



OHDSI Tuesday 20-May-2025

Metastatic Bladder Cancer Guideline Study





# Integration of RWE into clinical guidelines

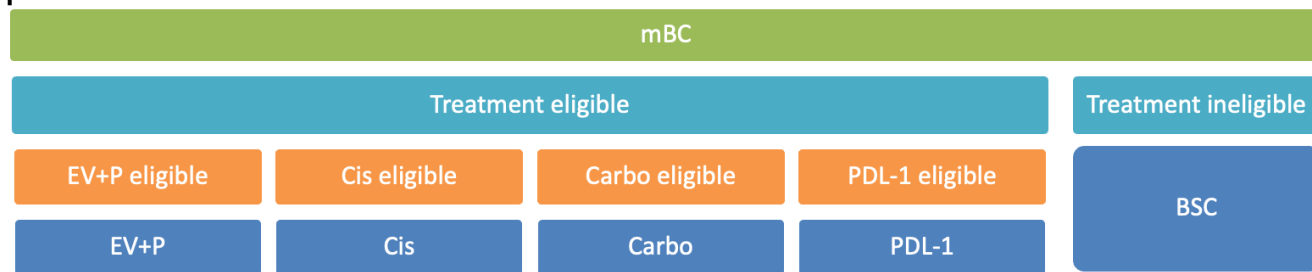
Our approach:

1. decompose guideline recommendations into structured decision nodes
  2. evaluate the feasibility and validity of addressing questions in the research networks
  3. perform targeted studies to inform recommendations where high-quality RWE can fill significant evidence gaps
-

