

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

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Digital Transformation



Analytics & Reporting

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



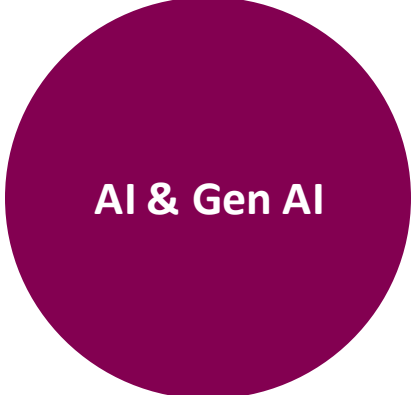
Process, Tool & Workflow Automation

- 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

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

Summary Page for Study Plans



This reports presents summary of different study plans at study level. It includes AZ sponsored, interventional internal studies only with a CSP date after 01/01/2021. Note that due to a temporary limitation of VCV functionality, we are not able to check whether a given study plan is required for a study and thus the status is returned as if the plan was required. Note also that the Data Management plan for studies that have been functionally outsourced to IQVIA cannot be included for technical reasons. If you are concerned by the status listed for your study, please drill through [right click on your study] to the dedicated report within Study Quality Oversight - if your study does not appear there, then it is out of scope for that status. The data is refreshed weekly.

Study

Business Unit, TA

Study Management Unit

Department Description

Universal Status

Trial Status

Date Document Due

All

All

All

All

All

All

01/01/19000104/06/2042

Study Plan Status by Study

Classification Map

Study	Data Management Plan		Edit Check Plan		GSMOP		IQRMP		Medical Monitoring Plan		Mon Plan		Protocol Deviations		Statistical Analysis Plan		Study Integrity Plan		Trial Master File Plan		TSDV	
	Status	URL	Status	URL	Status	URL	Status	URL	Status	URL	Status	URL	Status	URL	Status	URL	Status	URL	Status	URL	Status	URL

