African Union Smart Safety Surveillance (AU-3S) Programme

Terms of Reference for the AU-3S Joint Signal Management Group

1. Overview

1.1 Background

- The African Union Smart Safety Surveillance (AU-3S) programme, led by AUDA-NEPAD, aims to create a sustainable continental safety monitoring system to improve the safety of priority medical products for patients across Africa
- Due to historically relatively low levels of adverse event reporting in African countries, a focus of the programme is to combine safety data across countries to strengthen signals identified and enable the identification of signals that potentially would not be picked up in a single country's data
- The AU-3S Joint Signal Management (JSM) Group has been set-up to identify and assess these cross-country signals
- The AU-3S JSM Group will report into the AU-3S's Steering Group
- These Terms of Reference aim to ensure effective operations of the AU-3S JSM Group through defining aspects such as structure and functions, governance, and meetings

1.2 Objectives of the AU-3S JSM Group

- The overarching objective of the AU-3S JSM Group is to facilitate cross-country signal management in Africa on combined safety data for priority medical products, to support action in the interest of public health and safety
- To fulfil this aim, the AU-3S JSM Group will:
    - Assess signals from safety data on priority medical products combined across countries; initially, priority medical products will be limited to COVID-19 vaccines
    - Promote collaboration on safety surveillance amongst African member countries
    - Be a forum for technical support from reference regulatory authorities to African regulatory authorities
    - Strengthen the capabilities of AU-3S JSM Group members through working with the MHRA and learning from good practice across member countries

1.3 Principles

- Decisions and recommendations made by the AU-3S JSM Group should be based on science and evidence
- Decisions taken by the AU-3S JSM Group should be based on consensus amongst AU-3S JSM Group members and, if relevant, invited experts
- Safety data inputs to the AU-3S JSM Group remain owned by the member countries
- The AU-3S JSM Group is designed to complement national committees' work, not to replace it
- There should be open and timely communication amongst national committees, the AU-3S JSM Group and other relevant stakeholders
- The AU-3S JSM Group's work should be collaborative, with member countries working together to improve safety surveillance in Africa

1.4 Scope

- The initial scope of the AU-3S JSM Group is COVID-19 vaccines, with the potential to extend to other priority medical products at a later stage

- Any scope extension should be agreed upon by AU-3S JSM Group members in consultation with the AU-3S Steering Group
- Decisions and actions taken based on recommendations from the AU-3S JSM Group remain the responsibility of member countries' national committees, regulatory authorities, and immunisation programmes

1.5 Roles

- The AU-3S JSM Group's key roles include:
  - Validating and assessing signals from member countries' combined data
  - Sharing findings on signals and recommendations with member countries' national committees and key continental and global stakeholders through African Union channels
  - Supporting national committees, if asked, in providing a forum for discussion of signals found in-country
  - Enabling knowledge and experience sharing on signals and other safety surveillance topics from reference regulatory authorities
  - Providing input into requirements for relevant cross-country data analysis

2. Structure and functions

2.1 Structure

- The AU-3S JSM Group's key roles are performed by its members with support from the secretariat
- The AU-3S JSM Group's members and its secretariat will be invited to all meetings of the AU-3S JSM Group
- The number of members in the AU-3S JSM Group should remain relatively limited to ensure the effective and agile functioning of the Group
- Additional experts will be called upon for specific topics as required

2.2 Secretariat

- The AU-3S JSM secretariat is led by AUDA-NEPAD
- The secretariat includes representation from reference regulatory authorities from outside the African continent to provide technical support as required
- The secretariat can also include a representative from each member country
- The representative can come from a member country's national regulatory authority or immunisation programme
- These member country representatives on the secretariat will work with AUDA-NEPAD on signal validation and prioritisation activities
- The secretariat:
  - Detects signals using the interim Data Integration and Signal Detection (DISD) system and other relevant data sources
  - Validates signals from member countries' data and prioritises them in preparation for AU-3S JSM Group meetings where prioritised signals will be assessed
  - Organises the meetings of the AU-3S JSM Group
  - Takes minutes of AU-3S JSM Group meetings
  - Communicates relevant information to key stakeholders
  - Regularly reports to the AU-3S Steering Group

2.3 AU-3S JSM Group members

- The JSM Group's members include representation from member countries':
  - regulatory authorities and immunisation programmes; and

- national committees, represented through their chairperson, deputy chairperson, or an assigned representative
- The AU-3S JSM Group can also include additional expert members to ensure core expertise areas are covered
- Core expertise areas for the AU-3S JSM Group include (in alphabetical order) biostatistics with training in epidemiology, clinical pharmacology, epidemiology, immunology, microbiology, pathology, pharmacy, public health, toxicology, and vaccinology
- AU-3S JSM Group members are responsible for clinical assessment of potential signals from member countries' combined data
- If required, further clinical assessment of these signals can be conducted by continental safety assessment committees, including the African Advisory Committee on Vaccine Safety (AACVS), in consultation with national committees where additional information is required
- If expertise not covered in the AU-3S JSM Group's members is required for the assessment of a specific signal, additional experts can be sourced to attend a specific meeting
- Decision to invite additional experts will be taken by the AU-3S JSM Group's secretariat in consultation with the AU-3S JSM Group's chairperson, based on a review of the proposed expert's expertise

