


Spotlight
An Update on Smart Safety
Surveillance in Africa

Edition 4

January 2023



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1. AU-3S Programme Support to Participating Countries

Summary

As part of the AU-3S programme, each pilot country conducted a gap assessment for safety surveillance systems accordingly. The identified opportunities were diverse and some country-specific by nature, which highlighted the need for centralized cross-country solutions as well as country-specific ones to adequately address individual gaps.

Among many activities, the AU-3S programme established capacity-strengthening exercises with the technical partner MHRA for in-country support along with the governance body for seamless implementation across all pilot countries.

Each pilot country reported significant achievement under the support of the AU-3S programme including the improvement of AEFI reporting in quantity and quality of the data, along with enhanced capacity in safety data collection and management, signal detection and management, and regulatory decision-making. These improvements are also supported by the establishment of legal frameworks and guidance that effectively supported the entire safety surveillance systems strengthening.

With the approval of new funding from the BMGF, each country will be able to tackle even more challenges in preparing for the longer-term strengthening and sustainability of the safety surveillance systems.



The unprecedented nature of the COVID-19 pandemic and the record timelines for the COVID-19 vaccine rollout further strengthen the importance of safety surveillance. This resulted in the re-prioritization of the AU-3S programme to meet the current needs and urgent demand for a strong, coordinated, multi-country approach to vaccine safety monitoring in Africa. Presently, the AU-3S programme supports five (5) Member States – Ethiopia, Ghana, Nigeria, Kenya, and South Africa.

At the onset of the COVID-19 pandemic and upon joining the AU-3S programme on COVID-19 response, the AU-3S Countries – Ethiopia, Ghana, Nigeria, and South Africa, identified their country-specific gaps in safety surveillance systems. A similar exercise was done by Kenya prior to onboarding to the AU-3S programme, highlighting their in-country challenges hampering safety surveillance. There was an urgent need to address these gaps to strengthen the systems in-country and to enable them to participate effectively in the AU-3S programme to achieve successful outcomes.

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The success of the African Union Smart Safety Surveillance programme and the work they do has hinged on the commitment of the country CEOs.”

-Prof Bartholomew Dicky Akanmori, Vaccine Research, Regulation and Safety Director, WHO-AFRO



What are the identified gaps in AU-3S countries' safety surveillance systems?

Some of the identified gaps were common to all the countries, such as bringing awareness on the importance of safety reporting amongst healthcare workers and the public– corroborating the known historically low levels of adverse event reporting in African countries; making electronic reporting tools available for adverse events reporting – rather cumbersome paper reporting and phone-in were the norms, resulting in poor data quality. All recognized another opportunity to improve resources and capacity for pharmacovigilance skills and activities such as data collection and management, signal detection and management, and regulatory decision-making.

Countries also determine the use of Med Safety App for safety data collection. Three countries (Ethiopia, Ghana, and Nigeria) had subscribed to the Med Safety App for adverse event reporting for drugs before the inception of the AU-3S programme while South Africa subscribed to the Med Safety App following awareness from the AU-3S programme. However, the Med Safety App usage compared to other reporting platforms, particularly in Ghana, was relatively low, which shed light on the importance of bringing awareness of the App to the public and healthcare workers.

In addition, Ghana identified an opportunity to improve its database (Safety Watch System – SWS) for advanced search and statistical analysis functions. Feedback from Nigeria stated

that one of the factors contributing to potentially lower reporting is the perceived fear of litigation following safety reporting by healthcare workers, which made healthcare workers shy away from reporting. Kenya stated two additional needs related to having a more comprehensive legal framework to ensure enforcement of pharmacovigilance-related activities and conducting active surveillance to address the gap of spontaneous reporting to adequately capture safety information on the novel vaccines.

