



AFRICAN VACCINE REGULATORY FORUM (AVAREF): ROLE IN RESEARCH AND INNOVATION

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African Region

UHC/UCN

Universal Health Coverage/Communicable
and noncommunicable Diseases



Four points to be covered...

Global Health Context

Overview of AVAREF

AVAREF: Role in Vaccine Research
and Innovation

Key messages

Global Health Context

- Biomedical research in Africa has surged in the past decade
- A regulatory platform is needed to improve expertise, access to therapies, and regulatory efficiency
- Regulatory efficiency is critical

OVERVIEW OF AVAREF

A Network of 55 member countries

Overview of the African Vaccines Regulatory Forum (AVAREF)

Established as an informal network 17 years ago by WHO

A Vision of An African population with timely access to safe and efficacious medical products of assured quality.

Uses a network approach (driven by member states) to build technical/scientific expertise, competence, and skills required to support regulatory decision making.

Capacity building and training in member countries for both NRAs and NECs including clinical trial optimization exercises...

Collaborating effectively with several partners and stakeholders including AU agencies such as AUDA-NEPAD, US-FDA, European Medicines Agency, German Paul Ehrlich...

National Immunization strategies



African Vaccine regulatory Forum (AVAREF)

- **The African Vaccine Regulatory Forum (AVAREF)**, a network of National Regulatory Authorities (NRAs) and Ethics Committees (ECs).
- Established in 2006 by the WHO to build capacity & improve the harmonization of practices in support of product development.
- Help NRAs, ECs, and sponsors to achieve consensus on regulatory and ethics questions surrounding R&D of medical products.

AVAREF Objectives

To increase the efficiency and quality of reviews and inspections and the timeliness and transparency of regulatory decisions for all interventional trials conducted in Africa

To promote patient safety

To accelerate the African Medicines Regulatory Harmonization (AMRH) process, linking all Regional Economic Communities (RECs)

To stimulate innovation and research in Africa

To enhance emergency preparedness on the continent, in RECs and in individual countries

AVAREF Renewed Context

Effects (Impacts) of Globalization, Modernization, Advances in Technology, Demographic Changes in Africa, etc., on Results for Africans

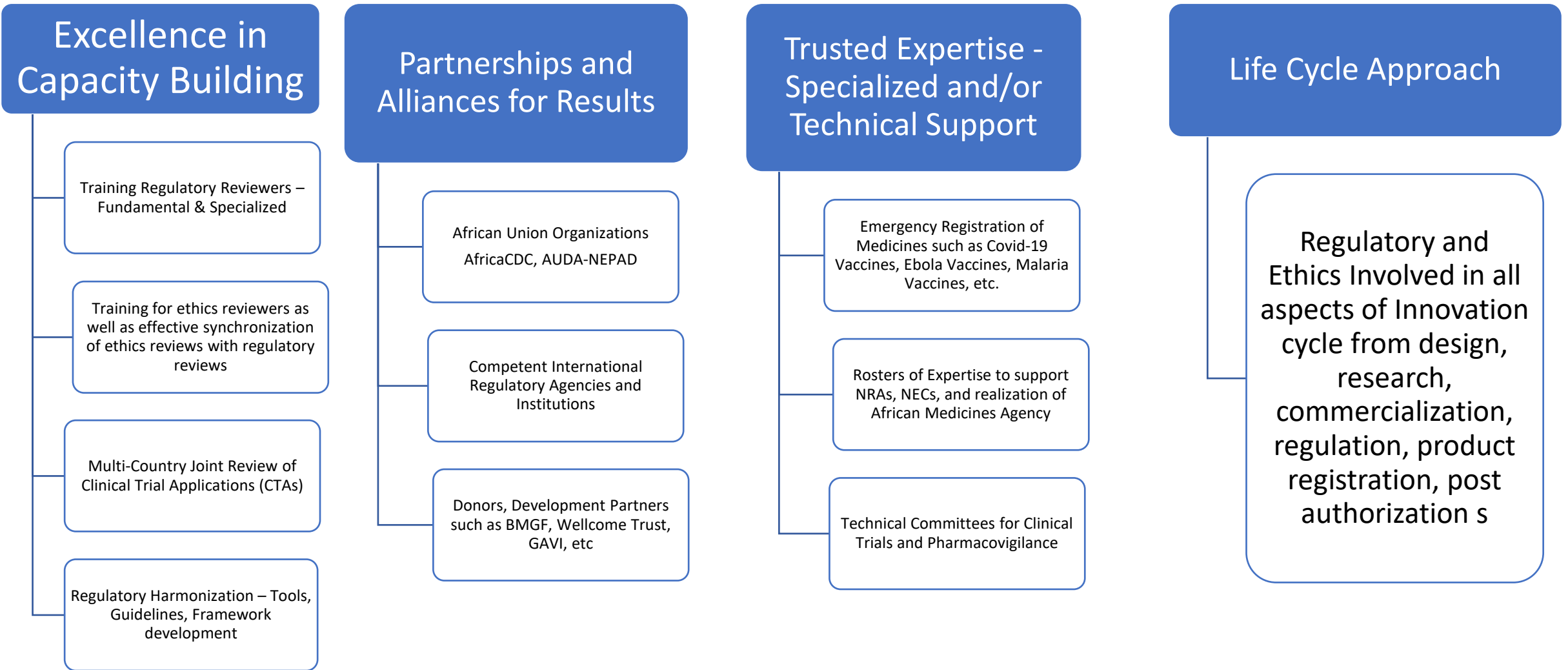
Emerging ecosystem which is complex, dynamic, and in its infancy hence requires a renewed approach towards effective capacity building for results and impacts

