

# Vulcan Accelerator FHIR IG: Retrieval of real-world data for Clinical Research

Scott Gordon, US Food and Drug Administration



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## Who am I?

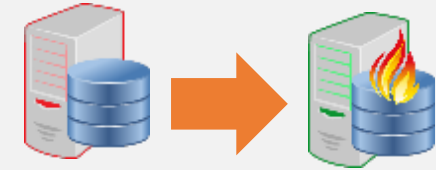


- G. Scott Gordon, Ph.D
- Senior Health Informatics Officer
- US Food and Drug Administration

# What is the Vulcan FHIR Accelerator?

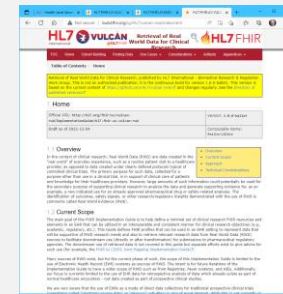
WHY

- FHIR is an enabling technology for harmonising and processing data.
- Vulcan exists to help Clinical and Translational Research start using FHIR to manage the vast amount of data they have to work with.
- Vulcan also exists to bring Clinical and Translational Research and Clinical Care closer together through FHIR.



HOW

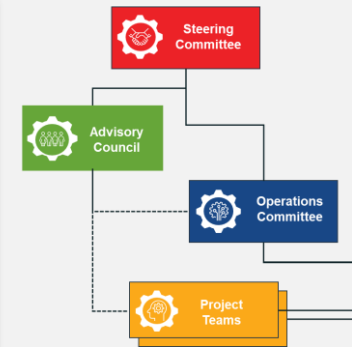
- Vulcan:
- Creates a community
  - Supports projects that have a clear and practical objective and short timescale
  - Creates Implementation Guides
  - Uses connectathons to test the Implementations Guides
  - Provides Events & Education



SoA, RWD, ePI, AE, FHIR to OMOP, Phenotypic Data

WHO

- Over 40 members drawn from Pharma, Academic, Vendors, Regulators, SDOs.
- Operations Committee formed from Members
- Supported by Project Management Office
- International scope



# What is Real-World Data?

*Informally: data created in the “real world” of everyday experience, such as a routine patient visit to a healthcare provider, as opposed to data created under clearly defined protocols typical of controlled clinical trials.*

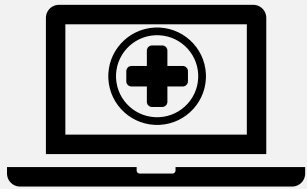
Example:

- A person goes to a doctor for a typical healthcare reason (not as part of a clinical trial). Information is put into an EHR.
- A corner pharmacy dispenses a medication to that person, recorded in an insurance claims database as well as a pharmacy data system
- That person or their doctor enters information into a patient-powered disease Registry

Example Uses:

- Retrospective analysis of existing EHR data
- Observational / non-interventional studies

