ePI on FHIR

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Product (Medicinal) Information Pathway

Sources

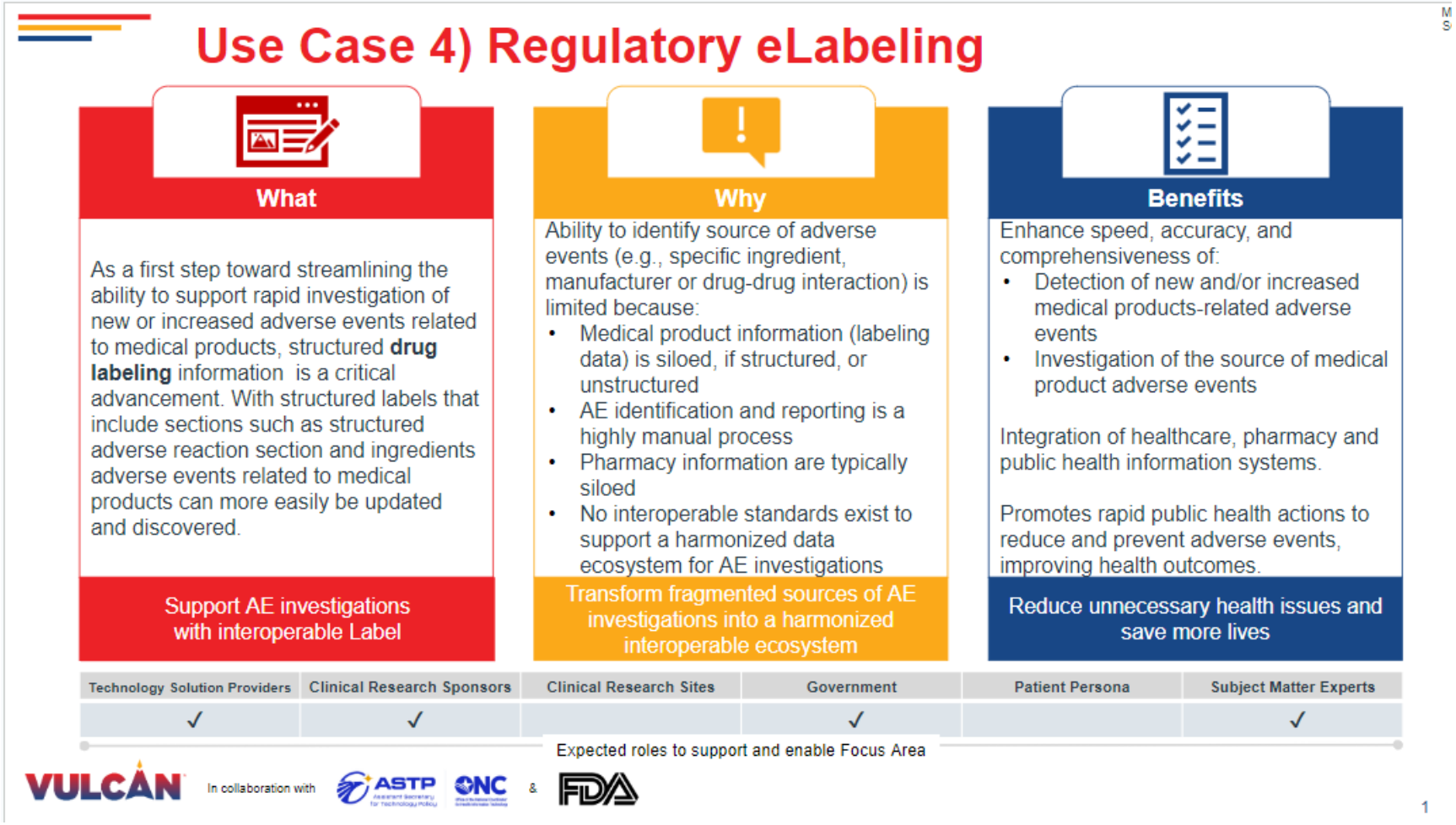
Drug Compendia

EHR and eRX

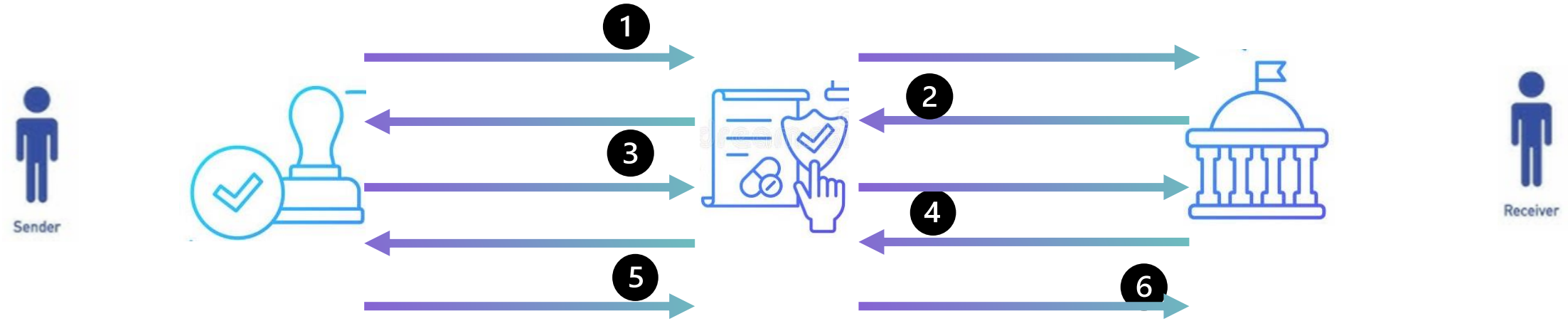
