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 सत्यमेव जयते 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India		
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	Section	Signal Detection	SOP No. IPC/PvPI/SD/003
	Effective Date	01/02/2017	Revision No. 01
		Review Date	31/01/2020
Title: SOP for Suspected Unexpected Serious Adverse Reactions Identification			

1.0 OBJECTIVE

1.1 To lay down a procedure for operational functioning of SUSARS/SAE identification.

2.0 SCOPE

2.1 This SOP shall be applicable to NCC-PvPI.

3.0 RESPONSIBILITY

3.1 All technical personnel engaged in PvPI shall be responsible for adhering to this SOP.

3.2 All officers and Section-Incharge shall be responsible for compliance of this SOP.

3.3 Quality-Manager/ Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

4.1 Officer Incharge- PvPI

5.0 PROCEDURE

5.1 All the personnel at NCC-PvPI shall commit ICSRs of their allotted AMCs within one month.

5.2 Every serious ICSR shall be committed within 15 working days of current month and the same shall be communicated to SAE division of Central Drugs Standard Control Organisation.

	Name	Designation	Signature	Date
Prepared by	A. PRAMOD KUMAR	Sr. PVA	A. Pramod Kumar	24/01/2017
Reviewed by	Dr. Pawan K. Saini	SO	[Signature]	25/01/2017
Approved by	Dr. Kalajit Banerjee	PSO	[Signature]	30/01/17

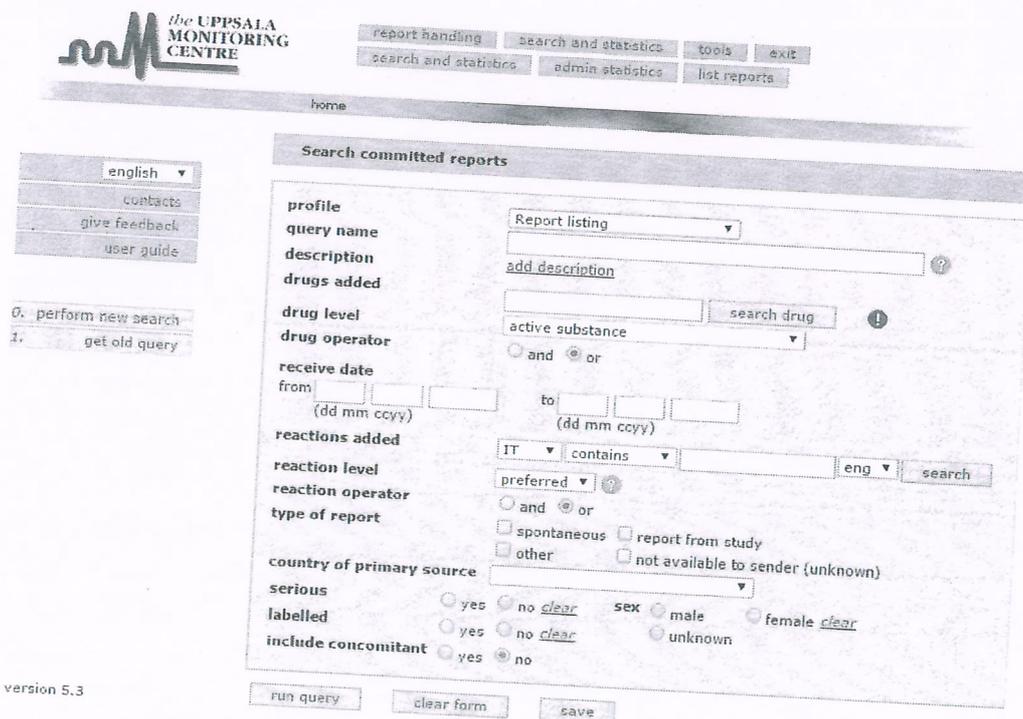
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- 5.3 SUSARs identification shall be done biweekly for serious ICSRs and data is refined from Vigiflow database.
- 5.4 **Data Analysis**
 - 5.4.1 Log in into Vigiflow with user ID & password (as provided by NCC) from the web page <https://adr.who-umc.org/>
 - 5.4.2 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, tools and exit** option.
 - 5.4.3 Select **search and statistics** in drop down menu, three options will come like **search and statistics, admin statistics and list reports** and below click option search and statistics then find page as figure-1.



	Name	Designation	Signature	Date
Prepared by	A. PRAMOD Kumar	Sr. I/A	<i>A. Pramod Kumar</i>	29/01/2017
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>PK</i>	25/01/2017
Approved by	Dr. V. Kalaiselvan	P.S.O.	<i>VK</i>	30/1/17

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National Coordination Centre-Pharmacovigilance Programme of India

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5.4.4 Search report listing in profile menu, fill the date and click yes on serious then click on run query to generate excel sheet.

5.5 Clinical Relevance

5.5.1 Labelled or Unlabelled drug-ADR combination shall be cross checked with drug information resources like NFI, BNF, WHO Formulary, UKeMC and drug@FDA.

5.5.2 Strength of evidence for a causal effect (e.g. number of reports, exposure, dechallenge /rechallenge, alternative explanation/confounders).

5.5.4 Seriousness and severity of the adverse reaction and its outcome.

5.6 Literature Review shall be done by using reviewing different peer review national/International journals on Pharmacovigilance.

5.9 Serious unlabelled ADRs are identified as SUSARs and further process it for drug alert/signal/Label change.

6.0 SAFETY AND PRECAUTION

6.1 Do not use any SOP if it is not signed and issued by quality assurance Personnel or the authorized signatories:

6.2 Do not use adhesive tape or whitener on SOP.

6.3 Do not share the SOP information with anybody outside the organizations.

7.0 REFERENCES: In-house

	Name	Designation	Signature	Date
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Reviewed by	Dr. Lawan K. Saini	S.O.	[Signature]	25/01/2017
Approved by	Dr. V. Kalaijelan	PIO	[Signature]	30/1/17

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8.0 ABBREVIATIONS

PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
SUSARs	:	Suspected Unexpected Serious Adverse Reactions
SAE	:	Serious Adverse Event
ICSR	:	Individual Case Safety Report
UKeMC	:	Electronic Medicines Compendium
WHO	:	World Health Organization
NFI	:	National formulary of India
BNF	:	British National Formulary
US FDA	:	U.S. Food and Drug Administration

9.0 ANNEXURE:

Annexure I : Drug Alert Form Format No. IPC/PvPI/SD/003-F01

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Prepared by	A. PRAMOD KUMAR	Sr. PVA	A. Pramod Kumar	24/01/2017
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	25/01/2017
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