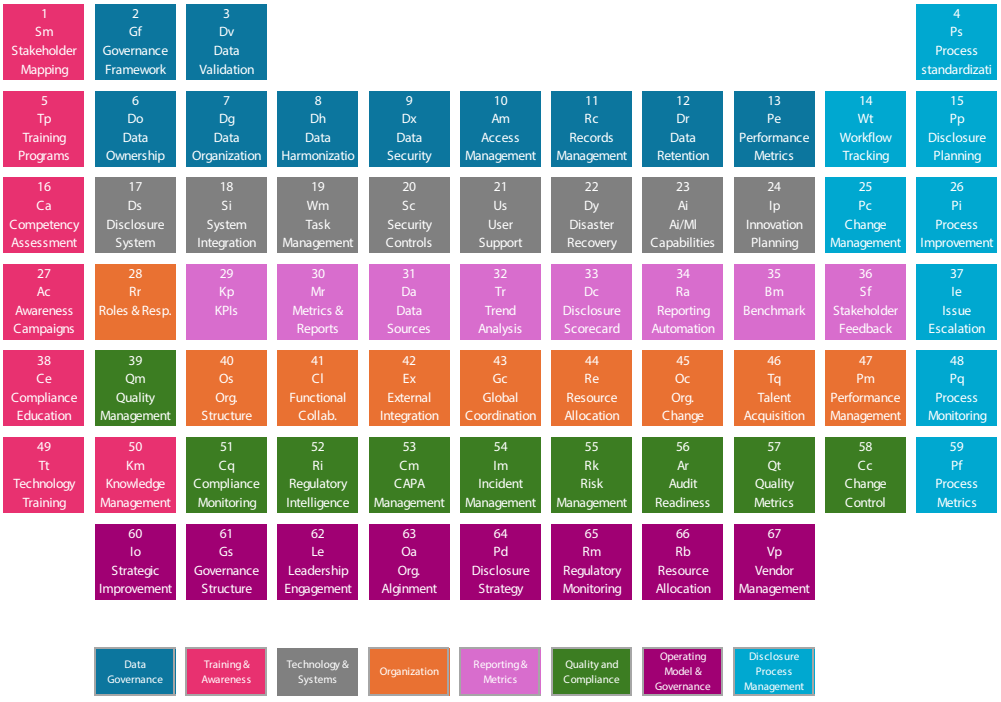
CITELINE
REGULATORY

Article 1

Why Disclosure Matters Now: Presenting the Maturity Model for Clinical Trial Transparency

September 2024

Why Disclosure Matters Now: Presenting the Maturity Model for Clinical Trial Transparency



Clinical trial disclosure and transparency have become important considerations in today's biopharmaceutical landscape. A comprehensive maturity model for clinical trial disclosure and transparency offers biopharmaceutical companies a strategic tool to assess and enhance their practices in an increasingly complex regulatory environment. This model becomes critical as the industry faces intensifying scrutiny, expanding disclosure requirements, and emerging trends that demand proactive management of clinical trial transparency. Organizations must navigate a rapidly changing landscape, from evolving global regulations to integrating new technologies.

The disclosure imperative in today's clinical trial landscape

Ensuring reliable disclosure practices has evolved beyond a mere regulatory requirement for clinical trial professionals. In today's environment, it's a strategic necessity. Stakeholders across the spectrum — regulators, patients, investors, and the public — are demanding greater transparency in clinical research. This intensified scrutiny elevates clear, accurate, and accessible disclosure of clinical trial data to a cornerstone of building trust.

