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Single Day Event

Leveraging AI & ML in Clinical Development in AstraZeneca

By

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AI-Artificial intelligence, ML-Machine learning

Agenda

- Responsible AI in AstraZeneca
- Data & AI Ethics Principles
- Data Science & AI in AZ
- Case-Study AZ Compliant Generative AI and Proof of Concept in AZ

AI-Artificial intelligence, AZ-AstraZeneca

AstraZeneca's Data & AI Ethics and Principles

Private and Secure

Human Centric and Socially Beneficial

Fair

Explainable and Transparent

Accountable

Data Science & AI in AZ

AI & Knowledge Graphs for Drug Discovery

Data science to improve clinical practice and clinical trials

AZ Compliant Generative AI

Generative AI in AstraZeneca:

Proof of Concept

Gen AI Proof of Concept:

Executive Summary

Background: main output from Drug Projects is text

Departments:

- *Patient Safety*
- *Clinical*
- *Regulatory*

- *+50% of average member time spent on creating text*
- *Small efficiency gains = big impact on submissions*

Approach:

- *Grant access to entire drug project team to a secure AZ compliant Generative AI instance with Product-specific documentation embedded and provide agile technical support*

Introduction:

Project Objective and Structure

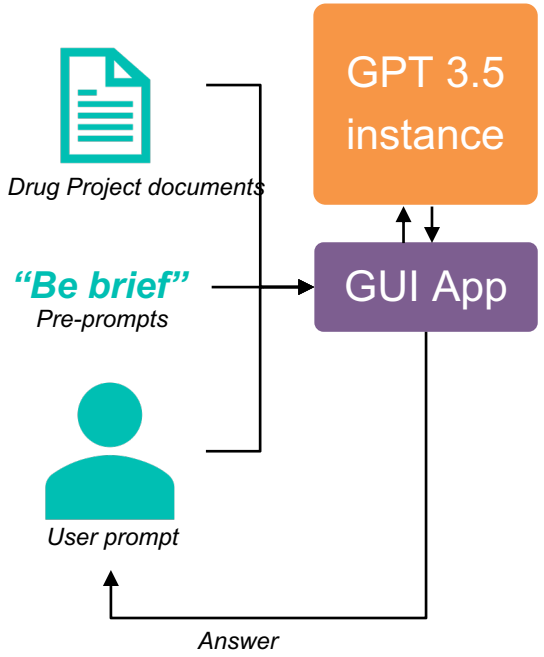
Introduction

Background:

- The main output from Drug Projects is text:
  - *Submissions*
  - *Briefing books*
  - *Reg response*
  - *QA docs*
  - *Reactive Q&As*
  - *Published papers*
  - *Presentation*
  - *Emails*
  - *(…)*

Approach:

- All global Drug Project team members (+50), across R&D and BBU, were given access to a secure version of AZ Compliant Generative AI for writing support
  - No restrictions on how to use the tech and a technical lead assigned to maximize value
  - Drug Project-specific contextual material was added to the AZ Compliant Generative AI "memory"
- A weekly virtual stand-up meeting was scheduled, project was continuously evaluated, and lessons learned documented



Objective

- 150+ business use cases were created across the organisation using Large Language Models (LLM)
- Assess efficiency gains in ***writing-based tasks*** by integrating AZ Compliant Generative AI model to a specific drug project

Inform introduction of similar models in the broader organisation:

- What are the key use-cases?
- What does and does not work?

Outcomes

- Key Results
- Impactful Use-Cases
- Architecture Considerations

Key Outcomes

Overall, the generative AI pilot demonstrated positive results and received favourable feedback from users

- *Model adoption was in line with expectations of summarising and information Retrieval*
- *Users generally expressed satisfaction with the model's performance and desired to retain access to the model in the future*
- *50% of users reported significant time savings*
- *Non-native English speakers found most value from the writing support*
- *Future requests include PowerPoint integration and improved document workflows*

Impactful Use Examples

FDA Rapid Response RSI: Large-scale Table QC in 5 days

- *PDF tables needed to be validated towards corresponding RDF in a spot-check fashion*
- *Pairwise table comparison greatly reduced manual efforts and increased confidence in results*
- ***Tool helped meet timelines and avoid submission withdrawal***

Email to EMA Reporting Preliminary Assessment of Annexa-I

- *Bullet points with all email topics*
- *Generate email in correct style and level of formality*
- ***Tool saved time and improved readability***

Regulatory Response: 15 Questions from EMA with 4 Days to Answer

- *Bullet-points in mixed Swedish and English to allow fast drafting*
- *Generate full text using AZ Compliant Generative AI and manual edits*
- ***Tool enabled meeting EMA deadlines and avoid submission withdrawal***

However, most value comes from use in everyday tasks

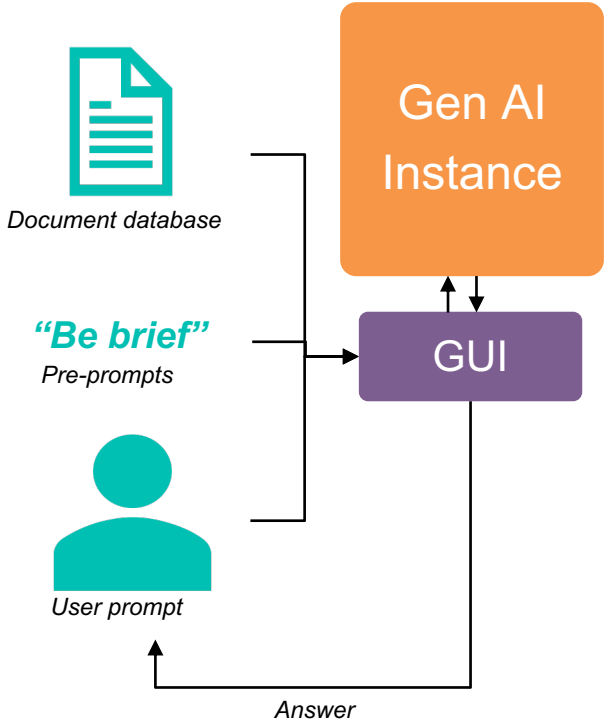
"It is easier to edit a text than to draft it from scratch"

