AlphaLife Sciences

World Leading GenAI-Powered Clinical Research Solutions

Supported by top innovation organizations

Johnson & Johnson INNOVATION | JLABS   NVIDIA. INCEPTION PROGRAM   Microsoft   Microsoft for Startups   Pegasus Program   Google for Startups

Global Leaders in Computer and Life Sciences Unite

Global Network and Support

- Delaware
- San Francisco
- Singapore (HQ)
- Shanghai
- Beijing
- Taipei

Leadership Team

Sharon Chen
CEO
Google verily

Murali Krishnam
SVP, GTM Strategy and Operation
saama

Pengcheng Xu
CTO
Google verily

Bogong Zhu
CPO
Google verily

Alice Hsu
SVP, Clinical Technology Services
IQVIA
Fortrea

Gavin Zhang
CBO
medidata
Microsoft

Supported by global innovation organizations

Johnson & Johnson INNOVATION | JLABS

Microsoft — Microsoft for Startup Pegasus Program

Google for Startups

NVIDIA INCEPTION PROGRAM

Advisory Board

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

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
RemeGen
CDE FDA

Kun He
CEO and Chief Statistician of R&G; Former Associate Division Director of the Division of Biometrics V at CDER, FDA (yr. 1999-2018)
R&G
FDA

About Company

AlphaLife Sciences leads AI-driven clinical research with our GenAI-powered SaaS platform. Supported by Microsoft, Google, JLABS, and Nvidia, and trusted by top pharma companies, we deliver advanced medical writing and data management solutions to accelerate drug development.

Selected Customers and Qualified Vendor List

AstraZeneca · GSK · Johnson&Johnson

MSD · CSPC · RemeGen BIOSCIENCES

BeiGene · Insilico Medicine · IMPACT THERAPEUTICS

IQVIA · ICON · parexel

Certificates for Compliance

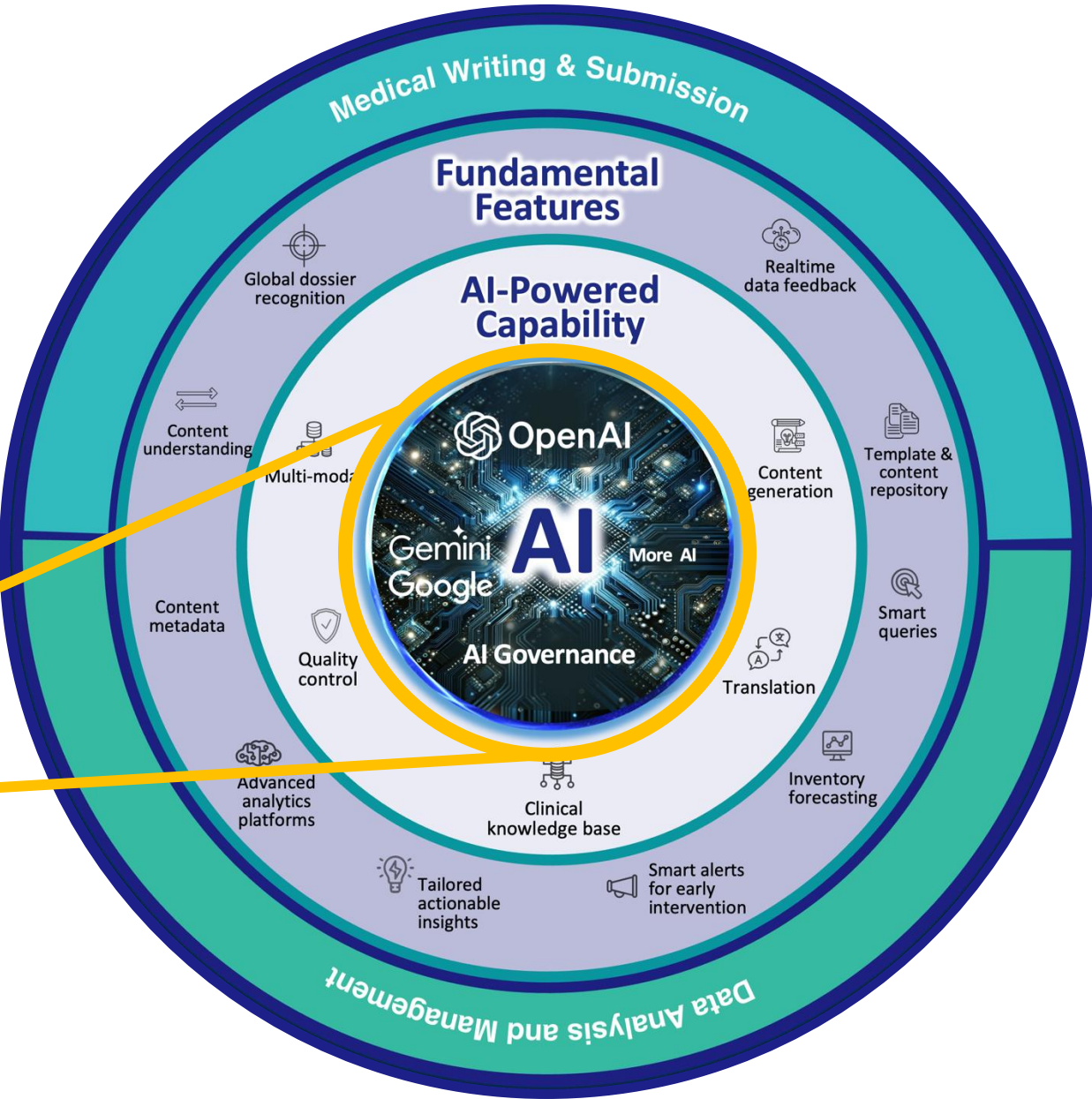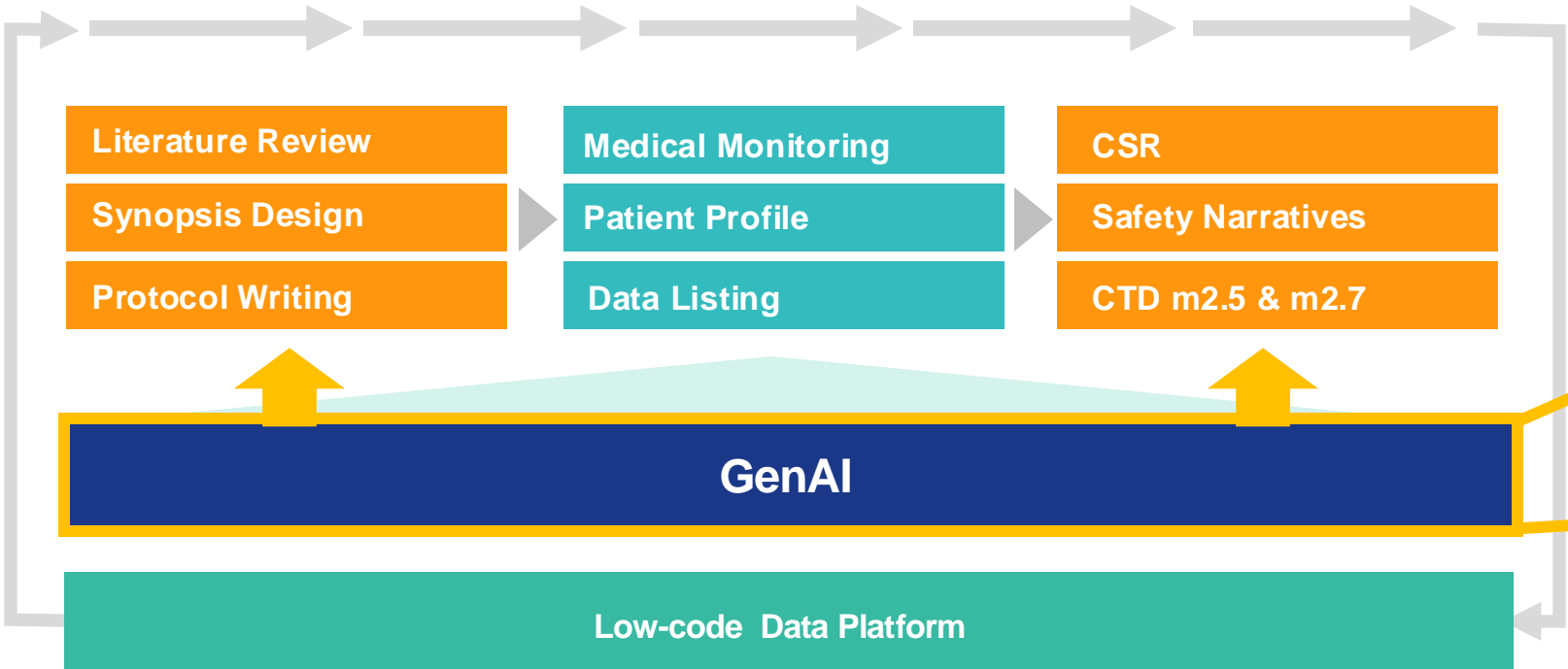FDA 21 CFR Part 11 · HIPAA COMPLIANT · GDPR · AICPA SOC / SOC 2 Type II · ISO 9001 · ISO 27001

