



EuroVulcan Conference & Connectathon

Welcome!
Day 1 Programme



Welcome & Opening Address

Amy Cramer, Hugh Glover





ARE

VULCAN
HL7 FHIR

EuroVULCAN

EuroVulcan Thanks Our Speakers

Across Industry, Across Perspectives

acodis

agencia española de
medicamentos y
productos sanitarios

AGENCE
DU NUMÉRIQUE
EN SANTÉ
la transformation commence ici

ASSISTANCE
PUBLIQUE
HÔPITAUX
DE PARIS

BIH Berlin Institute
of Health
@Charité

Clinical Innovation
PARTNERS

Docuvera™

ENTITECH
SOLUTIONS

EUROPEAN MEDICINES AGENCY

FELLESKATALOGEN

FDA

HL7
Europe

IgniteData

Janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

KAROLINSKA INSTITUTET
1810
Karolinska
Institutet

MEDIDATA

ORACLE

OSTHUS
A PHARMALEX Company

Pfizer

UNICOM

NIH U.S. National Library
of Medicine

UiO
UNIVERSITAS OSLOENSIS
1814
University of Oslo

VULCAN
HL7 FHIR

EuroVULCAN

EuroVulcan Thanks Our Contributing Partners

Supporting Vulcan from Many Perspectives



 **EuroVulcan Thanks Our Organising Committee**
Making it all Happen



Anne Moen



Catherine Chronaki



Christel Daniel



Amy Cramer



Darren Weston



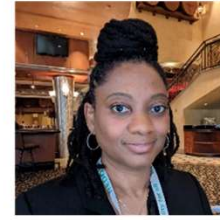
Hugh Glover



Michael van Campen



Stacy Tegan



Shani Sampson



Sandy Vance



Katleen Renders



Nikki Huysmans



Nicolas Riss



EuroVulcan Conference & Connectathon





2. Vulcan Overview

Amy Cramer, Vulcan co-Chair / J&J
9:45 – 10:10





Interoperability Case Study: Finance

Digital Lessons from the Finance Industry



We get paid electronically



The money goes directly to your bank



You are able to access your money from anywhere in the world



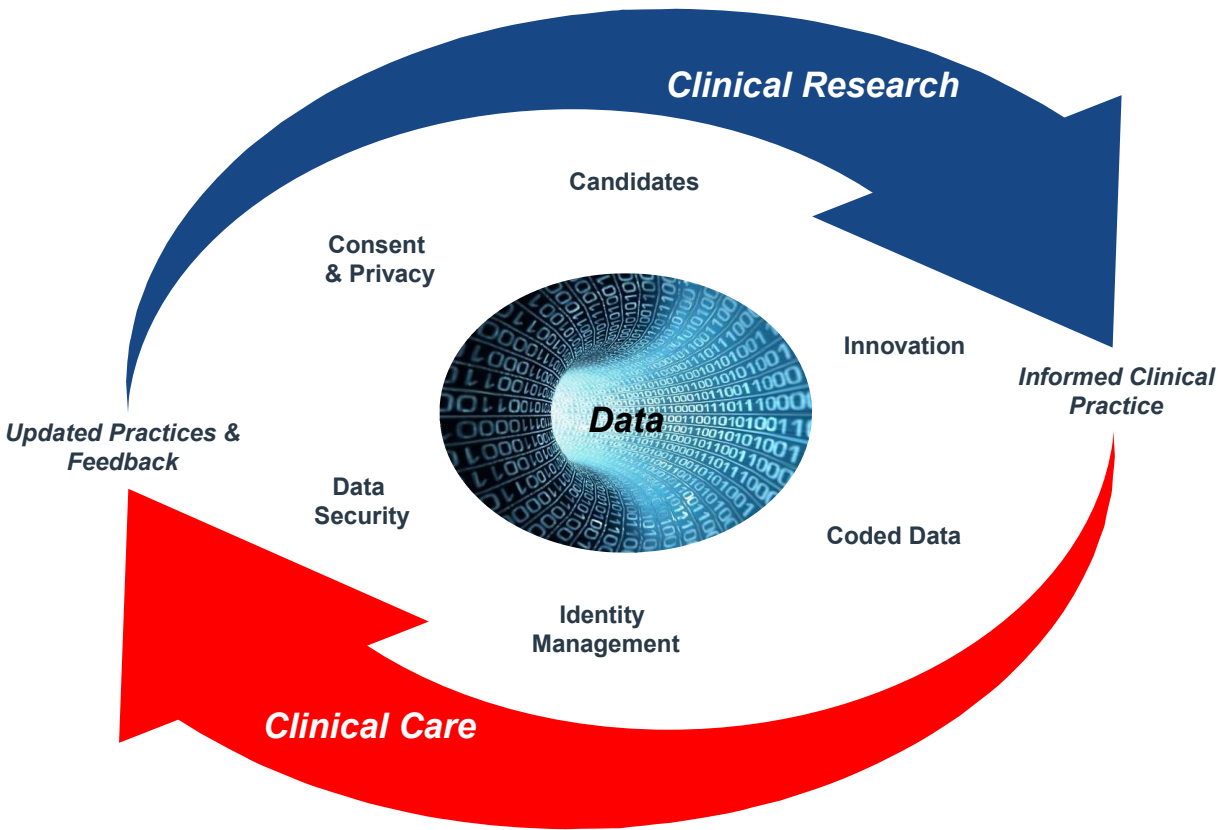
We can make transactions with the funds electronically even though we have never seen it physically

TRANSFER OF FUNDS

A world in which everyone can securely access and use the right data when and where they need it

The Need for Standards in Clinical Research

Data is the Key



- Health data is used for both Clinical Research and Clinical Care purposes
- However, **Clinical Research** has lagged behind other clinical care functions in the definition and use of Standards
- On the positive side, both share many common standards such as consent (to treatment, to research) and identity management
- Unique clinical research standards include candidate identification, clinical trials and phenotypic data (to name a few) that rely on health data curated by clinical care processes

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)

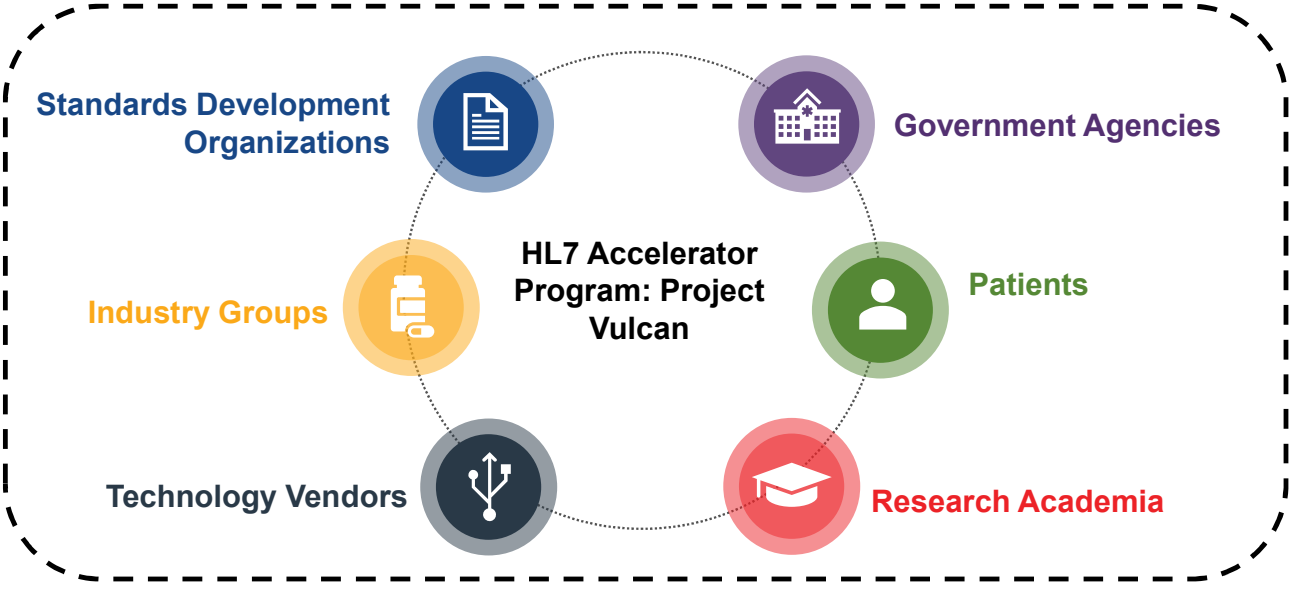
Experts Blazing the Path Forward for Research

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.

The Convening Members of Vulcan Represent a Wide Variety of Expertise



Current Member Organizations of Vulcan

As of February 2023



★ indicates a convening member of Vulcan

HL7 Accelerator Program

Focused Standards Development



Vulcan

Connecting translational and clinical research with healthcare



Helios

Equitable and effective use of data for the advancement of public health



Gravity

Identify and harmonize social risk factor data for interoperable electronic health information exchange



FAST

Define a scalable approach to deploying FHIR across interoperability use cases



Argonaut

Advance artifacts foundational to healthcare exchange: CDS Hooks, Bulk Data, Subscriptions, Clinical Notes, and US Core



CARIN

Advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information



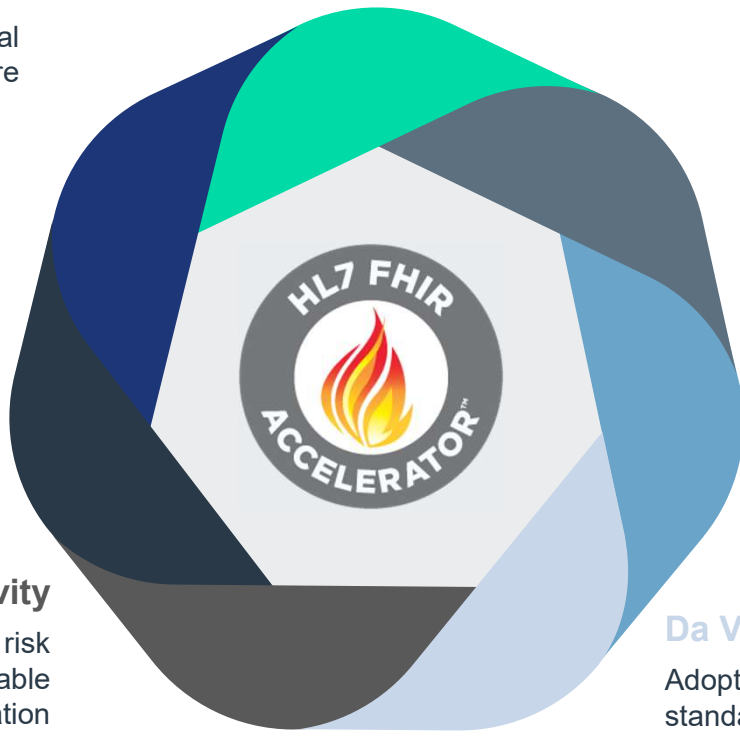
CodeX

Accelerate interoperable data modeling and applications cancer patient care and research



Da Vinci

Adoption of HL7® FHIR® as the standard to support and integrate value-based care (VBC) data exchange across communities





Vulcan Vision Statement



Why Vulcan?

Fully integrate research into the delivery of healthcare by streamlining data collection and exchange into a singular process.



What are we doing to reach that vision?

- Collaborating with the international research community to align clinical data and clinical research data at the point of collection.
- Developing out the HL7 FHIR standard to support the bidirectional flow of data.



How will we accomplish this?

- Bridge existing gaps
- Strategically connect industry collaborations
- Maximize collective resources
- Deliver integrated tools and solutions





The Goals of Vulcan



BRIDGE EXISTING GAPS

Work to close gap between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency



STRATEGICALLY CONNECT COLLABORATORS

Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups including EMA, FDA, NCATS, NLM, SCDM, TransCelerate, and academic research sites



MAXIMIZE COLLECTIVE RESOURCES

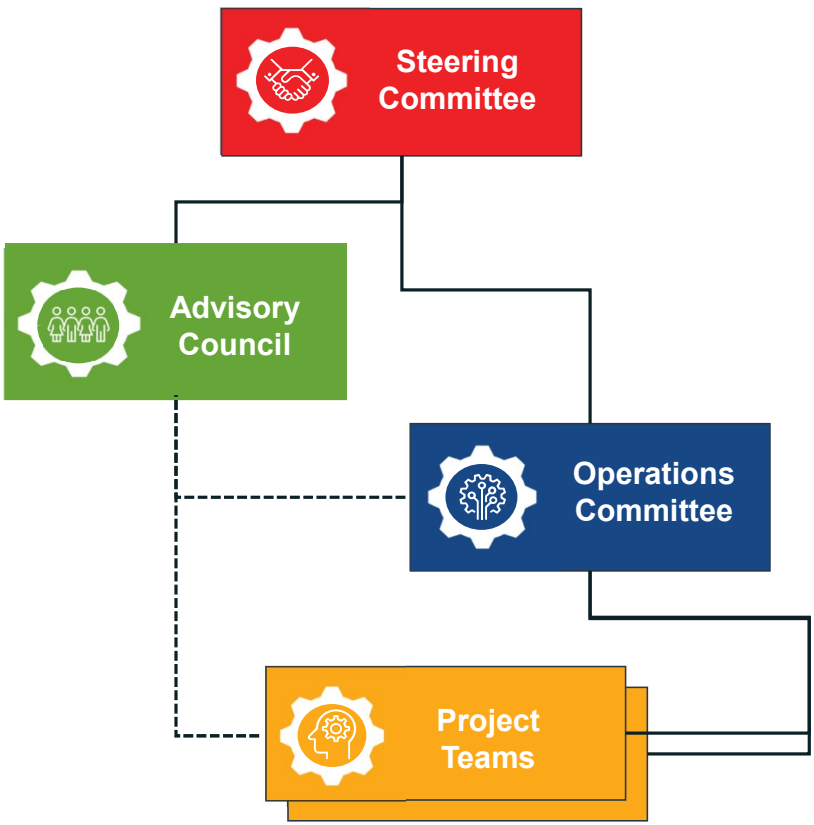
Leverage shared community and resources to be able to communicate the return on investment and return on value that a unified network could realize to various parties, and provide comprehensive recommendations to global regulators



DELIVER INTEGRATED TOOLS AND SOLUTIONS

Develop necessary FHIR Research Resources to maturity. Vulcan will handle identified and prioritized use cases for secondary use of EHR data that meet interested parties needs and goals

Vulcan Structure and PMO Team Membership



Vulcan Leadership

Amy Cramer Darren Weston

Becky Kush

Maryam Garza Mike Hamidi

— Reporting
 - - - Advisory

Vulcan PMO

Michael van Campen

Stacy Tegan

Hugh Glover

Shani Sampson



Vulcan – Moving Forward

Inflection Point



Foundation

- Implementation Guides for Real World Data, Schedule of Activities, electronic Product Information, Phenotypic Data, Adverse Event, FHIR to OMOP (in progress)
- Connectathons (ongoing)
- Governance, Membership, Financial models



Go Global

- Expand outreach into Europe, Asia Pacific and other regions
- Regional activities, membership & promotion
- Showcase global HL7 FHIR efforts in clinical research



Implement It

- Adoption Strategy: Proof of Concept / Pilot, Tooling
- Maintain Implementation Guides



New Content

- Use Case Map (Big Picture)
- Additional Use Cases
- Collaborate with other HL7 FHIR Accelerators

2023 & Beyond

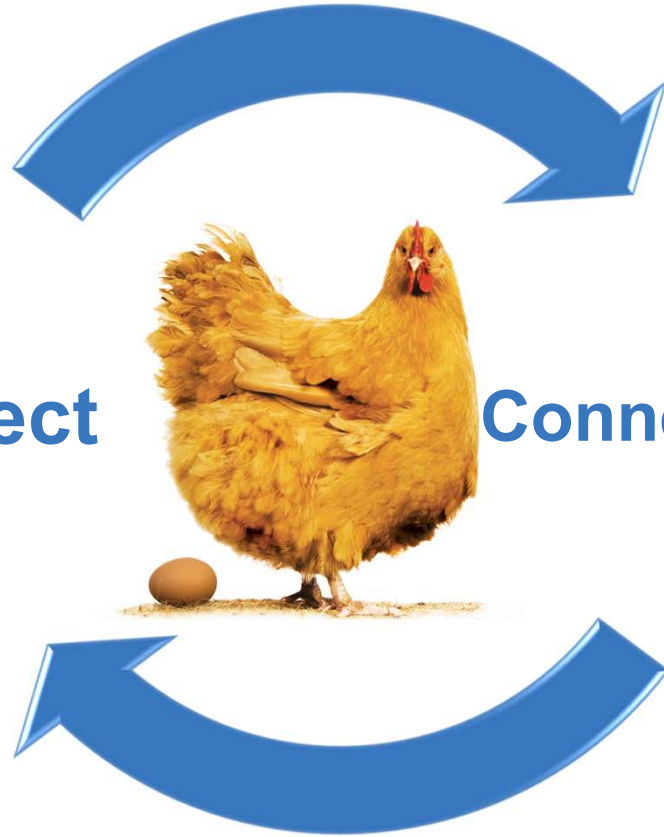


3. Connectathon Overview

Hugh Glover, Vulcan
10:10 – 10:30 (20 minutes)

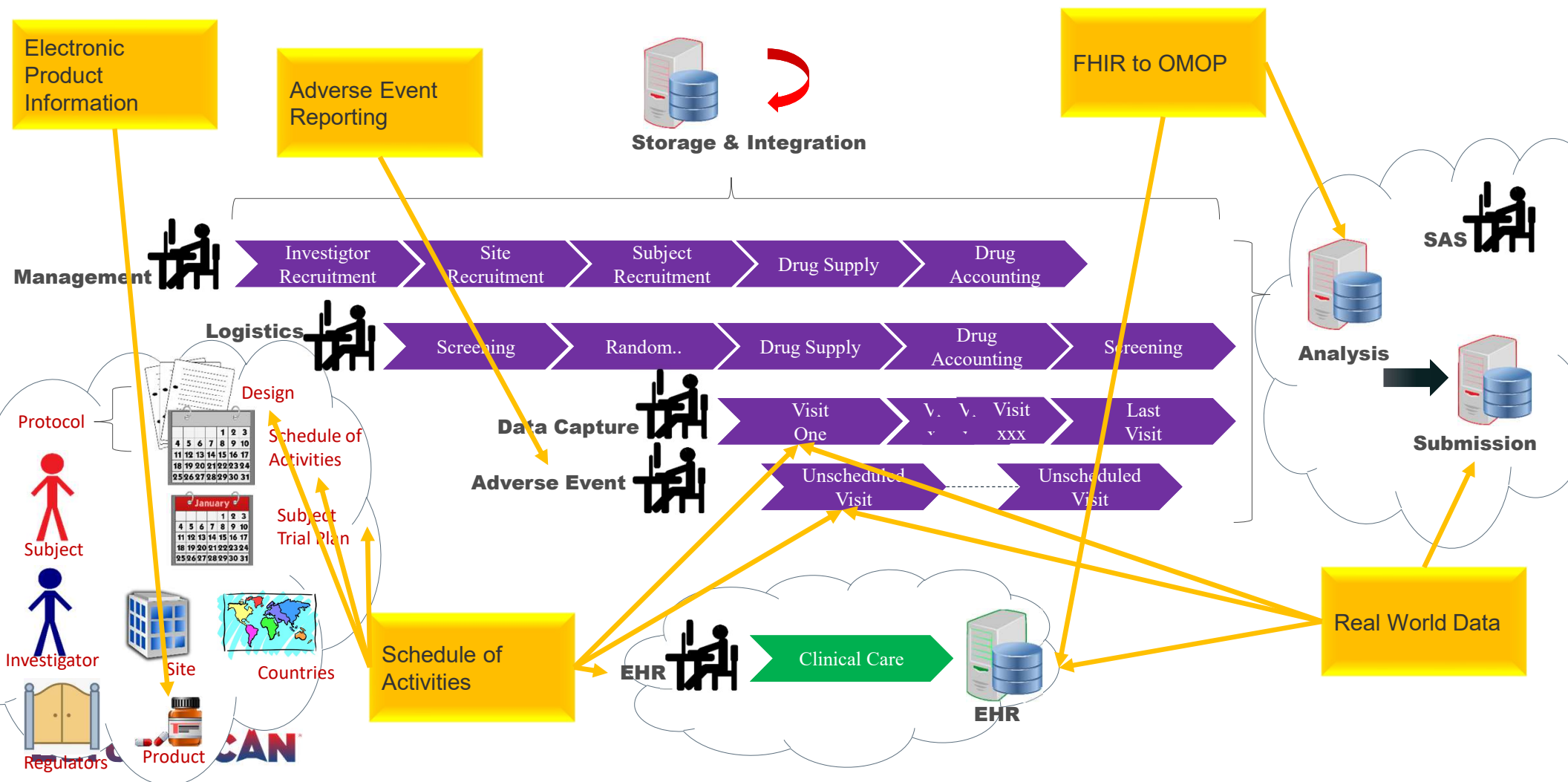


Project



Connectathon

Clinical Research Business Processes



Schedule of Activities

Deals with things:

- *Design,*
- *Schedule of Activities,*
- *Subject trial plan*

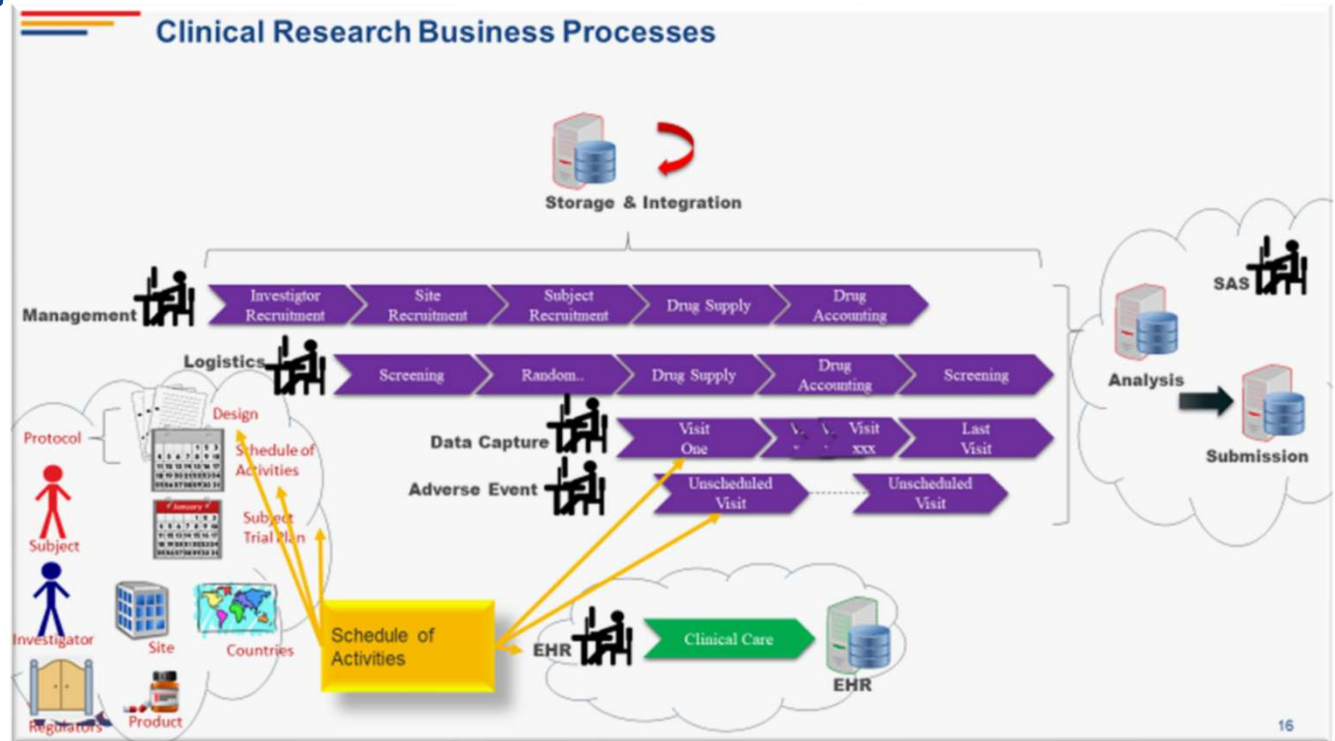
Deals with processes:

- *Visits,*
- *Encounters,*
- *Care Events*

Spans:

- *Clinical Research activities*
- *Clinical Care ones*

IG first draft in January 2023



Schedule of Activities

**Protocol Attachment LZTZ.1
Schedule of Events for Protocol H2Q-MC-LZZT(c)**

ACTIVITY	VISIT	1	2	3	4	5	7	8
WEEK	WEEK	-2	-3	0	2	4	6	8
Informed consent		X						
Parent number assigned		X						
Hachinski 54		X						
MMSE 10-23		X						
Physical examination		X						
Medical History		X						
Habits		X						
Chest x-ray		X						
Apo E genotyping					X			
Parent randomized			X					
Vital signs/Temperature		X	X	X	X	X	X	X
Ambulatory ECG placed			X					
Ambulatory ECG removed				X				
ECG		X			X	X	X	X
Placebo TTS test		X						
CT Scan (if not within last year and patient has all other screens)		X						
Concomitant Medication		X	X	X	X		X	X
Laboratory (Chem/Hemat)		X			X	X	X	X
Laboratory (Urinalysis)		X			X			
Plasma Specimen (Xanon)				X	X	X		X

Apo E genotyping								
Parent randomized			X					
Vital signs/Temperature		X	X	X	X	X	X	X
Ambulatory ECG placed			X					
Ambulatory ECG removed				X				
ECG		X			X	X	X	X

Abbreviations:
X = Present
X0 = Present at baseline
P = Present
and N = Not present

```

date : 2021-05-20T14:52:13+00:00 ,
"observationRequirement" : [
  {
    "reference" : "Vital-signs-Temperature-Observations"
  }
],
"observationResultRequirement" : [

```



```

generated",
  "xmlns":"http://www.w3.org/1999/xhtml"><p><b>Generated Narrative</b></p>
),
"uri":"http://example.org/br-and-r/soa/ActivityDefinition/H2Q-MC-LZZT-Vital-signs-Temp
"identifying": "Vital-signs-Temperature-Observations",
  "use": "standard",
  "type": "Observation",
  "coding": [
    {
      "system": "http://www.cdisc.org/ns/odm/v1.3#",
      "display": "Vital signs/Temperature"
    }
  ]
},
"system": "http://www.cdisc.org/ns/odm/v1.3/FormDef#",
"value": "F.VS_3"
}
],
"version": "0.1.1",
"status": "active",
"observationRequirement" : [
  {
    "reference" : "Vital-signs-Temperature-Observations"
  }
],
"observationResultRequirement" : [
  {
    "reference" : "Vital-signs-Temperature-Observations"
  }
]

```



Can we agree ? ...

New software being freshly made, has not had time to acquire bugs ...

Software engineers always understand what the users want ...

A written set of instruction is always easy to follow ...

People rarely make mistakes ...

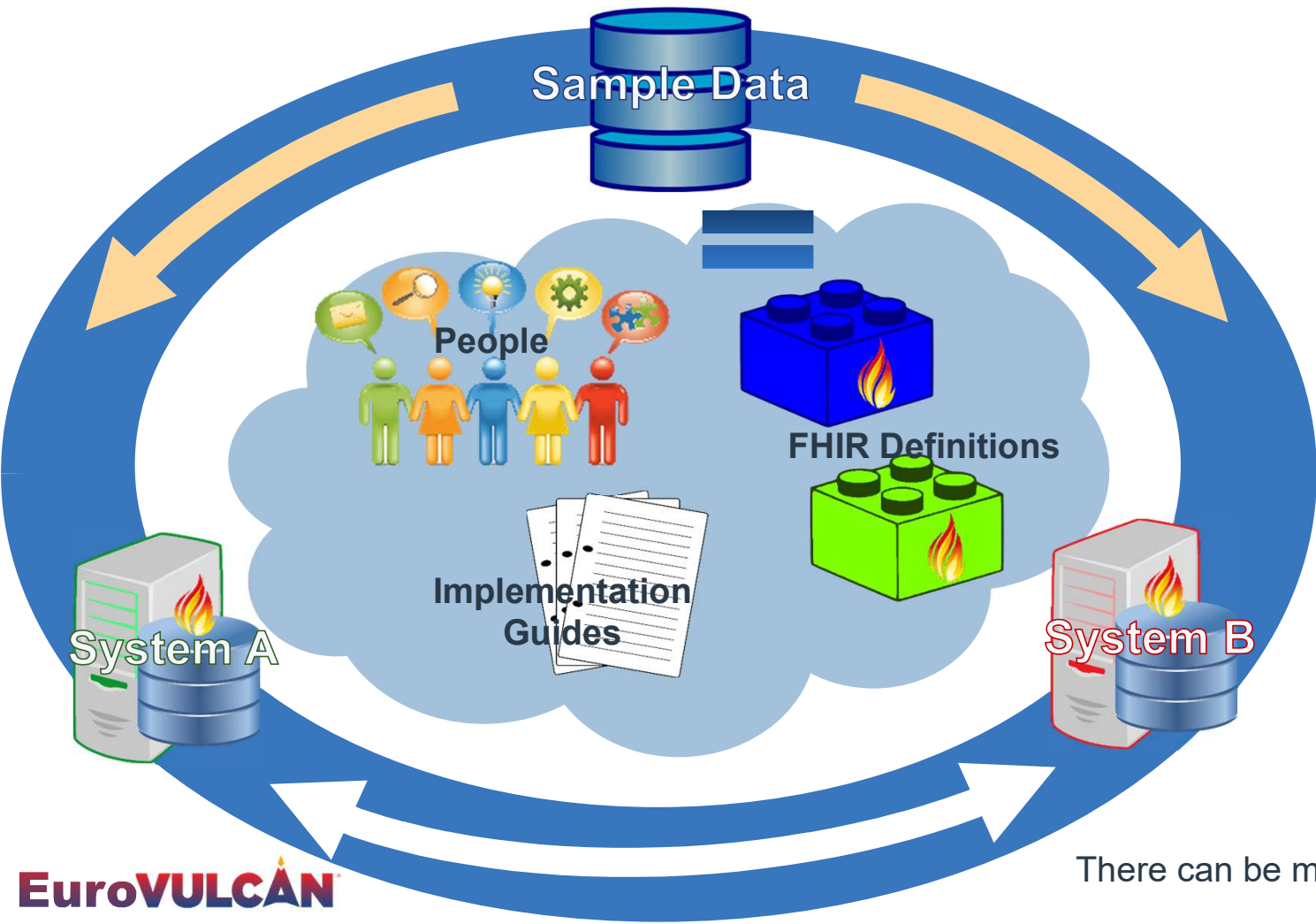
NO?

So we know that when we write an Implementation Guide it won't be completely clear and the resulting software won't work!

This is life as we know it So what do we do?

HAVE CONNECTATHONs !!!!

