

Generative AI in Biometrics: Transforming Clinical Trials with Supercharged Efficiency and Innovation

Kevin Lee, ClinVia, San Francisco, CA

ABSTRACT

The pharmaceutical industry stands at the beginning of a transformative era, with Generative AI (e.g., ChatGPT) revolutionizing clinical trial development. The paper will explore the integration of Generative AI in Biometrics, highlighting its potential to streamline workflows, redefine clinical trial development, and lead innovation.

The paper will start with the introduction of Generative AI and its wide-ranging applications in Biometrics, such as information query, codes generation (e.g., SAS, R & Python), codes conversion (e.g. SAS to R/Python), document generation (e.g., SAP, CSR), data analysis, data visualization, patient profiling and many more. The paper will also explore the tools, systems, processes and people that are reshaping clinical trials with Gen AI integration.

Looking toward the future, the paper will evaluate the lasting impact of Generative AI on Biometrics department. By strategically adopting these cutting-edge technologies, Biometrics teams can dramatically enhance operational efficiency, optimize trial outcomes, and expedite regulatory approval processes. The paper will culminate in a forward-looking exploration of how Biometrics teams can evolve into "super Biometrics teams"—leveraging Generative AI to achieve unprecedented levels of innovation, precision, and effectiveness in clinical trial development.

Introduction of Gen AI

In the rapidly evolving landscape of artificial intelligence, Generative AI, often referred to as Gen AI, has emerged as a groundbreaking force, revolutionizing the way we create and innovate. With its ability to generate entirely new content, Gen AI is poised to shape the future of Pharma industries and transform the way we interact with technology.

Gen AI harnesses the potential of trained machine learning models to produce a wide array of outputs like the following.

- Text: Content Writing, Chatbots, Assistants, Search
- Code: Code Generation, Data Set Generation
- Image: Image Generation, Image Edit
- Audio: Voice Generation/Edit, Sound creation, Audio Translation
- Video: Video Creation/Edit, Voice Translation, Deepfake

Its impact is already being felt across various sectors, and its potential for growth is immense. Industry experts predict a significant surge in Gen AI market, projecting a rise from \$67 billion in 2024 to a staggering \$960 billion by 2032.

Introduction of ChatGPT

ChatGPT is one of the most popular Gen AI, and it is developed by OpenAI. It is trained on large corpus of text about 300B words, and its main strength lies in

- The ability to generate human-like response in various contents.
- The ability to understand and generate content in a wide range of domains.

Why Gen AI in Biometrics?

Biometrics team can greatly benefit from implementing Gen AI and the implementation of Gen AI in Biometrics teams has the potential to revolutionize clinical trial processes, leading to more efficient, effective, and innovative outcomes.

- Enhanced Efficiency and Automation
- Easy Transition to Opensource Transition
- Improved Data Analysis and Visualization
- Streamlined Clinical Trial Processes
- Super Biometrics Team

By embracing these technologies, Biometrics teams can become "super teams," driving the industry forward and ultimately accelerating the development of life-saving treatments.

How to Start Gen AI in Biometrics Team

Implementing Gen AI in Biometrics teams requires a strategic approach that considers the system, process, and people.

1. The system integration of Gen AI tools and platforms must come from the use cases from Biometrics team such as content development, code development and data analysis. In addition, Biometrics teams should invest in robust and GxP compliant infrastructure to support the Gen AI tools/systems, ensuring they can handle regulatory compliant tasks.
2. Biometrics team need to build new process, specific to Gen AI driven workflow. Biometrics teams should identify risks and benefits in Gen AI workflows and redesign processes to leverage Gen AI's capabilities and risks. This can also involve automating process driven by Gen AI, such as data development and report generation, providing how Gen AI and humans could collaborate together where Gen AI drive the initial automation to allow humans to focus on more complex and value-added activities. In addition, Biometrics team should develop the validation process of Gen AI driven outputs. So, establishing clear protocols and guidelines for Gen AI usage ensures consistent and compliant results.
3. Biometrics teams should upskill and reskill their workforce to embrace the benefits and potentials of Gen AI. The training on responsible Gen AI practices, prompt engineering and specific Gen AI tools will empower Biometrics team members to utilize these technologies effectively. Furthermore, fostering a culture of innovation and collaboration encourages the adoption of Gen AI, enabling Biometrics teams to become 'super teams' that drive efficiency and excellence in clinical trials.

