ACCESS AFRICA

UNIVERSITY OF OSLO

Access Africa Guidelines on Post-Trial Access for international Clinical Trials in Sub-Saharan Africa

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Global Health EDCTP3

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Improving post-trial access arrangements in clinical trials in Sub-Saharan Africa

Project coordinator: Prof. Rosemarie Bernabe
Center for Medical Ethics
University of Oslo, Norway

Global Health EDCTP3

Participating organizations

- University of Oslo (coordinator – Prof. Rosemarie Bernabe)
- Jimma University - **Ethiopia**
- St Paul's Hospital Millennium Medical College - **Ethiopia**
- Armauer Hansen Research Institute - **Ethiopia**
- Uganda Virus Research Institute - **Uganda**
- Uganda National Council For Science & Technology - **Uganda**
- Ministry of Science and Higher Education (MoSHE) - **Ethiopia**

There is limited practical experience and guidance on post-trial access (PTA) in clinical trials in LMICs

Project objectives

The general objectives of AccessAfrica are threefold:
1) investigate the status quo of PTA in high-priority clinical trials within the region; 2) provide practical guidance on how PTA can be enforced within the region;
3) develop and pilot-train a one-day workshop for funders, drug regulators, and RECs to enforce PTA as an ethical imperative.

Specific objective

- Propose guidelines on feasible measures to incorporate PTA in clinical trials in Sub-Saharan Africa

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Principle 1

- PTA arrangements must be included in the planning of CTs

  - ✓ Provision of PTA must be standard
  - ✓ If any deviation, must be ethically justifiable and approved by REC

Principle 2

- PTA refers to access to knowledge and intervention

  - ✓ Research participants
  - ✓ Community
  - ✓ Host country

Principle 3

❑ PTA is multi-stakeholder responsibility

- Provision arrangement
  - ✓ Led by sponsors or PI
  - ✓ In close collaboration with different stakeholders—REC, CT regulators, community
  - ✓ Planning and execution must include all relevant stakeholders—to optimize PTA benefits

Principle 4

- To best serve the interest of the participants and the community

  - ✓ The planning and details of post trial arrangements must be continuously reconsidered by the sponsors and the PI through out the study
  - ✓ In close collaboration with the community
  - ✓ Any changes to PTA plan must be reviewed and approved by REC

Principle 5

- PTA arrangements should include access to relevant study findings

  - ✓ For participants, community, host country, general public
  - ✓ CTs must provide this Knowledge efficiently to the host country stakeholders
  - ✓ Facilitate its use for community benefits
  - ✓ Disseminate to scientific community, and general public in host country – enable widespread accessibility to knowledge

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCTP3 Joint Undertaking and its members.

Principle 6

- If therapeutic products meant for commercial distribution (as medical device) are involved in the trial:

  - ✓ Therapeutic products must be provided to research participants who still need the intervention
  - ✓ The community and/or the host country must have access to the therapeutic intervention

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Principle 7

- PTA provision of therapeutic products ranges from cost-free provision to research participants, to availability and accessibility of the product for the community and/or host country

- The sponsor, in cooperation with the community and the host country, must also ensure that the associated medical care and infrastructure are in place

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Principle 8

- Providing PTA to individual participants will be dependent on the risk benefit profile of the investigational product in comparison with the standard.

- PTA for individual participants lasts until the therapeutic product is authorized, marketed, and accessible in the host country

- The plans for transition from individual PTA to sourcing the appropriate medicinal product from the national healthcare system must be clearly stipulated in the clinical trial's PTA plans.

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Principle 9

❑ To ensure PTA for the community/host country

- ✓ PTA plan must include provision of a formal agreement between the sponsor and the host country that the sponsor will apply for marketing authorization for a therapeutic product, once proven safe and effective

- ✓ the product is marketed in an agreed period—not more than 5 years from the last pivoted CT
- ✓ Agreement should cover pricing mechanism, and must be equitable
- ✓ Equity must be determined by sponsors and PI—concordance with REC and host country regulatory body

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