



Standard Operating Procedures

Active Pharmacovigilance Surveillance:

Drug Safety Monitoring for New Medicines and Novel Regimens of the National TB Program in the Philippines

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About the Systems for Improved Access to Pharmaceuticals and Services

The goal of SIAPS 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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Acronyms

FDA	Food and Drug Administration (of the Philippines)
MDR-TB	multidrug-resistant tuberculosis
NTP	National TB Control Program
PV	pharmacovigilance
TB	tuberculosis
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
USAID	US Agency for International Development
WHO	World Health Organization

1 Introduction

The Philippines is one of the high-burden tuberculosis (TB) and multidrug-resistant TB (MDR-TB) countries in the world. Although the country has been a leading implementer in MDR-TB programming, the management of MDR-TB requires new and innovative strategies to overcome challenges in inadequate access to optimal therapy, difficult and costly regimen, poor adherence to treatment, and limited studies to establish formal and substantial guidelines.

The Philippines is committed to introducing evidence-based novel medicines and treatment strategies that are likely to benefit TB and MDR-TB patients. . The National TB Control Program will do this in a comprehensive way that reinforces the principles of World Health Organization (WHO) guidelines for the programmatic management of drug-resistant tuberculosis, ensuring that the introduction of the novel medicines and regimens in the Philippines maximizes the benefits and minimizes the risks to patients and communities.

Pharmacovigilance (PV) is defined by WHO as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects and other drug-related problems.” An adverse event is any new clinical experience that occurs after initiating treatment with a medicine regardless of its severity or seriousness and without judgment on its causality. Active safety medicine monitoring requires observation of any untoward medical occurrences that may present during treatment caused by a pharmaceutical product but which does not necessarily have a causal relationship with this treatment. Active surveillance measures are taken to detect adverse events and events are managed by active follow-up after treatment by asking patients directly or screening patient records.

2 Purpose

The purpose of this standard operating procedure is to outline a step-by-step approach for undertaking active drug safety monitoring for the 9-month MDR-TB treatment regimen and other novel medications and regimens for TB and MDR-TB.

