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Article 9

Training and Awareness Domain of the Clinical Trial Disclosure Maturity Model

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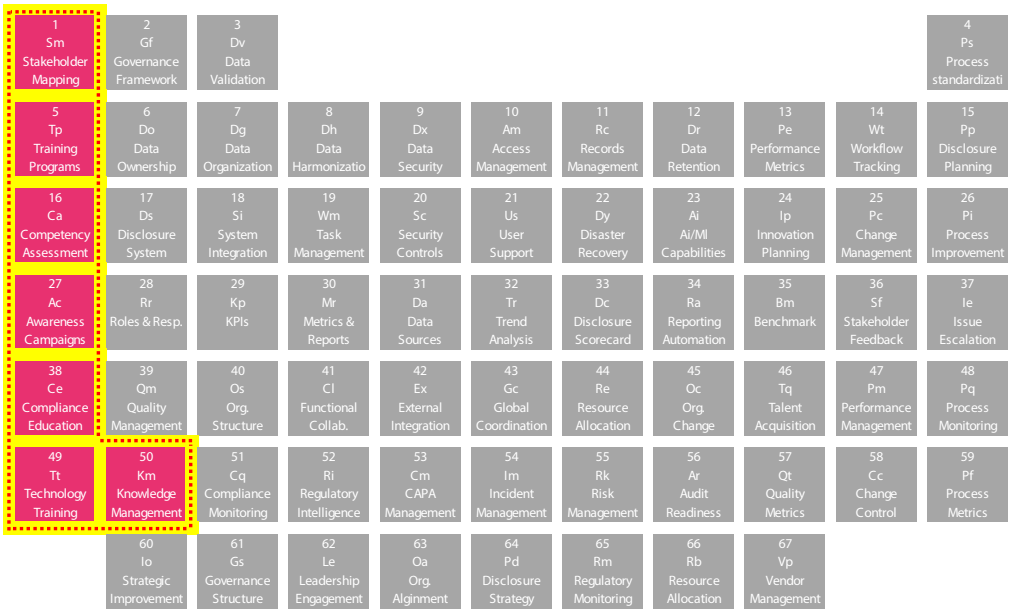

Executive summary

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.

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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:

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.

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

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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.

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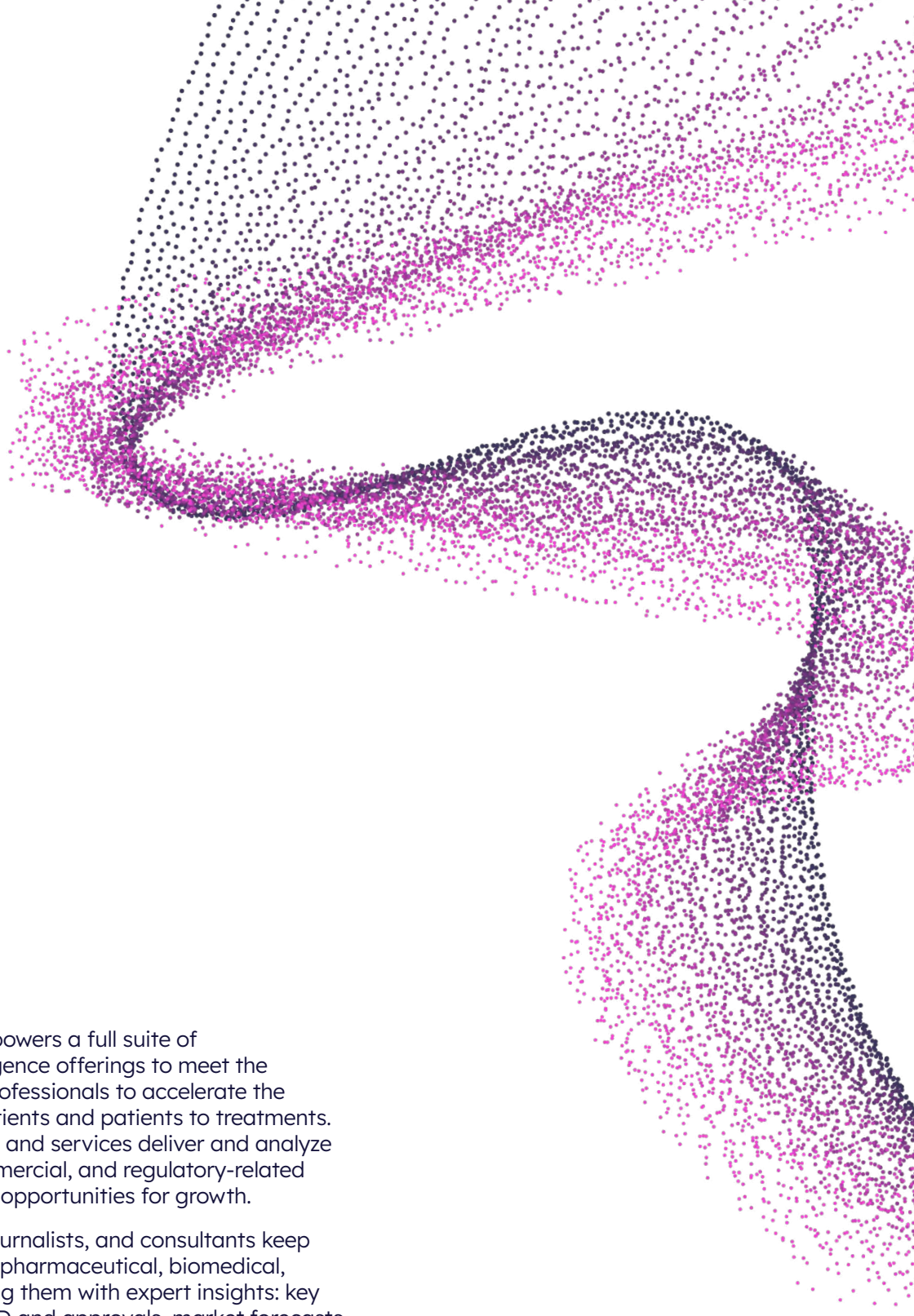

