Welcome!

Day 1 Programme

EuroVulcan Conference & Connectathon
Welcome & Opening Address

Amy Cramer, Hugh Glover
ARE
EuroVulcan Thanks Our Speakers
Across Industry, Across Perspectives
EuroVulcan Thanks Our Contributing Partners
Supporting Vulcan from Many Perspectives
EuroVulcan Thanks Our Organising Committee
Making it all Happen

Anne Moen
Catherine Chronaki
Christel Daniel
Amy Cramer
Darren Weston
Hugh Glover
Michael van Campen
Stacy Tegan
Shani Sampson
Sandy Vance
Katleen Renders
Nikki Huysmans
Nicolas Riss
EuroVulcan
Conference & Connectathon
2. Vulcan Overview

Amy Cramer, Vulcan co-Chair / J&J
9:45 – 10:10
Interoperability Case Study: Finance
Digital Lessons from the Finance Industry

We get paid electronically
The money goes directly to your bank
You are able to access your money from anywhere in the world
We can make transactions with the funds electronically even though we have never seen it physically

TRANSFER OF FUNDS

A world in which everyone can securely access and use the right data when and where they need it
The Need for Standards in Clinical Research
Data is the Key

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

The goal of the forum was to help the research community align toward leveraging HL7 FHIR® for more effective acquisition, exchange and use of data for clinical research.
The Convening Members of Vulcan
Represent a Wide Variety of Expertise

HL7 Accelerator Program: Project Vulcan

- Standards Development Organizations
- Government Agencies
- Industry Groups
- Technology Vendors
- Patients
- Research Academia

Convening Members:
- HL7 International
- TransCelerate Biopharma Inc.
- Lægemiddelstyrelsen
- FDA
- NIH: National Center for Advancing Translational Sciences
- NIH: U.S. National Library of Medicine
- EuroVULCAN
- Society for Clinical Data Management

The Convening Members of Vulcan represent a wide variety of expertise, including industry groups, technology vendors, government agencies, patients, research academia, and standards development organizations.
Current Member Organizations of Vulcan
As of February 2023

* Lægemiddelstyrelsen
  Danish Medicines Agency

* ACCO
  Alliance of Clinical Research Organizations

* BioVeras
  Blockchain for Life Science

* Cedars Sinai

* CDISC
  Foundation

* CRON’S & COLUMITIS
  Foundation

* Duke University
  School of Medicine

* Droice Labs

* Epic

* FDA

* Fujitsu

* GSK
  International

* HL7

* IgniteData

* Infor

* InterSystems
  Health | Business | Government

* Johnson & Johnson

* Medidata

* Microsoft

* MITRE

* NIH
  National Center for Advancing Translational Sciences

* NIH
  U.S. National Library of Medicine

* OpenClinica

* Oracle

* Parexel

* PatientLink
  MyLinks

* Pfizer

* Phuse

* Roche

* SCDM
  Society for Clinical Data Management

* TransCelerate Biopharma Inc.

* UAMS
  University of Arkansas for Medical Sciences

* UiO
  University of Oslo

* University of Colorado Anschutz Medical Campus

* UT Health
  San Antonio

* Vanderbilt University

* EuroVULCAN

* indicates a convening member of Vulcan
**HL7 Accelerator Program**
Focused Standards Development

**Vulcan**
Connecting translational and clinical research with healthcare

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

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

**FAST**
Define a scalable approach to deploying FHIR across interoperability use cases

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

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

**CodeX**
Accelerate interoperable data modeling and applications cancer patient care and research

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

**EuropVULCAN**

**HL7 FHIR ACCELERATOR**

**FAST**
FHIR AT SCALE TASKFORCE

**HL7 FHIR**

**ARGONAUT PROJECT**

**carin**
Creating Access to Real-time Information Now through Consumer-Directed Exchange

**CodeX**

**Da Vinci**

**HL7 FHIR**

**Accelerator Program**
Focused Standards Development
Why Vulcan?
Fully integrate research into the delivery of healthcare by streamlining data collection and exchange into a singular process.

What are we doing to reach that vision?
• Collaborating with the international research community to align clinical data and clinical research data at the point of collection.
• Developing out the HL7 FHIR standard to support the bidirectional flow of data.

How will we accomplish this?
• Bridge existing gaps
• Strategically connect industry collaborations
• Maximize collective resources
• Deliver integrated tools and solutions
### The Goals of Vulcan

<table>
<thead>
<tr>
<th>BRIDGE EXISTING GAPS</th>
<th>STRATEGICALLY CONNECT COLLABORATORS</th>
<th>MAXIMIZE COLLECTIVE RESOURCES</th>
<th>DELIVER INTEGRATED TOOLS AND SOLUTIONS</th>
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</thead>
<tbody>
<tr>
<td>Work to close gap between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency</td>
<td>Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups including EMA, FDA, NCATS, NLM, SCDM, TransCelerate, and academic research sites</td>
<td>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</td>
<td>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</td>
</tr>
</tbody>
</table>
Vulcan Structure and PMO Team Membership

Vulcan Leadership
- Amy Cramer
- Darren Weston
- Becky Kush
- Maryam Garza
- Mike Hamidi

Vulcan PMO
- Michael van Campen
- Stacy Tegan
- Hugh Glover
- Shani Sampson

Steering Committee
Advisory Council
Operations Committee
Project Teams
Vulcan – Moving Forward
Inflection Point

