer data Model is in progress, we believe it appropriate to wait until it is published before taking further actions in this field.

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7. Conclusions

The work carried out focuses on bridging the gap between the primary and secondary use of data, particularly for public health purposes. Through the presented use cases, we identified key variables, and value sets relevant to public health that could be considered for inclusion in IPS+R. We also provided mapping to international standards such as SNOMED CT, LOINC and FHIR for the three prioritized use cases.

We have initiated a collaboration with the ECDC to support the standardisation of infection-related data. This collaboration goes beyond the scope of Use Cases 1 and 2, aiming for a more comprehensive approach to the standardisation of public health data also in collaboration with HL7 Europe. As part of the next steps we intend to connect ECDC with the ongoing HL7 Europe´s efforts to develop specific recommendations for a common standard model for microbiology data, including for the complex definition of type of HAIs. If possible, these will be integrated in the revision of Annexes I and II, particularly with respect to FHIR mapping, which will be part of Working paper 4.4.

A common data model based on FHIR for cancer is under development under the guidance of HL7 Europe. Should these artefacts become available in time, a review of the value sets in Annex III will be included in D4.4 to ensure consistency and alignment with the latest standards.

The pilots described in Chapter 6 serve as the starting point for building the dashboards that will be released as Working paper 4.3. These dashboards will demonstrate how the EEHRxF can leverage data collected for primary use to generate useful, real-time analyses that support interventions as well as predictions to minimize risks and improve population health.

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8. Annexes

- Annex I Standardisation of the European Antimicrobial Resistance Surveillance Network (EARS-Net) dataset
- Annex II, Standardisation of the Protocol for the surveillance of healthcare-associated infections and prevention indicators in European intensive care units HAI-Net ICU
- Annex III, Standardisation of the Data Protocol for European Population-Based Cancer Registries

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