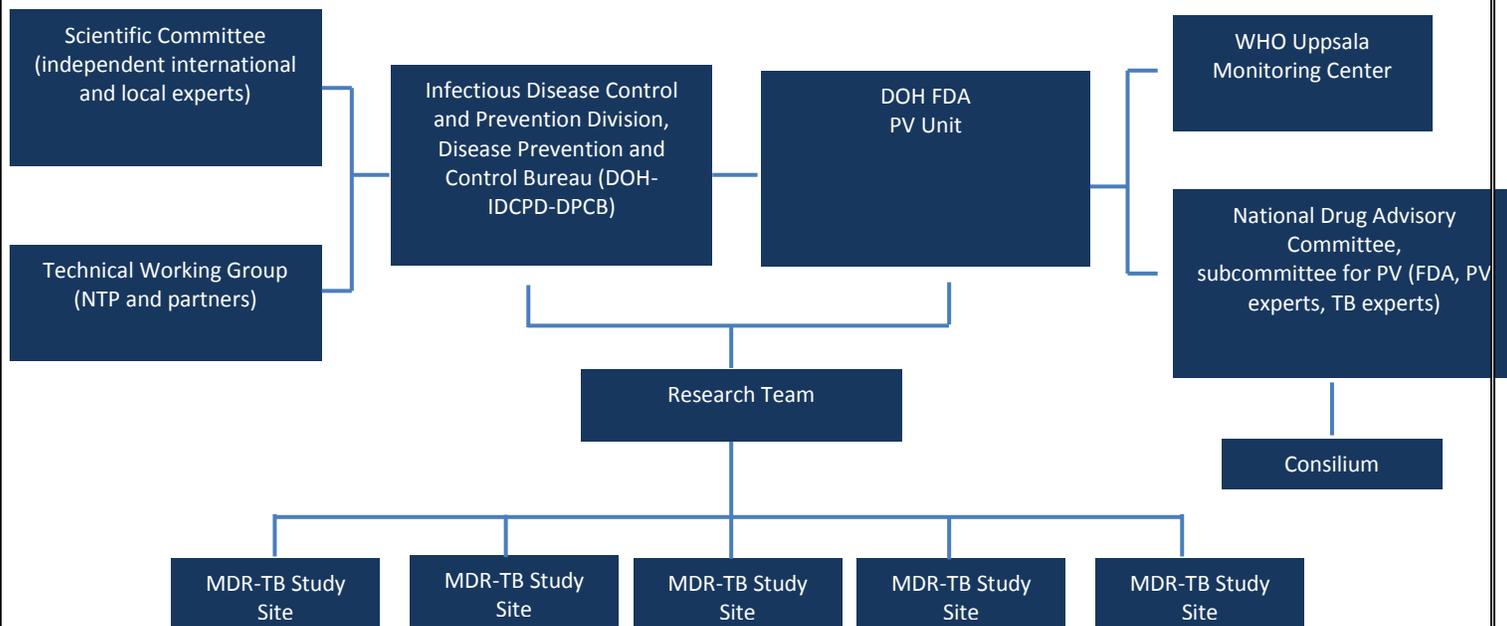
3 Scope

The procedure applies to the active drug safety monitoring of the 9-month MDR-TB treatment regimen and other novel regimens for the treatment of TB. It is applicable to personnel intending to establish or are managing a PV unit. This includes the National TB Program (NTP), Food and Drug Administration (FDA) of the Philippines, Department of Health Pharmaceutical Division (formerly the National Center for Pharmaceutical Access and Management), and other implementing partners.

4 Pharmacovigilance Structure

A schematic diagram (Figure 1) depicts the structures and stakeholders involved in the active PV surveillance active drug safety monitoring for new medicines and novel regimens of the NTP in the Philippines.

Figure 1. Active surveillance pharmacovigilance structure



Abbreviations: DOH = Department of Health; FDA = Food and Drug Administration; MDR-TB = multidrug-resistant tuberculosis; NTP = National Tuberculosis Control Program; PV = pharmacovigilance; WHO = World Health Organization

5 Responsibilities

This section describes the roles and responsibilities in the management and coordination of active PV at the national level both for the NTP and FDA, the research team of the NTP, and the facility levels.

The main activities at the health facilities are detection, management, and reporting of adverse events, whereas the national level is responsible for the coordination, monitoring, causality analysis, and decision-making.

5.1 Treatment facility

Treatment facility clinicians, nurses, and other staff have the responsibility to collect PV data during the treatment initiation visit and subsequent clinical examination appointments. The PV data collection should be done carefully following the approved protocol. The health care provider consulted by the patient should collect any relevant information indicated on the PV forms during the patient interview and clinical examination. Adverse events experienced by the patients should be managed clinically and according to the protocol. The treatment facility is also responsible for the recording and reporting of all adverse events. Data must be recorded completely and accurately, and should be reported timely using appropriate forms.

5.2 Research team

The research team is responsible for preparing all requirements for the introduction of novel drugs in general. This includes the adaptation of WHO guidance on new MDR-TB drugs/regimens and development of a national plan for introduction, revision of treatment guidelines and clinical tools, training of the study sites on the protocol, and ensuring that medicines and other supplies required are available.

The responsibilities of the research team also include the translation of the data dictionary into the local language and adaptation of the data collection tools, preparation of the software elements within an electronic registry, and pilot testing of the data collection.

During implementation, the research team is responsible for the consolidation of accurate and complete reports from the treatment facilities. They will also conduct preliminary causality analysis, and through the consilium, advise the treating clinicians on potential relationships between the medicine or regimen and the reported adverse event. A consilium is a group of experts who manages the patient profile and decides on the course of action, including patient enrollment, clinical treatment and management of outcomes. The research team will review the completeness and consistency of forms, and submit consolidated reports to the FDA. Any follow-up and additional information required by the FDA needs to be managed by the research team.

Data encoders, as part of the research team, have the responsibility of checking the completeness and consistency of the collected data. They are also responsible for the data storage and quality, timely data transfer to the research team, and regular feedback to the clinicians. They shall notify the treatment facility clinicians if quality, quantity, or timeliness of the PV data collected standards are not met. The data entry staff is also responsible for entering the data in the national PV database at regular intervals, according to national regulations.

5.3 National level

The Department of Health, NTP, and FDA are the main agencies involved in PV for new TB drugs at the national level. There needs to be regular and strong coordination between these institutions to ensure information-sharing.

