

THE INTEGRATION OF AI INTO THE CLINICAL TRIAL SUBMISSION PROCESS IS NOT JUST A TREND

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What invokes into our Mind when we think of AI?

Data



AI



Result

What it is?

Data

AI

Value

Selection

Sourcing

Synthesis

Data Engineering

Exploration

Cleaning

Normalizing

Feature

scaling

Modeling

Model select

Training

Evaluation

Tuning

Registration

Deployment

Monitoring

Retraining

Constraints

Legal

Ethical/Transparency

Historical (bias)

Security

AI in Clinical Trials



■ Study Design

■ Patient Recruitment

■ Monitoring Trial Progress

■ Data Management

■ Data Analysis

■ Submission

INTRODUCTION TO AI IN CLINICAL TRIALS

- AI is Transformative force in enhancing clinical trials.
- AI helps to Streamline data analysis.
- Improves in identifying patient populations and optimizing protocols.
- The strategic integration of AI in clinical trials is vital for optimizing processes and enhancing efficiency.
- By leveraging AI-driven insights, researchers can streamline recruitment, tailor trial protocols, and improve data analysis.
- This integration not only reduces costs but also accelerates timelines, ultimately leading to faster delivery of innovative treatments to patients.



CURRENT AI TECHNOLOGIES IN CLINICAL TRIALS

- Today, various AI technologies are making a significant impact in clinical trials.
- Machine learning algorithms enhance patient recruitment by analyzing diverse data sets for optimal participant selection.
- Natural language processing streamlines data extraction from clinical texts, ensuring accurate information flows.
- Additionally, predictive analytics aids in identifying potential trial outcomes, optimizing resource allocation, and improving adaptability to unforeseen challenges. These tools are revolutionizing how trials are conducted, shaping the future of healthcare.





AI APPLICATIONS IN PATIENT RECRUITMENT

AI technologies streamline patient recruitment by analyzing vast datasets to identify eligible candidates swiftly.

Through predictive analytics and machine learning algorithms, we can enhance targeting and engagement strategies, increasing recruitment speed and success rates.

Case studies reveal how AI has transformed traditional methods, ensuring that trials are not only more efficient but also more representative of diverse patient populations, ultimately leading to better outcomes.

AI IN MONITORING TRIAL PROGRESS

- AI technologies are revolutionizing the monitoring of clinical trial progress.
- By integrating real-time analytics, AI can swiftly identify deviations and trends, allowing researchers to adjust protocols as needed.
- This proactive approach not only boosts trial efficiency but also ensures participant safety, making it a crucial element in the modern clinical research landscape.

Epidemic Outbreak Prediction

ML and AI technologies are also being applied to monitoring and predicting epidemic outbreaks around the world, based on data collected from satellites, historical information on the web, real-time social media updates, and other sources. The opioid epidemic is a direct example of AI technology being utilized today.



ENHANCING DATA ANALYSIS WITH AI

- AI facilitates comprehensive data analysis in clinical trials by leveraging advanced algorithms to detect patterns and insights from multifaceted datasets.
- This capability enables real-time monitoring, identifying anomalies, trends, potential issues and predictive modeling, enhancing the reliability of trial outcomes.
- As we explore further, we'll discuss specific case studies demonstrating how AI-driven analytics have significantly improved data interpretation and decision-making processes in clinical research.



CASE STUDY I: MAYO CLINIC FINDS IBM WATSON INCREASES ENROLLMENT OF CLINICAL TRIALS

- IBM Watson leading AI platform, has been used to improve the clinical trial matching process for cancer patients.

https://www.ibm.com/mysupport/s/topic/0TO500000002PWuGAM/watson-for-clinical-trial-matching?language=en_US

- The Mayo Clinic has released the results of a new study, which show an 80 percent increase in enrollment of clinical trials for breast cancer when using IBM's Watson for Clinical Trial matching system. <https://www.mobihealthnews.com/content/mayo-clinic-finds-ibm-watson-increases-enrollment-clinical-trials>
- The Watson system uses artificial intelligence to analyze unstructured information and pull-out insights from the data.
- In addition to the uptake in participants, the trial showed that the technology could significantly reduce the time it takes to screen an individual patient for clinical trial matches. The system could generate a ranked list of relevant trials for each patient without making clinicians read through EMRs or long lists of eligibility criteria, according to the IBM webpage.
- The technology can integrate clinical notes, pathology reports, labs, and more data about how to include or exclude a participant. As a result of this trial, the Mayo Clinic has announced a new plan to continue their partnership with the Watson system while targeting trials for additional cancers, including breast, lung colon, and GI cancers. https://ascopubs.org/doi/10.1200/JCO.2018.36.15_suppl.e18598

