Table 2: CTTI Recommended Strategies for Optimizing Data Quality

Data should be collected by digital technologies in such a way as to optimize the quality of the data. This table outlines CTTI recommended strategies for optimizing data quality at the point of collection when using a digital technology. Strategies should be developed prospectively, and this tool is organized to highlight recommended approaches and additional considerations at each critical step of the protocol design process. For additional considerations pertaining to data quality, please reference CTTI Recommendations for Managing Data.

Critical Step in Protocol Design	Recommended Strategy	Data Quality Aspect(s) this Strategy Addresses	Additional Considerations
Formulation of Research Question	To encourage participants to use the digital technology in the way they are instructed to do so, sponsors should ensure the relevance of the scientific question to participants.	▶ Promoting correct data attribution ▶ Minimization of data variability ▶ Minimization of missing data	Click here for detailed considerations and a tool to support the selection of a technology derived endpoint to answer the research question of interest.
Digital Technology Selection	To optimize study participant adherence to the trial requirements for data collection, digital technologies should be selected with the needs, preferences and abilities of the study participant population in mind.	▶ Promoting correct data attribution ▶ Minimizing data variability ▶ Minimizing missing data	Click here for detailed considerations on digital technology selection
Determination of Participant Incentives	To discourage participants from intentionally misusing the digital technology, sponsors should design protocols in such a way to avoid any undue incentives to 'game the system'.	▶ Promoting correct data attribution ▶ Minimization of data variability	
Developing Informed Consent Language	To ensure participants are willing to use the digital technology in the way they are instructed to do so, the informed consent should include language indicating that use of the	▶ Promoting correct data attribution ▶ Minimization of data variability ▶ Minimization of missing	Click here for CTTI's considerations on improving the informed consent process.

Critical Step in Protocol Design	Recommended Strategy	Data Quality Aspect(s) this Strategy Addresses	Additional Considerations
	digital technology is a requirement for participation in the trial.[1]	data	
Developing the Training Plan	To optimize study participant adherence to the trial requirements for data collection, CTTI recommends that sponsors ensure the delivery of effective training for all study participants as well as study staff, where applicable.	▶ Promoting correct data attribution ▶ Minimization of data variability ▶ Minimization of missing data	Click here for detailed considerations on how to develop effective technology training for study participants and staff
Pilot Testing the Protocol	To identify any unanticipated potential issues associated with data collection as outlined in the protocol, sponsors should consider conducting feasibility (or pilot) studies of their protocol prior to launching the trial.	▶ Promoting correct data attribution ▶ Minimization of data variability ▶ Minimization of missing data	
Study Screening Process	To optimize the likelihood that participants are willing to use the digital technology in the way they are instructed to do so, sponsors should consider including a run-in period that evaluates whether participants' adherence in using the digital technology meets a pre-determined level.	▶ Promoting correct data attribution ▶ Minimization of data variability ▶ Minimization of missing data	

[1] This strategy expands on a recommendation proposed by the ePRO Consortium for optimizing ePRO data capture in the field. Fleming, Sarah, et al. "Optimizing electronic capture of clinical outcome assessment data in clinical trials: the case of patient-reported endpoints." *Therapeutic Innovation & Regulatory Science* 49.6 (2015): 797-804.