

AVAREF Webinar Series – May/June 2021

AU Smart Safety Surveillance – COVID-19 response and Country Experience Sharing

6 May 2021



World Health
Organization

REGIONAL OFFICE FOR
Africa

Agenda

	UTC/GMT
Opening Remarks	2:30PM-2:35PM
Introductions	2:35PM-2:40PM
Short remarks by Partners	2:40PM-2:45PM
Introduction of Speaker	2:45PM-2:50PM
AU Smart Safety Surveillance - COVID-19 response and Country Experience Sharing	2:50PM-3:30PM
Questions, Answers, and Discussion	3:30PM-3:50PM
Closing Remarks	3:50PM-3:55PM
Announcements	3:55PM-4:00PM

Opening remarks:

Dr Shanthi Pal

Agenda

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Introductions:

Prof. Dicky Akanmori

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Short remarks by Partners:

Dr. Ambali Aggrey

Senior Advisor, AU Development Fund

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Speaker



Mr. Hudu Mogtari
Programme Lead,
African Union Smart Safety Surveillance
(AU-3S)

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AU Smart Safety Surveillance COVID-19 response and country experience sharing

Agenda

- Presentation of AU-3S programme

COVID-19 safety surveillance & benefits of AU-3S

- Ghana
- South Africa
- Nigeria

Q&A

Hudu Mogtari

George Sabblah

Florah Matlala

Uchenna Elemuwa

The AU-3S programme aims to strengthen safety surveillance in Africa



Pharmacovigilance is still at an early stage in most African countries



Limited safety data packages before product launch (data only from pre-approval trials, targeted only to LMICs, release in emergency situations)



Low adverse event reporting across countries despite recent improvements



Siloed pharmacovigilance systems with data often not fully shared between the EPI and NRA, fully analysed, or acted upon



Limited safety expertise to support signal detection & risk-assessment; focus on signal management of serious adverse events rather than signal detection



AU-3S is a 10-year programme to develop a continental end-to-end safety surveillance system for priority medical products for Africa

AU-3S has been launched by AUDA-NEPAD to:

- 1 Improve medicines and vaccine safety for patients in Africa and globally
- 2 Enable African ownership and the ability to act on their own data (e.g. AfriVigilance database - data integration, analysis, and decision making)
- 3 Strengthen PV expertise among country and continental stakeholders
- 4 Increase confidence in accelerated product development and in an emergency response

To do so, regulators and AUDA-NEPAD are collaborating with continental and global partners



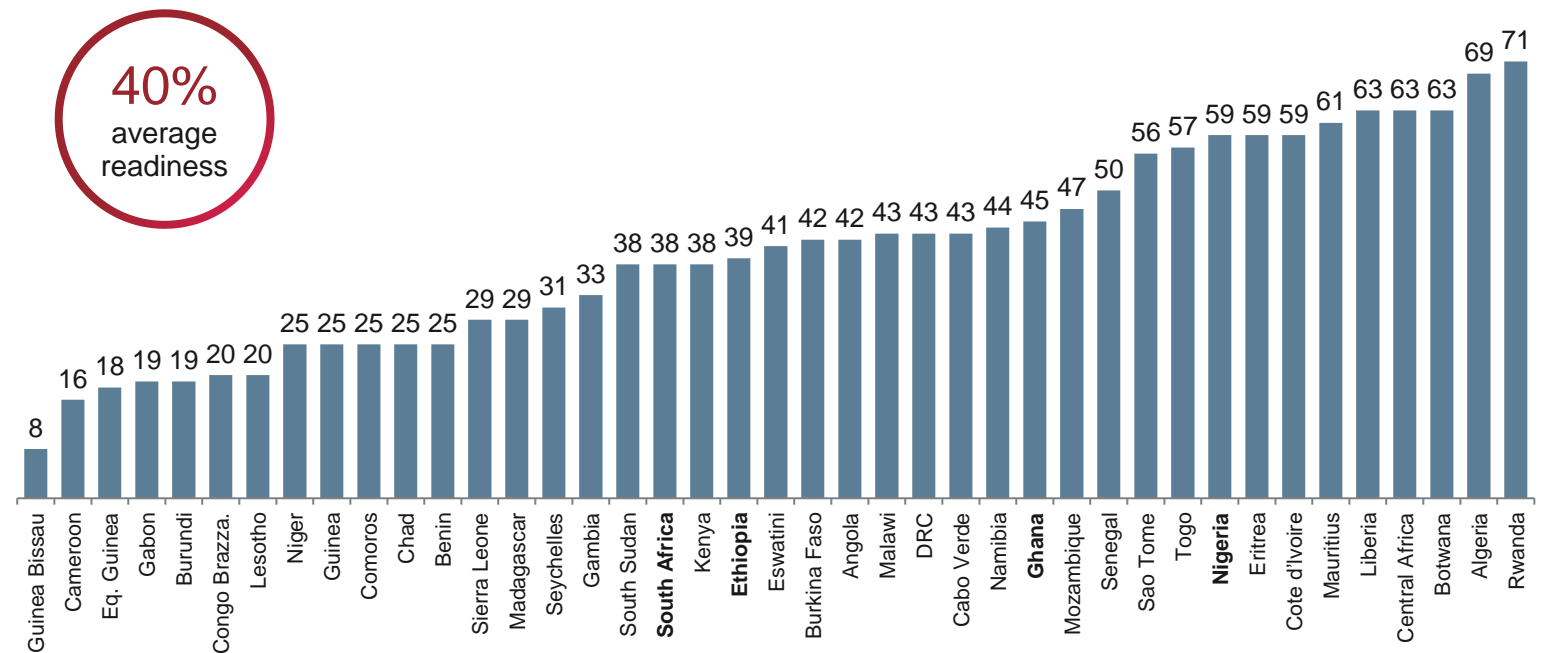
COVID-19 reinforced the need for strong African Pharmacovigilance

