



**EuroVulcan 2**  
18th January 2024  
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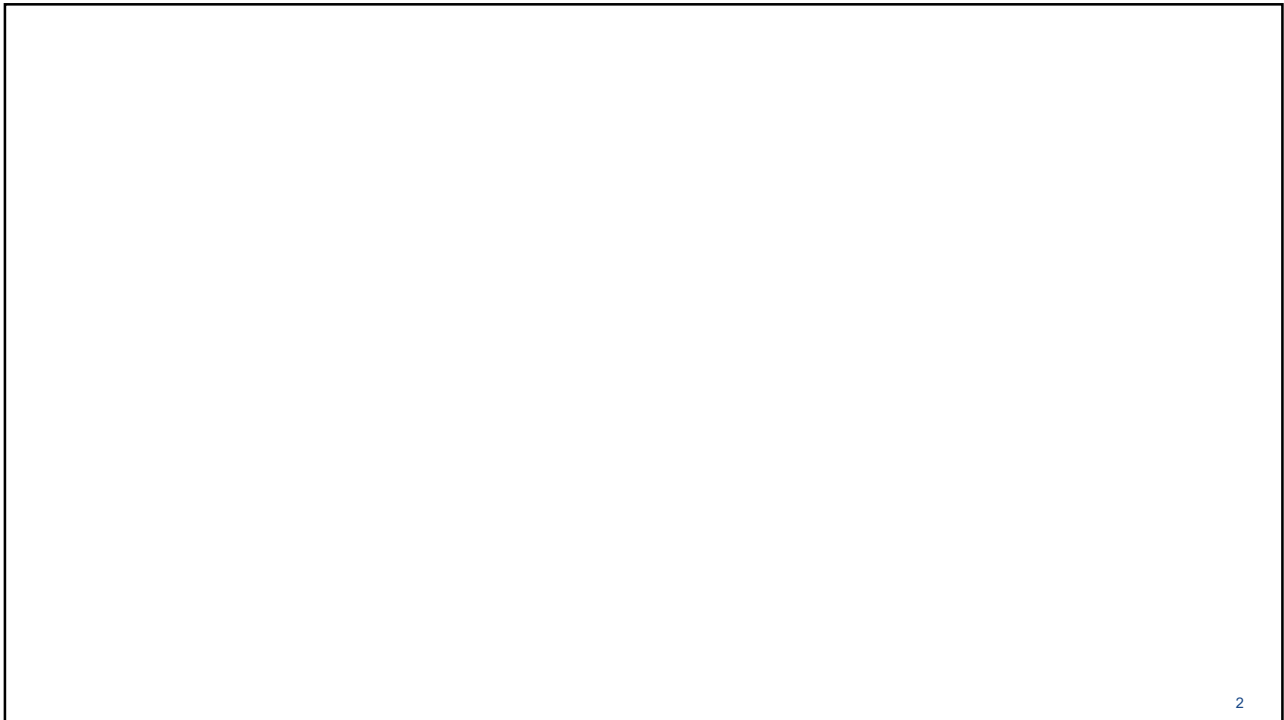
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# Q4 Panel: Regulators Moving to FHIR with support from the Vulcan Accelerator

Session Chair: Hugh Glover, Vulcan Technical Director

January 18, 2024



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## Q4 Panel: Regulators Moving to FHIR with support from the Vulcan Accelerator

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### Panelists

1. What's next in CDISC for Vulcan? Focus on Utilizing Digital Protocol: *Peter Van Reusel, Chief Standards Officer, CDISC*
2. What's next in US Policy for Vulcan: *Stephen Konya (online), ONC, United States*
3. What's next in personalized eLabeling for Vulcan?: *João Almeida presenting for Craig Anderson (online), coLead Vulcan ePI/eLabeling*
4. What's next in the HL7 FHIR Connectathon for GIDWG/UNICOM/ePI?: *João Almeida product owner Gravitare Health*
5. Can Clinical Care Data Replace Clinical Research Data?: *W. Ed Hammond, Ph.D., Director, Duke Center for Health Informatics, Clinical and Translational Science Institute*
6. Implications for Joint Action Xt-EHR for Primary & Secondary use of health data in the EHDS: *Christos N. Schizas, Coordinator of Xt-EHR and President of the National eHealth Authority – Cyprus*

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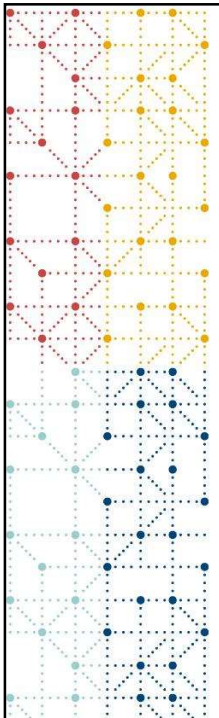
## Q4.1 What's next in CDISC for Vulcan? Focus on Utilizing Digital Protocol

