



UNIVERSITY *of the*
WESTERN CAPE



CEPSA
Centre of Excellence for
Pharmacovigilance in
Southern Africa



**INSTITUTE
OF TROPICAL
MEDICINE**
ANTWERP

Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+)

- ❑ Africa currently imports over 99% of the vaccines and 94% of the medicines it uses.
- ❑ Call from African leaders to produce 60% of vaccines in Africa by 2040
- ❑ Launch of MAV+ in 2021
- ❑ The overall objective: to facilitate access to quality, safe, effective and affordable health products - UN's SDG Target 3.8.
- ❑ MAV+ is funded by the European Commission, Belgium, France, Germany and the European Investment Bank.
- ❑ MAV+ partners include African Union agencies (e.g., Africa CDC, AUDA-NEPAD), African Union Member State National Regulatory Authorities, Regional Economic Communities, African universities and training programs and pharmaceutical manufacturing plants.



Centre of Excellence for Pharmacovigilance in Southern Africa

Rationale for CEPSA

- Establishing the Centre of Excellence is aligned with the strategy of the African Medicines Regulatory Harmonization (AMRH) and African Medicines Agency (AMA)
- Lessons learned from partners indicate that pharmacovigilance is an area where mutual learning and collaboration can be particularly beneficial
- Helps build harmonization and consistency in decision making across countries
- Opportunity to build on already established relationships
- Opportunity to use existing networks established through education activities

CEPSA is a partnership between ITM and School of Public Health and School of Pharmacy at the University of the Western Cape (UWC)



Structure and governance of CEPSA

- Physically located at the University of the Western Cape, Cape Town, South Africa
- Dedicated staff – Centre Manager (2 PV Experts - UWC and ITM), post-doctoral fellow, and part-time support from ITM and UWC (SOPH & SoP) staff
- Quality and excellence ensured by a Scientific Board
 - Co-chairs: Hannelie Meyer & Albert Figueras
- Collaborate closely with PV Centres in South Africa and across Southern Africa
- Leverage learning and expertise from RCOREs in PV in Africa and selected PV Centres in Europe



Aim of CEPSA

Strengthen all components of pharmacovigilance for medicines and vaccines throughout their lifecycle, thereby contributing to global efforts to build local pharmaceutical research and development (R&D) and manufacturing in South Africa and Southern African region

Specific objectives:

1. Advanced PV training and capacity strengthening
2. Providing support to operational research in the field of PV
3. Enhancing PV information and communication systems



Inter-connected triad of activities



1. Advanced training and capacity strengthening to *build a new generation of PV experts and opinion leaders in Southern Africa: short course; Mobility programme practical experience in PV at recognized centres; Mentoring programme*

2. Support to operational research in PV to *maximise the generation and sharing of new local knowledge: Methodological support to PV research; Policy support to PV centres*

3. Enhancing information and communication systems to *enable timely and participatory communication on safety of medicines and vaccines with communities and policymakers*

