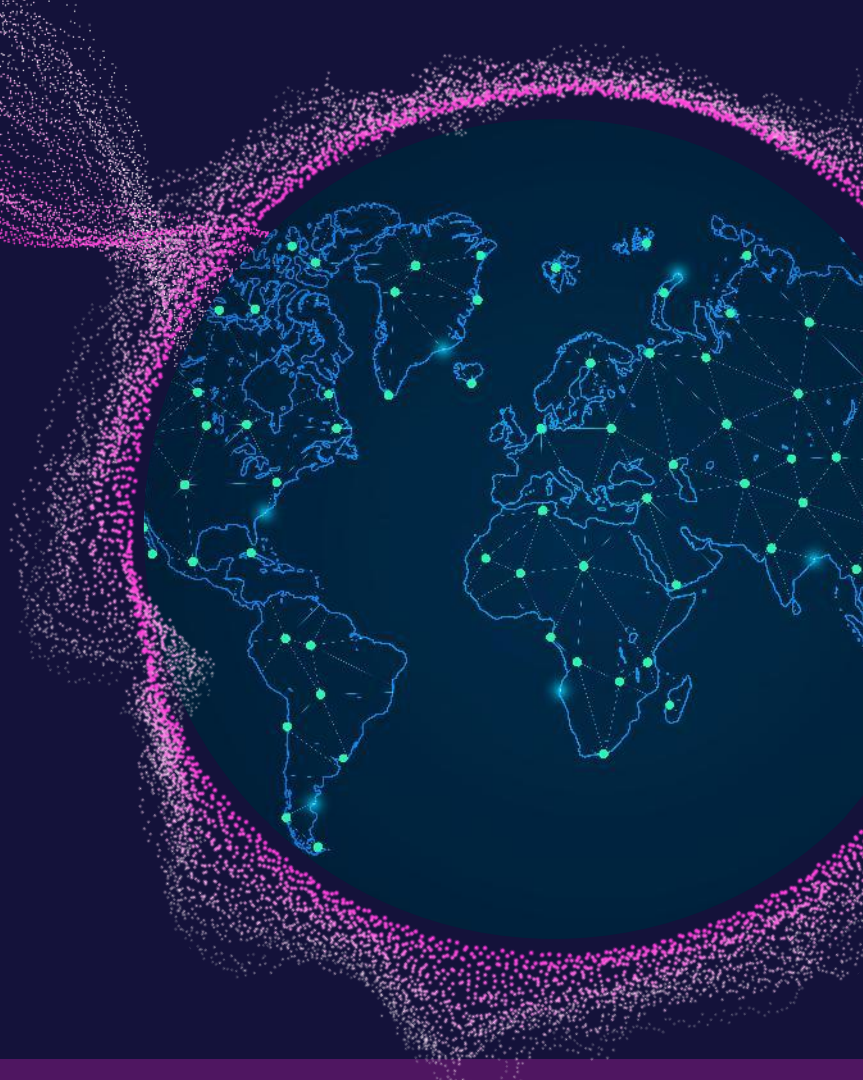
CITELINE
REGULATORY

Lost in Translation

Decoding Clinical Trial Disclosure Across Africa and Latin America



Over 25% of the world's population, under 8% of global trials

Combined, Africa and Latin America accounted for **9.3% of global clinical trial initiations in 2015 (1,334 of 14,327)**, declining to **7.3% by 2024 (1,987 of 27,351)**, even as total global initiations nearly doubled over the same period.

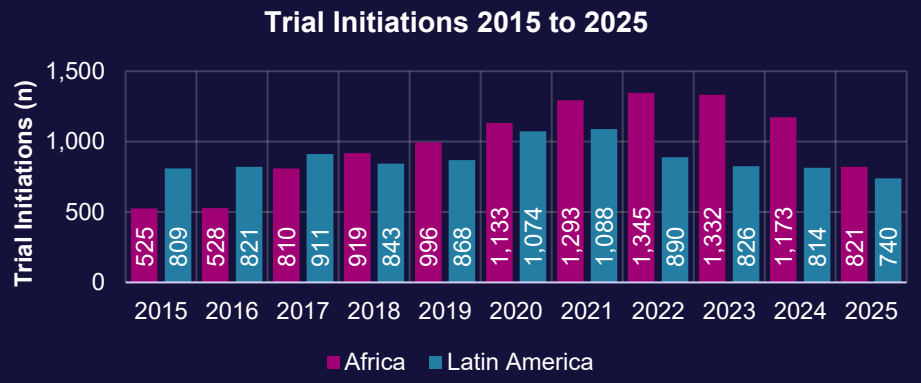
Africa reached its peak share in 2022 at **5.2% (1,345 initiations)**, while Latin America's share fell from **5.6%** (**809 initiations**) in 2015 to **3.0%** (814) in **2024**.

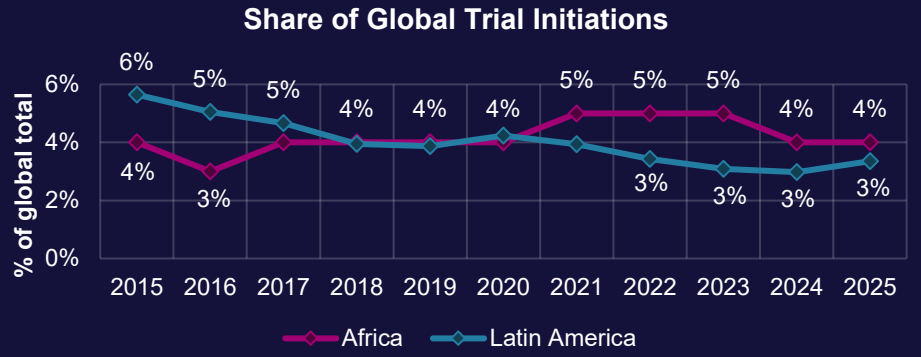
The **challenge**: Each jurisdiction has developed distinct regulatory frameworks for transparency, resulting in:

- Mandatory versus voluntary registration requirements
- National versus internationally recognized registries
- Inconsistent results disclosure obligations and timelines

To navigate this landscape, sponsors must understand:

- **What** to disclose
- **When** obligations are triggered
- **Where** registration must occur
- **Why** compliance matters and how enforcement is applied





Source: Trialtrove, Citeline (Sept. 1, 2026)

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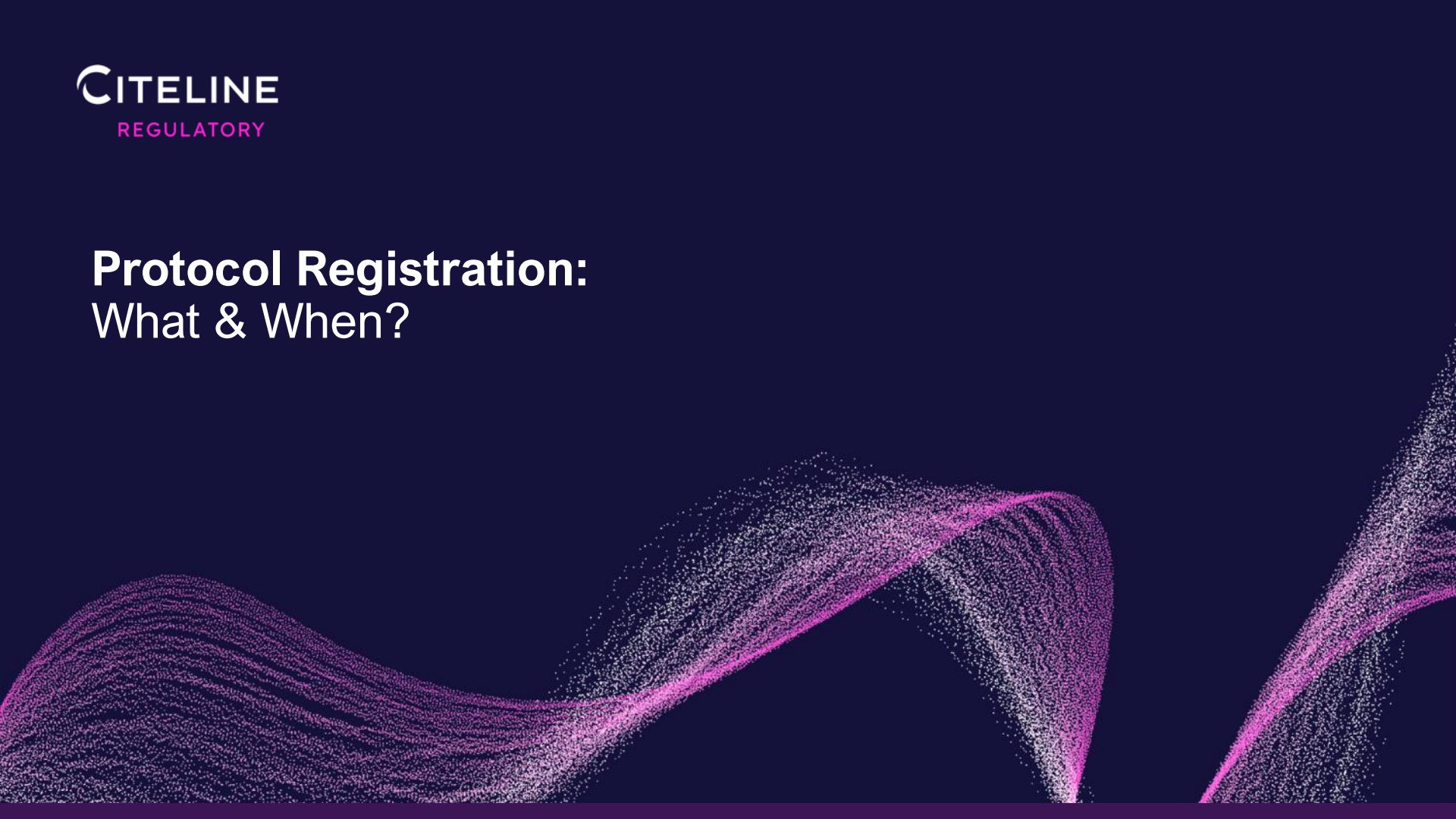
Protocol Registration: What & When?



