



REPORT ON NIGERIA COUNTRY SPECIFIC KICK OFF MEETING.

ABUJA, 24TH – 28TH
SEPTEMBER 2018



NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL
NAFDAC



NATIONAL TUBERCULOSIS & LEPROSY
CONTROL PROGRAMME (NTBLCP)

Federal Ministry of Health



UNIVERSITY OF BENIN
BENIN CITY, NIGERIA
Knowledge for service



**INSTITUTE OF HUMAN
VIROLOGY, NIGERIA**



KNCV
TUBERCULOSIS FOUNDATION

To eliminate TB

List of abbreviations

ABUTH	ahmadu bello university teaching hospital
EDCTP	european-developing countries clinical trials platform
FMoH	Federal Ministry of Health
IHVN	institute of human virology
LUTH	Lagos university teaching hospital
MAH	marketing authorization holder
MDR-TB	multi drug resistant tuberculosis
NAFDAC	national agency for food and drug administration and control
NASCP	national aids and sexually transmitted diseases control program
NMRA	national medicines regulatory authority
PHPs	public health programs
PMDT	programmatic development of drug resistant tuberculosis
PRD	poverty related diseases
PV	pharmacovigilance
PV/PMS	pharmacovigilance and post market surveillance directorate
TB	tuberculosis
UniBen	university of benin
WHO	world health organization

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Kick off meeting 24th September 2018



1. INTRODUCTION

PAVIA is a consortia funded by the EDCTP. The project aims to **improve the readiness of sub-Saharan Africa (SSA) health systems to effectively deliver new medicinal products and to monitor their post-market safety**. PAVIA's activities focus on cooperation and linkage between countries' regulatory authorities responsible for pharmacovigilance (PV) and infectious disease control programs responsible for introduction of new drugs and vaccines for PRDs. This is because new treatments are introduced into countries despite limited safety data from clinical trials. The project aims to ensure that introduction of these treatments are done in a unified manner according to WHO's guidance.

The projects specific objectives are:

- (1) To strengthen governance of PV systems, by strengthening regulatory and organizational structures and defining clear roles and responsibilities for all stakeholders.
- (2) To improve efficiency and effectiveness of national surveillance systems, by strengthening active (sentinel) surveillance of adverse drug reactions and implementation of tools and technologies for their detection, reporting, analysis and dissemination.
- (3) To build capacity and skills to sufficiently conduct safety-monitoring activities throughout the country.

(4) To improve readiness of health systems within SSA, by improving performance assessment of PV systems allowing identification of enablers and barriers for implementation.

PAVIA's strategy is to strengthen national pharmacovigilance (PV) systems in a collaborative effort with PHPs building up medicines safety surveillance activities in the introduction of new drugs for Multidrug-Resistant-Tuberculosis.

The University of Benin (UniBen) being a Medical research institute in Nigeria is collaborating with the National PV Centre of NAFDAC as well as the NTBLCP at the national level over a four (4) year period to build capacity at the PV Centre taking the PV activities for Tuberculosis as the "building and training ground" for a generic PV system which will include data collection, database entry, data analysis, signal identification and causality assessment. The results and lessons learned from this project will be transferred by PAVIA to the PHPs for HIV and malaria. The PAVIA project is determined to ensure the quality and safety of medicines through a strengthened health care system.

The Nigeria country-specific kick off meeting was organized in a collaboration between the NAFDAC, NTBLCP, UniBen, IHVN and KNCV Tuberculosis foundation Nigeria. The kick off meeting was held at the KNCV Conference Hall, Abuja on the 24th of September 2018, while the baseline assessments were held from 25th – 28th September 2018.

1.1 OBJECTIVE OF THE KICK OFF MEETING

The main objective of the meeting was to sensitize the key stakeholders in the Nigerian health care sector about the Pharmacovigilance Africa (PAVIA) Project and to seek their collaboration and support towards effective implementation of the project in Nigeria.

