Ethics, regulatory and pharmacovigilance

PO - (8300) - REGIONAL CENTER FOR REGULATORY EXCELLENCE CLINICAL TRIALS TRAINING 2017

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Background

The competencies of the various National Medicines Regulatory Agencies (NMRAs) in Africa vary leading to generally porous regulatory systems in clinical trial oversight. Consequently, many trials have been conducted under unacceptable conditions compromising on participants’ safety and data credibility resulting in questionable outcomes that are used for making scientific judgement in addressing issues of public health in Africa.

To improve the safety and quality of health technologies in Africa, the New Partnership for African Development (NEPAD) agency launched a program to designate Regional Centres of Regulatory Excellence (RCOREs) with the specific objective of bridging existing gaps between African NMRAs through strengthening regulatory capacity of African Union member states. The Food and Drugs Authority (FDA), Ghana, was designated as RCORE in Clinical Trials oversight in May 2014.

Methods

To achieve the RCORE objectives, the FDA collaborated with the School of Public Health (SPH), University of Ghana to develop a training manual and also piloted a training programme with funds from International AIDS Vaccine Initiative (IAVI) through NEPAD.

The programme, consisting of 4 compulsory modules, was organized from 6th – 30th November 2017 for 10 participants from Zambia, Sierra Leone, Liberia, Rwanda and Ghana. Interactive training methods in the form of theoretical and practical sessions were employed.

Results

The pilot RCORE training was successful with expected training objectives achieved. Participants gained hands-on experience through activities like observing GCP inspection and Technical Advisory Committee Meeting. Participants were given template tools to assist in developing regulatory Guidelines and Forms in their various countries.

A follow-up training questionnaire was circulated for participants to assess the impact of the training on their work. Feedback indicates that regulation of clinical trials has improved in their various institutions.
Conclusion
The maiden Fellowship training was successful, leading to the improvement of Clinical Trial regulation in the participating countries.