Peter Van Reusel, Chief Standards Officer, CDISC

January 18, 2024



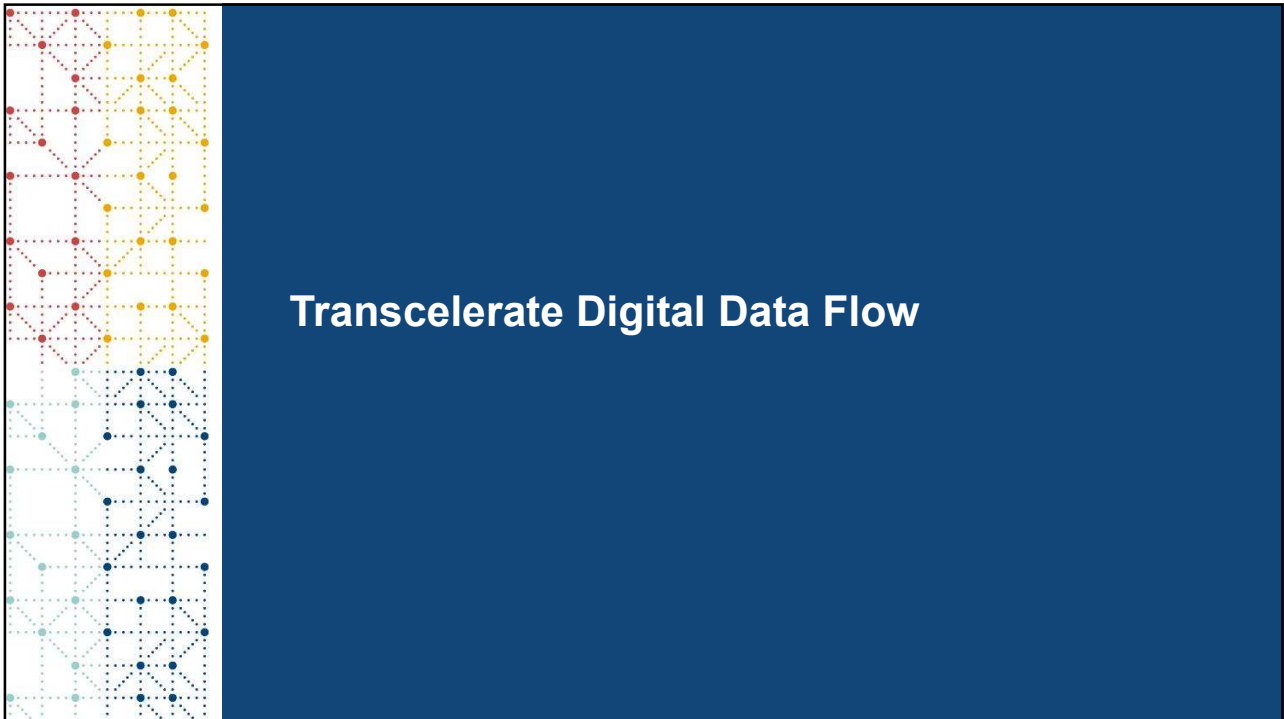
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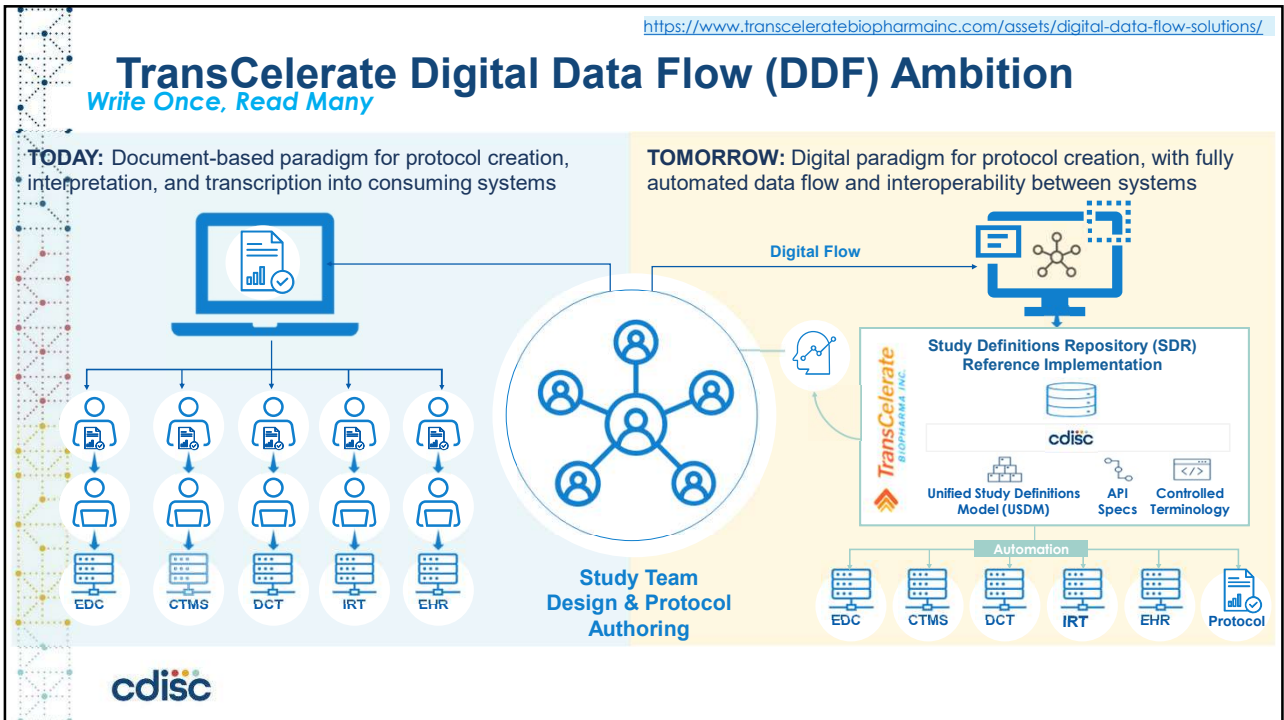
### Agenda

- Transcelerate Digital Data Flow
- CDISC and ICH M11
  - Content model
  - Controlled terminology
  - Define Trial Design mappings
  - Conformance rules for M11 model
  - Partner with Vulcan FHIR: exchange standard for ICH M11

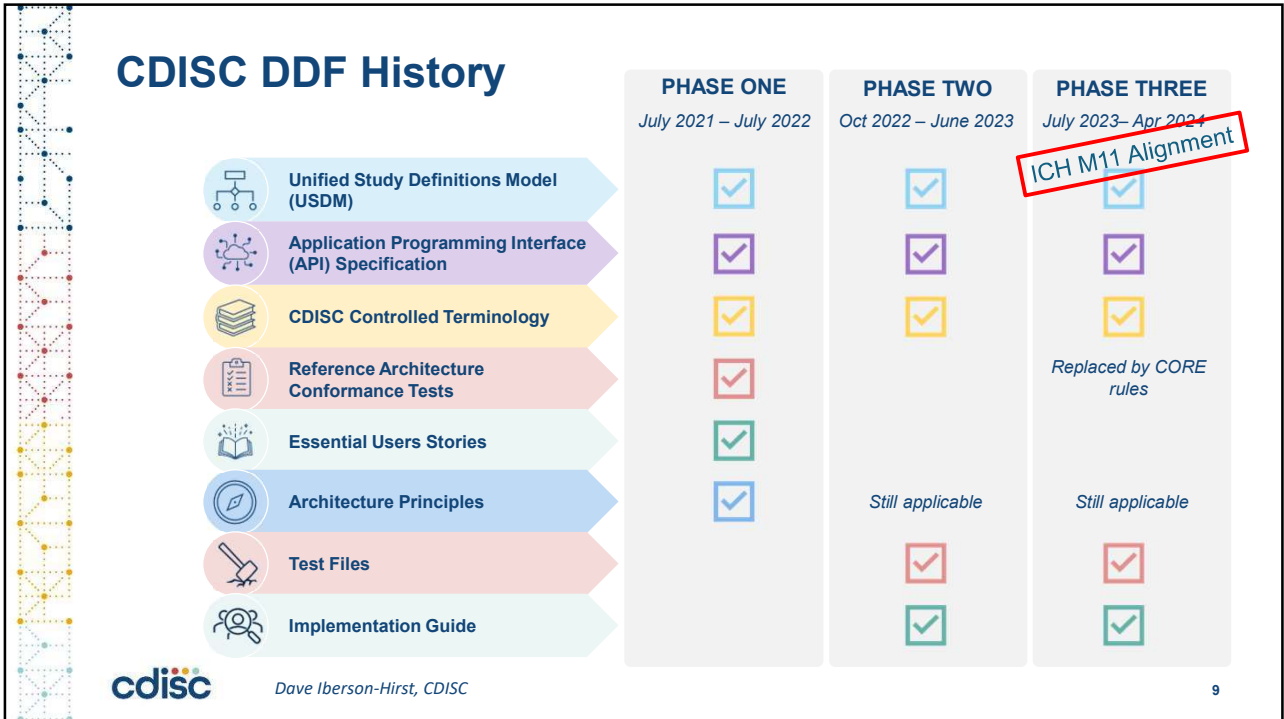
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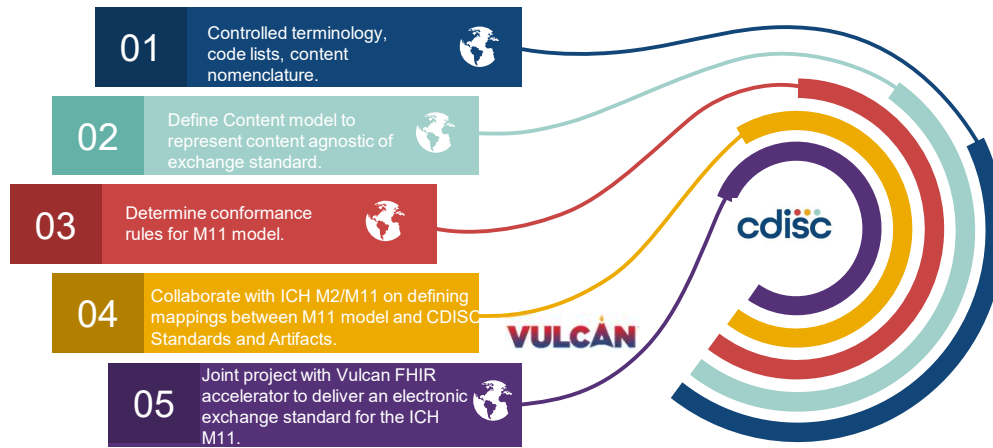
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## CDISC ICH M2/M11 Engagement

