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Review Article

Adoption of Artificial Intelligence in Biopharmaceutics

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Abstract

The use of AI has transformed the approaches of a pathway or target identification to treat ailments. This was conceivable owing to the incorporation of genomics information, biochemical attributes, and target tractability. The use of AI has significantly caused pharma companies with increasing productivity, reproducibility, and repeatability of manufacturing as well as clinical trial processes. AI has considerably reduced the cost and time required to achieve the target required.

Introduction

Artificial intelligence (AI) is the imitation of the human intellect employing computers. The process comprises of attaining information, evolving rules for using the information, drawing estimated or definite conclusions, and self-correction. The progression of AI can be seen as a double-edged sword: many fear that it will jeopardize their employment; by contrast, every development in AI is celebrated because of the credence that it will massively contribute to the betterment of society. AI is used in various sectors from innovating educational methods to automating business processes [1]. The year 1956 is usually considered to be the year when AI was born, as it was in 1956 that Dartmouth College had organized the famous conference. However, the preceding year, that is, 1955, saw its first AI system that was called Logic Theorist, and the people who developed it were Allen Newell, Herbert A. Simon. Nearly, 40 theorems of Principia Mathematica by Alfred N. Whitehead and Bertrand Russell were proved using this system. However, the designers of the system could not get it published [2]. Artificial intelligence, predictive, and other superior technologies are speedily being integrated into pharmaceutical companies across the world. The interest in AI-centered solutions for early at the time of drug invention is steadily picking momentum among biopharma in which there are a projected market volume of approximately $10B by 2024 across all AI-driven medical diagnostics, medical imaging, drug discovery, genomics, and personal AI assistants [3]. In the past few years, there has been a tremendous wave of modern R&D partnerships between potential biopharma stakeholders and AI-based corporate, especially startups. Since the majority of AI-centered companies maximize various techniques and use interdisciplinary sources of data in modeling their work, the paper looks into different ways AI can be used in the pharmaceutical industry. AI has stimulating opportunities to flourish in the biopharmaceutical arena. Current AI initiatives by the top biopharmaceutical companies include [2, 3].

a) Mobile platform to rally health outcomes-the competence to endorse patient role utilizing real-time data assortment and thus progress patient outcomes.
b) Personalized medicine-the expertise to assess a big database of the patient to extricate cure possibilities using a cloud-based system.

c) Acquisitions Galore-New start-up establishments are compounding the artificial intelligence and healthcare to sustain the innovation provisions of large biotech firms.

d) Drug discovery-Pharma corporations in concurrence with software companies are trying to maneuver the most cutting-edge technologies in the expensive and all-embracing course of drug discovery [4].

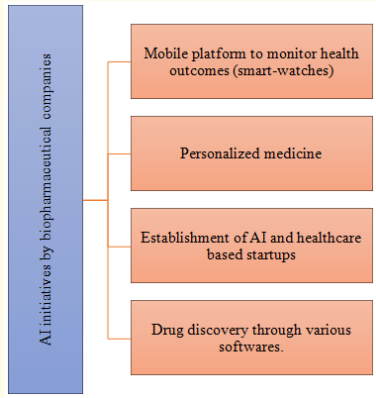

Figure 1: Current AI-based initiatives.

Drug Discovery and Design

Research partnerships with different healthcare facilities have identified and validated novel cancer medication targets relying on simulation AI platforms and casual machine learning. So, AI plays a significant role in the validation and identification of drugs. Some healthcare facilities have AI-driven equipment responsible for the automation of healthcare data and several streams of biomedical information such as next-generation sequencing, longitudinal electronic medical records, and other 'omic data systems [5]. AI helps in the alteration of these 'omic data into computer models and mechanistic models representing individual patients. Companies can use multi-stage and high interactive drug discovery procedures involving the use of reinforcement learning algorithms and generative adversarial networks. The process involved in AI during drug discovery is elaborated as a closed-loop having different stages, among them hypothesis generation, data mining, optimization, and lead compound identification. Such a process allows for the careful advancement of the general output prediction outcome over a given duration and with adequate data present [6].

