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Summary on BERC-Africa Project funded by EDCTP

The Clinical Trials Department in November 2019 applied for an European and Development Countries Clinical Trials Partnership (EDCTP) grant purposefully to build regulatory capacity in the area of clinical trials in Africa. The application received favorable evaluation in April 2020 and subsequently full approval in September 2020. The project officially commenced on is 1st October, 2020.

The project titled, *Building and Enhancing Regulatory Capacity in Africa* (BERC-Africa) is expected to last for 36 months with the following objectives:

a) Train regulators from National Medicines Regulatory Agencies (NMRAs) under the RCORE Fellowship Training in Clincal Trials, including those from Francophone countries.

b) Provide training for African regulators, including trainers of RCORE trainees in relevant short term courses.

c) Provide regulators with coordination and support actions such as industrial attachments to enhance regulatory activities.

To be able to achieve the objectives of the project, the FDA Ghana is collaborating with the underlisted institutions:

1. **University of Ghana School of Public Health (SPH), Legon –** provide resource persons for the Regional Centre of Regulatory Excellence (RCORE) Fellowship Training Programme in Clinical Trials.

2. **Kumasi Centre for Collaborative Research (KCCR) into Tropical Medicine, KNUST** – provide a site for Good Clinical Practice (GCP) inspections where possible.

3. **Paul-Ehrlich-Institute, Germany –** offer RCORE trainers with regulatory/industrial attachments to enhance regulatory skills and knowledge.

4. **Coalition for Epidemic Preparedness Innovation (CEPI) –** provide resource persons for regulatory training in early phases of vaccine clinical trials, complex and adaptive trials.

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At the end of the 36 month period, it is expected that FDA regulators in clinical trials would have enhanced their skills with current or up-to-date technical knowledge to effectively assess clinical trial related documents. These regulators would also be equipped to provide the requisite trainings to local and international clinical trial researchers and stakeholders.

Also, regulators from other African National Medicines Agencies would benefit from the skills and knowledge acquired from these trainings in order to apply them in their various countries, thereby ensuring harmonization of clinical trial regulatory activities.
Presentations on the project will be made at forums relevant to clinical trials, such as the EDCTP Forum. Results/data from the trainings will also be published on FDA's website as well as in its DrugLens newsletter with a full comprehensive report being made available to EDCTP.

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