AlphaLife Sciences

Generative AI-Powered Clinical Research Platform

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

Proud to Partner With

Microsoft | Microsoft for Startups **Pegasus Program** | Google for Startups

⬆ **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."

⬆ **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

Google
verily

Alice Hsu
SVP, Clinical Technology Services
Former Head of Project Management and Clinical Operation, WuXi Clinical; Former PD of Project Management at Covance (Fortrea)

IQVIA
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.

ICON
FRONTAGE

Gavin Zhang
CBO, JAPAC
Former Head of Channel Sales Asia Pacific, Medidata; Former Key Account Solution Sales

medidata
Microsoft

Pengcheng Xu
CTO
The first engineer at Google China Former Architect at Verily China

Google
verily

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

Google
verily

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

vmware
Sun microsystems

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

ORACLE
Veeva

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

RemeGen
CDE FDA

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

cdisc
AstraZeneca

David Kiger
Former VP Strategy at Parexel Former CCO at Bioclinica

parexel
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.
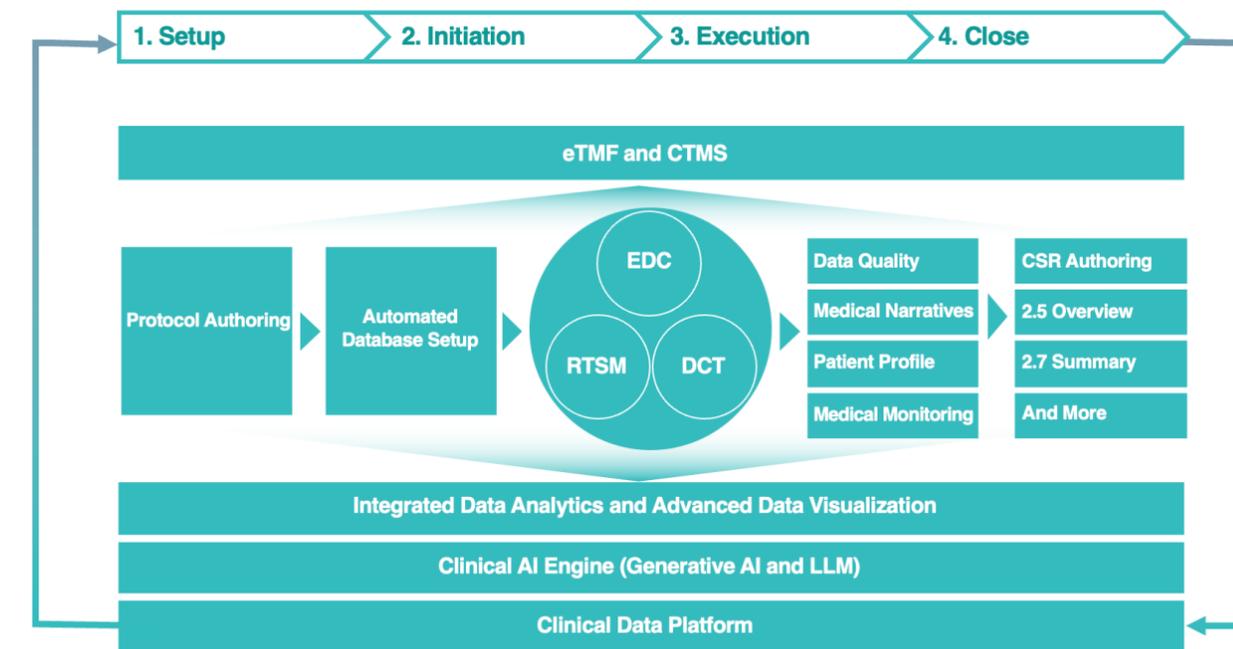
As an authoritative figure in life sciences and consumer health, we are dedicated to propelling AuroraPrime to the forefront of global digital clinical research platforms. Our reliance on the latest AI models, cloud computing, and big data technologies underpins our commitment to providing robust technical 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✕ Prime

AI-Powered End-to-End Clinical Trials

1. Setup	2. Initiation	3. Execution	4. Close

eTMF and CTMS

Protocol Authoring → Automated Database Setup → EDC / RTSM / DCT →

Data Quality	CSR Authoring
Medical Narratives	2.5 Overview
Patient Profile	2.7 Summary
Medical Monitoring	And More

Integrated Data Analytics and Advanced Data Visualization

Clinical AI Engine (Generative AI and LLM)

Clinical Data Platform

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**

GDPR — FDA 21 CFR Part 11 — HIPPA — AICPA SOC 2

ISO 9001 — ISO 27001 — ISO 20000-1 — DJCP

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.

Azure — aws — Google Cloud — Gemini — OpenAI — Alibaba Cloud — ZHIPU·AI

Trusted Data Security

1. **Token-Based Security**
2. **Encrypted Data Streams**
3. **Secure Data Storage**
4. **Robust Account Safety**
5. **Reliable Data Backup**

Client Side → Encryption → Firewall → Encryption → Network Load Balancer / Load Balancing

Database storage ← Encryption ← Service Programs ← Encryption
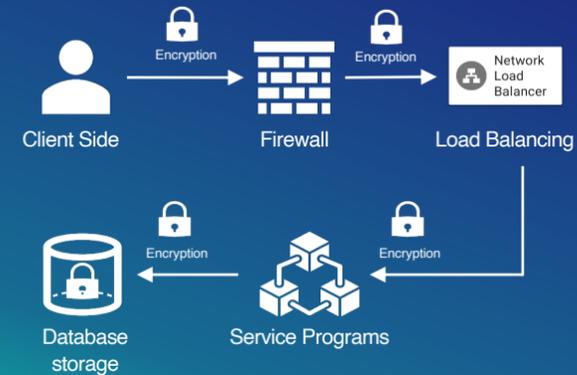
Comprehensive Customer Support

