Claims Data for Post-Market Safety Investigations: Lessons from a Real-World Oncology Cohort

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Introduction and objectives

Post-marketing assessments provide important insight into the safety profile of medications beyond the controlled setting of clinical trials.

Administrative claims data are a valuable source of detailed, longitudinal healthcare data for post-marketing drug safety surveillance.

This analysis evaluated the real-world safety profile of a novel intravenous medication recently approved in the US for use as part of combination therapy for a hematologic cancer.

Methods

Data were obtained from Komodo Healthcare Map®, a nationally representative U.S. administrative claims database.

The total analysis set (i.e., claims cohort) included patients with ≥1 medical or pharmacy claim for the novel medication between August 2022 and March 2026.

Sociodemographic characteristics of the claims cohort were compared with those of patients enrolled in the key Phase 3 clinical trial that evaluated the efficacy and safety of the novel medication.

The frequency of the following commonly reported adverse events in the clinical trial were assessed in the period following drug initiation using ICD10 diagnosis codes.

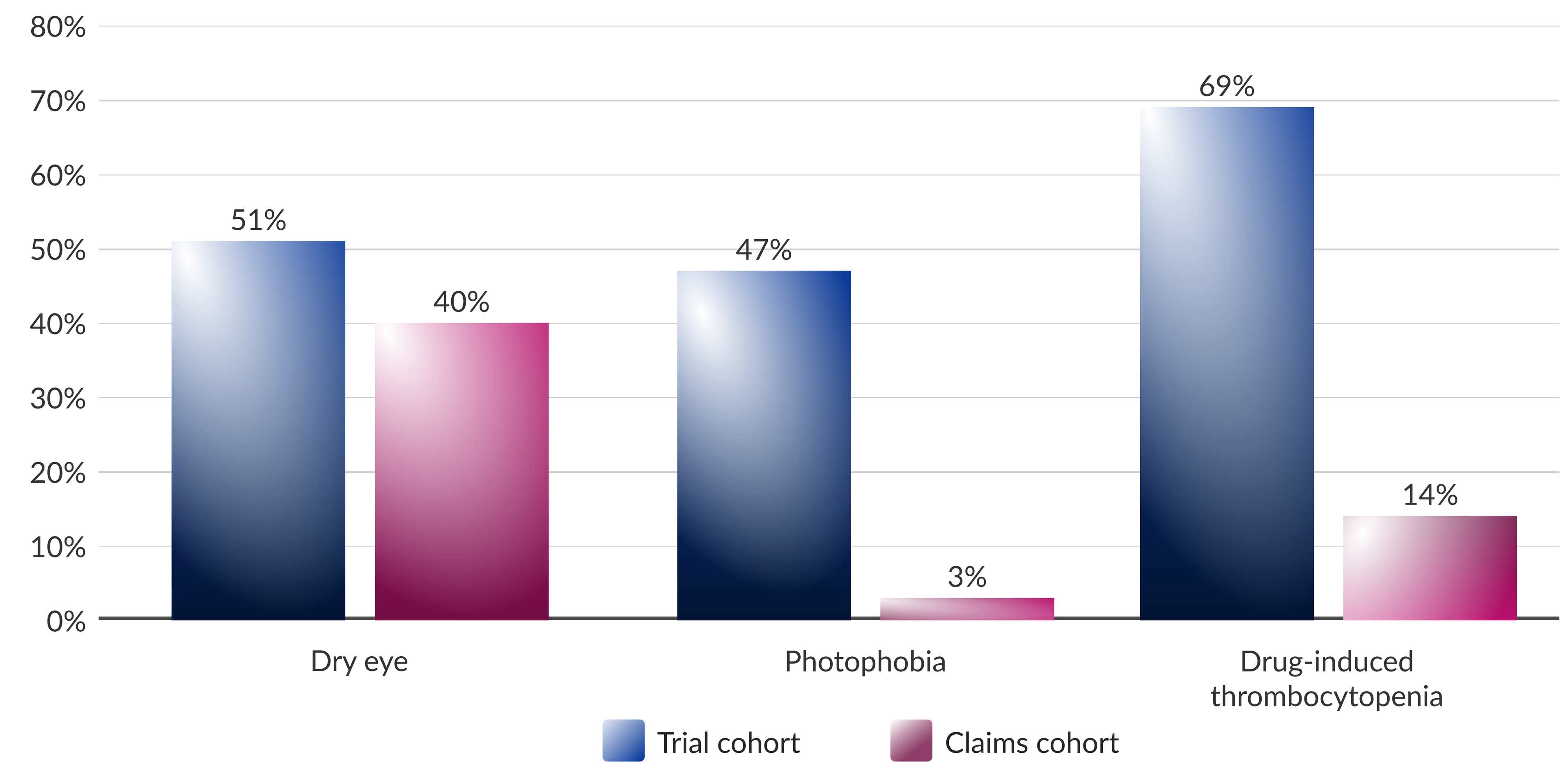
- Dry eyes (H04.12)
- Photophobia (H53.1)
- Drug-induced thrombocytopenia (D69.6 + T45.1X5)