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

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

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

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

2023 & Beyond
3. Connectathon Overview

Hugh Glover, Vulcan
10:10 – 10:30 (20 minutes)
Project Connectathon
Deals with things:

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

Deals with processes:

- Visits,
- Encounters,
- Care Events

Spans:

- Clinical Research activities
- Clinical Care ones

IG first draft in January 2023
## Schedule of Activities

### Protocol Attachment LZTT.1

**Schedule of Events for Protocol H2G-MC-LZTT(c)**

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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**Notes:**
- Ambulatory ECG placed
- Ambulatory ECG removed
- ECG
- CT Scan (if per req)

---

**JSON Representation:**

```json
{
  "date": "2021-03-28T14:52:19Z",
  "observationRequirement": [
    {
      "reference": "Vital-signs-Temperature-Observations"
    }
  ],
  "observationResultRequirement": [
    {
      "reference": "Vital-signs-Temperature-Observations"
    }
  ]
}
```

---

**EuroVULCAN**
Can we agree? ...

New software being freshly made, has not had time to acquire bugs ...
Software engineers always understand what the users want ...
A written set of instruction is always easy to follow ...
People rarely make mistakes ...

NO?

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

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

HAVE CONNECTATHONs !!!!
What’s in a Connectathon?

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

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

There can be many other tests
HL7 January 2023 Connectathon

HL7 FHIR Connection 32
IN-PERSON EVENT!
Henderson, Nevada | January 14-15, 2023
9:00 AM PT to 5:00 PM PT
Montelago Event Center Table Layout
Newcomer Orientation - Recording here!
Event contact: Sandy Vance
Reach Sandy at sandy@counterpointsol.com
or HL7Connectathon@hl7.org

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

Participant Check List
1. Register for the Connection before the Early Bird Cut-off December 16th
2. Review the Connectathon Track List below

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

Jan 2023
35 Tracks
250 Participants
EuroVulcan – Example Track Details

2023 - 03 Electronic Product Information

- 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

Short Description

The track is part of an ongoing series, spanning multiple Connections, to test the creation, exchange and display of electronic Product information (ePI) and the International Patient Summary (IPS) as PHR Documents, as well as potential UNICOM scenario's for EMR implementation.

Each phase will include increased numbers of product information and increasingly complex healthcare/EMR scenarios.

Track Objective is to test and gather feedback on the following:
1. Links to the ePI and IPS – basics and connection between them
2. Searching ePI and IPS documents
3. Linking of terminologies and clinical to regulatory terminology
4. Structured Annotation
5. Persuasion Dimensions as PHR artifacts
6. Creating and validating ePI

The track is supported by the EU IMI Project Gravita Health, the EU funded project UNICOM and supports the ePI pilot project at the European Medicines Agency.
Vulcan Connectathons to Date

Jan 2021
- SOA
- RWD
- Med
- Pheno

Sept 2021
- SOA
- RWD

May 2022
- SoA
- ePI

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

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

Jan 2022
- RWD
- ePI
- AE

Sept 2022
- SoA
- RWD
- ePI
- Pheno
- ...

7 Events
7 Topics
24 Tracks
Real World Data

May 2021
• Continuing the work from January – identifying concomitant medication from an EHR
• PatientLink kindly provided an update of the reference implementation

Jan 2022
• Move beyond medication
• Query an existing study in FHIR to find data and transform to SDTM
• Identify a minimum data set
• Evaluate generated SDTM data set

Jan 2023
• Updated React app that displays activities in visit windows to incorporate administrations and unscheduled activities
• Additionally, progressed
• Investigational Product Administration
• Unscheduled Activities

Jan 2021
• Comparing Patient vs ResearchSubject resources
• Looking at sources of data: MedicationStatement vs MedicationRequest
• Active vs Historic Medication

Sept 2021
• Primarily retrospective analyses of EHR data
• Develop HL7 FHIR capabilities
• Development of US Core to support RWD

Sept 2022
• Created a synthetic data set to help develop EHR queries
• Successfully queried the data using inclusion / exclusion criteria for patients of interest
• Compared retrieved data to source data to confirm that queries were working correctly
• Compared queried data to other EHR sources
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
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)
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 than 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.

Next Steps
• Begin preparing final version of the Implementation Guide for year end ballot.
• Finalize global profile and regional profiles (EMA, FDA and Japan).
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
A connectathon is:

- Contact sport
- Structured
- Practical - Works with understandable applications
- Finds out what works and what doesn’t
- Updates the specifications as required
Questions?
Networking Break

10:30 – 11:00
4. Vulcan Fundamentals

Stacy Tegan, Vulcan / TransCelerate Biopharma
11:00 – 11:20
Let’s take an inside tour of Vulcan
# Current Member Organizations of Vulcan

As of February 2023

<table>
<thead>
<tr>
<th>Academic Institutions</th>
<th>Consortia</th>
<th>Government Agencies</th>
<th>Implementers</th>
<th>Pharma</th>
<th>SDOs</th>
<th>Others (e.g., thought leaders, SMEs, CROs, Patient Advocates)</th>
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<td>phuse</td>
<td>Lægemiddelstyrelsen</td>
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<td>GSK</td>
<td>cdisc</td>
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<tr>
<td>Duke University School of Medicine</td>
<td>Society for Clinical Data Management</td>
<td>FDA</td>
<td>BioVeras</td>
<td>Johnson &amp; Johnson</td>
<td><em>HL7</em> International</td>
<td>CROHN'S &amp; COLITIS FOUNDATION, FELLESKATALOGEN</td>
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<tr>
<td>University of Colorado - Anschutz Medical Campus</td>
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<td>NIH</td>
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* indicates a convening member of Vulcan
Vulcan Structure and PMO Team Membership

