Eswatini: Key Achievements & Closing Report

PAVIA Annual Consortium and Closeout Meeting 2023

20 – 21 February, Amsterdam, Netherlands

The EDCTP2 programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.

Outline

- Key PAVIA Achievements
- Best Practices
- Closing Plans
- Sustainability

Key PAVIA achievements

- Establishment of the National Pharmacovigilance Centre (NPC)
- Development of Pharmacovigilance Policy & Implementation Framework, National PV Guidelines & other documents
- Development of draft amendments and regulations with PV to the Medicines & Related Substances Control Act of 2016
- Increased capacity in PV (NPC staff & other healthcare workers in the country). Capacity building approaches included onsite PV trainings and sensitization
- Streamlining process for data management-cleared backlog at one point

Key PAVIA achievements

- Decision to transition to Vigiflow® as national PV database
- Vigibase® visibility also increased
- Increased visibility of PV both at country level and PIDM
- Increased collaboration with the various PV stakeholders
- Partaking in AEFI investigations and Causality assessments

Key PAVIA achievements

1. Establishment of National PV centre

- Dedicated and capacitated PV focal person (previously the focal person has additional duties)
- There was engagement of additional PV personnel
- Infrastructure:
  - Desktops, Server , Printer, Desks and chairs

Key PAVIA achievements

2a. Development of Standalone PV Policy

- Development of PV Policy completed in 2021. Also launched
- In 2022, the NPC sensitized stakeholders on Policy. Stakeholders included:
  - Pharmaceutical industry in Eswatini
  - Healthcare workers from private health institutions
  - Regional Health Management Teams in the 4 regions
  - Healthcare workers from public health facilities in all regions in the country
  - Development partners

The Kingdom of Eswatini

Eswatini National Pharmacovigilance Policy and Implementation Framework

June 2021

Key PAVIA achievements

2b. National PV Guidelines, Job Aids & Posters

- Development of National PV guideline completed in 2022
- Development of the AE severity scale
- PV Guideline is yet to be disseminated
- Job aids & posters were developed, printed and disseminated in 2021

The Kingdom of Eswatini

Eswatini National Pharmacovigilance Guideline

June 2022

KINGDOM OF ESWATINI
MINISTRY OF HEALTH

Adverse Event Definitions & Grading

A QUICK REFERENCE GUIDE FOR SELECTED ADVRSE DRUG EVENTS

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Procurement and Supply Management

ESWATINI MEDICINES PAVIA
(EMRA)
REGULATORY AUTHORITY

Ministry of Health

Pharmacovigilance

The science and activities relating to the detection, assessment, understanding and prevention of **adverse effects** or any other medicine – related problem.

WHY IS Pharmacovigilance NEEDED?

- To improve patient care and safety in relation to all medicines and para-medical interventions.
- To contribute to the assessments of benefit, harm, effectiveness and risk of medicines.
- To encourage the safe and rational use of medicine.
- To capture adverse effects (AE) that are not documented during Clinical Trials.
- To capture rare AEs.

An **Adverse event (AE)**, is any negative or harmful occurrence that takes place during treatment, that may or may not be associated with a medicine.

Know the difference!

Side effect, adverse effect, adverse event, adverse drug reaction

Side effect	Adverse effect	Adverse Event	Adverse drug reaction
Needs to be mentioned during dispensing	Needs to be reported.	Needs to be reported.	Determined after a causality assessment.
Any unintended outcome that seems to be associated with treatment, including negative or positive effects	A negative or harmful patient outcome that seems to be associated with treatment, including there being no effect at all.	Any negative or harmful occurrence that takes place during treatment, that may or may not be associated with a medicine.	A harmful effect suspected to be caused by a medicine.
E.g. Drowsiness associated with antihistamines	E.g. QT prolongation associated with Ketoquine	E.g. A fall that may, or may not, have any association with a medicine	E.g. Peripheral neuropathy associated with ART

Who reports AEs?

- Healthcare professionals (HCPs)
- Doctors
- Pharmacists
- Nurses
- Manufacturers
- Patients

What to report?

- Serious reactions
- Unexpected reactions
- Unusually severe reaction.
- Product quality
- Medication errors
- Effects of New drugs in the market

How a HCP can report AEs?

The National Pharmacovigilance Centre (NPC) has AE forms that are available in facilities for HCP to report AEs.

- Active Adverse Event Form (ongoing surveillance)
- Passive Adverse Event Form (spontaneous "on the spot" surveillance.)