Challenges in Clinical Development & Opportunities with GenAI

Accelerating Clinical Trials with GenAI-Powered Medical Writing Solutions

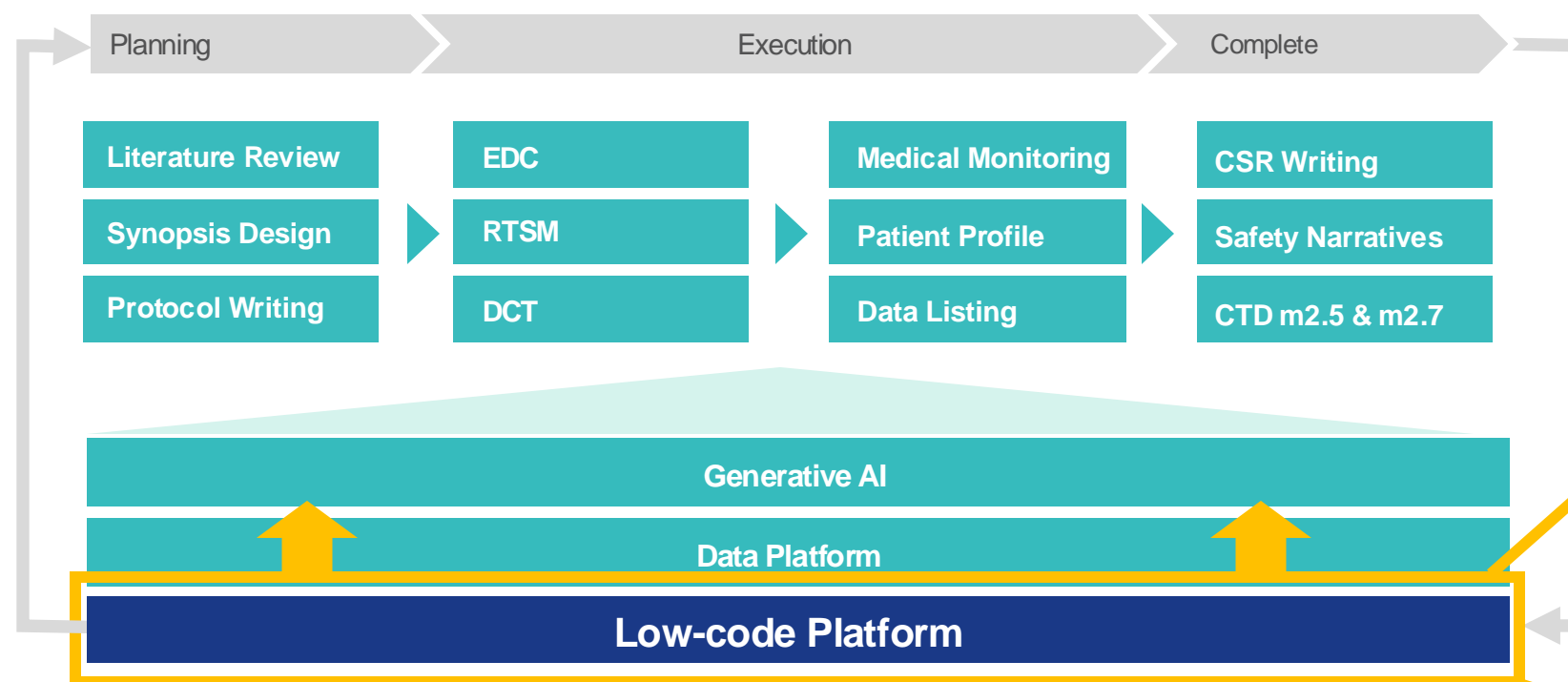**AuroraPrime**

GenAI-Powered Clinical Trial Platform

Literature Review	Medical Monitoring	CSR
Synopsis Design	Patient Profile	Safety Narratives
Protocol Writing	Data Listing	CTD m2.5 & m2.7

GenAI

Low-code Data Platform

Medical Writing & Submission

Fundamental Features

AI-Powered Capability

Global dossier recognition

Realtime data feedback

Content understanding

Multi-modal

Content generation

Template & content repository

Content metadata

Quality control

Smart queries

Translation

Advanced analytics platforms

Clinical knowledge base

Inventory forecasting

Tailored actionable insights

Smart alerts for early intervention

OpenAI

Gemini Google

AI

More AI

AI Governance

Data Analysis and Management

Powerful low-code platform enables rapid iteration and development of new applications to support critical business cases.

AuroraPrime

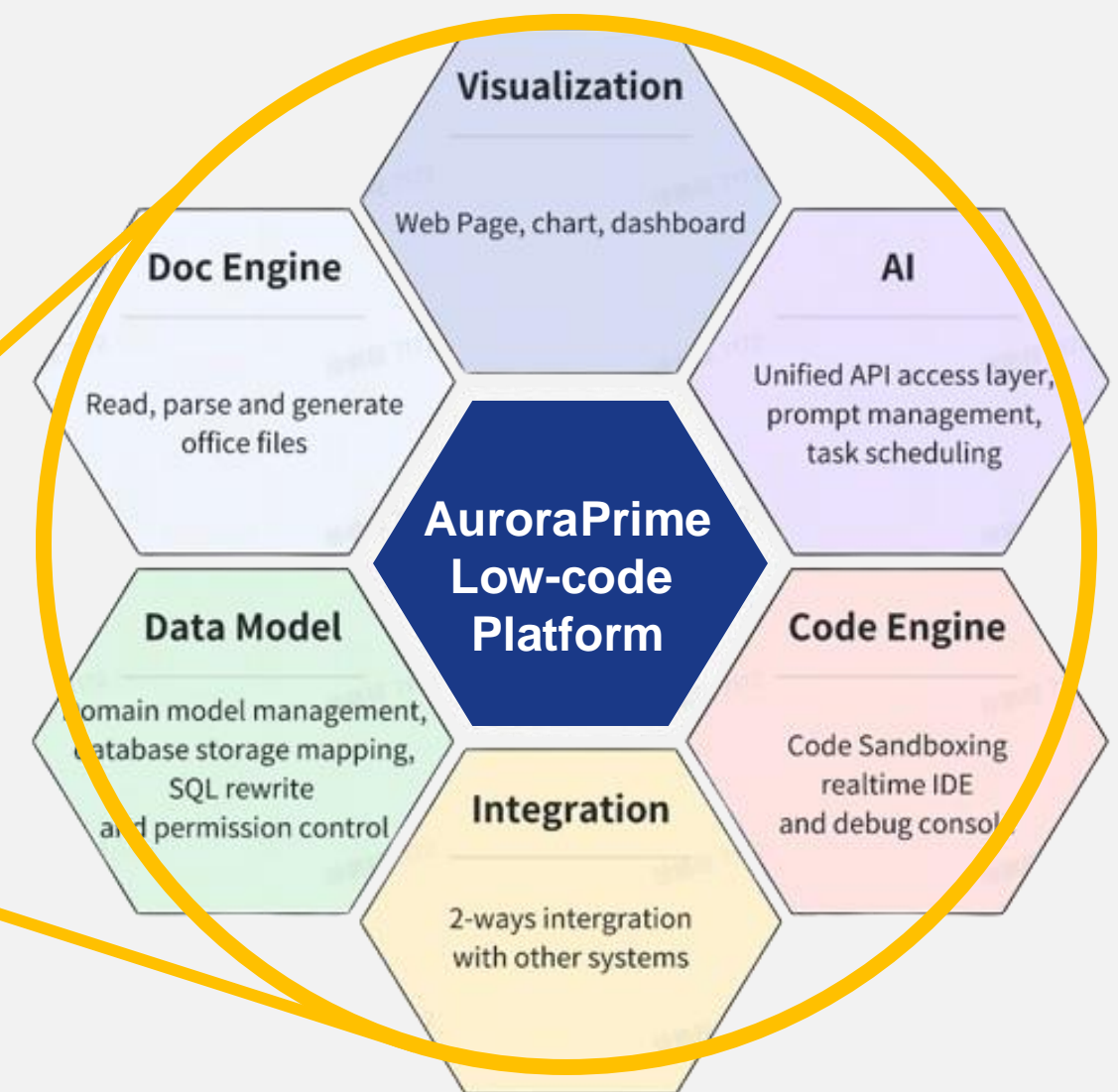### Leading Low-code, Agile, Feature-rich Platform