A surge in regulatory scrutiny and expanding scope

Regulatory bodies, including the US Food and Drug Administration (FDA) and the European Union (EU) local health authorities, are taking a stricter stance on disclosure compliance. Evidence of this shift lies in increased inspections and the growing number of countries that have published enforcement plans. Companies face potential penalties for noncompliance with registration requirements on CTIS in the EU, jRCT in Japan, ClinicalTrials.gov in the US, and other registries. The scope of disclosure itself is broadening as well. New

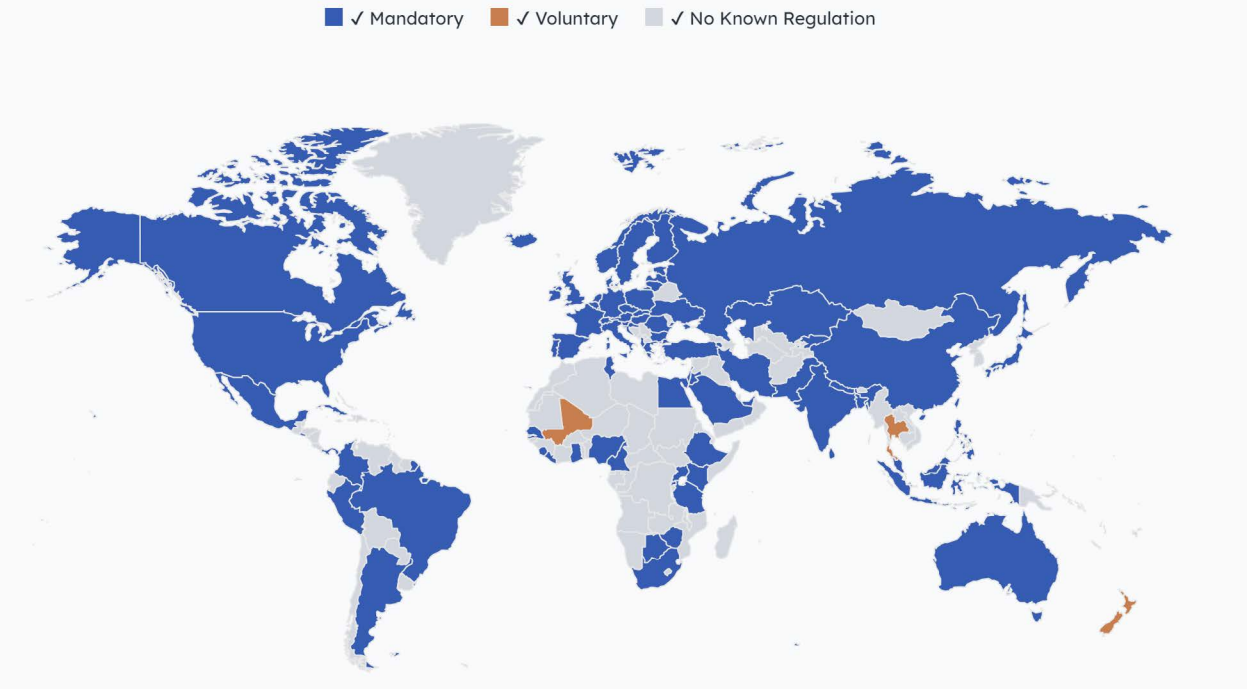
regulations and guidance documents now require a wider range of information to be disclosed, including patient-facing clinical trial documents and anonymized patient-level data.

Beyond registries: a broader transparency horizon

Initiatives such as the mandatory publication of full clinical study reports and data-sharing platforms demonstrate a push for transparency that extends to more than just clinical protocol registration. This aligns with the growing emphasis on open science and collaborative research, where sharing data across institutions can accelerate scientific discovery. Leading biopharmaceutical companies are taking this further by launching transparency initiatives that showcase their commitment beyond regulatory mandates.

Recent developments and future trends: a call for proactive action

Figure 1. Protocol registration requirements



Source: TrialScope Intelligence July 2024

The past year has seen significant developments that underscore the importance of proactive management. Consider these key trends:

- **Constantly evolving requirements:** New and updated disclosure requirements are published continuously. For example, in the past 12 months, over 130 regulatory guidance documents and laws related to clinical trial disclosure have been published, of which around 30% have already been superseded. This shows just how quickly the requirements are evolving. Not only is it a challenge to find these documents in the first place, but tracking/analyzing the changes is a full-time job.

