



The APAC-VALUE study

**A global characterisation study of VALproate Utilisation and Exposure
among men and women of childbearing age**

The VALUE2026 R package
August 2026



April 2026
Kick-Off

May 2026
Preparation

- ✓ Characterisation & Treatment Pathways
- ✓ Setting the Scene for our Study

June 2026
Framing the Research Question

- ✓ Cohort Development
- ✓ Protocol Design

July 2026
Building

- ✓ Creating & Execution of Analysis

August 2026
Interpretation

- ✓ Interpreting & Communicating the Results

Scientific Forum May 7

Theory on characterization and treatment pathways

Scientific Forum June 4

Framing the research question

Scientific Forum July 2

Building characterization and treatment pathways in ATLAS

Scientific Forum August 6

Introduction to VALUE2026

Community Call May 21

Review of treatment guidelines

Community Call June 18

Finalising the Protocol

Community Call July 16

Execution!

Community Call August 20

Interpretating the evidence



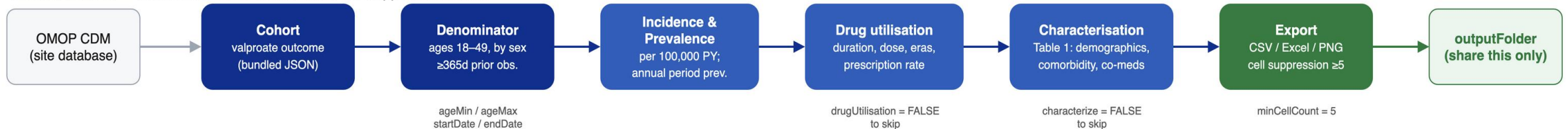
Running the study: the VALUE2026 R package

- **Instructions for APAC data partners**

One function call — from CDM to shareable results

VALUE2026::execute() — analysis pipeline

One function call — from OMOP CDM to shareable, cell-suppressed results



Optional overrides: startDate, endDate, ageMin / ageMax, minCellCount, drugUtilisation = FALSE, characterize = FALSE

No ATLAS / WebAPI required — the cohort definition ships with the package. Credentials and patient-level data never leave the site.

Under-development and lock protocol to finalize the analysis cohort



What you will produce

- **Combine multiple packages into 01 study package**

- IncidencePrevalence
 - annual new users per 100,000 person-years (365-day washout)
 - annual % of denominator with any valproate use
- DrugUtilisation — duration, dose, treatment episodes, prescription rate
- Characterisation — demographics, comorbidities, co-medications (Table 1)



- **Treatment cohort**

- Ages 18–49, both sexes, ≥ 365 days prior observation
- Study period 2005–2023 (adjustable to your data coverage)

1. Raventós B, Català M, Du M, Guo Y, Black A, Inberg G, Li X, López-Güell K, Newby D, de Ridder M, Barboza C, Duarte-Salles T, Verhamme K, Rijnbeek P, Prieto-Alhambra D, Burn E (2024). "IncidencePrevalence: An R package to calculate population-level incidence rates and prevalence using the OMOP common data model." *Pharmacoepidemiology and Drug Safety*, **33**(1), e5717.
2. Burkard, Theresa, López-Güell, Kim, Gorbachev, Artem, Bellas, Lucía, Jödicke, M. A, Burn, Edward, de Ridder, Maria, Mosseveld, Mees, Gratton, Jasmine, Seager, Sarah, Vojinovic, Dina, Mayer, Angel M, Ramírez-Anguita, Manuel J, Machín, Leis A, Oja, Marek, Kolde, Raivo, Bonadt, Klaus, Prieto-Alhambra, Daniel, Reich, Chistian, Català, Martí (2024). "Calculating daily dose in the Observational Medical Outcomes Partnership Common Data Model." *Pharmacoepidemiology and Drug Safety*, **33**(6), e5809. doi:10.1002/pds.5809.
3. Reps J, Ryan P, Knoll C (2026). Characterization: Implement Descriptive Studies Using the Common Data Model. R package version 4.0.0, <https://ohdsi.github.io/Characterization/>.