Planning	Execution	Complete

Literature Review	EDC	Medical Monitoring	CSR Writing
Synopsis Design	RTSM	Patient Profile	Safety Narratives
Protocol Writing	DCT	Data Listing	CTD m2.5 & m2.7

Generative AI

Data Platform

Low-code Platform

Speed & Agility
Rapidly develop and deploy applications.

Flexibility
Easily customize and integrate systems.

Scalability
Quickly scale to manage data complexity.

Examples of applications built on the low-code platform

Literature Review	Medical Monitoring	Data Listing	ICSR Extraction
Synopsis Design	Data Monitoring	Patient Profile	Medical Translation

Visualization
Web Page, chart, dashboard

Doc Engine
Read, parse and generate office files

AI
Unified API access layer, prompt management, task scheduling

AuroraPrime Low-code Platform

Data Model
Domain model management, database storage mapping, SQL rewrite and permission control

Code Engine
Code Sandboxing realtime IDE and debug console

Integration
2-ways intergration with other systems

Fully Compliant with GCP/GxP and Trusted Data Security

Regulatory Certifications

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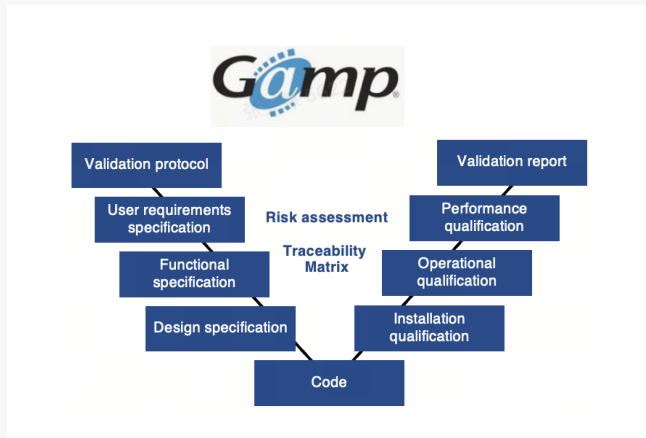

FDA 21 CFR Part 11

HIPAA COMPLIANT
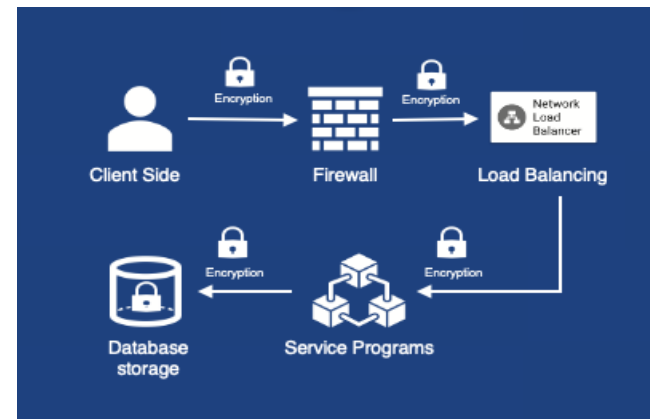
CERTIFIED ISO 9001:2015 COMPANY — ISO 9001

CERTIFIED ISO 27001:2022 COMPANY — ISO 27001

GDPR

AICPA SOC — 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.

Gamp

- Validation protocol
- Validation report
- User requirements specification
- Performance qualification
- Risk assessment
- Traceability Matrix
- Functional specification
- Operational qualification
- Design specification
- Installation qualification
- Code

Trusted Data Security

- **Token Security:** Certified hardware encryption (HSM) ensures secure user and service tokens.
- **End-to-End Encryption:** Adheres to zero trust principles, securing both data streams and storage.
- **Account Security:** SSO support, Role-Based Access Control, and VPN-compatible IP restrictions ensure stringent access control.
- **Data Backup:** Real-time database sync, daily backups, offsite storage, and rigorous recovery protocols.

