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Article 5

Technology and Systems Domain of the Clinical Trial Disclosure Maturity Model

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Executive summary

The technology and systems domain focuses on the digital infrastructure and tools that support clinical trial disclosure processes. This domain encompasses dedicated disclosure systems, integration with other clinical trial data management tools, and workflow automation. Effective technology and systems are essential for efficient, accurate, and compliant disclosure practices in an increasingly complex regulatory landscape.

Why this domain matters

Technology and systems are the engines that drive efficient and accurate clinical trial disclosure. This domain encompasses the digital tools and infrastructure that support, automate, and enhance disclosure activities. By leveraging appropriate technology, organizations can streamline processes, reduce errors, and gain valuable insights into their performance, supporting efficient clinical disclosure processes and enabling:

- **Process automation** that reduces manual effort and human error in disclosure activities, improving accuracy and efficiency
- **Data consistency** through integrated systems, ensuring consistency across disclosure documents and registries
- **Scalability** based on robust technology solutions that can handle increasing disclosure requirements as trial portfolios grow and expand into new countries, supporting sponsors conducting trials across more diverse regulatory environments
- **Real-time compliance tracking** with advanced systems, providing up-to-date compliance status and alerts for upcoming deadlines
- **Audit trails** that support inspection readiness through detailed logs of disclosure and systems administration activities

Potential risks of underinvestment in technology and systems

Underinvestment in technology and systems for clinical trial disclosure can significantly hinder an organization's ability to meet transparency

obligations efficiently and effectively. Reliance on outdated or inadequate systems can lead to manual errors, data inconsistencies, and missed deadlines, compromising compliance and data quality. Furthermore, the lack of robust technological infrastructure can impede an organization's ability to scale its disclosure activities, adapt to changing regulatory requirements, and gain valuable insights from disclosure data. Specific challenges include:

- **Inefficient resource utilization:** Without automation, staff may spend excessive time on repetitive tasks rather than value-added activities.
- **Missed deadlines:** A lack of automated tracking and alerts can result in overlooked disclosure deadlines.
- **Manual errors:** Reliance on manual processes increases the risk of data-entry errors and inconsistencies.
- **Siloed content:** Disconnected disclosure systems and processes can lead to inconsistent and even confidential information being disclosed across different registries.
- **Limited visibility:** Without centralized systems, organizations may struggle to view their disclosure status and compliance comprehensively.

Key elements of technology and systems

Dedicated clinical trial disclosure systems

Central to this domain is a purpose-built system for managing clinical trial disclosures. This system should include workflow management, dashboards, and reporting capabilities.

Maturity levels:

- **Lagging:** No dedicated disclosure system exists. The organization relies on manual processes and general-purpose tools like spreadsheets.
- **Developing:** A basic disclosure management system is in place but has limited functionality or is not fully utilized across the organization.
- **Leading:** A comprehensive, fully integrated disclosure management system with advanced features for workflow automation, compliance tracking, and reporting is in place.

The main capabilities of a disclosure system should include:

- Centralized data management for multiple global registries
- Automated compliance tracking and deadline alerts
- Workflow automation and task management
- Integration capabilities with other clinical trial systems
- Version control and audit trail functionality
- Real-time reporting and analytics dashboard
- Document management and storage
- Role-based access controls and permissions
- Automated data validation and consistency checks
- Multilingual support for global submissions

These components collectively form the backbone of an efficient and compliant clinical trial disclosure system. By automating key processes, ensuring data consistency, and providing comprehensive monitoring, such a system streamlines disclosure activities and significantly reduces noncompliance risk.

System integration

Integrating disclosure systems and other clinical trial management tools — e.g., clinical trial management systems (CTMS), SAS, electronic data capture (EDC), and regulatory systems — is valuable for data consistency and efficiency.

Maturity levels:

- **Lagging:** Systems operate in silos with manual copy/paste data transfer among platforms.
- **Developing:** Some integration exists but may be limited or require manual intervention.
- **Leading:** Seamless, automated integration among disclosure systems and other relevant platforms, ensuring real-time data synchronization.

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Workflow & task management tools
These tools automate and streamline the disclosure process, from initial registration to results posting.

Maturity levels:
- **Lagging:** No formal workflow tools exist. Tasks are managed manually or through basic tools like email and calendars.
- **Developing:** Basic workflow management is in place but may lack advanced features or full adoption.
- **Leading:** Sophisticated workflow tools automate task assignments, track progress, and provide real-time status updates.

Assessing your maturity

To evaluate your organization's maturity in the technology and systems domain, consider the functionality and integration of your current systems, including the key elements discussed above and the additional attributes listed in the sidebar. How automated are your disclosure processes? How well do your clinical data sources integrate with the disclosure system? Do you have real-time visibility into your disclosure status and compliance?

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 technology and systems in clinical trial disclosure varies significantly based on the size and complexity of a sponsor's trial portfolio. While all sponsors need some technological support for their disclosure activities, the scale of operations, available resources, and specific needs will influence the choice and implementation of these systems.

