

# USTEKINUMAB

2012

CERTIFI

Phase 2b RCT/ UST vs placebo/CD/ Induction& Maintenance

Conclusion:

**Moderate-to-severe CD resistant to TNF antagonists had an increased rate of response to induction with UST vs placebo. Patients with an initial response to UST had significantly increased rates of response and remission with UST as maintenance therapy.**

2016

UNITI 1&2

Phase 3 RCT/ UST vs placebo in mod-severe CD / Induction& Maintenance

Conclusion:

**UST better than placebo. Subcutaneous UST maintained remission in patients who had a clinical response to induction therapy.**

2016

IM-UNITI

Phase 3 RCT/ UST / CD / Safety & Maintenance

Conclusion:

**UST better than placebo to maintain remission in moderate-active CD.  
No safety concerns compared to placebo.**

2019

UNIFI

Phase 3 RCT/ UST vs placebo in mod-severe UC/ Induction & Maintenance

Conclusion:

**UST more effective than placebo for inducing & maintaining remission in patients with mod-severe UC.**

2021

UNISTAR

phase 1 RCT/pediatric CD/

Conclusion:

**Pharmacokinetics/safety profiles were generally consistent with those observed in adults with Crohn's disease**

USTEKINUMAB  
II

2022

STARDUST

OL-phase 3b trial/ T2T vs SoC (standard of Care) in CD with UST.

Conclusion:

**Timely escalation of UST in CD, based on early endoscopic response, clinical symptoms, and biomarkers, not better endoscopic outcomes at week 48 than symptom-driven decisions alone**

2022

SEAVUE

Phase 3b RCT/ ADA vs UST/ mod-severe CD naïve to biologics/ Induction & Maintenance

Conclusion:

**ADA and UST monotherapies highly effective in CD biologic-naïve, with no difference in the clinical remission w52 between the drugs.**

2022

SUSTAIN

Observational study/ UST/ CD / Effectiveness

Conclusion:

**UST was demonstrated to be effective in real-world use in the short and long run. Safety was consistent with the known profile of UST.**