Protocol registration requirements

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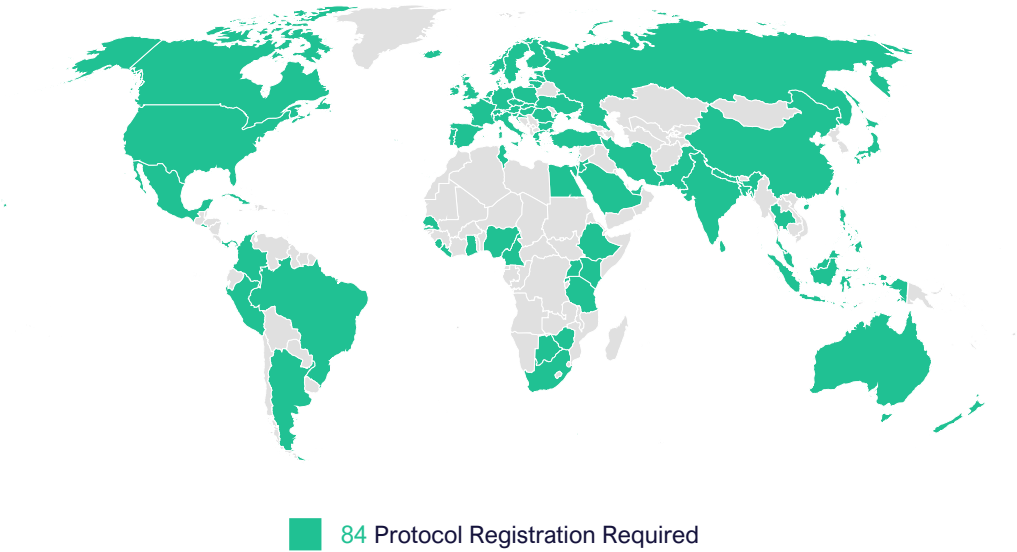
84+
countries require protocol registration



	Total	Public availability
Europe	**34**	32 fully · 1 mostly · 1 undefined
Asia	**21**	10 fully · 6 mostly · 2 not public · 3 undefined
Africa	**17**	3 fully · 6 mostly · 4 not public · 4 undefined
Americas	**10**	6 fully · 4 mostly
Oceania	**2**	2 fully

Protocol registration timing

CITELINE REGULATORY

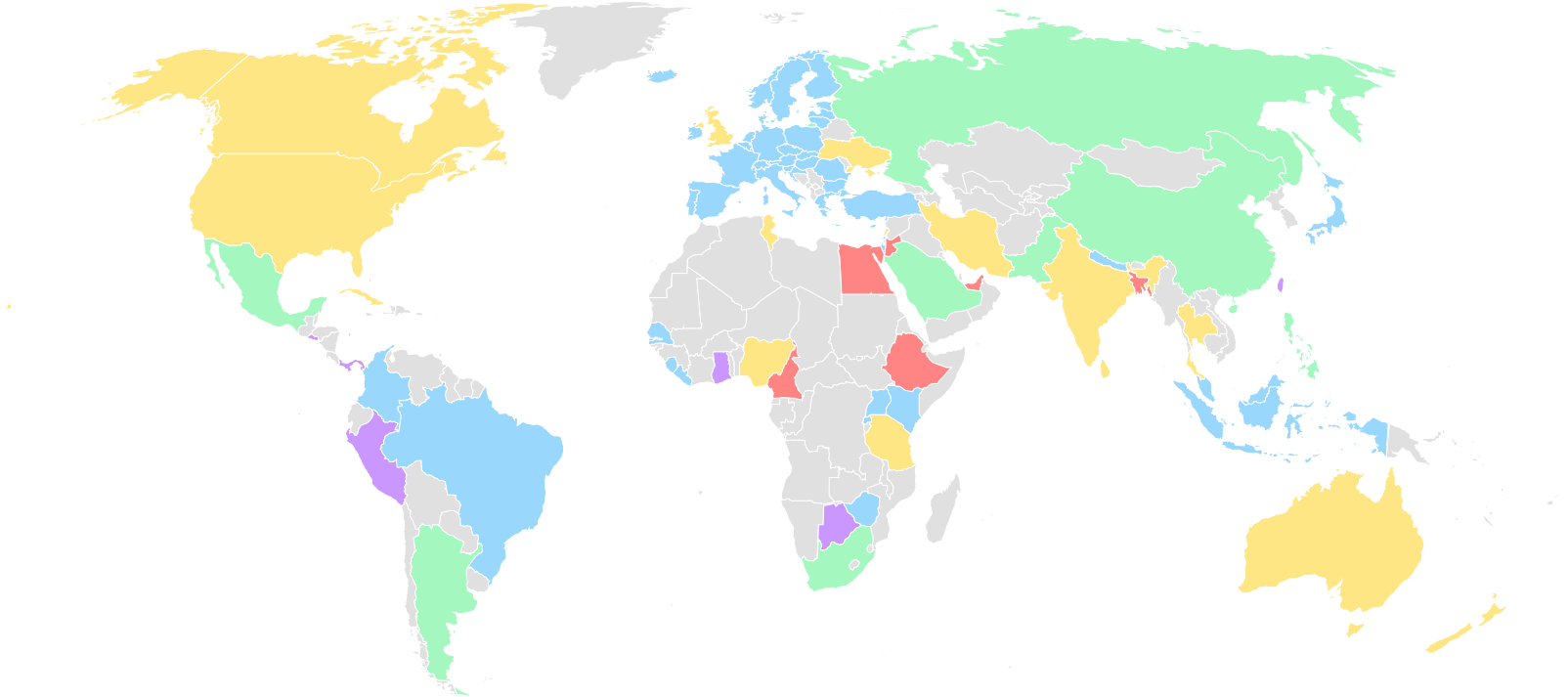
8 Before study submission

46 During approval process

8 After study approval

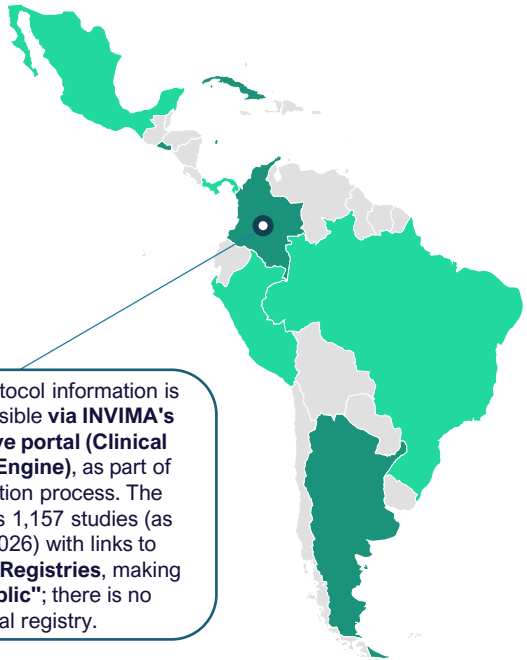
16 Relative to enrollment

6 Undefined



Protocol registration in Latin America

4 Fully Public 4 Mostly Public



Colombia: Protocol information is publicly accessible **via INVIMA's administrative portal (Clinical Trial Search Engine)**, as part of the authorization process. The portal contains 1,157 studies (as of Sept. 1, 2026) with links to **WHO Primary Registries**, making it **"Fully Public"**; there is no national registry.

Fully Public (4 countries)
Protocol information is completely publicly available through sponsor-submitted forms or health authority submissions.

Argentina • Colombia • Cuba • El Salvador

Mostly Public (4 countries)
Protocol information is largely publicly available with some restrictions; may include partial redactions or limited access to certain protocol elements.

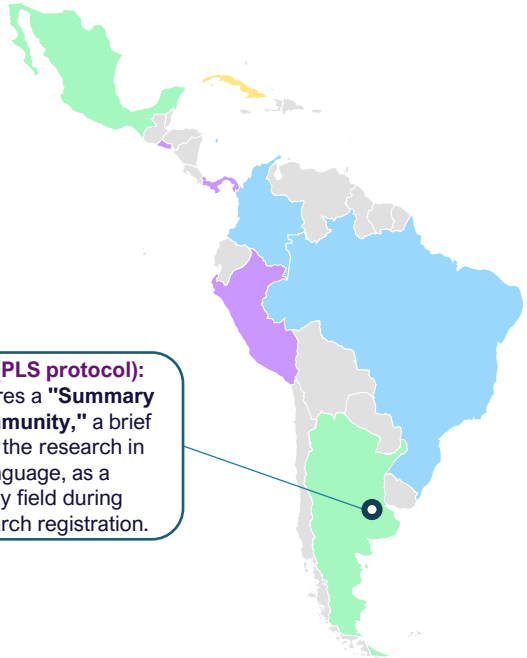
Brazil • Mexico • Panama • Peru

40%
of Latin American countries **(8 of 20)** have registration requirements

Registration timing in Latin America

CITELINE REGULATORY

3 Before Study Submission
2 During Approval Process
2 After Study Approval
1 Relative to Enrollment



Argentina (PLS protocol): **ReNIS** requires a **"Summary for the Community,"** a brief overview of the research in plain language, as a mandatory field during health research registration.

Before Study Submission (3 countries)

- **El Salvador:** Part of the initial CTA process
- **Panama:** Before HA & EC submission
- **Peru:** On issuance of a REPEC registration number

During Approval Process (2 countries)

- **Brazil, Colombia:** After ethics approval, before enrollment

After Study Approval (2 countries)

- **Argentina:** After ANMAT authorization
- **Mexico:** Within 5 days of COFEPRIS approval

Relative to Enrollment (1 country)

- **Cuba:** Before first participant enrollment

Protocol registration in Africa

CITELINE REGULATORY

Fully Public (3 countries)
Protocol information is completely publicly available through sponsor-submitted forms or health authority submissions.

Nigeria • Tanzania • Zimbabwe

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

Botswana • Kenya • Rwanda • Senegal • Sierra Leone • South Africa

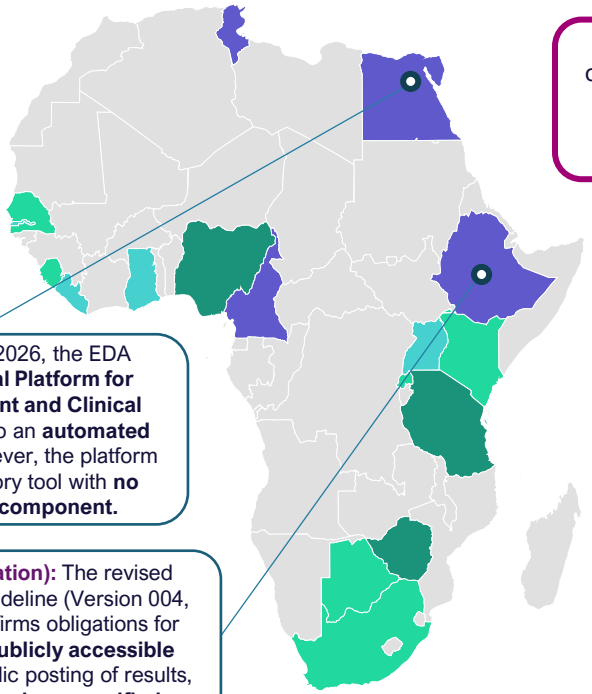
Not Public (4 countries)
Registration is mandatory, but protocol information remains confidential. Only regulatory authorities have access.

