CITELINE
REGULATORY

White Paper

The State of Clinical Trial Transparency: 2025 Developments and 2026 Predictions

January 2026

Contents

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2025 Global Disclosure Updates

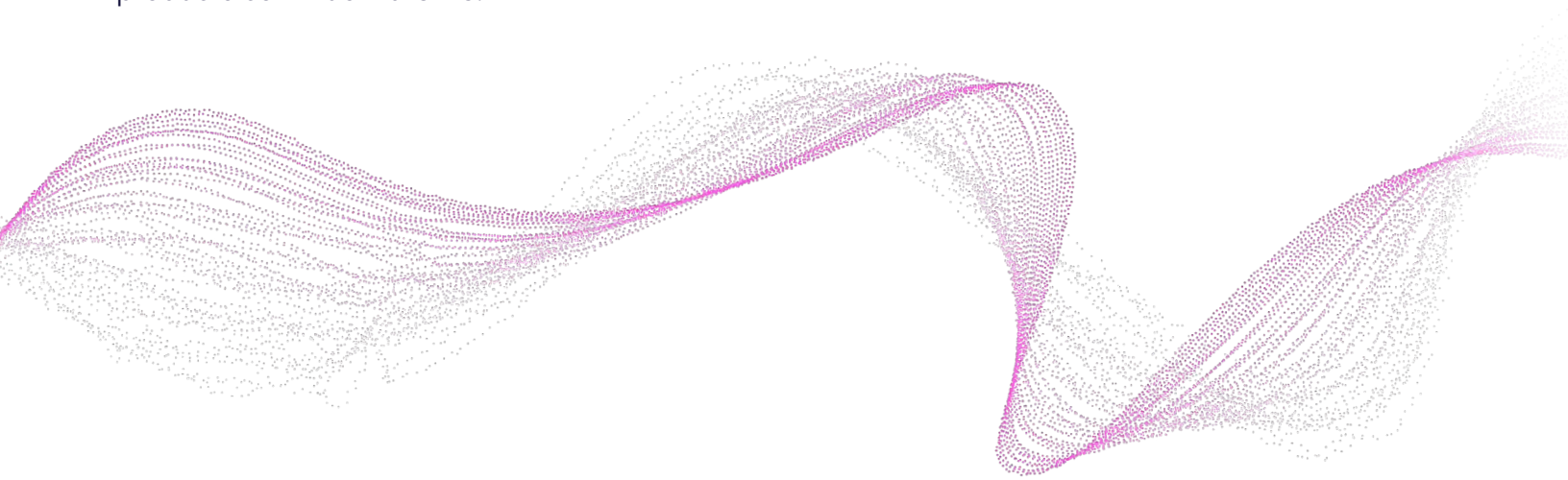
Europe

Switzerland revised trial disclosure requirements under the **Clinical Trials Ordinance (ClinO)**, effective March 2025, mandating lay-friendly summary results within one year for newly completed studies. The requirement applies only to trials completed after the effective date. To implement these changes, the Federal Office of Public Health launched HumRes on March 1, 2025, replacing the Swiss National Clinical Trials Portal (SNCTP). Trial submissions continue through the Business Administration System for Ethics Committees (BASEC).

The **European Union's** Clinical Trials Information System (CTIS) obtained WHO primary registry status within the **International Clinical Trials Registry Platform (ICTRP)** in April 2025, meeting International Committee of Medical Journal Editors (ICMJE) standards and clarifying its role in the global registry ecosystem.

The **United Kingdom** enacted the **Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025** in June, effective April 28, 2026. The Health Research Authority published final guidance in October clarifying that trials must be registered on WHO-recognized registries before first participant recruitment or within 90 days of approval (whichever is sooner). Results publication is required within 12 months, and plain language results summaries must be offered to all participants and published on the public registry within the same timeframe.

The Netherlands permanently discontinued **ToetsingOnline** on July 1, 2025. The **Research Portal**, launched in February 2025, became the sole platform for submitting medical scientific research to the Central Committee on Research Involving Human Subjects (CCMO). This includes studies under the Medical Research Involving Human Subjects Act (WMO), Embryo Law, Medical Device Regulation (MDR), In Vitro Diagnostic Regulation (IVDR), and non-WMO research. Clinical trials with medicinal products continue via CTIS.



