

HSRAA24 CONFERENCE

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Technical Information Governance & AI in Migrations across the GxP space

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About The Speakers



Nick Larsen

Director of Technical Services at Epista Life Science, specializing in delivering innovative projects and services within data migrations, data science, and AI.

With a robust background in IT and consultancy for the life sciences industry, Nick drives impactful technological solutions to meet complex regulatory demands.

In addition to this, works as a football talent scout at FC Copenhagen.



Karen Roy

TMF and Clinical Operations Consultant | Leading the TMF Reference Model for CDISC, Providing advice and consultancy and Board Director for the Institute of Clinical Research

Agenda

1. Introduction
 - Overview of the importance of information governance.
2. Information Governance Essentials
 - Key components and why it matters in regulated industries.
3. AI for Streamlining Data Management
 - How AI is transforming data quality and compliance.
4. Challenges in Data Migrations
 - Common issues and risks in regulated environments.
5. Practical Solutions for Smooth Migrations
 - Strategies and best practices for ongoing success.
6. Conclusion and Q&A
 - Recap and open discussion.

1. Introduction

1. The Role of Data in Regulated Industries

- Data is the foundation of **operations**, **decision-making**, and **compliance** in sectors like life science.

2. Challenges Faced by Organizations

- Increased Data Volumes: Rapid growth in data requiring better governance. **(30-50% pr. year)**
- Complex Regulations: Compliance with strict legal frameworks like GDPR and GxP.
- Evolving Technology: Managing AI, automation, and modern tools to streamline data handling.

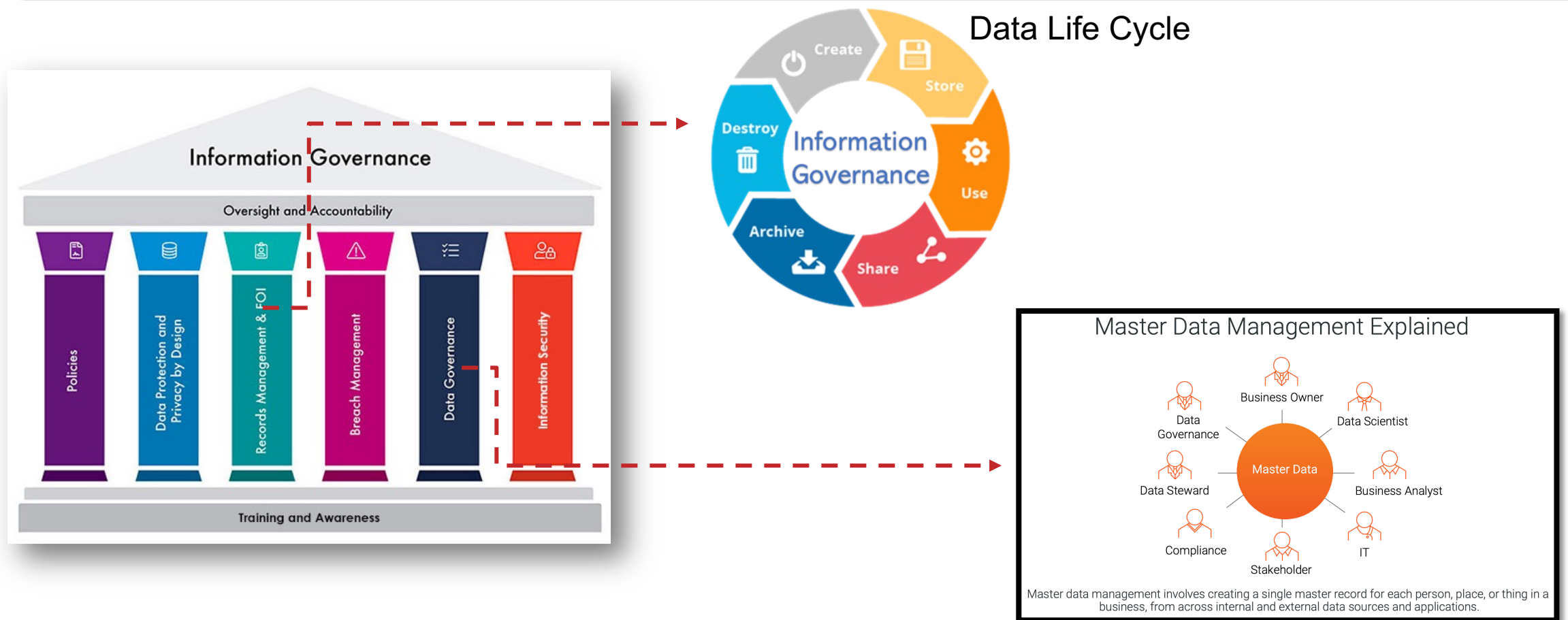
3. Focus of Today's Session

- Exploring the key elements of Information Governance.
- Understanding how AI can enhance data management.
- Overcoming challenges in Data Migrations for regulated environments.