Pending Milestone Actual

Not Due Yet

Document Not Filed

Coming Due Soon - Passed Planned Date

Achieved On-time

Achieved Late

Study Plan Status

Not Due Yet

Document Not Filed 8%

Coming Due Soon 5%

Achieved On-Time 72%

Achieved Late 9%



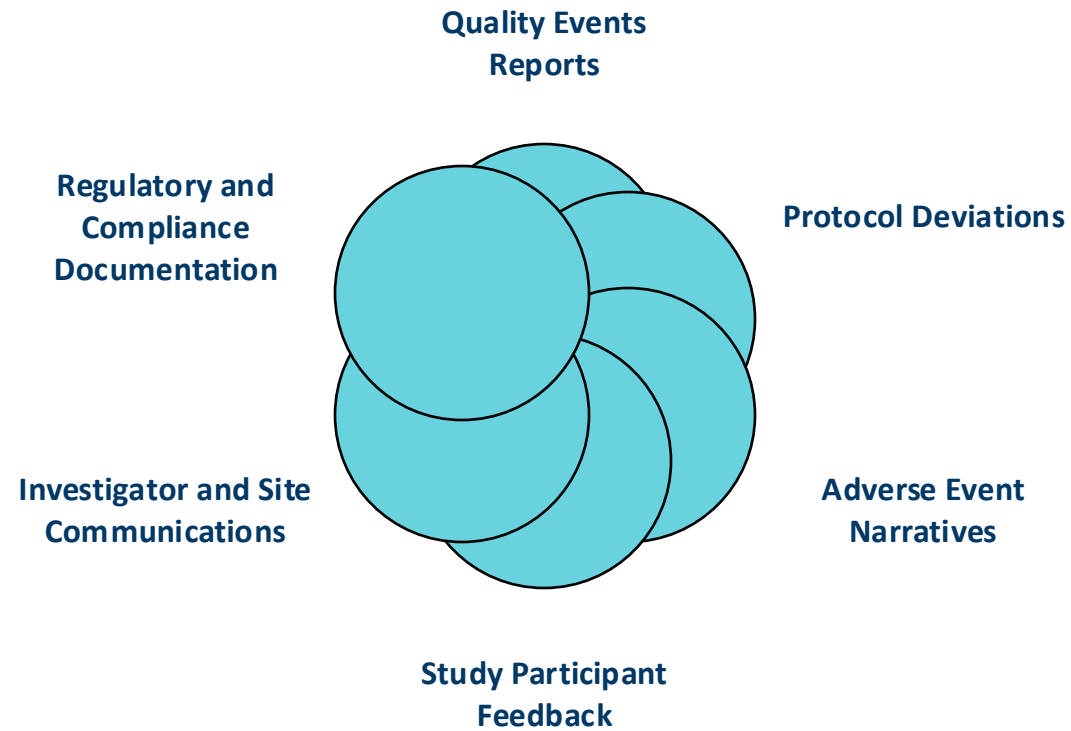
AI Capabilities and Use Cases

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...

[illegible]

Turning vast amounts of textual information into usable data

How do we turn this...

into this?

[illegible]

NATURAL LANGUAGE PROCESSING

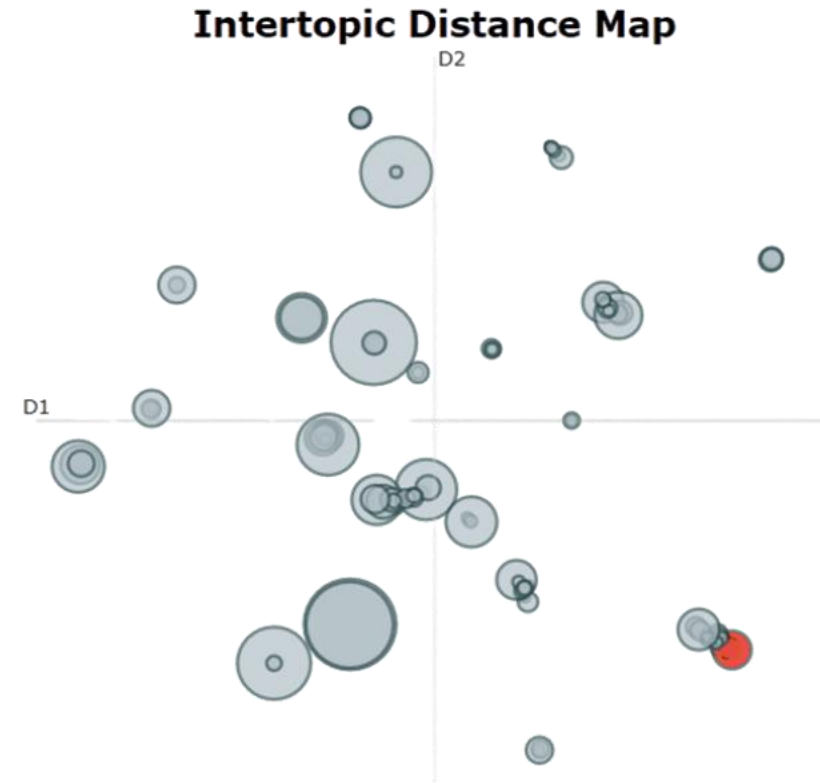


1. Topic Modelling

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

QEs specific category

This Power BI report allows us to delve deeper into the Quality Event (QE) categories, providing a more specific view of these events. We can now analyse detailed descriptions of each category, examine their distribution across different countries, and compare associated risks over the years. The report also highlights QEs that are similar in nature and groups them within relevant topics, enabling a more precise understanding of each individual QE.



Study Quality Oversight
Taking action when it counts

Select or drag fields to populate this visual

HumanReadableName
SAP FSI Amendment

country
All

quality_issue_type
All

department
All

risk_classification

Critical

Major

Minor

71
No. of QEs in this category

"Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum."