Client Side — Encryption — Firewall — Encryption — Network Load Balancer (Load Balancing)

Database storage — Encryption — Service Programs — Encryption
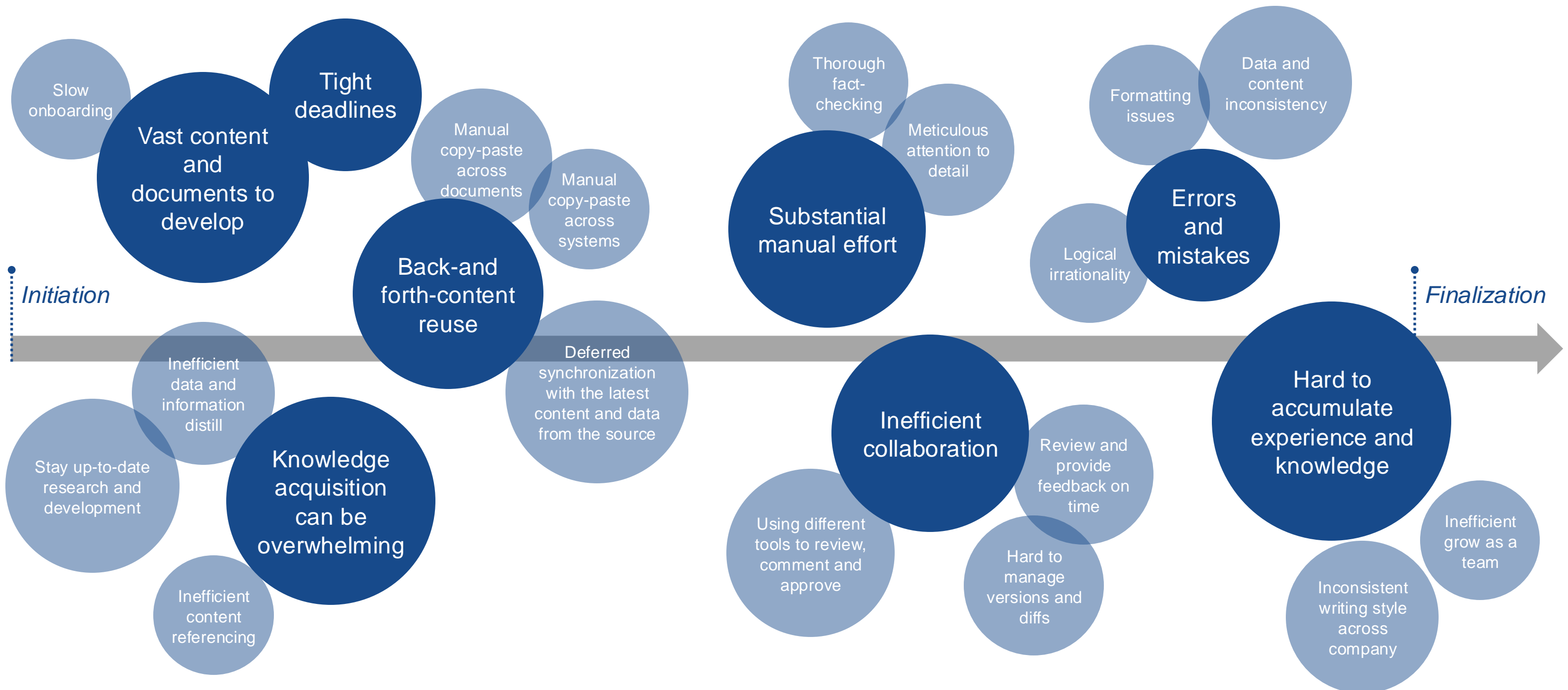
Regulation-Compliant SOPs

- **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.

GenAI-Powered Medical Writing Solutions

Medical writers encounter fragmented obstacles while orchestrating content

Slow onboarding

Tight deadlines

Vast content and documents to develop

Manual copy-paste across documents

Manual copy-paste across systems

Initiation

Inefficient data and information distill

Back-and forth-content reuse

Deferred synchronization with the latest content and data from the source

Stay up-to-date research and development

Knowledge acquisition can be overwhelming

Inefficient content referencing

Thorough fact-checking

Meticulous attention to detail

Substantial manual effort

Formatting issues

Data and content inconsistency

Logical irrationality

Errors and mistakes

Finalization

Inefficient collaboration

Review and provide feedback on time

Using different tools to review, comment and approve

Hard to manage versions and diffs

Hard to accumulate experience and knowledge

Inefficient grow as a team

Inconsistent writing style across company

Gen-AI Co-piloted Protocol Research, Design and Writing

AuroraPrime

1
AI-Assisted Literature Review

Literature Review

Accelerated by AI

1. AI accelerates literature reviews by auto-retrieving data from sources. **AI**

2. Auto-process and standardize unstructured and structure data **AI**

3. Easy-adds & configures data visualization to various TA/DA. **AI**

2
AI-Assisted Protocol Synopsis Design

Synopsis Storyline

Accelerated by AI

1. Auto-searches literatures, conducts in-depth reading and recommends key elements and SOA **AI**

2. Auto-review and assessed handwritten synopsis **AI**

3
AI-Assisted Protocol Writing

Protocol

Accelerated by AI

1. Auto-fills in the protocol template based on the provided protocol synopsis. **AI**

2. Creates a comprehensive list of abbreviations used throughout the protocol. **AI**

3. Auto-generates SoA table and description **AI**

GenAI-Copiloted Protocol Writing Solution

Streamline protocol writing with GenAI: auto-generate full protocol draft, auto-refine grammar and style, and auto-cross-check efficiently to save significant time.