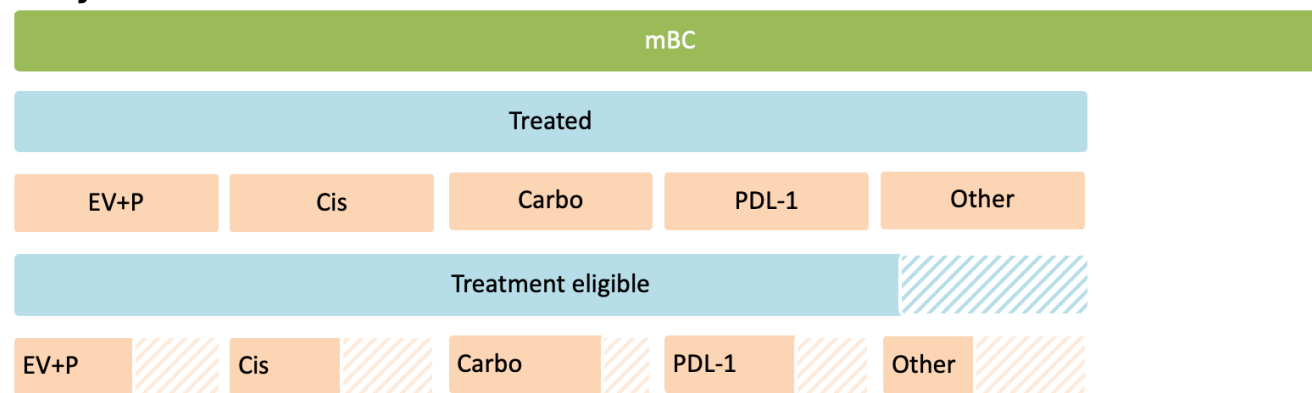


# Key Objective: Assessing Relevance, Adherence, and Generalizability

## Expectation



## Reality

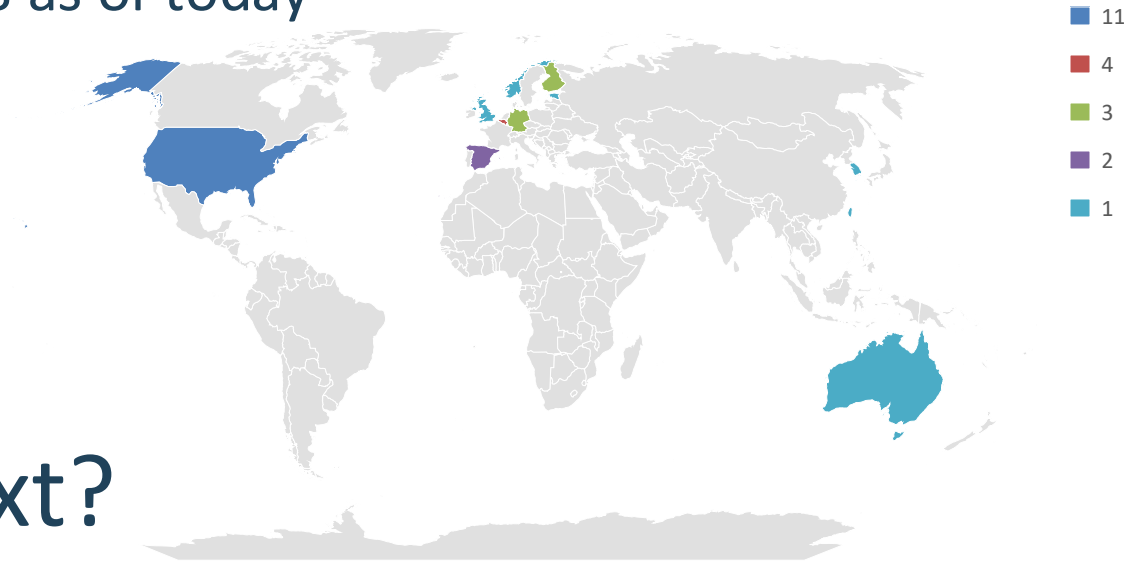


1. Are there patients eligible for each treatment group?
2. Are treatment eligible treated?
3. Are treatment eligible getting the recommended treatment?
  - By eligibility group, look at the treatment pattern to assess adherence.
4. Were treated eligible for treatment?
  - For each pair of treated and eligible & treated cohorts, assess
    - Cohort overlap
    - Cohort comparison
5. Outcomes for each treatment group irrespective of eligibility



# Where are we?

- Dissected decision nodes from the mBC guideline (available in [Teams](#))
- Reached out to data partners and recruited 28 as of today



## What's next?

- Data partners engagement:
  - 24 performed oncology data readiness assessment, 4 in progress
  - Additional quality assessment under way
- Study protocol will be distributed for comments on May 21

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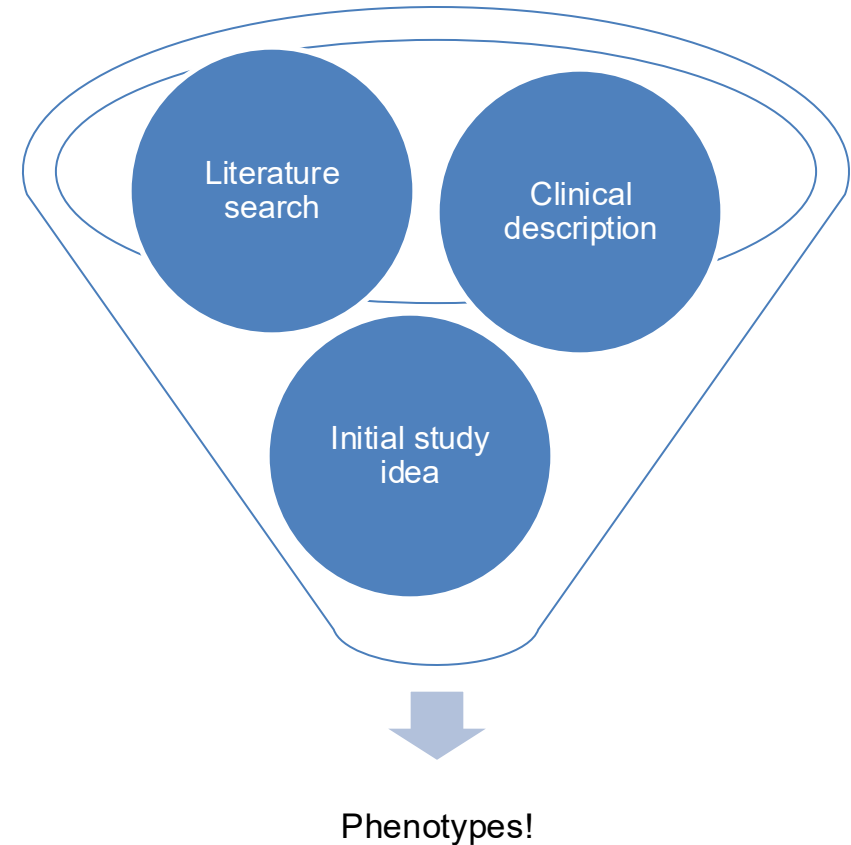
# FEP2 study progress

Tatsiana Skuhareuskaya



## Where we started

- In patients with **first-episode psychosis**, does exposure to **<antipsychotic 1>** have a different risk of **<rehospitalization>** within **<the following 6 months>** relative to **<antipsychotic 2>**?
- **Target:** antipsychotic 1
- **Comparator:** antipsychotic 2
- **Indication:** first-episode psychosis
- **Outcome:** rehospitalization
- **Time at Risk:** 6 months





# We faced challenges but were victorious😊

Cohort Entry Events

Events having any of the following criteria:

a drug exposure of [GDE2025] SCH Risperidone

+ Add attribute...

