Capacity development, training ans research uptake

OC - (8718) - WHAT DID WE LEARN FROM PANACEA 1 CLINICAL TRIALS?

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Background:
The Pan African Consortium for the Evaluation of Anti-Tuberculosis Antibiotics (PanACEA) was designed to build clinical tuberculosis (TB) trial capacity whilst conducting clinical trials on novel and existing agents to shorten and simplify TB treatment. One of the objectives was to conduct, mentor and monitor observational and clinical studies at sites in 6 Sub-Saharan TB-endemic countries (Gabon, Kenya, South Africa, Tanzania, Uganda and Zambia)

Methods:
Learning through experience.

All centres in the 6 countries self-assessed their requirements for capacity development in the following fields:
- Clinical staff availability and experience,
- TB laboratory infrastructure and staff,
- Safety laboratory infrastructure and staff,
- Clinical site facilities and equipment,
- Pharmacy facilities and staff,
- IT facilities and
- Overall training needs of site personnel

Results:
From March 2011 – June 2014, we conducted four epidemiological studies (characterizing TB patient populations in preparation for future studies) and five Phase II studies (GCP standard intervention trials).

By working together in epidemiological and clinical trials, the sites identified their needs for resources and training as well as developing capabilities to perform independent large scale TB clinical trials beyond PanACEA-initiated trials. Through the ReMoxTB study, for example, laboratories were brought to an international standard for safety and mycobacterial expertise. Furthermore, through developing skill-sets related to EBA studies, sites have since then attracted other sponsors for further studies.

Sites could be mentored to perform GCP-compliant clinical TB trials that is built on sound physical infrastructure, training and strong on-site leadership.

Conclusions:
The “learning by doing” approach meant that staff could be trained whilst acquiring new core competencies and revealing operational gaps. Our experience of conducting TB trials within an environment of mentoring, networking and training has provided a platform for establishing future sustainable research centres that has capacities to conduct highly regulated studies.