Steering Committee
- Amy Cramer
- Darren Weston
- Becky Kush
- Maryam Garza
- Mike Hamidi

Operations Committee

Advisory Council
- Hugh Glover
- Shani Sampson

Vulcan Leadership

Vulcan PMO
- Michael van Campen
- Stacy Tegan
- Hugh Glover
- Shani Sampson

Project Teams

Reporting

Advisory
Vulcan 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)

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<td>Emily Bachman</td>
<td>Microsoft</td>
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<td>Tom Yosick</td>
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Vulcan Operations Committee

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

Operations Committee Co-Chairs

Maryam Garza  Mike Hamidi

Membership

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

EuroVULCAN
Vulcan Advisory Council Committee

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

Advisory Council Chair

- Becky Kush

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

EuroVULCAN
What Value Awaits Behind the Curtain?
Vulcan Events and Educational Opportunities

Vulcan is powered by 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.

- Conferences (geographical)
- Connectathons (testing)
- Round Tables (topical)
- Vulcan 101 (full day course)
- Implementation Showcases

There are many opportunities to engage with the Vulcan community.
Implementation Showcases offer Vulcan members: forum highlighting innovations in using FHIR in clinical & translational research

Past showcases have included:

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

Have an idea for showcase? Contact Vulcan@hl7.org
Yes, those are “FHIR hats”!

EuroVULCAN
## Vulcan Projects

**March 2022**

<table>
<thead>
<tr>
<th>Project / Vulcan Leads</th>
<th>Objectives</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Schedule of Activities (SoA)** | • 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 |
| Mike Ward (TransCelerate) Geoff Low (PHUSE) | | |
| **Real World Data (RWD)** | • 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 |
<p>| Scott Gordon (FDA) Open | | |</p>
<table>
<thead>
<tr>
<th>Project / Vulcan Leads</th>
<th>Objectives</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electronic Product Information (ePI)</strong></td>
<td>- Collaboration with Gravitate Health to develop an international FHIR ePI standard&lt;br&gt;- 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.&lt;br&gt;- Make ePI more accessible; improve patient experience; and support international interoperability. &lt;br&gt;Note: This project operates in full alignment with other FHIR related activities at EMA, FDA and other regulators.</td>
<td>Implementation Guide Available</td>
</tr>
<tr>
<td><em>Craig Anderson</em> (Pfizer)&lt;br&gt;<em>Catherine Chronaki</em> (Secretary General at HL7 Europe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phenotypic Data</strong></td>
<td>- 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.&lt;br&gt;- Identify ways in which FHIR can enable EHRs to be appropriately extended with phenotypic information using the Phenopacket file format&lt;br&gt;- Utilize FHIR to improve mappings and functionality&lt;br&gt;- Enable automated population of computable elements and create opportunity for significant efficiencies over the current manual processes</td>
<td>In progress</td>
</tr>
<tr>
<td><em>Anita Walden</em> (University of Colorado Anschutz)&lt;br&gt;<em>Shahim Essaid</em> (University of Colorado Anschutz)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Vulcan Projects
### March 2022

<table>
<thead>
<tr>
<th>Project / Vulcan Leads</th>
<th>Objectives</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Adverse Events (AE)** | • 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 |
| Michelle Casagni        |                                                                                                                                                                                                          |            |
| (MITRE)                 |                                                                                                                                                                                                          |            |
| Ed Millikan (FDA)       |                                                                                                                                                                                                          |            |
| **FHIR to OMOP**        | • Support the development of FHIR to OMOP data transfer for better analysis of clinical data for research  
  • 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 |
| Davera Gabriel          |                                                                                                                                                                                                          |            |
| (Johns Hopkins)         |                                                                                                                                                                                                          |            |
| Catherine Diederich     |                                                                                                                                                                                                          |            |
| (Duke)                  |                                                                                                                                                                                                          |            |
Questions?
5. The Vulcan Project Process

Hugh Glover, Vulcan
11:20 – 11:35
Vulcan Project Work Cycle

- Priorities
  - XXXXX
  - XXXXX
  - XXX

Project Team
- Identify Connectathon Objectives
  - Month 0
- Find Connectathon Participants
  - Month 0
- Development
  - Months 1 to 3
- Connectathon
  - Month 4
- Lessons Learned
  - Month 5
- Showcase
January 2023 Connectathon

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

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
**Project Evolution**

**Clarifying the Process**

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

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

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

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

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

**Sample Data**
- Phenotypic Data
- FHIR to OMOP Adverse Events
- Real World Data
- Schedule of Activities
- Electronic Product Information
1. Publishing an Implementation Guide is not the end
2. If an Implementation Guide doesn’t get adopted it was a waste of time
3. When an Implementation Guide is adopted it will need to change

Vulcan is at a point of inflection as we go From start up to production
Making a Use Case Proposal

- Vulcan actively seeks new use case proposals – contact us at Vulcan@HL7.org or use the form shown here – Search **Vulcan Use Case Submission**

- Proposals are initially considered by the Project Management Office and we may seek further input from you, particularly if the suggestion appears to overlap with an existing proposal.