#Topics across countries

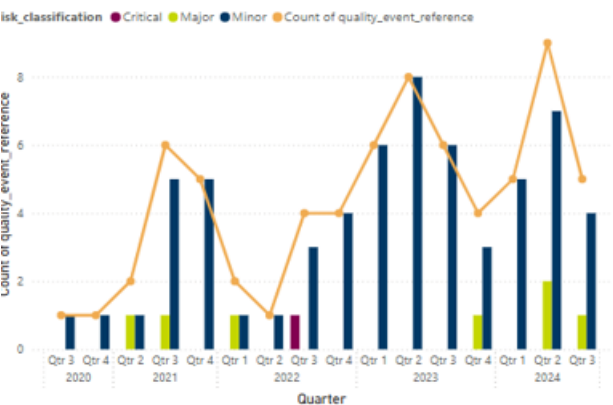
(Blank)

Spain

Germany

United States...

risk_classification Critical Major Minor Count of quality_event_reference



Count of quality_event_reference

Quarter

Qtr 3 2020 Qtr 4 2020 Qtr 1 2021 Qtr 2 2021 Qtr 3 2021 Qtr 4 2021 Qtr 1 2022 Qtr 2 2022 Qtr 3 2022 Qtr 4 2022 Qtr 1 2023 Qtr 2 2023 Qtr 3 2023 Qtr 4 2023 Qtr 1 2024 Qtr 2 2024 Qtr 3 2024

QEs within this topic

QE reference	Issue description
QE-136067	Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut
QE-363810	"Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum."



1. Topic Modelling

QE categories across QI, Audits, Inspections and Supplier Findings

These visuals show only those categories that are present across all Quality Event Types: Quality Issues, Audits, Inspection Findings and Supplier Findings