Word Add-in Solution
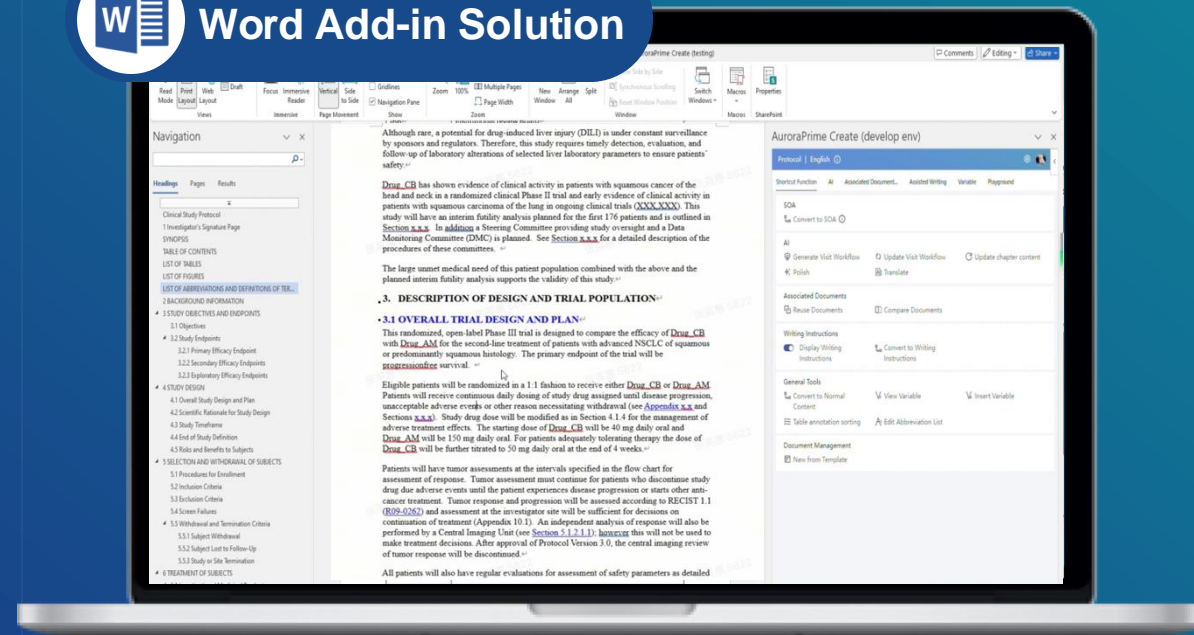
Auto-Generate the First Full Protocol Draft.

1. **Auto-Populate Content:**
   Auto-fill in the protocol based on the provided synopsis.
   GenAI

2. **Auto-Generate Abbreviations:**
   Auto-create a comprehensive list of abbreviations.
   GenAI

3. **Auto-Generate SoA**
   GenAI

Smart Template
- Custom enterprise adaptability
- Leverage external insights
- Content recommendation

Knowledge Library
- M11 template structures
- Style & variables management
- SOP guidelines

Our GenAI solution drastically reduces time in full protocol writing.

1 **First Draft Creation** — auto-generating the first protocol draft from the synopsis.
45% Time Reduction

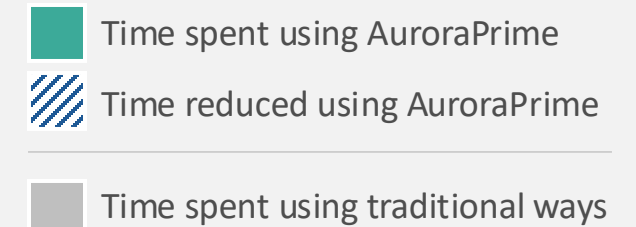2 **Content Adjustment** — automated grammar, style, and formatting refinements
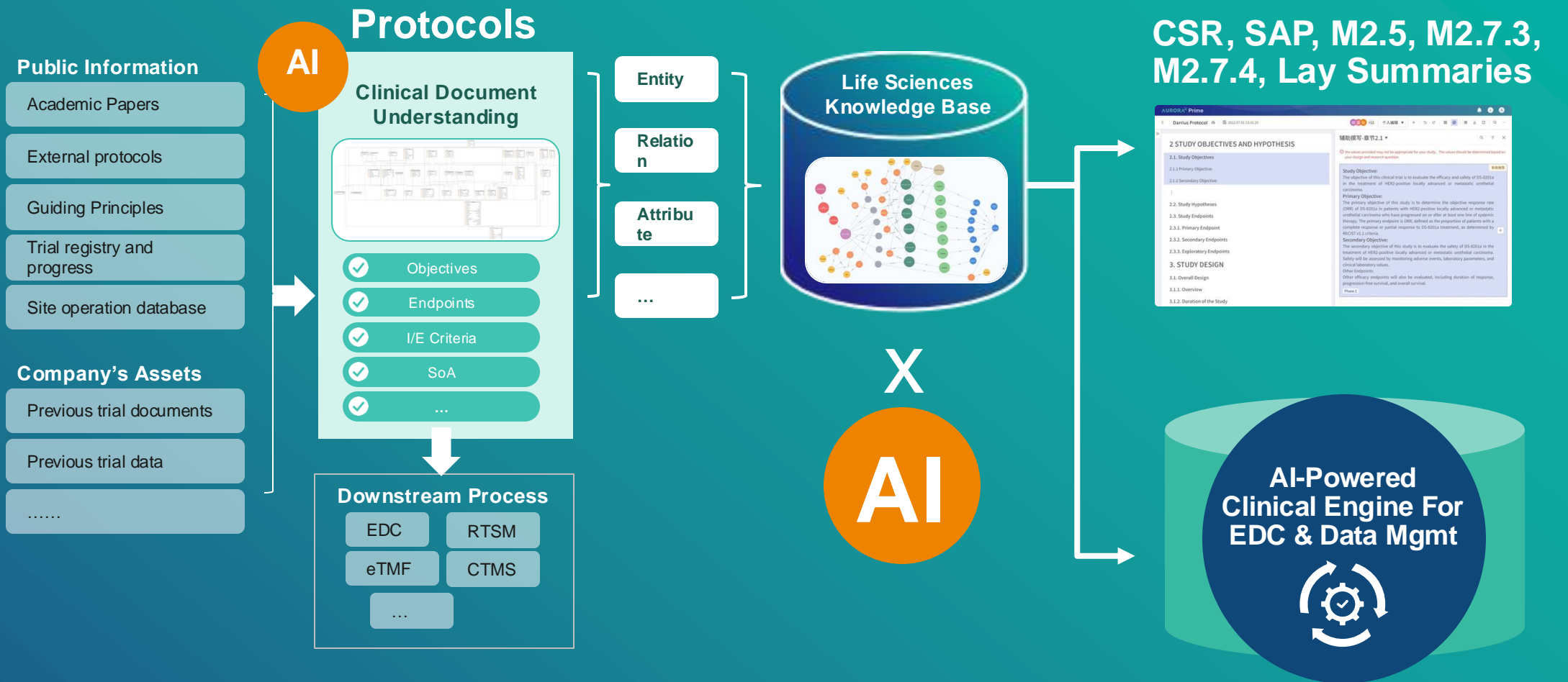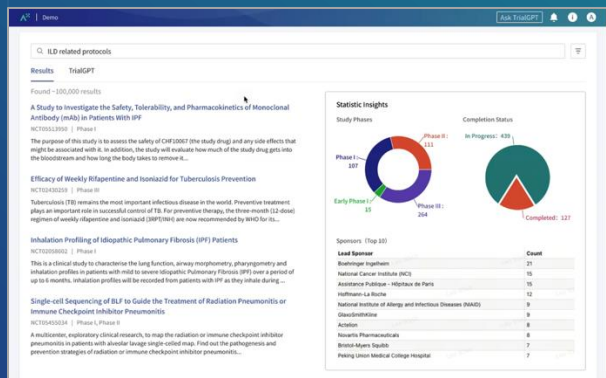**90%** Time Reduction

