WHITE PAPER

AI USE CASES IN THE CLINICAL TRIAL VALUE CHAIN

Abstract

Artificial intelligence (AI) is rapidly moving from an experimental phase to an implementation phase in many fields, including medicine. The combination of improved availability of large datasets, increasing computing power, and advances in learning algorithms has created major performance breakthroughs in the development of AI applications. In the last five years, AI techniques known as deep learning have delivered rapidly improving performance in image recognition, caption generation and speech recognition.

AI can help in enhancing patient selection by reducing population heterogeneity, prognostic enrichment, and predictive enrichment. It also helps in shortening recruitment time with a chatbot.

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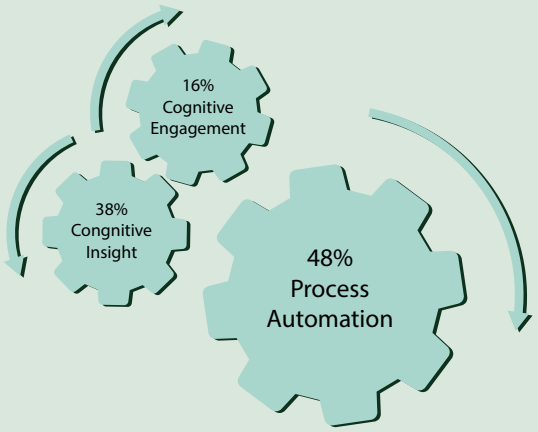
AI will be instrumental in innovating supply chain processes to build a more efficient, sustainable supply chain in the future. Businesses in every link of the supply chain can implement AI to automate processes, improve operations, strengthen security, and make better use of raw materials



AI can automate processes, gain insight through data analysis, and engage with users. A study shows projects utilized AI tasks with differing frequency.

Clinical Trials Value Chain

Protocol Design & Site Selection | Patient Recruitment | Patient Engagement & Data Collection | Data management, Analytics & Insights | Operations & Supply Chain Logistics

Protocol Design & Site Selection

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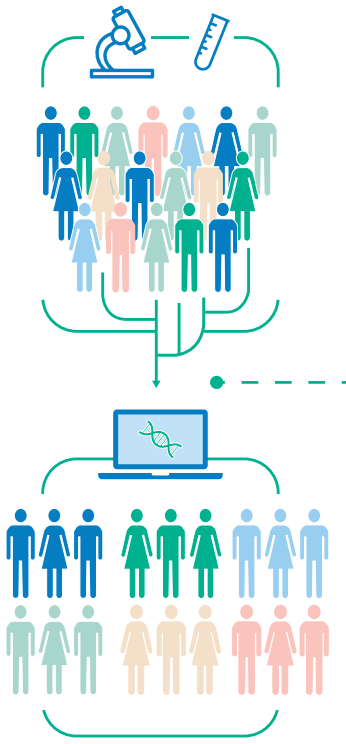


Trial enrichment strategies

REDUCED POPULATION HETEROGENEITY
Biomarker verification to reduce variability and increase study power.

PROGNOSTIC ENRICHMENT
Selecting patients more likely to have measurable clinical endpoints.

PREDICTIVE ENRICHMENT
Identifying patients more likely to respond to the treatment.

ML and DL methods can be applied to mine, analyse and interpret multiple data sources, including EHRs, medical imaging and 'omics' data.

AI can help in enhancing **patient selection**, here are some areas:

i. Reducing population heterogeneity. This could be done by harmonizing large EMR data from diverse formats and levels of accuracy y and leveraging electronic phenotyping.

ii. By prognostic enrichment – selecting patients who have a higher probability of having a measurable clinical endpoint. ML techniques, using key biomarkers of disease, are deployed for prognostic enrichment

iii. By predictive enrichment – choosing a population with a better likelihood of responding to treatment. For early-stage diseases, a clinical trial of a simulation tool developed by modeling the drug, disease, and progression of the disease, has undergone a regulatory review. This has helped in predictive enrichment.

