AURORA Prime

Regulatory & Medical Authoring (RMA) Whitepaper

Core capabilities and key technical specifications

April 2025

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Contents

1 Core Capabilities

1.1 Document Generation & Authoring

AuroraPrime RMA streamlines the clinical document authoring process by **leveraging automation and Generative AI (GenAI)** to enhance both **efficiency and quality**.

1.1.1 Core Capabilities

- **Automated Initial Draft Generation** Medical writers can **auto-generate initial drafts** using **AI-enabled templates**. Template Admins configure **content generation rules** for each section, directing the AI based on selected information sources. Tags—such as **therapeutic area**—can be applied during setup to **automatically populate relevant content**.
- **Large-Scale TFL Automation** The add-in simplifies the integration of **Tables, Figures, and Listings (TFLs)**. TFLs can be **batch imported** from source files or configuration formats such as Excel or DPS, or inserted individually. The system also **recognizes manually inserted TFLs** for streamlined management.
- **AI-Powered TFL Summary Generation** The add-in can **automatically generate summaries** of TFLs using AI. Users may provide **examples and custom prompts** to tailor output. For large tables, data filtering improves both **speed and accuracy**. Summaries can be **batch generated, updated, and validated asynchronously**, and existing summaries can be **converted into editable objects**.
- **Enhanced Document Editing and Finalization** A suite of tools supports tasks such as **content reuse**, **abbreviation list creation**, **tense conversion**, and **document comparison**—helping streamline the finalization process.
- **Human-in-the-Loop AI Interaction** Users can **engage with an AI chat assistant** to guide specific tasks and **monitor asynchronous AI progress**. The system supports **custom prompt management** and **feedback loops**, enabling continuous AI improvement.

By automating these essential tasks, **AuroraPrime RMA empowers pharmaceutical teams to reduce cycle times, lower costs, and drive greater efficiency in clinical trial documentation.**

1.1.2 Supported Document Types

AuroraPrime RMA is specifically designed to support the creation of a wide range of clinical documentation

It is tailored for regulatory and medical writers crafting documents such as **clinical study reports (CSRs), study protocols, synopsis, lay summaries, patient narratives**, and more.

Furthermore, AuroraPrime RMA's functionality extends to a wider range of document types through its AI-enabled document template system. Template Admins can create and configure templates for various clinical document types, allowing medical writers to leverage the add-in's features for generating initial drafts and managing content across different kinds of documents.

CLINICAL	**CSR**	**CSR Synopsis**	**Protocol**	**Protocol Synopsis**	**Patient Safety Narratives**
Regulatory Affairs	**Module 2.5 Clinical Overview**	**Module 2.7.3 Summary of Clinical Efficacy**	**Module 2.7.4 Summary of Clinical Safety**	**Module 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods**	**Module 2.7.2 Summary of Clinical Pharmacology Studies**
	Module 2.7.5 Literature References	**Module 2.7.6 Synopses of Individual Studies**	**Investigator Brochure**	**Lay Summary**	**IND documents**
Biostatistics & Data Management	**Statistical Analysis Plan**	**Case Report Form**	**Data Management Plan**	**Study Data Review Guide**	
Clinical Operation	**Informed Consent Forms**	**Project Monitoring Plan**	**Risk Based Monitoring Plan**	**Medical Monitoring Plan**	
Pharma-covigilance	**ICSR**	**Risk Monitoring Plan**	**DSUR/PSUR**	**PBRER**	
CMC	**Module 2.3 Quality overall summary**				
LABELING	**Package Insert**	**CCDS**	**SmPC**		
NON – CLINICAL	**Module 2.4 Nonclinical Overview**	**Module 2.6.2 Pharmacology Written Summary**	**Module 2.6.4 Pharmacokinetic written summary**	**Module 2.6.6 Toxicology written summary**	**Module 4 Nonclinical Study Reports**
POST – MARKETING	**Medical Information Letter**	**Conference Highlight Conclusion Slides**	**Post-Marketing Study Protocols**	**Post-Marketing Study CSR**	**Literature Knowledge Base**

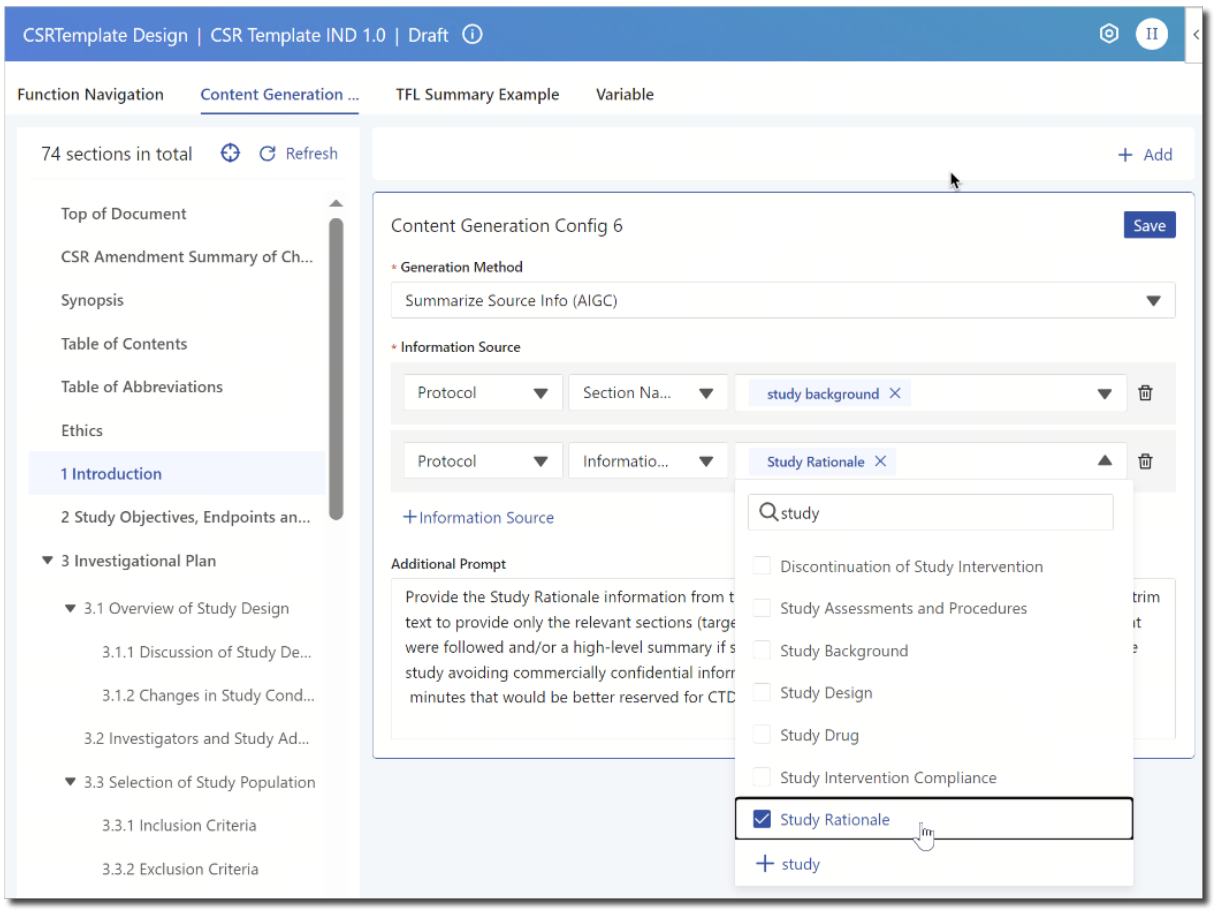
Under POC/Production Under Evaluation On the roadmap

