SPHARTI
(Structured Pharmacovigilance and Training Initiative)

Course Brief

SPHARTI Pharmacovigilance Course-2016, Abuja, Nigeria

The Institute of Human Virology, Nigeria (IHVN) and the National Agency for Food and Drug Administration Control (NAFDAC) are offering an innovative Structured Pharmacovigilance and Training Initiative (SPHARTI). The Initiative is a practical Pharmacovigilance Modular Course funded by the Special Programme for Research and Training in Tropical Diseases (TDR), co-sponsored by UNICEF, UNDP, the World Bank and WHO. Experts in different areas of Pharmacovigilance from SPHARTI partners will facilitate the training.

The course is modeled after a World Health Organization accredited operational research training course known as the Structured Operational Research Training Initiative (SORT IT). SORT IT is offered in low to medium income countries (LMICs) annually by a joint collaboration of the WHO-TDR, International Union Against Tuberculosis and Lung Disease (The Union) and Médecins sans Fronterès (MSF).

Practical skills needed for detecting, reporting and monitoring of adverse reactions of drugs in public health programs will be acquired through the course. The duration of the course is 10–12 months, divided into one week of intensive workshop and 9 months of mentoring and evaluation with clear milestones and measurable targets to achieve. Participants go through the whole course and complete it with a defined product, which is the submission of at least 20 accurately completed NAFDAC Yellow Forms.

The aim of the course is to promote public health safety through the detection, reporting and monitoring of adverse drug reactions in public health programs, notably the HIV/AIDS, Tuberculosis and Malaria. These diseases are the greatest killers of adults and children in sub-Saharan Africa and have been prioritized for special attention by the WHO-TDR.

Purpose: To develop the practical skills for detecting, reporting and monitoring adverse drug reactions in public health programs.

This work received financial support from TDR, the Special Programme for Research and Training in Tropical Diseases, co-sponsored by UNICEF, UNDP, the World Bank and WHO.
Course curriculum: The course comprises three modules and a monitoring and evaluation phase.

Venue: The training will be held at Abuja, Federal Capital Territory (FCT) as follows:

**Module 1: Introduction to Pharmacovigilance and Pharmacotherapy of HIV/AIDS, TB and Malaria–March 14th, 2016**

This will be a day module to help participants develop a thorough understanding of what pharmacovigilance and pharmacotherapy of the three diseases (AIDS, Tuberculosis and Malaria) are all about. The teaching will be through lectures, discussions, exercises and the use of completed NAFDAC Yellow Forms to report and monitor suspected adverse drug reactions from the public health programs. Participants will present and discuss completed Yellow Forms during the discussion session.

**Brief content overview**

- Introduction to SPHARTI
- Introduction to Pharmacovigilance
- Definition of terms in Pharmacovigilance
- History and importance of pharmacovigilance
- Pharmacotherapy: HIV/AIDS
- Pharmacotherapy: Tuberculosis
- Pharmacotherapy: Malaria

**Module 2: Adverse Drug Reactions in Public Health Programs – March 15th – 16th, 2016.**

This will be a two-day module to help participants understand the adverse reactions associated with the antiretroviral, anti-tuberculosis and anti-malaria drugs. Participants will understand the HIV/AIDS, Tuberculosis and Malaria public health programs and the potential harm the nation could face with an outbreak of adverse drug reactions from these programs. Participants will also be exposed to the adverse reactions of HIV/AIDS and Drug Resistance Tuberculosis (DR-TB) medications from public health programs that have been published in peer-reviewed articles. The module will consist of:

1 day: Published adverse drug reactions (ADR) from the HIV/AIDS and DRTB public health programs

1 day: Specific adverse reactions of anti-retroviral, tuberculosis and malarial medications

**Brief content overview**

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• Published adverse drug reactions from HIV/AIDs and DRTB public health programs in Nigeria

• Adverse reactions associated with anti-retroviral medication

• Adverse reactions associated with anti-tuberculosis medications

• Adverse reactions associated with anti-malarial medication

(Key Deliverable Output: Adverse Drug Reaction Medication Charts)

Module 3: March 17th – 18th, 2016

This will be a two-day module to help participants understand all the issues surrounding accuracy in reporting of individual case safety reports. They will be taught the Vigigrade system of estimating the correctness of a completed NAFDAC Yellow Forms. The NAFDAC system of reporting, and everything about NAFDAC will be taught in great details.

