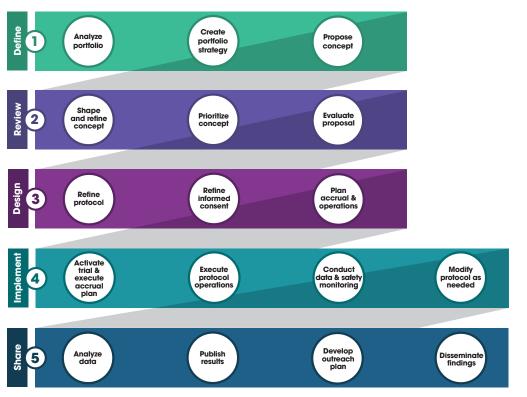
NATIONAL CANCER INSTITUTE

How Advocates Support the Clinical Trial Lifecycle

Clinical Trial Development Process



Advocate's Role



- Provide feedback that frames trial questions important to patients
- Provide support for balanced trial portfolios across treatment, prevention, and control, where science supports research



 Review trial inclusion and exclusion criteria for maximal patient participation where safe and possible



- Collaborate on protocol development
- Provide feedback on communications and patient-friendly materials
- Create awareness around need for patient accrual



• Provide input on trial accrual strategies and offer support



 Share study results with appropriate patient and advocacy groups through interviews, presentation, publication, and social media channels



Calibration Assessment for Patient Advocate Engagement

Advocate:		Date:					
Committee/Trial:		Calibration Date:					
Committee/Study Chair:		Level Of Patient Advocate Engagement					
		Study/Committee Chair Assessment			Patient Advocate Assessment		
Define	Feedback on trial questions and importance, shape concept Support balance of trial portfolio	None O	Some	Fully O	None O	Some	Fully
Review 5	Assess accrual feasibility Evaluate competing treatments and trials Review inclusion and exclusion criteria Assess benefits and risks, including burden Develop and present formal reviews (Committee, Sponsor, Executive Review)	•	•	•	•	•	•
Design	Collaborate on protocol Collaborate on consent form Collaborate and suggest patient collateral Support accrual planning	•	•	•	•	•	•
Implement	Guide and support accrual and accrual strategies	•	•	•	•	•	•
Share 2	Prepare and share study results	•	•	•	•	•	•
Other Q		•	•	•	•	•	•