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An AI-Driven Framework for Automated Statistical Analysis Plan Generation in Clinical Trials

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ABSTRACT

Statistical Analysis Plans (SAPs) are foundational documents in clinical trials, yet their creation is traditionally time-consuming, manual, and prone to inconsistency. We present an AI-driven framework that uses large language models (LLMs) to streamline and partially automate SAP generation from protocol documents. The system parses unstructured content to extract structured metadata, builds a clinical trial ontology, and applies reasoning logic to infer endpoints, analysis populations, estimands, and statistical methods. It adapts sponsor-specific SAP templates dynamically, generating high-quality, traceable sections that align with regulatory expectations. The framework balances automation with human oversight, enabling statisticians to refine and validate content through an interactive interface. This approach significantly reduces preparation time, improves consistency, enhances auditability, and ensures alignment between protocol intent and analysis plans. By integrating LLMs into clinical workflows, our solution modernizes SAP development and paves the way for scalable, AI-assisted regulatory documentation in clinical research.

INTRODUCTION

Statistical Analysis Plans (SAPs) are critical regulatory artifacts that formalize study objectives, estimands, analysis populations, statistical methods, and data handling rules prior to database lock. Regulatory agencies, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Pharmaceuticals and Medical Devices Agency (PMDA), emphasize the importance of SAP completeness, clear traceability to protocol objectives, and prespecification of analytical decisions to mitigate the risk of analysis bias.

Despite their importance, SAPs are still predominantly authored through manual, document-centric workflows. Clinical trial protocols are typically unstructured and heterogeneous, requiring extensive human interpretation to extract relevant statistical intent. Key design and analysis decisions are often distributed across multiple protocol sections, making them difficult to reconcile consistently. Reuse of prior SAP logic is generally limited to static templates rather than executable analytical knowledge, which hinders systematic application of precedent across studies. As a result, maintaining cross-study consistency remains challenging, and quality control activities are frequently applied retrospectively rather than embedded throughout the SAP development process.

Recent advances in large language models and knowledge graph technologies create an opportunity to fundamentally reframe SAP generation. Instead of treating SAP authoring as a text drafting task, these technologies enable a shift toward metadata-driven statistical reasoning, where analytical intent is explicitly represented, validated, and reused. This paper describes a framework that operationalizes this approach, supporting consistent, traceable, and scalable SAP generation aligned with regulatory expectations.

CHALLENGES IN TRADITIONAL SAP DEVELOPMENT

PROTOCOL INTERPRETATION COMPLEXITY

Clinical protocols embed statistical intent implicitly across multiple sections, including study objectives, endpoint definitions, trial design, eligibility criteria, assessment schedules, and estimand frameworks. These elements are often described using heterogeneous language, cross-referenced inconsistently, and refined through multiple protocol amendments.

Interpreting how these components translate into concrete analytical decisions—such as population definitions, censoring rules, analysis windows, covariate selection, or missing data handling—requires deep biostatistical expertise and extensive manual review. Differences in interpretation across statisticians or programming teams can lead to downstream inconsistencies, rework, and delayed alignment between protocol, SAP, and TLFs.

LACK OF STRUCTURED KNOWLEDGE REUSE

Although most sponsors maintain corporate SAP libraries, reuse is typically limited to static text templates or example sections rather than structured, executable knowledge. Statistical methods, decision criteria, and regulatory conventions are embedded in narrative prose rather than encoded as reusable rules, ontologies, or decision logic.

As a result, teams repeatedly re-interpret similar study designs, endpoints, and estimands across programs. Institutional knowledge remains siloed within individual authors or projects, making it difficult to systematically leverage historical precedent, enforce consistency, or accelerate SAP development for new studies.

LIMITED TRACEABILITY

Traditional SAP drafting workflows rely heavily on manual authoring and iterative document review, which obscures the provenance of key analytical decisions. It is often unclear which protocol statements, regulatory guidances, or prior studies informed a specific method choice, population definition, or analysis parameter.

This lack of end-to-end traceability becomes increasingly problematic during internal quality control, cross-functional review, and regulatory inspection. Responding to questions such as “why was this method selected?” or “where is this assumption defined in the protocol?” requires manual backtracking across documents, emails, and reviewer comments—introducing risk and inefficiency.

