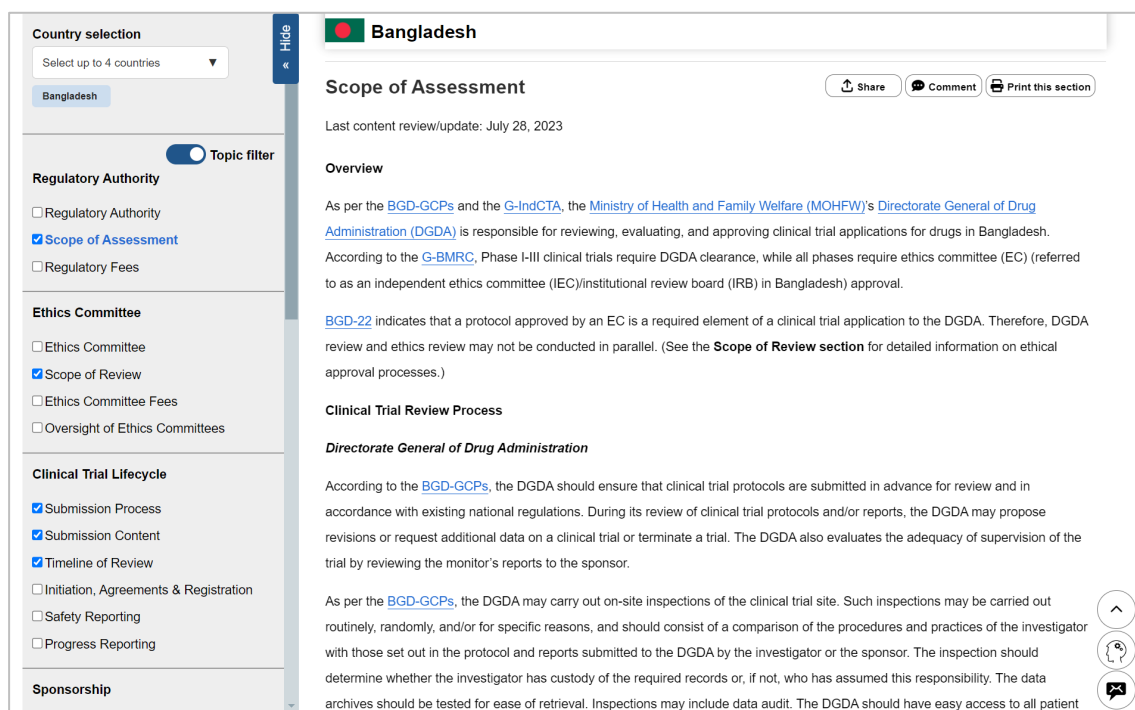


To provide a better user experience and make information easier to find, we have made the following improvements to ClinRegs:

- Country pages now include:
 - Tabular dashboard providing quick access to country-specific information
 - Topic filter enabling customized country profile views
- Search results page now includes country filter with option to view results for up to 4 countries side-by-side



Country selection
Select up to 4 countries
Bangladesh

Topic filter
Regulatory Authority
Ethics Committee
Clinical Trial Lifecycle
Sponsorship

