DCVMN AGM, 25th – 28th September 2017

Improving Regulatory capacity in Africa through joint reviews: Experiences from the African Vaccine Regulatory Forum (AVAREF)

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KEY Regulatory Challenges in LMICs

Clinical development

- **Processes confusing for product developers involving regulatory agencies and ethics committees, Example**
  - **Lack of clarity of roles between regulatory authorities and ethics committees**
  - **Lack-of/disparate application requirements**
  - **Overall lack of capacity / capabilities and transparency**

Registration & Licensure

- Rx/Vx: well-established "3-step" process, but slow and Redundant retarding timely Country introduction of needed Health products
- Dx: Unpredictable processes, lack of agreed-upon standards, multiple quality assurance mechanisms, slow registration and uptake of novel life-saving technologies

Post-licensure / Surveillance

- Limited pharmacovigilance Capacity in increasing number of vaccines and Drugs
- Increased inflow of counterfeit and falsified Substandard products due to low surveillance and enforcement

Why AVAREF?

- **Growing public health needs and limited resources**, demand faster, cheaper, and better treatments and vaccines.
- **Mosaic of regulations govern product development and oversight**, creating inefficiency and adding to costs of safe, innovative, and effective vaccines and therapies.
- **Duplication due to overlapping reviews and inspections** of clinical/ manufacturing sites for similar purposes.

What is the African Vaccine Regulatory Forum (AVAREF)

- ALL National Regulatory Authorities of African Region and national Ethics Committees (ECs)

- Established by WHO in 2006 to build capacity for vaccine clinical trials in 19 African countries

African Vaccine Regulatory Forum (AVAREF) HISTORY

Jan. '05: Network approach to regulation of clinical trials proposed at NRA workshop organized by WHO

2006: Joint reviews of CTAs, joint GCP inspection of phase II trial of Men. A. conjugate vaccine using model procedure

2005 | **2006** | **2007** | **2008...** | **...2014** | **2015** | **2016…**

2005/2006: Dev. of model reg. procedures for countries to adapt/ adopt

2007-2014: Annual meetings with review of RTS,S, TB vaccines, and others

2015: New AVAREF strategy developed

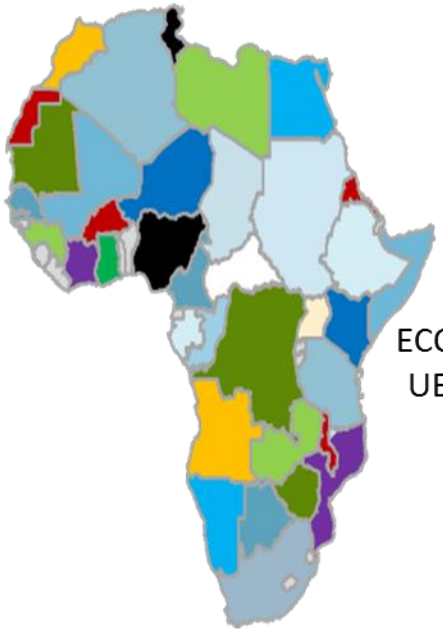
Nov. 16: New AVAREF strategy launched

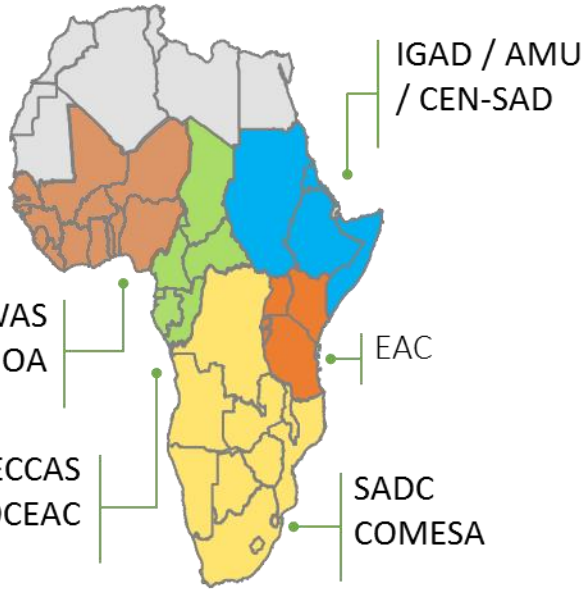
Sept. 06: Birth of AVAREF (Accra), managed by WHO-HQ/AFRO

2014/15: Joint reviews of CTAs for Ebola interventions

NEW African Vaccine Regulatory Forum (AVAREF)

- Arab Maghreb Union (UMA)
- SADC)
- East African Community (EAC)
- Economic Community of Central African States (ECCAS)
- Economic Community of West African States (ECOWAS)
- Intergovernmental Authority on Development (IGAD)