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Asia

Taiwan's **International Research-based Pharmaceutical Manufacturers Association (IRPMA)** Post-Marketing Study Registry was discontinued on Jan. 1, 2025, following an October 2024 **Code of Practice** revision. Post-marketing studies still require IRB review and medical director approval, but registry submission is no longer required. Records registered before Jan. 1, 2025 remain accessible.

Japan migrated four clinical research systems on April 1, 2025: Japan Registry of Clinical Trials (jRCT), Clinical Research Review Board Information (JCRB), Ethics Review Committee Reporting System, and Clinical Research Information Portal, from National Institute of Public Health servers (.niph.go.jp) to Ministry of Health, Labour and Welfare servers (.mhlw.go.jp).

India's **Clinical Trial Registry (CTRI)** introduced new requirements in September 2025, including ethics committee approval dated within one year at registration and a Declaration of Responsibility confirming no prior participant enrollment. CTRI also published a formal standard operating procedure (SOP) for modifying registered trials.

Indonesia completed its registry platform migration in 2025, transitioning **INA-CRR** from ina-crr.id to ina-crr.kemkes.go.id. Dual submission was permitted until April 30, 2025, after which all submissions moved to the new platform. Migration concluded in September.

China's **International Traditional Medicine Clinical Trial Registry** launched an AI-enabled registration tool in September 2025, incorporating intelligent content parsing, multilingual translation, and automated verification. In parallel, Brazil's **Brazilian Clinical Trials Registry ReBEC**, managed by Fiocruz, launched Rebec@ in March 2025, the world's first generative AI assistant aligned with ICTRP guidelines. These updates reflect a global trend toward AI-driven registry automation.

Oceania

The **Australian New Zealand Clinical Trials Registry (ANZCTR)** implemented enhanced registration requirements in March 2025, including multi-factor authentication and improved workflow guidance. In October 2025, ANZCTR announced a prioritization framework: **Australian** and **New Zealand** trials first, followed by trials from countries without WHO primary registries, then trials from countries with existing WHO primary registries. International submissions may experience processing delays of up to eight weeks per review cycle.

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2026 Clinical Trial Disclosure and Transparency Predictions

The Year Transparency Becomes Core Practice

The Shift from Compliance to Core Principle

Artificial intelligence has dominated clinical research conversations for two years, cycling from hype to disillusionment as organizations discovered that generative AI (GenAI) won't simply replace disclosure teams. But 2026 may be the year AI earns its place in transparency workflows — not because the technology suddenly matured, but because regulatory requirements are finally giving it concrete problems to solve.

The drivers? ICH E6(R3) implementation across major markets and the maturation of global standards like ICH M11 throughout 2026 fundamentally elevate transparency from compliance checkbox to core good clinical practice (GCP) principle. Plain language summaries shift from "nice to have" to expected. Treatment assignments must go back to participants. Disclosure scope expands beyond local regulations. Structured protocol requirements create new technical challenges. These aren't minor tweaks but represent a philosophical shift in how sponsors approach trial transparency.

And here's where AI becomes practical: When you must produce structured protocols for ICH M11, generate plain language summaries for multiple audiences, extract disclosure-relevant data from massive trial databases, and format everything to different regional requirements — that's when "augmenting workflows" stops being a buzzword and starts being a necessity.

In 2026, regulatory mandate and technology enablement will converge.

In 2026, regulatory mandate and technology enablement will converge. This article explores what that convergence means for disclosure professionals navigating an increasingly fragmented global landscape.

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The Game Changer:
ICH E6(R3) Elevates Transparency

Why it matters

With the final adoption of the **ICH E6(R3) GCP Guideline** in early 2025, the real impact arrives in 2026 as countries continue to implement these requirements into their regulatory frameworks. Transparency moves from scattered local regulations to a core principle of global clinical research. This isn't just another update; it's a fundamental reframing of what GCP means, and 2026 is when sponsors must operationalize these changes.

What's changing

Annex 1 of the GCP update includes significant upgrades in disclosure and transparency:

- Disclosure scope expands beyond local regulations into a global requirement
- Increased scope of studies requiring disclosure compared to many existing local regulations
- Plain language summaries of results shift from optional to expected
- Treatment assignments must be disclosed to participants

Annex 2, dealing with trial designs and real-world data (RWD), has gathered public comments and is awaiting a revised version for adoption. Movement forward on Annex 2 is expected in 2026.

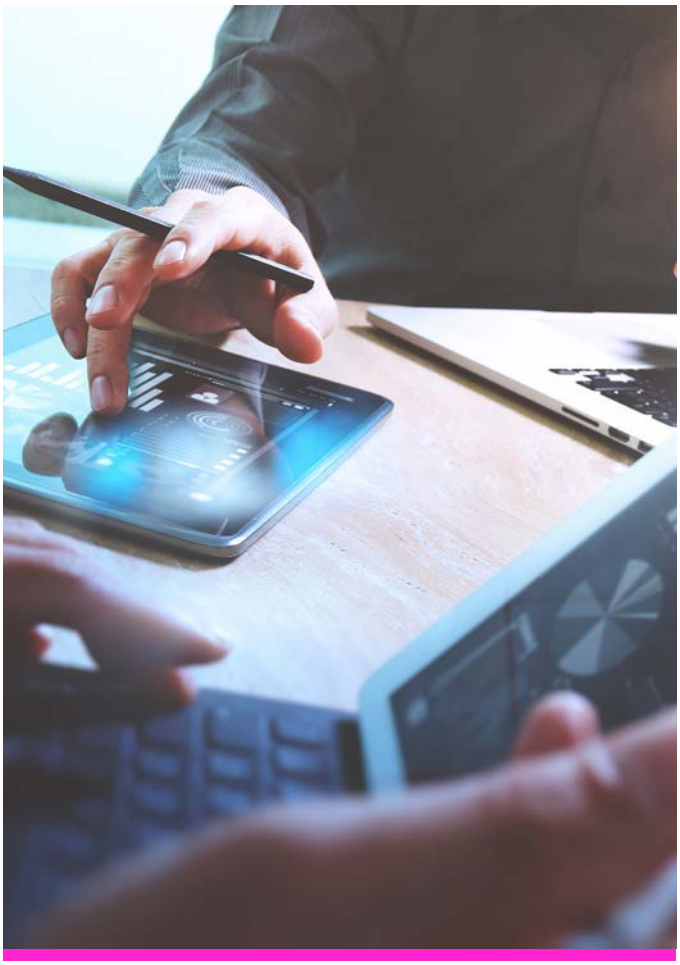
The 2026 implementation wave

Multiple countries bring E6(R3) into force throughout 2026:

- **Singapore:** Jan. 1 (Health Sciences Authority)
- **Canada:** April 1 (Health Canada)
- **United Kingdom:** April 28 aligned with new clinical trial regulations (MHRA)
- **EU and Switzerland:** Annex 2 expected early 2026 (Principles and Annex 1 already effective July/August 2025)
- **Australia:** Late 2026 (TGA consultation underway with 12-month transition period)

The practical impact

Sponsors must design disclosure strategy into protocols from day one, not bolt it on at the end. The era of treating transparency as an afterthought ends in 2026.



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The Maturation:
Europe Builds Its Transparency Infrastructure

The big picture

Europe is moving from "we have requirements" to "we have an enforced ecosystem." The year 2026 marks the first full year where multiple transparency initiatives mature simultaneously, creating a comprehensive regulatory framework that other regions will watch closely.

PASS framework reality check

Post-authorization safety studies (PASS) requirements have recently tightened. The PASS framework FAQ was updated Nov. 26, 2025, reflecting concrete, near-term compliance obligations that distinguish between imposed and voluntary studies.

For imposed PASS — studies required by the Pharmacovigilance Risk Assessment Committee (PRAC) or as a condition of marketing authorization — marketing authorization holders (MAH) must:

- Enter study protocols into the European Medicines Agency (EMA) electronic PASS study register
- Submit abstracts of final study reports
- Provide full final study reports

PRAC assesses both the protocols and outcomes of these imposed studies, making this a mandatory regulatory pathway.

For voluntary PASS (studies conducted by MAHs on their own initiative, including those in risk management plans), the EMA now recommends, though does not mandate, that companies submit protocols and study reports in the same manner as imposed PASS. This recommendation signals regulatory expectation even where not legally required.

The year 2026 will be the first full year under this updated PASS regime, bringing increased regulatory pressure, public visibility, and operational burden for sponsors managing both imposed and voluntary safety studies. The November 2025 FAQ timing signals EMA's preparation for active enforcement in 2026 inspections and regulatory reviews, moving from framework announcement to compliance verification.

EUDAMED becomes mandatory

The first four modules of EUDAMED (European Database on Medical Devices) become mandatory May 28:

- Actor registration
- UDI/devices registration
- Notified Bodies & Certificates
- Market surveillance

Device companies will need to be ready to accommodate these requirements by the end of May. The Vigilance module is expected to be completed with notification published in Q4 2026, with mandatory use starting in Q2 2027.

The Clinical Investigations and performance studies module, most relevant to disclosure teams, will be worked on in 2026, but don't expect notification until 2027. For disclosure professionals at device companies, May 2026 is a wake-up call.

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CTIS evolution

The Clinical Trials Information System (CTIS) is already the mandatory single-entry portal for EU/EEA clinical trials. As of 2025, the system is described as "fully implemented." But implementation is just the beginning.

The CTIS Simplification Task Force was formed in early 2024 to help the system become more efficient and future-proof. The task force's work plan anticipates changes being implemented from 2026 onward.

> **Prediction:** CTIS will move beyond "just registry/registration" toward enhanced data-sharing capabilities in 2026. Expect improvements around:
> - Structured results submission formats
> - Improved metadata and data quality tools
> - API or machine-readable access
> - Cross-registry mapping and interoperability

Frame this as the system moving from "it works" to "it works well."

Plain language summaries: the rising tide

Given the tightening of transparency requirements through PASS, CTIS, and stronger pharmacovigilance rules, there is structural incentive for regulators and sponsors to better communicate safety and efficacy data to patients.

While no public 2025–2026 document from the EMA mandates plain language summaries (PLS) across all new trials, the gap itself supports a prediction: Stakeholders will voluntarily push for PLS to meet growing transparency and patient-centricity demands.

> **Prediction:** PLS become increasingly expected emerging best practice in 2026, especially for post-authorization reports, PASS results, and CTIS registry entries. Sponsors who wait will be behind the curve.

Plain language summaries: from encouraged to mandatory

Plain language summaries, though already required in some jurisdictions, are becoming standard elements of any new or revised disclosure framework. The 2025–2026 period marks the normalization of PLS as a default transparency component rather than an exceptional addition.

> **Prediction:** New and revised disclosure requirements in 2026 and beyond will routinely mandate plain language summaries as standard components. Switzerland set this precedent in 2025 by embedding lay-friendly summaries in its revised Clinical Trials Ordinance. The United Kingdom follows in 2026, requiring plain language results summaries to be both offered to participants and published on public registries within the same 12-month timeline as structured results. This signals a clear shift: Plain language summaries are now core disclosure obligations, not optional engagement tools.

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The Uncertainty:
US Transparency at a Crossroads

ClinicalTrials.gov modernization: **the good news**

ClinicalTrials.gov continues its modernization project on both the public site and backend Protocol Registration and Results System (PRS). The new year will bring enhanced functionality as the modernized site now has full registration and results capabilities, and CTgov prepares to migrate fully off the "classic" site.

Radical transparency controversy: **the complicated news**

The FDA started releasing Complete Response Letters (CRLs) in 2025 as part of its Radical Transparency initiative. This has not been without controversy. Some disclosures appear to conflict with long-standing rules barring publication of an application before a decision is reached, creating regulatory uncertainty and potential legal exposure for both the FDA and sponsors.

> **Prediction:** Expect release of CRLs to continue in 2026, pending potential legal action. Watch for legal challenges questioning application disclosure timing.

The registry reliability question: **the wake-up call**

The recent government shutdown exposed a vulnerability in CTgov's role as the "world's registry." Studies not required in the US were not processed during the shutdown, leading to concerns about the reliability of using the platform to meet global registration obligations during future disruptions.

> **Radical prediction:** Some organizations will reconsider whether CTgov should remain their default primary registry. With the potential for another government shutdown in 2026, this would have been unthinkable five years ago but is now a serious strategic question.

ANZCTR's October 2025 announcement that it would prioritize Australian and New Zealand trials, with international applicants facing delays up to eight weeks per review cycle, further complicates backup registry strategies. ISRCTN emerged as the most viable alternative during 2025 CTgov disruptions, maintaining full WHO and ICMJE recognition without geographic prioritization.

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The Enabler:
AI Moves from Hype to Help

Reality check:
the trough of disillusionment

According to **Gartner**, despite billions being spent on GenAI initiatives, most organizations have found it difficult to find the right ways to use it and the right people to make it work. Gartner's Hype Cycle for AI has entered the "Trough of Disillusionment" phase.

Expectations are settling into a more realistic phase where AI delivers measurable value — especially as rising regulatory complexity creates workflow demands that cannot be met through manual effort alone. In disclosure and transparency, this shifts from "AI replacing all the people" to a more thoughtful approach: incorporating AI into existing workflows to augment rather than replace.

Where AI actually helps in 2026

The practical applications emerge where regulatory requirements create concrete workflow problems:

- **Protocol intelligence:** Extracting disclosure-relevant information from protocols to populate registries
- **Format conversion:** Translating between structured requirements for ICH E6(R3) and ICH M11 without requiring new authoring systems
- **Plain language summary generation:** Creating first drafts that need less editing than starting from scratch
- **Workflow integration:** Not replacing existing tools but enhancing them with intelligent assistance

These predictions are already materializing. **China's International Traditional Medicine Clinical Trial Registry** launched AI-enabled registration in September 2025 with intelligent content parsing and multilingual translation. Brazil's ReBEC launched Rebec@ in March 2025, the world's first generative AI assistant trained to ICTRP standards, operating 24/7 in three languages to help researchers identify fast-track priorities and detect field inconsistencies.

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The ICH M11 connection

The ICH M11 project aims to create an international standard for content and electronic exchange of clinical trial protocol information (Clinical Electronic Structured Harmonized Protocol – CeSHarP). The technical specification document collected a second round of public comments ending in July 2025.

While no additional timelines have been announced to date, moving in 2026 toward getting a version that can be implemented by countries is possible.

Here's the synergy: Structured protocols enable better AI, and AI makes structured adoption feasible. Clinical teams can continue authoring protocols in their tool of choice (often Word), with AI augmenting the process. An AI agent can then format it into the correct structured format conforming to technical requirements.

Key insight:
AI solves the adoption problem

Recall the history of protocol-writing tools that have failed to gain traction over the years as writers did not want to adopt inflexible tools. Now, the tool can integrate into their workflow instead of replacing it.

> **Old problem:** "We can't change our protocol writing system."
>
> **New solution:** "AI agent translates from Word to structured format."

This is why global standards might actually stick this time. Value-add, fit-for-purpose AI agents can strategically integrate into the right places to enhance workflows without requiring large system upgrades or investments.

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The Divergence:
Fragmentation Despite Harmonization

The paradox

There is a dichotomy in disclosure and transparency globally. On one hand, several countries are trying to harmonize their requirements, and global standards are coming into play. On the other hand, some countries where trials are increasing in number are not jumping on the bandwagon.

Regional approaches

- **Europe:** Clear leadership, with Policy 0070 clinical data publication, strengthened PASS requirements, EUDAMED milestones, and ongoing CTIS enhancements forming the most comprehensive transparency framework of any region
- **United States:** Uncertainty and controversial actions from what was once a predictable location; potential retreat from "world's registry" role
- **Canada:** Quietly aligning with global standards through ICH E6(R3) adoption and regulatory transparency proposals
- **United Kingdom:** Post-Brexit independence choosing harmonization with new regulations aligned to ICH standards
- **China:** Growing rapidly in trial volume but not aligning with global transparency approaches; instead focusing on data protection/ exclusivity and regulatory modernization
- **Rest of world:** Generally following ICH standards, but implementation speeds vary

The strategic question for sponsors

This creates an increasingly fragmented global landscape where sponsors must navigate different transparency expectations across regions. You can't design trials for the lowest common denominator anymore — you must plan for the highest transparency requirement in any region where you'll conduct the trial.

> **Recommendation:** Align with ICH E6(R3) and EU standards as your floor. These generally accepted global initiatives meet needs across most jurisdictions and position you ahead of regulatory curves rather than behind them.

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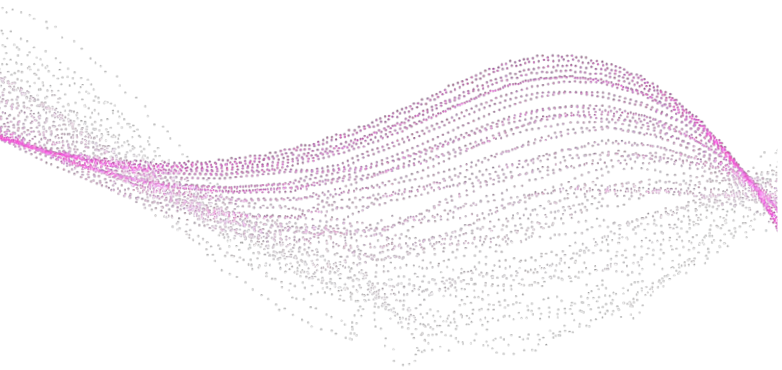
Enforcement for Noncompliance: Who Blinks First?

Despite comprehensive penalty frameworks across major jurisdictions, meaningful enforcement for disclosure noncompliance remains rare. Regulators have tools such as multimillion-dollar fines, marketing authorization holds, and trial approval suspensions, yet have been reluctant to use them.



Prediction: Implementation of ICH E6(R3) could trigger the first enforcement wave. By elevating transparency to an ethical imperative under GCP, authorities gain political and regulatory justification to act. The United Kingdom's new clinical trials regulations, effective April 28, 2026, include expanded enforcement powers and position the UK to lead. Other jurisdictions implementing E6(R3) in 2026 may follow, although initial approaches may favor warnings over penalties. A high-profile noncompliance case, particularly involving patient safety or data integrity, could accelerate action, shifting disclosure enforcement from a theoretical threat to operational reality by 2026.

What This Means for Disclosure Professionals

IMMEDIATE ACTIONS:
- Review protocols against ICH E6(R3) disclosure requirements
- Build disclosure strategy into protocol design from day one

Q1–Q2 2026 PRIORITIES:
- Prepare for Singapore (Jan. 1), Canada (April 1), and UK (mid-year) implementations
- If you work with devices: EUDAMED readiness by May 28
- If you're in EU: Ensure PASS framework compliance

THROUGHOUT 2026:
- Build AI into workflows strategically (PLS generation, data extraction, format conversion)
- Don't assume CTgov primacy for non-US required studies
- Develop plain language summary capabilities now; don't wait for mandates

WATCH CLOSELY:
- FDA enforcement signals and penalty actions
- CTIS enhancements and new functionality
- ICH M11 progress toward implementable versions

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Conclusion: From Compliance to Culture

In 2026, transparency becomes embedded in trial design, not added at the end. The philosophical shift from ICH E6(R3) combined with Europe's maturing ecosystem creates a new baseline for what good clinical practice means.

The tools are finally catching up to the requirements. AI won't replace disclosure teams, but it will enable them to meet expanded obligations without proportionally expanding headcount. This is the practical value that emerges when technology meets genuine workflow needs.

The divergence is real — the US introduces uncertainty while China pursues its own path. But global standards provide the foundation. ICH E6(R3) and harmonized European requirements give sponsors a defensible floor to build on.

For forward-thinking sponsors, this isn't burden — it's opportunity. Early adopters of comprehensive transparency strategies will find themselves better positioned with regulators, more attractive to patients, and more competitive in a global research landscape where transparency has become core practice.

Citeline Disclosure Resources

PUBLICATIONS

Trial and Consequence: The Global Enforcement Landscape of Clinical Trial Disclosure (March 18, 2025) surveys worldwide non-disclosure repercussions, highlighting the gap between penalties and enforcement, and examining regional trends in non-compliance across major jurisdictions.

GCP in 2025: A Transparency Revolution (April 16, 2025) examines ICH E6(R3) updates and their implications for disclosure requirements, plain language summaries, and participant trust in clinical research.

ClinicalTrials.gov and the US Government Shutdown: What Sponsors Need to Know (Oct. 17, 2025) analyzes ClinicalTrials.gov service disruptions during the US government shutdown, alternative WHO Primary Registry options, and strategies for maintaining compliance during registry interruptions.

FDA Clarifies Expanded Access and Transparency Obligations (Oct. 27, 2025) analyzes FDA guidance on expanded access programs and associated transparency requirements.

Connecting Patients with Plain Language Summaries (Oct. 30, 2025) provides an overview of evolving requirements for plain language summaries, covering protocol and results summaries with practical guidance for creating compliant, accessible content for diverse global audiences.

