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

May 23, 2024

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

National Institute of Allergy and Infectious Diseases

ClinRegs

Aggregating clinical research regulations from around the globe

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

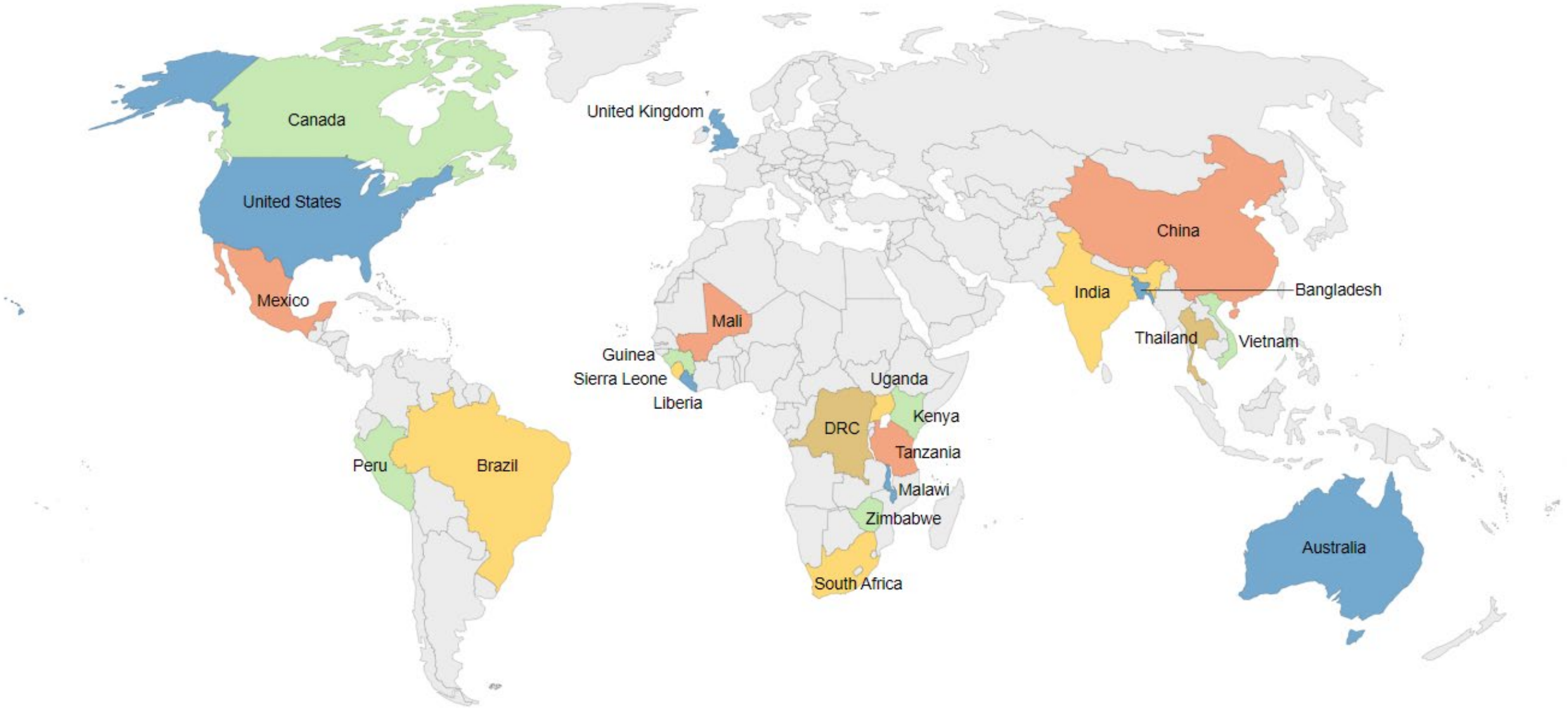
1. To increase awareness and understanding of clinical research regulatory and ethics requirements for a set of NIAID priority countries

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

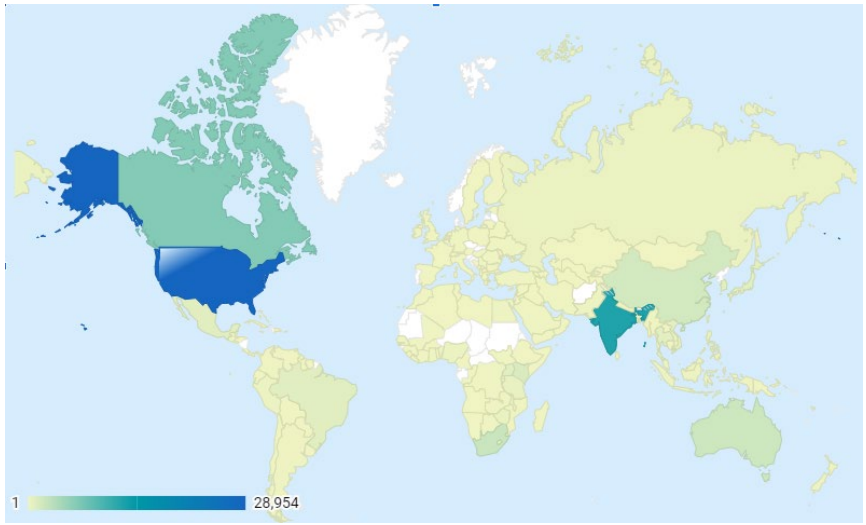
- All country profiles updated annually
- Interim updates completed when important requirements issued
- Country News tab updated as soon as we are made aware of new requirements
- Multi-pronged approach to detecting changes in a country
  - Regulatory research conducted by ClinRegs team
  - Engagement 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

