



Global Clinical Trial Transparency — from Compliance to Emerging Requirements

PART 1

Global Clinical Trial
Disclosure
Fundamentals

Recording Available

This foundational session covers global clinical trial disclosure requirements, timing variations, and enforcement consequences.

PART 2

Navigating the
Clinical Trial
Registry Ecosystem

Navigate the complex registry landscape: regional harmonization, national requirements, and strategic considerations for multi-jurisdictional studies.

PART 3

Beyond Clinical Trial
Registration

Wednesday, Sept. 3

Explore the growing importance of plain language summaries as a global transparency requirement, covering evolving regulatory expectations for protocol and results summaries.

Agenda

❑ **Registry vs. Authority Clinical Trial Database:**

Understanding clinical trial disclosure pathways and key differences

❑ **Global Registry Evolution:**

Timeline of registry development from 2000 to 2025 and international standards evolution

❑ **WHO/ICMJE Architecture:**

Primary registries, partner registries, and ICMJE-compliant platforms with compliance requirements

❑ **Regional Patterns:**

Mapping global registry acceptance patterns and permissible registries across jurisdictions

❑ **Strategic Selection:**

Country-specific case studies and multi-jurisdictional registry selection strategies

❑ **Next Steps:**

Preview of Part 3 – Plain Language Summaries and Beyond Registration

Part 1 Recap: Global Clinical Trial Disclosure Fundamentals

Key Topics Covered

- **Understanding the Framework:** Clinical trial disclosure is a transparency framework ensuring trial information is publicly accessible throughout the research lifecycle, making methodologies and findings available to all stakeholders.
- **Evolution of Standards:** Transparency has progressed from publication requirements (2005) to an ethical mandate (2008) and is now a core GCP principle (2025), highlighting its role in research integrity.
- **Global Registration Landscape:** Registration requirements across 80+ countries vary by timing, from pre-submission to post-approval or relative to enrollment.
- **Results Disclosure Requirements:** Over 60 countries mandate or encourage results posting, with timelines ranging from 3 to 12+ months after study completion, reflecting differing priorities between data analysis and rapid transparency.
- **Enforcement Mechanisms:** Regulatory consequences (including fines up to \$543,113 and criminal sanctions in seven countries) and increasing social accountability shape organizational compliance.

Core Insights

- ❑ Clinical trial transparency has evolved from a publication prerequisite to a core ethical obligation embedded in GCP principles.
- ❑ Compliance requirements cover the entire research lifecycle, with substantial global variation in timing and enforcement.
- ❑ The landscape is moving toward standardization while retaining regional differences.
- ❑ Organizations face both regulatory penalties and reputational risks from noncompliance.

Clinical Trial Disclosure Pathways

CLINICAL TRIAL REGISTRY

A platform or database providing comprehensive information on ongoing and completed clinical studies involving human participants. Researchers and sponsors can log in, enter, and manage trial data, which is disclosed to the public upon submission and is searchable. **The focus of this presentation.**



WHO 24-Item Dataset (TRDS):

1. Primary Registry and Trial Identifying Number; 2. Date of registration in Primary Registry; 3. Secondary identifying numbers; 4. Source(s) of monetary or material support; 5. Primary Sponsor; 6. Secondary Sponsor(s); 7. Contact for public queries; 8. Contact for scientific queries; 9. Public title; 10. Scientific title; 11. Countries of recruitment; 12. Health condition(s) or problem(s) studied; 13. Interventions; 14. Key inclusion and exclusion criteria; 15. Study type; 16. Date of first enrolment; 17. Sample size; 18. Recruitment status; 19. Primary outcome(s); 20. Key secondary outcome(s); 21. Ethics review; 22. Completion date; 23. Summary results; 24. Data sharing plan

AUTHORITY CLINICAL TRIAL DATABASE

Authority-compiled databases containing clinical trial information from sponsor submissions. These are authority-managed databases, with information compiled from regulatory submissions rather than direct sponsor registration. Sponsors do not directly manage or update register data, which may have restricted access or be released in static formats.



Key Characteristics:

Authority-managed databases with authority controlling data compilation and updates. Access may be restricted or delayed, often in static formats (Excel, PDF), with limited sponsor data management capabilities.

Typical Data Fields Captured:

Clinical trial authorization (CTA) number, study title, principal investigator, authorization date, trial duration, institution and sponsor information, study status (ongoing, terminated, closed-out), basic methodological details, and regulatory compliance information.

- **Data Source:** Regulatory submissions (not direct sponsor entry)
- **Updates:** Authority-controlled, periodic updates
- **Search Function:** Basic search with dropdown filters and text search by condition, drug, therapeutic area, and status
- **Trial Status:** Approved, ongoing, completed, terminated
- **Coverage:** All clinical trials authorized in Ukraine



State Expert Center of the Ministry of Health of Ukraine
Information on clinical trials in Ukraine

Patient's pathological condition (at least 3 letters)

Research locations (at least 3 letters)

Drugs (at least 3 letters)

KV code (at least 3 letters)

Status of the KV

Test profile:

Found - 598 records considering the filter: Oncology											
	KV code	Applicant	Sponsor	Text profile	Patient's pathological condition	Phases	Drugs	Status of the KV	Start date of the KV in Ukraine	Number of subjects studied in Ukraine	Number people studied in the world
More details	20950181	LLC "KDO InnoPharm-Ukraine"	"Amgen Inc." (Amgen Inc.)	Oncology	Metastatic colorectal cancer	III	Panitumumab, Investigational Drug	Completed KV in Ukraine	01/22/2007	Planned - 150	Planned - 150
More details	3144A1-203-WW	LLC "PAREXEL Ukraine"	Puma Biotechnology, Inc., a subsidiary of Pfizer Inc.	Oncology	solid tumors and breast cancer	I, II	HK1-272, Investigational Drug; Tencateb®, Investigational Drug	Completed KV in Ukraine	09/16/2008	Planned - 20; Actual - 0	04/04/2008 Planned - 20; 04/04/2008 Planned - 150
More details	B1771006 (3066K1-3311-WW)	LLC "PAREXEL Ukraine"	Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.	Oncology	Advanced renal cell carcinoma	III	Bevacizumab (Avastin®), Study Drug; Temsirolimus (Torisel®), Study Drug; Bevacizumab (Avastin®), Comparison Drug; Interferon-alpha (Roferon®), Comparison Drug	Completed KV in Ukraine	04.10.2008	12/06.2008 Planned - 50	12/06.2008 Planned - 800
More details	BAY 80-6946 / 1732	Bayer LLC, Ukraine	Bayer AG, Germany	Oncology	patients with relapsed indolent B-cell non-Hodgkin lymphoma	III	Copinativ®, Investigational Drug	Completed KV in Ukraine	10/15/2015	15/15/2015 Planned - 237	15/15/2015 Planned - 237
More details	VY022-02	LLC "CLS UKRAINE", Ukraine	Vector Vital LLC, USA	Oncology	Phase I: metastatic solid tumor, Phase II: cutaneous melanoma, prostate cancer, pancreatic cancer, chronic myelocytic leukemia	I, II	CLS-1, Investigational product; solvent Sodium chloride, Investigational product	KV started in Ukraine	08/29/2014	02/29/2014 Planned - 136	02/29/2014 Planned - 136

- KV Code
- Trial title
- Applicant/Sponsor
- Therapeutic area
- Phase
- Interventions/drugs
- Trial status
- Patient condition
- Age/sex eligibility
- Inclusion/exclusion criteria
- Start/completion dates
- Study duration (*Ukraine vs. global*)
- Study sites/investigators
- Enrollment numbers (*Ukraine vs. global*)
- Regulatory approvals/meetings
- Study objectives

Ukraine vs WHO Registry Standards

Ukraine State Expert Center

- ☐ Government-controlled data compilation
- ☐ Regulatory submission-based
- ☐ Captures ~13-16 of 24 WHO TRDS items
- ☐ Static data updates
- ☐ No direct sponsor management
- ☐ Focus on regulatory compliance