1.2 OVERVIEW OF ATTENDANCE

A total of 103 participants, including the PAVIA Nigeria Partners were in attendance at the kick off meeting. Participants included: Federal Ministry of Health, Emzor Pharmaceuticals, Federal Ministry of Health- National Aids and STDs Control Program, Nigerian National Assembly, Ranbaxy Pharmaceuticals, News Agency of Nigeria, Medical Laboratory Science Council of Nigeria, Ahmadu Bello University Teaching Hospital, Gericho Hospital Ibadan, SANOFI, GLAXO SMITHKLINE, SWIPHA, Jawa International Limited, Nigerian Medical Association, Association of Community Pharmacists of Nigeria, Nigerian Centre for Disease Control, FRCN News, Elawza News, Pharmacists Council of Nigeria, Babcock University, NEPAD Nigeria, Nigerian Representatives of Overseas Pharmaceutical Manufacturers, National Malaria Elimination Program, NAFDAC, UniBen, IHVN, Management Sciences for Health and NTBLCP.

1.3 OPENING CEREMONY

The opening ceremony was chaired by the representative of the Honorable Minister of Health, Pharmacist Lawal Mashood Oloku who gave the address on behalf of the Honorable Minister. Other guests of the high table were: Honorable Chike Okafor - Chairman House Committee on health services from the Nigerian National Assembly, representative of the Director General NAFDAC Dr. Gbenga Fajemirokun, CEO IHVN Dr. Patrick Dakur, Linda Harmark, Dr. Bassey Nsa Country Director KNCV, representative of the National Coordinator NTBLCP Dr. Babawale Kunle and representative of the Vice Chancellor UniBEN Professor Ambrose Isah. The opening ceremony involved mainly remarks from Partners, goodwill messages, presentations and technical sessions in the following order:

- Welcome address – Dr. Gbenga Fajemirokun, NAFDAC
- Opening remarks PAVIA – Linda Harmark , LAREB
- Remarks NTBLCP – Dr. Babawale Kunle
- Remarks KNCV – Dr. Bassey Nsa
- Remarks PAVIA Partners, Nigeria- CEO IHVN and Vice Chancellor UniBen
- Address/opening of ceremony- Pharmacist Lawal Moshood Oloku, FMOH
- Nigeria PV network – Pharmacist Ali Ibrahim, NAFDAC
- PAVIA Project Overview – Linda Harmark, LAREB
- Baseline assessment overview – Linda Harmark, LAREB
- Plenary discussion – Chaired by Prof. Ambrose Isah, UniBen
- Technical Session – Chaired by Linda Harmark and Prof. Ambrose Isah

1.4. CONCLUSION

1. The forum agreed that there is an increased incidence of MDR-TB and PAVIA is coming in at the right time to strengthen the PV system. PAVIA will key into current changes and improvements in Nigeria it is appreciated that PAVIA's activities would not only be limited to TB but ultimately all Public Health diseases across Nigeria.
2. Associations recommended that for future sensitization PAVIA could use their platforms to reach their members. Cited recommendations were :
 - Quarterly platforms by associations. Their members would be gathered at these forums and PAVIA can use this opportunity to and sensitized them on its activities.
 - Existing structure of active surveillance especially the Primary Health Care Development Agency across the country can be leveraged on. The active surveillance is available in all states, Local Government Areas and they are ready to work with PAVIA. PAVIA can leverage on surveillance officers working on other public health programs to help spread PAVIA.

- The association of community pharmacists, recommended that community pharmacist around the country should be sensitized on PAVIA due to the fact that they are first point of contact by patients.

BASELINE SITUATIONAL ANALYSIS 25th – 28th SEPTEMBER 2018



2. INTRODUCTION

The baseline situational analysis was conducted on the 25th – 28th September 2018. The situational analysis was conducted to identify the various aspects and needs of the PV systems in Nigeria at the start of the PAVIA project with a repeat of the analysis at the end of the project. The aims of the analysis are to understand the strengths and weaknesses of the current PV system in Nigeria and ascertain the training needs for PV Staff and Health Care Workers to be

addressed by the PAVIA project. The assessment was conducted by the Staff from KNCV Netherlands and Nigeria, LAREB and Nigeria PAVIA Partners.