COVID-19 vaccine roll-out will require efficient PV

- COVID-19 vaccines have been developed in record time
- Countries will have to deal with multiple vaccines from different developers and various manufacturing sites
- The African continent has hosted a limited number of clinical studies
- Safety surveillance will also be critical to support and advocate the immunisation campaign

In most African countries, PV systems were not ready for the roll-out of COVID-19 vaccines

VIRAT¹ results - Safety surveillance score per country (%), as per 26 Jan 2021



1. Vaccine Introduction and Readiness assessment; caveat: score reflects what has been reported by countries
Source: WHO AFRO VIRAT

AU-3S is currently supporting 4 countries' safety surveillance for COVID-19 vaccines

AU-3S COVID-19 response: Current focus

Countries



- Ethiopia**
Original entry point for COVAX
- Ghana**
Chair of AVAREF & ML3
- Nigeria**
Original entry point for COVAX
- South Africa**
Largest clinical trial base in Africa

AU-3S pilot countries comprise ~30% of Africa's population

AfriVigilance: Long-term objective of AU-3S



- Creating a **centralised African-owned** safety database (AfriVigilance)
- Integrating data** from siloed programmes
- Covering full **lifecycle** of **priority** medical products

Continental smart safety surveillance



Testing solutions to enable faster progress in long-term programme

Products

COVID-19 vaccines

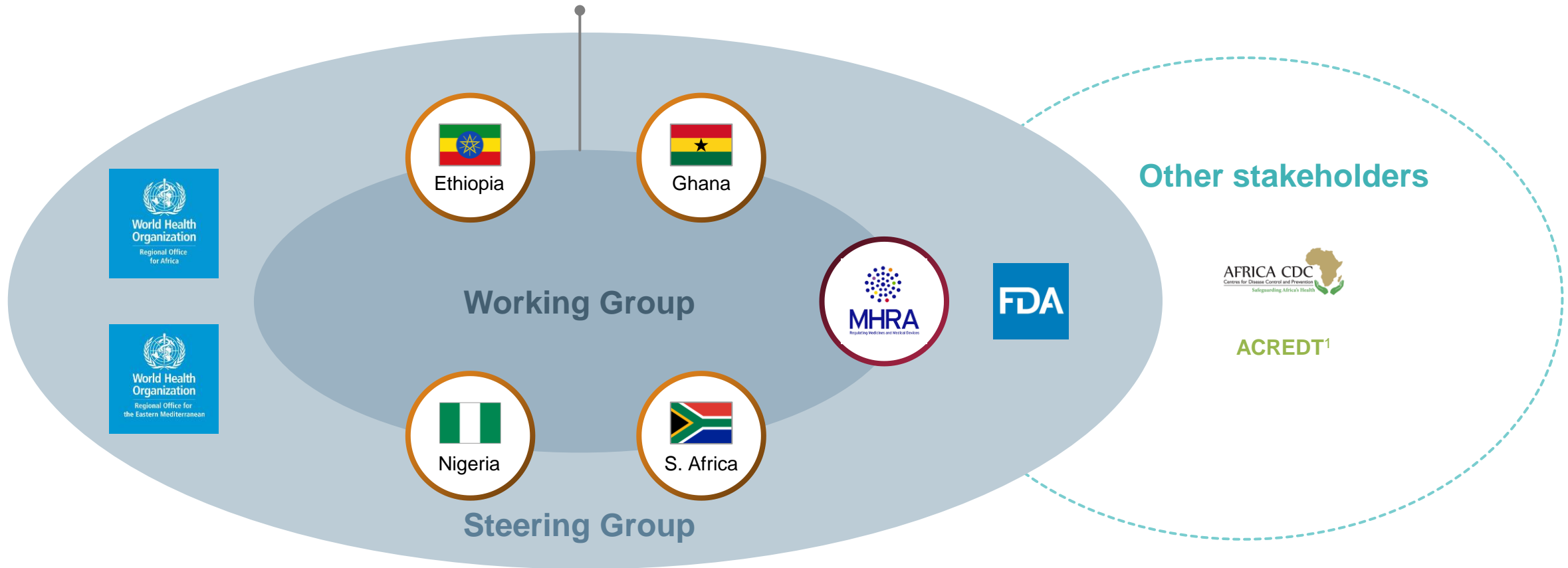


New & innovative products from the African Union priority disease areas¹

1. Malaria, Tuberculosis, HIV/AIDS, plus emergency diseases: Ebola, COVID-19

