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Artificial intelligence in healthcare system

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Abstract. Artificial intelligence (A.I.) represents various intelligent processes and behaviors, developed by computational models, algorithms or a set of rules that support the machine to imitate the cognitive functions of humans, such as learning, problem solving.
AI technologies in healthcare include machine learning (ML), natural language processing (NLP), physical robots, robotic process automation.
Regulators should collaborate with existing networks of ethics committees and AI expert groups on the ethical issues of AI in the development, use and regulation of human medicines, promoting collaboration between drug and medical device regulatory authorities to harmonize views, needs and requirements.

Keywords. Artificial intelligence, regulations, harmonization, drug and medical device regulatory authorities, ethic issues

1. Introduction

Artificial intelligence (AI) represents various intelligent processes and behaviors, developed by computational models, algorithms or a set of rules that support the machine to mimic the cognitive functions of humans, such as learning, problem solving (1 - 4).

AI is rapidly penetrating healthcare system and has a huge impact on clinical decisions, disease diagnosis and automation. Most common AI technologies in healthcare system include machine learning (ML), natural language processing (NLP), physical robots, robotic process automation.

There are opportunities for AI to explore pharmaceutical and health research due to its ability to investigate enormous data. Machine learning (ML) uses neural networks to search for data to find insights and patterns. Neural networks are programmed like the neural network of the brain – very complicated and complicated; although they cannot fully replicate the brain (1 - 4).

Deep learning is a type of AI that uses larger neural networks with different layers to process a large amount of data, repetitively to modify and edit the result.

Cognitive computing uses self-learning algorithms, natural language processing, and pattern recognition to create human-like interactions when communicating with machines (1 - 4).

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2. Artificial intelligence (AI) in healthcare system

AI in healthcare system covers different areas, such as: disease diagnosis, personalized or digital therapy, drug development, design of clinical trials, forecast of an epidemic/pandemic.

Deep learning technology can be used for establishing disease diagnosis, for classification of dermatological diseases and detection of atrial fibrillation, for use of cross-validation for random division into multiple sets to estimate algorithms, to establish accuracy, sensitivity and specificity (1, 4, 6).

Recently (2022) the algorithm was used by researchers in identifying and classifying cardiac arrhythmias by processing electrocardiogram signals (4).

In another study (2022), tuberculosis was classified and diagnosed using genetic optimization algorithm (GA) and vector classifier support machine (SVM) (4)

3. AI used in digital therapy/personalized treatment

Complex clinical problems must be solved with the challenge of acquiring, analyzing, and applying extensive knowledge. Systems such as ANNs (artificial neural networks) expert evolutionary computational systems, and hybrid intelligent systems can help healthcare manipulate data.

Automatic treatment planning is a recent technology used in radiotherapy that effectively improves plan quality, consistency and error rate (1, 4, 6).

Treatment workflow can be organized in automatic implementation of rules, multicriteria optimization, and a simple automatic computer program can implement clinical guidelines.

The treatment planning system can analyze the patient's anatomy and physiology, and also imitate the reasoning process, which is generally followed in manual treatment planning, three-dimensional dose distribution with promising accuracy (1, 4, 6).

AI natural language expert systems, can develop a combined therapy and adopt one of the treatment recommendations, by monitoring regularly, and through the use of AI, this monitoring is carried out using virtual nurses, virtual coaching via text messages with the use of mobile applications. Also we can use AI for nutritional recommendations based in particular on information provided by the gut microbiota. (1 - 4).

4. Artificial Intelligence (AI) in the field of pharmacy

In pharmaceutical product development, Model Wizard (MES), ANNs AI are used to: choose the right excipients, select the development process and ensure specifications are compliant during the process, etc. In production, AI is used in automated and customized production, and AI technologies such as meta classifier and tablet classifier are used to achieve the desired quality in the final product (1, 4).

AI technologies used in both drug screening and drug development are represented by ML, deep learning, quantitative correlation structure - activity based on artificial intelligence - (QSRL), virtual screening (VS), vector support machines (SVM), deep virtual screening, deep neural networks (DNN), recurrent neural networks (RNNs), etc. (1, 4).

5. Artificial Intelligence (AI) used in clinical trials

AI models can be used in improving the quality of study design, patient selection by reducing population heterogeneity, prognostic and predictive growth. AI provides opportunity to correlate patient data with electronic medical record (EMR), including other patient data, from different formats (1, 4).

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Such analysis uses computer vision algorithms such as optical character recognition (OCR) and Natural Language Processing (NLP) that allow patient identification and characterization (1, 4).

6. AI recommendations

In a report published in 2021, The International Coalition of Medicines Regulators (ICMRA) composed of the Italian Medicines Agency (AIFA), the Danish Medicines Agency (DKMA), the European Medicines Agency as leader of the working group (EMA), US Food and Drug Administration (FDA) as observer, Health Canada (HC), Irish Health Products Regulatory Authority (HPRA), Swissmedic and World Health Organization (WHO) sets out recommendations to help regulators address the challenges that the use of artificial intelligence (AI) poses to the global regulation of medicines (1, 5).

The report identifies key issues related to the regulation of future AI therapies and makes specific recommendations for regulators and stakeholders involved in drug development to drive AI adoption.

Some of the key findings and recommendations include:

1. a risk-based approach to AI assessment and regulation, which could be informed through exchange and collaboration in ICMRA;
2. governance structures of sponsors, developers and pharmaceutical companies to establish strengthened to monitor algorithms and implement of AI,
3. regulations for the development, validation and use of AI cover areas such as provenance, reliability, transparency and understanding, pharmacovigilance and monitoring.

The report emphasizes the need for international AI guidelines from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), this could include the development and use of AI in the context of the development and use of medicinal products for treatment and/or diagnosis (1, 5).

As for regulatory concerns, respectively areas of drug regulation and the lifecycle of medicines, scientific or clinical validation of the use of AI would require an appropriate level of understanding and legal and regulatory frameworks access to the algorithms used and the underlying datasets (1, 4, 5).

In addition, limits of validation and predictability can be identified and tolerated when, for example, AI is to learn, adapt or evolve autonomously; such deployments would also be considered higher-risk AI uses.

In this regard regulatory authorities should engage with existing networks of ethics committees and artificial intelligence expert groups on ethical issues of artificial intelligence in the development, use and regulation of medicinal products for human, promoting collaboration between medicines and medical device regulators to harmonize opinions, needs and requirements use (1, 5).

7. Conclusions

Artificial intelligence (A.I.) technologies in healthcare system include various intelligent processes and behaviors, developed by computational models, algorithms or a set of rules, such as machine learning (ML), natural language processing (NLP), physical robots, robotic process automation. These technologies are involved in different areas of healtcare system such as design of clinical trials, personalized therapy/ medicine, disease diagnosis.

There is concern about legal and regulatory framework of these areas, ethic issues that well be overcome by collaboration between medicines and medical device regulators to harmonize opinions, needs and requirements use.

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