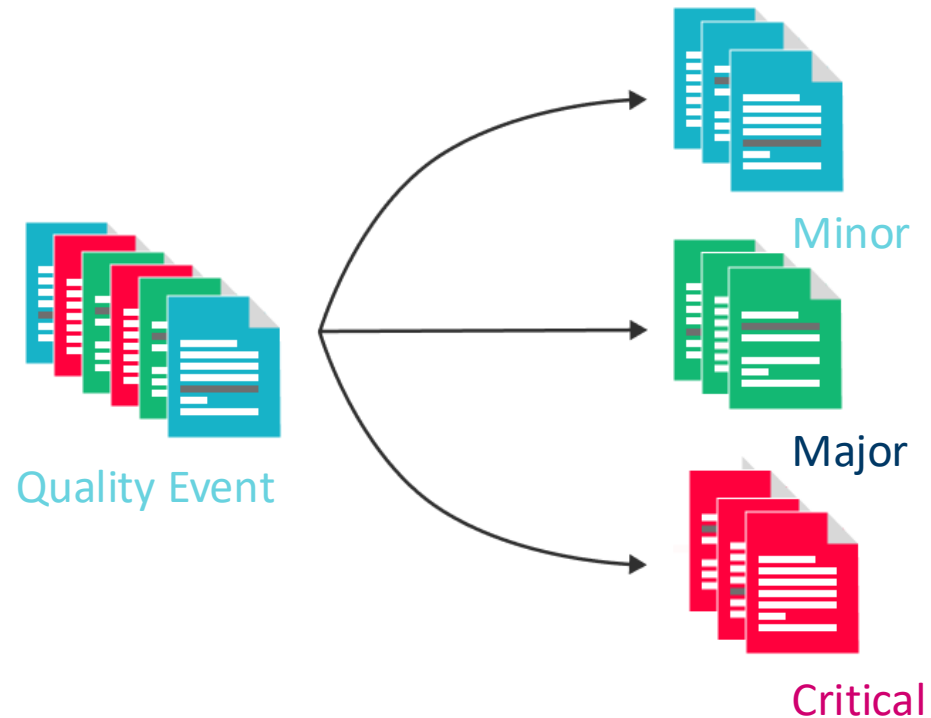


Study Quality Oversight
Taking action when it counts

Select or drag fields to populate this visual



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

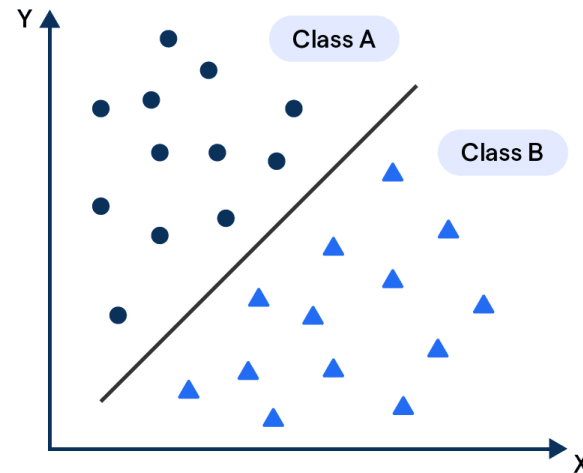
2. Text classification

example. Protocol Deviations

Protocol Deviations

Important Protocol
Deviations

Classification Algorithm



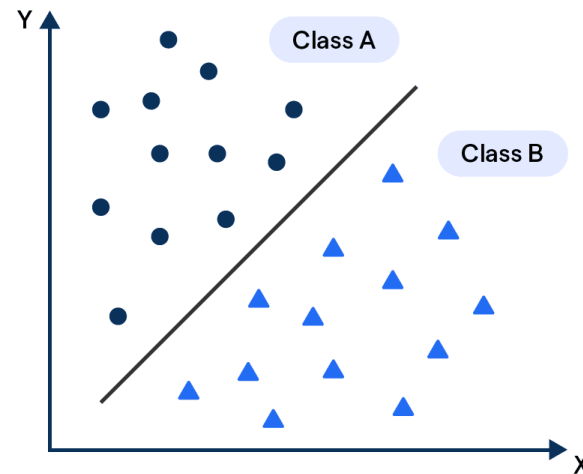
2. Text classification

example. Adverse Events

Serious AE

AE

Classification Algorithm



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. It 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)
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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
		India	48	41	88	1				High	98.44