What's in a Connectathon?



Things required

1. People
2. The FHIR standard
3. Implementation Guides
4. Sample Data
5. Test Systems

Example Tests

1. **Resource Development:** Can the sample data be represented in FHIR?
2. **Data Population:** Does the Implementation Guide provide the necessary guidance?
3. **Data Transfer:** Can the data be moved from one system to another?

There can be many other tests

HL7 January 2023 Connectathon

2023 - 01 Connectathon 32 - FHIR

confluence.hl7.org/display/FHIR/2023+-+01+Connectathon+32

Confluence Spaces People Glossaries Search Log in

PAGE TREE

- Administration
- Connectathons
 - 2023 - 05 Connectathon 33
 - Track Lead Resources
 - Previous Connectathons
 - 2023 - 01 Connectathon 32**
 - 2023 - 01 BFDR & VRCPL FHIR IG Testing
 - 2023 - 01 C-DA to FHIR Mapping Track
 - 2023-01 Cancer Electronic Pathology Reporting
 - 2023 - 01 CARIN IG for Blue Button®
 - 2023 - 01 CARIN IG For Digital Insurance
 - 2023 - 01 Clinical Reasoning Track
 - 2023 - 01 Da Vinci Burden Reduction (BR) Track
 - 2023 - 01 Da Vinci Clinical Documentation Excl
 - 2023 - 01 Da Vinci Member Attribution Track
 - 2023 - 01 Da Vinci Payer Data Exchange (PDex)
 - 2023 - 01 Da Vinci Patient Cost Transparency
 - 2023 - 01 Da Vinci Risk Adjustment
 - 2023 - 01 Da Vinci Value-Based Performance R
 - 2023 - 01 FAST Infrastructure (Security, Identity
 - 2023 - 01 Gravity SDOH Exchange
 - 2023 - 01 Helios Accelerator Bulk Data Track
 - 2023 - 01 Helios FHIR Accelerator Aggregate D
 - 2023 - 01 Imaging
 - 2023 - 01 International Patient Access (IPA) Tra

2023 - 01 Connectathon 32

Created by Sandy Vance, last modified on Feb 13, 2023

HL7 FHIR Connectathon 32
IN-PERSON EVENT!

Henderson, Nevada | January 14-15, 2023
9:00 AM PT to 5:00 PM PT

Montelago Event Center Table Layout

Newcomer Orientation - Recording [here!](#)

Event contact: Sandy Vance

Reach Sandy at sandy@counterpointsol.com or HL7Connectathon@hl7.org

HL7 Fast Healthcare Interoperability Resources (FHIR®) Connectathons feature hands-on FHIR development and testing. Implementers and developers come together to hold technical discussions that advance the FHIR specification, develop FHIR-based solutions, and exchange data with other FHIR interfaces. Connectathons are a great opportunity to work directly with FHIR developers and senior members of the FHIR standards development team.

Please note: The purpose of a Connectathon event is to engage in testing of the FHIR specification and implementations. While the FHIR Community thrives on perpetual learning, this environment demands preparation to participate in technical discussions, code review, and testing of a reference implementation or your own FHIR-based system. It is expected that by registering for this event you have adequately prepared by reviewing the FHIR specification and any artifacts specified on the track page, attended all participant information sessions, and established a connection with your track through the Track Kick Off or other work sessions.

Quick Links:

- Breakout Room Schedule
- Connectathon FAQ
- Connectathon Registration NOW OPEN
- Connectathon Participant List
- Con Man App
- ConMan Instructional Video
- FHIR Community Chat
- FHIR Overview
- FHIR Specification
- HL7 Slide Template
- Pre Connectathon Survey
- Track Report Out
- Connectathon Feedback Survey
- Wrap Up Slides

Participant Check List

1. Register for the Connectathon before the Early Bird Cut off, December 16th
2. Review the Connectathon Track List below

Track Lead Check List

1. Track Proposals are due by the date listed below. Click the Create New Track button below to propose a track!

Provide feedback



Jan 2023
35 Tracks
250 Participants

EuroVulcan – Example Track Details

The screenshot shows a Confluence page for '2023 - 03 Electronic Product Information'. A table of contents is highlighted with a red box, listing items such as Short Description, Long Description, Type, Related Tracks?, Call for participants, Track Prerequisites, Track Lead(s), Track Lead Email(s), Specification Information, Expected participants / Actual Participants, Zulip stream, Track Kick off Call, System Roles, and Testing Scenario. The main content area contains a 'Short Description' section with a paragraph about the track's purpose, a 'Track Objective' section with a numbered list of six items, and a 'Long Description' section with a 'Problem Statements' list of two items.

Short Description	This track is part of an ongoing series, spanning multiple Connectathons, to test the creation, exchange and display of electronic Product information (ePI) and the International Patient Summary (IPS) as FHIR Documents, as well as potential UNICOM scenario's for IDMP implementation. Each phase will include increased numbers of product information and increasingly complex healthcare/life scenarios.
Long Description	Problem Statements <ol style="list-style-type: none">1. Existing ePI formats are not meeting the needs of patients, professionals and developers.2. The lack of harmonization is leading to fragmented approaches where multiple differing standards are developing internationally e.g. eLabeling in HL7 SPL in North America, ePI in HL7 FHIR in the European Union; and custom XML

- Short Description
- Long Description
- Type
- Related Tracks?
- Call for participants
- Track Prerequisites
- Track Lead(s)
- Track Lead Email(s)
- Specification Information
- Expected participants / Actual Participants
- Zulip stream
- Track Kick off Call
- System Roles
- Testing Scenario:



Vulcan Connectathons to Date

7 Events
7 Topics
24 Tracks

Jan
2021

- SOA
- RWD
- Med
- Pheno

Sept
2021

- SOA
- RWD

May
2022

- SoA
- ePI

Jan 2023

- SoA
- RWD
- ePI
- FHIR 2 OMOP



May
2021

- SOA
- RWD
- Med
- RWD
- Pheno

Jan
2022

- RWD
- ePI
- AE

Sept
2022

- SoA
- RWD
- ePI
- Pheno
- ...



Real World Data

May 2021

- Continuing the work from January – identifying concomitant medication from an EHR
- PatientLink kindly provided an update of the reference implementation

Jan 2022

- Move beyond medication
- Query an existing study in FHIR to find data and transform to SDTM
- Identify a minimum data set
- Evaluate generated SDTM data set

Jan 2023

- Updated React app that displays activities in visit windows to incorporate administrations and unscheduled activities
- Additionally, progressed
- Investigational Product Administration
- Unscheduled Activities

Jan 2021

- Comparing Patient vs ResearchSubject resources
- Looking at sources of data: MedicationStatement vs MedicationRequest
- Active vs Historic Medication

Sept 2021

- Primarily retrospective analyses of EHR data
- Develop HL7 FHIR capabilities
- Development of US Core to support RWD

Sept 2022

- Created a synthetic data set to help develop EHR queries
- Successfully queried the data using inclusion / exclusion criteria for patients of interest
- Compared retrieved data to source data to confirm that queries were working correctly
- Compared queried data to other EHR sources

Schedule of Activities (SoA)

May 2022 Connectathon Readout

Activity

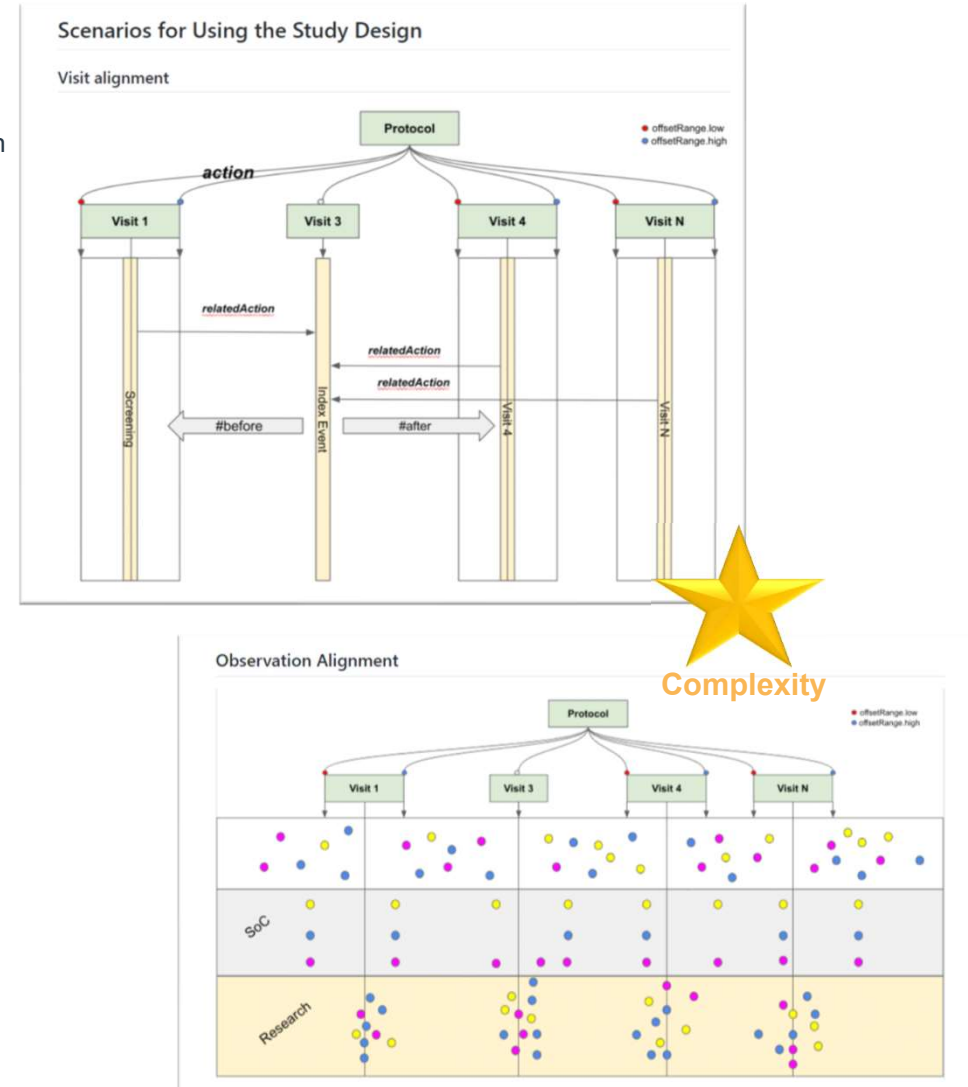
- Devised and implemented methodology for retrieval of patient resources for use in clinical research (pseudocode)
- Successfully executed all planned scenarios
- Created a set of resources that can be shared and reused for future events
- Published all developed code openly
- Identified an opportunity to improve approach to enable visit calendaring and to better identify when Encounters and Observations occur outside of acceptable time parameters needed for the protocol.

Take-Aways

- Generated more knowledge and content with which to populate the implementation guide.
- Connectathon provided opportunity for fruitful discussions with fellow Vulcan leaders on multiple topics including possible broader use cases for FHIR in the regulated research process

Next Steps

- Need greater exposure and input from vendors
- Expansion of ActivityDefinitions/ObservationDefinitions
- Expand testing to additional data types (eg Interventions, Adverse Events, Questionnaires)



Adverse Events (AE)

January 2022 Update

Activity

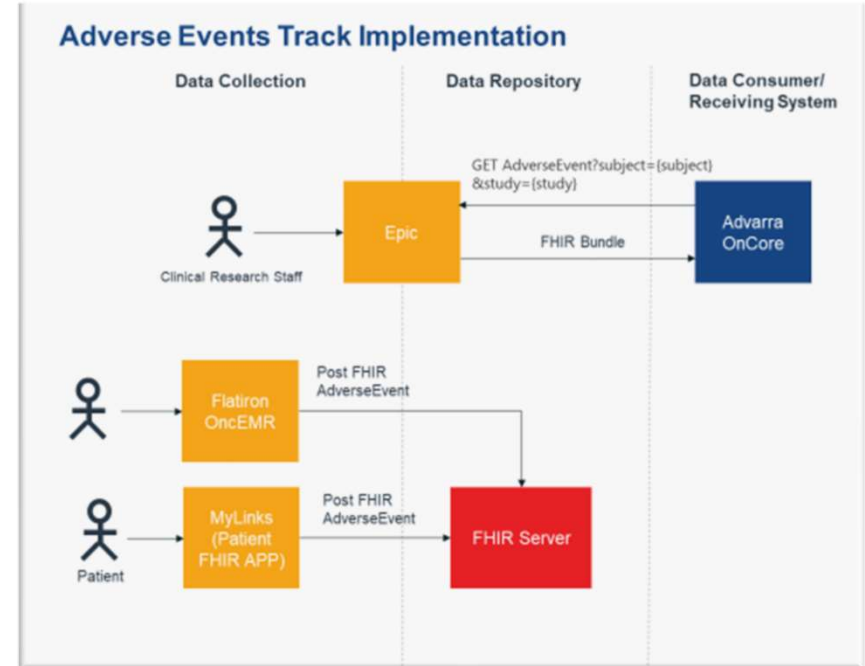
- Flatiron developed an Adverse Event capture form, translated data to R4 FHIR resource and posted to FHIR server
- PatientLink developed an Adverse Event capture form in MyLinks, translated data to R4 FHIR resource and posted to FHIR server
- Epic and Advarra exchanged Adverse Event resources using R4 with extensions
- Began to identify gaps in R4 AE base resource and cross reference those gaps in R5

Take-Aways

- Terminology needs to be appropriate to the users
- R4 Gaps identified generally are addressed by R5
- Continue using R4 resource with extensions informed by R5 standard
- Need input from downstream users and other standards (ICH, CTC-AE)

Next Steps

- Build recommended extensions for R4
- Build IG





Summary

A connectathon is:

- **Contact sport**
- **Structured**
- **Practical - Works with understandable applications**
- **Finds out what works and what doesn't**
- **Updates the specifications as required**



Questions?



Networking Break

10:30 – 11:00





4. Vulcan Fundamentals

Stacy Tegan, Vulcan / TransCelerate Biopharma

11:00 – 11:20





EuroVULCAN

Let's take an inside tour of Vulcan

Current Member Organizations of Vulcan

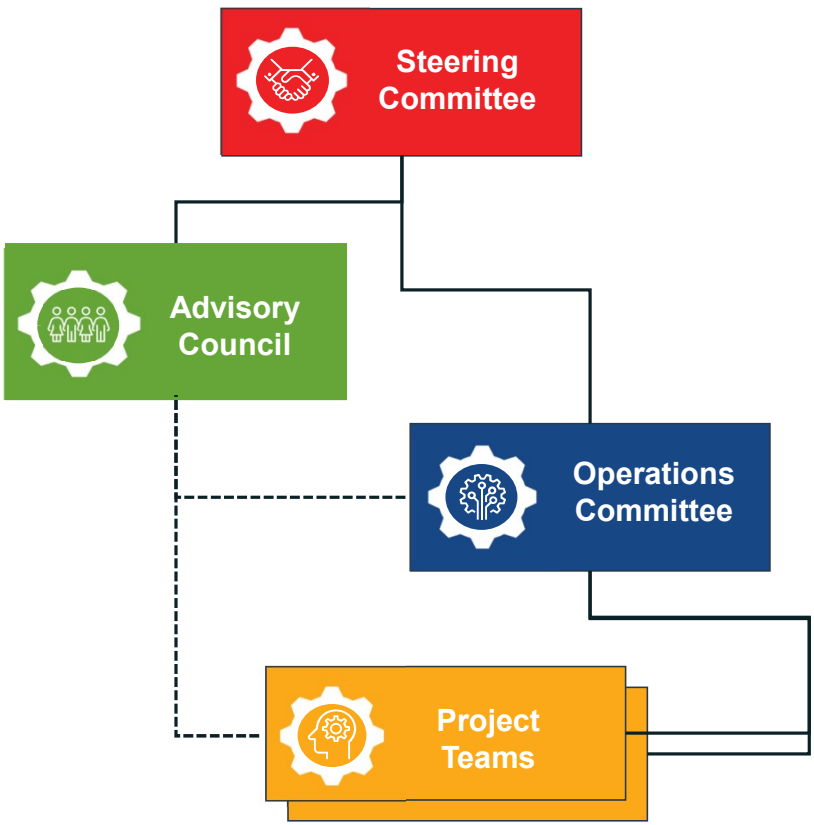
As of February 2023

Academia	         
Consortia	  
Government Agencies	   
Implementers	              
Pharma	   
SDOs	 
Others (e.g., thought leaders, SMEs, CROs, Patient Advocates)	  



★ indicates a convening member of Vulcan

Vulcan Structure and PMO Team Membership



Vulcan Leadership

Amy Cramer Darren Weston

Becky Kush

Maryam Garza Mike Hamidi

— Reporting
 - - - Advisory

Vulcan PMO

Michael van Campen

Stacy Tegan

Hugh Glover

Shani Sampson

Vulcan Steering Committee



Amy Cramer Darren Weston
Vulcan Co-Chairs



**Steering
Committee**

- Sets strategic direction for Vulcan
- Prioritizes activities and approves use cases and projects
- Makes financial decisions
- Comprised of convening member organizations

Membership

- 2 co-Chairs
- 3 from Pharma
- 3 from MedTech (see note)
- 3 from Consortia
- 3 from Academia
- 3 from Government Agency
- 3 from Implementers
- 3 from SDO (1 reserved for HL7)
- 1 Advisory Council Chair
- 1 Operations Committee co-Chair
- 4 At Large, nominated by co-Chairs (thought leaders / SMEs, CROs, patient advocacy)

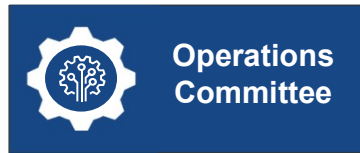
Emily Bachman	TransCelerate Biopharma
Rajya Bhaiya	Microsoft
Chris Chute	Johns Hopkins School of Medicine
Cal Collins	Open Clinica
Dave Evans	CDISC
Jose Galvez	FDA
Maryam Garza	University of Arkansas for Medical Sciences (UAMS)
Priya Gopal	Roche (Flatiron Health)
Mike Hamidi	Pfizer
Ed Hammond	Duke University
Charles Jaffe	HL7
Irene Joseph	Microsoft
Linda King	Society of Clinical Data Management
Jesper Kjær	Danish Medicines Agency (DKMA)
Rebecca Kush	Elligo
Sandrine Loiseau	Johnson & Johnson
Anne Moen	University of Oslo (UiO)
Jorine Putter	GSK
Mitra Rocca	FDA
Debi Willis	PatientLink
Tom Yosick	Epic

Vulcan Operations Committee



Maryam Garza Mike Hamidi

Operations Committee Co-Chairs



- Develops and recommends use case proposals
- Oversees operations and delivery of use case projects
- Comprised of all member organizations of Vulcan

Membership

- 2 co-Chair
- 1 Voting Member from each Vulcan member in good standing
- Open to all Vulcan Members



Vulcan Advisory Council Committee



Becky Kush

Advisory Council Chair

Membership

- 2 co-Chair
- 1 Voting Member from each Vulcan member in good standing
- Open to all Vulcan Members



Advisory Council

- Provides unbiased advice to Steering Committee on strategic matters
- Provides advice/input to Operations & Project Teams as requested

- Christel Anderson, HIMSS
- James Tcheng, Duke University
- Cal Collins, Open Clinica
- Christel Daniel, Assistance Publique - Hôpitaux de Paris (AP-HP)
- Rob DiCicco, Transcelerate Biopharma
- Toshohiko Doi, National Cancer Centre Hospital East
- Hugh Donovan, Advarra
- David Dorr, Oregon Health & Science University (OHSU)
- Dave Evans, CDISC
- Ron Fitzmartin, FDA
- Ken Gersing, NIH - National Center for Advancing Translational Sciences (NCATS)
- Charles Jaffe, HL7
- Dipak Kalra, European Institute for Innovation through Health Data (i-HD)
- Pierre-Yves Lastic, French Union of Data Protection Officers; European Federation of Data Protection Officers
- Russ Leftwich, Intersystems
- Josh Mandel, Microsoft
- Craig Lipset, Clinical Innovations Partners
- Cecil Lynch, Accenture
- Ben McAlister, Oracle
- Emily Pfaff, University of North Carolina at Chapel Hill
- Rachel Richesson, University of Michigan
- Maryann Slack, FDA
- Nancy Smider, Epic
- Nick Spring, BioVeras
- Pele Yu, Arkansas Children's Hospital



EuroVULCAN

What Value Awaits Behind the Curtain?

Vulcan Events and Educational Opportunities

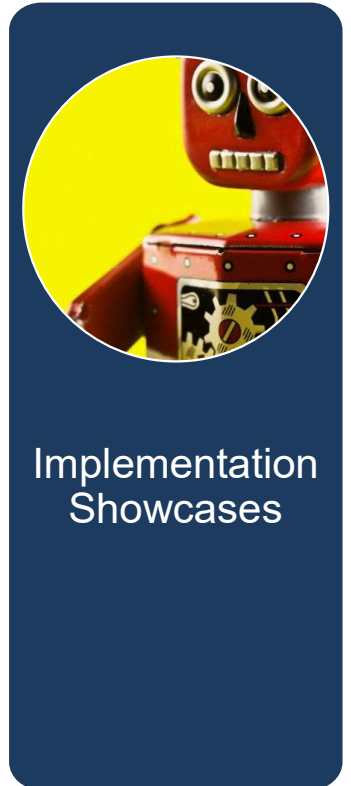
Vulcan is powered its members who contribute their expertise and resources (via fees or in-kind talent contribution). Vulcan aims to provide valuable opportunities to its members and the community.



Implementation Showcases offer Vulcan members: forum highlighting innovations in using FHIR in clinical & translational research

Past showcases have included:

1. Azure FHIR Service to enable Interoperability and Analytics for Clinical Research
2. OneSource: Automating Data Capture in Regulatory-grade Multicenter Trials
3. Converting ClinicalTrials.gov records to FHIR Resources
4. Demonstration of a FHIR Based Precision Medicine Platform for R&D in Translational Medicine
5. REDCap on FHIR: Empowering Investigators to Design Studies and Collect Data from Electronic Health Records
6. Source Data Capture from EHRs: Using Standardized Clinical Research Data (OneSource) in Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and moLecular analysis 2 (I-SPY 2) Breast Cancer Trial
7. Source CBER BEST Exchange Platform: a FHIR-based, HIPPA-compliant, connected platform to semi-automatically detect, validate, & report patients w/probable post-biologic AEs using RWD
8. IgNite Data's system-agnostic data conduit which connects EHRs and research systems such as EDCs
9. A Gravitate Health approach to adaptation of product information to individual needs
10. EMR to EDC (E2e) solution to increase efficiency, improve data quality, and lower site burden in clinical research
11. Ellie for Patient Screening with SMART on FHIR
12. The Open-Source Sandbox for Healthcare – Meld



January Connectathon





Yes, those are
“FHIR hats”!





Vulcan Projects

March 2022

Project / Vulcan Leads	Objectives	Status
<p>Schedule of Activities (SoA)</p> <p>Mike Ward (TransCelerate)</p> <p>Geoff Low (PHUSE)</p>	<ul style="list-style-type: none"> • Use FHIR to communicate a protocol’s SoA to EHRs & Electronic Data Capture (EDC) systems to support the research workflow and data exchange. • When a Patient is enrolled in a study, research personnel to attach Patient to the ResearchSubject and ResearchStudy, connecting CarePlan with the SoA • Enables care providers to plan and execute encounters and activities, providing visit windows to allow scheduling of patients and tests compliant with protocol 	<p>Implementation Guide Available</p>
<p>Real World Data (RWD)</p> <p>Scott Gordon (FDA) Open</p>	<ul style="list-style-type: none"> • Define FHIR profiles that can be used to retrieve relevant research data from Real World Data sources, specifically EHRs, and ultimately transform it into a format suitable for submission to regulatory agencies • Demonstrate how HL7 FHIR can directly support clinical research and regulatory uses • The intent is to be a Universal project, as such, consider the International Patient Summary (IPS) project for a baseline dataset on which to build profiles. 	<p>Implementation Guide Available</p>



Vulcan Projects

March 2022

Project / Vulcan Leads	Objectives	Status
<p>Electronic Product Information (ePI)</p> <p><i>Craig Anderson</i> (Pfizer)</p> <p><i>Catherine Chronaki</i> (Secretary General at HL7 Europe)</p>	<ul style="list-style-type: none"> • Collaboration with Gravitare Health to develop an international FHIR ePI standard • Develop instructions on how to create and exchange FHIR ePI documents; a common core profile for international use; region specific sub-profiles to accommodate unique local requirements; and recommendations for in-scope terminologies. • Make ePI more accessible; improve patient experience; and support international interoperability. <p>Note: This project operates in full alignment with other FHIR related activities at EMA, FDA and other regulators.</p>	<p>Implementation Guide Available</p>
<p>Phenotypic Data</p> <p><i>Anita Walden</i> (University of Colorado Anschutz)</p> <p><i>Shahim Essaid</i> (University of Colorado Anschutz)</p>	<ul style="list-style-type: none"> • Enable storage of phenotype information needed for genomic health in EHRs and allow it to be shared in a common a computable manner across the ecosystem. • Identify ways in which FHIR can enable EHRs to be appropriately extended with phenotypic information using the Phenopacket file format • Utilize FHIR to improve mappings and functionality • Enable automated population of computable elements and create opportunity for significant efficiencies over the current manual processes 	<p>In progress</p>



Vulcan Projects

March 2022

Project / Vulcan Leads	Objectives	Status
Adverse Events (AE) <i>Michelle Casagni</i> (MITRE) <i>Ed Millikan</i> (FDA)	<ul style="list-style-type: none"> Leverage EHRs and other types of real-world data (RWD), e.g., Electronic Patient Reported Outcomes (ePROs), as electronic source to collect adverse events that occur during clinical trials. Leverage HL7 FHIR standard identifying gaps between data elements in EHRs and clinical research artifacts such as adverse events data sets, Case Report Forms (CRFs), and existing standards (e.g. CDISC CDASH AE Domain, etc.). 	In progress
FHIR to OMOP <i>Davera Gabriel</i> (Johns Hopkins) <i>Catherine Diederich</i> (Duke)	<ul style="list-style-type: none"> Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research Identify & catalog preliminary work Identify overlaps / gaps between USCDI / ISP classes, content Match prior work elements in each USCDI / IPS class group Assemble proposed (draft) maps per domain / clas 	In progress



Questions?

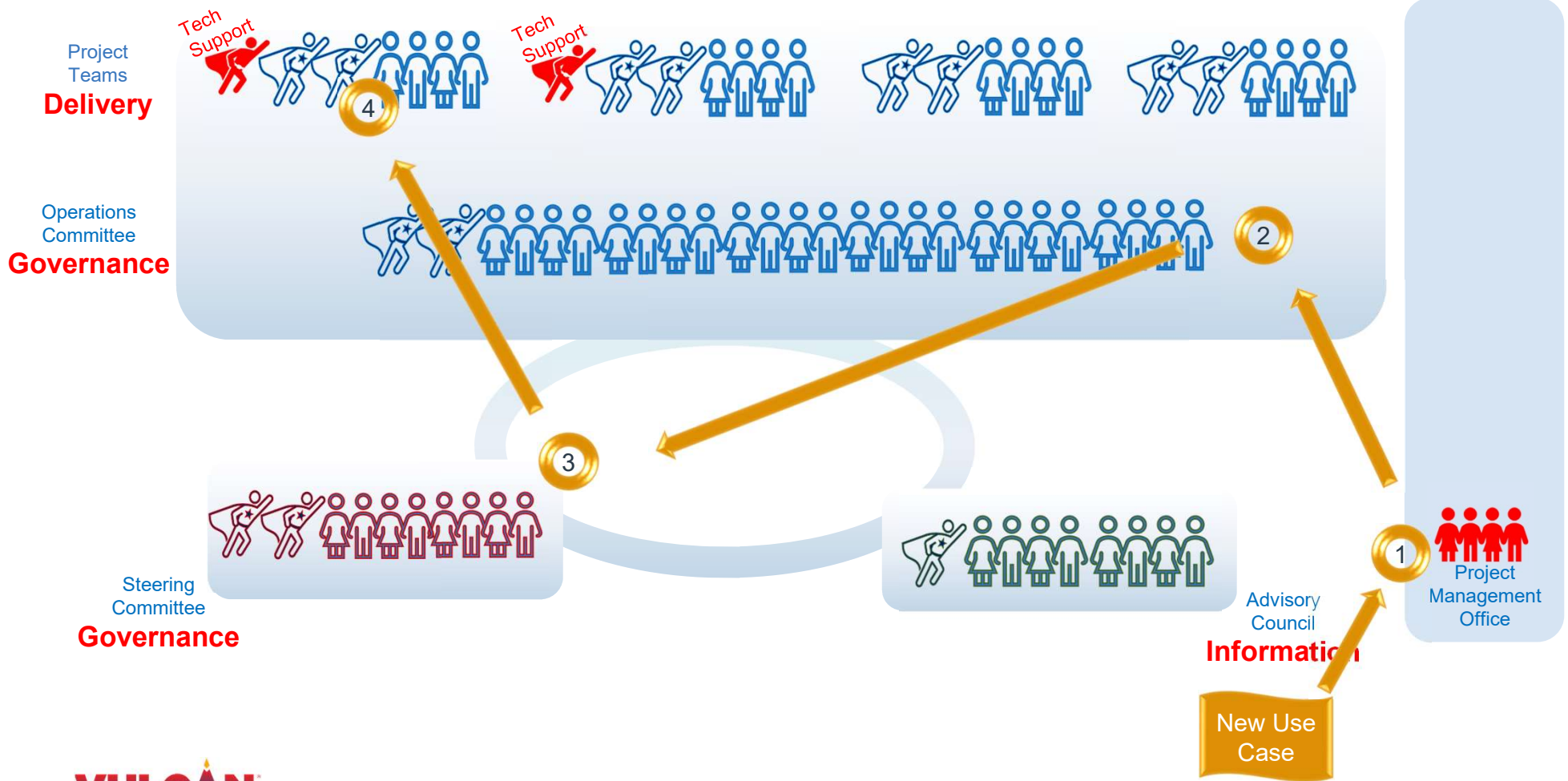


5. The Vulcan Project Process

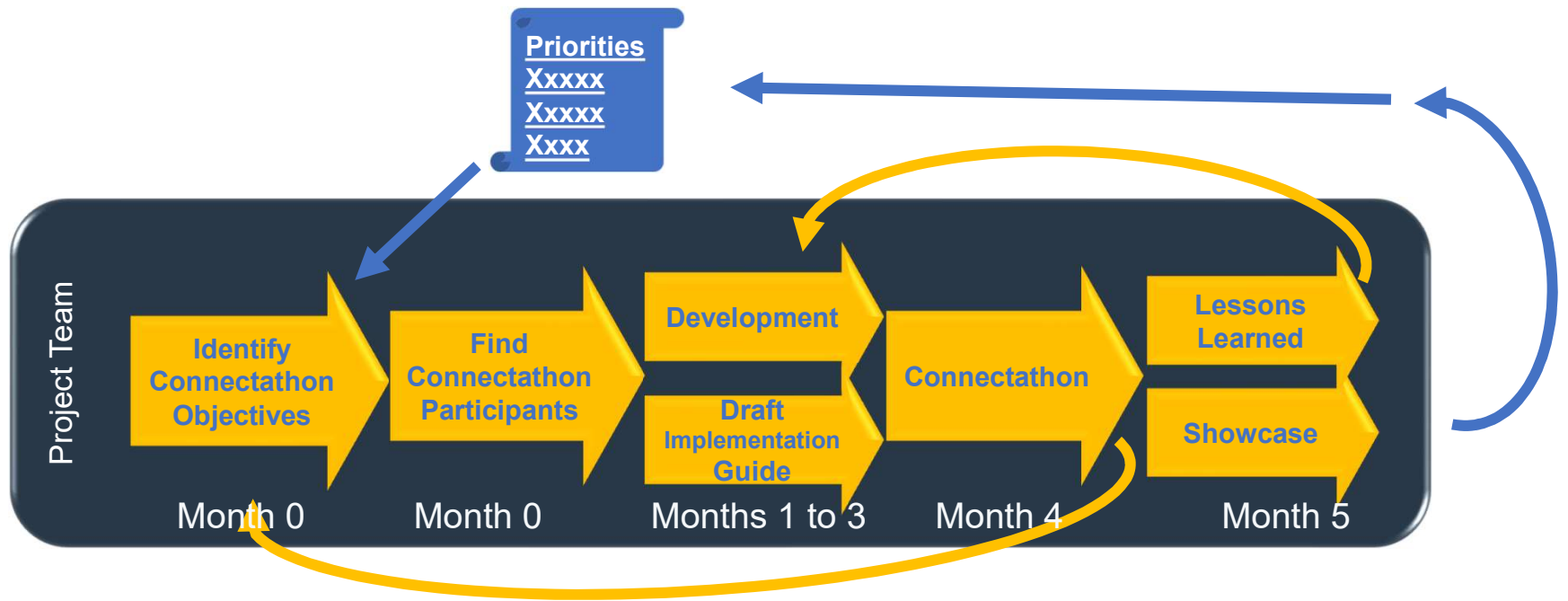
Hugh Glover, Vulcan
11:20 – 11:35



Organization and Responsibility



Vulcan Project Work Cycle



January 2023 Connectathon



Schedule of Activities

Schedule of Activities

- Updated React app that displays activities in visit windows to incorporate administrations and unscheduled activities
- Additionally, progressed
 - Investigational Product Administration
 - Unscheduled Activities

Real World Data

- Created a synthetic data set to help develop EHR queries
- Successfully queried the data using inclusion / exclusion criteria for patients of interest
- Compared retrieved data to source data to confirm that queries were working correctly
- Compared queried data to other EHR sources



Real World Data

FHIR to OMOP

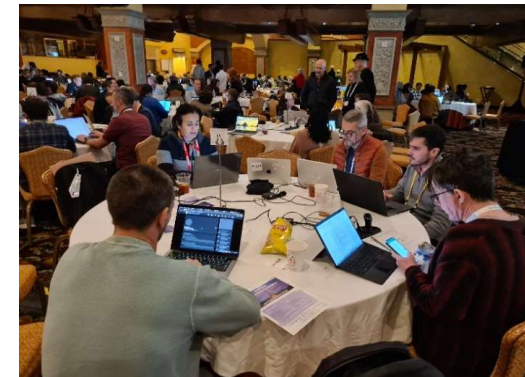
- Fixed various infelicities in the existing IG, for instance, adding severity and modifiers and specific named component slices
- Wrote HAPI FHIR Java code to convert GA4GH Phenotypic Data (JSON) to FHIR version, post this to a FHIR server, search and retrieve the FHIR message and translate back to GA4GH JSON
- Coordination FHIR Genomics Reporting IG version 2

Electronic Product Information

- Developed plans on how to handle allergens and interactions as a priority
- Decided to compare the patients' drugs with the list of interactions between those drugs.
- Decided on an operation to provide the EMA ePI in the full 'US style' format by combining the ePI plus SPOR product data
- Clarified how we plan to incorporate more SPL profile data into the Vulcan IG



FHIR to OMOP



Electronic Product Information

3 Vulcan Implementation Guides

The screenshot shows the HL7 Vulcan Schedule of Activities Implementation Guide page. The page title is "Clinical Study Schedule of Activities 1.0.0-ballot - ballot". The navigation menu includes Home, Core Model, Use Cases, Profiles, Examples, Downloads, and Credits. The main content area features a "Table of Contents" and a "Home" section. A yellow highlight box contains the text: "Clinical Study Schedule of Activities, published by HL7 International - Biomedical Research & Regulation Work Group. This is not an authorized publication; it is the continuous build for version 1.0.0-ballot. This version is based on the current content of https://github.com/HL7/vulcan-schedule-ig/d and changes regularly. See the Directory of published versions?". Below this, there is a "Home" section with a table containing metadata: Official URL, Version (1.0.0-ballot), Draft as of (2022-12-04), and Computable Name (StudyScheduleOfActivities). The page also includes sections for "1.1 Background" and "1.1.1 Vulcan Schedule of Activities (SoA) Project".

Schedule of Activities

The screenshot shows the HL7 Vulcan Electronic Medicinal Product Information (ePI) Implementation Guide page. The page title is "Electronic Medicinal Product Information (ePI) FHIR Implementation Guide 1.0.0-ballot - STU Ballot". The navigation menu includes Table of Contents, Introduction, Background, The Specification, Capability, Artifact Index, and Appendices. The main content area features a "Table of Contents" and an "Introduction" section. A yellow highlight box contains the text: "Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by HL7 International - Biomedical Research & Regulation Work Group. This is not an authorized publication; it is the continuous build for version 1.0.0-ballot. This version is based on the current content of https://github.com/HL7/emedical-product-info/d and changes regularly. See the Directory of published versions?". Below this, there is an "Introduction" section with a table containing metadata: Official URL, Version (1.0.0-ballot), Active as of (2022-12-04), and Computable Name (EPIIG). The page also includes sections for "1.1 Purpose", "1.2 Goals", "1.3 Objectives", and "1.4 Scope".

Electronic Product Information

The screenshot shows the HL7 Vulcan Real World Data for Clinical Research Implementation Guide page. The page title is "Retrieval of Real World Data for Clinical Research". The navigation menu includes TOC, Home, Cohort Building, Finding Data, Use Cases, Considerations, Artifacts, and Appendices. The main content area features a "Table of Contents" and a "Home" section. A yellow highlight box contains the text: "Retrieval of Real World Data for Clinical Research, published by HL7 International - Biomedical Research & Regulation Work Group. This is not an authorized publication; it is the continuous build for version 1.0.0-ballot. This version is based on the current content of https://github.com/HL7/vulcan-rwd/d and changes regularly. See the Directory of published versions?". Below this, there is a "Home" section with a table containing metadata: Official URL, Version (1.0.0-ballot), Draft as of (2022-12-04), and Computable Name (RealWorldData). The page also includes sections for "1.1 Overview" and "1.2 Current Scope".

Real World Data



Project Evolution

Clarifying the Process

Vulcan internal processes

Ideas

- How about ...
- This is a form for suggesting new use cases for consideration
- Anyone can make a suggestion

Sample Data

Proposal

- Operations Committee will discuss and vote on whether to adopt
- Steering Committee gives final approval

Discovery

- Many projects start as an "idea" that needs to be developed into a set of project steps
- The exact aims of the project may evolve during this process

Phenotypic Data

HL7 processes

Development

- The execution phase of the project where the Implementation Guide is being written and tested through **connectathons**
- This is an **open process**

FHIR to OMOP
Adverse Events

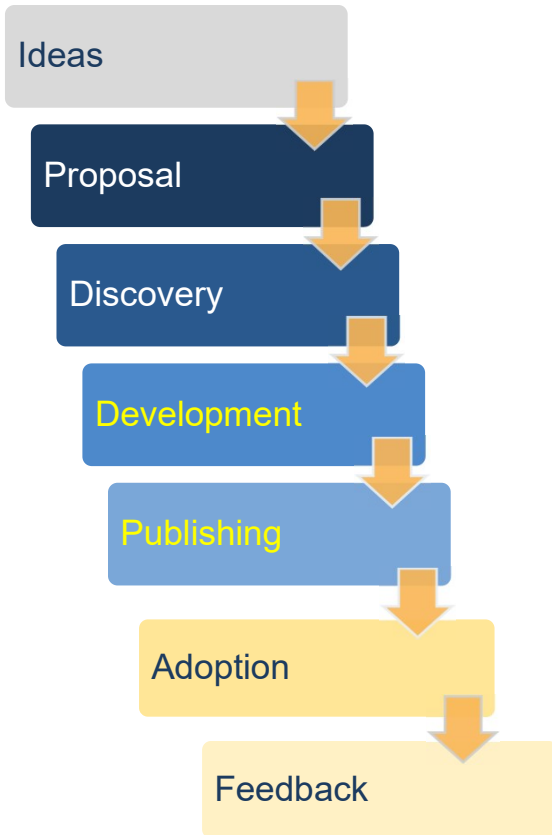
Publishing

- Content goes through the HL7 process to ballot the Implementation guide and respond to the comments raised

Real World Data
Schedule of Activities
Electronic Product Information



Evolution Three Principles



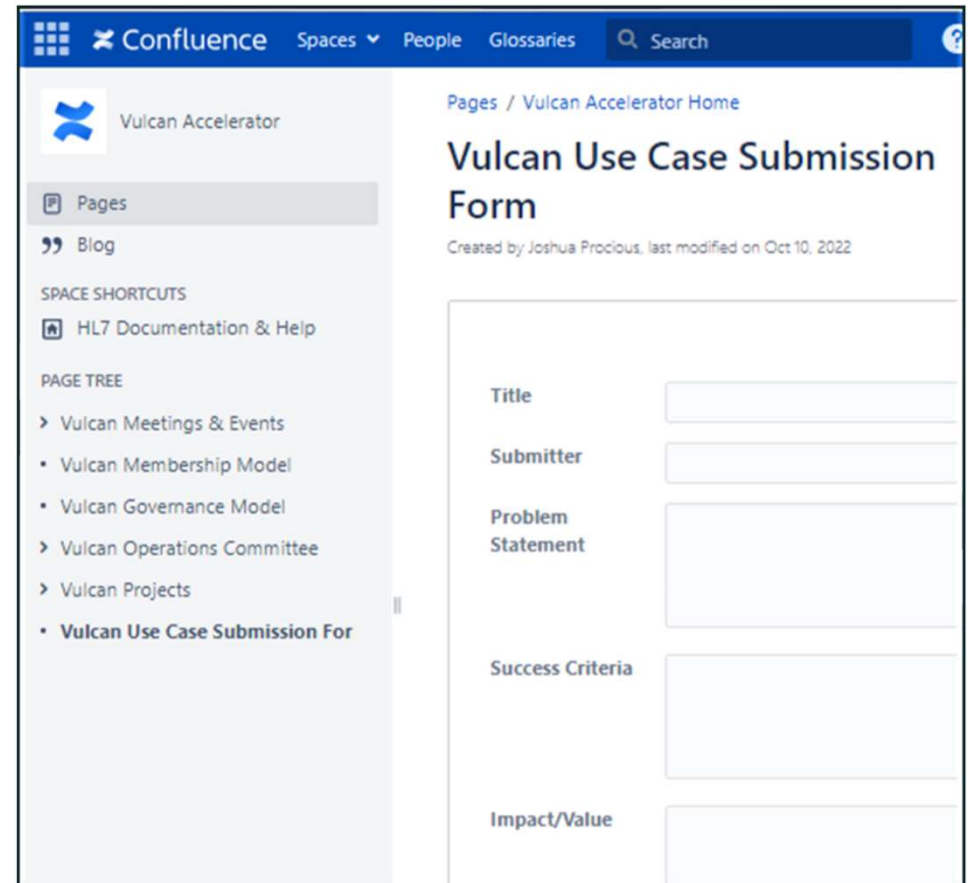
1. Publishing an Implementation Guide is not the end
2. If an Implementation Guide doesn't get adopted it was a waste of time
3. When an Implementation Guide is adopted it will need to change



Vulcan is at a point of inflection as we go
From start up to production

Making a Use Case Proposal

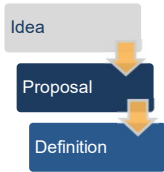
- Vulcan actively seeks new use case proposals – contact us at Vulcan@HL7.org or use the form shown here – Search ***Vulcan Use Case Submission***
- Proposals are initially considered by the Project Management Office and we may seek further input from you, particularly if the suggestion appears to overlap with an existing proposal.
- New proposals are then added to the project backlog for consideration and **prioritization by the Operations Committee** and subsequent recommendation to the **Steering Committee for final approval and any funding**.
- Adoption of new projects depends on priority and availability of resources.



The screenshot shows a Confluence page titled "Vulcan Use Case Submission Form" within the "Vulcan Accelerator" space. The page is created by Joshua Prociouk and last modified on Oct 10, 2022. The form contains several input fields: Title, Submitter, Problem Statement, Success Criteria, and Impact/Value. The left sidebar shows a navigation menu with "Pages" selected, and a "PAGE TREE" listing various documents, with "Vulcan Use Case Submission For" highlighted.

<https://confluence.hl7.org/display/VA/Vulcan+Use+Case+Submission+Form>

Project Evolution and Control – Initial Process Gates



0 > Suggest Use Case
Anybody

- Rough Use Case Description

> Review Use Case

1 PMO



- Clear & Distinct Use Case Description

2

> Review & Prioritize Use Case
Prioritization work group



- Clear & Distinct Use Case Description
- Strategic Aim
- Target Customers
- Product Area
- Impact, Effort & Difficulty Estimates
- Clear Project description

3

> Approve Use Case
Operations Committee



> Define Project
Project Leads

4

- Clear & Distinct Use Case Description
- Strategic Aim
- Target Customers
- Product Area
- Impact, Effort & Difficulty Estimates
- Clear Project description
- Project lead & Co-Lead
- Project team members
- Project Plan & Budget

5

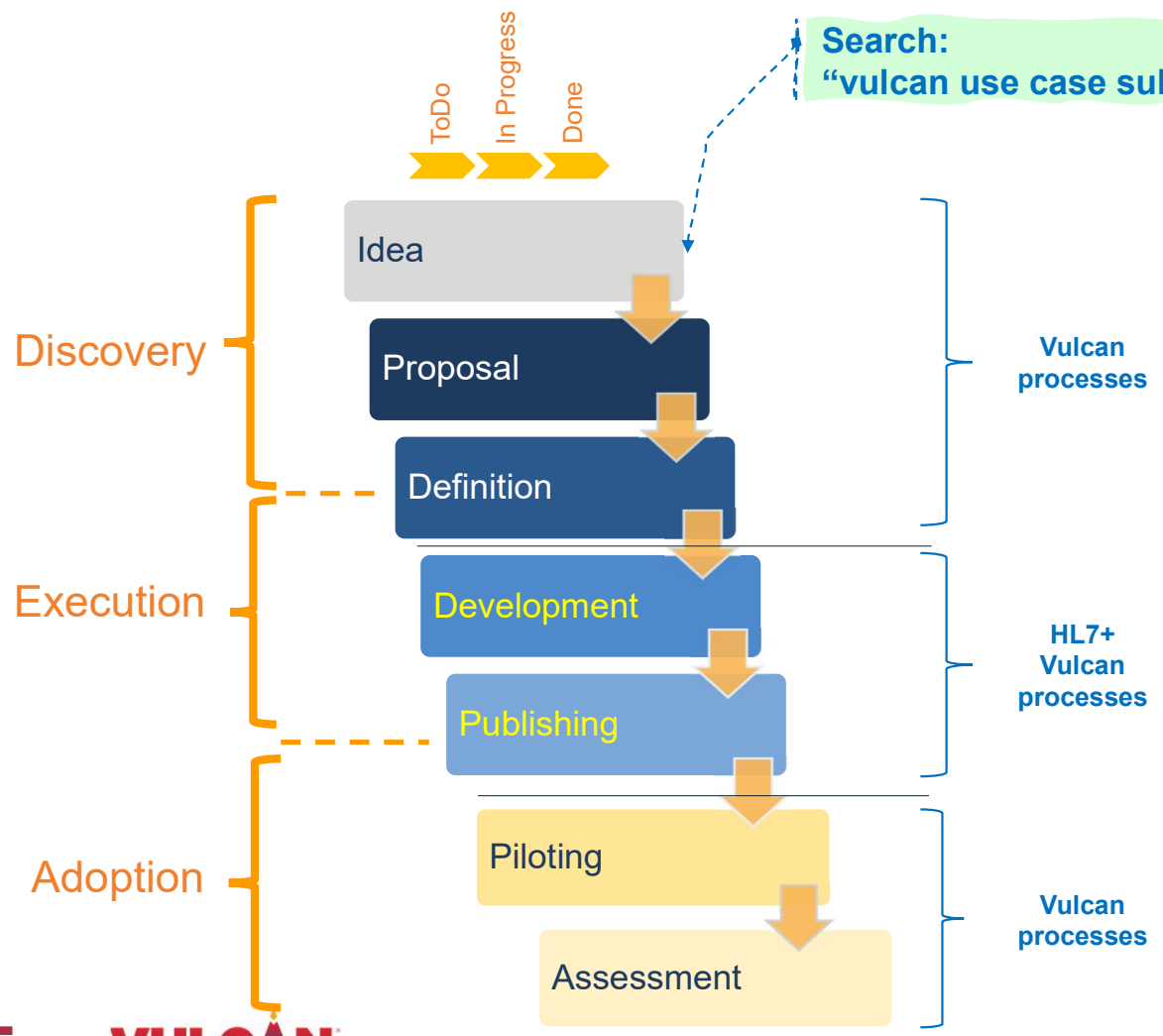
> Approve Project
Steering Committee



6

> Do Discovery
Project Team

Project Evolution and Control – Summary



Tech Support

Project Components

- Clear & Distinct Use Case Description
- Strategic Aim
- Target Customers
- Product Area
- Impact, Effort & Difficulty Estimates
- Clear Project description
- Project lead & Co-Lead
- Project team members
- Project Plan & Budget

Project Management Office



Questions?



6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA

Evinn Drusys, AEMPS

Jose Galves, FDA (remote)

11:35 – 12:20





6. Perspectives on FHIR (Part 1 – Regulators)

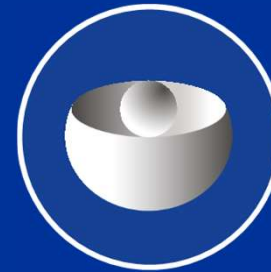
Elizabeth Scanlan, EMA

Evinn Drusys, AEMPS

Jose Galves, FDA (remote)

11:35 – 12:20





EUROPEAN
MEDICINES
AGENCY

Towards a harmonised EU ePI – the EMA perspective

EuroVulcan Conference March 2023

Presented by Elizabeth Scanlan on 14 March 2023
Public and Stakeholders Engagement Department

An agency of the European Union

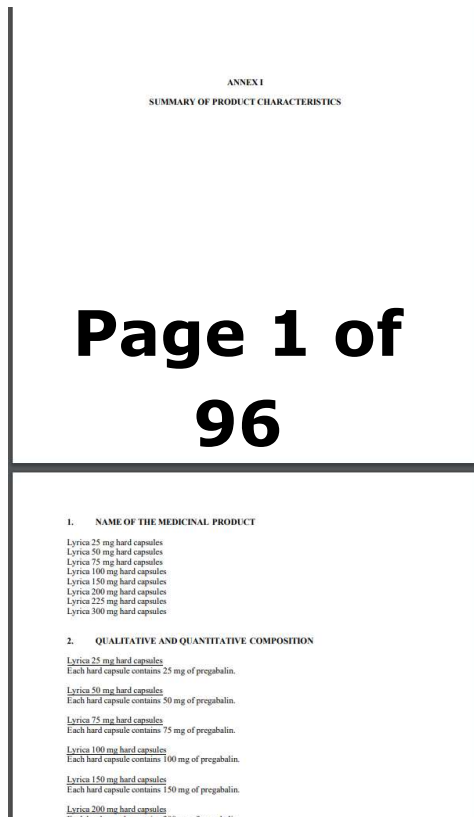


Disclaimer

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The presenter does not have any conflict of interests.

Today's PI in PDF

Moving towards harmonised semi-structured electronic PI




agencia española de medicamentos y productos sanitarios **cima** PROSPECTO LYRICA 25 MG CAPSULAS DURAS

Introducción

1. Qué es Lyrica y para qué se utiliza
2. Qué necesita saber antes de empezar a tomar Lyrica
3. Cómo tomar Lyrica
4. Posibles efectos adversos
5. Conservación de Lyrica
6. Contenido del envase e información adicional

Introducción

[Abschnitt vorlesen lassen](#)

Gebrauchsinformation: Information für Anwender

Lyrica® 20 mg / ml Lösung zum Einnehmen
Pregabalin

Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Einnahme dieses Arzneimittels beginnen, denn sie enthält wichtige Informationen.

- Heben Sie die Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Wenn Sie weitere Fragen haben, wenden Sie sich an Ihren Arzt oder Apotheker.
- Dieses Arzneimittel wurde Ihnen persönlich verschrieben. Geben Sie es nicht an Dritte weiter. Es kann anderen Menschen schaden, auch wenn diese die gleichen Beschwerden haben wie Sie.
- Wenn Sie Nebenwirkungen bemerken, wenden Sie sich an Ihren Arzt oder Apotheker. Dies gilt auch für Nebenwirkungen, die nicht in dieser Packungsbeilage angegeben sind. Siehe Abschnitt 4.

ieser Packungsbeilage steht

- [st Lyrica und wofür wird es angewendet?](#)
- [sollten Sie vor der Einnahme von Lyrica beachten?](#)
- [st Lyrica einzunehmen?](#)
- [ie Nebenwirkungen sind möglich?](#)
- [st Lyrica aufzubewahren?](#)
- [t der Packung und weitere Informationen](#)

[Abschnitt vorlesen lassen](#)

st Lyrica und wofür wird es angewendet?

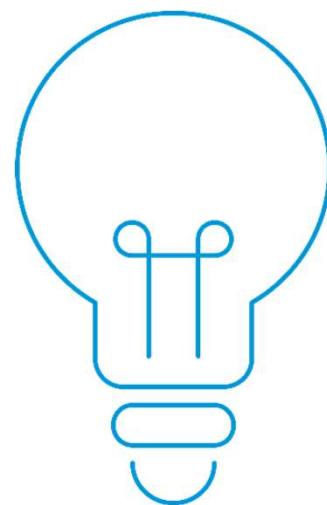
rt zu einer Gruppe von Arzneimitteln, die bei Erwachsenen zur Behandlung von über Gehörlos, bei Colic und bei ...

Towards a harmonised EU ePI – the EMA perspective

Classified as public by the European Medicines Agency

ePI Definition

ePI is authorised, statutory product information for human medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.



EU ePI common standard based on FHIR to support a harmonised ePI across the EU network



**Fast
Healthcare
Interoperability
Resources**

Adopted EU Common Standard for ePI published on GitHub:

<https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard>

Towards a harmonised EU ePI – the EMA perspective

Benefits for patients and healthcare professionals

Case 1

List of patient medicines
 ePI in phone app
 Does not remember
 how to take asthma
 medicine
 Goes to 'How to take
 your medicine' to
 downloadable video
 Receives alert when ePI
 updated e.g. new safety
 information

Case 2

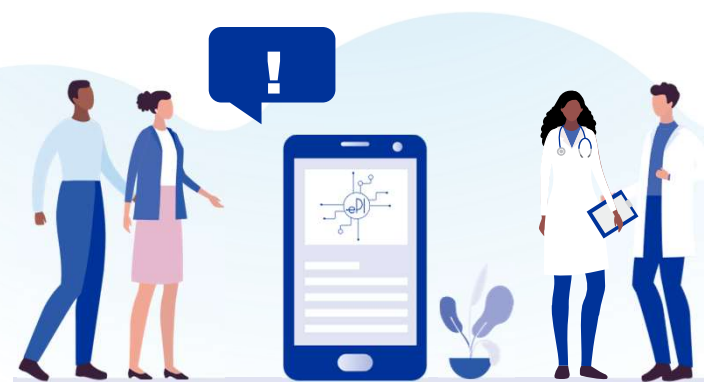
Rapid ePI updates for
 COVID-19 vaccines and
 therapeutics
 Use QR code to link to
 national language ePI
 Timely access to up-to-
 date information in
 patient's language at
 point of vaccination

Case 3

Pregnancy planning /
 Lactose intolerance
 Targeted ePI search
 Treatment decision

Towards a harmonised EU ePI – the EMA perspective

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Benefits for regulators, national authorities, companies

Case 1

Medicine shortage anticipated in country A
Import medicine from country B, link to ePI in language A
Shortage mitigated

Case 2

Change that affects multiple PI
Following variation change is simultaneously implemented in all affected PI annexes
Harmonised, up-to-date PI available to patient and healthcare professionals

Case 3

Signal detected
Facilitate search of existing side effects listed in all relevant PI
Optimised signal validation

Towards a harmonised EU ePI – the EMA perspective

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Developed with funding by the
European Union

Minimum Viable Product tooling in development

ePI authoring portal

enables ePI creation, preview,
update, upload (in FHIR) and
download (in FHIR, Word)

Rich text editing functionality

supports creation and editing
of ePI with all styling aspects
needed for PI documents

Repository and API

ePI to be stored in FHIR
server and made available to
websites and machines via
the ePI API



User: Companies



User: Companies

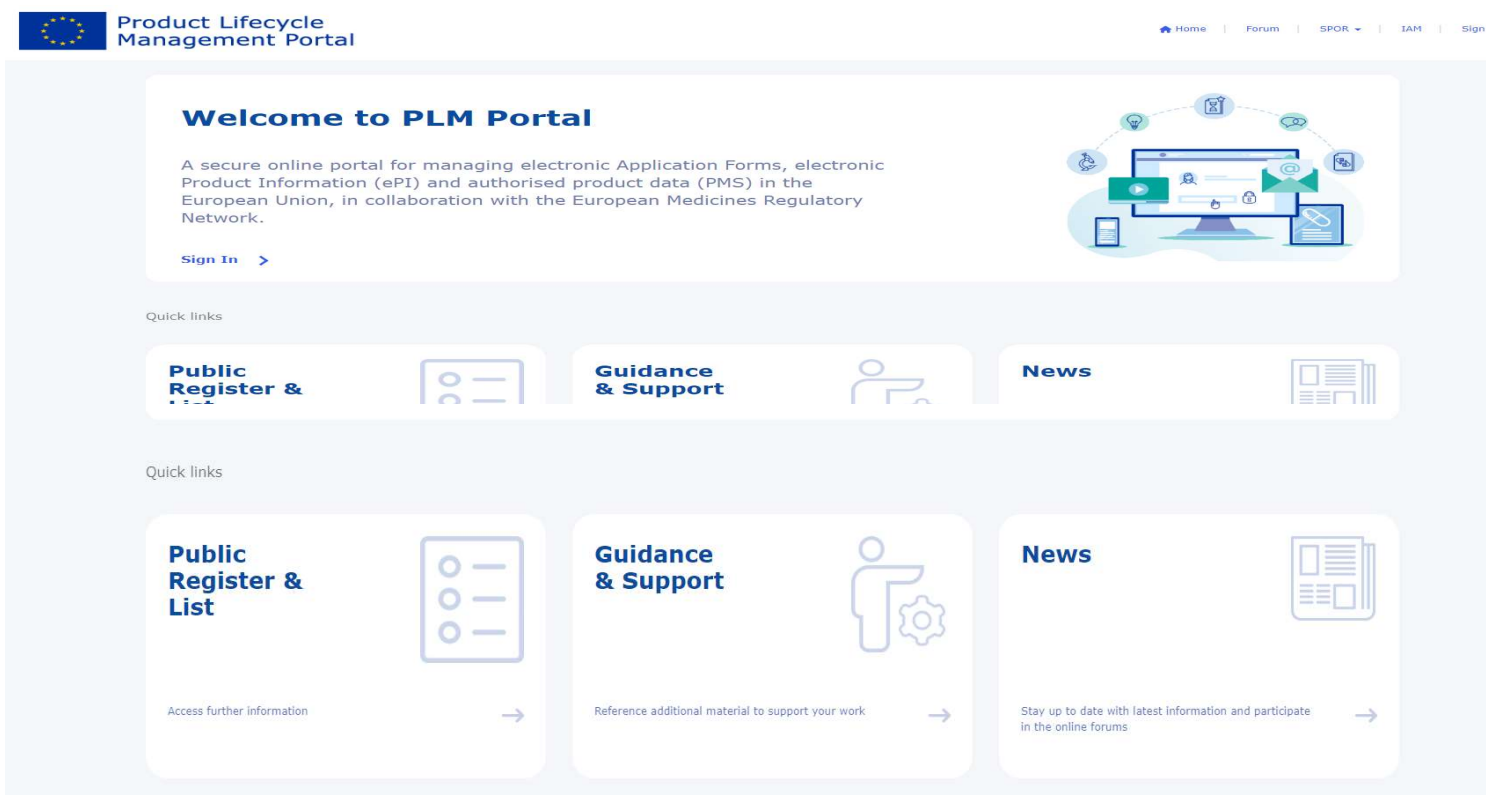


Users:
Companies
Regulators
eHealth developers

Towards a harmonised EU ePI – the EMA perspective

MVP in Product Lifecycle Management Portal

<https://plm-portal.ema.europa.eu/>



The screenshot shows the homepage of the Product Lifecycle Management Portal. At the top left is the EMA logo and the text "Product Lifecycle Management Portal". At the top right are navigation links: Home, Forum, SPOR, IAM, and Sign In. The main content area features a "Welcome to PLM Portal" section with a description: "A secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the European Union, in collaboration with the European Medicines Regulatory Network." Below this is a "Sign In" button and an illustration of a computer monitor with various icons. Underneath is a "Quick links" section with three buttons: "Public Register & List", "Guidance & Support", and "News". A second "Quick links" section below shows three larger cards for "Public Register & List", "Guidance & Support", and "News", each with an icon and a brief description of the service.

Towards a harmonised EU ePI – the EMA perspective

From the same portal, applicants can manage ePI, electronic application forms and product data.

Tree-view for authoring of PI documents

Home > ePI Portal - New ePI

EPI/23/73 / Draft
Pre authorisation (ePI for new medicine) / Human / CAP
Name of medicinal product - *Demo medicine* Procedure Number - *EMA/H/C/01234*

SmPC ANNEX II Label PL

Human-CAP Template SMPC (EN) ...

SUMMARY OF PRODUCT CHARACTERISTICS ...

1. NAME OF THE MEDICINAL PRODUCT ...

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS ...