3 **Cross-Check Procedure** — automatic cross-checks between synopsis and full protocol.
70% Time Reduction

- Time spent using AuroraPrime
- Time reduced using AuroraPrime
- Time spent using traditional ways

GenAI-Powered Clinical Knowledge Base: Protocol Case Study

Empowering Clinical Trials with AI-Powered Life Sciences Knowledge Base for Accelerated Success

Public Information
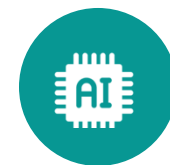- Academic Papers
- External protocols
- Guiding Principles
- Trial registry and progress
- Site operation database

Company's Assets
- Previous trial documents
- Previous trial data
- ....

AI

Protocols

Clinical Document Understanding
- ✓ Objectives
- ✓ Endpoints
- ✓ I/E Criteria
- ✓ SoA
- ✓ ...

- Entity
- Relation
- Attribute
- ...

Downstream Process
- EDC
- RTSM
- eTMF
- CTMS
- ...

Life Sciences Knowledge Base

X

AI

CSR, SAP, M2.5, M2.7.3, M2.7.4, Lay Summaries

AI-Powered Clinical Engine For EDC & Data Mgmt

BENEFITS
- Enhanced Data Integrity
- Streamlined Knowledge Access
- Intelligent Content Analysis
- Robust Knowledge Integration
- Advanced Search & AI Insights
- Automated Content Generation

GenAI-Copiloted CSR Writing Solution

Accelerate CSR with GenAI: automated content, seamless Word integration, accelerated processes, and revenue growth.

