

Health Information Exchange for RWD



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A Real World Example of Real World Data

Identify

- A cohort of patients: diagnosis, demographics, lab
- Condition under study: procedures (PCI) and medication (antiplatelets)
- Concomitant medications (18 months)


Retrieve study data points

- Medical history, vital signs, hospitalization

Example study:

<https://clinicaltrials.gov/ct2/show/NCT02190123>

REalWorld Insights on the INitiation and Treatment Duration of ticagrEloR & Other Oral Antiplatelets (OAP) in Patients With Acute Coronary Syndrome (ACS) in Be/Lux. (REWINDER)

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02190123

Recruitment Status  : Completed

First Posted  : July 15, 2014

Last Update Posted  : January 8, 2016

[View this study on Beta.ClinicalTrials.gov](#)

Sponsor:

AstraZeneca

Information provided by (Responsible Party):

AstraZeneca



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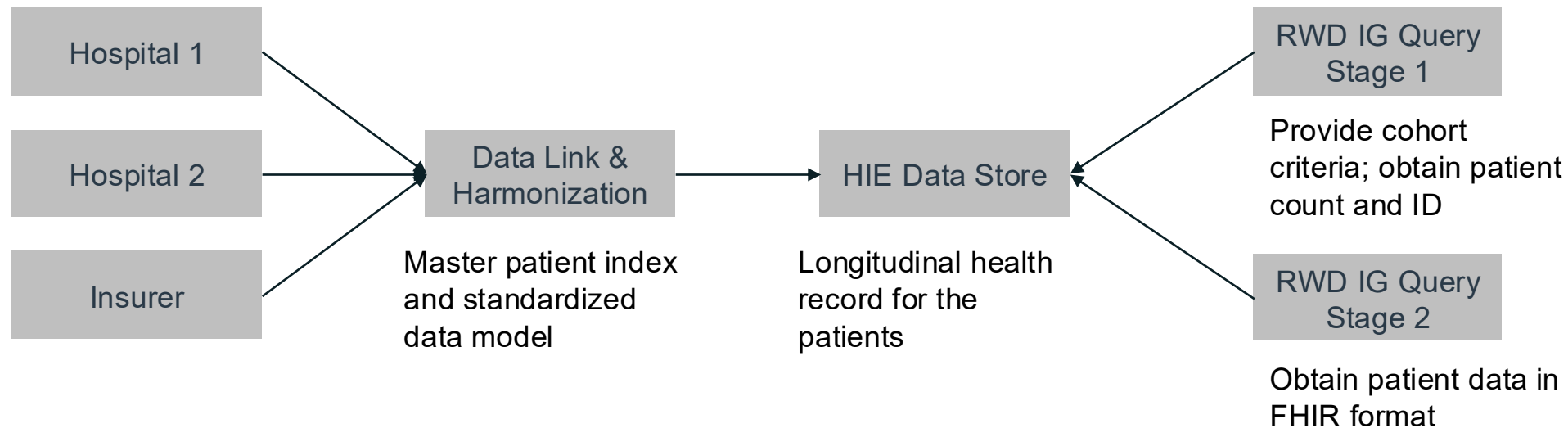


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Health Information Exchange (HIE) Workflow

- HIE workflow for clinical research is unique because
 - Public funded by stakeholders in the region (hospitals, payers, state agencies) to support healthcare and research with existing governance and process for research
 - Longitudinal health record is a common feature of data in HIE that links patient data from multiple clinical systems with data harmonization
 - Strong adoption of HL7 standards already
 - Interested in generating values from data through creative partnership with sponsors



FDA – RWD/RWE Framework and Programs

Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status.

Real-world evidence is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

FDA created a **Framework** in 2018 for evaluating the potential use of RWE to help support the approval of a new indication for a drug already approved under section 505(c) of the FD&C Act or to help support or satisfy drug post-approval study requirements.

Multiple FDA centers incorporate RWD and RWE into daily activities based on the nature of their work and the scope of their regulations: CBER/CDER, OCE

<https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>



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A Real World Prostate Cancer Study Example

Demographics: include all ages and all gender

Diagnosis:

Include individuals with diagnosis of prostate cancer

Exclude individuals with diagnosis of end-stage renal disease

Medication/treatment:

Must have record of receiving at least one of following Luteinizing hormone-releasing hormone (LHRH) agonists medications:

- Leuprolide Acetate
- Goserelin Acetate
- Triptorelin

Standard	Code
ICD10 CM	C61
ICD10 CM	N18.6
RxNorm	752899
RxNorm	309362
RxNorm	746991

