Regulatory Preparedness for the Next Infectious Disease Emergency

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Outline

- Existing Regulatory Framework
- Ebola Vaccine Trial - Wake up Call
- The Aftermath
- Lessons Learnt
- Actions Taken
- Way Forward
- Conclusion

Regulatory Preparedness

Simple Definition:

Being ready for action in sudden unforeseen crisis while operating according to rules and principles

- Clarity of Rules
- Capacity of the Regulator
  - Quality
  - Time
- Flexibility

Legislation

- Most countries have legislation in place for regulation of clinical trials [AVAREF 23]
- Most have Guidelines in place generally
- Countries authorize trials
- Some monitor/supervise by way of GCP Inspections
  - Most Guidelines adapted from ICH E6 R1
- No specific provisions or procedures in place for clinical trials during public health emergencies

Wake-up Call

-and-the-secret-ebola-vaccine/

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FDA and the Secret Ebola Vaccine

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THURSDAY, 11 JUNE 2015 07:24

Ghana should say NO to Ebola Vaccine trial

WRITTEN BY EDITORIAL TEAM

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THE BROUHAHA that delimited the planned Ebola vaccine trial to be held at Hohoe in the Volta Region was brought to an expected halt yesterday when the Minister of Health, Alex Segbefia directed that the exercise be suspended.

The directive which was communicated by the Public Relations Officer of the Ministry of Health, Tony Goodman stated that Mr Segbefia who is out of the country, suspended the program as a result of the widespread criticism of the exercise by members of the public and several civil society organizations including the Ghana Academy of Arts and Science and the Volta Regional branch of the National Democratic Congress.

"The Minister for Health is not in town. This whole thing is being done by Food and Drugs Authority (FDA) together with the Ghana Health Service.

"The Minister has got a lot of calls from numerous Ghanaians saying that they are not interested in any trial. So he said that since he's not in Ghana, the trial should be suspended until he returns to look at the issues."

The statement further said the minister understands that the FDA has the mandate to undertake the trial, but psychological health is very important, "psychologically Ghanaians are not ready for the trials.

"If a vaccine has been developed in Mali, will you expect that Ghanaians will benefit from it? What is wrong if Ghana also allows itself to be used?

"The most important thing is to establish whether the vaccine is safe and that has been established. It's also been established that this vaccine is not going to cause any Ebola diseases. There is no way we are going to get Ebola because of the trial." He added.

Ebola vaccine trial saga: What have young innocent students done to our leaders to deserve being used as guinea pigs?

By Bernard Buachi/rawgist.com
June 10, 2015 at 6:35 pm | 1 comment

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Many Ghanaians probably did not welcome the news of ebola trials in the Volta region with the kind of shock I did. But this is an issue that should not be left to go without a response from Ghanaians. This is in my opinion sinister and unnecessary sacrifice of Ghanaians on the alter of selfishness.

I'm amazed at our leaders who through selfish interest and spinelessness are serving this country on a platter.

My piece of mind is very simple on this matter; let our leaders right up from the President and his family through the parliamentarians and ministers and directors of the safe these vaccines are (even then, it won't be a

/2015/02/African-Child-Vaccine-Shot-Arm.jpg

Wake-up call


DailyGuide
Ghana's Favorite Newspaper
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Gov't suspends Ebola vaccine trial
June 10, 2015
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Laboratory
Testing of
Ebola
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The Ghanaian Times
GHANA'S MOST AUTHORITATIVE NEWSPAPER
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House orders 'secret' Ebola vaccination stopped
IN NEWS / BY TIMES / ON JUNE 11, 2015 AT 8:44 AM /
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The Aftermath

