Pharmacovigilance Monitoring System Readiness Assessment, Philippine Department of Health

April 2016

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SIAPS
Systems for Improved Access to Pharmaceuticals and Services

Pharmacovigilance Monitoring System Readiness Assessment, Philippine Department of Health

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

Philippines, pharmacovigilance, TB, active TB drug-safety monitoring and management, cohort event monitoring, pharmacovigilance software

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CONTENTS

ACRONYMS

ADR	adverse drug reaction
AE	adverse event
FDA	Food and Drug Administration
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
ICSR	Individual Case Safety Report
IT	information technology
ITIS	Integrated Tuberculosis Information System
LCP	Lung Center of the Philippines
LCP-NCPR	Lung Center of the Philippines–National Center for Pulmonary Research
MDR-TB	multidrug-resistant tuberculosis
MS	Microsoft
NTP	National Tuberculosis Control Program
PBSP	Philippine Business for Social Progress
PV	pharmacovigilance
PViMS	Pharmacovigilance Monitoring System
PMDT	programmatic management of drug-resistant tuberculosis
SAE	serious adverse event
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedure
TB	tuberculosis
USAID	US Agency for International Development
WHO	World Health Organization
9MTR	nine-month treatment regimen

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BACKGROUND

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is working with the NTP and the Philippines FDA in strengthening pharmacovigilance system in the country. With the introduction of new anti-tuberculosis (TB) medicines and novel regimens in the country, SIAPS is providing technical support to the FDA, NTP, and Lung Center of the Philippines–National Center for Pulmonary Research (LCP-NCPR) in implementing an active PV system to monitor safety and effectiveness of anti-TB medicines.

One common barrier to effective, active PV is the lack of available data collection and analysis tools. To help address this challenge, SIAPS developed a web-based application called Pharmacovigilance Monitoring System (PViMS) to support the NTP and FDA in streamlining and simplifying the PV data collection and analysis process.

SIAPS, in partnership with the FDA, NTP, and LCP-NCPR, conducted a readiness assessment to determine the current information technology (IT) infrastructure, human resources, processes, and data management and quality control mechanisms available and to identify gaps in the current PV recording and reporting of patients in the seven Programmatic Management of Drug-Resistant TB (PMDT) treatment facilities implementing the 9MTR for multidrug-resistant (MDR)-TB study. The results of this assessment will provide inputs for developing the PViMS implementation plan.

Methodology

The PViMS readiness assessment was conducted at two levels: central and peripheral. Key informant interviews at the central level were carried out with the FDA and LCP-NCPR staff, while interviews at the seven peripheral facilities were conducted with health staff managing the 9MTR study. Annex A provides the list of PViMS Readiness Assessment Sites; Annex B shows the standard questionnaire used during the assessment.

During and after key informant interviews, the health facilities demonstrated the process of recording adverse events (AEs) affecting patients enrolled in the study as well as non-study patients, both in paper form. The health facilities demonstrated recording patient data in the Integrated TB Information System (ITIS).

Three PMDT facilities—Ilocos Training Regional Medical Center (ITRMC), Zamboanga City Medical Center (ZCMC), and Batangas Medical Center (BatMC)—that are also implementing the 9MTR study were excluded in this assessment due to zero patient enrollment (ITRMC and BatMC) and logistical constraints.

FINDINGS

1. IT Infrastructure and Support

Health Facilities

All facility sites have at least one desktop computer that passed the minimum hardware and software requirements to use PViMS. All health facilities have an Internet connection they can use to access PViMS. Internet connection speed and stability vary among the seven facilities. Two facilities have a stable Internet connection throughout the day, while the other five facilities have an unstable Internet connection, particularly in the afternoon. Only five of seven health facilities have updated anti-virus software installed on their desktop computers. Four of seven facilities reported that their major problem is a slow computer.

