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TOGETHER FOR PATIENTS

Transforming the Regulatory ecosystem in Africa

SATELLITE SESSION

Development of Pharmacovigilance in Africa, Opportunities for Collaboration and Continued Learnings

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Participant guide

- The 5th AfRC conference is held in English.
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Development of Pharmacovigilance in Africa, Opportunities for Collaboration and Continued Learnings

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Session 1

Collaboration & Learnings Related to Pharmacovigilance Between Countries

Moderator:
Willemijn (Wim) van der Spuij
BMS, EFPIA IPVG Chair

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Presentation by:

Raj Long
Deputy Director Integrated Development, Global Health

BMGF

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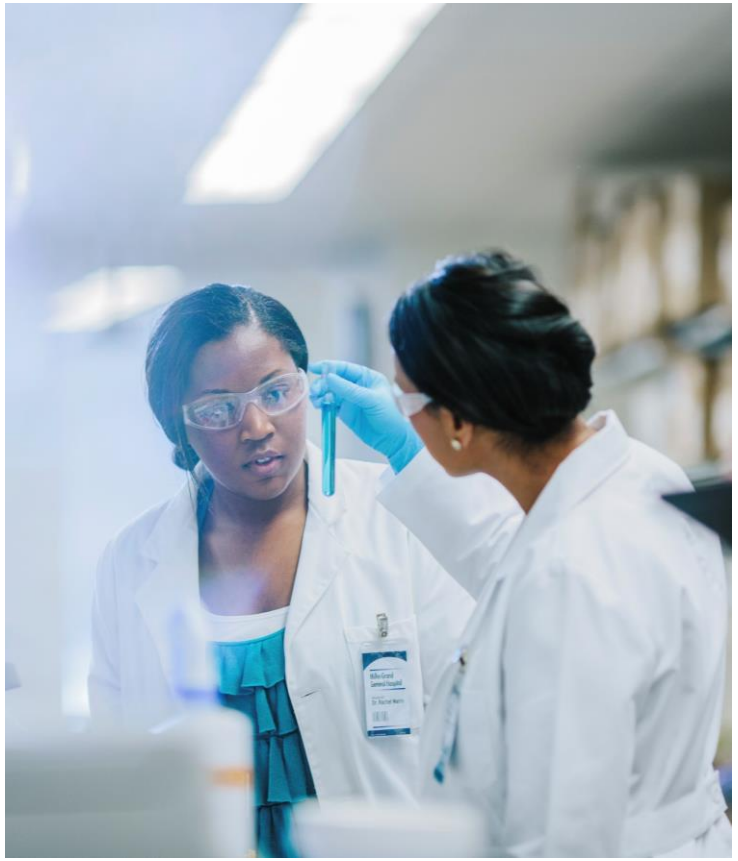
S3 SMART SAFETY SURVEILLANCE



Pharmacovigilance Activities: African Union Smart Safety Surveillance (AU-3S)

Raj Long - BMGF

AU-3S Safety Strengthening by Africa for Africa

SMART SAFETY SURVEILLANCE

Pharmacovigilance challenges in African countries

Limited safety data packages before product launch

Low adverse event reporting across countries despite recent improvements

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

Limited safety expertise to support signal detection & risk-assessment

AU-3S is a 10-year programme targeting a continental end-to-end safety surveillance system

1. **Improve medicines and vaccine safety** for patients in Africa and globally
2. **Strengthen PV expertise** among country and continental stakeholders
3. **Enable African ownership** and the ability to act on their own data
4. **Increase confidence in trust of public health safety**

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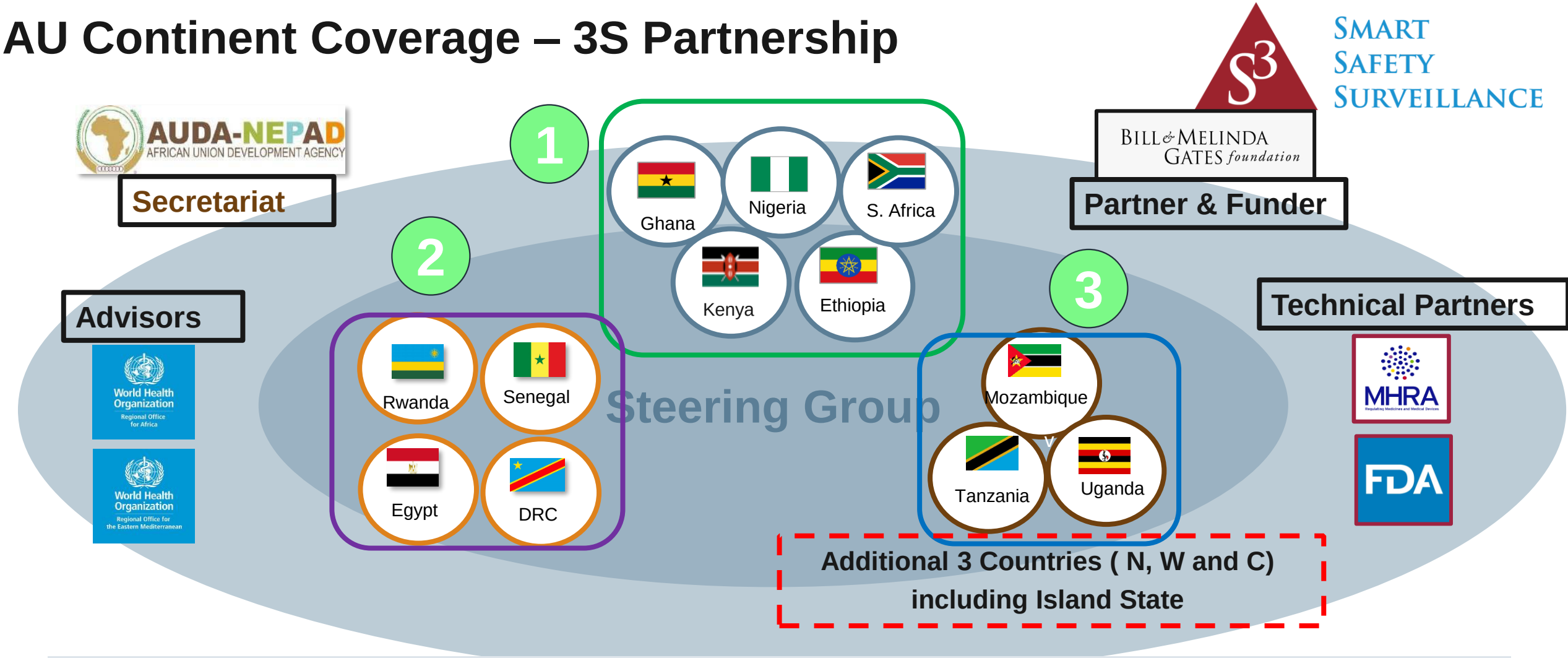
AU Continent Coverage – 3S Partnership



- **AU Continent Coverage - 5 Regional Economic Communities (9 countries) (West Africa, East Africa, North Africa, Central Africa and Southern Africa)**
- **Languages x 3 – English, French and Portuguese**
- **Population 15 countries – Approx. > 70% African Continent Coverage**

End-to-end solutions rolled-out, covering both cross-country and in-country levels

SMART SAFETY SURVEILLANCE

1

Data collection	Data storage & analysis	Signal management	Signal response & decision making	Safety communication

In-country

2

Continuous **capacity strengthening** with peer regulators (MHRA)

Expanded **electronic** data collection (through Med Safety App)

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

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

Creation of a COVID-19 therapeutics ADR reporting form for the Med Safety App

Funding for in-country safety strengthening activities

Cross-country

3

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

- Launched the **AU-3S Joint Signal Management Group** for aggregate signal reports
- Continuous **capacity strengthening**

