



Enhancing Regulatory Through AI Innovations

Doris Simcich, Global Senior Director
Operational Excellence

Betsy Luo, R&D IT Business Analyst

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AstraZeneca & The Role of AI in Shaping Innovation

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Q&A



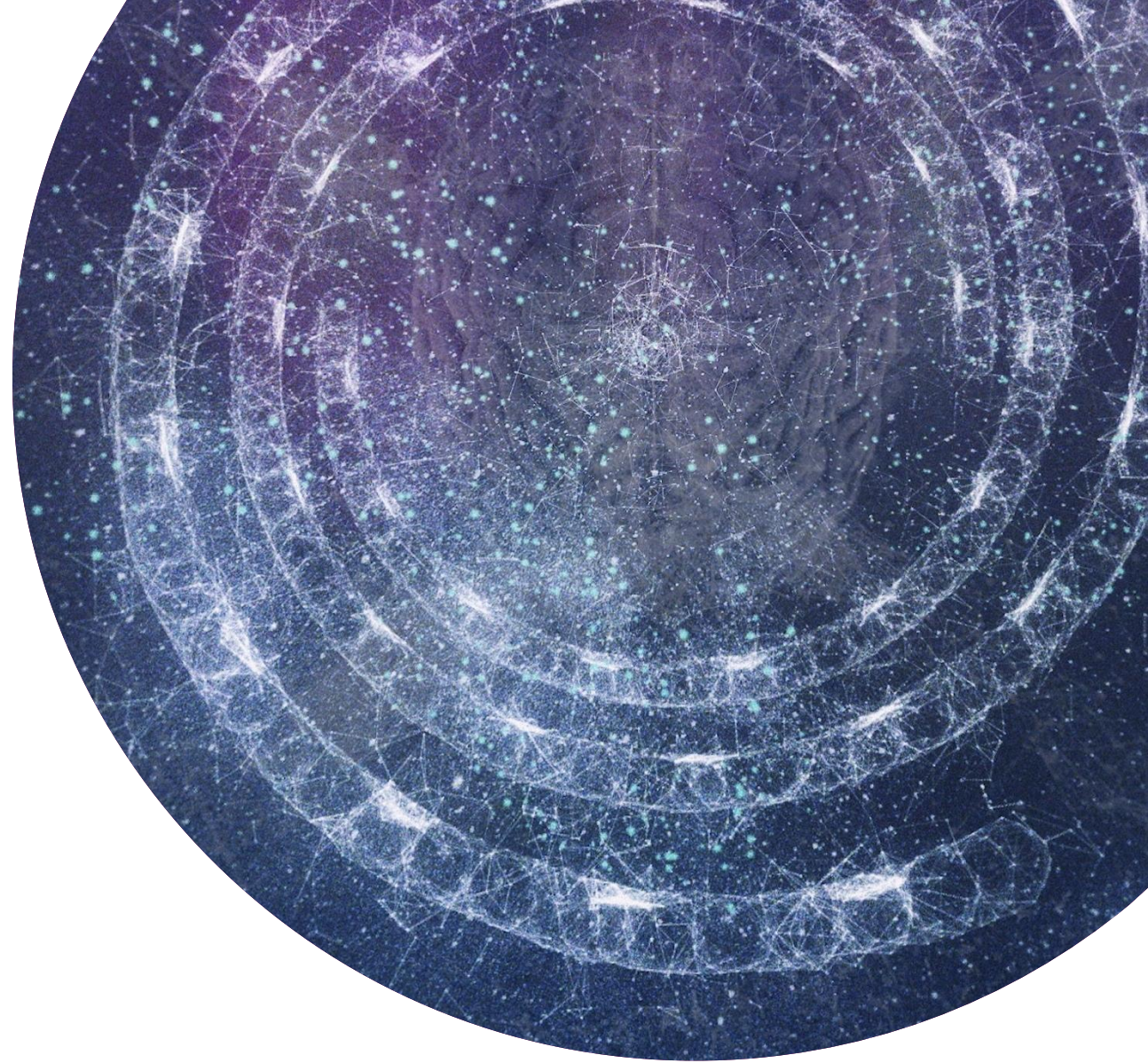
Data, AI and Technology support key goals in AstraZeneca R&D and beyond

