

IOT or IOMT?

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ABSTRACT

IOT or IOMT? We have all heard about the impending era of the internet of things (IOT) where smart devices will allow our homes, our cars, our businesses and countless other attributes of daily living to be managed via a click of a mobile device.

IoT has the capacity to change and simplify the process of clinical trial to be more cost-effective and efficient. Stakeholders are looking for reducing the time taken for research on new treatments and diagnostic methods while improving ways of conducting clinical trials. Implementing Electronic Clinical Outcome Assessments or eCOA can improve data collection, reduce costs and increase patient participation or retention rates. Adoption of digital health on IoT platform can create limitless opportunity for smart technology sensors and medical devices. The initial response from clinical researchers through patient experience is positive in collection of biometric data on trial subjects by using the devices that collect data more efficiently. These devices can help gather data for analysis by connecting to the internet and improve transmission to other machines wirelessly.

But how much has been said about the coming world of the internet of medical things (IOMT)? A world where patient, pharmacy, doctor, hospital, insurance company, pharma company and government are all connected, sharing data and information in real time and enabling virtual coordination of care regardless of physical location of the players? Only a fantasy, you say.? Perhaps it will arrive sooner than we think. Is pharma prepared to be part of a virtually managed health care system? What are the steps necessary to get ready and integrate with this future scenario?

INTRODUCTION

The internet of things is a system of interrelated computing devices, mechanical and digital machines, objects, animals or people that are provided with unique identifiers (UIDs) and the ability to transfer data over a network without requiring human-to-human or human-to-computer interaction.

The benefits of the IoT for business depend on the particular implementation, but the key is that enterprises should have access to more data about their own products and their own internal systems, and a greater ability to make changes as a result

POTENTIAL

At any given moment, there are more than 20,000 clinical trials underway in the United States alone, including both observational trials (those that simply monitor participants in specific areas to determine trends and draw conclusions) and interventional (those that involve a specific drug or treatment). The typical clinical trial costs an average of \$30 to 40 million dollars for the first three phases of research, and then another \$30 to 40 million for the post-approval phase. However, a significant number of trials – by some estimates, as many as half – never make it past phase three.

The high failure rates of clinical trials are due to a number of factors, ranging from a lack of participation to poor results in the early stages of the research. This has many researchers looking for a better way to conduct clinical trials, including implementing more eCOA technology solutions to improve data, reduce costs, and increase participation rates. To further improve the success rates of trials, researchers are also looking to the IoT.

Improved recruitment, management, and reporting

The IoT has a number of potential applications for clinical research, all of which have the potential to save money and time.

Recruitment

One of the tools being used to recruit patients for clinical trials, which is often the biggest challenge of any study, is big data. By analyzing big data, study recruiters can target the most appropriate patients more accurately. Study recruiters are beginning to see the value in strategies like search engine marketing and social media advertising to recruit subjects – and those tactics rely heavily on online behavioral profiles.

The IoT is constantly collecting data about individuals – data that allows recruiters to better pinpoint the patients that are best suited for a specific trial and target advertising and other recruitment tactics specifically to those individuals.

Study management

One of the most common reasons patients do not participate in clinical trials, or drop out of studies before they are complete, is that it can be cumbersome to fulfill the obligations of being a part of the study. Keeping diaries, filling in surveys, and visiting physicians are often part of a study, and failure to follow the study protocol in any of these areas can skew the results.

IoT has the ability to solve these problems. Researchers are now experimenting with relevant devices such as wearable and ingestible sensors, as a means of collecting study data without easily addressing the issue. It not only has the ability to increase retention, but also improves the accuracy of the data collected. Instead of relying on patients to record their own data, which is not always accurate, researchers can collect data at any time. Patient safety is also enhanced by IoT devices because researchers can prevent or change interventions at the first sign of potential harm and have the peace of mind to know that patients are constantly monitored.

Reporting

Rather than endure the time and expense (not to mention the potential errors) of manually inputting data, the IoT allows for that data to be collected and analyzed automatically.

With properly connected and managed devices, clinical trials stand to benefit greatly from the IoT. While there are still questions to consider about patient privacy and the security of devices and networks, not to mention barriers to overcome in terms of ensuring equal access to the technology necessary for this type of research, there is no question that the IoT is already changing clinical research and has the potential to completely transform the entire process.

ACCESSIBILITY AND RISK

Data correlation with clinical significance

Data being captured from smart devices needs to show consistency and accuracy to describe a practical importance of a treatment in a clinical study.

Isolated data and lack of actionable data

Our health systems are not fine-tuned to deal with multiple morbidities because we do not share information across the system. There are reams of public and private sector information, but most are stored in silo and not being used. Now the question is, can we - in a trustworthy way - unleash the power of this big data?

Commercial vs medical grade solutions/devices

There are many commercial devices on the market - i.e. consumer wearable technology that is being used to capture, track and monitor patients' physiological data. The rules and requirement of using such consumer devices, in which data is not regulated, versus medical grade devices, in which data is regulated, need to be streamlined or the intent of using the respective devices needs to be clearly stated.

Multiplicity of solutions- interchangeability and interoperability

With the different platforms - iOS vs Android for example - and different devices - Apple vs Android - one needs to be sure that the software and hardware are able to interoperate in order to include all demographics participating within a clinical study.

Security and privacy

Security is a huge umbrella, but it is the paramount within Internet of Things connectivity. It is essential to make sure that the IoMT device or server has proper authorization to send or receive that stream of data. In addition, encryption between devices and servers is crucial.

Connectivity Challenges

With connected IoT devices, reliable connection, bandwidth and signaling is essential for collecting and routing data between devices. Devices may be talking to a server to collect data, or the server may be talking to the devices, or maybe those devices are talking to one another. One needs to be confident that that stream of data is going to arrive at its destination every time.

Regulations

As with any software used in the healthcare setting, it will be important to consider whether any such technology is a medical device under the relevant legislation and guidance. In addition, it is important to understand the data privacy and security regulations that encompasses the digital health industry.

CONCLUSION

The Internet of Things has already begun to permeate clinical trials. It is not as mainstream as it is in other sectors because the technology is still evolving and advances still need to be made. Clinical researchers have also had a history of being hesitant to adopt new technology, as the accuracy of the data collected in clinical trials is critical and there is no room for error. With time, we will see its presence grow exponentially as more clinicians begin to realize the immense potential that smart devices and in turn IoT have in clinical research.

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