Consideration for Choosing Data Source

Geography

Population characteristics

Age

Sex

Race/ethnicity

SDoH

Available data domains

Diagnosis

Procedures

Treatments

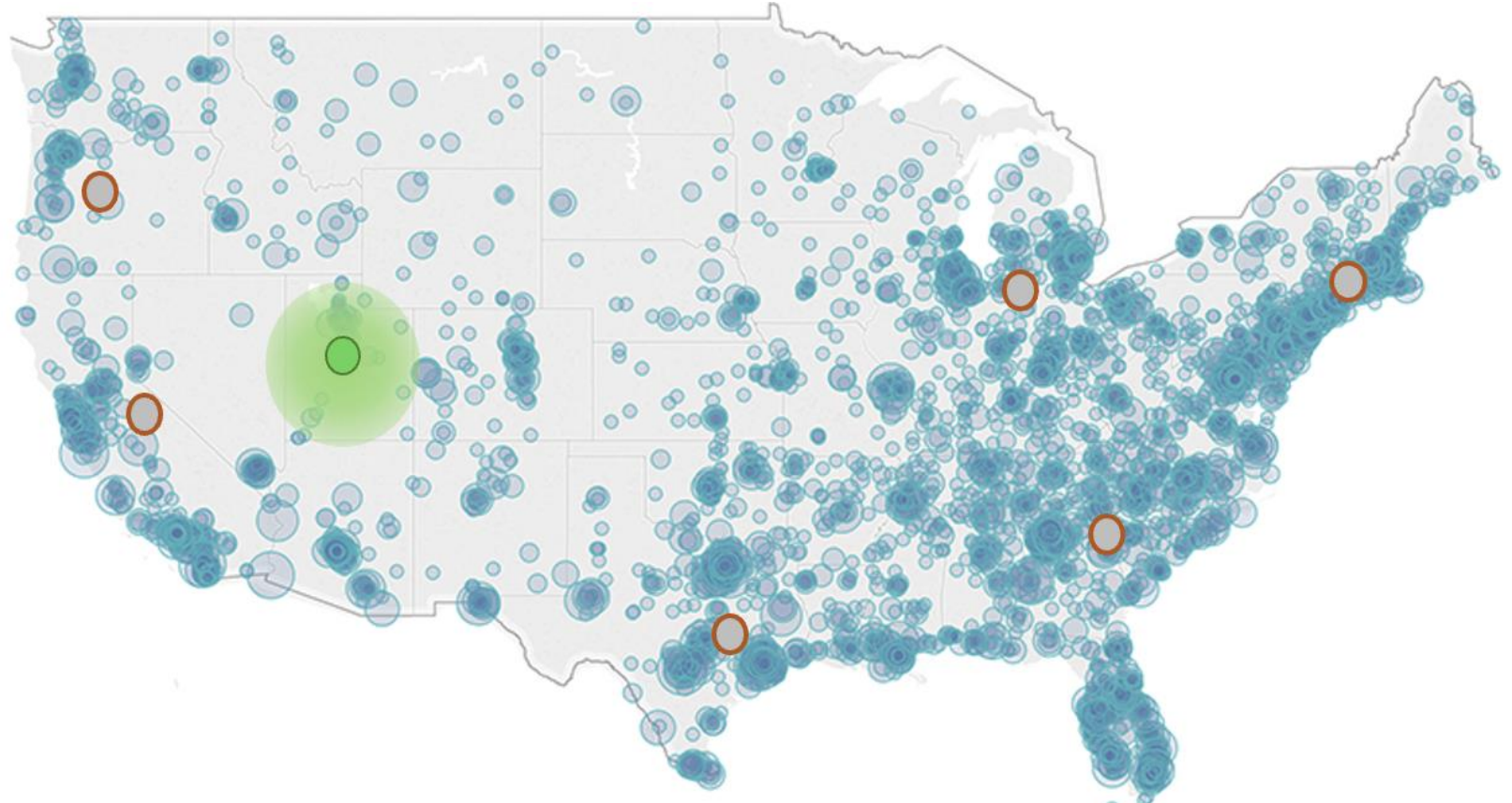
Labs

Longitudinal records

Connectivity

FHIR APIs

Compliance to RWD IG



Current State of HIE in US

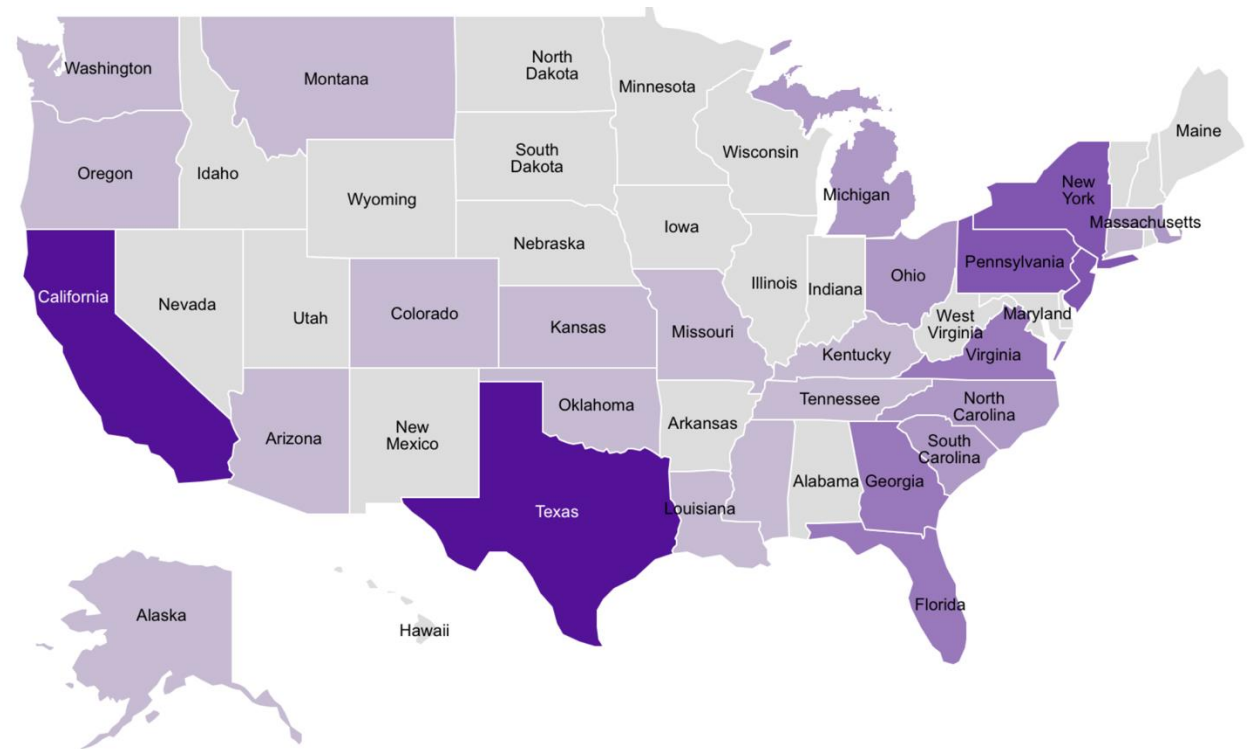
Number of HIEs in Each State

2004 AHRQ funded the first 6 state HIEs

92% of US population served by HIE (SHIEC survey 2019)

70% of hospitals engaged in HIE (ONC/ASTP 2023)

CIVITAS Network for Health was launched in 2021 with 175 HIE members



