



# THE TRACK, THE RACE AND THE TROPHIES.



**A PRESENTATION BY NIGERIA PAVIA PARTNERS  
AT  
ANNUAL CONSORTIUM MEETING IN AMSTERDAM,  
20<sup>TH</sup> FEBRUARY 2023.**



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

# The Track...

- The PAVIA journey in Nigeria started on 24<sup>th</sup> September 2018 with a Kick off Meeting and a Baseline Assessment.
- A Stakeholders consultations and meetings was carried out to create awareness on the PAVIA project.
- Continuous Advocacy to Ministry of Health and other Stakeholders.



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# The Track...

## PAVIA Partners in Nigeria

1. The National Agency for Food and Drug Administration and Control (NAFDAC),
2. Institute of Human Virology Nigeria (IHVN),
3. University of Benin (UniBEN),
4. National Tuberculosis and Leprosy Control Programme (NTBLCP)
5. KNCV Tuberculosis Foundation Nigeria





# The Race...

## Annual Consortium Meeting. (ACM).

The ACM is carried out yearly to discuss the activities, progress, challenges and way forward from the participating Countries, Working group, and Steering committee.

2018 opening meeting in Tanzania

2019 ACM in Ethiopia

2020 Virtual ACM

2022 ACM in South Africa.



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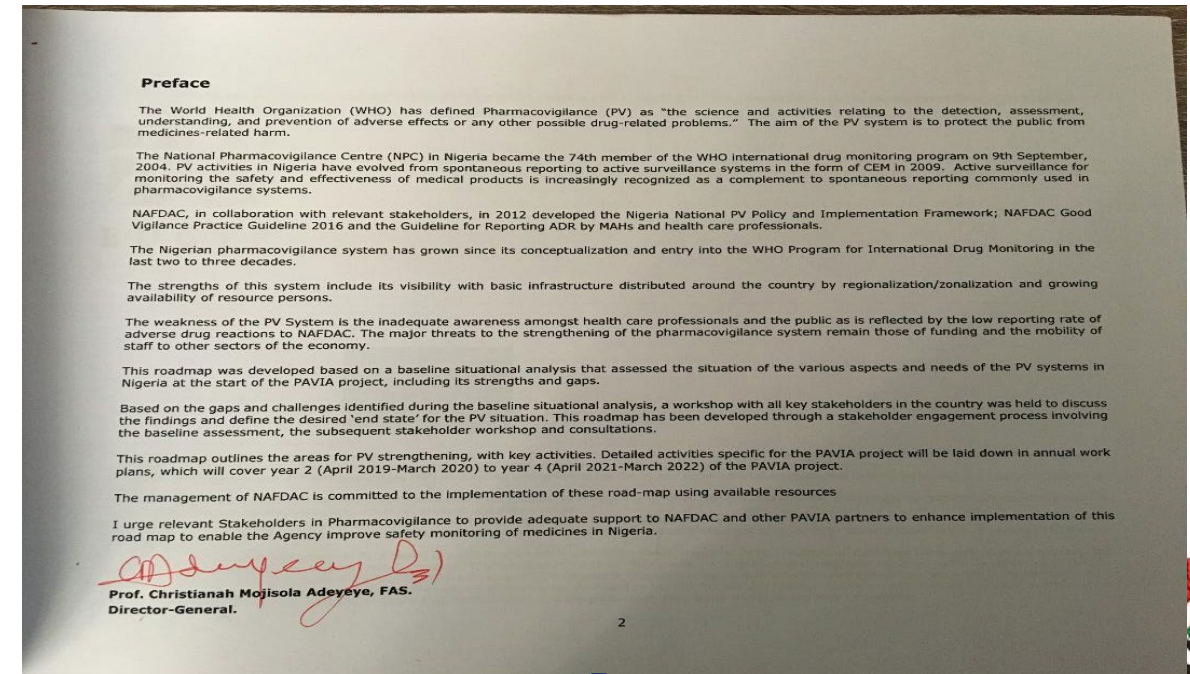
# The Race...

