

# Enhancing Quality Management Review through Automation

- A look into Feasibility and Implications

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The information presented is based on personal expertise and experience.*

1. Introduction
2. Re-thinking Quality Management Review
3. Data-driven QMS improvements
4. Methodology – automation & GenAI
5. Current experiments
6. Summary & perspectives

# Agenda

INTRODUCTION

# Quality in Data Science

## Quality Management System



GxP Documents

Quality Management Review

Inspection Readiness

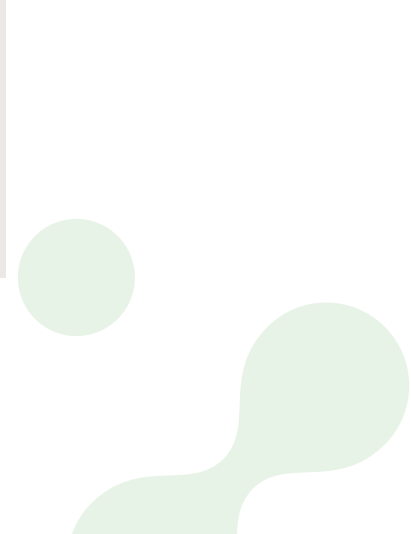
Process Improvements

Data Insights



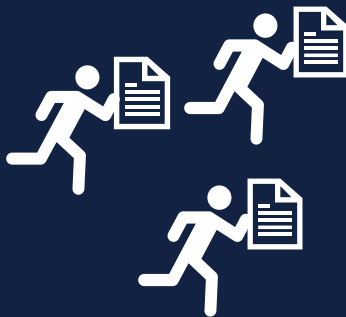
## Digital Transformation

Initiative	Tech transition
STUDYBUILDER	CDW-MMA & neo4j
DATANOW	ORACLE & Veeva
DATA CORE	Microsoft Azure & Microsoft Azure aws & databricks
AMACE	sas & sas viya & posit databricks
MAIA	aws & Microsoft Azure databricks
AUTOMATION FACTORY	Microsoft Azure & Microsoft Azure aws & databricks



## Now

- Quality Management Review  
2 times/year 'on demand'
- Growing organisation,  
growing trial portfolio

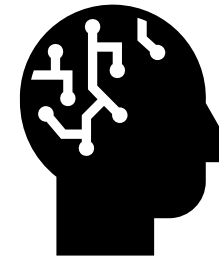


### But

- ... Manual data collection
- ... Data scattered across multiple  
source systems

