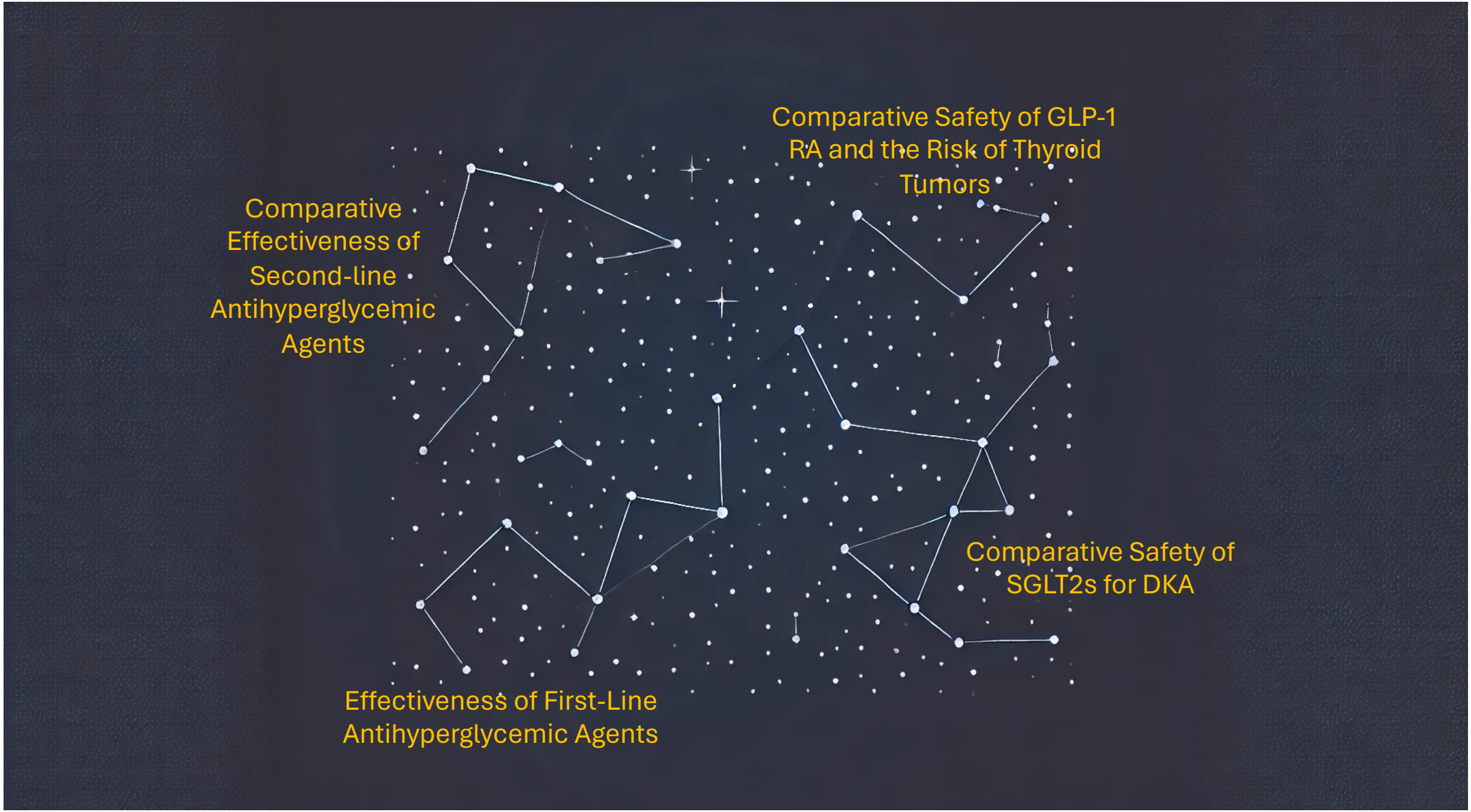
Value Proposition for OHDSI Network Studies

Clair Blacketer, Scott DuVall, Talita Duarte-Salles, Thanh-Phuc Phan, Atif Adam


Comparative Safety of GLP-1 RA and the Risk of Thyroid Tumors
Comparative Effectiveness of Second-line Antihyperglycemic Agents
Comparative Safety of SGLT2s for DKA
Effectiveness of First-Line Antihyperglycemic Agents


Baylor College of Medicine
IQVIA
University of Massachusetts Chan Medical Center
Johns Hopkins University
University of Minnesota
Columbia University
Dankook University Hospital
Inha University Hospital
Yonsei University
University of Colorado
Seoul National University Bundang Hospital
Semmelweis University
University of New Mexico
Ajou University
University of Florida
US Department of Veterans Affairs
Penn State Health
Washington University at St Louis
HealthPartners Institute
Cancer Registry of Norway
Taipei Medical University
Korea University Anam Hospital
Tufts University
Emory University
Stanford
Dana Farber Institute
Seoul National University Hospital
Clinical Hospital Center Zvezdara
University of Texas Southwestern
Johnson & Johnson
ECRAID
Papageorgiou General Hospital
Boeringer Ingelheim
University of Miami

JOIN THE OHDSI EVIDENCE NETWORK

Interest Form

Study Page

Scott DuVall

U.S. Department of Veterans Affairs (VA)

VA Mission

To fulfill President Lincoln's promise to care for those who have served in our nation's military and for their families, caregivers, and survivors.

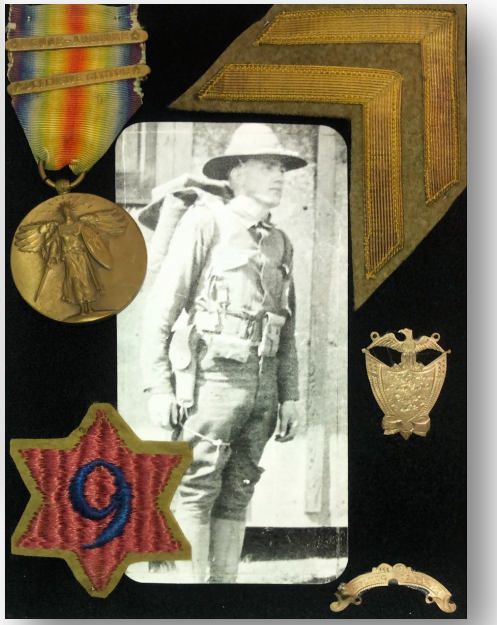
It’s Personal

Kenneth DuVall
U.S. Army Reserves
1971 - 1978

Presley DuVall
U.S. Army
1942 - 1943

Joseph Cummings
U.S. Army
1942 - 1945

Kaye Jensen
U.S. Marine Corps
1942 - 1945

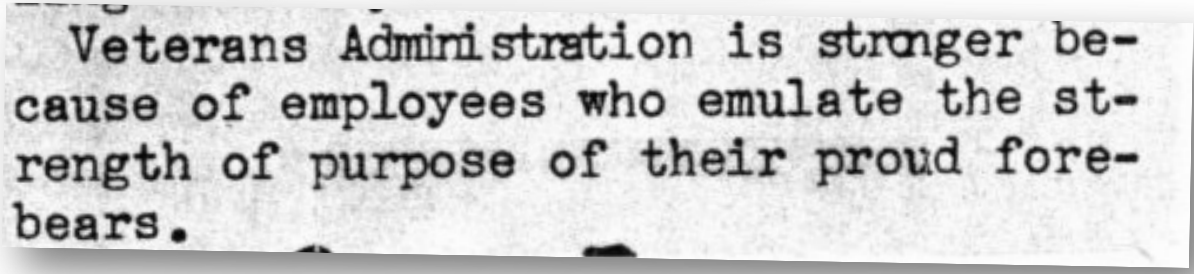


Lawrence Jensen
U.S. Army
1918 - 1919

It’s Personal

Joye Jensen Cummings and Sarah Faatz Jensen (not pictured), Naval Supply Depot, 1945 - 1946

Lawrence Jensen
Veterans Administration
Picture taken ~ 1930 - 1959


Veterans Administration is stronger be-
cause of employees who emulate the st-
rength of purpose of their proud fore-
bears.

