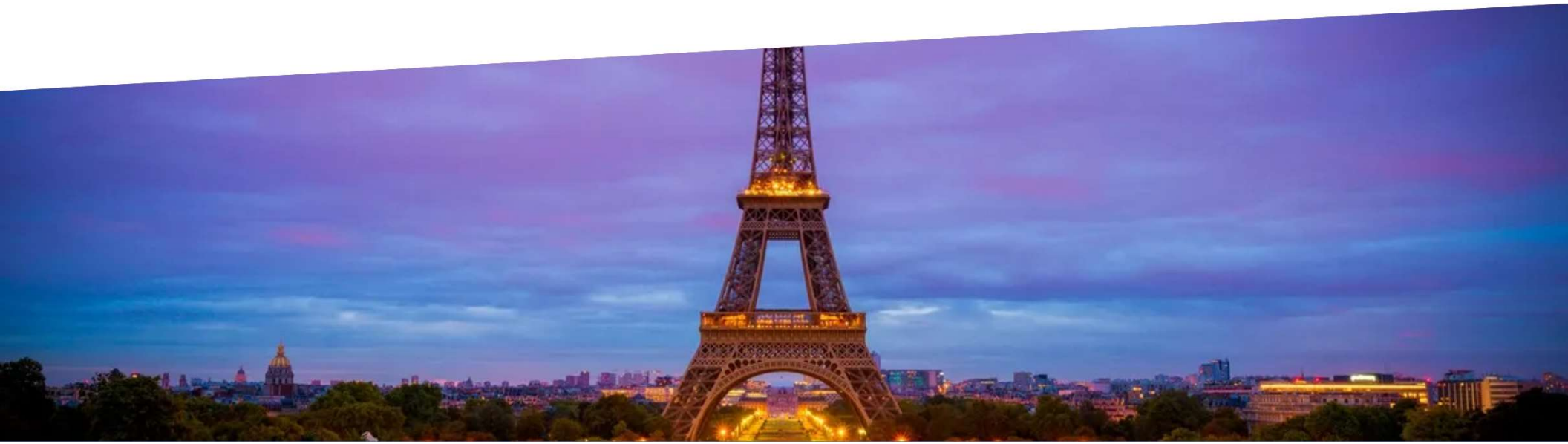

VULCAN
HL7 FHIR
EuroVulcan
Conference & Connectathon
Welcome!
Day 1 Programme

Welcome & Opening Address

Amy Cramer, Hugh Glover



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EuroVulcan Thanks Our Speakers

Across Industry, Across Perspectives

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EuroVulcan Thanks Our Contributing Partners

Supporting Vulcan from Many Perspectives

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EuroVulcan Thanks Our Organising Committee

Making it all Happen

Anne Moen

Catherine Chronaki

Christel Daniel

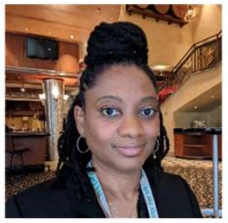
Amy Cramer

Darren Weston

Hugh Glover

Michael van Campen

Stacy Tegan



Shani Sampson

Sandy Vance

Katleen Renders

Nikki Huysmans

Nicolas Riss

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HL7 FHIR
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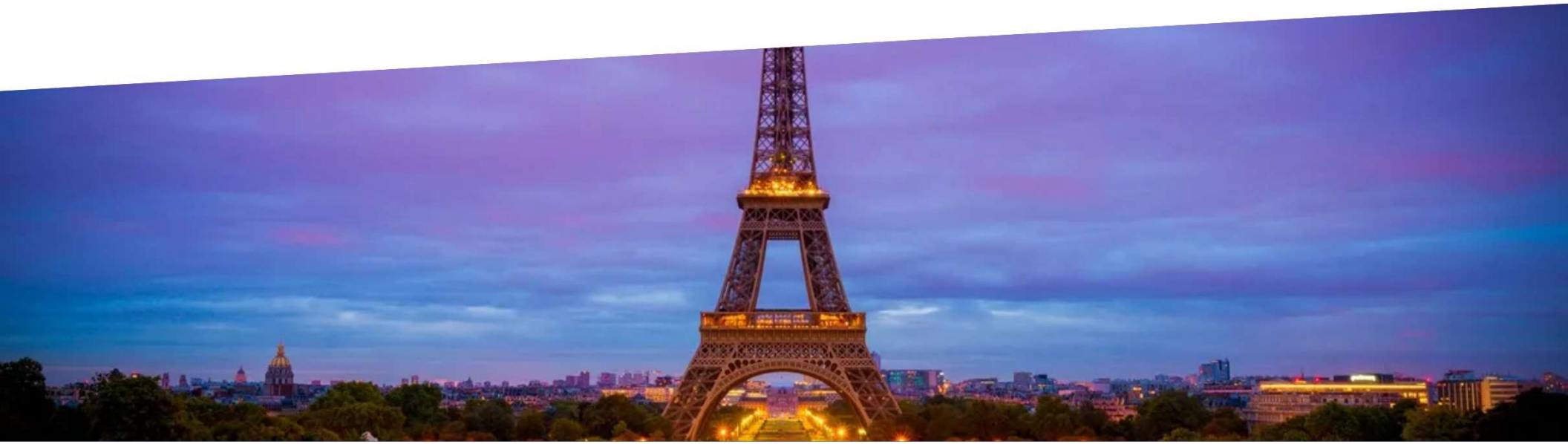
2. Vulcan Overview

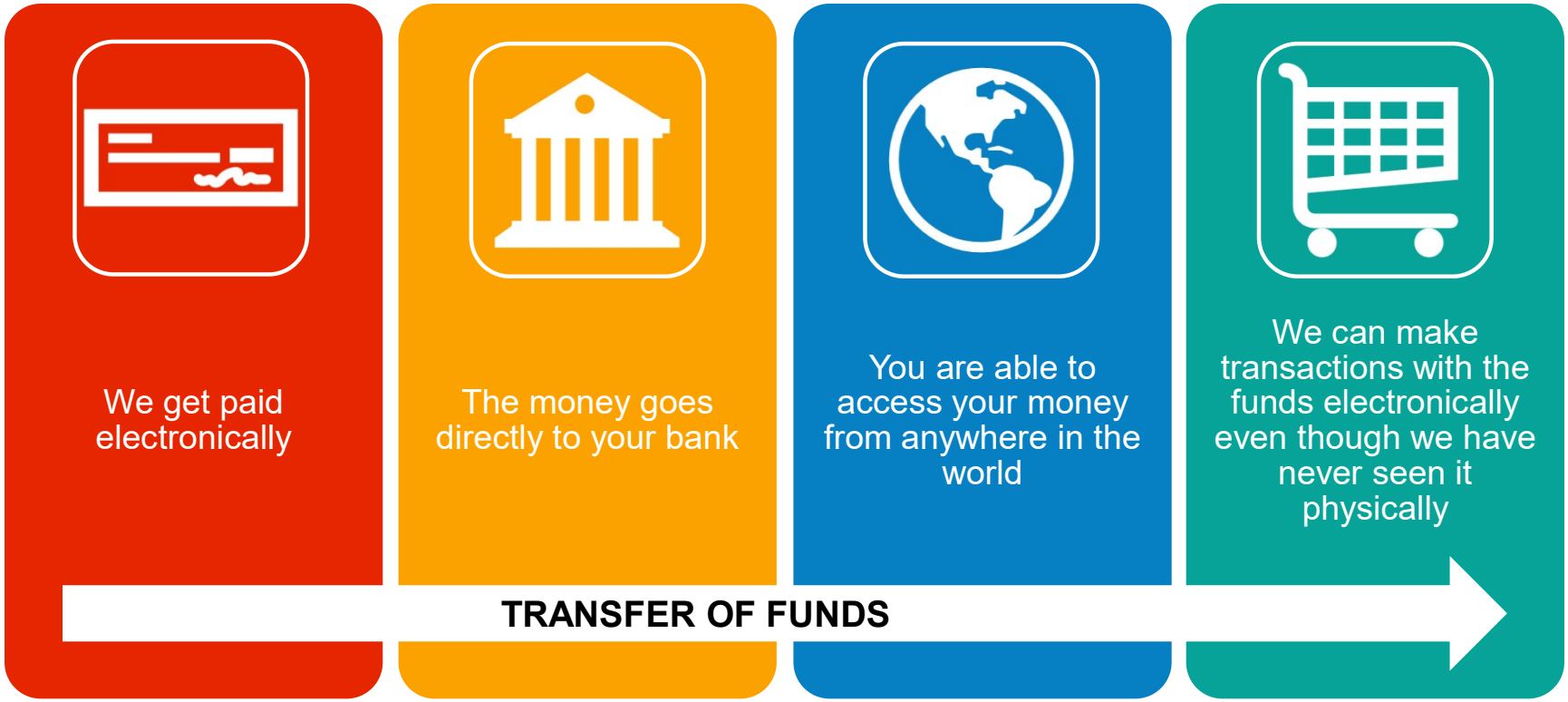
Amy Cramer, Vulcan co-Chair / J&J

9:45 – 10:10



Interoperability Case Study: Finance

Digital Lessons from the Finance Industry



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

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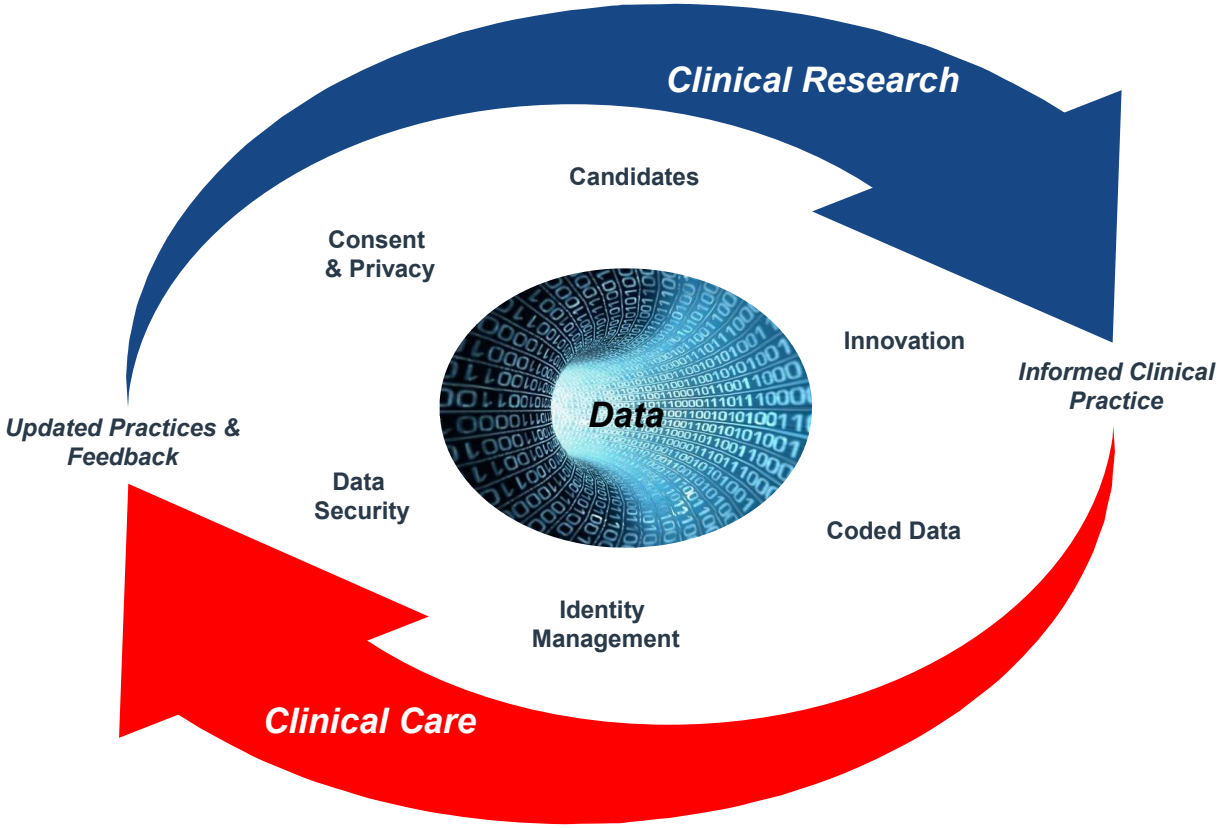
The Need for Standards in Clinical Research

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

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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.

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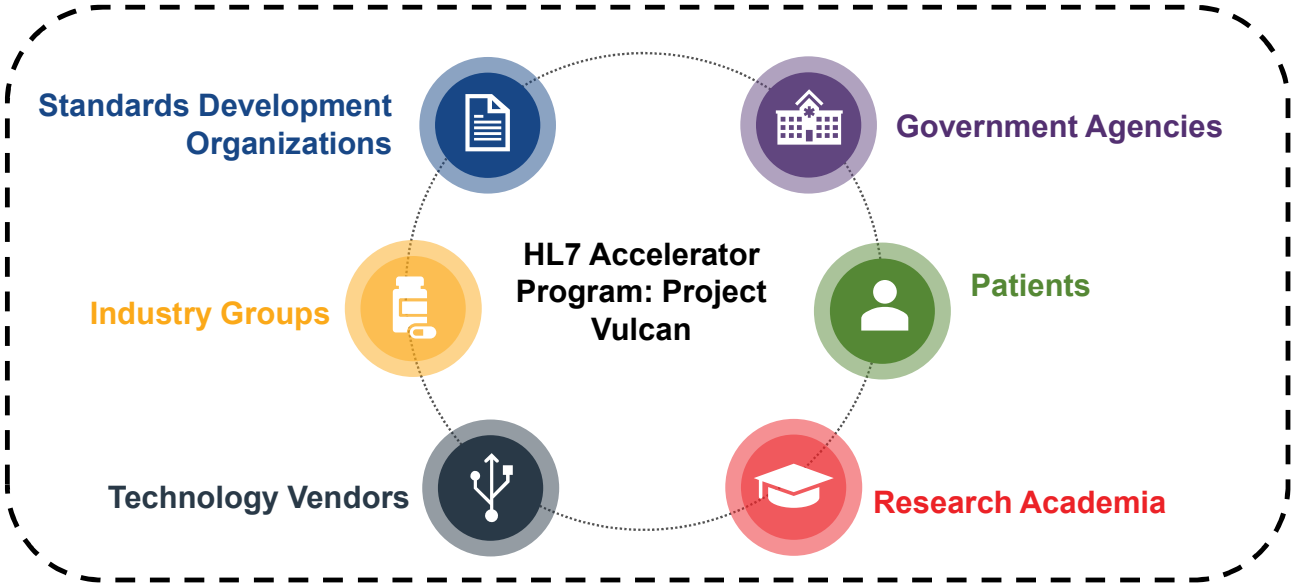
The Convening Members of Vulcan

Represent a Wide Variety of Expertise

HL7 International

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY



FDA

TransCelerate BIOPHARMA INC.

NIH National Center for Advancing Translational Sciences

SCDM Society for Clinical Data Management
DATA DRIVEN

NIH U.S. National Library of Medicine

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Current Member Organizations of Vulcan

As of February 2023

★ *indicates a convening member of Vulcan*

HL7 Accelerator Program

Focused Standards Development

FAST

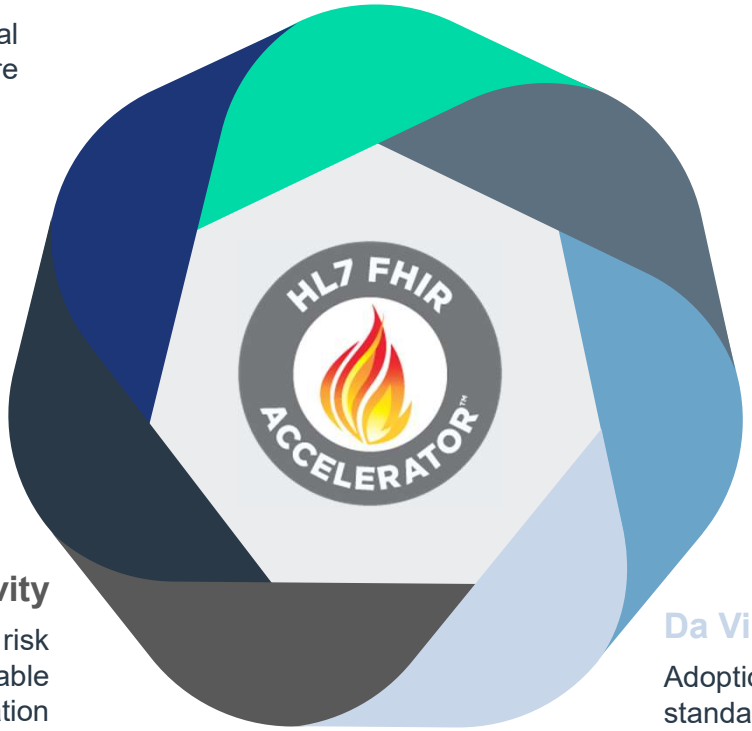
Define a scalable approach to deploying FHIR across interoperability use cases

Argonaut

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

Vulcan

Connecting translational and clinical research with healthcare



CARIN

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

Helios

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

CodeX

Accelerate interoperable data modeling and applications cancer patient care and research

Gravity

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

Da Vinci

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

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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

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The Goals of Vulcan

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

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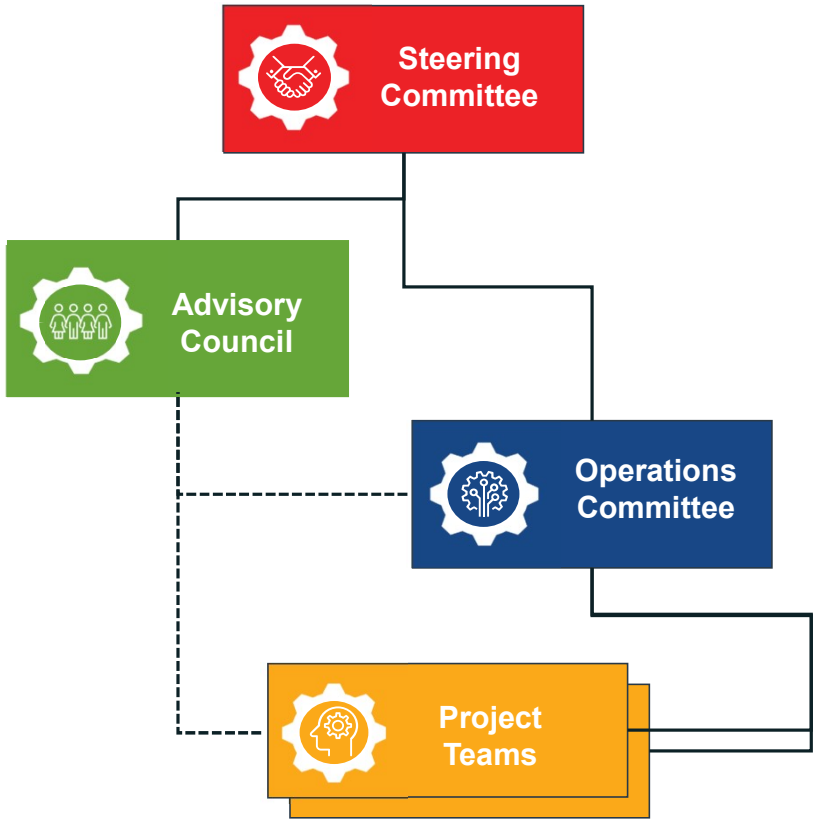
Vulcan Structure and PMO Team Membership



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

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Vulcan – Moving Forward

Inflection Point

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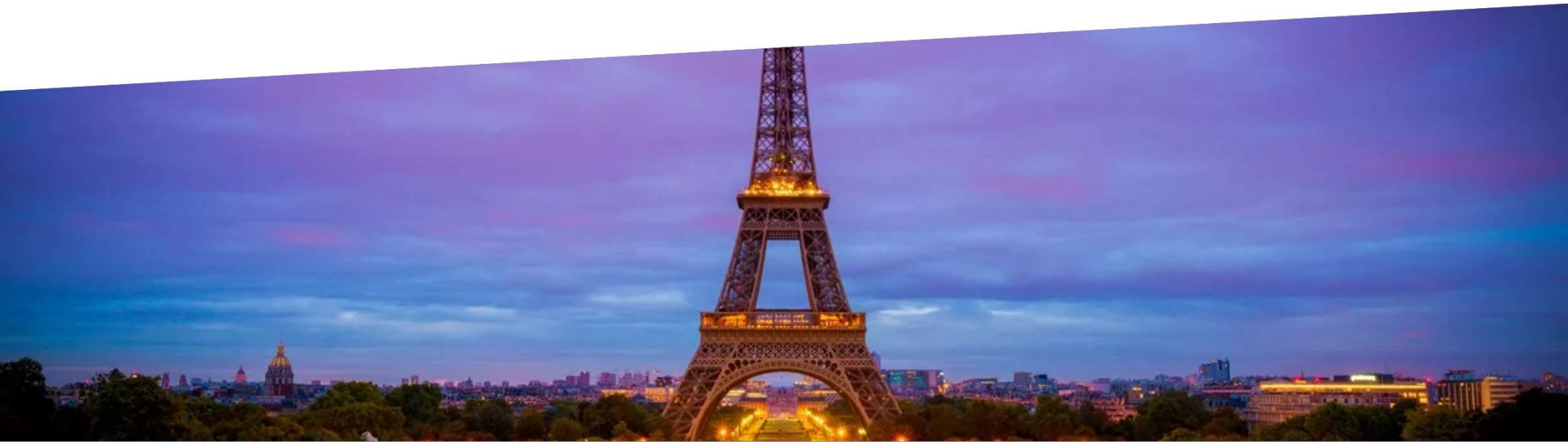
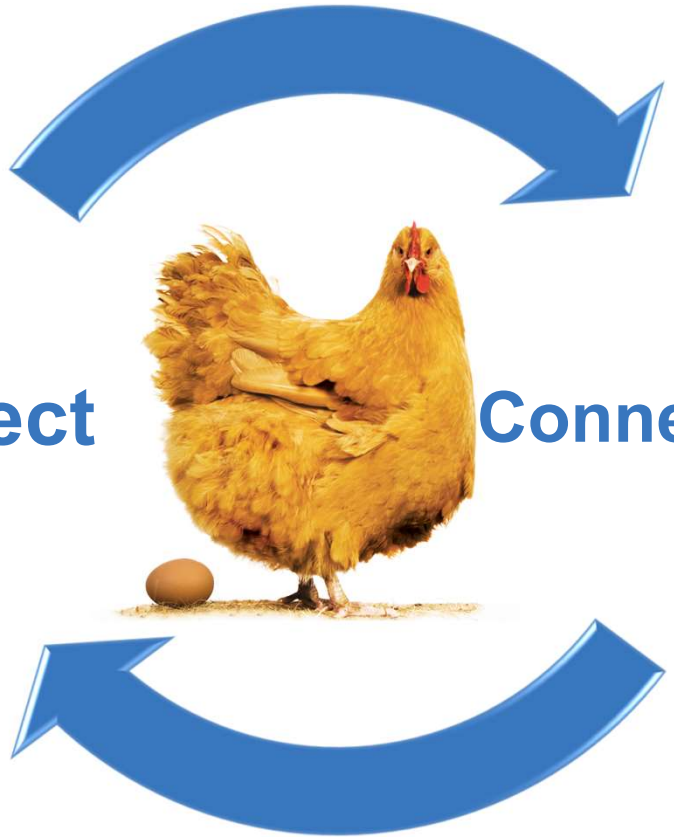
3. Connectathon Overview

Hugh Glover, Vulcan

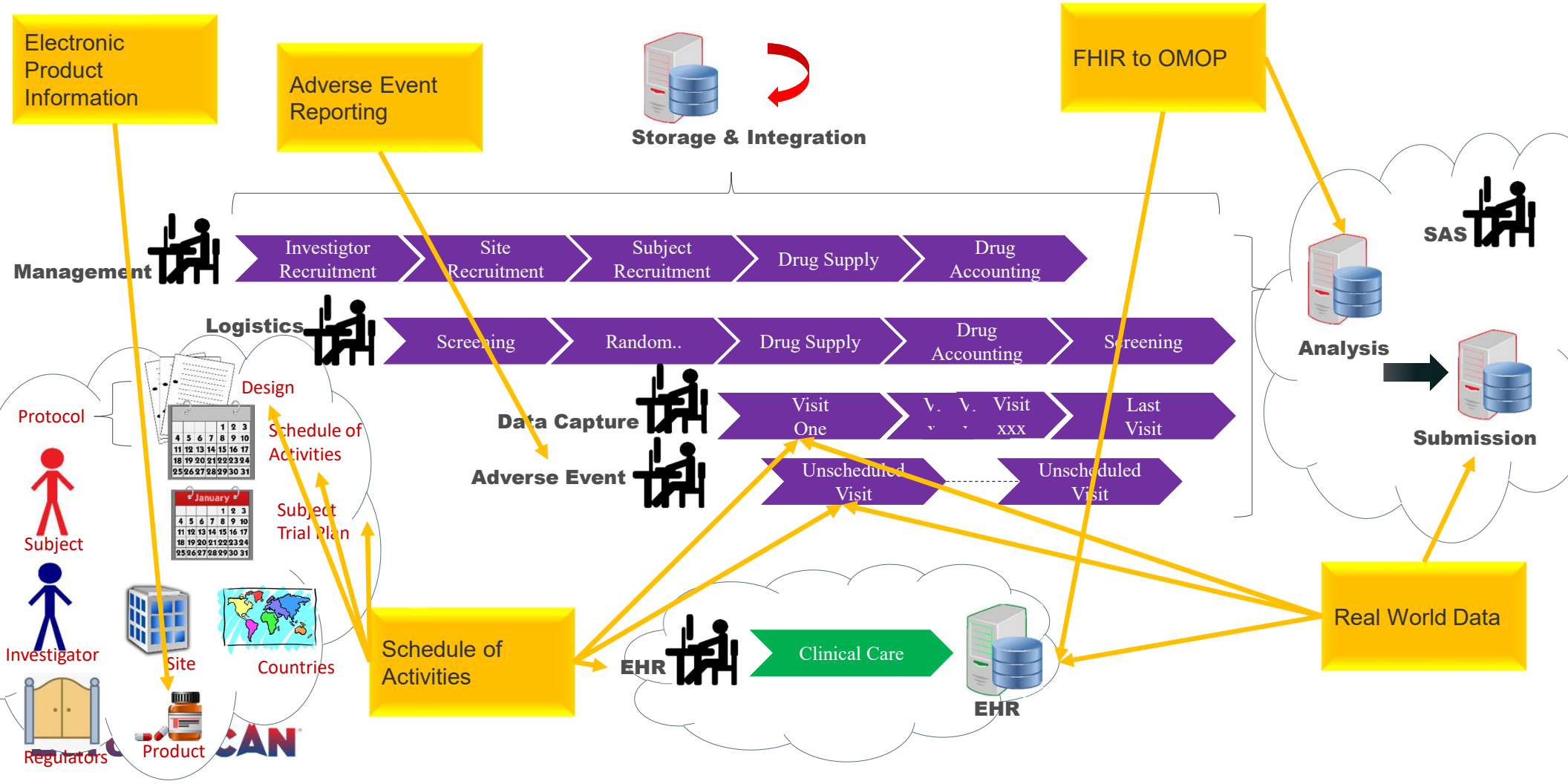
10:10 – 10:30 (20 minutes)



Project Connectathon



Clinical Research Business Processes



Schedule of Activities

Deals with things**:**

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

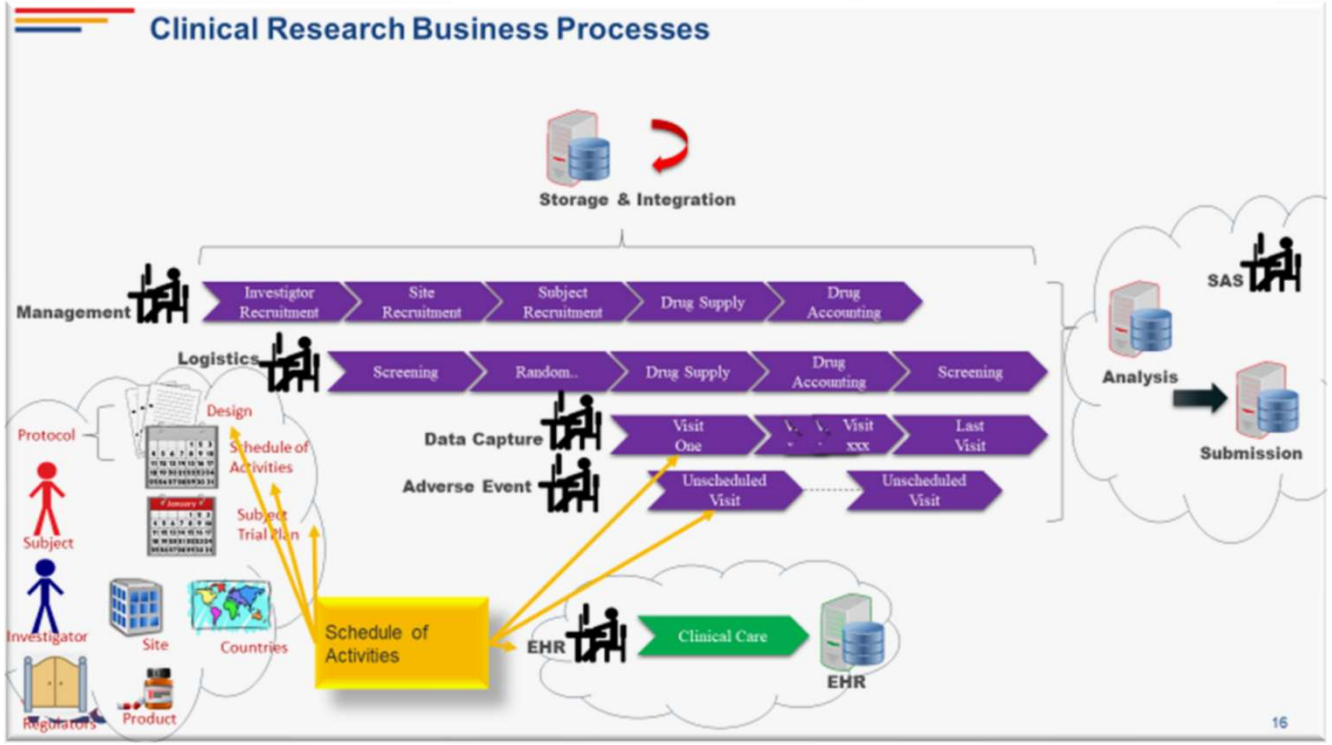
Deals with processes**:**

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

Spans**:**

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

IG first draft in January 2023



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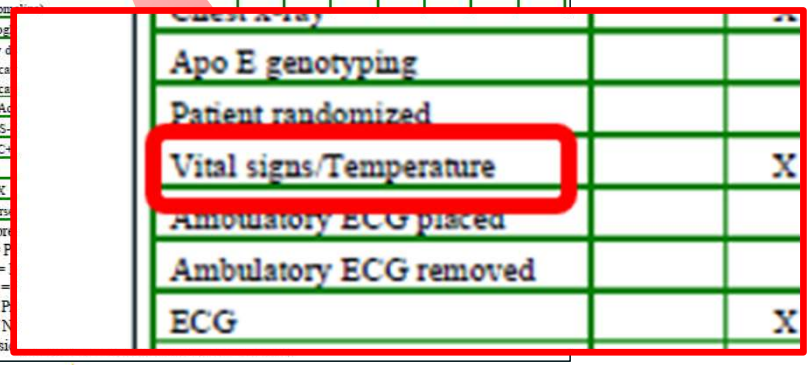
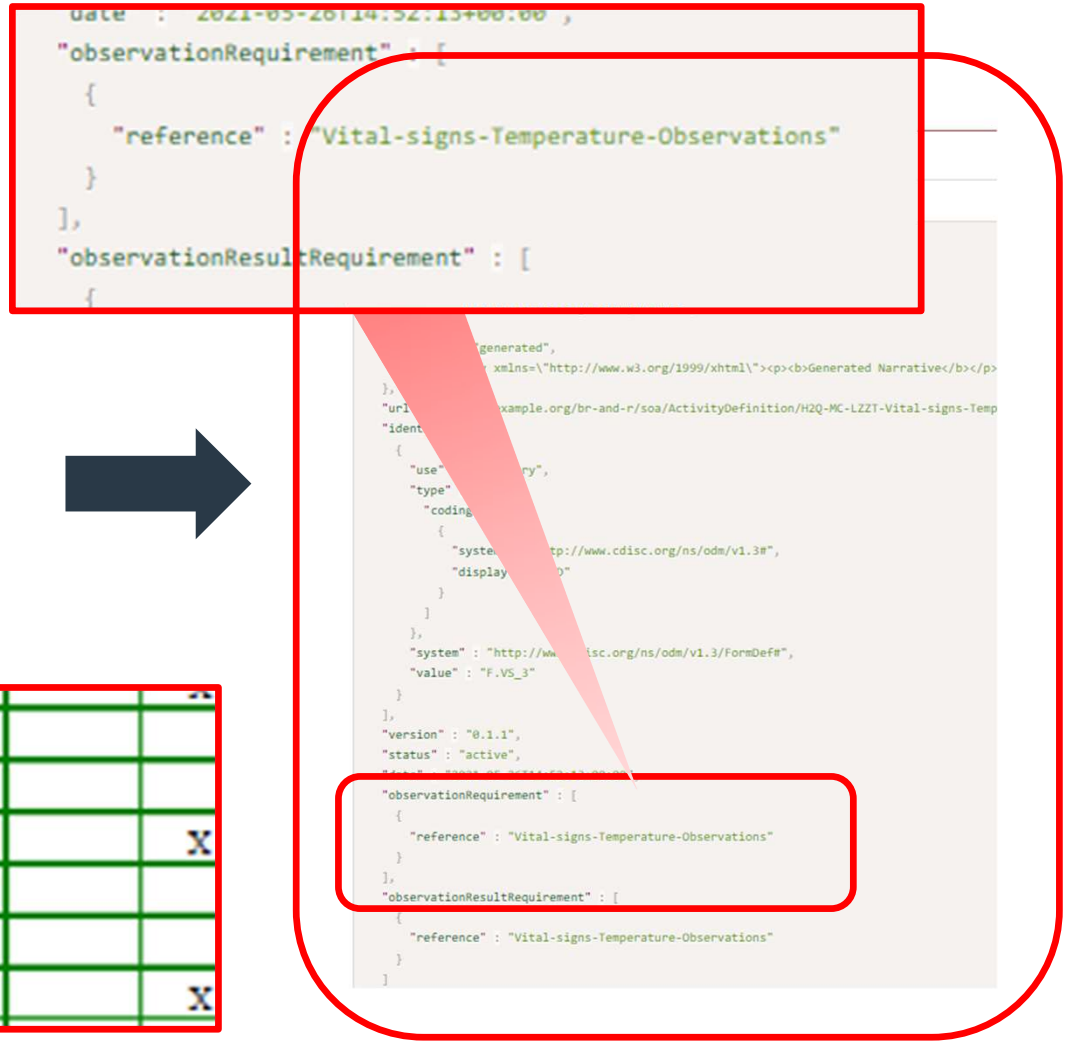
Schedule of Activities

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

	VISIT	1	2	3	4	5		7	8
ACTIVITY	WEEK	-2	-3	0	2	4		6	8
Informed consent		X							
Patient number assigned		X							
Hachinski ≤4		X							
MMSE 10-23		X							
Physical examination		X							
Medical History		X							
Habits		X							
Chest x-ray		X							
Apo E genotyping					X				
Patient 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 wit... last year and patient ... all other screens)		X							
Concomitant Medicatio...		X		X	X	X		X	X
Laboratory (Chem/Hemat...		X			X	X		X	X
Laboratory (Urinalysis)		X			X				
Plasma Specimen (Xanom...				X	X	X		X	
Hemog...									
Study d...									
Medica...									
Medica...									
TTS Ac...									
ADAS-...									
CIBIC-...									
DAD									
NPI-X									
Advers...									

Abbre...
X = P...
X[a] = ...
X[b] = ...
P = P...
and N...
consi...





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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 !!!!