# What's the problem we're trying to address? (actually there's quite a lot)



Healthcare Domain

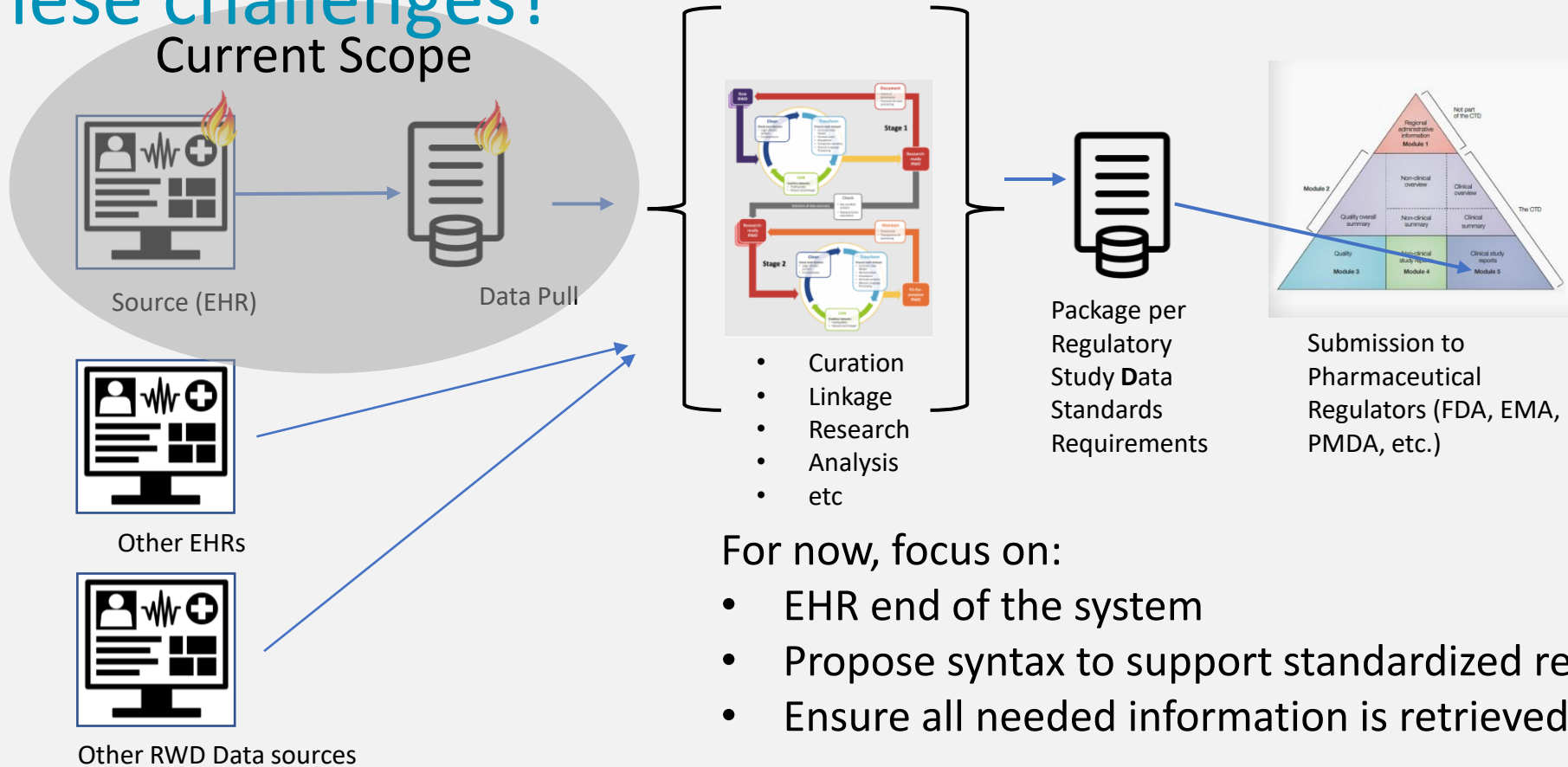


Pharmaceutical Research  
and Regulatory Domain

## GAPS to be bridged:

- Different semantic meaning
- Different syntax
- Different terminologies
- Different business practices
- Different default granularity and completeness
- (not an exhaustive list)