Reduce the
timelines for
drug
discovery and
development

Increase
the
probability
of success

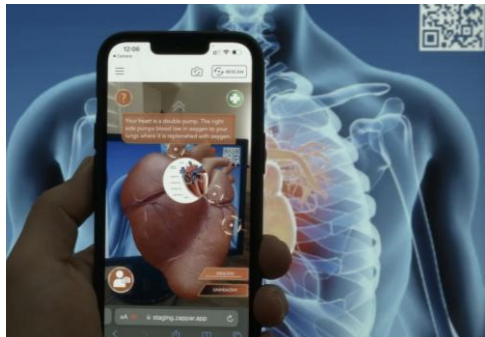
Improve
employee
experience

Increase
equitable
access to care



Technology that will accelerate scientific innovation

EMERGING TECHNOLOGY



Immersive Experiences



Artificial Intelligence

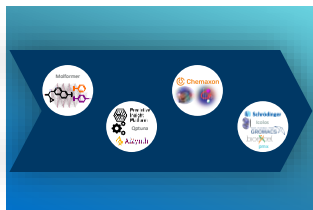


Connected Everything



Digital Twins

FOUNDATIONS



Scalable Platforms



Language Translation



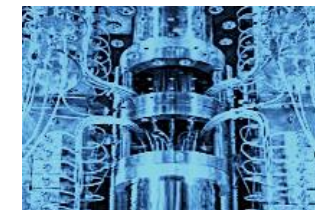
AI - ML/DL
NLP/ML Ops



Data
Foundations



Cyber &
Zero Trust



Quantum
Computing (PoC)



We are on a journey to leverage AI from bench to bedside

VALUE CHAIN



Common uses and impact



Save time



Help research processes



Improve communication



Aid as creative tool



Improve coding



Simplify



Compare content



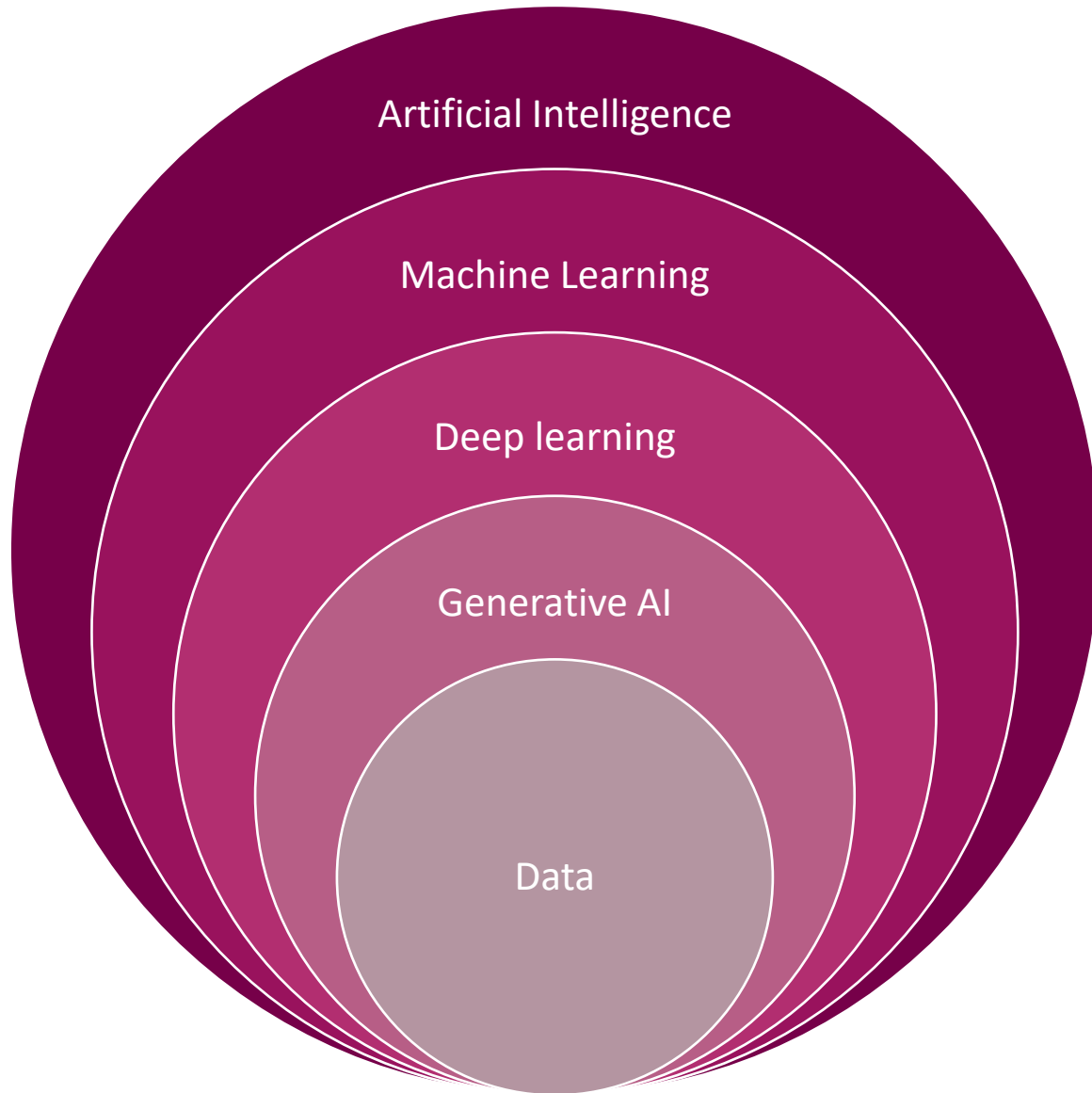
Educating and Bringing Employees along the journey...