SCALABILITY CONSTRAINTS

As development portfolios expand and study timelines compress, traditional SAP development does not scale linearly. Each new study requires proportional increases in senior biostatistical effort, document review cycles, and programming coordination.

This model increases cost and operational risk, particularly for large programs, adaptive designs, or studies with frequent amendments. Manual processes struggle to keep pace with accelerated development timelines, leading to longer SAP finalization cycles, increased revision churn, and downstream delays in database lock and submission readiness.

SYSTEM OVERVIEW

The proposed framework treats SAP generation as a reasoning and decision-making pipeline, rather than a pure text generation task. Instead of directly producing narrative SAP content, the system incrementally extracts structures, reasons over, and validates statistical intent encoded in the clinical protocol and external knowledge sources.

The architecture is composed of four tightly integrated layers, each responsible for a distinct transformation of information. Importantly, each layer produces structured, auditable outputs that feed downstream components, enabling traceability, reuse, and validation across the SAP lifecycle.

PROTOCOL INTELLIGENCE

The Protocol Intelligence Layer ingests clinical protocols in their native formats (e.g., PDF, Word) and transforms unstructured text and tables into structured representations. This layer focuses on identifying and normalizing key study elements such as objectives, endpoints, estimands, populations, trial design characteristics, assessment schedules, and protocol-defined analysis assumptions.

Rather than treating the protocol as a static document, this layer captures protocol content as machine-readable entities with explicit source references, versioning, and semantic labels. The output serves as a canonical, structured interpretation of protocol intent that can be consistently reused across statistical planning, programming, and downstream deliverables.

SAP ONTOLOGY

At the core of the system is an SAP ontology and knowledge graph that encodes standardized concepts, relationships, and precedents across studies. This layer formalizes entities such as endpoint types, estimand attributes, analysis populations, statistical methods, missing data strategies, and regulatory constraints.

By linking protocol-derived entities to this ontology, the system can align study-specific requirements with corporate standards, historical SAPs, and regulatory guidance. The knowledge graph enables structured reuse of statistical logic, supports consistency across programs, and provides a foundation for explainable, rule-based reasoning rather than ad hoc interpretation.

DECISION ENGINE

The Decision Engine applies deterministic rules, conditional logic, and probabilistic reasoning to the structured protocol inputs and ontology-linked knowledge. This layer is responsible for selecting appropriate statistical methods, defining analysis populations, determining estimand-specific handling (e.g., intercurrent events, censoring, missing data), and resolving design-dependent analysis choices.

Rather than embedding decisions in narrative text, analytical intent is represented as explicit decision outputs with documented inputs, applied rules, and justifications. This enables transparent reasoning, consistent application of standards, and systematic validation of analytical choices across studies.

SAP SECTION GENERATION AND VALIDATION

The final layer translates structured decisions and metadata into human-readable SAP sections while preserving full traceability to upstream sources. SAP content is generated in a controlled manner, with each paragraph, table reference, or parameter directly linked to protocol statements, decision rules, and knowledge graph entities.

In parallel, automated validation and quality checks are applied to ensure internal consistency, regulatory alignment, and completeness across SAP sections. This layer supports iterative review, targeted updates following protocol amendments, and efficient regeneration of affected sections without re-authoring the entire SAP.

PROTOCOL INTELLIGENCE

The Protocol Intelligence Layer is responsible for transforming the clinical protocol from an unstructured document into a structured, machine-interpretable representation of study intent. This layer establishes the foundation for all downstream reasoning, ensuring that statistical decisions are grounded in explicitly captured protocol evidence rather than implicit interpretation.

STRUCTURED PROTOCOL PARSING

Each extracted element retains full provenance, including references to source sections, tables, and line-level locations within the protocol. This structured representation allows protocol intent to be queried, reused, and validated consistently across analytical workflows.

The protocol is ingested as a complete document and parsed into multiple complementary representations that preserve both content and context. These representations include hierarchical sections that reflect the logical structure of the protocol, tabular content such as endpoint definitions, schedules of assessments, and analysis set descriptions, as well as free-text blocks enriched with precise source references.

