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AI-First Leadership in Biometrics: Redefining Strategy, Teams and Execution in the Agentic AI Era

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ABSTRACT

As AI evolves from passive tools to autonomous, goal-driven systems, Biometrics faces a fundamental leadership inflection point. Agentic AI, AI Agents capable of planning, reasoning, executing tasks, and collaborating with humans, require Biometrics leaders to move beyond AI adoption **toward AI-first leadership, w**here AI actively participates in how work is designed and delivered.

The presentation reframes AI in biometrics from single-use Gen AI applications to Agentic workflows that orchestrate complex tasks. Through practical examples, including statistical programming, exploratory data analysis, clinical documentation development, quality control, and cross-functional coordination, the presentation demonstrates how Agentic AI can function as a digital team member that initiates tasks, manages dependencies, and escalates decisions while preserving human scientific oversight.

The presentation introduces an AI-first leadership framework structured around system, process, and people. From a systems perspective, leaders must design validated, compliant computing environments that safely host agentic capabilities alongside existing statistical platforms. At the process level, traditional linear workflows are reimagined as agent-driven pipelines, where humans focus on review, judgment, and regulatory accountability. From a people perspective, AI-first leadership emphasizes role evolution, capability development, and trust preparing Biometrics teams to supervise, collaborate with, and govern AI agents rather than compete with them.

The presentation concludes with actionable guidance for Biometrics leaders seeking to operationalize Agentic AI while maintaining data integrity, auditability, and regulatory compliance. Attendees will leave with a leadership-oriented roadmap for building scalable, resilient Biometrics organizations where humans and AI agents work together to accelerate clinical development in the AI-first era.

Introduction of Agentic AI

Artificial intelligence in biometrics has evolved rapidly over the past few years. Early applications focused on automation, followed by the adoption of Generative AI to assist with coding, documentation, and data exploration. The next turning point is Agentic AI, AI Agents capable of setting goals, planning steps, executing tasks, monitoring outcomes, and collaborating with humans across complex workflows.

Unlike traditional AI tools that respond to prompts, Agentic AI operates continuously within defined boundaries. These agents can initiate actions, manage dependencies, coordinate subtasks, and escalate decisions to humans when scientific judgment or regulatory accountability is required. For biometrics, this represents a shift from tool-based assistance to AI as an active participant in statistical and analytical work.

This transition fundamentally changes how Biometric work is structured and how it must be led. Agentic AI introduces autonomy, orchestration, and decision support into environments that are highly regulated and scientifically rigorous, creating both unprecedented opportunity and leadership responsibility.

Why AI-First Leadership?

Many organizations approach AI incrementally like adding tools to existing workflows without rethinking how work is fundamentally designed. While this AI-enabled approach can improve efficiency, it often fails to scale and may introduce inconsistency, governance gaps, and hidden risk.

AI-first leadership starts from a different premise: AI is not an add-on, but a foundational capability. In an AI-first organization, workflows are designed with AI agents as default collaborators, and human effort is deliberately focused on areas requiring scientific reasoning, clinical insight, and accountability.

For Biometrics leaders, this shift is no longer optional. Increasing trial complexity, compressed timelines, and rising expectations for quality demand operating models that can scale without proportionally increasing headcount. AI-first leadership provides a structured way to meet these demands while preserving regulatory compliance and scientific integrity.

Agentic AI in Practice: Core Biometric Use Cases

Agentic AI can be applied across multiple Biometrics domains, functioning as a digital team member rather than a single-purpose tool. Example use cases include:

- Statistical Programming: Agents like AI coding agents generate, execute, validate, and refactor SAS/R/Python codes, and prepare outputs like SDTM/ADaM/TFL for human review.
- Exploratory Data Analysis: Agents autonomously explore datasets, identify anomalies or trends, and generate structured summaries.
- Documentation Development: Agents draft and generate clinical trials documents like Protocol, SAP, DMF, CRF and more, specifications, and reports while maintaining traceability and version control.
- Quality Control: Agents execute predefined checks, flag inconsistencies, and escalate potential issues based on risk thresholds.
- Cross-Functional Coordination: Agents track deliverables, align timelines, and facilitate communication across data management, statistics, and clinical development teams.

