PLANNING TRIALS USING MOBILE TECHNOLOGIES

Following are opportunities for patient and site input that are unique to, or important for, planning clinical trials that use mobile technologies for data collection. Patient and site input should be sought early and often.

TOPICS FOR PATIENT & SITE INPUT INCLUDE:	
 SELECTING OUTCOME MEASURES	Focus on measures that are meaningful to patients. Select a technology-derived assessment only if better (e.g., more meaningful to patients or more informative) than existing outcome assessments. See CTTI's MCT Novel Endpoints Recommendations
 DEFINING STUDY PARTICIPANT CHARACTERISTICS	Develop plans for participant inclusion and diversity, and identification of opportunities and risks related to technology access and literacy. See Section I, Recommendation 1
 SELECTING MOBILE TECHNOLOGIES	Weigh protocol elements against added participant burden; evaluate the acceptability, usability, and tolerability of mobile technologies; and plan for participant expectations. See Section I, Recommendation 2 As necessary, test mobile technologies with sites and a representative patient population. See Section I, Recommendation 3
 PLANNING TRIAL LOGISTICS	Identify and develop plans for addressing technical support needs of participants, as well as facilitating patient-site interactions. See Section II, Recommendations 6 and 7 Identify and develop plans to address challenges for investigative sites, including budgets and contracting, infrastructure, training, and technology malfunctions. See Section III, Recommendations 1-6
 DEVELOPING STUDY MATERIALS & COMMUNICATIONS	Seek input on informed consent materials, including specific considerations related to data and health monitoring, health and technical literacy, and patient privacy and confidentiality See Section II, Recommendations 1-5 Evaluate opportunities to return outcomes and other data, and determine how best to return value to study participants. See Section II, Recommendation 8

Resources that provide a broader examination of opportunities to engage stakeholders in the clinical research process include the CTTI Quality by Design Toolkit, CTTI Patient Groups & Clinical Trials Recommendations, PCORI Engagement Rubric, and NCATS Toolkit for Patient-Focused Therapy Development.

https://www.ctti-clinicaltrials.org/projects/engaging-patients-and-sites