

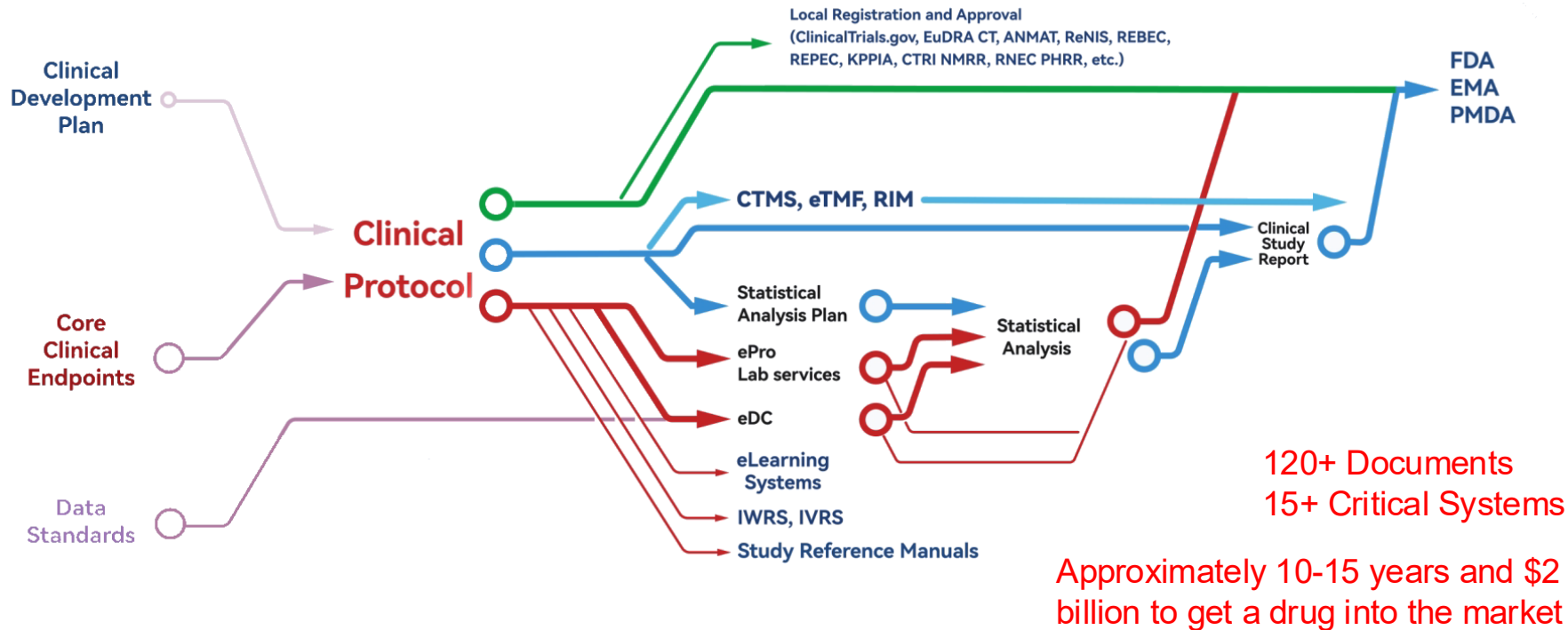
Single Day Event

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

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Global Statistics and Data Science (GSDS)
BeOne Medicines Co., Ltd.



Clinical Data Flow 临床数据流程





Industry Challenges 行业挑战

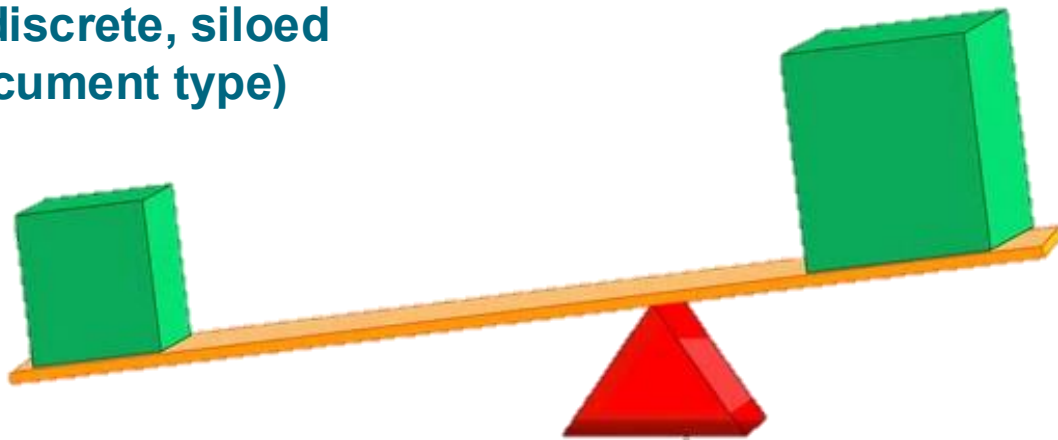
- ▶ **Protocol content has tripled in the past decade**, contributing to a 27 % increase in approval-to-FPFV timelines and prolonging downstream tasks such as EDC configuration and SDTM mapping.
十年来，方案内容增三倍，批准至 FPFV 延长 27%，下游流程受阻。
- ▶ Substantial protocol amendments have risen 113 %, with **studies now 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

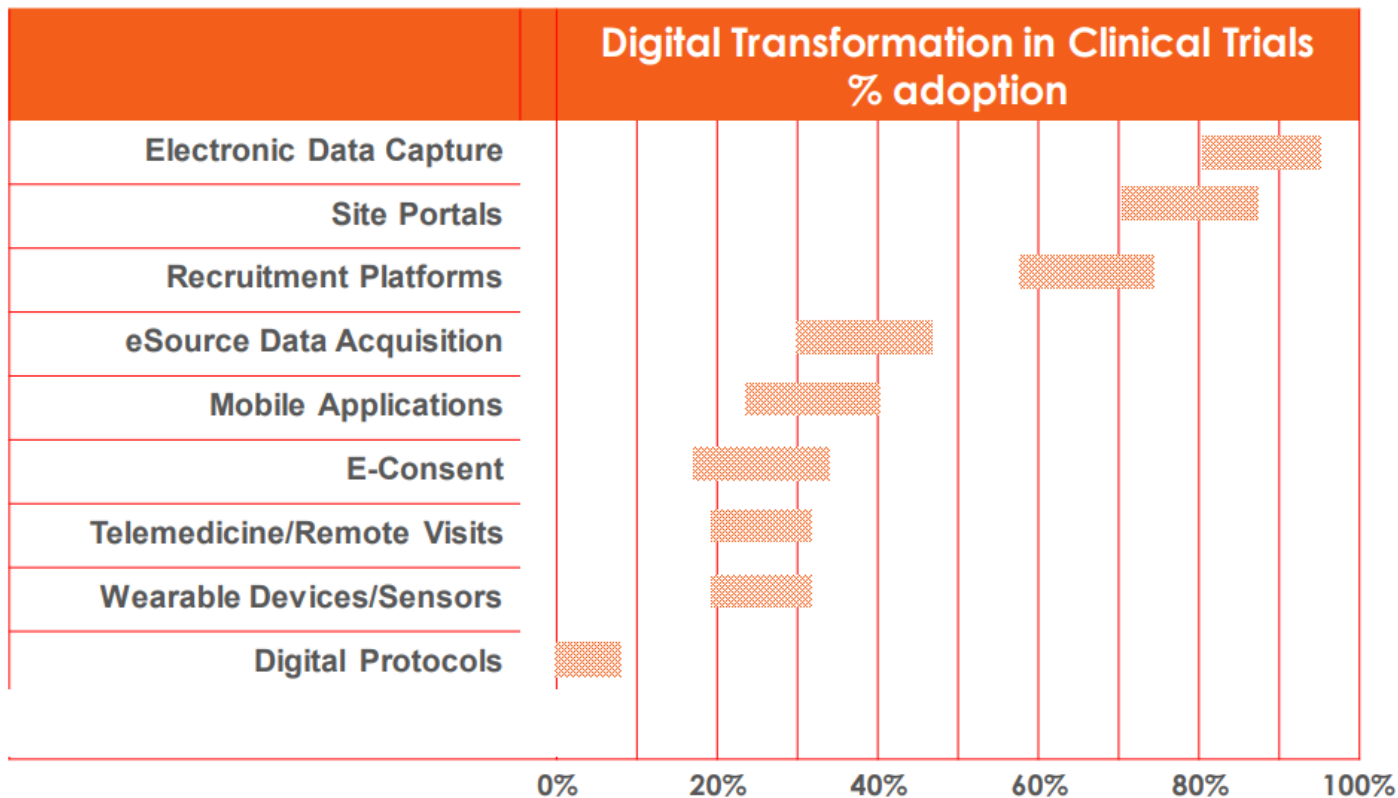
**AI/ML (disruptive,
content connectivity)**

**Content/data Standardization
+
Historical Studies**





Adoption (%) for Digital Transformation





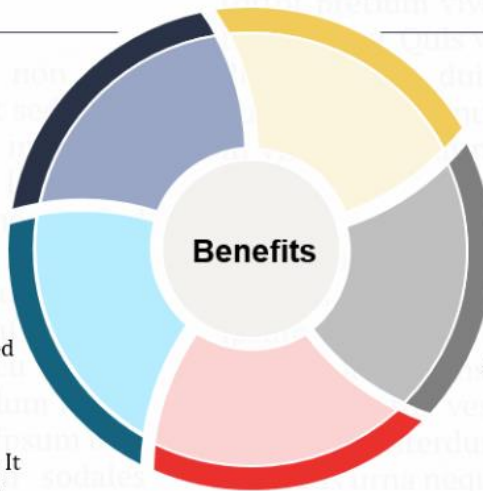
Start with Standardizing Protocol

Patient Centricity

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

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.



Compliance

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

Simplicity

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

Standardisation

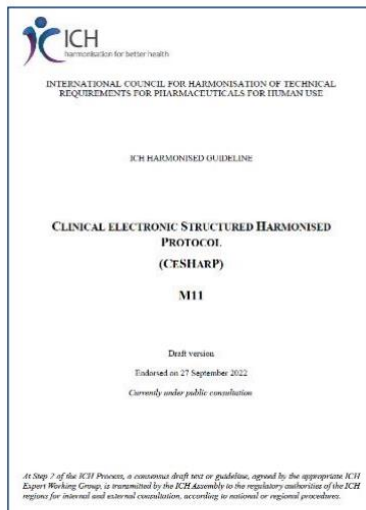
Documents and templates are available and applicable company-wide; they have **global applicability** and allow for **tailoring** for regional or country requirements, where needed

Aligning with Industry Standards

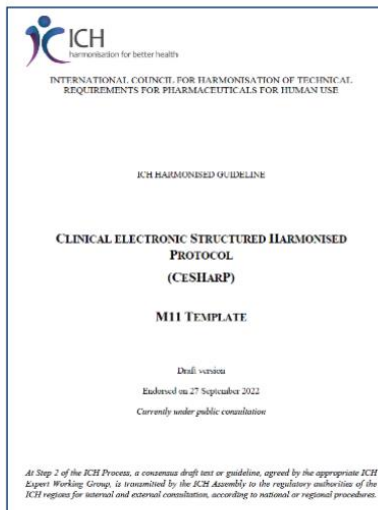
M11 Is ...

ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHaRP)

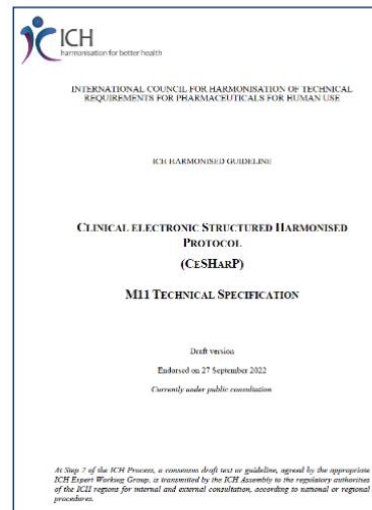
<https://www.ich.org/page/multidisciplinary-guidelines>



Provides background, purpose, and scope as a guideline



Provides the written format for the Interventional Clinical Trial Protocol Template



Provides the technical representation aligned with the guideline and protocol template



The Foundation



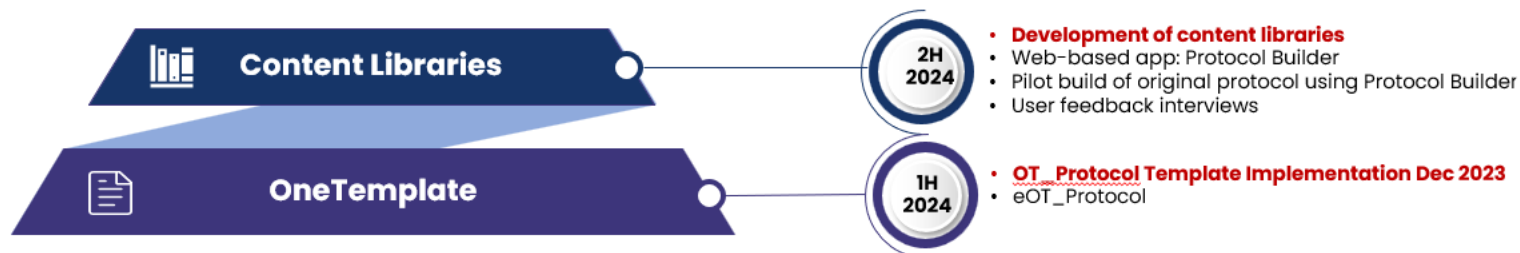
OneTemplate



- **OT_Protocol Template Implementation Dec 2023**
- eOT_Protocol



Reuse – Content Libraries



 **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**
SoA

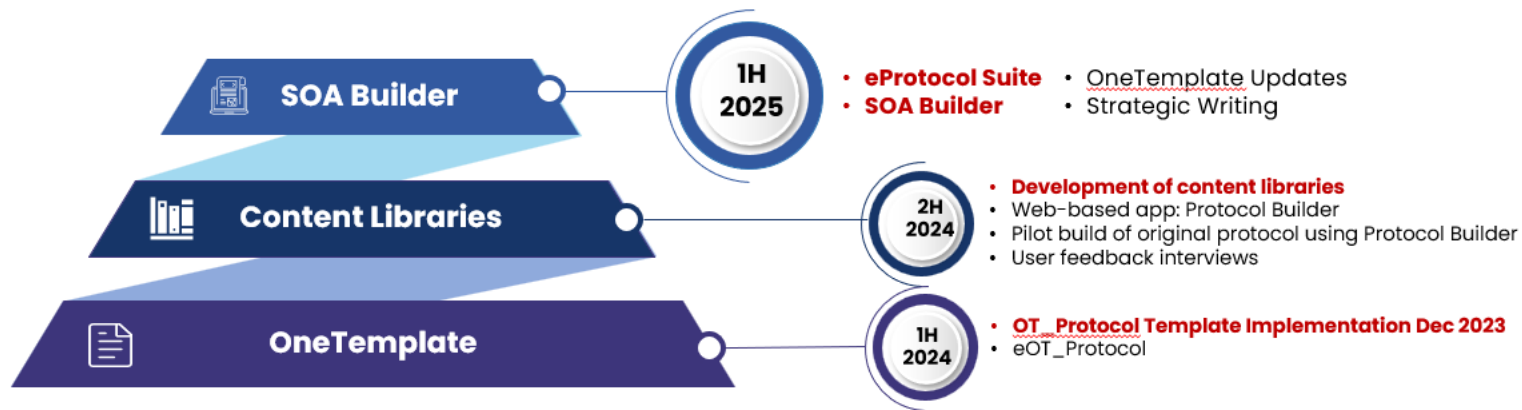
 **Developer Tags**
 **About**
 **Report Issue**
Utilities & Support



Select the icon or press Alt + i to draft with Copilot



Digitalizing Schedule of Activities





Protocol Copilot



AI Language Check



Connected



Launch SoA Builder

Protocol Number

TEST-Protocol

Amendment Number

Original Protoc



Insert Content



Populate Molecule Content



Manage Content



Insert SoA & Footnotes



Refresh SoA & Footnotes



Developer Tags



About



Report Issue

AI Assist

Connection & SoA Builder

Content Library Management

SoA

Utilities & Support

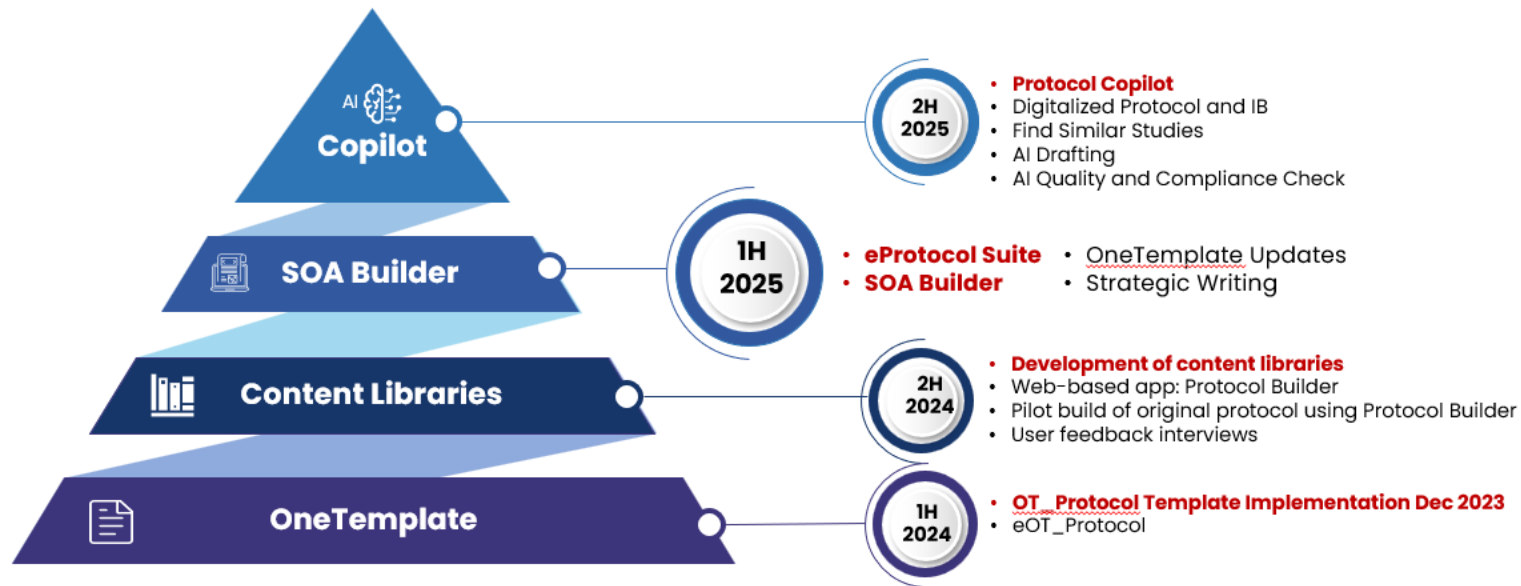
[BG/BGB-XXX-XXX]	[Company Name]
[Original Protocol or Protocol Amendment X.X]	



