DECISION TREE: OPTIMIZING YOUR PROTOCOL DESIGN

Study planners should spend the extra time necessary to engage with stakeholders and obtain their input upfront—this proactive approach can ensure a trial will not be delayed by protocol amendments needed to remove barriers hampering efficient enrollment. When considering the design and development of your clinical trial, ask yourself:

Is the scientific question relevant?

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.

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.

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.

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.

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

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

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

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