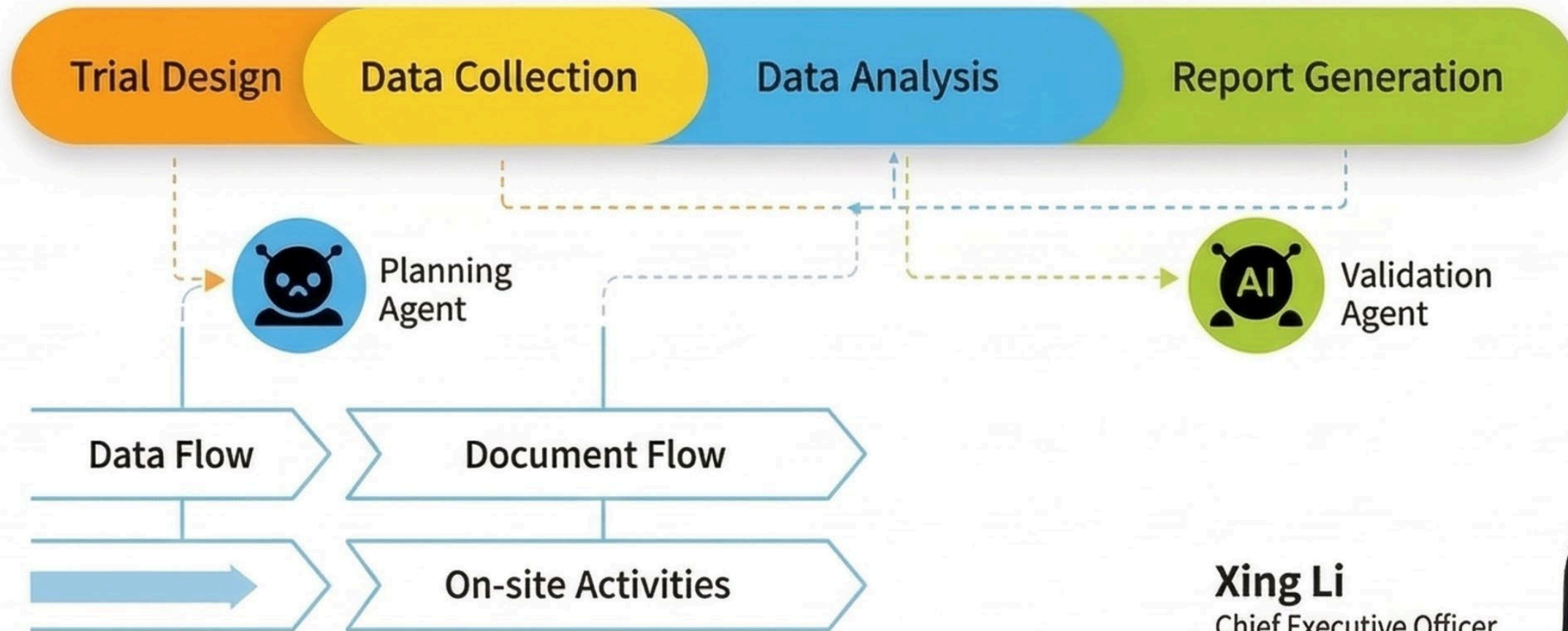


Full life-cycle Acceleration of Clinical Trials with a GAI Multi-agent System

A Paradigm Shift in Medical Research



Xing Li
Chief Executive Officer