The Department of Health, as the overall technical authority of health in the country, shall ensure that national health policies and regulatory responsibilities for PV are fulfilled by its agencies and public health programs. It shall maintain coordination with the FDA and NTP to guarantee safety, efficacy, and quality of health products.

5.3.1 Food and Drug Administration

Since the FDA has multiple responsibilities that need to be coordinated with other organizations, it will organize a subnational drug advisory committee for PV, which functions under the structure of the overall FDA national drug advisory committee and under supervision of the FDA.

The FDA subnational advisory committee for PV shall consist of representatives from the FDA, NTP, technical partners, academic, clinicians, and pharmacists, particularly in the discussion of the PV implementation of the TB studies.

The FDA PV unit of the Center for Drug Regulation and Research shall receive, verify, and review adverse events reports submitted by the NTP through the research unit. The PV unit shall also prepare the documents required for the causality analysis and evaluation of the subnational advisory committee for PV and prepare feedback reports to NTP through the research team.

5.3.2 National Tuberculosis Control Program

The NTP, the main agency responsible for the TB control in the country, shall manage and supervise all aspects of PV data collection including monitoring and supportive supervision of the participating sites through regular follow-up of the quality, quantity, and timeliness of data collection by email, telephone, and site visits. This task may be in coordination with participating technical partners.

The responsibilities of the different actors at the national level are outlined in Table 1.

Table 1. Responsibilities for pharmacovigilance implementation at the national level

Active PV component	Lead responsibility for active PV
Establish national drug advisory committee for PV	FDA
Plan and budget for PV activities	NTP, research team, FDA and partners
Prepare protocol	NTP, research team and partners

Ethical clearance of protocols and conformity to international regulations	NTP, research team and partners
Design and produce tools for data collection (preferably integrated into established reporting and recording systems)	NTP, research team and partners
Develop a training plan ensuring that all staff involved in active drug safety monitoring receives appropriate training	Research team
Train staff	Research team
Ascertain the availability that a new or existing electronic database for MDR-TB patients on treatment (adapted for the collection of PV data) is available and functioning adequately before the start of data collection	NTP, research team, FDA and partners
Integrate data entry checks within the system according to the data dictionary	
Develop standard operating procedures to be adapted by the national level to the facility level	Management Sciences for Health/SIAPS
Collect data	Treatment facility
Manage and supervise all aspects of PV data collection as outlined in the protocol, including monitoring of data collection and supportive supervision of the participating sites by follow-up through email, telephone, and site visits	Research team, FDA
Accurately process and manage all PV data collected, which includes data checks and validation and storage data collected	Research team
Transfer cleaned and validated data to WHO Uppsala Monitoring Center	FDA
Assess causality	Initially by research team. Final assessment by the FDA PV unit
Develop plans for data analysis, signal identification, and communication	Research team
Analyze data and provide feedback to health centers and clinicians	Research team, FDA PV unit
Signal detection	Research team, FDA PV unit
Coordinate issuance of press releases for professionals and the general public on overall safety, or about particular issues that have arisen, with proper risk management to prevent unfounded mistrust in the medicine under active drug safety monitoring	FDA, NTP
Report adverse events from patient interview and counseling	Treatment facility

Abbreviations: FDA = Food and Drug Administration; NTP = National Tuberculosis Control Program; PV = pharmacovigilance; SIAPS = Systems for Improved Access to Pharmaceuticals and Services

6 Procedure

The basic active drug safety monitoring procedures include:

- Establishing a cohort of patients for each drug and/or drug regimen.
- Detecting, managing, and recording adverse events experienced by patients in the cohort(s) before, during, and after medicine exposure.
- Conducting causality assessment and other statistical analyses.
- Implementing communication strategies.

6.1 Enrollment of patients

Patients eligible for the study will be assessed and reviewed by the implementing site clinicians. The clinicians will review the patient information and recommend enrollment to the study. The patient case will be presented to the consilium for approval of the regimen and treatment. The treating clinician, along with the consilium, will decide if the patient qualifies for study enrollment according to the protocol, and explicit reasons will be provided for inclusion or rejection.

Baseline information regarding the health status of the patients is very important and must be recorded in the patient's information form. Upon identification of an adverse event during the study period or post-treatment follow-ups, the clinician should manage the adverse event according to study protocol and treatment guidelines.

