亞洲臨床試驗區域聯盟論壇

REACTA 2024

From Ideation to Validation: Clinical Trials in the Digital Era

Supporting and Validating Clinical Trials through Global RWD/RWE Collaboration with OHDSI

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Executive Director, OHDSI Taiwan Society

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Supporting and Validating Clinical Trials through Global RWD/RWE Collaboration with OHDSI

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Outline

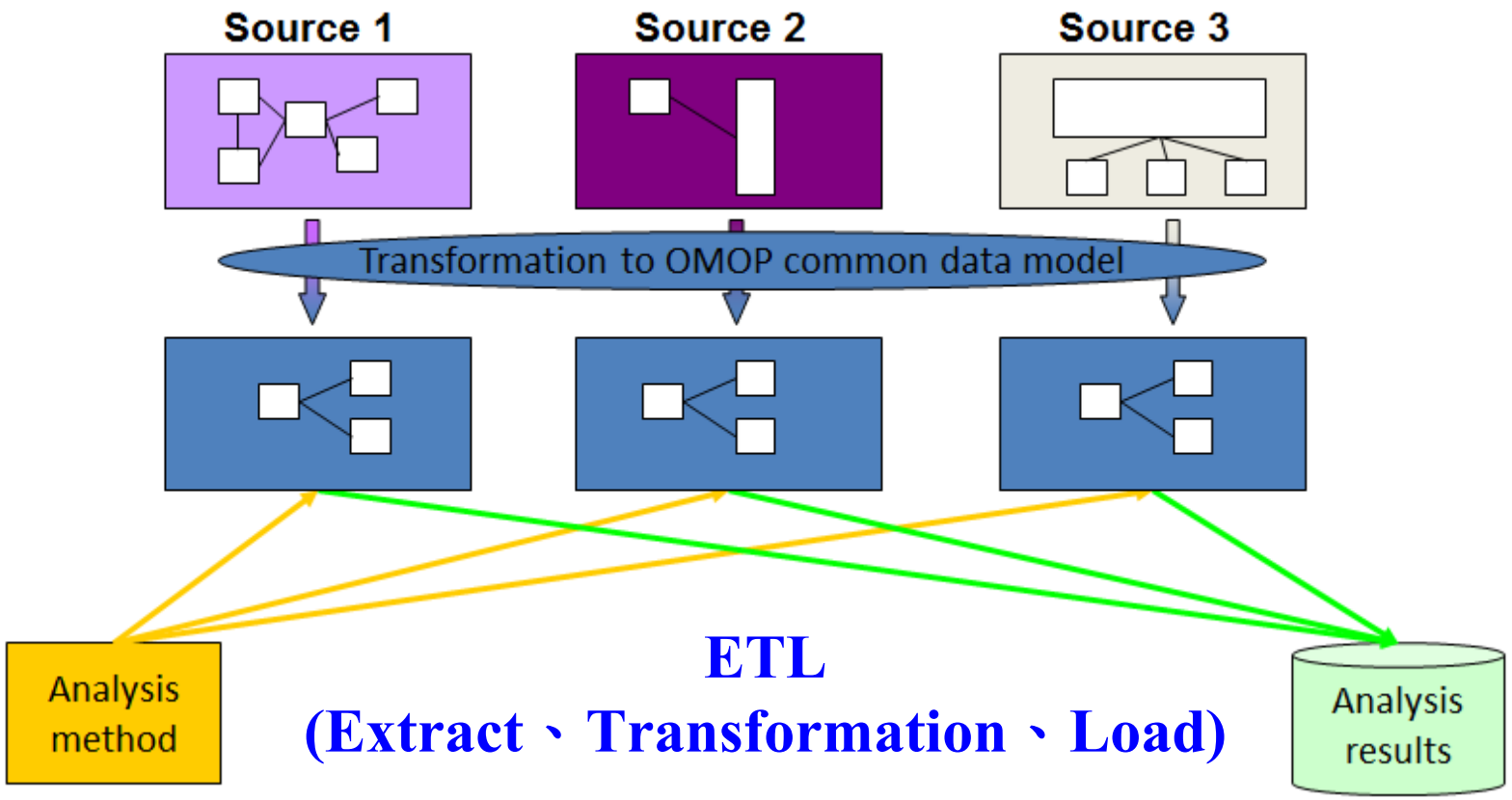
1. OHDSI's global network
2. Real World Data (RWD) and Real World Evidence (RWE)
3. How Does OHDSI Support Clinical Trials? (Successful Stories)
4. Future outlook

OHDSI's global network

The Observational Health Data Sciences and Informatics (OHDSI)

80 Countries / 440+ Institutes / 3266 collaborators / 800 million Cases

Data Standardization: OMOP Common Data Model

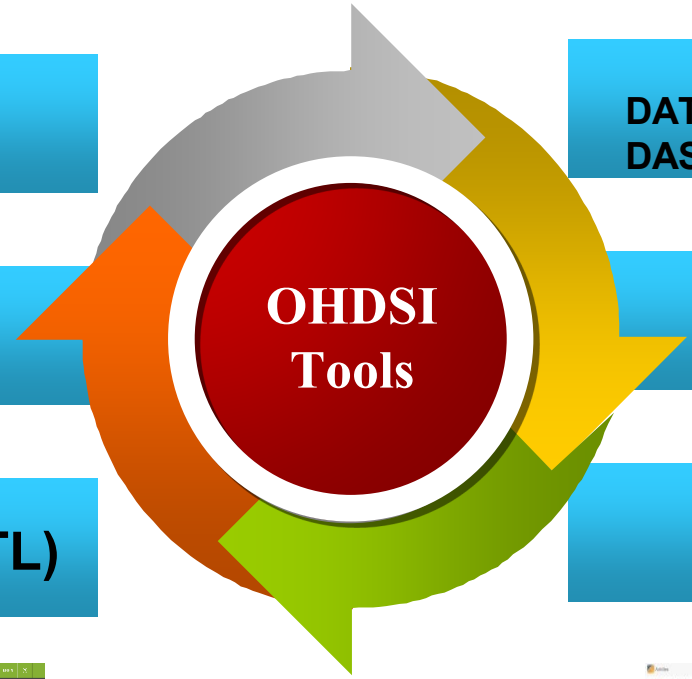


OHDSI Software and Tools

HADES

ATHENA

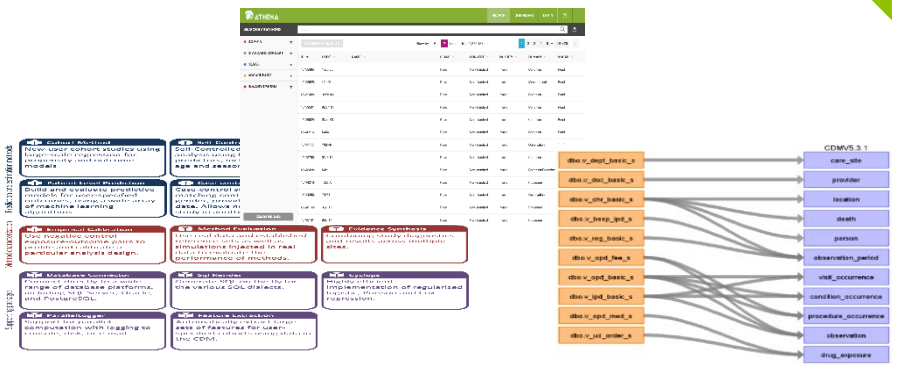
WHITERABBIT (ETL)