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

AURORA⋇ Prime
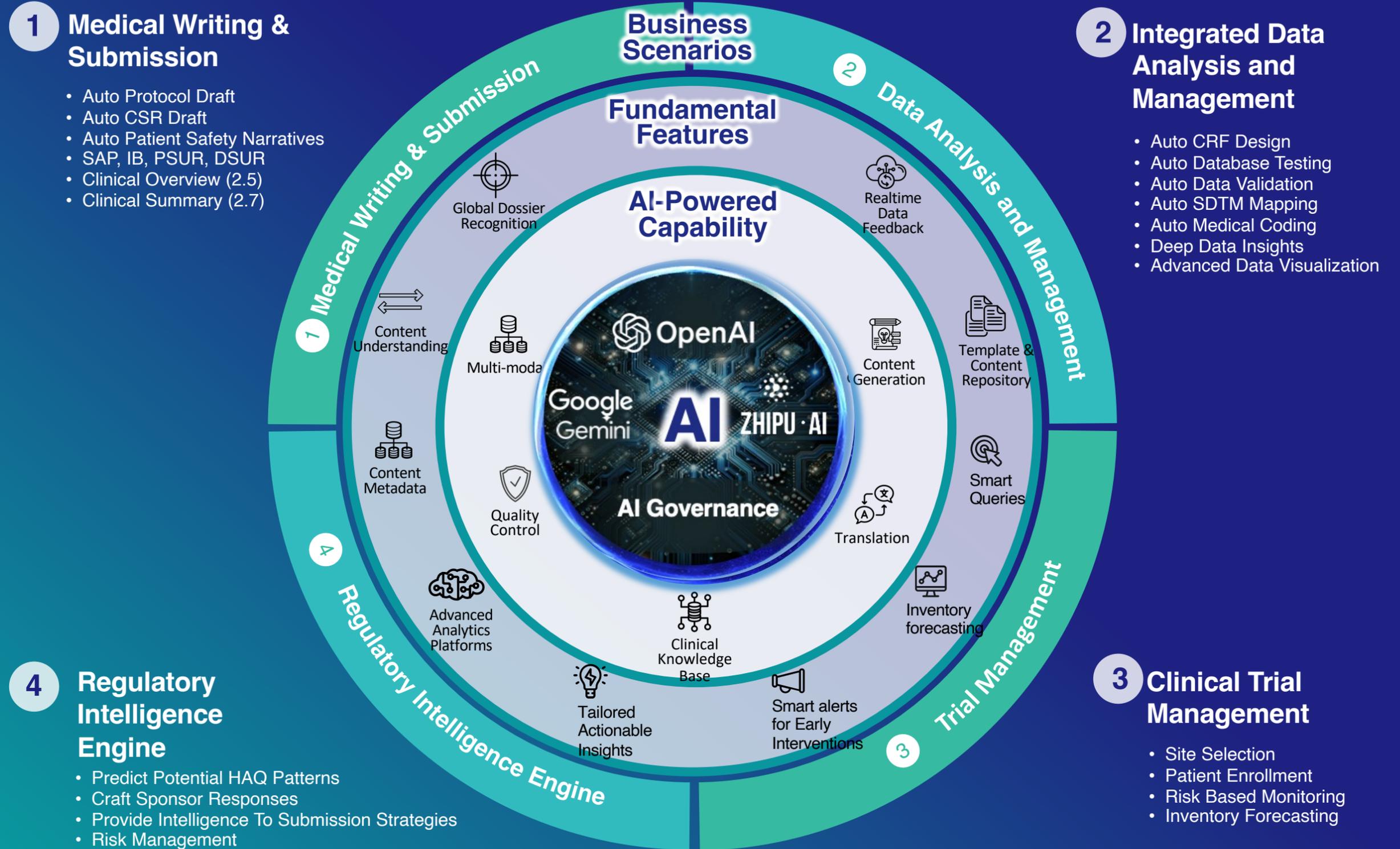
50% Cost Reductions

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

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