

Ask SANDY – Leveraging AI to Simplify SDTM Standards and streamline Clinical Data Management

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Leveraging AI to Simplify SDTM Standards and streamline Clinical Data Management

Presented by Bram Seigers, BIS Business Analyst
Ward Puttemans, Clinical Standards Manager,



Meet the Speakers

Bram Seigers

Title: Business Analyst, BIS Development

Organization: argenx

Working within Business Information Team at argenx, partnering with stakeholders within Regulatory, Clinical Operations and Clinical Data to deliver digital solutions with a co-creation mindset. Using his 10 years of experience in Life Sciences to deliver with value and in partnership with business teams.



Ward Puttemans

Title: Clinical Data Standards Manager

Organization: SolCur/argenx

Works as a data standards data manager and lab controlled terminology subject matter expert at SolCur outsourced to argenx, with over 10 year of experience in data management. Co-lead on the CDISC Controlled Terminology User Guide (CTUG) team, a member of the Lab SDS sub team and a CDISC instructor in Controlled Terminology.

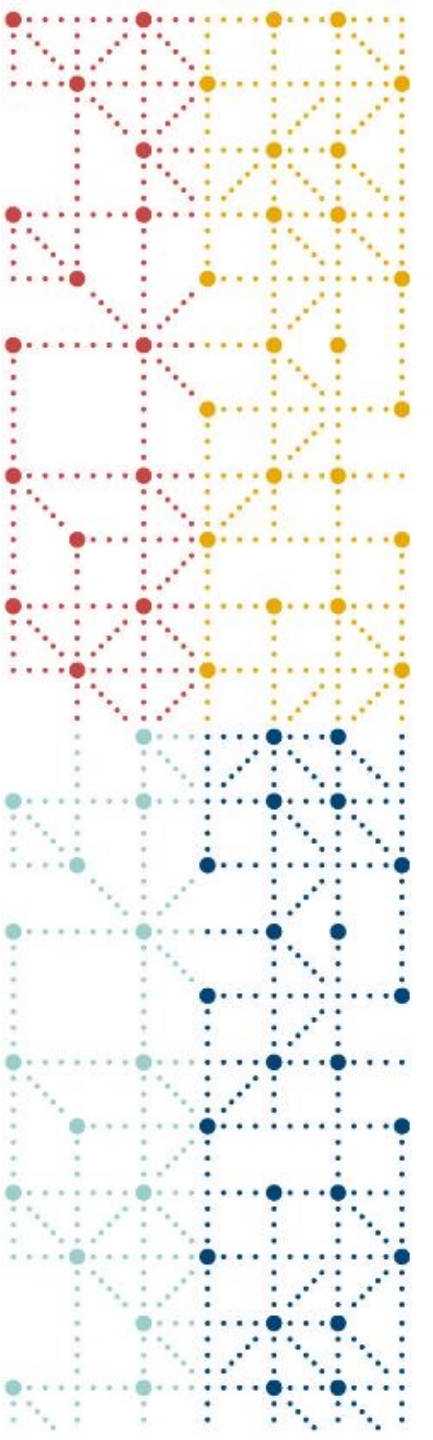
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- *The author(s) have no real or apparent conflicts of interest to report.*



Agenda

1. Setting the scene – What is ‘Ask Sandy’
2. Development & Technical Setup – How did we get there
3. Lessons Learned – What did we learn throughout our journey
4. Demonstration – What does it look like
5. Q&A – What do you want more information on



Setting the Scene – What is ‘Ask Sandy’

Ask Sandy provides Support on queries related Clinical Data Standards

ASK Standards ANswers Do it Yourself

Objectives

- Automate responses to generic and repetitive Data Standards Queries
- Provide faster and less resource intense answers
- Adherence to industry and argenx Data Standards
- Flexible development and scope extension
- Re-use components of argenx AI strategy