6.2 Essential data elements

The following essential data elements for PV should be included in the reporting forms. All adverse events (even if minor) shall be recorded, not just suspected adverse reactions. Clinicians or recorders should make no judgment regarding causality.

6.2.1 Patient details

- Patient Category IV number
- Full name or initials (patient identification is important for follow-up purposes and avoidance of duplication)
- Complete address (for follow-up and accurate identification)
- Sex
- Date of birth (preferred) or age
- Weight and height

- Past medical history
- Pregnancy status

6.2.2 Details of medicines

- Name (brand and generic)
- Formulation (e.g., tablets, syrup, injection)
- Mode of administration (e.g., oral, rectal, injection)
- Indication(s) for use
- Dose (size and frequency)
- Date of treatment start
- Date of withdrawal
- Duration of use
- All medicines being taken at the time of consultation should be listed. Any suspected medicine can be indicated by an asterisk or other notations.

6.2.3 Details of adverse event

- Full description of reaction/s including body site
- Description of signs and symptoms
- Specific diagnosis for the reaction
- Onset date and time of reaction

6.2.4 Reporter details

- Name (full name or initials)
- Address
- Telephone number and/or other contact details
- Profession

6.3 Adverse event reporting

6.3.1 All clinical events experienced by each patient should be recorded. This includes unexpected improvement of concomitant disease (favorable event) as well as adverse events.

6.3.2 All adverse events (even if minor) shall be recorded, not only suspected adverse reactions. Clinicians or data collectors should make no judgment regarding causality.

This does not replace the fact that the clinician should manage the adverse event detected according to study protocol and/or clinical guidelines.

6.3.3 At follow-up visits, any new events or worsening of pre-existing conditions that have occurred since the start of the treatment should be reported.

6.3.4 These events will be recorded on the specified study forms (Form 7 for adverse events and Form 8 for serious adverse events).

6.3.5 Normal clinical terms or descriptions should be used.

6.3.6 *A brief description* of each event should be recorded. The event descriptions should be reviewed by the research team, and standard adverse event terminology will be applied.

6.3.7 *Standardized codes* can be used for common events as per WHO guidelines for various disease states.

6.4 Reporting forms (questionnaires)

The following forms that can also be found in NTP Manual of Operations should be used to collect patient information for PV.

6.4.1 Study enrollment form (Form 3).

The study enrollment form is used to record:

- Study entry enrollment
- Patient demographics
- Tuberculosis history and treatment
- Patient medical history
- Concomitant diagnosis at the time of TB diagnosis
- HIV test
- Form completion

6.4.2 Drugs dose record form (Form 5).

Form 5 should record the study treatment dose.

6.4.3 Concomitant medication form (Form 6).

Form 6 should be used to record:

- Pre-study or non-study medications taken by the patient from 30 days prior to study enrollment and during the 9-month treatment regimen.
- Medicine re-challenges done with any medicines prescribed at enrollment.

6.4.4 Adverse event form (Form 7)

Form 7 is used to record all adverse events at any time during the study therapy or less than or equal to 12 months after the final study dose (post-treatment follow-up).

6.4.5 Serious adverse event form (Form 8)

Form 8 should record all serious adverse events experienced by the patients at any time during the study, or up to 12 months after the final study dose.

6.4.6 Notification of death form (Form 11)

Form 11 should record information concerning death (i.e., details regarding the circumstances of the patient's death and any relationship to the study treatment).

6.5 Data management

This chapter describes data collection and data management processes and procedures at facility, national, and supranational levels, including:

