

South Africa - Knowledge, Practices and Perceptions of Good Clinical Trials Collaborative (GCTC) Guidance in the Conduct of Clinical Trials in South Africa

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Identification

SURVEY ID NUMBER
AHRI.GCTC.Guidance

TITLE
Knowledge, Practices and Perceptions of Good Clinical Trials Collaborative (GCTC) Guidance in the Conduct of Clinical Trials in South Africa

COUNTRY

Name	Country code
South Africa	ZA

ABSTRACT

Participant recruitment and retention, as well as community engagement, are vital to the success of clinical trials, yet they are often approached as procedural rather than relational processes, limiting meaningful interaction between researchers and participants. This paper explores these dynamics as part of a broader initiative assessing knowledge and practice of the Good Clinical Trials Collaborative (GCTC) Guidance among clinical trial stakeholders in South Africa. A convergent parallel mixed-method design was adopted, with this paper focusing on the qualitative component. Purposeful sampling was used to recruit 22 key informants, including clinical trial researchers, regulatory specialists, implementation scientists, and administrative personnel. Data were analysed using thematic analysis to identify patterns and thematic structures, supported by NVivo 15 software for coding, organisation, and retrieval of qualitative data. Findings indicate that effective community engagement is often hindered by poor communication, language barriers, low research literacy, and historical mistrust stemming from past ethical breaches, contributing to misunderstandings and reduced participation. Participants highlighted the importance of transparency, including trial registration and the provision of clear, accessible information, as well as improved, contextually appropriate communication strategies to build trust, facilitate informed consent, and enhance participation. The study underscores persistent challenges related to communication and trust that affect recruitment, retention, and engagement. Addressing these challenges requires transparent, ongoing, and inclusive communication approaches that are sensitive to linguistic and cultural diversity. Strengthening relational, community-centred practices and aligning recruitment and engagement with GCTC Guidance principles are essential for promoting equity, inclusivity, and the conduct of high-quality clinical research in diverse settings such as South Africa.

Version

VERSION DESCRIPTION
v1.0.0

Scope

TOPICS

Topic	Vocabulary	URI
Clinical Trials as Topic: The overarching field of research, trial registration, and trial conduct.	Africa Health Research Institute	www.ahri.org
Patient Selection: Covers participant recruitment, purposeful sampling, and the inclusion/exclusion of research subjects.	Africa Health Research Institute	www.ahri.org
Community-Based Participatory Research: Encompasses community engagement, relational processes, and collaborative research	Africa Health Research Institute	www.ahri.org

KEYWORDS

Keyword	Vocabulary	URI
Good Clinical Trials Collaborative (GCTC) Guidance; Community Engagement; Participant Recruitment and Retention; Clinical Trials; Research Literacy; South Africa	Africa Health Research Institute	www.ahri.org

Coverage

GEOGRAPHIC COVERAGE

The dataset covers multiple provinces in South Africa, reflecting a broad geographic spread across key clinical research settings. Participants were drawn from diverse locations, ensuring representation across different provincial contexts.

UNIVERSE

Characteristic Description

Population (Universe) Professionals involved in clinical trials

Geographical Location Mainly South Africa (KZN, Gauteng, Western Cape, Eastern Cape, Free State), with one from the UK

Age Range Adult participants (approximately 30 years to over 70 years) [

Gender Both male and female

Sector of Work Clinical research organizations, academic institutions, research institutes

Professional Roles Principal investigators, research nurses, consultants, project managers, community engagement officers

Level of Experience Ranges from 0-4 years to over 20 years in clinical trials

Field of Study/Expertise Medical science, public health, management, social sciences

Disease Focus Areas HIV, tuberculosis (TB), vaccines, and other health conditions

Locality Type Mainly urban, with some peri-urban representation

Producers and sponsors

PRIMARY INVESTIGATORS

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Anne Derache	AHRI
Nompumelelo Ngobese	AHRI
Limakatso Lebina	AHRI

PRODUCERS

Name	Abbreviation
Africa Health Research Institute	AHRI

FUNDING AGENCY/SPONSOR

Name	Abbreviation	Role
Wellcome Trust	WT	Funder

Sampling

SAMPLING PROCEDURE

All clinical trials conducted in South Africa, along with their locations, are registered in two public online databases: sanctr.samrc.ac.za and Clinicaltrials.gov. These registers, along with Google searches and snowball sampling, were used to identify the major role players in clinical trials in SA. The implementers of clinical trials were categorised as follows: pharmaceutical companies, universities, contract research organisations (CROs), South African sponsors, independent research units, and regulatory organisations. A total of 552 key implementors of clinical trials were identified.

"Figure 1: Procedures for key informant interviews.

Of the 552 identified implementers of clinical trials, 105 were invited to participate in in-depth interviews. The ICF was shared with potential participants via Research Electronic Data Capture (REDCap) before their scheduled interviews. Briefly, REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.. The interviews were conducted either in person or via Microsoft Teams and were recorded. A semi-structured interview guide, along with a brief demographic questionnaire, was used to collect information from key stakeholders on the implementation of clinical trials in South Africa, including their experiences, the regulatory framework, laboratory and pharmacy infrastructure, clinical trial monitoring, and community perceptions. A total of 22 in-depth interviews were conducted"

Data collection

DATES OF DATA COLLECTION

Start	End
2024-09-01	2024-11-30

Data Processing

DATA EDITING

Qualitative interviews were audio-recorded and transcribed by the research team. All interviews were in English; therefore, translation of interviews was not required. Thematic analysis was used by reading through the transcripts, and codes were generated.

Both analyses used NVivo, a computer software program that allows researchers to manage, analyse, and visualise qualitative data and documents systematically and individually, as a tool to assist in generating the themes and codes. Used to indicate additional information about the methodology and processing involved in the production of the dataset.

The raw images have been stripped of the GPS coordinates and index data is completely anonymised.

Access policy

ACCESS CONDITIONS

Access to the data requires accurate completion of the online data access application form accessible on the AHRI Data repository(<<https://data.ahri.org/>>). Data users are required to abide by the data use conditions stipulated on the application for access to the data. Failure to do so may result in their data access privileges revoked by the Data Custodian. In order to recognise the effort and intellectual contributions of AHRI investigators in producing and curating the data, users of AHRI data must acknowledge the source of the data and abide by the terms and conditions under which the data is accessed. All analytical datasets published on the AHRI Data Repository are assigned digital object identifier (DOIs) and the DOIs can be found on the Data Repository under Study Description tab - Access policy. AHRI data users are required to always cite the dataset using the DOI.

CITATION REQUIREMENTS

Dayi, N., Ratshinanga, A., Mkwanazi, N., Dube, S., Gareta, D., Cloete, A., Nkosi, K., Shandu, L., Ehlers, E., Prenzler, E., Gilbert, B., Derache, A., Ngobese, N., & Lebina, L. (2026). Knowledge, Practices and Perceptions of Good Clinical Trials Collaborative (GCTC) Guidance in the Conduct of Clinical Trials in South Africa [Dataset]. Africa Health Research Institute.

DOI: <https://doi.org/10.23664/AHRI.GCTC.GUIDANCE>

Metadata production

DDI DOCUMENT ID
AHRI.GCTC.Guidance

PRODUCERS

Name	Abbreviation
Africa Health Research Institute	AHRI

Data Dictionary

Data file	Cases	Variables
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Download related resources

Technical documents

Document:GCTC_119_09 Oct 2024_Eng_AR_Transcr_LD

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