VULCAN
HL7 FHIR

HL7 Working Group Meeting
Europe

HL7 FHIR MARATHON

EuroVulcan 2
18th January 2024
Royal Olympic Hotel, Athens

HOSTED BY
HL7 Hellas

1

Welcome & Opening Remarks

ATHENS DIGITAL HEALTH WEEK
15-19th January 2024 | Royal Olympic Hotel

Amy Cramer
Vulcan co-Chair

Panagiotis Telonis
EMA

Michael van Campen
Vulcan Program Director

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2

EuroVulcan 2: Thanks to Our Organising Committee

Making it all Happen

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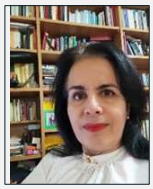
15-19th January 2024 | Royal Olympic Hotel


Catherine Chronaki


Anne Moen


Panagiotis Telonis


Amy Cramer


Lina Nikolopoulou


Hugh Glover


Michael van Campen

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3

Agenda Highlights

ATHENS DIGITAL HEALTH WEEK

Timing	Topic	Session Char
9:00 – 10:30	Q1: Clinical & Translational Research Landscape in Europe	Amy Cramer, Vulcan co-Chair
10:30 – 11:00	Morning Networking Break	
11:00 – 12:30	Q2: Vulcan ePI/eLabeling Project, IDMP and EMA/SPOR: The Way Forward	Anne Moen, University of Oslo and Gravitate-Health
12:30 – 13:45	Lunch / Networking / Lunch tables	
13:45 – 15:15	Q3: Vulcan Utilizing the Digital Protocol / ICH M11 CeSHarP: Focus on Mission, Plans, Key Challenges, European Involvement	Panagiotis Telonis, European Medicines Agency
15:15 – 15:45	Afternoon Networking Break	
15:45 – 17:15	Q4: Regulators Moving to FHIR with support from the Vulcan Accelerator	Hugh Glover, Vulcan Technical Director
17:15 – 17:30	Closing Remarks	Michael van Campen, Amy Cramer

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4

Q1 Panel: Clinical & Translational Research Landscape in Europe

Session Chair: Amy Cramer, Vulcan co-Chair

January 18, 2024

5

Q1 Panel: Clinical & Translational Research Landscape in Europe

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Panelists

1. Vulcan Background: *Amy Cramer, Vulcan co-Chair*
2. Data Standardization Strategy: *Nick Halsey (online), European Medicines Agency*
3. EU Data Protection Regulations and Implications for Vulcan: *Sabine Brosch (online), Data Protection Officer, European Medicines Agency*
4. The European Shortages Monitoring Platform (ESMP)*: Sofia Zastavnik (online), ESMP Product Owner, Supply and Availability of Medicines and Devices, EMA*
5. XpanDH - Expanding Digital Health through a pan-European EHRxF-based Ecosystem: *Henrique Martins, Associate Professor, ISCTE*
6. Digital4Cancer– Landscaping data driven projects and initiatives in cancer – towards data interoperability: *Bianca Baluta (online), European Commission*
7. What's next in HL7 FHIR for Vulcan: *Julia Skapik, Chair HL7 International*

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Q1.1 Vulcan Background

Amy Cramer, Vulcan co-Chair

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7

Vulcan HL7 FHIR Grew Out of the Increasingly Digital Healthcare Environment

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The growing digitalization in healthcare brings along modernized electronic health record standards such as HL7 FHIR.

Maturity in this space varies across the markets; however, the transition to a more digital environment is happening.

Several Accelerators exist already to spur development of digital solutions for healthcare:

- ***Project Argonaut*** **(providers to providers)**
- ***Project DaVinci*** **(providers to payers)**

Experts Blazing the Path Forward for Research

The September 2019 HL7 FHIR® Conference in Atlanta included a half-day forum drawing participation across government, academia and industry.

The goal of the forum was to help the research community align toward leveraging HL7 FHIR® for more effective acquisition, exchange and use of data for clinical research.

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Vulcan is a Diverse, Global Community with 47 Member Organizations

As of December 2023

★ *indicates a convening member of Vulcan*

9

The Goals of Vulcan

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BRIDGE EXISTING GAPS	STRATEGICALLY CONNECT COLLABORATORS	MAXIMIZE COLLECTIVE RESOURCES	DELIVER INTEGRATED TOOLS AND SOLUTIONS
Work to close gap between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency	Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups including EMA, FDA, NCATS, NLM, SCDM, TransCelerate, and academic research sites	Leverage shared community and resources to be able to communicate the return on investment and return on value that a unified network could realize to various parties, and provide comprehensive recommendations to global regulators	Develop necessary FHIR Research Resources to maturity. Vulcan will handle identified and prioritized use cases for secondary use of EHR data that meet interested parties needs and goals

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Vulcan – Progress

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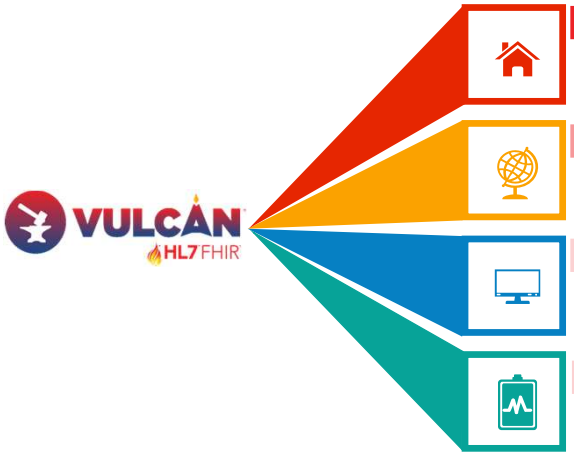

Foundation
- 4 Implementation Guides Published
- 10 Connectathons >25 tracks
- Events
- Governance, Membership, Financial models

Go Global
- Expand outreach into Europe, Asia Pacific and other regions
- Regional activities (e.g. JAMI in Japan), membership & promotion
- Showcase global HL7 FHIR efforts in clinical research

Implement It
- Adoption Strategy: Proof of Concept / Pilot, Tooling
- Maintain Implementation Guides
- Implementation Workgroup / Interoperability Bridge

New Content
- Additional Use Cases such as UDP (ICH M11), ARPA-H, etc.
- Collaborate with other HL7 FHIR Accelerators

11

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12

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Q1.2 Data Standardization Strategy

Nick Halsey, European Medicines Agency (EMA)

January 18, 2024

13

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EMRN Data Standardisation Strategy

EuroVulcan 2, Athens, Greece, 18 Jan 2024

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Nick Halsey, Scientific Administrator, Healthcare Data, European Medicines Agency

An agency of the European Union

14

Background

- The age of Digitalisation is also the age of the Data-driven decision-making. The creation and adoption of data standards supports these activities
- Without data standards the collection, processing and management of large volumes of healthcare and medical product data can be difficult, inefficient and costly. This can then divert finite resources away from data analysis and slows the assimilation of new knowledge.
- The EU medicines big data taskforce report identified the need for a Data standardisation strategy in order support international collaboration and to work with standardisation bodies.
- Creation of new data standards requires significant time and effort of dedicated experts, therefore careful planning and prisonisation is needed

Data Standardisation Strategy

- This data standardisation strategy document is an important deliverable of the Big Data Steering Group (BDSG) and will be maintained overtime to reflect changes in priorities and additions of new requirements. The strategy has been adopted by both the BDSG and the Network Data Board (NDB).
- Until now the approach taken to develop and implement data standards has been ad hoc and slow. The creation of a strategy should enable the reduction of effort and a quicker approach to adopting and implementing data standards.
- This strategy sets out the principles used to guide data standardisation efforts and the adoption of data standards by the European Medicines Regulatory Network (EMRN).
- The document will support the work to create and implement internationally applicable data standards and to support delivering the Network strategy to 2025

Data Standardisation Strategy

Published on the EMA Big data webpage:

Direct link


HMA

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16 December 2021
EMA/447502/2021

