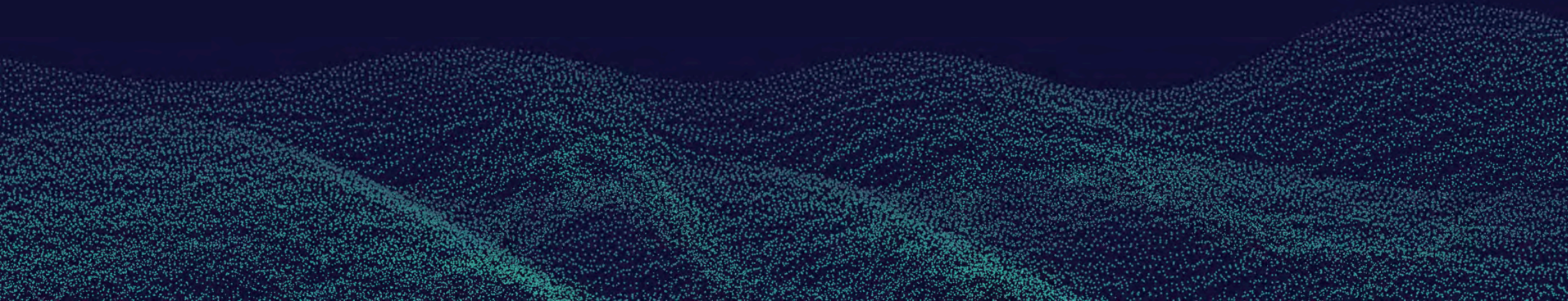


A business meeting scene with a dark table, laptops, and papers. Overlaid on the scene are various digital data visualizations including bar charts, pie charts, line graphs, and a world map composed of green dots. The overall color scheme is blue and green, with a bright light source in the center creating a lens flare effect.

# Maturity Model

eBook 2

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# Operating Model and Governance Domain of the Clinical Trial Disclosure Maturity Model

# Operating Model and Governance Domain of the Clinical Trial Disclosure Maturity Model

## Executive summary

The operating model and governance domain are central components of the clinical trial disclosure maturity model. They encompass the organizational structure, policies, and processes guiding and controlling disclosure activities. A robust operating model and governance framework ensures that clinical trial disclosure is managed effectively and consistently and complies with regulatory requirements.

## Why this domain matters

The operating model and governance domain is core to an organization's clinical trial disclosure efforts. It defines how disclosure activities are structured, managed, and overseen across the organization. By establishing a clear framework for decision-making and accountability, this domain empowers organizations to meet their

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disclosure obligations efficiently and effectively in an ever-evolving regulatory landscape:

- Ensures consistent and compliant disclosure practices across the organization
- Provides clear accountability and decision-making processes
- Enables effective resource allocation and prioritization
- Facilitates adaptation to changing regulatory requirements
- Supports a culture of transparency and ethical conduct

This element focuses on defining the overall governance structure, including executive sponsorship, steering committees, and decision-making authorities for disclosure policies and strategies.

### The consequences of a weak approach to operating model & governance

A poorly structured operating model and

governance framework for clinical trial disclosure can undermine an organization's ability to meet its transparency obligations effectively. With clear decision-making processes, well-defined roles, and robust oversight mechanisms, sponsors can maintain consistency and compliance across their disclosure activities. Lacking structured governance can lead to inefficiencies, compliance gaps, and difficulty adapting to evolving regulatory requirements, ultimately impacting the organization's reputation and stakeholder trust. Specific risks include:

- Uncoordinated disclosure across registries, potentially exposing confidential information and jeopardizing patent applications
- Missed regulatory deadlines due to unclear responsibilities
- Inefficient use of resources and duplication of efforts
- Increased risk of noncompliance with disclosure requirements
- Difficulty in adapting to new regulations or best practices

- Lack of organizational commitment to transparency

### Key elements of the operating model & governance

#### Policies/disclosure strategy

Comprehensive policies and strategies are the foundation of a practical clinical trial disclosure approach. They provide a clear framework for decision-making, ensure consistency across the organization, and demonstrate commitment to transparency. Well-developed policies and strategies guide all aspects of disclosure, from determining what information to share and when to outlining the processes for ensuring regulatory compliance. They also help organizations navigate complex scenarios, such as balancing transparency with protecting proprietary information.

The main components of disclosure policies and strategies are:

*Maturity levels:*

- **Lagging:** No formal disclosure policy or strategy exists. Disclosure decisions are made on an ad-hoc basis.
- **Developing:** A basic disclosure policy exists but may not cover all disclosure and data-sharing aspects. The strategy is reactive rather than proactive, and a summary of the transparency policy is not publicly available.
- **Leading:** Comprehensive, well-documented disclosure policy and strategy are in place, regularly reviewed, and fully integrated into organizational processes. A summary of the transparency policy is made public.

*The main components of disclosure policies and strategies are:*

- Clear statement of commitment to transparency
- Defined scope of disclosure and data sharing (e.g., which trials, what information, and at what time)

- Guidelines for handling company confidential information (CCI) and personal data
- An approach to voluntary disclosure beyond regulatory requirements
- Procedures for responding to disclosure-related requests and inquiries

**Organizational alignment\***

The organizational alignment for clinical trial disclosure varies across sponsors but is essential in effective disclosure management. While there's no one-size-fits-all approach, the disclosure function is typically housed within medical writing, clinical operations, or regulatory affairs. The structure often depends on the size of the organization and its trial portfolio.

