The Use of AI in the Drug Discovery and Clinical Research Continuum

Kevin Richards, Senior Director Clinical Quality

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Digital Transformation

Analytics & Reporting

- Business Intelligence Software
- Power Point
- Excel
- Collation of data

Process, Tool & Workflow Automation

- Automated workflows
- Embedding technology to improve processes

System Integration

- Integration of workflows, processes, core functions into systems e.g. EQMS

AI & Gen AI

- Increasing Capability by embedding AI
- Gen AI to automate tasks or to transform documents, text etc. into useable data

S&QO | Study & Quality Oversight

A new chapter for SQO...
one platform, five service areas

1 

Inspection Readiness

Monitor clinical study quality (formerly SQO)

2 

QA Oversight

Manage audits, CAPAs, and organisational quality metrics

3 

Storyboard

Keep everyone on the same page

4 

Forecasting Tools

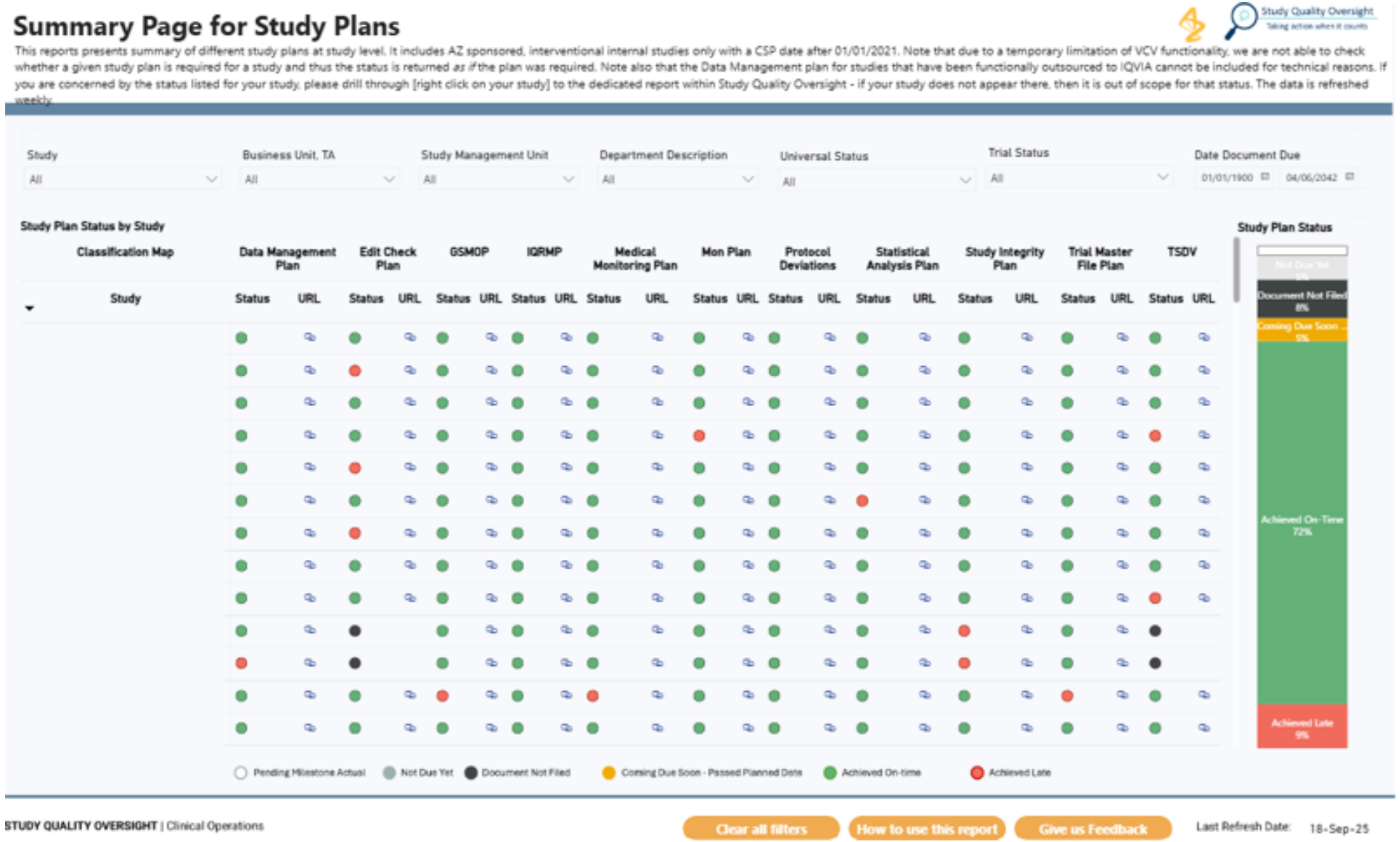
Anticipate inspections. Audit smarter.

