

# Observational, real-world study of INFLECTRA in patients with inflammatory bowel disease (IBD) in the United States and Canada (ONWARD)

**First published:** 08/02/2018

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS22444

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### Study ID

39469

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### DARWIN EU® study

No

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### Study countries

 Canada

 United States

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## Study description

To describe drug use patterns, treatment adherence and associated costs in adult UC and CD cohorts treated with INFLECTRA in a real-world setting

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Pfizer](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

[Multiple centres: 40 centres are involved in the study](#)

## Contact details

### Study institution contact

Arif Soonasra [arif.soonasra@pfizer.com](mailto:arif.soonasra@pfizer.com)

**Study contact**

[arif.soonasra@pfizer.com](mailto:arif.soonasra@pfizer.com)

## Primary lead investigator

Owens Edie

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/02/2017

Actual: 23/02/2018

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### Study start date

Planned: 19/02/2018

Actual: 23/02/2018

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### Date of final study report

Planned: 31/10/2019

Actual: 28/01/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

C1231006 PROTOCOL\_Amendment

2\_Pfizer\_Infectra\_ONWARD\_Study\_25Jan2018 V3.pdf (455.7 KB)

C1231006 AMENDMENT 3 PROTOCOL VERSION 3\_09SEP2020\_Redacted.pdf

(3.96 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:**

Drug utilisation

**Data collection methods:**

Primary data collection

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**Main study objective:**

The study will evaluate treatment patterns, adherence, disease activity, remission status, relapse status, treatment satisfaction, and healthcare resource utilization.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective, observational study,

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

INFLIXIMAB

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**Medical condition to be studied**

Inflammatory bowel disease

Colitis ulcerative

Crohn's disease

## Population studied

## **Short description of the study population**

Patients in the US and Canada initiating treatment with infliximab-dyyb for IBD.

Patients are eligible to participate if they have:

1. Initiated therapy with INFLECTRA as their first biologic;
2. Switched to INFLECTRA while in remission on a stable dose of REMICADE; or,
3. Switched to INFLECTRA from another biologic, due to non-responsiveness, intolerance, or other reasons.

Inclusion Criteria:

Patients must meet all of the following criteria to be eligible for inclusion in the study:

1. Patients with confirmed diagnosis of Ulcerative Colitis or Crohn's Disease.
2. Evidence of a personally signed and dated informed consent document indicating that the patient has been informed of all pertinent aspects of the study.
3. Patient eligible to receive INFLECTRA for the treatment of their disease per approved drug label (patients with fistula, or stoma are eligible).

Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. Patient age less than 18 years at the time of consent.
  2. Patient previously failed treatment with REMICADE or INFLECTRA/CT-P13.
  3. Any reported contraindications for INFLECTRA/CT-P13 or REMICADE.
  4. Known hypersensitivity (including severe, acute infusion reactions) to infliximab, its excipients or other murine proteins, at the time of enrolment.
  5. Patients with communication difficulties in reading or understanding the study consent or questionnaires
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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**

Immunocompromised

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## **Estimated number of subjects**

300

# Study design details

## **Outcomes**

Exposure variables are limited to the dosing and timing of administration of INFLECTRA, as well as the dose and frequency of disease related concomitant medications. Outcomes variables are primarily limited to the responses from various patients reported outcomes including the Harvey-Bradshaw Index (HBI), partial MAYO score, Simplified Inflammatory Bowel Disease questionnaire (SIBDQ), To describe real world clinical and economic outcomes in adult UC and CD cohorts who initiated therapy with INFLECTRA as their first biologic, switched to INFLECTRA from REMICADE or, switched to INFLECTRA from another biologic To describe real world patient reported quality of life in both the UC and CD cohorts who initiated therapy with INFLECTRA as their first biologic, switched to INFLECTRA

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## **Data analysis plan**

This study will be primarily descriptive in nature. All categorical endpoints will be summarized using both the number and percentage in each category. Continuous endpoints will be summarized in the form of means, standard deviation (SD), median, interquartile ranges (IQR) and range, a 95% confidence interval (CI) for the mean will also be computed. Pearson's chi squared tests will be used for bivariate statistical testing of categorical and ordinal outcomes. Student's t tests or 1 way ANOVA will be used for comparisons of continuous outcomes. For highly skewed, non normally distributed endpoints or sample sizes under 30 in either group, non parametric Wilcoxon rank sum test will be applied. All inferences will be made assuming a two sided test with an alpha of 0.05 without adjustment for multiplicity. Approaches to controlling for baseline differences between groups such as inverse probability weights may be considered.

## Documents

### Study results

[C1231006 NI Study Report Abstract.pdf](#) (1.72 MB)

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### Study report

[C1231006 NI Study Report.pdf](#) (1.51 MB)

## Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025.  
The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

## Data sources

### Data sources (types)

Other

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### Data sources (types), other

Prospective patient-based data collection

## 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