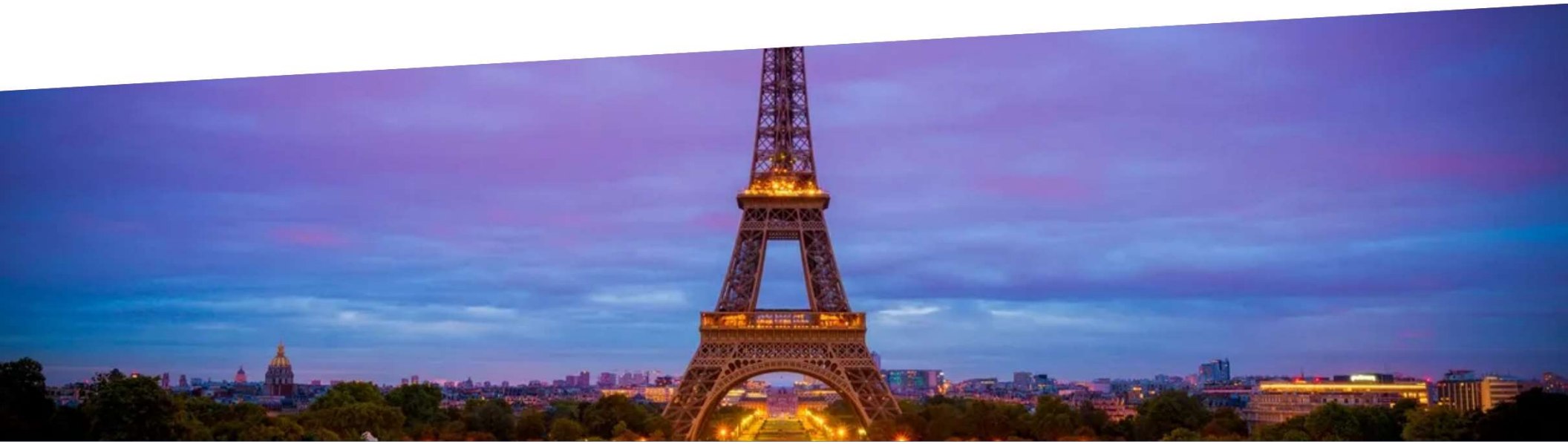

VULCAN
HL7 FHIR
EuroVulcan
Conference & Connectathon
Welcome!
Day 2 Programme

Welcome, Day 2

Amy Cramer, Vulcan co-Chair / J&J
9:30 – 9:40

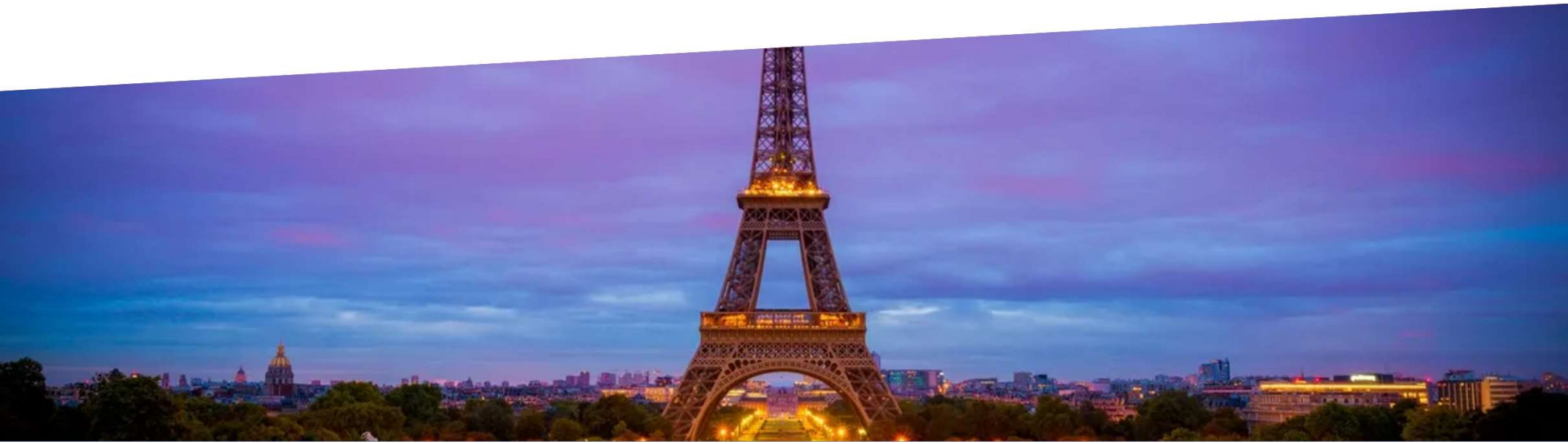


10. Day 1 Review & Day 2 Preview

Anne Moen, University of Oslo

Catherine Chronaki, HL7 Europe

16:20 – 16:30




EuroVulcan
Conference & Connectathon
VULCAN
HL7 FHIR
Join us in Paris March 14, 15 2023


Vulcan HL7 FHIR Grew Out of the Increasingly Digital Healthcare Environment
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.
EuroVULCAN

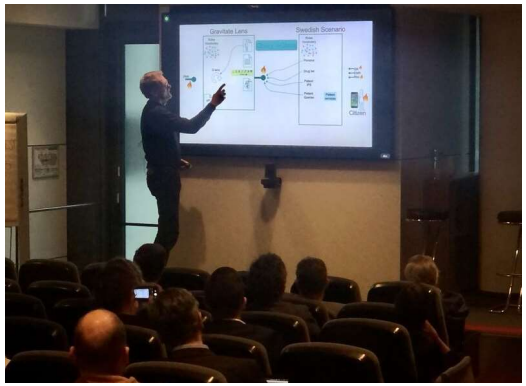
Day 1


Johnson & Johnson


Johnson & Johnson


Johnson & Johnson


Johnson & Johnson


Gravitate Lens
Swedish Scenario


Johnson

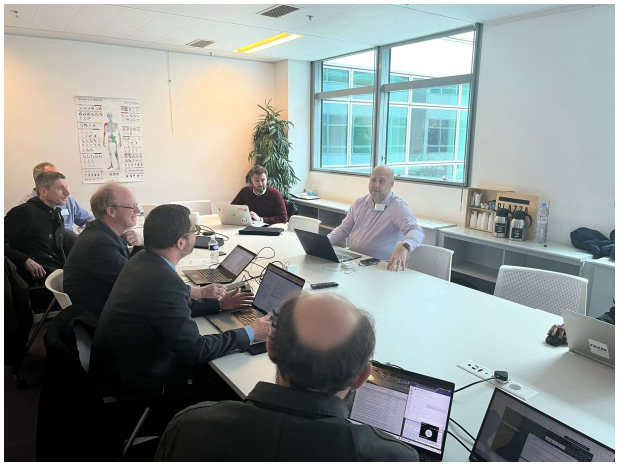
Lunch table discussions – thank you !

1. Enhancing clinical trial efficiency and success using hospital EHRs
   - Dipak Kalra and Nadir Ammor
2. How does privacy play into standards, and vice versa?
   - Pierre-Yves Lastic
3. How can different standards work together?
   - Peter van Reusel
4. Patient Access to Data use case for Vulcan
   - Amy Cramer
5. How can Vulcan support clinical research in Europe?
   - **Michael van Campen**
6. How do we accelerate the design of a digital clinical trial?
   - **Andy Richardson**

Networking reception

Connectathon

Connectathon Readout
Real World Data (RWD)
Schedule of Activities (SoA)
Electronic Product Information (ePI)



Day 2 – Vulcan in Europe – what to expect

- European Projects
  - Felleskatalogen on FHIR
  - FHIR4Research in University Hospitals
  - UK Clinical Research and FHIR Landscape
  - Creating Interoperability at the source - UNICOM
- Government
  - Accelerate with FHIR
- Pharma
  - What does FHIR offer for clinical trials

- Next steps – VULCAN in Europe

  “if you want to fast – go alone, if you want to go far – GO TOGETHER !

Gravitate Health

contact@gravitatehealth.eu

www.gravitatehealth.eu
@gravitatehealth

Get our newsletter

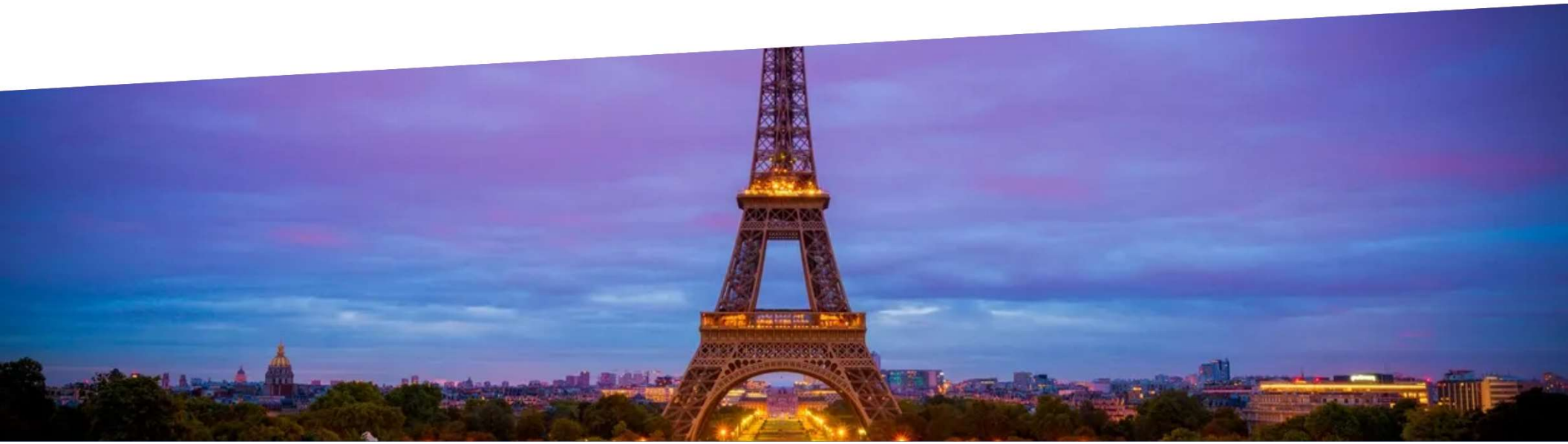
The Gravitate-Health project has received funding from the Innovative Medicines Initiative Joint Undertaking under grant agreement No 945334.

12. Connectathon Readout
Real World Data (RWD)

Shani Sampson, Vulcan / TransCelerate Biopharma

Jean Duteau, Vulcan

9:40 – 10:25 (1 of 4)



Track Objectives – What we were trying to achieve

With an Implementation Guide just balloted, the Real World Data track wants to continue to test its two major use cases - Cohort Creation and Finding Patient Data - while exploring NEW considerations to further enhance the IG.

Cohort Creation

Find patients that meet a set of cohort criteria via query of a server with representative medical patient data.

1. Search for patients with Acute Coronary Syndrome who:
   a) have been treated with oral anti platelets.
   b) are not deceased at the time of the discharge – explore how servers represent 'not deceased'
   c) have been given one of Ticagrelor, Prasugrel, or Clopidogrel after the diagnosis date – Explore feasibility with European code systems
2. Return one of the following:
   a) the patients who meet the criteria,
   b) a yes/no on whether patients who meet the criteria exist,
   c) the number of patients who meet the criteria,
   d) a list of ids of patients who meet the criteria.

Finding Patient Data

Using the results of the cohort, retrieve patient data to see if it meets the needs of the research goals.

3. Retrieve the following patient information from the identified cohort:
   a) demographics
   b) medications from date of diagnosis to 1 year after
   c) encounters from date of diagnosis to 1 year after
   d) conditions from date of diagnosis to 1 year after

EuroVULCAN

Achievements

Objective 1b:

Track attendees held discussion exploring the use case requirement to identify a cohort that was ‘discharged alive.’ How can we reliably determine patient status at time of discharge?

Objective 1c:

Discussion that revealed the difficulty of accounting for local coding systems which vary almost by country. How can we navigate this?

Objective 2:

Heavy discussion exploring the impact of data privacy on the implementation of the RWD IG. What should the EHR query return – individual data records, aggregate data, counts or binary yes/no in response to the query? How much data should be exposed to the researcher?

EuroVULCAN

Discovered Issues/ Questions

Unavailability of realistic sample data hinders the testing process.

Next steps

RWD IG:

Add to the Cohort Creation – method to ask an EHR to return us either a ‘yes/no’ or count, utilizing the ‘measure report’ resource.

Sample data:

Relay our use cases to small Vulcan team who is investigating this problem.

Aspirational:

Explore how we can assess “What is there?” Team agrees that understanding of what data elements are routinely available (or not) across EHR’s can help refine the IG. How can we conduct such a landscape analysis?

Participants

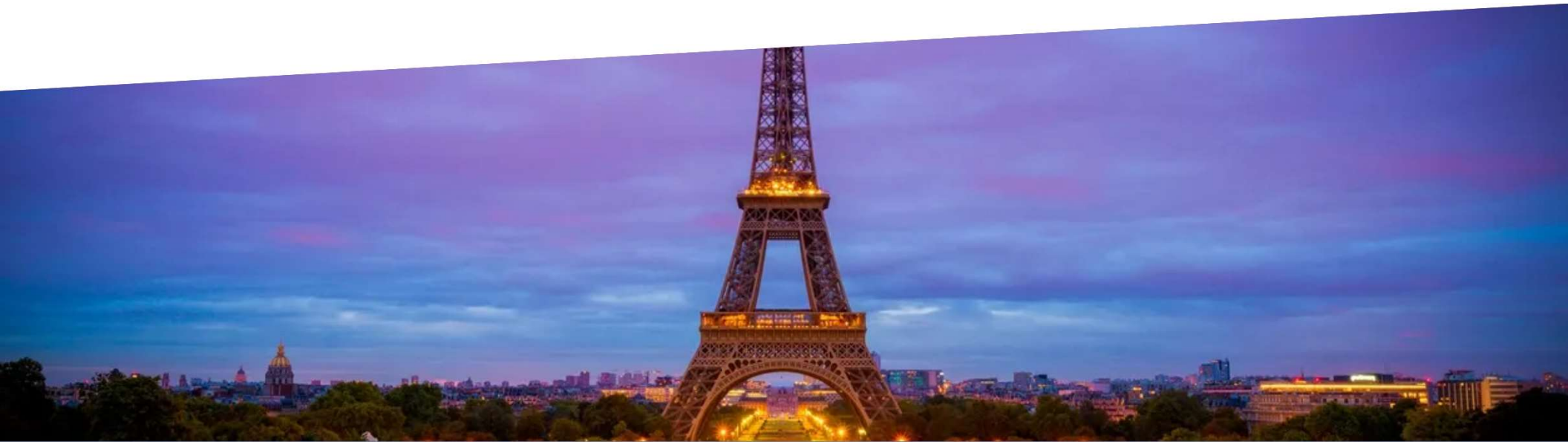
Name	Organization
Chris Brucker	Nammu
Peter Butterfill	Parexel
Guillaume Rongier	InterSystems
Sebastiaan van Sandijk	Odysseus Data Services
Cal Collins	OpenClinica
Ben McAlister	Oracle
Hassan Faour	Owkin

12. Connectathon Readout Eligibility Criteria

Gustav Vella, Carelane

Brian Alper, Computable Publishing

9:40 – 10:25 (2 of 4)



Joint Session (1h)

- Gave a **short Introduction**
- looked at **simple** and **complex examples** such as:
  - **combinations of criteria** (*all of*, *any of*, *at least n*, *exceptions*)
  - **quantitative observations**
  - **offset** by a **reference range**
  - **timing modifiers**

- Showed how to **Create own examples** with **publicly accessible tooling https://fevir.net/resources/Project/32444**

Why use FHIR for eligibility criteria?

Seperate the **criteria** from the **query implementation**

- **Define** criteria
- **Distribute** I/E definitions
- Let sites **transform** criteria expressed within the I/E definitions to generate queries based on implementations of their choice (FHIR Search, CQL, SQL,..)

EuroVULCAN

Joint Session (1h)

- **Questions**:
  - adaptability, reusability, compositionality of characteristics
  - how to use different code systems within the same expression reifying the same concept
  - authoring effort
  - using expression languages with different characteristic definitions (specifically SNOMEDs *Expression Constraint language*)
  - using NLP to align codes and valuesets with the textual expression

Touch Points with SoA

- **PlanDefinition**:
  - A container for **ActivityDefinitions** and **EvidenceVariables**.
  - It can contain two levels:
    - Top actions (actions) such as Diagnostics, Therapy, etc.
    - Sub actions (**ActivityDefinitions**) such as CT-Scan, Determine Risk Factors etc.
- **ActivityDefinition**:
  - A definition for an activity.
  - Its criteria are captured via '**subjectCanonical**' which points to an **EvidenceVariable**.

Next steps

- Eligibility Criteria Working Group Call - 17.03

Working together

- Members of the EC Working group will attend SoA Working group calls
- SoA Working group members will attempt to EC Working Group Calls

Goal

- Share needs for development and use cases

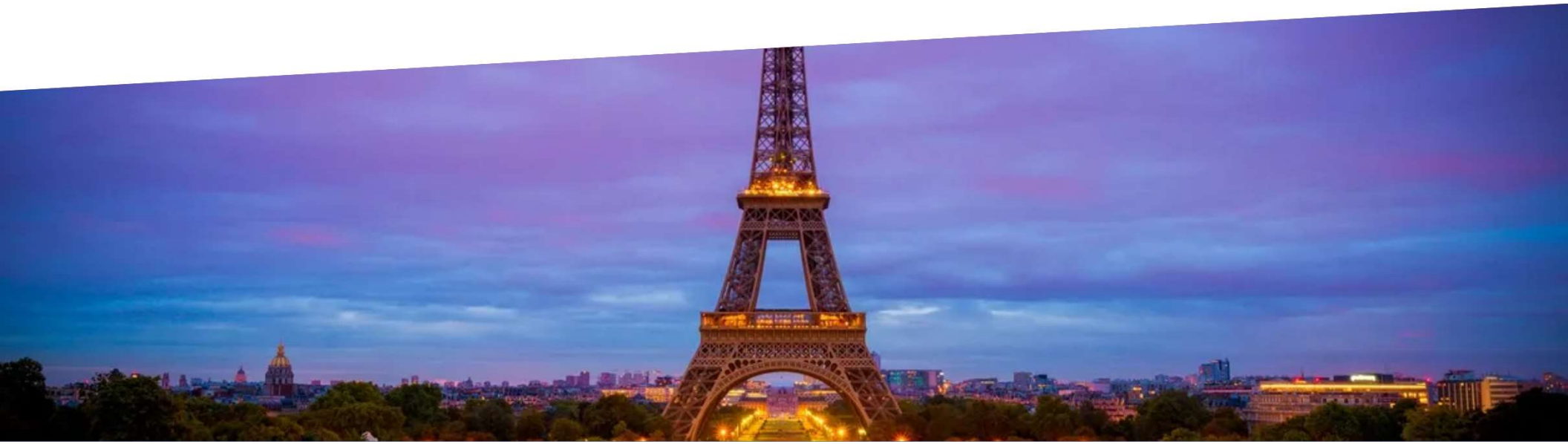
EuroVULCAN

12. Connectathon Readout Schedule of Activities (SoA)

Geoff Low, Medidata Solutions

Andy Richardson, Zenetar

9:40 – 10:25 (3 of 4)



Track Objectives – What we were trying to achieve

Objective 1

Model a simple activity (Systolic Blood Pressure) all the way though from Definition to Performed

Objective 2…

Model a simple activity (Systolic Blood Pressure) all the way though from Definition to Performed, but with no successful execution

EuroVULCAN

Achievements

Objective 1:

Sample ActivityDefinitions loaded into server

Many interesting discussions with team around the approach to alignment between Research and Healthcare representations of activities

Path forward for integration with Eligibility team

Objective 2:

No progress over mentioned above

EuroVULCAN

Discovered Issues/ Questions

Objective 1:

Reinforced working group findings that how we represent the desired activities is key;

- **too much detail risks 'over-prescribed' activities which make integrations with systems more challenging**
- **Too little detail risks the inability to specify what is needed and what value is going to be delivered**

EuroVULCAN

Participants

Name	Organization
Geoff Low	3DS
Andy Richardson	Zenetar
Gustav Vella	Carelane/Eligibility
Marco Schaarschmidt	Berlin Institute of Health at Charité
Michael Muzoora	Berlin Institute of Health at Charité

ZENETAR

CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN

3DS MEDIDATA

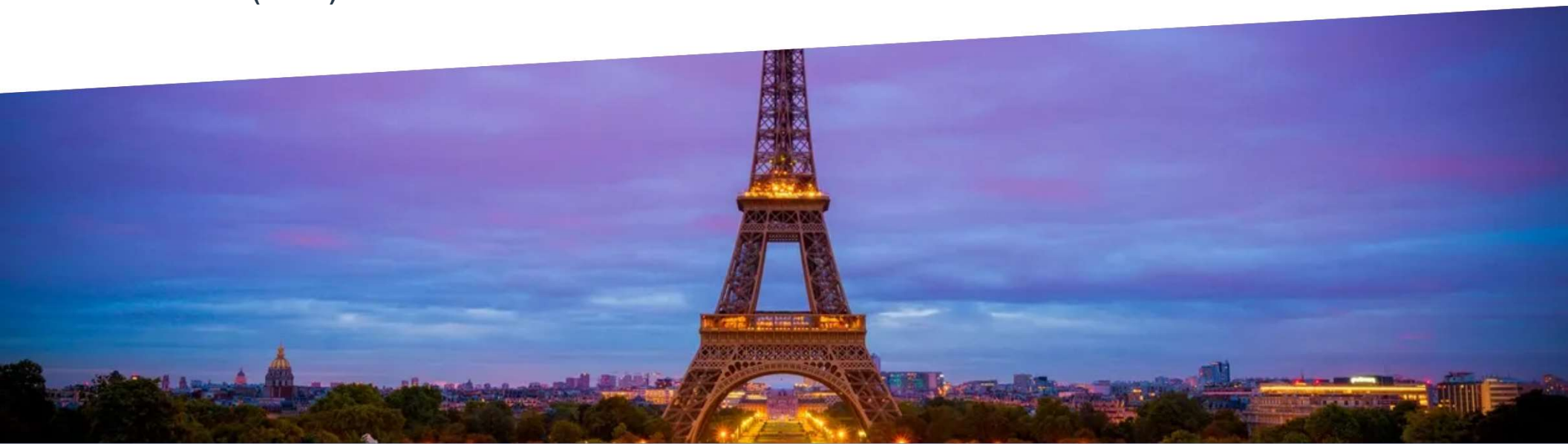
EuroVULCAN

12. Connectathon Readout
Electronic Product Information (ePI)

Giorgio Cangioli, HL7 Europe

João Almeida, FHIR Consultant, HL7 Europe

9:40 – 10:25 (4 of 4)



Track Objectives – What we were trying to achieve

Objective 1

Intro to the ePI and IPS – basics and connection between them

Objective 2

Searching ePI and IPS documents

Objective 3

Linking of terminologies and clinical to regulatory terminology.

Objective 4

Semantic Annotation

Objective 5

Persona Dimensions as FHIR artifacts

Objective 6

Creating and validating ePI

EuroVULCAN

Achievements

Objective 1

Showed the details of building ePIs and IPS, bringing more people onboard the issues

Objective 4

Semantic Annotation

Objective 5

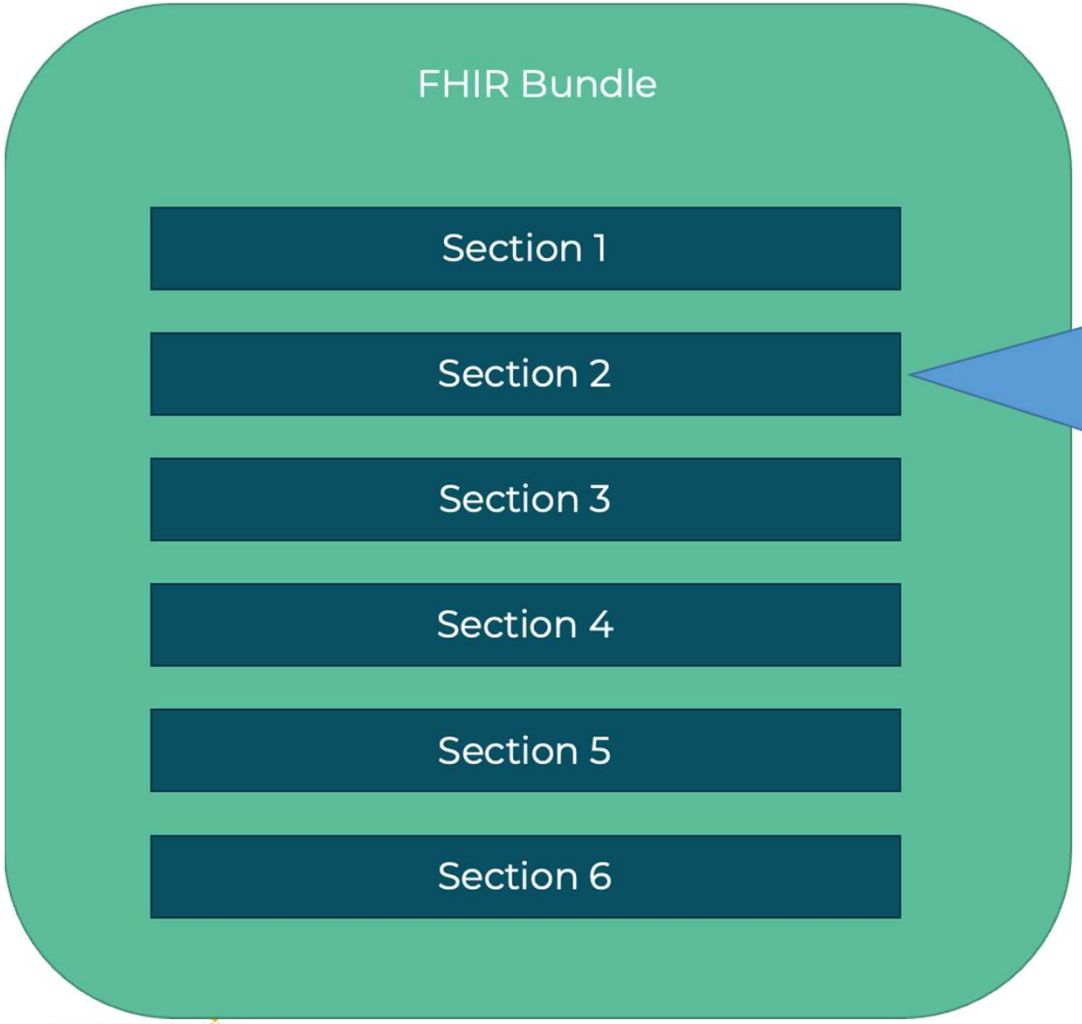
Persona Dimensions as FHIR artifacts – how to convey information in FHIR format – revolved around questionnaire and observation/Conditions

Objective 6

Seen and compared different methodologies for creating and fast-tracking authoring ePIs

EuroVULCAN

Achievements



Using RDFa Standard for embeding semantic resources in html:
https://www.w3.org/TR/xhtml-rdfa-primer/

```
<div prefix=" ty: http://some.where/thing/ lan: http://other.place/terms/" >
<h1>Section</h1>
The content of this section is plain <span about="lan:markup">HTML</span> content which may contain things like
<ul>
  <li> plain text </li>
  <li about="ty:item"> html markup for bullets</li>
  <li about="ty:head"> html markup for headers</li>
  <li about="ty:Font-mod"> html markup for bold and italics</li>
</ul>
</div>
```

AND/OR HL7 FHIR htmlElementLink extension could be used:
http://build.fhir.org/ig/HL7/emedicinal-product-info/branches/master/annotation.html#linking-structured-resources-to-text-with-the-htmlelementlink-extension

EuroVULCAN

Discovered Issues/ Questions

Objective 4

1.Should the semantic annotation be fully automatic? There are several regulatory and clinical issues to address for something like that to happen.

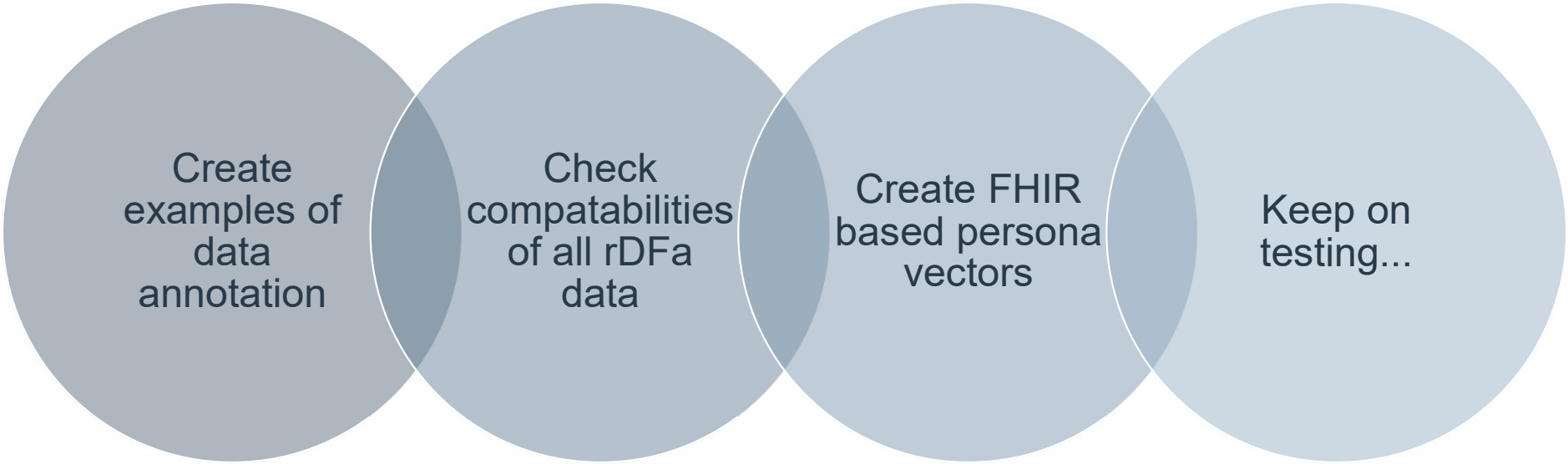
2. Which proposed annotation mechanisms are more suitable (if any)?

A) RDFa or htmlelementLink

B) should we annotate "the concept" or "something related to the concept"

3. How to make sure the annotation data is compatible / cross-linked to other sources of data (i.e IPS)

Next steps



EuroVULCAN

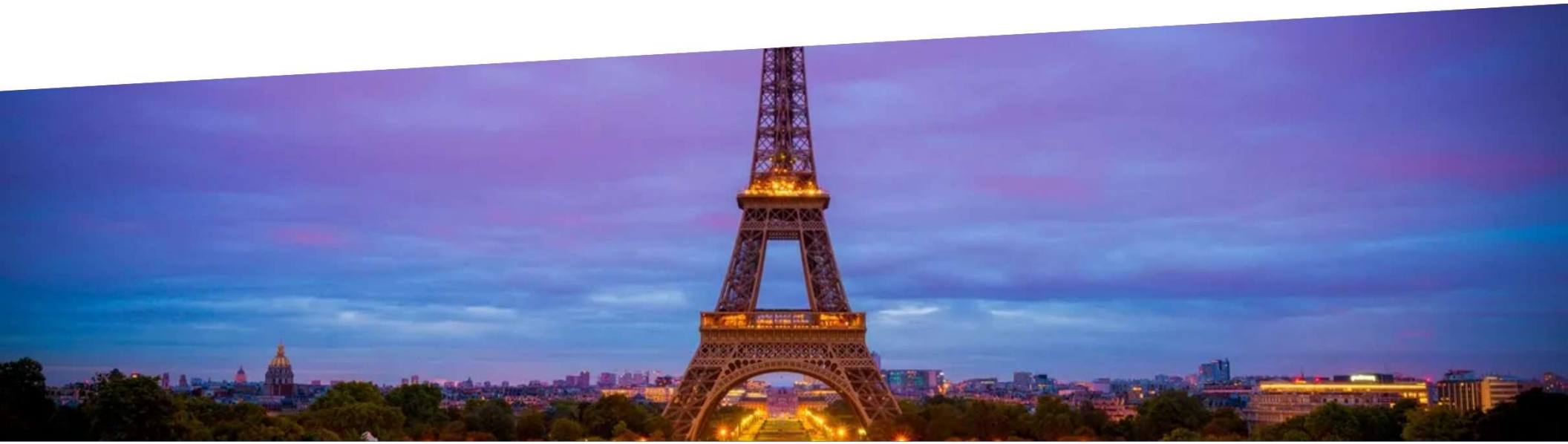
Participants

Name	Organization
Catherine Chronkai	HL7Europe
Giorgio Cangioli	HL7Europe
Paolo Pierantozzi	Datawizard
Sandro Conte	Datawizard
Martin Ingvar	Karolinska Institutet
Alejandro Medrano Gil	UPM
Guillermo Mejías Izquierdo	UPM
Bente By Jansen	felleskatalogen

13. Implementing Vulcan

Michael van Campen, Vulcan

10:25 – 10:40



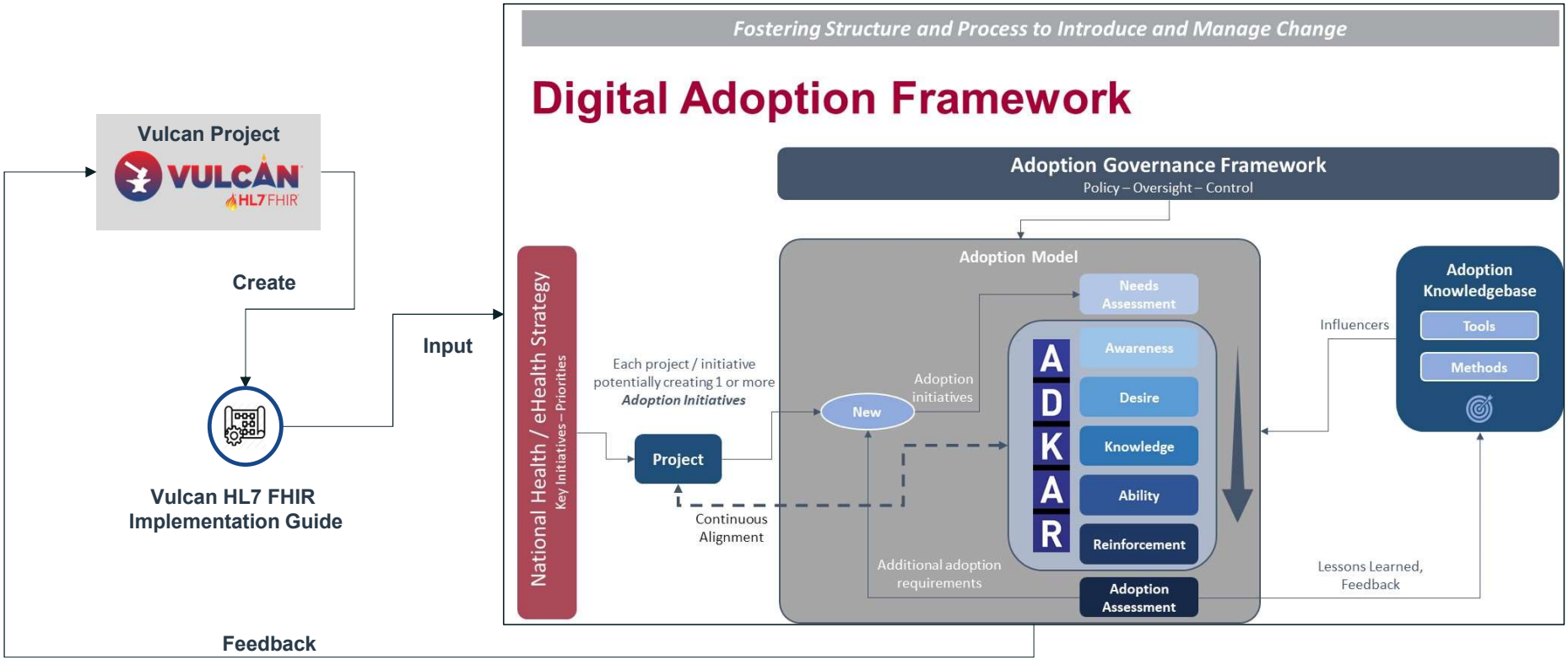
Vulcan Inflection Point

Implement It

EuroVULCAN

Generic Adoption Framework as Background

Leveraging PROSCI's ADKAR Methodology



EuroVULCAN

Adoption of Vulcan Implementation Guides (Standards)

Adoption Strategy

23 adoption challenges / opportunities / barriers (source: Advisory Council, February 2022)

1. Funding (or lack of)
2. Legal barriers
3. Data ownership
4. Data Privacy
5. Lack of Standards
6. Egos
7. One more model
8. Misalignment between sources & beneficiaries
9. Workflow
10. Benefits (or lack of) to clinicians
11. Consistency (or quality) of data
12. Minimum Data Sets
13. Market forces & regulations
14. Fidelity loss of data through transforms / mappings
15. Involvement (or lack) of EHR venders
16. More than unidirectional (EHR -> research)
17. Different models / mappings
18. Use of FHIR to make it accessible
19. Transparent to researchers (no extra burden)
20. Guide notices tied to funding
21. Mismatch of expectations and capabilities
22. Lack of awareness / understanding
23. FHIR training / understanding

EuroVULCAN

Implementation Perspectives

Components of an Implementation Strategy

Some of the elements of an Implementation Strategy include…

Implementation

1. Pilots (EPI Pilot Spain/Netherlands/Sweden?)
2. Proof of Concept
3. Live systems
4. Implementation community
5. Tooling support
6. Community building (e.g. technology summit)
7. Conformance / compliance

to be reviewed later…

EuroVULCAN


Questions?

Networking Break

10:40 – 11:00

14. Perspectives on FHIR (Part 2 – European Projects)

Bente By Jansen Felleskatalogen

Christel Daniel, Assistance Publique – Hôpitaux de Paris (remote) + Nicolas Riss, French National Agency of Digital Health (ANS), Chair HL7 France

Ben McAlister, Oracle, Chair HL7 UK

Rafail Kasapis, OSTHUS GmbH – a PharmaLex Company

Michael Muzoora, Berlin Institute of Health + Marco Schaarschmidt, Berlin Institute of Health

Luc Nicolas, UNICOM

11:00 – 12:30

14. Perspectives on FHIR (Part 2 – European Projects)

Bente By Jansen Felleskatalogen

Christel Daniel, Assistance Publique – Hôpitaux de Paris (remote) + Nicolas Riss, French National Agency of Digital Health (ANS), Chair HL7 France

Ben McAlister, Oracle, Chair HL7 UK

Rafail Kasapis, OSTHUS GmbH – a PharmaLex Company

Michael Muzoora, Berlin Institute of Health + Marco Schaarschmidt, Berlin Institute of Health

Luc Nicolas, UNICOM

11:00 – 12:30

Felleskatalogen on FHIR

Bente By Jansen
Managing director and Chief editor
15th of March 2023

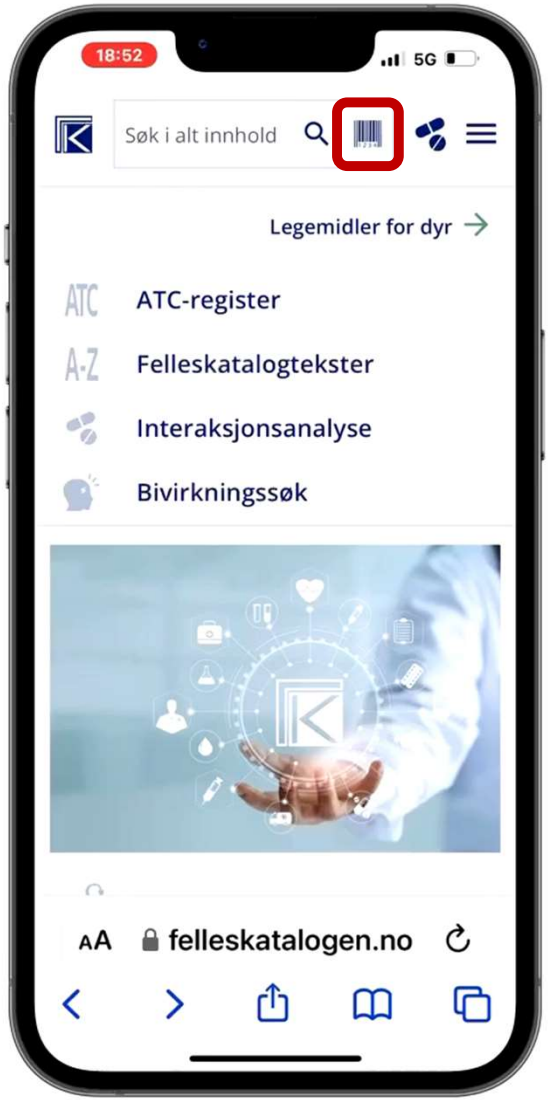
Felleskatalogen is a private non-for-profit company owned by The Association of the Pharmaceutical Industry in Norway (LMI).

Our mission is to deliver freely available drug information of high semantic and medical quality, adapted to all digital platforms used by healthcare professionals and patients in Norway.

LMI

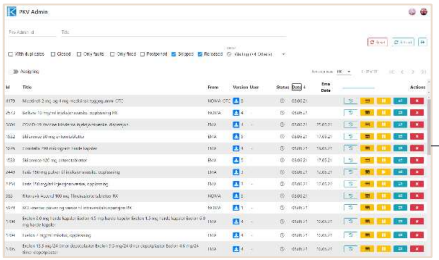
Why be involved in the ePI project?

Share experience



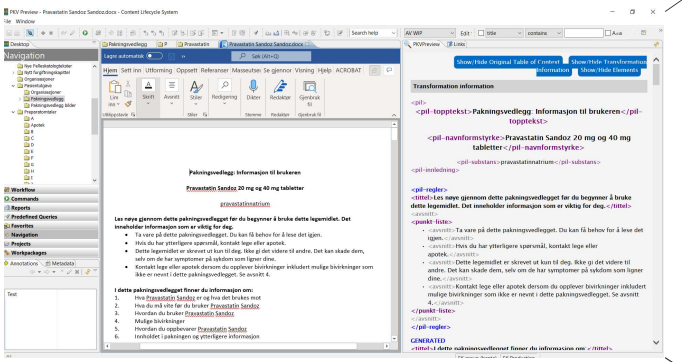
Ensure the best outcome

PDF



Admin application

DOCX

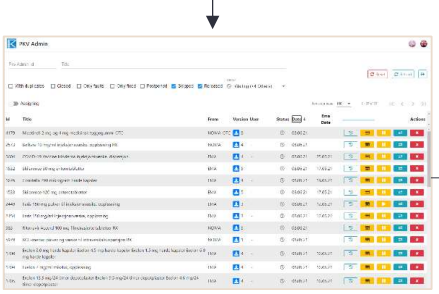


Content Management System

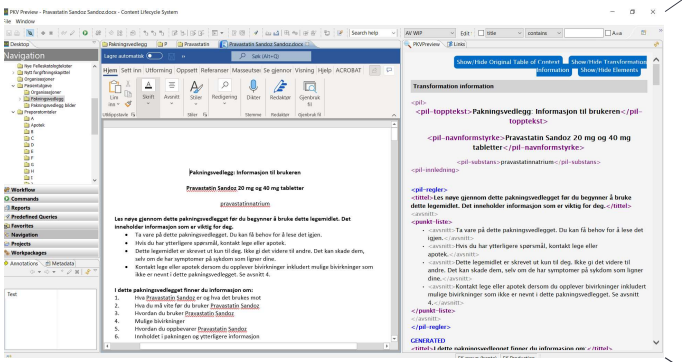
XML

JSON

Learn about FHIR



Admin application



Content Management System

The Norwegian Directorate of eHealth recommended using HL7 FHIR for data sharing in 2019!

Using FHIR in new projects?

Photo interface

It is not usual to prescribe a red tablet with an "X" on it, so it is clear that this resource is not needed for the prescribing workflow itself. However it may be useful during a patient consultation (or perhaps in response to an adverse event), to look up which tablet is the red triangle with an "X" imprint. These definitional facts can be captured with this resource. They would likely never be on a prescription, but

HL7 FHIR Snapshot 3: Connectathon 32 Base

Medication Definition > **ManufacturedItemDefinition**

This is Snapshot #3 for FHIR R5, released to support Connectathon 32. For a full list of available versions see the Directory of published versions.

Content | Examples | Detailed Descriptions | Mappings | Profiles & Extensions | Search Params

15.4 Resource ManufacturedItemDefinition - Content

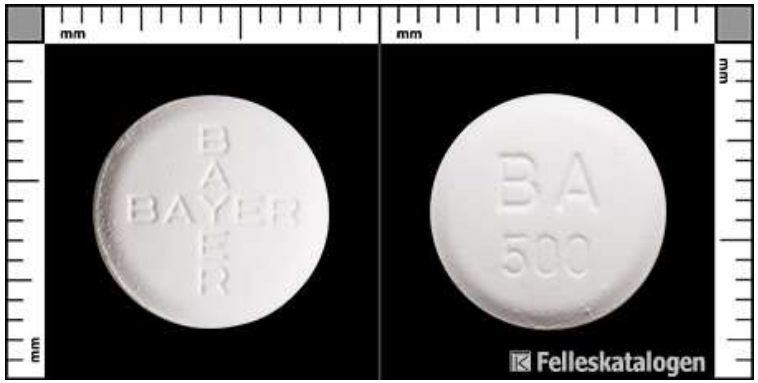
Biomedical Research and Regulation Work Group	Maturity Level: 2	Trial Use	Security Category: Anonymous	Compartments: Not linked to any defined compartments

For an overview of this resource and others in the Medication Definition domain, also see the module page

ManufacturedItemDefinition is to be used when you need to describe an actual physical medication item such as a tablet or capsule. This is typically for regulatory or manufacturing use cases, rather than day to day prescribing or dispensing.