CASE STUDY 2: MENDEL.AI FOR CLINICAL TRIAL DESIGN

- Mendel.ai is an AI platform that is transforming the way clinical trials are designed and conducted. By analyzing vast amounts of medical literature, patient data, and other sources of information, Mendel.ai can help researchers design more effective and efficient clinical trials.
- One case study involving Mendel.ai and a diagnostic company was able to build a clinico-genomic database in a week.

The Problem:

- The diagnostic company problem came down to time and scale. They had a list of 60k patients and were looking for 120 variables. Their team of 4 abstractors took 1.5 hours per patient and abstracted between 200 to 400 patients a month. They wanted to be able to scale their abstraction efforts and move faster, increasing the team's productivity.

Solution:

- Mendel helped the customer scale their abstraction efforts. The team leveraged Mendel's proprietary AI pipeline and abstraction workspace to index their unstructured data and extract key clinical attributes such as Cancer Diagnosis, Staging, Metastasis, Date of Diagnosis, Biomarkers, Surgeries, Diagnostic Procedures, Outcomes, and Response.

<https://www.mendel.ai/post/how-a-diagnostic-company-was-able-to-build-a-clinico-genomic-database-in-a-week>

AI IN DATA MANAGEMENT



1. Smart Queries: Machine Learning (ML) algorithms identify potential queries by comparing entered trial data against learned value ranges for specific therapeutic areas. This proactive approach not only facilitates the generation of legitimate queries but also aids in the elimination of false positives.



2. Medical Coding: AI can automatically code medical terms using established dictionaries, and medical coders review and refine results. Machine learning learns from coding libraries, enhancing accuracy in term matching.



3. Query Management: ML plays a pivotal role in streamlining query management. By clustering redundant queries and pinpointing issues stemming from misconfigured edit checks, we can effectively address multiple queries simultaneously or make targeted configuration adjustments. This capability not only saves valuable time but also reduces the effort required in handling complex query scenarios.

AI IN REGULATORY SUBMISSION

AI in CSR generation:

■ Automating repetitive tasks:

AI algorithms can automatically extract relevant information from clinical trial data sources like protocols, statistical analysis plans, and data tables, significantly reducing manual data entry and streamlining the CSR writing process.

■ Generating initial drafts:

AI can generate initial drafts of the CSR by structuring the information based on regulatory guidelines and study protocol specifications, allowing medical writers to focus on critical analysis and interpretation.

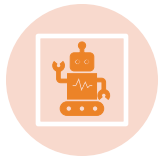
■ Quality control:

AI can be used to identify potential inconsistencies, errors, or missing data within the CSR, improving the overall quality and accuracy of the document.

■ Faster turnaround times:

By automating large portions of the CSR writing process, AI enables faster submission timelines, potentially accelerating the drug development process.

CHALLENGES AND CONSIDERATIONS



While the benefits of AI integration in clinical trials are substantial, several challenges must be addressed.



Ensuring the confidentiality and integrity of patient data is paramount in clinical settings, and AI applications must comply with regulations such as HIPAA.



Data privacy concerns, regulatory compliance, and the need for robust training data can hinder implementation.



Additionally, ensuring stakeholder buy-in and managing the transition for clinical staff require careful planning.



Recognizing and strategizing around these challenges is crucial for maximizing the potential of AI in advancing clinical trial success.





