Paper ET03

Empowering healthcare through Generative AI

Aman Bahl, Syneos Health®, Burlington, Canada
Ravindra Shukla, Syneos Health®, Virginia, USA

ABSTRACT

Generative AI has the potential to empower healthcare in various innovative ways. By leveraging the power of machine learning and deep learning algorithms, generative AI can contribute to improving patient care, disease diagnosis, drug discovery, and personalized medicine.

Artificial intelligence (AI) has been transforming health and medicine for several decades, whether through diagnostics, personalized medicine, data analytics or other innovations. The advent of generative AI is now reshaping drug discovery, diagnostics, clinical decisions and delivery of care.

Generative Artificial Intelligence (AI) is emerging as a disruptive wave with implications that span across diverse business sectors. As one of the most rapidly growing advanced AI technologies, generative AI offers valuable opportunities ranging from personalised health programs to pivotal healthcare cost reduction strategies. From natural language processing (NLP) to autonomous vehicles, generative models are being used to solve complex problems across a wide range of industries including healthcare.

INTRODUCTION

As quoted by RhythmX AI CEO Deepthi Bathina "Providing the right care at the right time to the right patient is more challenging than ever"[Ref:1].

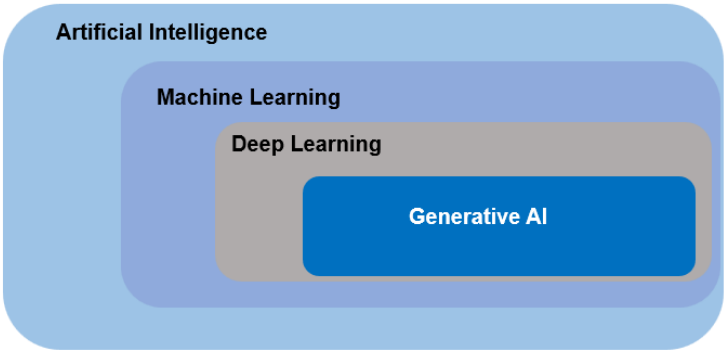

Figure 1: Generative AI

Generative AI is a subset of deep learning models (as shown in figure-1 above) that focuses on creating or generating new content, such as images, text, music, or videos, based on patterns and examples from existing data. At a time when health care costs are a growing concern for many consumers, generative AI may be the key to reducing costs, improving access, and leveraging it to improve their well-being. The technology holds immense promise for improving patient care, diagnosis accuracy, and treatment outcomes.

This paper will briefly focus on the benefits of generative AI and its applications in healthcare, and specific noteworthy challenges. Some of the key differences between traditional AI and generative AI are shown in the table-1 below.

Characteristic	Traditional AI	Generative AI
Objective	Perform tasks based on predefined rules and patterns	Create new data

Strengths	Effective, easily understandable, adept at solving specific tasks.	Creative, innovative, can handle uncertainty, novel applications
Weaknesses	May lack creativity and innovation, and exhibit challenges in managing uncertainty	Not as good at pattern recognition and task-specific problem-solving as traditional AI systems
Applications	Fraud detection, medical diagnosis, self-driving cars, voice assistants, gaming, trading etc.	Drug discovery, design creation, Image and video generation, medical diagnosis, code generation, Music, art, creative writing etc.

Table 1: Traditional AI vs Generative AI

Traditional AI and generative AI, though serving different functions, can complement each other rather than being mutually exclusive. The integration of generative AI with traditional AI can result in more potent solutions. For example, traditional AI may analyze user behavior data, and generative AI can leverage this analysis to generate personalized content. This collaborative approach enhances the overall capabilities and effectiveness of AI systems.

GENERATIVE AI POISED TO REVOLUTIONIZE THE EFFICIENCY OF CLINICAL TRIALS

Here are few examples of how Generative AI has potential to transform clinical trial efficiencies.

Improved Research and Development

The process of discovering new treatment options often involves extensive scientific research, but Gen AI has the potential to significantly accelerate drug development. Through data analysis and integration, Gen AI may help researchers quickly identify patterns and biomarkers related to diseases and treatment responses. The use of AI extends to repurposing existing drugs by identifying new applications based on molecular properties. In drug development, AI assists medicinal chemists in generating novel molecular structures, while also predicting potential side effects and adverse reactions for safer development.
One of the example is DiffDock built by MIT researchers, a model that may one day be able to find new drugs faster than traditional methods and reduce the potential for adverse side effects [Ref:2].
CogMol is one of several chemical foundation models that IBM has developed. The largest, MoLFormer-XL, was trained on a database of more than 1.1 billion molecules and is currently being used by Moderna to design mRNA medicines.[Ref:3].

