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Single Day Event

Protocol Copilot: An AI-Powered Word Add-in for Streamlined Clinical Protocol Development

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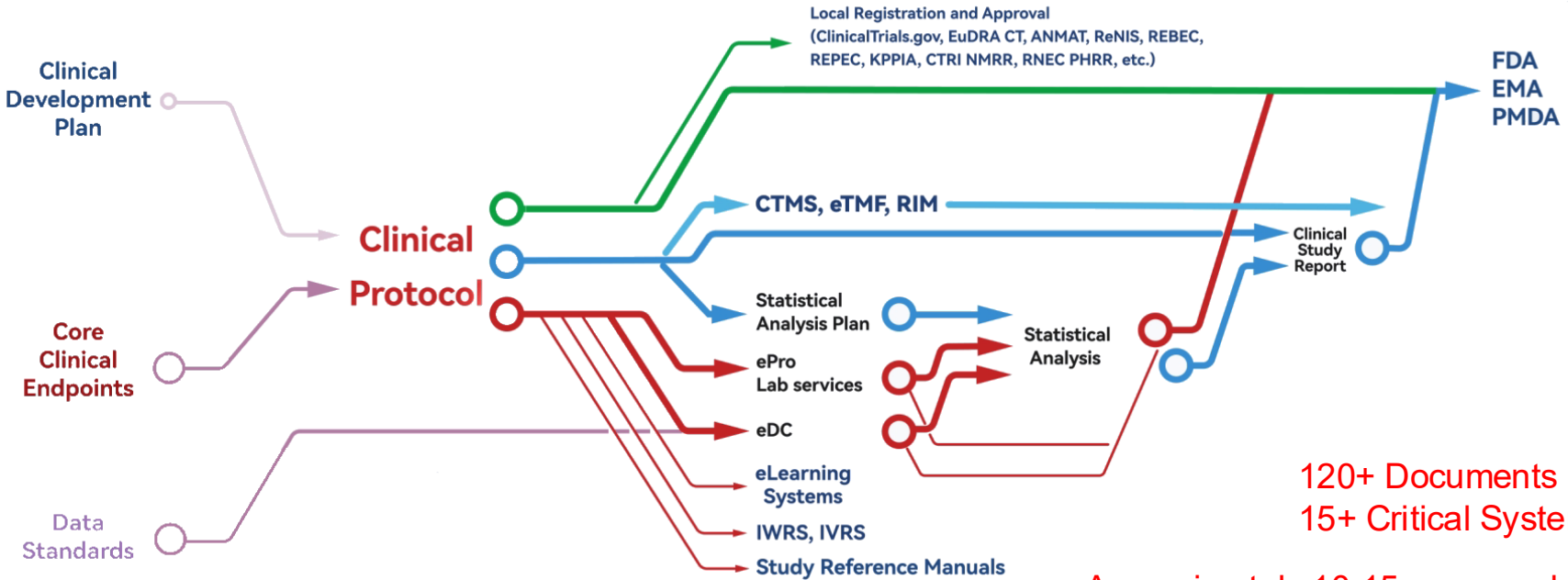
Associate Director, Product Management
Global Statistics and Data Science (GSDS)
BeOne Medicines Co., Ltd.

Clinical Data Flow 临床数据流程



120+ Documents
15+ Critical Systems

Approximately 10-15 years and $2 billion to get a drug into the market

Industry Challenges 行业挑战

- **Protocol content has tripled in the past decade**, contributing to a 27 % increase in approval-to-FPFV timelines and prolonging downstream tasks such as EDC configuration and SDTM mapping.
  十年来，方案内容增三倍，批准至 FPFV 延长 27%，下游流程受阻。

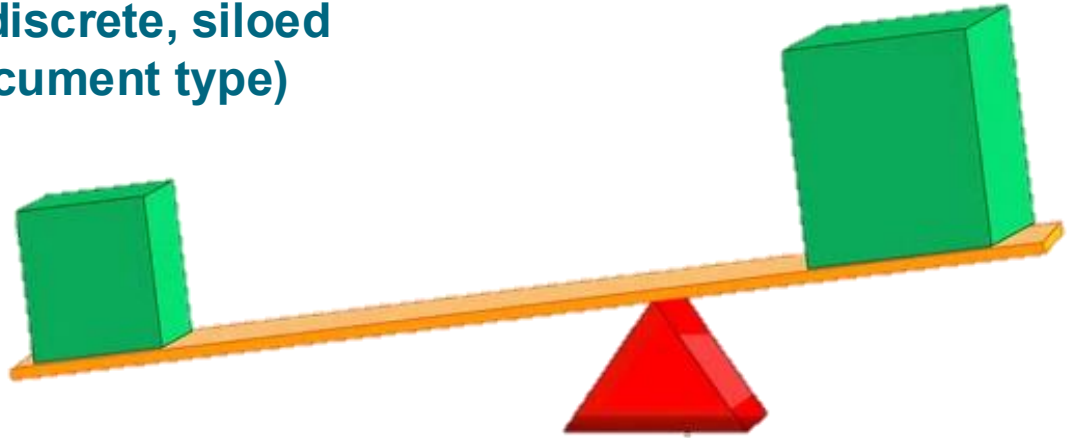
- Substantial protocol amendments have risen 113 %, with **studies now averaging 4 amendments**, driving higher costs and patient drop-out rates.
  大修订增 113%，每项研究平均 4 次，成本与受试者流失同步上升。