Joye Jensen Cummings, Veterans Administration, 1948 - 1949

OHDSI Officer Candidate School


BE ALL
YOU
CAN BE.
U.S. ARMY

VA may be the only healthcare system that can answer long-term, multi-dimensional risk

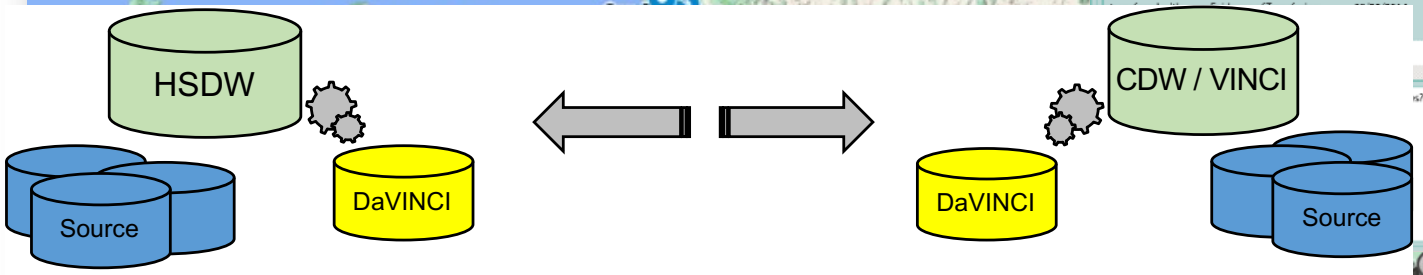
* Part of a panel response at a VA sponsored precision medicine conference, Aug 24, 2016

Robert C. Green, MD, MPH
Harvard Medical School

VA Health Care

163 medical centers **985** outpatient clinics **82** nursing homes **128** state Veteran homes

4,955,500+ Genetic Tests



Department of Defense
11.4 million service women and men

Department of Veterans Affairs
27.2 million Veterans

CMS CDC NDI

68 residential psychiatric centers **111** domiciliary rehabilitation centers **308** Veteran centers

Communication

Communication

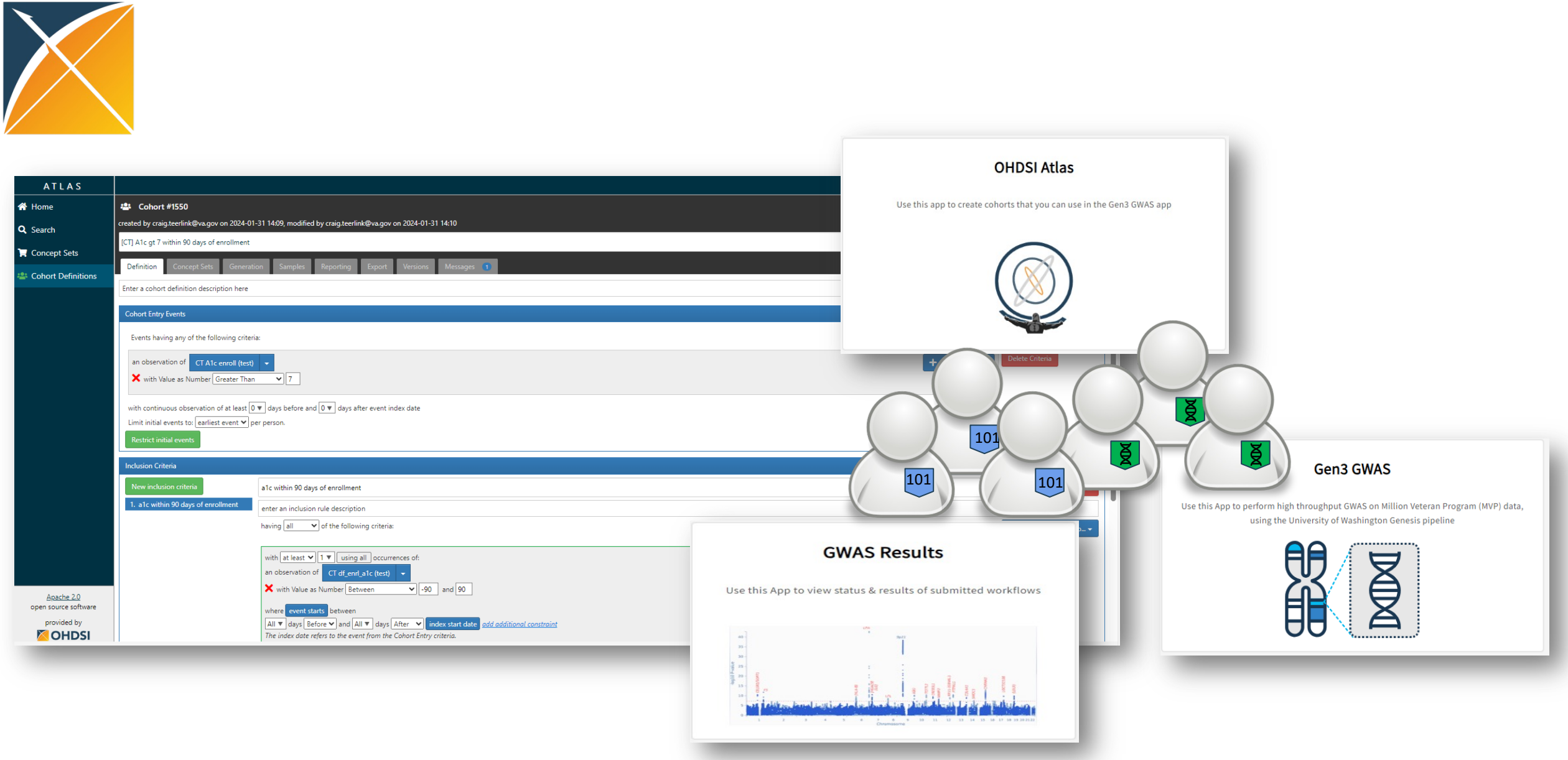
VA has some of the most complex and comprehensive medical data in the world. This creates a huge learning curve for anyone to get up to speed with each source of VA data.

