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INDIAN PHARMACOPOEIA COMMISSION  
National Coordination Centre-Pharmacovigilance Programme of India

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Effective Date	01/04/2016	Review Date	31/03/2016

Title: SOP to enter data from Suspected ADR Reporting Form to VigiFlow.

**1.0 OBJECTIVE**

1.1 To lay down a procedure to enter ADR data from suspected ADR reporting form to VigiFlow Software.

**2.0 SCOPE**

2.1 This SOP shall be applicable to Personnel working at NCC and AMCs under PvPI.

**3.0 RESPONSIBILITY**

- 3.1 The personnel engaged in the PvPI activity shall be responsible for adhering to this SOP.
- 3.2 All AMC's Co-ordinators who works for Pharmacovigilance Programme of India at their respective AMCs shall be responsible for adhering to this SOP.
- 3.3 Quality Manager, Technical Manager, Section-In-charge & AMC Coordinator shall ensure overall implementation of this SOP.

**4.0 ACCOUNTABILITY:**

4.1 Officer Incharge –Pharmacovigilance Programme of India

**5.0 PROCEDURE:**

5.1 To enter the data from Suspected ADR Reporting Form to VigiFlow Software, the VigiFlow user (Coordinator and Technical Associate) at AMC and NCC have to log-in into VigiFlow with respective user id and password (as provided by NCC) from the web-page <https://adr.who-umc.org/container.asp?sSessionId=&sPage=>

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Prepared by	Rishi Kumar	Tech. Associate	<i>[Signature]</i>	14/03/2016
Reviewed by	Dr. Prasad Thota	S.D	<i>[Signature]</i>	15/03/2016
Approved by	Dr. Kalai Selvan	PSO	<i>[Signature]</i>	16/3/2016

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- 5.2 After log-in, the menu page of VigiFlow will display. The top row of the menu is constant and contains **report handling, search and statistics and exit** option. At NCC level an additional menu of **tool** is also available.  
**Note:** Filled Suspected ADR Reporting Form containing information on an individual patient is considered as Individual Case Safety Report (ICSR of that particular patient).
- 5.3 To enter an ICSR, go to the top menu and select **report handling** and choose **new report**. A choice between entering a **standard case** or a **parent-child case** will be given.
- 5.4 Select the case according to the ICSR to be entered (a parent-child case will be used primarily when a foetus has suffered the reaction after the mother has taken the drug else select standard case).
- 5.5 A menu while entering a new report will be shown on the left side as in Figure 1.

Figure 1

	Name	Designation	Signature	Date
Prepared by	Rishikumar	Tech. Associate	[Signature]	14/03/2016
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Approved by	Dr. Kalyaneshwar	PSO	[Signature]	16/03/2016

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5.6 The VigiFlow software contain 10 number of sections (starting from 0 to 9) to be filled (i.e. report info, patient, tests and procedures, relevant medical history, relevant past drug therapy, reactions, drugs, assessment, overview and save). Click on each section and fill the respective information.

**Note:** The number of fields required to fill in VigiFlow are more as compared to Suspected ADR Reporting Form. Maximum information is available in the filled ADR form which is to be fill in VigiFlow as it is mentioned on the form and rest of the information have to collect from patient's case reports, treatment chart or from the respective reporter.

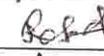
**5.6.1 Report Info**

5.6.1.1 Write the **Report Title** for an ICSR. The report title must include the suspected reaction (s) and suspected medication(s). A reaction term will come first followed by suspected medication. The reaction term and suspected medication must be separated by a colon (:). For e.g. Gum hyperplasia: Phenytoin. In Case of Fixed Drug Combination the Brand Name of the medicine may be added in the Report Title and if the Fixed Drug combination is the generic version then the entire drugs may be added in the report title. E.g Antiretroviral Drugs combination causing Anaemia, Then Report Title would be **Anaemia: Lamivudine + Zidovudine** or Brand Name.

5.6.1.2 Choose the appropriate option for **Type of Report** depending upon the report.

5.6.1.3 Mention the seriousness status of the report as mentioned in the Suspected ADR Reporting Form. If yes, provide the reason for seriousness. The options for country of occurrence and country of primary source will be pre-filled as India.