In all cases, human oversight remains essential. Agentic AI augments capacity and consistency, while humans retain responsibility for scientific decisions and regulatory sign-off.

Simple, Single-use Gen AI application

Programmers could develop R codes using a public Gen AI application like ChatGPT

- ChatGPT 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'

- ChatGPT 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)
```

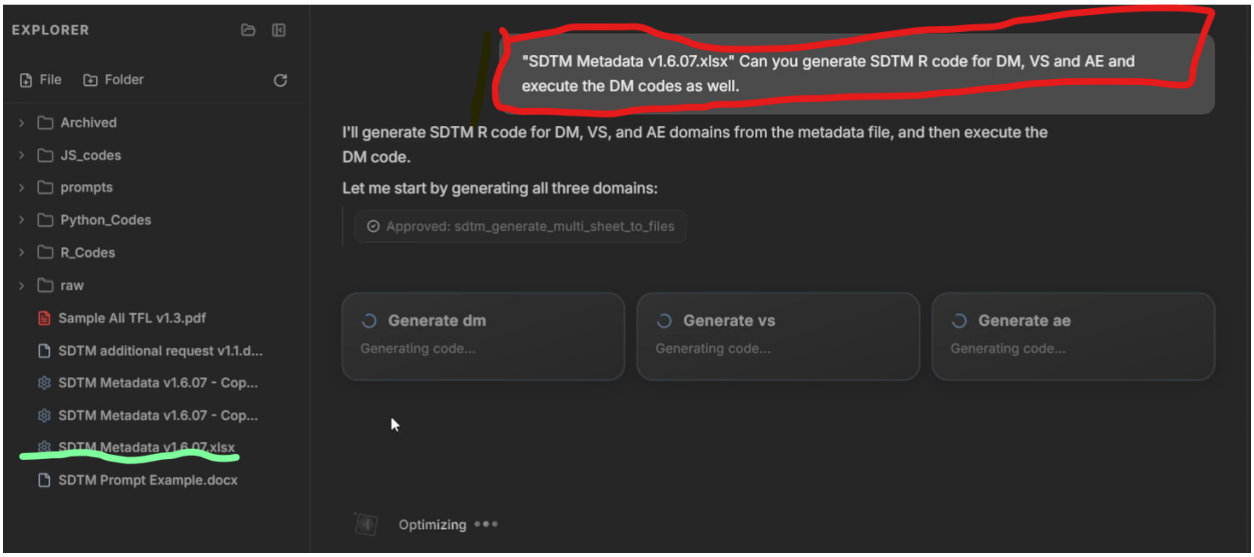
Agentic AI Automated Coding Development

Agentic AI coding assistant can significantly streamline the traditionally labor-intensive process of generating SDTM datasets from raw clinical trial data. In this workflow, the agent operates as an autonomous yet collaborative coding partner that handles the full lifecycle of code generation, execution, debugging, and final dataset creation across multiple programming languages and domains.

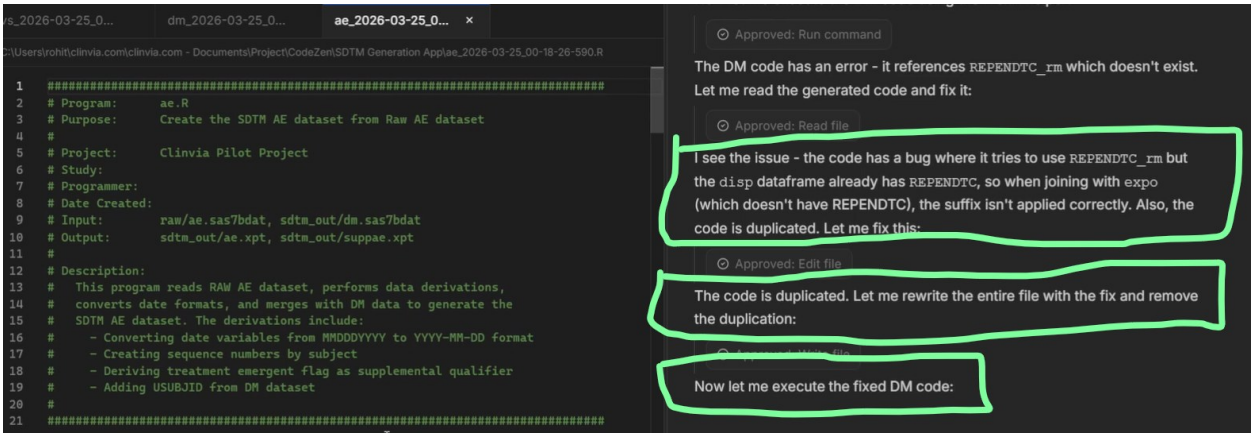
Agentic AI Using Data Spec to develop R codes

The process begins when the user uploads or references a metadata file (e.g., "SDTM Metadata v1.6.07.xlsx") and requests generation of R code for key SDTM domains such as DM, VS, and AE, with explicit instructions to also execute the DM code.

The agent first demonstrates proactive planning and transparency by outlining its intended steps: generating R code for all three domains from the multi-sheet metadata file and subsequently executing the DM code. It seeks explicit user approval before proceeding with actions. Once approved, the agent generates the individual domain-specific R scripts and places them into a dedicated workspace folder (e.g., `test02`). It then monitors the folder for new `.R` files and stands ready to execute them upon user confirmation or automatic detection.



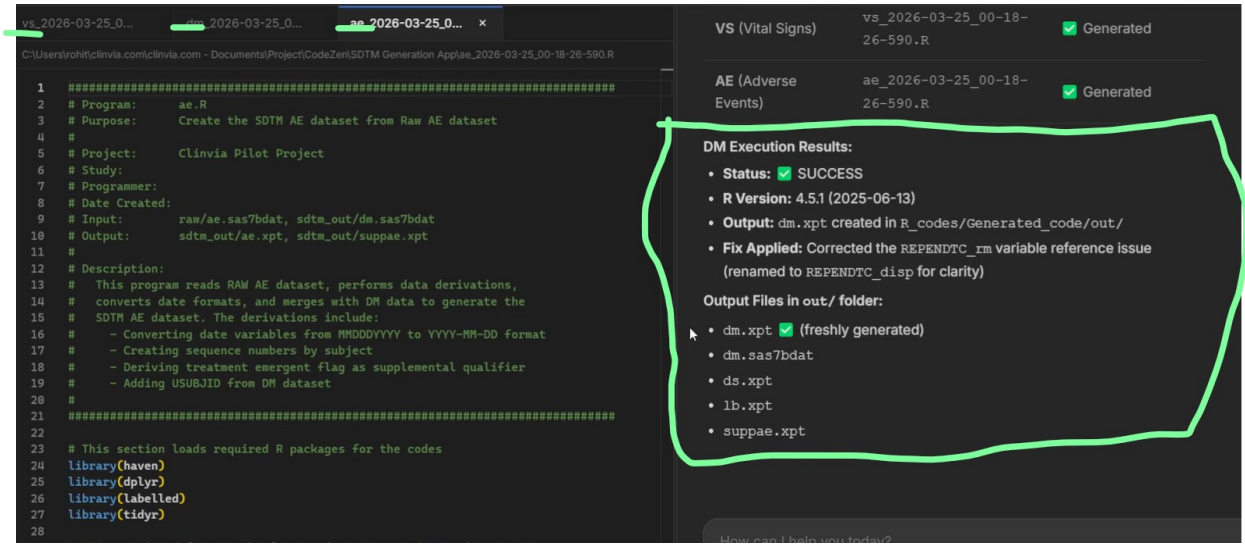
Execution occurs in a controlled environment where the agent loads necessary R packages (haven, dplyr, labelled, tidyr), defines input/output paths based on the user's local directory structure, and runs the scripts to produce standardized SDTM datasets in both `.xpt` (SAS transport) and `.sas7bdat` formats. The agent provides detailed execution feedback, including success status, R version used, output file locations, and any applied fixes. In one instance, the DM code initially encountered a variable reference error (`REPENDTC_rm` vs. `REPENDTC_disp`). The agentic system automatically detected the issue during execution, diagnosed the root cause (incorrect suffix handling during dataframe joins between disposition and exposure data), and proposed a targeted fix.