OMOP reduces the curve and supports correct use of VA data.

Tactical and Strategic Planning

What if you weren’t bound by an 8.5”x11” page?

How could you tell the story of the study in an interactive way?


ATLAS
Home
Search
Concept Sets
Cohort Definitions
Cohort #1550
created by craig.teerlink@va.gov on 2024-01-31 14:09, modified by craig.teerlink@va.gov on 2024-01-31 14:10
[CT] A1c gt 7 within 90 days of enrollment
Definition
Concept Sets
Generation
Samples
Reporting
Export
Versions
Messages
Enter a cohort definition description here
Cohort Entry Events
Events having any of the following criteria:
an observation of
CT A1c enroll (test)
with Value as Number
Greater Than
7
with continuous observation of at least
days before and
days after event index date
Limit initial events to:
earliest event
per person.
Restrict initial events
Inclusion Criteria
New inclusion criteria
1. a1c within 90 days of enrollment
a1c within 90 days of enrollment
enter an inclusion rule description
having
all
of the following criteria:
with
at least
using all
occurrences of:
an observation of
CT df_enrl_a1c (test)
with Value as Number
Between
-90
and
90
where
event starts
between
days
Before
and
days
After
index start date
add additional constraint
The index date refers to the event from the Cohort Entry criteria.
Apache 2.0
open source software
provided by
OHDSI
OHDSI Atlas
Use this app to create cohorts that you can use in the Gen3 GWAS app
Delete Criteria
101
101
101
GWAS Results
Use this App to view status & results of submitted workflows
Gen3 GWAS
Use this App to perform high throughput GWAS on Million Veteran Program (MVP) data, using the University of Washington Genesis pipeline

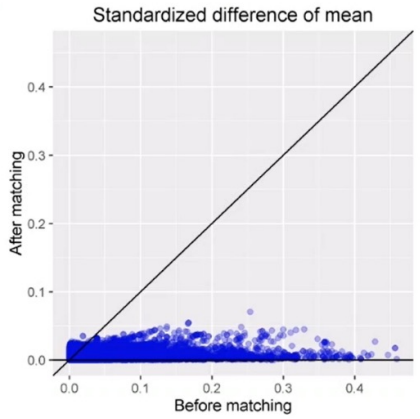
Decision-Making and Critical Thinking

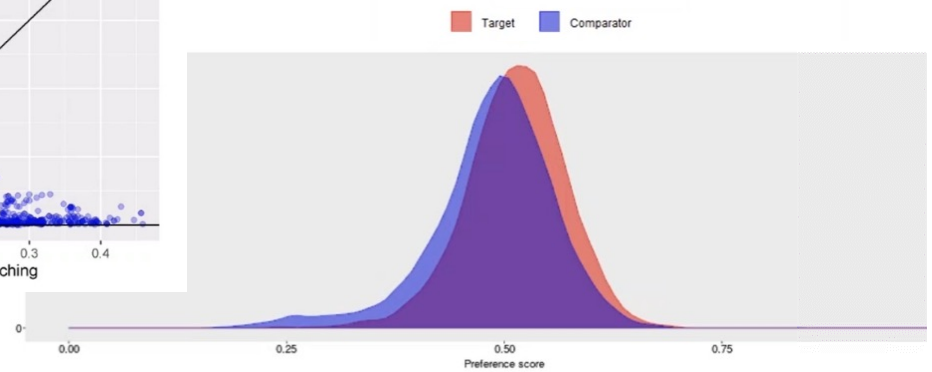
Decision-Making and Critical Thinking

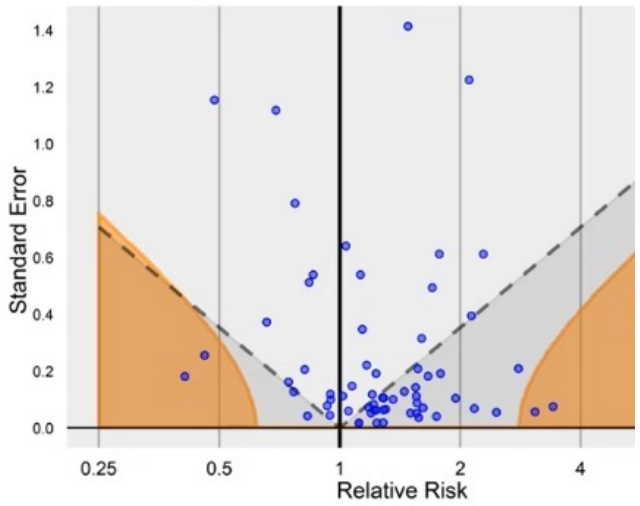
Understand Target Population Characteristics

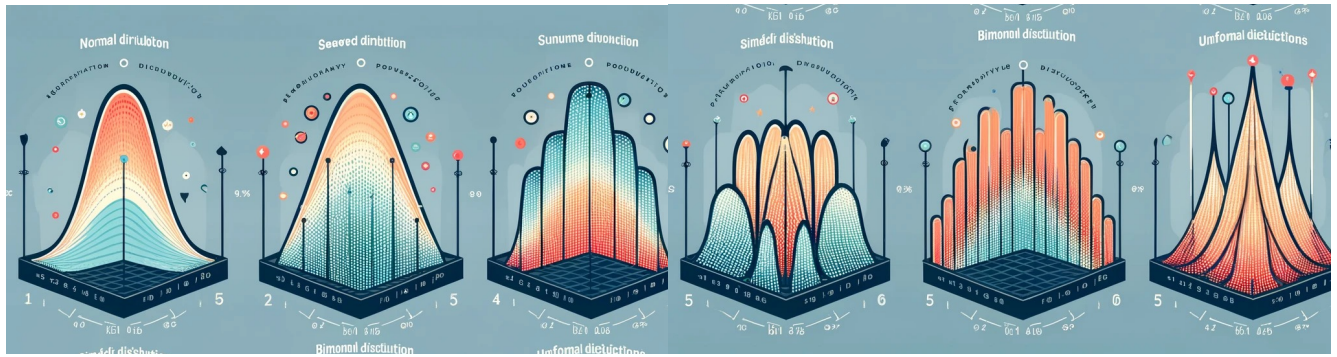
Anticipate Care Workflow

Ensure Underlying Data are Representative









Team Building and Collaboration

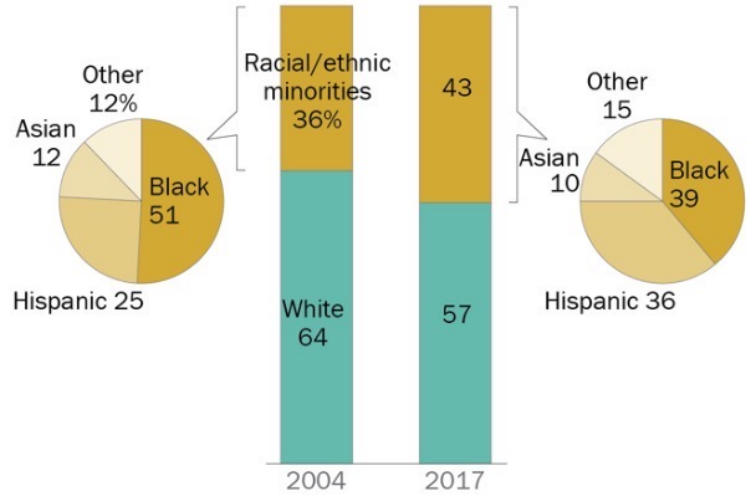

VINCI
OHDSI
VINCI

Team Building and Collaboration

https://www.pewresearch.org/short-reads/2019/09/10/the-changing-profile-of-the-u-s-military/

Demographic shifts in today's military show growing representation of racial and ethnic minorities

% of active duty forces that are ...



