

**Activity Outline**  
**FDA Drug Topics: FDA Adverse Events Reporting System (FAERS) Public Dashboard**  
**January 30, 2018**  
**FDA/WO**

**Series Description**

This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety.

**Lecture Description**

This webinar will provide an overview of the FAERS Public Dashboard, a highly interactive web-based tool that allows for the querying of FAERS data in a user-friendly fashion. The intention of this tool is to expand access of FAERS data to the general public to search for information related to human adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers. FDA anticipates that this increased transparency will help to spur the submission of more detailed and complete reports from consumers, health care providers and other members of the public.

**References**

- FDA Adverse Events Reporting System (FAERS) Public Dashboard at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>
- FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm>
- Questions and Answers on FDA's Adverse Event Reporting System (FAERS) at <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugs/ucm2007060.htm>

**Series Objectives**

- Explain how to utilize FDA's Drug Information, medication safety resources, and regulatory guidances to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

**Learning Objectives** After completion of this activity, the participant will be able to:

- Describe the FAERS public database
- Demonstrate how to use the FAERS public dashboard to view adverse event reporting metrics
- Illustrate use of FAERS public dashboard to view adverse event information on a specific product

**Target Audience**

This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, and students other healthcare professionals.

**Agenda**

**Lecture 1 January 30, 2018**

Time	Topic	Speaker
1:00 - 2:00 PM	FDA Adverse Events Reporting System (FAERS) Public Dashboard	Suranjan De

**Continuing Education Accreditation**



JOINTLY ACCREDITED PROVIDER™  
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.



This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

## CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

## CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number J0002895-0000-18-011-L05-P, and ACPE Universal Activity Number J0002895-0000-18-011-L05-T for 1.00 contact hour(s).

## CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

## Requirements for Receiving CE Credit

**Physicians, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME:** participants must attest to their attendance and complete the final activity evaluation via the CE Portal ([ceportal.fda.gov](http://ceportal.fda.gov)). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

**Pharmacy participants:** partial credit cannot be awarded, therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

## Important Note regarding completion of evaluations and receiving credit

Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

## Disclosure

### Faculty

- De, Suranjan, SUPERVISORY HEALTH SCIENCE, FDA - nothing to disclose

### Planning Committee

- Burke, Kara, PharmD, Pharmacist, CDER/OCOMM/DDI - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, CDER/OCOMM/DDI - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Navin, Lesley, RN, MSN, CSO, FDA/CDER/DDI - nothing to disclose
- Weinstein, Edward, M.D., Ph.D., Medical Officer, CDER FDA *My spouse received Salary from EndoCentre of Baltimore for a role as Employee.*

### CE Consultation and the Accreditation Team

- Gorinson, Justin, B.S., CHES, ORISE Fellow, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

## Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.