AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

SMART SAFETY SURVEILLANCE

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Spotlight

An Update on Smart Safety Surveillance in Africa

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1. Introduction

In our rapidly evolving world, medical product safety surveillance has become an integral component of health care delivery systems geared towards safeguarding the well-being of society. With recent technological advancements and the growing complexity of health care systems vis-a-vis emergencies, the demand for a robust and effective safety surveillance has reached new heights. Recognizing this, the African Union Smart Safety Surveillance (AU-3S) programme provides a platform for the identification of emerging risks associated with medicines through monitoring potential adverse events. The critical gaps the AU-3S programme aims to address are the limited pre-approval safety data packages, low adverse event reporting across countries and siloed pharmacovigilance systems. Other gaps include the limited safety expertise to support signal detection and risk assessment within AU Member States. To effectively deliver on the programme's long-term goal of strengthening the safety surveillance of priority medical products across Africa, AU-3S, under the leadership of the African Union Development Agency (AUDA-NEPAD) and funding from the Bill & Melinda Gates Foundation (BMGF), works closely with the UK Medicines Health Regulatory Authority (MHRA) as a key technical partner and US Food and Drug Administration (USFDA) as an advisor.

Over the past two years, the AU-3S programme has worked assiduously to establish as a continental safety surveillance system for Africa. Its primary focus has been collaborating closely with participating countries, Ethiopia, Ghana, Kenya, Nigeria, and South Africa, to provide strategic and technical support to improve vigilance functions and safety surveillance capacity across Africa for COVID-19 vaccines. While the programme currently operates in these five member countries, AU-3S has initiated the process of engaging additional member states to expand its geographical coverage. These expansion plans are integral to the programme's second phase, which marks a transition from the pilot phase to a continental programme. Phase 2 is currently underway and entails the optimization of the solutions, ongoing collection and analysis of safety data, and scale-out of solutions to other additional member states and identified priority medical products.

2. AU-3S Pivoting from Pilot to a Continental Safety Surveillance Platform

2.1 AU-3S Ad-hoc Continental Safety Platform Working Group (CWG)

During the AU-3S Steering Group (SG) meeting in Accra, Ghana, on March 29th and 30th, 2023, the SG approved the establishment of an Ad Hoc Continental Safety Platform Working Group (CWG). The CWG was tasked to create a roadmap to guide AU-3S to a functional and sustainable continental safety monitoring platform to serve the safety needs of medicines and vaccines for Africa. The established AU-3S CWG comprised expert nominees from participating countries and the African Union Commission (AUC). The working group focused on six strategic areas: expanding to more countries, increasing the number of products for central monitoring, developing a sustainable future monitoring platform (AfriVigilance), signal management post-expansion, stakeholder engagement, and ensuring the sustainability of the programme.

The AU-3S CWG was commissioned to serve for 12 weeks, from May 22, 2023, to August 11, 2023. The CWG presented its report on the "Draft Roadmap to Guide AU-3S to a Functional and Sustainable Continental Platform" to the Steering Group. AU-3S SG commended the dedication and commitment of the CWG members and the successful outcomes. The recommendations made by CWG participants sparked productive conversations for the AU-3S expansion and its journey to become a continental safety monitoring platform. The CWG recommendations and the subsequent SG discussions will inform the AU-3S's journey toward a continental safety monitoring platform.

2.2 AU-3S Country Expansion Strategy

The AU-3S programme, pivoting from a pilot to a continental safety surveillance platform, has had a significant public health impact by strengthening the safety surveillance system across its member states, particularly during the deployment of COVID-19 vaccines. This effort increased knowledge and confidence in safety monitoring, promoted public confidence in regulators, and elevated the recognition of pharmacovigilance.

The programme's expansion efforts include onboarding additional member states, and the AU-3S Steering Group has approved a set of selection criteria to determine candidate countries. These criteria encompass the existence of a functional safety system, geographic representation, language representation, and participation in other continental initiatives.

Following a successful COVID-19 vaccine pilot with Ethiopia, Ghana, Kenya, Nigeria, and South Africa, the programme welcomed the 2nd wave of member states, including DRC, Egypt, Rwanda, and Senegal, expanding the member states to nine countries. The SG also approved a 3rd wave of six countries, including Mozambique, Tanzania, and Uganda, and three others to be determined. This brings the total member states to 15 (representing all five regions and language groups) by 2024. The programme plans to align its expansion with product scope, technology, AfriVigilance, and sustainability before adding more countries.