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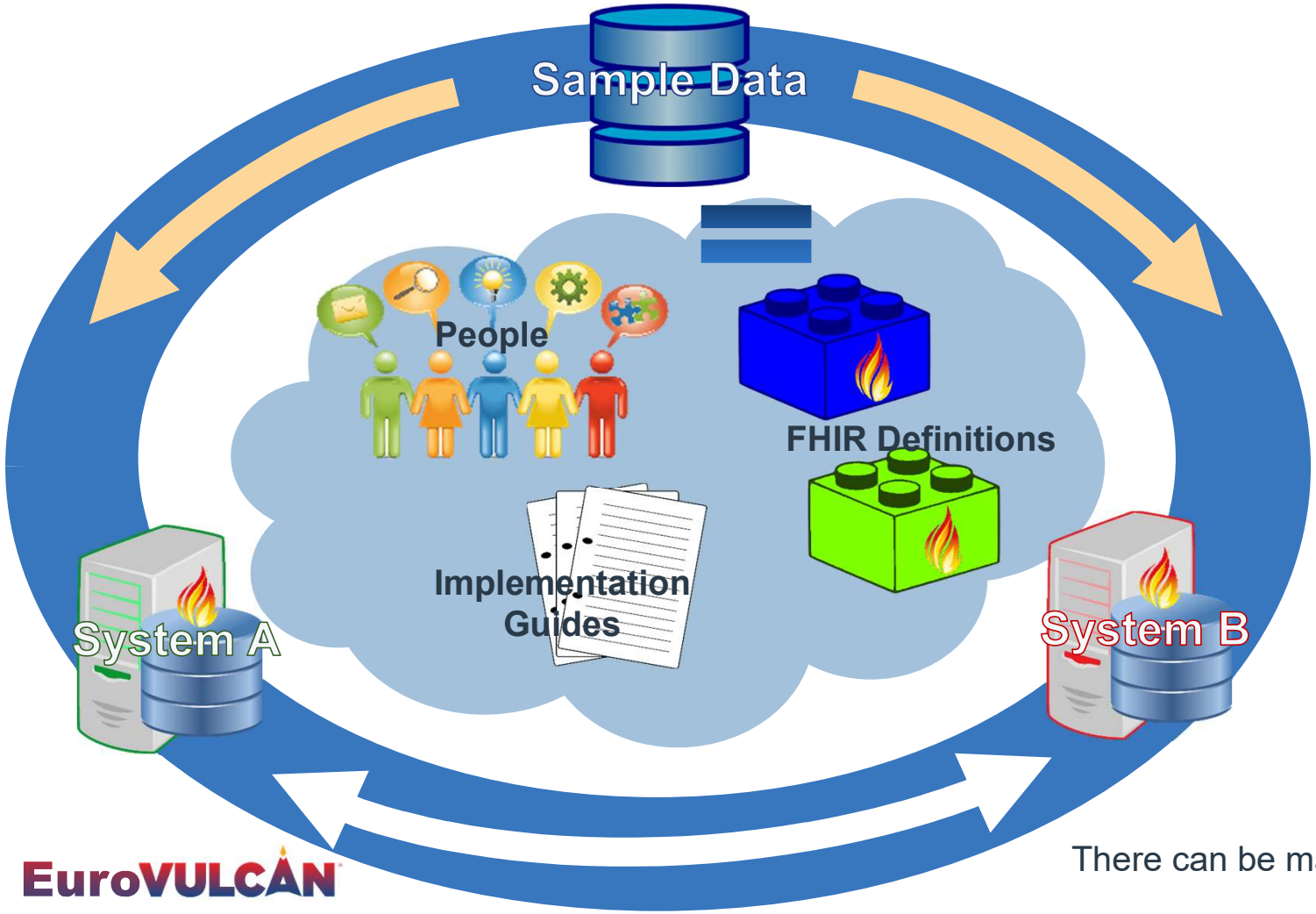
What's in a Connectathon?



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

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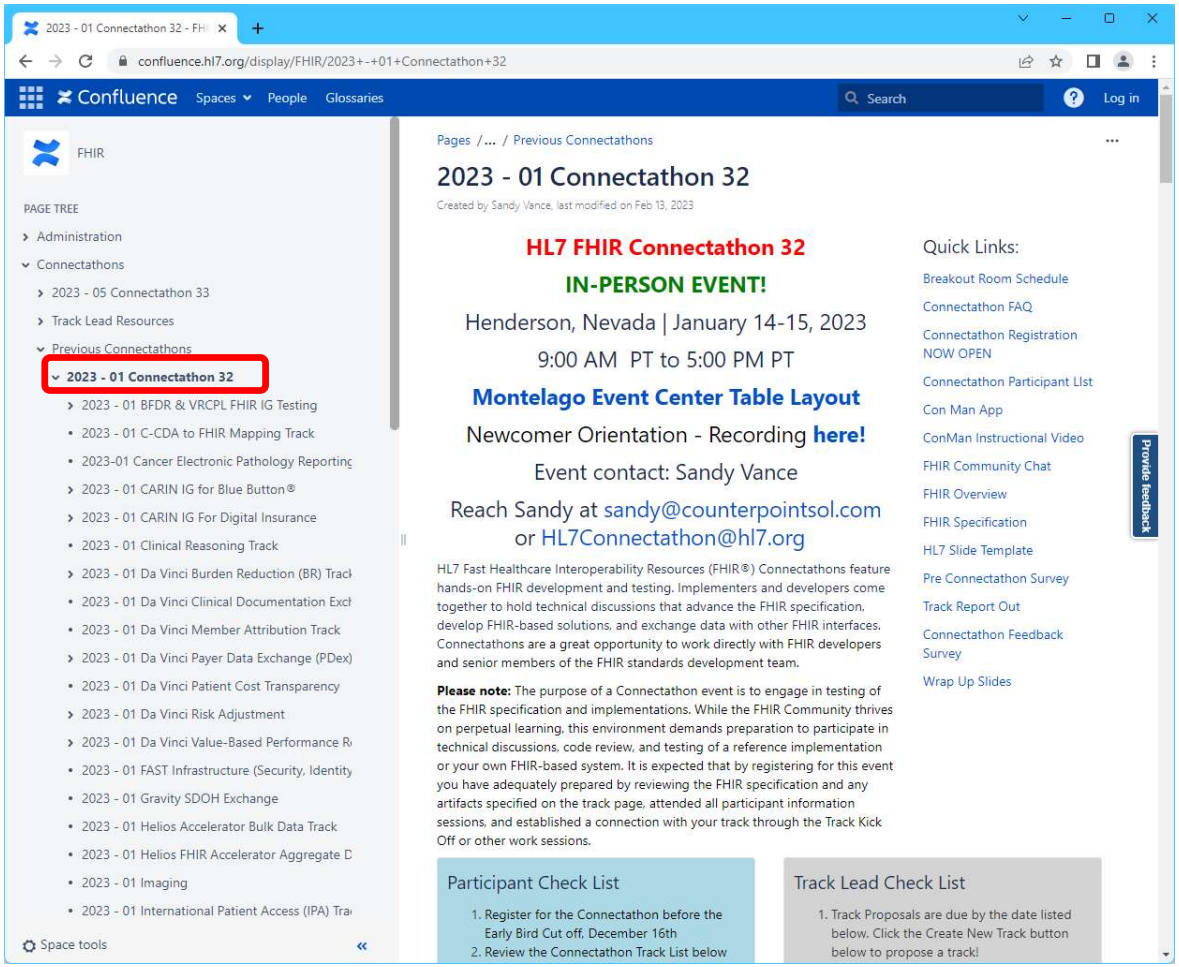
HL7 January 2023 Connectathon



Jan 2023

35 Tracks

250 Participants

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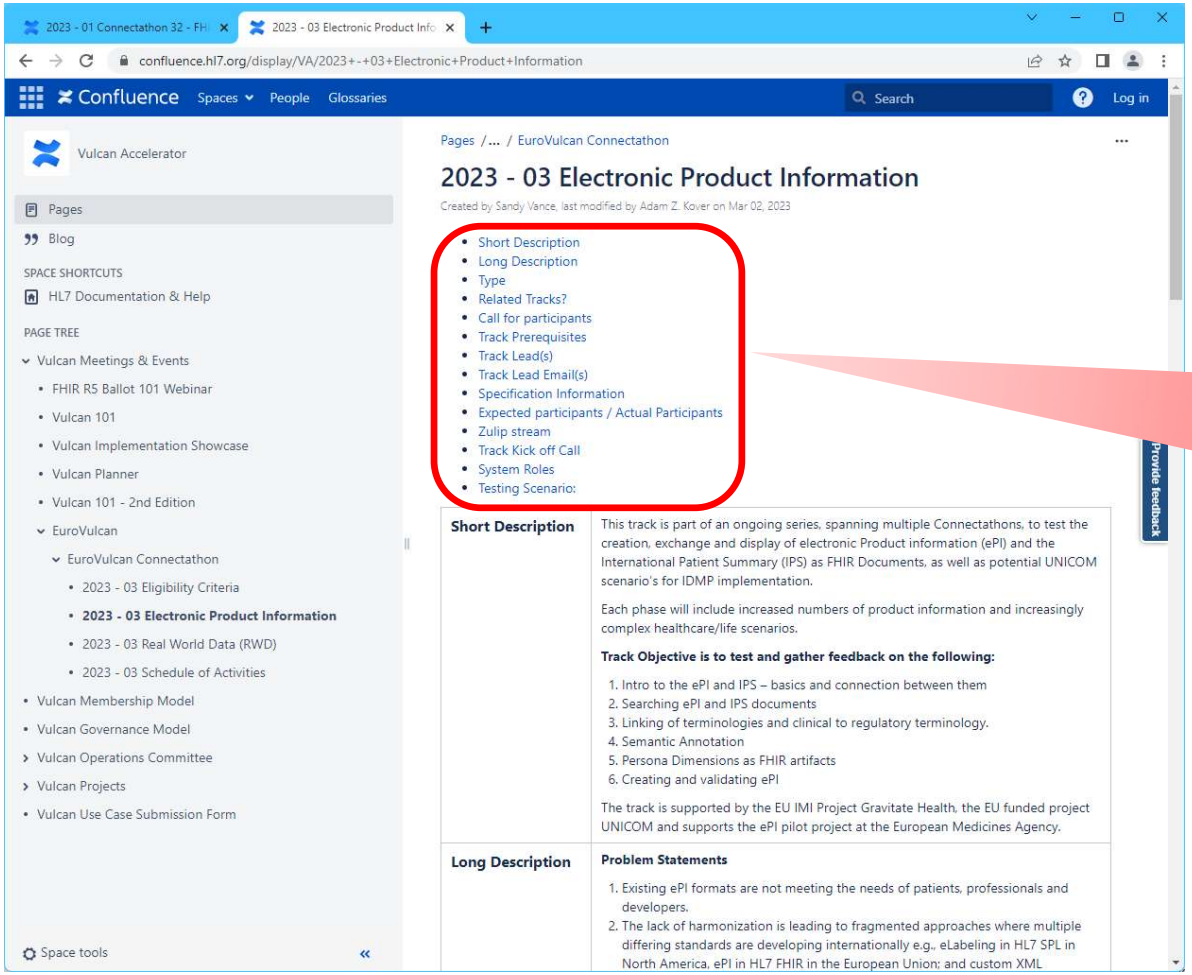
EuroVulcan – Example Track Details



- 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:

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Vulcan Connectathons to Date

7 Events
7 Topics
24 Tracks

Jan 2021
- SOA
- RWD
- Med
- Pheno

May 2021
- SOA
- RWD
- Med
- RWD
- Pheno

Sept 2021
- SOA
- RWD

Jan 2022
- RWD
- ePI
- AE

May 2022
- SoA
- ePI

Sept 2022
- SoA
- RWD
- ePI
- Pheno
- …

Jan 2023
- SoA
- RWD
- ePI
- FHIR 2 OMOP

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Real World Data

Jan 2021

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

May 2021

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

Sept 2021

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

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

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

Jan 2023

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

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Real World Data (RWD)

January 2022 Update

Activity

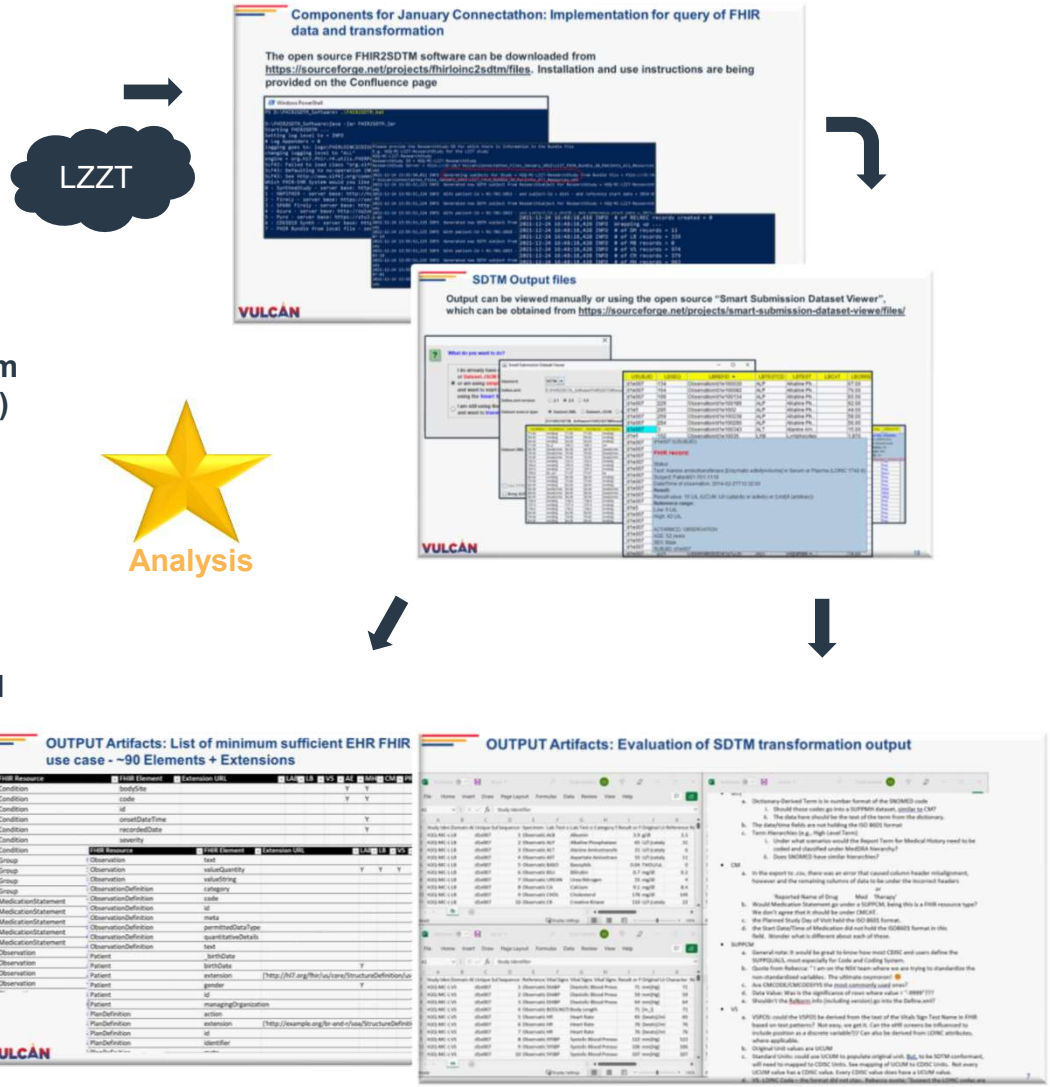
- All the details of the H2Q-MC LZZT study are in the public domain
- Data for 10 subjects has been loaded into FHIR to make a synthetic source and Software exists to extract the data from FHIR and put into SDTM (thanks to Jozef Aertz for this work)
- The track then set out to validate this work
  - Was the SDTM output appropriate and “correct”
  - What attributes in existing resources are actually used

Take Aways

- Standard terminology (eg LOINC) can provide several SDTM values from a single code, but this is underutilized
- FHIR is richer than SDTM and results in much use of Supplemental SDTM data sets

Next Steps

- Use the LZZT study as a basis for a first draft IG
- Iterate the IG using other studies



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Schedule of Activities (SoA)

May 2022 Connectathon Readout

Activity

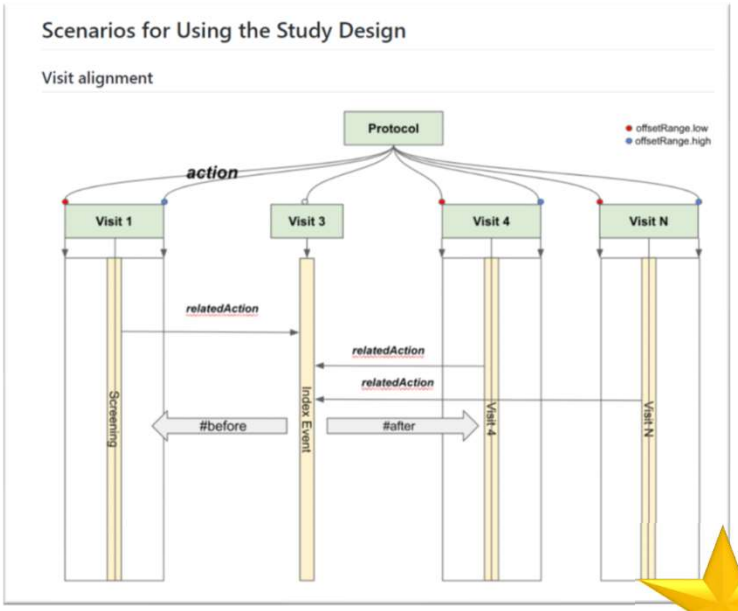
- Devised and implemented methodology for retrieval of patient resources for use in clinical research (pseudocode)
- Successfully executed all planned scenarios
- Created a set of resources that can be shared and reused for future events
- Published all developed code openly
- Identified an opportunity 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.

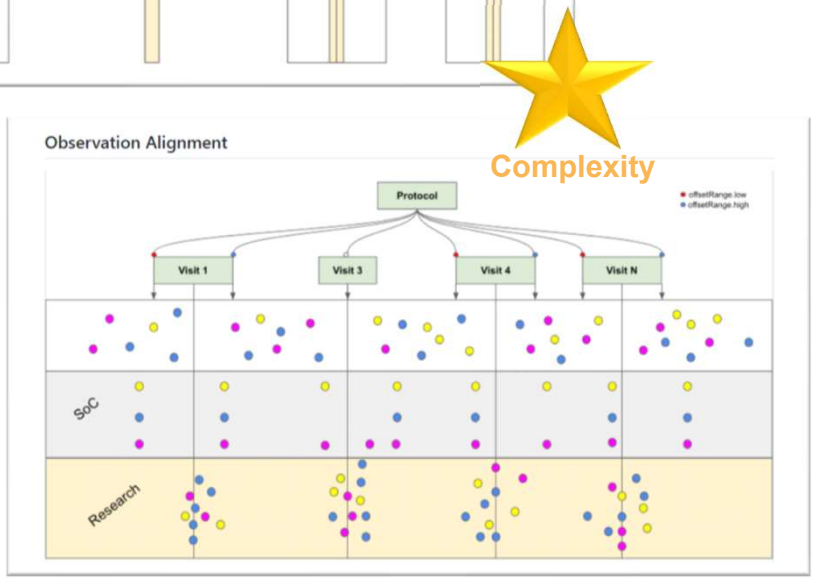
Take-Aways

- 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)





Complexity

Electronic Product Information (ePI)

May 2022 Connectathon Readout

Activity

- Successfully tested ePIs on a server with EU, US and Japanese labels.
- Testing confirmed that EMA and UNICOM scenario use cases are viable.
- No showstoppers; i.e., proven ability to consistently create and use FHIR ePIs.

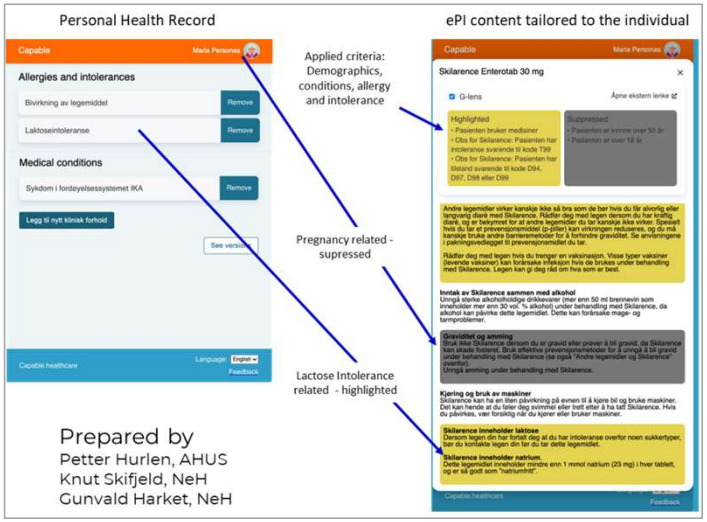
Take-Aways

- Productive collaboration between Gravitate Health, Vulcan, UNICOM and EMA.
- Connectathon is more valuable as a testing, learning and discussion forum rather a forum for building tools.
- High confidence that FHIR ePI can be used to support any global product label.
- Confirmed IDMP's Pharmaceutical Product Identifier (PhPID) is effective in ePI.

Application

Next Steps

- Begin preparing final version of the Implementation Guide for year end ballot.
- Finalize global profile and regional profiles (EMA, FDA and Japan).



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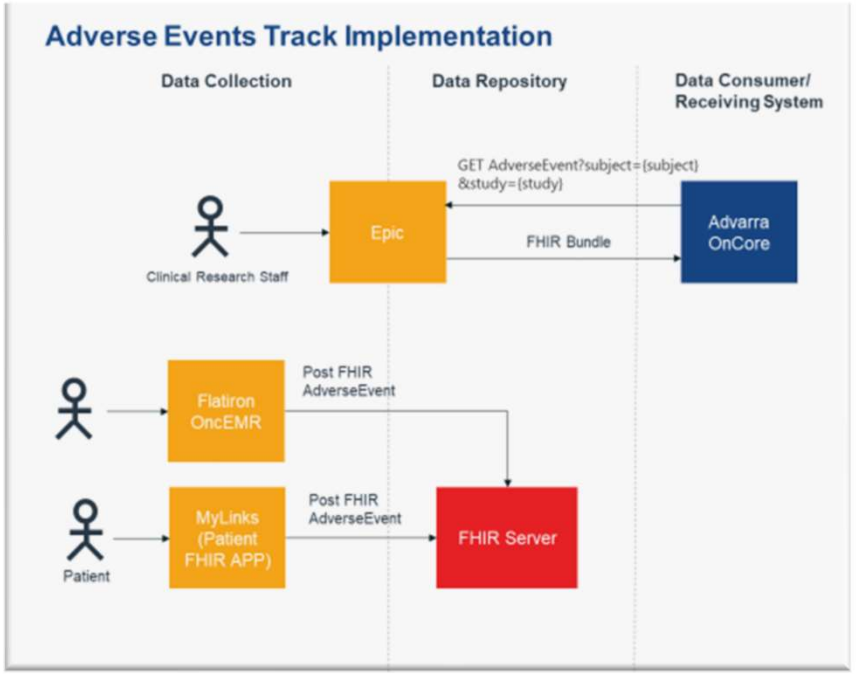
Adverse Events (AE)

January 2022 Update

Contribution

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

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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

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Questions?

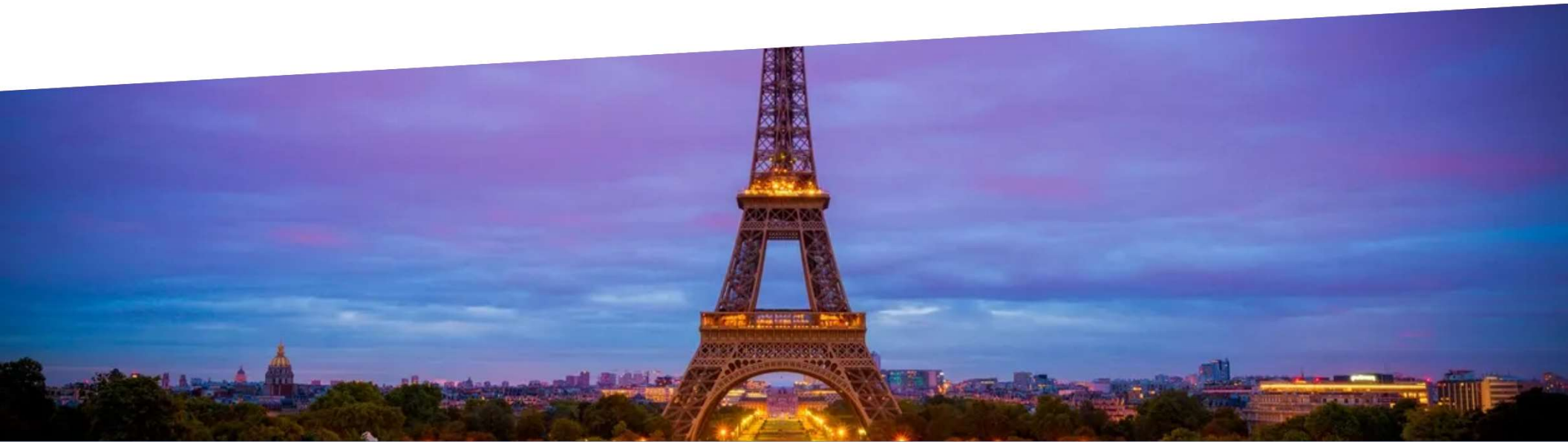
Networking Break

10:30 – 11:00

4. Vulcan Fundamentals

Stacy Tegan, Vulcan / TransCelerate Biopharma

11:00 – 11:20



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Let's take an inside tour of Vulcan

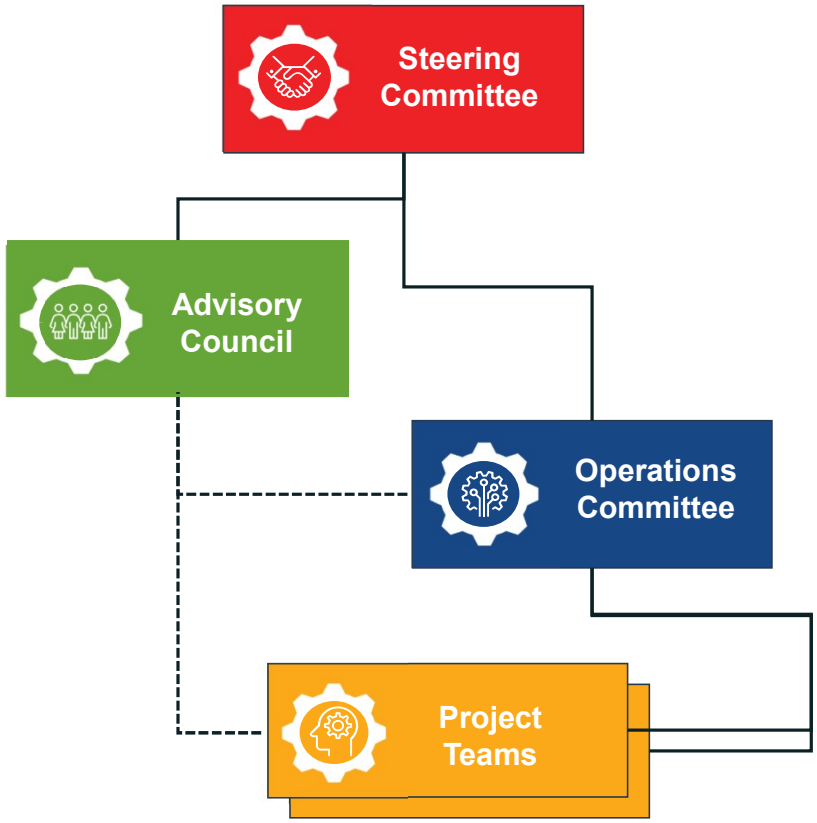
Current Member Organizations of Vulcan

As of February 2023

VULCAN

★ *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

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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

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Vulcan Operations Committee


Maryam Garza Mike Hamidi

Operations Committee Co-Chairs

Operations Committee

- 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

accenture, ACRO, BioVeras, Cedars Sinai, cdisc, Crohn's & Colitis Foundation, Lægemiddelstyrelsen Danish Medicines Agency, Duke University School of Medicine, Droice Labs, Epic, FDA, Felleskatalogen, Fujitsu, GSK, HL7 International, IgniteData, infor, InterSystems Health | Business | Government, Johns Hopkins School of Medicine, Johnson & Johnson, medidata, Microsoft, MITRE, 国立がん研究センター 東病院 National Cancer Center Hospital East, NIH National Center for Advancing Translational Sciences, NIH U.S. National Library of Medicine, OpenClinica, ORACLE, Oregon Health & Science University, parexel, patientlink MyLinks, Pfizer, phuse, Roche, SCDM Society for Clinical Data Management DATA DRIVEN, TransCelerate BIOPHARMA INC., UAMS University of Arkansas for Medical Sciences, UiO University of Oslo, University of Colorado Anschutz Medical Campus, UT Health San Antonio Joe R. & Teresa Lozano Long School of Medicine, Vanderbilt University

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Vulcan Advisory Council Committee

Becky Kush

Advisory Council Chair

Advisory Council

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

Membership

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

- 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

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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.

Member Benefit

Conferences
(geographical)

Connectathons
(testing)

Round Tables
(topical)

Vulcan 101
(full day course)

Implementation Showcases

There are many opportunities to engage with the Vulcan community

VULCAN

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

Implementation Showcases

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Have an idea for showcase? Contact Vulcan@hl7.org

January Connectathon

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Yes, those are "FHIR hats"!

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Vulcan Projects

March 2022

Project / Vulcan Leads	Objectives	Status
Schedule of Activities (SoA) **Mike Ward** (TransCelerate) **Geoff Low** (PHUSE)	• 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	Implementation Guide Available
Real World Data (RWD) **Scott Gordon** (FDA) **Open**	• 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.	Implementation Guide Available

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Vulcan Projects
March 2022

Project / Vulcan Leads	Objectives	Status
Electronic Product Information (ePI) ***Craig Anderson*** (Pfizer) ***Catherine Chronaki*** (Secretary General at HL7 Europe)	• Collaboration with Gravitate 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. Note: This project operates in full alignment with other FHIR related activities at EMA, FDA and other regulators.	Implementation Guide Available
Phenotypic Data ***Anita Walden*** (University of Colorado Anshutz) ***Shahim Essaid*** (University of Colorado Anschutz)	• 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	In progress

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Vulcan Projects
March 2022

Project / Vulcan Leads	Objectives	Status
Adverse Events (AE) ***Michelle Casagni*** (MITRE) ***Ed Millikan*** (FDA)	• 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 ***Davera Gabriel*** (Johns Hopkins) ***Catherine Diederich*** (Duke)	• 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

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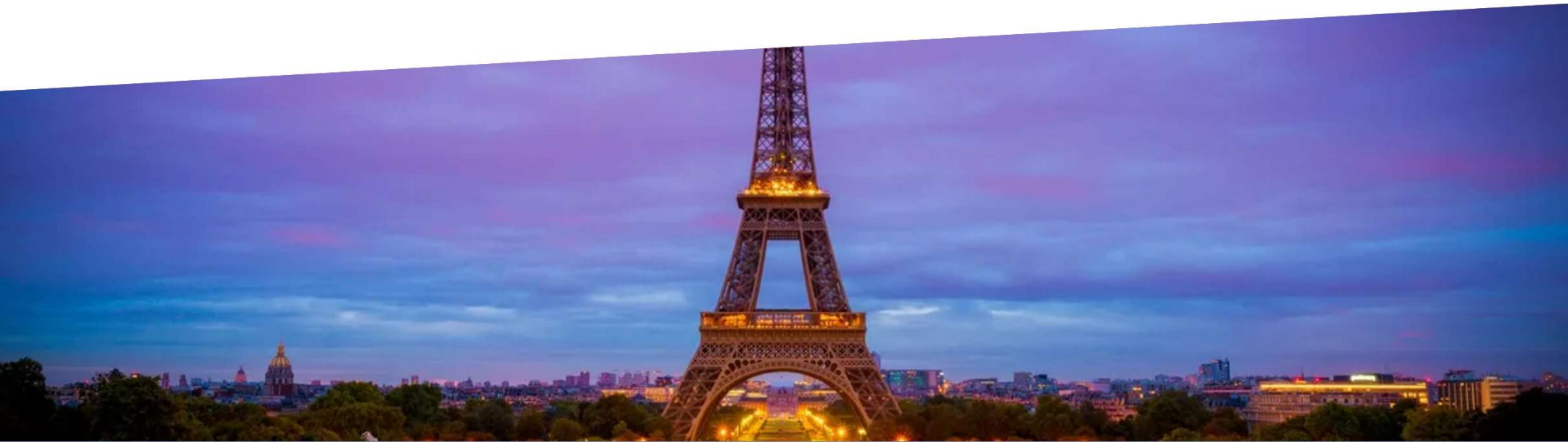
Questions?

