Maturity Model

eBook

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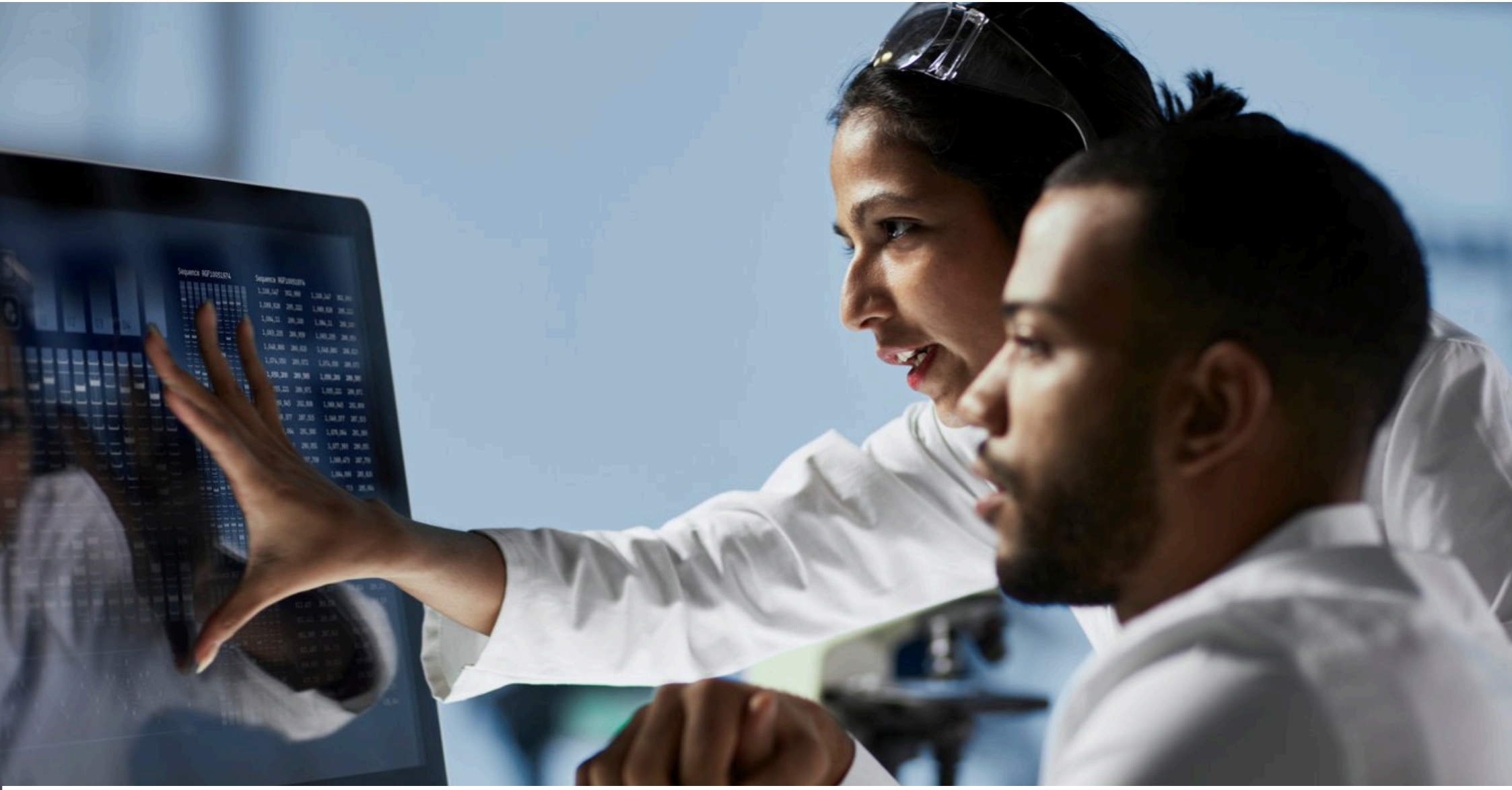
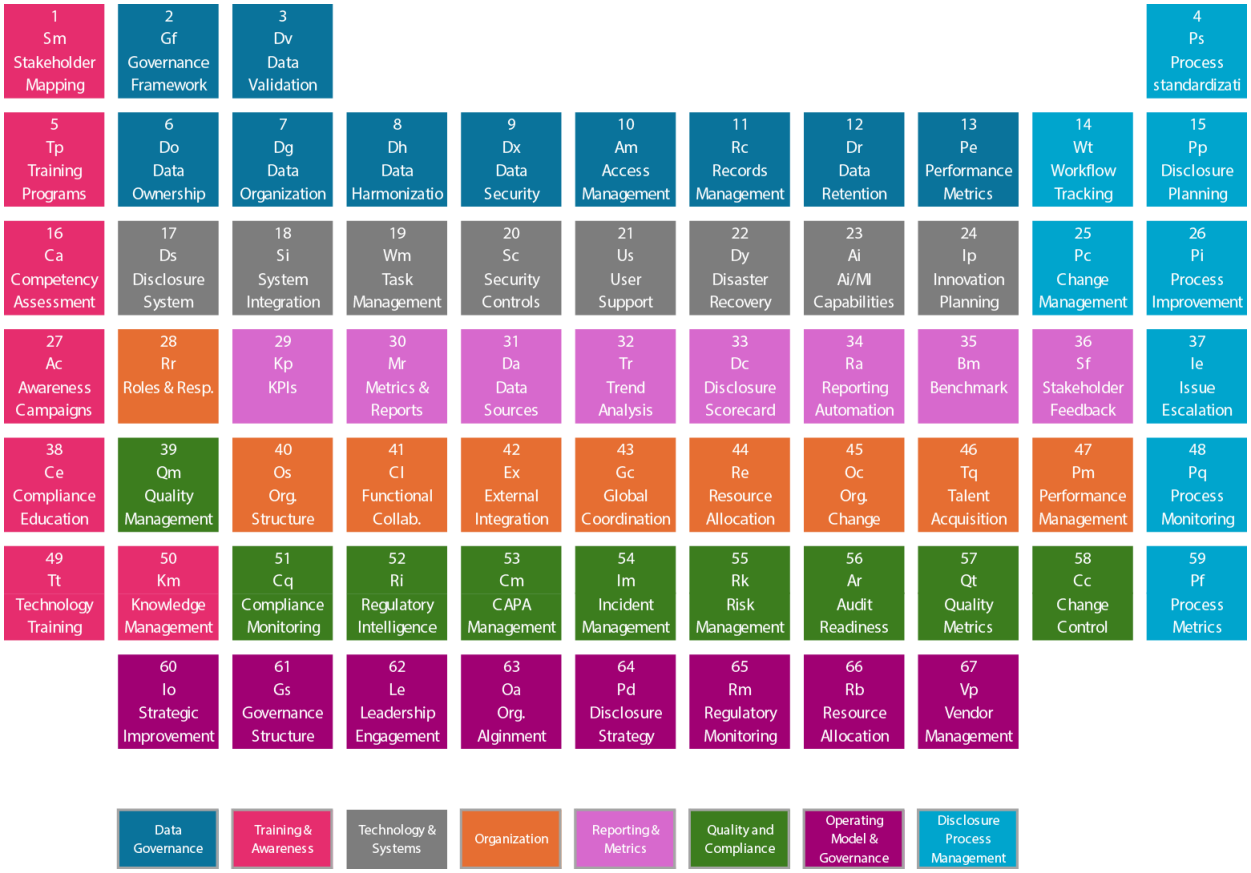


Why Disclosure Matters Now: Presenting the Maturity Model for Clinical Trial Transparency

Why Disclosure Matters Now: Presenting the Maturity Model for Clinical Trial Transparency

Clinical trial disclosure and transparency have become important considerations in today's biopharmaceutical landscape. A comprehensive maturity model for clinical trial disclosure and transparency offers biopharmaceutical companies a strategic tool to assess and enhance their practices in an increasingly complex regulatory environment. This model becomes critical as the industry faces intensifying scrutiny, expanding disclosure requirements, and emerging trends that demand proactive management of clinical trial transparency. Organizations must navigate a rapidly changing landscape, from evolving global regulations to integrating new technologies.



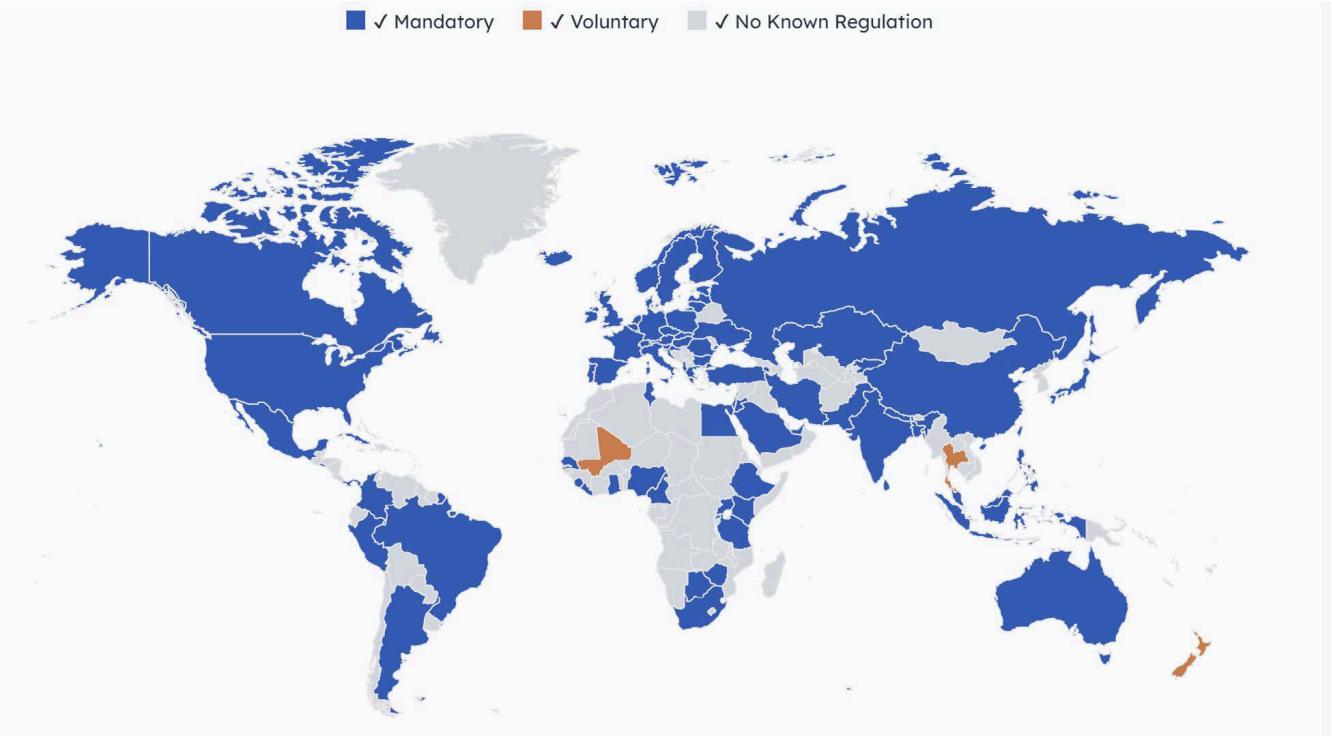
The disclosure imperative in today's clinical trial landscape

Ensuring reliable disclosure practices has evolved beyond a mere regulatory requirement for clinical trial professionals. In today's environment, it's a strategic necessity. Stakeholders across the spectrum — regulators, patients, investors, and the public — are demanding greater transparency in clinical research. This intensified scrutiny elevates clear, accurate, and accessible disclosure of clinical trial data to a cornerstone of building trust.

A surge in regulatory scrutiny and expanding scope

Regulatory bodies, including the US Food and Drug Administration (FDA) and the European Union (EU) local health authorities, are taking a stricter stance on disclosure compliance. Evidence of this shift lies in increased inspections and the growing number of countries that have published enforcement plans. Companies face potential penalties for noncompliance with registration requirements on CTIS in the EU, jRCT in Japan, ClinicalTrials. gov in the US, and other registries. The scope of disclosure itself is broadening as well. New regulations and guidance documents now require a wider range of information to be disclosed, including patient-facing clinical trial documents and anonymized patient-level data.