The Gambia • Ghana • Liberia • Uganda

Undefined (4 countries)
Public availability requirements are not specified in regulations, creating ambiguity about data accessibility.

Cameroon • Egypt • Ethiopia • Tunisia

3 Fully Public | 6 Mostly Public | 4 Not Public | 4 Undefined



31%
of African countries **(17 of 54)** have registration requirements

Egypt: In February 2026, the EDA launched the **"Digital Platform for Protocol Management and Clinical Trials,"** transitioning to an **automated digital workflow**; however, the platform is an internal regulatory tool with **no public disclosure component.**

Ethiopia (registration): The revised June 2025 GCP guideline (Version 004, section 4.9.7) confirms obligations for **registration on publicly accessible databases** and public posting of results, even where **timing is unspecified.**

Registration timing in Africa

CITELINE REGULATORY

Before Study Submission (3 countries)

- **Botswana, Ghana:** With proof of PACTR or WHO registry listing as part of the CTA
- **The Gambia:** Before approval from the authority

During Approval Process (7 countries)

- **Kenya, Zimbabwe:** After ethics approval
- **Liberia, Rwanda, Senegal, Sierra Leone, Uganda:** Before HA & EC approval

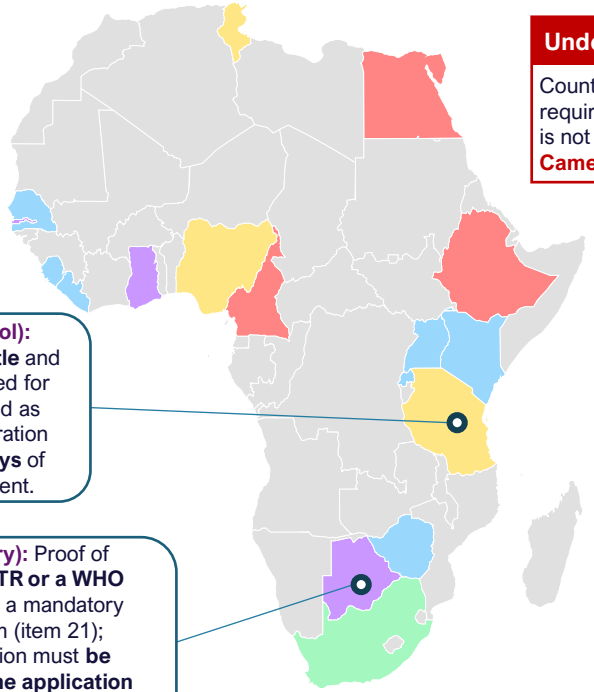
After Study Approval (1 country)

- **South Africa:** After HA (SAHPRA) & EC approval, before enrollment

Relative to Enrollment (3 countries)

- **Nigeria, Tunisia:** Before first participant enrollment
- **Tanzania:** Within 21 days of first participant enrollment

3 Before Study Submission | 7 During Approval Process | 1 After Study Approval | 3 Relative to Enrollment | 3 Undefined



Undefined (3 countries)

Countries have registration requirements, but the timing is not defined in regulations: **Cameroon**, **Egypt**, **Ethiopia**

Tanzania (PLS protocol): **TzCTR** requires a **brief title** and a **brief summary** intended for the **lay public**, submitted as part of mandatory registration information within **21 days** of first participant enrollment.

Botswana (registry): Proof of registration on **PACTR or a WHO Primary Registry** is a mandatory CTA checklist item (item 21); therefore, registration must **be completed before the application can be filed** — hence the "**Before Study Submission**" classification.

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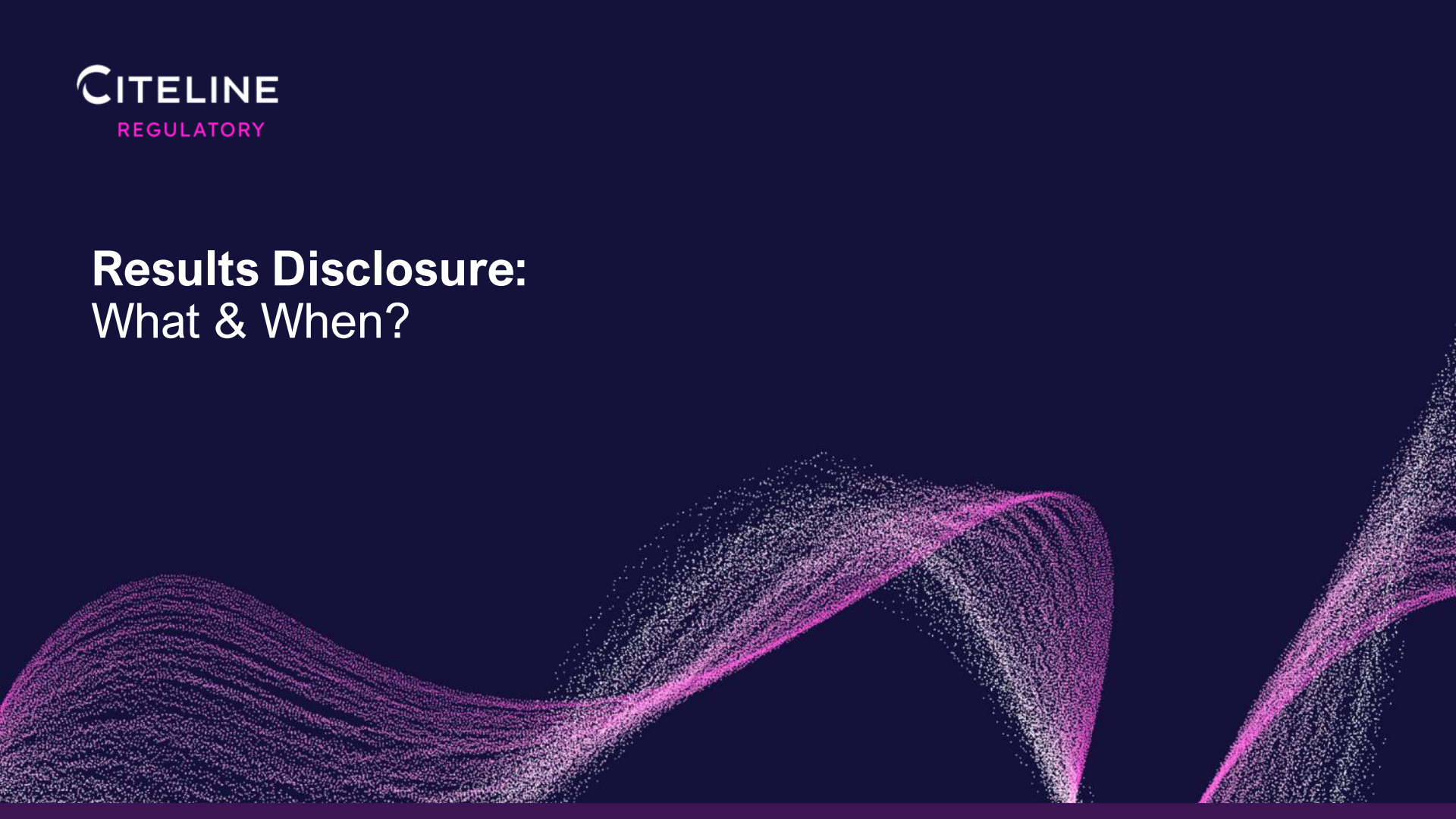
Results Disclosure:
What & When?

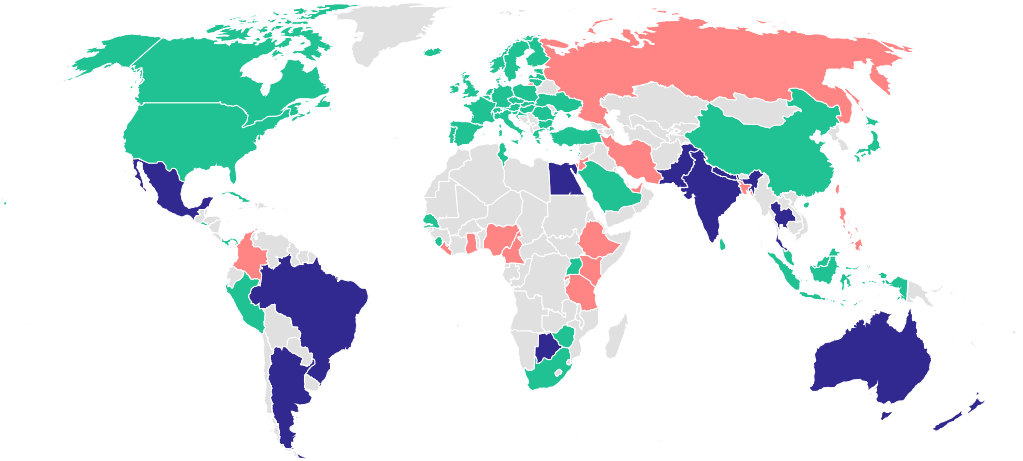


Results disclosure requirements

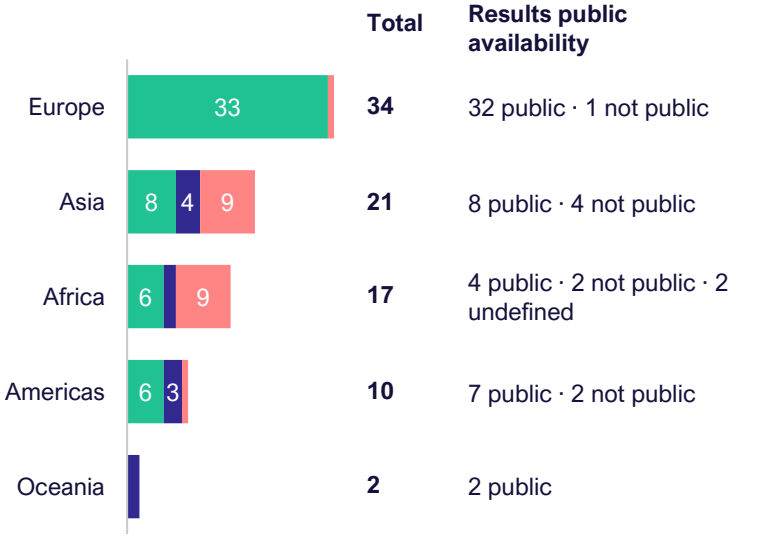
CITELINE REGULATORY

64+
countries require results disclosure

20+
countries with protocol registration not results disclosure



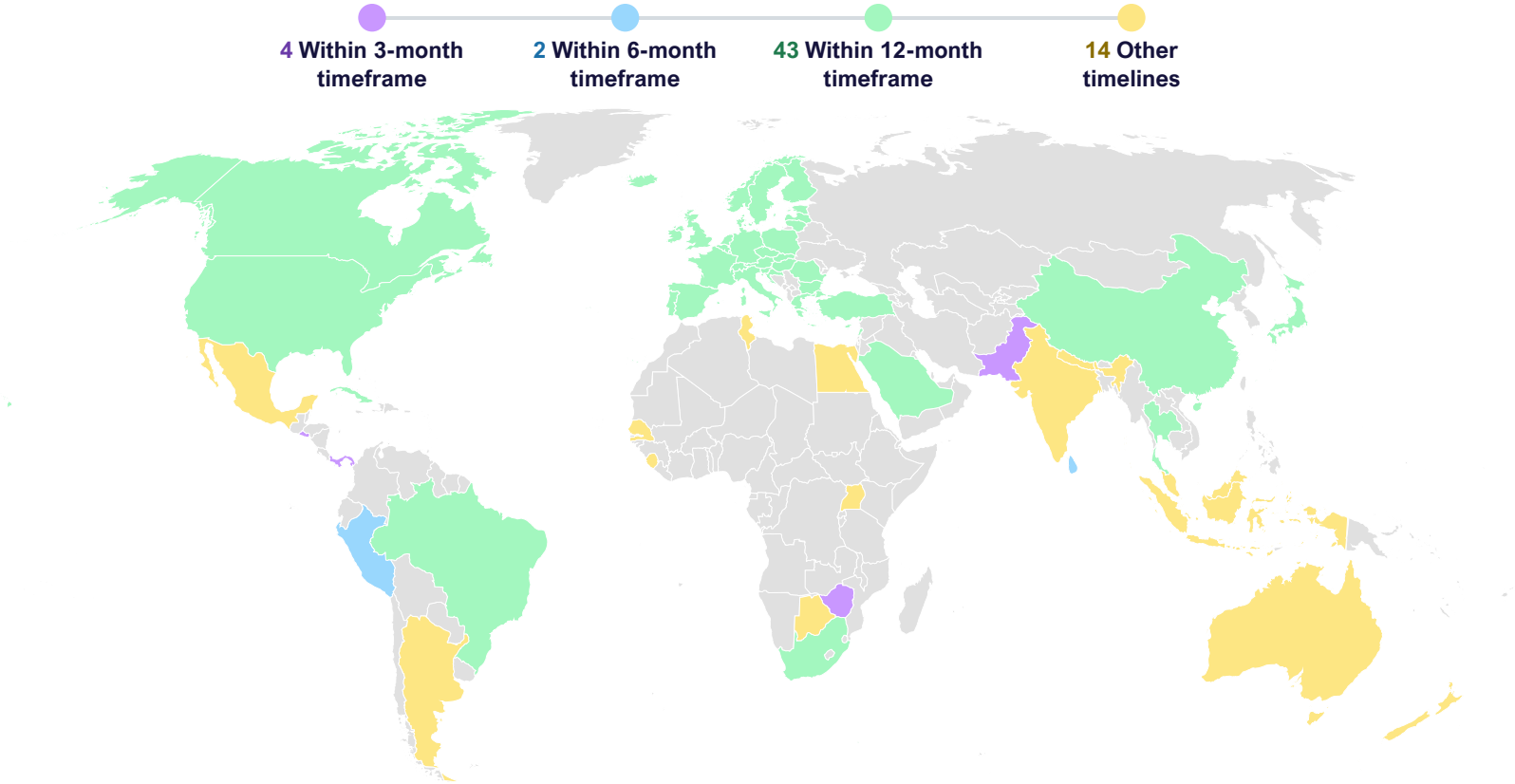
53 Mandatory 11 Voluntary 20 Protocol Not Results Disclosure



	Total	Results public availability
Europe	34	32 public · 1 not public
Asia	21	8 public · 4 not public
Africa	17	4 public · 2 not public · 2 undefined
Americas	10	7 public · 2 not public
Oceania	2	2 public

Results disclosure timing

CITELINE REGULATORY



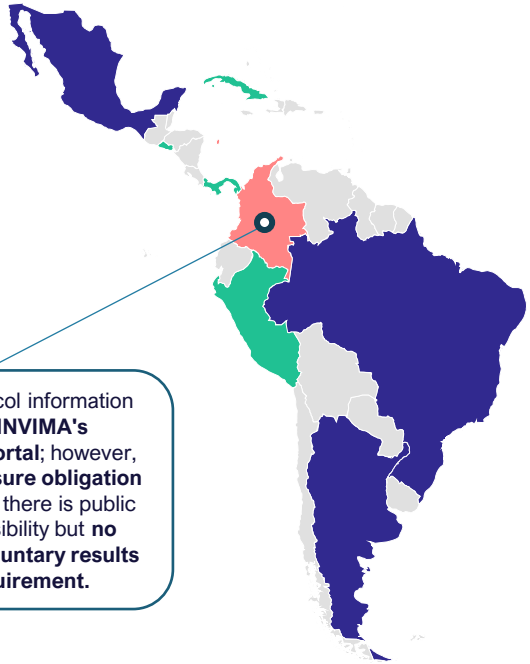
Results disclosure in Latin America

CITELINE REGULATORY

4 Mandatory Results Posting

3 Voluntary Results Posting

1 Protocol NOT Results Disclosure



Colombia: Protocol information is public via **INVIMA's administrative portal**; however, **no results disclosure obligation applies**, meaning there is public protocol accessibility but **no mandatory or voluntary results posting requirement.**

Mandatory Results Posting (4 countries)
Results submission is required by regulation with specific timelines. Sponsors must submit trial results within defined timeframes.

Cuba • El Salvador • Panama • Peru

Voluntary Results Posting (3 countries)
Results submission is encouraged but not mandated by regulation. Sponsors may choose to submit trial outcomes.

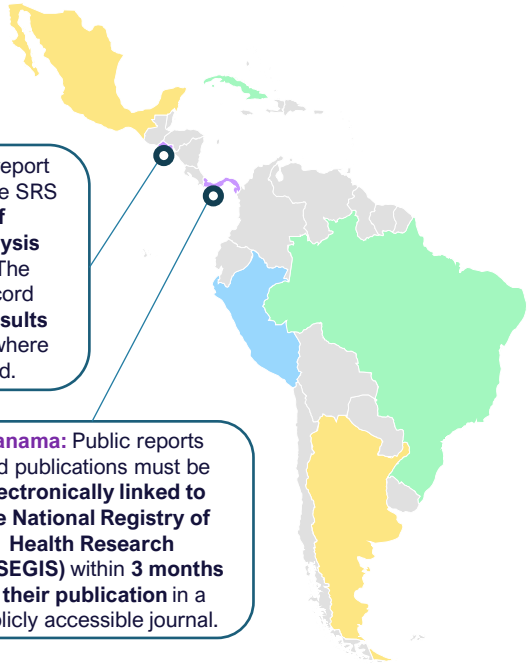
Argentina • Brazil • Mexico

Results Publicly Available (5 countries) Posted results are made accessible.	**Results Not Publicly Available (2 countries)** Results are submitted to regulatory authorities but not made public.
Cuba • El Salvador • Mexico • Panama • Peru	**Argentina • Brazil**

Results disclosure timing in Latin America

CITELINE REGULATORY

2 Within 3-month Timeframe | 1 Within 6-month Timeframe | 2 Within 12-month Timeframe | 3 Other Timelines



El Salvador: The final report must be submitted to the SRS within **3 months of completing data analysis and interpretation**. The RNEC registration record includes a field for a **results summary** or a **link** to where results are published.

Panama: Public reports and publications must be **electronically linked to the National Registry of Health Research (RESEGIS)** within **3 months of their publication** in a publicly accessible journal.

Within 3-month Timeframe (2 countries)

- **El Salvador:** After completing the analysis and interpretation of data
- **Panama:** After publication in a publicly accessible journal

Within 6-month Timeframe (1 country)

- **Peru (domestic trials):** Final report after the end of the clinical trial

Within 12-month Timeframe (2 countries)

- **Cuba, Peru (international trials):** After study/clinical trial completion

Other Timelines (3 countries)

- **Argentina, Mexico:** On completion, no specified timeline (voluntary)
- **Brazil:** Voluntary after completion (12-month recommended)

Results disclosure in Africa

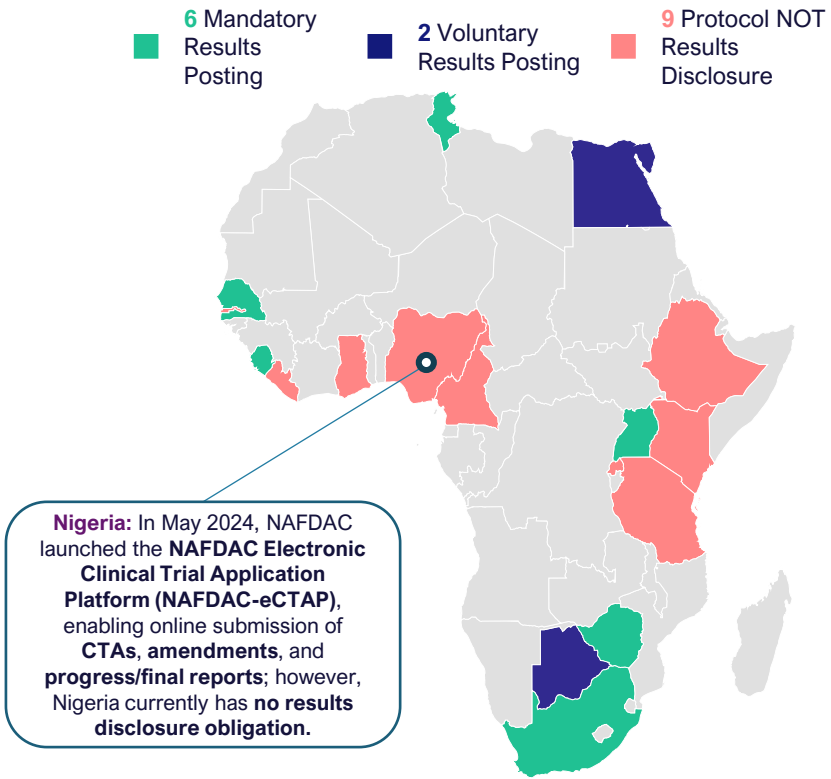
Mandatory Results Posting (6 countries) Results submission is required by regulation with specific timelines. Sponsors must submit trial results within defined timeframes.