HCP's and Patients

VULCAN

Vulcan Interoperability Bridge (VIB)



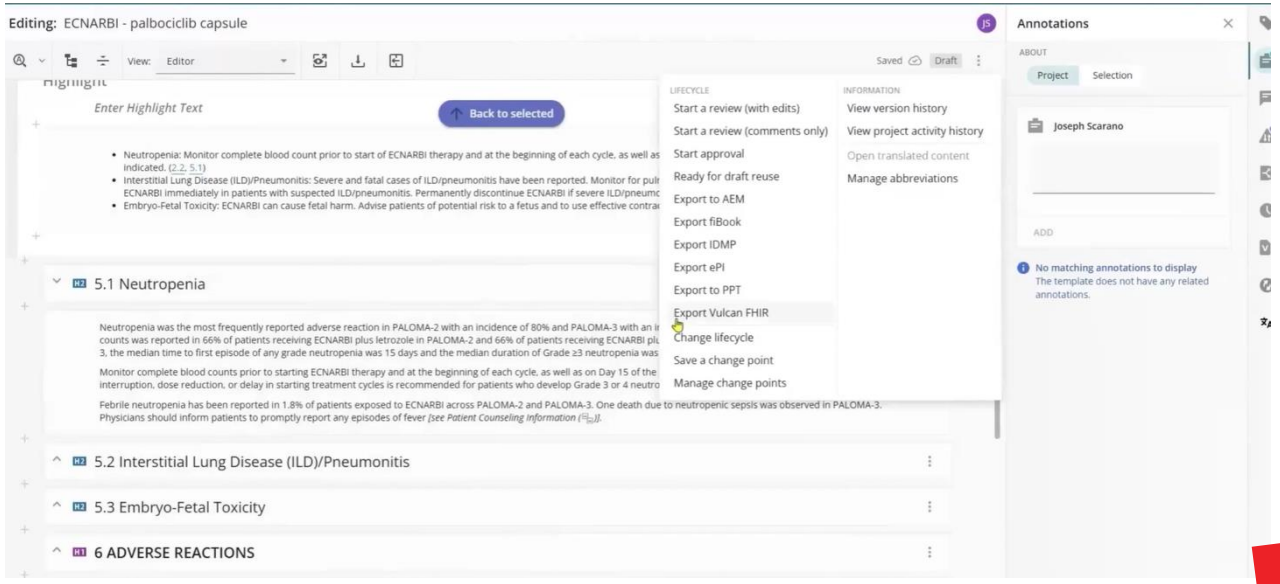
FHIR Regulatory Labeling: This is the story and the actors for the connectathon….

