



How To Find Country-Specific Regulatory Requirements

Select a country of interest by scrolling over the map and choosing from a list of countries available for each continent.



Click on the “+” links to expand the topic and subtopic content, which provides detailed information on the country’s requirement(s).

South Africa

[Expand All](#) | [Close All](#)

- Competent Authority Oversight
- Ethics Committee Oversight
- Clinical Trial Lifecycle
- Submission Process
- Content of Clinical Trial Authorization

Applicable Regulatory Requirements

(1) (Legislation) **Act No. 61/2003: National Health Act, 2004 (NHA)** (July 23, 2004)
Department of Health, Republic of South Africa

Relevant Sections: Chapter 9, Sections 72 and 73

Relevant Provisions

Overview

In accordance with the [NHA](#), the [SA-GCPs](#), and the [G: EthicsHS](#), a sponsor (or the principal investigator when there is no sponsor) must apply to the [Medicines Control Council \(MCC\)](#) and an accredited ethics committee (EC) to conduct a clinical trial for a non-registered drug or a registered drug for new indications.

MCC Requirements

As per [Additional Resource \(A\)](#), the following documentation

Additional Resources

(A) (Form) **Application to Conduct Clinical Trials (CTF1)** (May 2003) (Version 1)

Medicines Control Council, Department of Health, Republic of South Africa

Available at:

http://www.mccza.com/genericDocuments/6.05_CTF1_May03_v1.zip (English)

How To Compare Regulatory Requirements Across Countries

Comparison Search

View summary information for two countries side-by-side.

Select Two Countries

- | | |
|--|--|
| <input type="checkbox"/> Brazil | <input type="checkbox"/> China |
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| <input type="checkbox"/> Malawi | <input type="checkbox"/> Peru |
| <input type="checkbox"/> Sierra Leone | <input checked="" type="checkbox"/> South Africa |
| <input type="checkbox"/> Tanzania | <input type="checkbox"/> Thailand |
| <input type="checkbox"/> Uganda | <input type="checkbox"/> United Kingdom |
| <input type="checkbox"/> United States | <input type="checkbox"/> Vietnam |

Select One or More Topics

- Competent Authority Oversight
- Ethics Committee Oversight
- Clinical Trial Lifecycle
- Sponsorship
- Informed Consent
- Investigational Products
- Specimens

Go

Comparison: India | South Africa

Clinical Trial Lifecycle

India	South Africa
<p>Submission Process</p> <p>Overview The Drugs Controller General of India (DCGI) review and approval process is conducted in parallel with the ethics committee (EC) review and approval. The sponsor must submit the clinical trial application to both the DCGI and the EC. The EC must grant a separate approval for each trial site to be used, and the DCGI must be informed of each approval. The process for submitting the clinical trial application to the DCGI is outlined below, whereas each EC has its own process.</p> <p>Assembly and Number of Copies Two hard copies and two soft copies (i.e., CDs in PDF format). Electronic submissions have not yet been fully implemented.</p> <p>Language requirement: English</p>	<p>Submission Process</p> <p>Overview The review and approval of clinical trial applications by the Medicines Control Council (MCC) and an accredited ethics committee (EC) may be conducted in parallel. The applicant must notify each regulatory body of the other’s approval once it has been received. In addition, each EC has its own required submission procedures, which can differ significantly regarding the number of copies to be supplied and application format requirements.</p> <p>Assembly and Number of Copies All applications must be submitted in duplicate with two electronic copies (including, but not limited to: application form (sections 1-3), the protocol, the investigator’s brochure, and/or other relevant documents). An additional 25 copies of the application form itself must also be submitted, and labeled diskette(s)/CD-ROM(s) (MS-Word or rich text format) with a list of files included on the diskette/CD-ROM(s).</p> <p>Language requirement: English</p>