ALTERNATIVE SITE MODEL

POP-UP SITE MODEL

WHAT IS A DIRECT-TO-PATIENT SITE?

A RESEARCH LOCATION WHERE RESEARCH ASSESSMENTS CAN BE COMPLETED IN A TEMPORARY LOCATION (SUCH AS A TENT OR SHORT-TERM LEASED SPACE E.G. SCREENING EVENTS

WHAT PROBLEMS DOES THIS MODEL AIM TO SOLVE IN TRIALS?

Patient
...accessibility
...recruitment
...retention

Access
...to diverse and rare disease patients
...to underserved/represented
...improve geographic reach for sites
...decrease patient burden

Cost
...may increase costs initially

HOW CAN THIS SITE MODEL BE USED IN TRIALS?

- ✓ As an additional location for a traditional site
- ✓ Tent units used as supplemental space in times of increased activities
- ✓
- ○
- ○

WHERE ARE THESE SITE MODELS AVAILABLE FOR USE IN TRIALS?

- United States of America
- Canada

SPECIAL CONSIDERATIONS/LIMITATIONS

INVESTIGATIONAL PRODUCT (IP) PREPARATION

- Limited based on the nature of the IP shipment / storage and admin.
- Site and/or vendor will need SOP describing how to manage IP chain of custody and IP management.
- Sufficient power, water + internet access, and “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

- Ensure data can be safely, securely and privately captured.
- Temporary unit will need to have sufficient power, back up power, internet access, security and equipment (e.g. charged tablet for eConsent, eCOA or other electronic applications) 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

- Site and/or vendor should have SOP describing workplace safety and security pertaining to the use of a temporary location/ unit
- SOP for the management of trial materials and the collection, processing, storage, and shipment of specimens

TRIAL SPECIFIC ASSESSMENTS

- If any trial specific assessments cannot be performed in the unit, a clear, documented plan for how to assess those should be defined before the use of the temporary location/ unit.
- Clearly document data capture, review, and management expectations

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.
- Minimum requirements at a clinic might be important to consider for a pop up site (e.g. rest room access, ADA Accomodation)