

# Switching to the IL-23 inhibitor guselkumab for people with active inflammatory bowel disease (IBD) who previously used ustekinumab (SHIFT-IBD)

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<b>Registration date</b> 07/11/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/01/2026	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The SHIFT-IBD Study is looking at how well a medicine called guselkumab (also known by its brand name Tremfya) works for people with inflammatory bowel disease (IBD) who haven't had enough improvement with another medicine called ustekinumab. Researchers hope this study will help find better treatment options for people whose IBD is still active despite current therapies.

### Who can participate?

Adults aged 18 and over who have had a confirmed diagnosis of IBD (Crohn's disease, ulcerative colitis, or IBD unclassified) for at least six months may be eligible. Participants must have been treated with ustekinumab for at least 14 weeks and either still be on it or have stopped it recently. They must also have ongoing signs of disease activity seen during a recent colonoscopy and be starting guselkumab based on their doctor's recommendation.

### What does the study involve?

Participants will begin treatment with guselkumab as part of their regular care. Doctors can adjust the treatment as needed. The study will follow participants for one year, monitoring symptoms, test results, and overall health. The goal is to see how well guselkumab works and whether it helps control symptoms without worsening test results.

### What are the possible benefits and risks of participating?

Participants may benefit from improved symptom control if guselkumab works better for them than previous treatments. As with any medication, there may be side effects or risks, but guselkumab will be given according to standard medical guidelines, and doctors will monitor participants closely.

### Where is the study run from?

TIDHI Innovation Inc. (Canada)

When is the study starting and how long is it expected to run for?  
The study began in September 2024 and is expected to run until December 2027.

Who is funding the study?  
Janssen Canada.

Who is the main contact?  
kstaikin@tidhi.ca

## Contact information

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

NCT07245394

**Protocol serial number**

TIDHI\_001

## Study information

**Scientific Title**

SHIFT-IBD: Switching to high-efficacy anti-IL-23 guselkumab in ustekinumab-exposed persons with active IBD

**Acronym**

SHIFT-IBD

**Study objectives**

The goal is to explore better treatment options for people whose IBD has not been well controlled with current therapies.

Researchers believe that switching to guselkumab may be as effective as other advanced treatments. For those who saw some improvement on ustekinumab but not enough, guselkumab may offer better symptom control—without worsening results on medical tests like endoscopy.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 07/11/2025, Advarra IRB (125 Don Hillock Drive, Unit 18, Aurora, ON, L4G 0H8, Canada; +1 905-727-7989; info@advarra.com), ref: Pro00090978

**Study design**

Multicenter prospective observational non-interventional single-arm cohort study

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Inflammatory Bowel Diseases (IBD)

**Interventions**

Guselkumab:

Induction: 200 mg IV or 400 mg SQ at week 0, 4 and 8.

Maintenance: 200 mg SC every 4 weeks from week 12 onwards.

Follow up until week 52.

**Intervention Type**

Biological/Vaccine

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Guselkumab

**Primary outcome(s)**

1. Deep remission measured using clinical symptom assessment (absence of symptomatic worsening) and endoscopic evaluation, at Week 52, reported both overall and stratified by treatment cohorts.

**Key secondary outcome(s)**

Current secondary outcomes as of 02/01/2026:

1. Absence of symptomatic worsening measured using average daily stool frequency score (SFS) and abdominal pain score (APS) for Crohn's disease, and average daily stool frequency score (SFS) and rectal bleeding score (RBS) for ulcerative colitis, at Week 52

2. Endoscopic remission measured using Simple Endoscopic Score for Crohn's Disease (SES-CD) for Crohn's disease and Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score for ulcerative colitis, at Week 52

3. Endoscopic response measured using change from baseline in SES-CD for Crohn's disease and UCEIS for ulcerative colitis, at Week 52

4. Absence of symptomatic worsening at any study visit measured using SFS and APS for Crohn's disease, and SFS and RBS for ulcerative colitis, at Week 4, Week 12, Week 32, and Week 52

5. Symptomatic remission among participants not in remission at baseline measured using SFS

and APS for Crohn's disease, and SFS and RBS for ulcerative colitis, at Week 12 and Week 52

6. Steroid-free remission among corticosteroid users at baseline measured using absence of corticosteroid use and meeting symptomatic remission criteria (SFS and APS for Crohn's disease, SFS and RBS for ulcerative colitis), at Week 52

7. Discontinuation of guselkumab therapy measured using study treatment records, at Week 4, Week 12, Week 32, and Week 52

Previous secondary outcomes:

1. Absence of symptomatic worsening measured using average daily stool frequency score (SFS) and abdominal pain score (APS) for Crohn's disease, and modified partial Mayo score (m-pMS) for ulcerative colitis, at Week 52
2. Endoscopic remission measured using Simple Endoscopic Score for Crohn's Disease (SES-CD) for Crohn's disease and Mayo endoscopic subscore for ulcerative colitis, at Week 52
3. Endoscopic response measured using change from baseline in SES-CD for Crohn's disease and Mayo endoscopic subscore for ulcerative colitis, at Week 52
4. Absence of symptomatic worsening at any study visit measured using SFS and APS for Crohn's disease, and m-pMS for ulcerative colitis, at Week 4, Week 12, Week 32, and Week 52
5. Symptomatic remission among participants not in remission at baseline measured using SFS and APS for Crohn's disease, and m-pMS for ulcerative colitis, at Week 12 and Week 52
6. Steroid-free remission among corticosteroid users at baseline measured using absence of corticosteroid use and meeting symptomatic remission criteria (SFS and APS for Crohn's disease, m-pMS for ulcerative colitis), at Week 52
7. Discontinuation of guselkumab therapy measured using study treatment records, at Week 4, Week 12, Week 32, and Week 52

