Framework of Specifications to Consider During Mobile Technology Selection

Selection of a mobile technology for data capture should be specification-driven, collaborative and occur after the identification of the aspect or experience that the assessment is intended to measure (i.e., an individual's clinical, biological, physical, or functional state). This framework is intended to support sponsors in making this multi-factorial decision, highlighting specifications they should consider during mobile technology selection for each specific trial. This framework is also intended to support discussions and collaborations with technology manufacturers and relevant patient groups. For additional considerations pertaining to mobile technology selection, please reference Section I-2 of the recommendations.

	Specification	Definition	Considerations	Associated Recommendations
Technical Performance Specifications				
Measurement Performance The specific measurement of interest should inform the required measurement performance specifications.	Accuracy	Amount of uncertainty in a measurement with respect to a reference standard.	The environment for data capture, for example temperature, can affect mobile technology accuracy. Technology accuracy may also vary across the measurement range and with battery charge.	See recommendations on mobile technology verification.
	Precision	Reproducibility of the measurement.	Precision should be considered over time in a single mobile technology and across like technologies.	See recommendations on mobile technology verification.
	Sampling frequency	The number of samples per second (or per other unit) taken from a continuous signal to make a discrete or digital signal.	There will be a tradeoff between level of detail in information and subsequent required data storage and analysis capabilities.	See recommendations on data collection.
	Resolution	The smallest absolute amount of change that can be detected by a measurement.	There will be a tradeoff between sensitivity of the measure and noise.	
	Data Processing	Operations performed on a given set of data to extract the required information in an appropriate form.	Several levels of data processing may occur, depending on the nature of the mobile technology and required output.	See recommendations on mobile technology verification.

	Specification	Definition	Considerations	Associated Recommendations
	Metadata	Data that describes and gives information about other data.	Sufficient and appropriate meta-data is required to provide context for the data captured by mobile technologies, allow it to be readily interpreted, and determine its clinical meaningfulness.	See recommendations on data collection.
Mobile Technology Communication and Data Transfer The nature of the data and participant population should inform the required mobile technology communication and data transfer specifications.	App Pairing	Wearables and remote sensors not embedded in participants' smartphones typically pair via Wi-Fi or Bluetooth to an app prior to transmission to a central server.	Connectivity and quality of the app can effect data collection and completeness as well as security.	See recommendations on ▶ data collection ▶ data security
	Transfer to Data Gathering Platform	The transfer of individual participant data to a central server or other data gathering platform for the trial.	Connectivity requirements, such as access to Wi-Fi, should be considered. Data is typically transferred to the technology manufacturer's servers prior to transfer to the retriever servers. As such, mobile technology selection should also consider 1) strategies for handling unreliable data streams and 2) the specifications of the technology manufacturer servers, if relied upon.	See recommendations on ▶ data security ▶ data integrity
Data Management Specifications				
	21 CFR Part 11 Compliant	Regulations in part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11) apply to records in electronic form that are	While data management processes may be outsourced to electronic service providers, sponsors remain ultimately responsible for the authenticity, integrity and confidentiality of data generated by mobile technologies. A number of FDA	See recommendations on ▶ data authenticity, integrity and confidentiality ▶ data accessibility and protection ▶ data security

	Specification	Definition	Considerations	Associated Recommendations
		created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in FDA regulations.	Guidance documents exist to support the application of these regulations.*	
Data Access	Mobile Technology Manufacturer Access to Study Data	Data collected by mobile technologies will often flow through the technology manufacturer's server prior to being made available to the sponsor.	Informed consent cannot be accurate if sponsors are uncertain of how data captured by the mobile technology may be accessed and used by the manufacturer.	See recommendations on data access
	Sponsor Access to Study Data	What data will be provided to the sponsor by the technology manufacturer	Sponsors should consider: ▶ Whether they will have access to the raw data generated by the mobile technology ▶ What levels of processed data (see Table 1) they will have access to, ▶ Whether they will have access to the algorithm(s) used to process the data, and ▶ What format the data is provided in.	See recommendations on data access
	Third Party Access to Study Data	Access to study data for secondary use	All of the ways in which participants' data may be used should be clearly communicated to participants in the informed consent.	See recommendations on data access
Safety Specifications				
Study participant	Safety	The risk to the study	Participant safety is paramount.	For mobile technologies being used

* See the FDA Guidance on Electronic Source Data in Clinical Investigations, Computerized Systems Used in Clinical Investigations, and DRAFT Guidance on the use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers.

	Specification	Definition	Considerations	Associated Recommendations
safety is always the priority.		participant.		solely for data capture, only minimal safety risk should be tolerated.
Human Factors Specifications				
The participant population should inform the human factors specifications.	Acceptability	The degree to which the mobile technology meets the needs and preferences of the participant population. For example, the appearance, bulkiness and placement of the technology.	Participants' acceptance of the mobile technology will likely impact recruitment and adherence.	Participants are the best source of information when evaluating the acceptability and usability of a mobile technology. Where appropriate, feasibility studies examining the acceptability and usability of the technology should be conducted with the participant population of interest.
	Tolerability	The degree to which any adverse effects of the mobile technology may exist and can be tolerated by the patient. For example, an irritation or rash due to prolonged wearing of a mobile technology.	Due to their health status, participants may be more vulnerable to adverse effects than a typical, healthy population.	Where appropriate, feasibility studies examining tolerability should be conducted with the participant population of interest.
	Usability	The degree to which the participant population is willing and able to interact with the mobile technology as required for its effective use.	The usability of the technology by the participant population of interest will likely impact adherence. If the mobile technology is paired with an app, usability of the app should also be considered.	Good Manufacturing Practice regulations require that human factors techniques or data be included in the design process for medical devices.† While not all mobile technologies must adhere to these regulations, selected portions may be valuable to mobile technology manufactures and sponsors seeking to develop and select appropriate mobile technologies for data capture.
Operational Specifications				
	Firmware	Firmware is permanent software programmed	Updates to firmware can change all aspects of	Approaches to ensuring that firmware is managed in such a way to 1)

† 21 CFR 820.30 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=820.30

	Specification	Definition	Considerations	Associated Recommendations
		into the mobile technology that serves as its operating system.	functionality, including how the sensor data is processed and security features.	maintain data equivalence throughout the trial and 2) ensure data security is optimized should be determined through collaboration between the sponsor and technology manufacturer prior to distribution of the mobile technology to study participants.
	Failure rate	The frequency with which the mobile technology, or a component of the technology, fails.	Impacts of technology failure may include missing data, participant and investigator dissatisfaction and potentially increased dropout rates from the trial.	See recommendations on data collection.
	Battery life	Run time of the mobile technology on full charge.	Battery life is determined by both the power available on a full charge and the power consumption of the mobile technology. There will be a tradeoff between power consumption and technical performance.	See recommendations on data collection.
Non-Performance Specifications				
	Cost	Cost of mobile technology procurement and technology management during the study.	In addition to the per-unit cost of the mobile technology, exposures to technology management costs during the study should also be considered.	
	Customer Service	The services supporting mobile technology use that the technology manufacturer may (or may not) provide to the technology users (participants and study staff).	Support for mobile technology users may be provided by either the technology manufacturer or taken on in-house by the sponsor or CRO.	To minimize the burden on study participants and site staff, and to preserve the integrity of the trial, plans for monitoring and responding to mobile technology failure should be in place before administering mobile technologies to study participants.