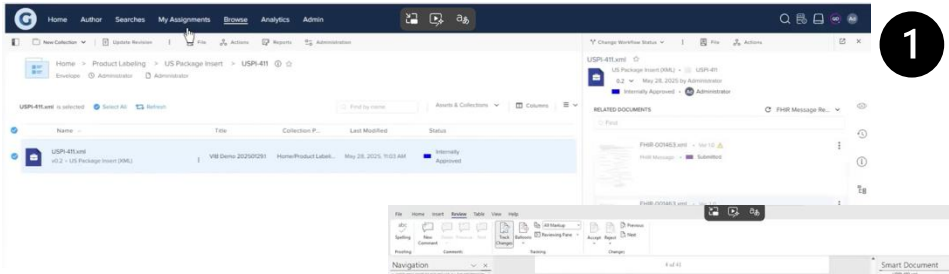


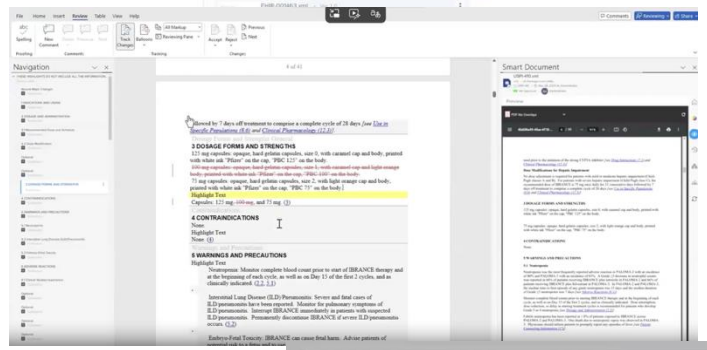
1. Company 1 (Glemser) sends proposed label to FDA (i4i) and Company 2 (Docuvera) sends proposed label to FDA (i4i) (via Application Program Interface (API))
2. FDA responds with comments in annotated label (i.e., tracked changes) to Company 1 and Company 2 (via API)
3. Company 1 and Company 2 respond 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)

