



NAVIGATING THE INTRICACIES OF DATA GOVERNANCE AMIDST CHANGING REGULATIONS AND EVOLUTION OF AI



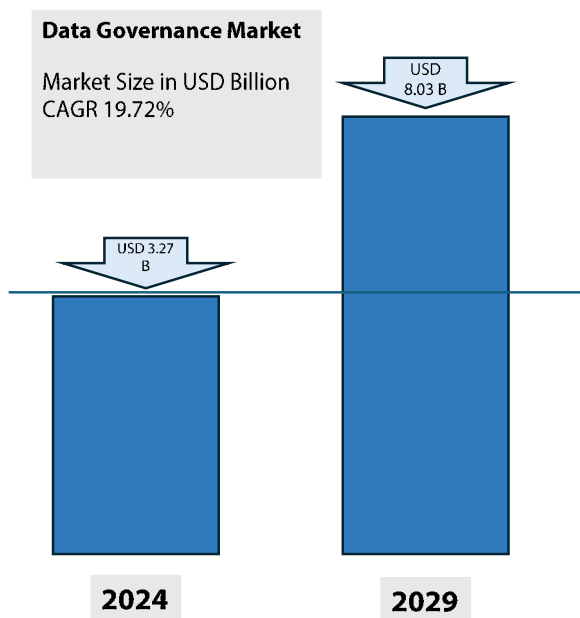
INTRODUCTION

Data governance is like having a skilled conductor leading an orchestra - it ensures that everyone is working together harmoniously, following the right tempo, and staying in tune. It allows organizations to unleash the full potential of their data assets, while also ensuring that all regulations and compliance requirements are met seamlessly. Far from being a hindrance, modern data governance empowers users to innovate and excel within a framework of security and privacy. It's not about saying "no" all the time, but rather about creating a sturdy foundation for growth and success.

Data governance provides oversight and management of an organization's information, while data quality is focused on the integrity and value of the information itself.

DATA GOVERNANCE WILL CONTINUE TO RAPIDLY GROW...

The Data Governance Market size is estimated at USD 3.27 billion in 2024, and is expected to reach USD 8.03 billion by 2029, growing at a CAGR of 19.72% during the forecast period (2024-2029). The aim of data governance is to promote the availability, quality, as well as security of an organization's data through various policies and standards.



Study Period	2019-2029
Market Size (2024)	USD 3.27 B
Market Size (2029)	USD 8.03 B
CAGR (2024-2029)	19.72%
Fastest growing market	Asia Pacific
Largest market	North America

MAJOR PLAYERS

IBM

ALATION

TIBCO

COLLIBRA

MICROSOFT

Source : Mordor Intelligence

The pandemic has also acted as a catalyst to the growth of data usage. Enterprises across various end-user industries, especially telecom companies across emerging nations, have seen a surge in data usage due to lockdowns imposed by the governments. In such times, organizations that have an established data governance program in place have fared much better than those without.

According to Cisco, around 5 quintillion bytes of data is produced every day, which, in turn, drives the need for a data governance solution to ensure that an organization's information assets are formally, properly, proactively, and efficiently managed throughout the enterprise to secure its trust and accountability.

Big data and digital transformation efforts are among the primary drivers of data governance programs. With the increase in the volume of data from new data sources, such as the Internet of Things (IoT) technologies, organizations are reconsidering their data management practices scaling their business intelligence.

Data governance solutions help institutions handle different challenges with effective data management solutions that can prevent data duplication and data loss. Moreover, data governance solutions help industries with enormous volumes of personal and confidential data, to support an edge in the market, with constant updates to their policies and procedures.

SPECIFIC CONSIDERATIONS FOR “REGULATORY” AS DATA DRIVEN SUBMISSIONS GROW

Regulators in the Life Sciences industry are increasingly emphasizing the importance of data-driven submission processes for marketing authorization. This shift has led to the implementation of new standards that are pushing drug and device companies to improve their regulatory information management practices throughout the product development lifecycle.