1.1.3 AI-Powered Templates

AuroraPrime RMA includes a **flexible and intelligent templating engine** that provides **granular control over document generation**.

Template Admins can define detailed **content generation rules** for each document section, including:

- Specifying **information sources** (e.g., related study documents or the current document)
- Choosing the **generation method**, such as **lean summary**, **tense conversion**, or **direct content reuse**
- Embedding **writing instructions** directly within templates
- Using **document tags** (e.g., therapeutic areas) to **automatically populate relevant sections**



Published templates are stored in the **AuroraPrime RMA Content Library**—an **expandable repository** that supports templates for various clinical document types, including but not limited to Clinical Study Reports (CSRs), Study Protocols, and Therapeutic area–specific templates.

The system is designed to be **highly adaptable**, enabling organizations to build and maintain a **comprehensive, reusable template collection** that meets diverse documentation needs.

1.1.4 Version Control

AuroraPrime RMA offers **Advanced Document Comparison**, enabling users to **quickly generate a side-by-side comparison** ("diff") between two documents. This feature highlights all differences and makes it easy to **review and incorporate changes** into a working draft.

It also supports **three-way comparisons**, allowing users to:

- **Triangulate tracked changes** between versions
- Reference a **second-language source document**

- Gain **additional context** for more accurate revisions and quality control

As a **Microsoft Word add-in**, AuroraPrime RMA fully leverages **Native Word capabilities** for document handling as well as Microsoft environment features for version control and file management

Additionally, AuroraPrime RMA can be **integrated with third-party content management systems** such as **Veeva RIM**, allowing teams to maintain **version control**, streamline **document management workflows**, and work seamlessly within the client's **existing IT ecosystem**.

1.1.5 Ease of Use

AuroraPrime RMA is designed for **ease of use**, making advanced functionality accessible to users with varying levels of technical expertise. By integrating directly into **Microsoft Word 365**, it allows regulatory and medical writers to take full advantage of AI-driven features **within a familiar environment**—eliminating the need to learn a new platform.

Key usability features include:

- **Simplified user interface** with easy-to-navigate table views and clean layout
- **Intuitive workflows and AI-powered automation** for tasks like draft generation, TFL integration, and TFL summary creation—minimizing manual work
- **Pre-configured, AI-enabled templates**, built by Template Admins from existing Word documents, reduce setup time and allow writers to focus on content
- **In-place editing of content generation rules** directly within the Word interface for seamless configuration

Together, these features empower medical and regulatory writers to **create high-quality clinical documentation efficiently**, without requiring deep technical knowledge.

1.2 Data Handling

AuroraPrime RMA supports the ingestion of **diverse data types** to generate and enrich clinical and regulatory documentation. Its multimodal approach allows medical writers to efficiently utilize both **textual and structured data**, tailored to clinical writing needs.

1.2.1.1 Textual Data Sources AuroraPrime RMA can ingest and process unstructured text from various sources to guide AI content generation:

- **Existing Word documents** – Used to create AI-enabled templates

- **Source documents** – Referenced when configuring content generation rules
- **Textual examples** – Extracted from documents to train and guide the AI
- **Custom prompts** – Provide targeted instructions for content generation
- **Embedded writing instructions** – Offer guidance for human writers within templates
- **Content reuse** – Enables reusing sections from previously authored documents

1.2.1.2 Structured Data (Tables, Figures, Listings) A core strength of AuroraPrime RMA is its robust handling of tabular data:

- **TFLs (Tables, Figures, Listings)** – Parsed from RTF files and incorporated into documents
- **In-text table generation** – Populate document tables directly from structured sources
- **Excel-based ingestion** – Import in-text tables using structured Excel files
- **Editable table views** – Users can modify and format tables as needed

1.2.1.3 Configuration and Specification Files AuroraPrime RMA supports ingestion of files used to configure automation:

- **TFL tracker/config files** – Define incorporation rules and settings
- **DPS (Data Package Specification) files** – Enable batch incorporation of TFLs
- **RTF parsing templates** – Re-parse and customize extraction from TFL sources

1.2.1.4 Data from External Systems (Medical Narratives and More) The add-in also supports ingestion from clinical data systems and standard datasets:

- **EDC systems** (e.g., Prime Collect, third-party systems via ODM or Excel)
- **Standard datasets** – SDTM (.xpt), ADaM (.xpt), SAE, CIOMS, medical coding data
- **Script-generated datasets** – Such as those from **SAS workflows**

In summary, AuroraPrime RMA streamlines clinical document creation by enabling intelligent ingestion of both **textual and structured data**, ensuring flexibility, efficiency, and accuracy across various document types and clinical data sources.

