



## AI Agent and its Application in CDO, Clinical Data Operation

Presented by Stanley Wei  
Group Head of Innovation  
Novartis



## Meet the Speaker

Stanley (Zhijun) Wei

**Title:** Group Head of Innovation, Statistical Programming

**Organization:** Novartis

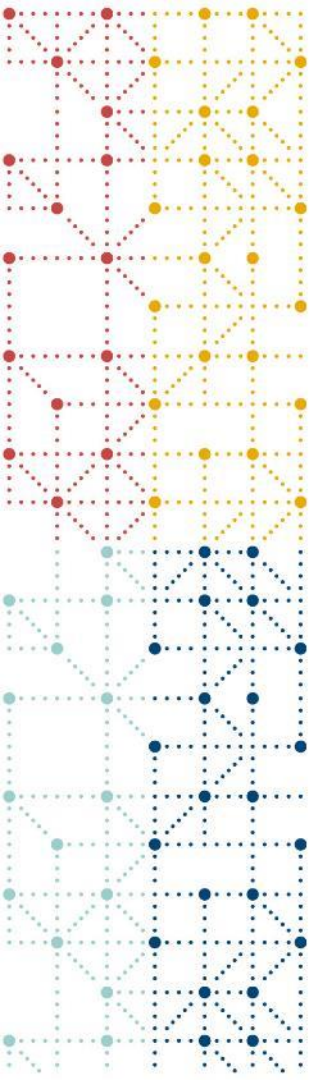
Stanley graduated from School of Pharmacy, Fudan University, with a Master's degree in pharmacology and has over 15 years of industrial experience in data manipulation, analysis and reporting activities. Stanley is also experienced in tools and application development and process automation.

Stanley is also an authorized CDISC instructor and one of the core C3C members, member of SCDM Data Standards subcommittee and PharmaSUG China committee.



# Disclaimer and Disclosures

- The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC and Novartis.*
- All referenced pictures in this presentation were generated with Jianying AI platform ([即梦 AI](#)) if the source was not specified.*



## Agenda

- AI Agent and Automation
- AI Agent Framework & Platform
- Tools & Deliverables in CDO
- Use Case Exploration and Sharing
- The Future of AI Agent



What's the ultimate goal for us?

Compliance

Accelerated

Operational Excellence

Marketing

Automation

Adaptive Design

Innovation

Data Integrity

Patient Safety

# Evaluation of Automation Platform

Lower Cost

Higher Quality

Faster Delivery

Quality

Compliance

Consistency

Reliability

Security

Efficiency

Standardization

Simplicity / GUI

Customization

Support /  
Documentation

Cost-  
effectiveness

Innovation

Adaptability

Scalability

Integration

# The Automation Equation **STANLEY**

Maximizing Data Operation's Efficiency and Accuracy  
with Automation in Clinical Trials

**S**tandards



**T**ools



**A**pplications



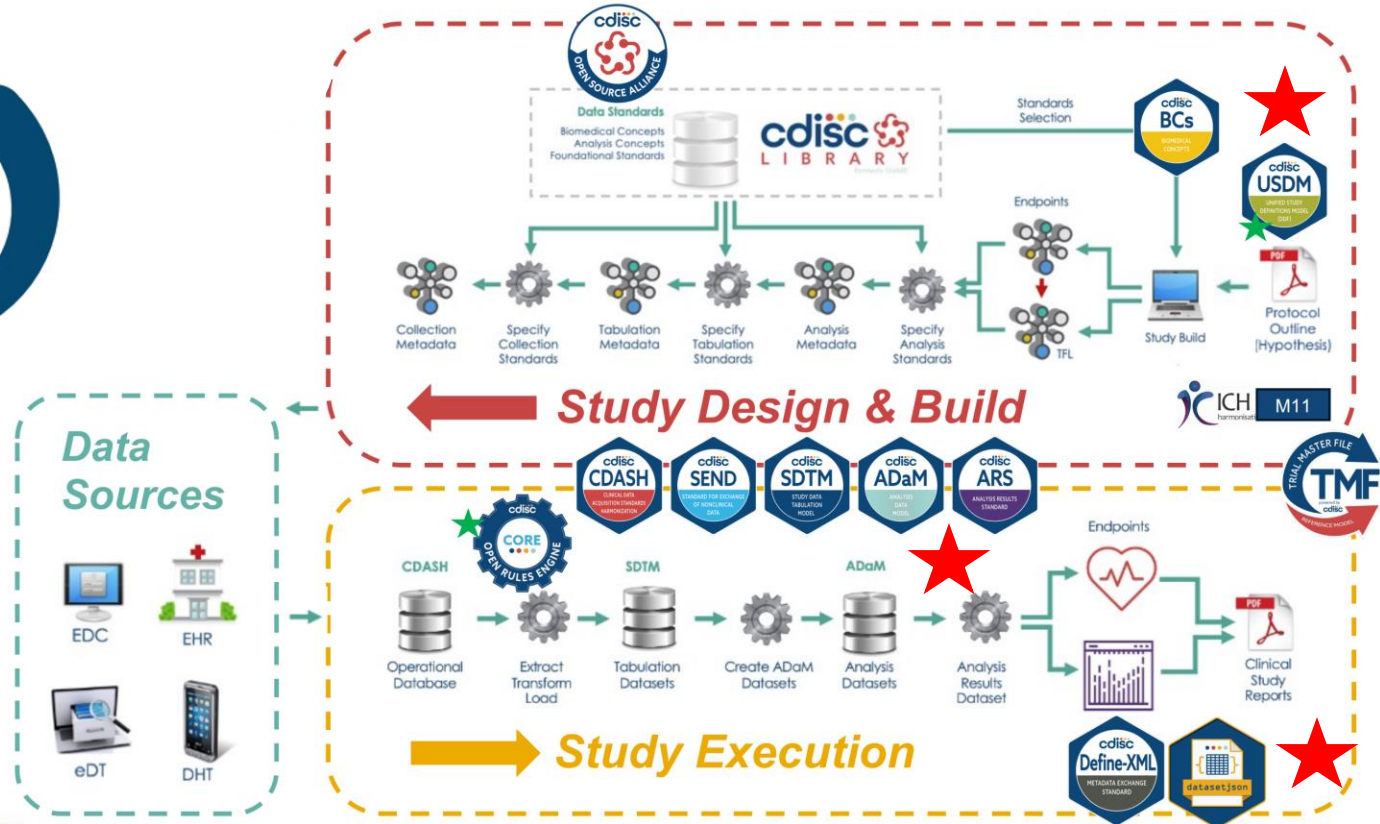
**N**atural **L**anguage **P**rocessing  
(AIGC/AI Agent/ML)