# Where does the Vulcan RWD track fit in addressing these challenges?

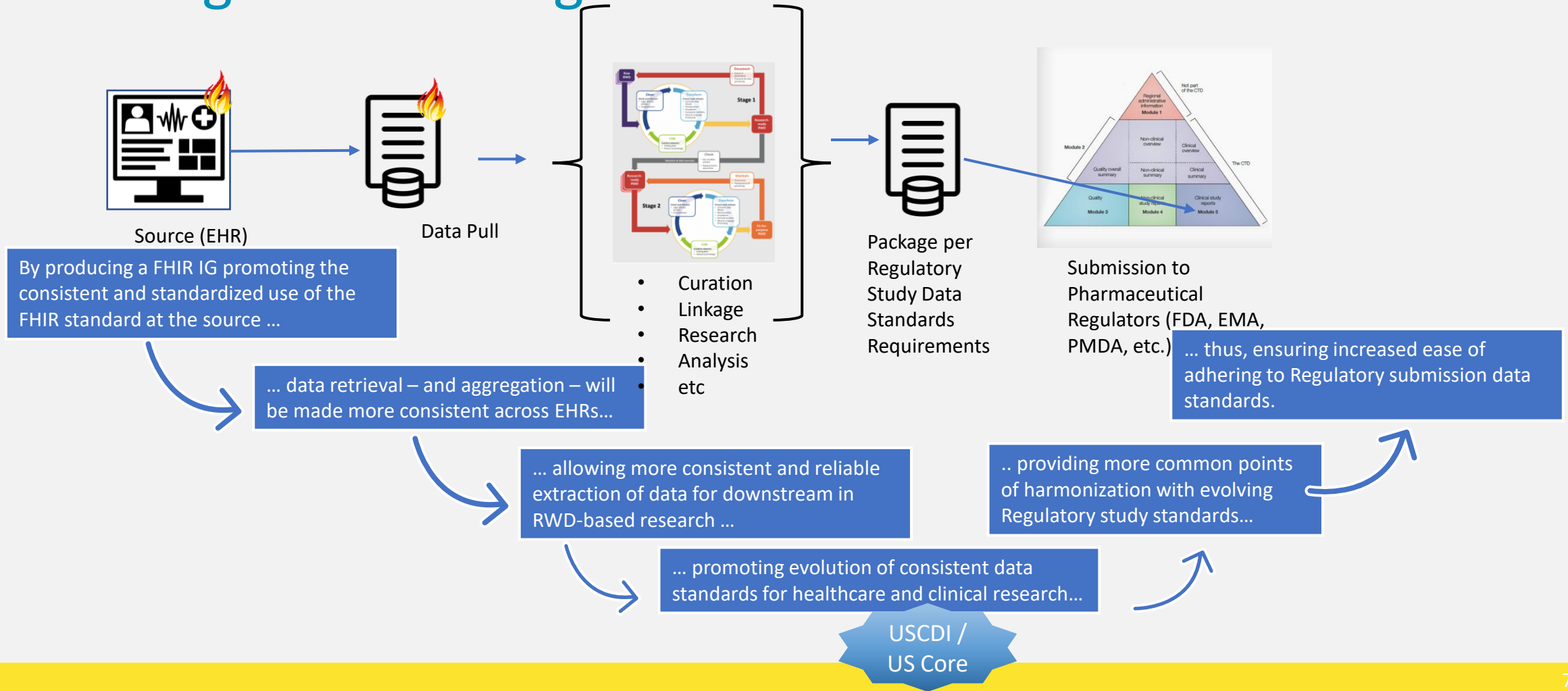


For now, focus on:

- EHR end of the system
- Propose syntax to support standardized retrieval
- Ensure all needed information is retrieved



# How might the Vulcan RWD work help address RWD challenges in the long term?





# Approach to creating an RWD Implementation Guide

- Collect a range of RWD-amenable research questions (use cases); start with a first question
- Evaluate data needed to answer the use case question
- Evaluate if and how FHIR supports each data need
- Establish reasonable requirements for FHIR Profiles
  - Intentionally pushing – if needed - above and beyond the minimum requirements in current Cores (US Core, Canada Baseline, etc.)
- Repeat with a new use case question
  - Aim for a question demanding additional data needs
- (Theoretically) Repeat until nothing new shows up

# Current Implementation Guide

v 1.0.0 STU Implementation Guide:

<http://build.fhir.org/ig/HL7/vulcan-rwd/index.html>

Based on International Patient Access (IPA) Profiles

- Supports use of US Core and other national “Cores”

Uses supported:

- Cohort Building: finding patients matching inclusion/exclusion criteria
- **Finding Data: from an existing cohort of patients, retrieving all required information for research needs**

