

Generative AI-Powered Clinical Research Platform

Smarter Trials, Better Data, Quicker Results
Fueled by Generative AI and Large Language Models.

Proud to Partner With




↑ 100%
CSR Authoring Efficiency Increase

Medical Writing Team, Top Global MNC:
"With AuroraPrime Create, we save 50% in labor time through content reuse and automated TFL synchronization and summary generation in CSR authoring." (Equivalent to a 100% efficiency increase.)

↑ 45%
Overall Medical Writing Efficiency Increase

CMO, Big Biopharma:
"AuroraPrime Create boosts our authoring productivity by 40-50% with its efficiency and quality."

“ *"Historically, our clinical trial data management faced challenges primarily in three key areas: human resources, time management, and data handling. AuroraPrime's integrated solution adeptly assists us in effectively addressing these challenges."* **”**



CMO, Big Biopharma

90%
UAT Time Reduction

80%
Database Build Time Reduction

90%
Data Listing Time Reduction

99%
Patient Safety Narratives Time Reduction

Global Leaders in Computer and Life Sciences Unite

LEADERSHIP TEAM



Sharon Chen
CEO

Former Director of Google Shanghai R&D Institute; Former General Manager of Verily China



Alice Hsu
SVP, Clinical Technology Services

Former Head of Project Management and Clinical Operation, WuXi Clinical; Former PD of Project Management at Covance (Fortrea)



Larry A Veal
Head of Marketing and BD,
North America and Europe

Formerly, SVP, Sales and Marketing at Frontage Laboratories; Global Head, Business Development, Commercialization and Outcomes at ICON Clinical.



Gavin Zhang
CBO, JAPAC

Former Head of Channel Sales Asia Pacific, Medidata; Former Key Account Solution Sales



Pengcheng Xu
CTO

The first engineer at Google China
Former Architect at Verily China



Bogong Zhu
CPO

Former Cloud AI Tech Lead at Google Shanghai; Former Clinical Software Tech Lead at Verily China



Alan Ren
Principle Architect

VMWare Head of Engineering and Ecosystem, AI Labs; General Manager, China R&D Head of Engineering and Ecosystem, AI Labs; General Manager, China R&D



Jason Xie
China Sales Head

Former Head of Business Development China at Veeva; Former Key Account Solution Sales at Oracle



ADVISORY BOARD



Ruyi He

Chief Medical Officer of RemeGen; Former Deputy Director of FDA's Division of Gastrointestinal and Coagulation Drug Products, Former MD Chief Scientist of CDE



Névine Zariffa

Board member of CDISC.; Former SVP, Head of Biometrics & Information Sciences at AstraZeneca



David Kiger

Former VP Strategy at Parexel
Former CCO at Bioclinica



AlphaLife Sciences Group: Pioneering AI-Powered Digital Clinical Research Solutions

About Company

AlphaLife Sciences Group, with its global headquarters in Singapore, represents the pinnacle of innovation in the realm of digital clinical research. Our flagship offering, AuroraPrime, is a testament to our leadership in integrating Generative AI and Large Language Models (LLMs) into a comprehensive AI-powered SaaS platform. Globally acknowledged and bolstered by prestigious collaborations with Microsoft's Pegasus Program and Google for Startups, AuroraPrime seamlessly blends advanced integrations such as EDC, RTSM, DCT, CTMS, eTMF, along with Medical Writing, Translation, Analytics, Knowledge Base, and an exhaustive Data Platform. These groundbreaking innovations are pivotal in hastening drug development and facilitating smoother market entry, earning the trust of pharmaceutical giants like GSK and MSD.

As an authoritative figure in life sciences and consumer health, we are dedicated to propelling AuroraPrime to the forefront of global digital clinical research platforms. Our reliance on the latest AI models, cloud computing, and big data technologies underpins our commitment to providing robust technical support across all phases of clinical trials and real-world research. This, coupled with our unparalleled consulting and system implementation services, significantly accelerates R&D innovation and expedites the introduction of new therapeutics.

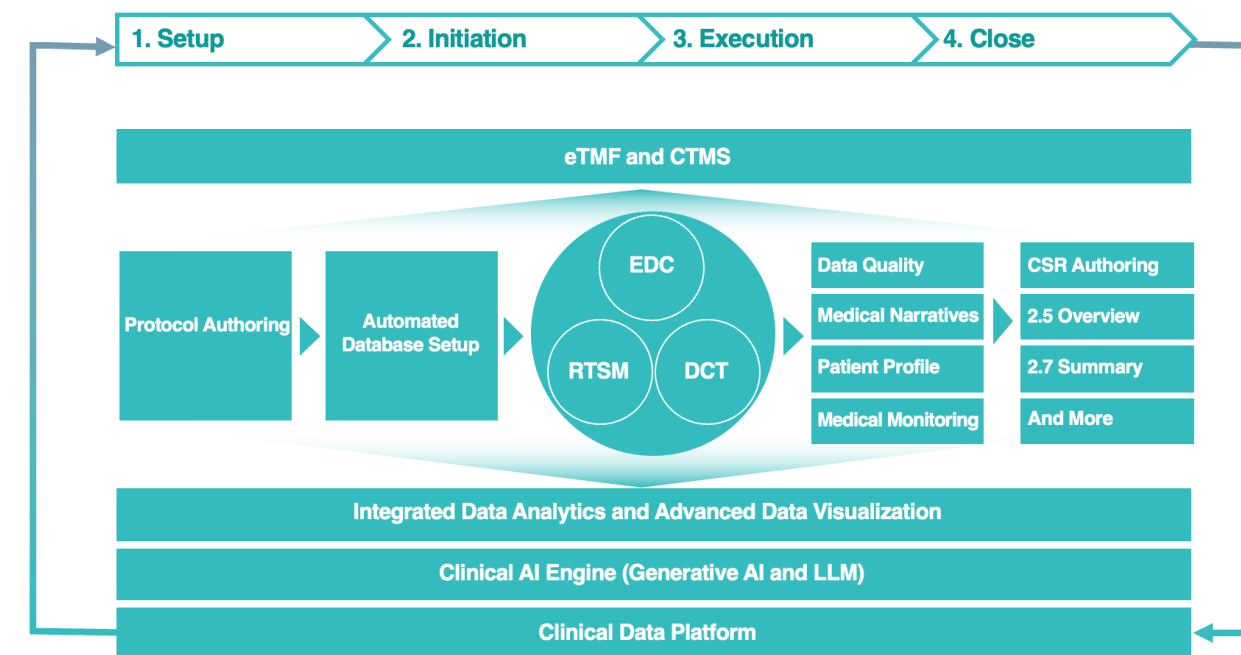
Our collaborative ecosystem is extensive, involving partnerships with multinational pharmaceutical companies, leading domestic firms, biotech entities, and mainstream CROs across a spectrum of therapeutic domains worldwide. Endorsed by both the Microsoft and Google Accelerator programs, we've garnered substantial technological support, which has culminated in the acquisition of numerous patents and software copyrights by the end of 2023.

Embodying a truly Global Company with Multinational Operations, AlphaLife Sciences Group boasts offices across the United States, China, and Singapore. Our diverse team, enriched by over 30 ex-Google employees and top talents from renowned companies like Google, Microsoft, Verily, Splunk, Medidata, Veeva, Oracle, Convance, and Iqvia, brings unparalleled expertise in computer science applications and extensive clinical research experience.



AURORA^x Prime

AI-Powered End-to-End Clinical Trials



Global Technology and Services: Trusted and Compliant



GCP/GxP Compliance

1. Regulation-compliant SOPs

- SOPs with Level 3 security, GCP
- Yearly continuity, recovery drills
- Monthly backup, annual recovery tests

2. GAMP5 Verifications

- Validate software using GAMP5 and GCP.
- Keep all validation records.
- Prepare for regulatory reviews.