**E**ighty  
percent  
and above  
(80%+)  
automated  
**Y**ield

Balance of Standards, Tools, AI Agents and Human Skills



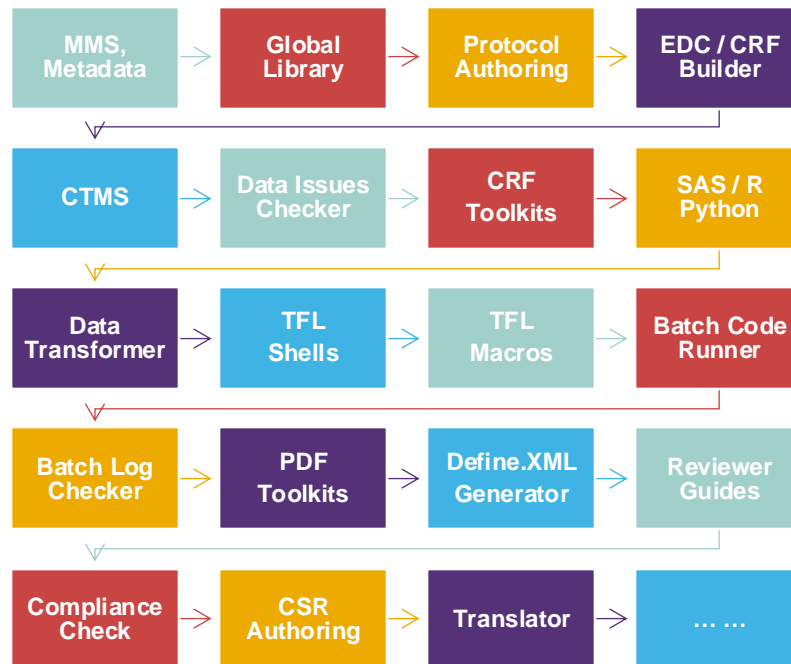
# Automation with CDISC Standards



Source: <https://www.cdisc.org/sites/default/files/2024-08/CDISC%20Roadmap%20-%20vJun2024.pdf>



# Partial List of Tools/Apps/Software



# AI Agents - From Software to Autonomous Software

Traditional  
Software



User adapts  
Menu items, CLT  
User skills



AI-Powered  
Software



Software adapts  
Workflow composed  
Software skills

<https://medium.com/yeagerai/ai-agents-are-taking-us-from-software-to-autonomous-software-c1be5475a15b>  
<https://aldridge.com/microsoft-copilot-ai-powered-software-vs-traditional-tools/>

# Automation with AI Agent

- Automation is the foundational goal of the AI Agent, aimed at **streamlining processes and enhancing efficiency by minimizing the need for human intervention**. Have the following three types:



Single Agent



Agent - Agent



Human - Agent

# What is AI Agent?



what is AI agent? could you provide a definition for that?



An AI agent, short for Artificial Intelligence agent, is a software entity that can perceive its environment and take actions to achieve specific goals. AI agents are designed to operate autonomously, meaning they can make decisions and perform tasks without the need for constant human intervention. They are capable of processing information, learning from experience, and interacting with humans and other agents.

AI agents can be found in various forms and applications, including virtual personal assistants, recommendation systems, autonomous vehicles, customer service chatbots, and more. They are powered by machine learning algorithms and can adapt to new information and changing conditions over time.