This resource represents (for example) a single physical tablet. It can also represent physical liquids, powders, capsules etc. When prescribing, it is not usually necessary to represent the physical properties of the tablet that the patient will eventually receive and consume. Prescriptions make statements about types of products or substances, in general terms or more specific, which may be fulfilled by tablets (in some cases) but usually without directly talking about the details of the tablets. It is not usual to prescribe a red tablet with an "X" on it, so it is clear that this resource is not needed for the prescribing workflow itself. However it may be useful during a patient consultation (or perhaps in response to an adverse event), to look up which tablet is the red triangle with an "X" imprint. These definitional facts can be captured with this resource. They would likely never be on a prescription, but

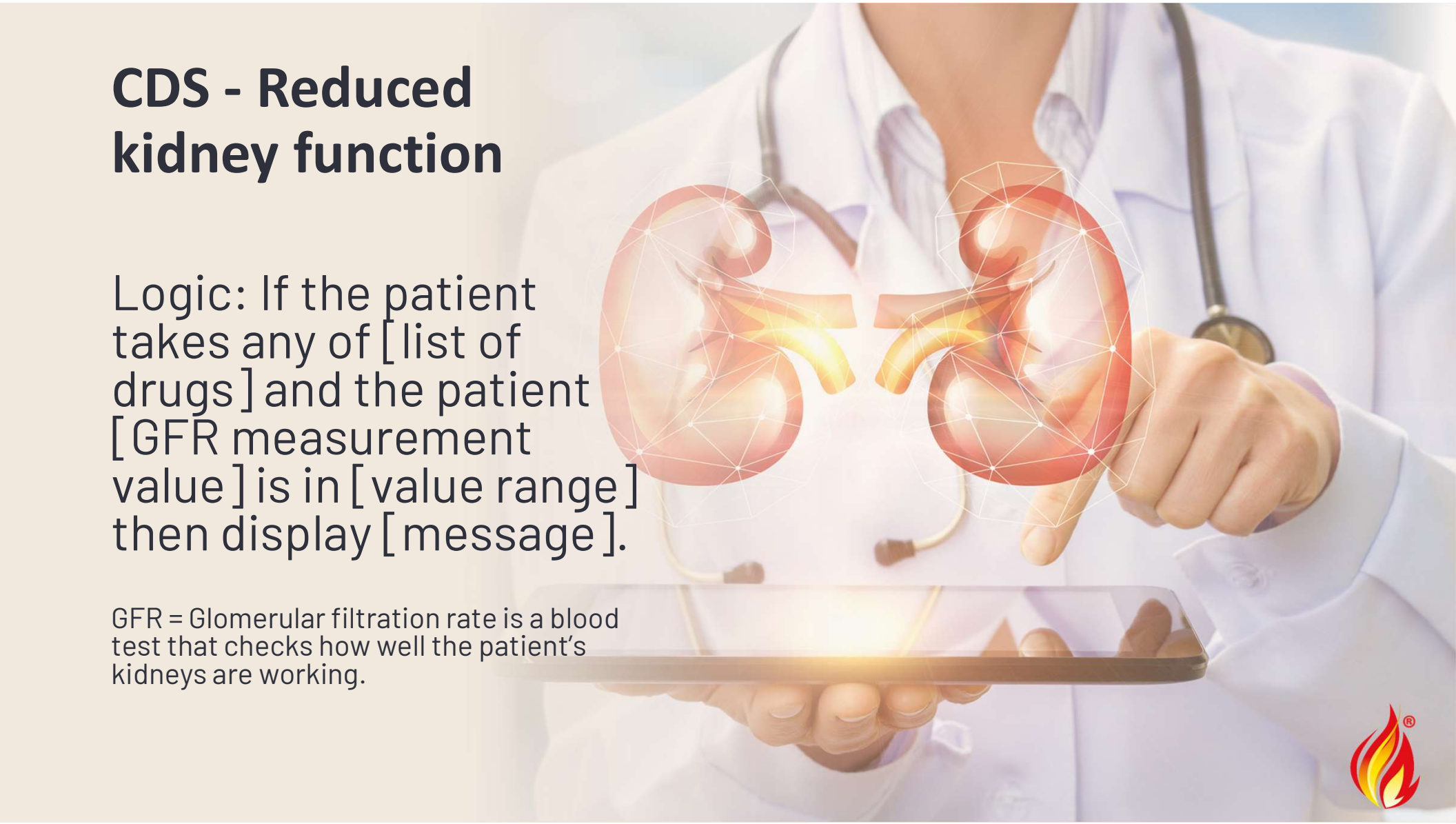
```
{
  "resourceType": "ManufacturedItemDefinition",
  "id": "40213165",
  "extension": [ {
    "url": "https://felleskatalogen.no/fhir/r5/legemiddelfoto/StructureDefinition/Extension-Hash",
    "valueString": "6b4556d225b966407bf0bc05047c8bcec6852cc60e48e79283c66d8d66a80491"
  } ],
  "identifier": [ {
    "system": "https://farmalogg.no/varenummer",
    "value": "125232"
  } ],
  "status": "active",
  "name": "Aspirin",
  "manufacturedDoseForm": {
    "coding": [ {
      "system": "https://felleskatalogen.no/fkid",
      "code": "40500014",
      "display": "tabletter, drasjerte"
    } ]
  },
  "property": [ {
    "type": {
      "coding": [ {
        "system": "http://terminology.hl7.org/CodeSystem/medicationknowledge-characteristic",
        "code": "color"
      } ]
    },
    "valueCodeableConcept": {
      "coding": [ {
        "system": "https://felleskatalogen.no/fkid",
        "code": "40300004",
        "display": "Hvit"
      }, {
        "system": "https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C54453",
        "code": "C48325",
        "display": "WHITE"
      } ]
    }
  } ]
}
```

CDS - Reduced kidney function

Logic: If the patient takes any of [list of drugs] and the patient [GFR measurement value] is in [value range] then display [message].

GFR = Glomerular filtration rate is a blood test that checks how well the patient's kidneys are working.



This logic is converted into three FHIR resources:

1. **PlanDefinition** - Contains the warning message, metadata and references to the other resources

2. **Library** - Contains the logic expressed in CQL

3. **ValueSet** - Representing the list of drugs

Resources loaded into a cqf-ruler server, and cqf-ruler creates a CDS Hooks endpoint for the PlanDefinition

Does our solution match other real-world implementations?

We must extend cqf-ruler to search through all rules (drug list and GFR value range combinations that have a warning message defined). Was this done before?

Is this implementation useful and useable for any EHR partner?

LMI

14. Perspectives on FHIR (Part 2 – European Projects)

Bente By Jansen Felleskatalogen

Christel Daniel, Assistance Publique – Hôpitaux de Paris (remote) + Nicolas Riss, French National Agency of Digital Health (ANS), Chair HL7 France

Ben McAlister, Oracle, Chair HL7 UK

Rafail Kasapis, OSTHUS GmbH – a PharmaLex Company

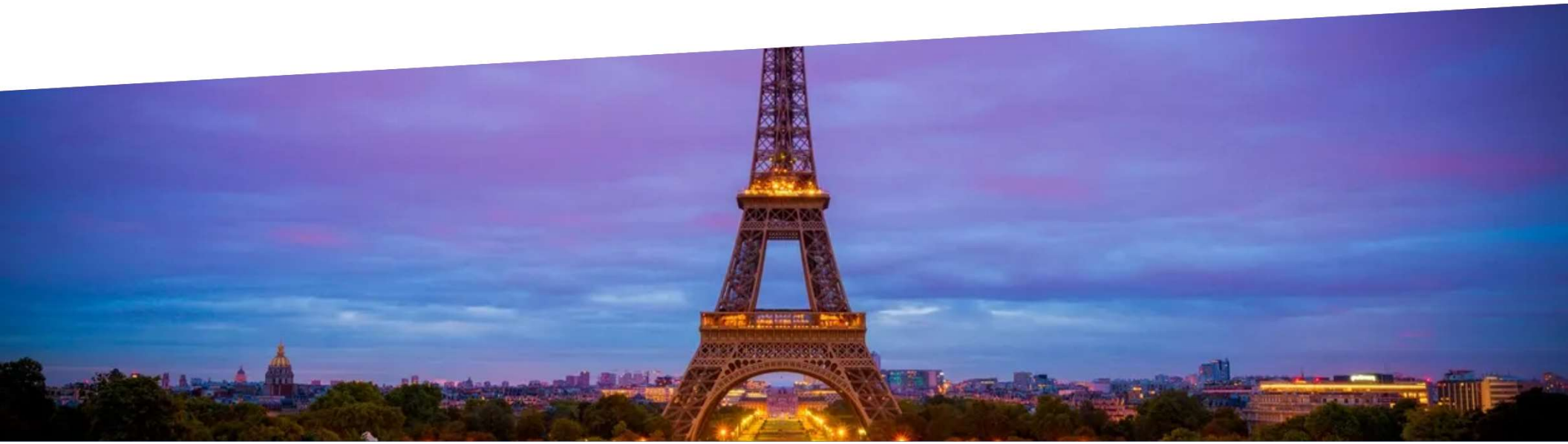
Michael Muzoora, Berlin Institute of Health + Marco Schaarschmidt, Berlin Institute of Health

Luc Nicolas, UNICOM

11:00 – 12:30

Data enabled innovation

Sponsor perspective: Nadir Ammour, Sanofi R&D, Clinical Operations
University hospital perspective: Dr Christel Daniel, AP-HP, Sorbonne University, INSERM



Data enabled innovation - Context

1

Two contexts of use of routine care data for research

Real-world evidence generation (RWE)

2

Reinventing clinical trials

Objectives

Use cases from both sponsor & investigator site perspective

(Needs, process, workflow and actors involved, IT infrastructure and digital services)

Interoperability challenge

EuroVULCAN

RWE – Sponsor perspective – the needs

1

Many use cases

Epidemiology/Pharmacoépidemiology

Patient characterization, disease incidence, treatment pathways, population-level effect estimation (using comparative cohort, case-control, self-controlled case series, self-controlled cohort, or case-crossover designs), and patient-level prediction studies.

RWD for clinical trials : control arms of clinical trial/generalizability of clinical trials

Market access (early access programme, conditional market access (efficacy & safety)

Phenome-wide association studies

Health care management (quality indicators)

Digital innovation

Development/assessment of algorithms (including AI/ML algorithms)

EuroVULCAN

Use case #1 – RWD for AI/ML

1

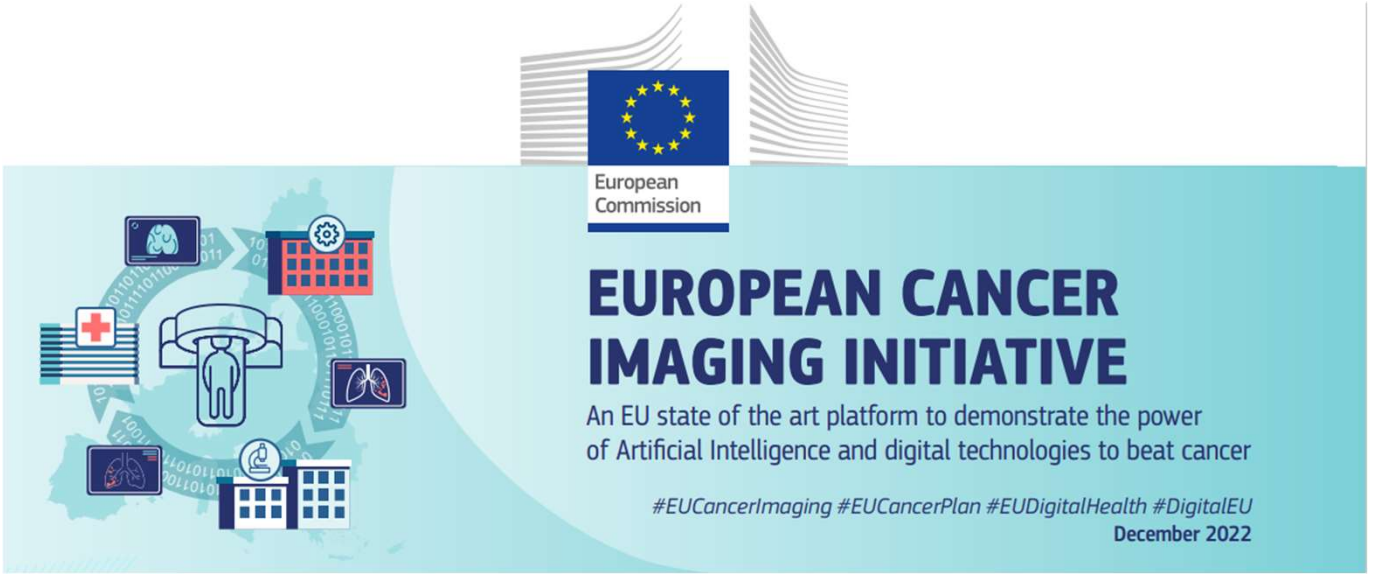
EUropean Federation for CAncer IMages (EUCAIM) (https://www.eibir.org/projects/eucaim/)

4-year project started in January 2023, 76 partners

Objectives

to deploy a pan-European digital federated infrastructure of FAIR cancer-related, de-identified, real-world images

to foster innovation and deployment of digital technologies in cancer treatment and care



EuroVULCAN

Use case #1 – RWD for AI/ML

1

*A **cohort builder**, interfaced to the data source (EHR/Clinical Data Warehouse/Registry) is used to build the relevant cohort for AI/ML*

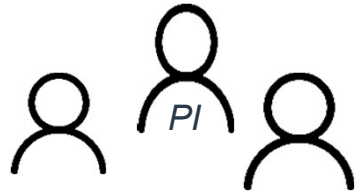
Laura, principal investigator, uses cohort builder to request the creation of the cohort

with the support of Mary, biomedical informatician, and Nathanael, data scientist

Patients of interest + Data of interest (availability, quality)

Metada of big data (medical imaging) are key to guarantee the provision of medical images that fit for purpose (development of the AI/ML algorithm)

Principal inverstigator (PI)



PI

Biomedical informatician (BMI)

Data scientist (DS)

Steven and Vince in the research IT department, set up the workspace for the research team

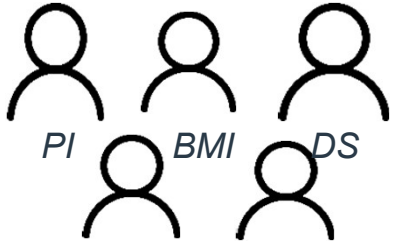
Requested data, tools and services (computing/storage capacity (GPU), etc)

Research IT staff

A multidisciplinary team develops and asseses the AI/ML algorithms

Step 1 : data exploration/curation

Step 2 : algorithm development and assessment



PI *BMI* *DS*

Biostatistician *DS (computer vision)*

EuroVULCAN

Clinical trial optimization

2

2a Feasibility study/site selection (EHR4CR, EU-PEARL, PENELOPE)

2b Pre-screening (EHR4CR, EU-PEARL, PENELOPE)

2c Data collection (EHR4CR, EHR2EDC)

EuroVULCAN

Use case #2a – Site selection - Sponsor perspective

2a

Optimize study budget and timelines : Find the right sites and PI

1	2	3
Proxy data and information	**Reported data and information**	**Objective data and information**
Claims data **Epidemiology data** **Publications** **Others..**	• **Investigators' survey** • **Feasibility Questionnaire**	**Mine Electronic Health Records to match number of potential patients**

Weak Signal

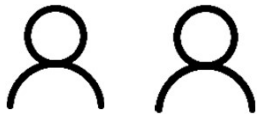
Strengthen the Signal

EuroVULCAN

Use case #2a – Feasibility study/site selection

2a

*A **querying tool**, interfaced to the data source (EHR/Clinical Data Warehouse/Registry) is used for eligibility determination*



Feasibility manager
Study manager (Pharma, CRO)

John, feasibility manager (global), and Virginia, study manager (local) need to estimate – among other criteria - the recruitment capacity of potential investigation sites

Using routinely collected care data

Virginia sends to the site (targeted Principal Investigators (PI) and/or global site) **the eligibility criteria (EC) of the clinical trial**

Local study manager

Hopefully, the EC relevant for automatic patient eligibility assessment are standardized into a computable format

Laura, principal investigator, queries the data source (EHR/Clinical Data Warehouse/Registry) to estimate the recruitment capacity

With the support of Mary, biomedical informatician, and Nathanael, data scientist

Laura sends patient counts to the local study manager

Local study manager

EuroVULCAN

Use case #2b – Prescreening - Sponsor perspective

2b

Once the study site and primary investigator is confirmed, a contract needs to be set up and logistics planning is initiated.

Both are based on expected number of patients to be enrolled.

During Site Initiation Visit, sponsor expect to see a list of potential patients pre-screened (pre-identified) and ready to be invited for a screening visit.

During the time open for enrollement, pre-screening and recruitment is regularly monitored – sponsor expect to see an active list of potential patients to secure enrôlement target is met sooner than planned

EuroVULCAN

Use case #2b – Pre-screening

2b

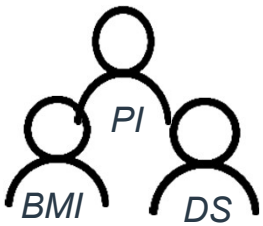
*A **prescreening tool**, interfaced to the data source (EHR/Clinical Data Warehouse/Registry) is used – among other supportive interventions - to automatically identify potential eligible patients (automatic prescreening)*

Laura sets up the query/algorithm for patient identification in the prescreening tool

With the support of Mary, biomedical informatician, and Nathanael, data scientist

Hopefully, the EC relevant for automatic prescreening are standardized into a computable format

The patient eligibility determination query is executed on a daily basis



Audrey, Clinical Research Assistant, regularly checks the list of automatically prescreened patients and assesses their eligibility (chart review)

If the potential eligibility is confirmed, additional actions are conducted to invite the patient to the inclusion visit

Clinical Research Assistant

Audrey regularly sends counts of prescreened/recruited patients to the local study manager

Local study manager

Use case #2c – Data collection - Sponsor perspective

2c

Up to 50% of the data that are entered in the clinical trial eCRF are also present in a structured way in the EHR.

Avoiding manual data entry at site will

- **not only reduce the burden due to the data entry,**
- **but also could help identifying information store in the EHR that can be hard to find (e.i. medication), hence improve safety monitoring**
- **And finally reduces the workload/stress due to queries management (for site and sponsors).**
- **opens new opportunities for EHR-based registry trials and use of EHRs-data as external control arm in comparative studies**

EuroVULCAN

Use case #2c – Data collection

2c

*The **Electronic Data Capture (EDC)** system used to collect the data of the CT is interfaced to the EHR (directly or through a connectivity module)*

Mrs. Robinson arrives for a clinical trial visit and Laura logs into the EHR, pulls up her record, and identifies the scheduled clinical trial visit

Because Mrs. Robinson informed consent indicated that it was permissible to do so the EHR/connectivity module recognizes Mrs. Robinson as a subject in Trial #1234, and requests an eCRF from trial #1234, using the EHR/connectivity module's capability to retrieve an external form for data capture

Principal inverstigator (PI)

Because the query population was previously set up and enabled, new EHR data (demographic, lab results, vital signs, concomitant medication, etc) automatically populate the clinical trial data fields.

Laura reviews and approves the EHR data, captures additional data via the forms and hits the submit button.

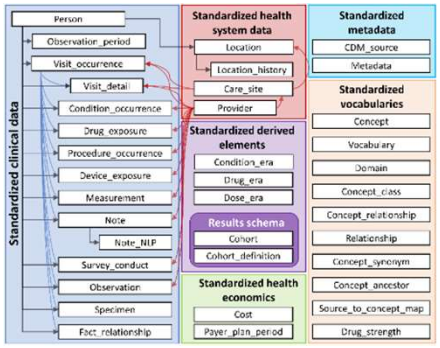
A copy of the document is archived in the site clinical trial document vault as part of the permanent source record of the trial.

EuroVULCAN

Interoperability challenge

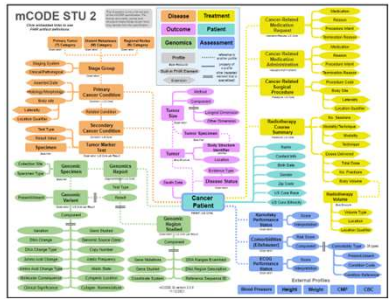
Interoperability, a prerequisite for digital innovations

Hospital data shall be FAIR (Findable, Accessible, Interoperable, Reusable)



https://ohdsi.github.io/TheBookOfOhdsi/CommonDataModel.html

http://hl7.org/fhir/uv/ips/



https://hl7.org/fhir/us/mcode/index.html

The need of FHIR implementation guides

To query EHR/CDW/registries

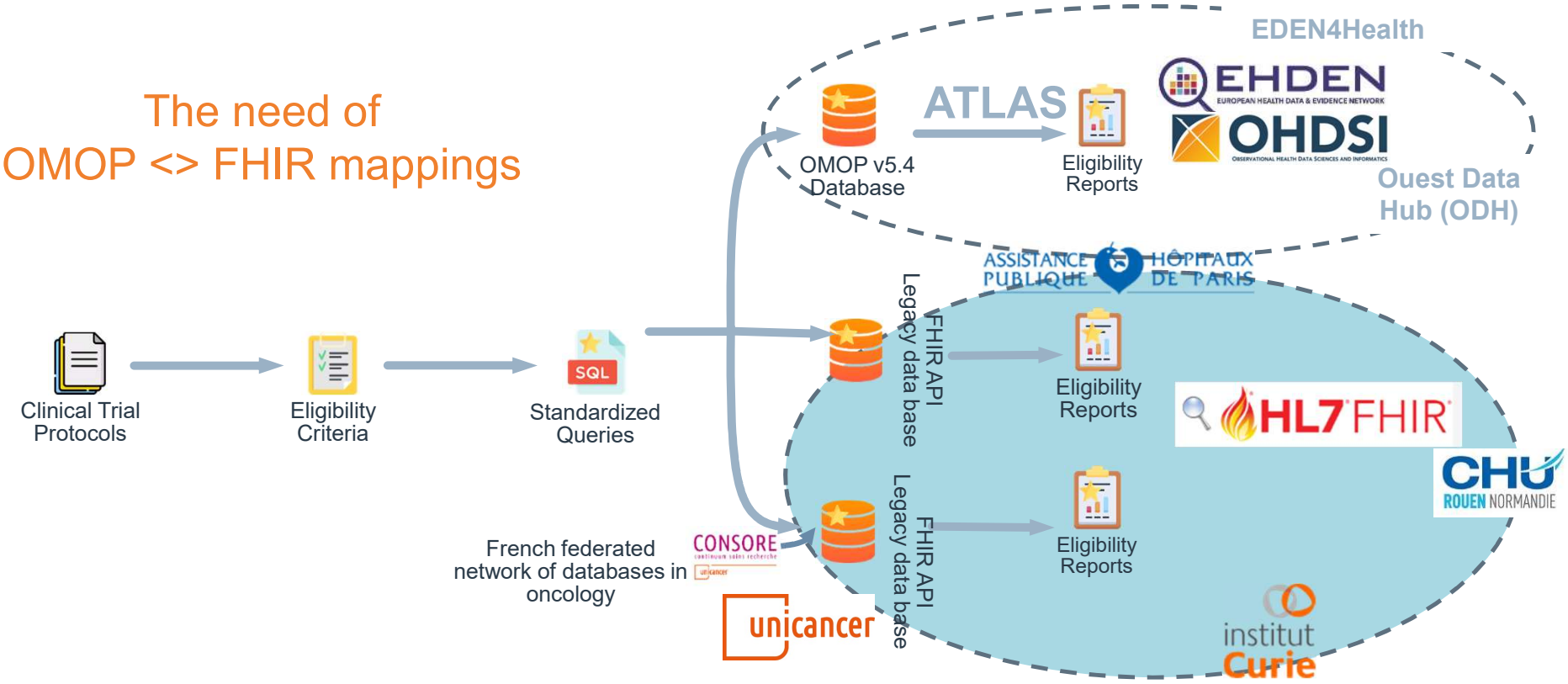
To interface EHR to EDC systems

EuroVULCAN

Interoperability challenge

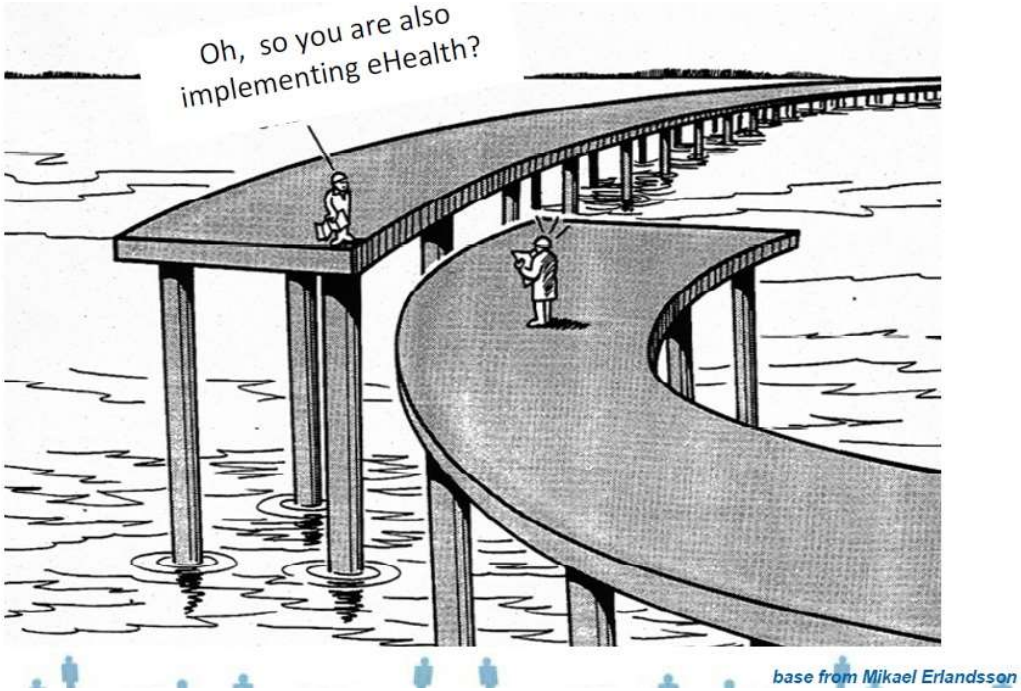
Example : PENELOPE project

The need of
OMOP <> FHIR mappings



EuroVULCAN

HL7 FHIR



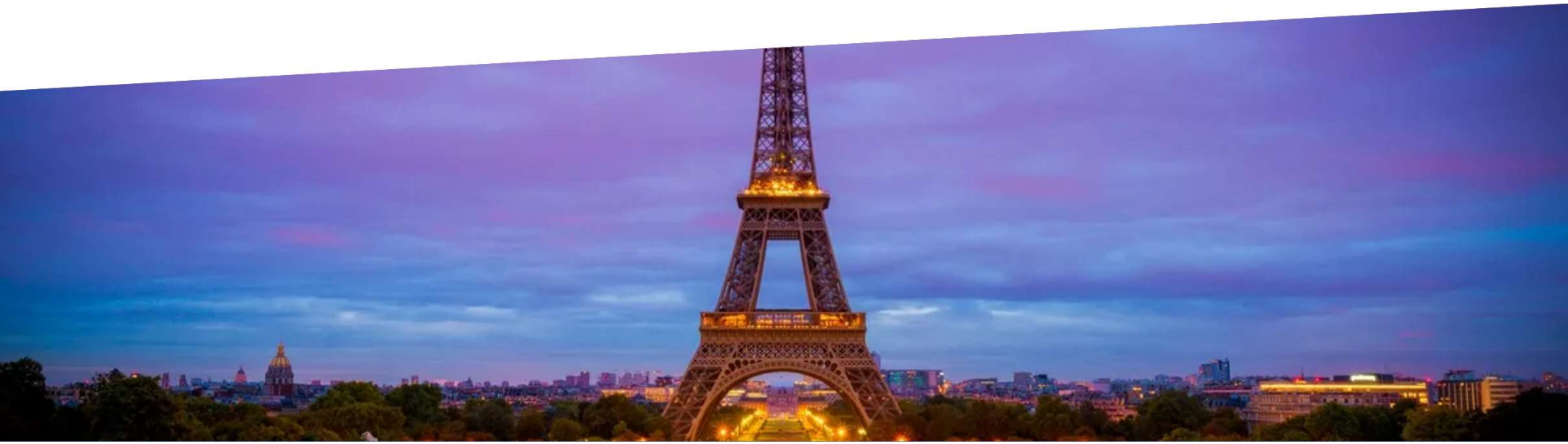
The need of FHIR <> CDISC mappings

cdisc

EuroVULCAN

Development of collaborative French Implementation Guides

Last Updated: March 2023



Nicolas Riss, PharmD, Developer

Interoperability Expert at the French National Agency of Digital Health (ANS)

PariSanté Campus startups support on interoperability & standards

Chair HL7 France (Interop'Santé)

AGENCE DU NUMÉRIQUE EN SANTÉ
La transformation commence ici

PariSanté campus

Interop'Santé
Pour des systèmes d'information communicants

EuroVULCAN

Initial State

- Usage of word / PDF without
- No validation pipeline

Improvement perspective

- Collaboration using GitHub to take advantage of collective thinking
- Conformance resource quality

EuroVULCAN

Our strategy

FHIR® Short™

IG Publisher

EuroVULCAN

Why using GitHub ?

- Habits of developers, Open Source
- Allow users to report issues at any time
- Collaboration using Pull Requests
- Facilitates versioning
- Creation of GitHub workflows

Issues
- Developers
- …

Create Branch
- ANS/Kereval

Pull Request

Workflow
- Check FSH grammar
- Launch the FHIR Validator
- Publication a ci-build version on github.io

Deploy
- Release on « interop.esante.gouv.fr »

@Mael Priour

EuroVULCAN

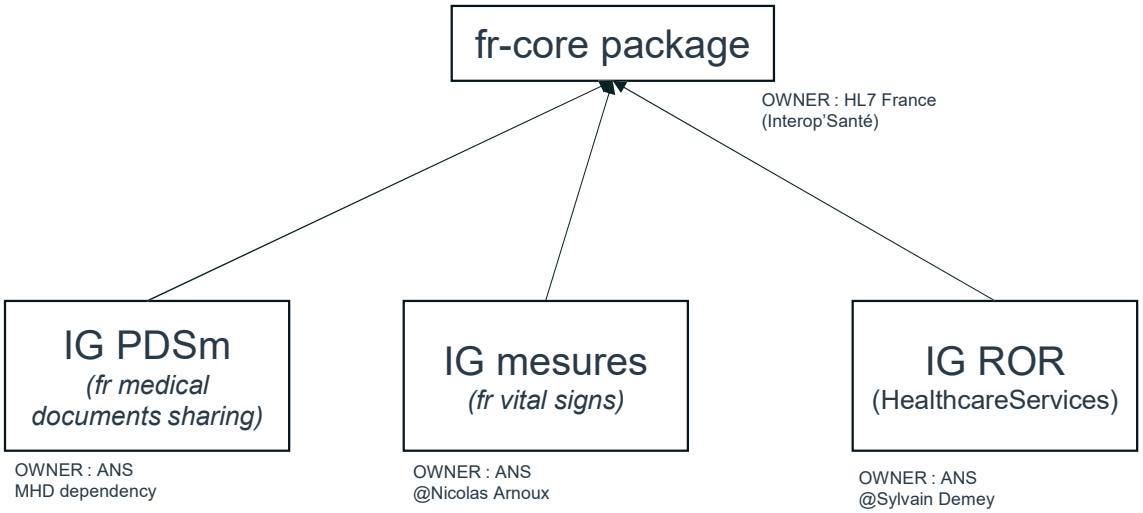
First POC of collaboration – HealthcareService

- Collaborative work with Kereval using PRs
- See every changes made, have discussion / comment on a particular context
- Automatic control & validation with the GitHub workflows

@Sylvain Demey

Dependency graphs and list of projects

@Yohann Poiron



Next specs to adapt :

- CareTeam management
- Schedule
- Event notification
- …

EuroVULCAN

Collaboration and clinical trials

- Wide variety of medical data for clinical trials
- Usage of collaborative thinking is mandatory to create interoperability specifications (interoperability expert, medical expert, developers)

Next steps

- Publish the first release of an Implementation Guide (this month)
- How to benefit from medical expert knowledge ?
- Develop a maturity model for Implementation Guide

EuroVULCAN

Thanks for listening!

14. Perspectives on FHIR (Part 2 – European Projects)

Bente By Jansen Felleskatalogen

Christel Daniel, Assistance Publique – Hôpitaux de Paris (remote) + Nicolas Riss, French National Agency of Digital Health (ANS), Chair HL7 France

Ben McAlister, Oracle, Chair HL7 UK

Rafail Kasapis, OSTHUS GmbH – a PharmaLex Company

Michael Muzoora, Berlin Institute of Health + Marco Schaarschmidt, Berlin Institute of Health

Luc Nicolas, UNICOM

11:00 – 12:30

UK Clinical Research and FHIR Landscape

… a whistle-stop tour

Ben McAlister, HL7 UK Chair

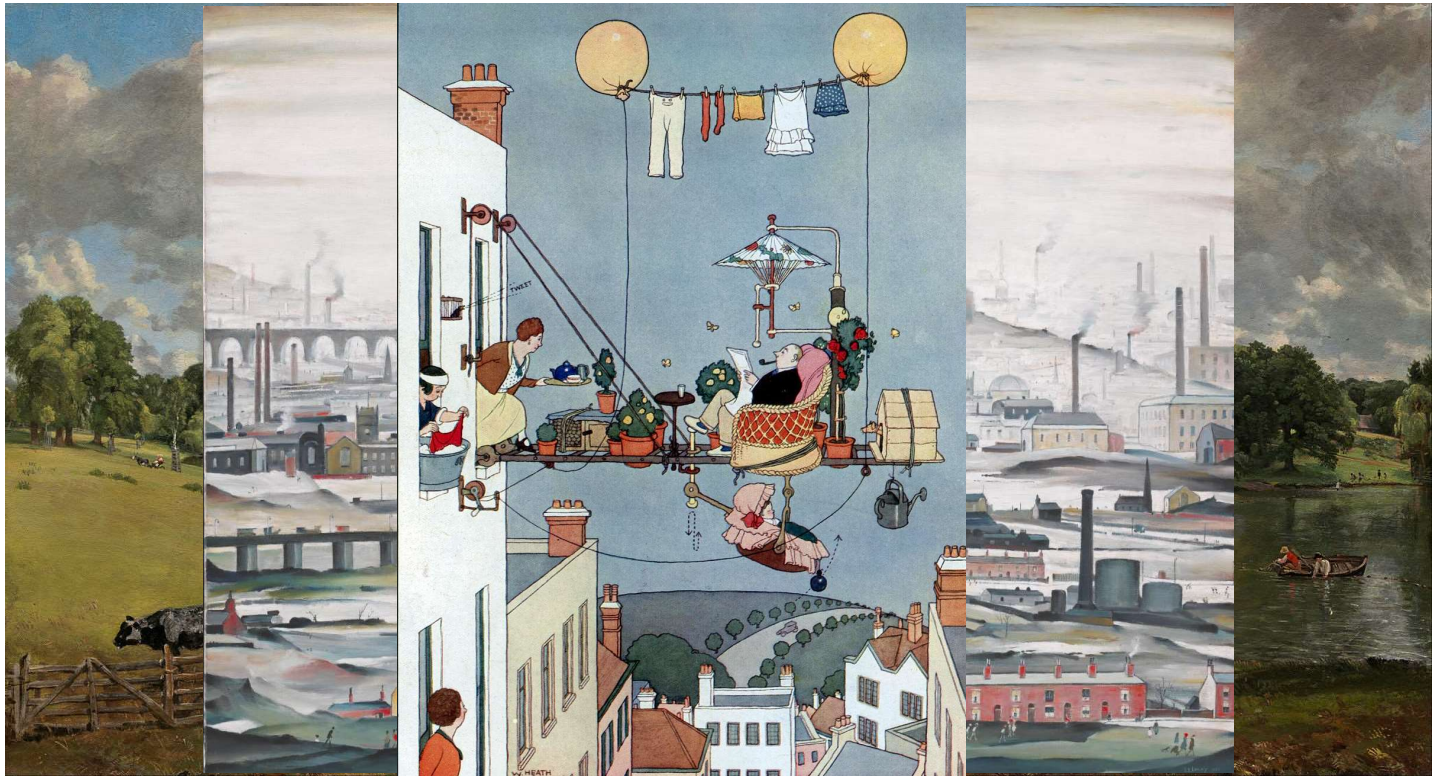
15th March 2023

PO Box 7230, Hook RG27 9WX, UK
Tel (+44) (0)8700 112 866 Web www.hl7.org.uk
Registered in England no. 04026136 VAT Number GB 742 5286 29

UK Landscape

UK Landscape

UK Landscape



UK Landscape

UK Landscape

UK FHIR Landscape

- HL7 UK
  - Ballots
  - Training
  - Bi-annual interop forums
  - Collaborations
- HL7 UK FHIR Board (May 2021)

UK FHIR Landscape

- UK Core FHIR
  - HL7 International – National IG Implementations
  - NHS digital, data and technology standards framework
    - 7. All NHS digital, data and technology services should support FHIR-based APIs to enable the delivery of seamless care across organisational boundaries
  - NHS England Information Standard Notice DAPB4020: UK Core Fast Healthcare Interoperability Resources (FHIR) Release 4 (R4) Governance (March 2022)
  - UK Core Implementation Guide (Profiles, R4)
    - STU1 - UK Core Implementation Guide 1.0.0 - STU1 (Jan 2023,12 Profiles)
    - STU2 Candidate - UK Core Implementation Guide 1.1.0 - STU2 Release for Ballot 2 (March 2023, additional 18 profiles)
    - STU3 Candidate- UK Core Profiles Development Sprint 6 (March 2023, additional 7 diagnostic related resource profiles)
  - UK Core Access Implementation Guide (Jan 2023, Direct Care and Subject of Care Access API)
    - International Patient Access Implementation Guide
  - 14th March 2023 - FHIR UK Core Hackathon 2023

UK FHIR Landscape

- HL7 UK Community Process
- HL7 UK FHIR Community Implementation Guidance Project Registry

- Nov 2022 - HL7 UK response to How Standards Will Support Interoperability response to NHS Transformation Directorate Standards & Interoperability programme Strategy Review & Consultation
- Nov 2022 - UK Mobilising Computable Biomedical Knowledge (MCBK) National Institute of Clinical Excellence (NICE) Collaborathon on computable guidelines

UK Clinical Research Landscape

- Department of Health and Social Care (DHSC)
  - Covers health and adult social care matters in England + few elements of matters not otherwise devolved to the Scottish Government, Welsh Government or Northern Ireland Executive.
  - Functions carried out by arms-length bodies (ALBs) include executive non-departmental public bodies such as NHS England (now incorporates NHS Digital) and the Health Research Authority (HRA), and executive agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA).
  - Manages the work of the National Institute for Health and Care Research (NIHR)
  - Policy
    - June 2022 - The Future of UK Clinical Research Delivery: 2022 to 2025 implementation plan
      - March 2021 Saving and Improving Lives: The Future of UK Clinical Research Delivery
      - June 2021 The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan

      Developed by UK Clinical Research Recovery, Resilience and Growth (RRG) programme
    - April 2022 - Better, broader, safer: using health data for research and analysis (The Goldacre Review)
    - Dec 2022 - Genome UK: 2022 to 2025 implementation plan for England

UK Clinical Research Landscape

- Department of Health and Social Care (DHSC)
  - Legislation
    - Health and Care Act 2022
      - Integrated Care Boards (ICBs) and Integrated Care Systems (ICSs)
    - Data Protection and Digital Information Bill

UK Clinical Research Landscape

- Department of Health and Social Care (DHSC)
  - Policy
    - March 2021 Saving and Improving Lives: The Future of UK Clinical Research Delivery
      - Vision
        - ✓ Clinical research delivery embedded in the NHS
        - ✓ Patient-centred research
        - ✓ Streamlined, efficient and innovative clinical research
        - ✓ Research delivery enabled by data and digital tools
        - ✓ A sustainable and supported research delivery workforce
      - Strategy and plans for delivery
        - ✓ Improving the speed and efficiency of study set-up
        - ✓ Building upon digital platforms to deliver clinical research
        - ✓ Increasing the use of innovative research designs
        - ✓ Aligning research programmes and processes with the needs of the UK health and care systems
        - ✓ Improving visibility and making research matter to the NHS
        - ✓ Making research more diverse and more relevant to the whole UK
        - ✓ Strengthening public, patient and service user involvement in research

UK Clinical Research Landscape

- Department of Health and Social Care (DHSC)
  - Policy
    - April 2022 - Better, broader, safer: using health data for research and analysis (The Goldacre Review)
      - Trusted Research Environments (TRE)
      - Reproducible Analytic Pipelines (RAP)
        - ✓ https://analysisfunction.civilservice.gov.uk/support/reproducible-analytical-pipelines/
        - ✓ https://nhsdigital.github.io/rap-community-of-practice/
      - Bennet Institute for Applied Data Science
        - ✓ OpenSAFELY, OpenPrescribing, TrialsTracker

UK Clinical Research Landscape

- Medical Research Council (MRC) 

  - UK Research and Innovation (UKRI) Council
  - Institutes, Units and Centres
    - 5 Institutes
      - Laboratory of Molecular Biology
      - London Institute of Medical Sciences
      - Health Data Research UK
      - UK Dementia Research Institute
      - The Francis Crick Institute

UK Clinical Research Landscape

- National Institute of Health Research

  - Work directed by the Chief Scientific Adviser at the Department of Health and Social Care (DHSC) and by the Director and Senior Management Team of DHSC's Science Research and Evidence Directorate.
  - Centered on England but collaborate closely with the devolved administrations in Scotland, Wales and Northern Ireland. We are also a major funder of applied health research in low and middle income countries, work that is principally funded through UK aid from the UK government.
  - 15 Clinical Research Networks (CRNs), 30 Specialties

UK Clinical Research Landscape

- National Institute of Health Research

  - Governance

UK Clinical Research Landscape

- National Institute of Health Research NIHR | National Institute for Health and Care Research
  - Clinical Research Network Coordinating Centre (CRNCC)
    - Integrated Research Intelligence System - Policies
      - Funding System Integration (Hosted by another NIHR department)
      - Central Portfolio Management System (CPMS)
      - Local Portfolio Management Systems (LPMS) Integration (Edge, ReDA, R-Peak, Studyline/Siteline, Documas)
      - Reference Data and Terminology Service (RTS)
      - International Standard Registered Clinical/soCial sTudy Number (ISRCTN) Integration -> WHO International Clinical Trials Registry Platform (ICTRP)
      - Integrated Research Application System (IRAS) (Hosted by NHS Health Research Authority (HRA)
      - Be Part of Research (Subject registration/recruitment/matching UK wide) BE PART OF RESEARCH

UK Clinical Research Landscape

- National Institute of Health Research NIHR | National Institute for Health and Care Research
  - Clinical Research Network Coordinating Centre (CRNCC)
    - Integrated Research Intelligence System
      - Open Data Platform (ODP) (Qlik, mostly internal)
      - NIHR Open Data (Qlik)
      - Identity Gateway (IDG) (Identity Authentication)
  - NIHR BioResource
    - Coordinating centre is located in Cambridge and is hosted by Cambridge University Hospitals NHS Foundation Trust in partnership with the University of Cambridge.
    - 18 local BioResource Centres across England
    - Cohorts – Common diseases, Rare diseases, DNA, Children + Young People's Health Resource(D-CYPHR), COVID-19

UK Clinical Research Landscape

- NHS Health Research Authority (HRA)
  - Arm's length body of the Department of Health and Social Care (DHSC) in England. The HRA exists to provide a unified national system for the governance of health research.
  - Integrated Research Application System (IRAS)
  - Research Ethics Service (RES) and Research Ethics Committees (RECs)
    - Approved REC Summaries

UK Clinical Research Landscape

- Medicines and Healthcare products Regulatory Agency (MHRA)

  Medicines & Healthcare products Regulatory Agency

  - Executive agency of the Department of Health and Social Care in the United Kingdom, responsible for ensuring that medicines and medical devices work and are acceptably safe.
  - 3 main centres:
    - MHRA Regulatory – the regulator for the pharmaceutical and medical devices industries
    - Clinical Practice Research Datalink (CPRD) – licences anonymised health care data to pharmaceutical companies, academics and other regulators for research
      - Speedy Patient Recruitment INto Trials (SPRINT)
    - National Institute for Biological Standards and Control – responsible for the standardisation and control of biological medicines
  - Guidance
    - Dec 2021 - MHRA guidance on the use of real-world data in clinical studies to support regulatory decisions
  - Nov 2022 – Announced12 Month delay to new UK Medical Device Regulations (MDR) July 2023 -> Jul7 2024 Implementation of the Future Regulations

UK Clinical Research Landscape

- NHS England
  - Accelerated Access Collaborative (ACC)
    - 'Our ambition is to help make the UK one of the most pro-innovation health systems in the world.'
    - Formed in response to the Accelerated Access Review published in October 2016, the AAC is chaired by Lord Ara Darzi
      - 'Our goal is simple: speeding up access to the best technologies and products – leading to better care for patients. We are excited by this challenge and are proud to have such a prestigious and wide-ranging number of member organisations working with us.' Lord Darzi, Chair of the AAC
    - Includes an 'Embedding research in the NHS' Track
  - DigiTrials
    - Feasibility Service
  - NHS Genomic Medicine Service (GMS) Research Collaborative
    - Partnership between the NHS GMS, Genomics England and the National Institute of Health Research (NIHR)
  - Jan 2023 - NHS Federated Data Platform

UK Clinical Research Landscape

- Genomics England 

  - Company fully owned by Department of Health and Social Care (DHSC)
  - Projects
    - 100,000 Genomes Project

- UK Biobank biobank uk
  - Long-term biobank study investigating the respective contributions of genetic predisposition and environmental exposure (including nutrition, lifestyle, medications etc.) to the development of disease. Began in 2006.
  - Following around 500,000 volunteers in the UK, enrolled at ages from 40 to 69. Initial enrollment took place over four years from 2006, and the volunteers will be followed for at least 30 years thereafter.