5.6.1.4 The report information page consists of following three questionnaires:

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/03/2016
Reviewed by	Dr. Anand Sarda	S-A		15/03/2016
Approved by	Dr. Kalidharan	PSO		16/3/2016

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- does this case fulfil local criteria for an expedited report.- Select 'Yes' if the report is a case of SUSAR, else select 'No'.
- additional documents held by sender- Select 'Yes' if any document related to reaction is attached with the report and mention the list of document as free text in the box appeared, else select 'No'.
- was the case medically confirmed- Select 'Yes' if the reporter is a non healthcare professional and the reaction is confirmed by the physician, else select 'No'.

**Note:** Leave this option blank if the primary source or reporter is a healthcare professional.

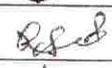
5.6.1.5 Select **regional pharmacovigilance centre** for Information on Sender and provide the date first received at the regional centre as indicated in the point no 17 of the Suspected ADR Reporting Form. The worldwide unique number column should leave as blank. It will be filled automatically after generating the report id.

5.6.1.6 The primary source of the information is the person reporting the event. Write name, address and qualification of the reporter as mentioned in the Suspected ADR Reporting Form.

## 5.6.2 Patient

5.6.2.1 Write the age at time of onset of event, patient initials, body weight, and gender of the patient as mentioned in the Suspected ADR Reporting Form.

5.6.2.2 If the outcome of the reaction is fatal then must provide the information of patient death date, death cause and autopsy information (if performed).

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**5.6.3 Tests and Procedures**

Mention all the tests relevant to the reaction either in free text or in structured form. And it is mandatory to mention tests results if the reaction is related to lab results. E.g Hypoglcemia, Bradycardia, Tachycardia, Hyperglycemia, Anaemia etc.

**5.6.4 Relevant medical history**

Write the medical history of the patient such as allergies, smoking, alcohol, pregnancy, hepatic or renal dysfunction, pre-existing medical conditions (e.g. hypertension, Diabetes) or existing medical condition of the patient as mentioned in the ICSR either in free text or structured form.

**5.6.5 Relevant past drug therapy**

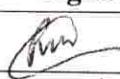
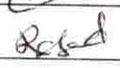
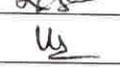
Provide the details on the past drug therapies (if any) of the patient in this section.

**5.6.6 Reactions**

5.6.6.1 Add the reaction mentioned on the Suspected ADR Reporting Form as an Included Term (IT) or Preferred Term (PT). If a patient experienced multiple reactions, the Vigiflow user have to add all the reactions in a single ICSR (though captured in different Suspected ADR Reporting Forms).

5.6.6.2 While adding a reaction use the search functions to find and select a **reaction term** (WHO-ART term). A reaction term can be searched in 3 ways:

- a. Search text content by entering a term (or part of it), set the drop-down choices to reflect your preference and click on the search button. Note that you need to enter at least three characters in the field to perform a search (Figure 2).

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Approved by	Dr. Kaloujelvan	PdO		16/3/16

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reaction term

IT contains flush eng search

- SOC Vascular (extracardiac) disorders
  - HLT VASODILATATION
    - PT FLUSHING select
      - IT FLUSHING select
      - IT FLUSHING AGGRAVATED select
      - IT SKIN FLUSHED select
- SOC Body as a whole - general disorders
  - HLT No HL-term
    - PT TEMPERATURE CHANGED SENSATION select
      - IT HOT FLUSHES select

Figure 2

- b. Enter a WHO-ART code, either the four digits of the adverse reaction record number or the seven digit full code and click on the search button (Figure 3)

reaction term

IT contains 1705008 eng search

- SOC Body as a whole - general disorders
  - HLT No HL-term
    - PT TEMPERATURE CHANGED SENSATION select
      - IT HOT FLUSHES select

Figure 3

- c. Browse for a term by setting the first drop-down list to 'SOC', leave the text field blank and click on search. All SOC terms will be displayed and you can browse

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down to the term you want by clicking on the plus signs and select the appropriate reaction term (Figure 4).