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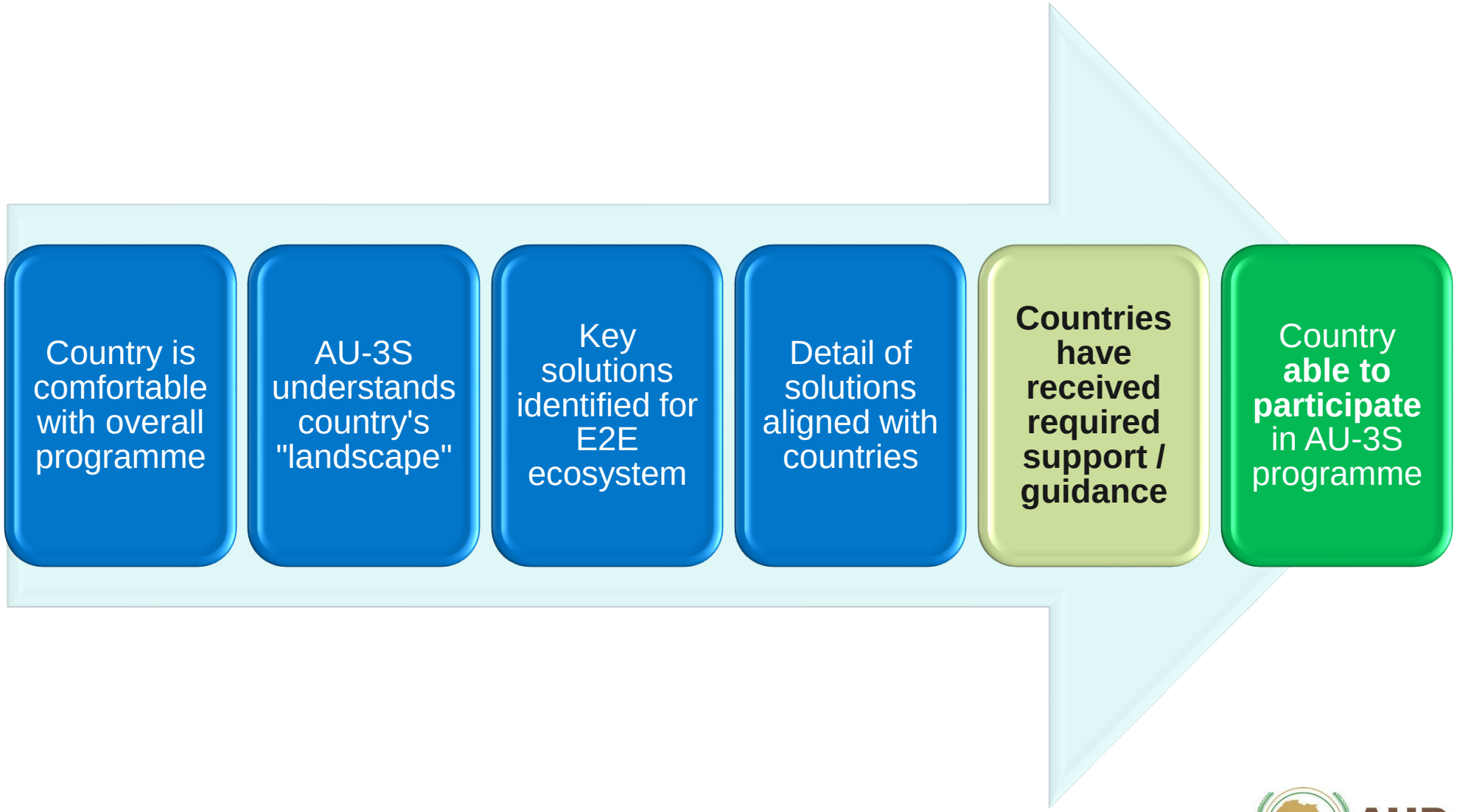
Onboarding Process for Members



AU-3S Joint Signal Management (AU-3S JSM)

SMART SAFETY SURVEILLANCE

JSM Secretariat

- **Analyse** cross-country safety data and **validate** possible **signals**
- **National representatives** from 5 member countries, supported by AU-3S and MHRA

JSM Committee

- Review and advise on **signals** and **items of interest** from the cross-country data
- Forum for **cross-country knowledge-** and **experience-sharing** on COVID-19 vaccine safety surveillance
- **21 JSM members**, representing NRAs, EPIs, and national PV committees from 5 member countries
- Wide range of expertise, **supplemented by subject matter experts as needed**

Enables African Evidence Based Decision Making – African Ownership

FDA MHRA Regulating Medicines and Medical Devices

AU-3S Original Membership

SMART SAFETY SURVEILLANCE

Countries' safety data

- Ethiopia
- Ghana
- Nigeria
- South Africa
- Kenya

Cross-country signal detection

Interim Data Integration and Signal Detection system

Automated cross-country signal detection is done in the interim DISD system

Fortnightly report summarising data for each vaccine-event combination shared with JSM secretariat(AUDA and member states)

Management of cross-country signals

AU-3S JSM secretariat → **AU-3S JSM Group**

Currently, the JSM secretariat performs the "**centralized**" signal management activities.

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Countries share their data to the interim DISD system through the Vigilance Hub

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AU-3S Current Membership

SMART SAFETY SURVEILLANCE

Countries' safety data

- Ethiopia
- Ghana
- Nigeria
- South Africa
- Kenya
- Senegal
- Egypt
- Rwanda
- DRC
- Additional 6 Counties

Cross-country signal detection

Interim Data Integration and Signal Detection system

Automated cross-country signal detection is done in the interim DISD system

Fortnightly report summarising data for each vaccine-event combination shared with JSM secretariat(AUDA and member states)

Management of cross-country signals

AU-3S JSM secretariat

AU- PRAC

Process and Membership Work Ongoing.

Countries share their data to the interim DISD system through the Vigilance Hub

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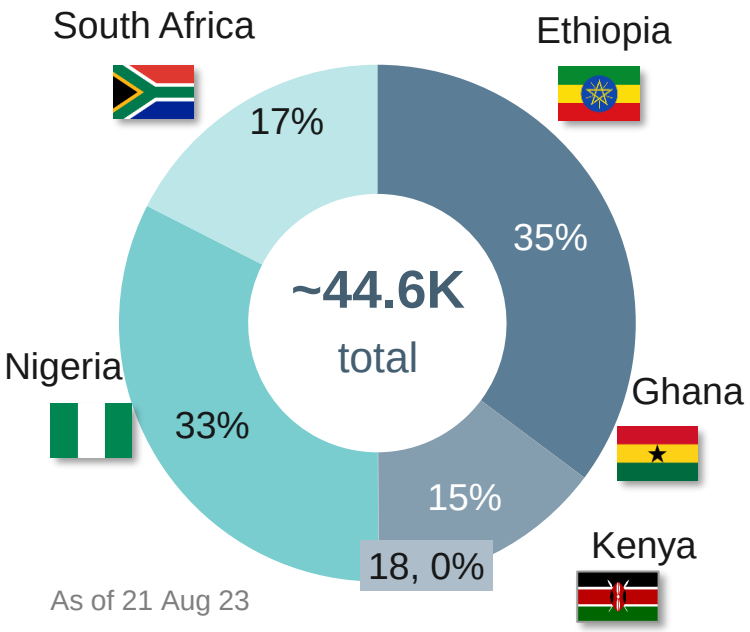
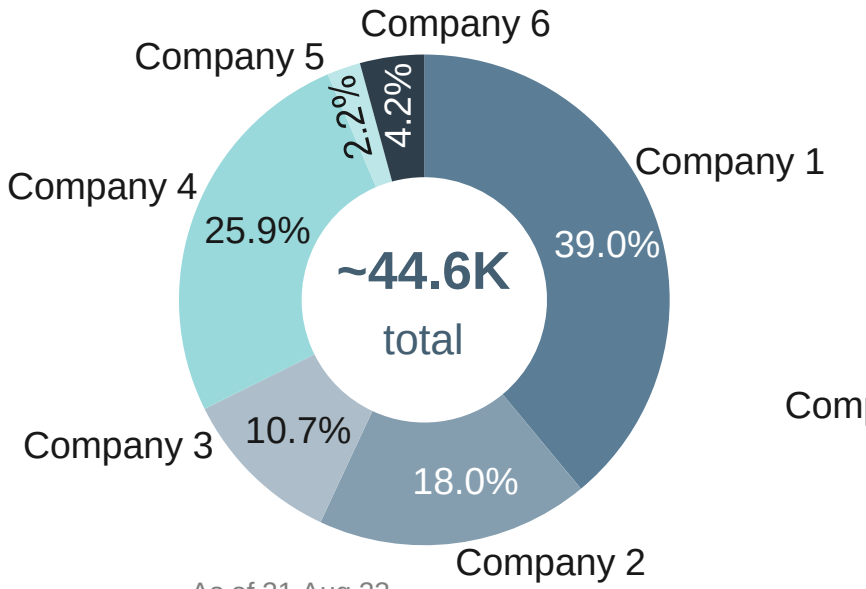
African-owned cross-country safety data integration & analysis platform

SMART SAFETY SURVEILLANCE

of AEFI reports in DISD[1] system

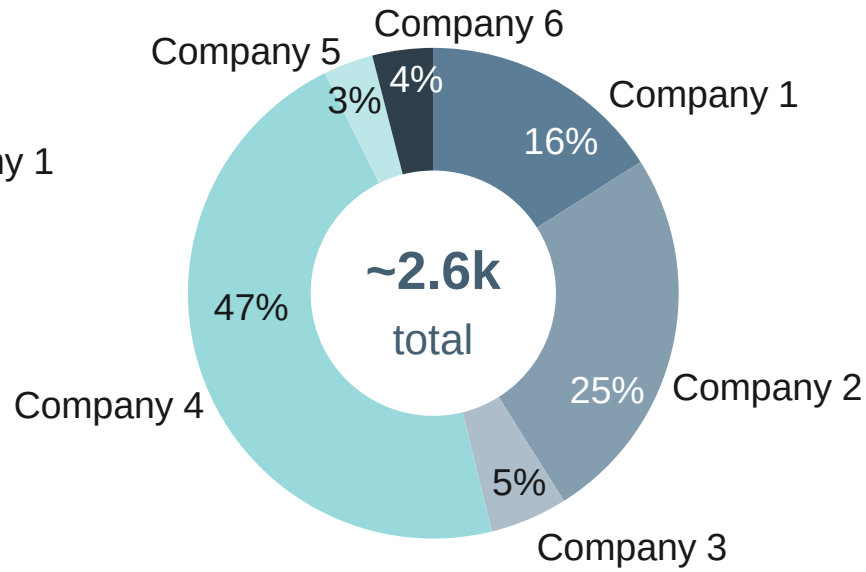


As of 21 Aug 23



As of 21 Aug 23

Vx-event combinations analysed



As of 21 Aug 23

- Continuing to work with countries on **decentralizing** data collection, **linking** national systems to DISD system, converting backlogs of **paper forms into electronic** format, correcting **coding issues**, and process improvements in **data validation**
- Based on expected XML file transfer of reports backlog of, project **≈ 60K AEFIs by the end of 2023**
- **≈ 13% is coming directly from patients via apps**

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1. DISD = Data Integration and Signal Detection System

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Most common vaccine event combinations reported by vaccine

SMART SAFETY SURVEILLANCE

Company 1	Company 2	Company 3	Company 4	Company 5	Company 6
Total cases: 17,302 Total DECs[1]: 424	Total cases: 7,978 Total DECs[1]: 663	Total cases: 4,755 Total DECs[1]: 135	Total cases: 11,494 Total DECs[1]: 1,232	Total cases: 979 Total DECs[1]: 87	Total cases: 1,878 Total DECs[1]: 106
Pyrexia	Headache	Pyrexia	Headache	Headache	Injection site pain
Headache	Pyrexia	Local reaction	Pyrexia	Injection site pain	Headache
Injection site pain	Injection site pain	Injection site pain	Local reaction	Fatigue	Asthenia
Local reaction	Fatigue	Headache	Fatigue	Pyrexia	Pyrexia
Fatigue	Arthralgia	Pain	Injection site pain	Arthralgia	Dizziness
Asthenia	Chills	*Asthenia	Pain	Local reaction	Pain
Pain	Local reaction	Myalgia	*Dizziness	*Back pain	Chills
Arthralgia	Pain	*Abscess	*Dyspnoea	*Hyperhidrosis	*Nasopharyngitis
Chills	Asthenia	*Pain in extremity	Pain in extremity	*Oropharyngeal pain	*Pain in extremity
Myalgia	Pain in extremity	*Malaise	Nausea	Chills	Fatigue

DECs in the graphs common to at least 2 vaccines

DECs in the graphs unique to a vaccine

*Not listed in SmPC[2]

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1. DECs: Drug event combinations; 2. SmPC: Summary of Product Characteristics;

The AU-3S Covid-19 pilot has **delivered across 5 key areas**

SMART SAFETY SURVEILLANCE

1 **Digital health ecosystem enabling real time data access & downstream analysis**

- **400M** Patients covered by the safety tools
- **92.0k** New users of Med Safety App[1]
- **~15x** 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
- **44.6k** AEFI reports in integrated system[4]
- **2.6k** Drug-event combinations analyzed[4]

3 **African-led evidence-based decision making on their own African data**

- **64** JSM Secretariat meetings held[3]
- **15** JSM Group meetings held[3]
- **16** Items of interest identified, raised, and reviewed

4 **End-to-end safety system strengthening and collaboration across EPI & NRA**

- **14** Training sessions delivered[5]
- **100** Average attendees per session
- **95%** Satisfaction rate from trainees

5 **Critical safety coordination and alignment across country and global stakeholders**

- **250+** 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

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1. Cumulative from Nov 2020 to Mar 2023; 2. Ethiopia and South Africa baseline missing; 3. Kick-off meetings included; 4. As of 21 Aug 2023; 5. Only MHRA virtual training sessions, excl. JSM Gp & secretariat training and other in-country training sessions;

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Proposed requirements from countries to participate in the AU-3S programme

AU-3S provides tailored support and in-country support to enable a country to build/strengthen its system to achieve these requirements for effective participation

- Policy and legal framework for medicine regulation including mandate for safety surveillance
- Willingness and availability of DG/CEO to join peer DGs/CEOs of participating countries as members of the AU-3S Steering Group
- Existing pharmacovigilance function within the NRA system
- E2B compliant data collection tools and databases
- Data sharing agreement with AUDA-NEPAD, other participating countries, and MHRA
- Facilitating interaction between national safety advisory committee(s) and the AU-3S JSM Group
- Includes support for ambition to progress towards ML3/4 for PV
- Request from the NRA DG/CEO to participate in the programme

Continental expansion mandate from STC-EST

SMART SAFETY SURVEILLANCE

"The Ministers[1]:

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."

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Expansion | Countries, Products, Product Life cycle, Technology

SMART SAFETY SURVEILLANCE

Short-term

- **Expanding geographical coverage:**
  - 5 current countries to ~11 by end of 2023
- **Expanding language coverage:**
  - To initially include French and Portuguese
- **Expanding priority product coverage (therapeutics & vaccines** for priority disease areas**):**
  - Scale and modify current vaccine tools to include therapeutics
  - Expanding product coverage for cross-country monitoring
    - ✓ **COVID-19 vaccines & therapeutics**
    - ✓ **nOPV2**
    - ✓ **Dolutegravir-based regimen, Molnupiravir, Cabotegravir/Rilpivirin**
    - ✓ **Bedaquilline, Pretomanid**
    - ✓ **Malaria vaccine**
  - **Scale learnings from EPIs to PHPs of the priority disease areas**

Medium-term

- **Develop AfriVigilance database:**
  - Business and functional requirements defined
  - Identify African technical partners
  - Secure funding
- **Expand the digital toolbox:**
  - Active surveillance app to complement passive reporting

Long-term

- **AfriVigilance is fully functional & sustainable**
- **Integrated with national & global systems**
- **Continental coverage**
- **Priority product coverage**
- **Complete toolbox for end-to-end safety**
- **Align with continental stakeholders – AVAREF, PAVM, AMA, etc.**

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Priority disease areas: Malaria, TB, HIV, emergency diseases (Ebola & COVID-19), innovative products