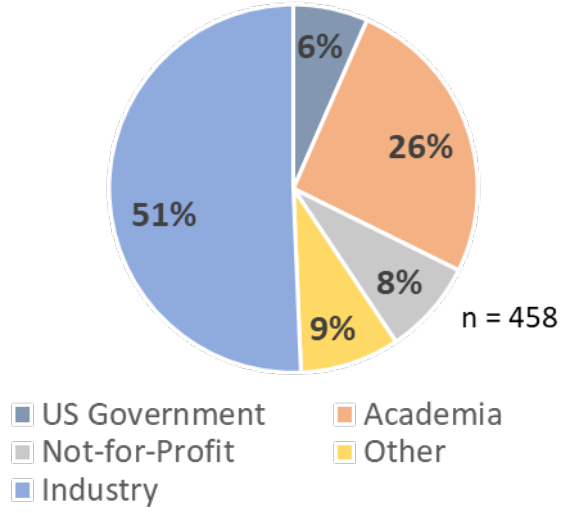
Category	Monthly Average
Users	6,410
Sessions	10,278
Page Views	13,286

User Location

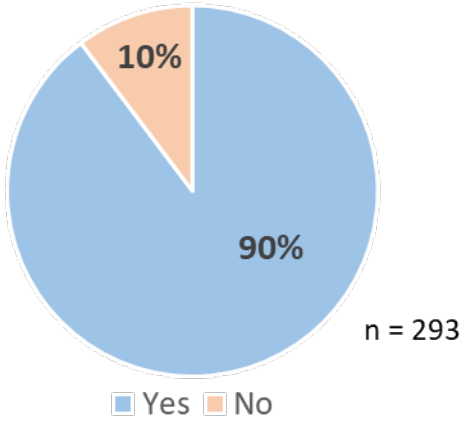


58% of users are outside the United States

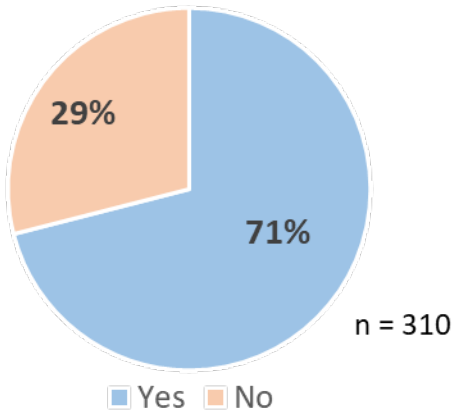
What is your primary organizational affiliation?



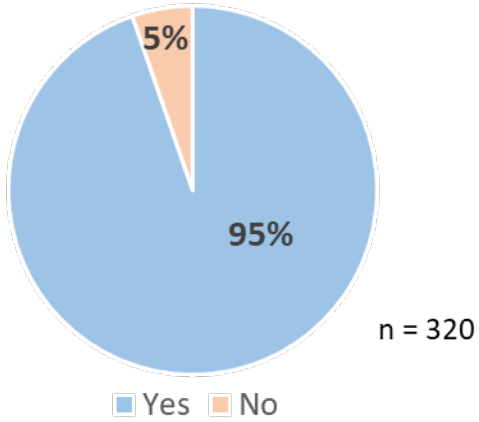
Has ClinRegs saved you time?



Did you find the information you need?



Would you recommend ClinRegs?