5 

Advanced Quality Intelligence

Framework for Organizational Quality Signals (FoQus), and more

Study Quality Oversight



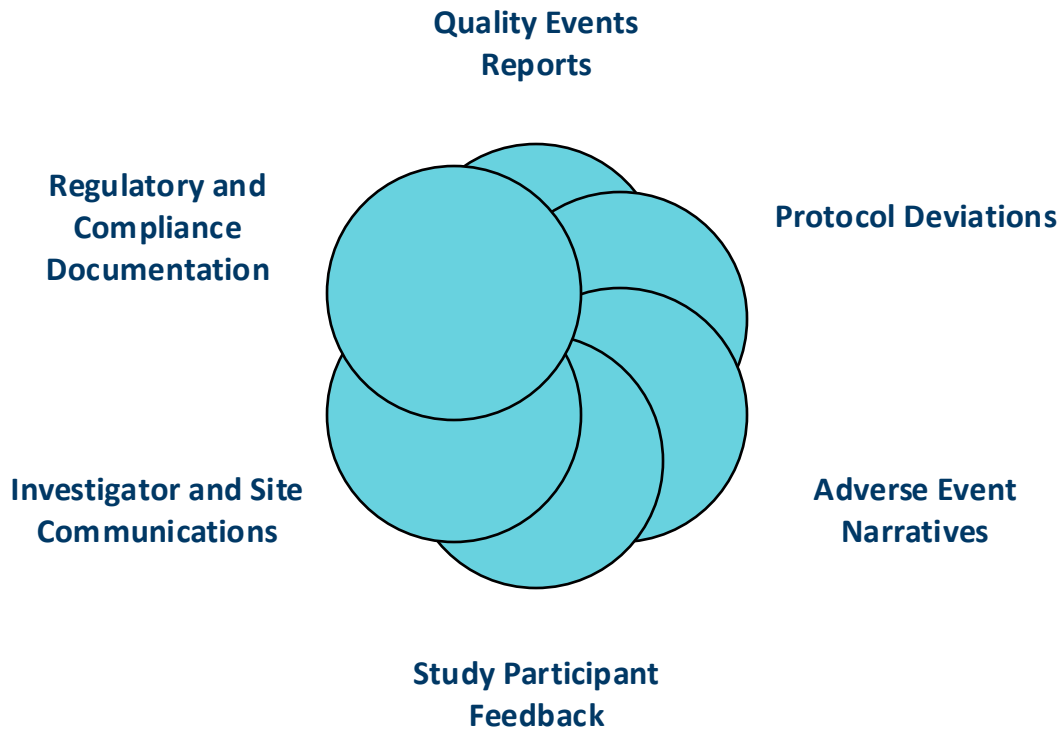
AI Capabilities and Use Cases

Automation & Productivity

- Creating Meeting Minutes Automatically
- Summarizing Documents

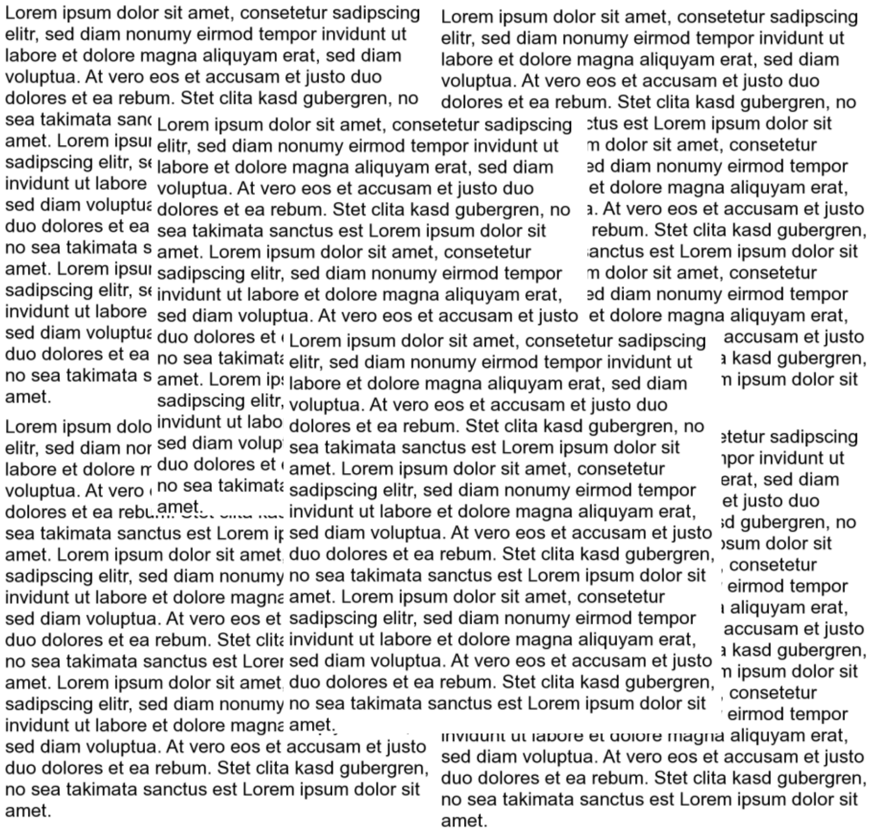
Problem