Streamlined Clinical Trial Operations

Generative AI can significantly expedite the creation of clinical trial protocols by meticulously analyzing historical trial data. It identifies trends, successful strategies, and pitfalls, which may enable researchers to design more effective trials. This streamlined protocol design has the potential to positively impact all drug development stages, which may lead to more successful clinical trials.

Gen AI offers the advantage of predicting potential issues in clinical trials by utilizing pattern recognition. By analyzing extensive medical literature, patient records, and historical trial data, Gen AI can identify statistical patterns, informing trial protocols for increased success likelihood. Additionally, Gen AI can create predictive models to simulate participant behavior and anticipate outcomes under various scenarios, potentially aiding in risk mitigation and enhancing trial efficiency.

Enhanced Enrollment and Participant Retention

Clinical trial patient recruitment challenges contribute to delays in bringing life-saving treatments to market. Gen AI has the potential to tackle these issues by aiding in patient recruitment and retention. Utilizing patient matching, it can integrate Electronic Health Records (EHRs) and healthcare providers' NPI numbers (in US) to identify potential candidates and analyze patterns in diagnoses and treatment information. Gen AI also acts as a virtual assistant for participants, offering information, reminders, and support to boost engagement. Furthermore, it may be able to help trial designers implement a patient-centric approach, optimizing assessment schedules to enhance enrollment and retention.

Improving real-time monitoring of data quality

GenAI is capable of scrutinizing audit trails to pinpoint inconsistencies, examining signals across patients within sites to detect potential processing or operational issues. Additionally, it can compare patient data with the expanding realm of real-world data (RWD) to recognize variations in data collection and identify protocol deviations. In essence, AI may be able to play a crucial role in enhancing accuracy, consistency, and completeness, making continuous data quality surveillance more efficient than traditional manual methods. With its proficiency in handling substantial volumes of disparate data, AI is likely to facilitate broader utilization of RWD, extending beyond mere data collection to continuous evidence generation.

Streamlined Regulatory Compliance Responsibilities

Gen AI's rapid analysis of vast regulatory information is poised to reshape compliance procedures in the life science field. It facilitates document generation, which can enable compliance teams to swiftly create essential trial documents. AI may be able to assist in risk assessment by identifying potential compliance gaps and violations, offering recommendations for mitigation. With an AI-powered chatbot, real-time responses to compliance queries have the potential to enhance information accessibility for employees, customers, and stakeholders. The capability to understand complex regulatory language and translate it into plain language is particularly valuable for non-experts. Gen AI also supports regulatory monitoring, alerting companies to real-time changes in regulations that may impact operations. Furthermore, AI may aid in audit preparation by organizing and facilitating accessibility to necessary documents and evidence.

An example is Med-Palm 2, a large language model (LLM) designed and trained by Google to provide high-quality answers to medical questions. [Ref:4]

KEY GENERATIVE AI USE-CASES IN HEALTHCARE

While artificial intelligence (AI) has been transforming the healthcare industry for decades, the emergence of generative AI is set to reshape critical aspects of healthcare, from drug discovery and diagnostics to the delivery of care. Some key areas where generative AI can drive transformation in healthcare is shown in figure-2 below.

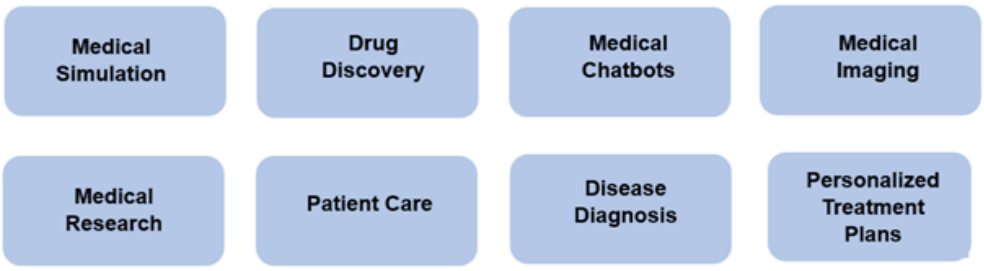

Figure 2: Key Generative AI use-cases in healthcare

Medical Simulation

Simulations provide a controlled setting for medical professionals to enhance their skills and knowledge. Generative AI can contribute by creating realistic models for medical training, enabling healthcare professionals to practice complex procedures without real-world risks. Additionally, synthetic data is highlighted for its potential in estimating the effectiveness of screening, healthcare policies, and clinical interventions. It can also enhance machine learning algorithms, pre-train models for specific patient populations, and improve public health models for predicting infectious disease outbreaks.