Understanding AI in Regulatory

What AI means in the regulatory landscape



Artificial Intelligence

Enhances regulatory decision-making and strategic thinking through efficient data analysis.

Machine Learning

Predicts regulatory timelines, detects anomalies, and aids in document review.

Deep Learning

Automates extraction of key insights from complex documents for regulatory compliance.

Generative AI

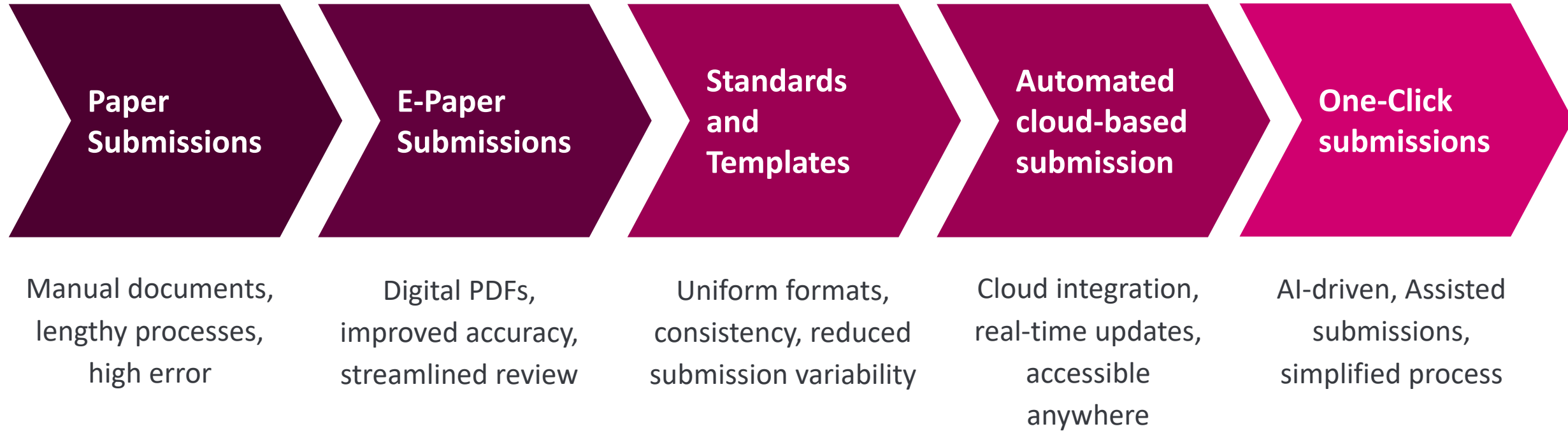
Drafts regulatory submission templates, ensuring consistency and adherence to formatting standard

Data

Data integrity and traceability is crucial for regulatory compliance and decision-making.