## PAVIA road map

- This roadmap was developed based on a baseline situational analysis .
- A workshop with all key stakeholders in the country was held to discuss the findings and define the desired 'end state' for the PV situation.



### ROADMAP TOWARDS A STRENGTHENED NATIONAL PHARMACOVIGILANCE SYSTEM IN NIGERIA 2019 -2022



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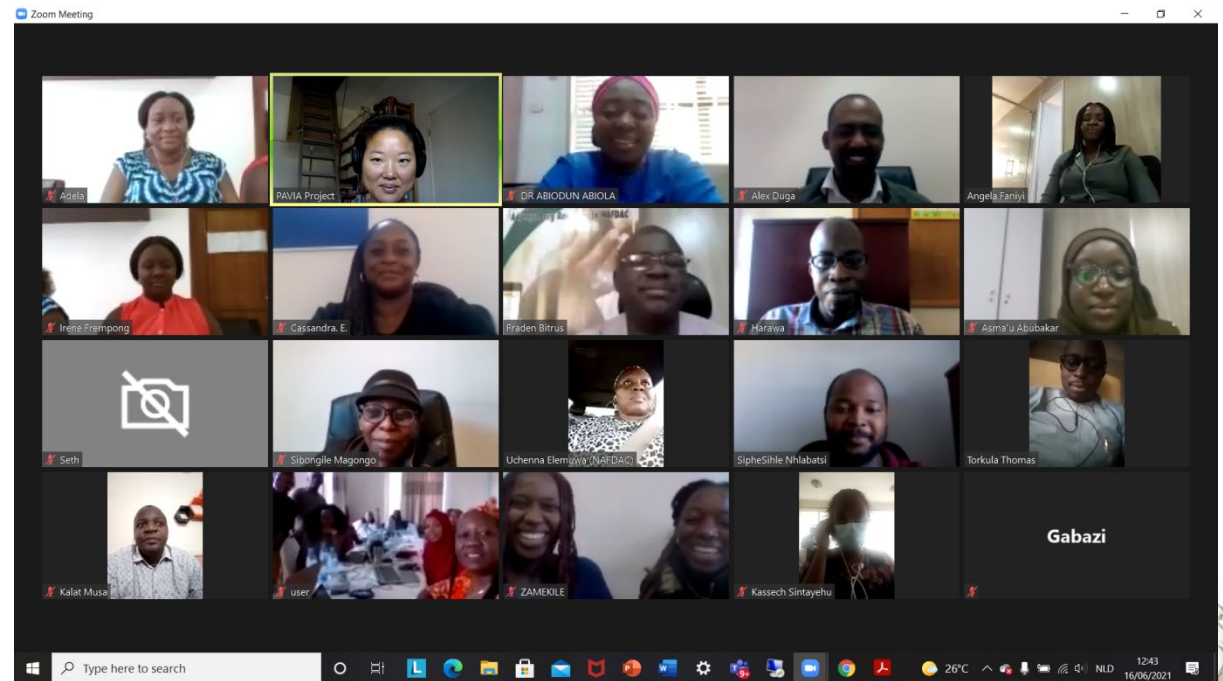
# The Race...

## Trainings

- 1<sup>st</sup> and 2<sup>nd</sup> PAVIA training organised in Ethiopia and Netherlands.
- Training on Financial and Project Management of EDCTP grant in Senegal, Jan 2019.
- Online 3<sup>rd</sup> PAVIA training 14<sup>th</sup> 18<sup>th</sup> June 2022.
- PAVIA blended Learning Training by University of Verona.



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# The Race...

## Step Down Trainings

- Step down training on causality assessment and Signal Detection to NPC staff.
- 540 Health care provider were Trained during Quarterly assessment of PV systems in selected health facilities.
- Blended learning Step down training with participants from NTBLCP, NAFDAC and IHVN.
- Ongoing training of HCP and NPC staff



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# The race...

