# Advanced treatment of ulcerative colitis using an Italian healthcare administrative database: drug utilization patterns, healthcare resource use and costs The MICHELANGELO study

**First published:** 04/05/2021

**Last updated:** 23/05/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS40896

**Study ID**

42877

**DARWIN EU® study**

No

**Study countries**

☐ Italy

**Study description**

This study will describe the population of users of advanced treatments for Ulcerative Colitis in Tuscany (Italy) between January 1st 2015 to December 31st 2019, including history of disease modifying anti rheumatic drugs (DMARDs) use, accesses to Emergency Department (ED), hospitalizations, access to specialist gastroenterology encounters by means of real world data. This study will also analyze health direct costs associated with the management of this population when treated with advanced treatment.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Unit of adverse drug reactions monitoring (UADRM), University Hospital of Pisa

Italy

**First published:** 08/01/2014

**Last updated:** 16/02/2024

**Institution** **Educational Institution** **Hospital/Clinic/Other health care facility** **ENCePP partner**

### Unit of adverse drug reactions monitoring (UADRM), University Hospital of Pisa

Italy

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

## Contact details


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Study contact

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**Primary lead investigator**

Matteo Fornai

Primary lead investigator


## Study timelines

**Date when funding contract was signed**

Planned: 23/04/2021

Actual: 23/04/2021

**Study start date**

Planned: 26/04/2021

Actual: 26/04/2021

**Date of final study report**
Planned: 17/05/2021

Actual: 04/09/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Galapagos Biopharma Italy S.r.l.

## Study protocol

MICHELANGELO study - protocol.pdf(1.33 MB)

## Regulatory

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

No

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

This study will describe the population of users of advanced treatments for Ulcerative Colitis in Tuscany (Italy) by means of real world data. This study will also analyze health direct costs (drugs, hospitalizations, ED accesses, specialist encounters) associated with the management of this population when treated with advanced treatment.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

ADALIMUMAB

GOLIMUMAB

INFLIXIMAB

TOFACITINIB

VEDOLIZUMAB

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**Medical condition to be studied**

Colitis ulcerative

# Population studied

**Short description of the study population**

Tofacitinib cohort

Inclusion criteria

Patients will be new users of tofacitinib between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a co-payemnt exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterological ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of tofacitinib in the look-back period (5 years before the index date). Patients will be followed up for one or two years after the index date.

Exclusion criteria

a) Patients with less than 5 years of records in the look back period

b) Patients with less than 1 year of follow-up

c) Patients receiving more than one of the advanced therapy (table 1) at the index date

d) patients with a diagnosis or a co-payment exemption code for Crohn’s

disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-), hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time in the look-back period. This criterion will identify only patients with prompt record (clinically relevant conditions)

e) patients aged ≤ 18 at index date

f) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 year before the index date

Adalimumab cohort

Inclusion criteria

Patients will be new users of an adalimumab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a co-payment exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of adalimumab in the look-back period (5 years before the index date). Patients will be followed up for

one or two years after the index date.

Exclusion criteria

a) Patients with less than 5 years of records in the look back period

b) Patients with less than 1 year of follow-up

c) Patients receiving more than one of the advanced therapy (table 1) at the index date

d) Patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-),

hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back period. This criterion will identify only patients with prompt record (clinically relevant conditions)
e) patients aged ≤ 18 at index date
f) patients with record of use of oral budesonide (box 1) in the 5 years before cohort entry
g) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 years before cohort entry

Golimumab cohort

Inclusion criteria
Patients will be new users of an golimumab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a tax exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of golimumab in the lookback period (5 years before the index date). Patients will be followed up for one or two years after the index date.

Exclusion criteria
a) Patients with less than 5 years of records in the look back period
b) Patients with less than 1 year of follow-up
c) Patients receiving more than one of the advanced therapy (table 1) at the index date
d) patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-),

hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back period. This criterion will identify only patients with prompt record (clinically relevant conditions)
e) patients aged ≤ 18 at index date
f) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 years before index date

Infliximab cohort
Inclusion criteria
Patients will be new users of an infliximab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a co-payment exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of infliximab in the look-back period (5 years before the index date). Patients will be followed up for one or two year after the index date.

Exclusion criteria
a) Patients with less than 5 years of records in the look back period
b) Patients with less than 1 year of follow-up
c) Patients receiving more than one of the advanced therapy (table 1) at the index date
d) patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-), hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back period. This criterion will identify only patients with prompt record (clinically

relevant conditions)
e) patients aged ≤ 18 at index date
f) patients with record of use of oral budesonide (box 1) in the 5 years before cohort entry
g) patients with records of visits in rheumatology ward (071) or dermatology ward (052) in the 1 years before index date.

Vedolizumab cohort
Inclusion criteria
Patients will be new users of an vedolizumab between January 1st, 2015 and December 31st, 2019 AND with a diagnosis OR a tax exemption code for UC in the lookback period or in the follow up OR a visit in a gastroenterology ward (code: 058) in the year before the index date. Index date will be the date of the first supply. We define new users each subject without supply of infliximab in the look-back period (5 years before the index date). Patients will be followed up for one or two years after the index date.

Exclusion criteria
a) Patients with less than 5 years of records in the look back period
b) Patients with less than 1 year of follow-up
c) Patients receiving more than one of the advanced therapy (table 1) at the index date
d) patients with a diagnosis or a co-payment exemption code for Crohn’s disease, rheumatoid arthritis, psoriasis, multiple sclerosis (G35.-), axial spondyloarthritis and ankylosing spondylitis (M45.-), psoriatic arthritis (L40.-), hidradenitis suppurativa / acne inversa (L73.2), uveitis intermedia, uveitis posterior und panuveitis (H20.-, H30.-) at any time during in the look-back period. This criterion will identify only patients with prompt record (clinically relevant conditions)

e) patients aged ≤ 18 at index date

f) patients with record of use of oral budesonide (box 1) in the 5 years before index date

**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)

**Special population of interest**

Immunocompromised

**Estimated number of subjects**

500

## Study design details

**Data analysis plan**

Descriptive analysis

## Documents

**Study results**

Report MICHELANGELO study (Final).pdf(1.98 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 source(s)**

ARS Toscana

**Data source(s), other**

ARS

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No