Activity Outline
FDA Grand Rounds: Project Orbis: Global Collaborative Oncology Review Program
May 13, 2021
Adobe Connect

Activity Coordinators:
Sharron Watson (Sharron.Watson@fda.hhs.gov),

Series Description

The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
FDA Oncology Center of Excellence (OCE) launched Project Orbis in May 2019 with international regulatory authorities as a global collaborative review program for oncology marketing applications. Current Project Orbis partners include the regulatory health authorities of Australia, Brazil, Canada, Singapore, Switzerland, and the United Kingdom. The program aims to facilitate the submission, review, and approval of high impact oncology marketing applications across the participating countries.

References

- de Claro RA, Spillman D, Hotaki LT, Shum M, Mouawad LS, Santos GML, Robinson K, Hunt M, Healy C, Chan A, Looi YH, Rodrigues C, Rohr UP, Walther C, Pazdur R. Project Orbis: Global Collaborative Review Program. Clin Cancer Res. 2020 Dec 15;26(24):6412-6416.
- de Claro RA, Spillman D, Hotaki LT, Shum M, Mouawad LS, Santos GML, Robinson K, Hunt M, Healy C, Chan A, Looi YH, Rodrigues C, Rohr UP, Walther C, Pazdur R. Project Orbis: Global Collaborative Review Program. Clin Cancer Res. 2020 Dec 15;26(24):6412-6416.

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

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

- Discuss the general framework of Project Orbis.
- Explain how other FDA and OCE review programs interact with Project Orbis.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 May 13, 2021

Time	Topic	Speaker
12:00 - 1:00 PM	Project Orbis: Global Collaborative Oncology Review Program	R. Angelo De Claro, MD

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 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 JA0002895-0000-21-016-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.

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 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 Claro, R. Angelo, MD, Division Director, FDA *nothing to disclose*

Planning Committee

- Dinatale, Miriam, Team Leader, Food and Drug Administration *nothing to disclose*
- Pfundt, Tiffany, PharmD, Pharmacist, FDA *nothing to disclose*
- Wheelock, Leslie, RN, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD *nothing to disclose*

CE Consultation and Accreditation Team

- Bryant, Traci, M.A.T., 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.