Eligibility Criteria for Clinical Trial (Phases 1, II or III) Contract Research Organization (CRO) in Nigeria – June 2025

The clinical trial process is increasingly complex, with evolving regulatory requirements, growing competition for eligible patients, and the demand for innovative therapies. Having a CRO that understands NAFDAC regulatory requirements, therapeutic area, operational goals, and complex trial designs is crucial

Having a good Contract Research Organization (CRO) to conduct clinical research is critical to the success of a clinical trial. A reliable and qualified CRO brings expertise, regulatory knowledge, and operational efficiency to the conduct of clinical trials.

This document outlines key requirement of a CRO who intends to apply to NAFDAC for approval to conduct clinical trials in Nigeria.

Below are the criteria that must be met by CROs to conduct clinical trials in Nigeria

1. The CRO must be registered by the Corporate Affairs Commission, in Nigeria or any recognized government entity.
2. Members of the Top Management of the CRO must have a second or third degree in pharmaceutical or medical sciences, or vast experience in clinical trials studies with background in other sciences.
3. Other members of the CRO team must be medical scientist and have and show evidence of basic knowledge in Good Clinical Practice(GCP), and ethical principles of health research.

4. A CRO must have a strong understanding of NAFDAC regulatory requirements, particularly for clinical trials and able to manage studies spanning multiple regions. The CRO should demonstrate expertise in navigating approvals, managing regulatory submissions, and ensuring compliance with Good Clinical Practice (GCP) standards.
5. A CRO must show experience in different therapeutic areas, such as small molecules, biologicals, vaccines or medical devices, with required unique expertise in those areas.
6. A CRO must demonstrate capabilities to provide end-to-end services, from clinical operations and site selection to data collection and monitoring of clinical trials.
7. A CRO must demonstrate technological capabilities since technology drives efficiently in modern trials. E.g. the CRO should demonstrate their use of:
    - Electronic Data Capture (EDC) systems for real-time data collection.
    - Remote monitoring tools for decentralized trials.
    - Platforms that improve patient engagement and retention.
8. A CRO must show strategies and capacity in the protocol to recruit and retain participants during trials.
9. A CRO must present its track record and reputation in managing clinical trials (i.e. Past successes in managing trials, clients' testimonials and reviews, and Case studies demonstrating operational excellence and innovative solutions)
10. CRO must demonstrate having a robust Quality Management System farmwork in place to ensure it adheres to regulatory requirements and

industry standards. A robust quality management system ensures the integrity of the trial data and compliance with regulatory standards.

11. A semi-independent pre-inspection of a new facility or a new application shall take place before the study can begin
12. A CRO must have a robust clinical, bionalytical and computerized system that will be demonstrated during a pre-inspection for new applications or a new facility.
13. The CRO must demonstrate engagement of a biostatistician to guarantee proper analysis of data
14. A CRO must have robust communication department in order to be responsive to the sponsor's needs and regulatory authority's demands and maintain open communication throughout the trial.
15. A mandatory Annual Report of Compliance of the above is required for continued function as a CRO.

Having a CRO to conduct and manage clinical trials in Nigeria is essential to adherence to NAFDAC regulatory requirements, ensure efficiency, compliance, and quality. By evaluating key factors such as therapeutic expertise, regulatory knowledge, service capabilities, and technology adoption, the Agency can confidently trust a CRO to drive successful clinical trials in Nigeria.