3. Regional Regulatory Certifications



Multi-Cloud Deployment

1. Ensure Regulatory Compliance:

Ensures adherence to local laws for each country's data storage.

2. Protect Data Security:

Minimizes cross-border data transfer risks, protecting information

3. Provide Operational Resilience:

Provides consistent data access, mitigating downtime risks.



Trusted Data Security

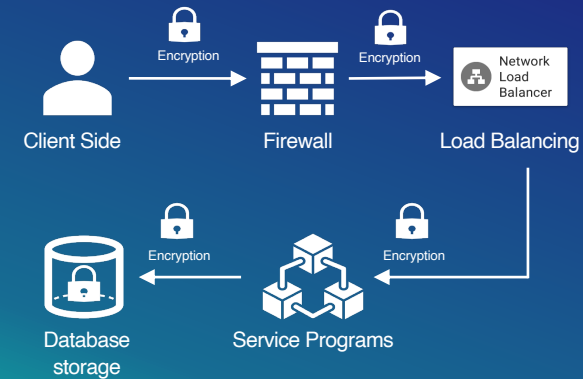
1. Token-Based Security

2. Encrypted Data Streams

3. Secure Data Storage

4. Robust Account Safety

5. Reliable Data Backup



Comprehensive Customer Support

1. Offer 24/7 Support

2. Global Offices

3. Comprehensive Training

4. Quick Response Time

5. Dedicated Account Management

- New Jersey, USA
- San Francisco, USA
- Singapore
- Shanghai, China
- Beijing, China



Generative AI-Copiloted Clinical Research Platform

 50% Cost Reductions

 12 Months Acceleration

 20% NPV Increase

Generative AI will create an annual economic value of **\$13 billion to \$25 billion** on the clinical development.

Source: McKinsey 2024 report

AURORA^x Prime

1 Medical Writing & Submission

- Auto Protocol Draft
- Auto CSR Draft
- Auto Patient Safety Narratives
- SAP, IB, PSUR, DSUR
- Clinical Overview (2.5)
- Clinical Summary (2.7)

2 Integrated Data Analysis and Management

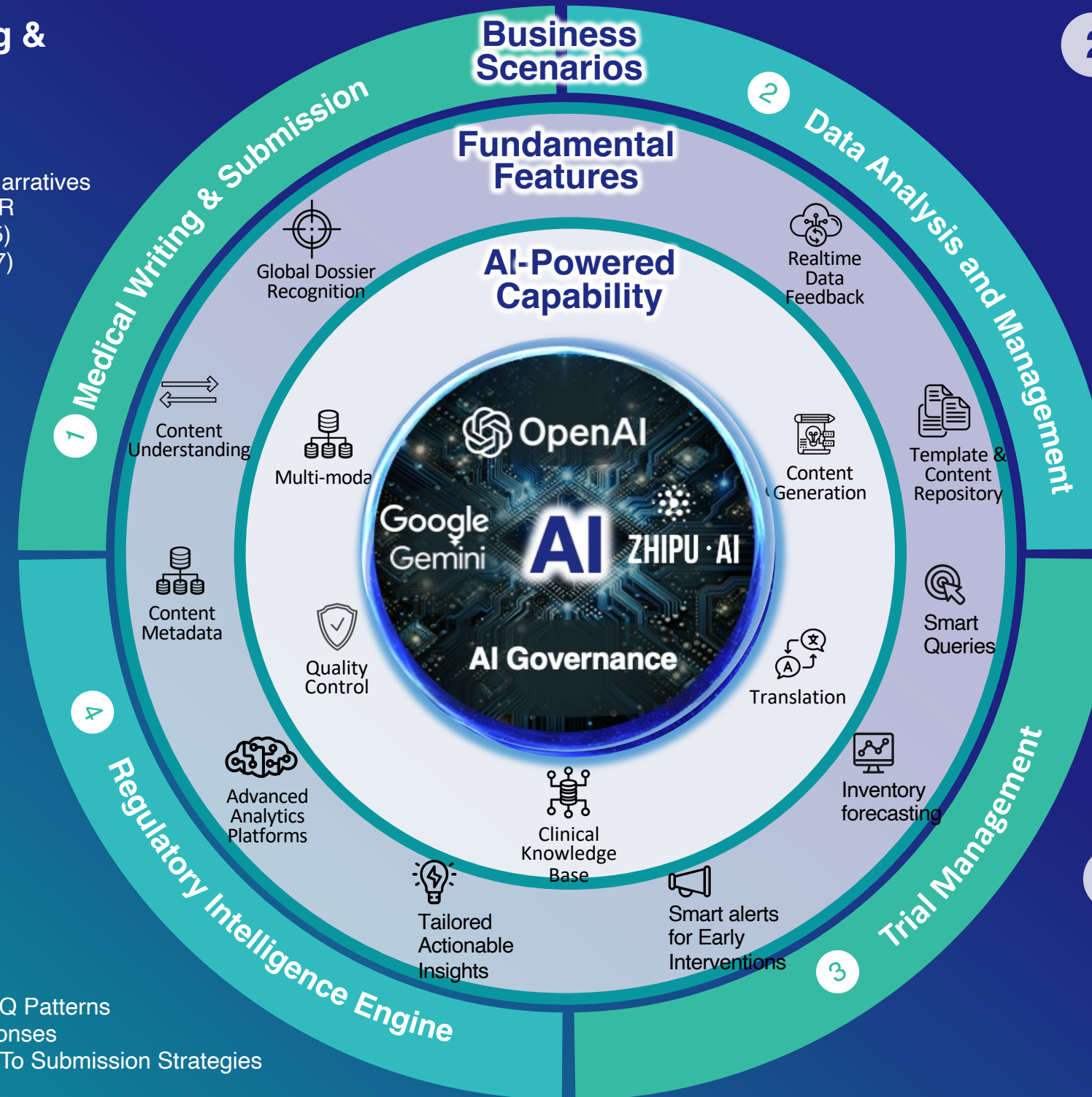
- Auto CRF Design
- Auto Database Testing
- Auto Data Validation
- Auto SDTM Mapping
- Auto Medical Coding
- Deep Data Insights
- Advanced Data Visualization

4 Regulatory Intelligence Engine

- Predict Potential HAQ Patterns
- Craft Sponsor Responses
- Provide Intelligence To Submission Strategies
- Risk Management

