Review Article

World J Curr Med Pharm Res. 2022; 4(3): 29-32

WORLD JOURNAL OF CURRENT MEDICAL AND PHARMACEUTICAL RESEARCH

www.wjcmpr.com ISSN: 2582-0222

Artificial Intelligence based Software as Medical Device

Gade Ahalya[1], Ramaiah Maddi[2]

[1,2]Department of Pharmaceutical Regulatory Affairs, Hindu College of Pharmacy, Amaravathi Road, AP, India

Abstract

Even the most basic of artificial intelligence (AI) systems can outperform humans in some milestone tasks. The following article will present the study on how AI-based software can be used in medical devices. The medical industry has seen astounding advances in AI is used extensively in medical sciences and many other sectors. AI-based software as a medical device will deliver safe and effective software functionality that improves the quality of care that patient receives. Along with its benefits, it also faces challenges, including the need for regulation to keep up with the pace of technology.

Article History:

Received: 25.03.2022
Revised: 15.04.2022
Accepted: 08.05.2022

Keywords:

Artificial Intelligence; Medical Devices; Software as Medical Devices.

*Corresponding Author
Gade Ahalya

DOI: https://doi.org/10.37022/wjcmpr.v4i3.212

Introduction

Artificial Intelligence is a combination of two words Artificial and Intelligence, which refers to man-made intelligence. In the year 1956, for the first time, the term Artificial Intelligence was coined by the American Computer scientist John McCarthy at the Dartmouth Conference. John McCarthy is also known as the Father of AI. Artificial Intelligence is a branch of computer science that deals with developing intelligent machines which can behave like human, think like human, and has ability to take decisions by their own The goal of Artificial Intelligence is Reasoning, Knowledge Representation, Planning, Learning Natural Language Processing, perception and the ability to move and manipulate the objects [1, 2]

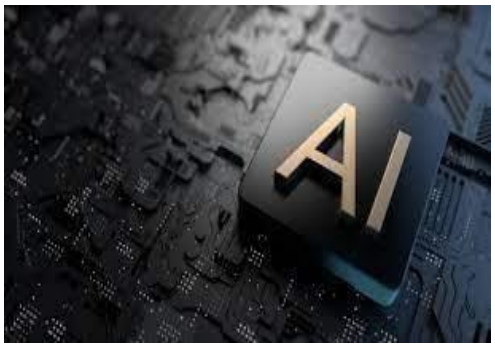

Figure: 01 Artificial Intelligence [1]

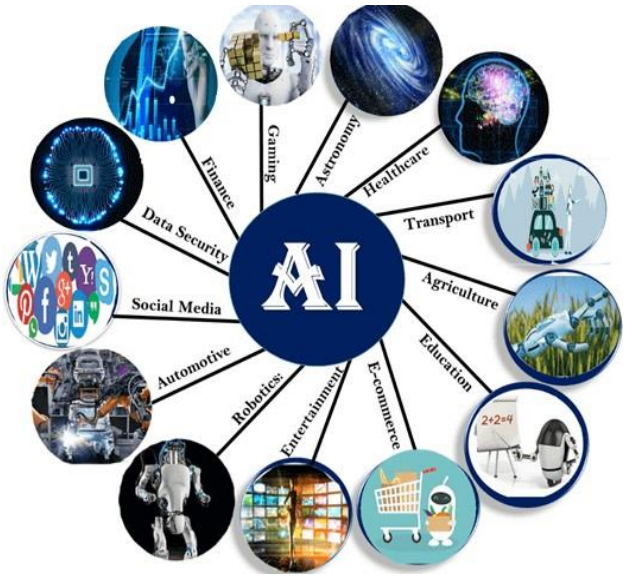

Figure: 02 Applications of Artificial Intelligence [2]

1.1 Types of Artificial Intelligence:

Based On Functionality:

1. Reactive Machines
2. Limited Memory
3. Theory of Mind
4. Self-Aware [3, 4]

Based On Technology:

1. Artificial Narrow Intelligence
2. Artificial General Intelligence
3. Artificial Super Intelligence [3, 4]

2. Medical Device

The FDA defines a medical device as:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

3. **SOFTWARE AS A MEDICAL DEVICE:**
   - According to the International Medical Device Regulatory Forum (IMDRF) Defined the term Software as a Medical Device as Software intended to be used for one or more medical purposes without being part of a hardware medical device.
   - SaMD provides unique features that extend beyond those of the traditional Medical Device or Hardware. Unlike other devices; SaMD is able to leverage technology and connectivity to devices as well as people that can continuously monitor safety, effectiveness, and performance [5]