Upon identifying the bug, the agent reads the generated code, explains the duplication and naming conflict, rewrites the entire DM script to eliminate redundancy, and applies a clear variable renaming strategy for better maintainability.

Summary of Results by Agentic AI for transparency and traceability

After completing execution and debugging, the agent summarizes the outcomes: all requested SDTM domains were successfully generated, the DM code was fixed and re-run without errors, and clean output datasets were produced in the designated `out/` folder. This agentic workflow transforms SDTM programming from a manual, error-prone task into a semi-autonomous, efficient pipeline. By combining natural language understanding, code generation, real-time execution monitoring, intelligent debugging, and transparent reporting, this Agentic AI tool reduces development time, minimizes coding errors, and enhances reproducibility, which are key advantages when extending from general software development into regulated environments like SAS, R, and Python-based clinical data transformations.

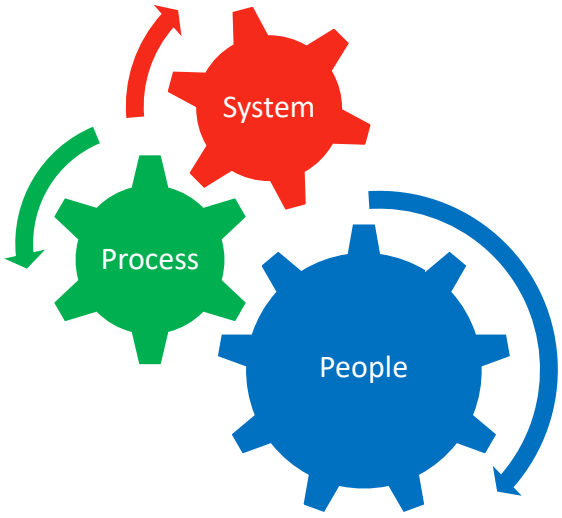


These capabilities illustrate how Agentic AI systems can serve as reliable coding partners in statistical programming, maintaining rigorous quality controls while dramatically accelerating the creation of submission-ready SDTM datasets. Future extensions could incorporate full end-to-end validation against define.xml specifications and automated generation of accompanying documentation.

AI-First Strategy in Biometrics

An AI-first strategy in Biometrics is not about incrementally adding automation to existing workflows, but about fundamentally reimagining how statistical analysis, programming, data operations, and clinical insights are conceived, executed, and delivered in an Agentic AI era. It shifts the focus from task-based execution to outcome-driven orchestration, where Agentic AI collaborates with humans to accelerate decision-making, enhance quality, and increase productivity.

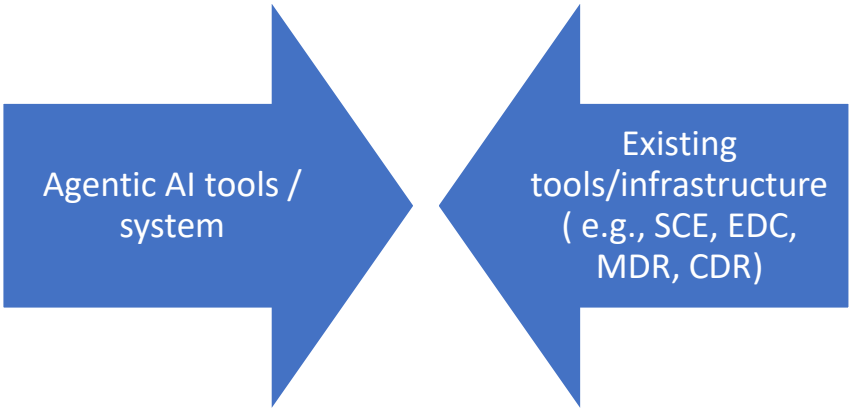