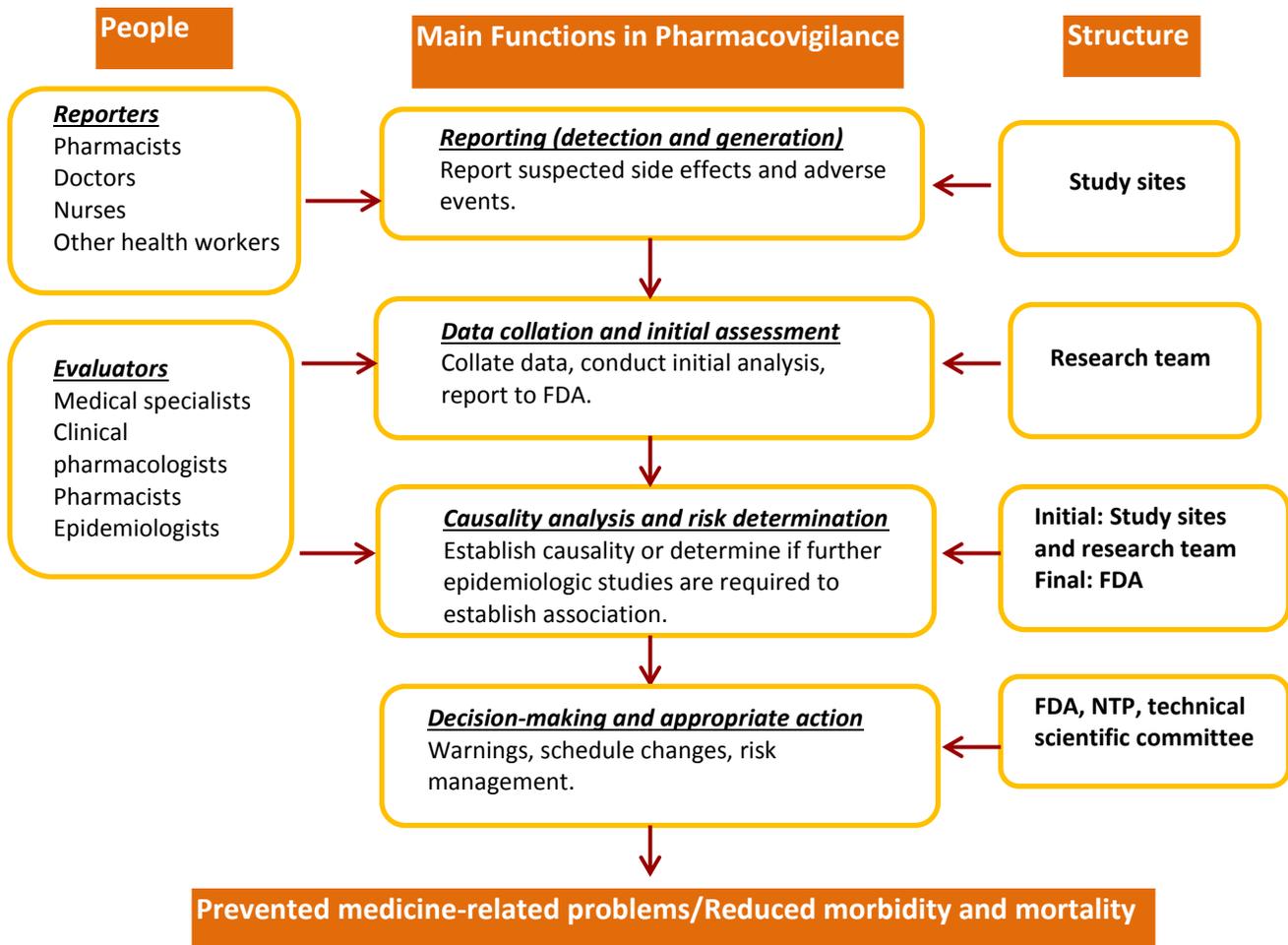
- The overall data flow within and between these levels;
- Data management:
 - Facility level: Data collection, data entry, and data quality and validation;
 - National level: System management, monitoring of facility data including quality, and analysis and reporting;
- Data security and patient confidentiality;
- System requirements;
- Pilot test data; and
- Standard operating procedures.

6.5.1 Data flow

Creation or adaptation of data collection tools (e.g., paper forms) or electronic database requirements shall be in place and consistent with the NTP recording and reporting system before the PV data collection starts to facilitate the data flow.

A schematic overview describing the data flow from data collection at the facility level to analysis and reporting at the supranational level is shown in Figure 2.

Figure 2. Pharmacovigilance System Framework



Source: Management Sciences for Health (Strengthening Pharmaceutical Systems). Pharmacovigilance System Framework: Ensuring the Safe Use of Medicines, August 16-18, 2010, Nairobi, Kenya.

Abbreviations: FDA = Food and Drug Administration; NTP = National Tuberculosis Control Program

An adverse event is detected and generated by the study/facility level. This is through active interviews, examinations, and initial assessment by the health staff (i.e., clinician, pharmacist, nurses, and other health workers). A PV report will be generated and sent to the research

team. The research team will collate the data from all study sites and submit reports to the FDA according to timelines. The research team shall conduct initial analysis to guide the study sites in the risk management.