Resource	Profile
Patient	IPA Profile
Encounter	RWD IG Profile
Condition	IPA Condition and IPA Problem List Item Profiles
Observation	RWD IG Profile
Procedure	RWD IG Profile
MedicationStatement	IPA Profile
MedicationRequest	IPA Profile
MedicationDispense	RWD IG Profile
MedicationAdministration	RWD IG Profile

# RWD IG highlights areas for further standardization of the use of the FHIR standard

All Profiles are built off common medical concept Resources (“bread and butter” healthcare information)

Requirements for must support and mandatory are higher than current US Core

Most seem reasonable within the context of healthcare practice

US Core Profile (6.1.0)	RWD IG Profile (1.0.0)	Element Required more than US Core	
US Core Condition Problems and Health Concerns	IPA-Condition / IPA Problem-list-item		1
US Core Encounter Profile	EncounterRwd		2
US Core MedicationRequest Profile	IPA-MedicationRequest		3
MedicationAdministrationRwd	MedicationAdministrationRwd	Use of Resource, 4 elements	
MedicationDispenseRwd	MedicationDispenseRwd		1
MedicationStatementRwd	IPA-MedicationStatement	Use of Resource, 2 elements	
ObservationLaboratoryResultsRwd	ObservationLaboratoryResultsRwd		5
ProcedureRwd	ProcedureRwd		1

Number of additional . elements mandatory or must support vs US Core

Resource is Must Support (Not in US Core)

# Challenge: Similar but not exactly the same (needs semantic clarity)

Healthcare Domain

When did a person take a medication?

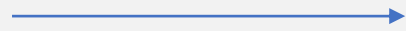
Encounter-based records: Could be a record of prescription, dispense, administration (in some cases), or assertion by patient, doctor, or caregiver

Date from drug prescription record

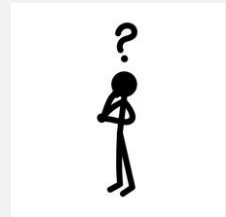
Research/Regulatory Domain

When did a person take a medication?

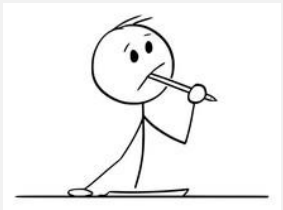
Protocol defined assumptions: date represents best account of ingestion of medication.



Date



So this is when the person took the drug, right?



Hmm...

# Challenge Addressed: IG promotes semantic clarity

Healthcare Domain

When did a person take a medication?

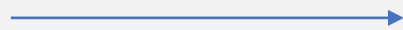
Date from drug prescription record

Research/Regulatory Domain

When did a person take a medication?

Date

Encounter type: prescription



Ah! That helps clarify what the date means

# Challenge: Some concepts not yet standardized (needs standardized use of standards)

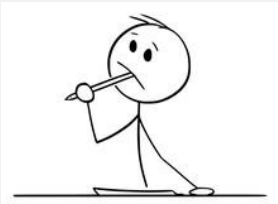
Healthcare Domain

When did a person  
take a medication?

Research/Regulatory Domain

When did a person  
take a medication?

Date from drug Administration record



... Maybe...???



OK, now lets pull Administered medication records. In-patient hospital EHRs all represent this the same way right? With the MedicationAdministration Resource ?

# Challenge Addressed: IG promotes more consistent use of core FHIR Resources

Healthcare Domain

When did a person take a medication?

Date from drug Administration record

Research/Regulatory Domain

When did a person take a medication?



YES!!!



How about now?