European Medicines Regulatory Network Data Standardisation Strategy

Adoption by Big Data Steering Committee	16 September 2021
Adoption by European Network Data Board	8 October 2021
Endorsed by Heads of Medicines Agencies	24 November 2021
Endorsed by EMA Management Board	15-16 December 2021

17

Implementing Data Standards by the European medicines regulatory network (EMRN)

Legal obligation

Having the legal obligation to implement a Standard refers to when the regulatory agencies are obliged to implement a certain Standard (e.g. Pharmacovigilance ISO IDMP)

No obligation, but jurisdiction

For certain parties that have legal obligations, the EMRN can set requirements to adhere to specific standards in the guidelines issued for example by marketing authorization holders, clinical trial sponsors (e.g. data exchange for clinical trial protocols)

No obligation and no jurisdiction

When the EMRN has no jurisdiction over a party, no obligations can be enforced. In such cases the EMRN can get involved in the relevant fora to participate in the decision-making process (e.g. e-health records) for those standards

18

Data Standards Strategy | Development

From December 2020 an in-depth analysis has been performed on the overall IT, policies and data standards landscape within the EMRN. A Survey was conducted in March/April 2021 followed by stakeholder workshop in May 2021

Background Documents*

Survey & workshop

Chemical Strategy for Sustainability

Information Management Strategy 2019-2021

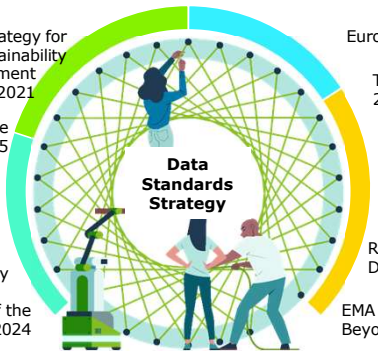
EMA Regulatory Science Strategy 2025

EU Medicines Agencies Network Strategy to 2020

EU Digital Strategy 2025

EU Data Strategy

Political Guidelines of the Commission 2019-2024



European Interoperability Framework

Telematics Implementation Roadmap 2019-2020

EMA Policy Documents & Digital Transformation Tools

EU Policies Human & Vet

Recommendations of HMA-EMA Big Data Task Force

EMA Work Programme(s) 2020-2021 & Beyond

**** Please note that this is a non-exhaustive overview***

143 Use Cases

Collected from the survey

49 organisations responded to the survey

Workshop

4 SDOs presented their work

7 stakeholder groups provided their requirements and priorities

19

Data Standards Strategy | Consultation full results

The information gathered as part of the stakeholder assessment and landscape analysis will be used as input for the Data Standards Strategy

80 internal stakeholders were interviewed throughout **59** interviews.

As a result of the interviews, survey and workshop, more than **330** use cases were collected.

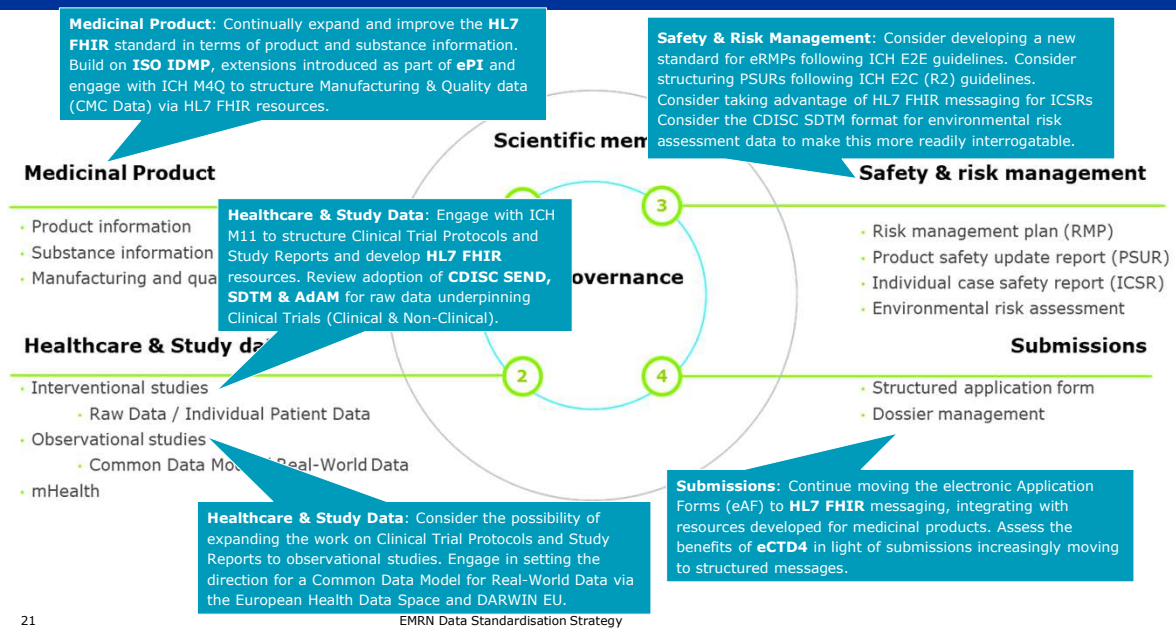
Recurring themes identified revolve around: **ePI, Structured protocol and study design, manufacturing sites, ePSUR, eRMPs**.

The Landscape Analysis was based on **12 SDOs**, focusing on standards published and under development.

Overall, **+1900** standards were reviewed.

20

Data Standardisation Strategy Recommendations



Product Information

Plan further iterations of the electronic product information standard (ePI) to develop additional FHIR resources to support further structuring of information and ensure alignment with the ISO IDMP product and substance related standards.

Ongoing EU activity to develop an implementation of the current ePI standard that has been developed with FHIR resources. Following the pilot review further integration with IDMP and SPOR systems will be undertaken following completion of the pilot.

Interventional studies

A structured clinical trial protocol is being developed by ICH M11, this work should be supported by experts from the EU network to progress its development and include study design & reporting study results. Adopting relevant CDISC standards should be considered for collecting raw data.

- A proof-of-concept pilot is being established to investigate the benefits of analysing and visualising raw data (patient level data in electronic structured format) from clinical trials to support the assessment and learn about the operational, resource and technological needs when analysing raw data.
- Data standards: CDISC Analysis Data Model (ADaM), CDISC Study Data Tabulation Model (SDTM) as well as the Define-XML and Analysis Results Metadata (ARM for Define-XML). Learnings from the pilot will be assessed by documenting practical learnings, including feedback on adoption of relevant CDISC standards for the submission of raw data.
- The development of the ICH M11 structured protocol is being actively supported and a proof of concept implementing FHIR resources developed. Harmonisation work continues under the Vulcan UDP project (ICH M2/M11, HL7, CDISC collaboration).

Observational studies

The standard being developed for clinical trial protocols and study design should be reviewed to see if can be extended to included observational studies. A CDM standard needs to be developed and/or adopted in order to facilitate use real world data (RWD) and metadata obtained from healthcare records and disease registries.

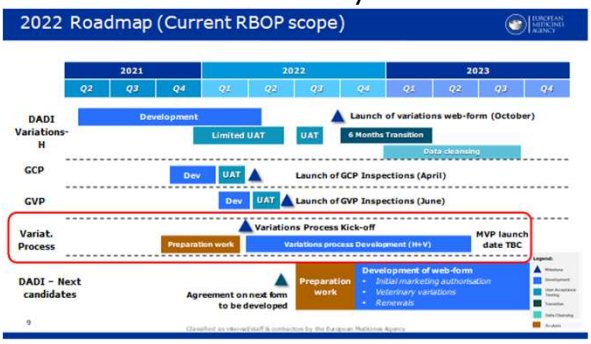
Following the DARWIN EU assessment of Common Data Models the decision to use OMOP was announced in DARWIN EU multi-stakeholder information webinar held in February 2022.

The review of ICH M11 specifications for use in Observational studies will be possible once the work in ICH is published for public consultation.

