FDA-CERSI Collaborative Research: Impacts on Advancing Public Health

Friday, September 13, 2019

FDA White Oak Building 31, Great Room

Welcome to the Office of Regulatory Science and Innovation's (ORSI's) first Center of Excellence in Regulatory Science and Innovation (CERSI) Collaborative Research Impacts Presentations Directed at Advancing Public Health.

FDA's CERSIs are joint efforts between FDA and academic institutions to work collaboratively on projects that promote regulatory science, including innovative research, training, and scientific exchange under a cooperative agreement grant.

The CERSIs play an increasingly vital role in helping FDA solve regulatory science challenges or fill knowledge gaps in areas where we have lacked the in-house resources to do so. The purpose of this session is to showcase the results and impacts of research projects in each of our four CERSIs, based on our CERSI Research Metrics:

Johns Hopkins University CERSI

Yale University – Mayo Clinic CERSI

University of Maryland, Baltimore and College Park, CERSI

University of California, San Francisco (UCSF) – Stanford University CERSI

AGENDA

10:45 AM – 11:00 AM

CERSI Projects: Highlights & Coming Attractions

Carol D. Linden, Ph.D.

Director, Office of Regulatory Science and Innovation, Office of the Chief Scientist, Office of the Commissioner

Impacts Presentations

11:00 AM – 11:15 AM

Eliciting Patient Preferences: A Case Study on Innovative Upper Limb Prostheses

This project assessed patient views of novel upper limb prosthesis benefits and risks using several different preference elicitation approaches, including interviews, focus groups, and surveys. The work contributed to developing science of patient input by helping to identify the advantages and challenges associated with different preference-elicitation approaches. This collaboration focused on building capacity to measure and incorporate patient and caregiver preferences within the context of regulatory benefit-risk assessments.

- **CERSI Presenter: John F. P. Bridges, Ph.D.**

  Johns Hopkins University CERSI

  Departments of Biomedical Informatics and Surgery, The Ohio State University College of Medicine, Professor (Adjunct), Division of Epidemiology, The Ohio State University College of Public Health, and Professor (Adjunct), Department of Health Behavior and Society, The Johns Hopkins Bloomberg School of Public Health

- **FDA Presenter: Heather Benz, Ph.D.**

  Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health (CDRH)

11:15 AM – 11:30 AM

Characterizing Potentially Unsafe Prescribing of Opioid Analgesics Using Linked EHR and Claims Data

Transmucosal immediate-release fentanyl products and some extended-release opioid analgesics require prior opioid tolerance for safe use. Prior studies using insurance claims data found low rates of prior tolerance; however, claims data can miss some prescriptions

(e.g., those paid for with cash). We used linked electronic health record (EHR) and claims data to look for evidence of tolerance in EHR prescription records and clinical notes, finding that less than half of patients had evidence of prior tolerance. Linked EHR data did not contribute substantial additional evidence of prior tolerance beyond that found in claims.

- **CERSI Presenter: Molly Jeffery, Ph.D.**

  Yale University-Mayo Clinic CERSI

  Scientific Director of Emergency Medicine Research, Research Associate, Department of Health Sciences Research, Mayo Clinic

- **FDA Presenter: Tamra Meyer, Ph.D., MPH**

  Office of Surveillance and Epidemiology (OSE), Center for Drugs Evaluation and Research (CDER)

11:30 AM – 11:45 AM

Evaluation of Bioequivalence of Lamotrigine Tablets in Epileptic Patients

Some neurologists have questioned whether bioequivalence in healthy volunteers ensures therapeutic equivalence of brand and generic antiepileptic drugs in patients with epilepsy. This randomized, double-blind, multiple-dose, steady-state, fully replicated bioequivalence study compared generic lamotrigine to brand-name Lamictal in "generic-brittle" patients with epilepsy who were already taking lamotrigine. Generic demonstrated bioequivalence to brand. Bioequivalence results in "generic-brittle" patients with epilepsy under clinical conditions support the soundness of the FDA bioequivalence standards. The American Epilepsy Society changed its position statement on generic substitution of antiepileptic drugs and acknowledges generics do not compromise efficacy.

- **CERSI Presenter: James E. Polli, Ph.D.**

  University of Maryland CERSI

  Professor and Ralph F. Shangraw/ Noxell Endowed Professor of Industrial Pharmacy and Pharmaceutics, University of Maryland School of Pharmacy

- **FDA Presenter: Wenlei Jiang, Ph.D.**

  Office of Generic Drugs (OGD), Center for Drugs Evaluation and Research (CDER)

11:45 AM – 12:00 PM

Text Processing to Detect Medication Error Information in Reports Submitted to the FDA Adverse Event Reporting System (FAERS)

Error reports about the use of medications (such as wrong medication, wrong dose or other mistakes in use) are an important class of safety reports that are different than reports of adverse events based on the physiological effects of medications. Medication error reports

submitted to FAERS can be difficult to retrieve and assess because of inconsistencies in how the medication error information is captured and coded. Using a set of manually labeled reports with medication errors, text processing methods and machine learning was used to create a simple classifier that scores individual sentences in a report for the likelihood that they refer to medication errors. Our classifier had an accuracy of 74% and provides preliminary evidence that automated methods can be used to evaluate FAERS reports for possible errors in medication use.

- **CERSI Presenter: Russ Altman, MD, Ph.D.**

  UCSF-Stanford University CERSI

  Professor, Departments of Bioengineering, Genetics, Medicine and Computer Science Stanford University, Schools of Engineering and Medicine

- **FDA Presenter: Jo Wyeth, PharmD**

  Office of Surveillance and Epidemiology (OSE), Center for Drugs Evaluation and Research (CDER)

Mix and Mingle

12:00 PM– 12:45 PM

Mix and Mingle in Great Room Atrium