



ALTERNATIVE SITE MODEL

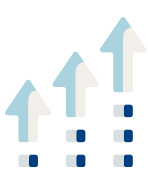


HEALTH CARE PROVIDER SITE

WHAT IS A HEALTH CARE PROVIDER SITE?

AN ADDITIONAL RESEARCH LOCATION WHERE A PATIENT IS ALREADY RECEIVING CARE

WHAT PROBLEMS DOES THIS MODEL AIM TO SOLVE IN TRIALS?



Patient

- ...recruitment
- ...retention
- ...accessibility
- ...decrease burden



Access

- ...to rare disease patients
- ...to diverse patients
- ...to underserved/represented
- ...to geographic reach for sites



Cost

- ...may increase costs initially

HOW CAN THIS SITE MODEL BE USED IN TRIALS?



As an additional location for a traditional site



Integrated to other site locations



SPECIAL CONSIDERATIONS/LIMITATIONS



INVESTIGATIONAL PRODUCT PREPARATION

- Confirm HCP location has ability to properly store, refrigerate, and destroy IP in a safe and restricted way



INVESTIGATIONAL PRODUCT ADMINISTRATION

- IP is limited to Standard of Care (SOC) medications:
 - Ensure proper drug accountability procedures
 - PCP location needs to fit needs of IP administration



PRIVACY

- Assume licensed medical practice has appropriate measures to manage patient records and privacy



PI OVERSIGHT

- Recommend PI oversight is documented in a formal oversight plan
- Ensure a clear RACI is agreed upon between sponsor and site team, including consent, screening and eligibility assessments, enrollment, and trial assessment processes
- Ensure trial-required documentation standards are met



BIOSPECIMEN COLLECTION

Lab processing may require protocol knowledge and training:

- Limit to standard of care (SOC) biospecimen collection
- **OR** executed by service provider (eg phlebotomist) with protocol specific training
- Alignment with local lab ranges may be required



TRIAL SPECIFIC ASSESSMENTS

- Trial specific assessments will be limited to physician's standard of care practice



MEDICAL WASTE MANAGEMENT

- Assume primary care provider with an established practice has proper medical waste management services



ACCESS

- Minimal considerations
- Assume water, electricity, and technology needs will be met in an established practice