



## 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) may differ from traditional trials. As such, investigators should maintain a Delegation of Authority log or equivalent list of individuals, including local HCPs, with delegated responsibilities.
2. Ensure that trials conducted using digital technologies for data capture have the ability to be readily reconstructed (i.e., end-to-end traceability).
3. Determine whether or not to list healthcare providers as investigators or sub-investigators (e.g., on Form FDA 1572) based on country-specific regulations.

Additional considerations for interacting with regulators are included in [Considerations for Advancing the Use of Digital Technologies for Data Capture & Improved Clinical Trials](#).

#### RESOURCES

- ▶ [Considerations for Advancing the Use of Digital Technologies for Data Capture & Improved Clinical Trials](#)
- ▶ Figure: [Data Processes & Information to Provide to FDA](#)
- ▶ Figure: [Data Availability for FDA Inspection](#)