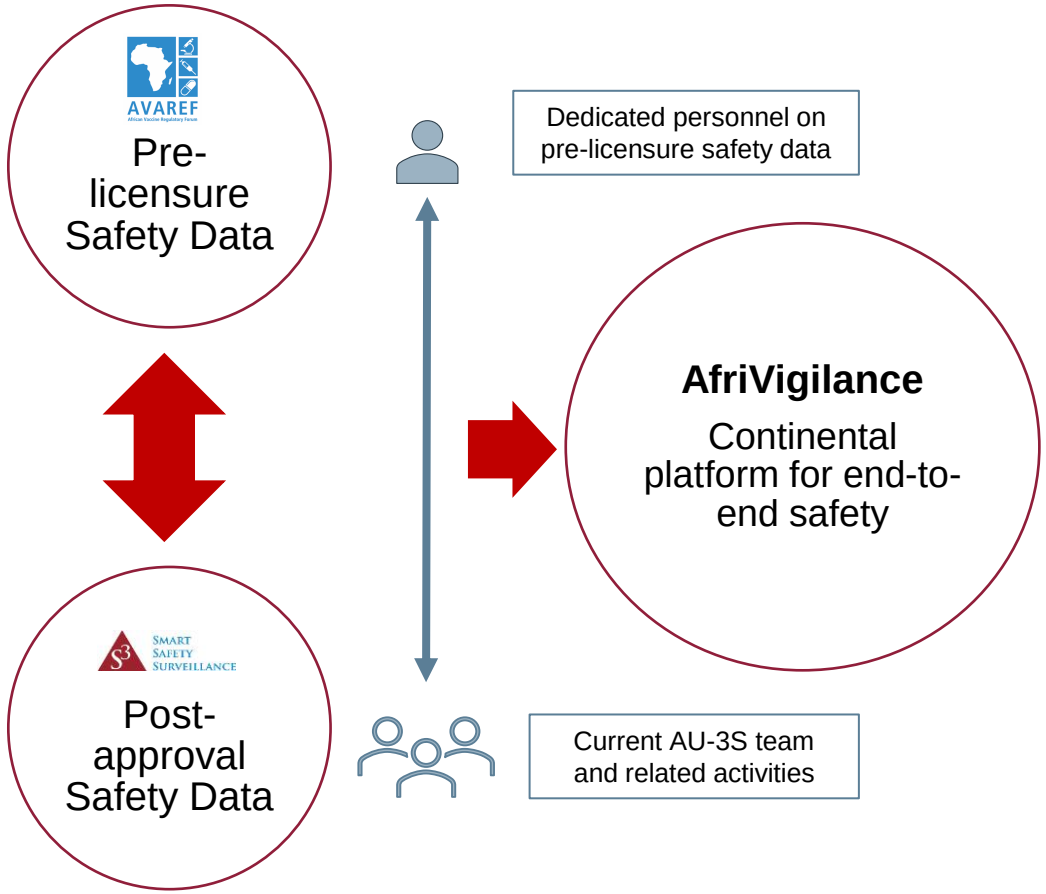
AU-3S CWG (Continental Working Group) Focus Areas

- Seven (7) focus areas that would affect the future of the continental safety platform formed the basis for CWG's assignment
- The CWG was established with an inaugural meeting held virtually on 22 May 2023 with specific Terms of Reference[1] to be delivered within 12 calendar weeks (22 May to 11 August 2023)

AVAREF (CTs) –TCC Recommendations

Linkage between AVAREF safety data flow and the AU-3S

1. **<u>AVAREF to work with the AU-3S</u> to address the need for collection of safety data for CTs so that all future safety data from CTs from NRAs can be hosted on the AU-3S database**
2. **<u>Establish a joint WG between AVAREF and AU-3S</u> to work on the modality and <u>explore a pilot</u> and <u>phased approach</u>**
3. **All ongoing and future initiatives and projects on <u>CT safety strengthening activities should be aligned with the AU-3S</u> continental initiative to avoid duplication and to optimize in-country resources**



Diverse Stakeholder Engagement

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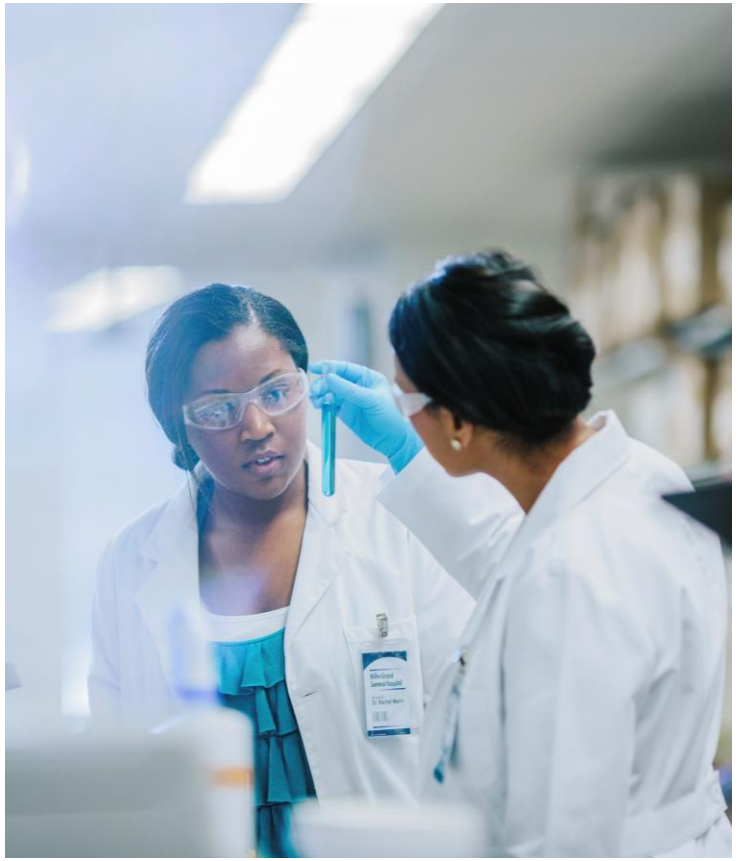

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Presentation by:

Florah Matlala
Pharmacovigilance Manager
SAHPRA

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Contents

- Baseline challenges
- Strategies implements & Benefits
- Challenges
- Lessons learnt
- Value

Baseline Challenges

Limited reporting

- Tools
- Awareness and training
- Poor quality

Limited resources

- Case assessment and feedback to reporters
- Capabilities to analyze data collected & identify signals
- Committing of reports received
- Benefit-risk assessment capabilities

Pharmacovigilance budget

COVID-19 Challenges

Medicines Safety Awareness

- Increased poor reports
- Need to accommodate patient reporting
- Myths and misinformation
- Media

Limited resources

- Case investigations
- Need to coordinate activities & set-up safety committees
- Frequency of meetings

Strategies & Benefits of AU-3S

Training

- Strengthening internal capacity
  - Benefit-risk assessment
  - Signal detection skills & capabilities
  - ICSR assessment & feedback provision

Access to tools

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

Collaboration

- Use of big data compared to single country's data
- Opportunity to learn from others
- Strengthened existing collaboration with EPI
- Sharing of data in real-time – expedite case investigation and causality assessment

Awareness

- Launch of the Med Safety App
- Increased visibility on social media, TV, and radio
- Training of healthcare professionals in partnership with EPI

Sponsorship

- Prioritization of pharmacovigilance activities e.g., training
- Opportunities to increase human resources

Challenges during implementation

- Integration & harmonization with in-country systems
- Operationalisation challenges
  - Gadgets
  - Data issues
- Feedback to reporters/facilities
- Inability of the system to provide various access levels to users
- Native languages
- Data protection laws

Lessons Learnt

Collaboration/harmonisation = Improved and resilient system

Reporting tools

- easily accessible
- easy to use
- customized to local languages

Feedback from/to reporters is key

Joint review

- share learnings among regulators
- validation of signals

Trusted technical support

- Guidance & sustainability

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Value

Support informed benefit-risk decisions relevant to local settings

Maintain public confidence in medicines safety & supporting uptake of public health interventions

Enable access to innovative treatments, tacking major public health challenge

Improved and strengthened system supporting attainment of WHO maturity level 3

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QUESTIONS AND ANSWERS

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Virtual coffee/tea break

We will be back in 5 mins

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Session 2

Pharmacovigilance inspectorate activities and QPPV training

Moderators:

Jayesh Manharlal Pandit

Bayer / EFPIA IPVG Africa/ME WS

Benita Morar

Abbvie / EFPIA IPVG Africa/ME

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GVP INSPECTIONS IN UGANDA

Transforming the Regulatory ecosystem in Africa

Helen Byomire Ndagije, PhD
Director Product Safety
National Drug Authority Uganda

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LEGAL REQUIREMENTS

- The National Drug Policy and Authority Act, CAP 206 establishes the NDA, which is responsible for safety, quality and efficacy of medicines in the country
- Regulation 3 of the Pharmacovigilance regulations (Statutory Instrument no. 37) of 2014 provides for the following:
- Requirement for a pharmacovigilance system.