4. **Artificial Intelligence-Based Medical Devices**
   - Automate tasks, synthesize data from multiple sources, and pinpoint trends
   - Process and analyze information from wearable sensors and identify disease or the onsetof medical conditions
   - Predict which patients are at an increased risk for disease, complications, or negative outcomes based on their medical records
   - Support research by evaluating large amounts of data and monitoring treatment efficacy [6]

5. **Trends in Medical Devices with Artificial Intelligence**

As technology advances, medical device companies are developing AI medical devices that serve three main functions:

- **Chronic disease Management**
  Medical devices with artificial intelligence could monitor patients and deliver treatmentor medication as Needed. For example, diabetes patients could wear sensors to monitor their blood sugar levels and administer insulin to regulate them.
- **Medical Imaging:**
  Companies are developing medical devices with artificial intelligence to conduct medical imaging with better image quality and clarity. These devices would also reduce a patient's exposure to radiation.
- **Internet of Things (IoT)**
  The Internet of things is a system of wireless, interrelated, and connected digital devices used by medical professionals to manage data, keep patients informed, reduce costs, monitor patients, and work more effectively and efficiently. Companies are using IoT in collaboration with medical devices with artificial intelligence to improve patient outcomes [7]

6. FDA AI Guidance

As with any technology, AI can be flawed, creating a greater danger that medical devices with artificial intelligence could misdiagnose a patient or administer incorrect treatment. And because medical devices involve risk to a person's health and life, they are highly regulated. Creating regulations and approval processes takes time, and the U.S. Food and Drug Administration (FDA), the governing body for medical device approval, has been unable to match the pace of technology advancement.

The current governing system is not fully equipped for FDA regulation of artificial intelligence or machine learning, which is an AI technique used to design and train software to Learn from and act on data. The FDA currently approves medical devices based on their risks through one of three processes – the de-novo premarket review for low and moderate-risk devices, the 510(k) process for a new device improving on an existing device or process, or the premarket approval pathway that provides the most stringent review for high-risk devices and/or brand-new technology that has never been done before. This leaves no current, specific path to approval by the FDA for artificial intelligence and machine learning in software as part of a medical device. Earlier this year, the FDA released an action plan drafted based on stakeholder feedback gathered in April of 2019 that outlines the five actions the government entity intends to take relating to artificial intelligence at the FDA. According to the report, these five steps include:

- Further developing the proposed regulatory framework, including through the issuance of draft guidance on a predetermined change control plan (for software's learning over time);
- Supporting the development of good machine learning practices to evaluate and improve machine learning algorithms;
- Fostering a patient-centered approach, including

- device transparency to users;
- Developing methods to evaluate and improve machine learning algorithms; and
- Advancing real-world performance monitoring pilots [8].

7. **EU AI Guidance**

- The analysis of the EU legislation and relevant guidelines demonstrates that AI can be deemed as software.
- Although the MDR itself does not provide any definition of software, the MEDDEV's "Guidelines on the Qualification and Classification of Stand Alone Software used in Healthcare within the regulatory framework of medical devices" 2.1/6 as of July 2016 provide the software definition that is highly relevant to AI.
- According to the guidelines, "software" is defined as a set of instructions that processes input data and creates output data.
- Although AI constantly does self-learning and thus might adapt its algorithms to the real-world environment, the currently existing type of AI, narrow AI, is always limited to the set of instructions initially described by its developer.
- In other words, a software developer creates a specific framework for AI, which transforms inputs into the desired outputs. While learning, the framework itself does not change algorithms adapt within this limited framework.
- Therefore, AI falls under the definition of software provided by the MEDDEV. Althoughthe guidelines are not legally binding and were issued with respect to previously applied medical devices framework, it is expected that the guidelines are to be followed, including in relation to the new Regulation

The Guidelines put forward a set of 7 key requirements that AI systems should meet in order to be deemed trustworthy. A specific assessment list aims to help verify the application of each ofthe key requirements:

- Human agency and oversight: AI systems should empower human beings, allowing them to make informed decisions and fostering their fundamental rights. At the same time, proper oversight mechanisms need to be ensured, which can be achieved through human-in-the-loop, human-on-the-loop, and human-in-command approaches.
- Technical Robustness and safety: AI systems need to be resilient and secure. They need to be safe, ensuring a fall back plan in case something goes wrong, as well as being accurate, reliable and reproducible. That is the only way to ensure that also unintentional harm can be minimizedand prevented.
- Privacy and data governance: besides ensuring full respect for privacy and data protection, adequate data governance mechanisms must also be ensured, taking into account the quality and integrity of the data, and ensuring legitimized access to data.
- Transparency: the data, system and AI business models should be transparent. Traceability mechanisms can help achieving this. Moreover, AI systems and their decisions should be explained in a manner adapted to the stakeholder concerned. Humans need to be aware that they are interacting with an AI system, and must be informed of the system's capabilities and limitations.
- Diversity, non-discrimination and fairness: Unfair bias must be avoided, as it could have multiple negative implications, from the marginalization of vulnerable groups, to the exacerbation of prejudice and discrimination. Fostering diversity, AI systems should be accessible to all, regardless of any disability, and involve relevant stakeholders throughout their entire life circle.
- Societal and environmental well-being: AI systems should benefit all human beings, including future generations. It must hence be ensured that they are sustainable and environmentally friendly. Moreover, they should take into account the environment, including other living beings, and their social and societal impact should be carefully considered.
- Accountability: Mechanisms should be put in place to ensure responsibility and accountability for AI systems and their outcomes. Audit ability, which enables the assessment of algorithms, data and design processes, plays a key role therein, especially in critical applications. Moreover, adequate an accessible redress should be ensured [9].

