HARMONIZATION OF CLINICAL TRIALS REGULATION IN AFRICA THROUGH AFRICAN VACCINE REGULATORY FORUM (AVAREF): THE NAFDAC EXPERIENCE

By.

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NAFDAC Nigeria
Introduction

NAFDAC:
• The National Agency for Food and Drug Administration and Control (NAFDAC) was created by Act of parliament and has the mandate to regulate the conduct of clinical trials in Nigeria.
  – Regulatory framework exist to support our mandate
  – The Agency developed clinical trial guidelines

AVAREF:
• The African Vaccine Regulatory Network (AVAREF) was created 2006 and comprises of National Regulatory Authorities (NRAs) and Ethics Committees (ECs).
Introduction

• AVAREF was aimed at:
  – Improving harmonization of practices in support of product development and regulation of clinical trials in the continent
  – Providing information to countries targeted for clinical trials of vaccines, therapeutics and medical devices,
  – Building capacity to NRAs and ECs for reviews of clinical trial applications,
  – Promoting collaboration between ECs and NRAs and,
    • Though began as an informal network, it was necessary for quick decision-making, achieved results, minimized delays implementation of decision on new vaccines.
    • It played a crucial role in the successful development of several vaccines
• AVAREF was formalized in 2010 involving Heads of NRAs and Chairs of ECs, with clear ToRs,
• In 2016, the scope was expanded to include Clinical Trial regulation of all medical products, thus new AVAREF ToRs was developed with new model and governance.
Regulation of Clinical Trials by NAFDAC

Pre-AVAREF:

• CT regulation started in 2002
  • New chemical entities
  • Extended indications
  • Extended patient population.
  • Fixed dose combination products
  • Innovative vaccines/Biologics
  • Dosage regimen for which safety/efficacy profiles have not been determined.
• Review of BA/BE date
• GCP inspections
Regulation of Clinical Trials by NAFDAC

Challenges:

• Had no defined regulatory pathway/requirements
• Inadequate capacity for assessment of CTA and study monitoring.
• No defined process timelines for CTA assessment
• No defined channel of collaboration between NAFDAC and ethics committees
NAFDAC’s Efforts

• Developed framework to support CT function;
  – with good governance structure
  – Committed leadership
  – Led to global engagement

• Committed to building capacity through:
  – WHO Global Learning Opportunities (GLO) trainings,
  – Local trainings,
  – Attending international regulatory fora (e.g. Health Canada Regulatory fora, US-FDA CBER, EMA-GCP working group meetings, etc.).

• Engagements with relevant stakeholders through consultative meetings
NAFDAC’s Efforts

• Joining AVAREF:
  – NAFDAC is a founding member of AVAREF,
  – Participation at joint trainings and workshops,
    • the Pan African Clinical Registry workshop
  – Active participation in joint CTA reviews, joint GCP inspections, e.g.:
    • Conjugate meningitis A vaccine clinical trial – 2006
    • RTS, S malaria vaccine clinical trial - 2008
    • Expedited review of conjugate men A and registration, 2011
      – NAFDAC participation led to joining WHO collaborative Procedure for registration of Vaccines – reliance mechanism
NAFDAC’s Efforts

• Expedited review of inactivated polio vaccine and registration – 2012

• NAFDAC chaired the forum between 2014 -2016 (old AVAREF) and currently chairing the AVAREF Technical committee.

• Joint reviews of Ebola vaccine clinical trial application in Geneva 2014, Tanzania 2015, Sierra Leone and Ghana, 2015
  – NAFDAC’s participation helped built capacity in joint reviews
NAFDAC’s Efforts

– Joint development of guidelines, and other working tools: Exs.
  • AVAREF Clinical Trial Application Form
  • AVAREF Clinical Trial Application Checklist,
  • AVAREF Joint Review Guidelines,
  • AVAREF GCP inspection Guide,
  • AVAREF GCP Inspection Checklist,
  • Clinical Assessment Template
  • Non-clinical Assessment template
  • Quality Assessment template
  • AVAREF Terms of reference.
  • Clinical Trial Evaluator’s guide
NAFDAC’s Experience

- The knowledge gained in joint review of novel vaccine candidates during emergency helped to build confidence and expertise to deal with future public health emergencies.
- NAFDAC has adopted all AVAREF documents.
- Development and use of common guidelines and templates promote harmonization in line with AMRH initiatives.
- The participation in the Forum has helped built trust on other AVAREF members and create reliance.
- Working together in the network afforded NAFDAC the opportunity to identify possible challenges and plans to address such together with other members.
NAFDAC’s Experience

– Helping to built trust amongst our stakeholders through quality and efficient reviews.
– We have built efficient, transparent & flexible processes -Better quality and shorter review and approval timelines for CTAs.
– We have learned to own our processes, be accountable and shall sustain the gains.
Conclusions

NAFDAC’s participation in AVAREF is a good example of the impacted need for collaboration and reliance

As a technical working group, AVAREF’s achievements align very much with AMRH initiatives which included harmonization and ensuring that quality medicines are accessible to peoples in the continent
Thank you