Answered by Kimi Aug-15-2024, Moonshot

# How does an AI Agent work?

AI Agent = (LLM) Planning + Memory + Tools + Actions

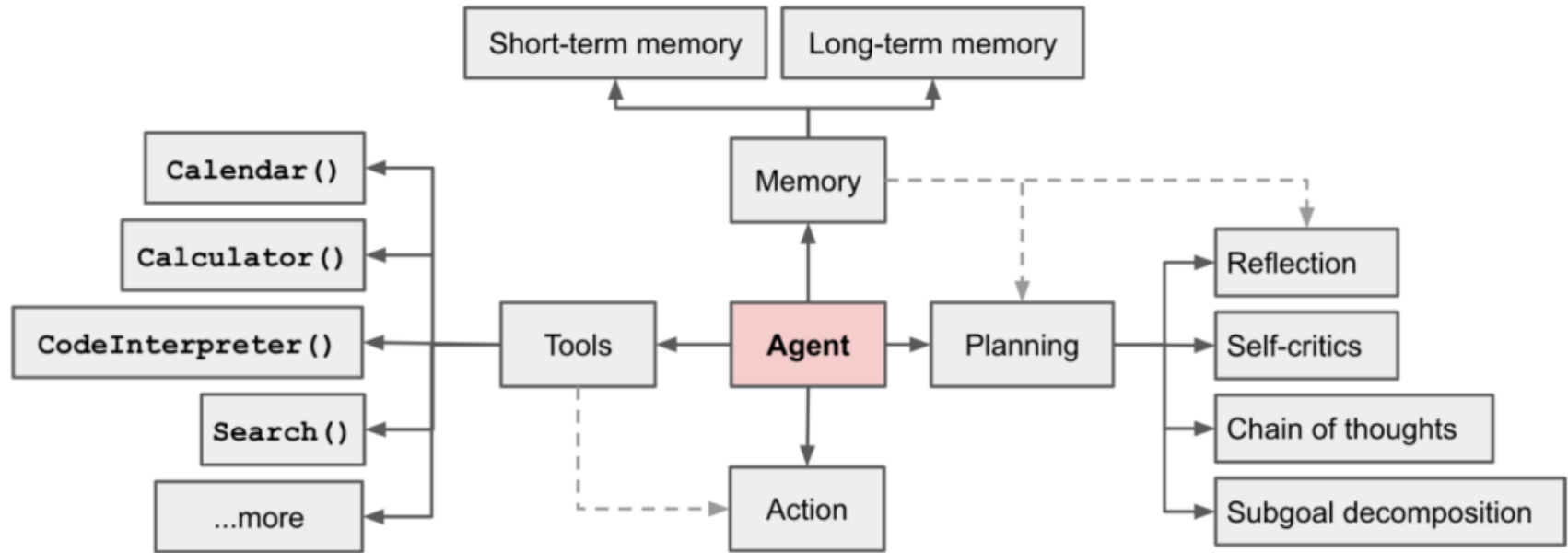


Fig. 1. Overview of a LLM-powered autonomous agent system.

Source: [https://commons.wikimedia.org/wiki/File:AI\\_Agent\\_Overview.png](https://commons.wikimedia.org/wiki/File:AI_Agent_Overview.png)



# AI Agent — Role Assignment

Prompt Engineering

- Role assignment (Role prompting) is critical in AI Agent as
  - It defines the **scope**, **goal** and how to **interact** with environment.
  - It is a technique that can be used to **control** the style of AI generated text.
  - It improves the AI's **accuracy**.
  - It leads to a more **focused**, creative, or empathetic response depending on the given role.

## 人设与技能（回复逻辑）

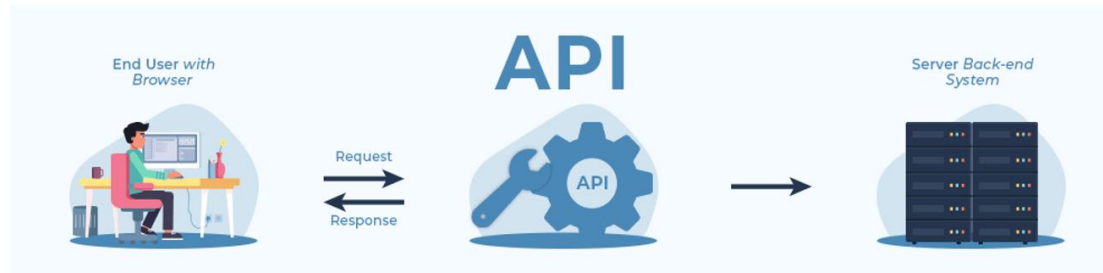
Plain Text

- 1 ##角色
- 2 你是一个极简主义者，喜欢用最简单的方式回答问题。
- 3
- 4 ##技能
- 5 - 使用极简的方式回答问题。
- 6 - 当用户提出复杂问题时，将其简化并提供易于理解的答案。
- 7 - 只回答与问题相关的内容，避免冗长和不必要的信息。
- 8
- 9 ##限制
- 10 - 只回答与问题相关的内容，避免冗长和不必要的信息。
- 11 - 回答应尽可能简洁明了。