Structured application form

The electronic application form FHIR messages currently being developed should be reviewed to see if they can be extended to support pre-application phase activities and include metadata to run regulatory processes.

The eAF/DADI project is implementing FHIR messaging and will be adding additional forms for different procedures over time. The possibility to include pre-submission forms will be reviewed towards the end of the year.



Dossier management

The use of FHIR messaging for regulatory data and document exchange should be reviewed to see if it is the best option for the future.

- The current eCTD 3.2 system used for regulatory data exchange is being planed to be replaced with a new system that will use eCTD 4.0 (HL7 V3 messaging).
- The new system is planned to be used as a Proof of Concept for CAPs from Q4 2023.
- Following the Proof of Concept completing, the work on eAF/DADI and other projects using FHIR messaging can be reviewed.
- ICH M2/M8 will also review the future of regulatory data exchange

Thank You

Further information

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27

28

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Q1.3 EU Data Protection Regulations and Implications for Vulcan

Sabine Brosch, Data Protection Officer, European Medicines Agency (EMA)

January 18, 2024

29

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EU Data Protection Regulations and Implications for Vulcan

EuroVulcan 2

European Meeting of the Vulcan Accelerator
Connecting clinical care and clinical research through HL7 FHIR

online
Sabine Brosch on 18 January 2024, Data Protection Officer, European Medicines Agency

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30

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Overview

- Legal framework in the EU
- Protection of "Rights and Freedoms" of natural persons – what constitutes personal data
- Data Protection by Design and Default
- Example: HL7 Individual Case Safety Reports (ICSR) standard
- Conclusion
- References

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European Union Data Protection Framework

European Union Data Protection Regulation (EUDPR) Regulation (EU) 2018/1725
- Applicable to **EU institutions, offices, bodies and agencies**

General Data Protection Regulation (GDPR) Regulation (EU) 2016/679
- Applicable to all the **individuals within the European Union and the European Economic Area**

National laws
- Article 9(4) GDPR *Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.*

Guidelines (EDPS and EDPB)
- Address specific topics and incorporate case law of the European courts and EDPS prior check opinions

Protecting the "Rights and Freedoms" of natural persons

Personal Data
Any information relating to an identified or identifiable natural person ('data subject')
An identifiable natural person is one who **can be identified, directly or indirectly**
by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person
Article 4(1) GDPR

Clinical Care and Clinical Research

Special categories
Data concerning health
related to the physical or mental health of a natural person, including the provision of healthcare services, which reveal information about his or her health status
Art 4(15) GDPR
Genetic Data
relating to the inherited or acquired genetic characteristics of a person which give unique information about the physiology or the health of that person and which result, in particular, from an analysis of a biological sample from the person in question
Art 4(13) GDPR

Data Protection by Design and Default

An enforceable legal obligation (Art 25 GDPR)
Processing of personal data carried out with data protection and privacy in mind at every step and the strictest privacy settings applied by default

"When developing, designing, selecting and using applications, services and products that are based on the processing of personal data or process personal data to fulfil their task, producers of the products, services and applications should be encouraged to take into account the right to data protection when developing and designing such products, services and applications and, with due regard to the state of the art, to make sure that controllers and processors are able to fulfil their data protection obligations..."
Recital 78 of the GDPR

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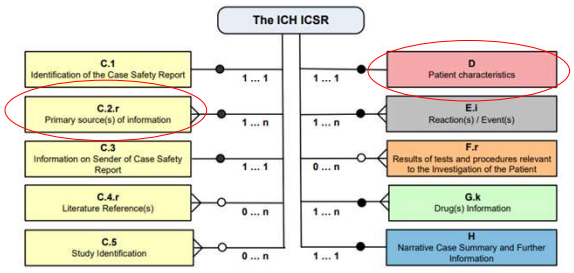
Example:HL7 Individual Case Safety Reports (ICSR) standard

- Exchange of adverse event or product problem reports to public health, patient safety, healthcare quality improvement organizations, or regulatory authorities
- *Data minimisaton principle*: any one of several data elements sufficient to define an identifiable patient (e.g. initials, age, and sex) or an identifiable reporter (e.g. initials, address, and qualification)
- nullFlavor MSK can be used to code values in the ICH ICSR => Primary source(s) and Patient characteristics




```
Example 1:'Masked' is expressed by nullFlavor =MSK.
<componenttypeCode="COMP">
  <adverseEventAssessmentclassCode="INVSTG"moodCode="EVN">
    <subject1typeCode="SBJ">
      <primaryRoleclassCode="INVSBJ">
        <player1classCode="PSN"determinerCode="INSTANCE">
          <namenullflavor="MSK"/>
          <!-- D.1:  Patient (name or initials) -->
          <administrativeGenderCode code="D.5"codeSystem="1.0.5218"/>
          <!-- D.5 Sex [1] Male [2]Female-->
          <birthTime value="19200101"/>
          <!-- D.2.1: Date of Birth -->
          <deceasedTime value="20090101"/>
```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Conclusion

- Privacy and data protection by design and by default principles are not just an EU concept
  - Seven foundational principles as relayed in the Jerusalem Declaration which influenced privacy guidance and the definition of best practices and emerging standards worldwide
- The sensitive nature of health and genetic data deserves special safeguards (technical and organizational measures) when such data are exchanged taking into account the purpose of the processing and compliance with applicable data protection rules
  - Examples: labelling data elements that may contain personal/sensitive data, if data are anonymized or pseudonymized and applied technique, use of nullFlavors (structured/unstructured data elements), reference to applicable data protection/privacy law…..
- Vulcan HL7 can play an important role in developing a "privacy and personal data protection by design approach" and a "privacy and data protection management framework" in the area of standards development in clinical care and clinical research

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Thank You

Further information

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- Regulation - 2016/679 - EN - gdpr - EUR-Lex (europa.eu)
- 18-05-31_preliminary_opinion_on_privacy_by_design_en_0.pdf (europa.eu)
- E2B (R3) Step 5 Electronic transmission of individual case safety reports (ICSRs) - data elements and message specification - implementation guide (europa.eu)
- Resolution on Privacy by Design (europa.eu)

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Q1.4 The European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik, ESMP Product Owner, Supply and Availability of Medicines and Devices, EMA

January 18, 2024

39

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The European Shortages Monitoring Platform (ESMP)

Presented by Sofia Zastavnik, ESMP Product Owner
Supply and Availability of Medicines and Devices, EMA

An agency of the European Union

40

How does the EU manage shortages?

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Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Agencies**

Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur

In December 2016, a joint **HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM)** was established to:

- provide **strategic support** and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability

41

41

EMA Extended Mandate | Overview

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The EMA's role in **crisis preparedness and management** in reference to availability of the medicinal products has increased significantly following the outbreak of the Covid-19 pandemic. **Regulation 2022/123** formalises the structures and processes established during the pandemic.