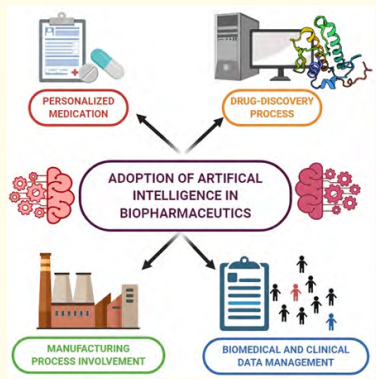

Figure 2: Application of Artificial Intelligence.

Furthermore, AI is used in target-centered and phenotypic drug discovery using exscientia design with the help of new molecules in the AI-system. According to Shah et al. (2019), the system employs high content screening and phenotypic data as well as examining their potency, binding, and selective affinity regarding certain targets. These projects are massively backed by exscientia enormous data resources from large scale bio-assays and medical chemistry. An outstanding opportunity for AI to get integrated into patient data, biomedical and clinical data is to draw unintuitive concepts regarding drug candidates or even trying to model the entire biological system to identify biomarkers, novel pathways, and targets. Companies can also use real-world biomedical data like the expression of gene measurements, clinical records, and protein interaction sequences. By assessing a billion series of data, companies dealing with pharma and biomedical structures will be able to dissociate relevant and irrelevant processes hence leading to the effectiveness of particular small molecules [7].

Current Context in Drug Development

Drug discovery has various facets, and naturally, the pharmaceutical industry has established a portfolio of diverse policies and tools to identify and optimize principal contenders. Generally, these approaches fall into two key categories: systems-based phenotypic screening and target-based design. Both categories have their benefits and challenges. Collectively, these strategies have been behind the discovery of more than 90% of all FDA approved (between 1999 and 2008) first-in-class drugs [8]. Drug development is unevenly riven into four key stages, called phases. Phase 0 comprises rudimentary research/drug discovery, and preclinical tests, which aim at evaluating the competence and body processing of the drug candidate. The latter three stages are clinical trials: the study of dose-toxicity, short-lived side effects, and kinetic associations (Phase I); fortitude of drug performance (Phase II), and assessment of the molecule to the standard-of-care (Phase III). An elective Phase IV can set post-drug marketing to monitor long-term side effects, and drug combination with other treatments for the entire drug development timeline. This whole drug assessment pipeline takes at least 5 years and can last up to 15 years. The nominal expanse of time covers the arrangement of preclinical and clinical tests (Phases 0 up to III), that is, the time to contemplate upon and write down the study design, to recruit and select patients, to analyze the consequences, and so on, let alone to perform the definite wet-lab experiments [9]. The technologies that integrate AI have become adaptable tools that can be applied universally in numerous phases of drug development, such as identification and validation of drug targets, designing of novel drugs, drug repurposing, refining the R&D efficiency, amassing and scrutinizing biomedicine information, and refining the decision-making course to recruit patients for clinical trials. These probable uses of AI provide the prospect to counter the inadequacies and uncertainties that ascend in the classical drug development methods while reducing bias and human intervention in the process [19, 20, 21]. Further uses of AI in drug development comprise the prediction of feasible synthetic routes for drug-like molecules [21], pharmacological properties [19], protein features as well as effectiveness [20], drug combination also drug–target association [21], and drug repurposing [20]. Correspondingly, the identification of innovative pathways and targets using omics analysis becomes possible via the generation of novel biomarkers and therapeutic targets, personalized medicine based on omics markers, and discovering the association amid drugs and diseases [7].

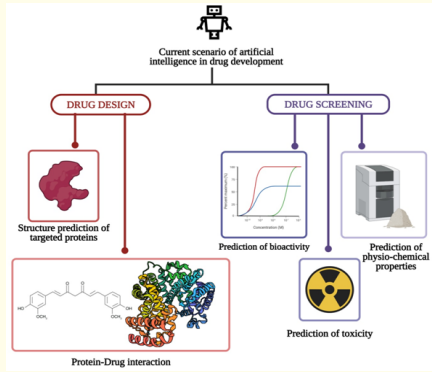

Figure 3: Current scenario of artificial intelligence in context to drug design and drug screening process.