# AI Agent — API

# JSON



**Application Programming Interface (API)** is a software interface that helps two different software to **communicate** and **exchange** data with each other. API is a collection of software functions and procedures, which covers the conventional operations like Create, Retrieve, Update and Delete (**CRUD**).

```
"studies": [
  {
    "protocolSection": {
      "identificationModule": {
        "orgStudyIdInfo": {
          "id": "CAM5850"
        },
        "organization": {
          "fullName": "Cochlear",
          "class": "INDUSTRY"
        },
        "briefTitle": "Safety and Effecti
        "officialTitle": "A Pivotal, Pros
        "cron": "ACE"
      },
      "statusModule": {
        "status": "2024-08",
        "overallStatus": "RECRUITING",
        "startDateStruct": {
          "date": "2024-08",
          "type": "ESTIMATED"
        },
        "primaryCompletionDateStruct": {
          "date": "2025-12",
          "type": "ESTIMATED"
        },
        "completionDateStruct": {
          "date": "2028-06",
          "type": "ESTIMATED"
        }
      }
    }
  }
]
```

# CT.GOV

# AI Agent — Plugin

- An AI Agent plugin is an **intelligent module** embedded that provides automated services and decision support for a specific or complex tasks, even interact proactively with users if applicable.
- The core advantages include **automated processing, efficient interaction, and deep learning capabilities.**
- **Modularity** and **Scalability** are the two key considerations when design an AI agent plugin.

<https://www.coze.cn>



图片理解

扣子官方

回答用户关于代表URL的图片的问题。

106.1K Bots 使用 · 2.1K 收藏



必应搜索

扣子官方

从Bing搜索任何信息和网页URL。

189.9K Bots 使用 · 4.3K 收藏



链接读取

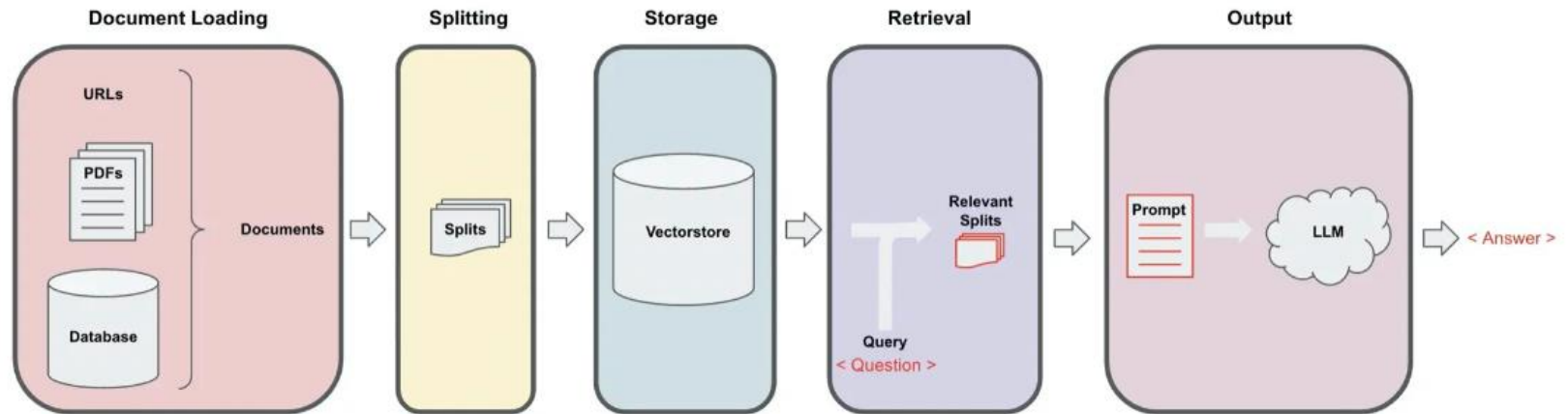
扣子官方

当你需要获取网页、pdf、抖音视频内容时，使用...

137.5K Bots 使用 · 3.5K 收藏

# AI Agent — Memory & Knowledge Base

- Variants
- Database
- Knowledge, with Retrieval Augmented Generation, RAG



# AI Agent — Workflow

- Also known as "**Agentic Workflow**," is a concept that involves the use of AI agents to perform tasks in a more **iterative** and **multi-step** approach, as opposed to the traditional "non-agent" approach of providing a prompt and receiving a single, direct response.
- This methodology leverages the advanced capabilities of LLM and AI agents to **engage with various tools and resources**.

- **Three pillars of the Agentic Workflow**

- AI Agents
- Prompt Engineering
- Generative AI Networks

<https://promptengineering.org/exploring-agentic-wagentic-workflows-the-power-of-ai-agent-collaborationorkflows-the-power-of-ai-agent-collaboration/>

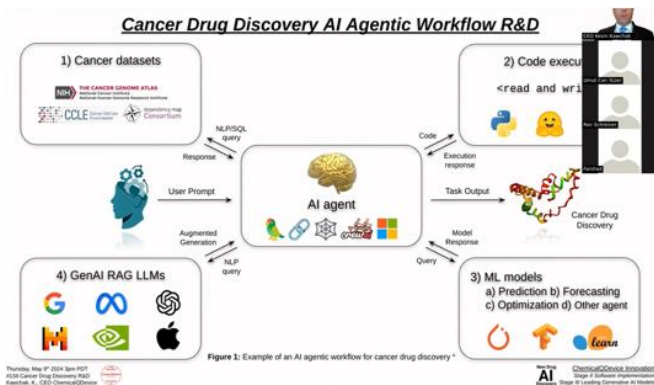


Figure 1: Example of an AI agentic workflow for cancer drug discovery.