AUDA-NEPAD works with a range of partners and stakeholders in AU-3S

Working with NRAs and EPIs from pilot countries



○ Pilot countries ○ Technical partner

1. ACREDIT = African COVID-19 Vaccine Readiness and Deployment Taskforce

Phases of work in AU-3S COVID-19 response and beyond



Engage with NRAs & EPIs to identify challenges to readiness for COVID-19 vaccine safety surveillance



Oct – Dec '20



Design solutions to address identified gaps, and develop a roll-out strategy for them



Nov '20 – Feb '21



Support in-country teams to rapidly roll-out the solutions in the 4 countries



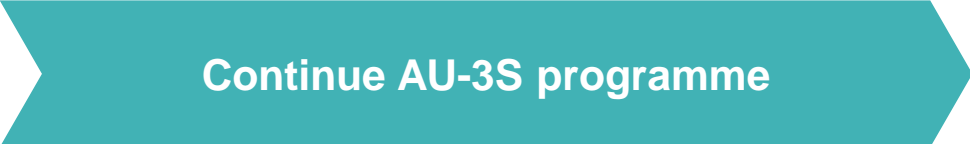
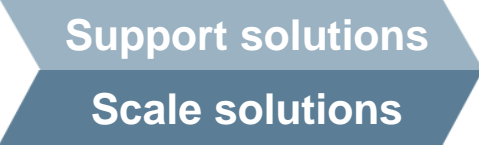
Feb – May '21



Support to 4 countries to optimise solutions; scale the COVID-19 solutions to other African countries



May '21 – Apr '22



'21 onwards Continue on to objectives and activities of longer-term AU-3S programme

First, the AU-3S team identified safety surveillance gaps to close

Landscape assessment was conducted by AU-3S team...

Held **15** meetings with NRAs and other key stakeholders

Reviewed **31** safety monitoring-related policies, laws, guidelines and forms

Synthesised findings to determine areas for project support

...to identify critical safety surveillance gaps in each of the 4 pilot countries



Capabilities

- Capability & capacity gaps across all countries in safety monitoring



Tools and policies

- Need to move from paper reporting to e-reporting to help drive data quality and reporting rates
- Safety monitoring gaps in policies & guidelines



Collaboration

- Limited coordination between NRA & EPI
- Limited ability to share information between countries