A research team led by Dr. Kim, Hyungmin of the Bionics Research Center (KIST) has now developed a real-time acoustic simulation technology based on generative AI to predict and correct the distortion of the ultrasound focus position caused by the skull in real-time during focused ultrasound therapy. [Ref:5]

Drug Discovery and Development

In the realm of drug discovery, the capacity of generative AI models to generate fresh data samples by leveraging patterns from their training data may prove instrumental in revealing innovative molecular structures or potential drug candidates.
In drug development, Generative AI processes vast amounts of data, providing critical insights and aiding in creating informed trial designs. It can enhance precision and control by proactively identifying challenges and allowing real-time strategy adjustments, with the goal of reducing the time to bring new drugs to market. This technological advancement has the potential to not only streamline processes but may also help accelerate the availability of new treatments for patients in need.

Insilico's INS018_055 is a potentially first-in-class anti-fibrotic drug candidate that has reached clinical Phase II, and it is fully delivered by generative AI, with a novel AI-discovered target and a novel AI-generated molecular structure. [Ref:6]
Mitsui and NVIDIA announced Japan's First Generative AI Supercomputer for Pharmaceutical Industry to accelerate drug discovery. [Ref:7]

Medical Chatbots

Generative AI can create medical chatbots that provide patients with personalized medical advice and recommendations.
A generative AI-powered counseling chatbot available on demand from Serena delivers accessible and affordable mental health care. [Ref:8]
Dr. GenAI is a personal medical chatbot designed to give people a new way to obtain fast and personalized medical information based on a person's unique medical condition.[Ref:9]
Forward Health launched CarePods, a self-contained, AI-powered doctor's office [Ref:10]

Enhanced Medical Imaging

In the realm of medical imaging, the utilization of generative AI models can enhance image quality, diminish noise, and improve resolution. Additionally, Generative adversarial networks (GANs) can be applied to image-to-image translation tasks, such as synthesizing CT images based on an MRI image.

A team of Northwestern Medicine researchers have created a generative AI tool capable of interpreting chest radiographs with accuracy on par with or above radiologists for some conditions. [Ref:11]
Generative models such as DALL-E 2, a novel deep learning model for text-to-image generation, could represent a promising future tool for image generation, augmentation, and manipulation in health care. [Ref:12]
REMEDIS leverages large-scale supervised learning using natural images and self-supervised learning using unlabeled medical data to create strong foundation models for medical imaging. [Ref:13]

Medical Research

Utilizing generative AI has the potential to expedite medical research. The algorithm can assimilate knowledge from a vast dataset of scientific literature, discerning patterns linked to particular research topics.
Ordaōs is developing a class of miniproteins with enhanced biological and therapeutic attributes to treat uniquely challenging rare cancers that primarily afflict ethnic minorities.[Ref:14]
Absci is using deep-learning AI and synthetic biology to design new antibodies against cancers and immune diseases.[Ref:14]
By investigating the neural basis of diffusion models, neuroscientists can gain insights into how the brain generates and processes information. These insights can be applied to improve AI algorithms, facilitate brain-machine interfaces, and even enhance the diagnosis and treatment of neurological disorders. [Ref:15]

Patient Care

Generative AI is revolutionizing patient communication and healthcare interaction, aiming to significantly improve patient satisfaction. With clinician oversight, it has the potential to generate discharge summaries, care coordination notes, and real-time checklists in the patient's language. Furthermore, it can enhance electronic health records by synthesizing language. In the future, generative AI could support real-time patient monitoring, data analysis, and provide personalized insights, promoting healthier behaviors and timely interventions to prevent the worsening of medical conditions.

RhythmX AI announced precision care platform for doctors to deliver hyper-personalized care to the right patient at the right time. [Ref:16]
NextGen™ Ambient Assist is an ambient listening solution that interprets patient-provider conversations in real time to summarize appointments and document care plans at unprecedented speeds. [Ref:17]

Disease Diagnosis

Generative AI is aiding healthcare professionals in precise diagnoses by analyzing varied patient data, offering recommendations for additional tests or treatments. Functioning as a medical knowledge assistant, it can generate symptom checklists and propose treatment options for different diseases. Additionally, Large Language Models with generative AI can be fine-tuned in medical datasets, leveraging sensors like phone cameras or health watches to facilitate early diagnosis.