Gen AI Use Cases in Biometrics

Gen AI has emerged as a transformative force, which can revolutionize the Biometrics team with its versatile applications. From code generation to automated document creation and advanced data analysis, this technology is empowering Biometrics team to streamline processes and enhance efficiency.

Below are some examples of Gen AI use case in Biometrics, and there are a lot more use cases that could utilize Gen AI capabilities.

- Information Inquiry
 - Prompt:

What is CDISC? Tell me in 50 words.
 - Output:

CDISC (Clinical Data Interchange Standards Consortium) is a global organization that develops data standards for clinical research. Its models, like SDTM and ADaM, ensure standardized data collection, submission, and analysis, improving regulatory compliance, interoperability, and data quality in clinical trials, facilitating efficient drug development and approvals by agencies like the FDA.
- Content Development (e.g., SAP, Mock-up tables, CSR)
 - Prompt:

Write clinical trial **protocol synopsis** based on below "title of study".
 "title of study" : A phase 3, randomized, double-blind, placebo controlled study to evaluate the efficacy of drug A in schizophrenia patients.
 - Output:

****Clinical Trial Protocol Synopsis: Phase 3 Study on the Efficacy of Drug A in Schizophrenia Patients****

****1. Study Title:****
 A phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy of drug A in schizophrenia patients.

****2. Objective:****
 The primary objective of this clinical trial is to assess the efficacy of drug A in treating schizophrenia in comparison to a placebo. Secondary objectives include evaluating the safety, tolerability, and overall clinical benefit of drug A.

****3. Study Design:****
 This study will adopt a randomized, double-blind, placebo-controlled design. Participants will be randomly assigned to either the treatment group receiving drug A or the control group receiving a placebo. The double-blind nature of the study ensures that both investigators and participants are unaware of the assigned treatment.

****4. Participants:****
 The study will enroll adult participants diagnosed with schizophrenia according to standardized diagnostic criteria. Inclusion and exclusion criteria will be defined to ensure the homogeneity of the study population.

****5. Interventions:****
 - Treatment Group: Participants will receive drug A in the prescribed dosage.

- Control Group: Participants will receive a placebo identical in appearance to drug A.

****6. Primary Outcome Measure:****

The primary efficacy endpoint is the reduction in the severity of schizophrenia symptoms, as measured by a standardized assessment tool, at the end of the treatment period.

****7. Secondary Outcome Measures:****

Secondary endpoints include:

- Changes in cognitive function.
- Improvement in overall functioning and quality of life.
- Incidence and severity of adverse events.
- Assessment of treatment adherence.

****8. Study Duration:****

The trial will be conducted over a specified period, with defined time points for participant recruitment, treatment administration, and follow-up assessments. The duration of the study will be determined based on the anticipated rate of symptom improvement and the need for robust data collection.

****9. Statistical Analysis:****

Statistical methods, including intention-to-treat analysis, will be employed to evaluate the primary and secondary endpoints. Sample size calculations will ensure the study's power to detect meaningful differences between the treatment and control groups.

****10. Ethical Considerations:****

The study will be conducted in accordance with ethical principles outlined in the Declaration of Helsinki and local regulatory requirements. Informed consent will be obtained from all participants, and measures will be taken to ensure participant confidentiality and safety.

****11. Data Monitoring and Safety:****

An independent Data Monitoring Committee (DMC) will oversee the trial's progress, ensuring participant safety and data integrity. Adverse events will be monitored and reported according to regulatory guidelines.

****12. Conclusion:****

This phase 3 clinical trial aims to contribute valuable insights into the efficacy and safety of drug A in the treatment of schizophrenia. The results of this study may have implications for improving the management of schizophrenia and enhancing the overall well-being of affected individuals.