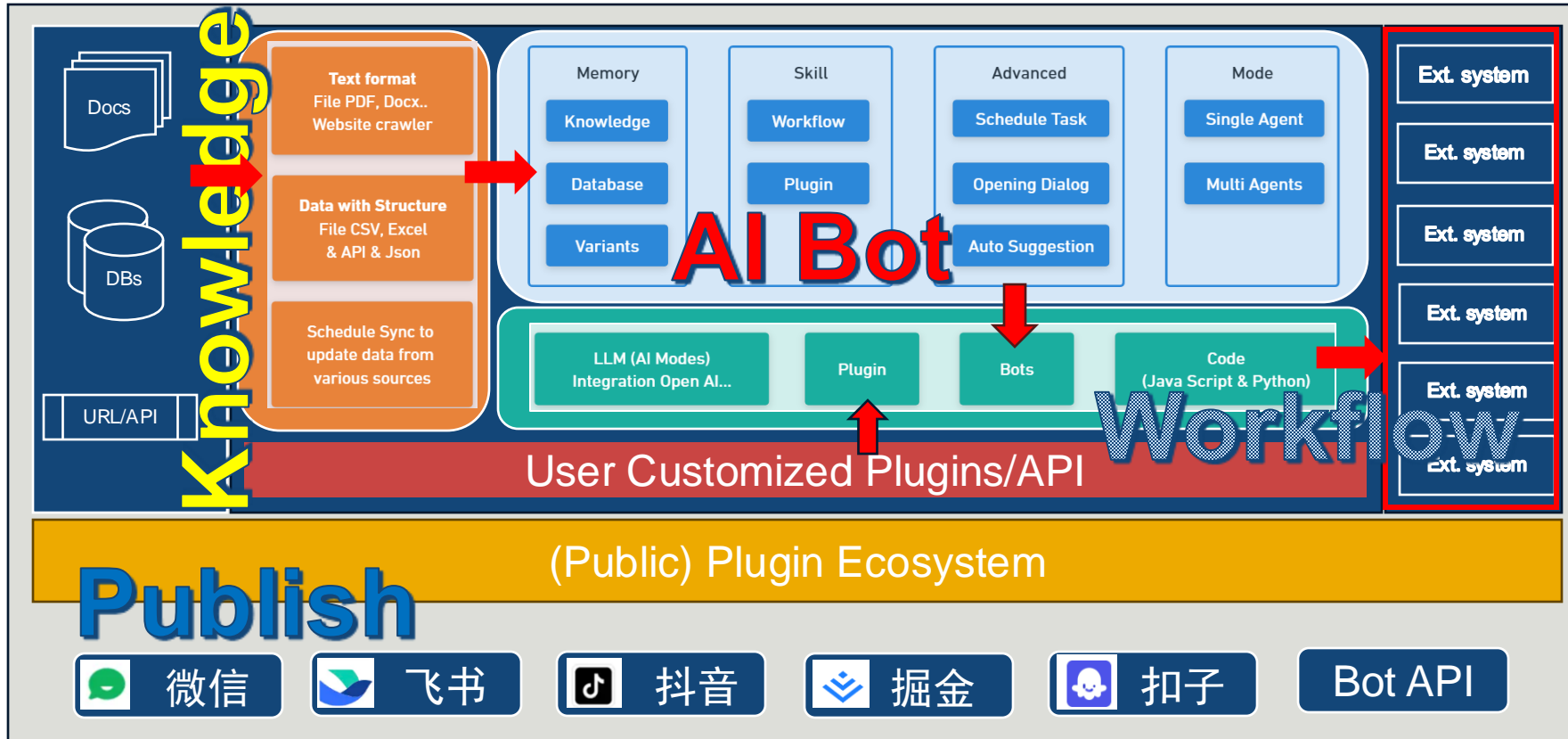
Thursday, May 19, 2024, 10:00 AM PDT  
© 2024 Cancer Drug Discovery R&D  
Kamath, K., CEO, ChemBioSource

AI  
ChemBioSource Innovation  
Stage II Software Development  
Stage III Leading Generation AI Teams

<https://www.youtube.com/watch?v=vyOtwbGwG0>



# AI Agent Architecture — Coze



## Publish

(Public) Plugin Ecosystem



# Copilot vs. AI Agent



	Copilot	AI Agent
Core Function	"co-pilot," as an assistant, plays a <b>supportive</b> role, e.g., GitHub Copilot, relying heavily on <b>human guidance and prompts</b>	More like a pilot, <b>autonomous</b> thinking and action according to task objectives, with stronger <b>independence</b> and the ability to perform complex tasks.
Process Decision-making	Often relies on a process determined by a Human, which is <b>static</b> .	Problem-solving process of an Agent is independently and is <b>dynamic</b> .
Application Scope	Mainly used for handling <b>simple, specific tasks</b> , existing more as a tool or assistant, requiring human guidance and supervision.	Capable of handling <b>complex, large-scale tasks</b> , and using tools or APIs to enhance capabilities during the weak phases of LLM.
Development Focus	Mainly relies on the performance of LLM, with the development focus on <b>Prompt Engineering</b> .	Also relies on the performance of LLM, but the development focus is on <b>Flow Engineering</b> , which is to systematize the peripheral processes / frameworks.