Note: Includes only the four military branches of the Department of Defense. "Other" includes American Indian, Native Hawaiian or Pacific Islander, multiracial, and other/unknown. The army does not report "multiracial." White, black, Asian and "other" include those who are non-Hispanic. Hispanics are of any race.
Source: U.S. Department of Defense 2004 and 2017 annual Demographics Reports.

PEW RESEARCH CENTER

Team Building and Collaboration

23 peer-reviewed, published or in-press paper (since March 2020)

› Nat Commun. 2020 Oct 6;11(1):5009. doi: 10.1038/s41467-020-18849-z.

Deep phenotyping of 34,128 adult patients hospitalised with COVID-19 in an international network study

Edward Burn [#1,2], Seng Chan You [#3], Anthony G Sena [4,5], Kristin Kostka [6], Hamed Abedtash [7], Maria Tereza F Abrahão [8], Amanda Alberga [9], Heba Alghoul [10], Osaid Alser [11], Thamir M Alshammari [12], Maria Aragon [1], Carlos Areia [13], Juan M Banda [14], Jaehyeong Cho [3], Aedin C Culhane [15], Alexander Davydov [16,17], Frank J DeFalco [4], Talita Duarte-Salles [1], Scott DuVall [18,19], Thomas Falconer [20], Sergio Fernandez-Bertolin [1], Weihua Gao [21], Asieh Golozar [22,23], Jill Hardin [4], George Hripcsak [20,24], Vojtech Huser [25], Hokyun Jeon [26], Yonghua Jing [21], Chi Young Jung [27], Benjamin Skov Kaas-Hansen [28,29], Denys Kaduk [16,30], Seamus Kent [31], Yeesuk Kim [32], Spyros Kolovos [33], Jennifer C E Lane [33], Hyejin Lee [34], Kristine E Lynch [18,19], Rupa Makadia [4], Michael E Matheny [35,36], Paras P Mehta [37], Daniel R Morales [38], Karthik Natarajan [20,24], Fredrik Nyberg [39], Anna Ostropolets [20], Rae Woong Park [3,26], Jimyung Park [26], Jose D Posada [40], Albert Prats-Uribe [2], Gowtham Rao [4], Christian Reich [6], Yeunsook Rho [33], Peter Rijnbeek [5], Lisa M Schilling [41], Martijn Schuemie [4,42], Nigam H Shah [40], Azza Shoaibi [4], Seokyoung Song [43], Matthew Spotnitz [20], Marc A Suchard [42], Joel N Swerdel [4], David Vizcaya [44], Salvatore Volpe [20], Haini Wen [45], Andrew E Williams [46], Belay B Yimer [47], Lin Zhang [48,49], Oleg Zhuk [16], Daniel Prieto-Alhambra [50], Patrick Ryan [4,51]

› J Am Med Inform Assoc. 2023 Feb 24;ocad009. doi: 10.1093/jamia/ocad009.
Online ahead of print.

Reproducible variability: assessing investigator discordance across 9 research teams attempting to reproduce the same observational study

Anna Ostropolets [1], Yasser Albogami [2], Mitchell Conover [3], Juan M Banda [4], William A Baumgartner [5], Clair Blacketer [3], Priyamvada Desai [6], Scott L DuVall [7,8], Stephen Fortin [3], James P Gilbert [3], Asieh Golozar [9], Joshua Ide [10], Andrew S Kanter [1], David M Kern [3], Chungsoo Kim [11], Lana Y H Lai [12], Chenyu Li [13], Feifan Liu [14], Kristine E Lynch [7,8], Evan Minty [15], Maria Inês Neves [16], Ding Quan Ng [17], Tontel Obene [18], Victor Pera [19], Nicole Pratt [20], Gowtham Rao [3], Nadav Rappoport [21], Ines Reinecke [22], Paola Saroufim [23], Azza Shoaibi [3], Katherine Simon [24], Marc A Suchard [25,26], Joel N Swerdel [3], Erica A Voss [3], James Weaver [3], Linying Zhang [1], George Hripcsak [1,27], Patrick B Ryan [1,3]

Several on-going clinical and informatics projects with OHDSI

Congratulations!

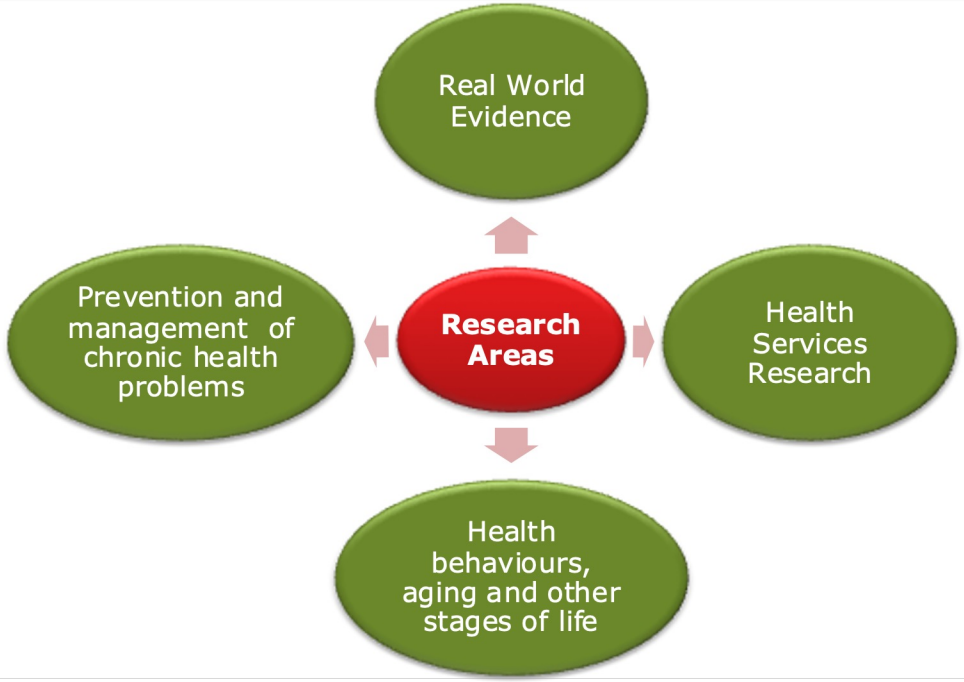
and

Thank You OHDSI!

