



Trial and Consequence: The Global Enforcement Landscape of Clinical Trial Disclosure

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A close-up photograph of a laboratory experiment. A hand wearing a blue nitrile glove is holding a glass pipette, carefully dispensing a clear liquid into the neck of a glass Erlenmeyer flask. In the foreground, there are several other empty Erlenmeyer flasks of different sizes. In the background, two white laboratory bottles with clear stoppers are visible on a white surface. The lighting is bright and even, highlighting the glassware and the liquid being added.

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disclosure standards in their Recommendations. These standards play a key role in promoting clinical trial transparency worldwide. Since 2005, ICMJE member journals—including many of the world’s leading medical publications—have required that clinical trials be registered in a public registry before participant enrollment begins. To meet this requirement, registration must occur in a World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) primary registry or ClinicalTrials.gov.

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Executive Summary

The Global Landscape of Clinical Trial Reporting Enforcement

Executive Summary:

The Global Landscape of Clinical Trial Reporting Enforcement

Clinical trial transparency stands as a cornerstone of scientific integrity, patient safety, and evidence-based healthcare decision-making. As regulatory frameworks evolve globally, sponsors and researchers face an increasingly complex landscape of disclosure requirements, enforcement mechanisms, and potential penalties for noncompliance. This comprehensive assessment maps the enforcement approaches and consequence structures implemented across major jurisdictions worldwide, highlighting both commonalities and significant regional variations in how authorities ensure adherence to clinical trial reporting obligations.

KEY FINDINGS

- **Enforcement varies significantly:** While most jurisdictions have established clinical trial disclosure requirements, enforcement intensity varies dramatically, from purely administrative actions to severe penalties including imprisonment.
- **Monetary penalties range widely:** Financial penalties for noncompliance range from nominal fines of a few hundred dollars to substantial penalties of up to \$14,724 per violation per day in the US and up to €500,000 (\$543,113) in Belgium for serious cases.
- **Non-monetary consequences:** Beyond financial penalties, consequences include imprisonment (up to three years in some jurisdictions), trial suspension, license

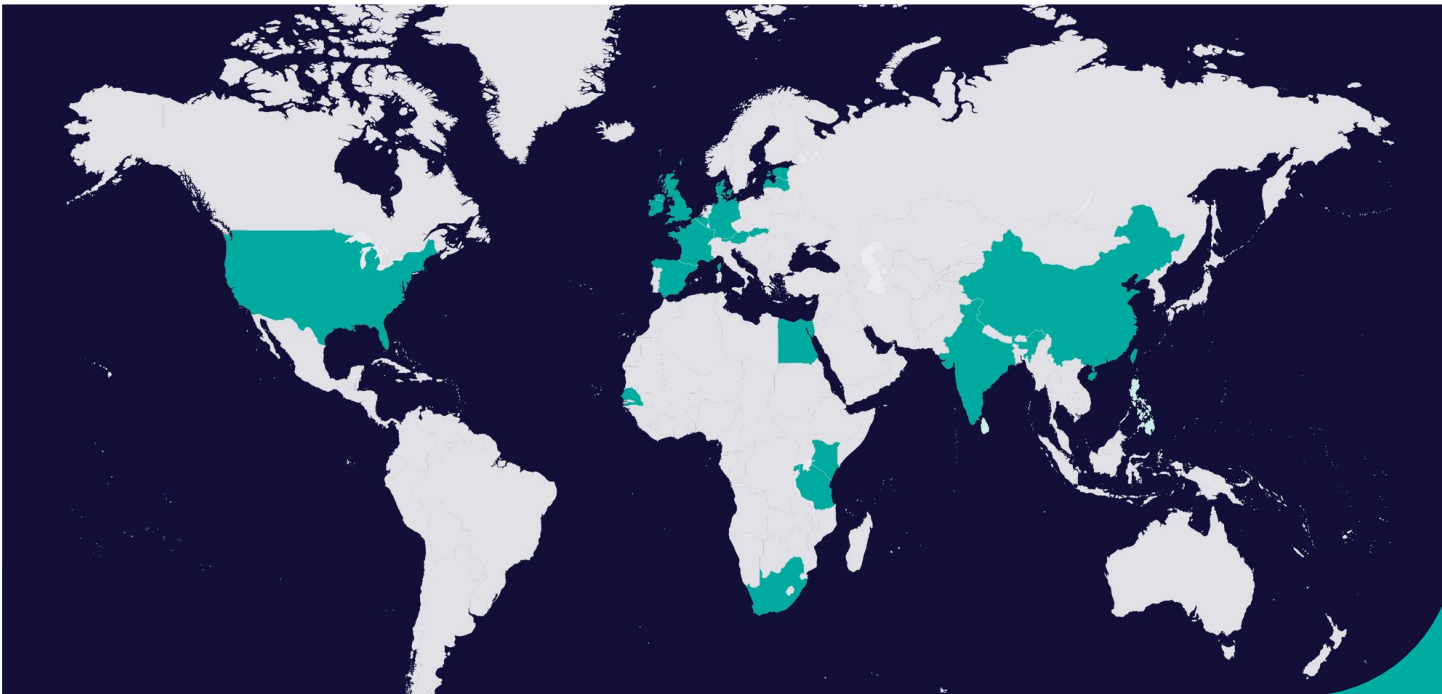
revocation, blacklisting of sponsors and investigators, and public naming of violators.