Figure 1. Protocol registration requirements



Source: TrialScope Intelligence July 2024

Beyond registries: a broader transparency horizon

Initiatives such as the mandatory publication of full clinical study reports and data-sharing platforms demonstrate a push for transparency that extends to more than just clinical protocol registration. This aligns with the growing emphasis on open science and collaborative research, where sharing data across institutions can accelerate scientific discovery. Leading biopharmaceutical companies are taking this further by launching transparency initiatives that showcase their commitment beyond regulatory mandates.

Recent developments and future trends: a call for proactive action

The past year has seen significant developments that underscore the importance of proactive management. Consider these key trends:

- **Constantly evolving requirements:** New and updated disclosure requirements are published continuously. For example, in the past 12 months, over 130 regulatory guidance documents and laws related to clinical trial disclosure have been published, of which around 30% have already been superseded. This shows just how quickly the requirements are evolving. Not only is it a challenge to find these documents in the first place, but tracking/analyzing the changes is a full-time job.
- **Expanding global requirements:** To date, 75 countries mandate clinical trial disclosure across over 50 registries. This represents a significant expansion from two decades ago when only two registries required public posting of protocols. Current disclosure requirements have grown to encompass a broader range of clinical documents and data, including:
  - Full protocols
  - Clinical study reports (CSRs)
  - Anonymized patient data
- **Continued regulatory focus:** Expect stricter enforcement actions and penalties for noncompliance with disclosure regulations.
- **Focus on patient-centric disclosure:** Disclosure formats will likely become more user-friendly and accessible to lay audiences, catering to patient needs for clear and concise information.
- **Evolving use of artificial intelligence (AI) and machine learning (ML) in disclosure:** AI and ML are expected to play a larger role in analyzing data, preparing content for publication, and improving the quality and efficiency of clinical trial disclosure processes. However, while the capabilities of these systems are improving rapidly, they are still limited by their lack of deep domain knowledge compared to human experts. Additionally, AI/ML models may struggle with interpreting ambiguous legal language and handling references to other laws, regulations, or specific scenarios, which can lead to compliance issues.

Looking ahead to the near future, we anticipate growing regulatory enforcement, with more frequent inspections and potential penalties for noncompliance. Based on the past three years, we expect approximately

250 new regulatory and requirements documents globally, of which around 30% will likely be superseded within two years. While Phase 4 of the unified study definitions model (USDM) is expected to launch in the coming year with support for the registries in the US (ClinicalTrials.gov), EU (CTIS), and possibly Japan (jRCT), it may be years before most registries and sponsors adopt this standard.

With these growing and evolving requirements, a focus on pragmatic and cost-effective disclosure processes is crucial, where exploring technology solutions and streamlining workflows can optimize resource allocation.

The value of a maturity model: a roadmap for improvement

A clinical trial disclosure maturity model is valuable in this dynamic environment. Consider the ever-increasing challenge of constantly evolving requirements. New and updated disclosure regulations are published frequently. Keeping track of these changes can be a full-time job, and failing to comply with the latest regulations can lead to penalties.

The maturity model: addressing evolving requirements

This is where the clinical trial disclosure maturity model comes in. By assessing your organization's performance in domains like quality and compliance, the model helps ensure you have a systematic process for staying up to date on the latest regulations. A strong focus on this area ensures that the organization monitors regulatory changes and implements them effectively in its disclosure practices.

But regulatory monitoring is just one piece of the puzzle. The maturity model can also help you evaluate your organization's operating model and governance. An effective operating model clearly defines roles, responsibilities, and processes for disclosure activities across the organization. A robust governance structure ensures there are appropriate oversight mechanisms, decision-making frameworks, and escalation pathways to address complex disclosure challenges and maintain consistency.

Additionally, the model considers technology and systems. Leveraging technology solutions can automate tasks like regulatory change alerts and streamline the process of updating disclosure content. By investing in appropriate technology, organizations can free up valuable time and resources while ensuring that their disclosure practices comply with the latest requirements.

Identifying opportunities for improvement

The maturity model evaluates your organization's performance across key domains such as:

- **Disclosure process management:** clearly defined and up-to-date policies and standard operating procedures (sops) are the foundation for consistent and compliant disclosure practices.
- **Quality & compliance:** a robust quality

management system and compliance monitoring process safeguard adherence to regulatory requirements and maintain high standards in disclosure activities.

- **Technology & systems:** investing in appropriate technology solutions can streamline all aspects of disclosure processes, from data collection and management to reporting and content creation, enhancing disclosure efficiency and accuracy.
- **Operating model & governance:** a well-defined operating model and governance structure provide clear roles, responsibilities, and oversight for effective disclosure management.
- **Data governance:** effective management of clinical trial data throughout its lifecycle ensures accuracy, integrity, and security, supporting reliable and transparent disclosure practices.

Understanding your strengths and weaknesses across these critical areas can help you prioritize investments and optimize your disclosure strategy. While company size doesn't necessitate a different maturity model, it can influence prioritization within the framework. For instance, sponsors with smaller trial portfolios across a limited geographic scope may initially focus on foundational elements like policies and SOPs. In contrast, larger sponsors with complex trials might prioritize areas like technology and advanced reporting.

A measured approach to compliance

Developing pragmatic processes and systems to ensure compliant transparency is a collaborative effort. The disclosure maturity model allows organizations of all sizes to identify areas for improvement, invest strategically, and create a proactive approach to clinical trial disclosure. This is the first of 10 articles presenting a comprehensive maturity model to manage clinical trial disclosure.

1. Why disclosure matters now
2. The disclosure maturity model: a brief overview
3. Disclosure process management
4. Quality & compliance
5. Technology & systems
6. Operating model & governance
7. Data governance
8. Reporting & metrics
9. Training & awareness
10. Organization

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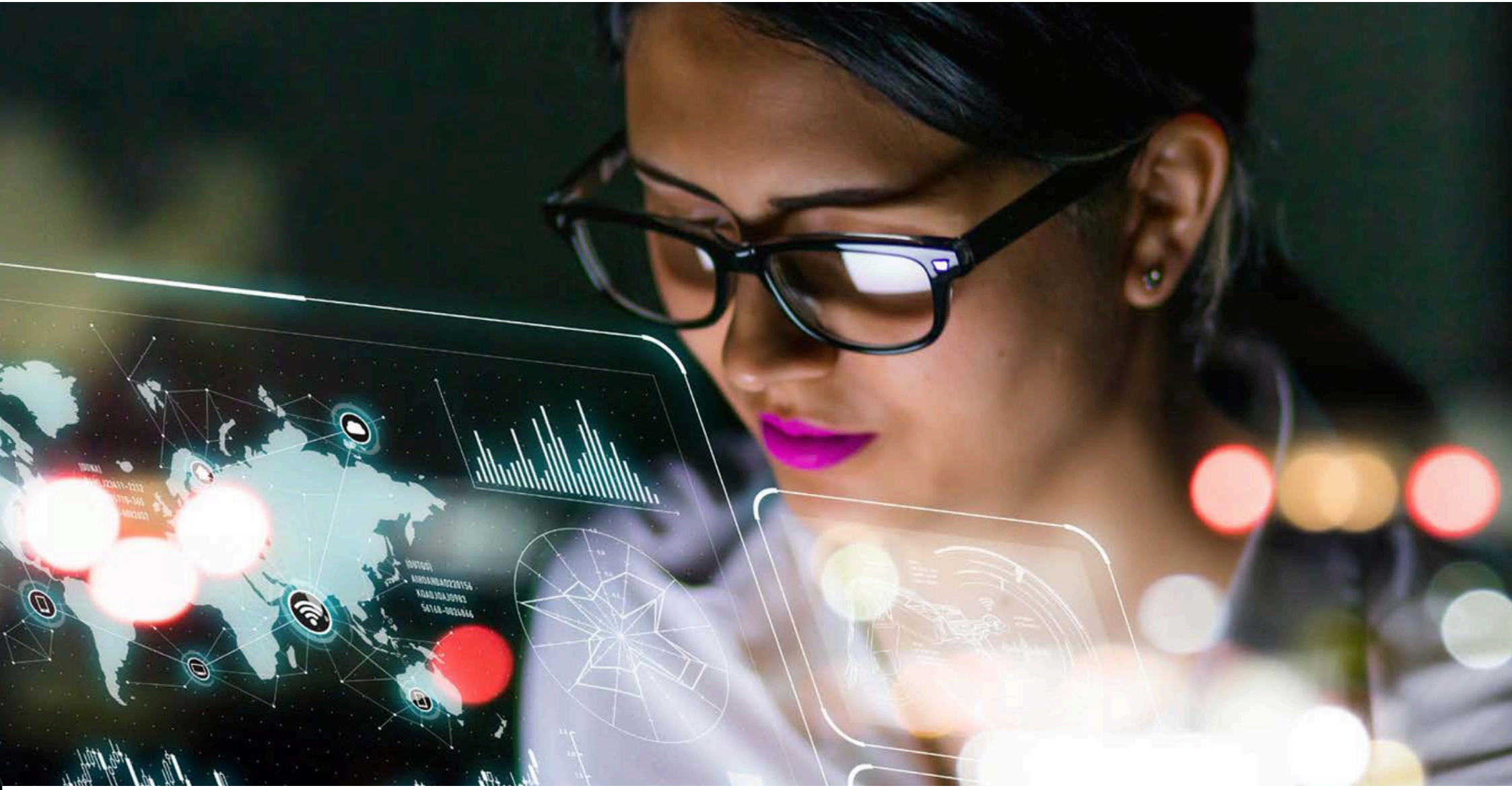


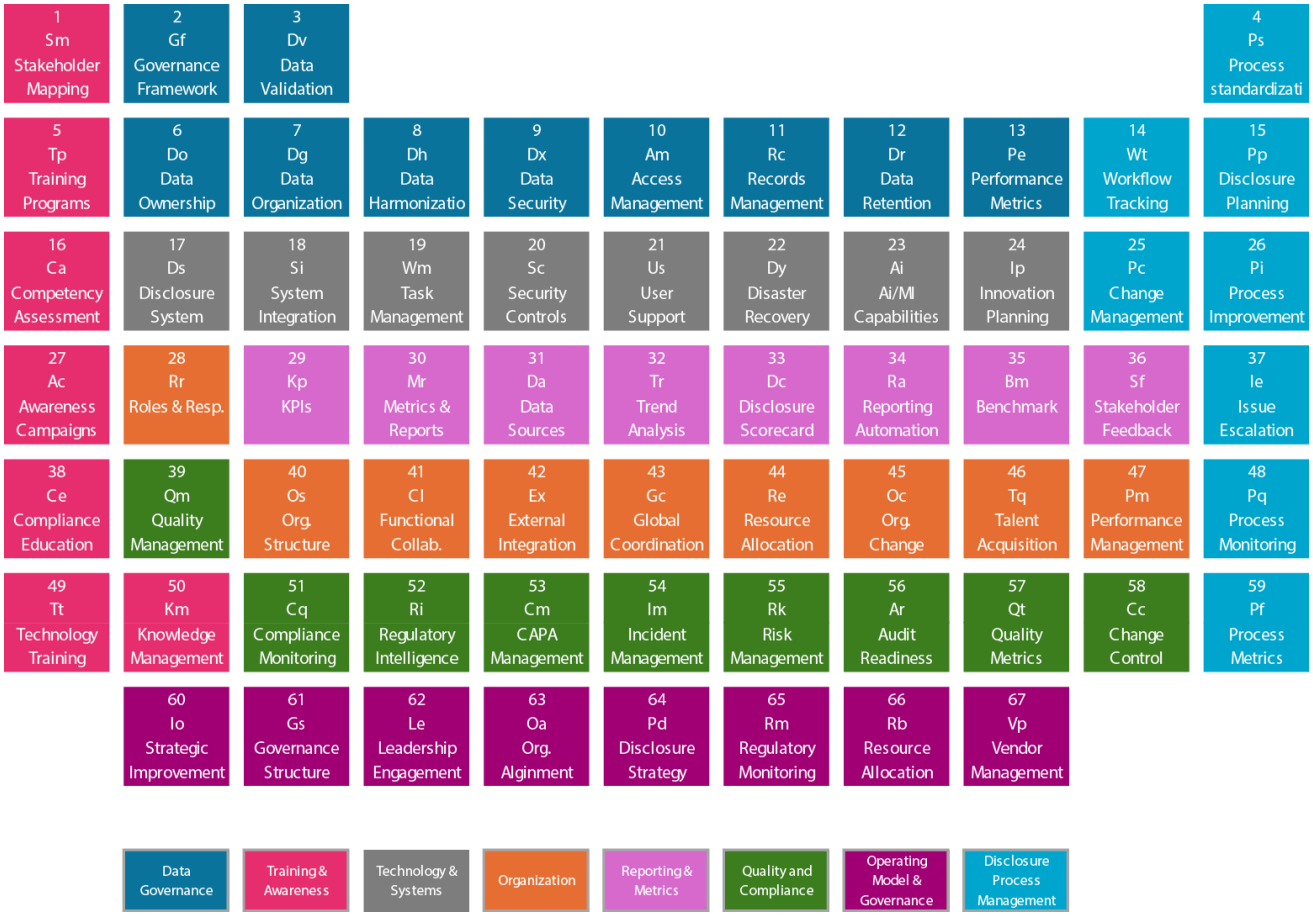
The Clinical Trial Disclosure Maturity Model: A Framework for Excellence

The Clinical Trial Disclosure Maturity Model: A Framework for Excellence

In today's complex and highly regulated clinical trial landscape, ensuring robust disclosure and transparency practices is more critical than ever. As stakeholders demand greater access to clinical trial information, organizations must establish strong processes and governance structures to meet these expectations while maintaining compliance and efficiency. This is where the clinical trial disclosure maturity model comes into play.