*Maturity levels:*

- **Lagging:** Disclosure responsibilities are assigned to individuals with limited clinical trial data disclosure expertise. These people often struggle to gain support from

clinical teams and executive management. Contract Research Organizations (CROs) and affiliates primarily handle disclosure activities at the local level, with minimal coordination across different registries and jurisdictions. This fragmented approach leads to content inconsistencies and potential compliance risks.

- **Developing:** A designated individual or small team oversees disclosure activities but may lack comprehensive organizational support or sufficient resources. Their focus is primarily on meeting disclosure requirements in major markets like the USA and the EU. While some efforts are made to coordinate disclosure activities in other jurisdictions, these are often inconsistent or reactive. There's growing awareness of the need for a more structured approach, but implementation remains challenging.
- **Leading:** A clear governance structure exists, with well-defined oversight roles and decision-making processes for disclosure activities across the organization. A dedicated disclosure team or clearly

defined disclosure roles exist, with strong cross-functional collaboration. For smaller organizations, at least one person “owns” disclosure and has explicit support from leadership. Effective coordination with local affiliates, CROs, and specialized disclosure service providers is in place.

### Regulatory monitoring

Staying abreast of regulatory changes across relevant jurisdictions is necessary in the rapidly evolving landscape of clinical trial disclosure. Effective regulatory monitoring involves tracking new requirements, interpreting their impact on current practices, and implementing necessary changes. This proactive approach helps organizations maintain compliance, avoid penalties, and adapt their disclosure strategies to meet emerging standards. It also positions the organization to participate in shaping industry best practices and potentially influence future regulations.

While regulatory monitoring has significant

implications for quality and compliance (as discussed in the article on the quality and compliance domain), its role in governance and operational model design is equally important. This domain focuses on how regulatory intelligence shapes organizational structure, decision-making processes, and planning.

#### *Maturity levels:*

- **Lagging:** There is no formal process for monitoring regulatory changes, and awareness of new requirements is often reactive or delayed.
- **Developing:** Basic processes exist for tracking significant regulatory changes but may not be comprehensive or timely.
- **Leading:** Robust systems are in place to proactively monitor the global regulatory landscape. Transparent processes exist to interpret and rapidly implement new requirements.

### Governance structure

This element involves establishing clear roles, responsibilities, and decision-making processes for managing clinical trial disclosure activities.

#### *Maturity levels:*

- **Lagging:** No formal governance structure for disclosure exists. Responsibilities are unclear or fragmented.
- **Developing:** A basic governance structure is in place but may lack transparent decision-making processes or full organizational buy-in.
- **Leading:** A comprehensive governance structure with clearly defined roles, responsibilities, and decision-making processes has been implemented. The structure is regularly reviewed and optimized.

### Assessing your maturity

To evaluate your organization’s maturity in the operating model & governance domain, consider how well you perform in each of the key elements discussed above and the



additional attributes listed in the sidebar. Are your policies comprehensive and widely implemented? How proactive and

### Additional domain elements

- **Leadership engagement:** active involvement and support from senior management for disclosure initiatives.
- **Strategic improvement initiatives:** organization-wide programs to enhance the overall effectiveness and compliance of clinical trial disclosure, aligning with long-term goals.
- **Resource allocation & budgeting:** appropriate allocation of financial and human resources for disclosure activities.
- **Vendor & partner management:** effective oversight and coordination of external parties involved in disclosure.

comprehensive is your regulatory monitoring? Is your governance structure clear and effective?

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.

Please refer to the accompanying maturity [self-assessment worksheet](#) for more detailed information. The assessment will help you identify your current maturity level and areas for improvement in the operating model & governance domain.

### Considerations for sponsor size

The operating model and governance approach in clinical trial disclosure varies considerably based on the size and

complexity of a sponsor's trial portfolio. While all sponsors need effective governance structures and operating models, the scale of operations, available resources, and organizational complexity will influence how these are implemented. Regardless of size, sponsors must develop an approach that ensures compliance, promotes efficiency, and allows for adaptability in the face of evolving regulatory requirements. The key is to create a structure that is appropriate for the organization's current needs while also allowing for scalability as the trial portfolio grows or regulatory landscapes change:

Sponsors with smaller trial portfolios might focus on developing core policies and establishing basic governance structures. They typically appoint at least one person to "own" disclosure responsibilities, often as part of a broader role. These sponsors may rely more on external resources for regulatory monitoring and engage specialized disclosure service providers to supplement their in-house capabilities.

Sponsors with more extensive trial portfolios typically benefit from more comprehensive governance structures, including dedicated disclosure teams and formal committees. They often implement more sophisticated regulatory monitoring systems and have detailed policies covering multiple scenarios. These sponsors usually have a dedicated disclosure team, which may be part of the medical writing, clinical operations, or regulatory affairs departments. They work closely with their local affiliates and CROs for global disclosures, particularly outside the EU and USA.

Organizations of all sizes often engage disclosure service providers to leverage their expertise and resources to enhance their disclosure capabilities, particularly for specialized tasks such as authoring plain language summaries, redacting confidential information, and anonymizing patient data.

### Getting started: practical tips

- Develop a comprehensive disclosure policy that aligns with your organization's values

and regulatory requirements.