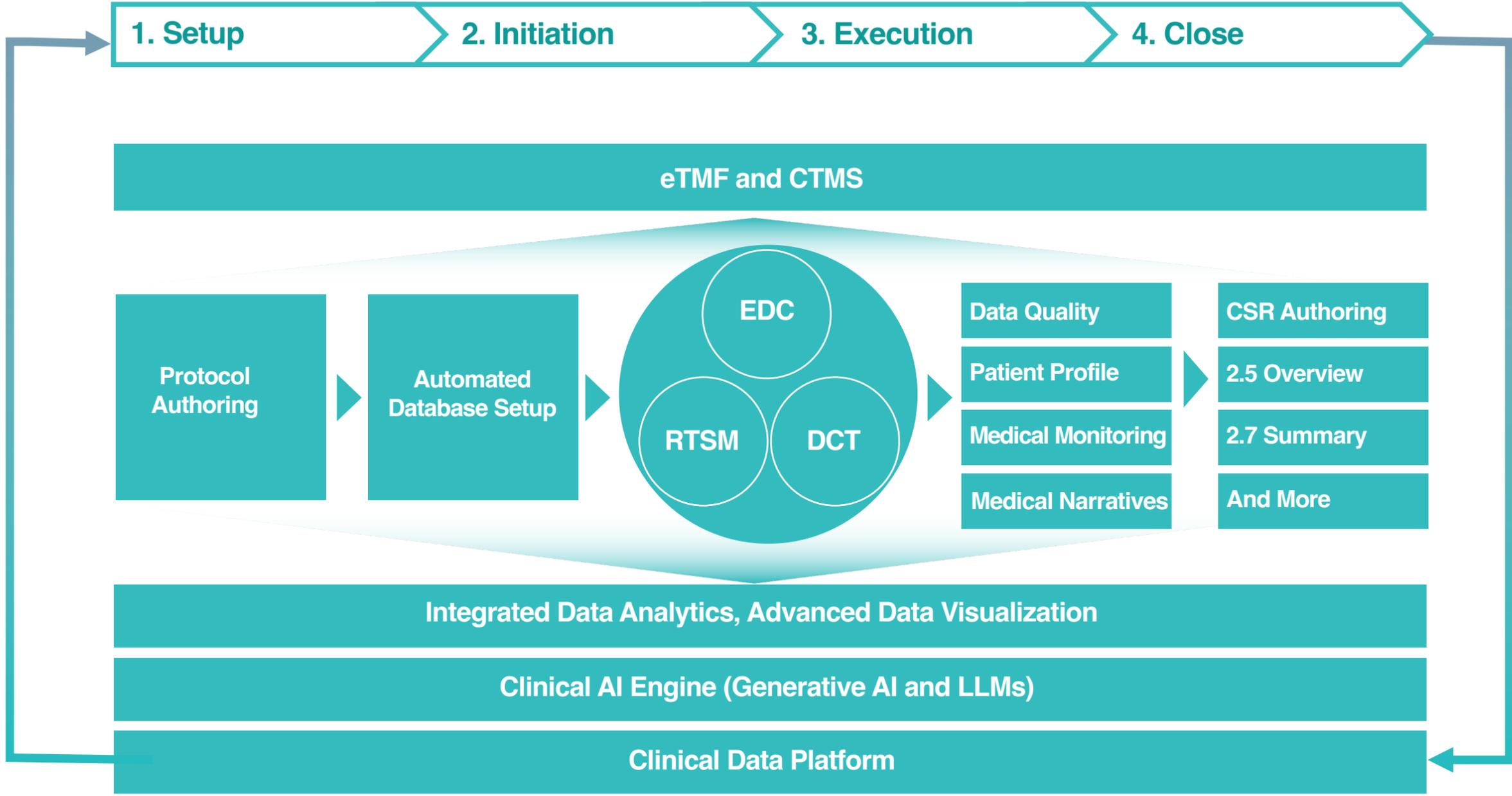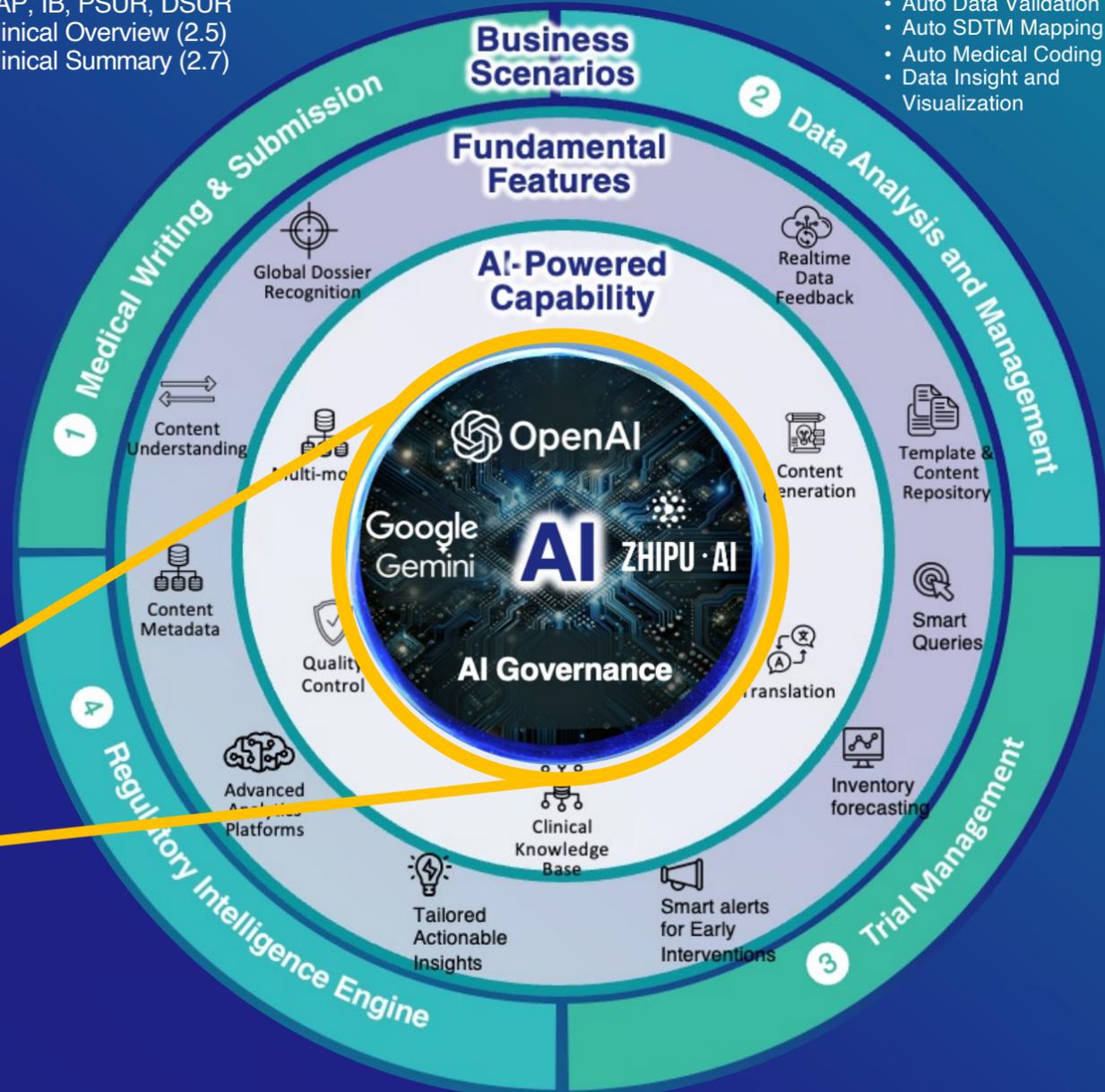
- Auto Protocol Draft
- Auto CSR Draft
- Auto Patient Safety Narratives
- SAP, IB, PSUR, DSUR
- Clinical Overview (2.5)
- Clinical Summary (2.7)