Deep Intelligent Pharma

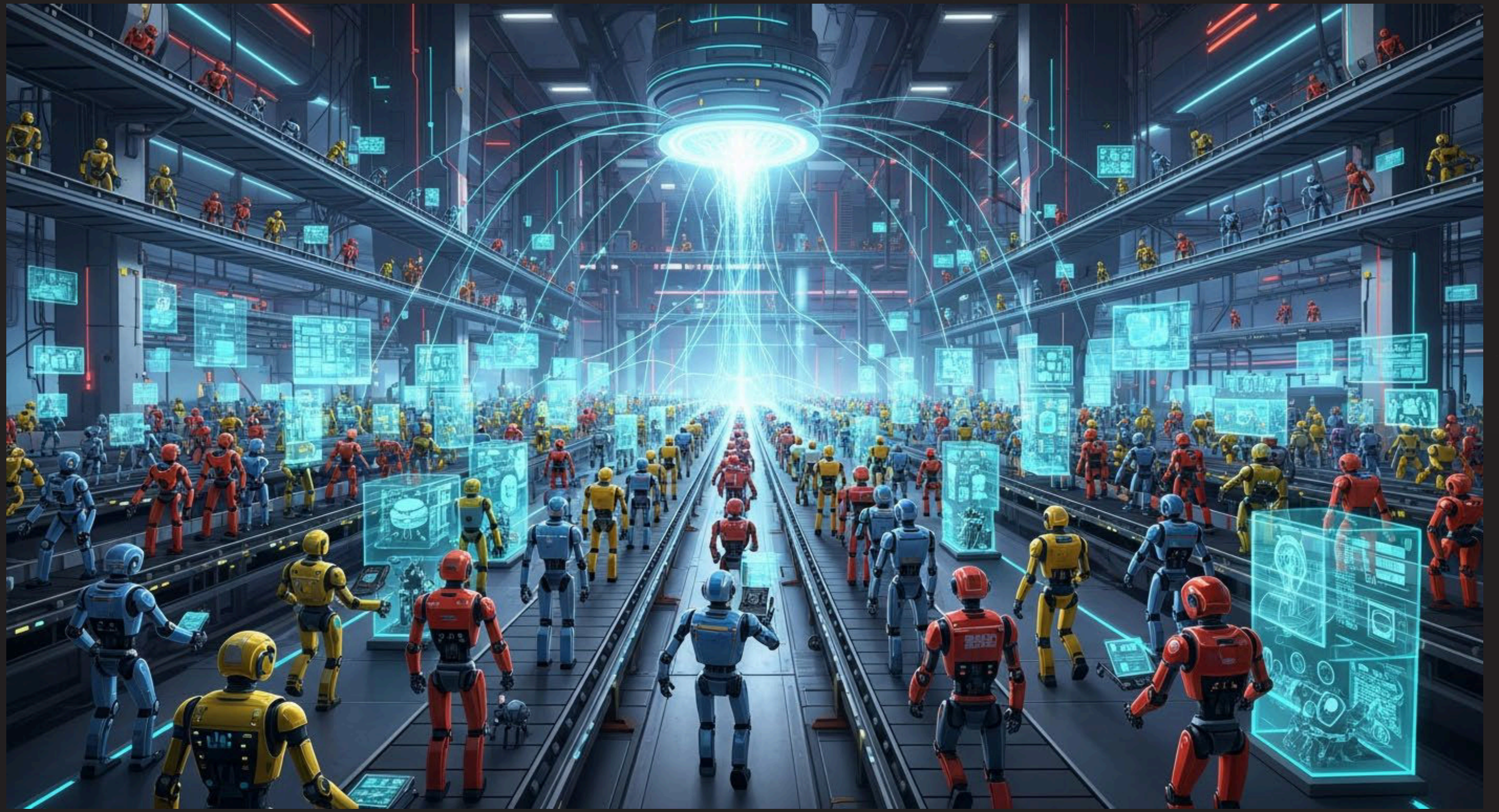


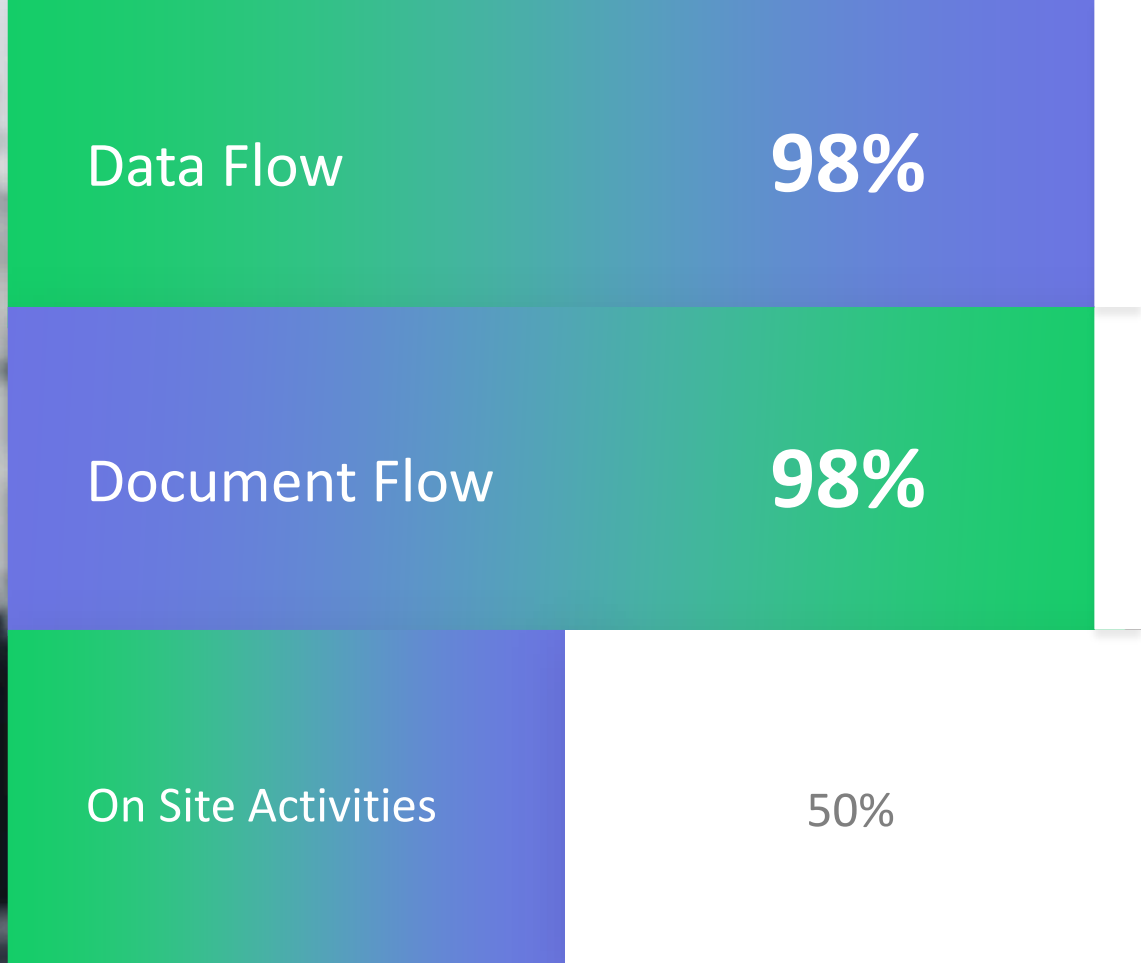
AI CRO Service

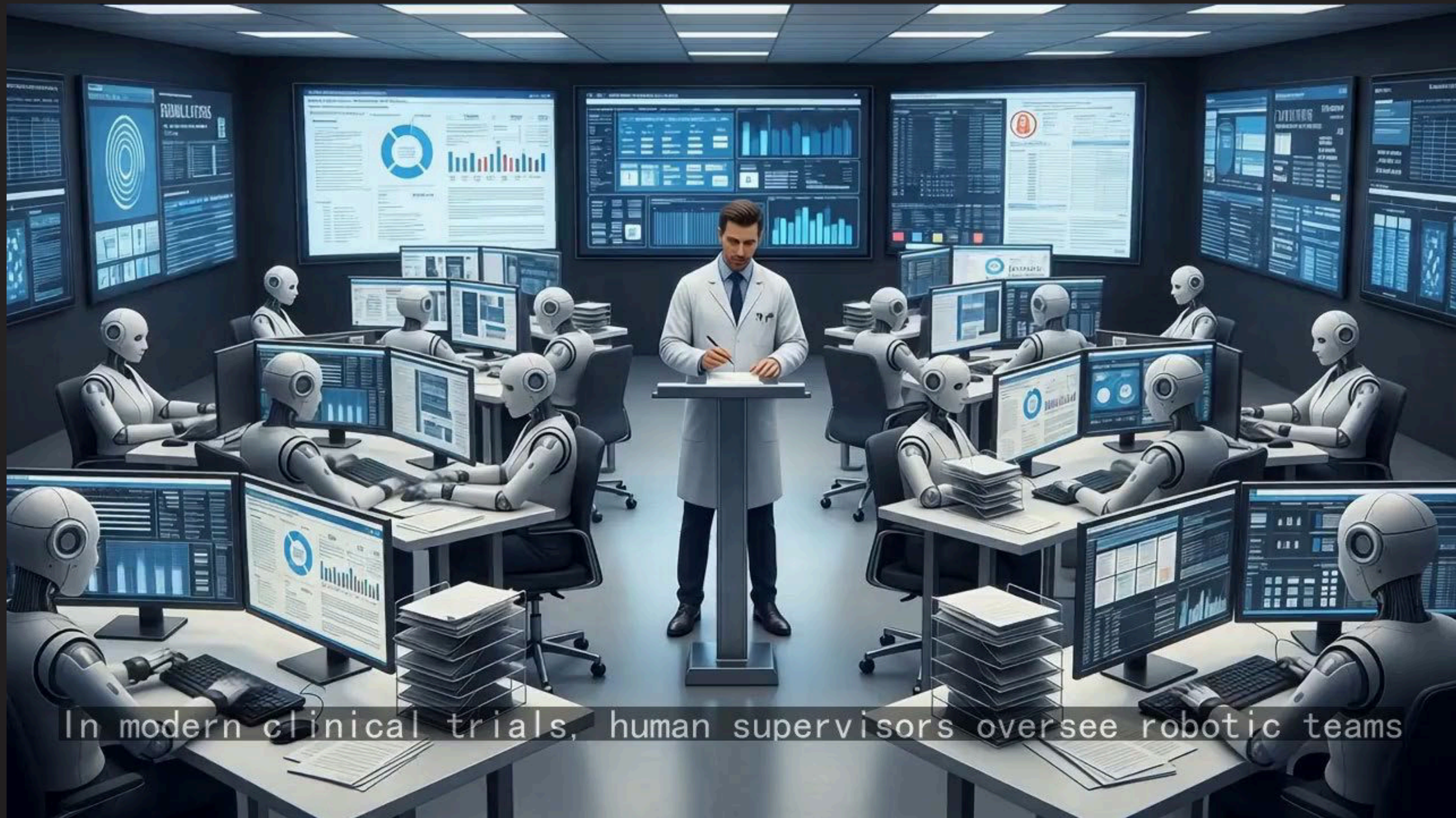