The Internet connection subscription and maintenance of computers at the facilities visited are all supported by the Philippine Business for Social Progress (PBSP)—the principal recipient of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) grant—or a local government unit (LGU) or a nongovernment organization (NGO) (e.g., German Doctors). PBSP's IT support in the past two years include Internet troubleshooting, repair, and replacement of the hardware parts and preventive maintenance. All facilities escalate any IT support issue to PBSP through telephone or email. Depending on the urgency of the problem, PBSP usually responds within a week. Annex C provides the IT Infrastructure Status of Health Facilities visited during the assessment.

Lung Center of the Philippines–National Center for Pulmonary Research

The power source is 99% constant at the LCP-NCPR office. There is no backup power available in case of power interruption. All five laptops of the research team have passed the minimum hardware and software requirements to use PViMS. All laptops have updated anti-virus software.

Financial support for Internet connection, hardware, and software is provided by PBSP. IT issues are reported and addressed by PBSP. Although the LCP-NCPR has access to the Internet, the connection tends to slow down between 1 and 2 p.m.

Food and Drug Administration

Electricity is constantly available at the FDA office and there is a backup power supply. Each PV unit staff has a desktop computer that meets the minimum hardware and software requirements to use PViMS.

The FDA has their own in-house IT personnel to maintain and troubleshoot hardware, software, and network-related issues. The agency has its own data center, which hosts the FDA website. All software programs installed on the FDA servers are open source. Internet connection speed is stable and Internet is available in the FDA office at all times. The Internet connection subscription is paid by FDA.

According to interviewees at the FDA, the current IT infrastructure of the administration's data center is sufficient to support the initial deployment of PViMS in 10 health facilities; they have plans to upgrade the capacity of their data centers.

2. Human Resources

Health Facilities

Each facility has at least one staff member trained in recording data related to AEs and serious adverse events (SAEs) of enrolled patients via the software or paper forms. However, all facilities expressed a need for further orientation in the proper recording of study data.

Some staff are funded by the Global Fund, LGUs, or NGOs. All staff work a regular shift from 8 a.m. to 5 p.m., Monday to Friday. All staff are familiar with Microsoft (MS) Windows and the use of computers.

Lung Center of the Philippines–National Center for Pulmonary Research

The research team has five staff managing 9MTR data. These staff include two data encoders, one data specialist, one monitoring officer, and one research specialist. Currently, the LCP-NCPR research specialist is in charge of PV. The LCP-NCPR has yet to fill the PV monitoring officer position that has been vacant since March 2016.

All staff of the research team are hired and funded by PBSP-GF, and work a regular shift from 8 a.m. to 5 p.m., Monday to Friday.

Two persons from the research team were able to attend a PV training on causality assessment. All staff have been trained on the data collection requirements for SAE/AE reporting for the study.

Food and Drug Administration

The PV unit has seven staff who manage all AE reports from the industry, consumers, and public programs. Three staff are assigned to manage the 9MTR study active surveillance, as well as perform causality assessment and other regulatory tasks. One of these is funded by NTP. All staff were able to attend a PV training on causality assessment.

3. Processes, Data Management, and Quality Control

Identified key stakeholders involved in PV are the NTP, FDA, PBSP, and SIAPS. The organogram, or flow chart, that maps out the coordination of PV activities among stakeholders can be found in the 9MTR study protocol and PV standard operating procedures (SOPs) document called *Active Pharmacovigilance Surveillance: Drug Safety Monitoring for New Medicines and Novel Regimens of the National TB Program in the Philippines*.

Health Facilities

All seven facilities record patient data in both paper and electronic form. For paper-based recording, health facilities record patient data in the Patient Progress Report Form (PPRF) and additionally in 9MTR study forms (Annex D) for the patients enrolled in the study. The forms are standardized and all facilities reported that paper forms are always readily available.

Electronically, the facilities encode patient data using the web-based application ITIS. All demographic data in the seven facilities are up-to-date in ITIS. However, for patients enrolled in 9MTR, only limited data can be encoded in ITIS, as the study requires more data to be captured, particularly on clinical evaluations and AEs. (Annex E shows the breakdown of staff who maintain patient information.) ITIS has an adverse drug reaction (ADR) module but it does not capture the FDA's minimum required data on either active or passive PV surveillance. Its purpose is to monitor ancillary drug consumption per ADR. This module is not fully utilized by the facilities, as it has the same purpose as the MS Excel–based spreadsheet called Drug Supply Management (DSM) report submitted by PMDT facilities to the NTP central office every month. Only ADRs that were treated with ancillary drugs are recorded in the spreadsheet.