Background rates of these adverse events any time prior to treatment initiation were also evaluated.

TABLE 1: DEMOGRAPHIC CHARACTERISTICS

		TRIAL COHORT (N=243)	CLAIMS COHORT (N=635)
Median age (range) (years)		65 (34 - 86)	74 (28 - 88)
Age category			
	18 to <65 years	121 (50)	136 (21.4)
	65 to <75 years	85 (35)	225 (35.4)
	>75 years	37 (15)	268 (42.2)
	Unknown	0	6 (1.0)
Sex, n (%)			
	Male	128 (53)	288 (45.4)
	Female	115 (47)	336 (52.9)
	Unknown	0	11 (1.7)
Race, n (%)			
	White	206 (85)	375 (59.1)
	Black	8 (3)	125 (19.7)
	Asian	28 (12)	26 (4.1)
	Others	0	78 (12.3)
	Unknown	0	31 (4.8)

Figure 1: Proportion of patients with select adverse events in the trial and claims cohorts.



RESULTS

Six hundred and thirty-five patients with exposure to the therapy were identified in the claims dataset.

Compared with the trial population, the claims cohort was much older and more racially diverse (**Table 1**).

The median observational periods in the Komodo database pre- and post-initiation of the novel therapy were 78.3 and 28.2 months, respectively. The post-treatment period was comparable with the median follow-up duration of the pivotal clinical trial (28.2 months).

In the post-initiation period, the proportion of patients in the claims dataset with >= 1 claim for each of the select adverse events was lower than that reported in the clinical trial:

- Dry eyes – 40% (n=256) in claims vs 51% in trial
- Photophobia – 3% (n=20) in claims vs 47% in trial
- Drug-induced thrombocytopenia – 14% (n=89) in claims vs 69% in trial (Figure 1).

Notably, a substantial proportion of the claims cohort also had claims for the assessed outcomes prior to treatment initiation, with ≥1 claim for dry eyes (61%), photophobia (5%) and drug-induced thrombocytopenia (31%) in the pre-initiation period (**Figure 2**).

In a sub-group analysis restricted to patients with closed claims coverage for both novel therapy use and select adverse events (n=291), similar proportions were observed for dry eyes (46%, n=135), photophobia (3%, n=9), and drug-induced thrombocytopenia (14%, n=42).

DISCUSSION

Large sociodemographic differences between the trial and claims cohorts possibly reflect the more restrictive subject selection in the clinical trial setting.

Differences in adverse event occurrence between cohorts, particularly for photophobia and drug-induced thrombocytopenia, are likely to be due to different methods of outcome identification (ICD-10 codes in real-world vs clinical examination in the clinical trial).

A substantial proportion of patients in the claims cohort already had these adverse events prior to initiating the novel therapy, highlighting the importance of background rate assessment in safety evaluation.

Figure 2: Number (%) of patients reporting adverse events at various timepoints in the claims database.