4.1. Therapeutic indications

4.2. Posology and method of administration ...

Posology ...

Paediatric population

Method of administration

4.3. Contraindications

4.4. Special warnings and precautions for use

4.5. Interaction with other medicinal products and other forms of interaction

4.6. Fertility, pregnancy and lactation

Demo medicine

NAME OF THE MEDICINAL PRODUCT

File Edit View Insert Format Tools Table Help

Paragraph B I [Color] [Align] [List] [Table] [Link] [Image]

|

Towards a harmonised EU ePI – the EMA perspective

Regulator view

Home > ePI List

[Draft](#)
[Complete Pre Opinion](#)
[Complete Post Opinion](#)
[Published](#)
[Deactivated](#)
[All](#)

[Column visibility](#)
[Refresh](#)
[Download](#)

Search

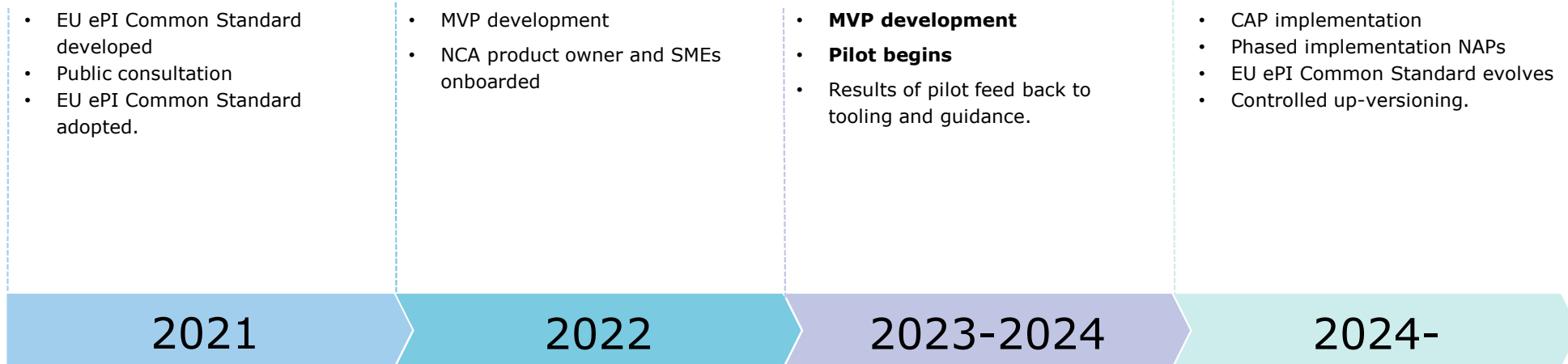
EPI ID	Name of medicinal product	Procedure no.	Authorisation type	Reference MAH	Approved by	Approved on	Published by	Published on	Status	Action
Manage ePI	Test		CAP	test org	AV	19/01/2023 12:07 PM			Complete Post opinion	<input type="checkbox"/>
Manage ePI	TestDevmed	1234	CAP	test org	Test	23/01/2023 11:12 AM			Complete Post-opinion	<input type="checkbox"/>
EPI/23/54	QRD template		CAP	UAT ORG					Complete Post-opinion	<input checked="" type="checkbox"/>
EPI/23/41	Test.	copy	CAP	European Medicines Agency					Com	<input type="checkbox"/> View/Manage ePI <input type="checkbox"/> Deactivate ePI <input type="checkbox"/> Approve for publication

Towards a harmonised EU ePI – the EMA perspective

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Pilot planning begins

- Small number of real-time procedures
- CAP (EMA) and NAP (Denmark, Netherlands, Spain, Sweden)
- Beginning H2, 2023 & first outcome report Q1, 2024
- Portal user guide & procedural guidance in preparation



Towards a harmonised EU ePI – the EMA perspective

Thank you for your attention

Further information

Contact us at ePI@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA

Evinn Drusys, AEMPS

Jose Galves, FDA (remote)

11:35 – 12:20





AEMPS - National
regulator
perspective of ePI

Presented by: Evin Drusys
AEMPS IT Division

Reasons for ePI

- Provide up-to-date regulator approved product information to patients and HCPs.
- ePI will allow product information to be updated instantaneously
 - Updates to product information will not be bogged down by supply chain logistics.
- ePI is machine readable and can be easily communicated to downstream apps.
- Accessibility will be greatly improved allowing users with sight impairments to consume ePI with the help of a screen reader or enlarged Font size.
- Allows for better searching of product information content.

Trademark ® Use Case



<https://cima.aemps.es/cima/publico/home.html>

Registered trademark symbols in Spanish PI

disponibles para el ensayo cromogénico de Rotachrom® Heparin.
ixabán, alcanzando los valores máximos al mismo tiempo que las c

Excerpt from QRD template

{(Invented) name strength pharmaceutical form}

[No ® ™ symbols included here and throughout the text; “tablets” and “capsules” in plural.]

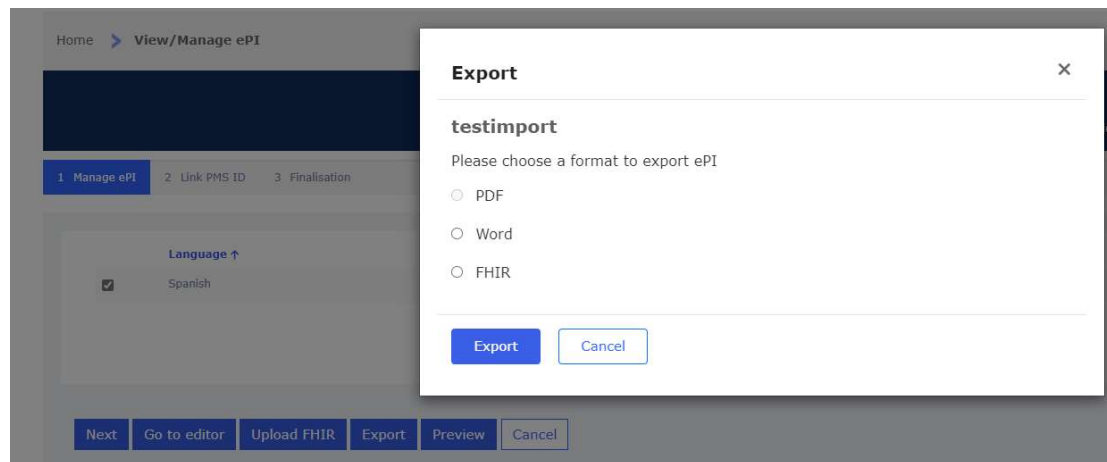
ePI trademark ® Use Case

Because the AEMPS has SmPC and PL data structured into a relational database, we can easily query to find what medicines have the ® symbol in the PI and even the section of the document where it is located.

23054	DILURANT 250 MG SOLUCION INYECTABLE EN JERINGA PRECARGADA EFG	AUTORIZADO	2015-10-02 00:00:00.000	6.6	Precauciones especiales de eliminación y otras manipulaciones
23713	MAGARAT 0,05 mg/ml SOLUCION PARA PERFUSION	AUTORIZADO	1999-07-28 00:00:00.000	4.2.2	Forma de administración
08113	MAGARAT 0,05 mg/ml SOLUCION PARA PERFUSION	AUTORIZADO	1999-07-28 00:00:00.000	6.5	Naturaleza y contenido del envase
00969	WIKIs 25 MG SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	2019-04-15 00:00:00.000	5.1	Propiedades farmacodinámicas
88883	WIKIs 25 MG SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	2019-04-15 00:00:00.000	5.2	Propiedades farmacocinéticas
09372	WIKIs 50 MG SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	2019-04-15 00:00:00.000	5.1	Propiedades farmacodinámicas
08163	WIKIs 50 MG SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	2019-04-15 00:00:00.000	5.2	Propiedades farmacocinéticas
02913	WIKIs 75 MG SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	2019-04-15 00:00:00.000	5.1	Propiedades farmacodinámicas
09173	WIKIs 75 MG SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	2019-04-15 00:00:00.000	5.2	Propiedades farmacocinéticas

ePI portal and API services

- ePI authoring for NAPs, CAPs, and MRP/DCP products
- Rich text editing capabilities
- Exporting ePI in FHIR and Word formats
- Submitting ePI to regulators for approval and publishing



ePI API services

Consuming API

- Get ePI by title(name)
 - `api/Retrieval/ListByTitle?title=Elocta`
- Get ePI list by ID
 - `api/Retrieval/ListById?id=49119f4e-c9b1-46b5-ae92-e070669963ir`
- Get ePI bundle by ID
 - `api/Retrieval/BundleById?id=49119f4e-c9b1-46b5-ae92-e070669296bh`
- Get ePI by authority
 - `List?notes:contains=AEMPS`

EU ePI Common standard and global use via Vulcan Core ePI

EU ePI - FHIR Resource Names ¹	
1	List
2	Bundle
3	Composition
4	Binary
5	Organization
6	RegulatedAuthorization
7	MedicinalProductDefinition
8	PackagedProductDefinition
9	AdministrableProductDefinition
10	ManufacturedItemDefinition
11	Ingredient
12	ClinicalUseDefinition
13	Substance

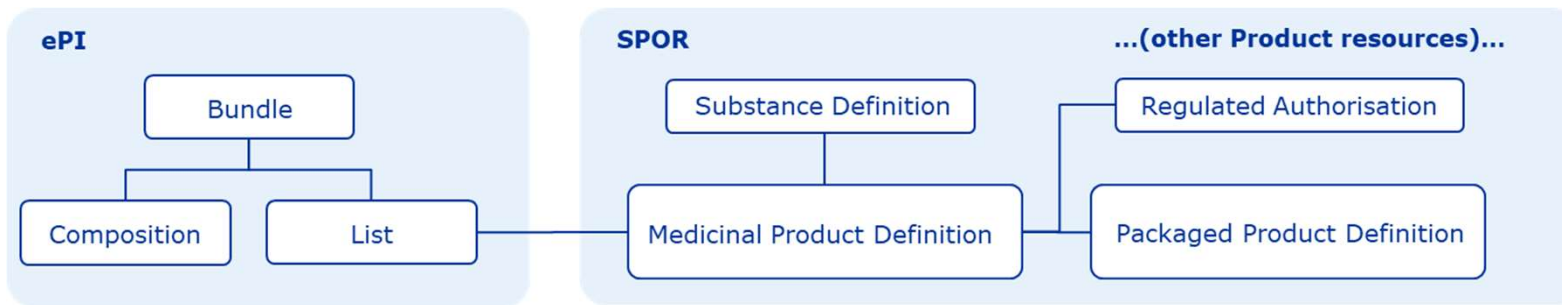
¹ Rows 1 to 4 make up the ePI. The ePI cross references out to SPOR, which can provide the data of rows 5 to 13. Product data are from PMS, one of the 4 SPOR services.

Vulcan ePI - FHIR Resource Names ²	
1	List
2	Bundle
3	Composition
4	Binary
5	Organization
6	RegulatedAuthorization
7	MedicinalProductDefinition
8	PackagedProductDefinition
9	AdministrableProductDefinition
10	ManufacturedItemDefinition
11	Ingredient
12	ClinicalUseDefinition
13	Substance

²Core ePI is managed as a single self-contained document.

EPI and SPOR Master Data

- SPOR uses FHIR to represent IDMP-compatible Products and Substances
- ePI uses FHIR to represent unstructured documents in a more structured way
- ePI and SPOR resources do not currently overlap, they interconnect
- Both systems share data interoperability principles, standard, conventions and best practices
- The same FHIR tools and expertise can be leveraged by both systems



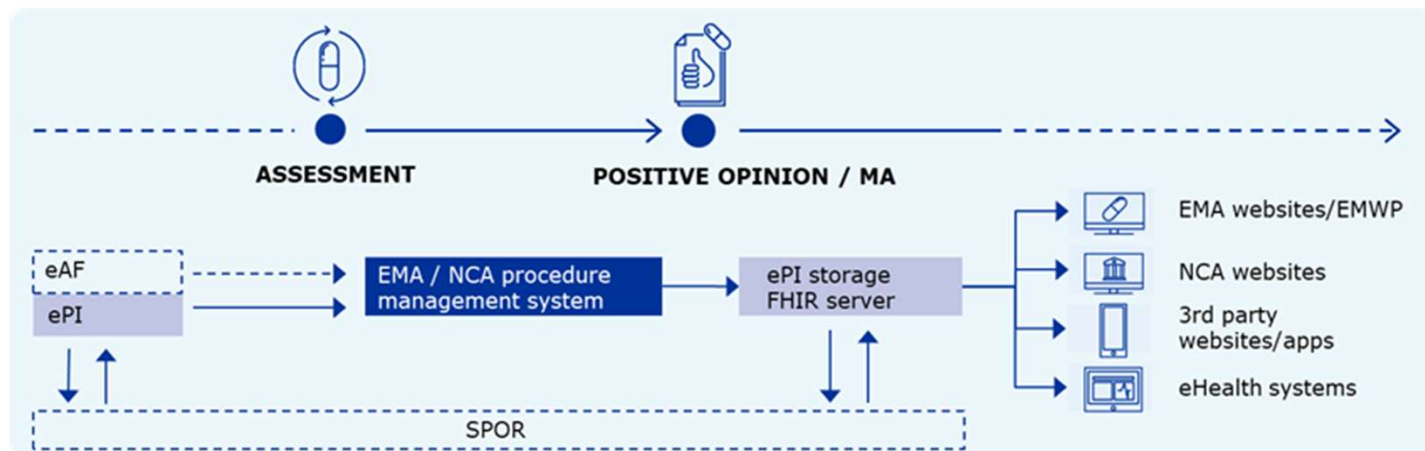
PMS data and ePI

The screenshot shows a web application interface. At the top, there is a breadcrumb navigation: "Home > View/Manage ePI". Below this is a dark blue header bar. A progress indicator shows three steps: "1 Manage ePI ✓", "2 Link PMS ID" (highlighted in blue), and "3 Finalisation". The main content area is titled "Link PMS ID" and is currently empty. At the bottom, there are three buttons: "Previous", "Next" (highlighted in blue), and "Cancel".

- Linking ePI with PMS ID
- However, incorporating PMS data in ePI is more complicated
 - New MAA don't have a PMS ID, so when will the connection to PMS be made?
 - Will PMS data be inserted into the PI? If it is how will it be maintained?
 - Will there be a duplication of data causing confusion?

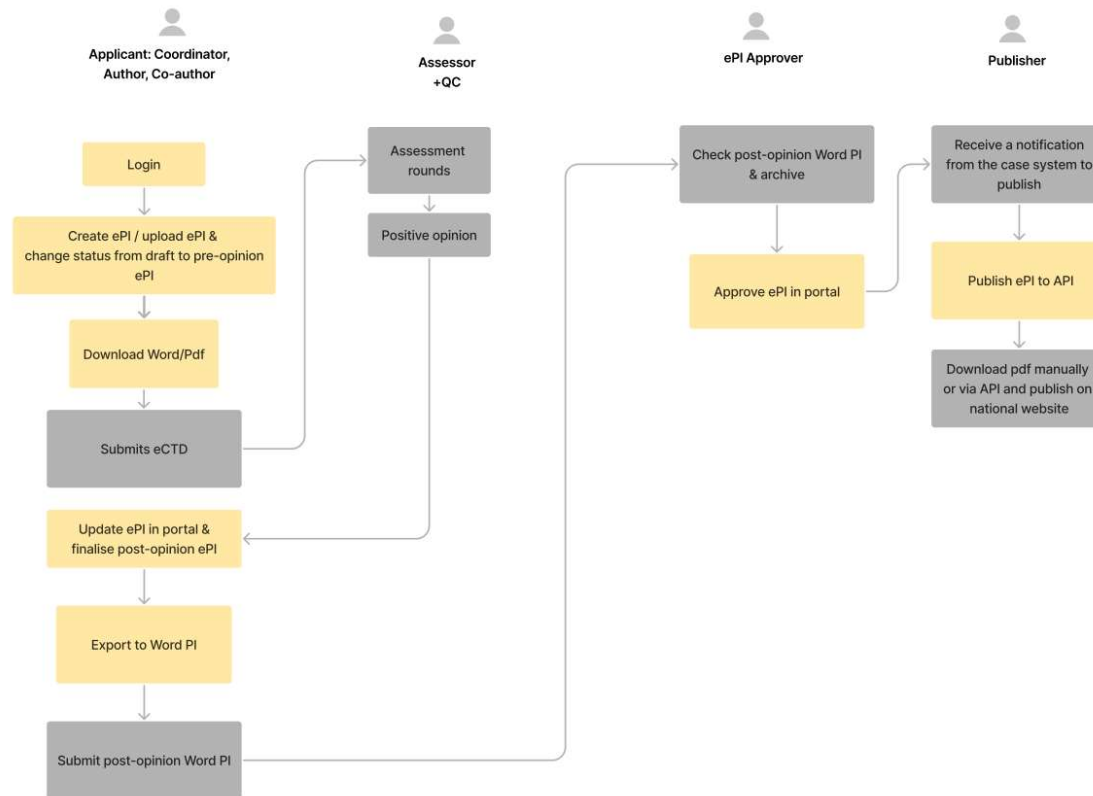
EPI Pilot Minimum Viable Product (MVP)

- MVP will be piloted for CAPs and some NAPs (Denmark, Netherlands, Spain, Sweden).
- The MVP enables an early version of ePI with limited features that can be used by early adopters. The MVP is a ready-to-use, first release of a product to be used in the business process, and not a prototype.
- The MVP enables creation of ePI at point of application and update following positive opinion.



Example regulatory procedure

Pure NAP - initial



ePI System Demos

- Most recent [demo 21st December](#)
- Recording available on EMA website/YouTube
- No invitation needed: join livestream on YouTube
- [Next demo March 22nd](#)

Quarterly system demo - Q3 2022 [← Share](#)

Table of contents

- [Event summary](#)

📅 **Date:** 28/09/2022

📍 **Location:** Online, 09:00 - 12:30 Amsterdam time (CEST)

Event summary

This is the third system demo of 2022, the fourth ever held by EMA as part of its [Agile transformation](#).

A system demo is an event held at the end of a programme increment (a three-month period of work) to demonstrate the developments achieved in that period and collect stakeholder feedback.

Participants have the opportunity to review what has been delivered, comment and ask questions on future product increments (planned chunks of work on the final system).

EMA will demonstrate developments with its [DADI project](#), [Product Management Service](#), [Electronic Product Information \(ePI\)](#), [Emergency Task Force Support](#), [Veterinary Signal Management](#), [Inspections](#), [Parallel distribution](#) and [Medicines Shortages](#).

The event is broadcast live.

A video recording will be made available after the event.



Thank you for your time

If you have any questions please contact: efoster_externo@aemps.es



6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA

Evinn Drusys, AEMPS

Jose Galvez, FDA (remote)

11:35 – 12:20





Disclaimer

- **The opinions expressed are solely my own and should not be interpreted as an endorsement of any technology or product by the FDA.**
- **The opinions expressed in this presentation are not meant to imply any changes to guidance, or regulations.**
- **I have no financial interests in any of the technologies discussed**
- **Gravitate-Health**
The Gravitate-Health project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 945334. This joint undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations [EFPIA] and IMI Associated partner Datapharm Limited.



What will we cover

- **Current state**
 - Process
 - Standards
 - Data
 - Submission
- **FHIR – Regulatory Agency Perspective**



Current state of data standards used by regulators (FDA example)

Current data standards used at FDA for crucial functions are built on older technological approaches to data standards and informatics

- **Tabular based standards for Clinical data**
 - SDTM/ADaM
 - SAS transport
- **XML based structured data**
 - HL7 v3 multiple submission types
 - (SPL) Product labelling
 - AE reporting
 - Facility and Establishment registration/information
 - Risk Evaluation and Mitigation Strategies (REMS)

Some critical data activities have no structured data standards

- All of eCTD Module 3: data on Pharmaceutical Quality, Chemical Manufacturing, and Controls



Current state of data for regulatory agencies (FDA example)

With some exceptions, regulators like FDA are stuck in the “paper” paradigm.

- **Much is now “digital paper” (PDF/Word) but not much more useful for computation**
- **Large amount of submitted still in narrative form - even in Cover Letters**
- **We still have banks of fax machines**
- **Even structured data often conforms to a “document” paradigm**

It's 2022!

Sponsors must send a range of information to regulators requested in different formats

- **Cover Letters, PDFs, Office docs, .xml files, Structured Data Files, etc.**

Packaged in various “wrappers”

- **SAS Transport, electronic Common Technical Document (eCTD) folders, etc.**

And then... regulators must unpack all that, manage it, and finally review it.



A better vision

A future where:

- Using modern data technologies and information technology conventions,
- sponsors can clearly, reliably, and accurately convey the details of the narrative,
- allowing regulators to clearly, reliably, and accurately understand the narrative,
- all while minimizing the need for subjective decisions and interpretations
- and minimizing the burden on sponsors and regulators



Health
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Santé
Canada



VULCAN



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH



Health
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Santé
Canada



独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency



FHIR as an enabling technology

In this context, FHIR is an enabling technology.

Significantly different than older HL7 standards and CDISC standards:

Using modern 21st Century informatics technology

- HL7 V2 developed in the late '80s, HL7 V3/CDISC: '00s
- FHIR: Began 2014 – during the solidification of the modern internet technologies that power nearly all IT transactions worldwide

Core paradigms:

- API supported “streaming data” just like everything else on the internet
- Future-proofed: Clearly versioned iterations of FHIR can be revised to respond to changes in data requirements, internet technology, etc.
 - HL7 Community is a central part in this

FHIR (1) represents data and (2) incorporates IT technology to support:

- FHIR Resources = Packaging
- Transport/Transmission
- Validation
- Receiving



Implementation-ready and aligned with evolving information technology

FHIR is being developed for maximum implementation options:

- Supports backwards-compatible solutions (ie, Document paradigm) to integrate FHIR into older architectures
- Extensions and other options allow FHIR to be usable for many use cases outside of the core healthcare use case
- Any internet-savvy developer can easily/quickly learn FHIR, since it's based on current technologies

FHIR is primed for continuous alignment with changing technologies:

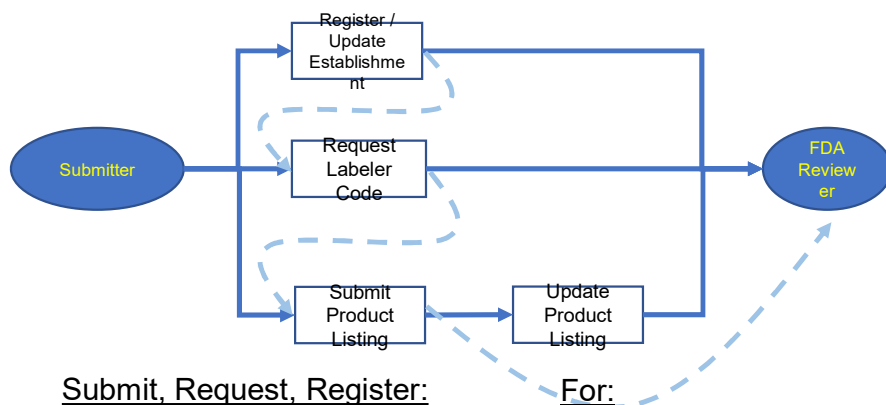
- The entire FHIR ecosystem (data standard and the supporting technology) is community driven
- FHIR has global IT industry infrastructure buy-in ensuring both continuous support from critical IT building blocks (ie AWS, Azure, EHR vendors)
- Can shift to keep up with other underlying technologies if internet tech demands it

Selected FHIR examples

SPL FHIR (FDA)

SPL is used for many activities at FDA

High-level processes (example use case):
Establishment Registration and Product Listing



Submit, Request, Register:

- Drug/Biologic Label
- NDC Labeler code
- Establishment information
- GDUFA Self-Identification
- REMS
- Etc.

For:

- Drugs
- Biologics
- Veterinary
- Devices
- Medical Food and Supplements
- Cosmetics

SPL needs be able to keep up with changes in data standards support

SPL is based on HL7's Version 3 (V3) Standard

V3 is not in active support mode at HL7

FHIR is the emerging HL7 Standard

CDER is:

- Exploring the ability of FHIR to support SPL uses
- Considering potential implementation approaches use of FHIR for SPL is warranted

A current draft IG can be found at

- <http://build.fhir.org/ig/HL7/fhir-spl/branches/main/index.html>

ePrescriptions (ePI)

- Connectathon – example of Basic G-lens focusing

Applied G-lens criteria:
Demographics, conditions, allergy and intolerance

Capable healthcare prototype showing patient profile for Maria Personnas. The profile includes sections for Allergies and intolerances, and Medical conditions. A blue arrow points from the 'Laktoseintoleranse' entry to the 'Lactose Intolerance related - highlighted' annotation.

Capable.healthcare prototype

ePI from Felleskatalogen for Skilarence Enterotab 30 mg. The interface shows G-lens criteria and various text blocks. Annotations include:

- 'Applied G-lens criteria: Demographics, conditions, allergy and intolerance' pointing to the G-lens section.
- 'Pregnancy related - suppressed' pointing to the 'Graviditet og amming' section.
- 'Lactose Intolerance related - highlighted' pointing to the 'Skilarence inneholder laktose' section.

ePI from Felleskatalogen

Case:

- Highlight and suppress ePI sections based on patient information

Approach:

- Identifiable ePI sections from Felleskatalogen
- Manually extracted knowledge, coded by ICPC-2, linking sections, represented as *FHIR ClinicalUseIssue*
- Patient information, coded as ICPC-2, represented as *FHIR AllergyIntolerance* and *Conduction* resources
- Demographic information
- Software for highlighting and suppressing text

Prepared by
Petter Hurlen, AHUS
Knut Skifjeld, NeH
Gunvald Harket, NeH



Pharmaceutical Quality, Chemical Manufacturing, and Controls (PQ/CMC)

All of eCTD Module 3 (information on Pharmaceutical Quality, Chemical Manufacturing, and Controls) is mostly submitted as a big pile of unstructured PDF documents

- massive time to extract (copy/paste, hand notes, etc.) before analysis can begin

Goal: establish electronic standards for submitting Pharmaceutical Quality (PQ) and Chemistry & Manufacturing Controls (CMC) data.

- Develop structured data standards for PQ/CMC
- Develop a data exchange standard for submitting the structured PQ/CMC data to the FDA

FHIR is being used as the exchange standard for submission

Ultimately will have a full PQ/CMC FHIR Implementation Guide

Draft mapping to FHIR resources can be seen in a 2022 FRN for public comment: [Draft PQCMC Data Exchange and FHIR representation](#)

Project overview page: [Pharmaceutical Quality/Chemistry, Manufacturing & Controls \(PQ/CMC\) | FDA](#)

REMS Integration Use Case

Problem

Multiple stakeholders play an important role in the REMS administration process:

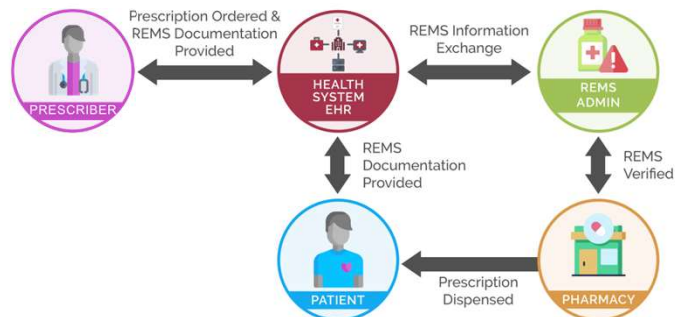
- Verification of variable completed REMS requirements
- Dispensing of the drug with no unified way to:
 - Coordinate the process
 - Share data amongst one another

Gaps in data interoperability make REMS communication and coordination burdensome

Not in current workflow - increased burden for stakeholders and the healthcare system overall

Solution

- Leverage FHIR and other data standards and create a data infrastructure to integrate REMS processes into stakeholder workflows
- Facilitate integration, enabling:
 - Prescribers and pharmacists to:
 - Be alerted to a REMS requirement
 - Complete requirements (training, education, clinical actions)
 - Attest and easily confirm in workflow that REMS requirements have been met





Questions?

Lunch

Lunch + Facilitated Discussions

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

Topic	Facilitator(s)
How can different standards work together?	Peter van Reusel Catherine Chronaki
How does privacy play into standards, and vice versa?	Pierre-Yves Lastic
Enhancing clinical trial efficiency and success using hospital EHRs	Dipak Kalra Nadir Ammour
How can Vulcan support clinical research in Europe?	Michael van Campen
How do we accelerate the design of a digital clinical trial?	Andy Richardson



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7. Implementation Insights / Showcase

Jessica Jeffries, IgniteData

Mitra Rocca, FDA (remote)

Peter Casteleyn, J&J

Martin Ingvar, Karolinska Institutet

13:20 – 14:40





7. Implementation Insights / Showcase

Jessica Jeffries, IgniteData

Mitra Rocca, FDA (remote)

Peter Casteleyn, J&J

Martin Ingvar, Karolinska Institutet

13:20 – 14:40





EHR-to-EDC Transformation of Modern Clinical Trials

Jessica Jeffries
Strategic Account Director



Agenda

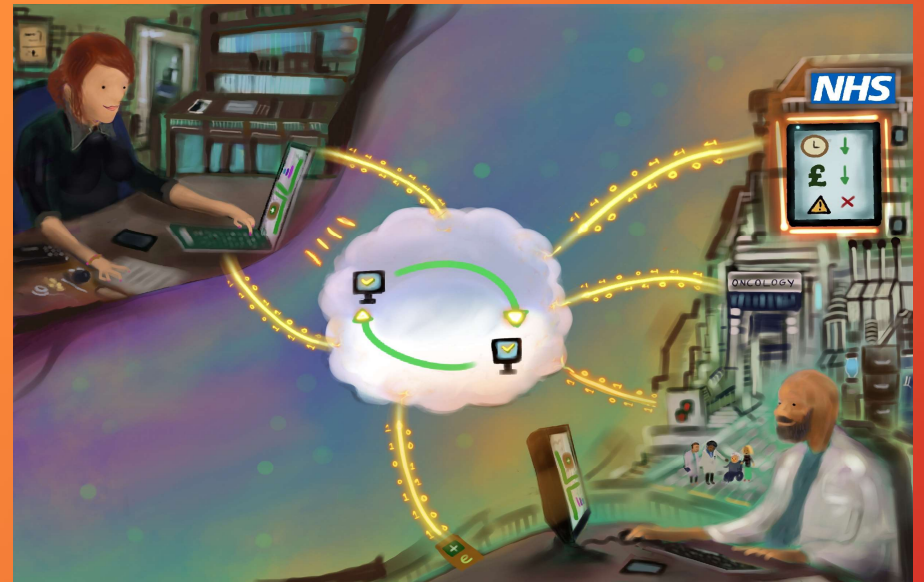
- Why?
- How?
- What?
- Where?
- Archer in Action



BEFORE ARCHER



WITH ARCHER



How Archer enables EHR2EDC



Archer works well with structured data domains

1

Laboratory

The most valuable use case for Archer. The system is able to rapidly export lab data and this is often the largest burden in many study designs.