Delete Criteria

with continuous observation of at least 365 days before and 0 days after event index date

Limit initial events to: earliest event per person.

Restrict initial events

Inclusion Criteria

New inclusion criteria

1. Age 18-40  
*Patients 18-40 years old*

2. Exclude noncompliance to treatment  
*Exclude patients with recorded noncompliance with treatment during the time period for entry ...*

3. Exclude APs prior  
*Exclude antipsychotic exposure prior to entry event*

4. Exclude SCs non-excludable otherwise  
*Exclude ICD10CM codes for dementia mapped to psychotic disorder*

5. 1 IP or 2 OP visits  
*1 IP or 2 OP visits with psychosis within 30 days, 30 days prior to drug exposure*

6. Exclude prior psychoses  
*No psychoses prior to the inclusion visit*

7. No other APs on the first day  
*Exclude patients taking other APs on day 1*

8. No other APs covering day 0  
*Excluding multiple drugs with long exposures*

9. No organic psychotic conditions during the diagnosis period  
*Additional exclusion of organic and drug-induced psychoses*

1 IP or 2 OP visits

Copy Delete

1 IP or 2 OP visits with psychosis within 30 days, 30 days prior to drug exposure

having any of the following criteria:

+ Add criteria to group...

with at least 1 using all occurrences of:

a visit occurrence of [GDE2025] SCH Inpatient Visit ...

+ Add attribute...

having all of the following criteria:

+ Add criteria to group...

with at least 1 using all occurrences of:

a condition occurrence of [GDE2025] SCH First-episode ps...

+ Add attribute...

where event starts between 0 days Before and All days After index start date

and event starts between All days Before and 0 days After index end date

The index date refers to the visit of [GDE2025] SCH Inpatient Visit & ER.

☐ restrict to the same visit occurrence

☐ allow events from outside observation period

where event starts between 30 days Before and 0 days Before index start date

The index date refers to the event from the Cohort Entry criteria.

☐ restrict to the same visit occurrence

☐ allow events from outside observation period

or with at least 2 using all occurrences of:

a condition occurrence of [GDE2025] SCH First-episode ps...

+ Add attribute...

where event starts between 30 days Before and 0 days Before index start date

The index date refers to the event from the Cohort Entry criteria.

☐ restrict to the same visit occurrence

☐ allow events from outside observation period

Delete Criteria

Delete Criteria

Delete Criteria

ing events to: earliest event per person.

Link to the latest CohortDiagnostics results



# DataDiagnostics

- We have found the potential Data Partners and are already in contact with some of them







# Repository, protocol and script

- The study repo has been created
- The first version of the protocol is published
- Study specifications script is in testing

The screenshot shows the GitHub interface for the repository 'ohdsi-studies / FepPharmacotherapy'. The repository is public and was generated from the template 'ohdsi-studies/StrategusStudyRepoTemplate'. The navigation bar includes links for Code, Issues, Pull requests (1), Actions, Projects, Wiki, Security, Insights, and Settings. The browser address bar shows the URL 'ohdsi-studies.github.io/FepPharmacotherapy/'.




1 List of Abbreviations
2 Responsible Parties
3 Abstract
4 Amendments and Updates
5 Milestones
6 Rationale and Background

## RESEARCH PROTOCOL

First-episode psychosis pharmacotherapy: an antipsychotics comparative effectiveness study

Version: 1.0.0



## Next steps

- Finishing touches to the protocol and scripts
- Reach out to the data partners with the final version of the protocol and specifications
- Run the study
- Gather and assess the results

*Huge thanks to the Phenotyping and Psychiatry WGs and Clair Blacketer for your work, support and ideas!*

*If you are interested to contribute, please reach out to me via OHDSI Teams (**Tatsiana Skuhareuskaya**) or email **[tatsiana\\_Skuhareuskaya@epam.com](mailto:tatsiana_Skuhareuskaya@epam.com)***

# OHDSI Network Study 2025: Rheumatic Disease Treatment and Infection Risk

Coordinating Site: Johns Hopkins University

PI: Chris Mecoli

Ben Martin, Will Kelly, Christelle Xiong, Erik Westlund

# Recap Background for Study

- Infection is a major cause of morbidity and mortality in rheumatic disease
- Little known about 'less common' rheumatic diseases and infection risk with various immunosuppression medications (most in RA)
- Almost nothing known about combination therapy (real life)
- Reflected in absence of evidence-based guidelines
  - “need for additional studies”

