FAERS Q2-2025 Data Catalogue

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Dataset Source: FDA Adverse Event Reporting System (FAERS) Q2 2025

Purpose

- This document provides a structured description of all FAERS (FDA Adverse Event Reporting System) quarterly data files for 2025 Q2.
- Each table describes file contents, key fields, and their intended use in pharmacovigilance data analysis.

1. DEMO25Q2 — Demographic Information

Purpose: Contains patient and report-level demographic details.
Primary key: ***primaryid, caseid*** (unique report ID)

Column	Description
primaryid	Unique case identifier assigned by FDA.
caseid	Unique case number, can have multiple versions.
caseversion	Version number of the case (higher = latest).
i_f_code	Initial or follow-up code (I = Initial, F = Follow-up).
event_dt	Date the adverse event occurred.
mfr_dt	Date manufacturer received the report.
init_fda_dt	Date FDA first received the case.
fda_dt	Date of the latest case version received by FDA.
rept_cod	Type of report (EXP, MANU, LIT, etc.).
auth_num	Authorization or reference number.
mfr_num	Manufacturer's internal reference number.
mfr_sndr	Manufacturer sender code.
lit_ref	Literature reference if reported from literature.
age	Patient age.
age_cod	Unit of age (YR, MON, WK, DY, HR).
age_grp	Derived age group (child, adult, etc.).
sex	Patient gender (M, F, UNK).
e_sub	Electronic submission flag.
wt	Patient weight.
wt_cod	Weight unit (KG, LB).
rept_dt	Report date entered by reporter.
to_mfr	Indicates if report sent to manufacturer.
occp_cod	Reporter's occupation (PH, MD, OT).
reporter_country	Country of the reporter.
occr_country	Country where the event occurred.

2. DRUG25Q2 — Drug Information

Purpose: Lists all drugs involved in each adverse event case.
Primary key: ***primaryid, caseid***

Column	Description
primaryid	Unique report identifier.
caseid	Case number to link with DEMO file.
drug_seq	Sequence number of drug in the case.
role_cod	Role of drug (PS = Primary Suspect, SS = Secondary Suspect, C = Concomitant, I = Interacting).
drugname	Name of the drug as reported.
prod_ai	Active ingredient(s).
val_vbm	Validation status for verbatim term.
route	Route of administration (ORAL, IV, TOPICAL, etc.).
dose_vbm	Verbatim dose text as reported.
cum_dose_chr	Cumulative dose as text.
cum_dose_unit	Unit of cumulative dose.
dechal	Dechallenge result (Y = event abated on withdrawal).
rechal	Rechallenge result (Y = event recurred on reintroduction).
lot_num	Drug lot/batch number.
exp_dt	Expiration date of the product.
nda_num	NDA (New Drug Application) number if applicable.
dose_amt	Numeric dose amount.
dose_unit	Unit of dose (MG, ML, etc.).
dose_form	Form of drug (TAB, CAP, SOLN, etc.).
dose_freq	Frequency of dosing (1X, BID, TID, etc.).

3. INDI25Q2 — Indication Information

Purpose: Shows the medical indications (reasons) for using the drug.
Primary key: ***primaryid, caseid***

Column	Description
primaryid	Unique report identifier.
caseid	Case number to link with DEMO file.
indi_drug_seq	Drug sequence number linked to drug_seq in DRUG file.
indi_pt	Medical indication term (e.g., “Hypertension”, “Diabetes Mellitus”).

4. OUTC25Q2 — Outcome Information

Purpose: Records outcomes for each case (patient results).
Primary key: ***primaryid, caseid***

Column	Description
primaryid	Unique report identifier.
caseid	Case number to link with DEMO file.
outc_cod	Outcome code: • DE = Death • LT = Life-threatening • HO = Hospitalization • DS = Disability • CA = Congenital anomaly • RI = Required intervention • OT = Other serious outcome

5. REAC25Q2 — Reaction Information

Purpose: Lists all reported adverse reactions using MedDRA terms.
Primary key: ***primaryid, caseid***

Column	Description
primaryid	Unique report identifier.
caseid	Case number to link with DEMO file.
pt	Preferred term (reaction name) from MedDRA.
drug_rec_act	Indicates if a drug action was taken (e.g., withdrawn, dose reduced).

6. RPSR25Q2 — Report Source Information

Purpose: Identifies who reported the case.
Primary key: ***primaryid, caseid***

Column	Description
primaryid	Unique report identifier.
caseid	Case number to link with DEMO file.
rpsr_cod	Report source code: • HP = Health Professional • CS = Consumer • FD = Foreign • LW = Lawyer • OT = Other

7. THER25Q2 — Therapy Dates

Purpose: Provides drug treatment duration and timing info.
Primary key: ***primaryid, caseid***

Column	Description
primaryid	Unique report identifier.
caseid	Case number to link with DEMO file.
dsg_drug_seq	Drug sequence number matching drug_seq in DRUG file.
start_dt	Therapy start date.
end_dt	Therapy end date.
dur	Duration of therapy.
dur_cod	Duration unit (DY, WK, MO, YR).

Each file links through ***primaryid*** and ***caseid***, with drug-related files.

Summary

This catalogue provides a structured overview of the FAERS Q2-2025 dataset, enabling efficient data cleaning, integration, and pharmacovigilance signal analysis.
It forms the foundation for dashboard creation and further statistical evaluation.