VOICE Study Factsheet

Early response to vedolizumab and interleukin (IL)-23 antagonist therapy in participants with Crohn's disease: A prospective observational study

TRIAL STATUS
Active, Recruiting

START DATE
March 20th 2024

PLANNED COMPLETION DATE
September 2026

PHASE:
1 2 3 **4**

CLASS
Gut-selective immunosuppressive biologic[1]

Learn more at clinicaltrials.gov

Dosage & Administration[2]

Population[2]
Patients residing in Canada and the USA with CD who are prescribed vedolizumab or IL-23 antagonist therapy for the first time as SOC

Study Design[2]
✔ Prospective ✔ Observational

Primary Outcome Measures[2]

Select Secondary Outcome Measures[2]

CD, Crohn's disease; **SOC**, standard of care; **US**, United States; **IL-23**, interleukin-23

References

1. Takeda Pharmaceuticals. Entyvio® (vedolizumab) SmPC. Swissmedic: June 2024 [Accessed January 2026]. Available from: https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=63285
2. VOICE-Early Response to Vedolizumab and Ustekinumab in Participants With Crohn's Disease: A Prospective Observational Study. ClinicalTrials.gov Identifier: NCT06249555. Last updated: 8 January 2026. Last accessed: 26 January 2026. https://clinicaltrials.gov/study/NCT06249555

Contact: Takeda Pharma AG, Thurgauerstrasse 130, 8152 Glattpark (Opfikon)
VV-MEDMAT-132577 | February 2026

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Dosage & Administration[2]

- **Vedolizumab:** Dose, frequency, and duration are not mandated as part of the study and are determined by the health care provider.
- **IL-23 antagonist therapy:** Dose, frequency, and duration are not mandated as part of the study and are determined by the health care provider.

IL-23, interleukin-23

Population[2]

Patients residing in Canada and the USA with CD who are prescribed vedolizumab or IL-23 antagonist therapy for the first time as SOC

Estimated enrollment
300 participants

Select Inclusion criteria[2]

- Adult with confirmed CD as per standard clinical criteria
- Has active CD, has been prescribed SOC, and is due to begin treatment with vedolizumab or IL-23 antagonist therapy for the first time
- Has baseline PROMIS pain interference-SF score ≥15, which corresponds to T-score ≥55
- Has completed all SOC assessments
- Has full comprehension of consent language

Select Exclusion criteria[2]

- CD-related surgery planned or anticipated
- Prior exposure to advanced therapy other than anti-TNF
- Prior failure of >1 anti-TNF (infliximab, adalimumab, or certolizumab pegol) therapy
- Active infection at baseline requiring intravenous systemic antibiotics
- Evidence of *C. difficile* toxin or receiving treatment for *C. difficile* or other intestinal pathogen infection ≤2 weeks prior to screening
- Has chronic non-inflammatory bowel disease pain

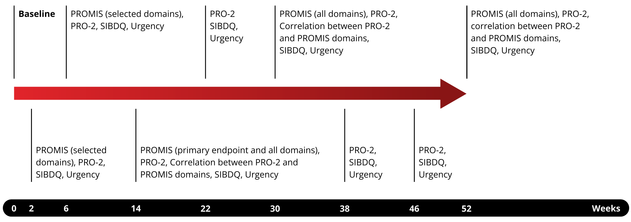
This is not a complete list of Inclusion and Exclusion Criteria. Before making any decision regarding trial enrollment, please consult the complete list at: https://clinicaltrials.gov/study/NCT06249555

CD, Crohn's disease; **IL-23**, interleukin-23; **PROMIS**, patient reported outcomes measurement information system; **SF**, short form; **SOC**, standard of care; **T-score**, number of standard deviations away from the mean of the t distribution; **TNF**, tumor necrosis factor; **US**, United States

Study Design[2]

✔ Prospective ✔ Observational

A prospective, observational study to explore the time course of early response to newly prescribed vedolizumab treatment, as measured by PROMIS Pain Interference-SF, as well as other PROMIS domain SFs and assessment of other PRO measures



Primary endpoint: Time-to-improvement for the primary endpoint will be calculated as the first timepoint at which the PROMIS Pain Interference-SF T-score shows a ≥2-point decrease from baseline, for both vedolizumab and IL-23

Figure created based on the study design of the clinical trial[2]

PROMIS, patient-reported outcomes measurement information system; **PRO**, patient-reported outcome; **PRO-2**, 2-item patient-reported outcome; **SF**, short form; **SIBDQ**, Short Inflammatory Bowel Disease Questionnaire; **IL-23**, interleukin-23; **VDZ**, vedolizumab; **W**, week

Primary Outcome Measures[2]

- Time to meaningful clinical improvement in pain interference, defined as a ≥2-point decrease from baseline in the PROMIS Pain Interference-SF T-score

PROMIS, patient reported outcomes measurement information system; **SF**, short form; **T-score**, number of standard deviations away from the mean of the t distribution

Select Secondary Outcome Measures[2]

- Time to meaningful clinical improvement for each individual PROMIS domain, defined as a ≥2-point change in the direction of improvement in the respective PROMIS domain T-score
- Meaningful clinical improvement in each individual PROMIS domain at W14, W30, and W52
- Early changes across PROMIS domains at W2, W6, and W14
- SIBDQ improvement, SIBDQ remission, PRO-2 clinical response, and PRO-2 clinical remission at W2, W6, W14, W22, W30, W38, W46, and W52

PRO-2, 2-item patient-reported outcome; **PROMIS**, patient reported outcomes measurement information system; **SF**, short form; **SIBDQ**, Short Inflammatory Bowel Disease Questionnaire; **T-score**, number of standard deviations away from the mean of the t distribution; **W**, week

CD, Crohn's disease; **SOC**, standard of care; **US**, United States

References

1. Takeda Pharmaceuticals. Entyvio® (vedolizumab) SmPC. Swissmedic: June 2024 [Accessed January 2026]. Available from: https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=63285
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