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Article 8

The Reporting and Metrics Domain of the Clinical Trial Disclosure Maturity Model

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Executive summary

The reporting and metrics domain focuses on measuring, analyzing, and communicating the performance of clinical trial disclosure activities. It encompasses the development of key performance, the creation of insightful reports, and the ensuring of data integrity. Relevant metrics and reports enable organizations to track compliance, identify areas for improvement, and demonstrate the value of their disclosure efforts.

Why this domain matters

Effective reporting and metrics form the foundation for data-driven decision-making in clinical trial disclosure. Clear visibility into disclosure performance and compliance status enables organizations to identify improvement areas, allocate resources efficiently, and demonstrate the value of transparency efforts. Well-designed metrics drive continuous process enhancement, helping sponsors adapt to evolving regulatory requirements and enhancing an organization's ability to respond to audits or inquiries. In a complex disclosure landscape, the ability to measure, analyze, and report on disclosure activities is both a regulatory necessity and a strategic advantage, allowing sponsors to optimize processes, mitigate risks, and build trust with stakeholders:

- Enables data-driven decision-making and resource allocation
- Provides visibility into disclosure performance and compliance status
- Facilitates continuous improvement of disclosure processes
- Supports stakeholder communication and regulatory reporting
- Helps demonstrate the value of disclosure activities to leadership

Potential risks of a weak approach to reporting and metrics

Inadequate reporting and metrics practices in clinical trial disclosure can significantly impair an organization's ability to manage and improve its transparency efforts. Without robust measurement and analysis, sponsors may

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struggle to identify compliance issues, process inefficiencies, or areas requiring improvement, potentially leading to regulatory violations and missed opportunities for optimization. Moreover, the lack of clear, data-driven insights can hinder decision-making, resource allocation, and the ability to demonstrate the value of disclosure activities to stakeholders, ultimately undermining the organization's overall transparency strategy. Specific risks include:

- Inability to accurately assess compliance status and disclosure performance
- Missed opportunities for process improvement and efficiency gains
- Difficulty in justifying resources for disclosure activities
- Challenges in responding to audits or regulatory inquiries
- Lack of visibility into emerging trends or recurring issues

Key elements of reporting and metrics

1. Key performance indicators

KPIs are quantifiable measures used to evaluate the success of an organization's clinical trial disclosure activities. Well-designed KPIs provide insights into compliance rates, timeliness of disclosures, data quality, and process efficiency. They serve as a compass for disclosure teams, highlighting successes and guiding efforts toward areas that need improvement. Effective KPIs are aligned with organizational goals, regulatory requirements, and industry best practices, providing a comprehensive view of disclosure performance.

Maturity levels:

- **Lagging:** Few or no KPIs are defined for disclosure activities, and performance measurement is ad hoc and inconsistent.
- **Developing:** Basic KPIs are established, primarily focusing on compliance rates. Measurement is more consistent but may not cover all aspects of disclosure performance.
- **Leading:** Comprehensive KPIs cover compliance, quality, efficiency, and stakeholder satisfaction. KPIs are regularly reviewed and updated to align with evolving organizational needs and regulatory requirements.

The main components of KPIs in clinical trial disclosure include:

Essential elements for effective KPIs:

- Clear definition and calculation method for each KPI
- Alignment with organizational goals and regulatory requirements
- Regular review and updating process to ensure continued relevance

Relevant KPIs for clinical trial disclosure:

- Percentage of trials registered within required timeframes
- Percentage of results posted within required timeframes
- Average number of quality control comments and requests for information per protocol and results submission
- Average time from study completion to results posting
- Number of ongoing and completed disclosure tasks per user

2. Metrics and reports

Metrics and reports transform raw data into meaningful clinical trial disclosure performance insights. They involve collecting, analyzing, and presenting data in formats that facilitate understanding and decision-making. Effective metrics and reports go beyond simple compliance statistics to provide a nuanced view of disclosure activities, including trends over time, comparisons across different trial types or registries, and predictive analytics to anticipate future challenges.

Maturity levels:

- **Lagging:** There is minimal reporting, often limited to basic compliance statistics. Reports

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are generated manually and infrequently.
- **Developing:** Regular reports covering key compliance metrics are produced. Some automation may be in place but reports lack depth or context.
- **Leading:** A comprehensive, automated reporting system provides real-time dashboards and in-depth analytical reports. Reports are tailored to different stakeholder needs and include predictive analytics.

3. Data sources

High-quality, reliable data are the foundation of effective reporting and metrics. This element focuses on identifying and integrating relevant data sources, ensuring data accuracy and completeness, and maintaining data integrity throughout the reporting process. It involves establishing data governance practices, implementing data quality checks, and creating a single source of truth for disclosure-related information.

Maturity levels:
- **Lagging:** Data are collected from disparate sources with little validation. Data integrity issues are common and often undetected.
- **Developing:** Primary data sources are identified, and some validation processes are in place. Efforts are made to reconcile data discrepancies, but a unified data management approach is lacking.
- **Leading:** A comprehensive data governance framework ensures data integrity. Automated systems integrate data from multiple sources with robust validation and reconciliation processes, establishing and maintaining a single source of truth for disclosure data.