Vision of Regulatory Submissions in the Industry



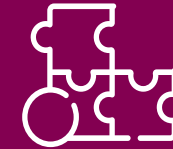
Regulatory Landscape Use Cases



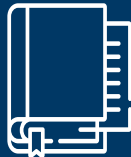
Regulatory Strategy and
Intelligence



Submission Management



Health Authority Interactions



Post-Approval and Lifecycle
Management

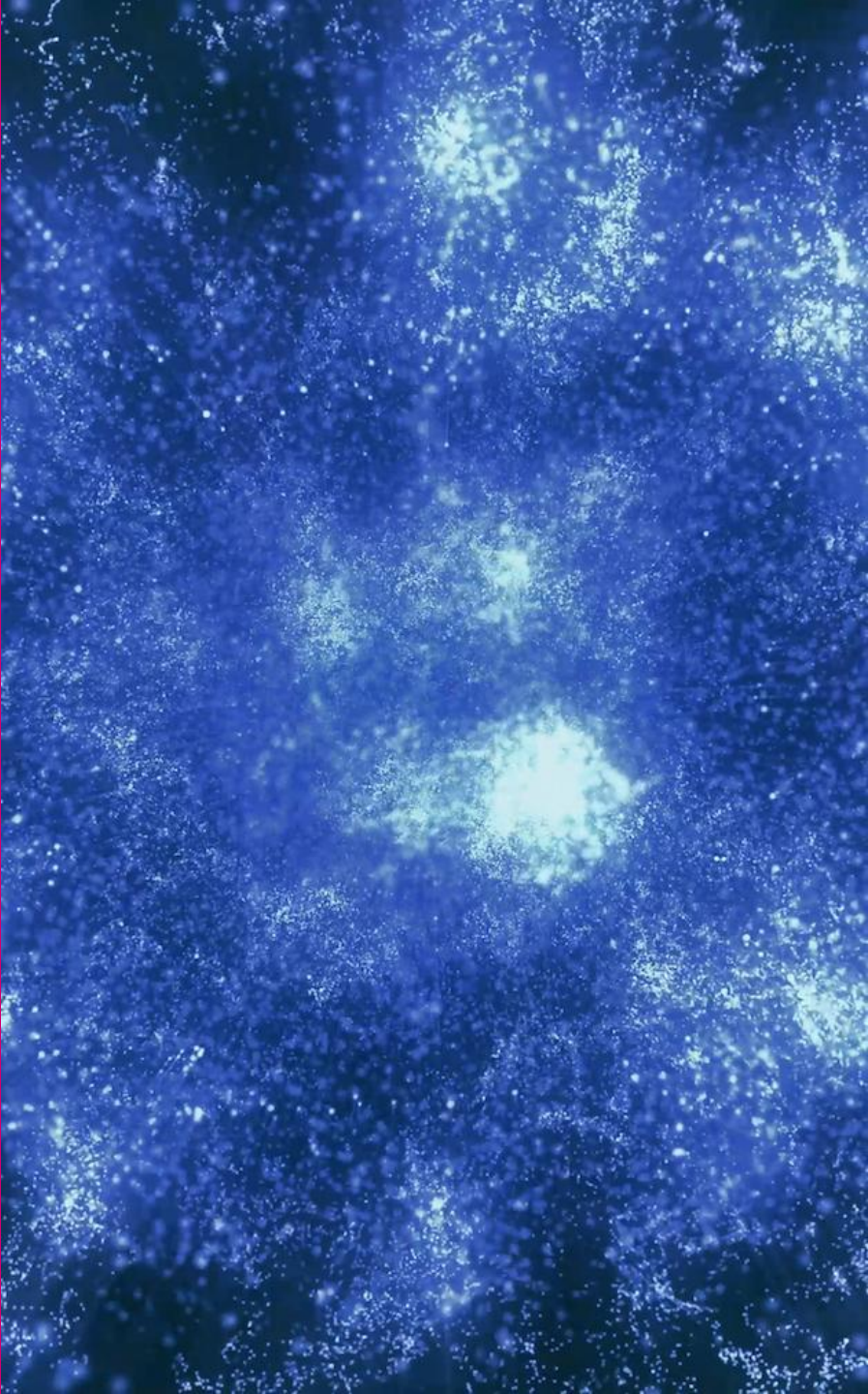


Documentation Management



Collaboration and Training

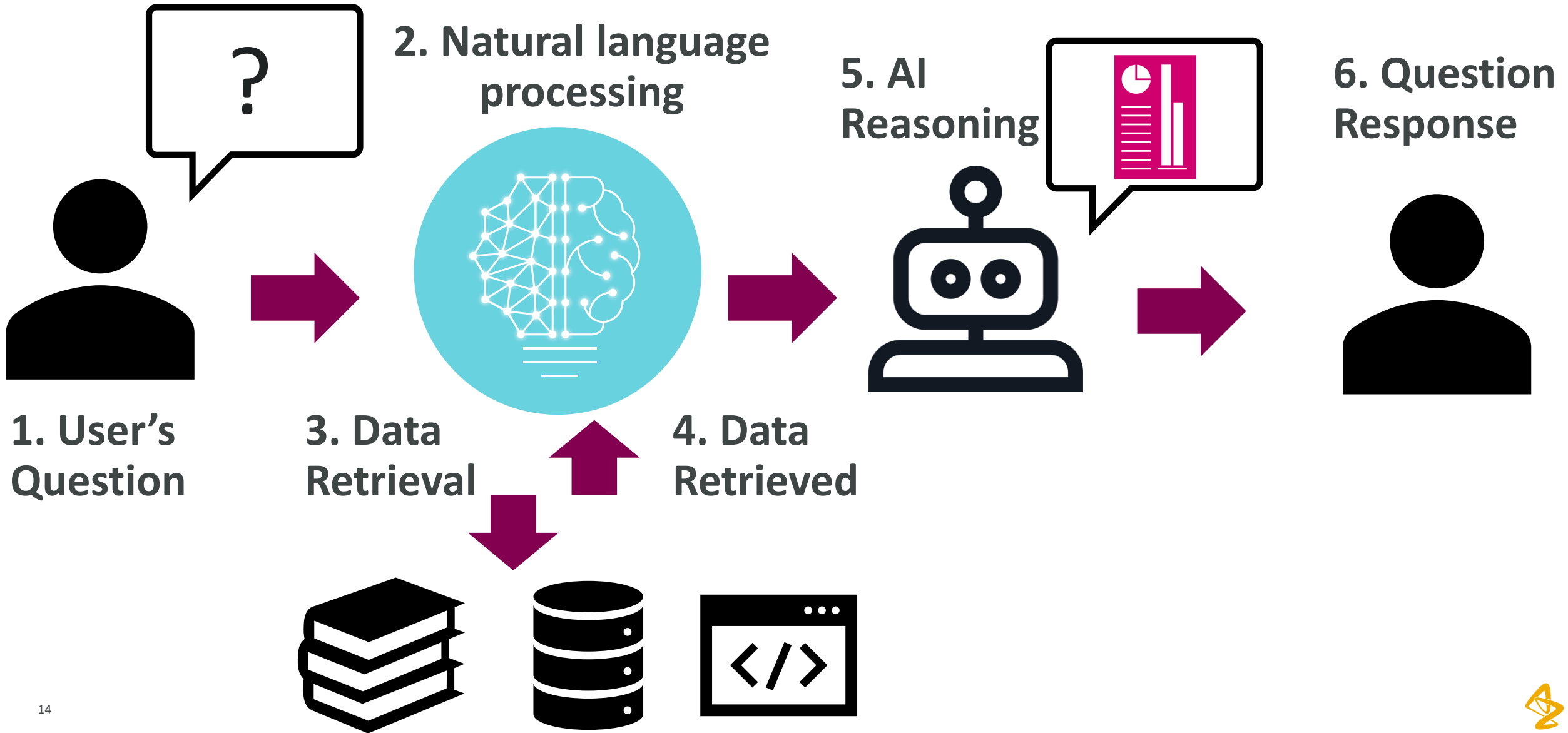




AI Initiatives at AstraZeneca for the Regulatory Team



AI Approach 1: Retrieval-Augmented-Generation



Initiative 1: Regulatory Health Authority Questions (RHAQ)

HAQ Library

Reduce time to research historical HAQs and improve search effectiveness when responding to health authority questions. Use of semantic searching returns results ranked by relevancy



Response Generation

Increase efficiency in drafting of response for Historical HAQ questions using library content



Visualization Processing

Inclusion of AI extracted questions and responses by visualizing Tables and Figures in-line within historical HAQs