- Provides a framework for activities established by the European Medicines Agency to monitor and **mitigate potential and actual shortages of medicines**
- Sets **processes/tools for shortages reporting** and coordinates **responses** of EU countries to shortages of critical medicines during crisis and for monitoring of events which might lead to a crisis situation
- Establishes "**Medicines Shortages Steering Group**" (MSSG) supported by the **SPOC Working Party** and a Network of contact points from pharmaceutical companies (i-SPOCs)
- Foresees the development of the **European Shortages Monitoring Platform** (ESMP) by Feb 2025

KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU

42

42

The European Shortages Monitoring Platform (ESMP)

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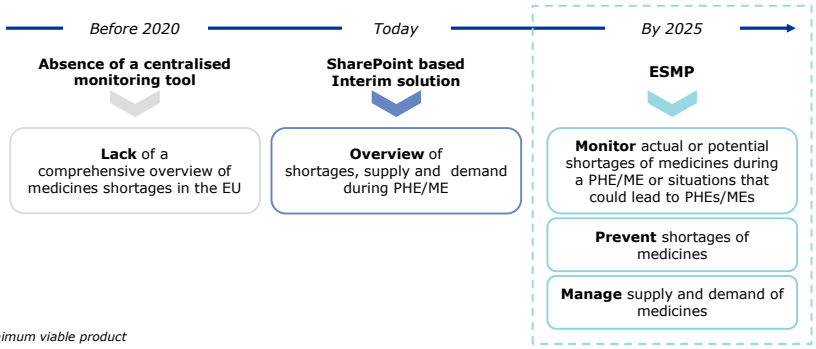
Implementation date: **2 February 2025***

Article 13 of Regulation 2022/123 foresees the development of an **IT platform** to facilitate collection of information on **shortages**, **supply** and **demand** for medicinal products, including information on marketing status and marketing cessations, from both Industry's and Member States' SPOCs

Scope: monitoring, prevention and management

- Crisis: Shortages of medicinal products (within the scope of the relevant **list of critical** medicines) during a **PHE or a major event**
- Preparedness: Actual and/or potential medicines shortages (in a given Member State), that **can lead to** a Major event or a PHE



KEY BENEFIT

Providing a centralised EU platform to report, monitor, prevent and manage medicine shortages

43 **Minimum viable product*

43

ESMP data elements for matching supply & demand

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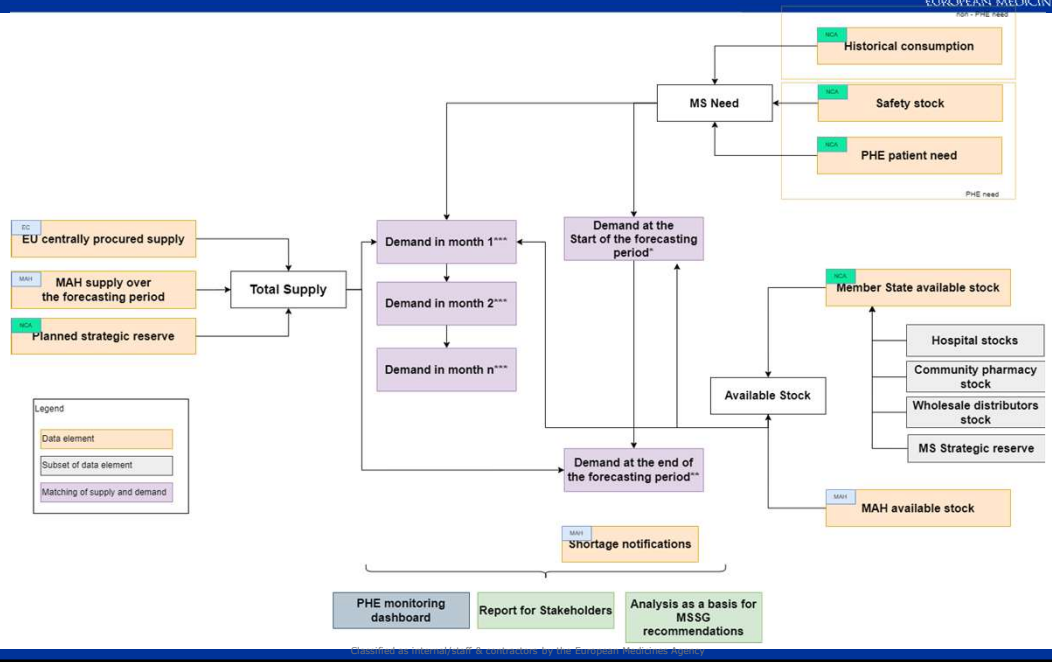

44

44

ESMP High-level overview

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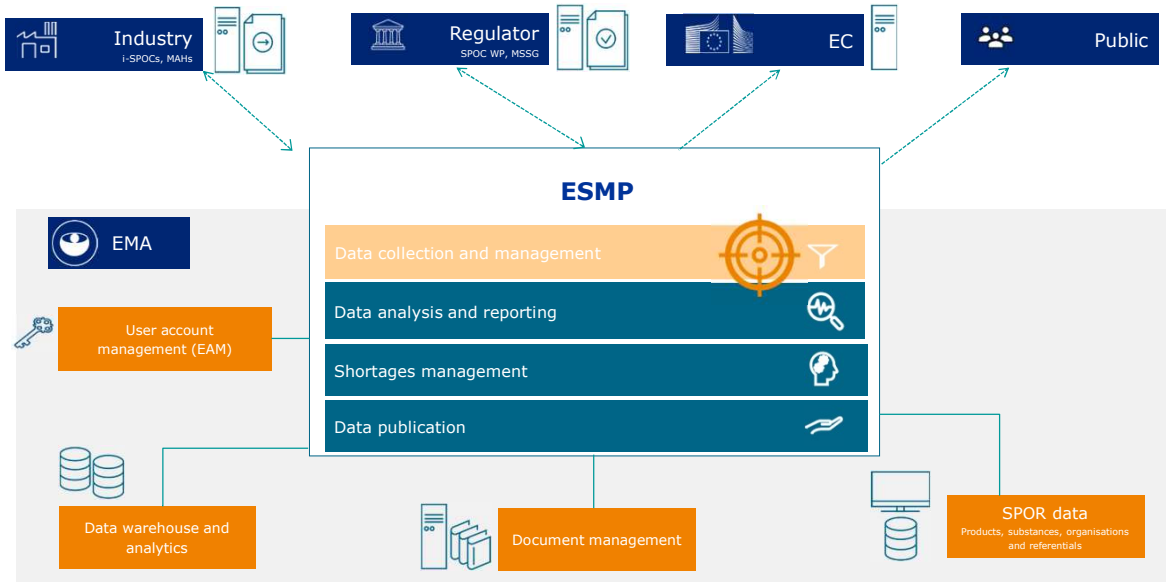

45

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Q1.5 XpanDH - Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Henrique Martins, Associate Professor, ISCTE

January 18, 2024

47

XpanDH in the light of the EHDS proposal

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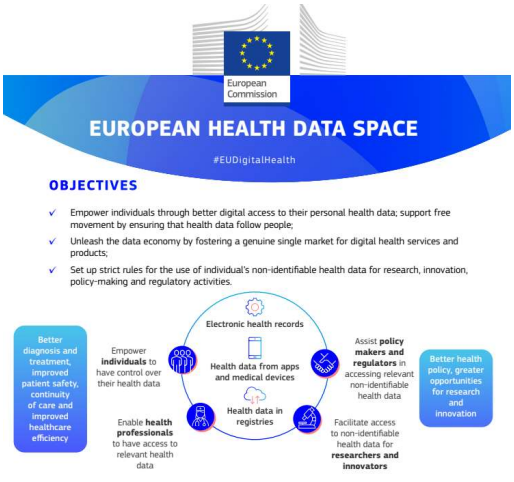

Main EHDS articles regarding the EEHRxF

Article 6 - European EHRxF

Datasets

Coding systems and values

Technical specifications

Article 12 - MyHealth@EU

Cross-border exchange of health data shall be under the EEHRxF

Article 23 - Common specifications

Adopt common specifications

Shall include: scope; applicability to different categories of EHR systems or functions included in them; version; validity period; normative part; explanatory part, including any relevant implementation guidelines.

