CITELINE

REGULATORY

Article 6

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

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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.

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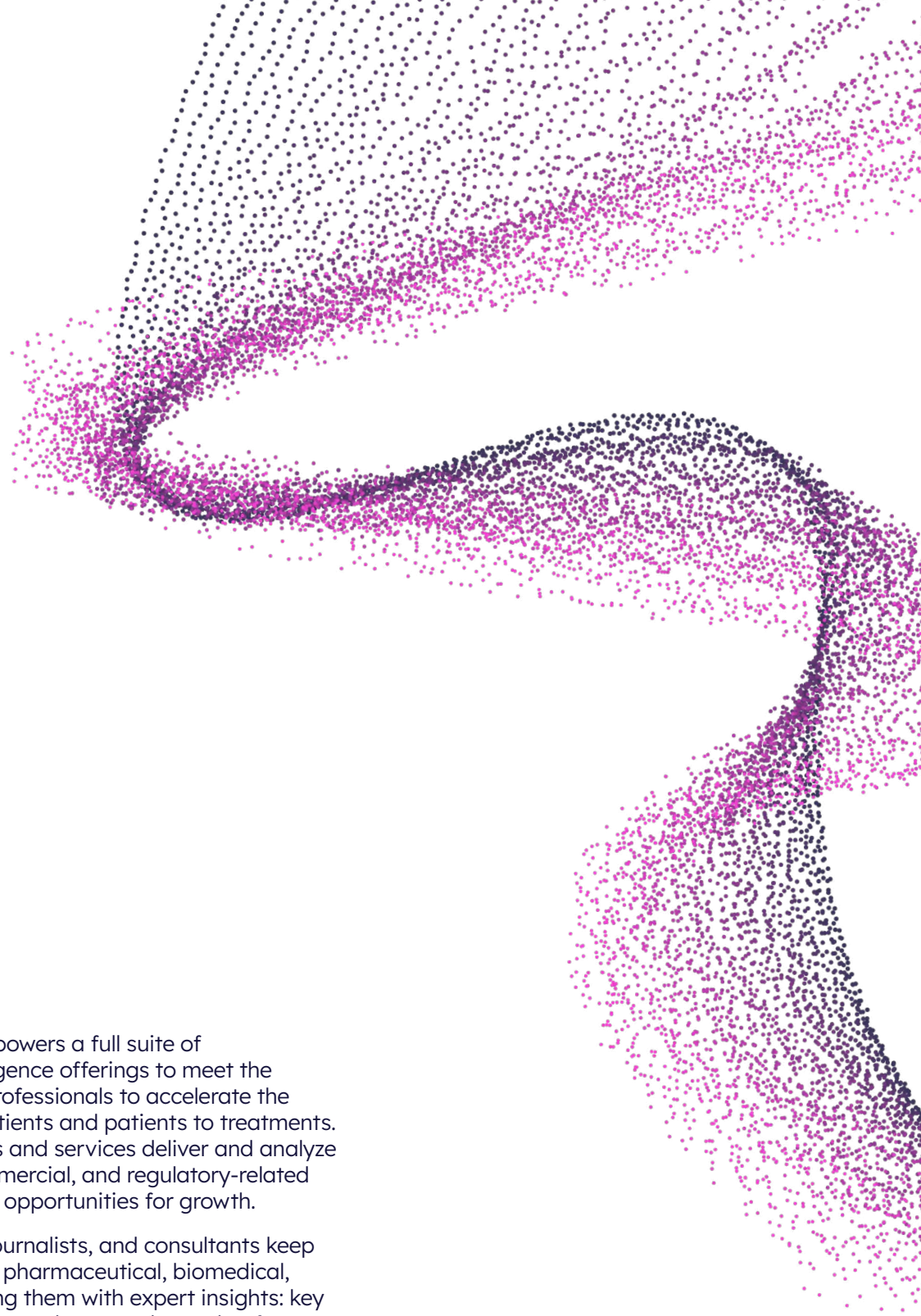
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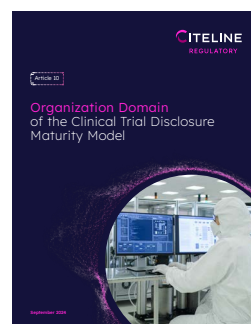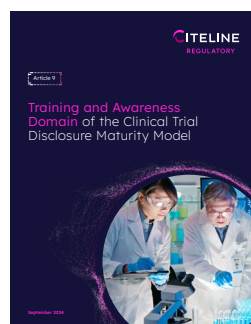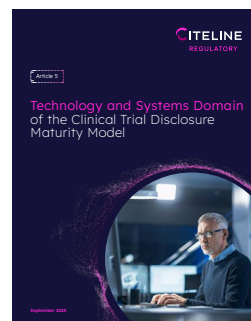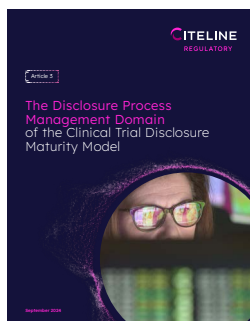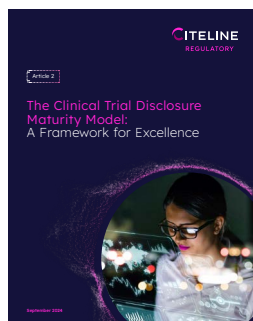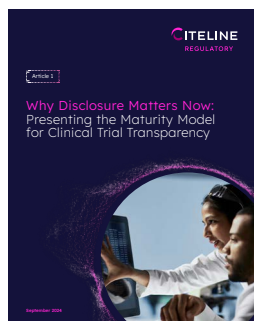
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About the Author

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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.

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