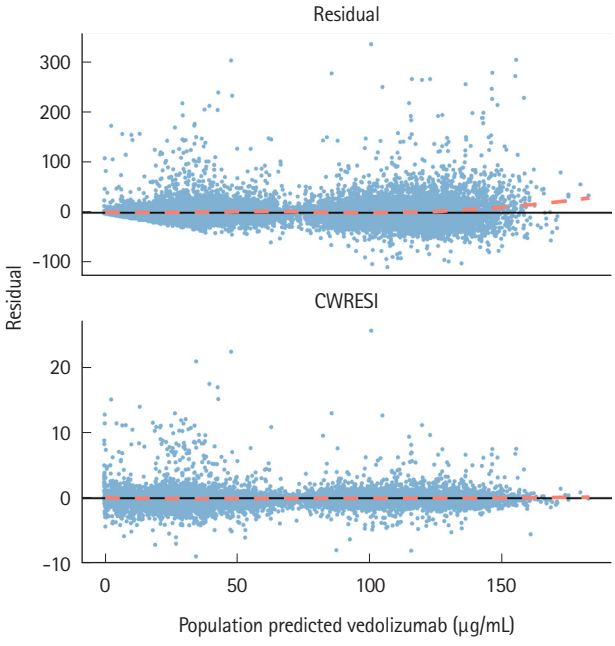
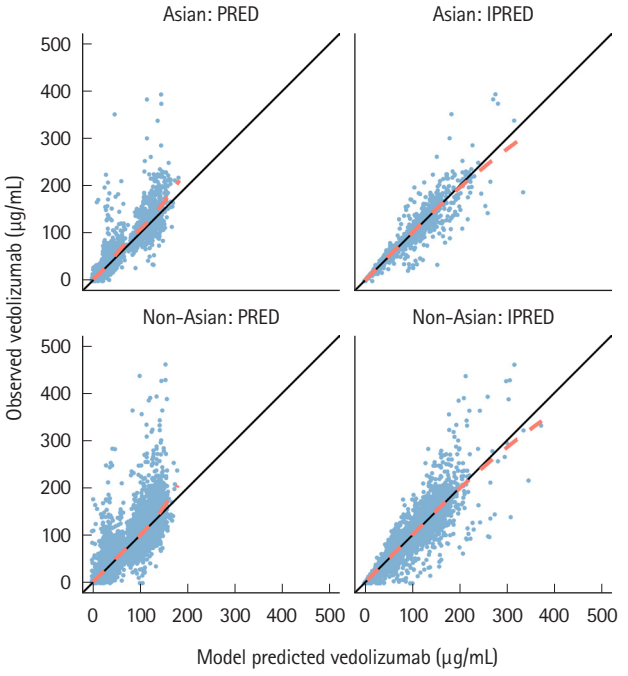
Supplementary Table 1. Continued

Study identifier	Study design/study population/ geographic region	Dosing regimen	Participants enrolled/ with PK	Sampling times†
GEMINI 2 (NCT00783692)	Phase 3, 52-wk, randomized, placebo-controlled, double-blind, multicenter study of efficacy and safety of VDZ induction and maintenance therapy. Patients with moderately to severely active CD and demonstrated inadequate response to, loss of response to, or intolerance of 1 or more of the following agents: corticosteroids (ex-US only), immunomodulators, or TNF-α antagonists (aged 18–80 yr). Sites in North America, Western/ Northern Europe, Central Europe, Eastern Europe, and Asia/Australia/ Africa.	Multiple IV doses Induction (wk 0, 2): VDZ 300 mg Placebo Maintenance (wk 6-52): VDZ 300 mg Q4W VDZ 300 mg Q8W Placebo	Induction ITT: VDZ = 220 Placebo = 148 Induction non-ITT: VDZ = 747 Maintenance ITT: VDZ Q4W = 154 VDZ Q8W = 154 Placebo = 153 Maintenance non-ITT: VDZ Q4W = 506 Placebo = 148 PK = 827	PK: wk 0, 2, 6, 22, and 46 (predose [within 30 min before start of infusion] and postdose [within 2 h after start of infusion]); wk 14 and 38 (predose); wk 4 and 52 (anytime during visits). AVA: wk 0, 6, 14, 26, 38, 52 (or ET), 66 (or Final Safety visit) and at the time of disease exacerbation. Samples were collected predose, if applicable.

PK, pharmacokinetics; IV, intravenous; VDZ, vedolizumab; AVA, anti-vedolizumab antibody; Q8W, every 8 weeks; ET, early termination; Q4W, every 4 weeks; ITT, intent to-treat; CD, Crohn's disease; UC, ulcerative colitis.



Supplementary Fig. 1. Goodness-of-fit plots for the vedolizumab final population pharmacokinetic model: residual and conditional weighted residual with interaction (CWRESI) versus population predicted vedolizumab concentration. Values are shown as points with a dashed red loess trend line through the data. A solid black line at y = 0 is shown for reference.



Supplementary Fig. 2. Goodness-of-fit plots for the vedolizumab final population pharmacokinetic model: observed vedolizumab concentrations versus population (PRED) and individual predicted (IPRED) vedolizumab concentration. Results are stratified by race. Values are shown as points with a dashed red loess trend line through the data. The line of identity (solid black) is shown for reference.