Gravitate-Health and HL7 Vulcan ePI Project

TECHNOLOGY COMMUNITY EVENTS – KICK OFF MEETING

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2023-03-20

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This meeting is taking place on Zoom video conferencing. The meeting will be recorded.

This means the following data will be recorded about you:

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- your image if you choose to turn on your camera at any time

- your voice if you choose to ask a question or make a comment orally, as well as any text you may choose to write in the zoom tool

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Practicalities – Zoom etiquette

Please connect 5 - 10 min early for each session

Add company short-name before your name:
- (functionality found as settings by your name):

"Pfizer-Giovanna Ferrari" , "UiO-Anne Moen"

Q&A - post questions in Chat.

Mute microphone, consider your camera
Recording - if presentations are recorded, they will be posted in YouTube channel "**Gravitate Health**"

Gravitate Health

AGENDA

1. The reason we are here

2. Objectives, Roadmap and Next Steps

3. Overview of the Gravitate-Health/Vulcan ePI project

4. Background on Gravitate-Health and HL7's Vulcan Accelerator

Introduction – The reason we are all here

Maria and her medicines
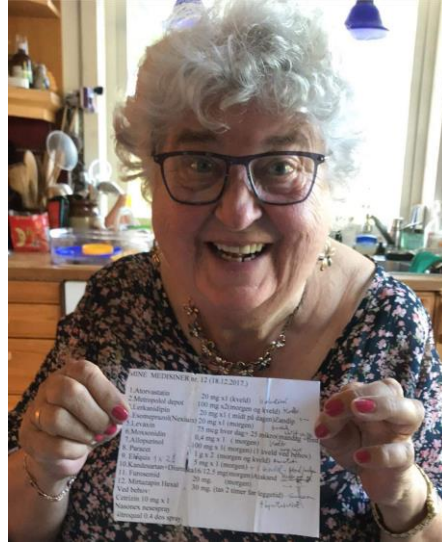
Picture: Line H. Linstad, NSE
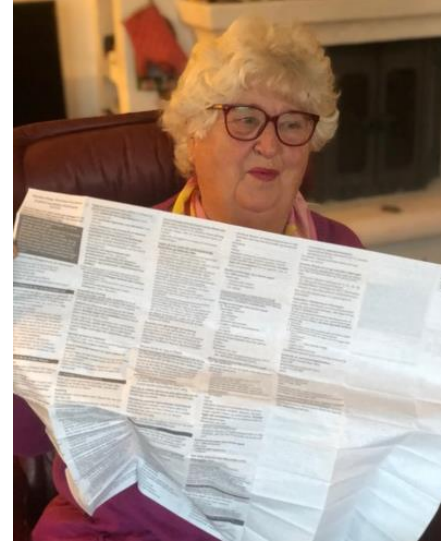
Picture: Hanne Bjertnes, UiO

MISSION

The Gravitate Health mission is to equip and empower citizens with digital information tools that make them confident, active, and responsive in their patient journey, specifically encouraging safe use of medicines for better health outcomes and quality of life.

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.

Cross-project collaboration: International FHIR ePI

Innovative Medicines Initiative (IMI) - Gravitate-Health

- o 40 partners in Europe and USA; 60 months 11/20 – 10/25; €18.5m
- o Delivering the Gravitate Lens (G-Lens) which focuses on ePI content and offers patients access to trustworthy, up-to-date information that better meets their individual needs

HL7 Vulcan - FHIR Accelerator Program

- o Designed to facilitate the creation and adoption of FHIR Implementation Guides (& related standards) that support global health data interoperability

HL7 Biomedical Research and Regulation (BR&R)

- o Creates standards that facilitate biomedical research and any subsequent regulatory evaluation of the safety, efficacy and quality of medical products.

Univocal Identification of Medicinal Products (UNICOM)

- o UNICOM aims to advance implementation of ISO IDMP (ID of Medicinal Products) standards in EU Member States drug databases to support safe cross-border ePrescription/eDispensation and effective pharmacovigilance.
- o 19 countries are represented, including 26 national Drug and eHealth Agencies. budget € 21 MEuros.

Objectives

Goals

1. Develop a path to achieve critical mass (i.e., 80% of ePIs converted to FHIR) within two years.

2. Gain support from tech industry to help achieve Goal #1

For discussion

What is needed to achieve these goals?

