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Article 3

The Disclosure Process Management Domain of the Clinical Trial Disclosure Maturity Model

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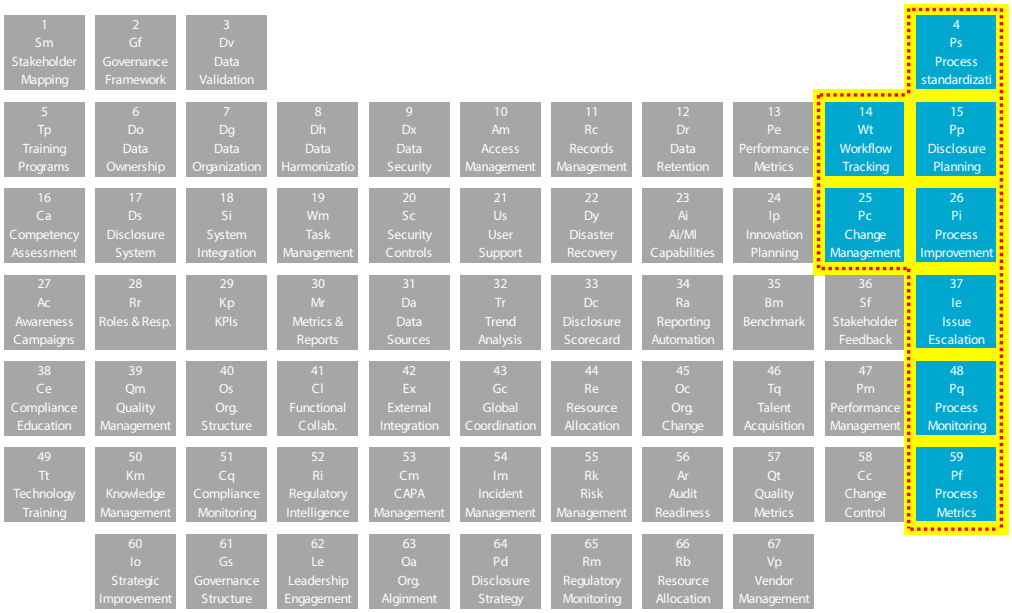

Executive summary

Disclosure process management is the systematic way of organizing and carrying out activities related to clinical trial disclosure. This includes creating, implementing, and overseeing clear and consistent processes for the accurate and timely disclosure of clinical trial information. Disclosure process management is not merely an administrative task but the foundation of effective clinical trial transparency. Strong performance in this domain is a prerequisite for consistent, efficient, and compliant disclosure practices. By implementing standardized processes, organizations can minimize errors, improve efficiency, and consistently meet regulatory requirements.

Why this domain matters

The disclosure process management domain is the operational core of clinical trial transparency efforts. It shapes how organizations execute their disclosure activities, from initial planning to final publication. Effective process management ensures disclosure tasks are performed consistently, efficiently, and in compliance with regulatory requirements, regardless of the complexity of the trial or the variety of disclosure obligations. Well-defined disclosure processes are essential for several reasons:

- **Defending inspections:** Health authorities are increasingly scrutinizing disclosure compliance, so sponsors must be ready to defend inspections, especially in the US, the EU, and the UK.
- **Operational efficiency:** Standardized workflows streamline disclosure activities, saving time and resources.
- **Improved compliance:** Established processes ensure adherence to evolving regulatory requirements.
- **Reduced errors:** Clear procedures minimize the risk of inconsistencies and inaccuracies in disclosure documents.
- **Stronger collaboration:** Defined roles and responsibilities facilitate seamless collaboration among teams involved in disclosure.

Potential risks of weak disclosure processes

Inadequate disclosure process management can expose organizations to significant regulatory, operational, and reputational risks. Sponsors need well-defined, standardized processes to meet disclosure requirements consistently across various registries and jurisdictions. The absence of a systematic approach often results in errors, inefficiencies, and compliance failures that undermine the integrity of clinical trial transparency efforts. Specific risks include:

- **Delayed disclosures:** Missed deadlines can hinder public access to important clinical trial information.
- **Inconsistent data:** Inconsistencies in reported data can erode trust and raise questions about the validity of the trial results. Without global coordination, sponsors may inadvertently disclose company-confidential information, making it impossible to redact the information later and risking rejection of patent applications.
- **Regulatory violations:** Noncompliance with disclosure requirements can lead to penalties and reputational damage.

