COVID 19 Vaccine Safety Ecosystem Workshop

9th September 2020

COVID-19 vaccine safety monitoring: Challenges & Opportunities: The African Vaccine Regulatory Forum (AVAREF)

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REGIONAL OFFICE FOR Africa

The African Vaccine Safety Landscape

Multiple Vaccine Introductions in past 10 years

- Pneumococcal conjugate, rotavirus, meningitis conjugate, HPV etc..
- Only region implementing malaria vaccine with active surveillance for AESIs
- New vaccine against Ebola Virus Disease
  - Clinical Development to Licensure, WHO PQ
- Awaiting vaccines against COVID-19

Vaccine safety Monitoring systems

- Varying capacities to detect, report, investigate, analyze, manage risk and communicate
- Experience with pilots/ implementation –HPV, RTS,S, Conjugate meningitis
- NRAs vary in maturity levels and capacity to fulfill regulatory functions
- Varying resources and immunization programme performance

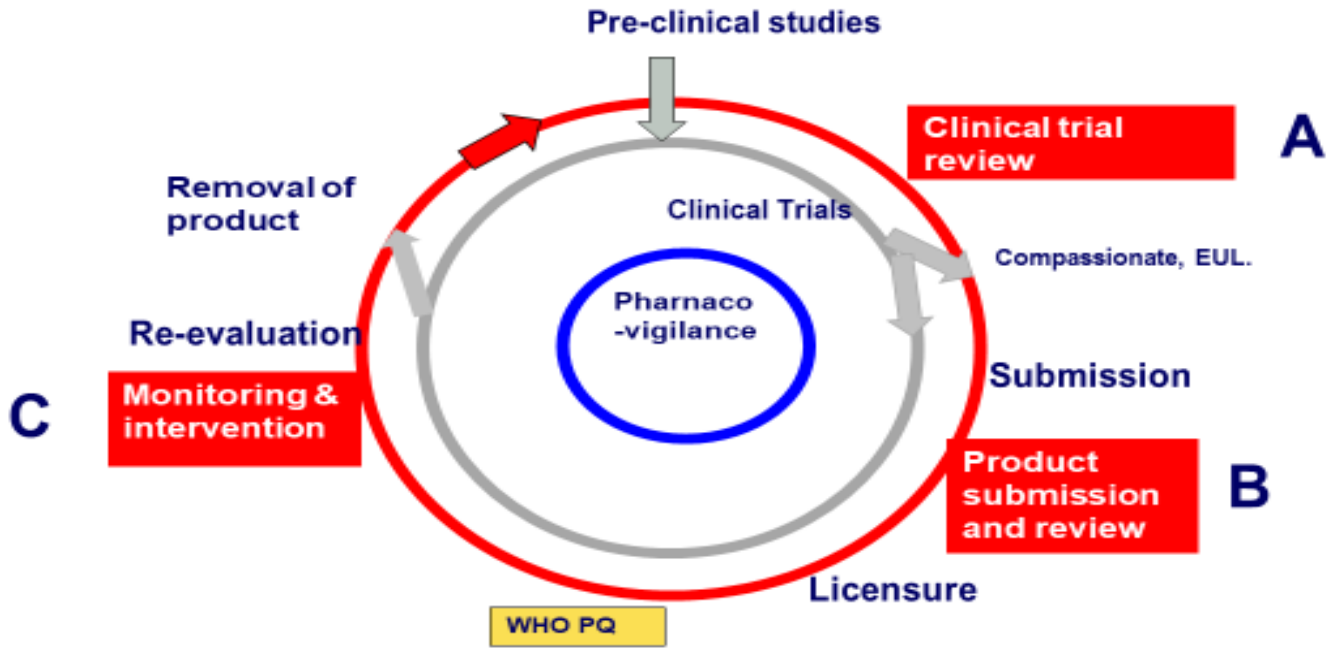
Additional Demands of COVID-19 vaccines

- New vaccine platforms and technologies
- Limited Clinical Trial Safety Data – 2 Trials of one candidate
- LICs & LMICs

