

# **PRED4**

# **Immunogenicity to biologic drugs in IBD (IMGEN)**

## **Case Report Form**

**Study (bar) Code**

NB: You may also enter data via the web-based portal on [www.ibdresearch.net](http://www.ibdresearch.net)

**On completion, please return to:**  
Exeter IBD and Pharmacogenetics Research Office  
The Research, Innovation, Learning and Development Centre (RILD)  
Barrack Road  
Exeter  
EX2 5DW

## PRED4 Immunogenicity to biologic drugs in IBD (IMGEN)

---

### 1.1 Inclusion Criteria

- Patient currently aged  $\geq 6$  years
- History of ulcerative colitis (UC) or Crohn's disease (CD)
- Biologic drug and antibody concentrations previously measured in Exeter, or patient prepared to give sample for this purpose.
- At time of drug and antibody measurement:
  - a. Biologic treatment duration  $>24$  months
  - Or
  - b. Treatment duration  $\leq 24$  months with episode of loss of response requiring escalation of immunomodulatory, steroid or biologic therapy, or withdrawal of current biologic therapy.
- Drug and antibody level taken at one of the following time points:
  - a. For patients still on drug: within 72 hours prior to the next dose of drug (trough level)
  - Or
  - b. For patients who have stopped drug: no sooner than 72 hours before and no later than one month after their next dose would have been due and before starting next biologic
- Patient has not participated in PANTS study.
- Patient is able to provide informed consent.

### 1.2 Patient eligibility

Is the participant eligible to take part in the research project based on the above criteria?

- Yes
- No

If no, please give reason(s) for screen failure:

Investigator's name (print)

Date

dd / mm / yyyy

## PRED4 Immunogenicity to biologic drugs in IBD (IMGEN)

---

### 2.1 Patients Details

Date of Birth

dd / mm / yyyy

Sex

M

F

Weight at 1st dose of current biologic drug

kg

### 2.2 Ethnicity – Please tick as appropriate

#### White

British

Irish

Any other white background  
(please specify)

#### Black or Black British

Caribbean

African

Any other Black background  
(please specify)

#### Mixed

White and Black Caribbean

White and Black African

White and Asian

Any other mixed background  
(please specify)

#### Asian or Asian background

Indian

Pakistani

Bangladeshi

Any other Asian background  
(please specify)

#### Chinese or Other Ethnic group

Chinese

Any other ethnic group (please specify)

Bangladeshi

Not stated

### 2.3 Participant informed consent

Date participant signed written consent form

dd / mm / yyyy

Date of blood sample taken

dd / mm / yyyy

Name of person taking consent (print)

Designation

Hospital name:

## PRED4 Immunogenicity to biologic drugs in IBD (IMGEN)

---

### 3.1 Other significant medical history

 Yes No

If yes please give details here

### 3.2 Smoking History

 Never Smoked Ex Smoker Current Smoker

3.2.1 Start date

3.2.2 End date

3.3.3 Maximum number of cigarettes per day

### 4.1 Diagnosis of IBD

 Crohn's disease

Date of diagnosis

 Ulcerative Colitis

Date of diagnosis

 IBD unclassified

Date of Diagnosis

## PRED4 Immunogenicity to biologic drugs in IBD (IMGEN)

---

### 5.1 Current biologic treatment

Infliximab    Adalimumab    Golimumab    Vedolizumab    Ustekinumab

### 5.2 Past Biologic treatment

#### Biologic

#### Reason for stopping

1. Primary non-response
2. Secondary loss of response
3. Adverse Events (specify)
4. Surgery (specify)
5. Elective withdrawal
6. Other (specify)

1<sup>st</sup> Biologic

2<sup>nd</sup> Biologic

3<sup>rd</sup> Biologic

4<sup>th</sup> Biologic

### 5.3 Start date of current biologic drug

dd / mm / yyyy

### 5.4 Starting dose of current biologic drug:

### 5.5 Stop date of current biologic drug (if applicable):

dd / mm / yyyy

### 5.6 Reason for stopping (if applicable):

- Primary non-response
- Secondary loss of response
- Adverse Events (specify):
- Surgery (specify)
- Elective withdrawal
- Other (specify):

## PRED4 Immunogenicity to biologic drugs in IBD (IMGEN)

---

### 5.7 Immunomodulator drugs at start of current biologic drugs:

Yes       No

### 5.8 Concomitant immunomodulator drug?

Drug	Dose, route and frequency
<input type="checkbox"/> Azathioprine	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Mercaptopurine	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Methotrexate	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Other (specify) <input style="width: 300px;" type="text"/>	<input style="width: 100%;" type="text"/>

### 5.9 Adverse reactions to biologic drugs (please specify):

### 6.1 Date serum sample sent to Exeter Lab:

### 6.2 Disease activity at time of serum sample:

Harvey Bradshaw Index       Simple Clinical Colitis Activity Index

#### Crohn's Disease- Harvey Bradshaw Index (HBI)

Number of liquid stools/day (score 1 per movement)		
Abdominal pain	None Mild Moderate Severe	0 1 2 3
Abdominal mass	None Dubious Definite Definite and tender	0 1 2 3
General wellbeing	Very well Slightly below par Poor Very poorly Terrible	0 1 2 3 4
Number of extra GI manifestations of IBD (score 1 per item)	Mouth ulcers Anal fissure, new fistula, perianal abscess, Erythema nodosum, Pyoderma gangrenosum	
<b>Total Score</b>		

## PRED4 Immunogenicity to biologic drugs in IBD (IMGEN)

### UC- Simple Clinical Colitis Activity Index

Symptom	Score	Symptom	Score
<b>Bowel frequency(day)</b>		<b>Blood in stool</b>	
1-3	0	Trace	1
4-6	1	Occasionally frank	2
7-9	2	Usually frank	3
>9	3	<b>General wellbeing</b>	
<b>Bowel frequency(night)</b>		Very well	0
1-3	1	Slightly below par	1
4-6	2	Poor	2
<b>Urgency of defecation</b>		Very poor	3
Hurry	1	Terrible	4
Immediately	2	Extra-colonic features	1 point each
Incontinence	3	<b>Total Score</b>	

### 6.3 Medications at time of serum sample

Medications	Dose, route and frequency

### 7.1 Other comments

If you have any other comments regarding this patient please give them here.

## PRED4 Immunogenicity to biologic drugs in IBD (IMGEN)

---

I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by myself or by a person under my supervision who have signed the delegation log .

Principal Investigator's signature

Date

dd / mm / yyyy

Principal Investigator's name (print)