Source: Definitive Healthcare 2024





ABOUT MANIFEST MEDEX

As the largest nonprofit health data network in California, Manifest MedEx (MX) is an integral part of the state's health data infrastructure, combining and delivering crucial health information for more than 38 million Californians across every county throughout the state.



38M

integrated patient
records

81%

of records with both
claims and clinical data

1.9M+

ADT notifications delivered
monthly

580%

growth in participants since
2019



A TRUSTED PARTNER FOR INFORMATION SHARING & GROWTH

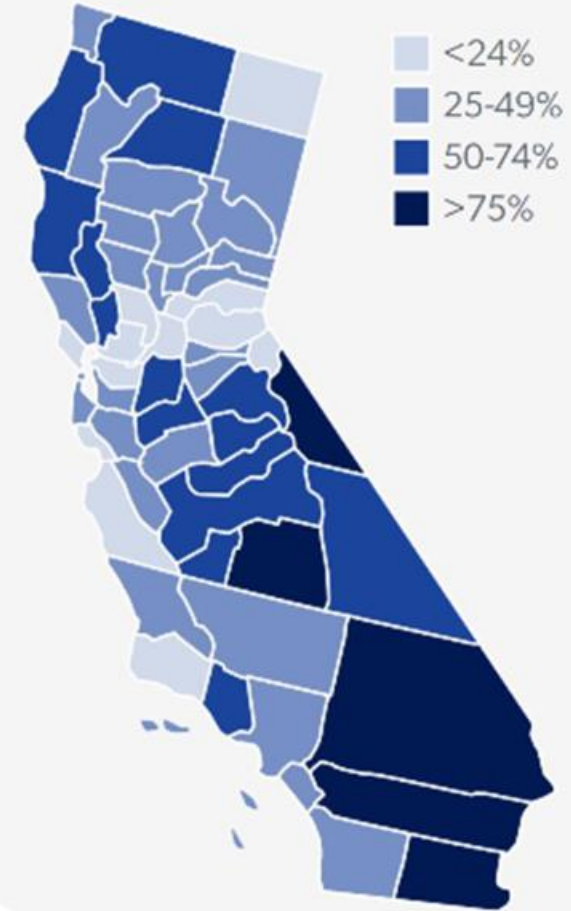
3,100+ CURRENT PARTICIPANTS:

- ✓ 17 health plans
- ✓ 24 IPAs (46 locations)
- ✓ 140+ hospitals
- ✓ 2,600+ ambulatory practices, state/counties, ACOs, EMS, & many more

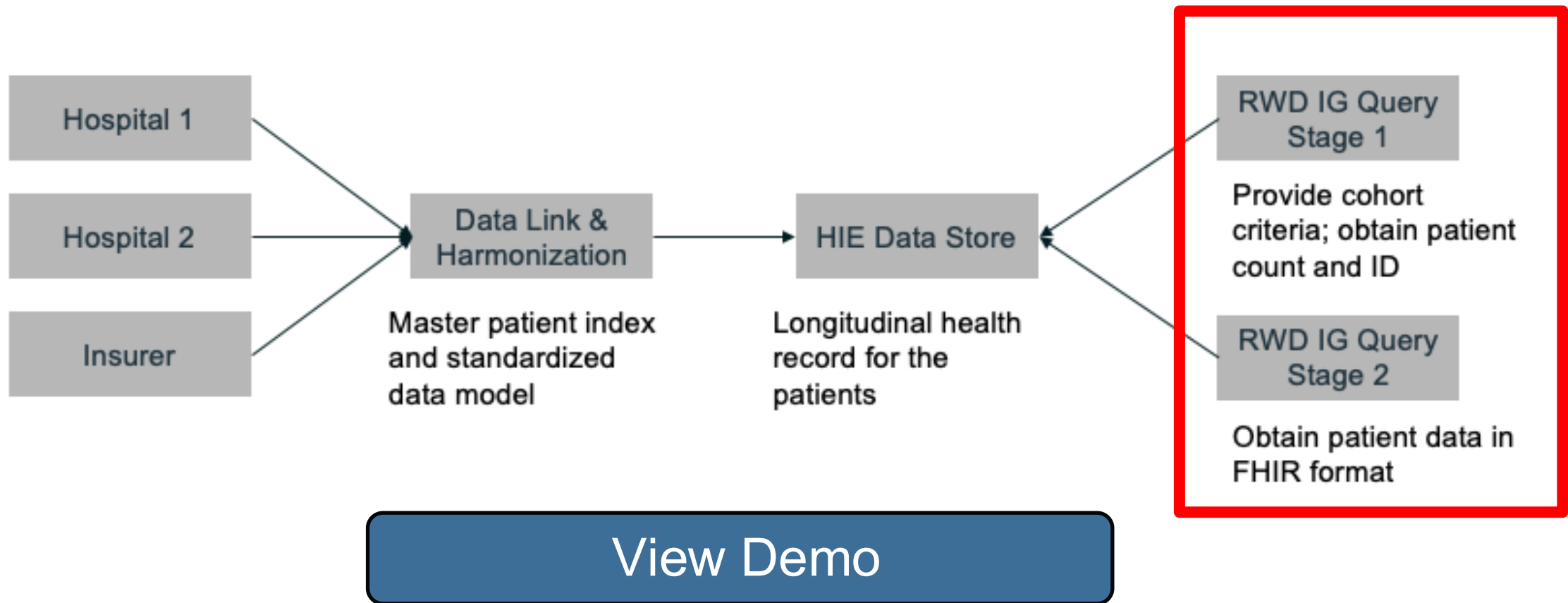
Data to Serve Every County in California

The MX network had an active health record for more than 18 million Californians in 2023 alone, demonstrating the opportunity for a digital health data safety net that bridges large urban centers and rural communities alike.

Active Records on MX Network in 2023 as a Percent of County Population*



Vulcan RWD IG API In Action – J2 Interactive



RWD Application in Action – Parexel

The screenshot displays the 'Vulcan FHIR Demo 2025-01-17' interface. At the top right is the 'parexel' logo. Below it are navigation tabs: 'Cohort Criteria' (active), 'List of Patients', and 'Patient Details'. A left sidebar contains icons for home, search, notifications, refresh, folders, grid, tablet, and a bottom section with a refresh icon, a question mark, and the initials 'SK'. The main content area has three input fields for criteria: 'INCLUDE ICD10', 'EXCLUDE ICD10', and 'INCLUDE RXNORM', each containing a single period '.'. A blue button labeled 'Query FHIR Server' is positioned below the third field.

RWD Data Channels in a Study

