



# PEOPLE'S UNIVERSITY

(Established by MP Act No. 18 of 2011 & approved u/s 2 (f) of UGC Act 1956)

ISO 9001 : 2008 Certified

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## SCHOOL OF PHARMACY & RESEARCH

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No: SOP&R/GL/21/1734

Date: 29/06/2021

### REPORT OF THE EVENT

To sensitize students of School of Pharmacy and Research, more on Pharmacovigilance which has been opted as Elective subjects by some of the Bachelor of Pharmacy, 8th Semester students, series of guest lecture was organized between 04th June 2021 to 20th June 2021. Guest speaker for series was Mr. Tarani Prakash Shrivastava, Research Associate, Pharmacovigilance at Immunization Technical Support Unit, Ministry of Health & Family Welfare, New Delhi. The basic objective of this Lecture series was to sensitize students on “Pharmacogenomics” through which students would be able to learn more about the basic knowledge of Pharmacogenomics, Central Drugs Standard Control Organization (CDSCO), Council for International Organizations of Medical Sciences (CIOMS) with their working and various methods of Drug safety evaluation in special population. Lecture shall also provide students with an understanding of the principles and applications of human genetics and genomics in drug therapy optimization, patient care, and counseling. He started lecture series with basic knowledge of Genetics and Pharmacogenomics with suitable examples and with the discussion about various databases for Genomics. He also discussed about some case studies regarding various diseases and also reviewed considerations for specific cases. At the end of Lecture series, Dr. Neeraj Upmanyu, Principal, School of Pharmacy and Research, People’s University, expressed gratitude to Mr. Tarani Prakash Shrivastava for his untiring effort and accepted invitation to deliver the students about the nitty gritty of the subject. He also appreciated the efforts of Mr. Atul Tripathi, Assoc. Professor, SOPR, PU for co-ordination and sincere follow-ups for successful completion of the event.



**Principal**

# SOP&R

## IMAGES OF EVENT:

dwi-umsh-bzv (2021-06-12 at 04:07 GMT-7)

Case Study- Carbamazepine.pdf - Adobe Reader

Rare disease



the Naranjo algorithm. The total score was 8. The patient was treated with hydrocortisone followed by prednisone. Other treatments were given which included paracetamol, antacids, antihistamines, mouth gargles, nasal sprays and topical preparations. The severity-of-illness score for toxic epidermal necrolysis (SCORTEN) was 1 (mortality rate: 3.2%).

**OUTCOME AND FOLLOW-UP**  
After 13 days of hospitalisation, the patient was discharged with signs of improvement. One year posthospitalisation, DNA was extracted from the patient's saliva samples. Genetic testing for HLA was found to be positive for the HLA-B\*75 serotype. Specifically, the patient tested positive for HLA-B\*1521 and was negative for HLA-B\*1502.

**DISCUSSION**  
Carbamazepine is used for the treatment of epilepsy, bipolar disorder and neuropathic pain.<sup>6</sup> In this case, carbamazepine was prescribed to manage behavioural changes as manifested by increased irritability. As a mood stabiliser, carbamazepine was



tarani prakash Shrivastava

22:53 / 1:29:04

dwi-umsh-bzv (2021-06-13 at 03:54 GMT-7)

CIOMS:  
Perspectives in  
Pharmacovigilance



Tarani Prakash Shrivastava

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tarani prakash Shrivastava

13:57 / 1:32:20

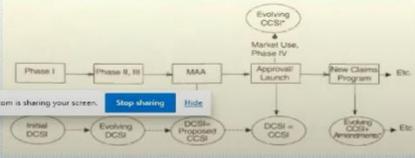




### Guideline for Preparing Core Clinical Safety Information on Drugs

- Harmonize Company Core Safety Information (CCSI) by all manufacturers
- Conceptualize Development Core Safety Information (DCSI)

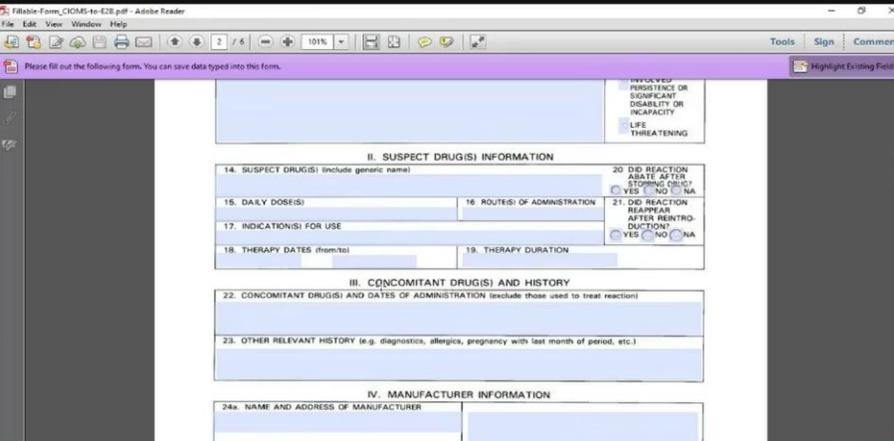
- Minimizing confusion among investigators, prescribers and other healthcare professionals due to inconsistencies between the drug safety information of different countries and manufacturers;
- Facilitating access to important information for making rational clinical decisions;
- Eliminating the diversity of national alert/expedited reporting requirements of different regulators, which result from differences in what constitute unexpected ("unlabelled") adverse drug reactions.



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graph LR; P1[Phase I] --> P2[Phase II, III]; P2 --> MAA[MAA]; MAA --> A[Approval/ Launch]; A --> NCP[New Claims Programs]; NCP --> Etc1[Etc.]; P1 --> EDCI[Initial DCSI]; P2 --> EDCI; MAA --> EDCI; A --> EDCI; NCP --> EDCI; EDCI --> EDCI2[Evolving DCSI]; EDCI2 --> EDCI3[DCSI-Proposed CCSI]; EDCI3 --> EDCI4[DCSI + CCSI]; EDCI4 --> EDCI5[Evolving CCSI Assessment]; EDCI5 --> EDCI6[Evolving CCSI]; EDCI6 --> EDCI7[Evolving CCSI + Market Use, Phase IV]; EDCI7 --> EDCI8[Evolving CCSI + Market Use, Phase IV]; EDCI8 --> EDCI9[Evolving CCSI + Market Use, Phase IV]; EDCI9 --> EDCI10[Evolving CCSI + Market Use, Phase IV]; EDCI10 --> EDCI11[Evolving CCSI + Market Use, Phase IV]; EDCI11 --> EDCI12[Evolving CCSI + Market Use, Phase IV]; EDCI12 --> EDCI13[Evolving CCSI + Market Use, Phase IV]; EDCI13 --> EDCI14[Evolving CCSI + Market Use, Phase IV]; EDCI14 --> EDCI15[Evolving CCSI + Market Use, Phase IV]; EDCI15 --> EDCI16[Evolving CCSI + Market Use, Phase IV]; EDCI16 --> EDCI17[Evolving CCSI + Market Use, Phase IV]; 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tarani prakash Shrivastava



Fillable Form\_CCSM to E2S.pdf - Adobe Reader

File Edit View Window Help

Please fill out the following form. You can save data typed into this form.

Involved in persistence or significant disability or incapacity life threatening

### II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

15. DAILY DOSE(S)

16. ROUTE(S) OF ADMINISTRATION

17. INDICATION(S) FOR USE

18. THERAPY DATES (from/to)

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG? YES  NO  NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? YES  NO  NA

### III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (include those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

### IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER



tarani prakash Shrivastava



**Tarani Prakash Shrivastava**  
M. Pharm. (Pharmacology)



**Current Affiliation:**

**Research Associate-Pharmacovigilance at Immunization Technical Support Unit,  
Ministry of Health & Family Welfare, New Delhi (April 2021- Present)**

**Job Responsibilities:**

- Signal Processing and Validation for Vaccine AEFIs
- Coordinating with different ministries for creating awareness about Pharmacovigilance
- Collaborating with research based organization for optimizing vaccine safety

**Experience:**

- **Senior Pharmacovigilance Associate at Pharmacovigilance Programme of India (PvPI), IPC, Ghaziabad (Sep 2016-April 2021)**
- **Assistant Professor at School of Pharmacy & Research, People's University, Bhopal (Aug 2010- Sep 2016)**