Senegal • Sierra Leone • South Africa • Tunisia • Uganda • Zimbabwe

Voluntary Results Posting (2 countries)
Results submission is encouraged but not mandated by regulation. Sponsors may choose to submit trial outcomes.

Botswana • Egypt

Results Publicly Available (4 countries) Posted results are made accessible.	**Results Not Publicly Available (4 countries)** Results are submitted to regulatory authorities but not made public.
Botswana • Senegal • Sierra Leone • South Africa	**Egypt • Tunisia • Uganda • Zimbabwe**



Nigeria: In May 2024, NAFDAC launched the **NAFDAC Electronic Clinical Trial Application Platform (NAFDAC-eCTAP)**, enabling online submission of **CTAs**, **amendments**, and **progress/final reports**; however, Nigeria currently has **no results disclosure obligation.**

Results disclosure timing in Africa

CITELINE REGULATORY

Within 3-month Timeframe (1 country)

- **Zimbabwe:** Preliminary report after study completion

Within 6-month Timeframe (1 country)

- **Zimbabwe:** Final report after study completion (including publications)

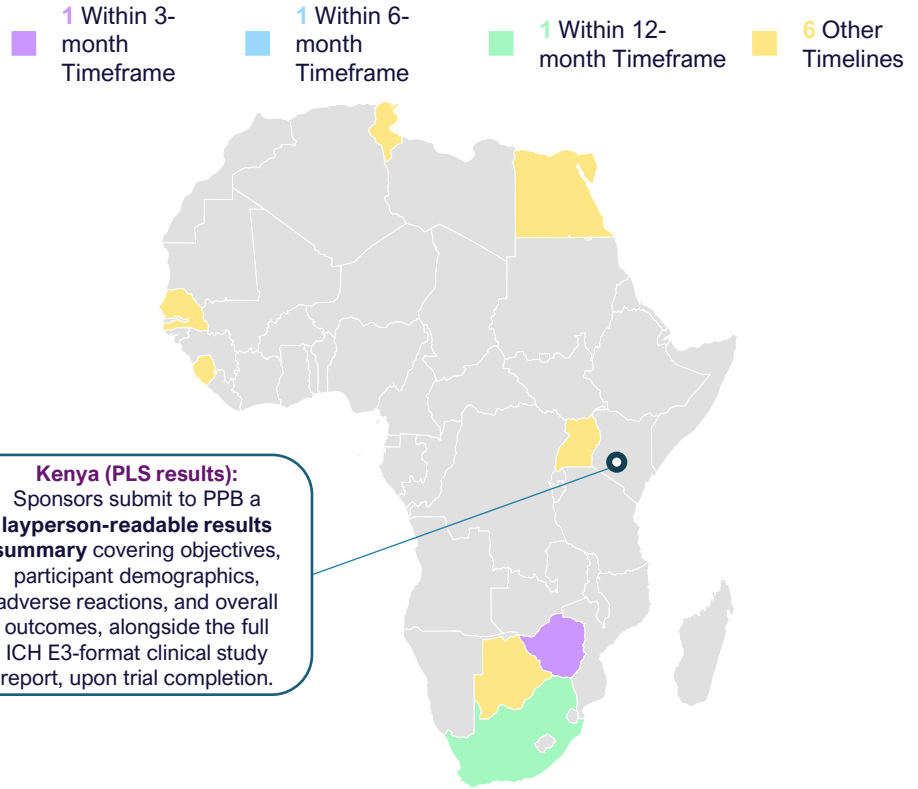
Within 12-month Timeframe (1 country)

- **South Africa:** After study/clinical trial completion

Other Timelines (6 countries)

Mandatory:
- **Senegal, Sierra Leone, Tunisia, Uganda**

Voluntary:
- **Botswana, Egypt**



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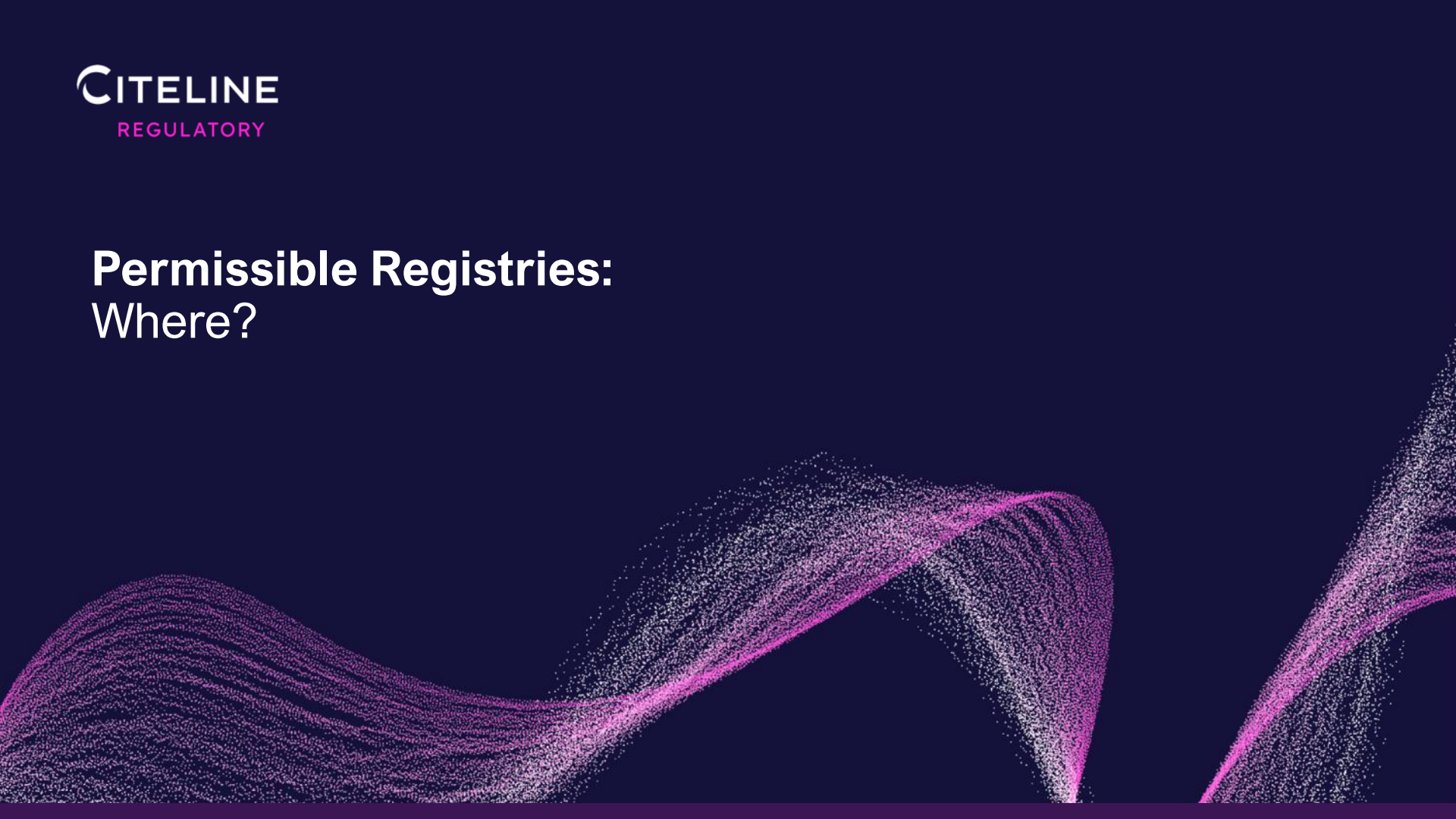
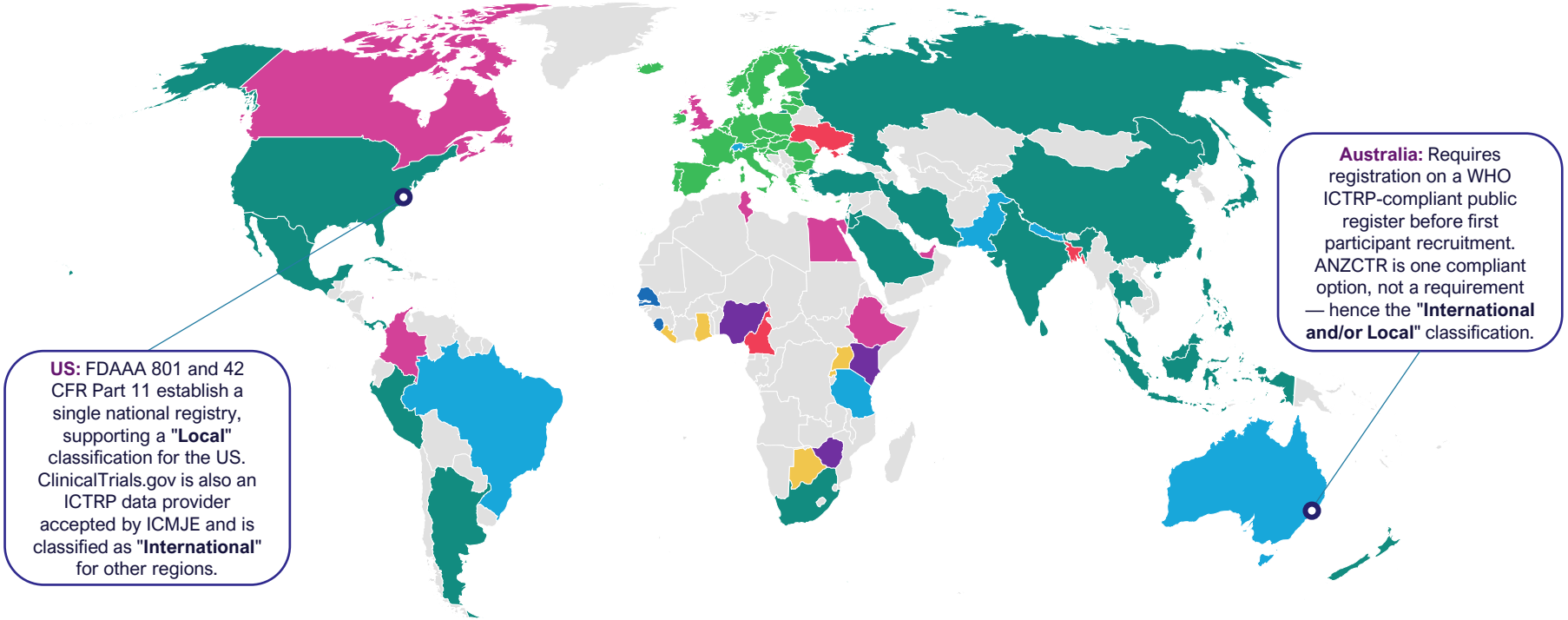
Permissible Registries: Where?



