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National Coordination Centre-Pharmacovigilance Programme of India

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Section	QA Section	Revision No.	04
Effective Date	01/04/2016	Review Date	31/03/2019

Title: SOP for Reporting and Processing Individual Case Safety Reports

1.0 OBJECTIVE

1.1 To lay down a procedure to process Individual Case Safety Reports.

2.0 SCOPE

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

3.0 RESPONSIBILITY

3.1 The personnel's 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 The ICSRs shall be send to NCC by the Vigiflow user (Coordinator/Technical Associate) at the respective AMCs.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Technical Associate		14/3/2016
Reviewed by	Dr. Prasad Thota	SA		15/3/2016
Approved by	Dr. Kalaiselvan	PSO		16/3/16

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5.2 To send an ICSR to NCC, log-in into VigiFlow with the user-id and password from the web-page <https://adr.who-umc.org>. All the ICSRs entered in the VigiFlow will be available under **report handling** → **list reports** in the top menu (Figure 1).

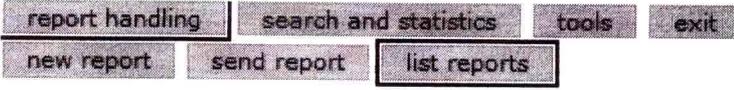


Figure 1

5.3 Click on the send icon of the respective ICSR to be sent. A page with report id and report title will appear with a note. After reading the note click on the 'send report'.

5.4 Click on the option 'Send the report to central assessment'. The report will come under central assessment for quality review and no editing can be done thereafter at AMC level.

5.5 Take an internal print-out of the ICSR in the PDF format and save a soft copy of the same.

5.6 To view and process an ICSRs, the Vigiflow user at NCC have to log-in with respective user id and password from the web-page <https://adr.who-umc.org>.

5.7 Review the ICSRs received from all AMCs for quality and completeness of the data provided in the ICSRs as per documentation grading system.

5.8 The ICSRs may be send back to AMC or may be commit to UMC, for sending ICSRs back to AMC click on send report → then again click on send report after that a list of regional AMCs shall be displayed on screen then VigiFlow user can send the ICSRs to desired regional centre by clicking on mark and for sending report to UMC click on commit as shown in figure 02.

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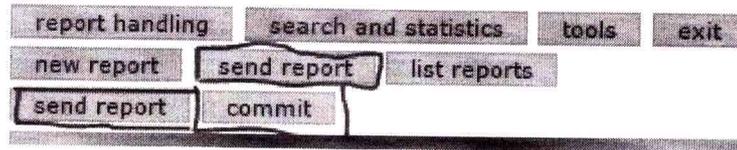


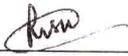
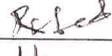
Figure-02

5.9 The ICSRs having incomplete information and those which require additional information shall be revert back to the respective AMC as explained in previous point with the comments in the comment box along with his/her name of VigiFlow user as given in figure 03. The technical associate at AMC can also write in the comment box if there is a justification for lacking of information or any other comment with his/her name at the last.

Report comments	
comment <i>(shown together with the report in the report list)</i>	<div style="border: 1px solid #ccc; padding: 5px;"> <p>Dear VigiFlow user(Name)</p> <p>Please provide the information on.....</p> <p>With Regards</p> <p>Name</p> <p>NCC-PvPI</p> </div> <div style="text-align: center; margin-top: 5px;"> <input type="button" value="save"/> </div>

Figure03

5.10 Take an internal print out (soft copy) of ICSRs after committ to UMC & PDF file of ICSR shall be save in a separate folder with the name of AMC & the Year wise/Month wise sub folder shall be maintained under AMC folder. For example ICSR received from AIIMS, New Delhi shall be saved in folder name by **AIIMS, New Delhi &** the ICSRs of March 2016 month shall be saved in subfolder with name March 2016.