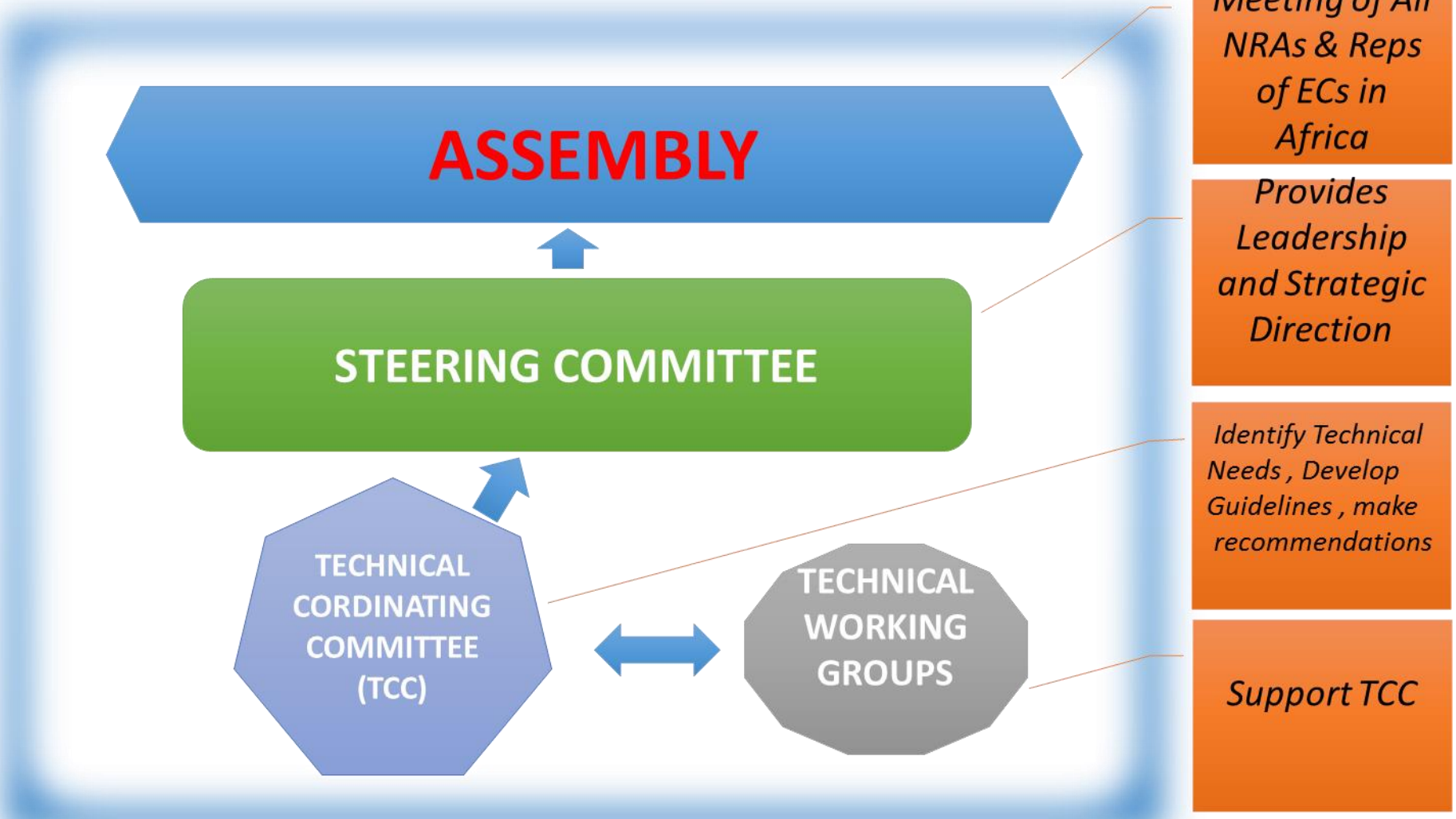




54 countries → **6(8) regions** → **1 continent**

FROM VACCINES TO ALL PRODUCTS

New AVAREF Governance Model



Core Values and Guiding Principles

- Values –
  - Transparency & integrity,
  - responsiveness,& innovativeness
  - Ownership & collaboratio
- Guiding Principles
  - Strong Partnerships and alignment with AMRH and other initiatives
  - National ownership, stewardship and leadership
  - Reliance on competent work and decisions of functional ethics committees and regulatory authorities
  - Upholding confidentiality
  - Efficiency and sustainability

What is a Joint Review?

- Review whether for approval of products or clinical trials carried out by NRAs with or without ECs to provide outcomes ina short time without sacrificing the quality of assessment.
    - Multi-country/multi-site
    - One country assisted by others
    - Clinical trial applications/marketing authorization
    - Face-to-face sessions and closed sessions

Joint Reviews

- 2006: Joint reviews of CTAs, joint GCP inspection of phase II trial of Men. A. conjugate vaccine using model procedure
- 2008: Joint review of malaria vaccine, RTS,S,
- 2011: Joint review of CTA of candidate TB vaccine
- Joint reviews for MenAfriVac
- December 2014: CTA of vaccine against Ebola
- February 2015:
- March 2015: Assisted Reviews
- 2016: Assisted review of therapy against eumycetoma, Neglected disease
- Joint review of combination treatment for lesihmaniasis

Joint/Assisted Reviews and GCP Inspections

"Process has been widely viewed as successful, improving the capacity and coordination and encouraging the use of defined review timelines and common documentation" -

Source: *Safer, Faster, Cheaper Improving Clinical Trials and Regulatory Pathways to Fight Neglected Diseases - Report of the Center for Global Development's Working Group on Clinical Trials and Regulatory Pathways*

Upcoming Review

- Special Approval of malaria vaccine Mosquirix
- Three countries – Ghana, Kenya and Malawi
- Issue special limited authorization for a pilot of the new vaccine.
- Implement pharmacovigilance readiness
- Jointly receive and review safety data for 3 countries

Challenges and Opportunities……..

- From decision to import permit
  - Advocacy & leadership training
- Secure electronic platform
- Sequential to parallel submissions
- Addressing Epidemics
  - CEPI & BMGF supporting Table Top exercise to develop framework by AVAREF
- Sustainability
  - Funding from WHO to countries and RECs.
  - Common formats for use in RECs and countries

Conclusion

- Joint reviews, improve worksharing, promote harmonization, efficiency and transparency
- Effective in emergencies/outbreaks - Ebola
- Limitations
- Further improvements required