- **Submission packages are increasingly complex**, prompting the question: how much of the data collected truly supports the target indication?
  庞杂的申报资料包引出疑问：真正支撑适应症的数据还有多少？

Widely Used Approach

Industry Strategy: AI/ML (discrete, siloed by document type)

Content/data Standardization

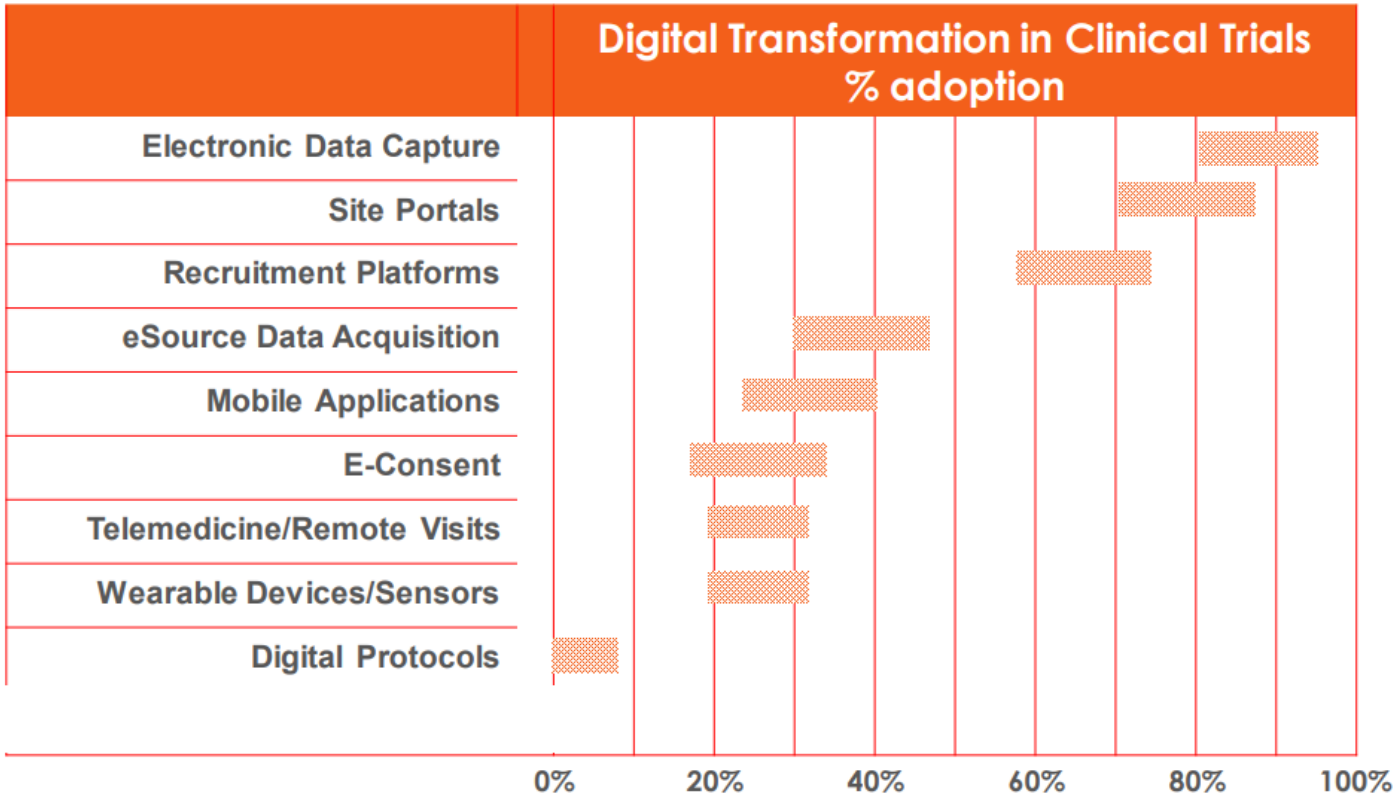


BeOne Strategy

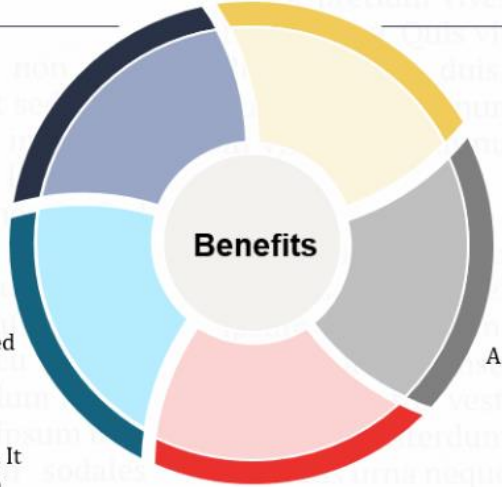
AI/ML (disruptive, content connectivity)

Content/data Standardization + Historical Studies

Adoption (%) for Digital Transformation



Start with Standardizing Protocol



Patient Centricity

Building protocols and informed consent forms with a **patient first** mindset, using simple **language** in a **standardised format**

Compliance

Responding to our **Health Autoririties commitment** and **building compliance into our processes** so we can move towards compliance maturity

Efficiency

The process enables efficiencies: removing the need to go back to reference document templates, allowing for parallel development of protocol and ICF, accelerating submission timelines, and enabling modular input for contributing functions. It also facilitates the country and local customization process for ICF.