Understanding the maturity model

The clinical trial disclosure maturity model is a comprehensive framework designed to help organizations assess and improve their disclosure practices. Unlike the traditional five-level capability maturity model integration (CMMI), our model employs a simplified three-level maturity assessment: lagging, developing, and leading.



Why a three-level model?

We opted for a three-level model to streamline the assessment process and provide clear and actionable insights. This approach allows organizations to:

- Quickly identify their current state across key domains
- Focus on significant areas for improvement rather than incremental changes
- Set clear, achievable goals for advancing their maturity level

The three levels are defined as:

1. **Lagging:** Organizations at this level typically have informal or inconsistent processes, limited oversight, and a reactive approach to disclosure requirements.
2. **Developing:** At this stage, organizations have established basic processes and some level of governance but may struggle with consistency or proactive management.
3. **Leading:** Organizations at this level demonstrate comprehensive, fully integrated processes, strong governance, and a proactive approach to disclosure and transparency.

Key domains of the maturity model

In this maturity model, a domain represents a distinct area of clinical trial disclosure practices, encompassing related processes, capabilities, and responsibilities that collectively contribute to an organization's overall disclosure maturity. The model assesses maturity across eight key domains:

1. Disclosure process management
2. Quality & compliance
3. Technology & systems
4. Operating model & governance
5. Data governance
6. Reporting & metrics
7. Training & awareness
8. Organization

Within each domain, elements are specific attributes or components that define relevant aspects of that domain, allowing for a more detailed assessment of an organization's capabilities and practices.

These domains are interconnected, each influencing the others to create a holistic view of an organization's disclosure maturity. For example, robust data governance supports effective disclosure process management, enhancing quality and compliance. Similarly, advanced technology and systems can improve reporting and metrics capabilities, leading to better decision-making in the operating model and governance domain.

Tailoring the maturity model to the size of the organization

While the clinical trial disclosure maturity model provides a comprehensive approach, its application can be tailored based on organizational size and trial portfolio. Here's how different-sized sponsors might approach the model:

Small sponsors (1–5 active trials)

- Focus on foundational elements such as "policies & SOPs," "data governance," and "quality & compliance"
- Emphasize "leadership engagement" to ensure organizational buy-in
- Aim for at least a "developing" level in core domains while maintaining awareness of other areas

Medium sponsors (6–25 active trials)

- Prioritize "quality & compliance," "disclosure process management," "regulatory monitoring," and "data governance"
- Invest in "technology & systems" and "reporting & metrics" to support growing data management and reporting needs
- Strive for a "leading" level in "regulatory monitoring" and "disclosure process management"

Large sponsors (25+ active trials)

- Aim for a "leading" level of maturity across all domains, given operational scale and complexity
- Prioritize "technology & systems," "reporting & metrics," and "continuous improvement" to drive efficiency
- Invest in "risk management" and "training & awareness" to ensure consistency across global operations

These guidelines should be adapted to each sponsor's unique circumstances, goals, and risk profile. By considering the organization's size and trial portfolio when applying the maturity model, sponsors can allocate resources more effectively for maximum impact.

It's recommended for growing organizations to reassess their maturity levels and adjust priorities regularly. This ensures their disclosure practices evolve in tandem with changing needs and regulatory requirements, maintaining compliance and efficiency as they scale

Assessing your current state

We've developed a self-assessment workbook to help organizations assess their current state. This consists of multiple-choice questions covering each element across the domains, enabling stakeholders to evaluate their practices objectively. The questions are designed to be straightforward yet informative, providing a clear picture of where an organization stands in its disclosure maturity journey. For example, in the policy and sops element of the operating model & governance domain, respondents might be asked to select the statement that best describes their organization:

1. Our policies, strategies, and SOPs are not disclosure-specific or out of date.
2. Our transparency policy and disclosure standard operating procedures (SOPs) only cover the US and EU requirements. We don't have a defined disclosure strategy.
3. Our transparency policy and disclosure SOPs only cover the UA and EU requirements. We have a defined

disclosure strategy.

4. Our transparency policy and disclosure SOPs address global trial disclosure and data sharing. We have a defined disclosure strategy.

By completing this assessment across all domains, organizations can gain a comprehensive understanding of their current maturity level and identify key areas for improvement.

Benefits of the maturity model

Implementing the clinical trial disclosure maturity model can yield significant benefits, including:

- Enhanced compliance with regulatory requirements
- Improved data quality and integrity
- Increased operational efficiency and effectiveness
- Better risk management and mitigation
- Strengthened stakeholder trust and confidence

Moreover, the model provides a roadmap for continuous improvement, allowing organizations to set clear goals and track their progress over time.

Summary

The clinical trial disclosure maturity model offers a robust framework for organizations seeking to elevate their disclosure and transparency practices. It provides a clear assessment of current capabilities and a roadmap for improvement, enabling organizations to enhance their compliance, efficiency, and stakeholder trust in an increasingly complex regulatory landscape.

In the upcoming articles in this series, we'll delve deeper into each domain, providing detailed insights and practical strategies for advancing your organization's disclosure maturity. Stay tuned as we explore the path to disclosure excellence.

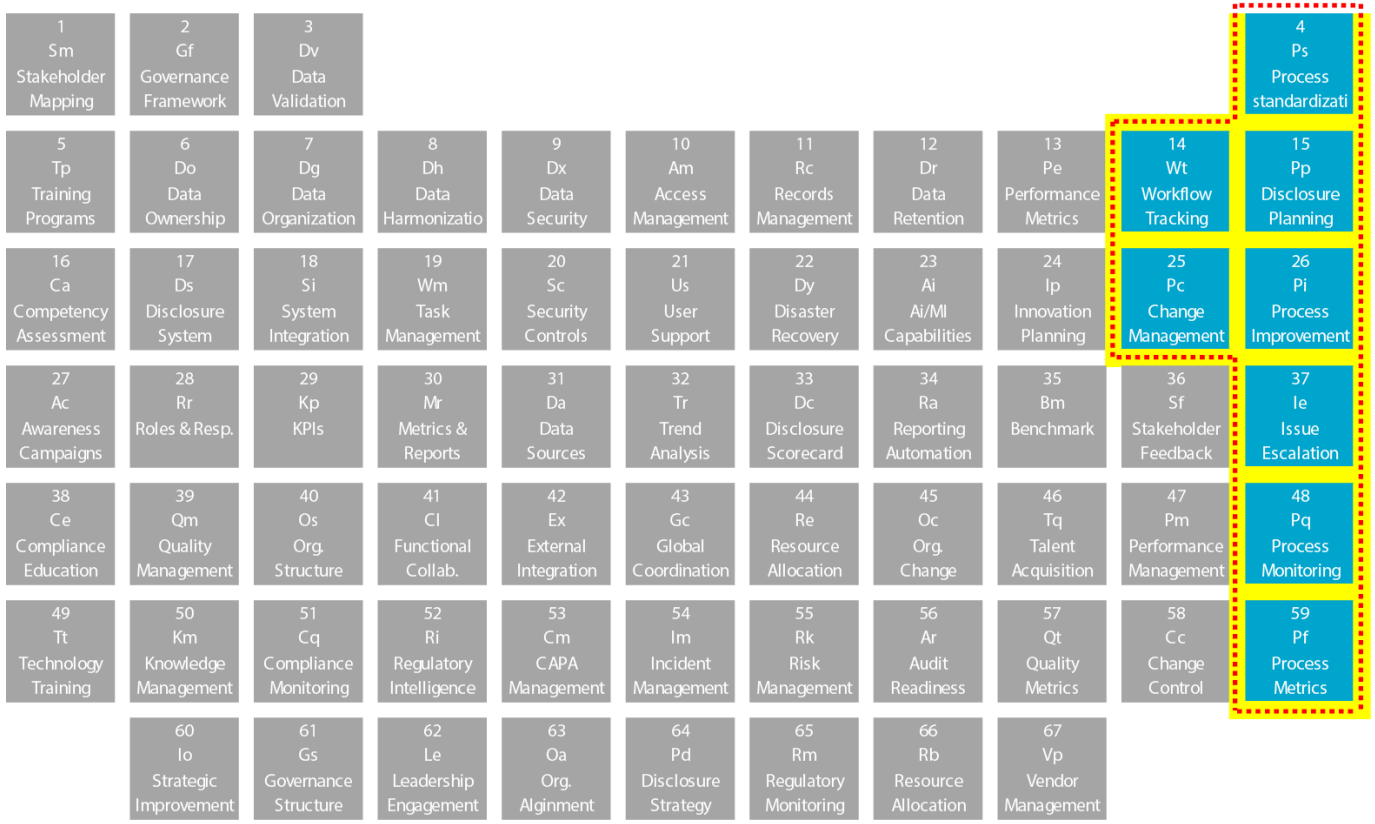
Contact our DISCLOSURE EXPERTS to learn more.

The Disclosure Process Management Domain of the Clinical Trial Disclosure Maturity Model

The Disclosure Process Management Domain of the Clinical Trial Disclosure Maturity Model

Executive summary

Disclosure process management is the systematic way of organizing and carrying out activities related to clinical trial disclosure. This includes creating, implementing, and overseeing clear and consistent processes for the accurate and timely disclosure of clinical trial information. Disclosure process management is not merely an administrative task but the foundation of effective clinical trial transparency. Strong performance in this domain is a prerequisite for consistent, efficient, and compliant disclosure practices. By implementing standardized processes, organizations can minimize errors, improve efficiency, and consistently meet regulatory requirements.



Why this domain matters

The disclosure process management domain is the operational core of clinical trial transparency efforts. It shapes how organizations execute their disclosure activities, from initial planning to final publication. Effective process management ensures disclosure tasks are performed consistently, efficiently, and in compliance with regulatory requirements, regardless of the complexity of the trial or the variety of disclosure obligations. Well-defined disclosure processes are essential for several reasons:

- **Defending inspections:** Health authorities are increasingly scrutinizing disclosure compliance, so sponsors must be ready to defend inspections, especially in the US, the EU, and the UK.
- **Operational efficiency:** Standardized workflows streamline disclosure activities, saving time and resources.
- **Improved compliance:** Established processes ensure adherence to evolving regulatory requirements.
- **Reduced errors:** Clear procedures minimize the risk of inconsistencies and inaccuracies in disclosure documents.
- **Stronger collaboration:** Defined roles and responsibilities facilitate seamless collaboration among teams involved in disclosure.

Potential risks of weak disclosure processes

Inadequate disclosure process management can expose organizations to significant regulatory, operational, and reputational risks. Sponsors need well-defined, standardized processes to meet disclosure requirements consistently across various registries and jurisdictions. The absence of a systematic approach often results in errors, inefficiencies, and compliance failures that undermine the integrity of clinical trial transparency efforts. Specific risks include:

- **Delayed disclosures:** Missed deadlines can hinder public access to important clinical trial information.
- **Inconsistent data:** Inconsistencies in reported data can erode trust and raise questions about the validity of the trial results. Without global coordination, sponsors may inadvertently disclose company-confidential information, making it impossible to redact the information later and risking rejection of patent applications.
- **Regulatory violations:** Noncompliance with disclosure requirements can lead to penalties and reputational damage.

Key elements of disclosure process management

Process standardization & harmonization

Create standard operating procedures (SOPs) and practices across the disclosure processes. Aligning methods across departments and organizations ensures consistency, improves efficiency, and reduces errors. These SOPs should be up to date and consistently applied across all trials and registries.