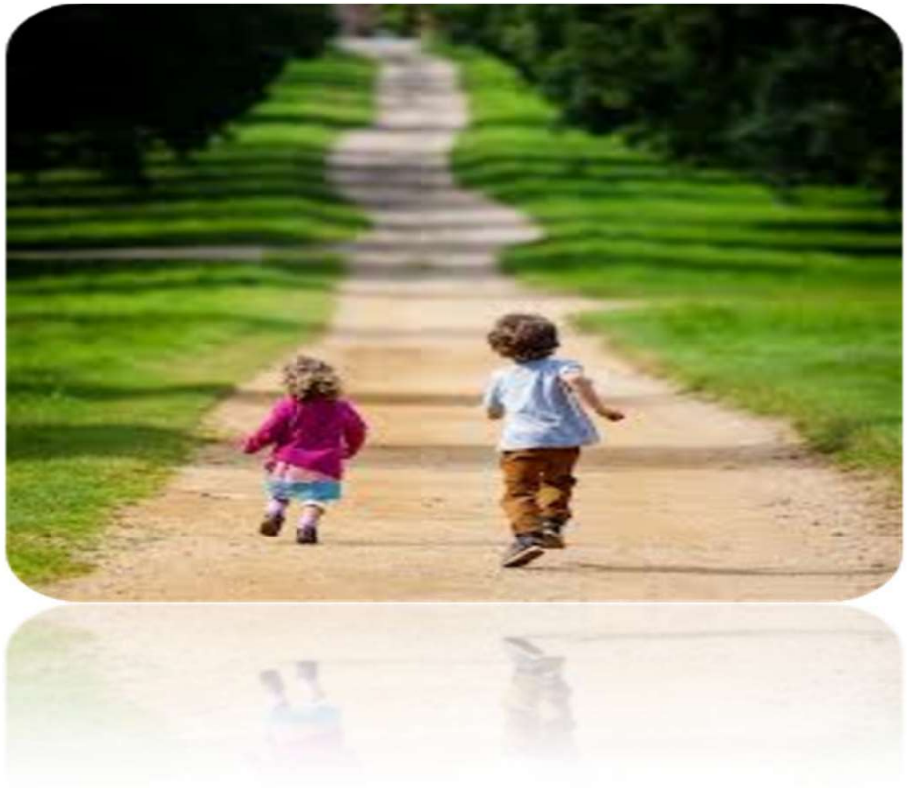
- Unpreparedness
- Lack of coordination among African regulators
- Delays
- Loss in capacity building opportunities
- Wasted resources
- Ethical misconceptions
- Confusion
- Mistrust

Lessons Learnt

Need for:-

- Wider and more proactive stakeholder engagement for clinical trials
- Joint inter country efforts in reviews [AVAREF?]
- Agreed timelines for approval should be respected
- Clear and specific guidelines for conduct of trials in such emergencies
- Clear policies and procedures in managing clinical trial related crisis

Way Forward



- Update Existing Legislation
  - Provisions for accelerated reviews in emergencies
  - Provision for trials in paediatric populations
- New Guidelines for Joint Reviews [Routine? Before emergency occurs?]
  - In country between NRAs and Ethics
  - Multiple NRAs in multicentre trials
    - Harmonized format and timelines
    - Country Ownership and buy in**
    - Encompass existing in-country procedures
    - *Adopt WHO/AVAREF Guidelines*

- Capacity Building Across Countries
  - Countries at different levels of regulatory capacity
    - Discourage “shopping”
  - Robust functional Expert Committees in place
- In-Country Capacity Building
  - Gap assessment to identify individual needs
  - Address needs
    - AMRH/NEPAD Regional Centre of Regulatory Excellence [RCORE]
    - Joint Review Process [reference NRAs]
    - Joint GCP Inspections

Registration: Harmonization & Networking

- Regional Capacity Building
  - Formation of synergies between regulatory authorities within the sub region (twinning)
- WAHO harmonization of registration etc procedures
  - Steering Committee, Working groups/regulatory activity
  - Ownership and buy-in
- Plans to establish a Secretariat for medicine registration at West African Health Organization
  - Process similar to EMA
  - Guidelines and systems for fast-track approvals
  - Regional joint reviews for ECOWAS as with other regional blocks [east, south]

Preparedness: Post-Approval Safety

- *First post-market safety data likely in developing countries
  - Strengthen Pharmacovigilance System (spontaneous, active)
    - Legislation; Guidelines; Enforce; Inspect
    - Awareness creation; training;
  - Develop strong collaboration with Expanded Programme on Immunization
  - Patient reporting (non existent in most countries)
  - Integration of PV
    - Healthcare assessment models
    - Schools Curricula

Stakeholder/Community Engagement

- Engage
  - Government, Scientific Community, Patient Community, General Public, Media
- Better understanding of drug development process
- Build trust among stakeholders
- Preparedness for Joint Reviews
  - Communication Plan for each review
  - Communication after results of review
  - Communication between countries during and after trials?
    - Mechanism to be put in

Conclusion

- Significant effort made by regulators in the region
- Both individual country efforts and also cooperation and coordination among various countries regulators
- Result is creation of a potential single platform of entry, critical for research applications during product development in emergencies
- Next steps is early engagement of regulators by researchers
- In emergencies, Communication, Transparency, Trust, Information Sharing between ALL stakeholders are key
- COMMON GOAL -Shorten time to availability of live-saving products

THANK YOU