2.1 METHODOLOGY

There were two teams:

Team 1:

1. Dr. Edine Tiemersma, epidemiologist, KNCV Tuberculosis foundation, PAVIA WP4 lead
2. Pharmacist Yohanna Avong, , IHVN
3. Dr. Abiodun Abiola, PV/PMS NAFDAC
4. Ms. Cassandra Elagbaje, Pharmacist, PV Coordinator for PAVIA in Nigeria

Team 2:

1. Dr. Linda Harmark, LAREB, PAVIA WP3 lead
2. Prof. Ambrose Isah, Department of Medicine, UniBen, PAVIA WP2 lead
3. Dr. Abimbola Opadeyi, Technical Advisor/Assistant to WP2 leader, UniBen
4. Pharmacist Ali Ibrahim, Director PV /PMS, NAFDAC
5. Mrs. Helga Nosiri, Pharmacist, Deputy Director PV / PMS, NAFDAC

The following stakeholders were interviewed:

1. PV/PMS Directorate Staff
2. Pharmacist Ganiyu Abideen – GCH Ibadan, MDR-Tb Treatment Centre
 - Dr. Abdullahi Adamu –MDR-TB treatment center in Zaria
 - Staff of IHVN
 - Staff of NTBLCP
 - Dr. Useni Sani - The PMDT focal person of KNCV /Challenge TB, Nigeria
 - Pharmacist Foluke Garnett- Staff of ABUTH
 - Dr. A. Adewunmi – Staff of LUTH

2.2 CHALLENGES

Due to security and logistics challenges the baseline analysis for the following health facilities was conducted in Abuja with designated Staff and as a result there were no site visits.

- ABUTH, Zonal PV Centre North West Zone, Nigeria
- LUTH, Zonal South West Zone, Nigeria
- Gericho Hospital Ibadan, MDR-TB Treatment Centre, Ibadan, Oyo State
- MDR- Tb Treatment Centre Sayi, Zaria, Kaduna State

Baseline assessments for the MAH and Zonal PV Centres was conducted on the 24th of September immediately after the kickoff meeting. All adjustments lead to changes in the initial agenda submitted for the baseline situational analysis. On the 27th of September the country's labor union went on a nationwide strike and the FMOH was not visited.

3. THE LOOK AHEAD

At the debriefing meeting the findings of the assessments was presented to all the PAVIA Nigeria team members highlighting strengths and gaps in the PV health care system. The meeting then went on to discuss and agree on the next steps, timelines and responsibilities.

3.1 TIMELINES

Activity	When	Who
Full baseline situational analysis report ready	End Oct	Full core team
Baseline situational analysis report approved by head of NMRA (DG NAFDAC)	End Nov	Head of NMRA
Full report disseminated as paper/pdf to all key stakeholders	Mid Dec	PV coordinator
Stakeholder meeting to start PV roadmap drafting process	Early Mar	All key stakeholders
Full PV roadmap developed based on input stakeholders	End Mar	In country PAVIA team
Presentation of draft PV roadmap to key stakeholders	Early April	In country PAVIA team

PV roadmap finalized	End April	In country PAVIA team
Final PV roadmap endorsed by Minister of Health	April/May	