1.2.2 Data Source Integration

AuroraPrime RMA enables seamless data integration by supporting **specific formats** and providing **clear input requirements** to ensure consistent and reliable use across clinical documents.

To maintain platform efficiency and accuracy, AuroraPrime RMA defines expected input formats and quality standards for various data types. This helps ensure compatibility and successful ingestion of content.

AuroraPrime RMA supports integration of TFL data through RTF and Excel-based inputs, with detailed formatting guidance to support accurate parsing:

- **RTF-Based TFLs** The system offers comprehensive **guidelines** for preparing RTF files to optimize AI recognition and data parsing. These include:
  - Caption structure and nomenclature
  - Proper placement and format of tabular data
  - Layout and formatting for footnotes
  - Special handling for complex or merged tables
- **TFL Configuration via Excel** TFL integration can also be managed through structured Excel files.
- **In-Text TFL Import from Excel** In addition to TFL config files, users can import **in-text tables** directly from Excel documents for seamless integration.
- **Re-parsing Capabilities** If TFLs from RTF files are not parsed correctly, users can select a suitable **RTF parsing template** to reprocess the file and ensure accurate data extraction.

By defining these input standards, AuroraPrime RMA ensures reliable integration of complex data types—especially TFLs—into the authoring workflow, ultimately enhancing document accuracy and reducing manual rework.

1.2.3 Data Traceability

AuroraPrime RMA ensures **transparent and auditable traceability** throughout the document generation process—critical for maintaining quality, compliance, and confidence in clinical content.

- **Reused Content Source Display** For reused content, AuroraPrime RMA displays the **source reference directly beneath the content segment**, enabling users to verify the origin of the information with ease.

- **AI Task Logging & Feedback History** All **AI-generated content** is traceable via the **AI Tasks pane**, where user feedback and rationale for edits are recorded. This creates a clear audit trail for review and validation.
- **Editable Rule Tracking** When **content generation rules** are edited during document authoring, all changes are:
  - **Auto-saved**
  - **Displayed in a dedicated change tracking pane**
  - Logged as part of the document's **audit history**
- **TFL Summary Updates & Synchronization** Upon updating source data for a **TFL**, users can:
  - Automatically **trigger and track summary updates**
  - View update activities in the **AI Task pane**, establishing a link between source data and AI-generated summaries
  - **Roll back to previous summary versions** if needed
- **AI Task Details and Rule Visibility** The **AI task detail view** provides extended insight into the rules and logic behind tasks like **content generation** and **tense conversion**, enhancing interpretability and transparency.

Beyond the add-in, AuroraPrime's **Medical Narratives** solution provides additional data traceability: When viewing downloaded narratives, hovering over specific sections displays the **original data source** (e.g., EDC or PV systems), supporting comprehensive **source attribution** across the AuroraPrime ecosystem.

In summary, AuroraPrime RMA supports full document traceability by:

- Tracking reused and AI-generated content origins
- Logging rule changes and synchronization events
- Managing version history and rollback options
- Providing transparency into AI decision-making

These capabilities help ensure regulatory-grade quality control and accountability across clinical documentation workflows.

1.3 Multilingual Document Support

AuroraPrime RMA is designed to support the creation of clinical documentation in multiple languages, including the ability to generate and translate content into specified languages such as German.

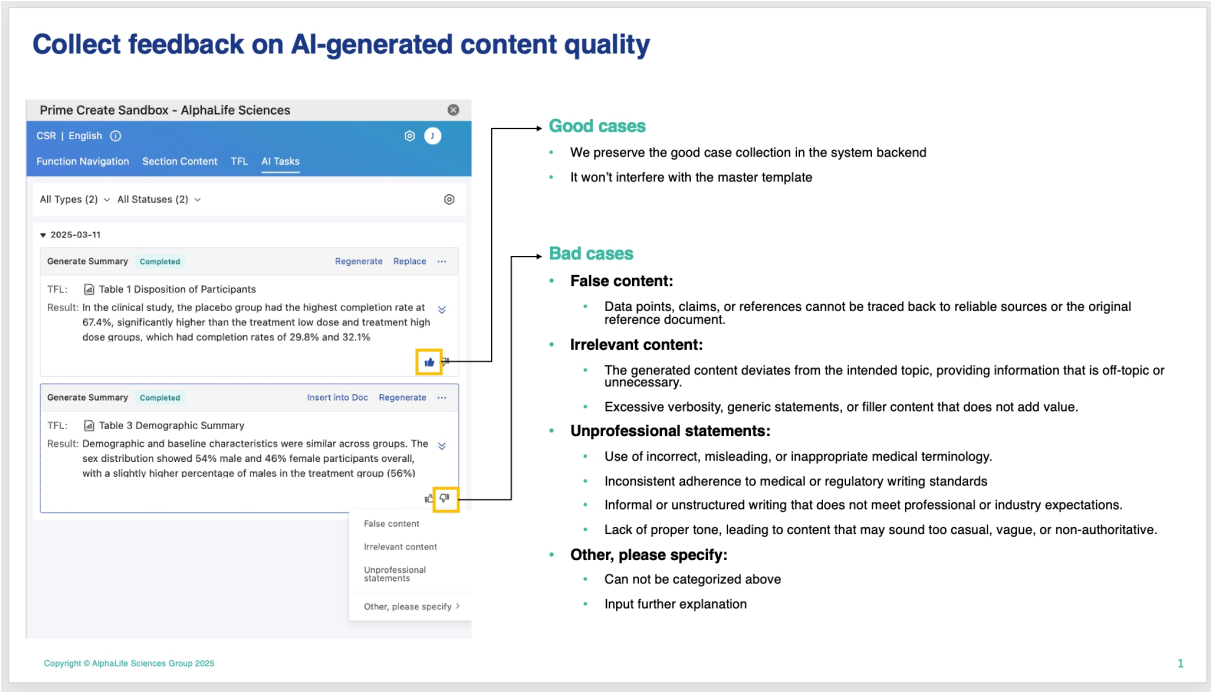
- Users can define the **Document Language** when generating an initial draft or creating a document template.
- The platform includes a **"Translate text"** feature that enables translation of selected content into supported languages.
- For TFL source translation, the target language is automatically aligned with the document's language. Users can specify the translation scope to include elements such as captions, footnotes, and row/column headers. All translations can be reviewed and manually refined.
- To ensure consistency across documents, users can contribute to an **organization-level translation dictionary** by adding preferred terms.