Organizations must carefully consider their current requirements and future growth plans when selecting and deploying disclosure technologies, balancing functionality with cost-effectiveness, efficiency, and scalability:

Sponsors with smaller trial portfolios might start with solutions that offer core functionality without significant upfront investment or implementation effort. They should focus on systems that provide up-to-date intelligence on disclosure requirements, automate core disclosure tasks, and provide basic compliance tracking.

Sponsors with more extensive trial portfolios typically benefit from comprehensive and configurable solutions. These typically include advanced analytics, global registry support, and extensive integration with other clinical systems.

Additional domain elements

- **Security controls:** measures to protect sensitive information, manage user permissions, and maintain a detailed history of system activities and changes
- **User support:** processes for keeping users proficient, addressing issues, maintaining system health, and implementing improvements
- **Disaster recovery:** plans and capabilities to ensure system availability during disruptions and support for accessing systems from various locations and devices
- **AI/ML capabilities:** advanced technologies for automating complex tasks, predicting outcomes, and enhancing decision-making in disclosure processes
- **Innovation planning:** strategic planning for future technological needs and adoption of emerging technologies to improve disclosure processes

Getting started: practical tips

- **Conduct a systems audit:** evaluate your current technology landscape and identify gaps in disclosure management capabilities.
- **Embrace automation:** look for opportunities to automate repetitive tasks in your disclosure processes, such as data population and consistency checks across multiple registries.
- **Start with core functionalities:** when implementing a new system, begin with essential features and gradually expand capabilities.
- **Evaluate specialized solutions:** consider replacing general-purpose or home-grown systems with a targeted disclosure management platform to meet evolving regulatory requirements.
- **Prioritize integration:** to reduce manual data entry, integrate your disclosure system with data sources like your CTMS or trial status reports from contract research organizations (CROs).

How we can help

TrialScope Disclose: provides a centralized platform for managing global clinical trial disclosures, offering automated workflows, compliance tracking, and integration capabilities. It streamlines processes across multiple registries, reducing manual effort and improving data consistency.

TrialScope Intelligence: this solution offers a comprehensive database of global disclosure requirements, helping sponsors stay updated on regulatory changes. It supports informed decision-making in system configuration and process automation to meet evolving compliance needs.

TrialScope Disclosure Services: bridges the gap for sponsors without integrated disclosure systems by offering expert-managed disclosure processes. Our team leverages advanced tools and best practices to handle disclosure tasks efficiently, allowing sponsors to benefit from streamlined and reliable processes.

Trial Summaries Portal: this provides a dedicated platform for sharing plain-language summaries, automating the distribution of trial results to participants and the public.

Conclusion

Investing in technology and systems is essential for efficient, accurate, and compliant clinical trial disclosure. By leveraging advanced tools and integrating data across systems, organizations can streamline processes, reduce errors, and maintain a comprehensive view of their disclosure activities.

Next steps

The next article in this series will explore the operating model & governance domain of the clinical trial disclosure maturity model, discussing how organizational structures, policies, and processes guide and control disclosure activities. We'll examine policy development, regulatory monitoring, and governance structures that ensure effective and compliant disclosure practices. We encourage you to use the insights from this article and the self-assessment workbook to assess and enhance your current technology and systems for clinical trial disclosure.

Contact our DISCLOSURE EXPERTS to learn more.