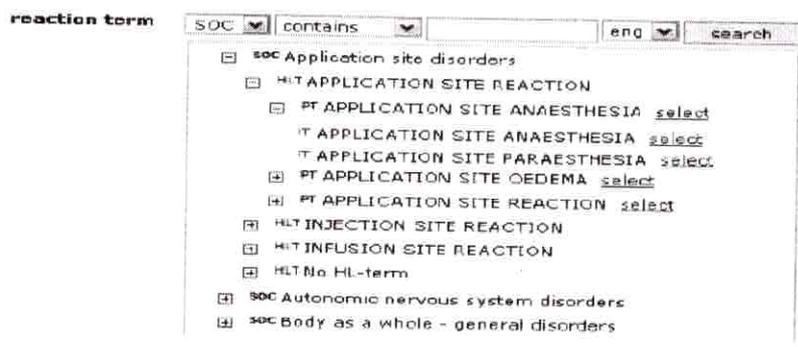


Figure 4

Note: Suggest a new WHO-ART term if suitable term is not found.

- 5.6.6.3 Write the original wording about the specific reaction as reported by the reporter (Point no 7 of the Suspected ADR Reporting Form) in the field reaction/event as reported by the primary source.
- 5.6.6.4 Enter the onset date of the reaction and if the reaction recovered then enter the end date of the reaction. The other fields to be filled are treatment of reaction (if any), outcome of reaction. Also highlight the reaction as reported by the reporter.
- 5.6.6.5 Reporter's comment is a common field for all added reactions/events. This field should be used for comments from the primary source (i.e. reporter of the event) that are relevant for all reactions.
- 5.6.6.6 Select the AEFI Category from the drop down list, if the reaction is related to vaccination as shown in Figure 5.

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This section is only intended for vaccine data within the "WHO PMS Network on prequalified vaccines".

**AEFI category**

Figure- 5

**5.6.7 Drugs**

5.6.7.1 Add all the suspected and concomitant drug(s) in this section as mentioned in the Suspected ADR Reporting Form.

5.6.7.2 The WHO-DD is used for entering the drug name. To add a drug name, click on **search drug**. Below display (Figure 6) will appear on the search page.

**Search for drug**

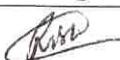
drug name  Begins with   
 substance  Begins with   
 MA holder  Begins with   
 country  Include unspec.   
 ATC code  pick ATC code   
 sort by  drug name

**Find a drug**  
 Use the search options to find a drug from the WHO Drug Dictionary. If not the specific MA holder/country/form/strength can be found by clicking on the plus sign, it is possible to add the drug at a higher, less specified level.  
 If no matching drug exists, it is possible to suggest a new drug to be added to the WHO Drug Dictionary:

Figure 6

5.6.7.3 Enter the whole or part of the name of the drug to find in the drug name field and click **start search**. Add the drug from the search results as mentioned on the Suspected ADR Reporting Form.

**Note:** If a drug is reported with brand name in the Suspected ADR Reporting Form, search and add the brand name by confirming the active ingredient. Also suggest a new drug (with details and references/authorized website link) if suitable drug is not found in the WHO-DD.

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5.6.7.4 Select characterization, suspected ingredient, and route of administration. Mention the pharmaceutical form, batch number, authorization holder, dose, dosage regimen, start date of administration and end date of administration of the suspected drug(s) as mentioned on the Suspected ADR Reporting Form. The dose of FDC shall be entered in the free text section by clicking on **expand** in drugs section no. 6 of VigiFlow. The Dose and Dosage regimen of suspected drug/FDC may be included as per the examples given in the following figure 7.

Example 1

The patient was given 200 mg tablets with the instruction to take two three times a day.

dose	400	mg
dosage regimen	3	1 day(s)
	doses in interval	definition of interval

The dose is 400 mg (=two tablets\*200 mg) and the dosage regimen is 3 doses per 1 day.