- New proposals are then added to the project backlog for consideration and prioritization by the Operations Committee and subsequent recommendation to the Steering Committee for final approval and any funding.

- Adoption of new projects depends on priority and availability of resources.
Project Evolution and Control – Initial Process Gates

0. Suggest Use Case
   - Anybody

1. PMO
   - Rough Use Case Description

2. Prioritization work group
   - Clear & Distinct Use Case Description

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

4. Define Project
   - Project Leads

5. Steering Committee
   - Project lead & Co-Lead
   - Project team members
   - Project Plan & Budget

6. Do Discovery
   - Project Team

Anybody can suggest a use case, which is reviewed by the PMO. The prioritization work group reviews and prioritizes the use case. The Operations Committee approves the use case, and the Steering Committee approves the project plan and budget. Finally, the project team is formed to do discovery.
Project Evolution and Control – Summary

Discovery
- Idea
- Proposal
- Definition

Execution
- Development
- Publishing

Adoption
- Piloting
- Assessment

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

Tech Support

Vulcan processes

HL7+ Vulcan processes

Vulcan processes

Search: “vulcan use case submission”
Questions?
6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA
Evinn Drusys, AEMPS
Jose Galves, FDA (remote)
11:35 – 12:20
6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA
Evinn Drusys, AEMPS
Jose Galves, FDA (remote)
11:35 – 12:20
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

These PowerPoint slides are copyright of the European Medicines Agency. Reproduction is permitted provided the source is acknowledged. The presenter does not have any conflict of interests.
Moving towards harmonised semi-structured electronic PI

Towards a harmonised EU ePI – the EMA perspective
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](https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard)

Towards a harmonised EU ePI – the EMA perspective

*Classified as public by the European Medicines Agency*
Benefits for patients and healthcare professionals

**Case 1**
- List of patient medicines
- ePI in phone app
- Does not remember how to take asthma medicine
- Goes to ‘How to take your medicine’ to downloadable video
- Receives alert when ePI updated e.g. new safety information

**Case 2**
- Rapid ePI updates for COVID-19 vaccines and therapeutics
- Use QR code to link to national language ePI
- Timely access to up-to-date information in patient’s language at point of vaccination

**Case 3**
- Pregnancy planning / Lactose intolerance
- Targeted ePI search
- Treatment decision

Towards a harmonised EU ePI – the EMA perspective
Benefits for regulators, national authorities, companies

**Case 1**
Medicine shortage anticipated in country A
Import medicine from country B, link to ePI in language A
Shortage mitigated

**Case 2**
Change that affects multiple PI
Following variation change is simultaneously implemented in all affected PI annexes
Harmonised, up-to-date PI available to patient and healthcare professionals

**Case 3**
Signal detected
Facilitate search of existing side effects listed in all relevant PI
Optimised signal validation

Towards a harmonised EU ePI – the EMA perspective
Minimum Viable Product tooling in development

- **ePI authoring portal**
  enables ePI creation, preview, update, upload (in FHIR) and download (in FHIR, Word)

- **Rich text editing functionality**
  supports creation and editing of ePI with all styling aspects needed for PI documents

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

**Users:**
- Companies
- Regulators
- eHealth developers

Towards a harmonised EU ePI – the EMA perspective
Towards a harmonised EU ePI – the EMA perspective


From the same portal, applicants can manage ePI, electronic application forms and product data.
Tree-view for authoring of PI documents

Towards a harmonised EU ePI – the EMA perspective
### Regulator view

#### Towards a harmonised EU ePI – the EMA perspective

**Table: ePI List**

<table>
<thead>
<tr>
<th>EPI ID</th>
<th>Name of medicinal product</th>
<th>Procedure no.</th>
<th>Authorisation type</th>
<th>Reference MAH</th>
<th>Approved by</th>
<th>Approved on</th>
<th>Published by</th>
<th>Published on</th>
<th>Status</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manage ePI</td>
<td>Test</td>
<td></td>
<td>CAP</td>
<td>test.org</td>
<td></td>
<td>15/01/2023 12:07 PM</td>
<td></td>
<td></td>
<td></td>
<td>Complete Post-opinion</td>
</tr>
<tr>
<td>Manage ePI</td>
<td>TestDevmed</td>
<td>1234</td>
<td>CAP</td>
<td>test.org</td>
<td></td>
<td>23/01/2023 11:12 AM</td>
<td></td>
<td></td>
<td></td>
<td>Complete Post-opinion</td>
</tr>
<tr>
<td>EPI/23/54</td>
<td>QRD template</td>
<td></td>
<td>CAP</td>
<td>UAT ORG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>View/Manage ePI</td>
</tr>
<tr>
<td>EPI/23/41</td>
<td>Test</td>
<td>copy</td>
<td>CAP</td>
<td>European Medicines Agency</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Deactivate ePI</td>
</tr>
</tbody>
</table>

*Classified as public by the European Medicines Agency*
## Pilot planning begins

- Small number of real-time procedures
- CAP (EMA) and NAP (Denmark, Netherlands, Spain, Sweden)