UK Clinical Research Landscape

- NHS Confederation 
  - Membership body for organisations that commission and provide National Health services in England, Wales and Northern Ireland founded in 1990.
  - Joint Action Towards the European Health Data Space (TEHDAS) nominated UK Partner

UK Clinical Research Landscape

- Devolved administrations
  - Northern Ireland
    - Health and Social Care, Northern Ireland (HSCNI)
      - Public Health Agency
        - ✓ Research and Development Division
      - Clinical Research Network

UK Clinical Research Landscape

- Devolved administrations
  - Scotland
    - NHS Scotland
      - NHS Research Scotland
        - ✓ The Scottish Health Research Register and Biobank (SHARE)
    - Public Health Scotland
    - National Records Scotland
      - National Health Service Central Register (NHSCR)
    - Research Data Scotland (Charity)
  - Wales
    - Health and Care Research Wales (HCRW)
      - SAIL Databank (Powered by Secure eResearch Platform (SeRP))
    - Digital Health and Care Wales (DHCW)
      - National Data Resource (NDR)

UK Clinical Research Landscape

- Health Data Research UK
  - Independent, charity organisation supported by 10 funders, with work based at 31 locations across the UK
  - HDR UK Gateway
    - Metadata schemata https://github.com/HDRUK/schemata
    - Datasets https://github.com/HDRUK/datasets
    - Cohort Discovery
      - COVID-Curated and Open aNalysis aNd rEsearCh plaTform (CO-CONNECT)
      - Convenient and Reusable Rapid OMOP Transformer (CaRROT)
    - Phenotype Library
    - Phenoflow

UK Clinical Research Landscape

- Health Data Research UK

  - National Projects
    - National Multimorbidity Resource
    - National Phenomics Resource
    - National Text Analytics Resource
    - Reproducible Machine Learning in Health Data Science

UK Clinical Research Landscape

- Health Data Research UK
  - The UK Health Data Research Alliance (co-ordinated by HDR UK)
    - Members include organisations representing national organisations, NHS trusts, research institutes and charities.
    - Projects
      - Data Standards and Quality
        - ✓ April 2021 Principles for Data Standards Green Paper
      - Alliance Governance Consultation
      - Using Linked Data for Research: Challenges with UK Health Ecosystem
      - Data Access and Governance
      - Improving transparency in data use
      - Diversity in Data
      - Engaging and involving practitioners, patients and public
      - Aligning approach to Trusted Research Environments
      - Supporting Health Data Research Innovation Gateway development

UK Clinical Research Landscape

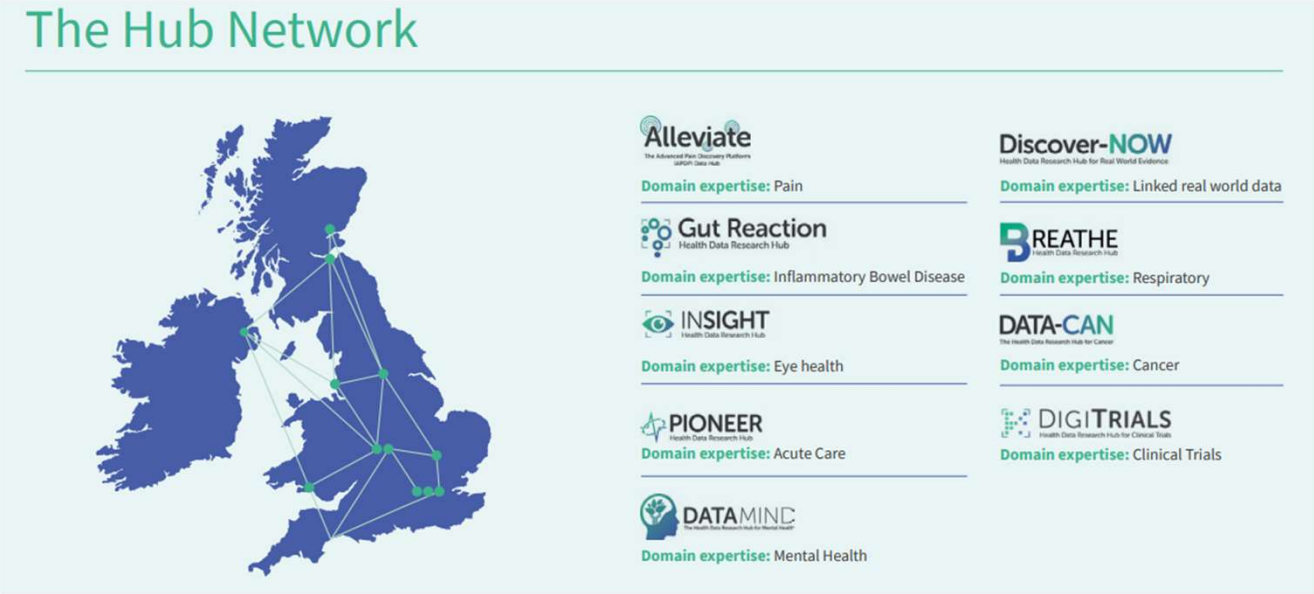
- Health Data Research UK
  - Data and Analytics Research Environments UK (DARE UK)
    - Funded by UK Research and Innovation with Phase 1 led by Health Data Research UK (HDR UK) and Administrative Data Research UK (ADR UK)
    - Phases
      - Phase 1: Design and Dialogue (July 2021 – March 2024)
      - Phase 2: Build, Test and Establish (timelines TBC)
      - Phase 3: Deliver, Optimise and Federate (timelines TBC)

UK Clinical Research Landscape

- Health Data Research UK

  HDRUK
  Health Data Research UK

  - HDR UK Hubs



- Alleviate
- Gut Reaction
- INSIGHT
- PIONEER
- DATAMIND
- Discover-NOW
- BREATHE
- DATA-CAN
- DigiTrials

UK Clinical Research Landscape

- Health Data Research UK
  - HDR Global
    - International COVID-19 Data Alliance (ICODA) (Convened by HDR UK)
    - Partnering with The Global Health Network

UK Clinical Research Landscape

- Office for Strategic Coordination of Health Research (OSCHR)
  - Strategic Coordination of Health of the Public Research (SCHOPR)

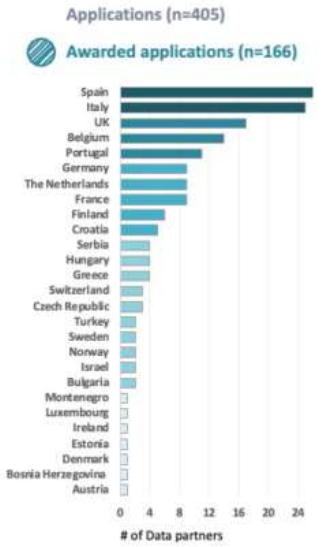
UK Clinical Research Landscape

- Other
  - Wellcome Trust (Research Funding)
    - Wellcome Sanger Institute
  - Association of the British Pharmaceutical Industry (ABPI)
  - Association of Medical Research Charities (AMRC)
  - Newcastle University -> Data to Knowledge (D2K) Research Group -> DataSHIELD
    - https://www.datashield.org/ implementations
  - ...

UK Clinical Research Landscape

- Observational Health Data Sciences and Informatics (OHDSI) Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) adoption in the UK
- European Health Data & Evidence Network (EHDEH)
  - A federated network of Data Partners - the EHDEN project aims to collaborate with diverse institutions, data sources and data custodians across the EU, with a goal of harmonising source data to the OMOP common data model locally, within a federated network.

Geographic spread of data partners. The shade of blue indicates the # of data partners in that country (darker = more)



UK Clinical Research Landscape

- European Health Data & Evidence Network (EHDEH)
  - https://www.ehden.eu/datapartners/

Ireland (1)

Dublin

- Trinity St James's Cancer Institute

United Kingdom (17)

England

- Akrivia Health
- Barts Health NHS Trust
- Clinical Practice Research Datalink
- Connected Bradford
- GOSH
- Harvey Walsh Ltd
- King's College London
- Leeds Teaching Hospitals
- Optimum Patient Care
- Queen Mary University of London
- Royal College of General Practitioners Research and Surveillance Centre
- UK National Neonatal Research Database
- University College London
- University College London Hospitals

Scotland

- Health Informatics Centre
- University of Edinburgh

Wales

- SAIL Databank

UK Clinical Research Landscape

- Observational Health Data Sciences and Informatics (OHDSI) Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) adoption in the UK
  - Clinical Practice Research Datalink (CPRD)
    - Clinical Practice Research Datalink GOLD (CPRD) to OMOP CDM ETL Documentation
      - https://ohdsi.github.io/ETL-LambdaBuilder/docs/CPRD
  - UK Biobank
    - 2021 OHDSI Global Symposium
      - Conversion of UK Biobank into the OMOP CDM: New Data for Inferences Between Episodic Care
      - Mapping UK Biobank to the OMOP CDM: challenges and solutions using the delphyne ETL framework
      - https://thehyve.github.io/ukbiobank-omop-etl/
  - …

Thank You!

Ben McAlister
chair@hl7.org.uk
https://www.hl7.org.uk/

HL7 UK

14. Perspectives on FHIR (Part 2 – European Projects)

Bente By Jansen Felleskatalogen

Christel Daniel, Assistance Publique – Hôpitaux de Paris (remote) + Nicolas Riss, French National Agency of Digital Health (ANS), Chair HL7 France

Ben McAlister, Oracle, Chair HL7 UK

Rafail Kasapis, OSTHUS GmbH – a PharmaLex Company

Michael Muzoora, Berlin Institute of Health + Marco Schaarschmidt, Berlin Institute of Health

Luc Nicolas, UNICOM

11:00 – 12:30

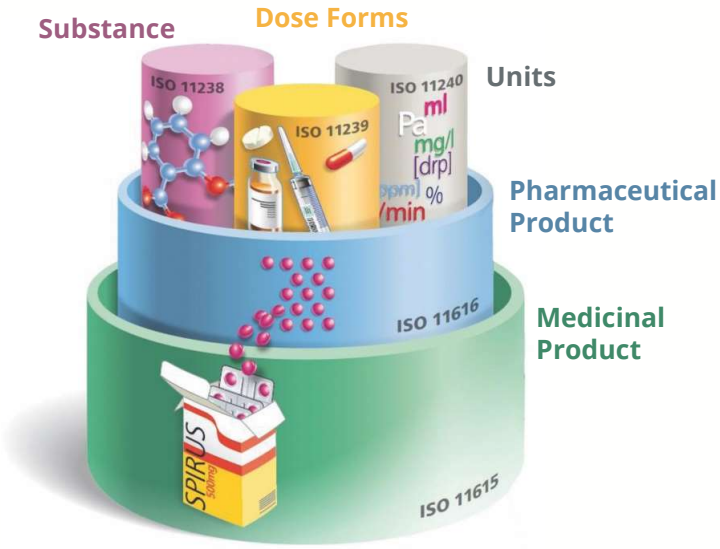
IDMP Ontology

Collaborative Implementation of IDMP in Pharma … *connecting to FHIR*

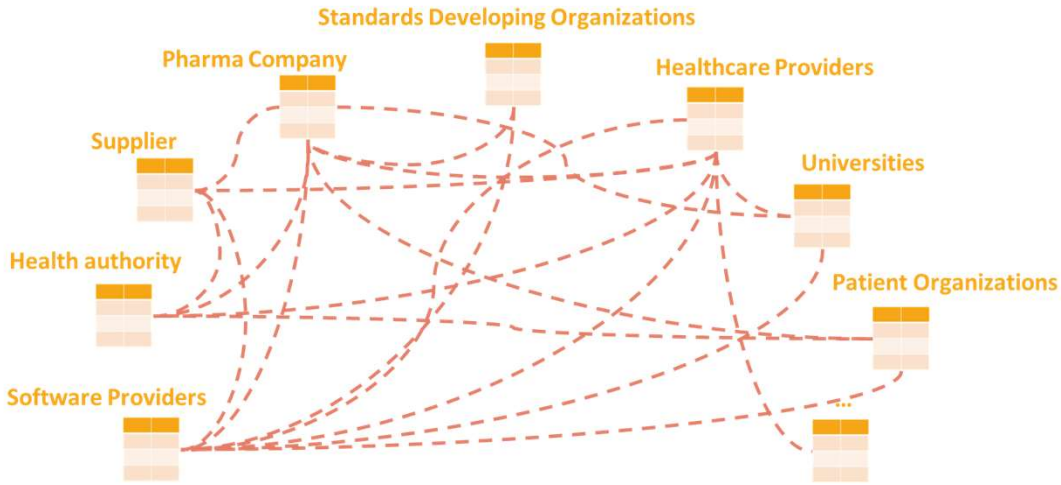
March 15, 2023, EuroVulcan

Rafail Kasapis, OSTHUS GmbH

The Problem: Diverging IDMP implementations create more silos and are a risk for envisioned standardization benefits of IDMP for drug safety, innovation and operational efficiency.

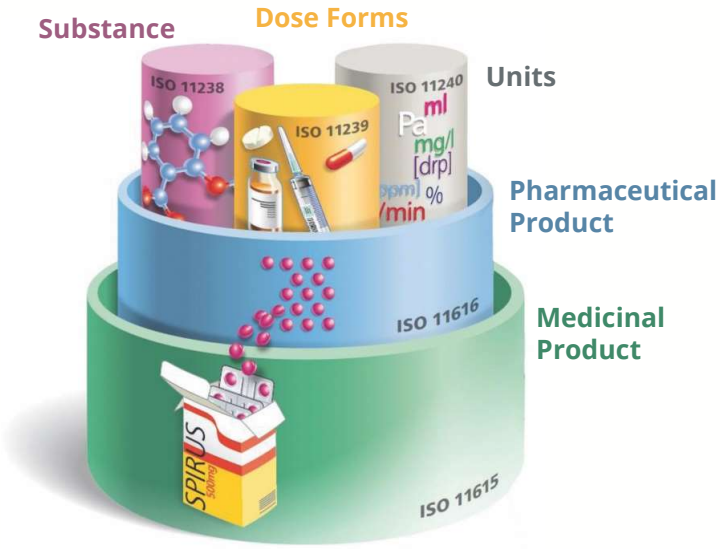


ISO IDMP Standards

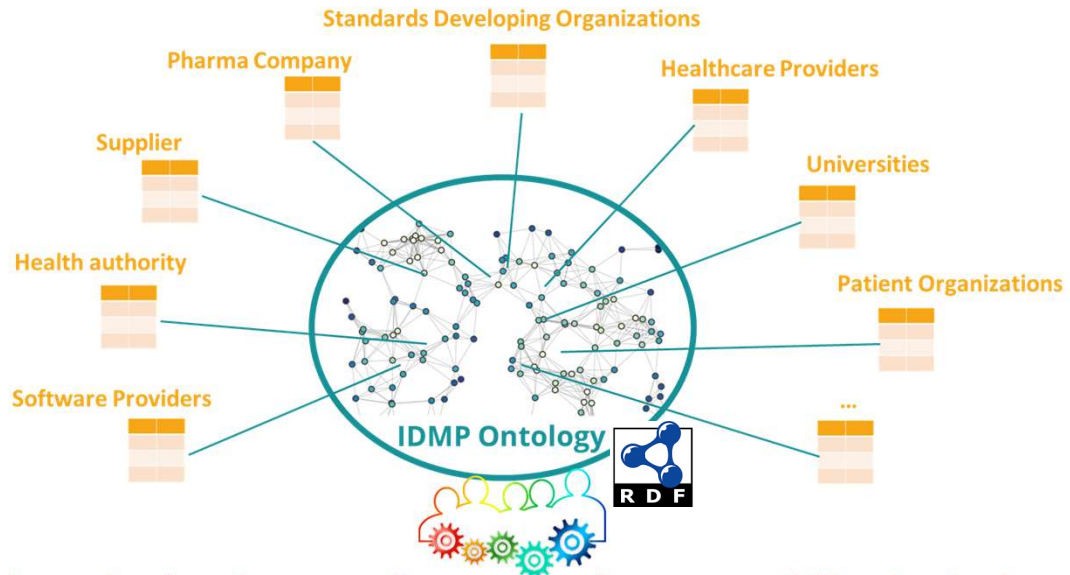


Silos and many costly point-to-point integrations

The IDMP Ontology provides a universal implementation of the IDMP product data model as a common language to effectively bridge the gap between people, processes, and systems.

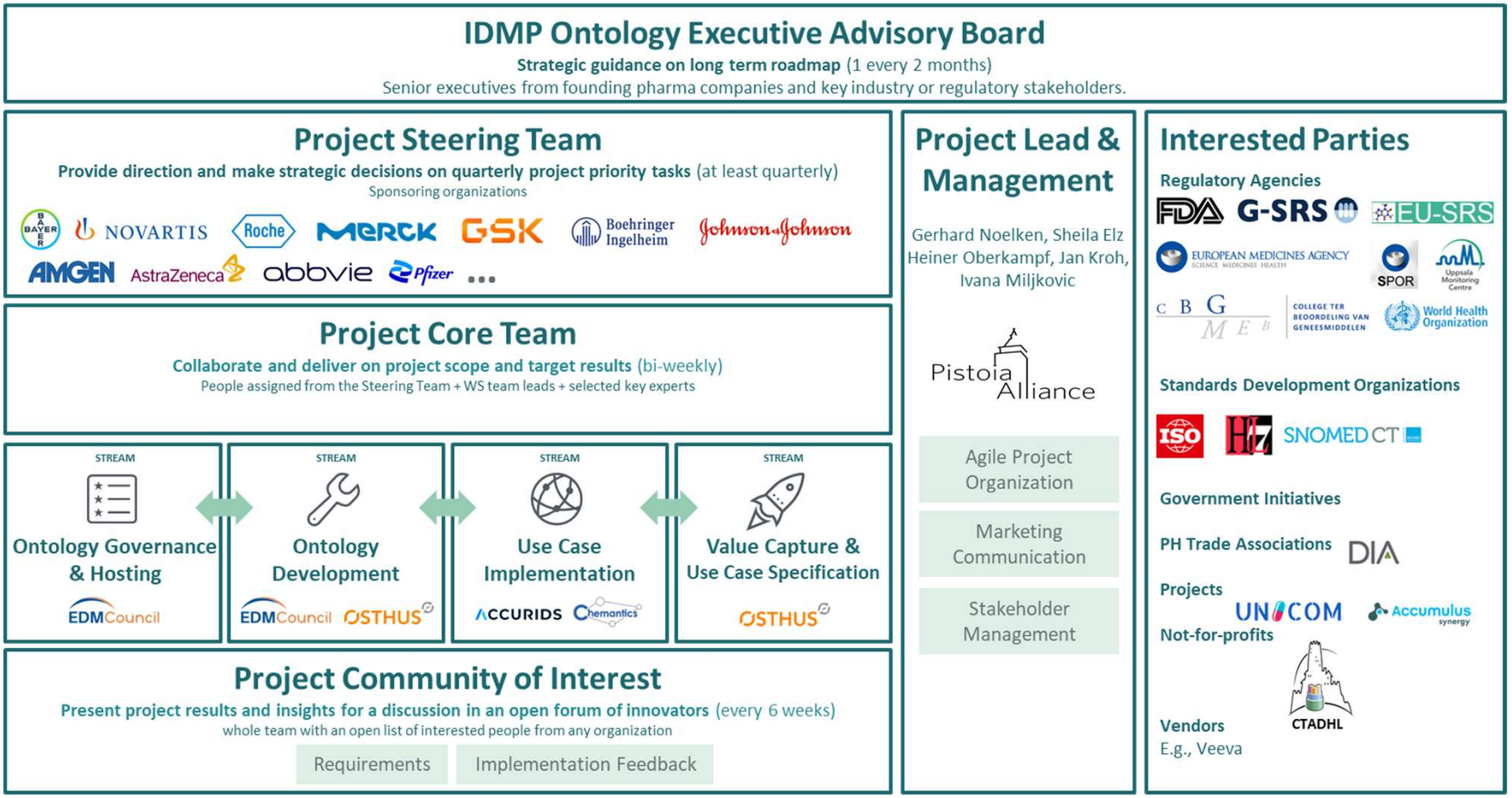


ISO IDMP Standards

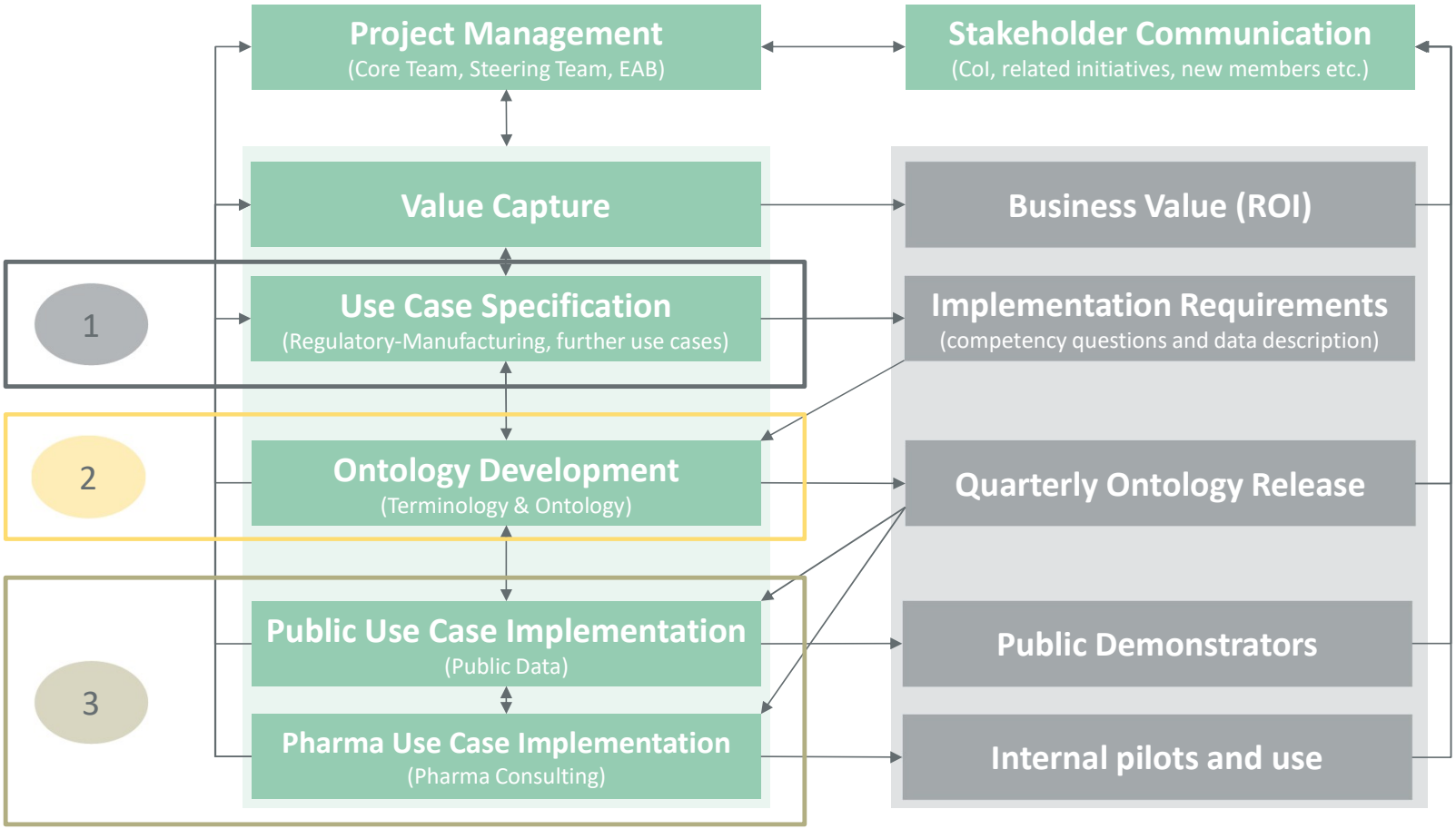


Collaborative implementation creates interoperability by design

Our agile governance framework ensures effective industry alignment.



Main Work Streams and Deliverables

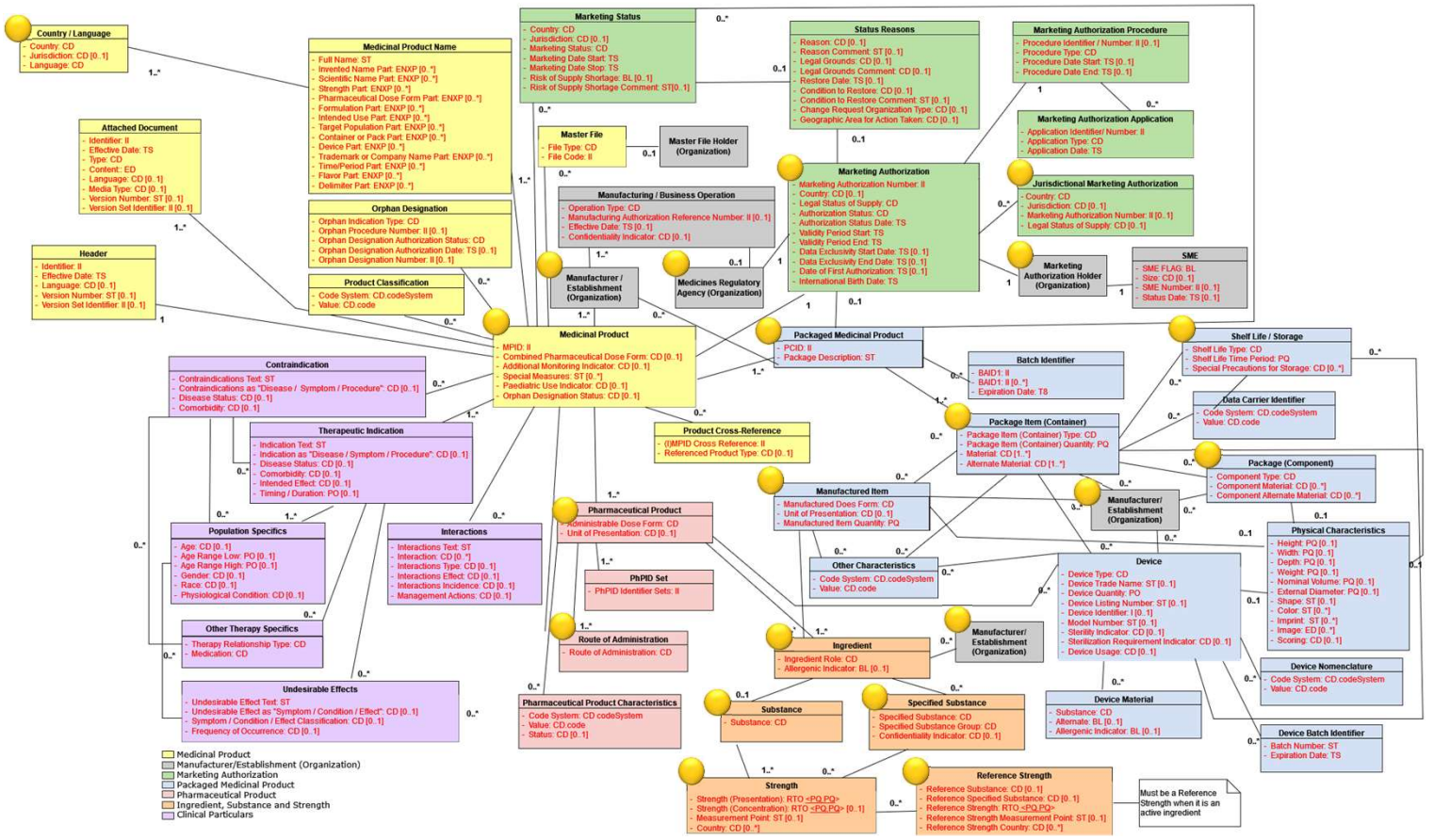


Collaboration is aligned in agile meetings within a 2 week sprint cycle

UC = Use Case
CQ = Competency Question
EAB = Executive Advisory Board

Deliverable Workstream

Use Cases relate and cover to the IDMP Data Model



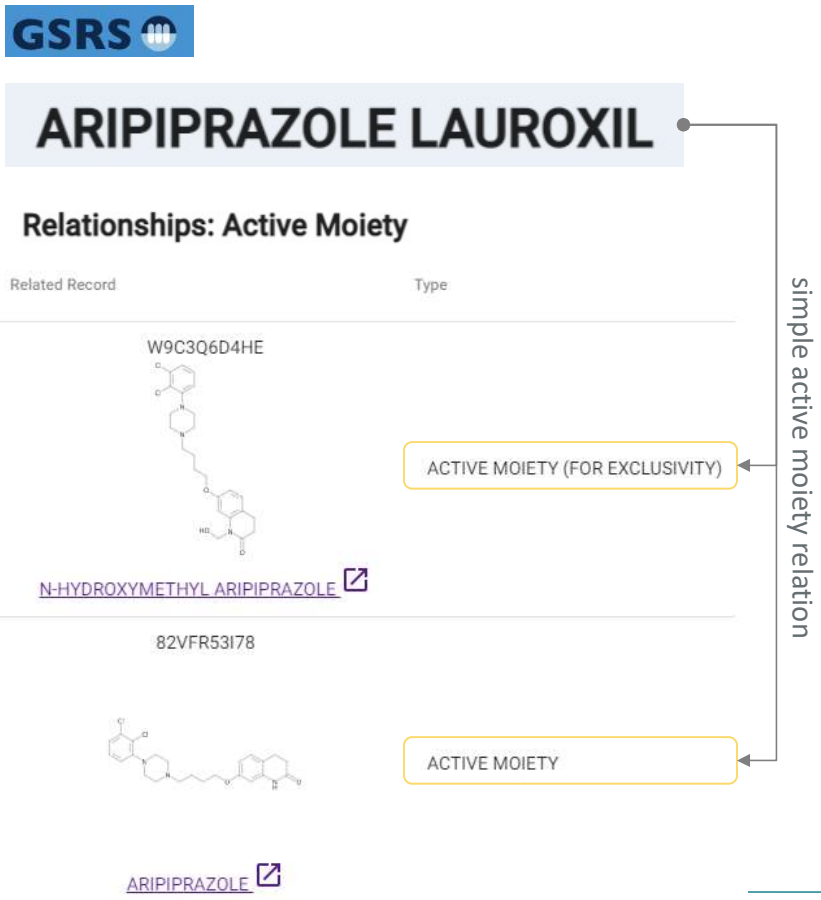
- **Ongoing Work**

  Iteratively covering the ISO standards
  - *UC1: Substance*
  - *UC2: Reg-Manuf.*
  - *…*

ID Competency Question

ID	Competency Question	
UC1-CQ1	Which substances have the common active moiety <X>?	CQs from MVP Phase (refinements)
UC1-CQ2	What is the active moiety of substance <X>?	
UC1-CQ3	What are the products that contain substances with common active moiety <X>?	
UC1-CQ3.1	What is the basis of strength for substance <S> in product <P>?	
UC1-CQ4	Which EV code (future SMS code) does the substance <S> have?	
UC1-CQ4.1	In addition to CQ4: What FDA UNII code, ATC Codes, ... Does the substance <S> have?	
UC1-CQ5	In which clinical trials were the authorized medicinal products <P> administered?	
UC1-CQ6	Which investigational/authorized medicinal products contain the substance <S> or its active moiety <M> or any other substance related to active moiety <M>?	
UC1-CQ7	Which manufactured items contain substance <S> as an ingredient of type “active”?	
UC1-CQ8	Which investigational medicinal products are related to manufactured item <M>?	
UC1-CQ9	What is the molecular structure of substance <S>?	Further substance CQs (ongoing)
UC1-CQ10	Are two substances <A> and <B> the same? If not, what is their relationship, if any?	
UC1-CQ11	What is the non-salt, non-hydrated, non-ester form of substance S? (aka: What is the parent substance of substance <S>?)	
UC2-CQ1.1	In which manufactured item is substance <S> used?	Phase 2: 2023-Q1 Scope (ongoing)
UC2-CQ1.1a	In which substances (active, excipient, packaging materials etc.) is substance <S> found?	
UC2-CQ1.1b	In which (Global) SKUs is substance <S> used?	
UC2-CQ1.1c	In which materials (package item (container) constituent) is substance <S> used?	
UC2-CQ1.1d	In which packaging is substance <S> used?	
UC2-CQ1.2	In which production/manufacturing steps is substance <S> used?	
UC2-CQ2.1	Which Marketing Authorization Number(s) does a sellable article (Material in ERP) have?	
UC2-CQ2.2	Which marketing authorization does this supply material <M> relate to?	

Ontology Modeling Example: accurate representation of active moiety



ISO-11238 Definition (Substance)

moiety = "Entity within a substance that has a complete and continuous molecular structure"

"The **active moiety** of a stoichiometric or non-stoichiometrical substance molecule is considered that part of the molecule that is the base, free acid or ion molecular part of a salt, solvate, chelate, clathrate, molecular complex or ester."

Challenges in accurately modelling (active) moiety

- **The term "active" moiety leads to confusion** -> many parts of a substance can have some pharmacological or physiological impact.
- **Moieties cannot be classified as "active" without context** -> the same molecule can be "active" as part of one substance and "not active" in another.

Finding

Active moiety concept (aka 'parent substance') is different in different organizations or even within one organization. This requires **specifying roles and contexts correctly**, e.g. regulatory, chemical, biological..

2

Ontology Modeling Example: Interoperability between Regulatory with Manufacturing

GSK: Remove HSA from all **manufacturing steps of Varicella vaccine**

Novartis: Remove a toxic/restricted substance - Identify all manufacturing processes containing a potential source of Nitrosamine or Titanium dioxide

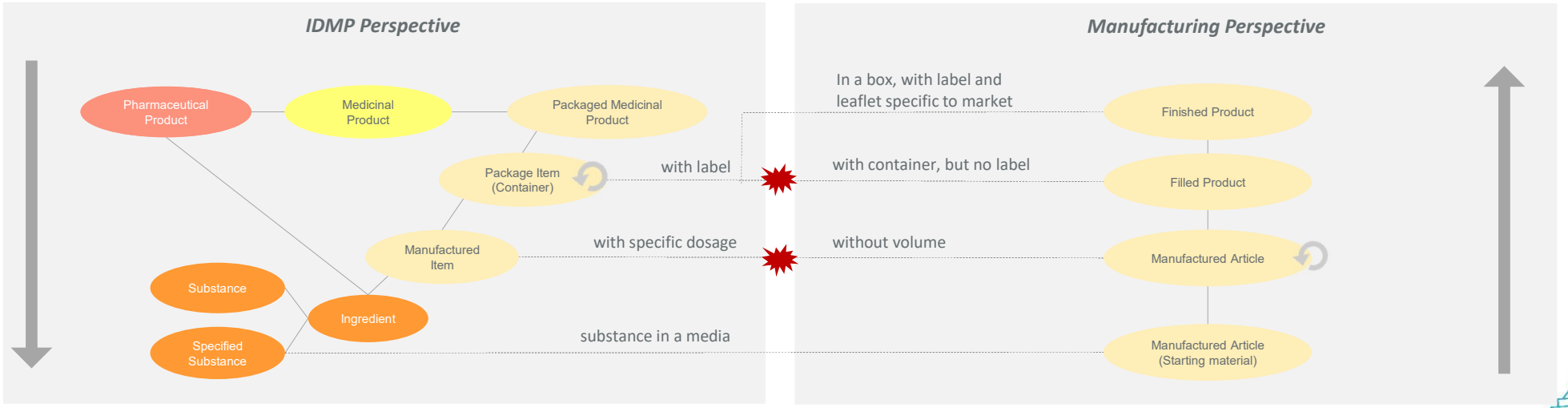
Bayer: A supplier gets replaced – identify which substances are procured from this supplier and in which products these are used, to access impact

Roche/J&J/Merck/…: Enable **back traceability** from late product lifecycle stages back to the earliest molecule stages

IDMP Ontology

IDMP ISO Standards

Enrichment of ISO Standards to define **standardized concise** definitions needed to create a **bridge to the Manufacturing domain**



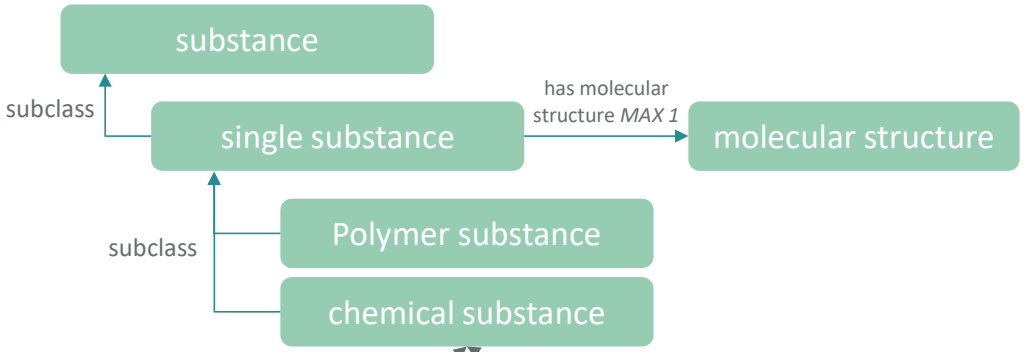
IDMP Knowledge Graph: IDMP Ontology + IDMP Data Graph

Testing the ontology along concrete use cases and data

IDMP Ontology

Formal semantic definition of concepts, relationships and attributes from the ISO IDMP standards.

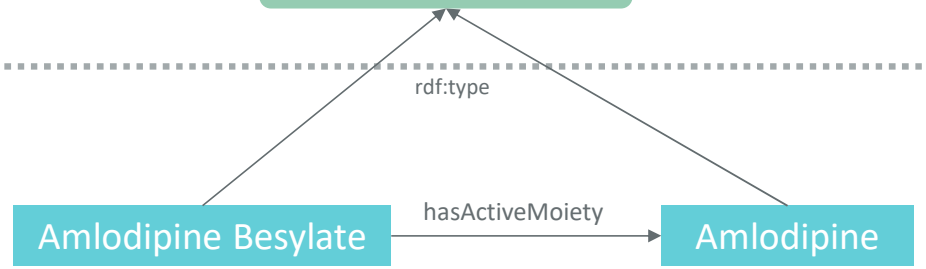
→ A few hundred concepts
→ Need accurate and agreed patterns



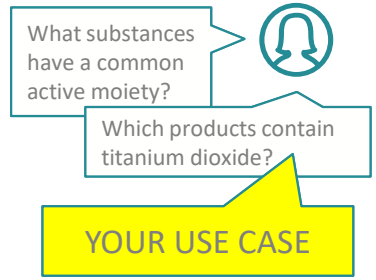
IDMP Data Graph

Any data object that are described by the concepts of the IDMP Ontology

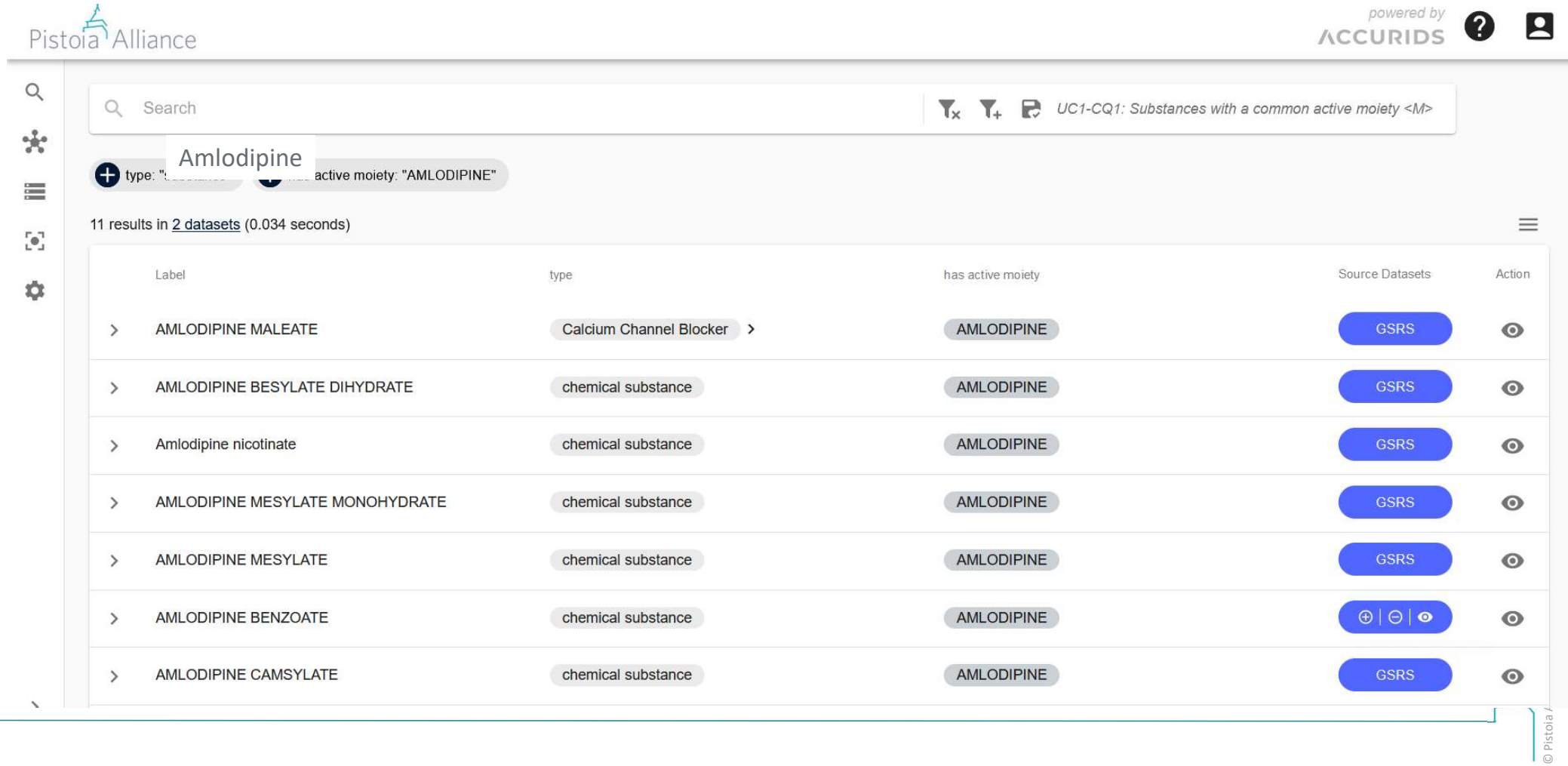
→ Many millions of objects
→ Our test data



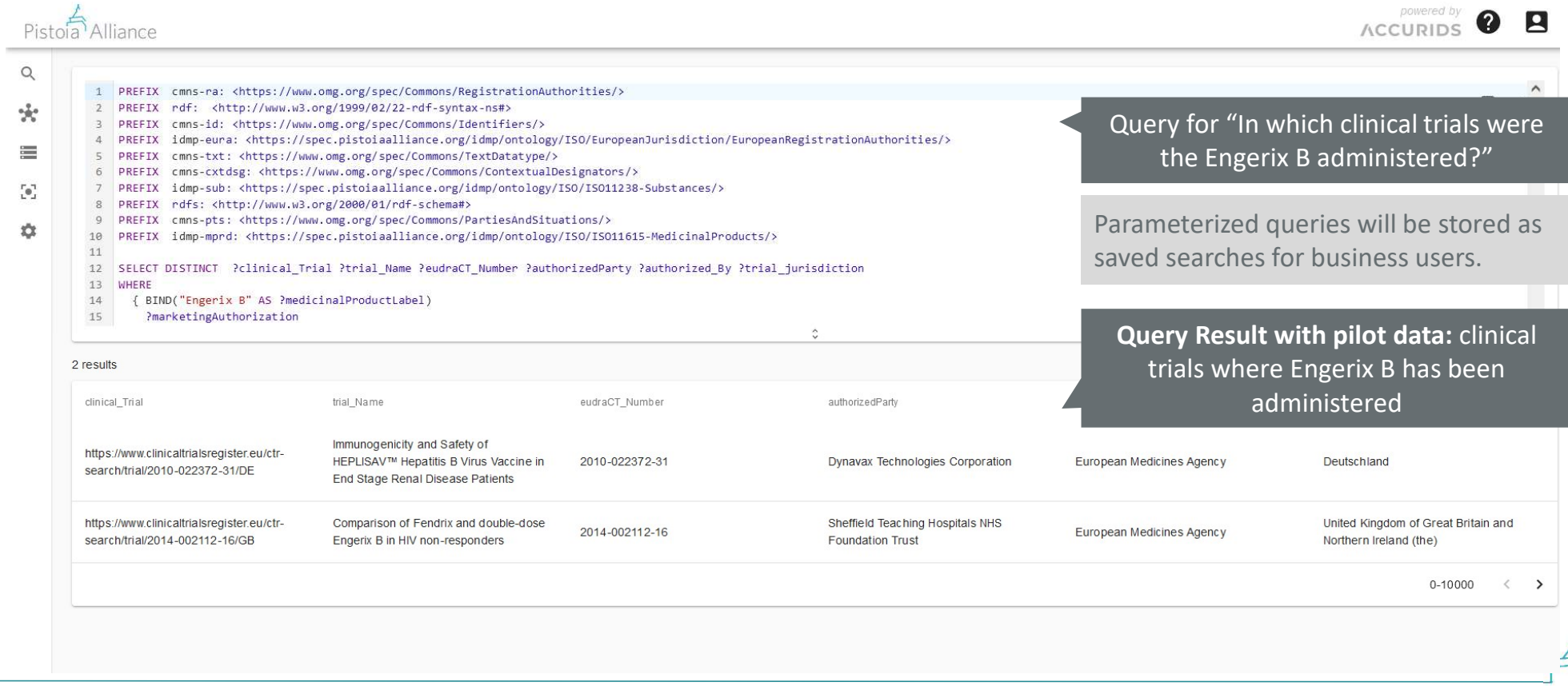
Enable business users to answer questions



Demo: Give me all substances with a common active moiety Amlodipine

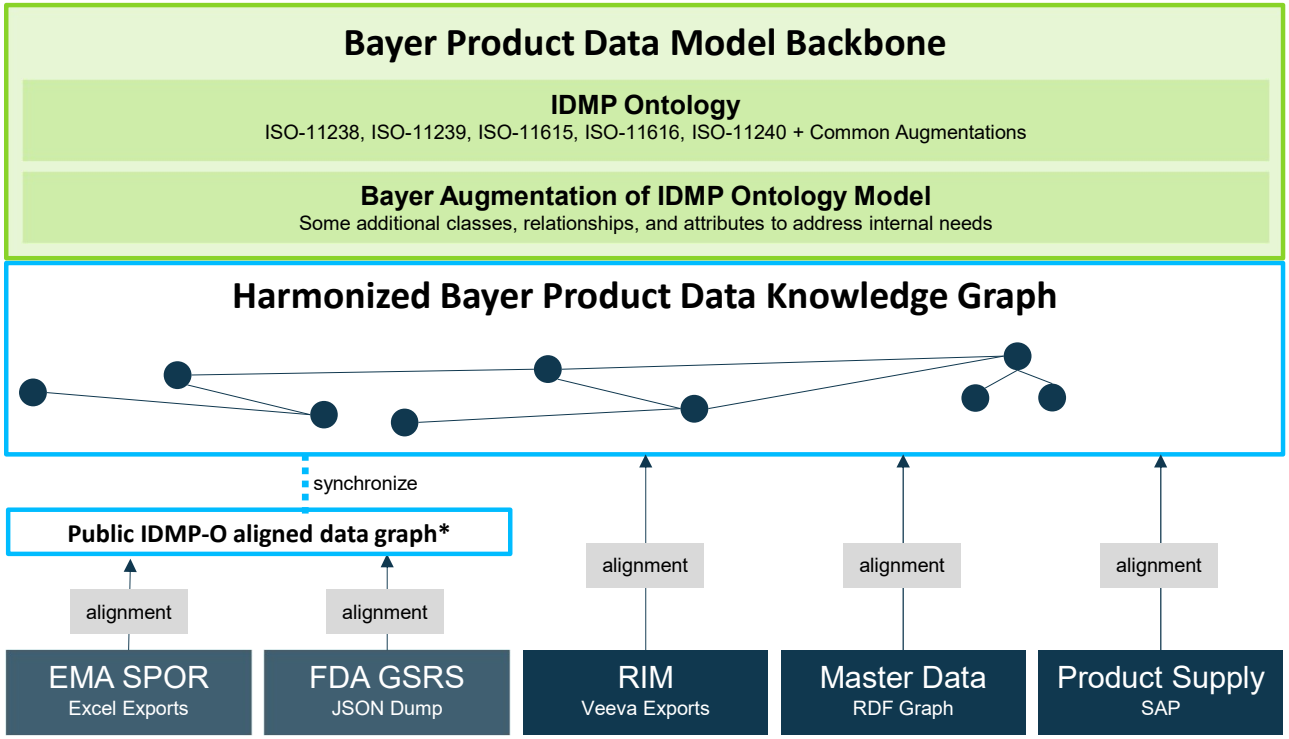


Demo: In which clinical trials were the registered products administered?