2

Concomitant Medications

Some studies can have hundreds on conmeds per patient. Archer is able to move these with limited ease.

3

Vital Signs

A strong use case for Archer, often required in interventional studies and certain study designs (especially critical care) have a large burden here.

4

Demographics

A less valuable example as the volume of data required is often fairly low, but Archer can still help if required.

What impact can Archer have on a study?

ONCOLOGY STUDY – GASTRIC AND GASTROESOPHAGEAL JUNCTION CANCER

- 900 patients
- 20 visits per patient
- Archer used for 16 forms (15% of total forms)
 - 6 vital signs forms
 - 9 lab forms
- 1 conmeds form (avg. of 50 medications)

For this study example, from the 15% of mapped total forms, Archer is transferring 45% of all data for the study.

Total number of data items per patient	1374
Average time taken to enter each data item manually	3 minutes*
Average time taken per patient to enter data manually over 20 visits	4122 minutes = 68.7 hours



Estimated time gained by using Archer** over 20 visits

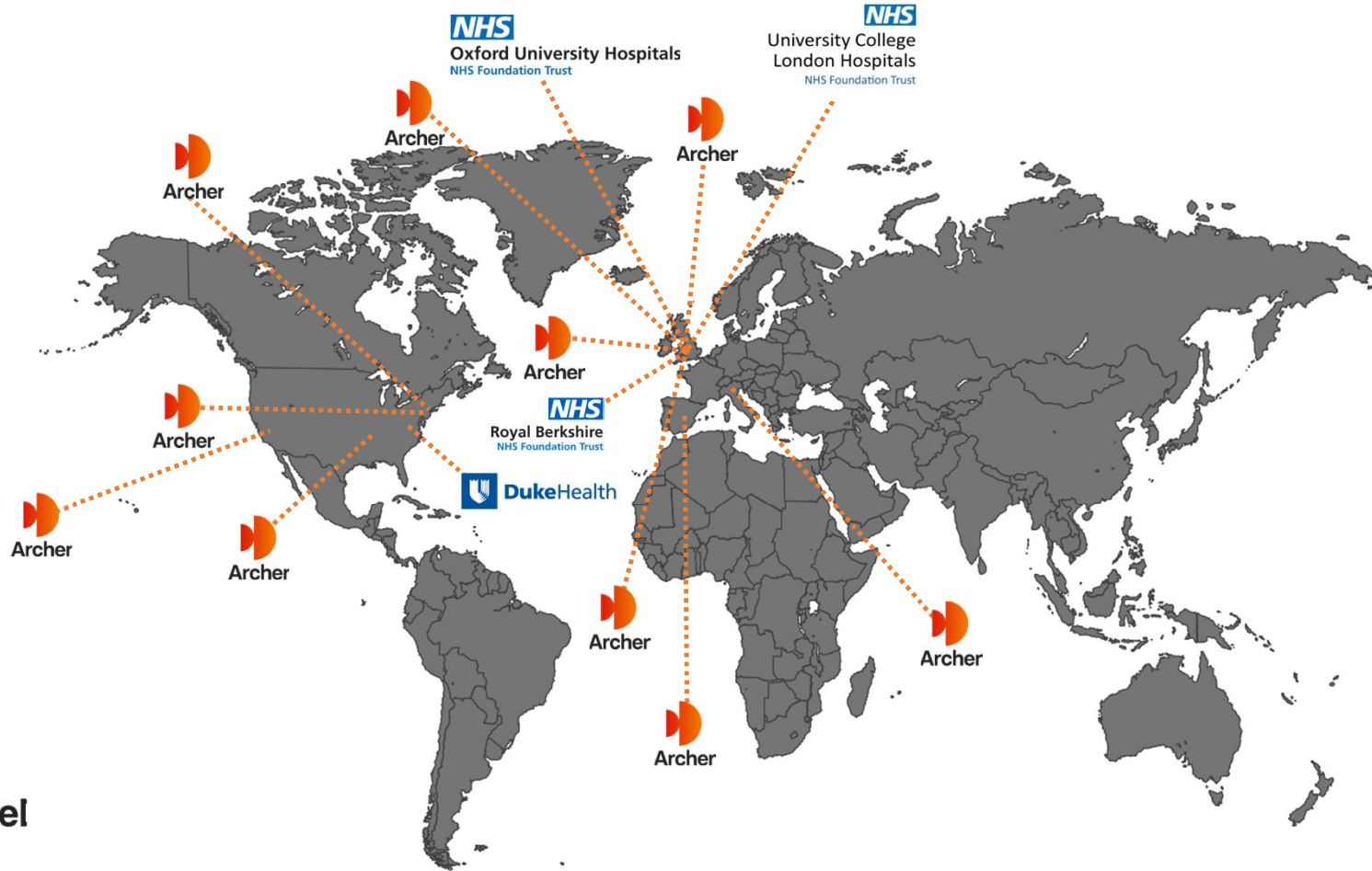


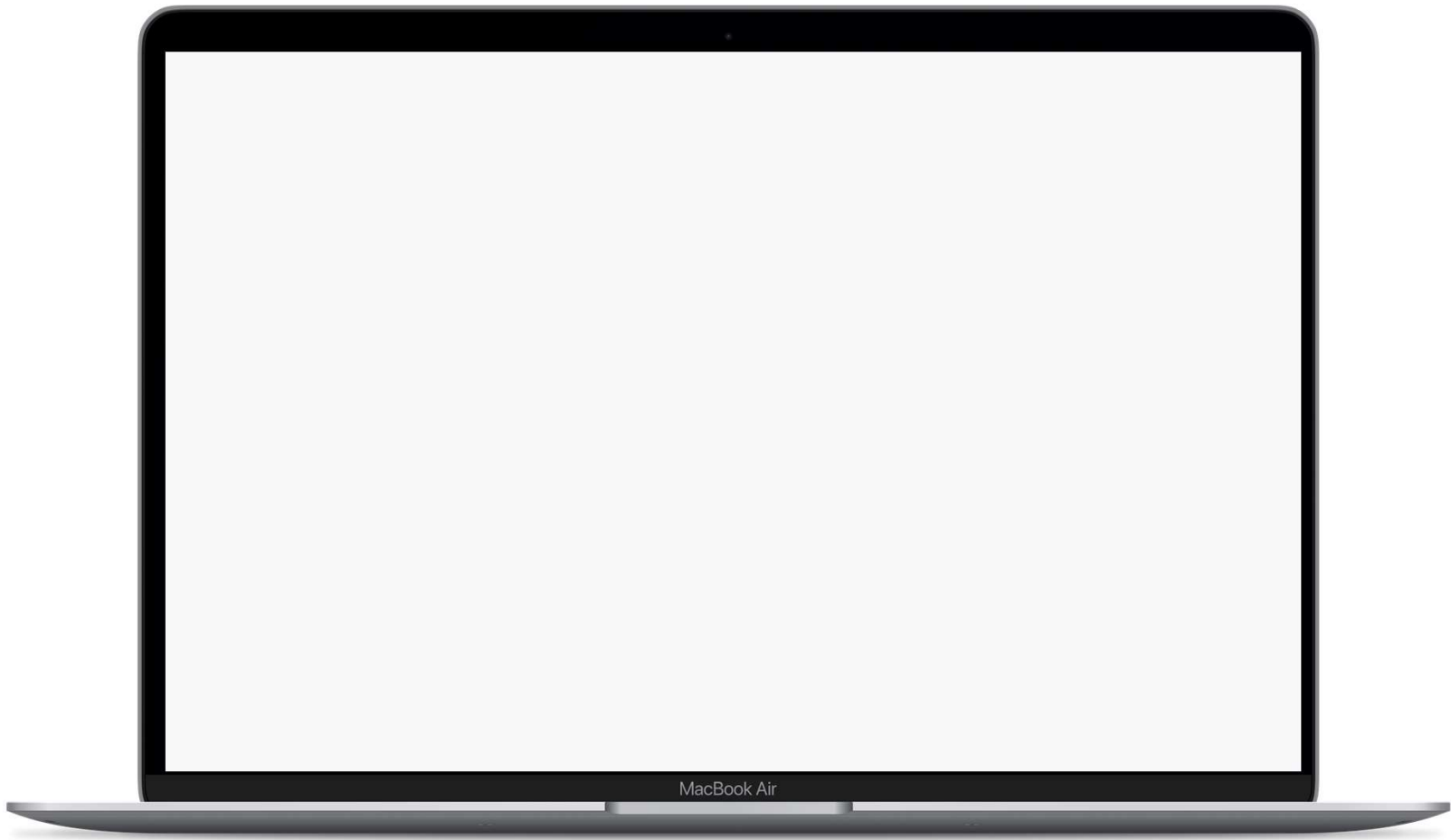
66.8 hours = 96.5% time-saving

*Source: Sanofi, EHR2EDC consortium project

** Time per visit using Archer automation benchmarked at 7 minutes per visit / 2.3 hours across 20 visits

Where?





Thank you!

Questions?

Contact

For more information on IgniteData, contact us
on:
hello@ignitedata.co.uk

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www.ignitedata.co.uk



Supported by:

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13:20 – 14:40





Use of Real-World Data in Clinical Research

Mitra Rocca, Dipl. -Inform. Med., FAMIA
Senior Medical Informatician
Office of Translational Sciences, CDER
Food and Drug Administration

Disclaimer



This presentation reflects the views of the speaker
and should not be construed to represent FDA's views or policies

Outline



- 21st Century Cures Act
- FDA Real World Evidence (RWE) Program
- Demonstration Projects Leveraging Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)
 - Source Data Capture from EHRs: Using Standardized Clinical Research Data (OneSource)
 - I-SPY COVID-19 Trial and OneSource
 - Common Data Model Harmonization (CDMH)

21st Century Cures Act – December 2016



Public Law 114-255 (December 16, 2016)

[This Photo](#) by Unknown Author
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U.S. 21st Century Cures Act (2016)



- Food & Drug Administration (FDA) shall establish a program to evaluate the potential use of real-world evidence (RWE) to:
 - Support new indication for a drug approved under section 505(c)
 - Satisfy post-approval study requirements
- Draft framework to be issued by Dec 2018:
 - Describe sources of RWD/RWE, challenges, pilot opportunities, etc.
- Draft guidance for industry to be issued by Dec 2021
- Standard for *substantial evidence* remains unchanged; commitments are aligned with Prescription Drug User Fee Act (PDUFA)

FDA RWE Framework (2018)



- Applies to Center for *Drug* Evaluation and Research (CDER) and Center for *Biologics* Evaluation and Research (CBER), not to Center for Devices and Radiological Health (CDRH)
- Multifaceted program to implement RWE:
 - internal processes
 - external stakeholder engagement
 - demonstration projects
 - guidance development

'Real-World' Definitions (from FDA's 2018 Framework)

Real World Data (RWD) are data relating to patient health status and/or delivery of health care routinely collected from a variety of sources

electronic health records (EHRs)

medical claims data

product and disease registries

patient-generated data, including from in-home settings

other sources that can inform on health status, such as "wearable" devices

Real World Evidence (RWE) is clinical evidence regarding the usage and potential benefits/risks of a medical product derived from analysis of RWD

Generated using different study designs, including but not limited to randomized trials (e.g., large simple trials, pragmatic trials), externally controlled trials, or observational studies



SOURCE DATA CAPTURE FROM EHR'S: USING STANDARDIZED CLINICAL RESEARCH DATA (ONESOURCE)

Source Data Capture from EHRs: Using Standardized Clinical Research Data (OneSource)



- Conceptual approach of OneSource: improve the quality of real-world data; “enter the right clinical data once, use the data many times” (including for research)
- Focus on integration of standards-based tools within the EHR, to bring together health care and research (e.g., populate electronic case report forms directly from EHR)
- Ongoing demonstration in breast cancer clinical trials
- Ongoing demonstration in COVID-19 clinical trials





Electronic Source Data Capture from EHRs

- Improve the efficiency, speed, and quality of clinical trials
- Demonstrate the use of Real-World Data (RWD) for Real-World Evidence (RWE) generation to enhance regulatory decision making
- Present significant opportunities to streamline medical product development
- Incorporate new technologies into clinical trials to make them more agile and accessible to patients and FDA, including through checklists to ensure that we have the reliable data we need to confidently assess safety and efficacy

Project Background

Led by FDA CDER in collaboration with the University of California, San Francisco (UCSF)

Phase I

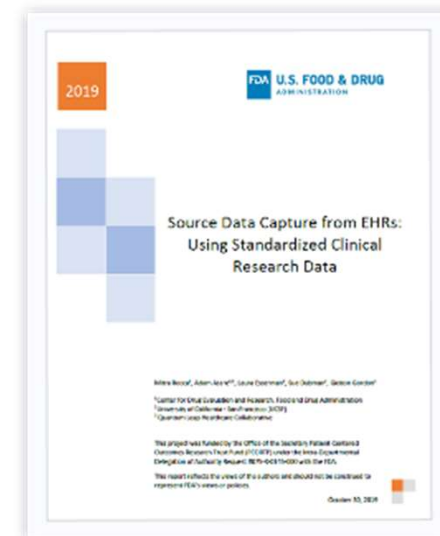
Populated Electronic Case Report Forms (eCRFs) for a phase II breast cancer clinical trial, (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2 (I-SPY 2 TRIAL)).

Phase II

Further development of the OneSource standards platform focusing on adverse events occurred in clinical trials.

Phase III

Reuse of OneSource standards platform in COVID-19 clinical trials.



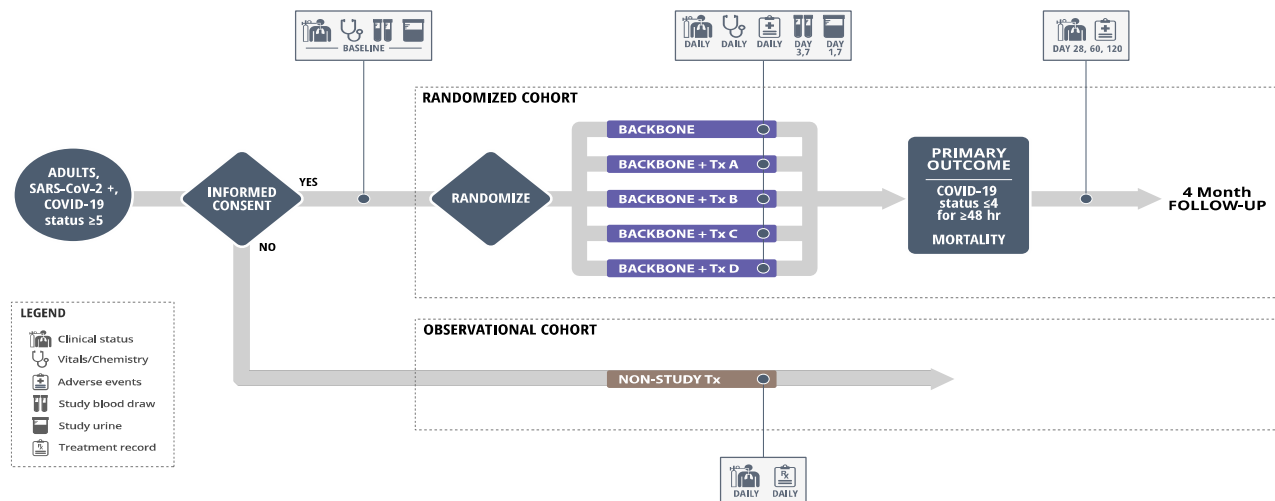
<https://www.fda.gov/science-research/advancing-regulatory-science/source-data-capture-electronic-health-records-ehrs-using-standardized-clinical-research-data>

<https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund-reports>

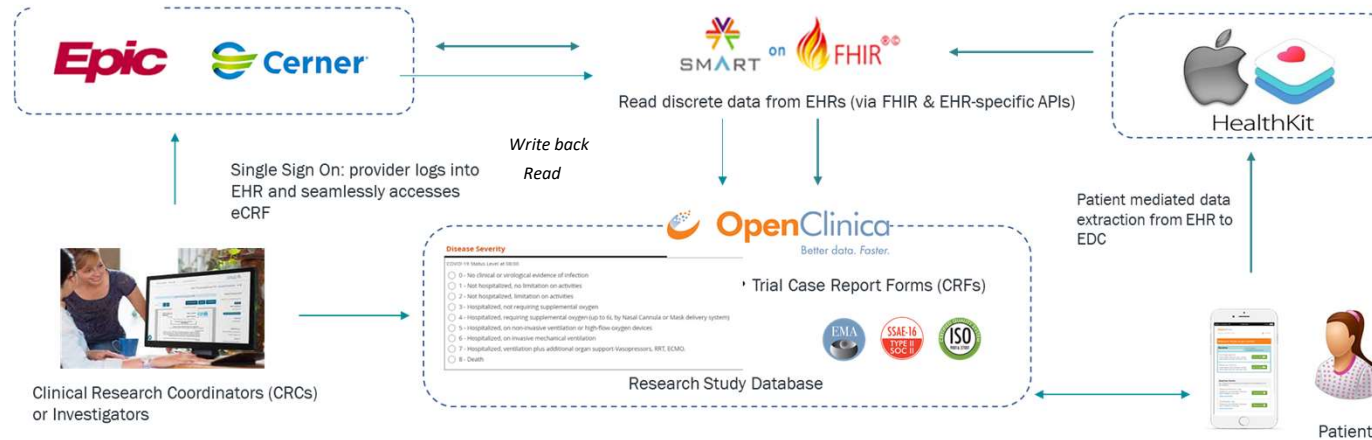
I-SPY COVID-19 Trial



- Platform Trial for Critically Ill patients with COVID-19
- Over 3,300 patients enrolled
- Patients admitted to ICU, WHO COVID-19 Scale >5

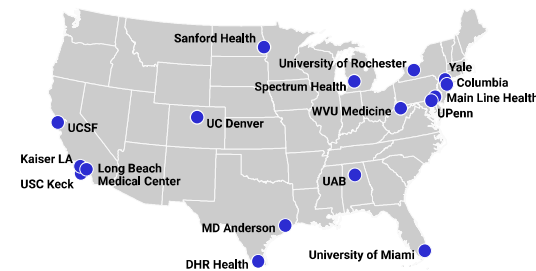


OneSource: SMART on FHIR integration with EHRs



SMART App Launch in EHR

- Authorizes a user-facing client application (“App”) to connect to a FHIR Server
- Data sharing facilitated by **FHIR Resources**
 - FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir)
 - CMS Interoperability and Patient Access final rule presented guidelines that require most public payer entities and healthcare organizations to adopt standards
- Successful implementation at 16 of 42 I-SPY COVID sites



Summary



- Structured data capture directly from the EHR for reuse in clinical trials
- Expansion of USCDI to include additional data elements currently in draft USCDI V4 specification
 - Adverse Events, Research Data
- Alignment with existing clinical research standards
 - Clinical Data Interchange Standards Consortium (CDISC)
 - FHIR Resources for clinical research (Vulcan): Adverse event clinical research IG, based on adverse event resource
- What is missing? Incentive to capture this at Point of Care (POC)



COMMON DATA MODEL HARMONIZATION (CDMH)

Common Data Model Harmonization (CDMH)



- **Common Data Model Harmonization (CDMH) Project (Phase I)**
 - Goals and Objectives
- **Common Data Model Harmonization (CDMH) Project (Phase II)**
 - Deliverables

PROJECT GOAL AND OBJECTIVES



Goal:

Build a data infrastructure for conducting patient-centered outcomes research using Real-World Data (RWD) derived from the delivery of health care in routine clinical settings.



Objective:

Develop the method to harmonize the Common Data Models of various networks, allowing researchers to simply ask research questions on much larger amounts of Real-World Data than currently possible, leveraging open standards and controlled terminologies to advance Patient-Centered Outcomes Research.

GOALS



1. Develop a common data architecture as the intermediary between various Common Data Models

Harmonize the 4 Common Data Models (CDMs) to an intermediary model

2. Build upon existing resources, standards and tools

Map to open, consensus-based standards (e.g., Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR))

GOALS (CONTINUED)



3. Validate the common data architecture through a specific **use** case that would evaluate the safety of newly approved oncology drugs
4. Establish methods and develop processes, policies and governance for ongoing curation, maintenance and sustainability of the common data architecture, building upon existing resources, standards and tools

SOLUTION USING THE ADAPTER ANALOGY

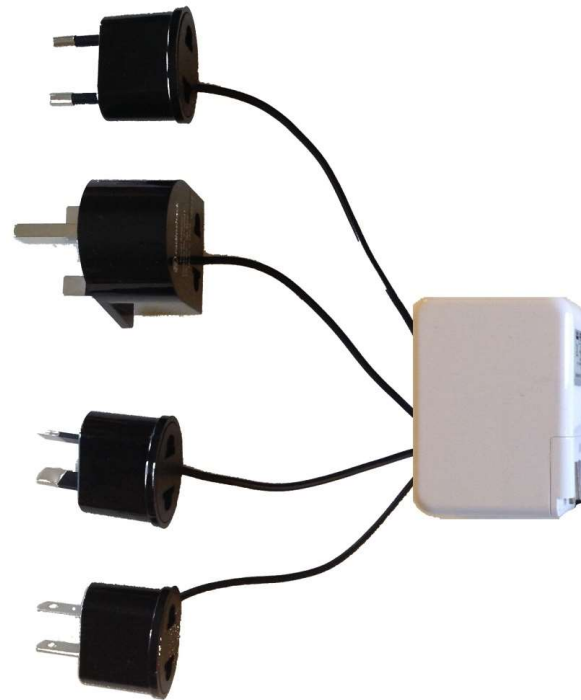


Sentinel

i2b2/ACT

PCORNET

OMOP



- Different countries use different “outlets”.
- There is a need for travel adapters.

The Solution:

- Use a converter between various adapters.
- Allow researchers to ask a question once and receive results from many different sources using a common agreed-upon standard structure, or a Common Data Model.

Phase II Deliverables



1. Collaborated with new data partners leveraging the CDMH architecture as well as direct query from Electronic Health Records and Clinical Data Repositories.
2. Enhanced the existing infrastructure to leverage Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) standard as the exchange data standard.
3. Submitted Real-World Data (RWD) leveraging clinical trial study data, leveraging Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) via the FDA Gateway.

Summary



- Developed an infrastructure to harmonize several CDMs
- Mapped CDMs to open, consensus-based standards
- Registered the Common Data Elements (CDEs) within caDSR for public use producing significant tools
- Developed the HL7 FHIR IG for CDMH data elements
- Developed the architecture to query and executed it by the data partners participating in the CDMH project.
- Enhanced the CDMH architecture for phase II.
- Leveraged the CDMH architecture in two COVID-19 initiatives.



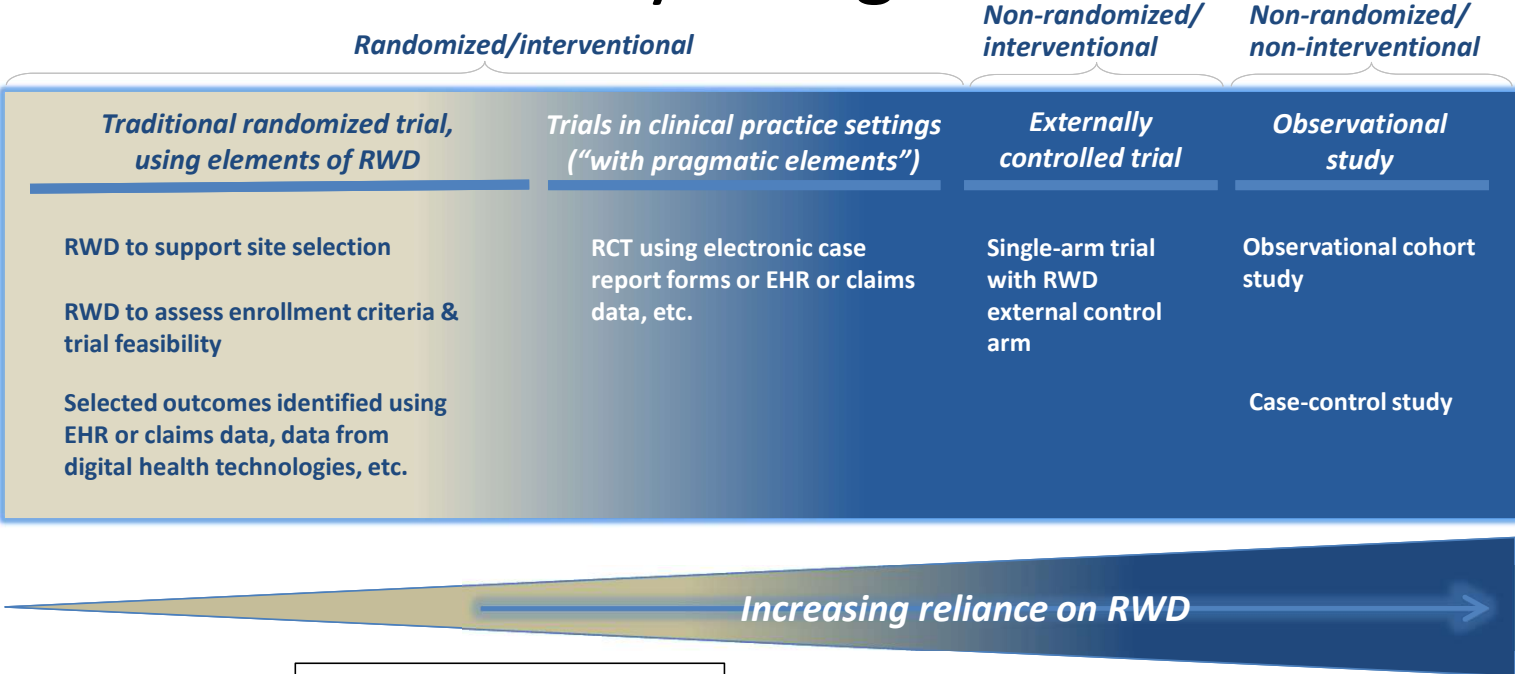
THANK YOU



BACK UP



Overview of Real-World Data and Study Design



Office of Med Policy Aug 2021

Seamless interoperability within EHR systems



- OneSource user interface launched directly from the EHR using the “OneSource” tab.
- Automate extraction of laboratory results and concomitant medications by CRCs.
- Investigators have additional decision support displays that summarize the patient summary and the daily summary
- 50% reduction in data entry times and improved data quality

The screenshot displays the OneSource user interface within an EHR system. The interface is divided into several sections:

- Header:** Shows the study name "OPENCLINICA FOUR", patient demographics (DOB: 04/02/1976, Sex: Male), and clinical information (Age: 47 years, Adverse Direction: Available, Clinical Inst./Not Data Available: Available).
- Left Sidebar:** Contains navigation options such as "Provider View", "Results Review", "Orders", "Documentation", "Concomitants", "Allergies", "Clinical Media", "Diagnoses and Problems", "Team Overview", "Growth Chart", "History", "Interactive View and IBC", "MMS Summary", "Medication List", "Patient Information", "Recommendations", "Open Clinics", and "SMART APP VALIDATOR".
- Main Content Area:**
 - Visits:** Shows "Study Drug Administration" and "As Needed".
 - Adverse Events:** A section for reporting adverse events.
 - Labs from EHR:** A table showing lab results extracted from the EHR. The table has columns for "Actions", "Study Day", and "Effective Date of Lab (UTC-00)".

Actions	Study Day	Effective Date of Lab (UTC-00)
	Day 014	2022-03-15 03:52 PM
	Day 014	2022-03-15 03:52 PM
	Day 014	2022-03-15 03:52 PM
	Day 014	2022-03-15 03:51 PM
 - Meds from EHR:** A section for reporting medications extracted from the EHR.
 - General Information:** A table with columns for "Participant ID", "Status", "Availability", "First Name", and "Last Name".
 - Patient Info:** Displays patient details for Participant ID 770007, including Age (71 years old), Sex (Male), Race (Not Reported), Ethnicity (Hispanic), and First date of COVID-19 Related Symptoms (2021-04-29).
 - Daily Summary for March 2, 2022:** A summary of the patient's status on that date, including COVID-19 status (Hospitalized, on non-invasive ventilation or high-flow oxygen devices) and COVID-19 symptoms (History of fever, Headache).
 - COVID Scale by Lab Value:** A line graph showing the COVID-19 scale by lab value over time. The y-axis represents the COVID-19 scale (0 to 5), and the x-axis represents time (03/01/2022 to 03/05/2022). The graph shows a red line for "WHO COVID Scale" and a blue line for "Creative".
 - Disease Severity:** A section for reporting disease severity, including COVID-19 disease severity and COVID-19 related symptoms.



7. Implementation Insights / Showcase

Jessica Jeffries, IgniteData

Mitra Rocca, FDA (remote)

Peter Casteleyn, J&J

Martin Ingvar, Karolinska Institutet

13:20 – 14:40





Exchange of clinical trial data

from a site's electronic health record (EHR) to sponsor

Peter Casteleyn

Director Data Collection Solutions - EHR

14 March 2023

Disclaimer

This presentation is for informational purposes only and does not represent professional guidance or advice. Any views and opinions expressed during this presentation are those of the presenters and do not necessarily reflect the views or policies of Janssen Research & Development, LLC, or any other company in the Johnson & Johnson Family of Companies.

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Agenda



The opportunity



Janssen's approach

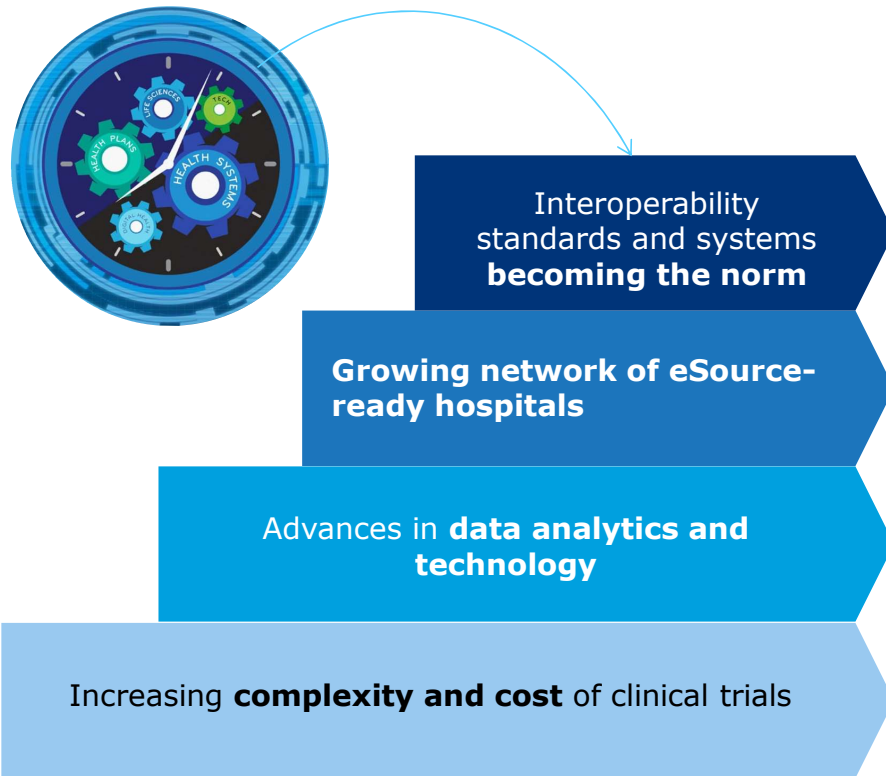


Learnings



Relying on FHIR

Current industry trends & the opportunity



Structured electronic data capture in clinical trials requires today a **very high manual effort**, whilst the clinical source data is most often the EHR. This introduces **significant costs in terms of data processing and cleaning**.

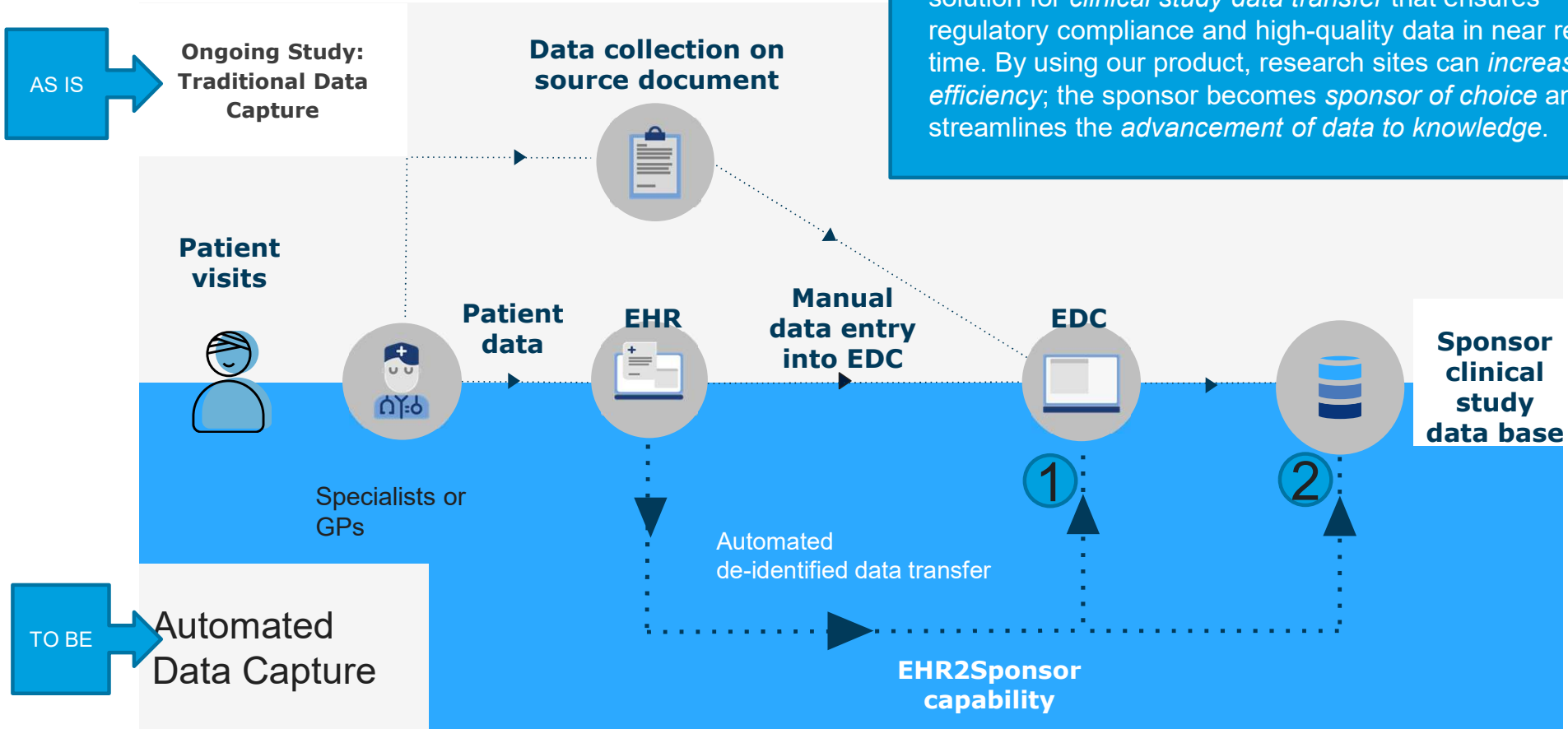
Up to **+70% of data is duplicated** between an institution's EHR and clinical trial systems.

Data verification, management and monitoring represent **25-40% of trial costs**.

70% of research sites say **staffing** is their **most prevalent challenge**.

EHR2Sponsor Objective

Vision: provide a streamlined, *scalable, automated* solution for *clinical study data transfer* that ensures regulatory compliance and high-quality data in near real-time. By using our product, research sites can *increase efficiency*; the sponsor becomes *sponsor of choice* and streamlines the *advancement of data to knowledge*.





Janssen's approach

- 1 Conducted market scan and solicited vendor interest via RFI / RFP
- 2 Selected vendors based upon specific criteria
- 3 Solicited feedback and interest from +70 sites across Europe and US
- 4 Developed wiki on data standards and introduced concept of FHIR specified eCRF
- 5 Conducted Conference Room Pilots gaining insight on technology feasibility and process impact (including site perspective)
- Next Pioneer with specific sites



What We've Learned so Far

Automating the transfer of clinical study data in a scalable way is **still in an early adoption**. There is an opportunity to shape it.

Site and sponsor readiness **implies more than technical readiness**. It involves process changes and increased reliance on standards (internal and external).

Working with **sites allows gaining their perspective and provides insights** for a possible scalable approach.

Different solutions offer different approaches to transfer data automatically. There is a need to **balance the pros and cons** of each way of working.

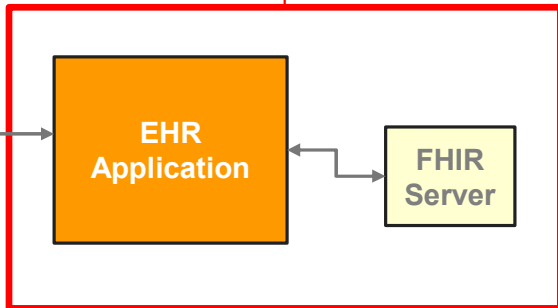
Bypassing the EDC to collect at scale is **a long-term opportunity**. Making this viable involves addressing the dependencies internally and increased eSource adoption externally.

FHIR enabling efficiency in mapping setup

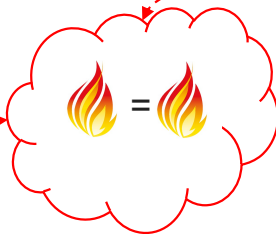


2-Pronged Approach

What study data can be obtained from the EHR?

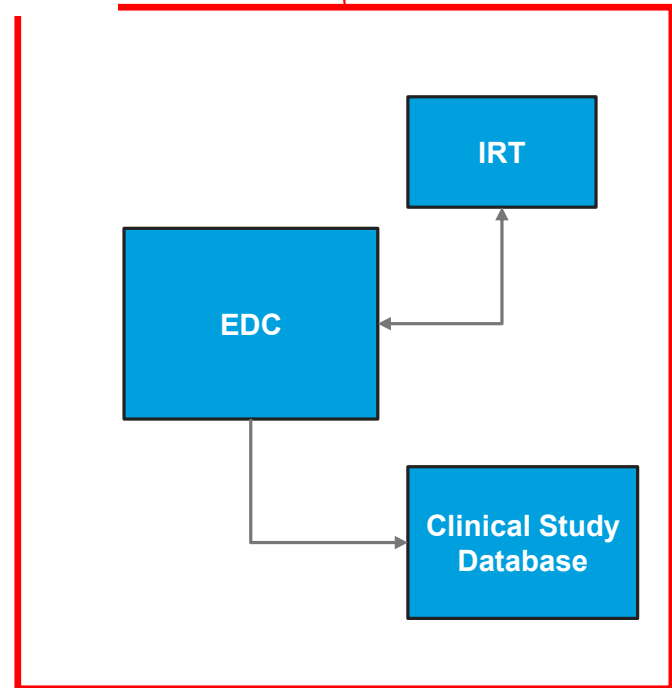


"Available FHIR"



"Requested FHIR"

What data does the study require?





'Outgoing FHIR' – Study described in FHIR

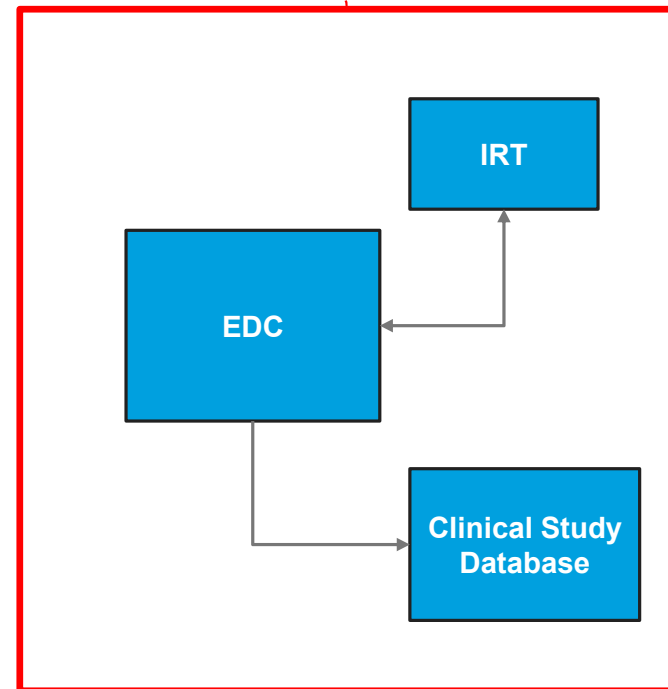


External / Industry Initiatives

- Common approaches and methods
HL7 Vulcan Projects – SoA, Adverse Event...

Internal / Study Focused

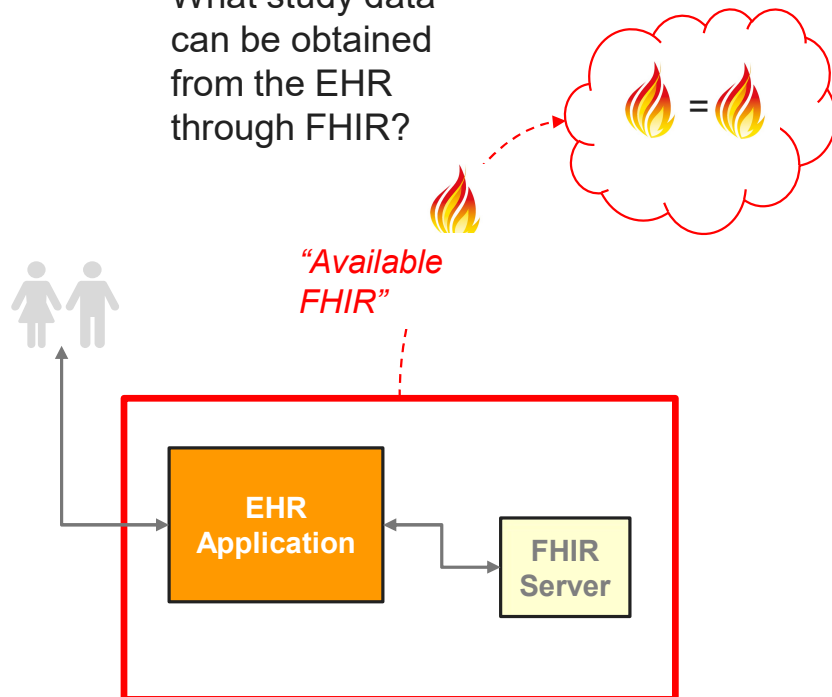
- Support mapping:
FHIR-specified eCRF as part of our Global Standard eCRF Library
- Support testing:
Extend FHIR-specified eCRF resources with synthetic study subject data





'Incoming FHIR' – What is available?

What study data can be obtained from the EHR through FHIR?



- What Resources are exposed by the EHR API?
- What study data is available?
- Are the EHR / site coding systems and practice compatible with study expectations?
- Allows to compare, contrast and develop necessary mappings and/or conversions

Thank you



Contact:

Peter Casteleyn

pcastel1@its.jnj.com

janssen 

PHARMACEUTICAL COMPANIES OF

Johnson & Johnson

Acronyms

API: Application Programming Interface

eCRF: electronic Case Report Form

EHR: Electronic Health Record

EHR2Sponsor: name of the Janssen program to transfer clinical data from EHR to us

EDC: Electronic Data Capture

FHIR: Fast Healthcare Interoperability Resources – HL7 standard

IRT: Interactive Response System

RFI: Request for Information

RFP: Request for Proposal

SoA: Schedule of Activities



7. Implementation Insights / Showcase

Jessica Jeffries, IgniteData

Mitra Rocca, FDA (remote)

Peter Casteleyn, J&J

Martin Ingvar, Karolinska Institutet

13:20 – 14:40



Swedish Scenario in Gravitate Health

Martin Ingvar
May 26, 2022

Note: These slides have been removed from the official EuroVulcan presentations

For any inquiries, please send an email to Vulcan@hl7.org



DISCLAIMER: The presentation reflects the authors view. IMI JU, European Union, EFPIA, or Datapharm Limited are not liable for any use that may be made of the information contained herein.

Networking Break

14:40 – 15:00





8. Vulcan Implementation Guide Overview

Hugh Glover, Vulcan

15:00 – 15:20



Current Vulcan Implementation Guides

The screenshot shows the 'Clinical Study Schedule of Activities' implementation guide. The page includes a navigation menu with 'Home', 'Core Model', 'Use Cases', 'Profiles', 'Examples', 'Downloads', and 'Credits'. A 'Table of Contents' section is visible, along with a 'Home' section containing metadata like 'Official URL' and 'Version: 1.0.0-ballot'. The main content area is titled '1 Background' and '1.1 Vulcan Schedule of Activities (SoA) Project', describing the project's purpose and goals.

Schedule of Activities

Search:
Vulcan-schedule-ig

The screenshot displays the 'Electronic Medicinal Product Information (ePI) FHIR Implementation Guide'. It features a navigation menu with 'Table of Contents', 'Introduction', 'Background', 'The Specification', 'Capability', 'Artifact Index', and 'Appendices'. A 'Downloads' section is present. The main content area includes an 'Introduction' section with metadata and a '1.1 Purpose' section. A sidebar on the right lists 'Purpose', 'Goals', 'Objectives', 'Scope', 'How to use this guide', 'Status', 'Governance', and 'Authors and Contributors'.

Electronic Product Information

Search:
emedicinal-product-info

The screenshot shows the 'Retrieval of Real World Data for Clinical Research' implementation guide. It has a navigation menu with 'TOC', 'Home', 'Cohort Building', 'Finding Data', 'Use Cases', 'Considerations', 'Artifacts', and 'Appendices'. A 'Table of Contents' section is visible, followed by a 'Home' section with metadata. The main content area is titled '1 Overview' and '1.1 Overview', discussing the context of clinical research and the 'real world' of everyday experiences. A sidebar on the right lists 'Overview', 'Current Scope', 'Approach', and 'Technical Considerations'.

Real World Data

Search:
Vulcan-rwd

Sections of an Implementation Guide

HL7 International VULCAN HL7 FHIR Clinical Study Schedule of Activities 1.0.0-ballot - ballot

Home Core Model Use Cases Profiles Examples Downloads Credits

HL7 International Electronic Medicinal Product Information (ePI) FHIR Implementation Guide 1.0.0-ballot - STU Ballot

Table of Contents Introduction Background The Specification Capability Artifact Index Appendices Downloads

HL7 International VULCAN HL7 FHIR Retrieval of Real World Data for Clinical Research

TOC Home Cohort Building Finding Data Use Cases Considerations Artifacts Appendices

Discussion

Artifacts

Credits
References
Downloads



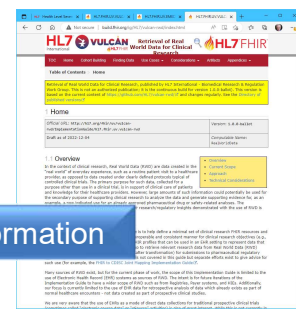
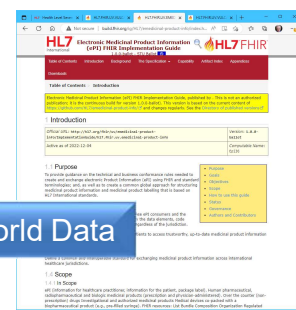
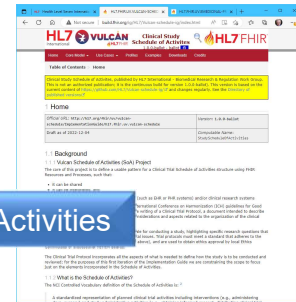
Schedule of Activities



Real World Data



Electronic Product Information



Discussion

Discussion

Artifacts

Credits
References
Downloads

- States the problem
- Lays out the solution

2 Background

2.1 ePI

A medicine's product information is a pivotal source of regulated and scientifically validated information that assists healthcare professionals in prescribing and dispensing the medicine and informs consumers about its safe and effective use.

ePI is presented in three forms:

1. Information for healthcare professionals
2. Information for patients
3. Information on the package label

ePI goes by different names depending on the region of the world. For example,

- USA - Prescription Drug Label or Package Insert (USPI)
- Europe - Summary of Product Characteristics (SmPC) or Package Leaflet
- Japan - Package Insert (JPI)

Since these documents are often represented as a PDF, they are unstructured electronic paper. As a result, they are difficult to search, and the content does not meet patient needs (e.g., larger fonts, accessibility support, multimedia, multiple languages).

- ePI
- Gravitare Health
- HL7 Vulcan Accelerator
- HL7 Biomedical Research and Regulation (BR&R)
- Conformance and Validation

5 Steps to create a Core FHIR ePI [↗](#)

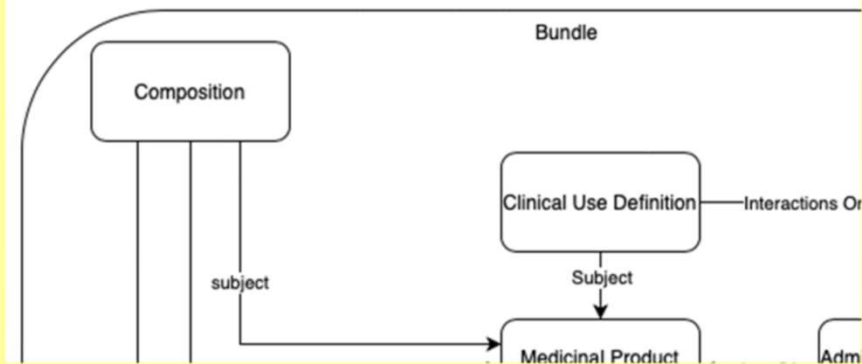
NOTE:

- This model is meant as a demonstration. Refer to national or regional guidance for local rules about what resources are in or out of scope.

5.1 Step 1: Create foundation resources

Create the Core ePI document by completing and then bundling these FHIR resources in the order described below.

- Step 1: Create foundation resources
- Step 2: Create Bundle
- Step 3: Create List (of ePIs)



Artifacts

Discussion

Artifacts

Credits
References
Downloads

Artifacts are the technical specification

- Search Parameters
- Profiles
- Extensions
- Terminology
- Examples



12 Artifacts Summary

12.0.2 Structures: Resource Profiles [↗](#)

These define constraints on FHIR resources for systems conforming to this implementation guide.

ConditionRwd	A profile on Condition that indicates the minimum set of attributes for use in research studies.
EncounterRwd	A profile on Encounter that indicates the minimum set of attributes required for finding patients who were hospitalization.
MedicationAdministrationRwd	A profile on MedicationAdministration that indicates the minimum set of attributes required for finding patients who may be taking certain medications.
MedicationDispenseRwd	A profile on MedicationDispense that indicates the minimum set of attributes required for finding patients who may be taking certain medications.
MedicationRequestRwd	A profile on MedicationRequest that indicates the minimum set of attributes required for finding patients who may be taking certain medications.
MedicationStatementRwd	A profile on MedicationStatement that indicates the minimum set of attributes for use in research studies.
ObservationLaboratoryResultsRwd	A profile on Observation that indicates the



What is a Profile?

Taking a FHIR resource and constraining how it is used ...

For example there is a general FHIR resource for Consent, if we wanted to profile this to specifically apply to *Consent to take part in a study* we might make the following sorts of changes

this is just for illustration:

Tighter definition: *Consent becomes StudyConsent*

Tighter cardinalities: *Subject of the consent was 0..1 now becomes 1..1*

Limit on references: *Subject is constrained to only apply to a Patient*

Implementation requirements: *Subject is marked as “Must Support”*

The terminology associated with `Category` is just an Example Binding in the base resource and is now *bound to a specific terminology*

Reading FHIR Resource Definitions

11.4.3 Resource Content

Name	Flags	Card.	Type	Description & Constraints
MedicationStatement	TU		DomainResource	Record of medication being taken by a patient Elements defined in Ancestors: id, meta, implicitRules, language, modifierExtension
identifier	Σ	0..*	Identifier	External identifier
medication[x]	Σ	1..1		What medication was taken SNOMED CT Medication Codes (Example)
medicationCodeableConcept			CodeableConcept	
medicationReference			Reference(Medication)	
subject	Σ	1..1	Reference(Patient Group)	Who is/was taking the medication
context	Σ	0..1	Reference(Encounter EpisodeOfCare)	Encounter / Episode associated with MedicationStatement

Data item

Cardinality

Data type

Definition

Reading the Profile

Profile from RWD

Original 

12.9.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

Differential Table | Key Elements Table | Snapshot Table | Statistics/Reference

All

This structure is derived from **MedicationStatementIPS**

Name	Flags	Card.	Type	Description & Constraints
MedicationStatement		0..*	MedicationStatementIPS	Record of medication being taken by a patient
context	S	0..1	Reference(Encounter EpisodeOfCare)	Encounter / Episode associated with MedicationStatement
Slices for derivedFrom	S	1..*	Reference(Resource)	Additional supporting information Slice: Unordered, Open by type:\$this
derivedFrom: medicationSource		1..*	Reference(MedicationRequestRwd MedicationDispenseRwd MedicationAdministrationRwd)	Additional supporting information

11.4.3 Resource Content

Structure | UML | XML | JSON | Turtle | R3 Diff | All

Structure

Name	Flags	Card.	Type	Description & Constraints
MedicationStatement	TU		DomainResource	Record of medication taken by a patient
context		Σ 0..1	Reference(Encounter EpisodeOfCare)	Encounter / Episode associated with MedicationStatement
derivedFrom		0..*	Reference(Any)	Additional supporting information
reasonCode		0..*	CodeableConcept	Reason for why

Derivation of the profile

Modified attributes

Reading the Profile

Profile from RWD

Original 

12.9.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work

Differential Table | Key Elements Table | Snapshot Table | Statistics/Reference

All

This structure is derived from [MedicationStatementIPS](#)

Name	Flags	Card.	Type	Description & Constraints
MedicationStatement		0..*	MedicationStatementIPS	Record of medication being taken by a patient
context	S	0..1	Reference(Encounter EpisodeOfCare)	Encounter / Episode associated with MedicationStatement
Slices for derivedFrom	S	1..*	Reference(Resource)	Additional supporting information Slice: Unordered, Open by type:\$this
derivedFrom:MedicationSource		1..*	Reference(MedicationRequestRwd MedicationDispenseRwd MedicationAdministrationRwd)	Additional supporting information

11.4.3 Resource Content

Structure | UML | XML | JSON | Turtle | R3 Diff | All

Structure

Name	Flags	Card.	Type	Description &
MedicationStatement	TU		DomainResource	Record of medication taken by a patient
context		Σ 0..1	Reference(Encounter EpisodeOfCare)	Encounter / Episode associated with MedicationStatement
derivedFrom		0..*	Reference(Any)	Additional supporting information
reasonCode		0..*	CodeableConcept	Reason for why

derivedFrom attribute is now mandatory

derivedFrom attribute can only be one of 3 possible types rather than Any

Artifacts

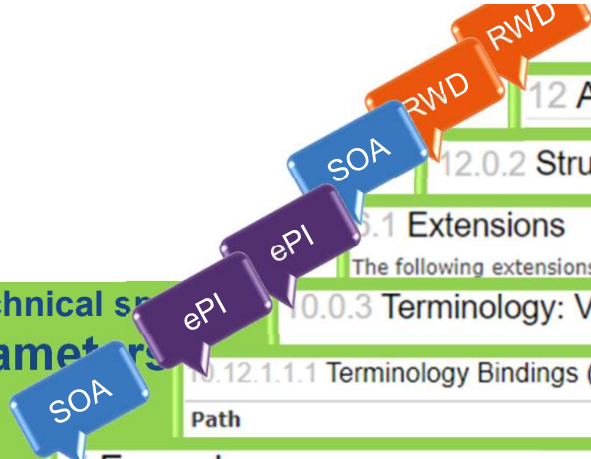
Discussion

Artifacts

Credits
References
Downloads

Artifacts are the technical specifications for:

- Search Parameters
- Profiles
- Extensions
- Terminology
- Examples



12 Artifacts Summary

12.0.2 Structures: Resource Profiles

12.0.1 Extensions

The following extensions are defined to enable data elements that are not

12.0.3 Terminology: Value Sets

12.12.1.1.1 Terminology Bindings (Differential)

Path	Conformance	ValueSet
Examples		VsMedProductIdSystems
		VsMedProductType (a valid code from https://spor.ema.europa.eu/rmswi/2006)
		MedicinalProductDomain
		PublicationStatus
		VsPharmaceuticalDoseForm (a valid code from https://spor.ema.europa.eu/rmswi/2006)
		VsRouteOfAdministration (a valid code from https://spor.ema.europa.eu/rmswi/1006)
		VsLegalStatusOfSupply (a valid code from https://spor.ema.europa.eu/rmswi/1006)
		VsAdditionalMonitoringIndicator (a valid http://example.org)

7.1 H2Q-MC-LZZT Research Study

H2Q-MC-LZZT was a study to evaluate the Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease. It was carried out by [Eli-Lilly and Company](#). It is a commonly used sample study that features regularly in Clinical Research data modelling exercises so is advantageous for providing realistic anonymised datasets.

- H2Q-MC-LZZT Research Study
- H2Q-MC-LZZT Study Plan

7.1.1 Example Resources

- [ResearchStudySoa/H2Q-MC-LZZT-ResearchStudy](#)
- [Organization/EliLillyAndCompany](#)

	MedicationStatement that indicates the minimum set of attributes for use in research studies.
ObservationLaboratoryResultsRwd	A profile on Observation that indicates the



Artifacts

Discussion

Artifacts

Credits
References
Downloads

- Credits
- References
- Downloads gives resource definitions for use with the Validator



Questions?



9. Vulcan Electronic Product Information (ePI)

Giorgio Cangioli, HI7 Europe + Craig Anderson, Pfizer (remote)

Sonja Steiner, Acodis + Patrick Bürkle, Acodis

Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20





9. Vulcan Electronic Product Information (ePI)

Giorgio Cangioli, HI7 Europe + Craig Anderson, Pfizer (remote)

Sonja Steiner, Acodis + Patrick Bürkle, Acodis

Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20





ePI Implementation Guide Overview & Relationship with Gravitare Health

Presented by: Giorgio Cangioli & Craig Anderson





Agenda



Electronic Product Information (ePI) project overview



ePI Implementation Guide overview



Relationship with Gravitare Health



Timeline, Collaborations and Next Steps

01

Electronic Product Information (ePI) Project Overview

The ePI Project: a collaborative effort



The UNICOM project is helping to ensure that any medicine and what it contains can be accurately identified anywhere in the world. We are working to improve patient safety and enable better healthcare for all.

Vulcan 101: Bringing FHIR to Clinical Research

Date: April 20, 2022
Presented by: Giorgio Cangili and Craig Anderson

Webinars

HL7 International Electronic Medicinal Product Information (ePI) FHIR Implementation Guide
1.0.0-ballot - CI Build

Table of Contents Introduction Background The Specification ▾ Capability Artifact Index Appendices Downloads

Table of Contents Introduction

Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by HL7 International. This is not an authorized publication; it is the continuous build for version 1.0.0-ballot. This version is based on the current content of <https://github.com/HL7/emedical-product-info> and changes regularly. See the Directory of published versions.

1 Introduction

Official URL: https://hl7.org/fhir/uv/emedical-product-info/ImplementationGuide/hl7.fhir.uv.emedical-product-info	Version: 1.0.0-ballot
Active as of 2023-02-23	Computable Name: EpiIG

1.1 Purpose
To provide guidance on the technical and business conformance rules needed to create and exchange electronic Product Information (ePI) using FHIR and standard terminologies; and, as well as to create a common global approach for structuring medicinal product information and medicinal product labelling that is based on HL7 International standards.

1.2 Goals
The immediate goal of this specification is to expose ePI consumers and the vendor community to a set of profiles that identify the data elements, code systems and value sets commonly used in ePIs regardless of the jurisdiction.
The strategic goal is to offer a better route for patients to access trustworthy, up-to-date medicinal product information that better meets their individual needs.

1.3 Objectives
Define a common and interoperable standard for exchanging medicinal product information across international healthcare jurisdictions.

1.4 Scope
1.4.1 In Scope
ePI (information for healthcare practitioner, information for the patient, package label), Human pharmaceutical, radiopharmaceutical and biologic medicinal products (prescription and physician-administered), Over the counter (non-prescription) drugs Investigational and authorized medicinal products Medical devices co-packed with a biopharmaceutical

- Purpose
- Goals
- Objectives
- Scope
- How to use this guide
- Status
- Governance
- Authors and Contributors

HL7 FHIR Implementation Guide



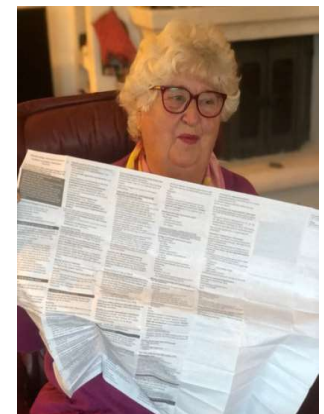


What is an electronic Product Information (ePI)

- **Regulated and scientifically validated information about medicinal products.**
- **Informs healthcare professionals and consumers about safe use. Often presented in three forms:**
 - Information for health professionals
 - Information for patients
 - Information for the package label
- **Different names depending on the region/country:**
 - EMA/EU = Summary of product characteristics (SmPC), Package Leaflet
 - FDA/USA = Drug Product Label, Patient Package Insert



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO

Why the ePI HL7 FHIR Implementation Guide



Global standardized electronic format for ePI



Ready to be adapted and used by different jurisdictions and/or initiatives

Gravitate Health

The screenshot shows the Gravitate Health FHIR Implementation Guide website. It features a navigation menu with options like 'Table of Contents', 'Introduction', 'Background', 'The Specification', 'Capability', 'Artifed Index', 'Appendices', and 'Downloads'. A yellow highlight is present on the 'Introduction' section. The main content area includes an 'Introduction' section with a yellow highlight on the first paragraph, which states: 'Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by... This is not an authorized publication; it is the continuous build for version 1.0.0-ballet. This version is based on the current content of https://github.com/HL7/emedicinal-product-info (2 and changes regularly. See the Directory of published versions (2'.