Talita Duarte-Salles

IDIAP Jordi Gol

- Foundation Institute for Primary Health Care Research Jordi Gol i Gurina – IDIAP Jordi Gol
- >1500 researchers
- 35 research groups



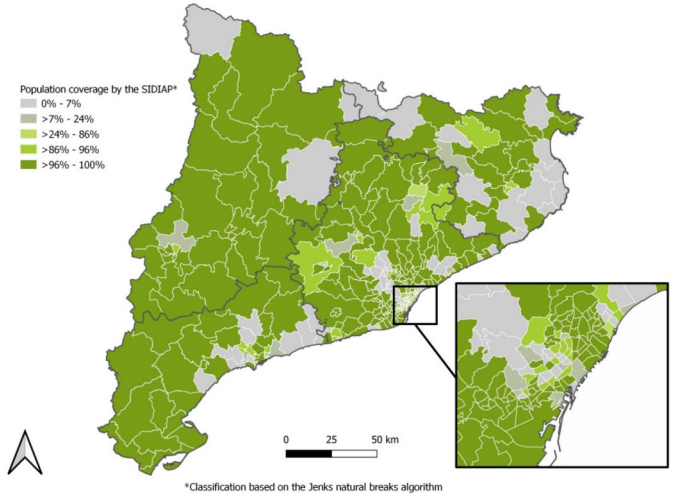
Spanish healthcare system

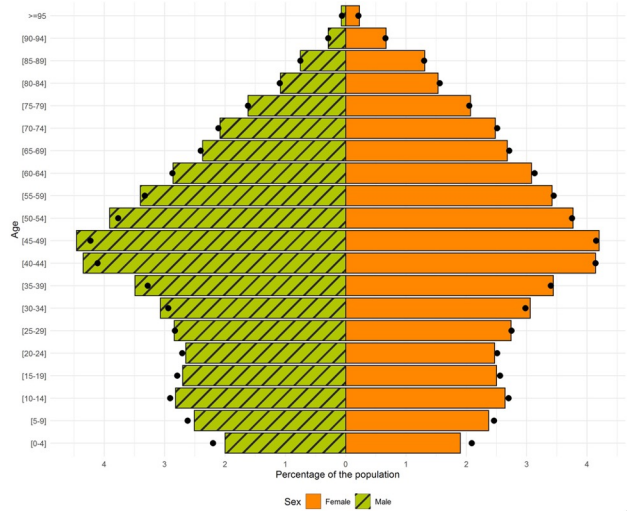
- Spain has a **public health system free of charge,** aside from medicines (co-payment system)
- Primary care centres are the first point of contact for accessing healthcare services
- The health system is decentralized to **17 autonomous communities**

Source: Wikipedia

SIDIAP

- The Information System for Research in Primary Care
- Data collected by >10,000 healthcare professionals from 328 primary care centres
- >8 million people (5.8 million active)
- Data since 2006 and updated on a 6-monthly basis
- Mean follow-up time 16.5 years
- Representative of the general population living in Catalonia





SIDIAP

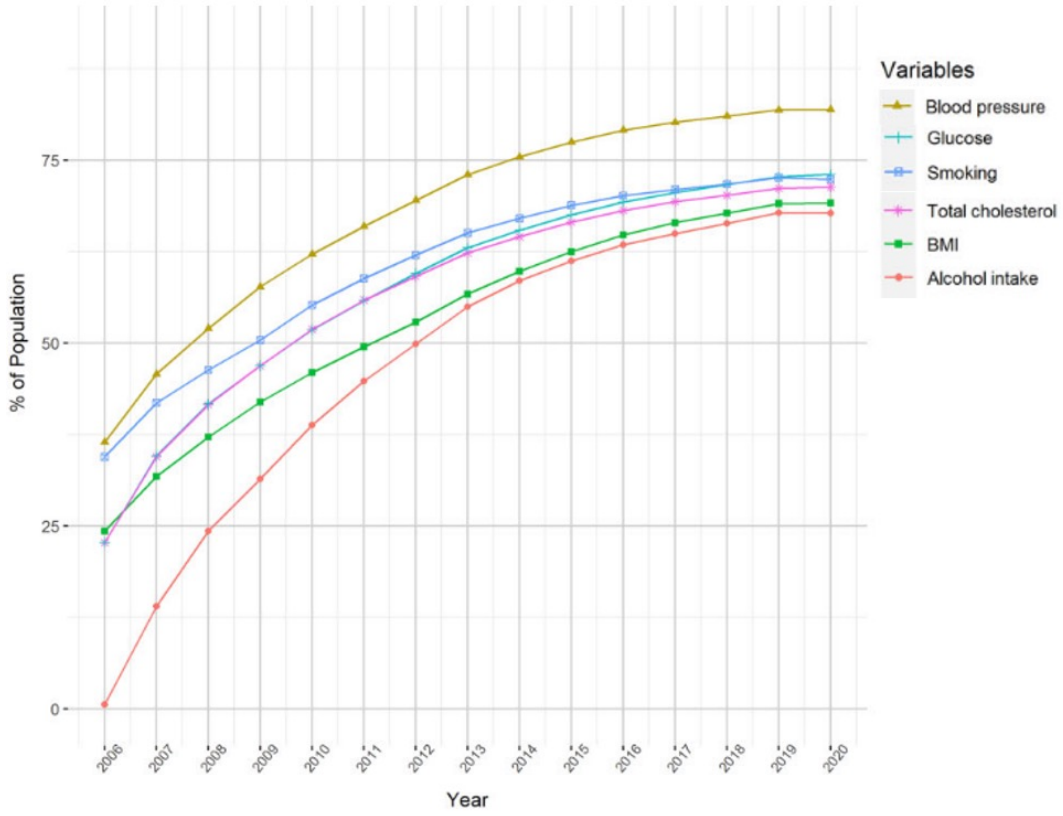
www.sidiap.org

Recalde M et al. Data Resource Profile: The Information System for Research in Primary Care (SIDIAP). Int J Epidemiol, December 2022, Pages e324–e336, https://doi.org/10.1093/ije/dyac068

SIDIAP data

- **Demographics**: age, sex, nationality, SES
- **Lifestyle factors**: smoking, alcohol intake
- **Clinical measurements:** BMI, blood pressure
- **Medical diagnoses** – using ICD10-CM codes
- **Medicines:** prescriptions and dispensations
- **Laboratory test results**
- **Sick leaves**
- **All-cause mortality**

% of the SIDIAP population with at least one registry of key variables, by year



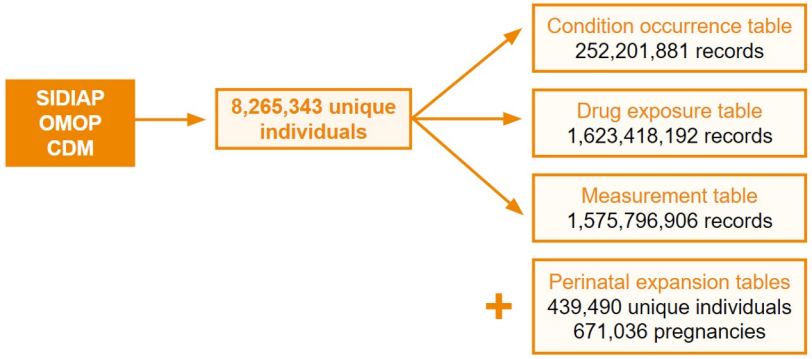
Source: Recalde et al (2022)

