



ALTERNATIVE SITE MODEL



PATIENT SERVICE CENTER/ LAB-BASED RESEARCH SITE

WHAT IS A PATIENT SERVICE CENTER?

A PLACE WHERE PATIENTS GO FOR LAB TEST SAMPLE COLLECTION
E.G. QUEST / LABCORP LOCATIONS

WHAT PROBLEMS DOES THIS MODEL AIM TO SOLVE IN TRIALS?



Patient

- ...accessibility
- ...retention
- ...decrease patient burden



Access

- ...to diverse patients
- ...to underserved/underrepresented
- ...improve geographic reach for sites



Cost

- ...cost may be increased depending on any atypical staffing, sample collection / processing needs

HOW CAN THIS SITE MODEL BE USED IN TRIALS?



Integrated to other site locations



As an additional location for a traditional trial site



United States of America

SPECIAL CONSIDERATIONS/LIMITATIONS



INVESTIGATIONAL PRODUCT PREPARATION

- Not recommended for this site model unless it is a standard of care (SOC) oral medication



INVESTIGATIONAL PRODUCT ADMINISTRATION

- Not recommended for this site model unless it is a standard of care (SOC) oral medication



CONFIDENTIALITY

- Assume this is already in place as the PSC/Lab has current health care patients



PI OVERSIGHT

- PI oversight plan documenting clear roles and responsibilities
- Explicit workflow and clear timelines on appointment scheduling
- Reminders need to be scheduled for staff to set up appointments and for patients
- Esource tools to capture simple data



BIOSPECIMEN COLLECTION

- Clear SLA in place
- Clarify and automate study-specific documentation to meet GCP/ALCOA+ standards
- Determine and adhere to biospecimen processing/storage needs



TRIAL SPECIFIC ASSESSMENTS

- Limited. Alignment with SOC Phlebotomy assessments/biospecimen collections
 - May have other assessments if nurses are on site
- Plan for GCP and protocol specific training if trial assessments are not SOC



MEDICAL WASTE MANAGEMENT

- Assume this is already in place as the PSC/Lab has current health care patients.



ACCESS

- Assume this is already in place as the PSC/Lab has current health care patients