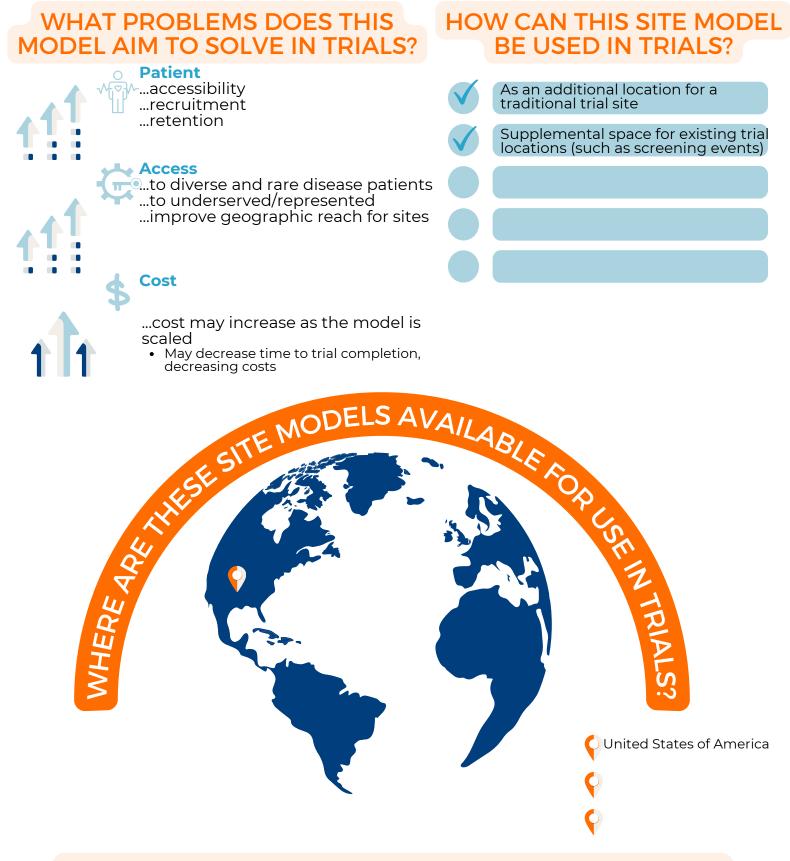
ALTERNATIVE SITE MODEL

RETAIL SETTING SITE



WHAT IS A RETAIL SETTING SITE?

A RESEARCH SITE WHICH PROVIDES CONVENIENT TRIAL ACCESS TO LOCAL COMMUNITIES



CDE

CIAL 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



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



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



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 setup, receive, and process any lab specimens or lab supplies

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.



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



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



ACCESS

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