Where are we today? Rolling-out cross-country and in-country solutions



Data collection

Data storage
& analysis

Signal
management

Signal response &
decision making

Safety
communication

Apr-May 21

Develop an interim cross-country **data integration & signal detection system**

Launched

Launch the **Joint Signal Management Group** for aggregate signal reports

Cross-country

Jan-May 21

Facilitate **capability strengthening** trainings with the MHRA

In-country

Expand **electronic** vaccine data collection (through Med Safety App)

Completed

Creation of a vaccines AEFI reporting form for the Med Safety App

Ongoing

Support NRA & EPI in roll-out of Med Safety App for COVID-19 vaccine (including communications, training & operating model changes)

Roll-out timeline

AU-3S is encouraging e-reporting of adverse events through the Med Safety App

The Med Safety App is a **mobile application** for strengthening **spontaneous reporting** of adverse events and two-way **information sharing**

AU-3S developed a form for reporting of **adverse events** from **vaccines**



Can be used by both **healthcare professionals** and the **general public**



Replaces the need for paper forms and as such strengthens **data quality**



The Vigilance Hub back-end allows the **NRA & EPI** (for vaccines) to analyse safety data in **near real-time**

The AU-3S Joint Signal Management Group has recently launched

Key objectives



- **Validate** and **assess** signals from member countries' combined data
- Share **findings** and **recommendations** with member countries' national committees¹
- Be a forum for **knowledge** and **experience sharing** on signals and other safety surveillance topics

Scope



- **COVID-19 vaccine AEFIs** to start, with future scope expansion to be agreed upon
- AU-3S JSM Group to review **aggregate signal reports** from the interim DISD system, i.e. from an aggregated dataset across the 4 countries
- National committees¹ to keep their **full scope** of responsibilities & activities

Participants

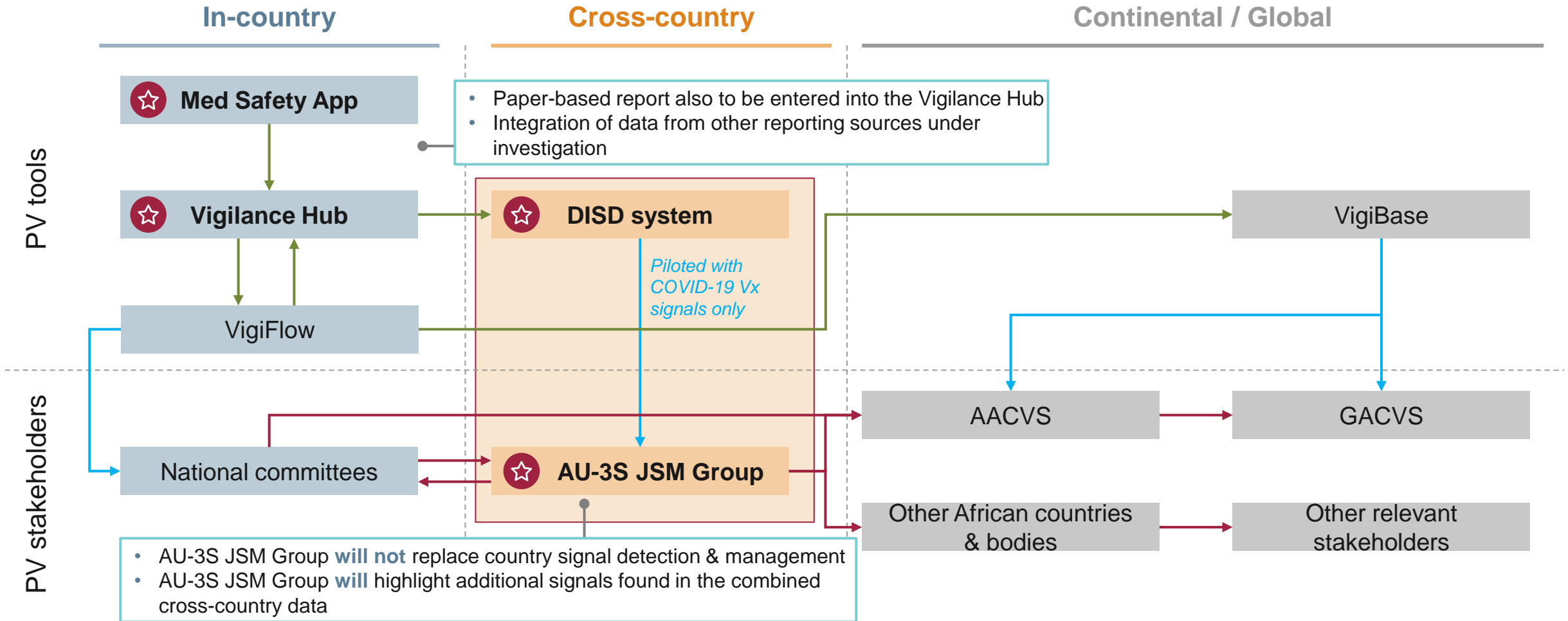


- AU-3S JSM Group **members** from 4 pilot countries:
 - **NRA & EPI** representatives
 - **National committee**¹ representatives
 - Additional **experts**
- Members are supported by a **secretariat**:
 - Run by **AUDA-NEPAD**, with support from the **MHRA**
 - Participants from 4 pilot countries to **build capabilities**

The AU-3S JSM Group was launched late April, with initial meetings held successfully

1. Ethiopia = National AEFI Committee; Ghana = Technical Advisory Committee; Nigeria = National Expert Committee; South Africa = National Immunisation Safety Expert Committee; DISD = Data Integration & Signal Detection; JSM = Joint Signal Management

AU-3S solutions work as part of a larger, inter-connected system



☆ AU-3S COVID-19 response solution → AEFI reports → Signal reports → Safety findings & recommendations

AACVS = African Advisory Committee on Vaccine Safety; DISD = Data integration & signal detection; GACVS = Global Advisory Committee on Vaccine Safety; JSM = Joint Signal Management; Vx = Vaccine

Additional AU-3S activities to support 4 pilot countries



Provide **funding** for in-country **safety strengthening** activities

Completed



Review in-country **PV regulations & policies** compared to **WHO's COVID-19 safety surveillance policy**

Completed



Identify relevant **stakeholders, resources & tools** to support countries in non-safety areas, notably advocacy

Completed



Publish **reflections & recommendations** to implement safety surveillance in the African context

May '21



Support **experience sharing** between countries to strengthen capabilities

Ongoing

Objectives of the AU-3S programme

Short-term



Continue support to 4 pilot countries to **entrench** and **optimise** the AU-3S solutions

Medium-term



Scale-up the AU-3S solutions for COVID-19 vaccines to **additional African countries**

Longer-term



Develop **AfriVigilance**, a centralised African safety database, & expand to additional **priority products**

For more information on AU-3S, please get in contact with us



Contact details

AU-3S Programme Office at au3s@nepad.org
Hudu Mogtari (Programme Lead, AU-3S) at HuduM@nepad.org



AU-3S microsite

Access: www.nepad.org/microsite/african-union-smart-safety-surveillance-au-3s



AU-3S newsletter

We will be soon releasing the first AU-3S newsletter, which will be distributed to the AVAREF network



We will now hear
from our NRA
representatives,
engaged in AU-3S



George Sabblah

Head of Safety Monitoring Department, Ghana
Food and Drugs Authority



Florah Matlala

Head of PV Unit, South African Health Products
Regulatory Authority



Uchenna Elemuwa

Deputy Director PV/PMS, National Agency for
Food and Drug Administration and Control

