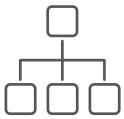
NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Communicating With Health System Partners During The Lifecycle Of A Trial

	Health system leaders	Clinic-level managers	Front-line staff
Selecting study questions 	• Explore organizational care improvement priorities in this clinical area • Identify relevant "report card" and incentive reimbursement measures in this clinical area • Identify existing or planned resources that could support potential interventions • Understand organizational culture and support for innovation	• Identify most important "pain points" in this clinical area • Understand organizational culture and support for innovation	• Identify most important "pain points" in this clinical area • Explore perceived priorities of patients and families/ caregivers • Understand organizational culture and support for innovation
Study design 	• Identify most salient outcomes (including differences that would be "actionable") • Identify legal and regulatory constraints on intervention delivery, data collection, or informed consent • Identify quality improvement plans that might conflict with or augment study interventions	• Explore barriers to potential strategies for inviting or enrolling participants • Explore barriers to delivery of potential study interventions • Discuss acceptability of trial intervention conditions (e.g., intervention, care as usual, "attention" or inactive control)	• Explore acceptability of potential study interventions to front-line staff • Explore perceived acceptability of potential study interventions to patients and families/caregivers • Discuss acceptability of trial intervention conditions (e.g., intervention, care as usual, "attention" or inactive control)
Preparation 	• Identify changes in leadership structure or priorities since study design • Identify new quality improvement plans that might conflict with study interventions • Identify changes in resource availability since study design	• Explore successful strategies for implementing similar interventions or programs • Identify changes in resource availability since study design • Develop understanding and enthusiasm for research process, goals, and outcomes	• Develop understanding and enthusiasm for research process, goals, and outcomes (work with front-line champion) • Provide regular study updates • Co-develop optimal workflows for identifying and inviting potential participants • Co-develop optimal workflows for delivery of study interventions

	Health system leaders	Clinic-level managers	Front-line staff
Startup 	• Advise regarding startup timelines	• Advise regarding startup timelines • Engage in developing form and content of invitation/ recruitment materials	• Engage in co-developing form and content of invitation/ recruitment materials • Finalize form and content of any materials or tools for front-line staff
Maintenance 	• Advise regarding study progress (especially regarding uptake and fidelity of interventions) • Identify changes in leadership structure or priorities since study design • Identify new quality improvement plans that might conflict with or augment study interventions	• Advise regarding study progress (especially regarding uptake and fidelity of interventions) • Explore strategies for maximizing uptake and fidelity of study interventions	• Identify and co-develop needed changes in study workflows • Revise invitation and recruitment materials • Revise materials or tools with front-line staff
Analysis & interpretation 	• Invite suggestions regarding interpretation (especially regarding unexpected findings) • Identify concerns regarding risk to health system reputation or market position • Identify concerns regarding disclosure of proprietary information	• Invite suggestions regarding interpretation (especially regarding unexpected findings) • Explore reasons for incomplete uptake/adoption or gaps in fidelity	• Invite suggestions regarding interpretation (especially regarding unexpected findings) • Explore reasons for incomplete uptake/adoption or gaps in fidelity
Public dissemination 	• Share planned publications/ presentations and invite comments • Inform leaders regarding timing of presentations and publications • Identify public-facing publications and presentations that would best serve the health system itself and produce these for health system leader use	• Entertain questions regarding and discuss final results • Explore suggestions for improved study procedures • Identify clinic- and patient-facing publications and presentations that would best serve the clinics and produce these for clinic use	• Entertain questions regarding final results • Explore suggestions for improved study procedures • Identify clinic- and patient-facing publications and presentations that would best serve the clinics and produce these for clinic use