

The European and Developing Countries Clinical Trials Partnership (EDCTP)



Evaluation of the EDCTP Ethics Grants
Programme

November 2013





Outline



- Evaluation aim
- Methodology
- Findings
 1. Mapping African research ethics and drug regulatory capacity (MARC)
 2. Promoting the establishment and strengthening of National Ethics Committees (NECs) and Institutional Review Boards (IRBs)
 3. Supporting ethics training activities, including development of online training programmes
 4. Networking
 5. Grant management
- Overall recommendations



Evaluation Aim



Primary purpose:

- To establish the achievements and impact of EDCTP's support in strengthening ethics activities employed in various ethics programmes.
- Creative Consulting and Development Works (CC&DW) conducted a comprehensive and purposive evaluation of the EDCTP Ethics Grants Programme.
- The evaluation analysed the achievements of 75 EDCTP funded ethics grants programmes scattered across sub-Saharan countries.

Methodology

DESKTOP REVIEW (of all 75 Ethics Projects)

BENEFICIARY SURVEY (to all 75 Ethics Projects)

SITE VISIT

Mapping African Research Ethics and Drug Regulatory Capacity (MARC) project office based in Botswana (COHRED Africa office)

- Face-to-face interviews
- Tour of the facilities and premises, conduct observations of schedules
- Investigate partnership relationships established
- Data collection

COUNTRY VISIT

Southern Africa: Botswana, South Africa

Central Africa: Cameroon

Eastern Africa: Ethiopia

Western Africa: Nigeria

- Face-to-face interviews
- Tour of the facilities and premises, conduct observations of schedules and
- Investigate partnership relationships established
- Data collection

TELEPHONIC INQUIRY

19 Ethics Projects

- Telephonic interviews

Findings

Mapping African research ethics and drug regulatory capacity (MARC)

Promoting the establishment and strengthening of National Ethics Committees (NECs) and Institutional Review Boards (IRBs)

Supporting ethics training activities, including development of online training programmes

Networking

Grant management

Mapping African research ethics and drug regulatory capacity (MARC)



Aim:

- To develop a continuously updated, systematic map of African research ethics review committees and clinical trial-related regulatory activities
- To report on the health research ethics activities
- To create an online networking forum for research ethics committees through HRWeb

Findings

- Mapped 166 IRBs in 34 African countries
- Developed an EthiCall - a 'professional social network/discussion' - function on the MARC website
- Developed an online information management system forming part of the ethics review management module of the program the Research for Health and Innovation Organiser (RHinnO Ethics)
- Mapped 26 countries' Medicines Regulatory Authority Bodies
- Gained global recognition through uptake in Latin America , with over 1,000 Latin American IRBs mapped by the Pan-American Health Organisation (PAHO) on the research-ethics-web platform
- Received positive mention of the programme in the US Presidential Commission for the Study of Bioethics Issues, titled "MORAL SCIENCE - Protecting Participants in Human Subjects Research" commissioned by President Obama

Recommendations

- Upgrade the monitoring process to ensure that African countries update their information on time
- Employ a full-time administrator on the MARC project
- Secure funds to host African Administrators of Research Ethics Conference (AAREC) 2
- Increase traffic on the MARC website
- Actively promote MARC
- Fund IRBs for purchasing RHinnO

Promoting the establishment and strengthening of National Ethics Committees (NECs) and Institutional Review Boards (IRBs)



Aim:

- To support activities of establishing and strengthening of NECs and IRBs through training, infrastructure development and networking
- To positively contribute to the quality of research being conducted within a country or district

Findings

- *Functionality*
 - All IRBs who completed this section of the survey (16) had SOPs, policy for appoint a chair, a quorum. However, it is not entirely clear how to assess the functionality of the IRBs.
- *Independence*
 - There are no clear indicators to assess the independence of IRBs; additionally, no IRBs were measuring their level of independence.
- *Transparency and Deliberations*
 - Transparency is ensured through having open discussions and identifying conflicts of interest. However, transparency is not measured.
- *Local Expertise in Ethics*
 - What constitutes local expertise is not well defined. Advise suggestions around the need for training and experience in field research, as well as in research ethics.

Findings

- *Efficiency*
 - Overall, the number of protocols reviewed annually has increased over the years – this growth in workload and attracting relevant expertise in committee membership has presented challenges.
- *Sustainability*
 - EDCTP funding assisted IRBs in accessing adequate infrastructure as well as capacity . As most work on IRBs is unpaid, retaining expertise is challenging. Sustainability of retaining an administrative officer without continued funding is of concern.
- *Relevance*
 - Monitoring of the ethical status of medical research is on an on-going basis and communities are meaningfully involved in deliberations about ethical research.
- *Effectiveness/Impact*
 - The data presented in the report supports the claim that ethics has made a solid entrance into research ethics in Africa.