AI In Advancing Pharmaceutical Product Development

The discovery of a novel drug molecule necessitates its subsequent assimilation in an appropriate dosage form with desired delivery characteristics. In this area, AI can substitute the former trial and error approach. Several computational tools can answer problems encountered in the formulation design area, such as stability complications, dissolution, porosity, and so on [11]. The integration of AI in manufacturing can attest to be an improvement for the pharmaceutical industry. Tools, such as CFD, uses Reynolds-Averaged NavierStokes solvers technology that studies the influence of agitation and stress levels in diverse equipment (e.g., stirred tanks), exploiting the automation of numerous pharmaceutical operations. Analogous systems, such as direct numerical simulations and large-eddy simulations, include innovative methods to solve complex flow problems in manufacturing [7]. As of late, Amgen, a biopharmaceutical organization, began utilizing AI to distinguish producing deviations. The organization is steering a procedure utilizing AI to improve its capacity to recognize designs in assembling deviations and to anticipate their repeat. This apparatus would supplant a work escalated process with one that can look crosswise over enormous informational indexes and discover relationships between's dark signs and occasions. Moreover, quality and consistency are a significant territory of worry for pharmaceutical organizations. Organizations cause substantial misfortune in their income exclusively because of item reviews. To defeat this challenge, they are actualizing start to finish arrangements that give a practical and comprehensive perspective on manufacturing, quality, and consistency. These arrangements empower them to send cost decrease techniques while keeping up quality compliance and item security [9, 16].

Manufacturing Process Improvement

The adoption of AI in the biopharmaceutical industry can assist in improving the manufacturing process in development and production. AI can execute quality control, reduce wastage of materials, shorten design perform predictive maintenance, and advance production reuse. Also, AI can be adopted in various ways to increase the efficiency of the production process with higher output and reduce wastage of materials. Many clinical studies depend on paper and manual diaries in which patients are expected to log every time they a drug, what other types of medications they use as well as different severe reactions these medications may cause. Everything appears handwritten notes, and the test outcomes concerning the environmental factors and the imaging scans can be gathered and interpreted using AI [17]. With the rising interest in innovation, the industry is seeing expanding number of third-party players offering different inventory network arrangements. E.g.: a US-based programming arrangements organization, offers store network arrangement which empowers the utilization of prescient examination in pharmaceutical production network he executives by utilizing important information and supporting gauge the board, necessities arranging, retail, deals, and activities arranging. The appro-

priation of innovations, for example, AI and AI could robotize different procedures counting drugs coordination's, following, bundling, and handling, giving less space for a human mistake [13].

Processing Biomedical and Clinical Data

Numerous cognizant studies have demonstrated that about 80 percent of all clinical trials fail to satisfy enrollment timelines and enrollment challenges cause approximately a third of all phase three clinical study terminations. Approximately 62% of new chemical entities (NCEs) in Phase II and Phase III clinical trials do not reach the clinic. The chief fundamental sources of attrition in late clinical stages are accredited to clinical safety and effectiveness followed by formulation, pharmacokinetics, bioavailability, and toxicity. The lack of effectiveness that arose in therapeutic areas with high Phase II and Phase III failure rates comprises drugs for central nervous systems (CNS) and oncology applications, principally owing to the lack of accessible fit-for-purpose animal models in preclinical development. Furthermore, an additional contributing factor for attrition is the 'narrow clinical research' policy adopted by pharmaceutical companies. This term denotes the extensive use of *in-vitro* and *in-silico* models instead of animal models in the initial phases of the drug development process. The prospects for opportune discovery are also restricted with the prevailing system because the current system contemplates a drug contender that employs other pharmacological effects than the intended effect as a clinical trial failure. Besides, multicentre clinical trials across the world are also favoured with the objective of obtaining diverse data [18]. The failure rate of clinical trials contributes to the inadequacy of the drug development sequence: Clinical trials can take up to 7-10 years, with an expense of $1.46 billion out of $2.56 billion in capitalized costs for bringing a new drug to the marketplace. Each unsuccessful trial ruins not only the investment into the trial itself but also preclinical development expenses, rendering the loss for each failed clinical trial from $800 million to $1.4 billion. Incompetent patient selection and recruiting, shared with an inability to effectually monitor patients throughout trials are two of the focal causes for high failure rates [20]. For instance, IBM Watson has established a system for Clinical Trial Matching which uses the large extent of structured and unstructured patient EMR data and the abundance of accessible trails to generate comprehensive profiles of clinical findings for the patients to compare to trial suitability criteria. As the arrangement integrates all the intricate protocol criteria to consider, it abolishes the necessity to manually sort through and analyze complex enrolment criteria and allows clinicians to optimize their quest for clinical trials for an eligible patient or for finding patients eligible for a specified trial. Those two duties being otherwise challenging and time-consuming. The enhancement in screening efficiency and more effective patient recruitment help upsurge clinical trial enrolment targets. This system can also be beneficial to help attain and track patients through the recruitment procedure and share growth across networks in near real-time [21].