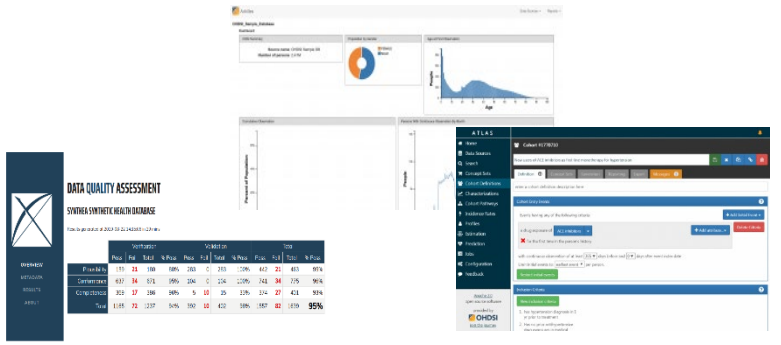


DATA QUALITY DASHBOARD

ACHILLES

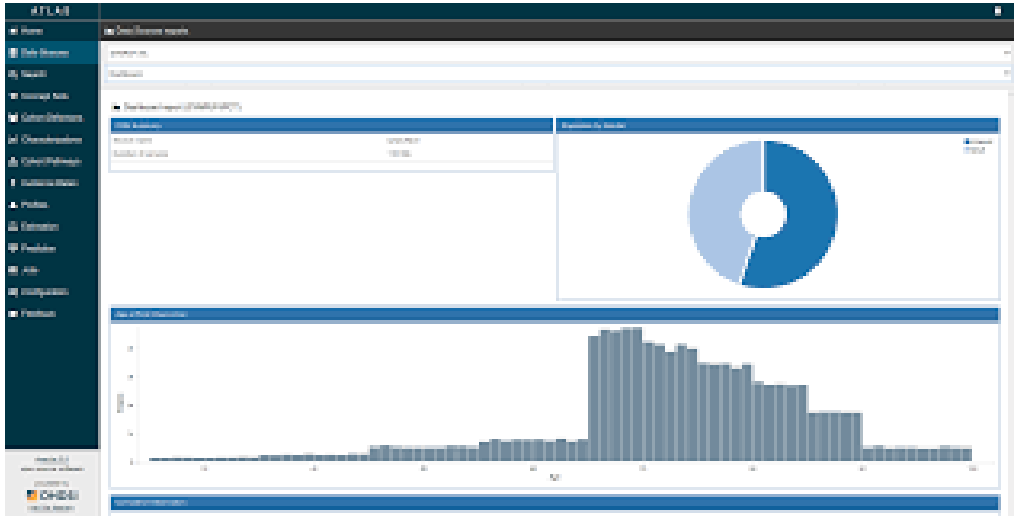
ATLAS



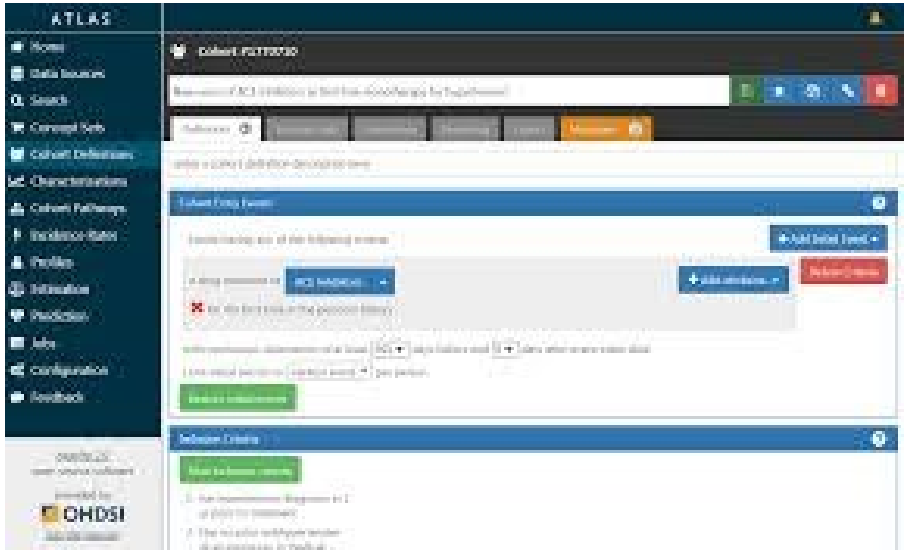


Application of OHDSI Tools

Achilles: data visualization

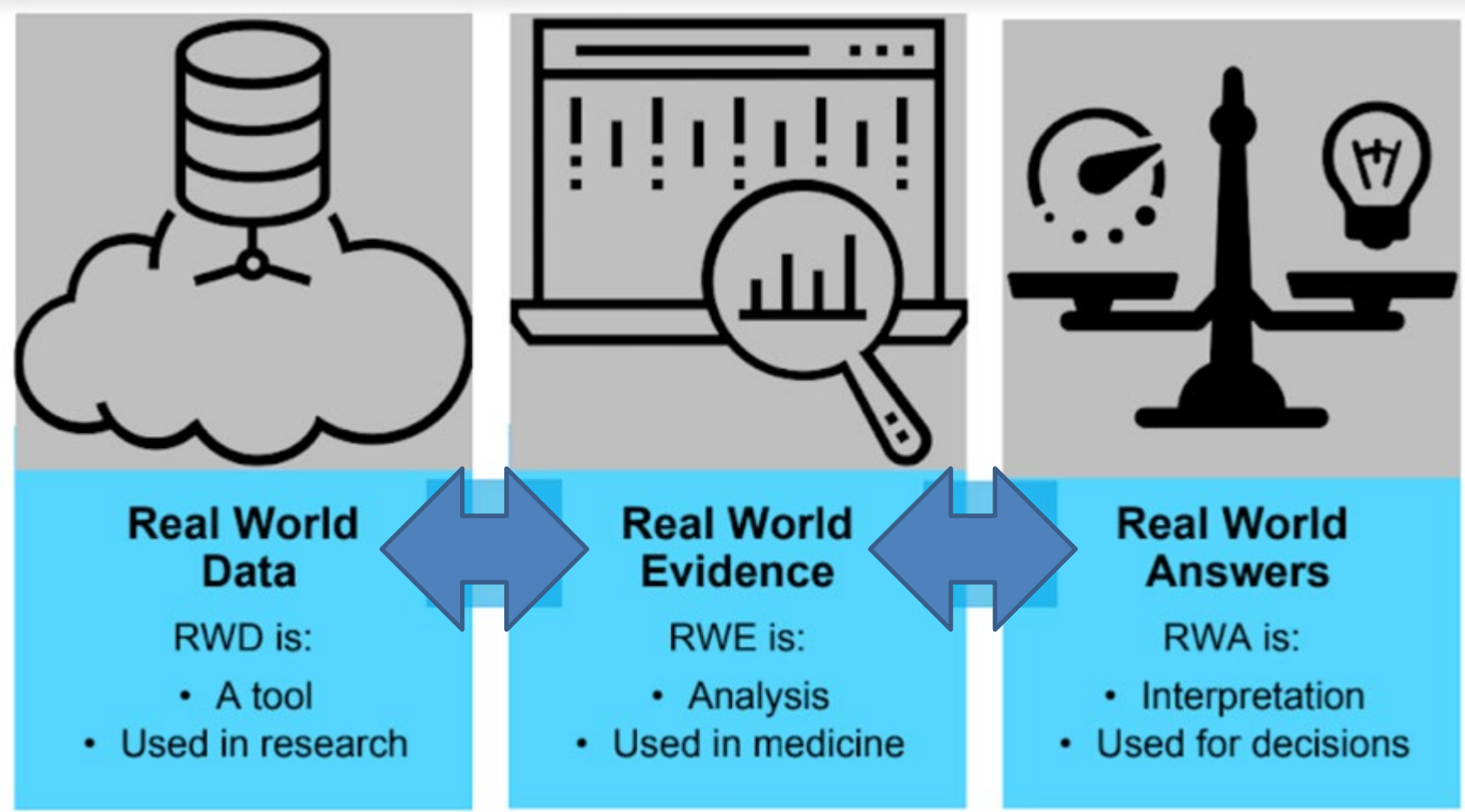


ATLAS: data screening, processing and analysis



RWD and RWE

Definition of RWD/RWE



RWE vs. RCT

Features	RCT	RWE
Purpose	Results under ideal circumstances (efficacy/safety)	Results in natural settings (efficacy/safety)
Application	Premarket Drug Regulatory Decisions (FDA)	Drug Post-Market Management Decisions (FDA/Clinical Practice)
Data source	[Standardization] Prospective collection	[Diversity] Retrospective (database), prospective collection
Condition	Under strictly controlled conditions (GCP)	under actual clinical conditions
Design	Large sample, multi-center randomized controlled trial	Observational studies, pragmatic randomized controlled trials
Population	Simple and strict inclusion and exclusion conditions for the population	Diverse groups of people, loose inclusion and exclusion conditions
Intervention	Fixed plan	Flexible plan (adjustable)
Control group	placebo	conventional treatment
Outcomes	Interim endpoints (ex. blood pressure, blood sugar)	Long-term endpoints (cardiovascular events, complications)
Advantages	High intrinsic authenticity and small selection bias	Large sample size, real conditions and environment, high extrapolability of results, and low cost
Shortages	Small sample size, homogeneous patients (excluding special populations), differences with the real environment, low extrapolation of results, and high cost	The experimental design is simple, the conditions are not strict, and the results are prone to deviation

How Does OHDSI Support Clinical Trials? (Successful Stories)

The role of RWD/RWE in drug clinical trials

Premarket clinical trials (Phase 1-3)

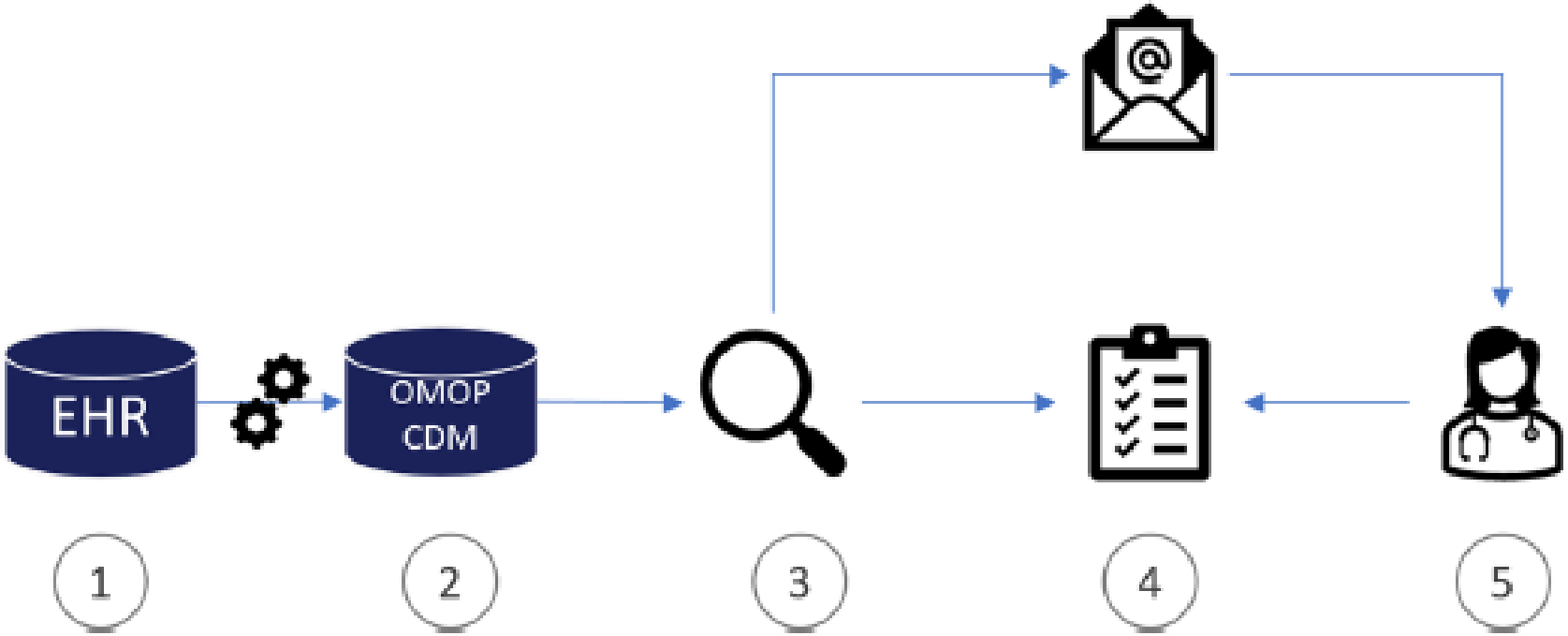
1. Screen candidates (number)
2. Recruitment