- Establish a cross-functional committee to oversee the integration of regulatory insights into governance and operational processes.
- Implement a system for regular monitoring and assessing the impact of regulatory changes on your organization's disclosure practices.
- Clearly define roles and responsibilities for all aspects of disclosure management.
- Regularly review and update your operating model and governance structure to ensure they remain effective and aligned with evolving needs.

### How we can help

[TrialScope Disclosure Services](#) support developing an organization's transparency & disclosure policy and optimizing its operational structure. Our experts can help you create comprehensive, effective policies tailored to your specific needs and regulatory environment. We can also assist in defining your RACI (Responsible, Accountable, Consulted, Informed) matrix for disclosure

activities, ensuring clear roles and responsibilities across your organization.

[TrialScope Disclose](#) supports this domain with workflow, tasks, and compliance tracking features that help with vendor/partner management. The platform's capabilities can enhance your governance structure by providing clear visibility into disclosure activities and supporting consistent processes across your organization.

### Conclusion

A mature operating model and governance domain are essential for effective and consistent clinical trial disclosure. By investing in robust policies, proactive regulatory monitoring, and transparent governance structures, organizations can be well-positioned to meet disclosure requirements and demonstrate their commitment to transparency.

### Next steps

The following article in this series will explore

the organization domain of the clinical trial disclosure maturity model. We encourage you to use the insights from this article to assess and improve your current operating model and governance for clinical trial disclosure.

[Contact our DISCLOSURE EXPERTS to learn more.](#)

*\*NOTE: The final article in this series discusses the recommendations related to the disclosure organization in more detail.*



# Data Governance Domain of the Clinical Trial Disclosure Maturity Model

# Data Governance Domain of the Clinical Trial Disclosure Maturity Model

## 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

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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 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 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

#### 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

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.

clearly defined and understood across your organization?

### 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.](#)



# The Reporting and Metrics Domain of the Clinical Trial Disclosure Maturity Model

# The Reporting and Metrics Domain of the Clinical Trial Disclosure Maturity Model

## Executive summary

The reporting and metrics domain focuses on measuring, analyzing, and communicating the performance of clinical trial disclosure activities. It encompasses the development of key performance reports, the creation of insightful reports, and the ensuring of data integrity. Relevant metrics and reports enable organizations to track compliance, identify areas for improvement, and demonstrate the value of their disclosure efforts.

## Why this domain matters

Effective reporting and metrics form the foundation for data-driven decision-making in clinical trial disclosure. Clear visibility into disclosure performance and compliance status enables organizations to identify improvement areas, allocate resources efficiently, and demonstrate the value of transparency efforts. Well-designed metrics

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drive continuous process enhancement, helping sponsors adapt to evolving regulatory requirements and enhancing an organization's ability to respond to audits

or inquiries. In a complex disclosure landscape, the ability to measure, analyze, and report on disclosure activities is both a regulatory necessity and a strategic advantage, allowing sponsors to optimize processes, mitigate risks, and build trust with stakeholders:

- Enables data-driven decision-making and resource allocation
- Provides visibility into disclosure performance and compliance status
- Facilitates continuous improvement of disclosure processes
- Supports stakeholder communication and regulatory reporting
- Helps demonstrate the value of disclosure activities to leadership

## Potential risks of a weak approach to reporting and metrics

Inadequate reporting and metrics practices in clinical trial disclosure can significantly impair an organization's ability to manage and improve its transparency efforts. Without robust measurement and analysis, sponsors may struggle to identify compliance issues, process inefficiencies, or areas requiring improvement, potentially leading to regulatory violations and missed opportunities for optimization. Moreover, the lack of clear, data-driven insights can hinder decision-making, resource allocation, and the ability to demonstrate the value of disclosure activities to stakeholders, ultimately undermining the organization's overall transparency strategy. Specific risks include:

- Inability to accurately assess compliance status and disclosure performance
- Missed opportunities for process improvement and efficiency gains
- Difficulty in justifying resources for disclosure activities
- Challenges in responding to audits or

regulatory inquiries

- Lack of visibility into emerging trends or recurring issues

## Key elements of reporting and metrics

### 1. Key performance indicators

KPIs are quantifiable measures used to evaluate the success of an organization's clinical trial disclosure activities. Well-designed KPIs provide insights into compliance rates, timeliness of disclosures, data quality, and process efficiency. They serve as a compass for disclosure teams, highlighting successes and guiding efforts toward areas that need improvement. Effective KPIs are aligned with organizational goals, regulatory requirements, and industry best practices, providing a comprehensive view of disclosure performance.

*Maturity levels:*

- **Lagging:** Few or no KPIs are defined for

disclosure activities, and performance measurement is ad hoc and inconsistent.

- **Developing:** Basic KPIs are established, primarily focusing on compliance rates. Measurement is more consistent but may not cover all aspects of disclosure performance.
- **Leading:** Comprehensive KPIs cover compliance, quality, efficiency, and stakeholder satisfaction. KPIs are regularly reviewed and updated to align with evolving organizational needs and regulatory requirements.

