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

Bram Seigers / BIS Business Analyst - Ward Puttemans / Clinical Data Standards Manager

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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

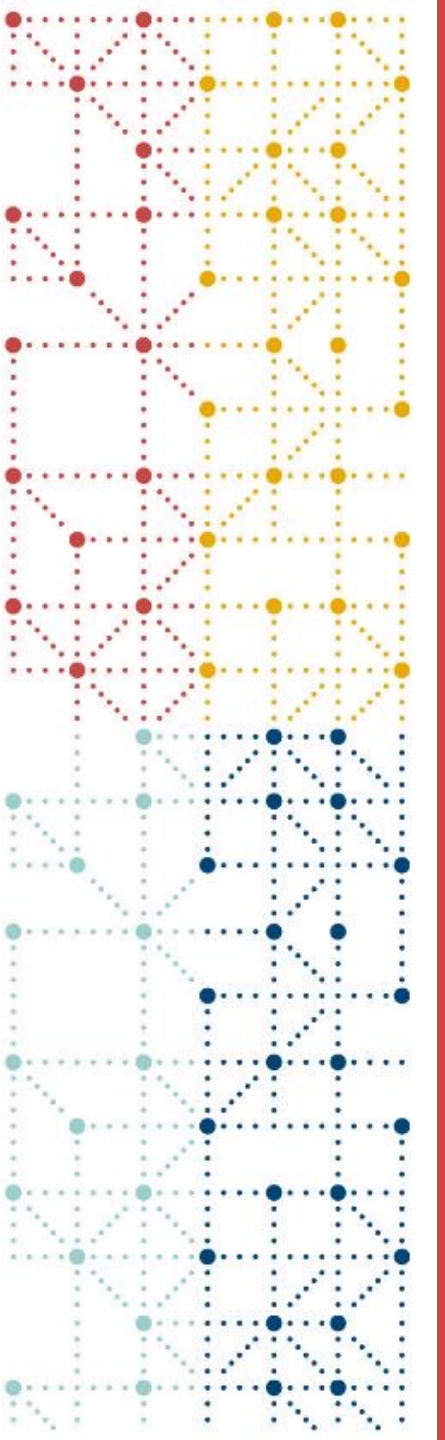
Organization: SolCur/argenx

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.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *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