<table>
<thead>
<tr>
<th>2021</th>
<th>2022</th>
<th>2023-2024</th>
<th>2024-</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU ePI Common Standard developed</td>
<td>MVP development</td>
<td>MVP development</td>
<td>CAP implementation</td>
</tr>
<tr>
<td>Public consultation</td>
<td>NCA product owner and SMEs onboarded</td>
<td>Pilot begins</td>
<td>Phased implementation NAPs</td>
</tr>
<tr>
<td>EU ePI Common Standard adopted.</td>
<td></td>
<td>Results of pilot feed back to tooling and guidance.</td>
<td>EU ePI Common Standard evolves</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Controlled up-versioning.</td>
</tr>
</tbody>
</table>

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

Follow us on  @EMA_News
6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA
Evinn Drusys, AEMPS
Jose Galves, FDA (remote)

11:35 – 12:20
AEMPS - National regulator perspective of ePI

Presented by: 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

Registered trademark symbols in Spanish PI disponibles para el ensayo cromogénico de Rotachrom® Heparin. 

Excerpt from QRD template

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

<table>
<thead>
<tr>
<th>EU ePI - FHIR Resource Names¹</th>
<th>Vulcan ePI - FHIR Resource Names²</th>
</tr>
</thead>
<tbody>
<tr>
<td>1   List</td>
<td>1   List</td>
</tr>
<tr>
<td>2   Bundle</td>
<td>2   Bundle</td>
</tr>
<tr>
<td>3   Composition</td>
<td>3   Composition</td>
</tr>
<tr>
<td>4   Binary</td>
<td>4   Binary</td>
</tr>
<tr>
<td>5   Organization</td>
<td>5   Organization</td>
</tr>
<tr>
<td>6   RegulatedAuthorization</td>
<td>6   RegulatedAuthorization</td>
</tr>
<tr>
<td>7   MedicinalProductDefinition</td>
<td>7   MedicinalProductDefinition</td>
</tr>
<tr>
<td>8   PackagedProductDefinition</td>
<td>8   PackagedProductDefinition</td>
</tr>
<tr>
<td>9   AdministrableProductDefinition</td>
<td>9   AdministrableProductDefinition</td>
</tr>
<tr>
<td>10  ManufacturedItemDefinition</td>
<td>10  ManufacturedItemDefinition</td>
</tr>
<tr>
<td>11  Ingredient</td>
<td>11  Ingredient</td>
</tr>
<tr>
<td>12  ClinicalUseDefinition</td>
<td>12  ClinicalUseDefinition</td>
</tr>
<tr>
<td>13  Substance</td>
<td>13  Substance</td>
</tr>
</tbody>
</table>

¹Rows 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.

²Core ePI is managed as a single self-contained document.
EPI and SPOR Master Data

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

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

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

Pure NAP - initial

Applicant: Coordinator, Author, Co-author

- Login
- Create ePI, upload ePI, change status from draft to pre-opinion ePI
- Download Word/Pdf
- Submits eCTD
- Update ePI in portal & finalise post-opinion ePI
- Export to Word PI
- Submit post-opinion Word PI

Assessor +QC

- Assessment rounds
- Positive opinion

ePI Approver

- Check post-opinion Word PI & archive
- Approve ePI in portal

Publisher

- Receive a notification from the case system to publish
- Publish ePI to API
- Download pdf manually or via API and publish on national website
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
Thank you for your time

If you have any questions please contact: efoster_externo@aemps.es
6. Perspectives on FHIR (Part 1 – Regulators)

Elizabeth Scanlan, EMA
Evinn Drusys, AEMPS

Jose Galvez, FDA (remote)
11:35 – 12:20
Disclaimer

• The opinions expressed are solely my own and should not be interpreted as an endorsement of any technology or product by the FDA.

• The opinions expressed in this presentation are not meant to imply any changes to guidance, or regulations.

• I have no financial interests in any of the technologies discussed

• Gravitate-Health

The Gravitate-Health project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 945334. This joint undertaking receives support from the European Union’s Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations [EFPIA] and IMI Associated partner Datapharm Limited.
What will we cover

• **Current state**
  • Process
  • Standards
    • Data
    • Submission

• **FHIR – Regulatory Agency Perspective**
Current state of data standards used by regulators (FDA example)

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

- **Tabular based standards for Clinical data**
  - SDTM/ADaM
  - SAS transport

- **XML based structured data**
  - HL7 v3 multiple submission types
    - (SPL) Product labelling
    - AE reporting
    - Facility and Establishment registration/information
    - Risk Evaluation and Mitigation Strategies (REMS)

Some critical data activities have **no structured data standards**
- All of eCTD Module 3: data on Pharmaceutical Quality, Chemical Manufacturing, and Controls
Current state of data for regulatory agencies
(FDA example)

With some exceptions, regulators like FDA are stuck in the “paper” paradigm.
• Much is now “digital paper” (PDF/Word) but not much more useful for computation
• Large amount of submitted still in narrative form - even in Cover Letters
• We still have banks of fax machines
• Even structured data often conforms to a “document” paradigm

It’s 2022!

Sponsors must send a range of information to regulators requested in different formats
• Cover Letters, PDFs, Office docs, .xml files, Structured Data Files, etc.
Packaged in various “wrappers”
• SAS Transport, electronic Common Technical Document (eCTD) folders, etc.
And then… regulators must unpack all that, manage it, and finally review it.
A better vision

A future where:
• Using modern data technologies and information technology conventions,
• sponsors can clearly, reliably, and accurately convey the details of the narrative,
• allowing regulators to clearly, reliably, and accurately understand the narrative,
• all while minimizing the need for subjective decisions and interpretations
• and minimizing the burden on sponsors and regulators
FHIR as an enabling technology

In this context, FHIR is an enabling technology.