Rather than generating narrative summaries, the system extracts typed metadata objects that explicitly represent key study elements. These include study objectives, endpoint definitions and associated attributes, trial design characteristics, eligibility criteria, analysis population definitions, and assessment timing and analysis windows. Each extracted element retains full provenance, including references to source sections, tables, and line-level locations within the protocol.

By representing protocol content as structured, machine-interpretable metadata rather than unstructured text, protocol intent can be queried, reused, and validated in a consistent manner across statistical reasoning, SAP generation, and downstream analytical workflows.

DOMAIN-BASED SEMANTIC TAGGING

To support efficient reasoning and selective retrieval, protocol content is semantically classified into predefined analytical domains. These domains include trial design, endpoints, estimands, safety, efficacy, statistics, and data handling, each representing a distinct aspect of analytical intent within the protocol.

This domain-based tagging allows downstream components to operate on relevant subsets of protocol content without requiring repeated processing of the entire document. For example, reasoning related to endpoint definition and analysis can be performed independently of eligibility logic, while safety analyses can be evaluated separately from efficacy considerations.

By organizing protocol content into semantically meaningful domains, the system improves interpretability, reduces computational overhead, and enables modular, explainable decision-making across the SAP generation pipeline.

SAP ONTOLOGY

The SAP Ontology layer provide the structured foundation that enables consistent, explainable, and reusable statistical reasoning across studies. Rather than encoding statistical knowledge implicitly in narrative SAP text, the system represents analytical intent as formalized entities and relationships that can be queried, validated, and reused programmatically.

ONTOLOGY DESIGN

The system formalizes SAP-relevant concepts as strongly typed, domain-specific entities that capture the essential components of statistical planning. These entities include, but are not limited to, endpoints, estimands, analysis populations, statistical methods, missing data strategies, multiplicity strategies, and approaches for handling intercurrent events.

Each concept is defined using a structured schema that specifies explicit attributes, allowed values, constraints, and illustrative examples. These schemas encode both established statistical best practices and sponsor-specific conventions, ensuring that analytical decisions are represented in a standardized, machine-interpretable form rather than embedded implicitly in narrative text. For example, a primary efficacy endpoint defined as a continuous outcome at Week 24 can be explicitly linked to a treatment-policy estimand, an ITT analysis population, and a mixed model for repeated measures as the primary analysis method.

By separating what a statistical entity represents from how it is described linguistically, the ontology enables consistent interpretation and application of statistical concepts across clinical protocols, SAPs, and downstream analytical outputs.

Entity Type	Key Attributes	Examples
Endpoint	Type, Scale, Timepoint	Primary efficacy, binary, Week 24
Estimand	ICE handling, Population	Treatment policy, ITT
Method	Model, Assumptions	MMRM, MAR

KNOWLEDGE GRAPH INTEGRATION

Ontology entities persisted within a knowledge graph to explicitly represent relationships and dependencies across statistical concepts. This includes logical and analytical linkages between endpoints, estimands, and statistical methods, as well as alignment with corporate SAP libraries and organizational standards. The knowledge graph also captures connections to historical study implementations and established precedents, together with regulatory constraints and guidance-driven requirements that inform analytical decision-making.

By representing these relationships explicitly rather than embedding them implicitly in narrative text, the knowledge graph enables advanced capabilities such as impact analysis following protocol amendments, cross-study harmonization of analytical approaches, and systematic reuse of validated statistical logic. This graph-based representation supports scalable SAP generation while maintaining transparency, consistency, and regulatory confidence across studies and programs.

DECISION AND REASONING ENGINE

The Decision Logic and Reasoning Engine is responsible for transforming structured protocol inputs and ontology-aligned knowledge into explicit, defensible statistical decisions. Rather than relying on free-form text generation, this layer applies controlled reasoning to ensure analytical choices are consistent, explainable, and aligned with regulatory expectations.

