



# Utilizing NIAID's ClinRegs Website to Support International Clinical Research Regulatory Compliance

May 23, 2024

<https://clinregs.niaid.nih.gov/>



# Background & Rationale

- Regulatory compliance is challenging for multinational clinical trials.
- Conflicts between country requirements impedes research and slows the approval of medicines, leading the pharmaceutical industry to devote significant resources to this area.
- Many NIAID-sponsored projects cannot support industry-level investment and are vulnerable to noncompliance.
- To address an insufficiency in public access to this information, NIAID developed ClinRegs—a public access database of clinical research regulations.

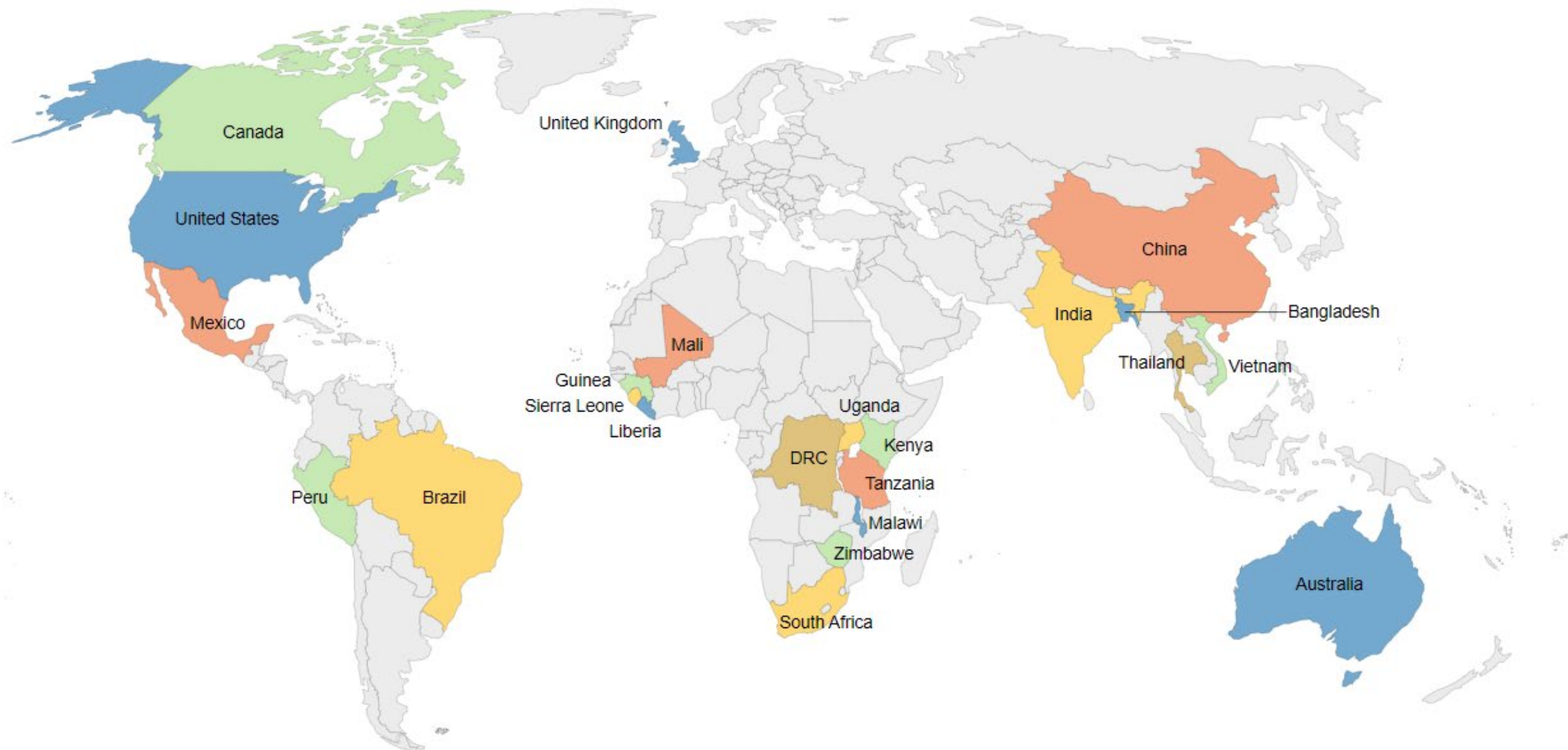
**Today's presentation will address: 1) ClinRegs objectives; 2) demonstration of site design and functionality; 3) how the site is kept current; 4) usage metrics and user feedback; 5) keeping users engaged**