**Education:**

- Pursuing PhD from Delhi Pharmaceutical Sciences & Research University, New Delhi
- Masters in Pharmacy (Pharmacology) from Sikkim Central University (2008-2010)
- Bachelor of Pharmacy from Laxmi Narain College of Pharmacy, Bhopal (2003-2007)

**Previous Experience:**

Teaching –over 6 years  
Pharmacovigilance- 5 Years

Published 15 national/International articles and presented papers in 25 nationwide conferences

**School of Pharmacy and Research, People's University**

Cordially invited and Welcomes You to attend

Invited Lecture Series

on

Pharmacovigilance

Guest Speaker

Mr. Tarani Prakash Shrivastava

Research Associate-Pharmacovigilance at Immunization Technical Support Unit,

Ministry of Health & Family Welfare, New Delhi

Time - 16:30 Onwards

Date & Day - Friday, June 4, 2021 to Sunday, June 20, 2021 (on Fridays, Saturdays and Sundays)

Time Table for Pharmacovigilance Lecture series

<https://drive.google.com/file/d/1FvrpHKJWp2dh8iZOXGG9R6OaZRpxwRnZ/view?usp=sharing>

Facebook Link

<https://forms.gle/qs8LcMjwcDhAx1Js5>



## Details of topics discussed during lecture series

S. No.	Date	Topic Covered	Link of Lecture
1.	04-06-2021	Basic Introduction of Pharmacovigilance	<a href="https://drive.google.com/file/d/1lavb1m_UrUUcxYScR0vhyoML7x5qfd3J/view?usp=sharing">https://drive.google.com/file/d/1lavb1m_UrUUcxYScR0vhyoML7x5qfd3J/view?usp=sharing</a>
2.	05-06-2021	Genetics and its involvement in causing adverse drug reactions	<a href="https://drive.google.com/file/d/1ik1V7Dji6nb3IouQQYz-37M7SRVXr3Sp/view?usp=sharing">https://drive.google.com/file/d/1ik1V7Dji6nb3IouQQYz-37M7SRVXr3Sp/view?usp=sharing</a>
3.	06-06-2021	Impact of Genetics in affecting Pharmacokinetic parameters of Drugs	<a href="https://drive.google.com/file/d/1czIF8W8H9RXzkizxMfhNuNv5f512LKqI/view?usp=sharing">https://drive.google.com/file/d/1czIF8W8H9RXzkizxMfhNuNv5f512LKqI/view?usp=sharing</a>
4.	12-06-2021	Case Study on steven Johnson syndrome	<a href="https://drive.google.com/file/d/1ZstCHR FON-zfThEKDyMERZOkOWNqdnU1/view?usp=sharing">https://drive.google.com/file/d/1ZstCHR FON-zfThEKDyMERZOkOWNqdnU1/view?usp=sharing</a>
5.	13-06-2021	CIOMS Perspectives in Pharmacovigilance	<a href="https://drive.google.com/file/d/18XHxTq1r0nvZNuVkmWxNpAowG2Q8giXU/view?usp=sharing">https://drive.google.com/file/d/18XHxTq1r0nvZNuVkmWxNpAowG2Q8giXU/view?usp=sharing</a>
6.	18-06-2021	CDSCO and its Role in Pharmacovigilance	<a href="https://drive.google.com/file/d/1i_by2Bsx05oym05ez3x8v-E7W9tugFN/view?usp=sharing">https://drive.google.com/file/d/1i_by2Bsx05oym05ez3x8v-E7W9tugFN/view?usp=sharing</a>
7.	19-06-2021	New Drugs and Clinical Trial Rules	<a href="https://drive.google.com/file/d/1Rc0pEdFT2Nrm53V3M7tfUHLfdzOyPsS6/view?usp=sharing">https://drive.google.com/file/d/1Rc0pEdFT2Nrm53V3M7tfUHLfdzOyPsS6/view?usp=sharing</a>
8.	20-06-2021	Case Study Adverse Reaction Report	<a href="https://drive.google.com/file/d/1HdtCbRqNur9WJQRnB-sqFN2eC_s4o2cA/view?usp=sharing">https://drive.google.com/file/d/1HdtCbRqNur9WJQRnB-sqFN2eC_s4o2cA/view?usp=sharing</a>