Embracing enhanced process and data quality rigor can bring several benefits to companies. These include improved trust in data for decision-making, better integration of data with business processes and reporting, faster interactions with health authorities, enhanced regulatory intelligence, and smoother data exchange between different business functions.

To fully leverage these benefits, companies need to rethink their current system capabilities and processes for capturing, managing, and utilizing data. It is crucial for companies to shift towards using original data as the foundation for submissions and regulatory exchanges, as well as for internal decision-making. This requires a focus on ensuring the quality and completeness of data.

When upgrading their regulatory information management systems (RIMS), companies should take a holistic approach rather than treating it as a technology-specific project. Common challenges that may arise during RIM solution upgrades include system issues, process challenges, and difficulties related to data governance.

By addressing these challenges proactively and implementing targeted recommendations, companies can effectively realize the full business benefits of a robust, data-driven RIM capability. This approach will help companies stay ahead in a rapidly evolving regulatory landscape and ensure compliance with increasingly stringent requirements.



DATA GOVERNANCE CHALLENGES & SOLUTION FRAMEWORK - SYSTEM IMPLEMENTATION LIFECYCLE

New regulatory policies and systems make it complicated to manage data properly. This can involve figuring out who's responsible for what, creating clear rules, and making things more efficient. It's also important for the new system to work smoothly with existing ones.

1. Regulatory Compliance



Regulatory requirements for data management in the pharmaceutical industry are constantly evolving. Maintaining a data governance framework that is adaptable and readily aligns with these latest regulations is a significant challenge.

Understand the specifics of the regulations and identify areas where your current practices fall short. Then, take stock of your data landscape – what data you have, where it is, and how it flows.

During the maintenance/post Go-live of the system, educate your employees about the regulations and their data handling responsibilities. Regularly monitor and audit your data governance practices identifying areas for improvement.

SOLUTION:

- The system should be adaptable to accommodate specific data needs without compromising existing functionalities, workflows, or business rules.
- The design should proactively incorporate potential regulatory changes from Health Authorities into the system's governance framework, ensuring long-term compliance.
- Compliance with new regulations from Agency poses significant challenges in the data governance requiring strict adherence to data handling and privacy protocols.

SOLUTION:

- Any updates or new additions to the Master data must undergo validation through verification approval workflows. The Data Governance board, in collaboration with relevant process owners, should approve these workflows. The verification process can be implemented either externally or within the system, if provisions exist. Additionally, routine monitoring of data quality on transactional data is recommended.
- Wherever AI is not functional, human intervention is necessary for data enrichment to prevent and detect errors.
- Consider implementing controlled user access to restrict updates and modifications to master data. Establish access controls and a verification and approval workflow to ensure data integrity and maintain an audit trail.
- Leverage Data Quality tools & techniques to achieve continuous improvement and proactive Data Maintenance.
- Third-Party Validation for Additional Assurance: Consider incorporating a third-party validation service to provide an independent layer of verification for cleansed data. This adds an extra level of confidence in the data's accuracy and compliance.

2. Data Quality Standards



High-quality data is the backbone of both regulatory compliance and sound decision-making. However, ensuring data across various systems remains accurate, complete, and consistent can be challenging. Robust data quality standards and processes are crucial to overcome this hurdle.

Develop or update data policies to reflect the new regulations. This includes how data is collected, stored, accessed, retained, and disposed of. Assign clear data ownership and accountability within your organization.

During the maintenance/post Go-live of the system, implementing stringent Data Governance measures ensures ongoing integrity, accuracy, and relevance of the information. This involves regular data validation checks and establishing clear ownership and accountability for Data maintenance. Requisite trainings on managing and enhancing Data quality.

3. Data Integration



Pharmaceutical regulatory systems typically involve a multitude of data sources with diverse formats. Seamless integration of this varied data presents a challenge, requiring compatibility between disparate systems, data standardization efforts, and effective data mapping strategies.

During the maintenance/post Go-live of the system, implementing robust Data Integration strategies ensures that data is accurately transferred, transformed, and synchronized to establish consistency in Data hubs.