Maturity levels:

As with other domains in the disclosure maturity model, process standardization and harmonization can be categorized as lagging, developing, or leading.

- **Lagging:** Disclosure processes are ad hoc and inconsistent. SOPs may be missing or outdated.
- **Developing:** Documented SOPs exist but may not be consistently followed or lack sufficient detail.
- **Leading:** Comprehensive and up-to-date SOPs govern all disclosure activities. Processes are harmonized across trials and registries, ensuring consistent and reliable disclosure practices.

The main components of process standardization and harmonization in clinical trial disclosure include:

- Standardized workflows for disclosure activities (e.g., protocol registration, results disclosure, updating trial records)
- Consistent processes for collecting and validating disclosure data from various internal sources
- Harmonized data-entry processes for various disclosure platforms
- Standardized timelines and milestone tracking for disclosure tasks
- Standardized procedures for updating and maintaining disclosed information

Workflow management & tracking

Focus on designing, implementing, and monitoring the flow of tasks in the disclosure process. It includes tools and systems to track progress, assign responsibilities, and manage deadlines throughout the disclosure lifecycle. Effective disclosure requires precise and efficient workflows that track the progress of disclosure activities. This includes assigning tasks, managing deadlines, and monitoring completion.

Maturity levels:

- **Lagging:** Workflows are manual and lack oversight. There is no systematic tracking of disclosure activities.
- **Developing:** Essential workflow tools may be used, but processes are not fully optimized. Tracking may be inconsistent.
- **Leading:** Automated workflow management systems are implemented, ensuring efficient task assignment, progress tracking, and timely completion of disclosure activities.

Disclosure planning

Effective planning is crucial for managing complex clinical trials and ensuring timely disclosure. This involves defining the scope of disclosure, setting timelines for each stage, allocating resources, and assigning responsibilities. For instance, the plan should detail what information must be made public, where the data will be disclosed, who will be responsible, and by what deadline.

Maturity levels:

- **Lagging:** Disclosure activities are reactive

and unplanned. Deadlines are frequently missed. Developing: Basic project plans may be used but not comprehensive or consistently followed.
- **Leading:** Formal project management methodologies are used to create and manage detailed disclosure plans that consider all aspects of the disclosure process.

Assessing your maturity

Beyond the three elements listed above, assessing the level of maturity in disclosure process management requires looking at all eight components of the domain, especially the capabilities around process monitoring and performance metrics.

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.

Considerations for sponsor size

The approach to disclosure process management may vary based on the size and complexity of a sponsor's trial portfolio. While all sponsors need to establish effective processes for clinical trial disclosure, the scale of operations and available resources will influence the implementation of these processes. Both smaller and larger sponsors must adapt their strategies to meet their unique needs and capabilities:

Sponsors with smaller trial portfolios should focus on developing core, precise, and up-to-date Standard Operating Procedures (SOPs) for essential disclosure activities. They may have simpler workflows but should still ensure that processes are well-documented and consistently followed. Smaller sponsors might prioritize manual quality checks and rely more on individual expertise, focusing on cross-training team members to ensure coverage of all disclosure responsibilities.

Additional domain elements

- Process change management: Handle process modifications, assess impacts, and ensure smooth transitions during implementation
- Issue escalation and resolution: Establish protocols to identify, report, and address problems efficiently in the disclosure process
- Process improvement cycle: Continuously analyze and refine specific disclosure processes, using feedback and metrics to enhance operational efficiency
- Process monitoring: Identify potential risks, evaluate their impact, and implement controls to minimize adverse effects
- Process performance metrics: Define and analyze KPIs to evaluate efficiency and drive improvements in disclosure management

Sponsors with more extensive trial portfolios typically benefit from more sophisticated process management approaches. They often prioritize the automation of routine tasks and implement advanced project management techniques to handle the complexity of numerous concurrent trials. These sponsors usually invest in comprehensive workflow management systems, develop detailed SOPs covering various disclosure scenarios, and may have dedicated teams for different aspects of the disclosure process. They focus on scalability and consistency across many disclosures and implement centralized oversight mechanisms to ensure uniform practices across different therapeutic areas or global regions.

Getting started: practical tips

- **Identify gaps:** complete the disclosure process management worksheet to evaluate your company's maturity in this domain and identify areas for improvement.
- **Develop core SOPs:** start by creating or updating SOPs for core disclosure activities, such as content creation, submission, and amendment processes. For example, develop an SOP outlining the steps to create and submit the initial trial registration on a public registry.

How we can help

TrialScope Disclose: our centralized platform automates data entry and reporting for global trial registries. This automation reduces manual effort and potential errors, allowing your team to focus on strategic tasks rather than paperwork. TrialScope Disclose can significantly improve your process standardization and workflow management, which are critical elements of mature disclosure process management.

TrialScope Intelligence: this solution provides a centralized, interactive repository of critical regulatory knowledge for global clinical trial disclosure compliance. It can help you stay up-to-date with evolving disclosure requirements, supporting your efforts to maintain compliant and efficient processes. TrialScope Intelligence is valuable for enhancing regulatory monitoring capabilities and informing disclosure planning.

TrialScope Disclosure Services: our team of experts can act as an extension of your team, handling time-consuming disclosure activities from protocol registration through results posting, redaction, and anonymization. We also offer advisory services to help draft corporate transparency policies, disclosure SOPs, and compliance assessments to audit past disclosures. These services can be invaluable in establishing and maintaining robust processes, especially for organizations looking to standardize and harmonize their approach to global disclosure.

Conclusion

Strong disclosure process management is critical to a mature clinical trial disclosure program. By investing in well-defined processes, organizations can achieve greater efficiency, accuracy, and compliance in their disclosure practices.

Next steps

Next, we will explore the quality and compliance domain, exploring how organizations can ensure accuracy, consistency, and regulatory adherence in their clinical trial disclosures. We'll examine quality management systems, compliance monitoring, and regulatory intelligence strategies. We strongly encourage you to assess your current disclosure processes and identify areas for improvement using the insights provided in this article and the self-assessment workbook. This proactive approach will help you enhance your work and contribute to your organization's overall success.

Contact our DISCLOSURE EXPERTS to learn more.

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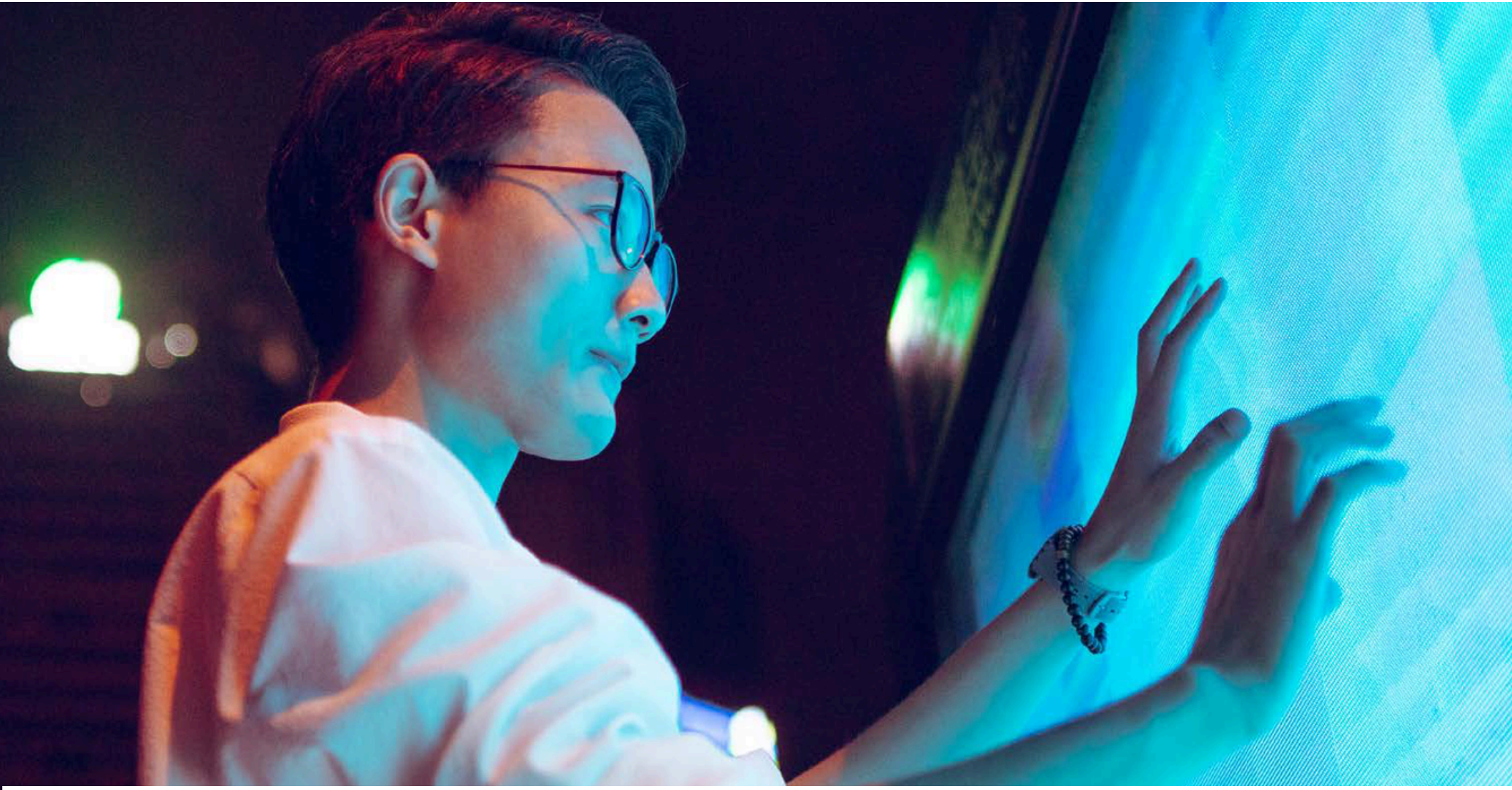
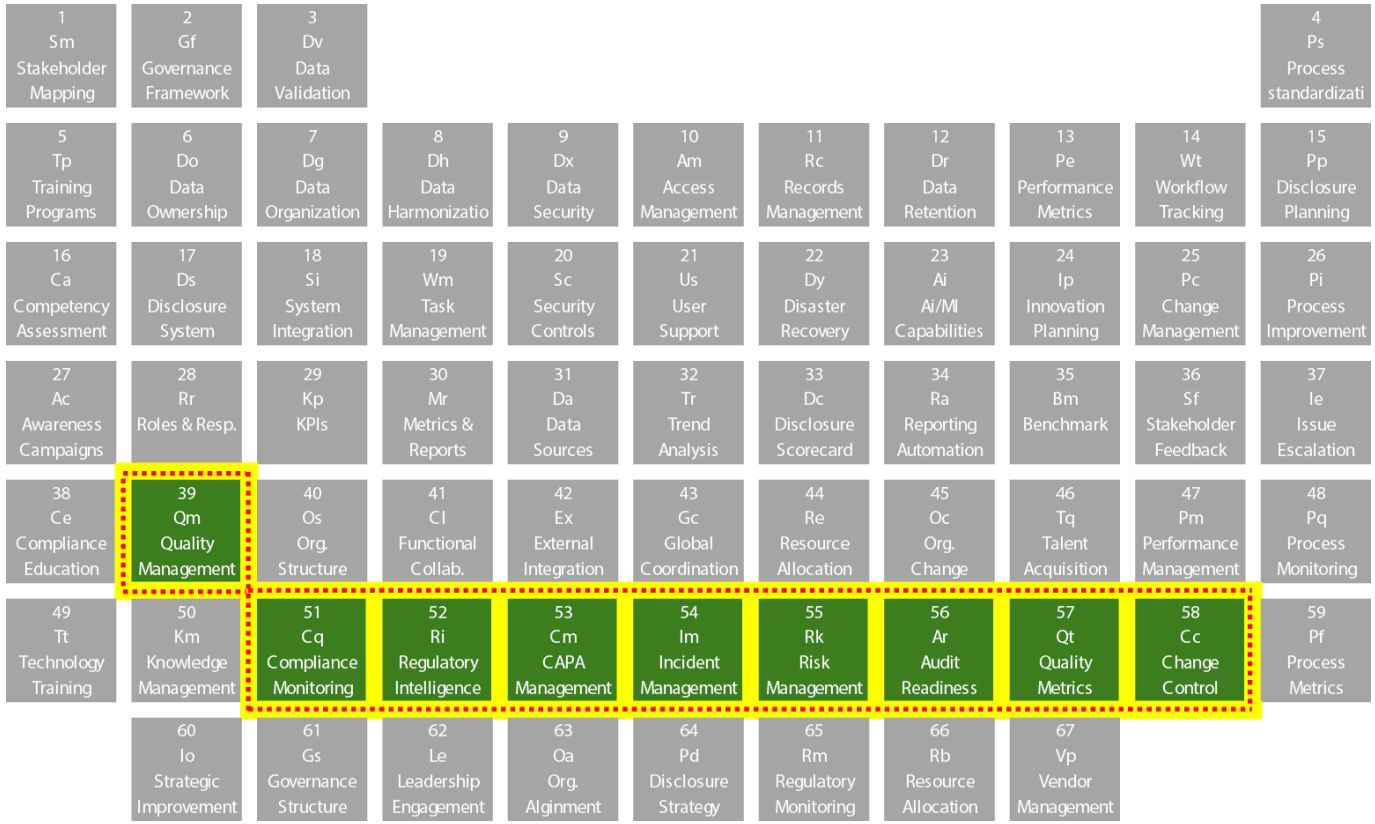


Quality and Compliance Domain of the Clinical Trial Disclosure Maturity Model

Quality and Compliance Domain of the Clinical Trial Disclosure Maturity Model

Executive summary

The quality and compliance domain encompasses the systems, processes, and practices that ensure the accuracy, consistency, and regulatory adherence of clinical trial disclosure. This is fundamental to maintaining the integrity of disclosed information and building trust with regulators, healthcare professionals, and the public. Effective quality and compliance management in clinical trial disclosure goes beyond mere regulatory adherence. It involves creating a quality culture, implementing robust systems, and continuously improving processes to ensure that disclosed information is accurate, timely, and meets all applicable standards and regulations.