1) A licensed person shall have an appropriate system for pharmacovigilance, to manage the safety of the data for the drugs for which the licensed person is responsible.

2) The following shall have appropriate mechanism of monitoring the safety of the drugs that are handled in their day to day activities—

   - **a manufacturer or importer of drugs** who is licensed to do so under the Act and regulations made under the Act;

TECHNICAL CAPACITY

- NDA is the AMRH RCORE for cGMP inspections
- PV staff participate in other inspections like GCP and GMP
  - Background knowledge for conducting inspections
  - 8 PV officers
  - Dedicated PV manager
  - Director Product Safety
  - All qualified in health sciences and MSc
- Trainings undertaken with regard to GVP
  - WHO training on conduct of GVP inspections
  - EMA training
  - Secondments and placements to SRAs – Swissmedic

WHERE ARE WE?

- ❑ Guidelines for establishing a pharmacovigilance system
- ❑ SOP for conducting PV inspections
- ❑ Tools for conducting GVP inspections
  - Checklist, GVP report template
- ❑ Conducted sensitization of MAHs on GVP requirements
- ❑ Amendment of the NDPA Act to improve provisions for GVP
- ❑ Conducted pilot GVP inspections

PILOT INSPECTIONS

- NDA has conducted 4 pilot inspections earlier this year
  - AbbVie, Pfizer, Intas & Norbrook
- Inspections were routine announced in nature
- Inspection teams were structured to include a lead inspector and other inspectors
- Objectives
  - Capacity building for PV officers – practical skills
  - Support LTRs to improve existing systems and compliance to PV regulations

PILOT INSPECTIONS

- Key aspects examined
  - Organization and responsibility of the PV department(s)
  - Quality management systems
  - Signal detection and risk minimization strategies
  - Quality Management Systems
  - Operational procedures
  - Personnel training
  - PSMF
- Non conformances classified as critical, major and other

EXAMPLES OF NON-CONFORMANCES

- No evidence of training for the pharmacovigilance staff
- No contractual agreement for outsourced pharmacovigilance activities
- Limited facilities and resources for implementation of Pharmacovigilance systems \
  - low Pharmacovigilance human resource,
  - limited financial resources allocated to Pharmacovigilance activities
- Limited initiative to tailor processes and procedures to Uganda requirements
- No verifiable evidence to indicate that the QPPV participates in the review of local signals. This was also not stated in the job description or safety review section of the PSMF
- The job description for the QPPV not indicating their role in post authorization safety studies conducted locally

EXAMPLES OF NON-CONFORMANCES

- The delegation of tasks in the PSMF not specifying the tasks for each role in the organization structure
- Limited evidence to support the implementation of the local pharmacovigilance system
  - absence of distribution records for reporting tools,
  - absence of safety reports in the database
  - absence of local safety data in the periodic safety update reports.
- QPPV not involved in signal management for signals generated from Uganda.
- No procedure in place to evaluate effectiveness of safety communication systems

CHALLENGES

- Inadequate technical capacity for both MAHs and regulators
  - Number of technical personnel to implement GVP and conduct GVP inspections
  - Inadequate PV structures for local MAHs
  - Interpretation and classification of non conformances
  - No evaluation criteria to assess competence of QPPVs
  - Regulatory personnel appointed QPPVs – workload burden
- Legislation gaps
  - Responsibility for fees regarding GVP inspections
  - No provisions for PASS studies
- LTR system facilitates multiple representation of MAHs by single QPPV
- Diverging PV systems, knowledge, and experiences among MAHs

MOVING FORWARD

- ❑ Full GVP inspection schedule will be based on risk assessment
- ❑ Support inspected facilities to Implement CAPA
- ❑ Design assessment criteria for competence of QPPV
- ❑ Engage with local MAHs concerning establishment of PV structures
- ❑ Take advantage of existing regional blocs i.e. EAC and IGAD to pool resources and conduct joint GVP inspections
- ❑ Conduct operational research to improve GVP framework in Uganda
- ❑ Amend the regulation to include
  - Fees to facilitate GVP inspection
  - Regulatory action against non-compliant facilities
  - Requirements for PASS studies

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Presentation by:

Martha Mandale
Principal Regulatory Officer

Pharmacy & Poisons Board Kenya

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REPUBLIC OF KENYA

Qualified Person for Pharmacovigilance Training in Kenya

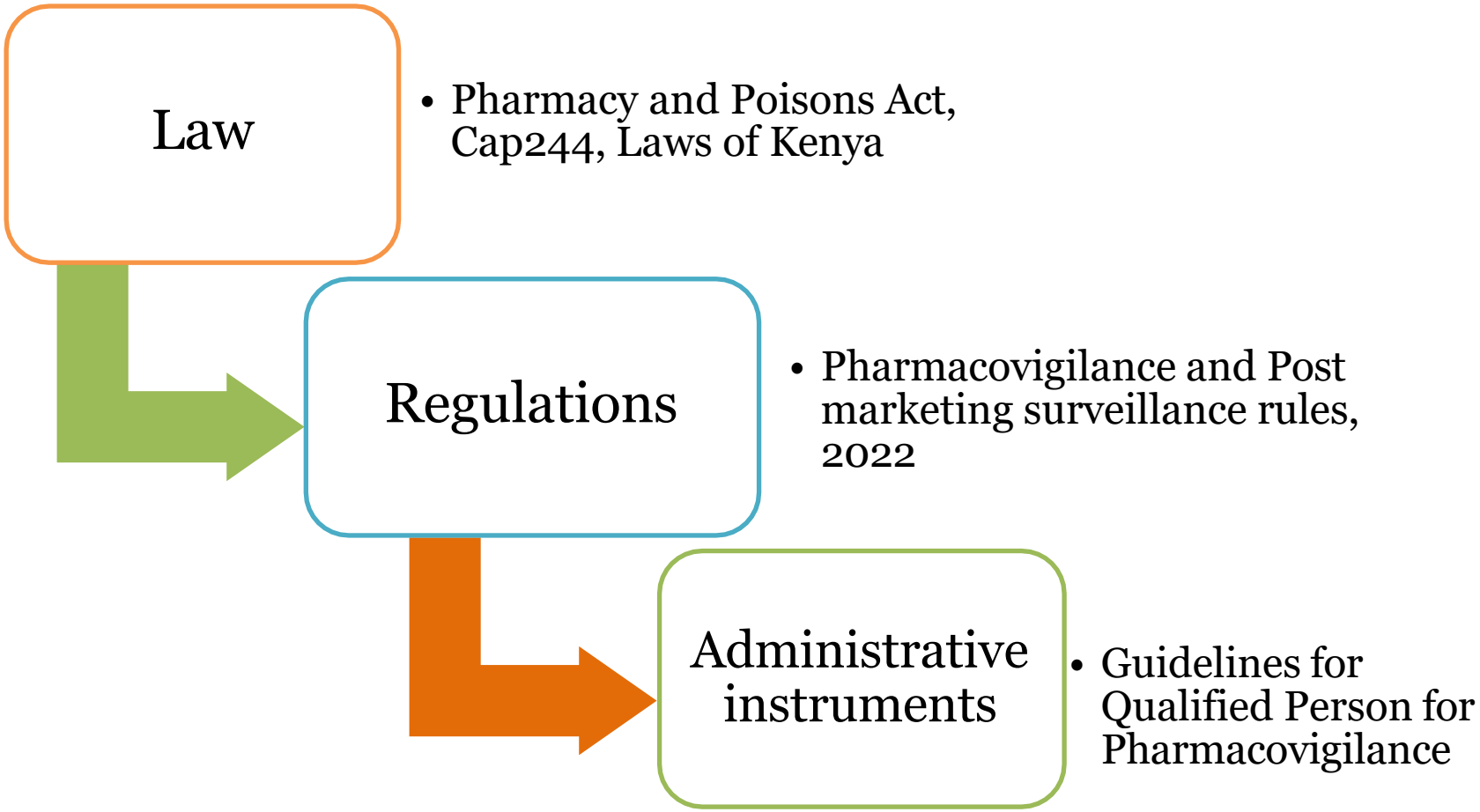
Martha Mandale
Principal regulatory officer
Product safety department
Pharmacy and Poisons Board, Kenya

REPUBLIC OF KENYA

Background of PV system in Kenya

REPUBLIC OF KENYA

Legal framework for the establishment of the QPPV



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Who is a Qualified person for Pharmacovigilance?

The QPPV is an individual, usually an employee of a pharmaceutical company, who is responsible for the safety of the human pharmaceutical products marketed by that company

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General requirements of the QPPV in Kenya

The marketing authorization holder shall permanently and continuously have at his/her disposal an appropriately qualified person responsible for Pharmacovigilance (QPPV) residing in Kenya.

The QPPV shall in addition receive a mandatory refresher GVP training facilitated by the MAH in accredited/recognized institutions by the Board

Have knowledge of applicable Kenyan safety monitoring legislation and guidelines and international standards for GVP.

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Journey towards implementation of the QPPV course

The PPB PV staff received QPPV training by the African Collaborating Centre for Pharmacovigilance (ACC) in collaboration with the Ghana FDA.

The PPB in collaboration with University of Nairobi developed an in country QPPV curriculum

Launched and conducted the first QPPV training in May 2023.

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QPPV course

- 2 weeks interactive course, face to face, once every year
- Consists of 15 modules:
  - ✓ lectures
  - ✓ small group discussions
  - ✓ case studies
  - ✓ participant – presentations
  - ✓ practicum
- In addition to the above, there is a field visit to an MAH
- At the end of the training, the participants are awarded with certificates

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Modules

Include the following:

- Introduction to Pharmacovigilance
- Qualified person for Pharmacovigilance
- Quality management systems and Pharmacovigilance
- Individual case safety reports and data management
- Vaccine vigilance
- PSURs/PBRERs
- RMPs
- Pharmacovigilance system master file
- Signal management
- Safety Communication and crisis management
- Post authorization safety and efficacy studies
- Quality in PV
- Pharmacovigilance inspections

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Learning outcomes

At the end of the training the participants are expected to:

- Design and implement an efficient pharmacovigilance system and be able to compile safety reports.
- Monitor the effectiveness of the PV system established

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Achievements

- A total of 12 participants were trained with representation from both the local and international pharmaceutical companies
- Establishment of PV systems in the local pharmaceutical industry
- Collaborations with teaching institution (UoN), development partners, Pharma industry (Norvatis, Kenya field visit) towards implementation of training

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What does the future look like?

- Capacity building not only in-country but within the region-EAC, IGAD and Africa
- More collaborations and partnerships with stakeholders to strengthen functional and robust PV systems in Africa

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Acknowledgements

- University of Nairobi
- AUDA-NEPAD AU-3S Programme
- Bill & Melinda Gates Foundation
- USAID-MTaPS
- African Collaborating Centre for Pharmacovigilance (ACC)
- Ghana FDA

Asante sana!

THANK YOU!

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12–15 SEPTEMBER | VIRTUAL CONFERENCE

Presentation by:

Felix Mochache
Country Patient Safety Head East & South Africa (Kenya)
Novartis

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Kenya QPPVs Training Feedback

- 2 week long HA facilitated training, a first of it's kind in Kenya.
- A lot of positives to draw from it;
  - Draft curriculum shared with the industry for comments/input.
  - Good mix of participants (both foreign and local MAHs), providing an avenue for best practice sharing and knowledge transfer
  - Well structured sessions, including both practical and theoretical experience
  - Choice of physical versus online; more engaging discussions and collaboration in practical activities
  - Relevance of the agenda – designed to suit the local set up of PV regulations
  - Variety of experience from facilitators; opportunity to learn from all angles, as facilitators were drawn from academia, HA, and the industry
  - Creation of an exchange platform – a network of local QPPVs created
  - Feedback collected on areas of improvement for the next cohort.
- Suggested improvement opportunities;
  - Increase the number of participants/increase the number of cohorts per year
  - Advance notice to allow for planning on absence and costs

Some pictures

Participants and Facilitators

Some cake to celebrate

Certificates to participants

NOVARTIS | Reimagining Medicine

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12–15 SEPTEMBER | VIRTUAL CONFERENCE

Presentation by:

Adela Ashie
Principal Regulatory Officer

Food & Drugs Authority Ghana

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Pharmacovigilance Inspection Programme and Future Collaborations, Ghana

Adela Ashie
Food and Drugs Authority, Ghana

Outline

- Setting the stage: Pharmacovigilance in Africa
- Overview of Ghana's Pharmacovigilance (PV) System
- Implementation of the Good Pharmacovigilance Practice Requirements in Ghana
- Ghana's Pharmacovigilance Inspection Programme
- Pharmacovigilance Collaborations (now and the future)
- Summary

Pharmacovigilance in Africa

- Increasingly new medical products are being first introduced in Africa. Pipelines medicines are being introduced faster and in the case of pandemics e.g. COVID-19, with limited safety data.

- This emphasises the need for better involvement of the pharmaceutical industry in monitoring the safety of the products. However, only a few African countries have frameworks to implement the Good Pharmacovigilance Practice requirements.

- Strengthening of country vigilance capacity is critical as vigilance data from outside the country may not be wholly generalizable. Collaboration within the continent is needed for stronger more efficient PV systems.

- Increased recognition of need for country participation and collaboration in global PV efforts.
  - Currently 50 of the 54 countries are members of the WHO Programme for international drug monitoring.

Overview of Ghana's Regulatory System

Food and Drugs Board (FDB), the National Regulatory Authority of Ghana, was established in August 1997 as the Food and Drugs Board (FDB) under the Food and Drugs Law, 1992 (PNDCL 305B).

PNDCL 305B in 2012 was integrated into the Public Health ACT 2012 ACT851 and with the name Food and Drugs Authority (FDA)

The FDA is mandated by Parts 6, 7 & 8 of the Public Health Act 2012, Act 851 to *protect public health and safety*.

