

Article 7

Data Governance Domain of the Clinical Trial Disclosure Maturity Model



Data Governance Domain of the Clinical Trial Disclosure Maturity Model

1 Sm Stakeholder Mapping	2 Gf Governance Framework	3 Dv Data Validation								4 Ps Process standardizati
5 Tp Training Programs	6 Do Data Ownership	7 Dg Data Organization	8 Dh Data Harmonizato	9 Dx Data Security	10 Am Access Management	11 Rc Records Management	12 Dr Data Retention	13 Pe Performance Metrics	14 Wt Workflow Tracking	15 Pp Disclosure Planning
16 Ca Competency Assessment	17 Ds Disclosure System	18 Si System Integration	19 Wm Task Management	20 Sc Security Controls	21 Us User Support	22 Dy Disaster Recovery	23 Ai AI/ML Capabilities	24 Ip Innovation Planning	25 Pc Change Management	26 Pi Process Improvement
27 Ac Awareness Campaigns	28 Rr Roles & Resp.	29 Kp KPIs	30 Mr Metrics & Reports	31 Da Data Sources	32 Tr Trend Analysis	33 Dc Disclosure Scorecard	34 Ra Reporting Automation	35 Bm Benchmark	36 Sf Stakeholder Feedback	37 Ie Issue Escalation
38 Ce Compliance Education	39 Qm Quality Management	40 Os Org. Structure	41 Cl Functional Collab.	42 Ex External Integration	43 Gc Global Coordination	44 Re Resource Allocation	45 Oc Org. Change	46 Tq Talent Acquisition	47 Pm Performance Management	48 Pq Process Monitoring
49 Tt Technology Training	50 Km Knowledge Management	51 Cq Compliance Monitoring	52 Ri Regulatory Intelligence	53 Cm CAPA Management	54 Im Incident Management	55 Rk Risk Management	56 Ar Audit Readiness	57 Qt Quality Metrics	58 Cc Change Control	59 Pf Process Metrics
	60 Io Strategic Improvement	61 Gs Governance Structure	62 Le Leadership Engagement	63 Oa Org. Alignment	64 Pd Disclosure Strategy	65 Rm Regulatory Monitoring	66 Rb Resource Allocation	67 Vp Vendor Management		

Executive summary

The data governance domain focuses on the integrity, data quality, and security of clinical trial disclosure information. This domain encompasses the policies, processes, and structures that govern how data is collected, validated, stored, and managed throughout the clinical trial lifecycle. Effective data governance is essential for maintaining regulatory compliance, enhancing decision-making, and building trust with stakeholders in the clinical trial disclosure process.

Why this domain matters

Data governance is necessary for reliable and compliant practices to meet regulatory disclosure requirements, maintain data privacy, and protect confidential data. It establishes the rules and standards for data management, ensuring consistency and data quality across all disclosure activities. By implementing robust data governance, organizations can enhance the accuracy of their disclosures, streamline their processes, and build confidence in their

reported clinical trial information:

- **Ensures data quality**, consistency, and reliability across all disclosure activities
- **Protect personal and confidential data**
- **Reduces the risk** of data-related violations
- **Improves decision-making** through access to accurate and timely information
- **Builds trust** with stakeholders by demonstrating a commitment to data integrity
- **Facilitates efficient data sharing** and collaboration within the organization and with external partners

Potential risks of a weak approach to data governance

Inadequate data governance in clinical trial disclosure can compromise the integrity, consistency, and reliability of the disclosed information. Poor data management practices may lead to inaccuracies, inconsistencies across registries, and difficulty tracking and updating disclosure information throughout the clinical trial lifecycle. These issues not only increase the risk of noncompliance with

Data Governance Domain of the Clinical Trial Disclosure Maturity Model

regulatory requirements but also undermine stakeholder trust and the overall credibility of the organization's research efforts. Specific risks include:

- Inconsistent or inaccurate data across different registries and disclosure platforms
- Increased risk of disclosing protected personal or confidential information
- Difficulty in tracking and managing data throughout the clinical trial lifecycle
- Inefficient use of resources due to data duplication or inconsistencies
- Loss of stakeholder trust caused by data quality issues or inconsistencies in disclosed information
- Challenges in adapting to new regulatory requirements and technological changes

Key elements of data governance

Data Governance framework

A governance framework provides the overarching structure for managing data within an organization. It defines the policies, procedures, and standards that guide data management practices across the clinical trial disclosure process.