Survey responses 5.01.23 to 4.30.24

Keeping Users Engaged

Communications

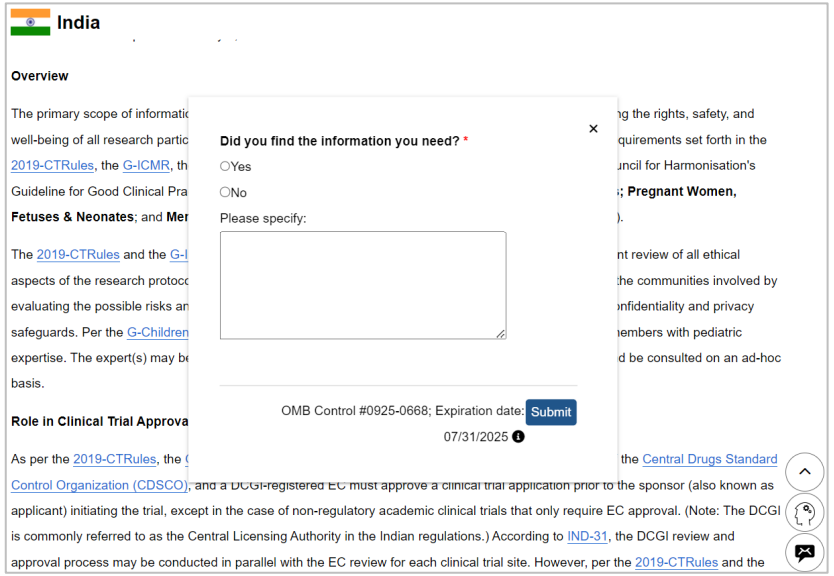
- Email Notification Updates (18,460 subscribers)
  - 31 country profile update notifications in 2023
  - 34 notifications of country regulatory changes in 2023
- Social Media
  - Utilizing NIAID's LinkedIn page
  - Weekly Twitter/X posts