# (1) What's been done

- Created target phenotypes/cohorts informed by literature
  - Lupus, dermatomyositis, scleroderma, uveitis (prevalent)
  - Drug exposures (bunch of different immune suppressing drugs)
  - Infectious outcomes (shingles [VZV], pneumocystis [PCP], progressive multifocal leukoencephalopathy [PML])
- Iterated phenotypes via Cohort Diagnostics run by OHDSI (Thanks Anna et al!)
  - Modified also based on expert input (rheum, infectious diseases)
- Feasibility check across OHDSI Evidence Network (Thanks Clair!)
  - >30 potential data partners can probably run at least some of our analyses

## (2) What we are working on

- Study design / protocol
  - Probably bit off more than we can chew → focus more on infection than cancer
  - Soliciting feedback from pharmacoepidemiologists in the rheum/ID world
  - Trying to take into account EHR and claims data strengths/weaknesses
    - E.g. vaccination status
- Working on creation of Strategus test package
- Working on contacting/confirming data partners

### (3) What we could use help with

- Reviewing our study design/protocol
  - Epidemiologic rigor? Additional sensitivity analyses?
  - Feasible analytical plan?
  - Red flags?
- Reviewing our Strategus test package code
- Confirming data partners that may be interested
  - [cmecoli1@jhmi.edu](mailto:cmecoli1@jhmi.edu) email me!

# Timeline

- Plan to have finalized protocol/Strategus test package by mid/end of summer (or sooner!)



# GDE2025: Diabetic Retinopathy Screening Network Study

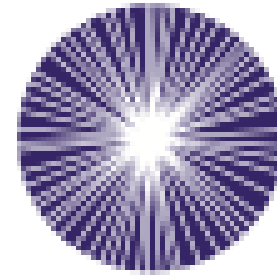
Cindy X. Cai, MD

The Jonathan and Marcia Javitt Rising  
Professor

Assistant Professor of Ophthalmology, Retina  
Division, The Wilmer Eye Institute

Assistant Professor of Medicine, Biomedical  
Informatics and Data Science, Division of  
General Internal Medicine, Department of  
Medicine

Johns Hopkins University School of Medicine



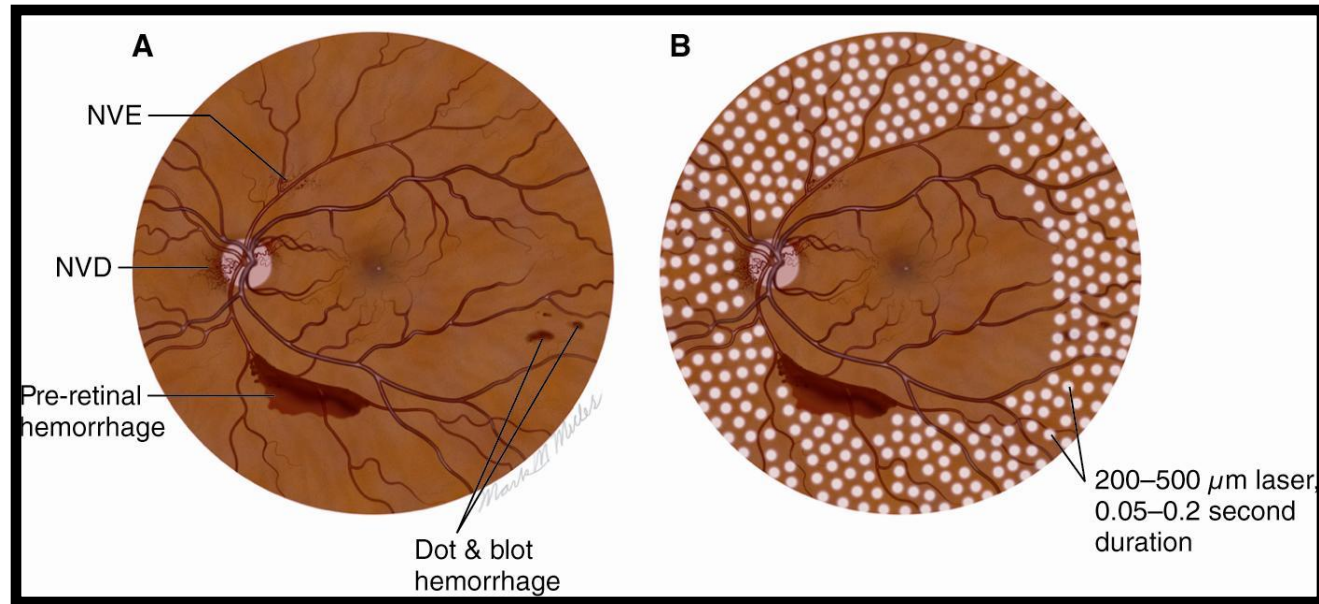
AMERICAN ACADEMY  
OF OPHTHALMOLOGY®

Guideline recommend eye exam at time of  
T2DM diagnosis & at least annual eye exams