3. Governance

3.1 Nomination of chairperson and deputy chairperson

- At the first regular meeting of the AU-3S JSM Group, a chairperson and deputy chairperson should be nominated
- The chairperson should be a member of the AU-3S JSM Group, and the deputy chairperson of the AU-3S JSM Group should come from AUDA-NEPAD
- The chairperson and deputy chairperson should be appointed for a 1-year period
- The chairperson's roles include:
  - Presiding over meetings
  - Approving the invitation of required experts in consultation with secretariat
  - Ensuring feedback on the AU-3S JSM Group's activities is provided to the AU-3S Steering Group
- The deputy chairperson should act in the absence of the chairperson or when the chairperson requests him/her to do so

3.2 Confidentiality and conflict of interest

- All AU-3S JSM Group members and invited experts are expected to conduct themselves appropriately
- All AU-3S JSM Group members and invited experts will be required to sign a confidentiality agreement (see Appendix A), which will be reviewed annually
- All AU-3S JSM Group members and invited experts will be required to sign a conflict of interest (COI) declaration (see Appendix B), which will be reviewed annually
- All AU-3S JSM Group members and invited experts must verbally declare all interests which may constitute a COI – real, potential, or perceived – at the start of every meeting of the AU-3S JSM Group, and disclose any circumstances that may place or be seen to place the member in a real, potential, or perceived COI
- The chair will decide, after discussion with the attendee, whether or not this constitutes a COI
- All AU-3S JSM Group members should not be affiliated with the medical product industry

3.3 Reporting

- The AU-3S JSM Group's chairperson or a designated representative should attend AU-3S Steering Group meetings to brief the Steering Group on the activities of the AU-3S JSM Group

3.4 Membership review

- The structure of the AU-3S JSM Group, and its membership, may be reviewed with future scope changes and/or on request by countries
- Members of the AU-3S JSM Group should be appointed for a 2-year period
- Membership of individual representatives may be reviewed by the AU-3S JSM Group chairperson, the secretariat and the AU-3S Steering Group based on criteria including:
    - Absence from 3 consecutive meetings
    - Conflict of interest arising from change in affiliation
    - Breach of confidentiality

3.5 Terms of Reference review

- The AU-3S JSM Group Terms of Reference may be reviewed as and when required by AU-3S JSM Group members and/or the AU-3S Steering Group

4. Meetings

4.1 Frequency

- AU-3S JSM Group meetings should be as frequent as required to ensure signals are assessed without delay, enabling national committees and other bodies to effectively act on the JSM Group's recommendations
- Required frequency will be determined by the volume of data, and corresponding number of signal reports, to be assessed

4.2 Format

- AU-3S JSM Group meetings will be held virtually, over a platform agreed-upon before the first official meeting of the AU-3S JSM Group
- An annual strategy meeting or extraordinary meeting could be held physically if agreed upon by members and the AU-3S Steering Group

4.3 Agenda

- AU-3S JSM Group meetings' exact agendas will be determined by the signal(s) under discussion
- Generally, AU-3S JSM Group meetings should include:
    - Attendance and apologies
    - Confidentiality undertaking and declarations of interest of members
    - Adoption of meeting agenda and minutes of previous meeting
    - Presentation of signal validation report
    - Discussions on validated signals
    - Collation of recommendations
    - Any other business
    - Adjournment

4.4 Quorum

- The quorum of the AU-3S JSM Group shall be minimum of 7 members with representation from at least 3 AU-3S countries
- In the absence of a quorum, the meeting shall be rescheduled to a new date within a maximum period of two (2) weeks from the initially planned date

- Each member has a responsibility to confirm his/her availability for a meeting not later than 48 hours prior to the meeting date

4.5 Communication

- Information sharing should occur regularly and without delay from the AU-3S JSM Group's secretariat to national committees' secretariats, and vice versa

- Information shared should include preliminary findings for discussion where this facilitates prompt reaction to potential signals by the AU-3S JSM Group or national committees
- The AU-3S JSM Group will also communicate to key continental and global stakeholders through the AUDA-NEPAD network
- Communication to other stakeholders, including the media and the public, will remain the responsibility of national committees and organisations, and not the AU-3S JSM Group

Appendices

Appendix A: Confidentiality agreement

Please complete this confidentiality agreement and submit it to the AU-3S JSM secretariat at AU3S@nepad.org.