User Feedback

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

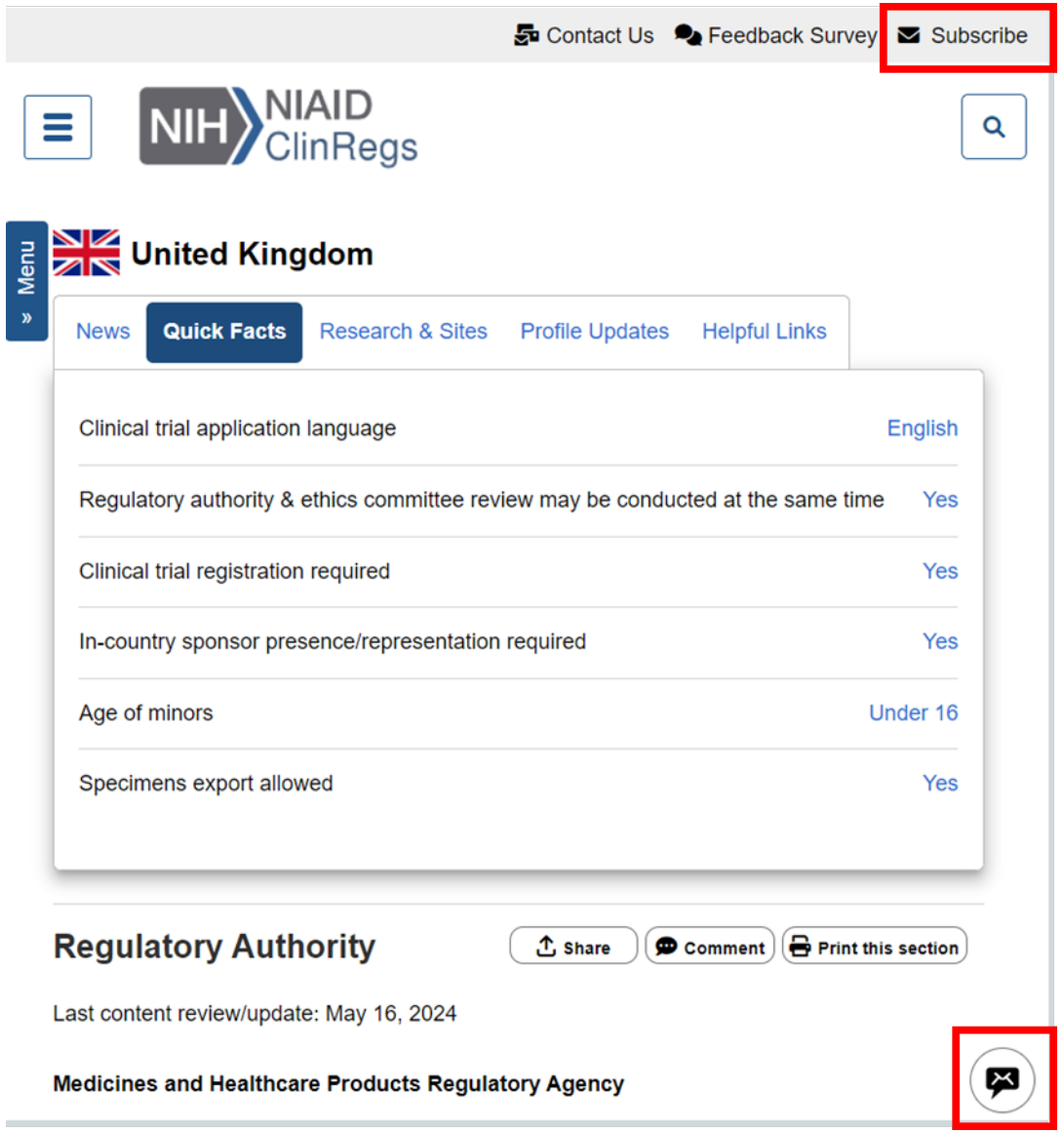
Improving User Experience

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



How to Get Notifications

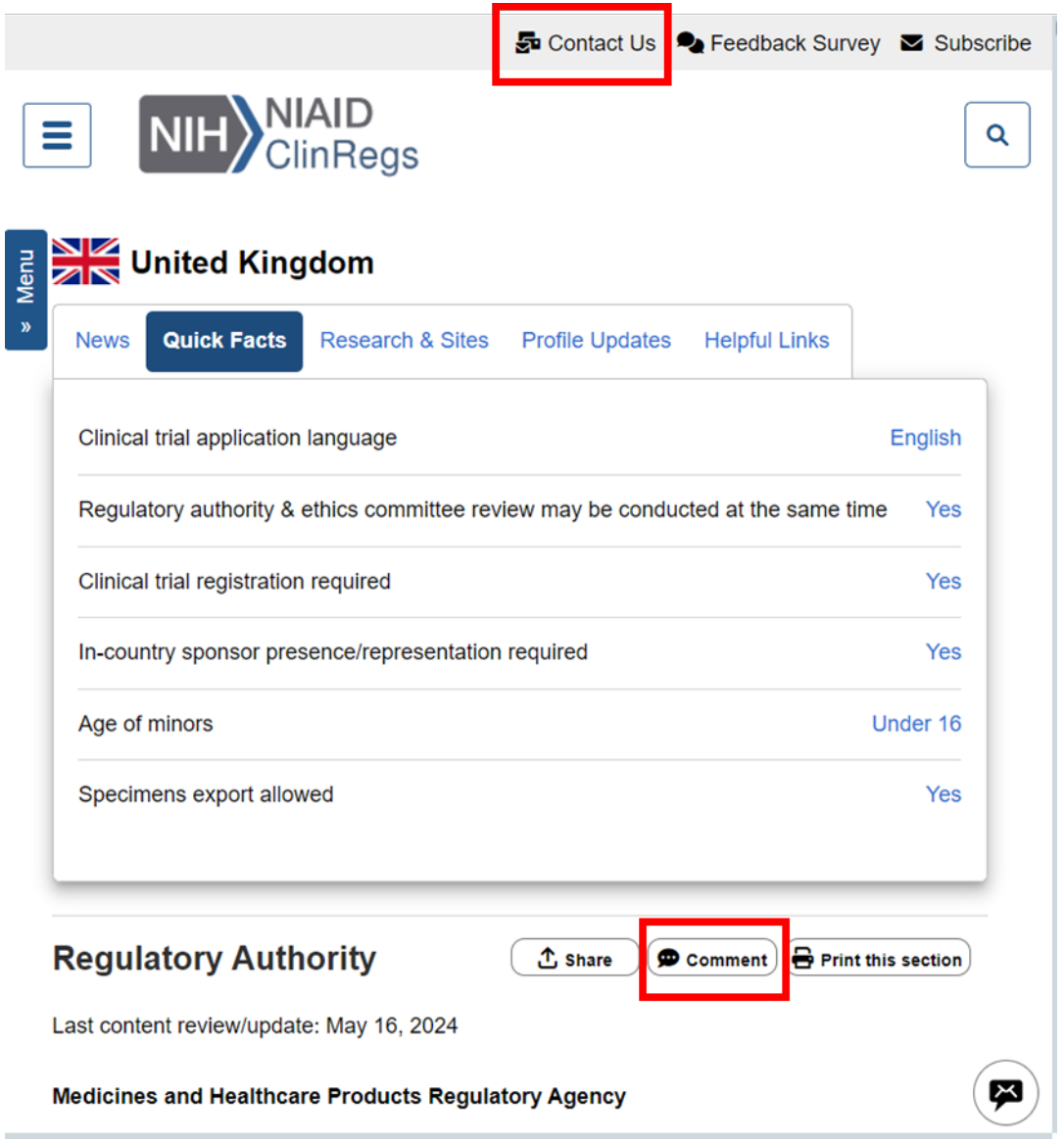
- Sign up for email notifications about country profile updates (2 ways)
  - At the top of every web page
  - On every country page along the right-hand side
- Follow NIAID on LinkedIn (https://www.linkedin.com/company/national-institute-of-allergy-and-infectious-diseases-niaid/)
- Follow us on Twitter/X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



How to Give Feedback

- Email us directly at 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



Questions & Answers

Please put your questions in the chat

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