Moreover, to determine required interventions at the central level for all participating countries, the AU-3S team carried out landscape assessments through engagement with safety monitoring experts from National Regulatory Authorities (NRA) and Expanded Programme on Immunization (EPI) leads from the four countries. The EPI leads are critical to obtaining the end-to-end safety data flow. The outcome of the landscape assessment identified areas for improvement to include strengthening the safety surveillance systems, strengthening human and resource capacities, establishing effective and efficient safety data collection tools to help drive data quality and reporting rates, improving coordination between NRA and EPI, facilitating information sharing between and among countries, and standardizing related policies & guidelines. Besides, engagements with the participating NRA Chief Executive Officers (CEOs) also revealed the need for a shared data repository and capacity to make evidence-based safety decisions.



What is the support from AU-3S programme to address the gaps?

Based on this knowledge, the funding partner of the AU-3S programme – the Bill and Melinda Gate Foundation (BMGF) approved the establishment of grants to the five participating countries to enable direct implementation of in-country solutions to address the country-specific challenges. Enhancing in-country safety systems strengthening to enable system changes is critical for countries to fully participate in the program and complement the work done at the central level for post-marketing surveillance.

The support from AU-3S ranged from the implementation of capacity strengthening modules with support from MHRA, the launch of the Adverse Events Following Immunization (AEFI) reporting form in the Med Safety App and related data collection implementation support to EPI officers, the launch of Vigilance Hub as the back-end for Med Safety App for data management, record-time development and implementation of data integration and signal detection (DISD) system for cross-country data pooling and management, and inauguration of the Joint Signal Management (JSM) group and secretariat for signal assessment, review and safety recommendations. However, consideration and subsequent decisions on the recommendations remain the responsibility of individual countries' NRA.

The programme also established a governance body led by the NRA CEOs to provide strategic direction for implementation. Ongoing support is facilitated through regular country engagements and knowledge and experience sharing, including

partners' platforms such as the WHO African Vaccine Regulatory Forum (AVAREF).

Notably, during the ordinary session in September 2022, the Ministers of the 4th African Union Bureau of the Specialized Technical Committee on Education, Science and Technology (STC-EST 4) made the following recommendations regarding the AU-3S programme:

- (a) **NOTE** the establishment of a continental platform through the AU Smart Safety Surveillance (AU-3S) programme with representation from five countries to monitor the safety of COVID-19 therapies and other medical products of priority diseases.
- (b) **CALL UPON** the AUDA-NEPAD through the AU-3S programme to develop a guidance framework for safety monitoring, of existing and potential medicines and vaccines.
- C) **URGE** AUDA-NEPAD to continue to ensure that more countries are included in the AU-3S programme.

AU-3S programme will implement these recommendations during its longer-term implementation, along with expansion to additional countries and health products already being planned for Phase 2 starting in January 2023.

What are the achievements recorded in the AU-3S countries?

The grants and other support highlighted above resulted in significant achievements as reported by the countries (see Figure 1).







- | | |
|---|--|
| <p> Availability of human resources and logistics for safety monitoring activities</p> <ul style="list-style-type: none"> • Engagement of temporary support staff • Purchase of laptop and desktop computers, other IT goods and services, and internet data | <p> Improved safety communication</p> <ul style="list-style-type: none"> • Development and dissemination of communication strategy, and COVID-19 vaccine media campaign protocol and plan • Training of media practitioners in Ethiopia |
| <p> Effective collaboration and integration of in-country stakeholders on vaccine safety surveillance</p> <ul style="list-style-type: none"> • Improved visibility of AEFI monitoring in the health facilities in Nigeria • Supportive supervision at vaccination sites for effective data collection in Ethiopia | <p> Increased AEFI reporting and improved data quality</p> <ul style="list-style-type: none"> • Improved awareness of the Med Safety App (MSA) for reporting AEFIs • Acquisition of the MSA in South Africa • Acquisition of data collection equipment for active safety surveillance of COVID-19 vaccines in Kenya |
| <p> Establishment of pharmacovigilance legal framework, revision of processes and dissemination of updates</p> <ul style="list-style-type: none"> • Development and gazette of legal provisions (PV/PMS rules, 2022) to support the implementation of pharmacovigilance activities in Kenya • Printing and distribution of revised AEFI guidelines and reporting format, standard operating procedure (SOP) for case investigation, and terms of reference (TOR) for the safety advisory committee in Ethiopia | <p> Enhanced capacity in safety data collection and management, signal detection and management, and regulatory decision-making</p> <ul style="list-style-type: none"> • Improved search and statistics functions of the SWS in Ghana • Data analytics function of the Vigilance Hub for all the countries • Various capacity-strengthening activities in-country and continued access to AU-3S/MHRA training modules • Conduct active surveillance for the COVID-19 vaccine |