RULE-BASED AND MODEL-ASSISTED REASONING

Statistical decisions are generated using a hybrid reasoning approach that combines deterministic logic with model-assisted inference. Deterministic rules encode well-established statistical conventions, such as mapping endpoint types and measurement scales to candidate analysis methods, while regulatory constraints ensure alignment with applicable guidance, including the ICH E9(R1) estimand framework and relevant CDISC standards. Model-assisted inference, supported by large language models, is applied selectively to resolve ambiguity in cases where protocol language is incomplete, inconsistent, or open to interpretation.

This hybrid approach ensures that stable and repeatable analytical decisions are governed by explicit, auditable rules, while flexible inference is reserved for scenarios requiring contextual judgment rather than hard-coded logic. Representative decision tasks include selecting appropriate estimand strategies based on the presence and handling of intercurrent events, choosing primary analysis models according to endpoint scale and trial design, and determining suitable sensitivity or supplementary analyses in accordance with assumed missing data mechanisms.

Each decision yields structured outputs that explicitly capture the selected option, the rules or assumptions applied, and the supporting rationale. These outputs serve as validated inputs to downstream SAP section generation and quality control processes, ensuring transparency and reproducibility throughout the analytical workflow.

DECISION ENGINE EXECUTION MODEL

Reasoning workflows are implemented as a directed decision graph in which each node represents a discrete analytical decision or validation step within the SAP generation process. This structure makes dependencies between decisions explicit and ensures that statistical logic is applied in a controlled and repeatable manner across studies.

Within this execution model, each decision node consumes structured inputs produced by upstream layers and produces validated, schema-compliant outputs. Decision outcomes, applied rules, and supporting justifications are recorded as part of the execution process, creating a persistent and auditable record of analytical reasoning.

The decision graph supports parallel evaluation of independent decisions, modular updates to individual logic components, and full auditability of the end-to-end reasoning workflow. By externalizing statistical decision logic from narrative text, the system enables traceable, reproducible, and scalable statistical decision-making across studies and programs.

SAP SECTION GENERATION

SAP section generation is treated as a controlled realization step, where validated decisions and structured metadata are translated into SAP content. This layer does not introduce new analytical intent; it materializes previously reasoned outputs into standardized, reviewable SAP sections.

SECTION-SPECIFIC GENERATION

Each SAP section is generated independently using a well-defined set of structured inputs derived from upstream components of the framework. These inputs include study objectives and endpoint definitions, trial design and analysis population metadata, derived statistical decisions produced by the reasoning engine, and sponsor-specific corporate templates and formatting rules.

By decoupling SAP sections from one another, the system supports selective regeneration when inputs change, such as following protocol amendments or updates to analytical assumptions, without requiring full SAP re-authoring. This enables targeted updates while preserving unaffected sections and their associated review history.

The system is capable of generating all major SAP sections, including analysis objectives and endpoints, analysis populations, general statistical considerations, primary and secondary efficacy analyses, safety analyses, and sensitivity and subgroup analyses. This modular generation approach improves consistency across sections while reducing manual editing effort and review burden during SAP development and maintenance.

TRACEABILITY AND JUSTIFICATION

To support regulatory inspection and internal quality control, every generated SAP paragraph is accompanied by structured traceability metadata. This metadata captures the source protocol sections and line-level references from which the content was derived, the ontology entities and definitions applied during reasoning, and the decision rules, constraints, or assumptions that informed the analytical statement.

By embedding justification directly alongside generated SAP content, the framework ensures that each analytical statement can be traced back to its evidentiary basis. This approach enables efficient review, defensible decision-making, and inspection-ready documentation without the need for manual backtracking across protocols, SAP drafts, and review comments.

QUALITY CONTROL AND VALIDATION

Quality control and validation are embedded as first-class components of the SAP generation pipeline rather than applied as a post hoc review step. The framework adopts a defense-in-depth approach, combining automated validation with expert oversight to ensure analytical rigor, consistency, and regulatory readiness.

MULTI-LAYER QC FRAMEWORK

Validation checks are applied continuously across all layers of the system to ensure the integrity, consistency, and regulatory completeness of SAP outputs. Schema-level validation is performed using strongly typed models to verify completeness, data integrity, and structural correctness of extracted metadata and decision outputs. In parallel, logical consistency checks assess alignment across study objectives, endpoint definitions, analysis populations, and selected statistical methods.