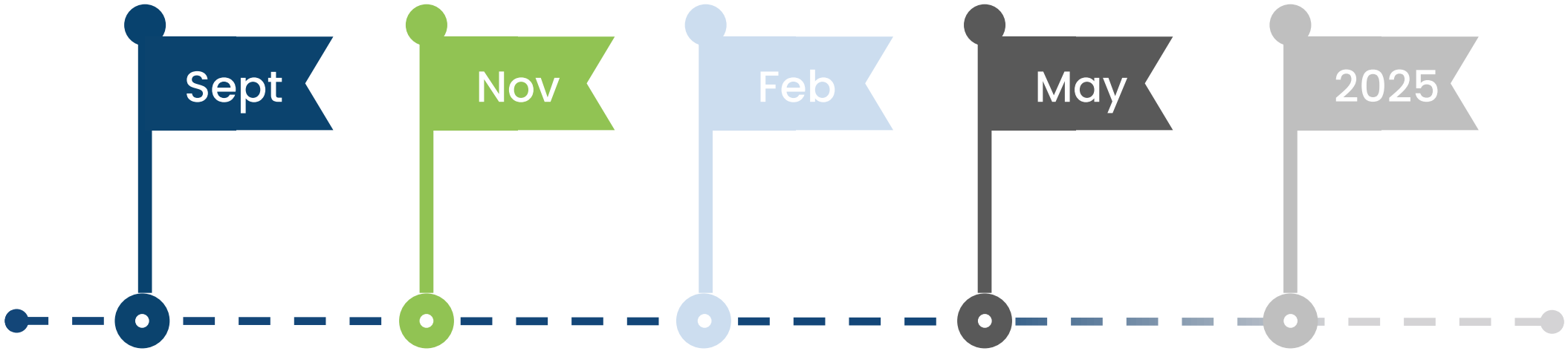
Scope

- 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



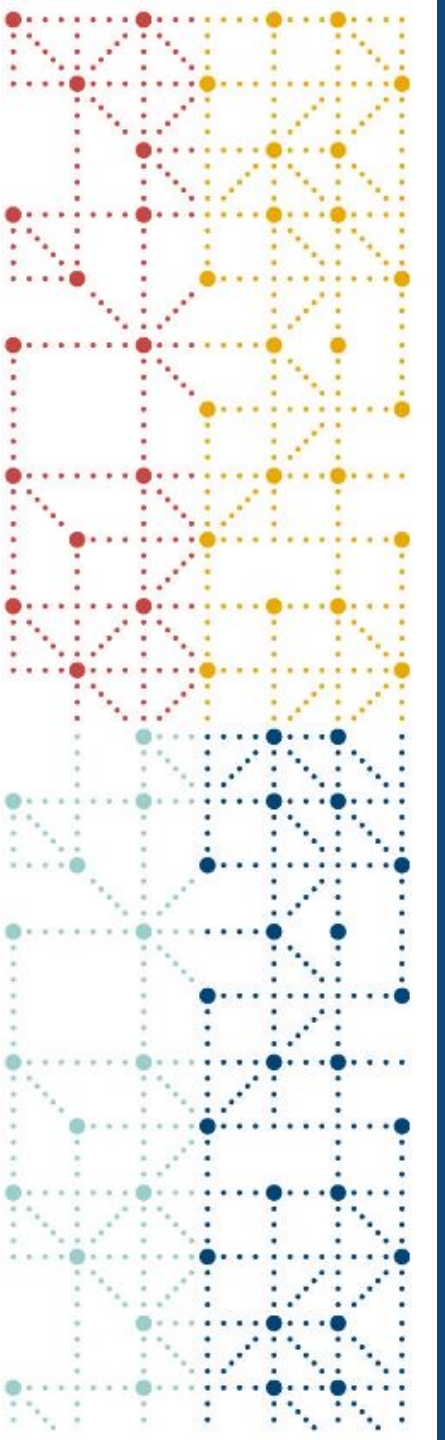
Sept
Proof of concept Setup, Minimum Viable Product based on argenx AI platform

Nov
PoC to Project Transition with monthly development cycles

Feb
Test Design – Feedback sessions to drive evaluation in group

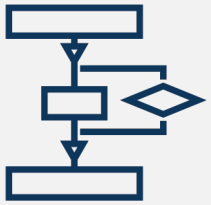
May
Go-Live planning – based on feedback ready for evaluation by broader user group

2025
Continue development in sprint approach, based on user community input



Technical Setup – How did we get there

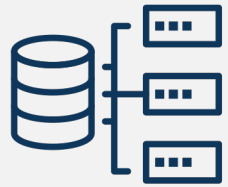
Ask Sandy is co-created as a custom AI application re-using components from the argenx AI Factory