FDA-Food and Drug Administration, RSI- Reference Safety Information, RDF-Response Document Format, EMA- European Medicines Agency

Architecture considerations

Retrieval Augmented Generation - RAG

- *LLM models lack information about things happening after their training or that is not part of their test set*
- *Re-training models are often infeasible due to size*
- *Different approaches have been proposed to address this problem by giving the model access to relevant context*
- *Model needs to be "aware" of Drug Project-specific information*



LLM-Large language models

How does Retrieval Augmented Generation Work?

1. Prepare Text Data	2. Create Embeddings	3. Retrieve Context & Generate

• *Get a corpus (generally PDFs)*
• *Parse them to relevant format in markdown*
• *Optionally add metadata tags*
• *Split them into smaller chunks = documents*
	• *Pass documents to pretrained word-embedding model*
	  • *We use general-purpose model*
	  • *Can be specific to e.g. scientific text*
	• *Receive vector set*
		• *Embed prompt and fetch k closest document neighbours. k is a hyperparameter, we use 5*
		• *Pass documents to model alongside prompt*
		• *Typically, together with other "pre-prompts"*

Standard architecture. Used for e.g., Question-answering.

Overview of Lessons Learned

Technical

- *RAG architecture needs more work to fulfil user needs and Query across several documents of different types*
- *Token limitation is often a challenge*
- *Rate limits make tool slow (instance shared with other Proof of Concepts)*
- *Unstructured documents (e.g. PDFs) a challenge*
  - *Need parsing into e.g. markdown format*
  - *Not possible to handle documents where some numbers are images (OCR difficult)*

Project Management

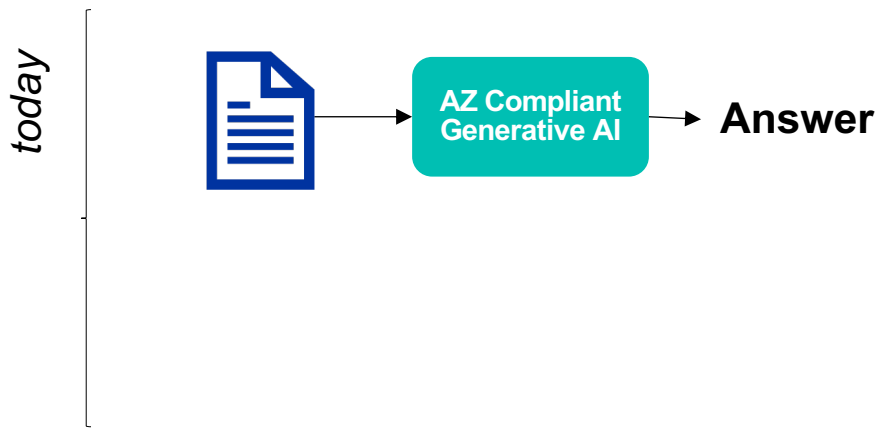
- *Timelines of instance access need to allow for development and testing before users expect access*
  - *Certain requirements must be set even if the approach is iterative and experimental*
  - *E.g. logging requirements for a complete analysis at readout*
- *Locating and processing documents best done before instance access is granted*

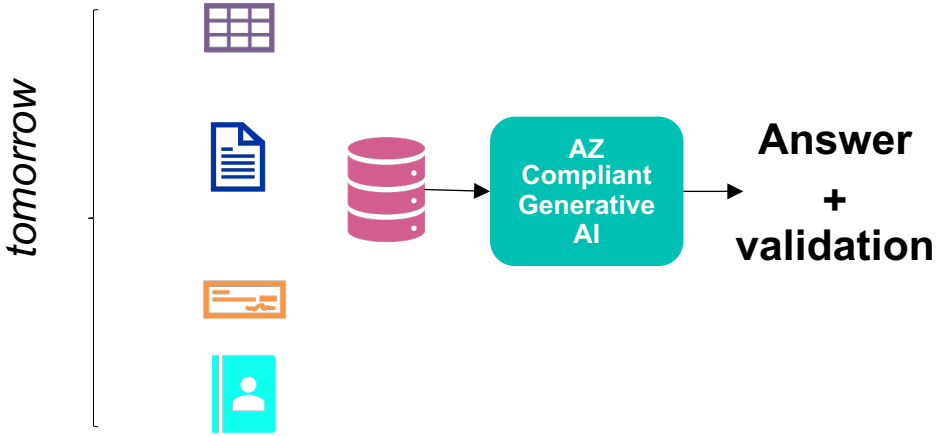
OCR-Optical Character Recognition

Conclusion

- *The Generative AI instance was successfully deployed and appreciated by end-users*
- *This was the first time Generative AI was introduced within a drug-project, making it a notable milestone*
- *Around 50% of users report saving at least 10% of time ~ 1/3 use AZ Compliant Generative AI daily or weekly*

Evolving Landscape





Example use: *What information do you have on Thrombotic Events in the ANNEXA-I CSP?*

Example use: *How many Thrombotic Events are there across all Drug Project studies?*

Thank you

The Global Healthcare Data Science Community

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