

AI is coming for you: New Biometric Leadership in the era of Gen AI

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ABSTRACT

In the contemporary landscape of technological advancements, the integration of Gen AI like ChatGPT has ushered in a new era of innovation and development. This paper will discuss how these cutting-edge technologies influence biometrics department, then how biometrics leadership will lead this innovation.

The paper will start with the introduction with Gen AI, then the use case of ChatGPT in Biometric tasks such as coding, data analysis and exploration, contents development, and more. It will also provide how ChatGPT has contributed to a remarkable 40% increase in productivity among skilled workers, indicating the transformative power of ChatGPT.

To harness this transformative potential, biometrics leadership must evolve beyond traditional management paradigms. The paper will explore how effective leaders are reimagining their roles as AI integration architects, focusing on three critical dimensions: system, process and people. First, Leaders must establish a robust system that seamlessly integrates Gen AI tools with existing statistical computing and regulatory compliance systems. Secondly, leaders need to redesign workflows to optimize the synergy between AI and traditional biometric methodologies, ensuring human oversight and regulatory compliance. Finally, leadership must prioritize change management, fostering a culture of innovation while addressing concerns about AI integration and upskills rather than replaces, human expertise in biometrics.

Finally, the paper outlines how biometrics leadership can optimize the impact of Gen AI integration, ensuring sustainable transformation while maintaining the current biometrics tasks and offering valuable insights into the transformative possibilities and future directions of the symbiotic relationship between Gen AI and biometrics.

Introduction of Gen AI

The landscape of artificial intelligence (AI) has been dramatically transformed by the rise of Generative AI (Gen AI) - a revolutionary technology that creates entirely new contents rather than simply searching. This innovative branch of AI stands to fundamentally reshape the pharmaceutical industry and redefine our relationship with technology.

At its core, Gen AI leverages sophisticated machine learning models to produce diverse outputs across multiple domains:

- **Text:** From sophisticated content creation to intelligent chatbots, virtual assistants, and enhanced search capabilities
- **Code:** Automated programming and synthetic dataset generation
- **Images:** Creation of new visuals and modification of existing imagery
- **Audio:** Voice synthesis, audio editing, sound design, and language translation
- **Video:** Video production, editing, voice translation, and realistic simulations

The transformative influence of Gen AI is already evident across industries, with its economic footprint expected to expand dramatically. Financial forecasts suggest the Gen AI market will experience explosive growth - expanding from \$67 billion in 2024 to approximately \$960 billion by 2032.

Biometrics Leadership in Driving Gen AI Use Cases

Biometrics leadership plays a critical role in preparing and guiding the adoption of Gen AI within Biometrics, ensuring that innovation aligns with regulatory standards, data integrity, and clinical development rigor. By fostering a strategic and ethical approach, Biometrics leaders can maximize the potential of Gen AI while maintaining high-quality standards.

Gen AI has emerged as a transformative force, offering immense opportunities to revolutionize our works through its diverse applications. From intelligent code generation and automated document creation to advanced data analysis and predictive modeling, this technology empowers Biometrics teams to enhance efficiency, improve decision-making, and accelerate clinical development timelines.

Below are some examples of Gen AI use cases in Biometrics, with the potential for many more innovative applications:

- 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

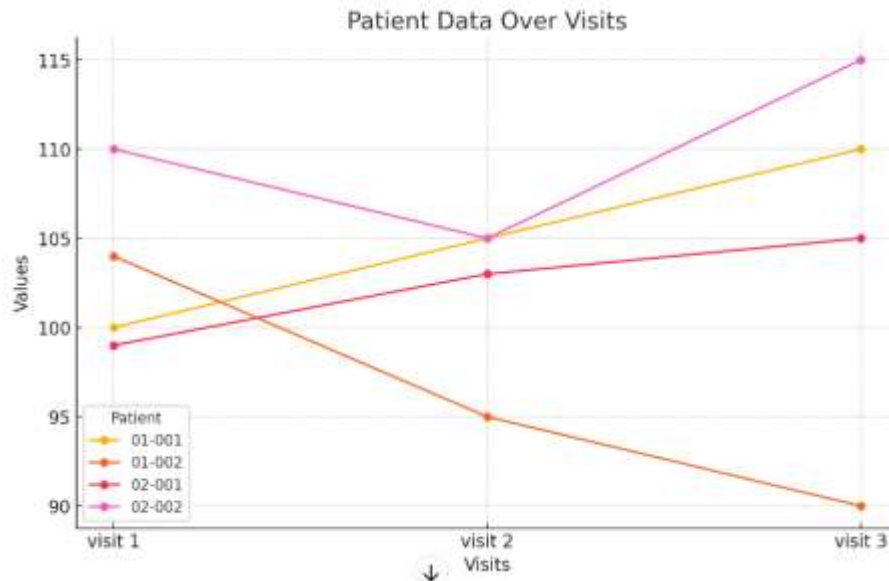
- Prompt:

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).

Why Gen AI in Biometrics Leadership?

Biometrics leadership faces a critical inflection point with the emergence of Generative AI, and must embrace and lead Gen AI initiatives because:

- Competitive necessity - organizations that fail to adapt will fall behind more agile competitors
- Strategic opportunity - first-movers gain outsized benefits and industry influence
- Organizational imperative - only leadership has the authority to drive meaningful change
- Resource justification - executive support is essential for securing necessary investments
- Risk management - potential regulatory and compliance issues require leadership oversight
- Talent motivation - teams look to leadership for vision and direction in times of these Gen AI changes/transformation

- Stakeholder expectations – upper leaderships / sponsors increasingly expect AI-enhanced capabilities

Gen AI Implementation roadmap for Biometrics department

Effective implementation of Generative AI in Biometrics function requires leadership that addresses three interconnected dimensions: systems, processes, and people. Biometrics leaderships need to build the comprehensive roadmap, which should ensure that technological innovation will translate into tangible improvements in biometric works such as clinical trial development efficiency and data quality while maintaining regulatory compliance and scientific integrity.

Systems & Infrastructure Roadmap

Biometrics leadership must create a robust technical infrastructure that supports Gen AI implementation while maintaining compliance with regulatory requirements and data integrity standards. This involves:

- **Integration with existing infrastructure:** Leaders must ensure seamless integration between Gen AI capabilities and established statistical computing environments (SAS, R, Python), electronic data capture systems, clinical data repositories, and other clinical development system. This integration should maintain study continuation, data lineage and auditability while enabling the benefits using Gen AI
- **Validation framework:** Given the critical nature of regulatory compliance in clinical development, Biometrics leadership must establish rigorous validation protocols / systems specific to Gen AI implementation. These frameworks should verify that AI-generated outputs meet the same quality standards as traditionally produced outputs, with appropriate documentation of validation process and results.
- **Security and compliance architecture:** Biometrics leadership must implement technical safeguards that ensure patient data confidentiality when utilized by Gen AI tools. This includes developing clear data security and governance policies/system, implementing appropriate access controls, and maintaining compliance with global regulations such as GxP, 21 CFR Part 11, GDPR, HIPAA, and emerging AI-specific guidance from regulatory authorities.
- **Scalable Infrastructure planning:** Rather than implementing static solutions, Biometrics leadership should establish a scalable technical architecture that can evolve as Gen AI capabilities mature. This forward-looking approach prevents technical debt and enables progressive implementation across the Biometrics function.

On many occasions, these system and infrastructure implementation should be coordinated and implemented with IT. Biometrics can't do this alone so the collaboration and partnership with IT become very important.

Process Development Roadmap

The true value of Gen AI will be accomplished when Biometrics processes are thoughtfully redesigned rather than simply accelerating existing workflows.

- **Validation and Quality Control:** Biometrics leadership must implement appropriate validation process specific to Gen AI outputs. The output generated by Gen AI should be regarded as a starting point not the final output, a catalyst for further exploration and refinement. The Biometrics leadership 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 leadership can harness its potential while maintaining the integrity, compliance and quality expected in the biometric works.