- For the purposes of validating and assessing cross-country signals, the AU-3S Joint Signal Management Group (JSM Group) will have access to potentially sensitive information, including:
  - o Combined signal reports with non-identifiable personal information from the interim Data Integration and Signal Detection (DISD) system
  - o Other safety information shared by member countries' representatives and other AU-3S JSM Group participants
- The AU-3S JSM Group will share its findings and recommendations through specific, identified channels; namely:
  - o To national committees' secretariats
  - o To identified continental or global committees or groups through official African Union (AU) channels
- Communication to other stakeholders, including the media and the public, will remain the responsibility of national committees and organisations, and not the AU-3S JSM Group
- All sharing of information from the AU-3S JSM Group should be done through the AUDA-NEPAD secretariat
- The undersigned undertakes to regard the information shared with him/her as part of his/her duties on the AU-3S JSM Group as confidential
- The undersigned agrees to take all reasonable measures to ensure that the information is not used, disclosed or copied, in whole or in part, other than for the purposes of fulfilling his/her work on the AU-3S JSM Group
- If requested to do so, the undersigned agrees to return to AUDA-NEPAD any and all copies of information received in his/her work on the AU-3S JSM Group

Signature:

Name & surname:

Date:

Place:

Appendix B: Conflict of interest declaration

Please complete this conflict of interest declaration and submit it to the AU-3S JSM secretariat at AU3S@nepad.org. Please ensure you include all actual, potential, or perceived conflicts of interest.

Where do you work?	
What position do you hold?	
Are you a member of a Board of Directors of an organisation? If so, please list the organisation(s)	
Are you the owner, co-owner or stockholder of a private health products or safety-related business? If so, please list the business(es)	
Do you serve on another safety-related committee or group? If so, please list the committee(s) or group(s)	
Please list any other affiliation or situation you believe may cause a conflict of interest for you	

To the best of my knowledge and belief any actual, perceived, or potential conflicts to my involvement with the AU-3S Joint Signal Management Group have been fully disclosed in this form.

Signature:

Name & surname:

Date:

Place:

AU-3S Joint Signal Management Group (JSM Group) members as of 28 October 2022:

Expertise area	Name	Organisation	Country
Clinical pharmacology	Prof Blockman	Pharmacovigilance Advisory Committee	South Africa
	Dr Hannah May Gunter	University of Cape Town	South Africa
Clinical pharmacy	Uchenna Elemuwa	National Agency for Food & Drug Administration and Control (NAFDAC)	Nigeria
Epidemiology	Dr Kwame Amponsa-Achiano[1]	Ghana Health Service (GHS)	Ghana
	Prof John Gyapong	Technical Advisory Committee	Ghana
	Dr Garba Ahmed Rufai	National Primary Health Care Development Agency (NPHCDA)	Nigeria
Geriatrics	Dr Henry Lawson	Technical Advisory Committee	Ghana
Infectious diseases	Assoc Prof Workeabeba Abebe[2]	National AEFI Committee	Ethiopia
Immunisation expertise	Marione Schonfeldt[3]	National Department of Health (NDoH)	South Africa
Immunology	Dr Tamrat Abebe	College of Health Sciences, Addis Ababa University	Ethiopia
Microbiology	Dr Kerrigan McCarthy	National Institute for Communicable Diseases	South Africa
Pathology	Prof Abdullahi Mohammed	National Expert Committee	Nigeria
Pharmacoepidemiology	George Sabblah	Ghana Food & Drug Authority (FDA)	Ghana
Pharmacology	Asnakech Alemu	Ethiopia Food & Drug Authority (EFDA)	Ethiopia
Pharmacy	Florah Matlala[4]	South Africa Health Products Regulatory Authority (SAHPRA)	South Africa
Public health	Prof Hannelie Meyer[5]	National Immunisation Safety Expert Committee	South Africa
	Yohannes Lakew	Expanded Programme on Immunisation (EPI)	Ethiopia
Toxicology	Dr Alexander Nyarko	University of Ghana	Ghana

Appendix D: Acronyms

Acronym	Meaning
AACVS	African Advisory Committee on Vaccine Safety
AU-3S	African Union Smart Safety Surveillance
AUDA-NEPAD	African Union Development Agency
COI	Conflict of interest
DISD	Data Integration and Signal Detection
JSM	Joint Signal Management
MHRA	Medicines and Healthcare products Regulatory Agency
UK	United Kingdom

Term	Definition
AU-3S Steering Group	Steering Group for the African Union Smart Safety Surveillance programme, which includes representatives from AUDA-NEPAD, member countries, WHO's Regional Office for Africa (WHO-AFRO), WHO's Regional Office for the Eastern Mediterranean (WHO-EMRO), the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), and the United States Food and Drug Administration (FDA)
Member countries	African countries represented on the JSM Group
National committees	Member countries' national expert committees for medical product safety and/or causality assessment
Priority medical products	Novel medicines and vaccines with a significant impact on public health and safety in Africa, which may require increased safety surveillance