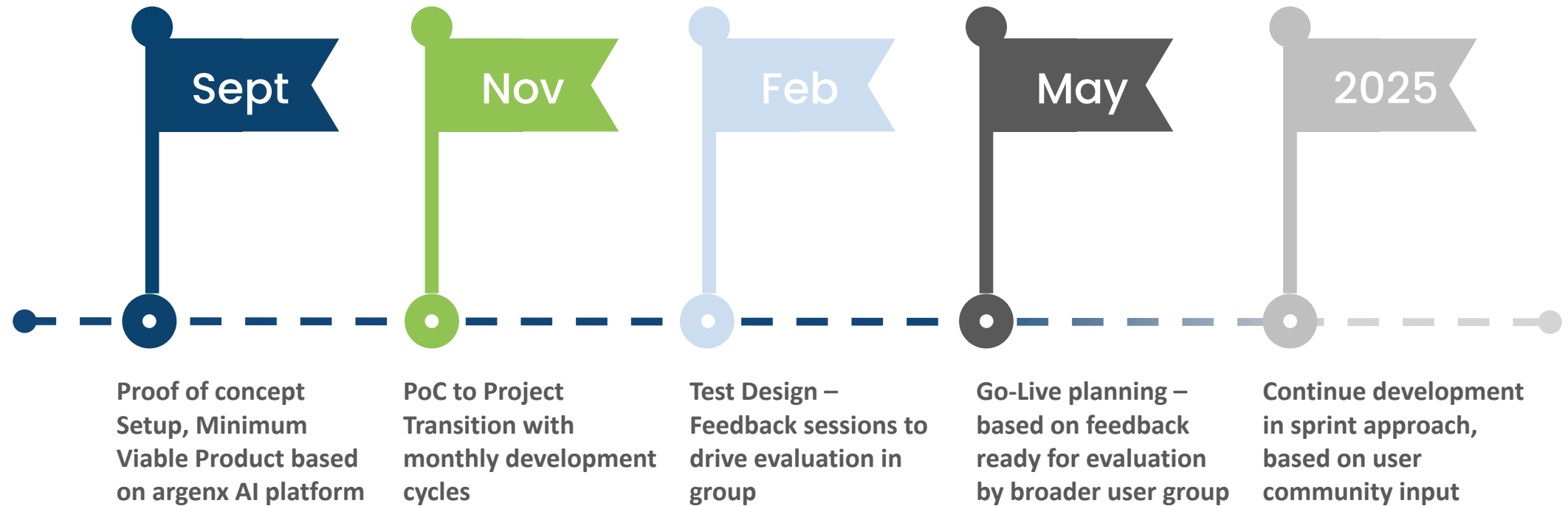
Scope

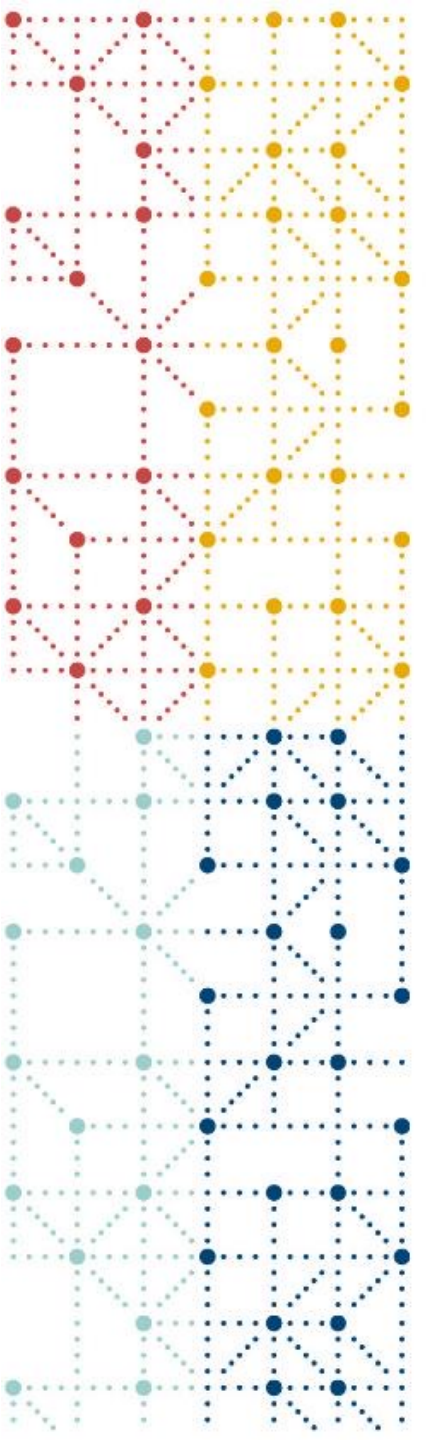
- Evolving Data Standards documentation (e.g.)
 - Regulatory guidelines
 - CDISC SDTM docs (model, IG, rules)
 - argenx Data Standards
- Version management of standards documents
- User Base consisting out of Clinical Data Management, Standards managers, Stats Programming and Data Analysts