Why this domain matters

Quality and compliance are essential for trustworthy clinical trial disclosure. This domain focuses on the systems and practices that ensure the accuracy, completeness, and timeliness of the disclosed information. By prioritizing quality and compliance, organizations meet regulatory requirements and build credibility with stakeholders, from regulators and healthcare professionals to patients and the public. Strong performance in the quality and compliance domain supports:

- **Regulatory compliance** through adherence to increasingly complex and evolving disclosure requirements across jurisdictions

- **Quality assurance** by implementing systematic quality checks and balances throughout the disclosure process, maintaining high accuracy and completeness of disclosed information
- **Audit readiness** fosters continuous preparedness for regulatory inspections and audits, allowing organizations to demonstrate their compliance efforts confidently
- **Compliance risk management** enabling proactive identification and mitigation of compliance-specific risks, reducing the likelihood of regulatory violations and associated penalties
- **Stakeholder confidence** based on a commitment to transparency and compliance that builds trust with regulators, healthcare professionals, patients, and the public

Potential risks of a weak approach to quality & compliance

Failure to establish robust quality and compliance processes in clinical trial disclosure can have far-reaching consequences for sponsors. Weak quality control and compliance monitoring can lead to inaccurate or incomplete disclosures, potentially violating regulatory requirements and eroding stakeholder trust. Moreover, quality management systems support more efficient processes that can decrease costs and facilitate adapting to evolving regulatory landscapes. Specific risks include:

- **Regulatory violations:** Noncompliance with disclosure requirements, including missed deadlines, can result in fines, penalties, increased regulatory scrutiny, and delayed access to important clinical trial information for stakeholders.
- **Reputational damage:** Public discovery of compliance failures or quality issues can erode trust in the sponsor and its research.
- **Increased costs:** Addressing quality issues retrospectively is often more time-consuming and expensive than preventing them through adequate processes.

Key elements of quality & compliance management

Quality management system (QMS)

A comprehensive quality management system forms the foundation of effective quality and compliance in clinical trial disclosure. In addition to standard operating procedures (SOPs) discussed in detail in our

disclosure process management domain article, it includes policies, guidelines, and overarching quality principles that govern all aspects of the disclosure process. A robust QMS provides a framework for continuous improvement, risk management, and organization-wide quality culture.

Maturity levels:

- **Lagging:** No formal QMS exists. Quality-related documents are either absent, outdated, or do not address disclosure-related processes.
- **Developing:** Basic disclosure-related quality documents are in place, but the QMS does not necessarily document the actual daily processes. Quality principles are recognized but not fully integrated into daily operations. There may be gaps in coverage or inconsistencies across different parts of the organization.
- **Leading:** A comprehensive, integrated QMS with a clear transparency policy, well-defined quality objectives, and robust guidelines covering all aspects of clinical trial disclosure is in place. The QMS includes mechanisms for continuous improvement, such as management reviews and quality risk management processes. Quality principles are embedded in the organizational culture, with strong leadership support and employee engagement. Regular reviews and updates ensure alignment with current regulations and best practices.

The main components of a leading QMS in clinical trial disclosure include:

- A clear quality policy and objectives specific to disclosure activities
- Disclosure-specific SOPs
- Defined roles and responsibilities for quality management
- Risk-based approaches to quality assurance
- Training and competency management programs
- Document control and records management systems
- Change-management processes
- Supplier and outsourcing controls
- Performance monitoring and measurement systems

This holistic approach to quality management ensures that all aspects of clinical trial disclosure are consistently executed to high standards, fostering a culture of quality and compliance throughout the organization.

Compliance monitoring/auditing and quality control

Compliance monitoring requires the ongoing assessment of disclosure activities to meet quality standards and regulatory requirements. It includes regular audits, quality checks, documented disclosure processes, and outcomes monitoring.

Maturity levels:

- **Lagging:** Compliance monitoring is reactive or nonexistent. Quality checks are inconsistent or only performed in response

to identified issues.
- **Developing:** Basic monitoring and auditing processes are in place but may not be comprehensive or proactive. Quality-control measures exist but may not cover all critical aspects of disclosure.
- **Leading:** Proactive, risk-based compliance monitoring and regular (typically biannual) audits are conducted. Comprehensive quality-control measures are integrated into all stages of the disclosure process, with clear escalation pathways for identified issues.

Regulatory intelligence

With disclosure regulations rapidly evolving, staying informed about current and upcoming regulatory requirements is crucial. This includes the processes for locating and interpreting relevant requirements, tracking changes, and implementing processes to comply with the requirements across different jurisdictions.

Maturity levels:

- **Lagging:** No systematic process exists for monitoring regulatory changes or assessing their impact on quality and compliance measures.
- **Developing:** Basic processes exist for discovering and tracking significant regulatory key markets such as the US, EU, and Japan. However, these do not cover all countries where trials are conducted and have limited integration with a quality management system.
- **Leading:** Robust systems are in place to proactively monitor global regulatory landscapes for new and changing requirements and seamlessly integrate them into quality management and compliance processes.

Key components of regulatory intelligence in quality and compliance:

- Processes for integrating new regulatory requirements into existing quality management systems
- Methods for assessing the impact of regulatory changes on current compliance status
- Procedures for updating quality control measures and compliance checks based on regulatory updates

Assessing your maturity

To evaluate your organization's maturity in the quality and compliance domain, consider how well you perform in each of the key elements discussed above and the additional attributes listed in the sidebar. Are your processes proactive or reactive? How comprehensive and integrated are your quality management systems? How quickly and effectively do you adapt to regulatory changes? How effectively do you integrate regulatory changes into your quality management and compliance processes?

With the increasing scrutiny and frequent inspections in multiple jurisdictions, ensuring adequate maturity in quality management is necessary for inspection readiness and compliance management.

Additional domain elements

- **CAPA management:** implement a systematic Corrective and Preventive Action (CAPA) process to identify root causes of quality issues, correct them, and prevent recurrence
- **Incident management:** establish procedures for reporting, investigating, and resolving deviations and incidents in the disclosure process
- **Risk management:** identify, assess, and mitigate potential disclosure quality and compliance risks through proactive strategies
- **Audit readiness:** prepare the organization for regulatory inspections and audits, including business continuity and disaster recovery plans
- **Quality metrics:** define and track key performance indicators to measure and improve the effectiveness of quality and compliance efforts
- **Change control:** manage changes to processes, systems, and documentation, including qualification of vendors and suppliers involved in disclosure activities

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.

Considerations for sponsor size

While a reliable approach to quality and regulatory compliance is necessary for all trial sponsors, the approach to quality and compliance may vary based on sponsor size:

Sponsors with smaller trial portfolios should focus on developing a core set of essential SOPs for critical disclosure activities. They might start with a basic QMS framework and gradually expand it. Smaller sponsors benefit from templated SOPs that can be customized to their specific needs. To ensure regulatory compliance, companies of this size should consider assigning a single point person or contractor to monitor the requirements for the countries where they are currently conducting trials and disseminate updates to relevant team members.

Sponsors with more extensive trial portfolios typically implement a more comprehensive QMS system with complete SOP libraries covering various disclosure and data-sharing scenarios. These sponsors often rely on electronic QMS management systems for better version control and distribution. Larger sponsors have a dedicated regulatory intelligence team or function specifically for clinical trial disclosure. This team typically relies on a global regulatory monitoring system to analyze and interpret new requirements and update company-wide disclosure processes.

Getting started: practical tips

- **Conduct a gap analysis:** assess your organization's quality and compliance processes against regulatory requirements and industry best practices. Identify areas for improvement in your overall quality management system.
- **Develop a compliance monitoring plan:** establish a systematic tracking approach and ensure adherence to all relevant disclosure regulations. This could include creating a regulatory calendar and assigning responsibility for monitoring changes.
- **Establish a CAPA process:** develop a system for corrective and preventive actions (CAPA) to address any quality or compliance issues that arise and prevent their recurrence.
- **Set up quality metrics:** Define and implement key performance indicators (KPIs) to measure the effectiveness of your quality system and compliance efforts. Review these metrics regularly to drive continuous improvement.
- **Conduct internal audits:** schedule regular audits of your disclosure processes to identify and proactively address quality or compliance issues.
- **Implement a regulatory intelligence system:** implement a solution to continuously monitor, analyze, and disseminate updates on global clinical trial disclosure regulations. This should include a method for translating regulatory changes into actionable updates to your quality management system and compliance measures.

How we can help

TrialScope Intelligence provides up-to-date information on 195 countries and over 50 trial registries, supporting your regulatory intelligence and monitoring efforts.

TrialScope Disclose includes built-in workflows, quality control measures, and compliance reports, helping to ensure the accuracy and completeness of your disclosures.

TrialScope Disclosure Services conducts disclosure audits to assess past compliance and establish revised transparency policies and SOPs.

Conclusion

A mature quality and compliance domain is essential for effective and consistent clinical trial disclosure. By investing in robust quality management systems, proactive compliance monitoring, and diligent regulatory intelligence, organizations can ensure the integrity of their disclosures and maintain compliance with evolving regulatory requirements.

Next steps

The following article in this series will explore the technology and systems domain, discussing how digital infrastructure and tools can support efficient, accurate, and compliant disclosure practices. We'll examine dedicated disclosure systems, system integration, and workflow management tools. We encourage you to use the insights from this article and the self-assessment

workbook to assess and improve your current quality and compliance processes in clinical trial disclosure.

Contact our DISCLOSURE EXPERTS to learn more.

CITELINE

Technology and Systems Domain of the Clinical Trial Disclosure Maturity Model

Technology and Systems Domain of the Clinical Trial Disclosure Maturity Model

Executive summary

The technology and systems domain focuses on the digital infrastructure and tools that support clinical trial disclosure processes. This domain encompasses dedicated disclosure systems, integration with other clinical trial data management tools, and workflow automation. Effective technology and systems are essential for efficient, accurate, and compliant disclosure practices in an increasingly complex regulatory landscape.