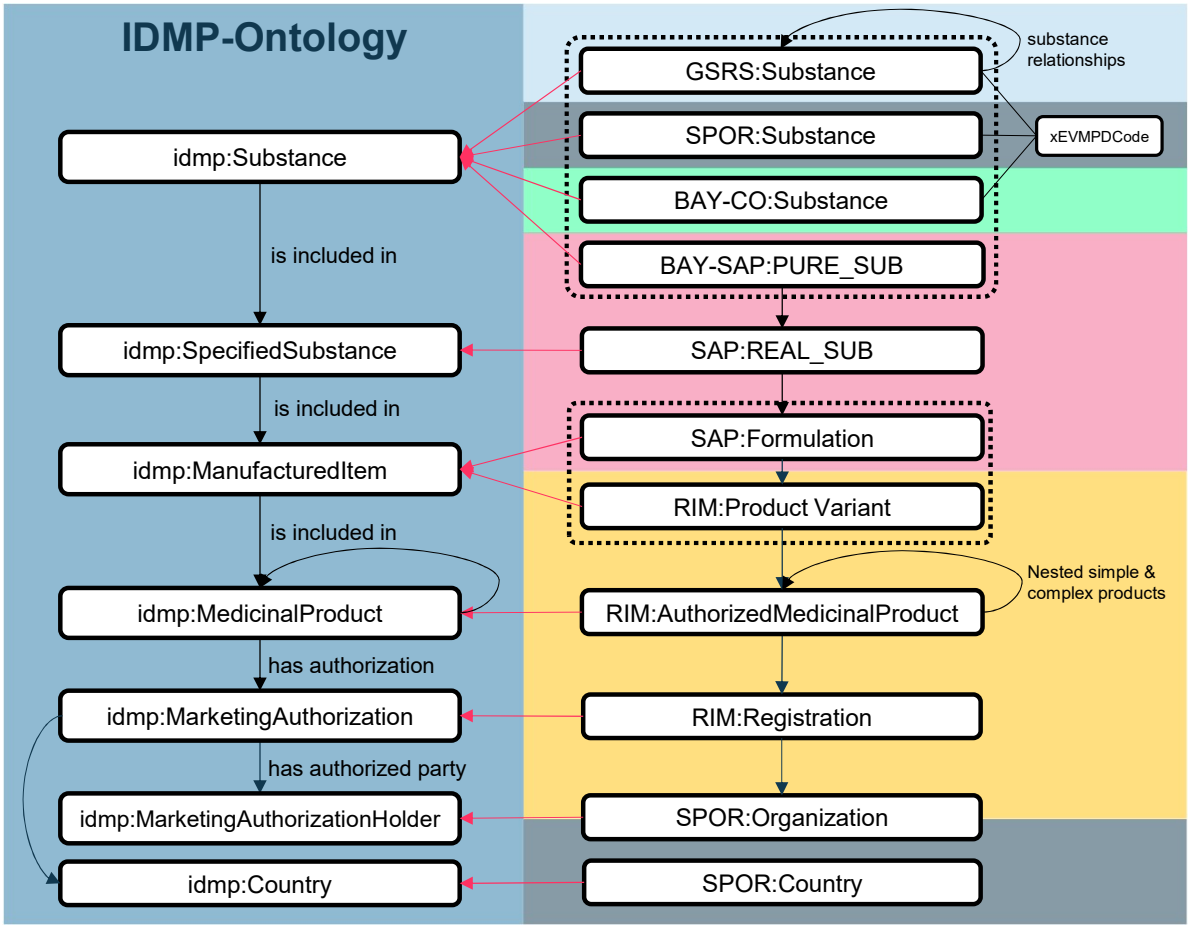
Pilot Implementation Setup for initial Feasibility Assessments

Business question: “Which products contain titanium dioxide and where are these products registered?”



* Accurids hosted instance available at https://pistoiaalliance.dev.accurids.com/

Alignment to IDMP Ontology Concepts

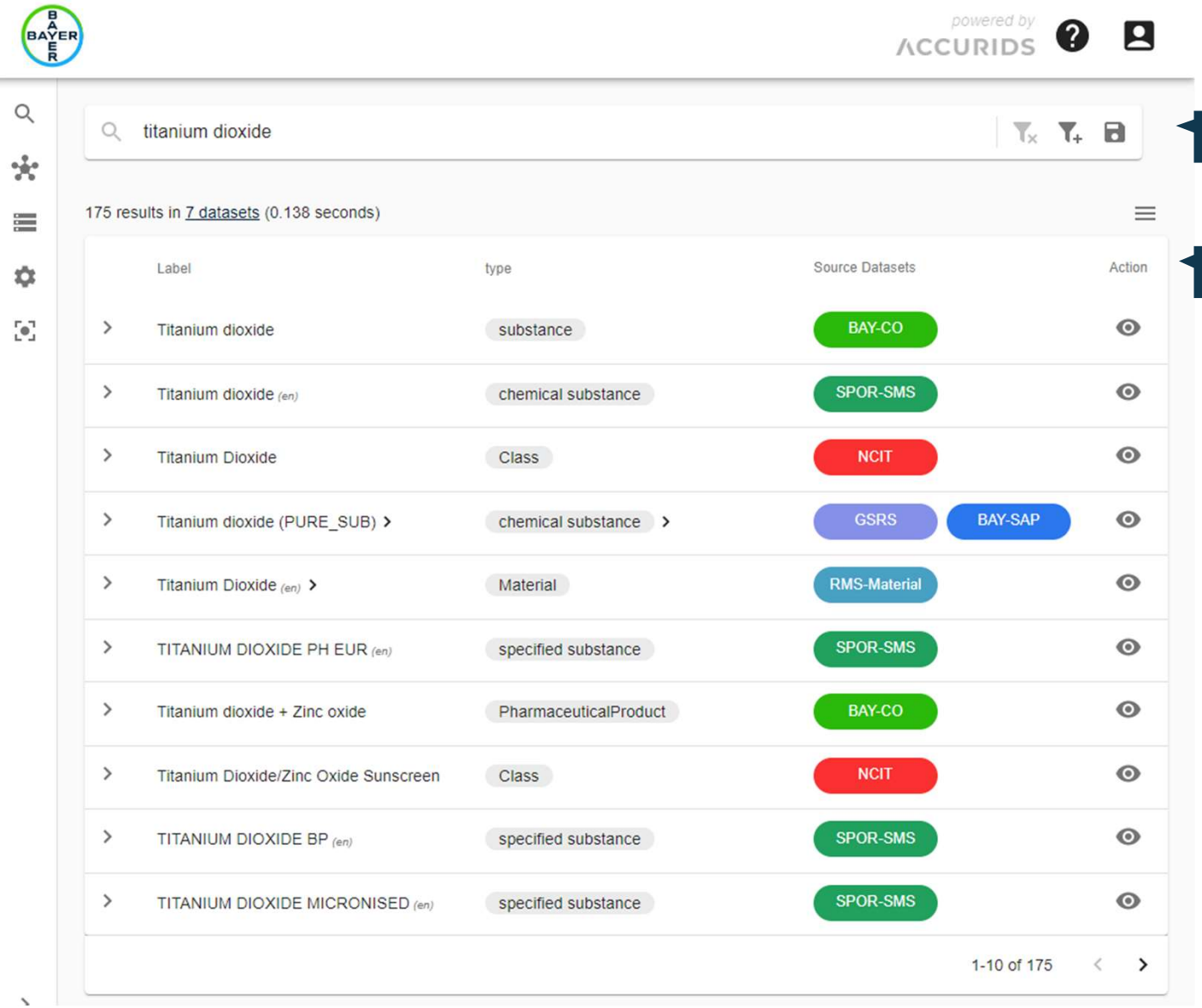


Business Questions:

- "In which manufactured items is titanium dioxide used?" (UC2-CQ1a)
- "In which medicinal products is substance "titanium dioxide (xEVMPD:SUB12611MIG) used, and where are they registered?"
- …

FDA: GSRS
EMA: SPOR & xEVMPD
Bayer: Compound Ontology & Master Data
Bayer: SAP
Bayer: RIM
IDMP Ontology

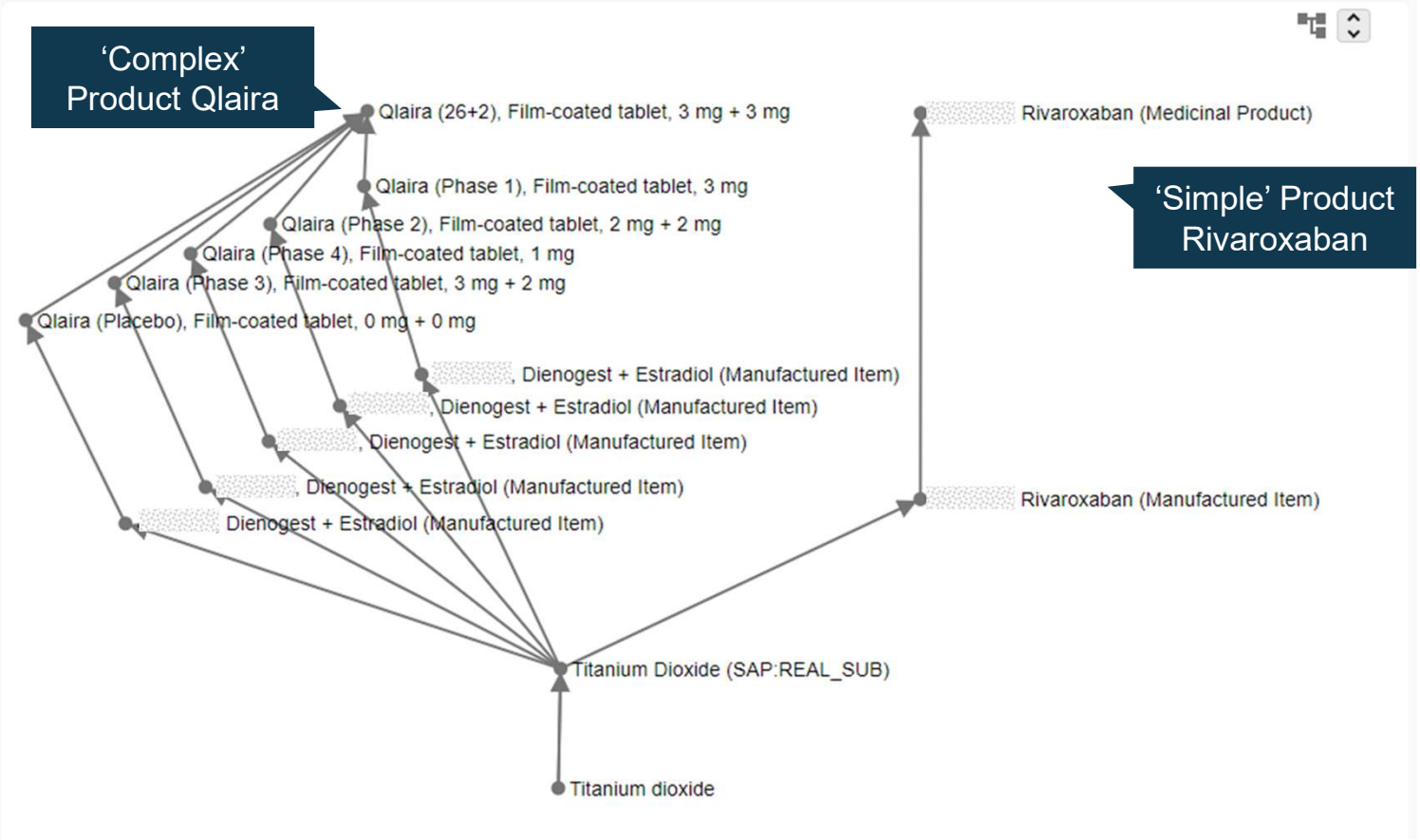
Cluster Object
Alignment source-target
Object relationship

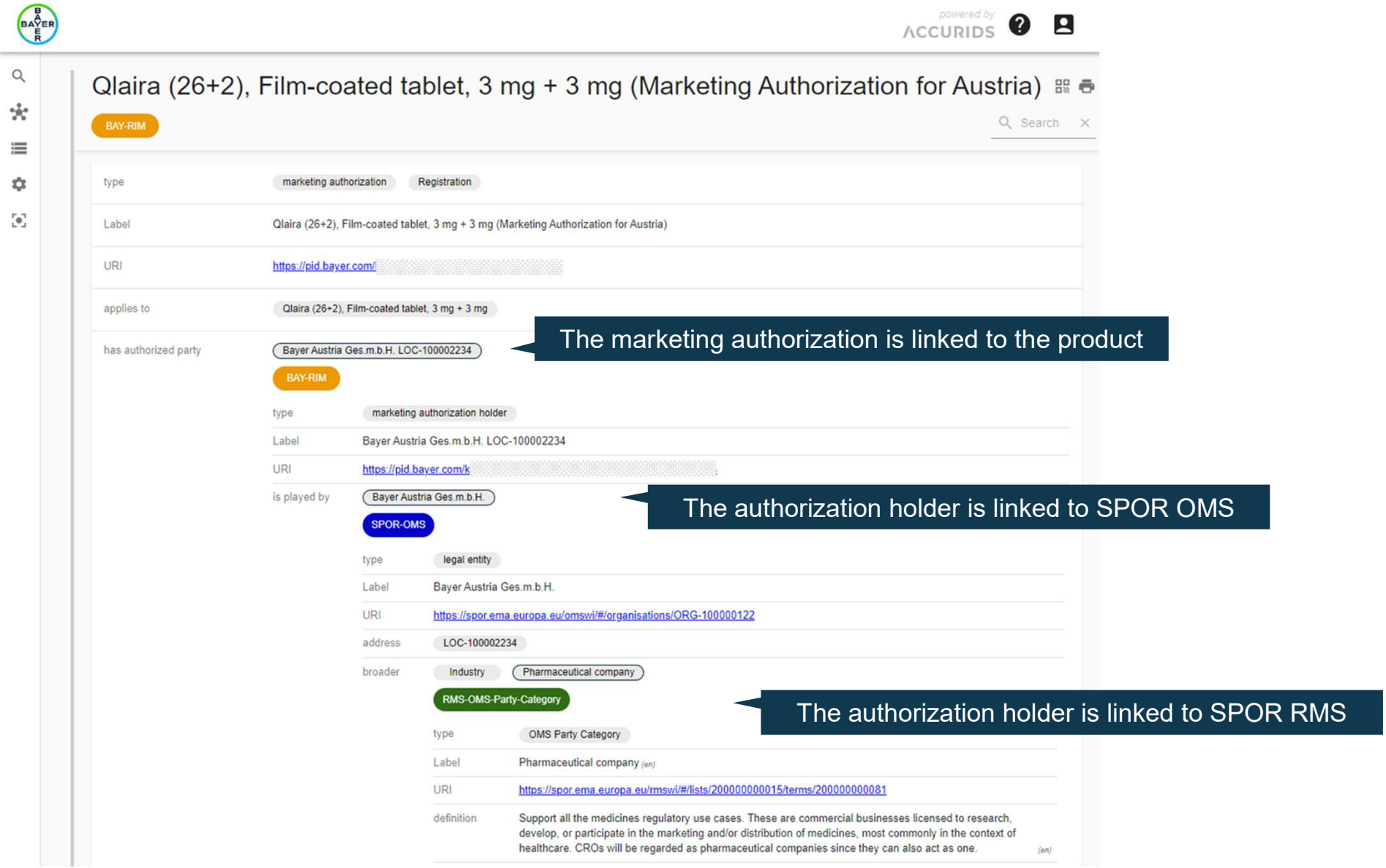


Search for “titanium dioxide“

Found 175 entities in 7 data sets

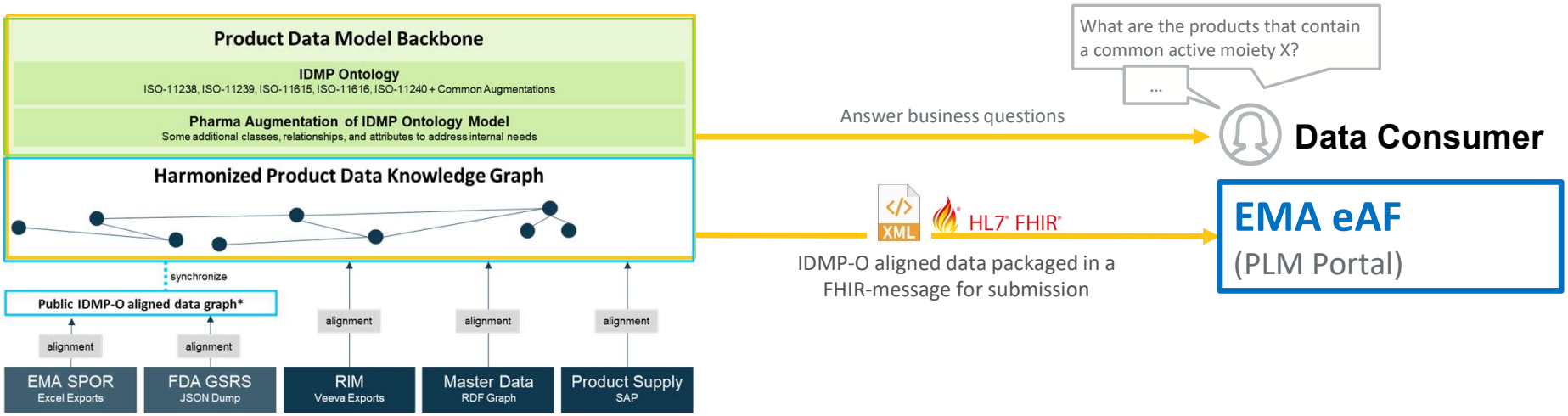
isIncludedIn




powered by ACCURIDS
Qlaira (26+2), Film-coated tablet, 3 mg + 3 mg (Marketing Authorization for Austria)
BAY-RIM
Search
type
marketing authorization
Registration
Label
Qlaira (26+2), Film-coated tablet, 3 mg + 3 mg (Marketing Authorization for Austria)
URI
https://pid.bayer.com/
applies to
Qlaira (26+2), Film-coated tablet, 3 mg + 3 mg
has authorized party
Bayer Austria Ges.m.b.H. LOC-100002234
BAY-RIM
type
marketing authorization holder
Label
Bayer Austria Ges.m.b.H. LOC-100002234
URI
https://pid.bayer.com/k
is played by
Bayer Austria Ges.m.b.H.
SPOR-OMS
type
legal entity
Label
Bayer Austria Ges.m.b.H.
URI
https://spor.ema.europa.eu/omswi/#/organisations/ORG-100000122
address
LOC-100002234
broader
Industry
Pharmaceutical company
RMS-OMS-Party-Category
type
OMS Party Category
Label
Pharmaceutical company (en)
URI
https://spor.ema.europa.eu/rmswi/#/lists/200000000015/terms/200000000081
definition
Support all the medicines regulatory use cases. These are commercial businesses licensed to research, develop, or participate in the marketing and/or distribution of medicines, most commonly in the context of healthcare. CROs will be regarded as pharmaceutical companies since they can also act as one.
(en)
The marketing authorization is linked to the product
The authorization holder is linked to SPOR OMS
The authorization holder is linked to SPOR RMS

Outlook

Enable semi-automated creation of FHIR messages for submissions



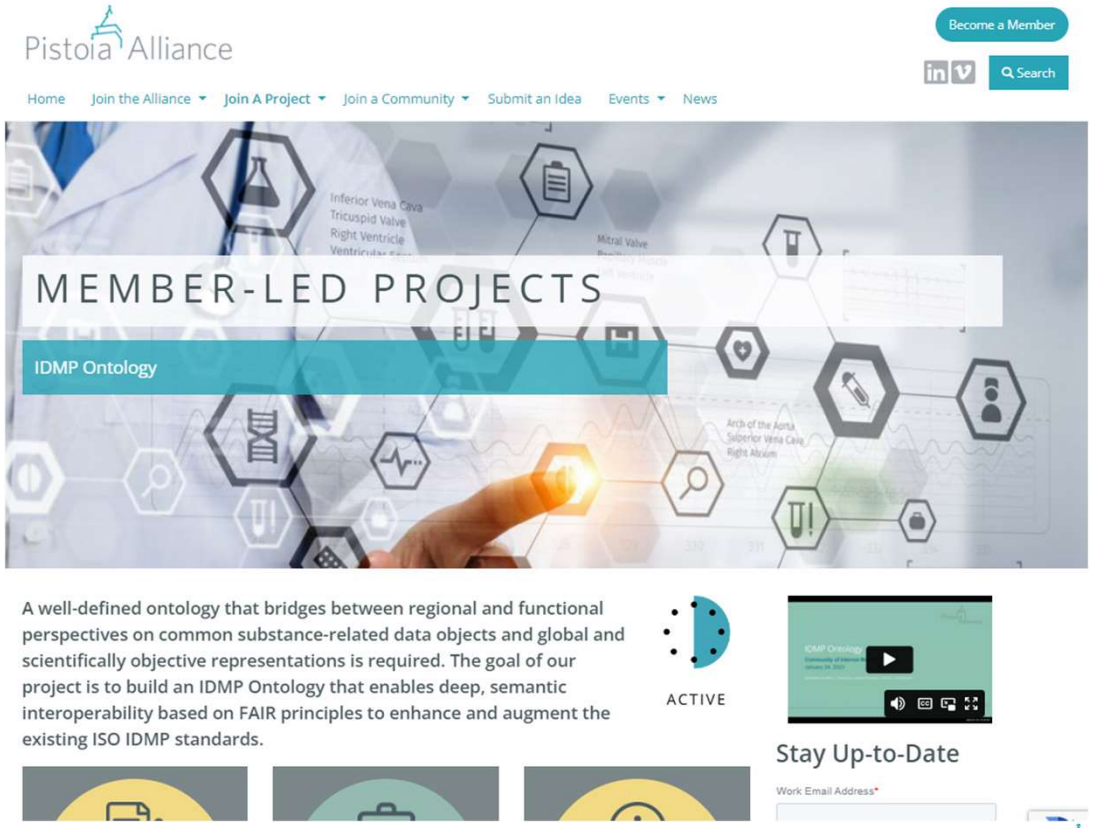
Getting Started with the IDMP Ontology

Visit the Project Website:

https://www.pistoiaalliance.org/projects/current-projects/idmp-ontology/

Rafail Kasapis, OTSHUS GmbH
rafail.kasapis@osthus.com

Gerhard Noelken, Pistoia Alliance
gerhard.noelken@pistoiaalliance.org



14. Perspectives on FHIR (Part 2 – European Projects)

Bente By Jansen Felleskatalogen

Christel Daniel, Assistance Publique – Hôpitaux de Paris (remote) + Nicolas Riss, French National Agency of Digital Health (ANS), Chair HL7 France

Ben McAlister, Oracle, Chair HL7 UK

Rafail Kasapis, OSTHUS GmbH – a PharmaLex Company

Michael Muzoora, Berlin Institute of Health + Marco Schaarschmidt, Berlin Institute of Health

Luc Nicolas, UNICOM

11:00 – 12:30

The smart hospital - where are we today, where is our near future?

Marco Schaarschmidt & Michael Rusongoza Muzoora - Representing Prof. Dr. med. Dipl.-Ing. Sylvia Thun

Paris 2023

EuroVulcan Conference

Berlin Institute of Health @Charité

BIH @ CHARITÉ

Our Mission: Translation!

The mission of the BIH is medical translation: The BIH aims to translate findings from biomedical research into new approaches for personalised prediction, prevention and therapy and, conversely, to develop new research approaches from clinical observations.

WORLD HEALTH SUMMIT 2022 | OCTOBER 16-18 BERLIN, GERMANY & DIGITAL

CHARITÉ UNIVERSITÄTSMEDIZIN BERLIN

17,615 Charité employees, including
68 percent women | 32 percent men
employees from 119 countries, 3001 beds

- total revenues 2021: € 2.3 billion
- financial result 2021: € 7.8 million

BIH Berlin Institute of Health @Charité

A SMART HOSPITAL

facilitates decision-making based on data-driven insights

Money-centered

Analog

Communication Servers

FAX

Administrative

Data Black Box

Slow

HIS

EHR

Patient Centered

Transparent

Technology-driven

Fast/Smart/Agile

Data Driven: AI

Empathic

Precise & Accurate

Today → Tomorrow

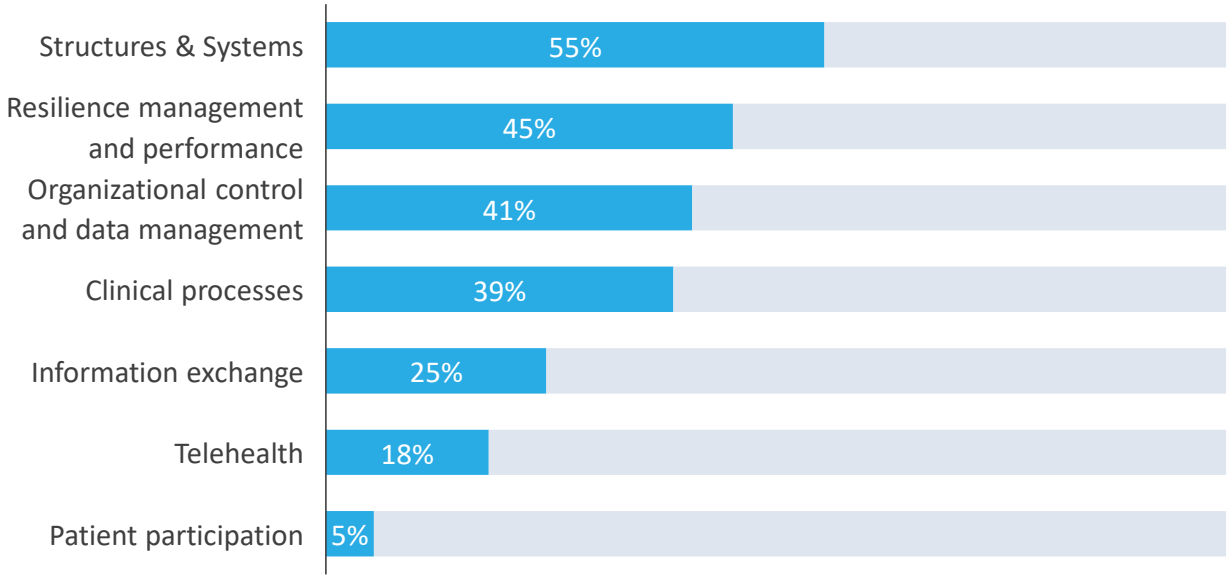
BIH Berlin Institute of Health @Charité

DigitalRadar Hospital

Bundesministerium für Gesundheit

DigitalRadar

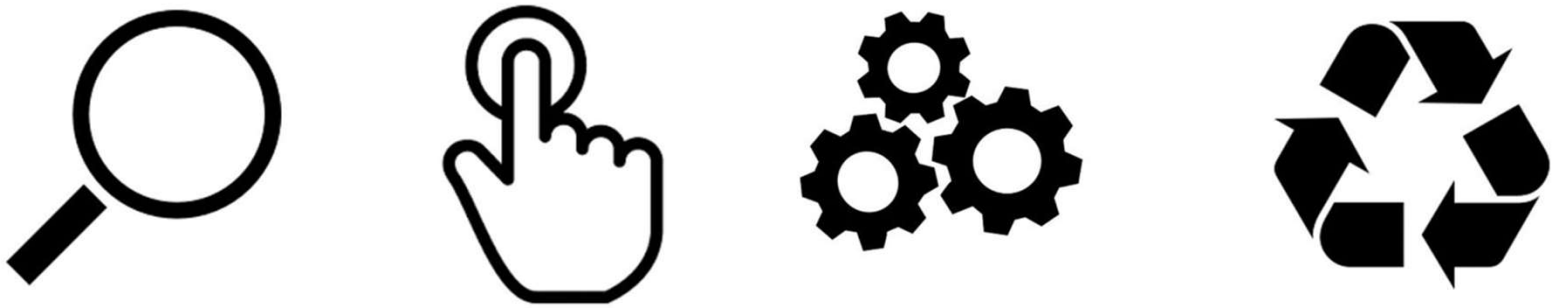
Mean points achieved by dimension in %.



BIH Berlin Institute of Health @Charité

Medical decision making is the most complex task done still by human, experience and art

Findable Accessible Interoperable Reusable

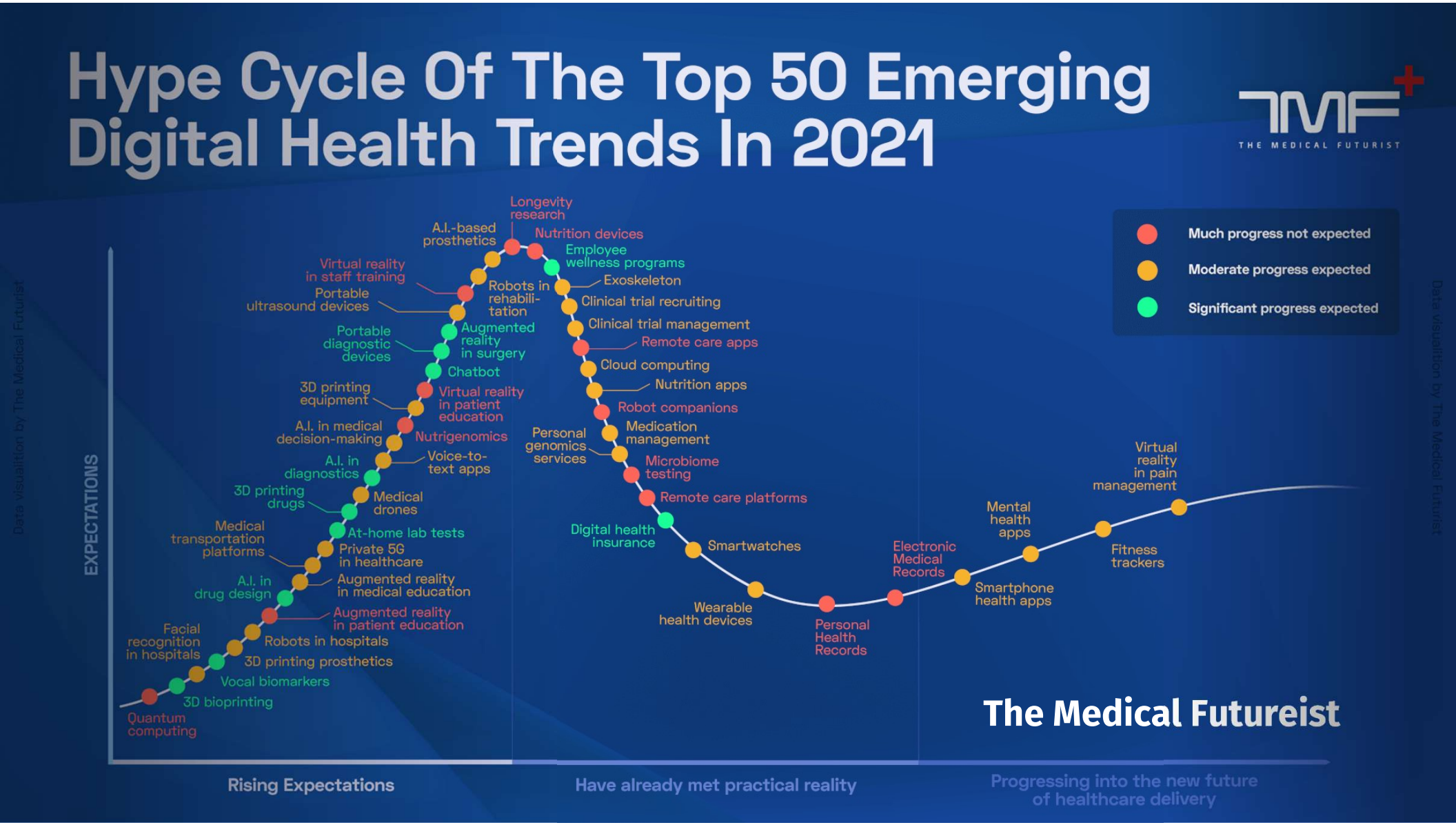


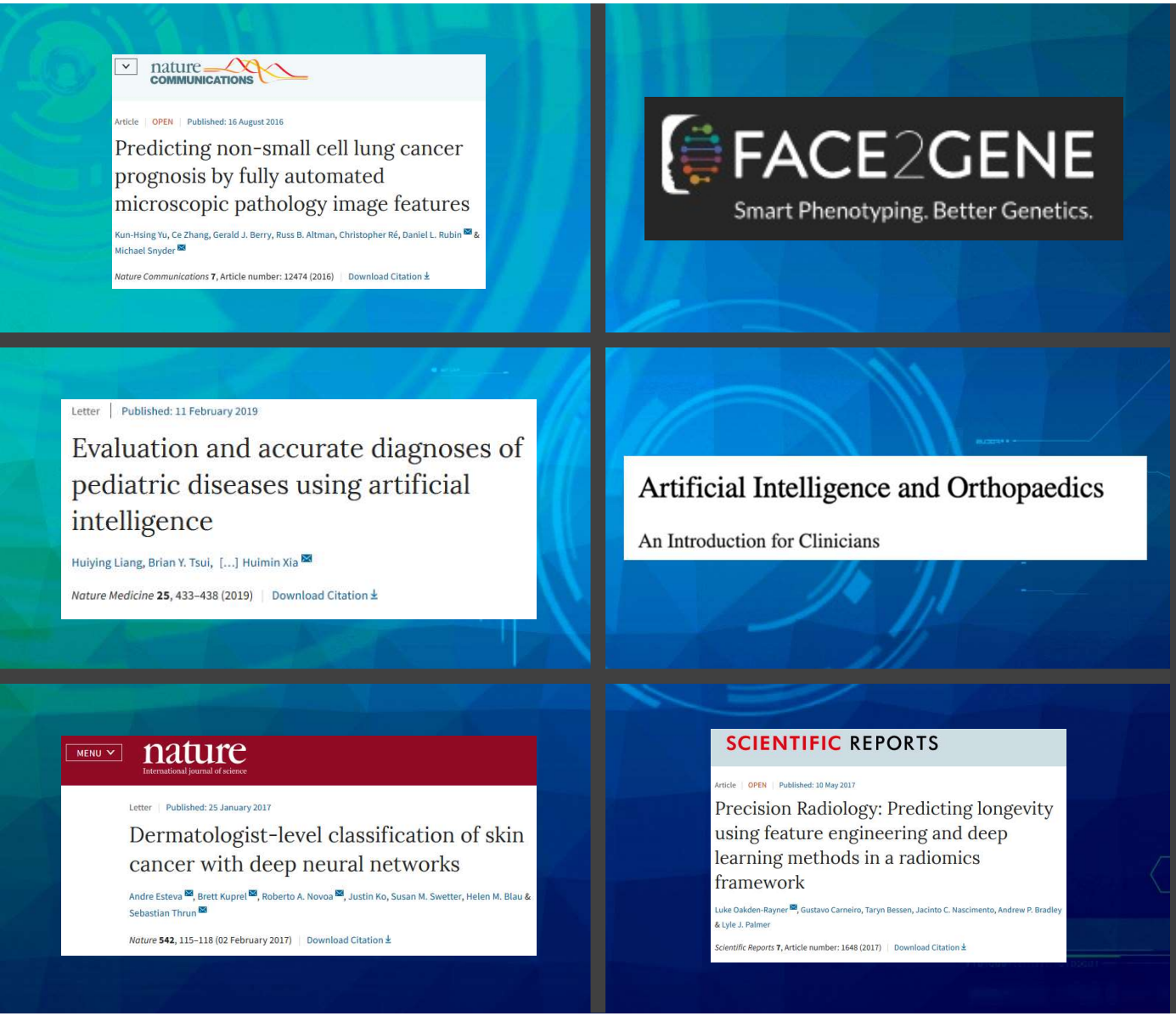
BIH Berlin Institute of Health @Charité

FUTURE

The Enabler: Digitalization

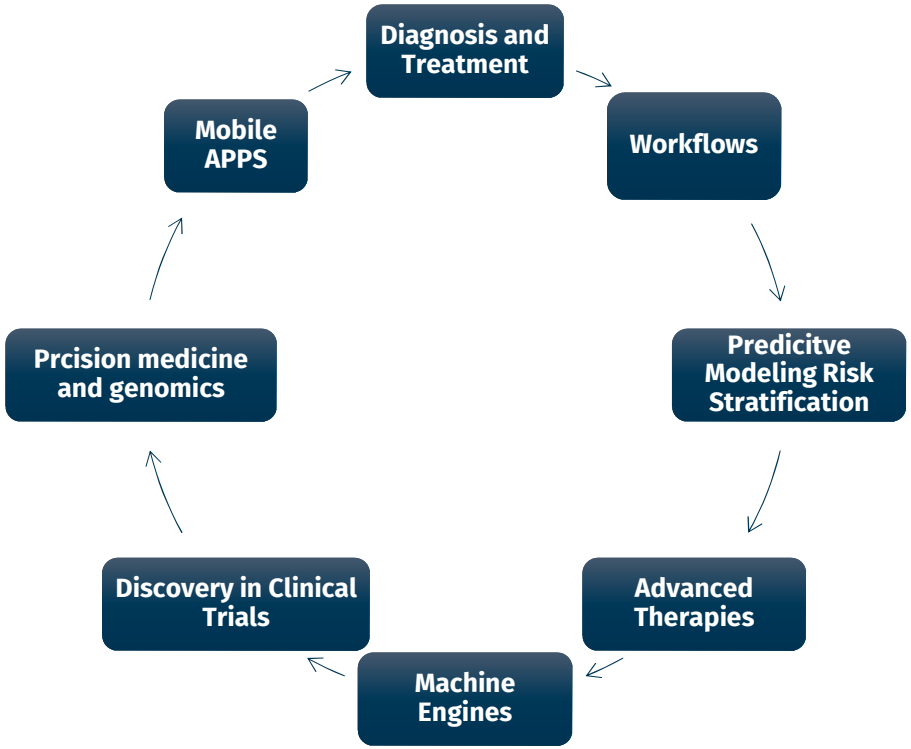
Hype Cycle Of The Top 50 Emerging Digital Health Trends In 2021





AI (Machine Learning, Deep Learning), Data Analytics in Medicine

Applications of AI in Healthcare



Digital Medicine Depends on Interoperability

AI and Big Data

- provides algorithms with clear data structure and semantics
- ensures validity of results
- creates trust in digital technologies

Communication

- Enables information exchange
- prevents errors due to communication barriers
- reduces documentation effort
- Patient empowerment

Research

- Use of real-world data
- Generation of new research hypotheses (with data mining and AI)
- Facilitates remote data processing

International cooperation

- Linking of data across organizations (e.g. rare diseases, precision medicine)
- global coordination in public health (e.g. infection control, epidemics)
- Global availability of new technologies

Lehne M, Sass J, Essenwanger A, Schepers J, Thun S (2019). Why digital medicine depends on interoperability. *npj Digital Medicine*.