Large sample size, long-term

Postmarket clinical trials (Phase 4)

1. Treatment (Prescription) Pattern
2. Validation (Effectiveness / Safety)
3. Special populations not included in CT: children/pregnancy/elderly/liver/ kidney
4. Rare diseases
5. Drug repurposing
6. Personalized risk prediction

Clinical Trial Recruitment Support System (1)



Data source: Boeker et al. (2024) Trials

Clinical Trial Recruitment Support System (2)

Meystre et al.
BMC Medical Research Methodology (2023) 23:88
https://doi.org/10.1186/s12874-023-01916-6

BMC Medical Research Methodology

RESEARCH Open Access

Piloting an automated clinical trial eligibility surveillance and provider alert system based on artificial intelligence and standard data models

Stéphane M. Meystre[1*], Paul M. Heider[2], Andrew Cates[2], Grace Bastian[2], Tara Pittman[2], Stephanie Gentilin[2] and Teresa J. Kelechi[2]

Abstract

Background To advance new therapies into clinical care, clinical trials must recruit enough participants. Yet, many

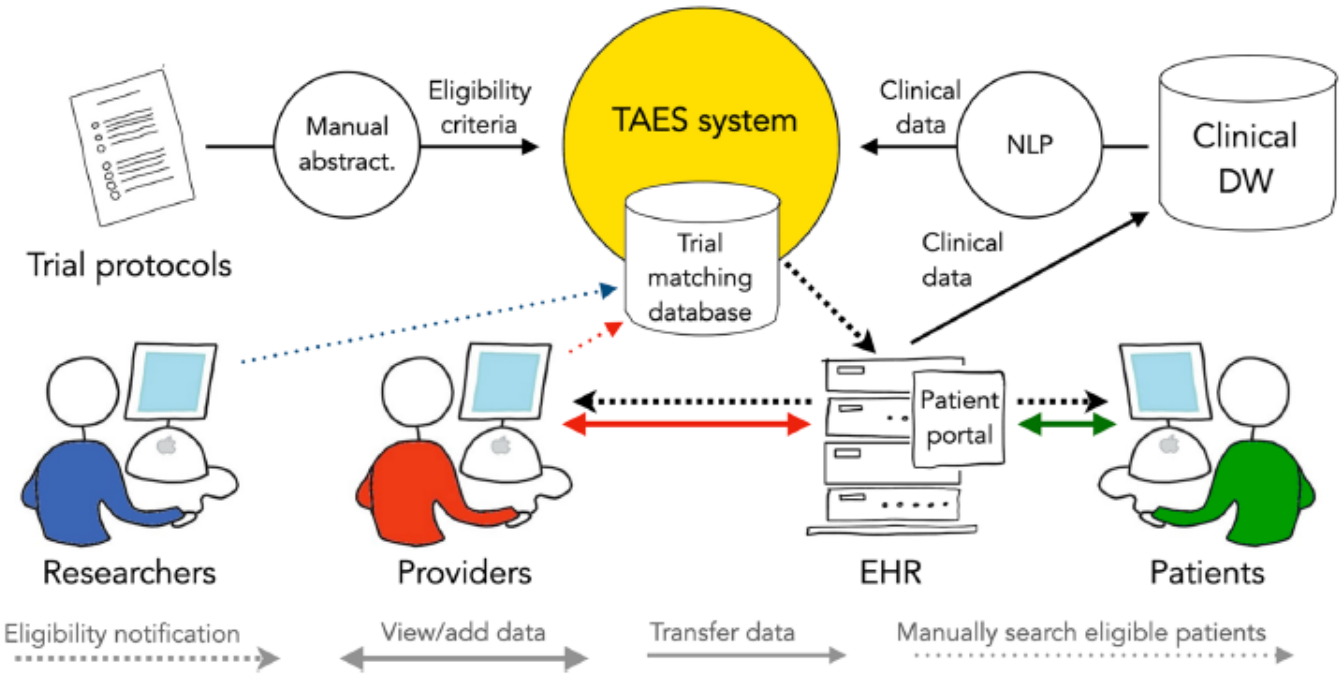
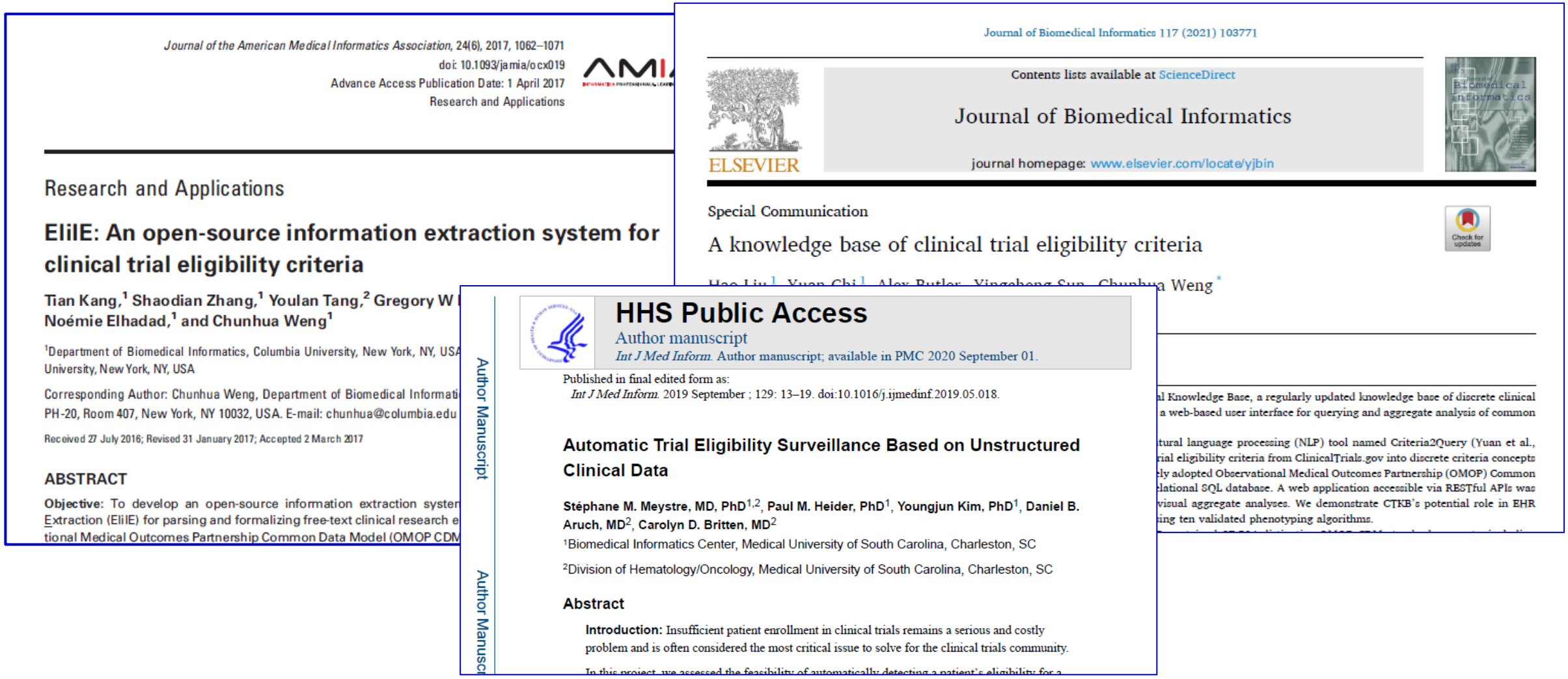


Fig. 1 Trial Eligibility Surveillance (TAES) system overview. DW = data warehouse; NLP = natural language processing

Data source: Meystre et al. (2023) BMC Medical Research Methodology

Standardized CT conditions are the future trend for global clinical trials



Journal of the American Medical Informatics Association, 24(6), 2017, 1062–1071
doi: 10.1093/jamia/ocx019
Advance Access Publication Date: 1 April 2017
Research and Applications

Research and Applications

EliIE: An open-source information extraction system for clinical trial eligibility criteria

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University, New York, NY, USA

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Received 27 July 2016; Revised 31 January 2017; Accepted 2 March 2017

ABSTRACT

Objective: To develop an open-source information extraction syster
Extraction (EliIE) for parsing and formalizing free-text clinical research e
tional Medical Outcomes Partnership Common Data Model (OMOP CDM

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journal homepage: www.elsevier.com/locate/yjbin

ELSEVIER

Special Communication

A knowledge base of clinical trial eligibility criteria

Weng *

l Knowledge Base, a regularly updated knowledge base of discrete clinical
a web-based user interface for querying and aggregate analysis of common

tural language processing (NLP) tool named Criteria2Query (Yuan et al.,
rial eligibility criteria from ClinicalTrials.gov into discrete criteria concepts
ly adopted Observational Medical Outcomes Partnership (OMOP) Common
elational SQL database. A web application accessible via RESTful APIs was
visual aggregate analyses. We demonstrate CTKB's potential role in EHR
ing ten validated phenotyping algorithms.

Author Manuscript

Author Manuscript

HHS Public Access
Author manuscript
Int J Med Inform. Author manuscript; available in PMC 2020 September 01.

Published in final edited form as:
Int J Med Inform. 2019 September ; 129: 13–19. doi:10.1016/j.ijmedinf.2019.05.018.

