DIGITAL HEALTH TRIALS
Recommendations for Supporting Decentralized Trial Approaches

Your approach to running a decentralized clinical trial doesn’t have to be all or nothing. Decentralized clinical trials sit on a wide spectrum – they can be completely virtual, partially decentralized with hybrid approaches, or very similar to traditional “brick and mortar” trials.

Regardless of where a trial is on the spectrum, there are four critical recommendations for designing a decentralized clinical trial.

RECOMMENDATIONS

1. Plan Ahead
   - Determine which study activities can be performed remotely
   - Consider the indication and whether a disease assessment can be conducted in a virtual manner
   - Consider the study drug dosing/study treatment: assess the feasibility of drug shipment, consider the stability of the product, and assess regulations; for example, can the drug be shipped to the home?
   - Determine the most appropriate method of conducting activities; for example, video visits or telehealth, in-person activities at less crowded locations, telephone contact
   - Maintain methods and conduct of remote assessments as consistently as possible across sites, trial participants, and visits to minimize variability in the data
   - Provide resources and training to sites and patients; test telehealth platforms and train patients, caregivers, and sites on using the platform; know how to handle system failures
   - Follow regulations
   - Be flexible

2. Involve All Stakeholders, Early & Often
   - Communicate with the IRB/IEC and regulatory authorities
   - Involve patient organizations to assist in reviewing the protocol and provide broader outreach and guidance

For more information on CTTI’s Digital Health Trials work, please visit http://www.ctti-clinicaltrials.org/our-work/digital-health-trials
3. **Use A Quality Approach**
   - Focus on what really matters; define critical data collection
   - Refer to CTTI’s *Quality by Design* recommendations

4. **Communicate & Be Transparent**
   - Develop a communication plan, process, and decision-making method; the plan should include who informs participants, when, and how
   - Provide support and training necessary for digital tools, monitoring, home data collection, and information given at the patient level
   - Make communication efficient, non-duplicative, and consistent
   - Maintain clear and ongoing communication