The screenshot shows the HL7 FHIR Implementation Guide website. It features a navigation menu with options like 'Table of Contents', 'Introduction', 'Background', 'The Specification', 'Capability', 'Artifed Index', 'Appendices', and 'Downloads'. A yellow highlight is present on the 'Introduction' section. The main content area includes an 'Introduction' section with a yellow highlight on the first paragraph, which states: 'Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by... This is not an authorized publication; it is the continuous build for version 1.0.0-ballet. This version is based on the current content of https://github.com/HL7/emedicinal-product-info (2 and changes regularly. See the Directory of published versions (2'.

FDA

EMA

8.47.1 Example Bundle: Vulcan FHIR Japanese Package Insert Test - Aromasin (exemestane) Tablets 25 mg

8.47.2 禁忌(次の患者には投与しないこと)

2.1 妊娠又は妊娠している可能性のある女性(3.8参照) 2.2 授乳中(3.8参照) 2.3 本剤の成分に対し過敏症の既往歴のある患者

8.47.3.3 組成・性状

3.1 組成 3.2 製剤の性状

8.47.4 4. 効能又は効果

剤形・包装

8.47.5 6. 用法及び用量

通常、成人にはエキセメスタンとして1日1回50mgを食後に経口投与する。

8.47.6 8. 重要な基本的注意

8.1 本剤はホルモン療法剤であり、がんに対する薬物療法において十分な知識・経験を持つ医師のもとで、本剤による治療の適切と判断される患者についてのみ使用すること。8.2 本剤は黄体アロケータゼを阻害することにより治療効果を発揮するものであり、両剤が対照薬を有する閉経前の患者ではアロケータゼを阻害する効果は不十分であると予想されること、並びに閉経前の患者では使用経験がないことを考慮して、閉経前患者に対し使用しないこと。8.3 本剤の投与によって、骨粗鬆症、骨折のリスクが増加すること、骨髄抑制(骨髄減少症)の発症が観察されることがあり、必要に応じて適切な観察(全血算、尿検査)を行うこと。8.4 本剤は乳がんの治療に使用される。8.5 本剤は乳がんの治療に使用される。8.6 本剤は乳がんの治療に使用される。8.7 本剤は乳がんの治療に使用される。8.8 本剤は乳がんの治療に使用される。8.9 本剤は乳がんの治療に使用される。8.10 本剤は乳がんの治療に使用される。8.11 本剤は乳がんの治療に使用される。8.12 本剤は乳がんの治療に使用される。8.13 本剤は乳がんの治療に使用される。8.14 本剤は乳がんの治療に使用される。8.15 本剤は乳がんの治療に使用される。8.16 本剤は乳がんの治療に使用される。8.17 本剤は乳がんの治療に使用される。8.18 本剤は乳がんの治療に使用される。8.19 本剤は乳がんの治療に使用される。8.20 本剤は乳がんの治療に使用される。8.21 本剤は乳がんの治療に使用される。8.22 本剤は乳がんの治療に使用される。8.23 本剤は乳がんの治療に使用される。8.24 本剤は乳がんの治療に使用される。8.25 本剤は乳がんの治療に使用される。8.26 本剤は乳がんの治療に使用される。8.27 本剤は乳がんの治療に使用される。8.28 本剤は乳がんの治療に使用される。8.29 本剤は乳がんの治療に使用される。8.30 本剤は乳がんの治療に使用される。8.31 本剤は乳がんの治療に使用される。8.32 本剤は乳がんの治療に使用される。8.33 本剤は乳がんの治療に使用される。8.34 本剤は乳がんの治療に使用される。8.35 本剤は乳がんの治療に使用される。8.36 本剤は乳がんの治療に使用される。8.37 本剤は乳がんの治療に使用される。8.38 本剤は乳がんの治療に使用される。8.39 本剤は乳がんの治療に使用される。8.40 本剤は乳がんの治療に使用される。8.41 本剤は乳がんの治療に使用される。8.42 本剤は乳がんの治療に使用される。8.43 本剤は乳がんの治療に使用される。8.44 本剤は乳がんの治療に使用される。8.45 本剤は乳がんの治療に使用される。8.46 本剤は乳がんの治療に使用される。8.47 本剤は乳がんの治療に使用される。8.48 本剤は乳がんの治療に使用される。8.49 本剤は乳がんの治療に使用される。8.50 本剤は乳がんの治療に使用される。8.51 本剤は乳がんの治療に使用される。8.52 本剤は乳がんの治療に使用される。8.53 本剤は乳がんの治療に使用される。8.54 本剤は乳がんの治療に使用される。8.55 本剤は乳がんの治療に使用される。8.56 本剤は乳がんの治療に使用される。8.57 本剤は乳がんの治療に使用される。8.58 本剤は乳がんの治療に使用される。8.59 本剤は乳がんの治療に使用される。8.60 本剤は乳がんの治療に使用される。8.61 本剤は乳がんの治療に使用される。8.62 本剤は乳がんの治療に使用される。8.63 本剤は乳がんの治療に使用される。8.64 本剤は乳がんの治療に使用される。8.65 本剤は乳がんの治療に使用される。8.66 本剤は乳がんの治療に使用される。8.67 本剤は乳がんの治療に使用される。8.68 本剤は乳がんの治療に使用される。8.69 本剤は乳がんの治療に使用される。8.70 本剤は乳がんの治療に使用される。8.71 本剤は乳がんの治療に使用される。8.72 本剤は乳がんの治療に使用される。8.73 本剤は乳がんの治療に使用される。8.74 本剤は乳がんの治療に使用される。8.75 本剤は乳がんの治療に使用される。8.76 本剤は乳がんの治療に使用される。8.77 本剤は乳がんの治療に使用される。8.78 本剤は乳がんの治療に使用される。8.79 本剤は乳がんの治療に使用される。8.80 本剤は乳がんの治療に使用される。8.81 本剤は乳がんの治療に使用される。8.82 本剤は乳がんの治療に使用される。8.83 本剤は乳がんの治療に使用される。8.84 本剤は乳がんの治療に使用される。8.85 本剤は乳がんの治療に使用される。8.86 本剤は乳がんの治療に使用される。8.87 本剤は乳がんの治療に使用される。8.88 本剤は乳がんの治療に使用される。8.89 本剤は乳がんの治療に使用される。8.90 本剤は乳がんの治療に使用される。8.91 本剤は乳がんの治療に使用される。8.92 本剤は乳がんの治療に使用される。8.93 本剤は乳がんの治療に使用される。8.94 本剤は乳がんの治療に使用される。8.95 本剤は乳がんの治療に使用される。8.96 本剤は乳がんの治療に使用される。8.97 本剤は乳がんの治療に使用される。8.98 本剤は乳がんの治療に使用される。8.99 本剤は乳がんの治療に使用される。9.00 本剤は乳がんの治療に使用される。

Define rules for using HL7 FHIR for describing ePI

<https://build.fhir.org/ig/HL7/emedicinal-product-info>



https://build.fhir.org/ig/HL7/emedicinal-product-info

HL7 International Electronic Medicinal Product Information (ePI) FHIR Implementation Guide 1.0.0-ballot - CI Build

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Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by HL7 International. This is not an authorized publication; it is the continuous build for version 1.0.0-ballot. This version is based on the current content of <https://github.com/HL7/emedicinal-product-info> and changes regularly. See the [Directory of published versions](#)?

1 Introduction

Official URL: <http://hl7.org/fhir/uv/emedicinal-product-info/ImplementationGuide/hl7.fhir.uv.emedicinal-product-info> Version: 1.0.0-ballot
Active as of 2023-02-23 Computable Name: EpiIG

1.1 Purpose
To provide guidance on the technical and business conformance rules for the use of Electronic Product Information (ePI) using FHIR and standard terminologies; and, as well as the use of medicinal product information and medicinal product labeling that is consistent with the standards defined in the FHIR specification.

1.2 Goals
The immediate goal of this specification is to expose ePI consumers to the data elements, code systems and value sets commonly used in the exchange of medicinal product information and medicinal product labeling that is consistent with the standards defined in the FHIR specification.

The strategic goal is to offer a better route for patients to access trust better meets their individual needs.

1.3 Objectives
Define a common and interoperable standard for exchanging medicinal product information and medicinal product labeling that is consistent with the standards defined in the FHIR specification.

1.4 Scope
1.4.1 In Scope
ePI (information for healthcare practitioner, information for the patient and physician-administered). Over the counter (non-prescription) drugs.

10.0.2 Structures: Resource Profiles
These define constraints on FHIR resources for systems conforming to this implementation guide.

AdministrableProductDefinition (ePI)	AdministrableProductDefinition (ePI)
Bundle - ePI	Medicinal product information is a pivotal source of regul prescribing and dispensing the medicine and informs con to the Bundle resource used in the Electronic Product Inf
ClinicalUseDefinition Contraindication (ePI)	ClinicalUseDefinition Contraindication (ePI)
ClinicalUseDefinition Indication (ePI)	ClinicalUseDefinition Indication (ePI)
ClinicalUseDefinition Interaction (ePI)	ClinicalUseDefinition Interaction (ePI)
ClinicalUseDefinition Undesirable Effect (ePI)	ClinicalUseDefinition Undesirable Effect (ePI)
ClinicalUseDefinition Warning (ePI)	ClinicalUseDefinition Warning (ePI)
Composition (ePI)	The Composition captures the section headings, sub-sect ePI.
Ingredient (ePI)	Ingredient (ePI)
ManufacturedItemDefinition (ePI)	ManufacturedItemDefinition (ePI)
MedicinalProductDefinition (ePI)	Description of the packaged authorized medicinal produc
Organization (ePI)	Organization (ePI)
PackagedProductDefinition (ePI)	PackagedProductDefinition (ePI)
RegulatedAuthorization (ePI)	RegulatedAuthorization (ePI)
SubstanceDefinition (ePI)	SubstanceDefinition (ePI)

Name	Flags	Card.	Type	Description & Constraints
Bundle	C	0..*	Bundle	Electronic Product Information Bundle Document bd1-epi-1: An ePI document must have no additional Composition (including Composition subclass) resources besides the first. Persistent identifier for the bundle
identifier		1..1	Identifier	document message transaction transaction-response batch batch-response history searchset collection subscription-notification Fixed Value: document Persistent original date of approval
type		1..1	code	
timestamp		1..1	Instant	
link		0..0		
Slices for entry		1..*	BackboneElement	Entry resource in the ePI bundle Slice: Unordered, Open by type:\$this.resource Content/Rules for all slices
entry:All Slices				
entry:resource		1..1	Resource	A resource in the bundle
entry:search		0..0		
entry:request		0..0		
entry:response		0..0		
entry:composition		1..1	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	CompositionUvEpi	A set of resources composed into a single coherent clinical statement with clinical attestation
entry:list		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:organization		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	OrganizationUvEpi	A grouping of people or organizations with a common purpose
entry:authorization		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	RegulatedAuthorizationUvEpi	Regulatory approval, clearance or licencing related to a regulated product, treatment, facility or activity e.g. Market Authorization for a Medicinal Product
entry:medicinalProduct		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	MedicinalProductDefinitionUvEpi	Detailed definition of a medicinal product
entry:administrableProduct		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	AdministrableProductDefinitionUvEpi	A medicinal product in the final form, suitable for administration - after any mixing of multiple components
entry:manItem		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	ManufacturedItemDefinitionUvEpi	The definition and characteristics of a medicinal manufactured item, such as a tablet or capsule, as contained in a packaged medicinal product
entry:ingredient		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	IngredientUvEpi	An ingredient of a manufactured item or pharmaceutical product
entry:packagedProduct		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	PackagedProductDefinitionUvEpi	A medically related item or items, in a container or package
entry:substanceDefinition		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	SubstanceDefinitionUvEpi	The detailed description of a substance, typically at a level beyond what is used for prescribing
entry:binary		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	Binary	A resource in the bundle
entry:clinicalUse		0..*	BackboneElement	Entry in the bundle - will have a resource or information
entry:resource		0..1	ClinicalUseDefinition	A resource in the bundle
signature		0..1	Signature	Digital Signature.



02

ePI Implementation Guide overview

HL7 International Electronic Medicinal Product Information (ePI) FHIR Implementation Guide 1.0.0-ballot - CI Build

Table of Contents Introduction Background The Specification Capabilities Artifact Index Appendices Downloads

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Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by HL7 International. This is not an authorized publication; it is the continuous build for version 1.0.0-ballot. This version is based on the current content of <https://github.com/HL7/electronic-product-info/> and changes regularly. See the [Directory of published versions](#).

1 Introduction

Official URL: http://hl7.org/fhir/uv/medicinal-product-info/ImplementationGuide/hl7.fhir-uv.medicinal-product-info	Version: 1.0.0-ballot
Active as of 2023-02-23	Computable Name: ep116

1.1 Purpose

To provide guidance on the technical and business conformance rules needed to create and exchange electronic Product Information (ePI) using FHIR and standard terminologies; and, as well as to create a common global approach for structuring medicinal product information and medicinal product labeling that is based on HL7 International standards.

1.2 Goals

The immediate goal of this specification is to expose ePI consumers and the vendor community to a set of profiles that identify the data elements, code systems and value sets commonly used in ePIs regardless of the jurisdiction.

The strategic goal is to offer a better route for patients to access trustworthy, up-to-date medicinal product information that better meets their individual needs.

1.3 Objectives

Define a common and interoperable standard for exchanging medicinal product information across international healthcare jurisdictions.

1.4 Scope

1.4.1 In Scope

ePI (Information for healthcare practitioner, information for the patient, package label), Human pharmaceutical, radiopharmaceutical and biologic medicinal products (prescription and physician-administered). Over the counter (non-prescription) drugs Investigational and authorized medicinal products Medical devices co-packaged with a biopharmaceutical

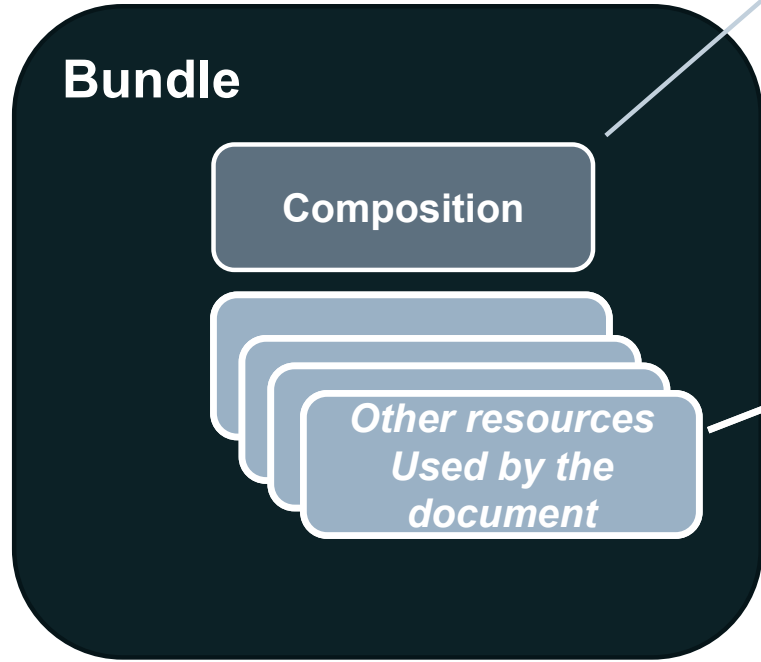
- Purpose
- Goals
- Objectives
- Scope
- How to use this guide
- Status
- Governance
- Authors and Contributors



How the HL7 FHIR ePI looks like

ePI is a HL7 FHIR Document

The container →



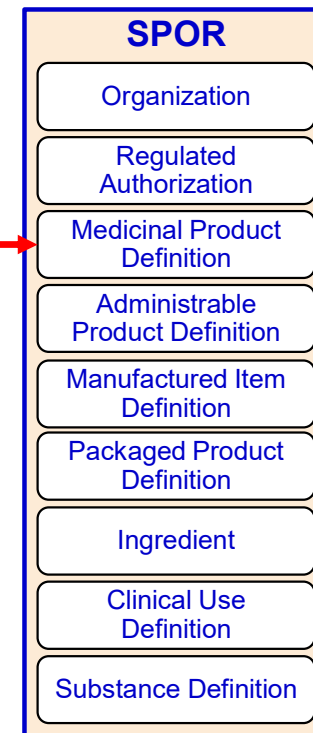
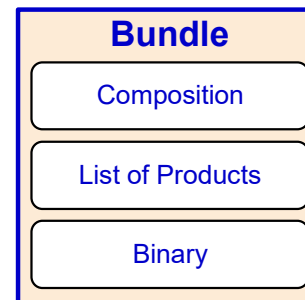
**Textual Narratives
(Sections)
+
References to the
Structured Data**

**Structured Data
(Medicinal Product;
Package Product;
Administrable Product;
Indications; Contra-
indications; Warnings;
MaH; etc...)**



Same foundation, two implementation models

- 'Common' Approach**
- All resources self contained in one Bundle.
 - Same resources as the SPOR approach.

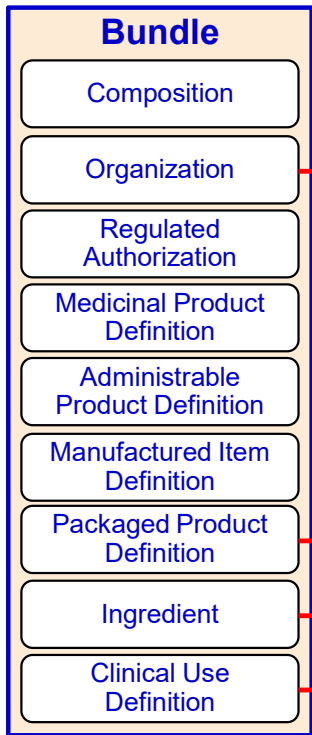


EMA's SPOR Approach

- Bundle cross-references out to SPOR
- Same resources as common approach.



Example: Product Label on FHIR and IDMP



Name	Flags	Card.	Type	Description & Constraints
PackageProductDefinition	TU		DomainResource	A medically related item or items, in a container or package Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension
name			String	
type			CodeableConcept	
subject			Reference(MedicinalProductDefinition Medication ActivityDefinition PlanDefinition Device DeviceDefinition Substance)	
status			CodeableConcept	
category			CodeableConcept	
subject			Reference(MedicinalProductDefinition Medication ActivityDefinition PlanDefinition Device DeviceDefinition Substance)	
status			CodeableConcept	
contraindication			BackboneElement	
diseaseSymptomProcedure			CodeableReference(ObservationDefinition)	
diseaseStatus			CodeableReference(ObservationDefinition)	
comorbidity			CodeableReference(ObservationDefinition)	
indication			Reference(ClinicalUseDefinition)	
otherTherapy			BackboneElement	
relationshipType			CodeableConcept	
therapy			CodeableReference(MedicinalProductDefinition Medication Substance SubstanceDefinition ActivityDefinition)	
indication			BackboneElement	
diseaseSymptomProcedure			CodeableReference(ObservationDefinition)	
diseaseStatus			CodeableReference(ObservationDefinition)	
comorbidity			CodeableReference(ObservationDefinition)	
intendedEffect			CodeableReference(ObservationDefinition)	
duration			Quantity	
undesirableEffect			Reference(ClinicalUseDefinition)	
otherTherapy			see otherTherapy	
interaction			BackboneElement	
interactant			BackboneElement	
item[x]			Reference(MedicinalProductDefinition Medication Substance ObservationDefinition) CodeableConcept	
itemCodeableConcept			CodeableConcept	
type			CodeableConcept	
effect			CodeableReference(ObservationDefinition)	
incidence			CodeableConcept	
management			CodeableConcept	
strengthRatio			Ratio	
strengthQuantity			Quantity	

HL7 FHIR Profiles for Organizations

HL7 FHIR Profiles for Packaging

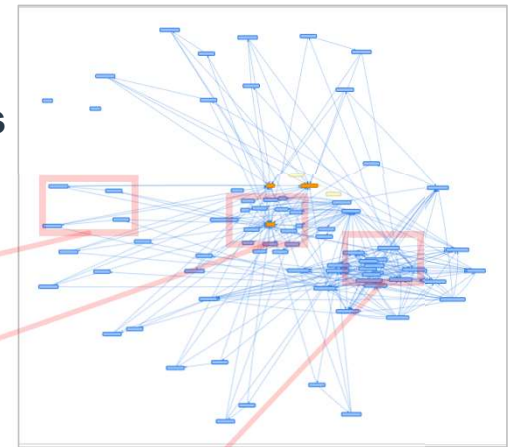
HL7 FHIR Profiles for Ingredients

HL7 FHIR Profiles for Clinical Use

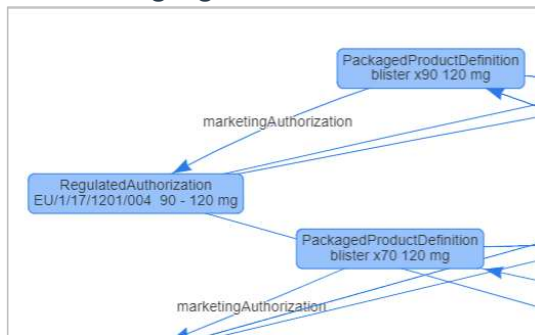



Use case example 1: Viewing ePI content as a graph

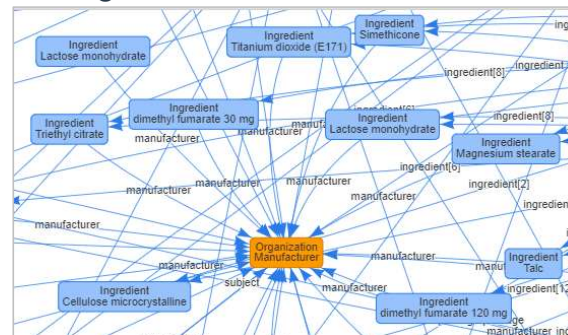
Graphs showing ePI data and data relationships.
This graph shows the 90+ data objects in a single ePI.
Graphing your drug portfolio leads to benefits like rapid impact analysis changes (e.g., Safety updates, formulation, packaging).



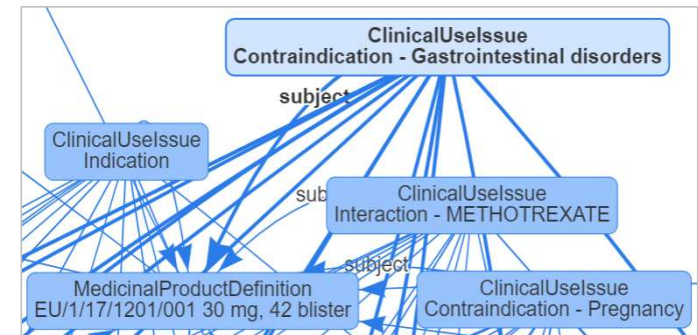
Packaging and Authorization



Ingredients and Manufacturer

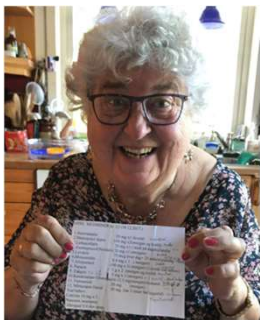


Clinical Details and Medicinal Product

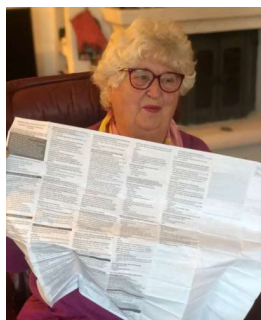


The Goal

Maria and her medicines



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO

VISION



Engagement of citizens in their own health can only be achieved with access to actionable, understandable, relevant, reliable and evidence-based information that meets their specific needs, health context, and literacy level.

AMBITION



To provide a key piece to advance this vision: the **Gravitate Lens (G-Lens)**, which focuses (but does not conceal or filter) approved electronic product information (ePI) content, and offers a route for patients to access trustworthy, up-to-date information that better meet their individual needs.

Personal Health Record

Capable Maria Personals

Allergies and intolerances

- Bivirkning av legemiddel Remove
- Laktoseintoleranse Remove

Medical conditions

- Sykdom i fordøyelsessystemet IKA Remove

Legg til nytt klinisk forhold See version

Capable healthcare Language: English Feedback

Applied criteria: Demographics, conditions, allergy and intolerance

Pregnancy related - suppressed

Lactose Intolerance related - highlighted

ePI content tailored to the individual

Capable Maria Personals

Skilarence Enterotab 30 mg

G-lens Åpne eksterne lenke

Highlighted

- Pasienten bruker medisiner
- Obs for Skilarence: Pasienten har intoleranse svarende til kode T99
- Obs for Skilarence: Pasienten har tilstand svarende til kode D94, D97, D98 eller D99

Suppressed

- Pasienten er kvinne over 50 år
- Pasienten er over 18 år

Andre legemidler virker kanskje ikke så bra som de bør hvis du får alvorlig eller langvarig diaré med Skilarence. Rådfer deg med legen dersom du har kraftig diaré, og er beredt på at andre legemidler du tar kanskje ikke virker. Spesielt hvis du tar et prevensjonsmiddel (p-piller) kan virkningen reduseres, og du må kanskje bruke andre barrieremethoder for å forhindre graviditet. Se anvisningene i pakningsvedlegget til prevensjonsmidlet du tar.

Rådfer deg med legen hvis du trenger en vaksinasjon. Visse typer vaksiner (levende vaksiner) kan forårsake infeksjon hvis de brukes under behandling med Skilarence. Legen kan gi deg råd om hva som er best.

Inntak av Skilarence sammen med alkohol
Unngå sterke alkoholdrigevarer (mer enn 50 ml brennevin som inneholder mer enn 30 vol. % alkohol) under behandling med Skilarence, da alkohol kan påvirke dette legemidlet. Dette kan forårsake mage- og tarmproblemer.

Graviditet og amming
Bruk ikke Skilarence dersom du er gravid eller prøver å bli gravid, da Skilarence kan skade fosteret. Bruk effektive prevensjonsmetoder for å unngå å bli gravid under behandling med Skilarence (se også "Andre legemidler og Skilarence" overfor). Unngå amming under behandling med Skilarence.

Kjøring og bruk av maskiner
Skilarence kan ha en liten påvirkning på evnen til å kjøre bil og bruke maskiner. Det kan hende at du føler deg svimmel eller trett etter å ha tatt Skilarence. Hvis du påvirkes, vær forsiktig når du kjører eller bruker maskiner.

Skilarence inneholder laktose
Dersom legen din har fortalt deg at du har intoleranse overfor noen sukker typer, bør du kontakte legen din før du tar dette legemidlet.

Skilarence inneholder natrium.
Dette legemidlet inneholder mindre enn 1 mmol natrium (23 mg) i hver tablett, og er så godt som "natriumfritt".

Capable healthcare Feedback

Prepared by
Petter Hurlen, AHUS
Knut Skifjeld, NeH
Gunvald Harket, NeH





How to achieve it - focusing

ePI

Pure FHIR.
contains
structured
free text

p(ePI)

Semantically
annotated.

f(ePI)

Standardised
coded Lenses
are attached.

e(ePI)

Additional
information is
attached

Render

Visualization of
focused ePI
with
personalization,
or use for other
processes

Trust Framework

Annotation of terms
using standard
terminologies (e.g.
SNOMED)

Add clinical
Knowledge
(lenses)

Add Extra
information
(IPS, user
choices)

Personalized ePI

Gravitate  Health

VULCAN

03

Next Steps



Next Steps

- **Finalize the Implementation Guide (H1 2023)**
- **Progress critical mass plan (i.e., convert 80% of labels to FHIR within two-years)**
- **Develop additional prototypes for US and JP ePIs.**
- **Collaborate with UNICOM to develop test scenarios for next HL7 FHIR connectathons.**
- **Schedule ePI summit to discuss development roadmap (includes technology vendor summit).**
- **Discuss best practices for quality assurance and patient safety (e.g., confirm ePI bundle was compiled correctly)**



9. Vulcan Electronic Product Information (ePI)

Giorgio Cangioli, HI7 Europe + Craig Anderson, Pfizer (remote)

Sonja Steiner, Acodis + Patrick Bürkle, Acodis

Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20





Turning Patient Leaflets Into HL7 FHIR

Implementation Insights / Showcase

EUROVULCAN - MARCH 2023



Introduction

Thank you for having us in Paris!



