DIGITAL HEALTH TRIALS
Recommendations for Delivering an Investigational Product

Delivering an intervention to participants in a 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.

Using CTTI’s recommendations, you can properly assess the landscape of applicable laws and take the appropriate steps needed – from assessing the feasibility of drug shipment, to pathway planning and documentation – to deliver an intervention to trial participants.

RECOMMENDATIONS

1. Formalize SOPs for the IMP accountability chain
2. If desired, engage an IMP management vendor with experience in direct-to-trial participant shipment
3. Ensure that procedures for direct-to-trial participant IMP shipment are described in the protocol so that the process is clear to the investigator, IRB, and applicable regulatory agencies
4. Review state law requirements for direct-to-trial participant shipping
5. Check state board of pharmacy guidelines; for example:
   ▶ 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

For more information on CTTI’s Digital Health Trials work, please visit [http://www.ctti-clinicaltrials.org/our-work/digital-health-trials](http://www.ctti-clinicaltrials.org/our-work/digital-health-trials)