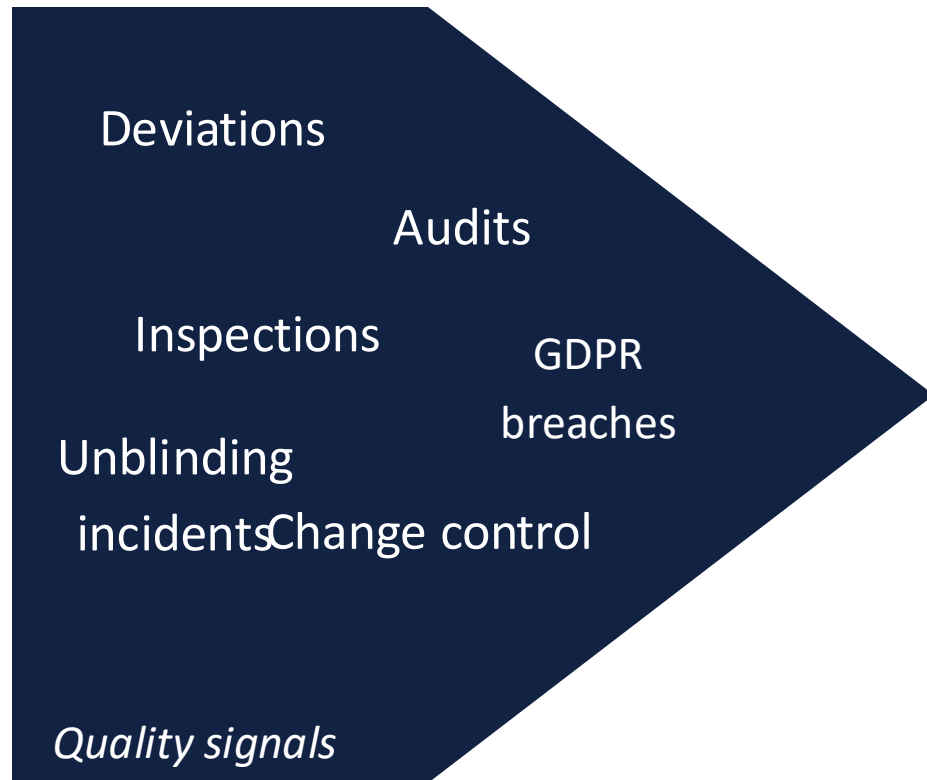
## Aspiration

- Continuous quality oversight
- Data-driven QMS improvements

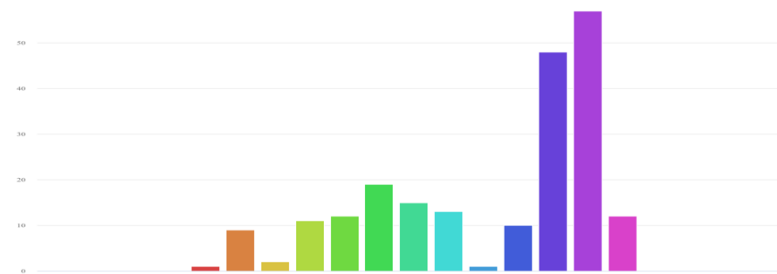


DATA-DRIVEN QMS IMPROVEMENTS

# Stronger signal detection by combining quality data into one



**Analyse**  
by SOPs, roles,  
IT systems



METHODOLOGY

# Automation & GenAI to achieve our aspirations

**Data Foundation & Sources** - Leverage existing data sources



**Methodology & Analyses** - Pull, enrich and analyse data



**Results** - Static displays to intelligent ways of looping back



CURRENT EXPERIMENTS

# Static Output – Unstructured data

level_04_name	Number of Deviations
Digital Data Infrastructure & Processes	14
CKAD & RD - Biometrics	5
Diabetes & Obesity - Biometrics	4
AI & Analytics	
Biostatistics	
Data Science Executive Office	
	<b>23</b>

SOP ID	Number of Deviations
Q0300375	7
Q110041	5
Q110043	2
Q110162	2
110162	1
Q0663497	1
Q110128	1
Q110161	1
	<b>23</b>

## Use of LLM for classifications

**Topic**

**Basic information**

**Deviation headline?**  
 Delayed finalisation of Data Management Plan for [redacted] deviation to SOP Q110041, version 12, section 5 action 3

**Deviation description?**  
 The Initial final version of Data Management Plan was finalised by CTDM on 02Dec2020 whereas the First Patient First Visit took place on 25Nov2020. This was due to human error. No changes was done from draft to final version.

The deviation was discovered by inspector during [redacted] February 2024.

**Date**

**SOP**

Due to human error the CTDM working on the trial at that time did not finalise the DMP before FPFV which is a deviation from the SOP: Q110041 Data Management Setup version#12 which states in section 5: 'Finalise the first version of the DMP before planned first patient first visit (FPFV)'.  
**Role**

Finally the late approval of the deviation is due to delay from CTDM. The study is closed, and the incident is very old and CTDM was not sure if a deviation can be/ should be filed at this late stage. Furthermore, CTDM was not made aware of the incident before it was highlighted in the inspection. CTDM was also not immediately aware of the timelines of reporting deviations however, a recent training has apprised/reminded of the timelines.  
**Trial Time**

# Summary & perspectives

- **Automation and GenAI** to enable continuous quality oversight
- **Combining data sources** for stronger signal detection
- Unstructured data requires special consideration
- **Faster, data-driven QMS improvements**

## Next steps

- More experiments
- Regulatory expectations
- Scalability

The background is a dark blue color. It features several decorative elements: large, flowing green abstract shapes on the left side; a horizontal row of five circular patterns in shades of green and yellow in the upper right; and a single circular pattern in the lower right, partially overlapping the word 'Thanks'.

# Thanks



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