FDA currently performs all the regulatory functions (except lot release) and is a WHO Maturity Level (ML) 3 Authority

- ML 4 for vigilance

Ghana's PV Legislation

FDA's PV mandate is found in Part 7, Public Health Act, 2012 Act 851

Section 125 :– Safety Monitoring (Pharmacovigilance)

Subsection 1: Requirements for local representatives (or MAHs) to have Qualified Person for Pharmacovigilance

Subsection 2: Safety monitoring and reporting of adverse reactions to marketed products

Subsection 3: Responsibilities of the Food and Drugs Authority

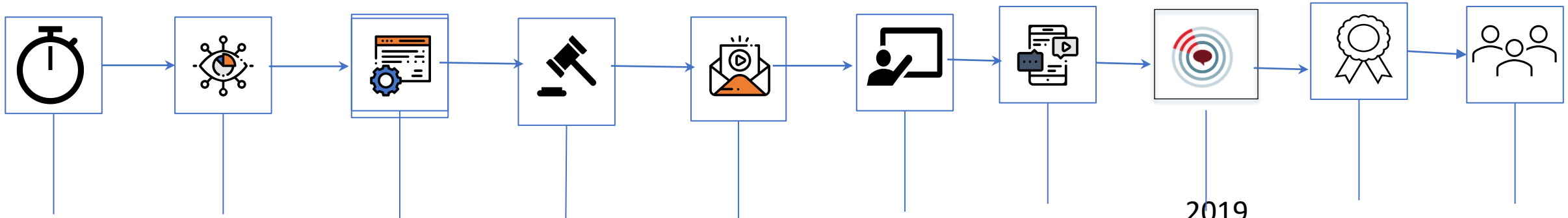
Section 148 – Guidelines

Section 142 - Penalties

Subsections 1 & 2: Guidelines and mandatory compliance by marketing authorization holders

Reporting is voluntary for patients and healthcare professionals, and mandatory for pharmaceutical industry

Milestones of Ghana's PV system



1999
Formal collation of ICSRs

2001
Joined WHO Program for International Drug Monitoring

2005
First Technical Advisory Committee on Safety of Medicines

2012
Law revised to include GVP requirements

2013
New guidelines to align with the new law

First edition of the Drug Safety Newsletter

2015
First QPPV training

2016
First GVP inspection

Lauch of direct patient reporting

2019
Launch of Med Safety App

2020
WHO Maturity level 4

2020
Participation in AU3S Pilot

ICSRs-Individual Case Safety Reports
QPPV-Qualified Person for Pharmacovigilance
GVP-Good Vigilance Practice

Implementation of Good Pharmacovigilance Practice Requirements in Ghana

QPPV Training

- Collaboration with academia (ACC)
- 12 Training programmes
- 193 QPPVs Trained
  - 106 designated by MAHs

GvP Inspection

- 98 GVP Inspection
  - 17 Innovator MAHs
  - 81 Generic MAHs

Regulatory documents submission (2018)

- **91 RMPs**
  - 49 Innovator
  - 42 Generic

- **277 PSURs**
  - 234 Innovator
  - 38 Generic

Ghana's GVP Inspections Program

Objectives on GVP Inspections

- Improve pharmacovigilance system established by Local Representative or the MAH
- Ensure compliance with the pharmacovigilance obligations
- Enforce regulatory requirements

When

- Pre or Post authorization

Where and who

- Local representative or MAH's location or 3rd party in country
- QPPV and other PV staff

