Artificial Intelligence and the Internet of Things in Clinical Research

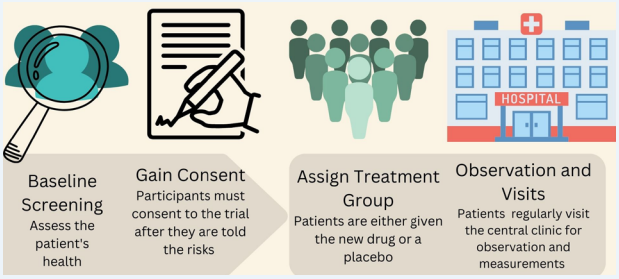
Lab 58 Technology Research Brief

January 2023

To ensure patient outcomes consistently improve, the medical industry constantly researches more effective treatments. When medical professionals use people in their research, it is called clinical research. There are two types of clinical research[1]: observational studies and clinical trials. Researchers use observational studies to gather information and study characteristics across samples. These studies could be conducted through medical exams, tests, or surveys. Using this data, researchers develop best practices and identify opportunities for clinical trials. Clinical trials are traditionally designed to evaluate the safety and effectiveness of new medical interventions.[2] In this context, clinical trials compare the outcomes and side effects of a new treatment with the standard treatment. In other cases, clinical trials are used to detect diseases or test methods of preventing future health problems.

Applications of AI-IoT in Clinical Research

Recently, Internet of Things (IoT)-connected devices and artificial intelligence (AI) applications have been rapidly deployed in the clinical research industry. Specifically, they have been integral in the rise of decentralized clinical trials, clinical trials conducted without physical interaction, and research automation software. This brief will highlight those use cases, as well as provide a high-level description of how advanced algorithms and IoT technologies work. It will also explore technical and ethical limitations facing AI algorithms and IoT-connected devices, before concluding with a discussion about the future of AI and IoT applications in clinical research.



Source: Made in Canva

Figure 1. Traditional Clinical Trial Process

In this figure, the standard process for a clinical trial is outlined. In the last stage, participants must return to a physical location for observation. This is not the case for decentralized clinical trials.

KEY TAKEAWAYS

1. **Decentralized clinical trials are likely to grow in popularity due to COIVD-19's dramatic effect on patient mobility and the rise of IoT-connected devices.**
2. **In recent years, experts have created machine learning and deep learning algorithms with diagnosis capabilities comparable to human experts[3] and strong predictive capabilities. These algorithms are generally known as downstream AI algorithms.**
3. **AI algorithms are used to automate certain tasks within clinical trial procedures like signature identification. These algorithms are known as upstream AI algorithms.**

[1] National Institute on Aging. (2022). What are Clinical Trials and Studies?

[2] National Institute on Aging. (2022)

[3] Balyen, L., & Peto, T. (2019, May-June). Promising artificial intelligence-machine learning-deep learning algorithms in ophthalmology. *Asia-Pacific Journal of Ophthalmology, 8*(3), 264–272.

Technical Breakdown: What is the Internet of Things?

It is easier to understand the Internet of Things as a concept, rather than a physical piece of technology like a computer monitor. The IoT is a sensor-based technology revolving around the idea of connecting any electronic device[4] to the internet and other connected devices. Once connected, these devices can collect, share, store, and analyze data in real time, essentially monitoring any setting without human intervention. When multiple IoT devices are connected, it is called an IoT platform. These platforms exist in many settings. For example, a smart coffee pot can be set to turn on in conjunction with your morning alarm, or sensors can track customer behavior in an automobile showroom. Lab 58 has written extensively on IoT platforms; if you are interested in learning more, please, consider reading our Edge computing technical brief, and other relevant publications, which are available on our website.