The FDA PV unit upon receipt of the reports shall prepare the documents, ensuring all required and relevant information are complete and accurate, for causality assessment of the FDA subnational advisory drug committee. The unit will organize quarterly or ad hoc meetings with the committee, depending on the urgency. Recommendations will be submitted by the FDA national drug advisory committee. The FDA will release the final decision to NTP and report to Uppsala.

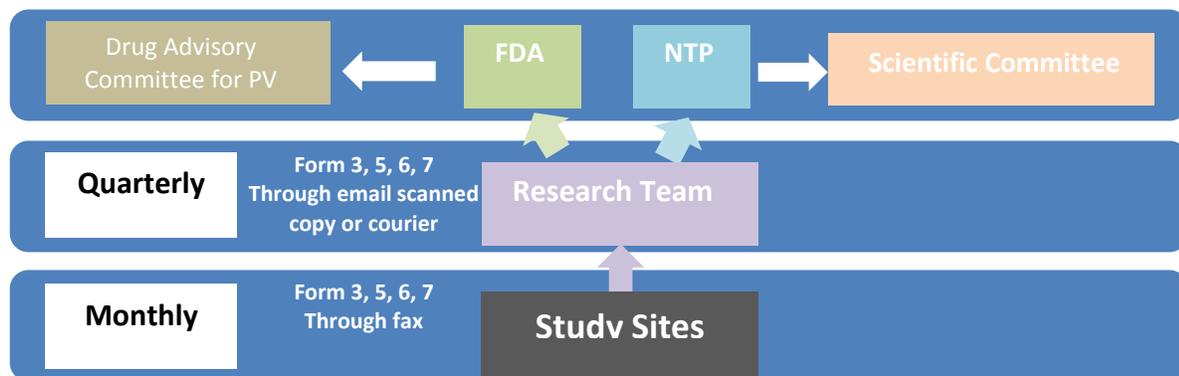
Decision-making and appropriate actions will be done collectively by the FDA and NTP, with assistance and guidance by the scientific committee. A scientific committee is an external group composed of national and international experts who will review the progress of the study implementation and conduct site monitoring, if necessary.

6.5.1.1 Reporting of adverse events

Reporting flow for *all adverse events* is described and represented in Figure 3.

- Study sites will send information with initial assessment to research team in hard copies (Form 7) to be encoded in the database monthly. The research team will submit all electronic adverse event reports quarterly to the FDA and. The research team will also conduct preliminary causality assessment of the adverse events.
- From the database, SIAPS will work on linking information automatically to the FDA VigiFlow®. VigiFlow® is a web-based Individual Case Safety Report management system designed for use by the national centers in the WHO Programme for International Drug Monitoring. VigiFlow® is in compliance with the preferred reporting format ICH E2B, and maintained by the Uppsala Monitoring Centre in Sweden.

Figure 3. Reporting flow for all adverse events



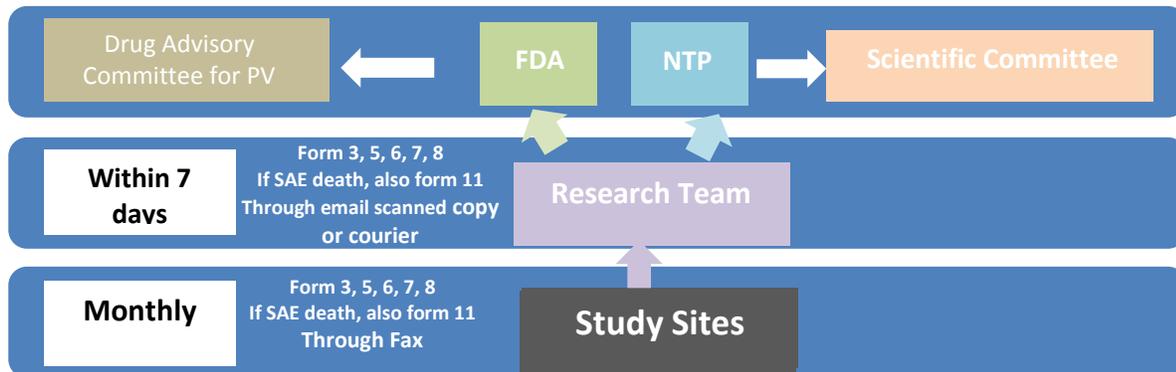
Abbreviations: FDA = Food and Drug Administration; NTP = National Tuberculosis Control Program; PV = pharmacovigilance

Reporting of serious adverse events

Reporting flow for *serious adverse events* is described and represented in Figure 4.

