AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

SMART SAFETY SURVEILLANCE

Spotlight

An Update on Smart Safety Surveillance in Africa

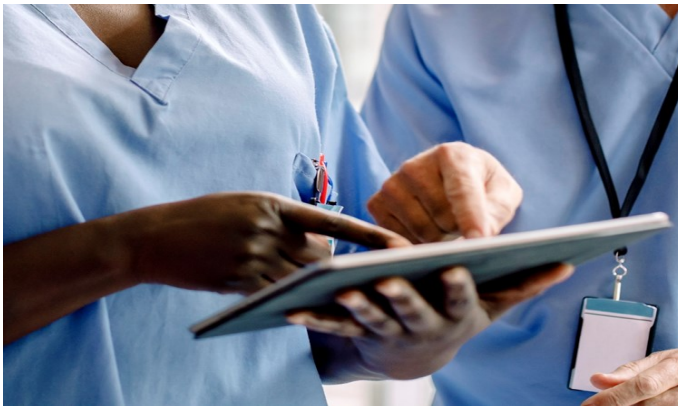
Edition 3 **June 2022**

In this edition:

1. Introduction

To tackle continental challenges in the health ecosystem, the African Union Development Agency-NEPAD (AUDA-NEPAD) launched the African Union Smart Safety Surveillance (AU-3S) programme at the beginning of 2020 with MHRA as a technical partner. Since the programme's establishment, the focus has been on testing the principles of addressing continental challenges such as low adverse event reporting rates, limited capacity of safety expertise and siloed pharmacovigilance systems.

With the programme approaching a solid two-year mark since inception, we must continue to take stock of how far we have come. As a programme, COVID-19 did not slow us down; it served as an accelerator for the proof of concept to develop a robust continental safety surveillance system for advancing the health development agenda in Africa.



> ***"With the AU-3S programme, we are constantly striving to bring together different safety stakeholders from diverse backgrounds and use fit-for-purpose tools to meet a common goal: to realize the programme's vision: sustainable safety surveillance of priority medical products for Africans. While we have made significant progress in the programme dating from its origination, there is still great headway to address some pressing health issues and opportunities in the African continent."***
>
> **-Mr. Hudu Mogtari**
>
> **AU-3S Programme Lead**

This edition explores the feasibility of expanding our scope to include COVID-19 therapeutics, adding one more country to those already participating in the programme, and re-visiting some of 2021's highlights relating to the programme's impact and a glimpse of what we have planned for 2022.

Enjoy reading as we work together to continuously build 'the Africa we want' through health systems and structures that contribute to the overall development of the African people.

2. An overview of 2021 highlights

The advent of the COVID-19 pandemic in 2020 revealed how ill-prepared and unequipped African countries were in responding to disease outbreaks. Some of the significant challenges included deficiencies in the quality and safety of medical products, weak health information systems leading to limited evidence to inform interventions and panic. It became increasingly evident that regulatory bodies needed urgent interventions within the health ecosystem. The AU-3S programme seeks to tackle some of the crucial policy framework goals and capitalize on the opportunity to solve some of the previously outlined health issues that the pandemic amplified whilst aligning these efforts with the AUDA-NEPAD's overall mission and the AU's policy frameworks, such as Agenda 2063. The programme contributes significantly to the policy goal and target under Agenda 2063, which pursues a 'high standard of living, quality of life and well-being for the people of Africa. In 2021, the programme worked tirelessly with regulatory bodies, technical partners and other stakeholders to assess the safety of the COVID-19 vaccines.