Automatic Trial Eligibility Surveillance Based on Unstructured Clinical Data

Stéphane M. Meystre, MD, PhD[1,2], **Paul M. Heider, PhD**[1], **Youngjun Kim, PhD**[1], **Daniel B. Aruch, MD**[2], **Carolyn D. Britten, MD**[2]

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[2]Division of Hematology/Oncology, Medical University of South Carolina, Charleston, SC

Abstract

Introduction: Insufficient patient enrollment in clinical trials remains a serious and costly problem and is often considered the most critical issue to solve for the clinical trials community.

In this project, we assessed the feasibility of automatically detecting a patient's eligibility for a

Clinical Trial Recruitment Support System

Computers in Biology and Medicine 174 (2024) 108411

Contents lists available at ScienceDirect

Computers in Biology and Medicine

journal homepage: www.elsevier.com/locate/compbiomed

recruIT: A cloud-native clinical trial recruitment support system based on Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) and the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM)

Christian Gulden [a,*], Philipp Macho [b], Ines Reinecke [c], Cosima Strantz [a], Hans-Ulrich Prokosch [a], Romina Blasini [d]

[a] Friedrich-Alexander-Universität Erlangen-Nürnberg, Department of Medical Informatics, Biometrics and Epidemiology, Medical Informatics, Erlangen, Germany
[b] Medical Informatics, Institute of Medical Biostatistics, Epidemiology and Informatics, University Medical Center of the Johannes Gutenberg-University Mainz, Mainz, Germany
[c] Carl Gustav Carus Faculty of Medicine, Center for Medical Informatics, Institute for Medical Informatics and Biometry, Technische Universität Dresden, Dresden, Germany
[d] Institute of Medical Informatics, Justus Liebig University, Giessen, Germany

ABSTRACT

Background: Clinical trials (CTs) are foundational to the advancement of evidence-based medicine and recruiting a sufficient number of participa

Implemented simultaneously in five hospitals in Germany, with a final satisfaction rate of 79.9%.

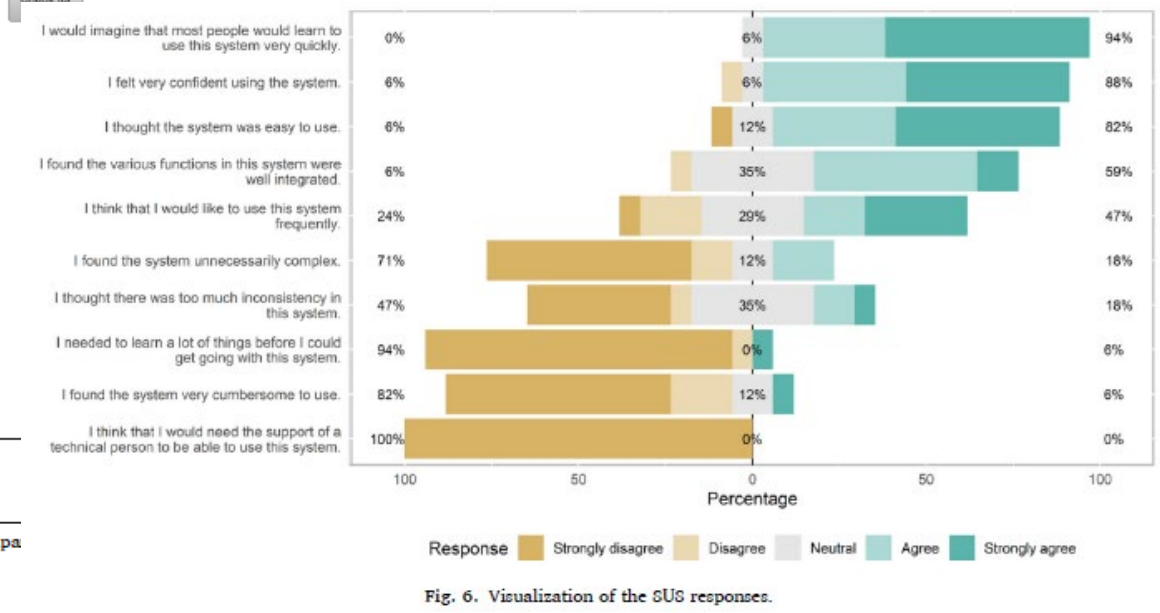


Fig. 6. Visualization of the SUS responses.

Data source: Meystre et al. (2023) BMC Medical Research Methodology

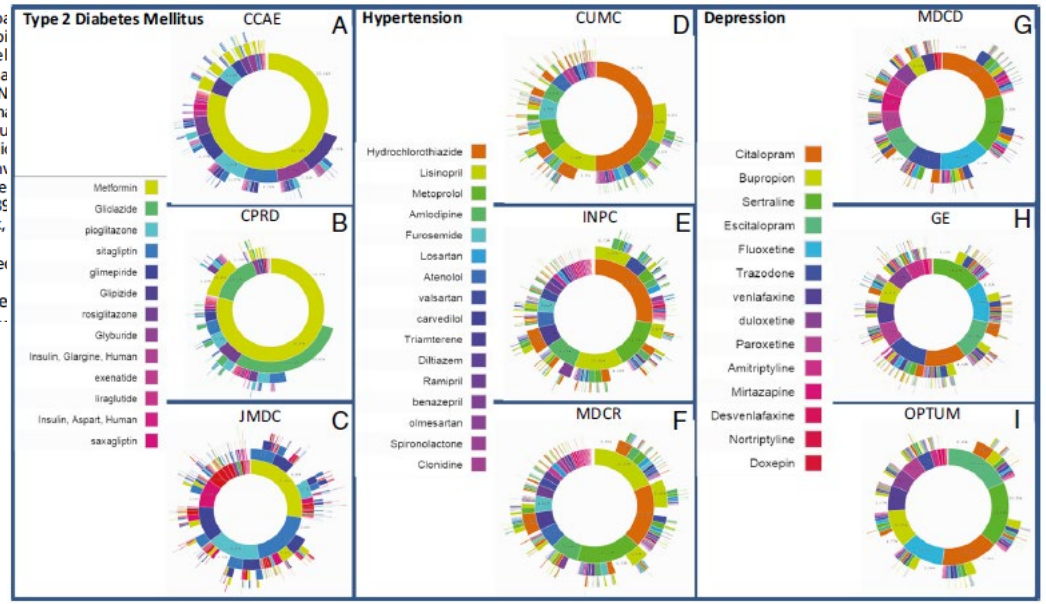
Treatment (Prescription) Pattern

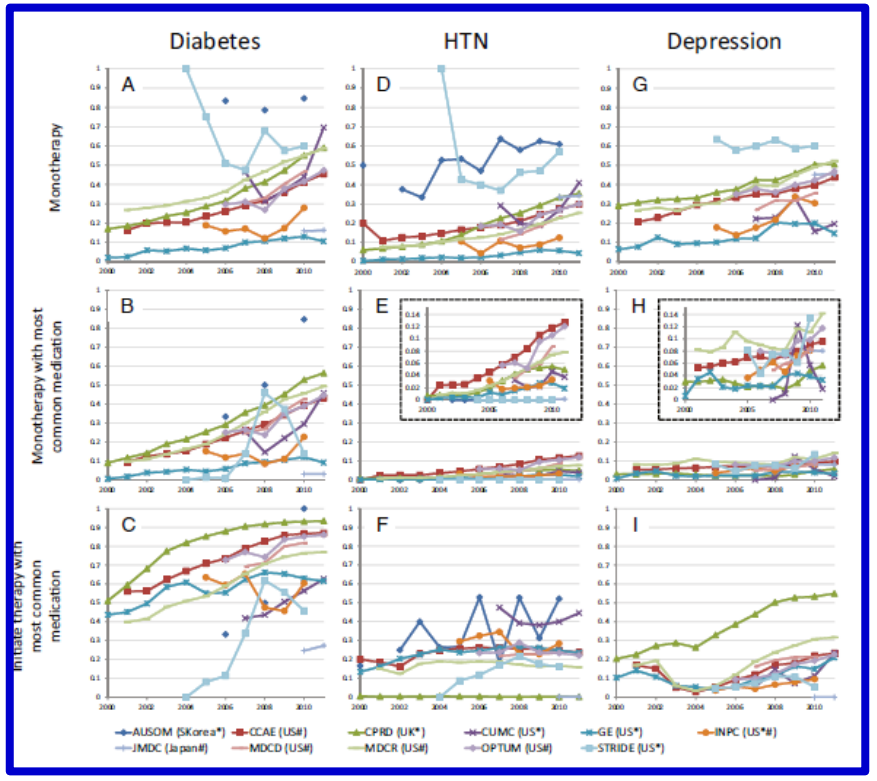
PNAS

COLLOQUIUM PAPER

Characterizing treatment pathways at scale using the OHDSI network

George Hripcsak[a,b,c,1], Patrick B. Ryan[c,d], Jon D. Duke[c,e], Nigam H. Shah[c,f], Rae Woong Park[c,g], Vojtech Huser[c,h], Marc A. Suchard[c,i,j,k], Martijn J. Schuemie[c,d], Frank J. DeFalco[c,d], Adler Perotte[a,c], Juan M. Banda[c,f], Christian G. Reich[c,l], Lisa M. Schilling[c,m], Michael E. Matheny[c,n,o], Daniella Meeker[c,p,q], Nicole Pratt[c,r], and David Madigan[c,s]





