Establishing Use of RWD as a Standard Process in Study Planning and Recruitment

The following suggestions are intended to help sponsors establish the use of real-world data (RWD) as a standard process for planning eligibility criteria and recruitment.

Early Stages of Implementation

When potential uses of RWD are unfamiliar to study teams, incorporating RWD into planning eligibility criteria and recruitment may meet with initial resistance or disinterest. Sponsor RWD/real-world evidence (RWE) teams can consider approaches such as the following to enhance familiarity and buy-in:

▶ Start conversations with study teams as early as possible, focusing on early phase trials or early clinical development.

▶ Be prepared to explain capabilities and demonstrate value. If internal examples of value are not yet available, CTTI has developed three case examples (Using Real-World Data to Expand Eligibility Criteria for Phase II Inflammation Trial, Using Real-World Data to Expand Eligibility Criteria for Phase III Endocrinology Study, and Using Real-World Data to Solve Mid-Study Recruitment Challenges for Phase Ib/II Breast Cancer Trial) showing how sponsors are using RWD to enhance eligibility criteria and reduce recruitment challenges.

▶ Consider focusing pilot projects on early phase / feasibility trials for which the impact of important eligibility criteria can be evaluated against available RWD sources. Identifying and addressing areas of high uncertainty for study teams can help demonstrate value.

Establishing a Standard Process

As the organization becomes more familiar with and supportive of various uses of RWD, sponsors can consider the following:

▶ Establish budgets, priorities, and responsibilities for bringing in necessary data, as well as building out and supporting software infrastructure. Plan for ongoing curation of data to ensure continued relevance to organizational priorities.

▶ Establish an operating model that shows how internal stakeholders (e.g., clinical, operations, data science, regulatory) will work together and sets expectations for early engagement.

▶ At a leadership level, understand the value and limitations of RWD for making data-driven decisions about eligibility criteria and supporting recruitment. Leaders should also hold study teams accountable for utilizing cost-effective, efficient, and high-quality approaches.

▶ Dedicate resources to identifying, internally or externally, staff with necessary technical abilities in areas such as programming, analysis, and epidemiology.

▶ Prepare examples of successful RWD use cases sourced from your own organization and others.