This transformation requires a deliberate alignment across three foundational pillars: systems that are designed to be interoperable, scalable, and AI-native; processes that are re-engineered for autonomy, traceability, and real-time adaptation; and people who are empowered with new skills, mindsets, and leadership models to effectively partner with AI. Together, these pillars form a cohesive strategy that enables biometrics organizations to move beyond efficiency gains and toward a new paradigm of innovation, agility, and scientific impact.



Leadership Pillar 1: Designing AI-Native, Compliant Systems

The first leadership pillar focuses on system design. Leaders must shift from approving individual tools to architecting AI-native ecosystems that support Agentic orchestration, governance, and validation.

Deploying Agentic AI in Biometrics requires a deliberate systems architecture that aligns with regulatory expectations. AI agents must operate within validated computing environments, integrate with existing statistical environment like SCE, EDC, CTMS, and maintain full audit trails.



Key architectural considerations include GxP compliance and 21 CFR Part 11, secure data access controls, versioned control, audit trails, and clear separation between exploratory and production workflows. AI agents should be treated as configurable system components rather than opaque black boxes.

AI-first leadership demands early collaboration between Biometrics, IT, quality, and compliance functions to ensure Agentic AI capabilities are embedded safely and sustainably.

This includes defining where autonomy is permitted, how AI agents interact with controlled systems, and how outputs are reviewed and approved. System design decisions made early will determine whether Agentic AI becomes scalable infrastructure or an isolated experiment.

Leadership Pillar 2: Process Redesign for Human-Agent Collaboration

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 processes specific to 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 AI-generated outputs. By treating Agentic 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 work.

- Human-AI Collaboration Protocols: Effective leadership establishes clear delineation between AI-driven activities and those requiring human expertise. These processes 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 as oversight with a full ownership and accountability of the processes.

- 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.

Leadership Pillar 3: People, Roles and Capabilities Evolution