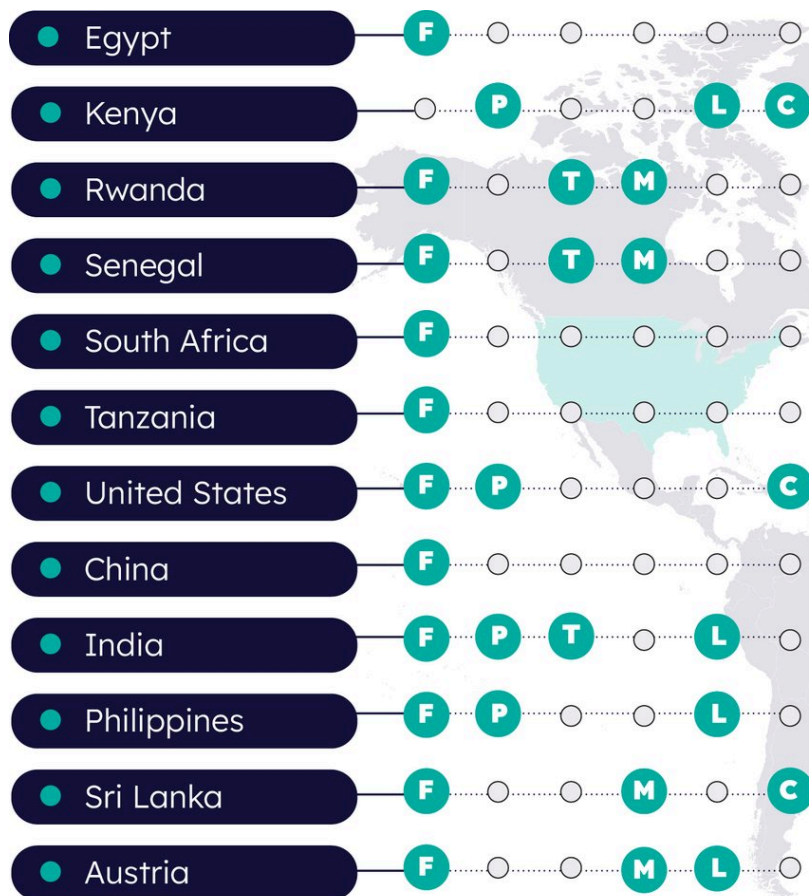
- **Enforcement gap:** Despite substantial regulatory penalties on paper, actual enforcement remains limited. The [FDAAA Trials Tracker](#) estimates the US government could have imposed fines over \$62 billion for noncompliance, yet the actual fines claimed stand at \$0.
- **Regional trends:**
 - **Africa:** Countries such as Kenya and Rwanda have established clear requirements with substantial penalties including imprisonment.
 - **Americas:** The US has detailed requirements and significant potential penalties, though enforcement has been limited.

- **Asia:** China and India have implemented specific disclosure frameworks with moderate penalties.
- **Europe:** The EU Clinical Trials Regulation (EU CTR) provides a unified framework, but enforcement and penalty structures vary significantly among member states.
- **Emerging social accountability:** Beyond regulatory enforcement, social accountability mechanisms through initiatives like the [EU TrialsTracker](#) project are creating reputational incentives for compliance.

IMPLICATIONS

The diverse approaches to enforcement create a complex landscape for sponsors conducting multinational trials. While regulatory enforcement remains inconsistent, growing public awareness and social accountability are driving increased transparency. Understanding this regulatory landscape is essential for sponsors to navigate compliance obligations and manage the reputational risks associated with nondisclosure. Stakeholders need comprehensive information about the potential consequences of noncompliance across jurisdictions to support informed decision-making in both clinical trial disclosure practices and geographic site selection strategies.





Clinical Trial Reporting

The Compliance Gap Continues

Clinical Trial Reporting:

The Compliance Gap Continues

Clinical trials are fundamental to medical research, providing critical insights into the safety and efficacy of new treatments. However, the integrity and value of these trials depend significantly on the transparent and timely reporting of their results. Recent analyses continue to show that clinical trial sponsors and investigators do not meet requirements for disclosure and reporting. The landscape of clinical trial reporting is complex, as different countries and regions implement varied approaches to ensure compliance. The consequences of failing to report trial results can be significant, ranging from monetary fines to funding restrictions, public notices of violation and potential imprisonment.

A 2022 audit by the Office of Inspector General found that the National Institutes of Health (NIH) in the US failed to ensure that all NIH-funded clinical trials complied with federal reporting requirements. Only 35 out of 72 trials (48.6%) that were required to report results did so within the mandated timeframe. Of the remaining trials, 12 reported their results late, and 25 did not report at all. The audit revealed that the NIH did not have adequate procedures in place to ensure that responsible parties submitted the results of clinical trials and took limited enforcement action in cases of noncompliance.

Similarly, a 2024 study published in Frontiers in Medicine uncovered discrepancies between data from the Indian drug regulator

and the Clinical Trials Registry India (CTRI), highlighting inconsistencies in trial site and investigator information. For instance, in 52% of cases, there were more sites listed in the registry than in the regulatory approval letters. The study found that out of 151 paired records, only 60 (40%) had the same number of sites in both the regulatory letter and the CTRI record. In 79 cases (52%), there were more sites listed in the CTRI, while in 12 cases (8%), there were fewer sites in the CTRI.

In Europe, a comprehensive analysis published in The BMJ in 2018 revealed that only 49.5% of the 7,274 clinical trials registered on the EU Clinical Trials Register reported results as required. This widespread noncompliance affects both commercial and non-commercial sponsors, with academic

institutions performing particularly poorly — only 11% of trials sponsored by academia or government reported results. The study also identified significant variations in reporting rates between countries, with Denmark (69%) and Austria (63%) having the highest compliance rates, while Italy (18%) and Germany (22%) had the lowest.

The EU Trials Tracker, an ongoing initiative, has developed tools to monitor compliance with reporting requirements across various registries. Its FDAAA TrialsTracker¹ found that, as of 8 February 2024, 77.4% of applicable trials (16,135 out of 20,855) had reported results. However, this still leaves a significant number of trials noncompliant. The tracker estimates that the US government could have imposed fines over

\$62 billion for noncompliance. Strikingly, the actual fines claimed by the US government stand at \$0, highlighting a stark gap between potential and actual enforcement. Additionally, the EU TrialsTracker¹, another tool developed by the project, monitors compliance with EU regulations monthly.

This white paper aims to provide an overview of the penalties for noncompliance with clinical trial reporting requirements across major global jurisdictions. Unless otherwise specified, local currencies will show conversions to dollars based on conversion rates on Oct. 18, 2024.

[1] EBM DataLab, "EU Trials Tracker," University of Oxford, <https://eu.trialstracker.net/> (accessed February 24, 2025)





Africa

Africa

EGYPT

Egypt's clinical trial disclosure requirements are governed by **Law No. 214 of 2020 Regulating Clinical Medical Research**. The law mandates that the principal investigator register their research protocols in public registry before initiating a clinical trial. However, Egypt does not have a clinical trial registry, and the specific database for registration is not defined in the law.

The Supreme Council is responsible for enforcing these disclosure regulations. Although the law does not specify inspection processes solely for compliance with disclosure requirements, the Council has the authority to conduct periodic reviews to ensure adherence to good medical practice standards, which may include disclosure

practices. The Council can suspend, refuse to renew, or terminate research early in cases of noncompliance.

Failure to comply with any provision related to the publication of results or the submission of required reports can result in imprisonment and fines ranging from **EGP 50,000 (\$1,029)** to **EGP 500,000 (\$10,290)**. Additionally, conducting research without meeting the requirements of research bodies is punishable by fines ranging from **EGP 100,000 (\$2,056)** to **EGP 1,000,000 (\$20,561)**.



Sponsors must submit an executive summary report within 30 days of study closure, followed by a full clinical study report within 180 days. Annual progress reports must be submitted throughout the trial's duration.

KENYA

Kenya's clinical trial disclosure requirements are governed by the **Pharmacy and Poisons (Conduct of Clinical Trials) Rules, 2022**. The Pharmacy and Poisons Board (PPB) oversees clinical trials and their disclosure. All clinical trials must be registered on the PPB's online registry and the Pan African Clinical Trials Registry (PACTR) before they commence.

Sponsors must submit an executive summary report within 30 days of study closure,

followed by a full clinical study report within 180 days. Annual progress reports must be submitted throughout the trial's duration. The PPB may conduct inspections before, during, or after the trial to ensure compliance with regulations and good clinical practice. Following the conclusion of a trial, the PPB may conduct a review that includes scrutiny of any interim and final reports.

Enforcement mechanisms and penalties for noncompliance are detailed in the **Guidelines for the Conduct of Clinical Trials in Kenya**. The Board has the authority to suspend, refuse to renew, or terminate a clinical trial for noncompliance. The PPB can issue warnings, blacklist noncompliant sponsors or investigators, or publish lists of those found to be noncompliant. Any person who contravenes the provisions of the rules may be liable to a fine not exceeding **KES 1 million (\$7,752)**, imprisonment for up to **two years**, or both.



The Rwanda FDA maintains a list of all approved clinical trials conducted in Rwanda, including protocol details, trial certificate numbers, and investigator information.

RWANDA

Rwanda's clinical trial disclosure requirements are governed by the **Regulations Governing the Conduct and Inspection of Clinical Trials in Rwanda**, overseen by the Rwanda Food and Drugs Authority (Rwanda FDA). Sponsors or investigators must register their clinical trials in a World Health Organization (WHO)-recognized, publicly accessible registry before approval, with a preference for the PACTR. The Rwanda FDA maintains a list of all approved clinical trials conducted in Rwanda, including protocol details, trial certificate numbers, and investigator information. The Rwanda FDA publishes and updates information on application decisions, approvals, rejections, suspensions, and terminations.

The Rwanda FDA enforces disclosure through administrative sanctions and fines. Penalties for noncompliance are significant. Publishing findings from an unauthorized clinical trial results in mandatory retraction and a fine of **RWF 10,000,000 (\$7,386)**. Publishing findings that differ from the authorized trial leads to content deletion and a minimum fine of **RWF 1,000,000 (\$739)**.

SENEGAL

Senegal's clinical trial disclosure is governed by the **Guideline on the Conduct of Clinical Trials in Senegal**, issued by the Senegalese Pharmaceutical Regulatory Agency (ARP). The ARP is required to record all clinical trial implementation requests and their final decisions in a database. Sponsors or

investigators must register their clinical trials in the PACTR and provide the registration number to the ARP. While specific registration timeframes are not outlined, registration should occur before or at the time of submission to the ARP.

The ARP is responsible for enforcing these regulations. Noncompliance may result in the suspension or withdrawal of ethical approval or administrative research authorization, a ban on marketing products evaluated during clinical trials, and/or financial penalties determined by the ARP and the National Ethics Committee for Health Research (CNEHS).

SOUTH AFRICA

South Africa's clinical trial disclosure requirements are governed by the **South African Good Clinical Practice: Clinical Trial Guidelines**. The South African Department of Health has established the South African National Clinical Trials Register (SANCTR), a

publicly accessible, web-based clinical trial registry. The South African Health Products Regulatory Authority (SAHPRA) and Research Ethics Committees (RECs) oversee clinical trials and their disclosure. Sponsors or principal investigators (PIs) must register all trials conducted in South Africa on the SANCTR before they commence, with registration requiring approval from both SAHPRA and the relevant REC. A unique study number is allocated to each trial upon registration, and no trial may begin without this Department of Health (DoH) number.

Sponsors must ensure that trial results and outcomes are reported to Investigators, SAHPRA, and the Department of Health via the SANCTR within one year of completing the analysis of trial results. There are inspection requirements, as SAHPRA is



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responsible for inspecting all documents related to clinical trials, including clinical study reports. However, the guidelines do not specify penalties for noncompliance with disclosure requirements or detail the frequency of inspections.

TANZANIA

Tanzania's clinical trial disclosure is governed by the Tanzania Food and Drugs Authority (TFDA) under the **Tanzania Food, Drugs, and Cosmetics (Clinical Trials Control) Regulations**. The regulations require applicants conducting clinical trials to register their trials in the National Registry established by the TFDA, known as the Tanzania Clinical Trial Register (TzCTR). The Guidelines for Application to Conduct Clinical Trials in Tanzania, a separate

document, indicates that trials can be registered in any registry recognized by the WHO. Registration must be completed no later than 21 days after the first patient is enrolled in the clinical trial. TzCTR requires detailed information about the trial, including descriptive information, recruitment information, location and contact details, and administrative data.

The regulations state that the TzCTR shall ensure that clinical trial results are made publicly available, although specific timeframes for reporting results are not provided. The TFDA has the authority to inspect clinical trials at any reasonable time to ensure compliance with the regulations. Any person who contravenes any provision of these regulations is considered guilty of an offense under the Act. The TFDA may settle

offenses without court proceedings by accepting a fine or other penalty from those who admit to the offense using a standardized “Compounding of Offences” form, after which no further criminal or civil proceedings shall be taken against them for that specific violation. The regulations do not specify the exact penalties for

noncompliance with disclosure requirements or detail the frequency of inspections.



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A world map is centered on the Atlantic Ocean, with North and South America on the left and Europe and Africa on the right. The map is rendered in a light blue color against a dark blue background. Overlaid on the map is a pattern of binary code (0s and 1s) in a lighter blue shade, creating a digital or data-themed aesthetic.

Americas

Americas

UNITED STATES

The Food and Drug Administration (FDA) and the National Institutes of Health (NIH) oversee clinical trial disclosure in the United States. The primary regulations governing this process are **Section 801 of the Food and Drug Administration Amendments Act (FDAAA) of 2007** and the **Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)**.

Applicable clinical trials (ACTs) must be registered on [ClinicalTrials.gov](https://clinicaltrials.gov) within 21 days of enrolling the first participant. The responsible party — typically the sponsor or principal investigator — must submit results within one year of the primary completion date (the date that data collection completes for primary outcomes), with extensions available for unapproved products or

indications.

The US NIH has an additional Policy on the Dissemination of NIH-Funded Clinical Trial Information that requires all NIH-funded clinical trials to register and report results on [ClinicalTrials.gov](https://clinicaltrials.gov) on the same timelines, even the trial would not be required under the US regulation.

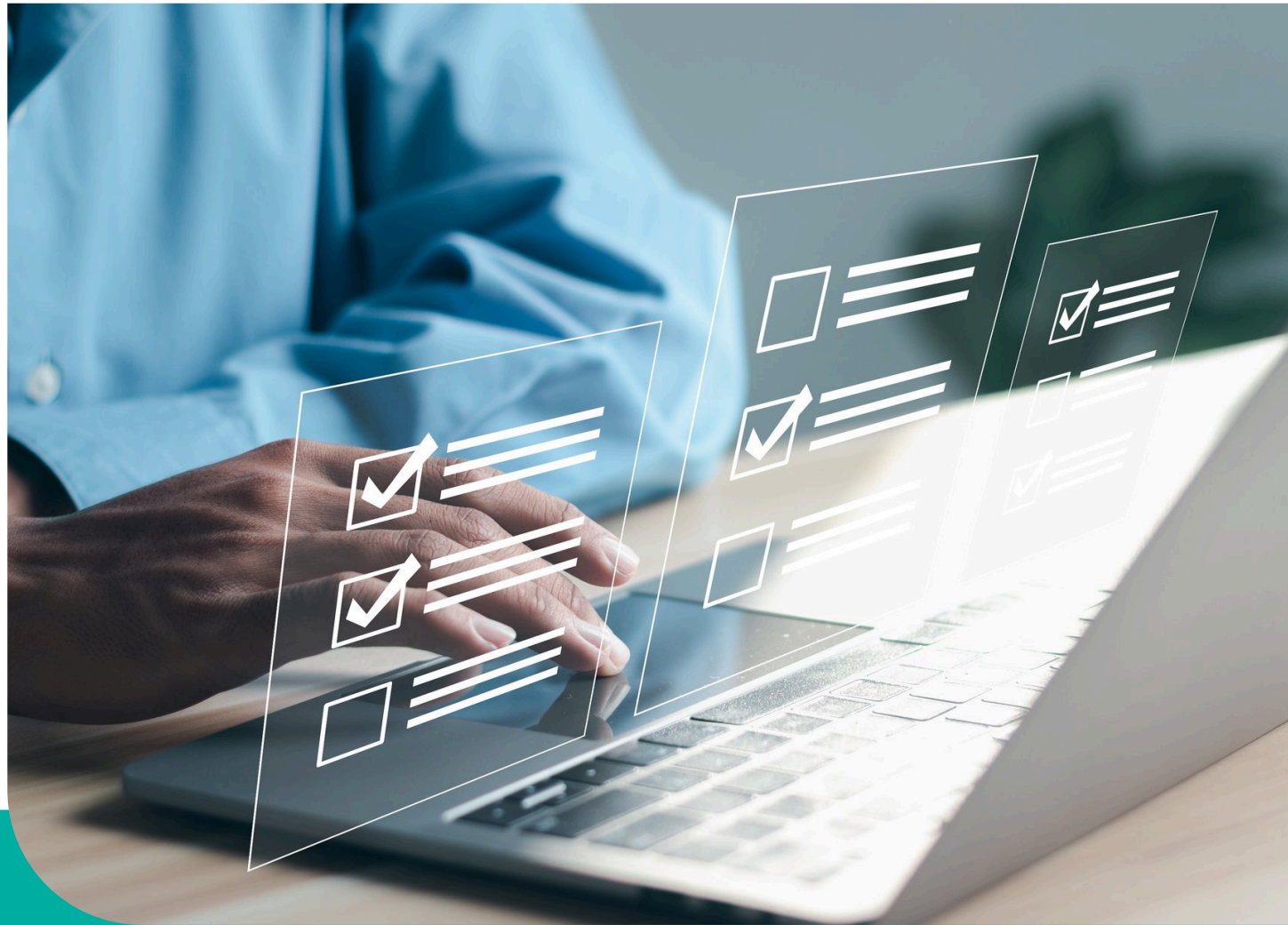
The FDA Centers (CDER, CBER, CDRH) identify potential violations through inspections conducted under the Bioresearch Monitoring Program (BIMO). Inspectors examine whether studies are properly

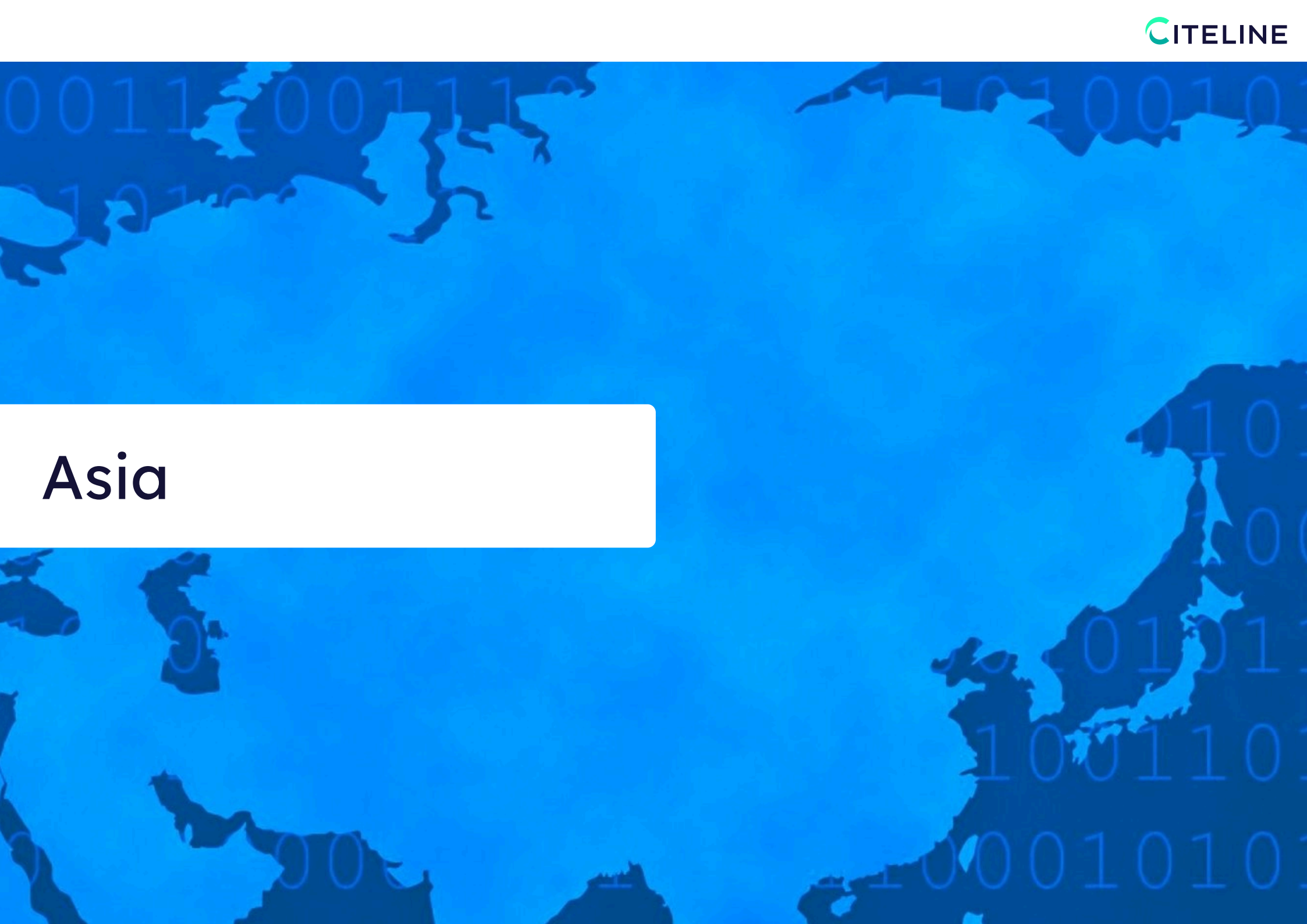
registered, results are submitted on time, and informed consent documents contain required statements about [ClinicalTrials.gov](https://clinicaltrials.gov). Inspectional observations associated with [ClinicalTrials.gov](https://clinicaltrials.gov) requirements are documented in the narrative of the Establishment Inspection Report (EIR). If violations are identified, the FDA issues a non-public preliminary notice of noncompliance, giving the responsible party 30 days to address the identified issues. If the issues remain unresolved, a public Notice of Noncompliance is issued. The FDA may then seek civil money penalties if noncompliance continues.



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Penalties for noncompliance can include civil monetary fines of up to **\$10,000** per violation, adjusted for inflation (§ 102.3 Penalty adjustment and table) to **\$14,724** (2024). These fines can accrue daily for ongoing violations, up to **\$10,000** per day adjusted for inflation to **\$14,724** (2024) for continuing violations after the 30-day notice period. For NIH-funded trials, grant funds may be withheld or terminated in addition to the penalties indicated above. In egregious cases, criminal prosecution is possible. The FDA has indicated that it prioritizes compliance over penalties and typically issues warnings — which are published on its website — before imposing fines.





Asia

Asia

CHINA

The National Medical Products Administration (NMPA) and its Center for Drug Evaluation (CDE) oversee clinical trial disclosure in China. The primary regulations are in the **Specification for Administration on Registration and Publicity of Information of Clinical Trials**. Sponsors must register their trial protocols and relevant information on the platform for Registration and Publicity of Information of Clinical Trials (ChinaDrugTrials), which is established, maintained, and updated by the CDE based on the general requirements of the NMPA.

Sponsors must register their protocol and clinical trial application information before enrolling the first subject. Registration can

only occur after obtaining a clinical trial approval document, provided the trial is still within the validity period which expires automatically if no subjects sign an informed consent form within three years from the date of approval, or after receiving a filing number for bioequivalence studies. Clinical trial results must be registered on the registration platform within 12 months after completion.

The NMPA enforces these regulations through the **Drug Registration Management Measures**. Sponsors violating registration requirements will be ordered to make corrections within a specified timeframe. Noncompliance may result in penalties, including required corrections within a specified timeframe. Failure to register before conducting a trial, submit required safety updates, or register results after completion



Clinical trial results must be registered on the registration platform within 12 months after completion.

may incur fines ranging from **RMB 10,000** (\$1,405) to **RMB 30,000** (\$4,214). Sponsors must make corrections within a specified time limit. These penalties also apply to other instances of noncompliance, such as failing to submit required safety update reports during the trial.

INDIA

India has established requirements for clinical trial disclosure, overseen by the Central Drugs Standard Control Organization

(CDSCO) under the Ministry of Health and Family Welfare. The primary regulation governing this process is the **New Drugs and Clinical Trials Rules**. According to these rules, all clinical trials conducted in India must be registered with the Clinical Trial Registry of India (CTRI), maintained by the Indian Council of Medical Research (ICMR). This registration is mandatory before enrolling the first subject and applies to all trials, including global trials with Indian participation. Even multi country trials already registered in international registries must also be registered in the CTRI.

Enforcement of these regulations is outlined in the **Frequently Asked Questions (FAQs) on New Drugs and Clinical Trials**.

Noncompliance with any provision of the Act, including the registration requirement, may result in various penalties. These can include



Even multi country trials already registered in international registries must also be registered in the CTRI.

written warnings, rejection of clinical trial results, suspension or cancellation of permissions, or barring the investigator or sponsor from future clinical research for a period determined by the Drugs Controller General of India (DCGI).

MALAYSIA

Clinical trial registration in Malaysia is governed by the Drug Control Authority (PBKD) under **Regulation 29 in the Drug and Cosmetic Control Regulations 1984**. The National Pharmaceutical Regulatory Agency (NPRA), part of the Malaysian Ministry of Health (KKM), oversees this process and mandates the prospective registration of all clinical trials conducted in the country.

The National Medical Research Register (NMRR) is the system for clinical trial registration. All clinical investigations involving drugs must be prospectively registered with the NMRR as part of the

clinical trial application process. Specific penalties for noncompliance are not provided.

PHILIPPINES

Clinical trial disclosure in the Philippines is regulated by the Food and Drug Administration (FDA) under **Administrative Order No. 2020-0010**. The order mandates that all clinical trials be registered in the Philippines Clinical Trial Registry (PHRR). Sponsors or Contract Research Organizations (CROs) must upload trial information to the registry within 30 days of receiving FDA clinical trial approval or approval of amendments. The registry must also be updated within 30 days of study termination.

According to the **Rules and Regulations Implementing Republic Act No. 9711**, the FDA can conduct routine or "for cause" inspections to ensure compliance with Good Clinical Practice and other regulations. Violations, responsible entities, and

regulatory actions are uploaded to the registry. Violation of any provisions of the Clinical Trials Regulation is subject to administrative penalties ranging from **PHP 50,000 (\$865)** to **PHP 500,000 (\$8,6500)**, depending on the severity, and a fine of **PHP 1,000 (\$17)** for each day thereafter. Suspension of the License to Operate or other authorizations for up to one year may also be imposed.

SRI LANKA

The National Medicines Regulatory Authority (NMRA) of Sri Lanka oversees clinical trials under the **National Medicines Regulatory Authority Act, No. 5**, and the **National Medicines (Clinical Trials) Regulations**. Principal investigators must register trials in

the **Sri Lanka Clinical Trials Registry (SLCTR)** and other applicable registries after receiving approvals and before initiating patient screening.

The NMRA may conduct inspections at any time based on suspected violations or for enforcement purposes. All trial sponsors, investigators, and authorization holders must comply with NMRA regulations and guidelines. Penalties for noncompliance include fines of up to **INR 100,000 (\$342)** and/or imprisonment of up to **three months** for the first offences and fines of up to **INR 200,000 (\$683)** and/or imprisonment of up to **six months** for subsequent offences. Offenders may also be required to issue a public apology. Conviction could result in the cancellation of any license or registration issued for the distribution of medicine under

this Act. However, it is unclear if these penalties specifically apply to failures in registration or reporting.





Europe

Europe

EUROPEAN UNION AND MEMBER STATES

The European Medicines Agency (EMA) oversees clinical trial disclosure in the EU in collaboration with EU Member States and the European Commission. The key regulation governing this process is Regulation (EU) No 536/2014, also known as the Clinical Trials Regulation (CTR). Before starting a clinical trial, sponsors must register it in the Clinical Trials Information System (CTIS). Sponsors are required to submit a summary of trial results to CTIS within one year of the trial's completion in all concerned Member States. For trials linked to marketing authorization applications, the clinical study report must be submitted within 30 days after authorization is granted, the procedure is completed, or the application is withdrawn.

EU Member States appoint inspectors to ensure compliance with the regulation, which may include validating disclosure-related aspects. Enforcement of the regulation is the responsibility of each Member State, and penalties for noncompliance, such as failure to submit publicly available information, are determined individually by each country:

AUSTRIA

The Federal Office for Safety in Health Care (BASG) oversees clinical trials in Austria. It enforces regulations by ordering corrections for deficiencies, suspending or revoking trial authorizations, and closing establishments if necessary. Penalties for noncompliance with the EU CTR under the Austrian Medicines Act include fines of up to **€25,000 (\$27,151)** and **€50,000 (\$54,311)** for repeat offenses, potential revocation of marketing authorizations, and prohibition of qualified persons from their activities after repeated violations. These penalties apply to various infractions, including failure to submit required information to the EU database.

BELGIUM

The Federal Agency for Medicines and Health Products (FAMHP) oversees clinical trials in Belgium. The **Acts on Clinical Trials of Medicines for Human Use** authorize FAMHP staff to conduct inspections to ensure compliance with the EU CTR. Penalties for noncompliance, such as failing to submit required public information to the EU database, include fines ranging from **€500 (\$543)** to **€250,000 (\$271,611)** and imprisonment for **one month to two years**. For repeat offenders, cases causing death or harm to subjects, offenses by healthcare professionals abusing their position, involvement of criminal organizations, or previous convictions for similar offenses, the penalties increase to fines of **€1,000 (\$1,086)** to **€500,000 (\$543,113)** and imprisonment for **three months to three years**. Additionally, a judge may prohibit convicted individuals from participating in clinical trials as sponsors, investigators, or in any other capacity for **three to ten years**.

CROATIA

The Ministry of Health and the Agency for Medicinal Products and Medical Devices (HALMED) oversee clinical trials in Croatia. HALMED conducts inspections per the EU CTR under the **Act implementing Regulation (EU) No. 536/2014**, with authorized pharmaceutical inspectors overseeing all trial-related sites. Croatia has established misdemeanor provisions for violations of clinical trial regulations, including disclosure requirements. Legal entities that fail to submit a summary of clinical trial results to the EU database within one year of trial completion can face fines ranging from **HRK 50,000** to **HRK 200,000**. Fines may also be imposed on individuals within legal entities for such violations.

CYPRUS

The Medicines Council is the competent authority responsible for overseeing clinical trials in Cyprus. Under the **Medicines for Human Use (Control of Quality, Supply and Prices) Law**, the Medicines Council conducts inspections to verify compliance with disclosure requirements. Inspectors are appointed to carry out these inspections and have the authority to access relevant documents and data. The Medicines Council can enforce compliance through various measures, including imposing administrative fines and requiring corrective actions. Failure to submit a summary of clinical trial results to the EU database may result in an administrative fine of up to **€25,000 (\$27,156)**, with an additional fine of up to **€200 (\$217)** for each day until the noncompliance is resolved.

DENMARK

The Danish Medicines Agency (DKMA) is responsible for overseeing clinical trials in Denmark. Under the **Act on Clinical Trials of Medicinal Products**, DKMA conducts inspections to ensure compliance with the EU CTR. Inspectors have access to clinical trial sites and can order the release of all information about the trial. DKMA checks those obligations to notify about the start, interruption, etc., of trials and to submit a summary of the results that are complied with. For noncompliance, DKMA can impose fines or imprisonment for up to **four months**, unless a more severe punishment is warranted under other legislation.

ESTONIA

The Estonian State Agency of Medicines (Ravimiamet) oversees clinical trials in Estonia. Under the Pharmaceuticals Act (RavS), Ravimiamet has the authority to conduct inspections to verify compliance

with requirements. It can take corrective measures, including revoking the authorization of a clinical trial, suspending a clinical trial, or requiring the sponsor to modify any aspect of the clinical trial if the requirements set out in the Regulation are no longer met. Violation of the requirements of a clinical trial, including provisions governing the submission of data intended for disclosure through the EU database, is punishable by a fine of up to 300 fine units (€2,400, as one fine unit equals 8 euros according to § 47 of the Penal Code [\$2,500]) for individuals or up to **€32,000 (\$34,766)** for legal entities.

FRANCE

The National Agency for the Safety of Medicines and Health Products (ANSM) is the competent authority for clinical trials in France. Specific penalties for noncompliance are outlined in the French **Public Health Code**. According to Article L1128-11 of the Public Health Code, failure to comply with

Articles 37, 42, 43, and 93 of EU CTR regarding the communication of information intended for public availability in the EU database is punishable by **one year's imprisonment** and a fine of **F15,000 (\$16,297)**.

GERMANY

Under the **Medicinal Products Act (AMG)** the competent higher federal authority can inspect the collection and evaluation of drug risks in companies conducting clinical tests on medicinal products. Inspectors may enter business premises during normal business hours to inspect documents and request information. Intentional or negligent failure to provide clinical trial results reports, or providing them incorrectly, incompletely, or not in time, is considered an administrative offense punishable by a fine of up to **€25,000 (\$27,161)**.

IRELAND

The Health Products Regulatory Authority (HPRA) oversees clinical trials in Ireland. HPRA can appoint authorized officers to conduct inspections before, during, or after clinical trials. Enforcement is managed under the European Union (Clinical Trials on Medicinal Products for Human Use), allowing the issuance of infringement notices. Penalties for noncompliance with regulations, including failure to comply with the provisions in the EU CTR on the submission of information intended for public disclosure and the submission of results of a clinical trial, can result in fines ranging from **€3,000 (\$3,253)** to **€300,000 (\$325,290)**, imprisonment for **six months** to **three years**, or both.

LATVIA

The State Medicines Agency oversees clinical trials in Latvia. Under the Pharmacy Law, the Health Inspectorate is responsible for

monitoring and controlling compliance with pharmaceutical regulations, including those related to clinical trials. Penalties for violations of the procedures for clinical trials and non-interventional studies of medicinal products may result in a warning or a fine of **5** to **40** fine units (**€25–200/\$5–\$216**) for natural persons and **50** to **400** (**€250–2,000/\$271– #2,169**) fine units for legal persons.

NETHERLANDS

The Central Committee on Research Involving Human Subjects (CCMO) oversees clinical trials in the Netherlands. Under the Medical Research Involving Human Subjects Act, the Minister of Health, Welfare, and Sport can impose administrative fines for noncompliance with various aspects of EU Regulation 536/2014, including results reporting requirements. Administrative sanctions for failing to meet these obligations can include fines and corrective actions deemed necessary by the Inspectorate. An administrative fine of up

to **€33,500 (\$36,324)** can be imposed for failing to submit results following the completion of a clinical trial.

SLOVAKIA

The State Institute for Drug Control (SIDC) oversees clinical trials in Slovakia. Under the Act on Medicines and Medical Devices, SIDC can impose fines for administrative offenses related to clinical trials. Specifically, for non-submission of the protocol and results from a non-interventional study to the National Center for Health Information, the State Institute may impose a fine ranging from **€300 (\$325)** to **€35,000 (\$37,951)**.

SPAIN

The Spanish Agency of Medicines and Medical Devices (AEMPS) is the primary regulatory body overseeing clinical trials and their disclosure in Spain. AEMPS maintains the Spanish Clinical Studies Registry (REec)

on its website. Under the **Law on Guarantees and Rational Use of Medicines and Health Products**, failure to submit clinical trial information in a timely manner is considered a serious infraction and may be subject to a monetary fine of between **€30,000 (\$32,530)** to **€90,000 (\$97,578)**. Additionally, AEMPS may choose to make partial information about a clinical trial or a non-interventional post-authorization study public. In such cases, AEMPS explicitly states the sponsor's details and the reasons why the information in the registry is incomplete. This is separate from any punitive actions that may be applicable under current legislation.





Non-regulatory Requirements

Non-regulatory Requirements

DECLARATION OF HELSINKI

The World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants establishes fundamental ethical standards for medical research involving humans. Many clinical trial sponsors and investigators explicitly commit to following these principles. The Declaration was updated in October 2024, and the current version requires that all clinical trials be registered before recruiting patients, and that all results are published — positive, negative, or inconclusive — in a timely, complete, and accurate manner.

JOINT STATEMENT ON PUBLIC DISCLOSURE OF RESULTS FROM CLINICAL TRIALS

In May 2017, the Joint Statement on Public Disclosure of Results from Clinical Trials was issued and endorsed by numerous international research organizations and funders. It establishes critical transparency standards to reduce reporting bias and research waste. The signatories commit to ensure all clinical trials are registered in public databases before recruitment begins, with results published within 12 months of completion (with limited extensions for products in active development). The statement outlines specific enforcement measures that include monitoring compliance with current studies and evaluating past reporting history when considering future funding.

WORLD HEALTH ORGANIZATION (WHO)

The World Health Organization (WHO) Statement on Public Disclosure of Clinical Trial Results affirms transparency as a “scientific and moral responsibility.” The WHO, which oversees the International Clinical Trials Registry Platform (ICTRP), requires that all interventional clinical trials be registered in a publicly accessible database before the first patient receives treatment. Trial results must be reported through two channels: publication in a peer-reviewed journal within 12 months of completion (preferably open-access) and posting key outcomes to the trial registry within the same timeframe.

WHO PRIMARY REGISTRIES

A WHO primary registry is a clinical trial registry that meets its specific criteria, established by the World Health Organization, including free public access, open to all registrants, managed by a not-for-profit organization, and having mechanisms to ensure data validity, and serving as a recognized data provider to the WHO's International Clinical Trials Registry Platform (ICTRP). Primary Registries meet the requirements of the International Committee of Medical Journal Editors (ICMJE).

INDUSTRY ASSOCIATIONS

Industry associations, including the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA), and the Pharmaceutical Research and Manufacturers of America

LIST OF WHO PRIMARY REGISTRIES

1. Australian New Zealand Clinical Trials Registry (ANZCTR)
2. Brazilian Clinical Trials Registry (ReBec)
3. Chinese Clinical Trial Registry (ChiCTR)
4. Clinical Research Information Service (CRiS), Republic of Korea
5. Clinical Trials Registry – India (CTRI)
6. Cuban Public Registry of Clinical Trials (RPCEC)
7. EU Clinical Trials Register (EU-CTR), European Economic Area (EEA)
8. German Clinical Trials Register (DRKS)
9. Iranian Registry of Clinical Trials (IRCT)
10. ISRCTN (United Kingdom)
11. International Traditional Medicine Clinical Trial Registry (ITMCTR)
12. Japan Registry of Clinical Trials (jRCT)
13. Lebanese Clinical Trials Registry (LBCTR)
14. Pan African Clinical Trial Registry (PACTR)
15. Peruvian Clinical Trial Registry (REPEC)
16. Sri Lanka Clinical Trials Registry (SLCTR)
17. Thai Clinical Trials Registry (TCTR)
18. US: ClinicalTrials.gov (CTgov) – while United States of America. While not an official WHO Primary Registry, CTgov is accepted by many organizations and regulatory authorities to fulfill their requirements due to the size of the registry (over 500,000 global studies registered) and close alignment with WHO Primary Registry criteria.