FUTURE TRENDS IN AI INTEGRATION

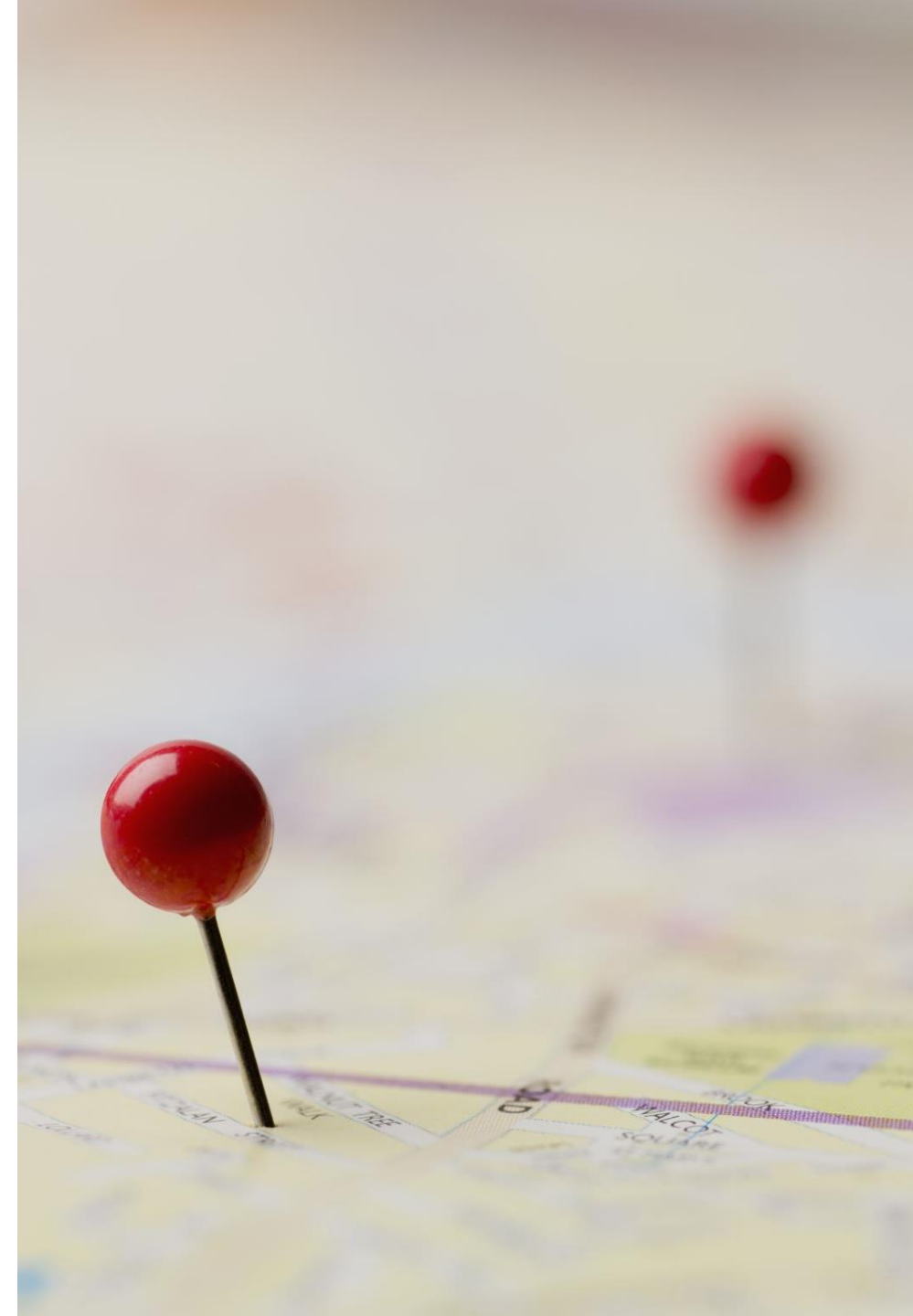
- As we look ahead, the integration of AI in clinical trials is poised for significant advancements.
- Emerging trends include increased personalization of patient data, enhanced predictive analytics for trial outcomes, and the use of AI-driven virtual trials.
- Patient Recruitment Optimization.
- Enhanced Predictive Analytics, Data Processing, and Real-Time Monitoring
- These developments will not only streamline processes but also drive innovative solutions to improve patient engagement and trial efficiency, reinforcing AI's pivotal role in reshaping clinical research

CONCLUSION AND KEY INSIGHTS

- In conclusion, the integration of AI in clinical trials promises transformative benefits.
- Key insights reveal that predictive analytics are revolutionizing patient recruitment, while machine learning enhances data accuracy and decision-making.
- These advancements not only streamline trial processes but also pave the way for tailored treatment approaches.
- Embracing AI is essential to drive innovation and improve patient outcomes in clinical research.

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THANK YOU



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