80% CSR First Draft time reduction

DBL

1. Setup Template
- Easy Template Setup
- Flexible Configuration for TAs

2. Develop Mock CSR
- Auto-refer to Protocol & SAP
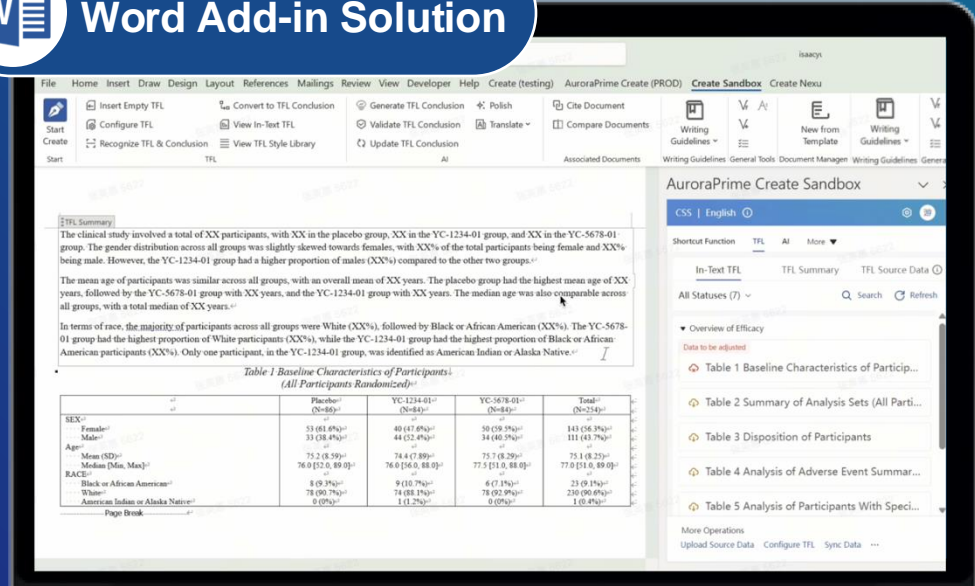- Auto-insert TFL Mock Shell

3. Draft CSR
- Auto-generate TFL Summary
- Auto-update TFL & Summary

4. Review & Finalize
- Auto-check Quality
- Integrate with RIM & Microsoft 365

Gen-AI Automation	Efficiency Boost
Quality Assurance	Seamless Integration

Word Add-in Solution

GenAI-Powered Automation

1. Auto-populate SAP and Protocol content into data-independent sections. **GenAI**

2. Auto-insert in-text TFLs, keeping them synchronized with their source files. **GenAI**

3. Auto-generate TFL summaries and maintain synchronization with TFL data. **GenAI**

Accelerate Revenue

"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

Reduce Cost

**$2.6B** estimated development cost of a single drug over 10 years = **$700K+/day** ($21M+/month)

Tufts Center for the Study of Drug Development clinicalresearch.io

GenAI-Copiloted Safety Narratives Solution

Automatically delivers precise drafts, streamlines processes, and ensures consistent, high-quality safety narratives.
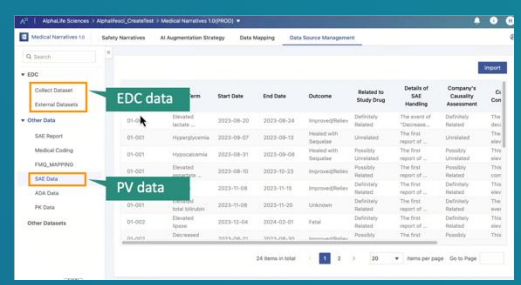
AuroraPrime

Customize Templates AI

1. Enables template customization with rules, examples, and medical coding.
2. Standardizes writing to ensure consistency and quality.
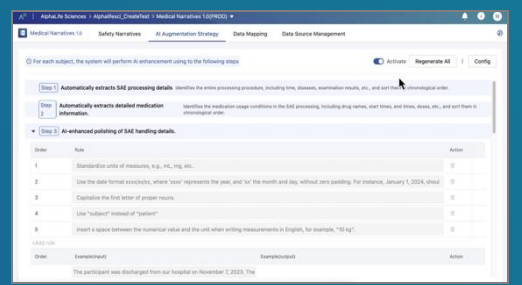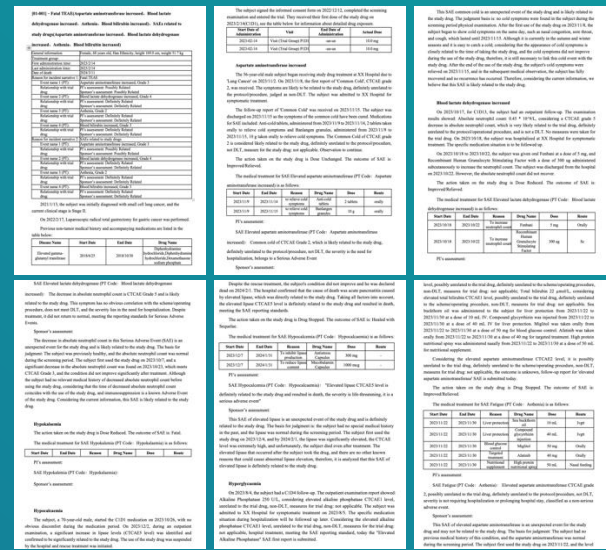
Batch-Generate Narratives AI

1. Auto-generates the first draft in minutes by integrating data from EDC and PV systems.
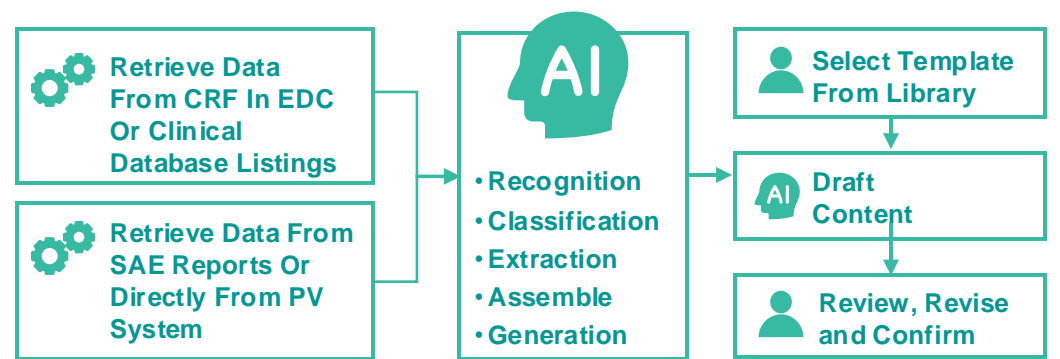2. Configures criteria for streamlined batch generation.

Narratives Completion ✓

Acceleration:

Generate the **first draft** in seconds and **batch drafts** within minutes.

Automation Process

- Retrieve Data From CRF In EDC Or Clinical Database Listings
- Retrieve Data From SAE Reports Or Directly From PV System

AI
- Recognition
- Classification
- Extraction
- Assemble
- Generation

- Select Template From Library
- Draft Content
- Review, Revise and Confirm

Time Reduction Comparison

Compared to manual transcription method
90%
Time Reduction

Compared to traditional programming approach
70%
Time Reduction

- Time spent using traditional ways
- Time spent using AuroraPrime
- Time reduced using AuroraPrime

Thank You

Contact Us   +1 833-429-9852
                Sales@alphalifesci.com

Website   AlphaLifeSci.com

Linkedin   linkedin.com/company/alphalife-sciences/