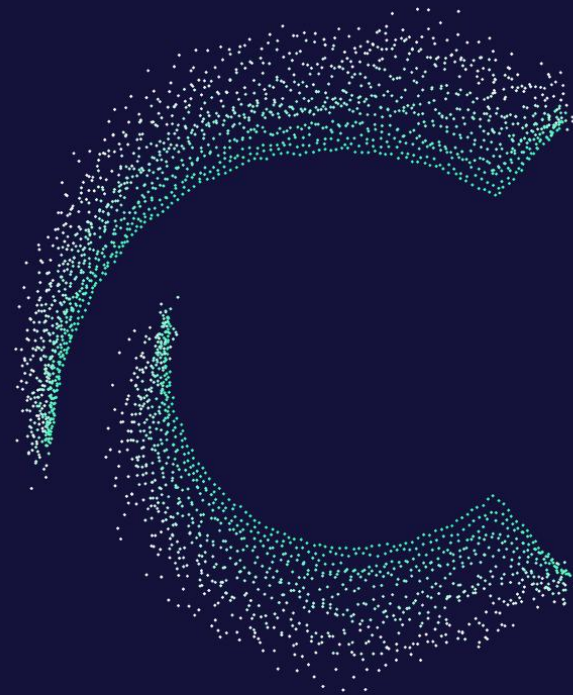


Regul-*ASIAN* Uncovered

Navigating Reporting
Requirements in Asian Markets



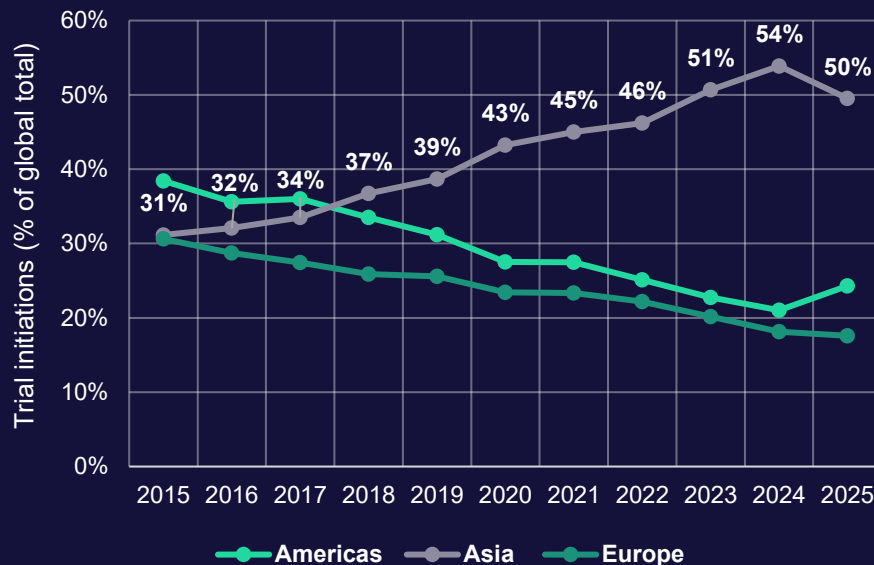
Agenda

- ❑ **INTRODUCTION:** Asia's Clinical Trial Disclosure Landscape
- ❑ **PROTOCOL REGISTRATION:** What & When? • Global requirements • Timing variations • Public availability
- ❑ **RESULTS DISCLOSURE:** What & When? • Mandatory vs. voluntary • Posting timelines • Format requirements
- ❑ **PERMISSIBLE REGISTRIES:** Where? • Local vs. international • Registry landscape • Compliance mapping
- ❑ **ENFORCEMENT LANDSCAPE:** Why? • Penalties & fines • Consequences • Country comparisons
- ❑ **COUNTRY DEEP DIVES** • India • China • Japan • Philippines • Thailand
- ❑ **FUTURE OUTLOOK:** What Next? • ICH E6(R3) implementation
- ❑ **KEY TAKEAWAYS** • Streamlined compliance strategies • Success factors

Navigating Asia's Clinical Trial Disclosure

- Asia's share of global clinical trial initiations has grown substantially over the past decade, rising from **31% (4,464)** in **2015** to a peak of **54% (14,737)** in **2024**, overtaking the Americas and outpacing Europe, both of which have seen their relative shares decline over the same period. An estimated **60–70%** of Asian trials are **single-country studies** conducted in China alone.
- The challenge:** Despite this growth, each Asian jurisdiction has distinct regulatory frameworks for clinical trial transparency, resulting in:
 - Mandatory vs. voluntary disclosure requirements
 - National vs. international registry use
 - Varied results posting timelines
- To navigate this landscape, sponsors must understand:
 - **What** must be disclosed
 - **When** disclosure is required
 - **Where** registration must occur
 - **Why** compliance is enforced

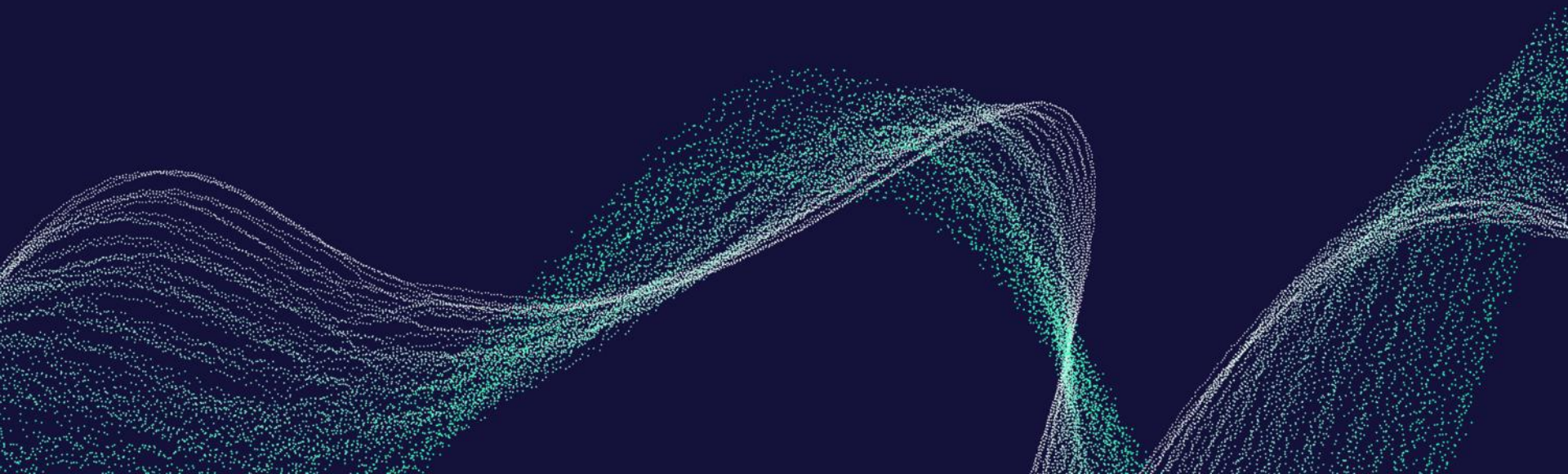
Share of Global Trial Initiations



*Trial initiations (by start date) from 2015 to 2025, excluding trials with a status of 'planned' or those terminated before initiation. Global initiations range from 14,327 in 2015 to 27,351 in 2024. Regional figures are not mutually exclusive, as trials with sites in multiple regions are counted in each region. Data for 2025 may be subject to reporting lag.
Source: TrialTrove, Citeline*

PROTOCOL REGISTRATION

What & When?



Overview of Global Protocol Registration

- Over 80 countries require protocol registration, each with varying disclosure obligations:



AFRICA

17 countries require registration

Public availability: 9 fully/mostly public, 4 not public, 4 undefined



AMERICAS

10 countries require registration

Public availability: 6 fully public, 4 mostly public



ASIA

21 countries require registration (20 mandatory, 1 voluntary)

Public availability: 10 fully public, 6 mostly public, 2 not public, 3 undefined



EUROPE

35 countries require registration (all mandatory), 27 EU Member States, plus 3 EEA countries

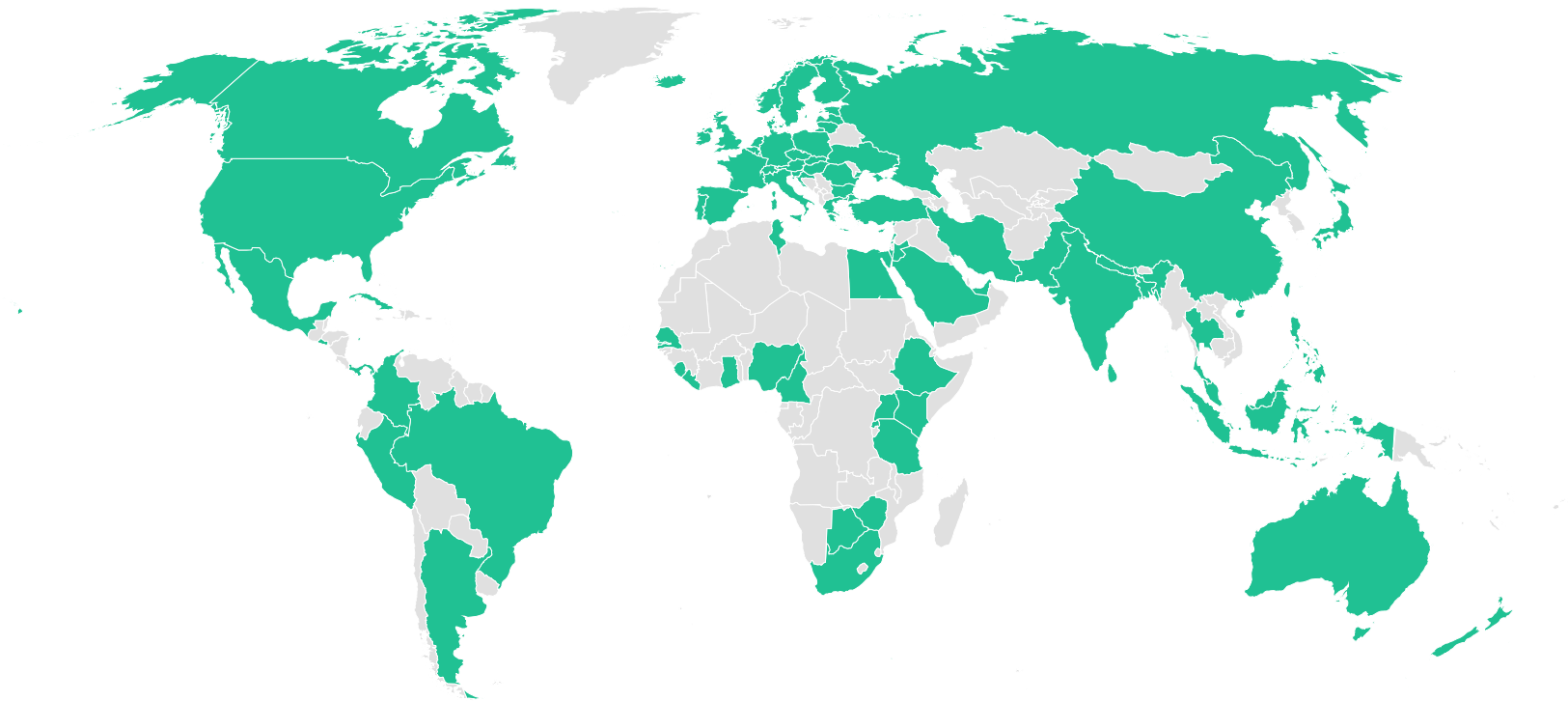
Public availability: 32 fully public, 1 mostly public, 2 undefined



OCEANIA:

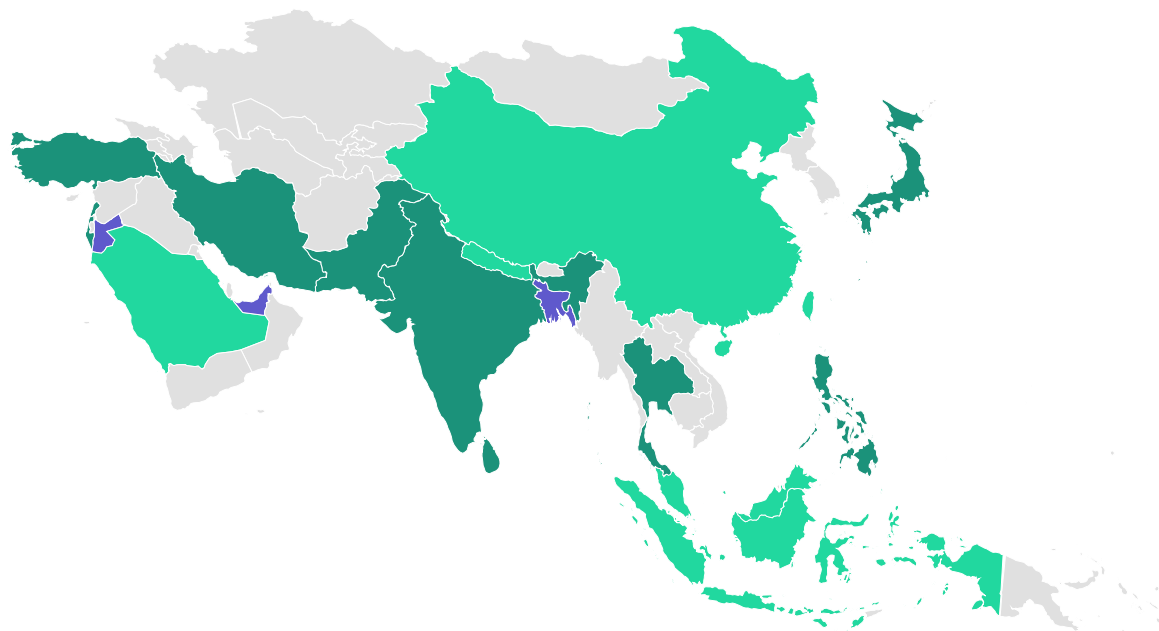
2 countries (1 mandatory, 1 voluntary)

Public availability: Both fully public



Protocol Registration in Asia

■ Fully Public ■ Mostly Public ■ Not Public ■ Undefined



Fully Public (10 countries) Protocol information is completely publicly available through sponsor-submitted forms or health authority submissions.

India • Iran • Israel • Japan • Lebanon • Pakistan • Philippines • Sri Lanka • Thailand (voluntary) • Turkey



Mostly Public (6 countries) Protocol information is largely publicly available with some restrictions. May include partial redactions or limited access to certain protocol elements.

China • Indonesia • Malaysia • Nepal • Saudi Arabia • Taiwan



Not Public (2 countries) Registration is mandatory, but protocol information remains confidential. Only regulatory authorities have access.

Bahrain • Singapore

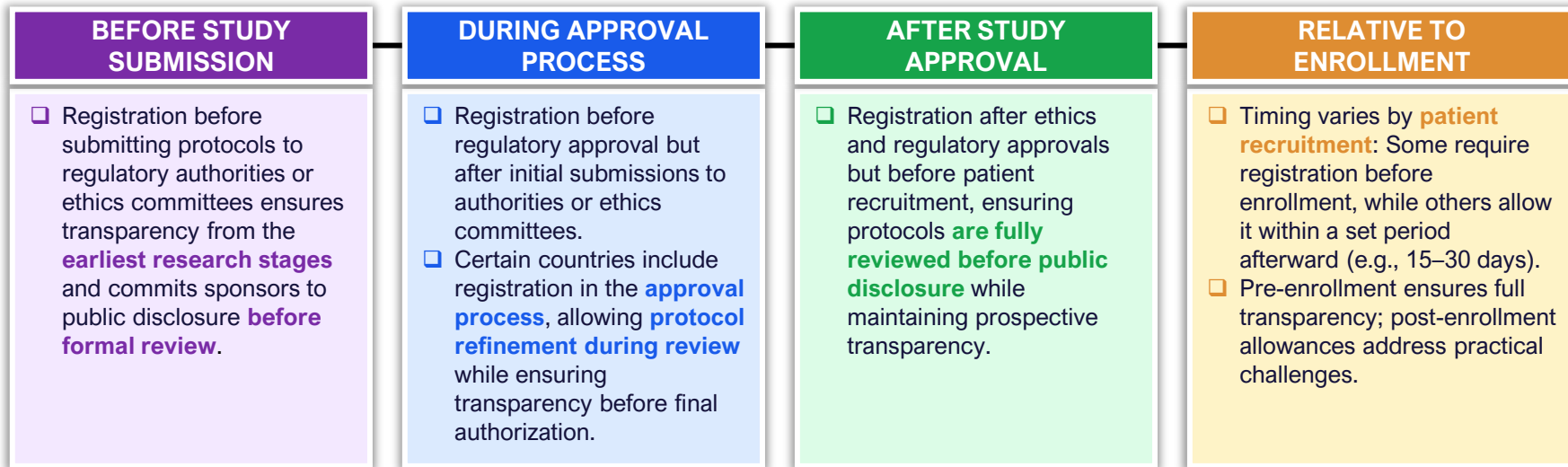


Undefined (3 countries) Public availability requirements are not specified in regulations, creating ambiguity about data accessibility.

Bangladesh • Jordan • UAE

Global Protocol Registration Timing

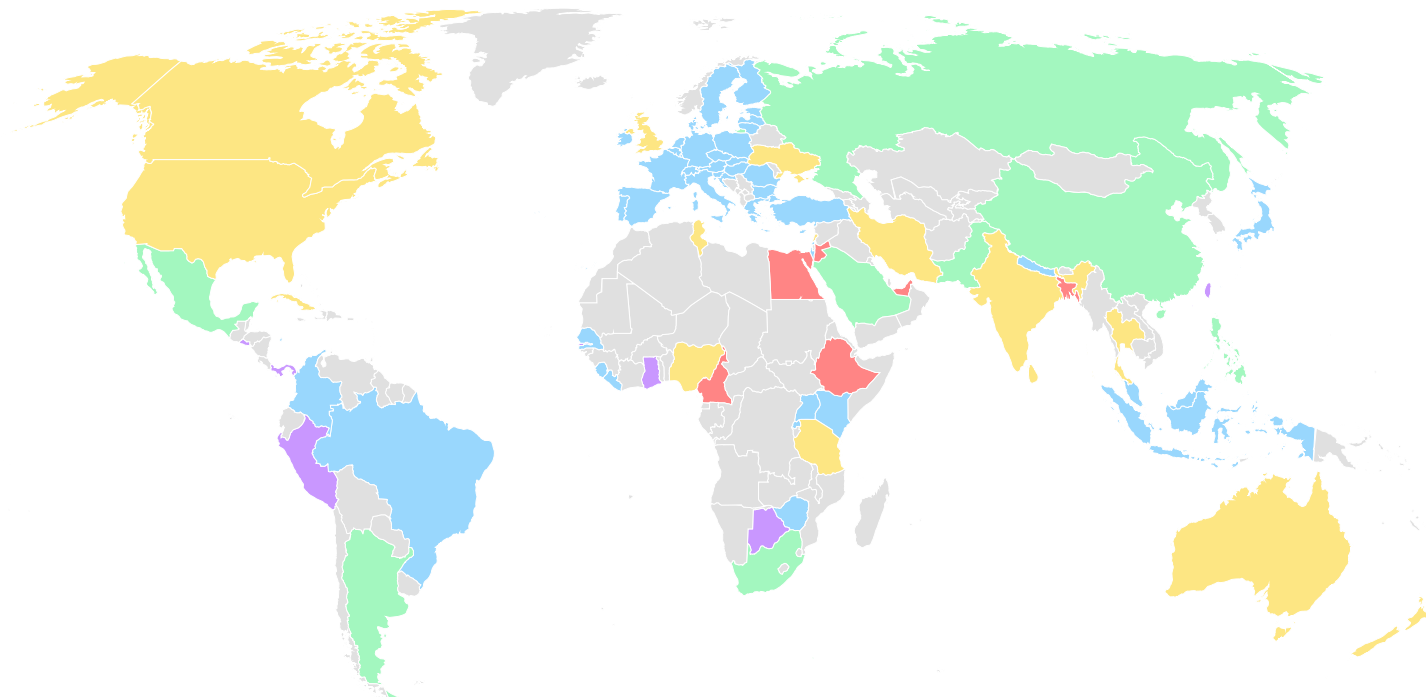
Clinical trial **registration timing requirements** vary significantly across **global regulatory jurisdictions**, reflecting different approaches to transparency and oversight. Countries have adopted distinct models when this obligation must be met. The timing for protocol registration can fall into one of the following categories:



*Note: In certain cases, regulations mandate protocol registration but **do not specify a clear deadline**.*

Mapping Global Protocol Registration Timing

Before Study Submission During Approval Process After Study Approval Relative to Enrollment No Defined Timing



Core Documents Required

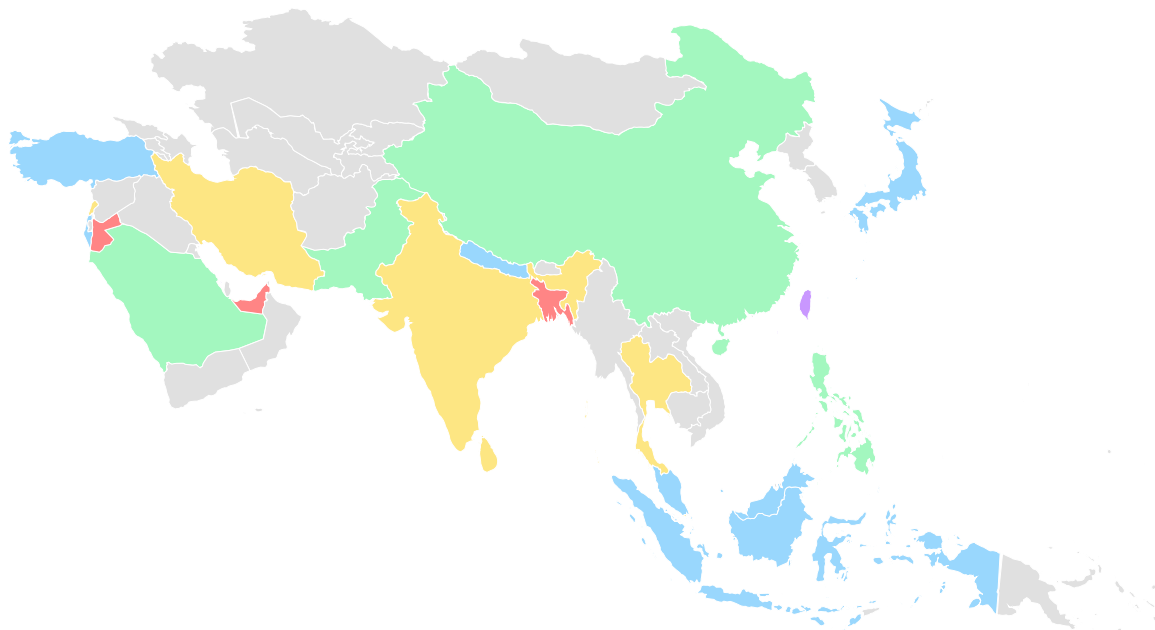
- ☐ **Full protocol:** 52+ countries
- ☐ **Ethics committee approval letter:** 47+ countries
- ☐ **Informed consent forms:** 45+ countries
- ☐ **Primary endpoints:** 57+ countries
- ☐ **Secondary endpoints:** 52+ countries

Unclear Timing

- ☐ The following countries have registration requirements, but the specific timing is not clearly defined in regulations:
Cameroon, Egypt, Ethiopia, Bangladesh, Jordan, UAE

Protocol Registration Timing in Asia

- Before Study Submission
- During Approval Process
- After Study Approval
- Relative to Enrollment
- No Defined Timing



BEFORE STUDY SUBMISSION

- ☐ **Bahrain:** Before trial starts
- ☐ **Taiwan:** Before submission for review



DURING APPROVAL PROCESS

- ☐ **Indonesia, Malaysia, Nepal:** Before EC & HA approval
- ☐ **Israel:** Before trial approval by the director
- ☐ **Japan:** Before implementation
- ☐ **Turkey:** As part of the application submission