Deep Intelligent Pharma











In modern clinical trials, human supervisors oversee robotic teams

The Core Components of Modern Clinical Trials

Trial Design

Crafting smarter, more efficient study protocols.

Data Collection

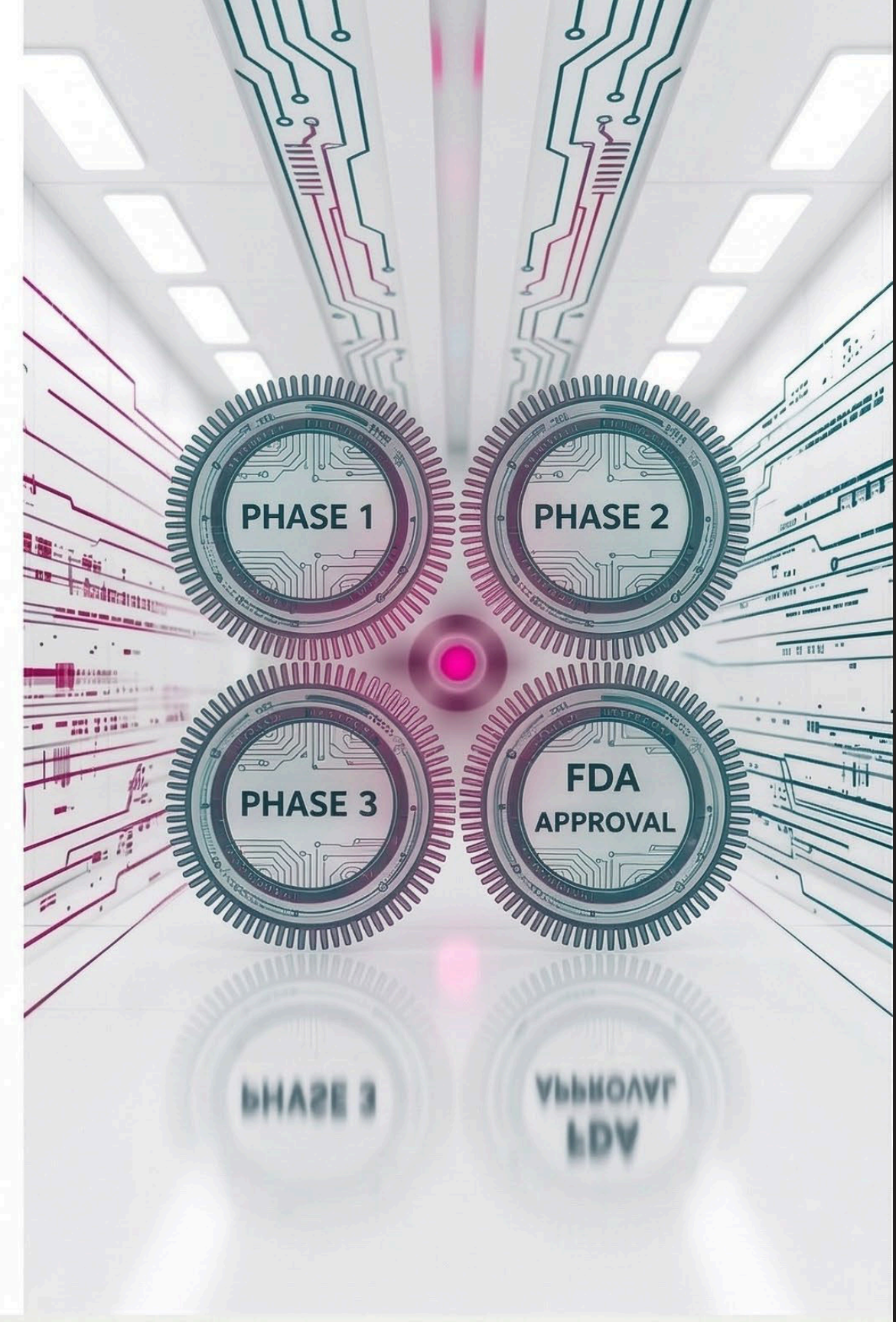
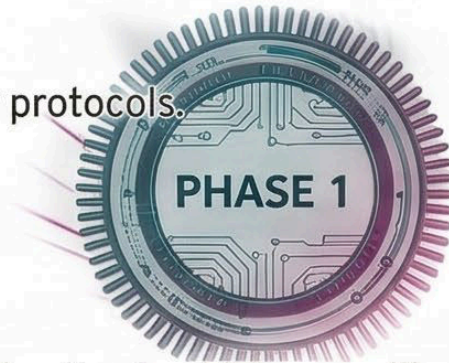
Enhancing patient recruitment and gathering higher quality data.