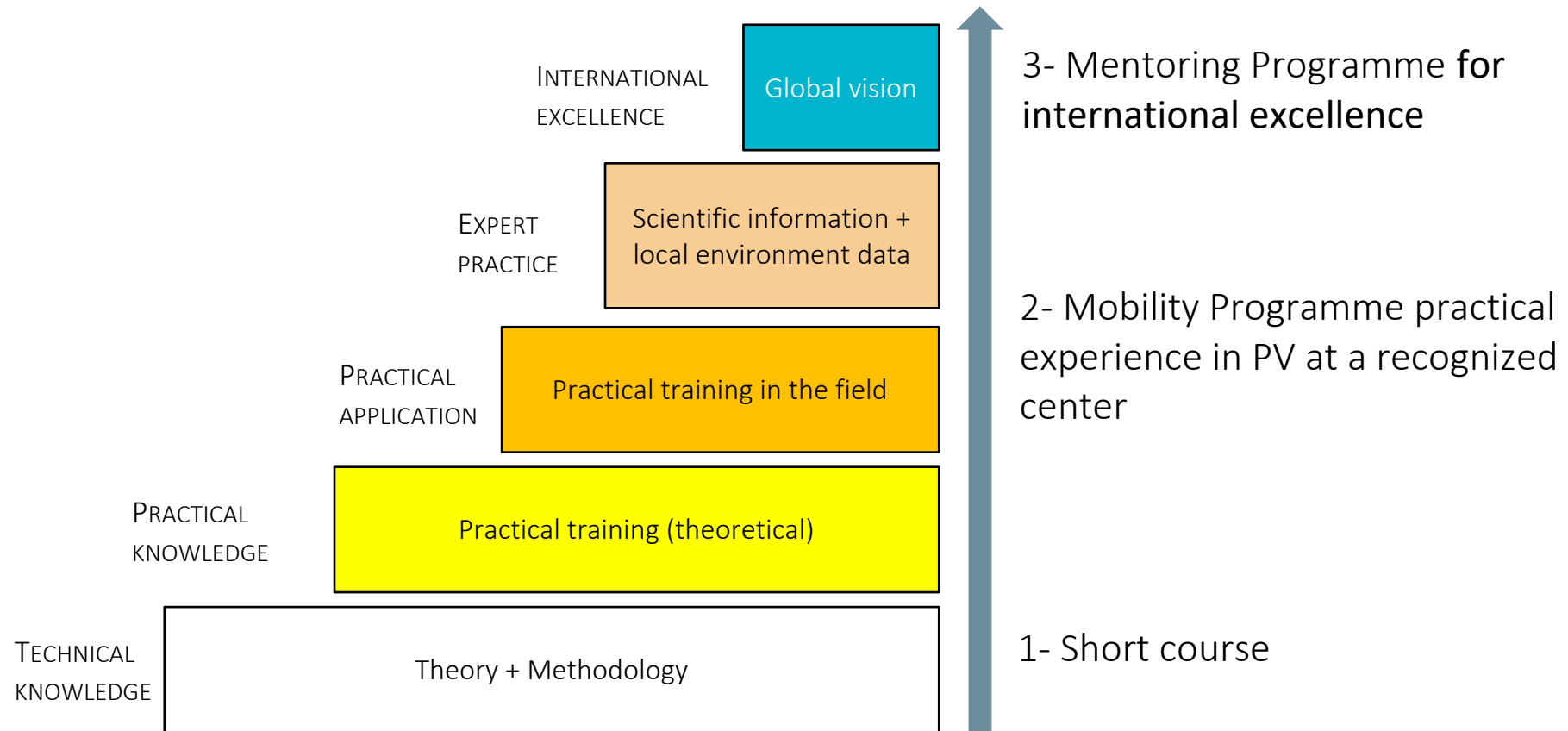


Network of excellence: Building a community of practice among existing PV experts in Southern Africa



Advanced training and capacity strengthening ...

... to build a new generation of PV experts and opinion leaders in South Africa



Training workshop on pharmacovigilance

In collaboration with Africa CDC

17 – 21 November 2025

Cape Town, South Africa

Target population: PV officers from national regulatory authorities (ML3 and other selected countries) and PV technical officers from Africa CDC, actively working with Member States in the area of signal detection and risk communication.

Main Workshop Objectives:

- Strengthen participants' practical skills in detecting, validating, and assessing pharmacovigilance signals.
- Enhance capacity to design and implement effective risk management strategies based on identified safety concerns.
- Improve competencies in communicating safety signals and risk information to diverse stakeholders.
- Foster collaboration and knowledge sharing among African pharmacovigilance professionals



Training workshop on pharmacovigilance

	Workshop topics
Day 1	<p>Analysing data, identifying errors, gaps, etc.</p> <p>Using algorithms to assess causality.</p> <p>Describing differences and similarities of using different algorithms.</p>
Day 2	<p>Identifying a potential signal and analyse the signal.</p> <p>Searching for the clinical and pharmacological basis to support that signal.</p> <p>Describing the signal and plan how to amplify it.</p>
Day 3	<p>How will the signal be handled?</p> <p>(a) If the signal is confirmed, risk management strategy</p> <p>(b) If the signal is not yet confirmed, risk management strategy</p>
Day 4	<p>Communicating with different stakeholders.</p> <p>Draft different types of reports: e.g. press release, report to Ministry of Health, information bulletin to healthcare professionals, radio spot, etc.</p>
Day 5	<p>Presentation of the communication strategies and materials.</p> <p>Group discussion.</p> <p>Closing of workshop.</p>



Baseline survey

Desk review, online questionnaire, in-depth interviews

- Current best practices
- Challenges
- Strategies to strengthen pharmacovigilance

Ultimately → Learn more about the current PV activities and gaps in SADC to inform the Training, Research, and Information and Risk Communication focus of CEPISA







Thank you!

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