There is no standard dictionary/terminology for recording ADRs/AEs in the health facilities. The terms for ADRs/AEs used per health facility vary. The health facility staff are aware of the timelimes for submitting ADRs of patients under study, but not for non-study patients

None of the facilities is aware of the latest PV safety alerts from FDA or where to access them.

Lung Center of the Philippines–National Center for Pulmonary Research

LCP-NCPR receives the scanned copies of study forms via email from the health facilities. Data encoders encode received study-form data in the FoxPro-based 9MTR electronic database, wherein data fields correspond to the study forms. The research team practices double encoding, whereby encoders enter the same data in the database with different user accounts. The data specialist will then check the database validation module to find data entries made by the encoders that do not match, and marks or updates which entry is correct. As of April 2016, the 9MTR database is not yet fully functional and in use because of software bugs that first need to be resolved. Therefore, data in the 9MTR database, including data on SAEs, are not up-to-date. In addition reports are not generated through this database because of inconsistencies found in the data output.

The following challenges were identified by LCP-NCPR in receiving study forms: (1) legibility of writing, (2) missing information, and (3) irregular submission. The health facilities send scanned copies of the study forms even if not they are not completely filled in, as some laboratory tests may be awaiting results. Results of these laboratory tests are not immediately communicated to LCP-NCPR upon availability. Adherence to required submission of non-serious AEs within 30 days is not observed by some facilities. However, adherence to reporting of SAEs within 24 hours is maintained by all facilities. Per protocol, the research team performs a causality assessment and forwards the SAE study form to the FDA. As of April 1, 2016, the

research team has not yet received any feedback from the FDA on the causality assessment of any SAEs reported from October 2015 forward.

To consolidate the required quarterly report defined in the protocol, it takes 15 working days for the research specialist to manually count all the AEs and group them by system organ class. Only the summary count of all AE is disseminated to the NTP, FDA, and other stakeholders.

The research team monitors the 9MTR sites once a month with focus on the compliance of the health facility to the protocol, but not on PV specifically. Data quality gaps are immediately corrected and 9MTR staff are mentored on deviations from the 9MTR protocol.

Food and Drug Administration

The 9MTR study is the first clinical trial in the country requiring active surveillance. Since the National Drug Advisory Committee has yet to convene, the FDA PV unit will conduct the causality assessment on the SAEs experienced by the patient under the study. Although the health facility and research team complies with the designated timeline in reporting SAEs, the data FDA receives reports from the research team are insufficient for performing a causality assessment. Other study forms containing the clinical evaluations, conditions, and medications of the patient are not readily available. The FDA has to communicate back to LCP-NCPR to ask for further information that they require to perform the causality assessment.

Every quarter, the FDA receives the summary count of AEs experienced by study patients per system organ class. This report has revealed to the FDA the need to improve the categorization of AEs, as too many are placed in the "Others" category, which can be broken down further by system organ class. The SOPs also state that upon receipt of quarterly adverse event reports, the FDA needs to provide feedback to the NTP through the research team on the causality assessment. However, since the FDA receives only the summary count of AEs and the other required data (i.e., AEs, patient demographics, clinical evaluations, conditions, medications) are not readily available and the AE count is not sufficient, the FDA is not able to perform the causality assessment. It was only in March 2016 that the FDA began receiving the scanned study forms containing details of non-serious adverse events from the health facilities.

The forms remain in their scanned form and are not encoded in any electronic database unless and AE is serious. For SAEs, the FDA PV unit encodes data in VigiFlow® and submits reports to the Uppsala Monitoring Centre in Sweden. Vigiflow is a web-based Individual Case Safety Report (ICSR) management system designed for use by the national centers in the World Health Organization (WHO) Programme for International Drug Monitoring.

