Activity Outline
FDA Grand Rounds: Some Perspectives on Data Science and Coronaviruses
June 9, 2022

Activity Coordinators:
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Series Description
The FDA Grand Rounds is webcast monthly 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
This lecture will present some perspectives, illustrated with recent COVID-19 experience and examples, on how in silico modelling and data science techniques could strengthen nonclinical (in vitro and animal) models for existing and emerging coronaviral diseases. Four peer-reviewed case studies will be reviewed briefly: 1. Could alignment-free approaches complement traditional phylogenetic analysis of coronavirus variants? 2. Why big data on viral genome sequences are less useful without metadata? 3. Could we predict if certain hosts are likely susceptible to infection by an emerging coronavirus variant? 4. Can AlphaFold2 artificial intelligence predictions of protein structure aid our understanding of viral antigens?

References

- Supporting pandemic response using genomics and bioinformatics: A case study on the emergent SARS-CoV-2 outbreak, https://doi.org/10.1111/tbed.13588
- Interoperable medical data: the missing link for understanding COVID-19, https://doi.org/10.1111/tbed.13892
- But Mouse, you are not alone: On some severe acute respiratory syndrome coronavirus 2 variants infecting mice, https://doi.org/10.1093/ilar/ilab031
- Highly thermotolerant SARS-CoV-2 vaccine elicits neutralising antibodies against Delta and Omicron in mice, https://doi.org/10.3390/v14040800

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:
- Examine how coronavirology can benefit from alignment free kmer approach and dimensionality reduction methods.
- Explain the potential of big data on GISAID and other platforms by overcoming metadata barriers.
- Discuss the value of bringing together in silico, in vitro, in vivo and in situ data on coronavirus mutations to predict susceptibility of target hosts.
- Discuss the benefits and current limitations of novel AI tools such as AlphaFold2 in coronaviral protein structure prediction and countermeasure development.

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

Agenda

Lecture 1 June 9, 2022

TIME	TOPIC	SPEAKER
9:00 - 10:00 AM EDT	Some Perspectives on Data Science and Coronaviruses	Seshadri Vasan, , DPhil(Oxon)

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.

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 JA0002895-0000-22-006-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
- Vasan, Seshadri, , DPhil(Oxon), Honorary Professor, University of York - *nothing to disclose*

Planning Committee
- Dinatale, Miriam, Team Leader, Food and Drug Administration - *nothing to disclose*
- Pfundt, Tiffany, PharmD, Senior Advisor, HHS/ASPR - *nothing to disclose*
- Wheelock, Leslie, RN, MS, Director, OSPD, FDA, OC, OCS, OSPD - *nothing to disclose*

CE Consultation and Accreditation Team
- Bueide, Rachel E., MPhil, 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.