# Automating Statistical Analysis Plan Development and Demographic Descriptive Analyses in Clinical Trial Data Using Generative Artificial Intelligence

MSR243

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## INTRODUCTION

- A Statistical Analysis Plan (SAP) is a critical regulatory document that defines the statistical methodology, objectives, and data-handling procedures for clinical trials, serving as a foundational component of transparent, reproducible, and methodologically rigorous research[1]
- However, traditional SAP development is inherently time-consuming and resource-intensive, requiring specialized expertise in biostatistics, medical terminology, and regulatory standards - contributing to delays in analytical timelines and increased operational burden on statisticians and clinical researchers[2]
- Clinical trials are becoming increasingly complex, with rising protocol complexity and data volume associated with longer timelines, higher costs, and greater burden on research teams - further intensifying the need for efficient analytical solutions[3]
- Recent advances in Large language model(s) (LLMs) demonstrate capability in generating structured, context-sensitive technical content - presenting a tractable pathway to automating both SAP drafting and baseline descriptive analyses while preserving methodological rigor and regulatory alignment[4]

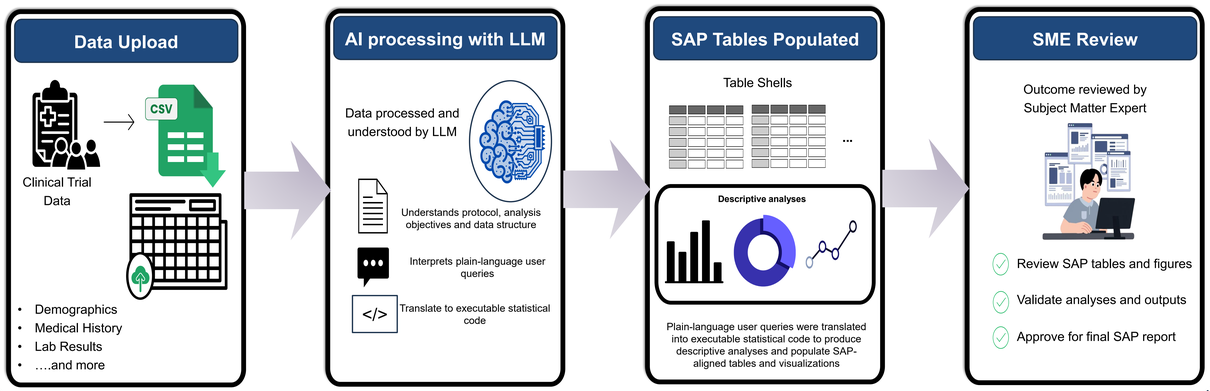
## OBJECTIVES

- To evaluate the accuracy and regulatory alignment of an LLM-based pipeline in automating SAP development - encompassing structured document drafting, table shell generation, and population of shells with descriptive statistics derived from patient-level clinical trial data - conducted under continuous human expert oversight
- To compare the operational efficiency of the Artificial intelligence (AI)-assisted workflow against conventional manual SAP authoring, quantified by time-to-completion and volume of expert-led revisions required to achieve a regulatory-compliant output

## METHODS

- An LLM-based pipeline was developed to automate SAP drafting and execution of descriptive statistical analyses, operating within a structured prompt framework incorporating regulatory context, output format constraints, and domain-specific instructions to ensure consistency and reproducibility across tasks
- SAP table shells were generated in accordance with predefined specifications, structured to align with regulatory reporting standards and clinical trial documentation requirements[1,2]
- Plain-language user queries were translated by the LLM into executable [R/Python/SAS] code to perform descriptive analyses and populate SAP-aligned table shells; outputs were benchmarked against manually derived reference values (Figure 1)
- A standardized prompt framework was implemented to ensure consistency, reproducibility, and alignment of outputs across all analytical tasks
- All outputs were independently reviewed by a human subject matter expert (SME) to assess analytical accuracy, numerical correctness, completeness, and reproducibility - with iterative refinement applied wherever required to meet SAP presentation standards

**Figure 1: Detailed process of SAP tables generation and validation**




AI: Artificial Intelligence; LLM: Large Language Model; SAP: Statistical Analysis Plan; SME: Subject Matter Expert