# ClinRegs Objectives

1. To increase awareness and understanding of clinical research regulatory and ethics requirements for a set of NIAID priority countries
2. To provide a trustworthy, easy to use, secure, public access resource
3. To establish broad-based sustained usage, saving users time and resources
4. To maintain the site efficiently and sustainably

# ClinRegs Provides Regulatory and Ethics Information for 23 Countries





# Country Profiles Organized into 7 Topics and 36 Sections

## Regulatory Authority

Regulatory Authority

Scope of Assessment

Regulatory Fees

## Ethics Committee

Ethics Committee

Scope of Review

Ethics Committee Fees

Oversight of Ethics Committees

## Clinical Trial Lifecycle

Submission Process

Submission Content

Timeline of Review

Initiation, Agreements & Registration

Safety Reporting

Progress Reporting

## Sponsorship

Definition of Sponsor

Site/Investigator Selection

Insurance & Compensation

Risk & Quality Management

Data & Records Management

Personal Data Protection

## Informed Consent

Documentation Requirements

Required Elements

Participant Rights

Emergencies

Vulnerable Populations

Children/Minors

Pregnant Women, Fetuses & Neonates

Prisoners

Mentally Impaired

## Investigational Products

Definition of Investigational Product

Manufacturing & Import

Quality Requirements

Labeling

Product Management

## Specimens

Definition of Specimen

Specimen Import & Export

Consent for Specimen



# ClinRegs Demo



# Keeping ClinRegs Current

- All country profiles updated annually
- Interim updates completed when important requirements issued
- Country News tab updated as soon as we are made aware of new requirements
- Multi-pronged approach to detecting changes in a country
  - Regulatory research conducted by ClinRegs team
  - Engagement with in-country subject matter experts
  - Weekly automated scanning of external regulatory websites
  - Monthly broken link scanning and mitigation

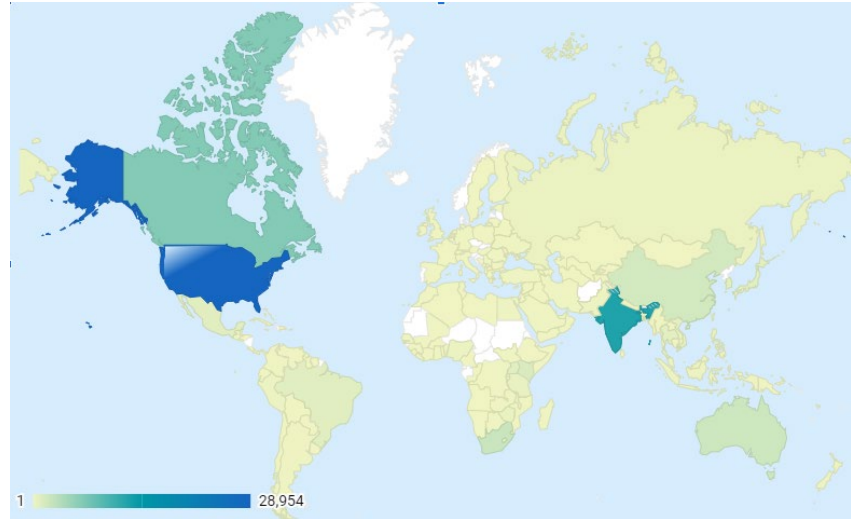


# Metrics (May 2023 – April 2024)

## Website Traffic

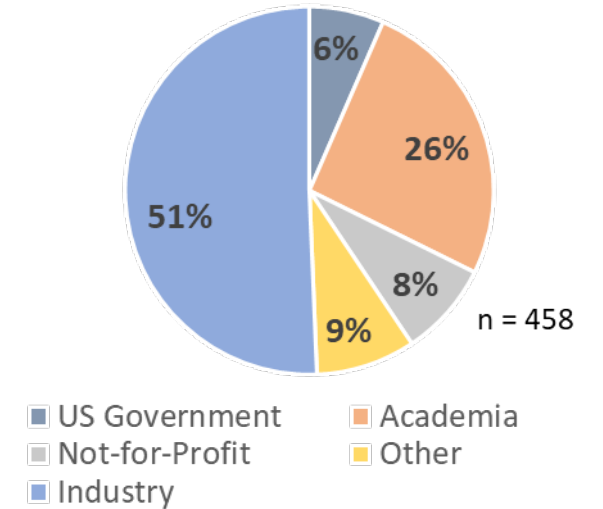
Category	Monthly Average
Users	6,410
Sessions	10,278
Page Views	13,286