Permissible registries

CITELINE REGULATORY

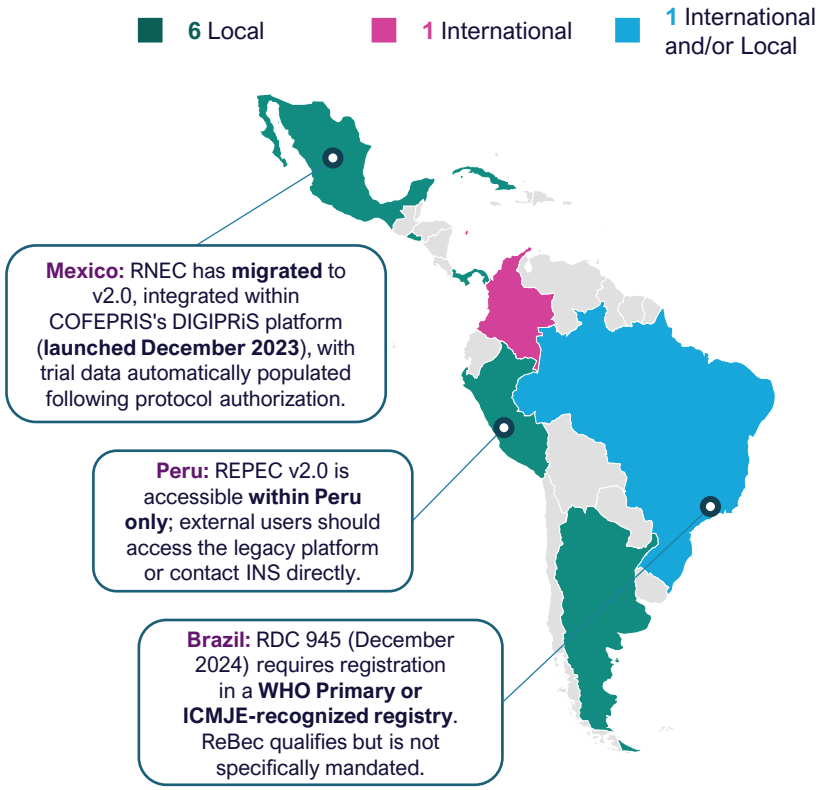
- **26** Local
- **8** International
- **6** International and/or Local
- **3** PACTR
- **3** PACTR and/or Local
- **5** PACTR and/or International
- **30** CTIS
- **3** Undefined

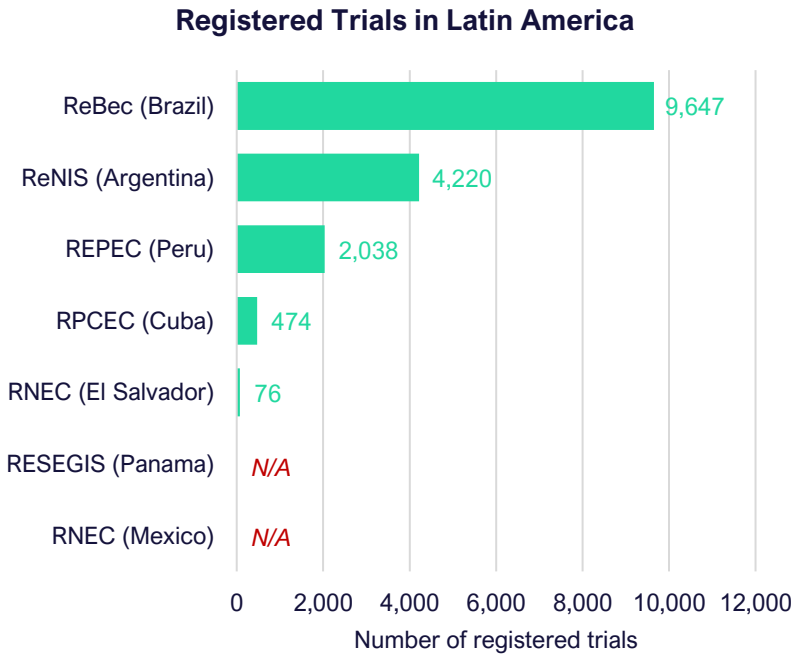


US: FDAAA 801 and 42 CFR Part 11 establish a single national registry, supporting a "**Local**" classification for the US. ClinicalTrials.gov is also an ICTRP data provider accepted by ICMJE and is classified as "**International**" for other regions.

Australia: Requires registration on a WHO ICTRP-compliant public register before first participant recruitment. ANZCTR is one compliant option, not a requirement — hence the "**International and/or Local**" classification.

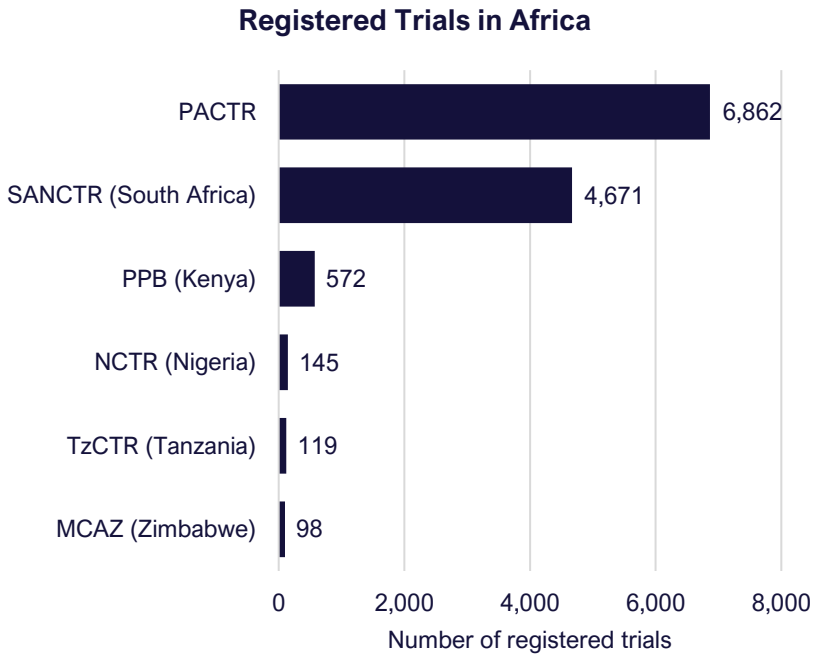
Permissible registries in Latin America





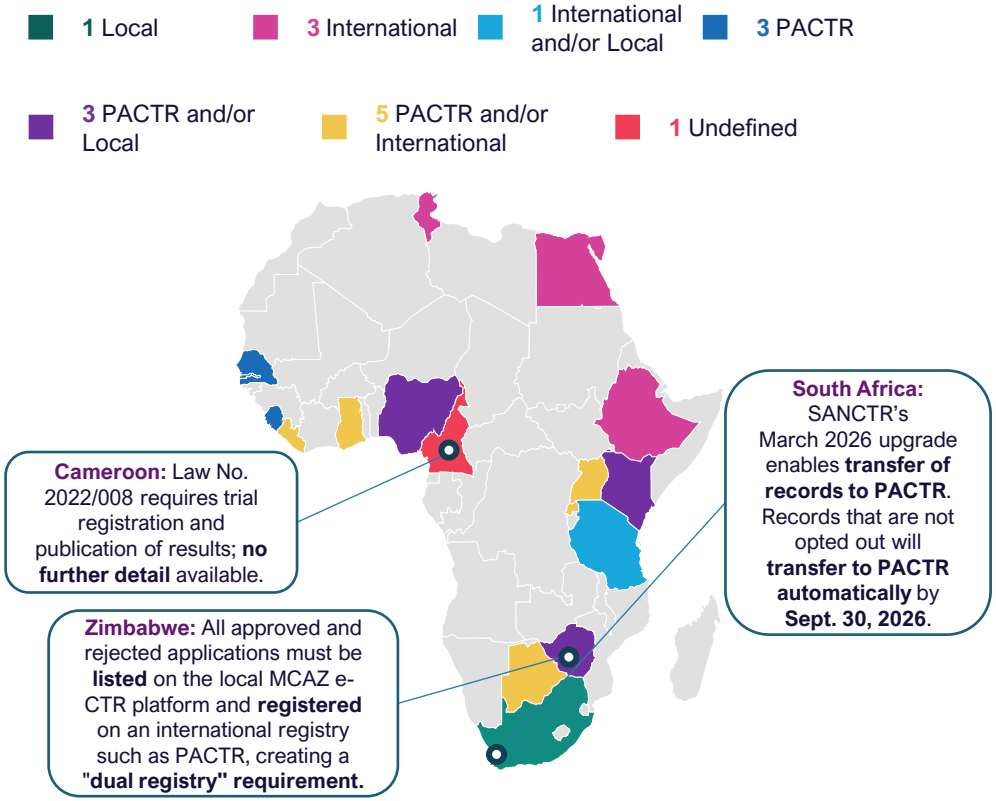
***3 of 7 local registries** are **WHO Primary Registries**:*
***ReBec** (Brazil) founded December 2010, WHO Primary Registry since April 2011;*
***REPEC** (Peru) founded 2007, WHO Primary Registry since July 2016; and*
***RPCEC** (Cuba) founded June 2007, WHO Primary Registry since February 2011.*
Trial count as of Sept. 1, 2026

Permissible registries in Africa



***PACTR** (Pan African Clinical Trials Registry): Founded 2007 as the AIDS, Tuberculosis and Malaria (ATM) Clinical Trials Registry; expanded to all diseases in June 2009. It has been a WHO Primary Registry since September 2009 and is the **only African registry** meeting WHO Primary Registry and ICMJE requirements.*