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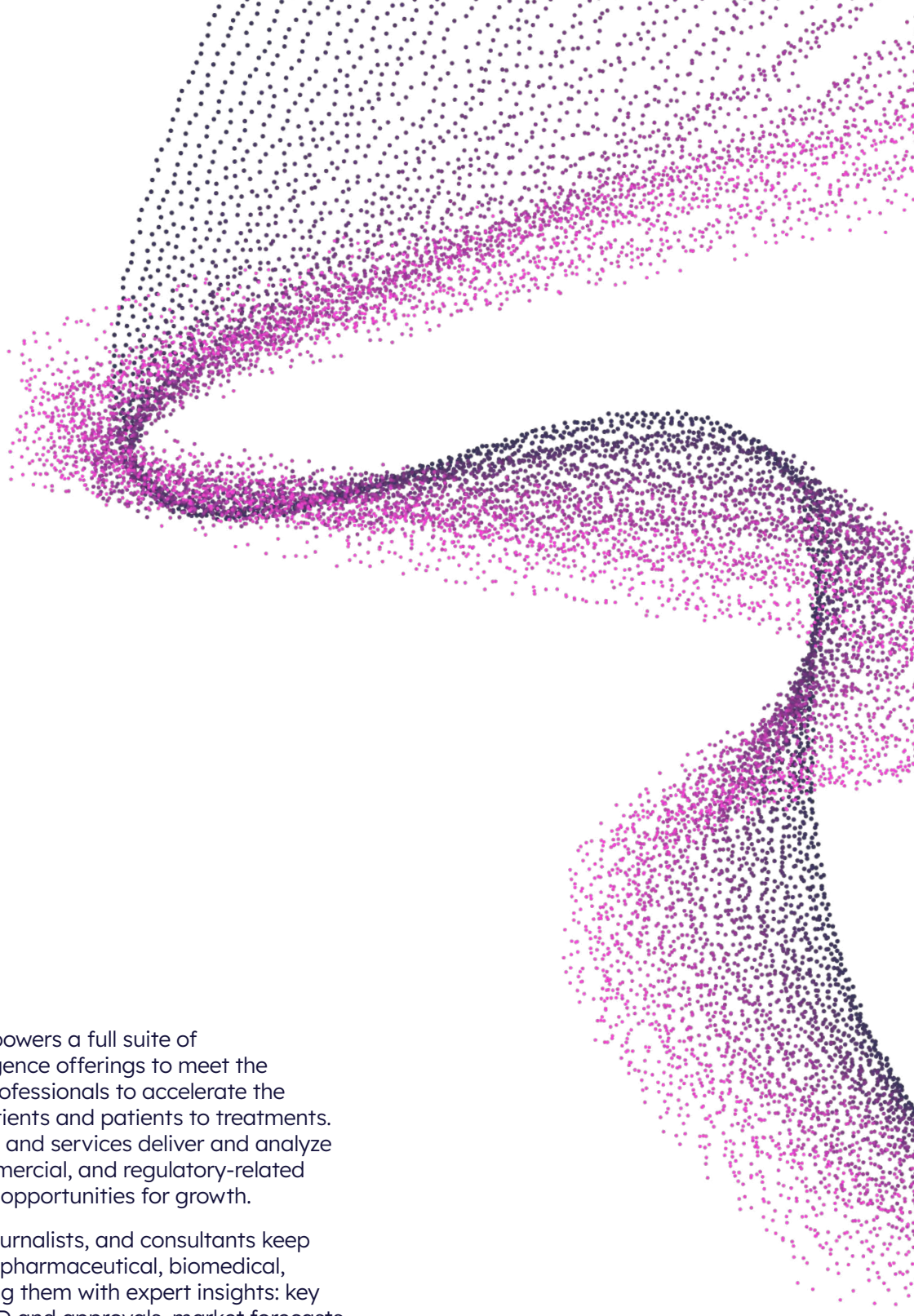

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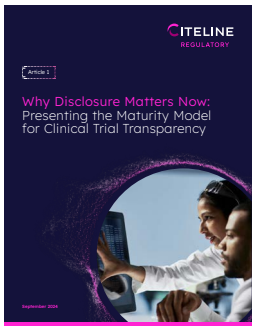

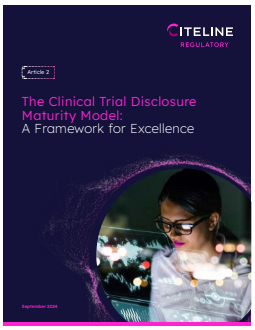

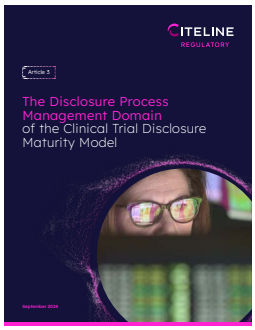

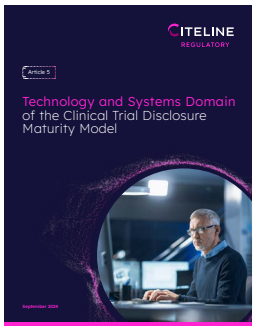

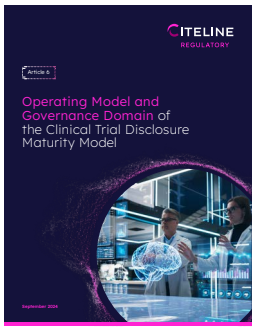

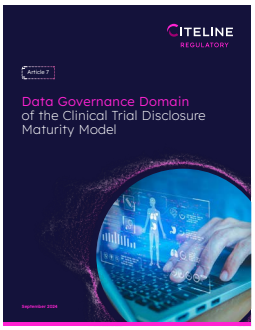

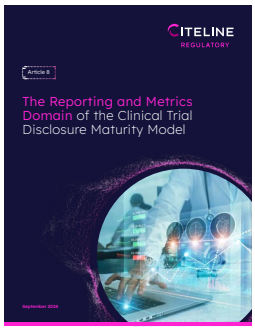

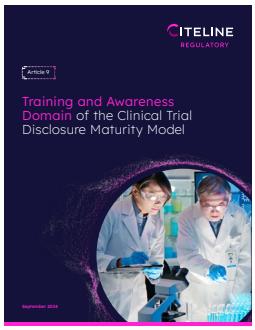

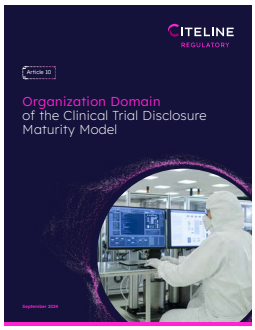

About the Author

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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.