Controlled terminology, Semantics  
 Trial Design Datasets  
 Executable Conformance Rules with CORE  
 CDISC and FHIR UDP Collaboration

## CDISC M2/M11 Engagement



Panagiotis Telonis, CDISC EU Interchange 2023

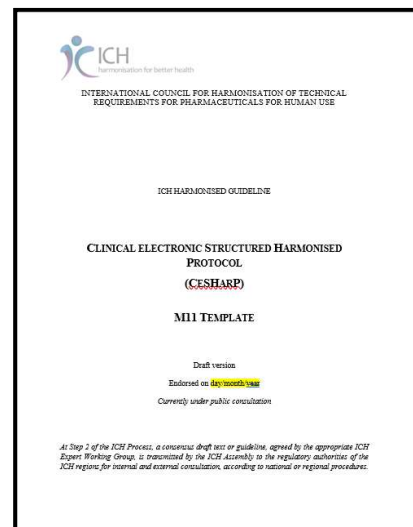


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## ICH M11 Terminology

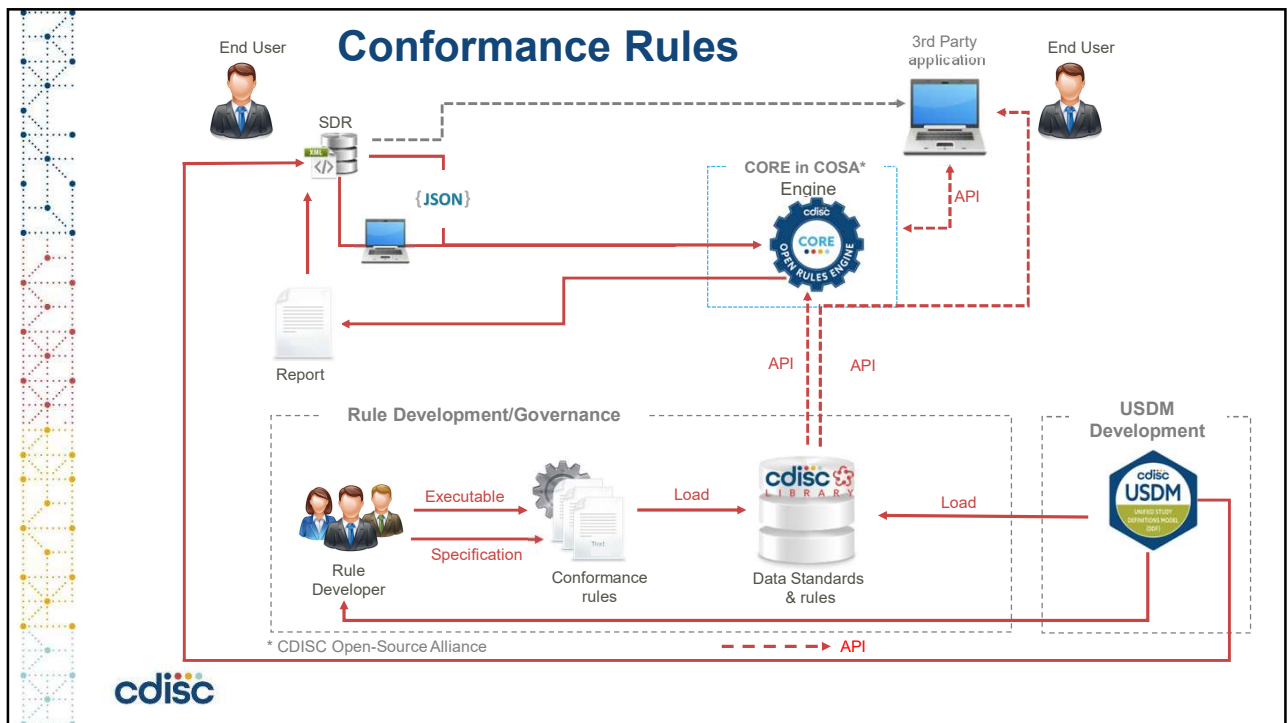
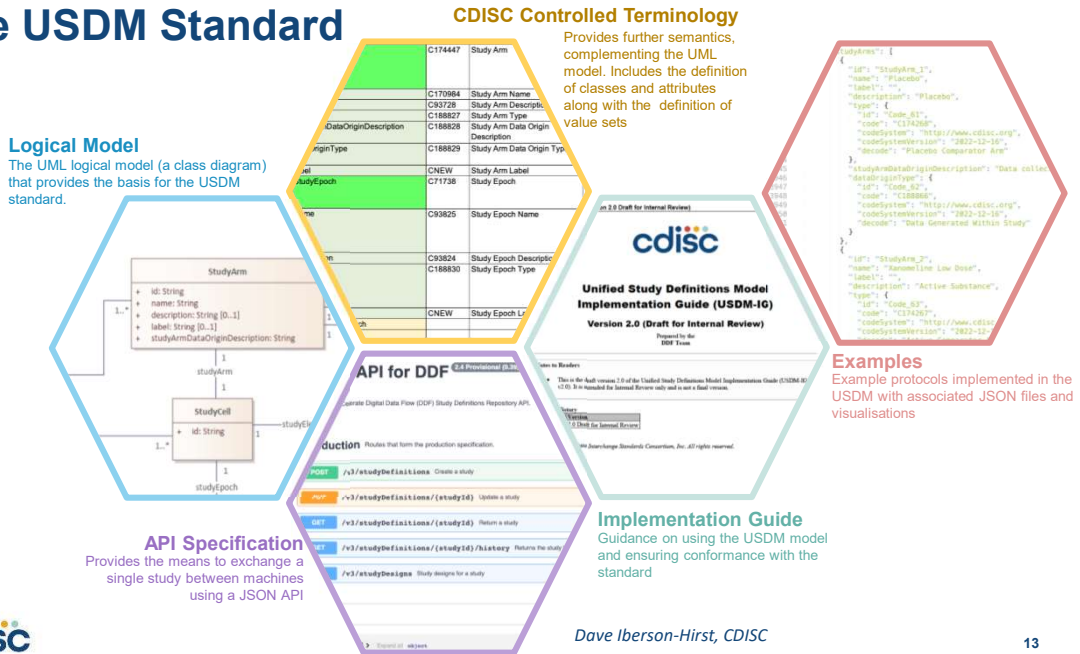
- CDISC is working with the ICH M11 working group to create draft semantics for the *ICH M11 Protocol Template*
  - 257 Data Elements
  - 22 Valid Value Sets comprising 112 terms
- Aligns with/harmonizes to CDISC terminology where appropriate
  - SDTM, DDF, Protocol, Glossary
- Will be undergoing CDISC public review and regulatory review in the next couple of months.