BIH Berlin Institute of Health @Charité

Semantic Interoperability

Tower of Babel

Source: Wikipedia

Semantic

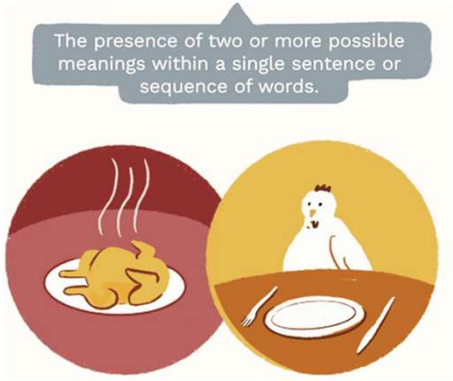
Source: latimes

Syntactic

Lexical ambiguity

"I saw her duck"

Syntactic ambiguity



"The chicken is ready to eat"

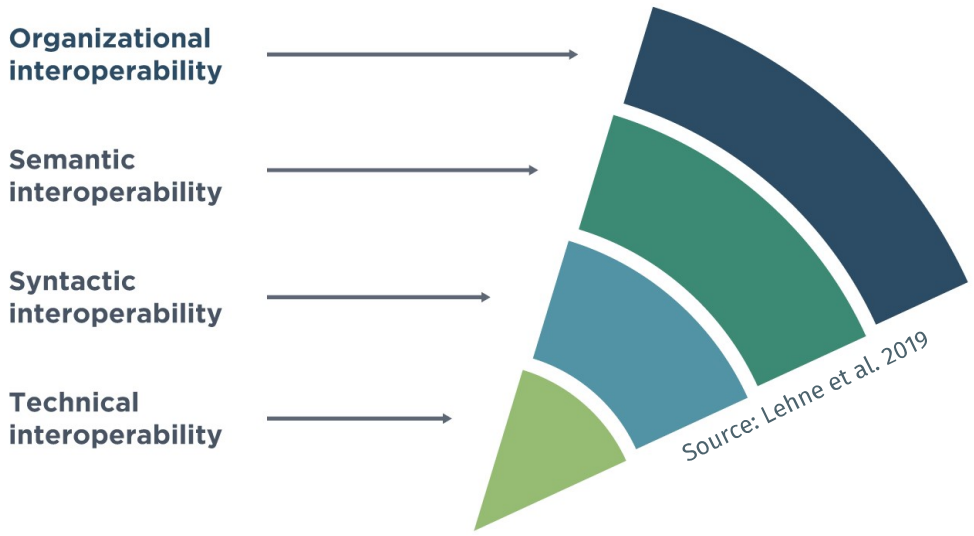
Source: ThoughtCo

BIH Berlin Institute of Health @Charité

Interoperability

“ the ability of two or more systems or components to exchange information and to use the information that has been exchanged ”

IEEE Std 610 1–217 (1991)



BIH Berlin Institute of Health @Charité

EHR 2.0 and Medical Information Objects (MIO)

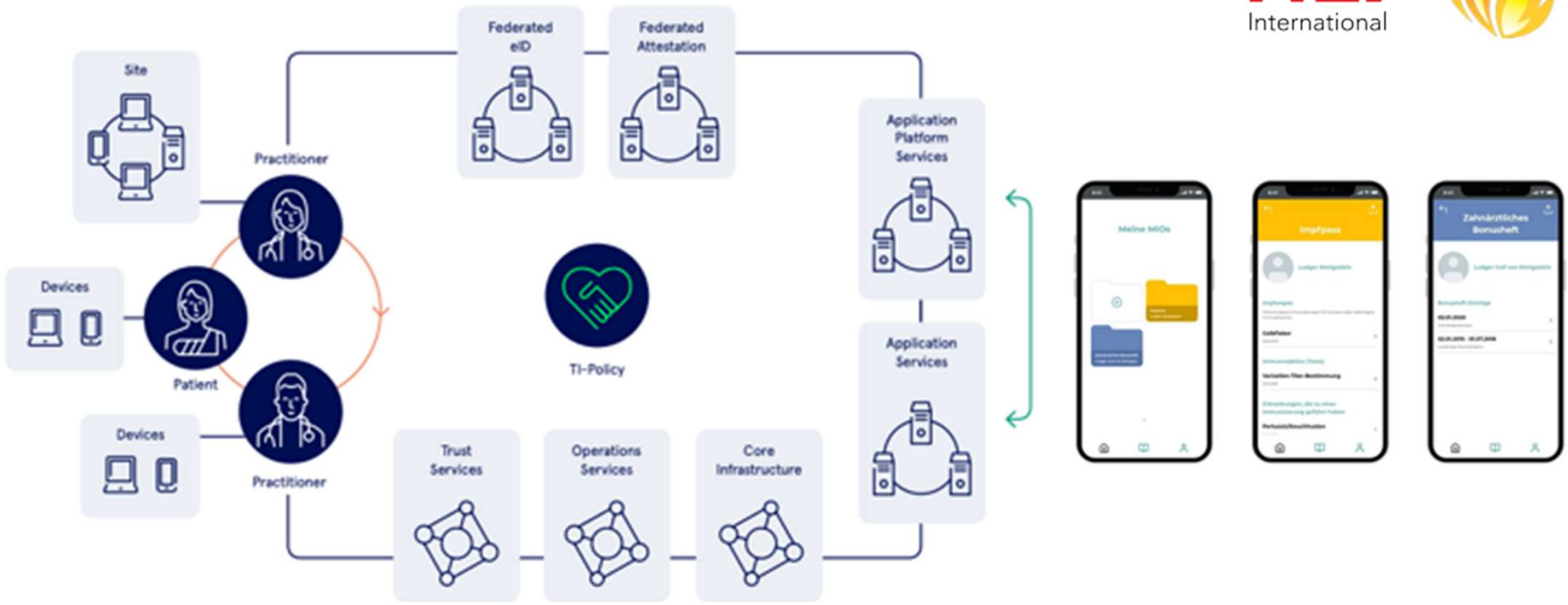
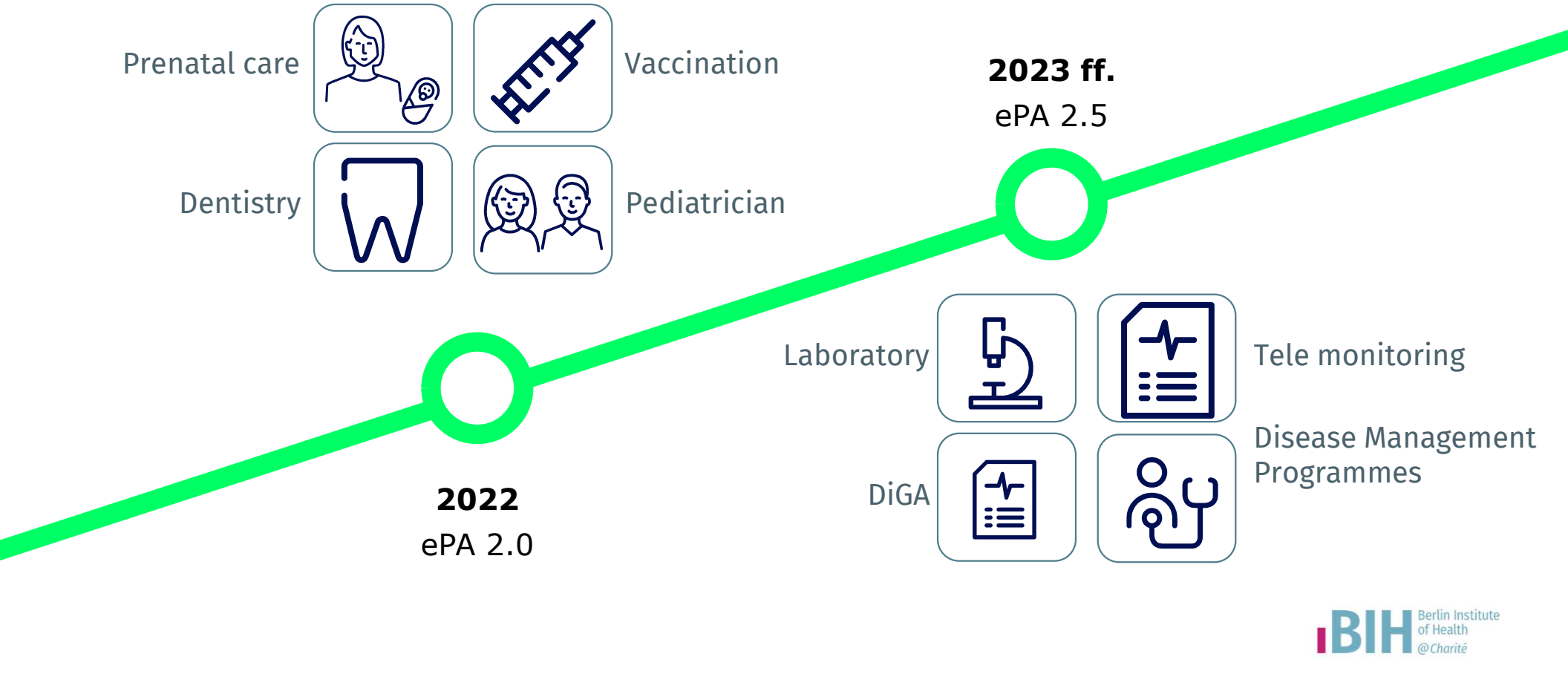


Abbildung 3 – Gesamtbild der Architektur der TI 2.0

Document standardisation using SNOMED CT and FHIR (MIO)



BIH Berlin Institute of Health @Charité

gematik

Gematik & Gematik Infrastructure in Germany

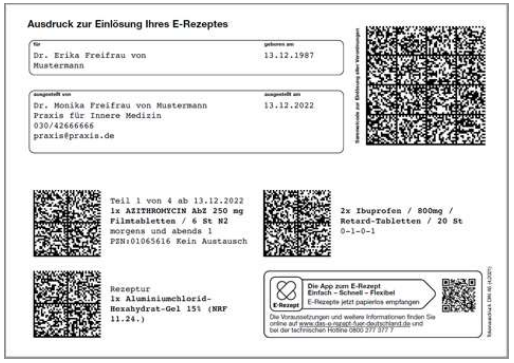
ePrescription

HL7® FHIR®

ePrescription and patient app

- In the medium term: **standard route** for transmission to the pharmacy
- **No printout** in the practice: patient manages prescription independently
- **Direct added value** for patients in the administration of the ePrescription

ePrescription & Token-Printout



- Important scenario in the **introductory phase**
- Standard route for insured persons **without smartphone**
- **No doctor's signature**: no independent prescription

The "classic" paper Prescription

- **Only in certain cases** (e.g. home and Care home visits, technical problems).
- **No added value** for insured persons
- Processing by pharmacies and health insurance companies as before

BIH Berlin Institute of Health @Charité

KIM – „Communication in Medicine“

Secure email and data exchange

Secure communication between all institutions connected to the telematics infrastructure (TI)

APP

Suitable for applications/payloads such as eAU, eHKP, billing, laboratory data, findings, doctor's letters, DMP, etc.

First **nationwide and cross-sector** service
Out of the Box - **Authenticity, Integrity and Confidentiality**

Application register at gematik, overview of all KIM applications

kim

Successive **expansion of the user groups**

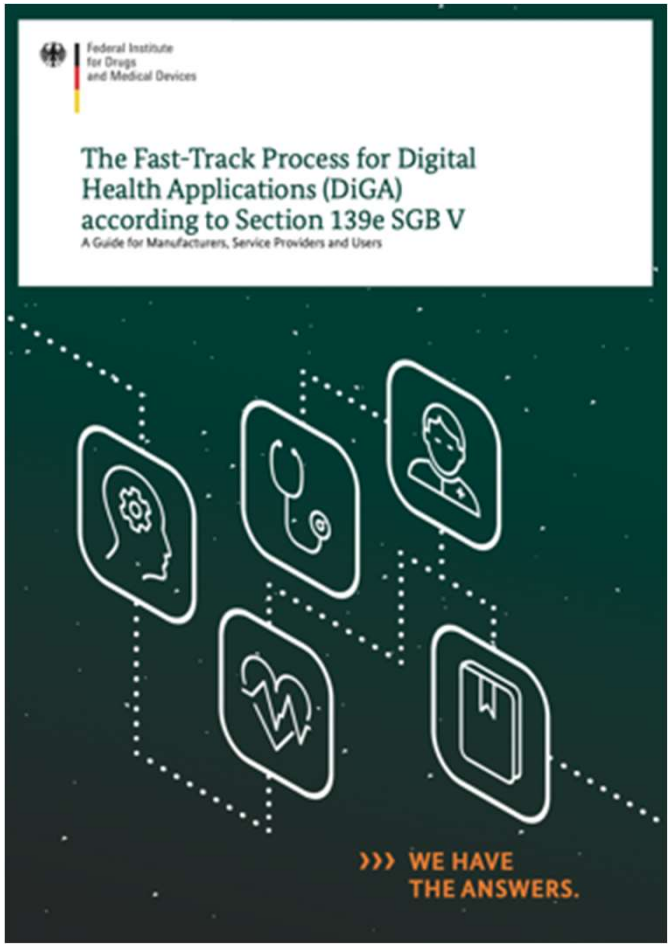
Sending confidential messages, data and other documents, protection of patient data

Potential through further specification development by gematik with **additional features**, e.g. file dispatch over 25 MB, primary system integration

Automation of workflows through service identification

BIH Berlin Institute of Health @Charité

Digital Health Applications (DiGA)



DiGA is a CE-marked medical device & "digital assistants" in the hands of the patient.

BIH Berlin Institute of Health @Charité

Scientific Projects: German Corona Consensus Dataset (GECCO)

netzwerk universitäts medizin

TECHNICAL ADVANCE Open Access

The German Corona Consensus Dataset (GECCO): a standardized dataset for COVID-19 research in university medicine and beyond

Julian Sass[1], Alexander Bartschke[2], Moritz Lehne[1], Andrea Essenwanger[1], Eugenia Rinaldi[2], Stefanie Rudolph[2], Kai U. Heitmann[3], Jörg J. Vehreschild[4,5,6], Christof von Kalle[1,2] and Sylvia Thun[1,2,7*]

BIH Berlin Institute of Health @Charité

H2020 ORCHESTRA

BIH Berlin Institute of Health @Charité

Projects: NFDI4Health

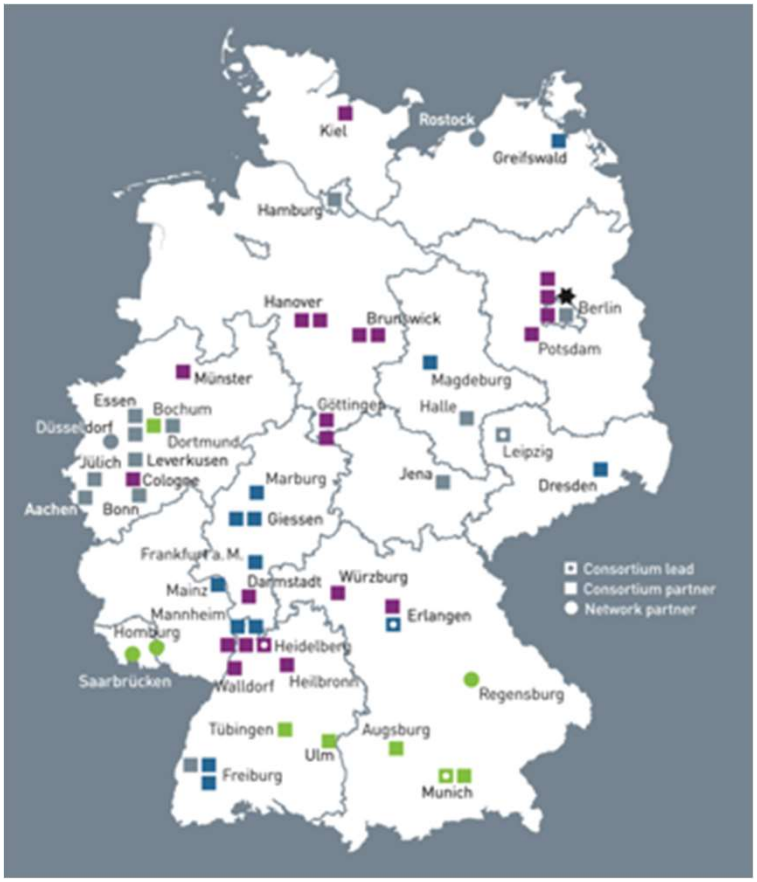
National Research Data Infrastructure for Personal Health Data

The mission of NFDI4Health is to provide new opportunities for the scientific use of personal health data while respecting privacy requirements. Based on the FAIR principles, services are provided to researchers to permanently store, semantically enrich and share data in interoperable formats and to merge data from different sources.

ZB MED · Leibniz-Institut für Präventionsforschung und Epidemiologie – BIPS · BIH Berlin Institute of Health Charité & MDC · DIfE Deutsches Institut für Ernährungsforschung Potsdam-Rehbrücke · Fraunhofer · HITS Heidelberg Institute for Theoretical Studies · Hochschule Mittweida University of Applied Sciences · MDC Max Delbrück Center for Molecular Medicine in the Helmholtz Association · KKS Netzwerk Koordinierungszentren für Klinische Studien · Robert Koch Institut · TMF · Universität Bonn · Universität Bremen · Universität Greifswald · Universitätsmedizin Göttingen UMG · Universität Leipzig · Partner

BIH Berlin Institute of Health @Charité

Medical Informatics Initiative



Source: TMFEV

Interoperability working group

The interoperability working group is the platform for agreeing amongst consortia the basis for ensuring interoperability between the proposed data integration centres.

Goals and tasks

The group was established in order to create a platform for coordination and agreement of interoperability between the proposed data integration centres, to plan concrete steps for achieving interoperability, and to agree corresponding minimum requirements.

Activities

The working group members held discussions in physical meetings and conference calls. Several task forces were formed within the working group to produce a number of documents, and to prepare the ground for an agreement within the national steering committee:

- Task force DIC concepts
- Task force core data set
- Task force consent implementation
- Task force process models
- Task force meta data

Results

→ Metadata on data availability, analysis options and collaboration options

→ Core data set

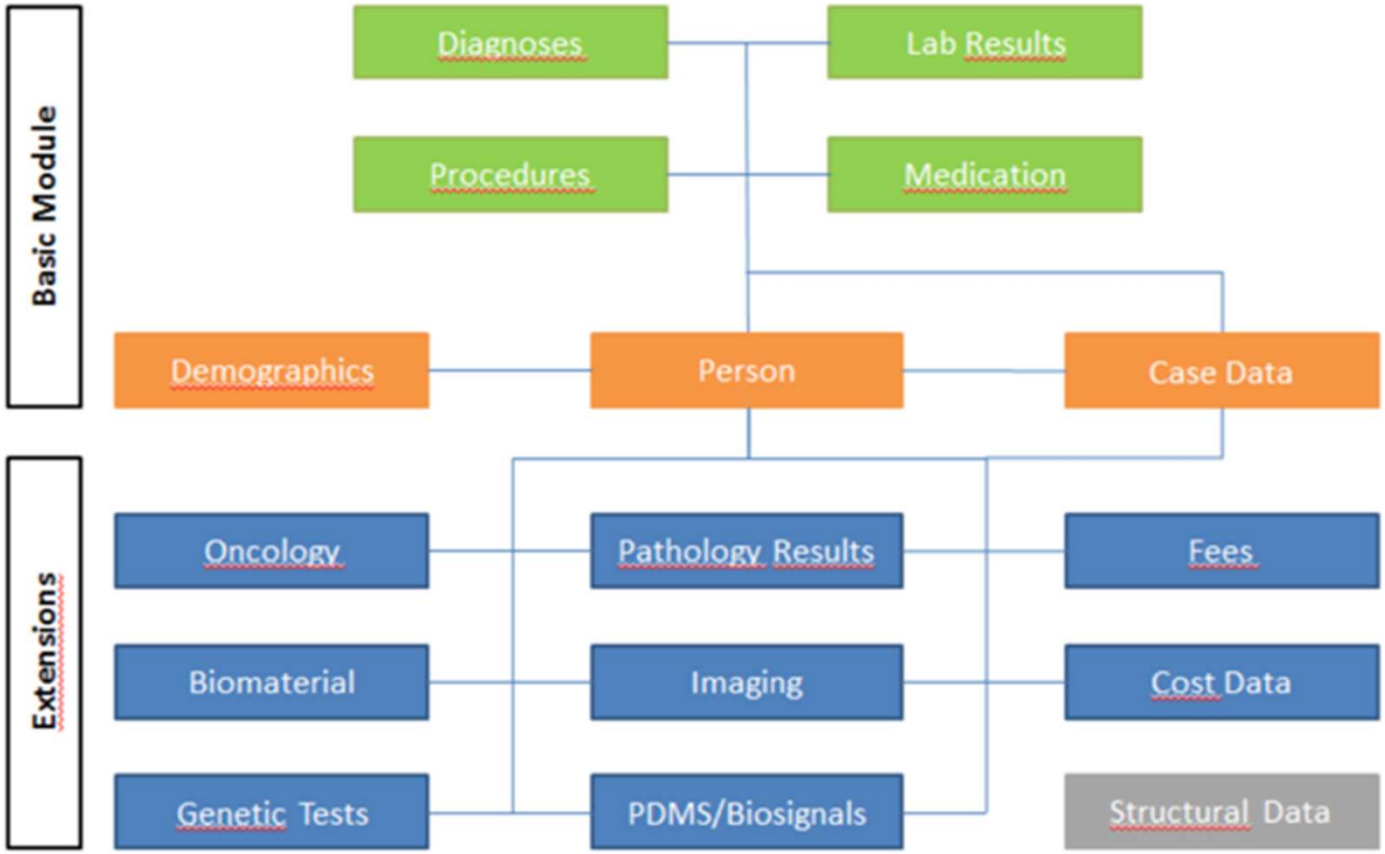
→ Paper summarising key points on interoperability

Working group chairpersons:

- Prof. Dr. Thomas Ganslandt (Universitätsmedizin Mannheim)
- Prof. Dr. Sylvia Thun (Hochschule Niederrhein/BIH)

BIH Berlin Institute of Health @Charité

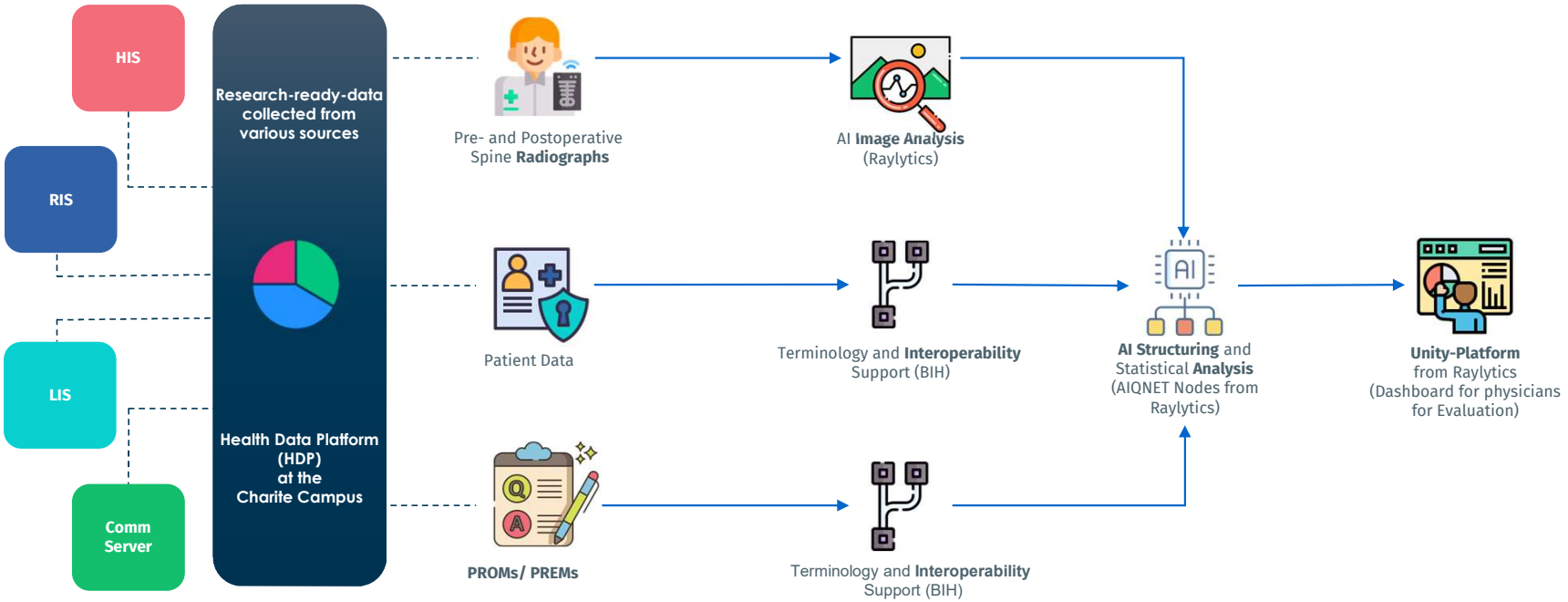
Core Data Set @ International Patient Summary



Source: TMFEV

BIH Berlin Institute of Health @Charité

AIQNET - medical data ecosystem



AIQNET

heartbeat MEDICAL SOLUTIONS

RAYLYTIC medical data automation

BIH Berlin Institute of Health @Charité

Digital Interfaces

Data from Devices

SDC → HL7 FHIR

Dräger

Medication Data/ Wearables/ PROMS

→ Early-Warnings for ARDS / AKI

BIH Berlin Institute of Health @Charité

HL7 International

DICOM
Digital Imaging and Communications in Medicine

orphanet

LOINC®
from Regenstrief

IHE INTERNATIONAL
Making Healthcare Interoperable

SNOMED CT

Strategy -> HL7 FHIR & Terminologies

- Specifications related to data representations are to be defined as HL7 FHIR Ressources and within FHIR implementation guides.
- If a difference from the FHIR standard is necessary for technical or organisational reasons, it must be justified by the applicant.

BIH Berlin Institute of Health @Charité

International Cooperation

GLOBAL DIGITAL HEALTH PARTNERSHIP

World Health Organization

Joint Initiative Council

cdisc
Clinical Data Interchange Standards Consortium

cen Health Informatics TC251
European Committee for Standardisation

DICOM
Digital Imaging and Communications in Medicine

GS1
GS1

HL7 International
Health Level Seven International

IHE Integrating the Healthcare Enterprise
Integrating the Healthcare Enterprise

ISO HEALTH INFORMATICS TC215
International Organisation for Standardisation

LOINC from Regenstrief
Logical Observation Identifiers Names and Codes

SNOMED International
SNOMED International

Global Alliance for Genomics & Health

Collaborate. Innovate. Accelerate.

BIH Berlin Institute of Health @Charité

Bundesministerium
für Gesundheit

INTEROP COUNCIL

for digital health in Germany


Prof. Dr. Sylvia Thun


Ralf Degner


Prof. Dr. Siegfried Jedamzik


Simone Heckmann


Prof. Dr. Martin Sedlmayr


Jörg Studzinski


Dr. Anke Diehl

BIH Berlin Institute of Health @Charité

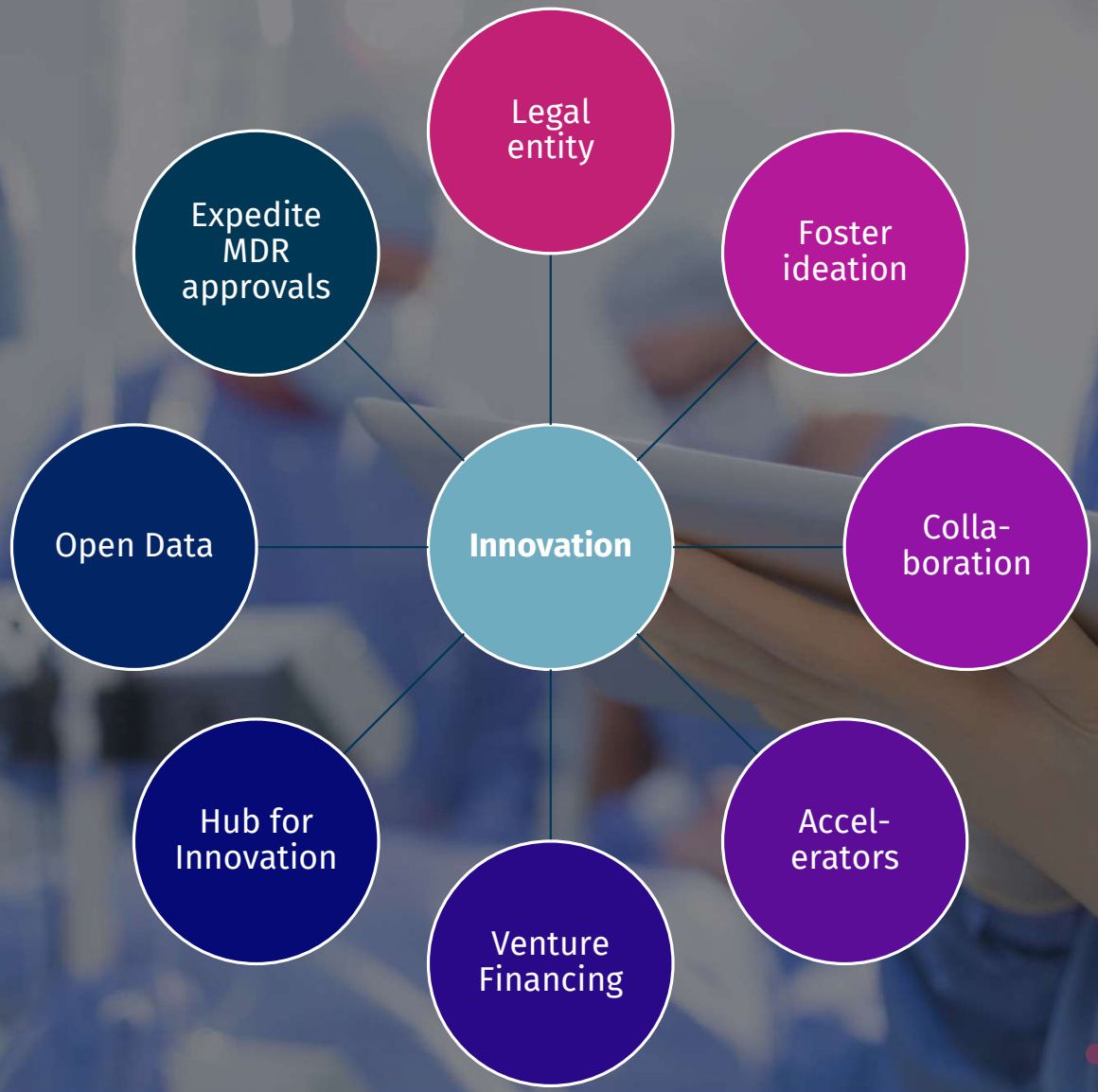
Take away message

- **Use FAIR principles:**
  - **F**indable
  - **A**ccessible
  - **I**nteroperable
  - **R**eusable
- **Enhance reusability of scientific data**
- **Extract maximum benefit from digital data sources**
- **Allow automatic processing (e.g. AI / machine learning)**

This can aid the “democratization” of medicine: making health technologies (globally) accessible, improving healthcare, fostering innovations to enable Translational Medicine

BIH Berlin Institute of Health @Charité

Nourish Innovation Culture!



Marco Schaarschmidt & Michael Muzoora
– Representing Prof. Dr. Sylvia Thun

Core Unit “eHealth & Interoperability”
Berlin Institute of Health (BIH) at Charité

BIH Berlin Institute of Health @Charité

14. Perspectives on FHIR (Part 2 – European Projects)

Bente By Jansen Felleskatalogen

Christel Daniel, Assistance Publique – Hôpitaux de Paris (remote) + Nicolas Riss, French National Agency of Digital Health (ANS), Chair HL7 France

Ben McAlister, Oracle, Chair HL7 UK

Rafail Kasapis, OSTHUS GmbH – a PharmaLex Company

Michael Muzoora, Berlin Institute of Health + Marco Schaarschmidt, Berlin Institute of Health

Luc Nicolas, UNICOM

11:00 – 12:30

Creating interoperability at the source: UNICOM a global game changer !

HL7 FHIR VULCAN ACCELERATOR - PARIS MEETING
15th March 2023
Luc Nicolas (EHTEL) - Dissemination lead

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

What if ?

We would be able to identify any medicinal product from anywhere in the world anywhere in the world ?

That is the ambition of 5 ISO/CEN Standards !

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

ISO standards for IDentification of Medicinal Products: IDMP

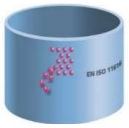
UNICOM

Set of 5 ISO IDMP standards establishes *definitions and concepts, common vocabularies* and describes *data elements and their structural relationships* that are required for the unique identification of medicines. Developed to ensure worldwide **interoperability** across regulatory and healthcare communities.

Substances (Substance ID/Specified Substance ID) - ISO 11238

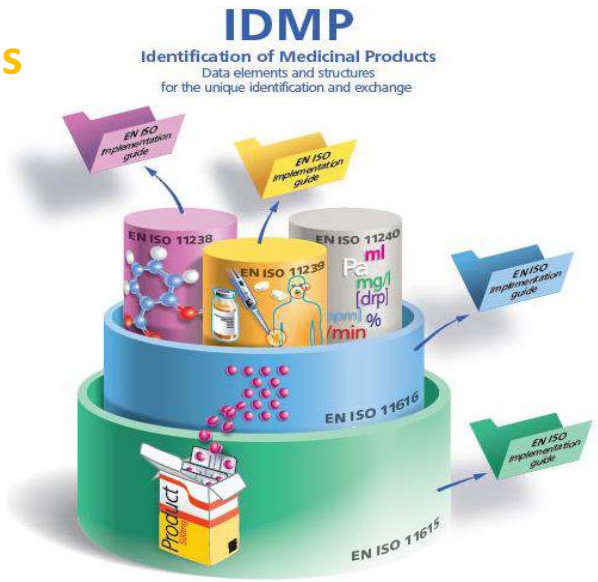
Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239

Units of measurement - ISO 11240



Pharmaceutical product (PhPID) - ISO 11616

Medicinal product (MPID/PCID) - ISO 11615



This project has received funding from the Europe
Horizon 2020 research and innovation programme

UNICOM

Aims to break down barriers hindering the free flow of

- **detailed**
- **semantically coded**
- **interoperable**

medicinal product information across the globe

Objectives:

Implementation of IDMP for Marketing Authorization in EU countries and at EU level

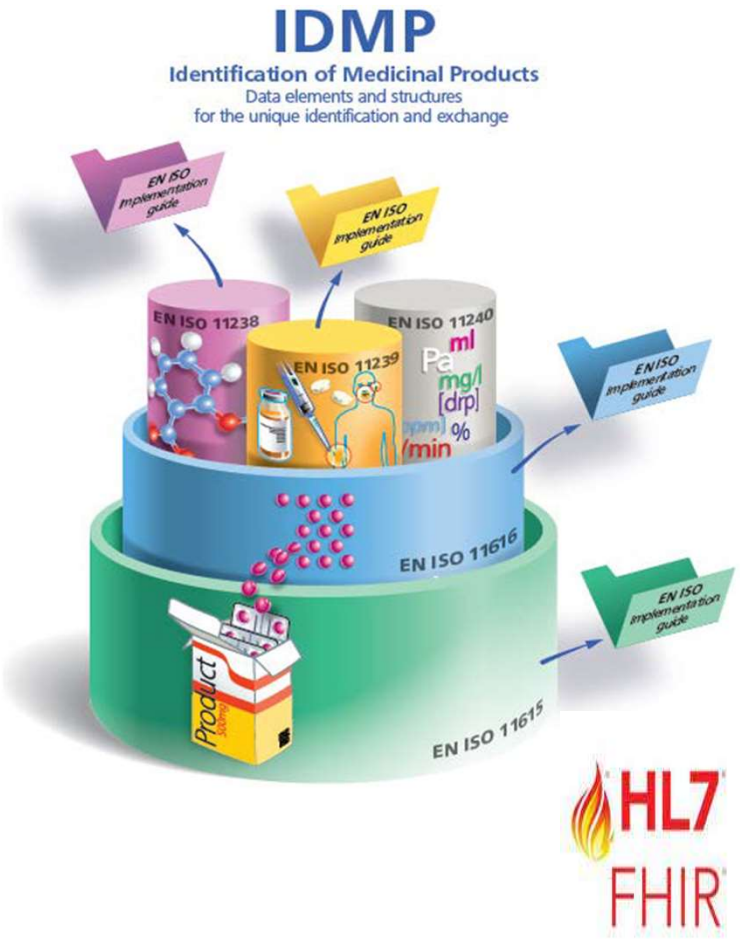
Adaptation of Member States' cross-border digital health services to include IDMP

- ePrescribing and eDispensing
- Patient Summary

Exploration and implementation of IDMP in clinical practice:

- pharmacovigilance reporting
- medicinal product dictionaries
- digital health services

The «*wedding cake*»



What is your role in the life-cycle of a medicinal product? Which of the high-level processes are you engaged in?

UNICOM

- EC supported Innovation Action on the implementation of IDMP standards
- A broad consortium of partners
  - **14 National Competent Authorities for Medicinal Products** – including support from the European Medicines Agency
  - 7 National eHealth Competence Centers / National eHealth Contact Points
  - 5 Industry Partners (Health IT)
  - 5 Research Organisations
  - 2 Medicinal Database Providers
  - 11 Standards Developing Organizations
- 4 year program: 2020-2024
- 13 work packages
- 21 M€ total budget

- **National implementations in:**
  Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden, The Netherlands

The UNICOM project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

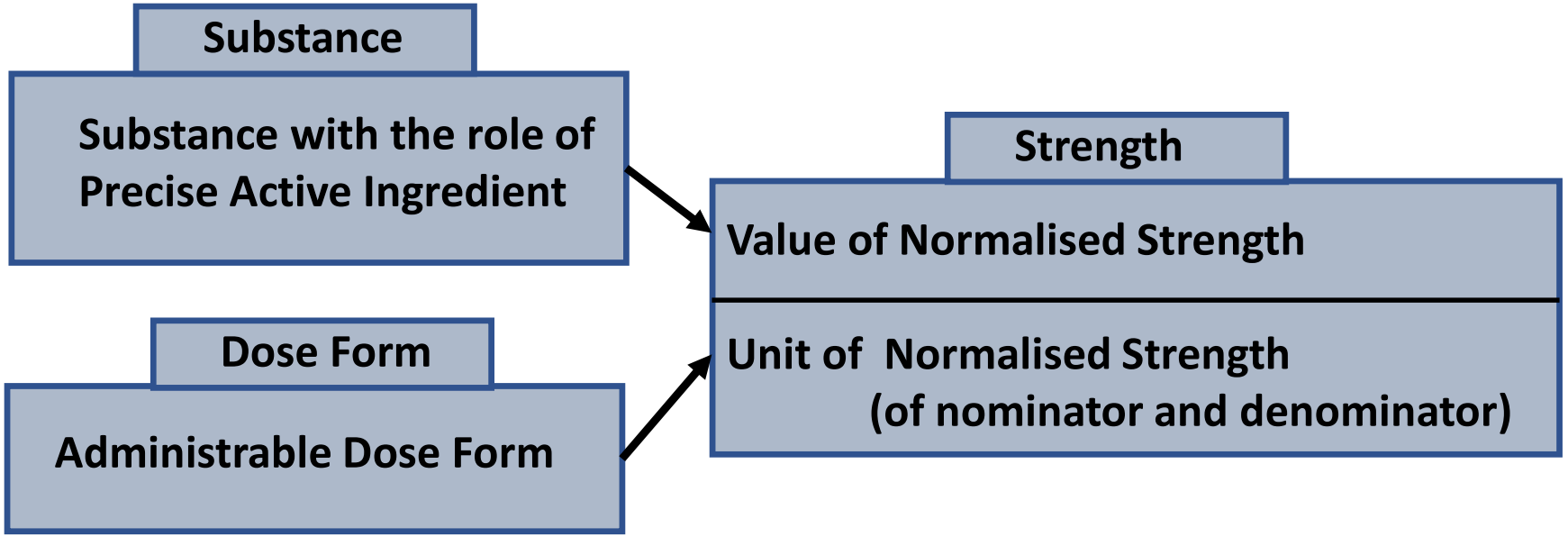
Inconsistencies

- Pharmacovigilance
  - Same medicinal product
    - Different name, expression of dosage, pharmaceutical dose form, route of administration
  - Same medicinal product?
    - What about substance(s)?
- Cross border prescriptions
  - How to identify medicinal products un-ambiguously?
  - How to decide which medicinal product is identical to another?
- Decision support
  - Decision support systems based on local product master data?
  - How to develop multimarket systems?
- Shortage
  - How to aggregate medicinal products which seem to be identical/different?

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

3 key elements of medicinal products

Substance, together with dose form, determines
the normalisation of strength expression of medicinal products



Note: Substance with dose form and strength determine the effect of the medication

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

How to ensure interoperability in the way medicinal products are represented internationally ?

UNICOM

- **For 3 core identifying concepts of medicinal products :**
  - ✓ Substance
  - ✓ Dose form
  - ✓ Strength,

We will need standardized terminologies, and business rules to govern also the relationships between these concepts

To be implemented by the national Agencies for Marketing Authorisation
In US, in Europe, and globally

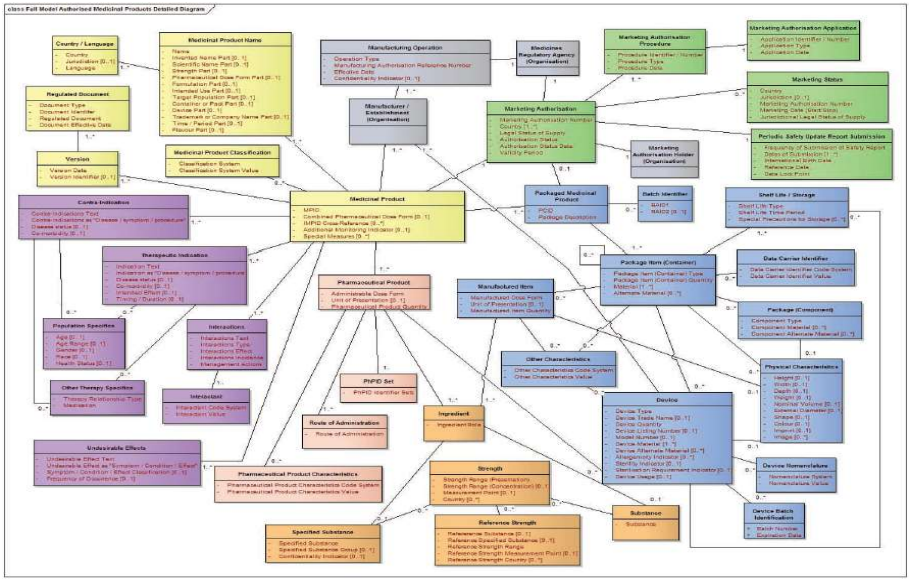
To flow seamlessly into the medicinal product dictionaries, used in clinical systems all over the world

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

IDMP: from data models and terminologies to identifiers

UNICOM

5 ISO Standards
containing ~250 data attributes

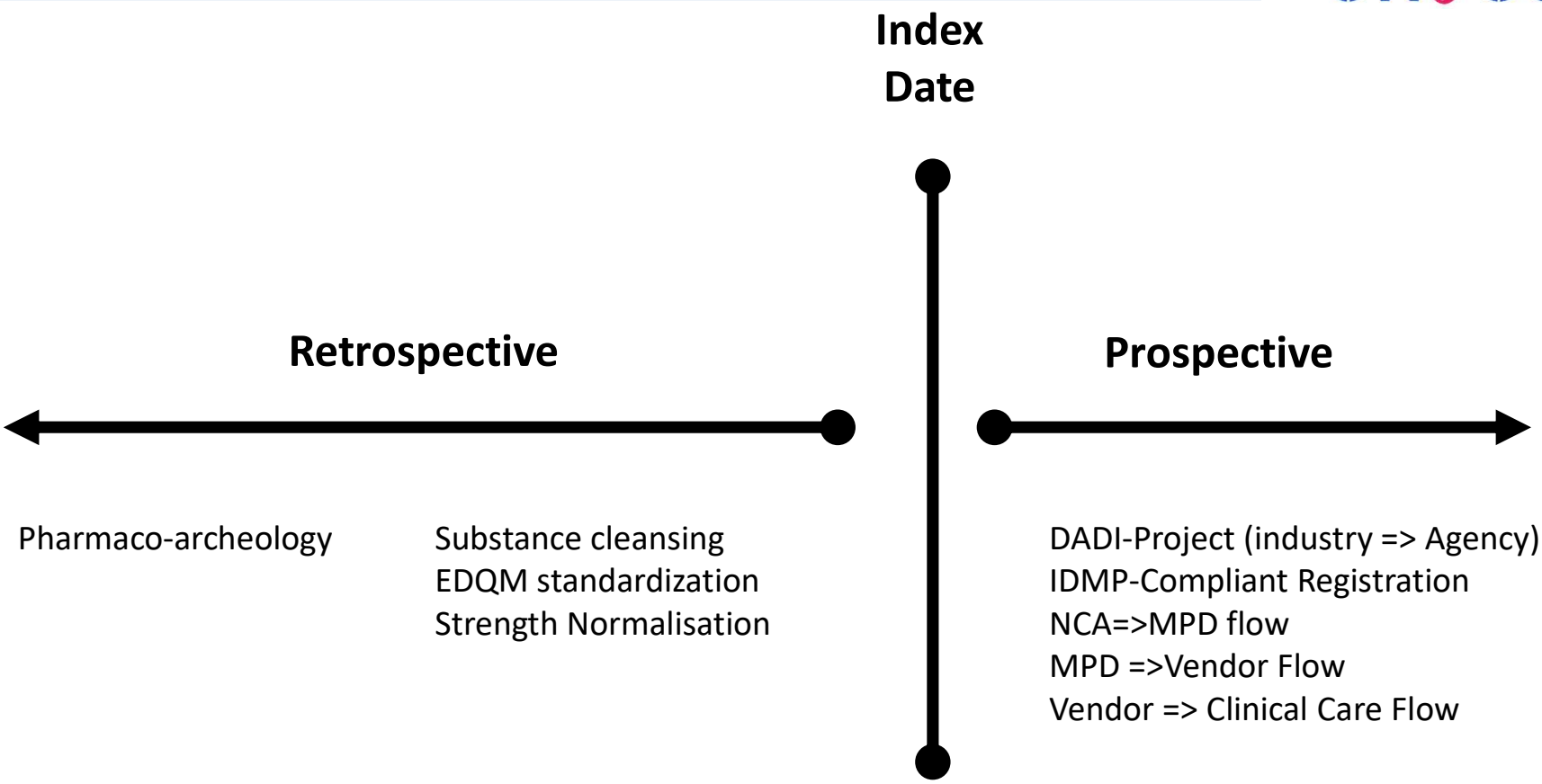


Unique Product Identifiers

PHPID	Pharmaceutical Product ID
MPID	Medicinal Product ID
SID	Substance ID
PCID	Medicinal Product Package ID
BAIDs	Medicinal Product Batch IDs

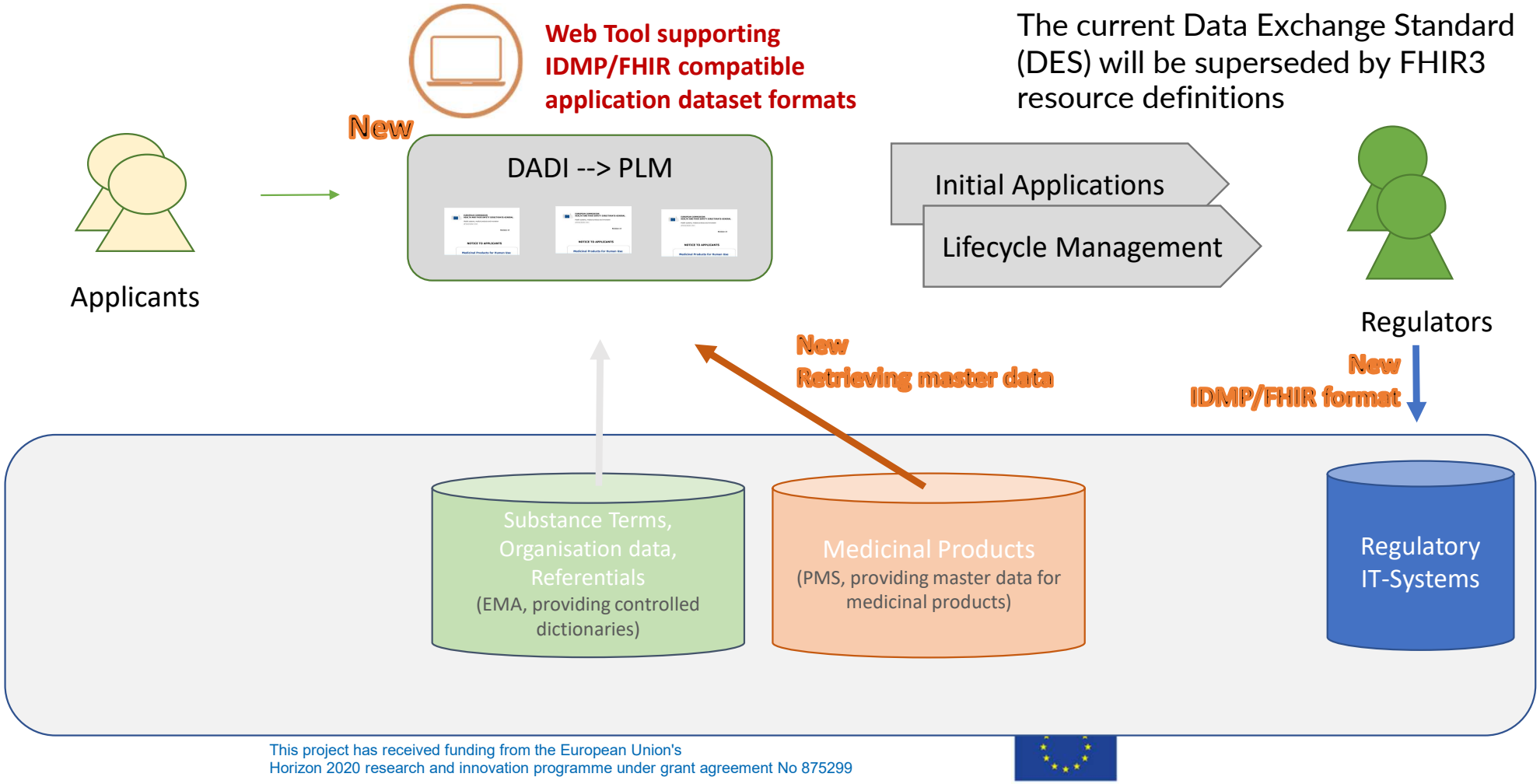
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Perspective on Future and history of IDMP implementation



This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

TO-BE: IDMP/FHIR compatible Electronic Application Forms



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

TO-BE: Status of development

UNICOM

WP 3

UAT partly achieved, **first Variation Application From release in production since 04/11/2022**

In progress

pending

Web Tool supporting IDMP/FHIR compatible application dataset formats

DADI

Variation Application

Initial Application

Renewal Application

Initial Applications

Lifecycle Management

Regulators

New Retrieving master data

New IDMP/FHIR format

Substance Terms, Organisation data, Referentials (EMA, providing controlled dictionaries)