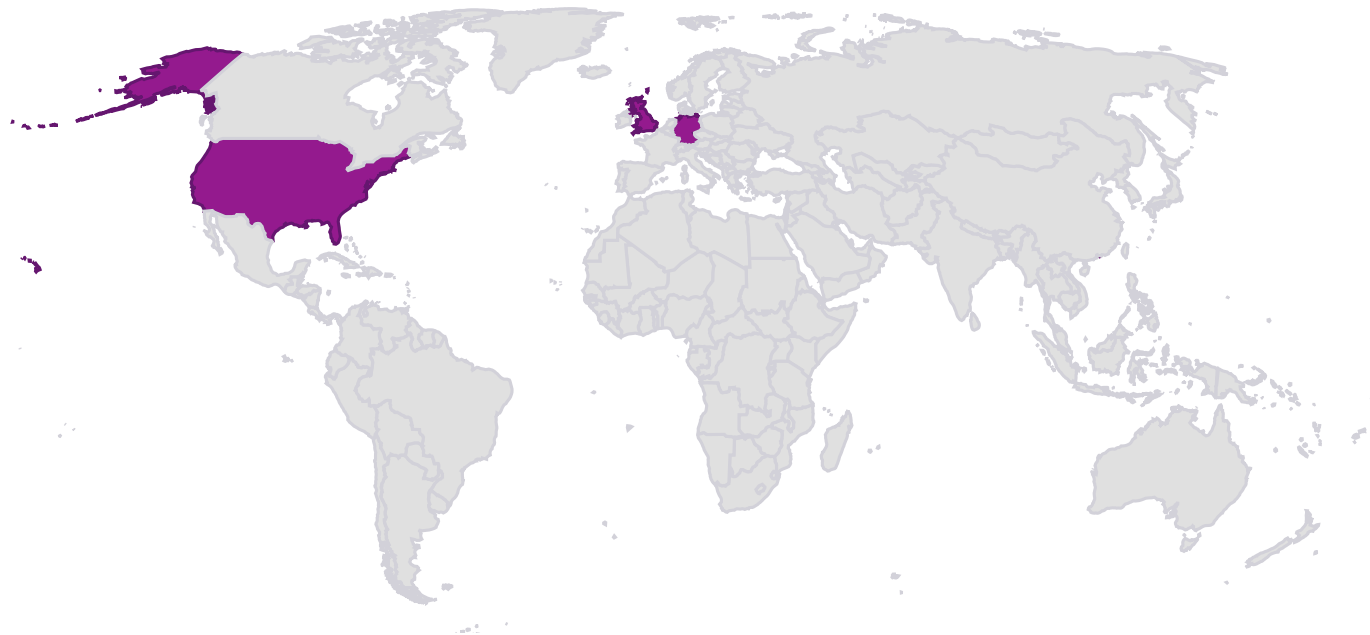
WHO Registry Standards

- ❑ Sponsor-controlled data entry
- ❑ Real-time updates and audit trails
- ❑ Complete 24-item TRDS compliance
- ❑ Interactive, searchable platforms
- ❑ Direct sponsor responsibility
- ❑ Focus on transparency and accessibility

Registry Location by Country

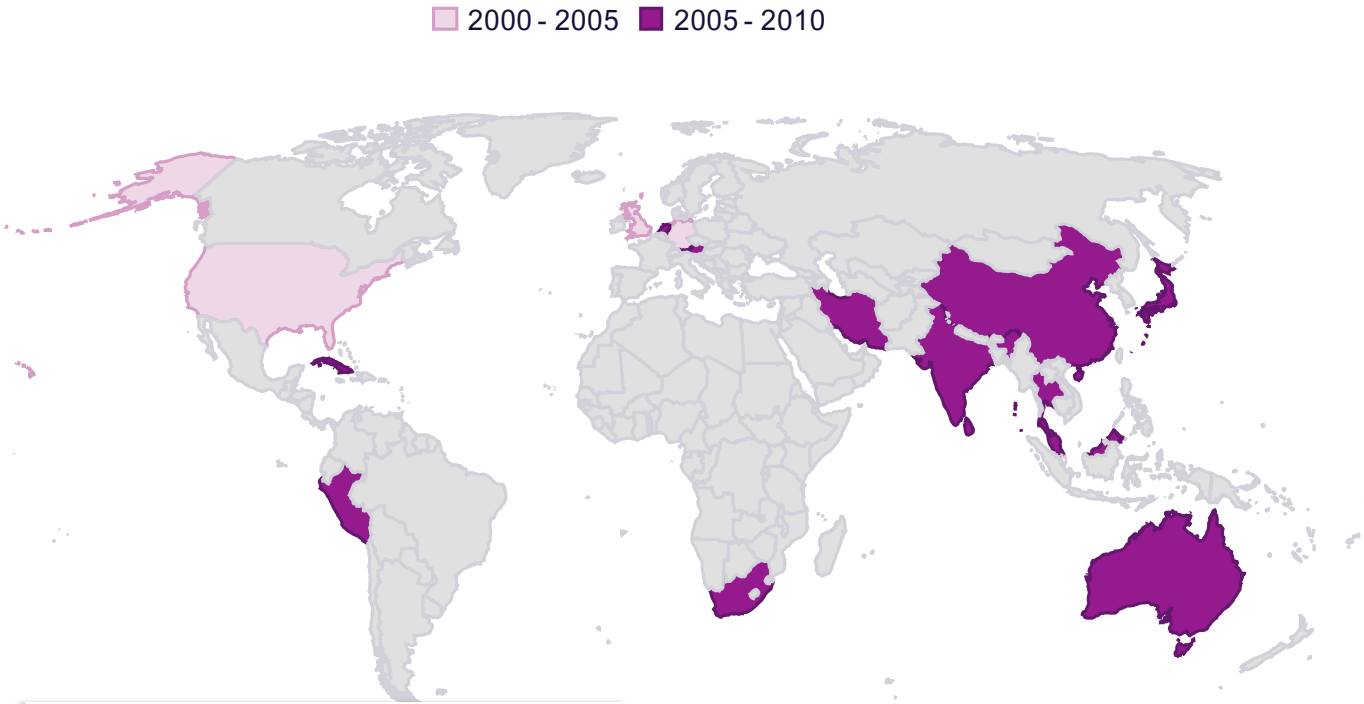
■ 2000 - 2005

REGISTRY	LOCATION	LAUNCH
ISRCTN	London, UK	Jan. 1, 2000
ClinicalTrials.gov	Maryland, US	Feb. 29, 2000
PharmNet.bund	Cologne, Germany	Aug. 1, 2004
HKUCTR	Hong Kong	Dec. 31, 2004



REGISTRY	LOCATION	LAUNCH
CTRI	Jakarta, Indonesia	Jan. 1, 2010
JFDA CTR	Amman, Jordan	Jan. 1, 2010
CRiS	Cheongju, South Korea	Jan. 1, 2010
RESEGIS	Panama City, Panama	Jan. 1, 2010
GRLS	Moscow, Russia	Jan. 1, 2010
DCTIN	Taipei, Taiwan	Jan. 1, 2010
IRPMA PMS	Taipei, Taiwan	Jan. 1, 2010
EU PAS – ENCePP	Amsterdam, Netherlands	Nov. 1, 2010
ReBec	Rio de Janeiro, Brazil	Dec. 16, 2010
ReNIS	Buenos Aires, Argentina	Jan. 1, 2011
EudraCT	Amsterdam, Netherlands	Mar., 22, 2011
MFDS	Cheongju, South Korea	Jan. 1, 2012
PHRR	Manila, Philippines	Aug. 1, 2012
ChinaDrugTrials	Beijing, China	Nov. 1, 2012
RNEC	Mexico City, Mexico	Jan. 1, 2013
SCTR	Riyadh, Saudi Arabia	June 21, 2013
SNCTP	Bern, Switzerland	Jan. 1, 2014