Simplicity

A **simplified document family** that detangles the complex interrelation of documents where clear roles and responsibilities are defined.

Standardisation

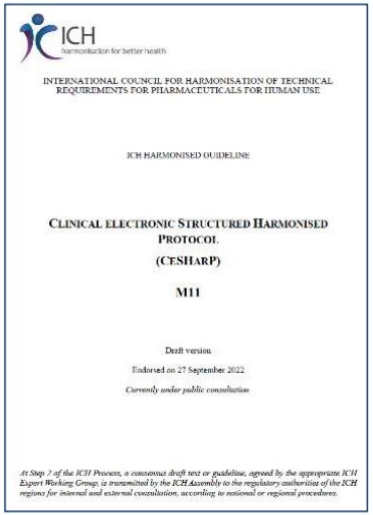
Documents and templates are available and applicable company-wide; they have **global applicability** and allow for **tailoring** for regional or country requirements, where needed

Aligning with Industry Standards

M11 Is …

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

https://www.ich.org/page/multidisciplinary-guidelines


ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11

Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Provides background, purpose, and scope as a guideline


ICH harmonisation for better health

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ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

(CESHARP)

M11 TEMPLATE

Draft version

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Provides the written format for the Interventional Clinical Trial Protocol Template


ICH harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL

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M11 TECHNICAL SPECIFICATION

Draft version

Endorsed on 27 September 2022

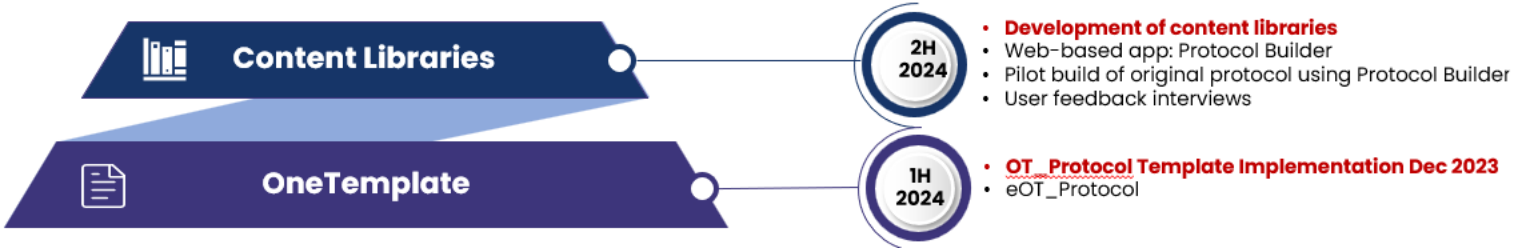
Currently under public consultation

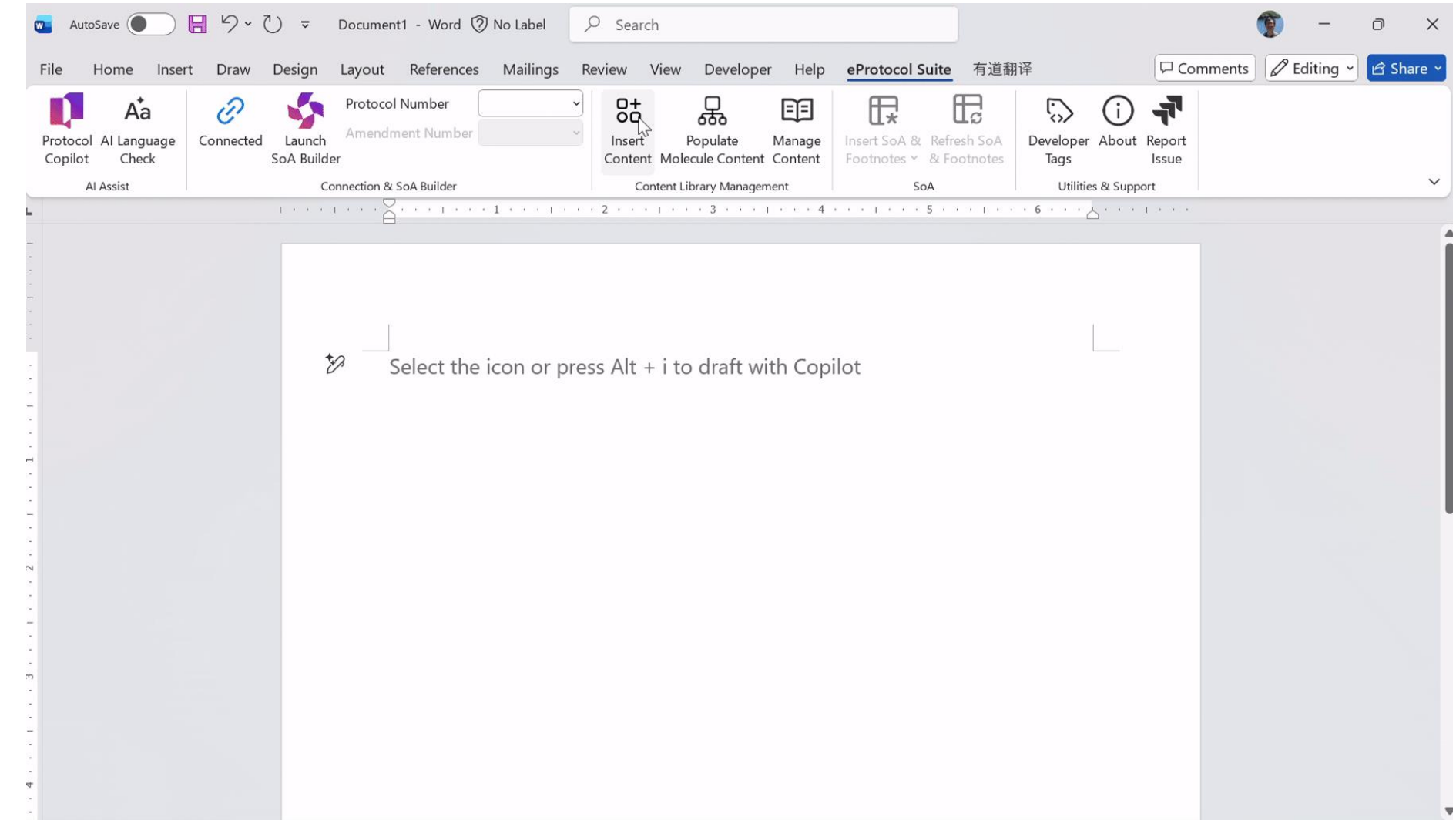
At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