Data source: Hripcsak et al. (2016) PNAS

Treatment (Prescription) Pattern

JAMA Network Open

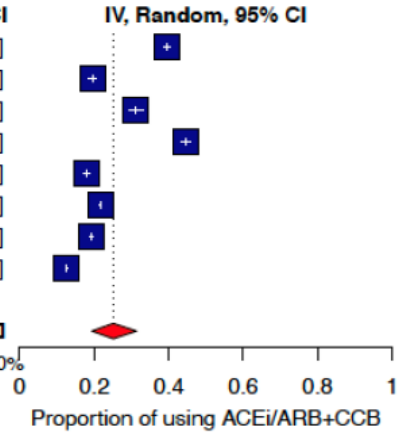
Original Investigation | Cardiology

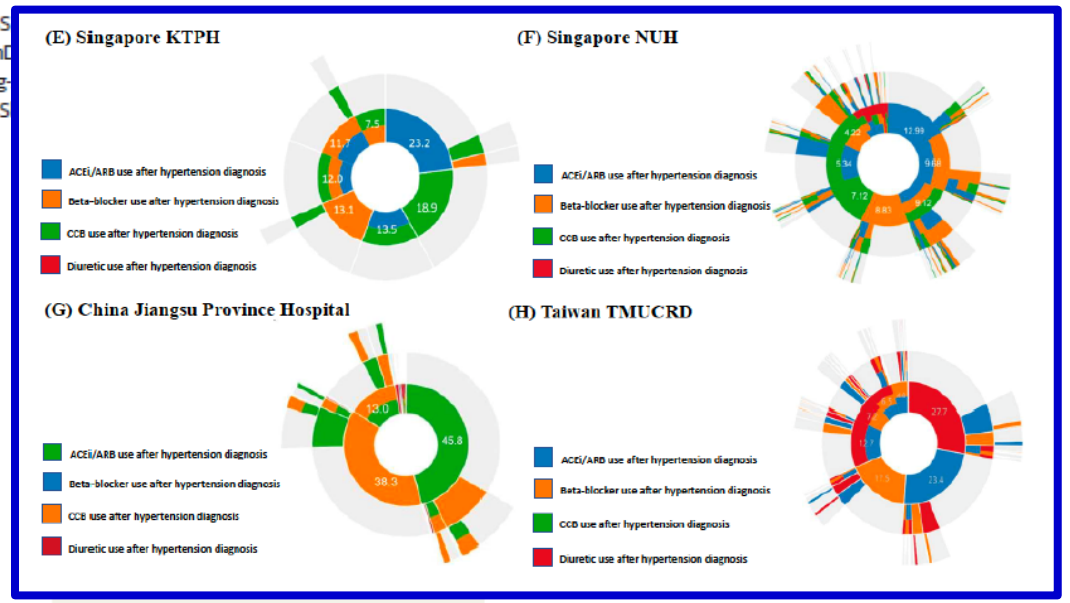
Analysis of Dual Combination Therapies Used in Treatment of Hypertension in a Multinational Cohort

(A) ACEi/ARB + CCB

Study	Events	Total	Weight	IV, Random, 95% CI
Australia	4540	11494	12.5%	0.395 [0.386; 0.404]
Korea	1363	6980	12.5%	0.195 [0.186; 0.205]
Singapore	655	2096	12.4%	0.312 [0.293; 0.333]
China	3127	7008	12.5%	0.446 [0.435; 0.458]
Taiwan	1545	8544	12.5%	0.181 [0.173; 0.189]
France	22523	103994	12.5%	0.217 [0.214; 0.219]
Italy	14628	76082	12.5%	0.192 [0.189; 0.195]
United States	95284	754137	12.5%	0.126 [0.126; 0.127]
Total (95% CI)		**970335**	**100.0%**	**0.251 [0.194; 0.314]**

Heterogeneity: $Tau^2 = 0.0100$; $Chi^2 = 14730.92$, df = 7 (P = 0); $I^2 = 100\%$





2000 and December 2019. Included participants were adult patients (ages ≥18 years) who newly

databases, 12 dual combinations of

Data source: Lu et al. (2022) JAMA Network Open

Postmarket clinical trials
(Phase 4)

Validation (Effectiveness)

Korean Circ J. 2022 Dec;52(12):853-864
https://doi.org/10.4070/kcj.2022.0294
pISSN 1738-5520-eISSN 1738-5555

kcj
Korean Circulation Journal

State of the Art Review

Check for updates

Establishment of an International Evidence Sharing Network Through Common Data Model for Cardiovascular Research

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[1]Department of Biomedical Systems Informatics, Yonsei University College of Medicine, Seoul, Korea
[2]Institute for Innovation in Digital Healthcare, Yonsei University, Seoul, Korea
[3]Department of Biomedical Informatics, Ajou University School of Medicine, Suwon, Korea
[4]Department of Biomedical Sciences, Ajou University Graduate School of Medicine, Suwon, Korea

OPEN ACCESS

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Correspondence to

AUTHOR'S SUMMARY

A distributed research network refers to a research network wherein multiple institutions unite for joint research based on common data model wherein the structure and meaning

REGULAR ARTICLE

blood advances

ASH Research Collaborative: a real-world data infrastructure to support real-world evidence development and learning healthcare systems in hematology

William A. Wood,[1] Peter Marks,[2] Robert M. Plovnick,[3] Kathleen Hewitt,[4] Donna S. Neuberg,[5] Sam Walters,[6] Brendan K. Dolan,[7] Emily A. Tucker,[4] Charles S. Abrams,[8] Alexis A. Thompson,[9] Kenneth C. Anderson,[10] Paul Kluetz,[2] Ann Farrell,[2] Donna Rivera,[2] Matthew Gertzog,[3] and Gregory Pappas[2]

[1]Division of Hematology, Department of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC; [2]U.S. Food and Drug Administration, Silver Spring, MD; [3]The American Society of Hematology, Washington, DC; [4]ASH Research Collaborative, Washington, DC; [5]Department of Data Science, Dana-Farber Cancer Institute, Boston, MA; [6]Breakthrough Healthcare, Baltimore, MD; [7]The University of Wisconsin School of Medicine and Public Health, Madison, WI; [8]Department of Medicine, University of Pennsylvania, Philadelphia, PA; [9]Department of Pediatrics, Northwestern University, Chicago, IL; and [10]Department of Medical Oncology, Dana Farber Cancer Institute, Boston, MA

Key Points

- The ASH Research Collaborative includes a patient-level data platform for SCD and MM, expanding to

The ASH Research Collaborative is a nonprofit organization established through the American Society of Hematology's commitment to patients with hematologic conditions and the science that informs clinical care and future therapies. The ASH Research Collaborative houses 2 major initiatives: (1) the Data Hub and (2) the Clinical Trials Network (CTN). The Data Hub is a program for hematologic diseases in which networks of clinical care delivery sites are developed in specific disease areas, with individual patient

Postmarket clinical trials
(Phase 4)

Validation (Safety)

Shin and Lee *BMC Med Inform Decis Mak* (2021) 21:159
https://doi.org/10.1186/s12911-021-01520-y

BMC Medical Informatics and Decision Making

RESEARCH ARTICLE Open Access

An OMOP-CDM based pharmacovigilance data-processing pipeline (PDP) providing active surveillance for ADR signal detection from real-world data sources

Hyunah Shin[1] and Suehyun Lee[1,2*]

Abstract

Background: Adverse drug reactions (ADRs) are regarded as a major cause of death and a major contributor to public health costs. For the active surveillance of drug safety, the use of real-world data and real-world evidence as part of the overall pharmacovigilance process is important. In this regard, many studies apply the data-driven approaches to support pharmacovigilance. We developed a pharmacovigilance data-processing pipeline (PDP) that utilized electronic health records (EHR) and spontaneous reporting system (SRS) data to explore pharmacovigilance signals.

Methods: To this end, we integrated two medical data sources: Konyang University Hospital (KYUH) EHR and the

Received: 31 March 2020 | Accepted: 20 April 2020
DOI: 10.1002/pds.5022

BRIEF REPORT

WILEY

Nintedanib and ischemic colitis: Signal assessment with the integrated use of two types of real-world evidence, spontaneous reports of suspected adverse drug reactions, and observational data from large health-care databases

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Email: rebecca.chandler@who-umc.org

Abstract

Purpose: Statistical screening of Vigibase, the global database of individual case safety reports, highlighted an association between the MedDRA Preferred Term (PT) "colitis" and nintedanib. Nintedanib is a protein kinase inhibitor authorized in accelerated regulatory procedures for the treatment of idiopathic pulmonary fibrosis (IPF). The aim of this report is to describe the integration of two types of real-world evidence, spontaneous reports of adverse drug reactions (ADR), and observational health data (OHD) in the assessment of a post-authorization safety signal of ischemic

Postmarket clinical trials (Phase 4)

Validation (Safety)

JAMA Network Open

Original Investigation | Pharmacy and Clinical Pharmacology

Ranitidine Use and Incident Cancer in a Multinational Cohort

Seng Chan You, MD; Seung In Seo, MD; Thomas Falconer, MSc; Chen Yanover, PhD; Talita Duarte-Salles, PhD; Sarah Seager, BA; Jose D. Posada, PhD; Nigam H. Shah, PhD; Phung-Anh Nguyen, PhD; Yeesuk Kim, MD; Jason C. Hsu, PhD; Mui Van Zandt, BS; Min-Huei Hsu, MD; Hang Lak Lee, MD; Heejoo Ko, MD; Woon Geon Shin, MD; Nicole Pratt, PhD; Rae Woong Park, MD; Christin G. Reich, MD; Marc A. Suchard, MD; George Hripcsak, MD; Chan Hyuk Park, MD; Daniel Prieto-Alhambra, MD

Abstract

IMPORTANCE Ranitidine, the most widely used histamine-2 receptor antagonist (H_2RA), was withdrawn because of N-nitrosodimethylamine impurity in 2020. Given the worldwide exposure to this drug, the potential risk of cancer development associated with the intake of known carcinogens is an important epidemiological concern.

OBJECTIVE To examine the comparative risk of cancer associated with the use of ranitidine vs other H_2RAs.

