

Recruitment Strategy Documents – Potential Key Performance Indicators (KPIs)

Output indicators

- Trial-level recruitment plan for diversity available at site, including all the proposed elements to consider (See Achieving Diversity, Inclusion and Equity in Clinical Trials Guidance Document, Table 12, Part E, Section 13.5)
- Site-specific recruitment plan for diversity available at site
- Monitoring mechanisms for recruitment targets by demographic established
- Suggested recruitment strategies tailored to target population(s) available at site

Outcome indicators

- Site investigator-reported understanding of diversity enrollment objectives
- Data on demographic profile of enrolled participants available to sponsor in a suitable amount of time
- In the case that demographic profile data indicate site will not meet target enrollment of target subpopulation, contingency plan implemented