Provides the technical representation aligned with the guideline and protocol template

The Foundation

Reuse – Content Libraries




AutoSave
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Draw
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Layout
References
Mailings
Review
View
Developer
Help
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有道翻译
Comments
Editing
Share
Protocol Copilot
AI Language Check
AI Assist
Connected
Launch SoA Builder
Protocol Number
Amendment Number
Connection & SoA Builder
Insert Content
Populate Molecule Content
Manage Content
Content Library Management
Insert SoA & Footnotes
Refresh SoA & Footnotes
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About
Report Issue
Utilities & Support
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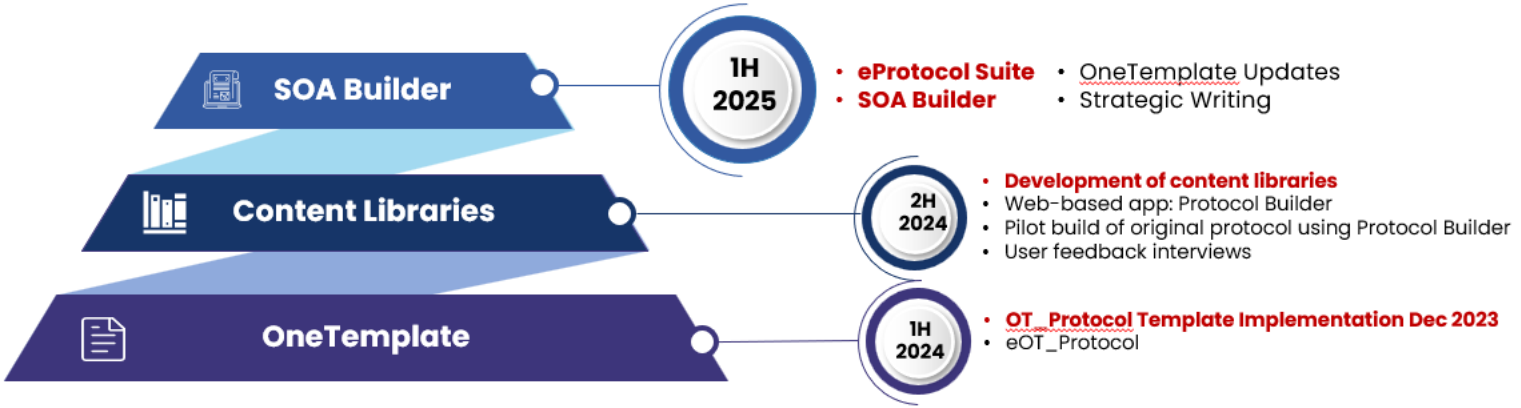
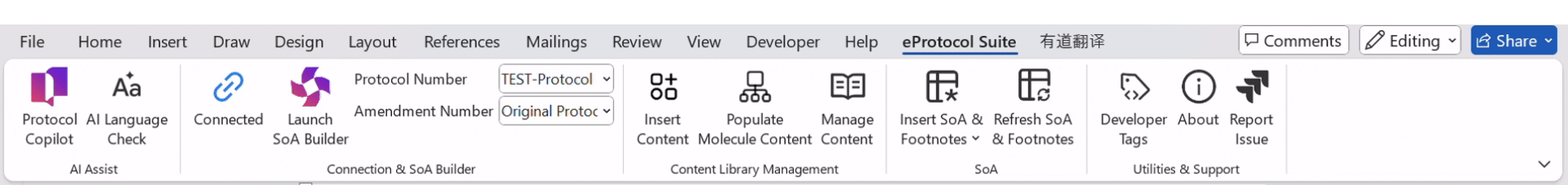
Digitalizing Schedule of Activities