SOLUTION:

- Implement data standardization across all systems and ensuring standard data governance is mapped with internal dictionary.
- Ensure that the mapping of attributes from source systems to the target system is well-defined and validated for all upstream integrations.

- Identify and establish appropriate triggers for receiving data from source systems, including Document Management Systems (DMS), Product Management Tools, Regulatory Intelligence tools, Labelling application (LMS), Quality management systems, and User Provisioning Systems.

4. Data Privacy and Security



The highly sensitive nature of regulatory data necessitates robust data privacy and security measures. Implementing protocols to safeguard against unauthorized access, data breaches, and ensuring compliance with data protection laws is an ongoing challenge.

During the maintenance/post Go-live of the system to safeguard sensitive data, implement robust security measures like encryption and access controls. Regularly monitor and update these measures.

SOLUTION:

- Role based Access Provisioning:** Establishing user access management ensures that content is verified and accepted by all users.
- Implement cybersecurity measures such as Multi-Factor Authentication (MFA) and Single Sign-On (SSO) for secure remote access by employees and partners via VPNs.
- Develop a data classification framework to categorize data based on sensitivity. This framework enables the application of appropriate security controls according to the defined classification.
- Conduct employee training on cybersecurity best practices and raise awareness about phishing threats.

5. Cross-Functional Collaboration



Data governance is a multi-stakeholder endeavour, involving regulatory affairs, IT, legal, and other departments, each with unique priorities and expertise. Facilitating collaboration across these departments requires effective communication and a clear alignment of goals, which can be challenging to achieve.

SOLUTION:

- A cross-functional Data Governance team (IT, SMEs, Integration, Project Management, System Owners) will be established to define policies, standards, and oversee data quality.
- Regular meetings and training will ensure clear communication and stakeholder alignment.
- Data Stewards in each department will champion data governance practices.

6. Data Governance Framework Design



Designing a comprehensive and effective data governance framework tailored to the specific needs of Pharma Regulatory systems is a challenge. It involves defining roles and responsibilities, establishing policies, and creating processes that align with industry best practices.

SOLUTION:

- Assemble the Team:** Establish a cross-functional Data Governance team to define policies and oversee data quality (IT, SMEs, Integration, Project Management, System Owners).
- Assign Responsibilities:** Clearly define roles within the team to ensure efficient data governance.
- Develop Policies & Standards:** Create data privacy/sharing policies, data standards, and naming conventions.
- Foster Collaboration:** Drive discussions on Master Data, picklist updates, business processes, and integration/migration impacts.
- Maintain Transparency:** Collect and track attributes, publish Master lists regularly to keep stakeholders informed.
- Manage Requests:** Implement a change management process to handle custom stakeholder requests.
- Ensure Data Integrity:** Address data discrepancies across systems for consistency.
- Foster Communication:** Establish clear communication channels between the Steering Committee and stakeholders for updates and feedback.

7. Data Lifecycle Management



During the maintenance/post Go-live, regulatory systems present unique challenges for data lifecycle management, the process of overseeing data from creation to archiving. Ensuring data traceability, which means tracking the history and movement of data, is crucial. Additionally, maintaining version control, allowing for the identification and access of specific data versions, and implementing proper archival processes to comply with regulatory retention requirements are all essential but complex tasks.

Regular audits and monitoring are essential for ensuring the ongoing compliance and effectiveness of data governance processes within the Pharma regulatory function. However, this presents challenges. Developing robust mechanisms for continuous improvement is key, allowing the framework to adapt to evolving regulatory requirements.

SOLUTION:

- A systematic approval workflow should be established for any modifications in Master data to ensure Data integrity, quality, and accountability.

- Routine data quality checks and audits to ensure that data is accurate, complete, and consistent across different systems.
- Establish clear policies for how many versions of data to retain and for how long.
- Enrich data with detailed metadata tags that document its origin, purpose, and modifications to track life cycle of the document.
- Implement software that help to tracks data movement and transformation throughout its lifecycle. This creates an audit trail for regulatory purposes.

