

# VEDOLIZUMAB

2013

GEMINI I

Phase 3 RCT/ VDZ vs placebo /active UC/ Induction+ Maintenance.

Conclusion:

**VDZ more effective than placebo as induction and maintenance therapy for UC.**

2014

GEMINI II

Phase 3 RCT/ VDZ vs placebo/ active CD/ Induction+ Maintenance

Conclusion:

**VDZ in CD better than placebo to achieve remission but not CDAI-100 response w6.  
Those who responded to induction & continued on VDZ more likely to be in remission at w52.**

2014

GEMINI III

Phase 3/ VDZ/ CD-failed to antiTNF/ Induction

Conclusion:

**VDZ not more effective than placebo in inducing clinical remission at w6 in CD with previous TNF antagonists exposure. The therapeutic benefits of VDZ in these patients were detectable at week 10.**

2019

VARSHITY

Phase 3b/ VDZ vs ADA/ active UC/ Induction of remission

Conclusion:

**VDZ was superior to ADA in mod-sev UC with respect to clinical remission and endoscopic improvement but not steroid-free clinical remission.**

2019

VERSIFY

Phase 3b / VDZ / CD / Endoscopic remission

Conclusion:

**Treatment with Vedolizumab in moderate-severe CD induces endoscopic, radiologic and histologic healing at 26 and 52w.**

VEDOLIZUMAB  
II

2019

LOVE-CD

OL/ active CD / endoscopy and clinical outcomes

Conclusion:

**One-third of patients with CD achieve remission after 52w treatment of Vedolizumab. Two-thirds achieved histologic remission at w26.**

2020

GEMINI LTS

Phase 3 OL/ UC and CD active disease/ from previous GEMINI trials

Conclusion:

**The safety profile of VDZ remains favourable with no unexpected or new safety concerns. These results further establish the safety of VEDO and support its long-term use**

2020

VISIBLE 1

Phase 3/ VDZ IV vs SC vs placebo/ active UC / efficacy and safety

Conclusion:

**Subcutaneous VDZ is effective as maintenance therapy in mod-sev active UC who had a clinical response to IV VDZ induction therapy. It has a favorable safety and tolerability profile.**

2020

CONCEIVE

Observational/ VEDO IV and TNFinh exposure/ pregnant IBD / Safety

Conclusion:

**No new safety signal was detected in VDZ pregnancies.**

2020

PIANO

Observational/Biologics &/or thiopurines/ IBD pregnant/ Safety

Conclusion:

**Biologic, thiopurine, or combination therapy exposure during pregnancy was not associated with increased adverse maternal or fetal outcomes at birth or within the first year of life.**

VEDOLIZUMAB  
III

2021 TRAVELESS

Observational/ VEDO IV vs SC / CD and UC/ Maintenance  
Conclusion:  
**Transitioning patients established on IV VDZ to SC appears to be safe and effective, with high patient satisfaction and multiple benefits for the health service.**

2021 CLARITY

Observational/ Biologics and immunosuppressants/ IBD and SARS-CoV2/ antibody response  
Conclusion:  
**IFX is associated with attenuated serological response to SARS-CoV-2 that were further blunted by immunomodulators used as concomitant therapy.**

2022 VISIBLE 2

Phase 3b/ VEDO IV vs SC/ active CD / efficacy and safety  
Conclusion:  
**Vedolizumab SC is an effective and safe maintenance therapy in patients with CD who responded to two infusions of vedolizumab intravenous induction therapy**

2022 ENTERPRISE

Phase 4 / VDZ IV (0,2,6,14 &22) vs VDZ IV (0,2,6,10,14,22)/ perianal CD /reduction fistula drainage at w30  
Conclusion:  
**Sustained improvements (over 50%) in fistulizing CD were seen with both vedolizumab regimens.**

2022 VIP

Observational /Biologics & immunosuppressants/ IBD and COVID vaccine / Response to vaccine  
Conclusion:  
**For patients with IBD, the immunogenicity of COVID-19 vaccines varies according to immunosuppressive drug exposure, and is attenuated in recipients of IFX, IFX+thiopurines and TOFA.**

VEDOLIZUMAB  
IV

2022  
HUBBLE

Phase 2/ VDZ pediatric IBD/ pharmacokinetics  
Conclusion  
**Vedolizumab exposure increased in an approximate dose-proportional manner. No clear dose-response relationship was observed in this limited cohort. No new safety signals were identified.**

2023  
VEDOKIDS

Prospective cohort/ VDZ in kids with IBD/Induction of remission  
Conclusion  
**VDZ safe and effective at inducing remission in children with IBD at 14 weeks, especially those with UC. In children who weigh less than 30 kg, VDZ should be dosed by the child's body surface area (200 mg/m<sup>2</sup>) or weight (10 mg/kg)**

2023  
EARNEST

RCT/ VEDO IV vs placebo / UC pouchitis/ Induction  
Conclusion:  
**Treatment with vedolizumab was more effective than placebo in induction in patients who had chronic pouchitis after undergoing IPAA for ulcerative colitis.**

2022  
VISIBLE 2

Phase 3b/ VEDO IV vs SC/ active CD / efficacy and safety  
Conclusion:  
**Vedolizumab SC is an effective and safe maintenance therapy in patients with CD who responded to two infusions of vedolizumab intravenous induction therapy**