Recommendations

- Remuneration of committee members
- Training of committee members
- Addressing problems of sustained monitoring of on-going research
 - Regular submission of progress reports from principal investigators
- Implementation of independent systematic evaluations of NECs and IRBs
- Increase awareness of role of ethics committees to researchers and communities
- Regulate “IRB shopping” by researchers through encouraging guidelines for identifying appropriate IRBs for the research at hand

Supporting ethics training activities, including development of online training programmes



- Training was provided via three different methods:
 1. workshops
 2. courses offered by tertiary institutions
 3. online training
- Approximately 6,700 beneficiaries were trained by the 65 EDCTP grantees funded for training between 2005 and 2012.

Findings

- *Relevance:*
 - Online training reached the highest number of people trained (+/- 3600)
 - A major weakness of workshops is that it is hard to assess their quality
- *Effectiveness/ Impact:*
 - Online training is only effective when beneficiaries are computer literate, have access to computers and have access to the internet
 - Effectiveness of online training is undermined by the sustainability of the organisations hosting the website

Findings

- *Sustainability:*
 - Follow-up support by those facilitating workshops is important to assess whether the beneficiaries have implemented what they have learned appropriately. This support needs to be a key part of future practice.

Recommendations

- EDCTP to help raise general awareness around the importance of ethics
- Grantees must participate in mainstream health research ethics as part of undergraduate and post graduate training
- Develop partnerships with other institutions in order to standardise introductory training courses to ensure common knowledge and skills amongst researchers and members of IRBs
- Supplementary training could be made available based on the needs of the IRB
- Grantees should ensure that there is an assessment of knowledge, especially post-workshop, to assess competency
- Assess training needs in other countries
- Scholarships for tertiary training
- Promote training in French speaking countries

Networking



- Networking was recognised by all 75 projects as being very important by grantees.
- Networking provided opportunities for acquiring technical guidance, exchange of tools and training by collaborating partner institutions.

Findings

- All grantees were involved in national networking, with 47% networking with NECs.
- More than half (63%) of grantees were involved in networks beyond their national border, on the African continent.
- 49% of grantees were involved in international networks other than EDCTP.
- Sharing of experience and best practices has also improved the development of higher quality and comprehensive training modules for capacity building.

Recommendations

- Networking is recognised to be a valuable space for sharing ideas and expertise. However, given the vast geographical region that the grant covers, networking through face to face meetings is an expensive mechanism for networking. Therefore online discussion forums need to be explored as a means for networking.
- The evaluation recognised the need for a higher governing body that can regulate good practice within the field of ethics in Africa. Such a body could also look at trying to improve the minimum standards for ethics.