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

Business Scenarios
Fundamental Features
AI-Powered Capability

Medical Writing & Submission
- Global Dossier Recognition
- Content Understanding
- Multi-modal
- Content Metadata
- Quality Control

Data Analysis and Management
- Realtime Data Feedback
- Content Generation
- Template & Content Repository
- Smart Queries
- Translation

Regulatory Intelligence Engine
- Advanced Analytics Platforms
- Clinical Knowledge Base
- Tailored Actionable Insights

Trial Management
- Inventory forecasting
- Smart alerts for Early Interventions

OpenAI
Google Gemini
AI
ZHIPU·AI
AI Governance

5

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

AURORA✕ Prime

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eTMF and CTMS

- Protocol Authoring
- Automated Database Setup
- EDC
- RTSM
- DCT
- Data Quality
- Patient Profile
- Medical Monitoring
- Medical Narratives
- CSR Authoring
- 2.5 Overview
- 2.7 Summary
- And More

Integrated Data Analytics ,Advanced Data Visualization

Clinical AI Engine (Generative AI and LLMs)

Clinical Data Platform
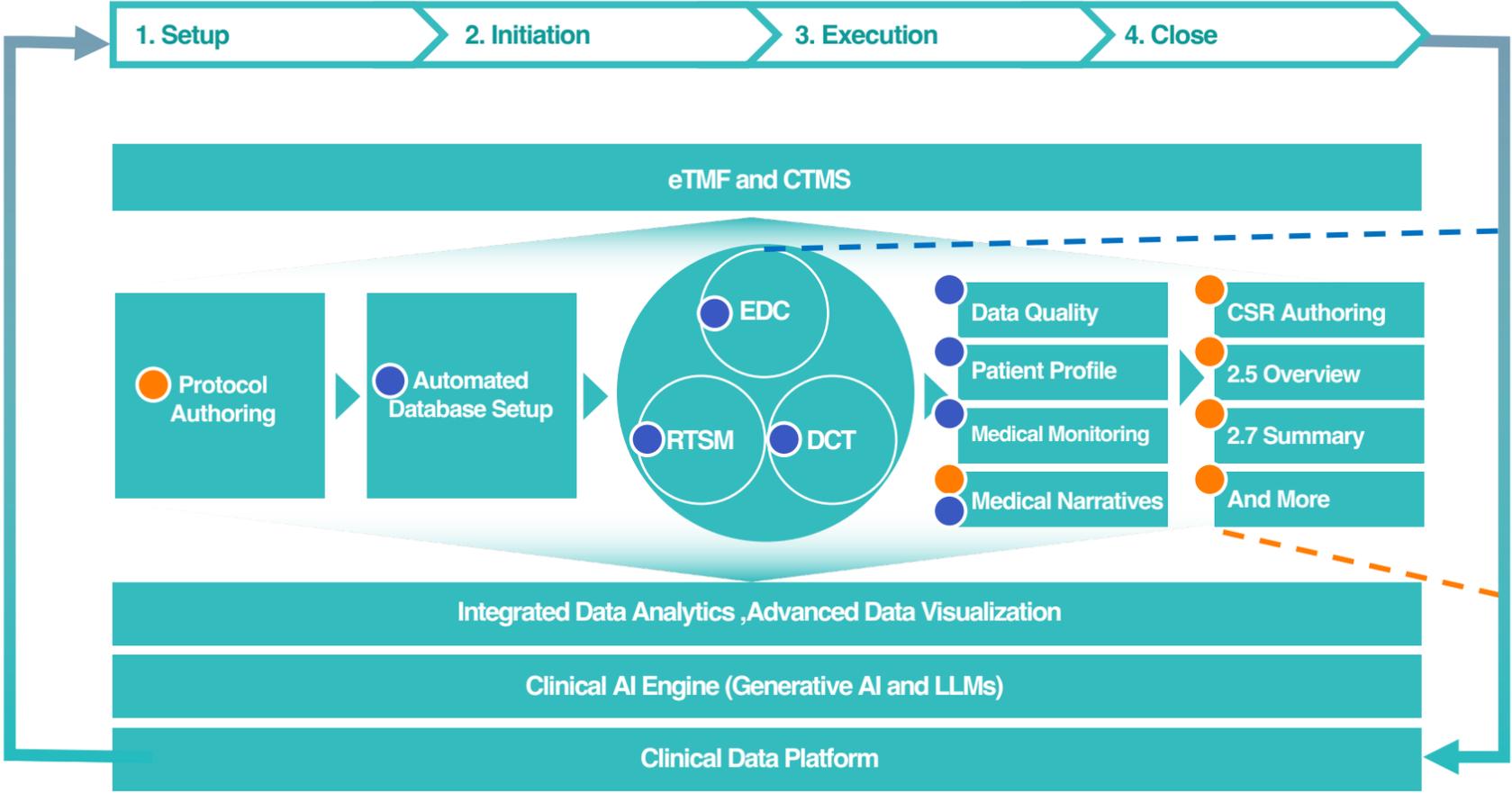
Seamless Document-Data Integration