Registry Location by Country



International Standards

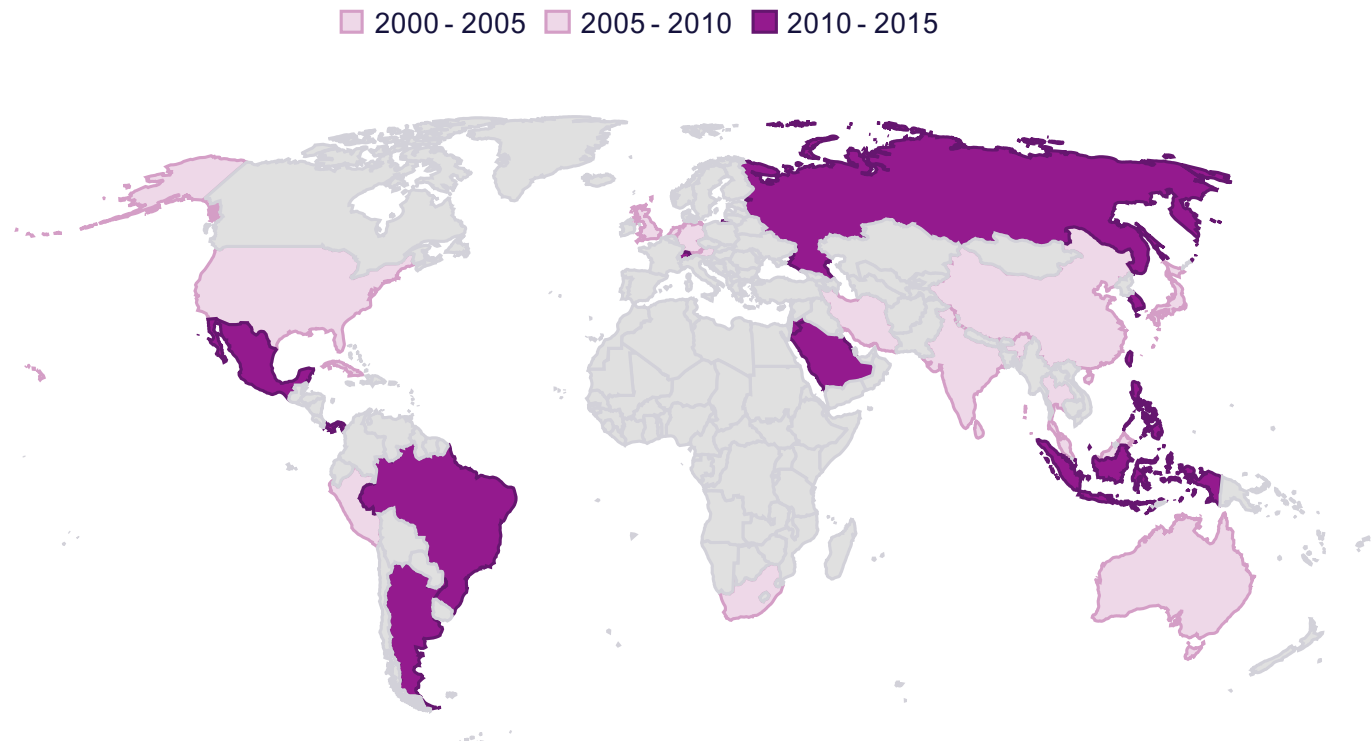
☐ ICMJE Policy (July 2005)

☐ WHO ICTRP (August 2005)

☐ Declaration of Helsinki 7th Revision (October 2008)

REGISTRY	LOCATION	LAUNCH
ANZCTR	Camperdown, Australia	Jan. 1, 2005
UMIN-CTR	Tokyo, Japan	June 1, 2005
ChiCTR	Chengdu, China	Oct. 1, 2005
SANCTR	Cape Town, South Africa	Dec. 1, 2005
BASG	Vienna, Austria	Jan. 2, 2006
SLCTR	Colombo, Sri Lanka	Nov. 1, 2006
RPCEC	Havana, Cuba	Jan. 1, 2007
REPEC	Lima, Peru	Jan. 1, 2007
NMRR	Putrajaya, Malaysia	May 1, 2007
CTRI	New Delhi, India	July 20, 2007
DRKS	Cologne, Germany	Oct. 1, 2008
CCMO	The Hague, Netherlands	Dec. 1, 2008
IRCT	Tehran, Iran	Dec. 4, 2008
TCTR	Bangkok, Thailand	Jan. 1, 2009
PACTR	Cape Town, South Africa	June 1, 2009
CCRBCTR	Hong Kong, Hong Kong	Dec. 1, 2009

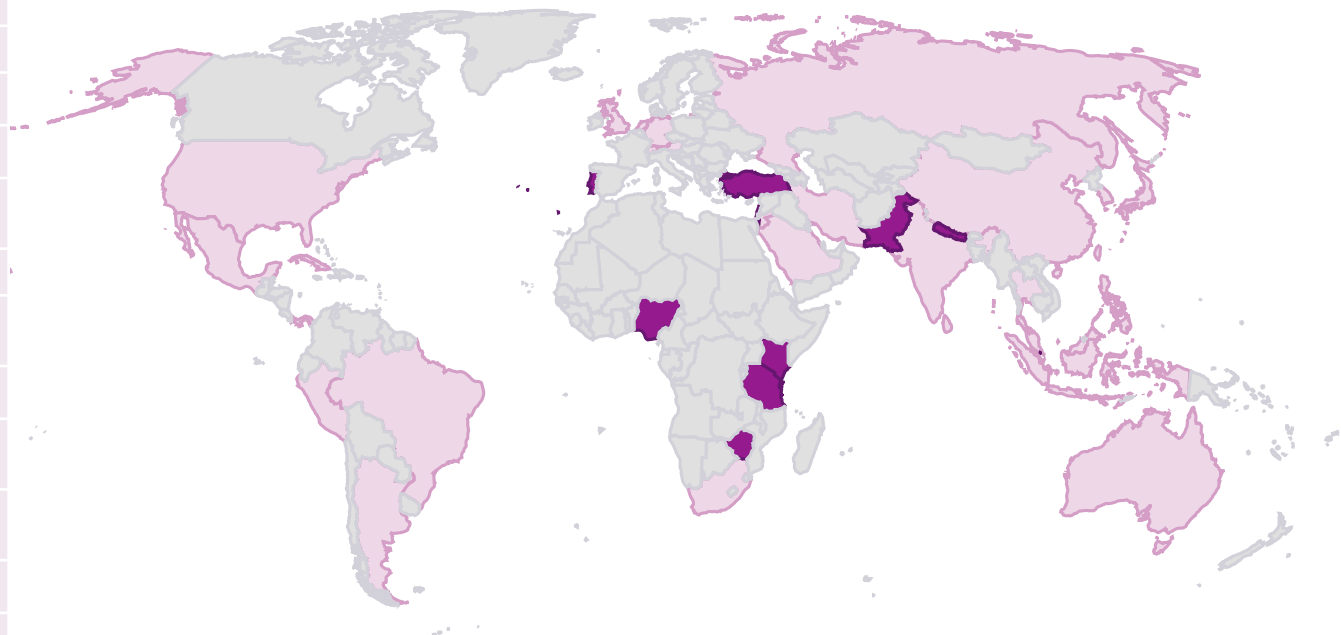
Registry Location by Country



Registry Location by Country

REGISTRY	LOCATION	LAUNCH
MyTrial	Jerusalem, Israel	Jan. 1, 2015
PPB	Nairobi, Kenya	Jan. 1, 2015
LBCTR	Beirut, Lebanon	Jan. 1, 2015
NCTR	Abuja, Nigeria	Jan. 1, 2015
NCTR	Kathmandu, Nepal	Jan. 1, 2015
PCTR	Pakistan, Pakistan	Jan. 1, 2015
HSA	Singapore, Singapore	Jan. 1, 2015
KAP	Ankara, Turkey	Jan. 1, 2015
TzCTR	Dar es Salaam, Tanzania	Jan. 1, 2015
MCAZ	Harare, Zimbabwe	Jan. 1, 2015
BfArM AWB	Langen, Hesse, Germany	March 26, 2015
PEI AWB	Langen, Hesse, Germany	March 26, 2015
RNEC	Lisbon, Portugal	Dec-2016
JRCT	Tokyo, Japan	April 1, 2018

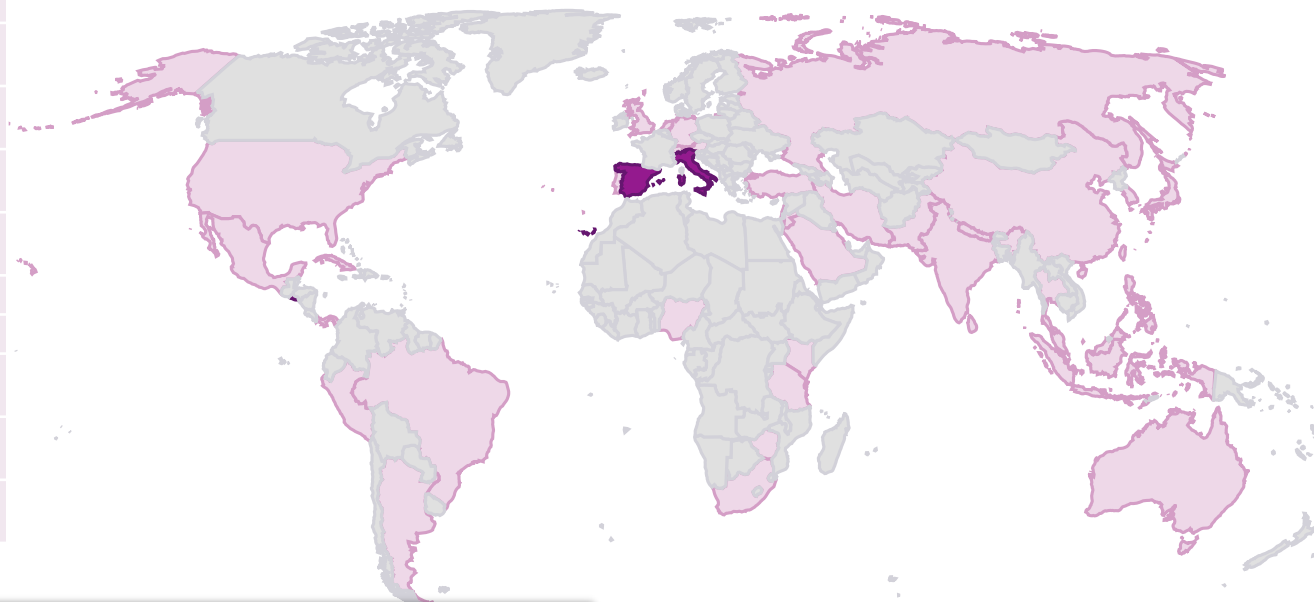
2000 - 2005
 2005 - 2010
 2010 - 2015
 2015 - 2020



