

Logic Model: Study Design

Audience: Sponsors/CROs, sites/investigators

Purpose: To provide a sample of activities, linked to their intended effects (outputs, outcomes and impact), that might be considered during study design for a clinical trial aiming to enroll a representative population. A non-exhaustive sample of key performance indicators for such a study design is also provided in order to demonstrate how this logic model can be used to construct performance metrics.

Considerations for use:

- See *Introduction to Logic Models* for detailed instruction on the use of logic models in general and as related to the *Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document*.
- Most activities defined in this logic model are routine in a typical study design process. The logic model provides a framework for thinking about these activities through the lens of diverse enrollment.

Logic Model: Study Design

Audience: Sponsors/CROs, sites/investigators