Effective interactions required from the involvement of multiple actors from multiple sectors within the emerging ecosystem

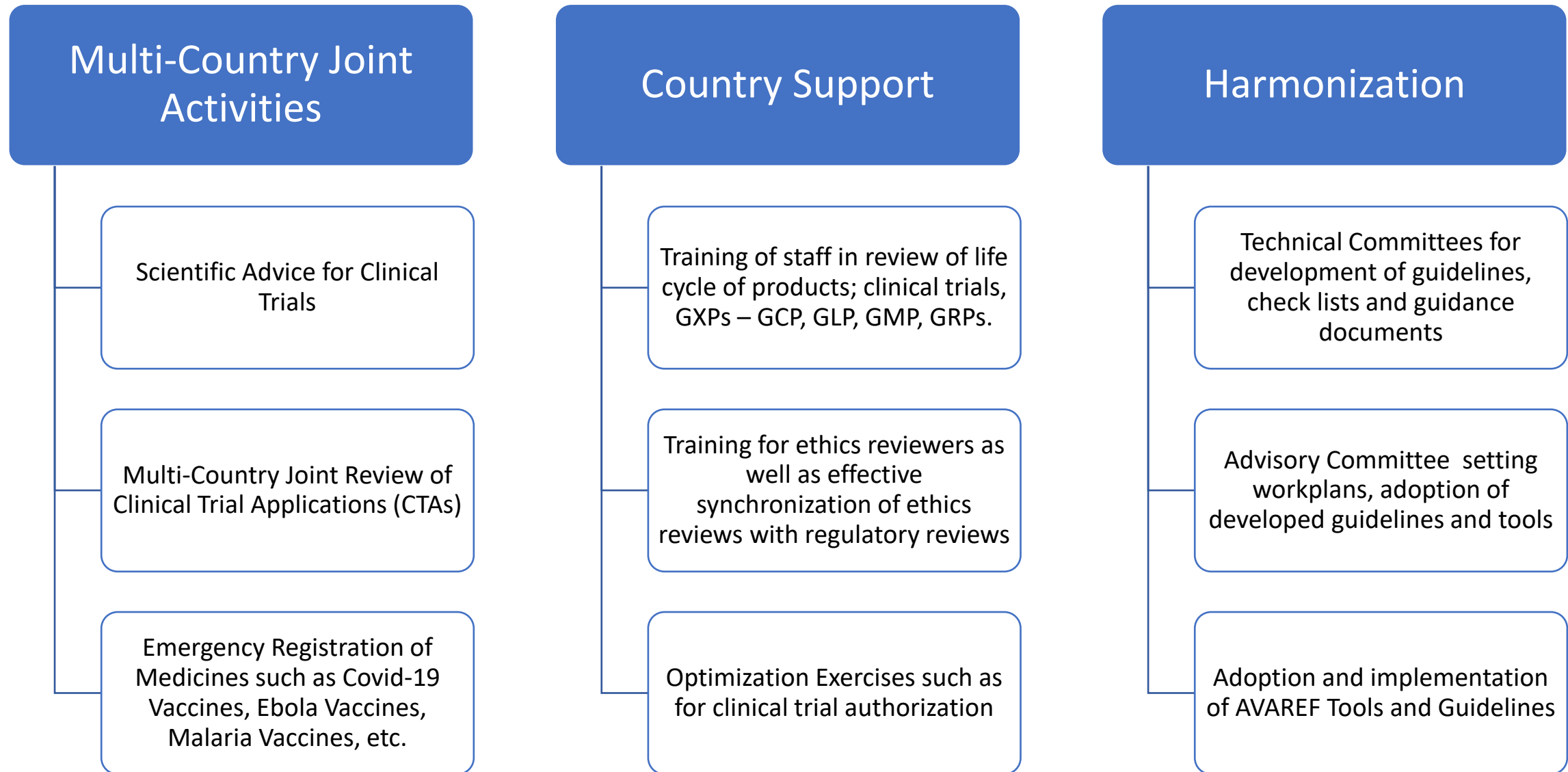
AVAREF has a Renewed Strategic Approach based on 4 Reinforcing Pillars of Action