Figure 1. Achievements from AU-3S safety surveillance system strengthening support as reported by countries

What are the next steps?

While recognizing the outstanding achievements made in the five AU-3S countries from the utilization of the grants and implementation support at the central level, the countries have noted that there are a few pending gaps still to be addressed. To further support the countries, BMGF approved a supplementary grant to the four pilot countries (Ethiopia, Ghana, Nigeria, and South Africa), and the agreement is currently being processed by AUDA-NEPAD.

Furthermore, BMGF has confirmed the approval of an additional grant to support the strengthening of the longer-term in-country safety surveillance system for original pilot countries and any new countries for the expansion phase. For each country, work is underway in developing a priority work plan and related budgets to deliver on the high-level goals for 2023-2025. Further updates on the impact of the in-country sub-delegation agreement grants will be provided as it evolves.

2. AU-3S Programme Impact to Date

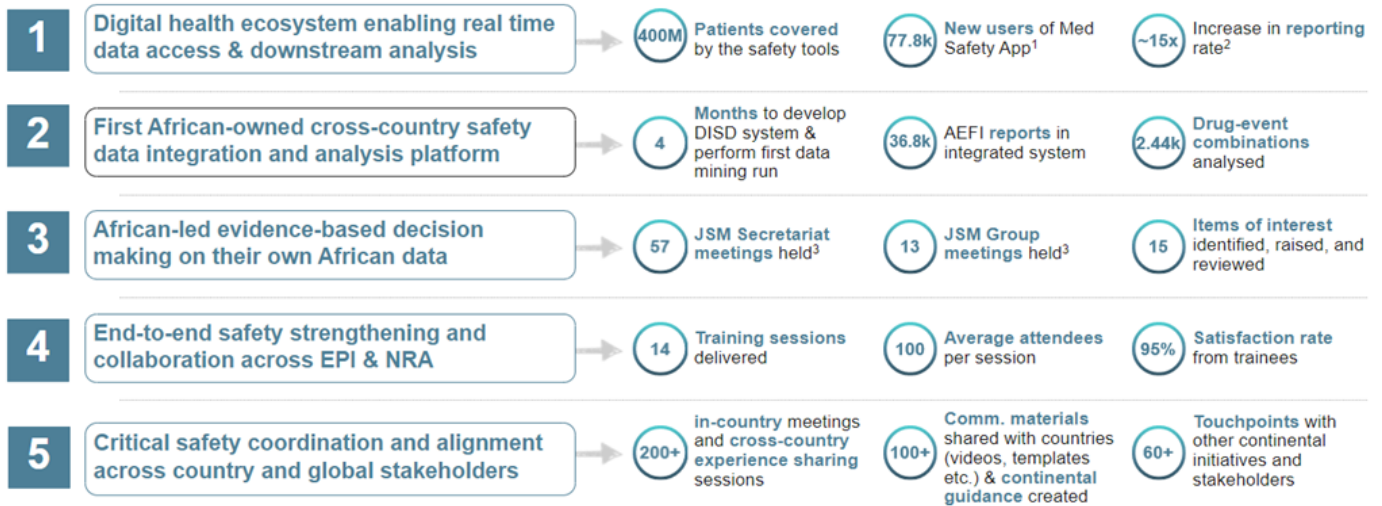


Figure 2. The five key areas of impact for the AU-3S programme

Note: As of 9 December 2022, there are 36,781 AEFI reports in the interim DISD system

