Logic Model: Participant & Community Engagement

**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 a diversity-oriented community and patient engagement strategy during clinical research. A non-exhaustive sample of key performance indicators for such a strategy 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

**ACTIVITIES**
- Establish process for inclusion of target subpopulation(s) voice in trial design
- Create sustainable partnerships with patient advocacy and community organizations relevant to target subpopulation(s)
- Hold in-person meetings with patients of target subpopulation(s) to guide study design and recruitment planning
- Engage patients and advocates of target subpopulation(s) to review all participant-facing materials
- Implement feedback process at end-of-study with participants of target subpopulation(s)
- Establish community advisory board(s) with target subpopulation(s) for consistent engagement across product development

**OUTPUTS**
- Process established for target subpopulation(s) voice inclusion during trial design
- Partnerships established with patient advocacy and community organizations relevant to target subpopulation(s)
- In-person meetings held with patients of target subpopulation(s) to guide study design and recruitment planning
- All participant-facing materials reviewed by patients and advocates of target subpopulation(s)
- Feedback process implemented at end-of-study with participants of target subpopulation(s)
- Community advisory board(s) established with target subpopulation(s)

**OUTCOMES**

**SHORT**
- Trial design and planning engages and integrates perspective of target subpopulation(s)
- Clinical trial population representative of patient population
- Study protocol or recruitment materials adjusted based on patient engagement activities
- All participant-facing materials reviewed by patients and advocates of target subpopulation(s)
- Patient input represented at company annual review

**MED/LONG**
- Clinical trial population representative of patient population
- Target subgroup community relationships and engagement materials sustained for future use
- Drug with efficacy and safety/risk evidence in representative populations
- Increased trust of clinical research within target subgroup (aspirational)

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