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
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WHERE ARE THESE SITE MODELS AVAILABLE FOR USE IN TRIALS?

- Canada
- United Kingdom (UK)
- United States

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