Agenda

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Q&A

Status of Ghana's COVID-19 vaccine roll-out and safety surveillance

Vaccine roll-out

~850k

Total doses of
Covishield
administered



~2.8

Doses
administered
per 100 people

Priority groups



Health workers



Adults 60+



Frontline staff



Prominent persons

Safety surveillance training

Extensive roll-out of data collection training to vaccinators

- National, regional, & district level

MHRA capability strengthening for Ghana FDA & EPI

- Training on end-to-end safety monitoring activities across 5 modules¹

Adverse event reporting tools



Paper forms



Hotlines



Med Safety App



Online portal



Email



WhatsApp

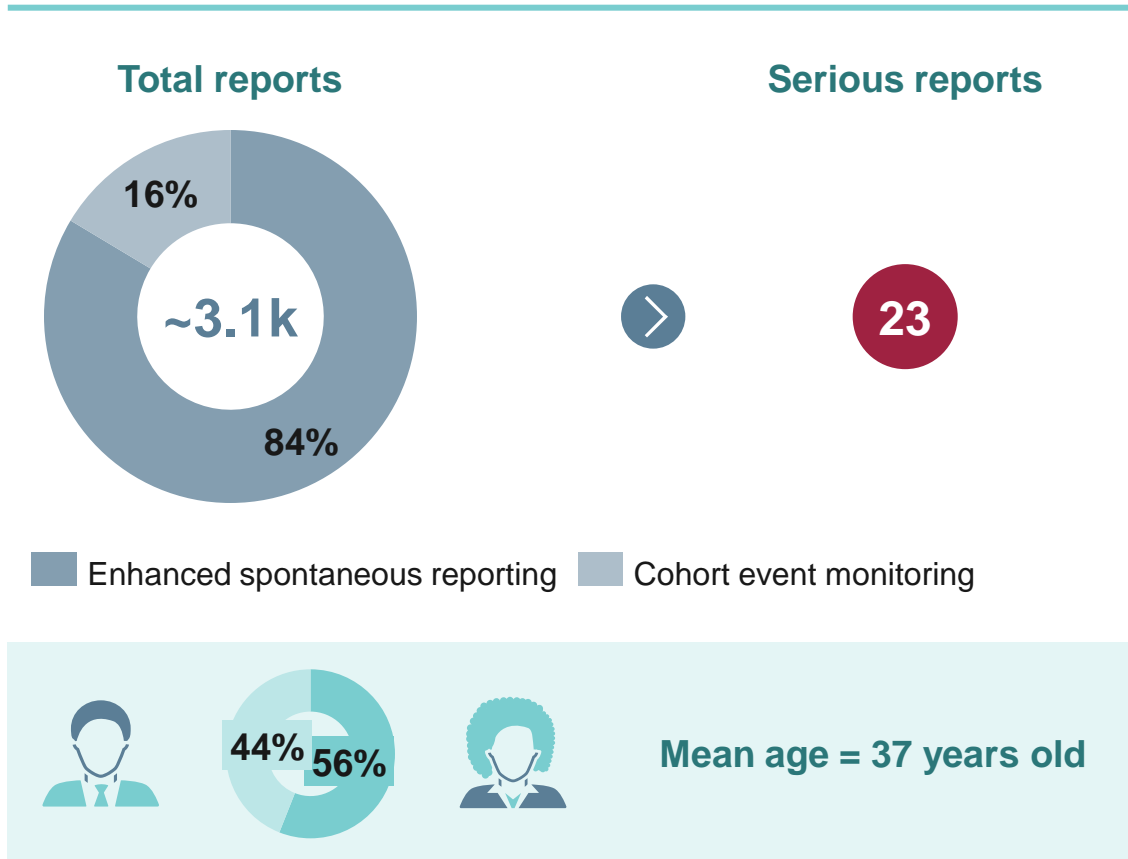
Causality assessment committee

Joint COVID-19 Vaccine Safety Review Committee

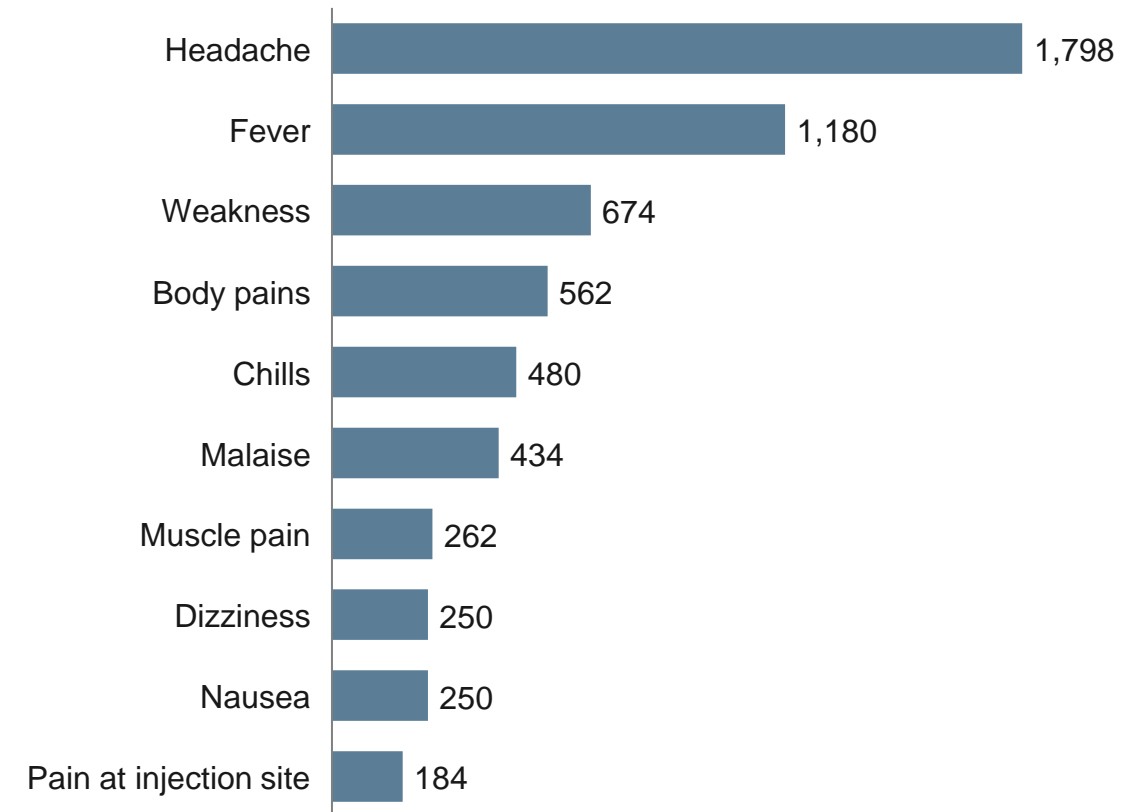
- 11-member independent committee of experts
- Advises the FDA based on review of COVID-19 vaccine safety information
- Meets fortnightly

~3.1k adverse event reports have been received to date

Breakdown of adverse event reports received



Top 10 most commonly reported adverse events



Benefits of AU-3S for Ghana safety surveillance



Ownership of our data within an African database, helping us identify safety issues that are specific to the African continent and the African population



Experience sharing between countries, sharing best practices as well as building confidence in our safety surveillance system



Pick up your phone and have your own safety in your hand: HCW and public having access to a very simple tool to report, and regulator receiving timely AE reports



Consolidated safety dataset with other African countries and cross-country Joint Signal Management Group, allowing us to identify safety signals that might have been missed otherwise



Strengthening of our PV capabilities through our involvement in the Joint Signal Management Group



Access to detailed and **practical trainings** for our staff, learning from MHRA experience (successes and challenges faced)