The newly welcomed countries will actively participate in onboarding activities, establishing points of contact, and conducting a landscape assessment of their respective country's safety surveillance systems to ensure tailored solutions for effective participation.

2.3 Products Scope Expansion

Since the launch of the COVID-19 vaccine pilot, AU-3S has played a vital role in ensuring the safety of the vaccines during the pandemic and beyond. As part of the expansion, the AU-3S Steering Group (SG) determined that HIV/AIDS, Tuberculosis, Malaria, and other emergency diseases (including COVID-19) were to be given priority for the product scope expansion. Based on risk-based criteria, Covid-19 therapeutics, nOPV2, Dolutegravir (DTG) based regimen, Bedaquilline (BDQ), Pretomanid, Malaria vaccine, and Cabotegravir/Rilpivirin were selected early this year for the cross-country safety monitoring.

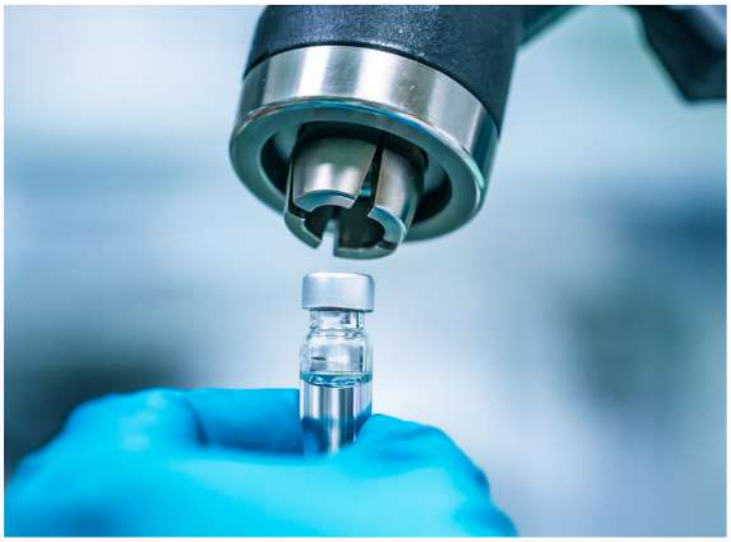
Furthermore, the Lassa fever, Group B Streptococcus (GBS), and the Respiratory Syncytial Virus (RSV) vaccines will be considered for product expansion as they become available on the continent. The SG also recently approved two additional selection criteria for product selection: new products critical for unmet medical needs in Africa and products manufactured for use in Africa. Along with the product scope expansion, the programme will determine a framework for a regular, structured and strategic review mechanism for the product list for effective and relevant cross-country safety monitoring.

3. AU-3S Technology Optimization

The AU-3S programme emphasizes that a sound digital technology ecosystem is one of the most critical assets for the programme. As a technical partner to the programme, UK MHRA's Sentinel database currently houses the AU-3S's interim Data Integration and Signal Detection (DISD) system, successfully serving AU-3S through the pilot phase across five member states. The safety data has been collected through mobile applications, web-based platforms, and Application Programming Interface (API) connections with other systems. The Sentinel database and Empirica analytics have equipped the signal assessment processes with reliable data through data mining. So far, the system has facilitated the collection, storage, and analysis of safety data and processed nearly 50,000 COVID-19 vaccine reports from the African population.

When UK MHRA planned to revamp its pharmacovigilance system to the Safety Connect platform, the DISD system also acquired a critical optimization opportunity to address changing needs for expansion. Several consultation sessions were held, both virtual and face-to-face meetings, between the five member states and the technical partner (MHRA) to discuss the technical feasibility of the envisaged improvements and to plan a timeline for their implementation. Based on the outcomes of the consultations, the programme developed a roadmap and was approved by the AU-3S Steering Group (SG) during its meeting in March 2023. The DISD system will be migrated seamlessly to the new Safety Connect platform.

The features planned as part of the technology optimization effort include, but are not limited to:



- **Application Programming Interface or Platforms:** A functionality that will allow reports to be more flexible in sending on to 3rd party systems. Reports can be sent to different receivers/database based on pre-set conditions. Development is ongoing and it is planned to be available for adoption in July 2023.

- **Application Programming Interface or Platforms such as Conditional Receivers:** This functionality will enable flexible reporting when shared with third-party systems. Reports can be sent to different receivers or databases based on pre-set conditions. The development took place in July 2023.

