Satisfying clinical Research guidance and regulations for mHealth Technologies

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Abstract

The Office of Cyber Infrastructure and Computational Biology (OCICB) of the National Institute of Allergy and Infectious Diseases (NIAID) at the NIH has been developing a solution that complies with current guidance frameworks and regulatory requirements while leveraging the potentials offered by mHealth technologies for data collection. OCICB has designed an mHealth solution that maps to the paper processes developed over the past century for clinical research. We designed the system for use in regions of low to middle-income countries where the patients often have no other clinical record. For our pilot, we selected a natural history study that does not have the same regulatory requirements as an Investigational New Drug (IND) study. We retained our existing paper-based clinical data capture management system in order to compare quality control reports between paper-based and mobile electronic capture methods. The solution complies with regulatory frameworks and requirements such as Good Clinical Practices and 21 CFR Part 11, which requires full audit trails of the data collection process at the source and the validation stages. It also provides the capacity for workflows that support the data validation process within the field research framework. We expect to show that the accuracy of data collection improves using mobile source data collection. This will reduce the time and cost of validating the collected data before final analysis for clinical research while maintaining the regulatory framework that protects patient interests. The solution will further provide clinical monitors with the ability to remotely access the source data and thus reduce the cost of travel for monitoring as well as reducing the impact on patients due to mistakes made while entering the data.