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.
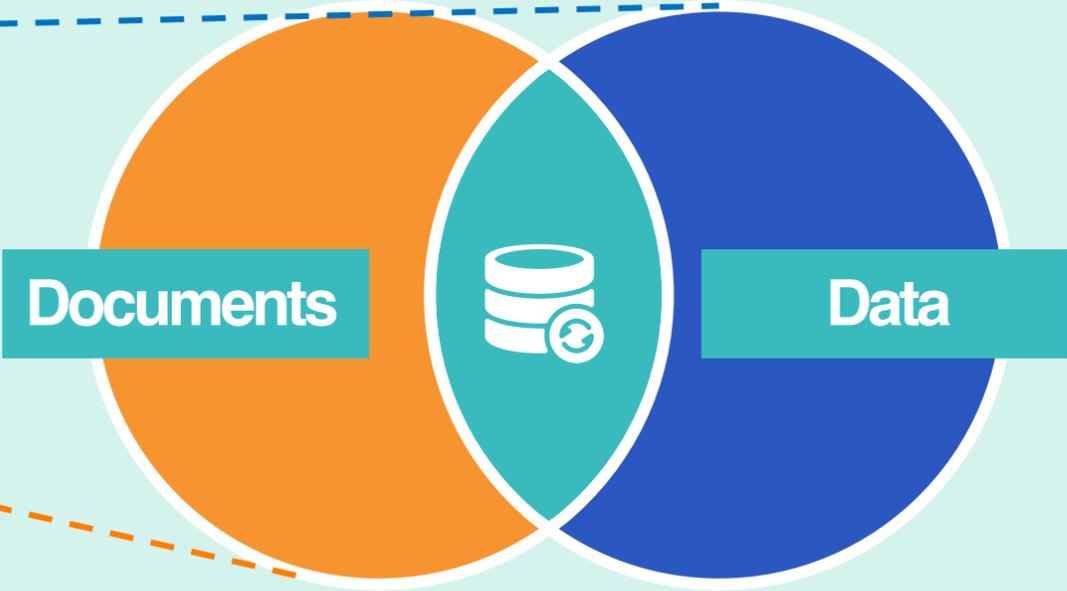
Documents — **Data**

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

AURORA Prime
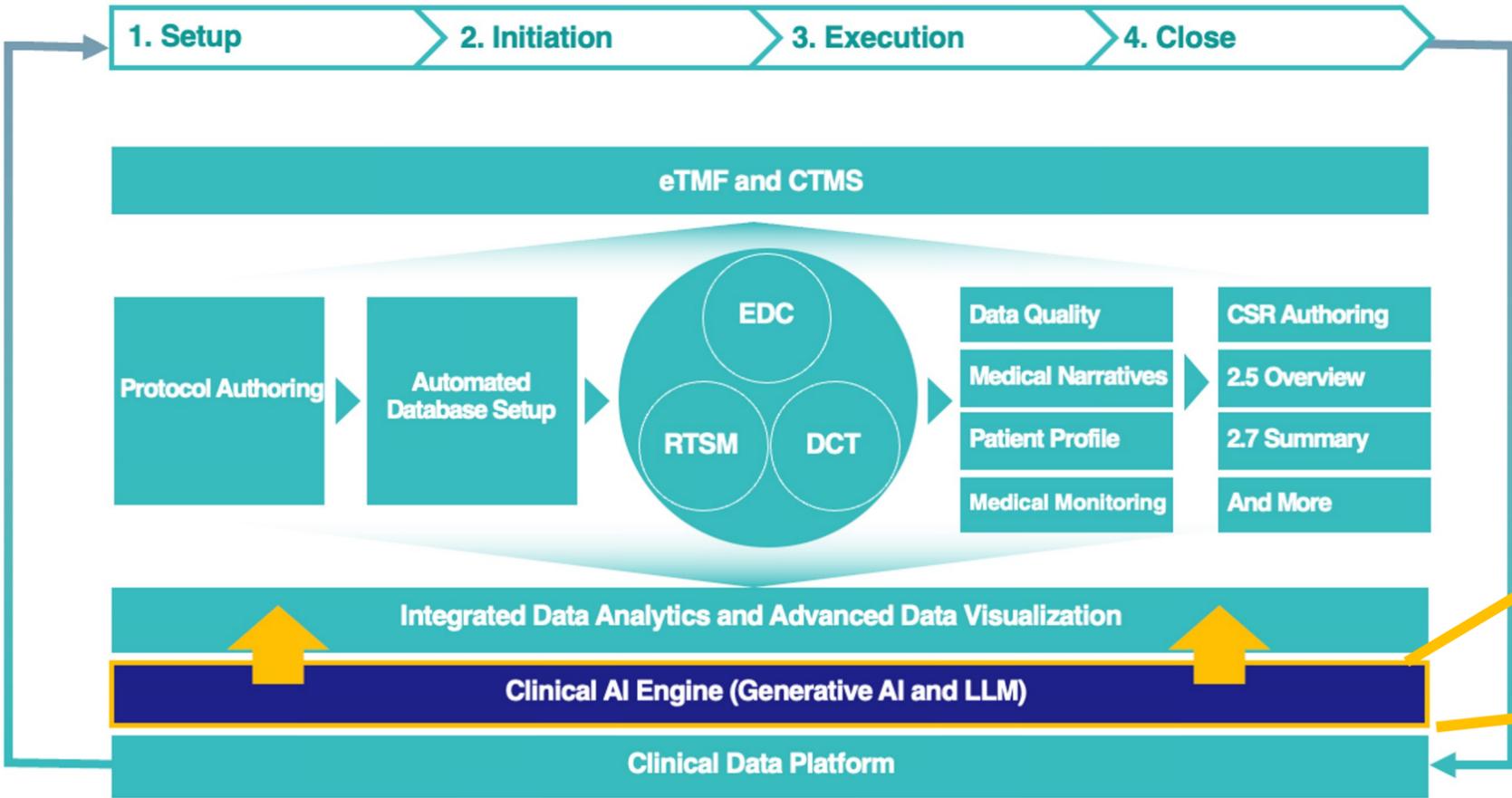
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eTMF and CTMS