- **Enhancement of Web-Based Data Collection Mechanisms:** Deploying the Med Safety Website on top of the mobile Med Safety App will widen data collection opportunities. Clinicians and members of the public can report more easily through their desktop computers.

- **Conditional Questions and Automated Follow-ups:** Implementing conditional questions will allow tailored questions to be asked at the point of reporting to collect relevant data in real time. Automated follow-ups will reduce the resource pressure of routine follow-ups with reporters through calls, emails, and visits. These features will require a harmonized approach for their implementation.

4. 2nd Phase of Sub-Delegation Agreement to Support In-Country Safety Surveillance System Strengthening in the Founding Member States

During the first phase (2020 and 2021) of the COVID-19 vaccine pilot of the AU-3S programme, in-country funding was disbursed to address country-specific needs. Followed by further assessment by each member state, BMGF approved a second phase of supplementary grants to the four pilot countries (Ethiopia, Ghana, Nigeria, and South Africa) in 2022. The second phase also included Kenya, which joined at the latest around the time of the 2nd sub-delegation agreement. The sub-delegation agreement has been signed by the five countries, and AUDA-NEPAD, and the first tranche of disbursements has been paid to the beneficiaries. Furthermore, BMGF is committed to providing additional grants to support the longer-term in-country safety surveillance system strengthening for AU-3S member countries, which includes new countries joining the expansion phase.

The goal of the 2nd phase of sub-delegation agreements for in-country safety surveillance system strengthening is to achieve strengthened capacity for safety surveillance, adequate human resource and enhanced expertise for safety surveillance, improved coordination amongst key stakeholders involved in safety surveillance processes, and increased public awareness to promote the rational use of medicines and safety reporting, among others.

The AU-3S programme organized a 2-day sub-delegation kick-off meeting and training on implementation and reporting for the five participating countries in May 2023. It aimed to address the identified challenges during the implementation of the 1st phase of sub-delegation agreements with the four pilot countries and the ongoing sub-delegation agreement with Kenya. For this round, the team improved the reporting process to help support the implementation of the identified objectives for each sub-delegation agreement.

Further updates on the implementation and impact of the in-country sub-delegation agreements will be continuously updated.

5. Key Highlights and Engagements

5.1 Ethiopia, Nigeria, and South Africa National Medicines Regulatory Authorities (NRAs) attained WHO GBT ML3 for Vigilance Function

National Regulatory Authorities (NRAs) are responsible for ensuring the safety, effectiveness, and quality of medicines for pre- and post-approval. Ensuring the safety of medicines entails understanding the potential adverse events relevant to the medicines and detecting any adverse effects that may arise when the products are marketed to the general population. The regulatory bodies' role is invaluable in maintaining a favourable benefit-risk profile for health products, which ultimately protects the health and wellbeing of the public.

Low and middle-income countries often face unfortunate hurdles in regulating medical products effectively and efficiently. As part of the AU-3S programme's safety surveillance system strengthening goal, the programme has supported member states technically and financially, which has enabled them to improve their pharmacovigilance processes significantly. The programme is happy to share the news from Nigeria, South Africa, and Ethiopia's national medicine regulatory agencies for attaining WHO Maturity Level 3 (ML3) for the Vigilance function in 2022 (NAFDAC & SAHPRA) and 2023 (EFDA) – a remarkable achievement that highlights the program's impact. The AU-3S programme is committed to supporting countries on the continent to advance their PV function to the next level.

5.2 Participation in the DIA Europe Conference

The AU-3S programme participated in the MHRA-facilitated session at the DIA Europe Conference on 24 March 2023. The country representative from SAHPRA, the technical partner from MHRA, and the AU-3S programme co-presented. This engagement enhanced the visibility and recognition of the AU-3S programme and its impact to external stakeholders.

5.3 AU-3S In-Person Technology Support Consultation

To build a better understanding of the opportunities available for the optimization of appropriate technology for continued effective delivery of programme objectives, AU-3S hosted a technology consultation in collaboration with the programme technical partner, UK Medicines and Healthcare Products Regulatory Agency (MHRA), in Cape Town, South Africa on the 7th- 8th March 2023.

The consultation provided a platform for member states to share their experiences on vigilance systems for vaccines and medicine, highlighting relevant legislation, supporting systems and processes, data sharing requirements, and system integration requirements. Through this, the member states were able to have a holistic idea of crucial data requirements in their respective countries while framing feasible solutions to address gaps and strengthen these systems.