Patient Recruitment

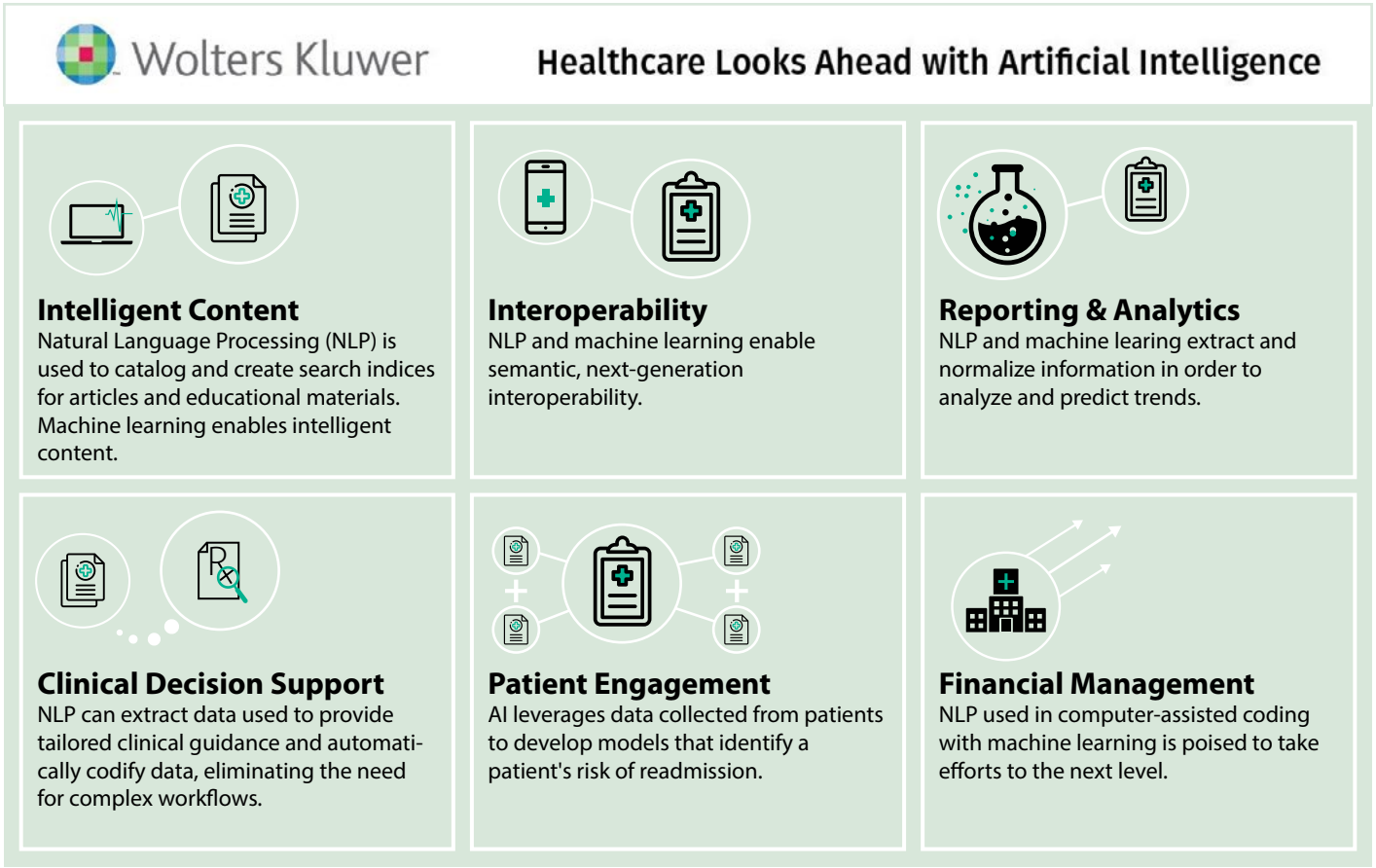
i. Assess the feasibility of protocol design for patient recruitment using RWD.

ii. Assess site performance (for example, enrollment and dropout rates) with real-time monitoring.

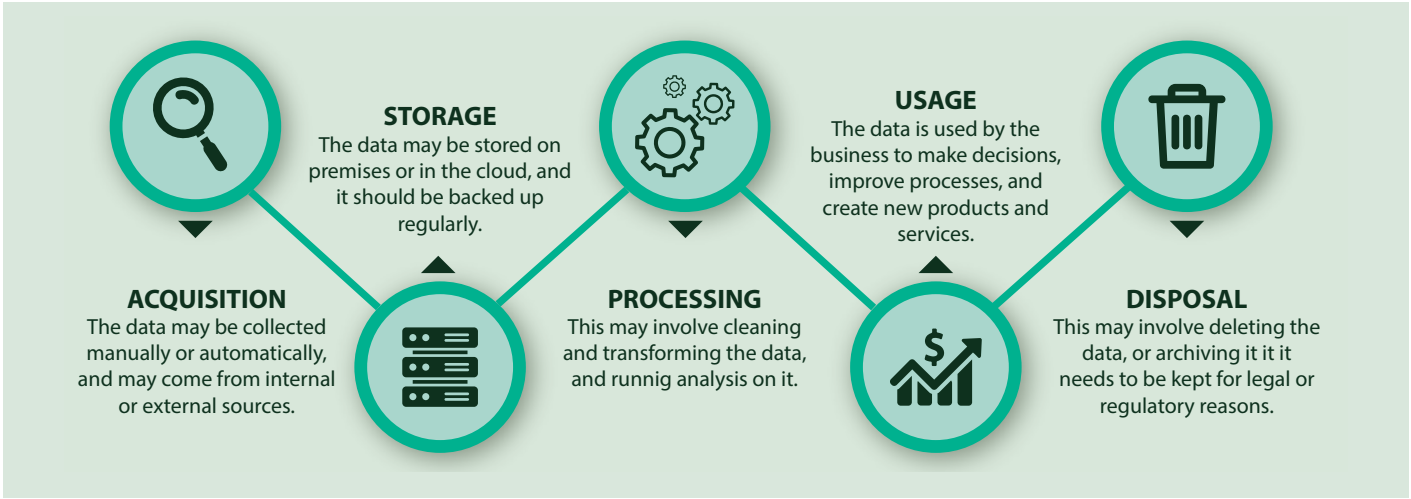
iii. Mine EHRs and publicly available content, including trial databases and social media to help match patients with trials using NLP and ML.

