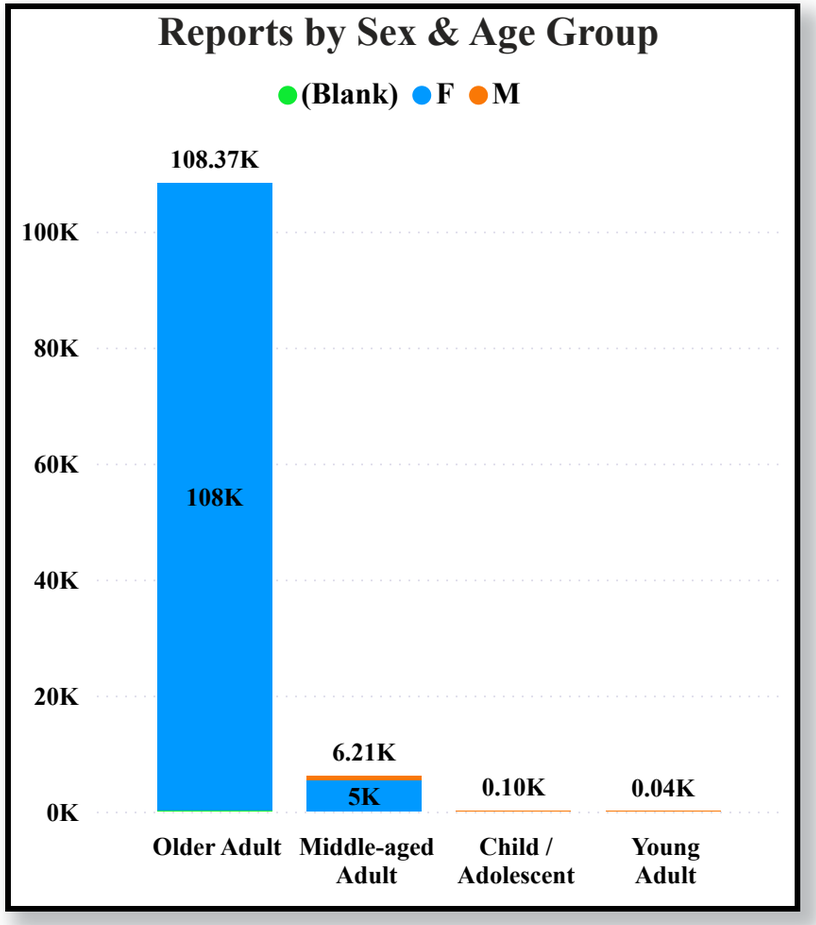
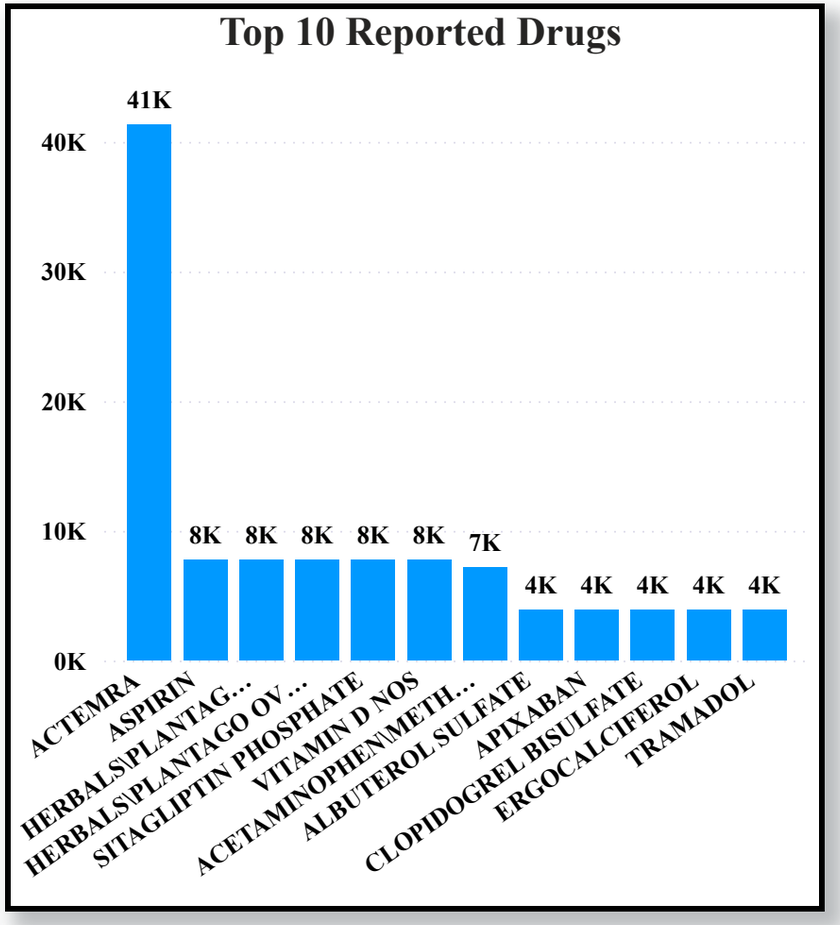
FDA Adverse Event Reporting System (FAERS) – Q2 2025 Analysis