There is no information system used by the FDA for active surveillance of patients under the study. For spontaneous reporting, the administration has a standard ICSR form. AEs or suspected ADRs are voluntarily reported to FDA via fax, telephone, or email. An electronic reporting form for ICSR can also be accessible via website.

The Philippine FDA has been a member of WHO Collaborating Centre for International Drug Monitoring since February 1995. The FDA adopts the International Conference on

Harmonisation (ICH) Safety and Efficacy guidelines and advocates the voluntary submission of AEs in ICH-E2B standard format from the private and public sectors. Only the multinational pharmaceutical companies have the capacity to conform in the E2B submission, as the database that they use are E2B-ready.

The FDA future plans involve (1) the ICH-E2B standard for electronic submissions of ICSRs; (2) moving from passive to active surveillance; (3) integration of all public health programs with PV; (4) strengthening linkages at the facility, national, and international levels; (5) strengthening SAE/AE/ADR reporting from the different clinical trials conducted in the country; and (6) issuance of newsletters

The FDA has not conducted PV-specific monitoring visits in the 9MTR facilities prior to this assessment.

RECOMMENDATIONS

SIAPS recommends the following—

- Ensure that FDA leads the standardization of minimum PV data collection in the country for active surveillance.
- Update the current PV SOPs for the study based on the current implementation of PV for the study.
- Ensure the availability of the latest FDA PV safety alerts and SOPs at all levels.
- Improve the dissimination of PV SOPs at the health facilities.
- Mandate that the FDA and NTP standardize PV implementation monitoring alongsside regular auditing, to help ensure that monitoring is taking place.
- Provide support via SIAPS to the migration of 9MTR database data to the PViMS for reporting and analysis.
- Assign responsibility to the Knowledge Management Information Technology Service (KMITS) and SIAPS to establish interoperability between ITIS and PViMS.
- Assign responsibility to the FDA to ensure the upgrade of their IT infrastructure for scale-up of PViMS.

ANNEX A. PViMS READINESS ASSESSMENT SITES, APRIL 2016

Name of Facility	City/Province
Lung Center of the Philippines (LCP)	Quezon City, Metro Manila
Dr. Jose N. Rodriguez Memorial Hospital (DJNRMH)	Caloocan City, Metro Manila
Dr. Jose B. Lingad Memorial Hospital (JBLMH)	San Fernando, Pampanga
Sorsogon Medical Mission Group (SMMG)	Sorsogon City, Sorsogon
Eversley Child Sanitarium (ECS)	Cebu City, Cebu
West Visayas Medical Center (WVMC)	Iloilo City, Iloilo
Xavier University (XU)	Cagayan de Oro, Misamis Oriental

ANNEX B. PV MONITORING SYSTEM SITE ASSESSMENT TOOL FOR HEALTH FACILITY

Date of Interview:				
Name of Facility:				
Respondent:	Name	Position	Email	Contact no.

Instruction: Kindly encircle your answer.

Infrastructure

1. **Is there reasonably constant power at the site(s) where Pharmacovigilance Monitoring System (PViMS) is to be installed?**
   25% of the time or less
   50% of the time
   75% of the time
   100% of the time

2. **Is there a provision for backup power?**
   Yes, there is a backup power source available.
   Yes, there is a backup source available, but it does not provide power to the dispensing point.
   No, there is no backup power source available.

3. **Do (es) the site(s) currently have computers now available for PViMS use?**
   Yes
   No

4. **If Yes, how many computers?** ☐

5. **If the site has computers, does the destination hardware meet the following minimum specifications? (Check all that apply.)**
   Computer: 4GB RAM, 160 GB Hard Drive with at least 15 GB of free space, Intel T2500 CPU
   UPS: Minimum 650 VA with at least 10 min. backup at full load
   Windows 7–64 bit with all updates
   Antivirus software that is currently maintained with all updates

   If not, what is the specification of the computer? (List operating system, anti-vrus, control unit (CPU), UPS, etc.)

6. **Is it possible to maintain computers locally?**
   Yes
   No

7. **If Yes, specify what is the agreement and with whom.**

8. **If Yes to 6, then specify what support has been provided in the last 2 years.**

9. **If it is not possible to maintain computers locally, how long would repair take in case of breakdown?**

10. **Does the site have Internet connection or have access to one?**
    Yes
    No

11. **If Yes, is the Internet connection stable?**

12. **If Yes to 10, what is the Internet connection speed?**

13. **If Yes to 10, are there enough funds to pay for the Internet connection?**

14. **If Yes to 10 and 13, who pays for the Internet funds? What part of the budget is allocated to this?**

15. **Is there budgetary provision for repair and maintenance for computers that meet consumable expense requirements? (Example: printer breakdowns, printer toners, papers, etc.)**
    Yes
    No

16. **Who pays for the repair and maintenance? (Budget allocation is from where?)**

17. Hardware (HW)/software (SW) problems encountered in the computers? If Yes, what is the frequency? (Please enter in the "Other" box)

Yes
No
Other

18. What are the other SW that you maintain in the facility? Please specify if online or offline.

19. What are the challenges that you encounter in using these SW?

Data Migration Needs

20. Do you maintain information/history of patients enrolled in the study? What other data is currently maintained? (Please describe in "Other" field.)

Yes.
No
Other

21. If Yes to 20, how are the data collected?

Paper-based form
Electronic form

22. If electronic form, what software/application is the facility currently using?

23. If electronic form, are the existing software packages or Excel tool used in the 9MTR/bedaquiline study has updated data to be imported into PViMS?

Yes
No

24. If electronic form, please list all the reports and analysis the software is currently.

25. In number 24, which of the reports/analysis generated is complete/accurate/standard?

26. If electronic form, please indicate the information the software is currently capturing (please check all that apply).

Patient's basic biographical information (name, address, date of birth, current weight, etc.)
History of patient encounters
Medicines dispensed to patient
Adverse events
Clinical laboratory results
DST
Medical history
Others:

27. If paper-based recording of ADRs/AEs, which forms/templates do you use?

28. Are the paper-based forms always readily available in the health facility?

Human Resources

29. What is the level of staff using the current application or maintaining information/history of patients enrolled in the study? (Please check all that apply.)

Doctor
Pharmacist
Pharmacist assistant
Nurse
Nurse aid
Data encoder
Other (please specify)

30. How many staff are there in the health facility recording in the current application or in paper the information/history of patients enrolled in the study?

1
2
3
More than 3
More than 6

31. With regard to the frequency of data entry, please choose from the following:

Data are updated on a daily basis
Data are updated every other day
Data are updated every 5 business days
Data are updated every 7 business days
More than 7 business days lapse between data updates
Data updates occur infrequently
Other:

32. Does the staff work with other health programs or software or will they be dedicated to PViMS?

The staff works with other health programs.
The staff works with other software.
The staff will be dedicated to PViMS.

33. Will all staff work at the same time or in shifts?

34. If in shifts, how many per shift?

35. Are all the staff who will be using PViMS computer literate (familiar with MS Windows, use of keyboard/mouse, etc)?

Yes
No

NOTE: If personnel have not used computers prior to using PViMS, they will need to receive introductory training on this prior to PViMS training.

36. Is there a third-party available to provide basic IT support to end-users in your site?

Yes.
No

37. If yes, what is the response time?

38. If yes, what is the process to call for the service and issue escalation?

39. Is there a dedicated resource in your health facility that records and prepare reports for PV? If yes, how many? ☐

Yes.
No

Processes

40. Do the sites being considered for PViMS currently have good PV data collection practices and SOPs, if so, are they used? (relate to completeness of data collection)

Sites do not currently have SOPs.
Sites currently have SOPs displayed on the wall, and staff are following them
Sites have SOPs that are currently being followed by staff, but SOPs are not displayed on the wall.
Sites have SOPs that staff is occasionally following.

41. Does a local electronic database or manual log book exist for tracking ADR/AE reports for patients enrolled in the study aside from the patient treatment card? Please specify if local electronic database or manual log book.