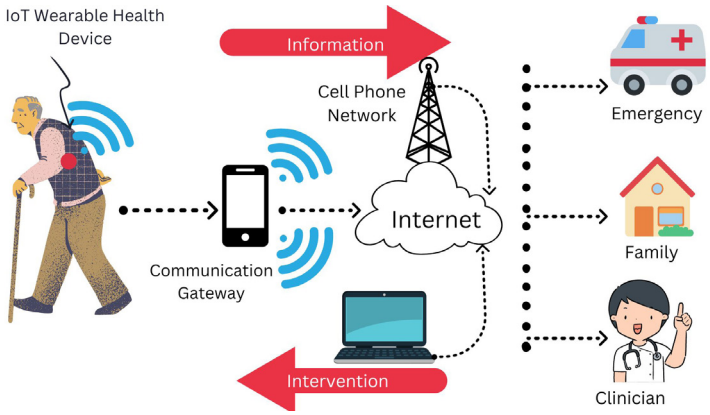


Image Created on Canva

Figure 2. Possible IoT Remote Health Network.

In this graphic, a basic IoT wearable health platform is shown. The patient wears an IoT connected device that assesses his health in real time. If there is a concern, or someone wants to manually check his results, they will be connected through other electronic devices.

Algorithms Breakdown: Machine Learning and Deep Learning

There are many impactful healthcare AI algorithms, but currently some of the most significant are machine learning (ML) algorithms. ML is a subfield of AI that "uses computational algorithms to analyze large data sets to classify and predict without explicit instructions."[5] To learn how to recognize patterns, first ML models are trained with input and outputs of real-world data. Then, the models are asked to create predictions for a new set of inputs with known outcomes. These predictions are then validated by comparing them to the known outcomes. If the model is accurate, the predictions will match the known outcomes. If these predictions do not match the outcomes, then the model is retrained. In medical settings, these algorithms have become popular in decision support systems within diagnosis settings.

Deep learning (DL) algorithms are newer to the medical industry but have a very exciting future, as they are considered the fastest-growing field in machine learning.[6] Deep Learning is a subset of ML and has grown significantly with the rise of "big data." DL models use artificial neural networks which "simulate the electrical activity of the brain and nervous system."[7] In an artificial neural network, elements known as neurodes, or nodes, are organized into layers, with each node able to process and communicate input data to other nodes. Layers of nodes can perform complex operations like representation and abstraction of images, sounds, and texts.[8] These capabilities allow DL algorithms to aid image classification, language translation, and other operations.[9] In medical settings, the predictive power of DL algorithms have made them useful in triage situations within medical fields like radiology.[10]

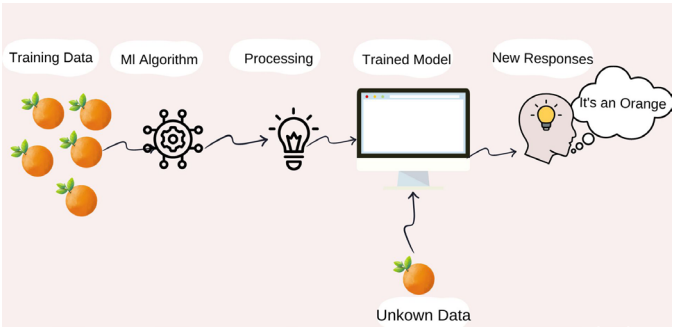


Image Created on Canva

Figure 3. Training a Basic ML Algorithm

In this depiction, a machine learning algorithm is trained to recognize a picture of an orange. The algorithm uses historical data of oranges to recognize patterns. Then, when unknown data are inputted, the algorithm will recognize the image if it is an orange.

[4] Clark, J. (2016). What is the Internet of Things (IOT)? IBM Business Operations Blog.

[5] Ramkumar, P. N. et.al. (2021, May 1). Clinical and research medical applications of artificial intelligence. *Arthroscopy: The Journal of Arthroscopic & Related Surgery, 37*(5), 1694–1697.

[6] Reyes, Kate. (2022, November 18). What is deep learning and how does it work [explained]. *Simplilearn*.

[7] Walczak, S., & Cerpa, N. (2003). Artificial neural networks. In: R. A. Meyers (Ed.), *Encyclopdia of Physical Science and Technology* (3rd ed., pp. 631–645)

[8] Reyes (2022, November 18).

[9] Weissler, E. H. et.al. (2021). The role of machine learning in clinical research: transforming the future of evidence generation. *Trials*, 22(1).