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Q&A

Background information

- Medicines safety monitoring system in South Africa - 1987
- South Africa joined the WHO PIDM - 1992
- The EPI Programme - 1995
- 56,528 Individual Case Safety Reports (ICSRs) - May 2021
- No signals have been detected/identified

Challenges



Limited reporting

- Tools
- Awareness and training



Low capacity and capabilities to analyse collected data



Previously relied more on external evaluators



Pharmacovigilance budget

Benefits of AU-3S



Training

- Strengthening internal capacity
 - Review of pharmacovigilance submissions e.g., PSURs
 - Signal detection skills & capabilities
 - Informed decision-making



Access to tools

- Signal detection system
 - Joint Signal Management Group
- Med Safety App
 - Promote ADR/AEFI reporting
 - Interactive – feedback
 - Language translations



Collaboration

- Use of big data compared to single country's data
- Opportunity to learn from others
- Strengthened existing collaboration with EPI programme



Awareness

- Launch of the Med Safety App
- ADR/AEFIs reporting by the public & HCPs
- Increased visibility on social media, TV, and radio
- Training of healthcare professionals in partnership with NDoH



Sponsorship

- Prioritize pharmacovigilance activities
- Opportunities to have funding for active surveillance of COVID-19 vaccines

Origins of ICSRs in the Vigibase



North America 52%



Europe 28%



Asia 13%



Latin America 2%



Africa 1%



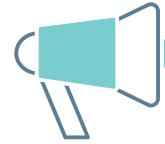
Oceania 4%

Expectations of the AU-3S Programme



African safety database

- African safety data available at a single point
- Enhanced & improved detection of new or changing safety issues
- Identifying safety issues that affect Africans
- Comparisons between regions that will inform decision-making and treatment modalities
- Standardised ICSR reporting requirements
- Better interoperability & data analysis
- Collaboration