*The main components of KPIs in clinical trial disclosure include:*

Essential elements for effective KPIs:

- Clear definition and calculation method for each KPI
- Alignment with organizational goals and regulatory requirements
- Regular review and updating process to ensure continued relevance

Relevant KPIs for clinical trial disclosure:

- Percentage of trials registered within required timeframes
- Percentage of results posted within required timeframes
- Average number of quality control comments and requests for information per protocol and results submission
- Average time from study completion to results posting
- Number of ongoing and completed disclosure tasks per user

## 2. Metrics and reports

Metrics and reports transform raw data into meaningful clinical trial disclosure performance insights. They involve collecting, analyzing, and presenting data in formats that facilitate understanding and decision-making. Effective metrics and reports go beyond simple compliance statistics to provide a nuanced view of disclosure activities, including trends over time, comparisons across different trial types or

registries, and predictive analytics to anticipate future challenges.

*Maturity levels:*

- **Lagging:** There is minimal reporting, often limited to basic compliance statistics. Reports are generated manually and infrequently.
- **Developing:** Regular reports covering key compliance metrics are produced. Some automation may be in place but reports lack depth or context.
- **Leading:** A comprehensive, automated reporting system provides real-time dashboards and in-depth analytical reports. Reports are tailored to different stakeholder needs and include predictive analytics.

## 3. Data sources

High-quality, reliable data are the foundation of effective reporting and metrics. This element focuses on identifying and integrating relevant data sources, ensuring

data accuracy and completeness, and maintaining data integrity throughout the reporting process. It involves establishing data governance practices, implementing data quality checks, and creating a single source of truth for disclosure-related information.

*Maturity levels:*

- **Lagging:** Data are collected from disparate sources with little validation. Data integrity issues are common and often undetected.
- **Developing:** Primary data sources are identified, and some validation processes are in place. Efforts are made to reconcile data discrepancies, but a unified data management approach is lacking.
- **Leading:** A comprehensive data governance framework ensures data integrity. Automated systems integrate data from multiple sources with robust validation and reconciliation processes, establishing and maintaining a single source of truth for disclosure data.

## Assessing your maturity

To evaluate your organization's maturity in this domain, consider:

- How comprehensive and relevant are your disclosure KPIs?
- What are the quality and depth of your metrics and reports?
- How reliable and integrated are your data sources?

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

- **Trend analysis & root cause analysis:** systematically examining disclosure performance trends and investigating underlying causes for deviations or issues
- **Disclosure performance scorecard:** consolidated view of key disclosure metrics, providing an at-a-glance assessment of overall performance
- **Reporting automation and integration:** using technology to automate data collection, analysis, and report generation and integrate with other clinical systems
- **Benchmarking:** comparison of disclosure performance against industry standards or peer organizations to identify areas for improvement
- **Stakeholder feedback & satisfaction:** collection and analysis of feedback from internal and external stakeholders on disclosure processes and outputs

## Considerations for sponsor size

The approach to reporting and metrics may vary based on the size and complexity of the sponsor's trial portfolio. Both smaller and larger sponsors must adapt their strategies to meet their unique needs and resources:

Sponsors with smaller trial portfolios should establish core KPIs for compliance and performance. They might start with basic, manually generated reports and gradually introduce automation. For data management, smaller sponsors might rely on centralized spreadsheets or simple databases, ensuring data integrity through consistent data entry practices and regular audits.

Sponsors with more extensive trial portfolios typically benefit from more sophisticated reporting and metrics systems. They often implement comprehensive KPI frameworks covering multiple dimensions of disclosure performance. These sponsors usually invest in advanced analytics tools and automated reporting systems, providing real-time

dashboards and in-depth analytical capabilities. Larger sponsors frequently implement robust data governance frameworks to ensure data integrity across their complex trial portfolios.

## Getting started: practical tips

- Define a core set of KPIs aligned with your organization's disclosure goals and regulatory requirements
- Implement a regular reporting schedule, starting with key compliance metrics
- Conduct a data source audit to identify and validate primary data sources for disclosure metrics
- Develop a basic disclosure performance scorecard for executive leadership
- Establish a process for collecting and acting on stakeholder feedback about disclosure reports and metrics

## How we can help

TrialScope Disclose offers built-in analytics and reporting capabilities, providing real-time visibility into disclosure performance across multiple registries. Its dashboards

and customizable reports support data-driven decision-making and efficient stakeholder communication.

## Conclusion

Mature reporting and metrics practices are essential for effective management and continuous improvement of clinical trial disclosure activities. By investing in well-designed KPIs, comprehensive reports, and robust data management practices, sponsors can enhance their disclosure performance, demonstrate compliance, and drive strategic decision-making.

## Next steps

As we continue our series on the clinical trial disclosure maturity model, we encourage you to:

1. Use the / how our solutions and services can support your journey toward disclosure excellence.
2. Based on your assessment results, develop an action plan, prioritizing key areas for enhancement in your reporting

and metrics practices.

3. Contact us to learn more about how our solutions and services can support your journey towards disclosure excellence.

The following article in this series will explore the training and awareness domain, focusing on building and maintaining the knowledge and skills necessary for effective clinical trial disclosure.

[Contact our \*\*DISCLOSURE EXPERTS\*\* to learn more.](#)





## Training and Awareness Domain of the Clinical Trial Disclosure Maturity Model

# Training and Awareness Domain of the Clinical Trial Disclosure Maturity Model

## Executive summary

The training and awareness domain focuses on developing and maintaining the knowledge, skills, and understanding necessary for effective clinical trial disclosure across an organization. This domain encompasses comprehensive training programs, strategies for raising awareness about disclosure requirements and best practices, and methods for assessing and improving disclosure competency.