Figure: 03 AI ECG Platform [10]

Description

The AI-ECG Platform is an AI-powered analysis system that is designed to assist physicians in measuring and interpreting ECG, and the interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. Used with compatible resting ECG devices that can export ECG recordings in various formats, it is intended to be used in hospitals and other healthcare facilities for the assessment of common cardiac abnormalities [11].

Procedure

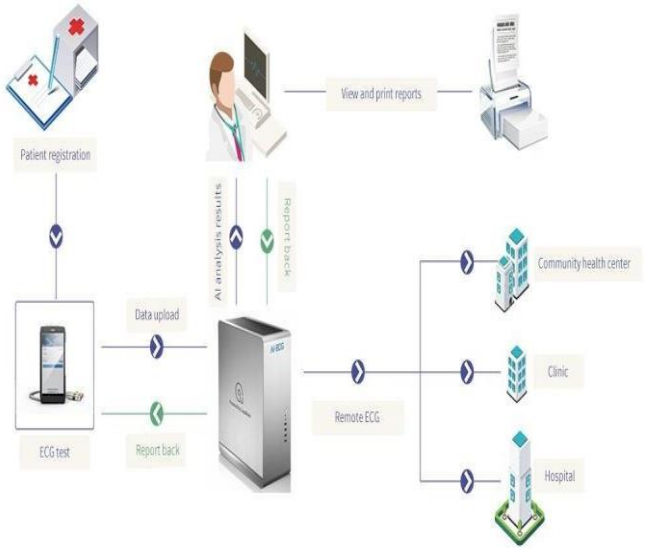

Figure: 04 procedure of AI ECG Platform [12]

9. Limitations

As with any technology, AI can be flawed, creating a great danger that medical devices with Artificial Intelligence could misdiagnose a patient or administer incorrect treatment. Creating Regulations and Approval processes takes time, and the U.S Food Drug Administration(FDA) the governing body for medical device approval, has been unable to match the pace of technology. As more connected medical devices are built on AI, Cyber security risks will increase as well – and it's more important than ever before for manufacturers to implement advanced security protections in the design phase to ensure the safety of health care organizations, providers and patients.

Conclusion

By incorporating Artificial intelligence systems into the development process of medical devices can predict its performance and reduce the failure rate before it gets to the market. It can also faster the device manufacturing time and less cost .For sure, AI has earned its spot at the medical device development process table, even though it's still a work in progress. With major roadblocks and lapses in the development framework removed, biomedical engineers and research experts can focus on novel medical technologies. This will reduce the incidence of lawsuits faced by medical device companies, and their consumers also enjoy better health outcomes.

References

1. https://www.state.gov/artificial-intelligence/
2. https://www.javatpoint.com/application-of-ai
3. https://www.javatpoint.com/artificial-intelligence-essay < Accessed on March 23,2022>:
4. https://www.jigsawacademy.com/what-are-the-different-types-of-ai/amp/#Introduction- To-%20%20%20%20%20%20AI-(A-2021-Update) < Accessed on March 24, 2022>
5. .https://www.fda.gov/industry/regulated-products/medical-device-overview < Accessed on March 25, 2022>
6. https://www.selecthub.com/medical-software/ehr/software-medical-device-samd/ <Accessed on March 25, 2022 >
7. https://www.selecthub.com/medical-software/ehr/software-medical-devices <Accessed on March 25, 2022>
8. https://sterlingmedicaldevices.com/the-use-of-artificial-intelligence-in-medical-device <Accessed on March 26,2022>
9. https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai <Accessed on March 27, 2022>
10. https://www.trademed.com/products/7780/ECG-Platform.html
11. https://www.trademed.com/products/7780/ECG-Platform.html < Accessed on March 28, 2022>
12. https://www.carewell.com.cn/en/AI-ECG.html
13. https://www.carewell.com.cn/en/AI-ECG.html <Accessed on March28, 2022 >