## User Location

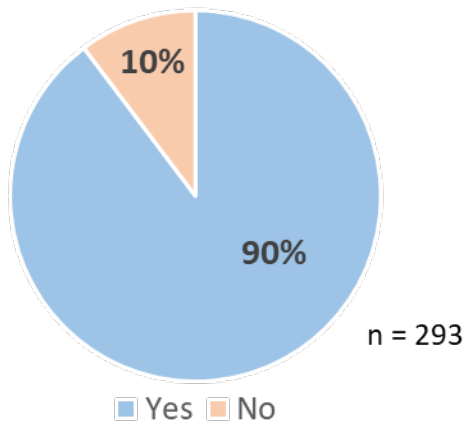


58% of users are outside the United States

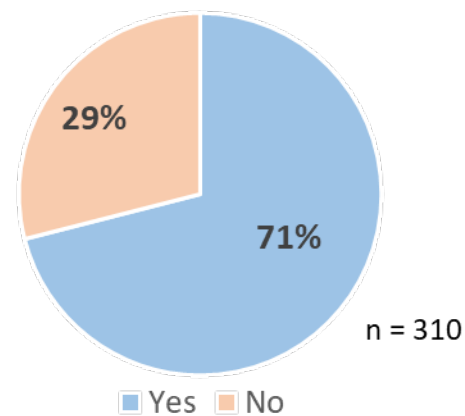
## What is your primary organizational affiliation?



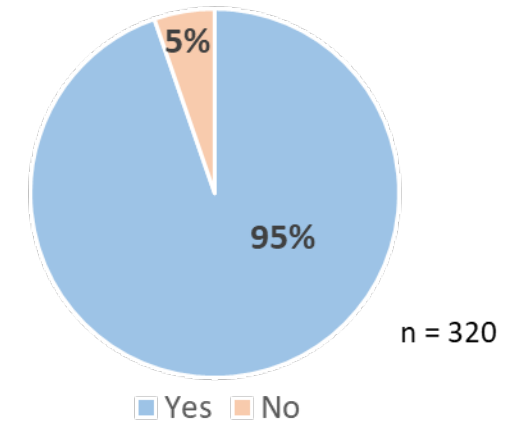
## Has ClinRegs saved you time?



## Did you find the information you need?



## Would you recommend ClinRegs?







# Keeping Users Engaged

## Communications

- Email Notification Updates (18,460 subscribers)
  - 31 country profile update notifications in 2023
  - 34 notifications of country regulatory changes in 2023
- Social Media
  - Utilizing NIAID's LinkedIn page
  - Weekly Twitter/X posts

## User Feedback

- Pop-up survey questions
- 1,981 responses from May 2023 - April 2024
- Comment button in each topic area

## Improving User Experience

- Website design and functionality updates implemented in February and May 2024

**NIH** National Institute of Allergy and Infectious Diseases | **ClinRegs** Aggregating clinical research regulations from around the globe

### Australia Profile Updated

The [Australia](#) profile in [ClinRegs](#) has been reviewed and updated with the following information:

- Revised National Health and Medical Research Council (NHMRC) guidance on ethics committee requirements and research governance responsibilities of institutions (See the [Ethics Committee topic](#), [Submission Content](#), [Progress Reporting](#), [Risk & Quality Management](#), [Documentation Requirements](#), and [Required Elements](#))
- Updated Therapeutic Goods Administration (TGA) payment instructions (See [Regulatory Fees](#))
- Revised user guide for submitting a clinical trial notification (CTN) form (See [Submission Process](#), [Submission Content](#), and [Progress Reporting](#))
- TGA pre-submission resources for clinical trial approval (CTA) scheme applications (See [Scope of Assessment](#) and [Submission Process](#))
- New form for reporting a significant safety issue or urgent safety measure (See [Safety Reporting](#))

**India**

**Overview**

The primary scope of information is the well-being of all research participants. This includes the 2019-CTR rules, the G-ICMR, the Guideline for Good Clinical Practice, **Fetuses & Neonates**; and **Mer**

The 2019-CTR rules and the G-ICMR aspects of the research protocol evaluating the possible risks and safeguards. Per the [G-Children](#) expertise. The expert(s) may be consulted on an ad-hoc basis.

