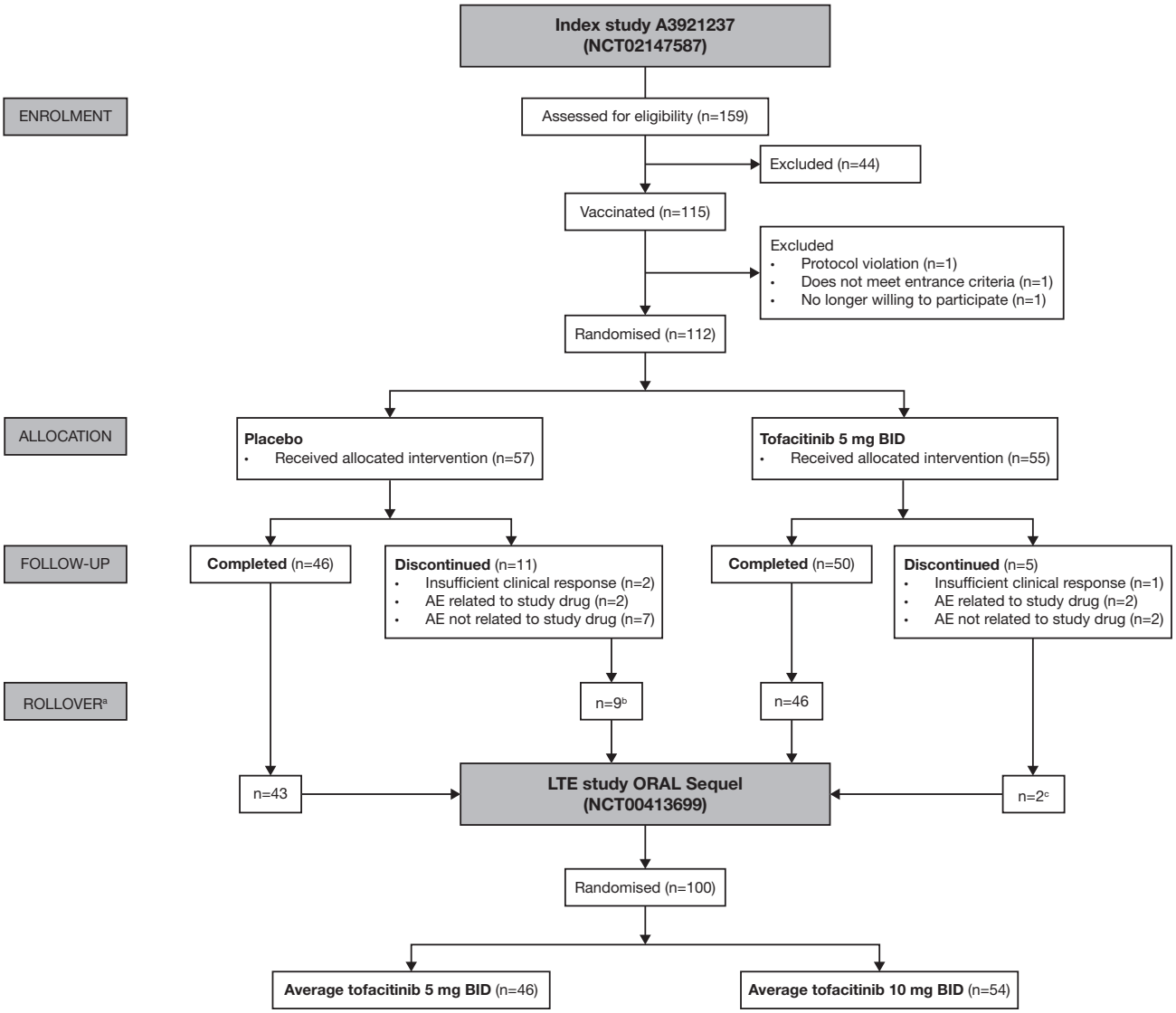
Figure S1 CONSORT flow diagram



[a]In total, 12 patients from Study A3921237 did not roll over into ORAL Sequel; reasons for non-participation: investigator decision (n=2); patient no longer willing to participate (n=4); patient had serious AE (n=2); other reason (e.g. patient resides too far from study site; n=4);

[b]Includes two patients who discontinued due to insufficient clinical response and seven patients who discontinued due to AEs;

[c]Includes one patient who discontinued due to insufficient clinical response and one patient who discontinued due to AEs

AE, adverse event; BID, twice daily; LTE, long-term extension