## Why this domain matters

Well-informed staff across various functions enhance an organization's ability to meet regulatory requirements and streamline disclosure processes. Training programs help mitigate risks, reduce errors, and promote consistent disclosure practices by fostering a culture of transparency and compliance. In

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an evolving regulatory landscape, ongoing education ensures that organizations can adapt quickly to new requirements and industry best practices, enhancing their reputation for transparency.

Training and awareness in clinical trial disclosure are helpful for several reasons:

- Ensure consistent understanding and application of disclosure requirements across the organization
- Enhance protocol development by integrating disclosure considerations early in the process
- Reduce the risk of noncompliance due to human error or misunderstanding
- Improve the quality and timeliness of disclosed information
- Facilitate faster adoption of new regulatory requirements and best practices
- Foster cross-functional collaboration by creating a shared understanding of disclosure processes

## Potential risks of a weak approach to training and awareness

Inadequate training and awareness in clinical trial disclosure can lead to significant compliance risks, operational inefficiencies, and potential reputational damage. Staff may need proper education to understand regulatory requirements and avoid errors. Lack of awareness about the scope and timing of disclosure can deprioritize planning, causing delays and potentially releasing sensitive information.

However, adequate training can lead to consistent practices across the organization, making it easier to maintain data quality and meet evolving regulatory expectations. Specific risks include:

- Unnecessary disclosure of overly detailed and potentially sensitive information
- Increased likelihood of noncompliance due to misunderstanding of requirements
- Inconsistent disclosure practices across different teams or regions

- Delays in disclosure timelines due to a lack of process understanding
- Difficulty adapting to new regulatory requirements or best practices
- Reduced stakeholder trust due to transparency failures

## Key elements of training and awareness

### Training programs

Comprehensive training programs are the cornerstone of building and maintaining disclosure competency within an organization. These programs should cover all aspects of clinical trial disclosure, from regulatory requirements to practical implementation of disclosure processes.

*Maturity levels:*

- **Lagging:** Training is sporadic and limited in scope, often reactive to compliance issues. No structured program exists.
- **Developing:** A core training program

covering the main regulatory requirements is in place. Some role-specific training may be available.

- **Leading:** A comprehensive, role-specific training program is maintained with regular updates. It includes practical exercises, assessments, and continuous improvement based on feedback and evolving needs.

*The main components of clinical trial disclosure training programs include:*

- Regulatory requirement training covering global disclosure regulations
- Role-specific training tailored to different functions involved in disclosure
- Early disclosure training for protocol authors to minimize the need for later redactions
- Hands-on training for disclosure systems and tools
- Process-oriented training covering standard operating procedures (SOPs)
- Scenario-based training to handle complex disclosure situations

- Regular refresher courses to reinforce knowledge and cover updates
- New hire onboarding programs with disclosure-specific components
- Assessment mechanisms to evaluate training effectiveness

### **Competency assessment**

Competency assessment evaluates staff's knowledge, skills, and abilities in disclosure activities. It helps identify gaps in understanding and informs targeted training efforts.

*Maturity levels:*

- **Lagging:** No formal competency assessment exists for disclosure activities. Skills gaps are identified reactively when issues arise.
- **Developing:** Infrequent assessments are conducted, primarily focusing on regulatory knowledge. The results may be used to improve training and manage access to clinical trial disclosure systems.

- **Leading:** Competency assessments are incorporated into the learning management system. Disclosure software users must show competency before being authorized to work in the system, and assessment results are used to tailor training programs.

### **Awareness campaigns**

Awareness campaigns promote the importance of clinical trial disclosure across the organization, fostering a culture of transparency and compliance.

*Maturity levels:*

- **Lagging:** Little to no effort exists to raise awareness about disclosure importance beyond the immediate disclosure team.
- **Developing:** Occasional awareness initiatives such as emails or presentations exist but are not part of a standard process.
- **Leading:** Ongoing, multichannel awareness campaigns are tailored to different

stakeholder groups. Proactive engagement with corporate communications, investor relations teams, and publications helps coordinate disclosure activities.

### Assessing your maturity

To evaluate your organization's maturity in the training and awareness domain, consider the following:

- How comprehensive and tailored are your disclosure training programs?
- How effectively do you assess and address competency gaps?

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.

- What methods do you use to raise awareness about the importance of disclosure across the organization?

### Considerations for sponsor size

The approach to training and awareness in clinical trial disclosure may vary significantly based on the size and complexity of a

sponsor's trial portfolio. While all sponsors need to ensure their staff are well-trained and aware of disclosure requirements, the resources available and the scale of operations will influence the implementation of training programs and awareness initiatives. Both smaller and larger sponsors must adapt their strategies to meet their unique needs and capabilities:

#### Additional domain elements

- **Compliance education:** focused training on regulatory requirements and the consequences of non-compliance
- **Technology adoption training:** specialized training on disclosure-related systems and tools to maximize their effective use
- **Cross-functional awareness:** efforts to educate teams outside the core disclosure function, such as aligning disclosure activities with corporate communications, investor relations, and publication teams
- **Stakeholder communication:** initiatives to inform stakeholders about clinical trial disclosure processes, requirements, and the importance of transparency, ensuring ongoing support and participation in disclosure initiatives
- **Knowledge management:** systems and processes for capturing, sharing, and maintaining disclosure-related knowledge within the organization

Sponsors with smaller trial portfolios should focus on developing core training modules covering essential regulatory requirements and disclosure processes. They might supplement internal training efforts with external resources, such as industry webinars or workshops. Awareness campaigns can be integrated into company communications to maximize impact with limited resources.