LEVERAGING AI IN DATA GOVERNANCE FOR ENHANCED COMPLIANCE AND EFFICIENCY

By combining AI and automation with strong data governance practices, you can achieve a more efficient, scalable, and compliant approach to data management in the face of evolving regulations. AI can design a plan that fits the company's specific needs, automate repetitive tasks, and keep improving how data is managed over time.

AI (Artificial intelligence) and automation tools and techniques can address compliance challenges arising from new data governance regulations.



AI-powered Transactional Data Quality Monitoring:

Leverage AI for routine data quality checks on transactional data. AI can effectively identify anomalies, inconsistencies, and potential errors.



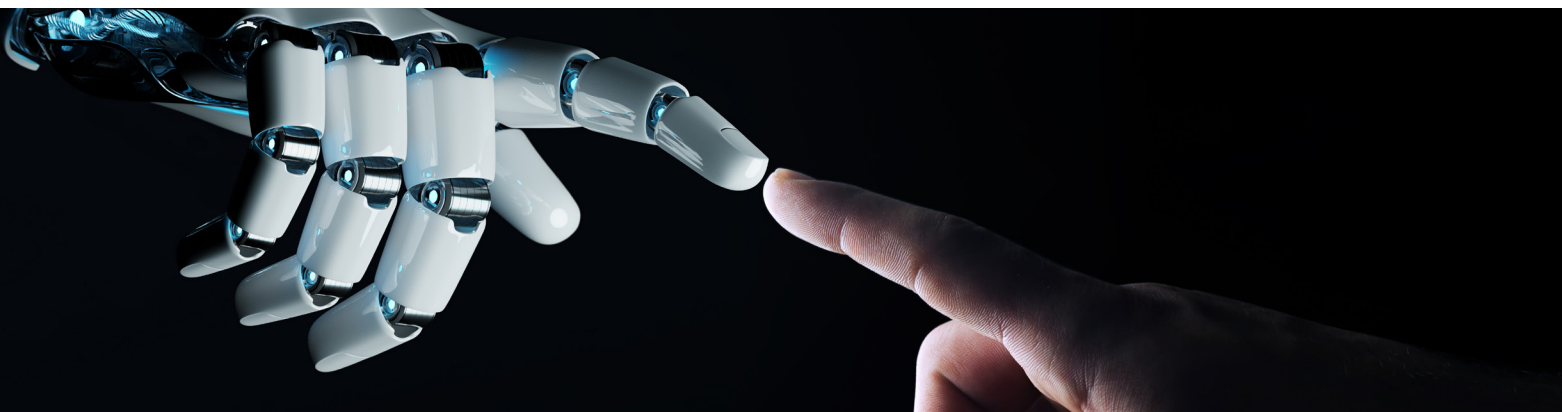
AI for Data Cleansing Prediction:

While AI can't predict the exact scope of data cleansing needs, it can be helpful in identifying data patterns and trends that suggest areas where human intervention might be necessary.



Focus on Collaboration:

Combine AI's strengths in data analysis with human expertise for data cleansing tasks that require judgment and domain-specific knowledge.



Streamlined Data Integration with AI-powered Triggers

- Establish a clear and well-documented mapping between attributes in source systems and the target system. This ensures data consistency and avoids integration errors.
- Leverage AI-assisted Trigger Identification to analyse data patterns and system behaviour to identify optimal triggers for receiving data from source systems. AI can help determine the most efficient frequency and conditions for data ingestion based on factors like data volume, volatility, and business needs.

Data Discovery and Classification:



Automated data discovery and classification tools can help to identify and classify data assets across the organization, providing insights into the types of data that are being stored and used. This can help to improve the visibility and control over data assets.

Data Quality Automation:



Implementing automated data quality checks can help to ensure that data is accurate, complete, and consistent across different systems. This can include data profiling, data cleansing, and data enrichment processes.

Metadata Management:



AI can help to capture and manage the metadata associated with data assets, providing insights into data lineage, data usage, and data quality. This can help to improve the traceability and accountability of data changes.