3 Clinical Trial Management

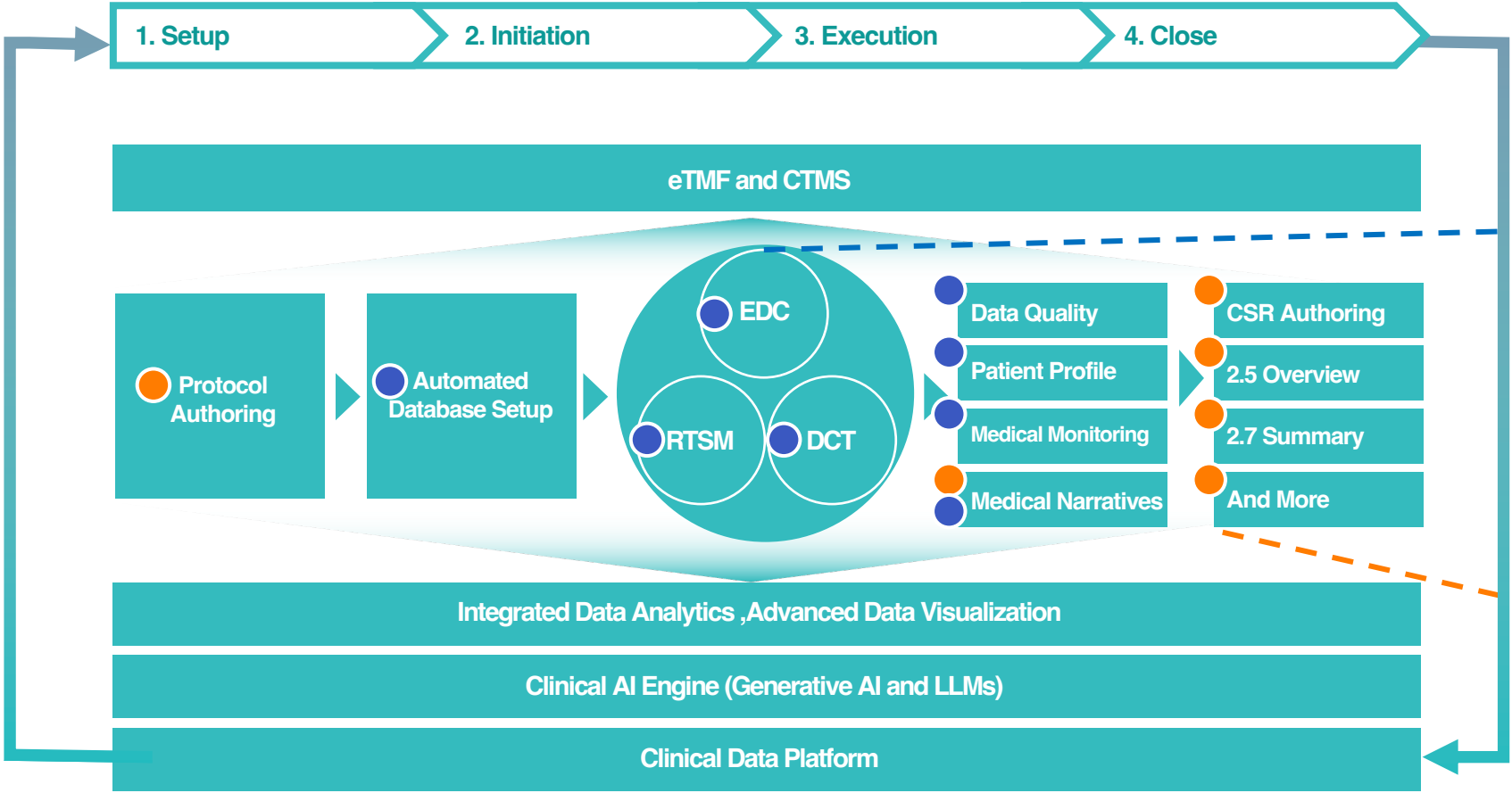
- Site Selection
- Patient Enrollment
- Risk Based Monitoring
- Inventory Forecasting



AuroraPrime Boosts Clinical Research With Seamless Document-Data Integration, Enhancing Data And Document Quality And Efficiency.

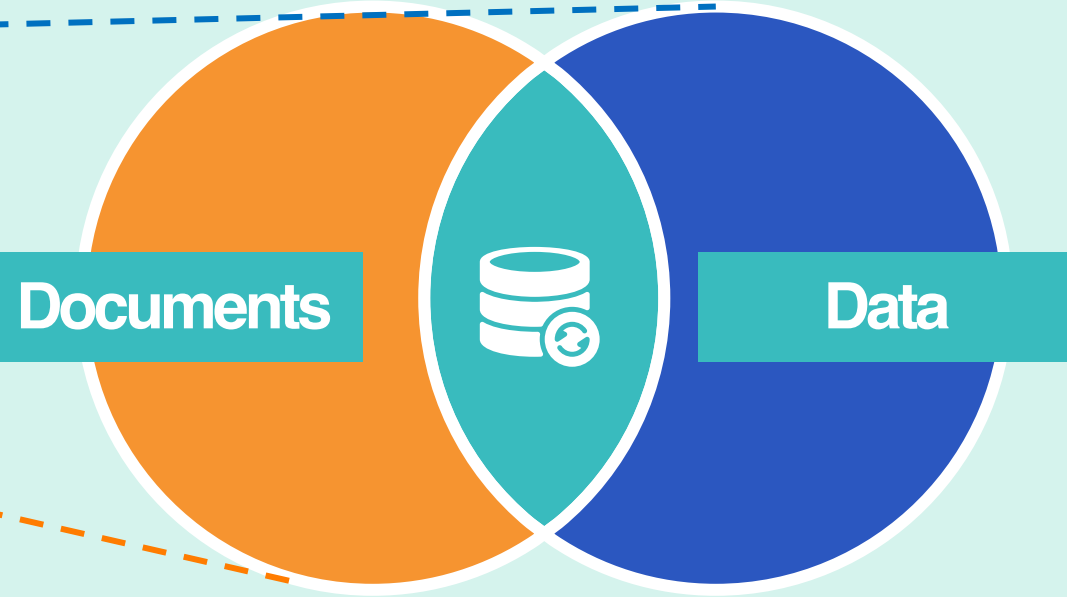
AURORA[®] Prime

AI-Powered End-to-End Clinical Trials



Seamless Document-Data Integration

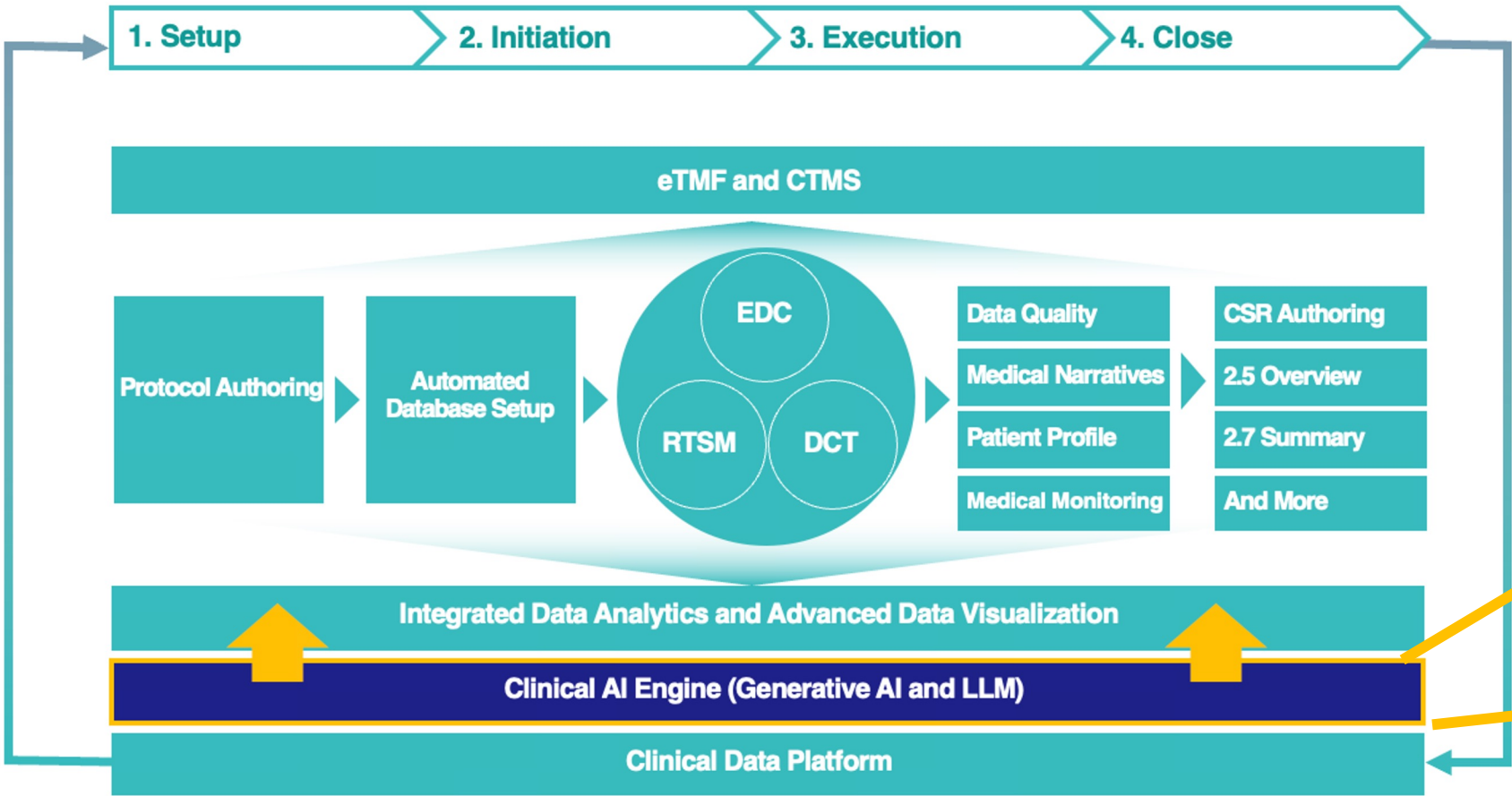
AuroraPrime, a one-stop digital clinical research platform, features intelligent document writing and data management capabilities, achieving seamless integration of clinical research documents and data. This platform significantly enhances the efficiency of clinical research processes, as well as the quality of data and documents, providing comprehensive strong support for clinical research.