**Role in Clinical Trial Approval**

As per the 2019-CTR rules, the [Central Licensing Authority \(CDSCO\)](#); and a DCGI-registered EC must approve a clinical trial application prior to the sponsor (also known as applicant) initiating the trial, except in the case of non-regulatory academic clinical trials that only require EC approval. (Note: The DCGI is commonly referred to as the Central Licensing Authority in the Indian regulations.) According to [IND-31](#), the DCGI review and approval process may be conducted in parallel with the EC review for each clinical trial site. However, per the 2019-CTR rules and the

g the rights, safety, and requirements set forth in the Council for Harmonisation's **Pregnant Women**.

nt review of all ethical the communities involved by confidentiality and privacy members with pediatric d be consulted on an ad-hoc

**Did you find the information you need? \***

Yes

No

Please specify:

OMB Control #0925-0668; Expiration date: 07/31/2025 **Submit**

the [Central Drugs Standard](#)



# How to Get Notifications

- Sign up for email notifications about country profile updates (2 ways)
  - At the top of every web page
  - On every country page along the right-hand side
- Follow NIAID on LinkedIn (<https://www.linkedin.com/company/national-institute-of-allergy-and-infectious-diseases-niaid/>)
- Follow us on Twitter/X (@NIAIDClinRegs)

The screenshot shows the NIAID ClinRegs website interface. At the top right, there are links for 'Contact Us', 'Feedback Survey', and 'Subscribe' (highlighted with a red box). Below this is the NIAID ClinRegs logo and a search icon. The main content area is for the 'United Kingdom' profile, with a 'Menu' button on the left. The 'Quick Facts' tab is active, displaying a table of regulatory requirements:

Clinical trial application language	English
Regulatory authority & ethics committee review may be conducted at the same time	Yes
Clinical trial registration required	Yes
In-country sponsor presence/representation required	Yes
Age of minors	Under 16
Specimens export allowed	Yes

Below the table, there are buttons for 'Share', 'Comment', and 'Print this section'. The text 'Regulatory Authority' is displayed, followed by 'Last content review/update: May 16, 2024' and 'Medicines and Healthcare Products Regulatory Agency'. At the bottom right, there is a 'Subscribe' icon (highlighted with a red box).



# How to Give Feedback

- Email us directly at [niaidclinregssupport@mail.nih.gov](mailto:niaidclinregssupport@mail.nih.gov) or click the Contact Us button
- Provide feedback on regulatory updates using the Comment button at the top of each profile section

The screenshot displays the NIAID ClinRegs website interface. At the top right, the 'Contact Us' button is highlighted with a red box. Below the main navigation, the 'United Kingdom' section is visible, with a 'Menu' button on the left. The 'Quick Facts' tab is selected, showing a list of regulatory requirements with corresponding 'Yes' or 'Under 16' answers. At the bottom of the 'Regulatory Authority' section, the 'Comment' button is highlighted with a red box, alongside 'Share' and 'Print this section' buttons. The footer includes the text 'Medicines and Healthcare Products Regulatory Agency' and a small icon in the bottom right corner.

Contact Us Feedback Survey Subscribe

NIH NIAID ClinRegs

Menu United Kingdom

News Quick Facts Research & Sites Profile Updates Helpful Links

Clinical trial application language	English
Regulatory authority & ethics committee review may be conducted at the same time	Yes
Clinical trial registration required	Yes
In-country sponsor presence/representation required	Yes
Age of minors	Under 16
Specimens export allowed	Yes

Regulatory Authority Share Comment Print this section

Last content review/update: May 16, 2024

Medicines and Healthcare Products Regulatory Agency



# Questions & Answers

**Please put your questions in the chat**

*This project has been funded with federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. 75N9101D00024, Task Order 75N91019F00004 (National Institute of Allergy and Infectious Disease, Division of Clinical Research) through the Frederick National Laboratory / Leidos Biomedical Research subcontract with General Dynamics Information Technology (\$2,290,874.92).*