The framework also includes regulatory completeness checks to confirm that required analyses, estimand attributes, and documentation elements are present based on study design and applicable regulatory guidance. Cross-section dependency validation is applied to ensure coherence across SAP sections, such as consistency between population definitions and analysis methods.

By detecting issues early and at multiple levels of the pipeline, the system minimizes downstream rework and improves confidence in the accuracy, consistency, and inspection readiness of final SAP outputs.

QC Layer	What is checked?	When
Schema	Required Field	Extraction
Logic	Consistency	Reasoning
Regulatory	Completeness	Generation
Cross-section	Alignment	Final QC

HUMAN-IN-THE-LOOP REVIEW

The system is explicitly designed to augment, rather than replace, the work of biostatisticians and statistical programmers. Human experts remain accountable for final analytical decisions and for the approval of SAP content, ensuring that professional judgment and regulatory responsibility are preserved throughout the process.

Within this framework, experts are able to review structured decisions, underlying assumptions, and supporting justifications prior to SAP text generation. Where appropriate, they may override automated logic with documented rationale and approvals or initiate targeted regeneration of affected SAP sections following expert input or protocol changes.

By embedding expert oversight directly into the workflow, the human-in-the-loop design ensures that automation enhances efficiency and consistency while maintaining scientific rigor, regulatory accountability, and the integrity of statistical decision-making.

EVALUATION AND RESULTS

To assess the value of the proposed framework, we compared it against a baseline approach based on direct prompt engineering, where a large language model is instructed to generate SAP sections directly from protocol text without structured intermediate representations or decision logic.

EVALUATION SETUP

Two SAP generation approaches were evaluated to assess the effectiveness of the proposed framework relative to prompt-based methods. In the baseline approach, SAP sections were generated using single-step or multi-step prompt engineering, in which a large language model was instructed to draft SAP content directly from protocol text based on narrative interpretation and implicit reasoning.

The proposed approach employed the full reasoning-driven framework described in previous sections, incorporating structured protocol parsing, ontology alignment, explicit decision logic, and controlled section generation. Both approaches were applied to the same set of representative clinical trial protocols spanning different study designs and endpoint types.

The evaluation focused on practical SAP development outcomes, including consistency of statistical decisions, traceability of analytical rationale, and maintainability under protocol changes, rather than stylistic or linguistic quality of the generated text.

QUALITATIVE COMPARISON

Dimension	Prompt-Based Generation	Proposed Framework
Interpretation consistency	Variable across runs	Deterministic and repeatable
Decision transparency	Implicit in text	Explicit, logged decisions
Traceability	Manual, ad hoc	End-to-end automated
Handling of amendments	Full re-generation	Targeted section regeneration
Reuse across studies	Copy/paste prompts	Executable knowledge reuse
Regulatory defensibility	Reviewer-dependent	Inspection-ready lineage

This comparison highlights a fundamental limitation of prompt-only approaches: while they may produce fluent text, they do not reliably encode or preserve statistical intent.

QUANTITATIVE COMPARISON

To complement the qualitative advantages described above, we evaluated the proposed framework against a prompt-based SAP generation approach using 100 public available clinical trial protocols from clinical gov. The comparison focused on measurable outcomes relevant to SAP development quality, maintainability, and review efficiency.

Dimension	Prompt-Based SAP Generation	Reasoning-Driven Framework
Decision consistency across SAP sections	~70–80%	~96–99%
Reviewer rework items per SAP section	~2–3	<1
SAP paragraphs with explicit traceability	<20%	100%
SAP sections impacted by protocol amendments	~65–90%	~10–25%
Relative effort to review-ready SAP	1.0× (baseline)	~0.4–0.6×

Together, these quantitative results demonstrate that embedding structured reasoning, validation, and traceability upstream delivers measurable improvements over prompt-only SAP generation—particularly in consistency, review efficiency, and change management.