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Our global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them with expert insights: key diseases, clinical trials, drug R&D and approvals, market 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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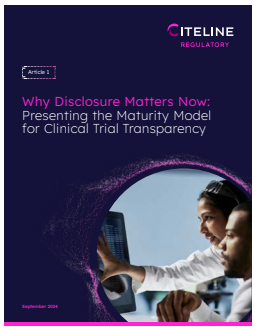

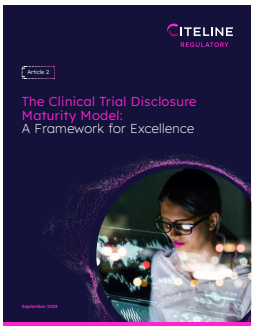

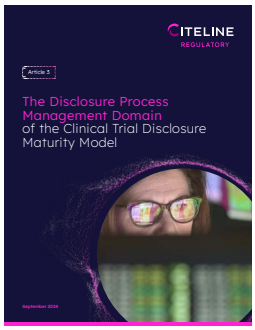

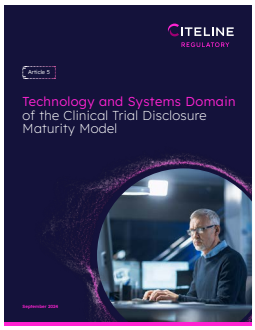

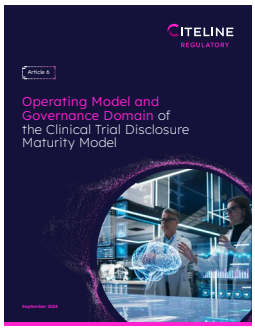

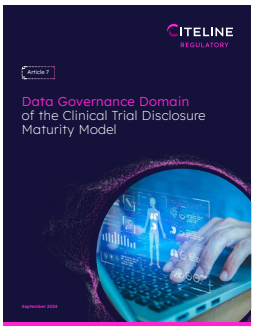

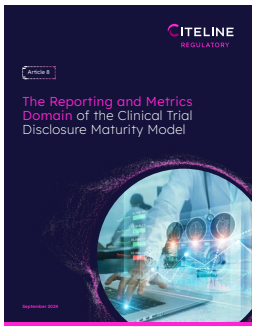

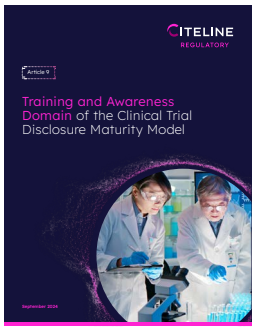

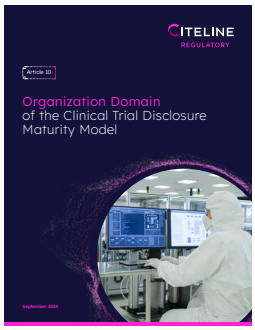

About the Author

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.