Registry Location by Country

2000 - 2005 2005 - 2010 2010 - 2015 2015 - 2020 2020 - 2025

REGISTRY	LOCATION	LAUNCH
REEC	Madrid, Spain	Jan. 2, 2021
RNEC	El Salvador, El Salvador	Oct. 25, 2021
CTIS	Amsterdam, Netherlands	Jan. 31, 2022
LTR	The Hague, Netherlands	Dec. 15, 2022
OMON	Amsterdam, Netherlands	Dec. 15, 2022
RSO	Rome, Italy	Jan. 31, 2023
ITMCTR	Beijing, China	Feb. 20, 2023
Catalogue of RWD studies	Amsterdam, Netherlands	Feb. 15, 2024
INA-CRR	Jakarta, Indonesia	Oct. 16, 2024
HumRes	Bern, Switzerland	March 1, 2025

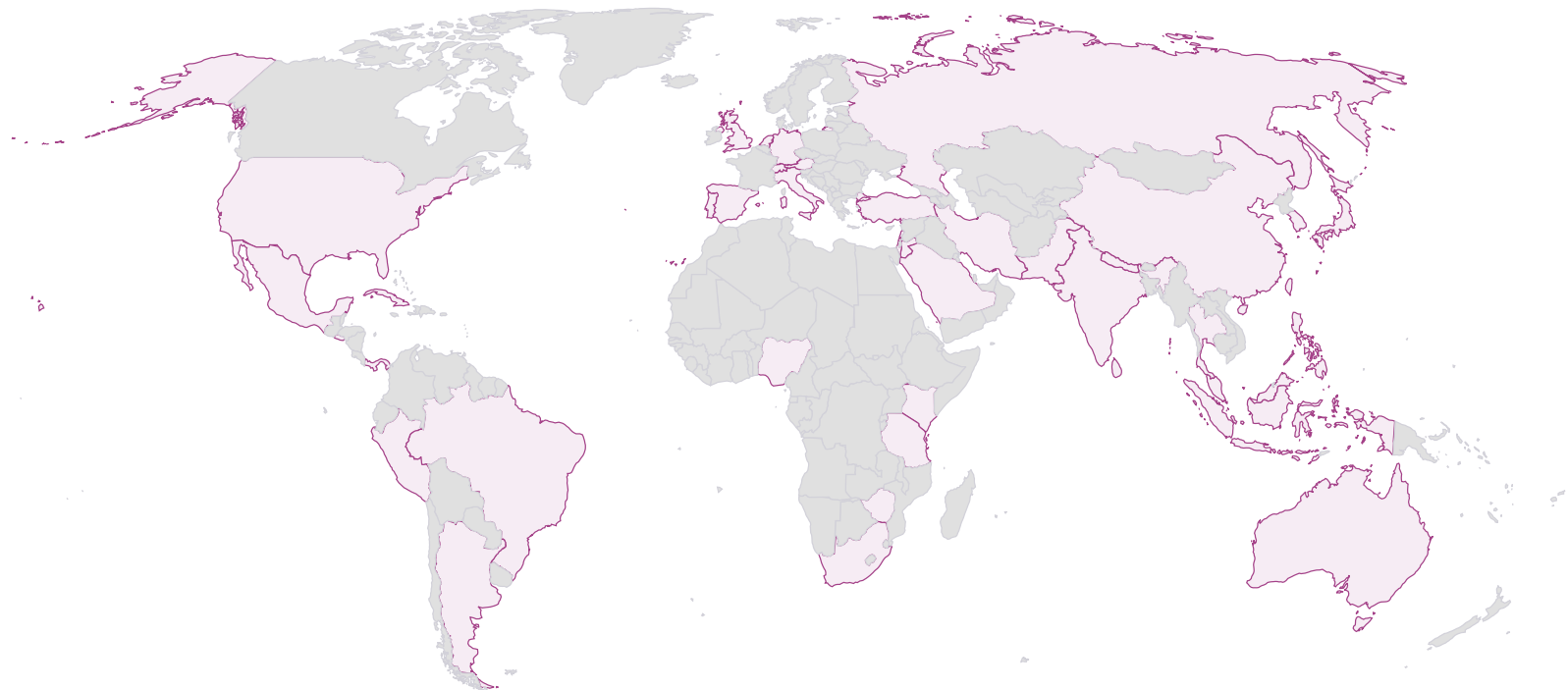


International Standards

- ☐ ICH E6(R3) Transparency Requirements (January 2025)

Registry Location Overview by Country (2000 to 2025)

 Countries/Location of Clinical Trial Registries



WHO/ICMJE Registry Architecture

WHO Primary Registries

Definition: Registries meeting the highest WHO standards for trial registration

- **Content:** 24 mandatory WHO Trial Registration Dataset fields
- **Quality & Validity:** Standard operating procedures, audit trails for data changes
- **Accessibility:** Free public access with a publicly accessible audit trail
- **Unique ID:** Universal Trial Number (UTN) assignment
- **Technical Capacity:** Direct ICTRP submission capability
- **Administration:** Not-for-profit management with government support
- **Scope:** National/regional remit with Ministry of Health support letter required
- **Open to:** All prospective interventional clinical trials from responsible registrants
- **ICMJE Status:** Automatically meets ICMJE requirements for journal publication

WHO Partner Registries

Definition: Regional/specialized registries affiliated with primary registries

- Meet the same WHO registry criteria as Primary registries
- **Exception:** Do NOT require national remit or government support
- **Exception:** Do NOT require being open to all prospective registrants
- May focus on specific conditions, interventions, or geographic regions
- **MUST affiliate** with either WHO Primary Registry or ICMJE-approved registry
- Submit data via affiliated Primary Registry only
- **Cannot directly submit** to ICTRP Secretariat
- **Do NOT independently meet** ICMJE requirements (require Primary Registry affiliation)

ICMJE-Compliant Registries

Definition: Registries specifically accepted by International Committee of Medical Journal Editors

- **WHO Primary Registries:** All 18 automatically qualify
- **ICMJE-Approved Non-Primary:** ClinicalTrials.gov, selected others
- **Requirements:** Meet ICMJE's clinical trial definition and registration standards
- **Publication Eligibility:** Required for manuscript submission to ICMJE member journals
- **Registration Timing:** Must occur before first patient enrollment (prospective registration)

WHO/ICMJE Registry Architecture

Registry Type	ICMJE Compliant	Direct ICTRP Access	Independent Registration	Not-for-Profit Required	Open to All Trials
WHO Primary	✓ Yes	✓ Yes	✓ Yes	✓ Yes	✓ Yes
WHO Partner	✗ No*	✗ No	✗ No	✓ Yes	○ May be limited
ICMJE-Approved	✓ Yes	○ Variable	✓ Yes	✓ Yes	✓ Yes
Independent National	✗ No	✗ No	✓ Yes	○ Variable	○ Variable

**Partner registries require affiliation with Primary Registry for ICMJE compliance*

A **WHO Primary Registry** is a clinical trial registry that meets **WHO criteria**, including **free public access**, **openness to all registrants**, **not-for-profit management**, **data validity safeguards**, and **recognition as a data provider** to the WHO International Clinical Trials Registry Platform (ICTRP). Primary Registries also meet the requirements of the **International Committee of Medical Journal Editors (ICMJE)**.