## **Completion date**

31/12/2027

# **Eligibility**

## **Key inclusion criteria**

Current inclusion criteria as of 02/01/2026:

1. Subjects of any gender aged  $\geq 18$  years.
2. Confirmed diagnosis of IBD (CD, UC, or IBDU) for at least 6 months prior to baseline visit. Subjects with IBDU will be grouped with subjects with UC. The CD proportion of patients will be capped at 75%.
3. Subjects have received ustekinumab for at least 14 weeks and who are currently on or recently discontinued ustekinumab therapy.
4. For subjects that have recently discontinued ustekinumab, the last dose of ustekinumab must have been within 12 weeks before Week 0, and no other advanced therapy (i.e., infliximab, adalimumab, golimumab, certolizumab pegol, vedolizumab, natalizumab, risankizumab, mirikizumab, tofacitinib, upadacitinib, ozanimod, etrasimod) was started since stopping ustekinumab.
5. Subjects with an inadequate response to ustekinumab who require a change in advanced therapy and are initiating guselkumab, as determined by the treating physician.
6. For subjects on off-label ustekinumab dosing (90 mg every 4 or 6 weeks (off-label dosing), enrollment will be capped at 60%.
7. Ability and willingness to give written informed consent and comply with the requirements of this study protocol.
8. Subjects who have evidence of ongoing endoscopic evidence of disease activity within 3 months prior to Week 0, defined as:

\* For Crohn's Disease: Colonoscopy showing SES-CD score (excluding the presence of narrowing component) of  $\geq 6$  (or  $\geq 4$  for participants with isolated ileal disease), OR presence of ulcers larger than 5 mm in any segment.

\* For Ulcerative Colitis: Colonoscopy showing Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score  $\geq 4$ , OR presence of erosions or ulcers in any segment.

Previous inclusion criteria:

1. Subjects of any gender aged  $\geq 18$  years

2. Confirmed diagnosis of IBD (CD, UC, or IBDU) for at least 6 months prior to baseline visit.

Subjects with IBDU will be grouped with subjects with UC. The CD proportion of patients will be capped at 75%.

3. Subjects have received ustekinumab for at least 14 weeks and who are currently on or recently discontinued ustekinumab therapy.

4. For subjects that have recently discontinued ustekinumab, the last dose of ustekinumab must have been within 12 weeks before Week 0, and no other advanced therapy (i.e., infliximab, adalimumab, golimumab, certolizumab pegol, vedolizumab, natalizumab, risankizumab, mirikizumab, tofacitinib, upadacitinib, ozanimod, etrasimod) was started since stopping ustekinumab.

5. Subjects with an inadequate response to ustekinumab who require a change in advanced therapy and are initiating guselkumab, as determined by the treating physician.

6. For subjects on off-label ustekinumab dosing (90 mg every 4 or 6 weeks (off-label dosing), enrollment will be capped at 60%.

7. Ability and willingness to give written informed consent and comply with the requirements of this study protocol.

8. Subjects who have evidence of ongoing endoscopic evidence of disease activity within 3 months prior to Week 0, defined as:

\* For Crohn's Disease: Colonoscopy showing SES-CD score (excluding the presence of narrowing component) of  $> 6$  (or  $> 4$  for participants with isolated ileal disease), OR presence of ulcers larger than 5 mm in any segment.

\* For Ulcerative Colitis: Colonoscopy showing Mayo endoscopic subscore  $\geq 2$  in any segment, OR presence of erosions or ulcers in any segment.

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Mixed

## **Lower age limit**

18 years

## **Upper age limit**

100 years

## **Sex**

All

## **Total final enrolment**

**Key exclusion criteria**

1. History of prior exposure to any anti-p19 inhibitor (risankizumab or mirikizumab).
2. Subjects with formal contraindication to guselkumab per the drug label.
3. Use of guselkumab for an off-label indication, dosing regimen, or route of administration. Subjects who did not receive guselkumab induction will be excluded.
4. Subjects with an ostomy or ileo-anal pouch.
5. Subjects with a history of bowel surgery within 6 months prior to Week 0.
6. Subjects displaying clinical signs of acute severe UC, fulminant colitis or toxic megacolon within 3 months prior to Week 0.
7. Subjects who are expected to require bowel surgery by their IBD physician within the year of enrollment.
8. Subjects on 1 or more concomitant biologics.
9. Subjects with a history of colonic dysplasia (low-grade dysplasia, high-grade dysplasia, or colorectal cancer). Note: Patients with a history of indefinite for dysplasia would be eligible.
10. Subjects with formal contraindication or unwilling to undergo lower endoscopy.
11. The patient is considered by the Investigator, for any reason, to be an unsuitable candidate for the study.

**Date of first enrolment**

29/12/2025

**Date of final enrolment**

31/12/2026

**Locations****Countries of recruitment**

Canada

**Study participating centre**

**Toronto Immune and Digestive Health Institute**

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**Sponsor information****Organisation**

TIDHI Innovation Inc.

**Funder(s)**

**Funder type**

Industry

**Funder Name**

Janssen Canada

**Alternative Name(s)**

Janssen Inc., Janssen, Janssen Ortho Inc

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Canada

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes