TFDA
Tanzania Food & Drugs Authority

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Control and Regulation of Clinical Trials in Tanzania : TFDA perspectives

DAMAS MATIKO (B.Pharm., MSc.)
TANZANIA FOOD & DRUGS AUTHORITY

Presentation Outline

- Background
- Tanzania Food, Drugs and Cosmetics Act, 2003
- Roles of Tanzania Food and Drugs Authority (TFDA)
- Clinical trial Applications and Approval
- Requirements post approval
- GCP Inspections
- Current development
- Challenges and gaps

Background

- Enactment of the Tanzania Food, Drugs & Cosmetics Act, No.1, 2003 in 2003 laid down the legal framework for regulation of clinical trials.

- Previously the Pharmacy Board the then medicines regulatory body controlled only the importation of trial medicines.

- Clinical trials were “controlled” by issuance of ethical clearance by the Institute for Medical Research

Tanzania Food, Drugs and Cosmetics Act, No.1, 2003

- The Act established the Tanzania Food and Drugs Authority (TFDA)

- TFDA regulates food, medicines, medical devices and cosmetics

Tanzania Food, Drugs and Cosmetics Act, 2003

- Section.5.1(d) empowers TFDA to regulate clinical trials . TFDA ensures that clinical trials on drugs, medical devices are conducted in accordance with prescribed standards.

- Section.61 prohibits procurement, importation, manufacture, sale or supply of any medicines or medical device for the purposes of clinical trial unless the person holds a clinical trial certificate issued by TFDA

Tanzania Food, Drugs and Cosmetics Act, 2003

- Section 62 prohibits the conduct of a clinical trial without written authorization of the Director General
- Section.63, 68 and 69 empowers the Authority to issue guidelines, monitor, suspend or stop clinical trials for any reasonable cause
- Section. 71 Creates offences and penalties for violations- fine of > Tsh10 million or imprisonment for five years or both
- Section.122 (p). Empowers the Minister to provide regulations for undertaking clinical trials

The Roles of TFDA

- TFDA has issued guidelines for the conduct of clinical trials in Tanzania.
- In the guidelines TFDA has set the following Standards:
  - Standards for research and development of medicines by adopting the ICH Harmonized Tripartite Guidelines for Good Clinical Practice
  - standards for investigational medicinal product's quality, manufacturing processes (GMP) including labelling
  - Application procedures for Clinical Trial Application (CTA) and data requirements

The Roles of TFDA

- TFDA provides oversight of clinical trials which include:
  - Approving the conduct of clinical trial-issues Clinical Trial Certificate.
  - Receives and evaluates serious adverse reactions
  - Maintains a register of all clinical trials conducted in the country
  - Conducts inspections of trial sites, sponsors. On the average 10 inspections are conducted a year
    - Main focus is at study sites

