LIONBRIDGE

EMA'S GUIDELINE ON COMPUTERISED SYSTEMS AND ELECTRONIC DATA IN CLINICAL TRIALS*

5.3. Training	Each individual involved in conducting a clinical trial should be qualified by education, training, and experience to perform their respective task(s). This also applies to training on computerised systems. Systems and training should be designed to meet the specific needs of the system users (e.g. sponsor, investigator or service provider). Special consideration should be given to the training of trial participants when they are users.
A2.7 Release for production	The responsible party should sign off the release prior to initial use. Training materials, user guides and any other resources required for users should be available at the time of release.
A2.10 Change control	As part of the change control process, all documentation should be updated as appropriate (e.g. requirements, test scripts, training materials, user guide) and a report of the validation activities prepared and approved prior to release for production. The system should be version controlled.
A5.1.1.4 Data changes	It is expected that the number of changes to ePRO data are limited; however, this requires both designs of ePROs that are appropriate to ensure proper understanding by trial participants and appropriate training of trial participants, thereby avoiding entry errors.
A5.1.3.3 Installation and support	Independently of whether the BYOD solution is based on an application installed on the device or a website/web application, the software and the use should be explained thoroughly via targeted training, which may include user manuals, one-to-one training, and multimedia tools. Users of the system should have access to user support e.g. from a help desk. There should be a procedure in place in case an application cannot be installed, or the web service is unavailable on a device, if the device has malfunctioned or the participant has purchased a new device. Helpdesk contacts by users should be logged (participant or site staff study ID, purpose of contact, etc.) with due consideration of protecting participant information.

U.S. FDA'S DRAFT GUIDANCE ON DIGITAL HEALTH TECHNOLOGIES FOR REMOTE DATA ACQUISITION IN CLINICAL INVESTIGATIONS**

Line nos. 643-647	The sponsor should: • Ensure training of trial participants and trial personnel (see section IV.H.4 of this guidance) on using DHTs and, as applicable, the general-purpose computing platforms, according to the protocol (e.g., wearing the DHT for the specified time period).
Line nos. 680, 687-688	Investigators should: • Ensure training of participants on using the DHT according to the protocol (e.g., wearing the DHT for the specified time period).
Line nos. 692-741	3. Training Training trial participants and trial personnel on the appropriate use of DHTs and, as applicable, general-purpose computing platforms, including training on responsibilities for data collection in a clinical investigation, is critical for appropriate use of the DHT and to maintain data integrity and data quality throughout the investigation. Any training materials should be included as part of the submission. Training should: • Occur before participants begin using the DHT to collect data for the purposes of the clinical investigation • Be scheduled, provided, and documented during the investigation, as appropriate (e.g., if changes or updates to the DHT and, as applicable, the general-purpose computing platform alter the way sponsors, clinical investigators, other trial personnel, or trial participants interact with the DHT) • Be available to trial personnel and trial participants having difficulty using DHTs or, as applicable, general-purpose computing platforms during the investigation Sponsors should consider addressing the following as part of the training for trial participants and trial personnel, as appropriate: • Setting up, activating, and operating DHTs and, as applicable, general-purpose computing platforms • Collecting data at appropriate time intervals • Uploading or syncing data • Ensuring the security and privacy of data collected by the DHT • Wearing DHTs appropriately (e.g., location and duration), if applicable • Properly cleaning the DHTs before or after use, if applicable • Sharing of the same DHT and, as applicable, general-purpose computing platform with other individuals • Connecting to wireless networks • Handling known adverse events associated with the DHT (e.g., rash from actigraphy bands) • Responding to DHT signals, notifications, and errors, including procedures for troubleshooting and elevating unresolved issues • Verifying that DHTs are being used appropriately and that data are being collected, uploaded, or synchronized as planned

U.S. FDA'S DRAFT GUIDANCE ON DECENTRALIZED CLINICAL TRIALS FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES***

Line nos. 77-79	Appropriate training, oversight, and up-front risk assessment and management will be key to implementing a DCT successfully.
Line nos. 250-252	The decentralized features of the trial may necessitate additional training, coordination, and standard operating procedures to ensure consistent implementation.
Line nos. 506-507	Training should be provided to all parties (e.g., trial personnel, local HCPs, and trial participants) using software to support the conduct of DCTs.

* https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-electronic-data-clinical-trials_en.pdf

** https://www.fda.gov/media/155022/download

*** https://www.fda.gov/media/167696/download