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MANAGING DATA FLOW FOR WEARABLES, APPS AND SENSORS

Exponential growth is expected in the wearable devices market in the coming years. Data from these Wearables, Apps and Sensors are very unique due to the personal nature of the device. Wearables have the ability to transform clinical trials by passively collecting continuous high-quality endpoint data.

To validate and transform big sets of raw data streams, a backbone computing support is required. In the US, data obtained via medical devices are covered by the HIPAA Act, which requires patient consent for data collection and sharing. Big steps in user authentication with technologies such as fingerprint (touch-ID), iris scanner, facial recognition have emerged lately.

From a regulatory perspective, we will get to a point where these apps/devices will need to undergo calibration or be standardized for acceptance of results. To overcome these challenges, Data Manager should contemplate newer workflows and metrics for data collection, quality, transformation, review and storage.

INTRODUCTION

Clinical Research is witnessing transformational shifts in study execution at sites in recent years. Two critical areas undergoing significant change are:

- Digitization of essential clinical research processes
- Increased adoption of mHealth components

Both of these are generating new systems, data sources and an unprecedented volume of patient data. On the technology front, conventional data handling practices cannot process voluminous data from wearables. Many organizations are beginning to achieve process maturity in effectively using Connected Devices in Clinical trials.

The purpose of this presentation is to understand newer perspectives and enable the audience to be ready with a framework when connected devices trials are implemented.

DATA FLOW FROM WEARABLES, APPS AND SENSORS

Clinical Research is fast moving away from relying on traditional sources of data like Electronic data capture / Case Report form to collecting data real-time using different digital technologies. The conventional operating space of clinical data and analytics are being challenged by a revolution in these digital health space.

The Variability, Variety, Volume and Velocity of data from these Technologies require traditional models to re-scale to harness the full potential. The aim of this session is to explore some of the best practices to adopt given the advancements in this field.

SETTING UP SYSTEMS FOR DATA FLOW

The point of origin of data is the Digital Health device worn by the subject. Data from these devices are transmitted to a Receiver device through Bluetooth/RFID/WIFI. The receiver transmits data to servers via the internet/mobile data network. Wearable devices can also continuously stream the data to the servers due to technological advancement. Data from the servers is later extracted for review and analysis.

In a general setting, interaction is probably limited between the caregiver and device wearer to monitor health. However, in a clinical research setting, there are several stakeholders (Sites, Subjects, Monitors, Data Manager, Statistician, Sponsor, Vendor etc). There are also steps to be taken as per Regulatory requirements – Informed consent, Randomization, Treatment Allocation, Scheduling visits, Data Collection, Cleaning, Monitoring etc. A custom-designed, study management suite is required to orchestrate all trial-related activities and the presentation covers an overview of it.

BEST PRACTICES ON DATA INTEGRITY AND QUALITY

In the Data Life Cycle from Raw Data Acquisition to Reporting and Analysis, data is crossing multiple devices, systems, networks and stakeholders, and it is susceptible to Quality and Integrity risks. To ensure security and integrity of the data, several best practices are recommended. It is unlikely that any single approach at any stage of the data lifecycle will adequately ensure its security. A multi-prong, step by step approach covering end-to-end of the data life cycle is suggested.

DATA COLLECTION AND STORAGE

Traditionally, data collection occurs during clinical trial site visits. The use of mobile technologies for data capture offers the possibility of gathering real-time information from study participants in their homes, workplaces, or other convenient settings, potentially over long periods of time, yielding a more complete picture of the investigational product.

However, the ability to realize benefits is contingent on collecting high-quality, 'clinically meaningful' data. This section provides recommendations for optimizing data collection and cleaning while using mobile technologies.

METRICS

Metrics', a verifiable measure, provides a quantitative assessment and keeps us updated with the issue (s) or performance of various steps. The challenges are to identify the right metrics for desired parameters, how to perform measurements, and how to interpret results. Metrics recommended in this presentation for Wearables, Apps and Sensors cover Compliance, Quality, Device Configurations and App performance. Some of the metrics come 'Inbuilt' in the App or firmware while others have to be Custom designed for the trial requirement.

REGULATORY LANDSCAPE

ICH GCP, 21CFR Part 11, GDPR and HIPAA do apply even for the Wearable device trials. 21 Century Cures Act came into existence in Dec 2016 that recommends interoperability of systems and FDA has recently released a Guidance in Sep 2019.

CASE STUDY

We at IQVIA Connected Devices are fully aligned with our sponsors' goals and vision to bring new drugs to market in reduced time and cost using new technologies. The key factors that facilitated the build of the device portfolio for a leading pharmaceutical company are as below:

- Early engagement
- Aligned road maps
- Agile technology
- A robust and lean vendor onboarding process
- Scalable model

An early engagement with the therapeutic strategy leads of the leading pharmaceutical company helped us understand their protocol requirements and timelines for the year. We then aligned our strategic and innovative IT roadmap to qualify and implement technology solutions in geographies before the study start. For this study, it was challenging to manage dosing of an elderly, compromised patient population with a drug known to have a hypertensive effect in a combination of home and site setting. We deployed globally configured solutions including wireless blood pressure, ambulatory blood pressure, actigraphy and ECG devices to sites and patients. We compiled these data sets into a common database in order to extract insights / understand correlations. We also provided 24/7 site and patient support and training to enrich adherence

CONCLUSION

Digital endpoints are transforming drug development. Mobile technology offers unique opportunities to improve the quality and efficiency of clinical trials, in part through high-quality data collection in settings outside of the healthcare facility or clinic, such as in the study participant's home or workplace. There is a need to re-scale the clinical data and analytics workflows in order to adapt to the rapid innovation in the digital health space.

REFERENCES

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