CLINICAL TRIALS TRANSFORMATION INITIATIVE

CTTI Tool
Decision Tree For Optimizing Protocol Design

Is the scientific question relevant?

NO → Identify and engage with stakeholders to ensure the question is relevant and meaningful; Make sure you are meeting the needs of the patients and providers according to their perception of the disease

YES →

Eligibility Criteria:
Are the I/E criteria carefully designed to ensure feasibility?

NO → Consult with stakeholders, ensure the criteria are feasible; Refine the eligibility criteria to broaden the available population; Eliminate any criteria that are not necessary for the safety of participants or relevant to directly answering the research question.

YES →

Procedural Burden:
Have you minimized the procedural burden to only those necessary to answer the scientific question/endpoints?

NO → Solicit feedback from stakeholders regarding important outcomes, motivations, barriers, the schedule of events and feasibility of accomplishment based on disease burden and state, workflow as well as the perceived risks and benefits of participation.

YES →

Data Parsimony:
Have you minimized the burden of data collection to only those necessary to answer the scientific questions / endpoints?

NO → Consider the incremental cost (financial, time, effort) of each additional data element and its utility to answering the study question; Collect only the minimum data set necessary to address study endpoints and meet the needs of various stakeholders.

YES → Goal: a well-designed, minimally burdensome protocol that is poised to provide data to answer a meaningful scientific question