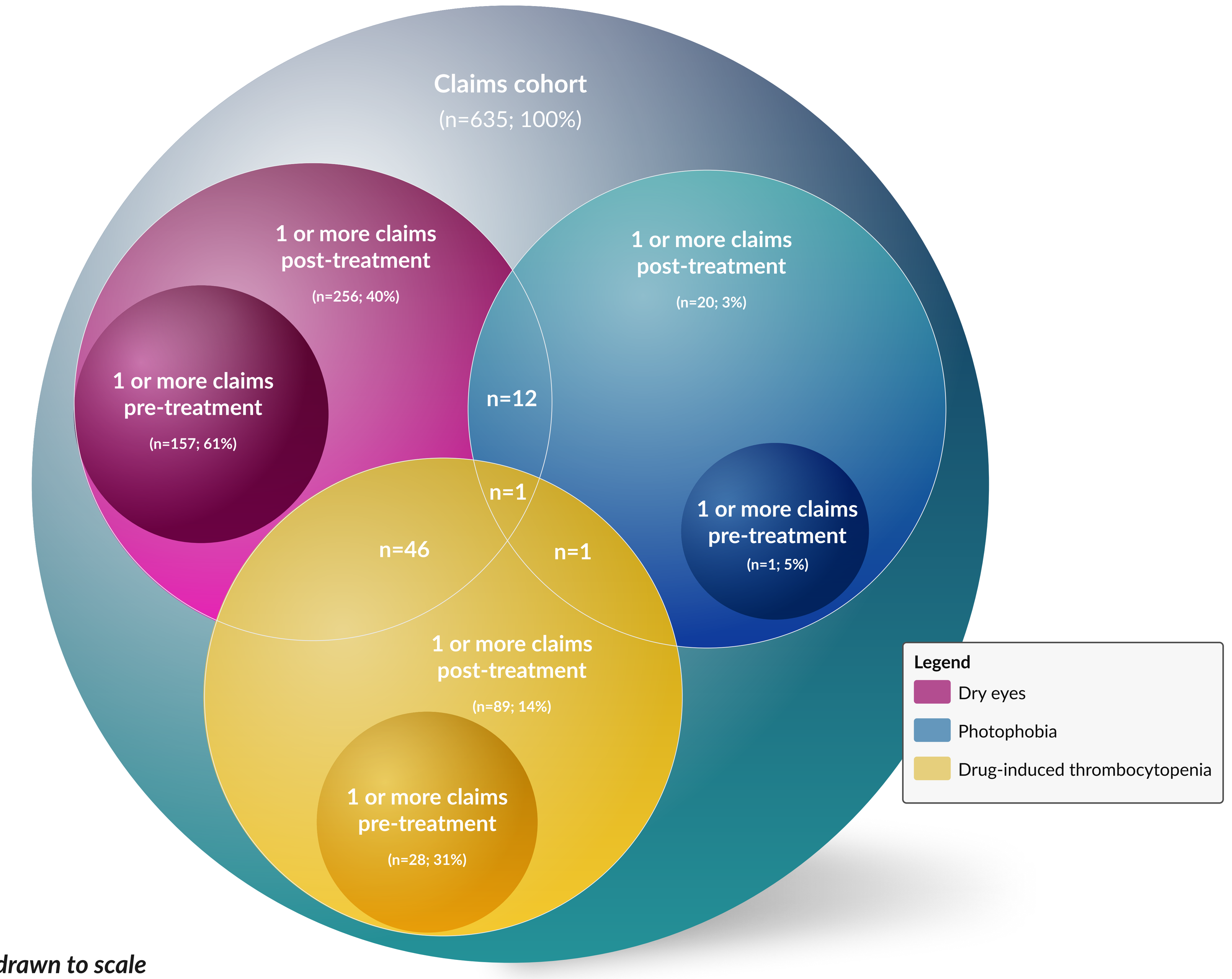


Figure not drawn to scale
Percentages are calculated using the patient count of the immediately surrounding (outer) circle as the denominator.

LIMITATIONS

The proportion of patients experiencing adverse events may be underestimated in real-world settings, especially for events with lower clinical impact. This is particularly true for assessments based on claims data, which are primarily designed for billing purposes and not safety monitoring.

Evaluation of safety outcomes using claims data is limited to assessment of type and frequency of events; ratings/algorithms that enable the ascertainment of outcome severity (such as disease risk scores) are typically not available.

Application of the full trial eligibility criteria to the claims cohort was not feasible, as information on some criteria (such as evidence of disease progression or prior treatment with investigational drugs) was not available in claims data.

KEY TAKEAWAYS

Despite limitations, claims data can provide early, informative insights on the safety of novel therapies in real-world use in the immediate post-market period, and can complement other methods of real-world post-marketing safety assessments.

Assessment of background rates when interpreting post-marketing safety signals is essential, as the events of interest might have been pre-existing in a substantial proportion of patients.

Results should be interpreted with caution when comparing trial versus real-world (e.g., claims data) adverse event rates, as it might not be possible to fully replicate the trial eligibility criteria in real-world cohorts. Also, adverse events might be underreported by patients, especially if the clinical relevance is lower.

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Disclosures: SI, IP, and IC are employees of United BioSource LLC