For Successful Safety Monitoring of COVID-19 Vaccines in LICs and LMICs, Will Require:

- **Work, expertise, resources, and information sharing among countries in Africa**
- **Streamlined processes for consistent monitoring of AEFIs and AESIs**
- **Predictable timelines for all activities**
- **Strong collaboration and partnerships to address gaps and ensure readiness and adequate monitoring of safety of COVID-19 vaccines**
- **Capacity building; Common Tools and Guidelines for harmonized approach to monitoring the safety of COVID-19 vaccines**
- **Strong commitment at national and regional levels, and intense engagement of all Stakeholders**
- **Expert advice from the African Advisory Committee on Vaccine Safety**
- **Standardization of safety monitoring systems**
- **Better coordination of current harmonization programmes at sub-regional levels.**

Role of Regulators and Product Lifecycle



Key Decision Points Addressed at 9th Annual AVAREF Meeting November 2014, Pretoria

African Vaccine Regulatory Forum (AVAREF)

- Established in 2006
- Network of Ethics Committees and National Regulatory Authorities of 55 Countries
- Works towards capacity building, work and expertise sharing, and harmonization
- Facilitates clinical trials and product development for priority diseases

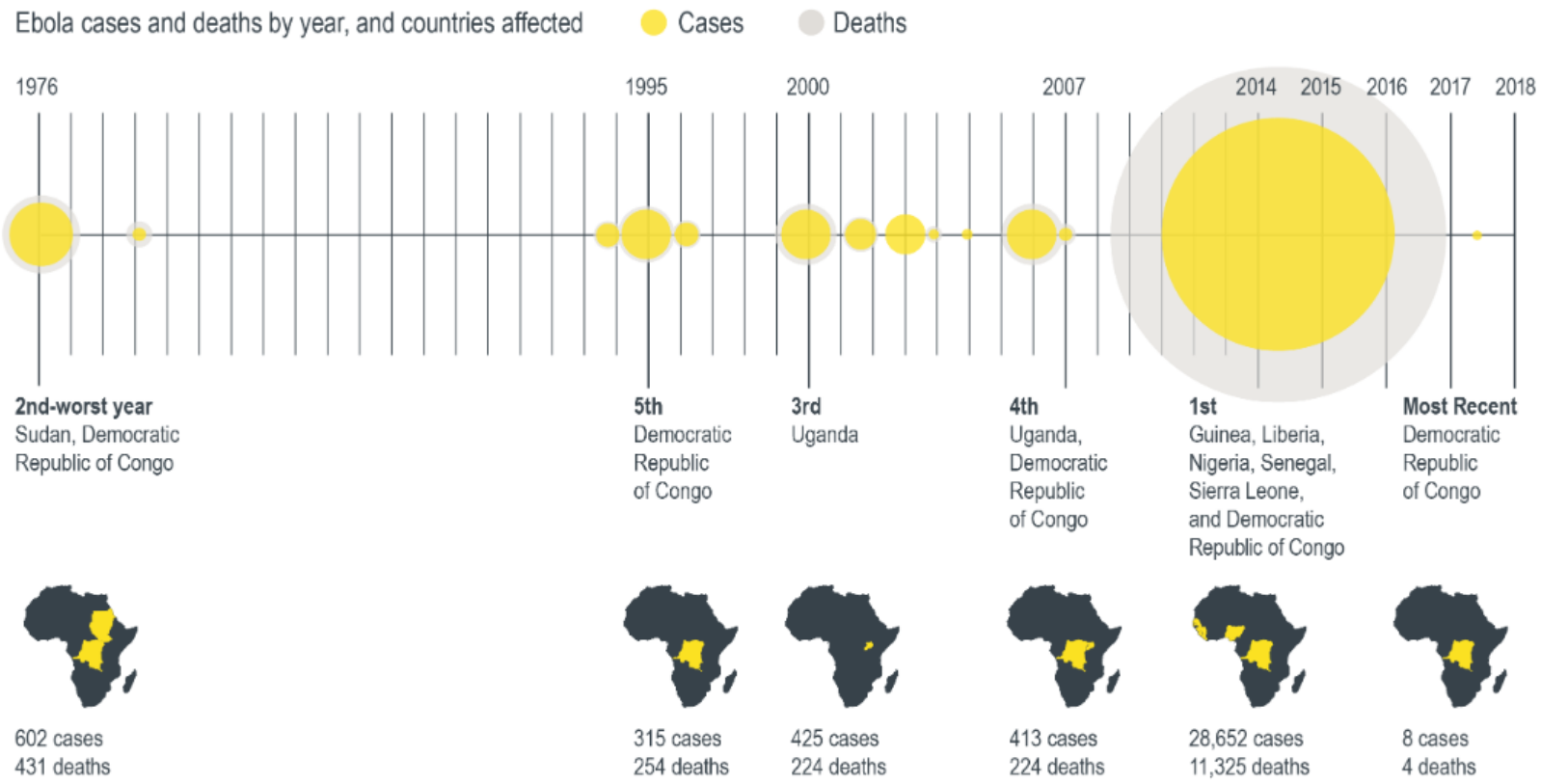
AVAREF Governance –
Clinical Trials Technical Working Group of AMRH Recognized by ICH

Steering Committee
- Heads of NRAs and Chairs of Ethics Committees
- Selected from the RECs – EAC, ECOWAS, IGAD, OCEAC, SADC
- Adopts recommendations, Guidance documents and policies
- Reports to the AMRH Steering Committee

Technical Coordinating Committee
- Selected from Ethics Committees and regulators of the RECs
- Develops tools and guidance documents
- Recommends strategy and workplan to Steering Committee

Partners
- Bill and Melinda Gates Foundation
- Paul Erhlich Institute (Biologics) - Germany
- US Food and Drugs Administration
- European Medicines Agency
- EDTCP
- Medicines and Healthcare Products Regulatory Authority UK

2014-2016: Largest Ebola Outbreak In History - Lessons Learned



Courtesy of MSD

AVAREF and Ebola Response

- Clear Roles and Responsibilities for NRAs, Sponsors other stakeholders
- Designated focal points and reviewers
- Facilitated joint reviews by 15 December 2014
- Involved NRAs of EVD-affected countries in reviews
- Harnessed expertise, tools and resources
- Proactively brokered interactions with sponsors and countries
- Engaged heads of institutions
- Supported institutions to monitor trials.

Akanmori BD, Bellah A, Ward, M & Rägo, L. (2015). WHO Drug Information 29 (2), 127-132

Implementation of Actions Agreed

- Pre-submission meetings
- Joint Reviews of clinical trial applications
- Participation in licensure and WHO Prequalification assessments of Ebola Vaccine
- Post-licensure and WHO PQ National Approvals of Ebola vaccine

AVAREF Contribution to COVID-19 Research and Development

- **AVAREF virtual forums** for engagement of product developers, scientists, and key research centers in Africa
- **Capacity building of members** through weekly updates on regulatory status of product development for COVID-19
- **Providing scientific advice** to COVID-19 sponsors and Product Development Partnerships (PDPs)
- **Expedited Joint/Assisted reviews of** CTs for products against COVID-19
- **Common Tools and Guidelines** to facilitate harmonized CTA processing

The Added Value of AVAREF

Early scheduling of meetings and meeting deadlines

Expedited response and availability of all stakeholders along the process steps

Efficient communication through digital tools (SharePoint, video conferencing, etc.)

Strengthened collaboration and cooperation to allow each stakeholder to meet the deadlines

Adaptation of Process to the emergency and remote working context

- Electronic submission and electronic completion of administrative requirements
- Remote online meetings

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Monitoring Safety of COVID-19 Vaccines: WHO Role

- **Implementation, Monitoring and Evaluation through WHO Country Presence**
- **Seamless Collaboration across Offices, WCOs to ROs to HQ**
- **WHO Leadership and Engagement of Partners**
- **WHO Technical Expertise and Broad Partnerships**
- **Stakeholder Engagement**

END

Thank You

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