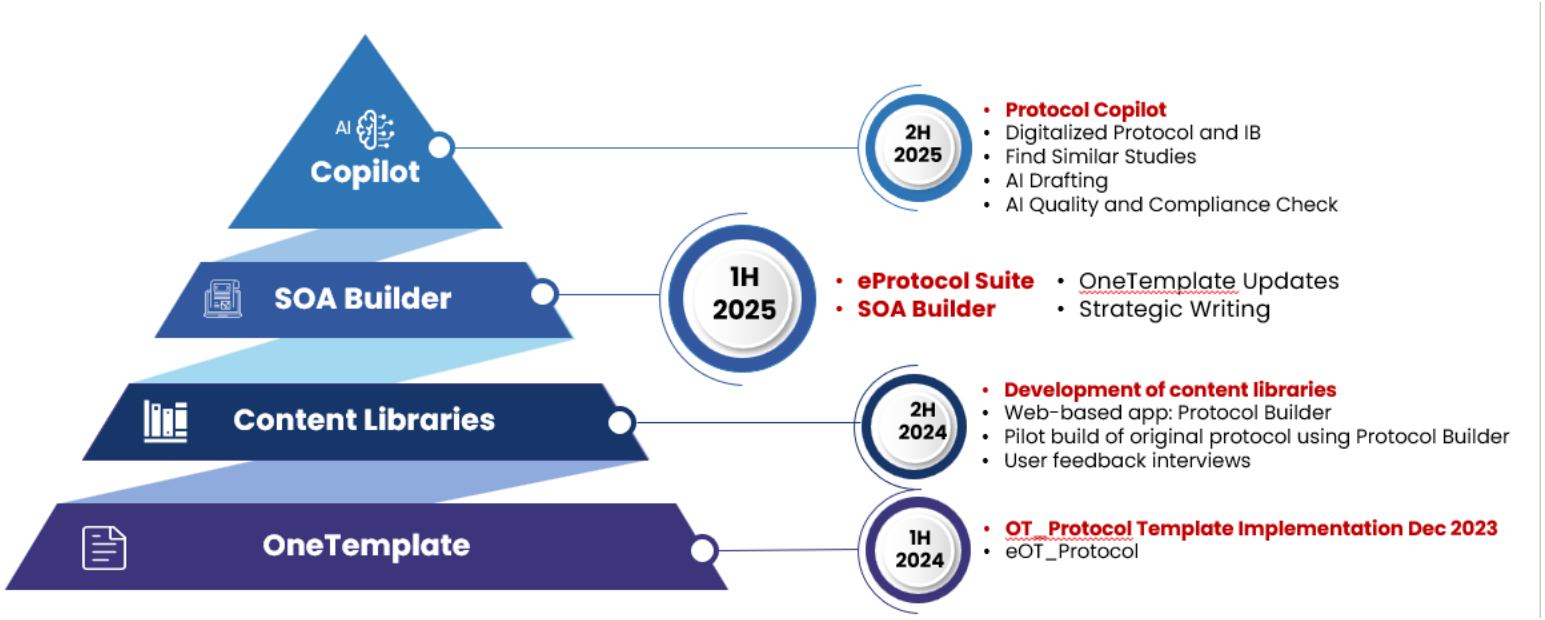




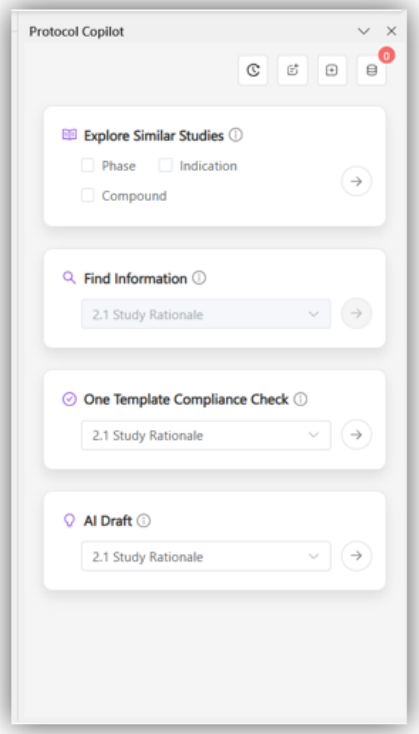
[BG/BGB-XXX-XXX] [Company Name]

[Original Protocol or Protocol Amendment X.X]

Copilot


AI
Copilot
SOA Builder
Content Libraries
OneTemplate
2H 2025
• Protocol Copilot
• Digitalized Protocol and IB
• Find Similar Studies
• AI Drafting
• AI Quality and Compliance Check
1H 2025
• eProtocol Suite
• SOA Builder
• OneTemplate Updates
• Strategic Writing
2H 2024
• Development of content libraries
• Web-based app: Protocol Builder
• Pilot build of original protocol using Protocol Builder
• User feedback interviews
1H 2024
• OT_Protocol Template Implementation Dec 2023
• eOT_Protocol

