J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-020

Clinical research conducted through computerized system integrated with wearable and/or smart devices – consideration on supplier management

Yumi Wakabayashi[1] and Hitoshi Matsui [2]
[1]Osaka City University, Japan
[2]CAC Croit, Japan

Wearable device and/or smart device such as watch-type healthcare monitor and e-PRO (patient reported outcome) tool come in handy to collect patient data and outcomes in clinical investigation in a timely manner. When clinical investigators manage data through clinical data management system integrated with wearable and/or smart device during conducting clinical research, they can check subject condition and adherence to study protocol easily. If researchers realize a patient has difficulty to follow protocol, they can perform site management by talking to responsible investigator. That would contribute to risk-based quality management of the study. On the other hand, such computerized system integrated wearable and/or smart devices are usually built by cooperating with many suppliers, wearable device manufacturers, smart device manufacturers, data management service providers, network infrastructure providers, and so on. Sometimes wearable device manufacturer's operation is not manageable for clinical researcher because it is controlled under agreement between the wearable device manufacturer and the smart device supplier. When clinical researcher conduct clinical trial through data management system integrated with wearable and/or smart devices, supplier management skill is essential for the researcher. Supplier assessment before the study initiation is one of key activities in computerized system validation. It is also necessary for clinical researchers to monitor supplier(s) during the study. Periodic communication in person or via teleconference would be also helpful.

wakabayashi.yumi@med.osaka-cu.ac.jp