AuroraPrime, Leveraging AI And Large Language Models, Offers Comprehensive Support For Clinical Research Data And Documents.

AURORA^x Prime

AI-Powered End-to-End Clinical Trials



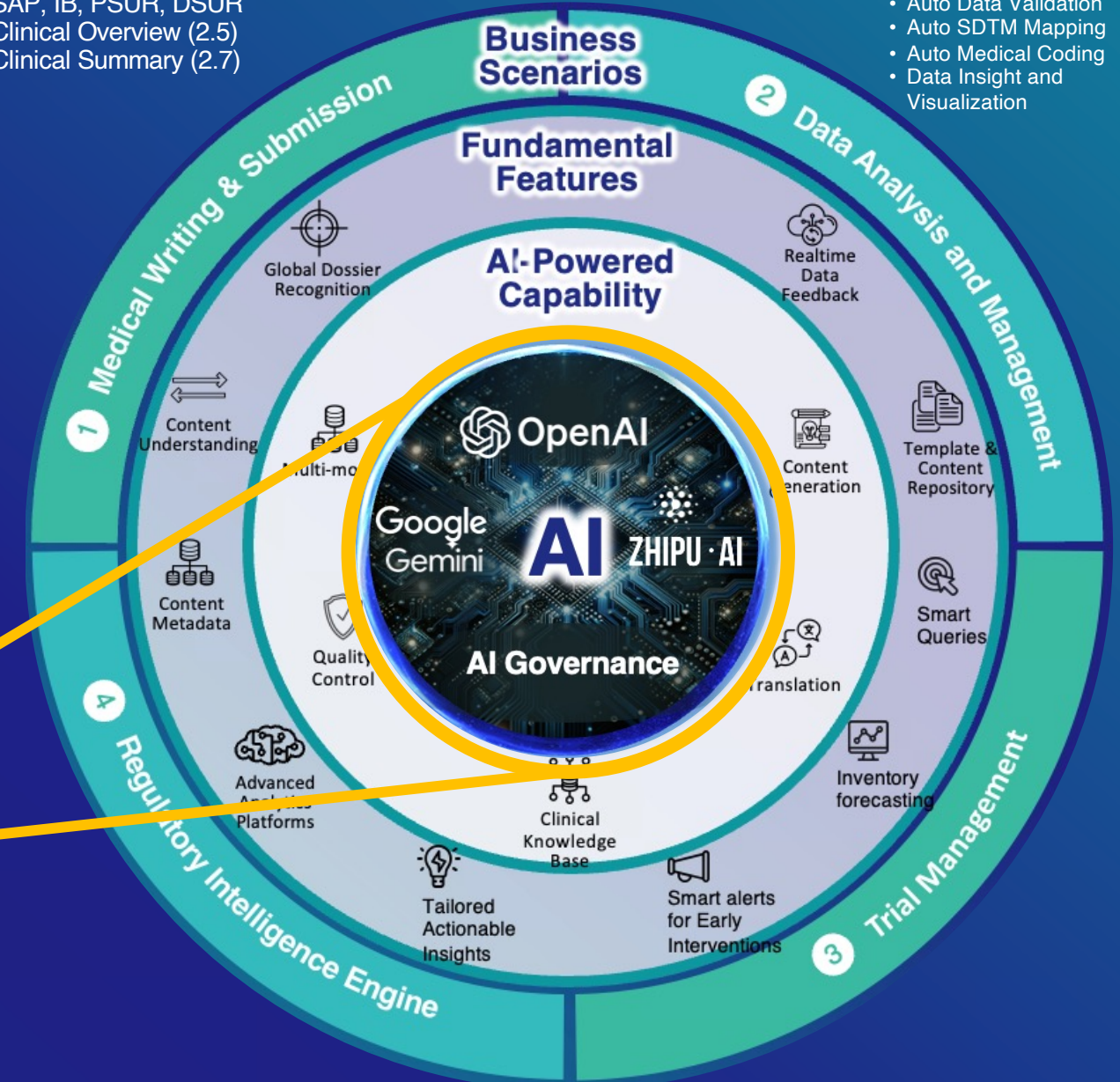
Medical Writing & Submission

- Auto Protocol Draft
- Auto CSR Draft
- Auto Patient Safety Narratives
- SAP, IB, PSUR, DSUR
- Clinical Overview (2.5)
- Clinical Summary (2.7)

AURORA^x Prime

Integrated Data Analysis and Management

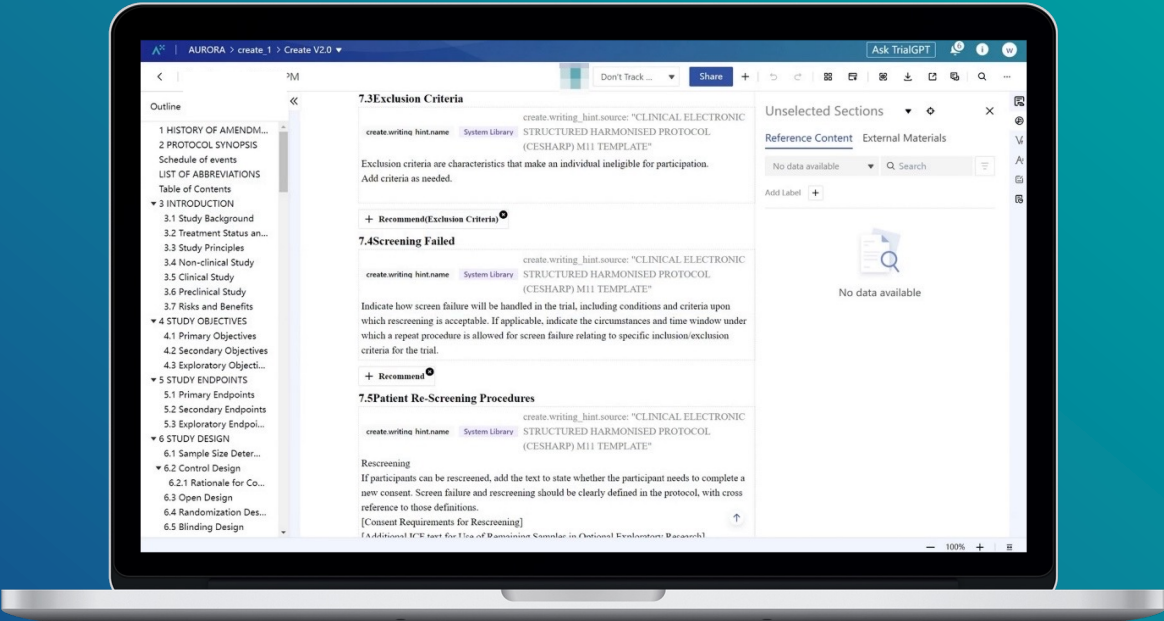
- Auto CRF Design
- Auto Database Testing
- Auto Data Validation
- Auto SDTM Mapping
- Auto Medical Coding
- Data Insight and Visualization