(PhRMA), have established voluntary principles and commitments for clinical trial disclosure.

Members are committed to registering all clinical trials conducted on patients on public registries no later than 21 days after the initiation of patient enrollment. Results from all clinical trials, regardless of outcome, should be publicly disclosed no later than one year after the medicinal product is first approved and commercially available in any country. For trials completed after initial approval, results should be disclosed no later than one year after trial completion. Additionally, companies commit to sharing patient-level data, study-level data, and protocols from clinical trials for medicines and indications approved in the US and EU, upon request from qualified scientific and medical researchers.

While there are no formal inspection processes or specific penalties for noncompliance, companies are encouraged to establish internal verification processes. Companies adhering to these principles must certify on a

publicly available website that they have established policies and procedures to implement these data-sharing commitments.

INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS (ICMJE)

The International Committee of Medical Journal Editors (ICMJE) has included disclosure standards in its Recommendations. These standards play a key role in promoting clinical trial transparency worldwide. Since 2005, ICMJE member journals — including many of the world's leading medical publications — have required that clinical trials be registered in a public registry before participant enrollment begins. To meet this requirement, registration must occur in a World Health Organization

(WHO) International Clinical Trials Registry Platform (ICTRP) primary registry or ClinicalTrials.gov.

This policy strongly encourages researchers to register their trials, as failure to do so can prevent publication in prestigious journals, regardless of local regulations. Additionally, the ICMJE has clarified that posting summary results in a registry that meets regulatory requirements does not count as prior publication, ensuring researchers can still publish their findings in academic journals.



A blurred background image showing three business professionals in an office setting. One person in a white shirt is holding a smartphone, while another is holding a pen over a document. The scene is brightly lit, suggesting a window in the background.

Discussion and Conclusion

Discussion and Conclusion

This paper highlights a global trend toward increased transparency and more stringent enforcement of clinical trial reporting requirements. The specific mechanisms and penalties differ significantly across various regions and countries, resulting in a complex regulatory environment for sponsors and researchers to navigate. While there is consensus on the importance of trial registration and results reporting, the specifics of enforcement vary widely across jurisdictions. Penalties in many regions underscore regulators' commitment to disclosure requirements, though actual enforcement levels often lag stated policies.

Our analysis reveals a complex interplay of formal regulations and emerging social expectations. While countries have established various regulatory frameworks, there is an increasing social demand for transparency that transcends compliance. Initiatives like the TrialsTracker Project demonstrate how social pressure is exerted through public monitoring and reporting of compliance rates. Despite substantial penalties in many jurisdictions (e.g., fines of up to \$10,000 per day in the US), actual enforcement of compliance actions is often limited. This enforcement gap is partially addressed by social accountability mechanisms, where noncompliance is publicly exposed, potentially impacting reputation and trust.

This trend is evidenced by voluntary

commitments from industry associations like IFPMA, EFPIA, JPMa, and PhRMA, which often exceed regulatory obligations. As public awareness increases, noncompliance poses a significant reputational risk for sponsors and institutions. This risk may represent a more immediate and tangible consequence than regulatory penalties, given the current low levels of enforcement. The growing importance of transparency in funding decisions, institutional rankings, and public perception of research entities further reinforces this shift towards a culture of openness in clinical research.

Australia's approach to clinical trial oversight contrasts with those reviewed in this paper, highlighting the diversity in global approaches. The Therapeutic Goods Administration (TGA) has established a

robust compliance and enforcement framework, including warning letters, suspensions, cancellations, recalls, and various penalties for noncompliance. However, these measures focus primarily on ensuring the safety, quality, and efficacy of therapeutic goods and the proper conduct

and authorization of clinical trials rather than the public disclosure of trial information in registries. Unlike the US and EU, Australia's compliance actions are not explicitly linked to trial registration in publicly accessible registers. This difference underscores the challenges in achieving a truly global

standard for clinical trial transparency and emphasizes the need to consider both regulatory frameworks and social expectations in different cultural and regulatory environments when developing and implementing clinical trial disclosure policies.

¹ Updates to the FDAAA TrialsTracker website have become periodic with the last update in February 2024 and the next update planned in February 2025.

² Law on Administrative Liability coming into force on 20 December 2019, indicates that one unit of fine = €5.



The background features a stylized globe with a blue and white pixelated texture. Overlaid on the globe is a complex network of thin white lines connecting various points, suggesting a global communication or data network. The overall color scheme is dark blue with white and light blue highlights.

How Citeline Can Help

How Citeline Can Help

TrialScope Intelligence from Citeline offers a centralized, interactive repository of critical and accurate insight on global clinical trial disclosure, empowering sponsors of all sizes to efficiently manage disclosure compliance in both development and post-marketing phases.

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Benedict Evans is a regulatory professional with expertise in clinical trial disclosure, medical technology, and biotechnology. As Disclosure Regulations Research Manager at Citeline, Benedict works on the content development and expansion of TrialScope Intelligence, ensuring that sponsors have access to reliable, up-to-date regulatory insights to inform actionable regulatory intelligence. With a strong foundation in science, regulation, and project management, Benedict has worked across the biotech, life sciences, and medical technology sectors, helping organizations navigate regulatory requirements.



FRANCINE LANE

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Francine Lane helps TrialScope Disclose customers meet and exceed current disclosure expectations globally, giving them the tools they need to meet all the requirements in this evolving industry. Francine also dedicates her time building relationships with external stakeholders — including sponsors, investigators, regulators, and transparency and patient advocates — to help align the goals and expectations of these groups, as well as help identify more consistent ways sponsors can meet industry standards. She is immediate past chair of the Drug Information Association (DIA) Clinical Trial Disclosure Community.

Thank you for reading

Trial and Consequence: Global Enforcement Landscape of Clinical Trial Disclosure