Define the Use Case

Iteratively build

Test-Test-Test

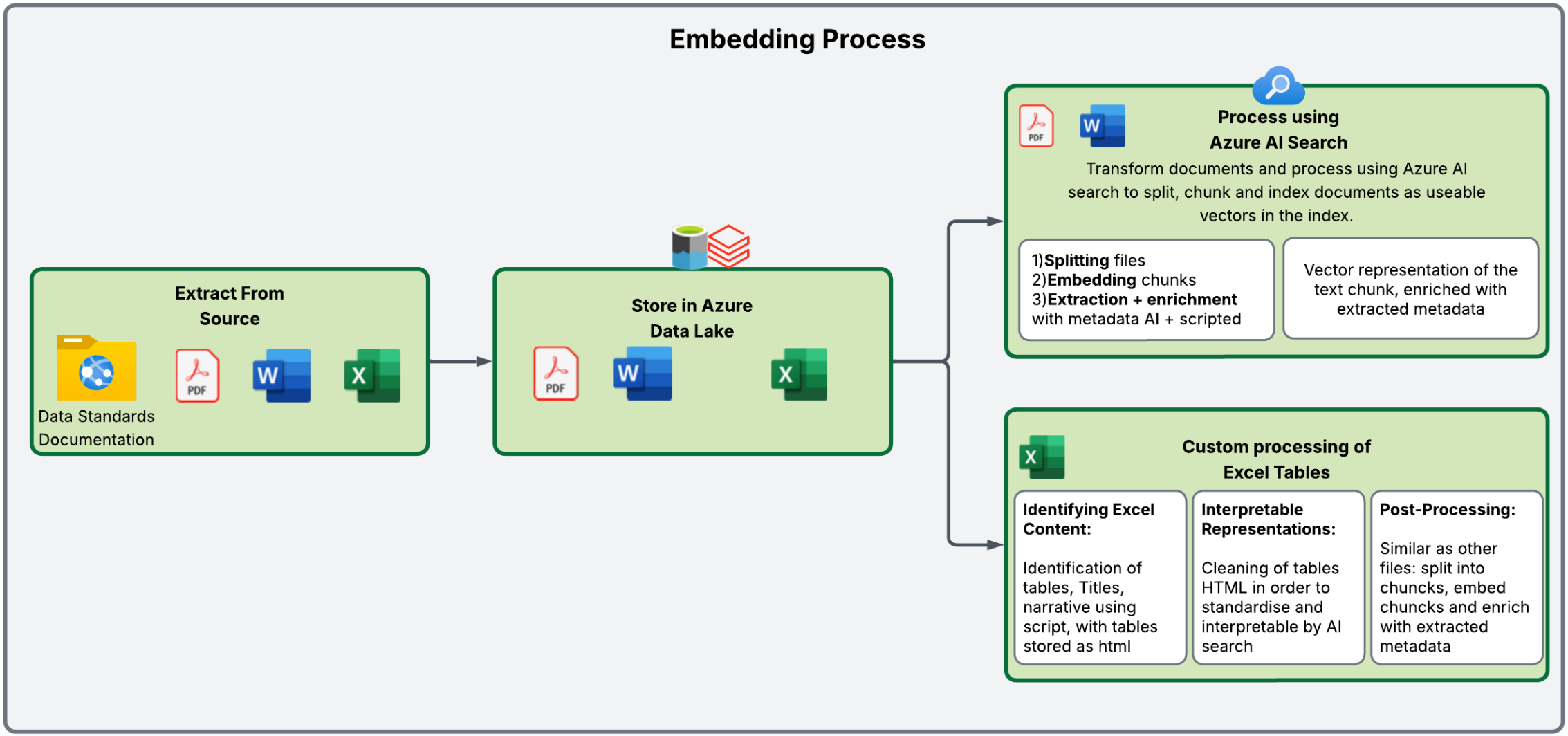


Technical Setup

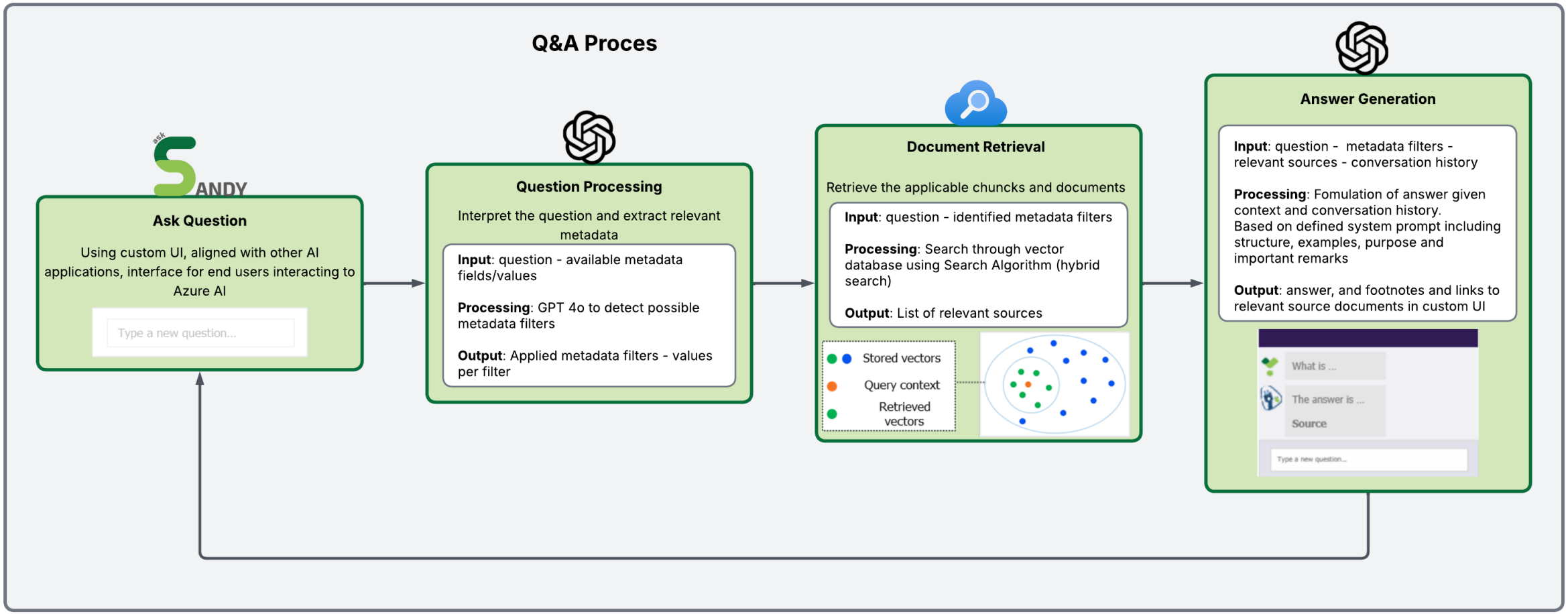
Defining the building blocks