Protocol Copilot

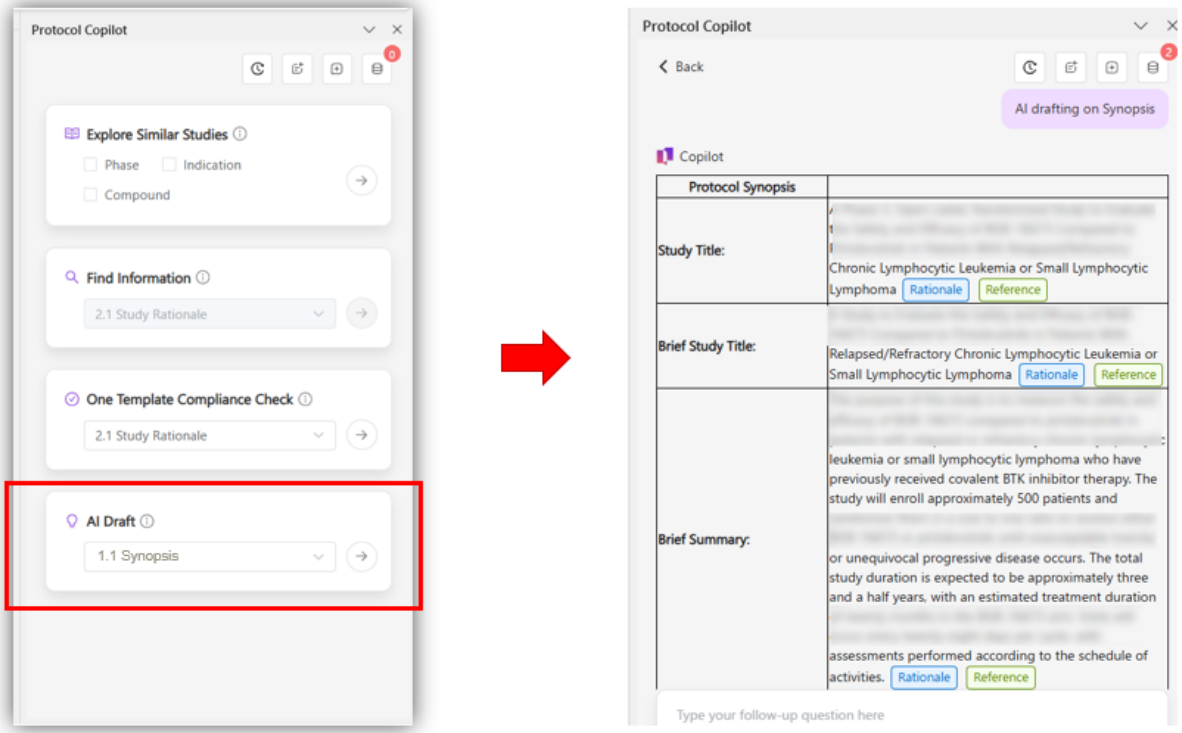


Protocol Copilot as part of eProtocol Suite is a Microsoft Word Add-in designed to streamline the drafting of clinical documents, enhancing efficiency, accuracy, and quality in the creation of clinical study documentation and supporting users in meeting regulatory standards.

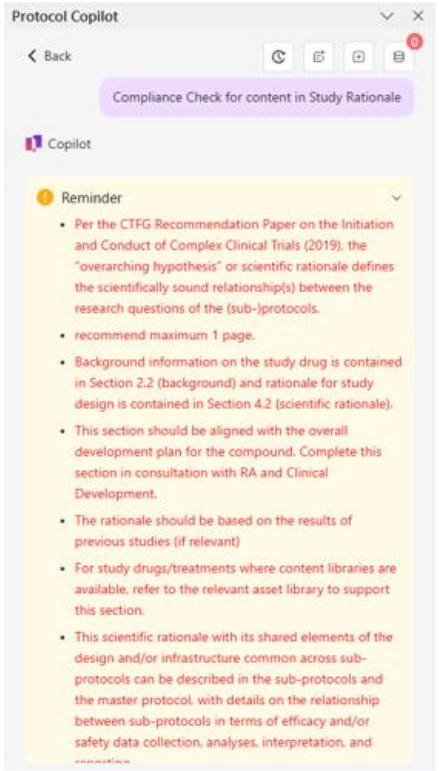
Key Features of Protocol Copilot include

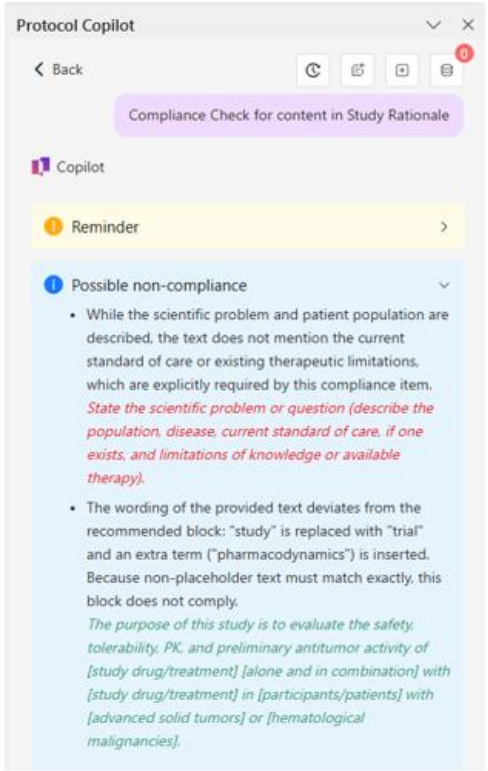
- Suggest similar studies
- Find specific information (based on internal sources)
- AI template compliance check
- AI drafting
- AI chat
- AI Deep Research

