

# Comparative Effectiveness of Tofacitinib Versus Ustekinumab and Vedolizumab among Ulcerative Colitis Patients With Prior Anti- Tumor Necrosis Factor (TNF) Failure

**First published:** 23/02/2022

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/46622>

### EU PAS number

EUPAS45035

### Study ID

46622

### DARWIN EU® study

No

### Study countries

United States

### Study description

To perform a retrospective matched cohort study to compare clinical outcomes of these agents among anti-TNF exposed patients with Ulcerative Colitis in our health system.

### Study status

Finalised

## Research institution and networks

## Institutions

**Pfizer**

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Institution

## Networks

**Mass General Brigham (MGB)**

## Contact details

**Study institution contact**

**Puza Sharma**

Study contact

[Puza.Sharma@pfizer.com](mailto:Puza.Sharma@pfizer.com)

**Primary lead investigator**

**Edith Owens**

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned:

29/10/2021

Actual:

06/12/2021

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**Study start date**

Planned:

01/03/2022

Actual:

24/02/2022

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## Date of final study report

Planned:

30/03/2023

Actual:

13/01/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[A3921415 Non Interventional Study Protocol Final 08Feb2022\\_Redacted.pdf\(1.87 MB\)](#)

[A3921415 Non Interventional Study Protocol Amendment 1 \(clean\) 08Apr2022 \(1\)\\_Redacted.pdf\(1.98 MB\)](#)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product  
Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary data collection

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**Main study objective:**

To assess how tofacitinib, ustekinumab and vedolizumab compare in real world safety and effectiveness of anti-TNF-experienced ulcerative colitis patients.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective study

## Study drug and medical condition

**Name of medicine**

Xeljanz

Entyvio

Stelara

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**Medical condition to be studied**

Colitis ulcerative

## Population studied

## Short description of the study population

Patients with ulcerative colitis (UC) aged 18 years or older initiated treatment with tofacitinib, ustekinumab, or vedolizumab therapy on or after 01 May 2018 through 01 February 2022 identified from the Mass General Brigham (MGB) health system.

Inclusion Criteria:

1. Age of 18 years or older.
2. Initiation of tofacitinib, ustekinumab, or vedolizumab therapy for UC on or after 01 May 2018 through 01 April 2022.
3. Prior anti-TNF exposure.
4. Patient within the MGB health system.

Exclusion Criteria:

1. History of prior colectomy.
  2. Primary indication of tofacitinib, ustekinumab, or vedolizumab therapy is not UC.
  3. Diagnosis of Crohn's disease or indeterminate colitis.
  4. Dual therapy with tofacitinib and a biologic (eg, tofacitinib and vedolizumab or ustekinumab simultaneously) or vedolizumab/ustekinumab and a second biologic.
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## Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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## Special population of interest

Other

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## Special population of interest, other

Patients with ulcerative colitis

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## Estimated number of subjects

360

# Study design details

## Outcomes

Compare proportions of corticosteroid-free clinical remission 8-12 weeks and 52 weeks after tofacitinib, ustekinumab or vedolizumab initiation by using either SCCAI or Mayo score by greater than or equal 2 or physician global assessment. Compare drug survival (time to treatment discontinuation or colectomy) of tofacitinib versus ustekinumab and vedolizumab. Compare proportions of endoscopic response, endoscopic remission. Assess proportions of biochemical response and remission. Compare proportions of colectomy,

IBD-related hospitalization, and corticosteroid use, proportions of patient-reported improvement in extra intestinal manifestations, proportions of potential complications and treatment discontinuations.

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### **Data analysis plan**

After patient cohorts are identified in the MGB RPDR using the pre-specified inclusion and exclusion criteria, vedolizumab patients will be frequency matched 2:1 to tofacitinib patients by age ( $\pm 3$  years) and sex. The matched sample will be used for all subsequent analyses for this comparison. All eligible ustekinumab patients will be used in the tofacitinib vs ustekinumab comparison. De identified data will be imported into StataSE 17 for statistical analysis.

## Documents

### **Study results**

[A3921415 Non Interventional Study Report Abstract 22 December 2022\\_Redacted.pdf](#)  
(1.54 MB)

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### **Study report**

[A3921415 Non Interventional Study Report 22 December 2022\\_Redacted.pdf](#)(4.08 MB)

### **Study, other information**

[A3921415 Non Interventional Study Abstract\\_Amendment 1 08Apr2022\\_Redacted.pdf](#)(1.7 MB)

[A3921415 Non Interventional Study Abstract\\_Final 08Feb2022\\_Redacted.pdf](#)(1.7 MB)

## Data management

### Data sources

#### **Data source(s), other**

Mass General Brigham (MGB) Research Patient Data Registry (RPDR)

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#### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

### Use of a Common Data Model (CDM)

#### **CDM mapping**

No

### Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No