SIDIAP – linkages

- **Disease registries** (e.g., cancer registries)
- **Environmental exposures** – air pollution, green spaces, built environment, food environment, daily temperatures
- **Public and private hospital discharge records** – diagnosis and procedures
- **Mother and child linkage** for more than 700k pairs

SIDIAP – OMOP CDM

- EMIF (2015) → EHDEN (2019 and 2020)



- Evidence generating in local and network studies

nature COMMUNICATIONS

ARTICLE

https://doi.org/10.1038/s41467-020-18849-z OPEN

Deep phenotyping of 34,128 adult patients hospitalised with COVID-19 in an international network study

Edward Burn et al.#

Open access Original research

BMJ Open Impact of the COVID-19 pandemic on diagnoses of common mental health disorders in adults in Catalonia, Spain: a population-based cohort study

Berta Raventós ,[1,2] Andrea Pistillo,[1] Carlen Reyes ,[1] Sergio Fernández-Bertolín,[1] Maria Aragón,[1] Anna Berenguera ,[1,2] Constanza Jacques-Aviñó,[1,2] Laura Medina-Perucha ,[1,2] Edward Burn ,[1,3] Talita Duarte-Salles [1]

thebmj covid-19 Research Education News & Views Campaigns Jobs

Research » Special paper

Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study

BMJ 2021 ; 373 doi: https://doi.org/10.1136/bmj.n1435 (Published 14 June 2021)
Cite this as: *BMJ* 2021;373:n1435

RESEARCH

Clinical Epidemiology Dovepress

ORIGINAL RESEARCH

Unraveling COVID-19: A Large-Scale Characterization of 4.5 Million COVID-19 Cases Using CHARYBDIS

nature communications

Article https://doi.org/10.1038/s41467-022-34669-9

Thrombosis and thrombocytopenia after vaccination against and infection with SARS-CoV-2 in Catalonia, Spain

Edward Burn [1,2,5], Elena Roel [1,3,5], Andrea Pistillo [1], Sergio Fernández-Bertolín[1], Maria Aragón [1], Berta Raventós[1,3], Carlen Reyes[1], Katia Verhamme[4], Peter Rijnbeek [4], Xintong Li [2], Victoria Y. Strauss[2], Daniel Prieto-Alhambra [2,4,6] & Talita Duarte-Salles [1,6]

Association between covid-19 vaccination, SARS-CoV-2 infection, and risk of immune mediated neurological events: population based cohort and self-controlled case series analysis

Xintong Li,[1] Berta Raventós,[2,3] Elena Roel,[2,3] Andrea Pistillo,[2] Eugenia Martinez-Hernandez,[4] Antonella Delmestri,[1] Carlen Reyes,[2] Victoria Strauss,[1] Daniel Prieto-Alhambra,[1,5] Edward Burn,[1,2] Talita Duarte-Salles[2]

BMJ: first published as 1

Value of network studies for IDIAP Jordi Gol and SIDIAP

- Improve knowledge about our own data – strengths and limitations
- Stablish new **collaborations**

Value of network studies for IDIAP Jordi Gol and SIDIAP

- Improve knowledge about our own data – strengths and limitations
- Stablish new **collaborations**

→ **LEGEND-T2DM**

Value of network studies for IDIAP Jordi Gol and SIDIAP

- Improve knowledge about our own data – strengths and limitations
- Stablish new **collaborations**
- Generating **reliable evidence** of high impact
  - Broader public health impact - potential to improve patient outcomes on a larger scale
  - Accelerate research - reducing duplication of efforts and increasing efficiency

Value of network studies for IDIAP Jordi Gol and SIDIAP

- Improve knowledge about our own data – strengths and limitations
- Stablish new **collaborations**
- Generating **reliable evidence** of high impact
  - Broader public health impact - potential to improve patient outcomes on a larger scale
  - Accelerate research - reducing duplication of efforts and increasing efficiency
- **Training and career development**
- Visibility – earning trust as data partners (and as a research group and institution)

DARWIN EU® Data Network

UK
- Clinical Practice Research Datalink (CPRD GOLD)
- UK Biobank

Netherlands
- Integrated Primary Care Information (IPCI)
- Netherlands Comprehensive Cancer Organisation

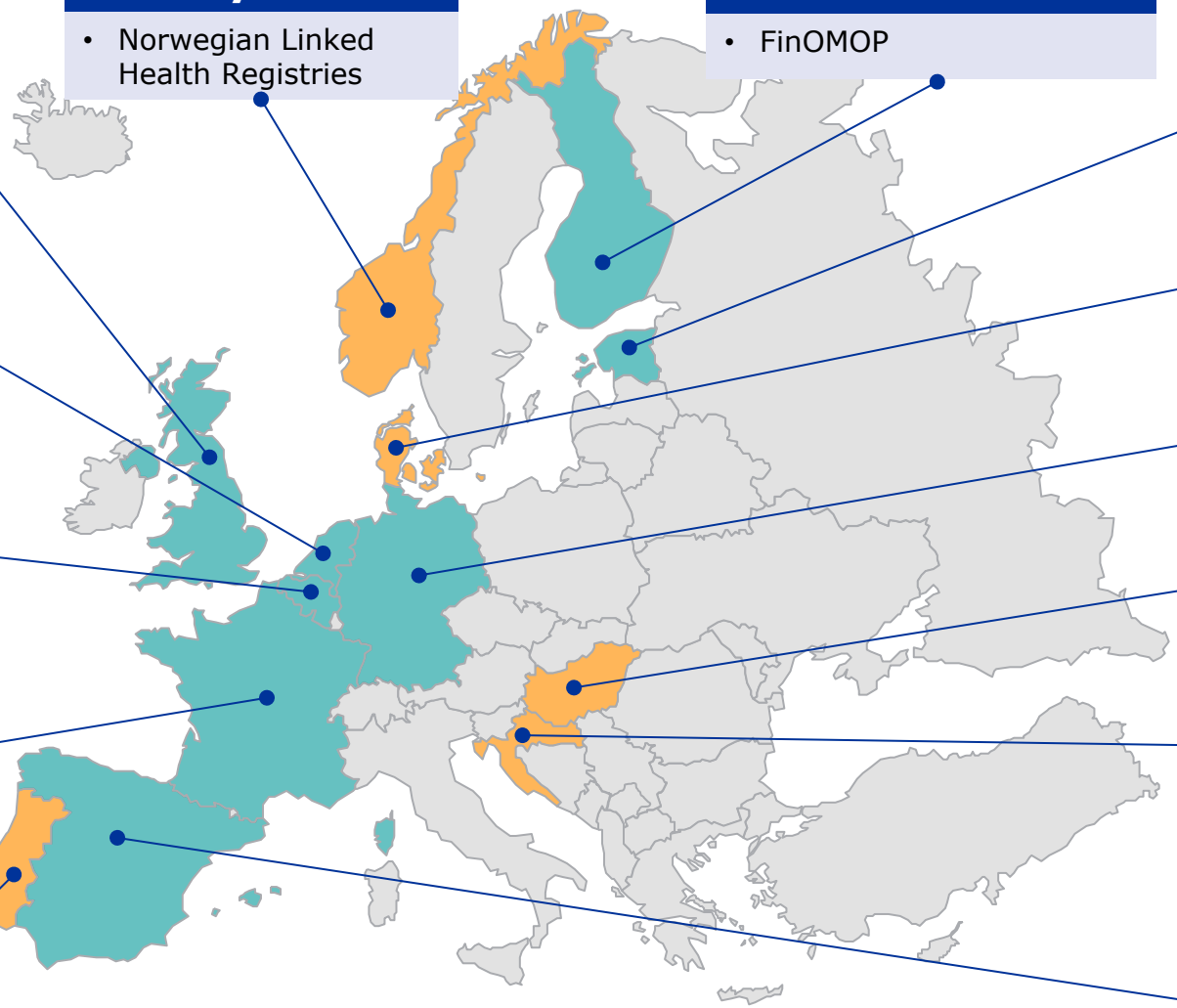
Belgium
- IQVIA Belgium Longitudinal Patient Data