Prerequisites

- **Database**

- OMOP CDM v5.x on SQL Server or PostgreSQL
- Write access to a results schema (for cohort + denominator tables)

- **R environment**

- $R \geq 4.2.3$
- JDBC drivers: `DatabaseConnector::downloadJdbcDrivers()`

- **No ATLAS / WebAPI instance required**

- The valproate cohort definition ships inside the package (`inst/cohorts/valproate.json`)
- Converted to OHDSI-SQL at runtime via `CirceR`



Installation

```
# 1. Install the study package
remotes::install_github("OHDSI-TAIWAN/VALUE2026")

# 2. Recommended: restore the exact validated environment
renv::restore()
```

renv.lock pins every dependency to its CRAN release as of 2026-06-16.

Why pin versions?

Results must be comparable across sites

R 4.2.3

CDMConnector 2.6.0

IncidencePrevalence 1.2.0

DrugUtilisation 1.2.0



Credentials

- **Never type credentials into the script**
 - No passwords, connection strings, or tokens in any file you share
- **Use environment variables or a private .Renviron**

```
Sys.setenv(  
  VALUE2026_DB_HOST      = "...",  
  VALUE2026_DB_USER      = "...",  
  VALUE2026_DB_PASSWORD  = "...",  
  VALUE2026_DB_NAME      = "..."  
)
```

The package never reads, stores, or logs credentials — you build the connection and pass it in.



Step 1 — Copy the CodeToRun template

Copy it OUT of the package

Edit your private copy, not the installed one

Only two sections need editing

Everything else is pre-filled

```
file.copy(  
  system.file("CodeToRun.R", package =  
    "VALUE2026"),  
  "~ /VALUE2026_CodeToRun.R"  
)
```

The template is fully commented — each field explains what your site needs to supply.



Step 2 — Fill in your site's settings

```
dbms <- "sql server"          # or "postgresql" – everything else adapts

cdm_name                      <- "MySite"      # short display code
cdm_database_schema           <- c(catalog = db_name, schema = "dbo")
vocabulary_database_schema    <- c(catalog = db_name, schema = "dbo")
write_database_schema          <- c(catalog = db_name, schema = "results")

temp_emulation_schema <- NULL    # usually NULL
output_dir             <- "~/VALUE2026_results"
```

PostgreSQL uses plain schema strings ("cdm", "results"); SQL Server uses catalog + schema pairs.



Step 3 — Run the study

```
VALUE2026::execute(  
  con                        = con,                # your DBI connection  
  connectionDetails         = connection_details,   # DatabaseConnector (JDBC)  
  cdmName                   = cdm_name,  
  cdmDatabaseSchema         = cdm_database_schema,  
  vocabularyDatabaseSchema = vocabulary_database_schema,  
  writeDatabaseSchema       = write_database_schema,  
  outputFolder              = output_dir  
)
```



What lands in your output folder

- **Tables (CSV + Excel)**

- valproate_prevalence_both_sexes.csv / _male_female.csv / .xlsx
- valproate_drug_utilization.csv / _by_year.csv / .xlsx
- valproate_prescription_rate_both.csv / _by_sex.csv
- valproate_exposure_per_patient_both.csv / _by_sex.csv
- valproate_characterization.xlsx (Table 1)

- **Figures (PNG)**

- Incidence_by_sex, Incidence_person_years, Prevalence_by_sex
- Drug_Utilization_Summary, Drug_Utilization_Trends_by_Year
- Prescription_Rate_Both, Prescription_Rate_by_Sex, Exposure_per_Patient_*



VALUE2026 report

- **Affiliation report**

- <https://ohdsi-taiwan.github.io/VALUE-study/> — this is what your site's output looks like
- Exclude from the package

VALUE Study — TMUCRD Report [Background](#) [Prevalence & Incidence](#) [Drug Utilization](#) [Characteristics](#)

VALUE Study — Background & Aim

Regulatory approaches to Valproate across Asia-Pacific countries using OMOP-CDM

Aim: Describe the real-world use of sodium valproate before, during, and after multi-wave safety warnings among women and men of reproductive age, and describe how prescribing dynamics varied across countries with differing regulatory approaches.

Design: The study includes males and females of reproductive age with evidence of valproate exposure during the study period.

Period: January 1, 2000 – December 31, 2025. Each participating database contributes data from the earliest date meeting data-quality requirements through the most recent date available at the time of study execution.

Treatment cohort: Valproate users are identified using OMOP standard concepts corresponding to sodium valproate / valproate / valproic acid and all descendant concepts (RxNorm ID 745466, Code 40254). Both monotherapy and combination (multicomponent) formulations containing valproate are included and tracked.