Sponsors with more extensive trial portfolios benefit from more comprehensive and sophisticated training programs. These may include dedicated e-learning platforms, role-specific training tracks, training for protocol authors, and formal coordination processes with corporate communications and investor relations teams. Larger sponsors often have the resources to develop extensive internal training materials and conduct organization-wide awareness campaigns.

### Getting started: practical tips

- Conduct a training needs assessment to identify key areas for improvement

- Consider integrating disclosure training into the protocol development process
- Develop a core set of training materials covering essential disclosure requirements and processes
- Implement a regular schedule for refresher training and updates on new regulations
- Create a simple competency assessment tool for key disclosure roles
- Launch a basic awareness campaign with email communications and team meetings

### How we can help

[TrialScope Disclose](#) includes built-in guidance and tooltips that serve as continuous training tools for users, enhancing their understanding of disclosure requirements as they work.

[TrialScope Intelligence](#) provides up-to-date information on global disclosure requirements, which can be used to inform and update training materials.

[TrialScope Disclosure Services](#) offers

disclosure workshops on authoring plain language summaries and redaction/anonymization.

### Conclusion

A mature approach to training and awareness is essential for maintaining effective and compliant clinical trial disclosure practices. By developing training programs, regular competency assessments, and ongoing awareness initiatives, sponsors can enhance their disclosure capabilities, reduce compliance risks, and foster a culture of transparency.

### Next steps

As we approach the conclusion of our series on the clinical trial disclosure maturity model, we encourage you to:

1. Use the comprehensive [maturity assessment workbook](#) to assess your organization's maturity across all domains, including training and awareness.

2. Develop an action plan based on your assessment results, prioritizing key areas for enhancement in your training and awareness practices.
3. Contact us to learn how our solutions and services can support your journey towards disclosure excellence, particularly in developing robust training and awareness programs.

Our final article in this series will explore the organization domain, completing our comprehensive overview of the clinical trial disclosure maturity model.

[Contact our DISCLOSURE EXPERTS to learn more.](#)



# Organization Domain of the Clinical Trial Disclosure Maturity Model



# Organization Domain of the Clinical Trial Disclosure Maturity Model

## Executive summary

The organization domain focuses on the structural elements that support effective clinical trial disclosure. It encompasses roles and responsibilities, cross-functional collaboration, and organizational alignment. A properly coordinated organization ensures efficient disclosure processes, clear accountability, and adaptability to evolving regulatory requirements.

## Why this domain matters

A well-structured organizational approach to clinical trial disclosure ensures consistency, efficiency, and compliance across all transparency efforts. Clear roles, responsibilities, and reporting lines enable effective decision-making and accountability, reducing the risk of missed deadlines or incomplete disclosures. Strong cross-functional collaboration facilitates the

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smooth flow of information and expertise among departments, enhancing the quality and timeliness of disclosed data. An optimized organizational structure allows for better resource allocation and scalability, enabling sponsors to adapt to changing regulatory landscapes and growing disclosure requirements. Finally, a mature organizational approach fosters a culture of transparency, aligning disclosure activities with broader corporate values and building trust with patients, healthcare professionals, and regulatory bodies:

- Clear roles and responsibilities ensure accountability
- Cross-functional collaboration improves efficiency and data quality
- Proper organizational structure supports compliance and adaptability
- Alignment across departments enhances overall disclosure effectiveness
- Well-defined roles attract and retain skilled disclosure professionals

## Potential risks of a weak approach to organization

A poorly structured organizational approach to clinical trial disclosure can lead to significant challenges and compliance risks. Organizations may struggle to meet regulatory requirements and maintain data quality without clear roles, effective collaboration, and proper governance. These issues can have far-reaching consequences, affecting regulatory compliance, stakeholder trust, and operational efficiency. Specific risks include:

- Unclear accountability, resulting in missed deadlines or incomplete disclosures because tasks fall between the cracks
- Inefficient processes due to a lack of coordination and follow-up among departments
- Inconsistent disclosure practices across the organization
- Difficulty in adapting to new regulatory requirements
- Potentially higher turnover of disclosure personnel

## Key elements of the domain organization

### Roles and responsibilities

Clearly defined operational roles and day-to-day responsibilities form the backbone of an effective clinical trial disclosure organization. This element concentrates on defining specific job functions, team structures, and individual responsibilities for executing disclosure tasks and processes. Defined roles ensure that every aspect of disclosure is covered, from data collection and submission to quality control and regulatory compliance. By establishing clear lines of accountability, organizations can streamline their processes, reduce errors, and respond more effectively to regulatory requirements.

### *Maturity levels:*

- **Lagging:** Disclosure responsibilities are poorly defined, with significant overlap or gaps. Staff often struggle to understand their roles in the disclosure process.

- **Developing:** Basic role definitions exist, but areas of ambiguity remain. Some staff members clearly understand their responsibilities, while others are less certain.
- **Leading:** Comprehensive, well-documented operational roles are defined for all disclosure tasks, including cross-functional collaboration and backup personnel. Regular reviews ensure alignment with organizational needs and regulatory requirements. Staff at all levels clearly understand their roles in the disclosure process.