1.4 Collaboration & Review

1.4.1 Integrated Reviews

In addition to Microsoft Word's native features for tracking changes and managing comments, the AuroraPrime RMA add-in provides enhanced capabilities to support collaborative review and feedback during document generation.

- **Review and Manual Adjustment of Translations**: When using the "Translate text" feature, the generated translations can be reviewed and manually adjusted as needed to ensure accuracy and clarity. Users can also delete generated translations and add terms to an organization-level translation dictionary for future consistency.
- **Feedback on AI-Generated Content**: Users are encouraged to provide feedback on AI-generated content (TFL summaries, polished text, translations, etc.) using thumbs up and thumbs down buttons. For negative feedback (thumbs down), users can categorize the issue (e.g., False Content, Irrelevant Content, Unprofessional Statements) and optionally provide additional explanations. This feedback is retained in the system under AI Tasks and is used to improve the AI's performance.



1.4.2 Propagation of Changes

AuroraPrime RMA enables dynamic and collaborative control over content generation through editable rules embedded within the authoring environment.

- **Custom Rule Definition**: Writers can define and modify **content generation rules** directly within the document writing mode. These rules govern how specific sections of content are produced, allowing for tailored automation.
- **Editable Template-Driven Documents**: When working with documents based on AI-enabled templates, users can view and adjust pre-configured generation rules and regenerate content as needed. This flexibility ensures that the generated output aligns with evolving document needs.
- **Template Admin Collaboration**: Template Admins can test, refine, and iterate on content generation rules, contributing to continual improvement of template logic and quality.
- **Automatic Change Tracking**: Any edits made to content generation rules within the document are **automatically saved**, and users are **notified of these changes** through a dedicated interface. This provides built-in traceability and ensures that updates are transparent and trackable.

AuroraPrime RMA supports continuous, user-driven refinement of automated content through editable rules and built-in change tracking—empowering writers and template admins to maintain both control and consistency throughout the document lifecycle.

1.4.3 Document Comparison

The AuroraPrime RMA Add-In includes a **Document Compare feature** designed to streamline the process of creating new documents. It allows you to **quickly generate a comparison or "diff" between two documents**, **identifying the differences** between them. This capability is listed as a key feature for **editing and finalizing documents**.

A notable capability is the ability to perform a **three-way comparison**. This allows you to triangulate the tracked changes against a **second language version** of the document. For example, this could be used to compare revisions of a clinical document written in German against the global English version from which it was adapted. This provides **more contextual information when reviewing and making revisions**, aiding effective alignment with the source document.

When comparing two versions, you would typically upload a baseline and a revised version of the document. The comparison results are displayed with **different types of edits color-coded** in the right pane, and you can also view a **full-view report** of the content delta. The process may take a moment to complete.

Furthermore, when comparing different versions of a document under "Associated Documents", you can **view the comments** on the updated parts (new additions, modifications), as well as **all comments in the latest version** of the document. The comparison report also allows you to **review tracked changes** and **tag changes** for further review or **ignore them** to dismiss them.

1.5 Human-in-the-Loop and Role-Based Access

AuroraPrime RMA incorporates Human-in-the-Loop (HITL) processes to ensure the accuracy, quality, and regulatory compliance of generated documents. The platform is designed to augment, not replace, human expertise—particularly that of regulatory and medical writers.

To maintain quality and ensure segregation of duties, AuroraPrime RMA uses a role-based access model with clearly defined responsibilities. While examples of pre-defined roles are provided, custom roles can also be created to suit specific organizational or project needs.

- **Template Admin**: Manages the RMA Content Library at the organizational level and provides writing examples that guide GenAI in adhering to preferred structures and styles for TFL summaries.
- **Writer (Content Author)**: Responsible for drafting documents such as CSRs and Protocols.
- **Reviewer (QC)**: Focuses on quality control through review and validation of content.

This separation of roles—spanning template management, content creation, access control, and dedicated review—supports robust governance and high-quality document generation within the platform.

Although many aspects of document creation are automated, human users remain responsible for overseeing the end-to-end process, from input to final approval, ensuring outputs meet the required standards for accuracy, clarity, and compliance.