- **Expanding global requirements:** To date, 75 countries mandate clinical trial disclosure across over 50 registries. This represents a significant expansion from two decades ago when only two registries required public posting of protocols. Current disclosure requirements have grown to encompass a broader range of clinical documents and data, including:
  - Full protocols
  - Clinical study reports (CSRs)
  - Anonymized patient data
- **Continued regulatory focus:** Expect stricter enforcement actions and penalties for noncompliance with disclosure regulations.
- **Focus on patient-centric disclosure:** Disclosure formats will likely become more user-friendly and accessible to lay audiences, catering to patient needs for clear and concise information.
- **Evolving use of artificial intelligence (AI) and machine learning (ML) in disclosure:** AI and ML are expected to play a larger role in analyzing data, preparing content for publication, and improving the quality and efficiency of clinical trial disclosure processes. However, while the capabilities of these systems are improving rapidly, they are still limited by their lack of deep domain knowledge compared to human experts. Additionally, AI/ML models may struggle with interpreting ambiguous legal language and handling references to other laws, regulations, or specific scenarios, which can lead to compliance issues.

Looking ahead to the near future, we anticipate growing regulatory enforcement, with more frequent inspections and potential penalties for noncompliance. Based on the past three years, we expect approximately 250 new regulatory and requirements documents globally, of which around 30% will likely be superseded within two years. While Phase 4 of the unified study definitions model (USDM) is expected to launch in the coming year with support for the registries in the US (ClinicalTrials.gov), EU (CTIS), and possibly Japan (jRCT), it may be years before most registries and sponsors adopt this standard.

With these growing and evolving requirements, a focus on pragmatic and cost-effective disclosure processes is crucial, where exploring technology solutions and streamlining workflows can optimize resource allocation.

The value of a maturity model: a roadmap for improvement

A clinical trial disclosure maturity model is valuable in this dynamic environment. Consider the ever-increasing challenge of constantly evolving requirements. New and updated disclosure regulations are published frequently. Keeping track of these changes can be a full-time job, and failing to comply with the latest regulations can lead to penalties.

The maturity model: addressing evolving requirements

This is where the clinical trial disclosure maturity model comes in. By assessing your organization's performance in domains like **quality and compliance**, the model helps ensure you have a systematic process for staying up to date on the latest regulations. A strong focus on this area ensures that the organization monitors regulatory changes and implements them effectively in its disclosure practices.

But regulatory monitoring is just one piece of the puzzle. The maturity model can also help you evaluate your organization's **operating model and governance**. An effective operating model clearly defines roles, responsibilities, and processes for disclosure activities across the organization. A robust governance structure ensures there are appropriate oversight mechanisms, decision-making frameworks, and escalation pathways to address complex disclosure challenges and maintain consistency.

Additionally, the model considers **technology and systems**. Leveraging technology solutions can automate tasks like regulatory change alerts and streamline the process of updating disclosure content. By investing in appropriate technology, organizations can free up valuable time and resources while ensuring that their disclosure practices comply with the latest requirements.

Identifying opportunities for improvement

The maturity model evaluates your organization's performance across key domains such as:

- **Disclosure process management:** clearly defined and up-to-date policies and standard operating procedures (sops) are the foundation for consistent and compliant disclosure practices.
- **Quality & compliance:** a robust quality management system and compliance monitoring process safeguard adherence to regulatory requirements and maintain high standards in disclosure activities.
- **Technology & systems:** investing in appropriate technology solutions can streamline all aspects of disclosure processes, from data collection and management to reporting and content creation, enhancing disclosure efficiency and accuracy.
- **Operating model & governance:** a well-defined operating model and governance structure provide clear roles, responsibilities, and oversight for effective disclosure management.
- **Data governance:** effective management of clinical trial data throughout its lifecycle ensures accuracy, integrity, and security, supporting reliable and transparent disclosure practices.