Total Reports	Total Drugs Reported	Countries Reporting	Most Common Outcome
114.71K	63	5	4





Note:

Age values were grouped into four categories — Child/Adolescent, Young Adult, Middle-aged Adult, and Older Adult — to enable clearer demographic comparisons.

The analysis shows 114.71K total case reports covering 63 distinct drugs, submitted from five countries.

Older Adults, predominantly female, make up the vast majority of reports, followed by Middle-aged Adults.

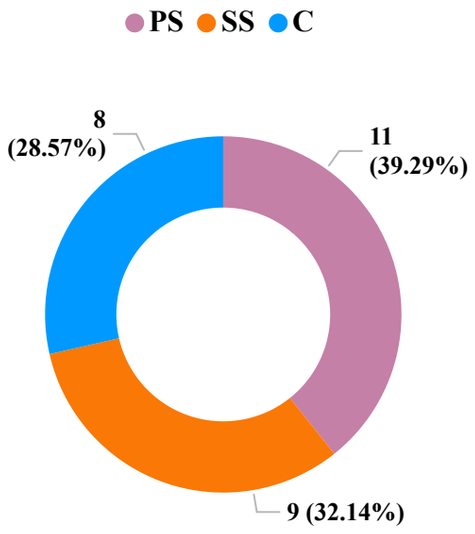
Actemra stands out as the most frequently reported drug, far exceeding the next most common drugs.

Outcomes, drug roles, and routes of administration have been visualized to highlight key reporting trends.

Indication vs. Outcome (Top 10)

indi_pt	DE	HO	OT	Total
Product used for unknown indication	48	6800	41343	48191
Hypertension		6700	6707	13407
Osteoporosis		4380	4380	8760
Rheumatoid arthritis		35	7890	7925
Diabetes mellitus		2660	2660	5320
Psoriasis		2660	2660	5320
Cerebrovascular accident		2000	2000	4000
Gout		1700	1700	3400
Glaucoma			2730	2730
Intraocular pressure increased			2730	2730
Total	48	26935	74800	101783

Outcome by Drug Role



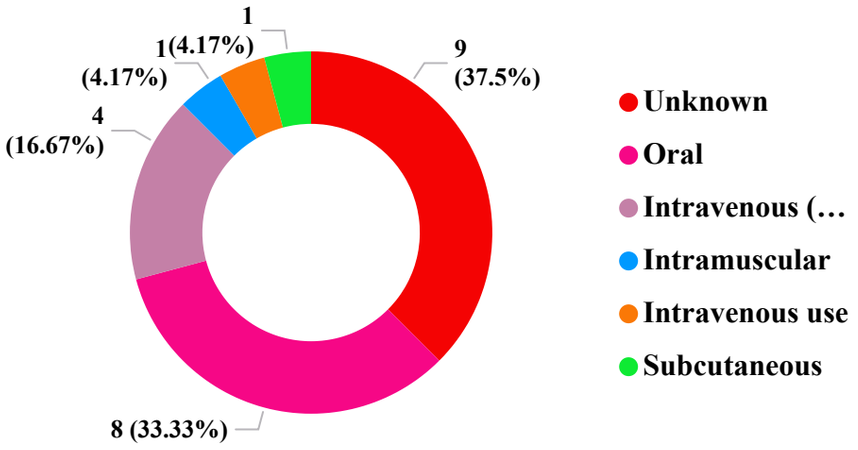
Note:

Primary Suspect (PS) drugs represent the largest share of reported outcomes (39.29%), followed by Secondary Suspect (SS) at 32.14% and Concomitant (C) at 28.57%.

