

## Improving clinical research data in Africa: The understanding and implementation of laboratory quality management systems (LQMS)

**Augustine A. Onyeaghala**  
University College Hospital, Nigeria

Clinical Research is a branch of medical science which focuses on the testing of the efficacy, safety and effectiveness of new drugs, medical devices and biologicals prior to approval for public use. The high cost of conducting clinical trial in the West, slow recruitment and retention of study subjects have made sponsors to relocate clinical trial to the emerging markets. The approval of new, efficacious and safe drugs for human consumption is premised on the generation of reliable and accurate laboratory data generated at both the pre-clinical and clinical phases of drug development using the good laboratory practice, good clinical laboratory practice and good clinical practice regulations. In most emerging markets, the quality of data generated from the laboratories has been questioned and these have been blamed on the poor understanding and implementation of the various GxPs regulations. The understanding of the entire quality management system in laboratory operations is very critical for the generation of reliable laboratory data which directly helps in the development and approval of effective treatment; with effect to reduce the impact of current disease burdens in the developing countries. What are the current challenges in implementing GxP quality management systems in the developing countries and how can it be improved with a view to actualizing reliable clinical research data? This shall be the focus of this presentation.

**Keywords:** Quality management systems, GxPs, clinical research, and laboratory data

### Biography

Augustine A. Onyeaghala is a biomedical scientist, clinical research scientist, quality assurance expert, GCP, GMP and GLP specialist. He holds a master's degree in Chemical Pathology, post graduate diploma in Clinical Research from Kriger Research International, Canada. He is a Doctorate in Clinical and Translational Research with research interest in predictive toxicology, toxicogenomics and drug development. He has mentored a great number of students to become biomedical scientists and clinical research professionals. He has authored more than fifty scientific abstract and presented over forty in both local and international conferences. He is a regular speaker and presenter at international and local conferences and meetings discussing clinical research, quality assurance, biomedical science and good clinical practice regulations. He is currently a laboratory director at Afriglobal Medicare, Lagos Nigeria, an assistant director in Biomedical Science at the University College Hospital, Ibadan, a freelance consultant in Clinical Research and the president of the Society of Quality Assurance, Nigeria Regional Chapter. He has published a reasonable number of research papers in both local and international journals and is also an author of a book in total quality management.

aonyeaghala@ymail.com