Understanding your strengths and weaknesses across these critical areas can help you prioritize investments and optimize your disclosure strategy. While company size doesn't necessitate a different maturity model, it can influence prioritization within the framework. For instance, sponsors with smaller trial portfolios across a limited geographic scope may initially focus on foundational elements like policies and SOPs. In contrast, larger sponsors with complex trials might prioritize areas like technology and advanced reporting.

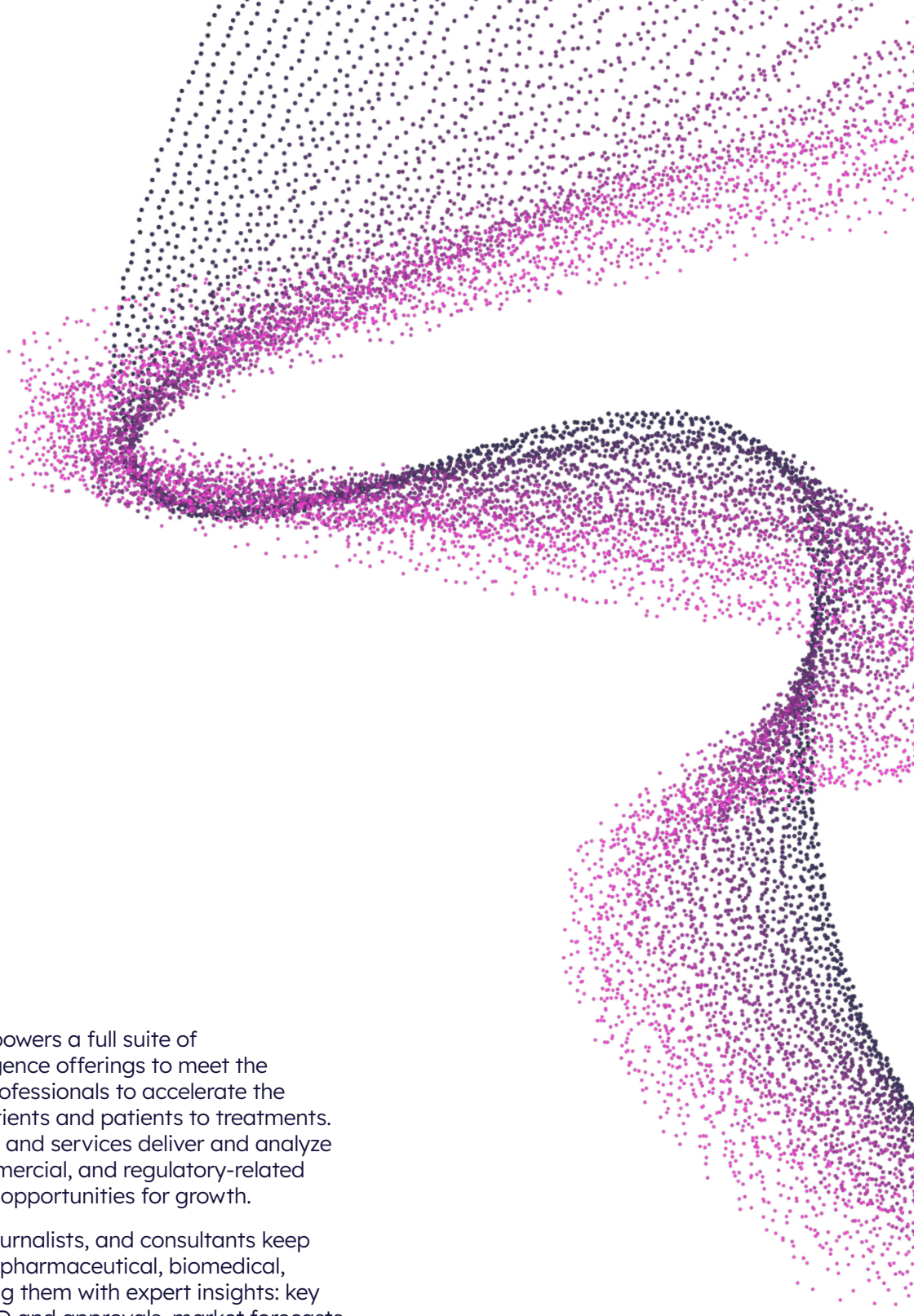
A measured approach to compliance

Developing pragmatic processes and systems to ensure compliant transparency is a collaborative effort. The disclosure maturity model allows organizations of all sizes to identify areas for improvement, invest strategically, and create a proactive approach to clinical trial disclosure. This is the first of 10 articles presenting a comprehensive maturity model to manage clinical trial disclosure.

1. Why disclosure matters now