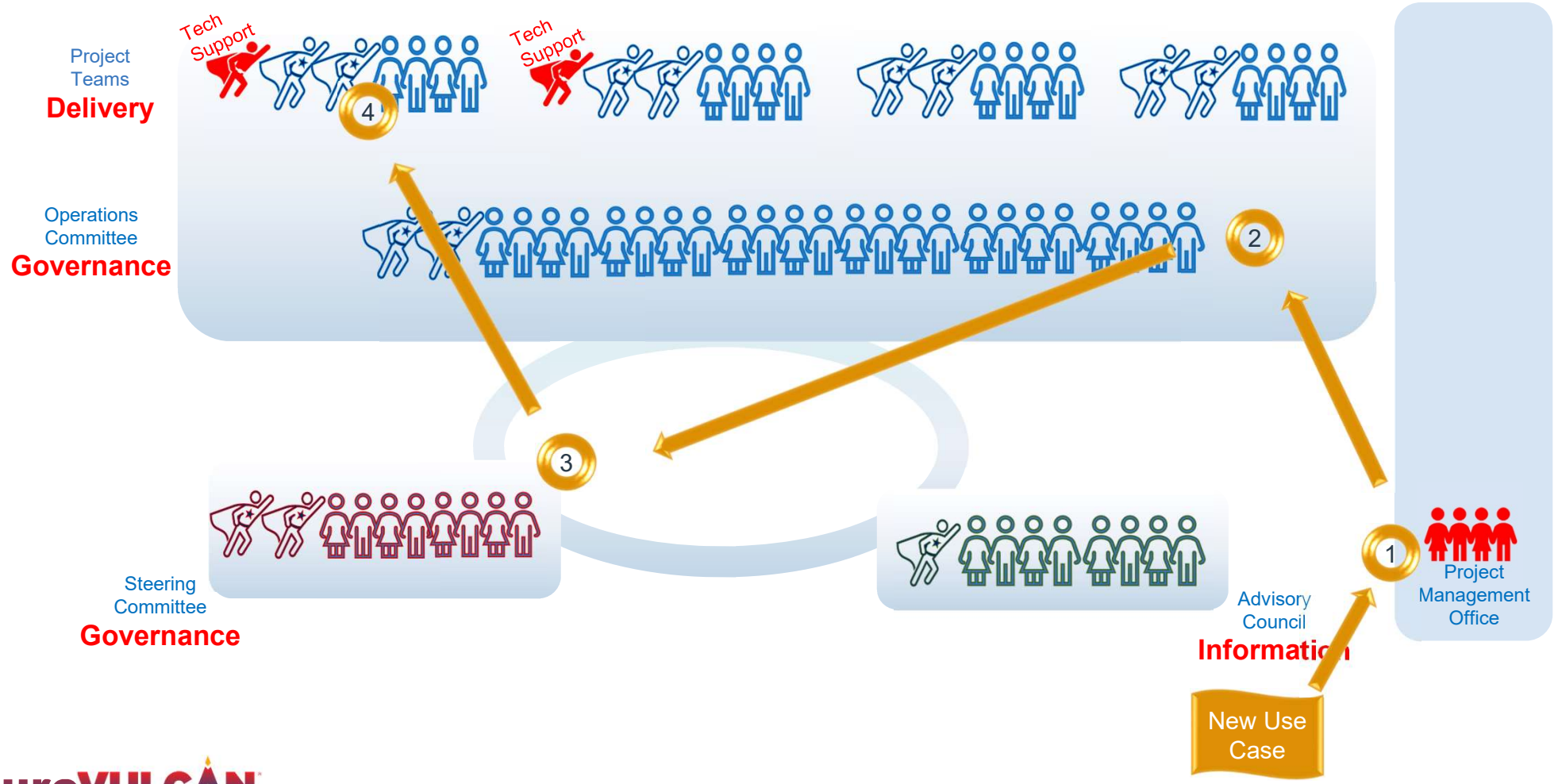
5. The Vulcan Project Process

Hugh Glover, Vulcan

11:20 – 11:35



Organization and Responsibility



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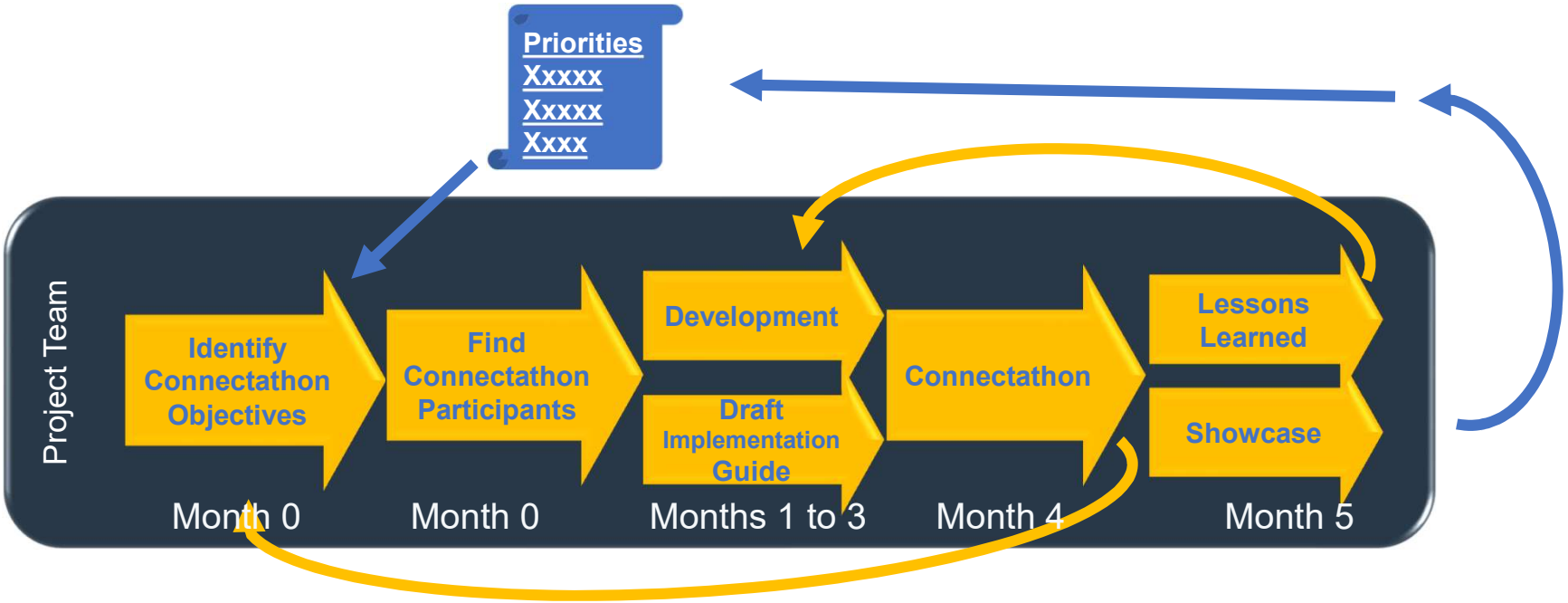
Vulcan Project Work Cycle



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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

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

Electronic Product Information

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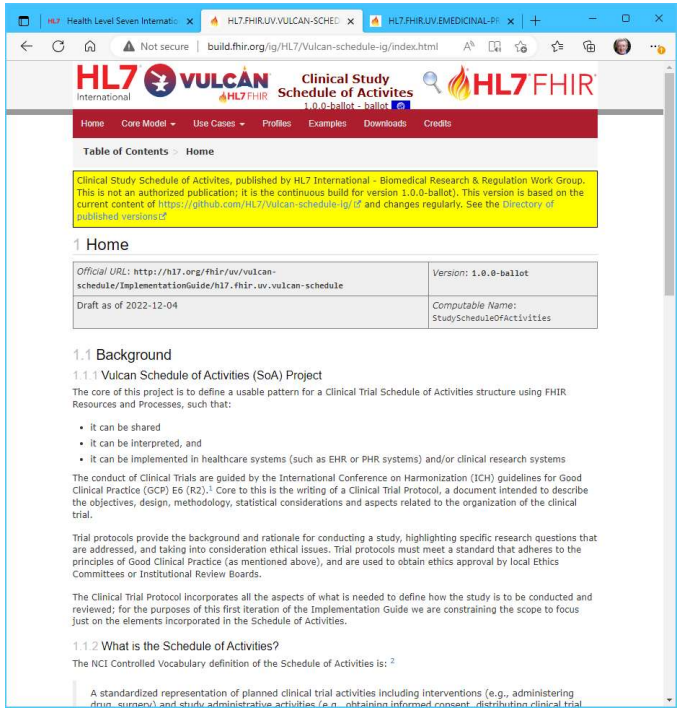
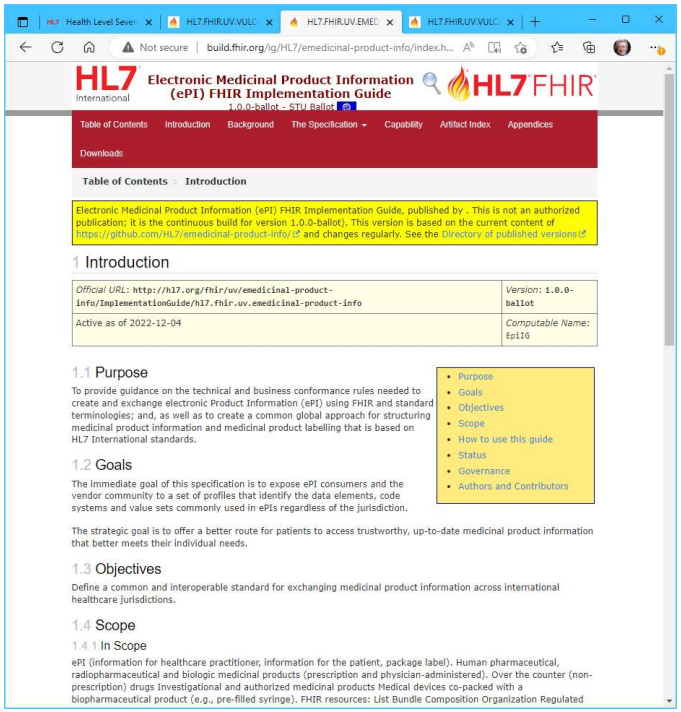
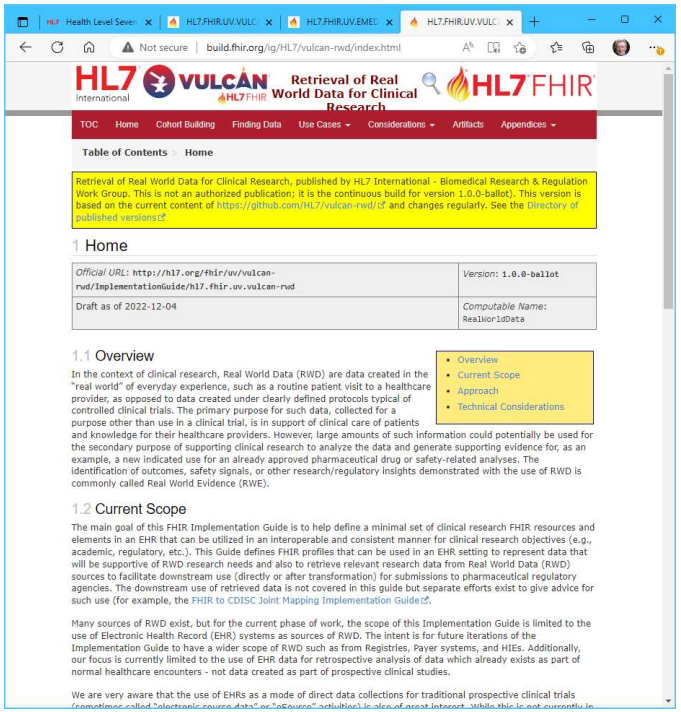
3 Vulcan Implementation Guides



Schedule of Activities



Electronic Product Information



Real World Data

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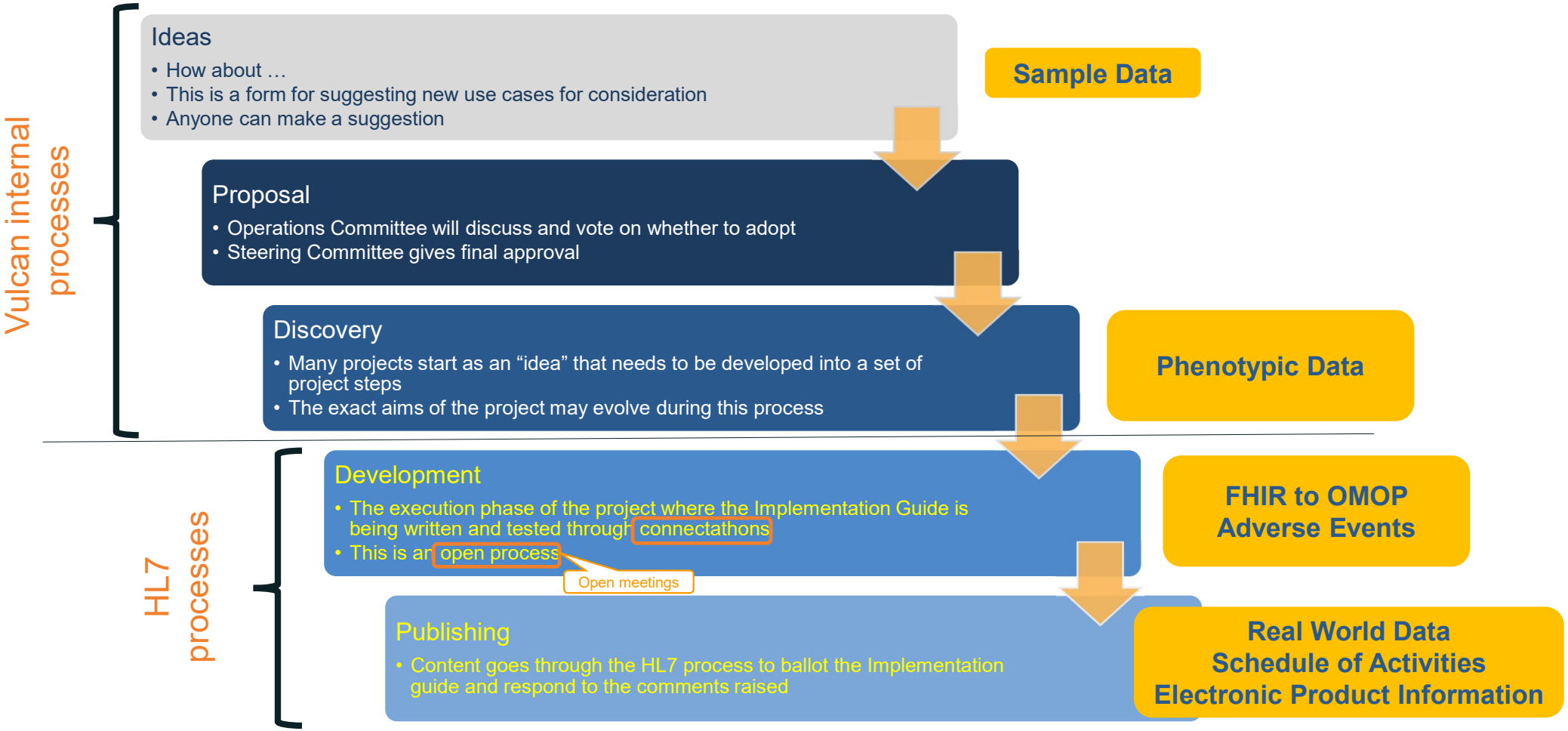
Project Evolution

Clarifying the Process



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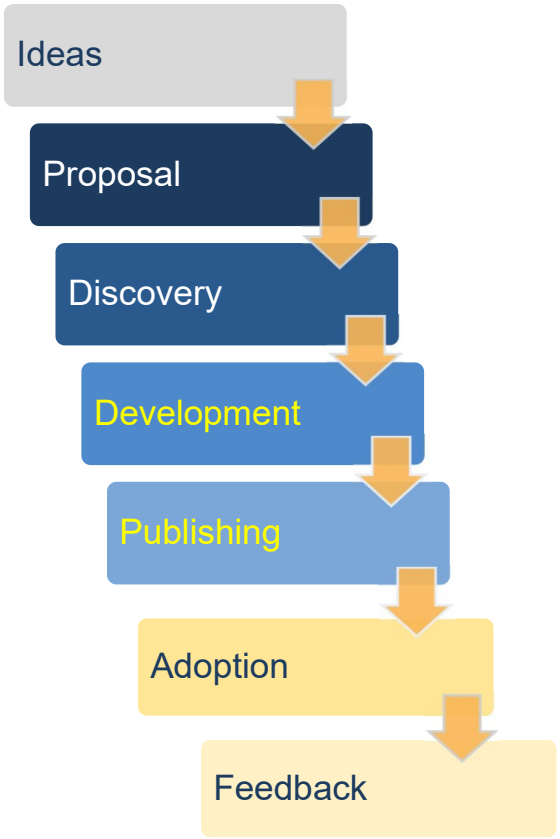
Evolution
Three Principles



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

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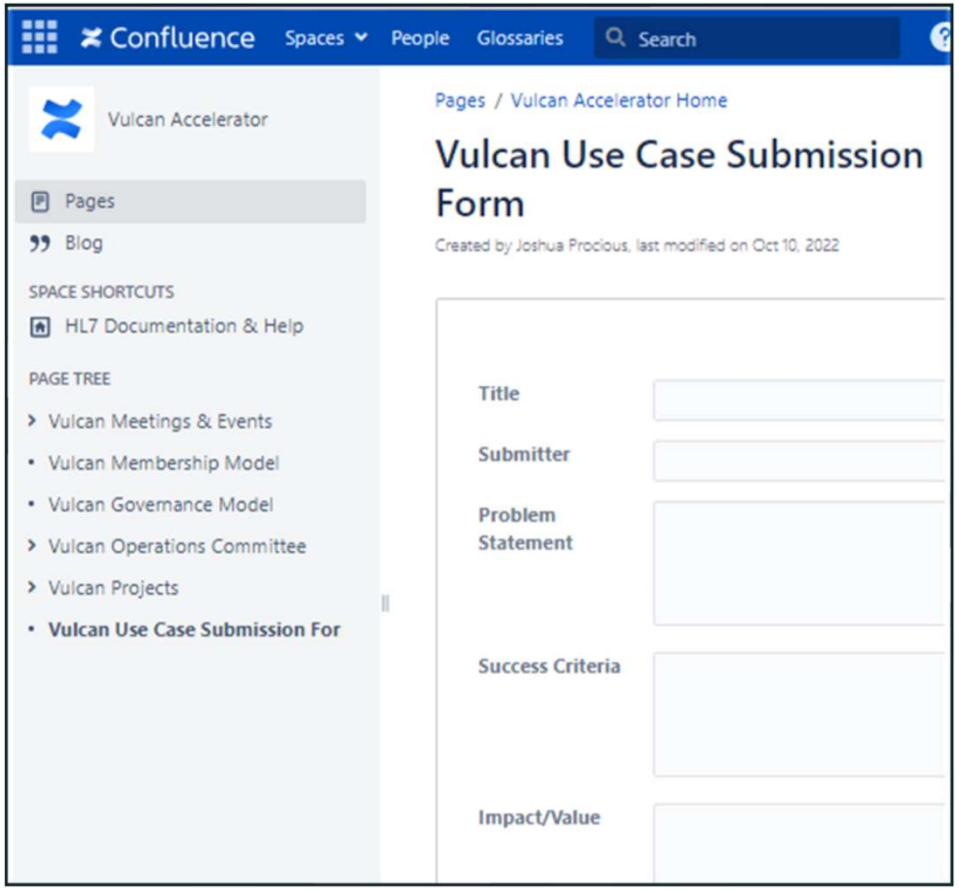
Making a Use Case Proposal

- 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.



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

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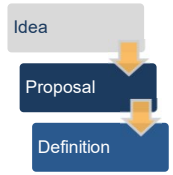
Project Evolution and Control – Initial Process Gates



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

- 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

➢ **Define Project**
Project Leads
4

5 ➢ **Approve Project**
Steering Committee

6 ➢ **Do Discovery**
Project Team

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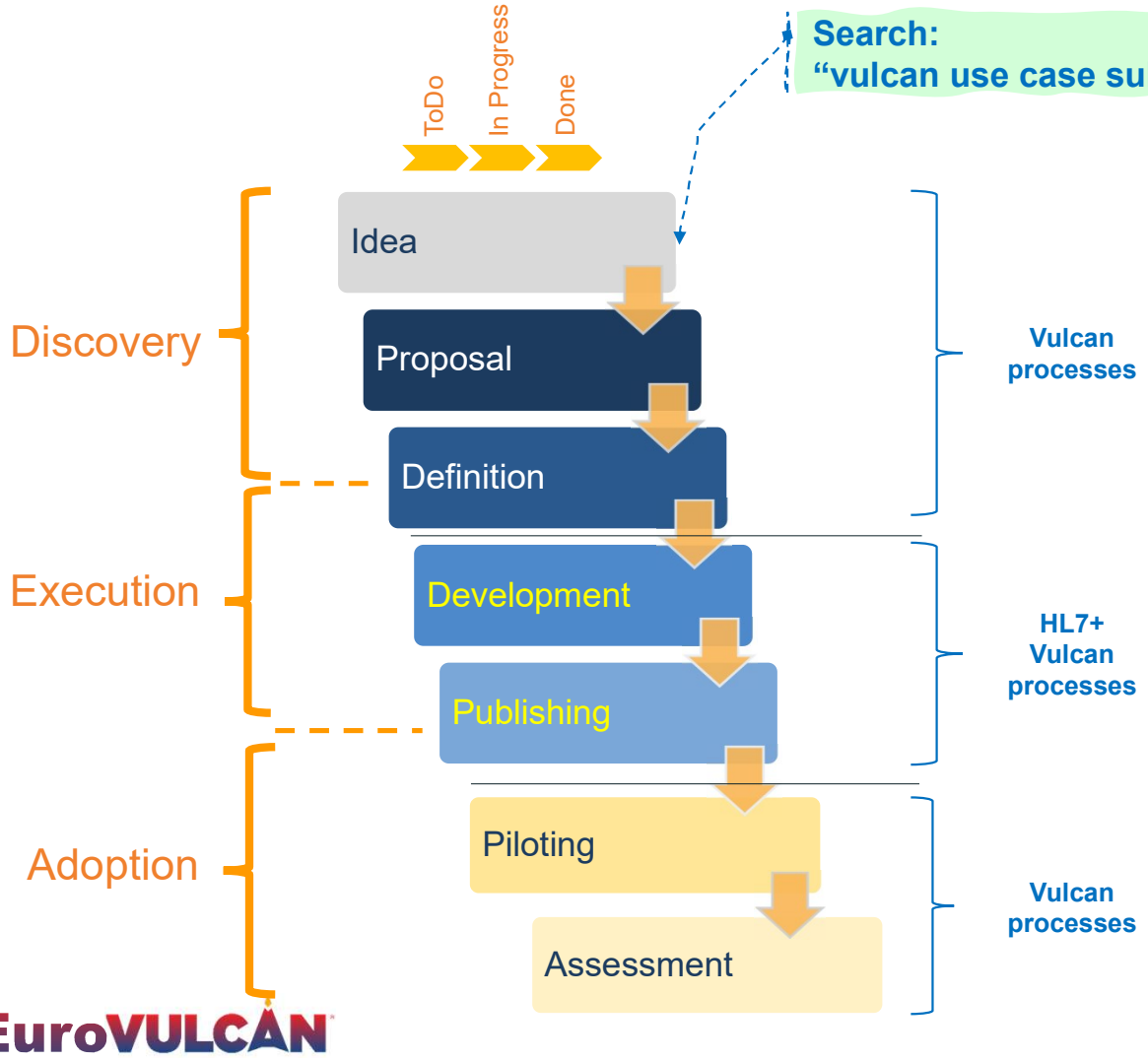
Project Evolution and Control – Summary



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

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Questions?

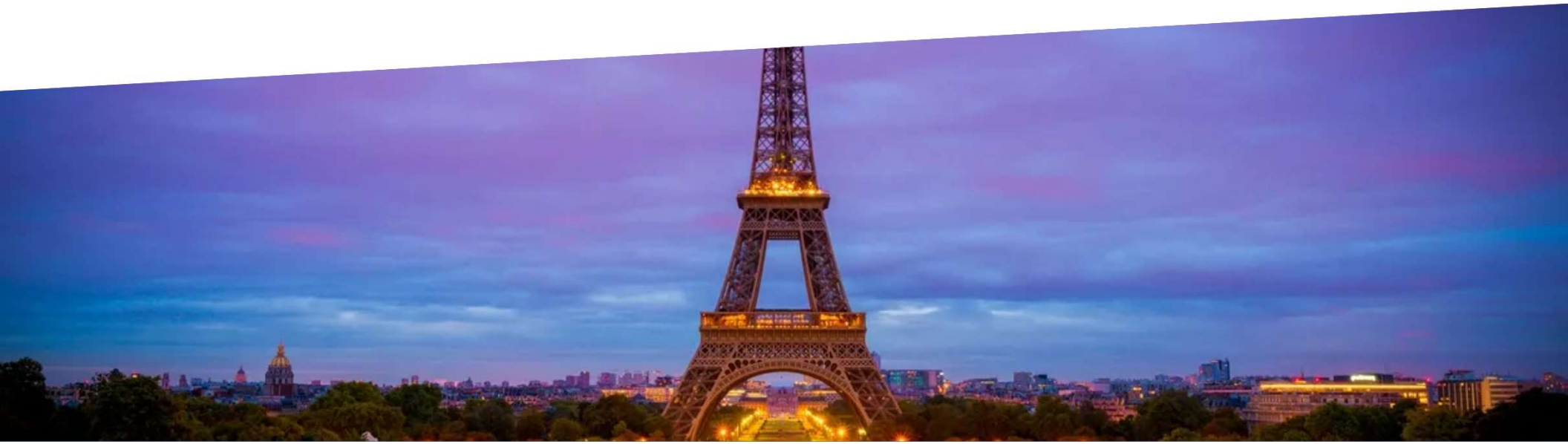
6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA

Evinn Drusys, AEMPS

Jose Galves, FDA (remote)

11:35 – 12:20



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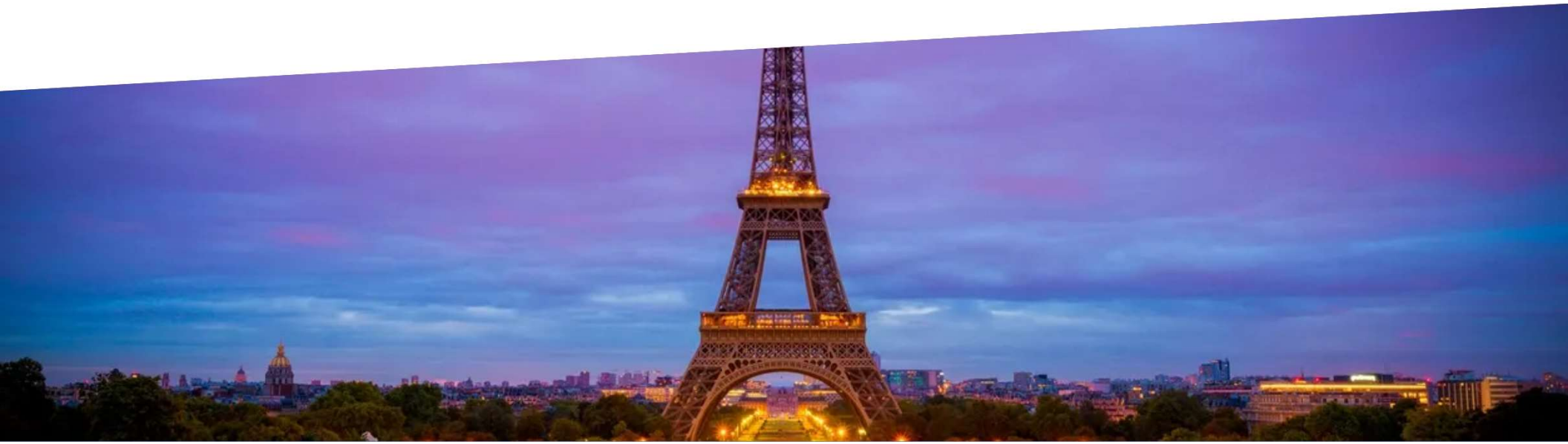


Towards a harmonised EU ePI – the EMA perspective

EuroVulcan Conference March 2023

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

Disclaimer

The presenter does not have any conflict of interests.

Today's PI in PDF

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

Page 1 of 96

1. NAME OF THE MEDICINAL PRODUCT

Lyrica 25 mg hard capsules
Lyrica 50 mg hard capsules
Lyrica 75 mg hard capsules
Lyrica 100 mg hard capsules
Lyrica 150 mg hard capsules
Lyrica 200 mg hard capsules
Lyrica 225 mg hard capsules
Lyrica 300 mg hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lyrica 25 mg hard capsules
Each hard capsule contains 25 mg of pregabalin.

Lyrica 50 mg hard capsules
Each hard capsule contains 50 mg of pregabalin.

Lyrica 75 mg hard capsules
Each hard capsule contains 75 mg of pregabalin.

Lyrica 100 mg hard capsules
Each hard capsule contains 100 mg of pregabalin.

Lyrica 150 mg hard capsules
Each hard capsule contains 150 mg of pregabalin.

Lyrica 200 mg hard capsules

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

Lea todo el prospecto detenidam

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?
ollten Sie vor der Einnahme von Lyrica beachten?
st Lyrica einzunehmen?
e Nebenwirkungen sind möglich?
st Lyrica aufzubewahren?
t der Packung und weitere Informationen

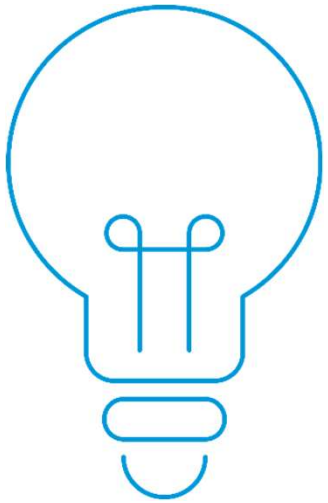
Abschnitt vorlesen lassen

st Lyrica und wofür wird es angewendet?

rt zu einer Gruppe von Arzneimitteln, die bei Erwachsenen zur Behandlung von

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

Benefits for patients and healthcare professionals

Case 1

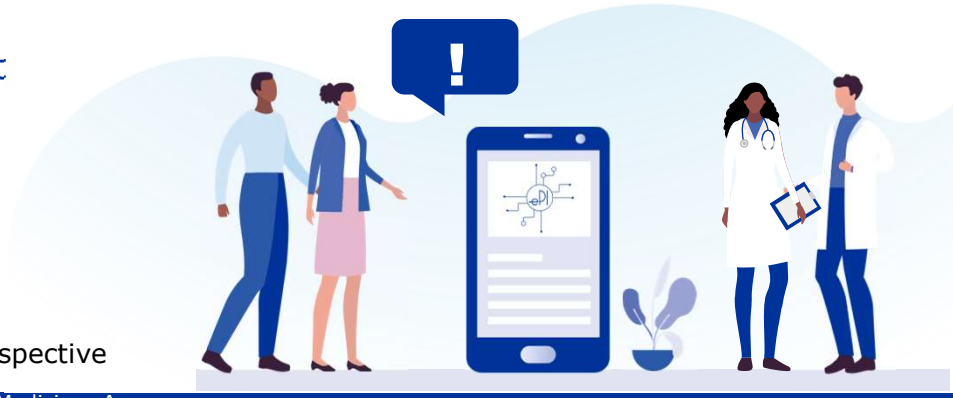
List of patient medicines ePI in phone app
Does not remember how to take asthma medicine
Goes to 'How to take your medicine' to downloadable video
Receives alert when ePI updated e.g. new safety information

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



Benefits for regulators, national authorities, companies

Case 1

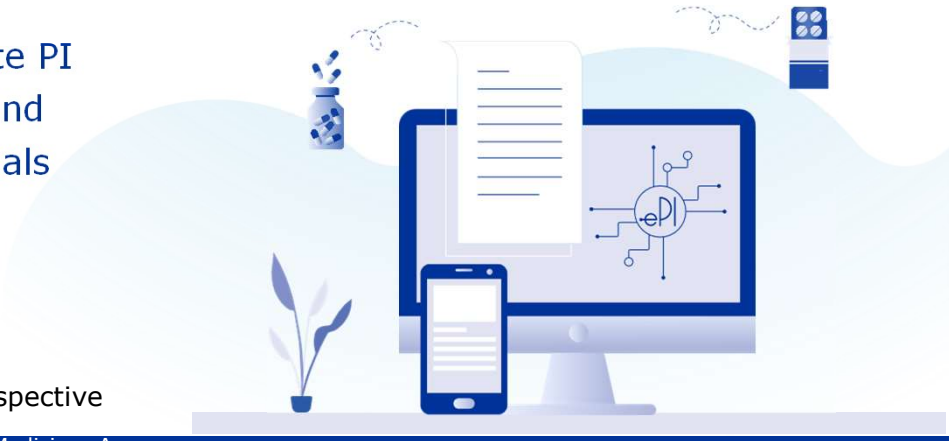
Medicine shortage anticipated in country A
Import medicine from country B, link to ePI in language A
Shortage mitigated

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



Minimum Viable Product tooling in development

Developed with funding by the European Union

ePI authoring portal

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

User: Companies

Rich text editing functionality

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

User: Companies

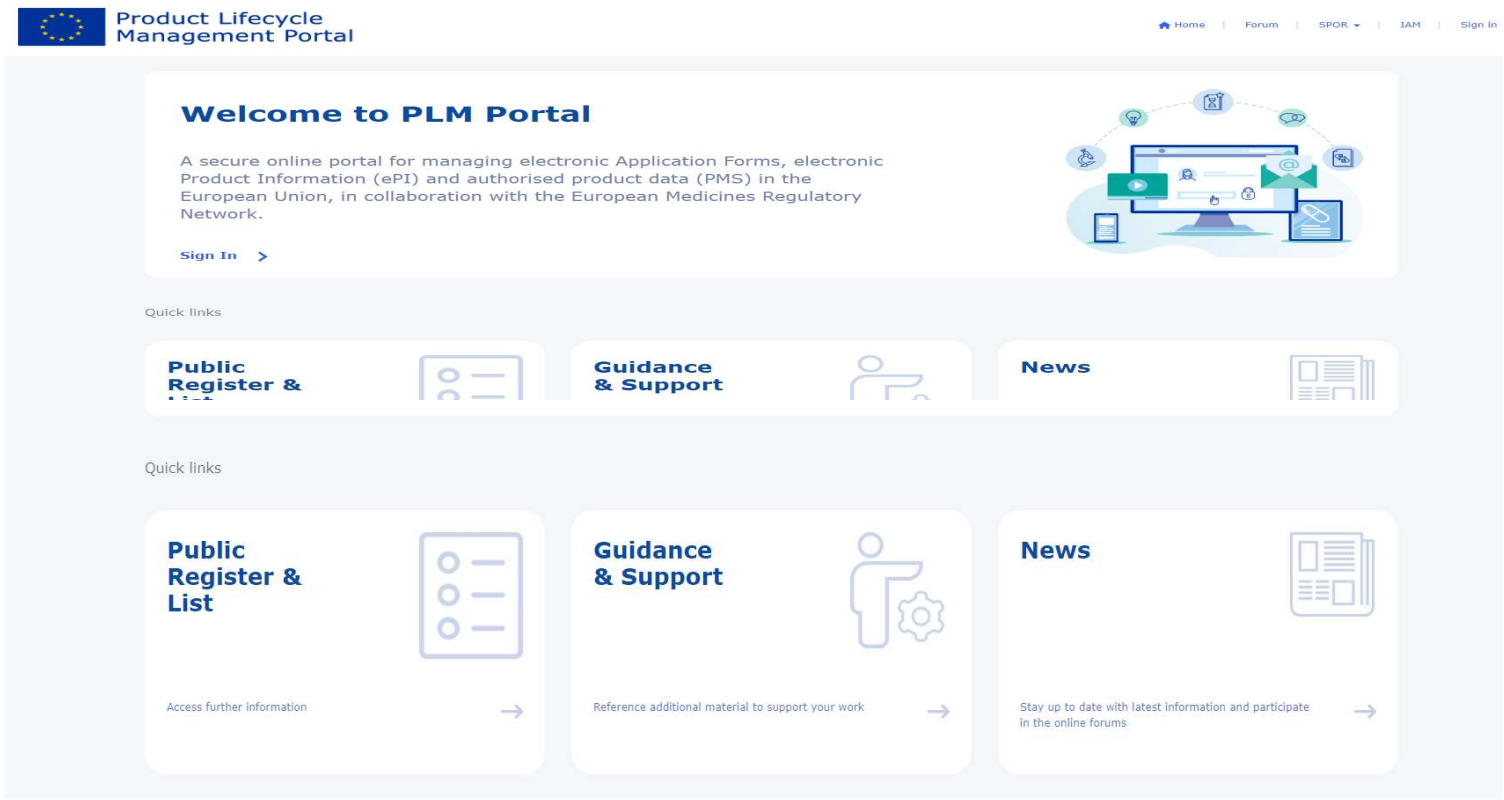
Repository and API

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

Users:
Companies
Regulators
eHealth developers

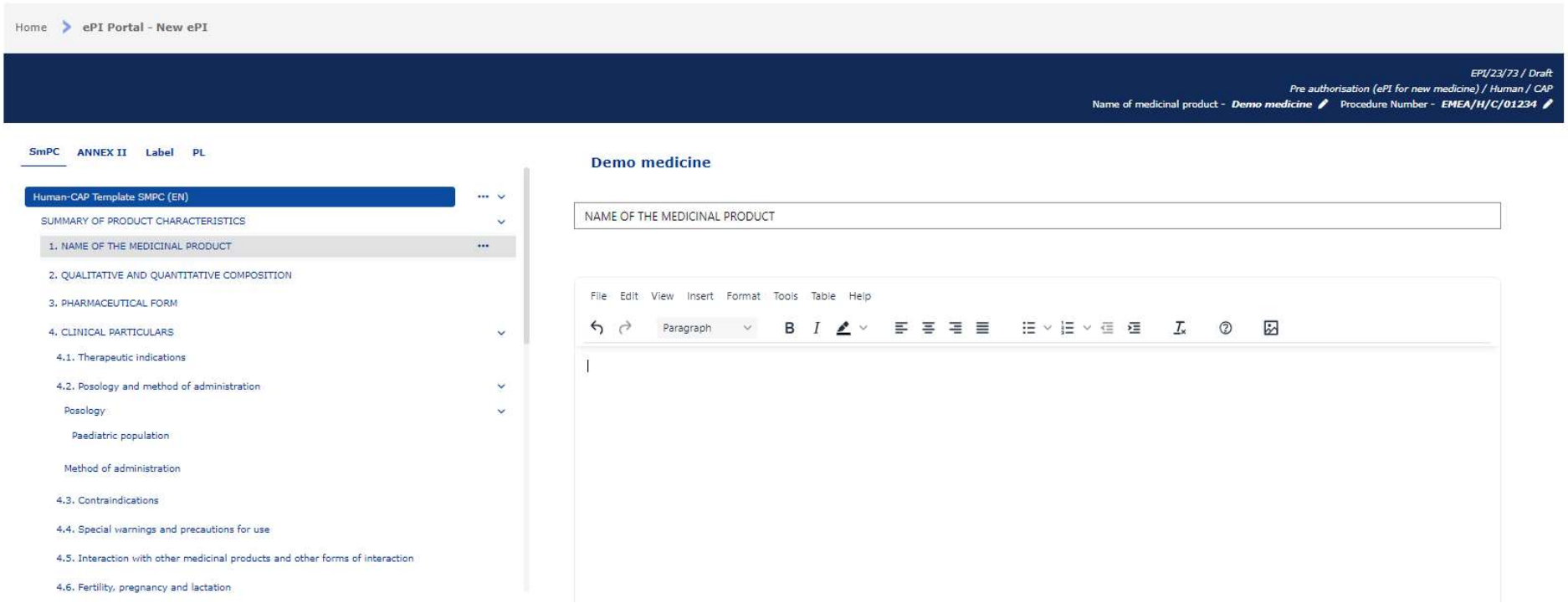
MVP in Product Lifecycle Management Portal

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

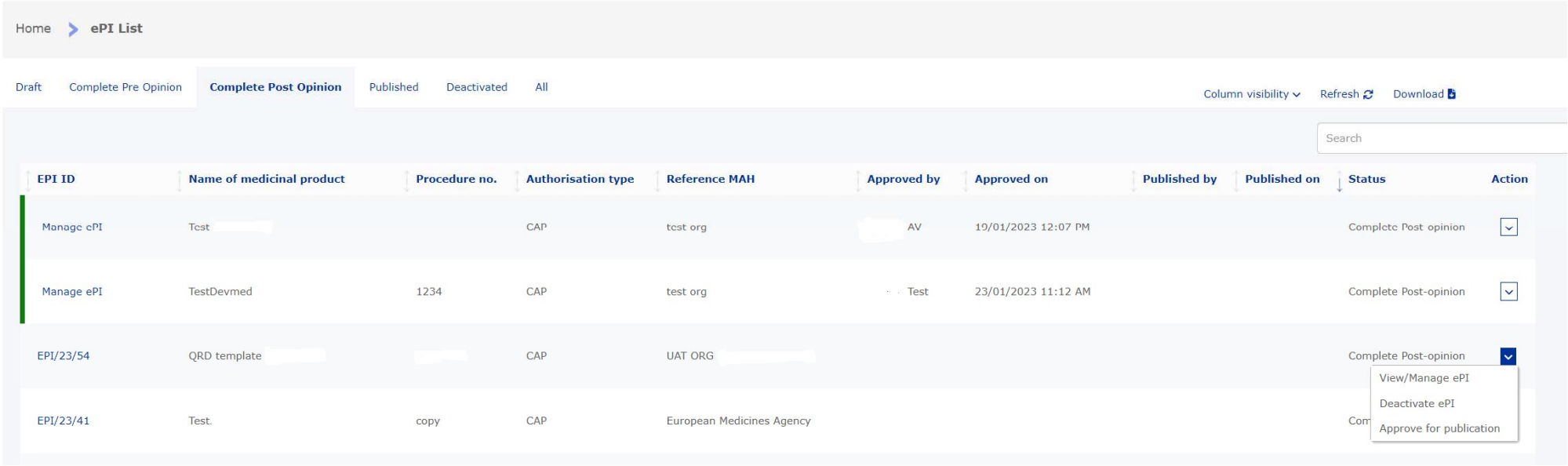


From the same portal, applicants can manage ePI, electronic application forms and product data.