1	Digital health ecosystem enabling real time data access & downstream analysis	400M **Patients covered** by the safety tools	56k **New users** of Med Safety App[1]	~12x Increase in **reporting** rate[2]
2	First African-owned cross-country safety data integration and analysis platform	4 **Months** to develop DISD system & perform first data mining run	33.2k AEFI **reports** in integrated system	2.2k **Drug-event combinations** analyzed
3	African-led evidence-based decision making on their own African data	44 **JSM Secretariat meetings** held[3]	10 **JSM Group meetings** held[3]	12 **Items of interest** identified, raised, and reviewed
4	End-to-end safety strengthening and collaboration across EPI & NRA	14 **Training sessions** delivered	100 **Average attendees** per session	95% **Satisfaction rate** from trainees
5	Critical safety coordination and alignment across country and global stakeholders	150+ **in-country** meetings and **cross-country experience sharing** sessions	100+ **Comm. materials** shared with countries (videos, templates etc.) & **continental guidance** created	60+ **Touchpoints** with other continental initiatives and stakeholders

[1.] *Cumulative from Nov 2020 to May 2022;* [2.] *Ethiopia and South Africa baseline missing;* [3.] *Kick-off meetings included*

What are the notable highlights from 2021?

As documented in the previous Spotlight editions, the AU-3S programme had its work cut out for 2021. Some of the notable highlights of 2021 are:

- Introducing sustainable reporting mechanisms through the expansion of electronic vaccine safety data collection through the Med Safety App
- The AU-3S programme launching the Joint Signal Management (JSM) Group for reviewing signals from aggregated cross-country data
- The significant increase of AEFI reporting rates. As it stands, the AEFI reporting rate in the interim DISD is over 32,200 which is a vast milestone from the 20,300 reports recorded in the last Spotlight edition.
- The successful roll-out of 5 modules with the pilot country representatives as a part of the AU-3S program's capacity strengthening trainings for improved safety surveillance capabilities.

In addition to the above-mentioned highlights, the AU-3S programme has participated in several engagements as a part of the programme's knowledge sharing, advocacy and communications activities. These sessions are listed as follows:

FORUM	DESCRIPTION	DATE
Pharmacovigilance Africa (PAVIA)	COVID-19 vaccines safety surveillance Africa and gave programme update.	19 April 2021
	The AU-3S programme presented on the programme, the Med-Safety App in relation to AEFI reporting and the programme's success during the PAVIA project annual consortium meeting.	28-31 March 2022
African Vaccine Regulatory Forum (AVAREF)	AU-3S presented in the AVAREF webinar with the theme: Building Capacity and promoting harmonization for facilitating Clinical Trials for Health Products for COVID-19 in Africa.	6 May 2021
	The AU-3S programme participated in the annual AVAREF webinar where the programme showcased its impact to date, as well as provided information on the AU-3S pilot countries experience sharing.	9 December 2021
International Society for Pharmacovigilance (ISOP) in collaboration with the Drug Safety Research Unit	The purpose of this engagement was to make the AU-3S programme work for COVID-19.	3 September 2020 and 11 May 2022
Pharmacovigilance Workshop at Virtual Extraordinary ICDRA – organized by WHO	AU-3S Programme Lead participated in a round table discussion on Pharmacovigilance of Medicinal Products related to COVID-19: Illustrating the value of regulatory reliance, work sharing and timely exchange of safety information.	23 September 2021
MHRA Pharmacovigilance Experts Advisory Group (PEAG)	This meeting was a part of the programme's knowledge sharing to facilitate JSM Group engagements. Two JSM Group Members (Prof. Meyer and Prof. Gyapong) attended as observers.	2 March 2022
AU-3S presentation to Africa CDC	Presentation made on the AU-3S programme.	01 June 2021
National Safety Committee of Ghana (Ghana NSC)	Presentation made on the AU-3S Joint Signal Management Group	07 May 2021
Presentation to AMRH Steering Committee	AU-3S presentation to Extraordinary AMRH Steering Committee Meeting.	22 April 2021
National Immunisation Safety Expert Committee (NISEC) of South Africa	Presentation made on the AU-3S Joint Signal Management Group	07 May 2021
WHO bi-weekly update meeting	Update on AU-3S Safety data in the DISD system presentation	30 May 2022