Significantly different than older HL7 standards and CDISC standards:

Using modern 21st Century informatics technology
- HL7 V2 developed in the late ‘80s, HL7 V3/CDISC: ‘00s
- FHIR: Began 2014 – during the solidification of the modern internet technologies that power nearly all IT transactions worldwide

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

FHIR (1) represents data and (2) incorporates IT technology to support:
- FHIR Resources = Packaging
- Transport/Transmission
- Validation
- Receiving
Implementation-ready and aligned with evolving information technology

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

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

SPL is used for many activities at FDA

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

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

**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 `Condition` 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](https://www.fda.gov/optimizing-the-fda-compliance-process-

Project overview page: [Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC) | FDA](https://www.fda.gov/optimizing-the-fda-compliance-process-
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 + Facilitated Discussions**

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

<table>
<thead>
<tr>
<th>Topic</th>
<th>Facilitator(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How can different standards work together?</td>
<td>Peter van Reusel</td>
</tr>
<tr>
<td></td>
<td>Catherine Chronaki</td>
</tr>
<tr>
<td>How does privacy play into standards, and vice versa?</td>
<td>Pierre-Yves Lastic</td>
</tr>
<tr>
<td>Enhancing clinical trial efficiency and success using hospital EHRs</td>
<td>Dipak Kalra</td>
</tr>
<tr>
<td></td>
<td>Nadir Ammour</td>
</tr>
<tr>
<td>How can Vulcan support clinical research in Europe?</td>
<td>Michael van Campen</td>
</tr>
<tr>
<td>How do we accelerate the design of a digital clinical trial?</td>
<td>Andy Richardson</td>
</tr>
</tbody>
</table>
7. Implementation Insights / Showcase
Jessica Jeffries, IgniteData
Mitra Rocca, FDA (remote)
Peter Casteleyn, J&J
Martin Ingvar, Karolinska Institutet
13:20 – 14:40
7. Implementation Insights / Showcase
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Martin Ingvar, Karolinska Institutet
13:20 – 14:40
• Why?
• How?
• What?
• Where?
• Archer in Action
How Archer enables EHR2EDC
Archer works well with structured data domains

1. Laboratorio
   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 of 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.
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.

<table>
<thead>
<tr>
<th>Total number of data items per patient</th>
<th>1374</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average time taken to enter each data item manually</td>
<td>3 minutes*</td>
</tr>
<tr>
<td>Average time taken per patient to enter data manually over 20 visits</td>
<td>4122 minutes = 68.7 hours</td>
</tr>
</tbody>
</table>

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
Thank you!

Questions?
For more information on IgniteData, contact us on:

hello@ignitedata.co.uk
7. Implementation Insights / Showcase
Jessica Jeffries, IgniteData
Mitra Rocca, FDA (remote)
Peter Casteleyn, J&J
Martin Ingvar, Karolinska Institutet
13:20 – 14:40
Use of Real-World Data in Clinical Research

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

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

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

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>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)).</td>
</tr>
<tr>
<td>Phase II</td>
<td>Further development of the OneSource standards platform focusing on adverse events occurred in clinical trials.</td>
</tr>
<tr>
<td>Phase III</td>
<td>Reuse of OneSource standards platform in COVID-19 clinical trials.</td>
</tr>
</tbody>
</table>


[https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund-reports](https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund-reports)
I-SPY COVID-19 Trial

- Platform Trial for Critically Ill patients with COVID-19
- Over 3,300 patients enrolled
- Patients admitted to ICU, WHO COVID-19 Scale >5
**OneSource: SMART on FHIR integration with EHRs**

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

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

- Common Data Model Harmonization (CDMH) Project (Phase I)
  - Goals and Objectives
- Common Data Model Harmonization (CDMH) Project (Phase II)
  - Deliverables
PROJECT GOAL AND OBJECTIVES

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

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

1. Develop a common data architecture as the intermediary between various Common Data Models
   Harmonize the 4 Common Data Models (CDMs) to an intermediary model

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

<table>
<thead>
<tr>
<th>Randomized/interventional</th>
<th>Non-randomized/interventional</th>
<th>Non-randomized/non-interventional</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traditional randomized trial, using elements of RWD</strong></td>
<td><strong>Trials in clinical practice settings (“with pragmatic elements”)</strong></td>
<td><strong>Externally controlled trial</strong></td>
</tr>
<tr>
<td>RWD to support site selection</td>
<td>RCT using electronic case report forms or EHR or claims data, etc.</td>
<td>Single-arm trial with RWD external control arm</td>
</tr>
<tr>
<td>RWD to assess enrollment criteria &amp; trial feasibility</td>
<td></td>
<td>Observational cohort study</td>
</tr>
<tr>
<td>Selected outcomes identified using EHR or claims data, data from digital health technologies, etc.</td>
<td></td>
<td>Case-control study</td>
</tr>
</tbody>
</table>

**Increasing reliance on RWD**

Office of Med Policy Aug 2021
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
Structured electronic data capture in clinical trials requires today a **very high manual effort**, whilst the clinical source data is most often the EHR. This introduces **significant costs in terms of data processing and cleaning**.