Turning vast amounts of textual information into usable data



Turning vast amounts of textual information into usable data

How do we turn this…



Turning vast amounts of textual information into usable data

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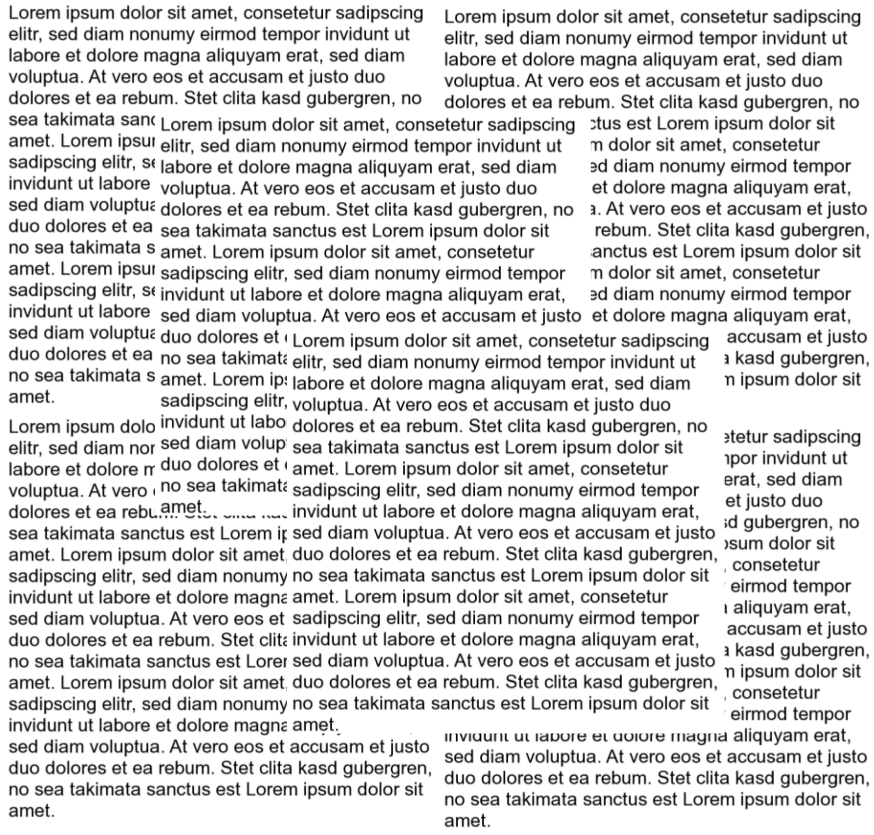
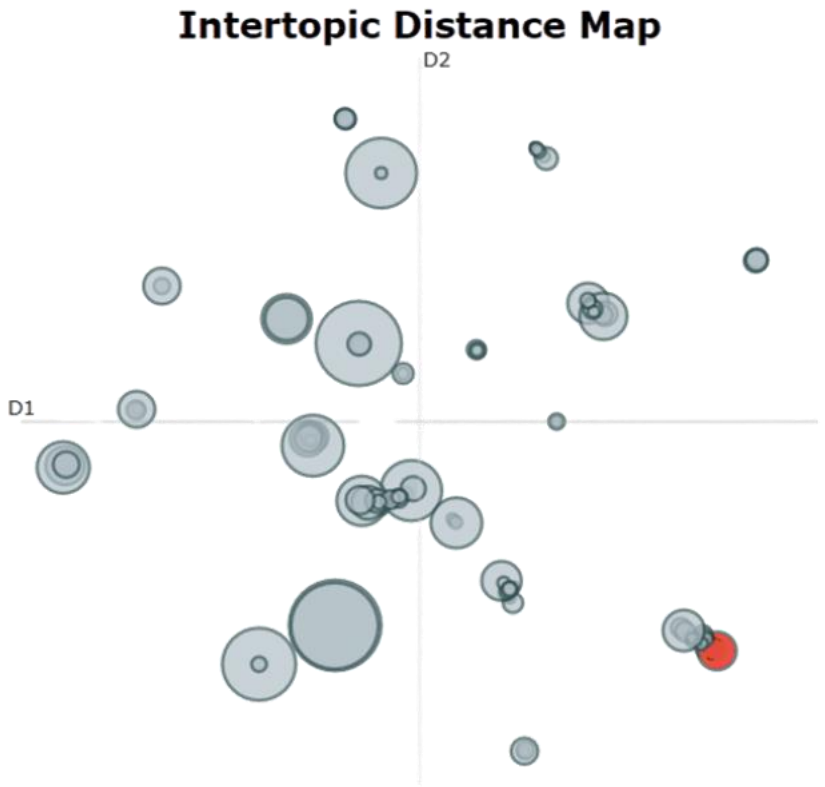