- If there is a serious adverse event, study sites will report to the research team **within 24 to 48 hours** upon identification. The research team will report to the NTP and FDA **within 7 days** upon the identification of a serious adverse event.

Figure 4. Reporting flow for all serious adverse events



Abbreviations: FDA = Food and Drug Administration; NTP = National Tuberculosis Control Program; PV = pharmacovigilance; SAE = serious adverse event

The next three paragraphs describe the guiding principles of the data management processes for each administrative level involved. Focus is on data quality and on uninterrupted and standardized flow of data among all three levels.

6.6 Facility level: Data collection and data entry

A data dictionary defining the minimum dataset required for PV active drug safety monitoring including the variable types, formats, and related validation rules should be decided by the research team and the FDA. It is not recommended to create full new data collection tools specifically for the collection of PV data. Data described in the data dictionary that are not yet included in existing (paper or electronic) data collection tools for MDR-TB patients should be integrated into existing data collection tools.

PV data collection and entry in the form is done at the facility level during clinical examination visits. By integrating PV data collection in the regular clinic visits, there is a minimum burden for patients and staff to collect PV data. Clinicians need to ensure that all data are completely, appropriately, and consistently collected before submitting to the data encoder within timelines set in the corresponding standard operating procedures.

Adverse event data that are collected later (e.g., laboratory results) should be submitted separately to the data encoder. Relevant data for patient management should also remain available in the patient's medical file.

Box 1. Immediate reporting of serious adverse events

In case of serious adverse events (see Definitions), all relevant information about the serious adverse event should be sent to the national pharmacovigilance unit at the FDA according to national regulations.

The frequency of PV data collection is mainly dependent on the regular schedule of assessment and follow-up clinic visits. The minimum frequency of PV data collection is once per month during the initiation phase of treatment, and once per quarter during the continuation phase of treatment. In addition to PV data collected during the scheduled visits, PV data should be collected during unplanned additional clinical examination visits in the occurrence of an adverse event. Because most countries already collect part of the minimum dataset for patient and treatment management, it is recommended to integrate PV data collection as much as possible within the existing data collection tools, to minimize overlap and ensure efficient data collection. Although the format of the data collection tools may be adapted to local preferences, it is a condition that the standardized format of the data fields is used in all countries. This will allow for accurate translation and back-translation of data across regions and countries enabling valid comparison. Countries can decide to collect additional set of PV data. As long as the minimum dataset is included, pooling can be done at the supranational level.

The processes of data collection and data entry are dependent on the country-specific setting and tools in place. Guiding principles for data entry and data collection in order to produce high-quality data are as follows.

- Minimize transcription errors:
 - By entering data directly in the system during data collection;
 - If data are not entered directly in the system during collection, data entry is done by the same staff member that collects the data;
 - If this is not feasible, local solutions should be developed ensuring that data entry is timely and close to the primary data source (i.e., in the same facility);
 - Relationship assessment between medicines and adverse events is done by the treating clinician;
- Minimize data entry errors and ensure completeness and accuracy:
 - If data are collected on paper, the electronic data entry fields should be the same as the paper forms;
 - Automatic data entry checks are in place such as mandatory fields, cross-checks, and follow-up questions if applicable (e.g., no question about pregnancy when gender is male); and

- A procedure for cross-checking PV data with patient’s medical files is in place.
- Minimize delay between collection and entry of data:
 - Enter data directly in the system during clinical examination visits;
 - Automatically link the laboratory results to the electronic recording and reporting system;
 - Add the laboratory results once available that are not to complete the PV dataset; and
 - Appoint a dedicated staff for the data entry.
- Optimize consistent data collection and entry:
 - Data collection and entry is done by the appointed dedicated staff members;
 - If data is first collected on paper, cross-check the paper and electronic records for any discrepancies;
 - Training of (new) staff using (locally adapted) guidance documentation;
 - Annual refresher training for all staff;
 - If data is collected on paper, paper forms are archived locally to enable retrospective cross-validation.