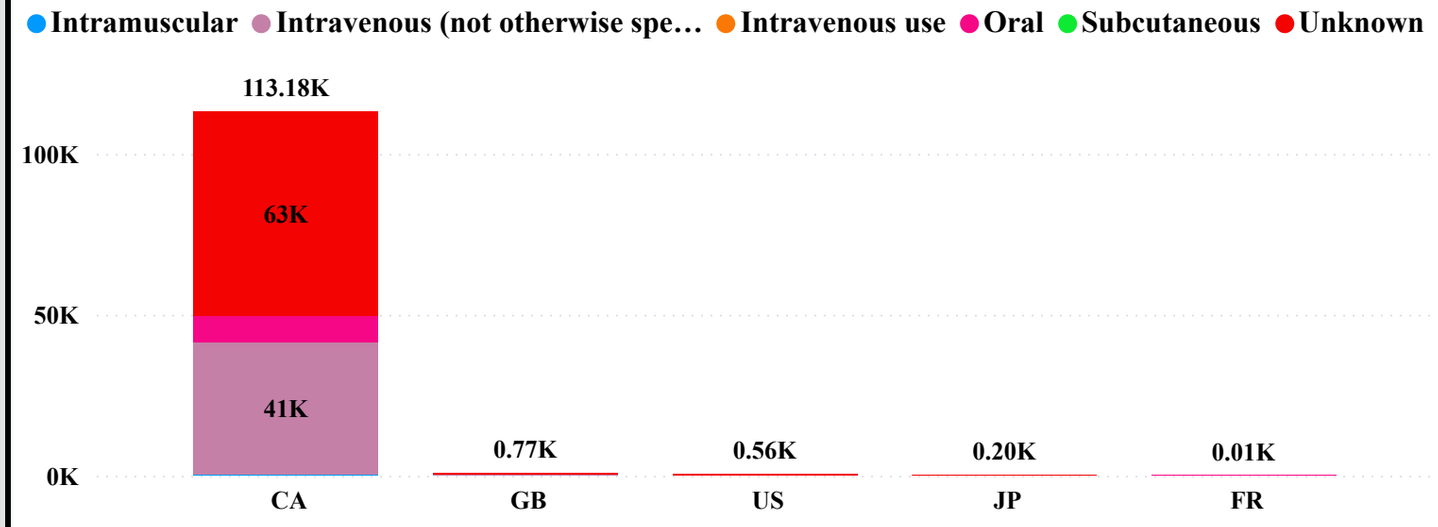
The most common route of administration is "Unknown" (37.5%), followed by oral (33.33%), with intravenous, intramuscular, and subcutaneous routes less frequent.

Canada reports the highest volume (113.18K), dominated by unknown (63K) and intravenous (41K) routes, then oral (8K). Other reporting countries include GB, US, JP, and FR (lowest at 0.01K). Outcome codes include DE, HO, LT, and OT, indicating varying severity levels.

Distribution of Route of Administration



Reports by Route of Administration and Reporter Country



Data Preparation & Integration:

The analysis is based on the FDA Adverse Event Reporting System (FAERS) 2025 Q2 dataset (April–June 2025, published July 29, 2025). The raw dataset comprised six separate tables — containing information on drug indications, outcomes, reactions, report sources, drug details, and patient demographics.

All tables were imported into MySQL Workbench, cleaned to remove irrelevant or redundant fields, standardized for consistency, and joined using key identifiers (*primaryid*, *caseid*) to create a single consolidated table.

Final Data Structure:

The merged dataset includes key attributes such as patient demographics (*age, sex, weight, country*), drug details (*drug name, role code, active ingredients, route of administration*), medical indications (*indi_pt*), reported outcomes (*outc_cod*), and reported reactions (*pt*).

Age groups were categorized into Child/Adolescent (<18), Young Adult (18–44), Middle-aged Adult (45–64), and Older Adult (65+), with "Unknown" assigned to missing values.

Analysis & Visuals:

- **KPI Cards: Total reports (114.71K), total distinct drugs reported (63), number of reporting countries (5), and most common outcome (4 categories).**
- **Demographic Analysis: Distribution of reports by sex and age group, showing older adults (mostly female) dominating the dataset.**
- **Top 10 Drugs: Highlighting *Actemra* as the most reported drug (41K cases), followed by *Aspirin* and herbal products (~8K each).**
- **Outcome by Drug Role: Share of Concomitant (28.57%), Secondary Suspect (32.14%), and Primary Suspect (39.29%) drugs.**
- **Route of Administration: Distribution across six routes, with "Unknown" (37.5%) and oral (33.33%) most common.**
- **Geographical Insights: Reports by route and country, showing Canada as the largest contributor (113.18K reports), with most being unknown or intravenous routes.**

This process provided a clean, analysis-ready dataset that was used to build a professional Power BI dashboard with clear KPIs, breakdowns by demographics, drug characteristics, outcomes, and geographical trends.