Annex – 1 List of participants

s.n	Name	Organization
1	Dr. Patrick Dakum	IHVN
2	Charles Mensah	IHVN
3	Dr. Adetiba Temitope	IHVN
4	Avong Yohanna Kambai	IHVN
5	Aliyu Ahmed	IHVN
6	Bolajoko Obembe	IHVN
7	Omigbesan Olaiton	IHVN
8	Helen Omuh	IHVN
9	Istafinus Usman	IHVN
10	Bola Adeniyi	IHVN
11	Vivian Ibeziako	IHVN
12	Chiagozie Mgbemena	IHVN
13	Dr. Kayode Gbenga	IHVN
14	Blessing Ukpabi	IHVN
15	Dr. Stephen Ayinbumwan	UniBen
16	Dr. Abimbola Opadeyi	UniBen
17	Prof. Ambrose Isah	UniBen
18	Dr. Linda Harmark	LAREB
19	Alhassan Shuiabu	NTBLCP
20	Olawunmi Olarenwaju	NTBLCP
21	Stephen Ologe	NTBLCP
22	Dr. Abdullahi Adamu	NTBLCP
23	Dr. Babawale Kunle	NTBLCP
24	Lawal Moshood Oluku	FMoH
25	Ologun Taiye Joseph	FMoH
26	Dagubug Ishiaku Ibrahim	FMoH
27	Atu Uzoma	NASCP/FMoH

28	Ogbeke Geoffrey	NASCP/FMoH
29	Nkiru Okoro	Emzor Pharmaceuticals Ltd
30	Collette Okwuchi	Emzor
31	Hon. Chike Okafor	NASS
32	Amarachi Iheonunekwu	NASS
33	Sameep Kapoor	Ranbaxy
34	Mustapha Sumaila	News Agency of Nigeria
35	Edeh. I.	MLSCN
36	Pharm. Foluke Garnett	ABUTH
37	Ganiyu Abideen	GCH Ibadan
38	Mohammed Jalloh	SANOFI
39	Dr. Val Uche	GSK
40	Pharm. Adikwu Ochai	SWIPHA
41	Imichael O. Adah	Jawa Int'L Ltd
42	Dr. Tijo K- Mingeh	NMA
43	Ogbaje O. Solomon	NMA
	Pharm. Samuel O.	
44	Adeigba	ACPN
45	Dr. Ayoola Olufemi	NCDC
46	Nancy Arika	FRCN
47	Prudence Ijah	Elawza News
48	Adagazu Emmanuel	PCN
49	Atinuke Olalaye	Babcock University
50	Busari Bashiru Yomi	NEPAD Nigeria
51	I.P. Davwet	NEPAd Nigeria
52	Ajiboye Temitope	NIROPHARM
53	Nnenna Ogboli	NMEP
54	Dr. Adewunmi Debo	LUTH
55	Mrs. Comfort Ogar	MSH
56	Mrs. N.B Ughanze	NAFDAC
57	Jude Elato	NAFDAC
58	Zainab Idris Muti	NAFDAC
59	Ogomuo Joy Kelechi	NAFDAC
60	Nimlan Tani Ali	NAFDAC
61	Dr. Gbenga Fajemirokun	NAFDAC
62	Anyakora Clementina	NAFDAC
63	Elizabeth Abdul	NAFDAC
64	Ephrem Ejembe	NAFDAC
65	Eze Johopamil	NAFDAC
66	Angela Faniyi	NAFDAC
67	Asaka Ofonmbuk	NAFDAC
68	Ebibi Chioma	NAFDAC
69	Umoro Deborah	NAFDAC