Key elements of disclosure process management

Process standardization & harmonization

Create standard operating procedures (SOPs) and practices across the disclosure processes. Aligning methods across departments and organizations ensures consistency, improves efficiency, and reduces errors. These SOPs should be up to date and consistently applied across all trials and registries.

Maturity levels:

As with other domains in the disclosure maturity model, process standardization and harmonization can be categorized as lagging, developing, or leading.

- **Lagging:** Disclosure processes are ad hoc and inconsistent. SOPs may be missing or outdated.
- **Developing:** Documented SOPs exist but may not be consistently followed or lack sufficient detail.
- **Leading:** Comprehensive and up-to-date SOPs govern all disclosure activities. Processes are harmonized across trials and registries, ensuring consistent and reliable disclosure practices.

The main components of process standardization and harmonization in clinical trial disclosure include:

- Standardized workflows for disclosure activities (e.g., protocol registration, results disclosure, updating trial records)
- Consistent processes for collecting and validating disclosure data from various internal sources
- Harmonized data-entry processes for various disclosure platforms
- Standardized timelines and milestone tracking for disclosure tasks
- Standardized procedures for updating and maintaining disclosed information

Workflow management & tracking

Focus on designing, implementing, and monitoring the flow of tasks in the disclosure process. It includes tools and systems to track progress, assign responsibilities, and manage deadlines throughout the disclosure lifecycle. Effective disclosure requires precise and efficient workflows that track the progress of disclosure activities. This includes assigning tasks, managing deadlines, and monitoring completion.

Maturity levels:

- **Lagging:** Workflows are manual and lack oversight. There is no systematic tracking of disclosure activities.
- **Developing:** Essential workflow tools may be used, but processes are not fully optimized. Tracking may be inconsistent.
- **Leading:** Automated workflow management systems are implemented, ensuring efficient task assignment, progress tracking, and timely completion of disclosure activities.

Disclosure planning
Effective planning is crucial for managing complex clinical trials and ensuring timely disclosure. This involves defining the scope of disclosure, setting timelines for each stage, allocating resources, and assigning responsibilities. For instance, the plan should detail what information must be made public, where the data will be disclosed, who will be responsible, and by what deadline.

Maturity levels:
Lagging: Disclosure activities are reactive and unplanned. Deadlines are frequently missed.
Developing: Basic project plans may be used but not comprehensive or consistently followed.
Leading: Formal project management methodologies are used to create and manage detailed disclosure plans that consider all aspects of the disclosure process.

Assessing your maturity

Beyond the three elements listed above, assessing the level of maturity in disclosure process management requires looking at all eight components of the domain, especially the capabilities around process monitoring and performance metrics.

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 disclosure process management may vary based on the size and complexity of a sponsor's trial portfolio. While all sponsors need to establish effective processes for clinical trial disclosure, the scale of operations and available resources will influence the implementation of these processes. 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, precise, and up-to-date Standard Operating Procedures (SOPs) for essential disclosure activities. They may have simpler workflows but should still ensure that processes are well-documented and consistently followed. Smaller sponsors might prioritize manual quality checks and rely more on individual expertise, focusing on cross-training team members to ensure coverage of all disclosure responsibilities.

Sponsors with more extensive trial portfolios typically benefit from more sophisticated process management approaches. They often prioritize the automation of routine tasks and implement advanced project management techniques to handle the complexity of numerous concurrent trials. These sponsors

Additional domain elements

- **Process change management:** Handle process modifications, assess impacts, and ensure smooth transitions during implementation
- **Issue escalation and resolution:** Establish protocols to identify, report, and address problems efficiently in the disclosure process
- **Process improvement cycle:** Continuously analyze and refine specific disclosure processes, using feedback and metrics to enhance operational efficiency
- **Process monitoring:** Identify potential risks, evaluate their impact, and implement controls to minimize adverse effects
- **Process performance metrics:** Define and analyze KPIs to evaluate efficiency and drive improvements in disclosure management

usually invest in comprehensive workflow management systems, develop detailed SOPs covering various disclosure scenarios, and may have dedicated teams for different aspects of the disclosure process. They focus on scalability and consistency across many disclosures and implement centralized oversight mechanisms to ensure uniform practices across different therapeutic areas or global regions.