2. The disclosure maturity model: a brief overview
3. Disclosure process management
4. Quality & compliance
5. Technology & systems
6. Operating model & governance
7. Data governance
8. Reporting & metrics
9. Training & awareness
10. Organization

Contact our DISCLOSURE EXPERTS to learn more.

CITELINE
REGULATORY

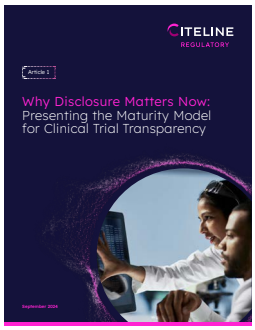


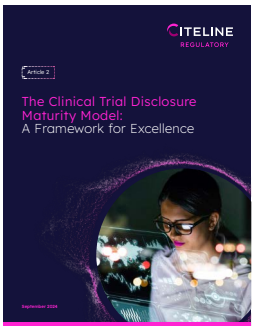
Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory-related decisions and create real-world opportunities for growth.

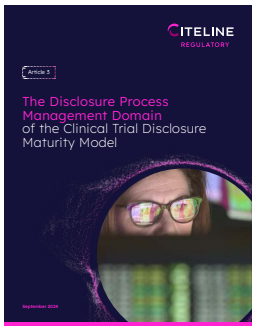
Our global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the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

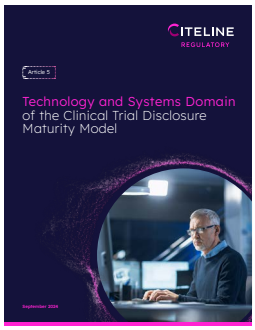
Articles Series: Maturity Model

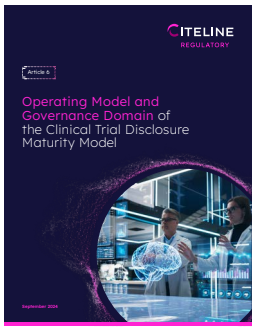
CITELINE REGULATORY

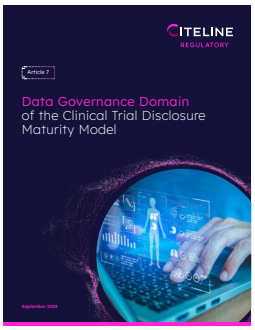


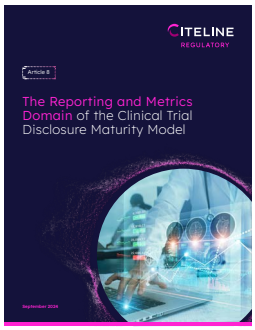


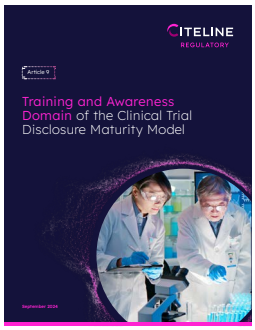


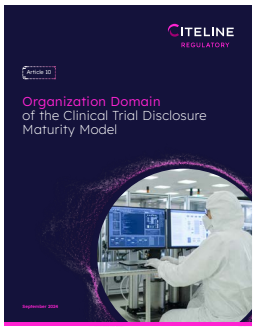












About the Author

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.