

South Africa

Njabulo Dayi, AHRI
Andani Ratshinanga, AHRI
Nompumelelo Mkwanazi, AHRI
Sweetness Dube, AHRI
Dickman Gareta, AHRI
Allanise Cloete, AHRI
Khethokuhle Nkosi, AHRI
Londiwe Shandu, AHRI
Eugene Ehlers, AHRI
Eugene Prenzler, AHRI
Brendan Gilbert, AHRI
Anne Derache, AHRI
Nompumelelo Ngobese, AHRI
Limakatso Lebina, AHRI

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

Study Documentation

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Metadata Production

Metadata Producer(s)	Africa Health Research Institute (AHRI)
Identification	AHRI.GCTC.Guidance

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

Overview	
Identification	AHRI.GCTC.Guidance
Version	v1.0.0
Abstract	
<p>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.</p>	

Scope & Coverage	
Keywords	Good Clinical Trials Collaborative (GCTC) Guidance; Community Engagement; Participant Recruitment and Retention; Clinical Trials; Research Literacy; South Africa
Topics	Clinical Trials as Topic: The overarching field of research, trial registration, and trial conduct., Patient Selection: Covers participant recruitment, purposeful sampling, and the inclusion/exclusion of research subjects., Community-Based Participatory Research: Encompasses community engagement, relational processes, and collaborative research
Time Period(s)	2024
Countries	South Africa
Geographic Coverage	
<p>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.</p>	
Universe	
<p>Characteristic Description</p> <p>Population (Universe) Professionals involved in clinical trials</p> <p>Geographical Location Mainly South Africa (KZN, Gauteng, Western Cape, Eastern Cape, Free State), with one from the UK</p> <p>Age Range Adult participants (approximately 30 years to over 70 years) [</p> <p>Gender Both male and female</p> <p>Sector of Work Clinical research organizations, academic institutions, research institutes</p> <p>Professional Roles Principal investigators, research nurses, consultants, project managers, community engagement officers</p> <p>Level of Experience Ranges from 0-4 years to over 20 years in clinical trials</p>	

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 & Sponsors

Primary Investigator(s)	Njabulo Dayi, AHRI Andani Ratshinanga, AHRI Nompumelelo Mkwanazi, AHRI Sweetness Dube, AHRI Dickman Gareta, AHRI Allanise Cloete, AHRI Khethokuhle Nkosi, AHRI Londiwe Shandu, AHRI Eugene Ehlers, AHRI Eugene Prenzler, AHRI Brendan Gilbert, AHRI Anne Derache, AHRI Nompumelelo Ngobese, AHRI Limakatso Lebina, AHRI
Other Producer(s)	Africa Health Research Institute (AHRI)
Funding Agency/ies	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

Data Collection Dates	start 2024-09-01 end 2024-11-30
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Data Processing & Appraisal

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.

Accessibility

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., Mkwazazi, 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>

Files Description

Dataset contains 0 file(s)

Variables List

Dataset contains 0 variable(s)