*The main components of defining roles & responsibilities in clinical trial disclosure include:*

- Detailed job descriptions for disclosure-related roles
- Clear delineation of responsibilities across departments
- Defined escalation pathways for issues and decisions
- Regular review and update of role

definitions

- Integration of disclosure responsibilities into performance evaluations

### **Organizational structure**

The organizational structure for clinical trial disclosure defines how disclosure activities are positioned within the broader company framework. This includes determining where the disclosure function sits within the organization, its reporting lines, and its level of authority. A well-designed structure ensures disclosure activities receive appropriate resources, attention, and strategic importance. It also facilitates clear communication channels between disclosure teams and other relevant parts of the organization, enabling more effective decision-making and execution of disclosure responsibilities.

*Maturity levels:*

- **Lagging:** Disclosure responsibilities are scattered across the organization without

a coherent structure. There is no clear leadership or strategic direction for disclosure activities.

- **Developing:** A basic disclosure function is in place, but it may lack sufficient resources or organizational support to meet the company's needs fully.
- **Leading:** A well-resourced, strategically positioned disclosure function operates with clear reporting lines and strong executive support. The structure adapts readily to changing regulatory landscapes and organizational needs.

### **Cross-functional collaboration**

Cross-functional collaboration ensures seamless and effective clinical trial disclosure by creating an environment where different departments — such as clinical operations, regulatory affairs, legal, and medical writing — work together cohesively. Effective collaboration ensures that all relevant expertise is leveraged, data flows smoothly between teams, and potential issues are identified and resolved quickly. By breaking

down silos and fostering a collaborative culture, organizations can improve the quality and efficiency of their disclosure processes.

*Maturity levels:*

- **Lagging:** Departments operate in silos, with minimal communication on disclosure matters. Collaboration, when it occurs, is typically reactive and inefficient.
- **Developing:** Some departments have informal collaboration channels. Cooperation is improving but remains inconsistent across the 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.

- **Leading:** A culture of proactive collaboration permeates all relevant departments. Well-established processes facilitate information sharing and joint decision-making, resulting in efficient and effective disclosure practices.

### Assessing your maturity

To evaluate your organization's maturity in this domain, consider:

- The clarity and comprehensiveness of role definitions for disclosure activities

#### Additional domain elements

- **Internal-external integration:** coordination between internal teams and external partners (e.g., CROs, service providers, partners) to ensure consistent and compliant disclosure practices
- **Global coordination:** harmonizing disclosure activities across different geographical regions and regulatory jurisdictions to maintain consistency and efficiency
- **Resource allocation:** the strategic distribution of personnel, budget, and tools across disclosure activities to optimize performance and meet regulatory requirements
- **Performance management:** ongoing evaluation and improvement of individual and team performance in disclosure-related roles to enhance overall organizational effectiveness
- **Organizational change management:** a structured approach to transitioning individuals, teams, and the organization to adapt to changes in disclosure processes, regulations, or technologies
- **Talent acquisition:** strategic recruitment and onboarding of skilled professionals with expertise in clinical trial disclosure to build and maintain a capable disclosure team

- The effectiveness of interdepartmental collaboration on disclosure tasks
- How well your organizational structure supports efficient and compliant disclosure processes

### Considerations for sponsor size

Smaller sponsors often have individuals wearing multiple hats, integrating disclosure responsibilities into broader roles. Organizations typically benefit from dedicated disclosure teams and more formalized cross-functional processes as they grow. Regardless of size, clear role definitions and effective collaboration remain necessary:

Sponsors with smaller trial portfolios should focus on establishing clear, basic roles and responsibilities for disclosure activities, even if these are integrated into broader job functions. They might designate a single point person to oversee disclosure activities, coordinating with other departments as needed. Cross-functional collaboration can be facilitated through regular, informal

meetings rather than formal committees. For organizational structure, smaller sponsors might position disclosure responsibilities within an existing department, such as regulatory affairs or clinical operations, rather than creating a standalone disclosure function.

Sponsors with more extensive trial portfolios benefit from a more comprehensive organizational approach. They often establish dedicated disclosure teams with specialized roles, such as disclosure managers, regulatory intelligence specialists, and quality control experts. These sponsors usually implement formal cross-functional committees or working groups to manage disclosure activities across departments. Regarding organizational structure, larger sponsors frequently create a dedicated disclosure function as a standalone unit or as a significant sub-group within a larger department like regulatory affairs. This function often has direct reporting lines to senior management, reflecting the strategic importance of disclosure activities.

### Getting started: practical tips

- Conduct a roles and responsibilities audit to identify gaps or overlaps
- Establish a cross-functional disclosure working group
- Develop clear job descriptions for key disclosure roles
- Implement regular cross-departmental meetings on disclosure topics
- Consider creating a dedicated disclosure function, even if small initially

### How we can help

[TrialScope Disclose](#) supports organizational efficiency with role-based access controls, collaborative workflows, and resource management tools. These features ensure relevant stakeholders are involved in review and approval tasks, enhancing cross-functional collaboration.

The [TrialScope Disclosure Services](#) team offers expert consultants who can facilitate cross-functional workshops to establish a shared understanding of disclosure requirements. Our team serves as the

designated disclosure group for many life sciences companies, especially those with smaller trial portfolios, providing specialized expertise and support.

## Conclusion

The organizational structure for clinical trial disclosure defines how disclosure activities are positioned within the broader company framework. This includes determining where the disclosure function sits within the organization, its reporting lines, and its level of authority. A well-designed structure ensures disclosure activities receive appropriate resources, attention, and strategic importance. It also facilitates clear communication channels between disclosure teams and other relevant parts of the organization, enabling more effective decision-making and execution of disclosure responsibilities.