Generative AI-Assisted Medical Writing

Generative AI-Powered Medical Authoring Platform For Clinical Research Documents

The AI-Powered Prime Create Medical Authoring Platform transforms medical document creation, significantly improving efficiency. It features a vast Template/Content Library for consistency, available as a Word plugin or web app, with advanced AI for quality control, content generation, and efficient summaries/drafts using LLM. This platform streamlines authoring, boosting productivity and quality in clinical document management.



Protocol Authoring	CSR Authoring
Patient Safety Narrative	2.5 Overview 2.7 Summary And More

↑ 100%

CSR Authoring Efficiency Increase

Medical Writing Team, Top Global MNC:
"With AuroraPrime Create, we save 50% in labor time through content reuse and automated TFL synchronization and summary generation in CSR authoring." (equivalent to a 100% efficiency increase.)

↑ 45%

Overall Medical Writing Efficiency Increase

CMO, Big Biopharma:
"AuroraPrime Create boosts our authoring productivity by 40%-50% with its efficiency and quality."

Template/Content Library
Streamline document creation with pre-existing knowledge.

Content Metadata
Ensures consistency within and across documents.

Word Add-in & Web Based
Available as a Word plugin or web application.

AI Quality Control
Automated cross-checks for data and content accuracy.

AI Translation
Enhances translation quality and speed.

AI Content Generation
Leverages LLM for summaries and drafts.

SOP Based Workflow
Controls review and approval with role-based permissions.

OOTB
Ready-to-use solution with minimal setup needed.

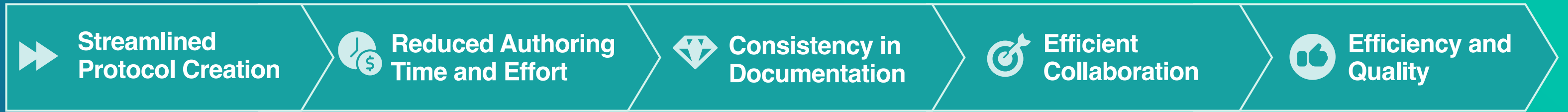
AI Content Recommendation
Recommends content using internal and external trial data.

Traditional Medical Writing Challenges

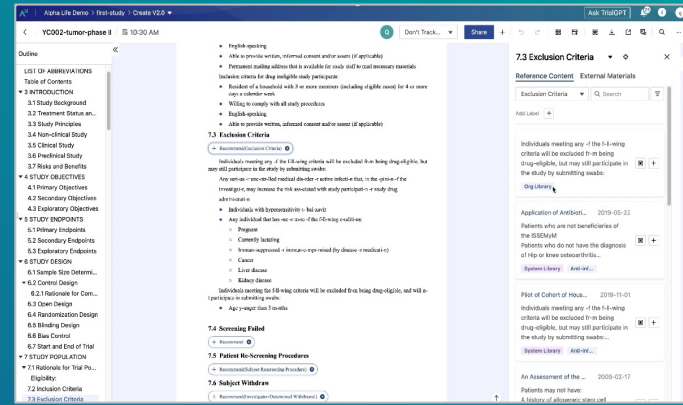
- Vast Content, Tight Deadlines
- Manual Efforts
- Consistency Checks
- Collaboration Hurdles
- Knowledge Silos
- Data Security Concerns
- Regulatory Compliance
- Many More...

Generative AI-Powered Protocol Authoring

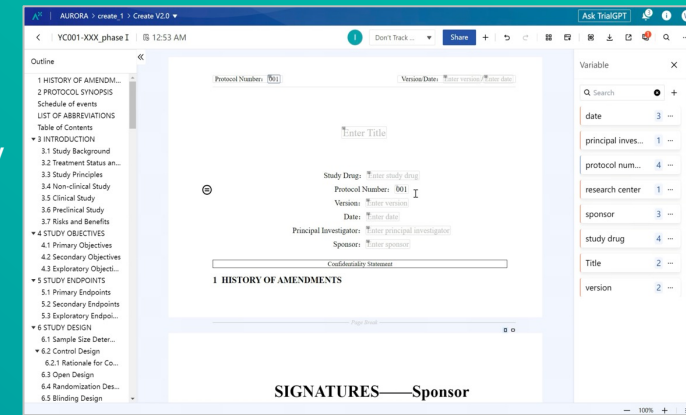
The AuroraPrime platform's AI-Powered Protocol Authoring product empowers biopharma companies with streamlined protocol creation. It features structured templates, batch content generation, one-click SOA setups, AI for precise content matching, and immediate access to writing techniques. This enhances efficiency, quality, and consistency in protocol documentation, significantly reducing authoring time and effort.



- Smart Template**
- Leverage external insights
 - Extract key information
 - Content recommendation
 - Record user choices
 - Optimize algorithm



- Knowledge Library**
- M11 template structures
 - Custom enterprise adaptability
 - Style management
 - SOP guidelines
 - Consistency variables



Streamline Protocol Authoring & Content Management

Enhances protocol authoring with structured templates, batch content creation, one-click SOA, AI content matching, and instant access to writing techniques for efficiency and quality.



Default Template Writing Guide

- Framework and style standards
- Chapter and paragraph structuring
- Example-based learning



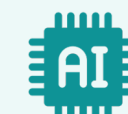
Standard Chapter Reuse

- Batch standard chapter creation
- Align content with protocol
- Eliminate copy-paste effort



SOA + Visit Description

- One-click SOA setup
- Custom SOA support
- Efficient content linking



AI-Generated Main Content

- Accurate content matching
- High-quality protocol content
- Quality enhancements: rephrase, reuse

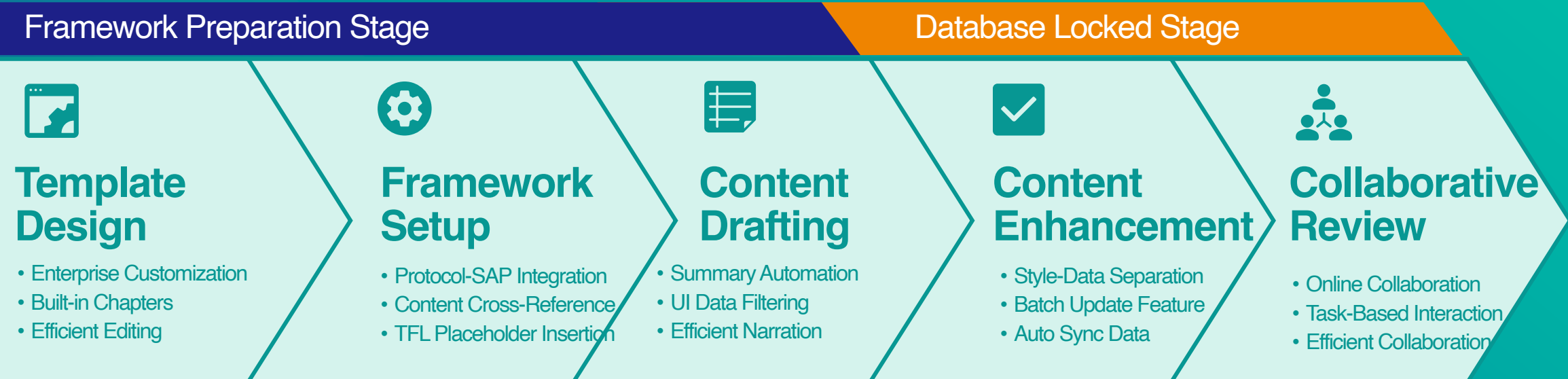


Reference Content DB

- Instant chapter technique access
- AI distills corporate insights
- Document creation support"

Generative AI-Powered CSR Authoring

The AuroraPrime AI-Powered CSR Authoring product enhances CSR creation through streamlined processes, improved document quality, and efficient collaboration. It leverages AI for automation and content improvement, offers flexible web and Word add-in integrations, ensures consistency across documents, and accelerates the CSR development cycle, significantly reducing manual effort and time.