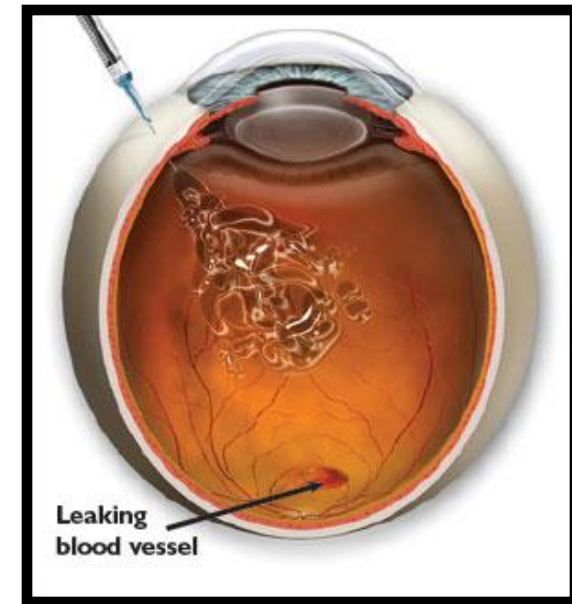
# <50% of patients with T2DM receive DR screening

## Diabetic retinopathy leading cause of vision loss

Timely treatment reduces risk of blindness by 90%



**Laser**



**Intravitreal  
injection**

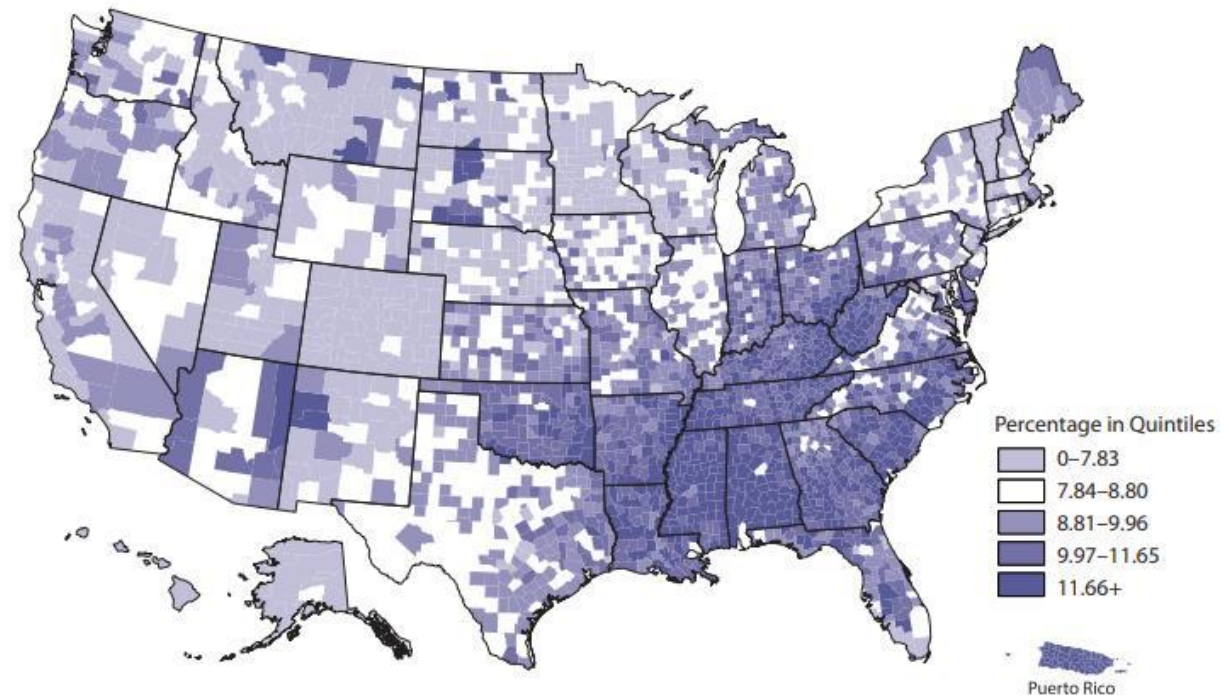


# There are not enough ophthalmologists

Density of Ophthalmologists



Prevalence of Diabetes

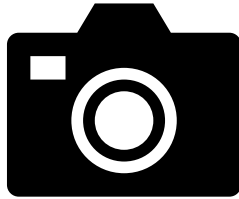


# Methods for diabetic retinopathy screening

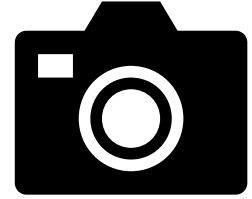
## In-Office



## Telemedicine



## Autonomous AI



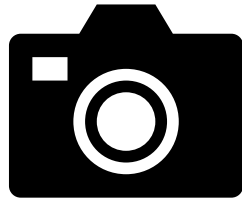
How is autonomous AI DR screening being used  
& are we doing a better job with DR screening?

# Purpose: characterize current landscape of diabetic retinopathy screening

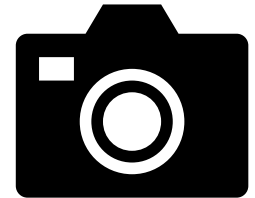
## In-Office



## Telemedicine



## Autonomous AI



### Newly diagnosed patients with type 2 diabetes mellitus (T2DM)

- Choice of initial DR screening method
- Sequence of DR screening in the years after diagnosis
- Compare baseline patient characteristics
- Compare time to initial diabetic retinopathy screening

# Where Are We in Network Study Execution?



- 9  Results Interpretation
- 8  Evidence Synthesis
- 7  Study Diagnostics
- 6  Network Execution
- 5  Analysis Specifications
- 4  Phenotype Evaluation
- 3  Phenotype Development
- 2  Data Diagnostics
- 1  Protocol Development
- 0  Base Camp Prep



## Purpose: characterize current landscape of diabetic retinopathy screening

### In-Office



### Telemedicine



### Autonomous AI



#### Newly diagnosed patients with type 2 diabetes mellitus (T2DM)

- Choice of initial DR screening method
- Sequence of DR screening in the years after diagnosis
- Compare baseline patient characteristics
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Home

1 List of Abbreviations

2 Responsible Parties

3 Abstract

4 Amendments and Updates

5 Milestones

6 Rationale and Background

7 Study Objectives

8 Research Methods