> ***Grateful for the AU-3S programme, without the AU-3S programme NAFDAC would have not attained ML3 status for the Vigilance function."***
>
> **-Prof Moji Adeyeye, Director General, NAFDAC**

3. Plans for AU-3S in 2022

COVID-19 Therapeutics

One of the long-term primary goals for the AU-3S programme is to characterize the safety profile of medical products across the African continent for priority disease areas. Currently configured, the programme's scope focuses on COVID-19 vaccines as a health priority. Although this is the case, in terms of a futuristic view, therapeutics to manage COVID-19 infections are likely to be available across the globe in parallel, mainly in high-income countries and lower-middle-income countries. Many of these therapeutics and novel technologies are based on industry and process advancements that make it imperative for surveillance systems to monitor the safety of these therapeutics.

AU-3S taking on therapeutics

The AU-3S programme intends to leverage the gains realized with the COVID-19 safety surveillance response for vaccines in four pilot countries in this regard. The programme proposes to build directly on the solutions tested and implemented in characterizing the safety profiles of COVID-19 therapeutics to guide signal detection and execute capacity strengthening activities with the participating national regulatory authorities through the AU-3S Joint Signal Management secretariat and other forums. While the discussions on therapeutics are still in their preliminary phase, the AU-3S programme convened a working group in April 2022 to discuss the matters surrounding the research and early implementation of this phase. Prior to this meeting, internal discussions were concluded surrounding the selection criteria and the matrix for therapeutics as a preparatory phase.

4. Country Focus: Med Safety App Use South Africa

As previously outlined in the second edition of Spotlight, there will now be a standing 'focus article' that features progress on a particular topic from one of the AU-3S programme pilot countries. This edition focuses on South Africa and its progress towards improved levels of electronic reporting.

Note: This article was jointly prepared by AU-3S and the South African Health Products Regulatory Authority (SAHPRA).

As stated in previous editions of Spotlight, the AU-3S team and the MHRA joined efforts to develop an Adverse Event Following Immunization (AEFI) reporting form for use in the Med Safety App. This aids in the e-reporting of AEFIs by healthcare professionals and the general public.

Initially, this form was only rolled-out to the four AU-3S pilot countries; however, it has been made available to all other countries that have the App. It is also essential to note that there has been a significant shift from paper form reporting to electronic reporting from when the pandemic began. The Med Safety App development counts as part of the efforts made in medical advancements that will help in reporting and monitoring processes.

South Africa is one of the African countries that has made noteworthy progress in using the Med Safety App, particularly in the past ten months. Subsequent to South Africa's participation in the AU-3S programme, the South African Health Products Regulatory Authority (SAHPRA) acquired the Med Safety App for reporting adverse events following immunization (AEFIs) and adverse drug reaction (ADR). The launch of the Med Safety App followed the roll-out of the COVID-19 vaccines by the National Department of Health to encourage and promote the reporting of AEFIs by the public and healthcare professionals.

In previous years, reporting of adverse events (AE) in South Africa was done mainly by pharmaceutical companies and healthcare professionals through paper-based, e-reporting and XML formats. Consumers submitted only a few reports prior to the use of the Med Safety App.

Following the Med Safety App launch, SAHPRA, in collaboration with the National Department of Health (NDoH), through the Expanded Programme on Immunization (EPI), trained healthcare professionals on the use of the Med Safety App. In addition, SAHPRA held public webinars to promote the use of the Med Safety App. Collaboration with media houses also intensified the promotion of the Med Safety App.

> ***"The AU-3S programme has helped SAHPRA identify and fix gaps in the system"***
>
> **- Dr. Boitumelo Semete, CEO at SAHPRA**

Furthermore, the back-end of the Med Safety App, Vigilance Hub, was used to harmonize the AE reporting system in South Africa. Healthcare professionals were trained on the use of the Vigilance Hub at the provincial and district level to ensure coordination of AE management. Training on the Vigilance Hub was also provided to the COVID-19 hotline administrators to assist in the coordination of efforts. Through the introduction and the use of the Vigilance Hub, AE coordination and management are enhanced between the SAHPRA, NDoH and provinces in South Africa.

