DIGITAL HEALTH TRIALS

Considerations for Delivering an Investigational Product

Delivering an intervention to participants in a decentralized or digital health trial can be complex. There are a number of federal and state telemedicine laws to be aware of, as well as regulations related to a product’s registration status with the FDA. Considerations for assessing the landscape and delivering an intervention to trial participants include the following:

1. Ensure that procedures for direct-to-trial participant shipping of investigational product are described in the protocol so that the process is clear to the investigator, IRB, and applicable regulatory agencies

2. If desired, engage an investigational product management vendor with experience in direct-to-trial participant shipment

3. Formalize SOPs for the investigational product accountability chain

4. Review state law requirements for direct-to-trial participant shipping

5. Check state board of pharmacy guidelines on topics such as the following:
   - Sending a study drug directly to a patient from the site
   - Packaging delivery services with a signature
   - Using home health for delivery and administration of parenteral products
   - Picking up an investigational product from the site or the hospital’s outpatient pharmacy