Draft Roadmap (Work in progress, need your input)

Gravitate Health

We are here

	1H 2023	2H 2023	1H 2024	2H 2024	2025+

Vulcan ePI Implementation Guide
- Finalize v1.0.0
- Gather requirements for v1.x.x
- Update to v1.x.x
- Update to v2.x (where needed)

Stakeholder Awareness, Improve ePI maturity
- Events (e.g., EuroVulcan, Connectathons, Hackathons, summit meetings)
- Sep International Proof of Concept

Support pilots / Implementations
- TBD

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Next Steps
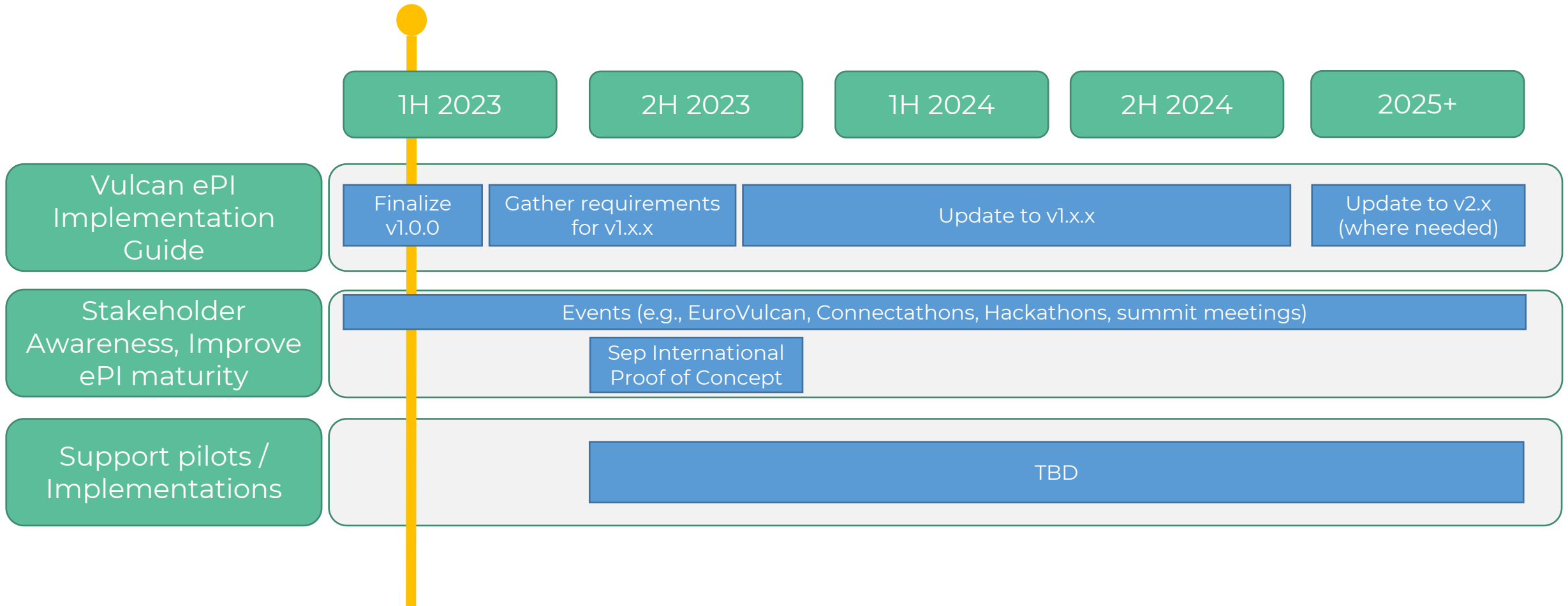
1. What do you think is needed to ensure we can achieve the alignment across stakeholders to implement ePI as we have described (critical mass)?

2. Are there any pre-requisites or critical success factors missing from the current picture from the technology / software perspective?

3. Would you be willing to take part in collaborative open innovation workshops with this community to develop solutions for achieving our goals?

SURVEY LINK: https://www.menti.com/alto13dje9mf

MENTI.COM 8109 1081

What is interoperability?

- The ability to easily access and exchange information across any systems.

- The internet, as a harmonized set of technical standards, introduced interoperability that revolutionized multiple sectors (e.g., eCommerce, eBanking).

- But the internet has not revolutionized health the way it did other sectors!

Internet

Wifi

email

FHIR

Health

FHIR Overview: Bringing the internet to health

- Standard for encoding and exchanging health data in a machine readable way.

- Based on common internet standards (e.g., same tech foundation commonly used by Microsoft, Amazon, Apple, Google).

- Significantly easier to work with and reduces implementation cost.

