Logic Model: Site Selection

**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 during a feasibility assessment being leveraged to enroll a representative population in a clinical trial. A non-exhaustive sample of key performance indicators for a site selection process 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*.

- See the “Feasibility Decision Tree” tool as well the “Feasibility Questionnaire Modification Checklist” tool. Each activity presented in this logic model is explored in more extensive detail within these tools.
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**Inputs**
- Value for resources
- Staff time

**Activities**
- Assess potential capacity of sites (i.e., geo-mapping technology)
- Modify feasibility questionnaire for diversity
- Assess historical capacity of sites and previous enrollment performance (using modified questionnaire)
- Assess projected capacity of sites (i.e., forecasting technology)
- Map out list of potential required site supports to achieve demographic goals

**Outputs**
- Data on potential capacity of sites
- Modified feasibility assessment available
- Data on historical capacity of sites
- Data on projected capacity of sites
- List of potential site supports available

**Outcomes**

**Short**
- Data-driven estimates of clinical site capacity to enroll target subpopulation
- Sites selected based on capacity considering target subpopulation

**Med/Long**
- Clinical trial population representative of patient population
- Target subgroup data-generating template strategies/materials 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)