[Download VALUE2026 R package \(GitHub\)](#)

Cohort definition

Name: Valproate (new user cohort)

Concept set: Valproate / valproate semisodium / valproate sodium (RxNorm ingredient 745466, Code 40254) and all descendant concepts, including monotherapy and multicomponent formulations.

Entry event: First qualifying drug exposure to a concept in the Valproate concept set, with quantity > 1, during an observation period between 2000-01-01 and 2023-12-31.

This report

This report presents results generated from the TMU Clinical Research Database (TMUCRD), one participating data partner in the VALUE study, covering 2005–2023 among ages 18–49.

Use the tabs above to explore:

- **Prevalence & Incidence** — interactive year-by-year prevalence and incidence of valproate use, overall and stratified by sex.
- **Drug Utilization** — treatment duration, dose, prescribing intensity, and recorded indications for valproate use.
- **Characteristics** — demographic, comorbidity, and co-medication profile of the valproate-user cohort (Table 1).

Cohort size

Patients

8,621

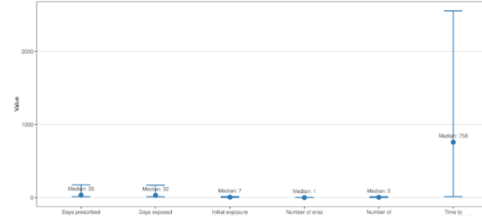
Records

8,621

Utilization summary (median, IQR)

Valproate drug utilization summary (TMUCRD, 2005-2023)

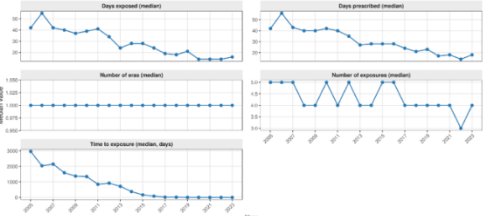
N = 8,621 patients | Sex = median, bars = IQR (25-75)



Trends over time (median by index year)

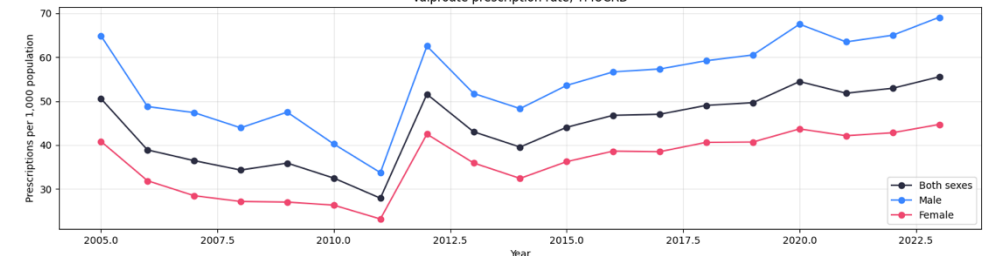
Valproate drug utilization trends over time (TMUCRD)

Median values by index year, ages 18-49



Prescription rate per 1,000 population, TMUCRD

Valproate prescription rate, TMUCRD





Privacy and what to share

- **Cell suppression is applied before anything is written**
 - Minimum cell count default = 5; counts below are set to NA
 - Adjust with minCellCount = if your governance requires a higher threshold
- **Share ONLY the contents of outputFolder**
 - Review the files before sending them
- **Never leaves your site**
 - Database credentials and connection strings
 - Patient-level data — the package only exports aggregates
 - Your edited CodeToRun.R script



Common issues

- **JDBC driver not found**
 - `DatabaseConnector::downloadJdbcDrivers("sql server", pathToDriver = "~/config/jdbc")`
- **Cohort generates zero rows on SQL Server**
 - Set `tempEmulationSchema` to a writable schema (temp-table scope issue)
- **Package versions don't match**
 - `renv::restore()` — installs the exact pinned set into a project-local library
- **Characterization unavailable**
 - Run with `characterize = FALSE` if `FeatureExtraction` cannot be installed



Support and next steps

- **Resources**

- Package + issues: github.com/OHDSI-TAIWAN/VALUE2026
- Demo report: ohdsi-taiwan.github.io/VALUE-study/
- Full protocol details: `vignette("value2026")`

- **What we need from you**

- Run `execute()` against your CDM
- Review the exported folder
- Share the folder with the coordinating team
- Please share output folder to: phanthanhphuc@ohdsi.org or phuc.pt@umc.edu.vn

Q&A



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