Protocol Authoring → Automated Database Setup →

EDC
RTSM DCT

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AURORA 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

Business Scenarios

Fundamental Features

AI-Powered Capability

1 Medical Writing & Submission
2 Data Analysis and Management
3 Trial Management
4 Regulatory Intelligence Engine

Global Dossier Recognition
Realtime Data Feedback
Content Understanding
Multi-mo...
Content Generation
Template & Content Repository
Content Metadata
Smart Queries
Quality Control
Translation
Advanced Analytics Platforms
Clinical Knowledge Base
Inventory forecasting
Tailored Actionable Insights
Smart alerts for Early Interventions

OpenAI
Google Gemini
AI
ZHIPU·AI
AI Governance

Intelligent Data Management Solution for Clinical Trials

Generative AI-Powered:
Automatically Generate logic check from "Data Validation Plan"

End-to-End Optimizations from Data to Knowledge:
Lower Costs, Enhance Efficiencies, Drive Innovations

Process to Achieve Data Intelligence Vision

1
Data Automation and Interoperability
- System Interoperability
- Data Interoperability

2
Data Driven and Insights
- Data Standardization
- Data Accumulation

3
Data and Knowledge Intelligence
- Data to Knowledge
- Data to Experience (know-how)

Maximize Benefits: From Data Silos to Enhanced Knowledge Intelligence

Shorten The Drug's Time To Market.

Reduce Drug R&D Costs

Increase R&D Success Rate

Traditional Database Construction: Complex and Manual

Key Challenges

Complex Integration

Data integration from varied sources demands extensive customization for flow

Data Standardization

Standardization absence complicates mapping, leading to errors, inconsistencies.

Manual Process

Manual data processes are error-prone and significantly time-consuming.

Regulatory Compliance

Database design compliance with evolving regulations is complex, resource-intensive.

Data Quality

Data source variability and potential for inaccurate entries challenge.

Efficiency & Speed

Speeding up construction without sacrificing quality is challenging

Traditional Process

Data Manager	CRF Design	DVP Design	
Database Builder	eCRF Build	Edit-Check Programming	
Quality Controller	UI Verification	Edit-Check Test Plan	Edit-Check Test
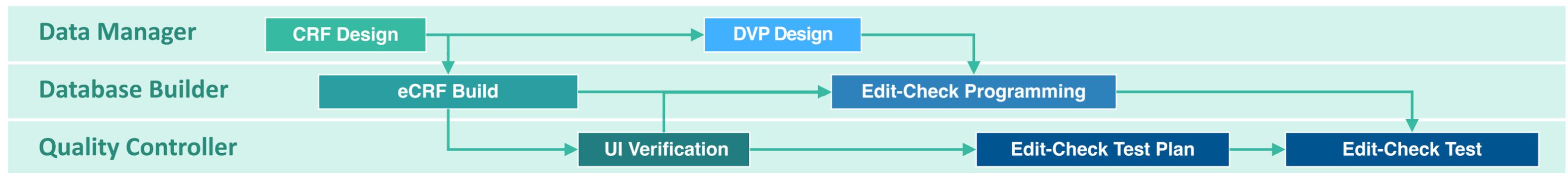
AuroraPrime Accelerates Database Construction with Innovative Technology

| 1 | Public & Private Library | 2 | CRF Auto Drafting | 3 | Edit-Check Auto Generation | 4 | Edit-Check Auto Testing |

AuroraPrime

V.S

Efficiency Improved

Other Systems

| CRF Design | eCRF Build | UI Verification | DVP Design | Edit-Check Programming | Edit-Check Test Plan | Edit-Check Test |