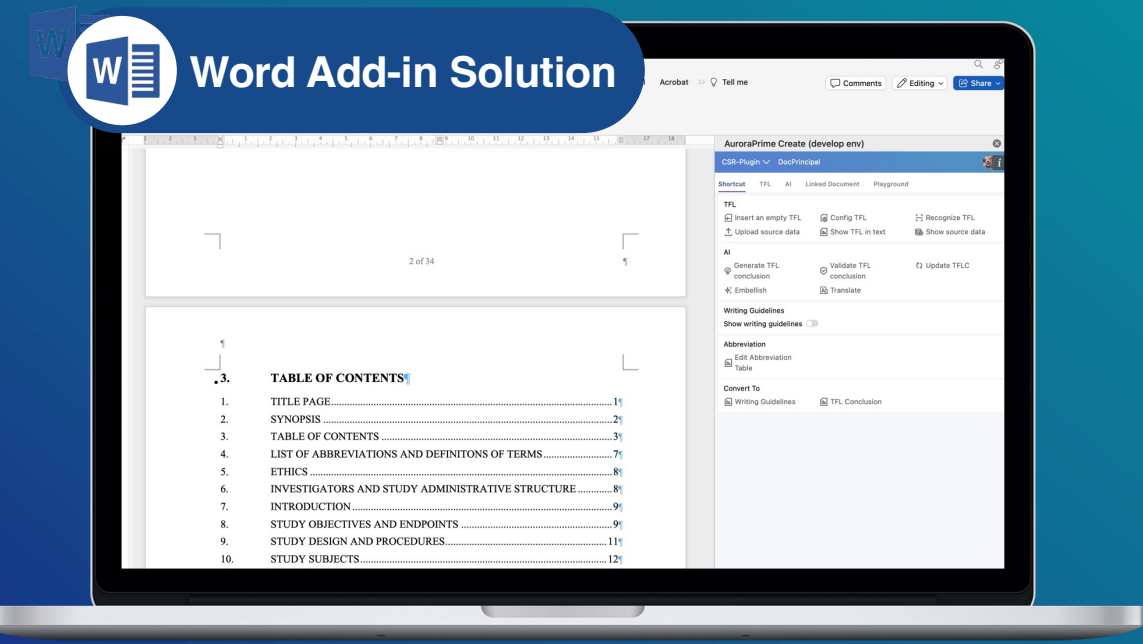
TIME IS MONEY

“Every delay costs pharmaceutical companies between **\$600,000 to \$8,000,000** everyday”

Source: Forbes: Patient-Centric Clinical Trials: The Acceleration Of Decentralized Patient Monitoring

“As soon as that **database is locked**, everyone's eagerly waiting for the CSR to be completed **as quickly as possible**. We definitely need technology to help us work more efficiently.”

Interview with CMO of Top 10 local Bio-pharma



Intelligent Automated
Increasing CSR Development Efficiency by
30-50%

<p>Efficiency Boost</p>	<p>Quality Assurance</p>
<p>Seamless Collaboration</p>	<p>AI Automation</p>

Generative AI-Powered Patient Safety Narratives

This product streamlines the creation of patient safety reports, ensuring efficient and accurate data handling. It facilitates rapid template configuration, seamless data mapping, and robust system integration, including EDC and PV. Automated report generation and effective data extraction from various sources significantly reduce preparation time, enhancing productivity and ensuring regulatory compliance.

1. Narrative Template Configuration

Streamline efficiency with enhanced report template setup.

2. Data Mapping Configuration

Seamless integration through precise data mapping.

3. System Integration

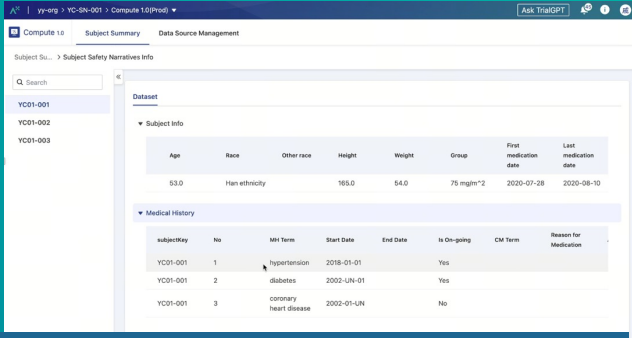
Boost interoperability with EDC, PV system connections.

4. Automated Report Generation

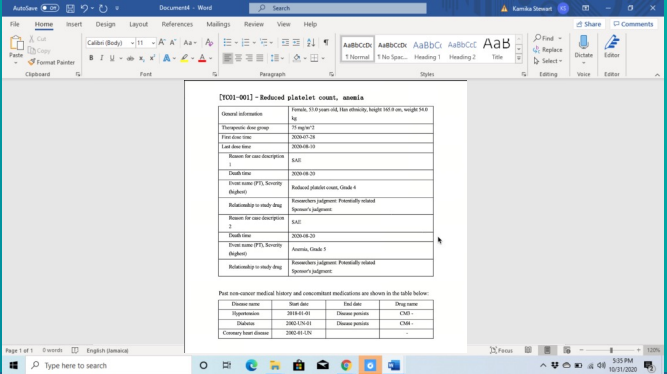
Simplify reporting with automated individual and batch processes.

5. Efficient Data Extraction

Enhance analysis with optimized information retrieval from SAEs.