Tree-view for authoring of PI documents

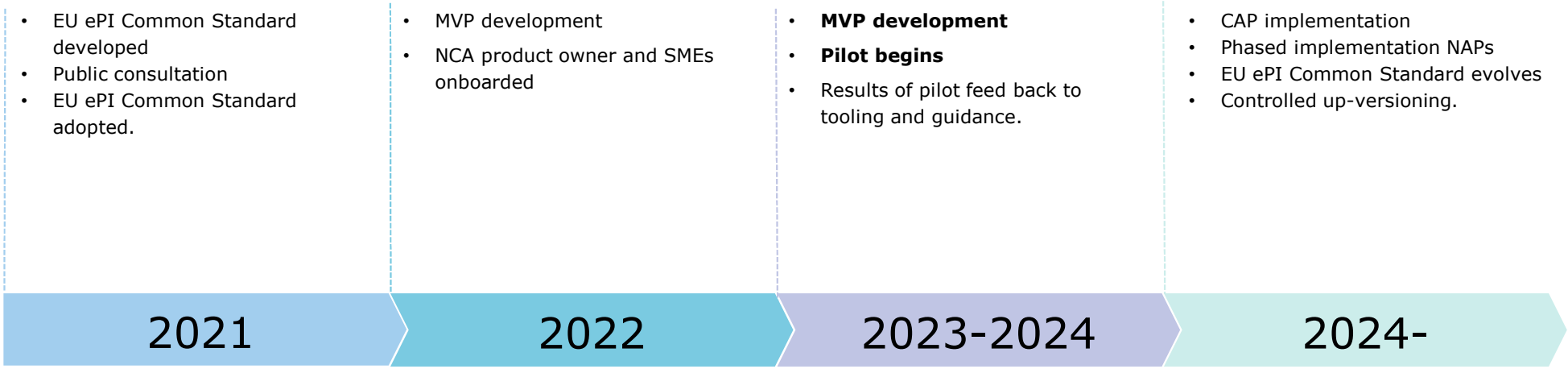


Regulator view



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

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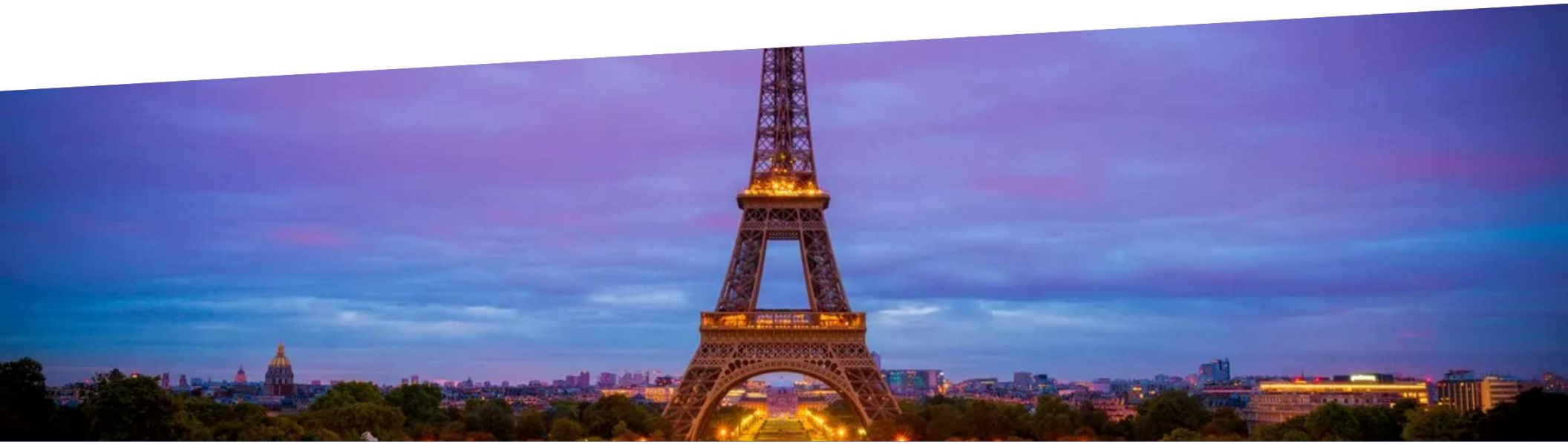
11:35 – 12:20



AEMPS - National regulator perspective of ePI

Presented by: Evinn 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.
ɔixabán, 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.]

MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

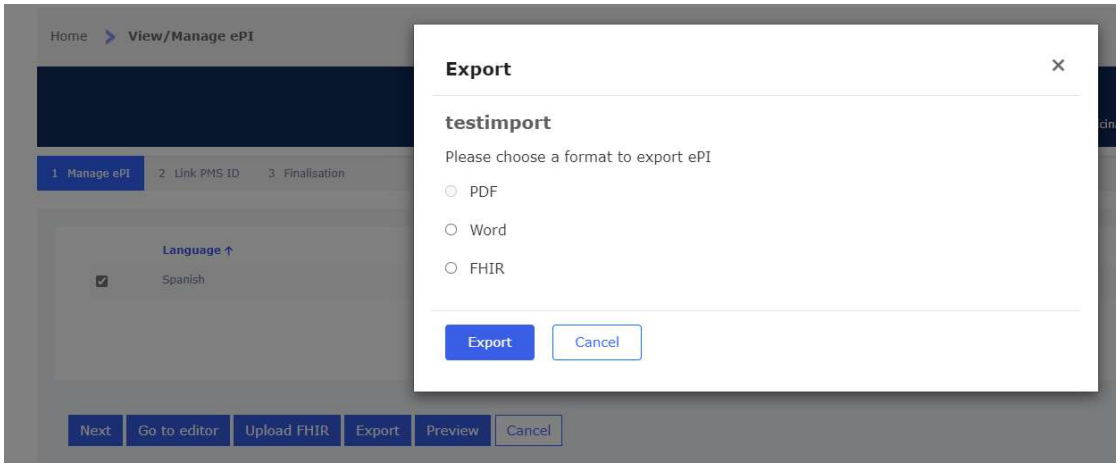
ePI trademark ® Use Case

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

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

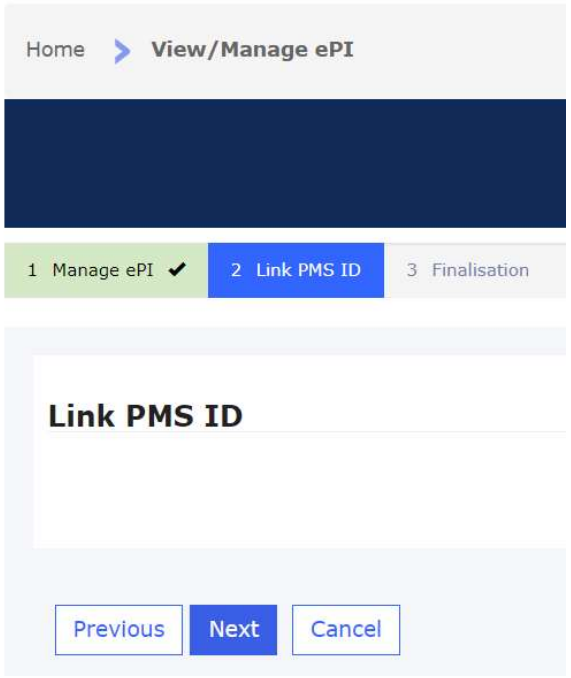
MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

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

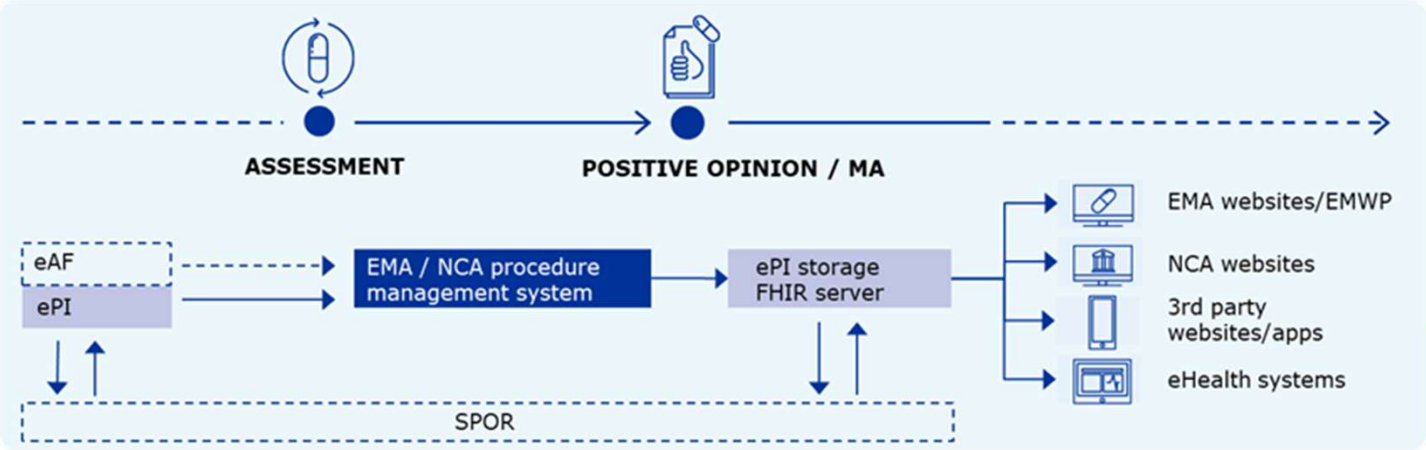
PMS data and ePI



- 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)

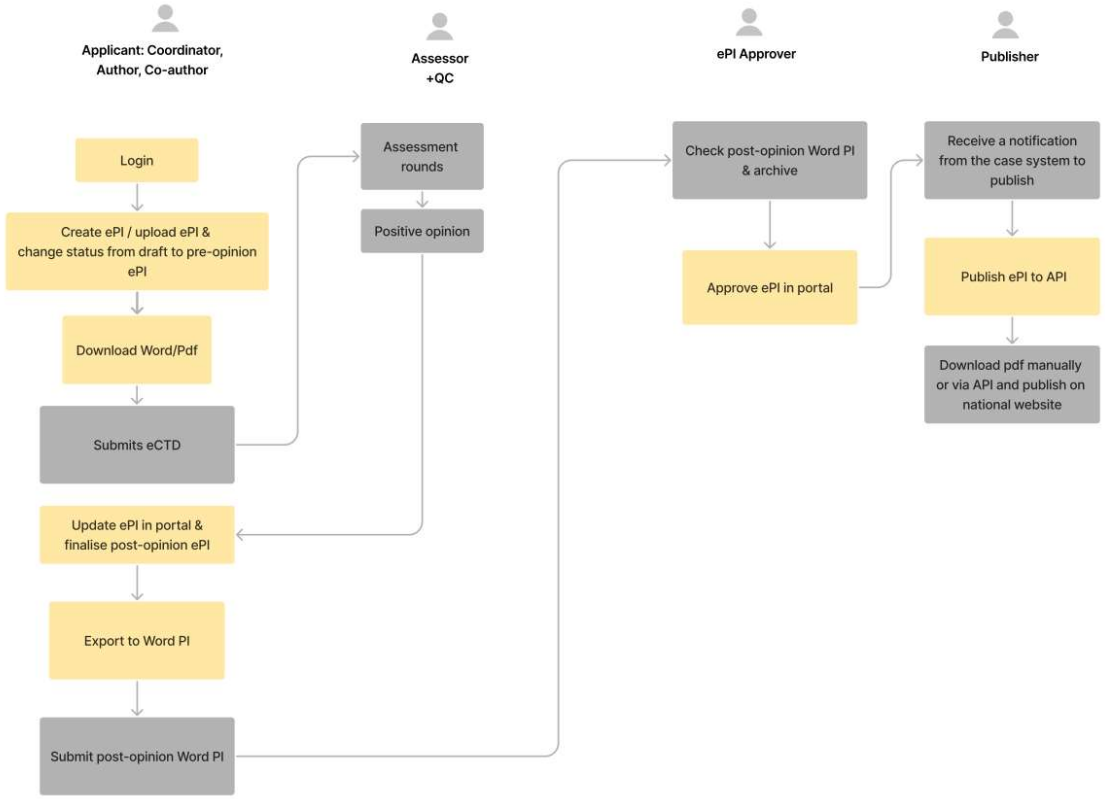
- MVP will be piloted for CAPs and some NAPs (Denmark, Netherlands, Spain, Sweden).
- The MVP enables an early version of ePI with limited features that can be used by early adopters. The MVP is a ready-to-use, first release of a product to be used in the business process, and not a prototype.
- The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



agencia española de medicamentos y productos sanitarios

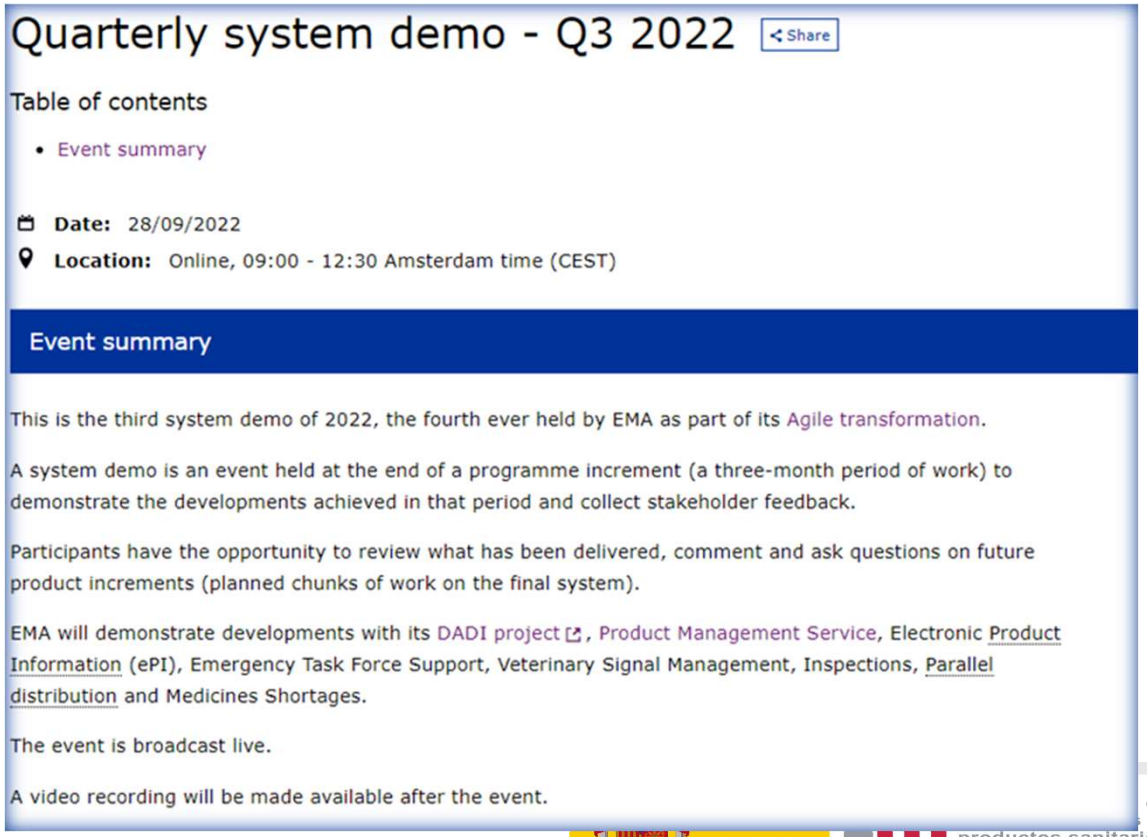
Example regulatory procedure

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

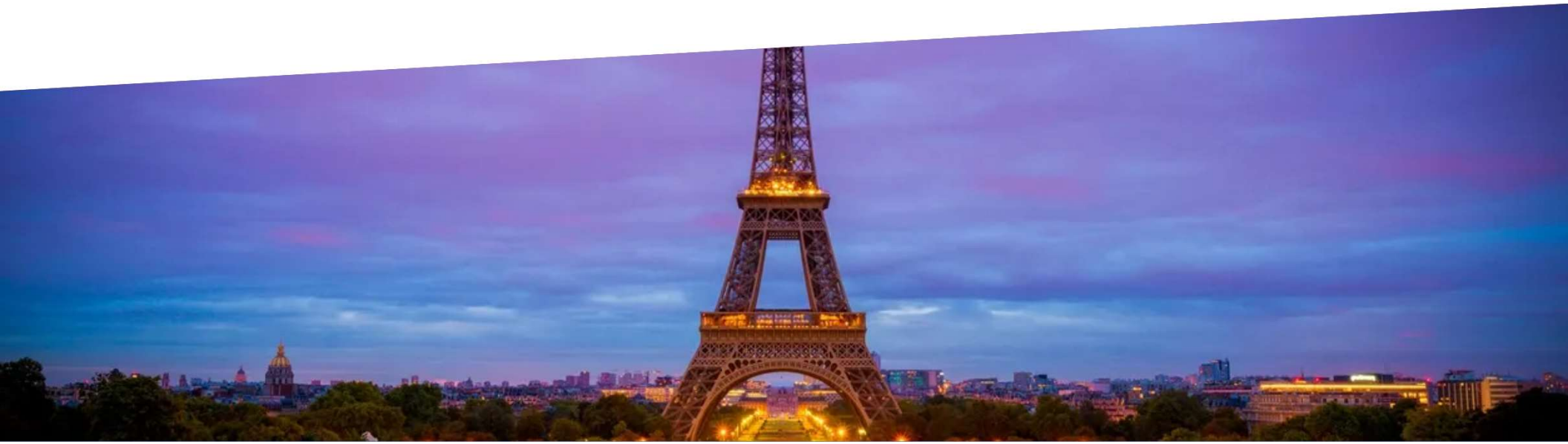
6. Perspectives on FHIR (Part 1 – Regulators)

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.

VULCAN

What will we cover

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

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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

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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**

<u>It's 2022!</u>

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.

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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**

VULCAN

FDA
U.S Food and Drug Administration

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Health Canada Santé Canada

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

VULCAN

FHIR

U.S Food and Drug Administration

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Health Canada Santé Canada

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

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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

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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

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Selected FHIR examples

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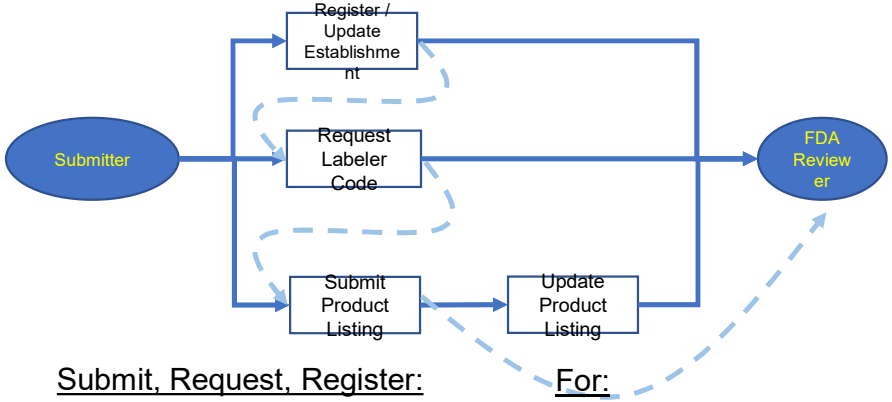
SPL FHIR (FDA)

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

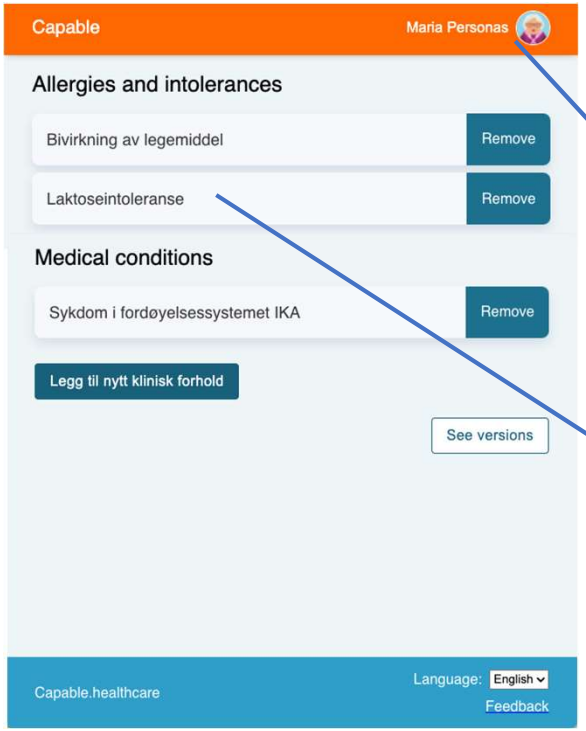
- http://build.fhir.org/ig/HL7/fhir-spl/branches/main/index.html

VULCAN

ePerscriptions (ePI)
- Connectathon – example of Basic G-lens focusing

Gravitate Health

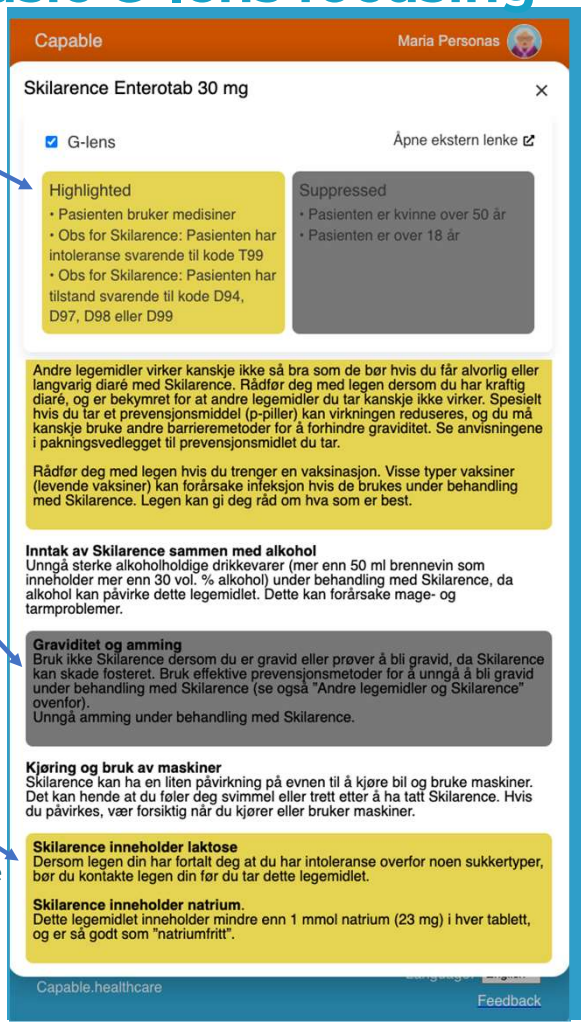
Applied G-lens criteria:
Demographics, conditions, allergy and intolerance



Capable.healthcare prototype

Pregnancy related - suppressed

Lactose Intolerance related - highlighted



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 *Condiction* 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

VULCAN

REMS Integration Use Case

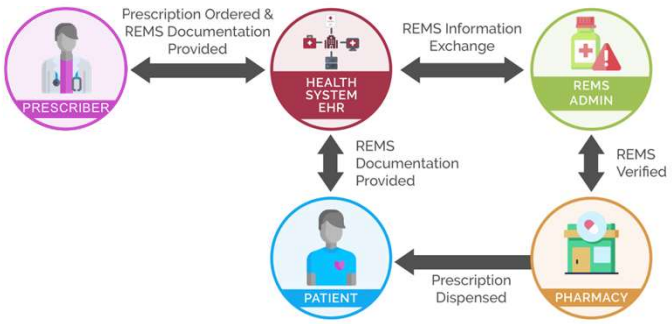
Problem

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**

7. Implementation Insights / Showcase

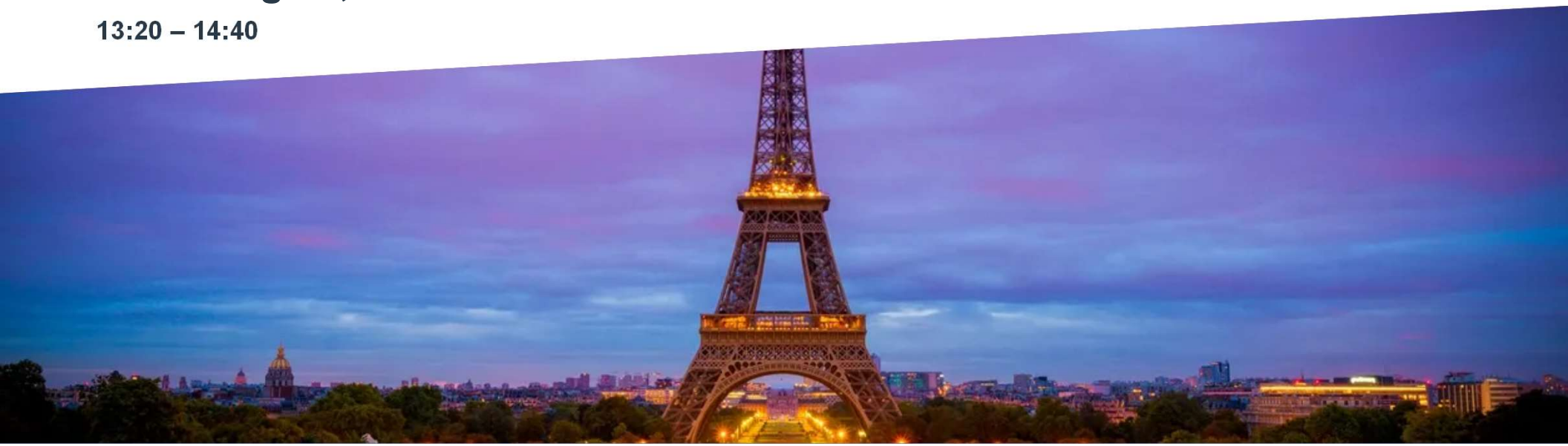
Jessica Jeffries, IgniteData

Mitra Rocca, FDA (remote)

Peter Casteleyn, J&J

Martin Ingvar, Karolinska Institutet

13:20 – 14:40



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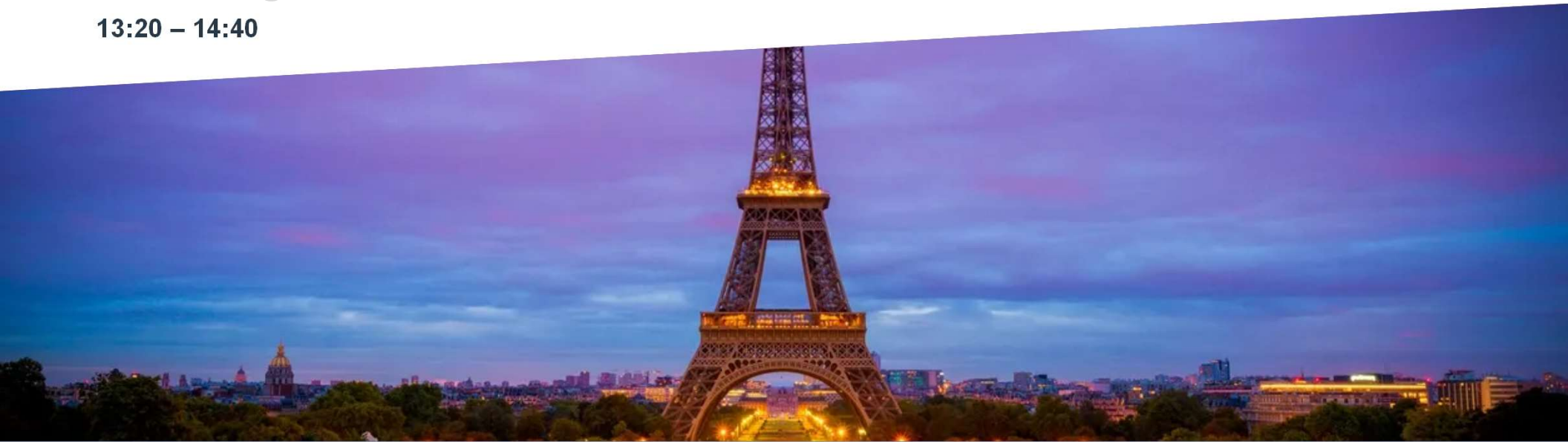


EHR-to-EDC Transformation of Modern Clinical Trials

Jessica Jeffries
Strategic Account Director

IgniteData

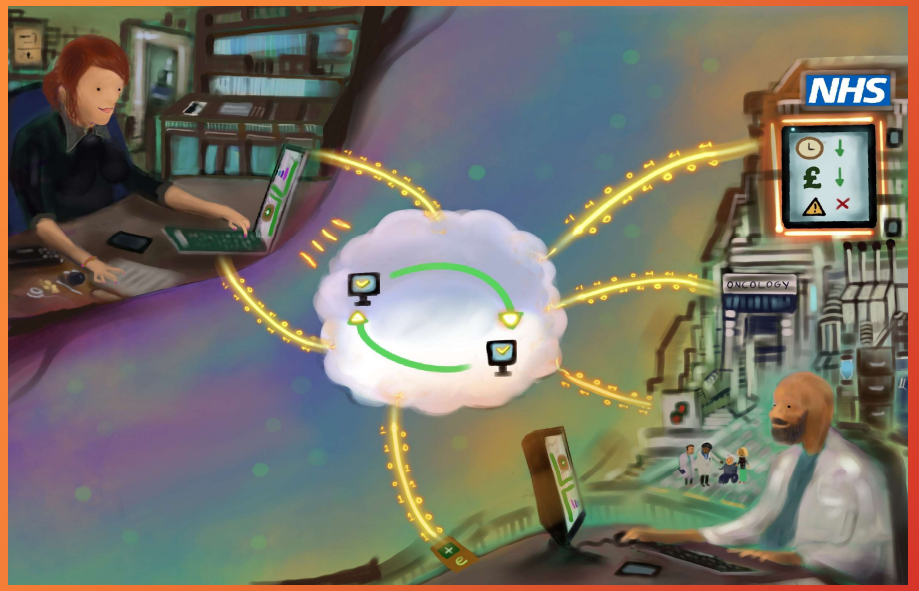
Agenda

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

IgniteData

BEFORE ARCHER

WITH ARCHER



IgniteData

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.

IgniteData

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.

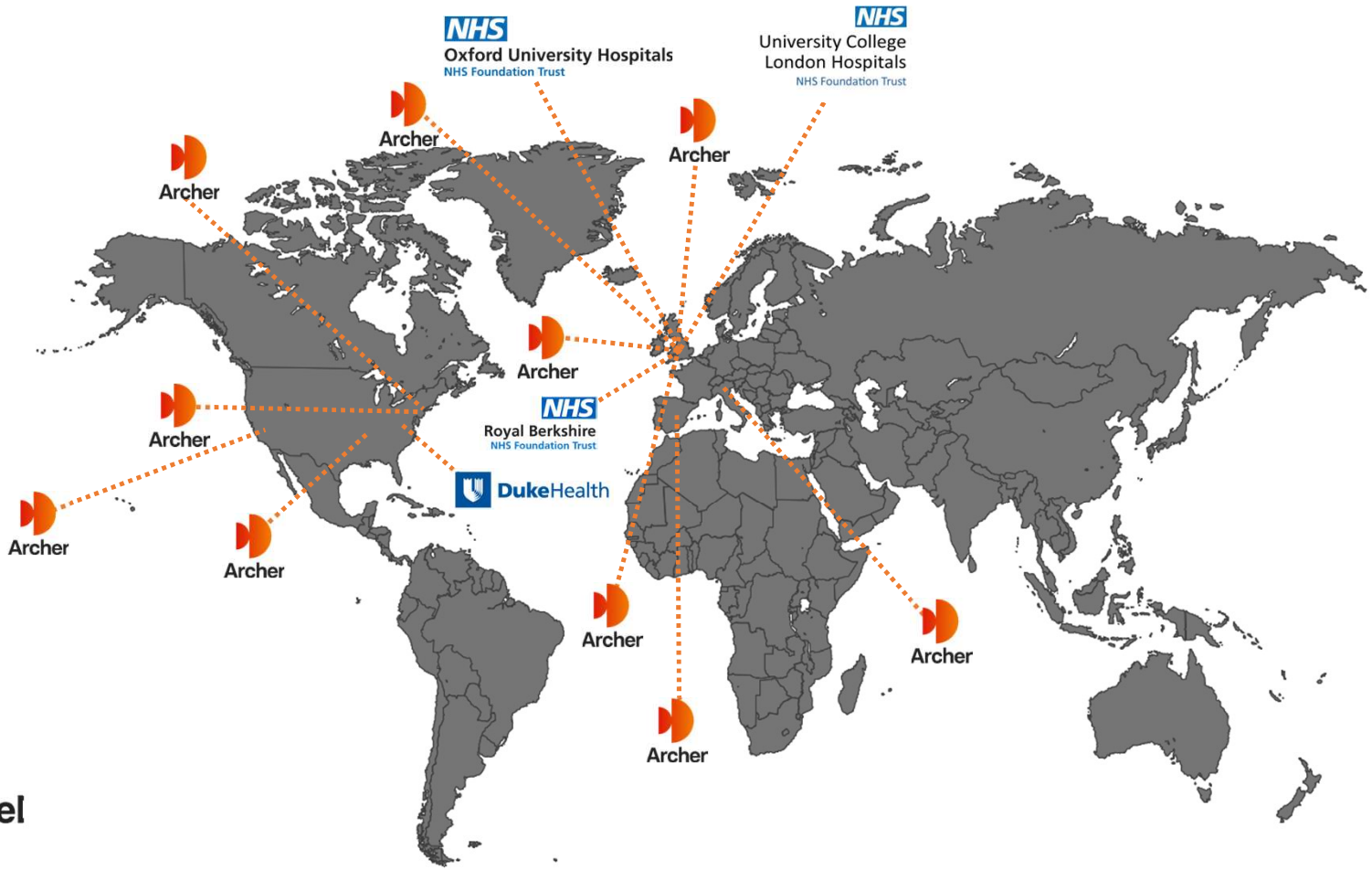
Total number of data items per patient	1374
Average time taken to enter each data item manually	3 minutes*
Average time taken per patient to enter data manually over 20 visits	4122 minutes = 68.7 hours
Estimated time gained by using Archer** over 20 visits	66.8 hours = 96.5% time-saving

*Source: Sanofi, EHR2EDC consortium project

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

IgniteData

Where?



