Written Presentation

AI Integration in Healthcare – Enhancing Privacy and Security in Clinical Drug Trials

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"I attest that this description is my own independent, original work. I prepared this on my own without the assistance or participation of anyone else."

Introduction

Technology implementation for day-to-day activities has become a customary practice. Healthcare has been accepting innovative technology every day where the advancements are at the forefront, and the world is accepting them to make its daily operations easy and effective. With the adoption of modern technology, patient care is becoming crucial because handling of sensitive personal data is utmost important. Clinical research is transforming because in today's digital world, advancements in technology are reshaping not just patient care but also transforming clinical research. Confidential data must be protected because the protection instills a sense of trust among the clinician and the patient (Aizenberg & Brandolini, 2023).

Development of drugs is one of the biggest contributors of higher rates of decline in drug trials because only 1 of 10 drugs enters market (Hay et al., 2014). A study has estimated $2.6 billion is the cost for a drug to be developed and the highest sum of money goes into recruitment of patients, screening and retaining the patients up to final stage of drug development (DiMasi et al., 2016). For execution of clinical trials, it is needed that perfect cohort is recruited which can lead to accurate and efficient results of the drug. Researchers over the years of studies have implemented a strict qualification criterion where 5% candidates can become a part of the cohort in clinical trials. According to the Center for Information and Study on Clinical Research Participation (CISCRP), 80% of the trials are delayed due to problems in recruitment of the patients. Longer phases for recruiting patients prolong the duration of the trial. These in turn lead

to a reduction in the innovation of medicines and hence leading to reduced innovation in newer treatment plans (*Home*, n.d.).

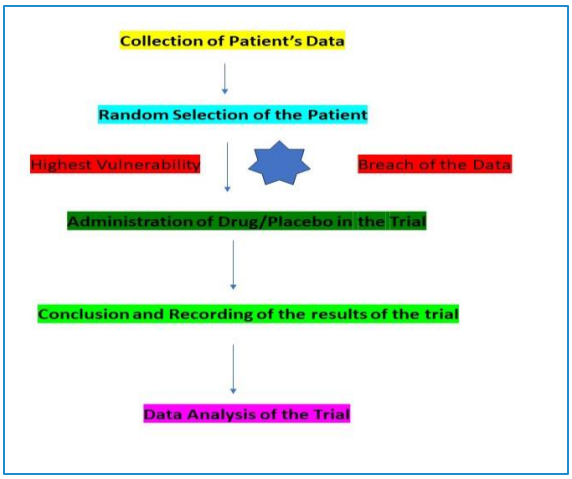
The attitude of the patients and clients of sharing personal information has led to a barrier in information exchange. In an online survey where investigation about consumer attitudes towards sharing health information was done the respondents express concerns related to privacy and security to their sensitive personal health information. In the survey, half or more than half respondents were concerned about re-identification of their masked and sensitive data and if that properly secured then more than 50% respondents were willing to share their personal information with researchers (Pickard & Swan, n.d.). Hence, masking the sensitive information and personal health information during clinical trials is utmost important because data sharing can lead to harm to privacy and confidentiality of the patient's personal health information (Angeletti et al., 2018).

Problem Identification and Statement

Recruitment of patients in a drug trial is an overly complex process and introduction of bias is possible when the accessibility of patient data becomes easier via staff of a healthcare organization (Borschmann et al., 2014). A study identified other reasons in delayed recruitments such as delays related to central staff of the research team, delays due to ethics, delay due to supply of study drugs/placebo, delay in development of clinical guidelines impacting the clinical trial and many others (McDonald et al., 2006). Selection bias is one of the biggest barriers in a drug trial where it compromises the generalizability (Borschmann et al., 2014). Drug trials include sharing of sensitive personal health information where privacy and security concerns can

lead to harm to patients in an economic, social, financial, or personal way (Angeletti et al., 2018). Hence, it becomes important for the clinicians, healthcare personnel and other paramedical staff involved in the process of drug trials to be very discreet. The staff needs to be mindful of their accessibility to records and should not misuse the access they have to the patient's information included in the trial and participate in the protecting their patient's information in a lawful manner by abiding to the rules of state and federal government of their country. Hence, development of tools which can provide protection to the personal data of every patient participating in trials leading to completion of a successful drug trial is required where security and privacy issues faced are eliminated which will help patients to grow a sense of trust among clinicians and other clients involved.

A grave problem has been discovered in the drug trials held in Sunshine Hospital where issues related to privacy and security in the selection process of the patients has led to a risk of breach of data and violation of rules and regulations. In every stage of the process, starting from the collection of patient data to the conclusion of trial, there is a risk of human bias and errors, but most breaches or errors occur in the selection of the patients. A risk to the reputation of the hospital, fear of losing the license / accreditation of conducting drug trials, compromise in the safety of the data of the patients, lack of anonymity in data, increased vulnerability of errors and major threat to integrity of the trials are major problems due to inclusion of human bias or human errors in a drug trial. Hence, Development of a solution where AI integrated/ AI driven electronic tool for selection of patients that can provide fairness, randomness, and secure exchange of information is the proposal for the project.



Risks are associated with recruitment in a drug trial, but the most vulnerable phase is the selection of patients where human error and selection bias can compromise the privacy of the patient's data. Various instances such as the team involved will select friends and family members or their known people to enter a drug trial so that they can receive the experimental drug, which leads to selection bias and breaches set protocols. On another instance, access to medical records without authorization from the Hospital Information System can lead to unauthorized access to medical data along with non-essential personnel who are not related to drug trial can access the files just to know which patient is allotted for drug or placebo violating HIPAA rules and decreasing the regulatory compliance.