Why this domain matters

Technology and systems are the engines that drive efficient and accurate clinical trial disclosure. This domain encompasses the digital tools and infrastructure that support, automate, and enhance disclosure activities. By leveraging appropriate technology, organizations can streamline processes,

reduce errors, and gain valuable insights into their performance, supporting efficient clinical disclosure processes and enabling:

- **Process automation** that reduces manual effort and human error in disclosure activities, improving accuracy and efficiency
- **Data consistency** through integrated systems, ensuring consistency across disclosure documents and registries
- **Scalability** based on robust technology solutions that can handle increasing disclosure requirements as trial portfolios grow and expand into new countries, supporting sponsors conducting trials across more diverse regulatory environments
- **Real-time compliance tracking** with advanced systems, providing up-to-date compliance status and alerts for upcoming deadlines
- **Audit trails** that support inspection readiness through detailed logs of disclosure and systems administration activities

Potential risks of underinvestment in technology and systems

Underinvestment in technology and systems for clinical trial disclosure can significantly hinder an organization's ability to meet transparency obligations efficiently and effectively. Reliance on outdated or inadequate systems can lead to manual errors, data inconsistencies, and missed deadlines, compromising compliance and data quality. Furthermore, the lack of robust technological infrastructure can impede an organization's ability to scale its disclosure activities, adapt to changing regulatory requirements, and gain valuable insights from disclosure data. Specific challenges include:

- **Inefficient resource utilization:** Without automation, staff may spend excessive time on repetitive tasks rather than value-added activities.
- **Missed deadlines:** A lack of automated tracking and alerts can result in overlooked disclosure deadlines.
- **Manual errors:** Reliance on manual processes increases the risk of data-entry errors and inconsistencies.
- **Siloed content:** Disconnected disclosure systems and processes can lead to inconsistent and even confidential information being disclosed across different registries.
- **Limited visibility:** Without centralized systems, organizations may struggle to view their disclosure status and compliance comprehensively.

Key elements of technology and systems

Dedicated clinical trial disclosure systems

Central to this domain is a purpose-built system for managing clinical trial disclosures. This system should include workflow management, dashboards, and reporting capabilities.

Maturity levels:

- **Lagging:** No dedicated disclosure system

exists. The organization relies on manual processes and general-purpose tools like spreadsheets.
- **Developing:** A basic disclosure management system is in place but has limited functionality or is not fully utilized across the organization.
- **Leading:** A comprehensive, fully integrated disclosure management system with advanced features for workflow automation, compliance tracking, and reporting is in place.

The main capabilities of a disclosure system should include:

- Centralized data management for multiple global registries
- Automated compliance tracking and deadline alerts
- Workflow automation and task management
- Integration capabilities with other clinical trial systems
- Version control and audit trail functionality
- Real-time reporting and analytics dashboard
- Document management and storage
- Role-based access controls and permissions
- Automated data validation and consistency checks
- Multilingual support for global submissions

These components collectively form the backbone of an efficient and compliant clinical trial disclosure system. By automating key processes, ensuring data consistency, and providing comprehensive monitoring, such a system streamlines disclosure activities and significantly reduces noncompliance risk.

System integration

Integrating disclosure systems and other clinical trial management tools — e.g., clinical trial management systems (CTMS), SAS, electronic data capture (EDC), and regulatory systems — is valuable for data consistency and efficiency.

Maturity levels:

- **Lagging:** Systems operate in silos with manual copy/paste data transfer among platforms.
- **Developing:** Some integration exists but may be limited or require manual intervention.
- **Leading:** Seamless, automated integration among disclosure systems and other relevant platforms, ensuring real-time data synchronization.

Workflow & task management tools

These tools automate and streamline the disclosure process, from initial registration to results posting.

Maturity levels:

- **Lagging:** No formal workflow tools exist. Tasks are managed manually or through basic tools like email and calendars.
- **Developing:** Basic workflow management is in place but may lack advanced features

or full adoption.
- **Leading:** Sophisticated workflow tools automate task assignments, track progress, and provide real-time status updates.

Assessing your maturity

To evaluate your organization's maturity in the technology and systems domain, consider the functionality and integration of your current systems, including the key elements discussed above and the additional attributes listed in the sidebar. How automated are your disclosure processes? How well do your clinical data sources integrate with the disclosure system? Do you have real-time visibility into your disclosure status and compliance?

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.

Considerations for sponsor size

The approach to technology and systems in clinical trial disclosure varies significantly based on the size and complexity of a sponsor's trial portfolio. While all sponsors need some technological support for their disclosure activities, the scale of operations, available resources, and specific needs will influence the choice and implementation of these systems.

Organizations must carefully consider their current requirements and future growth plans when selecting and deploying disclosure technologies, balancing functionality with cost-effectiveness, efficiency, and scalability:

Sponsors with smaller trial portfolios might

Additional domain elements

- Security controls: measures to protect sensitive information, manage user permissions, and maintain a detailed history of system activities and changes
- User support: processes for keeping users proficient, addressing issues, maintaining system health, and implementing improvements
- Disaster recovery: plans and capabilities to ensure system availability during disruptions and support for accessing systems from various locations and devices
- AI/ML capabilities: advanced technologies for automating complex tasks, predicting outcomes, and enhancing decision-making in disclosure processes
- Innovation planning: strategic planning for future technological needs and adoption of emerging technologies to improve disclosure processes

start with solutions that offer core functionality without significant upfront investment or implementation effort. They should focus on systems that provide up-to-date intelligence on disclosure requirements, automate core disclosure tasks, and provide basic compliance tracking.

Sponsors with more extensive trial portfolios typically benefit from comprehensive and configurable solutions. These typically include advanced analytics, global registry support, and extensive integration with other clinical systems.

Getting started: practical tips

- **Conduct a systems audit:** evaluate your current technology landscape and identify gaps in disclosure management capabilities.
- **Embrace automation:** look for opportunities to automate repetitive tasks in your disclosure processes, such as data population and consistency checks across multiple registries.
- **Start with core functionalities:** when implementing a new system, begin with essential features and gradually expand capabilities.
- **Evaluate specialized solutions:** consider replacing general-purpose or home-grown systems with a targeted disclosure management platform to meet evolving regulatory requirements.
- **Prioritize integration:** to reduce manual data entry, integrate your disclosure system with data sources like your CTMS or trial status reports from contract research organizations (CROs).

How we can help

TrialScope Disclose: provides a centralized platform for managing global clinical trial disclosures, offering automated workflows, compliance tracking, and integration capabilities. It streamlines processes across multiple registries, reducing manual effort and improving data consistency.

TrialScope Intelligence: this solution offers a comprehensive database of global disclosure requirements, helping sponsors stay updated on regulatory changes. It supports informed decision-making in system configuration and process automation to meet evolving compliance needs.

TrialScope Disclosure Services: bridges the gap for sponsors without integrated disclosure systems by offering expert-managed disclosure processes. Our team leverages advanced tools and best practices to handle disclosure tasks efficiently, allowing sponsors to benefit from streamlined and reliable processes.

Trial Summaries Portal: this provides a dedicated platform for sharing plain-language summaries, automating the distribution of trial results to participants and the public.

Conclusion

Investing in technology and systems is essential for efficient, accurate, and compliant clinical trial disclosure. By leveraging advanced tools and integrating data across systems, organizations can

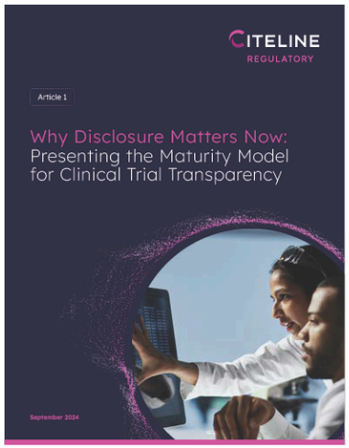
streamline processes, reduce errors, and maintain a comprehensive view of their disclosure activities.

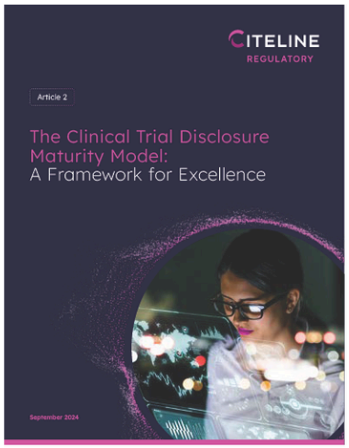
Next steps

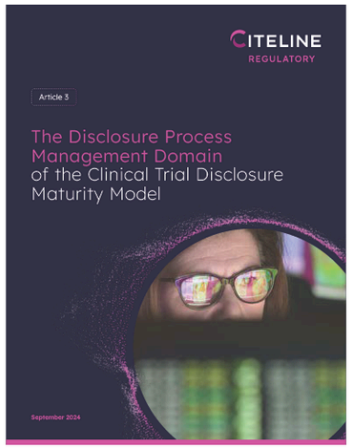
The next article in this series will explore the operating model & governance domain of the clinical trial disclosure maturity model, discussing how organizational structures, policies, and processes guide and control disclosure activities. We'll examine policy development, regulatory monitoring, and governance structures that ensure effective and compliant disclosure practices. We encourage you to use the insights from this article and the self-assessment workbook to assess and enhance your current technology and systems for clinical trial disclosure.

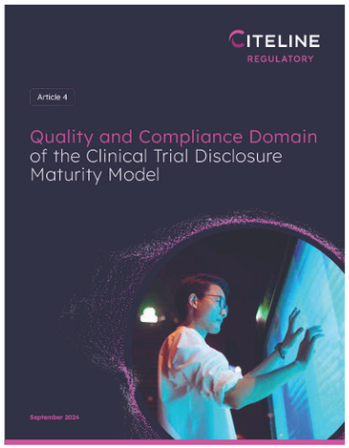
Contact our DISCLOSURE EXPERTS to learn more.

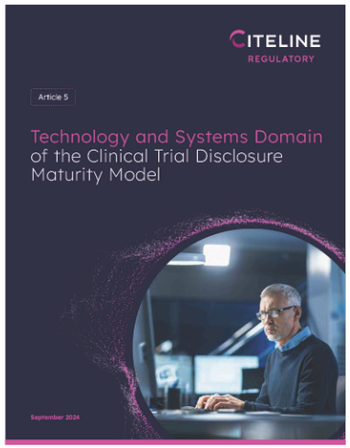
Articles Series: Maturity Model

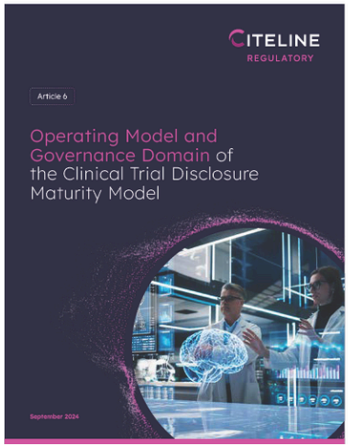


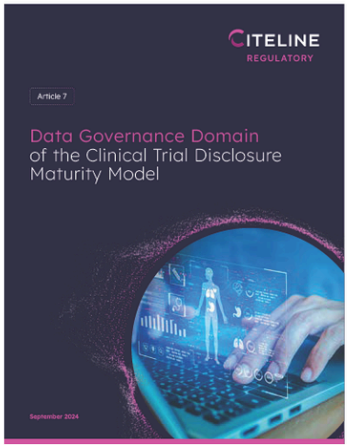


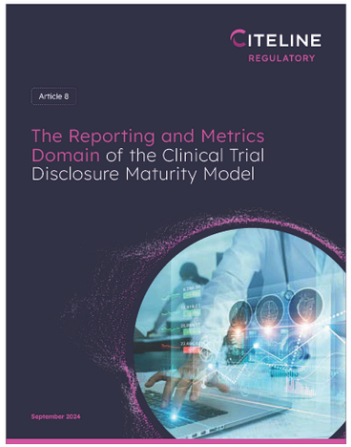


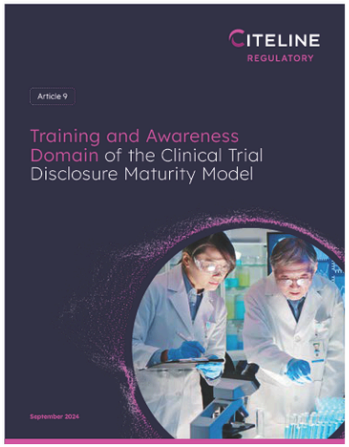


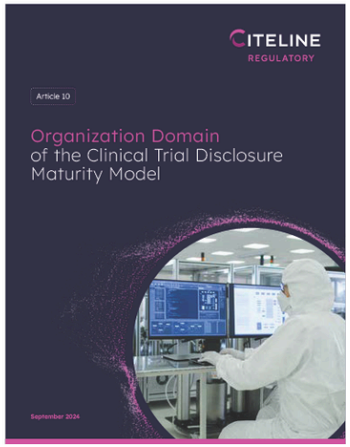












About the Author

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.