AFTER STUDY APPROVAL

- ☐ **China:** After approval, before enrollment
- ☐ **Pakistan:** Within 15 days after CSC approval
- ☐ **Philippines:** Within 30 days of FDA approval
- ☐ **Saudi Arabia:** After IRB and SFDA approval, before start



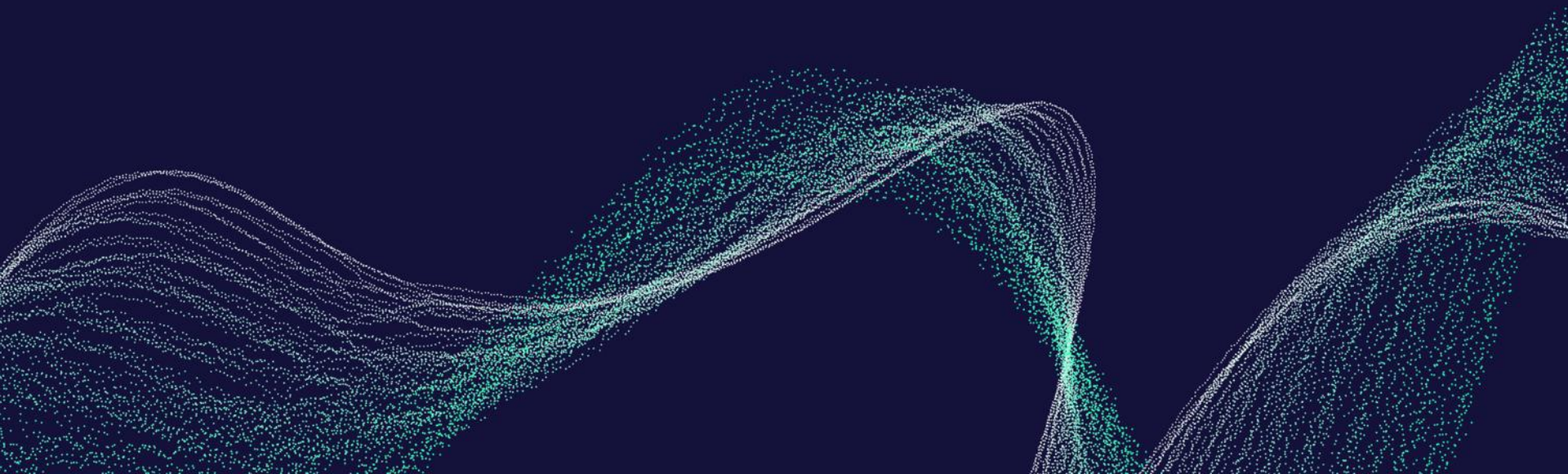
RELATIVE TO ENROLLMENT

Before Enrollment:

- ☐ **India, Iran, Lebanon, Singapore, Sri Lanka, Thailand** (voluntary)

RESULTS DISCLOSURE

What & When?



Overview of Global Results Disclosure

- Over 60 countries mandate or encourage (voluntary requirement) clinical trial results disclosure:



AFRICA

8 countries require results posting (all mandatory).

Public availability: 4 publicly available, 2 not publicly available, 2 undefined



AMERICAS

9 countries require results posting (6 mandatory and 3 voluntary)

Public availability: 7 publicly available, 2 not publicly available



ASIA

12 countries require results posting (8 mandatory and 4 voluntary)

Public availability: 8 publicly available, 4 not publicly available



EUROPE

33 countries require results posting (**all mandatory**), 27 EU Member States/3 EEA countries

Public availability: 32 publicly available, 1 not publicly available



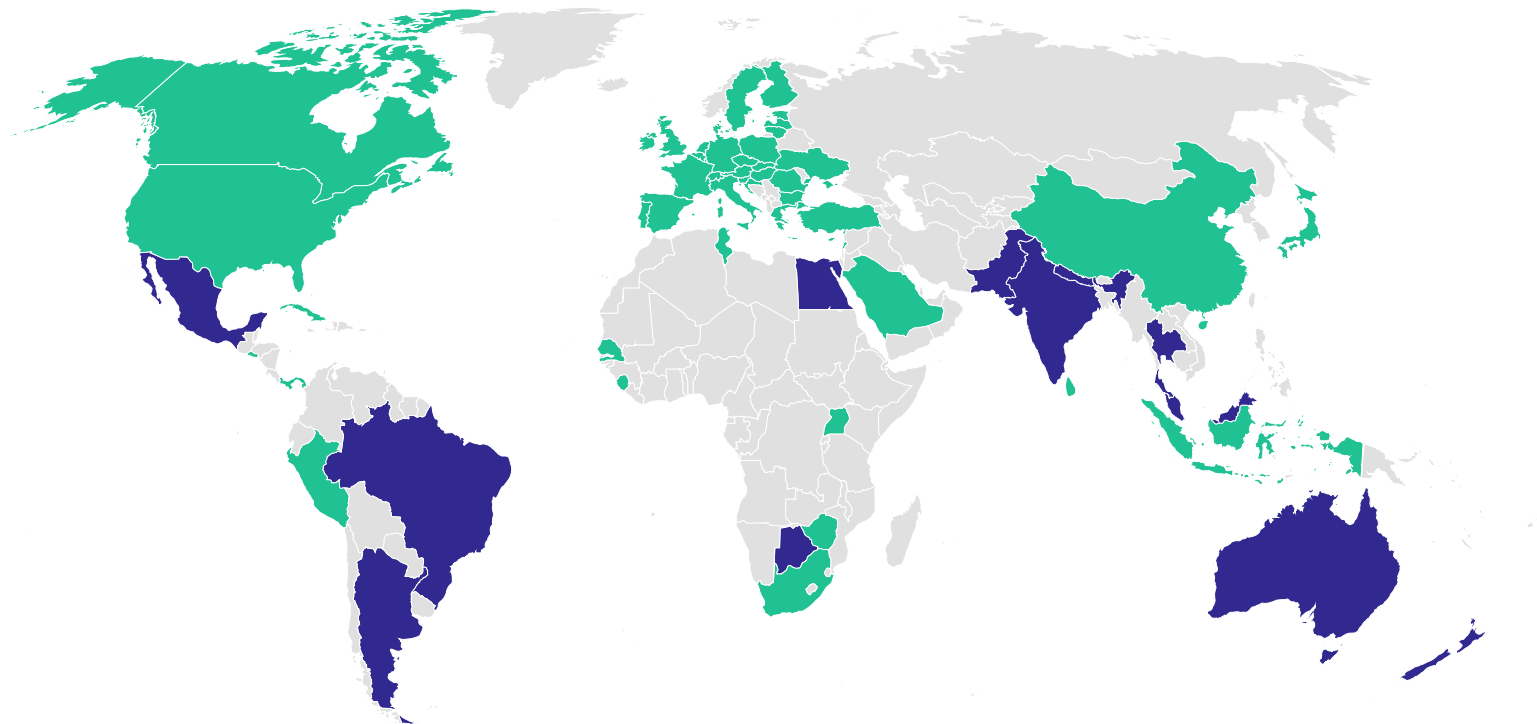
OCEANIA

2 countries require results posting (2 voluntary).

Public availability: Both are publicly available

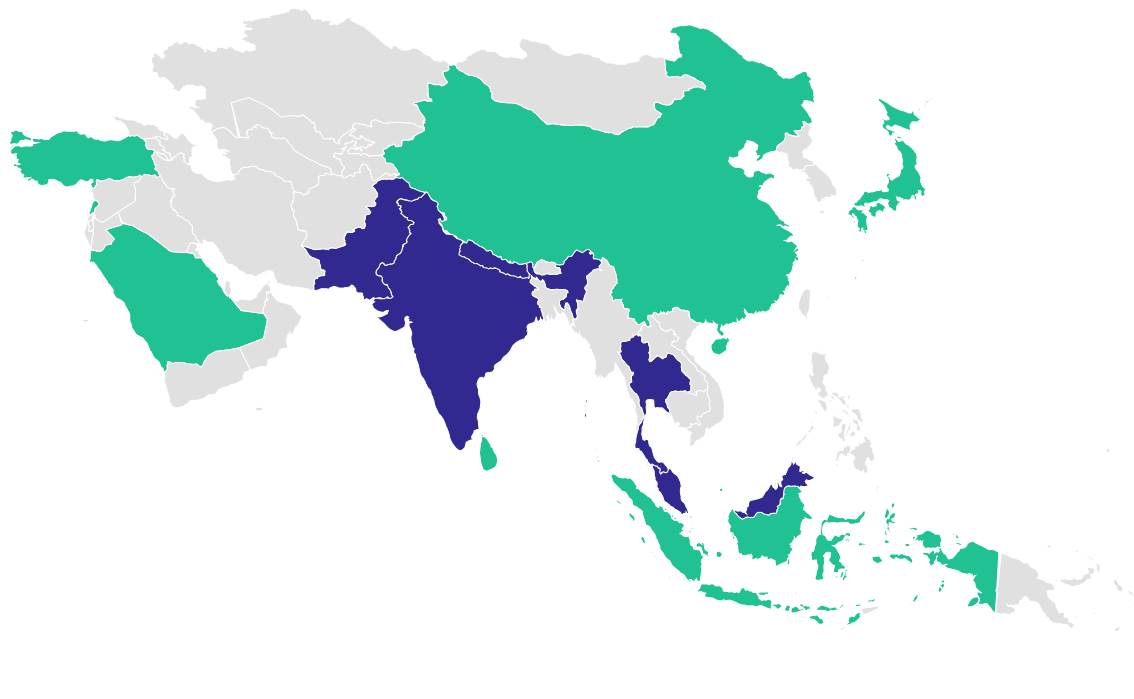
Mapping Global Results Disclosure

■ Mandatory ■ Voluntary



Results Disclosure in Asia

■ Mandatory Results Posting ■ Voluntary Results Posting



Mandatory Results Posting (8 countries) Results submission is required by regulation with specific timelines. Sponsors must submit trial results within defined timeframes.

China • Indonesia • Japan • Lebanon • Malaysia • Saudi Arabia • Sri Lanka • Turkey



Voluntary Results Posting (4 countries) Results submission is encouraged but not mandated by regulation. Sponsors may choose to submit trial outcomes.

India • Nepal • Pakistan • Thailand



Results Publicly Available (8 countries) Posted results are made accessible.

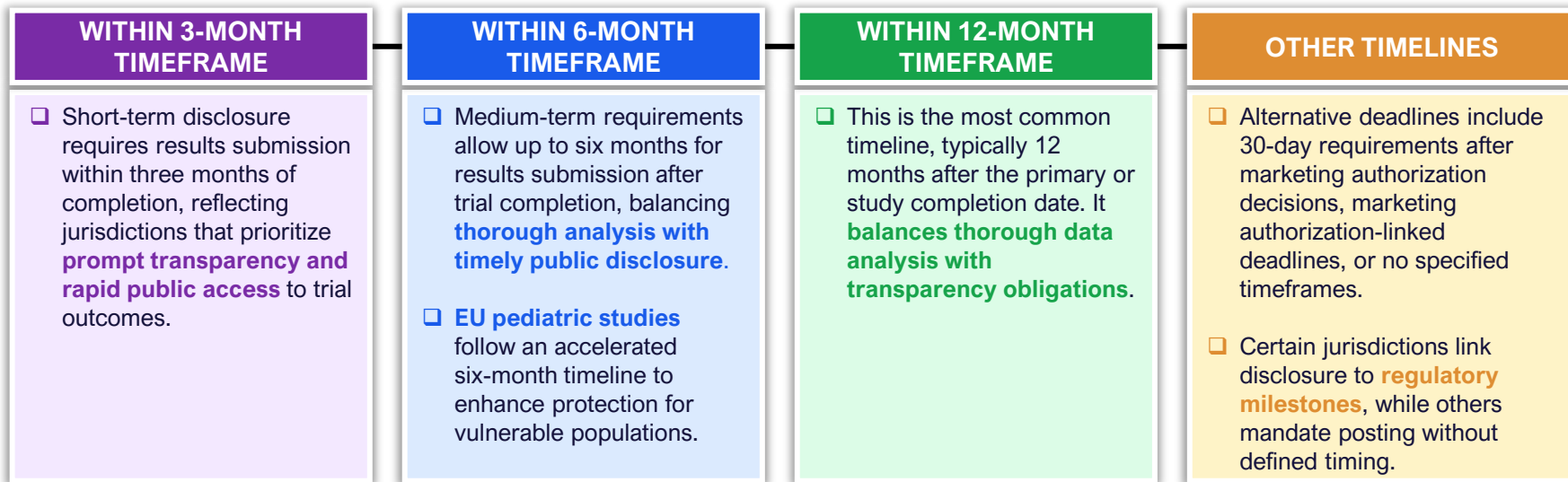
India • Indonesia • Japan • Lebanon • Pakistan • Sri Lanka • Thailand • Turkey

Results Not Publicly Available (4 countries) Results are submitted to regulatory authorities but not made public.

China • Malaysia • Nepal • Saudi Arabia

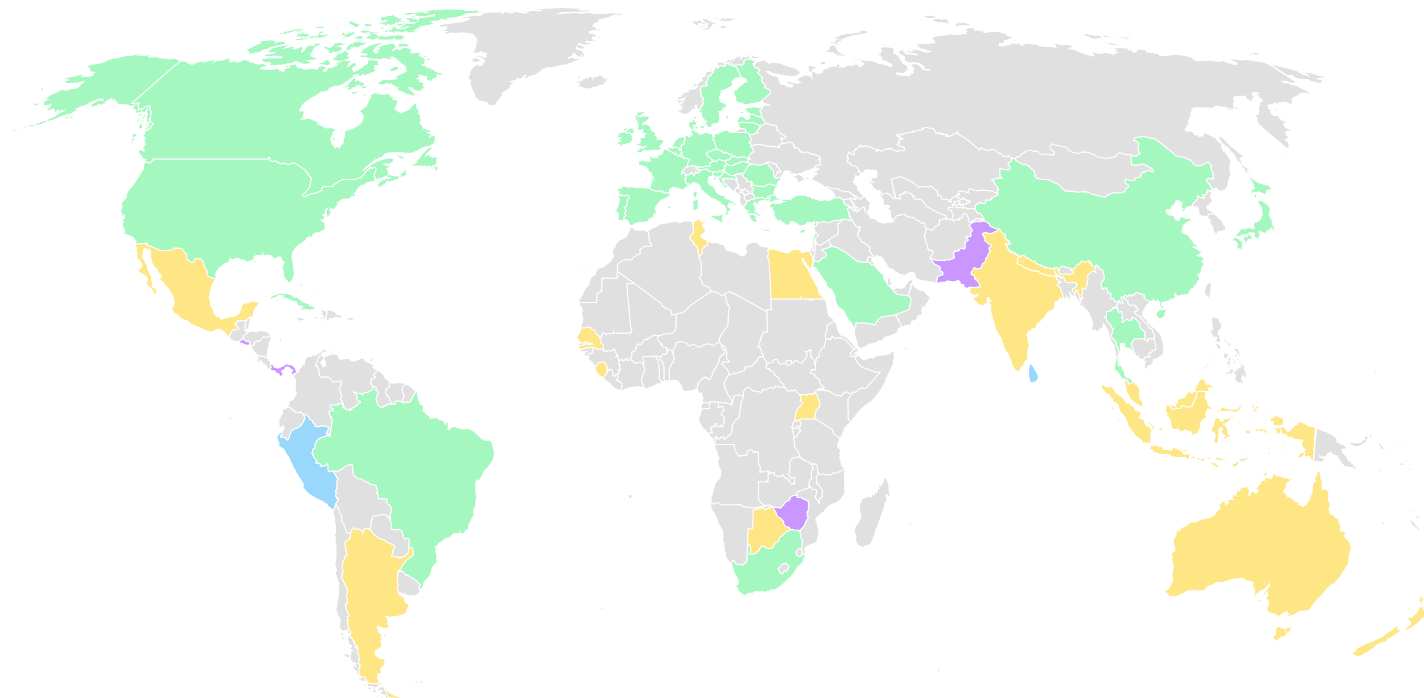
Overview Global Results Disclosure Timing

Clinical trial results posting **timing varies across global regulatory jurisdictions**, reflecting different priorities and approaches. Some countries set specific deadlines for mandatory or voluntary disclosure, while others require disclosure **without defined timelines**. When specified, timing requirements generally fall into these categories:



Mapping Global Results Disclosure Timing

■ Within 3-Month Timeframe ■ Within 6-Month Timeframe ■ Within 12-Month Timeframe ■ Other Timelines



Format Standardization

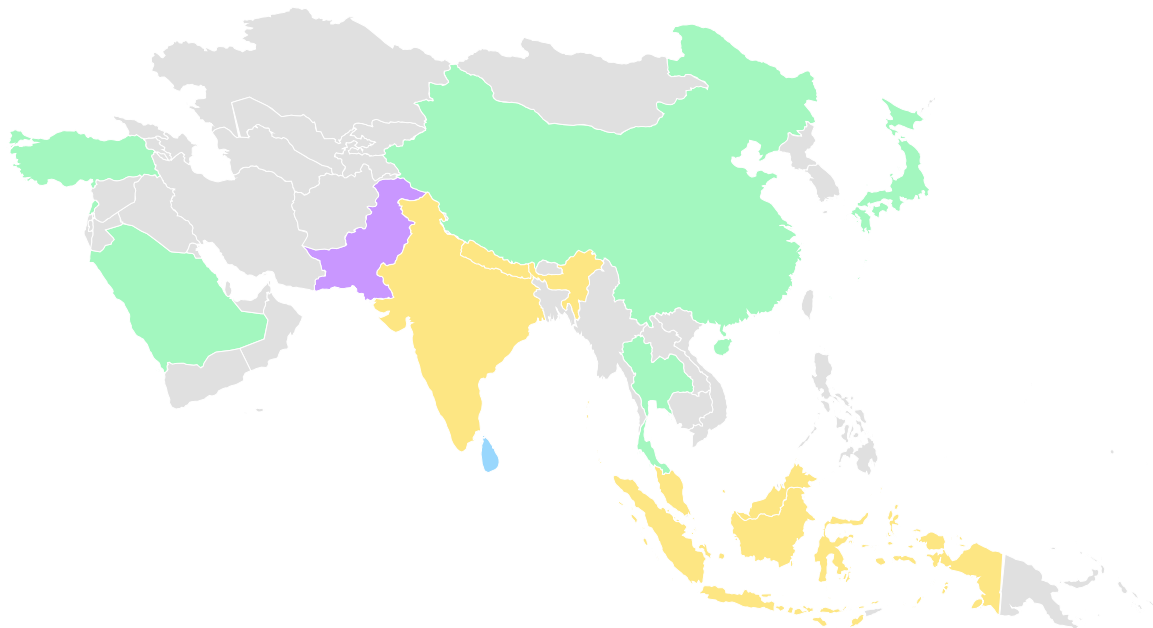
- ❑ **Format specifications:**
35+ countries (including the EU/EEA)
- ❑ **No specific format mentioned:** 10+ countries

National Registry Requirements

- ❑ **Results publicly available:**
~35 countries (including EU Member States)
- ❑ **Results not publicly available:** ~10–15 countries

Results Disclosure Timing in Asia

Within 3-month Timeframe Within 6-month Timeframe Within 12-month Timeframe Other Timelines



WITHIN 3-MONTH TIMEFRAME

- **Pakistan:** After trial completion

WITHIN 6-MONTH TIMEFRAME

- **Sri Lanka:** Final report after clinical trial completion

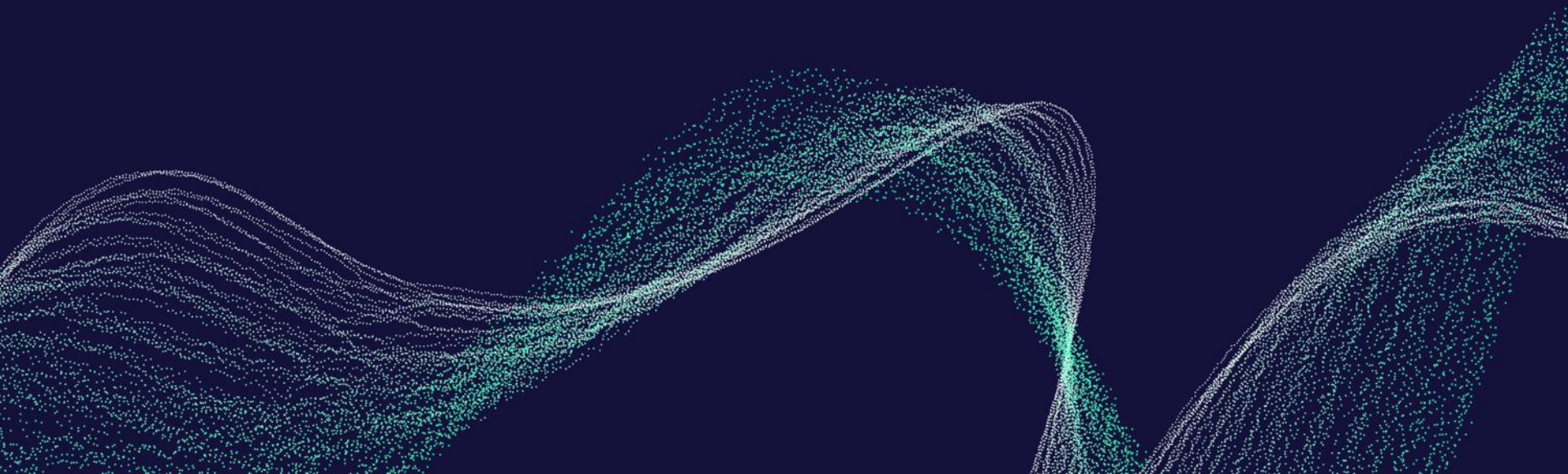
WITHIN 12-MONTH TIMEFRAME

- **China** (or before marketing application)
- **Japan**
- **Lebanon**
- **Saudi Arabia**
- **Thailand** (voluntary/recommended)
- **Turkey** (plain language summary)

OTHER TIMELINES

- | | |
|--------------------|-------------------|
| Mandatory: | Voluntary: |
| □ Indonesia | □ India |
| | □ Malaysia |
| | □ Nepal |

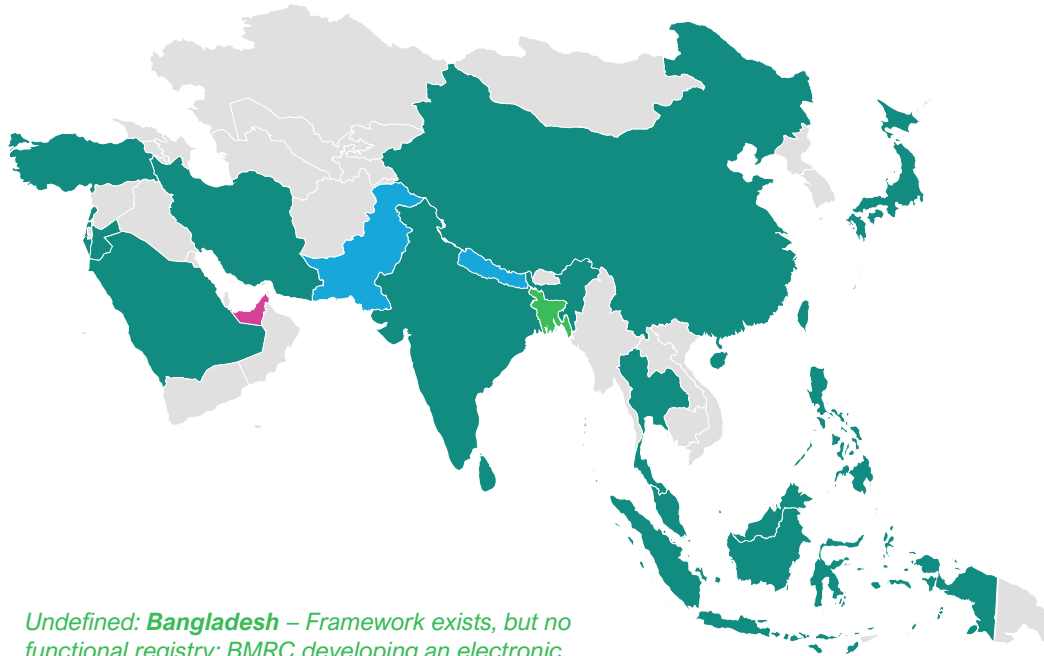
PERMISSIBLE REGISTRIES Where?



CITELINE
a norstella company

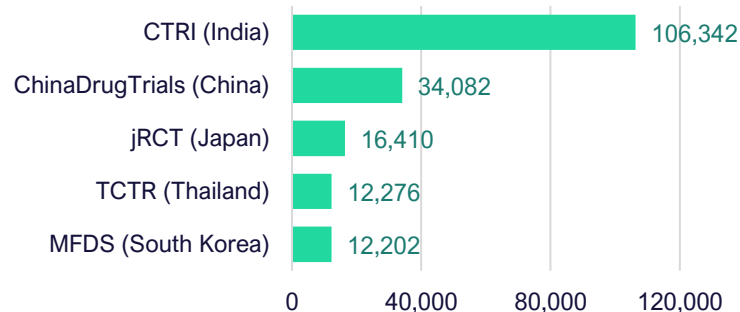


Registries in Asia

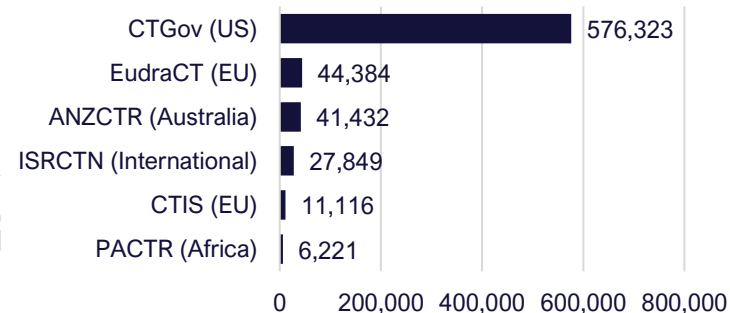


Undefined: **Bangladesh** – Framework exists, but no functional registry; BMRC developing an electronic system with a planned clinical trial registry

Registered Trials Asia

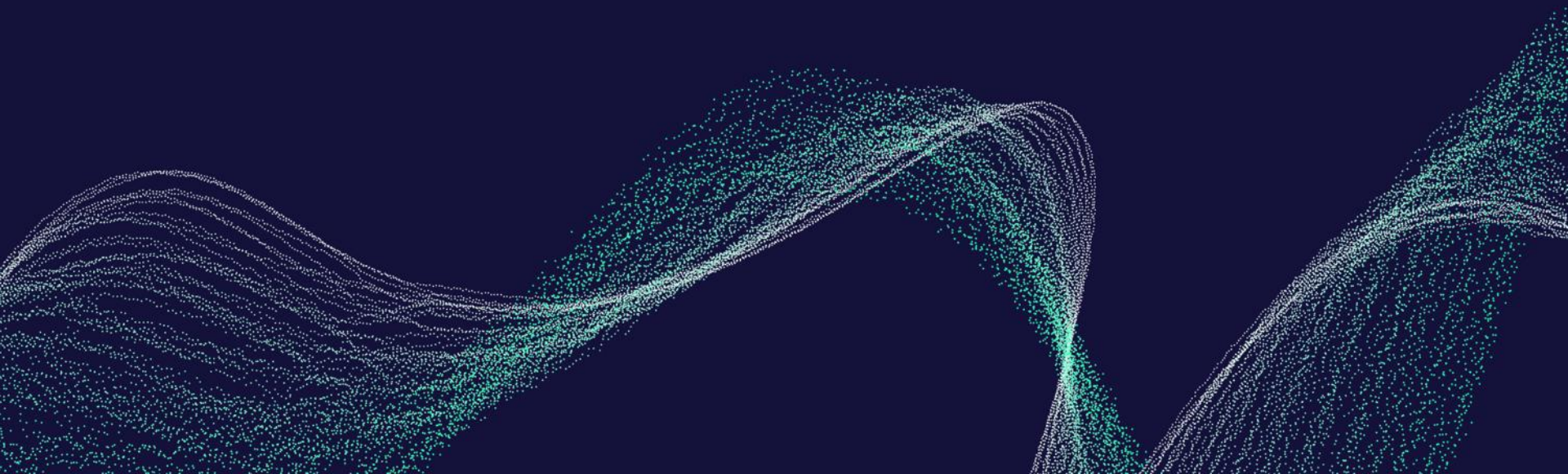


Registered Trials RoW

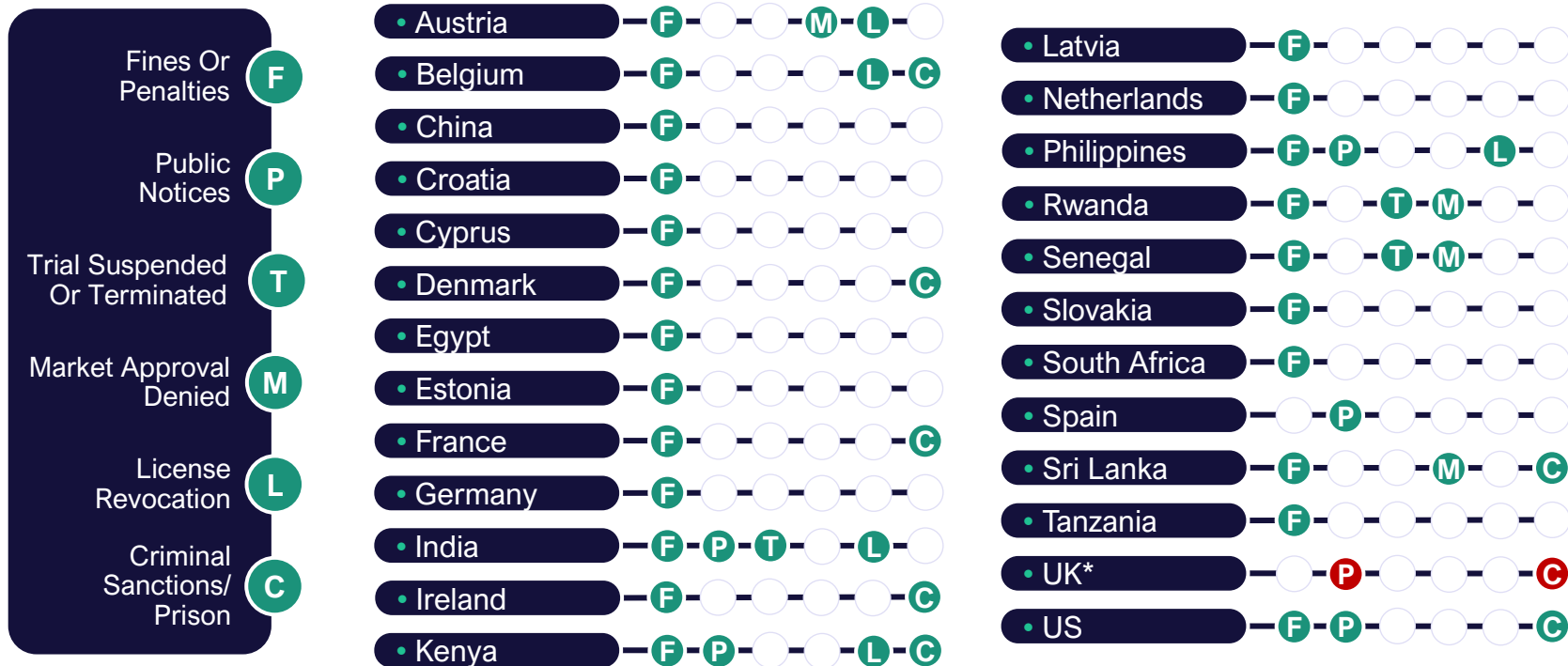


Trial count as of Mar. 16, 2026

ENFORCEMENT LANDSCAPE Why?



Global Enforcement Overview



*Applicable from Apr. 28, 2026 (SI 2025/538)

Asian Enforcement Landscape

• China



- **Fines or Penalties:** Fines ranging from **RMB 10,000** (USD 1,405) to **RMB 30,000** (USD 4,214) for failure to register before conducting a trial, submit required safety updates, or register results after completion

• India



- **Fines or Penalties:** Various administrative penalties may be imposed for noncompliance (not monetary fines)
- **Public Notices:** Written warnings
- **Trial Suspended or Terminated:** Suspension or cancellation of permissions; rejection of clinical trial results
- **License Revocation:** Barring the investigator or sponsor from future clinical research for a period determined by the DCGI

• Philippines



- **Fines or Penalties:** Administrative penalties ranging from **PHP 50,000** (USD 865) to **PHP 500,000** (USD 8,650), depending on the severity, and a fine of **PHP 1,000** (USD 17) for each day thereafter
- **Public Notices:** Violations, responsible entities, and regulatory actions are uploaded to the registry
- **License Revocation:** Suspension of the license to operate or other authorizations for up to one year

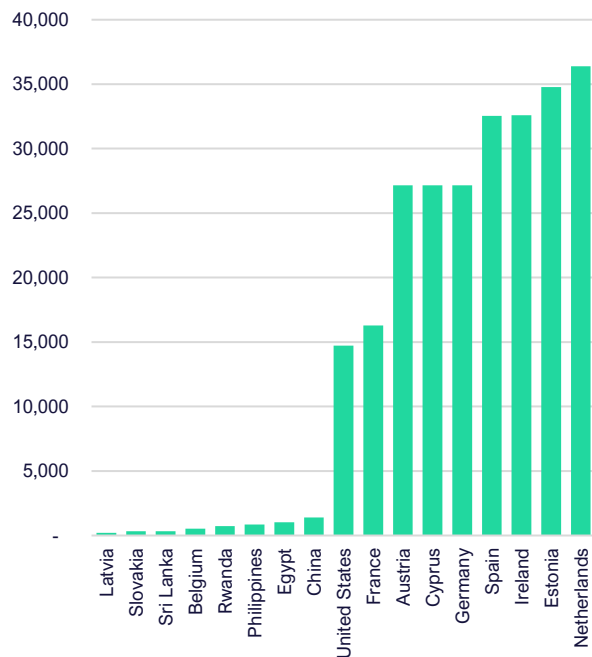
• Sri Lanka



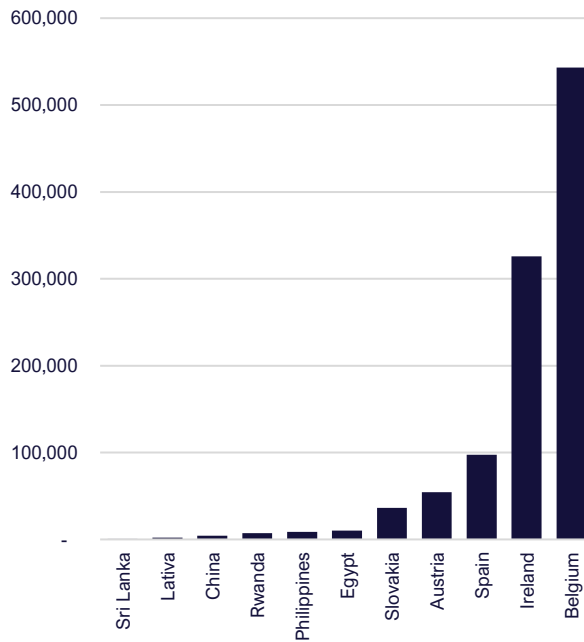
- **Fines or Penalties:** First offense: fines of up to **INR 100,000** (USD 342); subsequent offenses: fines of up to **INR 200,000** (USD 683); fines and/or imprisonment may be imposed; offenders may also be required to issue a public apology
- **Market Approval Denied:** Conviction may result in cancellation of any license or registration issued for the distribution of medicine
- **Criminal Sanctions/ Prison:** First offense: imprisonment of up to three months; subsequent offenses: imprisonment up to six months

Global Enforcement Penalties

Starting Fine for Noncompliance (USD)