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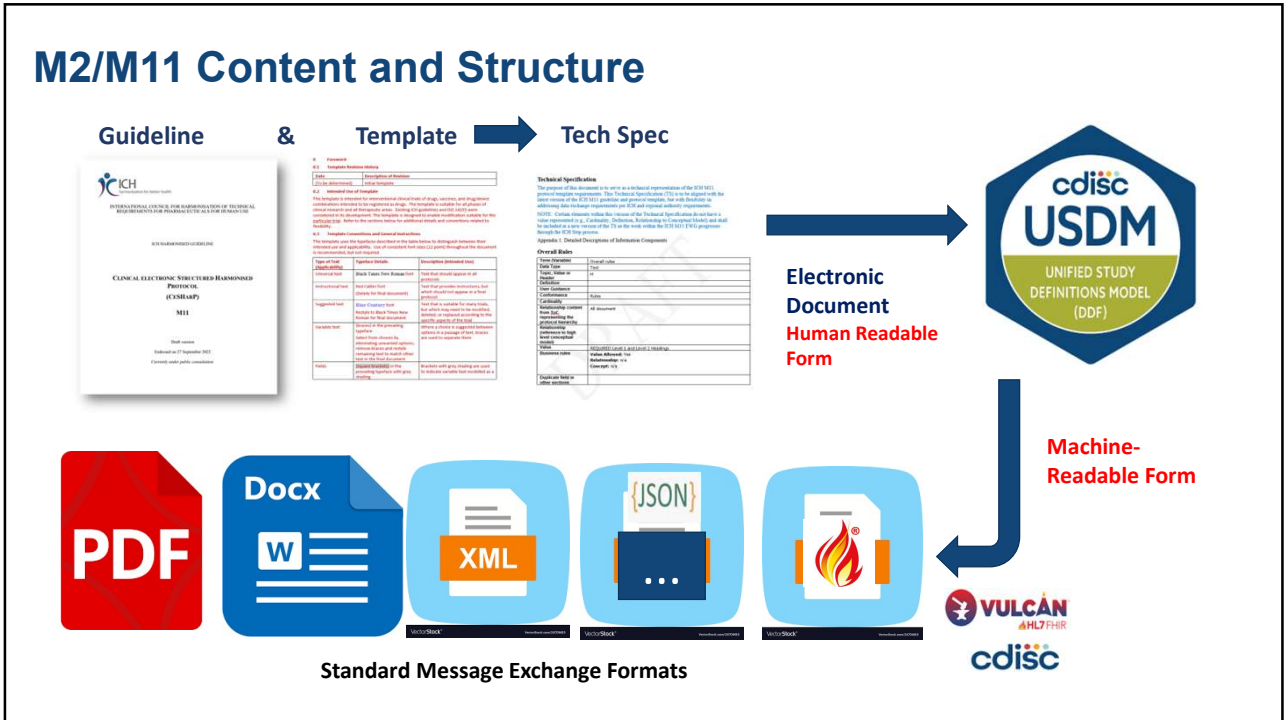
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# The USDM Standard










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## Use Cases: Digital Protocol and USDM will enable...

 Data Capture	Automate the setup of data capture systems, incl. RWE, and capture the data.	CTMS, TMF ...	The provision of protocol information to downstream systems needing "study" information.
SoA	Use the study design to build the FHIR SoA message.	Query	Having multiple studies that have a common structure allows for data export and query across the set of studies.
Data Import	Import data from a variety of sources. Can be re-exported thus allowing for conversion across versions.	 SDTM	Automate the generation of SDTM datasets using the study design and BCs, including the "T" Domains.
 Common Protocol Template (CPT)	Generation of the CPT from a study design. 		
Data Decay	Re-import data using the USDM as a framework to rebuild a study design & data using the SDTM Trial Design Domains.		
Scoring	The "scoring" of a study for such purposes as site impact, subject impact, environmental impact etc.		
Feasibility	The use of the design to determine study feasibility including subject recruitment. A study data template.		
 CT Registry	The provision of study information to a CT registry.		
FAIR Data	The use of the design to aid Findability, Accessibility, Interoperability, and Reusability.		



 In scope for DDF Phase 3

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# Thank You ...



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# Q4.3 What's next in personalized eLabeling for Vulcan?

João Almeida presenting for  
Craig Anderson, coLead Vulcan ePI/eLabeling

January 18, 2024



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## Implementation Guide defines how to create three Types of FHIR ePI

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### Type 1: eLabel only

- SmPC, Package Leaflet, Label
- Semi-structured narrative text (section/sub-section headings, paragraphs, tables, lists, images), document info (language, date), Organization details (Company address and contact information)

### Type 2: eLabel + product details

- Type 1 + structured product details (full name, class, dose form, strength, packaging, ingredient manufactured form and administrable form)

### Type 3: eLabel + product details + clinical details

- Type 1 + Type 2 + structured clinical details (Encoded indication, contraindication, interaction, warnings and precautions)

Simple Search

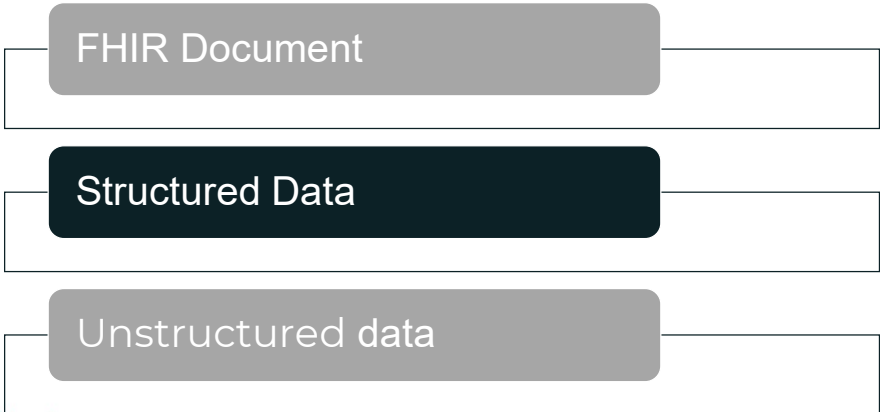
Intermediate Search

Advanced Search

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### So we have a ePI, what now?



Easy to deal with!



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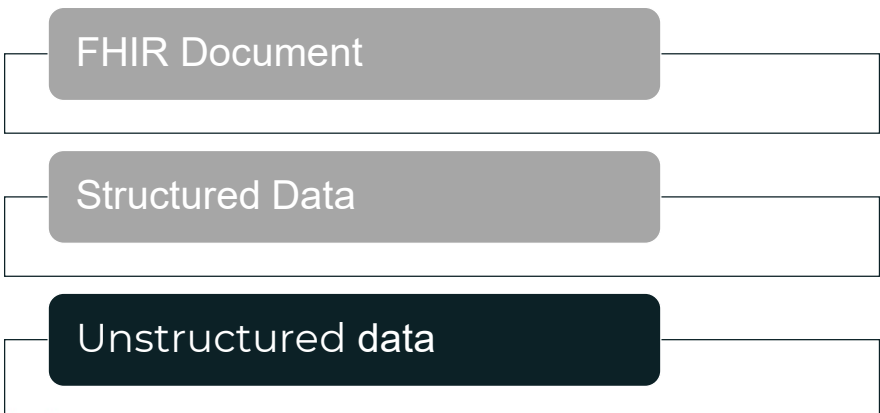
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### So we have a ePI, what now?



Not so easy ☹️



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**Electronic Product Information (ePI)**

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**Unstructured Data (free-text)**

Human-readable	Heterogeneous information
Semi - Heterogeneous structure	No semantic layer

And so...

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**Processed ePI - P(ePI)**

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**unstructured data**

**Pre-processing**

Semantic layer

“Adding” information

Drugs	observations	conditions	procedures	quantities	diseases	symptoms	More subsections	tagging specific information
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## Processed ePI - P(ePI)

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### Do not take

If you are allergic to irbesartan or any ingredients of this medicine

### Warning and precautions

Talk to your doctor if any of the following apply to you:

- If you get excessive vomiting or diarrhoea
- If you suffer from kidney problems
- If you suffer from heart problems
- If you are going to have an operation or be given anaesthetics

### Children and adolescents

This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

### This product contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicinal product.

### This product contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.



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## Processed ePI - P(ePI)

### Do not take

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product

symptom

disease

Product Class

quantity

procedure

subsection

ATC  
SNOMED  
PubChem  
LOINC  
RxNorm  
New IDs  
(sections)  
...