Trial count as of Sept. 1, 2026



Global permissible registries

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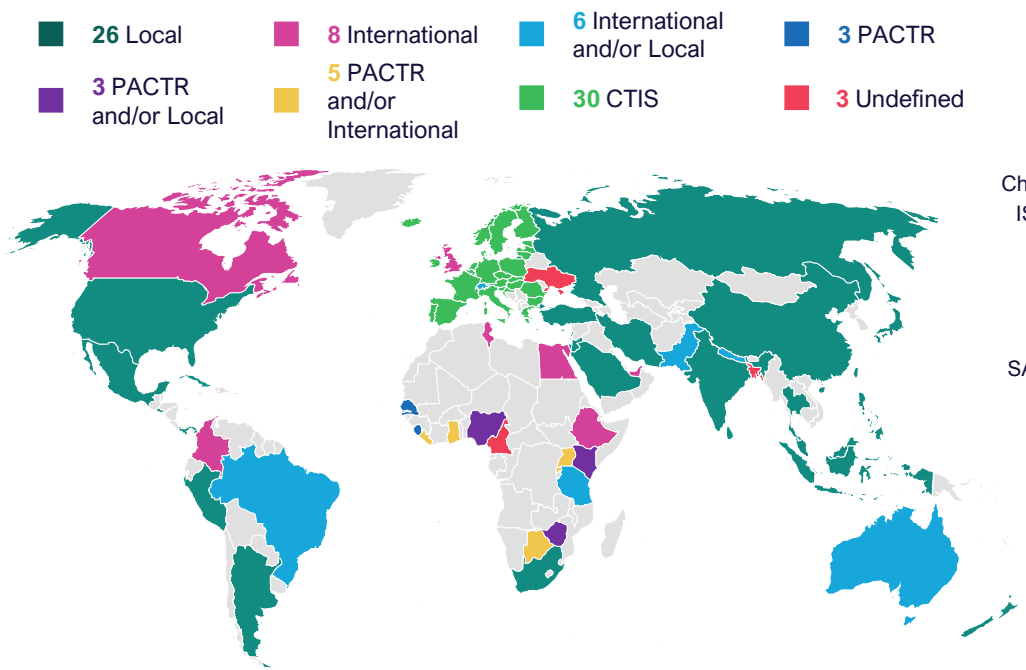

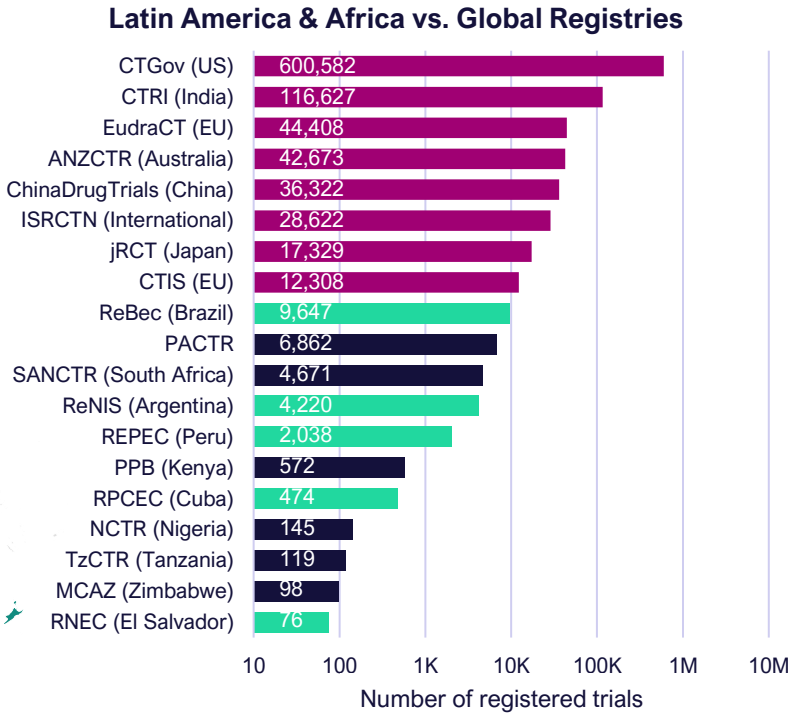

*Green bars = the five Latin American registries with published trial counts; **indigo bars** = the six African registries; **purple bars** = registries in neither region; log scale. Latin America and Africa together hold **28,922 trials**. For comparison with the larger registries plotted: CTgov (US) alone holds **600,582** (~21x both regions combined) and CTRI (India) 116,627 (12x ReBec, the largest regional registry).*
Trial count as of Sept. 1, 2026

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Enforcement Landscape: Why?

Global enforcement for noncompliance

CITELINE REGULATORY

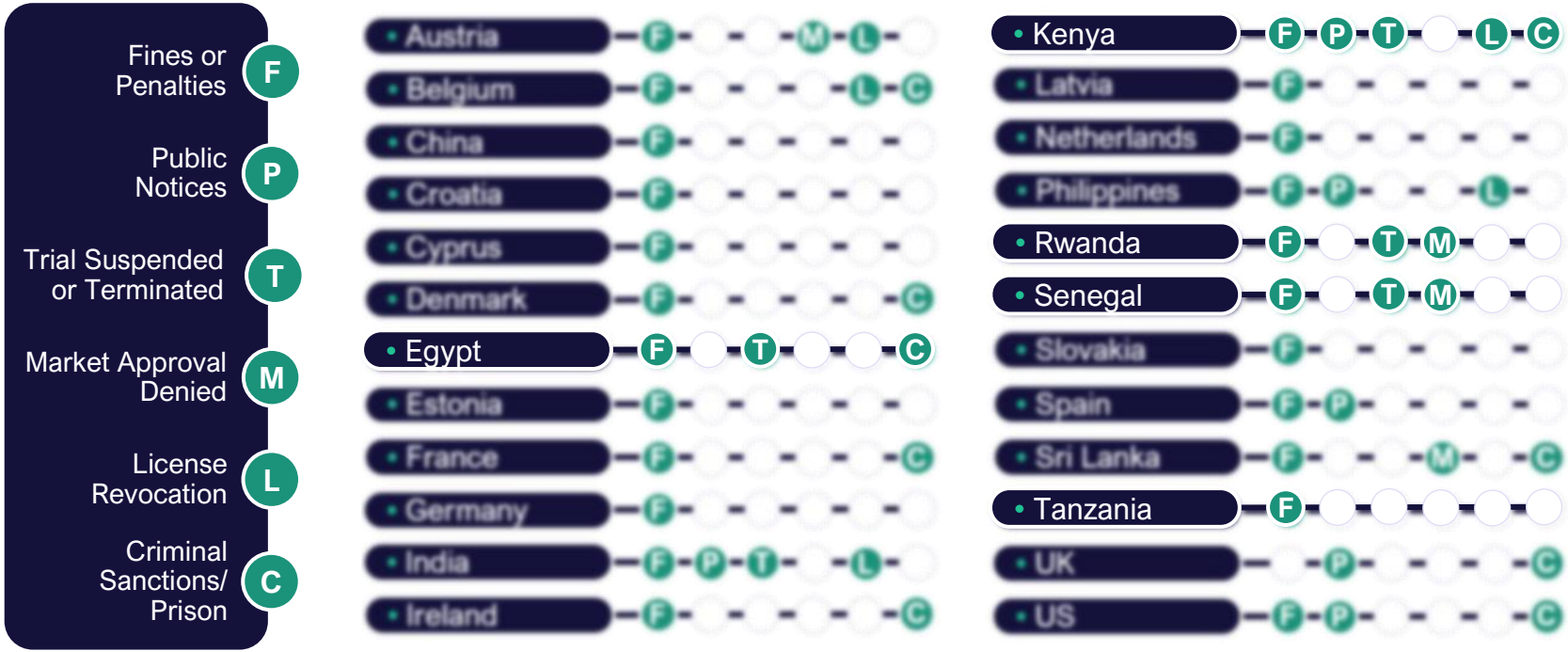
- Fines or Penalties (F)
- Public Notices (P)
- Trial Suspended or Terminated (T)
- Market Approval Denied (M)
- License Revocation (L)
- Criminal Sanctions/ Prison (C)

• Austria	F			M	L		
• Belgium	F				L	C	
• China	F						
• Croatia	F						
• Cyprus	F						
• Denmark	F						C
• Egypt	F		T				C
• Estonia	F						
• France	F						C
• Germany	F						
• India	F	P	T		L		
• Ireland	F						C
• Kenya	F	P	T		L	C	
• Latvia	F						
• Netherlands	F						
• Philippines	F	P			L		
• Rwanda	F		T	M			
• Senegal	F		T	M			
• Slovakia	F						
• Spain	F	P					
• Sri Lanka	F			M		C	
• Tanzania	F						
• UK		P				C	
• US	F	P				C	

US (Update Apr. 2026): The FDA contacted 2,200+ sponsors and investigators regarding their apparent failures to submit results or complete NLM quality control review for 3,000+ studies.

Global enforcement for noncompliance

CITELINE REGULATORY



Enforcement in Africa

CITELINE REGULATORY

• Egypt — F - T - C

- **Fines or Penalties:** Fines of **EGP** 50,000–500,000 (**USD** 1,029–10,290) for failure to publish results or submit required reports; fines of **EGP** 100,000–1,000,000 (**USD** 2,056–20,561) for conducting research without meeting requirements
- **Trial Suspended or Terminated:** The Supreme Council may suspend, refuse to renew, or terminate research early for noncompliance
- **Criminal Sanctions/Prison:** Imprisonment may be imposed for failure to publish results or submit required reports

• Rwanda — F - T - M

- **Fines or Penalties:** Maximum fines of **RWF** 10,000,000 (**USD** 7,386) for publishing findings from an unauthorized trial; minimum fine of **RWF** 1,000,000 (**USD** 739) for publishing findings differing from the authorized protocol
- **Trial Suspended or Terminated:** Mandatory retraction of findings from unauthorized trials; deletion of content differing from the authorized protocol
- **Market Approval Denied:** Ban on marketing products evaluated during unauthorized or noncompliant trials

• Kenya — F - P - T - L - C

- **Fines or Penalties:** Minimum fines of **KES** 1,000,000 (**USD** 7,752) for contravention of the rules
- **Public Notices:** Publication of lists of noncompliant sponsors or investigators; issuance of warnings
- **Trial Suspended or Terminated:** The PPB may suspend or refuse to renew a clinical trial authorization for noncompliance
- **License Revocation:** Blacklisting of noncompliant sponsors or investigators
- **Criminal Sanctions/Prison:** Imprisonment for up to **two years**

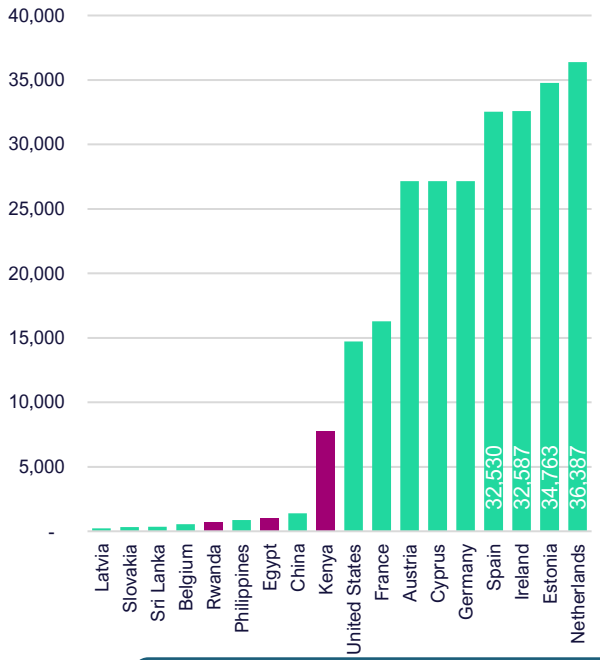
• Senegal — F - T - M

- **Fines or Penalties:** Financial penalties as determined by the ARP and the National Ethics Committee for Health Research (CNERS)
- **Trial Suspended or Terminated:** Suspension or withdrawal of ethical approval or administrative research authorization
- **Market Approval Denied:** Ban on marketing products evaluated during trials conducted in noncompliance