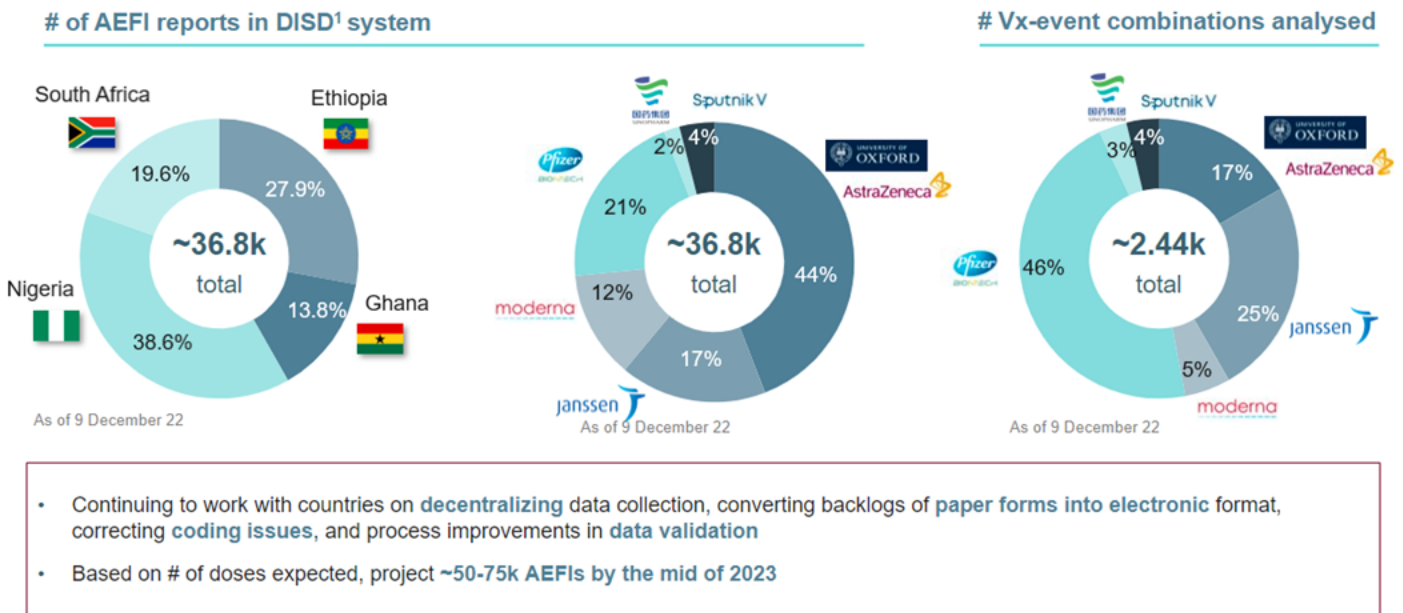


Figure 3. AEFI reports in the DISD system



3. AU-3S Engagement Updates to Date

What engagements has the programme had since June 2022?

Since publishing the AU-3S Spotlight Update Edition 3 in June 2022, the AU-3S programme has had several

engagements which have contributed to the programme's growth, visibility, and reach. To date, a series of over eight engagements have taken place successfully. See the details below;

July 2022	Presentation at the African Group meeting of the International Society for Pharmacoepidemiology was well received by the group with a request for further engagement/discussion with the AU-3S programme	
July 2022	Successful engagement with AUC to secure AU-3S participation to the STC Ministerial and expert sessions	
August 2022	Presentation at the AVAREF Workshop for implementation guide for Safety Monitoring for Clinical Trials on 30-31 August 2022	
September 2022	Held AU-3S Steering Group face to face meeting from 5 to 6 September in Abuja-FCT, Nigeria	
October 2022	AU-3S JSM secretariat held its first face-to-face meeting in Nairobi, Kenya on 31 October 2022	
November 2022	AU-3S JSM Group held its first face-to-face meeting in Nairobi, Kenya on 1 November 2022	
November 2022	Conducted a refresher training on causality assessment for the JSM Group and secretariat members in Nairobi on 2 November	
November 2022	Successful participation and facilitation of countries' experience sharing in the AVAREF webinar on AU-3S programme: Expansion plan and DISD system	