> ***"The AU-3S Vigilance Hub has helped us reduce the need for manual sharing of reports between our NRA and EPI as data can now be accessed at a central point."***
>
> **- Mafora Matlala, Head of PV Unit at SAHPRA**

As of April 2022, there have been over 5662 reports uploaded using the Med safety App in South Africa. Additionally, SAHPRA noted an average of 3530 Med Safety App active users per month dating from the launch in April 2021. There have been an additional average of 2314 new users of the app per month. The numbers of both active and new users steadily increased from April to August 2021. After that, a decrease in both numbers was noted. This fluctuation of numbers is thought to be linked to the vaccine uptake by the population.

Since the Med Safety App launch, reporting of AEs has increased during 2021 compared to other years. In the previous years, SAHPRA has received 5157 AEs with a reporting rate of 8.81 and 3233 AEs with reporting rate of 5.45 AE reports per 100 000 persons for 2019 and 2020, respectively. SAHPRA has received 10 954 AEs from 1 April 2021 to 31 December 2021, respectively, indicating an AE reporting rate of 18.26 AE reports per 100 000 persons. Of the 10 954 reports received, Med Safety App accounted for 74% of the AE reports. AEFIs accounted for 42% (4532) of the total reports received in the database. Furthermore, 30.68% of the Med Safety App reports were received from members of the public compared to 21.42% of consumer reports received in the previous year.

It is clear that the introduction of the Med Safety App has increased reporting of AEs in South Africa. This is indicated by the fact that more than 70% of the reports received by SAHPRA came through the Med Safety App. The reporting rate has tripled from the previous year's rating. The number of consumer reports received since the launch of the Med Safety App in South Africa is an indication that making reporting resources available at the community level encourages reporting of AEs to SAHPRA by the public. The SAHPRA, together with NDoH and other stakeholders, is currently working on mechanisms to drive the update of the Med Safety App.

5. Scaling up data sources into AU-3S DISD

The first African-owned data integration and signal detection (DISD) system is enabling in-country and cross-country near real-time data access, downstream analysis and signal detection. This is an innovative approach for strengthening health service delivery. Focusing on the longer-term plan for a continental database (AfriVigilance) containing data from numerous different data sources across the end-to-end product lifecycle, efforts are being geared towards enhancing flow of data from various other safety data platforms such as the Ghana Safety Watch system and Kenya pharmacovigilance electronic reporting system (PvERS) platform. This will ensure data in-flow from existing country platforms in addition to the established data flow via the Med Safety App and paper forms. In this way, the system will be scalable across countries and the data will be readily transferable from the interim DISD system to the long-term AU-3S continental system.

What is the current status?