DESIGN, SETTING, AND PARTICIPANTS This new-user active comparator international network cohort study was conducted using 3 health claims and 9 electronic health record databases from the US, the United Kingdom, Germany, Spain, France, South Korea, and Taiwan. Large-scale propensity score (PS) matching was used to minimize confounding of the observed covariates with negative control outcomes. Empirical calibration was performed to account for unobserved confounding. All databases were mapped to a common data model. Database-specific estimates were combined

Key Points

Question Is use of ranitidine associated with higher risk for incident cancer compared with other histamine-2 (H_2) receptor antagonists (H_2RAs)?

Findings In this cohort study including 1 183 999 individuals from 11 large databases across Europe, North America, and Asia, risk of cancer among ranitidine users did not differ from users of other H_2RAs. Ranitidine use was not associated with an increased risk of esophageal, stomach, or colorectal cancer, or 13 other subtypes of cancer.

Meaning These findings suggest that a

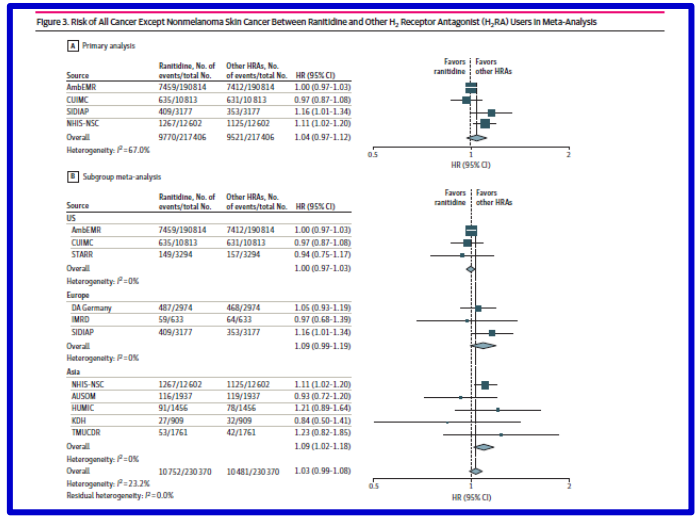
Figure 3. Risk of All Cancer Except Nonmelanoma Skin Cancer Between Ranitidine and Other H_2 Receptor Antagonist (H_2RA) Users in Meta-Analysis

A Primary analysis

Source	Ranitidine, No. of events/total No.	Other HRAs, No. of events/total No.	HR (95% CI)
AmbEMR	7459/190814	7412/190814	1.00 (0.97-1.03)
CUIMC	635/10813	631/10813	0.97 (0.87-1.08)
SIDIAP	409/3177	353/3177	1.16 (1.01-1.34)
NHIS-NSC	1267/12602	1125/12602	1.11 (1.02-1.20)
Overall	9770/217406	9521/217406	1.04 (0.97-1.12)

Heterogeneity: I^2 = 67.0%

B Subgroup meta-analysis

Source	Ranitidine, No. of events/total No.	Other HRAs, No. of events/total No.	HR (95% CI)
US			
AmbEMR	7459/190814	7412/190814	1.00 (0.97-1.03)
CUIMC	635/10813	631/10813	0.97 (0.87-1.08)
STARR	149/3294	157/3294	0.94 (0.75-1.17)
Overall			1.00 (0.97-1.03)
Heterogeneity: I^2 = 0%			
Europe			
DA Germany	487/2974	468/2974	1.05 (0.93-1.19)
IMRD	59/633	64/633	0.97 (0.68-1.39)
SIDIAP	409/3177	353/3177	1.16 (1.01-1.34)
Overall			1.09 (0.99-1.19)
Heterogeneity: I^2 = 0%			
Asia			
NHIS-NSC	1267/12602	1125/12602	1.11 (1.02-1.20)
AUSOM	116/1937	119/1937	0.93 (0.72-1.20)
HUMC	91/1456	78/1456	1.21 (0.89-1.64)
KDH	27/909	32/909	0.84 (0.50-1.41)
TMUCDR	53/1761	42/1761	1.23 (0.82-1.85)
Overall			1.09 (1.02-1.18)
Heterogeneity: I^2 = 0%			
Overall	10752/230370	10481/230370	1.03 (0.99-1.08)
Heterogeneity: I^2 = 23.2%			
Residual heterogeneity: I^2 = 0.0%			

Favors ranitidine | Favors other HRAs

0.5 1 2

HR (95% CI)

Data source: You et al. (2023) JAMA Network Open

Validation (Safety)

Articles

Renin–angiotensin system blockers and susceptibility to COVID-19: an international, open science, cohort analysis

Daniel R Morales, Mitchell M Conover, Seng Chan You, Nicole Pratt, Kristin Kostka, Talita Duarte-Salles, Sergio Fernández-Bertolín, Maria Aragón, Scott L DuVall, Kristine Lynch, Thomas Falconer, Kees van Bochove, Cynthia Sung, Michael E Matheny, Christophe G Lambert, Fredrik Nyberg, Thamir M Alshammari, Andrew E Williams, Rae Woong Park, James Weaver, Anthony G Sena, Martijn J Schuemie, Peter R Rijnbeek, Ross D Williams, Jennifer C E Lane, Albert Prats-Uribe, Lin Zhang, Carlos Areia, Harlan M Krumholz, Daniel Prieto-Alhambra, Patrick B Ryan, George Hripcsak, Marc A Suchard

Summary

Background Angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) have been postulated to affect susceptibility to COVID-19. Observational studies so far have lacked rigorous ascertainment adjustment and international generalisability. We aimed to determine whether use of ACEIs or ARBs is associated with an increased susceptibility to COVID-19 in patients with hypertension.

Methods In this international, open science, cohort analysis, we used electronic health records from Spain (Information Systems for Research in Primary Care [SIDIAP]) and the USA (Columbia University Irving Medical Center data warehouse [CUIMC] and Department of Veterans Affairs Observational Medical Outcomes Partnership [VA-OMOP]) to identify patients aged 18 years or older with at least one prescription for ACEIs and ARBs (target cohort) or calcium channel blockers (CCBs) and thiazide or thiazide-like diuretics (THZs; comparator cohort) between Nov 1, 2019, and Jan 31, 2020. Users were defined separately as receiving either monotherapy with these four drug classes, or monotherapy or combination therapy (combination use) with other antihypertensive medications. We assessed four outcomes:

Lancet Digit Health 2021; 3: e98–114

Published Online December 17, 2020 https://doi.org/10.1016/S2589-7500(20)30289-2

See Comment page e70

Division of Population Health and Genomics, University of Dundee, Dundee, UK (D R Morales MD); Observational Health Data Analytics, Janssen Research & Development, Titusville, NJ,

Data source: Morales et al. (2021) Lancet

Special populations not included in CT

ORIGINAL RESEARCH
published: 02 February 2022
doi: 10.3389/fneph.2021.821585

The Effect of Statins on Mortality of Patients With Chronic Kidney Disease Based on Data of the Observational Medical Outcomes Partnership Common Data Model (OMOP-CDM) and Korea National Health Insurance Claims Database

Ji Eun Kim[1,2†], Yun Jin Choi[3†], Se Won Oh[2,4], Myung Gyu Kim[2,4], Sang Kyung Jo[2,4], Won Yong Cho[2,4], Shin Young Ahn[1,2], Young Joo Kwon[1,2] and Gang-Jee Ko[1,2*]

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OPEN ACCESS

Edited by:
Michele Provenzano,
University of Catanzaro, Italy

Reviewed by:

Data source: Kim et al. (2022) Frontiers in Nephrology

Treatments for Rare Diseases

Received: 30 November 2023 | Revised: 3 March 2024 | Accepted: 4 March 2024
DOI: 10.1002/pds.5778

ORIGINAL ARTICLE

WIL

Increase transparency and reproducibility of real-world evidence in rare diseases through disease-specific Federated Data Networks

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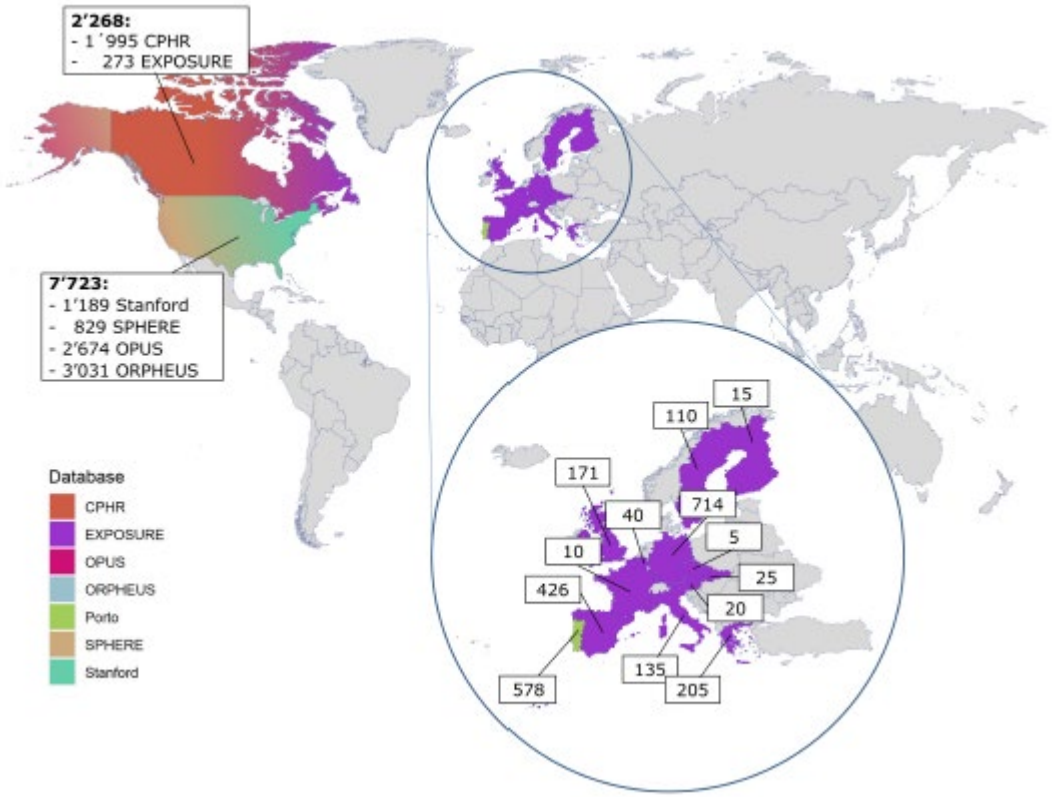
[2]Health Economics, Market Access and Reimbursement, EMEA Real-World Evidence and Value-based Health Care, Johnson & Johnson, Neuss, Germany

[3]Data Science, IT EMEA, Johnson & Johnson Technology, Beerse, Belgium

Correspondence
Valerie van Baalen, Global Epidemiology, Office of the Chief Medical Officer, Johnson & Johnson, Basel, Switzerland.