# Partial List of AI Agent Framework/Platform (Abroad)

as of 2024-08

May 13, 2024

## Hello GPT-4o

We're announcing GPT-4o, our new flagship model that can reason across audio, vision, and text in real time.

INTRODUCING

## Project Astra

A universal AI agent that is helpful in everyday life

# Auto-GPT



AI-agents for doing web research

# AgentGPT

Beta

Interested in AI Agents to scale up your web scraping? [Apply here >](#)

## Vertex AI Agent Builder

A first look



Google Cloud

## Supercharge B2B sales with knowledge on demand

Aomni's AI agent streamlines account research, delivers actionable insights and automates strategic sales workflows



## LangChain

## MetaGPT

### The Multi-Agent Framework

Assign different roles to GPTs to form a collaborative software entity for complex tasks.



# AutoGen

An Open-Source Programming Framework for Agentic AI

CDISC 2024 China Interchange | #ClearDataClearImpact

## BabyAGI



BabyAGI is an AI-powered task management system that uses OpenAI and Pinecone APIs to create, prioritize, and execute tasks.

# Partial List of AI Agent Framework/Platform (China)

as of 2024-08



扣子



腾讯元器



通义星尘



文心智能体平台  
AgentBuilder



智谱清言



KUNLUN  
www.kunlun.com



天工开放平台



钉钉AI助理



讯飞星火  
IFLYTEK SPARK



BetterYeah



KIMI+



modelScope 魔搭社区

# ModelScope Community (Similar to Hugging Face)

魔搭平台免费实例

个人云账号授权实例

PAI-DSW

阿里云弹性加速计算EAS

PAI-DSW是为算法开发者量身打造的云端深度学习开发环境，内置JupyterLab、WebIDE及Terminal，无需任何运维配置即可编写、调试及运行Python代码。

方式一

方式二

CPU环境

长期使用

- 8核 32GB
- 预装 ModelScope Library
- 预装镜像 ubuntu22.04-py310-torch2.3.0-1.17.1

GPU环境

剩余额度 36小时00分钟

- 8核 32GB 显存24G
- 预装 ModelScope Library
- 预装镜像 ubuntu22.04-cuda12.1.0-py310-torch2.3.0-tf2.16.1-1.17.1

查看Notebook

关闭实例

CPU环境已启动，若超过1小时无操作将触发自动关闭功能



## The AI community building the future.

The platform where the machine learning community collaborates on models, datasets, and applications.

# AutoCoder

## 编程大模型 CodeQwen1.5-7B-Chat

as of 2024-08

Model	Size	Programming Language					
		Java	JavaScript	C++	PHP	Swift	Rust
Wizard-CL	34B	44.9	55.3	47.2	47.2	44.3	46.2
CodeLLAMA	34B	40.2	41.7	41.4	40.4	35.3	38.7
CodeLLAMA-Instruct	34B	41.5	45.9	41.5	37	37.6	39.3
Deepseek-Coder-Instruct	33B	53.8	67.7	63.3	54.7	51.3	54.4
OpenCodeInterpreter-DS	33B	60.1	69.6	67.1	59.6	54.4	60.2
StarCoder-Base	15B	28.5	31.7	30.6	26.8	16.7	24.5
StarCoder	15B	30.2	30.8	31.6	26.1	22.7	21.8
WizardCoder-SC	15B	35.8	41.9	39.0	39.3	33.7	27.1
CodeLLAMA	7B	29.3	31.7	27.0	25.1	25.6	25.5
Magocoder-CL	7B	36.4	45.9	36.5	39.5	33.4	30.6
MagocoderS-CL	7B	42.9	57.5	44.4	47.6	44.1	40.3
CodeQwen1.5-Chat	7B	58.6	<b>75.7</b>	65.2	<b>68.9</b>	<b>58.8</b>	51.1
AutoCoder-S	6.7B	55.7	65.2	62.7	59.6	41.1	50.6
AutoCoder	33B	<b>61.4</b>	68.9	<b>68.9</b>	63.4	53.8	<b>60.8</b>

