

ePI on FHIR

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Sources


Drug
Compendia

EHR and
eRX

HCP's and
Patients




Use Case 4) Regulatory eLabeling



What

As a first step toward streamlining the ability to support rapid investigation of new or increased adverse events related to medical products, structured **drug labeling** information is a critical advancement. With structured labels that include sections such as structured adverse reaction section and ingredients adverse events related to medical products can more easily be updated and discovered.

Support AE investigations with interoperable Label




Why

Ability to identify source of adverse events (e.g., specific ingredient, manufacturer or drug-drug interaction) is limited because:

- Medical product information (labeling data) is siloed, if structured, or unstructured
- AE identification and reporting is a highly manual process
- Pharmacy information are typically siloed
- No interoperable standards exist to support a harmonized data ecosystem for AE investigations

Transform fragmented sources of AE investigations into a harmonized interoperable ecosystem



Benefits

Enhance speed, accuracy, and comprehensiveness of:

- Detection of new and/or increased medical products-related adverse events
- Investigation of the source of medical product adverse events





Integration of healthcare, pharmacy and public health information systems.

Promotes rapid public health actions to reduce and prevent adverse events, improving health outcomes.

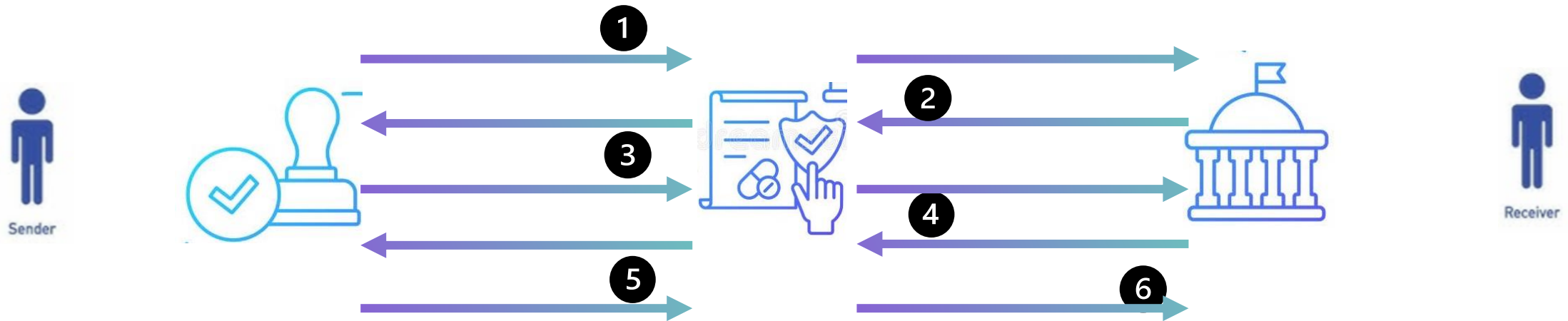
Reduce unnecessary health issues and save more lives

Technology Solution Providers	Clinical Research Sponsors	Clinical Research Sites	Government	Patient Persona	Subject Matter Experts
✓	✓		✓		✓

Expected roles to support and enable Focus Area


In collaboration with


&


FHIR Regulatory Labeling: This is the story and the actors for the connectathon....



1. Company 1 (Glemser) sends proposed label to FDA (i4i) and Company 2 (Docuvera) sends proposed label to FDA (i4i) (via Application Program Interface (API))
2. FDA responds with comments in annotated label (i.e., tracked changes) to Company 1 and Company 2 (via API)
3. Company 1 and Company 2 respond to FDA comments in an annotated label (via API)
4. FDA approves the proposed label from both Company 1 and Company 2 (via API)
5. Company sends FDA agreed final clean label (via API)
6. FDA approves final label (via API)

Potential Future Paths

Enable interoperability across healthcare, co-create patient-centred multi-modal outputs and data-driven approach to measuring the effects on outcomes

Scalable, interoperable medication information data flow

Having multiple sources of information for medication makes it confusing for patients



Personalised patient-centred medication information interface

Most people have problems reading and understanding medication labels & inserts



Measurable outcomes

The complexity of taking medications, for example understanding the impact of drug-drug interactions and adverse events can be overwhelming



From: City-wide electronic health records reveal gender and age biases in administration of known drug-drug interactions, NPJ Digital Medicine, 2019 <https://www.nature.com/articles/s41746-019-0141-x/figures/1>



How to get involved



[Vulcan Accelerator Home](#)



<https://build.fhir.org>



A program of work was initiated under Vulcan to deliver an Implementation Guide for this topic- [API Exchange for Medicinal Product Information \(APIX\)](#).



The IG explains how to manage regulatory workflows and regulatory transactions that include FHIR documents for [electronic Medicinal Product Information \(ePI\)](#), [Pharmaceutical Quality Information \(PQI\)](#), and [Regulatory Correspondence](#).