When completing the forms please make sure you complete these Mandatory fields

- Date of report,
- Patient details (initials, date of birth (age), gender)
- Generic name of suspect and concomitant medicine (dosage, initiation date, withdrawal date (if withdrawn), indication)
- Date and description of AE.
- Severity, Treatment (if any) of AE
- Significant lab results or regimen change (if any)
- Outcome (follow up of AE is highly encouraged)
- Reporter details: Sector of practice, occupation of reporter, Tel/Cell No, and email

Active Adverse Event form

Passive Adverse Event form

For more information please contact us at: eswatinipvcenter@gmail.com, Tel: +268 2518 1747/1774 Cell: +268 76557303

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ESWATINI MEDICINES REGULATORY AUTHORITY (EMRA)

EDCTP

Key PAVIA achievements

2c. Other PV Documents

- Amendments to Medicines and Related Substances Act to add provisions on PV (yet to be endorsed)
- PV regulation (draft stage)

Key PAVIA achievements

3. Capacity Building

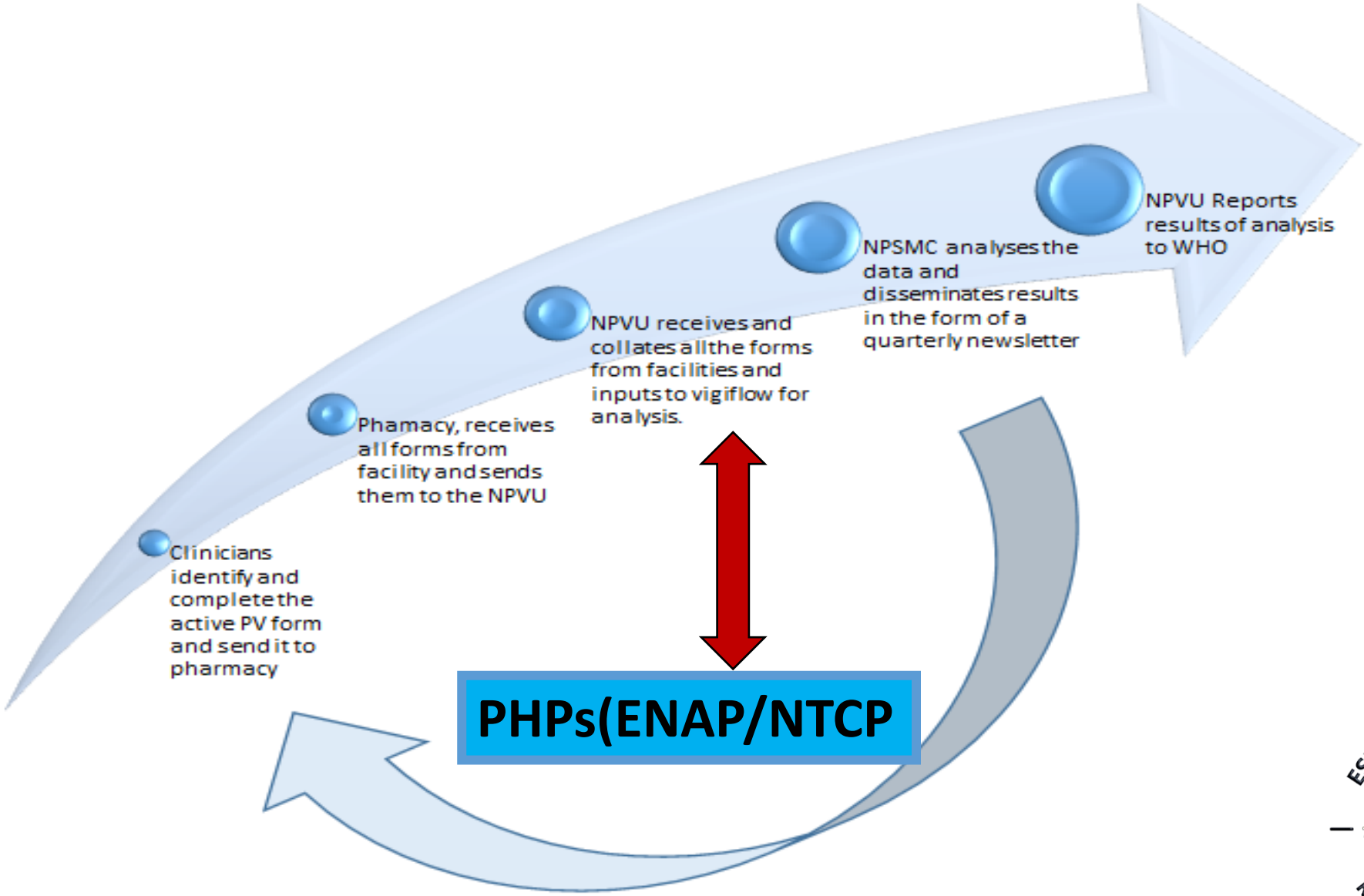
- PAVIA series of trainings for NPC staff(Three trainings)
- Health care workers training
- PAVIA blended training
- Pre-service trainings
- Onsite trainings
- Supportive supervision and mentorship