Access Control Automation:



Automating access control using AI can help to ensure that data is accessed and modified only by authorized individuals. This can include automated provisioning and de-provisioning of user access, as well as role-based access controls. Implementing **Dynamic Role-Based Access Control (RBAC)** access control system leverages AI to dynamically adjust user permissions based on their roles and activities. AI can analyse user behaviour patterns to identify potential risks and automatically restrict access to sensitive data that is not essential for their job function. **AI-assisted Data Classification for Tailored Security** can automate data classification based on pre-defined sensitivity levels. AI can analyse data content and context to automatically categorize data (e.g., financial, health records) and trigger appropriate security controls. This ensures a more robust and efficient data security posture.

Data Retention and Archiving:



AI implementation in data retention and archiving processes can help to ensure that data is retained for the appropriate period and then disposed of in a secure and compliant manner. This can include automated data classification, data retention policy enforcement, and data archiving.

Data Deletion Automation:



AI implementation for data deletion can help to ensure that data is deleted in a timely and secure manner when it is no longer needed. This can include automated data classification, data deletion policy enforcement, and data deletion auditing.

Change Management:



Implementing AI based automated change management processes can help to ensure that changes to data and data processes are managed in a controlled and auditable manner. This can include automated version control, change approvals, and rollback processes.

Automating data lineage processes can help to track the flow of data from its source to its destination, providing insights into how data is transformed and used across different systems.

Audit Trail Generation:

Automation can generate comprehensive audit trails that record all data activities, including who accessed the data, when it was accessed, and what changes were made. This is crucial for compliance and auditing purposes.



Data Anomaly Detection:

Automated anomaly detection tools can identify unusual data activities that may indicate potential security breaches or compliance issues. This can help in taking corrective action before a breach occurs.



Real-Time Data Monitoring:

Automated data monitoring tools can continuously monitor data activities across different systems and applications. This can help in identifying potential issues in real-time, allowing for immediate corrective action.



Automated Reporting:

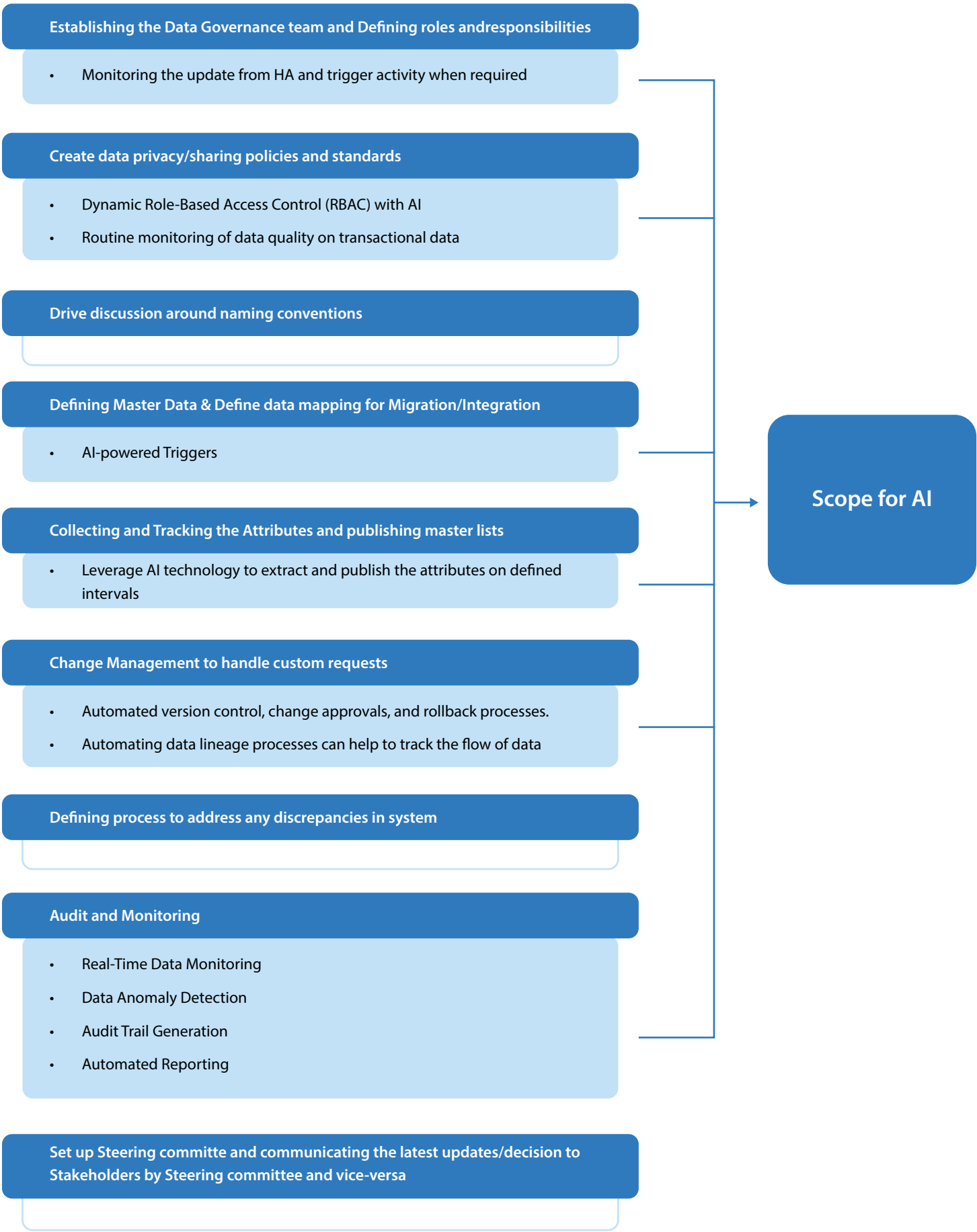
Automated reporting tools can generate reports on data governance activities, providing insights into data usage, compliance, and potential issues. This can help in identifying trends and patterns that may not be apparent from manual audits.