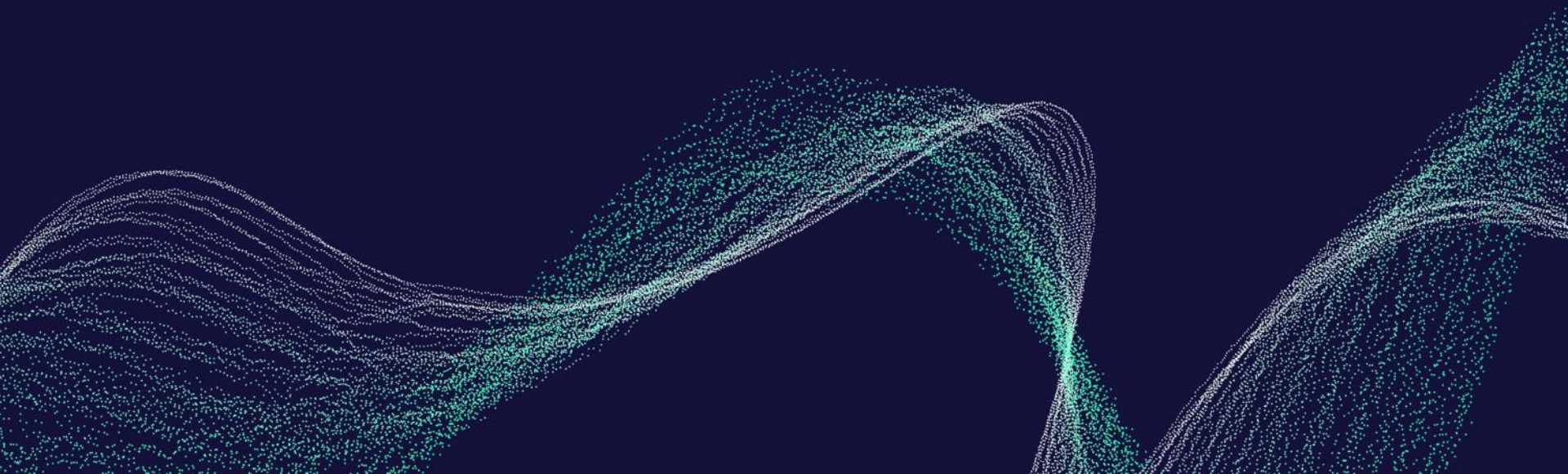
Maximum Fine for Noncompliance (USD)



COUNTRY	STARTING FINE (USD)	MAXIMUM FINE (USD)
Austria	\$ 27,156	\$ 54,311
Belgium	\$ 543	\$ 543,113
China	\$ 1,405	\$ 4,214
Cyprus	\$ 27,156	
Egypt	\$ 1,029	\$ 10,290
Estonia	\$ 34,763	
France	\$ 16,294	
Germany	\$ 27,156	
Ireland	\$ 32,587	\$ 325,874
Latvia	\$ 216	\$ 2,172
Netherlands	\$ 36,387	
Philippines	\$ 865	\$ 8,650
Rwanda	\$ 739	\$ 7,386
Slovakia	\$ 326	\$ 36,387
Spain	\$ 32,530	\$ 97,587
Sri Lanka	\$ 342	\$ 683
United States	\$ 14,724	
GLOBAL AVERAGE	\$ 14,973	\$ 99,152
ASIA AVERAGE	\$ 870	\$ 4,516

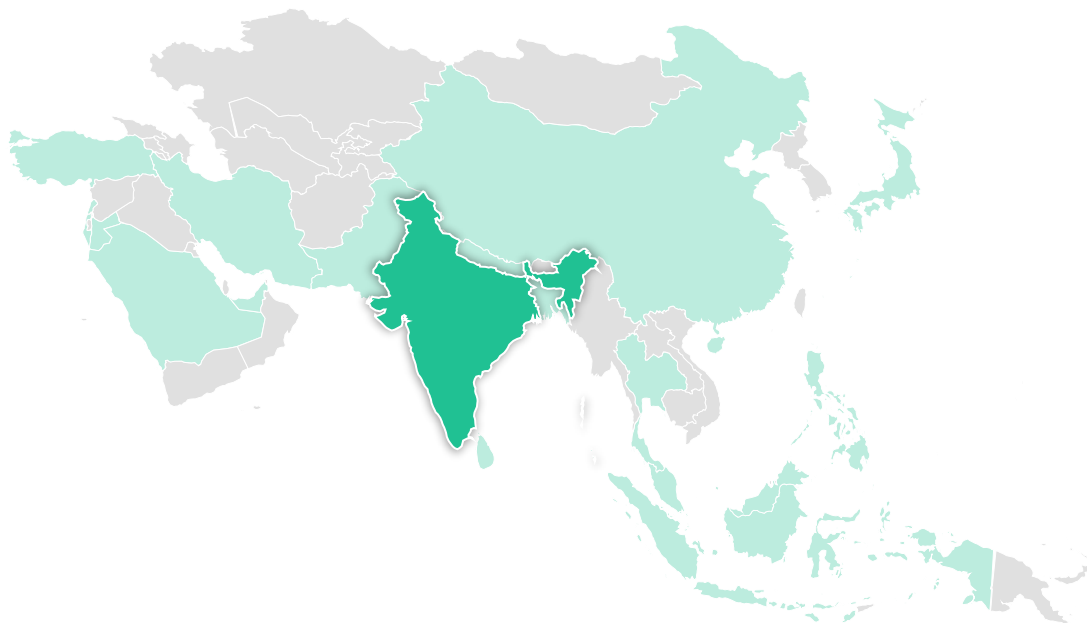
COUNTRY-SPECIFIC EXAMPLES

Deep Dives:



India: Overview

 Disclosure Requirements



Protocol Registration Required:

Yes (Mandatory)



Protocol Registration Timing:

Relative to enrollment



Results Posting Requirements:

Recommended (Voluntary)



Results Posting Timing:

Other timeline (no legal deadline)



Permissible Registry:

Clinical Trials Registry-India (CTRI)



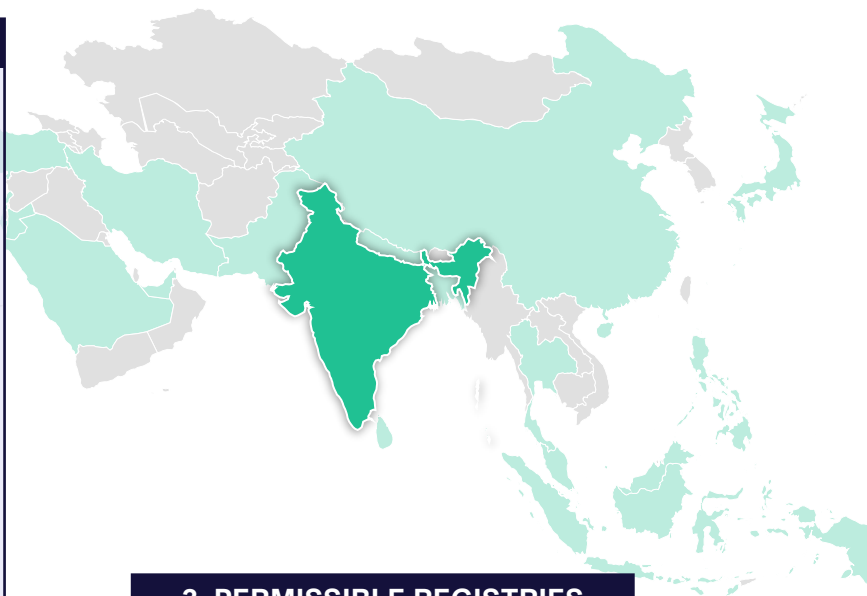
Enforcement:

Yes

India: Closer Look

1. PROTOCOL REGISTRATION

- ❑ Clinical trial registration is **legally mandated** for trials under the *Drugs and Cosmetics Act* and the *New Drugs and Clinical Trials Rules, 2019*. *Central Drugs Standard Control Organization (CDSCO)* made registration mandatory in **June 2009**.
- ❑ Registration with the Clinical Trials Registry-India (CTRI) must occur **before enrolling the first subject**. All global trials involving India must register with CTRI regardless of international registration. Registration is voluntary for non-regulatory biomedical and health research.



2. RESULTS POSTING

- ❑ *Indian Council of Medical Research (ICMR)* Ethical Guidelines recommend that researchers provide study results in CTRI's public database after completion.
- ❑ While **not legally mandated**, results disclosure is increasingly expected through international commitments: ICMR signed the WHO joint statement on public disclosure in **May 2017**. Major Indian journals declared that only trials registered in public databases would be considered for publication.

3. PERMISSIBLE REGISTRIES

- ❑ CTRI, launched **July 2007**, is maintained by ICMR and is linked to the WHO registry network. Only **prospective registration** has been permitted since **April 2018**.

China: Overview

■ Disclosure Requirements



Protocol Registration Required:

Yes (Mandatory)



Protocol Registration Timing:

After study approval



Results Posting Requirements:

Required (Mandatory)



Results Posting Timing:

Within 12 months



Permissible Registry:

Drug Clinical Trial Registration and Information Disclosure Platform (ChinaDrugTrials)



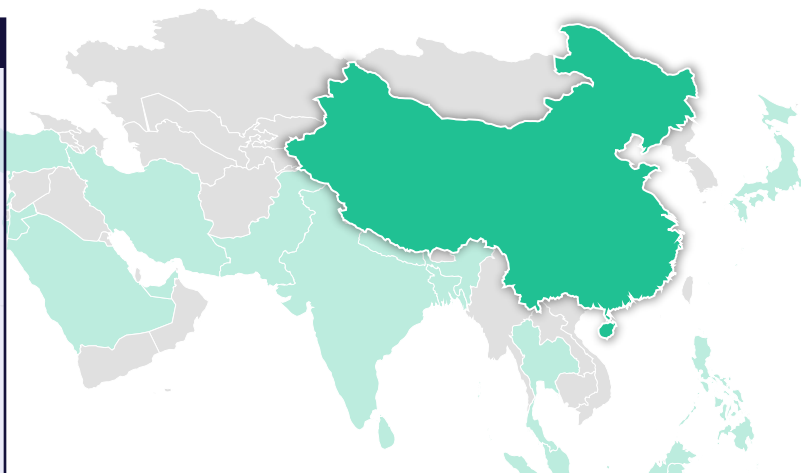
Enforcement:

Yes

China: Closer Look

1. PROTOCOL REGISTRATION

- ❑ Clinical trial registration is **legally required** for all drug clinical trials approved by the *National Medical Products Administration (NMPA)* under the *Drug Registration Management Measures*. Registration became mandatory in **July 2020**.
- ❑ Registration on the Drug Clinical Trial Registration and Information Disclosure Platform (ChinaDrugTrials) must occur **before enrolling the first subject**. This includes Phase I–IV clinical trials, bioequivalence studies (after filing), post-marketing studies (Phase IV), and other trials requiring regulatory approval or filing.



