Background

The competencies of the various national medicines regulatory agencies (NMRA)s in Africa vary which leads to generally porous regulatory systems for clinical trial oversight. Consequently, many trials have been conducted under unacceptable conditions compromising participants' safety and data credibility and resulted 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 programme to designate Regional Centres of Regulatory Excellence (RCOREs) with the specific objective of bridging existing gaps between African NMRA:s through strengthening regulatory capacity of African Union member states. The Food and Drugs Authority (FDA), Ghana, was designated as RCORE for 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 piloted a training programme with funds from the International AIDS Vaccine Initiative (IAVI) through NEPAD.

The programme, consisting of 4 compulsory modules, was organised from 6–30 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 Good Clinical Practice inspection and a Technical Advisory Committee Meeting. Participants were given template tools to assist in developing regulatory guidelines and forms in their respective countries. A follow-up questionnaire was circulated to participants to assess the impact of the training on their work. Feedback indicates that regulation of clinical trials has improved in their respective institutions.

Conclusion

This pilot fellowship training was successful, leading to the improvement of clinical trial regulation in the participating countries.