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## Focusing Operations

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**Highlight:** select certain sections to be highlighted

**Hiding/Collapsing:** select certain sections to be hidden/collapsed

**Add hypertext:** annotate information to link with other information (e.g., glossary; based on health literacy – connect with external service (FOSPS component or external services))

**Multimedia:** annotate to add icons, pictograms, images ... additional risk minimization materials – external service

**Questionnaire:** test your knowledge, validation purposes

**Explaining focusing**

**Summarize**



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# Q4.4 What's next in the HL7 FHIR Connectathon for GIDWG/UNICOM/ePI ?

João Almeida, HL7 Europe, Gravitare-Health

January 18, 2024



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## Tracks Scenarios

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#1 Cross Border  
ePI (Japan and  
others)

#2  
Pharmacovigilance

#3 Shortage of a  
medicinal product


#4 Substitution in  
cross border  
ePrescription:

#5 Test the PhPID  
operation model

#6 Placing the  
pharmacy in the  
loop


#7 ePIs Pilot and in  
alignment the  
Nordic Compedia

USE IDMP identifiers (PhPID, MPID, PCID) to provide better care to patients, provide better and more information to institutions and healthcare practitioners and support regulatory activities



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**IDMP**

Pharmaceutical Product Identifier (PhPID level 1) - substance

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Pharmaceutical Product Identifier (PhPID level 2) – substance + dose form

Pharmaceutical Product Identifier (PhPID level 4) – substance + Strength + dose Form

Pharmaceutical Product Identifier (PhPID level 3) – substance + Strength

Medicinal Product ID

Packaged Product ID

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**IDMP**

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Increase in specificity. Increase in “concreteness”! Tree / graph shaped structures

Substance: Paracetamol

PhPID 4 (Sub+Dose+strength): Paracetamol 500 mg Tablets, Paracetamol 1000 mg Tablets

Medicinal Product: Ben-U-Ron 500 mg tabs, Panadol 500 mg tabs, Ben-U-Ron 1000 mg tabs, Panadol 1000 mg tabs

Packaged Product: ... 16 tabs, ... 100 tabs, ... 16tabs, ... 30 tabs, ... 32 tabs, ... 16 tabs, ... 50 tabs, 100 tabs

What this enables???

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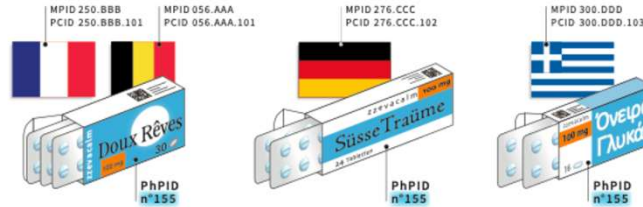
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## Relationship between drugs at global scale

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PhPID to aggregate info at national level



- #1,3,6 – I can use the PhPID to check significant drugs to prescribe and dispense in cross-border scenario
- #2 – I can use the PhPID to aggregate info from suspected ADR with MPID to PhPID level
- #3,4 – Use the PhPID to find reasonable substitutions for a certain drug
- #1,4,6 – Use these identifiers to include them in broader ecosystems (like CDSS, ePI, HIS, etc)



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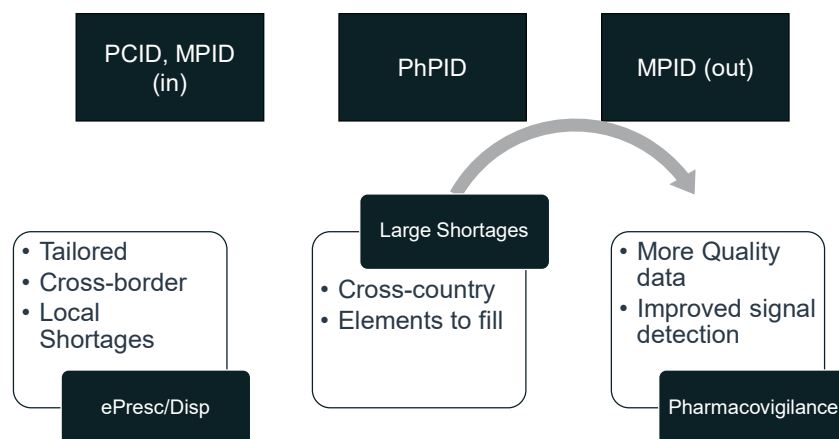
UNICOM – D1.5: ISO IDMP Handbook

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## Takeaways

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GTIN

PCID, MPID  
(in)

PhPID

MPID (out)


ePI

### Scenario #6


Placing the pharmacy in the loop: a pharmacy system needs to look up a cross-border medication, either for prescribing or for dispensing - how would that integrate into the workflow provided by the pharmacy system? Explore the use of GTINs in the context of dispensation and plan for future FHIR connectathons. Explore connections to the PhPID Operating model in relation to the Query/Retrieval PhPIDs from different countries.

I have this information: GTIN ▼ 7898919602230



Submit




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### Scenario #6

Placing the pharmacy in the loop: a pharmacy system needs to look up a cross-border medication, either for prescribing or for dispensing - how would that integrate into the workflow provided by the pharmacy system? Explore the use of GTINs in the context of dispensation and plan for future FHIR connectathons. Explore connections to the PhPID Operating model in relation to the Query/Retrieval PhPIDs from different countries.


I have this information: GTIN ▼

Submit


Show 10 entries Search:

Nr <sup>o</sup> *	Name	Identifier	ePI
1	<a href="#">Folitrax [Ica Laboratories] (India)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B93DFBAD671">http://www.who-umc.org/whodrug/productid#1B93DFBAD671</a>	<a href="#">View ePI</a>
2	<a href="#">Folitrax [Ica Laboratories] (India)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B93D53A1A91">http://www.who-umc.org/whodrug/productid#1B93D53A1A91</a>	<a href="#">View ePI</a>
3	<a href="#">Methotrexat teva onco [Teva Pharma AG] (Switzerland)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B887DB2FEC4">http://www.who-umc.org/whodrug/productid#1B887DB2FEC4</a>	<a href="#">View ePI</a>
4	<a href="#">Methotrexate [Hospira] (Bangladesh)</a>	<a href="http://www.who-umc.org/whodrug/productid#1B7E891D1941">http://www.who-umc.org/whodrug/productid#1B7E891D1941</a>	<a href="#">View ePI</a>
5	<a href="#">Methotrexate [Pfizer] (Canada)</a>	<a href="https://health-products.canada.ca/dpd-bdpp#02182971">https://health-products.canada.ca/dpd-bdpp#02182971</a> <a href="http://www.who-umc.org/whodrug/productid#1B7E88754E84">http://www.who-umc.org/whodrug/productid#1B7E88754E84</a>	<a href="#">View ePI</a>



Showing 1 to 5 of 5 entries Previous 1 Next



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NProgram

FHIR resource URL: <http://fhir.hl7.pt:8585/fhir/Composition?subject=mp16598f252d07b4784b82ba43c9e84> [Display Data](#)

**Composition**  
 Type: 100000155538 - Text: Package Leaflet  
 Category: Raw  
 Identifier: c90e140de2446df3b2a261762cf996c  
 Language: en  
 Date: 2022-02-16 Time: 13:28:17Z  
 Status: final  
 Title: TEST PURPOSES ONLY - Dovato 50 mg/300 mg film-coated tablets