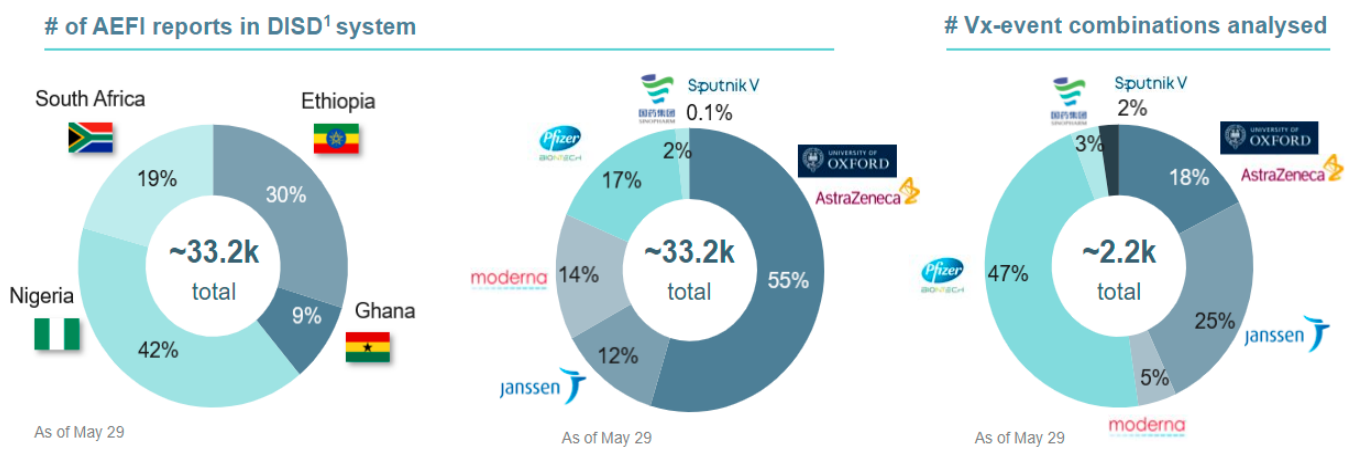
The DISD system now contains data from AstraZeneca, Janssen, Moderna, Pfizer, Sinopharm and Sputnik COVID-19 vaccines. As of 29 May 2022, the DISD system contains over 33,200 AEFI reports. The AU-3S programme continues to work with countries on decentralizing data collection, converting backlogs of paper forms into electronic format, correcting coding issues, and process improvements in data validation.

Other process improvement effort

Furthermore, the AU-3S programme, with support from UK MHRA and in collaboration with Uppsala Monitoring Center (UMC), has developed an XML download from VigiFlow that can then be readily uploaded into the Vigilance Hub. This means that any cases which have gone directly into VigiFlow can be added to the Vigilance Hub.

However, there is ongoing work to ensure that these cases can be included in the DISD system seamlessly. The Vigilance Hub maintains the VigiFlow case reference numbers, so no duplication of data occurs in either system.

Number of AEFI reports and drug-event combinations (DECs) in AU-3S's DISD system by country and vaccine as of 29 May 2022 are seen in the figure below.



6. Update on AU-3S JSM Group

AU-3S established a multi-country group of safety experts, known as the Joint Signal Management Group (the AU-3S JSM Group) which validates, prioritizes and assesses the cross-country signal reports from the interim DISD system as a way of improving medicines and vaccines safety for patients in Africa and globally.

The JSM Group meeting happens once every two months, with the discussions of the JSM Group being determined by the findings, insights and discussions observed by the Joint Signal Management Secretariat, which is a different group of health professionals who meet bi-weekly to serve as the group that does the groundwork within pilot countries.

To date, the JSM Group has had 9 meetings which resulted in informed safety recommendations. The most recent JSM Group meeting was held on 2 February 2022 where the Chairperson, Dr. Hannelie Meyer, informed members of Kenya's on-boarding and representation to the JSM Group as of 2 February 2022.

So far, 2,187 different vaccine-event combinations have been recorded from the data in the interim DISD system, across the AstraZeneca, Pfizer, Janssen, Moderna, Sinopharm and Sputnik COVID-19 vaccines. These vaccine-event combinations occurred from a total of over 83 million COVID-19 vaccine doses administered by the AU-3S pilot countries. The majority of which were Pfizer, administered in 3 countries, followed by Janssen, administered in 4 countries, then AstraZeneca, administered in 3 countries.

In addition, Moderna followed and was administered in 2 countries, then Sinopharm, administered in 1 country and lastly, Sputnik, administered in 1 country.

The JSM Secretariat has tirelessly reviewed these cases for information on new or changed risks, and to date, the AU-3S JSM Group has not identified any new signals in the African population that are not already known from these product's safety profiles globally. 8 items of interest being followed as more data is received.

For all 6 vaccines, the most frequently reported AEFIs are: headache, pyrexia, local reaction and injection site pain – these terms, or closely-related ones, are listed in the vaccines' product information.

7. AU-3S capacity strengthening training

As highlighted in the first Spotlight Edition, the AU-3S's capacity strengthening series, conducted by the UK Medicines and Healthcare products Regulatory Agency (MHRA), has been concluded, after successfully holding 5 trainings for the modules. The trainings were held with country representatives from Ethiopia, Ghana, Nigeria, and South Africa, with the aim to strengthen countries' safety surveillance capabilities across a comprehensive range of topics. These modules are recommended to anyone involved or interested in effectively monitoring the safety of medical products.

Where to access modules

The training recordings and associated materials have now been made available via the AUDA-NEPAD e-learning portal. To access as a first-time user, select the option titled "Click here to login as a guest". Once completed, navigate to the AU-3S Capacity Strengthening page by selecting the appropriate tile.

8. An Increase in AU-3S Pilot Countries — Kenya Onboarding

As the programme continues to develop, there will be changes made to the current structure to aid in its growth. As of March 2022, the AU-3S programme started implementing its expansion plans by officially welcoming Kenya as the newest pilot country under the programme after concluding the signing of an agreement between AUDA-NEPAD and Kenya. Kenya is joining through a grant from the Bill and Melinda Gates Foundation Africa office. These plans are in line with the medium-term objectives of the AU-3S programme to expand on its COVID-19 response. Dating back to the 24th of January 2022, the Chief Executive Officer of the Pharmacy and Poisons Board (PPB) Kenya, Dr Fred Siyoi, was formally introduced as the newest member of the AU-3S Steering Group.

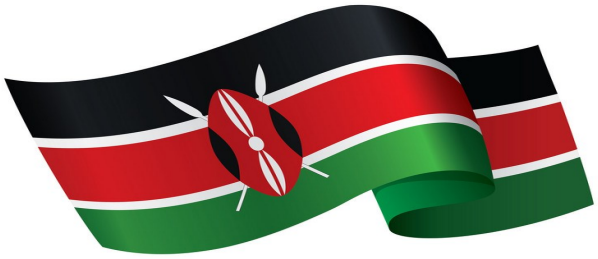
> ***We feel very welcome to the expanded group, and I promise that we will participate fully and contribute to the discussions going ahead"***
>
> **- Dr. Fred Siyoi says on behalf of PPB during the opening remarks of this year's first Steering Group meeting**

The Kenya Pharmacy and Poisons Board (PPB) is the National Regulatory Authority (NRA) charged with the mandate to regulate the practice of pharmacy, manufacturing, and trading of drugs and poisons, including vaccines. There have been many engagements between the programme and Kenya PPB to facilitate a smooth onboarding of the newest member to the programme and better understand the country's landscape of safety surveillance. This exercise will enable the AU-3S programme to provide fit-for-purpose intervention(s) to ensure that Kenya's COVID-19 vaccines' safety data is seamlessly integrated with the DISD system.

The members of the Steering Group expressed their warm welcome to Kenya, noting that Kenya's historically well-known and robust safety system as a part of their regulatory system will be an added advantage to the discussions. Kenya has actively participated in all meetings of the AU-3S programme, including the Joint Signal Management Secretariate meetings.

In the interim, the AU-3S programme's plan to continue expansion to additional geographies is on course. The additional countries will help to increase AU-3S's regional and language representation and test new data sources' integration with the DISD system. Furthermore, a plan is underway to engage the National Vaccines and Immunization Programme (NVIP) of Kenya, as the organization works closely with the NRA on vaccine safety surveillance.

Now that Kenya has successfully been onboarded, the AU-3S programme continues to work collaboratively with its stakeholders to guide the process and ensure that the best practices used by the four countries: Ethiopia, Ghana, South Africa and Nigeria- regarding collaboration are applied. As it stands, the pilot countries now make up 35% of Africa's population. With Kenya onboarded, there will undoubtedly be a lean toward achieving a more significant impact on the programme's success. The AU-3S programme will continue to communicate more details of the expansion process.