## Other funders of PV activities



BILL & MELINDA  
GATES *foundation*



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# The Trophies...

## Policy, Guidelines, and Regulation

- Revised Nigerian National Pharmacovigilance Policy and Implementation Framework.
- Gazzetted and Published PV regulations
- Revised Good Pharmcovigilance Practice (GVP) Guidelines.
- Guide for Implementation of PV Policy in resource Limited Setting.



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*Extraordinary*



## Federal Republic of Nigeria Official Gazette

No. 149 Lagos - 8th September, 2021 Vol. 108

Government Notice No. 175

The following is published as Supplement to this Gazette :

S. I. No.	Short Title	Page
74	Good Pharmacovigilance Practice Regulations, 2021 .. ..	B3187-3198

Printed and Published by The Federal Government Printer, Lagos, Nigeria  
FGP 165/092021/150

Annual Subscription from 1st January, 2021 is Local : N45,000.00 Overseas : N60,500.00 [Surface Mail]  
N75,000.00 [Second Class Air Mail]. Present issue N2,500 per copy. Subscribers who wish to obtain *Gazette*  
after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.



## Guide for Effective Implementation of the Pharmacovigilance Policy in Resource Limited Settings



PhArmacoVigilance Africa (PAVIA)

September 2021

# The Trophies...

## Reporting Tools

Printing of 10000 copies of Revised ADR form with support from MSH.

Deployment of Med Safety App in Nov 2020.

The E-reporting platform which is available on NAFDAC website.



ANNEXURE 1	PVPMS-003-01	SERIAL NO:
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National Agency for Food and Drug Administration and Control (NAFDAC)  
Corporate Headquarters,  
Plot 2032 Chisanga Okunjo Way  
Wuse Zone 7, Abuja

NAFDAC  
National Pharmacovigilance Centre

NAFDAC USE ONLY

A. PATIENT INFORMATION		
1. Patient's Full Name or Initials (in Confidence)		
2. Age	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight (kg)
Or Date of Birth (e.g. 03 May 1925) .. ..		
Hospital/Treatment Centre		Patient Record No
2. Indications for Use (Diagnosis)		
Dosage	Frequency	Route of Administration
3. Date Medication Started (dd-mm-yyyy)		4. Date Medication Stopped (dd-mm-yyyy)
5. Reaction Stopped or Reduced After Drug Withdrawal? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply		6. Reaction Reappeared After Drug Reintroduction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
D. CONCOMITANT MEDICINES		

Search Results | Emerald Insight

Pharmacovigilance & Post-Market Surveillance - NAFDAC

**NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL**  
**NAFDAC**

Home Food Drugs & Medical Devices Herbals & Cosmetics Vaccines & Biologics Chemicals Narcotics

Veterinary

Home > Our Services > Pharmacovigilance & Post-Market Surveillance

**Pharmacovigilance & Post-Market Surveillance Section**

Useful Resources

NAFDAC ADR e-Reporting Form

e-Registration

List of ADR Reports Received as at December 2018

List of ADR Reports Received as at December 2017

List of Safety Alert Published and Distributed in 2016-2018

Pharmacovigilance & Post-Market Surveillance

PVPMS is saddled with the following responsibilities;

- Implementation of National Policy on Pharmacovigilance and provision of science-based advice and information on safe use of medicines.
- Post Marketing Surveillance of all Regulated Products in collaboration with Marketing Authorization Holders (MAHs).
- Coordination of Pharmacovigilance activities Nationwide.
- Implementation of Risk Management Plans (RMP) in collaboration with the Pharmaceutical Industry and MAHs as appropriate
- Pharmacovigilance Inspections.
- Supporting the establishment of active Pharmacovigilance Centers in Healthcare Institutions in the Country.
- Creation of awareness on Pharmacovigilance among health professionals, healthcare providers, Marketing Authorization