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1. The Challenge at Hands: How to create structured data from unstructured source documents



How it started

Word 2 XML Conversion for PharmaLedger Project

for patient leaflet information not available in structured format

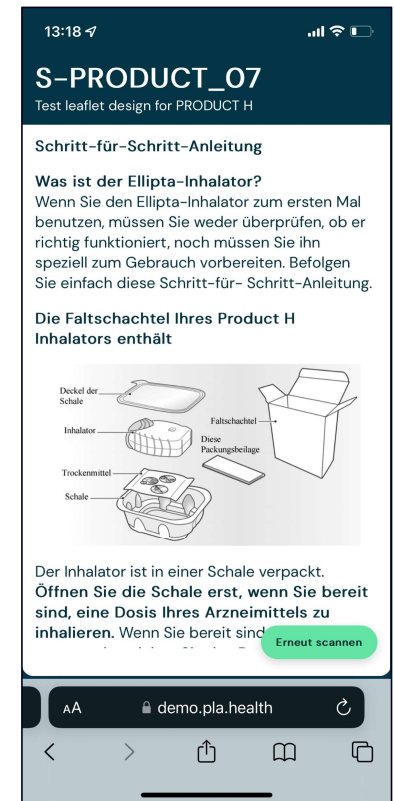
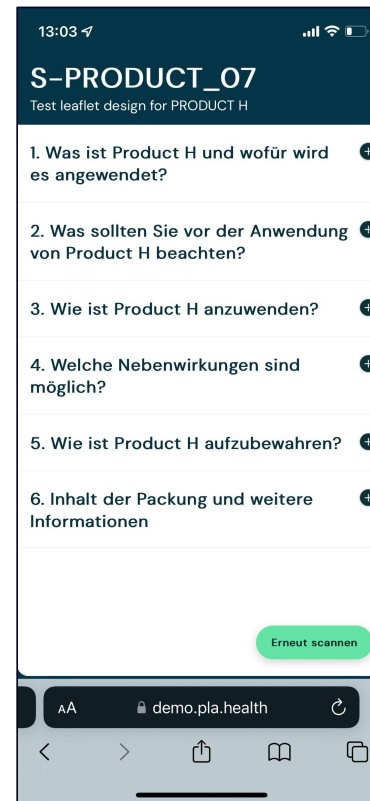
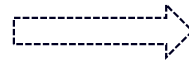
Patient Journey



DataMatrix Code



PharmaLedger app



The Challenge at Hands

A word file as single source of truth

- Word files are used for human interaction and collaboration
- Leaflet is approved by regulators “as it visually appears” – no deviations
- Word Files are highly unstructured even in QRD Standards
 - Title / Subtitel Structure
 - Irrelevant Information
 - Multi Column / Tables
 - Mobile usage optimization vs. physical leaflet
 - Image & Figures



2. Let's do it



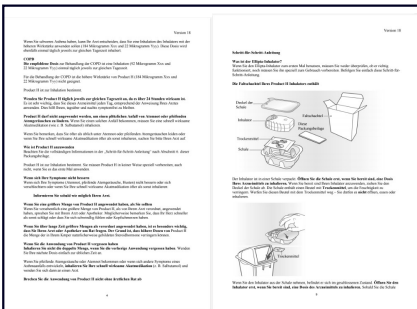
Demo Script for Sonja

1. Open Platform with Link in presentation
2. Quickly explain the GUI
3. Go to Folder with leaflets – explain the steps to be applied at an example – how to build a model
4. structure the leaflet of Product H
 1. Drag and Drop Document H / mention Automation via email or API
 2. See steps on lefthand side – what have we applied, why is this more than just OCR
 3. Structure detection: Table of Content / read instruction / Sections. what is shown will be decided
 4. Tags → Example for pilot, not finally decided on naming convention / number of tags
 5. Figures → See picture and view in export with text representation
 6. tables
5. Show customized export step for FHIR
6. Extract Document
7. Open FHIR XML
8. End

Let's do it Wrap up

Supplier Support Journey

Template* of Product H



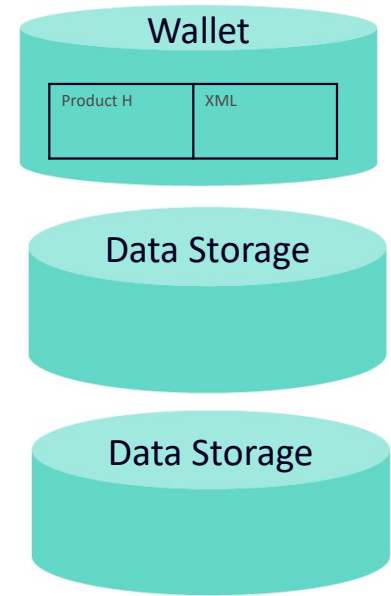
Structured Product H as XML

```
<?xml version="1.0" encoding="UTF-8" ?>
<product id="H">
  <name>Produkt H</name>
  <description>Produkt H ist ein Produkt, das...</description>
  <images>
    
    
  </images>
  <qr_code data-bbox="100 430 180 460" />
</product>
```



FHIR

...or any other requested format



Scope of Acodis

3. About Acodis

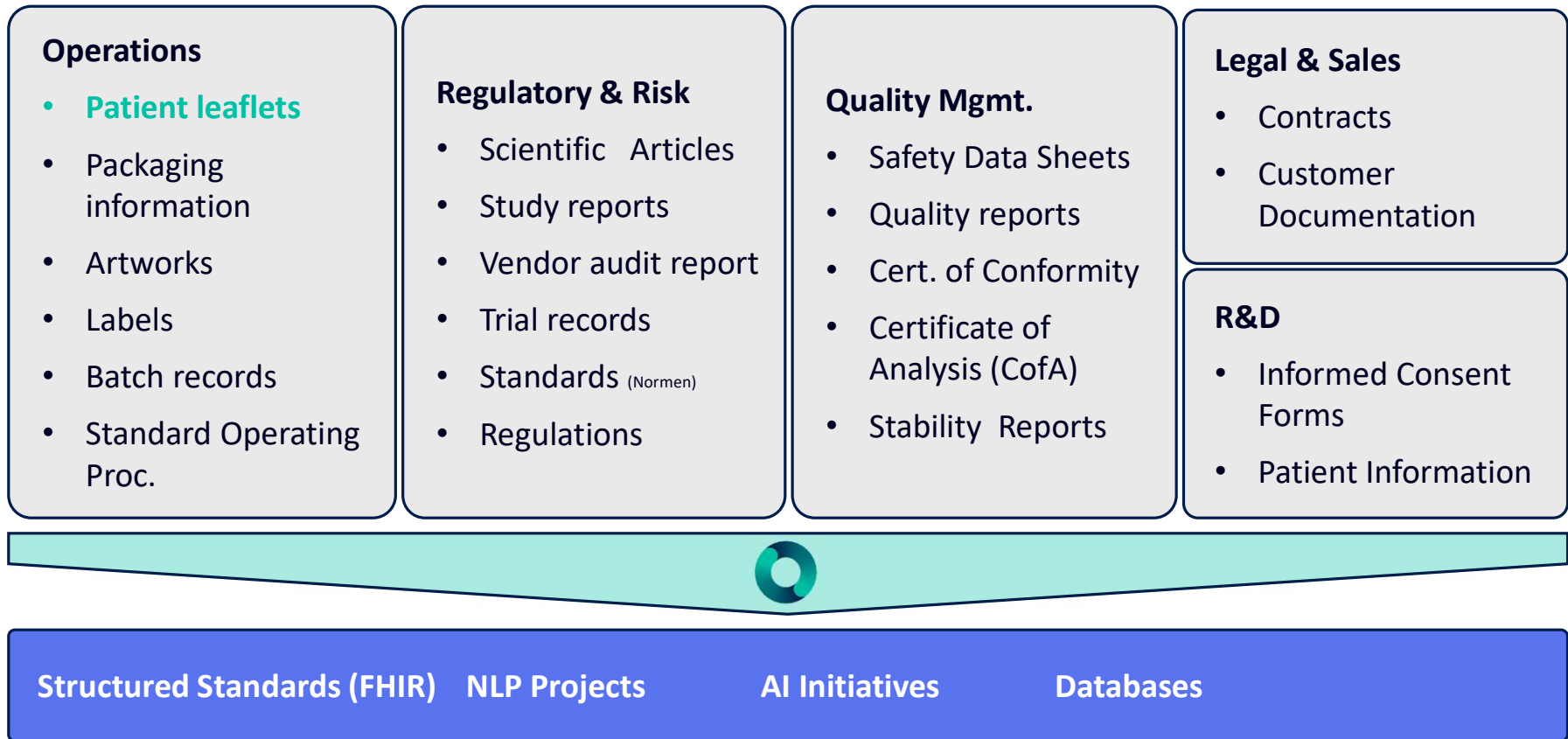




Turn Any Document Into Structured Data – in Seconds

Data Extraction from highly
complex documents within
regulated environments

We structure complex documents within Health, Pharma & Life Science



About Acodis

Acodis in a Nutshell

25

Experts



Information Security



Quality Management



Service Orga. Control 2



4. Q&A



Thank you!



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acodis



9. Vulcan Electronic Product Information (ePI)

Giorgio Cangioli, HI7 Europe + Craig Anderson, Pfizer (remote)

Sonja Steiner, Acodis + Patrick Bürkle, Acodis

Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20





Structured Authoring - Supporting IDMP Submissions using HL7 FHIR Standard

EuroVulcan Conference
March 14-15, 2023



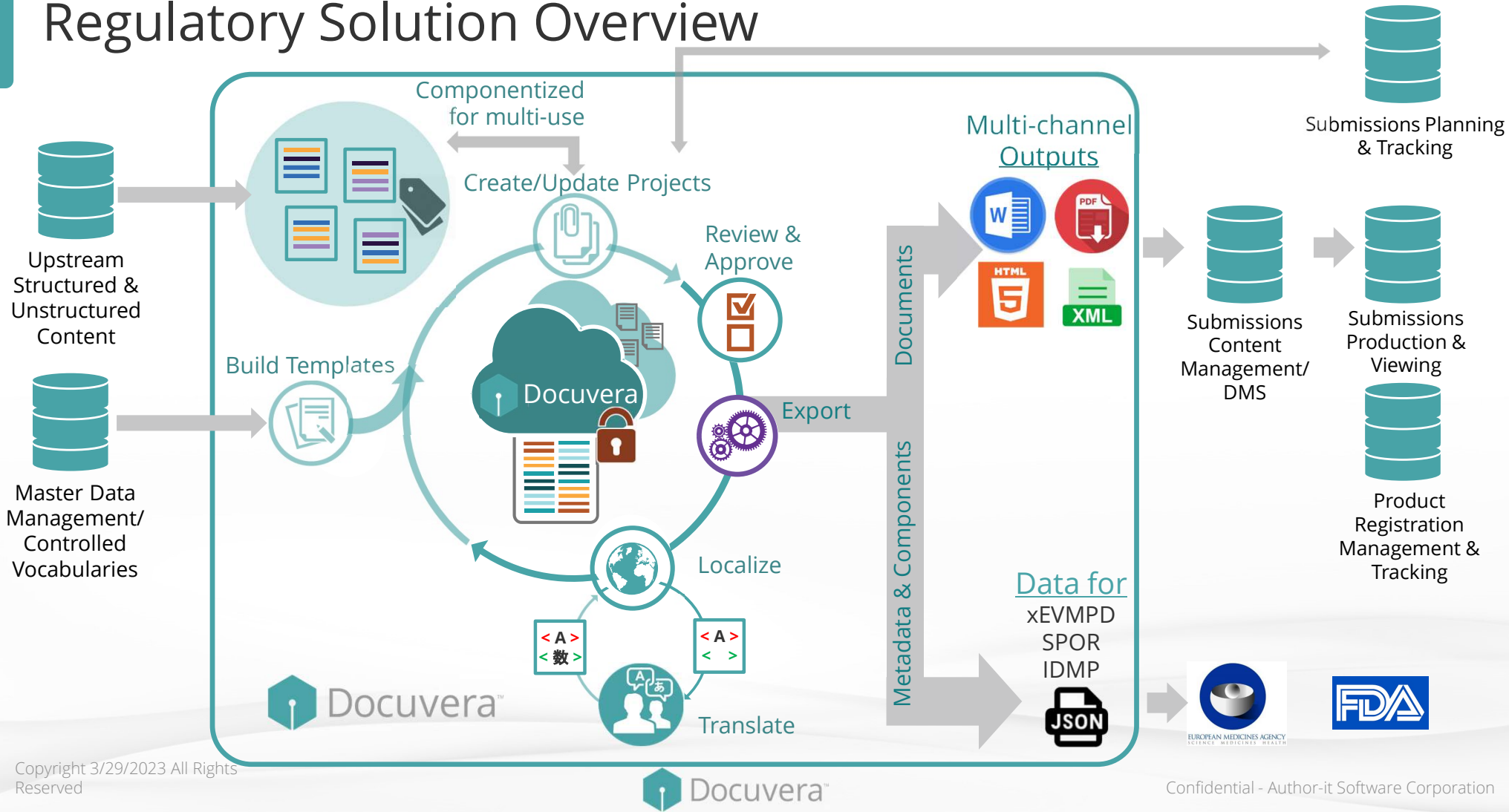
Presentation Objectives

- High-level demonstration of Docuvera
- Describe Structured Authoring with Docuvera in a Regulatory Setting
- Discuss Current Docuvera IDMP FHIR Export Capabilities
- Show FHIR Composition Export Capabilities to Support ePI
- Explain Findings from FHIR Composition Generation
- Show Production Use Cases of FHIR Compositions Beyond Regulatory (time permitting)

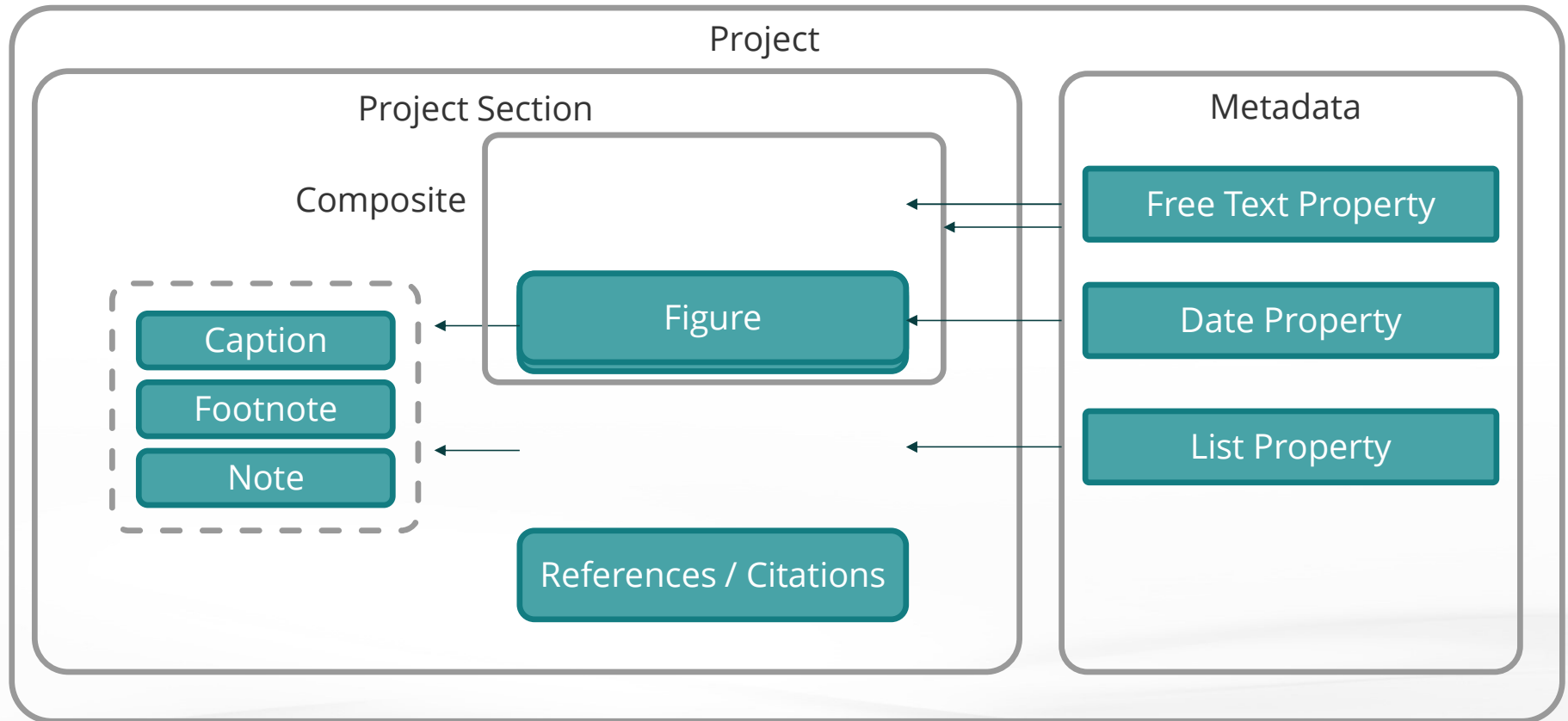
The image features a solid teal background. In the center, there is a faint, semi-transparent 3D cube graphic. The word "Demonstration" is written across the middle of the cube in a white, italicized serif font.

Demonstration

Regulatory Solution Overview



Anatomy of a Structured Document (Project)



Example SmPC Authored in Docuvera – 1 of 2

Docuvera | Library Assignments Tracking Tasks | John Jones

Editing: ema-Ofev-en Annex I SmPC

View: Editor

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Component status: **Approved version 1**. To edit, [create draft version 2](#)

<Local Trade Name> <Strength 1> soft capsules

<Local Trade Name> <Strength 2> soft capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Local Trade Name> <Strength 1> soft capsules

One soft capsule contains <Strength 1> <Active Pharmaceutical Ingredient - lower case> (as esilate)

Excipient with known effect

Each <Strength 1> soft capsule contains 1.2 mg of soya lecithin.

<Local Trade Name> <Strength 2> soft capsules

One soft capsule contains <Strength 2> <Active Pharmaceutical Ingredient - lower case> (as esilate)

Excipient with known effect

Each <Strength 2> soft capsule contains 1.8 mg of soya lecithin.

For the full list of excipients, see section 6.1.

Properties

PROPERTIES OF

Project Selection

Active Pharmaceutical Ingredient - lower case *
nintedanib

Active Pharmaceutical Ingredient - Upper case *
Nintedanib

'Nintedanib' is not valid for this property.

Substance *
nintedanib

Product BRDS *
nintedanib

Global Brand Name *
OFEV, VARGATEF

'OFEV, VARGATEF' is not valid for this property.

Local Trade Name *
Ofev

'Ofev' is not valid for this property.

ATC-Code *
L01XE31

'L01XE31' is not valid for this property.

Pharmacotherapeutic Group *
Antineoplastic agents - Protein-tyrosine ...

'Antineoplastic agents - Protein-tyrosine kinase inhibitors' is n...

Example SmPC Authored in Docuvera – 1 of 2

The screenshot shows the Docuvera interface for editing a Summary of Product Characteristics (SmPC). The main content area is titled "Editing: ema-Ofev-en Annex I SmPC". The interface is divided into sections, with the following annotations:

- Section Heading:** Points to the "1. NAME OF THE MEDICINAL PRODUCT" section.
- Topic:** Points to the "1. NAME OF THE MEDICINAL PRODUCT" section.
- Full Name with Placeholders:** Points to the text "<Local Trade Name> <Strength 1> soft capsules".
- Substance:** Points to the "nintedanib" selection in the Properties panel.
- ATC Code:** Points to the "L01XE31" selection in the Properties panel.

The Properties panel on the right shows the following details:

- Project: Selection
- Active Pharmaceutical Ingredient - lower case *: nintedanib
- Active Pharmaceutical Ingredient - Upper case *: Nintedanib
- Substance *: nintedanib
- Product BIRDS *: nintedanib
- Global Brand Name *: OFEV, VARGATEF
- Local Trade Name *: Ofev
- ATC-Code *: L01XE31
- Pharmacotherapeutic Group *: Antineoplastic agents - Protein-tyrosine ...

Example SmPC Authored in Docuvera – 2 of 2

Docuvera | Library | Assignments | Tracking | Tasks | John Jones

Editing: ema-Ofev-en Annex I SmPC

View: Editor | Saved | Draft

<Local Trade Name> <Strength 2> soft capsules
<Local Trade Name> <Strength 2> soft capsules are brown-coloured, opaque, oblong soft-gelatin capsules imprinted on one side in black with the Boehringer Ingelheim company symbol and "150".

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

<Local Trade Name> is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).

<Local Trade Name> is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see section 5.1).

<Local Trade Name> is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).

4.2 Posology and method of administration

Treatment should be initiated by physicians experienced in the management of diseases for which <Local Trade Name> is approved.

Posology

Properties

PROJECT SELECTION

PROPERTIES OF

Project Selection

Status
Draft

Version
2

Language
English (United Kingdom)

Description

Created by
Sue Ferreira on Jun 24, 2022 11:13 AM

Modified By
John Jones on Mar 05, 2023 12:47 PM

IDMP Indication as "Disease/Symptom/Procedure"
Interstitial lung ...

IDMP Intended Effect
treatment

ADD PROPERTY

SEARCH

Example SmPC Authored in Docuvera – 2 of 2

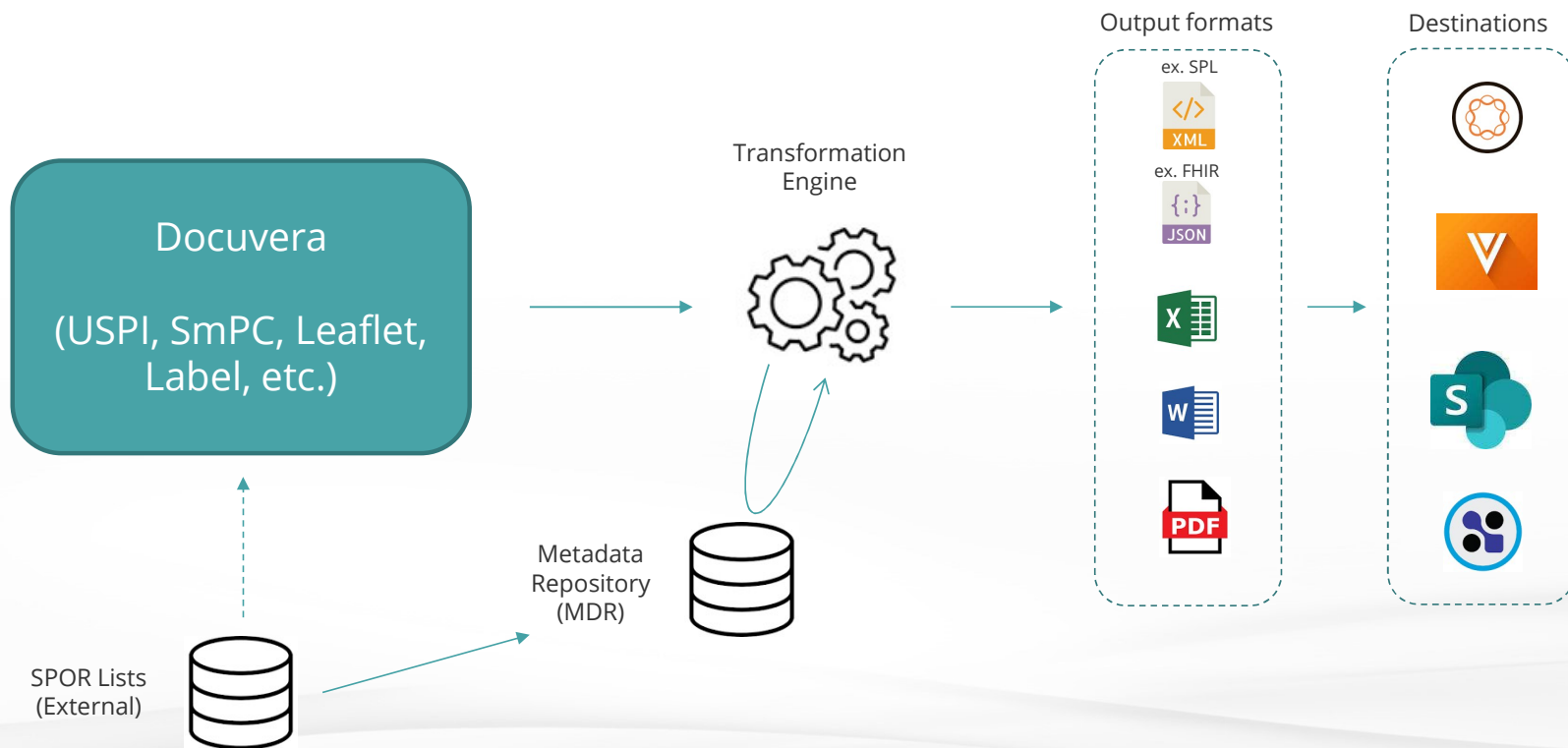
The screenshot displays the Docuvera interface for editing an SmPC document titled "ema-Ofev-en Annex I SmPC". The document content is shown in a structured view with sections for "4. CLINICAL PARTICULARS" and "4.1 Therapeutic indications".

Key elements highlighted with red boxes and arrows:

- Indication Text:** A red box highlights the text "<Local Trade Name> is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see section 5.1)." in the document content.
- Indication - Disease/Symptom/Procedure:** A red box highlights the text "<Local Trade Name> is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD)." in the document content. An arrow points from this box to the "Interstitial lung ..." entry in the IDMP Indication list in the Properties panel.
- Intended Effect:** A red box highlights the text "Treatment should be initiated by physicians experienced in the management of diseases for which <Local Trade Name>" in the document content. An arrow points from this box to the "treatment" entry in the IDMP Intended Effect list in the Properties panel.

The Properties panel on the right shows the document's metadata, including Project (Selection), Status (Draft), Version (2), Language (English (United Kingdom)), and a list of IDMP Indications and Intended Effects.

Docuvera Advanced Export Capability



Sample Export – SmPC FHIR Composition

The screenshot displays the Docuvera software interface for editing an SmPC FHIR Composition. The main editor shows a table of sections:

Section ID	Section Title
<Local Trade Name> <Strength 2> soft capsules	<Local Trade Name> <Strength 2> soft capsules are brown-coloured, opaque, oblong soft-gelatin capsules imprinted on one side in black with the Boehringer Ingelheim company symbol and "150".
4.	CLINICAL PARTICULARS
4.1	Therapeutic indications
	<Local Trade Name> is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).
	<Local Trade Name> is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see section 5.1).
	<Local Trade Name> is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).
4.2	Posology and method of administration
	Treatment should be initiated by physicians experienced in the management of diseases for which <Local Trade Name> is approved.
	Posology

The right-hand Properties panel shows the following details for the selected section:

- Project: Selection
- Status: Draft
- Version: 2
- Language: English (United Kingdom)
- Description:
- Created by: Sue Ferreira on Jun 24, 2022 11:13 AM
- Modified By: John Jones on Mar 05, 2023 12:47 PM
- IDMP Indication as "Disease/Symptom/Procedure": Interstitial lung ...
- IDMP Intended Effect: treatment




Sample Export – SmPC FHIR Composition

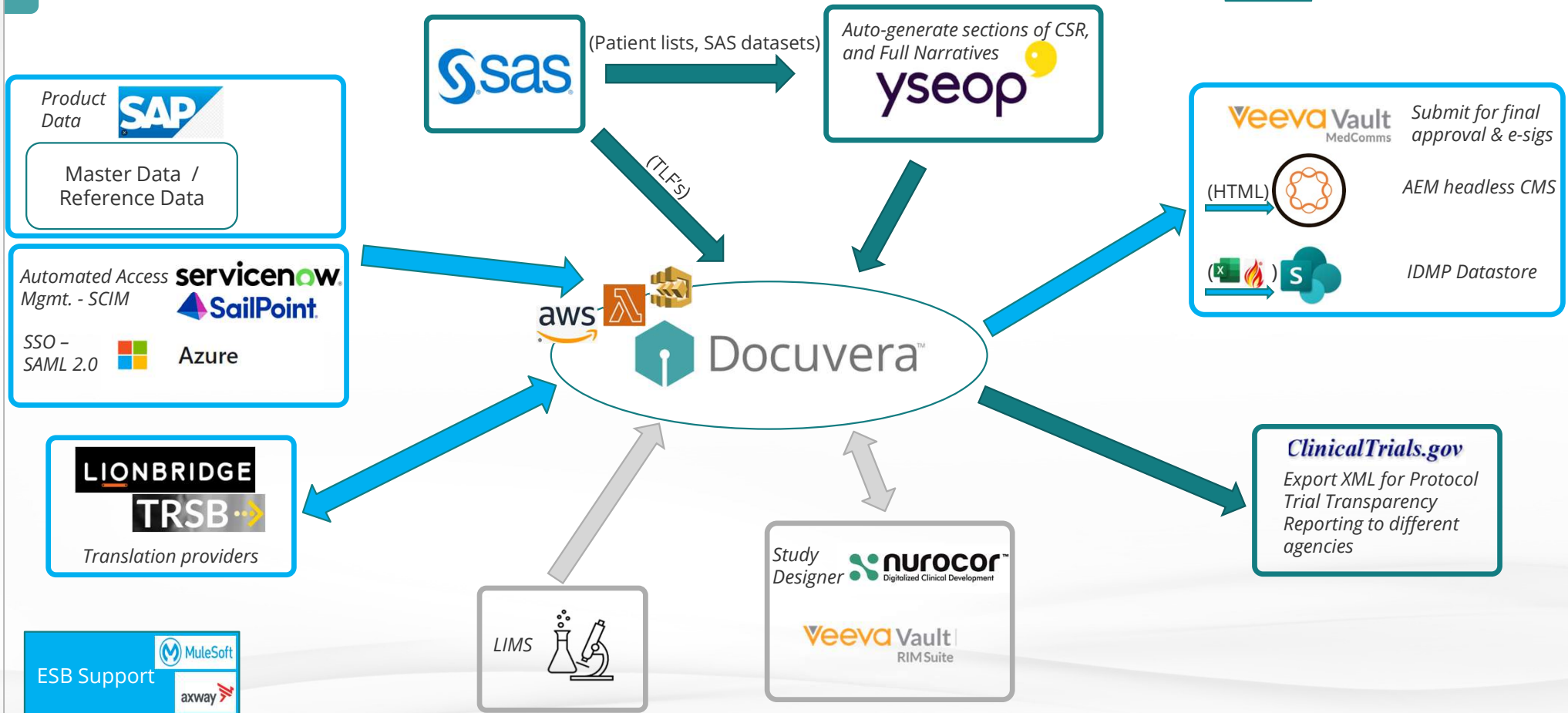
```
Docuvera | Library | Assignments | Tracking | Tasks
```

```
"section": [
  {
    "title": "4.1 Therapeutic indications",
    "code": {
      "coding": [
        {
          "system": "https://spor.ema.europa.eu/rmswi",
          "code": "100000155538"
        }
      ]
    },
    "text": "4.1 Therapeutic indications"
  },
  {
    "text": {
      "status": "additional",
      "div": "<div
xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is indicated in
adults for the treatment of idiopathic pulmonary fibrosis
(IPF).</p><p>OFEV is also indicated in adults for the
treatment of other chronic fibrosing interstitial lung
diseases (ILDs) with a progressive phenotype (see section
5.1). </p><p>OFEV is indicated in adults for the treatment of
systemic sclerosis associated interstitial lung disease (SSc-
ILD).</p></div>"
    }
  }
]
```

```
"text": [
  {
    "status": "additional",
    "div": "<div xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is
indicated in adults for the treatment of idiopathic pulmonary fibrosis
(IPF).</p></div>"
    "code": {
      "coding": [
        {
          "system":
"https://spor.ema.europa.eu/rmswi/#/lists/100000000006",
          "code": "10000015597"
        }
      ]
    },
    "text": "Idiopathic pulmonary fibrosis"
  },
  {
    "status": "additional",
    "div": "<div xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is
also indicated in adults for the treatment of other chronic fibrosing
interstitial lung diseases (ILDs) with a progressive phenotype (see section
5.1). </p></div>"
  },
  {
    "status": "additional",
    "div": "<div xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is
indicated in adults for the treatment of systemic sclerosis associated
interstitial lung disease (SSc-ILD).</p></div>"
  }
]
```

System Architecture- Enterprise Integrations

-  Existing Integrations
-  Implementing Integrations
-  Evaluating Integrations



The image features a solid teal background. In the center, there is a faint, light-teal hexagonal graphic. Overlaid on this hexagon is a vertical line with a solid teal circle at its top end. The word "Questions?" is written in a white, italicized serif font across the middle of the hexagon.

Questions?



Thank You

Susie Winn
Director, Life Sciences Solutions
Susie.winn@author-it.com

John Jones
CEO, Entitech Solutions
John@entitechsolutions.com



Networking Reception

<new> Coffee Corner 2nd Floor, 16:30 – 18:30