1.6 Quality & Compliance

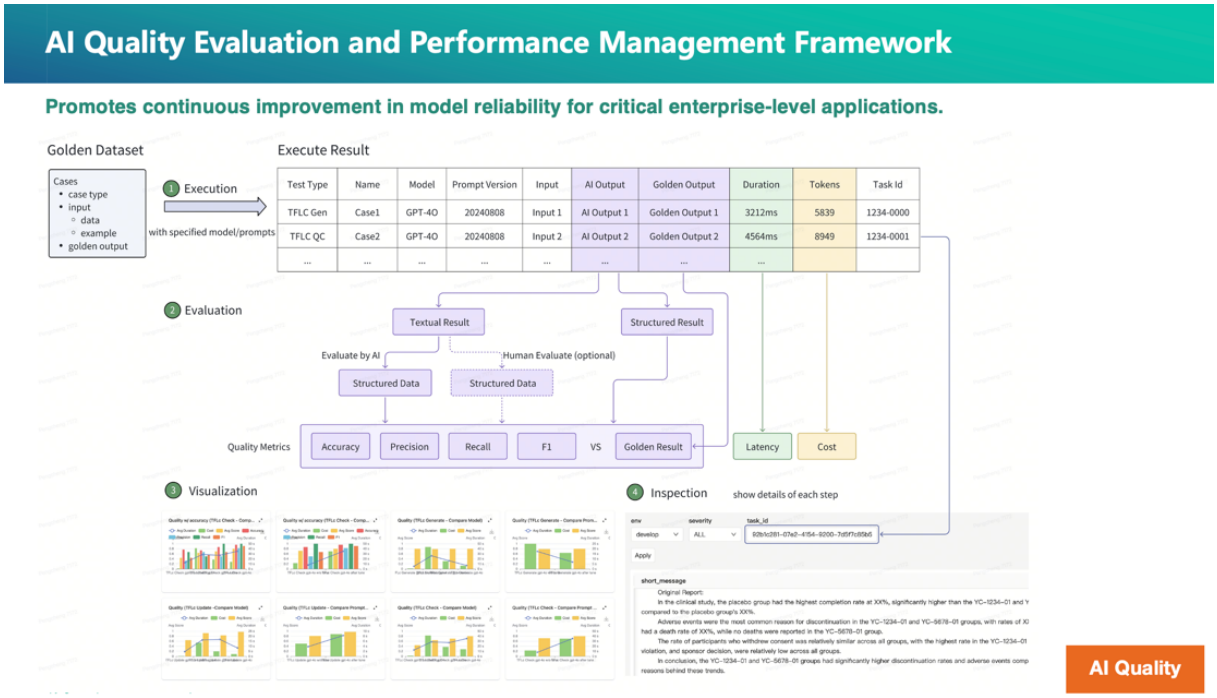
1.6.1 Automated Factualness Checking

AuroraPrime RMA ensures content accuracy through a combination of AI-driven generation, structured validation tools, and user feedback mechanisms. These capabilities help verify that generated content remains aligned with its source data.

- **TFL Summary Validation**: The RMA add-in includes a *Validate TFL Summaries* feature, which compares selected summary text against the corresponding TFL data. Any discrepancies are listed and visually highlighted in the in-text TFL object. Users can then choose to auto-update the summary, ensuring it accurately reflects the underlying data.
- **Reused Content Traceability**: For reused content, the platform displays the original source beneath each segment, allowing users to easily trace back and manually verify the accuracy of the reused information.
- **Source-Defined Content Generation Rules**: When setting up content generation rules in document templates, Template Admins must define the specific source documents and sections from which content should be derived. This emphasis on explicitly defined inputs helps ensure that all generated content is grounded in reliable, verified information.

1.6.2 Automated Quality Check

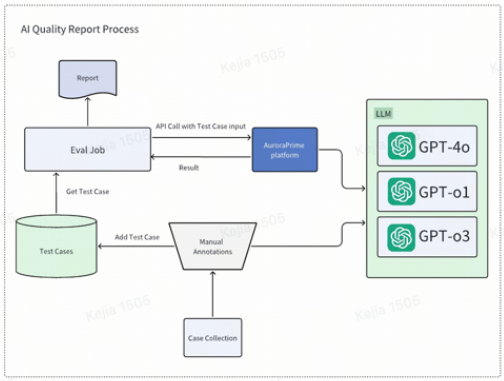
AuroraPrime RMA provides advanced automated quality check capabilities to validate both input data and generated documents. These features are designed to ensure accuracy, consistency, and compliance with regulatory standards.

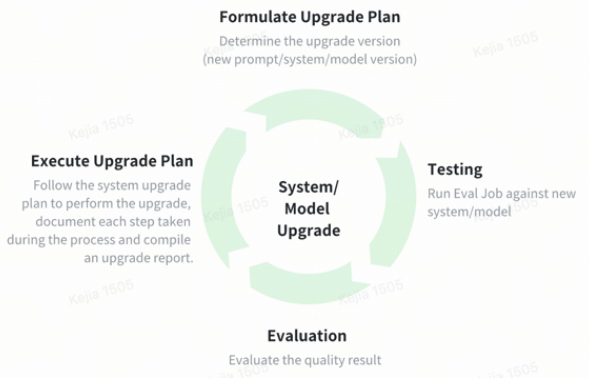


- **AI-Driven Quality Framework**: The platform uses an AI-powered quality control framework that continuously improves the accuracy and consistency of outputs.
- **Golden Dataset Benchmarking**: GenAI leverages a curated “golden dataset” of high-quality reference documents to evaluate generated content. Content is assessed against predefined quality criteria and task-specific metrics.
- **Granular Quality Metrics**: The platform supports detailed GenAI-driven evaluation metrics such as Accuracy, Precision, Recall, F1 score, and overall Quality Evaluation, enabling precise measurement of content quality.
- **Automated Integrity and Consistency Checks**: AI capabilities include validation of report integrity, logical flow, and consistency, benchmarked against internal content guidelines and external regulatory requirements.
- **Data-to-Content Validation**: The system performs automated checks to ensure logical consistency between source data and generated summaries, supporting factual alignment and reducing manual review effort.

AI Quality Evaluation and System/Model Upgrade Process

AuroraPrime platform provides golden test sets to regularly monitor and assess AI-generated content quality when the model is upgraded or changed.





1.6.3 Regulatory Compliance

Regulatory Compliance: Certifications, GAMP5 Validation, SOPs, and Secure Operations

Regulatory Certifications

Certification Compliance: Compliant with key standards, including 21 CFR Part 11, HIPAA, GDPR, ISO 9001, ISO 27001, and SOC 2 Type II.

GAMP5 Verifications

- **GAMP5 Validation:** Conducts Category 5 software validation per GAMP5 V-model and GCP standards.
- **Validation Records:** Maintains comprehensive validation records for regulatory audits.

Regulation-Compliant SOPs

- **Compliant SOPs:** Fully compliant SOPs aligned with Level 3 security and GCP standards.
- **Continuity & Recovery:** Regular business continuity, disaster recovery drills, and data backup inspections.