- Code Conversion
 - Prompt:
Convert below SAS® codes to R codes: Please show R codes only.
data dm;
merge demo rand;
by usubjid ;
run;
 - Output:
dm <- merge(demo, rand, by = "usubjid")
- Code Development
 - Prompt:
Write a **R script** that groups data by "trta" and "avisitn" columns in "advs.xpt" and calculates the mean of the "aval" column for each group at parmcd = 'WEIGHT'
 - Output:
```R  
# Load necessary libraries  
library(haven)  
library(dplyr)  
  
# Read the XPT file  
advs <- read\_xpt("path/to/advs.xpt")  
  
# Filter the dataset for parmcd == 'WEIGHT'  
advs\_weight <- advs %>% filter(parmcd == 'WEIGHT')

```
Group by 'trta' and 'avisitn' and calculate the mean of 'aval' for each group
mean_aval <- advs_weight %>%
 group_by(trta, avisitn) %>%
 summarise(mean_aval = mean(aval, na.rm = TRUE))

Print the result
print(mean_aval)
```

```

- Data Analysis

- Prompt:

Select patients whose sex is male. Use below "Patient Data". Provide me the answers and R codes only.

"Patient Data":

```
{ 'patient' : '01-001', 'sex' : 'male', 'age' : 25, 'race' : 'White'},
{ 'patient' : '01-002', 'sex' : 'female', 'age' : 28, 'race' : 'Asian'},
{ 'patient' : '02-001', 'sex' : 'female', 'age' : 50, 'race' : 'White'},
{ 'patient' : '02-002', 'sex' : 'male', 'age' : 40, 'race' : 'Black'}
```

- Output:

The selected patients whose sex is male are:

1. { 'patient': '01-001', 'sex': 'male', 'age': 25, 'race': 'White' }
2. { 'patient': '02-002', 'sex': 'male', 'age': 40, 'race': 'Black' }

Create data frame

```
patient_data <- data.frame(
  patient = c("01-001", "01-002", "02-001", "02-002"),
  sex = c("male", "female", "female", "male"),
  age = c(25, 28, 50, 40),
  race = c("White", "Asian", "White", "Black")
)
```

Filter male patients

```
male_patients <- subset(patient_data, sex == "male")
```

Print results

```
print(male_patients)
```

- Data Visualization

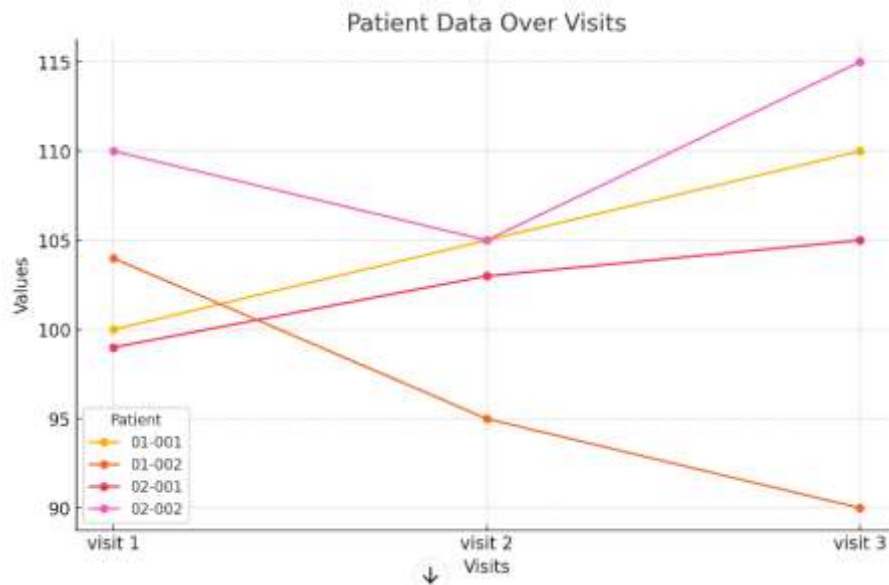
- Prompt:

Create line graph of "Patient Data"

"Patient Data":

```
{ 'patient' : '01-001', 'visit 1' : 100, 'visit 2' : 105, 'visit 3' : 110},
{ 'patient' : '01-002', 'visit 1' : 104, 'visit 2' : 95, 'visit 3' : 90},
{ 'patient' : '02-001', 'visit 1' : 99, 'visit 2' : 103, 'visit 3' : 105},
{ 'patient' : '02-002', 'visit 1' : 110, 'visit 2' : 105, 'visit 3' : 115}
```

- Output:



Above prompts and outputs have been created using free version of ChatGPT, and we could build relevant application using Gen-AI API (e.g., gpt-4o-mini).

