CHECKLIST FOR SPONSORS:

Considerations in Selecting and Equipping Sites for Clinical Trials with Mobile Technologies

Clinical trials that use mobile technologies have unique considerations with respect to site infrastructure requirements. The checklist below identifies factors specifically related to the use of mobile technologies that sponsors may wish to consider during the site identification process. It is important to consider site capacity not only with respect to the study in question, but also for all concurrent studies. Note that not all factors will apply to every trial.

FACTORS TO CONSIDER	PRACTICAL EXAMPLES
SITE STAFF TRAINING AND FAMILIARITY CONSIDERATIONS	
▶ Are site staff prepared to train participants on the use of mobile technologies and resolve minor issues?	▶ Sponsors assess site staff readiness using study-specific questionnaires prior to site selection. ▶ Site staff serve as the initial point of contact for trial participants who have technical issues.
▶ Will clinicians and site staff have sufficient comfort levels with mobile technologies being used?	▶ Clinicians and site staff are engaged early to determine their willingness to enroll patients in the mobile clinical trial. ▶ Site concerns related to device monitoring (e.g., safety signals) and other issues (e.g., patch reactions) are solicited and addressed prior to protocol implementation.
SITE SYSTEMS AND WORKFLOW CONSIDERATIONS	
▶ Are workflows in place to follow up, within required timeframes, on clinical events identified through mobile technologies?	▶ Clinical workflows are developed to respond to potential clinical alerts generated through signals from mobile technologies that require follow-up. ▶ Clear response timeframes are articulated, and ability of sites to respond is assessed, prior to study implementation.
▶ Will site staff have sufficient time available for required data entry?	▶ Expectations for time required from sites for data entry and review are identified. ▶ Site resources and personnel for data entry are assessed prior to site selection and protocol implementation.

FACTORS TO CONSIDER	PRACTICAL EXAMPLES
▶ Will sufficient space and time be available for consenting and training procedures?	▶ Time and space requirements associated with training and consenting patients on mobile technologies are identified based on piloting and/or prior experience. ▶ Associated site resources are assessed, accounting for additional requirements typical of mobile trials as compared to traditional trials.
▶ Are there other workflow issues that may arise due to the requirements associated with the mobile technologies?	▶ Sites are consulted during study planning to identify potential issues based on prior experience. ▶ Relevant procedures and/or devices are piloted to ensure optimal function within site workflow.
PHYSICAL AND IT INFRASTRUCTURE CONSIDERATIONS	
▶ Is sufficient space available to store and charge all devices?	▶ Availability of physical space and charging locations is assessed against requirements for all of the site's active studies using mobile technologies.
▶ If study participants will use mobile technologies on-site, is there sufficient Wi-Fi or cellular network coverage and speed?	▶ Consideration is given to all locations in which mobile technologies may be used, such as during consenting and training.
▶ If sites are expected to communicate with participants remotely, are the video, audio, and space requirements sufficient?	▶ Assessments are planned that examine ability to meet technical requirements, as well as availability of appropriate site facilities to conduct communications without compromising patient privacy.
▶ Is the site able to use required third-party hardware and software?	▶ Site IT restrictions and requirements related to third-party hardware and software are identified and considered against study requirements. ▶ Options for meeting site and study IT requirements are identified (e.g., options to install required software on site computers, or for sponsor to provide compatible computers).
PATIENT POPULATION CONSIDERATIONS	
▶ Will the site's patient population be willing and able to use the mobile technologies required for the trial?	▶ The patient population's willingness and ability to use the required mobile technologies are assessed through prior site experience and/or user testing conducted by the sponsor.

FACTORS TO CONSIDER	PRACTICAL EXAMPLES
▶ Will opportunities for communication and interaction with site staff meet patient expectations/preferences?	▶ General patient expectations/preferences for visit schedules, communication frequency, and technical support are identified and addressed during study planning. ▶ Sites are informed of general expectations/preferences and consulted to identify special considerations that may apply to local patient populations.
GEOGRAPHIC CONSIDERATIONS	
▶ What local laws and regulations will impact the use of mobile technologies at the site?	▶ National data privacy laws and regulations are identified that apply to site patient populations using mobile technologies.
▶ If manuals for mobile technologies are not available in local languages, does the site have someone who can read the manuals or otherwise access technical support?	▶ Sites are informed of languages in which instruction manuals for mobile technologies and live tech support will be available, and confirm availability of staff with required language abilities.
▶ Will technical support for any mobile technologies used be sufficiently available during the site's business hours?	▶ Through consultation with technology provider and investigative sites, hours of availability for technical support are confirmed to sufficiently align with site business hours in all relevant time zones.