Getting started: practical tips

- **Identify gaps:** complete the disclosure process management worksheet to evaluate your company's maturity in this domain and identify areas for improvement.
- **Develop core SOPs:** start by creating or updating SOPs for core disclosure activities, such as content creation, submission, and amendment processes. For example, develop an SOP outlining the steps to create and submit the initial trial registration on a public registry.

How we can help

TrialScope Disclose: our centralized platform automates data entry and reporting for global trial registries. This automation reduces manual effort and potential errors, allowing your team to focus on strategic tasks rather than paperwork. TrialScope Disclose can significantly improve your process standardization and workflow management, which are critical elements of mature disclosure process management.

TrialScope Intelligence: this solution provides a centralized, interactive repository of critical regulatory knowledge for global clinical trial disclosure compliance. It can help you stay up-to-date with evolving disclosure requirements, supporting your efforts to maintain compliant and efficient processes. TrialScope Intelligence is valuable for enhancing regulatory monitoring capabilities and informing disclosure planning.

TrialScope Disclosure Services: our team of experts can act as an extension of your team, handling time-consuming disclosure activities from protocol registration through results posting, redaction, and anonymization. We also offer advisory services to help draft corporate transparency policies, disclosure SOPs, and compliance assessments to audit past disclosures. These services can be invaluable in establishing and maintaining robust processes, especially for organizations looking to standardize and harmonize their approach to global disclosure.

Conclusion

Strong disclosure process management is critical to a mature clinical trial disclosure program. By investing in well-defined processes, organizations can achieve greater efficiency, accuracy, and compliance in their disclosure practices.

Next steps

Next, we will explore the **quality and compliance** domain, exploring how organizations can ensure accuracy, consistency, and regulatory adherence in their clinical trial disclosures. We'll examine quality management systems, compliance monitoring, and regulatory intelligence strategies. We strongly encourage you to assess your current disclosure processes and identify areas for improvement using the insights provided in this article and the self-assessment workbook. This proactive approach will help you enhance your work and contribute to your organization's overall success.

Contact our DISCLOSURE EXPERTS to learn more.

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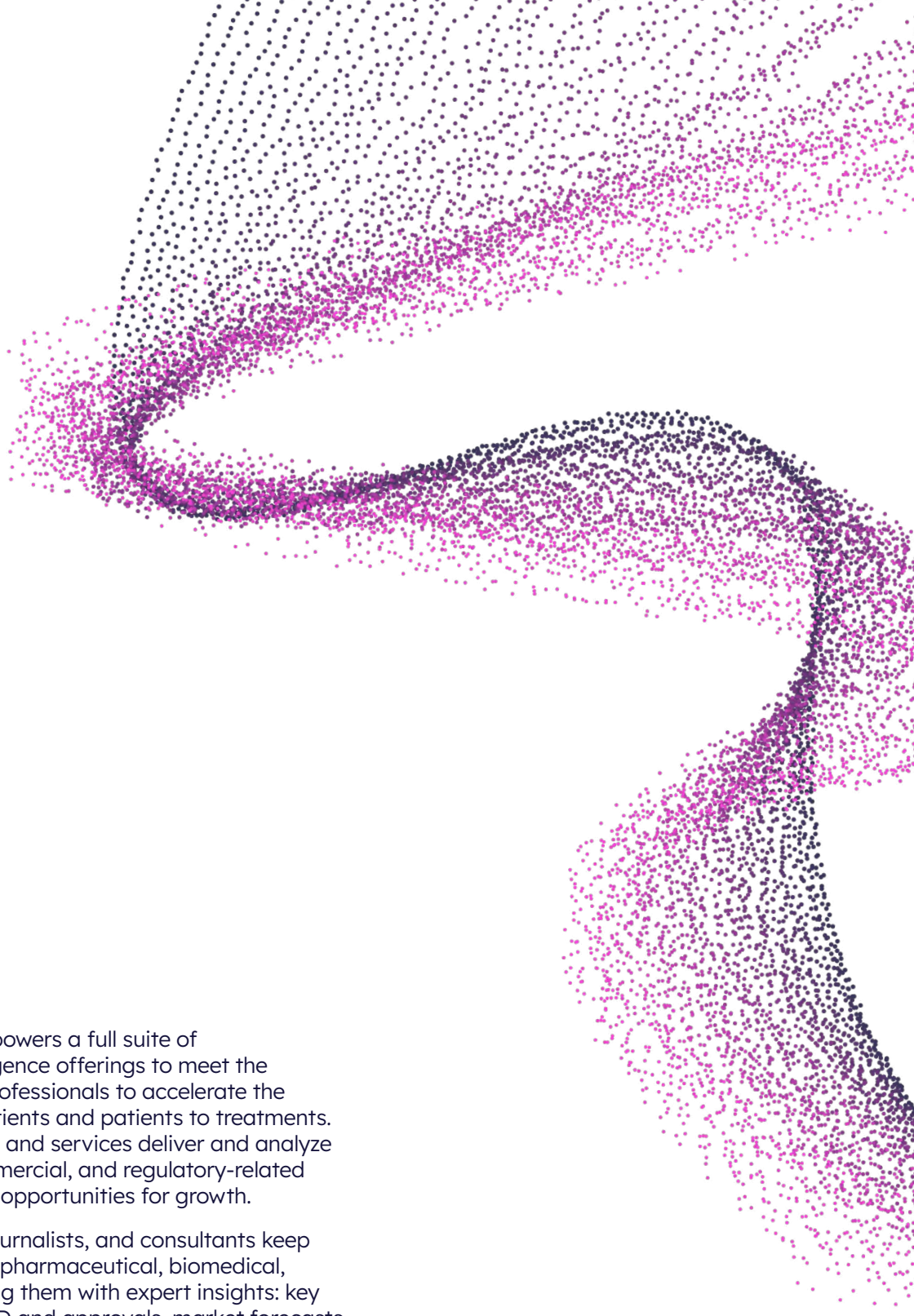

