African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

Africa Centres for Disease Control and Prevention (Africa CDC)

Africa CDC Consortium for COVID-19 Vaccine Clinical Trials (CONCVACT)

(Addendum to the Africa COVID-19 vaccine development and access strategy)

August 2020

Context

The *Africa Joint Continental Strategy for COVID-19* is underpinned by the need to limit transmission, prevent deaths and reduce associated harms. Participation by African nations in clinical trials is an essential step to ensure that sufficient data is generated on the safety and efficacy of the most promising vaccine candidates among the region's populations. While current COVID-19 clinical trial activity on the continent is limited, Africa has substantial experience and capabilities to conduct clinical trials for preventative vaccines across a range of diseases, and many organizations on the continent are working tirelessly to help prepare additional trials on potential COVID-19 vaccines. As the number of candidate vaccines in the development pipeline continues to increase, it will be important for organizations responsible for managing clinical trials in the region to partner with vaccine developers to identify potential and appropriate trial locations, provide support to remove any critical obstacles impeding commencement and progress of trials, and to provide oversight ensuring that trials are conducted safely and ethically.

The African CDC Consortium for COVID-19 Vaccine Clinical Trials (CONCVACT) has been established to convene the diverse organizations working across the continent under one umbrella, to help accelerate progress on planned and future COVID-19 vaccine trials that take place in African nations.

The CONCVACT is fundamentally an African initiative and is closely aligned with African priorities and interests. Vitally, it will partner with, and strengthen the capacity of, relevant institutions and networks throughout the continent. CONCVACT will focus primarily on research, and will promote the translation of scientific and clinical findings into substantive regional impact through political and regulatory engagement. In this way, the CONCVACT will provide regional stewardship and strengthen coordination in these urgent and important areas, and will not seek to exert control over them.

Objectives of CONCVACT

1. Facilitating the start and successful completion of clinical trials for *at least six* promising COVID-19 vaccine candidates.
2. Strengthening enablers of high-quality vaccine clinical trials on the continent.
3. Supporting the development of vaccine clinical trial sites/cohorts across all African sub-regions.
4. Accelerating post-trial regulatory approval, roll-out and uptake of safe and efficacious vaccines.
5. Fostering Africa-based vaccine manufacturing capacity.

Key activities under each objective of CONCVACT

1. **Facilitating the start and successful completion of clinical trials for *at least six* promising COVID-19 vaccine candidates**:

    a. Reach out to a **prioritized list of leading vaccine developers** to discuss the potential for partnering on clinical trials in Africa – include/focus on developers with varied candidate vaccine platforms.

    b. Identify the **most suitable potential trial sites,** which should have: (i) a track record of running high-quality trials (i.e. for stringent regulatory approval); (ii) availability of granular COVID-19 epidemiological data in the surrounding geography (including viral prevalence, case numbers, projected growth etc.); and (iii) information on circulating virus strains.

    c. Define the **necessary 'enablers'** to attract vaccine developers, such as resource sharing, help with coordination of local stakeholders, expedited timelines etc.

d. Negotiate and enter into **clinical trial partnerships** with committed developers and selected trial sites.

e. Plan for and **commence** appropriate and ethical trials.

2. Strengthening enablers of high-quality vaccine clinical trials on the continent

a. Establish an **independent review board** comprising highly-qualified technical experts to provide guidance, assistance and oversight to clinical trials on the continent, jointly covering a range of key issues (e.g. regulatory, ethics, safety, training and education, quality assurance, national laboratory strengthening, supervision and monitoring etc.).

b. Identify/mobilize required **resources** to both operate CONCVACT and direct funding towards individual clinical trials and capacity building activities. This can be done through engagement of global donors, African governments and other key stakeholders.

c. Increase **public awareness of and support for hosting well-regulated clinical trials** in African countries. This can be achieved by engaging with African and global media along with key opinion leaders to create messaging and provide support to communicating with and engaging communities effectively.

d. Ensure laboratories in Africa are **capable of analysing samples** collected through clinical trials, in order to help enable and safeguard related intellectual property.

3. Supporting the development of vaccine clinical trial sites/ cohorts across all African sub-regions

a. Facilitate the partnerships required among national, regional and global research institutions to develop vaccine trial sites.

b. Support the development of **experienced and qualified staff** to support clinical resource organizations and sponsors of target trial sites.

c. Support the training and deployment of **good clinical practice (GCP) investigators** to target trial sites (a key function of the clinical trial community).

d. Enable access to accurate, granular and regularly updated **epidemiological data** in potential trial site populations (e.g. by facilitating training of epidemiologists).

e. Advocate for national regulatory bodies to **improve approval processes** for trial sites, export licenses, patient samples, etc. in target countries.

4. Accelerating post-trial regulatory approval, roll-out and uptake of efficacious vaccines

a. Provide objective, fact-based **scientific and clinical guidance** on interpreting the results of clinical trials, to help inform future regulatory and public health decision-making regarding vaccine approval and roll-out.

b. Promote the standardization of **protocol review and regulatory approvals** for COVID-19 vaccines, by engaging national regulatory authorities (through the African Medicines Regulatory Harmonization Initiative) and with inputs from global public health bodies (e.g. World Health Organization).

c. Establish national **pharmacovigilance systems** to promptly capture details and report on the side-effects of approved COVID-19 vaccines.

d. Provide guidance on effective **community engagement** to ensure community support for and uptake of COVID-19 vaccines.

Organizational structure of CONCVACT

1. CONCVACT is **co-chaired** by Prof. Salim Abdool Karim (Head of the Ministerial Advisory Committee for COVID-19 in South Africa) and Prof Samba Sow (Director General of the Center for Vaccine Development in Mali).
2. Together with the co-chairs, a **Steering Committee** has responsibility for setting priorities and overseeing the operational execution of the CONCVACT strategic objectives. The Steering Committee will be made up of the chair and co-chairs of the sub-committees and five independent biomedical, anthropological, ethical, risk communications and community engagement experts.
3. The consortium will be supported by a **stakeholder group** with experts representing the five geographic regions of Africa. This will include representatives from key organizations working in the clinical and regulatory space, such as the Africa Academy of Science Clinical Trials Community, Institute Pasteur, the African Vaccine Regulatory Forum (AVAREF), the African Medicine Agency (AMA), the African Union Development Agency/New Partnership for Africa's Development (AUDA/NEPAD), the European & Developing Countries Clinical Trials Partnership (EDCTP) and others.
4. A **Technical Advisory Group (TAG)** will be established, comprising key international and local experts to support the preparation and execution of clinical trials, as well as the dissemination of results.
5. The five **sub-committees** are: Scientific review; research regulations, ethics and GCP; network and site evaluation; capacity development; and community engagement.
6. The consortium will be supported by a **secretariat** staffed by Africa CDC, who will be responsible for the operational execution of the key functions listed above.
7. The **seed cost** to run the consortium is yet to be determined.

Structure of the Africa CDC Consortium for COVID-19 Vaccine Clinical Trial (CONCVACT)

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