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## Improving clinical research operations: Optimizing the use of current biomarkers

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Clinical research is a branch of medical science which focuses on testing the efficacy, safety and effectiveness of new drugs, medical devices and biological prior to approval for human use. Many preclinical and clinical research studies conducted in most parts of the developed and developing world had relied on the use of 'obsolete' pathological markers for assessing renal, liver and cardiac pathology. The effects caused by most drugs are very insidious and not acute. Using very sensitive and organ specific biomarkers which predicts organ pathologies at the earliest possible time become inevitable. There is no doubt that translational research has assisted greatly in developing better and more sensitive biomarkers which have been evaluated and validated for predictive toxicities and pathology. In spite of the limitations inherent in the ability of certain analytes to detect toxicities or pathologies at the earliest possible time, biological analytes such as BUN, Creatinine, AST and Cholesterol are still obviously in use to assess most clinical research measurable end points, adverse events, quality of life and prognosis depending on the type of research design and clinical trial protocol. These parameters, though good to some extent, yet may not be the best predictors of an insidious toxicity or pathology. How does the use of current and validated biomarkers improve drug development process? What are the advantages associated with the use of such biomarkers in clinical research operations? These shall be the focus of this presentation.

### Biography

Augustine Onyeaghala is a Biomedical Scientist, Clinical Biochemist and a Doctorate in Clinical Research with specialization in herbal medicine clinical research and pharmacovigilance. He is a Canadian certified GCP, GLP & GMP Quality Assurance Professional. He is a member of Global Health Trial Faculty of the West and Central African Region. He has contributed greatly in developing capacity for clinical research in this emerging market through collaborative work with the GHT. He has assisted several organizations in developing and implementing GCP, GCLP and GLP quality management systems requirements. He is a passionate academic presenter and has been a resource person at several local and international meetings discussing Clinical Research, GCP, GCLP, GLP, GMP, ISOs, QMS, validations and audits in clinical research, biomedical science and laboratory operations. He has delivered over fifty presentations at both local and international conferences and has a good number of his research work and presentations published in peer review journals. He is an author of a book *Total Quality Management for Biomedical Scientists*.

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