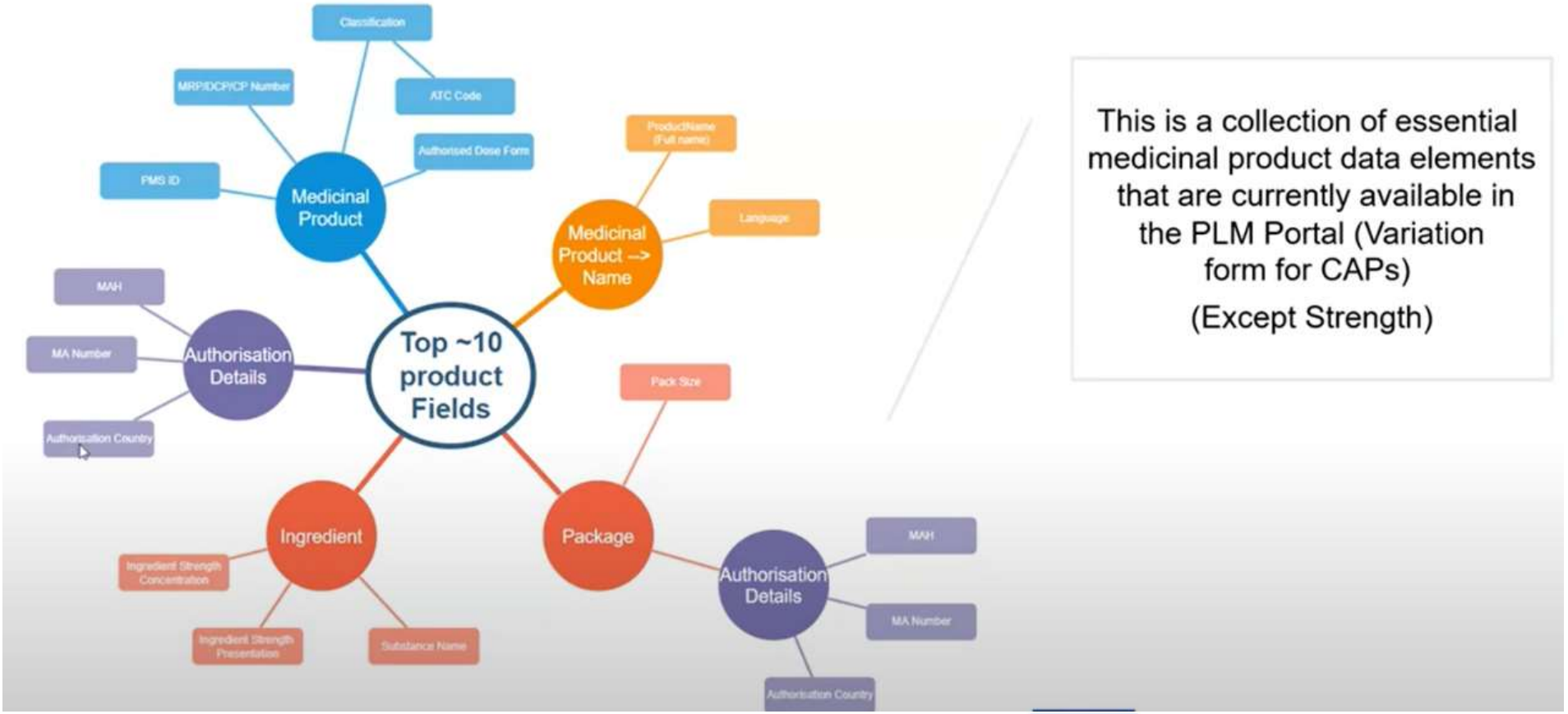
Medicinal Products (PMS, providing master data for medicinal products)

Regulatory IT-Systems

See also collaboration with UNICOM WP4

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

TOP 10 PRODUCT FIELDS

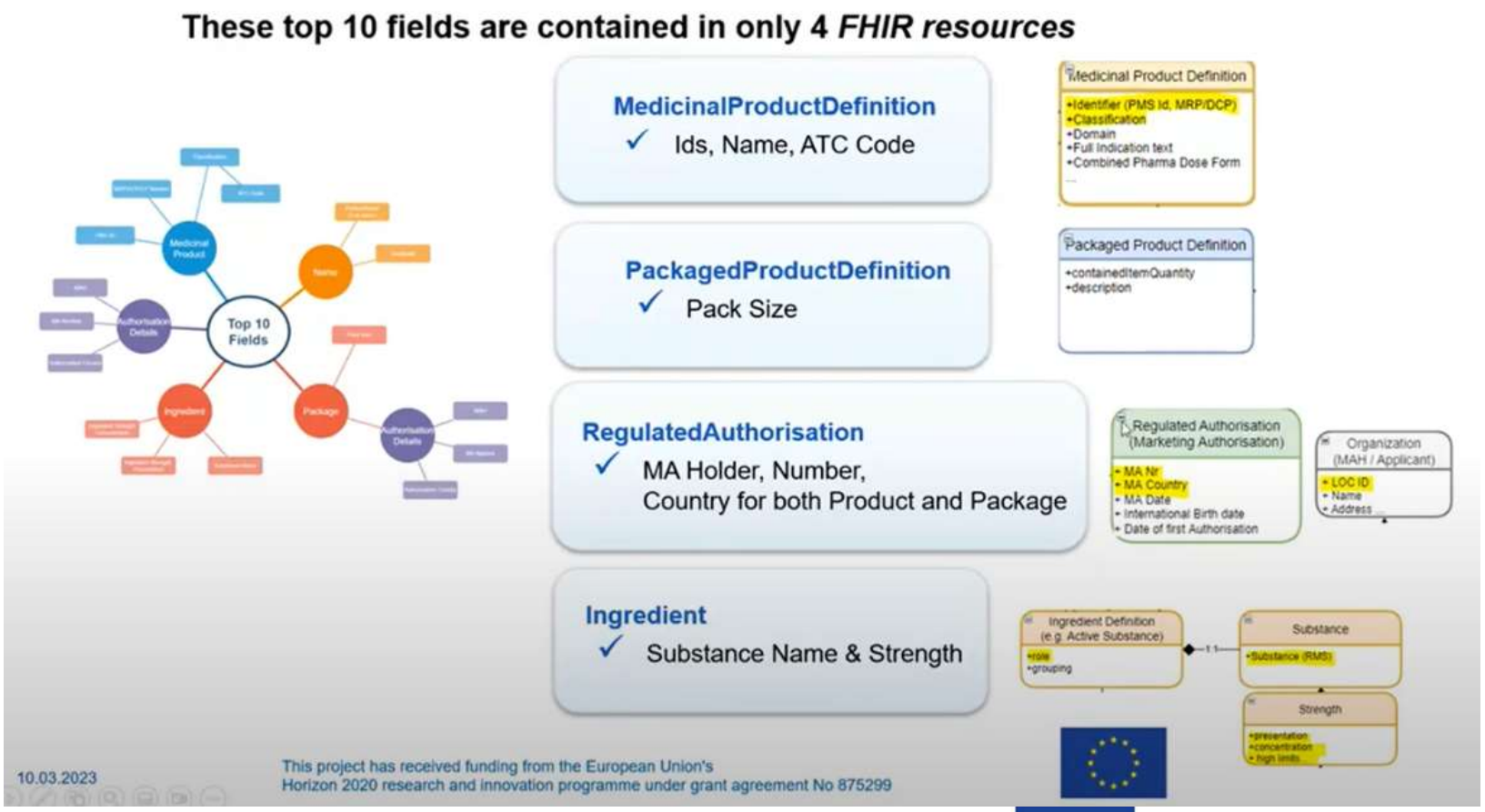


This is a collection of essential medicinal product data elements that are currently available in the PLM Portal (Variation form for CAPs)

(Except Strength)

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

4 FHIR RESOURCES

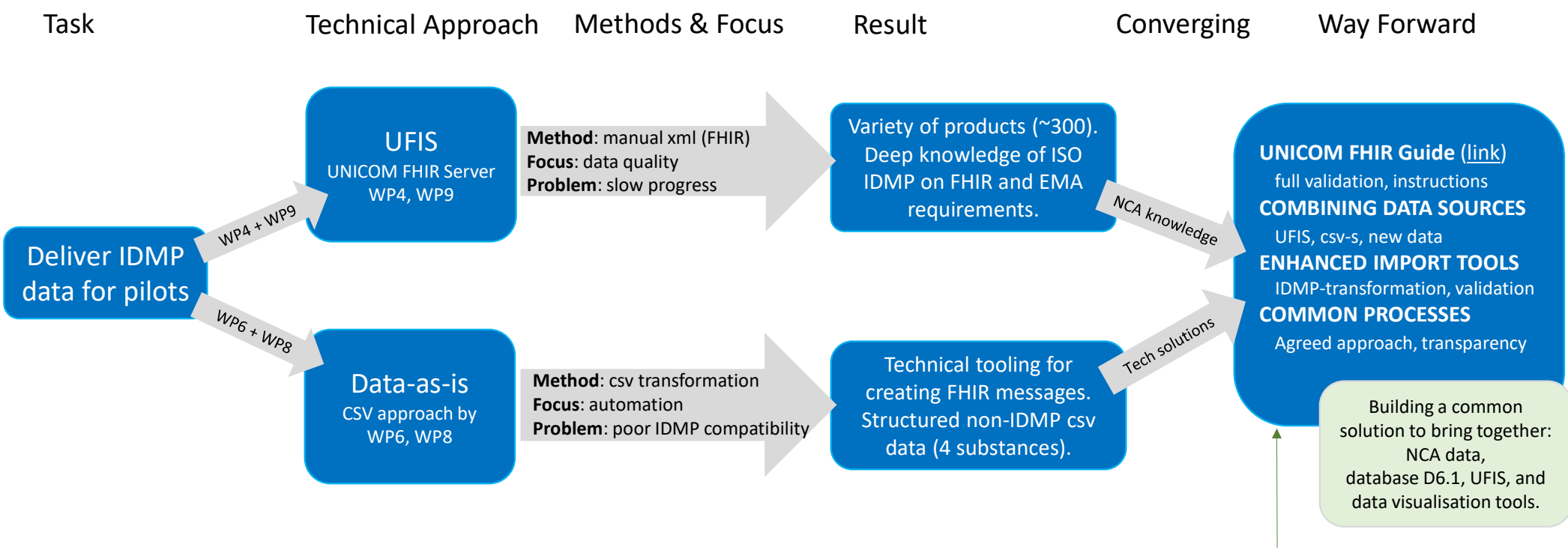


This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Delivery of selected ISO IDMP medicinal product data for cross-border pilots

UNICOM

WP 4



This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

NCA readiness and implementation progress Matrix

1. Analysis and modelling
GAP-analysis between current data model and IDMP
Datamodelling based on GAP-analysis
2. Mapping and transformation
Data-mapping to RMS dictionary
Data-mapping to OMS dictionary
Data-mapping to SMS dictionary
Data-transformation
3. SPOR-connection
Referentials RMS-connection
Organisations OMS-connection
Products PMS-connection
Substances SMS-connection
4. Prototype data feeds
Prototyping and piloting of data feeds

The Grand total will be filled out by the WP4 Lead based on the NCA reports

In progress according to plan or done
Risk to be mitigated
Progress in danger
Not applicable

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Burden of legacy conversion will be with the National Agencies

UNICOM

There is no substitute for hard work in legacy conversion: 10.000 to 15.000 medicinal product packages per country

- Install an IDMP layer above their current systems

oR

- Re-engineer their current systems from scratch To a new IDMP compliant system of Drug Information

Strongly supported by central coordination (EU)

- Implementation Guide
- SPOR services
- Guidance
- Technical support

Validated by testing

- Internal and external validity checks
- Cross border Services
- Feedback from users

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Taking trusted IDMP data and delivers it to patients and clinicians, through MPD – the “last link in the chain”

UNICOM

WP 9

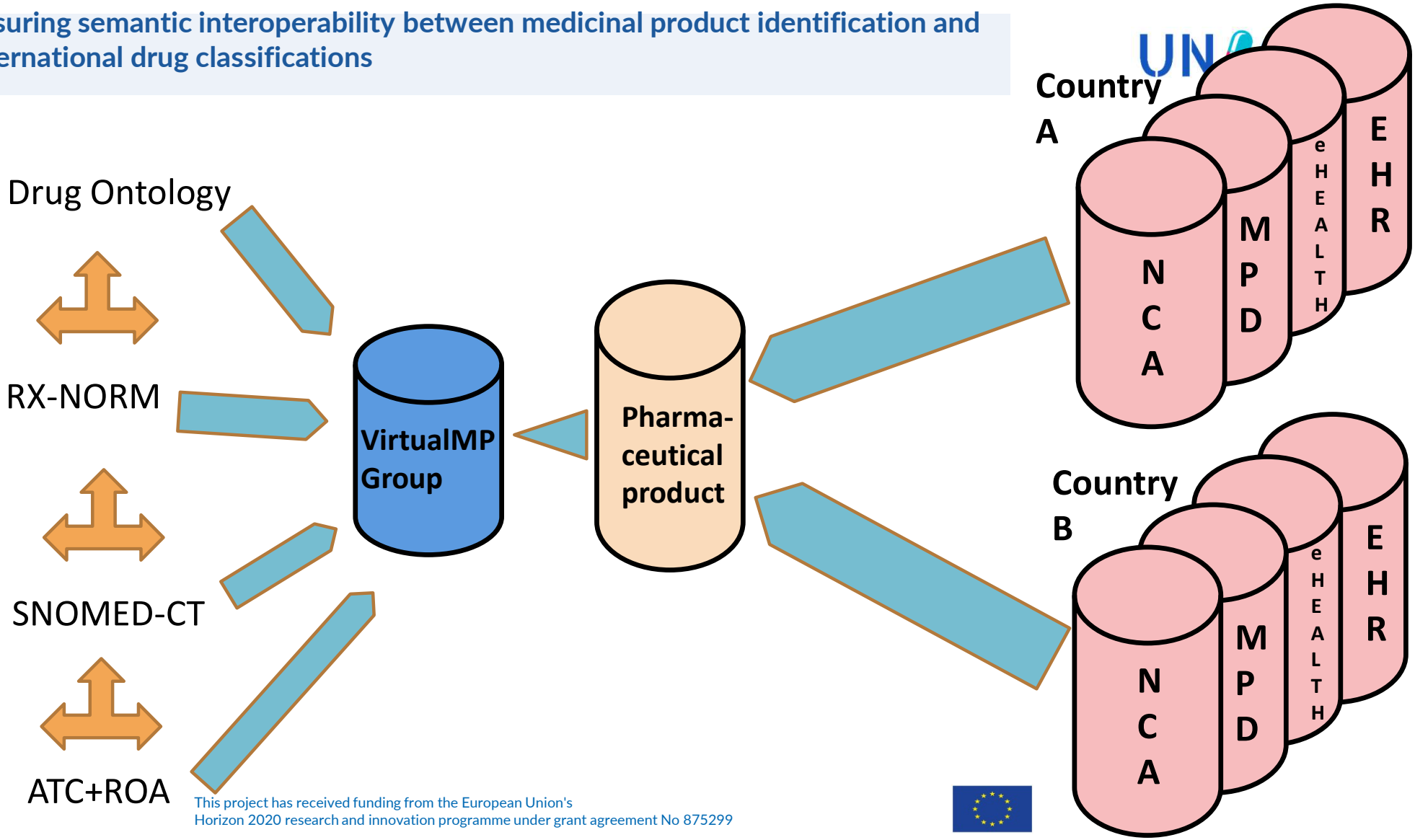
MPD = Medicinal Product Dictionary* – the things that clinicians and patients use “in real life” within their systems (or apps) to describe medicines

A **“common approach and operating model” for best practice in using trusted IDMP data in patient care** in the different environments and with the different existing MPD that the member states have

* ISO: TS 19256 – MPD provide a “consistent representation of medication concepts (set of identifiers) at various levels of detail and with meaningful relationships between the concepts, in order to support parts of several processes in healthcare in which medication plays a role

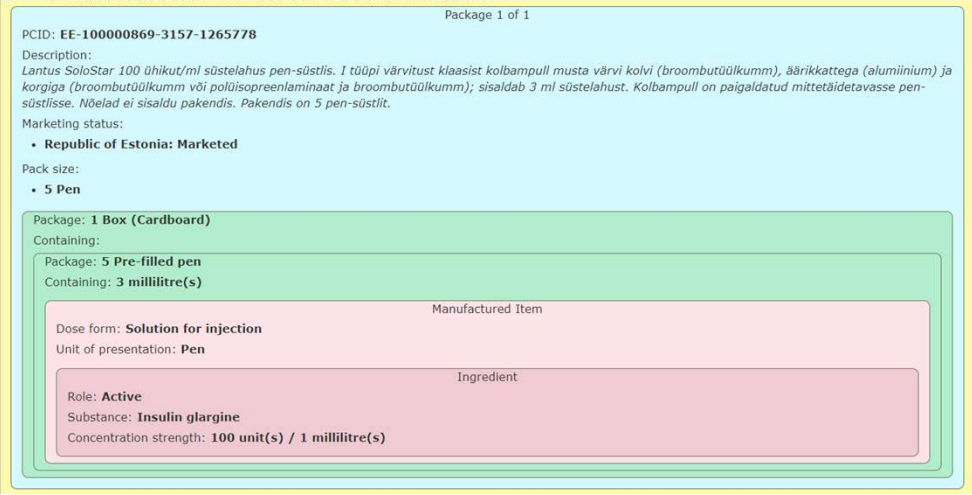
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Assuring semantic interoperability between medicinal product identification and international drug classifications



This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

- **FHIR [implementation guide contains](#)**
  - Logical models
  - FHIR profiles
  - EMA SPOR & EDQM terminology
  - Mappings
  - **Example data with new visualiser**
  - Custom search parameters
  - Guidance & known issues



Name	Flags	Card.	Type	Description & Constraints
ManufacturedItemDefinition		0..*	ManufacturedItemDefinition	The definition and characteristics of a medicinal manufactured item, such as a tablet or capsule, as contained in a packaged medicinal product
implicitRules	?! Σ	0..1	uri	A set of rules under which this content was created
modifierExtension	?! Σ	0..*	Extension	Extensions that cannot be ignored
status	?! Σ	1..1	code	draft | active | retired | unknown **Binding:** PublicationStatus (required): The lifecycle status of an artifact.
manufacturedDoseForm	Σ	1..1	CodeableConcept	Dose form of the manufactured item (before preparing for administration) **Binding:** Pharmaceutical Dose Form (required)
unitOfPresentation	Σ	1..1	CodeableConcept	Unit of presentation of the manufactured item (before preparing for administration) **Binding:** Unit of Presentation EMA (required)

ManufacturedItemDefinition profile defines cardinalities and terminology bindings

UNICOM is the first to use such visualisation of example data inside FHIR IG

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

CDA – New Identifiers for eHDSI Wave 6

UNICOM

WP 6

Reference implementation supports the new identifiers *

Medicinal Product Identifier (MPID)

Medicinal Product Identifier	MPID_LantusSolostar

Pharmaceutical Product Identifier (PhPID)

Pharmaceutical Product Identifier	PhPID_LantusSolostar

Package identifier (PCID)

Package Identifier	PCID_LantusSolostar

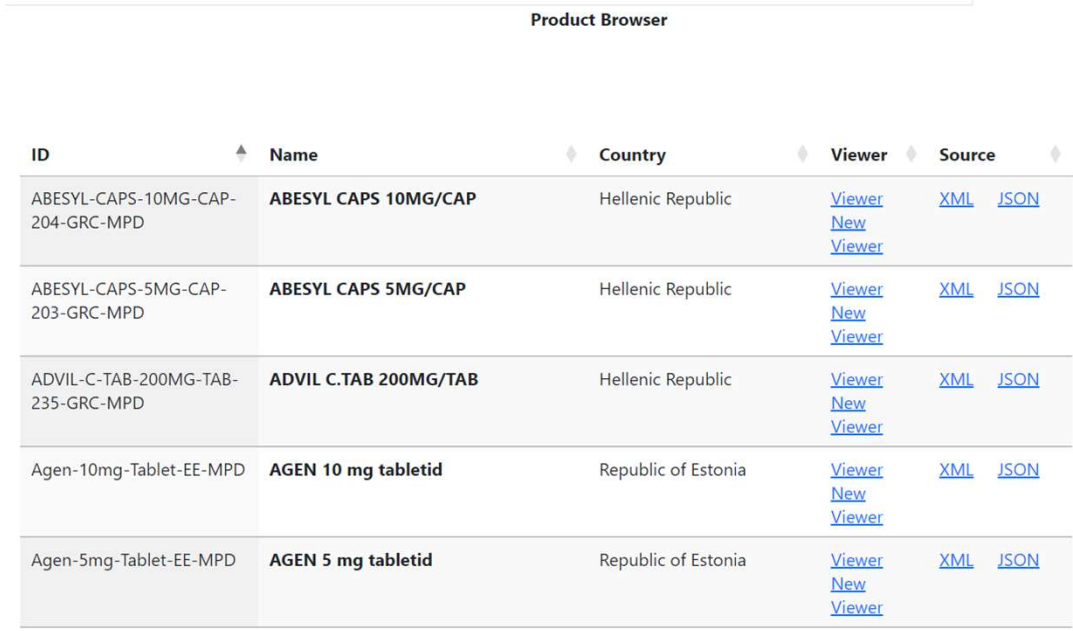
Package Size	• Box
	  ◦ 5 unit(s) Pre-filled syringe
	  ▪ 3 milliliter Solution For injection in pre-filled syringe

* Even though the IDMP identifiers are not yet in existence, the CDA display tool has included them into its architecture to assure the presentation once they are.

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

- **Usage: human view**
  - Specification & guidance
  - Data modelling help
  - Real-life examples
  - Bridge from regulatory domain to eHealth

- **Usage: machine-readable**
  - Automatic validation of data
  - Implementable specification for servers
  - Base template for new data
  - Custom search parameters
  - Mapping



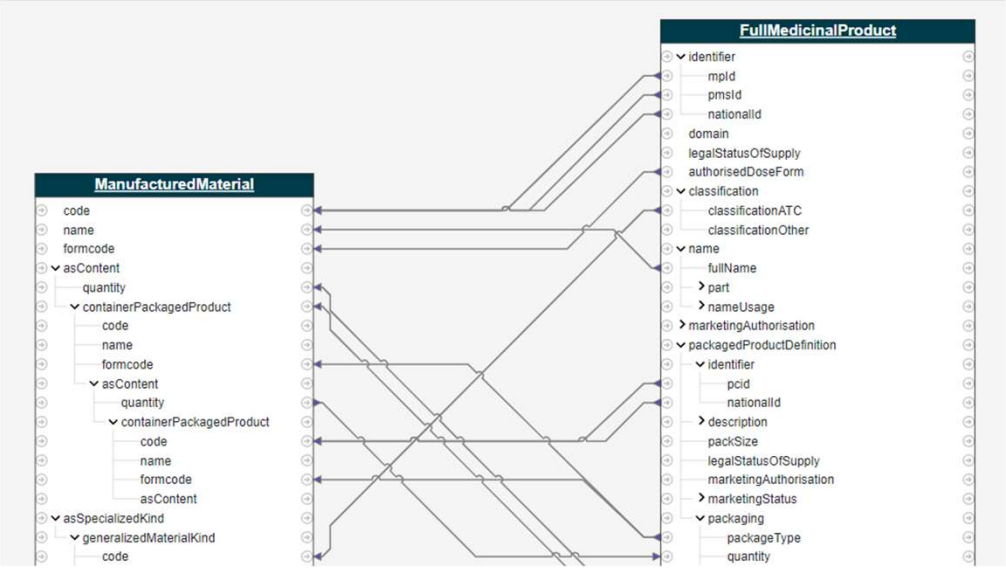
Product Browser

ID	Name	Country	Viewer	Source
ABESYL-CAPS-10MG-CAP-204-GRC-MPD	**ABESYL CAPS 10MG/CAP**	Hellenic Republic	Viewer New Viewer	XML JSON
ABESYL-CAPS-5MG-CAP-203-GRC-MPD	**ABESYL CAPS 5MG/CAP**	Hellenic Republic	Viewer New Viewer	XML JSON
ADVIL-C-TAB-200MG-TAB-235-GRC-MPD	**ADVIL C.TAB 200MG/TAB**	Hellenic Republic	Viewer New Viewer	XML JSON
Agen-10mg-Tablet-EE-MPD	**AGEN 10 mg tabletid**	Republic of Estonia	Viewer New Viewer	XML JSON
Agen-5mg-Tablet-EE-MPD	**AGEN 5 mg tabletid**	Republic of Estonia	Viewer New Viewer	XML JSON

DataWizard's new product browser uses the IG as the base specification and for data migration tooling.

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

- **Next steps**
  - Finalise CDA-FHIR mapping in UNICOM context
  - Add all relevant terminology mappings
  - New dedicated sections for:
    - eHealth-regulatory bridge
    - Data migration
    - SNOMED bridge (?)
  - Report lessons learned



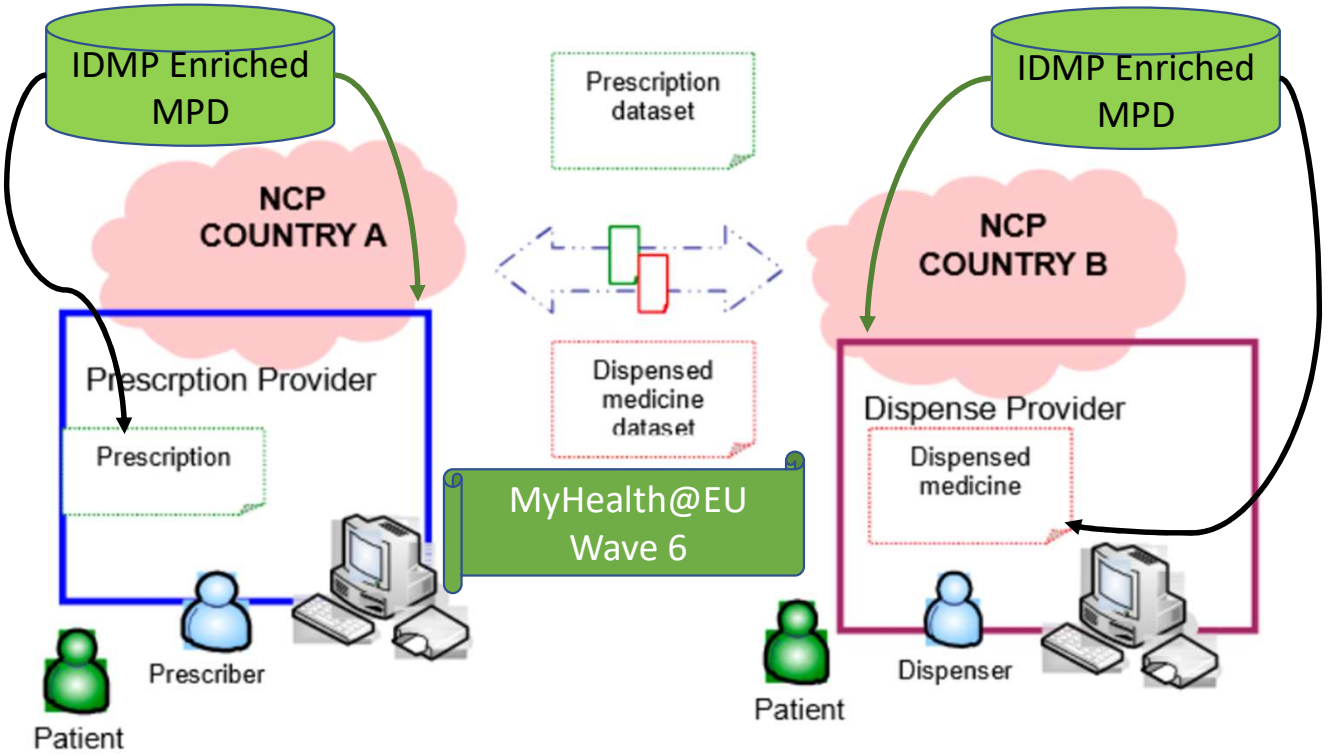
An exercise mapping between CDA medication template and PPL logical model

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Use Case ePrescription: IDMP Enhanced eP/eD & PS

UNICOM

WP 7



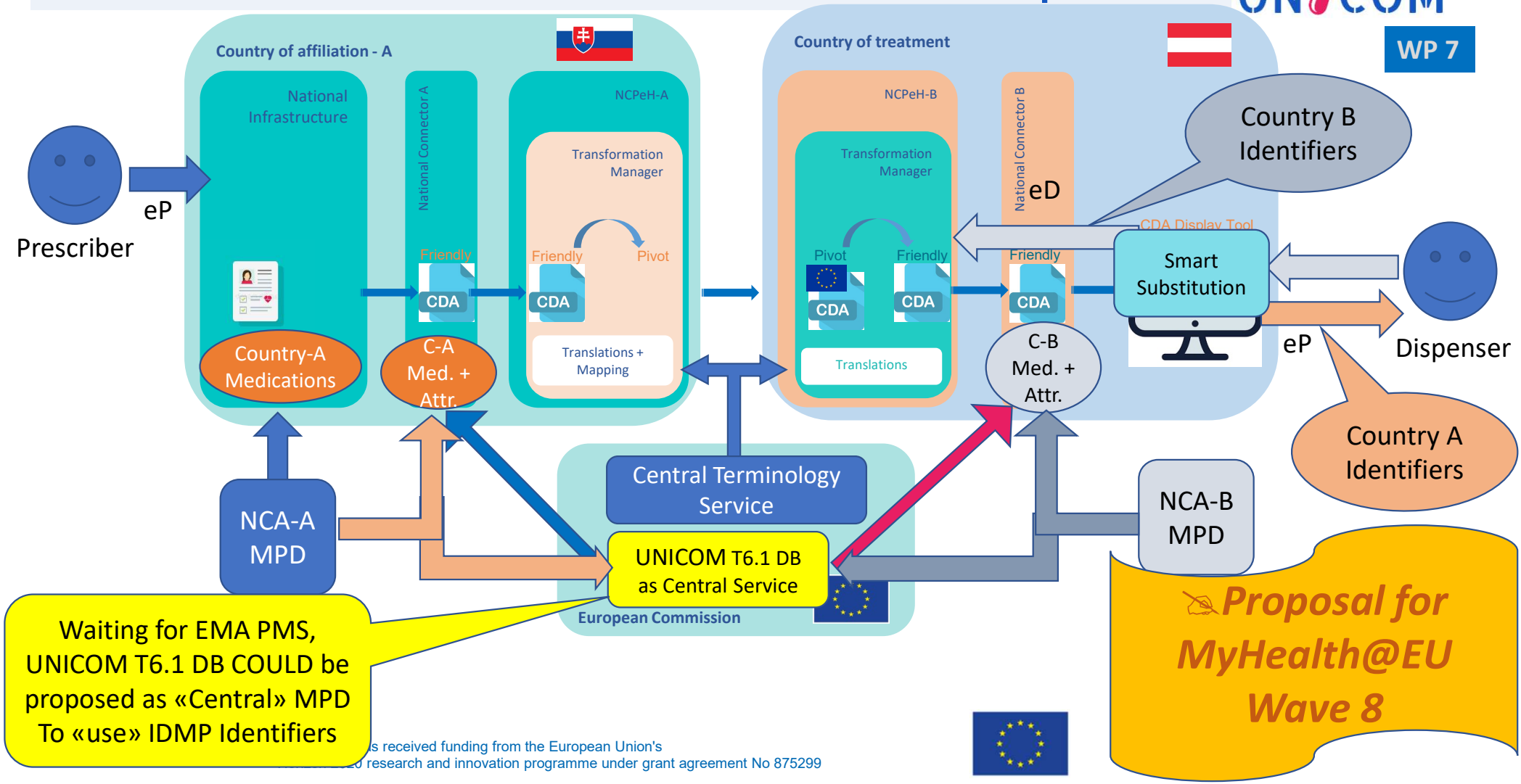
- Member States would adopt in future in the National ePrescription Systems the IDMP Identifiers / Attributes

- ✓ MyHealth@EU Wave 6: IDMP Enhanced eP/eD & PS

- IDMP Attributes may be added when the eP/eD for cross-border use are generated before being transferred to the other Member State

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

eHDSI Cross-Border Process: IDMP Identifiers - Operation



s received funding from the European Union's
0 research and innovation programme under grant agreement No 875299

PhPID generation and governance

UNICOM

Proposed Global PhPID service responsibilities

- Setting the service offer, maintenance framework & validation process
- Regular reviews

- Validation according to agreed process
- Responding to questions and escalating issues
- Data updates including cross-references needed for pharmacovigilance

- Oversee assignments and solving issues
- Identify needs for updates of business rules
- Escalates to ISO for updates of the standard

- Ensure the availability of the service from a technical perspective
- User/API administration

Uppsala Monitoring Centre

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

The UNICOM / GRAVITATE HEALTH Demonstrator

- Started with a personna based scenario: Elena's Journey
- Developed it into a technically testable scenario, with roles and interactions
- Developed the necessary **HL7 FHIR artefacts** to support the interactions during the September 2021 and Janary 2022 HL7 FHIR Connectathons
- **Collected test data, including the global PhPID for the relevant medications in different countries**
- Populated the UNICOM FHIR IDMP Server (UFIS) with the relevant test data
- Carried out tests during May 2022 HL7 FHIR Connectathon
  - Substitution at the hospital pharmacy in the country the patient is visiting
  - Retrieval of the electronic Product Information in the home language of the patient
- Used the scenario and the FHIR specifications to compile and submit a demonstrator presentation
- Presented the demonstrator during the Community of Expertise of August 2022
- Published a version of the demonstrator with a voice-over in January 2023 for broader communication

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

WP 1

The resulting demonstrator

UNICOM

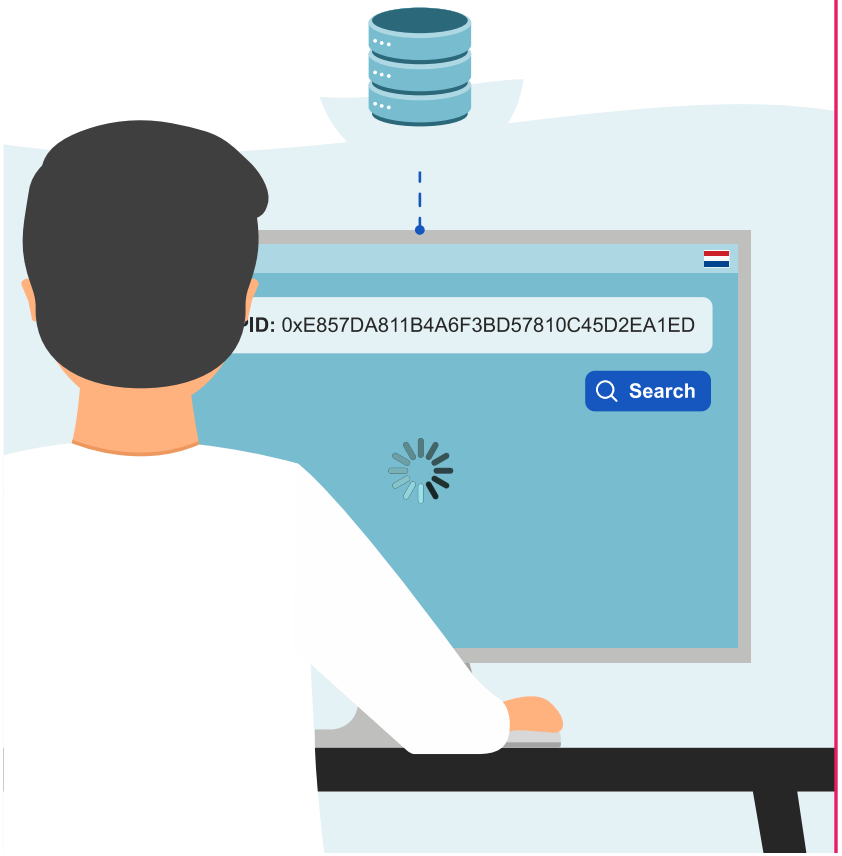
WP 1

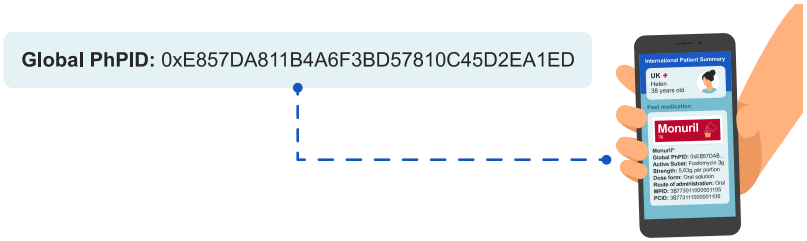
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

With actual interactions in HL7 FHIR format, using a global PhPID

UNICOM

WP 1





Pharmacy Information System

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

Resources: AdministrableProductDefinition
MedicinalProductDefinition

MPD Product Look-up

NL MPD (UFIS)

Global PhPID: 0xE857DA811B4A6F3BD57810C45D2EA1ED

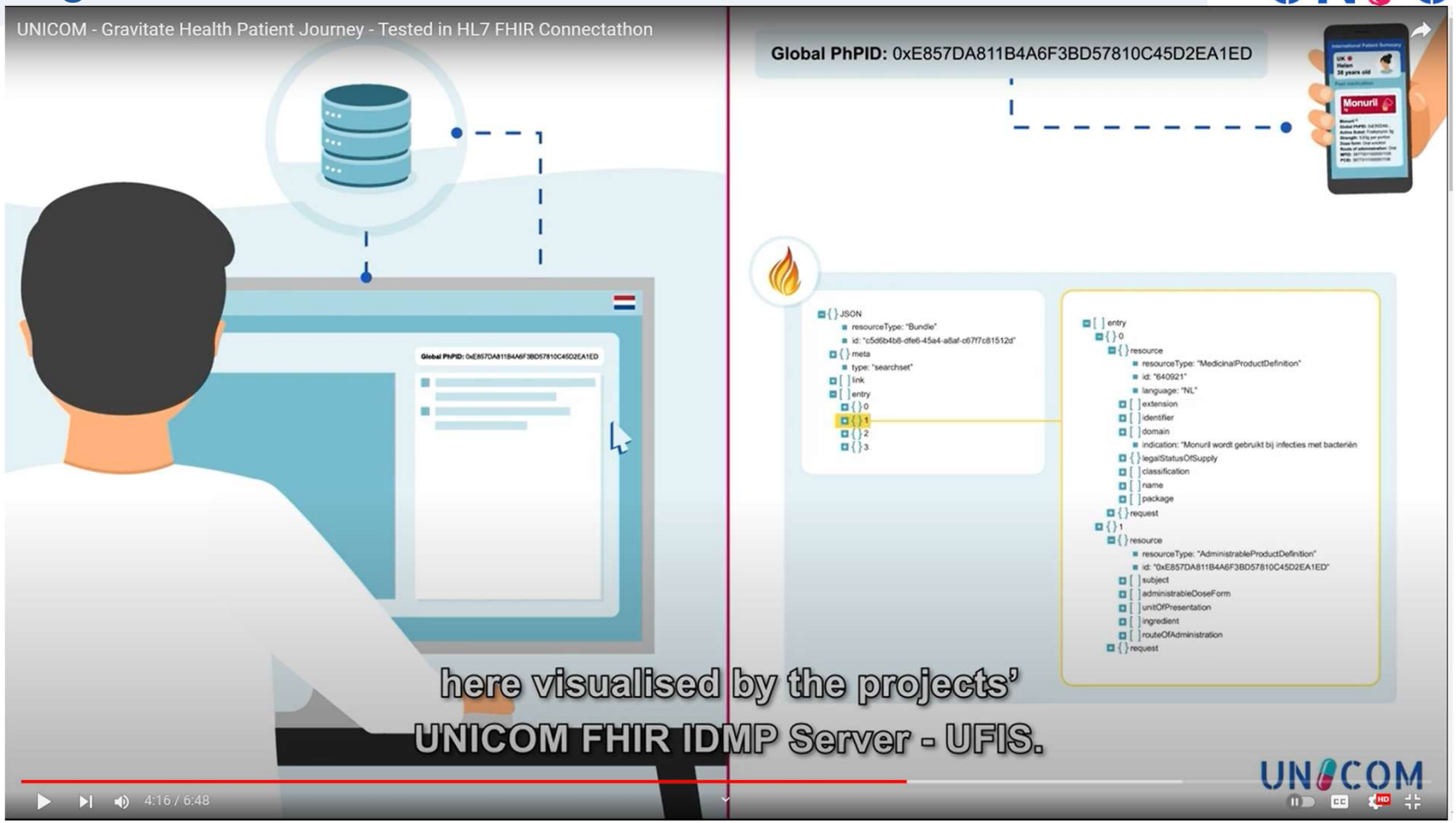
Search: [mpd fhir server]/AdministrableProductDefinition? identifier=https://www.who-umc.org/phpid|[PhPID]
&_include=AdministrableProductDefinition:form-of

FCAT May 2022, FHIR 4.6.0

UNICOM

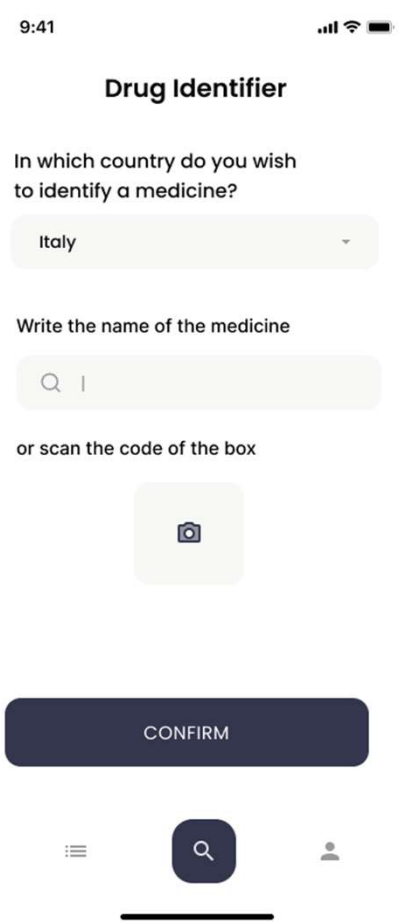
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

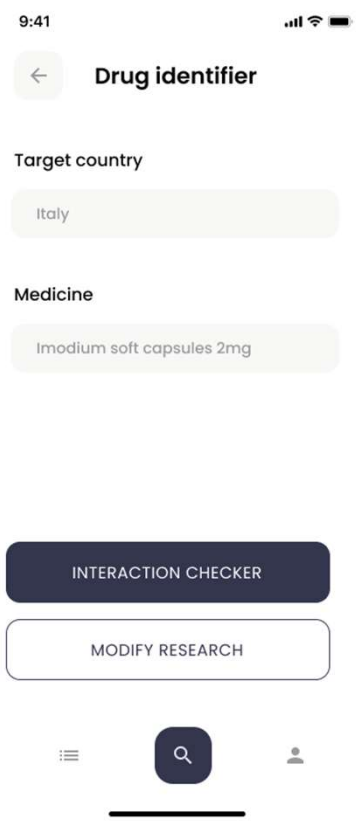
Connecting to the UNICOM FHIR IDMP

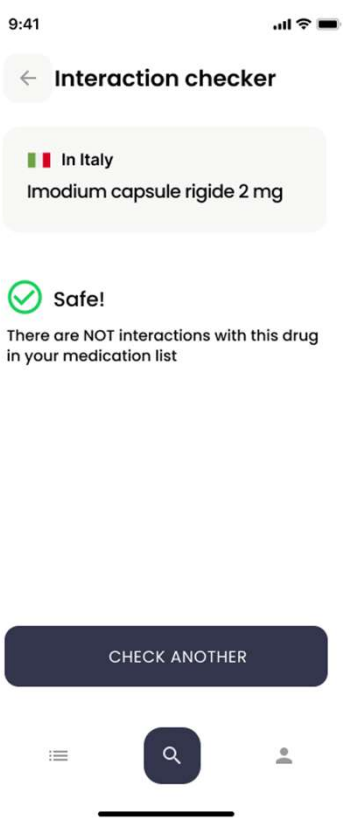


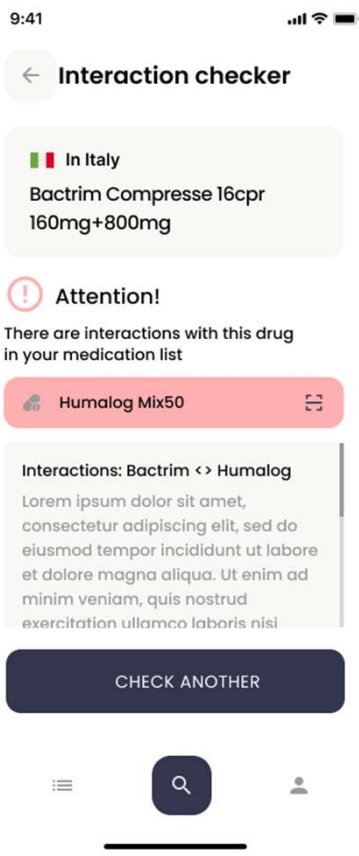
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

In an ideal world we will....