Maturity levels:

- **Lagging:** No formal data governance framework exists. Data management practices are ad hoc and inconsistent across the organization.
- **Developing:** Basic data governance policies are in place, but implementation may be inconsistent. Roles and responsibilities are defined but may not be fully followed.
- **Leading:** A comprehensive, well-documented data governance framework is consistently applied across all disclosure activities. Regular reviews and updates ensure the framework remains effective and aligned with best practices.

The main components of the governance framework in clinical trial disclosure include:

- Data governance policies and procedures
- Defined roles and responsibilities for data management
- Data quality standards and metrics
- Documented decision-making processes for data-related issues
- Data lifecycle management guidelines
- Compliance monitoring and reporting mechanisms

Data validation

Data validation involves processes and systems to ensure the accuracy, completeness, and consistency of trial data disclosed on public registries. It includes automated and manual checks to identify and correct data issues before disclosure.

Maturity levels:

- **Lagging:** Data validation is minimal or ad hoc, relying primarily on manual checks. There are no standardized validation processes across different data sets or disclosure activities.
- **Developing:** Basic automated validation checks are in place for key data elements. However, processes may not be comprehensive or consistently applied across all datasets.
- **Leading:** Robust, automated data validation processes are implemented across all disclosure activities. These are complemented by regular manual reviews and continuous improvement of validation rules based on identified issues and changing requirements.

Data ownership

Data ownership establishes clear accountability for the quality, integrity, and use of data throughout the clinical trial lifecycle. It involves defining roles and responsibilities for data stewardship across the organization.

Maturity levels:

- **Lagging:** Data ownership is unclear or undefined. There is little accountability for data quality or management across the

Data Governance Domain of the Clinical Trial Disclosure Maturity Model

disclosure process.

- **Developing:** Basic data ownership roles are defined but don't cover all data elements. Processes for correcting source-data issues exist but are not fully defined or consistently applied. There is growing awareness of the importance of data stewardship, but implementation may be inconsistent.
- **Leading:** Clear data ownership and stewardship roles are established and understood across the organization. Data owners actively ensure data quality, resolve issues, and drive improvements in data management practices.

Another aspect of data ownership is identifying and managing systems of record. These are the authoritative data sources for specific types of information within the clinical trial disclosure process. Identifying the systems of record helps ensure data consistency, reduces duplication, and provides a single source of truth for critical information. For example, organizations with a clinical trial disclosure system will typically designate it as the definitive source for disclosure-related data, such as clinical trial registry numbers and

disclosure dates. In a mature data governance framework, data owners are responsible for defining and maintaining these systems, ensuring all stakeholders know where to find the most up-to-date and accurate information. This practice significantly enhances data quality and reliability across the entire disclosure process.

Assessing your maturity

To evaluate your organization's maturity in the data governance domain, consider how well you perform in each of the key elements discussed above and the additional attributes listed in the sidebar. How comprehensive and well-implemented is your governance framework? How robust are your data validation processes? Is data ownership clearly defined and understood across your organization?

Please see the accompanying disclosure maturity [self-assessment worksheet](#) for more detailed information. The assessment will help you identify your current maturity level and areas for improvement in the disclosure process management domain.

Additional domain elements

- **Data organization:** structuring data for optimal use and integration across systems
- **Data harmonization:** ensuring consistency in data definitions and formats across different sources and registries
- **Data security:** protecting data from unauthorized access, breaches, and loss
- **Access management:** controlling and monitoring data access based on roles and responsibilities
- **Records management:** organizing and maintaining clinical trial records throughout their lifecycle
- **Data retention:** establishing policies for how long different types of data should be kept and when they should be disposed of
- **Performance metrics:** measuring and monitoring the effectiveness of data governance practices

Data Governance Domain of the Clinical Trial Disclosure Maturity Model

Considerations for sponsor size

The approach to data governance may vary based on organization size:

Sponsors with smaller trial portfolios might focus on establishing basic data governance policies and clear ownership for key data elements. They may rely more on manual validation processes and simpler governance structures.