9 Strengths and Limitations

10 Protection of Human Subjects


11 Plans for Disseminating and Communicating Study Results

References

Appendix

A. Indication Cohort

B. Outcome Cohorts

 OHDSI  
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

# RESEARCH PROTOCOL

## GDE2025 - Diabetic Retinopathy (DR) Screening Network Study

Version: 1.1.0

### 1 List of Abbreviations

GDE	Guideline Driven Evidence
OHDSI	Observational Health Data Sciences and Informatics
HADES	Health Analytics Data-to-Evidence Suite
T2D	Type 2 diabetes
DR	diabetic retinopathy
DME	diabetic macular edema
AI	artificial intelligence
CCI	Charlson Comorbidity Index
DCSI	Diabetes Complications Severity Index

Document by Hannah Last updated 3 days ago

Comments (-) Share Hide Toolbars

<https://github.com/ohdsi-studies/Gde2025DiabeticRetinopathyScreening?tab=readme-ov-file>



Clair Blacketer via email 4/4 10:02 PM  
To: GDE2025 - Bladder cancer treatment - OHDSI, Asieh Golozar, GDE2025 - Obesity management - O...



## Re: GDE Data Diagnostics Instructions

Dear GDE Teams,

Good news! The studies for which I have the completed data diagnostics templates all have results available. In your study channel in the Data Diagnostics folder you will find a file called "Data Diagnostics Results". You will see two different tables in the excel file, one that shows the number of potential databases per analysis variant and one that shows how many of the analysis variants in your study each database in the network can potentially contribute to. The file also shows the *ohdsi.org* email address for each database. With this information you are now able to reach out to data partners and invite them to join your study.

If you would like to see the full details of the results, you can find them here: <https://data.ohdsi.org/DataDiagnostics/>

I also walked through how to review the shiny app on a recent community call, which you can see here:

<https://youtu.be/Rv1arONKd9o>

Please let me know if you have any questions!