70	Dr. Audu Friday	NAFDAC
71	Okoye Obianuju	NAFDAC
72	Allice Attabor	NAFDAC
73	Chizoba Maduagwuna	NAFDAC
74	Chukwu Markdonald	NAFDAC
75	Ofojekwu Nneoma	NAFDAC
	Dr. Jennifer	
76	Chukwumerije	NAFDAC
77	Nwosu, Anulika Princess	NAFDAC
78	Hadiza Nagode	NAFDAC
79	Hauwa Hussain	NAFDAC
80	A.M Bashir	NAFDAC
81	P.M. Maikano	NAFDAC
82	Kehinde Abioye	NAFDAC
83	Alabi Bola	NAFDAC
84	Aaron Mako Mann	NAFDAC
85	Helga Nosiri	NAFDAC
86	Komolafe Oladayo	NAFDAC
87	Hauwa Abdullahi Maaji	NAFDAC
88	Musa M. Bashir	NAFDAC
89	Garba Usman	NAFDAC
90	Amadi C. Emmanuel	NAFDAC
91	Ibeakamo Comfort	NAFDAC
92	Pharm. F.M. Tatama	NAFDAC
93	Pharm. B.A. Yusuf	NAFDAC
94	Pharm. Yvonne Ikhide	NAFDAC
95	Dr. Fatima Jajere	NAFDAC
96	Okoi Obassam Owa	NAFDAC
97	Dr. Abiola Abiodun	NAFDAC
98	Fatima Adamu	NAFDAC
99	Serah O. Bello	NAFDAC
100	Cassandra Elagbaje	NAFDAC
101	Pharm. Ali Ibrahim	NAFDAC
102	Dr. Basseyy Nsa	NAFDAC
103	Dr. Abubakar Jimoh	NAFDAC

Annex 2

Agenda for country specific kick off meeting, 24th September, 2018

Duration	Time	Activity	Responsible Person	Coordinator
30 mins	9:30 -10:00	Arrival & Registration	All	Cassandra / Mrs. Nosiri
5 mins	10:00 - 10:05	<ul style="list-style-type: none"> • Prayer • Introduction of dignitaries 	All Mr. Ali Ibrahim	
10 mins	10:05-10:15	Welcome Address	Prof. Moji Adeyeye Director General, NAFDAC	
10 mins	10:15-10:25	Opening Remarks from PAVIA	Linda Harmark/Prof. Ambrose	
10 mins	10:25-10:35	Remarks NTBLCP	Dr. Adebola Lawanson National Coordinator	
5 mins	10:35-10:40	Remarks KNCV	Dr. Bassey Nsa	
5 mins	10:40-10:45	Remarks PAVIA Partners, Nigeria	Prof. F.F.O Orunwese Vice Chancellor UniBen	
5 mins	10:45-10:50		Dr. Patrick Dakum CEO IHVN	
15 mins	10:50-11:05	Address / opening of ceremony	Prof. Isaac Adewole Honorable Minister for Health	
30 mins	11:05-11:35	Nigeria PV Network	Pharm. Ali Ibrahim	
30 mins	11:35-12:05	PAVIA Project Overview	Linda Harmark	
30 mins	12:05-12:35	Baseline assessment Overview	Linda Harmark	
1 hour	12:35-13:35	Plenary Discussion		
1 hour	13:35	Close of ceremony/ Lunch	All	
		Technical Session		
1 hour	14:35-15:35	Familiarization of tool and BLA implementation strategy	Linda Harmark	

30 mins	15:35-16:05	Refreshments	All	
30 mins	16:05-16:35	Way forward	All	

Time table and Schedule of Activities for Nigeria PAVIA Kick off Meeting

Dates 24th – 28th September 2018

Day	Date	Activity	Location/responsible
Sunday	23rd September, 2018	Arrival in Abuja of PAVIA Team Pre- meeting of PAVIA Partners	Grand Pela Hotels
Monday	24th September, 2018	Opening Ceremony / Sensitisation Meeting PAVIA Overview Baseline assessment Overview Plenary discussion Technical session Baseline assessment MAH and Zonal PV Centres	KNCV Conference Hall
Tuesday	25th September, 2018	Baseline assessment site visits	NAFDAC KNCV NTBLCP and IHVN
Wednesday	26th September, 2018	Baseline assessment Site visits	NAFDAC (continued) MDR-TB Treatment Center (Ibadan)
Thursday	27th September, 2018	Baseline assessment - Site visits	Ministry of Health

		PAVIA DINNER 6:00 – 8:00 pm	
Friday	28th September, 2018	Debriefing/ presentation on findings/ way forward	KNCV