

Activity Outline
FDA Drug Topics: Reporting and Public Viewing of Individual Case Safety Reports (ICSRs)
May 24, 2022
FDA

Activity Coordinators:

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Series Description

FDA's Division of Drug Information in the Center for Drug Evaluation and Research (CDER) sponsors a series of educational webinars targeting the needs of health care professionals and students. The webinars cover a broad range of FDA drug regulation and medication safety topics. These focused webinars support FDA's mission of promoting and protecting public health through interaction and education to strengthen current and future partnerships and relationships with clinicians and researchers.

Lecture Description

The purpose of this webinar is to understand the reporting of Individual Case Safety Reports (ICSRs) to FDA and learn how to access and view the publicly available data in the FDA Adverse Event Reporting System (FAERS). This session also will focus on understanding data issues encountered in ICSRs and providing tips and methods to improve data quality.

References

- Reporting Serious Problems to FDA: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>
- FAQs: Safety Reporting Portal: <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/faqs-safety-reporting-portal>
- FDA Adverse Event Reporting System (FAERS) Public Dashboard: <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard>

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 reporting of ICSRs to the FDA
- Discuss data quality issues in FAERS
- Learn how to view the FAERS Public Dashboard

Target Audience

This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, Certified Public Health (CPH), and physician assistants.

Agenda

Lecture 1 May 24, 2022

| TIME | TOPIC | SPEAKER |
|--------------------|--|-------------|
| 1:00 - 2:00 PM EDT | Reporting and Public Viewing of Individual Case Safety Reports (ICSRs) | 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.



IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1 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)*[™]. 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 JA0002895-0000-22-011-L04-P, and ACPE Universal Activity Number JA0002895-0000-22-011-L04-T for 1.00 contact hour(s).

CNE

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

AAPA

This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

Requirements for Receiving CE Credit

Physicians, physician assistants, 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). 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.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

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, physician assistants, and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 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, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - *nothing to disclose*
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV - *nothing to disclose*
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - *nothing to disclose*
- Kapoor, Rama, MD, Medical Officer, FDA - *nothing to disclose*
- Nguyen-Chu, Thanh Tam, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI - *nothing to disclose*
- Paraoan, Dianne, MPH, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP - *nothing to disclose*

CE Consultation and Accreditation Team

- Littlefield, Jr, Kenneth P., Training Specialist, FDA/CDER/OEP/DLOD - *nothing to disclose*
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - *nothing to disclose*

All of the relevant financial relationships listed for these individuals have been mitigated.

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.