

ALTERNATIVE SITE MODEL

RETAIL SETTING SITE

WHAT IS A RETAIL SETTING SITE?

A RESEARCH SITE WHICH PROVIDES CONVENIENT TRIAL ACCESS TO LOCAL COMMUNITIES

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
- 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 an additional location for a traditional trial site
- ✓ Supplemental space for existing trial locations (such as screening events)
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WHERE ARE THESE SITE MODELS AVAILABLE FOR USE IN TRIALS?



United States of America



SPECIAL CONSIDERATIONS/LIMITATIONS

INVESTIGATIONAL PRODUCT (IP) PREPARATION



- Limited based on IP safety profile
- Additional SOPs may be required for IP Management (receipt, storage, accountability)
- IP security and additional equipment may be required

INVESTIGATIONAL PRODUCT ADMINISTRATION



- Site and/or vendor will need staff trained and delegated to manage IP
- May be best for post-market research with well-characterized IP safety and efficacy profile
- Local internet access, security, and specific equipment for dispensation of IP are required

CONFIDENTIALITY



- Private space for patient interaction and study assessment's conduct
- Ensure location offers suitable waiting room, exam room, and bathroom access to accommodate study assessments
- Ensure telehealth capabilities are suitable if location is supporting a traditional research center

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



- Including the management of trial materials and the collection, processing, storage and shipment of specimens.
- Clear lab manual, end-to-end SOPs and RACIs MUST be in place
- Clear SLA in place regarding timing to set-up, receive, and process any lab specimens or lab supplies

TRIAL SPECIFIC ASSESSMENTS



- Ensure site staff are qualified and trained to complete study assessments and data collection needs
- If needed, ensure telemedicine processes are ready and available
- Physical space must be able to accommodate study assessments

MEDICAL WASTE MANAGEMENT



- Site and/or vendor needs SOP describing workplace safety and security pertaining to the conduct in a commercial setting, including the management of medical waste.

ACCESS



- Assume the physical location is currently serving customers as standard business practice