Configuration



Automated Report Generation

Acceleration

99%

Time Reducing

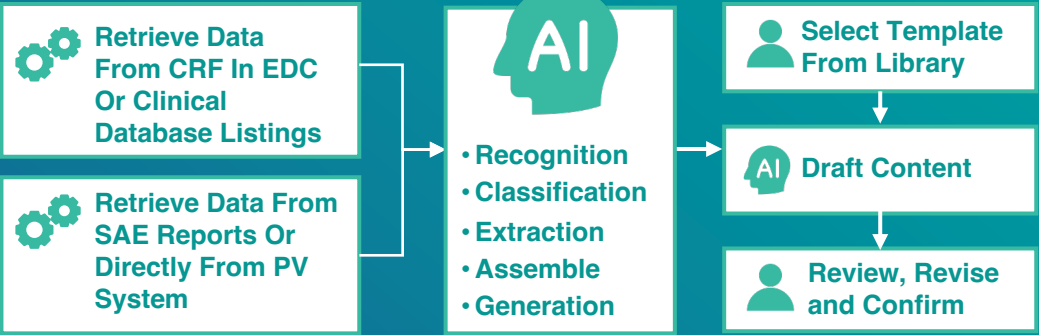


Reduce The Patient Safety Narratives Draft Development Time In A Study By 99%

Reduce Tasks From Days To Mere Minutes



- Generate the first draft within 1 minute
- Create batch drafts within minutes









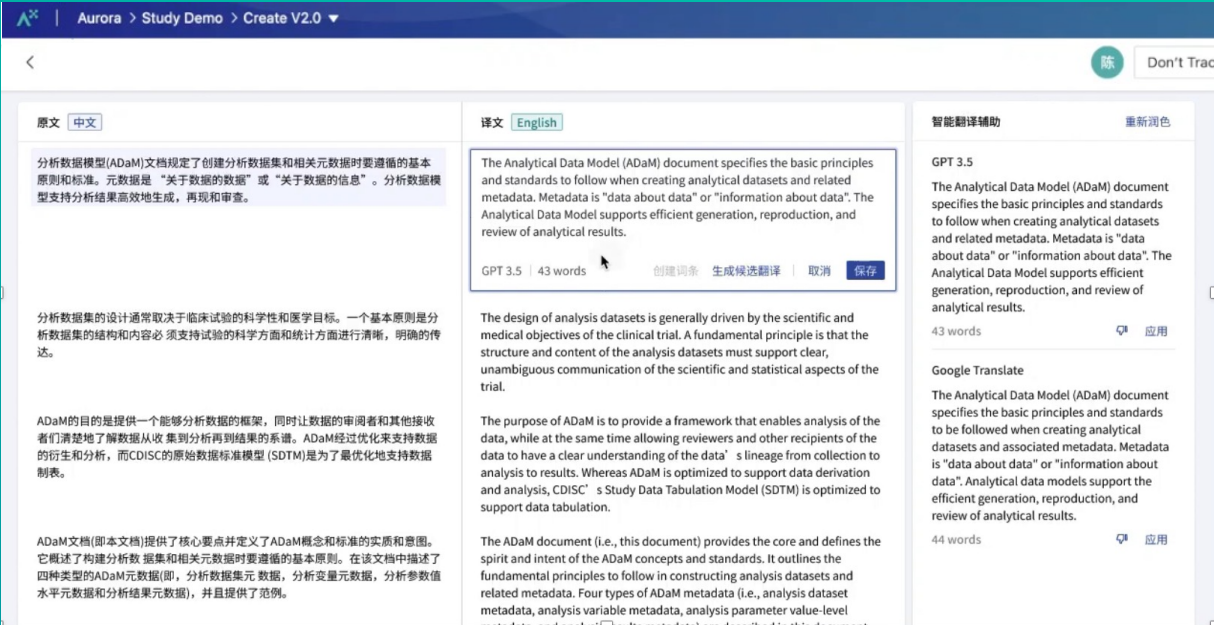
Traditional Pain Points

- Challenging data point selection across systems.
- Manual data transfer via copy-paste.
- Handwritten narrative rephrasing.
- Manual formatting adjustments.

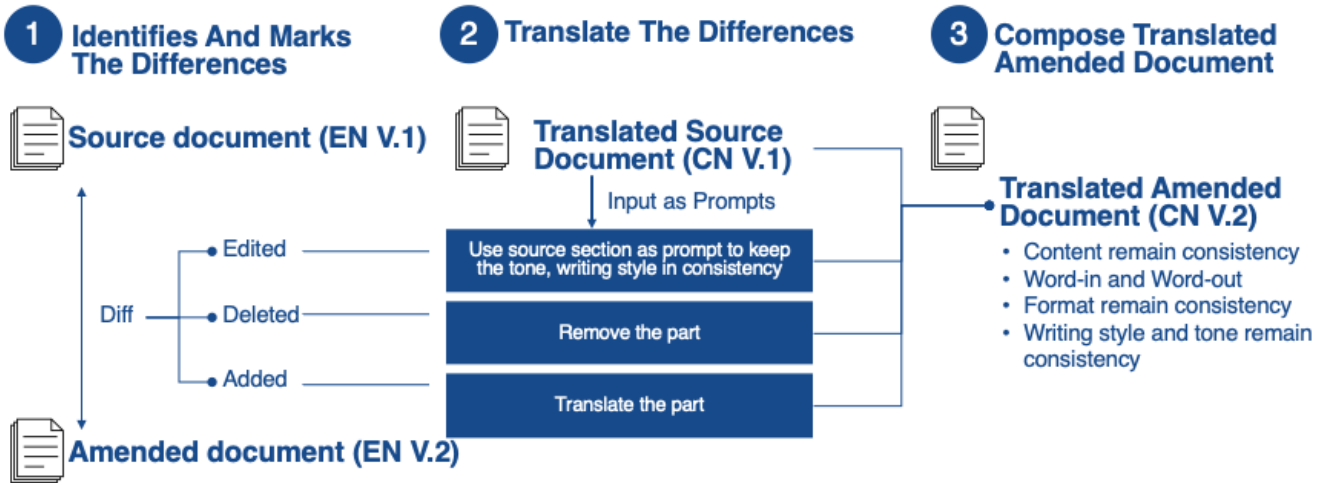
Generative AI-Powered Translation for Medical Authoring

The "AI-Powered Translation for Medical Writing" product streamlines the translation process in clinical documentation, ensuring accuracy and consistency. It harnesses AI for in-text and document translation, with specialized capabilities for tense and aspect conversion, maintaining the original format. Incorporating third-party technologies, it enhances efficiency in building multilingual content libraries for global clinical research, reducing manual review work, and elevating the quality and speed of medical document production.

 <p>In-Text and Document Translation Enhances swift medical translation.</p>	 <p>Differential Translation Streamlined Medical Content Translation</p>
 <p>Translation Memory Boosts Translation Efficiency, Quality</p>	 <p>Format Consistency Preserves Source Document Format</p>
 <p>Extensibility Multilingual Medical Content System</p>	 <p>Comprehensive Platform Automated Document Creation Suite</p>



Ensuring Consistency Across Amendments



Global Reach

Efficiency

Consistency

Streamlining medical writing for clinical trials by ensuring consistent terminology, speeding up the process, improving quality, and reducing costs and manual effort.

- Consistent Language
- Faster Work
- Improves with Use
- Saves Money
- Easy Setup
- Less Reviewing

Use Case 1

Generate TFL summary

Table 10.1.1.1 Demographic Summary

	Placebo (N=160)	Treatment Group (N=158)	Total (N=318)
Sex			
n	160	158	318
Male	85 (53%)	88 (56%)	173 (54%)
Female	75 (47%)	70 (44%)	145 (46%)
Age			
n	160	158	318
Mean	53.1	51.9	52.5
SD	12.5	11.23	12.01
Median	51	53	52
Min.	22	25	22
Max.	81	84	84
Age Group			
n	160	158	318
18-<40	53(33%)	37(23%)	90(28%)
40-<65	88(55%)	85(54%)	173(55%)
>=65	19(12%)	36(23%)	55(17%)
Race			
n	160	158	318
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	160(100%)	158(100%)	318(100%)
BLACK OR AFRICAN AMERICAN	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
WHITE	0	0	0
Height (cm)			
n	160	158	318
Mean	171.2	172.1	171.6
SD	12.5	11.3	11.9
Median	170	171	170.8

Using ChatGPT directly

- You are a clinical medical writer working on CSR. You need to write data summary and interpretation for the demographic data.
- Please draft a summary based on the data.**

Conclusion generated by ChatGPT



ChatGPT

The demographic summary for the clinical study, as detailed in Table 10.1.1.1, encompasses data from 318 participants, divided nearly equally between the placebo group (N=160) and the treatment group (N=158). The gender distribution across both groups was slightly male-dominated, with a combined total of 173 (54%) males and 145 (46%) females. Age metrics showed a mean age of 52.5 years across the cohort, with a standard deviation of 12.01 years, reflecting a broad age range from 22 to 84 years. The majority of participants (55%) were aged between 40 and <65 years. Notably, the entire study population identified as Asian, showcasing a homogeneous racial composition. Physical measurements indicated an average height of 171.6 cm and an average weight of 71.73 kg, leading to a mean Body Mass Index (BMI) of approximately 26.06 kg/m². This demographic snapshot provides a foundational understanding of the study's participant base, indicating a diverse age range within a specific racial group, with balanced gender distribution and a slightly overweight average BMI according to World Health Organization standards.