Traditional Process

Data Manager — CRF Design → DVP Design

Database Builder — eCRF Build → Edit-Check Programming

Quality Controller — UI Verification → Edit-Check Test Plan → Edit-Check Test
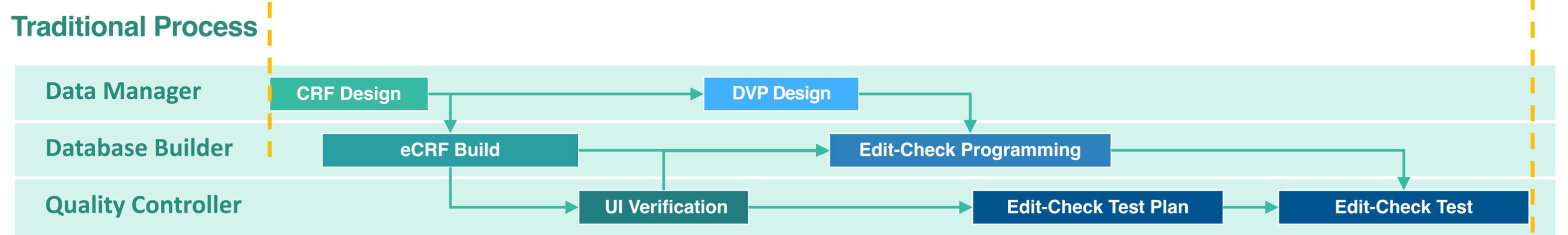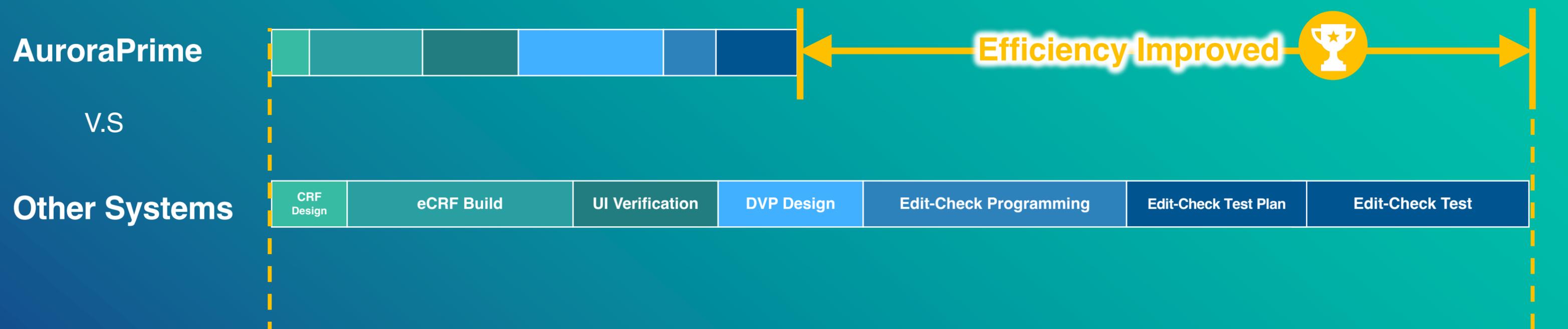
One-click Database Conversion: Start Easily with AuroraPrime

Effortlessly Convert & Reutilize

Maintain Productivity

1 Database
Facilitate Database Reutilization from Prior Trials

2 CRF Library
Permit Existing CRF Libraries Reuse

3 Edit Checks
Enable Recurrent Usage of Previous Edit Checks

4 Database Build Tools
Compatible with Existing Database Build Tools

Seamlessly Convert Medidata Rave Database with AuroraPrime's Advanced Technology

Medidata Rave

Database

Export

Exported Files

XLSX Lab Configration

XLSX Architect Load Spec

Upload

AuroraPrime

Intelligent Parser

Convert

Database

Analytes
Lab Normal Ranges
Visits | Forms
Items | Units
SoA | CodeLists
Edit Checks
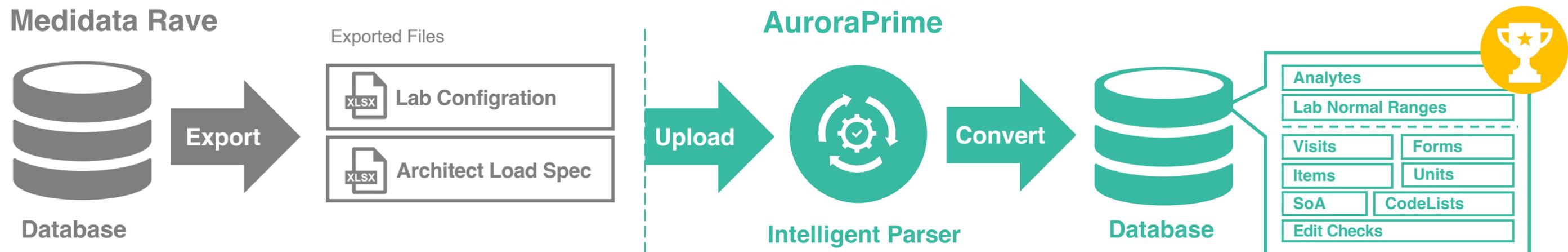
Seamless Downstream Data Monitoring

90%
Data Listing Time Reduction

40%
SAS Cost Reduction

EDC integration streamlines data management, **enhances decision-making speed,** ensures data integrity, and simplifies regulatory compliance.