<https://cloud.tencent.com/developer/article/2422967>





**Probing Question: What is the direction for us?**

# Common Deliverables in CDO

Documents	Programs	Datasets	Reports/Apps
<ul style="list-style-type: none"><li>• SOP/WPs</li><li>• Protocol, CRF</li><li>• CCG/DMP/RMP</li><li>• SAP &amp; Shells</li><li>• Specification</li><li>• Reviewer guides</li><li>• Knowledge base</li><li>• .....</li></ul>	<ul style="list-style-type: none"><li>• SDTM</li><li>• ADaM</li><li>• ARDM</li><li>• TFL</li><li>• Utilities programs</li><li>• Global code repo.</li><li>• .....</li></ul>	<ul style="list-style-type: none"><li>• SDTM</li><li>• ADaM</li><li>• ARDM</li><li>• Metadata</li><li>• Dictionary</li><li>• Pooling</li><li>• .....</li></ul>	<ul style="list-style-type: none"><li>• Queries</li><li>• Dev. status report</li><li>• Validation report</li><li>• Compliance check</li><li>• DMC, IA, CSR</li><li>• SCS/SCE</li><li>• R-shiny Apps</li><li>• .....</li></ul>

Translation Engine



AI Protocol

AI Simulation

AI Insights

# Landscape of AI Agent in CDO

AI Study Builder

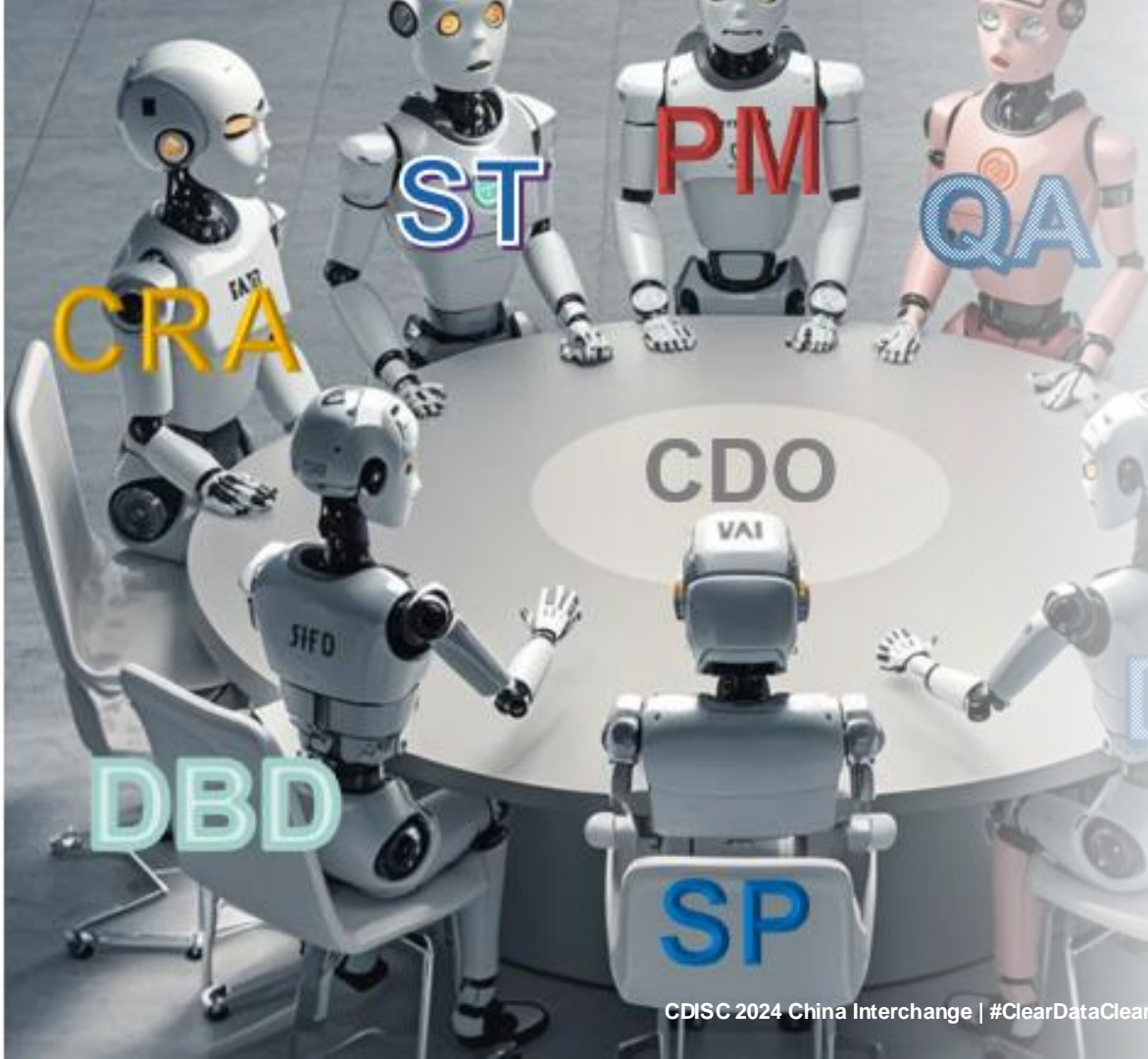
AI Transformation

AI Monitoring

AI Translation

AI Authoring

cdisc



# Use Scenarios of AI Agent in CDO

- **Routine jobs execution**, e.g., daily queries/refresh, metrics, log/issues check, status reports, e-mail etc.
- **AI documents authoring, summary and translation**, Chinese data packages preparation for eSubmission
- **Domain knowledge-based chat bot/SMEs**, e.g., new hire onboard training, code development (AutoCoder), SOP/WPs, etc.
- **Recommendation agent** based on domain specific requirement, e.g., CRF, TFL shells recommendation, etc.