2. RESULTS POSTING

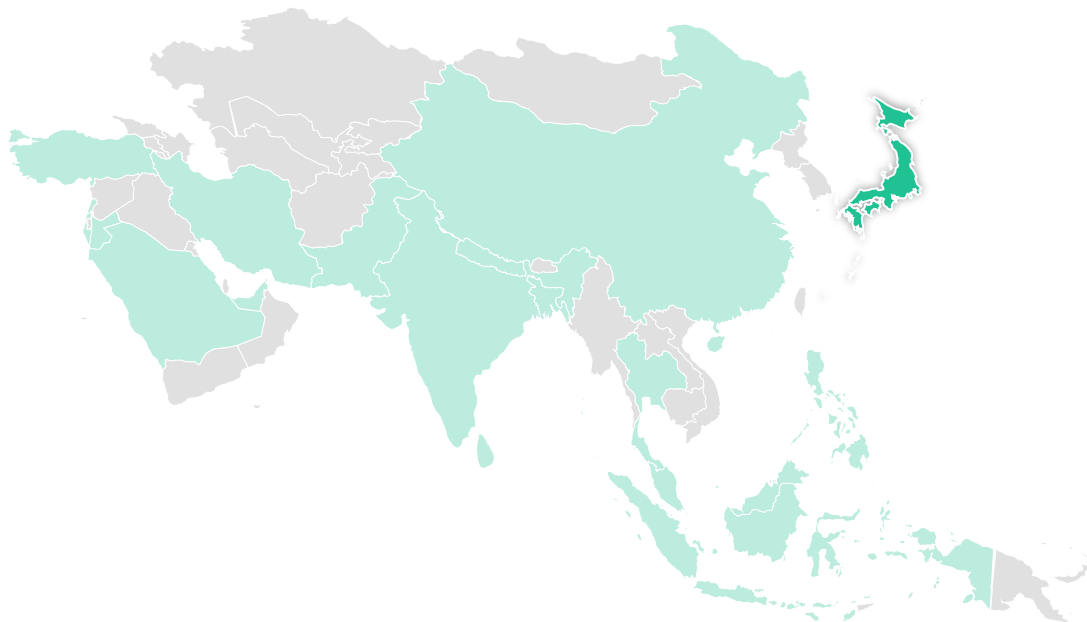
- ❑ Results disclosure is **mandatory** for drug clinical trials under the *Drug Clinical Trial Registration and Information Disclosure Management Standards*. Sponsors must post results summaries meeting ICH E3 standards **within 12 months after trial completion**. Sponsors must continuously update registration information and register clinical trial results after completion

3. PERMISSIBLE REGISTRIES

- ❑ ChinaDrugTrials, launched **September 2013**, is operated by NMPA's Center for Drug Evaluation, and is the official platform for drug clinical trial registration. It is **not a WHO Primary Registry or ICMJE compliant**.
- ❑ Note, the Chinese Clinical Trial Registry (ChiCTR), launched **October 2005**, is a WHO Primary Registry (since **July 2007**) and ICMJE compliant with **voluntary registration** for all biomedical research (including non-drug trials), operating independently from the NMPA-regulated ChinaDrugTrials platform.

Japan: Overview

 Disclosure Requirements



Protocol Registration Required:

Yes (Mandatory)



Protocol Registration Timing:

During approval process



Results Posting Requirements:

Required (Mandatory)



Results Posting Timing:

Within 12 months



Permissible Registry:

Japan Registry of Clinical Trials (jRCT)



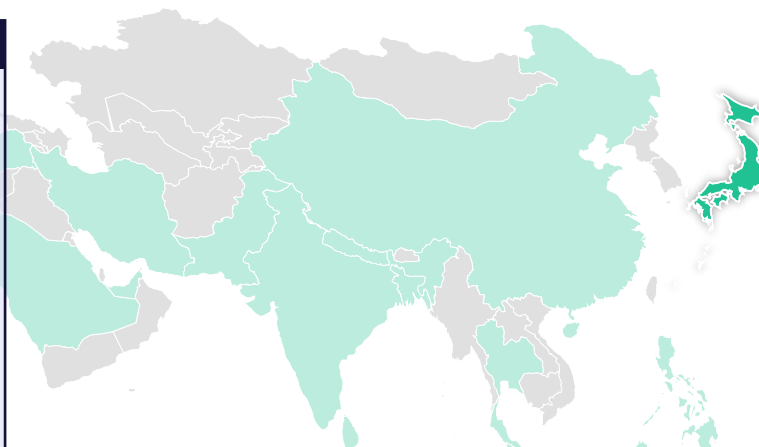
Enforcement:

No

Japan: Closer Look

1. PROTOCOL REGISTRATION

- ❑ Clinical trial registration is **legally mandated** for "Specified Clinical Research" under the *Clinical Research Act* as of **April 2018**. Specified Clinical Research includes trials using unapproved/off-label drugs/devices funded by manufacturers, or certain unapproved/off-label drugs/devices.
- ❑ Investigators must submit an implementation plan to the *Ministry of Health, Labour and Welfare (MHLW)* **before trial commencement** and register it in the Japan Registry of Clinical Trials (jRCT) database. Non-specified clinical research (including physician-initiated trials without manufacturer funding) has **voluntary registration** encouraged but not legally required.



2. RESULTS POSTING

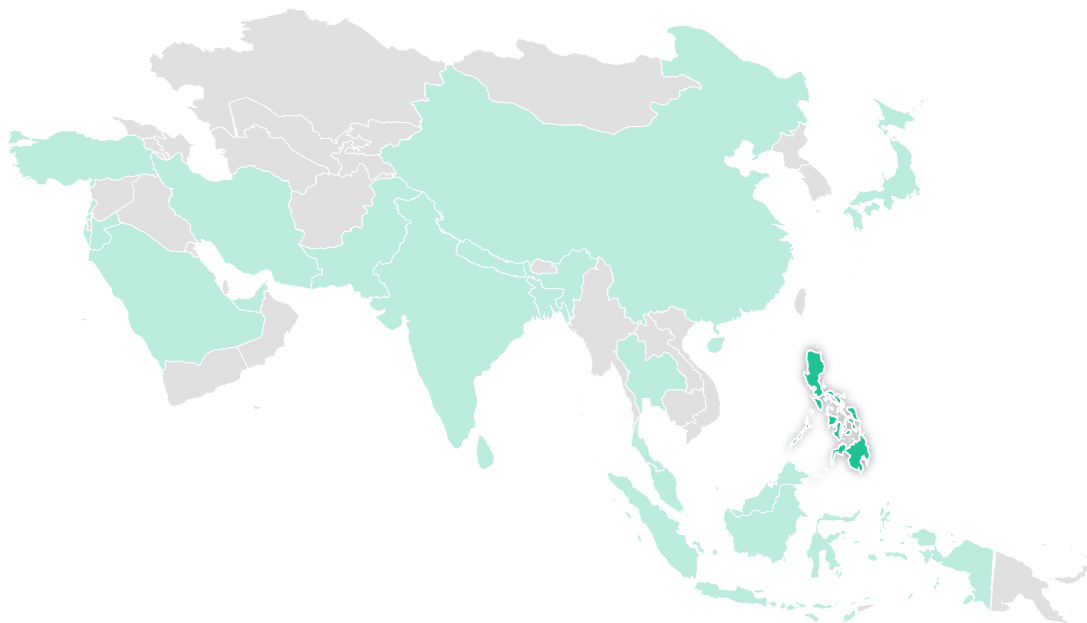
- ❑ Results disclosure is **mandatory** for Specified Clinical Research under the *Clinical Research Act Enforcement Regulations*. Investigators must prepare a primary endpoint report **within one year** of the end of data collection for the main evaluation items, and a summary report **within one year** of the end of all data collection. Summaries must be publicly disclosed in the jRCT database. Periodic reporting to MHLW is also required.

3. PERMISSIBLE REGISTRIES

- ❑ jRCT launched **2018** as the official registry operated by MHLW and is both a **WHO Primary Registry and ICMJE compliant**. University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) provides **voluntary registration** and has been a WHO Primary Registry and ICMJE recognized since **January 2006**.
- ❑ Historical registries operated 2005–2020 with data migrated to jRCT: Japan Pharmaceutical Information Center Clinical Trials Information (JAPIC-CTI) accepted trials **July 2005** through **August 2020**, closing **September 2020**; Japan Medical Association Clinical Trial Registry (JMACCT-CTR) accepted trials **June 2005** through **August 2020** with data migration completed in **March 2023**.

Philippines: Overview

 Disclosure Requirements



Protocol Registration Required:

Yes (Mandatory)



Protocol Registration Timing:

After study approval



Results Posting Requirements:

No



Results Posting Timing:

Not Applicable



Permissible Registry:

Philippine Health Research Registry (PHRR)



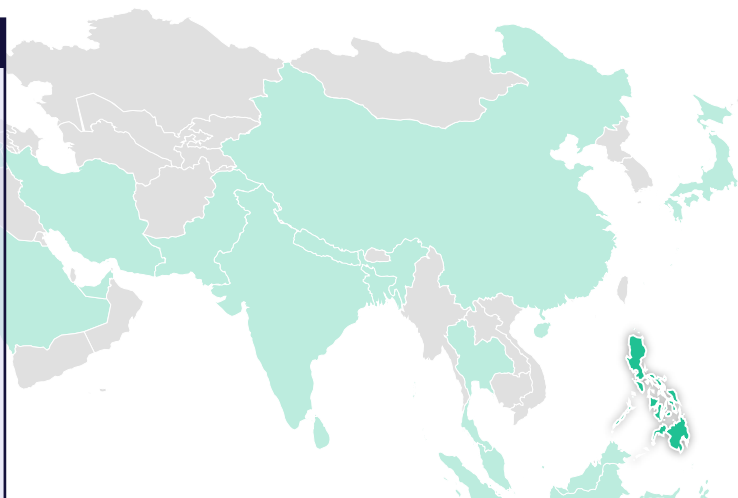
Enforcement:

Yes

Philippines: Closer Look

1. PROTOCOL REGISTRATION

- ❑ Clinical trial registration is **legally mandated** under *Administrative Order No. 2020-0010* as of **Aug-2020**. All clinical trials of investigational products intended for eventual product registration and marketing must be uploaded to the Philippine Health Research Registry (PHRR) **within 30 calendar days** after receipt of *Food and Drug Administration (FDA)* clinical trial approval.
- ❑ The sponsor or CRO is responsible for registration. Other studies not regulated by the FDA but approved by an appropriate Research Ethics Committee are encouraged (voluntary) to register. Once registered, studies cannot be removed and remain publicly viewable.



2. RESULTS POSTING

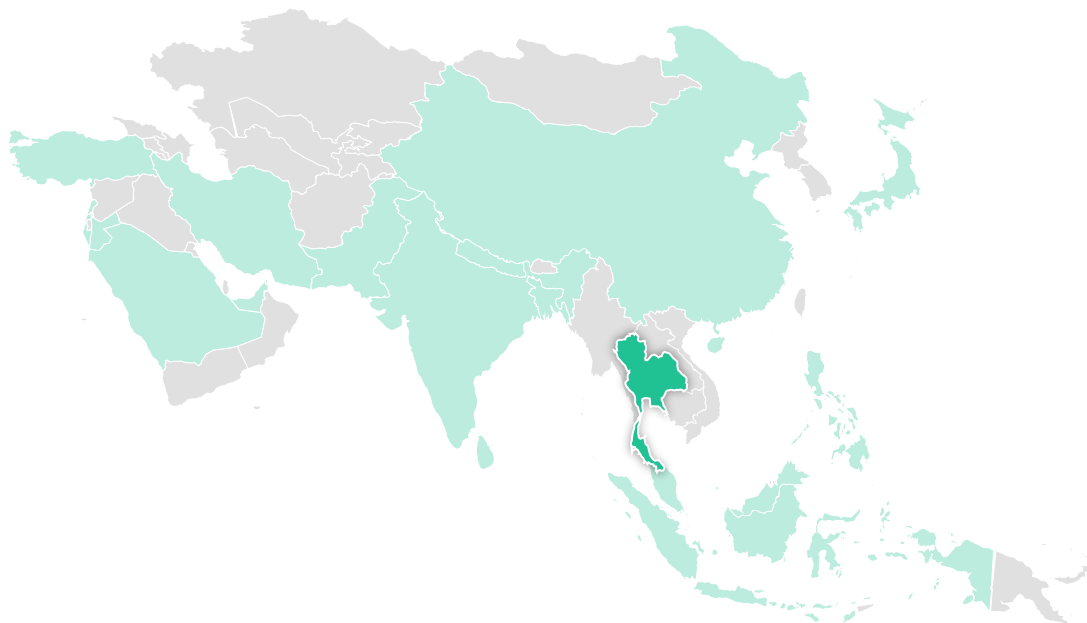
- ❑ Sponsors or CROs are required to update the registry **within 30 calendar days** after study termination. "Results" are a registry field (baseline characteristics, participant flow, adverse events, outcome measures), but **no explicit legal requirement** specifies that results summaries must be posted or establishes a specific timeline for results disclosure.

3. PERMISSIBLE REGISTRIES

- ❑ PHRR launched **2012**, is maintained by the *Department of Science and Technology (DOST)*'s Philippine Council for Health Research and Development in partnership with the *Department of Health (DOH)* and is compliant with WHO standards. It is **not a WHO Primary Registry** and does **not meet ICMJE requirements**. The registry assigns PHRR ID/Registry ID numbers upon approval of registration submissions.