Clair

Identified data partners in the OHDSI Evidence Network

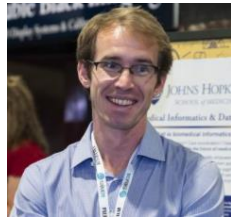
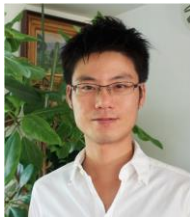


Worked with Azza Shoaibi to develop in Atlas & Phenotype Development Team to evaluate phenotypes



Indication Cohorts:  
Newly diagnosed T2DM

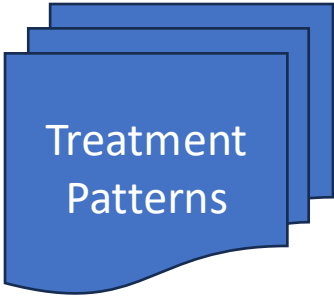
Outcome Cohorts:  
DR Screening: in-office  
DR Screening: telemedicine  
DR Screening: AI



Erik Westlund  
Ben Martin  
Haeun Lee



Anthony Sena  
Jenna Reps



Characterization  
CohortIncidence

# Back to Our Study Question...

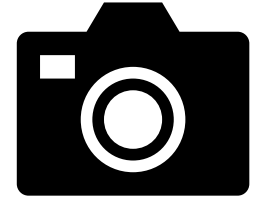
In-Office



Telemedicine



Autonomous AI



How is autonomous AI DR screening being used  
& are we doing a better job with DR screening?



# Help us with our Network Study...



- If you are a data partner:
  - Autonomous AI CPT 92229
  - Run study package
- If you have Study Package experience:
  - Help with TreatmentPatterns
  - Help with Strategus
- If you are a clinician:
  - [https://results.ohdsi.org/app/29\\_Gde2025](https://results.ohdsi.org/app/29_Gde2025)  
DiabeticRetinopathyScreening



# Pediatric Vision Screening

- Good vision is critical for child development and learning
- General guidelines for screening by pediatrician since 2016
  - Annual screening using instruments ages 1 – 3 years
  - Annual screening using chart ages 3-5 years
  - Biannual screening using chart ages over 5
- Little evidence for screening under 3
- Hypothesis: Using instrument based screening increased pediatric refractive error diagnoses post 2016
- Develop phenotypes for screening & pediatric refractive error diagnoses
- Need help with developing study!



# Osteoporosis Pharmacotherapy in the Older and Oldest Old: Bridging the Evidence Gap

Status: 20 May 2025

Chen Yanover

[yanover@ohdsi.org](mailto:yanover@ohdsi.org)

# Background

- Highest risk of osteoporosis-related fractures in the frail and elderly
  - Typically, poorly represented in or ineligible to RCTs; limited numbers in observational studies, rarely analyzed as subgroup
- ⇒ Guidelines are vague, incomplete, missing
- ⇒ Gaps include optimal treatment duration, discontinuation risks, long-term safety, and therapeutic sequencing

# Study components

- Osteoporotic medication patterns
- Comparative effectiveness (new user cohort study design) within and between drug classes (antiresorptive, anabolic)
  - General population, stratify by age groups, sex
- Safety and efficacy for long term use (10+ years)

# Status

- Phenotypes implemented + diagnosed
  - Osteoporosis, exposures, outcomes, covariates
- Potentially relevant DBs identified (Data Diagnostics)
- First draft of study protocol completed
  - [GDE2025 osteoporosis elderly protocol.docx](#) (in study Teams channel)
- Next, implement analysis specification in Strategus
  - TreatmentPatterns stats

# Collaborators

- Sourasky Medical Center, Tel Aviv, Israel
  - Vanessa Rouach
- KI Research Institute
  - Naama Parush Shear Yashuv, Tal El-Hay, Reuben (Ruby) Shamir, Maytal Bivas-Benita
- University of South Australia
  - Jack Janetzki

Join us!

- Teams Channel: [GDE2025 - Osteoporosis management](#)