Figure 2. Engagements had by the AU-3S programme dating from June 2022



4. Steering Group In-Person Meeting

The AU-3S Steering Group held its first in-person meeting on 5th and 6th September 2022 in Transcorp Hilton, Abuja Federal Capital Territory (FCT) in Nigeria, following a series of virtual meetings since its inauguration in October 2020.

The Steering Group meeting brought together the Chief Executive Officers (CEOs) from each of the National Regulation Authorities, the AU-3S programme technical partner MHRA, and the funders, BMGF. The Steering Group meeting provided a platform for the multi-country group to review current gaps, progress made, the programme strategy as well as future plans. In addition, the meeting served as a nexus for peer learning and best practice exchange.

During the meeting, the Steering Group reaffirmed the importance of generating an acceleration plan for Kenya, the newest pilot country of the AU-3S programme, to support them in reaching and maintaining similar progress and impact made by the other four pilot countries. Furthermore, the CEOs agreed that there is an urgent need to make the AU-3S Med Safety App available for all countries in Africa, particularly the countries currently listed in the geographic scale-up plan while noting that there are 12 countries in Africa already making use of the Med Safety App. At the same time, the Group reaffirmed the need to standardize safety data collection tools deployed in the AU-3S pilot countries in order to enable the collection of quality data and interoperability. The Group also called for additional discussions on how best to strengthen data analytics capacity at a continental level and/or within the countries.

In addition, the Group decided to move officially toward phase 3 of the programme, which involves the expansion of the programme with additional countries and products. As part of this decision, the CEOs discussed the selection criteria for additional pilot countries for the programme and some of the scale-up plans. It was noted that a deeper dive into the programme objectives and expansion plans is crucial in deciding on additional countries, and the Group would review the proposed selection criteria. The CEOs acknowledged that the criteria used in scaling up the AU-3S programme to additional countries would be weighted on; geographical location, language, data contributions, meeting minimum pharmacovigilance (PV) function and systems, willingness, past or current involvement in other continental initiatives, the status of WHO global benchmarking tools for the PV function (both for medicines and vaccines), as well as existing tools and sustainable applications feeding into a compliant system.

The Steering Group meeting was engaging, lively, and fruitful and had active participation from the NRAs and partners. The enthusiasm shown by the Group to share their country experiences and learn from each other led to concrete discussions and contributions, which helped to frame crucial next steps, actions as well as resolutions that will aid in advancing the programme toward its next phase of execution.

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We are very pleased with the progress made by the pilot countries and the hard work they continue to put into ensuring efficacy in the context of safety”

- Professor Aggrey Ambali, Senior Advisor at AUDA-NEPAD



5. JSM Group and Secretariat Face-to-Face Training

To foster cross-country signal management and to further deliver concrete scientific recommendations towards the safety of COVID-19 vaccines, AU-3S hosted the first Face-to-Face Joint Signal Management (JSM) meeting in Nairobi, Kenya on the 31st of October 2022 to 2nd of November 2022.

The Face-to-Face JSM meeting hosted representatives from the AU-3S programme's UK technical partner, the Medicines and Healthcare Products Regulatory Authority (MHRA), the representatives from the pilot countries' National Regulation Authorities (NRA) -Ethiopia, Ghana, Kenya, Nigeria, and South Africa - as well as the AU-3S in attendance.