Paige.AI, a digital pathology company, is incorporating generative AI into its products to enhance the precision and efficiency of prostate cancer detection. Notably, they are the first to receive FDA approval for utilizing generative AI in digital pathology.[Ref:14]
Glass Health has introduced an AI tool, driven by a Large Language Model (LLM) akin to OpenAI's ChatGPT, which generates diagnoses and provides "evidence-based" treatment options for patient consideration.[Ref:18]

Personalized Treatment Plans

Generative Artificial Intelligence can be used to develop personalized treatment plans for patients. The algorithm can analyze a patient's medical history, genetic information, and lifestyle factors to create a personalized treatment plan.

Babylon Health has created a digital health service that uses generative AI to understand patients' evolving risk profile, helping providers offer more personalized care at lower cost. [Ref:14]
Companies like ConcertAI are developing predictive models to identify and proactively manage high-risk segments based on patient medical history and demographic and social determinants of health.[Ref:14]

CHALLENGES OF USING GENERATIVE AI IN HEALTHCARE

While generative AI holds promise in healthcare, it also presents certain challenges and concerns. Here are some examples:

Inaccuracy and inconsistency: Generative AI models, while trained on extensive data, may lack mechanisms to prioritize or verify data sources for credibility. This absence of scrutiny can result in biased or inaccurate datasets, leading to the generation of erroneous and inconsistent content, commonly termed "hallucination."

Bias and discrimination: The potential for bias in AI algorithms is a concern, especially if the training dataset lacks full representation of the population. This could lead to inaccurate or even harmful results generated by the algorithm.

Misuse and over-reliance: Improper use of generative AI algorithms in healthcare poses risks of inaccurate medical decisions. Overdependence on these algorithms may compromise healthcare professionals' independent judgment. Moreover, generative AI models could generate misleading content, like fake news articles, potentially misinforming consumers about product effectiveness and causing confusion about legitimate treatments.

Ethical considerations: The application of AI for generating patient data raises ethical concerns regarding data ownership, consent, and the possibility of misuse. Establishing clear guidelines is crucial to ensure ethical practices. Additionally, there is a risk that synthetic data may be used to circumvent data privacy laws, as it is not subject to standard data protection legislation, allowing legal dissemination of information beyond organizational borders.

Privacy Concern: The use of generative AI in healthcare, which relies on substantial datasets, raises concerns about the ownership, confidentiality, and privacy of the medical and clinical data used for training. There are potential risks related to patient disclosures, opt-out options, and data deletion in the development and deployment of generative AI in healthcare.

Lack of Transparency: Regulatory agencies such as the FDA require transparency and reproducibility in clinical trials. Demonstrating the validity and reliability of generative AI-generated data might require new validation standards.

Generative AI applications function as black boxes, generating results without providing an explanation of the underlying process. This lack of transparency hinders the ability to verify the accuracy of outputs. Specifically, there are concerns in healthcare about organizations using generative AI algorithms that might lead to denials of benefits or prior authorizations without the ability to justify the rationale behind the application's recommendations.

POTENTIAL FUTURE USE CASES OF GENERATIVE AI IN HEALTHCARE

Generative AI algorithms are becoming increasingly powerful. As quoted by Robert Pearl, a clinical professor at Stanford University School of Medicine, “ChatGPT is doubling in power every six months to a year. In five years, it’s going to be 30 times more powerful than it is today. In 10 years, it will be 1,000 times more powerful. What exists today is like a toy. In next-generation tools, it’s estimated there will be a trillion parameters, which is interestingly the approximate number of connections in the human brain.” [Ref:19]

The future application of generative AI in healthcare holds potential for accelerating therapeutic access, particularly for rare and challenging conditions. It may aid in analyzing patient data for personalized treatment approaches, while payers leverage generative AI to reduce costs and enhance risk management. Applications include conversational AI for personalized communication, remote monitoring for effective interventions, and quality control for predicting equipment maintenance.

Generative AI could also play a role in public health monitoring, drug safety evaluations, and outbreak prediction. As the pharmaceutical industry focuses on complex therapies, the significance of generative AI is expected to grow, emphasizing the need for governance and trustworthiness in its implementation. The evolving landscape of AI innovation in healthcare promises transformative possibilities.

As quoted by Baba Shetty, president of technology and data solutions at Syneos Health "AI will have a massive impact on the work of clinical trials, and it can support many of the outcomes that everybody hopes to maximize - outcomes for patients, outcomes for sponsors and even outcomes for society." [Ref:20]

CONCLUSION

Generative AI, a rapidly evolving ecosystem of tools, is gaining popularity and holds significant potential to revolutionize healthcare. Beyond ChatGPT, it can handle diverse data types, from text to 3D modeling. The technology has transformative implications for drug discovery, diagnostics, and patient care. Despite its promise, challenges such as further development, public acceptance, and robust regulation need to be addressed. Developing safeguards against AI misuse is crucial for responsible deployment.