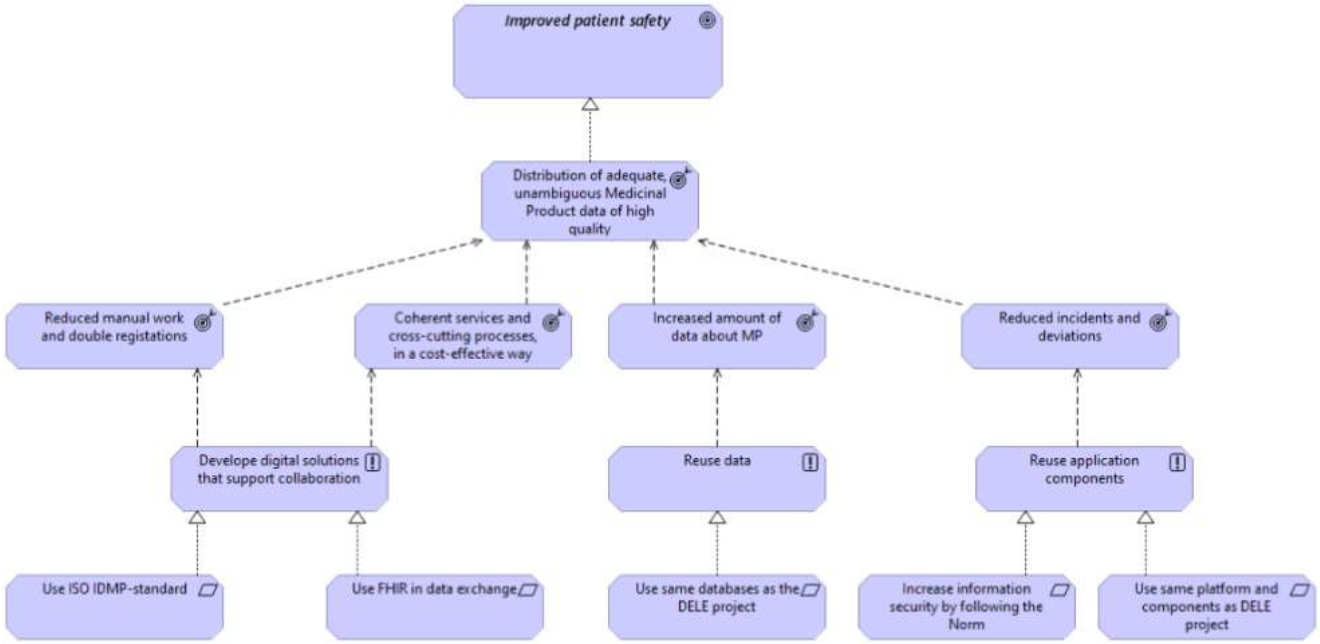




This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

The vision is improved patient safety

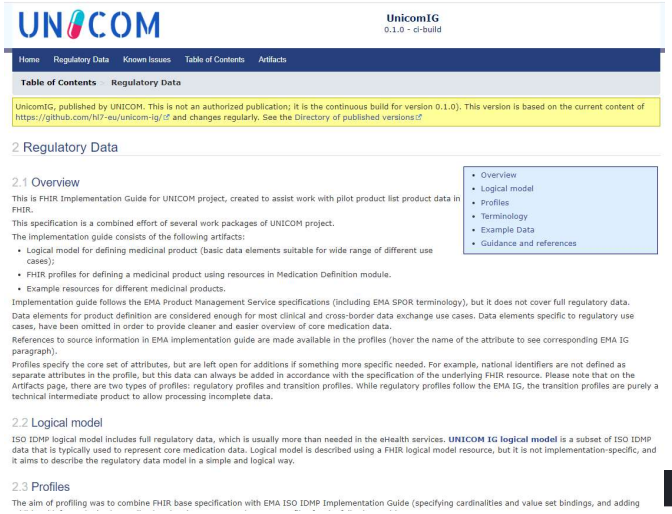
by distribution of adequate, unambiguous, high-quality data about medicinal products

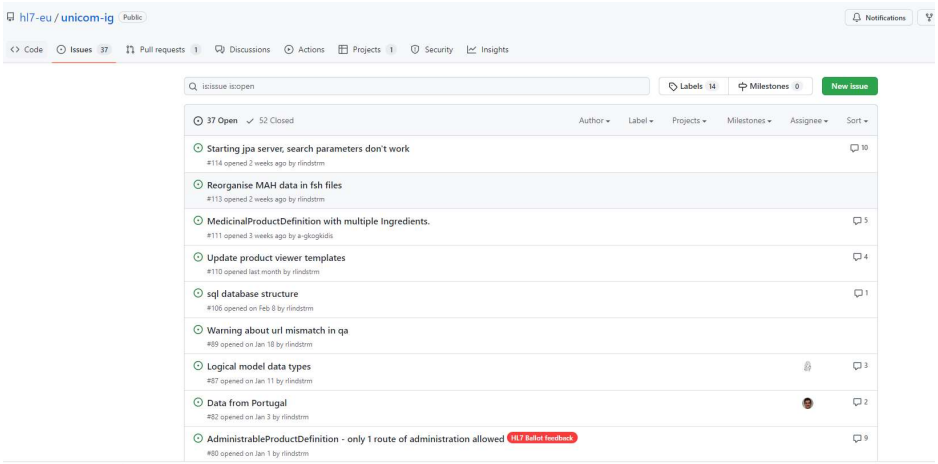


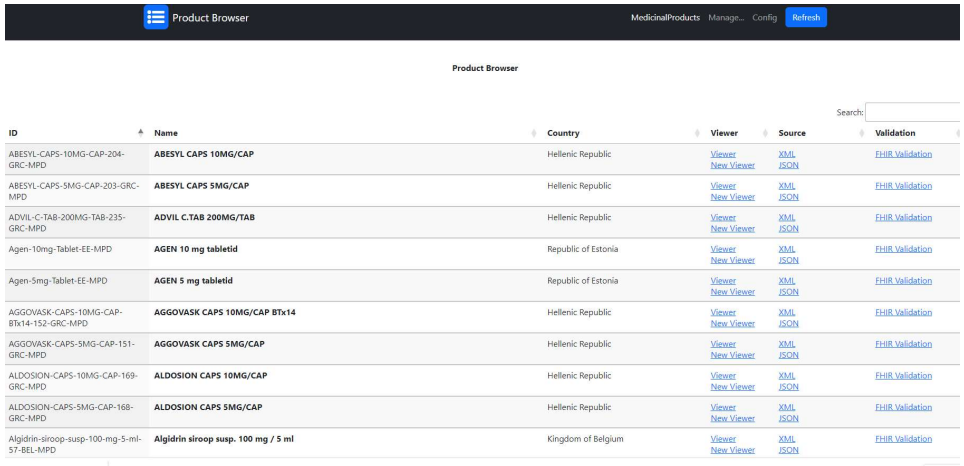
Norwegian Medicines Agency

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Access the key resources and be part of the adventure !







This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

THANK YOU

Our website
Our youtube channel

ISO IDMP Handbook "IDMP in a capsule" in English

With also French translation of "IDMP dans une capsule"

And even a Greek version: "IDMP σε κάψουλα »

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

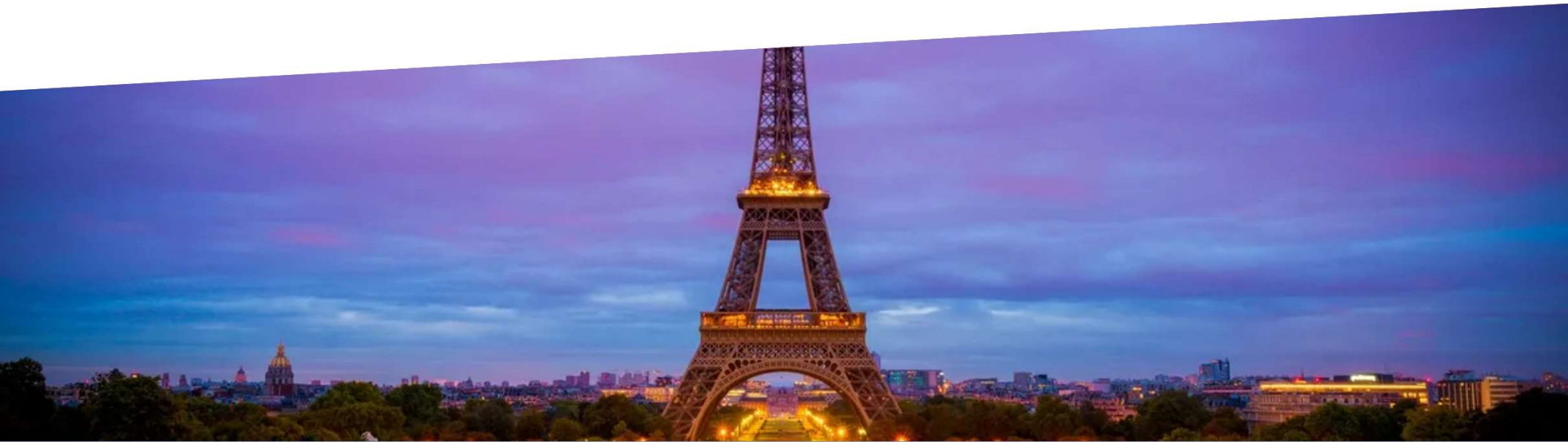
Lunch

Istanbul & Zagreb, Floor 1, 12:20 – 13:30

15. Future for Vulcan

Amy Cramer, Vulcan co-Chair / J&J

13:30 – 13:50



Vulcan Inflection Point

New Content

EuroVULCAN

Vulcan Projects
December 2022

Project	Objectives	Vulcan Lead
Schedule of Activities (SoA)	Represent the schedule of activities in FHIR from a spreadsheet. Enable the consistent description, timing and identification of each activity in a study	***Mike Ward*** (TransCelerate) ***Geoff Low*** (PHUSE)
Real World Data (RWD)	Extract data from EHRs in a standardized format to support clinical research and especially submission to Regulators	***Scott Gordon*** (FDA) [Open Position]
Phenotypic Data	To increase the availability of high-quality standardized phenotypic information for genomic research and genomic medicine.	***Anita Walden*** (University of Colorado Anshutz) ***Shahim Essaid*** (University of Colorado Anschutz)
Electronic Product Information (ePI)	Define a common structure for product information (monographs) that supports cross-border exchange of data for patients	***Craig Anderson*** (Pfizer) ***Catherine Chronaki*** (Secretary General at HL7 Europe)
Adverse Events (AE)	Support standardizing the reporting and format of an adverse event. Improve the maturity of the relevant FHIR resources	***Michelle Casagni*** (MITRE) ***Ed Millikan*** (FDA)
FHIR to OMOP	Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research	***Davera Gabriel*** (Johns Hopkins) ***Catherine Diederich*** (Duke)

EuroVULCAN

Use Case Review Criteria Recap

Under Review

Criteria	Explanation
Mission Fit	Does the proposed Use Case fit within the Vulcan mission and strategic goals / plan for Vulcan?
Leadership	Are there sufficient human resources to execute successfully? These would include leadership, volunteers, SMEs.
Funding	Is there funding to support the efforts outside of Vulcan?
Uniqueness	Is there anyone else working on this? If so, and if the project is not unique, should Vulcan collaborate with others?
Supportive Community	Is there a community of implementers willing to support and adopt the resulting standard / product?
Value	Will this standard / product bring value to the Vulcan community? Will it bring value to patients? Will it bring value to the people who do clinical trials?
Relationship with Current Projects	Will this project expand the success of existing Vulcan projects?
Feasibility	Is this feasible given the maturity (or lack of) of FHIR or other elements?

General Comments / Considerations

- Consider each on its own but also assess impact – both as the investment that is required as well as the benefit piece
- Spot the 'spaces between the projects' – a 'wider landscape' on where we are going in the future with Vulcan
- Where are the overlaps are among use cases and how they impact one another, i.e. interactions; a puzzle
- Go outside of the square of the puzzle itself; it is not just about Vulcan but also the collaborative organizations that surround this project
- Importance of building a community. Need a community of users. Consider who needs to put in the effort and who receives the benefit
- Need to address certain barriers such as terminology services and incompatible terminologies

EuroVULCAN

Potential Use Cases

Under Consideration

- **Data Collection & Transfer**
  - Common Data Sets
  - Decentralized Trials
- **Protocol Representation**
  - Protocol Feasibility
  - Recruitment Matching
- **Analysis & Visualization**
  - Statistical Analysis Plan (SAP)
  - Visualization Reporting

Products & Devices

- Devices in Studies
- Digital Therapeutics (DTx)

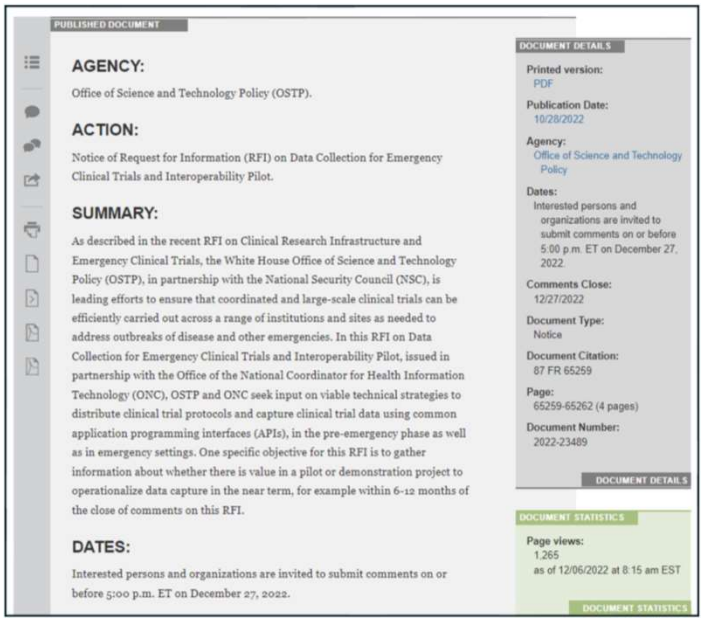
- **Data Models**
  - Digital Data Flow
- **Other**
  - Extending FHIR to CDISC Mappings
  - FHIR-based Eligibility Determination for Clinical Trials
  - Individual Data Control to Opt-In for Clinician Research
  - Adverse Event Reporting using Medwatch

EuroVULCAN

RFI from the Office of Science and Technology Policy

January 2023 – Follow Up

Request for Information on Data Collection for Emergency Clinical Trials and Interoperability Pilot



PUBLISHED DOCUMENT

AGENCY:

Office of Science and Technology Policy (OSTP).

ACTION:

Notice of Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot.

SUMMARY:

As described in the recent RFI on Clinical Research Infrastructure and Emergency Clinical Trials, the White House Office of Science and Technology Policy (OSTP), in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites as needed to address outbreaks of disease and other emergencies. In this RFI on Data Collection for Emergency Clinical Trials and Interoperability Pilot, issued in partnership with the Office of the National Coordinator for Health Information Technology (ONC), OSTP and ONC seek input on viable technical strategies to distribute clinical trial protocols and capture clinical trial data using common application programming interfaces (APIs), in the pre-emergency phase as well as in emergency settings. One specific objective for this RFI is to gather information about whether there is value in a pilot or demonstration project to operationalize data capture in the near term, for example within 6-12 months of the close of comments on this RFI.

DATES:

Interested persons and organizations are invited to submit comments on or before 5:00 p.m. ET on December 27, 2022.

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
10/28/2022

Agency:
Office of Science and Technology Policy

Dates:
Interested persons and organizations are invited to submit comments on or before 5:00 p.m. ET on December 27, 2022.

Comments Close:
12/27/2022

Document Type:
Notice

Document Citation:
87 FR 65259

Page:
65259-65262 (4 pages)

Document Number:
2022-23489

DOCUMENT DETAILS

DOCUMENT STATISTICS

Page views:
1,265
as of 12/06/2022 at 8:15 am EST

DOCUMENT STATISTICS

Vulcan Response

Vulcan provided 25 comments on 7 use case steps and 40 comments on 12 topics

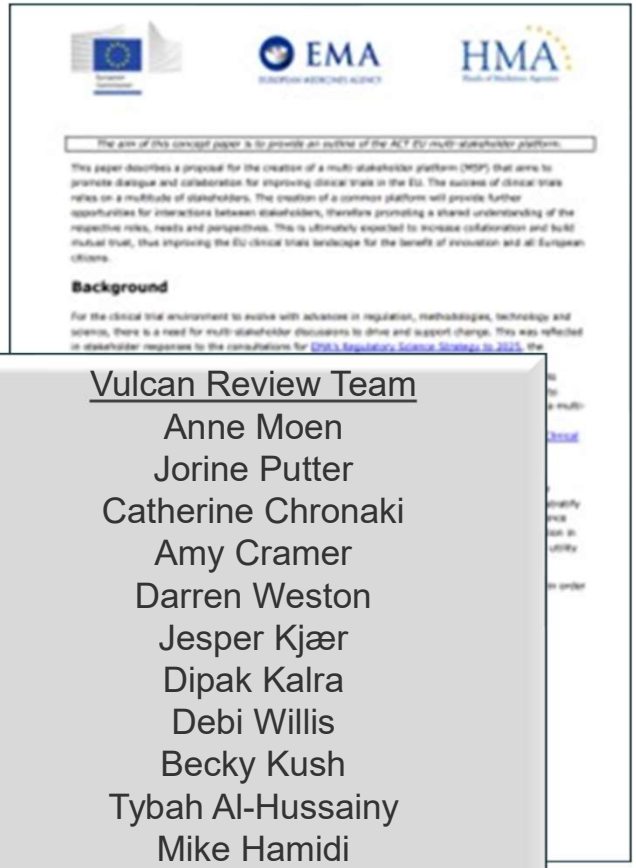
Vulcan Review Team

Cal Collins - OpenClinica
Amy Cramer – Johnson & Johnson
Tom Yosick - Epic
Nancy Smider - Epic
Debi Willis - PatientLink
Mike Hamidi - Pfizer
Maryam Garza – University of Arkansas for Medical Sciences (UAMS)
Henry Wei – TransCelerate/ Regeneron
Hugh, Stacy, Shani, Michael from PMO

In a follow-up call with the White House OSTP and HHS/ONC in February, Vulcan was complimented on the relevance, practicality and insightfulness of the comments provided. They were impressed and appreciated the overall response.

EuroVULCAN

Public consultation on a multi-stakeholder platform to improve clinical trials in the EU: Vulcan Response



Vulcan Review Team

Anne Moen
Jorine Putter
Catherine Chronaki
Amy Cramer
Darren Weston
Jesper Kjær
Dipak Kalra
Debi Willis
Becky Kush
Tybah Al-Hussainy
Mike Hamidi
Vulcan PMO

Comments submitted March 3, 2023 by Mike Hamidi, Operations Ctte co-Chair

Taking into consideration the ACT EU and MSP objectives, list any additional priority topic not included in the above selection. *1000 character(s) maximum*

Vulcan Response (Section 2.1)

Response: (822 characters with spaces)

Additional priority topics for consideration include:

[1] RWD exchange using FHIR to support clinical trials, in alignment with GDPR & FHIR privacy & security measures

[2] Evaluate how the Statistical Analysis Plan can be represented in FHIR (association with PBM/EBM)

[3] Patient friendly focus in trial design using FHIR-based interoperability using SMARTonFHIR

[4] Innovative products using Digital Medicine/Therapeutics (DMx/DTx) and associated digital markers/endpoints

[5] Digital representation of clinical trial eligibility criteria using FHIR

[6] Continuation of the ICH M11 CeSHaRP development (data exchange of the digitized protocol)

[7] Engage with the development and adoption of the European Electronic Health Record Exchange Format

Vulcan can also support efforts by EMA to decentralize Clinical Trials in the EU.

The ACT EU multi-stakeholder platform concept paper outlines the scope, objectives and organisation of the MSP. Please provide any comments you may have on the proposal. *2000 character(s) maximum*

Vulcan Response (Section 3)

Response: (1068 characters with spaces)

Some perspectives on scope, objectives and organisations of the MSP include:

[1] Organisation: Current MSP composition is missing data / standards organisations (and associated people) such as HL7 Vulcan Accelerator

[2] Organisation: Consider adding ICT trade associations, as they represent the organisations that will implement

[3] Organization: Standards Developing organizations, as they advance data standards

[4] Scope: Suggest that the scope should also explicitly include addressing the use and reuse of innovative technologies and devices in clinical trials (their use will only increase in the future)

The European Health Data Space Regulation currently under debate will no doubt affect the way clinical trials are set up in Europe, and the governance structures associated with it. Bridging primary and secondary use of Electronic Health Record data and influencing the capabilities Electronic Health Record systems is necessary to support higher quality of data for clinical trials, calls to link the MSP to the EHDS structures.

Vulcan, an HL7 Accelerator, provides a platform for the development of standards in clinical research that support the efforts of the ACT EU MSP. Vulcan provides a neutral, open, transparent and collaborative environment that is devoid of commercial interest. Vulcan comprises 40+ international members (and growing) and has balloted its first set of FHIR-based standards for RWD, Schedule of Activities and electronic Product Information - ePI (the latter being sponsored by the Gravitate-Health IMI2 project linked to the implementation and adoption of ePIs in collaboration with EMA).

We would be happy to discuss how Vulcan can support the EMA in the rollout of the MSP.

EuroVULCAN

What's Coming Next?

EuroVULCAN

OSTP/ONC
Opportunity

1. Through these 2 RFIs, the US Federal govt has been collecting feedback on what are the future health IT infrastructure needs and current data capture challenges that must be addressed to ensure the ability to effectively run diverse multi-site clinical trials in a response to a national / global emergency.
2. As stated in the joint blog post by OSTP and ONC, the challenge now is to develop strategies for electronic capture of clinical trial data that can be used by unrelated institutions and study sites that participate in the same clinical trial.
3. These strategies must be deployed in both the emergent and non-emergent settings.
4. It's also important to note that this is part of a larger goal of strengthening the overall clinical trials infrastructure and making clinical research opportunities available to all Americans.
5. As you can imagine, the Vulcan leadership and its members have a lot to say on this matter.
6. In fact, not only did we submit an official response to the 2 RFIs, but we also participated as SMEs on a panel for a public listening session hosted by ONC/OSTP.
7. Since then, we've also had a few follow up conversations with the team leading this work out of the White House and ONC, to explore further what a demonstration project / data capture pilot could look like, and in what ways specifically the Vulcan community might be able to help support such a project later this year.

https://www.whitehouse.gov/ostp/news-updates/2022/10/31/ostp-in-partnership-with-onc-seeks-input-on-optimizing-data-capture-for-clinical-trials/

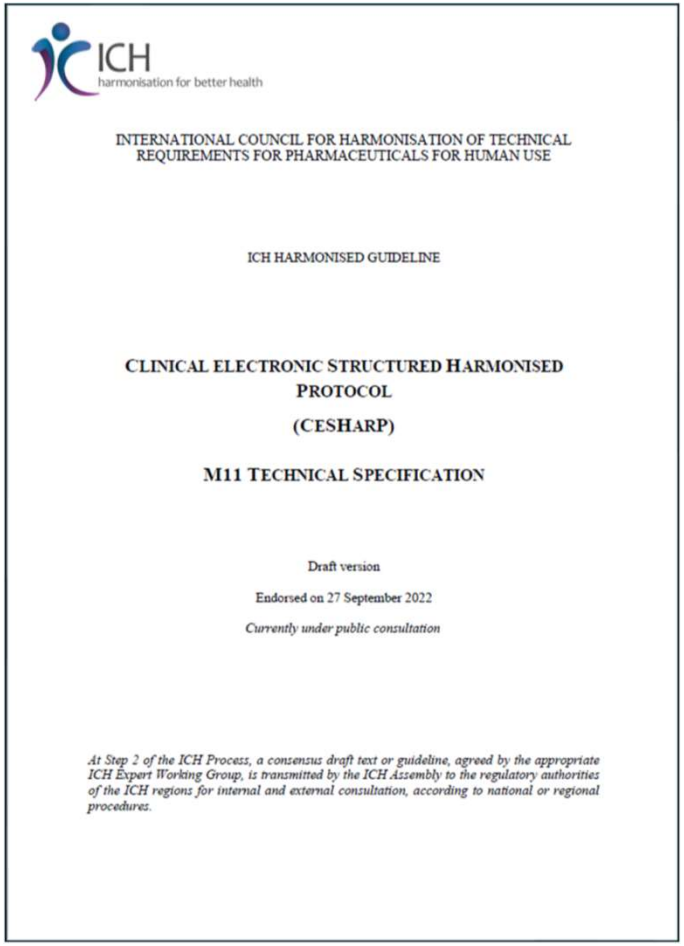
Opportunity for ICH M11 Vulcan Project

Background

ICH M11 / Vulcan meeting February 13

Observation: Ties very nicely with our existing Schedule of Activities (SoA)

Following slides provide additional background and context



ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TECHNICAL SPECIFICATION

Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

EuroVULCAN

Vulcan Project Proposal: ICH M11 Implementation

Clinical electronic Structured Harmonized Protocol

Problem Statement

- Clinical protocol describes processes/procedures for conduct and analysis of a clinical study.
- Lack of harmonization/standardization contributes to inefficiencies & difficulties in reviewing and assessing clinical protocols.
- ICH M11 Expert Working Group, established in 2018, developed draft guideline, template, and technical specification to facilitate its electronic exchange. Finalization planned for availability by end of 2023.
- Collaboration with an SDO(s) is needed to deliver the exchange standard based on M11's technical specification (including data models).

Impact & Value

- A harmonised data-driven digitized clinical protocol will enhance the ability of sponsors, regulators, investigators, and other stakeholders to initiate, review, and conduct clinical research, resulting in more efficient drug development and delivery of medicines to patients.
- Protocol data can be used to populate local, regional, and international clinical trial registries.
- Vulcan provides the unique opportunity to work with various stakeholders with knowledge of existing relevant data standards and the ability to curate them, as well as to rapidly mature the specifications for message exchange.
- Due to recent changes in ICH procedures, the proposed collaboration will occur in parallel with the final stages of the ICH process to deliver more rapidly than has previously been achieved.

EuroVULCAN

Vulcan Project Proposal: ICH M11 Implementation

Clinical electronic Structured Harmonized Protocol

Success Criteria:

1. Deliver FHIR Implementation Guide that is aligned with the ICH M11 Technical Implementation Guide (including data models)
2. Demonstrate the Electronic Delivery, Receipt, and Validation of the M11 requirements based on the FHIR IG for initial personas use cases: Regulator to Regulator, Sponsor to Regulator
3. Define a shared maintenance plan of the FHIR IG with the ICH Expert Working Group content experts

Effort: High/Medium/Low

- Low to Medium
- ICH M11 will provide Vulcan with a number of completed technical artifacts: technical specification and conceptual and logical models. A Vulcan project would use the ICH M11 artifacts to develop the TIG and conduct the testing and validation.

Difficulty: High/Medium/Low?

- Low to Medium
- Due to the amount of technical work that has been and will be completed by M11 prior to engagement with Vulcan we believe the difficulty is low to medium.

EuroVULCAN

Current Member Organizations of Vulcan

As of February 2023

All of these initiatives requires Vulcan to Grow and Continue to Attract a Broad Membership

★ *indicates a convening member of Vulcan*

Current Member Organizations of Vulcan

As of February 2023

You need to be a part of creating the future

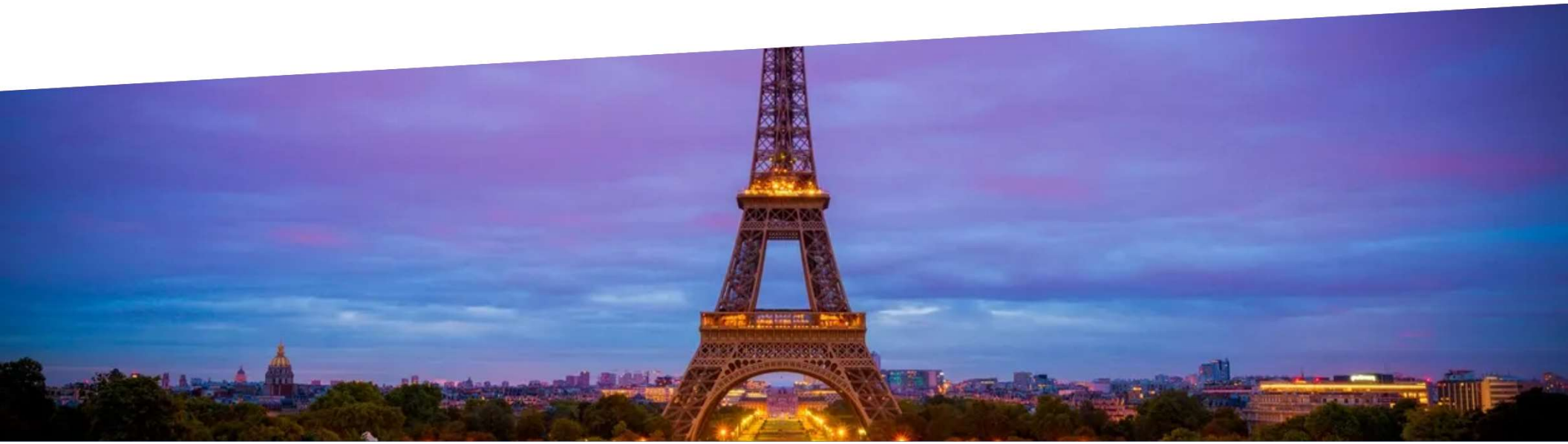
★ *indicates a convening member of Vulcan*


Questions?

16. Perspectives on FHIR (Part 3 – Government)

Teresa Zayas Cabán PhD, National Library of Medicine (remote)

13:50 – 14:10

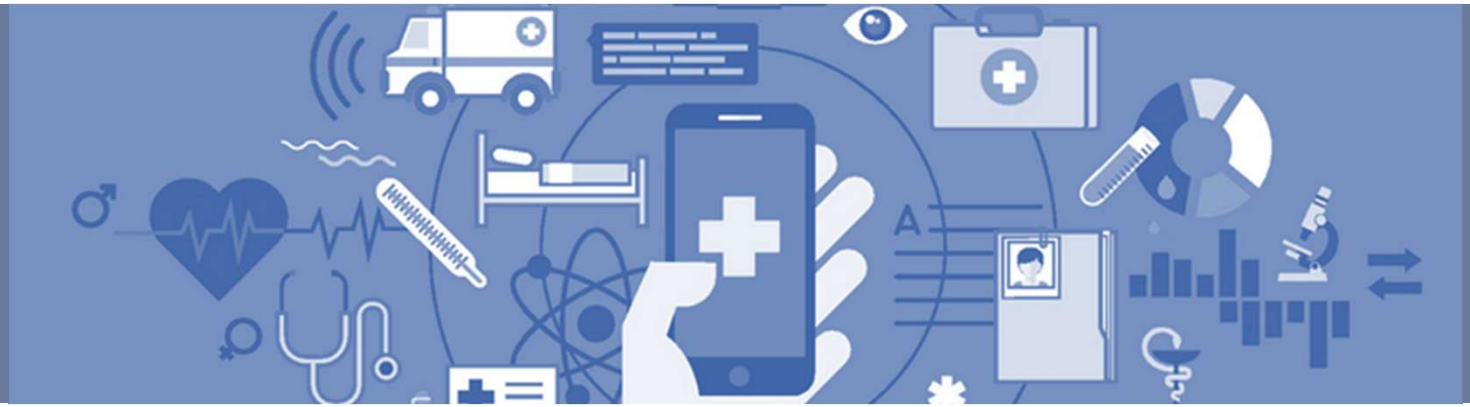


Accelerating Discovery through FHIR

Teresa Zayas Cabán, PhD
Assistant Director for Policy Development
National Library of Medicine (NLM)
National Institutes of Health (NIH)

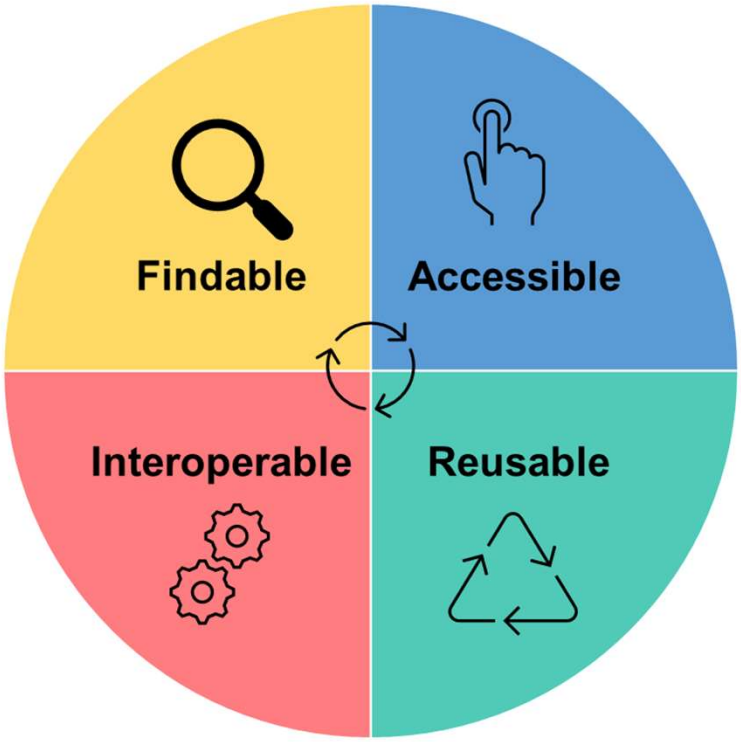
EuroVulcan Conference & Connectathon
~~Paris, France~~ *Virtually from* Maryland, USA
March 15, 2023

Data, Data Everywhere



Putting the *I* in FAIR

- Advancing interoperable data access, sharing, use, and reuse for research
- Standards key to interoperability and reusability of data
- Opportunity to leverage healthcare data standards in research



Adapted from National Institute of Environmental Health Sciences

Advancing Data Science and Open Science at NIH and NLM

Data Infrastructure	Modernized Data Ecosystem	Data Management, Analytics, and Tools	Workforce Development	Stewardship and Sustainability
•Optimize data storage and security •Connect NIH data systems	•Modernize data repository ecosystem •Support storage and sharing of individual datasets •Better integrate clinical and observational data into biomedical data science	•Support useful, generalizable, and accessible tools and workflows •Broaden utility of and access to specialized tools •Improve discovery and cataloging resources	•Enhance the NIH data-science workforce •Expand the national research workforce •Engage a broader community	•Develop policies for a FAIR data ecosystem •Enhance stewardship

Accelerating Discovery and Data-Powered Health

Accelerate discovery and advance health through data-driven research

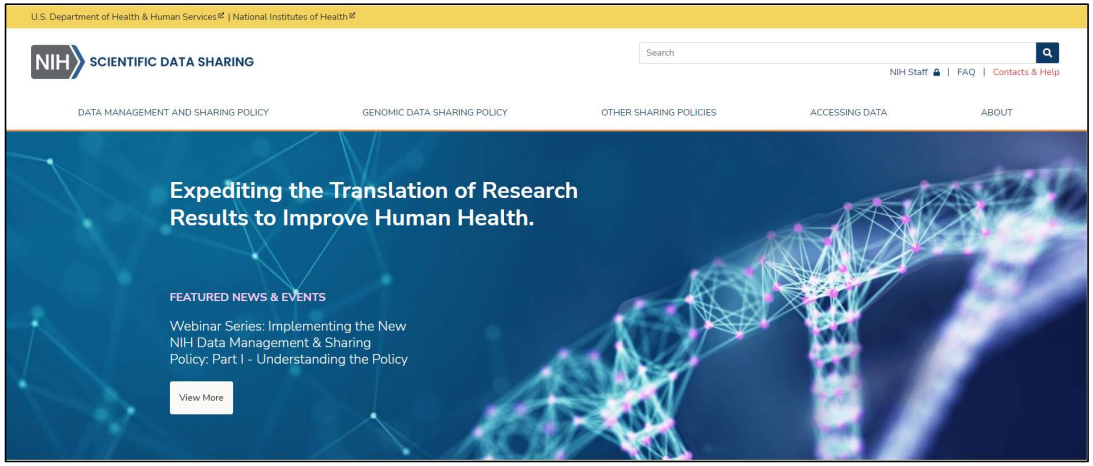
Reach more people in more ways through enhanced dissemination and engagement

Build a workforce for data-driven research and health

NLM Standards Work

- Support standards
- Test, research, and develop standards
- Maintain repositories
- Use standards in information services
- Lead policy and cross-NIH coordination

Role of Standards in Research Data Sharing

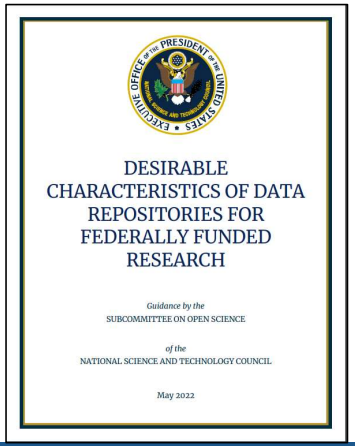


https://sharing.nih.gov/

PubMed Central

db GaP GENOTYPES and PHENOTYPES

ClinicalTrials.gov
A service of the U.S. National Institutes of Health


DESIRABLE CHARACTERISTICS OF DATA REPOSITORIES FOR FEDERALLY FUNDED RESEARCH

Guidance by the
SUBCOMMITTEE ON OPEN SCIENCE

of the
NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

May 2022

Advancing Use of FHIR in Research

Fast Healthcare Interoperability Resources (FHIR®) Standard

Notice Number: NOT-OD-19-122

Key Dates

Release Date: July 30, 2019

Related Announcements

NOT-HL-20-815
NOT-OD-19-014
NOT-OD-18-134
NOT-OD-19-150
NOT-OD-20-146
NOT-HL-21-010

Issued by

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES

Purpose

The purpose of this notice is to encourage NIH researche
clinical data for research purposes and to enhance capal

Request for Information (RFI): Use of the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) for Capturing and Sharing Clinical Data for Research Purposes

Notice Number: NOT-OD-19-150

Key Dates

Release Date: September 24, 2019
Response Date: November 23, 2019

Related Announcements

NOT-OD-19-122
NOT-OD-19-127

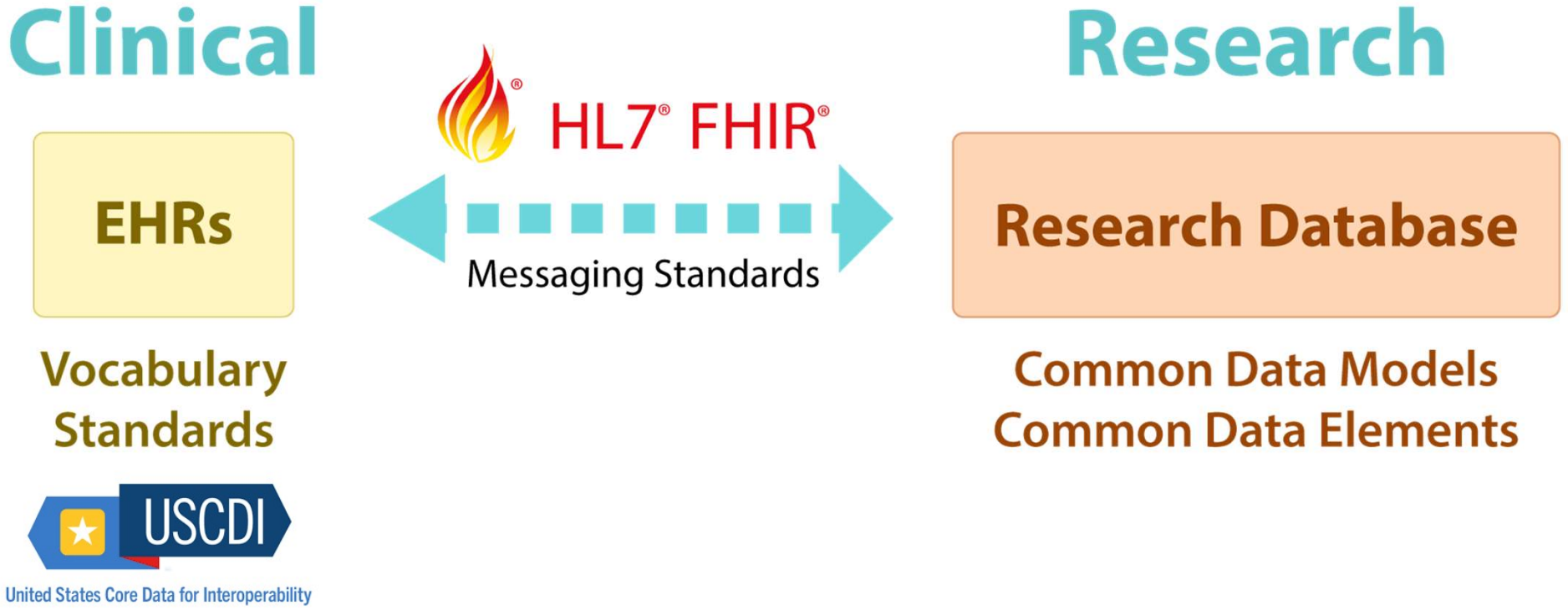
NIH Awards Contracts to Increase Availability of High-Quality Data Using FHIR Standard

The National Institutes of Health recently awarded two contracts related to the use of the Fast Healthcare Interoperability Resources (FHIR) standard in biomedical research.

FHIR is a standardized way of transmitting health data from one health information system to another through an application programming interface. Use of a standard such as FHIR could accelerate the use of clinical data for research. The FHIR standard is already broadly used in health care, and several federal health agencies are using FHIR to exchange data.

NIH would like to develop and test FHIR tools for researchers and advance the sharing of phenotypic information using the FHIR standard.

Sharing Clinical Data for Research Using FHIR



Engaging Stakeholders

- Overall support for NIH's direction
- Noted challenges in using FHIR "as is" for research
- Recommendations regarding
  - Engagement
  - Tool development
  - Research and development
  - Related policies

NIH FHIR Activities

- Convened Federal and external stakeholders
- Led initial projects
  - Mapping between common data models (CDMs) and FHIR
  - Catalogue of existing, internal NIH FHIR activities
- Conducted
  - External landscape analysis
  - Needs assessment for educational, outreach program

https://datascience.nih.gov/fhir-initiatives

Considerations for Using FHIR in Research

- Knowledge and understanding of FHIR
- Ability to capture certain research data elements in core FHIR Resources from a variety of sources
- Research-specific needs regarding data access, mapping, curation, aggregation, and analysis
- Expertise, resources, and infrastructure needed to adopt and use FHIR in research

Needs and Opportunities

- Educational and engagement opportunities
- Development of FHIR specifications, tools, resources, and capabilities that enable research
- Clinical research community participation in related efforts to further develop and align FHIR and research

NIH FHIR Training

- **General engagement:** Webinars to enhance awareness of FHIR
- **Introductory courses**: Introduction to FHIR, clinical data
- **Hands-on training**: Planned collaborations with tools development
- **Convening:** Workshops on using FHIR for research

FHIR Development and Resources

- Implementation Guide on complying with FAIR using FHIR
  - http://hl7.org/fhir/uv/fhir-for-fair/STU1/
- Catalog of common data model and FHIR harmonization resources
  - https://datascience.nih.gov/fhir-initiatives/resources/cdmcatalog

CDM and FHIR Harmonization Resources

Resource Name	Focus of Resource	Resource Description	Related CDMs	Source Name	Source Description	Funding
CDM - FHIR Gap Analysis	Mappings	List of mappings between FHIR and three CDMs: 1. ACT(i2b2) to FHIR Mappings Table, 2. OMOP to FHIR Mappings Resources, and 3. PCORnet(v4.1) to FHIR Mappings Table.	i2b2, OMOP, PCORnet	CD2H Data Harmonization Project	The CD2H Data Harmonization project, part of the CD2H Next Generation Data Repository Core, identifies and curates resources and tools that enable a common framework for rendering and querying clinical data. CD2H accelerates advancements in informatics by using FAIR principles to promote collaboration across the CTSA Program.	NIH
Federated Data Query Workshop	Educational	Presentations with video and slides from a two-day workshop focused on data harmonization and federated query and hosted by the CD2H Data Harmonization Working Group.	i2b2, OMOP, PCORnet	CD2H Data Harmonization Project	The CD2H Data Harmonization project, part of the CD2H Next Generation Data Repository Core, identifies and curates resources and tools that enable a common framework for rendering and querying clinical data. CD2H accelerates advancements in informatics by using	NIH

Looking Ahead

- Engagement with standards development efforts
- Development of educational and training resources
- Investment in FHIR development and related tools to facilitate research use

Questions?

Special Thanks To

Liz Amos, National Library of Medicine

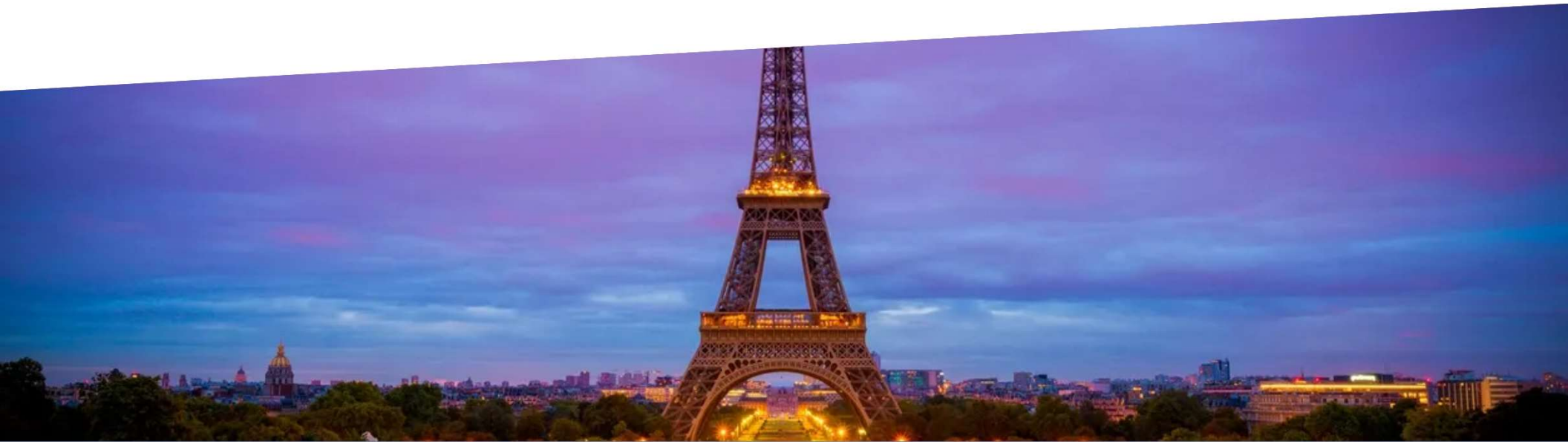
Belinda Seto and Steve Tsang,
NIH Office of Data Science Strategy

https://www.nlm.nih.gov/

17. Perspectives on FHIR (Part 4 – Pharma)

Darren Weston, Vulcan co-Chair / J&J

14:10 – 14:30



Pharma Perspectives On FHIR

Darren Weston

March 2023

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

FHIR Can Enable Macro R&D Challenges

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Some Key Areas Of Focus

- Faster Access To Data
- Effective Recruitment
- Reduced Costs

- Efficient Study Conduct
- Improved Patient Care
- Greater Data Transparency

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Deep Dive Into The Focus Areas

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Faster Access To Data

- Timely decision making
- Improved Efficiency
- Better insights
- Competitive Advantage
- Improved patient and site experience

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Effective Recruitment

Improved precision in patient identification

- Reduce time and resources required to recruitment patients

Enrich study populations

- Potential to recruit a more diverse patient population, improving the generalizability of study results

Increase speed of recruitment

- Identify patients faster, and reduce the overall enrollment period

Optimize study designs

- Better access study feasibility and optimize study designs, reducing risk of recruitment delays

Reduce The Cost Of R&D

Patient recruitment: Finding and enrolling enough patients who meet the inclusion and exclusion criteria can be a significant challenge resulting in delays.

