9th ANNUAL MEETING OF THE AFRICAN VACCINE REGULATORY FORUM (AVAREF)

Pretoria, 3 to 7 November 2014

Recommendations
The 9th annual meeting of the African Vaccine Regulatory Forum (AVAREF) was held in Pretoria South Africa, 3 to 7 November 2014.

The meeting brought together NRAs, EC/IRB, in Africa, Manufacturers, developers, Research Institutions, US-FDA, EMA and BMGF and representatives of NRAs and ethics committees of 20 AVAREF countries.

Participants reviewed progresses in development of vaccines and medicines for Ebola and other priority diseases.
AVAREF Response to Ebola

- Recommendations to SPONSORS/Manufacturers

1. To immediately release the planned time line for submission of clinical trial applications indicating specific trial sites

2. To hold pre-submission meetings with each participating NRAs, EC and to attend

3. Manufacturers to attend the joint review sessions with their appropriate staff;

4. Manufacturers to file clinical trial applications through the focal persons identified by Heads of NRAs

5. To use the AVAREF clinical trials format for the submissions of clinical trial applications.

6. To include in their submissions all pertinent data that is available at the time of submission

7. To respond swiftly to any query from NRAs or EC/IRB
AVAREF Response to Ebola

- Recommendations to supporting regulatory authorities (EMA, USFDA, HC)

1. In collaboration with WHO, do everything in their power to share data relevant to clinical trials with the NRAs of participating countries

2. To provide expertise to support NRAs in the joint reviews when requested
AVAREF Response to Ebola

Recommendations to WHO

1. To request Heads of regulatory Agencies to:
   1. Identify and named senior regulators staff as the agency entry focal points for Ebola
   2. Designate named reviewer(s) to participate in a joint review process with the mandate to take regulatory/ethics decisions (reviewers are empowered to take decisions during the joint review meeting).

2. To facilitate a joint review session of the clinical trial applications with a target date of 15 December 2014

3. To involve the NRAs of the Ebola affected countries in the joint review process

4. To provide expertise and develop briefing materials for ethics committees
AVAREF Response to Ebola

- Recommendations to WHO

5. To develop additional briefing materials on the vaccines, and novel clinical trial designs, to assist the national/regional reviews

6. To proactively play the needed broker role in facilitating the interaction between manufacturers and countries

7. Engage with heads of Institutions and research institutions and provide necessary support to countries to develop procedures for accelerated review of Ebola related research.

8. Ensure that ethics committees have the necessary support to follow up approved trials and research studies through site monitoring and having mechanisms to rapidly review amendments etc.
AVAREF Response to Ebola

- Recommendations to NRAs and EC/IRB
  1. To prioritize assessment of clinical trial applications in parallel (regulatory/ethics) to minimize delays and to apply fast-track procedures’
  2. To immediately release all national/regional provisions governing the area of clinical trials and highlight aspects favourable to fast track procedures
  3. To accept to review all clinical trials submitted by manufacturers/sponsors
Other recommendations from the meeting

- To NRAs and EC/IRB

1. To gradually strengthen Regional Harmonization of Technical processes and procedures

2. To emphasize on utilization of joint process implementation

3. To establish mechanisms for strengthening Transparency on processes/procedures and on country/regional performance (including adapting indicators for research ethics systems)

4. To interact actively with AMRH (EAC, SADC, WAHO, OCEAC, UEMOA)
Overall recommendations for the meeting

To WHO

1. To support and strengthen collaborative mechanisms among NRAs and ethics committees including capacity building through regular trainings

2. To encourage multiplication of joint implementation of regulatory activities including joint reviews and joint inspections

3. To host and manage the AVAREF virtual community platform developed by Health Canada, the secretariat to implement the transition by end January 2015

4. WHO to provide specific guidelines for evaluation of clinical trial applications for vaccines against TB and HIV, build Capacity to efficiently address other anticipated products in the pipeline
Issues to be considered by AVAREF

Bio-samples management and regulation at national, regional and global levels

WHO to support workshops on ethical issues in relation to bio-repositories
Acknowledgement

- Recommendations drafted by Dr Nikiema with input from
  - Dr D. Akanmori, Dr V Ahonkhai, Dr A. Bellah, Dr R. Cushman, Dr L. Elmgren, Dr T. M. Lapnet, Dr D. Wood
  - Representatives of GSK, NEW LINK, J&J
Thank you – Merci
www.who.int/medicines