Adversе Event Profile of Bispecific Antibodies in Relapsed/Refractory Multiple Myeloma: Analysis of the FAERS Database

N. POKHAREL[1], S. SHRESTHA[2], D.K. ROHITA[3], P. BUDHATHOKI[4], B. MEHTA[1], S. GURUNG[1], L.M.R. HERNANDEZ[1], M. MEGALY[1], M.B. PATEL[1]
[1] St. Francis Medical Center, Monroe, LA
[2] KIST Medical College, Nepal
[3] Wyckoff Heights Medical Center, Brooklyn, NY
[4] Moffitt Cancer Center, Tampa, FL

Introduction

Relapsed/refractory multiple myeloma (RRMM) remains a major therapeutic challenge despite recent advances in treatment. The emergence of bispecific antibodies targeting B-cell maturation antigen (BCMA) and G protein–coupled receptor class C group 5 member D (GPRC5D) has expanded available options. Teclistamab (FDA-approved 2022), Elranatamab (2023), and Talquetamab (2023) are three such agents currently in clinical use. This analysis reviews and compares their adverse event (AE) profiles using real-world post-marketing data from the FDA Adverse Event Reporting System (FAERS).

Aim

To compare the real-world adverse event profiles of Teclistamab, Talquetamab, and Elranatamab in patients with relapsed/refractory multiple myeloma.

Objectives

Extract and review adverse event reports for each agent from the FDA Adverse Event Reporting System (FAERS).

Quantify and compare the frequency of key adverse events, including cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS).

Identify trends in patient demographics and outcomes, including mortality, across the three agents.
Highlight potential safety concerns warranting ongoing clinical monitoring.

Methods

- Data source: FAERS database
- Time frame:
  - Teclistamab & Elranatamab — 2021 to March 2025
  - Talquetamab — 2022 to March 2025
- Inclusion: Reports identifying RRMM patients receiving these agents
- Analysis: AE frequencies, reported outcomes, demographics

Results

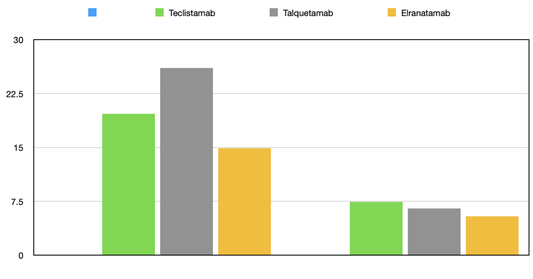
Agent	Reports(n)	CRS(%)	ICANS(%)	Deaths(n)
Teclistamab	1016	19.7	7.4	227
Talquetamab	353	26.1	6.5	46
Elranatamab	504	14.9	5.4	125

Other notable AEs

- Teclistamab: plasma cell myeloma progression (9.1%), pneumonia (8%), ICANS (7.4%).
- Talquetamab: weight loss (12.8%), dysgeusia (10.5%), plasma cell myeloma (9.9%).
- Elranatamab: pneumonia (5.6%), pyrexia (5.4%).

Overall Trends

- CRS most frequent with Talquetamab, followed by Teclistamab, then Elranatamab
- ICANS highest with Teclistamab, then Talquetamab, then Elranatamab
- Infections, immune-mediated AEs, and neurotoxicity common, especially in elderly patients



CRS and ICANS reporting rates differ between bispecific antibodies in FAERS

Discussion

Key AE signals (FAERS, RRMM bispecifics):

- Agent-specific toxicity: ↑ CRS with talquetamab, ↑ neurotoxicity with teclistamab (signals, not incidence).
- Elderly (65–85 yrs) dominate reports → greater susceptibility to infections/severe outcomes.

Clinical relevance:

- Distinct AE profiles → tailor monitoring (CRS vs neuro checks).

Immediate actions:

- Standardized CRS/ICANS checklists during early cycles.
- Early intervention: low threshold for tocilizumab/steroids.
- Infection prevention: vaccination, consider prophylactic antimicrobials, close pneumonia monitoring.

Limitations (FAERS):

- No denominator → cannot calculate incidence.
- Underreporting, duplicates, limited treatment context.

Future directions:

- Prospective registries, drug-specific safety cohorts (esp. elderly/comorbid).
- Mechanistic work on CRS/neuro differences (BCMA vs GPRC5D, dosing).

Take-home:

Bispecifics show *drug-specific AE patterns*. Vigilant CRS, ICANS, and infection monitoring — especially in older patients — is essential for safe use.

Summary

Bispecific antibodies for RRMM demonstrate distinct AE patterns in post-marketing surveillance. CRS and ICANS remain key safety concerns, requiring early recognition and proactive management. Continued pharmacovigilance is essential to identify emerging toxicities and optimize patient outcomes.

References

U.S. Food and Drug Administration. FDA Adverse Event Reporting System (FAERS) Public Dashboard. Accessed August 17, 2025. (https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard)