# LLMs in Clinical Development

### Introduction

Large Language Models (LLMs) have demonstrated substantial benefits across various sectors, offering enhanced efficiency through automation of text generation tasks – creation of commercial content, programming assistance, brainstorming partner.

However, the translation of these benefits to clinical development is not straightforward, due to industry-specific challenges such as:

#### Regulatory compliance

Can GenAI be validated for GxP use? Does it need to be validated? Can it be incorporated into existing process?

#### Data security and privacy

How do we handle sensitive patient data and comply with GDPR/HIPAA?

#### **Accuracy & Traceability**

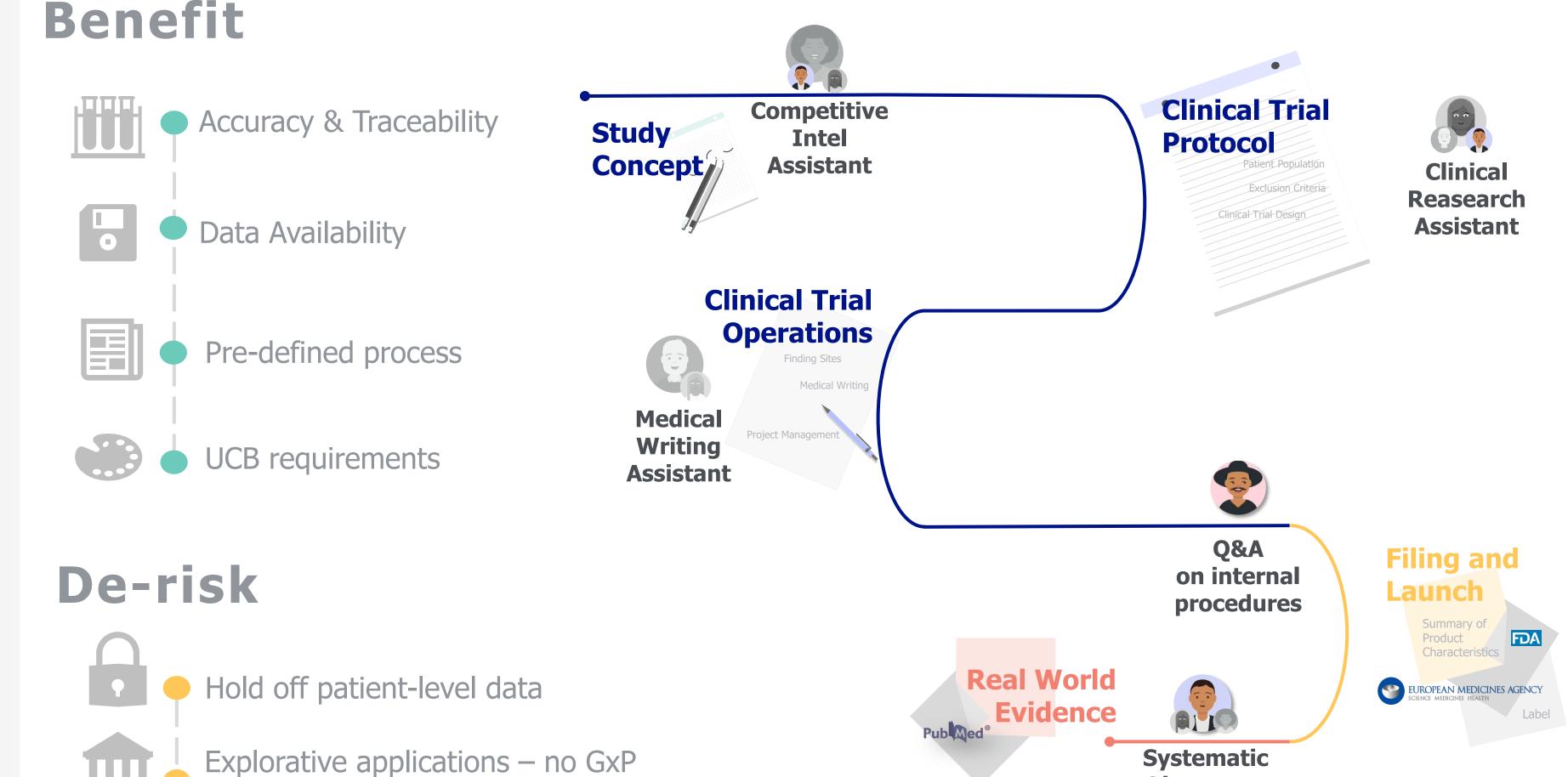
Can we guarantee it and how far can we push?

#### **Company requirements**

Specific templates and way of working

Can LLMs be effectively used in Clinical Development?

## **Clinical Development Flow and Opportunities**



Educate about Generative AI to excite and involve the subject matter hands-on experts

Encourage use of common LLMs (aka Copilot) in daily activities to appease the fears of AI yet avoid over-reliance

Build assistants from experimentation with end-users

Choose applications where human review is an inevitable part of the process

★ Enterprise support – OpenAI API secure endpoint

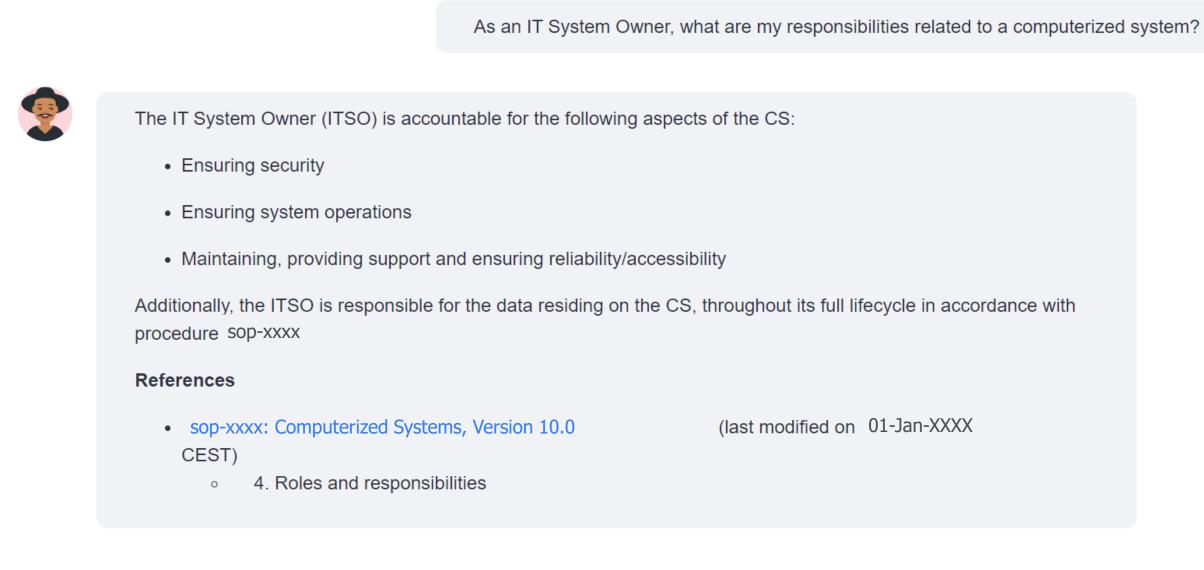
Literature

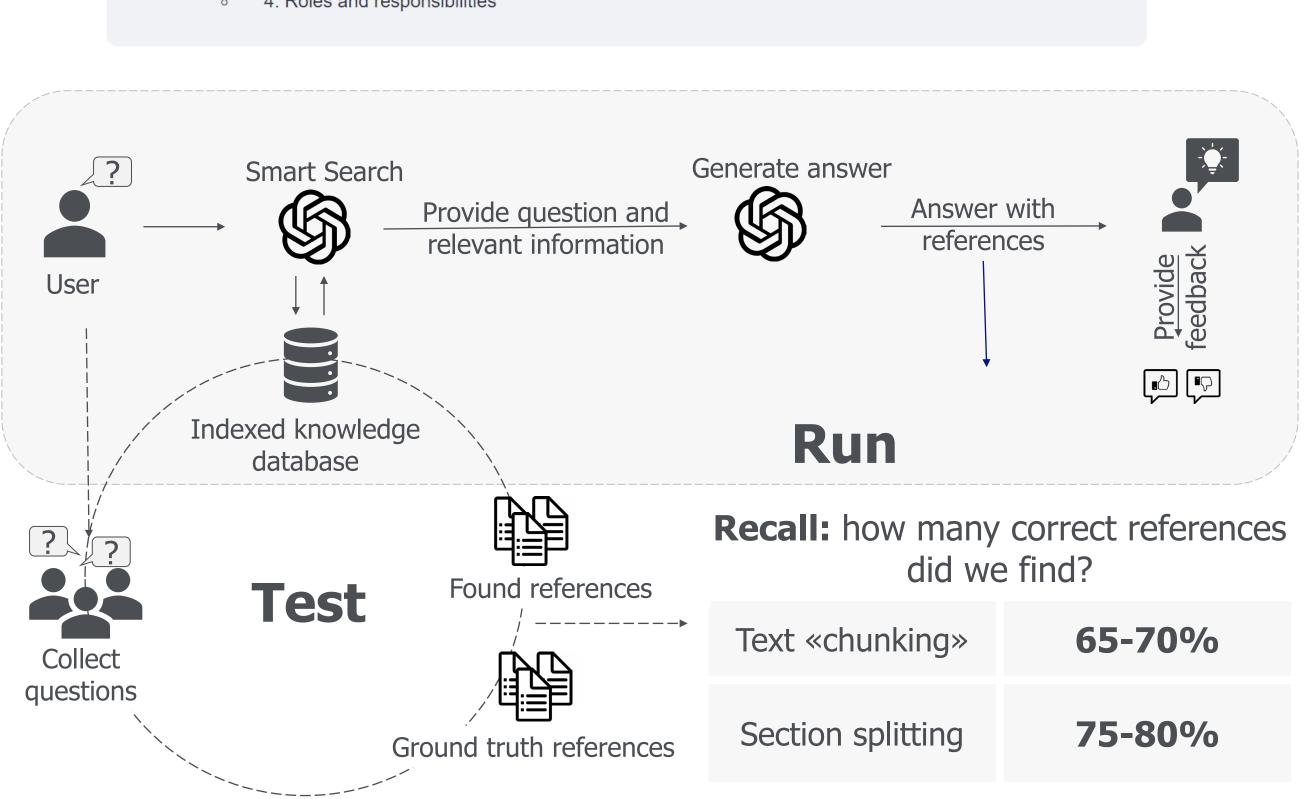
**Review** 

- Design a test strategy benchmark tests set and feedback support
- \* Availability of data for indexing and access control



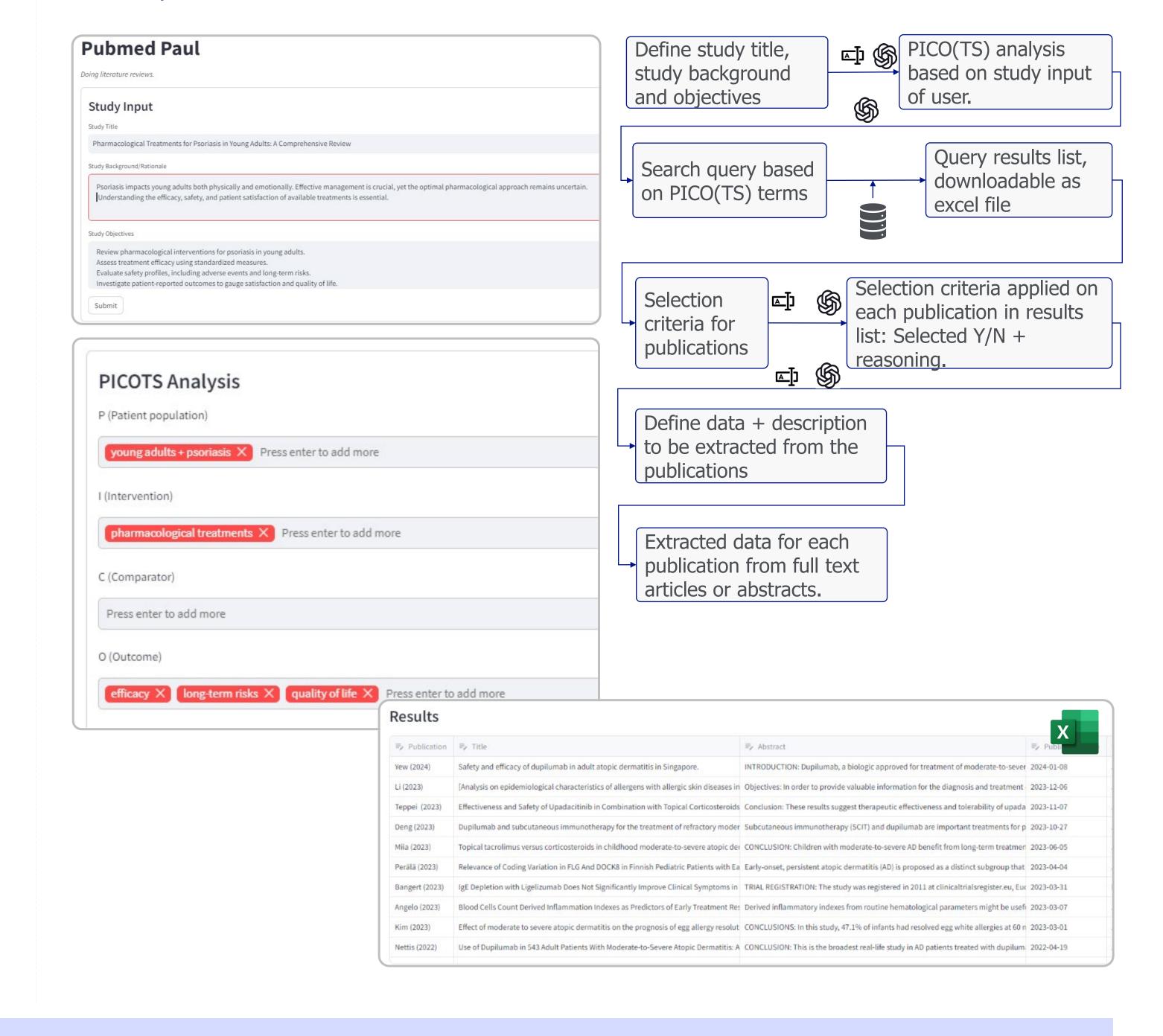
Augmenting LLMs with information from internal procedural documents for more efficient and user-friendly information retrieval







Utilizing generative AI to facilitate literature review execution by automating manual steps in the process.



## Conclusion

- LLMs can enhance efficiency but end-to-end apps will require custom configuration (from choice of model to embeddings to data preparation) for specific needs.
- Setting up a functional LLM is relatively easy, but optimizing performance is difficult.
- The importance of accuracy and explainability is paramount, yet there are scenarios where quality control can be organically integrated into user journeys
- Considering accuracy will never be perfect, human review becomes more important and should be included in ROI calculations.
- The prevalence of edge cases can pose a constraint on accuracy.
- A careful balance between generalizability and specificity, affecting the LLM's usefulness and correctness, must be maintained.