into this?

NATURAL LANGUAGE PROCESSING

1. Topic Modelling

Topic Modelling is a technique in NLP which enables it to understand the **context and meaning of words in sentences**, consequently grouping them into **topics**.

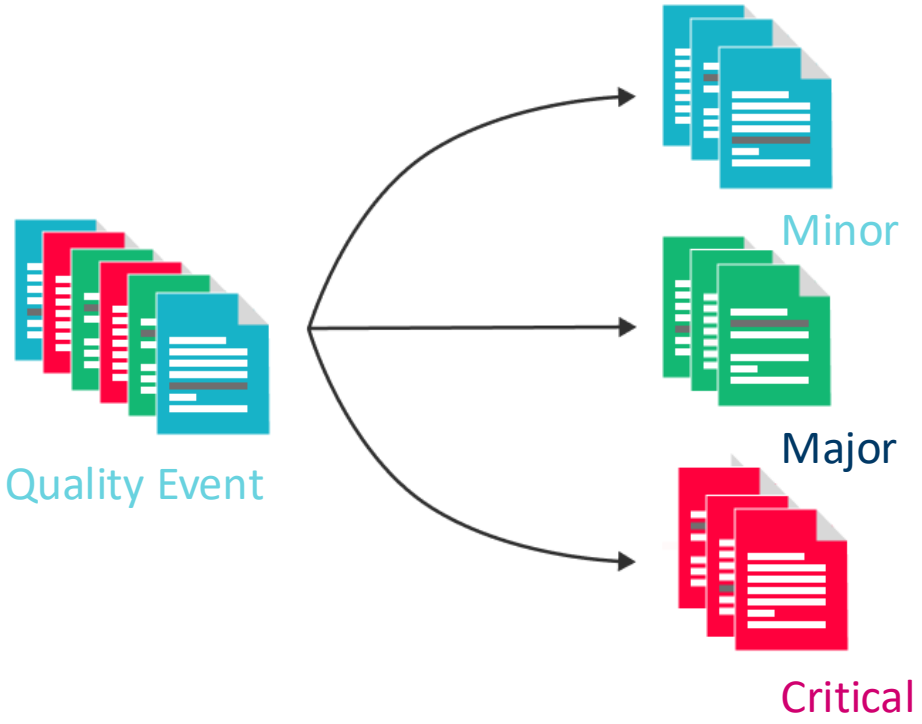


Uncovering hidden themes	Creating categories

1. Topic Modelling

1. Topic Modelling

2. Text classification



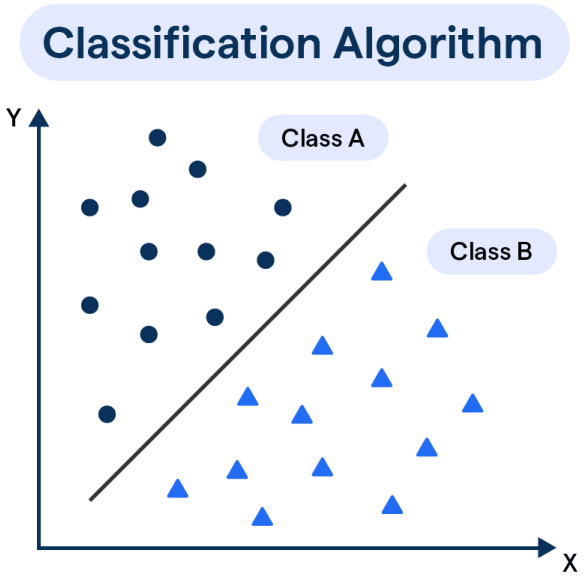
- is a supervised machine learning task using historical **labeled** training data
- involves categorizing new text data into predefined classes
- learns from examples and predicts the category a text belongs to based on its content

2. Text classification

example. **Protocol Deviations**

Protocol Deviations

Important Protocol Deviations

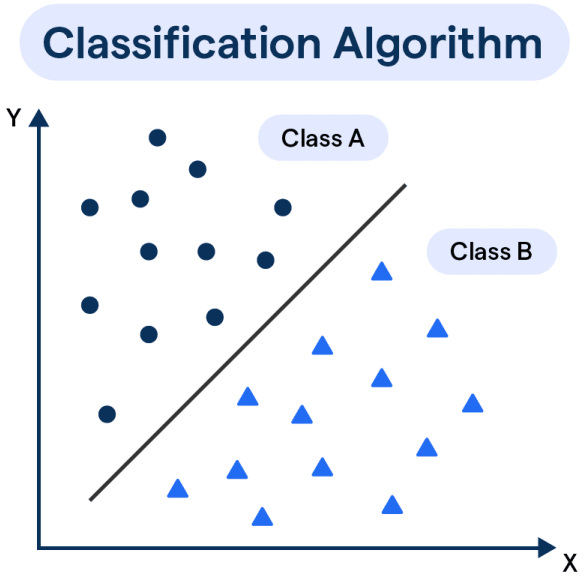


2. Text classification

example. **Adverse Events**

Serious AE

AE



AI Capabilities and Use Cases

Decision Support & Analytics

- Risk scoring
- Country/site selection based on factors

InSite Tool

InSite tool is used to predict likelihood of inspection at the site. I serves as a comprehensive repository for site-related information. Currently, our data is primarily sourced clinical operations data mart, which undergoes weekly refreshes. Audit and Inspections data also originate from VQV. The tool encompasses a wide range of information, including details on studies, site enrollment and adverse event, protocol deviations, and quality-related data. **Inclusion/Exclusion Criteria:** **Study Type:** Interventional Internal and Interventional Outsourced, **InSite Score** Only available for BioPharma and Oncology studies.