Example 2

The patient was given 50 mg tablets with the instruction to take one every three hours.

dose	50	mg
dosage regimen	1	3 hour(s)
	doses in interval	definition of interval

The dose is 50 mg and the regimen is 1 dose per 3 hours.

Example 3

The patient is given an injection (containing 10 microgram active ingredient) 3 times with one month

dose	10	µg
dosage regimen	1	1 month(s)
	doses in interval	definition of interval

The dose is 10 µg and the regimen is 1 dose per 1 month. The duration of three months is entered in the duration field, or as exact start and stop dates if known.

Example 4

The patient was given a combination tablet with 50 mg and 75 mg of the two active ingredients with the instruction to take one per day.

dosage (free text)	50mg/75mg of X/Y per day
cumulative dose to first reaction	

This is not possible to enter as dose since only one active ingredient can be entered there; instead the free text field is used.

Figure-7

	Name	Designation	Signature	Date
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5.6.7.5 For adding an indication for the drug prescribed (suspected or concomitant), click on the **search term** link to search and add for ICD-10 term of the given indication. If no suitable term is found, write the indication as free text in **additional information**.

5.6.7.6 Select the appropriate **action taken** from the options as indicated in the Suspected ADR Reporting Form. Consider the following description while optioning for action taken, **'drug withdrawn'**- if dechallenge performed by withdrawing the drug completely, **'dose reduced'**- if dechallenge performed by reducing the drug dose, **'dose not changed'**- if dechallenge was not performed, **'not applicable'**- if dechallenge was not applicable, **'unknown'**- if information on dechallenge was not known.

**Note:** Mention the reduced dose as free text in the additional information.

5.6.7.7 Fill in the field **did reaction recur after rechallenge**, if rechallenge is mentioned on the form. Consider the following description while optioning this point, **'yes'**- if reaction recur after rechallenge, **'no'**- if reaction was not recur after rechallenge, **'effect unknown'**- if effect after rechallenge was not known. Leave the field blank if rechallenge was not performed.

5.6.7.8 Consider the following description for the option **is the ADR adequately labelled**. Select 'Yes' if the reaction linked to the drug is adequately described in the product information for India, otherwise choose 'No'. If you do not know – leave blank.

5.6.7.9 Follow the same procedure as above for adding details of concomitant drug(s). The fields for entering a concomitant drug are almost the same as for a suspected drug. The only fields that differ are **suspected ingredient** and **did reaction recur after rechallenge** which are not present for the concomitant drugs.

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Approved by	<i>Dr. V. Kalai Selvan</i>	<i>PSO</i>	<i>[Signature]</i>	15/3/2016

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5.6.7.10 Enter the causality assessment as mentioned on the ADR form in the field **relatedness of drug(s) to reaction(s)**. Select the appropriate causality from the drop-down list (Figure 8).

Relatedness of drug(s) to reaction(s)		
	Acetylsalicylic acid	Paracetamol
Nausea	-	-
Dyspepsia	-	-

Figure 8

5.6.7.11 Enter the vaccine data if the suspected medicine is vaccine by clicking on vaccine data section in Vigiflow as shown in figure 9. The desired information shall be selected from the dropdown list.

This section is only intended for vaccine data within the "WHO PMS Network on prequalified vaccines".

**dose number**

**expiry date**     
(dd mm ccyy)

**site of administration**

**diluent name**

**diluent authorization holder**

**diluent expiry date**     
(dd mm ccyy)

**diluent batch number**

**vaccination session**

Figure-9

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/03/2016
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5.6.7.12 Select 'Yes' if the specified reaction recurred after a rechallenge of the drug, otherwise select 'No'. This field only appears if you have answered that the reaction recurred after rechallenge on the drugs page (Figure 10). **Note-** leave this column blank if the re-challenge is not performed.

did reaction recur after rechallenge  
 yes  
 no *clear* ?  
 effect unknown

is the ADR adequately labelled  
 ?

end of administration

Did reaction recur after rechallenge  
 'Effect unknown' indicates that a rechallenge was done but it is not known if the event recurred. Leave blank if it is unknown whether a rechallenge was done.

vaccine data section

Relatedness of drug(s) to reaction(s)  
 (\* = Yes - if reaction recurred after rechallenge)

Reaction	Acetylsalicylic acid	Paracetamol
Nausea	Certain yes *	
Dyspepsia	Possible unknown *	
	Unlikely no *	

If reaction recurred after rechallenge, you can specify which reactions did recur here.