Sponsors with more extensive trial portfolios typically benefit from more comprehensive governance frameworks, including dedicated data governance teams and sophisticated automated validation systems. These frameworks often include detailed policies and procedures covering various data management scenarios.

Getting started: practical tips

- Develop a basic data governance policy that outlines fundamental principles and responsibilities.
- Identify and document owners and the systems of record for critical data elements in the disclosure process.
- Implement basic automated validation checks for key data fields.
- Conduct a data quality assessment to identify areas for improvement.
- Provide training to staff on data governance principles, their role in maintaining data quality, and the potential consequences of poor data quality, such as regulatory noncompliance leading to penalties and impacting the organization's reputation.

How we can help

[TrialScope Disclose](#) supports robust data governance with built-in validation checks and comprehensive audit trails. The centralized platform maintains data consistency across multiple registries and serves as the designated system of record for disclosure-related data in many organizations.

[TrialScope Disclosure Services](#) can assist in developing and implementing data governance frameworks tailored to your organization's needs. Our experts can help establish effective policies, procedures, and validation processes.

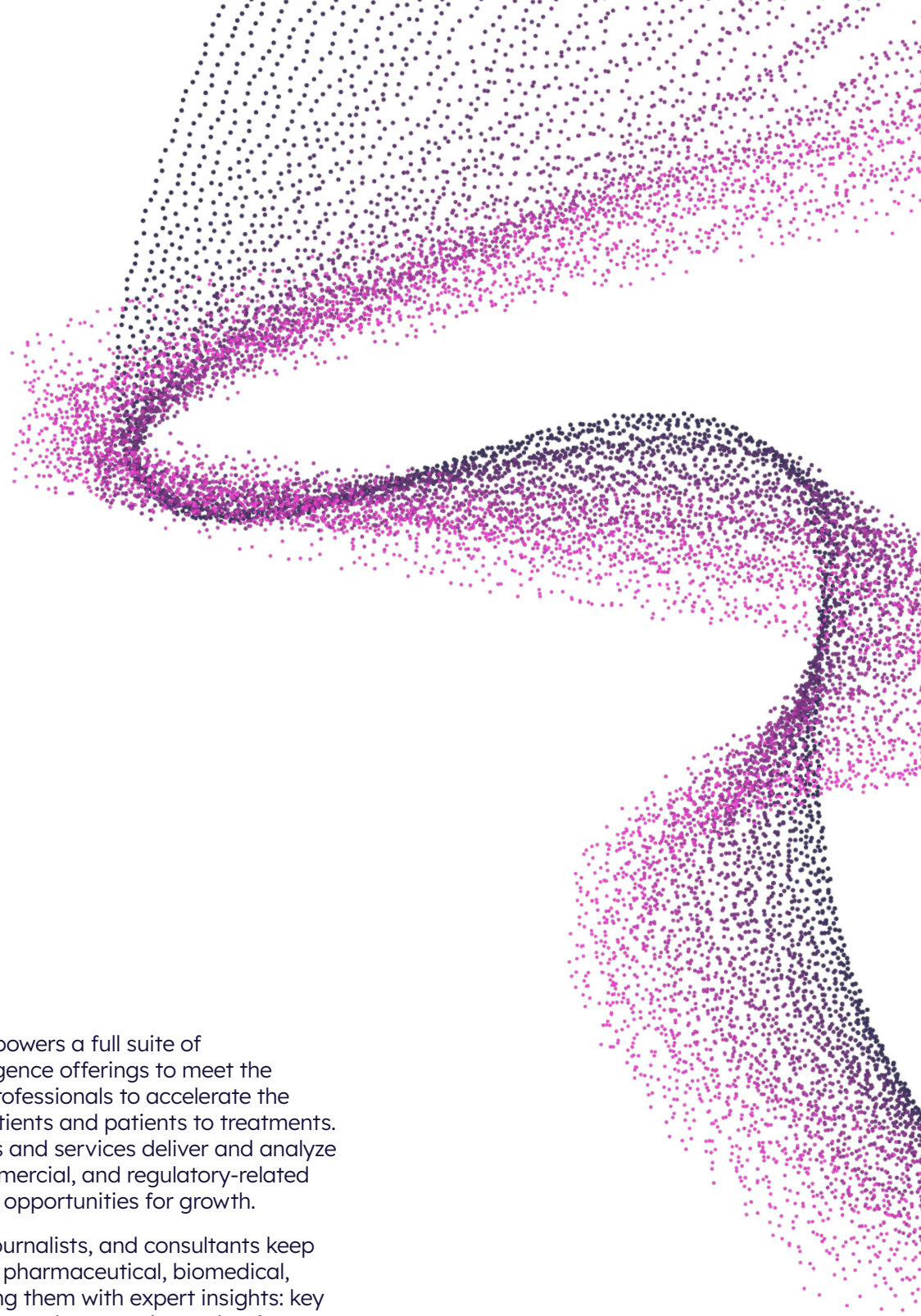
Conclusion

Effective data governance is crucial for maintaining the integrity, data quality, and reliability of clinical trial disclosure information. Organizations can enhance compliance, improve efficiency, and build stakeholder trust by investing in comprehensive governance frameworks, validation processes, and defined data ownership.