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 Excels & 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)

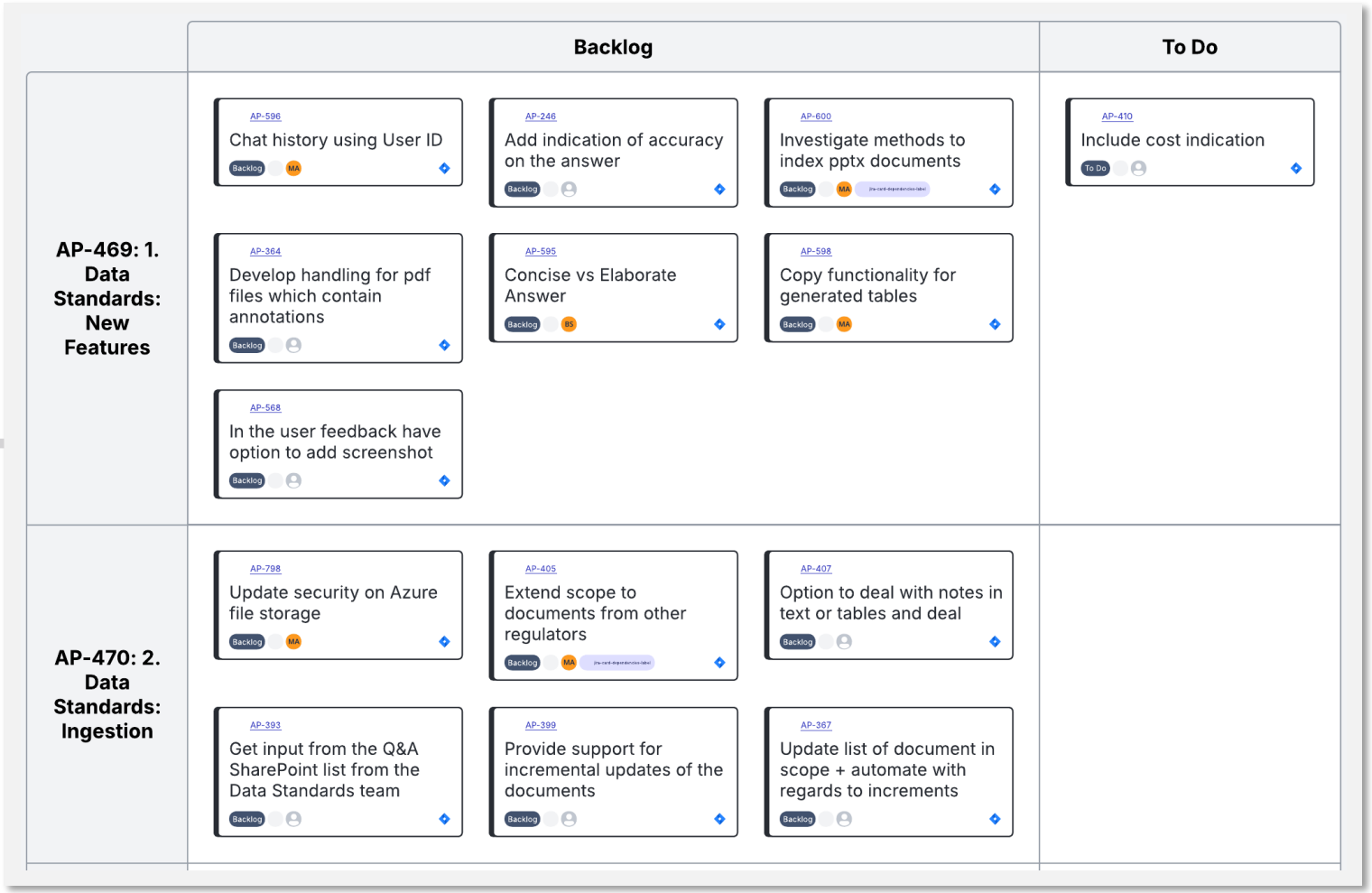
We are not done yet, we'll continue to learn, develop and maintain