I

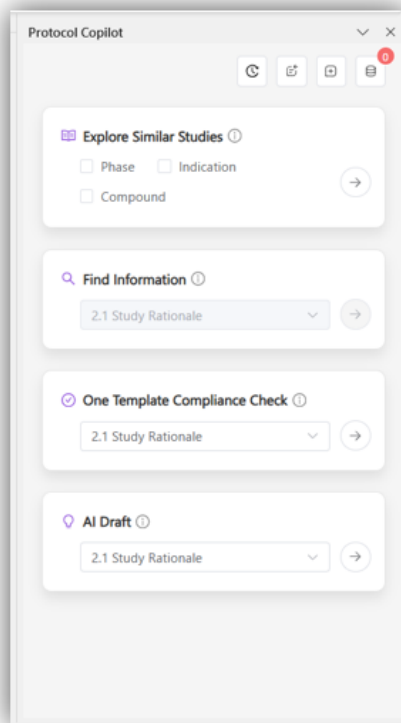


Copilot





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

Protocol Copilot

Explore Similar Studies ⓘ

☐ Phase ☐ Indication ☐ Compound

Find Information ⓘ

2.1 Study Rationale

One Template Compliance Check ⓘ

2.1 Study Rationale

AI Draft ⓘ

1.1 Synopsis



Protocol Copilot

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AI drafting on Synopsis

Copilot

Protocol Synopsis	
Study Title:	Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma Rationale Reference
Brief Study Title:	Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma Rationale Reference
Brief Summary:	leukemia or small lymphocytic lymphoma who have previously received covalent BTK inhibitor therapy. The study will enroll approximately 500 patients and or unequivocal progressive disease occurs. The total study duration is expected to be approximately three and a half years, with an estimated treatment duration assessments performed according to the schedule of activities. Rationale Reference

Type your follow-up question here



AI Compliance Check

Protocol Copilot

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Compliance Check for content in Study Rationale

Copilot

1 Reminder

- Per the CTFG Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials (2019), the "overarching hypothesis" or scientific rationale defines the scientifically sound relationship(s) between the research questions of the (sub-)protocols.
- recommend maximum 1 page.
- Background information on the study drug is contained in Section 2.2 (background) and rationale for study design is contained in Section 4.2 (scientific rationale).
- This section should be aligned with the overall development plan for the compound. Complete this section in consultation with RA and Clinical Development.
- The rationale should be based on the results of previous studies (if relevant)
- For study drugs/treatments where content libraries are available, refer to the relevant asset library to support this section.
- This scientific rationale with its shared elements of the design and/or infrastructure common across sub-protocols can be described in the sub-protocols and the master protocol, with details on the relationship between sub-protocols in terms of efficacy and/or safety data collection, analyses, interpretation, and presentation.

Protocol Copilot

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Compliance Check for content in Study Rationale

Copilot

1 Reminder

2 Possible non-compliance

- While the scientific problem and patient population are described, the text does not mention the current standard of care or existing therapeutic limitations, which are explicitly required by this compliance item.
State the scientific problem or question (describe the population, disease, current standard of care, if one exists, and limitations of knowledge or available therapy).
- The wording of the provided text deviates from the recommended block: "study" is replaced with "trial" and an extra term ("pharmacodynamics") is inserted. Because non-placeholder text must match exactly, this block does not comply.
The purpose of this study is to evaluate the safety, tolerability, PK, and preliminary antitumor activity of [study drug/treatment] [alone and in combination] with [study drug/treatment] in [participants/patients] with [advanced solid tumors] or [hematological malignancies].

Protocol Copilot

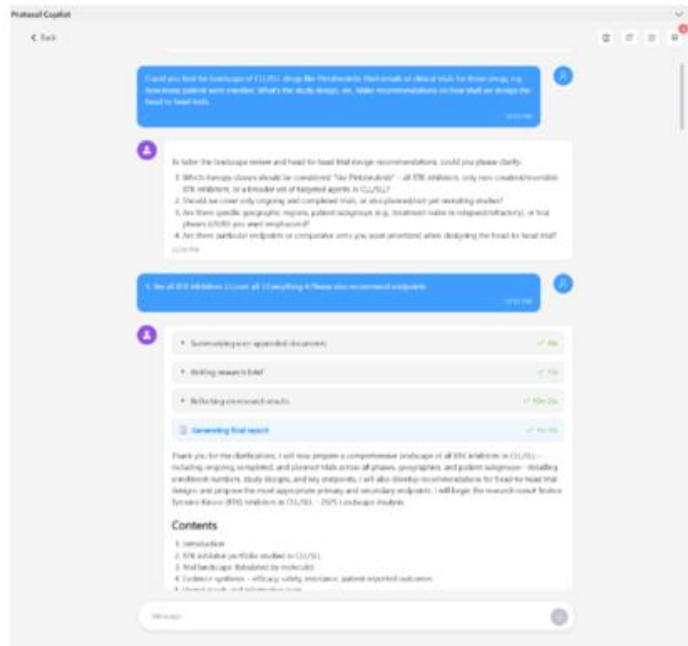
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3 Possible compliance