1.7 Technical Architecture

1.7.1 LLM API Switching Capability

AuroraPrime RMA includes built-in capabilities for seamlessly switching between different Large Language Models (LLMs). Its model-agnostic architecture supports integration with a wide range of leading LLMs and is designed to connect effortlessly with client-specific AI endpoints.

AlphaLife maintains a strong commitment to continuously monitoring and updating LLM integrations. The upgrade process includes AI-assisted regression testing, optional human evaluations, comprehensive AI quality metrics, and validation against golden test datasets—ensuring reliability, accuracy, and consistency when switching models.

1.7.2 Document Portal

AuroraPrime RMA offers streamlined access and management of documents through its intuitive web portal. The platform provides dynamic dashboards that allow users to track document progress and gain valuable insights. Through the web interface, users can easily monitor the status and key information of their documents in real-time.

1.7.3 Modular Build

The AuroraPrime platform and its AI & LLM Workbench are built with modularity and interoperability at their core, enabling smooth integration with third-party systems such as Veeva RIM, EDC, and PV platforms. This is achieved through robust, RESTful API interfaces that support scalable and flexible deployments.

Key integration capabilities include:

- **Seamless connectivity with regulatory ecosystems** such as Veeva RIM, enabling automated document generation through the assembly of structured content with minimal manual input.
- **Strategic partnership with Veeva** through AlphaLife's participation in the Veeva AI Partner Program. This ensures direct API integration for efficient data extraction and streamlined file management.

1.7.4 Architectural Fit

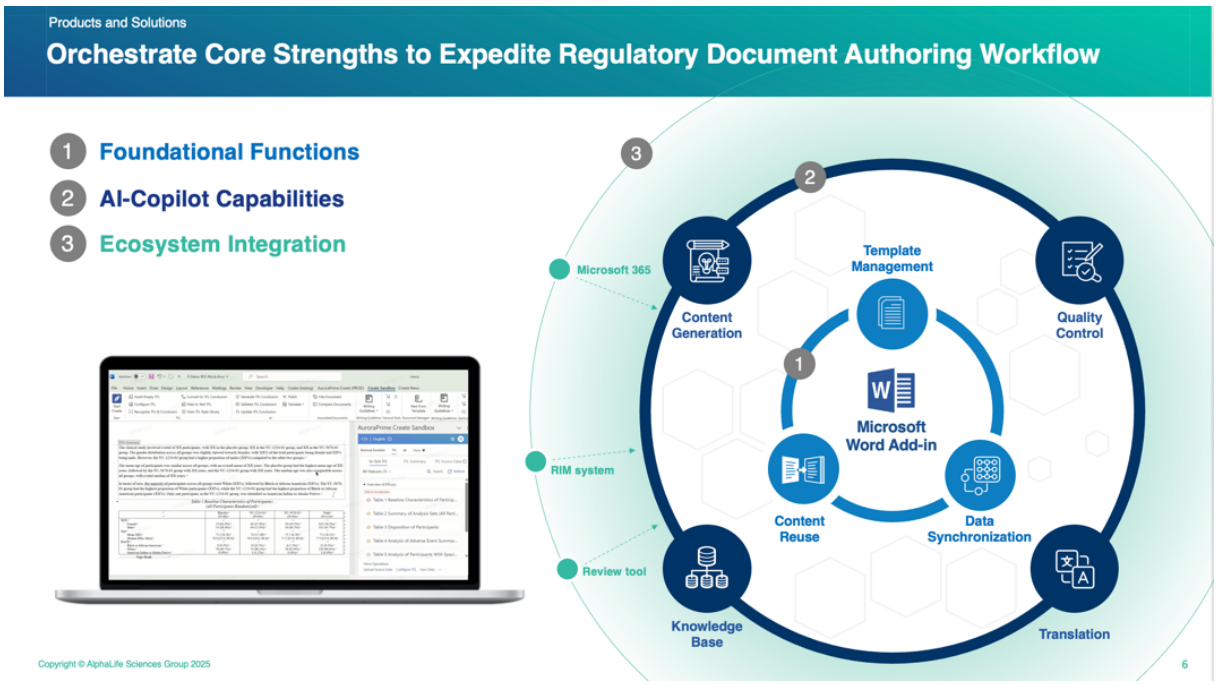
AuroraPrime RMA is engineered on a cloud-agnostic, Kubernetes-based microservices architecture, allowing for modular deployment across diverse environments. Its design fully supports multi-cloud de-

ployment, ensuring architectural compatibility with the client's development ecosystem—including AWS, Bitbucket, Jenkins, and related platforms.

2 Technical Specifications

2.1 API Integrations

AuroraPrime RMA is built for interoperability, offering robust **RESTful APIs** to support seamless integration with external systems and data sources across the clinical and regulatory landscape.



2.1.1 Veeva RIM Integration

As a **Veeva AI Partner**, AlphaLife Sciences has enabled deep integration between AuroraPrime RMA and **Veeva RIM**, with a focus on automating the end-to-end document generation lifecycle.

Key integration features include:

- **Direct API connectivity** for real-time data extraction and streamlined file management
- A structured **CSR plugin flow** that supports:
  - Project selection within Veeva
  - Detection of existing CSRs
  - Template selection from Veeva's repository

  - Automatic saving of final documents back into the Veeva system

2.1.2 Microsoft Ecosystem Integration

AuroraPrime RMA is natively integrated into the **Microsoft ecosystem**, offering:

- Availability as a **Microsoft Word add-in**, hosted on Azure and powered by OpenAI
- **Seamless compatibility** with Microsoft Word 365, preserving user familiarity
- **SSO integration** via Microsoft Entra ID for secure, enterprise-grade authentication

2.1.3 Integration with Additional Data Sources

Beyond Veeva and Microsoft, AuroraPrime RMA supports integration with a range of third-party systems critical to clinical document generation:

- **Other RIM systems** beyond Veeva
- **EDC (Electronic Data Capture)** platforms
- **Pharmacovigilance (PV)** systems
- Data sources for automating safety narratives and other content-rich regulatory documents

AuroraPrime RMA's API-first architecture ensures scalable, secure, and flexible connectivity with leading industry platforms—enabling streamlined workflows, real-time data access, and full lifecycle automation across clinical documentation processes.