May

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

2025

Continue development in sprint approach, based on user community input



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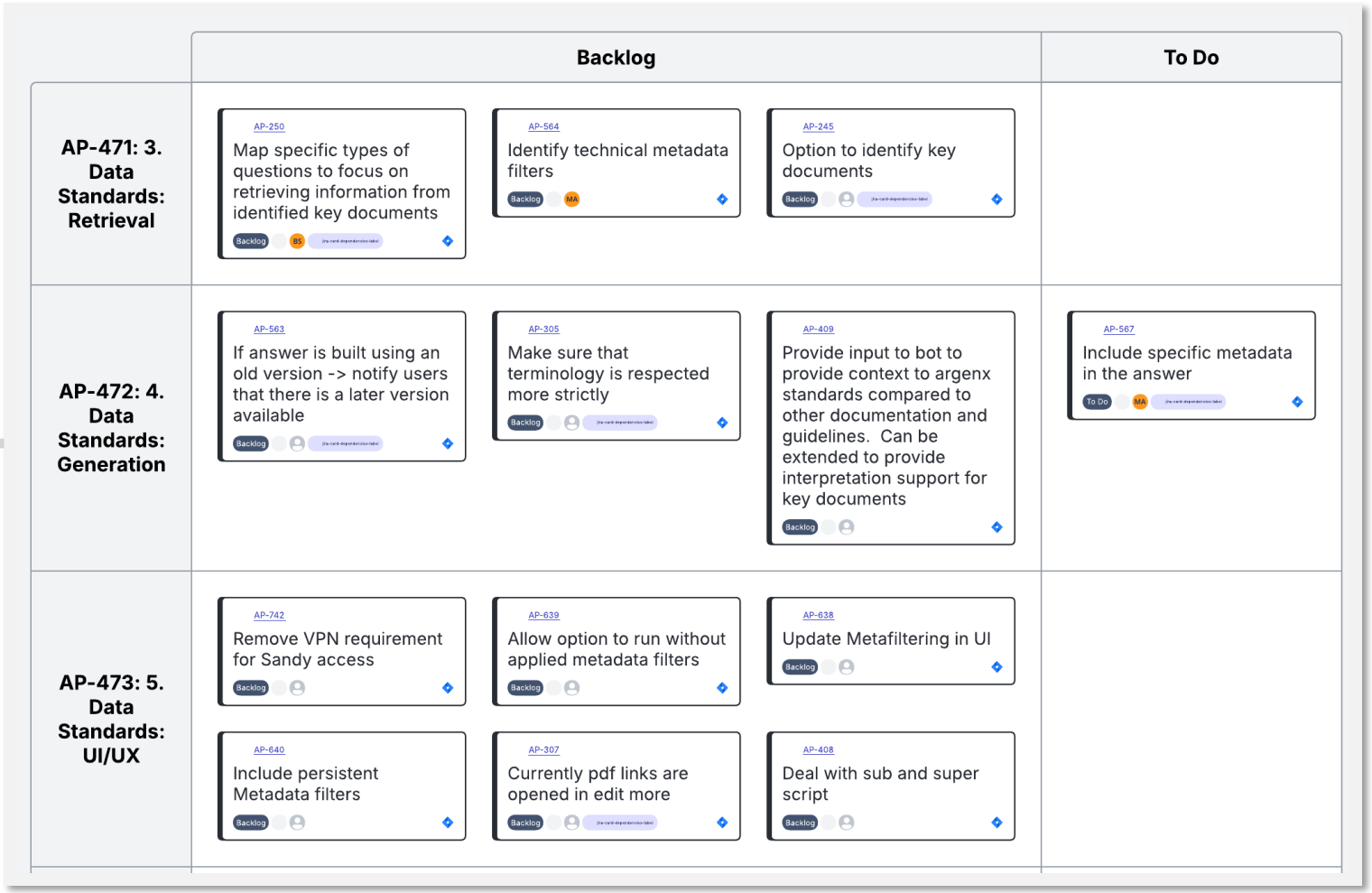