Following the meeting, the participants reported that they had a more detailed understanding of the needs and requirements of their countries for the technology optimization processes. Additionally, the exercise was beneficial in scoping the member country's expectations and providing a better overview of what needs to be understood from the data to ensure that the future direction of the systems in place is fit for purpose.

> *"We are trying to see to it that there is ownership of the process in terms of the national systems that countries have in place"*
> **- AU-3S Senior Advisor, Prof. Aggrey Ambali.**

5.4 AU-3S to Collaborate with AVAREF TWG on a Pilot to Create a System for Pre-Licensure Safety Data

AU-3S programme presented to the AVAREF Steering Committee and Technical Working Group (TWG) in April 2023 on the need to establish a repository for African clinical trial (CT) safety data. AU-3S and AVAREF agreed on the principles below, linking pre- and post-approval safety data for lifecycle signal detection and management. The parties will work together to address the need to collect and analyze safety data from African clinical trials. As a kickoff, the parties will establish a joint working group to discuss the modality and explore a potential pilot in phases. Both agreed that all ongoing and future initiatives and projects on CT safety strengthening activities should be aligned with the AU-3S continental initiative to avoid duplication and optimize in-country resources.

5.5 Risk Communication Capacity Strengthening Meeting

A Risk Communications Capacity Strengthening Meeting was held with the five member countries in Accra, Ghana, from May 24-26, 2023. The meeting brought together pharmacovigilance experts from each member country and the communication officers who work on the risk communications aspects to participate in a knowledge-sharing exercise.

The meeting sought to strengthen the capacity of the AU-3S member countries on risk communication to appropriately develop and disseminate safety information to the target audience. In addition, the meeting was an opportunity to enhance cooperation and collaboration by bringing together the communication experts from member countries to help them be better placed to (i) assess communication needs and (ii) align on key messages disseminated during the programme expansion process. The participating country PV and communication officers received in-depth training from three experienced pharmacologists and risk communications experts from the University of Campania to strengthen them with knowledge on how to effectively communicate factual, up-to-date, and sensitive medical information without causing unnecessary levels of alerts with the audience. Through this engagement, AU-3S can further improve its capacity to prevent safety misinformation and misperception on the use of health products, enabling necessary and timely utilization of relevant health interventions.

6. The 3rd Steering Group In-Person Meeting

The programme's success continues to be attributed to the strategic leadership of the SG, owing to the provision of guidance and direction since its inception. The AU-3S Steering Group (SG) convened its third in-person meeting on the 11th and 12th of September, 2023, at the Rockefeller Hotel in Cape Town, South Africa. The SG welcomed four new countries – DRC, Egypt, Rwanda, and Senegal to the programme, a significant milestone for the programme's expansion. The SG also discussed and approved the draft roadmap and recommendations from the ad-hoc Continental Safety Platform Working Group (CWG). This will inform the programmatic expansion toward a sustainable and functional continental safety surveillance system in Africa. The SG also evaluated the implementation status of the programme and provided strategic guidance for subsequent implementation.

As the host, CEO of the South African Health Products Regulatory Authority (SAHPRA), Dr. Boitumelo Semete, shared her experience on the invaluable benefits of participating in the AU-3S programme since its pilot phase. She emphasized that the participation has allowed SAHPRA to accumulate a wealth of information from the experiences of collaborating pilot countries, which ultimately helped them to achieve WHO maturity level (ML) 3 for their vigilance function.

> *"The lessons learned from the programme have positioned us at SAHPRA to provide enhanced support to the new countries joining the programme and has made us better positioned to provide guidance." -*
> ***SAHPRA CEO, Dr. Boitumelo Semete***

In his keynote address, Prof. Nicholas Crisp, the Deputy Director General of National Health Insurance in South Africa, affirmed the public health impact of the AU-3S programme by providing a surveillance mechanism to monitor the safety of COVID-19 vaccines. He reiterated that this effort enhanced collaboration among the key players in vaccine safety surveillance. He also described how the data collected is used in vaccine litigation and compensation claims in South Africa.

During the SG meeting, there was a unanimous commendation for the AU-3S programme's remarkable public health impact and its role in strengthening safety surveillance systems within member states.

Looking ahead, the SG reaffirmed the need to extend the programme's reach beyond COVID-19 vaccines. The NRAs emphasized the importance of broadening the programme's scope to encompass other priority health products, thereby ensuring comprehensive safety surveillance across various healthcare interventions.

