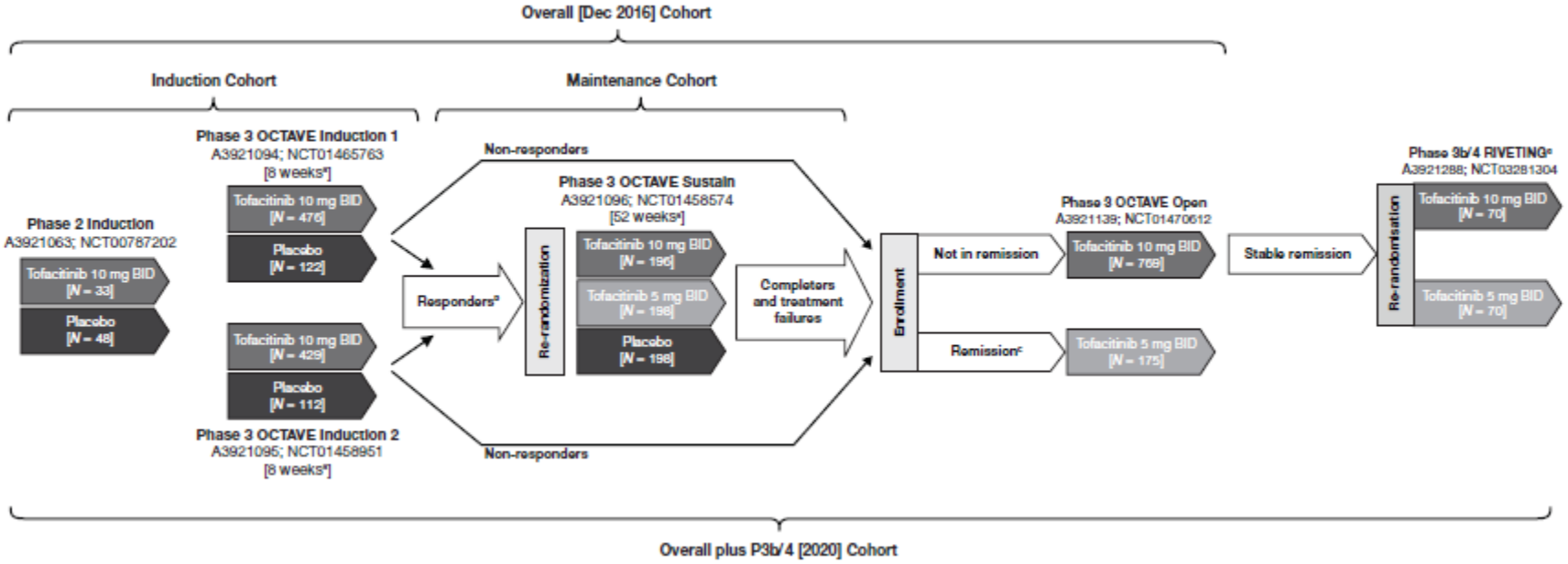
Supplementary Figure 1. Study design and analysis cohorts



Adapted from Winthrop et al 2018 [in accordance with the CC BY-NC license];[10] the Overall [Dec 2016] Cohort includes data from OCTAVE Open, as of December 16, 2016 [total tofacitinib exposure ≤4.4 years]; the Overall plus P3b/4 [2020] Cohort includes final data from OCTAVE Open [final data cut-off: August 24, 2020], and data from RIVETING [interim data cut-off: February 20, 2020; ≤7.8 years].

[a]Final complete efficacy assessment at Week 8/52. Treatment continued up to Week 9/53.

[b]Clinical response in OCTAVE Induction 1 and 2 was defined as a decrease from baseline total Mayo score of ≥3 points and ≥30%, plus a decrease in rectal bleeding subscore of ≥1 point or an absolute rectal bleeding subscore of 0 or 1.

[c]Treatment failure was defined as a ≥3-point increase in total Mayo score from baseline of OCTAVE Sustain, along with a ≥1-point increase in rectal bleeding and

endoscopic subscores after a minimum of 8 weeks of treatment.

[d]Remission was defined as a total Mayo score of ≤2 with no individual subscore >1, and a rectal bleeding subscore of 0.

[e]Patients entering RIVETING had previously received tofacitinib 10 mg BID for ≥2 consecutive years in OCTAVE Open, were in stable remission for ≥6 months prior to baseline, and had not received corticosteroids for UC for ≥4 weeks prior to baseline.

BID, twice daily; N, number of patients treated in the treatment group; UC, ulcerative colitis.