France
- Bordeaux University Hospital
- Système National des Données de Santé

Portugal
- Unidade Local de Saúde de Matosinhos
- Egas Moniz Database

Norway
- Norwegian Linked Health Registries

Finland
- FinOMOP



Estonia
- University of Tartu (Biobank)

Denmark
- Danish Health Data Registries

Germany
- IQVIA Germany Disease Analyser

Hungary
- Semmelweis University

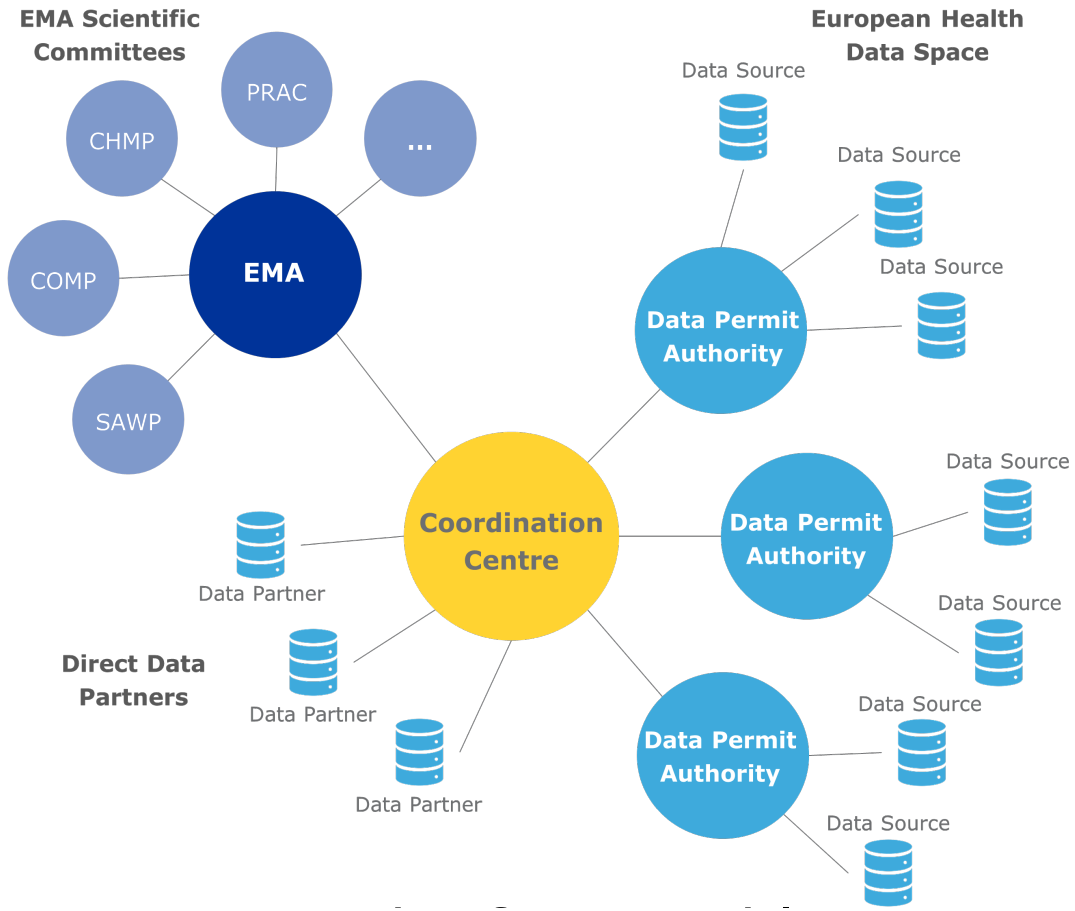
Croatia
- Croatian National public health information system

Spain
- **SIDIAP**
- Parc Salut Mar Barcelona, Hospital del Mar (IMIM)
- BIFAP
- Valencia Health System Integrated Database

DARWIN EU®

is a federated **network** of **data**, **expertise** and **services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real world healthcare data**

DARWIN Studies	SIDIAP
Off-the-shelf	24
Complex	9
Total	**33**



https://www.darwin-eu.org/index.php/studies

Leading our own network study

Characteristics, prevalence, incidence and survival of cancer over time in the OHDSI Network

Study objectives

1) To describe demographic and **clinical characteristics** of individuals with cancer.
2) To estimate **prevalence** rates of site-specific cancers by calendar year, age, sex, and comorbidities.
3) To estimate **incidence** rates of site-specific cancers by calendar year, age, sex, and comorbidities.
4) To estimate overall, short- and long-term **survival** of site-specific cancers by calendar year, age, sex, and comorbidities.

Irene López Sánchez
Real World Epidemiology Research Group, IDIAPJGol, Spain
ilopez@idiapjgol.org

Thank you!

Talita Duarte-Salles

Real World Epidemiology Research Group, IDIAPJGol, Spain

Department of Health Informatics, Erasmus MC, The Netherlands

tduarte@idiapjgol.org

Data Resource Profile

Data Resource Profile: The Information System for Research in Primary Care (SIDIAP)

Martina Recalde ,[1,2†] Clara Rodríguez,[1†] Edward Burn ,[1,3] Marc Far,[1] Darío García,[1] Jordi Carrere-Molina,[1] Mencia Benítez,[1] Anna Moleras,[1] Andrea Pistillo,[1] Bonaventura Bolíbar,[1,2] María Aragón,[1*‡] and Talita Duarte-Salles [1‡]

[1]Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain, [2]Universitat Autònoma de Barcelona, Bellaterra, Spain and [3]Centre for Statistics in Medicine, NDORMS, University of Oxford, Oxford, UK

Atif Adam

Leveraging RWE for Commercial Success: OHDSI's Role

by Atif Adam

The Evolving Role of RWE in Industry Strategy

Traditional Uses of RWE

Safety monitoring

Post-marketing studies

2. Emerging Applications

Portfolio strategy development

Market outreach and expansion

Comparative effectiveness research

3. RWE in Portfolio Strategy

Informing drug development pipelines

Guiding therapeutic area focus

Supporting investment decisions

4. Market Outreach and Expansion Through RWE

Identifying untapped markets and unmet needs

Understanding regional variations in treatment patterns

Informing market access strategies

5. Key Drivers of RWE Adoption

Increasing demand for real-world outcomes data

Regulatory acceptance of RWE for decision-making

Advancements in data analytics capabilities

6. Challenges and Considerations

Data quality and standardization

Methodological complexities in RWE studies

Integration of RWE insights into decision-making processes

The Evolving Role of RWE in Industry Strategy

Transition to RWE requires significant evolution in capabilities, culture, and strategic approach beyond traditional (trial) expertise.