**Author**  
**Organization**  
 Identifier: ORG-100012958  
 Name: Viiv Healthcare BV  
 Type: Marketing authorisation holder  
 Contact  
 Address: Van Asch van Wijckstraat 55H, Amersfoort, NL (Use: work) (Type: physical)  
 Text: Van Asch van Wijckstraat 55H Amersfoort NL

**Section**  
 Title: B. Package Leaflet  
 Code: 100000155538 - Text: B. PACKAGE LEAFLET  
 Text  
 Status: additional  
 Package leaflet: Information for the patient Dovato 50 mg/300 mg film-coated tablets dolutegravir/lamivudine Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**Section**  
 Title: Package leaflet: Information for the user  
 Code: 100000155538 - Text: Package leaflet: Information for the user  
 Text  
 Status: additional

**Dovato 50 mg/300 mg film-coated tablets**  
 dolutegravir/lamivudine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
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# Takeaways

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```

    graph LR
      MPD[MedicinalProductDefinition  
1  
Ingredient] -- POST --> MO((Maintenance.org))
      MO -- GET-status --> MPD
      MO -- Publish --> APD[AdministrableProductDefinition  
5  
PhPID]
      APD -- GET --> MPD
  
```

Merge IG and system  
FHIR supporting  
validation

Different tests  
throughout the week  
real data breaks stuff

notes for  
improvements and  
discussions  
bugs, discussion, new  
elements and  
architecture

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**What's next**

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**Thank You ...**

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## Q4.5 Can Clinical Care Data Replace Clinical Research Data?

W. Ed Hammond, Ph.D., Director, Duke Center for Health Informatics, Clinical and Translational Science Institute

January 18, 2024



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### What is Real World Data?

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- **Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources from a heterogeneous patient population.**
- **The most common sources of real-world data are:**
  - Electronic Health Records
  - Claims Data
  - Synthetic Data
- **Each of these sources has major problems associated with them.**
- **Real World Evidence derived from Real-World Data is very important.**

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## Challenges in using RWD for Research

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- **EHR Concerns**
  - Lack of Quality including missing data, inconsistency in what data is recorded, missing data, no common standard in data coding and representation, data entry errors, wrong patient, inconsistent units that get confused, little aggregation across institutes or even in different units of the same institute, and multiple records for the same patient.
  - New types of data are slow to be included in the EHR (SDoH).
- **Claims Data**
  - Organized to maximize reimbursement, only contains data required to get reimbursement, order of data reported influenced by reimbursement, not in clinical importance, often interpreted by encoders to maximize reimbursement.
  - On the positive side, it is the best source for tracking encounters.
- **Synthetic Data**
  - Relationships among multiple diseases are often not reflected.
  - Patients are more complicated than synthetic data can represent.
  - Can be useful for testing programs.



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## Research Data – Randomized Clinical Trials

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- **Research data is a defined set of data for a specific purpose. It is collected by a trained staff whose focus is on the data that is being collected. Usually, it is curated by trained staff, so missing data is negligible. Errors are much less, although they can exist.**
- **If research includes multiple sites, the same problems of missing data, errors, and patient duplication in the same institution and across institutions.**
- **The lack of a common set of data elements requires mapping among multiple terminologies with a loss of information.**



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## Challenges to Bridging Clinical Data and Research Data

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- Patient care providers are interested in recording the data that they think are important for the care of the patient for which they are responsible. Any additional data recording is labor-intensive work that is not part of their focus.
- Researchers are similarly focused on the data in which they are interested, and they want to use their representations and timing.