Rare diseases and individualized medicine can be achieved through the adoption of AI. Incorporating information from analytics, body scans, and patient biology AI can be used to detect various ailments such as cancer and prediction of health challenges people might encounter as a result of their genetics [10]. These advancements can use every patient's medical data and history to recommend personalized treatment schedules. The development of personalized drug treatments can be accomplished through AI to test results, reactions to previous medications as well as historical patient information for drug responses [14].

Increment in AI Investment and Staffing

Pharmaceutical companies regularly embrace new technologies but have been sluggish to invest in AI. Certain organizations may be strategically waiting for the turf to stabilize. The industry averages for emerging new medications stand at $2.6 billion and 10+ years. Pharma companies have capitalized on many technologies to accelerate and advance the process, but have not yet made a considerable investment in AI that offers state-of-the-art solutions [10]. The Tufts Centre for the Study of Drug Development (CSDD) and the Drug Information Association (DIA) in alliance with 8 pharmaceutical and biotechnology companies directed a study investigating the adoption and effect of artificial intelligence, respondents (59%) testified that their organization was intending to increase staff for AI use or implementation within the next 12 years. An extra 19% specified that they were scheduling staff increases for this purpose in the next 25 years, and 7% projected that staffing increase would take place in >5 years. Only 15% of respondents said that there was no growth to AI staff planned. Amongst those reporting to increase their staff, 61% specified that this would be a minor increase, 28%

a reasonable increase, and 11% a hefty increase. More than 60% of companies reported that they presently partner with alternative AI organizations. The top enterprises were technology or data providers (95%), academic organizations (58%), and CROs (clinical research organization) (56%). The most frequently designated partnership areas were clinical operations (71%), Pharmacovigilance or tolerability (68%), and drug discovery or preclinical (56%) [1].

OUTLOOK

AI has boosted clinical diagnosis and decision-making capability in various medical realms. How this performance will decipher to influence the landscape of medical practice, together with disease detection and treatments, will be contingent on how lithely AI applications co-evolve with a healthcare system that is under marvellous financial draining while obliging swift advances in molecular and genomic science. Clinicians will need to familiar with their new roles as information integrators, polyglots, and patient supporters, and the medical education arrangement will have to deliver them with the tools and approaches to do so. Who will end up governing, certifying, or profiting from the application of AI is still to be determined, and consequently the balance of regulatory safeguards and market forces to warrant that patients profit most must be a high priority?.

Result and Conclusion

In conclusion, the identification of clinical trials can also succeed through the adoption of AI. Other than assisting in creating a sense of clinical trial data, another way the adoption of AI can help in the pharmaceutical sector is locating patients to take part in trials. With the help of advanced predictive analytics, AI can be used in the analysis of genetic information to know the specific patient population suitable for use in the trials as well as determining the optimal sample size. Modern AI technology can interpret read free-form text that patients give during clinical trial procedures and unstructured data like intake documents and physician's notes. Is it believed that a staggering 86 percent of all the trials that take place in clinics during the recruitment of sufficient patients fail? Consequentially, slower research and patients' delays in accessing life savings drugs become the outcome. Therefore, AI can be adopted to enhance predictions of treatment results as well as predictive biomarkers.

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