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)

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

- Focus on optimizing adoption with sites / patients
- May decrease time to trial completion, decreasing costs

HOW CAN THIS SITE MODEL BE USED IN TRIALS?

- Supports sites, both brick and mortar or virtual. Location shifts to patient preference, as long as there is a PI with appropriate oversight authority.
- Mobile clinicians perform protocol-delegated tasks at a patient's preferred location, e.g. home, work, school

WHERE ARE THESE SITE MODELS AVAILABLE FOR USE IN TRIALS?

- North America
- EU (WEU, EEU) and UK
- APAC and Aus / NZ
- South and Central America

SPECIAL CONSIDERATIONS/LIMITATIONS

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)

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

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

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

- 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

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

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)

ACCESS

- 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