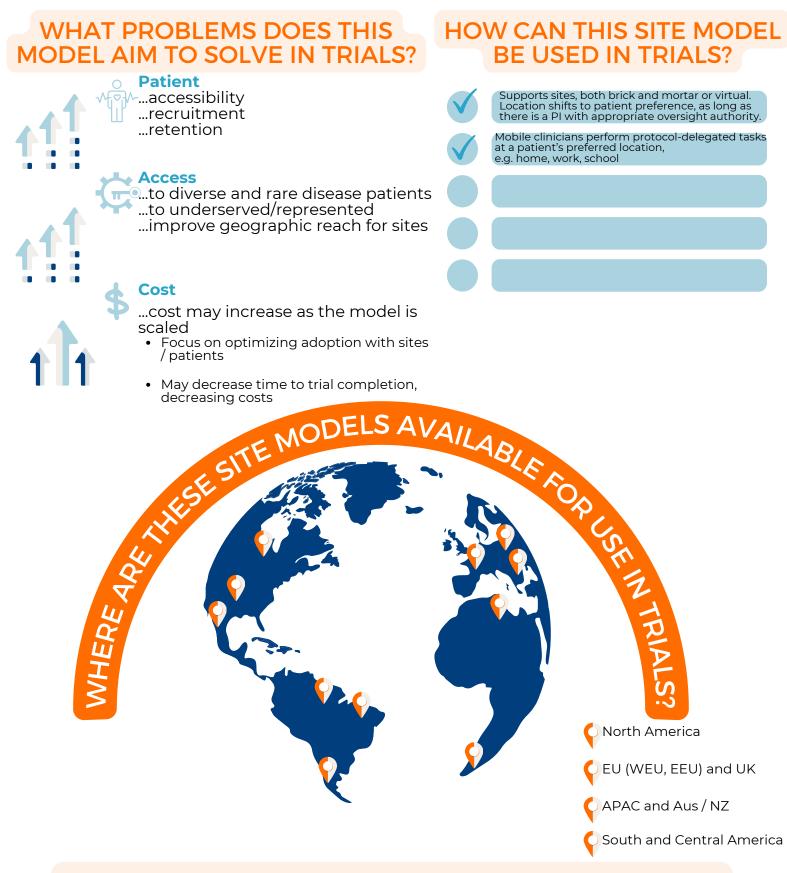
ALTERNATIVE SITE MODEL

IN-HOME TRIAL ASSESSMENTS

WHAT IS A DIRECT-TO-PATIENT SITE?

A RESEARCH LOCATION THAT TAKES ASSESSMENTS DIRECTLY TO THE PATIENT (E.G. AT HOME, SCHOOL, WORK, ETC)



CIAL CONSIDERATIONS/LIMITATIONS SPE



INVESTIGATIONAL PRODUCT (IP) PREPARATION

- IMP must be prepared per protocol. May be by pharmacist or qualified mobile clinician
- IP administration needs to be based on complexity of IP and it's safety profile
- Infusions are possible
 - If can be managed outside a traditional site based on the safety profile of the product(s)



CONFIDENTIALITY

- Ensure that patient and mobile research staff agree on safety of location, appointment timing and how to meet / confirm ID
- Ensure data can be safely, securely and privately captured.
- Ensure store and upload data processes in case of wifi / cellular connectivity gaps



BIOSPECIMEN COLLECTION

- Clarify logistics of blood, plasma, and other biologic materials collection, processing
- Mobile clinicians require protocol training for biosample and specimen collection / processing
- Plan equipment and supply workflows to minimize logistic issues



MEDICAL WASTE MANAGEMENT

- Provide appropriate collection materials or sharps containers
- Clarify site / vendor acceptance of medical waste from mobile visit
- Ensure clear understanding of local rules and limitations of medical waste management. (e.g who can transport, in what timeframe)

INVESTIGATIONAL PRODUCT ADMINISTRATION

- Align to requirements for clinical licensure, e.g IP routes of administration
- Consider patient population and comfort
- Align safety or signs/symptoms reporting and AE assessment based on clinician licensure
- Ensure PI and contract alignment on roles / responsibilities
- Define SAE management and reporting processes



- 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

- Protocol Specific Training is required if for clinical trial assessments
- Consider using the same clinician throughout a patient's trial visits. Builds trust and supports data consistency.
- Clearly document data capture, review, and management expectations



- Prior to a in-home visit, confirm with patient proper access to water, electricity, and other services needed for successful assessments to occur
- Have a clear plan to mitigate challenges,
- Consider geopolitical factors (e.g. conflict zones) and space considerations

