



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Dimensions Influencing End-of-Trial Decision-Making and Related Questions to Consider

Dimension	Questions
 <p>Ethical</p>	<ul style="list-style-type: none">• What effects (potential benefits or harms) could maintaining or not maintaining the intervention have on continuing care of trial participants?• What effects (potential benefits or harms) could maintaining intervention activities have on the care of nonparticipating patients treated in trial settings?
 <p>Relational or political</p>	<ul style="list-style-type: none">• How important is ongoing engagement with health system partners during the period of waiting for study results? How might ongoing engagement or withdrawal affect future collaborations?• What effects (potential benefits or harms) could maintaining or not maintaining intervention activities have on system staff and providers?
 <p>Timing</p>	<ul style="list-style-type: none">• How soon could investigators have a preliminary assessment of intervention benefits and harms? How long before a definitive assessment?
 <p>Intervention-specific</p>	<ul style="list-style-type: none">• To what degree have clinicians or other staff in participating health systems adopted intervention activities or practices as standard operations?• How long are intervention activities likely to continue with no additional support from the research team?• What, if any, active involvement of the research team would be necessary to discontinue intervention activities?
 <p>Resources</p>	<ul style="list-style-type: none">• What resources would be required to maintain intervention activities until results are known?• What resources are available to the research team to support ongoing intervention delivery?• What intermediate options (partial support requiring fewer resources) are possible?• Will health system partners have adequate resources to take over intervention delivery if trial results justify continuing it?
 <p>Trial design</p>	<ul style="list-style-type: none">• Have intervention activities been confined to only some patients (individually randomized trial), limited to some clinics or sites (cluster randomized trial), or spread to all participating health systems (stepped-wedge trial)?• How was maintenance of effects or effects of discontinuation addressed in the original trial design?