# GDE2025: Community-acquired pneumonia treatment pathways

Anna Ostropolets

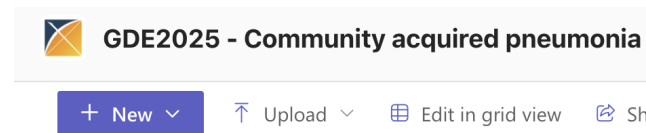
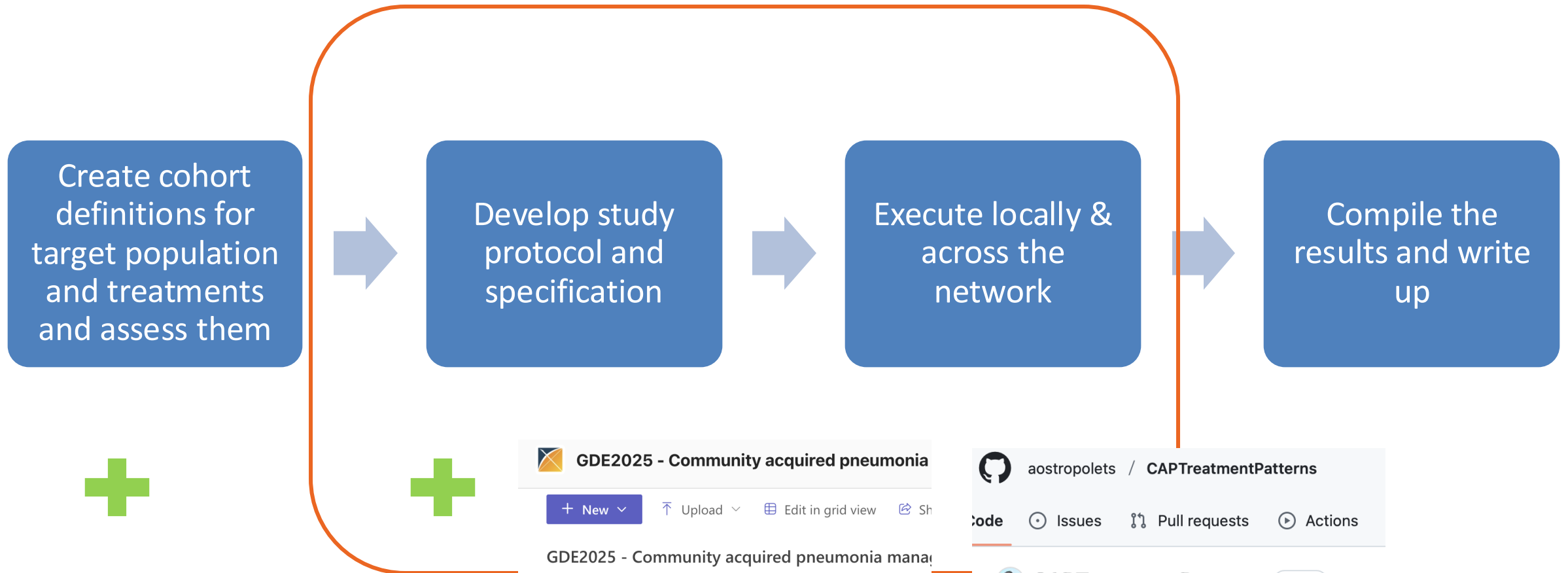


# Study objective

To characterize antibiotic treatment pathways of patients with CAP across the globe

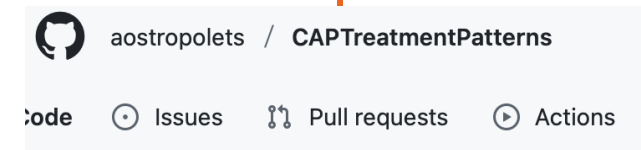


# Study steps



GDE2025 - Community acquired pneumonia management

Name	Modified
Data Diagnostics	M
GDE2025 CAP Treatment Pathways Protocol...	At



**CAPTreatmentPatterns** Public  
generated from [ohdsi-studies/StrategusStudyRepoTemplate](#)

[https://results.ohdsi.org/app/26\\_PhenotypePhebruary2025](https://results.ohdsi.org/app/26_PhenotypePhebruary2025)





# Study design

Patients with incident pneumonia (outpatient visit)  
365 days of prior observation  
Exclude tuberculosis a year prior  
Exclude non-CAP on day 0

Subgroup: patients with incident CAP subsequently hospitalized

Drugs:  
corticosteroids, cephalosporins stratified by generation, penicillins, macrolides, tetracyclines, trimetoprim, carbapenems, lincosamides, aminoglycosides, fluroquinolones  
Stratified by route of administration

Parameters:  
Follow-up starts right after dx  
Era collapse between exposures = 30 days  
Window for combinations = 1 day





# Place for community to engage

## GDE2025 - Community acquired pneumonia




+ New ▾

↑ Upload ▾

📄 Edit in grid view

🔗 Share

### GDE2025 - Community acquired pneumonia management

 Name ▾	Modified
 Data Diagnostics	Modified
 GDE2025 CAP Treatment Pathways Protocol...	Added

GDE2025 CAP Treatment Pathways

## Research Protocol

**Title:** GDE2025 – Community-acquired pneumonia (CAP) Treatment Pathways Study

### List of Abbreviations

- GDE: Guideline Driven Evidence
- OHDSI: Observational Health Data Sciences and Informatics
- HADES: Health Analytics Data-to-Evidence Suite
- CAP: community-acquired pneumonia

## Responsible Parties