Activity Outline
FDA Grand Rounds: Artificial Intelligence for Regulatory Science Research
May 14, 2020
FDA White Oak (or via webcast)

Activity Coordinators:
Devin Thomas (Devin.Thomas@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
Artificial Intelligence (AI) is a broad concept of training machines to think and behave like humans. It consists of a wide range of statistical and machinal leaning approaches to learn from the existing data/information to predict future outcomes. It has impacted a board range of scientific disciplines that are important to public health, ranging from clinical diagnosis and prognosis, drug and food safety, disease prevention, precision medicine and nutrition. The rise of AI has also offered both opportunities and challenges to regulatory agencies with questions such as (1) how to assess and evaluate AI-based products and (2) how to develop and implement AI-based application to improve the agencies functions. In this presentation, the current thinking and on-going efforts at NCTR in the area of AI will be discussed with examples from drug and food safety, natural language processing of regulatory documents, and biomarker discovery and development. The guiding principle and best practice of applying AI in regulatory science research will also be discussed with respect to the context of use and fit-for-purpose application.

References

- Belkum, S. & Brun, N. & Cleve, S. & McGovern, P. & Lumpkin, M. & Schaeffer, Paul-Etienne & Pauli, T. & Trethowan, Jonathan & Netzer, T.. (2018). Artificial intelligence in clinical development and regulatory affairs – Preparing for the future. Regulatory Rapporteur. 15. 17-21.

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:

- Explain the basic principle and methodologies of AI
- Describe different AI methods
- Describe ways in which AI methods can be applied for drug and food safety, biomarker development and text mining

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

Agenda

Lecture 1 May 14, 2020

Time	Topic	Speaker
12:00 - 1:00 PM	Artificial Intelligence for Regulatory Science Research	Weida Tong, PhD

Continuing Education Accreditation

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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 JA0002895-0000-20-022-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

- Tong, Weida, PhD, Division Director, NCTR - nothing to disclose

Planning Committee

- Dinatale, Miriam, Team Leader, Food and Drug Administration - nothing to disclose
- Pfundt, Tiffany, PharmD, Pharmacist, FDA - nothing to disclose
- Thomas, Devin, LCDR, MPH, CHES, Health Promotions Specialist, FDA/OC/OCS/OSPD - nothing to disclose
- Wheelock, Leslie, 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.