- The text clearly articulates the overall purpose of the study (to evaluate safety, tolerability, PK, pharmacodynamics, and preliminary antitumor activity of BGB-58067 alone or in combinations), thereby meeting the requirement to describe the reason for conducting the study.
The high-level rationale section should describe the reason (purpose) for conducting the study.
- The rationale details the biological background of MTAP deletions, their prevalence, and scientific significance, thereby covering the key disease characteristics and establishing scientific importance.
the characteristics of the disease and should be of scientific importance.
- The passage specifies the aim of the study (to evaluate safety, tolerability, PK, pharmacodynamics, and preliminary antitumor activity) and identifies key issues being addressed (eg. use of BGB-58067 as monotherapy and in combinations), fulfilling the requirement.
Include a brief description of the reasons (aim of the study). Include any key issues for the compound being addressed (eg. variable exposure addressed with a new formulation or dosing with food).
- Because this is an early-phase study, the text includes the compound's mode of action (MTA-cooperative PRMT5 inhibitor) and summarises pre-clinical antitumour activity, thus satisfying the early-phase requirements. Competitor data are optional ("if available") and their absence does not constitute non-compliance.
For early-phase studies, the rationale should also include the



Deep Research Tool



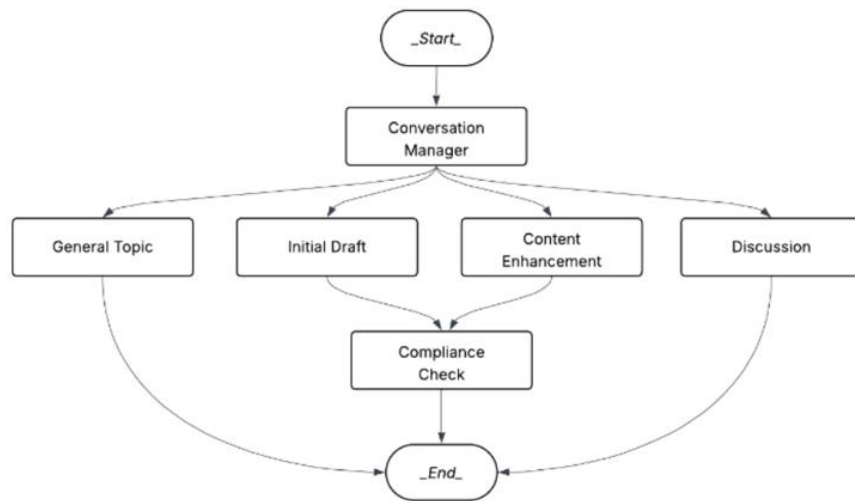


AI Drafting Agent

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

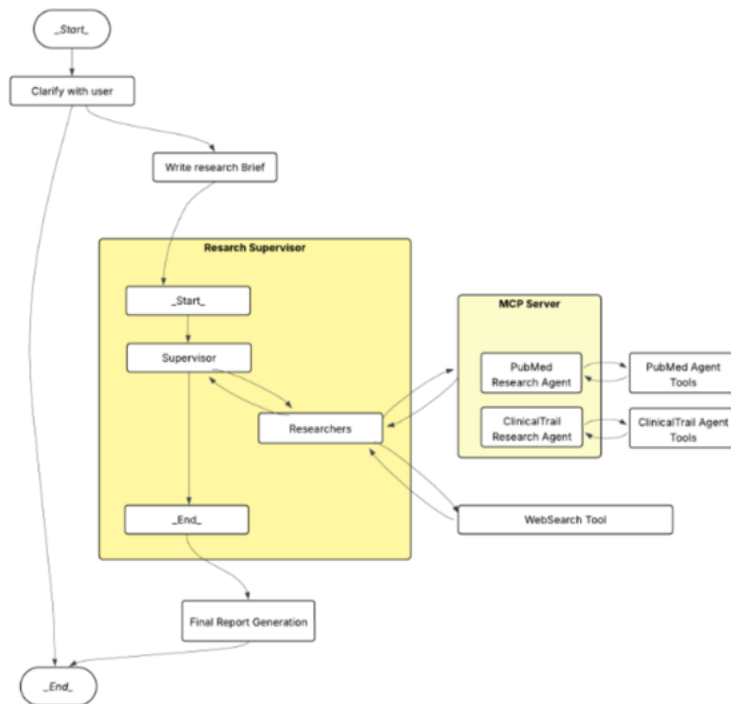
A deep research system is an AI tool that gathers, analyzes, and summarizes internet-sourced information to deliver clear, in-depth reports on complex topics.