The Heads of NRA from the newly onboarded countries expressed their excitement about joining the programme. They also reiterated their commitment to overcoming the unique challenges in safety monitoring they face, highlighting the programme's role in providing critical support and guidance during these transitional phases of the programme. Their excitement is a concrete recognition for the programme as it works to improve safety monitoring and protect public health in Africa.

Moreover, the key technical partners, UK MHRA and US FDA, reiterated their commitment to supporting the programme, focusing on ensuring safety and confidence in decision-making.

> *"The increasing number of participating countries is a positive development. However, our focus should now shift towards ensuring the programme's sustainability and effectiveness. This includes discussing the sustainability of the programme and how we can promote a balanced approach to implementation across all participating countries. Capacity building is essential, and we should consider sharing best practices."*
>
> – ***Dr Steve Anderson, Director of Biostatistics and Epidemiology at the US FDA.***

One of the highlights from the meeting outcomes is their approval of the Ad-hoc Continental Safety Platform Working Group (CWG) report, which will guide through the initial phase of the expansion. The AU-3S SG approved most of the recommendations, with a few highlighted for further discussion, such as the programme's sustainability.

7. Joint Signal Management (JSM) Group In-Person Meeting

The Joint Signal Management (JSM) Group convened from September 13th to 14th, 2023, shortly after the Steering Group meeting. Several important decisions were made during this meeting, marking a pivotal moment in the evolution of safety surveillance efforts across Africa. A highlight of these is the rebranding of the JSM as the African Union Pharmacovigilance Risk Assessment Committee (AU-PRAC), reflecting its broader and more comprehensive role in signal management for an expanded scope of products and across more countries. There will also need to be an update to the signal management model being used. It will move to a decentralized signal detection and validation process led by individual NRAs based on the product being considered, followed by signal assessment and regulatory/risk recommendation at the central level.

As the transition is in progress, safety surveillance will continue the expansion with the determined product scope described above for a systematic adaptation of the signal management process.
The discussions and decisions made during the JSM Group meeting reflect a commitment to strengthening safety surveillance processes across Africa. The eventual transition to the new model and the emphasis on collaboration and expertise underscore the continent's dedication to safeguarding public health with safety monitoring.

8. AU-3S Successfully Closes COVID-19 Vaccine Safety Surveillance Pilot

In a significant stride toward ensuring the safety and efficacy of COVID-19 vaccines, the AU-3S SG officially plans to close out the COVID-19 vaccine safety surveillance pilot at the end of 2023 by approving a focused plan addressing any outstanding reports due within the Data Integration and Signal Detection (DISD) platform. As of November 2023, the programme has collected and analysed 46,743 Adverse Events Following Immunisation (AEFI) reports for six COVID-19 vaccines administered in Nigeria (31.30% of total reports in the DISD), Ethiopia (35.6%), South Africa (16.7%), Ghana (13.9%), Kenya (2.30%). Out of these reports, 2,712 vaccine-event pairs were validated. Ten key safety-related recommendations were issued by the AU-3S Joint Signal Management Group, two of which involved educating patients and healthcare providers, and one required member countries to request additional information from the market authorisation holders.

The decision to formally close out the pilot comes with the AU-3S programme's commitment to completing a comprehensive review and resolution of all reports. The careful consideration of each report, without overlooking any potential signals, reflects the programme's dedication to maintaining the highest pharmacovigilance standards.

The closure of the COVID-19 vaccines safety surveillance pilot represents a step forward in the programme's ongoing commitment to the safety and well-being of the African population through the planned expansion. The programme remains dedicated to maintaining the highest safety monitoring standards, contributing to the broader global effort to safeguard public health.

9. The AU-3S Programme's Achievement in Pharmacovigilance: Winning the Sten Olsson Poster Prize

During the International Society of Pharmacovigilance (ISoP) Annual Meeting in Bali, between November 6th and 9th, 2023, the AU-3S Programme presented a poster about the Joint Signal Management (JSM) Group and its contribution to the COVID-19 vaccine safety surveillance pilot under the AU-3S programme. The presentation laid out the collaborative signal management process, which included signal detection on cross-country safety data, data integration and signal detection management, technical partnership with MHRA as peer regulator, as well as how members of the JSM Group worked together for signal assessment and mutual learning through the COVID-19 pandemic.