ICMJE COMPLIANT

WHO PRIMARY

- PACTR
- ANZCTR (Australia)
- ReBec (Brazil)
- ChiCTR (China)
- RPCEC (Cuba)
- DRKS (Germany)
- CTIS (European Union)
- EudraCT/EU CTR (European Union)
- CTRI (India)
- ISRCTN registry (International)
- ITMCTR (International)
- IRCT (Iran)
- jRCT (Japan)
- CRiS (South Korea)
- LBCTR (Lebanon)
- SLCTR (Sri Lanka)
- REPEC (Peru)
- TCTR (Thailand)

WHO PARTNER

- CUHK-CCRBCTR (Hong Kong)
- UMIN-CTR (Japan)
- HKU CTR (Hong Kong)
- NCTR (Nigeria)
- OMON (Netherlands)
- CTGov (United States)

Neither WHO primary/partner nor meets ICMJE requirements

- ReNIS (Argentina)
- AGES NIS Registry (Austria)
- HumRes (Switzerland)
- SNCTP (Switzerland)
- ChinaDrugTrials (China)
- BfArM AWB (Germany)
- PEI AWB (Germany)
- PharmNet.Bund-CT (Germany)
- REEC (Spain)
- Catalogue of RWD studies (European Union)
- EU PAS - ENCePP (European Union)
- CTRI (Indonesia)
- INA-CRR (Indonesia)
- MyTrial (Israel)
- RSO (Italy)
- JFDA CTR (Jordan)
- PPB CTR (Kenya)
- MFDS Registry (South Korea)
- RNEC (Mexico)
- NMRR (Malaysia)
- CCMO Register (Netherlands)
- LTR (Netherlands)
- NCTR (Nepal)
- RESEGIS (Panama)
- PHRR (Philippines)
- PCTR (Pakistan)
- RNEC (Portugal)
- GRLS (Russia)
- SCTR (Saudi Arabia)
- HSA CTR (Singapore)
- RNEC (El Salvador)
- KAP (Turkey)
- DCTIN (Taiwan)
- IRPMA PMS (Taiwan)
- TzCTR (Tanzania)
- SANCTR (South Africa)
- MCAZ-CTR (Zimbabwe)

Global Registry Acceptance Patterns

- **Recap:** During Part 1 of the webinar series, we explored the global landscape of clinical trial disclosure requirements, identifying that **more than 80 countries mandate clinical trial protocol registration**, each with varying disclosure obligations. Additionally, **over 60 countries mandate or encourage (voluntary) clinical trial results disclosure**.
- For these requirements, each jurisdiction specifies permissible registries to fulfil compliance, creating a varied network of registry acceptance patterns that sponsors must navigate.

80+

Countries requiring
protocol registration

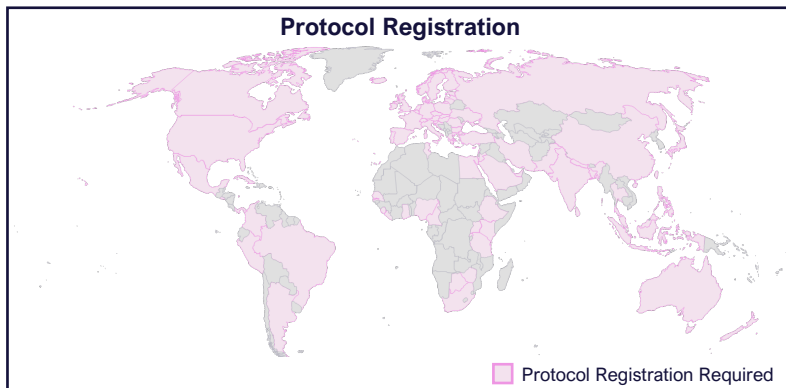
60+

Countries with
results disclosure requirements

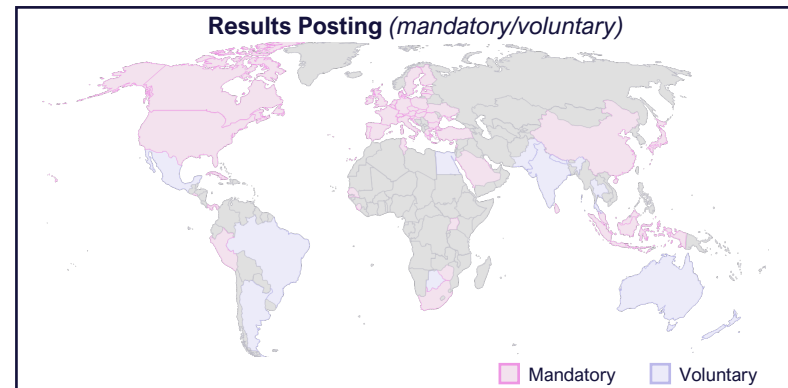
26

Countries with
enforcement mechanisms

Protocol Registration

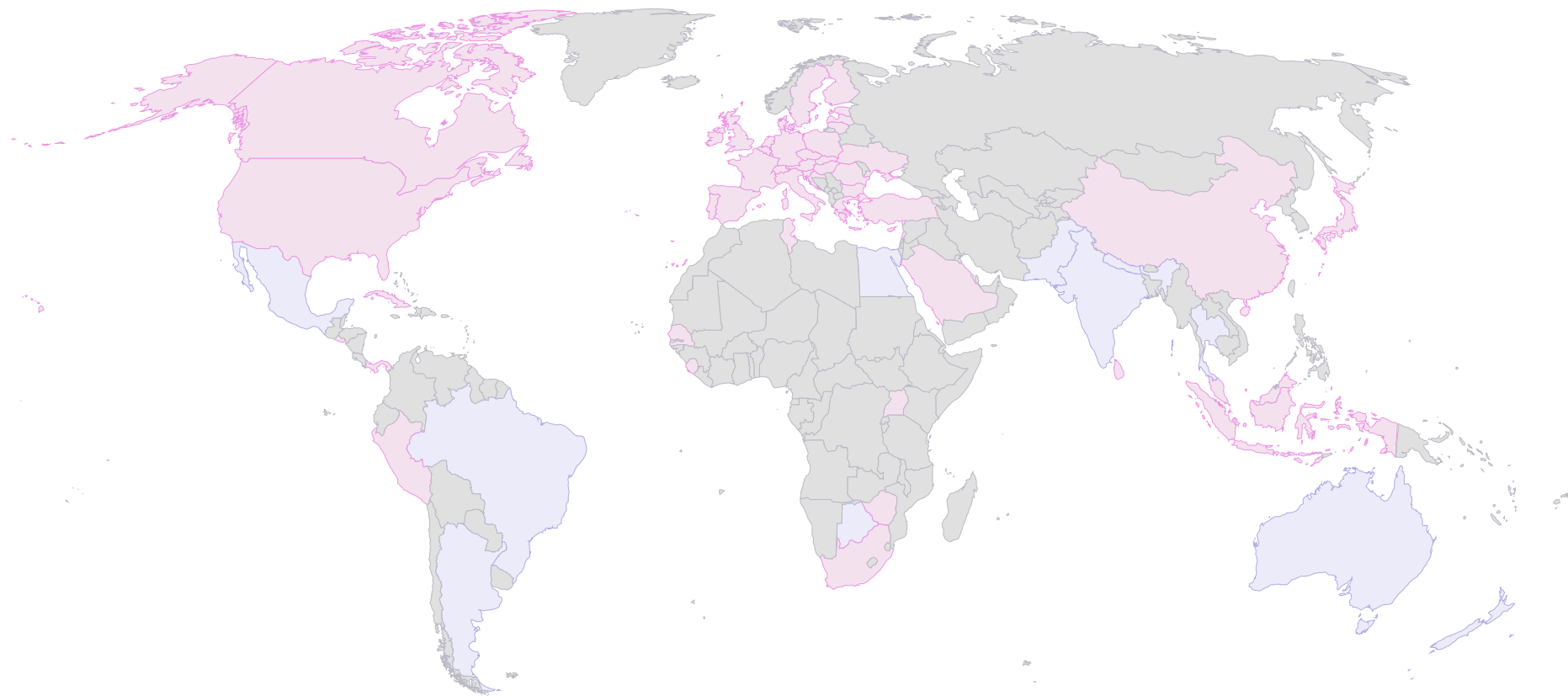


Results Posting (mandatory/voluntary)





Results Posting: Mandatory Voluntary



Permissible Registries in Requirements

Based on the regulatory landscape analysis, distinct patterns emerge in clinical trial registry requirements, showing strong regional harmonization trends alongside diverse national approaches.

Regional Harmonization:

- **CTIS: 30 countries** use the **Clinical Trials Information System (CTIS)** as their disclosure platform. This includes all EU Member States plus EEA countries, reflecting the unified approach mandated by **EU Regulation 536/2014**.
- **PACTR:** In Africa, **11 countries** require registration through the **Pan-African Clinical Trials Registry (PACTR)**; **8 countries** rely exclusively on the PACTR, and **3 countries** combine it with national/local registries operated by their health authorities.

National ("Local") Registries:

- **32 countries** maintain national registries. Of these, **26 countries** require disclosure exclusively in these registries, while 6 countries combine national registry disclosure with submission to international platforms.