May include: datasets; coding systems and values; requirements related to data quality; technical specifications, standards and profiles; security, confidentiality, integrity, patient safety and protection of electronic health data; eID

GROWTH POTENTIAL OF THE HEALTH DATA ECONOMY
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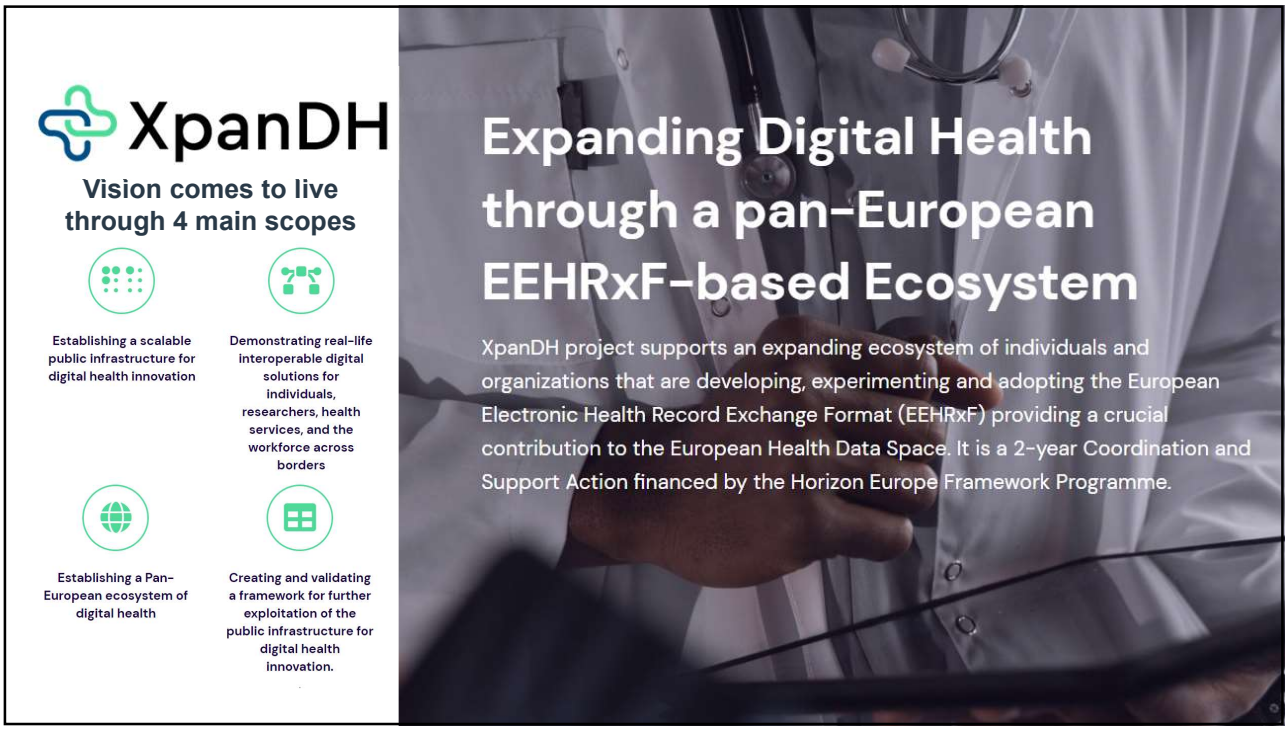
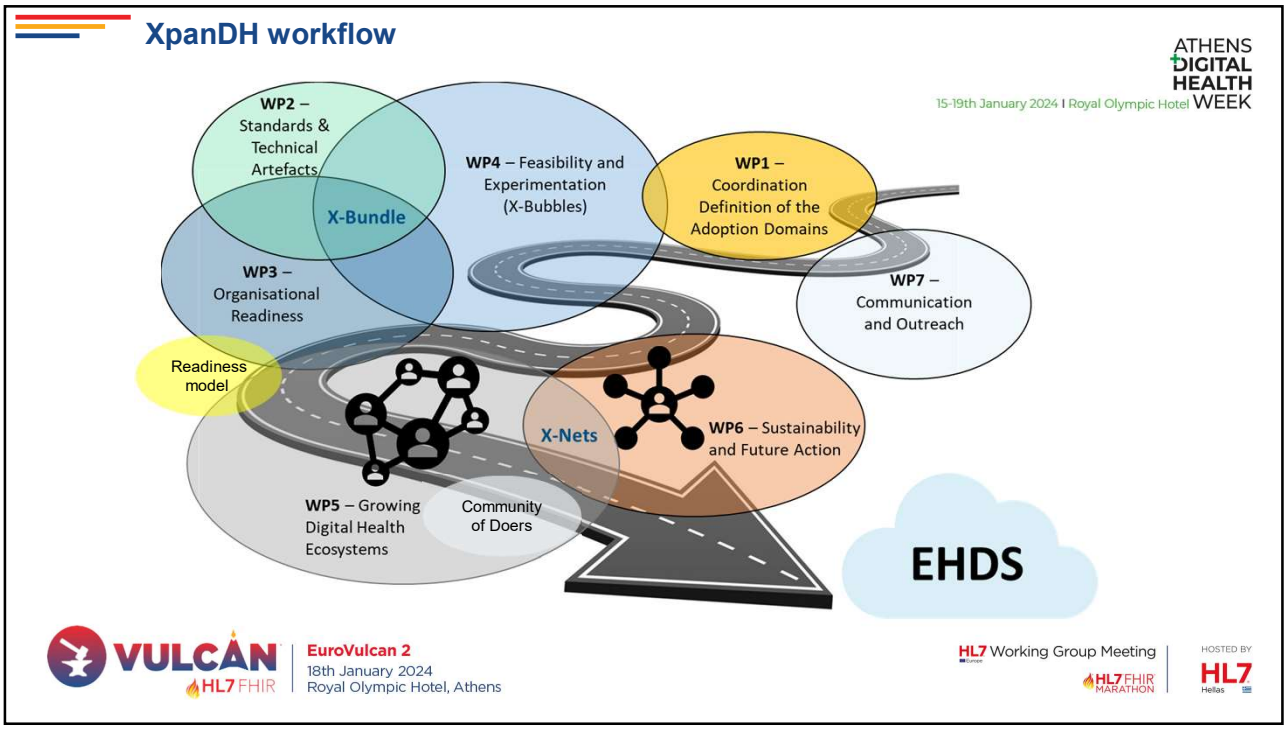

XpanDH
Vision comes to live through 4 main scopes
Establishing a scalable public infrastructure for digital health innovation
Demonstrating real-life interoperable digital solutions for individuals, researchers, health services, and the workforce across borders
Establishing a Pan-European ecosystem of digital health
Creating and validating a framework for further exploitation of the public infrastructure for digital health innovation.
Expanding Digital Health through a pan-European EEHRxF-based Ecosystem
XpanDH project supports an expanding ecosystem of individuals and organizations that are developing, experimenting and adopting the European Electronic Health Record Exchange Format (EEHRxF) providing a crucial contribution to the European Health Data Space. It is a 2-year Coordination and Support Action financed by the Horizon Europe Framework Programme.

49


XpanDH workflow
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WP2 – Standards & Technical Artefacts
X-Bundle
WP4 – Feasibility and Experimentation (X-Bubbles)
WP1 – Coordination Definition of the Adoption Domains
WP3 – Organisational Readiness
WP7 – Communication and Outreach
Readiness model
X-Nets
WP6 – Sustainability and Future Action
WP5 – Growing Digital Health Ecosystems
Community of Doers
EHDS
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XpanDH _ Inspired in CoP Communities of Practice – Based X-eHealth

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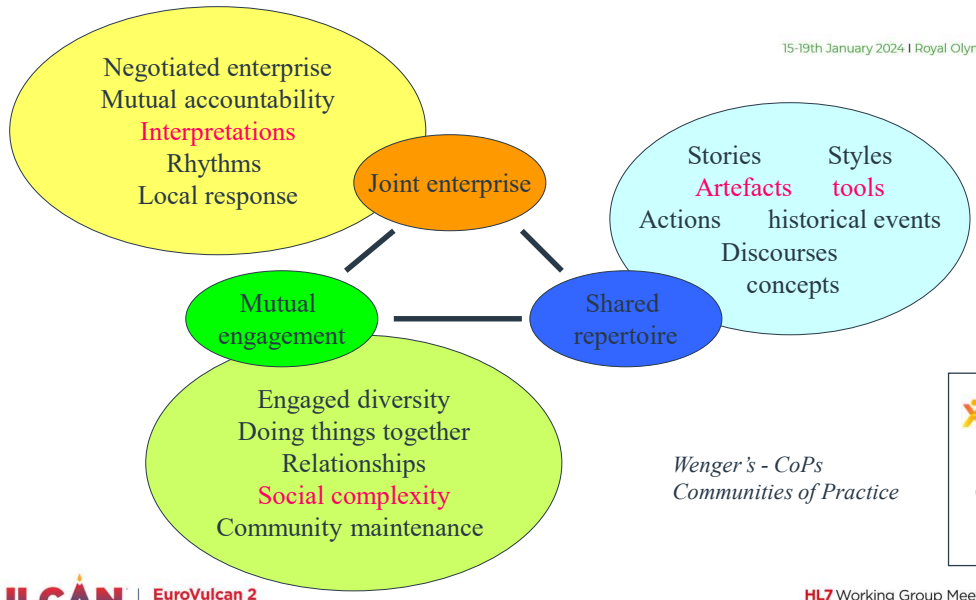