Collaboration between AI experts, researchers, clinicians, and regulatory bodies is vital to unlock the full potential of generative AI in clinical research. Embracing generative AI technology will pave the way for innovative opportunities in healthcare.

As quoted by Terttu Haring, president, clinical sites, and patients at Syneos Health, “We really shouldn’t be afraid, there are just so many ways where automated review can see things human eyes cannot. And if we miss these opportunities, we don’t do right by the patients who are either waiting for clinical trials or waiting for products to come to drugstore shelves. Every step of the way is ripe with opportunity: from product and protocol design to selection of populations, trial operationalization and data analysis. Now’s the time to dig in.” [Ref:20]

REFERENCE:

1. https://finance.yahoo.com/news/generative-ai-native-health-company-103000536.html
2. https://news.mit.edu/2023/speeding-drug-discovery-with-diffusion-generative-models-diffdock-0331#:~:text=MIT%20researchers%20built%20DiffDock%2C%20a,potential%20for%20adverse%20side%20effects
3. https://www.ndm.ox.ac.uk/news/strubi-researchers-validate-ibm2019s-ai-generated-covid-antivirals
4. https://sites.research.google/med-palm/
5. https://medicalxpress.com/news/2023-12-artificial-intelligence-lowers-barrier-ultrasound.html
6. https://www.eurekalert.org/news-releases/993844
7. https://blogs.nvidia.com/blog/2023/03/21/generative-ai-supercomputer-pharmaceutical-industry/
8. https://serena.chat/
9. https://www.globenewswire.com/news-release/2023/06/15/2688799/0/en/DiagnaMed-Launches-a-Generative-Artificial-Intelligence-Medical-Chatbot-Dr-GenAI.html
10. https://techcrunch.com/2023/11/15/forward-health-carepod-ai-doctor/?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8
11. https://healthitanalytics.com/news/generative-ai-may-facilitate-improved-chest-x-ray-interpretation
12. https://www.itnonline.com/content/new-research-suggests-ai-image-generation-using-dall-e-2-has-promising-future-radiology
13. https://blog.research.google/2023/04/robust-and-efficient-medical-imaging.html
14. https://www.bcg.com/publications/2023/how-generative-ai-is-transforming-health-care-sooner-than-expected
15. https://neuroflash.com/blog/exploring-generative-ai-dive-into-the-world-of-diffusion-models/
16. https://www.prnewswire.com/news-releases/new-generative-ai-native-health-company-rhythmx-ai-announces-precision-care-platform-for-doctors-to-deliver-hyper-personalized-care-to-the-right-patient-at-the-right-time-301947898.html
17. https://www.nextgen.com/company/newsroom/press-release/nextgen-healthcare-unveils-nextgen-ambient-assist--an-ai-solution-designed-to-boost-provider-effici
18. https://techcrunch.com/2023/09/08/glass-health-is-building-an-ai-for-suggesting-medical-diagnoses/#:~:text=Glass%20Health%20now%20offers%20an,options%20to%20consider%20for%20patients
19. https://journal.ahima.org/page/leveraging-chatgpt-and-generative-ai-in-healthcare-analytics
20. https://go.syneoshealth.com/l/63102/2023-11-20/4rzp4g/63102/1700516905210O9vN8J/Syneos_Health_Biopharma_Dive.pdf

ACKNOWLEDGMENTS

Sincere thanks to my Syneos Health senior management team including **Mike McDevitt**, SVP, Biometrics, **Sandra Vermeulen**, VP, Global FSP 360, **Ravindra Shukla**, Managing Dir, AI & Advanced Analytics, **Dan Strieter**, Senior Director, Biostatistics and **Andrew Cross**, Director, Biostatistics for their vision, great leadership, persistent support, and encouragement to make this paper possible.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Aman Bahl
Associate Director, Statistical Programming, Clinical Division, Syneos Health®
Phone: +1-905-399-6715
Email: Aman.Bahl@syneoshealth.com
Web: http://www.syneoshealth.com

Ravindra Shukla
Managing Director, Data Science & Analytics, Syneos Health®
Phone: +1-703-679-0117
Email: Ravindra.Shukla@syneoshealth.com
Web: http://www.syneoshealth.com