Business Impact

- Deliver an answer with focus on argenx standards
 - Summary
 - Extended information
 - Source references
 - Link to source documents
- Provide Data Standards information with limited Data Standards Managers direct involvement

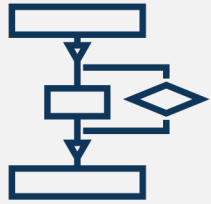
We developed using a milestone setup intertwined with monthly development cycles





Technical Setup – How did we get there

Ask Sandy is co-created as a custom AI application re-using components from the argenx AI Factory



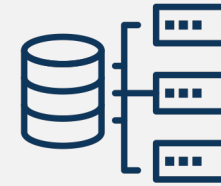
Define the Use
Case



Iteratively build



Test-Test-Test



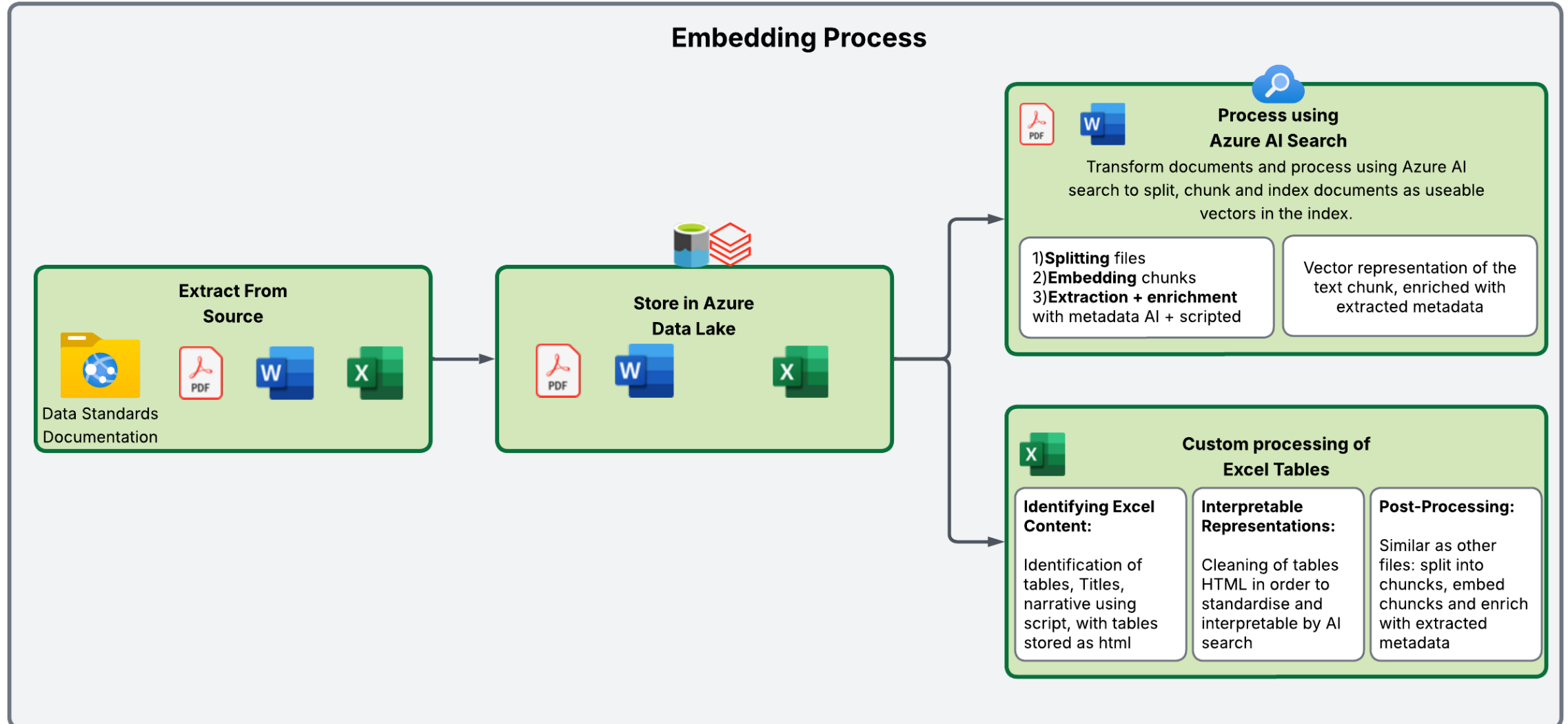
Technical Setup



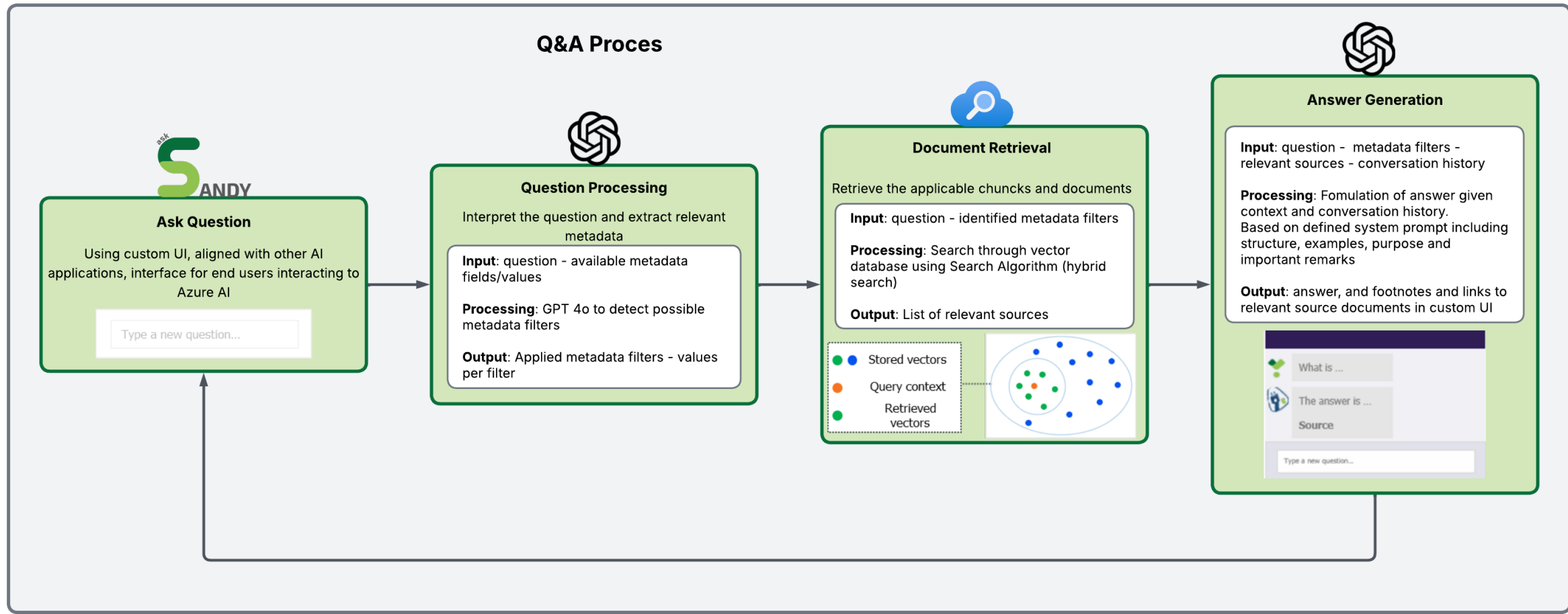
Defining the
building blocks

We are going step by step, re-using what is possible, building what is needed

The documents in scope are fed to and processed by a LLM in Azure



Based on the user question, metadata is extracted and relevant to the context answer is generated





Lessons Learned – What did we learn throughout our journey

Lessons learned are split between user interaction, development, and scope & context



User interaction

- AI literacy – how to deal with non-deterministic questions
- Testing the right things – reuse of questions
- Personal preferences – what is a good answer structure
- No Google – conversation based
- Quality Control, make sure users use the source to verify



Development

- Dealing with Excls & complex tables
- Focussed development vs continued effort
- Tracking of what is an improvement and technical cost – KPI's
- Link to argenx AI platform; re-use components but dev delays
- User bias to extensive coverage on AI



Scope & context

- Focus on certain key documents, build-in bias?
- Versioning & similarity of documents
- Definition of a good and acceptable answer
- Core team testing (tech and content) vs end user (content, applicability & sample size)

