ABSTRACTS OF ORAL PRESENTATIONS

OA-001 THE ADDED VALUE OF A MULTICOUNTRY NETWORK FOR PROMOTING ETHICAL AND REGULATORY STANDARDS IN CLINICAL TRIALS IN LOW- AND MIDDLE-INCOME COUNTRIES: THE EXPERIENCE OF THE 'SWITCHING THE POLES NETWORK'

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Background In 2008, we created the 'Switching The Poles' Clinical Research Network, by joining the forces of non-commercial clinical research groups in Benin, Burkina Faso, Cambodia, Cuba, the Democratic Republic of Congo, Ethiopia, India, Indonesia, Nepal, Peru, Rwanda, The Gambia and Vietnam. Our aim was to strengthen capacity to conduct non-commercial clinical trials that comply with ethical/regulatory standards.

Methods Our capacity building initiatives were designed to directly benefit the implementation of clinical trials, including various EDCTP-sponsored projects, e.g. 4ABC (7 countries), PREGACT (4), Microbicide Safety Biomarkers (3) and Ring Plus (1). Our training, coaching and networking activities targeted young researchers from the South as well as research professionals who are traditionally 'neglected' in trainings, such as data managers and laboratory staff. There were several thematic packages: Good Clinical Practice (GCP), Good Clinical Laboratory Practice, data management (DM), monitoring, and informed consent.

Results We developed a theoretical and practice-based GCP training that was adopted by WANETAM Plus in 2013, and a set of standardised DM procedures. Data managers used to working on their own, now benefit from an e-platform (admit-network.org) for collaboration and peer advice. We started coaching clinical monitors, for facilitating reciprocal monitoring schemes. We publicly spoke out about ethical issues, e.g. ethical

review of externally-sponsored trials, voluntariness in informed consent in vulnerable populations, and provided recommendations to the International Conference of Harmonization in its revision of GCP Guidelines. The inclusion of partners from so many diverse countries and settings resulted in cross-fertilisation and mutual learning. The Networks' small size facilitated interpersonal collaboration.

Conclusions Our experience shows that a relatively small, but focused international network provides an excellent platform for supporting young researchers across different professional disciplines and helps to strengthen capacity for clinical research. This approach has enabled partners in low- and middle-income countries to successfully conduct harmonised GCP-compliant clinical trials.