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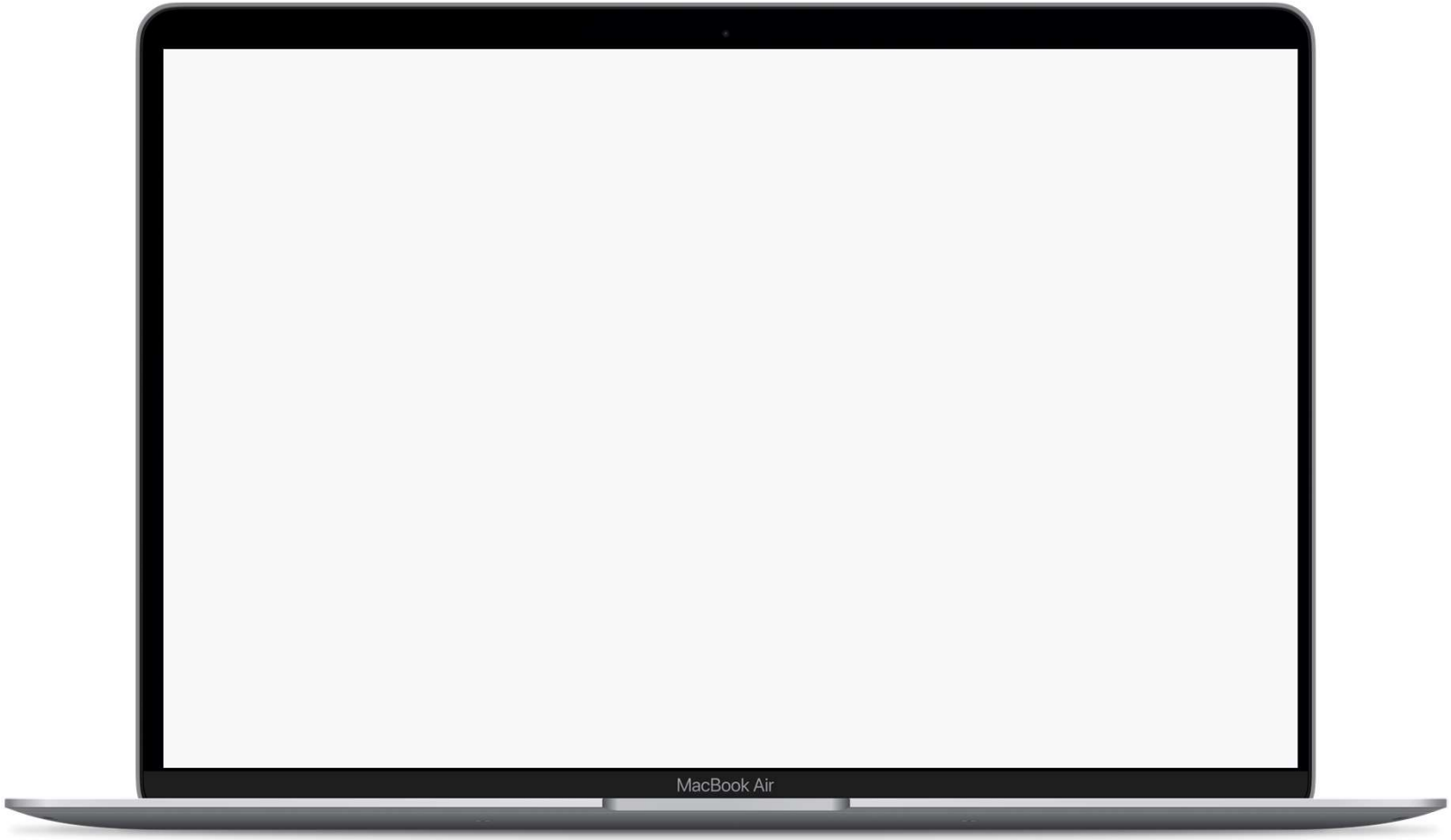

IgniteData

Thank you!

Questions?

IgniteData

Conta

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

Ignite Data Ltd. (Company number 09054143)
5a Frascati Way, Maidenhead SL6 4UY
www.ignitedata.co.uk

IgniteData

Supported by:

Innovate UK

Advised by:

NICE National Institute for Health and Care Excellence

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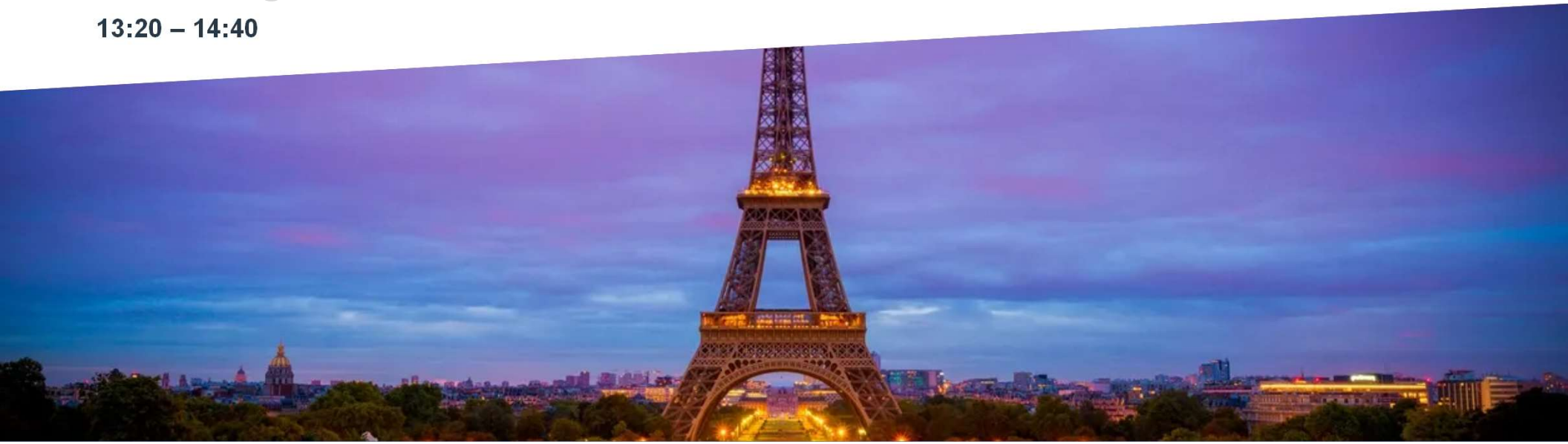


Use of Real-World Data in Clinical Research

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)

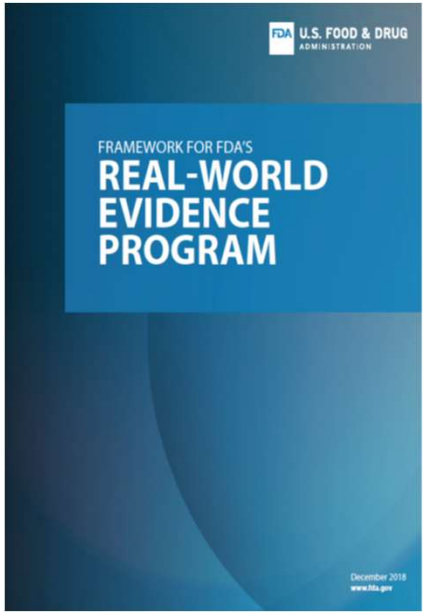
21st Century Cures Act – December 2016

Public Law 114-255 (December 16, 2016)

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 EHRS: 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

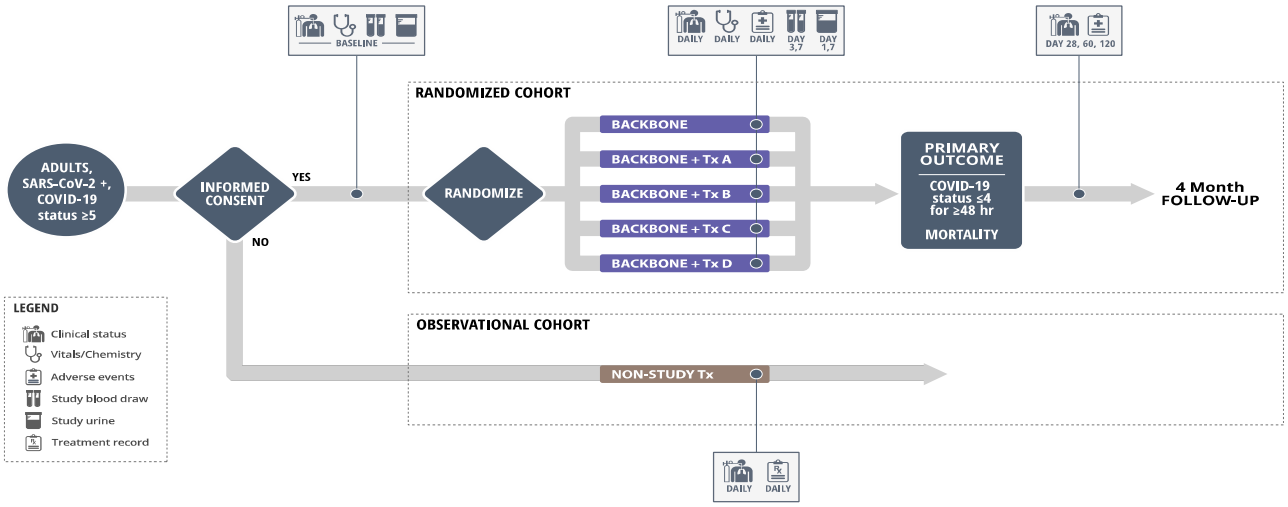
Reuse of OneSource standards platform in COVID-19 clinical trials.

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

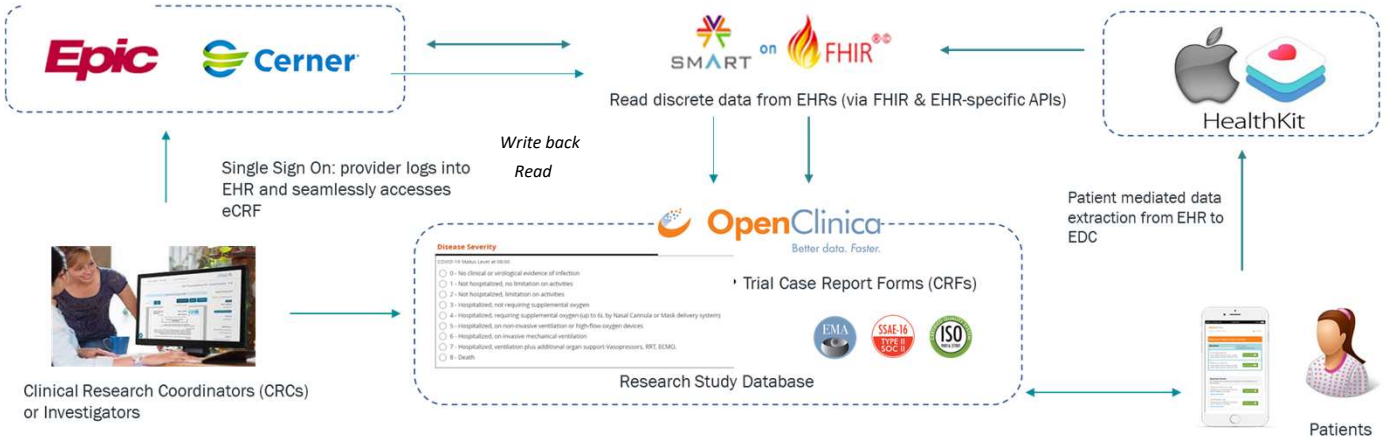
https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund-reports

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

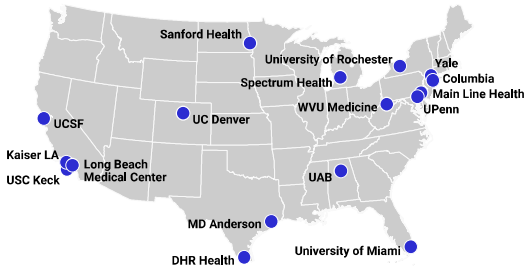


OneSource: SMART on FHIR integration with EHRs



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
- Sucessful 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

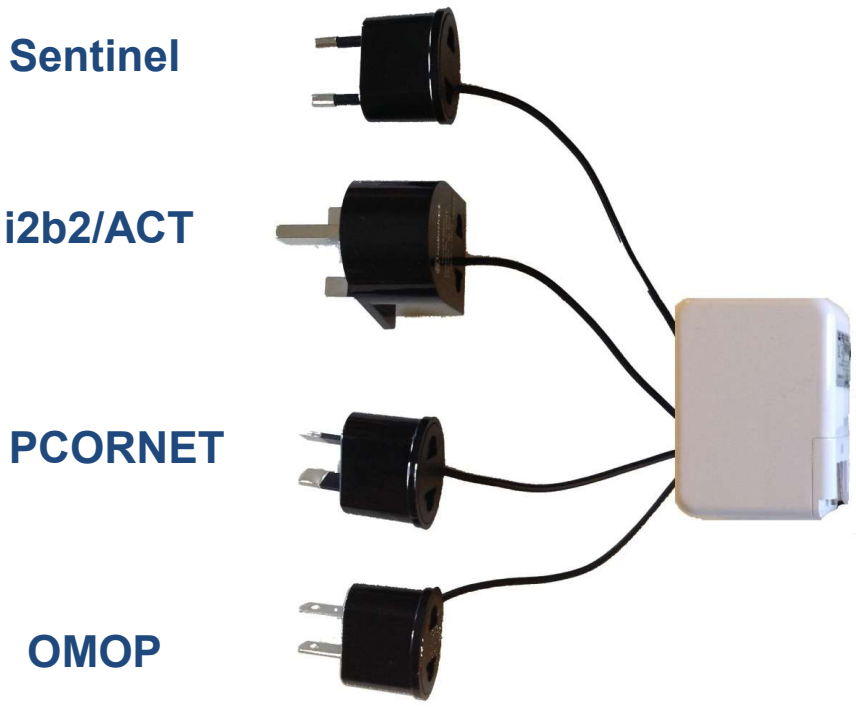
    Map to open, consensus-based standards (e.g., Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) and Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)

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



- 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.

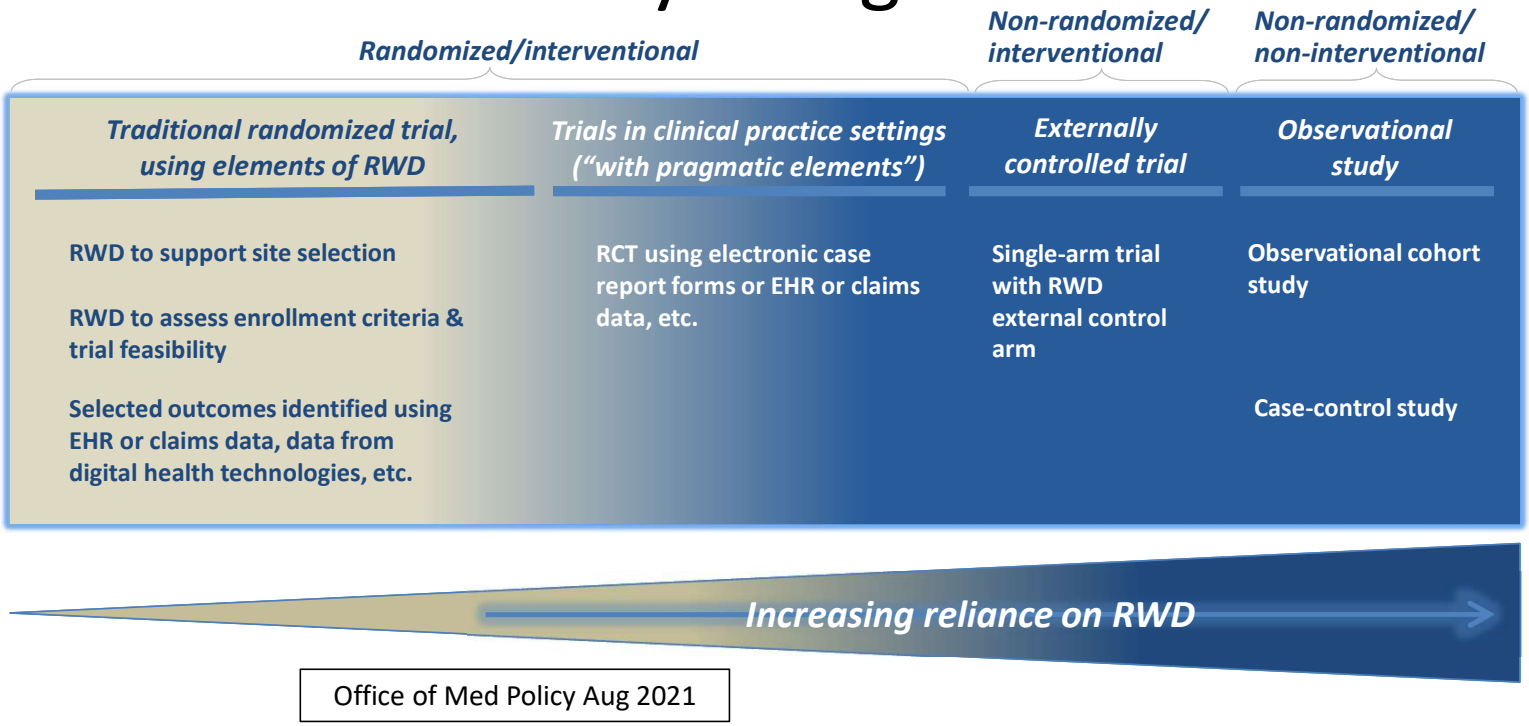
Summary

- 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

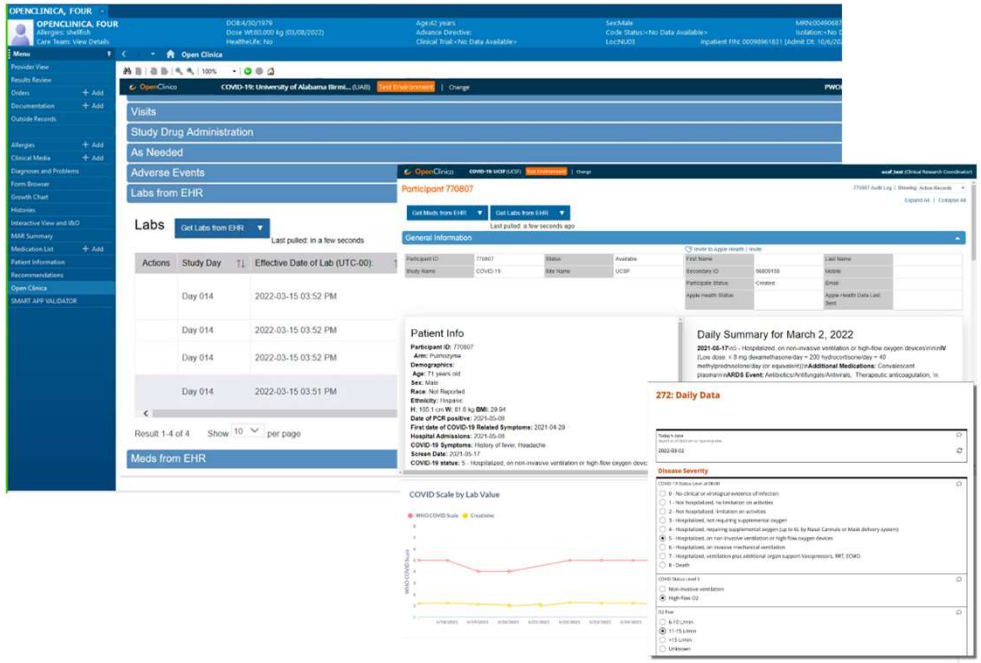
Overview of Real-World Data and Study Design



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



7. Implementation Insights / Showcase

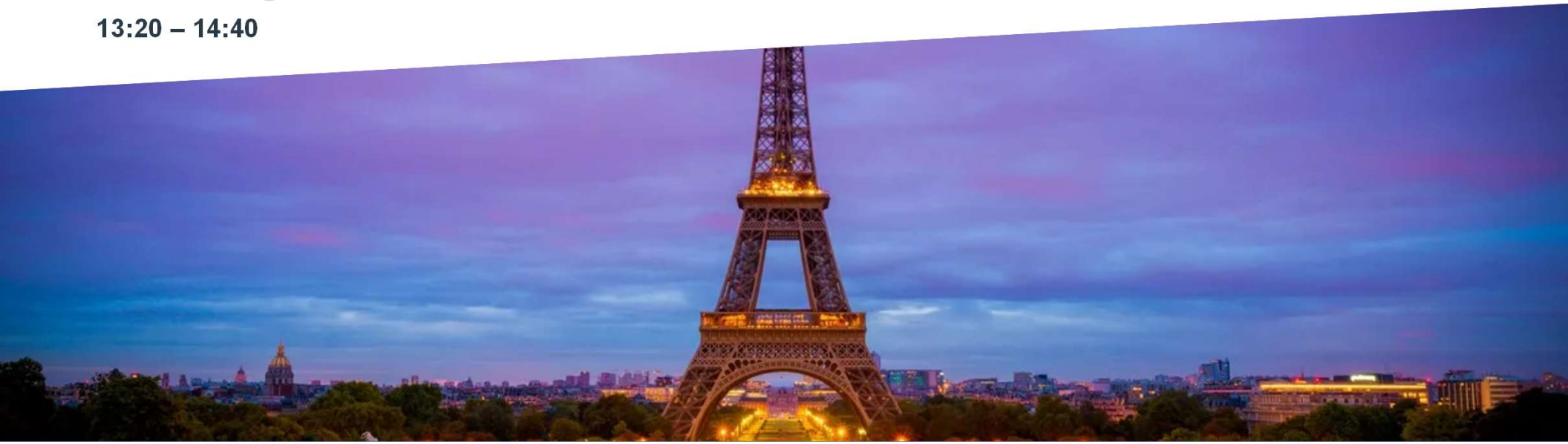
Jessica Jeffries, IgniteData

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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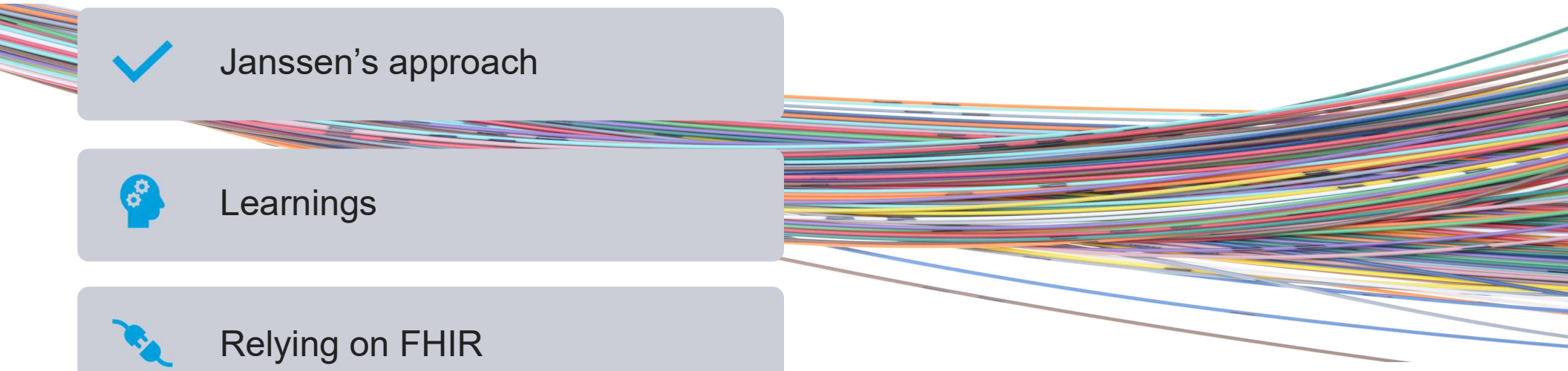
Agenda

- The opportunity
- Janssen’s approach
- Learnings
- Relying on FHIR



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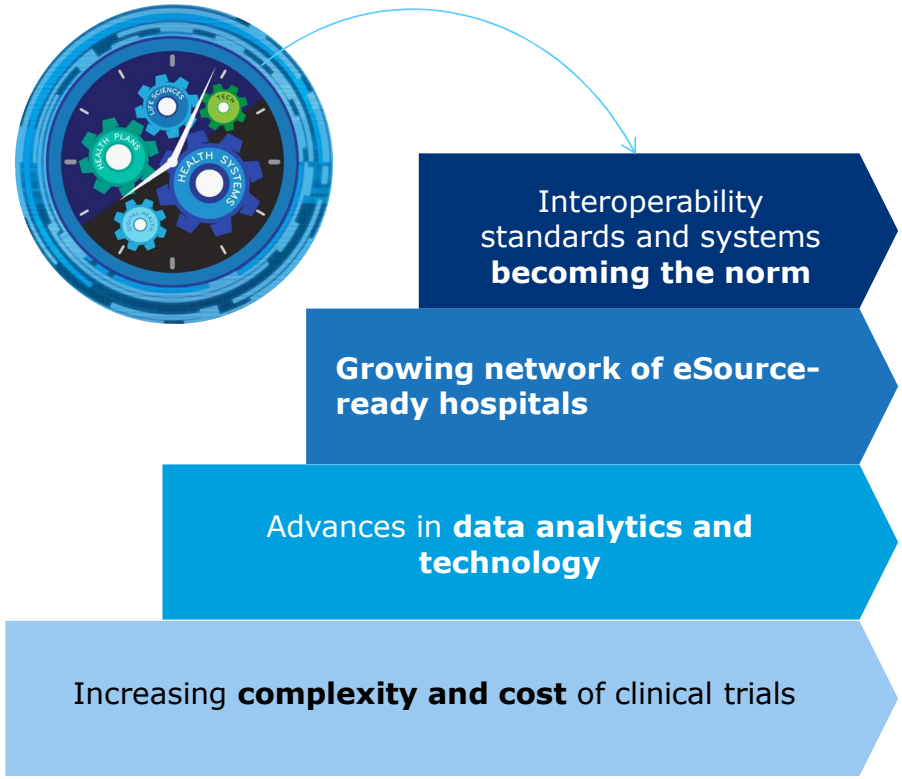
Current industry trends & the opportunity



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**.

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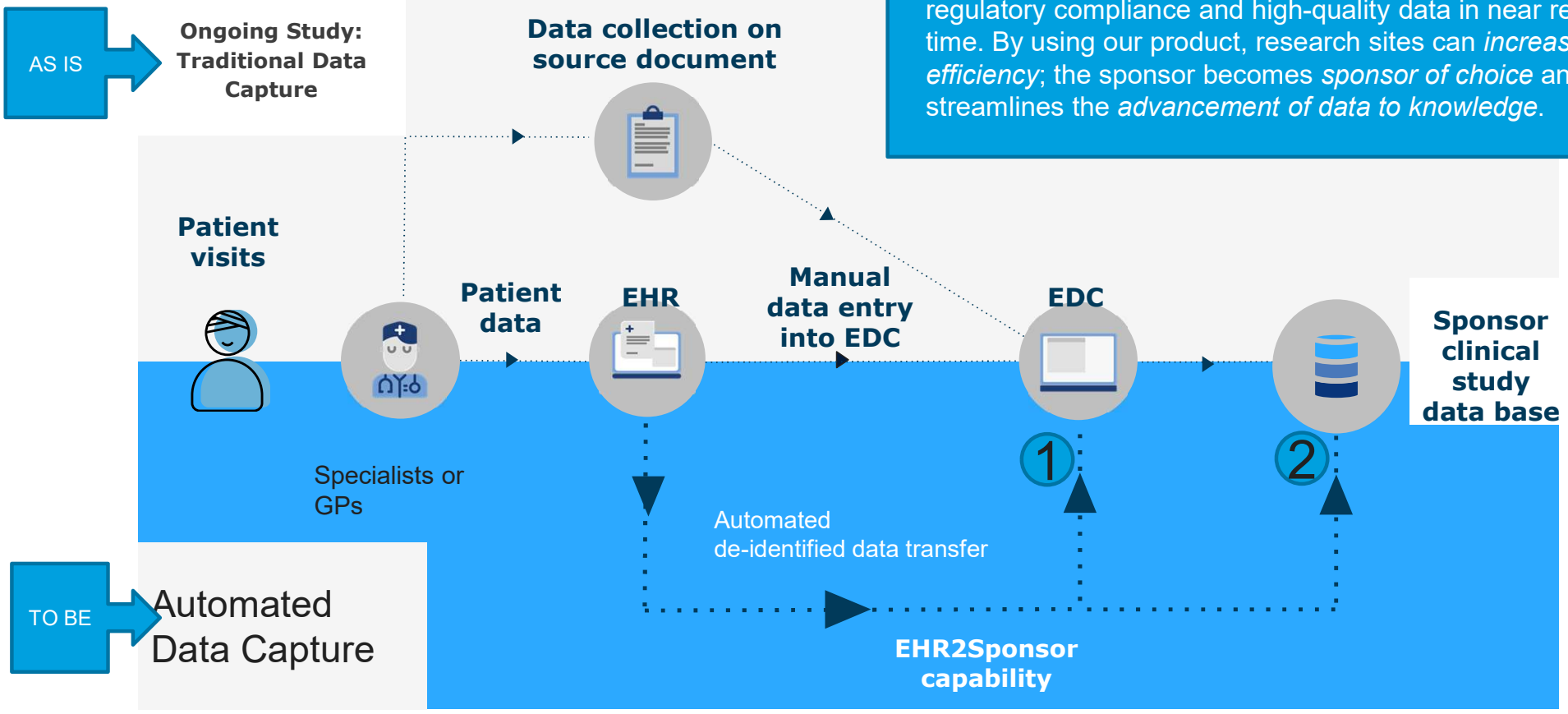
EHR2Sponsor Objective

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*.



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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

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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.

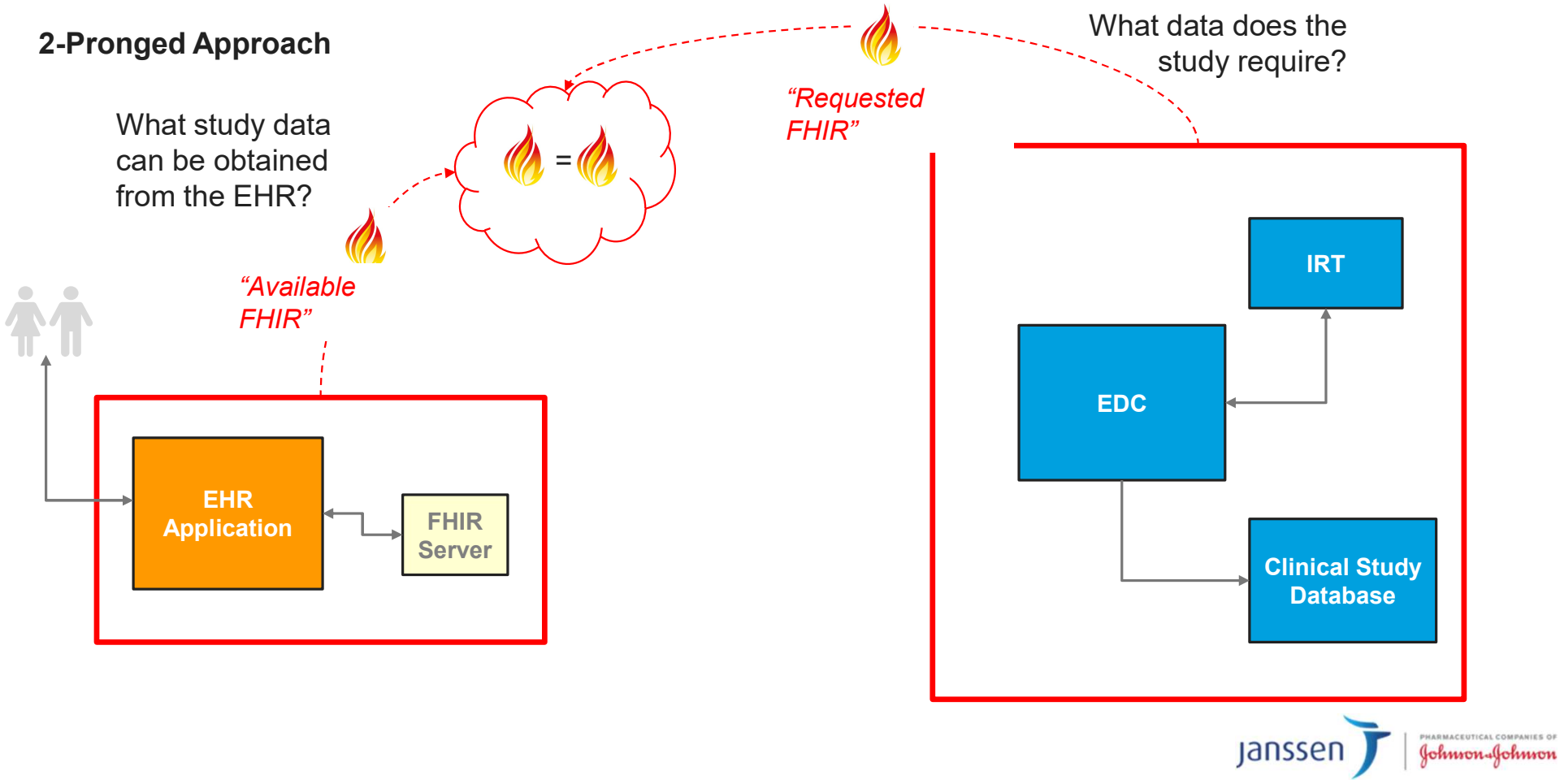
Site and sponsor readiness **implies more than technical readiness**. It involves process changes and increased reliance on standards (internal and external).

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

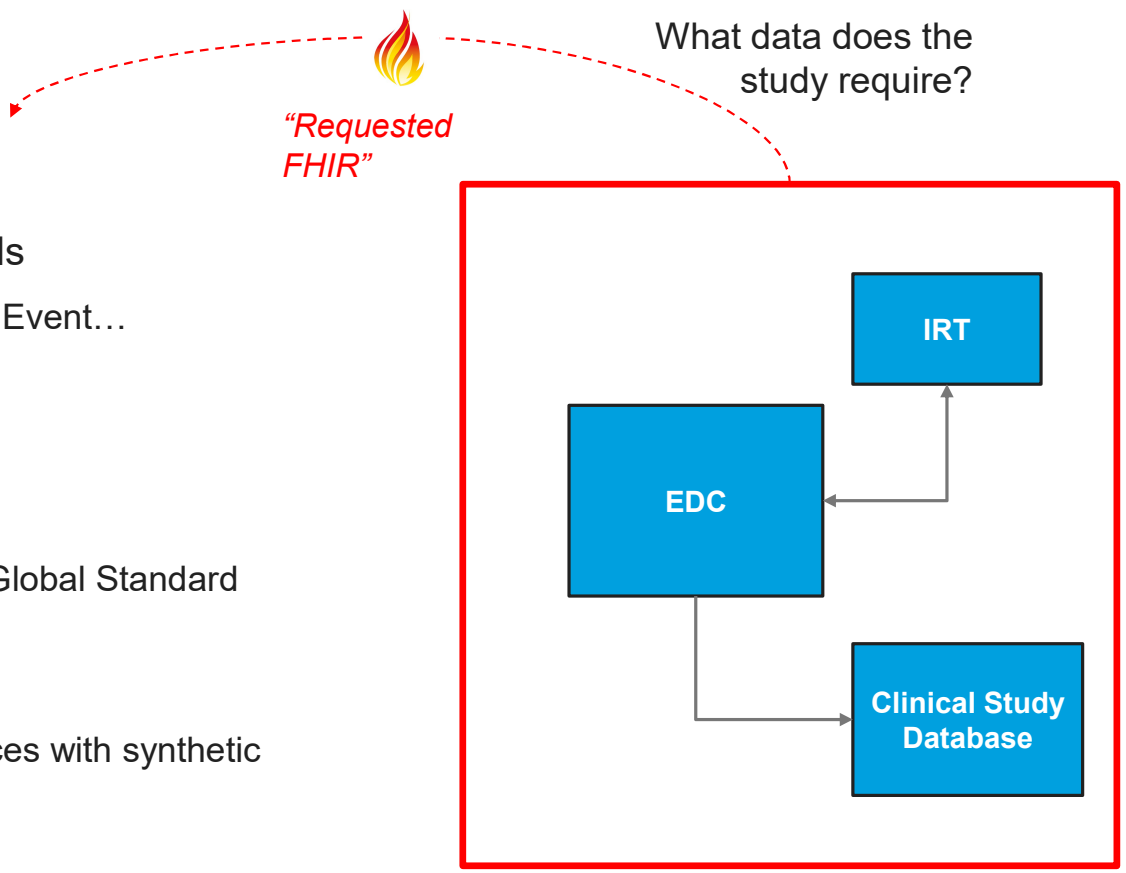
Different solutions offer different approaches to transfer data automatically. There is a need to **balance the pros and cons** of each way of working.