Handling Consumer Complaint

Handling Adverse Drug Reactions (ADRs)

Mobile Authentication Service (MAS)

Pharmacovigilance & Post-Market Surveillance Guidelines

Recalls & Safety Alerts

Pharmacovigilance Newsletter

About PVPMS



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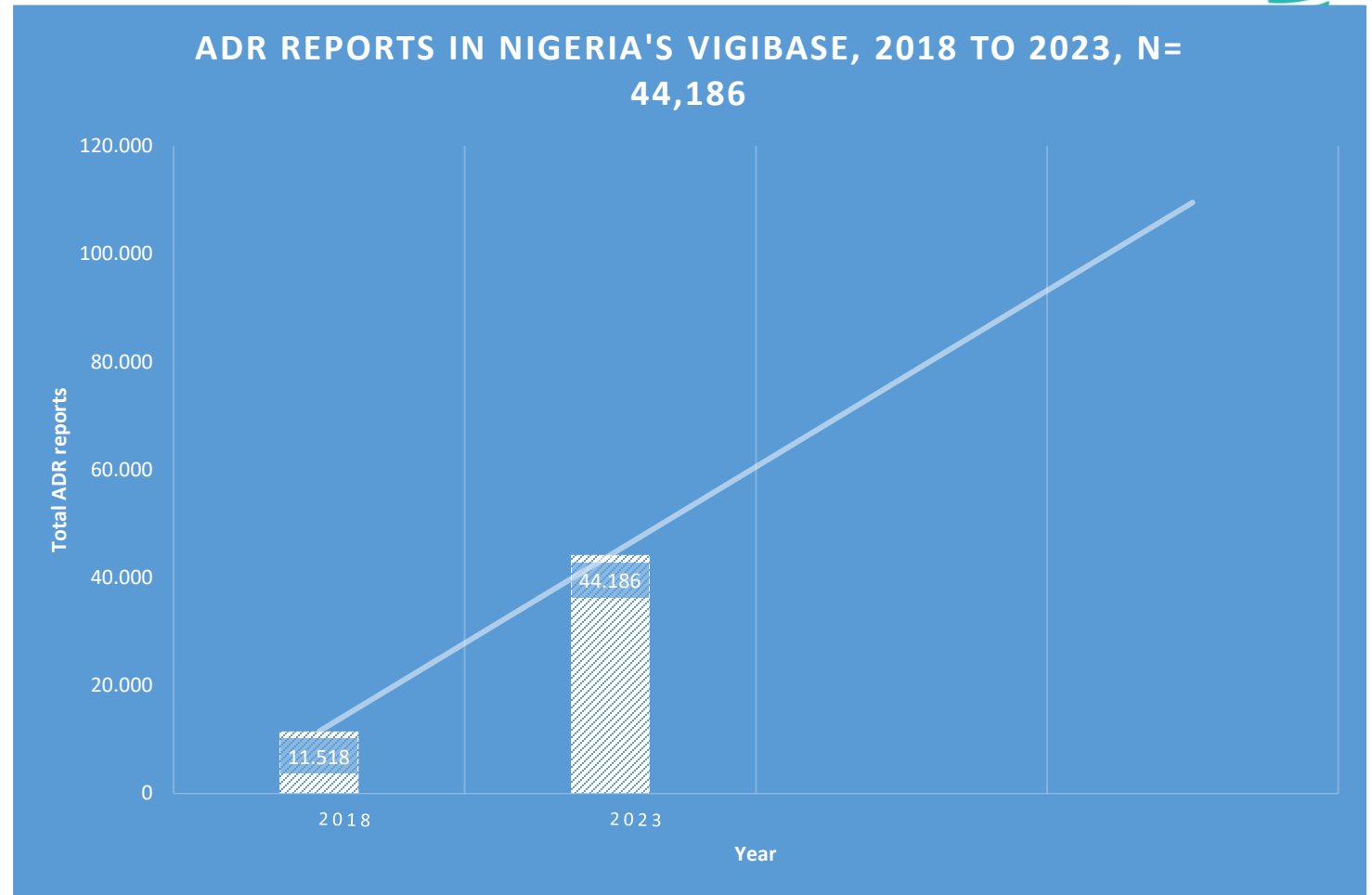