CITELINE

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

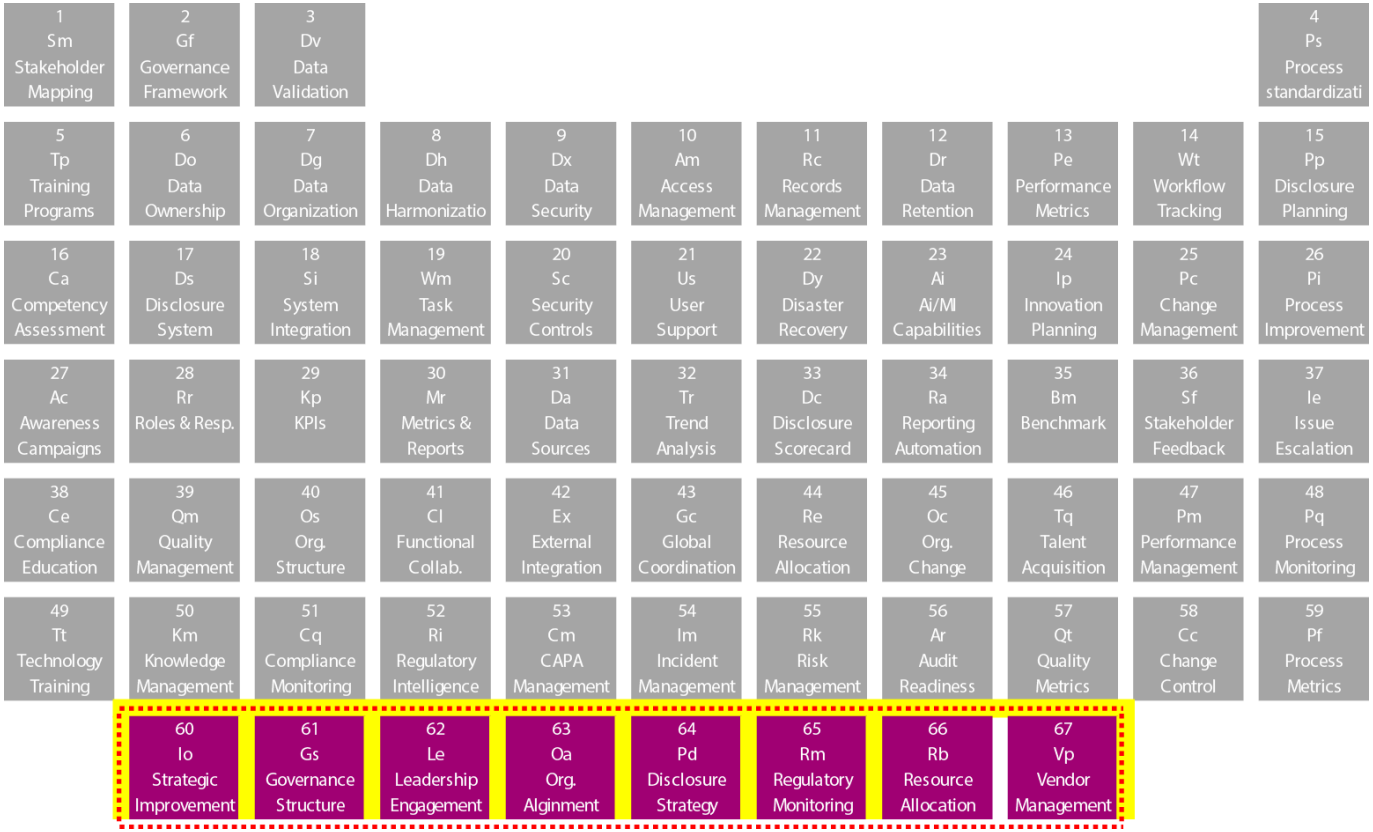
Operating Model and Governance Domain of the Clinical Trial Disclosure Maturity Model

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



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

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.

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.*

CITELINE

Data Governance Domain of the Clinical Trial Disclosure Maturity Model

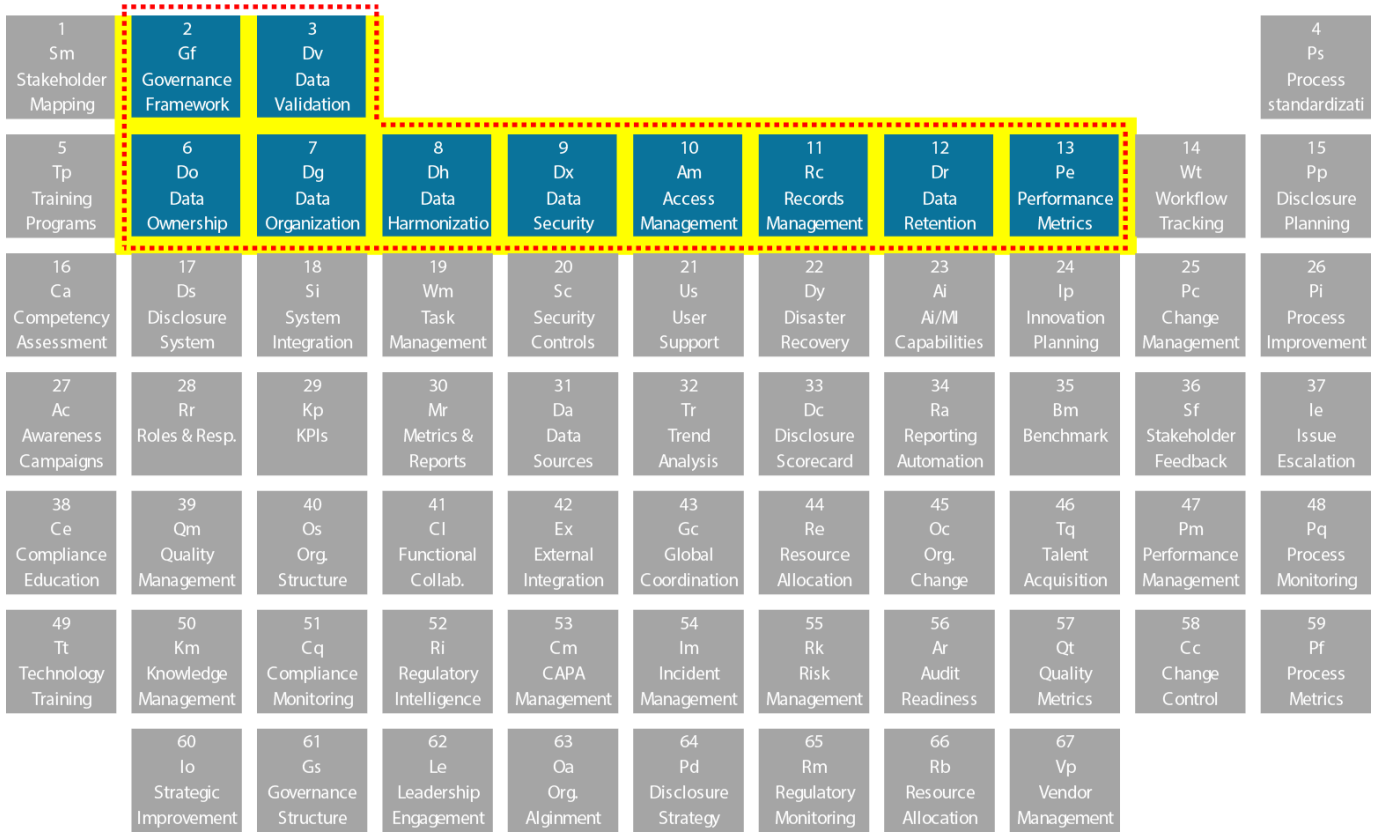
Data Governance Domain of the Clinical Trial Disclosure Maturity Model

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



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 clearly defined and understood across your organization?

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.

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.

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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, 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

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

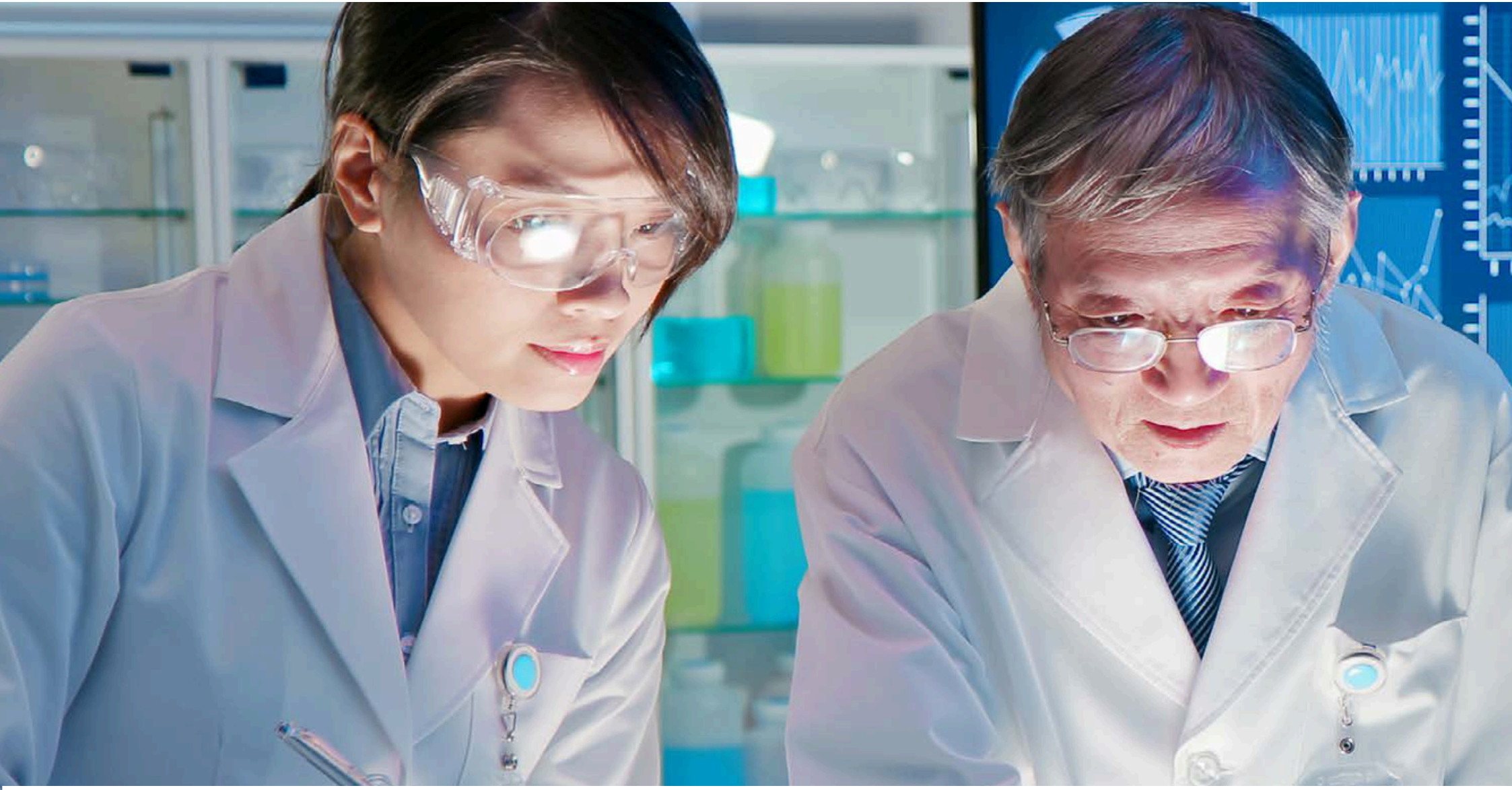
As we continue our series on the clinical trial disclosure maturity model, we encourage you to:

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.