Proposed Informatics Solution

The proposed solution is to use Artificial Intelligence and develop an electronic tool where the patients participating in several drug trials held in Sunshine Hospital located in Indianapolis can benefit. During the drug trials, it has been observed that human error and bias has affected selection of patients hence an electronic tool can attempt to solve this issue by creating randomness. The goal is to abide by the rules and regulations set by the hospital. Along with that, the medical history of the selected patients is considered via encouraging anonymity to make a logical and informed decision. Introducing this tool can automate the process and this can be built as an in-house tool by the IT team of the hospital, hence formation of a practical solution which can reduce the overall costs of the drug trials. The effectiveness of the solution can be quantified by tracking breaches in the data, tracking unauthorized access of patient's medical files, and by reducing the selection bias. The tool will identify medical history and personal health information from the database when used in trials so that machine learning techniques and algorithms will identify prime candidates and include them in the trial without any bias. All the information related to trial, the need for research, guidelines will be uploaded in the tool by the research team and hence it will ensure that the most accurate matching is done. Accessibility to these files will be the main feature in the tool where the people who are part of the team will only be able to access the files and their logins will be audited, hence maintaining regulatory compliance. For accessibility of the files, 3 factor authentication will be used where every personnel accessing the files will have to enter their unique username and password, OTPs generated in their hospital application and biometric identification (Iris recognition) would be used. The hospital application will be available just for the team involved in the drug trials, hence this will help to resolve the accessibility issues faced by the hospital.

Information Needed to Validate Solution

The methodology to make the solution validated and plausible is Quantitative Solution Proofing because this allows for statistical comparison of the patient selection done by the AI integrated tool to the human selection of patients. This will help in quantification of selection bias and help us understand the level of human error. This approach will provide evidence which would be numerical and hence will test the validity and reliability of the tool. This in turn will help in quantifying the effectiveness and efficiency of the solution. The solution can be validated with help of data such as Demographic information of the patients where variables such as Age, Gender, Race, Ethnicity, Disability, Medical History, Family History, Occupational Status, Genetic History, Laboratory Results, Radiographic Results, Support of the Family, Living Status, Income, Educational Background and other specific variables if needed according to the study can be decided and evaluation of these variables can be considered in an aggregated form. Names are not used so that patients' identity can be masked and thus randomization can be introduced by the tool. Machine Learning Algorithms will match the patients to drug trials as per selected variables. The variables would be collected from Electronic Health Records of the Sunshine Hospital. Under the HIPAA rule, the data of the patients would be taken only from the Hospital EMR and encryption along with triple authentication will be used for accessing the data files for the researchers, clinicians, analysts, and other team members involved in the trial. Previous accidents involved with unauthorized staff access to patient files in research trials and incidents of biased patient selection will become a baseline for measurement against the algorithm results produced. Statistical testing such as Propensity Score Analysis, T-tests, Regression Analysis will be used to validate the solution. Aggregated scores will be involved in the statistical evaluation as a baseline rather than person to person evaluation. Propensity score

analysis helps in the creation of matched pairs of patients within the groups who tend to have similar selection based on the given variables. T-tests and Regression analysis will help in understanding the difference between each variable selected across both the groups (AI selected groups and humans selected groups). These statistical testing will help us in understanding the effect of AI on bias reduction. Lastly, feedback from the patients, the research team, clinicians and other staff involved with previous trials can also give us insights for betterment of the AI tool.

Solution Validation Plan

Drug trials need more authenticity in patient selection and this AI tool will enhance the efficiency and effectiveness of the recruitment process. Metrics and data driven plan is needed in the Sunshine Hospital where quantitative methodology will allow enhancement of privacy, security and elevate integrity of the trial. The main aim of this AI tool is that it will remove the selection bias with the help of statistical testing (propensity score analysis) where the patients chosen for the drug trials after integration of tool will be compared with the cohorts selected in the previous trials held in Sunshine Hospital. The comparison of these groups will provide us with numerical scores and help us in assessment of the reduction of selection bias. This methodology will be HIPAA compliant in the selection of variables by de-identifying data and the process will be done after consent of the patient. With the help of quantitative methodology and statistical testing, there is a prediction that there would be a 35% - 40% reduction in the selection bias. This benchmark can be considered as a realistic goal because exact percentage cannot be determined hence the baseline or threshold for the tool can be considered at this range. 1/3 reduction in selection bias can be statistically significant for implementation of the solution and further steps can be taken to achieve 100% removal of selection bias.

Evaluation of security and privacy related to unauthorized access to electronic medical records will be evaluated. This will be done via evaluation of accidents which have occurred before the implementation of the tool and incidents reported after the implementation of the tool. Regular audits will also lead to an increase in compliance and help in assessing the compliance rate. Target to achieve compliance rate is 100% after implementation of tool as the entire system is getting electronically secured. In the first 6 months of implementation, the reduction rate is expected to be 25% fewer non-compliant accidents.

Lastly, Internal HIPAA audits along with patient and staff surveys will become a qualitative assessment where feedback captured will lead to an increase in overall fairness, an increase in trust among patients due to unbiased reporting. The aim is that there is an improvement of 10% ratings across the questionnaire categories in the first year. The goal is to achieve a combined 30% improvement after integration of the tool in the coming next 2 years.

Hence, adoption and integration of the tool in the system and use of an AI tool will lead to increased effectiveness and efficiency during drug trials in the Hospital. High standards of privacy and security will be maintained during drug trials by the removal of human errors and selection bias. This will in turn lead to regulation of ethics during drug trials in a regulated and compliant manner. Future clinical drug trials at Sunshine Hospital will be bias free, data-oriented, metrics calculated and compliant to the rules and regulations set by the government.

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