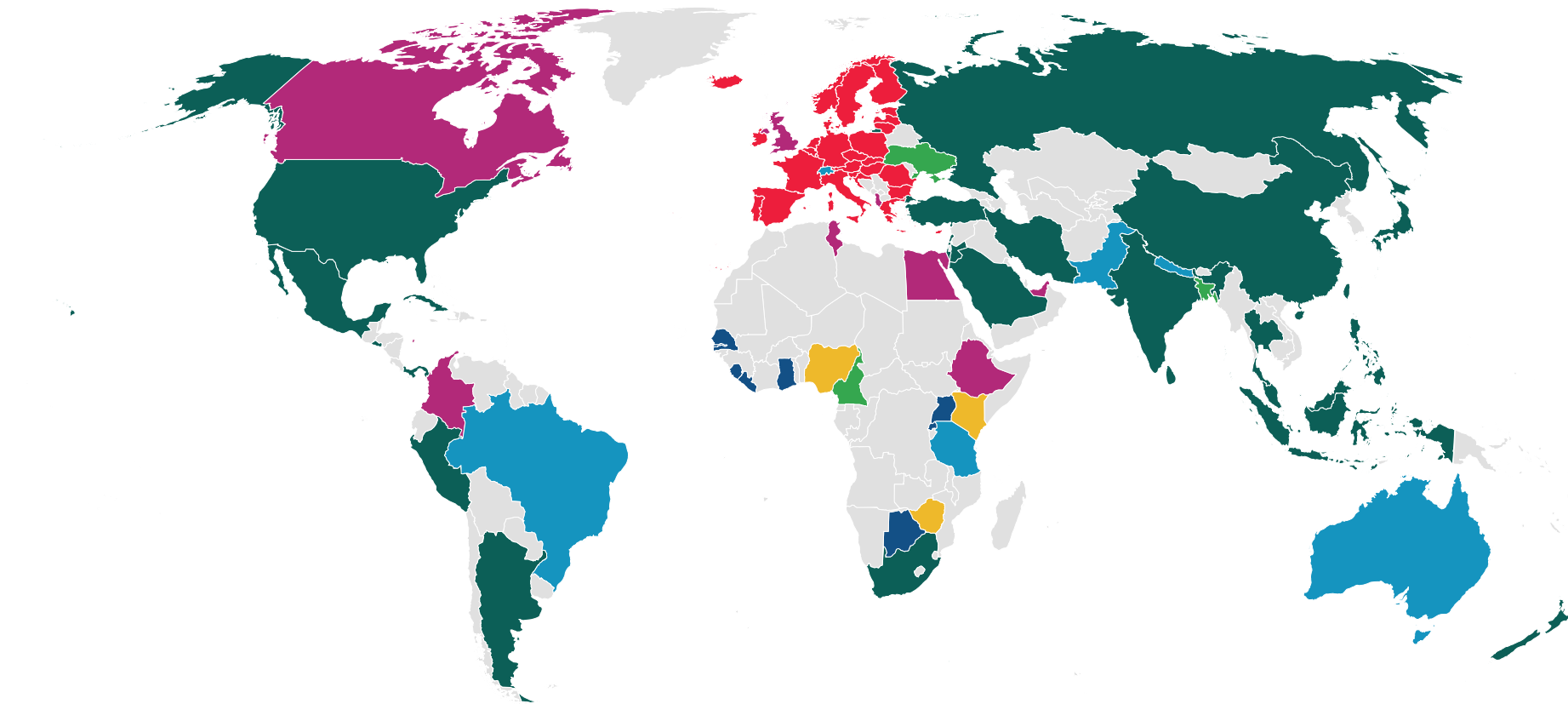
International Platforms:

- **9 countries** require disclosure in international registries, such as **ClinicalTrials.gov**, **WHO-recognized ICTRP registries**, or **ISRCTN**. These countries mandate registration in internationally recognized systems rather than maintaining their own.

Implementation Gaps:

- **3 countries** mandate disclosure but lack fully defined registry requirements:
 - **Bangladesh** – Framework exists, but no functional registry; BMRC developing an electronic system with a planned Clinical Trial Registry
 - **Cameroon** – Law requires registration, but no registry specified; only mandates publication of research findings
 - **Ukraine** – No registry; maintains a trial list on the SECMOH website

Local International International and Local PACTR PACTR and Local CTIS Not Defined