The programme's successful and innovative approach, demonstrated by the poster's content, relevance and impact, captured the ISoP scientific committee's attention, leading to the programme receiving the Sten Olsson Poster Prize. The Prize was created in 2022 to award posters that best demonstrate the advancement of pharmacovigilance in a low and middle-income setting. The ISoP Annual Meeting serves as a vital platform for experts, researchers, and professionals in the field to share insights and discuss the latest developments in pharmacovigilance. The recognition received by the programme is not only a celebration of its achievements but also underscores the importance of fostering innovation and excellence in pharmacovigilance across the African continent. We extend our sincere congratulations to the AU-3S Programme.

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An Update on Smart Safety Surveillance in Africa

10. AU-3S Staffing Update

The AU-3S team is growing! Help us welcome **Mr. Kudakwashe Dandajena,** our new **Principal Programme Officer for Technology Strategy.**

He has more than 14 years of experience in the non-profit, public sector, academic, and research space—leading and managing digital transformation, scientific, research, engineering, manufacturing, and mathematics programmes and projects. Kudakwashe implemented substantial global initiatives in more than 60 different countries across five worldwide regions. Kuda has a deep technical understanding of management principles, models, and strategies for programmes and projects.He is also well-versed in contemporary trends, opportunities, and difficulties that modern initiatives and programs face in the twenty-first century. Over the past decade, he developed an interest in the ethical use of cutting-edge emerging tech solutions to address current and future global challenges. He serves as the Global Partnership on Artificial Intelligence's (GPAI) Science Representative and Artificial Intelligence Expert Member. Kuda holds a Ph.D. in Computer Science at the University of the Western Cape South Africa, with a particular research focus on optimisation of Artificial Intelligence algorithms.

MR. KUDAKWASHE DANDAJENA, OUR NEW PRINCIPAL PROGRAMME OFFICER FOR TECHNOLOGY STRATEGY

"For me, it's a great opportunity and an honour to be a part of the continental movement that is taking concrete steps towards future Africa we all want which must be healthier, safer and prosperous. Personally, I'm anticipating an exciting journey that will bring about more transformational and significant deliverables for both current and future generations."

- **Mr. Kudakwashe Dandajena, our new Principal Programme Officer for Technology Strategy.**

10. AU-3S Staffing Update

Help us welcome **Mr. Kenneth Nkemakolam Onu,** our new **Principal Programme Officer for Therapeutics.**

He holds a Bachelor of Pharmacy degree from the University of Benin, Nigeria (2005) and an MSc in Pharmaceutical Analysis with distinction from the University of Strathclyde Glasgow, United Kingdom (2008). He began his career as an Intern Pharmacist at NAFDAC Nigeria (2006-2007). After a brief spell with GlaxoSmithKline Research and Development Ware in Hertfordshire, United Kingdom (2009-2010) and AstraZeneca Pharmaceuticals Nigeria (2011), he rejoined NAFDAC in 2012 as a Senior Regulatory Officer and rose to the rank of Chief Regulatory Officer in 2022. As a staff member of the National Pharmacovigilance Centre in Nigeria, Kenneth spearheaded the launch of the Med Safety App in November 2020, resulting in a significant improvement in adverse event reporting rates. His responsibilities included overseeing the collection, collation, and analysis of adverse event reports from medical products and vaccines. In addition, Kenneth served as the Programme Manager for the Global Fund Resilient and Sustainable Systems for Health grant. He successfully coordinated projects in pharmacovigilance system strengthening, laboratory support/quality control, and pharmaceutical traceability of HIV/AIDS, tuberculosis, and malaria. Prior to joining AUDA-NEPAD as Principal Programme Officer, Kenneth represented Nigeria in the AU-3S Joint Signal Management secretariat (March 2021 - July 2023). With over 18 years of experience in medical product regulatory sciences, including drug safety, pharmacovigilance, and quality assurance, Kenneth brings comprehensive expertise to his role.

"I am excited to contribute to the AU-3S programme expansion and I am committed to building an AfriVigilance ecosystem for the African continent. I also look forward to supporting medical products safety surveillance initiatives aligned with Agenda 2063 and ultimately create a better Africa that we all want."

- **Mr. Kenneth Nkemakolam Onu, our new Principal Programme Officer for Therapeutics.**

MR. KENNETH NKEMAKOLAM ONU, OUR NEW PRINCIPAL PROGRAMME OFFICER FOR THERAPEUTICS

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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