Promotion & awareness of PV in Africa

- NRA PV staff capacitation
- Improved access to reporting tools
- Improved reporting
 - Quality
 - Quantity
- Improved communication to the public on medicine & vaccine safety
- Political will – pharmacovigilance budget
 - Training of healthcare professionals
 - Public awareness

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Q&A

Launching and deployment of the Med Safety App



- Based on identified gaps of poor reporting, an electronic handheld mobile platform was developed to bridge this gap
- The Med Safety App was launched on 4 November 2020 in Nigeria to provide an electronic platform that operated on Android and iOS devices for reporting adverse drug reactions and AEFIs
- With the introduction of the COVID-19 vaccine, the need to get real time data that will aid informed regulatory decisions became expedient
- The App was expanded through our collaboration with AUDA-NEPAD and MHRA through the AU-3S programme to capture the AEFI reporting form
- The app can be used by both health workers and the public once they have downloaded it on their phones
- In order to effectively harness the benefits of the Med Safety App, NAFDAC is continually intensifying efforts on sensitization campaigns for the general public leveraging on conventional and social media platforms
- We organize quarterly zonal and state-level trainings for healthcare providers and health professionals and make provision of internet-enabled tablets for Zonal Pharmacovigilance Centers and health facilities in Nigeria
- NAFDAC also developed an electronic video guide for the Med Safety App to create wide public awareness on how to download and use the app. This was circulated widely through the social media

Enhanced passive pharmacovigilance of COVID-19 vaccines

- NAFDAC implemented a targeted/enhanced passive surveillance approach whereby training designated pharmacovigilance focal persons were deployed to the field to monitor the COVID-19 vaccine implementation
- They followed up identified vaccinees who had received their first dose of the vaccine through phone calls to monitor for some solicited AEFIs for the first seven days after immunization using a designed questionnaire. The reported AEFIs were then uploaded in the Med Safety App
- This evidenced the increase in the number of AEFIs reported in the Med Safety App within one month of implementation
- The objective of this is to allow for further characterization of the safety profile within our own population since the full safety profile of the vaccines is yet to be characterized globally
- A more detailed active cohort event monitoring of the vaccine is being planned for a further safety profile characterization

Trainings



Med Safety App training

- Several stakeholder groups trained to download and use the Med Safety App



AU-3S coordinated training

- A capability gap identified during the landscape assessment was bridged through the provision of capacity strengthening by MHRA through the AU-3S programme
- To improve the capacity of health workers in data collection and signal detection, the MHRA conducted a series of capability trainings on the data collection tools, signal detection and management, benefit-risk assessment, safety communication, and management of the Vigilance Hub
- These trainings have impacted on the number of reports received during the implementation of COVID-19 vaccines safety surveillance in Nigeria

Challenges

- Despite the deployment of the Med Safety App, a large number of AEFIs are not reported (particularly when they are considered mild or non-serious)
- Downloading and using the App is still a challenge even with literate users. Sustained awareness and sensitization required
- AEFI reports are mainly received from urban and semi-urban areas with good network coverage. There are few AEFI reports from rural areas due to poor internet penetration and low levels of literacy with the ownership and use of smartphones
- NAFDAC relies on other sister agencies to support data collection at the periphery
- Poor transmission of investigation forms for serious AEFIs from the States to NAFDAC
- Inadequate track and trace scanners

Conclusion

- Beyond Emergency Use Authorization, NAFDAC has put in place stringent regulatory controls to ensure the safety, quality profiling, and characterization of the novel COVID-19 vaccines in Nigeria
- The impact of the Med Safety App in stimulating increased reporting of AEFIs in real time situations and the traceability data obtained by scanning of the vaccines are evidence of these measures
- There is need for adequate data to support strategic investments in pharmacovigilance system strengthening at critical levels of healthcare delivery in resource-limited settings
- Hence, the need for drug safety monitoring using Pharmacovigilance and Quality Assurance tools is imperative for NAFDAC to advise the Federal, State, Local Government, private sector and other interested parties on the safety and quality of COVID-19 vaccines. In this way, the agency will be fulfilling its mandate of effectively safeguarding the health of the nation

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Ghana

George Sabblah

South Africa

Florah Matlala

Nigeria

Uchenna Elemuwa

 Q&A



Q&A

Do you have **any questions?**



THANK YOU

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Announcements:

AVAREF Secretariat



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