Post Trial Access in Clinical Trials

Gavin Steel
Medicines Control Council
Clinical Trials Committee

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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    • Harm if treatment is withdrawn without alternatives.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