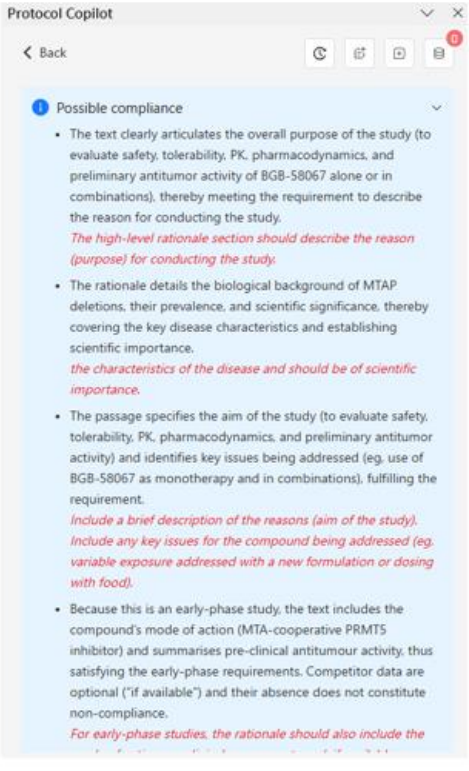
AI Draft Synopsis



AI Compliance Check



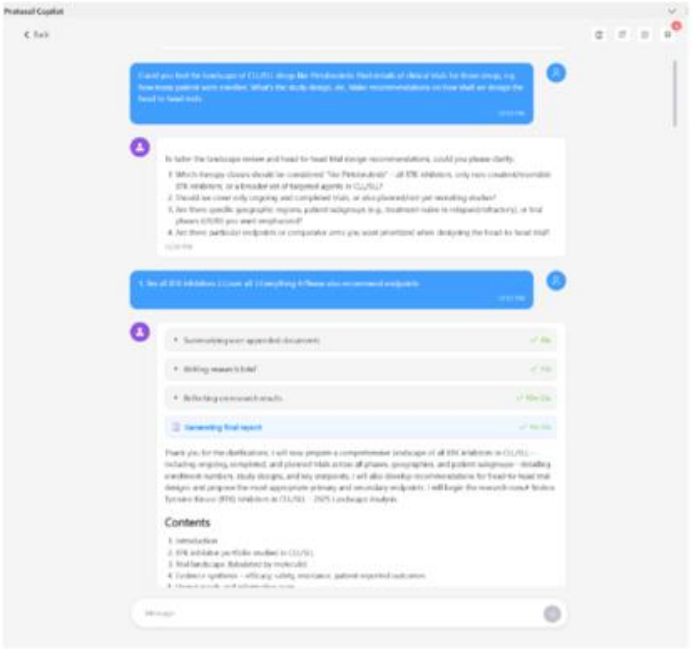




AI Deep Research

AI Drafting tool

Deep Research Tool

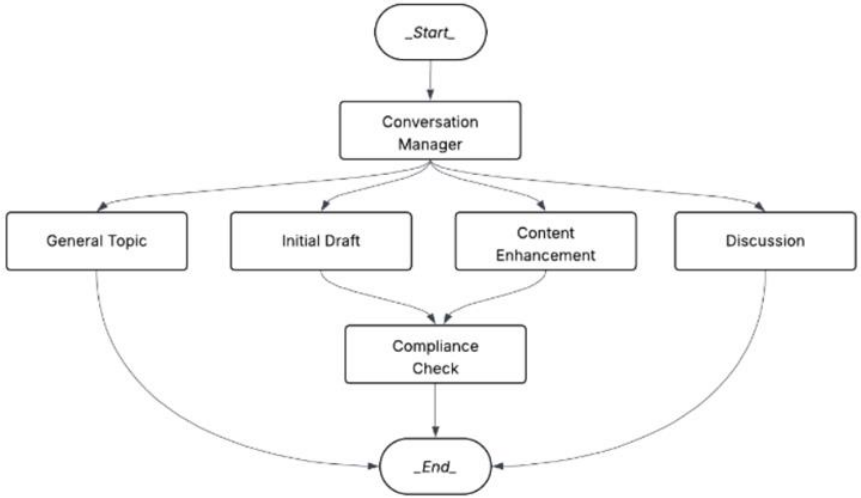


AI Drafting Agent

AI Drafting workflow is a multi-agent system that helps generate and refine clinical trial documents.

Sub Agents:

- **Conversation Manager Agent**: Interprets the writer's request (e.g., protocol section, intentions).
- **Initial Drafting Agent**: Produces the initial draft of the clinical text.
- **Enhancement Agent**: Polishes language for clarity, readability, and style.
- **Compliance Check Agent**: Ensures the draft follows regulatory, ethical, and internal compliance rules.
- **Discussion Agent**: Supports interactive back-and-forth drafting and brainstorming.
- **General Topic Agent**: Handles requests that don't fit a specific category.



