Activity Outline
FDA Drug Topics: Project Facilitate: Oncology Expanded Access Program Update
December 14, 2020
FDA

Activity Coordinator:
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Series Description

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

Lecture Description
This webinar will discuss Expanded Access, the regulatory pathway by which an oncologist may obtain access to an investigational drug product for the purposes of treating a patient with a life-threatening medical condition for which there is no acceptable treatment. The FDA Oncology Center of Excellence's Project Facilitate was established to meet the demand for oncology Expanded Access through increasing awareness of this pathway, increasing accessibility and establishing a single point-of-contact for the public. Project Facilitate is continually improving oncology Expanded Access to ensure everyone has personalized support when submitting their application.

References

- Lemery, S., Mailankody, S., Kazandjian, D., Demiette Smit, M., Blumenthal, G., Kim, T., Keegan, P., McKee, A., Pazdur, R. (2016, June). Food and Drug Administration analysis of 1332 single patient and emergency use expanded access (compassionate use) requests for patients with cancer over a duration of three years (2012-2014). Abstract accepted and poster presented as American Society of Clinical Oncology Annual Meeting, Chicago, IL.
- Project facilitate: A review of the FDA oncology center of excellence expanded access pilot program. Natasha L Kormanik, Mitchell Chan, Jessica Boehmer, Tamy Kim, Gideon Michael Blumenthal, and Richard Pazdur. Journal of Clinical Oncology 2020 38:15_suppl, 7023-7023
- Reagan-Udall Foundation (n.d.). Expanded Access Navigator. Retrieved from https://reaganudall.org/

Series Objectives

- Explain how to utilize FDA’s drug information, medication safety resources, and regulatory guidance, 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:

- Define expanded access and the key requirements for an expanded access request for an individual patient.
- Summarize the key responsibilities of the oncology healthcare professional when considering expanded access for a patient.
- Identify resources available to healthcare professionals considering submission of an oncology expanded access request for an individual patient.
- Describe how Project Facilitate is a resource to navigate the oncology Expanded Access pathway.

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, CPH - Certified Public Health, and physician assistants.

Agenda

Lecture 1 December 14, 2020

Time	Topic	Speaker
1:00 - 2:00 PM	Project Facilitate: Oncology Expanded Access Program Update	Mitchell Chan, PharmD, BCPS

Continuing Education Accreditation

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 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 JA0002895-0000-20-006-L04-P, and ACPE Universal Activity Number JA0002895-0000-20-006-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 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Chan, Mitchell, PharmD, BCPS, Clinical Analyst, 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
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI - nothing to disclose
- Nguyen-Chu, Thanh Tam, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, 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.