Key Differences: RCTs vs. RWE

1. Data: Homogeneous (RCTs) → Heterogeneous (RWE)
2. Bias: Minimized by randomization → Multiple sources to mitigate
3. Interpretation: Clear causality → Complex relationships

New Competencies for Internal Teams

1. Data management: Handling diverse, large-scale datasets
2. Epidemiological thinking: Observational study design
3. Regulatory knowledge: Evolving RWE standards

Organizational Adaptations

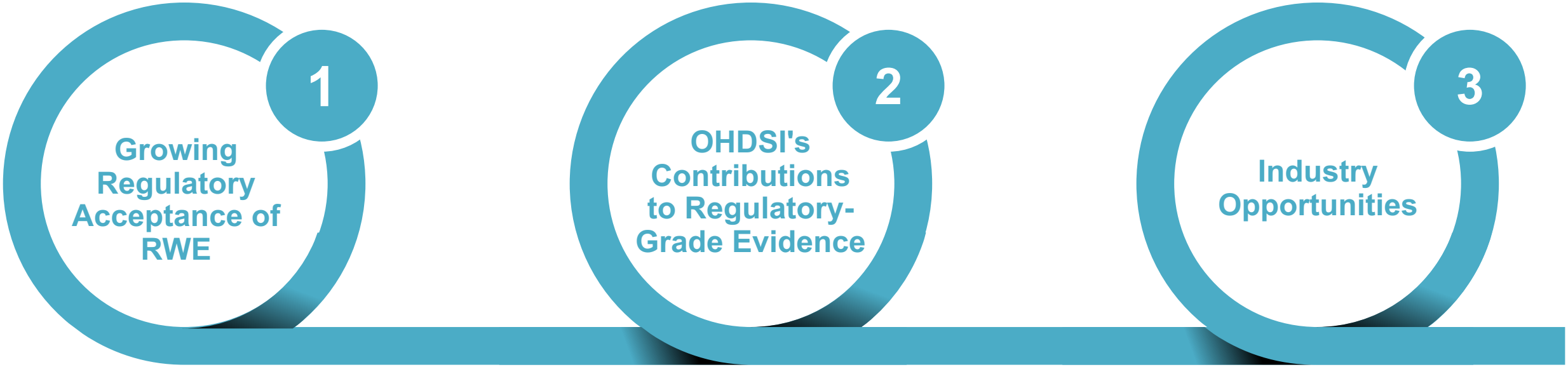
1. Cross-functional collaboration
2. Continuous learning environment
3. Leadership buy-in for long-term investment

Challenges in Translation

1. Skill gaps: RCT experience ≠ RWE proficiency
2. Ethical considerations: Privacy, responsible data use
3. Infrastructure: Need for robust data platforms

Regulatory Considerations and OHDSI

Aligning with OHDSI practices positions industry to meet evolving regulatory expectations for RWE.



FDA's BEST Program

EMA's DARWIN Initiative

Transparent methodologies

Reproducible research practices

Large-scale validation studies

Adopt OHDSI standards for regulatory submissions

Leverage OHDSI network for multi-database studies

Collaborate on method development for regulatory use

OHDSI: A Hub for Talent Development and Continuous Learning in RWE

OHDSI offers a unique ecosystem for talent acquisition, professional development, and organizational learning in RWE.

Talent Pipeline and Recruitment

- OHDSI as a breeding ground for skilled RWE researchers
- Identifying emerging talent through community contributions
- Bridging academia and industry through collaborative projects

Organizational Commitment to RWE

- Investing in OHDSI participation as part of RWE strategy
- Encouraging staff engagement in OHDSI activities
- Aligning internal practices with OHDSI standards

Continuous Learning for Industry

- OHDSI working groups as learning platforms
- Exposure to cutting-edge methodologies and tools
- Cross-pollination of ideas between industry and academia

Leadership's Role

- Supporting cross-functional team participation in network studies
- Fostering a culture of open collaboration and continuous learning
- Multiple avenues to support independent projects

Industry Leadership: Strategic Benefits of OHDSI Collaboration

Close collaboration with OHDSI provides industry leaders with unparalleled insights, capabilities, and strategic advantages in the evolving RWE landscape.

Access to Methods	Enhanced Decision-Making	Regulatory Alignment
Talent Development	Cost-Effective Innovation	Strategic Foresight

OHDSI: A Marketplace for Trusted Data and Insights through Industry Collaboration

1 **Curated Data Network**

OHDSI facilitates connections between researchers and reliable data sources.

2 **Tool Development**

Industry insights drive creation of new OHDSI tools and methodologies.

3 **Need Identification**

Industry input prioritizes critical gaps and focus areas for RWE research.

4 **Knowledge Exchange**

OHDSI facilitates sharing of RWE challenges and solutions across sectors.

5 **Regulatory Advancement**

OHDSI fosters collaboration on regulatory-grade evidence and RWE standards.

OHDSI and Industry: Building Global, Diverse Data Pools for Accelerated Research

OHDSI and industry collaboration creates a powerful synergy, building diverse, trusted global data pools that accelerate research and guide strategic investments in healthcare.

Expanding Global Data Representation

1. Collaborative efforts to identify and integrate diverse data sources
2. Industry insights on regional data gaps and needs
3. OHDSI's standardization enabling seamless global data integration

Enhancing Data Trust and Quality

1. Joint development of data quality assessment tools
2. Industry expertise in regulatory-grade data requirements
3. OHDSI's open science approach ensuring transparency and reproducibility

Accelerating Research Pipeline

1. Streamlined access to global data accelerating study initiation
2. Diverse data pools enabling rapid hypothesis testing
3. Collaborative studies leveraging combined OHDSI-industry expertise

Identifying Strategic Investment Areas

1. Industry perspective on commercial viability of research areas
2. Co-development of advanced analytics tools for diverse data
3. Shared learnings advancing the entire RWE ecosystem

OHDSI and Industry: The Strategic Imperative of RWE

1. RWE's expanding role in commercial strategy
2. The need for specialized knowledge and leadership commitment
3. OHDSI's role in enabling credible, scalable RWE research
4. Call to action: Embracing RWE as a core strategic asset