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



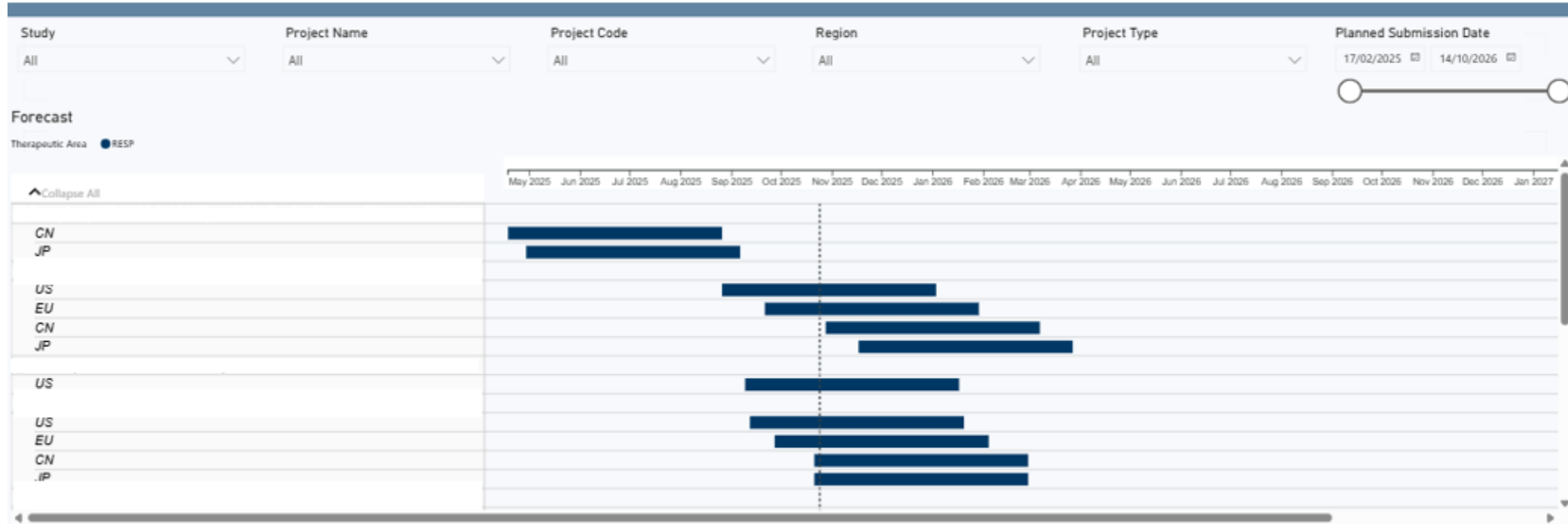
AI Capabilities and Use Cases

Planning

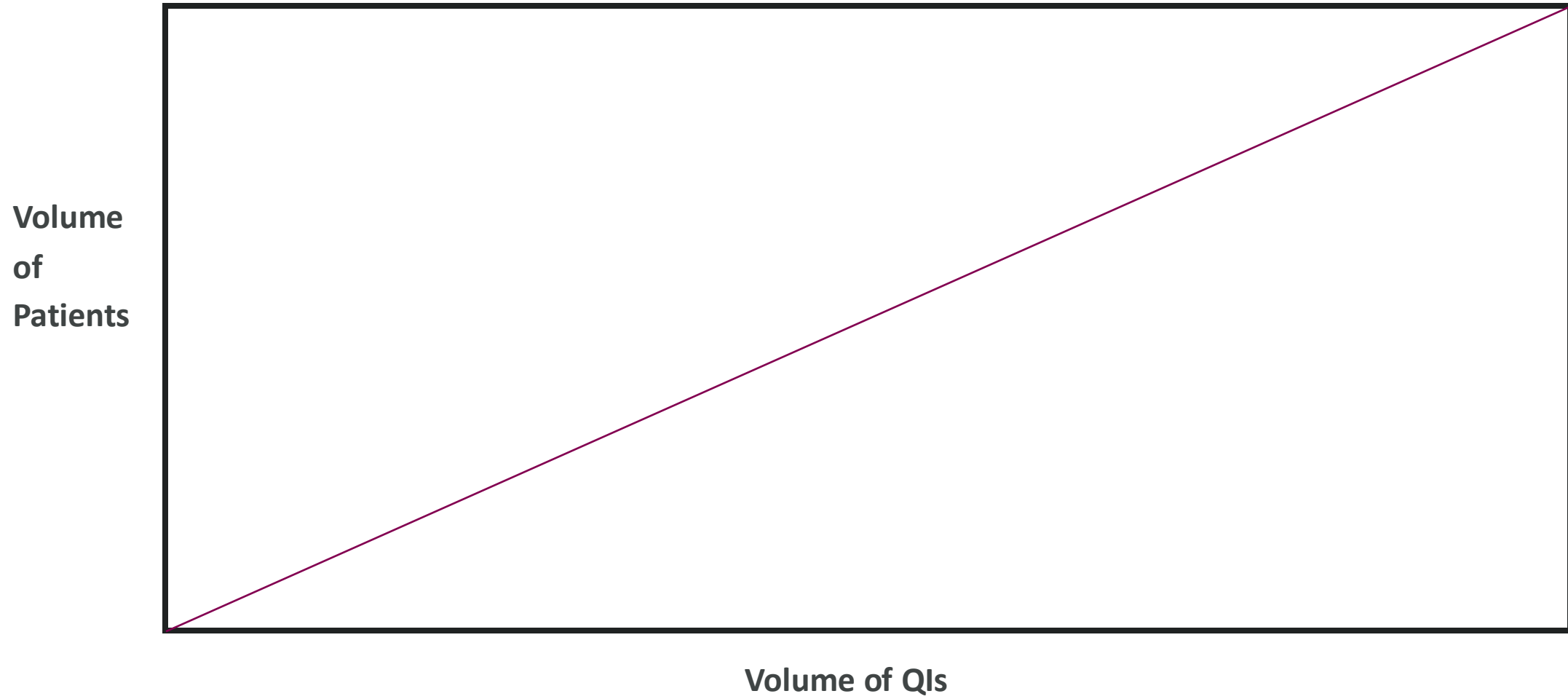
- Predictive analytics – demand planning
- Patient enrollment prediction by month

AI Capabilities and Use Cases

Pre-Approval Inspection Forecast



AI Capabilities and Use Cases





Thank You!

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