Brief content overview

• Reporting of ADRs within the Pharmacovigilance Committees in the health facility and public health programs

• Regulatory work of NAFDAC and how it fits into the Global Pharmacovigilance Centre in Geneva

• The magnitude of poor quality reporting of ADRs in Nigeria

• The Yellow Form – structure and functions

• How to complete the form

• The Vigigrade system of estimating accuracy in completed forms

• Communication

• Transmission of completed forms

(Key Deliverable Output: Completed Forms from each disease group)

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Mentoring and Evaluation: 9 months (April – December, 2016)

The one week intensive training will be followed by 9 months of continuous mentoring and evaluation of participants’ performance. During the continuation phase, participants will be expected to achieve the following:

a) Complete and dispatch the Yellow Forms to the National Pharmacovigilance Center and copy the IHVN through the reporting system. At least a total of 20 completed forms are expected from each participant. Participants that exceed the 20 baseline reports shall receive a special award to be delivered by a WHO country representative in Nigeria on the “round up” day.

b) Share the individual case safety reports with the Pharmacovigilance committee or other stakeholders in the hospital.

c) Step down the skills acquired during the training to peers at the health facilities.

Facilitators will use the following methods for the mentoring and evaluation of participants:

i) Visit specific participants that appear to be having difficulties in achieving any of the deliverables of the continuation phase

ii) Telephone conversations (facilitators will keep a register of all communication with participants, detailing what was discussed and the key knowledge imparted during the discussion) and

iii) Emails.

4. Certificate (10 months after completing the training)

Participants who complete the whole course (first and second phases) will be awarded the Pharmacovigilance Certified Professional (PcP) certificate at an elaborate event in Abuja. Those who did not achieve the mile stones and were expelled from the program are considered to have FAILED and would not be invited for the round-up day. Excuses for not meeting a milestone will be taken for the purpose of research but will not help the candidate in getting the PcP certificate.

5. Faculty for the Course

The course will be conducted by experienced and reputable faculty from the NAFDAC, Institute of Human Virology, Nigeria, Health Facilities treating HIV/AIDS, TB and Malaria and collaborating University partners and pharmacovigilance experts.

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6. **What does the participant’s organisation gain?**

- A person who is well trained in pharmacovigilance will improve patient safety and can help their health facility promote the safety of patients treated in the public health program. They may also help their facilities undertake relevant operational research to identify challenges and improve programme performance in a sustainable manner.

- This will open up better career opportunities including the possibility of pursuing a Master or PhD in the field of Pharmacovigilance and Pharmaco-epidemiology. The research studies should strongly complement “innovation” within routine operations and contribute to critical reflection on program orientation and its impact over time.

- The initiative would also foster health workers retention in program activities including pharmacovigilance. It should consequently attract qualified staff and reduce turn-over which may hamper continuity of research initiatives.

- Post- marketing safety surveillance of medications use in public health programs will improve Nigeria’s profile as a leader in the sub-region and probably in sub-Saharan Africa.

7. **What does the participant gain?**

- Practical skills for detecting, reporting and monitoring adverse drug reactions in public health programs.

- The experience of learning and sharing knowledge within a team of motivated participants and talented facilitators in pharmacovigilance (who act as mentors) from different parts of Nigeria.

- An opportunity to excel and gain visibility in pharmacovigilance and to prepare for increased research responsibilities and research leadership in Nigeria and sub-Saharan Africa.

- Possibilities of submitting published papers in pharmacovigilance and eventually acquiring a PhD in Pharmacovigilance and Pharmaco-epidemiology.

- Participants are strongly encouraged to help train and eventually lead others (as mentors) to maximise long term capacity development and impact. The philosophy used is “see one, do one, teach one and eventually many more”

8. **Criteria for successful applicants**

   a) Involved actively in a public health program or disease specific field ( TB, HIV, Malaria)
b) Provide written commitment to attend all three modules of the training course and 9 months of mentorship and evaluation at health facilities.

c) Provide a written statement from a referee describing how he/she knows the candidate and attesting to his/her ability to complete the course.

d) Ability to self-motivate for the successful completion of the course

e) Submit an **Outline a half page of text** that describes the participant’s experience in the detection, reporting and monitoring of adverse drug reactions in any of the three disease areas: HIV/AIDS, TB and Malaria.

f) A graduate qualification or an equivalent, or a strong recommendation

g) Fluent in written and spoken English

h) Computer literate

*Female candidates meeting the above criteria are strongly encouraged to participate.*

9. **Support for the course**

Participants will be provided per-diem, accommodation and transportation costs. Participants will also return to their health facilities with bound copies of the certified Pharmacovigilance Training Manual, CD-ROM, ADR Charts and downloaded Pharmacovigilance Handbooks in HIV/AIDS, TB and Malaria, prepared by the World Health Organization.

10. **Participants’ selection deadline: February 25th, 2016**

*Selected participants will receive their letter of invitation to the course on the February 25, 2016 and the training will commence on the 14th through 19th March, 2016. Questionnaires and pre-course materials as well as the quiz will also be sent to the selected participants on the 20th February, 2016. All enquiries concerning the course will be directed to:*

**CONTACT PERSON:**
Bola Obembe
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Contact person should also be contacted for any clarifications on the course.

To apply, control +click [http://goo.gl/forms/PEjK53qaZR](http://goo.gl/forms/PEjK53qaZR) and fill the application form.

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