New Process for Gen AI workflow in Biometrics

Much like an intern with exceptional potential, Gen AI models can provide valuable insights and assist in numerous tasks. However, it is crucial to approach this technology with a validation-focused mindset. The output generated by Gen AI should be regarded as a starting point, a catalyst for further exploration and refinement. The Biometrics team must implement a rigorous validation process to ensure the accuracy, reliability, and compliant use of these Gen AI-generated outputs. By treating Gen AI as a collaborative tool and subjecting its output to rigorous validation, the Biometrics team can harness its potential while maintaining the integrity, compliance and quality expected in the pharmaceutical industry.



Super Biometric Team

With the implementation of Gen AI tools, such as ChatGPT, the team can experience significant improvements in productivity and efficiency. According to the Boston Consulting Group's findings, ChatGPT users have demonstrated remarkable advantages over non-users. They have the ability to finish tasks at a faster rate, with an average of 12.2% more tasks completed and a 25.1% quicker turnaround time. Additionally, the quality of their work is notably higher, with an impressive 40% improvement.

With Gen AI as their ally, Biometrics team could be "Super Biometric team", which can leverage the benefits to gain a head start in their projects. By utilizing the power of AI, we no longer need to start from scratch. The Gen AI tool and practices, such as prompt engineering, can provide much better starting points in the tasks like codes or contents development. Biometrics team's expertise, combined with the intelligence of Gen AI, creates a formidable force, enabling them to achieve remarkable results and stay ahead in this innovation.

Future of Gen AI in Biometric team

The future of Gen AI in the Biometrics team holds immense potential and promises a transformative journey. The implementation of Gen AI raises intriguing questions about its role, whether it will replace us or enhance us. However, the benefits it brings suggest a harmonious collaboration. Gen AI can significantly boost productivity, enabling the team to achieve faster turn-around times and automate many tasks. This automation allows Biometrics teams to shift their focus towards strategic decision-making and innovative implementations, driving the efficiency forward. With Gen AI's assistance, the team can accelerate data analysis, visualize complex data interactively, and improve patient recruitment and retention strategies. Furthermore, automated communication systems can enhance efficiency and reduce administrative burdens. The Super Biometrics team, by combining Gen AI technology with their Biometric

expertise, can unlock new possibilities and achieve groundbreaking advancements in the field. This symbiotic relationship between Gen AI and Biometrics expertise paves the way for a future where Biometrics reaches new heights, offering improved clinical trial development.

CONCLUSION

The paper highlights the advantages of implementing Gen AI in Biometrics teams, emphasizing its potential to revolutionize clinical trial processes and create "super teams." By leveraging Gen AI, Biometrics teams can enhance efficiency, automate tasks, improve data analysis and visualization, and streamline better clinical development. The implementation of Gen AI is proposed as a collaborative tool, with a validation-focused mindset, ensuring accurate and compliant results. The paper also predicts a future where Gen AI and Biometrics expertise work together, leading to increased productivity, improved data handling, and enhanced clinical trial outcomes.

We would also ask the question where we want to be in terms of Gen AI adopter – Innovator, Early Adopters, Early majority, late majority or laggards. Based on our position, we should prepare strategies and timeline, which help to provide an opportunity to influence the direction and evolution of these technologies, ensuring they align with the specific needs and goals of the Biometrics team.

REFERENCES

- ChatGPT in <https://chatgpt.com/?ref=dotcom>
- Wikipedia - OpenAI in <https://en.wikipedia.org/wiki/OpenAI>
- Forbes – Opportunities and challenges of applying Gen AI to business in <https://www.forbes.com/councils/forbestechcouncil/2024/11/20/opportunities-and-challenges-of-applying-generative-ai-to-businesses/>
- Boston Consulting ChatGPT Use cases in <https://www.mi-3.com.au/20-09-2023/harvard-business-school-study-bcg-finds-knowledge-workers-using-chat-gpt-outperform>

CONTACT INFORMATION

Your comments and questions are valued and welcomed. Please contact the author at

Kevin Lee
Clinvia LLC
kevin@clinvia.com

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