1

2

3

4

- Inaccurate summary:** Replace "divided equally between groups" with "Inter-group balance" for clarity
- Unprofessional expressions:** Adopt the "mean (min-max)" format for precision
- Key Insight Overlooked:** Verbose expression, but missing the pivotal feature of "homogeneity" within the data
- Speculative conclusion:** Undue extrapolation beyond the reasonable scope of available data



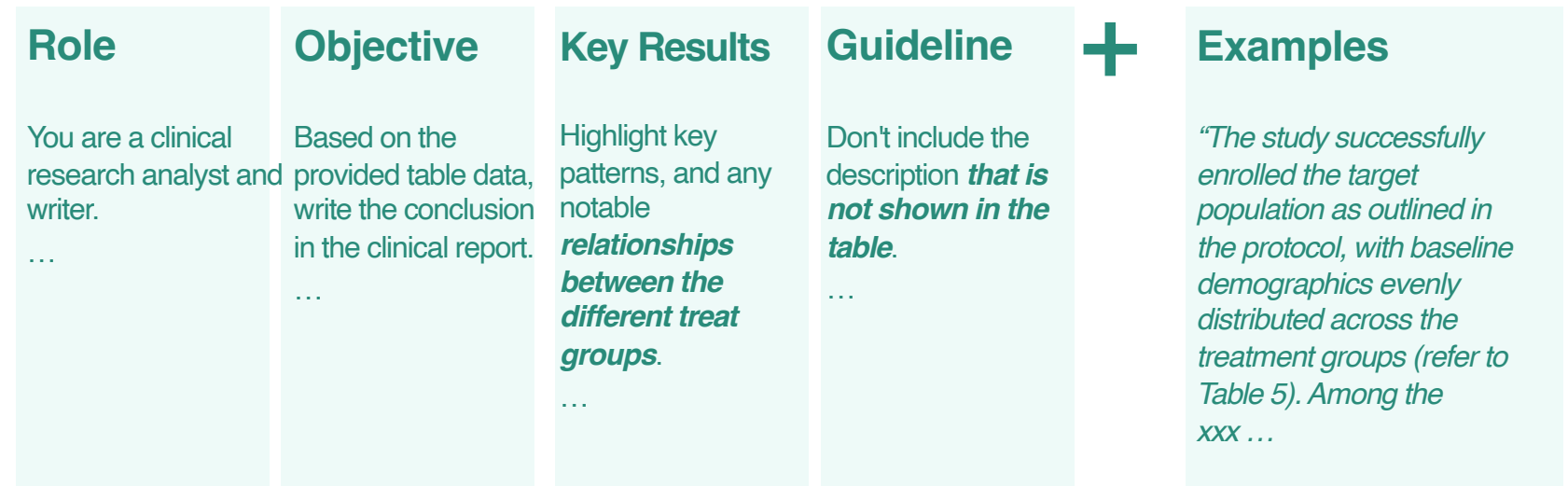
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NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
WHITE	0	0	0
Height (cm)			
n	160	158	318
Mean	171.2	172.1	171.6
SD	12.5	11.3	11.9
Median	170	171	170.8

Using Aurora Trial AI



Conclusion generated by Aurora Trial AI

The study successfully enrolled the target population as outlined in the protocol, with baseline demographics evenly distributed across the treatment groups. Among the 318 participants, a balanced 54% were male, and the median age was 52 years (22, 84); 46% were female. An age breakdown by predefined groups indicated that 55% were aged 40-<65 years, 28% were aged 18-<40 years, and 17% were above 65 years. All participants were Asian. The Treatment Group and Placebo group participants are similar in height, weight and BMI. ←

- 1
- 2
- 3

- 1 Accurate summary
- 2 Professional expressions
- 3 Precise and concise
- 4 Conclusion rooted in data without over-extrapolation



Use Case 2

Content Quality Control

The study successfully enrolled the target population as outlined in the protocol, with baseline demographics evenly distributed across the treatment groups. Among the 320 participants, 54% were male, 45% were female, and the median age was 52 years (22, 84). An age breakdown by predefined groups indicates that 55% were aged 40 - <65 years, 29% were aged 18 - <40 years, and 17% were above 65 years. All participants were Asian. The Treatment Group and Placebo group participants are similar in height, weight and BMI.

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Race			
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AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	160(100%)	158(100%)	318(100%)

Using ChatGPT directly

- You are a medical writer writing CSR. You are playing the role to QC the consistency and logic between the summary and data.
- Please review the summary and data, conclude issues if any.**

ChatGPT-generated result

ChatGPT

Based on the provided summary and data, there are a few inconsistencies and logical issues that need to be addressed:

- ✗** The summary states that the median age is 52 years, but the data shows different median ages for the Placebo (51 years) and Treatment Group (53 years), with a combined median of 52 years.
- ✓** The age group breakdown percentages in the summary do not match the data provided. According to the data, 28% were aged 18-<40 years, not 29% as stated in the summary.
- ✗** The summary indicates that all participants were Asian, which is consistent with the data.
- ✓** There's an inconsistency with the total number of participants: the data table lists N=318, while the summary mentions 320 participants.
- ✗** The summary does not mention the differences in BMI means between the Treatment Group and the Placebo group, which is significant according to the data (Treatment Group Mean = 26.421 vs. Placebo Mean = 24.613).
- ✗** There is a minor discrepancy in the minimum height reported. The summary indicates the participants are similar in height, but the data shows a slight difference in the minimum height (Placebo Min. 149 cm, Treatment Group Min. 152 cm).

These points should be reviewed and corrected to ensure consistency and accuracy in the clinical study report.

✗ Overlooked: "45% were female"



Use Case 2

Content Quality Control

The study successfully enrolled the target population as outlined in the protocol, with baseline demographics evenly distributed across the treatment groups. Among the 320 participants, 54% were male, 45% were female, and the median age was 52 years (22, 84). An age breakdown by predefined groups indicates that 55% were aged 40 - <65 years, 29% were aged 18 - <40 years, and 17% were above 65 years. All participants were Asian. The Treatment Group and Placebo group participants are similar in height, weight and BMI.

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AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	160(100%)	158(100%)	318(100%)

Using Aurora Trial AI

Key Results

Judge if the original report is reasonable according to the table.

...

Steps **

- Analyze the original summary to **understand its focus**.
- Check if the original conclusion is in accordance with the table data, and give the reason.

Use the following JSON format for output:

```
{"pass": true, "reason": "No discrepancies found."}
```

```
{"pass": false, "reason": "Found discrepancies: \n1. "}
```

- ...

Aurora Trial AI-generated result

The study successfully enrolled the target population as outlined in the protocol, with baseline demographics evenly distributed across the treatment groups. Among the **320** participants, 54% were male, **45%** were female, and the median age was 52 years (22, 84). An age breakdown by predefined groups indicates that 55% were aged 40 - <65 years, **29%** were aged 18 - <40 years, and 17% were above 65 years. All participants were Asian. The Treatment Group and Placebo group participants are similar in height, weight and BMI.

Demographic Summary --结论检查--

► 分析过程

结果

Found discrepancies:

- The total number of participants is 318, not 320 as stated in the report.
- The percentage of female participants is 46%, not 45% as stated in the report.
- The percentage of participants aged 18-<40 years is 28%, not 29% as stated in the report.



Thank You

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