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Approved by	Dr. Kalaiselvan	PIA		16/3/2016

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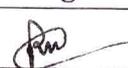
- 5.11 The Technical Associates at NCC and AMC have to make a record of all the ICSRs committed or reverted by them.
- 5.12 The Technical Associate at AMC has to send the reverted report within 10 working days of the date first reverted to their centre with requisite information.
- 5.13 ICSRs related to Haemovigilance are require to process in the same as like other ICSRs but the soft copy of the same need to be forwarded to National Institute of Biologicals, Noida, on email i.d. haemovigilance@nib.gov.in by the VigiFlow user at NCC and copy to NCC-PvPI on email i.d. pvpi@ipcindia.net
- 5.14 Various Icons used in VigiFlow software are explained in the **Annexure-I**, (Icons in VigiFlow) For more elaborate explanation of VigiFlow handelling the updated VigiFlow user guide may be referred which is available on <https://adr.who-umc.org/userguide.pdf>

Note: 1) Once the ADR information for a patient entered in the VigiFlow, it will be regarded as Individual Case Safety Report (ICSR) for that particular patient and the subsequent report id (or worldwide unique number) generated shall be used for all the future correspondences to NCC related to that patient or case for follow-up or amendment, if any required.

2) The VigiFlow user at AMC and NCC shall not use reverse arrow option of their computer during the use of VigiFlow software, they can use the and option present in VigiFlow software.

6.0 SAFETY AND PRECAUTIONS

6.1 Not Applicable

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7.0 REFERENCES

- 7.1 SOP to fill Suspected ADR Reporting Form.
7.2 SOP to enter data from Suspected ADR Reporting Form into VigiFlow.

8.0 ABBREVIATIONS

- SOP : Standard Operating Procedure
PvPI : Pharmacovigilance Programme of India
NCC : National Coordination Centre
ADR : Adverse Drug Reaction
AMC : Adverse Drug Reaction Monitoring Centre

9.0 ANNEXURE

Annexure- I Icons in VigiFlow

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Annexure-I Icons in VigiFlow

Icon:	Explanation:
	<i>Edit.</i> Opens a report for editing. When you have opened a report, it is 'checked out'. This means that no one else can change the contents until you have closed it. Click on the <i>check in</i> icon to close the report when you have finished editing.
	<i>Administrative information.</i> Opens the Administrative information page for a report.
	<i>View.</i> Opens a view of the report. You can only read the information on the report, <u>not</u> edit the report.
	<i>Send.</i> Click on the envelope to send the report to another centre (in list reports only available for Regional Centres).
	<i>Commit.</i> When the report is complete and correct, you can commit it (only for National Centres).
	<i>Check in.</i> After a user has edited or entered a report it has to be checked in to be available for other users.
	<i>Trash.</i> Removes the report. It can be 'delete', 'history mark' or 'nullify' depending on the report. It can also remove a drug name, reaction or other added information from a report.
 (or) 	<i>Comment.</i> This note contains comments on the report. To read the comment, point the cursor on the comment icon. To add or change a comment, click on the comment icon under list reports or, if the report is open, select save report in top menu and add the Report comments in the comments box.
	This icon has several meanings. Point the cursor on the warning icon to get a pop-up with context specific information. <i>Mandatory field / Warning.</i> Indicates a <i>Serious</i> ICSR in the List of reports under central or regional assessment See also the definition as a transmission acknowledgment code.
	<i>Help.</i> Point the cursor on the help icon to get a pop-up with context specific information.
	<i>Error.</i> Point on the error icon to get a pop-up with context specific information.
	<i>Calculator.</i> Click on the calculator when you have entered full onset/start and end dates. The calculator will calculate the duration (of reaction or administration).
	<i>Populate drug information fields.</i> If this icon is clicked, fields on the drug page will be filled with data from the WHO Drug Dictionary about the added drug. See section 2.8.1.
	<i>Nullification comment icon.</i> This icon gives quick access to the nullification/history marking comment.
  	<i>Discard version icon, promote version icon and the warning clock</i> are used to handle updates of previously received cases, see section 5.3.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate	<i>[Signature]</i>	14/3/2016
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Approved by	Dr. Kakisetan	PSO	<i>[Signature]</i>	16/3/2016