Assessing your maturity

To evaluate your organization's maturity in this domain, consider:
- How comprehensive and relevant are your disclosure KPIs?
- What are the quality and depth of your metrics and reports?
- How reliable and integrated are your data sources?

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.

Additional domain elements

- **Trend analysis & root cause analysis:** systematically examining disclosure performance trends and investigating underlying causes for deviations or issues
- **Disclosure performance scorecard:** consolidated view of key disclosure metrics, providing an at-a-glance assessment of overall performance
- **Reporting automation and integration:** using technology to automate data collection, analysis, and report generation and integrate with other clinical systems
- **Benchmarking:** comparison of disclosure performance against industry standards or peer organizations to identify areas for improvement
- **Stakeholder feedback & satisfaction:** collection and analysis of feedback from internal and external stakeholders on disclosure processes and outputs

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Considerations for sponsor size

The approach to reporting and metrics may vary based on the size and complexity of the sponsor's trial portfolio. Both smaller and larger sponsors must adapt their strategies to meet their unique needs and resources:

Sponsors with smaller trial portfolios should establish core KPIs for compliance and performance. They might start with basic, manually generated reports and gradually introduce automation. For data management, smaller sponsors might rely on centralized spreadsheets or simple databases, ensuring data integrity through consistent data entry practices and regular audits.

Sponsors with more extensive trial portfolios typically benefit from more sophisticated reporting and metrics systems. They often implement comprehensive KPI frameworks covering multiple dimensions of disclosure performance. These sponsors usually invest in advanced analytics tools and automated reporting systems, providing real-time dashboards and in-depth analytical capabilities. Larger sponsors frequently implement robust data governance frameworks to ensure data integrity across their complex trial portfolios.

Getting started: practical tips

- Define a core set of KPIs aligned with your organization's disclosure goals and regulatory requirements
- Implement a regular reporting schedule, starting with key compliance metrics
- Conduct a data source audit to identify and validate primary data sources for disclosure metrics
- Develop a basic disclosure performance scorecard for executive leadership
- Establish a process for collecting and acting on stakeholder feedback about disclosure reports and metrics

How we can help

TrialScope Disclose offers built-in analytics and reporting capabilities, providing real-time visibility into disclosure performance across multiple registries. Its dashboards and customizable reports support data-driven decision-making and efficient stakeholder communication.

Conclusion

Mature reporting and metrics practices are essential for effective management and continuous improvement of clinical trial disclosure activities. By investing in well-designed KPIs, comprehensive reports, and robust data management practices, sponsors can enhance their disclosure performance, demonstrate compliance, and drive strategic decision-making.

Next steps

As we continue our series on the clinical trial disclosure maturity model, we encourage you to:

1. Use the / how our solutions and services can support your journey toward disclosure excellence.
2. Based on your assessment results, develop an action plan, prioritizing key areas for enhancement in your reporting and metrics practices.
3. Contact us to learn more about how our solutions and services can support your journey towards disclosure excellence.

The following article in this series will explore the training and awareness domain, focusing on building and maintaining the knowledge and skills necessary for effective clinical trial disclosure.

Contact our DISCLOSURE EXPERTS to learn more.