Study Quality Oversight
Taking action when it counts

ACTION CARD

Study Code	Study Acronym	Country	TA Code	Study Status	Study Site Status	Investigator	Study Site Number	Inspection
	All	All	All	All	All	All	All	All

Table 1: Study Related Information

Study Type	Study Sponsor	Study Code	Study Acronym	Study Phase	Business Unit	Indication(s)

11
Inspections

732
Patients Randomized

Table 2: Site Data • InSite Score

Study Code	Study Site Number	Country	Screened	Randomized	Non_IPDs	IPDs	Quality Index Flag	Status	Inspection Reason	Inspection Likelihood	InSite Score
		France	28	21	243	11				High	99.66
		United States of America	24	19	63	3	Green	Audit + Inspection	Pre-Approval	High	99.57
		Spain	23	18	108	1	Green	Audit + Inspection	Pre-Approval	High	99.50
		South Korea	28	24	71	0		Inspection	Pre-Approval	High	99.34
		Italy	33	15	107	1	Green	Audit + Inspection	Pre-Approval	High	99.14
		Poland	18	17	16	1				High	98.59

1,003
Patients Screened

75
IPDs

Table 3: Site, Country and Investigators

Study Code	Study Site Number	Country	Study Site Status	Principal Investigator
		Canada	Cancelled	
		Canada	Cancelled	
		Canada	Cancelled	
		Canada	Cancelled	
		Canada	Cancelled	
		China	Cancelled	

Table 4: Sites with Audits and/or Inspections

Study Code	Study Site Number	Study Country	Status	Regulatory Authority	Inspection Date
		China	Inspection	NMPA - China	2024-08-20
		China	Audit		
		United Kingdom	Audit		
		Hungary	Audit + Inspection	EMA - European Medicines Agency	2024-07-15