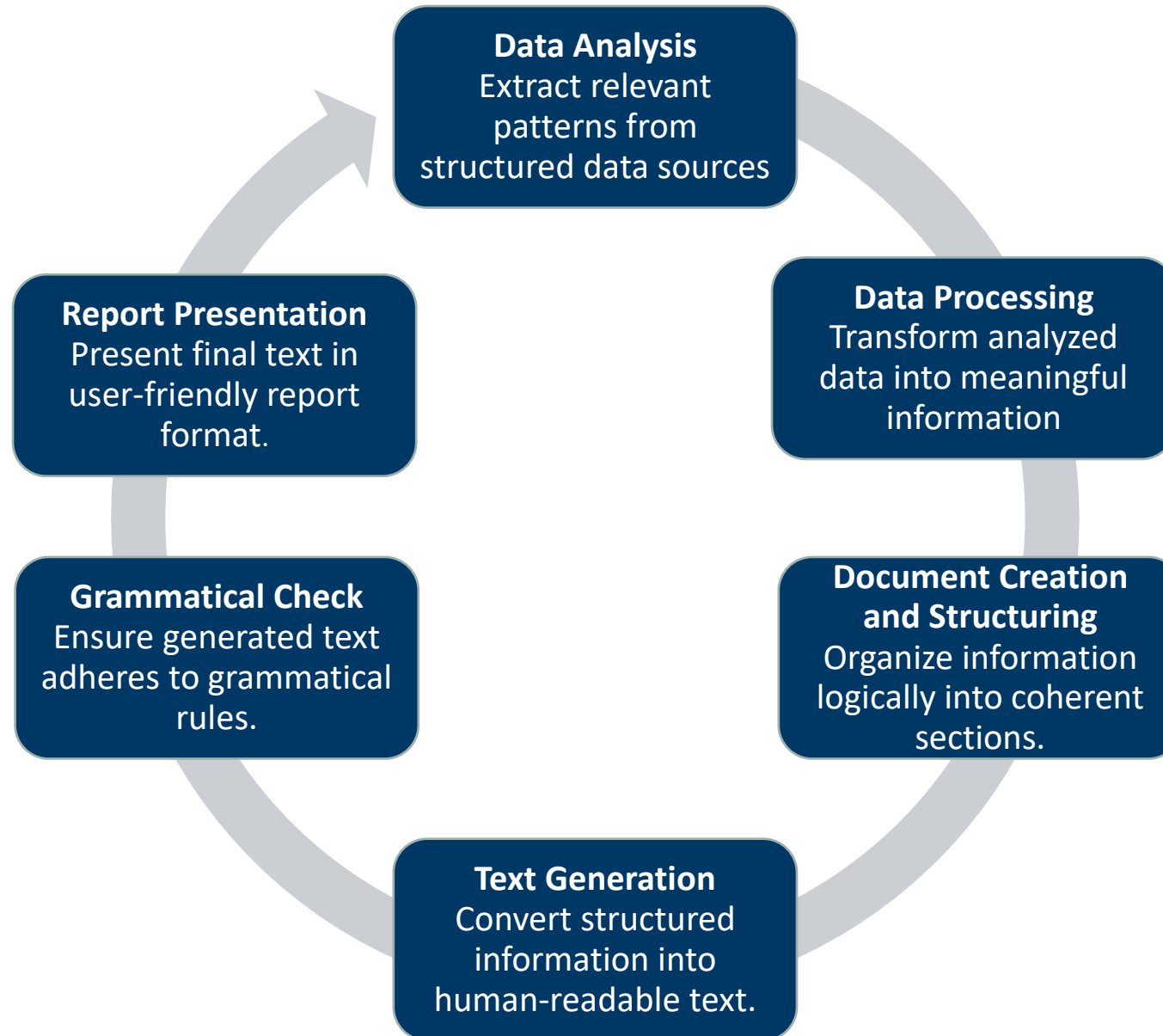


Data Extraction

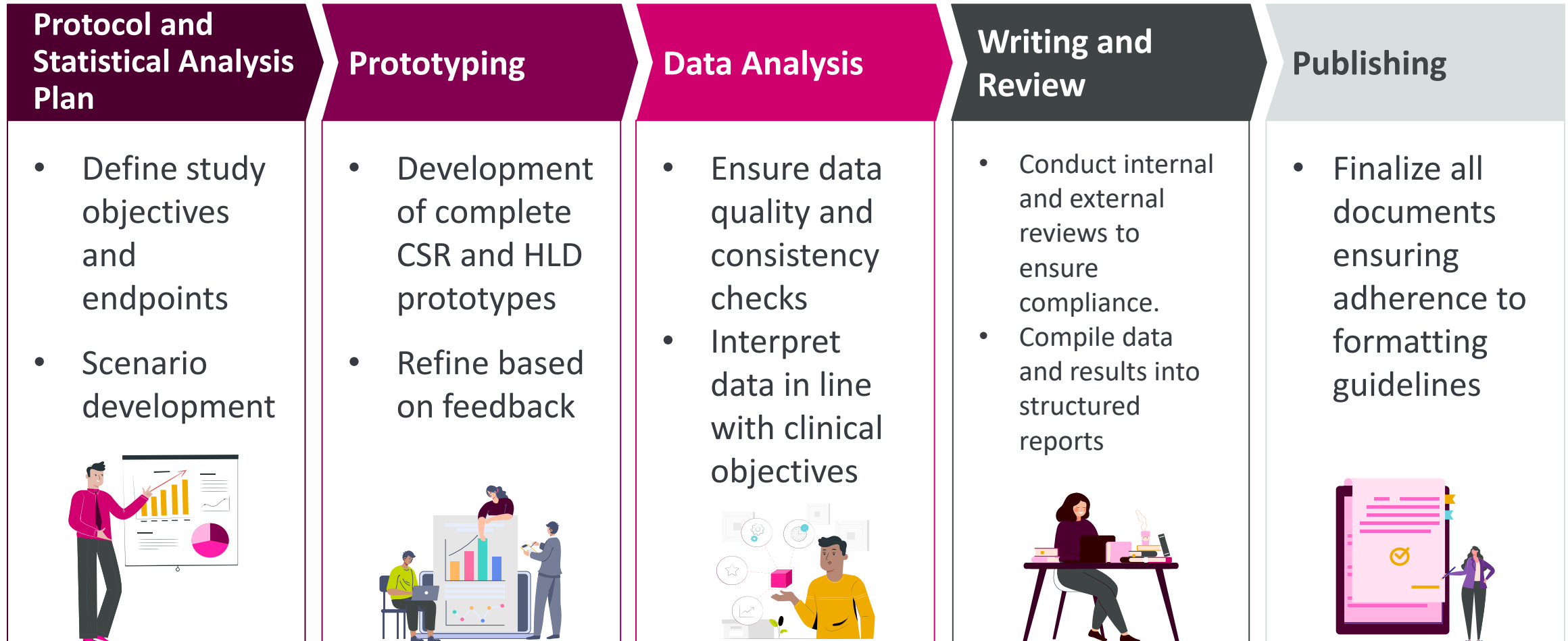
Improving the extraction efficiency of AI model and confidence of