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

Country selection
Select up to 4 countries
Bangladesh

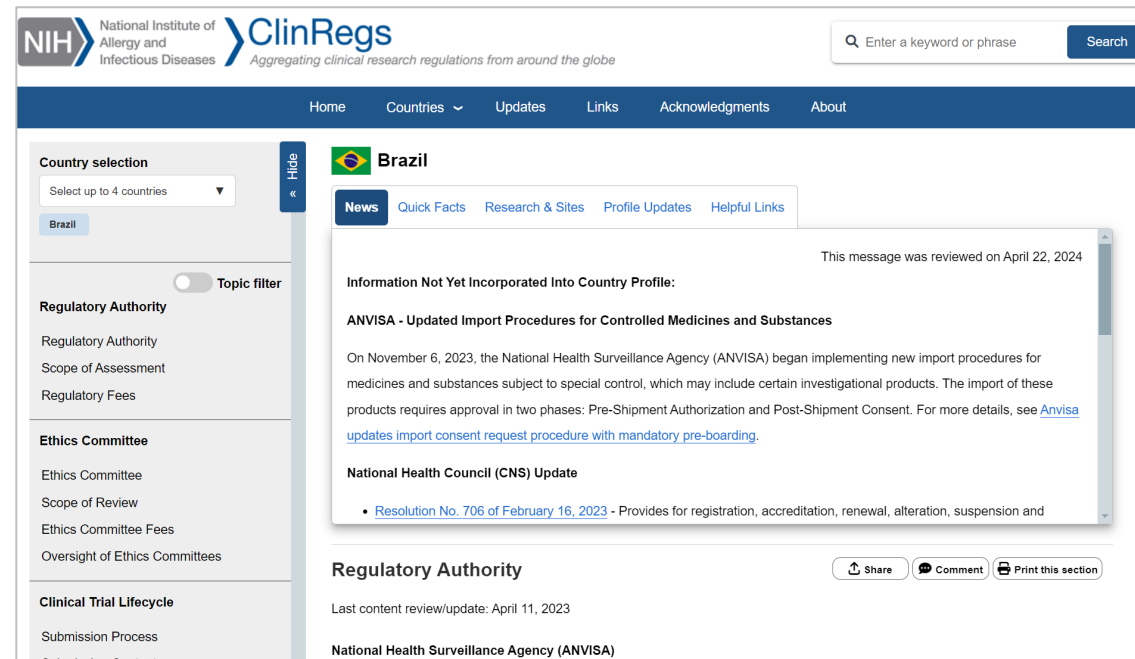
Scope of Assessment
Last content review/update: July 28, 2023

Overview
As per the [BGD-GCPs](#) and the [G-IndCTA](#), the [Ministry of Health and Family Welfare \(MOHFW\)](#)'s [Directorate General of Drug Administration \(DGDA\)](#) is responsible for reviewing, evaluating, and approving clinical trial applications for drugs in Bangladesh. According to the [G-BMRC](#), Phase I-III clinical trials require DGDA clearance, while all phases require ethics committee (EC) (referred to as an independent ethics committee (IEC)/institutional review board (IRB) in Bangladesh) approval.

[BGD-22](#) indicates that a protocol approved by an EC is a required element of a clinical trial application to the DGDA. Therefore, DGDA review and ethics review may not be conducted in parallel. (See the **Scope of Review** section for detailed information on ethical approval processes.)

Clinical Trial Review Process
Directorate General of Drug Administration
According to the [BGD-GCPs](#), the DGDA should ensure that clinical trial protocols are submitted in advance for review and in accordance with existing national regulations. During its review of clinical trial protocols and/or reports, the DGDA may propose revisions or request additional data on a clinical trial or terminate a trial. The DGDA also evaluates the adequacy of supervision of the trial by reviewing the monitor's reports to the sponsor.

As per the [BGD-GCPs](#), the DGDA may carry out on-site inspections of the clinical trial site. Such inspections may be carried out routinely, randomly, and/or for specific reasons, and should consist of a comparison of the procedures and practices of the investigator with those set out in the protocol and reports submitted to the DGDA by the investigator or the sponsor. The inspection should determine whether the investigator has custody of the required records or, if not, who has assumed this responsibility. The data archives should be tested for ease of retrieval. Inspections may include data audit. The DGDA should have easy access to all patient