Local: 26

International: 9

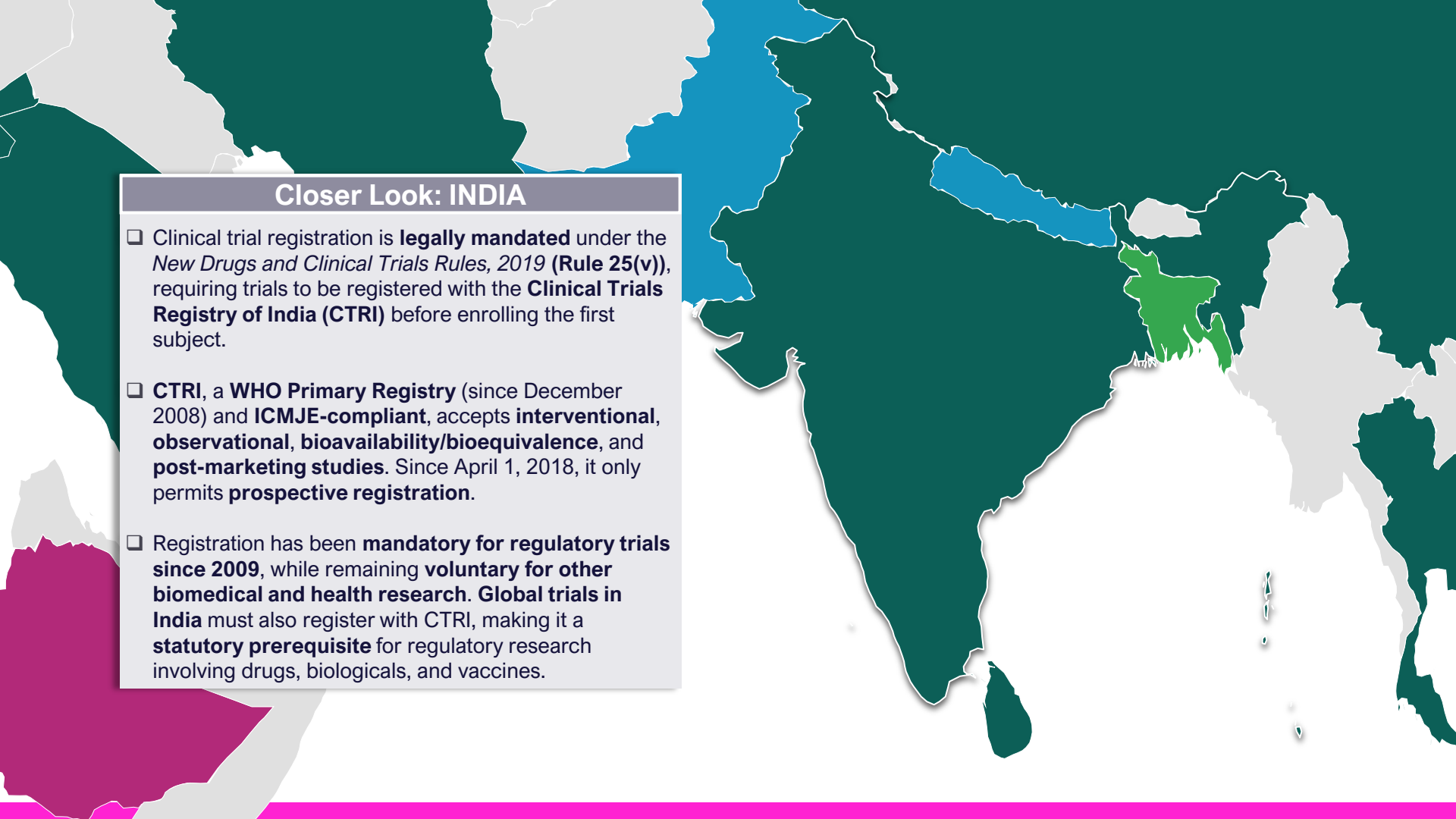
International and
Local: 6

PACTR: 8

PACTR and Local:
3

CTIS: 30

Not defined: 3

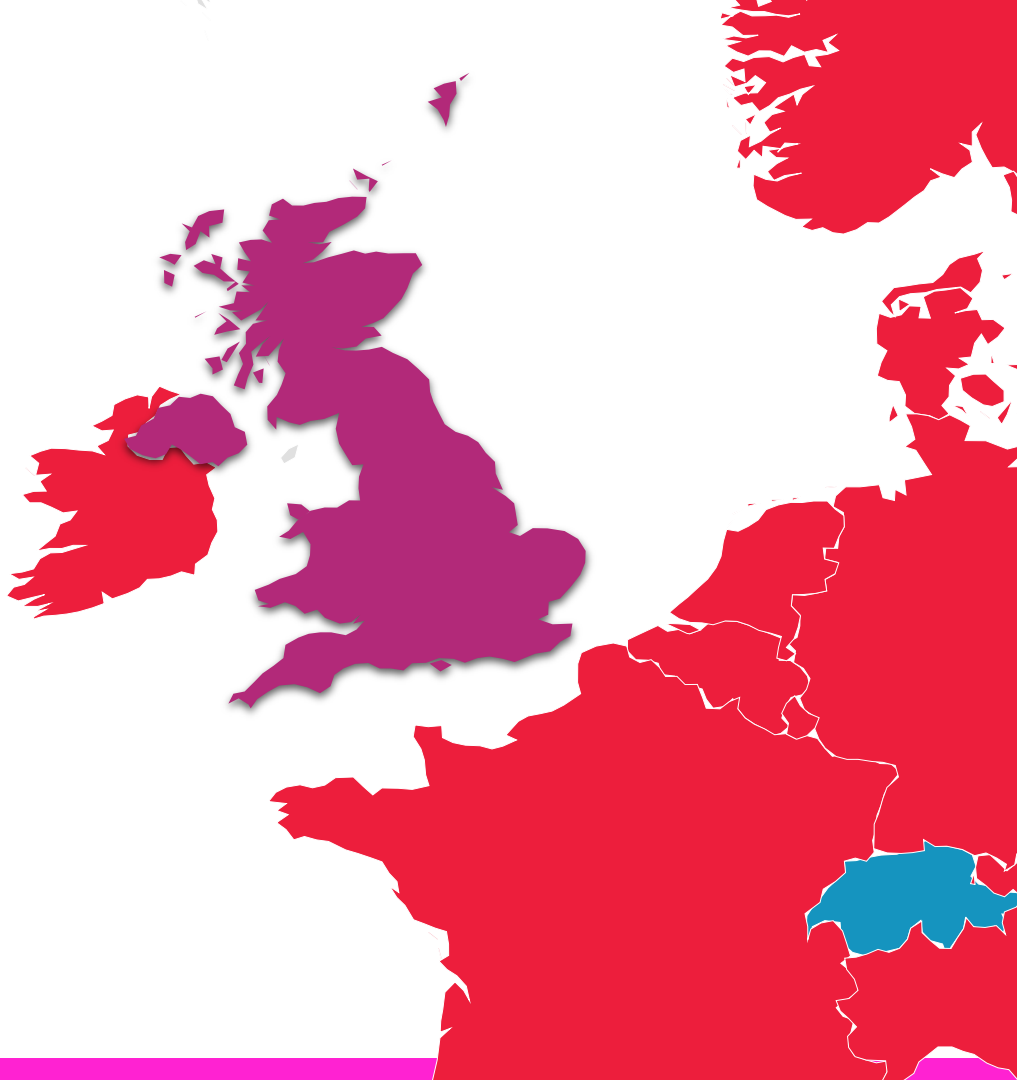


Closer Look: INDIA

- ❑ Clinical trial registration is **legally mandated** under the *New Drugs and Clinical Trials Rules, 2019 (Rule 25(v))*, requiring trials to be registered with the **Clinical Trials Registry of India (CTRI)** before enrolling the first subject.
- ❑ **CTRI**, a **WHO Primary Registry** (since December 2008) and **ICMJE-compliant**, accepts **interventional, observational, bioavailability/bioequivalence**, and **post-marketing studies**. Since April 1, 2018, it only permits **prospective registration**.
- ❑ Registration has been **mandatory for regulatory trials since 2009**, while remaining **voluntary for other biomedical and health research**. **Global trials in India** must also register with CTRI, making it a **statutory prerequisite** for regulatory research involving drugs, biologicals, and vaccines.

Closer Look: UK

- ❑ Clinical trial registration is **required as a condition of REC favorable opinion** under HRA policy, with registration on a **WHO Primary** or an **ICMJE-approved registry** before first participant recruitment and no later than six weeks after.
- ❑ From **April 28, 2026**, the ***Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025*** make this a statutory requirement under Regulation 25, mandating registration **before recruitment or within 90 days of approval (whichever is sooner)**. Regulation 25 introduces mandatory results disclosure within **12 months and participant result-sharing**.
- ❑ UK requirements are met by **ISRCTN** and **ClinicalTrials.gov** (WHO Primary Registry and ICMJE-compliant **Data Provider**, respectively). Trial details are accessible via HRA research summaries and the **"Be Part of Research" portal**. **Note: EU CTIS does not meet UK requirements due to limited UK trial visibility.**



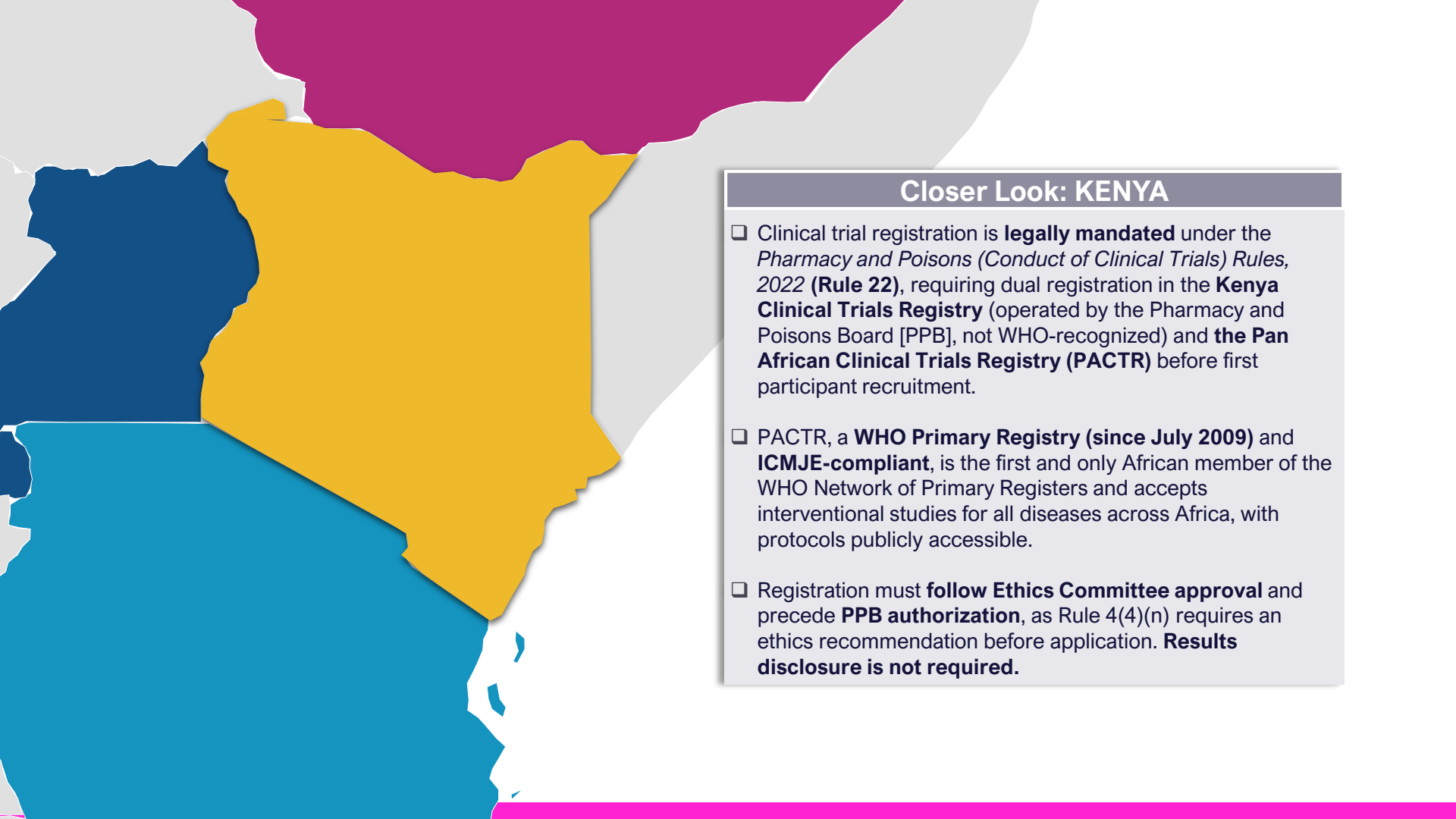


Closer Look: BRAZIL

- ❑ Clinical trial registration is **legally mandated** under *Resolution RDC No. 9 of 20 February 2015 (Article 38(VIII)(d))*, superseded by *Resolution RDC No. 945 of 29 November 2024 (Article 28(VI)(g))*, requiring registration with the **ICTRP/WHO or ICMJE-recognized registries before clinical trial submission** to Anvisa.
- ❑ **Brazilian Clinical Trials Registry (ReBec)**, a WHO Primary Registry (**since 2011**) and ICMJE-compliant, serves as the national registry option, though not explicitly specified in the regulation. Alternative ICTRP/WHO registries and ICMJE-recognized platforms are also acceptable.
- ❑ Registration proof must accompany the **Clinical Drug Development Dossier (DDCM)** submission, though delayed submission is permitted with the clinical trial start notification if unavailable initially. This requirement applies to all clinical trials seeking **drug registration approval through Anvisa's regulatory pathway**.