- Includes 151 pre-fabricated, ready to use templates (e.g., Medicinal Product, Organization, Ingredient).

- Multiple projects underway that will replace the technical foundation of health and biopharma (E.g., labelling, CMC, AE, Clinical)

Application Program Interface (API) — Replace gateways

Documents — Replace documents and Forms

Services — Replace automated workflows
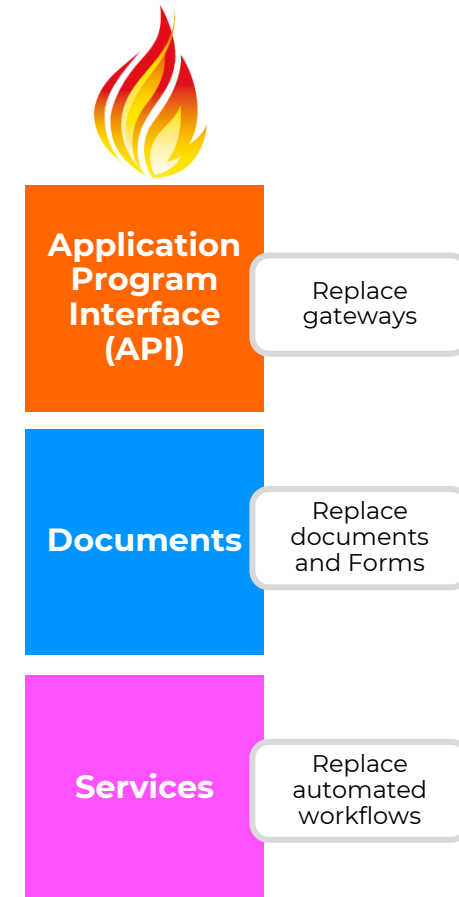
151 FHIR Resources (Prefabricated Templates)

GH/Vulcan FHIR ePI

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

FHIR template for Organizations

FHIR template for Packaging

FHIR template for Ingredients

FHIR template for Clinical Use

Use example 1: Same foundation, two implementation models

'Vulcan' 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 Vulca approach.

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

Bundle
- Composition
- List (Products)
- Binary

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

- The graph shows relationships between data objects.

- This graph shows 90+ data objects in a <u>single</u> ePI.

- Graphing all ePIs in a drug portfolio leads to benefits like rapid impact analysis of labelling or CMC changes (e.g., Safety updates; formulation or packaging changes).
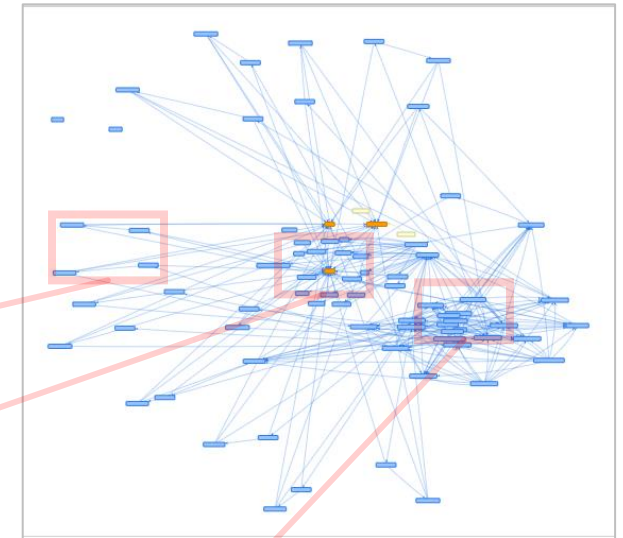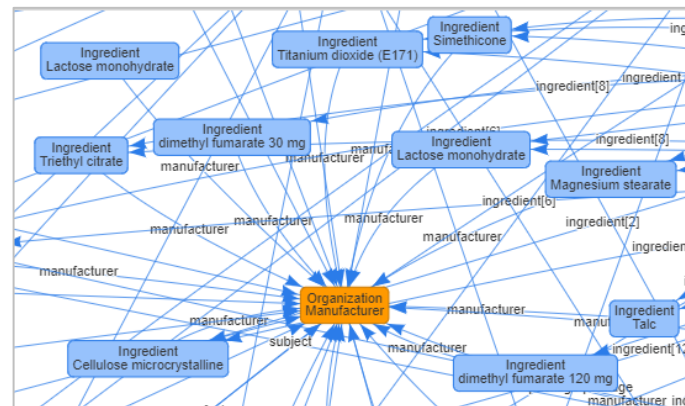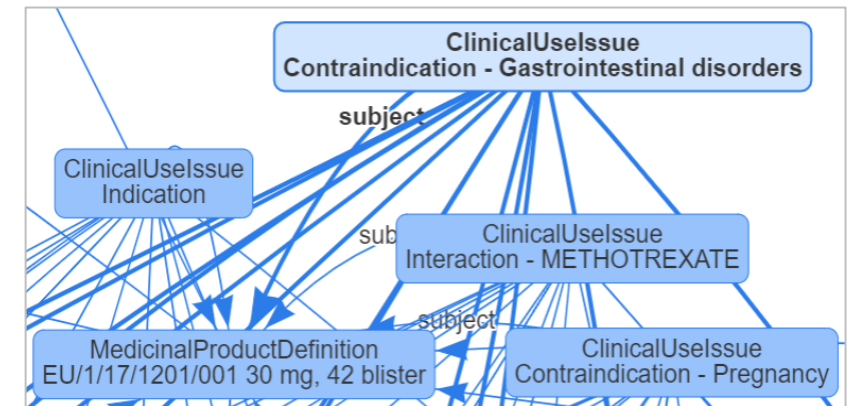

