DIGITAL HEALTH TRIALS

Recommendations for Interacting with Regulators

Determining the most appropriate, trial-specific strategy for collecting and sharing data with regulatory bodies requires an open dialogue during the design and conduct phases of the trial. Although every trial is different, you can use CTTI’s recommendations and resources to guide conversations and help ensure that trials using digital health technologies can be readily reconstructed.

RECOMMENDATIONS

1. Understand that delegation of authority and responsibilities in the context of decentralized clinical trials (DCTs) should not differ from traditional trials

2. Ensure that trials conducted using digital technologies for data capture should have the ability to be readily reconstructed (i.e., end-to-end traceability)

3. Provide source data to FDA during inspection

4. Determine whether or not to list the healthcare provider as an investigator or sub-investigator on Form FDA 1572 is dependent on FDA regulations

5. Make supporting material for digital technology–based claims available to FDA as part of the marketing application

6. For sponsors who are planning to incorporate telemedicine in clinical research, keep abreast of the complex and varying legal landscape of applicable state laws

RESOURCES

- Figure: Data Processes & Information to Provide to FDA
- Figure: Data Availability for FDA Inspection