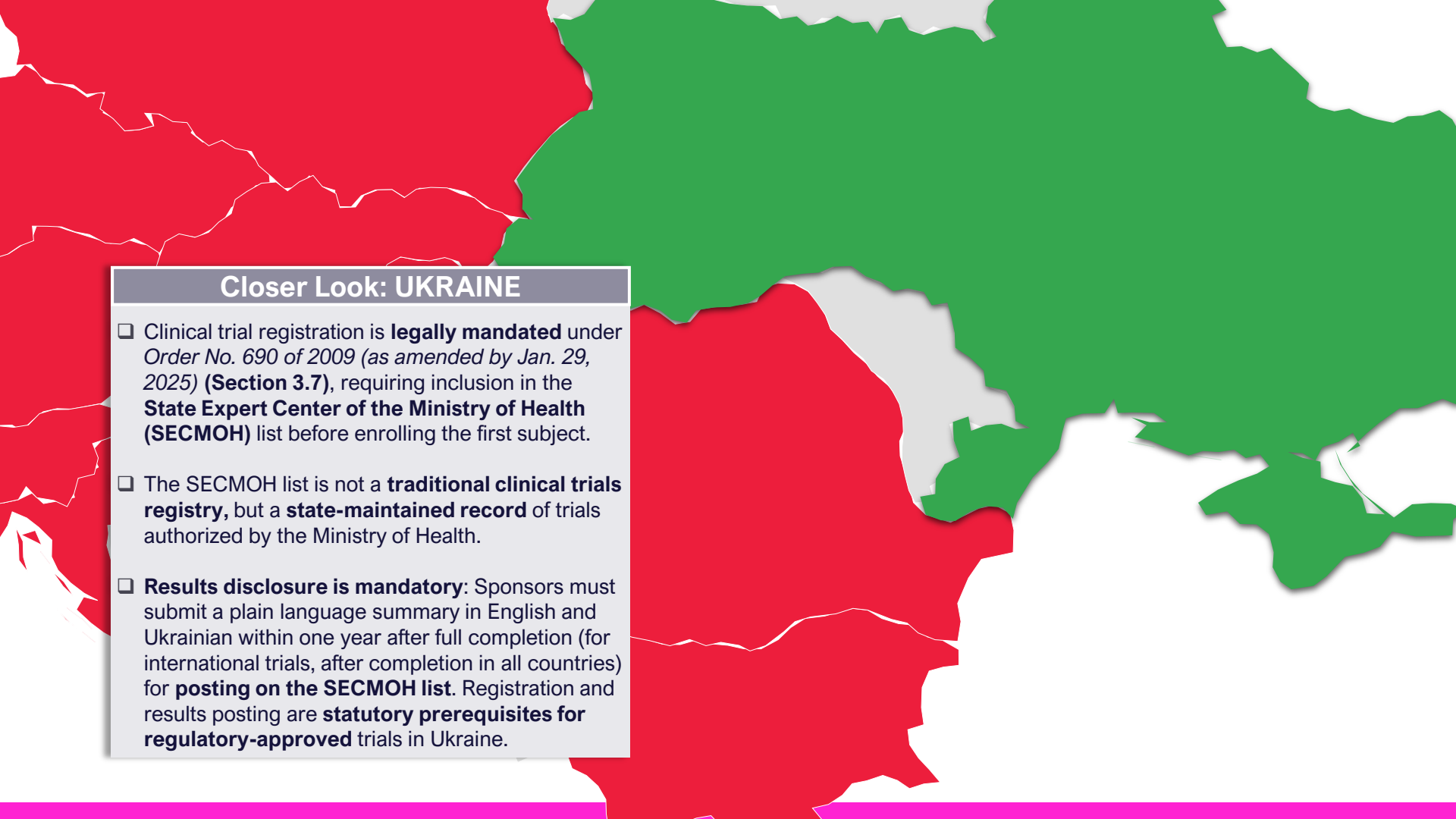
Closer Look: SWITZERLAND

- ❑ Clinical trial registration is **legally mandated** under the *Clinical Trials Ordinance (ClinO)* (**Article 64**), requiring registration with a **WHO Primary Registry** or **ClinicalTrials.gov** as well as the **Swiss Clinical Trials Portal (HumRes)** before trial conduct and **within six months of approval**.
- ❑ HumRes, which replaced the **Swiss National Clinical Trials Portal (SNCTP)**, is **not a WHO Primary Registry** and **not ICMJE-compliant**. It accepts **interventional** and **observational** studies, with data sourced from the **Business Administration System for Ethics Committees (BASEC)** platform.
- ❑ Significant 2024 revisions to ClinO introduced **mandatory results disclosure** (Article 65a) effective March 1, 2025. Only trials completed on or after March 1, 2025 must publish trial results summaries within **one year of completion** in both international registries and HumRes and **lay summaries** in relevant Swiss national languages used for recruitment. **Trials completed before March 1, 2025 are exempt** from these new requirements.



Closer Look: KENYA

- ❑ Clinical trial registration is **legally mandated** under the *Pharmacy and Poisons (Conduct of Clinical Trials) Rules, 2022 (Rule 22)*, requiring dual registration in the **Kenya Clinical Trials Registry** (operated by the Pharmacy and Poisons Board [PPB], not WHO-recognized) and **the Pan African Clinical Trials Registry (PACTR)** before first participant recruitment.
- ❑ PACTR, a **WHO Primary Registry (since July 2009)** and **ICMJE-compliant**, is the first and only African member of the WHO Network of Primary Registers and accepts interventional studies for all diseases across Africa, with protocols publicly accessible.
- ❑ Registration must **follow Ethics Committee approval** and precede **PPB authorization**, as Rule 4(4)(n) requires an ethics recommendation before application. **Results disclosure is not required.**

A stylized map of Europe is shown in the background. The landmasses are colored in a bright red and a vibrant green, with white lines indicating the borders between them. The map is partially obscured by a white rectangular box containing text.

Closer Look: UKRAINE

- ❑ Clinical trial registration is **legally mandated** under *Order No. 690 of 2009 (as amended by Jan. 29, 2025) (Section 3.7)*, requiring inclusion in the **State Expert Center of the Ministry of Health (SECMOH)** list before enrolling the first subject.
- ❑ The SECMOH list is not a **traditional clinical trials registry**, but a **state-maintained record** of trials authorized by the Ministry of Health.
- ❑ **Results disclosure is mandatory:** Sponsors must submit a plain language summary in English and Ukrainian within one year after full completion (for international trials, after completion in all countries) for **posting on the SECMOH list**. Registration and results posting are **statutory prerequisites for regulatory-approved** trials in Ukraine.

Useful Resources

Essential Tools for Clinical Trial Disclosure Compliance

- **TrialScope Intelligence:**
A comprehensive source for real-time regulatory intelligence, helping organizations track compliance trends and navigate the evolving global disclosure landscape.
Today's presentation draws on TrialScope Intelligence content to provide the latest regulatory insights.
- **Citeline Regulatory and Compliance Suite:**
A portfolio of disclosure-focused products and solutions to support your compliance strategy.
- **Citeline Maturity Model for Clinical Trial Disclosure:**
A framework to assess and improve clinical trial disclosure practices, helping organizations evaluate capabilities and identify areas for development to enhance transparency and compliance.
- **Enforcement Landscape Whitepaper:**
An in-depth analysis of global enforcement mechanisms and consequences for disclosure noncompliance, offering essential insights for risk management.

Session Summary and Next Steps

Key Takeaways:

- **The "Where":** Registry selection varies significantly by jurisdiction, with 85+ registries operating globally across distinct WHO/ICMJE compliance categories requiring strategic navigation.
- **The "How":** Regional harmonization trends (e.g., CTIS, PACTR) alongside national registries create both opportunities and complexities for multi-jurisdictional studies.
- **Strategic Planning:** Understanding registry architecture, from WHO Primary Registries to national platforms, enables efficient compliance while meeting ICMJE publication requirements.
- **Compliance Reality:** With permissible registries varying from exclusive national requirements to international platform acceptance, sponsors must develop jurisdiction-specific registration strategies.

Next Session Preview

Part 3 will explore the growing importance of plain language summaries as transparency requirements evolve beyond basic registration, covering regulatory expectations for protocol and results summaries.

Join us for Part 3: "Beyond Clinical Trial Registration – Plain Language Summaries," to complete your understanding of comprehensive transparency compliance strategies.
(Wednesday, Sept. 3 10 AM ET | 3PM BST)

Thank You.