Key PAVIA achievements

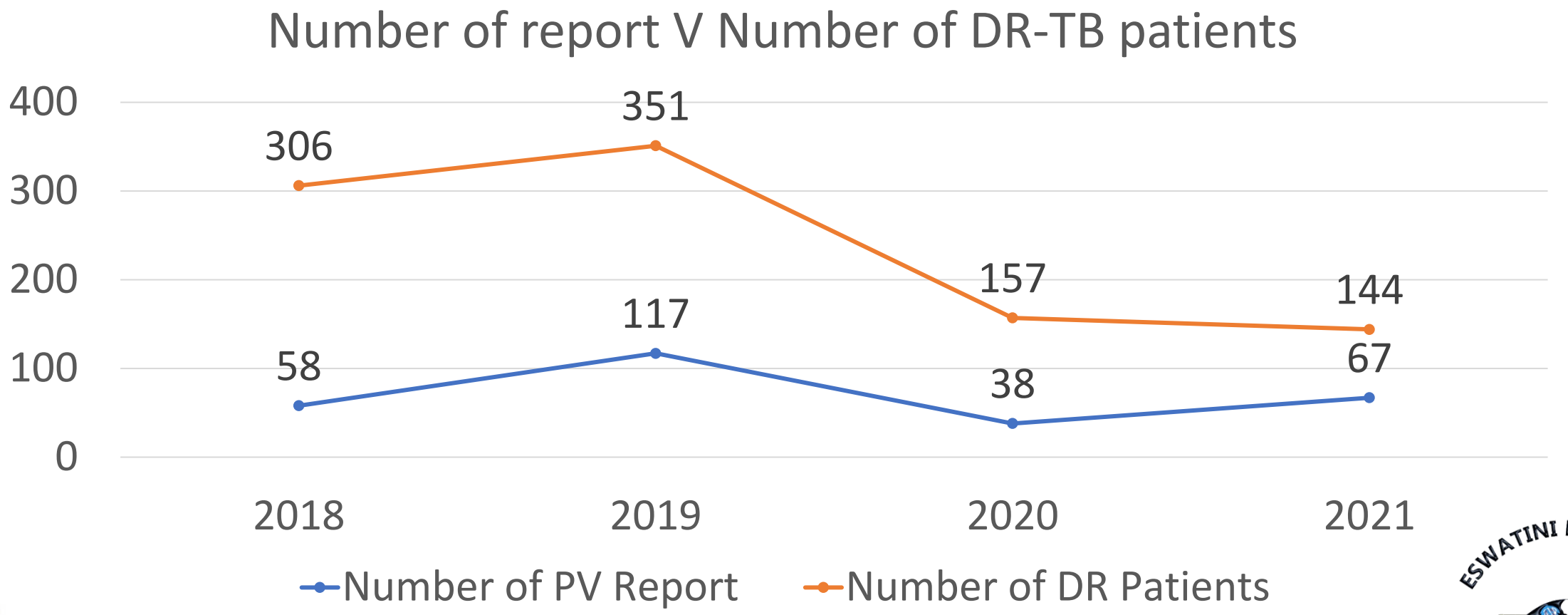
4. Streamlining of PV Data Management & Transitioning to use of Vigiflow® as the data management system

- Previously the country was using excel data base which was not properly organized and kept on personal laptop
- Now reports all captured to vigiflow therefore easier to visualize and produce reports
- Eswatini PV data also visible to UMC and globally.