questions and responses extraction, develop output that can be ingested by ERV



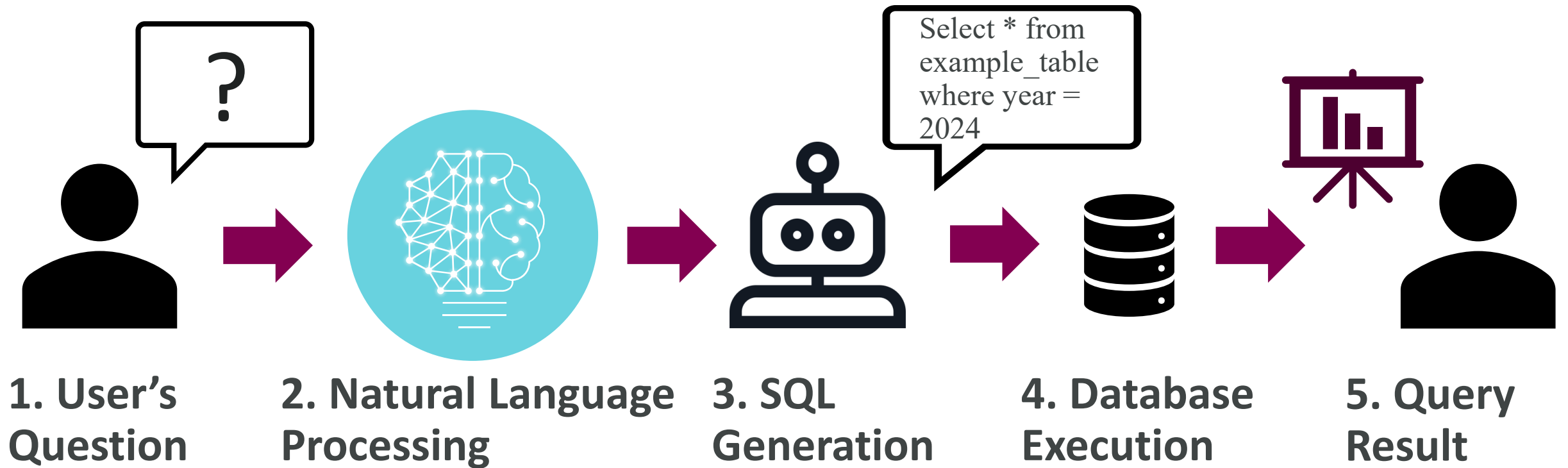
AI Approach 2: Natural Language Generation



