Comprehensive Logic Model:
Parts C, D, E of Guidance Document

**Audience:** Sponsors/CROs

**Purpose:** To provide a high-level operational overview of the activities being proposed in Parts C (Broadening Engagement), D (Data Standards and Analysis), and E (Study Design, Conduct, and Implementation) of the Guidance Document, linking these activities to their intended effects (outputs, outcomes and impact).

**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*.

- This particular logic model is especially high-level, presenting the strategy types within the clinical research domains covered in these sections of the *Guidance Document*. This is useful as an organizational framework but lacks the granularity of other logic models contained in the document possess.
Comprehensive Logic Model: Parts C, D, E

**Inputs**
- Value for resources
- Staff time

**Activities**
- Engage diverse patient groups and communities
- Implement awareness, knowledge and access strategies
- Establish internal workforce development initiatives
- Determine best data standards and specify intent for analysis
- Design study protocol to consider diverse participant inclusion

**Outputs**
- Diverse patients and communities contribute to clinical trial design, development and implementation
- Participant awareness of, knowledge of and access to clinical trials addressed
- Diverse, culturally aware and inclusive workforce
- Data standards included and data analysis methods selected are conducive to assessing heterogeneity
- Study design and study conduct consider how to recruit and retain a diverse participant population

**Outcomes**
- Diverse representation is addressed within upstream (participant engagement, workforce, study design) and downstream elements (study conduct and analysis)
- Clinical trial population representative of patient population
- Exemplar strategies to prioritize diverse representation available for future use
- Drug with efficacy and safety/risk evidence in representative populations
- Widespread understanding of heterogeneity of effect of marketed drug
- Decrease in health disparities for disease area (aspirational)

**Impact**