Why We Need Deep Researchers

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

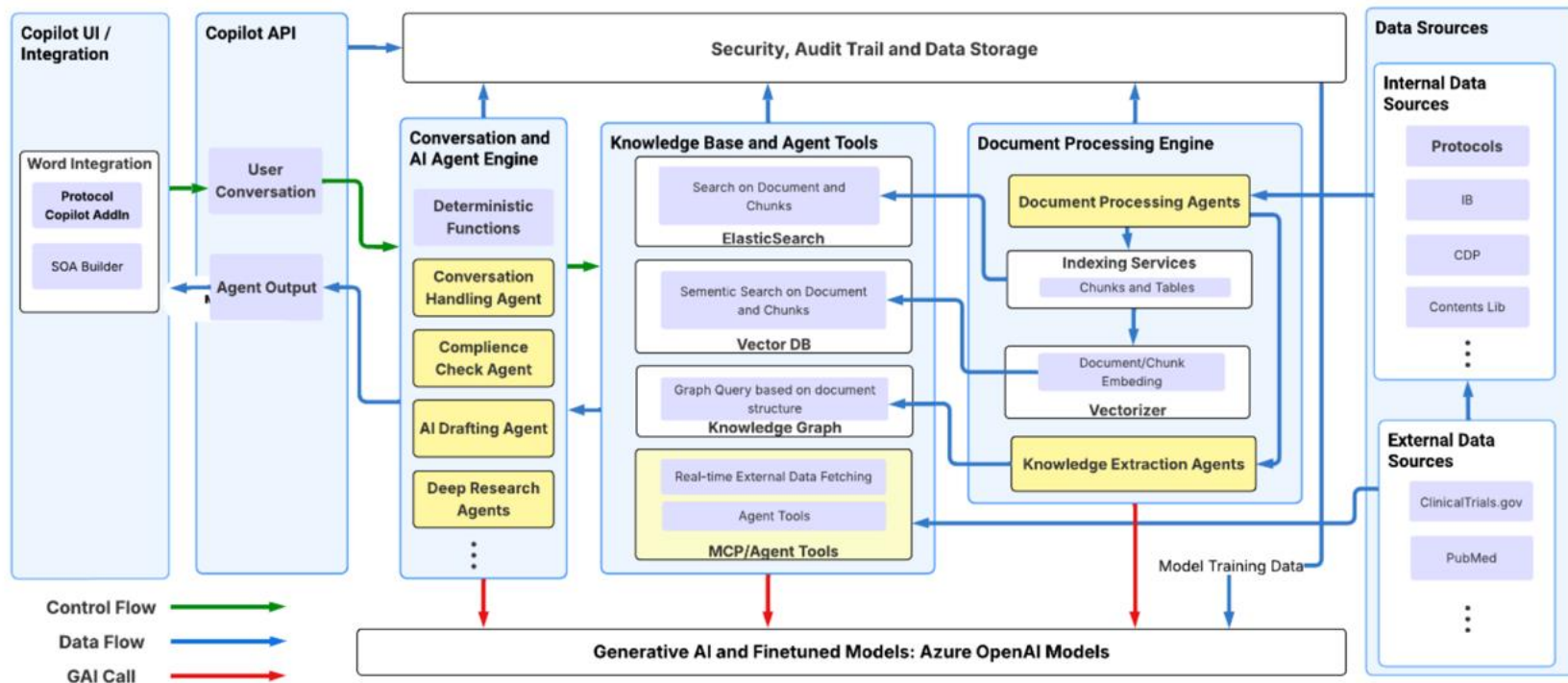
Deep Researcher Workflow

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**

Contact Channels

📞 UK +44 1843 609600
✉ office@phuse.global
🌐 phuse.global

Social Media

🐦 [@phusetwitta](https://twitter.com/phusetwitta)
📘 [/phusebook](https://facebook.com/phusebook)
▶ [/phusetube](https://youtube.com/phusetube)
🌐 [/company/phuse](https://company.phuse.com)