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

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

70% of research sites say **staffing** is their **most prevalent challenge**.
EHR2Sponsor Objective

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

**AS IS:**
Ongoing Study: Traditional Data Capture

Data collection on source document

**TO BE:**
Automated Data Capture

Sponsor clinical study data base

1. Automated de-identified data transfer
2. EHR2Sponsor capability
Janssen’s approach

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

Next

Pioneer with specific sites
What We’ve Learned so Far

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

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

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

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

Bypassing the EDC to collect at scale is a long-term opportunity. Making this viable involves addressing the dependencies internally and increased eSource adoption externally.
FHIR enabling efficiency in mapping setup

2-Pronged Approach

What study data can be obtained from the EHR?

“What Available FHIR”

“What Requested FHIR”

What data does the study require?

“Available FHIR” = “Requested FHIR”

EHR Application

EDC

Clinical Study Database

IRT

Janssen Pharmaceutical Companies of Johnson & Johnson
‘Outgoing FHIR’ – Study described in FHIR

External / Industry Initiatives
- Common approaches and methods
  HL7 Vulcan Projects – SoA, Adverse Event…

Internal / Study Focused
- Support mapping:
  FHIR-specified eCRF as part of our Global Standard eCRF Library
- Support testing:
  Extend FHIR-specified eCRF resources with synthetic study subject data
‘Incoming FHIR’ – What is available?

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

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

Contact:

Peter Casteleyn
pcastel1@its.jnj.com
Acronyms

API: Application Programming Interface
eCRF: electronic Case Report Form
EHR: Electronic Health Record
EHR2Sponsor: name of the Janssen program to transfer clinical data from EHR to us
EDC: Electronic Data Capture
FHIR: Fast Healthcare Interoperability Resources – HL7 standard
IRT: Interactive Response System
RFI: Request for Information
RFP: Request for Proposal
SoA: Schedule of Activities
7. Implementation Insights / Showcase
Jessica Jeffries, IgniteData
Mitra Rocca, FDA (remote)
Peter Casteleyn, J&J
Martin Ingvar, Karolinska Institutet
13:20 – 14:40
Swedish Scenario in Gravitate Health

Martin Ingvar
May 26, 2022

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

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

14:40 – 15:00
8. Vulcan Implementation Guide Overview

Hugh Glover, Vulcan
15:00 – 15:20
Sections of an Implementation Guide

Schedule of Activities

Real World Data

Electronic Product Information

Discussion

Artifacts

Credits

References

Downloads
Discussion

- 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).

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.
Artifacts are the technical specification

- **Search Parameters**
- **Profiles**
- **Extensions**
- **Terminology**
- **Examples**
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*
### 11.4.3 Resource Content

<table>
<thead>
<tr>
<th>Name</th>
<th>Flags</th>
<th>Cardinality</th>
<th>Type</th>
<th>Description &amp; Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedicationStatement</td>
<td>TU</td>
<td>1..1</td>
<td>DomainResource</td>
<td>Record of medication being taken by a patient</td>
</tr>
<tr>
<td>identifier</td>
<td>Σ</td>
<td>0..*</td>
<td>Identifier</td>
<td>External identifier</td>
</tr>
<tr>
<td>medication[x]</td>
<td>Σ</td>
<td>1..1</td>
<td></td>
<td>What medication was taken</td>
</tr>
<tr>
<td>medicationCodeableConcept</td>
<td></td>
<td></td>
<td>CodeableConcept</td>
<td>SNOMED CT Medication Codes (Example)</td>
</tr>
<tr>
<td>medicationReference</td>
<td></td>
<td></td>
<td>Reference(Medication)</td>
<td></td>
</tr>
<tr>
<td>subject</td>
<td>Σ</td>
<td>1..1</td>
<td>Reference(Patient</td>
<td>Group)</td>
</tr>
<tr>
<td>context</td>
<td>Σ</td>
<td>0..1</td>
<td>Reference(Encounter</td>
<td>Episode)</td>
</tr>
</tbody>
</table>
Reading the Profile

Profile from RWD

Derivation of the profile

Original

Modified attributes
Reading the Profile

Profile from RWD

Original

derivedFrom attribute is now mandatory

derivedFrom attribute can only be one of 3 possible types rather than Any
Artifacts are the technical specifications:

- Search Parameters
- Profiles
- Extensions
- Terminology
- Examples
• Credits
• References
• Downloads gives resource definitions for use with the Validator
Questions?
9. Vulcan Electronic Product Information (ePI)

Giorgio Cangioli, HL7 Europe + Craig Anderson, Pfizer (remote)
Sonja Steiner, Acodis + Patrick Bürkle, Acodis
Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20
9. Vulcan Electronic Product Information (ePI)

Giorgio Cangioli, HL7 Europe + Craig Anderson, Pfizer (remote)
Sonja Steiner, Acodis + Patrick Bürkle, Acodis
Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20
ePI Implementation Guide Overview & Relationship with 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
Electronic Product Information (ePI) Project Overview
The ePI Project: a collaborative effort
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
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

Define rules for using HL7 FHIR for describing ePI

https://build.fhir.org/ig/HL7/emedicinal-product-info
ePI Implementation Guide overview
How the HL7 FHIR ePI looks like

**The container**

- **ePI is a HL7 FHIR Document**
- **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; Contraindications; Warnings; MaH; etc...)
‘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**

- Profiles for Organizations
- Profiles for Packaging
- Profiles for Ingredients
- Profiles for Clinical Use
Use case example 1: Viewing ePI content as a graph

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

Maria and her medicines

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.