Clinical Trials Application and Approval

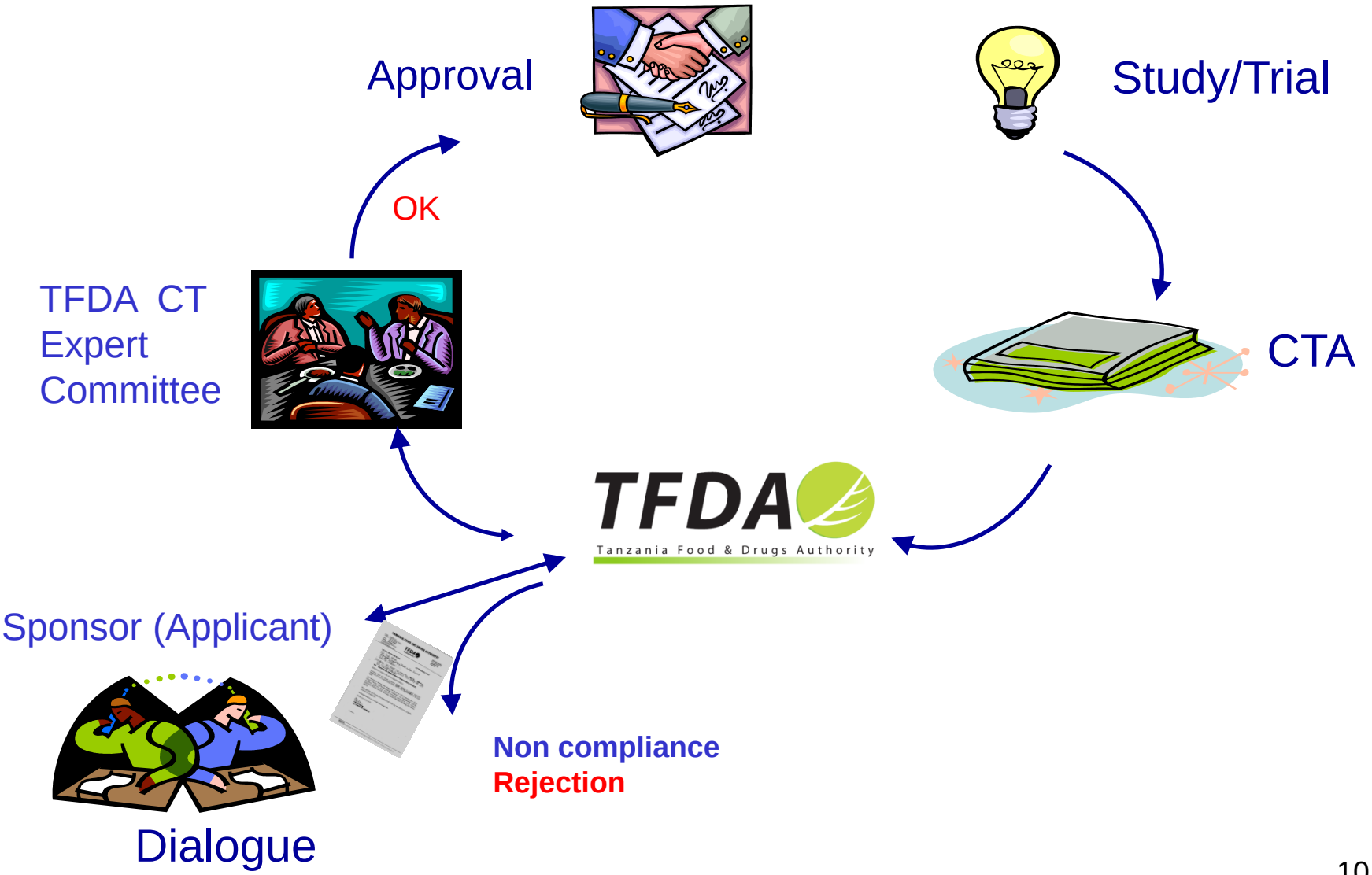
- All phase I, II, and III clinical trials involving unregistered medicines must apply and obtain approval from TFDA

- Filing and approval is also required for registered medicines where the proposed clinical trials are outside the approved labeling e.g. new indication and clinical use, target population, dosage regimen, route of administration e.t.c

- Phase IV trials are exempted from CTA filing but
  - Ethical Clearance is required
  - GCPs must be observed
  - Record-keeping and reporting required

- TFDA approval subject to ethical clearance from Ethics Committees

Overview of CTA Process



Clinical Trials Application and Approval

- In the last six years (2005-2012) over 55 clinical trials of medicinal products were approved
- Currently there 26 ongoing Clinical trials countrywide
- Majority of the trials for malaria, HIV/AIDS and TB investigational products.

Requirements post approval

- Reporting of Serious Adverse Events to TFDA
- Submission of 6 months Progress Report
- Submission of Protocol Amendments for approval
- Submission of updated Investigator's Brochure (IB)
- Adherence to ICH-GCP guidelines, regulatory and protocol requirements

GCP Inspections

- Started in 2009 by inspections of investigator sites
- Inspection Manual developed
- Over 30 GCP inspections conducted to date
  - Some of the findings includes
    - Inadequate laboratory services & reagents
    - Local ethics committee not monitoring studies
    - Inadequate archive & storage rooms

Current development

- Application fee revised to $3,000; amendment $ 200 (effected in 1 October 2011)
- Guidance to Conduct Clinical Trials in Paediatric populations developed (approved in May 2012)
- Clinical Trial Registry is being finalised
- Clinical Trial Regulations to be *gazzetted* this year (2012)
- Insurance & Indemnity Guidelines developed

Challenges and gaps

- Inadequate legislation regulations and guidelines
- Limited trained personnel, financial and infrastructure resources
- Increase in number, type and complexity of clinical trials and investigational medicinal products in Tanzania
- Lack or Inexperienced local insurers

Thank you (AHSANTE SANA)