2. Information Governance: The Foundation

- **What is Information Governance?**
A framework for managing and protecting data to ensure **quality, security, compliance, and integrity** throughout its lifecycle.
- **Key Elements of Information Governance:**
 - **Data Quality & Integrity**
Ensures accurate, reliable, and trusted data.
 - **Compliance & Regulations**
Adherence to industry regulations (e.g., GDPR, GxP).
 - **Data Security**
Protects sensitive information from breaches and unauthorized access.
 - **Data Lifecycle Management**
Manages data from creation to deletion.
 - **Ownership & Accountability**
Clear roles and responsibilities for data management.
- **Master Data Management (MDM)**
 - MDM is the cornerstone of data consistency and quality across the organization, enabling effective governance.

The Foundation



3. AI for Streamlining Data Management

1. How AI Enhances Data Management:

- Automation of Data Quality Checks
- Automated Data Classification
- Predictive Analytics for Compliance

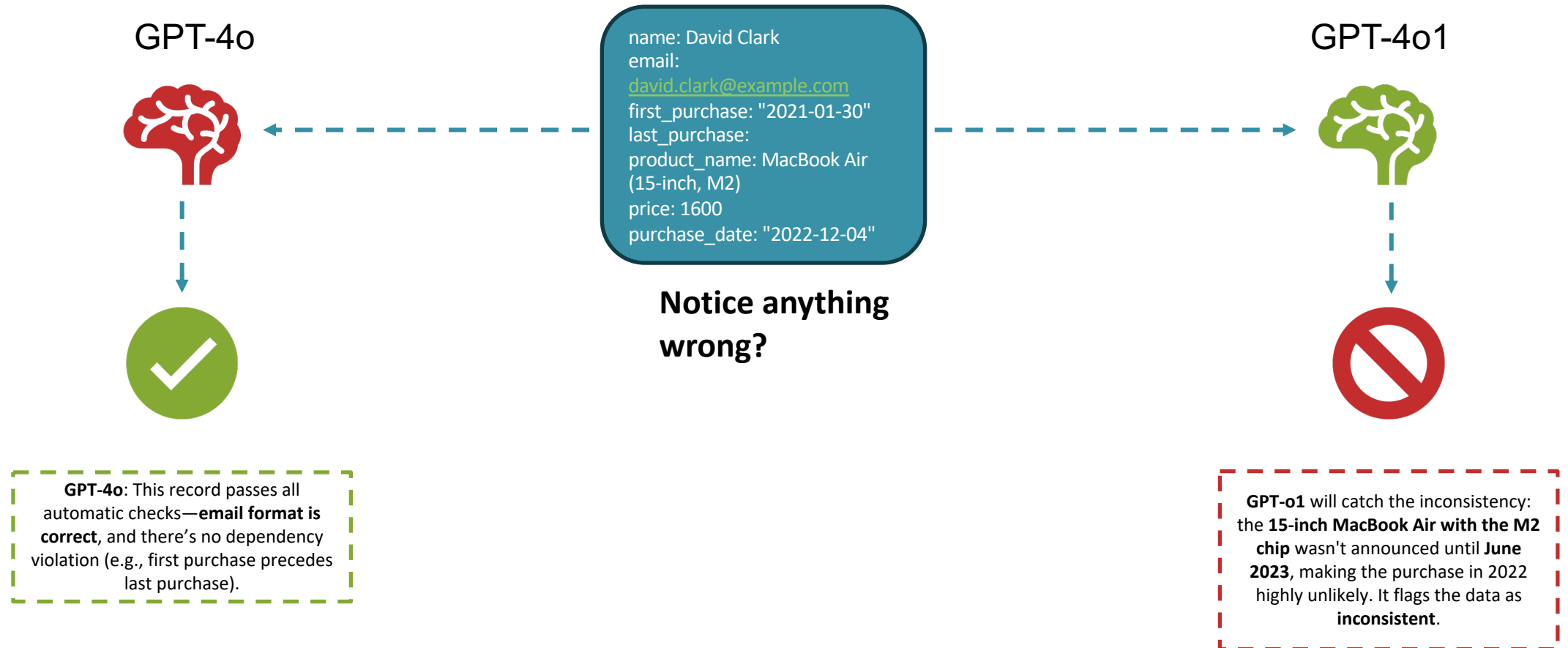
2. Key AI Use Cases:

- Data Cleansing
- Compliance Automation
- Data Integrity Monitoring

3. Benefits of AI:

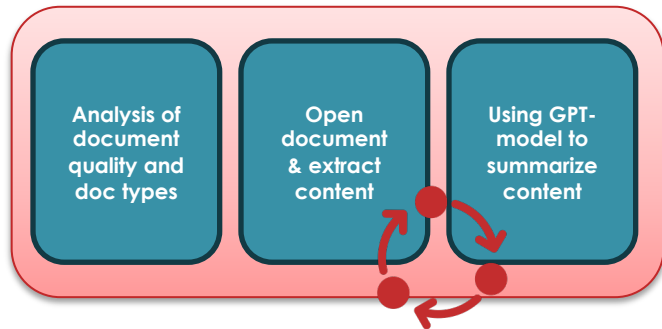
- Increased Efficiency: Reduces manual efforts and speeds up data processing.
- Enhanced Accuracy: AI minimizes errors, ensuring more reliable data.
- Scalability: AI-driven systems scale with the growing volume of data.

Automation of Data Quality Checks

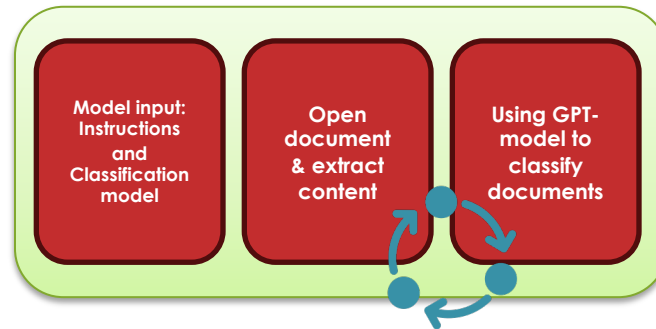


Automated Data Classification with LLM's

Dark data → Data insights



Data insights → Data structure



Data output in csv prepared for the migration process

Data insights

Data structure

Limitations

DATA QUALITY

The effectiveness of GenAI models is highly dependent on the quality of the data. Poor data can lead to inaccurate predictions and unreliable outputs.

BLACK BOX ISSUE

Many GenAI models, particularly deep learning models, lack transparency in their decision-making processes, making it difficult to explain their outputs to stakeholders.

HIGH COMPUTATIONAL COSTS

Training and running GenAI models require significant computational resources, which can be expensive and may necessitate specialized hardware.