An urgent need for innovation and real results for Africa

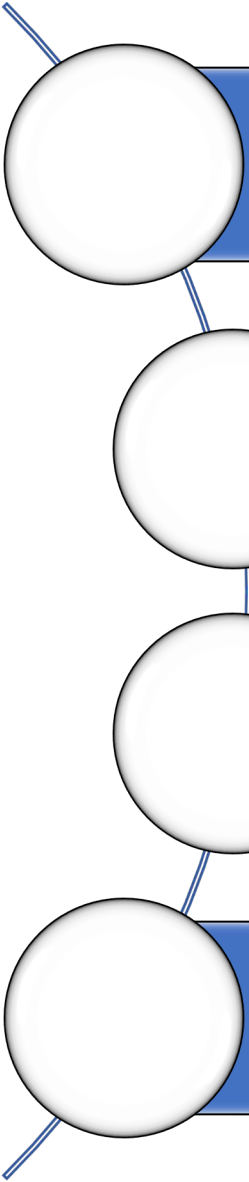
AVAREF 4 Pillars for Excellence in Capacity Building



A Strong Record of AVAREF Capacity Building Activities



AVAREF Achievements



Extensive contribution to regulatory harmonization through the development of tools and guidelines which have been adopted by over 26 member states

AVAREF has supported authorization several multi-country clinical trial applications for neglected diseases such as Monkeypox, Lassa fever, and Rift Valley Fever

AVAREF has used its platform in emergencies for the authorization of clinical trials as well as registration of products such as Ebola, Covid-19, Malaria vaccine, etc.

Active calendar of events including regular webinars, country support, etc.