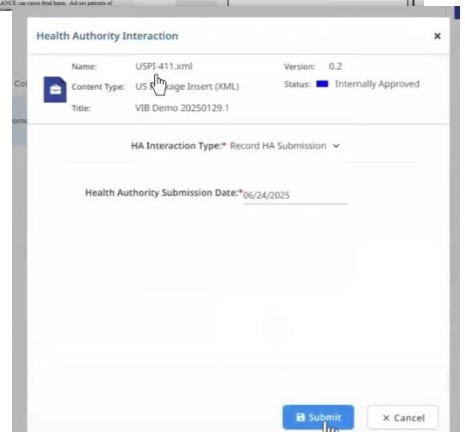
VULCAN

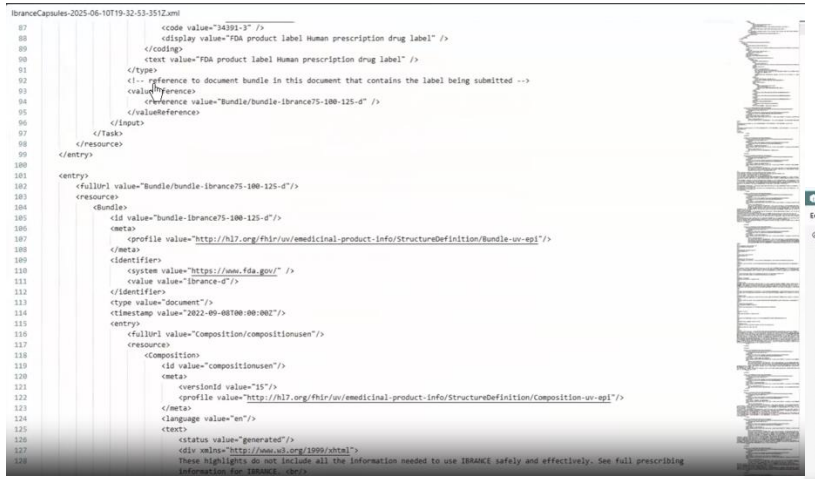
Component Authoring

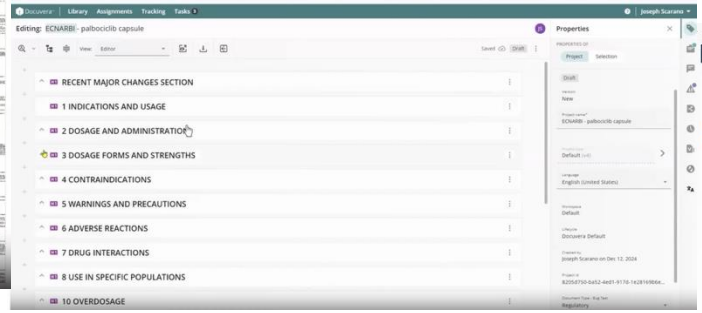


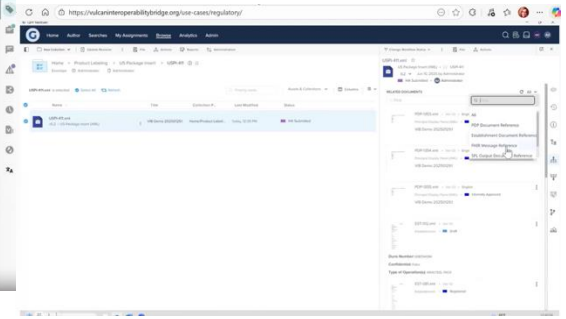










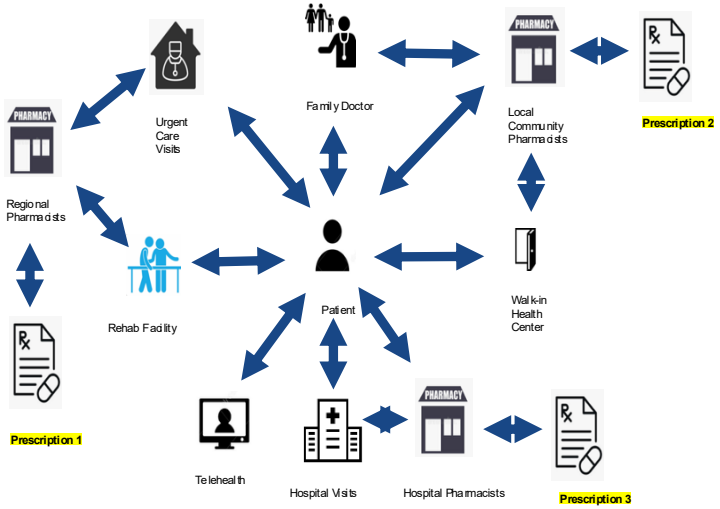


Potential Future Paths

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

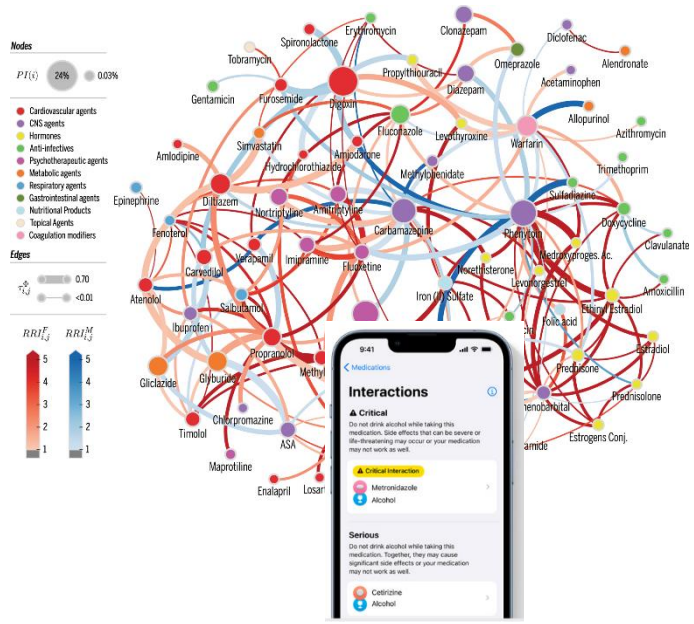


Personalised patient-centred medication information interface

Most people have problems reading and understanding medication labels & inserts

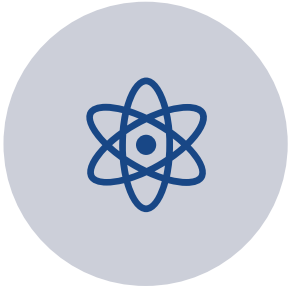
Measurable outcomes

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.