## Future work

- Current effort to find site interested in pilot testing
- Reviewing options for future improvement of the Implementation Guide
  - Support for more information (devices, SDOH, etc)
  - Support for terminology challenges
- Working to coordinate with aligned FHIR efforts

## Summary

- The use of healthcare data (as “real-world data”) to support pharmaceutical clinical research has numerous challenges
- The Vulcan Accelerator RWD track is focused on challenges:
  - at the source (how standardized is EHR use of the FHIR standard)
  - in retrieving enough information to keep the full “truth” of the original health record
- Current Implementation Guide is a first step, having presented the benefits of improved consistency in the FHIR representation of core health concepts
- IG pushes the boundaries of minimally sufficient use of FHIR
  - While being completely within the normal realm of EHR concepts
- RWD Track is interested in potential pilot partners

## Contact and Related Links

- Scott Gordon
  - Email: [Gideon.Gordon@fda.hhs.gov](mailto:Gideon.Gordon@fda.hhs.gov)
- Vulcan Real World Data Project Page
  - <https://confluence.hl7.org/display/VA/Real+World+Data>
- RWD Implementation Guide
  - <http://build.fhir.org/ig/HL7/vulcan-rwd/index.html>

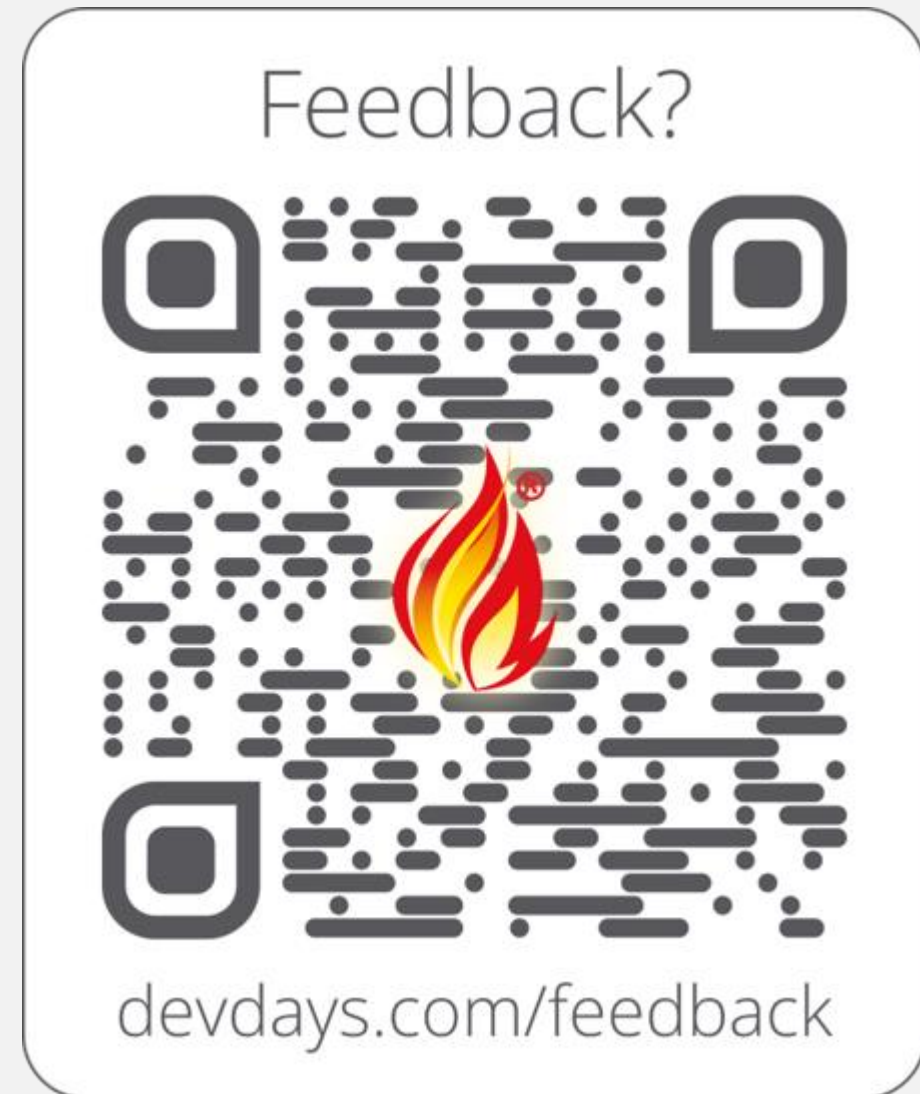
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