Study Design –
Potential Key Performance Indicators (KPIs)

Output indicators

☐ Proportion of exclusion criteria with ethical or scientific justification within study protocol
☐ Protocol contains study question, epidemiology of disease, and target population
☐ Adjustment to protocol or data collection/analysis based on patient input
☐ Case report forms available at site contains all relevant data variables
☐ Data analysis plan contains all planned subgroup analysis
☐ Data analysis plan contains all planned testing for heterogeneity of treatment effect

Outcome indicators

☐ Granular demographic and non-demographic data collected in trial per data analysis plan
☐ Planned subgroup analysis performed and reported
☐ Planned heterogeneity of treatment effect testing performed and reported