Introduction
Tofacitinib is an oral partially selective Janus kinase inhibitor approved for the treatment of refractory moderate to severe ulcerative colitis (UC). Real-world experience of patients with UC treated with tofacitinib is however limited, and safety concerns over the risk of venous thromboembolism (VTE) have recently emerged. Further, factors linked to primary non-response remain poorly defined. We therefore sought to define the effectiveness and safety of tofacitinib in a real-world cohort.

Methods
We conducted a retrospective observational cohort study of 134 patients with UC (64% male; median age 37 years [range 16–81]; 83% patients had previously received at least one biologic) treated with tofacitinib from October 2018 to October 2019 in four UK centres. Disease activity was assessed using the Simple Clinical Colitis Activity Index (SCCAI) or Partial Mayo Score (PMS) depending on study site. Response and remission were defined as a reduction in SCCAI or PMS of ≥3, and SCCAI ≤2 or PMS ≤1, respectively.

Results
Overall, 74% (88/119; 95% CI 65–81%) of patients responded to tofacitinib at week 8 and steroid free remission was observed in 44% (47/108; 95% CI 34%-53%) patients at week 26 (figure 1). Endoscopy was undertaken in 90 patients (67%) at baseline with routine follow-up endoscopy in 11 patients at week 8 and 34 patients at week 14. Median baseline UCEIS was 5 (IQR 4–6) falling to 2 (1–6) at week 8 and 2 (1–4) at week 14.

Primary non-response was independently associated with younger age (p=0.014) and higher baseline CRP (p=0.004). Prior biologic exposure did not influence response or remission rates. Continuing tofacitinib in the setting of primary non-response was rarely helpful. Dose escalation recaptured response in 9/19 patients who lost response. Dyslipidaemia was observed in 20% (27/134; 95% CI 14%-28%) of patients but no major adverse cardiovascular events occurred. Seven patients had serious infections, with herpes zoster in 3 patients. Overall, adverse events that curtailed treatment were uncommon and no VTE occurred.

Conclusions
In this multi-centre real-world cohort, tofacitinib was well tolerated and clinically effective in a treatment refractory UC population.