The JSM Group, which consists of safety experts from each of the AU-3S pilot countries, was formed to share insights and expertise on the best practices and knowledge, such as casualty assessments. The JSM Group discussions are informed by findings from the JSM Secretariat, which assesses safety issues on Adverse Events Following Immunization (AEFIs) and Adverse Events of Special Interest (AESIs).

During the meeting, many information exchanges and capacity-building activities occurred. Among a few notable ones were the JSM Secretariat's presentation and demonstration of the signal validation processes from biweekly data mining. Several interesting signals were also discussed with the entire JSM Group, such as appetite-related events, ocular disorders, ear disorders, myocarditis and pericarditis, Guillain-Barré Syndrome (GBS), anaphylaxis, and epistaxis.

In addition, a refresher training was organized by AU-3S for the JSM as a walk-through on causality and signal management to enable more effective signal management activities by the JSM. The pilot countries benefited tremendously from the refresher training as they continue to carry out actions that address safety issues effectively. The training activities are a part of the AU-3S programme's priority as continuous capacity-building efforts for the National Pharmacovigilance staff and the advisory committee.

Professor Elena Rocca from Oslo Metropolitan University and Dr. Rebecca Chandler from Clinical Development Vaccine Safety Lead with Coalition for Emergency Preparedness Innovation (CEPI) on causality assessment for small data sets using the DX3 causality assessment framework. The DX3 framework can help investigators to detect potential harm caused by a drug to qualitatively evaluate the relevant evidence of whether a particular medicine has or could have caused a certain adverse event. The approach will be useful for staff in the NRA and the JSM group to widen their methodological approach while assessing causality for both single individual case safety reports (ICSRs) and case series.

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The success of the AU-3S programme starts and ends with the JSM Group. That is where the data is assessed and monitored for the different populations in Africa.”

- Professor Hannalie Meyer, Chair of the JSM Secretariat

6. AVAREF Webinar on AU-3S Progress Update

AU-3S, through the WHO-AFRO AVAREF, held the third annual webinar to showcase current updates on the impacts of the AU-3S programme under the theme: AU-3S Progress Update – Expansion Plan and the Data Integration and Signal Detection (DISD) on the 17th of November 2022.

The webinar served to solidify the existing partnership with WHO-AFRO AVAREF as an AU-3S programme’s long-standing partner. In addition, the webinar provided a platform for several pilot countries -Kenya, Ghana, Nigeria, and South Africa- to share their country experiences, achievements to date, implementation challenges, the gaps identified since joining AU-3S as well as plans and priority activities for the near future.

The AU-3S programme continues to engage with WHO-AFRO AVAREF in the implementation of the programme while working collaboratively to improve the visibility of the programme. The engagement has also enabled effective dissemination of the programme impacts to facilitate sustained commitment and further support from partners.

AVAREF Webinar Series – November/December 2022
Building Capacity and promoting harmonization for facilitating Clinical Trials for Health Products in Africa

AU-3S Progress Update – Expansion Plan and DISD System



17 Nov
2022



1PM-2:30PM
GMT

Presented by:



Hudu Mogtari

Programme Lead for the AU Smart Safety Surveillance (AU-3S) programme

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7. Kenya Progress Update Since On-boarding

Since onboarding Kenya as the newest pilot country to the AU-3S programme in March 2022, the country has made immense progress in getting up to speed to meet other pilot countries' progress.

Recently, the AU-3S team had an in-person check-in meeting at the Kenya Pharmacy and Poisons Board (KPPB) on 28 September 2022. Since joining the programme, the KPPB has worked on active surveillance through cohort event monitoring and active patient follow-up. During the meeting, the participants reached a consensus on building a detailed report outlining the successful changes that have happened since Kenya joined the AU-3S programme. The grant received from the AU-3S programme has assisted KPPB to expand on their human resources by enabling them to carry out recruitment processes for six resource individuals who will provide research assistance on safety surveillance.

In addition, KPPB expressed that they have since been able to move pending procurement activities forward by acquiring equipment that will aid in the work being done swiftly.

