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Article 2

The Clinical Trial Disclosure Maturity Model: A Framework for Excellence

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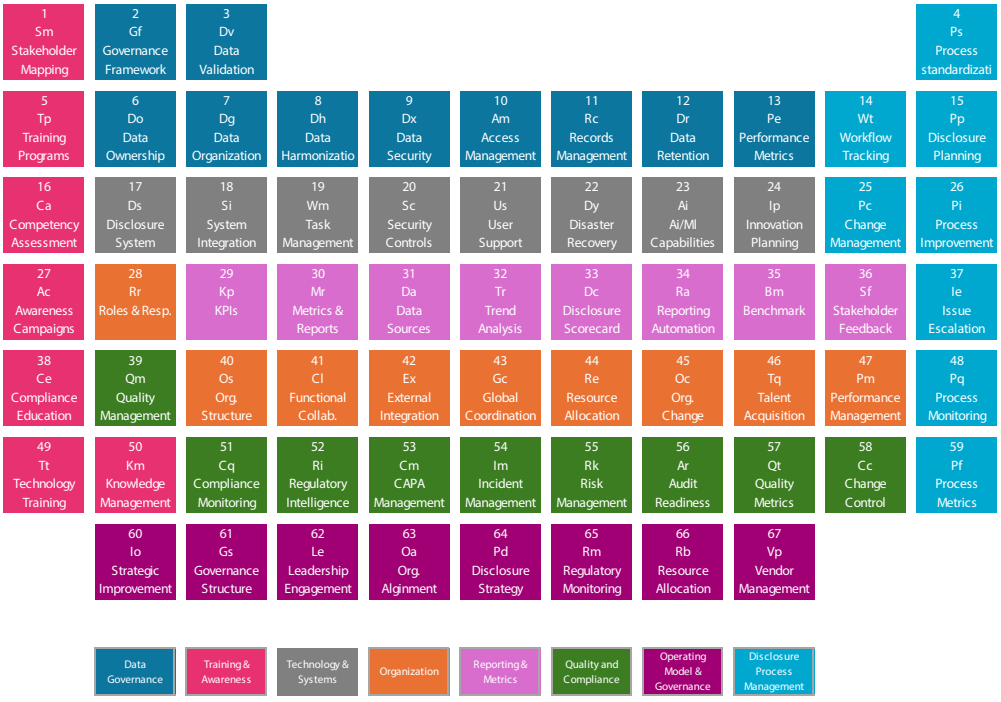

In today's complex and highly regulated clinical trial landscape, ensuring robust disclosure and transparency practices is more critical than ever. As stakeholders demand greater access to clinical trial information, organizations must establish strong processes and governance structures to meet these 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.

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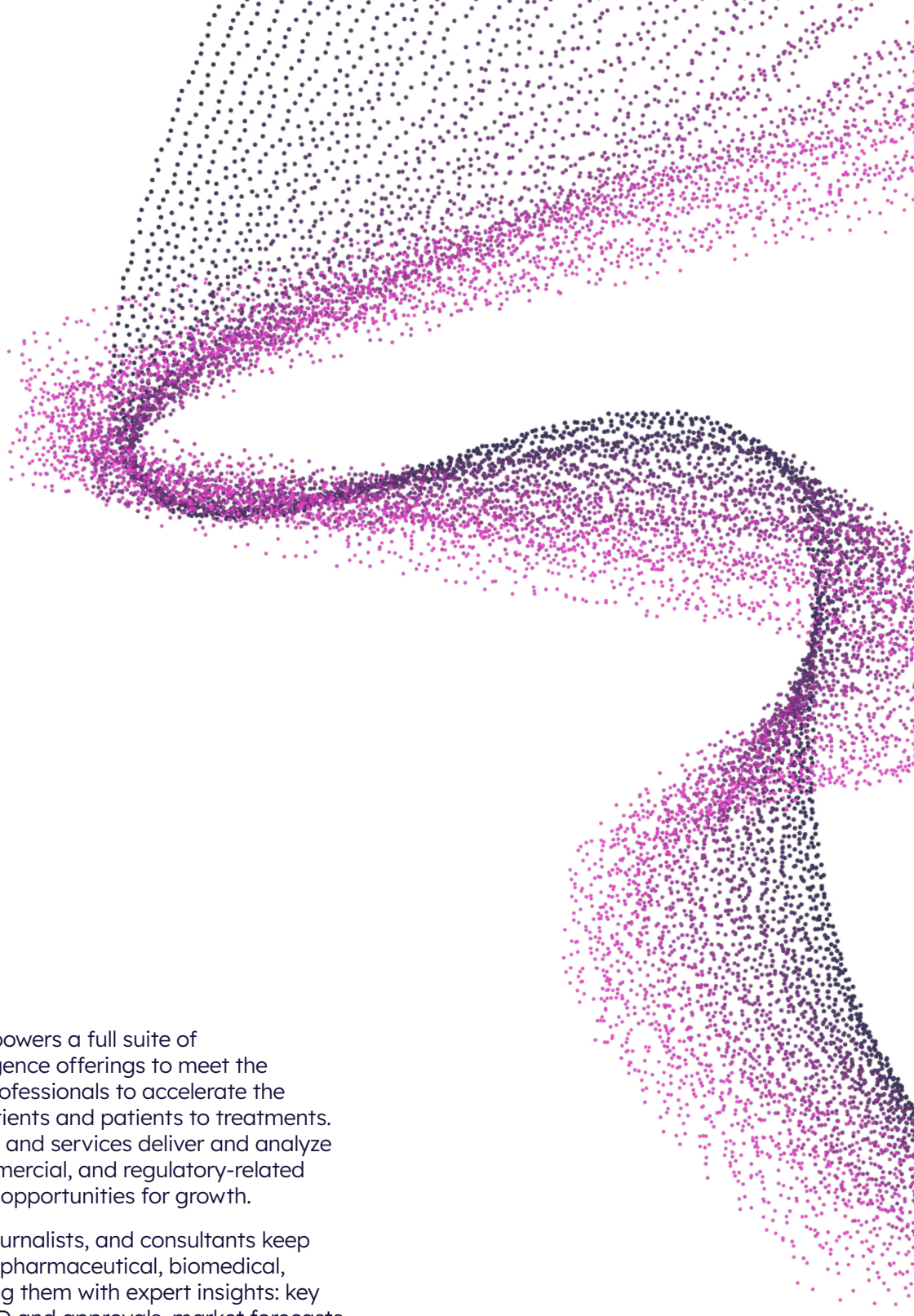

