

### A study to evaluate the safety and efficacy of ustekinumab maintenance therapy in patients with moderate to severe active CD (IM-UNITI)

Patients with moderate to severe CD who responded to induction in UNITI I and II entered IM-UNITI trial and were randomized to UST 90 SC q8w, UST90mg q12w or placebo.  
Patients followed to 44w.

Primary outcome: Remission w44

Secondary outcomes: response w44; free steroid remission

#### Results:

- Remission w44: 53.1% 90UST q8 vs 48.8% 90UST q12 vs 35.9% pbo;  $p=0.005$  /  $p=0.04$
- Adverse-event rates were similar among treatment groups.

#### Conclusions:

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

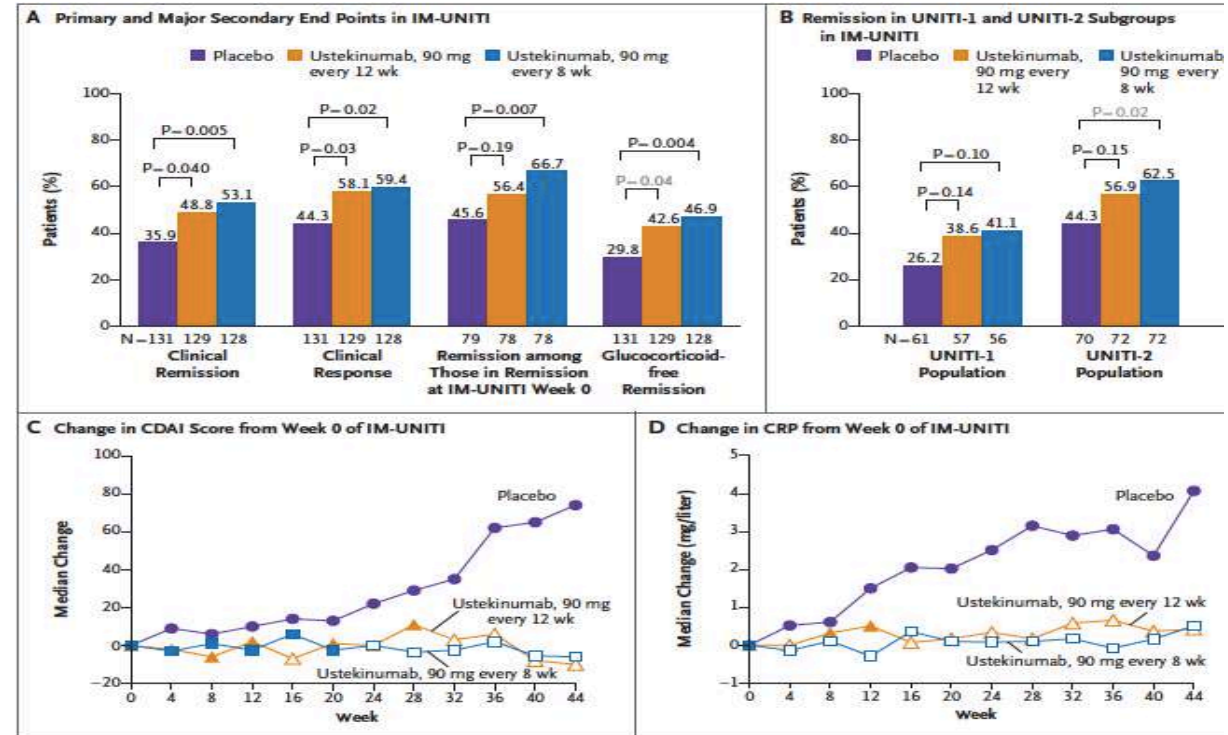


Figure 3. Patient Responses to Maintenance Therapy.