- **End-to-End Process Redesign:** Biometrics leadership should comprehensively review the entire biometric processes—from study design through database lock and submission - identifying high-impact opportunities for Gen AI integration. This systems-efficiency-thinking approach can improve efficient process in biometric works.
- **Human-AI Collaboration Protocols:** Effective leadership establishes clear delineation between AI-driven activities and those requiring human expertise. These protocols should define when AI serves as an assistant (e.g., generating initial code or report templates) versus when it operates with greater autonomy (e.g., routine quality checks or standardized visualizations), and also when human need to intervene.
- **Regulatory Strategy Development:** Forward-thinking leadership anticipates evolving regulatory requirements by developing proactive strategies with authorities. This includes preparing comprehensive documentation of validation approaches, developing SOP, Working Instruction and guidelines regarding Gen AI for Gen AI influenced outputs, and validating packages used by AI tools.

People and Change Management Roadmap

Perhaps the most critical dimension of successful Gen AI implementation is leadership's approach to Biometrics team such as talent development and organizational change management.

- **Comprehensive Capability Building:** Biometrics leadership must systematically assess existing skill gaps and implement targeted training initiatives across the department. This includes developing technical proficiency with Gen AI tools (e.g., ChatGPT, Copilot), building prompt engineering expertise, and enhancing validation skills for AI-generated outputs.
- **Culture Transformation:** Successful leaders actively shape organizational culture to balance innovation with the current culture. This involves creating psychological safety for experimentation using Gen AI tools while maintaining unwavering commitment to data integrity and regulatory compliance.
- **Role Evolution Management:** Rather than viewing Gen AI as a replacement for people, effective Biometrics leadership should articulate how traditional biometrics positions will evolve to new roles. This includes developing new career pathways that value both the traditional Biometrics expertise and Gen AI skills.
- **Cross-Functional Collaboration:** Biometrics leadership must foster deeper collaboration for Gen AI implementation in the clinical development between Biometrics department and other functions, including IT, clinical operations, data management, clinical scientists, and medical affairs. This collaborative approach ensures that Biometrics leadership can lead Gen AI implementation addressing the most valuable use cases rather than pursuing technology for its own sake.

Leading Super Biometrics Team

Visionary Biometrics leadership should recognize that implementing Gen AI tools fundamentally transforms team capabilities. For example, 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 leaderships could be effectively transforming and leading "Super Biometric Team", which can leverage the benefits of Gen AI. By deliberately cultivating "Super Biometrics Team" that combine Biometrics expertise with Gen AI, Biometrics leadership can create a formidable competitive advantage—enabling teams to improve efficiency, accelerate innovation, and respond more effectively to evolving clinical development priorities.

Biometrics Leadership: Preparing for the Future of Gen AI

The future of Gen AI in Biometrics is not just about technological advancement but about leadership - Biometrics leadership that embraces innovation while maintaining clinical development rigor and regulatory compliance. As Gen AI continues to evolve, it will not replace Biometrics team but empower them, fostering a leadership approach that blends Biometric expertise with AI-driven intelligence.

Biometric leadership must proactively integrate Gen AI into their workflows, leveraging its capabilities to enhance productivity, streamline processes, and drive strategic insights. By automating routine tasks, teams can redirect their focus to high-value activities such as critical thinking, decision-making, collaboration with other functions, complex data interpretation, innovative study designs, and people-centric strategies.

Moreover, Biometrics leadership must champion responsible AI adoption, ensuring transparency, compliance, and quality control in all AI-driven processes. By cultivating a culture of continuous learning and collaboration, Biometrics leadership can maximize the synergy between AI and Biometric expertise. This visionary approach will transform Biometrics teams into **Super Biometrics teams** - capable of harnessing Gen AI to unlock groundbreaking discoveries and elevate the standards. The future belongs to Biometrics leadership who can lead with agility, integrating Gen AI to shape a smarter, faster, and more efficient Biometric landscape.

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