ROBUSTNESS TO PROTOCOL AMEMDMENTS

Protocol amendments were used to evaluate the maintainability of SAP generation workflows. In the prompt-based approach, changes such as updated endpoint definitions or modified analysis population criteria typically required full or near-full regeneration of the SAP, followed by manual reconciliation to restore internal consistency.

In contrast, under the proposed reasoning-driven framework, regeneration was limited to impacted decision nodes and their dependent SAP sections, while unaffected sections were preserved. This demonstrated that structured reasoning enables localized updates, which is a critical requirement for real-world clinical development workflows where protocol amendments are common and timelines are compressed.

KEY OBSERVATIONS

Overall, the evaluation demonstrates that simple prompt engineering is effective for drafting fluent text, but insufficient for the requirements of statistical planning in regulated clinical development settings. Prompt-based approaches rely on implicit reasoning embedded within narrative output, which limits consistency, transparency, and reproducibility of analytical decisions.

By contrast, the proposed framework produces stable and repeatable statistical decisions through explicit reasoning, enforces a clear separation between analytical decision-making and language realization, and embeds traceability and validation as integral components of the generation process. Together, these properties address core regulatory expectations around prespecification, auditability, and consistency.

These observations support the central premise of this work: SAP generation is fundamentally a reasoning and knowledge management problem, rather than a language generation problem.

BENEFITS AND IMPACT

The proposed framework delivers measurable improvements across the SAP development lifecycle by transforming SAP authoring from a manual, document-centric activity into a structured, reasoning-driven process. Standardized statistical ontologies and explicit decision logic ensure uniform interpretation of endpoints, estimands, analysis populations, and statistical methods across studies and programs, thereby reducing variability introduced by individual authoring practices.

By externalizing statistical knowledge and automating decision workflows, the framework enables SAP generation to scale efficiently across large portfolios without requiring proportional increases in senior biostatistical effort. Traceability is embedded throughout the process, with every analytical decision and generated SAP paragraph explicitly linked to protocol sources, applied rules, and relevant regulatory context. This supports end-to-end audit readiness and enables efficient responses to regulatory inspection queries.

Efficiency is further improved through automated protocol extraction, structured reasoning, and controlled text realization, which collectively reduce manual drafting effort, shorten review cycles, and minimize downstream rework following protocol amendments. In addition, corporate SAP knowledge is captured as executable logic and structured entities rather than static narrative text, enabling systematic reuse of validated statistical approaches across studies, programs, and therapeutic areas.

LIMITATION

While the proposed framework addresses many challenges in traditional SAP development, several limitations and areas for future enhancement remain.

CURRENT LIMITATIONS

Despite the advantages of the proposed framework, several limitations remain. The accuracy and completeness of downstream reasoning are inherently dependent on the quality of the source protocol. Ambiguous language, incomplete definitions, or late-stage amendments can limit the effectiveness of automated extraction and reasoning and may still require human interpretation and intervention.

The effectiveness of ontology-driven reasoning also depends on the availability and ongoing maintenance of high-quality corporate statistical libraries. Initial curation, validation, and governance of these libraries require dedicated investment to ensure alignment with evolving regulatory standards and organizational practices.

In addition, regulatory acceptance of AI-assisted authoring continues to evolve. Although the framework emphasizes traceability, validation, and human oversight, clear documentation of system controls, decision provenance, and expert accountability remains essential to meet regulatory expectations and to support inspection readiness.

CONCLUSION

Automated SAP generation represents a fundamental shift from manual document drafting to metadata-driven statistical reasoning. By integrating protocol intelligence, ontological modeling, decision logic, and controlled language generation, the proposed framework transforms SAP authoring into a structured, transparent, and auditable process.

Rather than replacing biostatistical expertise, the system operationalizes it—capturing statistical intent as reusable knowledge, enforcing consistency through explicit rules, and preserving full traceability from protocol evidence to

analytical decisions and SAP text. This design supports regulatory compliance while reducing variability, rework, and cycle time across studies.

As clinical development programs grow in complexity and scale, this approach positions sponsors and CROs to meet increasing regulatory expectations with greater confidence, consistency, and speed—laying the foundation for an end-to-end, reasoning-driven clinical analytics ecosystem.

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