KPPB has also worked closely with the MHRA to ensure compatibility between the Med Safety App and the Vigilance Hub in Kenya. This process is now in the final stages of linking to the Vigilance Hub, which is anticipated to launch by the first quarter of 2023.

KPPB's data will be integrated in less than a month into the DISD system"

- Ms. Martha Mandale says on behalf of KPPB during her country presentation at the recent AVAREF webinar in November 2022





8. Country Focus: Med Safety App Use in Ghana

In this fourth Edition of Spotlight, we focus on Ghana's experience with the use of the Med Safety App.

Note: This article was drafted by the Ghana Food and Drugs Authority (Ghana FDA).

Ghana is one of the pilot countries of the AU-3S programme and launched the Med Safety App in June 2019 before joining the programme. The App was introduced as an additional tool to complement the existing mechanisms for reporting individual case safety reports, namely, paper forms for healthcare professionals and consumers, online reporting through the Food and Drug Authority's website for healthcare professionals and consumers, and telephone reporting by patients. At the time of the App launch, the target was for the App to contribute at least 20% of reports to the National Pharmacovigilance Center (NPC). Pharmacovigilance awareness creation during a clinical meeting of healthcare professionals was used as the leading platform for promoting the App. The pharmacovigilance training programme also provided opportunities for promoting the App.

During the deployment of the COVID-19 vaccination, the AU-3S programme supported promoting the App as the most preferred reporting tool. These promotional activities generally started in March 2021. The App was mentioned during every engagement on COVID-19 vaccination. The main promotional activity was a

nationwide campaign in all the administrative regions in Ghana with the 1st phase taking place from October till December 2021. The campaign strategy was to build recognition on the app on various forms of media such as print media, media houses and social media. These activities added 1,393 new users during October 2021 and 1,820 additional new users during November 2021.

Another campaign strategy worth mentioning was the one targeted at medical Institutions, with the campaign strategy to promote the app in targeted healthcare facilities and healthcare professional training institutions. The targeting of the healthcare professional institutions dubbed "Hospital drive" was part of the general "recognition strategy", however the targeting of the students dubbed "College and School drive" was to enable student healthcare professionals: doctors, nurses, pharmacists, know the App and introduce it to patients.

From January to February 2022, the Med Safety App Public Activation Drive was implemented as part of activities being supported by the AU-3S programme to ensure COVID-19 vaccine safety. In this campaign, public places including cinemas, hospitals, and clinics, were targeted. Visitors to these places were introduced to the App and assisted in downloading it.



Following the Public Activation Drive, there were over 87,561 impressions on FDA's Facebook page during February 2022 on the post "Have you heard about the Med Safety App and 52,897 impressions on the post "You can download the Med Safety App from your Google Play Store for Android Users and App store for IOS uses."

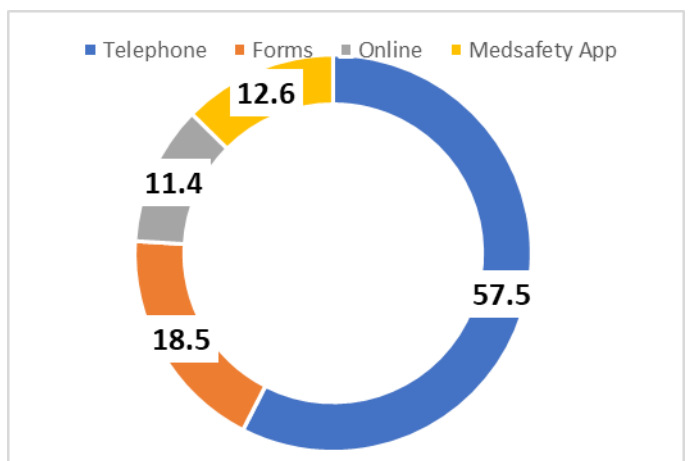
The average number of total users per month from June 2019 to February 2021 was 197, compared to 1,471 from the period March 2021 to October 2022.