We are not done yet, we'll continue to learn, develop and maintain

May

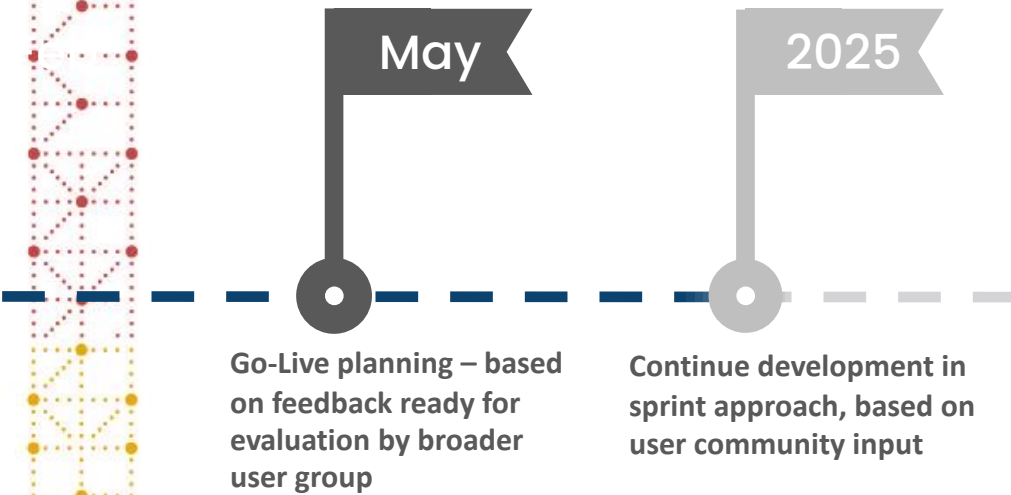
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Go-Live planning – based on feedback ready for evaluation by broader user group

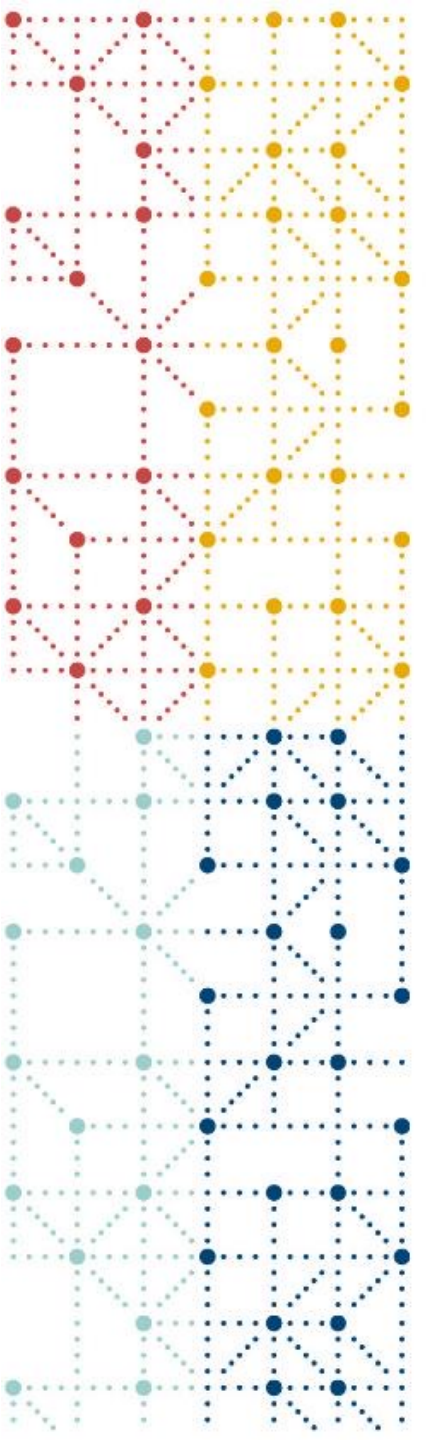
Continue development in sprint approach, based on user community input