The relation between 'paracetamol' and 'nausea' has been removed; it can be re-entered by clicking on the + sign.

Figure 10

5.6.8 Assessment

The assessment page includes **case narrative**, **sender's comments**, **sender's diagnosis** and **references**. The Vigiflow user has to write a case narrative for every report which gives summary of the whole case.

	Name	Designation	Signature	Date
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Approved by	Dr. Kalaiselvan	PDO	<i>Kal</i>	16/03/2016



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### 5.6.9 Overview

Click on **overview** in the left hand menu to see an overview of all information entered in the report. If there is any error in the report, text in **red** will appear to the right on the page.

### 5.6.10 Save report

5.6.10.1 The VigiFlow user can save a report at any time during the process of entering information, and resume later. Select **save** from the left hand menu to save a report. There is an option to **Generate report Id** by checking the box. Always tick (✓) the box after entering the information in VigiFlow data sets from the Suspected ADR Reporting Form (Figure 11).

**Report comments**

comment  
(shown together with the report in the report list)

Generate report Id  
(this means that the report will be entered into the system and that you will not be able to delete it)

**save**

Figure 11

5.6.10.2 Click the save button. A message saying 'The report was successfully saved' will be display together with the **Report Id** if an Id has been generated.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate	<i>Rishi</i>	14/03/2016
Reviewed by	Dr. Prasad Sheta	S.A	<i>Prasad</i>	15/03/2016
Approved by	Dr. Nikaloi Setvan	P.S.O	<i>Nikaloi</i>	16/03/2016



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5.7 To view the report go to the top menu and select **report handling** and choose **list of reports**. Find the report in the list under regional assessment and click on the edit icon to open and continue working on the report.

5.8 After entering all the information from the Suspected ADR Reporting Form to the VigiFlow and follow ups, the VigiFlow user have to send the report to NCC. Click on the send icon  of the respective report to be sent to NCC. A page with report id and report title will appear with a note. After reading the note click on the 'send report'.

## 6.0 SAFETY AND PRECAUTION

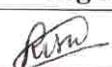
6.1 The VigiFlow user shall take care of each entry as it is mentioned in the reporting form any unwanted change might cause misinterpretation of said case.

## 7.0 REFERENCES

7.1 VigiFlow user guide (<https://adr.who-umc.org/userguide.pdf>)

## 8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
PvPI	:	Pharmacovigilance Programme of India
ADR	:	Adverse Drug Reaction
NCC	:	National Coordination Centre
AMC	:	Adverse Drug Reaction Monitoring Centre
QA	:	Quality Assurance
FDC	:	Fixed Drugs Combination
ICSR	:	Individual Case Safety Report

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/03/2016
Reviewed by	Dr. Prasad	SA		15/03/2016
Approved by	Dr. V. Kalaiselvan	PJO		16/03/2016

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16/03/2016

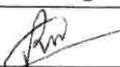
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 सत्यमेव जयते 	<b>INDIAN PHARMACOPOEIA COMMISSION</b> National Coordination Centre-Pharmacovigilance Programme of India		
	<b>STANDARD OPERATING PROCEDURE</b>		Page No. 15 of 15
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	Effective Date 01/04/2016	Revision No. 04	Review Date 31/03/2019
<b>Title: SOP to enter data from Suspected ADR Reporting Form to VigiFlow.</b>			

ICD : International Classification of Diseases  
SOC : System Organ Class

**9.0 ANNEXURE**

Not Applicable

	Name	Designation	Signature	Date
Prepared by	Rishi Kuma	Tech. Approval		14/03/2016
Reviewed by	Dr. Pankaj Singh	S.A		15/03/2016
Approved by	Dr. Kalai Selvaraj	PSO		16/03/2016