Automated Data Remediation:

Automation can remediate data issues that are identified during monitoring and auditing activities. This can help in ensuring that data is managed according to established policies and standards.





COMPREHENSIVE AI ENABLED - DATA GOVERNANCE FRAMEWORK

BENEFITS OF CHOOSING AI- ENABLED DATA GOVERNANCE

By combining AI and automation with strong data governance practices, you can achieve a more efficient, scalable, and compliant approach to data management in the face of evolving regulations. AI can design a plan that fits the company's specific needs, automate repetitive tasks, and keep improving how data is managed over time.

AI (Artificial intelligence) and automation tools and techniques can address compliance challenges arising from new data governance regulations.



CONCLUSION

Making sure pharmaceutical data follows the regulations can be complicated. People might resist new ways of doing things. The solution? Talk it out, train people, and keep improving. Although there's a secret weapon: AI! It can automate tasks, catch mistakes faster, and even warn of upcoming rule changes. This frees people up to focus on the bigger picture, saves money, and helps make better decisions based on real data. With AI on their side, pharmaceutical companies can build a strong data governance model for managing data, making it easier to follow the rules and improve the develop new pharmaceutical products.

Businesses are turning to AI for efficiency, however it's only valuable if the data used is reliable and well-managed. A strong data governance framework is the key. This ensures data quality and helps businesses make the most of their information, keeping them on the right track.



REFERENCE:

<https://www.mordorintelligence.com/industry-reports/data-governance-market/market-size>

<https://blog.erwin.com/blog/pharmaceutical-companies-data-governance/>

<https://www.linkedin.com/pulse/how-ai-transforming-data-governance-part-2-katrina-klier>

<https://blog.erwin.com/blog/pharmaceutical-companies-data-governance/>

<https://www.outsourcedpharma.com/doc/a-practical-look-at-data-governance-in-the-life-sciences-0001>

<https://www.qbdvision.com/data-governance-integrity-pharma-biotech-part-1/>

<https://www2.deloitte.com/content/dam/Deloitte/nl/Documents/risk/deloitte-nl-risk-iperion-whitepaper-RIMS-upgrade.pdf>

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