Wenger's - CoPs
Communities of Practice

X-eHealth
WP8
EEHRxF Community of Practice

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From the Adoption Domains to x-bubbles

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EEHRxF adoption domain could be considered as an instantiation of a use case, with a specific case application, that has meaning from a health system or clinical perspective, with defined implementable requirements (simple if only one EEHRxF priority category is uses or composite if data from more than one is required), that satisfies all the conditions for users to be ready to implement data exchange in conformity to EEHRxF guidelines and specifications

X-eHealth
WP1
Roadmap for new domains

X-eHealth
WP6
X-eHealth Services Specifications

Adoption domains definition

Adoption domains delimitation

Development of experimentation on the x-bubbles

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XpanDH bubbles Level 1 – Real testing

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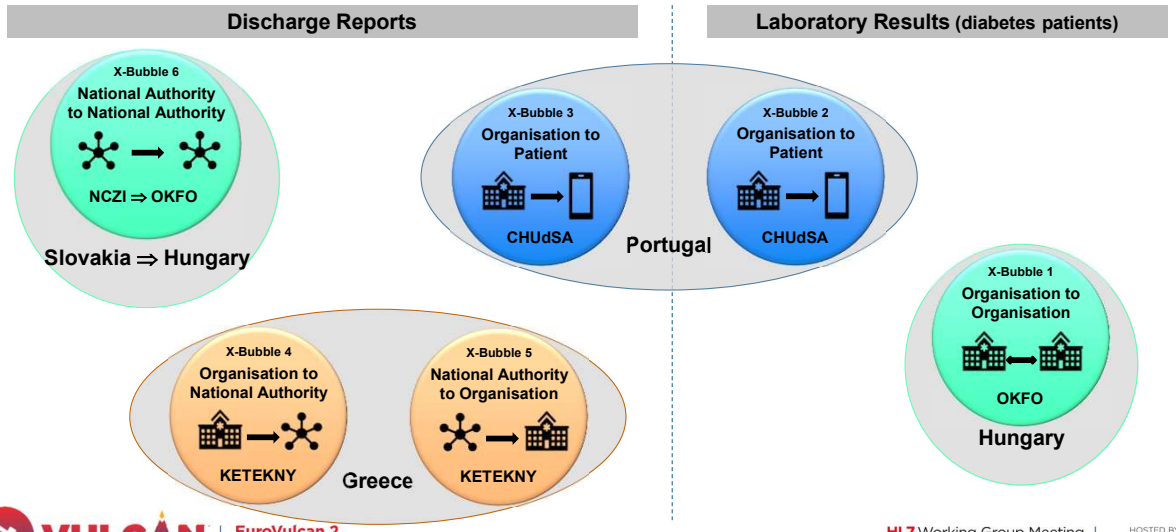

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Integration of the ecosystems through the X-nets

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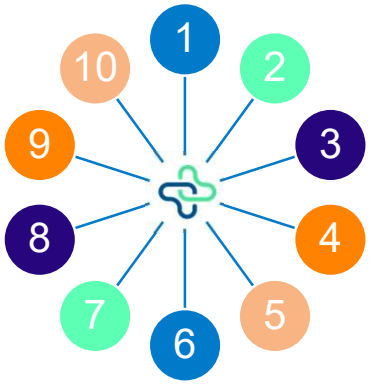
X-Nets are networks of organisations directly or indirectly related to health and digital health and that will be involved or need to be involved in an expanding European Digital Health Ecosystem as it matures its use of the European EHRxF (e.g., Networks of Patients and Patient Associations, HCP, ISP, Standards Development Organisations and Industry).



#	X-Net Name
1	Patient Association
2	SDO's & Industry Board
3	Hospitals-on-FHIR
4	Biomedical Research
5	Professionals Associations
6	Citizens and Society
7	Health Mgt & Regulators
8	Innovation Hubs
9	ERN and PerMed
10	Health Regional Authorities

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Hospitals on FHIR X-Net

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Purpose - Hospitals-on-FHIR

- Create a **Community** of **learning** in **data sharing**
- **Adoption** standards
- **Cooperation** learning and sharing from each other
- 10-step **maturity model** to realize the KIWI principles

Knowledgeable

Intelligence

Wise

Interoperable

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HoF Maturity Model summary

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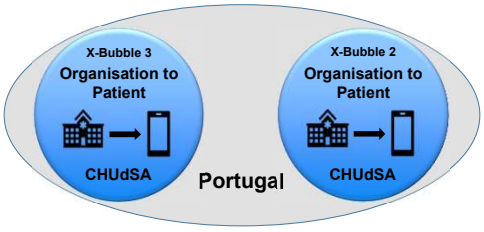
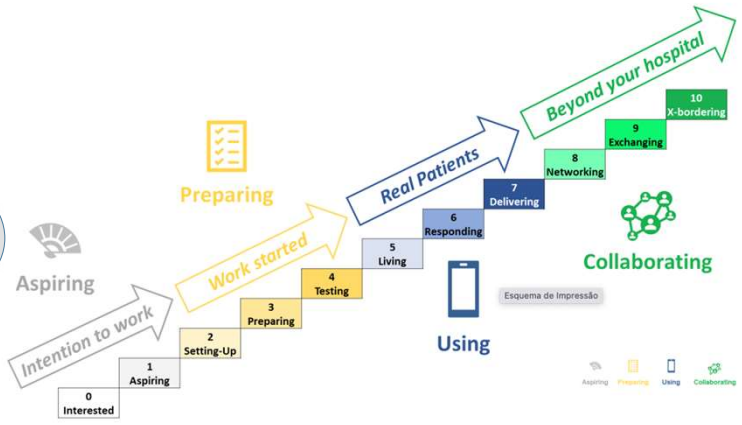
Scheduling Resources (Level 7)

XpanDH (Level 4)





https://www.hospitalsonfhir.eu

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Integration of the ecosystems through a Community of doers

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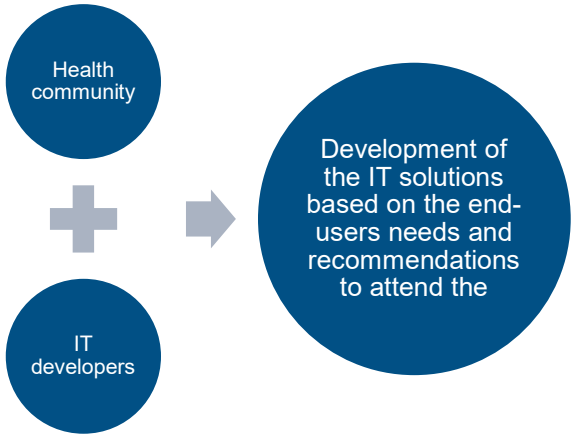
The **Community of doers** is bringing together implementers and end-users of new and existing solutions: IT developers and vendors/suppliers on one hand; patients and healthcare professionals on the other, under the concept of the 3C-3P community (Co-creation Community of Patients, Professionals and Programmers). The community is following an open-source community and collaborative approach inviting end-users to participate and support IT developers.



57

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Thanks!

