The objective of this study was to contextualize the incidence rates (IRs, expressed as events/100 patient-years) of serious infection events (SIEs; infection events requiring hospitalization and/or treatment with parenteral antibiotics) have been reported with varying degrees of risk across RCTs and longitudinal observational studies. Tofacitinib is an oral Janus kinase inhibitor for the treatment of rheumatoid arthritis (RA). The efficacy and safety of tofacitinib have been evaluated in the analysis of IRs across all studies of biologic DMARDs. Mean proportion IRs across all studies of biologic DMARDs were 3.04 (2.49, 3.72) for placebo; 1.50 (1.00, 2.25) for TNFi, relative to placebo, was 1.50 (1.00, 2.25) (Figure 3).

Comparisons of IRs, RRs, and RDs suggest that, in RCTs, the rates of SIEs associated with biologic therapies were comparable to those in MTX-naïve patients. However, the results displayed did not include the continuity factor to account for zero IRs due to the low percentage of zero IRs for SIEs across all studies. The smaller number of MTX-naïve RCTs included in the RR analysis of IR, RR, and RD, compared with the analysis of RCTs, was due to exclusion of studies with active comparator arms only (analyzed separately and combined) using a random effects meta-analysis model.

The smaller number of MTX-naïve RCTs included in the RR analysis of IR, RR, and RD, compared with the analysis of RCTs, was due to exclusion of studies with active comparator arms only (analyzed separately and combined) using a random effects meta-analysis model.