- New data types such as genetic data, social determinants of health, wearable sensor data, and patient-reported data are intrusions to both clinical care providers and researchers.



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## Three examples of RWD research

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- **Patient Centric Outcome Research Network (PCORNet)**
  - A network of networks consisting of 8 Clinical Research Networks, each comprising two or more healthcare centers. More than 40 health systems participate in Cornet through the CRNs.
  - The CRNs transform their data gathered from routine patient care into a consistent format, the Cornet Common Data Model (CDM) to enable rapid response to research-related questions.
- **NIH Pragmatic Trials Collaboratory**
  - Currently consists of 27 embedded pragmatic clinical trials, many of which collect patient-reported outcomes as primary or secondary outcomes.
  - Challenges include competing healthcare system priorities, clinician buy-in, low adoption and lack of suitable technology in low resource settings, and lack of consensus and standards.
- **National Covid Cohort Collaborative (N3C)**
  - N3C provides one of the largest collections of secure and deidentified clinical data in the US for COVID-19 research. More than 70 institutes submit data to develop a centralized national data resource. Data is submitted using one of OMOP, i2b2 (ACT), PCORNet, or TriNetX CDM. Data is converted to OMOP for the Data Enclave and is available for research.



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## What the Future Might Bring

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- Increased automation of data collection and documentation.
- Creation of a global master set of data elements with embedded computable knowledge.
- Creation of complex phenotypes and expanded definition of multiple data elements to be collected.
- Real-time quality checks on data entry.
- Focus on the patient as the center point of an encounter, and clinicians have the responsibility for collecting all data required.
- AI will solve the problem.



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# Thank You ...



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# Implications for Joint Action *Xt-EHR* for Primary & Secondary use of health data in the EHDS



**Christos N. Schizas, Coordinator of Xt-EHR  
President of the National eHealth Authority – Cyprus**

January 18, 2024



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## European Health Data Space (EHDS)

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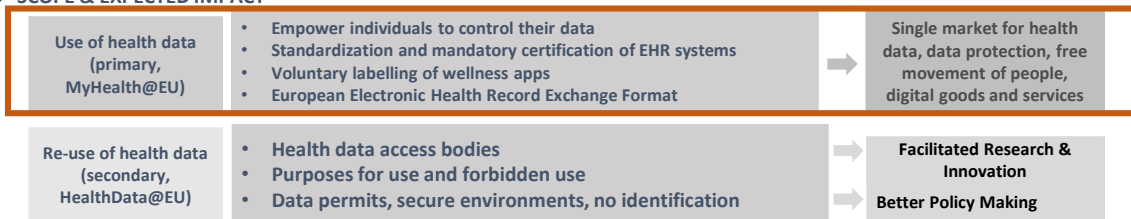
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### OBJECTIVES

Effective use of health data

### SCOPE & EXPECTED IMPACT

NeHA is Coordinating



### MEANS



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## Extended EHR@EU Data Space for Primary Use (Xt-EHR)

**Estimated Project Cost: 5,896,868 euros**  
**Funded by EU (HaDEA): 4,717,494 euros**




Co-funded by the  
European Union



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## European Health Data Space for Secondary Use @CY (CY-EHDS-2ND)

This project will be carried out by the main beneficiary, who is the appointed Competent Authority (**NeHA**), its Affiliated Entity (**UCY**) and chosen experts and subcontracting partners

**Estimated Project Cost: 1,497,465 euros**  
**Funded by EU (HaDEA): 1,197,972 euros**



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# Purpose of Xt-EHR

## 03

Definition of integration profiles of EHRs

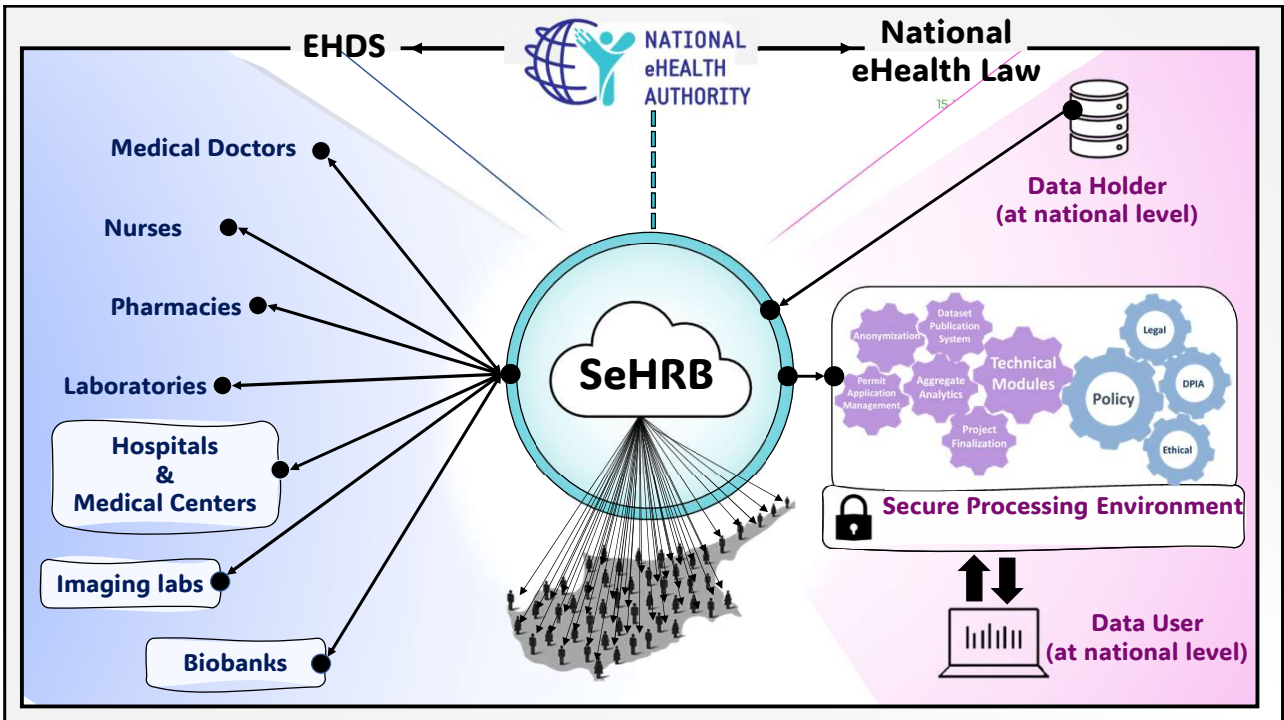
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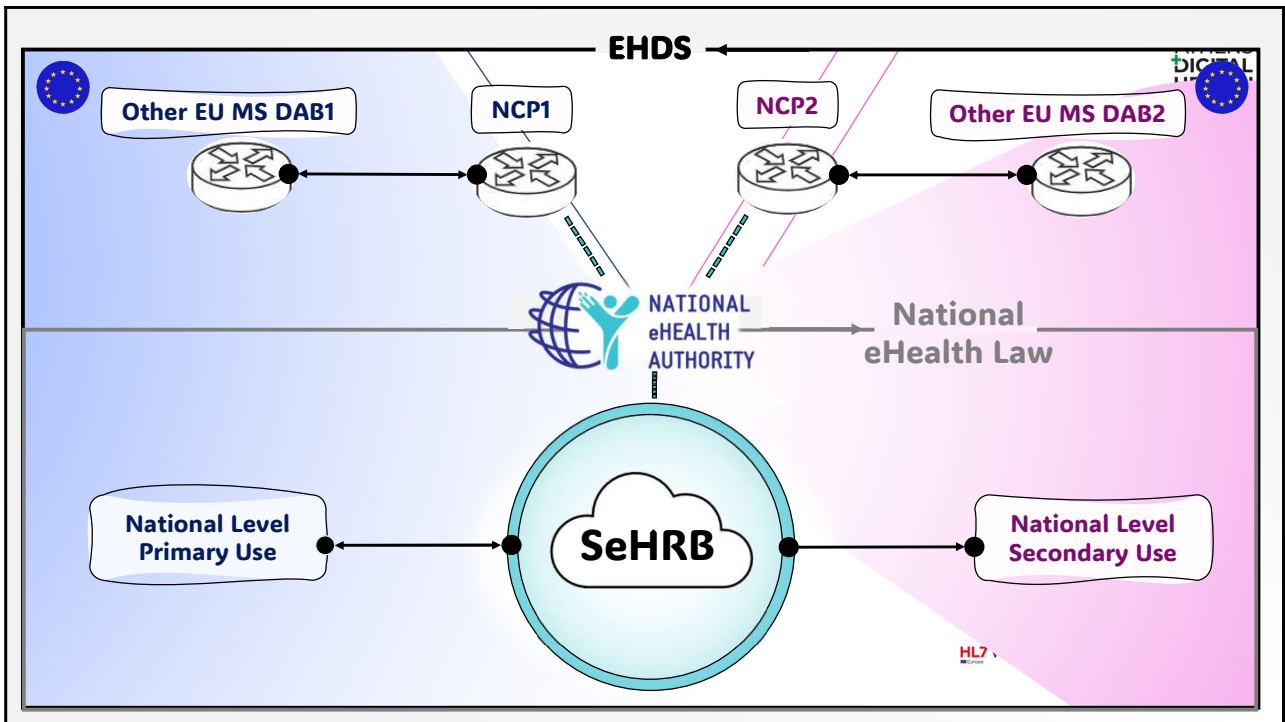
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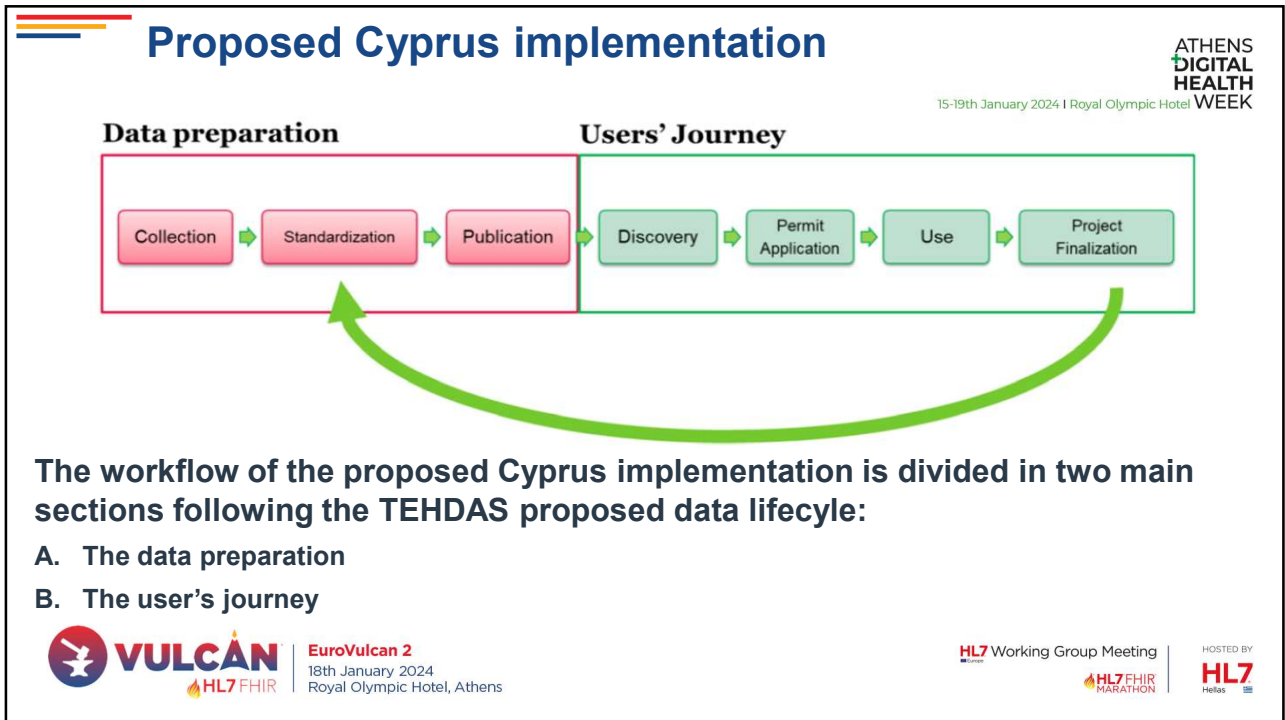
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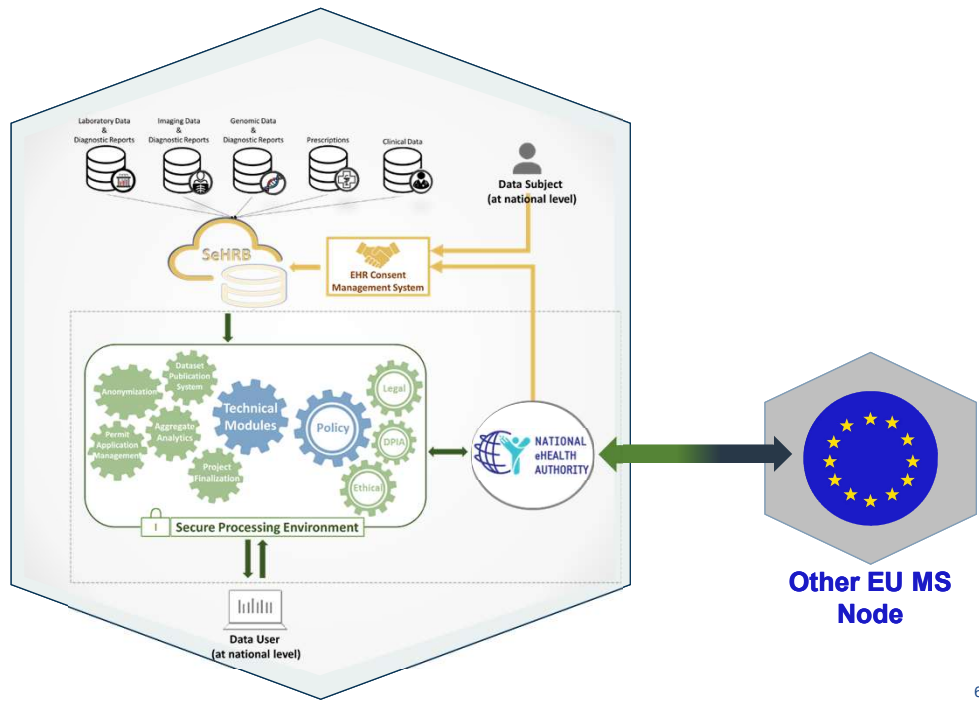
Proposed Cyprus implementation		
Data Lifecycle Section	Phase	Implementation Outline
Data Preparation	Collection	<ul style="list-style-type: none"> <li>Data will be collected from data banks of the healthcare providers in Cyprus (i.e. doctors, hospitals, diagnostic centers, laboratories, pharmacies, biobanks, research institutions).</li> <li>The data will be stored in the Single EHR Data Bank managed and maintained by the NeHA (HDAB).</li> </ul>