9. A growing AU-3S team

We are excited to not only be growing in terms of the number of pilot countries that we have onboard under the AU-3S programme, but to also be growing as the AU-3S internal team.

Victoria Nambasa

Senior Programme Officer

> *"When it comes to patient safety, the sky is the limit for me. Am thrilled to be a part of the AU-3S team and continue in my contributions to the continental agenda on health care product safety." - **Victoria Nambasa***

Nqobile Zwane

Public Relations Officer

> *"I am excited to be starting this new journey at AUDA-NEPAD, but I am even more enthusiastic about working under the AU-3S programme and expanding my knowledge on the safety surveillance eco-system." - **Nqobile Zwane***

Anthony Kapeta

Legal Officer

> *"I am excited to be part of this project, and work toward ensuring legality and safety of medical products in Africa." - **Anthony Kapeta***

Join the AU-3S team

We currently have the following positions available:

- **AU-3S Principal Programme Officer: Smart Safety Surveillance- Therapeutics**
- **AU-3S Programme Officer: Technology Strategy**

If you are interested in applying for any of the above roles or have any enquiries, please email au3s@nepad.org or visit the website to apply from there.

10. Links to additional safety-related resources

See what our team and the JSM Group experts are reading! Relevant links to COVID-19 vaccines safety-related resources on key topics over the past 6 months can be found below;

Below are some key links to COVID-19 related resources:

JAMA Health Forum, 10 August 2021 - COVID-19 mRNA Vaccines Blunt Breakthrough Infection Severity. Accessible: Link.

Clinical and Translational Allergy, 27 July 2021 – Patients with suspected allergic reactions to COVID-19 vaccines can be safely revaccinated after diagnostic workup. Accessible: Link.

WHO, 23 December 2021 – Statement of the Independent Allocation of Vaccines Group (IAVG) of COVAX on achieving 70% COVID-19 Immunization Coverage by mid-2022. Accessible: Link.

Monoclonal antibodies for COVID-19

Journal of Biomedical Science, 4 January 2022 – Monoclonal antibodies for COVID-19 therapy and SARS-CoV2 detection. Accessible: Link.

University of California San Francisco, 10 December 2020 – Monoclonal Antibodies for COVID-19 in Africa: Promise and Pitfalls. Accessible: Link.

Therapeutics

WHO, 07 December 2021 – A living guideline on Therapeutics and COVID-19. Accessible: Link.

General/ other

February 2022:

New HIV Variant Discovered: May be more infectious and severe. Assessable: Link.

Discovery of New HIV Variant Sends Warning for COVID Pandemic. Accessible: Link.

Claims of a new, deadlier HIV variant could be attempt to frighten people into accepting another pandemic. Accessible: Link.

European Medicines Agency—Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC). Accessible: Link

FDA—Joint COVID-19 Vaccine Safety Review Committee– Safety Monitoring . Accessible: Link.

Number of administered coronavirus (COVID-19) vaccine doses per 100 people in Africa as of 23 February 2022, by country. Accessible: Link.

24 February 2022:

SABC news - WHO aims to rollout mass vaccination campaigns in 10 African countries. Accessible: Link.

IOL – Court bid to halt roll-out of COVID-19 vaccine for children. Accessible: Link.

Centers for Disease Control and Prevention, 27 August 2021 – New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status – New York, May 3 – July 25, 2021. Accessible: Link.

Vast majority of breakthrough infections in vaccinated health workers are mild. Accessible: Link.

May 2022:

COVID Vaccines Administered in AU-3S Pilot Countries. Assessable: Link.

The African Union Development Agency - NEPAD (AUDA-NEPAD) was established in 2018 as part of the global reforms geared at improving the African Union's impact and operational efficiency

The African Union's Smart Safety Surveillance (AU-3S) programme was launched in 2020, with the long-term goal of strengthening the safety surveillance of medical products across Africa

Spotlight: The Smart Safety Surveillance Update is a progress report published by AU-3S which provides an update on safety surveillance in Africa and key progress made by the AU-3S programme

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