2.2 Performance

AuroraPrime RMA enables **highly automated document generation**, significantly reducing time and manual effort in producing key regulatory and clinical documents.

The platform can generate **initial drafts within minutes**, transforming a process that traditionally takes weeks.

This accelerated turnaround allows teams to focus more on scientific quality and strategic review rather than formatting and data transcription.

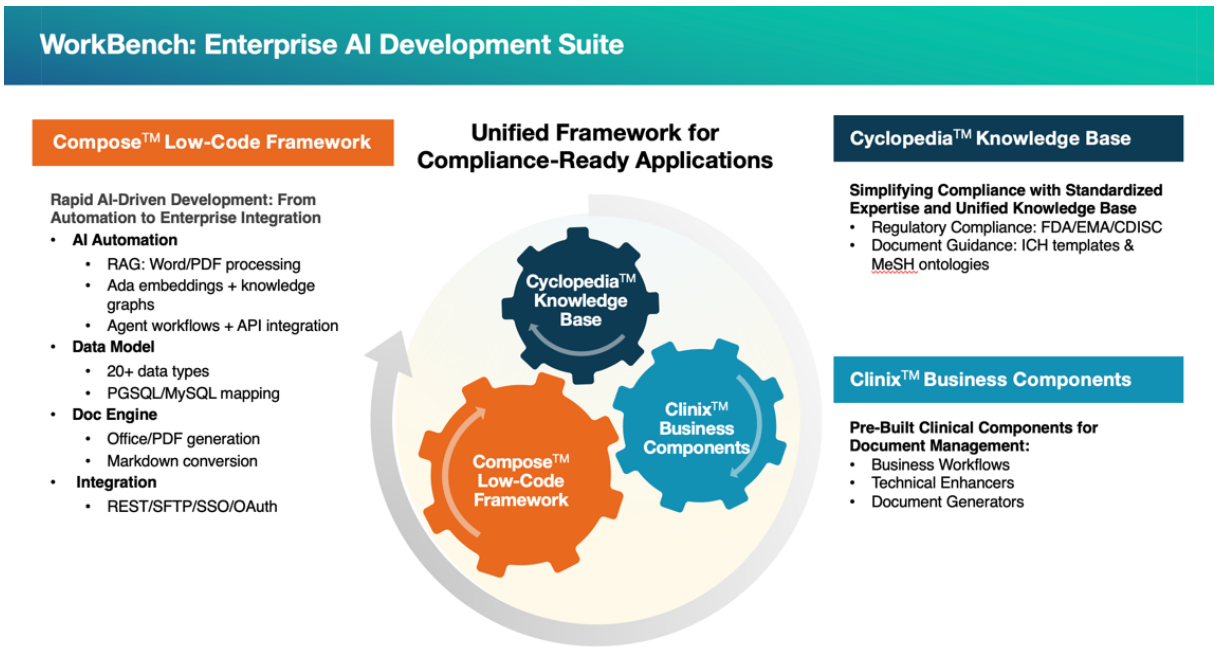
2.3 Scalability and Adaptability

AuroraPrime is designed with a **scalable and flexible architecture** to support a wide range of document types and therapeutic areas:

- Easily extendable to new **Therapeutic Areas (TAs)**, **study phases**, and **document categories**
- Rapid configuration and deployment for additional use cases through modular design
- Supports both **"off-the-shelf" document templates** and **customized pilot implementations**

The **AuroraPrime GenAI Workbench** provides a developer-friendly environment to **build and extend AI-powered applications**, enabling customization for diverse content authoring needs.

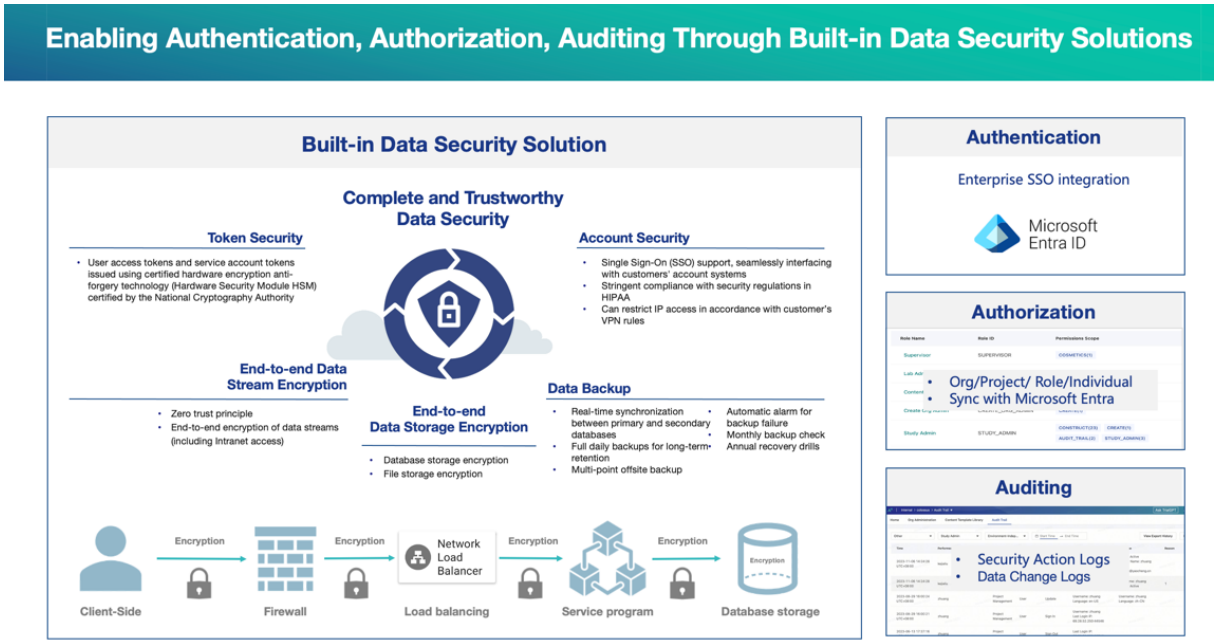
- AlphaLife Sciences regularly expands support to new document types as part of its platform roadmap
- For entirely new document types, a **4–6 week lead time** is typically required to prepare for a **Proof of Concept (POC)**



AuroraPrime RMA is not only optimized for rapid, AI-driven content creation but is also built to evolve with your organizational and regulatory needs—making it a future-ready solution for clinical and regulatory document automation.

