Activity Outline

FDA Grand Rounds:
GenomeTrakr: How a Large Network of Sequencing Laboratories is Advancing Food Safety and Public Health

July 13, 2017
12:00 PM-1:00 PM
FDA White Oak Building 2, Room 2031

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.

Session Description

In 2012, a pilot project, now a mature network called GenomeTrakr, was set up at the national level using whole genome sequence data (WGS) to track foodborne outbreaks. In this network, public health agencies collect and publicly share WGS data in real time. This high-resolution, rapidly growing database is being used in outbreak investigations at the state, national, and international level. The GenomeTrakr network demonstrates how desktop WGS data can be used in concert with traditional epidemiology for source tracking of foodborne pathogens. Along with the paradigm shift in technology, this new "open data" model enables greater transparency between federal/state agencies, our industry partners, academia, and international partners. The high-resolution WGS data together with solid epidemiological evidence has dramatically enhanced our ability to identify the food source of current outbreaks for Listeria monocytogenes, for which the Centers for Disease Control is also contributing clinical isolates in real time. The presentation will detail one of these outbreaks where WGS provided the lead in a 2015 Virginia sprout outbreak.

Results to date demonstrate two major contributions of GenomeTrakr:

1. WGS as a high-resolution sub-typing tool and
2. the global benefits of having an open data model.

Understanding the root causes of foodborne contamination will assist our academic, public health, and industry partners to develop preventative controls to make food safer globally.

Session References:

Pecora ND, Li N, Allard M, Li C, Albano E, Delaney M, Dubois A, Onderdonk AB, Bry L. 2015. Genomically informed surveillance for carbapenem-resistant enterobacteriaceae in a health care system. mBio 6(4):e01030-15. doi:10.1128/mBio.01030-15.

Marc W. Allard, Errol Strain, David Melka, Kelly Bunning, Steven M. Musser, Eric W. Brown, and Ruth Timme. 2016. The practical value of food pathogen traceability through building a whole genome sequencing network and database. J. Clin. Microbiol. doi:10.1128/JCM.00081-16

Maria Hoffmann, Yan Luo, Steven R Monday, Narjol Gonzales-Escalona, Andrea Ottensen, Tim Muruvanda, Charles Wang, George Kastanis, Christine Keys, Daniel Janies, Izzet Senturk, Umit V Catalyurek, Hua Wang, Thomas S Hammack, William J Wolfgang, Dianna Schoonmaker-Bopp, Alvina Chu, Robert Myers, Julie Haendiges, Peter Evans, Jianghong Meng, Errol Strain, Marc W. Allard, and Eric W. Brown. Tracing Origins of the Salmonella Bareilly strain causing a Foodborne Outbreak in the United States. J Infect Dis. (2016) 213(4):502-508. doi: 10.1093/infdis/jiv297.

E. Kurt Lienau, Ph.D., Errol Strain Ph.D., Charles Wang, B.S., Guojie Cao, M.S., Jie Zheng, D.V.M., Ph.D., Jianghong Meng, D.V.M., M.P.V.M., Ph.D., Andrea Ottesen, Ph.D., Christine Keys, M.S., Robert Stones, M.S., Thomas Hammack, M.S., Steven Musser, Ph.D., Eric W. Brown, Ph.D., and Marc W. Allard, Ph.D. Next-Generation Sequencing Provides High Resolution Clustering of Food and Clinical Sources during a Foodborne Outbreak of Salmonellosis. This letter (10.1056/NEJMc1100443) was published on February 23, 2011, at NEJM.org.

NCBI Pathogen Detection
https://www.ncbi.nlm.nih.gov/pathogens/

FDA WGS
https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/

Series Objectives:

1. Discuss the research conducted at the FDA.
2. Explain how FDA science impacts public health.

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

1. Describe what the whole genome sequencing (WGS) does and how the FDA uses it.
2. Discuss how WGS improves outbreak investigations and FDA responses.
3. Identify the broader uses of WGS for FDA as a whole.
4. Talk about the WGS data housed at NCBI NIH.
5. Discuss Antimicrobial resistance databases kept and how to query them.

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

Schedule

Date/Time/Place	Lecture Title	Lecturer
Thursday, July 13, 2017 12:00 PM-1:00 PM WO Bldg 2, Rm 2031	FDA Grand Rounds: GenomeTrakr: How a Large Network of Sequencing Laboratories is Advancing Food Safety and Public Health	Marc Allard, Ph.D. Senior Biomedical Research Services

Continuing Education
The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Food and Drug Administration – Center for Drug Evaluation and Research designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-17-104-L04-P). This program meets the criteria for 1 contact hour(s) of pharmacy education.

This activity is a knowledge -based activity**.** These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

Requirements for receiving CE credit
Physicians, pharmacists, nurses and those claiming non-physician CME: attendance is verified by a sign-in sheet and completion of the final activity evaluation. For multi-day activities, participants must sign in every day. Final activity evaluations must be completed within two weeks after the activity.

Pharmacy participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. 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.

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure
Faculty
Marc Allard, Ph.D., Senior Biomedical Research Services Officer, FDA/CFSAN, has nothing to disclose.

Planning Committee
Emannuel Fadiran, PhD, RPh, Intramural Research Program Director, FDA/OC/OWH, has nothing to disclose.
Eileen Parish, MD, Medical Officer, FDA/OC/OCS/OSPD, has nothing to disclose.
Rokhsareh Shahidzadeh, MSN, RN, Senior Regulatory Health Education Specialist, OC/OCS/OSPD, has nothing to disclose.
Leslie Wheelock, MS, RN, Director OSPD, FDA/OC/OCS/OSPD, has nothing to disclose.

CE Consultation and Accreditation Team
Traci Bryant, MAT, Education Specialist, FDA/CDER/OEP/DLOD, has nothing to disclose.
Virginia Giroux, MSN, ARNP, CE Program Administrator, CDER/DLOD, has nothing to disclose.
Karen Zawalick, CE Team Leader, FDA/CDER/OEP/DLOD, has nothing to disclose.

Registration Fees and Refunds
Registration is complimentary therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).

Initial Release Date: July 13, 2017

Remote Access Instructions:

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.
https://collaboration.fda.gov/july132017grandroundsreg/event/registration.html

For technical assistance please contact Jeffery Rexrode at Jeffery.Rexrode@fda.hhs.gov.

LMS Registration link:
https://lms.learning.hhs.gov/Saba/Web/Main/goto/RegisterCatalog?offeringId=class000000000125027&oneClickLearningON=true

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.