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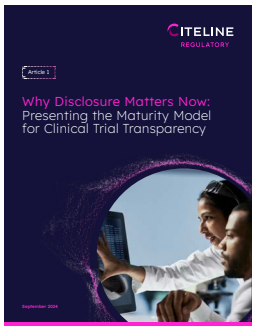

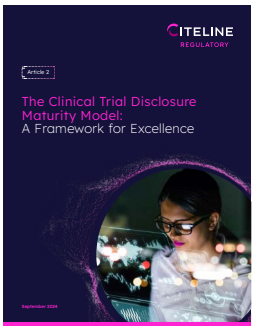

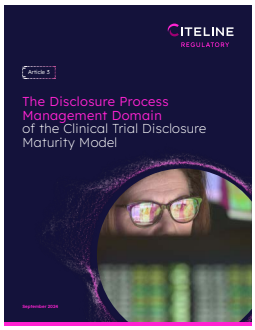

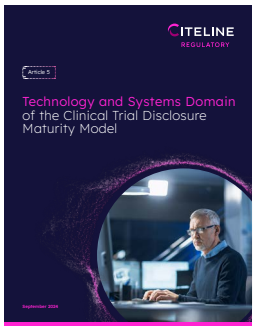

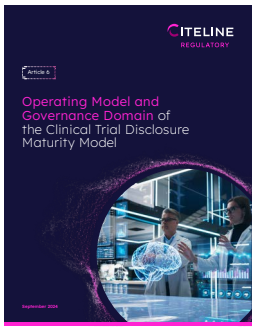

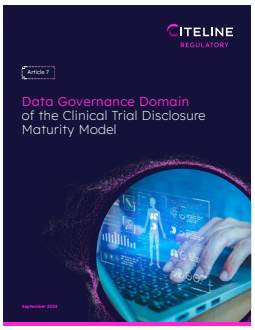

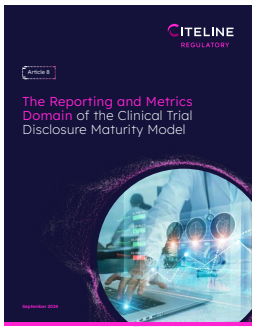

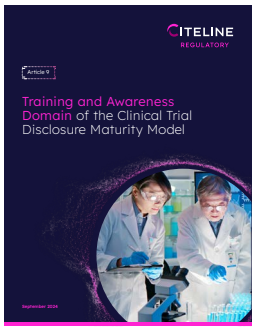

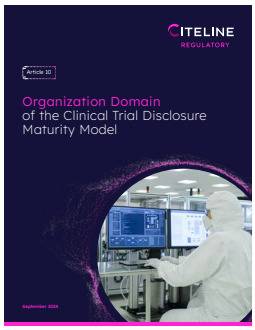

About the Author

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.