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Our global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them with expert insights: key diseases, clinical trials, drug R&D and approvals, market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

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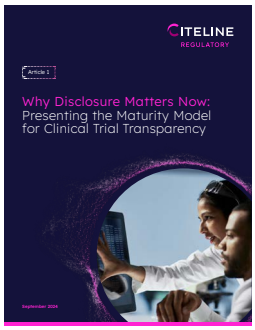

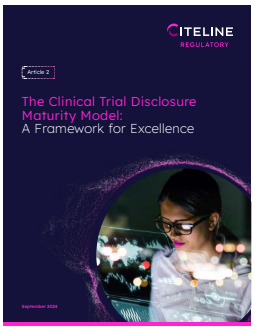

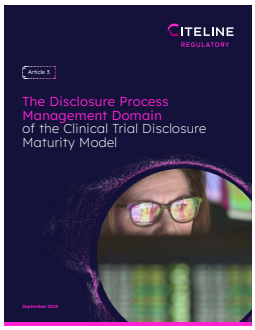

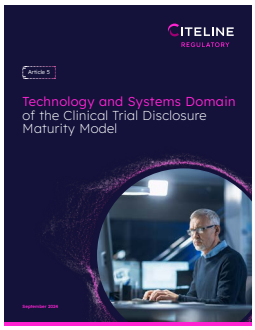

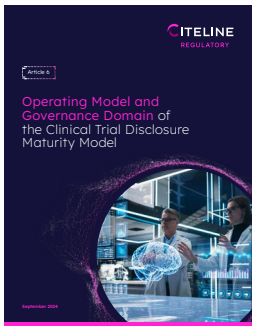

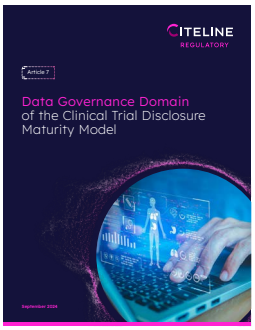

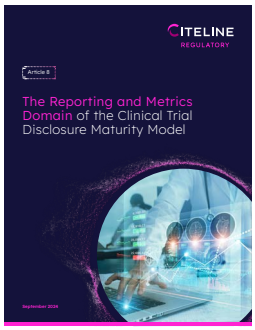

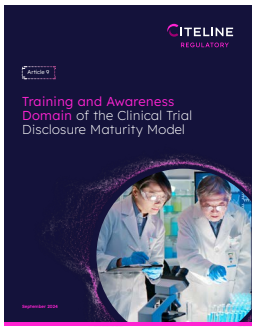

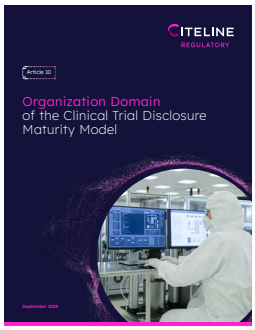

About the Author

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.