Post Trial Access in Clinical Trials

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Background

- Regulatory approval of Clinical Trials was introduced in 2000
- Post Trial access
  - Antiretroviral medicines
    - Harm if treatment is withdrawn without alternatives.
  - HIV prevention clinical trials
    - National consultation in 2003
  - Approach was expanded to all medicine in 2004
- Helsinki 2000 was used as point of reference

South African Regulatory approach

- Clinical Trial participants who are clearly benefiting from the clinical trial intervention should have post trial access until the medicine is freely available in the public health system
- This must be clearly articulated in the informed consent
- Date of registration in a resource constrained environment is not appropriate:
  - Affordability

South African Regulatory approach (2)

- The sponsor must, prior to approval, provide unambiguous evidence of provision for post trial access in the form of:
  - An undertaking to provide the product at no cost
  - A Memorandum of Understanding that the South African government aggress to provide access at not cost

South African Regulatory approach (3)

- Where the intervention is of considerable public health interest, e.g. novel vaccines, evidence of a reasonable approach to access pricing is sought:
  - Typically it takes the form of an undertaking for phase I to II
  - To date there has not been a test case for a phase III but in principle it is believed that some sort of agreement needs to be presented

South African Regulatory approach (4)

- Where the comparator is not standard of care the control arm poses a specific problem:
  - Sponsor can provide post trial access
    - There is considerable resistance to the option
  - A protocol for the stabilization on local standard of care
    - Memorandum of agreement for feeder clinics

South African Regulatory approach (4)

- The largest challenge is post trial access for preventative health technologies without proven safety and efficacy
  - The position of the MCC is that harm may accrue to the community where
    - Safety profile has not been adequately characterised
    - Therapeutic misconception may result in great risk taking
  - Recent case study has been the tenofovir gel

Amendments wrt post trial access

- Propose that the current provision be amended to reflect:
  - Identification of responsible agents
  - That Post trial access be concluded prior to approval
  - No participant who
    - is benefiting from the trial intervention
    - does not have reasonable access to alternatives

    should be denied access at no additional cost

Other considerations

- Bio banks
  - Separate informed consent
  - Exclusion is usually not allowed
- Vulnerable groups
  - Over researched communities
- Publication
  - Undertaking by the sponsor
- Ethics “shopping”
  - Nationally and internationally
  - Declaration with reasons for rejections

Thank you