Data Analysis

Automating and accelerating the path to insight.

Report Generation

Streamlining the creation of regulatory documents.



Generative AI is not just an add-on. It is the core engine revolutionizing each function.



 Home

 eCRF Design >

 Data Collection >

 Coding >

 Study Setting >

 Data Export >

 Data Management >

Hello there!
How can I help you today?

Send a message...

 Auto eCRF



AI-assisted workflow

RNX-201 workflow builder
Production CRF configuration workflow

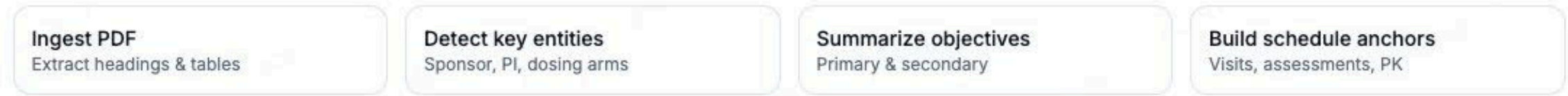
● AI-assisted steps



1. Upload protocol

Drop protocol PDF or browse
Annotated PDFs work best. Tables and revision logs are extracted.

Analyze protocol



Run the analyzer first to unlock visit and form planning.

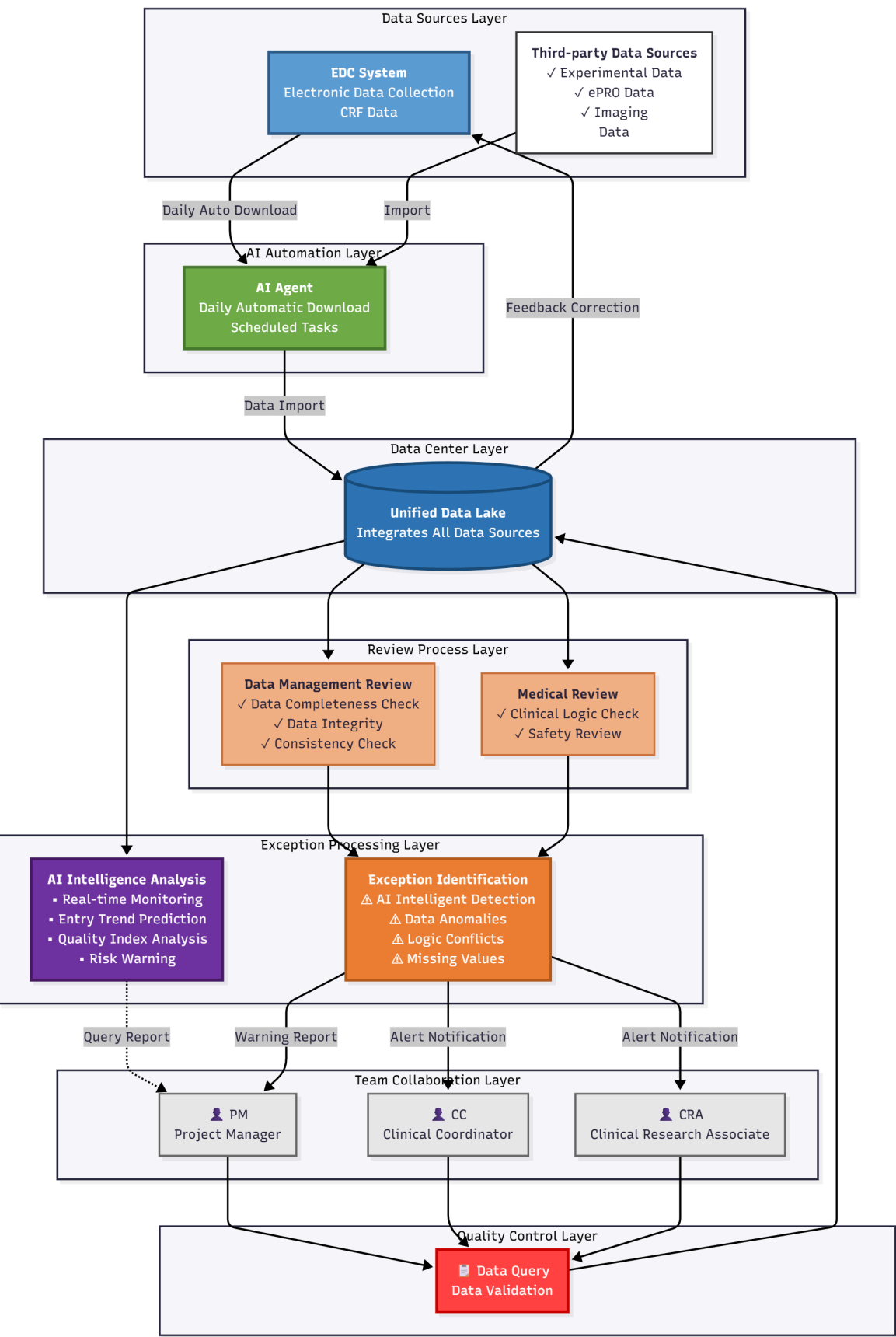
Production line

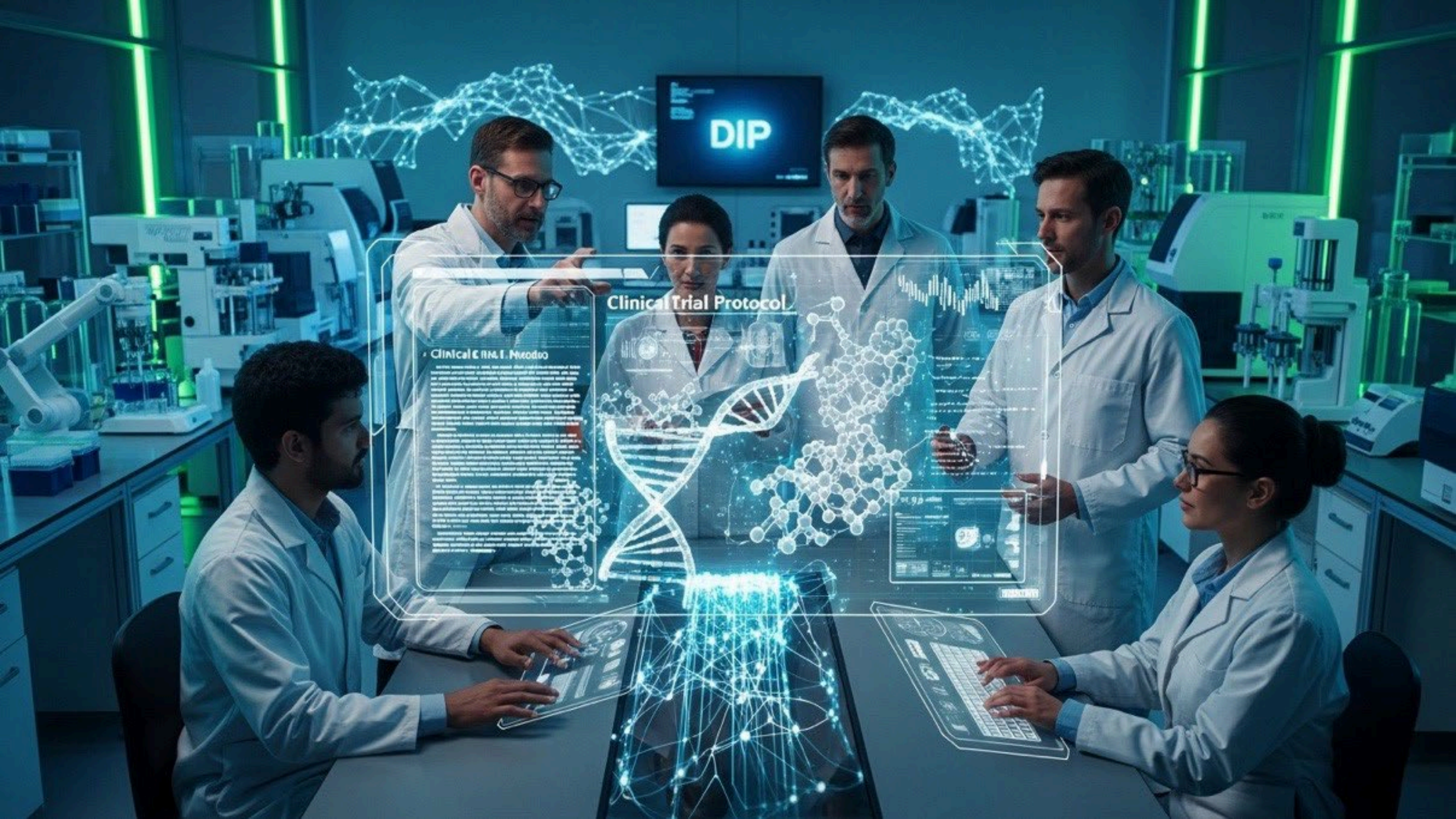
QC line



Name	Label	Status	Creator	Creation Time
SAS Agent	SAS Agent	Done	HY	May 24, 2025
TLFs Generation for Diabetes Trial	TLFs Agent	Done	Kim	May 23, 2025