iv. Expedite recruitment and create a more representative study cohort through cloud-based applications.

v. Simplify and accelerate the informed consent process using eConsent.



Patient Engagement & Data Collection



Conversational chatbots in clinical trials patient recruiting strategies can optimize lead generation, decrease costs, and shorten recruitment time. They can also help in the regulatory domain.

i. Omnichannel Conversational Chatbots: Using omnichannel chatbots in patient recruitment can help companies appeal to millennials, who respond more positively to devices, voice interfaces, and messaging platforms and are usually on more than one major platform at once compared to older generations. Millennials prefer the speed and instant response time offered by chatbots compared to more traditional human-based recruitment methods. By appealing to their target clientele, companies are more likely to obtain patients and follow through in the sign-up process.

ii. Shortening Recruitment Time: Chatbots can potentially decrease recruitment time for clinical trials by decreasing the workload of coordinators as well as increasing response time

iii. Regulatory Space: A regulatory professional performs various tasks such as maintaining files and data of various events for audit purposes and future reference, recommending strategies to achieve necessary compliance in the company, reporting compliance status, etc. A chatbot will help regulatory professionals to expedite the process of intelligence gathering with conversational AI.

Intelligent Notification Management & Trends

i. Adherence Monitoring: Tracking of a patient's adherence to trail instructions, such as medication intake, exercise, etc. using AI-powered wearables, connected devices, and digital assistants. Reminding patients about their medication

ii. Microlearning: Alerting about educational content and learning updates to maintain 80% high retention for each trial

iii. Behavior Change Engine: Notifications, recommendations, and follow-ups that promote behavior change.

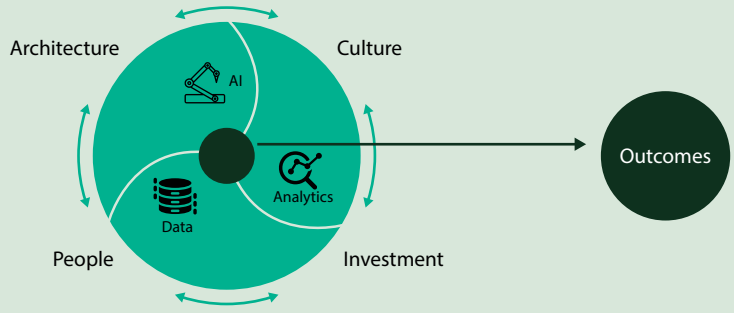
iv. Predictive Health Engine: Capturing, predicting and diagnosing disease and worsening health biomarkers.

v. Draft Confidentially Agreements: Create drafts of investigator and site contracts and confidentiality agreements by smart automation.

Protocol Design & Site Selection | Patient Recruitment | Patient Engagement & Data Collection | Data management, Analytics & Insights

Data Management, Analytics & Insights

Data and Analytics Strategies Driving the Future



Document extraction and conversion

i. Analyzing patient data to evaluate the impact of the tested treatment.

ii. Analyzing and interpreting unstructured data from previous trials and scientific literature.

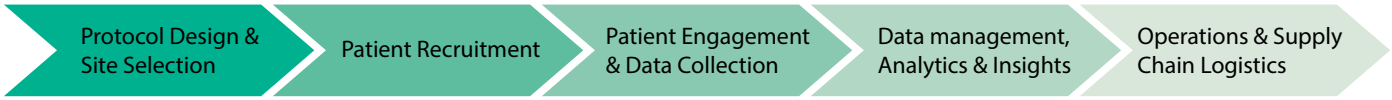
iii. Identifying patient cohorts within one trial that can be studied more closely or moved to a sub-trial.

iv. Revolutionizing medical data using BERT and GPT to help respond to medical questions posed by healthcare providers, key opinion leaders, and patients regarding drugs in their respective pipelines.