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



‘Outgoing FHIR’ – Study described in FHIR



External / Industry Initiatives

- Common approaches and methods

  HL7 Vulcan Projects – SoA, Adverse Event…

Internal / Study Focused

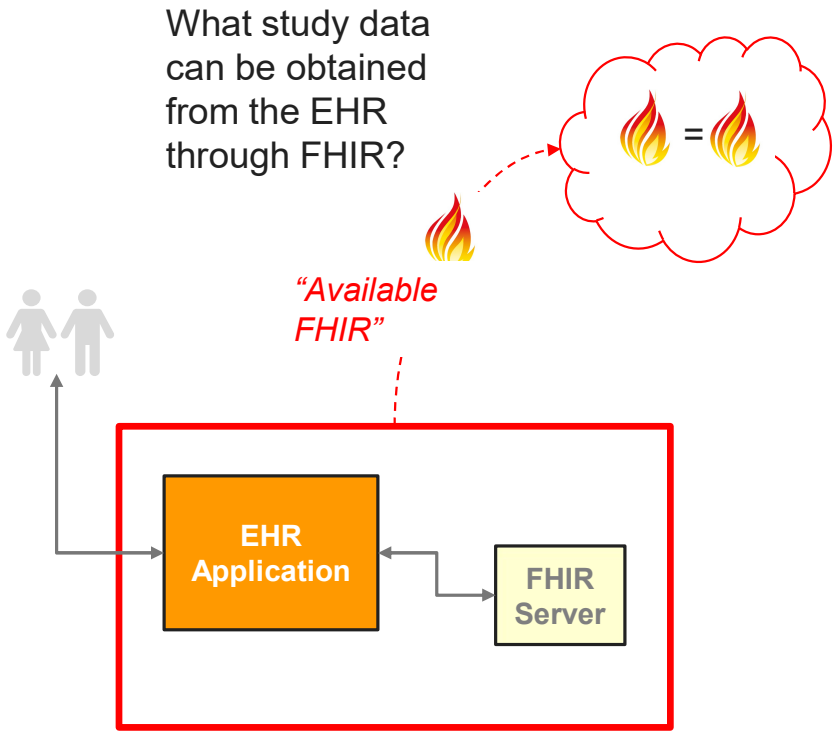
- Support mapping:

  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 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

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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)

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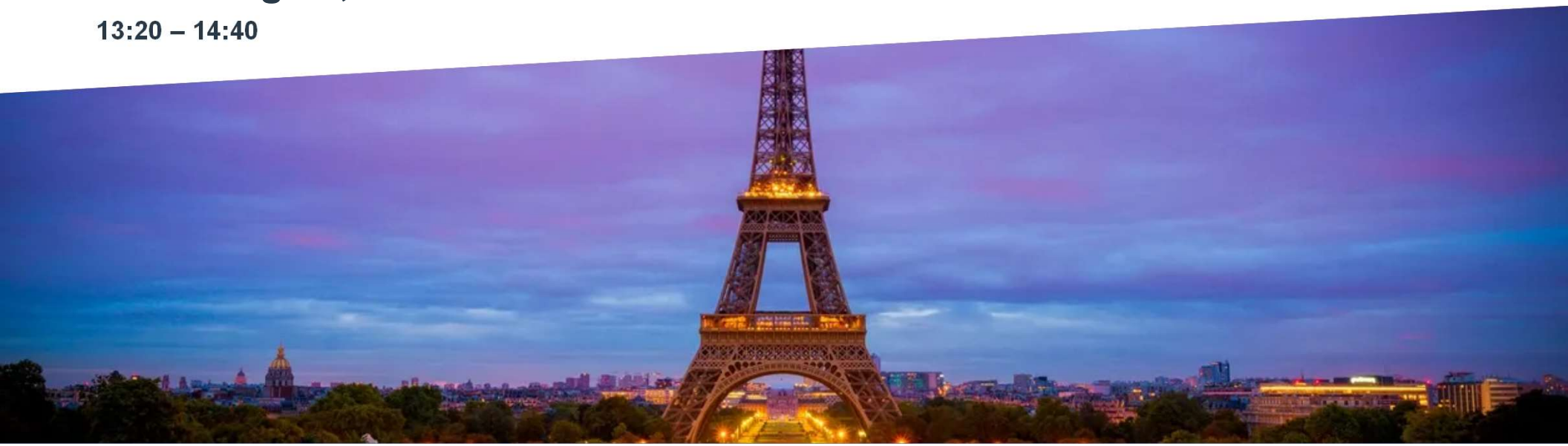
Martin Ingvar, Karolinska Institutet

13:20 – 14:40



Gravitate Health

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

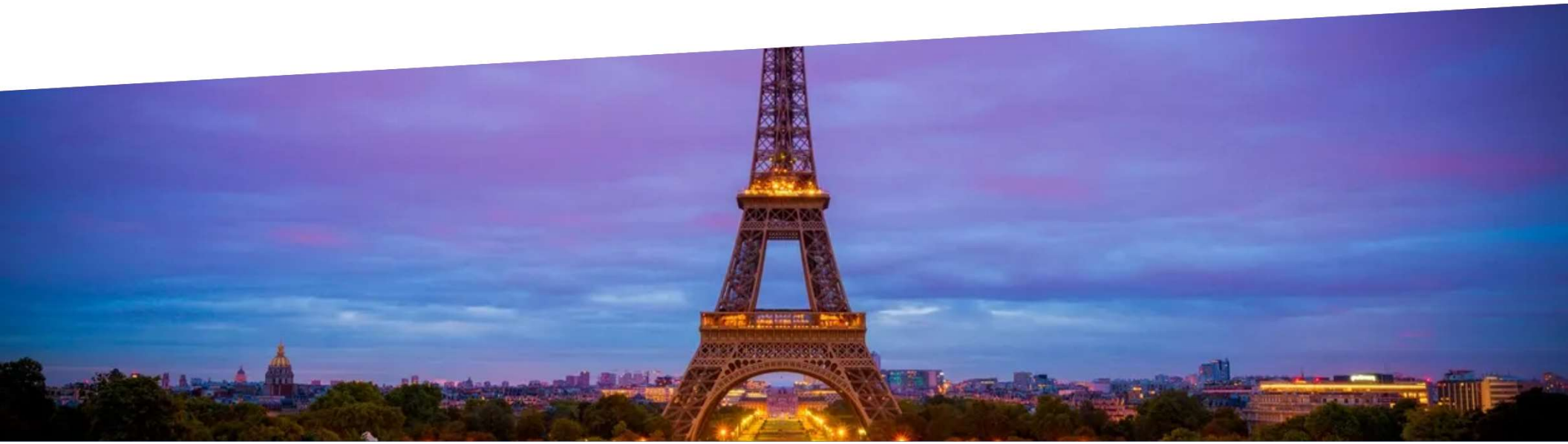
Networking Break

14:40 – 15:00

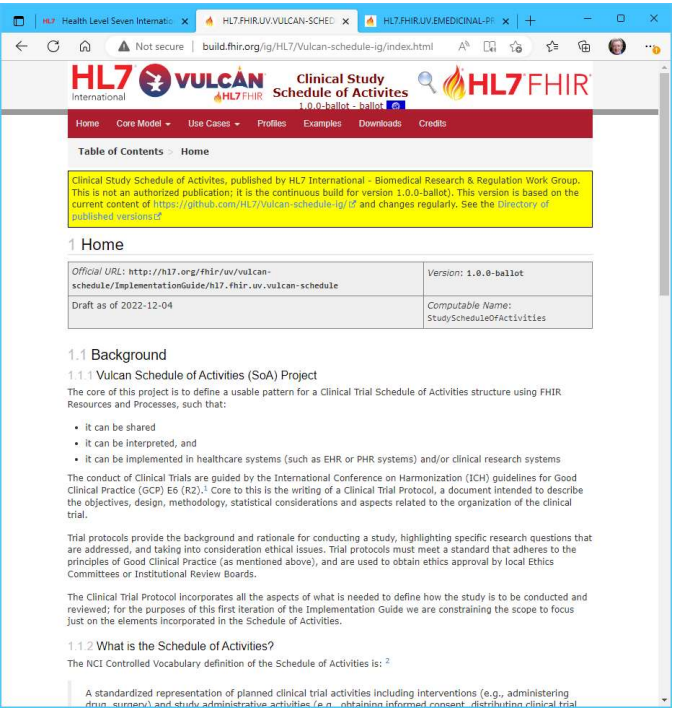
8. Vulcan Implementation Guide Overview

Hugh Glover, Vulcan

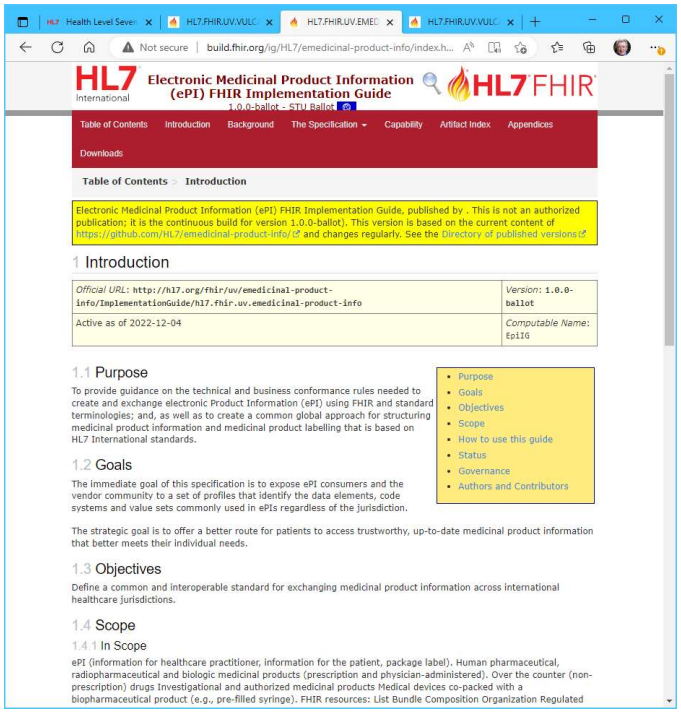
15:00 – 15:20



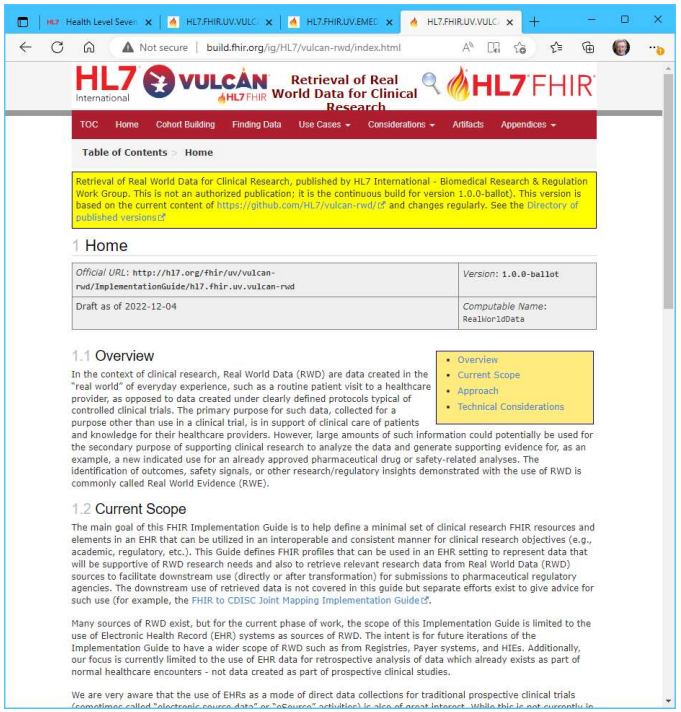
Current Vulcan Implementation Guides



Schedule of Activities



Electronic Product Information



Real World Data

Search:
Vulcan-schedule-ig

Search:
emedicinal-product-info

Search:
Vulcan-rwd

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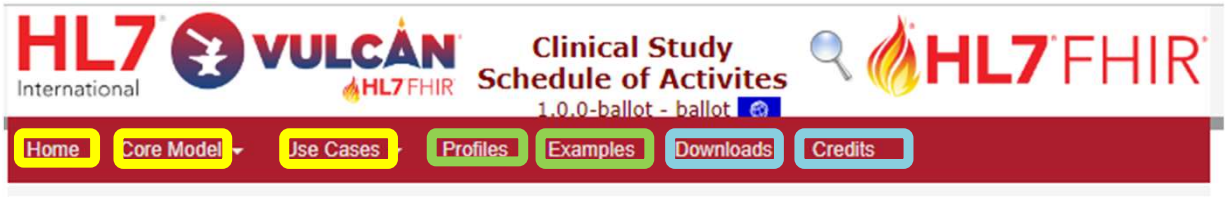
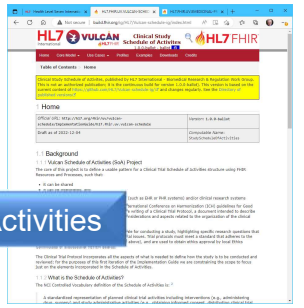
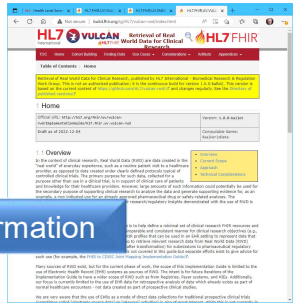
Sections of an Implementation Guide





Schedule of Activities

Real World Data



Electronic Product Information

Discussion

Artifacts

Credits
References
Downloads

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Discussion

Discussion

Artifacts

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

5 Steps to create a Core FHIR ePI

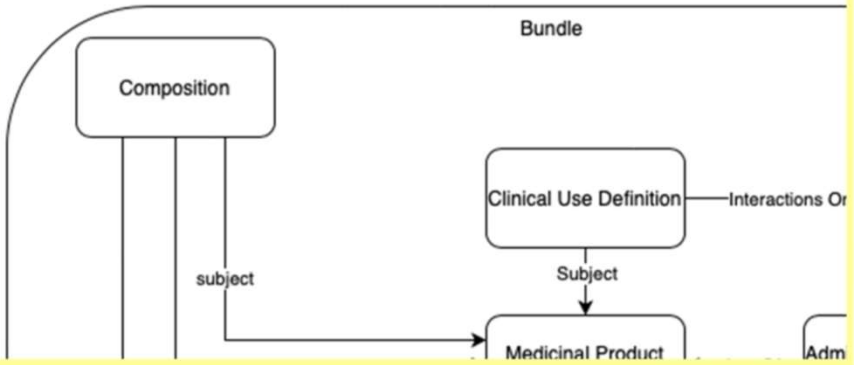
NOTE:

- 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)



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Artifacts

Discussion

Artifacts

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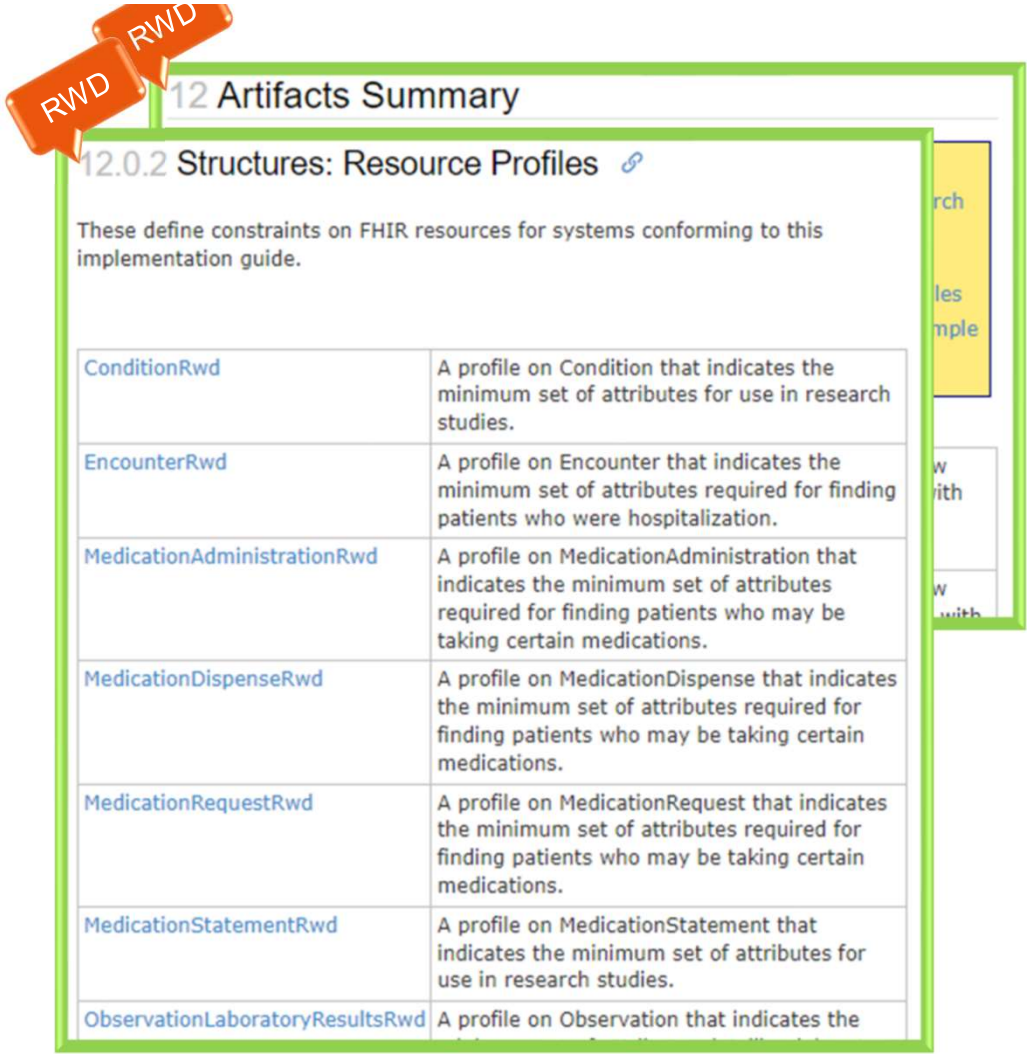
Artifacts are the technical specification

- **Search Parameters**
- **Profiles**
- **Extensions**
- **Terminology**
- **Examples**



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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*

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Reading FHIR Resource Definitions

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 being taken by a patient Elements defined in Ancestors: id, meta, implicitRules, langua 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 |	Encounter / Episode associated with MedicationStatement

Data item **Cardinality** **Data type** **Definition**

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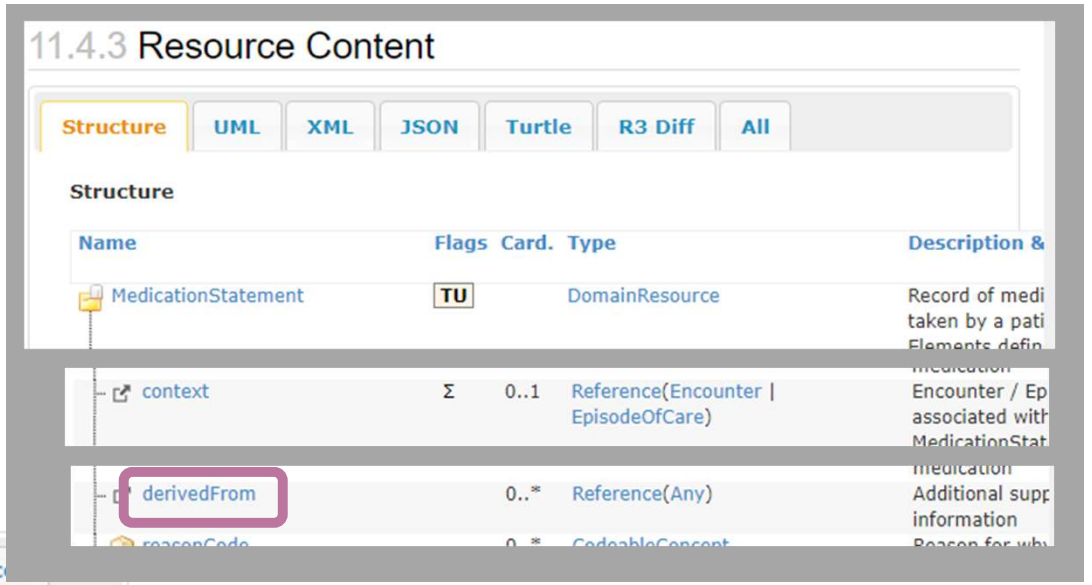
Reading the Profile

Profile from RWD

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/Referenc

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

Derivation of the profile

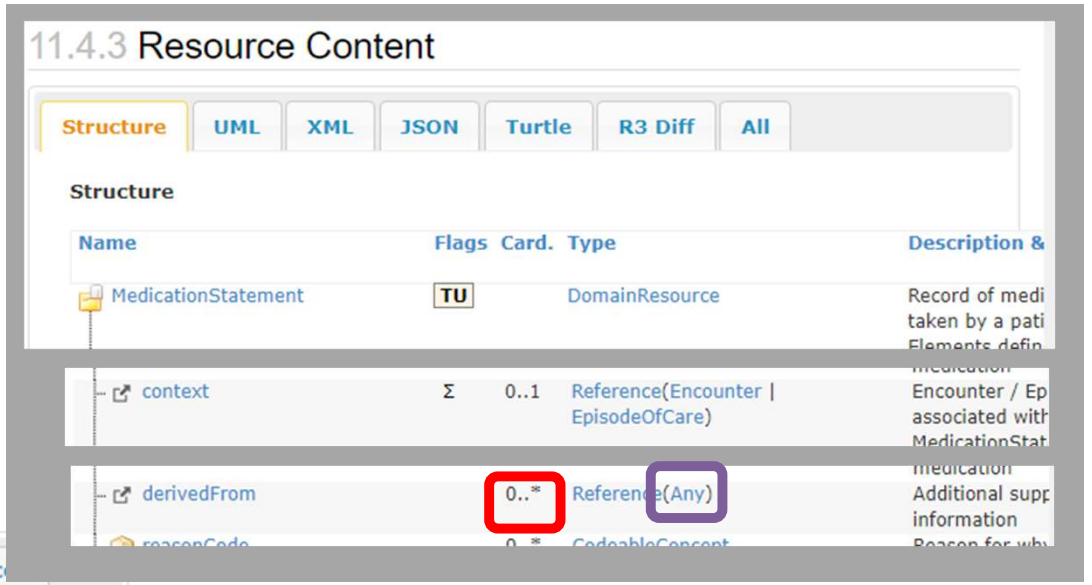
Modified attributes

Reading the Profile

Profile from RWD

RWD

Original



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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

`derivedFrom` attribute is now mandatory

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

Artifacts

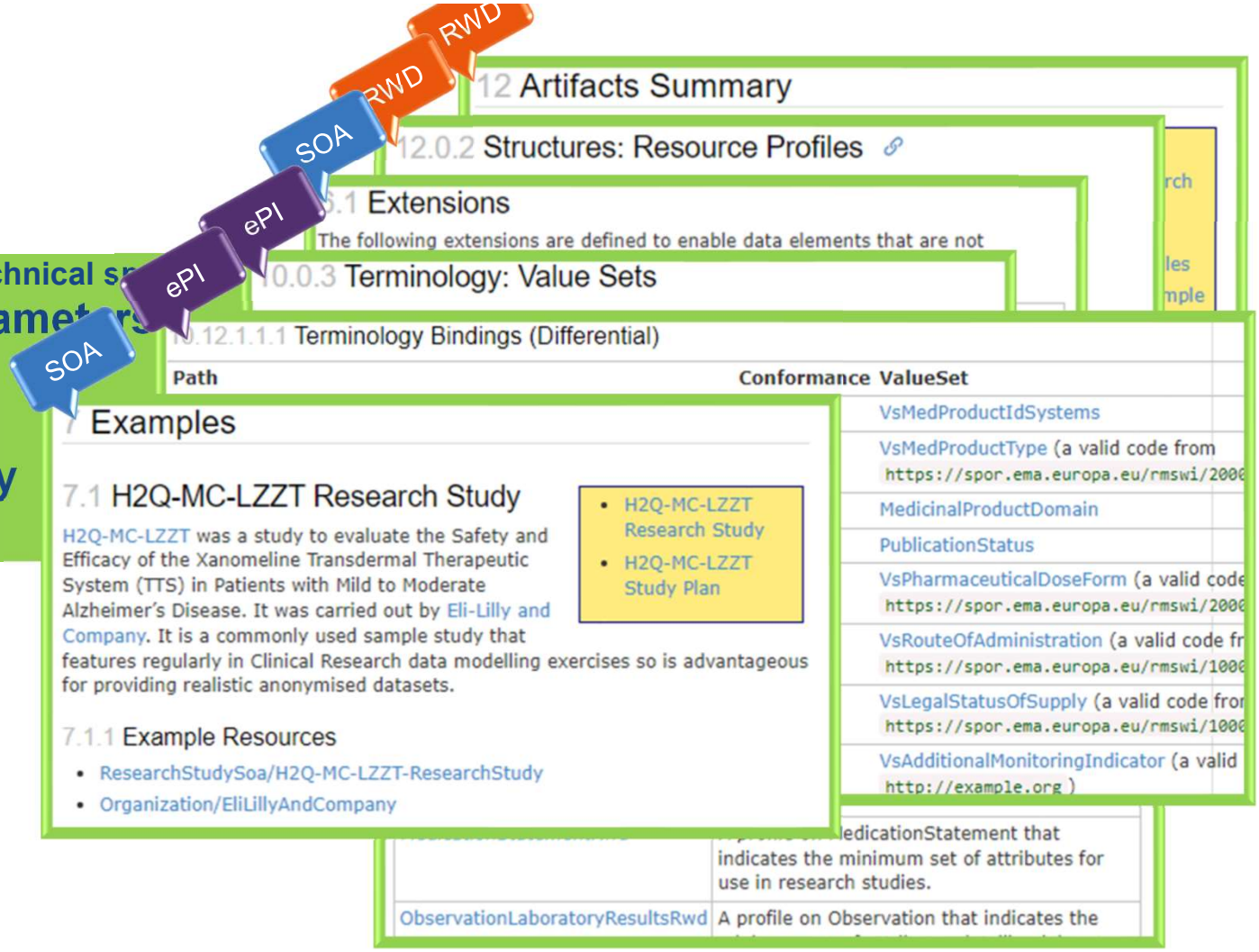
Discussion

Artifacts

Credits
References
Downloads

Artifacts are the technical sp

- **Search Paramet rs**
- **Profiles**
- **Extensions**
- **Terminology**
- **Examples**



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Artifacts

Discussion

Artifacts

Credits
References
Downloads

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

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Questions?

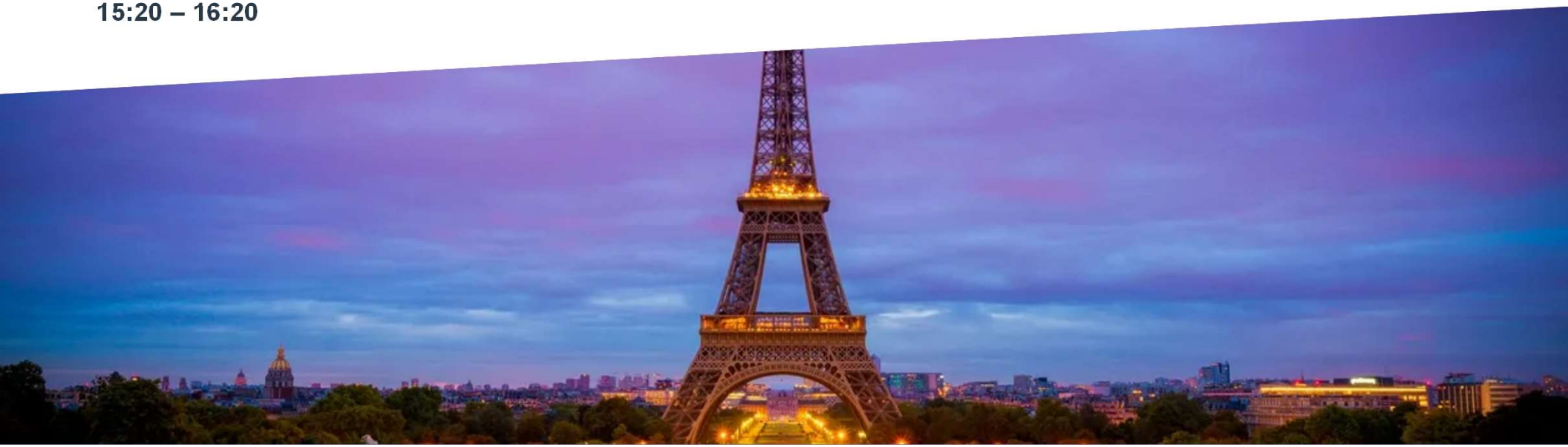
9. Vulcan Electronic Product Information (ePI)

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



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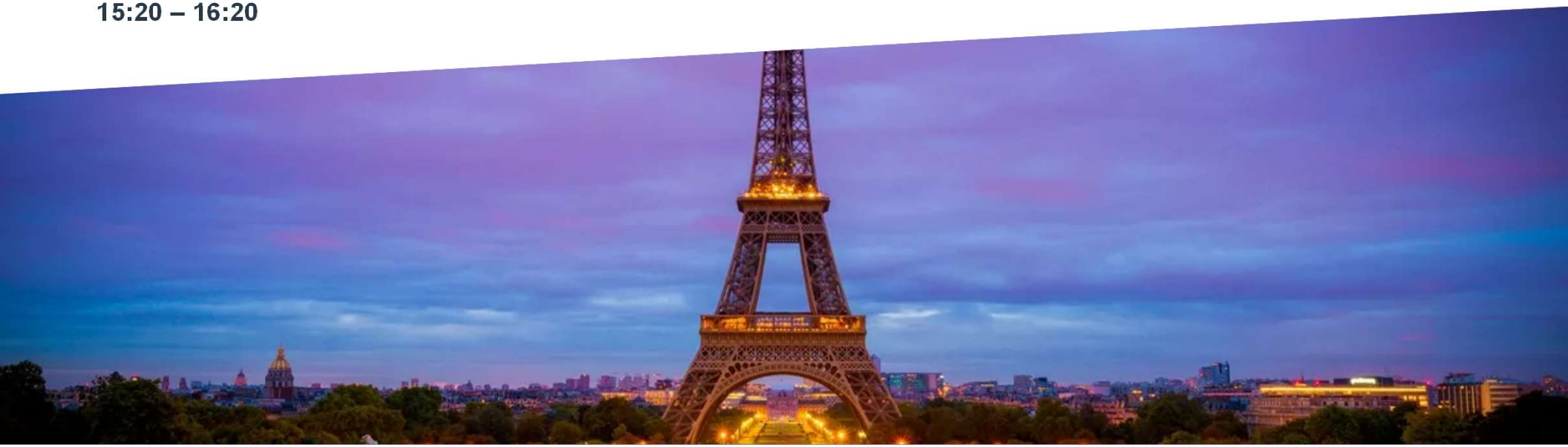
15:20 – 16:20



ePI Implementation Guide Overview & Relationship with Gravitate Health

Presented by: Giorgio Cangioli & Craig Anderson

Agenda

- Electronic Product Information (ePI) project overview
- ePI Implementation Guide overview
- Relationship with Gravitate Health
- Timeline, Collaborations and Next Steps

VULCAN

01

Electronic Product Information (ePI) Project Overview

VULCAN

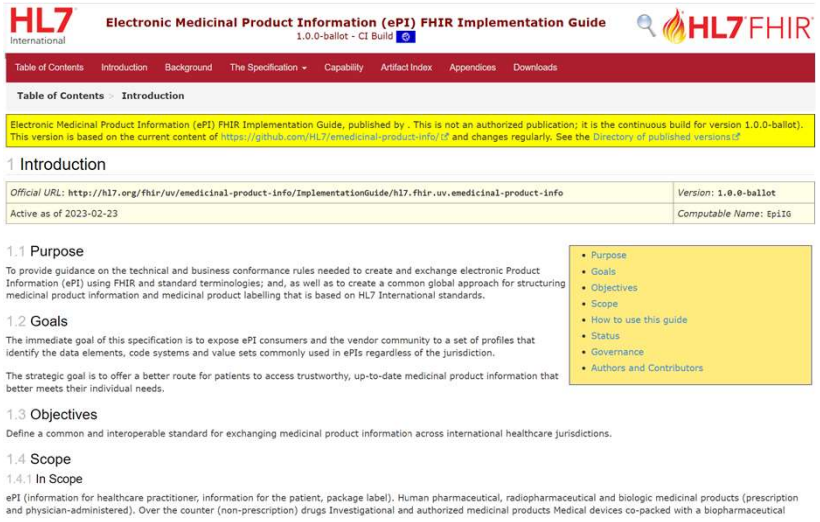
The ePI Project: a collaborative effort

VULCAN HL7 FHIR

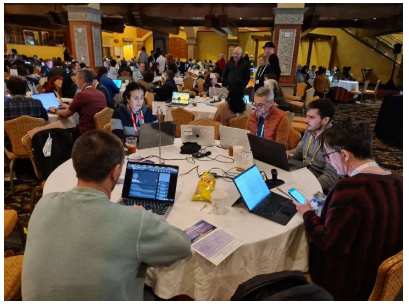
UNICOM

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.

