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Article 10

Organization Domain of the Clinical Trial Disclosure Maturity Model

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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.

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- **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.

Assessing your maturity

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

- The clarity and comprehensiveness of role definitions for disclosure activities
- The effectiveness of interdepartmental collaboration on disclosure tasks
- How well your organizational structure supports efficient and compliant disclosure processes

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

- **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

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.

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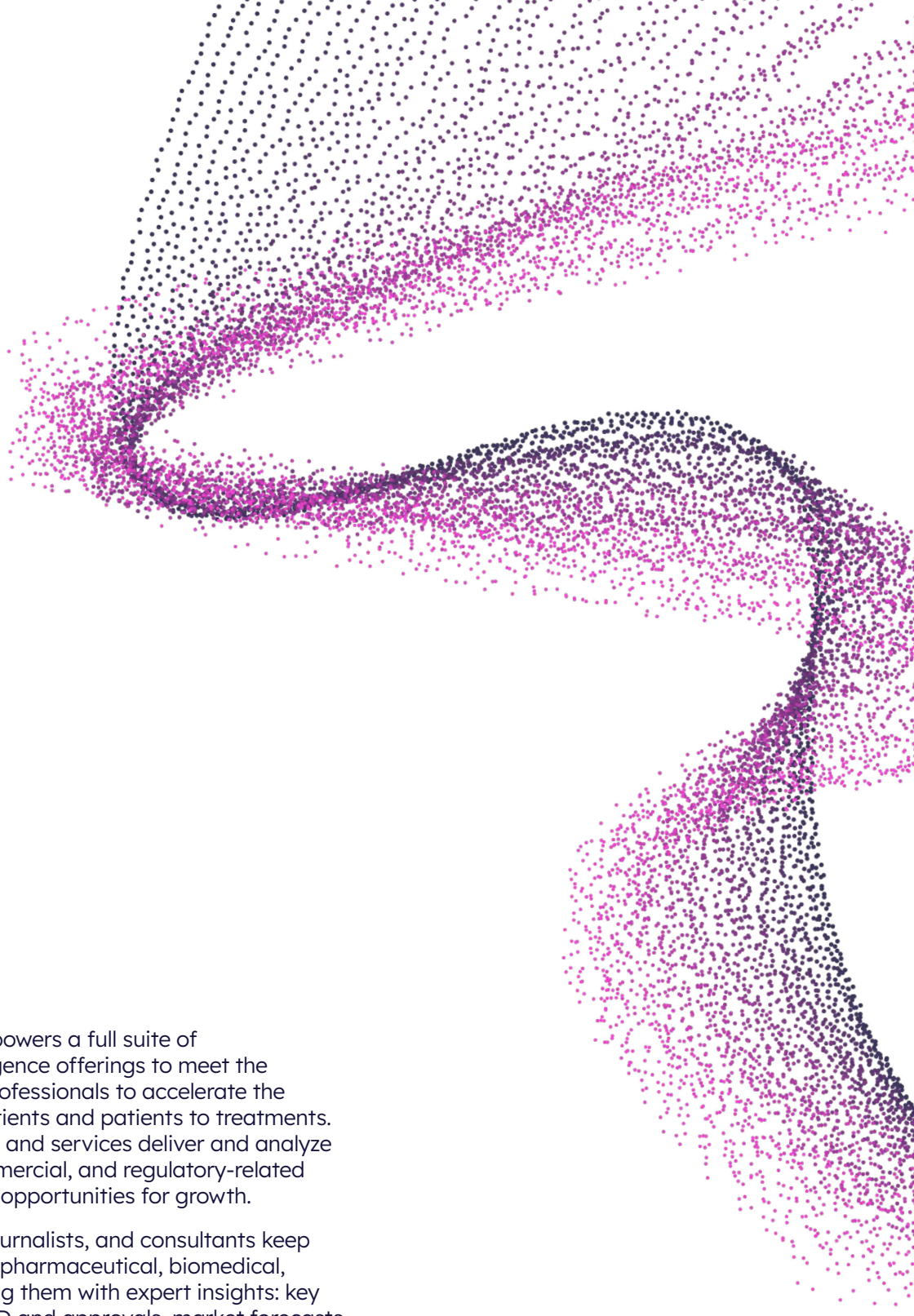

Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze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

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

Articles Series: Maturity Model

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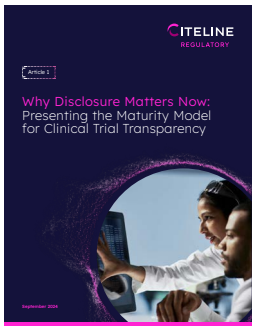

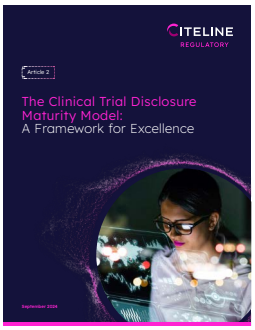

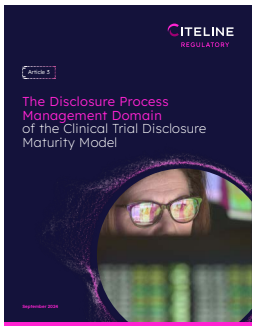

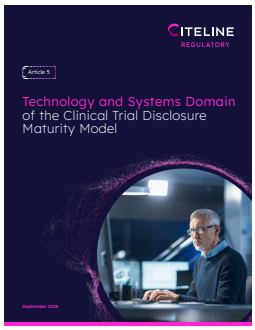

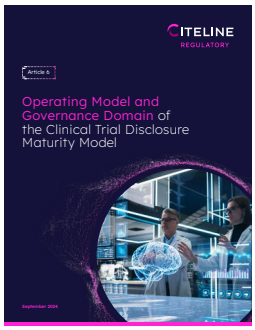

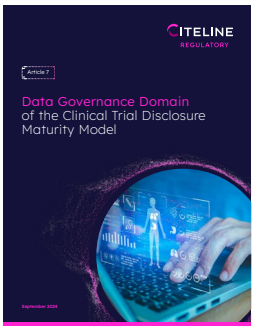

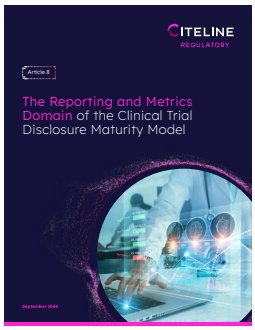

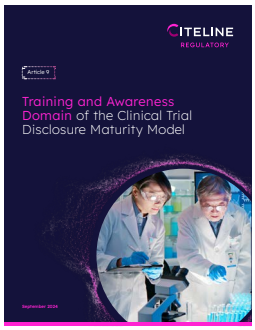

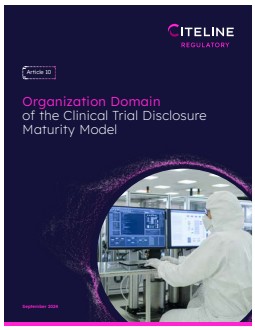

About the Author

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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.