Thailand: Overview

 Disclosure Requirements



Protocol Registration Required:

Recommended (Voluntary)



Protocol Registration Timing:

Relative to enrollment



Results Posting Requirements:

Recommended (Voluntary)



Results Posting Timing:

Within 12 months



Permissible Registry:

Thai Clinical Trials Registry (TCTR)



Enforcement:

No

Thailand: Closer Look

1. PROTOCOL REGISTRATION

- ❑ Clinical trial registration is **not legally mandated**. The Thai Clinical Trials Registry (TCTR) promotes **prospective registration** (before first participant recruitment) to meet ICMJE publication requirements, but registration remains **voluntary**.
- ❑ *Thai Food and Drug Administration (Thai FDA)* guidance issued in **February 2021** under the *Announcement on Requirements for Importing Drugs for Clinical Research* includes registry information in protocol documentation but uses permissive language ("may be registered"), confirming voluntary status. Ethics committee approval and FDA import authorization are **mandatory before trial commencement**, but public registry registration is encouraged rather than required.

2. RESULTS POSTING

- ❑ TCTR's registration guidelines state that registered trials should update results **within 12 months** of study completion, with updates encouraged every six months during the trial. However, this is a **registry operational policy** rather than a legal requirement.
- ❑ Thai FDA requires confidential regulatory reporting (annual progress reports and end-of-study summaries **within 60 days** of final site closure), but these are administrative submissions to authorities, not public postings.

3. PERMISSIBLE REGISTRIES

- ❑ TCTR, launched in **2009**, is maintained by the *Medical Research Foundation (MRF)*, and is a **WHO Primary Registry** within the WHO ICTRP and **ICMJE compliant**. TCTR accepts all biomedical and health research and requires prospective registration; trials registered on/after first participant recruitment are marked "retrospectively registered". TCTR maintains data integrity by never modifying or removing registered trials after ID issuance.

Evolving Requirements

TAIWAN (Post-Marketing Registry)

- Clinical trial registration is **legally mandated**. Applicants must register trial summaries on the Taiwan Drug Clinical Trial Information Network **within seven days before submitting paper applications** to TFDA. Closing reports must be submitted after completion. This applies to **all regulatory drug trials requiring TFDA approval (Phases I–IV for new drug registration)**.
- The IRPMA Post-Marketing Study (PMS) Registry requirement was removed in the **October 2024 Code of Practice revision (closed January 2025)**. Post-marketing studies (e.g., Phase IV and non-interventional) by research-based pharmaceutical companies still require IRB review and Medical Director approval but no longer need to be registered. Previously registered trials remain accessible.

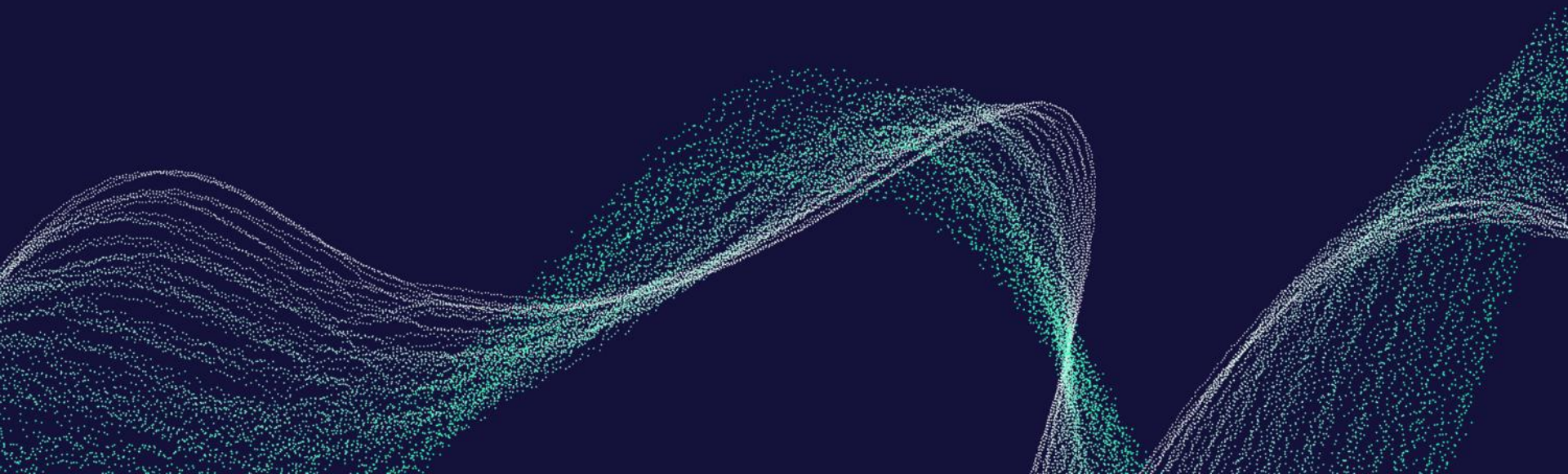
INDONESIA (Registry Migration)

- Clinical trial registration is **legally mandated**. Registration with the Indonesia Clinical Research Registry (INA-CRR) must occur **after obtaining ethics committee approval** and clinical trial authorization from BPOM, **before trial commencement**.
- The INA-CRR completed a **platform migration in 2025**, transitioning from **ina-crr.id** to **ina-crr.kemkes.go.id** under the Ministry of Health domain. Both platforms accepted **submissions until 30 April 2025**; from 1 May 2025, all registrations must be **made exclusively through the new government-hosted platform**. INA-CRR is working toward WHO ICTRP Primary Registry recognition.

TURKEY (Plain Language Results)

- Clinical trial registration is **legally mandated**. Applications are submitted through the **TITCK Electronic Application System** and published on the **Clinical Research Portal (KAP)**. Trials must be registered **before the first eligibility application**, and results must be submitted within **12 months of completion**.
- A **plain language results summary** is also mandatory: *"a version of this summary in a way that the volunteers can understand"* alongside the standard results report within 12 months. These summaries are made **publicly available through KAP**. Plain language is required only for results, not for protocol registration.

ICH E6(R3) IMPLEMENTATION What Next?



Future-proofing: ICH E6(R3) Implementation

ICH E6(R3) establishes transparency obligations under Principle 9.6, requiring trial registration, public results posting, and participant communication.

Key Disclosure Requirements:

- **Trial Registration:** Register before the first participant enrollment in publicly accessible databases
- **Public Results Posting:** Post results publicly on a recognized database
- **Participant Summaries:** Provide non-technical, understandable summaries (**Section 3.17.2(c)**)
- **Treatment Disclosure:** Inform participants of actual treatment received (**Sections 2.8.10(v), 2.9.3**)

Founding Regulatory

Member:

- **Japan** (MHLW/PMDA) - *GCP Ministerial Ordinance revision in progress.*

ICH REGULATORY

MEMBERS:

- **China** (NMPA) – *Effective 01-Apr-2026 (Notice No.*

125-2025)

- **Jordan** (JFDA)
- **Republic of Korea*** (MFDS)
- **Saudi Arabia** (SFDA)
- **Singapore** (HSA) – *Effective 01-Jan-2026 (GN-IOCTB-11 Rev. No. 004)*
- **Taiwan** (TFDA)
- **Turkey** (TITCK)

ICH OBSERVERS -

Legislative or

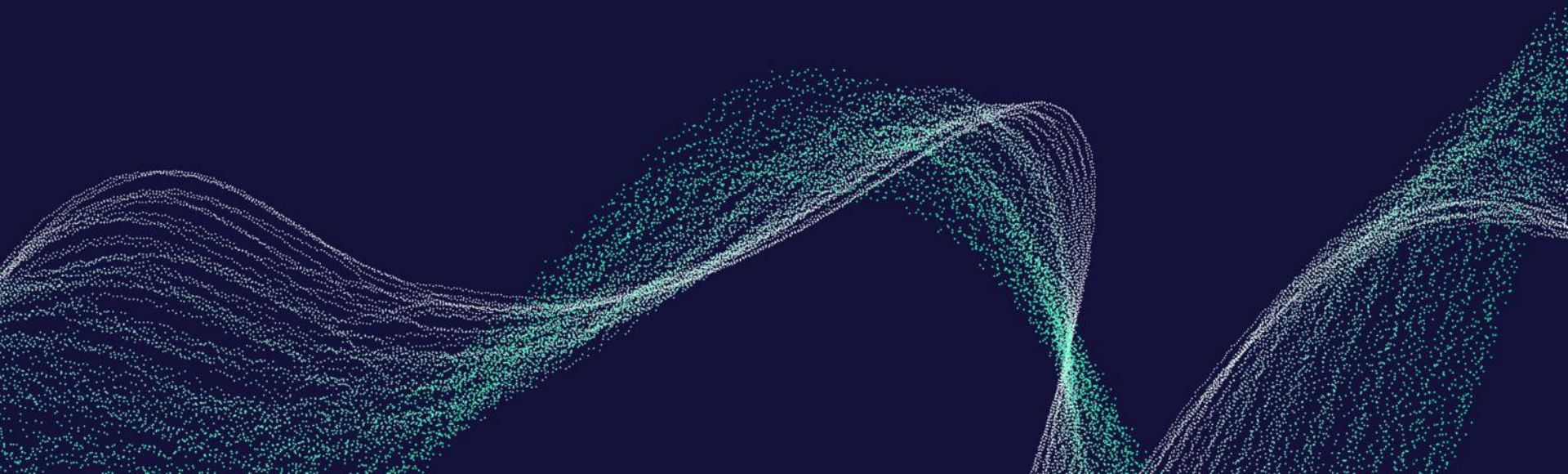
Administrative Authorities:

- **Armenia*** (SCDMTE)
- **Azerbaijan*** (AEC)
- **Hong Kong*** (PPBHK)
- **India** (CDSCO)
- **Indonesia** (Indonesian FDA)

- **Iran** (NRA)
- **Israel** (CPED)
- **Kazakhstan*** (National Center)
- **Kuwait*** (MOH)
- **Lebanon** (MOPH)
- **Malaysia** (NPRA)
- **Thailand** (Thai FDA)
- **Uzbekistan*** (CPPS)

**Countries without disclosure requirements (mandatory/ voluntary)*

WRAP-UP



From Complexity to Compliance: Translating Intelligence into Action



Compliance requires knowing **what** and **when** to disclose, **When Must Registration Occur?**, and **why** enforcement matters

KEY SUCCESS FACTORS FOR NAVIGATING REGIONAL COMPLEXITY

- ✓ Build jurisdiction-specific compliance strategies
- ✓ Implement cross-functional transparency workflows
- ✓ Establish robust multi-registry coordination systems
- ✓ Prepare for expanding communication requirements
- ✓ Monitor regional regulatory developments proactively

The transparency landscape will continue to evolve. Organizations that treat transparency as a **strategic advantage** will lead in **stakeholder trust, operational efficiency, and regulatory readiness**. By transforming regulatory intelligence into actionable practices, sponsors can turn disclosure obligations into opportunities for scientific leadership and patient engagement.

Regulatory Intelligence Best Practices

01

PRIMARY SOURCES

Official Health Authority documents are the only **"source of truth."** Secondary sources and AI-generated content may contain errors and do not protect against enforcement actions. When in doubt, submit queries directly to the relevant authority for clarification.

02

DOCUMENT

Maintain dated, version-controlled documentation for all regulatory sources. Track document titles, effective dates, regulatory dates, published dates, and URLs. Regulations do not change overnight; procedural documents (e.g., guidance, FAQs) are updated frequently.

03

CONTINUOUS MONITORING

Registries rarely appear overnight, but platforms undergo regular updates. Track URL migrations (Japan's jRCT: niph.go.jp → mhlw.go.jp [April 2025]), new platform launches (Indonesia's ina-crr.kemkes.go.id [September 2025]), and scheduled service disruptions to maintain uninterrupted access and compliance.

04

ANNUAL REVIEW

Review and validate all content and requirements at least annually against current source documents to ensure accuracy and currency. Regular record ageing catches regulatory changes that may be overlooked during routine monitoring and ensures ongoing compliance.

05

AN EYE ON EVOLUTION

Voluntary requirements today may become mandatory tomorrow. Monitor ICH guideline implementations, emerging registry requirements (e.g., plain language summaries), and enforcement trends. Proactive intelligence prevents reactive scrambling.

Ben Evans:

Ben.Evans@Citeline.com

Thank You.