2,915
Non IPDs

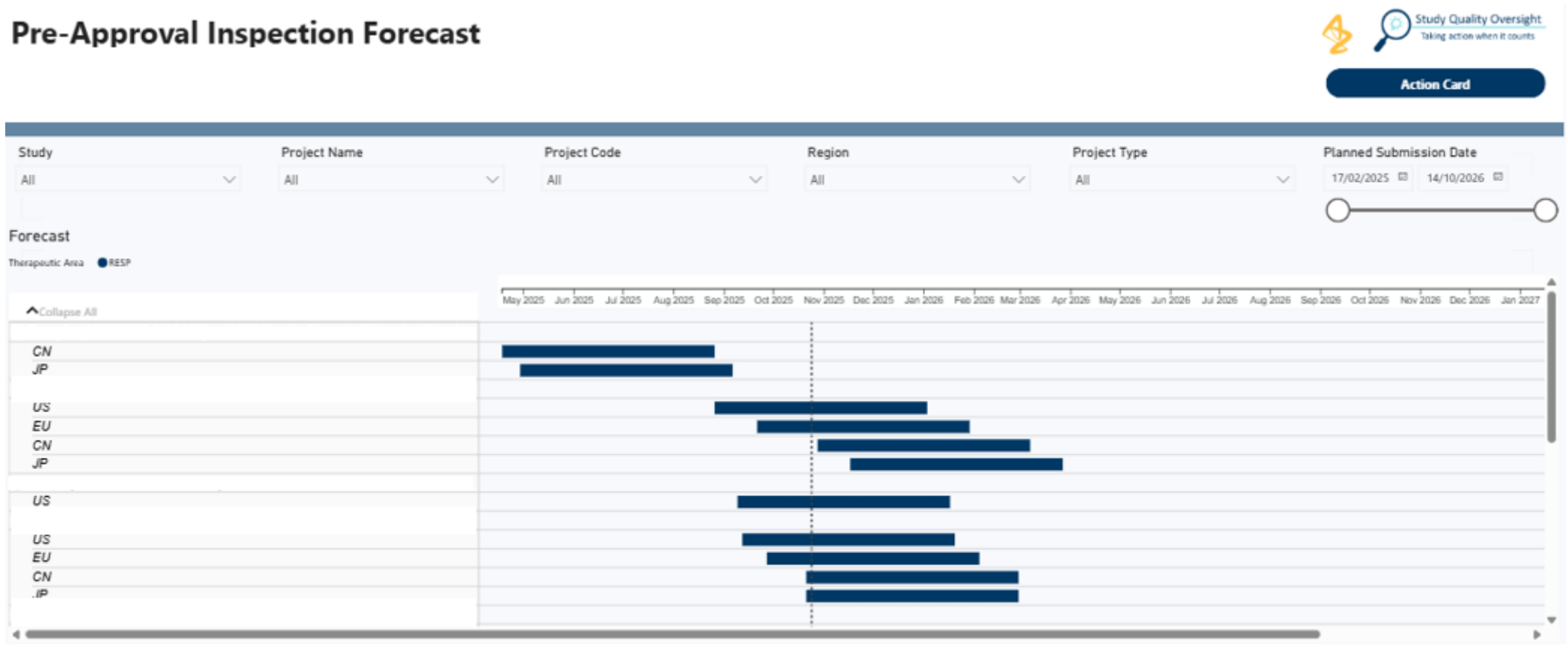
84
Median InSite Score

AI Capabilities and Use Cases

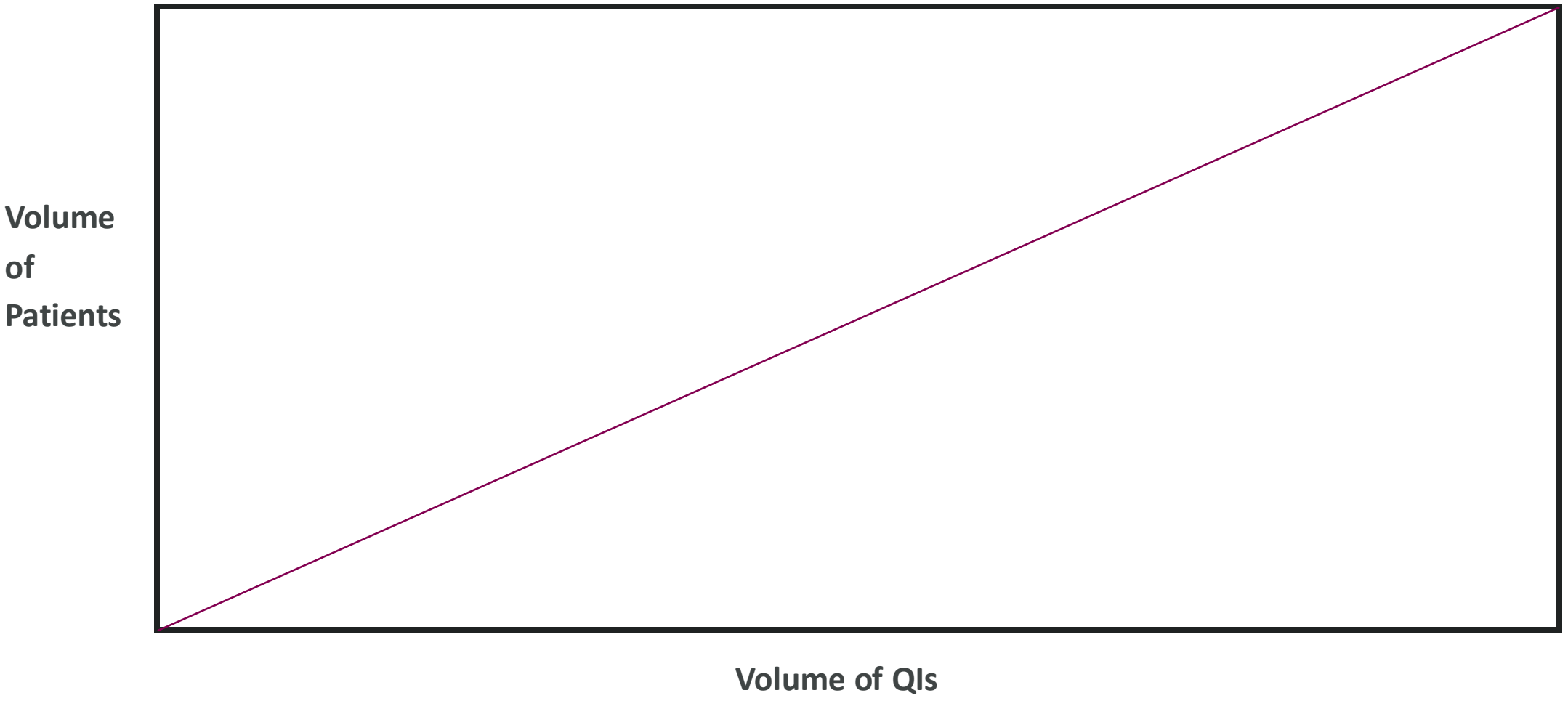
Planning

- Predictive analytics – demand planning
- Patient enrollment prediction by month

AI Capabilities and Use Cases



AI Capabilities and Use Cases



Thank You!

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