

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