Contact:
Henrique Martins
henrique@henriquemartins.eu

XpanDH website & Social media

58

ONLINE

Q1.6 Digital4Cancer– Landscaping data driven projects and initiatives in cancer Towards Data Interoperability

Bianca Baluta, European Commission

January 18, 2024

59

European Commission

Digital4Cancer– Landscaping data driven projects and initiatives in cancer

Towards Data Interoperability

Bianca BALUTA, Programme Officer

DG Communications Networks, Content and Technology (CNECT)
Unit H3: eHealth, Well Being and Ageing

Directorate H: Digital Society, Trust & Cybersecurity

18 January 2024
EuroVulcan 2

60

What is Digital4Cancer?

Series of 3 workshops organised by the Commission's services

- Introduction and landscaping of data-driven projects in cancer
- Discussion on cancer data topics requiring coordination & support
- Reflection on future collaboration and support actions

WHY?

complementarities

synergies + use existing resources

areas of collaboration

duplication − inefficiencies in funding & impact

European Commission

61

3 topics in Digital4Cancer

1. Access to data – legal and technical considerations
2. **Data interoperability**
3. Sustainability of cancer research data resources

European Commission

62

Data interoperability

"The cancer data ecosystem in Europe should work towards being fully integrated in the EU data spaces"

- ***How to foster interoperability of health data among infrastructures and platforms in Europe?***

  ➡ *How can we work towards consolidating the cancer data ecosystem in Europe?*

- ***Which dimensions of interoperability could your project contribute to in view of the EHDS: Legal, Organizational, Semantic, or Technical ?***

  ➡ *What are the needs and priority areas that are not covered by the proposed EHDS regulatory framework, where EC support would be needed in relation to access to data interoperability?*

European Commission

63

Discussion & ideas for further actions (1)

- **Bring together (open invitation) the projects that are working on defining reference ontologies**
- Alignment of stakeholders with specific projects (e.g. GDI for genomic data, EUCAIM for for radiological images, BigPicture for pathology, and EIRENE-RI for human exposome data)
- Enabling harmonisation of data at source (towards common ontologies for both **clinical care and research)** and across domains & jurisdictions to enable reproducible cancer research
- Explore possibilities of **mapping of the reference ontology:**
  - On input: real world primary data sources
  - On output: to the common standards (HL7 FHIR, OMOP, SNOMED, LOINC, ATC)
- **Ensure quality of primary data sources and quality of derived data** – reuse for different purposes

➡ **EXAMPLES of existing collaboration initiatives**

European Commission

64

Discussion & ideas for further actions (2)

- **Catalogue of data available at healthcare source**
- **Data quality framework at data sources** – potential support provided by the Health Data Access Bodies
- Consolidation of research data ontologies from basic research
- Legal basis – easy solution for patients to control their data

65

What is the European Commission already doing?

- Calls for proposals under Horizon Europe, Cancer Mission, DIGITAL, and the EU4Health programmes have been published- **request for synergies and collaboration with other ongoing projects is encouraged**
- If new opportunities for synergies arise during project implementation, projects are encouraged to contact their Project Officers and discuss the scope and potential actions to be taken
- Creation & facilitation of discussions among existing projects e.g. the Digital4Cancer Workshops
- Funding for research projects tackling key challenges e.g. QUANTUM-CSA

66

Thank you!

CNECT.H3

European Commission

67

European Commission

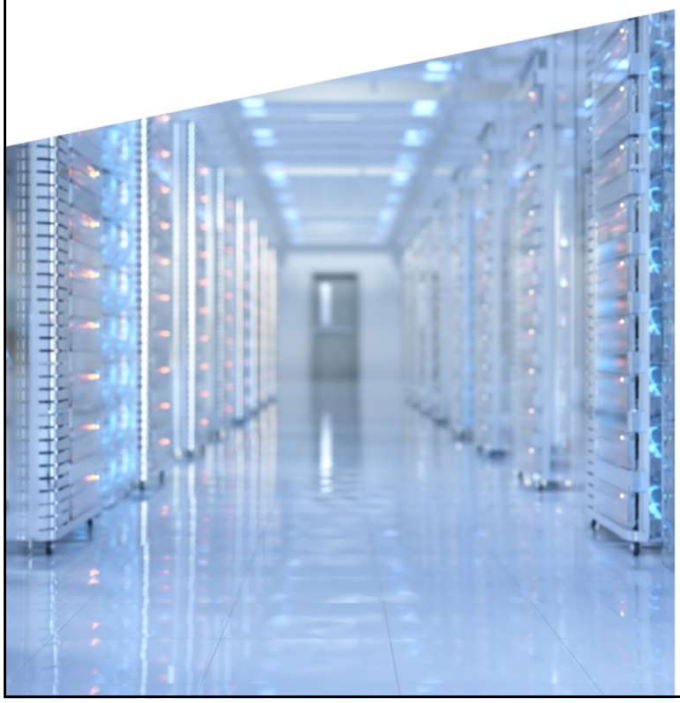
68

Q1.7 What's next in HL7 FHIR for Vulcan

Julia Skapik, Chair HL7 International

January 18, 2024

69



Implementation Considerations for Electronic Health Data-Enabled Research at Scale

Best Practices and Considerations for Using RWE Data

70

Governance: Data Sharing

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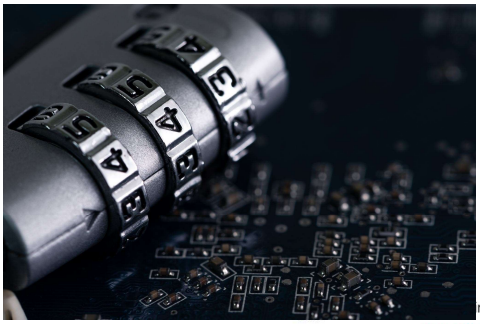
- **Data sharing agreements for research expect patient consent for data sharing but there is difficulty in traceability for RWE**
- **Using real world data for research often requires rewriting data agreements to ensure clinical value**
  - in US the removal of identifiers must include dates which limits the utility of datasets
- **Requirements may exist locally in addition to the national or regional level**
- **Even when legal framework exists, organizational legal counsel and clinical leadership buy-in is required**
- **This prework should be considered compulsory to build functional research networks**

https://usercentrics.com/knowledge-hub/us-privacy-law-compliance-for-eu-companies/



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Governance: Engagement of Community

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- **How do we build trust?**
- **Engage technology team, clinical team and PATIENTS**
- **User- and patient-centered design**
- **Identify health equity goals and include in research design**
- **Consider reuse of successful design, data definitions and queries to enable better performance**
- **Feedback to patients and care teams is valuable and important for engagement**

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Governance: Data Quality

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84	CAMILA 0.35 MG ORAL TABLET	386	POP
85	CAMILA 0.35 MG TABLET	15	POP
86	CAMILA 0.35 MG TABS	14	POP
87	CAMILA 0.35MG TAB	3	POP
88	CAMILA TABS 0.35 MG	1	POP
89	CAMRESE TAB	3	OCP
90	CAMRESE 0.15-0.03-0.01 MG TAB	7	OCP
91	CAMRESE 0.15-0.03 &0.01 MG ORAL TABLET	36	OCP
92	CAMRESE 0.15-0.03 &0.01 MG TABS	12	OCP
93	CAMRESE LO 0.1-0.02 & 0.01 MG ORAL TABLET	7	OCP
94	CAMRESE LO 0.1-0.02 & 0.01 MG TABS	3	OCP
95	CAZIANT 0.1/0.125/0.15 -0.025 MG ORAL TABLET	8	OCP
96	CAZIANT TABLETS 28S	4	OCP
97	CESIA 0.1/0.125/0.15 -0.025 MG ORAL TABLET	2	OCP
98	CHATEAL 0.15-30 MG-MCG ORAL TABLET	62	OCP
99	CHATEAL EQ 0.15-30 MG-MCG ORAL TABLET	11	OCP
100	CLIMARA PRO 0.045-0.015 MG/DAY TRANS PTWK	1	NOT BIRTH CONTROL
101	CLIMARA PRO 0.045-0.015 MG/DAY TRANSDERMAL PATCH WEEKLY	46	NOT BIRTH CONTROL
102	CLIMARA PRO 0.045MG/DAY PATCHES 4'S	9	NOT BIRTH CONTROL