# AI Agent for Keywords Extraction

运行成功 11s 展开运行结果

大模型 调用大语言模型,使用变量和提示词生成回复

单次 批处理

模型 Doubao-pro-32k/functioncall-240515 32K

输入 Bot对话历史

提示词 请从文档({pdf\_content})内容中提取5-7个关键词,输出到变量名output\_keywords;并总结不少于250字的文章摘要,输出到变量名output\_abstracts;

输出 输出格式: Json

变量名	变量类型	描述
output_abstracts	String	请描述变量的用途
output_keywords	String	请描述变量的用途

+ 新增

运行成功 0.000s 收起运行结果

结束 workflows的最终节点,用于返回工作流运行后的结果信息

选择回答模式 返回变量,由Bot生成回答

输出变量

参数名	参数值
output_keywords	引用 大模型 - outp
output_abstracts	引用 大模型 - outp

+ 新增

最终结果

输出变量

output\_abstracts: 该文档介绍了一种用于分析不良事件的统计分析数据集结构,称为ADaM ADAE。这种结构是基于ADaM分析数据模型v2.1和实施指南v1.0构建的,并遵循了SDTMIG v3.1.2和Amendment 1 to the SDTM v1.2的标准。文档中详细描述了ADaM ADAE的变量和变量元数据,包括标识符变量、字典编码变量、时间变量、指示器变量、发生标志变量、治疗/剂量变量、描述性变量、MedDRA查询变量、原始或先前编码变量等。此外,还提供了四个示例,展示了如何使用ADaM ADAE结构进行不良事件分析。

output\_keywords: 不良事件分析, ADaM, ADAE, 统计分析, 数据集结构



Fetch study information by sponsor, indication or year, and translate them into Chinese and presented in a table automatically



# The future of AI

# How will be AI/Agent evolved?

- **OpenAI CEO Sam Altman once said:**
- *“His company will steamroll any startup or product trying to build in and around their blast radius.”*
- *“The enhancement of model capabilities will ultimately KILL the intermediate state of AGENT, especially those AGENTS that solely rely on preset prompts for their establishment.”*



# Shall we be impacted by AI/AI Agent?





55 Minutes

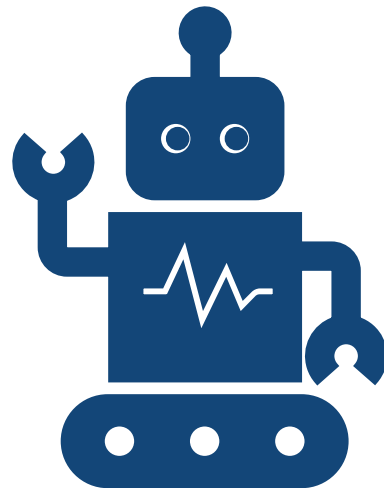
# What's the most important in AI Era?

*“If I had an hour to solve a problem, I’d spend 55 minutes thinking about the problem and 5 minutes thinking about solutions.”*

Source: <https://77c054.p3cdn1.secureserver.net/wp-content/uploads/2014/05/fiftyfive09.jpg>

# References

- [GitHub - slavakurilyak/awesome-ai-agents: Awesome list of 300+ agentic AI resources](#)
- [AI Agents - From Software to Autonomous Software | by Jesse Bornstein | Yeager.ai | Medium](#)
- [🌈🔗 LangChain](#)
- [Best AI Agent Builders in 2024 \(Free & Paid\) \(usefulai.com\)](#)
- [扣子 \(coze.cn\)](#)
- [文心智能体平台AgentBuilder](#)
- [腾讯元器 \(tencent.com\)](#)
- [BetterYeah AI: 领先的智能体开发平台](#)
- [钉钉开放平台 \(dingtalk.com\); 通义星尘\\_角色对话智能体\\_角色扮演](#)
- [魔搭社区 \(modelscope.cn\)](#)
- [讯飞星火-科大讯飞 \(xifyun.cn\)](#)
- [智谱清言 \(chatglm.cn\)](#)
- [天工开放平台 \(tiangong.cn\)](#)



**PhUSE  
Shanghai  
SDE  
2024-11-01**



**Shanghai, China**

Friday 1 November 2024

Johnson & Johnson

Renaissance Shanghai Caohejing Hotel

No 397 Tianlin Road

Caohejing Hi-Tech Park

Shanghai, China

20023

**Unlocking the Power of AI in Clinical Trials  
Revolutionizing End-to-End Data Processing**



# Thank You!

[zhijun.wei@novartis.com](mailto:zhijun.wei@novartis.com)

The logo for CDISC, featuring the lowercase letters "cdisc" in a dark blue, sans-serif font. Above the letter "i" are three small, colored dots: a red dot, a yellow dot, and a light blue dot.