# 2022-05 Vulcan/Gravitate Health - ePI/IPS (Phase 3)

- Short Description
- Long Description
- Type
- Submitting Work Group/Project/Accelerator/Affiliate/Implementer Group
- Track Lead(s)
- Track Lead Email(s)
- Related Tracks
- FHIR Version
- Specification(s) this track uses
- Artifacts of focus
- Expected participants
- Zulip stream
- Track Details

## Short Description
This track is Phase 3 of an ongoing series, spanning multiple Connectathons, to test the exchange and display of electronic Product information (ePI) and the International Patient Summary (IPS) as FHIR documents.

Each phase will include increased levels of product information and increasingly complex healthcare/life scenarios.

**Track Objective is to test and gather feedback on the following**

1. Vulcan ePI Profile.
2. ePI instances (EU, US and Japan).
3. Searching lists for a particular ePI.
4. Adjust presentation of the ePI to the profile of the individual personas.
5. Rules for the presentation of the ePI and classified extended materials.

## Long Description
**Problem Statements**

1. Existing ePI formats are not meeting the needs of patients, professionals and developers.
2. The lack of harmonization is leading to fragmented approach where multiple differing standards are developing internationally. E.g., HL7 SPL in North America, FHIR in the European Union; and custom XML standards in Asia.

**Vision**

The vision of Gravitate Health/Vulcan accelerator is to define a common structure for medicinal product information that improves the patient experience and supports interoperability across the international healthcare community.

ePI Track Phase 2 builds towards this vision by incorporating lessons learned from connectathon 28. Also, by testing more complex real-world scenarios; additional FHIR resources; and more advanced product label data.

**Background**

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 use.

ePI is often presented in two forms: Information for healthcare professionals and/or information for patients.

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

Only a few countries have XML ePI’s but the number and interest is growing. For example, US FDA uses HL7’s SPL; Japan’s PMDA uses custom XML; EU’s EMA is developing a FHIR XML ePI. Without harmonization, there is a high risk that

Hence the need to transition to a dynamic structured format that can be used as an international standard; i.e., FHIR documents.

**Type**

Test the design of a set of resources.

**Submitting Work Group/Project/Accelerator/Affiliate/Implementer Group**

HL7 Vulcan Accelerator and Gravitate Health

**Track Lead(s)**

Craig Anderson, Jens Villadsen, Catherine Chronaki, Amy Cramer
<table>
<thead>
<tr>
<th>Track Lead Email(s)</th>
<th><a href="mailto:Craig.Anderson2@pfizer.com">Craig.Anderson2@pfizer.com</a>; <a href="mailto:jvi@trifork.com">jvi@trifork.com</a>; <a href="mailto:chronaki@gmail.com">chronaki@gmail.com</a>; <a href="mailto:Amy.Nordo@pfizer.com">Amy.Nordo@pfizer.com</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Related Tracks</td>
<td>No direct relationships at this time</td>
</tr>
<tr>
<td>FHIR Version</td>
<td>FHIR Release 5.0.0-snapshot1</td>
</tr>
</tbody>
</table>
| Specification(s) this track uses | Vulcan/Gravitate Health ePI IG  
Github Repository with sample instances (in FSH).  
IPS IG  
EMA ePI Specification |
| Artifacts of focus | FHIR Vulcan ePI Profile  
FHIR Resources  
1. List  
2. Bundle  
3. Composition  
4. Organization  
5. RegulatedAuthorization  
6. MedicinalProductDefinition  
7. PackagedProductDefinition  
8. AdministrableProductDefinition  
9. ManufacturedItemDefinition  
10. Ingredient  
11. ClinicalUseDefinition  
12. Binary |
| Expected participants | Gravitate Health members, HL7 Vulcan Members, FDA, EMA, Project UNICOM, Adopters and implementers |
| Zulip stream        | https://chat.fhir.org/#narrow/stream/296557-Vulcan.2FePI  
#europe#GH |
| Track Details       | **Scenario 1 – Search a list of ePIs**  
This scenario is meant to test how different actors will search through multiple Lists that contain multiple ePIs (e.g., different versions, documents, and document languages).  
They will calculate the correct ePI for the patient using their IPS and search Lists for that particular ePI. Once found, the next step is to adjust the presentation of the ePI to suit the profile of the individual personas (e.g., highlight or suppress content).  
**Scenario 2 – UNICOM Helena**  
This scenario is meant to show how the IDMP standards add value to safer cross-border e-prescription processes, e-dispensation processes, and improve pharmacovigilance in general.  
This use case will show how various systems can be interconnected by using IDMP identifiers. Particularly with the global PhPID which establishes the connection between national identifiers (MPID, PCID) for medicinal products. The PhPID functions as the ‘glue’ between medicinal product dictionaries (MPD’s) and other databases like the EMA or FDA’s Substance Registration System (SRS) and healthcare provider IT-systems.  
We will also use IDMP identifiers to make connections between the International Patient Summary (IPS) and the ePI in a digital format to help improve patient experience.  
The scenario is built around the Helen persona. A UK resident who travels to Europe and is prevented from receiving the wrong medication as a result of the above mentioned systems, processes and standards. |