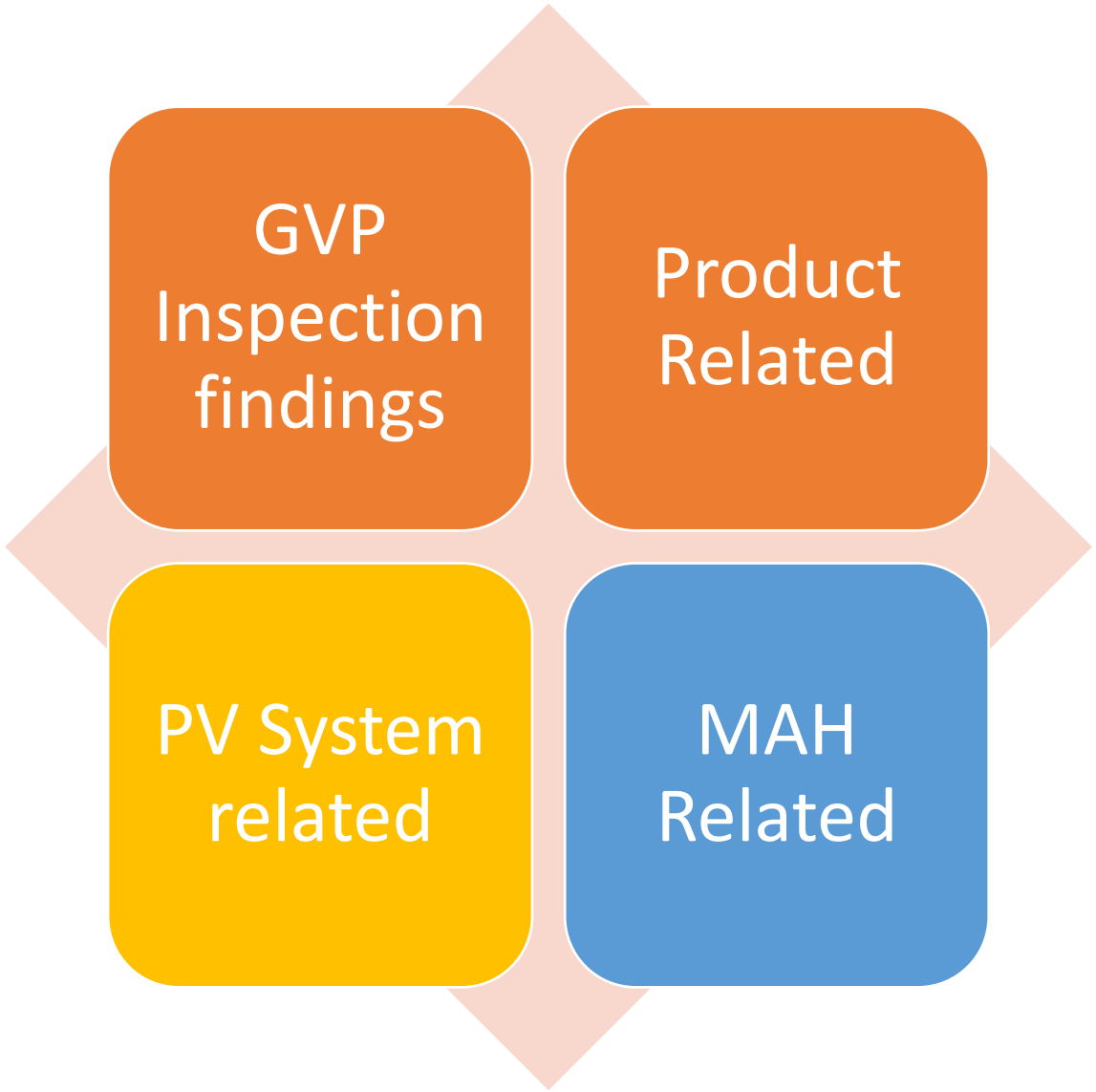
Type

- Routine or unannounced

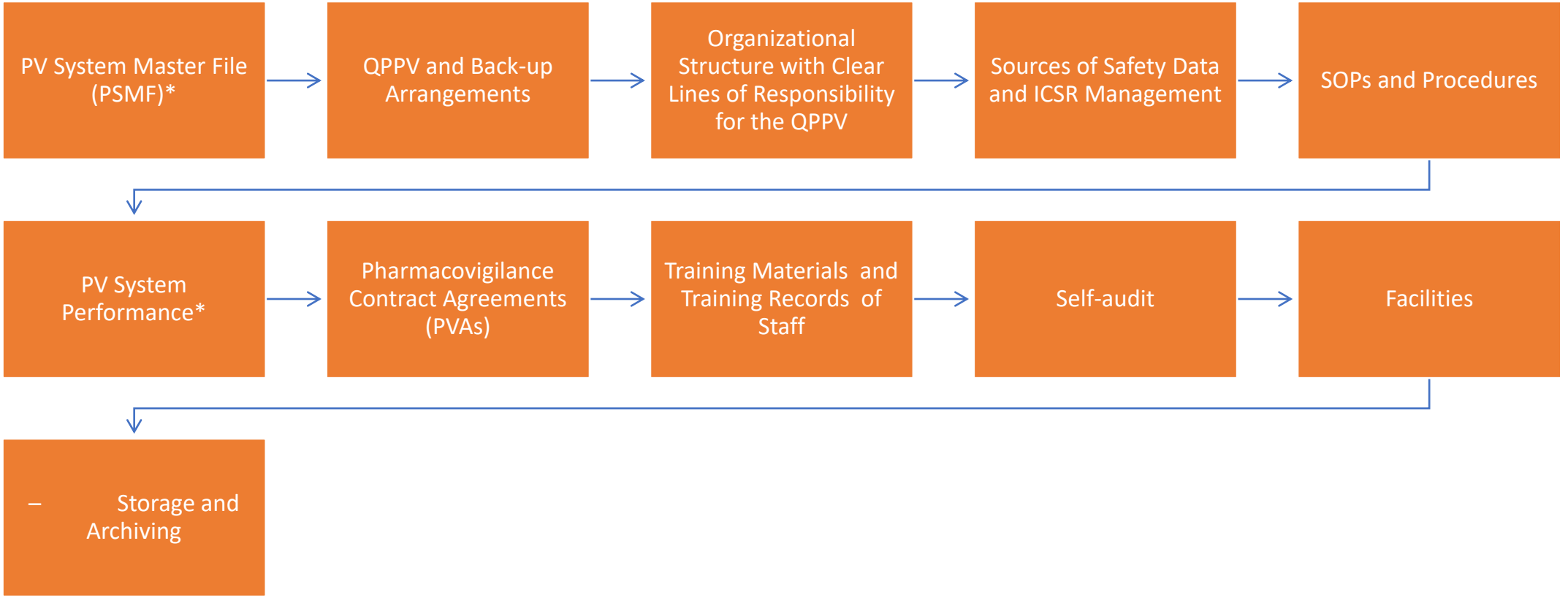
Scope based on

- Objective
- Type
- Inspection history, etc

Ghana's GVP Inspections Program: Risk Based Approach

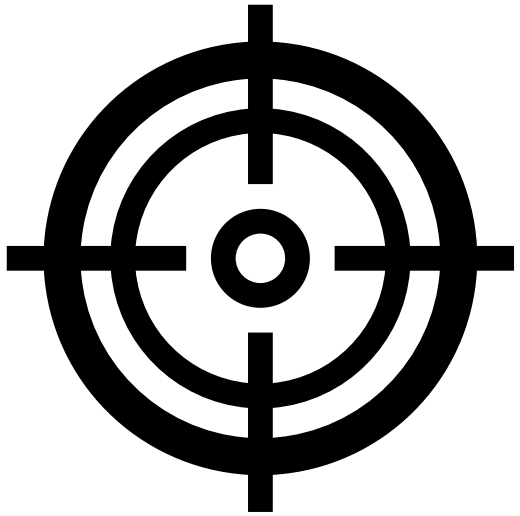


What is Reviewed



Ghana's GVP Inspections Program

- Grading of Inspection Findings
  - Objectives
    - Classify the level of severity of deviations noted as observations during inspection.
    - Ensure uniformity in the assignment of ratings on observations among inspectors
    - Inform MAH what the FDA considers unacceptable



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Ghana's GVP Inspections Program

- Three grading levels

Critical: A deficiency in pharmacovigilance systems, practices or processes **that adversely affects** the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation of Public Health Act, 2012 and applicable Food and Drugs Authority guidelines.

Major: A deficiency in pharmacovigilance systems, practices or processes **that could potentially adversely** affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of Public Health Act, 2012 and applicable Food and Drugs Authority guidelines

Minor: A deficiency in pharmacovigilance systems, practices or processes that would not be expected to adversely affect the rights, safety or well-being of patients

Support from Partners in Implementing GVP requirements

- Staff capacity building
  - MHRA: RMPs and PSUR review
  - Paul Ehrlich Institute: Pharmacovigilance fellowship under the GHPP programme
  - Lareb: Signal management
  - AU 3S: Signal management, review of RMP/PSUR

Collaboration During COVID-19 Pandemic

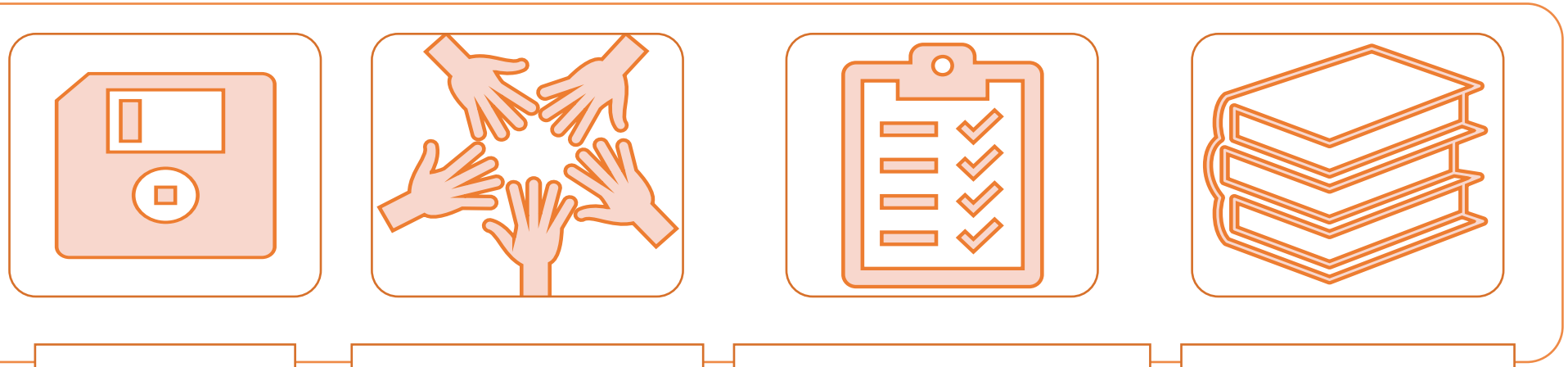
- AU3S Project
  - Funding agency: The Bill and Melinda Gates Foundation (BMGF)
  - Key technical partner: UK's Medicines and Healthcare products Regulatory Agency (MHRA)
  - Pilot countries: Ghana, Nigeria, South Africa, Ethiopia
- Benefits of AU3S Project
  - Joint signal management - strengthened signal detection process
  - Capacity strengthening of expert committee members and PV staff
  - Patient PV awareness programme- Improved awareness of PV by general public
- Expansion to include more countries and priority medicines

Other PV Collaboration

- WHO Afro Serious AEFI Management Peer Review
  - Peer review of Serious AEFI Management (investigation and causality assessment) process by expert team made up of representatives of the countries
    - Helped identify challenges with the system to be addressed, and best practices to e adopted
  - Development of harmonized causality assessment procedures,

- ECOWAS Pharmaceutical Web Portal
  - Exchange of pharmaceutical data including vigilance data to enable decision making
  - ECOWAS PV working group: Plans for work sharing and joint inspections

Future Collaboration



Safety Data sharing platform

Work Sharing: Review of regulatory documents e.g PSURs between countries/ Regional Economic Blocks

Joint Good Pharmacovigilance Practice Inspections

Knowledge sharing and capacity building among member countries e.g FDA's PV RCORE Programme

Summary

- Ghana has made good progress over the last 10 years implementing GVP requirements
- Support from and collaboration with local and internationals partners has facilitated the progress made.
- Although there has been improvement in involvement of African countries in PV over the years, only in few countries has pharma industry established PV systems. There is need for an acceleration in implementation of GVP requirements in Africa.
  - Collaboration within the continent is the key: safety data sharing, joint signal management, work sharing in review of regulatory documents, development and use of AI.
  - Twinning or benchmarking could be beneficial in building GVP inspection capacity on the continent.

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QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

If a question you would like to ask has already been raised, you can also “like” that question. "

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Virtual coffee/tea break

We will be back in 5 mins

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PANEL DISCUSSION

Focus on PV divergence and harmonisation in Africa

Moderated by:

Pat Harding
Eli Lilly & EFPIA IPVG

Sean Burke
MSD

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KEY TAKEAWAYS – PV session

- Evolving PV regulatory requirements: progress and important changes for the safety of us of medicines to be considered
- Collaboration and Learnings: despite diversity we have seen great examples of collaboration and the focus on Safety across countries. This is a great example for the future of PV regulatory collaboration.
- Inspection Program: practical focus on operational aspects of PV management by MAHs and the role of the QPPV in individual countries
- Future of PV in Africa: promising developments in safety that we have to follow closely.

THANK YOU!

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Join on 23 October

2nd AfRC satellite session

How can the regulatory landscape on biosimilars be navigated?

14:00 -15:30 CET

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