[10] Jang, B. S. et. al. (2020). Deep-learning algorithms for the interpretation of chest radiographs to aid in the triage of COVID-19 patients: A multicenter retrospective study. *Public Library of Science, 15*(11).

AI in Medical Settings: Clinical Research Automation

AI applications designed for clinical research tasks can be generally put into two groups: upstream AI and downstream AI. Upstream AI applications are involved in the logistic workflows of clinical research, like ordering, scheduling, patient screening, and operation analytics.[11] Logistical workflows are often a challenge. Currently, one out of every five clinical trials do not complete the enrollment phase due to complications.[12] However, upstream AI algorithms have the potential to improve the enrollment and recruitment process of clinical trials. For example, AI algorithms can select optimal subjects for clinical trials from large databases of electronic health records[13] or use Natural Language Processing to read clinical research and extract data. The optimization and automation of these processes are important to ensure subjects are randomly selected, which promotes trial outcomes and could lead to higher clinical trial retention rates.[14]

On the other hand, downstream AI is a term to describe AI applications used for automated detection or segmentation, automated interpretations of findings, and image postprocessing.[15] Downstream AI algorithms are often DL algorithms and are used as decision support systems for diagnosis, especially in the areas of radiology and ophthalmology. For example, during the COVID-19 pandemic, a learning AI algorithm was developed with the purpose of diagnosing COVID-19 in patients from radiographs, images created by X-rays or gamma rays.[16] Since that time, the algorithm has continued to perform as well as a panel of experienced thoracic radiologists.[17]

Decentralized Clinical Trials

IoT and AI algorithms are both being used in a new form of clinical research known as decentralized clinical trials. In a normal clinical trial, subjects are often physically observed in a predetermined setting. However, getting to these locations can be difficult, because patients involved with clinical trials often face logistical issues like travel costs or mobility challenges. These restrictions make patient recruitment and sustainment difficult. By using IoT remote monitoring devices, doctors can remotely monitor specific health data in real time, eliminating the need for subjects to travel long distances. These new contact-less trials are being called decentralized clinical trials. It is expected that decentralized clinical trials will increase access to remote subject populations and eliminate the need to staff central observation centers, thus reducing the costs of conducting clinical trials.[18]

Decentralized clinical trials became far more common during the COVID-19 pandemic, as limited mobility restricted participants from observation locations. AI and IoT technologies were rapidly integrated, and the benefits of decentralized clinical trials were brought to light.

Future Of AI-IoT in Clinical Research

As noted, the widespread disruptions caused by the COVID-19 pandemic forced the healthcare industry to lean on AI and IoT technologies more often. Due to this shift, decentralized clinical trials became more popular and are likely to continue to grow post-COVID-19. In 2020, the Food and Drug Administration (FDA) and more than 50 other international organizations partnered to create the Decentralized Trials and Research Alliance, which indicates to researchers that decentralized clinical trials are here to stay.[19] Likewise, the growth of decentralized clinical trials will almost certainly lead to the adoption and development of more advanced wearable IoT devices.

AI algorithms will only continue to improve and become more complex as well. The field of clinical research, like most things, has become far more data-driven, and AI algorithms will be required to make data useful. Therefore, researchers and investors will mostly likely develop better DL and ML algorithms, inevitably leading to improved patient outcomes and more efficient clinical research methods. Artificial neural networks will likely continue to be implemented into more and more algorithms. However, to validate increased investments into algorithms, medical professionals from various medical fields will have to internally determine the clinical tasks most likely to benefit from the use of AI algorithms.[20]

[11] Juluru, K. et al. (2021). Integrating AL algorithms into the clinical workflow. *Radiology: Artificial Intelligence, 3*(6).

[12] Ngayua, E. N. et al. (2020b). Applying advanced technologies to improve clinical trials: a systematic mapping study. *Scientometrics, 126*(2), 1217–1238.

[13] Juluru et al. (2021).

[14] Ngayua, E. N. et al. (2020b).

[15] Juluru et al. (2021).

[16] Wehbe, R. M. et.al. (2021). DeepCOVID-XR: An artificial intelligence algorithm to detect COVID-19 on chest radiographs trained and tested on a large U.S. clinical data set. *Radiology, 299*(1), E167–E176.