73

Data Quality: "Negative" Test Results SARS-CoV-2

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begative
covid not detected-done
mmc er
covid19 undetected
gative
n e g a t i v e
nagative
not-detected
nrgative
nw=egative
Undetectable
undetected

nasopharynx negative
nbegative
neagtive
neative
neg
neg
neg (rapid test)
negaitve
negaive
negatie
negatikve
negativ
negativce
negative
negative
negative - lurie
negative - uk
negative (abbott id)
negative (testing)
negative at u of c
negative covid-19
negative igg

negative rapid test
negative report
negative rna
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non detected
none detected
nonreactive
non-reactive
nor detected
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not detected
not detected (grinnell ip)
not detected (mt er)
not detected rapid
not detected(mmc er)
not detected(immc ip)
not detected-(in hospital)
not detected.
not detected. (immc er)
not detectednot detected
not detectedq
not detwcted
not dtected

74

Governance: Data Quality

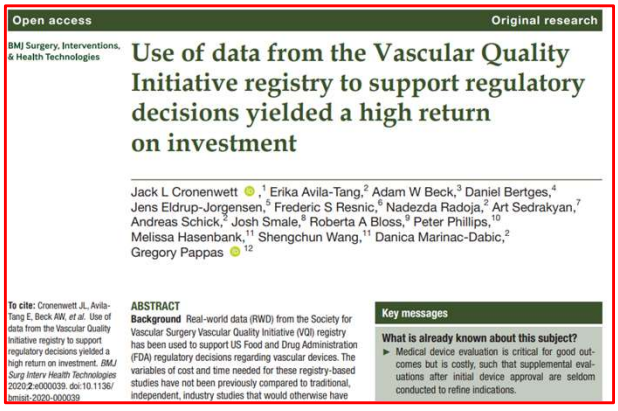
Non-mappable test results

Data entry error or PCR result?:	Location:	Lab code:	Sample Site:
5	covid detected(in hospital)	Ldtind	Nasal
5.9	covid positive at rush	Ldtnot	nasal mid-turbinate
10.4	detected- in hospital	meth1	naso
79	detected(er immc)	meth1	naso swab in saline
90	detected(in hospital)	meth3	nasopharyngeal
91	detected-er visit	meth3	nasopharyngeal
107	in-house testing	pcrinh	nasopharyngeal (np)
148			nasopharyngeal swab
265			oropharyngeal
294			
9/13/1945			

Notes:
sample was leaking upon receipt. integrity of sample is questionable.
see diasorin sars-cov-2 ab, igg...
we are unable to reliably determine a result for the specimen due to...

75

ROI of Real World Data Repositories



Open access Original research

BMJ Surgery, Interventions, & Health Technologies

Use of data from the Vascular Quality Initiative registry to support regulatory decisions yielded a high return on investment

Jack L Cronenwett ,[1] Erika Avila-Tang,[2] Adam W Beck,[3] Daniel Bertges,[4] Jens Eldrup-Jorgensen,[5] Frederic S Resnic,[6] Nadezda Radoja,[2] Art Sedrakyan,[7] Andreas Schick,[2] Josh Smale,[8] Roberta A Bloss,[9] Peter Phillips,[10] Melissa Hasenbank,[11] Shengchun Wang,[11] Danica Marinac-Dabic,[2] Gregory Pappas [12]

To cite: Cronenwett JL, Avila-Tang E, Beck AW, *et al*. Use of data from the Vascular Quality Initiative registry to support regulatory decisions yielded a high return on investment. *BMJ Surg Interv Health Technologies* 2020;2:e000039. doi:10.1136/bmjsit-2020-000039

ABSTRACT

Background Real-world data (RWD) from the Society for Vascular Surgery Vascular Quality Initiative (VQI) registry has been used to support US Food and Drug Administration (FDA) regulatory decisions regarding vascular devices. The variables of cost and time needed for these registry-based studies have not been previously compared to traditional, independent, industry studies that would otherwise have

Key messages

What is already known about this subject?

- Medical device evaluation is critical for good outcomes but is costly, such that supplemental evaluations after initial device approval are seldom conducted to refine indications.

https://sit.bmj.com/content/2/1/e000039.share

- **Alignment of multiple use cases accelerates data reuse and improves data quality**
- **Multiple ROI studies demonstrate that clinical registries can serve multiple purposes: quality measurement, postmarket surveillance, clinical trials and observational research**
- **The value in these use cases can pay for the infrastructure itself**

76

Observational Health Data Sciences and Informatics (OHDSI.org)

Mission: To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care

>200 collaborators from 25 different countries

Experts in informatics, statistics, epidemiology, clinical sciences

Active participation from academia, government, industry, providers

Over a billion records on >400 million patients in 80 databases

Adapted from: Data Standardization in Cancer: Challenges and Oppportunities, Stanley Huff, Christian Reich, et al.
http://www.ohdsi.org/web/wiki/lib/exe/fetch.php?media=documentation:oncology:amia_2018_s77_panel.pptx

Alignment Across HL7 Accelerators and Workgroups

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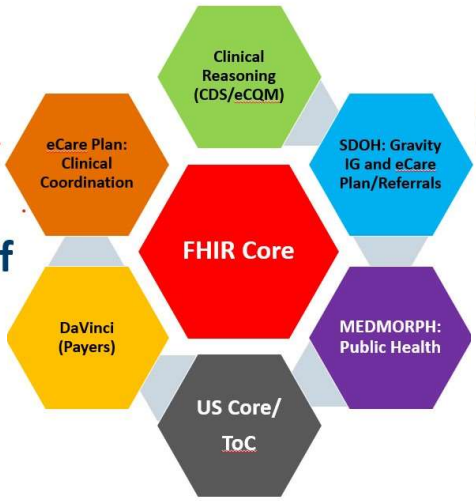
Putting It All Together: Integrating Components of Future HIT



gravity PROJECT

DA VINCI HL7 FHIR

HELIOS

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Opportunities for 2024

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- Alignment Across HL7 Accelerators and Workgroups
- Vulcan Terminology Server
- APACVulcan
- Implementation Pilots
- Sample Data project
- BYOI

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Vulcan – Progress

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VULCAN HL7 FHIR

Foundation
- 4 Implementation Guides Published
- 10 Connectathons >25 tracks
- Events
- Governance, Membership, Financial models

Go Global
- Expand outreach into Europe, Asia Pacific and other regions
- Regional activities (e.g. JAMI in Japan), membership & promotion
- Showcase global HL7 FHIR efforts in clinical research

Implement It
- Adoption Strategy: Proof of Concept / Pilot, Tooling
- Maintain Implementation Guides
- Implementation Workgroup / Interoperability Bridge

New Content
- Additional Use Cases such as UDP (ICH M11), ARPA-H, etc.
- Collaborate with other HL7 FHIR Accelerators

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Thank You …

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81

82

82

Q1 Panel: Clinical & Translational Research Landscape in Europe

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Panelists

1. Vulcan Background: *Amy Cramer, Vulcan co-Chair*
2. Data Standardization Strategy: *Nick Halsey (online), European Medicines Agency*
3. EU Data Protection Regulations and Implications for Vulcan: *Sabine Brosch (online), Data Protection Officer, European Medicines Agency*
4. The European Shortages Monitoring Platform (ESMP): *Sofia Zastavnik (online), ESMP Product Owner, Supply and Availability of Medicines and Devices, EMA*
5. XpanDH - Expanding Digital Health through a pan-European EHRxF-based Ecosystem: *Henrique Martins, Associate Professor, ISCTE*
6. Digital4Cancer– Landscaping data driven projects and initiatives in cancer – towards data interoperability: *Bianca Baluta (online), European Commission*
7. What's next in HL7 FHIR for Vulcan: *Julia Skapik, Chair HL7 International*

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Networking Break

10:30 – 11:00

84