Country selection
Select up to 4 countries
Brazil

Topic filter
Regulatory Authority
Ethics Committee
Clinical Trial Lifecycle

Regulatory Authority
 Regulatory Authority
 Scope of Assessment
 Regulatory Fees

Ethics Committee
 Ethics Committee
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 Ethics Committee Fees
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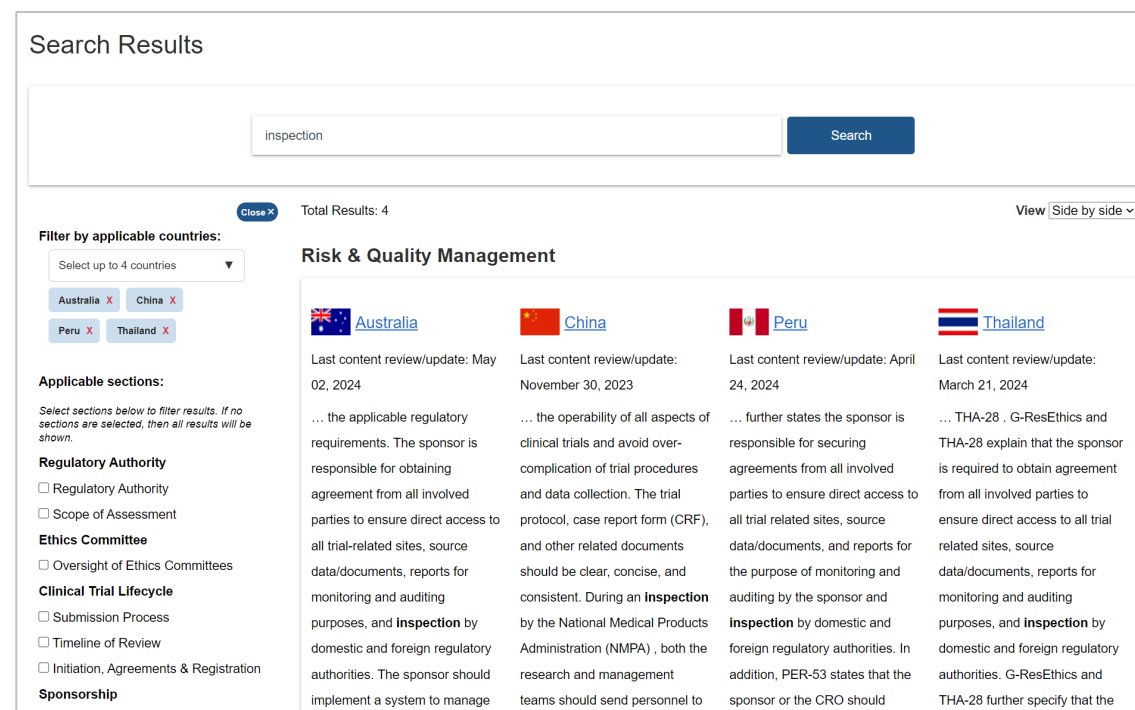
Country selection
Select up to 4 countries
Brazil

Regulatory Authority
Last content review/update: April 11, 2023

National Health Surveillance Agency (ANVISA)

Information Not Yet Incorporated Into Country Profile:
ANVISA - Updated Import Procedures for Controlled Medicines and Substances
 On November 6, 2023, the National Health Surveillance Agency (ANVISA) began implementing new import procedures for medicines and substances subject to special control, which may include certain investigational products. The import of these products requires approval in two phases: Pre-Shipment Authorization and Post-Shipment Consent. For more details, see [Anvisa updates import consent request procedure with mandatory pre-boarding](#).

National Health Council (CNS) Update
 • [Resolution No. 706 of February 16, 2023](#) - Provides for registration, accreditation, renewal, alteration, suspension and



Search Results
inspection Search

Filter by applicable countries:
Select up to 4 countries
Australia X China X Peru X Thailand X

Applicable sections:
 Regulatory Authority
 Scope of Assessment
 Ethics Committee
 Oversight of Ethics Committees
 Clinical Trial Lifecycle
 Submission Process
 Timeline of Review
 Initiation, Agreements & Registration
 Sponsorship

Risk & Quality Management

Australia	China	Peru	Thailand
Last content review/update: May 02, 2024	Last content review/update: November 30, 2023	Last content review/update: April 24, 2024	Last content review/update: March 21, 2024
... the applicable regulatory requirements. The sponsor is responsible for obtaining agreement from all involved parties to ensure direct access to all trial-related sites, source data/documents, reports for monitoring and auditing purposes, and inspection by domestic and foreign regulatory authorities. The sponsor should implement a system to manage	... the operability of all aspects of clinical trials and avoid over-complication of trial procedures and data collection. The trial protocol, case report form (CRF), and other related documents should be clear, concise, and consistent. During an inspection by the National Medical Products Administration (NMPA), both the research and management teams should send personnel to	... further states the sponsor is responsible for securing agreements from all involved parties to ensure direct access to the purpose of monitoring and auditing by the sponsor and inspection by domestic and foreign regulatory authorities. In addition, PER-53 states that the sponsor or the CRO should	... THA-28. G-ResEthics and THA-28 explain that the sponsor is required to obtain agreement from all involved parties to ensure direct access to all trial related sites, source data/documents, reports for monitoring and auditing purposes, and inspection by domestic and foreign regulatory authorities. G-ResEthics and THA-28 further specify that the