Deep Research Agent

What is Deep Research System

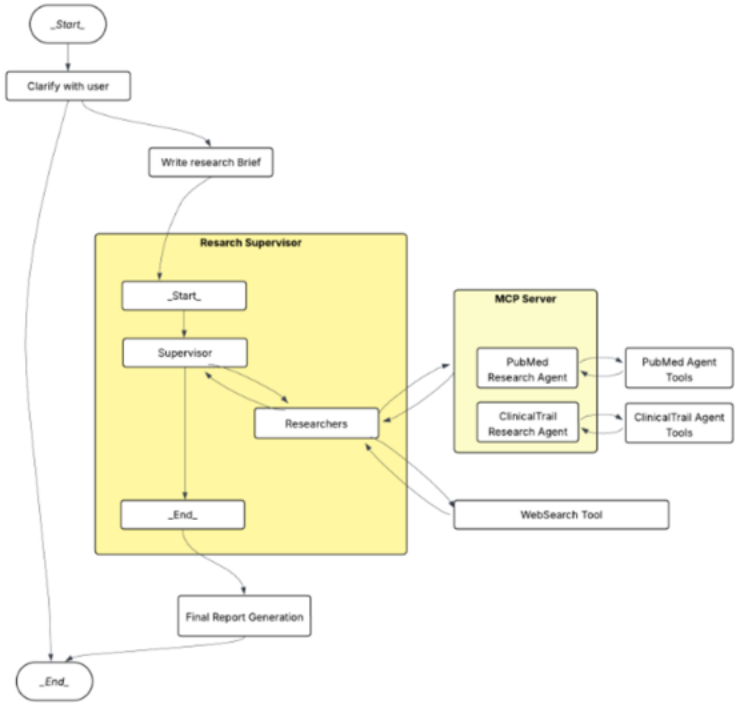
A deep research system is an AI tool that gathers, analyzes, and summarizes internet-sourced information to deliver clear, in-depth reports on complex topics.

Why We Need Deep Researchers

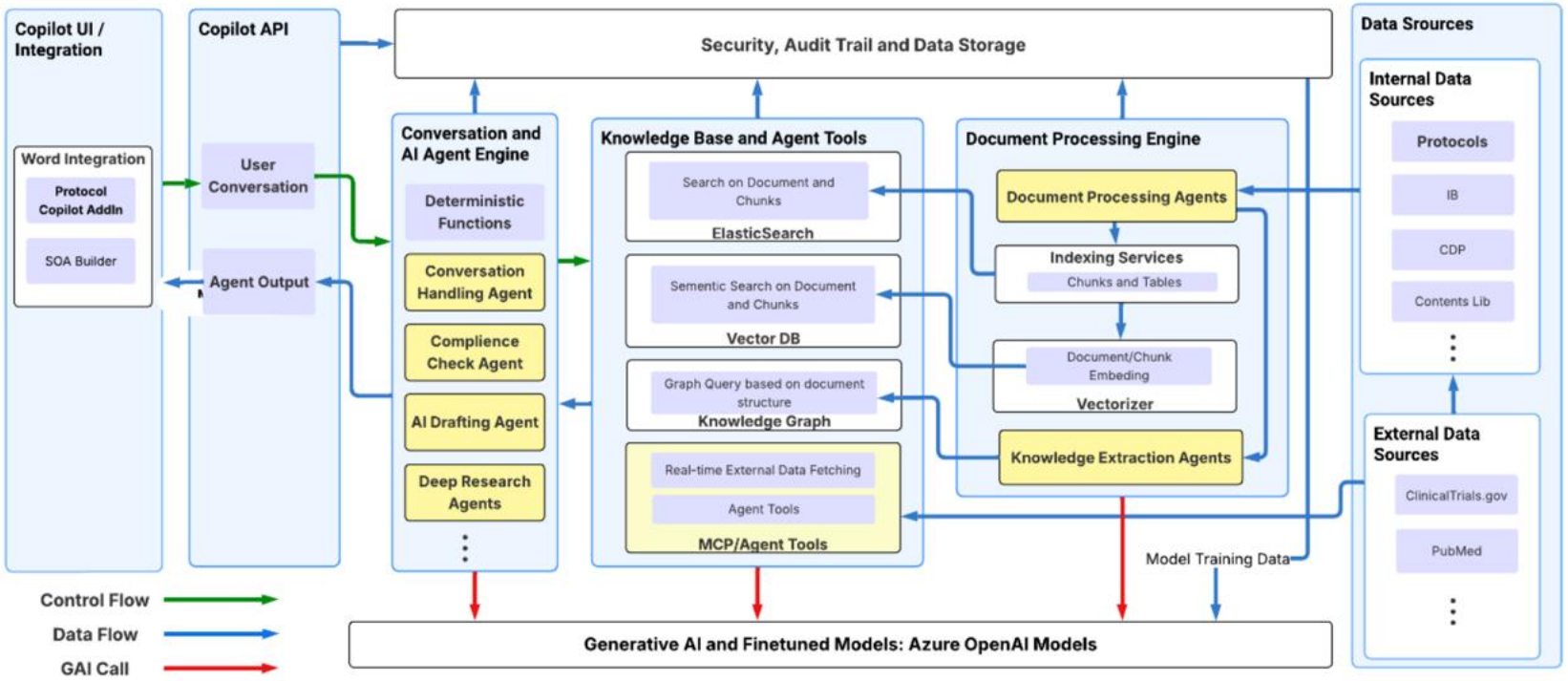
- High quality information synthesis is expensive.
- Requires a lot of efforts and time.
- Understands both internal and external context.

Deep Researcher Workflow

1. User submits research query.
2. Clarification Agent asks clarification questions.
3. Planning Agent writes research brief.
4. Research supervisor conducts rounds of research with multiple subagents.
5. Report Agent generates the final report with citations.



Architecture



Thank You

The Global Healthcare Data Science Community

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