Webinars



HL7 FHIR Implementation Guide

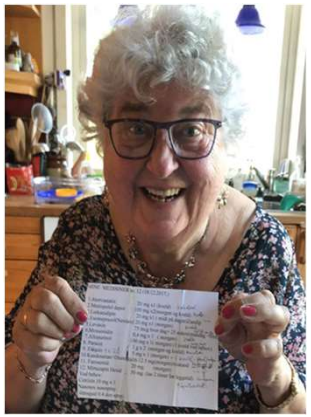


HL7 FHIR Connectathons

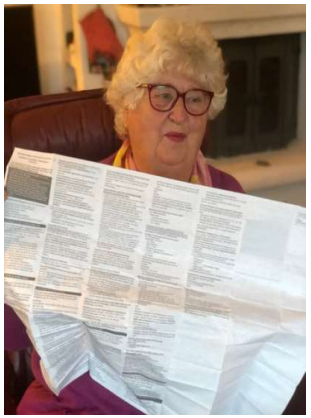
VULCAN

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



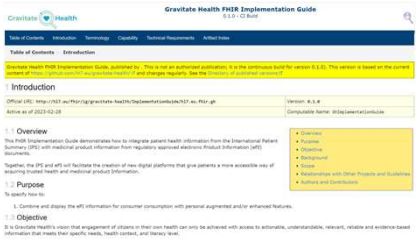
Picture: Hanne Bjertnes, UiO

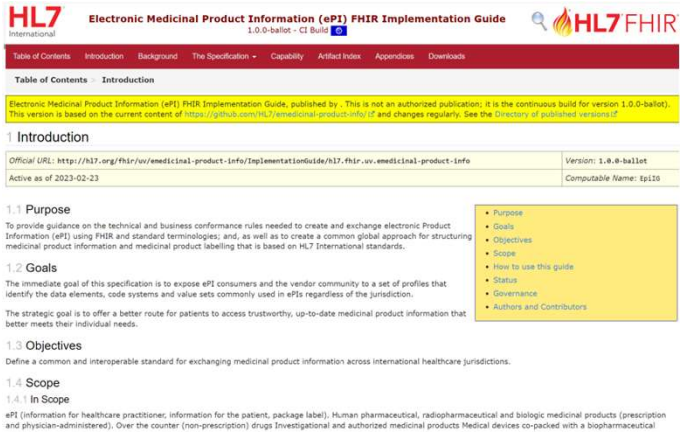
Why the ePI HL7 FHIR Implementation Guide

Global standardized electronic format for ePI

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

Gravitate Health





FDA

EMA

Define rules for using HL7 FHIR for describing ePI

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

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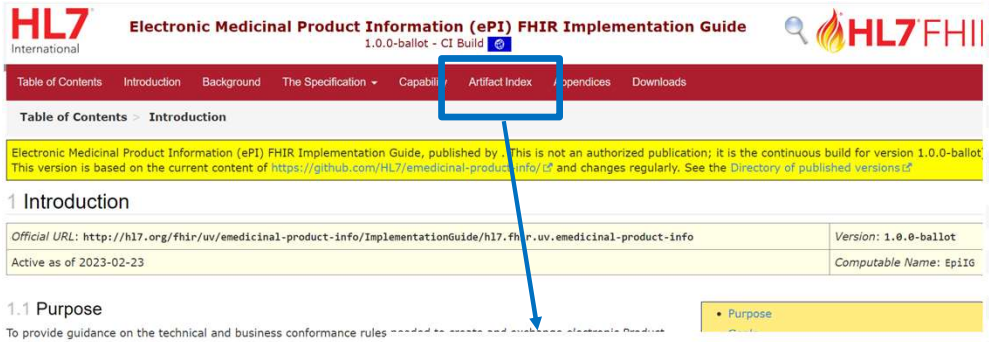
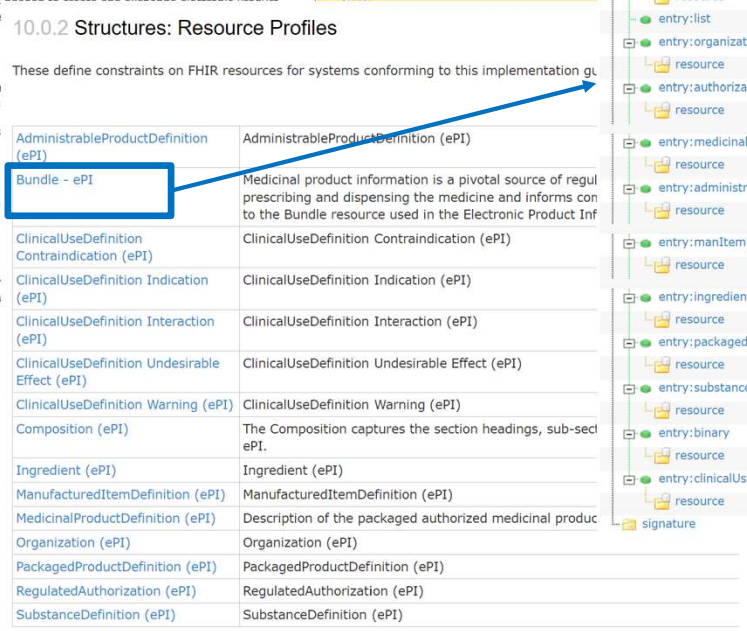
https://build.fhir.org/ig/HL7/emedicinal-product-info





Name	Flags	Card.	Type	Description & Constraints
Bundle	C	0..*	Bundle	Electronic Product Information Bundle Document **bdl-epi-1:** An ePI document must have no additional Composition (including Composition subclass) resources besides the first.
identifier		1..1	Identifier	Persistent identifier for the bundle
type		1..1	code	document | message | transaction | transaction-response | batch | batch-response | history | searchset | collection | subscription-notification **Fixed Value:** document
timestamp		1..1	instant	Persistent original date of approval
~~link~~		~~0..0~~		
Slices for entry		1..*	*BackboneElement*	*Entry resource in the ePI bundle* ***Slice:*** *Unordered, Open by type:$this.resource*
entry:All Slices				Content/Rules for all slices
resource		1..1	Resource	A resource in the bundle
~~search~~		~~0..0~~		
~~request~~		~~0..0~~		
~~response~~		~~0..0~~		
entry:composition		1..1	BackboneElement	Entry in the bundle - will have a resource or information
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
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
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
resource		0..1	MedicinalProductDefinitionUvEpi	Detailed definition of a medicinal product
entry:administrableProduct		0..*	BackboneElement	Entry in the bundle - will have a resource or information
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
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
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
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
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
resource		0..1	Binary	A resource in the bundle
entry:clinicalUse		0..*	BackboneElement	Entry in the bundle - will have a resource or information
resource		0..1	ClinicalUseDefinition	A resource in the bundle
signature		0..1	Signature	Digital Signature.

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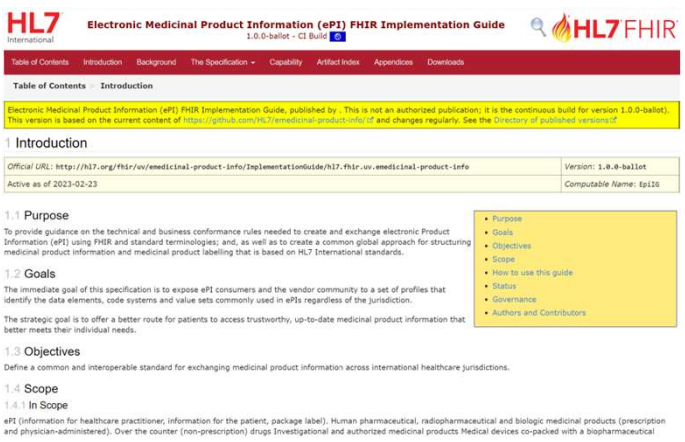
02

ePI Implementation Guide overview


HL7 International

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

HL7 FHIR

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 . 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 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.

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

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

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How the HL7 FHIR ePI looks like

ePI is a HL7 FHIR Document

The container

Bundle

Composition

Other resources Used by the document

Textual Narratives (Sections) + References to the Structured Data

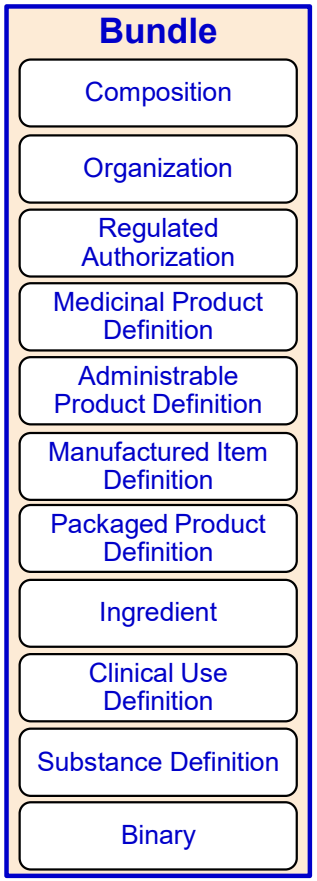
Structured Data (Medicinal Product; Package Product; Administrable Product; Indications; Contra-indications; Warnings; MaH; etc…)

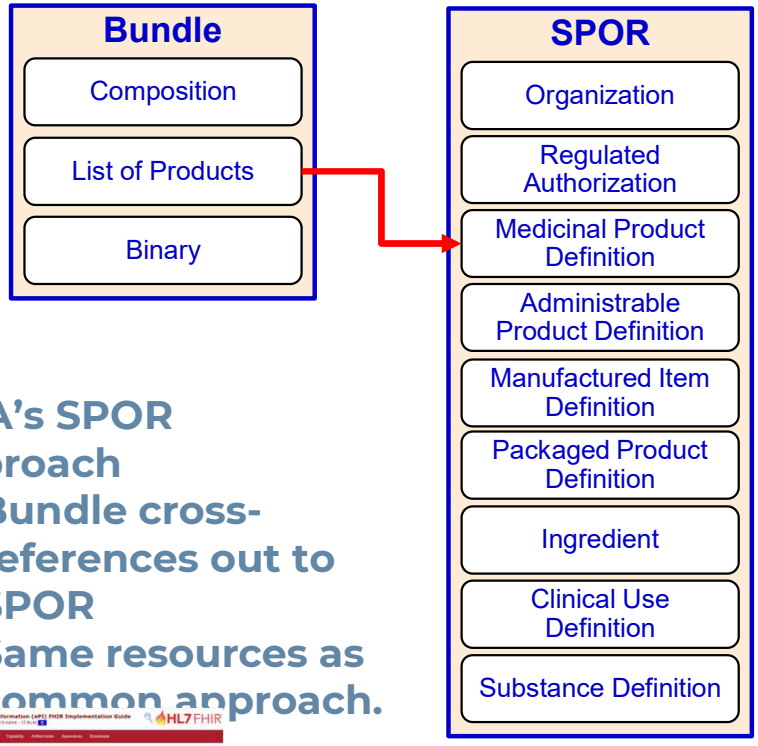
VULCAN

Same foundation, two implementation models

‘Common’ Approach

- All resources self contained in one Bundle.
- Same resources as the SPOR approach.





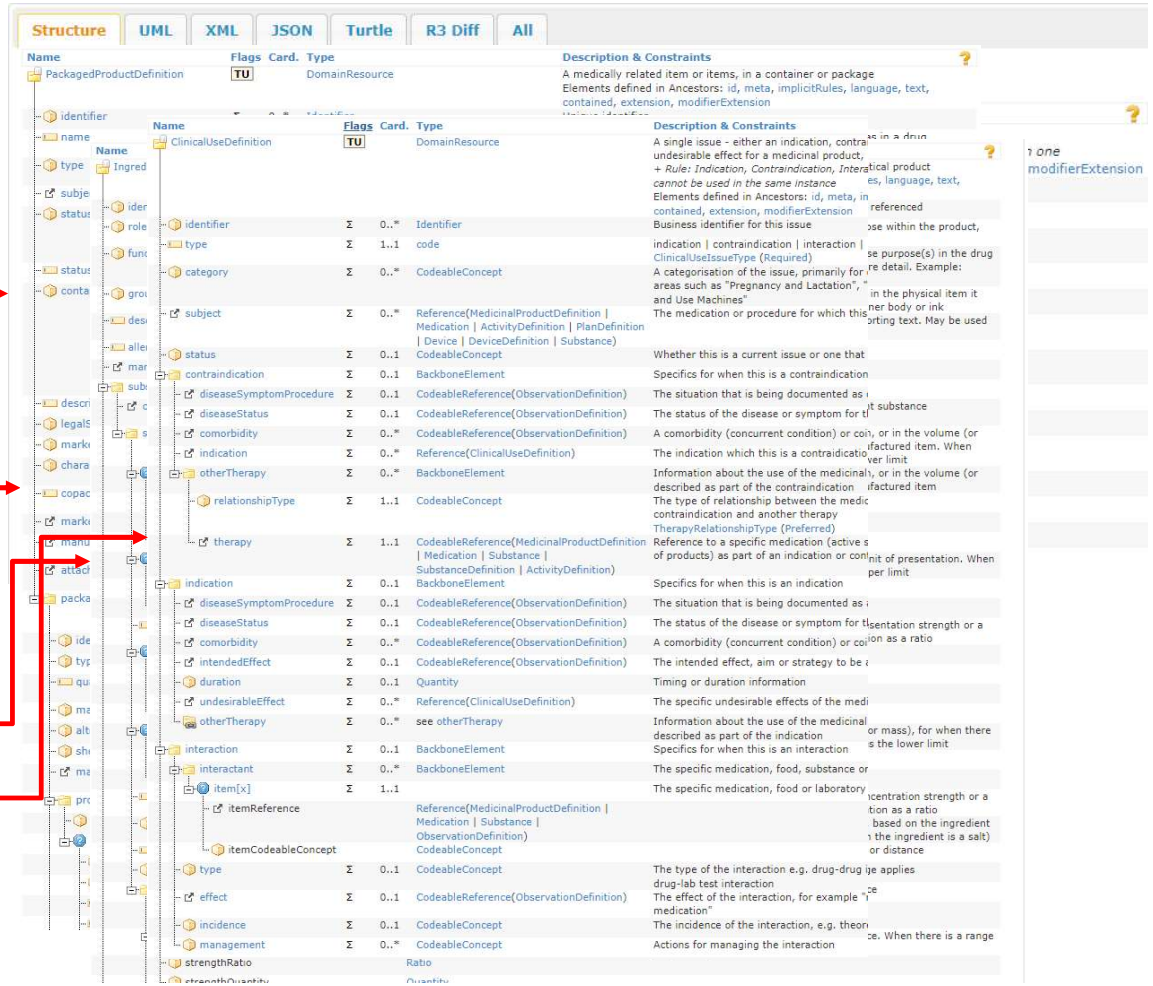
EMA’s SPOR Approach

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

Example: Product Label on FHIR and IDMP

Bundle

- Composition
- Organization
- Regulated Authorization
- Medicinal Product Definition
- Administrable Product Definition
- Manufactured Item Definition
- Packaged Product Definition
- Ingredient
- Clinical Use Definition

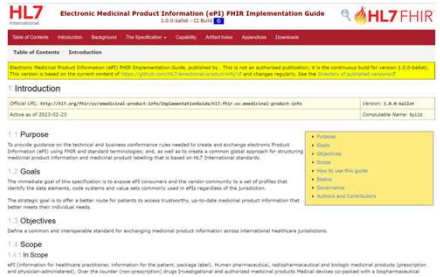


HL7 FHIR Profiles for Organizations

HL7 FHIR Profiles for Packaging

HL7 FHIR Profiles for Ingredients

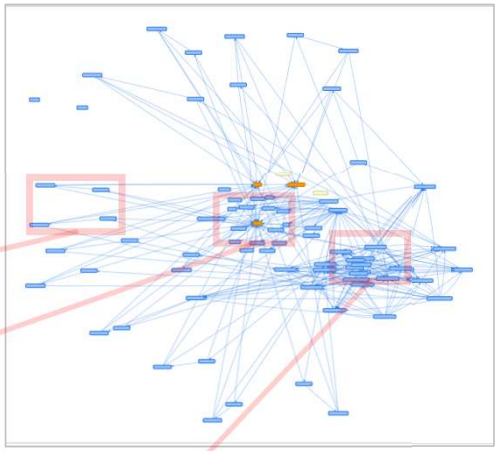
HL7 FHIR Profiles for Clinical Use



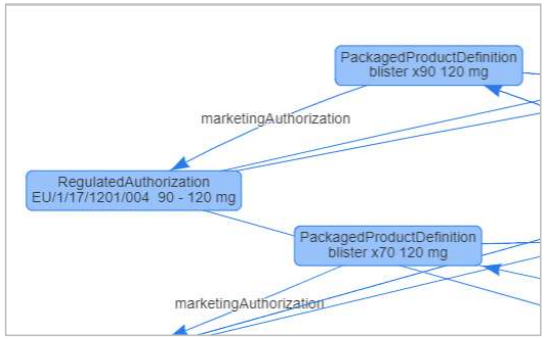
VULCAN

Use case example 1: Viewing ePI content as a graph

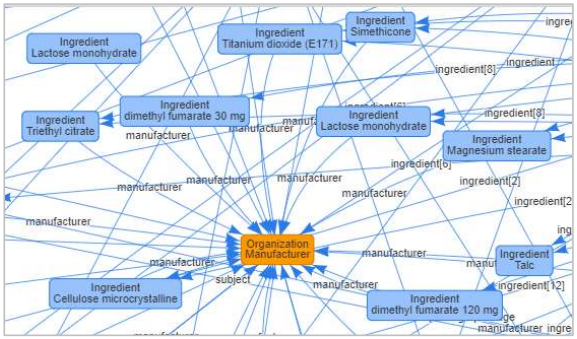
Graphs showing ePI data and data relationships.
This graph shows the 90+ data objects in a single ePI.
Graphing your drug portfolio leads to benefits like rapid impact analysis changes (e.g., Safety updates, formulation, packaging).



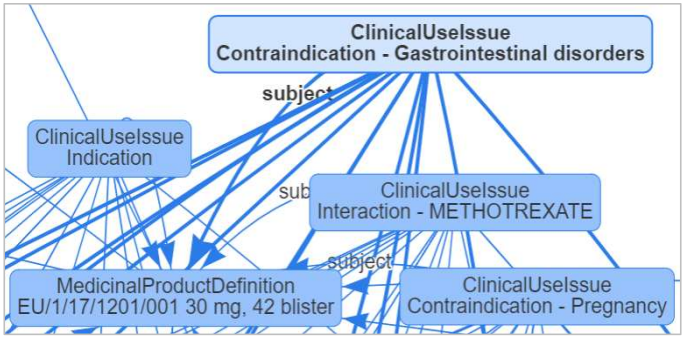
Packaging and Authorization



Ingredients and Manufacturer



Clinical Details and Medicinal Product



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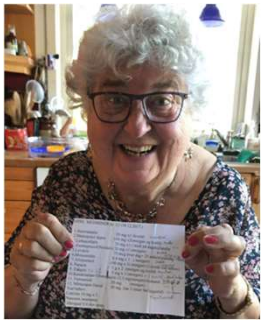
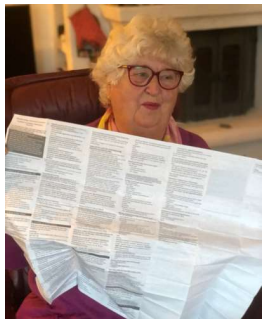
The Goal

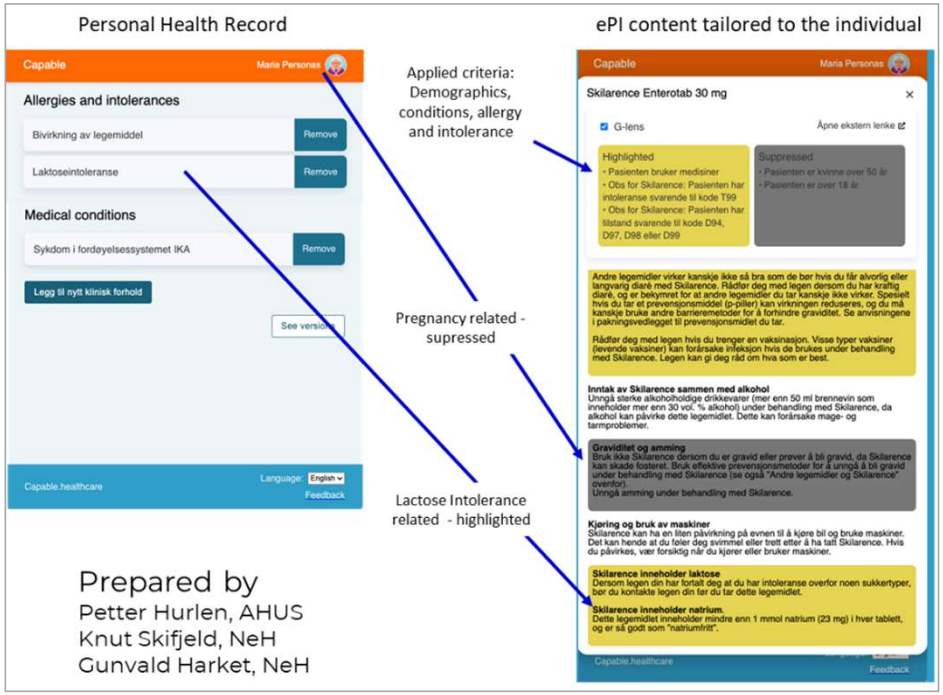
Maria and her medicines



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.

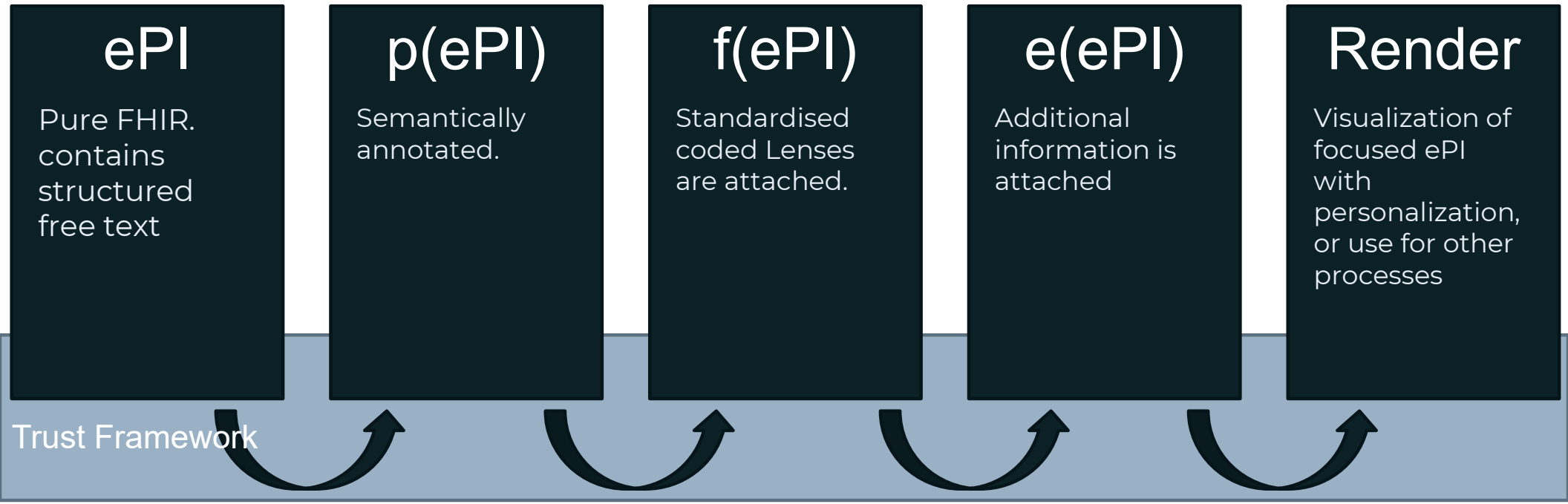
AMBITION

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.

VULCAN

Gravitate Health

How to achieve it - focusing



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

Add clinical Knowledge (lenses)

Add Extra information (IPS, user choices)

Personalized ePI

VULCAN

Gravitate Health

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)

VULCAN

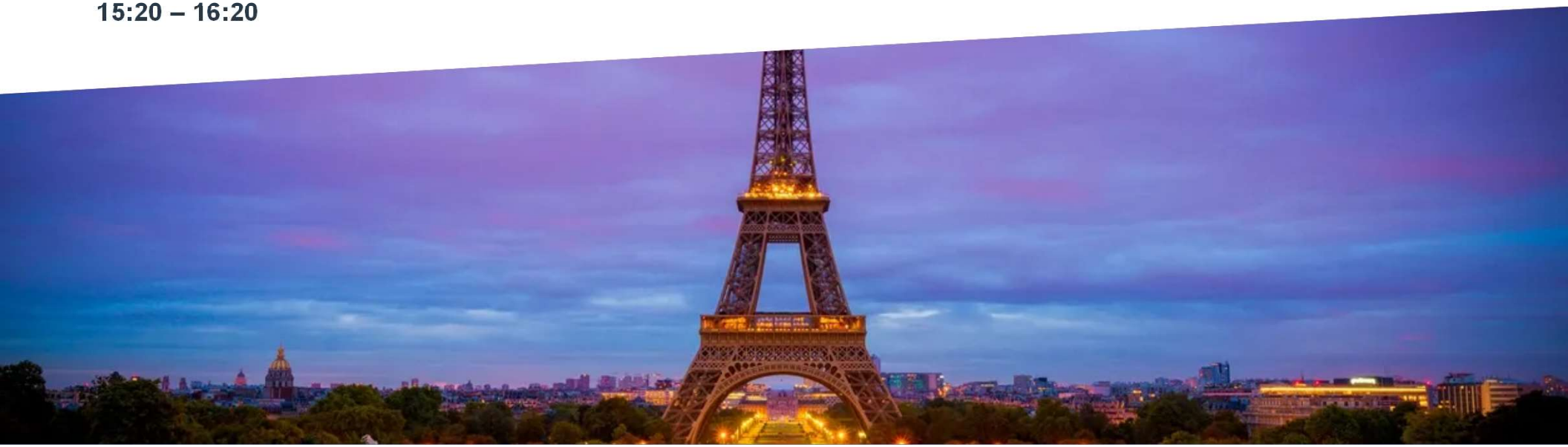
9. Vulcan Electronic Product Information (ePI)

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



acodis

VULCAN HL7 FHIR

Turning Patient Leaflets Into HL7 FHIR

Implementation Insights / Showcase

EUROVULCAN - MARCH 2023

Introduction

Thank you for having us in Paris!

Sonja Steiner
acons it consulting
CEO, Traceability Expert
+41 79 44 99 455
sonja.steiner@acons.ch

Patrick Bürkle
Acodis AG
Chief Customer Officer
+41 79 284 06 43
patrick.buerkle@acodis.io

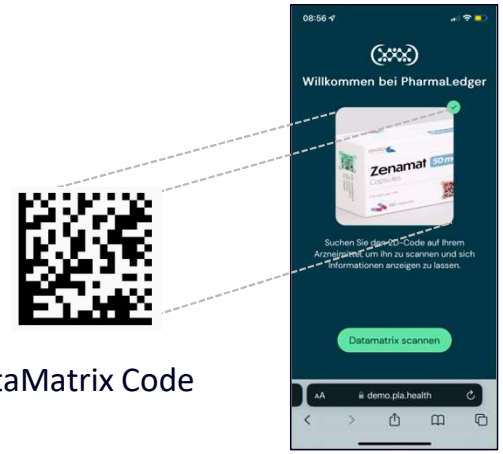
1. The Challenge at Hands:
How to create structured data from unstructured source documents

How it started

Word 2 XML Conversion for PharmaLedger Project

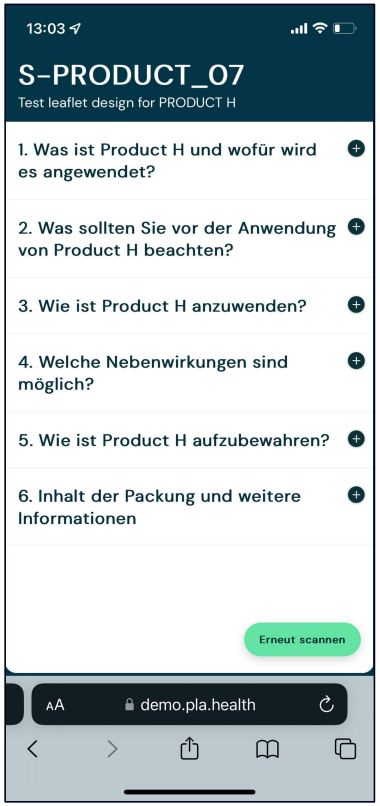
for patient leaflet information not available in structured format

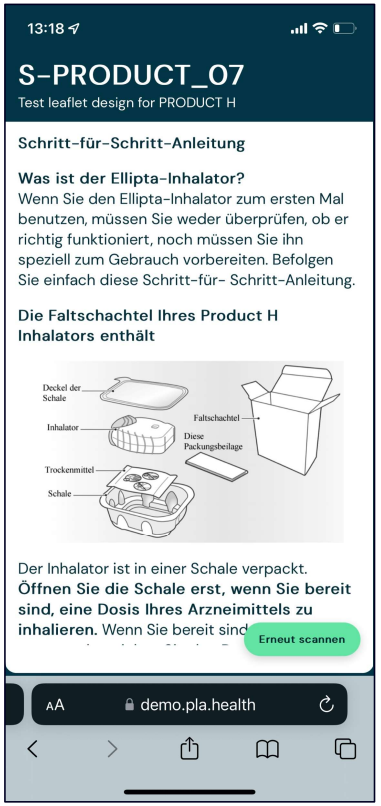
Patient Journey



DataMatrix Code

PharmaLedger app





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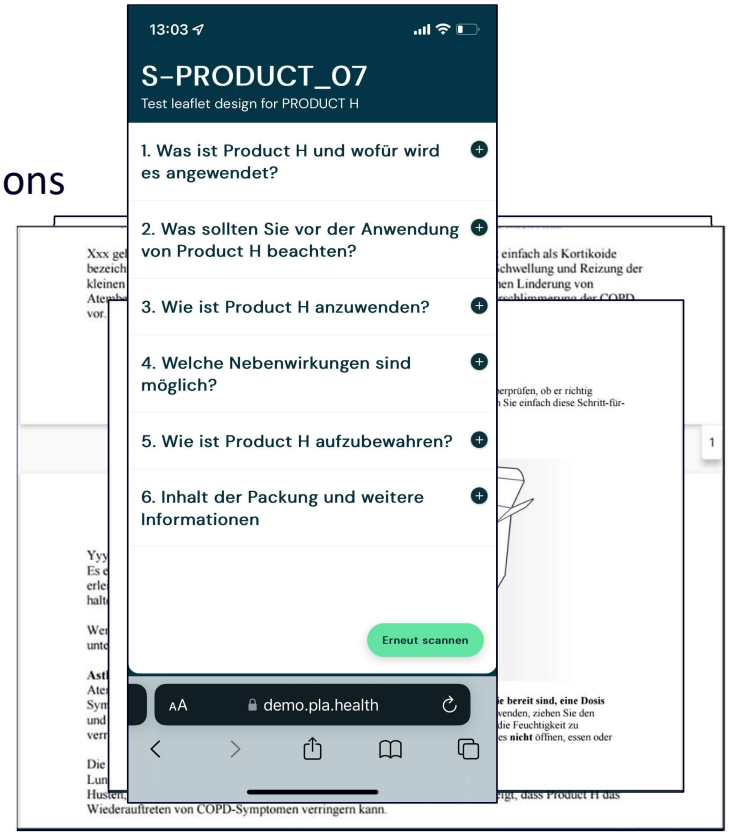
The Challenge at Hands

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

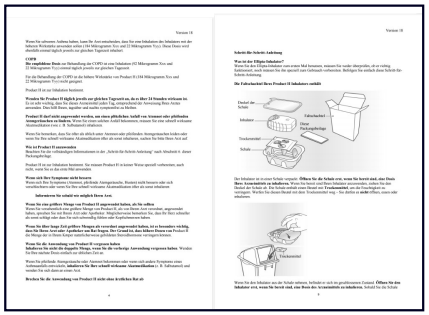
1. Open Platform with Link in presentation
2. Quickly explain the GUI
3. Go to Folder with leaflets – explain the steps to be applied at an example – how to build a model
4. structure the leaflet of Product H
    1. Drag and Drop Document H / mention Automation via email or API
    2. See steps on lefthand 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

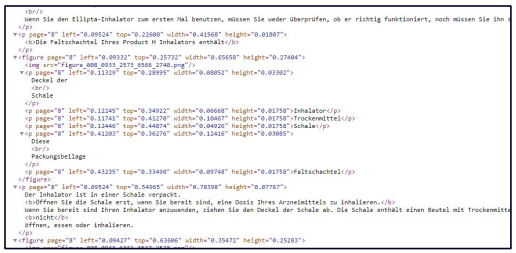
Supplier Support Journey

Template* of Product H



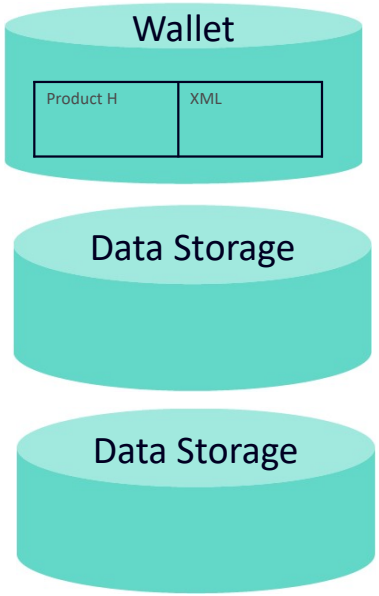
*Any template can be processed. For this demo, we used a QRD document

Structured Product H as XML



FHIR

...or any other requested format



Scope of Acodis

acodis

3. About Acodis

Turn Any Document Into Structured Data – in Seconds

Data Extraction from highly complex documents within regulated environments

About Acodis

We structure complex documents within Health, Pharma & Life Science

Operations

- Patient leaflets
- Packaging information
- Artworks
- Labels
- Batch records
- Standard Operating Proc.

Regulatory & Risk

- Scientific Articles
- Study reports
- Vendor audit report
- Trial records
- Standards (Normen)
- Regulations

Quality Mgmt.

- Safety Data Sheets
- Quality reports
- Cert. of Conformity
- Certificate of Analysis (CofA)
- Stability Reports

Legal & Sales

- Contracts
- Customer Documentation

R&D

- Informed Consent Forms
- Patient Information

Structured Standards (FHIR) NLP Projects AI Initiatives Databases

About Acodis

Acodis in a Nutshell

25

Experts

ETH zürich

swiss made software

TOP 30 AI STARTUP BY Forbes

Information Security

Quality Management

Service Orga. Control 2

Roche syngenta Novartis

EPI

UNIVERSITÄTS-KINDERSPITAL ZÜRICH

High Performer WINTER 2023

Best Support WINTER 2023

Easiest To Do Business With WINTER 2023

4. Q&A

Thank you!