2.4 Security

AuroraPrime delivers a robust, enterprise-grade security framework that ensures authentication, authorization, and auditing are deeply integrated into the platform through built-in data security solutions. The platform supports compliance, data integrity, and secure access control across clinical and regulatory environments.



2.4.1 Complete and Trustworthy Data Security

- **Token Security**
  - Access and service tokens are secured using certified hardware-based encryption (HSM).
  - Certified by the National Cryptography Authority for anti-forgery protection.
- **End-to-End Data Stream Encryption**
  - Follows a zero-trust principle.
  - Encrypts all data streams, including internal intranet traffic.
- **End-to-End Data Storage Encryption**
  - Encrypts both database and file storage to protect data at rest.
- **Account Security**
  - Supports Single Sign-On (SSO) and integration with client systems.
  - Compliant with HIPAA and customer VPN policies for IP-based access restrictions.
- **Data Backup**
  - Real-time synchronization between primary and secondary databases.

- Full daily backups with multi-point offsite storage.
- Monthly checks and automated alerts for backup failures.
- Annual recovery drills to ensure readiness.

2.4.2 Authentication

- Enterprise SSO integration via Microsoft Entra ID, enabling secure and centralized user access management.

2.4.3 Authorization

- Granular role- and project-based permission control.
- Supports individual, organizational, and project-level authorization scopes.
- Fully synced with Microsoft Entra for scalable identity management.

2.4.4 Auditing

- Built-in logging of security actions and data changes, supporting transparency, traceability, and compliance requirements.

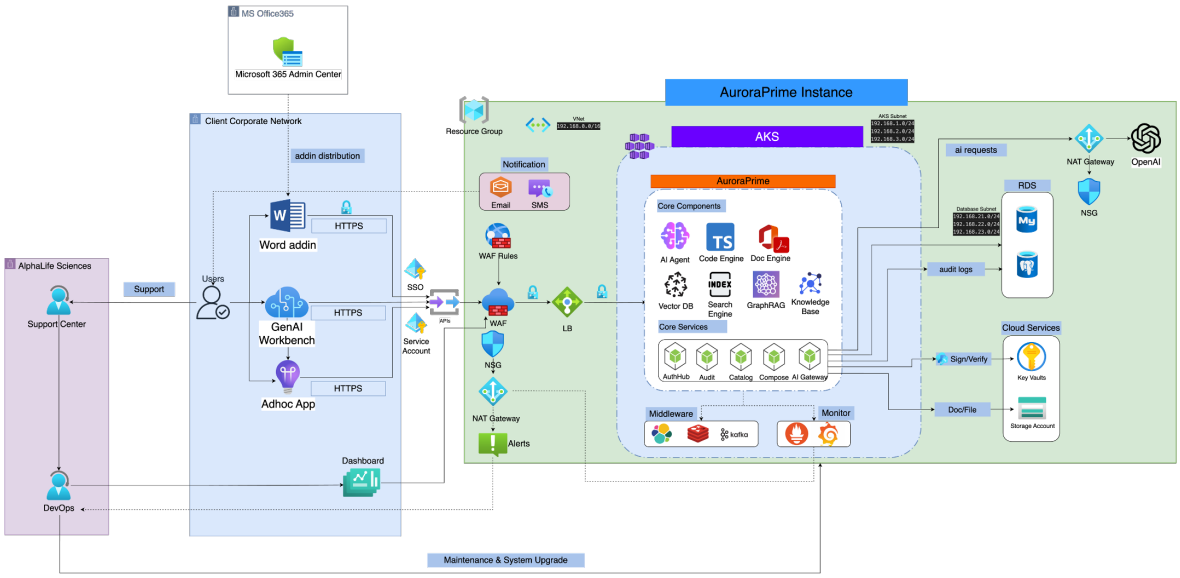
2.4.5 HPAA

AuroraPrime's security and compliance framework is built upon the **HIPAA Security Rule**'s requirements for administrative, physical, and technical safeguards, supported by specific governance structures, policies, procedures, and technical solutions designed to protect the confidentiality, integrity, and availability of **ePHI**.

For more details, please refer to AuroraPrime HIPAA Compliance Whitepaper.

2.5 Architecture and Hosting Requirements

AuroraPrime RMA is built on a cloud-agnostic, Kubernetes-based microservices architecture, enabling scalable, modular deployment across diverse environments. Its multi-cloud compatibility allows seamless integration with the client's development ecosystem, including AWS, Bitbucket, and Jenkins.


MS Office365
Microsoft 365 Admin Center
Client Corporate Network
addin distribution
Word addin
HTTPS
GenAI Workbench
HTTPS
Adhoc App
HTTPS
AlphaLife Sciences
Support
Support Center
Users
DevOps
Dashboard
SSO
Service Account
Resource Group
Notification
Email
SMS
WAF Rules
WAF
NSG
NAT Gateway
Alerts
LB
AuroraPrime Instance
AKS
AuroraPrime
Core Components
AI Agent
Code Engine
Doc Engine
Vector DB
Search Engine
GraphRAG
Knowledge Base
Core Services
AuthHub
Audit
Catalog
Compose
AI Gateway
Middleware
kafka
Monitor
ai requests
NAT Gateway
OpenAI
NSG
RDS
audit logs
Cloud Services
Sign/Verify
Key Vaults
Doc/File
Storage Account
Maintenance & System Upgrade