Next steps

The following article in this series will explore the reporting & metrics domain of the clinical trial disclosure maturity model. We'll examine how organizations can effectively measure, analyze, and report on their disclosure activities to drive continuous improvement and demonstrate compliance.

Contact our **DISCLOSURE EXPERTS** to learn more.



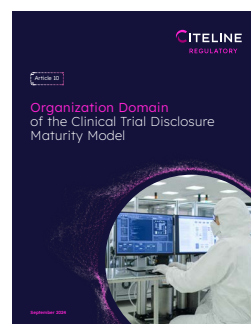
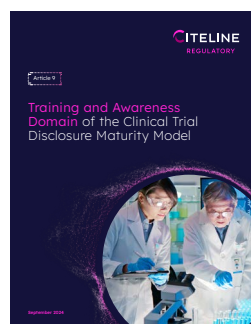
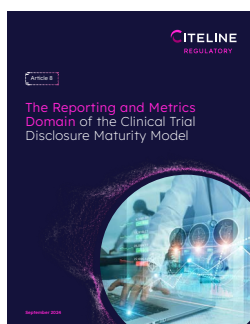
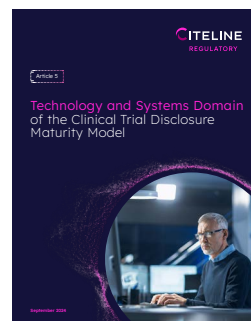
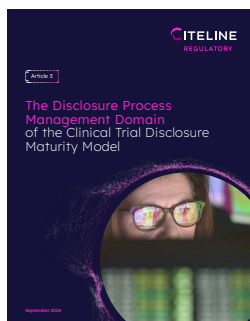
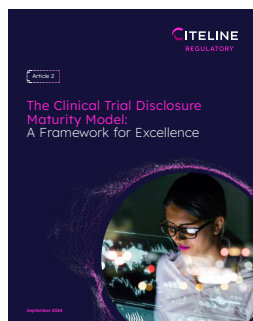
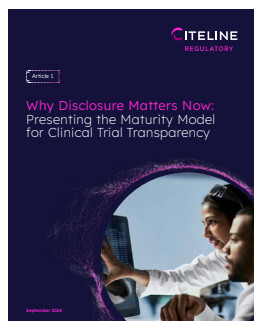
Citeline, a **Norstella** company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory-related decisions and create real-world opportunities for growth.

Our global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the world's most trusted life science partners, visit [Citeline.com](https://www.citeline.com).

Copyright © 2024 Citeline, a Norstella company.

Pharma Intelligence UK Limited is a company registered in England and Wales with company number 13787459 whose registered office is 3 More London Riverside, London SE1 2AQ.

Articles Series: Maturity Model



About the Author

Thomas Wicks

Thomas Wicks is the Head of Transparency Operations at TrialScope, a Citeline company, where he coordinates TrialScope's operations, consults on the business strategy, and leads the disclosure advisory services. He is responsible for tracking clinical disclosure and data-sharing trends that shape the company's clinical transparency solutions and services. Thomas has over 25 years of experience with compliance management solutions, specializing in applications for life sciences with a focus on clinical trial disclosure and transparency since 2007.