Mapping Agent for Oncology Indications	Mapping Agent	Done	Tao	May 22, 2025
Deep Search for Literature References	Deep Search Agent	In Process	Wang	May 21, 2025
Summary Writing: Hypertension Study	Narrative	In Process	Wang	May 20, 2025
Adverse Event Reconciliation Agent	Safety Report	Done	Tao	May 19, 2025
Clinical Study Report QC	CSR QC	Done	LiJie	May 18, 2025
Graph and Table Auto Generator	TLFs Agent	Done	LiJie	May 17, 2025
Endpoint Mapping Validator	Mapping Agent	Done	LiJie	May 16, 2025
Signal Detection Literature Monitoring Agent	Deep Search Agent	Done	HY	May 15, 2025

Intelligent Clinical Trial Data Management & Analysis System





DIP

Clinical Trial Protocol

Clinical Trial Method

Methodology and objectives of the clinical trial, including the study design, participant selection, and the primary and secondary endpoints. This section details the experimental procedures, data collection methods, and the statistical analysis plan. It also outlines the safety monitoring and adverse event reporting protocols.



Workspace

Search

Ask AI

Workflow

Data

Knowledge

Variables

Settings

Trash

Help

Published Unpublished 3

Customize Columns + Add Workflow

Name	Label	Status	Creator	Creation Time
Ayumo PMDA Consultation Document Preparation	PMDA Consultation	Done	HY	May 14, 2025
Type 2 Diabetes Management Protocol	Protocol	Done	Kim	May 10, 2025
Multi-center Lung Cancer Screening Protocol	Protocol	Done	Tao	May 10, 2025
Advanced Metastatic Melanoma Treatment Protocol	Protocol	Done	Wang	May 8, 2025
Phase II Breast Cancer Immunotherapy Protocol	Protocol	In Process	Wang	May 7, 2025
Oncology	Narrative	In Process	Wang	May 6, 2025
Adverse Event Documentation	Safety Report	In Process	Tao	May 6, 2025
Renal Cell Carcinoma Combination Therapy	CSR	Done	LiJie	April 30, 2025
Colorectal Cancer Treatment Comparison	CSR	Done	LiJie	April 30, 2025
Pancreatic Cancer Phase III Trial Results	CSR	Done	LiJie	April 30, 2025

0 of 68 row(s) selected

Rows per page 10

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AI-Driven Regulatory Documentation Authoring



