NON-INTERVENTIONAL/LOW-INTERVENTIONAL STUDY TYPE 1 STUDY REPORT ABSTRACT

Title: Risk of Safety Events Among Patients with ulcerative colitis (UC) and psoriatic arthritis (PsA) Treated with Tofacitinib and Other Advanced Treatments in the United States (US)

Date: 25 November 2025

Name and affiliation of the main author: [redacted].

Keywords: Ulcerative colitis, psoriatic arthritis, safety, tofacitinib

Rationale and background: This non-interventional study aimed to provide insights into incidence rates (IRs) of select safety outcomes in the UC and PsA populations using active comparator groups in routine clinical practice in the US. The results are intended to provide epidemiologic context for interpreting and applying the relative risk estimates for safety events in clinical decision making for real-world UC and PsA patients eligible for tofacitinib treatment.

Research question and objectives: The research questions of this study were:

What are the distributions of demographic and clinical characteristics of patients with UC and PsA treated with tofacitinib and other advanced treatments in the US?

What is the risk of select safety events (major adverse cardiovascular events (MACE), venous thromboembolic disease (VTE, defined as deep vein thrombosis (DVT) and pulmonary embolism (PE), malignancy (excluding (NMSC)) and serious infections) in UC and PsA patients receiving tofacitinib and other forms of advanced treatment in the US, and are these risks modified by factors of interest?

What are crude and adjusted relative risks of select safety events when comparing mutually exclusive comparator groups of tofacitinib and other forms of advanced treatment within UC and PsA populations in the US?

The objectives of the study were:

1. To estimate the frequency distributions of demographic and clinical characteristics among patients on tofacitinib and other forms of advanced treatment in UC and PsA populations.
2. To estimate crude incidence rates (IRs) of select safety events among UC and PsA populations on tofacitinib and other forms of advanced treatment.
3. To estimate the crude and adjusted hazard ratios (HRs) of select safety events comparing tofacitinib and other forms of advanced treatment in UC and PsA populations.

Study design: This was a population-based retrospective cohort study of adults with UC and PsA identified through Komodo's Healthcare Map, an administrative claims data source based in the US.

Setting: Identification of disease populations, safety outcomes of interest, and drugs prescribed were implemented using ICD-10 codes, CPT procedure codes, and prescribing data (e.g., NDC) in the patients' records.

Subjects and study size, including dropouts: Inclusion criteria for the study were as follows: aged ≥18 years, diagnosed with UC or PsA, at least 365 days of continuous enrollment in database prior to index date, and initiated at least 1 approved advanced treatment. Exclusion criteria were as follows: tofacitinib users with prescriptions of other approved JAK inhibitors, other advanced treatment users with history of any JAK inhibitor, and (for PsA only), evidence of rheumatoid arthritis.

Variables and data sources: Variables for exposure, baseline characteristics, weighting covariates, stratifications, and safety outcomes were included. Komodo's Healthcare Map is a patient-centered claims dataset.

Results: The mean age at index was 43.1 for the UC cohort and 48.9 for the PsA cohort; mean duration of follow-up was approximately one year in both studies. In the overall, adjusted UC analyses, tofacitinib was associated with lower rates of serious infection and VTE, but higher rate of malignancy, compared to TNFi; no significant differences were observed for any of the safety events between tofacitinib and vedolizumab. In the overall, adjusted PsA analyses, tofacitinib was associated with higher rates of VTE, DVT, and PE compared to TNFi and adalimumab; no significant differences were observed for any of the safety events between ustekinumab or risankizumab versus tofacitinib.

Discussion: This study utilized real-world retrospective claims data for UC and PsA to examine the incidence of safety events observed in individuals initiating tofacitinib and other advanced treatments. Based on this study, no differences were observed for most safety events between tofacitinib and other advanced treatments. For UC patients, tofacitinib was observed to have a higher incidence of malignancy compared to other treatments, primarily driven by patients remaining on prolonged induction dose (10 mg BID, ≥16 weeks). Given the limitations of administrative claims data and confounding by indication, it is likely that these patients may have had more severe and uncontrolled disease, resulting in channeling bias. For PsA patients, tofacitinib was associated with higher incidence of VTE compared to TNFi, consistent with findings from the Oral Surveillance study in RA.

Names and affiliations of principal investigators:

[redacted]

Document Approval Record

Document Name:	A3921431 Study Report Abstract_25Nov2025
Document Title:	A3921431

Signed By:	Date(GMT)	Signing Capacity
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]