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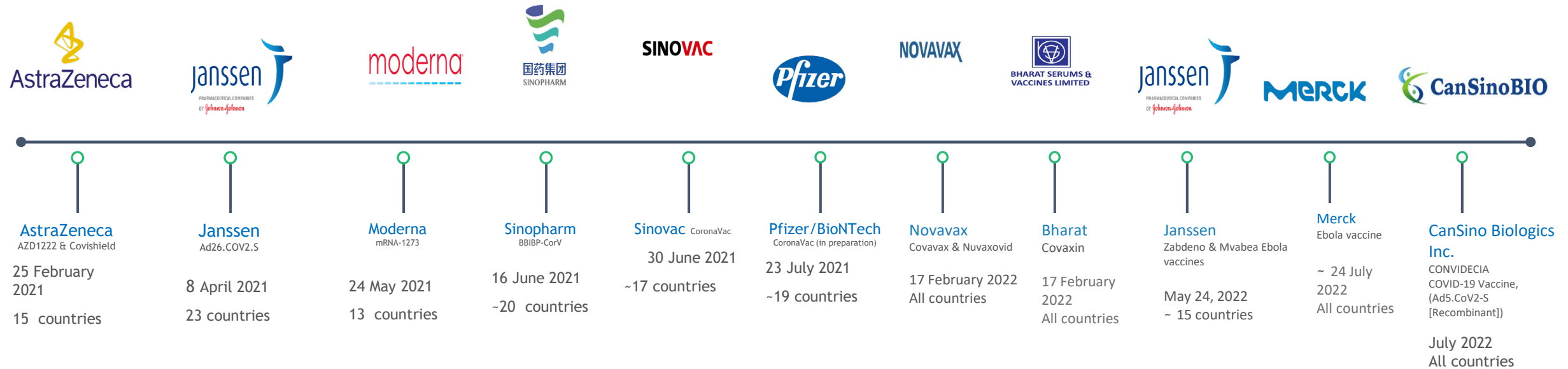
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AVAREF Platform used to facilitate emergency registration of COVID-19 vaccines 2021-2022



AVAREF: Role in Vaccine Research and Innovation

Vaccine Safety is of Paramount Importance



Disease prevention

Vaccines are given to **prevent** disease, this limits the tolerability of adverse events → risk/benefit assessment.

Risk benefit assessment

Vaccines are given to **healthy population** hence the risk benefit assessments are different from that of other medicines; hence the risk tolerance is very low.

Regulatory oversight key

Vaccines are administered to **large cohorts** of **healthy** infants and adults → enhanced regulatory oversight required



AVAREF's Role in Vaccine Research and Innovation

Use of Platform and network of National Regulatory Agencies, National Ethics Committee, and Institutional Review Boards for Clinical Trials as the basis of a network approach to Vaccine Research and Innovation

Establish network of major clinical trials and principal investigators involved in vaccine research for identification of research challenges, identification of research priorities, research gaps, and generation of potential solutions

Establish a Continental Expert Working Group on Vaccine Research and Innovation to guide the setting of a capacity building agenda as well as development of a strategic business and operational plan for action

- Mechanisms for identification or practical continental research priorities
- Mechanisms for stable funding for research and accountability

Building and developing a coalition of partners to drive the agenda for research innovation in the vaccine ecosystem in Africa

AVAREF's Role in Vaccine Research and Innovation (2)

Researcher capacity building geared towards increasing African-led or inspired internationally funded research proposals.

Platform for interface between Researchers, Industry, and Investors (Donors)

- Best practices in research – Good Research Designs, Informativeness, Statistical Support, etc.
- Training in writing effective grant proposals to be competitive in international granting marketplace

Use of a life-cycle approach for vaccine research and innovation

- Fostering vaccine research to enrich the ecosystem to support innovation
- Support for commercialization, patent protection
- Effective policy support for the research enterprise in Africa

Facilitating access to expertise, mentorship, and partnerships with major international research institutions interested in diseases of interest to Africa

Strategic Priorities of AVAREF Vaccine Research and Innovation

Develop/Expand partnerships and/or alliances to facilitate delivery of results

Development (and delivery) of enhanced technical/scientific training and capacity building activities to support vaccine researchers in Africa

Promote research and innovation in Africa to enrich the ecosystem that supports biotherapeutics, including vaccines.

Support the establishment of a dynamic Vaccine Research Network based on the AVAREF network model



Key messages

The level and extent of research and innovation in Africa is significantly lower than required and there is tremendous opportunities for growth

A need for all parties to enhance (ramp-up) its activities (approaches) to ensure that untapped resources ranging from talent of the scientist to untapped genetic diversity is harnessed for the production innovative products for global use

Establishment of a platform for the global research needs to be presented so that African researchers can effectively contribute has the potential to be a global game changer, especially when researchers meet industry and users of research results.

Life cycle approach required to ensure viability of the vaccine research ecosystem in Africa. Hence efforts should be along the innovation life cycle from design to product licensing, use, and disposal.

WHO (AVAREF) committed to use its network approach, experience, and ability to bring multiple stakeholders together to strengthen the technical capacity for this initiative.

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THANK YOU