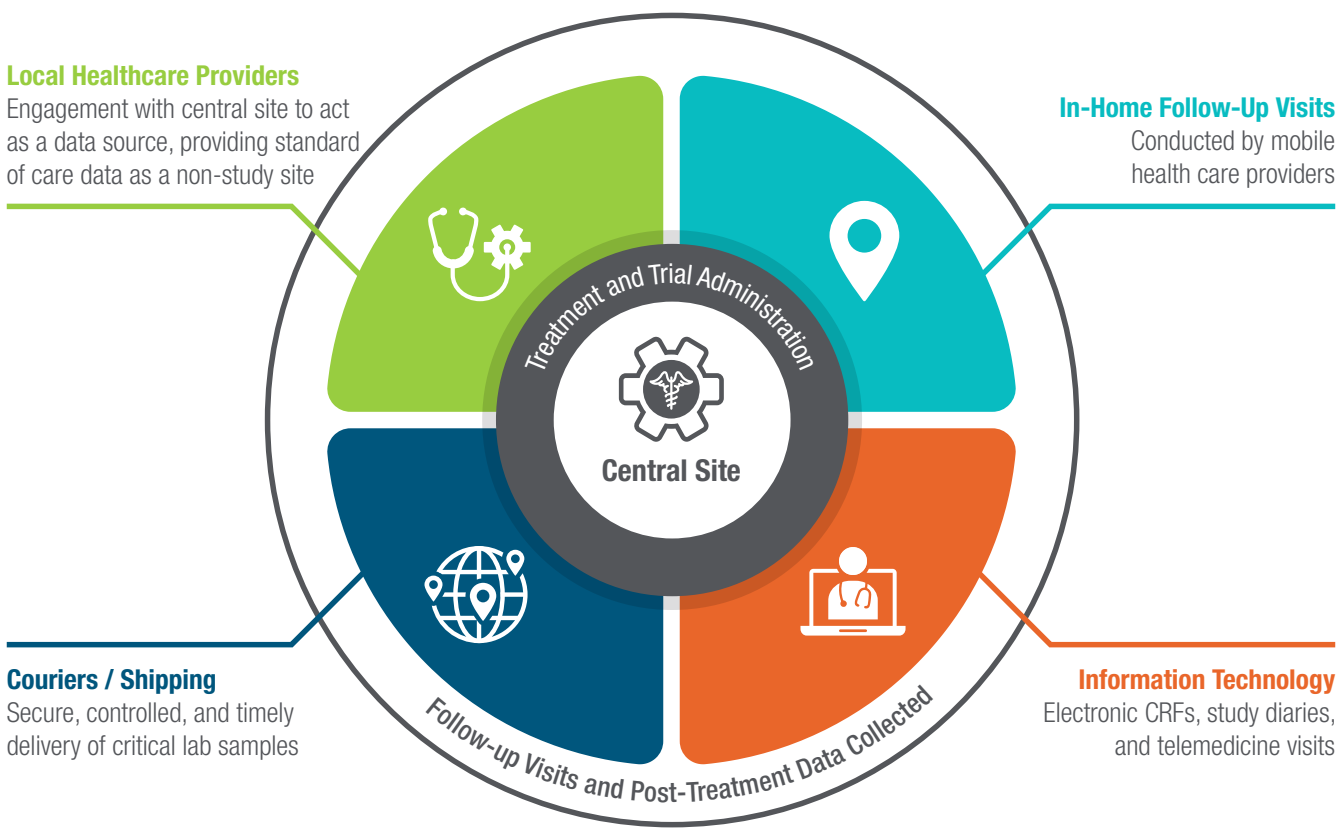
The Benefits of a Centralized Site Model

As the name indicates, a centralized site model allows patients to be treated at one or two central sites, which minimizes the travel burden on patients and caregivers. A combination of technology and/or mobile staff are employed to conduct follow-up visits in a convenient local setting or at the participant's home. This model supports Veristat's patient-centric philosophy, reducing the burden for trial patients while providing an innovative solution for sponsors. Benefits include greater consistency and operational efficiency that is more manageable and saves costs. Centralized trials are especially beneficial for rare disease programs.



CHECKLIST:

Five areas to address IN YOUR STUDY DESIGN to ensure your central site trial is a success.

1. Regulatory and Ethics Plan

- There are gray areas between regulatory definitions of "clinical sites" vs. "data sources" – avoid any confusion by defining it all upfront.
- Ensure all blood and specimen sample collections, processing and storage procedures are outlined in the protocol and consent documents, particularly where samples are being sent by local HCPs and may contain patient identifiers.
- When recruiting patients from outside of the central site country, check the local country regulations for any notification requirements and data privacy compliance.
- Informed Consent forms are needed for all clinical trials. For a centralized trial, there's a need for additional language in the Informed Consent forms to ensure clarity around the follow-up visit process, specifically data collection and transfer by the patient and local physician.

2. Data Collection Plan

- Think about the level of data you need and how you'll get it. It's usual practice to collect standard of care data. If more than that is required, a Hub and Spoke Model may be a better fit. The Central Site Model isn't designed to handle local site contracts and IRB/LEC approvals.
- How will you handle safety data collection? Working with standard of care data from multiple local centers can be a huge data management and programming challenge. Blood samples collected by local HCPs should be shipped and processed at the central site, avoiding inconsistent lab units/ranges. The central site will be responsible for collecting source data and data entry for consistency.

3. Site Management Plan

- How will missing local site data or other management challenges be addressed and escalated? Providing the Study Synopsis to the local physician ensures engagement and reduces the risk of missing data.
- How will patient data be collected from local centers? It's important to agree upon required patient data, the process for provision of this data, and timelines for data provision with the local physician up front.
- How will you engage and train central sites? Veristat has a robust training program aimed at engagement in the central site model and understanding around their additional responsibilities for local site management.

4. Privacy and Confidentiality Plan

- It's imperative to have a comprehensive patient privacy and confidentiality plan in place early.
- For example, if you're conducting a European study with a central site outside of the EU, you will trigger GDPR concerns.
- If you're using one global central site, they'll be receiving all patient data AND source documentation in other languages and formats, so translation will be critical. What is the most efficient translation process that will protect patient confidentiality and adhere to regulations such as GDPR and HIPAA?

5. Patient Safety Plan

- It's critical to plan for management of adverse events (AEs).
- Central site PI should discuss the definitions of S/AEs and reporting requirements with the local HCPs to ensure awareness.
- Local HCPs must be provided with information regarding the Investigational Product, including potential risks and any prohibited medications to ensure patient safety during follow-up.
- The central site is responsible for S/AE tracking and management, and the PI should be consulted by the local HCP for treatment of any SAEs, via the Emergency Contact card.

CENTRAL SITE MODEL BENEFITS

More cost-effective and efficient – IF these complex trials are set up correctly from the very start with consistent and expert administration

Access to expanded patient populations – a broader net for patient recruitment

Works for any therapeutic area, including rare disease and studies involving complex procedures where fewer sites are preferred

Reduces burden on the patient and their caregivers

Taps into the value of personalized medicine

Helps to ensure business continuity for your clinical development

Meet Veristat – Getting It Right, the First Time

A central site model can be an effective and efficient solution, but one that requires thorough planning for the best results. Veristat has assembled a global team of experts in this field to help set your study on the right path to avoid errors in design, data collection or analysis. We're here to help you get your compound to market faster and positively impact patients' lives.

CONTACT VERISTAT

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