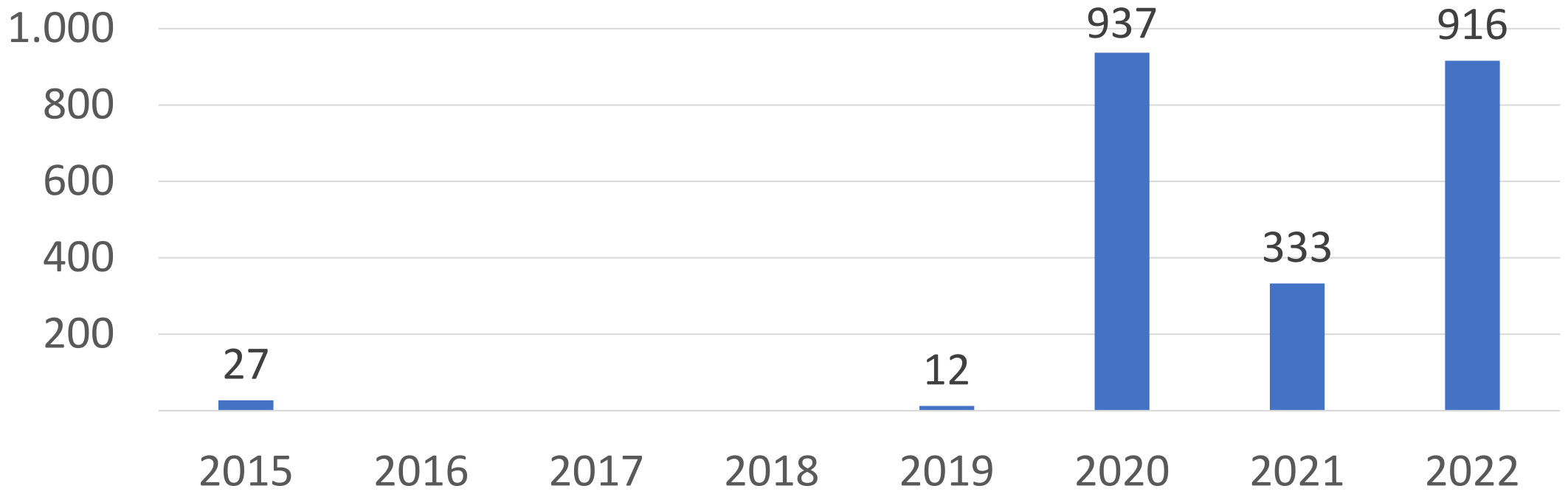
Key PAVIA achievements: ADR reporting flow



Number of reports received from facilities (MDR-TB tx ADRs)



Number of reports entered into Vigiflow®



Note: The number of reports increasing in 2021/22 due to the collaboration between EPI(AEFI)

Key PAVIA achievements

4. Establishment of aDSM Committee

- Historically only AEFI investigations and causality assessments had been conducted in the country including during COVID
- In August 2022 the NPC coordinated the 1st causality assessment meeting for the aDSM Committee. Two cases were discussed
- A 2nd meeting was conducted in October 2022. Eleven cases were discussed in this meeting

Best practices

1. Dissemination of newly developed PV policy to key stakeholders through targeted sensitization meetings
2. Focal persons at facility and Public health program/implementing partner level
3. Insight of PHP’s into Vigiflow.
4. Joint activities of PHP’s and NPC S S Visits and training.
5. Hotline

Closing plans

- Disseminate PV guidelines
- Supportive Supervision Visits
- In country PAVIA project results dissemination meeting
  - MOH senior management team?
  - PV stakeholder?

Sustainability post-PAVIA

- Country PV linkages with other PV stakeholders
  - Still have strong collaboration NTCP NMP ENAP
  - Causality assessments
  - Trainings
  - TWGs
- Cascading of PV activities??

  This part will be extremely difficult with current state of HR and fiscus of the country

Sustainability post-PAVIA

- Continuation of PV trainings and capacity building for HCW through existing platforms
  - IMAI/Nartis
  - NTP
  - NCD
- Continued strengthening of PV regulatory and policy frameworks
  - Advocate for funding for the implementation of PV Policy
  - Advocacy for the endorsement of the amendment of the Medicines and Related Substances Act (9) of 2016 and the regulations
  - Advocate for the establishment of the MRA
  - Advocate for vacant PV positions to be filled

Sustainability post-PAVIA

- Plans for sustainability of the PV triangle
  - This should continues as there are a number of platforms that foster this collaboration as highlighted above.
  - The research aspect will need to be improved

- Any other plans…
  - Advocate for funding for PV activities
  - Incorporating PV into CMIS

Siyabonga

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