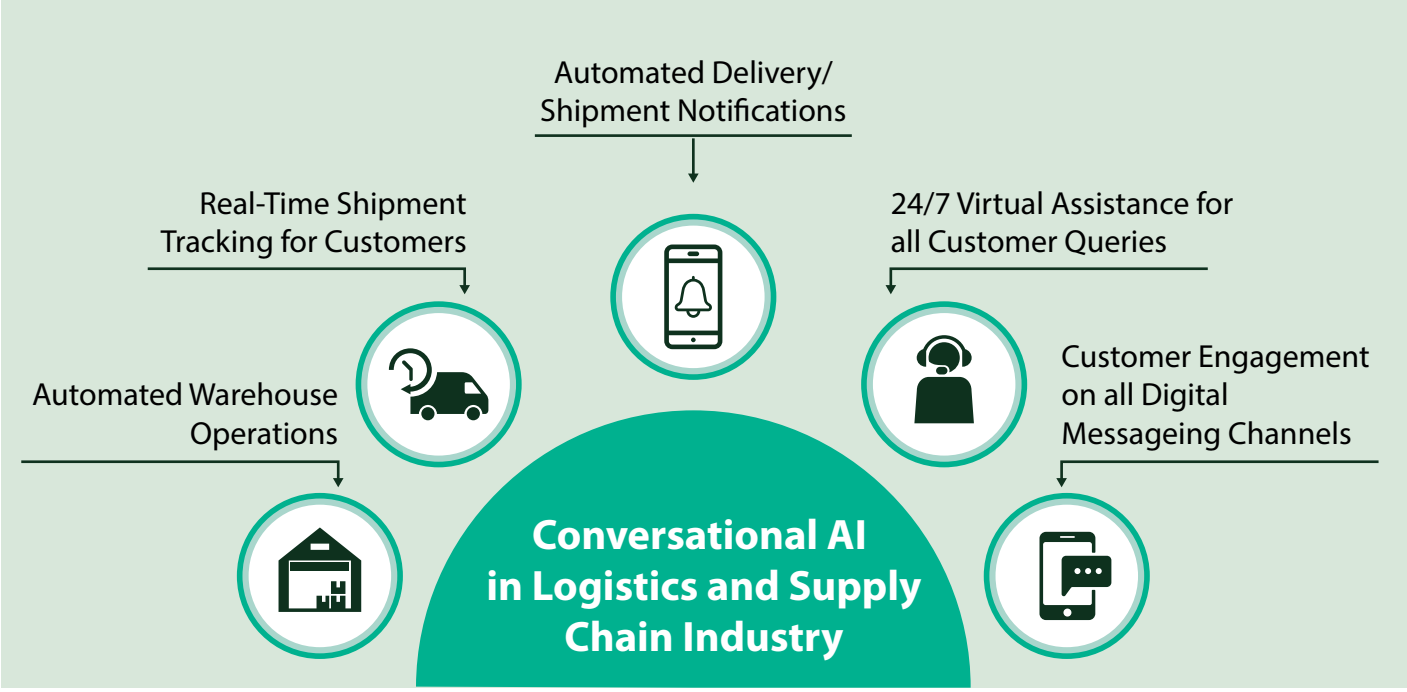
v. Accelerating many parts of the drug discovery and development pipeline by leveraging AI techniques.

vi. Clinical Concept Extraction using NLP and generating published medical literature. Studying closeout data cleansing by ML methods.

vii. Completing sections of the final clinical report for submission by using NLP.



Operations and Supply Chain Logistics



i. Digital Twins is an AI-based model that leverages historical standard-of-care data to predict the likely outcome of a patient going standard care. This is done by using baseline data and feeding it into an AI model that has been trained against historical standard of care data. By leveraging digital twins in pharmaceutical trials, we can see the following benefits: Reduction in the number of subjects needed to maintain the appropriate power to detect a pre-determined effect size.

ii. Protects against drops in enrollment or patient dropout throughout clinical trials by increasing power, without increasing type-1 error rates.

iii. Guards against ethical questions of placing subjects into standard care control groups that need an experimental treatment. Clinical supply forecasting – AI and machine learning can be used to continually update forecasting models as real-time conditions change to create more accurate supply forecasts.

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Madhavi Koppaka, M.Phil. Statistics has 22+ years of experience with strong Analytics Skills, Program

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