ON-DEMAND WEBINAR SERIES

Three-part webinar series providing comprehensive guidance on global clinical trial disclosure:

- **Part 1: Global Clinical Trial Disclosure Fundamentals** covers core requirements across major jurisdictions, including mandatory registration elements, timing requirements, and enforcement landscapes to support global compliance strategies.
- **Part 2: Navigating the Clinical Trial Registry Ecosystem** provides an overview of the registry landscape, exploring regional harmonization efforts, national registry requirements, and strategic considerations for multi-jurisdictional studies.
- **Part 3: Beyond Clinical Trial Registration — Plain Language Summaries** focuses on the growing importance of plain language summaries, covering protocol and results summaries.

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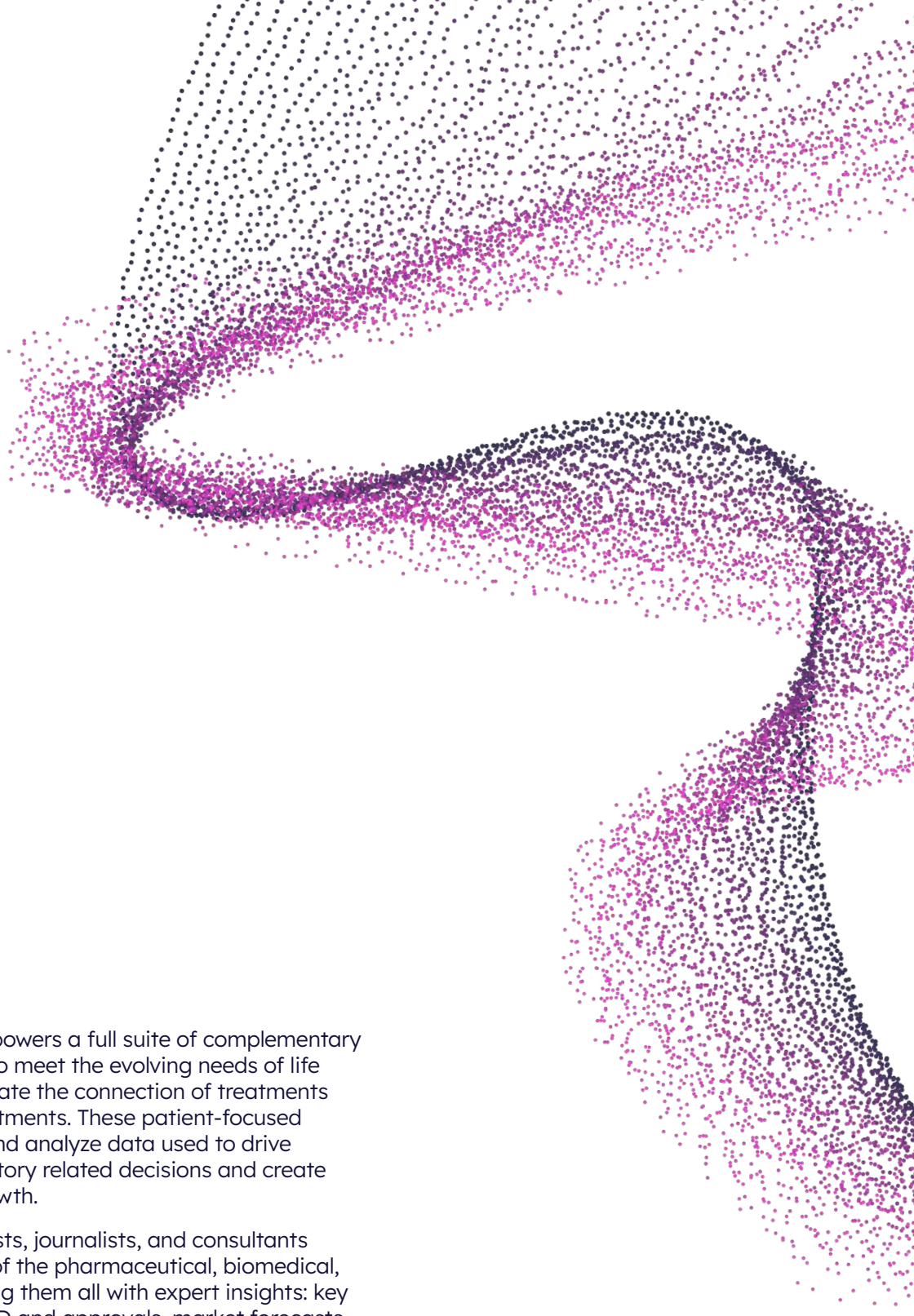

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