	Backlog			To Do
AP-469: 1. Data Standards: New Features	AP-596 Chat history using User ID Backlog Me	AP-246 Add indication of accuracy on the answer Backlog Me	AP-600 Investigate methods to index pptx documents Backlog Me Pre-Work Done/In Progress	AP-410 Include cost indication To Do Me
	AP-364 Develop handling for pdf files which contain annotations Backlog Me	AP-595 Concise vs Elaborate Answer Backlog Me	AP-598 Copy functionality for generated tables Backlog Me	
	AP-568 In the user feedback have option to add screenshot Backlog Me			
AP-470: 2. Data Standards: Ingestion	AP-798 Update security on Azure file storage Backlog Me	AP-405 Extend scope to documents from other regulators Backlog Me Pre-Work Done/In Progress	AP-407 Option to deal with notes in text or tables and deal Backlog Me	
	AP-393 Get input from the Q&A SharePoint list from the Data Standards team Backlog Me	AP-399 Provide support for incremental updates of the documents Backlog Me	AP-367 Update list of document in scope + automate with regards to increments Backlog Me	

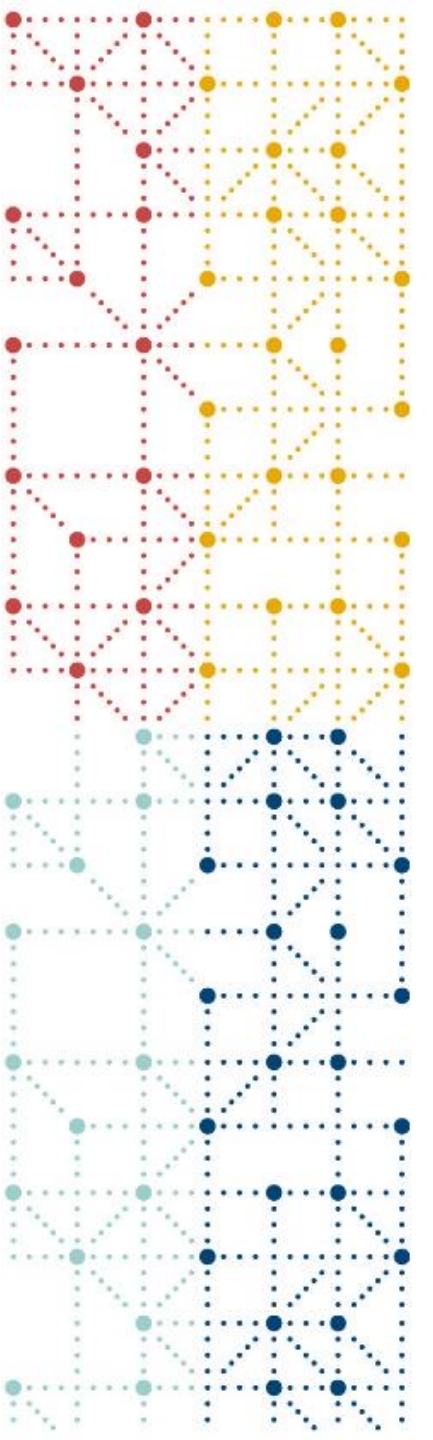
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	Backlog			To Do
AP-471: 3. Data Standards: Retrieval	<div>AP-250 Map specific types of questions to focus on retrieving information from identified key documents <small>Backlog</small></div>	<div>AP-564 Identify technical metadata filters <small>Backlog</small></div>	<div>AP-245 Option to identify key documents <small>Backlog</small></div>	
AP-472: 4. Data Standards: Generation	<div>AP-563 If answer is built using an old version -> notify users that there is a later version available <small>Backlog</small></div>	<div>AP-305 Make sure that terminology is respected more strictly <small>Backlog</small></div>	<div>AP-409 Provide input to bot to provide context to argenx standards compared to other documentation and guidelines. Can be extended to provide interpretation support for key documents <small>Backlog</small></div>	<div>AP-567 Include specific metadata in the answer <small>To Do</small></div>
AP-473: 5. Data Standards: UI/UX	<div>AP-742 Remove VPN requirement for Sandy access <small>Backlog</small></div>	<div>AP-639 Allow option to run without applied metadata filters <small>Backlog</small></div>	<div>AP-638 Update Metafiltering in UI <small>Backlog</small></div>	
	<div>AP-640 Include persistent Metadata filters <small>Backlog</small></div>	<div>AP-307 Currently pdf links are opened in edit more <small>Backlog</small></div>	<div>AP-408 Deal with sub and super script <small>Backlog</small></div>	



Demonstration – What does it look like



Q&A – What do you want more information on



Thank You!