01

Don't expect full coverage when running a classification process

02

70-80% coverage is a good benchmark due to quality issues

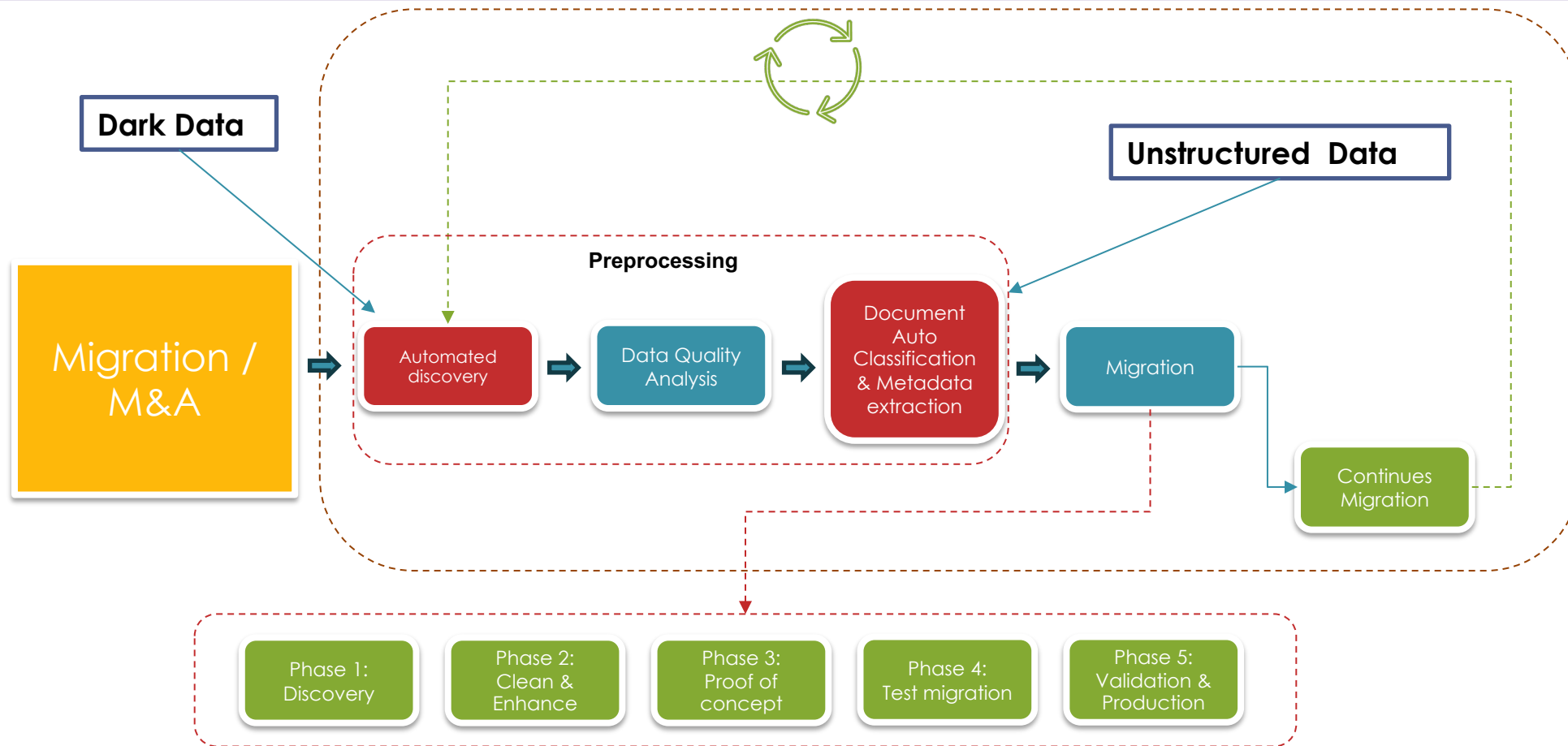
4. Challenges in Data Migrations

- **Complex Regulatory Requirements**
 - Migrations must ensure compliance with strict regulations (e.g., GDPR, GxP), which can vary across companies.
- **Handling Large Volumes of Data**
 - Migrating vast amounts of data, often across multiple systems, can increase complexity and risks.
- **Dark Data**
 - Addressing dark data during integrations & migrations requires significant internal resources from customers, including specialized expertise to uncover and evaluate “hidden” data.
- **Unstructured Data**
 - When migrating unstructured data, customers often face internal resource challenges, including the need for specialized expertise to identify and categorize diverse data types.
- **Time and Resource Constraints**
 - Continuous migrations can strain organizational resources, requiring careful planning and automation to reduce manual efforts.

5. Practical Solutions for Smooth Migrations

- **Phased Approach**
 - Break migrations into manageable phases to minimize risk, have gatekeepers and maintain control over the process.
- **Flexible Migration Framework & Tools**
 - Use AI and automation for tasks such as data mapping, transformation, and QC checks to ensure efficiency and reduce errors.
- **Validation & Testing**
 - Continuous validation of data integrity at every migration stage, using test environments to simulate potential issues.
- **MDM as a Centralized Source**
 - Use Master Data Management (MDM) if available to ensure consistent, high-quality data throughout the migration.

Continuous Migrations



6. Conclusion and Q&A

- **Importance of Information Governance**
 - Strong governance frameworks ensure data quality, security, and compliance, especially in regulated industries.
- **AI to increase efficiency**
 - AI simplifies data management by automating key processes, improving efficiency, and enhancing compliance.
- **MDM's Central Role**
 - Master Data Management is essential for ensuring data consistency, integrity, and governance throughout migrations.
- **Practical Migration Strategies**
 - Phased approaches, automation, and validation are critical to ensuring smooth and compliant data migrations.
- **Prepare for the Future**
 - Continuously refine governance practices, leverage AI, and ensure your teams are equipped to adapt to future data challenges.