Patient retention: Once patients are enrolled in a trial, it is important to keep them engaged and compliant with the study protocol. Dropout rates can be high, particularly in trials involving long-term treatments or complex protocols, which can impact the statistical power and validity of the study.

Data management and analysis: Collecting and analyzing clinical trial data can be a time-consuming and resource-intensive process. Ensuring data quality and integrity is critical to the success of a trial, and any issues with data collection or management can cause delays and impact the validity of the results.

Safety monitoring: Ensuring the safety of trial participants is a top priority, and any safety concerns that arise during a trial must be carefully monitored and managed. This can require additional resources and can impact the timeline of the trial.

janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Efficient Study Conduct

Streamlined data collection:

- Reduced data re-entry
- Reduced data queries
- Reduced Data Monitoring

Improved data quality

- Standard data exchange reducing the potential for errors or inconsistencies.

Facilitated data sharing

- Easier to share data between different trial management systems, EHRs, and other clinical trial applications

Enhancing collaboration

- Facilitate collaboration between different stakeholders involved in clinical trial conduct, including researchers, trial sponsors, and regulatory agencies.

Makes being a PI way more attractive

- Enable the creation of PIs of the future, helping increase diversity of recruitment

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

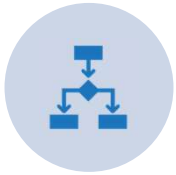
Improved Patient Care

Improved data sharing	• Easier to share information about patient diagnoses, treatments, and outcomes. This can help ensure that all stakeholders involved in the trial have access to the same information, which can improve patient care and safety.
Better clinical decision-making	• Provided clinicians with access to real-time patient data and analytics. This can help clinicians make more informed decisions about patient care and treatment, leading to better outcomes.
Enhanced patient engagement	• FHIR can be used to create patient-facing applications that provide patients with access to their own clinical trial data. This can help increase patient engagement and empower patients to take a more active role in their own care.
Improved safety monitoring	• FHIR can be used to integrate patient data from various sources, allowing for more comprehensive safety monitoring during a clinical trial, enabling early intervention

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Greater Data Transparency

IMPROVED PATIENT TRUST



BETTER DECISION-MAKING

INCREASED ACCOUNTABILITY

IMPROVED PUBLIC HEALTH

ENHANCED RESEARCH

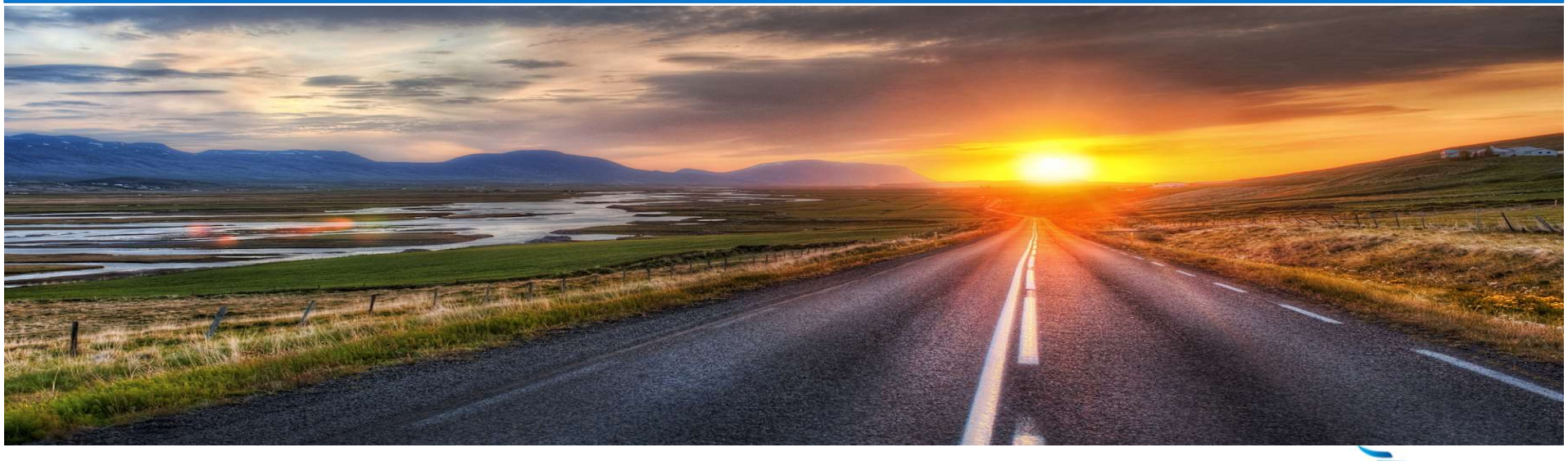
INCREASED EFFICIENCY

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Concluding Thoughts

Change management is needed in general. Some specific observations:

- Investment in developing FHIR expertise
- We don’t know enough about interoperability in general (good and bad)
- Machine readable protocol information will disrupt workflow

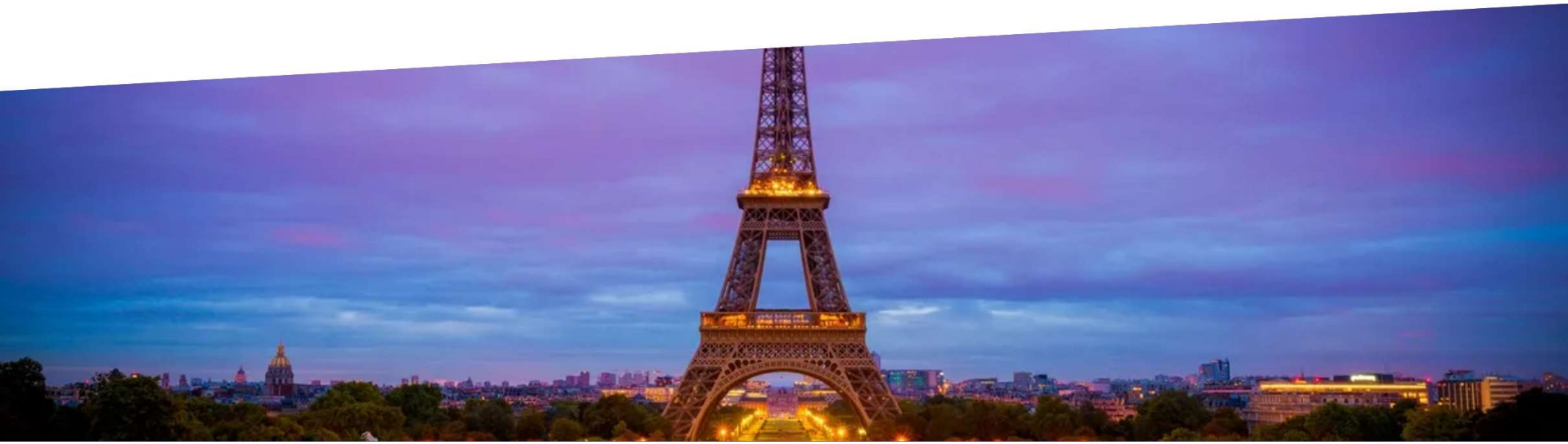


janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

18. New Data Challenges of Decentralized Trials

Craig Lipset, Clinical Innovation Partners (remote)

14:30 – 14:50



The New Data Challenge of Decentralized Trials

Craig H Lipset
@craiglipset
March 2023

Craig Lipset: About Me

Board Member

DTRA Decentralized Trials & Research Alliance

MedStar Health Research Institute

FSR Foundation for Sarcoidosis Research

Circuit Clinical

Empath Labs

MedVector

Faculty

Rutgers

University of Rochester

Advisor

Clinical Innovation Partners

imi

Trials @Home

IEEE Advancing Technology for Humanity

Formerly

Pfizer

TransCelerate BioPharma Inc.

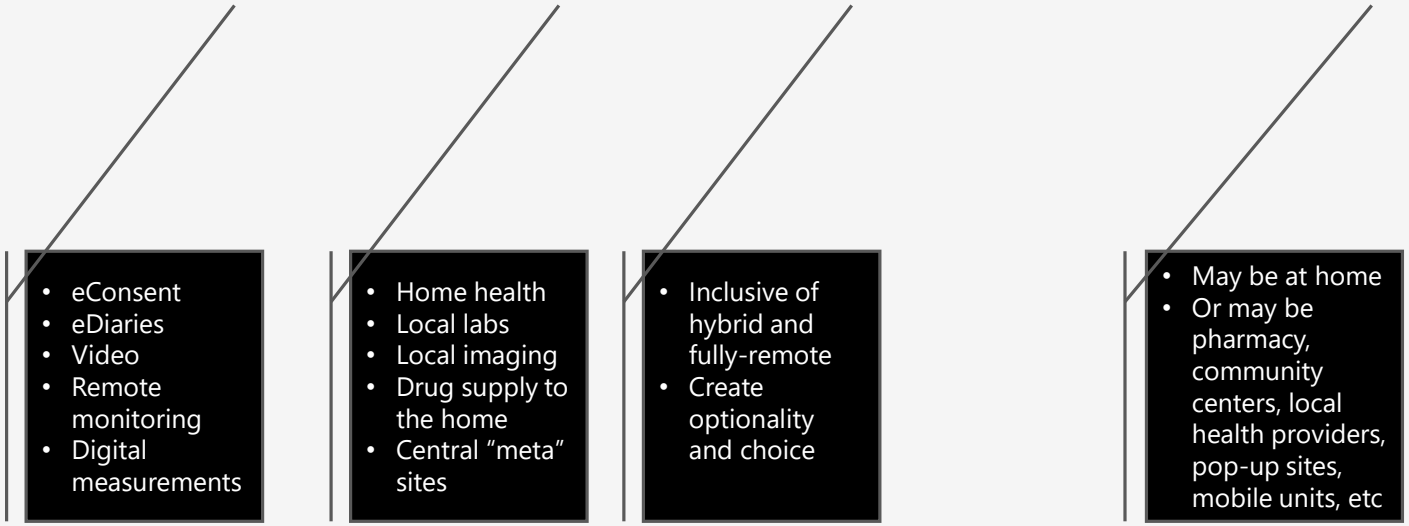
Parexel perceptive Informatics

Adnexus Therapeutics

Views and positions expressed represent those of the presenter and not necessarily of the affiliations above

Decentralized Clinical Trials [DCT]: Defined

DCT = use of **technology** and/or **processes** that **enable** visits to take place **outside of a traditional research site**



Participation “From Home” Catalyzed by the Pandemic

Pfizer Science Products Stories Newsroom About

Pfizer Conducts First “Virtual” Clinical Trial Allowing Patients to Participate Regardless Of Geography

Tuesday, June 07, 2011 - 05:30am

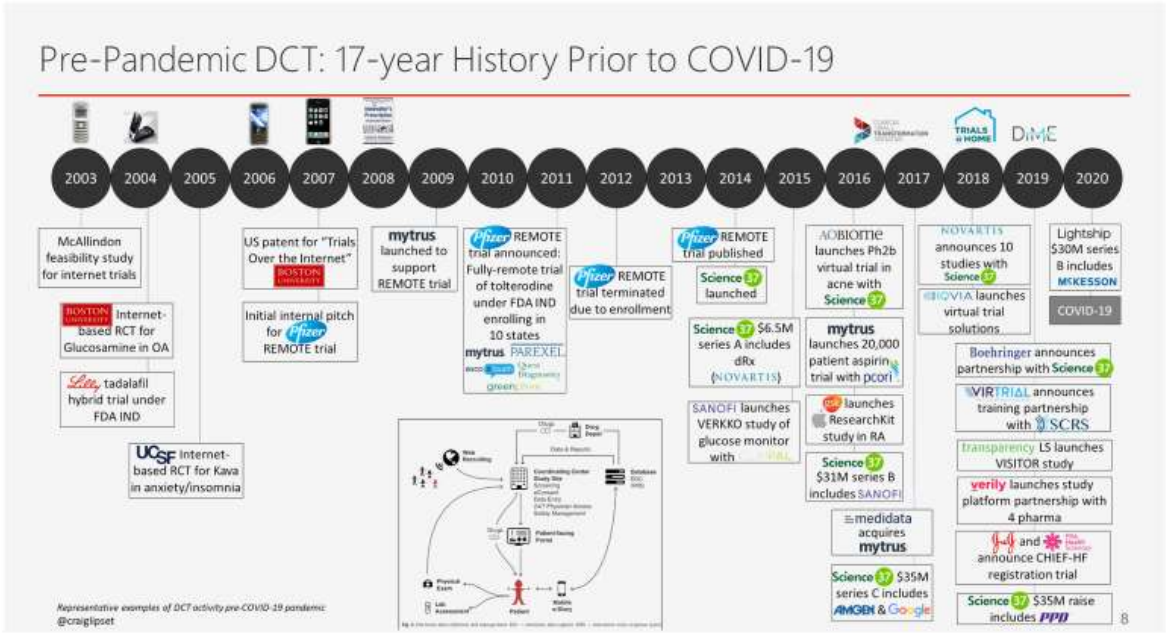
Pilot Study Will Compare Results to Previous Trial Data to Assess Validity of New Approach

"This program and similar programs that may f
patients to participate in trials and contribute t

CLINICAL TRIALS TRANSFORMATION INITIATIVE

CTTI Recommendations: Decentralized Clinical Trials

September 2018



COVID-19 Catalyzed *Adoption* (rather than *Innovation*)

Barriers to Scaled Adoption of Decentralized Trials

Regulatory ambiguity

Global variability

Technology interop & data flow

Investigator & patient readiness

Endpoint limitations

Organization culture

DCT1.0 → DCT 2.0

DCT1.0

- Clinic or home
- eConsent
- Video visits
- Home visits
- Limited remote monitoring
- Local specimens
- Supply chain home

DCT2.0

1. Locations beyond home
2. Next gen participant support
3. Participant choice & flexibility
4. Site BYO-HIT
5. Patients BYO-RWD
6. Endpoint modernization
7. Platform revolution

1 Locations Beyond "Home": HCPs Unlocked

The Treating Physician Matters

49% identify their own doctor as the source of advice they would trust most when considering research participation
(even higher among patients living in North America)

But They Are Not Engaged With Meaningful Options

Either become an Investigator

Or refer to an Investigator

Remote Investigators Open New Doors

Enable patients to participate from their trusted and accessible treating physician office via a remote / centralized investigator
Compensate the practice FMV

2019 CISCRP Perceptions and Insights Study: Engagement Preferences.

1 Location Beyond “Home”: Trials Going Mobile + Retail

2 Next Gen Participant Support

Leading patient concern regarding DCTs: Technical difficulties*

From…

Technical

Disparate
Disconnected
Device-Specific

…To

Technical

Clinical

Operational

Emotional

Meeting the Holistic Needs of the Participant

*2021 “The Patients’ Perspective on Decentralized Trials” (James Lind Care)

3 Participant Choice & Flexibility

Post-COVID Future Focused Options


Grocery


Education


Business


Healthcare

Define the options available for each visit in the protocol summary of assessment

Visits	Screening Pre-MS Review Panel	Screening Post-MS Review Panel	Baseline	Post-mobilization & Pre-conditioning	Day 0 (Transplant)	Day +1 to +28	Week 4 (Day 28)	Week 8 (Day 56)	Month 6	Month 12	Month 24	Month 36	Month 48	Month 60
	SC1	SC2	-1	PM	0	1[a]	2	3	4	5	6	7	8	9[b]
Informed Consent														
Signed Screening Informed Consent	X													
Signed Treatment Informed Consent			X											
MS Assessments														
Confirmation of MS Diagnosis	X													
MS History	X								X	X	X	X	X	X
Neurologic Exam and EDSS	X		X	X					X	X	X	X	X	X
MS Functional Composite (MSFC)[c]			X						X	X	X	X	X	X
QoL Questionnaire (MSIS-29)			X						X	X	X	X	X	X
Medical History and Physical Exam														
Medical History	X													
Physical Exam and Health Assessments[d]	X		X	X	X	X	X	X	X	X	X	X	X	X
Post-Mobilization or Post-Transplant Acute Toxicity Assessment				X			X	X	X					
Clinical Procedures & Assessments														
CBC with diff and platelets		X	X	X	X	X	X	X	X	X	X	X	X	X

[a]Clinical assessments are required twice a week until Day 28 or discharge from hospital (see MOP)

[b]The Month 60 Visit is the study primary endpoint evaluation visit and the Study Completion Visit. Subjects who meet the primary endpoint (Section 3.2.1) should undergo a complete end of study evaluation at the time of meeting the primary endpoint (see Section 6.3.7.2), and will, in addition, continue to be followed on the schedule listed in Section 6.3.7.1. Study subjects withdrawn from the trial for any reason prior to the 60-month evaluation should undergo a complete end of study evaluation if possible (see Section 6.3.7.2).

4 Site BYO-HIT

Clinics & Sites Are Investing in Telehealth…

64% Year-over-year increase in telehealth.

Frost & Sullivan, 2020

73% Sites will use telemedicine after COVID-19.

WCG CenterWatch

…Yet Sponsors & CROs "Pass Down" Study-Specific Technology.

How Do We Allow Sites to BYO-HIT*?

**Bring Your Own Health Information Technology*

Avoid re-learning

Use tools that fit site workflow

Recover site's investment

Reduce redundant cost

Provision only when necessary

Define Quality Standards

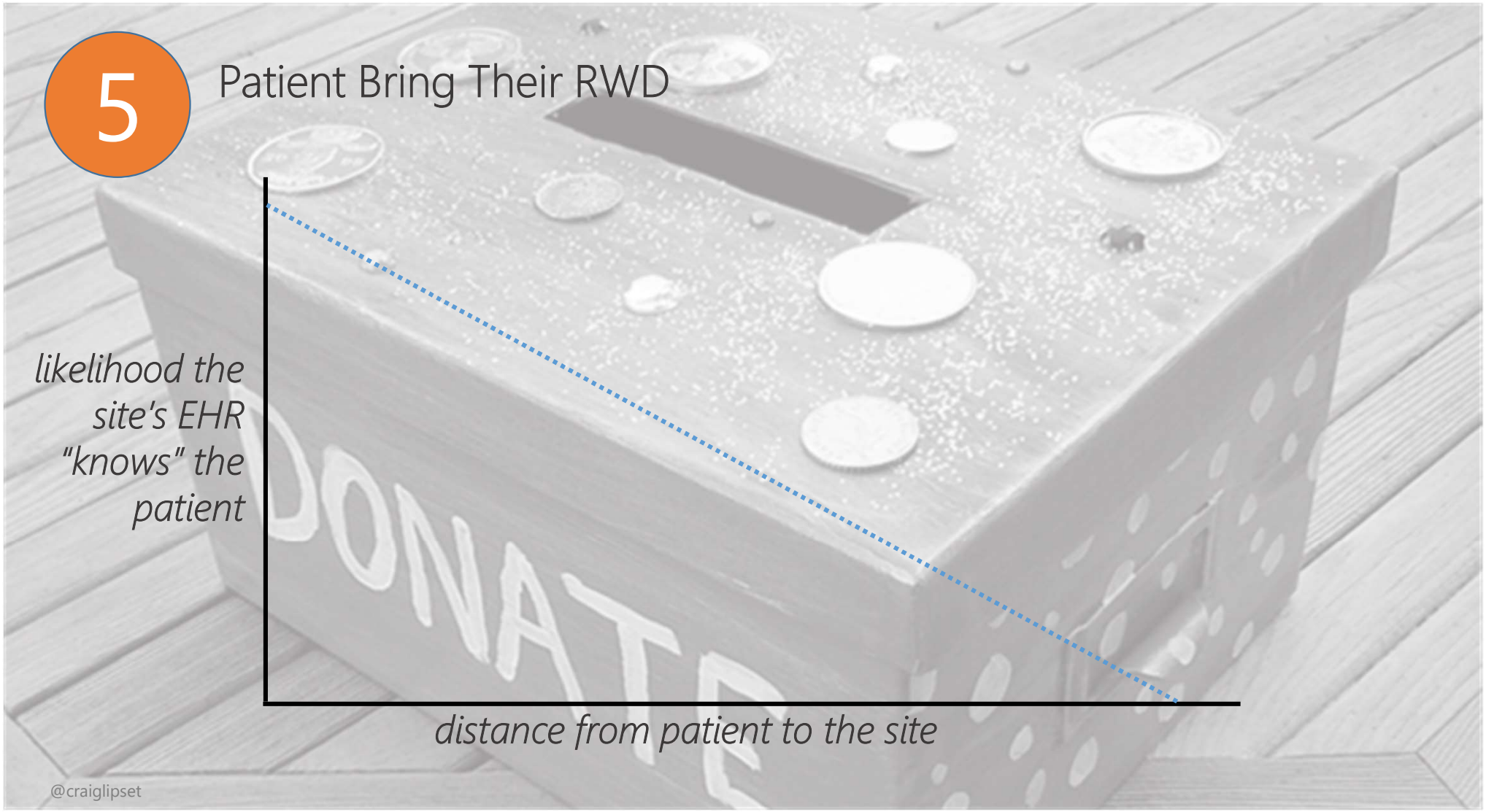
5 Patient Bring Their RWD

Decentralized trials can not compromise on diversity or integrity of patient data

Real world data brings the opportunity to:

Enhance recruitment
Accelerate screening & eligibility
Enable eSource
Ease long-term safety follow-up
Support precision medicine
Synthetic controls

5 Patient Bring Their RWD



@craiglipset

5 Patient Bring Their RWD

Patients are interested in sharing

Almost half of all patients will share their electronic health record with for-profit research organizations.

Patients are empowered to share

- Sharing via patient portals
- FHIR-based approaches
- HIPAA right-of-access
- Tokenization of RWD

Information flow should go both ways

64% of research participants want access to their individual data from the study.

Kim J, et al. Patient Perspectives About Decisions to Share Medical Data and Biospecimens for Research. *JAMA Netw Open.* 2019;2(8):e199550.
2019 CISCRP Perceptions and Insights Study: Engagement Preferences.

6 Endpoint Modernization

Critical "Visit Optionality" Challenge: Location-Agnostic Endpoints

Reliability and repeatability of a smartphone-based 6-min walk test as a patient-centred outcome measure

Jonathan Mak[1†], Neil Rens[1†], Dasha Savage[1], Helle Nielsen-Bowles[1], Doran Triggs[1], Julia Talgo[2], Neil Gandhi[1], Sebastian Gutierrez[3], Santiago Gutierrez[1], and Oliver Aalami [1,4*]

[1]Division of Vascular Surgery, Stanford University School of Medicine, 300 Pasteur Drive, Alway Bldg, M121, Stanford, CA, USA; [2]University of California, Berkeley, Berkeley, CA, USA; [3]University of Florida, Gainesville, FL, USA; and [4]Division of Vascular Surgery, Palo Alto VA Health Care System, Palo Alto, CA, USA

Received 12 October 2020; revised 28 December 2020; editorial decision 25 January 2021; accepted 3 February 2021; online publish-ahead-of-print 9 February 2021

Aims

The 6-min-walk test (6MWT) is a validated proxy for frailty and a predictor of clinical outcomes, yet is not widely used due to implementation challenges. This comparative effectiveness study assesses the reliability and repeatability of a home-based 6MWT compared to in-clinic 6MWTs in patients with cardiovascular disease.

Reliability and repeatability of a smartphone-based 6-min walk test as a patient-centred outcome measure

Jonathan Mak[1†], Neil Rens[1†], Dasha Savage[1], Helle Nielsen-Bowles[1], Doran Triggs[1], Julia Talgo[2], Neil Gandhi[1], Sebastian Gutierrez[3], Santiago Gutierrez[1], and

The Mobile-Based 6-Minute Walk Test: Usability Study and Algorithm Development and Validation

Dario Salvi[1], PhD; Emma Poffley[2], MSc; Elizabeth Orchard[2], Dr; Lionel Tarassenko[1], CBE, FREng, FMedSci

[1]Institute of Biomedical Engineering, Department of Engineering Science, University of Oxford, Oxford, United Kingdom

[2]Department of Cardiology, Oxford University NHS Foundation Trust, Oxford, United Kingdom

Wearable devices can predict the outcome of standardized 6-minute walk tests in heart disease

Charlotte Schubert[1,2], Gareth Archer[3], Jo M. Zelis[4], Sarah Nordmeyer[1], Kilian Runte[1], Anja Hennemuth[1,5], Felix Berger[2,5], Volkmar Falk[5,6,7,8], Pim A. L. Tonino[4], Rod Hose[3], Herman ter Horst[9], Titus Kuehne[1,2,5] and Marcus Kelm[1,2,10]

Wrist-worn devices with heart rate monitoring have become increasingly popular. Although current guidelines advise to consider clinical symptoms and exercise tolerance during decision-making in heart disease, it remains unknown to which extent wearables can help to determine such functional capacity measures. In clinical settings, the 6-minute walk test has become a standardized diagnostic and prognostic marker. We aimed to explore, whether 6-minute walk distances can be predicted by wrist-worn devices in patients with different stages of mitral and aortic valve disease. A total of $n = 107$ sensor datasets with 1,019,748 min of recordings were analysed. Based on heart rate recordings and literature information, activity levels were determined and compared to results from a 6-minute walk test. The percentage of time spent in moderate activity was a predictor for the achievement of gender, age and body mass index-specific 6-minute walk distances ($p < 0.001$; $R^2 = 0.48$). The uncertainty of these predictions is demonstrated.

npj Digital Medicine (2020)3:92 ; https://doi.org/10.1038/s41746-020-0299-2

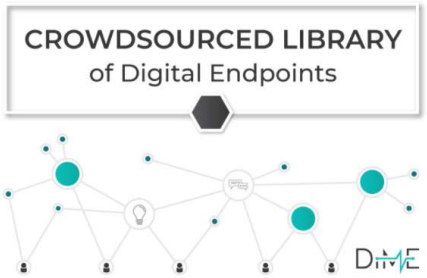
6 Endpoint Modernization

DiMe's Library of Digital Endpoints

DiMe has launched the crowdsourced Library of Digital Endpoints focused on industry-sponsored studies of new medical products or new applications of existing medical products.

Digital endpoints offer significant opportunities to improve what we know about patients' biologic processes and responses, as well as how they feel, function, and survive in both clinical trials and routine clinical care.

This first crowdsourced library is specifically focused on **industry-sponsored studies of new medical products or new applications of existing medical products.** We focused our first efforts here as the DiMe community expressed this is where there is the least transparency around measures currently being used and investigated. DiMe will add additional crowdsourced libraries to include non-industry sponsored studies in the coming months.



Accessing and Contributing to DiMe's Library of Digital Endpoints

DiMe's Library of Digital Endpoints is a work-in-progress, living document. It is intended to be both a reference resource for our DiMe community and a transparent library the community helps build and maintain.

View DiMe's Library of Digital Endpoints. For more information about how to use the library, click "Blocks."

Library of Digital Endpoints (Public View) — APPS

Library of Digital Endpoints | 2 hidden fields | Filter | Group | Sort

	Date First Listed	Endpoint (if known)	Technology Type	Health Concepts	Measurement
2	August 4, 2020	Change in total nocturnal sle...	Activity Monitor	Nocturnal Activity	Sleep Time
3	August 4, 2020	Change in wake time after sl...	Activity Monitor	Nocturnal Activity	Wake time after sleep
4	August 4, 2020	Change in sleep efficiency fro...	Activity Monitor	Nocturnal Activity	Sleep Efficiency
5	August 4, 2020	Change in mean nocturnal h...	Pulse Oximeter	Oxygen saturation	Overnight pulse oxim
6	August 4, 2020	Change in median number of...	Pulse Oximeter	Oxygen saturation	Overnight pulse oxim

DATAcc

Digital Health Measurement Collaborative Community

hosted by DiME Digital Medicine Society

Our Vision

To achieve the promise of digital health measurement to improve lives, for everyone

Our Mission

Hosted by the Digital Medicine Society (DiMe), the Digital Health Measurement Collaborative Community (DATAcc) will use interdisciplinary expertise, data, and use cases to develop and demonstrate best practices and advance harmonized approaches to speed the use of digital health measurement to improve health outcomes, health economics, and health equity.

7 Connect to Master Protocols

Movement toward Master Protocols

Big Data, "All-Comer" Studies

Project Baseline

All of Us RESEARCH PROGRAM

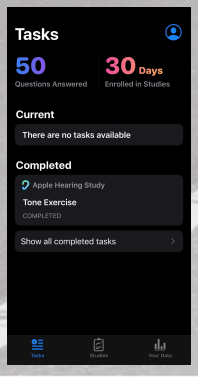
From incremental studies

To study platforms supporting both observation & intervention with one trusted journey for the participant

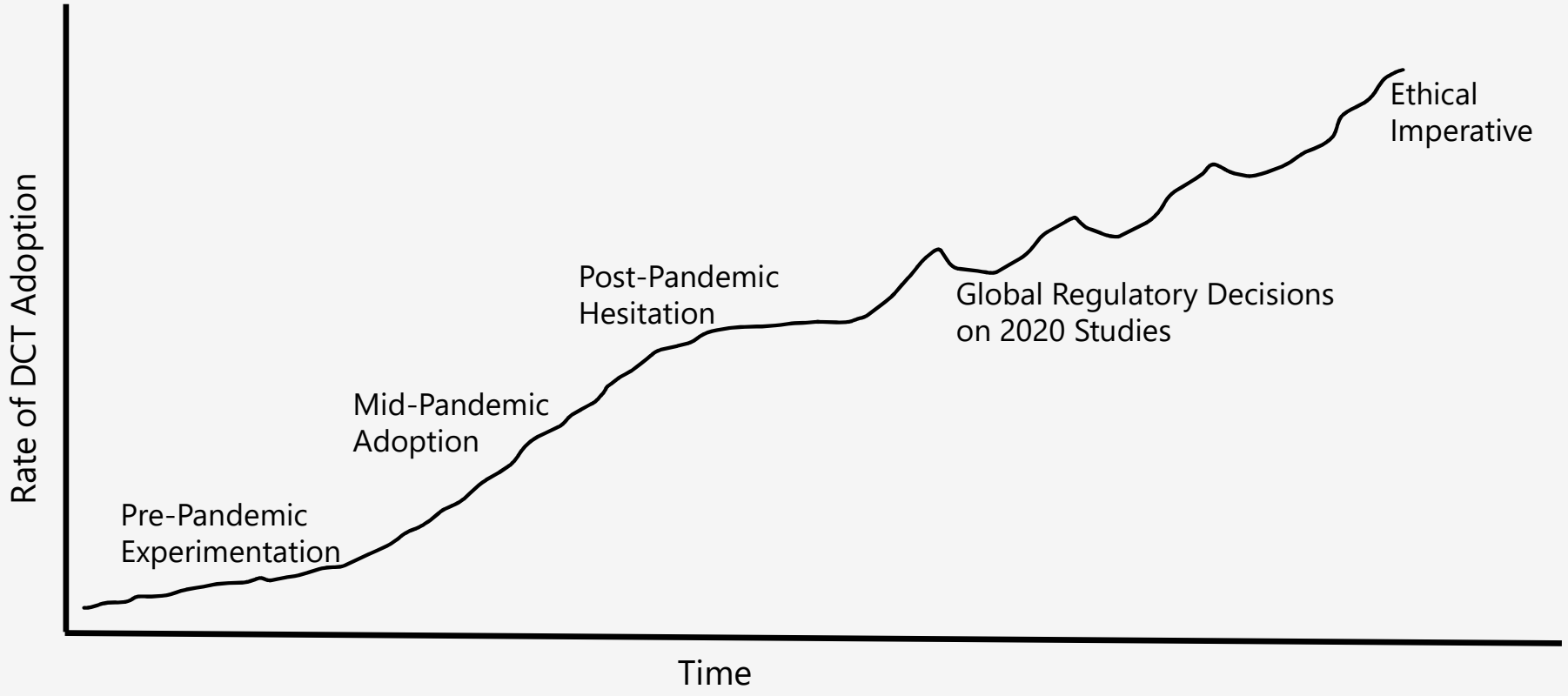
Example:

Apple Research app

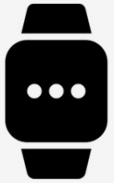
One app for multiple studies
One set of tasks across all studies
Access and share health data across studies



Continuing Non-Linear Adoption



Rise to the DCT Data Challenge



Diversity of Sources

Patient-Mediated

Site-Flexible

The New Data Challenge of Decentralized Trials

Craig H Lipset
@craiglipset
March 2023

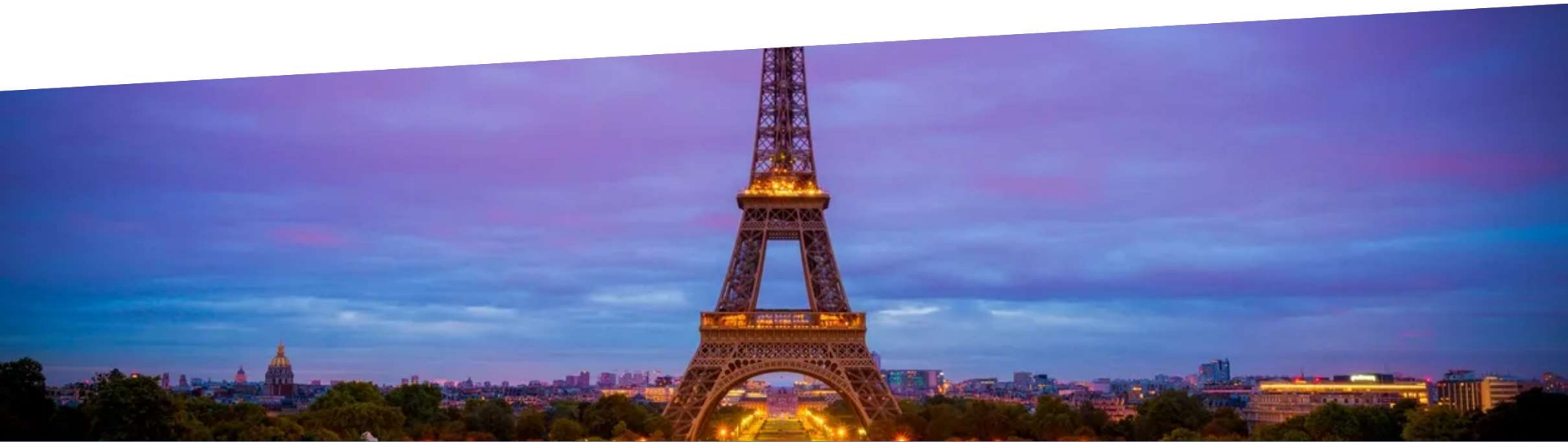
Networking Break

14:50 – 15:05

19. Day 1 Lunch Topic Recap

Michael van Campen, Vulcan

15:05 – 15:20



Thank you for the great engagement in our facilitated discussions!

Topic	Facilitator(s)	Note Takers
1. How can different standards work together?	Peter van Reusel Catherine Chronaki	Valerie Vandeweerd
2. How does privacy play into standards, and vice versa?	Pierre-Yves Lastic	Shani Sampson
3. Enhancing clinical trial efficiency and success using hospital EHRs	Dipak Kalra Nadir Ammour	Peter Casteleyn
4. How can Vulcan support clinical research in Europe?	Michael van Campen	Anne Moen
5. How do we accelerate the design of a digital clinical trial?	Andy Richardson	Stacy Tegan

EuroVULCAN

1. How can Different Standards Work Together?

Peter van Reusel and Catherine Chronaki

Context

- Very engaged discussion… more attendees than chairs. ~15+ people

Key Points

- Whenever there is a need to create a new standard, it is a priority to re-use terminology and standards that already exist rather than inventing something new
- Differentiate between technology / data transfer standards and content standards and focus on how these need to work together
- Some stories about the challenges on losing meaning ('lossiness') with mapping
  - It is not straightforward to 'map' data from one standard to another because the meaning of the information is different
  - Whenever mapping is exercised, we need to document the assumptions and 'lossiness'
- Semantic interoperability is not something that can be applied after data collection

2. How Does Privacy Play into Standards, and Vice Versa?

Pierre-Yves Lastic

Context

- Attendees had a range of experience and interests including a direct role within an organization protecting individuals' privacy, health informatics, policy discussions, clinical data sharing, and consideration of how data privacy impacts the execution of the Vulcan Real World Data project.

Key Points

- Privacy goes hand in hand with TRUST...and the trust is in both directions
- EHR's are responsible to protect their patients' data and entities like pharma typically are allowed only to query a curated data mart, not the EHR data itself
- Privacy is selective - patients overwhelmingly (99% in one poll) want to share data for research, but those same respondents hesitate or refuse to share data with employers or insurance
- There is both a legal AND technical side to data privacy
- In one country, the time needed to get the authorization to run a project over a pool of EHR data is 18 months... while in another country, the lag is 2 months; how do we make the process equitable across markets, especially with what we've learned about global pandemics?

3. Enhancing Clinical Trial Efficiency and Success using Hospital EHRs

Dipak Kalra and Nadir Ammour

Context

- Considered two cases:
  - Searching for patients in EHR - screening: requires high number of sites connected
  - Data collection for clinical trials: to make this scalable

Key Points

- Main barrier is cultural change both at supply side as well as demand side. Eg
  - Sponsor inclusion criteria are in many cases requiring a human interpretation, so not query able.
  - On the supply side, hospital data quality is variable, and most hospitals lack the resource and business justification to invest in improving this.
- What is the pathway?
  - Look for low hanging fruit – take small steps
  - Consider rare diseases where some work is already done on most valuable data
  - The need to enable connection to patient's data generated during the various interactions with healthcare services, hence collected in various places, hospitals, GPs, local lab, etc.
  - EU Patient Summary concept is evolving to an ISO patient summary

4. How can Vulcan Support Clinical Research in Europe?

Michael van Campen

Context

- How to continue the dialog showcased at EuroVulcan – grow and expand, virtual to F2F

Key Points

- Need to increase awareness of FHIR: support for vendors and hospitals expanding FHIR capabilities
- Lots of OMOP use in Europe – what is the relationship to FHIR?
- Continue to build connections between stakeholders and between partners
- Use the European experience to inform Vulcan around the world; presence → sustainability, longevity
- Branding / value propositions specific to European context
- Consumer centricity is not striking (yet), as the ultimate benefit is for citizens
- Cross border, e.g., ePI in language of choice, support mobility
- 1-800-VULCAN
- Conference presence: e.g. HIMSS, MedInfo, MIE, etc.
- Vulcan as a community; what would be do without such a community?

EuroVULCAN

5. How do we Accelerate the Design of a Digital Clinical Trial?

Andy Richardson

Context

- Benefits of FHIR to communicate protocol/SoA: cut down on interpretation (ERBs, site coordinator, etc) and related risk/quality issues.

Key Points

- How could it work at the site:
  - Today: Some sites read the SoA, then manually type in hospital orders - i.e., the "tasks" staff need to do with the patient at each clinical location in the hospital system
  - If could have the orders automatically populated in the EHR, it would save that time consuming step and & improve accuracy
- Implementation challenges:
  - High level of variability in the processes sites use will make it difficult to get full implementation.
  - Would be helpful to better understand the various processes that sites use in order to guide implementation options (some sites may be better suited to leverage for scheduling, others for EHR data extraction)

EuroVULCAN

For Consideration

BONUS: Idea for future EuroVulcan (or other Vulcan events)

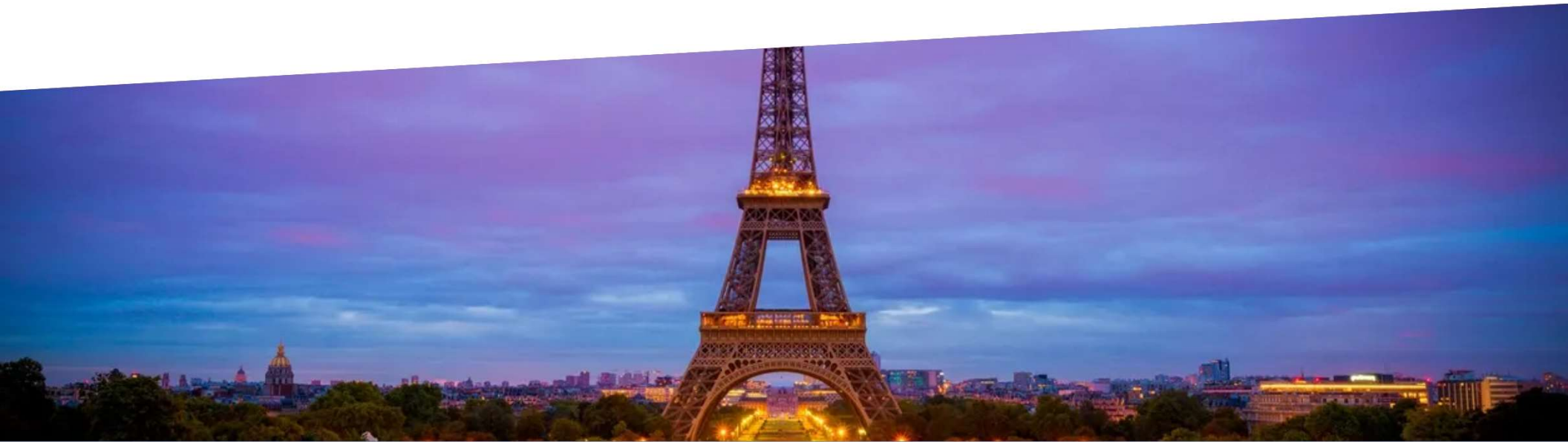
- Found lunch discussion engaging, hard to pick a table! Consider event where rotate through multiple roundtables

EuroVULCAN

20. Vulcan Engagement in Europe Open Discussion

Michael van Campen, Vulcan

15:20 – 16:05



Vulcan Inflection Point

Go Global

EuroVULCAN

1: Go Global

Europe is a Start, not an End

What Have we Done?

European - Led Projects

Gravitate Health

International Membership

International Project Participation

Where To Next?

Grow International Membership

Medical Informatics Europe MIE 2023 EFMI

EFMI 45 EUROPEAN FEDERATION MEDICAL INFORMATICS

Launch New International Projects

Grow International Project Participation

Asia Pacific Conference & Connectathon

EuroVULCAN

Vulcan in Europe
The Challenges Ahead

Challenges

- How will be grow Vulcan presence in Europe?
- What's next in Europe?
- Who is missing from the Conversation?
- What is the European-specific Value Proposition?

EuroVULCAN

Vulcan In Europe

Ideation

Awareness

1. EuroVulcan 2.0
2. Outreach specific to member categories
3. Clinical Research FHIR-based education / training
4. Social Media
5. Continued presence in Europe
6. FHIR & OMOP

Implementation

1. Pilots (EPI Pilot Spain/Netherlands/Sweden?)
2. Proof of Concept
3. Live systems
4. Implementation community
5. Tooling support
6. Community building (e.g. technology summit)
7. Conformance / compliance
8. Legal basis, including privacy

Operations / Content

1. European-led projects (driving the project like Gravitate/ePI)
2. Europe-sensitive calls for Vulcan projects
3. Vulcan Europe Office?
4. Vulcan branding
5. Clinical Research / Vulcan Core

Membership

1. Identifying members from European organizations / agencies
2. Consider broad stratification across member categories & countries
3. Patient perspective

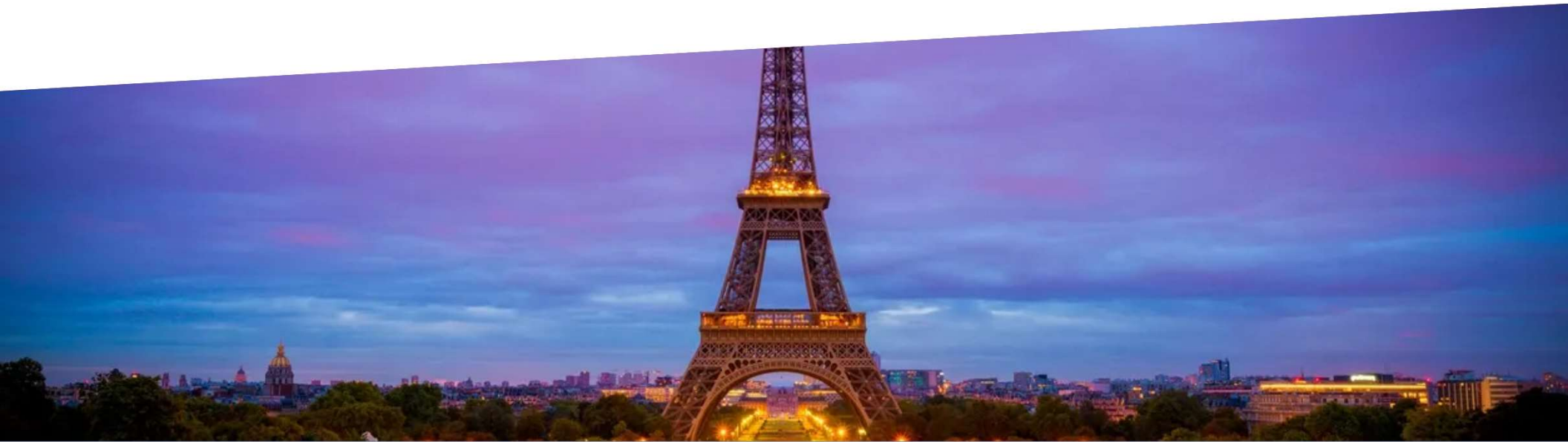
EuroVULCAN


Questions?

Where to Next? Wrap Up & Thanks

Amy Cramer, Vulcan co-Chair / J&J

16:05 – 16:20



Before We Go…

Coming in the Days Ahead

Survey
EuroVulcan Conference & Connectathon

Conference Presentations

EuroVULCAN


VULCAN
HL7 FHIR
EuroVulcan
Conference & Connectathon
Thanks and Safe Travels