



ALTERNATIVE SITE MODEL

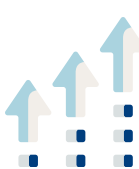


MOBILE RESEARCH SITE (SITE ON WHEELS)

WHAT IS A MOBILE RESEARCH SITE?

A RESEARCH LOCATION WHICH PROVIDES MOBILE TRIAL ACCESS IT CAN GO WHERE PATIENTS ARE

WHAT PROBLEMS DOES THIS MODEL AIM TO SOLVE IN TRIALS?



Patient

- ...accessibility
- ...recruitment
- ...retention



Access

- ...to diverse patients
- ...to underserved/represented
- ...increase the site catchment area and geographic reach



Cost

- .Cost may increase as the model is scaled
 - May decrease time to trial completion, decreasing costs

HOW CAN THIS SITE MODEL BE USED IN TRIALS?



As a stand-alone site



As an additional location for a traditional trial site



SPECIAL CONSIDERATIONS/LIMITATIONS



INVESTIGATIONAL PRODUCT PREPARATION

- Sufficient power, water + internet access
- "In-case-of-emergency" back-up access to typical medical supplies found at a traditional research site



INVESTIGATIONAL PRODUCT ADMINISTRATION

- Site and/or vendor need SOP(s) describing how to manage IP receipt, storage, chain of custody and IP management
- Site and/or vendor will need staff trained and delegated to manage IP



CONFIDENTIALITY

- Mobile unit will require security and equipment (e.g. charged tablet for eConsent, eCOA) and a comfortable, private area for consenting and interaction with site staff



PI OVERSIGHT

- Formal PI oversight plan documenting clear roles and responsibilities
- Clear RACI agreed upon between sponsor and site/ locations team(s)
- Tasks clearly delegated and trained per GCP/ICH needs



BIOSPECIMEN COLLECTION

- Sample collection and processing requires protocol knowledge and training:
- Including the management of trial materials and the collection, processing, storage and shipment of specimens.
 - SOP includes the management of biospecimen at a mobile unit.



TRIAL SPECIFIC ASSESSMENTS

- Ensure methodical evaluation to assess which study specific assessments can be done in the unit.
- Clear plan on how to complete any assessments that can't be done in the unit (e.g. home nurse visit, traditional site visit, etc)



MEDICAL WASTE MANAGEMENT

- Site and/or vendor should have SOP describing workplace safety and security pertaining to the use of a mobile unit, including the management of medical waste.



ACCESS

- Site and/or vendor will need SOP describing patient and workforce safety and security when using a mobile unit.