Artificial Intelligence Powered Clinical Trials

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ABSTRACT

The future of clinical trials is changing rapidly due to the introduction of Artificial Intelligence (AI) to study the clinically significant patterns and algorithms generated upon the input from the trial. The high failure rates in the clinical trials leads to inefficient drug development cycle which increases expenses of the pharmaceutical industry. The technique of artificial intelligence allows the decision makers to study the clinical trials in real life conditions which increases the accuracy of the trials. Thus, decreasing the burden of the pharmaceutical industry and increasing the success rates of the trial. Moreover, clinical trial is a much time-consuming process involving 10-15 years for just one drug molecule with lot of investment. The use clinical trial can reduce the time required for the trial and its investment reduces to one half. With the use of the AI powered clinical trials one drug from every 100 drugs passes this phase easily with genuine results which is much greater than the conventional procedure. Rather the use of clinical trials can help in automated documentation of the clinical trial data under the database of the concerned company be retrieved and accessed very easily. The future of AI will include generation of precision medicine and even prediction of drug resistance in clinical trials.

Keywords: drug development cycle, precision medicine, documentation, investment, time.

Artificial Intelligence (AI) ^[1]

Artificial Intelligence refers to the simulation of human intelligence with the help of machines which are programmed to think like humans or can be programmed to mimic the thinking procedure of any other organism. It may be utilized for any machine that can think and solve problem just like a human being.

Use of AI in healthcare ^[1]

The use of Artificial Intelligence is increasing. The following are some uses of AI in Healthcare sector:

- Unifying mind and machine through brain computer interfaces.
- Developing next generation radiology tools.
- Expanding access to care in undeveloping regions.
- Reducing the use of electronic health record use.
- Creating more precise analytics for pathology images.
- Advancing the use of immunotherapy for cancer treatment.
- Turing electronic health record into reliable risk predictors.
- Monitoring Health through wearables and personal devices.
- Making smartphone into powerful diagnostic tool.

Apple watches for health monitoring

Use of AI in Clinical Trials

DNA, RNA, Proteins & Pre-clinical Datasets ^[2]

The whole transcriptomic profiling of the patient's plasma and urine is possible to determine the possible with the help of certain biomarkers to detect and diagnose certain diseases. Automated targeted sequencing of DNA can be performed with the help of AI. This two processes lead to generation of the transcriptomic libraries which are useful to develop personalized medicines.

E.g. High-throughput sequencing using Ion Proton System (Life Technologies) to determine Prostate Cancer.

DNA-Data	Model	Accuracy	F-score	Precision	Recall
HOG100	SSAW	0.9576	0.9315	0.9326	0.9305
HOG100	WFPV	0.9574	0.9426	0.9475	0.9447
HOG100	K ₂ [*]	0.9587	0.9335	0.9472	0.9202
HOG200	SSAW	0.9548	0.9256	0.9366	0.9149
HOG200	WFPV	0.9544	0.9355	0.9430	0.9350
HOG200	K ₂ [*]	0.9439	0.9320	0.9331	0.9309
HOG300	SSAW	0.9509	0.9311	0.9354	0.9268
HOG300	WFPV	0.9402	0.9208	0.9286	0.9219
HOG300	K ₂ [*]	0.9328	0.9255	0.9229	0.9282

DNA Datasets

Clinical Trial Efficacy & Adverse Event information ^[3]

The clinical trial efficacy can be easily recorded along with Adverse event information from various applications and software by the healthcare professionals. The patients can also record the adverse effect through mobile based applications. This data can be easily assessed from the databases.

eHealthFlex
CONNECTING THE DOTS

eHealth Flex patient data recording software

Real World Data & Evidence ^{[1][3]}

The Real World Data and Evidence plays a very important role in the monitoring of the candidate molecule. It can be collected directly from EMR/EHR data, collected directly from the hospital data server recorded by physicians. Other modes of data collection include retina scan for personalized data fitness trackers and mobile applications.

Computational Analysis ^[4]

The Computational analysis can be performed with the help of machine learning (ML). ML leads to the generation of algorithms based on the patient data which help in the analysis of the drug's therapeutic action. AI can help in the analytics and visualization of the collected data. Neural Networking plays an important role in the generation of the patient based data through sequence of questions and answers.

Next Generation antibiotics and personalised medicines ^[5]

Due to growing drug resistance, the need for new generation of antibiotics is increasing and AI can help to access the patient's genomic data and create drug molecule with increased therapeutic effect and reduced side effects. The assessment of the patient's 'omics data helps to produce the next generation personalized medicine. This medicine will be based on patient's genome with reduced toxicity.

Novel Digital endpoints^[6]

With the help of Novel Digital endpoints it is possible to perform at home clinical trials, identifying new phenotypes and remote diagnostics. It is possible to conduct phenotypic screening at a distant area with reduced cost in clinical trials and with more accurate data.

Health Predictions^{[1][6]}

Now with the help of AI it is possible for real time tracking of the data collected from patient. This has a huge benefit because it has lower development times and with reduced cost. The predictive healthcare is necessary for minor diseases which can be treated with OTC products. The patient does not have to visit a doctor.

PvPI ADR reporting app from IPC, Govt. Of India

"Healthcare.ai" is a powerful ML Tool

Concept of Cancer Vaccine from personalized medicine

CONCLUSIONS^[1]

The concept of using Artificial Intelligence in Clinical Trials is an emerging field of research now. The major advantages of using AI in Clinical trials are:

- ✓ Decreased cost of conducting clinical trial on a large population.
- ✓ Increased accuracy of the candidate drug molecule.
- ✓ The data is easily accessible to the healthcare professionals and physicians.
- ✓ Increased comfort to the patient as they can participate in the trial from home.
- ✓ Larger phenotypic screening possible.
- ✓ Decreased rejection of the new drug molecule.

But the limitations to this technology is much more and it needs larger development in this field. Few of the limitations are listed below:

- Limitations of current computer science deep learning models to generalize to complex medical data sets and tasks.
- Necessities of high volumes of labeled data sets for training deep learning algorithms.
- Strategies and regulatory framework for dealing with relevant ethics issues (e.g., patient privacy, retaining anonymity, securing data)⁴⁵ and de-risk use of AI- and ML-based clinical prediction and decision support in health care.
- Need of new professionals trained in the new technology.
- Development of technology in the underdeveloped regions around the world.
- The initial investment is quite high.
- Security to the data is of much more importance to the company which leads to further investment.
- It is still under development so reliability is quite less.

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