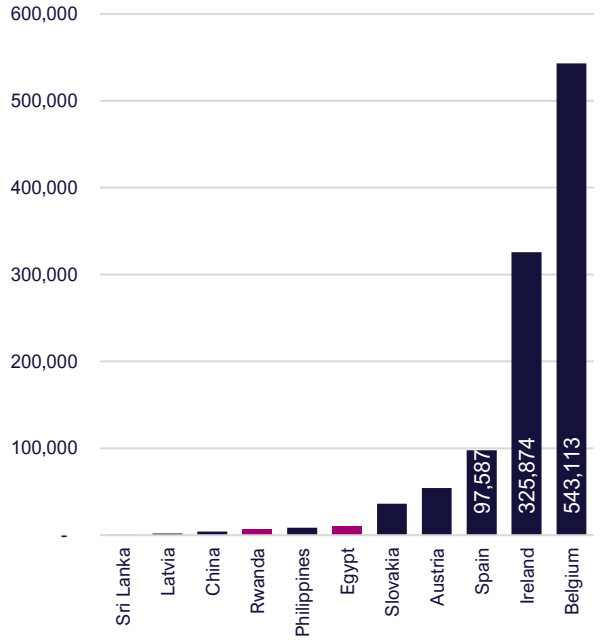
Global enforcement penalties

CITELINE REGULATORY

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
Kenya	7,752	
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	
AVERAGE	**14,554**	**99,152**

Fines are statutory amounts in national currency, converted to USD (Sept. 1, 2026). Blank cells indicate no statutory maximum is specified, not a zero penalty. **Highlighted entries are African jurisdictions**. The average is an unweighted mean of the countries shown with a published figure.

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ICH E6(R3) Implementation:
What Next?

ICH E6(R3) implementation

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

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

Africa

Members:

- **Egypt** (EDA)
- **Nigeria** (NAFDAC) – *Effective May 5, 2025 (NAFDAC GCP 2025)*
- **South Africa** (SAHPRA) – *New Member Nov. 18, 2025*

Legislative or Administrative Authorities:

- **Algeria*** (ANPP)
- **Tunisia** (DPM)

Latin America

Members:

- **Argentina** (ANMAT) – *Effective Dec. 1, 2025 (Resolution No. 7516/2025)*
- **Brazil** (ANVISA) – *Implementation in progress*
- **Mexico** (COFEPRIS) – *Implementation in progress*

Legislative or Administrative Authorities:

- **Colombia** (INVIMA)
- **Cuba** (CECMED)
- **Dominican Republic*** (DIGEMAPS)
- **El Salvador** (SRS)
- **Paraguay*** (DINAVISA)
- **Peru** (DIGEMID)

*Countries without disclosure requirements (mandatory/voluntary)

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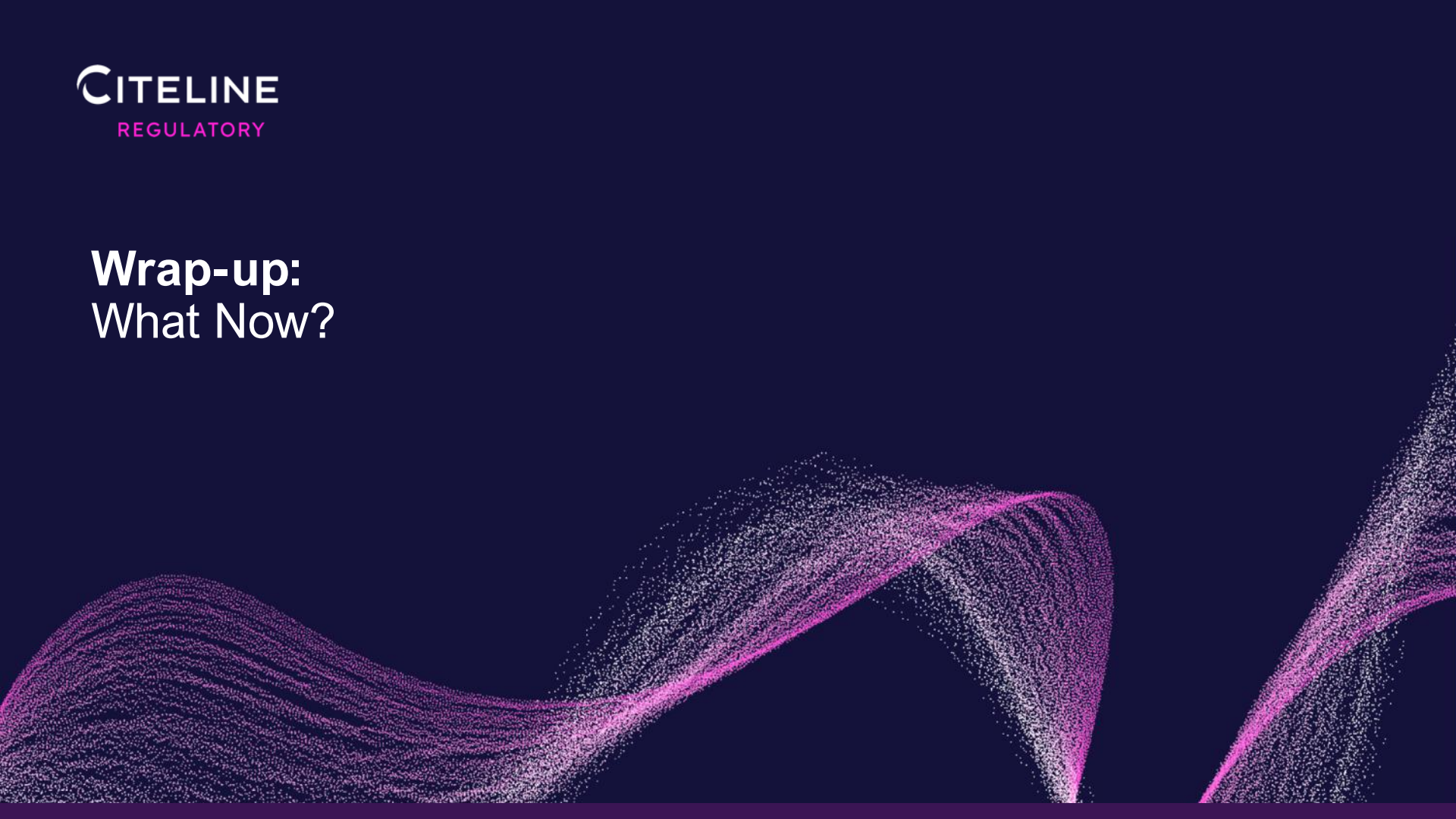
Wrap-up:
What Now?



From complexity to compliance: translating intelligence into action

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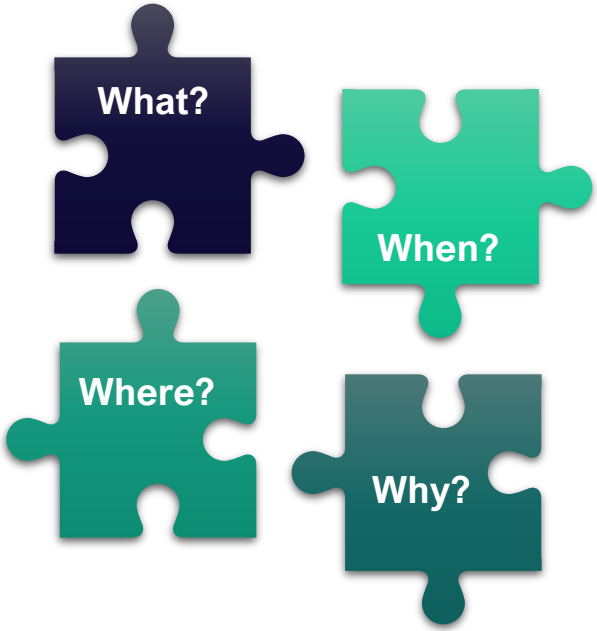

*Compliance requires knowing **what** to disclose, **when** obligations are triggered, **where** registration must occur, and **why** compliance matters and how enforcement is applied.*

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

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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 CONTROL

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 do not emerge overnight, but existing platforms change regularly. Track migrations (**Mexico's RNEC → v2.0** [Dec. 2023]), new launches (**Nigeria's NAFDAC-eCTAP** [May 2024]; **Egypt's EDA Digital Platform** [Feb. 2026]), and access restrictions (**Peru's REPEC v2.0**, internal use only) to maintain compliance.

04 ANNUAL REVIEW

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

05 EYES ON EVOLUTION

Voluntary requirements today may become mandatory tomorrow. Monitor ICH guideline implementations, including the new ICH membership of **Nigeria's NAFDAC** and **South Africa's SAHPRA** (Nov. 2025), emerging registry requirements, and enforcement trends. Proactive intelligence prevents reactive scrambling.

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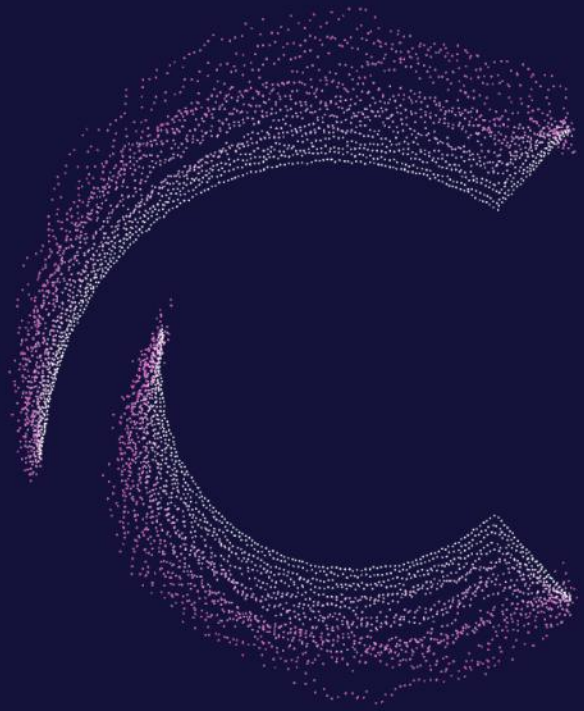
Thank You



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