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Article 4

Quality and Compliance Domain of the Clinical Trial Disclosure Maturity Model

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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.

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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.

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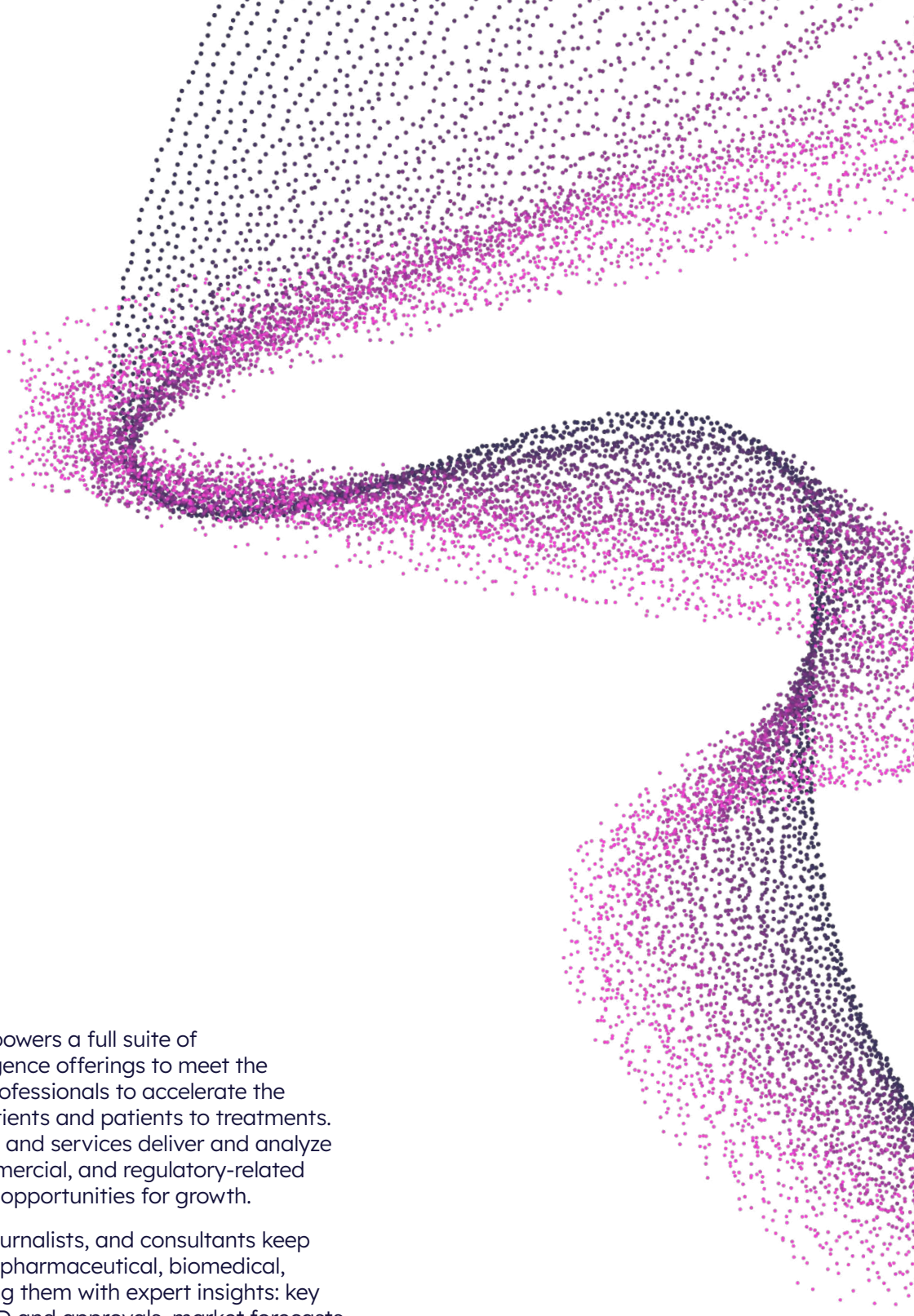

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Our global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them with expert insights: key diseases, clinical trials, drug R&D and approvals, market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

Articles Series: Maturity Model

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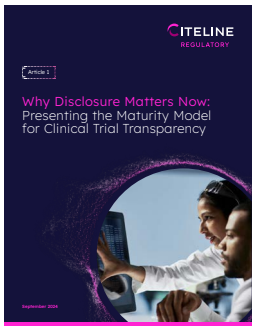

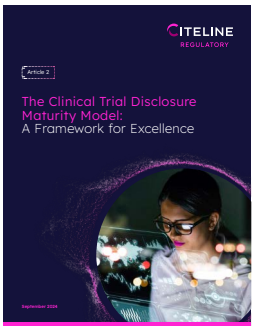

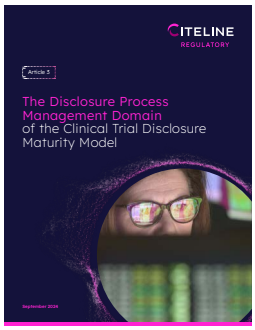

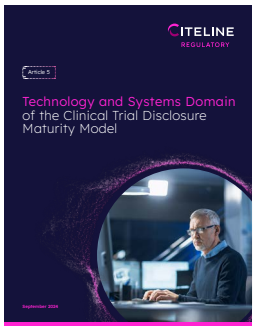

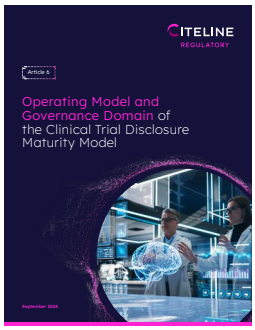

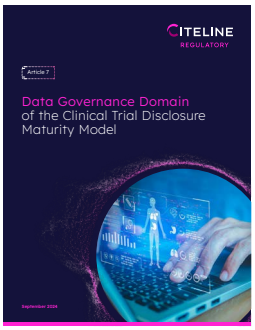

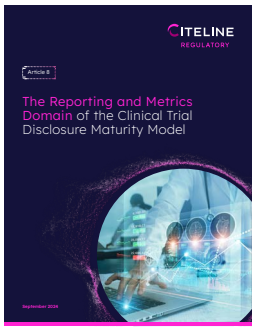

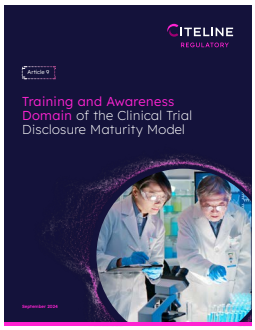

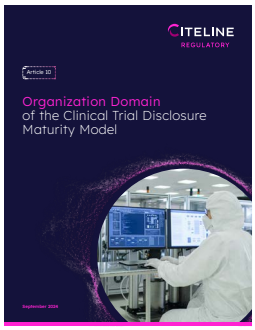

About the Author

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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.