Data Preparation	Standardization	<ul style="list-style-type: none"> <li>The collected data will be stored and exchanged in a standardized form using the HL7 FHIR interoperability standard.</li> <li>The terminology describing each data element will be defined by the NeHA and shall be aligned with the EU healthcare cross-border services requirements (i.e. eHDSI MVC).</li> <li>The data will also address the syntactic requirements of the International Patient Summary as specified by the ISO 27269:2021 - International patient summary.</li> </ul>
Data Preparation	Publication	<ul style="list-style-type: none"> <li>NeHA will set up a publication system which will publish all collected data for secondary use in the form of national dataset catalogues.</li> <li>The dataset catalogues will be searchable and accessible to potential data consumers (users) using particular metadata descriptors.</li> </ul>

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Proposed Cyprus implementation		
Data Lifecycle Section	Phase	Implementation Outline
Users' Journey	Discovery	<ul style="list-style-type: none"> <li>The user will be able to look for the data he or she needs to perform their work.</li> <li>The search will be executed on the published national dataset catalogues with the use of metadata descriptors in order to limit the resulting dataset catalogues to suit the needs of the work needed to be done.</li> </ul>
Users' Journey	Permit Application	<ul style="list-style-type: none"> <li>NeHa will establish a Permit Application Management System.</li> <li>The users will use this system to apply their request for permission to access certain data.</li> <li>The permit application request will be examined by the NeHA as the HDAB and either be approved or rejected.</li> <li>With the approval of the permit application the user can access the requested data.</li> </ul>
Users' Journey	Use	<ul style="list-style-type: none"> <li>The requested dataset is constructed by integrating the data included in the requested dataset catalogues (national and EU).</li> <li>NeHa (as the HDAB) provides the user with access to the integrated dataset via a secure processing environment.</li> <li>The user can either view or analyze the provided data to perform the work he or she desires.</li> </ul>
Users' Journey	Project Finalization	<ul style="list-style-type: none"> <li>When the work is done with the requested data, the user shall signal NeHA, as the HDAB, about the project finalization</li> <li>In this case, the project finalization process will be initiated asking the users for a proper disclosure of their findings following the FAIR principles for the results.</li> </ul>

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# EHDS for Secondary Use Proposed Solution for Cyprus



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**European Health Data Space for Secondary Use @ CY**

## Thank you!

Contact Details name  
Role  
National eHealth Authority

Contact email

<https://www.neha.gov.cy/>

**NATIONAL eHEALTH AUTHORITY**

**eHealth Lab**

**Πανεπιστήμιο Κύπρου**  
Ερευνητικό Κέντρο  
Βιοϊατρικής Μετασχημάτισης - ΕΚΒΜ

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## Q4 Panel: Regulators Moving to FHIR with support from the Vulcan Accelerator

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### Panelists

1. What's next in CDISC for Vulcan? Focus on Utilizing Digital Protocol: *Peter Van Reusel, Chief Standards Officer, CDISC*
2. What's next in US Policy for Vulcan: *Stephen Konya (online), ONC, United States*
3. What's next in personalized eLabeling for Vulcan?: *João Almeida presenting for Craig Anderson (online), coLead Vulcan ePI/eLabeling*
4. What's next in the HL7 FHIR Connectathon for GIDWG/UNICOM/ePI?: *João Almeida product owner Gravitare Health*
5. Can Clinical Care Data Replace Clinical Research Data?: *W. Ed Hammond, Ph.D., Director, Duke Center for Health Informatics, Clinical and Translational Science Institute*
6. Implications for Joint Action Xt-EHR for Primary & Secondary use of health data in the EHDS: *Christos N. Schizas, Coordinator of Xt-EHR and President of the National eHealth Authority – Cyprus*



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## Closing Remarks



**Michael van Campen**  
Vulcan Program Director



**Amy Cramer**  
Vulcan co-Chair



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## Before We Go... Coming in the Days Ahead



Survey



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**Stay in Touch!**  
How to Contact Vulcan

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 [hl7-vulcan](#)

 <http://www.HL7Vulcan.org>

 <https://confluence.hl7.org/display/VA/Vulcan+Accelerator+Home>

 [Vulcan@HL7.org](mailto:Vulcan@HL7.org)


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**Thanks & Safe Travels**

 **HL7 Hellas**

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