42. Once an ADR/AE has occurred for patients enrolled in the study, are they entered into the database or manual logbook within 30 days?

43. Are SAEs reported within 24 hours to the research team for patients enrolled in the study?

44. Does a local electronic database or manual log book exist for tracking ADR/AE reports for patients not enrolled in the study aside from the patient treatment card? Please specify if local electronic database or manual logbook. Are they entered into the database within 30 days?

45. Are SAEs reported within 24 hours for patients not enrolled in the study? To whom?

46. How often do you report ADRs/AEs of patients enrolled in the study to the Research team?

47. Do you report ADRs/AEs of <u>patients not enrolled</u> in the study to upper level?
Yes
No. Why?

48. If yes to 47, to whom do you submit the consolidated ADRs/AEs reports for TB of the facility?

49. If yes to 47, do you receive feedbacks on the submitted ADRs/AEs reports from the research team?

50. Do you report ADRs/AEs or serious drug reactions to FDA outside of 9MTR study?
Yes. Site example:
No

51. Are you required to submit ADRs/AEs reports of <u>patients not enrolled</u> in the study?
Yes. To whom?
No

52. What are the challenges that you encounter in the recording and reporting of ADRs/AEs?

53. Is the PV data recorded by the same staff member that collects the data?
Yes
No

<u>Quality Control</u>

54. Patient Care Checklist: Please check all that apply.
A follow-up date is given to patients.
Patients are able to repeat and remember vital instructions.
Patients are asked open ended questions about adverse events.
Patient responses are noted per clinical guidelines.

55. Does the facility have the latest copy of PV SOP or guidelines? Please specify year of publication of guide.

56. Does the facility have the latest PV Safety Alerts available for the staff?

57. Are the staff in the facility trained on causality assessment?

58. Has the staff been trained about data collection requirements for ADR/AE reporting?

59. If yes, what guidelines (release year) were they trained on?

60. When was the last training conducted regarding PV (ADR/AE)?

61. How many staff was trained in the last year regarding PV (ADR/AE)?

62. When was the last monitoring visit regarding PV (ADR/AE)?

63. Please comment on the data collection frequency quality post-assessment (monitoring).

64. Please comment on the data quality post-assessment (monitoring).

ANNEX C. IT INFRASTRUCTURE STATUS OF HEALTH FACILITIES VISITED, APRIL 2016

Health Facility	Electricity	Backup Power Availability	Computer Availability	Computer Specifica-tions	Anti-Virus	IT Maintenance	Internet Connection
LCP	100%	Available	Yes	Passed	Expired	Yes	Yes, unstable
DJNRMH	75%	Not Available	Yes	Passed	Active	Yes	Yes, stable
JBLMH	100%	Not Available	Yes	Passed	Expired	Yes	Yes, unstable
SMMG	100%	Available	Yes	Passed	Active	Yes	Yes, unstable
ECS	100%	Available	Yes	Passed	Active	Yes	Yes, unstable
WVMC	25%	Available	Yes	Passed	Active	Yes	Yes, stable
XU	25%	Not functional	Yes	Passed	Active	Yes	Yes, unstable

ANNEX D. 9MTR STUDY FORMS, APRIL 2016

Study Forms	Description
Form 1	Screening Form
Form 2	Non–Enrollment Form
Form 3	Enrollment Form
Form 4	Evaluation Form
Form 5	Concomitant Medication Form
Form 6	Drugs Dose Record Form
Form 7	Adverse Events Form
Form 8	Serious Adverse Events Form
Form 9	Treatment Completion Form
Form 10	Follow–up Completion Form
Form 11	Notification of Death Form

ANNEX E. FACILITIES/STAFF MAINTAINING PATIENT INFORMATION FOR THE 9MTR STUDY, APRIL 2016

Facility Staff	Number of Facilities (%) with Staff Currently Maintaining 9MTR Patient Information
Nurse	7 (100%)
Data encoder	3 (43%)
Doctor	3 (43%)