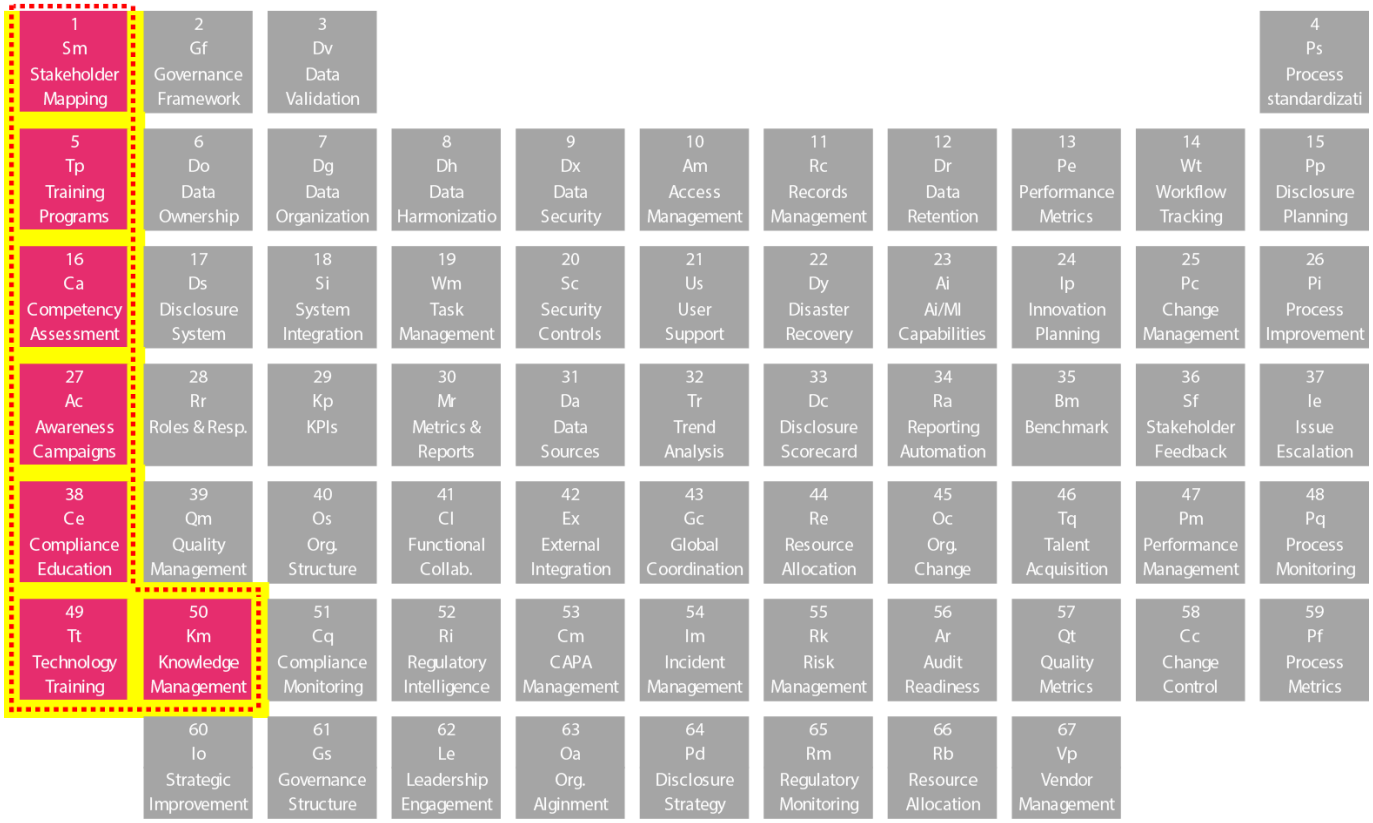


Training and Awareness Domain of the Clinical Trial Disclosure Maturity Model

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

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

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.

CITELINE

Organization Domain of the Clinical Trial Disclosure Maturity Model

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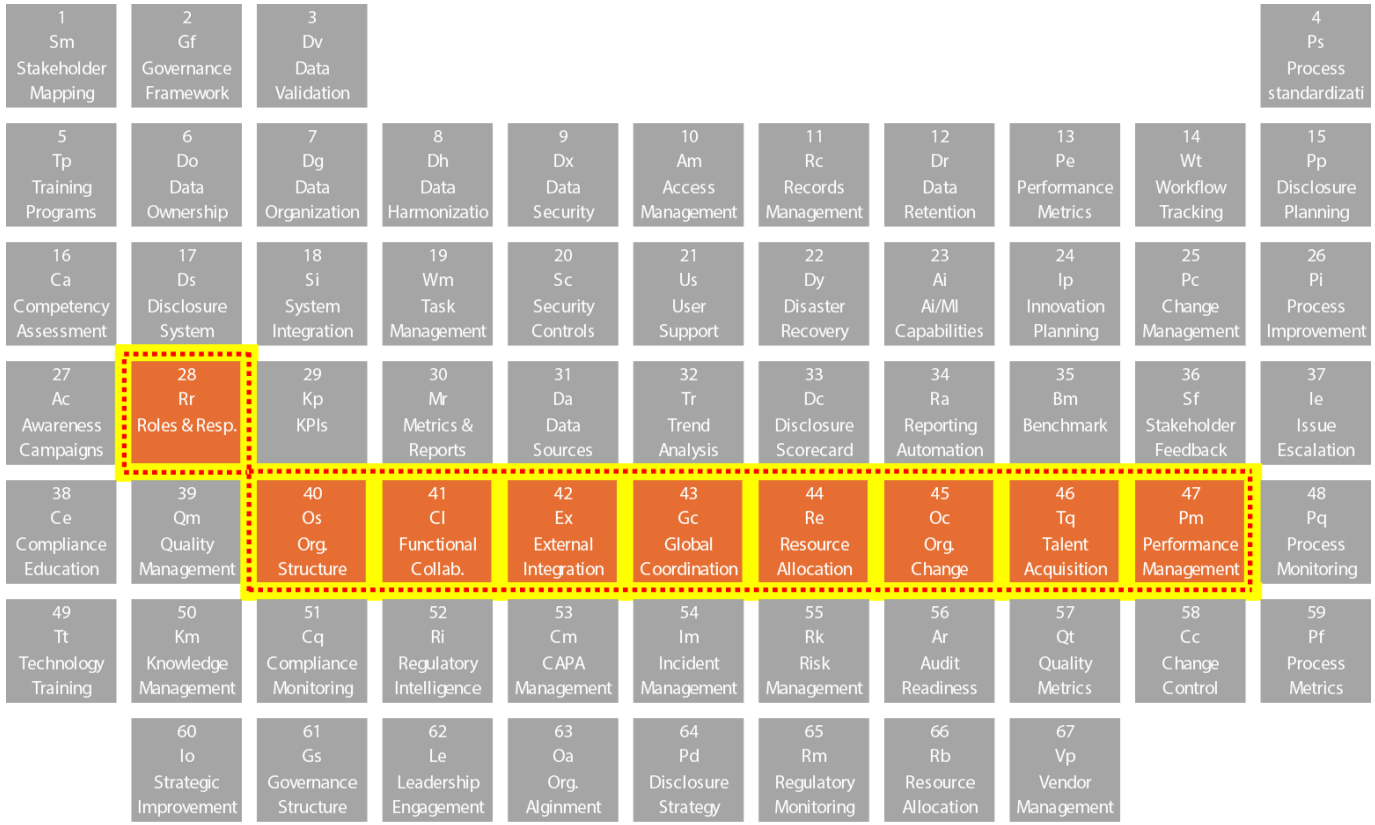
Organization Domain of the Clinical Trial Disclosure Maturity Model

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



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.
- **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.

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.

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:

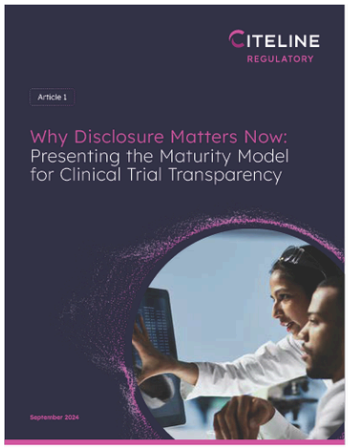
1. Use the comprehensive maturity assessment worksheet to assess your organization's maturity across all domains. This will provide valuable insights into your current state and areas for improvement.
2. Based on your assessment results, develop an action plan, prioritizing key areas for enhancement 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.

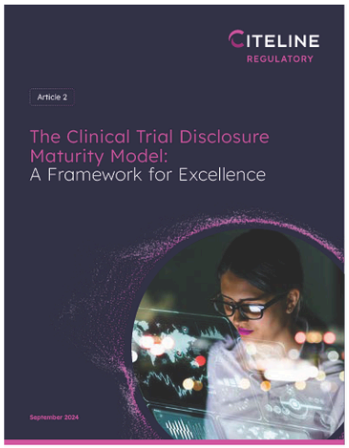
We hope this series has provided valuable insights into the various aspects of clinical trial disclosure maturity. Applying these concepts can enhance your organization's transparency, compliance, and effectiveness in clinical trial disclosure.

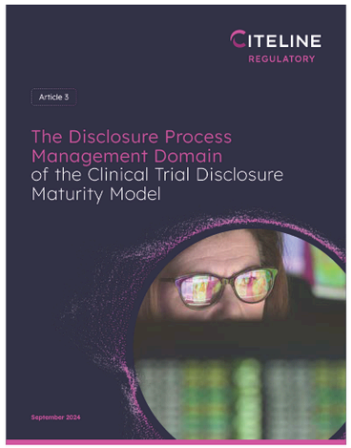
Remember, achieving disclosure maturity is an ongoing process. As the regulatory landscape evolves, so should your approach to clinical trial disclosure. Stay informed, remain adaptable, and strive for excellence in your disclosure practices.

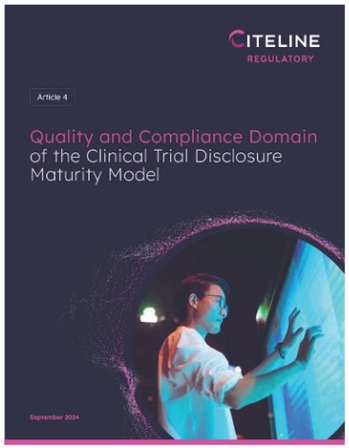
Contact our DISCLOSURE EXPERTS to learn more.

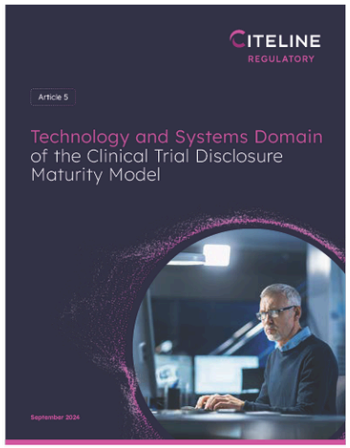
Articles Series: Maturity Model

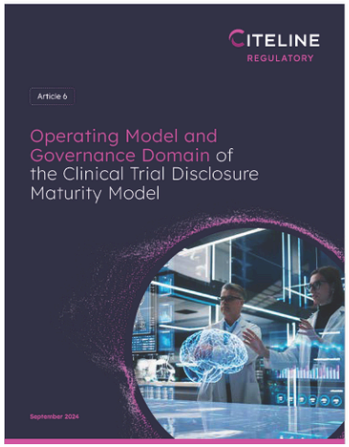


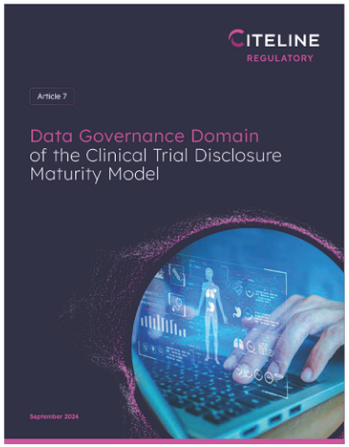


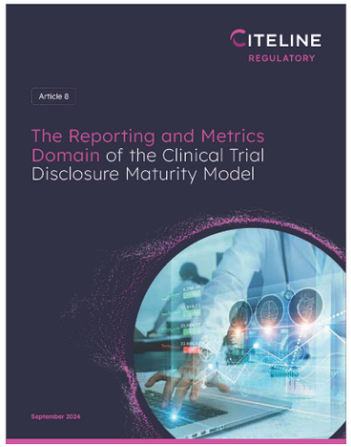


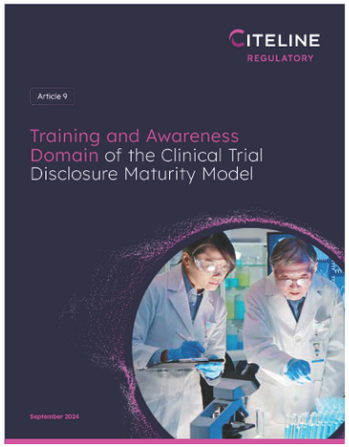


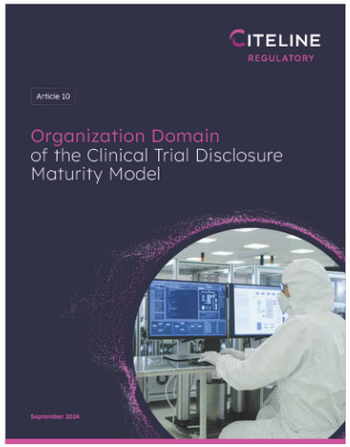












About the Author

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.