[17] Wehbe et al. (2021).

[18] Van Norman, Gail A. (2021, April). Decentralized clinical trials: the future of medical product development?*. *Journal of the American College of Cardiology Basic to Translational Science, 6*(4), 384–387.

[19] Van Norman (2021).

[20] Savadjiev, P. et al. (2018). Demystification of AI-driven medical image interpretation: past, present and future. *European Radiology, 29*(3), 1616–1624.

Technical Limitations

IoT devices and AI algorithms are not in more clinical research protocols because many of the products are still in early development stages. For example, IoT wearable devices are rapidly increasing in capabilities, but some biometric sensors are yet to be clinically validated by professionals.[21] Clinical validation is a process of ensuring a software system is accurate, reliable, and consistent. Without validation, a product cannot be adopted for mainstream use; therefore, medical professionals must wait for more advanced sensors to clear the validation process.

Additionally, to function properly, AI algorithms and IoT technologies depend on other technical factors like strong internet connectively. In some areas, these factors are not met, meaning patients may not be able to use wearable connected devices or upload data into web portals for an algorithm to analyze. Internet infrastructure is especially concerning as internet connectivity is linked to socioeconomic factors, and it is often important to have a diverse socioeconomic subject pool while conducting clinical research.

Current cybersecurity systems also represent a challenge for IoT connected devices. Keeping patient data secure is a must, but this can be a challenge when subjects are forced to interact with multiple health care providers who utilize separate electronic health record systems. Therefore, improvements in the methods that protect and send data on connected devices are needed before they can be fully utilized in clinical research. Currently, researchers are exploring blockchain technology as a potential solution to data transmittal and connectivity challenges. Blockchain is a decentralized platform for managing databases, which does not require a "trusted" centralized third party. By eliminating the third party, blockchain technology can reduce costs and improve the speed of transactions. Nevertheless, these sorts of blockchain-dependent solutions are in the early stages of development and in no position to be integrated throughout the industry.

Ethical Considerations

As usual, when dealing with AI algorithms, there is a question of possible bias as algorithms are trained with data that can be improperly labeled or contain natural bias. Biased algorithms make incorrect conclusions. Consequently, there will always need to be structures in place to identify opportunities for bias within algorithms. Likewise, data scientist will need to conduct regular bias audits to identify biased algorithms in need of repair.

However, even larger than the issue of bias may be the issue of balancing the reality of "big data" technologies like AI algorithms and IoT sensors with personal privacy expectations. "Big data" is all about collecting and analyzing as much data as possible. People want to have their personal data protected, and some data, like Personally Identifiable Information, are heavily regulated by legislation. Therefore, legislators, healthcare professionals, and the public will need to create obvious codes of privacy and ethics to govern the way we use AI algorithms to make decisions and collect human data using wearable IoT devices.[22] For example, if a doctor makes an improper medical decision because of an AI algorithm's suggestion, society must decide who is at fault.

Conclusion

AI algorithms and IoT connected devices will undoubtably change how clinical research is conducted. IoT devices will allow physicians to collect, share, and analyze data remotely, which will allow for more flexibility in clinical trial procedures. Algorithms will assist doctors conducting research and automate parts of their protocols. However, with these changes come questions of bias data and privacy. That is why Lab 58 and other research labs are working to create secure, efficient, and functional products from these technologies.

Work With Lab 58

Thanks for your interest in our work! We want to help you explore opportunities to work with AI-IoT in Clinical Research.

Please email us at Lab58@rti.org. We will set up a 30-minute, one-on-one chat to discuss opportunities and answer any questions. We are interested in partnering with you to find a solution that meets your needs.

For more information, contact Lab58@rti.org.

[21] Van Norman (2021).

[22] Bartoletti, I. (2019). AI in healthcare: ethical and privacy challenges. In: D. Riaño, S. Wilk, & A. ten Teije (Eds.), *Artificial Intelligence in Medicine*. AIME 2019. Lecture Notes in Computer Science (LNAI, vol. 11526). Springer, Cham.