NAFDAC EXECUTIVE SUMMARY FOR INTERNATIONAL COUNCIL FOR HARMONIZATION (ICH) E6(R3) GOOD CLINICAL PRACTICE TRAINING (APRIL 7-9, 2025)

Overview:

The National Agency for Food and Drug Administration and Control (NAFDAC) in collaboration with the International Council for Harmonization (ICH), organized an ICH E6(R3) training, which held from April 7 to 9, 2025 at the Marriott hotel, Ikeja, Lagos, Nigeria. This was a significant capacity-building initiative aimed at strengthening clinical trial oversight and regulatory practices in line with global Good Clinical Practice (GCP) standards.

Objectives

This comprehensive training focused on

- Providing clarity on the revised ICHE6(R3) guideline and emphasizing key updates.
- Promotion of the enhanced principles around data integrity, trial participant protection,
- Risk-based approaches to trial conduct and fit-for-purpose quality systems.
- Emphasized the importance of stakeholder responsibilities in clinical trial design, conduct, monitoring, and reporting under the evolving ICH framework.

Key features of the training included:

- **Expert-led Sessions:** Delivered by experienced international and local facilitators, including key contributors to ICH guideline development.
- **Practical Case Studies:** Real-world scenarios to contextualize and apply E6(R3) principles to the African clinical research environment.
- **Interactive Discussions:** Facilitated exchange of ideas on ethical oversight, sponsor-investigator responsibilities, and data quality management.
- **Stakeholder Engagement:** Fostered collaboration among regulators, sponsors, and research institutions to ensure harmonized implementation.

Participants:

The training had a total of 256 participants, with 120 attending in person. It brought together a diverse mix of participants, including regulators, clinical researchers, and representatives from the pharmaceutical and contract research sectors across Nigeria and the West African sub-region.

Participants feedback:

The training assessment record showed an improvement in the knowledge gained from 74.4% to 82.9%. Feedback reports highlighted the following;

- **Knowledge gained**: 98% of respondent reported significant improvement in their understanding of the ICH E6(R3) expectations and increased readiness to apply these concepts in real-time oversight and conduct of clinical trials.
- **Practical Application**: 97% of respondents felt confident in applying the knowledge gained.
- **Quality of training**: 95% of respondents valued the content and delivery of the presentations. They were satisfied with the expertise of the facilitators.

Impact:

This training marks a significant step toward enhancing the quality and credibility of clinical research in Nigeria and the broader region. It also aligns with ongoing efforts to strengthen regulatory systems and harmonize practices with international standards.

Next Steps:

- Continued stakeholder engagement and awareness.
- Development of localized implementation frameworks.
- Additional training sessions for targeted groups such as IRBs and site investigators.

Implementation:

The implementation of the ICH E6 (R3) is shown in the documents below.

- NAFDAC Good Clinical Practice Guideline
- Guideline for Labelling of Investigational Medicinal Product
- Guideline for Clinical Trials in the Paediatric Population

Conclusion

The ICH E6(R3) training successfully met its objectives, and NAFDAC reaffirms its commitment to ensuring ethical, scientifically sound, and globally compliant clinical trial practices through ongoing education and system strengthening.