# The trophies...



1. PAVIA was rolled out in Nigeria in 2018 with only 11,518 reports in the National database
2. In February 2023, the Report sharply increased to 44,186, equivalent to 284% increase.
3. Expected: A trajectory increase in reports post-PAVIA is expected.



# The Trophies...



## Studies

- Cohort Event Monitoring (CEM) for Safety Signal Detection after Vaccination with COVID-19 Vaccines. (Phase I & II)
- Trends of COVID 19 Vaccine AEFI; A Retrospective Review using the Passive Surveillance Data in The Nigeria National Database “Vigiflow” From March 2021 To June 2022 (Yet to be published).
- Impact of MEDSAFETY APP use on Adverse Event Reporting in Nigeria (Yet to be Published).



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# The Trophies...



## Studies

- Safety & Immunogenicity of Fractional Doses of Moderna-MRNA-1273, Oxford/AstraZeneca and Janssen COVID-19 Vaccines among Nigeria Adults- A randomised non-inferiority Double blind Trial (SIFCoVAN Trial)
- TORPEDO STUDY – Transitioning to Paediatrics Dolutegravir in Nigeria HIV program. The study seeks to better understand the experiences of the patients and caregivers who take/ administer pDTG and of providers that prescribe pDTG.



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# The Trophies...



## Other achievements.

- **WHO Global benchmarking:** WHO officially announced Nigeria's National Regulatory Agencies (NAFDAC and PCN) as a Stable, well-functioning and integrated regulatory system Maturity Level 3 rating scale of the Global Benchmarking Tool (GBT) in March 2022.
- Increased Staff Strength in NPC. PV focal persons in Thirty Six (36) state NAFDAC offices.
- At least Two Focal persons represents NAFDAC in different Public Health Programs.
- SOPs for carrying out PV activities
- Well motivated workforce.



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# The Sketch out -Post PAVIA.



- Develop a Post PAVIA Workplan and Implementation Plan.
- Sustain the Country Triangle Meeting.
- Include New Public Health Programs in the Triangle
- Continuous Training of NPC staffs and Public Health Practitioners
- Sustain Advocacy and Collaboration with Pharmacovigilance Stakeholders.
- UniBen will be hosting the Blended Learning training Post-PAVIA via Health[e] Foundation.



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# Picture Gallery





# Appreciations



EDCTP  
AUDA-NEPAD.  
The PAVIA Co-ordinating Body:  
Prof Frank Cobelens  
Mr Henry Tumwijukye  
Dr Linda Halmark  
Dr Edine Tiemersa  
Ms Diede Smith.



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# Appreciations



The Impeccable Director General NAFDAC –Prof Mojisola Adeyeye.

The Pioneer of PV in Nigeria- Prof Ambrose Isah.

The Pharmacovigilance New Dawn -Dr Rametu Momodu.

The Easy-going Cerebral Mentor- Pharm Ali Ibrahim.

The Intellectual, Clergy Mentor –Pharm Yohanna Avong.

The Charming Knowledgeable - Dr Abimbola Opadeyi

The Understanding Leader -Pharm Bitrus Fraden.

The TB Backbone- Pharm Alhassan Shiabu.

The Bulldozer Achiever- Mrs Uchenna Elemuwa.

The Dependable Coordinator – Pharm Cassandra Elagbaje.

The Compiler and Ever ready to Learn Dr Abiodun Abiola.



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We fondly  
Remember Mrs  
Helga Mbakwe  
Nosiri...May Her  
Soul Rest in  
Peace. ♡ ♡



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