Logic Model: Recruitment Strategy Documents (RSDs)

**Audience:** Sponsors/CROs, sites/investigators

**Purpose:** To provide a sample of activities, linked to their intended effects (outputs, outcomes and impact), that might be included in Recruitment Strategy Documents (RSDs) aimed at achieving representative enrollment during a particular clinical trial. A non-exhaustive sample of key performance indicators for the RSD 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*. 
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**Inputs**
- Value for resources
- Staff time
- Study design (epidemiologic profile of disease)
- Feasibility assessment

**Activities**
- Create and distribute trial-level RSD for diversity
- Create and distribute site-specific RSD for diversity
- Build monitoring mechanism for sites, with benchmarks based on feasibility assessment data
- Develop and distribute suggested recruitment strategies tailored to target population(s)
- Develop contingency plan for sites not expected to meet target population(s) enrollment targets

**Outputs**
- Trial-level recruitment plan for diversity available at site
- 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
- Contingency plan described in recruitment plan

**Outcomes (Short)**
- Study investigator(s) at site aware of diversity enrollment objectives, tailored recruitment strategies, contingency plan(s)
- Monitoring mechanisms for recruitment targets by demographic established
- Active monitoring and response to demographic profile of enrolled participants
- Contingency plan described in recruitment plan

**Outcomes (Medium/Long)**
- Target subgroup enrolled per recruitment plan objectives
- Target group recruitment plan materials, recruitment strategies available for future use
- Drug with efficacy and safety/risk evidence in representative populations

**Impact**
- Widespread understanding of heterogeneity of effect of marketed drug
- Decrease in health disparities for disease area (aspirational)