6.7 National level: Monitoring and reporting

At the national level, the NTP and FDA PV unit have an important role in monitoring the data collected and reported by the facilities and providing feedback. The roles and responsibilities at the national level are outlined in Section 5.3. The specific data management processes at the national level are dependent on the country-specific setting and tools. The following are the guiding principles for the national processes.

- Monitoring and validation of the facility level data:
 - Provide frequent (to be defined) feedback on the timeliness of reporting;
 - Provide frequent feedback on the completeness of the PV reports;
 - Use standardized system-generated notifications; and
 - Validate specific content of the reports (e.g., causality assessment).
- Training of facility staff:
 - Make an inventory of new staff for training; and
 - Use (locally adapted) guidance documentation.
- System management:
 - Ensure availability of data collection and entry tools;

- Ensure security of the system and confidentiality of patient data;
- Store pooled facility data; and
- Enable data extraction for analysis, reporting, and data transfer.
- Analysis and reporting to facilities. Provide feedback on:
 - Data/report quality (timeliness, completeness, and accuracy);
 - Comparison between facility data and national-level data;
 - Causality assessment between adverse event and medicines; and
 - Signals identified at national and supranational levels.
- Transfer data to the supranational level:
 - Extract, clean, and validate national data; and
 - Anonymize the dataset (e.g., remove person and facility identifiers).

6.8 Feedback

6.8.1 Feedback should be given to health professionals and health workers in order to encourage compliance.

6.8.2 Regular information will be sent by the FDA PV unit:

- Upon receipt of the quarterly adverse events reports, the FDA shall provide feedback in a formal letter template to NTP through the research team on the causality analysis results. This should be aggregated for all adverse events submitted, thus far. This report shall include information on the decision and recommendation of the FDA to the program.
- For serious adverse events, FDA PV unit will coordinate urgently with the program, research team, and reporter to investigate the serious adverse event. Upon receipt of the serious adverse event report, the FDA PV team shall gather all required available information to conduct causality assessment.

6.8.3 Upon receipt of the communication letter from the FDA, the research team and NTP shall ensure that information reaches the study sites. Results of causality analysis from the FDA should be disseminated to all study sites by the research team.

6.8.4 Occasional meetings to discuss the results are valuable.

7 Definitions

7.1 Pharmacovigilance

Pharmacovigilance has been defined by WHO as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”

7.2 Pharmacovigilance unit

The PV unit of an individual country is responsible for meeting the requirements for PV of all medicines, and is a unit of expertise for the art and science of monitoring and analysis, and use of the analyzed information for the benefit of patients. National and regional PV units should be set up with the approval of the authority responsible for the regulation of medicines (“regulatory authority”). The unit may function within the regulatory authority, a hospital, an academic institution, or as an independent facility such as a trust or foundation.

7.3 Signal

Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

Source: WHO. *Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre*. Uppsala, Sweden; 2000.

Available at: <http://apps.who.int/medicinedocs/en/d/Jh2934e/>

7.4 Adverse drug reaction

A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction, or modification of physiological function.

Source: WHO. *Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre*. Uppsala, Sweden; 2000.

Available at: <http://apps.who.int/medicinedocs/en/d/Jh2934e/>

7.5 Serious adverse reaction

Any untoward medical occurrence that at any dose results in death, is life threatening, requires or prolongs patient hospitalization, results in persistent disability/incapacity, or is a congenital anomaly/birth defect (International Conference on Harmonization). *Life threatening* refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe.

7.6 Adverse event

Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

Source: WHO. *Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre*. Uppsala, Sweden; 2000.

Available at: <http://apps.who.int/medicinedocs/en/d/Jh2934e/>

7.7 Health care provider

For the purposes of suspecting adverse reactions, health care professionals are defined as medically qualified persons such as physicians, dentists, pharmacists, and nurses.

8 Resources

World Health Organization

<http://www.who.int>

The Uppsala Monitoring Center

This site provides very useful information about practical pharmacovigilance including definitions and advice on pharmacovigilance policy.

<http://www.who-umc.org/>

International Society of Pharmacovigilance

www.isoponline.org

Systems for Improved Access to Pharmaceuticals and Services

This site provides tools and guidance for strengthening pharmacovigilance systems.

<http://siapsprogram.org>