Initiative 2: NLG in Regulatory



AI Approach 3: Text-to-SQL



Advantages:

- **User-Friendly:** No SQL knowledge required.
- **Efficient Data Retrieval:** Quick conversion from query to result.
- **Broad Accessibility:** Makes data querying accessible to a wider audience.



Initiative 3: Development Assistant

As a Regulatory Affairs Director, I'm seeking comprehensive insights on the regulatory submission process for {DRUG_NAME}. Can you analyze the approval submission data and related clinical trials? I'm particularly interested in understanding:

1. The current status of our submission
 2. How our submission compares to similar drugs in terms of review time and priority
- Come up with some next steps.



Based on the regulatory submission data and related clinical trial information for the {DRUG_NAME} study (DNNNN), I can provide the following insights:

The drug has successfully completed the regulatory review process., approved on Day MonthYear.

Data and Insights

Comparison to similar drugs

The review time for {DRUG_NAME} was approximately 7.5 months from submission to approval, which is relatively quick. This is consistent with its priority review status, which aims for a review time of about 6 months compared to the standard 10 months.

Next steps:

Post-marketing surveillance: Implement a robust pharmacovigilance plan to monitor the safety and efficacy of {DRUG_NAME} in real-world use.

Patient support programs: Develop programs to support patient access and adherence to {DRUG_NAME}.

Ongoing communication: Maintain open lines of communication with the FDA for any post-marketing commitments or requirements.