As of the end of October 2022, Ghana has administered 19,979,299 doses of COVID-19 vaccines, with 9,527 AEFI reported and the Med Safety App is the source of 12.6% of these reports. Although telephone reporting is the most preferred tool, since most of the paper reports are those from active monitoring, the App is the 2nd preferred mode of reporting. This is a significant improvement compared to the level in December 2021, as the App corresponded to only 1% of the total reports.

The Med Safety App is a convenient tool for reporting medicine safety issues for healthcare professionals, consumers, and the staff of the National Pharmacovigilance Centre. For healthcare professionals and patients, they may report safety issues in any locations and for staff of the National Pharmacovigilance Centre, the App has reduced the burden of entering all the reported cases manually into the national database hence improving staff productivity.

In addition, the data from the App is transferred directly into Ghana's national safety database for immediate signal detection, therefore has added confidence in the safety of the COVID-19 vaccines.

The App promotional campaigns have also improved knowledge of Ghana's medicine safety monitoring system. In order to see the App's impact and solidify the App as the preferred tool for safety reporting, ongoing campaigns and activities over time have been necessary. The next steps for improving the App will potentially include medical devices and haemovigilance reporting tools in the App for the expansion of the AU-3S programme.





9. Suspected GBS Case Review in DISD

Following Guillain-Barré Syndrome (GBS) is a rare but severe disorder in which our body's immune system mistakenly attacks its peripheral nerve systems . The exact cause of GBS is unknown, but certain common risk factors, such as infections by other viruses as well as some vaccination, were reported.

Following the reporting of suspected GBS cases post-COVID-19 vaccinations in South Africa, the AU-3S Joint Signal Management (JSM) Group facilitated cross-country signal assessment and reviewed all suspected GBS cases in the programme's Data Integration and Signal Detection (DISD) system. The DISD system contained COVID-19 vaccine safety reports from the four pilot countries – Ethiopia, Ghana, Nigeria, and South Africa – at the time. From the cross-country data collected by the AU-3S programme, GBS appears to be a rare event limited to 3 cases in total, reported by the four pilot countries, including one death in South Africa. Among the 3 cases, 2 cases were linked to the Janssen vaccine, and the other 1 case might be connected to the Comirnaty vaccine but needs further investigation.

South Africa's National Immunisation Safety Expert Committee (NISEC) conducted the causality assessment to determine the likelihood of the event being linked to vaccination following the WHO methodology. In addition, the medicine regulatory agency in South Africa (SAHPRA) issued a [media brief](#) about the events. Through the JSM review processes, Ethiopia also highlighted the suspected GBS case reports and agreed to investigate and carry out a causality assessment using the approach taken by South Africa. In addition, the JSM group plans to serve as an advisory group as needed by the country.



10. Pharmacovigilance Award Presentation

The AU-3S team would like to celebrate and congratulate Victoria Prudence Nambasa, a Senior Programme Officer serving under Product safety for AU-3S AUDA-NEPAD.

Ms. Victoria Nambasa received a Pharmacovigilance Award during the 2022 Heroes in Health Awards (HIHA). HIHA is a reward initiative instituted by the Ministry of Health Uganda to recognize outstanding individuals, entities, innovations, communities, partners, organizations, services, products, and programs.

The award was extended as a recognition for her contribution towards setting systems for drug safety monitoring and leading several efforts to mitigate adverse effects from medicine use.



Victoria Nambasa

Senior Programme Officer

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“This celebration is extremely important to us as we believe so many unsung heroes in the country’s healthcare system work tirelessly to ensure the wellbeing and safety of Ugandans. Your journey is inspirational. We see you; we celebrate you and today we recognize your efforts. You are part of the invisible threads that hold the tapestry of the health sector together. You matter and your work matters”

-The HIHA team.

We consider ourselves privileged to have Ms. Victoria Nambasa in our team. Join the AU-3S programme as we celebrate her recognition.



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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