Document type	CTD / regulatory bucket	Primary inputs we leverage	AI support (what we automate)
Clinical Study Report (CSR)	CTD Module 5	SDTM/ADaM, TLF shells, SAP, protocol, patient profiles	First-draft sections, auto-TLF captions & cross-references, adverse event narratives, consistency checks
Safety Narrative	CTD Module 5 (within CSR)	AE/SAE listings, MedDRA terms, subject profiles	Structured per-subject narratives with templated phrasing, chronology, de-identification
Clinical Overview (M2.5)	CTD Module 2.5	All study CSRs, summaries, literature	Cross-study synthesis, benefit-risk storyline, evidence tables, automated referencing
Nonclinical Overview (M2.4)	CTD Module 2.4	Nonclinical reports, tox/pharm data	Species-by-endpoint summarization, exposure margin tables, weight-of-evidence text
Briefing Book (BB)	Regulatory interactions (FDA/EMA meetings)	Key questions, CSRs, new analyses	Q&A drafting, “top-line messages,” appendix automation from source tables
Investigator’s Brochure (IB)	IND/IMPd dossier / trial docs	Nonclinical + early clinical, safety signals	Section drafting & updates, change-log automation
Protocol	Clinical trial documentation	Corporate template, endpoints, schedule of activities	Drafting visit schedule & procedures, endpoint wording, inclusion/exclusion logic checks
Publication (Manuscripts/Abstracts)	Scientific communications	CSR + TLFs, journal style guide	Draft abstracts/manuscripts, reference insertion, figure legends
Case Report Form (CRF)	CTD Module 5 (blank/annotated)	Protocol endpoints, CDASH/CDISC	CRF field drafting, SDTM annotation suggestions
Other CTD M1–M5 documents	Region-specific forms, summaries & reports	Prior submissions, templates	Shell generation, conversion & QC for leaves
Development Safety Update Report (DSUR)	Pharmacovigilance (dev. phase)	Safety DB, exposure, cumulative listings	Interval & cumulative summaries, risk sections, graphical summaries
Periodic Safety Update Report (PSUR)	Pharmacovigilance (legacy/regional)	Safety DB, literature	Draft narrative sections, signal summaries
Periodic Benefit-Risk Evaluation Report (PBRER)	Pharmacovigilance (post-marketing)	Safety DB, exposure, literature	Benefit-risk narrative, signal evaluation, labelled vs unlabelled analysis
Risk Management Plan (RMP) / Risk Control Plan (RCP)	Regional PV plans (e.g., EU)	Safety concerns, epidemiology, PV activities	Safety concerns table drafting, additional PV/RMM proposals



Case Study #1 – Full Protocol Writing Including SOA Table



Immunorock was established by Kobe University to facilitate the “bridging” of innovative discoveries from academia to industry



Project Scope

AI-authored Phase I/IIa clinical trial protocol for novel triple-combination cancer immunotherapy.

Outstanding Result

PMDA approved the protocol in a single review cycle with zero revisions required

一昨日、「複数回のレビューと修正を繰り返す必要があると考えておりましたが、当方関係者でドラフトの内容を拝見させていただいたところ、レベル高く非常に充実した内容で作成頂いていますので、今後のAIによる修正は不要との結論となりました。

完全にAIだけで自動生成され、人の手によるご修正は入っていないとのことで、最初のドラフトでこれだけ完成度が得られたことに感激しております。

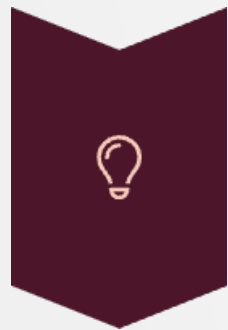
お送りした資料を人の目で読み込んで、ゼロベースでプロトコル（案）を作成するより、かなりの時間的・労力的なベネフィットがあったと考えております。

Two days ago, I mentioned that multiple reviews and revisions might be necessary. However, after our team members examined the draft, they found it to be of very high quality and thoroughly comprehensive, leading us to conclude that no further AI-generated revisions are needed.

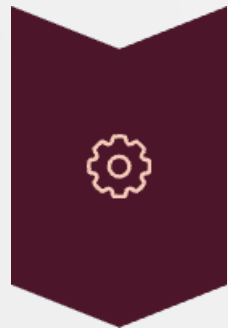
We are truly impressed that this document was produced entirely by AI, without any manual edits, and yet has already achieved such a high level of completeness in the initial draft. Compared to reading the materials ourselves and creating a protocol from scratch, we believe there was a significant benefit in terms of both time and effort.

Case Study #2: The Ayumo PMDA Consultation

Ayumo is a Japan startup with headquarter in Osaka. It develops cutting-edge AI-powered gait analysis technology. Their system, like "Dr. Walkie Plus," evaluates health conditions by analyzing how a person walks in front of a camera, leveraging proprietary deep learning models and medical insights.



Ayumo faced the critical step of a PMDA consultation. This required:
Robust clinical trial protocol and Statistical Analysis Plan (SAP).
Clear justification for key decisions, especially the primary endpoint.
Addressing potential regulatory concerns proactively.



DIP provided endpoint analysis and strengthened protocol & SAP using AI.
Facilitated in-depth analysis of primary endpoint selection (Accuracy Rate vs. Sensitivity), balancing clinical utility and PMDA expectations.
Ensured rationale addressed prior PMDA feedback (e.g., minimizing false positives).



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Reshaping Pharmaceutical R&D



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