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

Gravitate Health
VULCAN
How to achieve it - focusing

**ePI**
Pure FHIR. contains structured free text

**p(ePI)**
Semantically annotated.

**f(ePI)**
Standardised coded Lenses are attached.

**e(ePI)**
Additional information is attached

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

Trust Framework

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

Add clinical Knowledge (lenses)

Add Extra information (IPS, user choices)

Personalized ePI
Next Steps

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

Giorgio Cangioli, HI7 Europe + Craig Anderson, Pfizer (remote)
Sonja Steiner, Acodis + Patrick Bürkle, Acodis
Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20
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
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

Template* of Product H

Structured Product H as XML

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

Scope of Acodis
3. About Acodis
Turn Any Document Into Structured Data – in Seconds

Data Extraction from highly complex documents within regulated environments
We structure complex documents within Health, Pharma & Life Science

**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

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**Structured Standards (FHIR)**  **NLP Projects**  **AI Initiatives**  **Databases**
About Acodis

Acodis in a Nutshell

25 Experts

ISO 27001
ISO 9001
AICPA SOC

Information Security
Quality Management
Service Orga. Control 2

Roche syngenta Novartis

High Performer
Best Support
Easiest To Do Business With

WINTER 2023
WINTER 2023
WINTER 2023
4. Q&A
Thank you!

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9. Vulcan Electronic Product Information (ePI)

Giorgio Cangioli, HL7 Europe + Craig Anderson, Pfizer (remote)
Sonja Steiner, Acodis + Patrick Bürkle, Acodis
Susie Winn, Author-it Software Corp + John Jones, Entitech Solutions

15:20 – 16:20
Structured Authoring - Supporting IDMP Submissions using HL7 FHIR Standard

EuroVulcan Conference
March 14–15, 2023
Presentation Objectives

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

1. **Project**
   - **Project Section**
     - **Composite**
       - **Caption**
       - **Footnote**
       - **Note**
   - **Figure**
   - **References / Citations**

2. **Metadata**
   - **Free Text Property**
   - **Date Property**
   - **List Property**
## Summary of Product Characteristics

### 1. NAME OF THE MEDICINAL PRODUCT

Component status: Approved version 1. To edit, create draft version 2.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

- **Local Trade Name**: Strength 1 soft capsules
  - One soft capsule contains (Strength 1): Active Pharmaceutical Ingredient - lowest case (as esilate)
  - Active with known effect
  - Each (Strength 1) soft capsule contains 1.2 mg of soya lecithin.

- **Local Trade Name**: Strength 2 soft capsules
  - One soft capsule contains (Strength 2): Active Pharmaceutical Ingredient - lower case (as esilate)
  - Active with known effect
  - Each (Strength 2) soft capsule contains 1.8 mg of soya lecithin.

For the full list of excipients, see section 6.1.
4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

- Treatment should be initiated by physicians experienced in the management of diseases for which Local Trade Name is approved.
**Example SmPC Authored in Docuvera – 2 of 2**

**Indication Text**

- Local Trade Name: is also indicated in adults for the treatment of other chronic fibrosing interstitial lung disorders (ILDs) with a progressive phenotype (see section 3.1).

**Indication – Disease/Symptom/Procedure**

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

**Intended Effect**

- Treatment should be initiated by physicians experienced in the management of diseases for which Local Trade Name is indicated.
Docuvera Advanced Export Capability

Docuvera
(USPI, SmPC, Leaflet, Label, etc.)

Transformation Engine

Metadata Repository (MDR)

Output formats
- SPL
- FHIR
- JSON
- XML
- PDF
- Word

Destinations
- Microsoft Word
- Microsoft Outlook
- SharePoint
- Dropbox

SPOR Lists (External)
4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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

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

4.2 Posology and method of administration

- Treatment should be initiated by physicians experienced in the management of diseases for which Local Trade Name is approved.
Sample Export – SmPC FHIR Composition

"section": [
    {
      "title": "4.1 Therapeutic indications",
      "code": {
        "coding": [
          {
            "system": "https://spor.ema.europa.eu/rmswi",
            "code": "10000015538"
          }
        ],
        "text": "4.1 Therapeutic indications"
      },
      "text": {
        "status": "additional",
        "div": "<div xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).<br/><p>OFEV is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see section 5.1).<br/><p>OFEV is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).<br/></p></div>"
      }
    }
  ]
System Architecture - Enterprise Integrations

- **Existing Integrations**
- **Implementing Integrations**
- **Evaluating Integrations**

**Product Data**
- SAP
  - Master Data / Reference Data

**Automated Access**
- servicenow
- SailPoint
- SSO - SAML 2.0
- Azure

**Translation providers**
- LIONBRIDGE
- TRSB

**ESB Support**
- MuleSoft
- axway

**LIMS**

**Auto-generate sections of CSR, and Full Narratives**

**AEM headless CMS**

**Veeva Vault**
- MedComms

**IDMP Datastore**

**Submit for final approval & e-sigs**

**ClinicalTrials.gov**
- Export XML for Protocol Trial Transparency
- Reporting to different agencies

**Export XML for Protocol Trial Transparency**
- Reporting to different agencies
Questions?
Thank You

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