1 Out-of-the-box Data Listing Rules

2 Automated Data Flow

3 Interactive Patient Profile
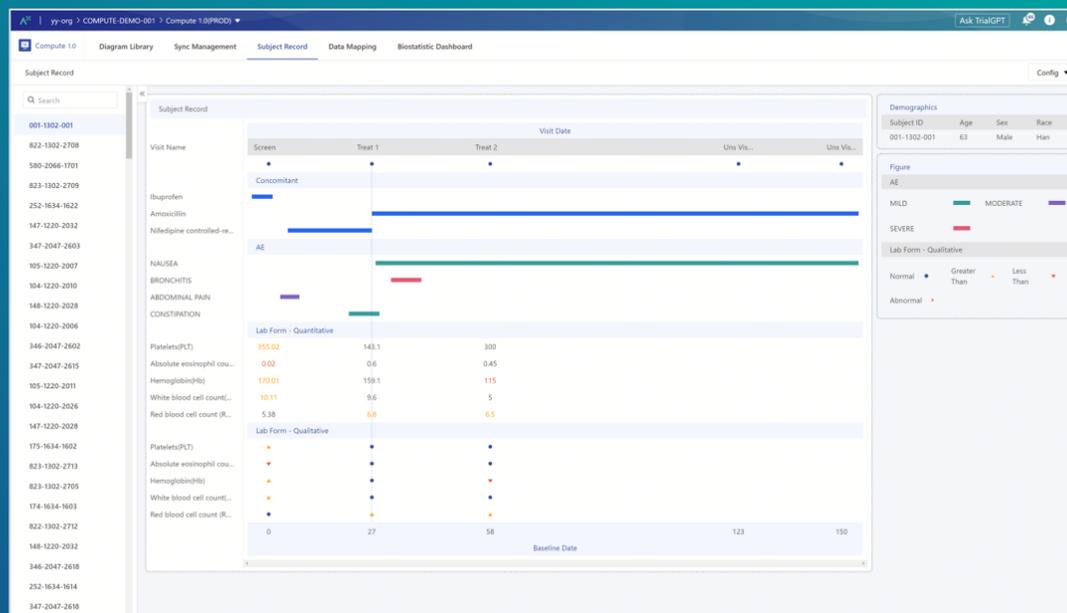
4 Seamless Integrated EDC Queries

On-going Trials Switched from Rave to AuroraPrime:
On-par in Functions, Ensured Data Integrity, and Immediate Cost Savings

Client A

- **Phase Ib**
- **90 subjects**
- 10 sites
- Solid tumor
- Open-label, Randomized
- 60 forms, 700 edit checks
- Suspend time in migration: 8 hours

Client B

- **Phase II**
- **50 subjects**
- 5 sites
- Melanoma
- Open-label
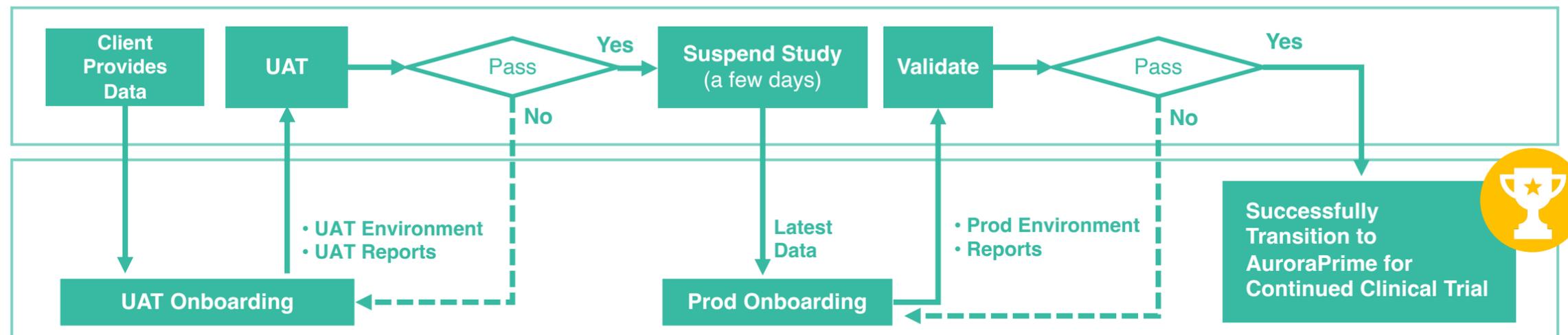- 60 forms, 800 edit checks
- Suspend time in migration: 6 hours

Client C

- **Phase III**
- **400 subjects**
- 40 sites
- Ovarian Cancer
- Randomized, Double-blind
- 70 forms, 1900 edit checks
- Scheduling migration time

Enhanced Secure Data Transfer Process

AuroraPrime offers a robust, secure data onboarding process, enabling seamless study transfers from other systems. This efficient migration not only ensures data integrity but also significantly reduces system costs immediately after transition.

Client Provides Data → UAT → Pass — Yes → Suspend Study (a few days) → Validate → Pass — Yes → Successfully Transition to AuroraPrime for Continued Clinical Trial

No → UAT Onboarding
- UAT Environment
- UAT Reports

No → Prod Onboarding
Latest Data

- Prod Environment
- Reports

CASE STUDY

RemeGen Amplifies Clinical Trial Efficiency Through AuroraPrime's Integrated and Intelligent Data Solutions: EDC, RTSM, Data Listing, and More.

RemeGen BIOSCIENCES

Accommodates Sino-US dual reporting for over 30 international clients.

	Challenges	AuroraPrime Solution	Outcome
1	Multiple collaborators, limited staff, rising labor costs.	Comprehensive database training, standard CRF library development, mock CRF design support.	Database build time reduced by **60%**
2	Tight system launch schedule, long data management cycle.	Automated logic rule parsing, test script generation and execution.	UAT time cut **from 10 to 4 days,** **97.5%** DVP pass rate.
3	Extended drug management cycle, manual stock checks, overlooked dispensing records.	Online order and dispensing, real-time statistics, auto-replenishment.	Reduced drug confirmation and communication, **50% lower drug supply costs.**
4	Large data volume, burdensome data management.	Built-in listings, standard algorithms, external data integration.	Automated anomaly detection**, 40% reduced SAS costs,** consistent external data checks.

" *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.* "

90%
UAT Time Reduction

80%
Database Build Time Reduction

90%
Data Listing Work Saving

Reduced Overall Drug Risks

Thank You

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