Patrick Bürkle
Acodis AG
Chief Customer Officer
+41 79 284 06 43
patrick.buerkle@acodis.io

Find me on LinkedIn:
https://www.linkedin.com/in/patrick-buerkle/

VULCAN HL7 FHIR

Stadthausstrasse 14, CH-8400 Winterthur
www.acodis.io

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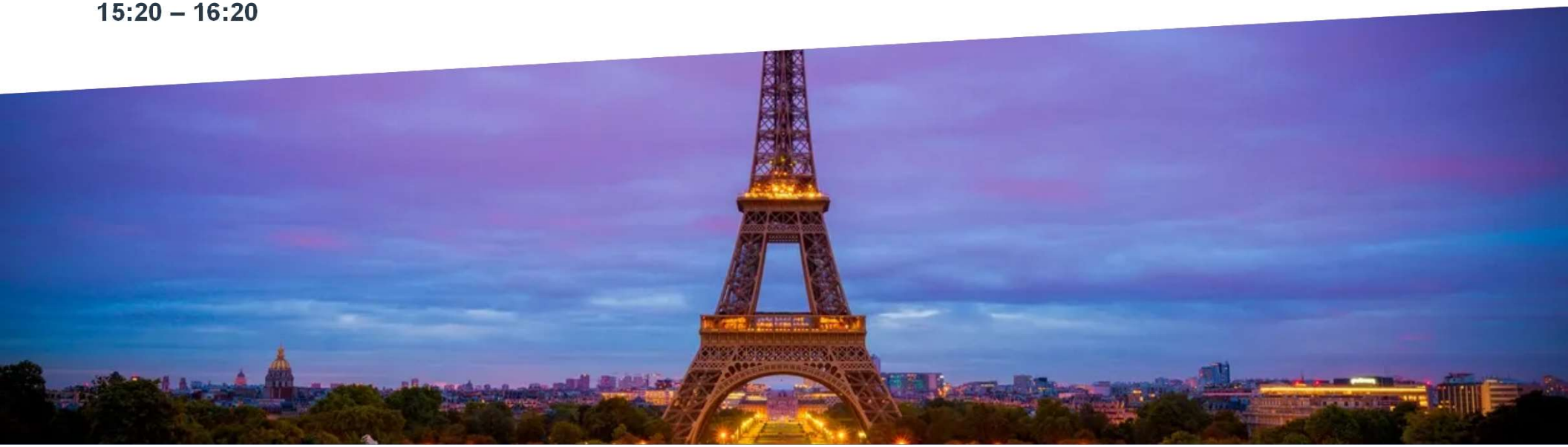


Docuvera™

Structured Authoring - Supporting IDMP Submissions using HL7 FHIR Standard

EuroVulcan Conference
March 14–15, 2023

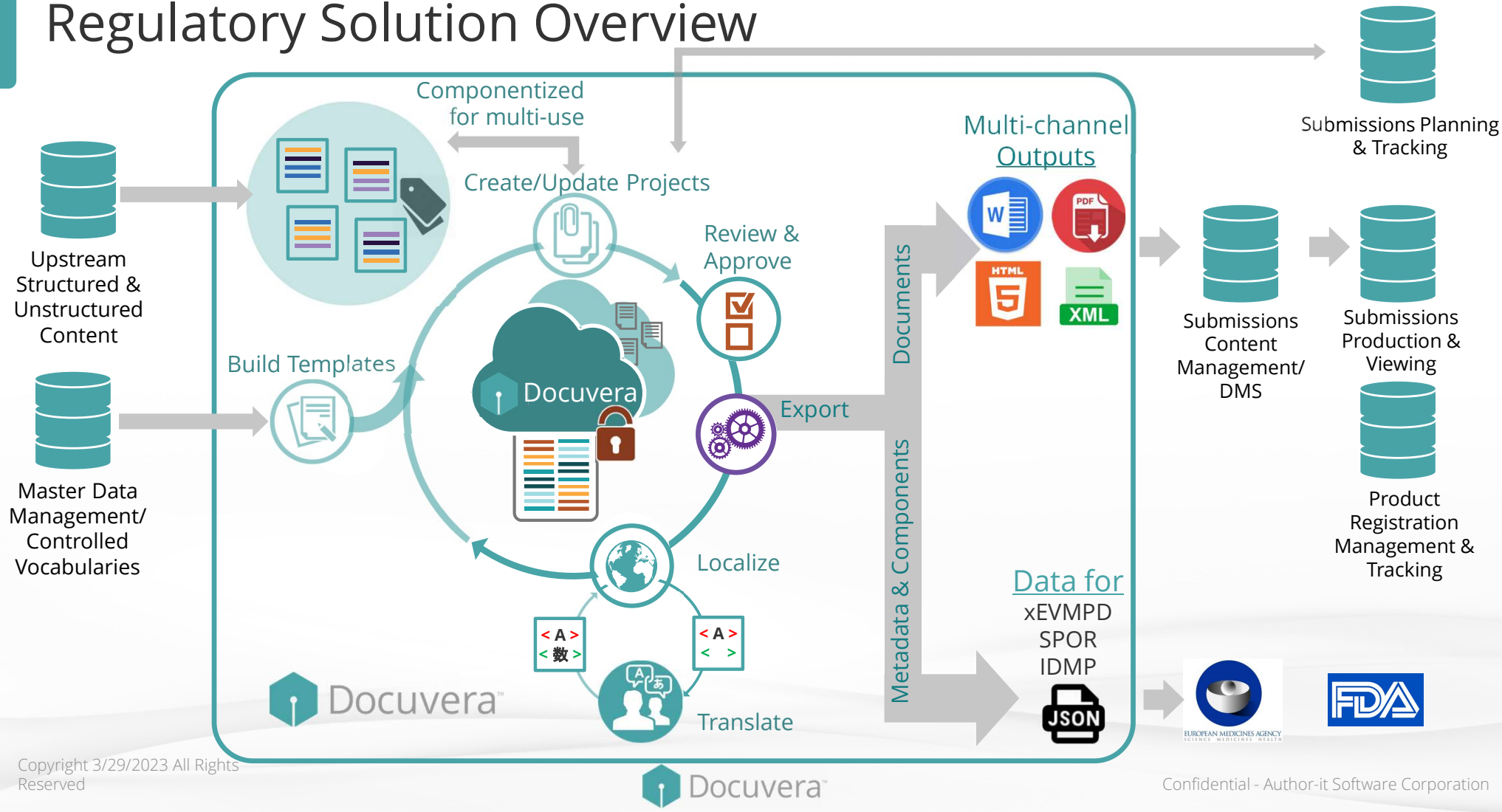
asc AUTHOR-IT SOFTWARE CO.

Presentation Objectives

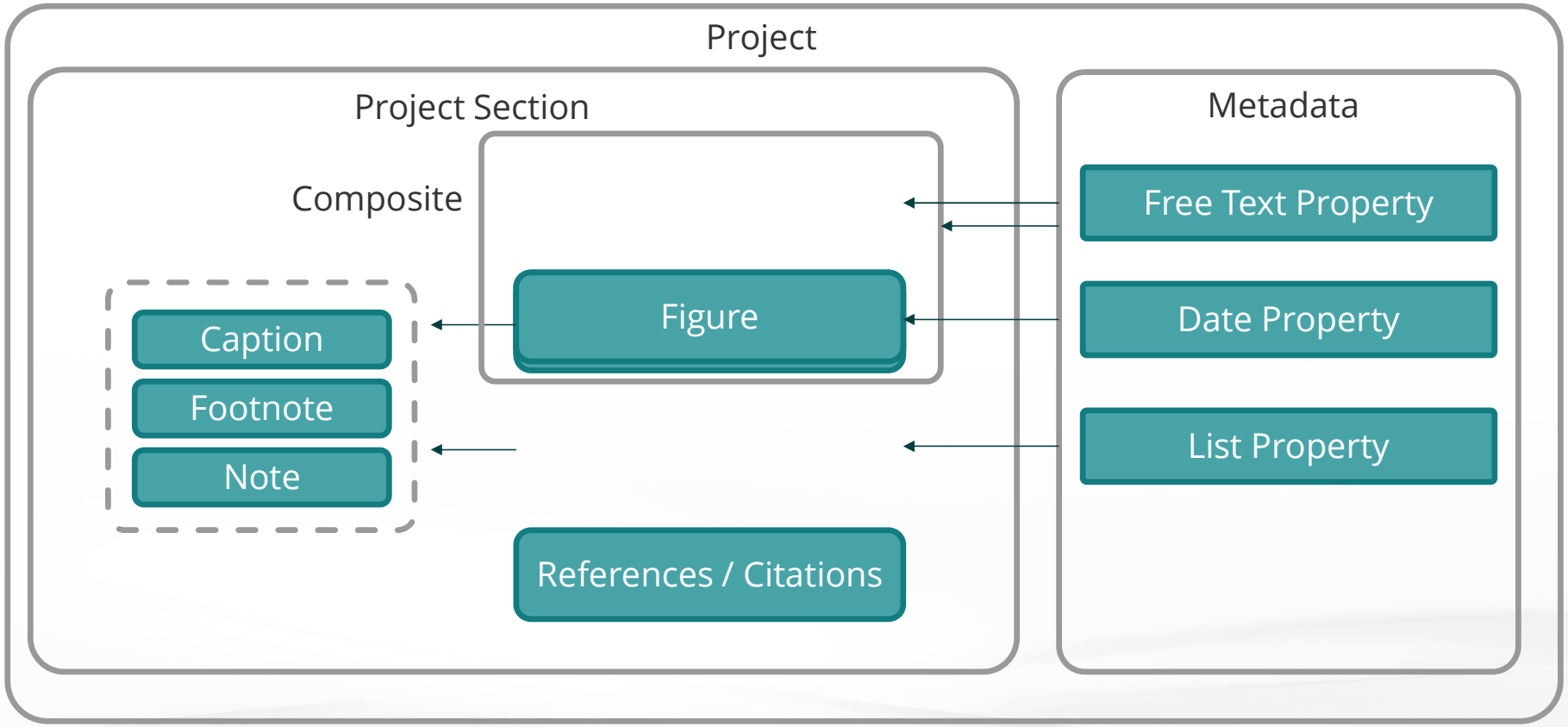
- High-level demonstration of Docuvera
- Describe Structured Authoring with Docuvera in a Regulatory Setting
- Discuss Current Docuvera IDMP FHIR Export Capabilities
- Show FHIR Composition Export Capabilities to Support ePI
- Explain Findings from FHIR Composition Generation
- Show Production Use Cases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


Demonstration

Regulatory Solution Overview

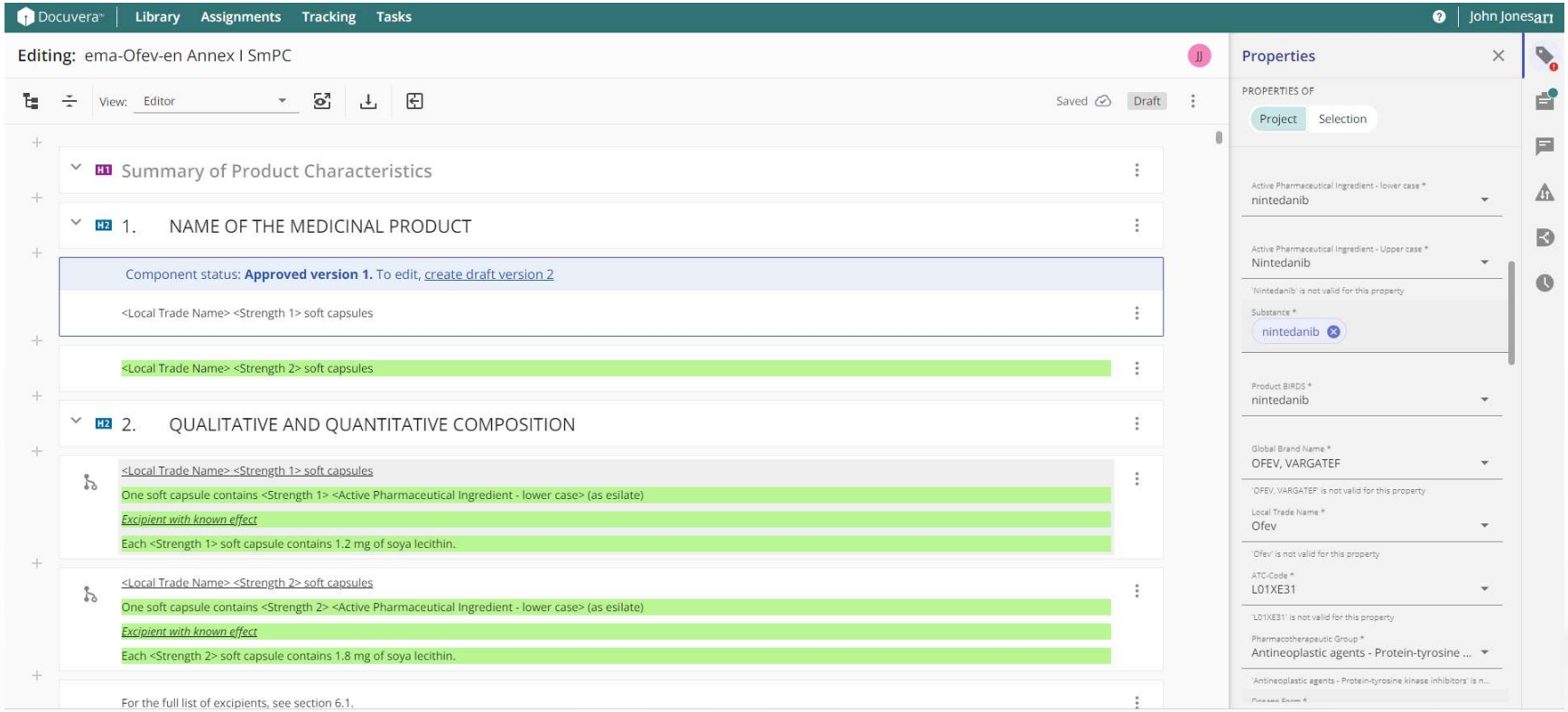


Anatomy of a Structured Document (Project)



Docuvera™

Example SmPC Authored in Docuvera – 1 of 2



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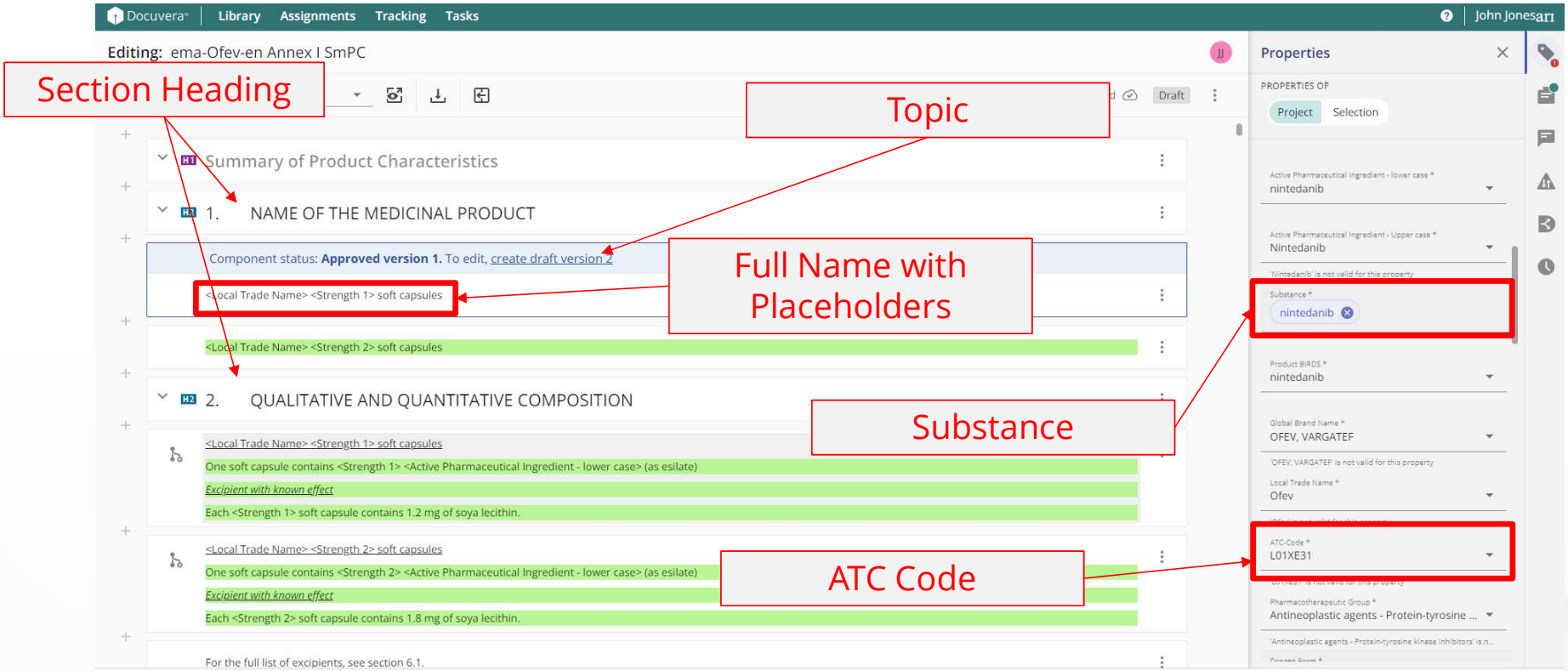
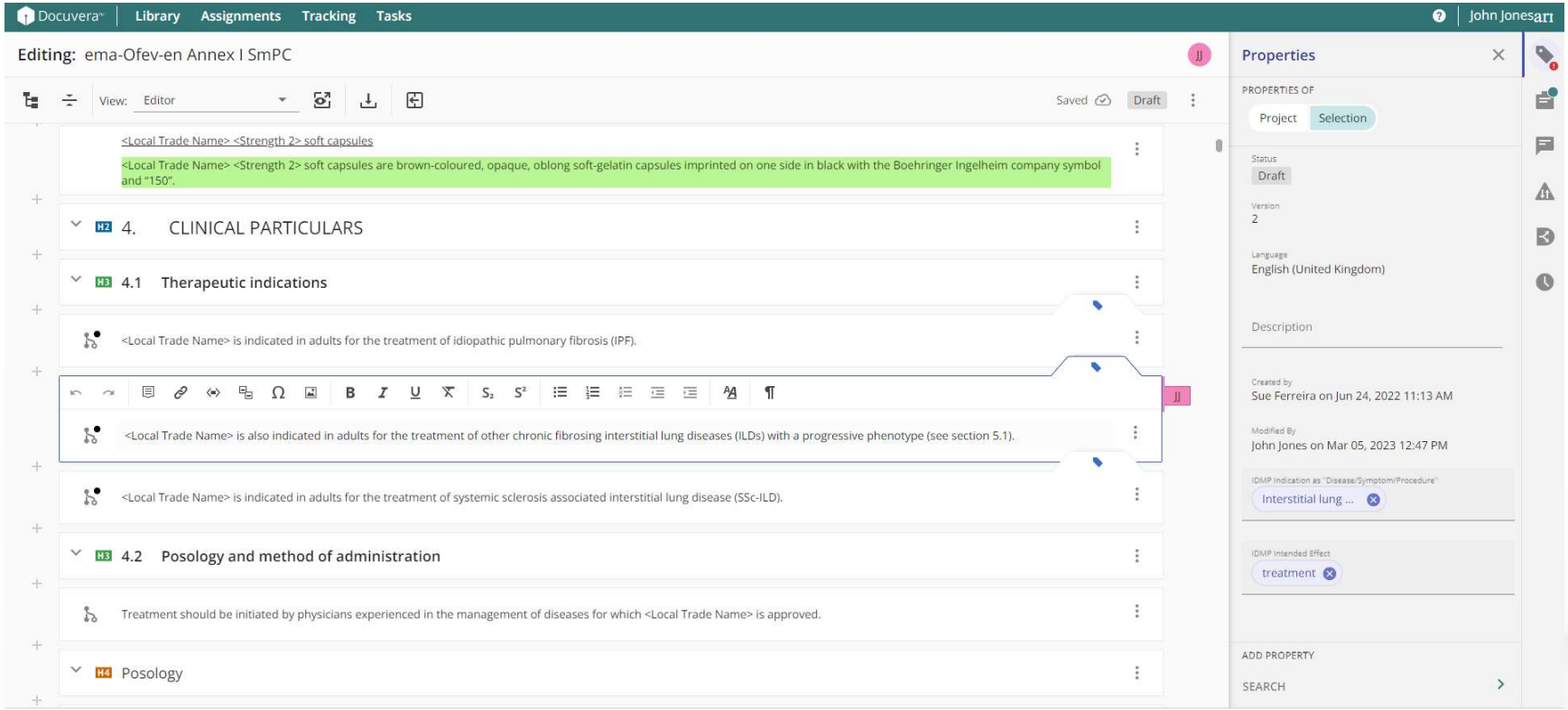
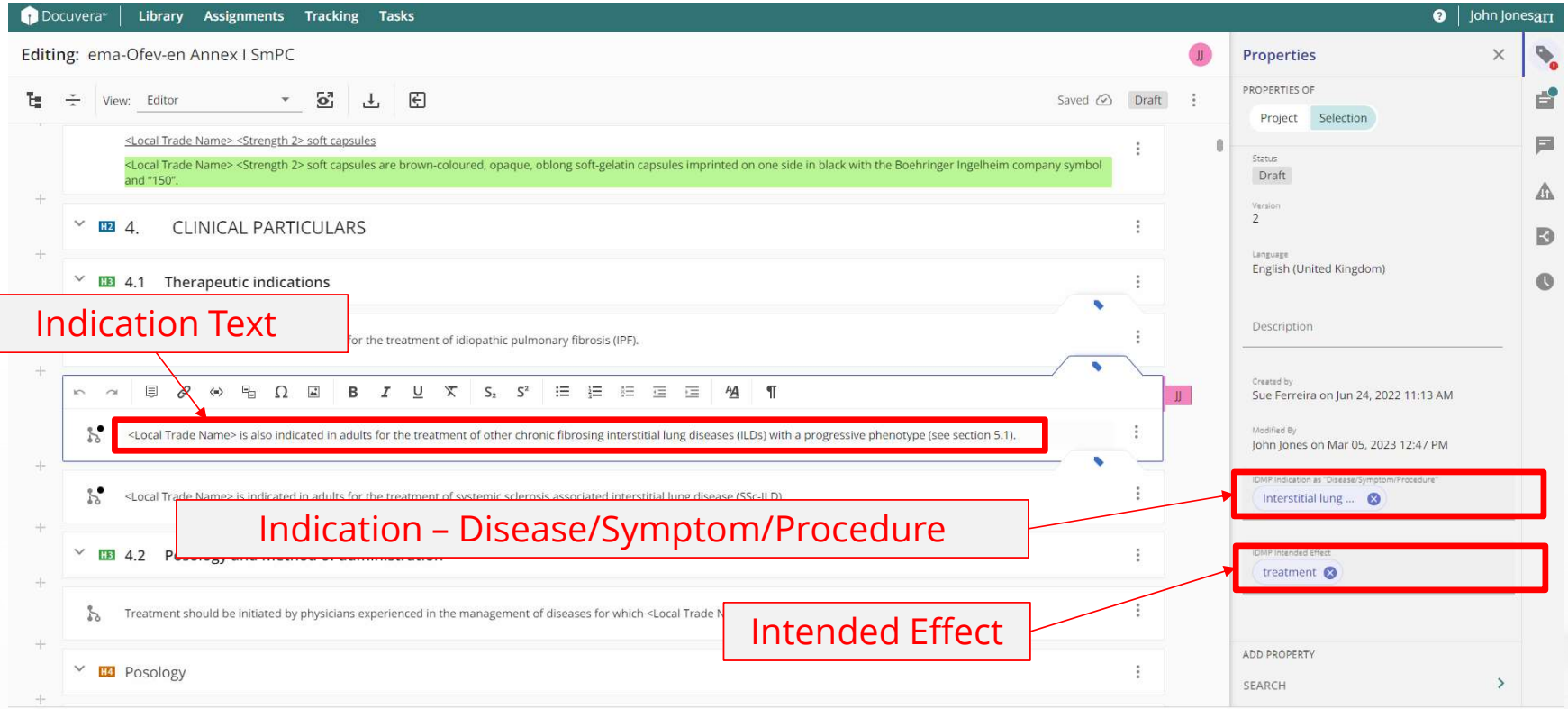
Example SmPC Authored in Docuvera – 1 of 2



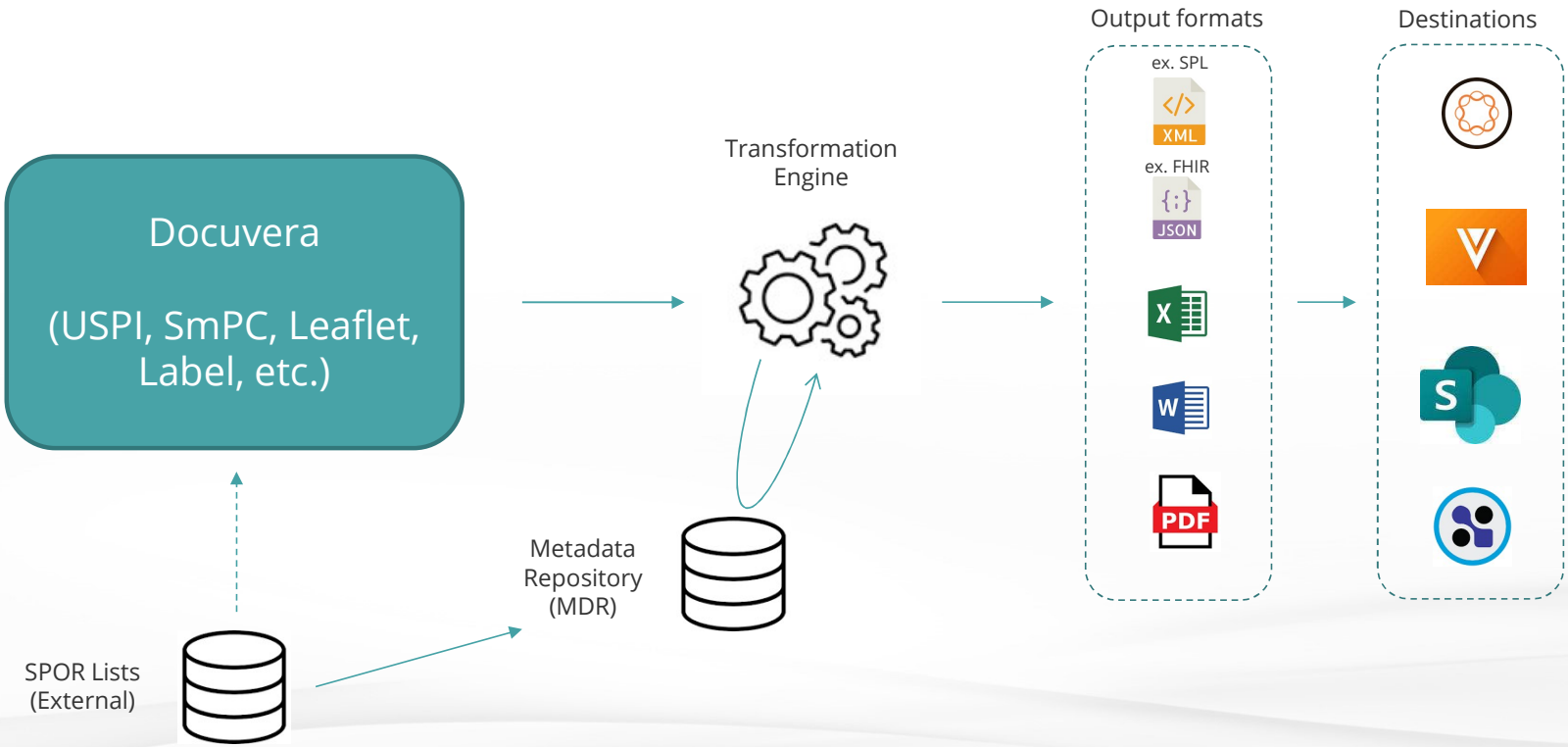
Example SmPC Authored in Docuvera – 2 of 2



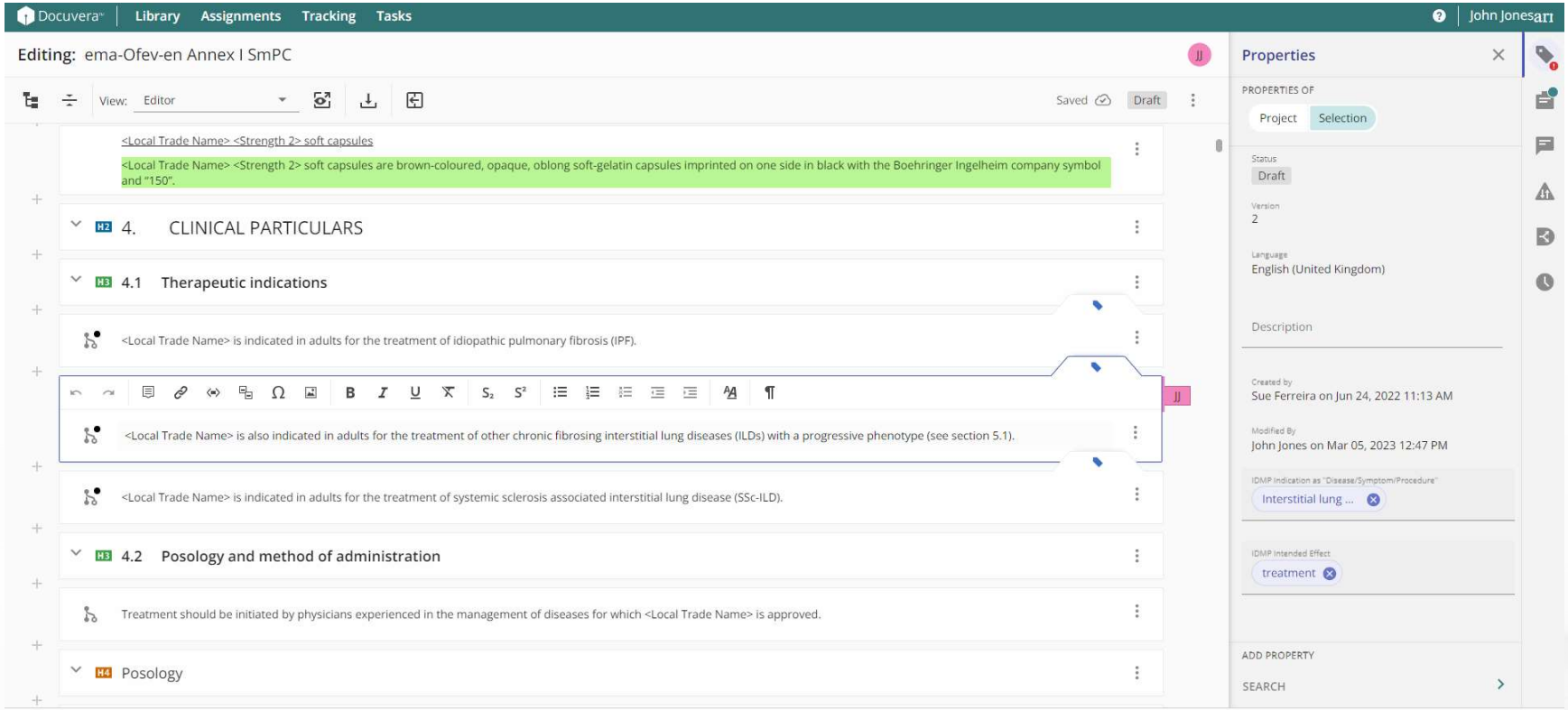
Example SmPC Authored in Docuvera – 2 of 2



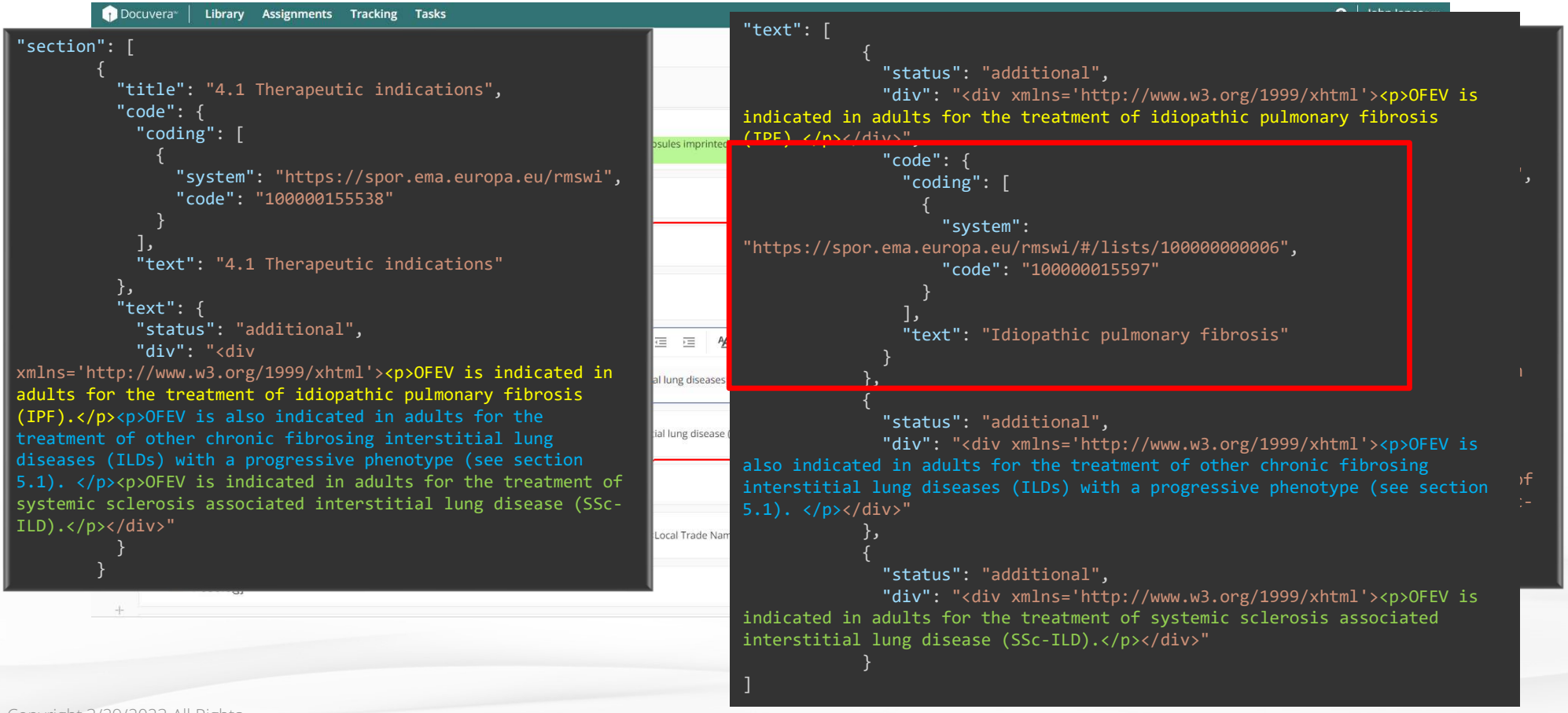
Docuvera Advanced Export Capability



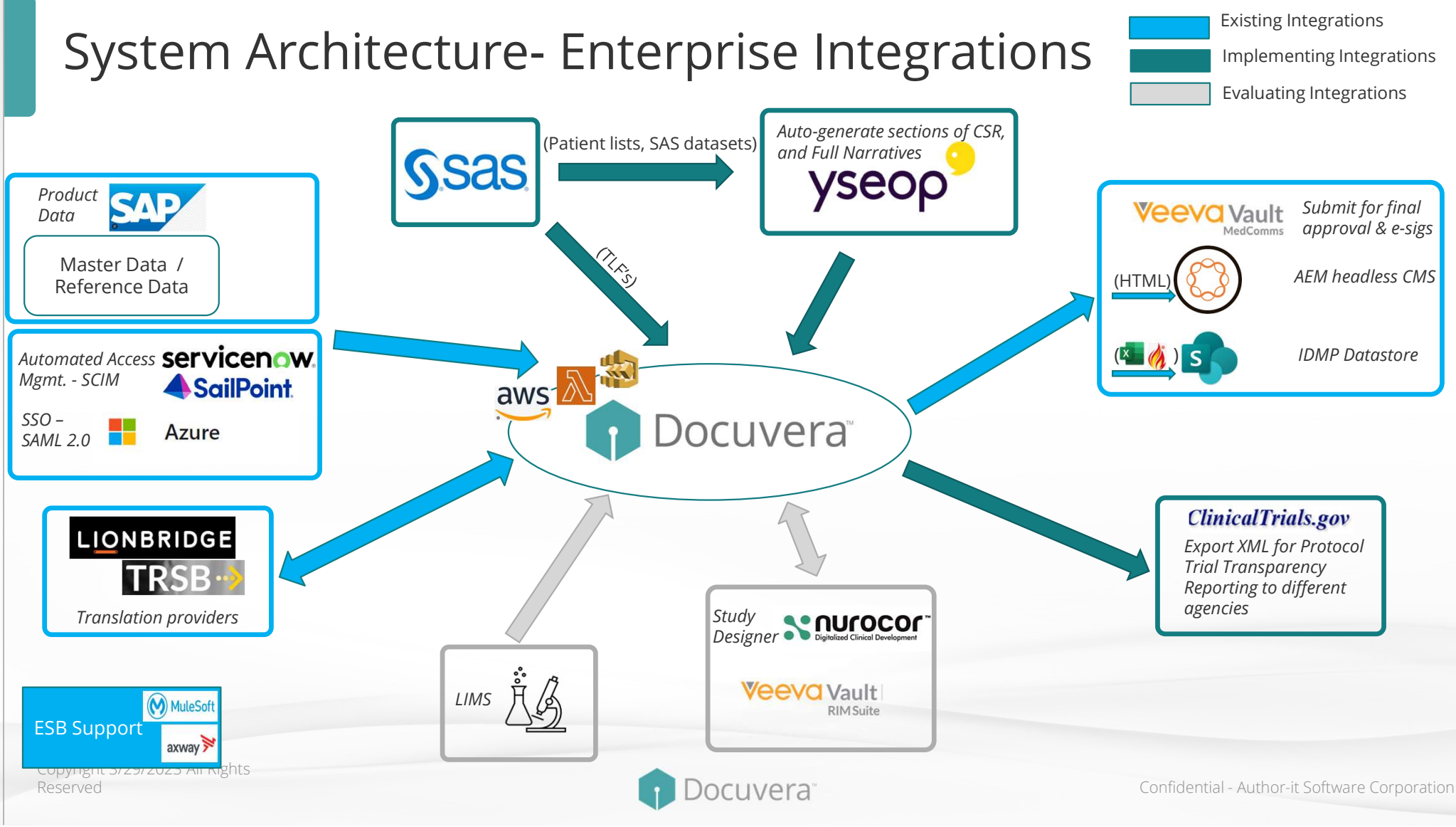
Sample Export – SmPC FHIR Composition



Sample Export – SmPC FHIR Composition



System Architecture- Enterprise Integrations




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