## RESULTS

- The AI-enabled analytical framework successfully generated 20 SAP table shells and produced complete descriptive statistical outputs for 15 predefined baseline variables across all tables, demonstrating robust automation, consistency, and scalability in clinical trial data processing (Figure 1)
- SME validation confirmed that all numerical outputs, summary statistics, and derived measures were accurate, reproducible, and aligned with predefined SAP specifications - reinforcing the methodological integrity and regulatory compliance of the framework (Figure 2 A & B)
- Minimal manual intervention was required in approximately 3-4% of cases, primarily to refine complex table structures, enhance figure formatting, and ensure adherence to SAP presentation standards and sponsor-specific reporting conventions - addressed through iterative human-in-the-loop validation cycles (Figure 2 A & B)
- Compared with traditional manual statistical programming and reporting workflows, the AI-driven approach resulted in an approximately 85% reduction in analytical development and reporting timelines, significantly enhancing operational efficiency and accelerating evidence generation (Figure 2 A & B)
- Overall, the AI-enabled framework demonstrated strong adaptability across diverse data formats and analytical scenarios, highlighting its potential to transform SAP-driven analyses by improving speed, standardization, and reproducibility while preserving critical expert oversight

**Figure 2 A: Comparative findings of the overall review process**

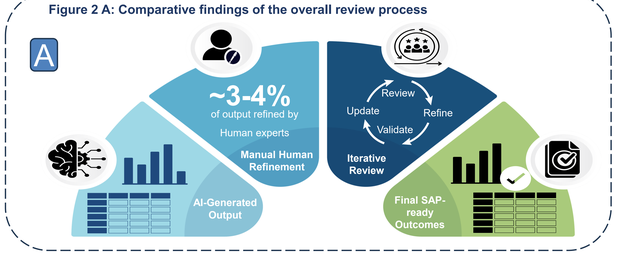
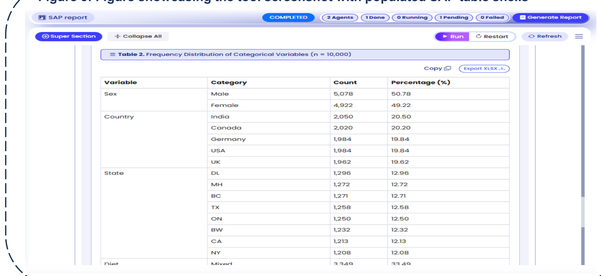



**Figure 2 B: Overall results from the case study**


**Figure 3: Figure showcasing the tool screenshot with populated SAP table shells**




AI: Artificial Intelligence; SAP: Statistical Analysis Plan

## Key Takeaways

### Time

AI-enabled SAP development reduced analytical and reporting timelines by ~85% - compressing weeks of manual statistical programming into hours

### Effort

Only 3-4% of AI-generated outputs required human refinement - demonstrating that expert effort can be redirected from routine analysis to critical review and decision-making

### Accuracy

All of the numerical outputs, summary statistics, and derived measures were validated as correct by an independent SME - confirming analytical reliability without compromise

### Compliance

All SAP table shells and descriptive outputs were generated in alignment with regulatory standards and predefined SAP specifications - supporting audit-ready, submission-quality deliverables

## CONCLUSIONS

- All AI-generated SAP outputs were produced in alignment with regulatory standards and predefined SAP specifications, with iterative human-in-the-loop refinement ensuring audit-readiness, reproducibility, and adherence to sponsor-specific presentation requirements - reinforcing the framework's suitability for regulatory-aligned clinical trial reporting
- Findings support the potential for LLM-based analytical pipelines to augment clinical trial statistical workflows at scale - reducing resource burden, accelerating evidence generation, and enabling expert effort to be redirected toward critical review and higher-order analytical decision-making
- However, continuous human expert oversight remains essential to ensure methodological integrity, regulatory compliance, and alignment with evolving reporting standards. Broader prospective validation across diverse trial designs, therapeutic areas, and jurisdictions is also warranted before routine adoption in clinical research settings

**References**

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