

Sneak Peek

AI Systems in Quality & Regulatory Affairs



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SYMMETRIC

What this course is not

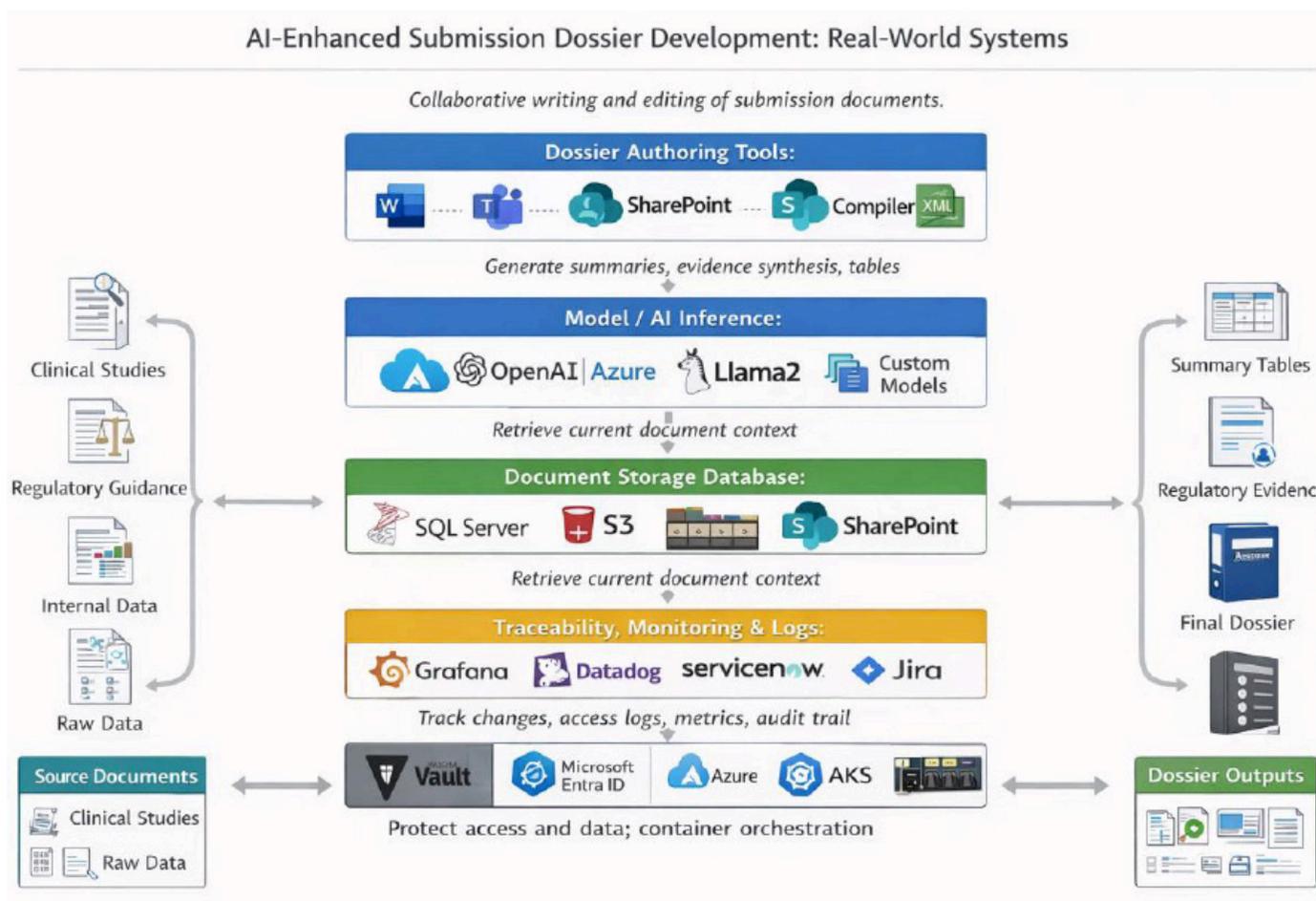
- Not a coding class
- Not AI hype
- Not replacing regulatory judgement

Agentic AI risks



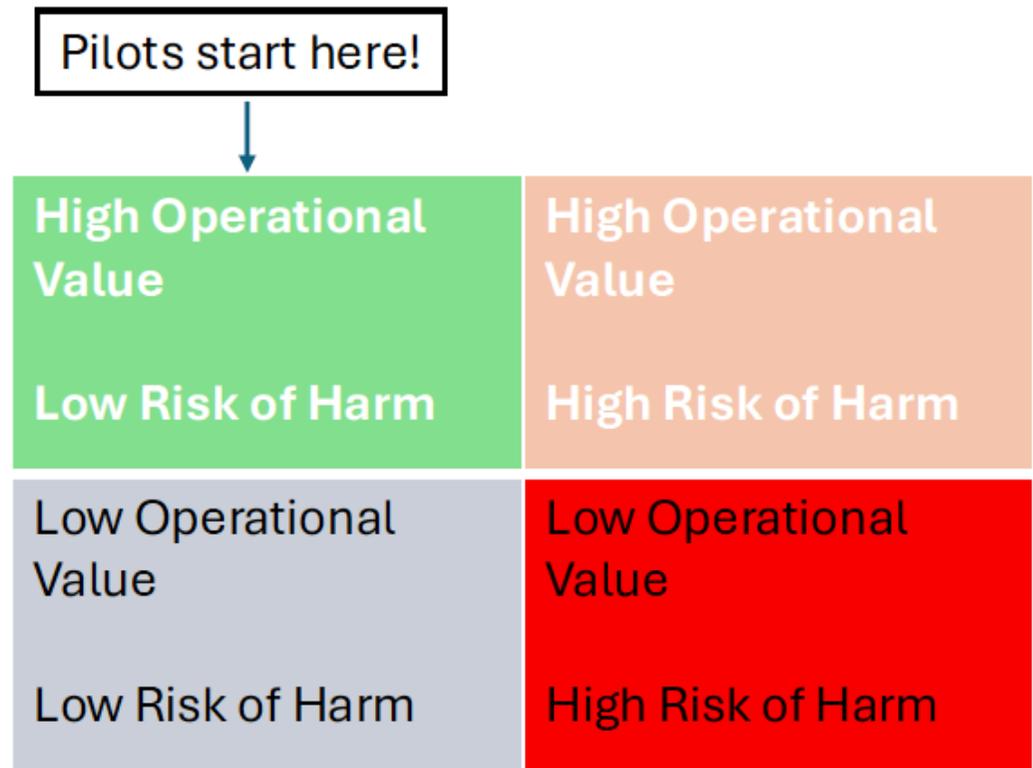
- Errors can compound
- It is difficult to oversee
- There is greater unpredictability

Understanding 'layers' of the system



Not everything needs AI!

- Is volume high?
- Is decision pattern-based?
- Is harm low if wrong?
- Is data reliable?



Categories of AI Risk

05



Data risk



Model risk



Process risk



Accountability
risk



Security risk



Ethical risk

Day 3 objectives



1

Use AI to improve risk-based prioritization

2

Design AI-enabled QA/RA workflows responsibly

3

Select appropriate performance metrics

4

Plan controlled AI adoption in regulated organisations

5

Lead AI change without undermining governance

Registration

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07

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