## Next steps

As we conclude this series on the clinical trial disclosure maturity model, we encourage you to take the following steps:

1. Use the comprehensive maturity assessment worksheet to assess your organization's maturity across all domains. This will provide valuable insights into your current state and areas for improvement.
2. Based on your assessment results, develop an action plan, prioritizing key areas for enhancement in your clinical trial disclosure practices.
3. [Contact us](#) to learn how our solutions and services can support your journey toward disclosure excellence. Our team of experts is ready to assist you in elevating your organization's disclosure capabilities.

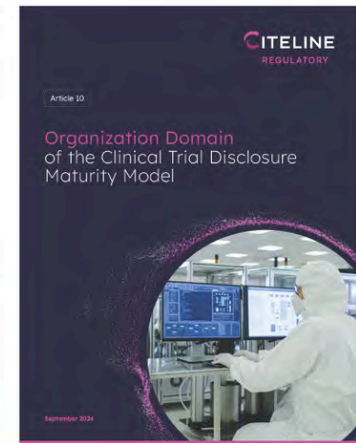
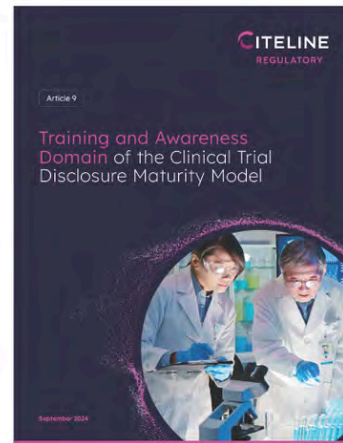
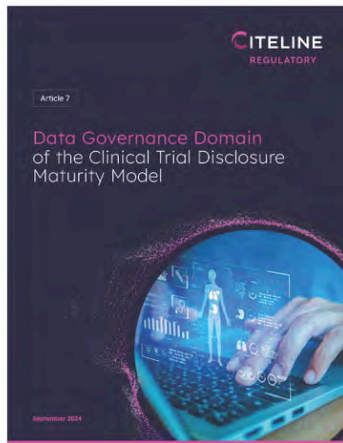
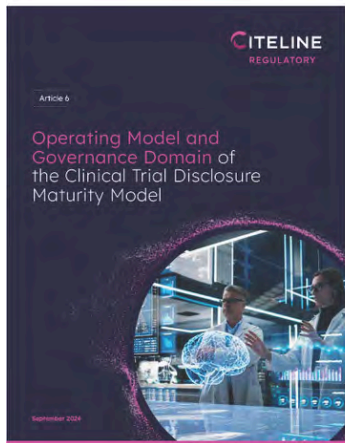
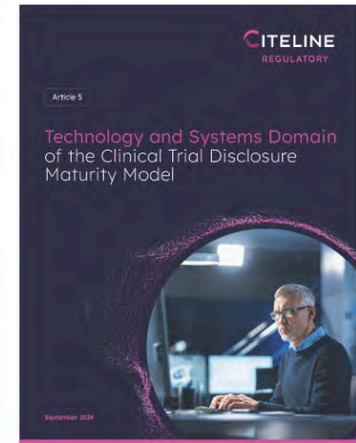
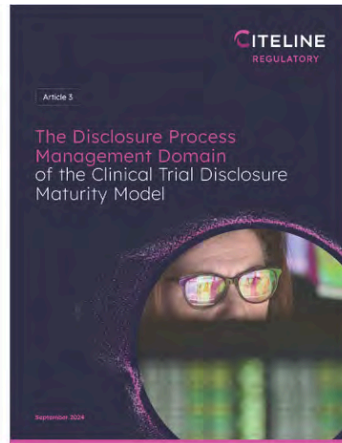
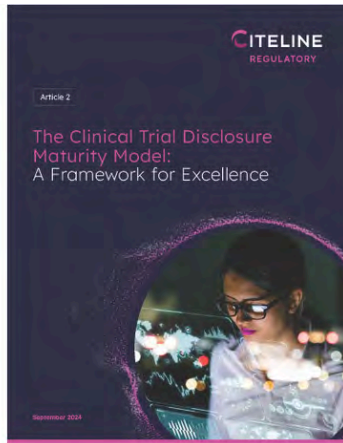
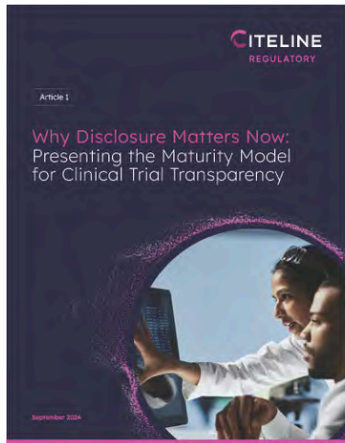
We hope this series has provided valuable insights into the various aspects of clinical trial disclosure maturity. Applying these concepts can enhance your organization's transparency, compliance, and effectiveness in clinical trial disclosure.

Remember, achieving disclosure maturity is an ongoing process. As the regulatory landscape evolves, so should your approach

to clinical trial disclosure. Stay informed, remain adaptable, and strive for excellence in your disclosure practices.

[Contact our DISCLOSURE EXPERTS to learn more.](#)

# 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.



Thank you for reading

# Maturity Model Articles