Activity Outline
Committee for the Advancement of Clinical and Scientific Education (CACSE): Annual Abrams Lecture: Clinical Implementation of Pharmacogenetics
May 14, 2020
Time: 1:30 pm-3:00 pm
FDA Online ADOBE Platform

Activity Coordinator:
Sharron Watson (Sharron.Watson@fda.hhs.gov), Rokhsareh Shahidzadeh (rokhsareh.shahidzadeh@fda.hhs.gov),

Series Description

The Committee for the Advancement of Clinical and Scientific Education lecture series (CACSE) gives the FDA scientific community and health professionals the chance to stay current with advances in therapeutics and applied scientific data in various clinical fields, as well as to hear the perspectives of scientists and clinicians on the application of regulatory scientific knowledge. The Committee for the Advancement of Clinical and Scientific Education (CACSE) creates a venue to discuss the cutting-edge technologies and therapeutic advances in various scientific and clinical areas.

Lecture Description

There are few select examples in pharmacogenetics for which the evidence from published research is already strong enough to support the use of genetic testing in the clinic. Pharmacogenetic testing in routine clinical care remains uncommon; one reason has been that the processes needed to move from genetic test results to specific prescribing recommendations have been unclear. This session will provide an overview of the Clinical Pharmacogenetics Implementation Consortium (CPIC®), developed in 2009, to write, curate, and update freely available, peer-reviewed, and detailed gene/drug pharmacogenetic clinical practice guidelines with accompanying computational tables to facilitate the appropriate use of pharmacogenetic tests in clinical care. In addition, the session will discuss implementation of the CPIC guidelines in a clinical protocol at St. Jude's, PG4KDS, with an aim to preemptively test all eligible children at the institute and implement all CPIC guidelines by placing test results, with the necessary clinical decision support tools to guide prescribing, in an electronic health record. The rationale for preemptive testing is that the lifetime use of pharmacogenetically actionable drugs is high, almost all patients have at least one actionable genotype, and the cost of preemptively testing all pharmacogenetically actionable genes is low. For PG4KDS, over 5500 patients have been enrolled, and St. Jude has clinically implemented 12 genes and > 35 drugs: TPMT and NUDT15 for thiopurines; CYP2D6 for opiates, antidepressants, and ondansetron; CYP2C19 for voriconazole, clopidogrel, proton pump inhibitors and tricyclics; DPYD for fluoropyrimidines; UGT1A1 for atazanavir; SLC01B1 for simvastatin; CYP3A5 for tacrolimus; CYP2C9 for celecoxib; mt-RNR1 and aminoglycosides; RYR1/CACNA1S and anesthetics.

References

- The Clinical Pharmacogenetics Implementation Consortium (CPIC®) www.cpicpgx.org [PMID: 21270786] https://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A++21270786
- PG4KDS: Clinical Implementation of Pharmacogenetics www.stjude.org/pg4kds [PMID: 31520409] https://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+31520409

Series Objectives

- Explain the therapeutic research conducted at the FDA
- Discuss the cutting-edge technologies and advancements in the science underlying the many professions contributing to the FDA regulatory science.

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

- Discuss the rationale for development and the purpose of the CPIC guidelines
- Identify the practical utility of the CPIC guidelines in a clinical protocol

Target Audience

This activity is intended for physicians, pharmacists, nurses, other health professionals who review medical products, perform regulatory science research, and set regulatory science policy.

Agenda

Lecture 1 May 14, 2020

Time	Topic	Speaker
1:30 - 2:30 PM	Annual Abrams Lecture: Clinical Implementation of Pharmacogenetics	Mary Relling, PharmD

Continuing Education Accreditation

In support of improving patient care, this activity has been planned and implemented by the FDA Center for Drug Evaluation and Research and the American Society for Clinical Pharmacology and Therapeutics. The 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 JA0002895-0000-20-042-L04-P 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, 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.

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

- Relling, Mary, PharmD, Chair, Pharmaceutical Department, St. Jude Children's Research Hospital *I received Research grant paid to employer/institution from Servier Pharmaceutical for a role as Other - investigator-initiated research funding.*

Planning Committee

- Gensheimer, Kathleen, MD, medical officer, FDA - nothing to disclose
- Imam, Syed, PhD, Staff Scientist, NCTR - nothing to disclose
- Jackson, Kia, PhD, Pharmacologist, FDA - nothing to disclose
- Kim, Insook, Clinical Pharmacology Team Leader, FDA - nothing to disclose
- Mada, Sripal, Pharmacologist, FDA - nothing to disclose
- Mendrick, Donna, Associate Director, Regulatory Activities, NCTR - nothing to disclose
- O'Carroll, Andrew, DVM, Regulatory Reviewer, FDA/CBER/OVRR - nothing to disclose

- Sahre, Martina, PhD, Reviewer, US FDA - nothing to disclose
- Shahidzadeh, Rokhsareh, MSN, Senior Regulatory Health Education Specialist, FDA - nothing to disclose
- Vaillancourt, Julienne, MPH, R. Ph, Rare Disease Liaison/Policy Advisor, FDA/CBER/OD - nothing to disclose
- Van Schoick, Andrea, DVM, Director of Scientific Curriculum, FDA CVM - nothing to disclose
- Wang, Qun, Reviewer & RPM, FDA - nothing to disclose
- Watkins-Bryant, Theresa, MD, Medical Officer, FDA/CTP/OS/DIHS/MEDICAL - nothing to disclose

CE Consultation and Accreditation Team

- Miller, Isaac J., 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.

Webcast Registration:

To register for the webcast, please click the link below and then follow the instructions on the registration page. After you register you will receive a link via email to access the live webinar. You must log in with your username and password which you create when you register. Please pre-register at least one day before the event to ensure you receive the access link email and outlook invitation for the session.

Register here: https://collaboration.fda.gov/cacse51420reg/event/registration.html

For technical assistance please contact Jeffery.Rexrode@fda.hhs.gov or Sharron.Watson@fda.hhs.gov

Reasonable Accommodations

The FDA provides reasonable accommodations for all individuals with disabilities who apply for training or developmental opportunities. If you need a reasonable accommodation for any part of the training application process please notify the training contact for this particular event. Reasonable accommodation requests are granted on a case-by case basis. Should you need sign language interpretation to attend this event, please send the request to Interpreting.Services@oc.fda.gov