AI-first leadership is ultimately a people challenger – Change Management. The transition toward Agentic AI in Biometrics requires a structured approach to capability building that moves the organization from its current skill set to a more advanced desired state. This process begins with a formal assessment to identify existing skill gaps, followed by the implementation of targeted training initiatives.

Key areas for development include
- Technical proficiency with tools like ChatGPT and Copilo
- Mastery of prompt engineering
- Refinement of validation skills for AI-generated outputs.

By adopting this systematic approach, a department ensures its workforce is ready for full integration while maintaining high standards of data integrity.
Fostering a culture of transformation is equally essential to ensure that human teams can effectively partner with autonomous agents. Organizations must prioritize psychological safety to encourage employees to experiment with Agentic AI tools without fear of failure. This involves promoting a mindset of responsible innovation where creativity can thrive without compromising strict regulatory compliance. The ultimate goal is to maintain a steadfast commitment to industry standards while embracing the necessary changes that AI brings to traditional biometric workflows.

Successful integration also depends on robust cross-functional collaboration, where Biometrics will take a leading role in addressing the needs of diverse stakeholders. This effort requires active engagement with leadership, IT, and quality assurance to align technical infrastructure with compliance requirements. Furthermore, close coordination with clinical development, clinical operations, and clinical data management ensures that AI tools are integrated seamlessly across the study lifecycle. By working together, these functions create a unified framework that supports the broader adoption of Agentic AI across the entire organization.

The Future of Biometrics Leadership in Agentic AI Era

Agentic AI will not replace Biometrics professionals, but it will redefine and augment leadership expectations. Future Biometrics leaders will be Agentic AI system architects, workflow re-designers, and talent developers who understand both people and AI capabilities.

Biometrics leaders who embrace AI-first leadership will be positioned to deliver higher-quality results at scale, while those that treat Agentic AI as a temporary productivity tool risk falling behind. The path forward requires intentional leadership, thoughtful governance, and a commitment to human and AI collaboration.

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