Grant Management



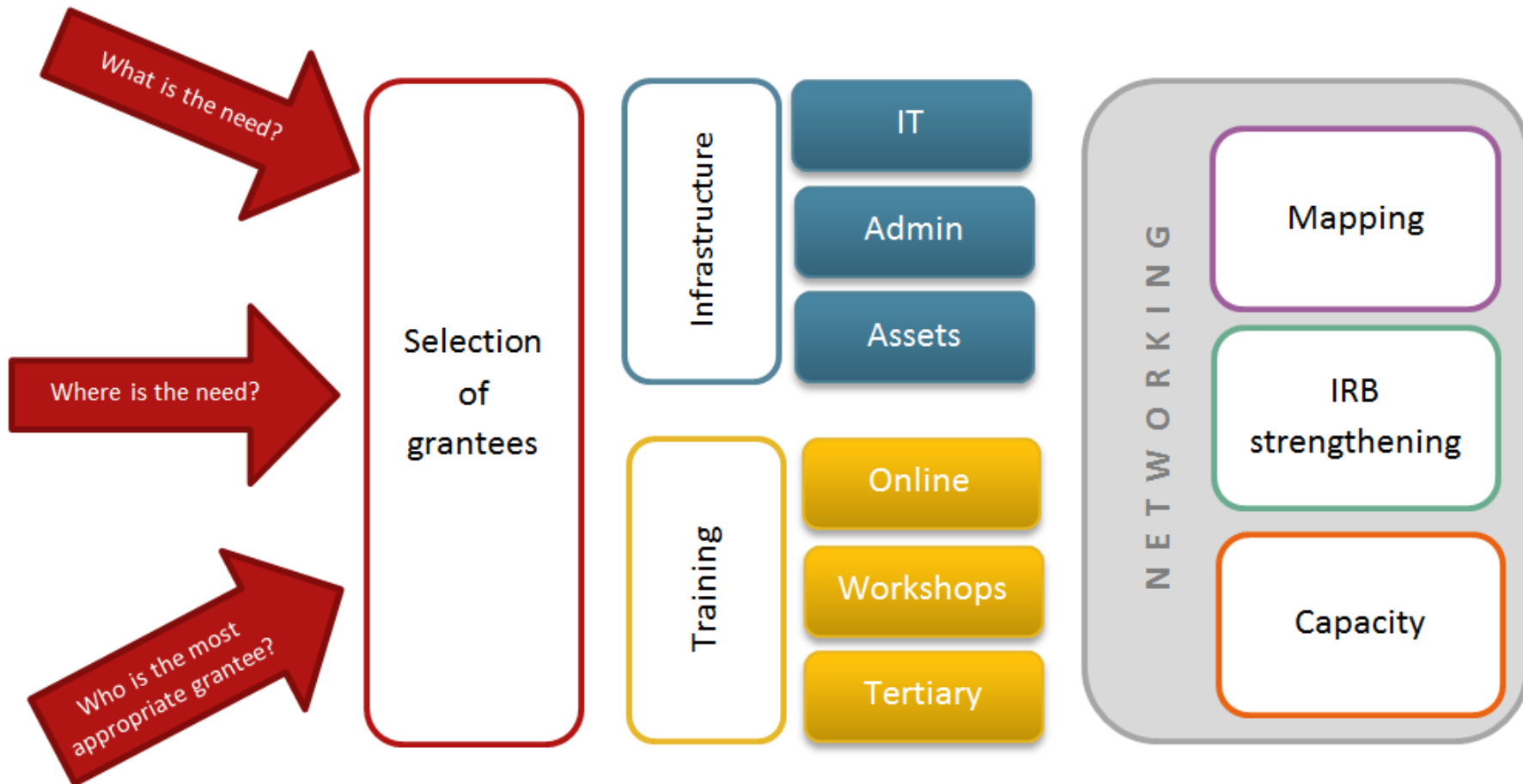
Overall finding:

The relationship between EDCTP and the grantees was reported to be very positive, with communication cited as excellent between grantees and project officers. Grantees felt there was a mutual respect between EDCTP and themselves.

Recommendations

- Increase the frequency of communication from EDCTP.
- Greater flexibility is needed in the budget. An overall review of budgets as well as across the board increases were recommended by grantees.
- Grantees that have fared well on their project should be considered for further funding support to enable them to build on success of their initial project.
- EDCTP to encourage greater collaboration and bring grantees together to formulate mutual basic standards they expect in terms of ethics, GCP, SOP and also relevant training/development in this field.
- EDCTP could play a greater role in improving the global visibility of the numerous valuable activities taking place in Africa.

Recommended EDCTP Strategy





Overall Recommendations



- Uneven capacity
 - EDCTP to recognise the uneven capacity of African countries with regard to ethics and strategise about where they would like a presence under Phase 2.
- Leverage from current relationships
 - EDCTP need to continue to foster existing relationships through continued support, to enable them to leverage off their investment under EDCTP 1.



Overall Recommendations



- Funding strategy
 - Strategise about how future funding arrangements will be made to ensure that countries with weaker capacity and countries where EDCTP would like to have a presence, are provided with support to write funding proposals that meet the required standard.
 - This may mean that EDCTP, or an intermediary that they appoint, provide support. Should the proposal be accepted, we recommend that on-going capacity and mentoring be made available to ensure that the grantee is supported throughout the process of the grant, to ensure they adhere to the rules, implement the grant according to the plan, and meet the reporting requirements.
 - Such grantees could be provided with seed funds, rather than be awarded large grants that they may not have the absorptive capacity to administer.



Overall Recommendations



- Strategic relationship with other donors
 - EDCTP to have a good understanding of the focus and overall budgets of other donors (e.g. NIH and Wellcome Trust), so that EDCTP can appropriately strategise about where to best invest their money.
 - Greater collaboration among funders will also minimise the potential for duplication of funding.



Overall Recommendations



- EDCTP a strategic roleplayer in Ethics
 - EDCTP have the opportunity to play a greater strategic role in their investment in ethics in Africa.
 - However to leverage from this opportunity, EDCTP will need to support this strategy with a greater
 - Internal human resource capacity
 - Operational budget
- Regular evaluation
 - EDCTP to conduct an evaluation to better understand the needs of researchers in clinical trials with regard to ethics. This was briefly explored under this evaluation as a supplementary piece of work.

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All grantees who were contacted telephonically or face-to-face



Thank you