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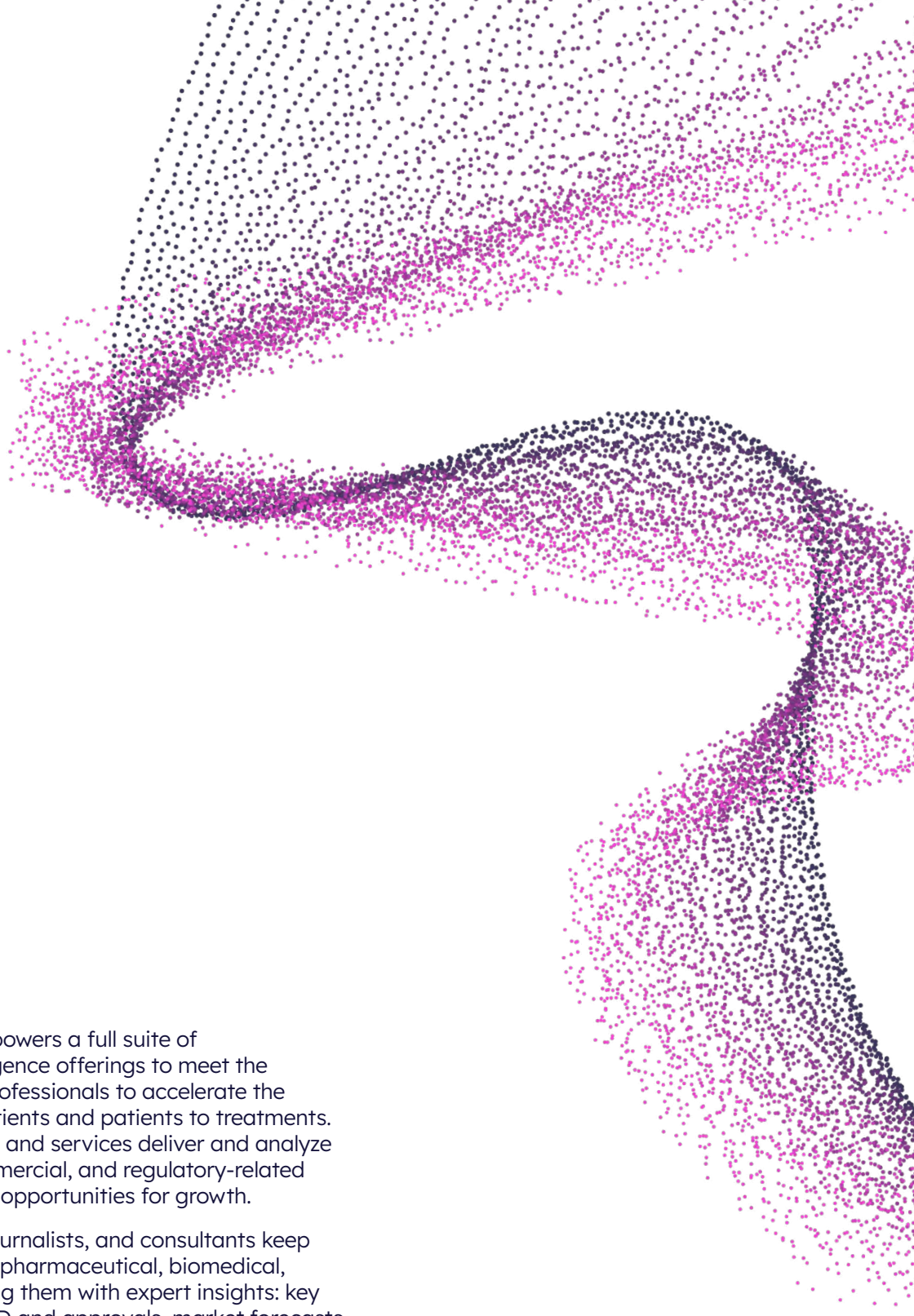

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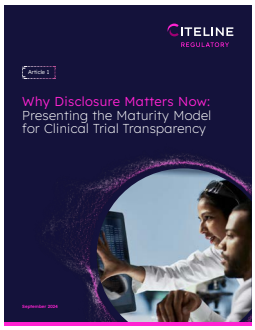

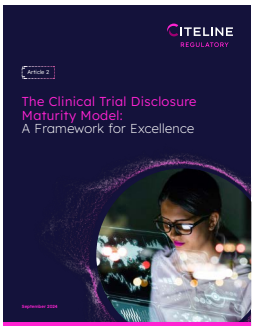

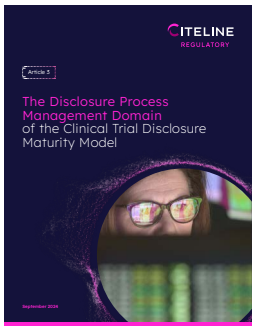

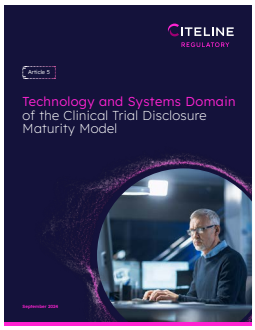

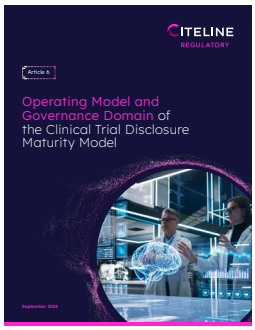

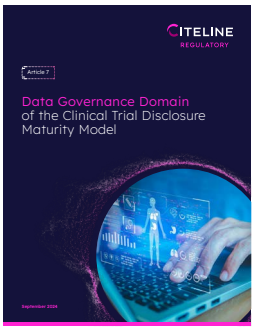

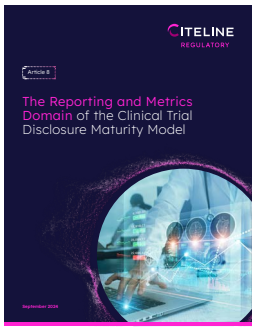

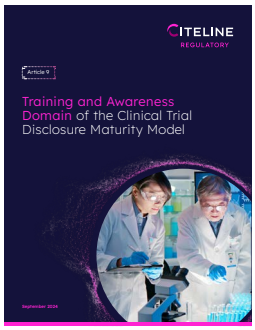

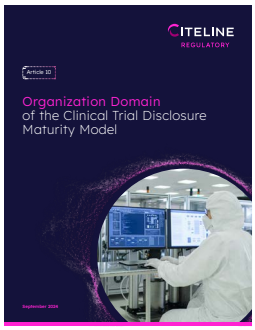

About the Author

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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.