Abstract

Purpose: In rare diseases, real-world evidence (RWE) generation is often restri



Data source: Baalen et al. (2024) Pharmacoepidemiol Drug Saf.

Drug Repurposing

RESEARCH

OPEN ACCESS

Check for updates

Use of repurposed and adjuvant drugs in hospital patients with covid-19: multinational network cohort study

Albert Prats-Uribe,[1] Anthony G Sena,[2,3] Lana Yin Hui Lai,[4] Waheed-Ul-Rahman Ahmed,[5,6] Heba Alghoul,[7] Osaid Alser,[8] Thamir M Alshammari,[9] Carlos Areia,[10] William Carter,[11] Paula Casajust,[12] Dalia Dawoud,[13,14] Asieh Golozar,[15,16] Jitendra Jonnagaddala,[17] Paras P Mehta,[18] Mengchun Gong,[19] Daniel R Morales,[20,21] Fredrik Nyberg,[22] Jose D Posada,[23] Martina Recalde,[24,25] Elena Roel,[24,25] Karishma Shah,[5] Nigam H Shah,[23] Lisa M Schilling,[11] Vignesh Subbian,[26] David Vizcaya,[27] Lin Zhang,[28,29] Ying Zhang,[19] Hong Zhu,[30] Li Liu,[30] Jaehyeong Cho,[31] Kristine E Lynch,[32] Michael E Matheny,[33,34] Seng Chan You,[35] Peter R Rijnbeek,[3] George Hripcsak,[36] Jennifer CE Lane,[5] Edward Burn,[1,24] Christian Reich,[37] Marc A Suchard,[38] Talita Duarte-Salles,[24] Kristin Kostka,[37,39] Patrick B Ryan,[2,40] Daniel Prieto-Alhambra[1]

For numbered affiliations see end of the article.

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ryan@ohdsi.org
(ORCID 0000-0002-9727-2138)

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2021;373:n1038
http://dx.doi.org/10.1136/bmj.n1038

Accepted: 16 April 2021

ABSTRACT

OBJECTIVE

To investigate the use of repurposed and adjuvant drugs in patients admitted to hospital with covid-19 across three continents.

DESIGN

Multinational network cohort study.

SETTING

Hospital electronic health records from the United States, Spain, and China, and nationwide claims data from South Korea.

in Spain), azithromycin (from 15 (4.9%) in China to 1473 (57.9%) in Spain), combined lopinavir and ritonavir (from 156 (<2%) in the VA-OMOP US to 2,652 (34.9%) in South Korea and 1285 (50.5%) in Spain), and umifenovir (0% in the US, South Korea, and Spain and 238 (78.3%) in China). Use of adjunctive drugs varied greatly, with the five most used treatments being enoxaparin, fluoroquinolones, ceftriaxone, vitamin D, and corticosteroids. Hydroxychloroquine use increased rapidly from March to April 2020 but declined steeply in May to June and remained low for

Data source: Prats-Uribe et al. (2021) BMJ

Personalized risk prediction

Computer Methods and Programs in Biomedicine 211 (2021) 106394

Contents lists available at ScienceDirect

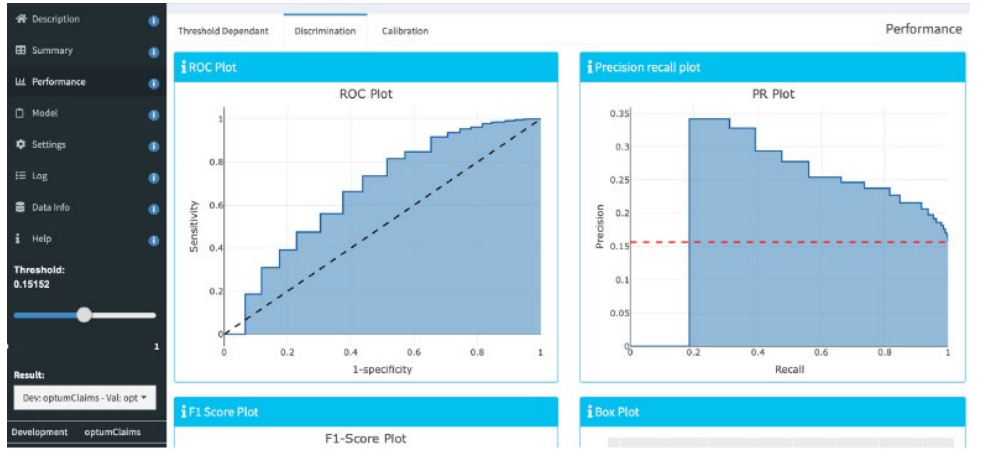
Computer Methods and Programs in Biomedicine

journal homepage: www.elsevier.com/locate/cmpb

A standardized analytics pipeline for reliable and rapid development and validation of prediction models using observational health data

USA (11)	EUROPE (8)	ASIA-PACIFIC (3)
Columbia University (NY – EHR)	CPRD (UK – EHR)	HIRA (South Korea – Administrative Claims)
Department of Veterans Affairs (National – EHR)	DA Germany (Germany – EHR)	DCMC (South Korea – EHR)
HealthVerity (Claims linked to diagnostic testing)	HM Hospitales (Spain – Hospital Billing)	Nanfang Hospital (China – EMR)
IQVIA Open Claims (National – Administrative Claims)	IPCI (Netherlands – EHR)	
Optum EHR (National – EHR)	LPD France (France – EHR)	
Optum SES (National – EHR linked to Socio-economic data)	LPD Italy (Italy – EHR)	
Premier (National – Hospital Billing)	SIDIAP (Spain – EHR)	
Stanford University (CA – EHR)	SIDIAP-H (Spain – EHR Hospital linkage)	
Tufts University (MA – EHR)		
University of Colorado Anschutz Medical Campus (CO – EHR)		
University of Washington Medicine COVID Research Dataset (WA – EHR)		

Together, OHDSI has studied:
- *>7.4m patients tested for SARS-CoV-2*
- *>1.6m patients diagnosed or tested positive for COVID-19*
- *>300k patients hospitalized with COVID-19*



Data source: Khalid et al. (2021) Computer Methods and Programs in Biomedicine

Personalized risk prediction

Received: 7 February 2024 | Accepted: 19 May 2024
DOI: 10.1111/add.16587

RESEARCH REPORT

ADDICTION SSA

Predictability of buprenorphine-naloxone treatment retention: A multi-site analysis combining electronic health records and machine learning

Fateme Nateghi Haredasht[1,2,3] | Sajjad Fouladvand[1,2,3] | Steven Tate[4] | Min Min Chan[5,6] | Joannas Jie Lin Yeow[5,6] | Kira Griffiths[5,6] | Ivan Lopez[1,2,3] | Jeremiah W. Bertz[7] | Adam S. Miner[4] | Tina Hernandez-Boussard[1,2,3] | Chwen-Yuen Angie Chen[8] | Huiqiong Deng[4] | Keith Humphreys[4] | Anna Lembke[4] | L. Alexander Vance[5,6] | Jonathan H. Chen[1,2,3]

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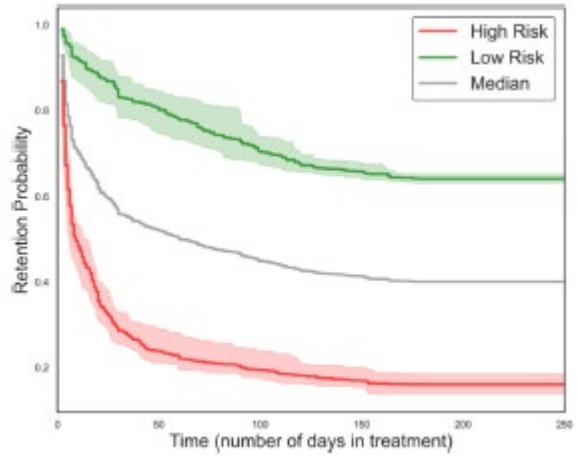
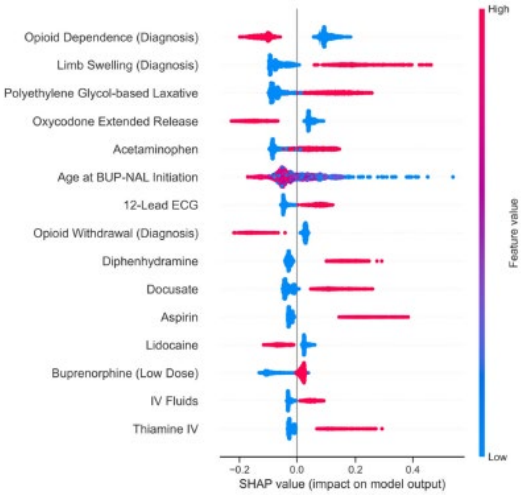
[3]Clinical Excellence Research Center, Stanford University, Stanford, California, USA
[4]Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine, Stanford, California, USA

Abstract

Background and aims: Opioid use disorder (OUD) and opioid dependence lead to significant morbidity and mortality, yet treatment retention, crucial for the effectiveness of medications like buprenorphine-naloxone, remains unpredictable. Our objective was to determine the predictability of 6-month retention in buprenorphine-naloxone treatment using electronic health record (EHR) data from diverse clinical settings and to identify key predictors.