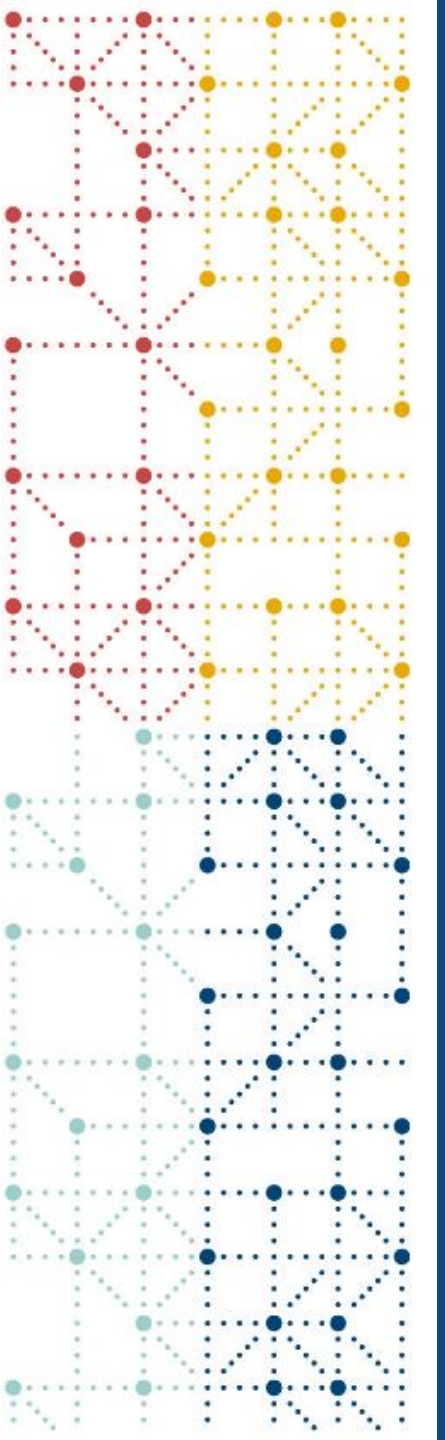
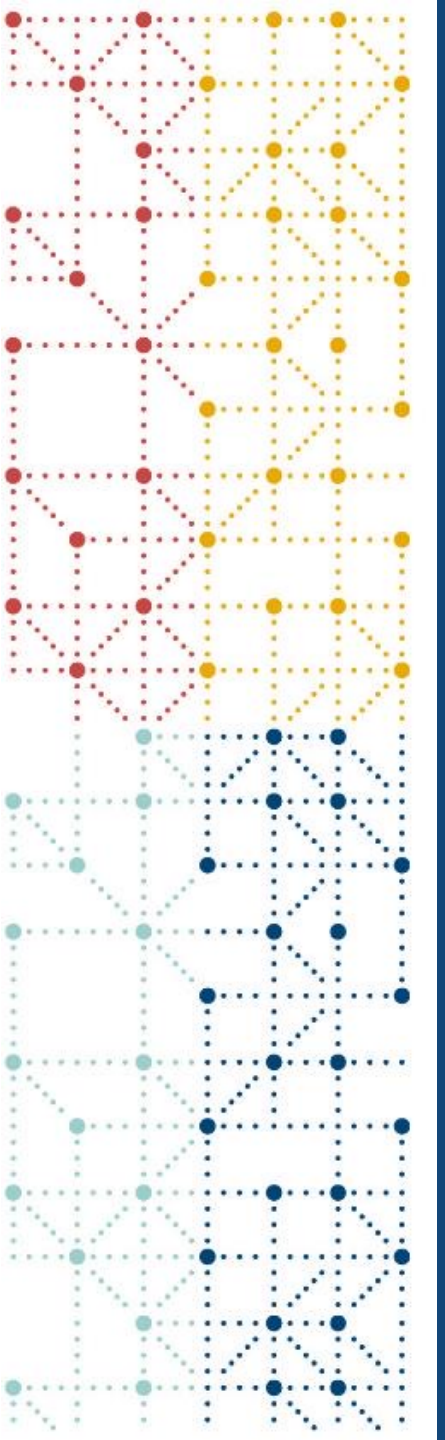




Demonstration – What does it look like



Q&A – What do you want more information on

Thank You!