AI Driving Value at AZ



Unlock Access to Our
Data Landscape



Reduce Application
Development



Drive **Cost Savings**



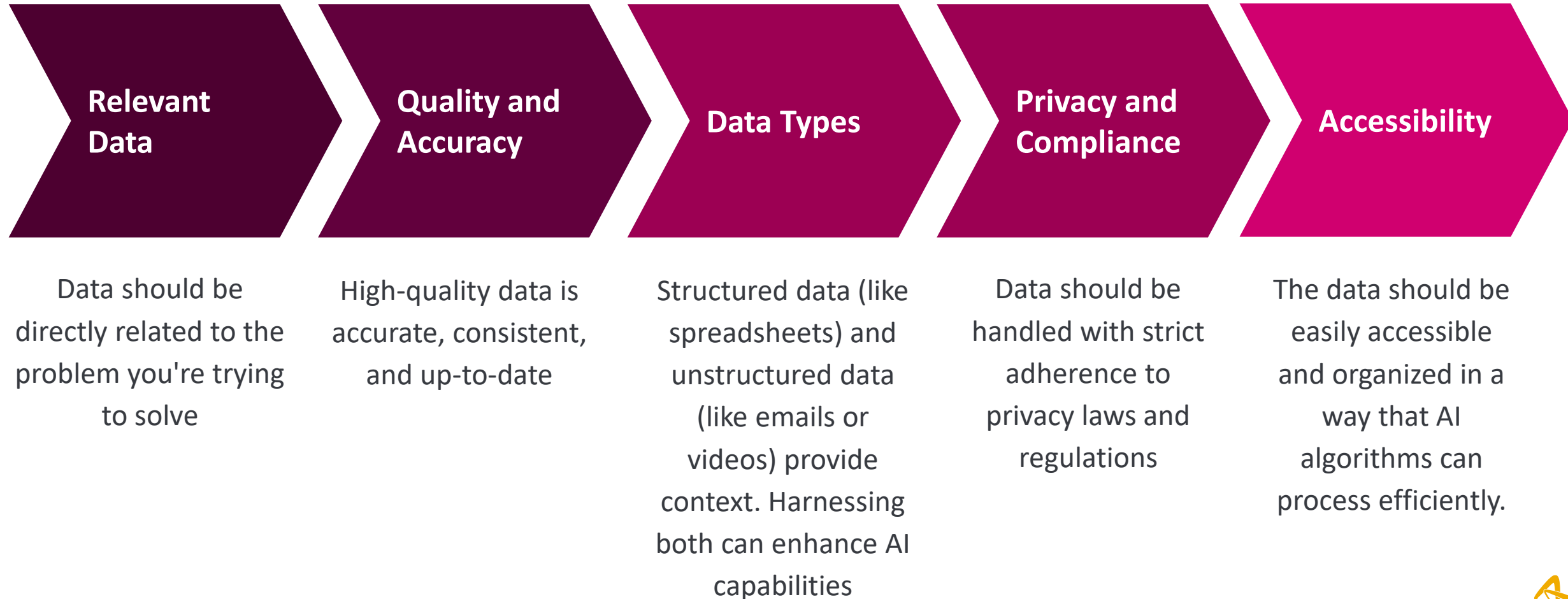
Accelerate Speed to
Deeper Insights



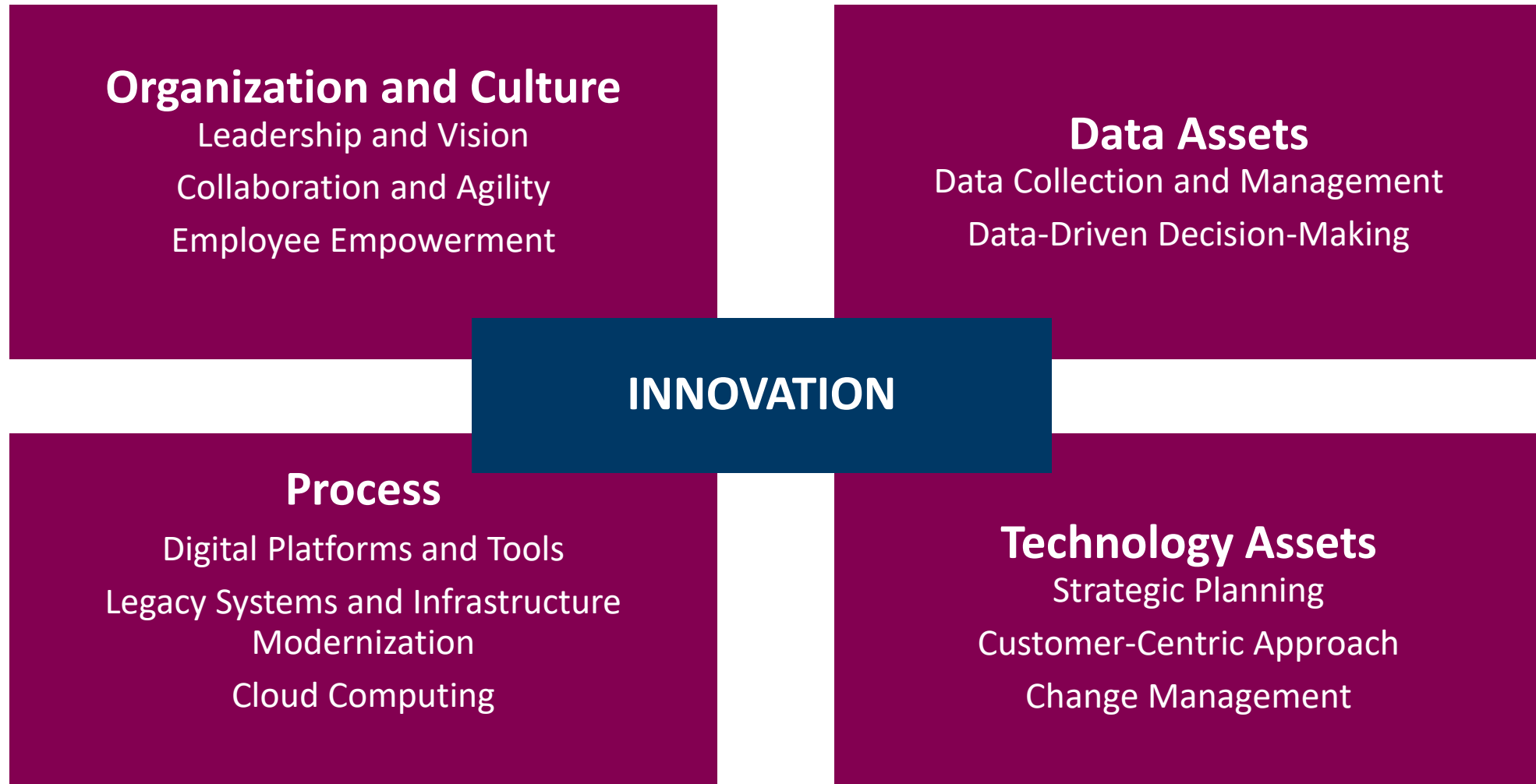


AI Considerations

Data Foundations Are Key Challenge



Key Takeaways to Drive AI Innovation



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AstraZeneca PLC, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA, UK
+44(0)203 749 5000
www.astrazeneca.com