Design: This retrospective observational study developed and validated machine





Data source: Haredasht et al. (2024) Addiction

Future outlook

The Automatic Clinical Trial Recruitment Support System is the future trend for global clinical trials

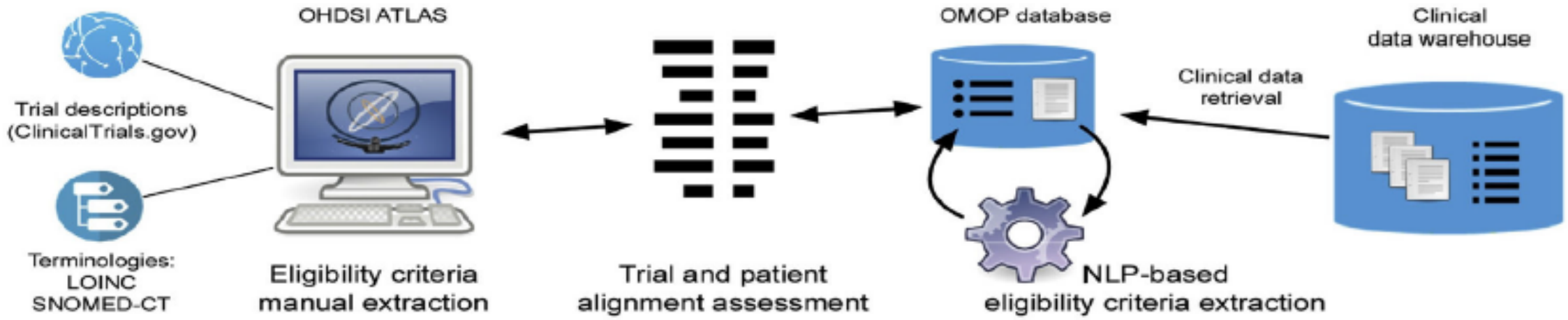


Figure 2:
Clinical trial eligibility automatic surveillance process

Data source: Meystre et al. (2019) Int J Med Inform

Data Quality Check of Databases with the Same CDM

Journal of the American Medical Informatics Association, 28(10), 2021, 2251–2257
doi: 10.1093/jamia/ocab132
Advance Access Publication Date: 27 July 2021
Research and Applications

Research and Applications

Increasing trust in real-world evidence through evaluation of observational data quality

Clair Blacketer [1,2] Frank J. Defalco,[1] Patrick B. Ryan,[1,3] and Peter R. Rijnbeek[2]

[1]Observational Health Data Analytics, Janssen Research and Development, LLC, Titusville, New Jersey, USA, [2]Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, The Netherlands, and [3]Department of Biomedical Informatics, Columbia University, New York, New York, USA

Corresponding Author: Clair Blacketer, MPH, Observational Health Data Analytics, Janssen Research and Development, LLC, 1125 Trenton-Harbourton Road, Titusville, NJ 08560, USA (mblacke@its.jnj.com)

Received 25 March 2021; Revised 25 May 2021; Editorial Decision 13 June 2021; Accepted 15 June 2021

ABSTRACT

Objective: Advances in standardization of observational healthcare data have enabled methodological breakthroughs, rapid global collaboration, and generation of real-world evidence to improve patient outcomes

IBM® MARKETSCAN® MULTI-STATE MEDICAID DATABASE
OVERVIEW
METADATA
RESULTS
ABOUT

DATA QUALITY ASSESSMENT

IBM® MARKETSCAN® MULTI-STATE MEDICAID DATABASE

DataQualityDashboard Version: 1.0.0
Results generated at 2020-08-24 15:44:34 in 3 hours

	Verification				Validation				Total			
	Pass	Fail	Total	% Pass	Pass	Fail	Total	% Pass	Pass	Fail	Total	% Pass
Plausibility	1849	6	1855	100%	281	6	287	98%	2130	12	2142	99%
Conformance	550	13	563	98%	80	0	80	100%	630	13	643	98%
Completeness	322	5	327	98%	12	0	12	100%	334	5	339	99%
Total	2721	24	2745	99%	373	6	379	98%	3094	30	3124	**99%**

Data source: Blacketer et al. (2021) Journal of the American Medical Informatics Association

OHDSI OMOP CDM can help for RWE

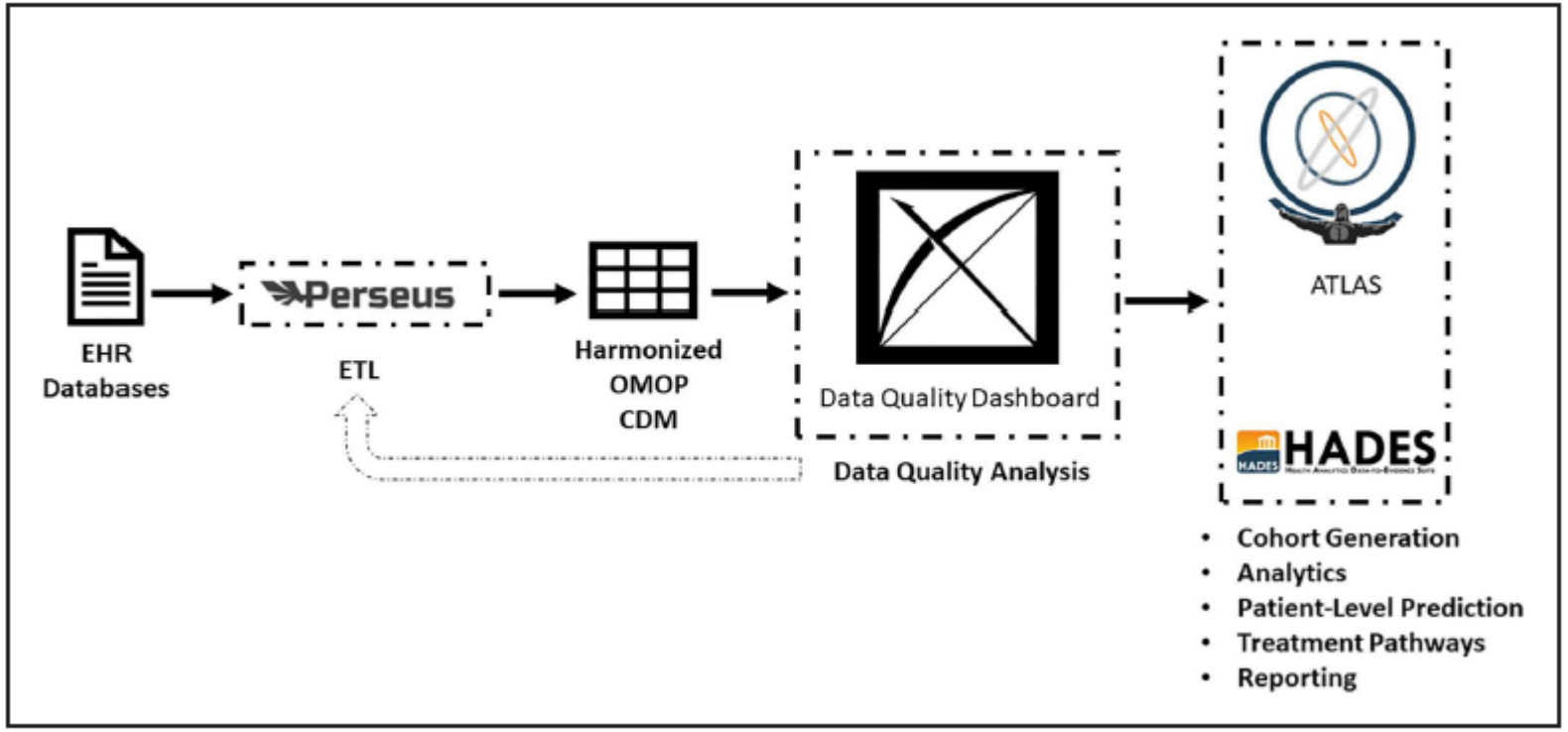
COMMENTARY

OPEN

A Path to Real-World Evidence in Critical Care Using Open-Source Data Harmonization Tools

ABSTRACT: COVID-19 highlighted the need for use of real-world d
in critical care as a near real-time resource for clinical, research, and p
Analysis of RWD is gaining momentum and can generate important e
policy makers and regulators. Extracting high quality RWD from elect
records (EHRs) requires sophisticated infrastructure and dedicated
We sought to customize freely available public tools, supporting all pha
harmonization, from data quality assessments to de-identification proc
generation of robust, data science ready RWD from EHRs. These dat
available to clinicians and researchers through CURE ID, a free plat
facilitates access to case reports of challenging clinical cases and
treatments hosted by the National Center for Advancing Translationa
National Institutes of Health in partnership with the Food and Drug Adr
This commentary describes the partnership, rationale, process, use c
in critical care, and future directions for this collaborative effort.

KEY WORDS: critical care; data harmonization; drug repurposing
health record; real-world data; Observational Medical Outcomes
(OMOP)



Data source: Heavner et al. (2023) Critical Care Explorations

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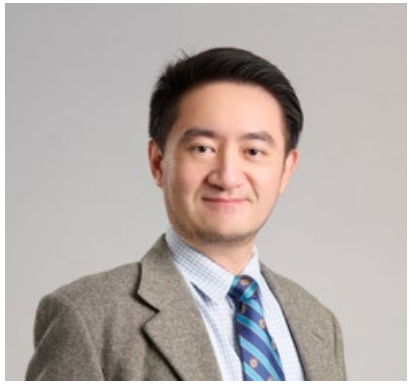
THANKS



Jason C. Hsu Ph.D.
E-mail: jasonhsu@tmu.edu.tw

亞洲臨床試驗區域聯盟論壇

REACTA 2024

From Ideation to Validation: Clinical Trials in the Digital Era