Vulcan Electronic Product Information FHIR Implementation Guide

- Committee Approval Date:
- August 29, 2022

- Publishing Lead:
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- Contributing or Reviewing Work Groups:
- BR&R, Vulcan Accelerator

- FHIR Development Project Insight ID:
- Pending

- Scope of coverage:

  **In Scope**
  - electronic Product Information (ePI) (information for healthcare practitioner, information for the patient, package label)
  - Human pharmaceutical, radiopharmaceutical and biologic medicinal products (prescription and physician-administered)
  - Over the counter (non-prescription) drugs
  - Investigational and authorized medicinal products
  - Medical devices co-packed with a biopharmaceutical product (e.g., pre-filled syringe)

  **Out of Scope**
  - Self-care products
  - Natural health products
  - Medical devices
  - Food
  - Veterinary drugs

- Content location:
  - HL7/vulcan-eProduct-info: Gravitate Health Project (github.com)

- Proposed IG Title:
  - Vulcan Electronic Product Information FHIR Implementation Guide
Proposed IG realm and code:
uv/vulcan-eproduct-info

FHIR Core version(s):
R5

Maintenance Plan:
BR&R

Short Description:
This guide provides best practice guidance for creating and representing electronic product information for medicinal products.

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

Long Description:
This Guide defines a set of FHIR profiles that will allow for the creation and exchange of electronic Product Information (ePI) documents.

This guide is primarily meant for developers of structured content authoring solutions; medicinal product manufacturers who author ePI documents; the national competent authorities who review and authorize ePI documents; and consumers of the ePI document’s content (e.g., eHealth developers or service providers).

A medicine’s product information is a pivotal source of regulated and scientifically validated information. Transitioning the ePI to FHIR format will make medicinal product information more available for use in systems or services that (1) assist healthcare professionals in prescribing and dispensing medicines; and (2) inform consumers about the safe use of their medicines.

Involved parties:
Vulcan Accelerator
HL7 BR&R
International health authorities
Biopharmaceutical companies/manufacturers
eHealth developers and solution providers
Public/private partnerships (i.e., Gravitate Health and UNICOM)

Expected implementations:
International health authorities will use this guide to facilitate development of local applications of structured product labelling solutions.

Biopharmaceutical companies will use structured authoring solutions to create and exchange FHIR ePI documents with health authorities, the local healthcare system, and ehealth developers/service providers.

Software developers will develop solutions to support the creation, exchange, presentation, and analysis of FHIR ePI documents.

Content sources:
Individuals from the following organizations contribute through Vulcan project meetings: Gravitate Health; UNICOM; pharmaceutical catalogers and medicinal product dictionaries; medicines information companies; eHealth developers and service providers; structured authoring developers and service providers; individual biopharma companies; academia; health authorities.

Example Scenarios:
Pharmaceutical company creates an ePI document for a prescription medicinal product by converting it from its original format in Word, PDF, or XML and converts it to FHIR XML.

The pharmaceutical company then submits that ePI document to a health authority via API.
The Health authority receives the ePI document, reviews its content, and eventually notifies the company that the document is approved; i.e., they grant to the company a regulatory authorization.

The health authority and the pharma company both publish copies of the authorized FHIR ePI document to a public FHIR server. The general public can now access authorized copies of the ePI document.

**IG Relationships:**
- International Patient Summary
- SPL Mapping FHIR Implementation Guide

**Timelines:**
- January 2023

**FMG Notes**