Packaging and Authorization

PackagedProductDefinition blister x90 120 mg

marketingAuthorization

RegulatedAuthorization EU/1/17/1201/004 90 - 120 mg

PackagedProductDefinition blister x70 120 mg

marketingAuthorization
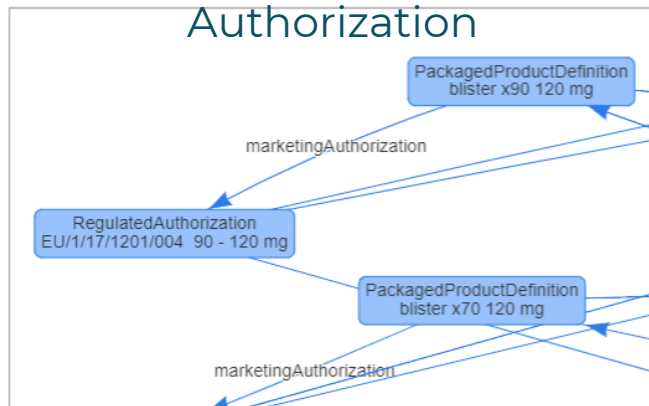
Ingredients and Manufacturer

Ingredient Lactose monohydrate

Ingredient Titanium dioxide (E171)

Ingredient Simethicone

Ingredient dimethyl fumarate 30 mg

Ingredient Triethyl citrate

Ingredient Lactose monohydrate

Ingredient Magnesium stearate

Organization Manufacturer

Ingredient Talc

Ingredient Cellulose microcrystalline

Ingredient dimethyl fumarate 120 mg

Clinical Use Details

ClinicalUseIssue Contraindication - Gastrointestinal disorders

subject

ClinicalUseIssue Indication

ClinicalUseIssue Interaction - METHOTREXATE

MedicinalProductDefinition EU/1/17/1201/001 30 mg, 42 blister

ClinicalUseIssue Contraindication - Pregnancy

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Use example 3: Tailored ePI

Case:
- Highlight and supress ePI sections based on patient information

Approach:
- Identify ePI sections from Felleskatalogen
- Manually extracted knowledge, coded by ICPC-2, linking sections, represented as *FHIR Clinical Use Templates*
- Patient information, coded as ICPC-2, represented as *FHIR AllergyIntolerance* and *Condiction* templates
- Demographic information
- Software for highlighting and supressing text

Personal Health Record

ePI content tailored to the individual

Applied criteria: Demographics, conditions, allergy and intolerance

Pregnancy related - supressed

Lactose Intolerance related - highlighted

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Vulcan Electronic Medicinal Product FHIR Implementation Guide

- Common technical standard for structuring and exchanging product information using FHIR and IDMP.

- A common starting point from which to build national ePIs.

- Received quorum in HL7's Jan '23 ballot

- [Link to 2023-Jan ballot version of the ePI FHIR Implementation Guide](#)

HL7 International — Electronic Medicinal Product Information (ePI) FHIR Implementation Guide
0.1.0-Ballot - CI Build

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Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by . This is not an authorized publication; it is the continuous build for version 0.1.0-Ballot). This version is based on the current content of https://github.com/HL7/vulcan-eproduct-info and changes regularly. See the Directory of published versions

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