U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Surveillance and Epidemiology 2023 Annual Report

Detecting, Assessing, Preventing, and Managing Risks

Table of Contents

Director's Message

Greetings,

It is my pleasure to share with you the 2023 Annual Report of the Office of Surveillance and Epidemiology (OSE) which highlights some of our major achievements in 2023.

OSE redoubled its commitment to integrating technology in the pursuit of enhancing public health with an emphasis on improving medication safety. As originally outlined in the FDA's 2019 Sentinel Strategic Plan, our focus was to explore the potential of artificial intelligence (AI) and machine learning (ML). Leveraging these technologies, our objective was to gain insights that are will help us to optimize medication safety for the public. We've employed natural language processing (NLP) for medical chart review, creating gold standard data and scalable computable phenotype algorithms. This approach to utilizing electronic health record data and ML methods aims to significantly reduce the labor-intensive demands of manual review and to streamline our operations.

Another milestone for this year was the development of our Information Visualization Platform (InfoViP). This tool, built on AI, enhances post-marketing safety surveillance by supporting OSE's safety reviewers and their work. InfoVIP incorporates NLP capabilities, ML, and advanced data visualization to present data more effectively. Using InfoVIP's NLP-based deduplication algorithm, we successfully de-duplicated the entire FAERS database and established a real-time system to process and deduplicate incoming FAERS reports as we receive them.

OSE contributed to 55 novel drug and therapeutic biologic approvals in 2023 and OSE staff were either the signal identifier or safety lead for approximately 80% of the 206 Newly Identified Safety Signals for marketed drugs opened in 2023. We also played a significant role in increasing access to opioid overdose reversal agents and maintained a steady information exchange with our international regulatory partners on a variety of topics, including artificial intelligence.

The success we experienced in 2023 can be attributed to the dedication, professionalism, and robust scientific commitment of our staff. On behalf of the OSE team, I hope you will find our annual report both informative and insightful, reflecting our unwavering commitment to advancing public health.

Best regards,

Gerald Dal Pan, MD, MHS

Organizational Structure

Office of Surveillance and Epidemiolgy

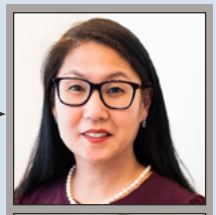
Gerald Dal Pan
Director

Robert Ball
Deputy Director

Donal Parks
Deputy Director,
Operations

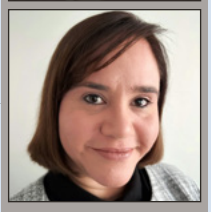
Immediate Office

Jana McAninch
Associate Director,
Public Health Intiatives

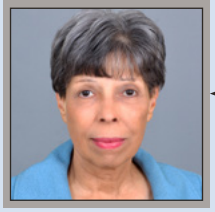


Grace Chai
Associate Director,
Special initiatives

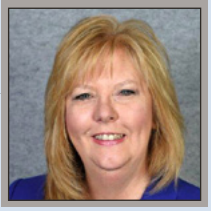
Linda Tran
Director,
Program Management
& Analysis



Germarie Sanchez-Pomales
Director,
Project Management Staff



Amarilys Vega
Director,
Regulatory Science
Staff



Maureen Melvin
Director,
Regulatory Affairs Staff

Office of Pharmacovigilance and Epidemiology

Judith Zander
Director

David Moeny
Deputy
Director

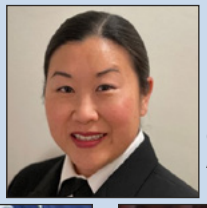
Monica Munoz
Director,
Division of
Pharmacovigilance I

Sukhminder Sandhu
Director,
Division of
Epidemiology I

Chris Jones
Director,
Division of
Pharmacovigilance II

Monique Falconer
Director,
Divsion of
Epidemiology II

Office of Medication Error Prevention and Risk Managment



Irene Chan
Acting Director
Deputy Director

Mishale Mistry
Director,
Division of
Medication Error
Prevention and
Analysis I

Sevan Kolejian
Director,
Division of
Mitigation
Assessment and
Medication Error
Sureillance

Danielle Harris
Director,
Division of
Medication Error
Prevention and
Analysis II

Cynthia LaCivita
Director,
Divsion of
Risk Managment

Who We Are and What We Do

OSE, within the Center for Drug Evaluation and Research (CDER), works to detect, assess, prevent, and manage the risks of medications so that they can be relied upon to treat disease and improve health without imposing unacceptable risks. OSE participates in the safety analysis of drugs before they are marketed to patients and consumers. After the drugs are marketed, we utilize a variety of approaches to identify and assess adverse events and medication errors that did not appear during the drug development process as well as to better understand and manage the known risks of medications.

OSE has four core functions – pharmacovigilance, pharmacoepidemiology, medication error prevention and analysis, and risk management (see Figure 1) – and operates across multiple disciplines to review and assess the safety of medicines. Everything in OSE is tied to these four core functions.

Pharmacovigilance

- Detection and assessment of safety-related issues for all marketed drug and therapeutic biological products.
- Use of surveillance tools such as the FDA Adverse Event Reporting System (FAERS) to identify new safety concerns with marketed products.

Pharmacoepidemiology

- Review of post-marketing study protocols and study reports submitted by manufacturers to inform drug safety and use.
- Conducting epidemiological studies to quantify risk and identify risk factors.
- Use of population-based data to evaluate the risks and uses of medications.

Medication Error Prevention and Analysis

- Review of proposed proprietary names for drugs and biological products, nonproprietary name suffixes for biological products, labels, labeling, and human factor studies to minimize use error.
- Review of medication error reports to identify trends in improper prescribing, dispensing, or usage of drug products.

Risk Management

- Evaluate the need for a risk mitigation strategy for all novel drugs.
- Review proposed REMS and modifications to approved REMS.
- Evaluate methods to assess the impact of mitigation strategies and review the results of those REMS assessments.

Figure 1: OSE's Four Core Functions

In 2023, OSE contributed to 55 novel biologic and drug approvals. Table 1 on page 5 highlights our involvement in proprietary name reviews (PNRs), packaging, and labeling for these novel biologic and drug approvals. Premarket reviews of human factor studies were also completed for nine of these novel biologic and drug approvals. Review of real-world evidence (RWE) supported approval of two drugs. In addition, 14 of these novel biologic and drug approvals had Postmarketing Requirements (PMRs) and six required Risk Evaluation and Mitigation Strategies (REMS).

Examples of OSE contributions to novel drug approvals include the accelerated and traditional approvals for lecanemab for treatment of early Alzheimer's Disease where OSE collaborated with the Office of New Drugs (OND) to update safety labeling and issue three PMRs at the time of full approval of lecanemab in July 2023. Furthermore, OSE played a key role in the evaluation of a new packaging configuration for Paxlovid (nirmatrelvir tablets; ritonavir tablets) that introduced single-dose blister cards to address medication errors identified with the emergency use authorization (EUA) packaging of Paxlovid.

In addition to working on novel drugs, OSE also contributed to the review of other important drug applications. For example, OSE was also instrumental in the review of human factors data that played a pivotal role in the first ever approval of a non-prescription naloxone nasal spray for emergency treatment of opioid overdose.

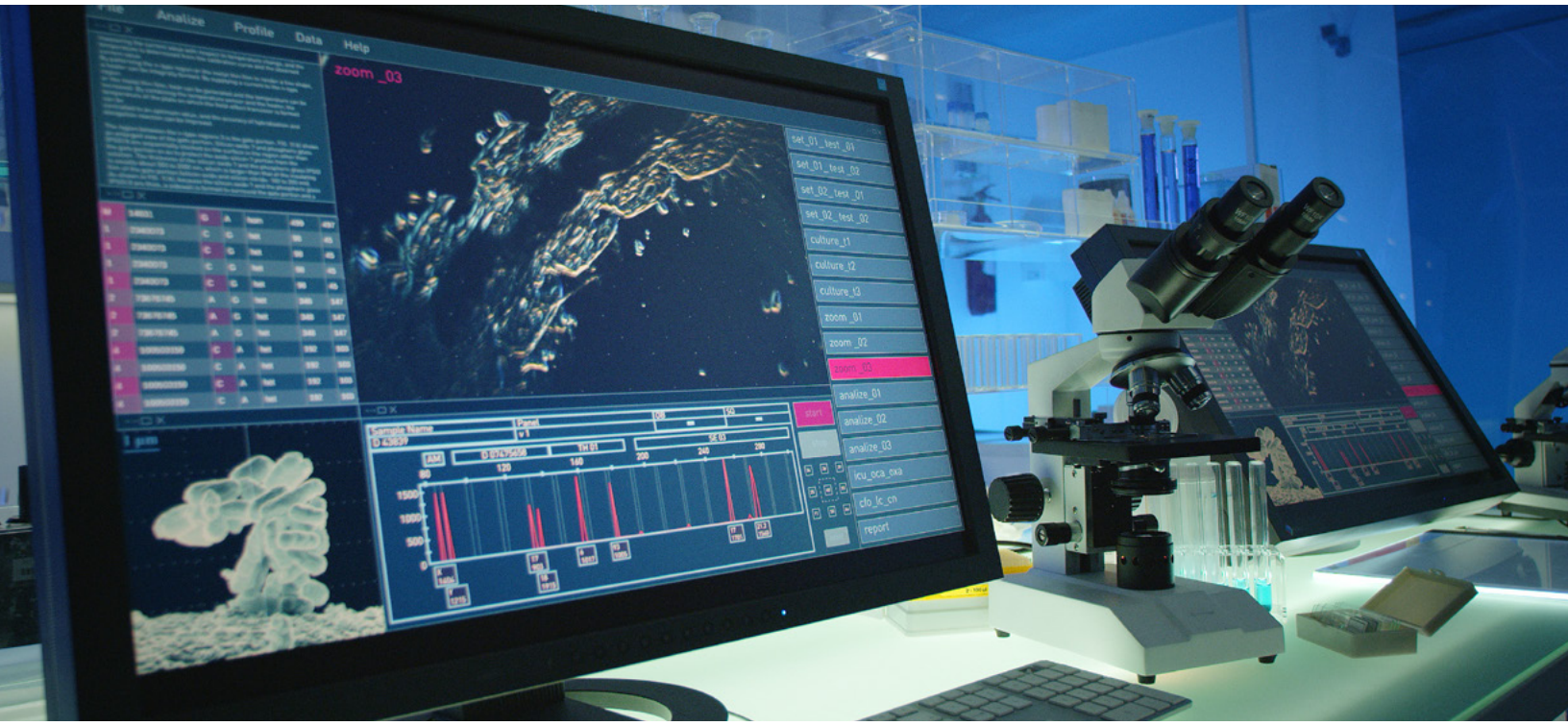


Table 1: **OSE Contributions** to 2023 Novel Drug and Biologic Approvals

Trade Name	Packaging	Labeling	Proprietary Name Review (PNR)	Human Factors Review	REMS	Postmarketing Requirement (PMR)	Real World Evidence
Agamree	●	●	●	●			
Aphexda	●	●	●				
Augtyro	●	●	●				
Beyfortus	●	●	●				
Bimzelx	●	●	●	●		●	
Brenzavvy	●	●	●				
Columvi	●	●	●				
Daybue	●	●	●				
Defencath	●	●	●				
Elfabrio	●	●	●			●	
Elrexfio	●	●	●		●		
Epkinly	●	●	●				
Exxua	●	●	●			●	
Fabhalta	●	●	●		●	●	
Filspari	●	●	●		●		
Filsuvez	●	●	●				
Fruzaqla	●	●	●				
Inpefa	●	●	●				
Izervay	●	●	●	●			
Jaypirca	●	●	●				
Jesduvroq	●	●	●			●	
Joenja	●	●	●				
Lamzede	●	●	●				
Leqembi	●	●	●			●	
Litfulo	●	●	●				
Loqtorzi	●	●	●				
Miebo	●	●	●				
Ngenla	●	●	●	●			
Ogsiveo	●	●	●				
Ojjaara	●	●	●				
Omvoh	●	●	●	●		●	
Orserdu	●	●	●				
Paxlovid	●	●	●				
Pombiliti	●	●	●				
Posluma	●	●	●				
Qalsody	●	●	●				
Rezzayo	●	●	●				
Rivfloza	●	●	●	●			
Rystiggo	●	●	●			●	
Ryzneuta	●	●	●				
Skyclarys	●	●	●				●
Sohonos	●	●	●			●	●
Talvey	●	●	●		●		
Truqap	●	●	●				
Vanflyta	●	●	●		●	●	
Velsipity	●	●	●			●	
Veopoz	●	●	●				
Veozah	●	●	●				
Wainua	●	●	●			●	
Xacduro	●	●	●	●			
Xdemvy	●	●	●	●			
Zavzpret	●	●	●			●	
Zilbrysq	●	●	●	●	●	●	
Zurzuvae	●	●	●				
Zynyz	●	●	●				

Responding to the Substance Use Crises

Approval of Three Opioid Overdose Reversal Products

OSE played a critical role in increasing access to opioid overdose reversal agents, including two non-prescription products. Because the non-prescription products are used in an emergency setting by nonmedical personnel, their design and accompanying instructions need to be carefully tested and reviewed to ensure their proper use. We participated in the review of two applications for naloxone nasal formulations, Narcan and RiVive, including review of the proprietary names, carton and container, user interface and product design, Drug Facts labeling, and human factors studies, leading to the approval of these two applications for non-prescription use. OSE participated in the February 15, 2023, Nonprescription Drugs Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee joint meeting to facilitate discussion on the adequacy of the human factors data submitted to support the Narcan application for non-prescription use. OSE also participated in the review of a prescription product for opioid reversal, Opvee (nalmefene hydrochloride) nasal spray, which included the review of the proprietary name, carton and container, user interface and product design, and human factors data leading to the approval of this application.

Mail-back Envelopes for Opioid Analgesics (OAs) Dispensed in Outpatient Settings

OSE led the review of data that supported a modification of the OA Risk Evaluation and Mitigation Strategy (OA REMS). OSE's review found that patients commonly report having unused OAs after the treatment of acute pain, such as pain following surgical procedures, and may have unused OAs when they are prescribed to treat chronic pain. When not properly disposed, these unused OAs provide opportunities for nonmedical use, accidental exposure, and overdose. In 2023, FDA notified all manufacturers of opioid analgesics that the OA REMS must be modified to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers and to revise the Patient Counseling Guide and Medication Guide to include information about the risk of unused OAs and the importance of safe disposal of unused OAs, among other changes.

Drug-Overdose Toxic-Surveillance (DOTS) Reporting Program

In January 2023, in collaboration with the American College of Medical Toxicology (ACMT), OSE launched a new program to assess the sociodemographic characteristics, clinical information, and contextual data on opioid and/or stimulant overdoses, as well as obtaining biological specimens (blood samples) from patients presenting to 17 participating medical centers across the United States. Through this collaboration, a partnership was also developed with the Center for Forensic Science Research and Education to perform qualitative blood analysis employing a panel of >1200 substances as well as quantitative measurements. Chart review and patient-provided data included clinical and behavioral information. ACMT maintains a proprietary database, the Toxicology Investigators Consortium (ToxIC) core registry, a repository of data on patients seen by medical toxicologists from January 2010 to present at 38 sites nationwide, in addition to five international sites. Four abstracts co-authored by OSE staff have been submitted for presentation at scientific meetings, including analyses of the case series to date. These analyses describe clinical and toxicologic characteristics of severe and life-threatening overdoses presenting to emergency departments within the surveillance network.

Supporting Evidence-Informed Clinical Practice Guideline Development for Management of Common Pain Conditions

In 2020, the FDA awarded the University of Pittsburgh and the American Dental Association Science & Research Institute a grant to develop a clinical practice guideline for the management of acute pain in dentistry in children, adolescents, and adults. The new clinical practice guidelines were published in the September 2023 issue of the Journal of the American Dental Association (ADA). Two additional grants were awarded in 2023, one for the development of evidence-based clinical practice guidelines on managing perioperative pain with abdominal laparoscopic surgery (University of Minnesota, September 2023), and one on management of acute low back pain (Oregon Health & Science Institute, September 2023). OSE participates in FDA advisory groups for these projects and continues to provide subject matter expertise.

Communicating about Safe Use of Controlled Substances

FDA made several advances in communicating about safe use of controlled substances, such as opioid analgesics and stimulants, in 2023, with contributions from OSE subject matter experts.

1. On April 13, 2023, as part of its ongoing efforts to address the nation's opioid crisis, the FDA announced several updates to the prescribing information of opioid pain medicines to provide additional guidance on their safe use. OSE contributed scientific evaluation and interpretation of multiple data sources and published literature relevant to these safety labeling changes.
2. On May 11, 2023, FDA announced several updates to the prescribing information of amphetamine and methylphenidate products, a class of stimulant medications used to treat attention deficit/hyperactivity disorder (ADHD), and other disorders, to update and standardize their prescribing information to inform

safe use. The labeling changes provide more consistent information for health care professionals, patients, and caregivers about risks of misuse, abuse, and addiction. OSE contributed scientific evaluation and interpretation of multiple data sources relevant to the labeling changes.

3. At a break-out session attended by about 300 people at the national Substance Abuse and Mental Health Administration's (SAMHSA) Prevention Day on January 30, 2023, OSE presented results on the prevalence, motivations, and sources for prescription stimulant nonmedical use and related harms, as well as the hazards posed by falsified stimulant products. The presentation was titled "Public Health Harms from Prescription Stimulant Diversion and Nonmedical Use."
4. During the Centers for Disease Control's (CDC) annual Prevention of Overdoses and Treatment Errors in Children Taskforce (PROTECT) meeting on November 30th and December 1st, 2023, OSE presented an analysis describing pediatric unintentional exposures to prescription medications resulting in Emergency Department (ED) visits using the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Project (NEISS-CADES) data. The PROTECT Initiative is a public-private partnership led by CDC that focuses on preventing unintentional overdoses of over-the-counter and prescription medications in children. OSE staff are collaborating with CDC staff to complete and submit a manuscript describing the findings.

Pharmacovigilance

OSE conducts post-marketing surveillance and risk assessment to identify adverse events and medication errors that may not have appeared during the drug development process, but which appear after a marketed product is used in a large population over time. OSE also monitors known adverse events and medication errors to see if their frequency or severity is changing. OSE maintains two primary systems for postmarketing drug safety surveillance, the FDA Adverse Event Reporting System (FAERS) and the Sentinel System. Each is discussed further below.

FAERS – the FDA Adverse Event Reporting System – is a database that contains adverse event reports, medication error reports, and product quality complaints related to drugs and therapeutic biological products. Drug product manufacturers and other entities are required to submit reports of adverse events that they receive or otherwise obtain associated with their products. In addition, the public (e.g., healthcare professionals and consumers) can voluntarily submit adverse event reports directly to FDA via the MedWatch Program. The collected reports are routinely monitored for emerging safety patterns.

FDA received 2,160,304 FAERS reports in 2023, slightly fewer than the 2,340,415 reports received in 2022. Of the over 2.1 million reports received in 2023, slightly more than 1.3 million were reported as serious adverse events not listed in the product labeling. OSE safety reviewers monitor the reports in FAERS, and if a potential safety signal is identified, further evaluation is performed. Based on the evaluation of the potential safety signal, OSE works with appropriate FDA staff to take regulatory action, when necessary.

In April 2020, CDER launched the Newly Identified Safety Signal (NISS) process. A NISS is a new safety signal prompting further evaluations and/or actions.

Safety reviewers in OSE identify signals from a variety of sources, with a majority of these coming from the surveillance of case reports in FAERS and the published medical literature. Among the 206 NISS opened in 2023, an OSE staff member was either the signal identifier or safety lead for approximately 80% of the NISS. Of these, OSE utilized FAERS data to contribute to the identification or evaluation of over 60 NISS.

FAERS Public Dashboard Web Statistics (2023)

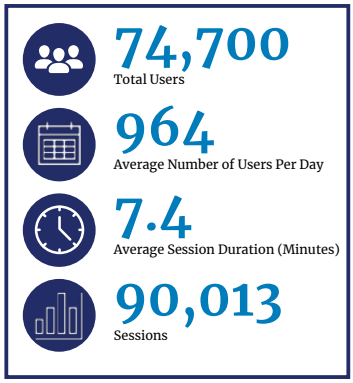


Figure 2: FAERS Public Dashboard Web Statistics

FAERS data contributed to the identification or evaluation of over 60 of the 206 NISS opened in 2023.

OSE maintains the FAERS Public Dashboard, which enables the public to search FAERS data for information on adverse events, medication errors, and product quality issues related to human drugs. The dashboard allows public users to query FAERS data in a highly interactive, user-friendly way. Data in the FAERS Public Dashboard is updated quarterly. In 2023, almost a thousand users per day accessed the dashboard.

Improvements to Pharmacovigilance Functionality

In June 2023, a new module was introduced to the FAERS platform. The Product Quality Module integrates product quality reports and adverse event reports in one platform, and provides a single source for intake, triage, and processing of Field Alert Reports, Biological Product Deviation Reports, MedWatch Product Complaint Reports, and consumer complaints received by FDA. This improved functionality now enables reviewers from both the safety and quality offices to review a single source of truth.

The number of Individual Case Safety Reports (ICSRs) added to FAERS continues to exceed 2 million annually. To address this large number of ICSRs, OSE developed the Information Visualization Platform (InfoViP), a decision support tool for postmarket safety surveillance, to improve the efficiency and scientific validity of the ICSR review and evaluation process. InfoViP incorporates artificial intelligence (AI) and advanced visualizations to support OSE safety reviewers' work.

The duplicate detection algorithm in InfoViP uses natural language processing (NLP) to efficiently compare numerous data points among a large group of ICSRs to detect potential duplicates and present them to the safety reviewer for confirmation. In 2023, the entire FAERS database, which includes 28 million reports, was de-duplicated. There is now a process in place to continually de-duplicate incoming reports. Even though all FAERS reports are de-duplicated for FDA analysis purposes, the publicly available FAERS data lists all reports including those identified as duplicates.

In 2023, the entire FAERS database, including 28 million reports, was de-duplicated. Now there is a process in place to continually de-duplicate incoming reports.

Evidence Synthesis for High-Quality Systematic Reviews

OSE staff launched a pilot to test a software tool that screens and extracts information from studies published in the biomedical literature to conduct systematic reviews of observational safety and effectiveness data. This online software tool is being used to streamline the process of conducting literature reviews in accordance with systematic review best practices, including searching multiple databases, managing references, and customizing data extraction and documentation. The goal of this pilot is to show that by using this software we can more quickly and efficiently conduct our safety assessments to increase the timeliness of regulatory actions in response to public health and safety concerns.

OSE staff also started piloting the application of large language models (LLM) in scientific literature review. Preliminary results suggest promising capability of LLM for automating literature screening tasks, which is expected to save a significant amount of time for reviewers. We will further explore the potential of LLMs in a follow-up project in 2024.

Pharmacoepidemiology

In addition to spontaneous adverse event and medication error reports in the FAERS database, FDA also operates the Sentinel System. The Sentinel System was developed to analyze large quantities of electronic healthcare data efficiently to monitor the safety of marketed drugs and to help inform regulatory decision making. Many of the projects done by Sentinel to improve data and methods available for generating real world evidence (RWE) for drug safety can also be used to advance FDA's understanding of how RWE can be generated for studying the effectiveness of drugs. For example, a Sentinel developed approach called PRINCIPLED (process guide for inferential studies using healthcare data from routine clinical practice to evaluate causal effects of drugs) is a stepwise process proposed to systematically consider key choices for study design and data analysis for non-interventional studies generating RWE. Another project developed a general framework that provides recommendations for developing algorithms for identifying patients with specific clinical conditions (computable phenotypes) through a variety of approaches, including artificial intelligence, using electronic health record data.

The "active surveillance" capabilities of the Sentinel System are an important complement to the FAERS system. Instead of waiting to receive safety data, the Sentinel System enables FDA to conduct specific analyses using large healthcare administrative claims databases. When a safety signal arises from FAERS or elsewhere, the Sentinel System can be used to systematically study the issue in a larger patient population.

The Sentinel System remains one of the world's largest multi-site, privacy-preserving, medical product safety surveillance systems with highly curated data capturing approximately 1.1 billion person-years of longitudinal data and more than 112 million patients actively accruing new data. During 2023, OSE utilized the Sentinel System in 65 medical product assessments.

Sentinel by the Numbers (2023)

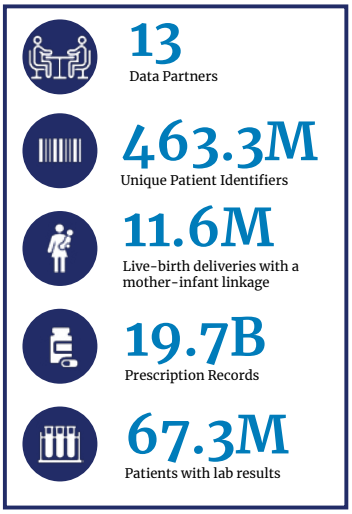


Figure 3: Sentinel System's Characteristics

Staff at the Sentinel System conduct workshops throughout the year:

- On March 8, 2023, the FDA conducted a workshop in conjunction with the Duke-Margolis Center for Health Policy to understand the use of negative controls to assess the validity of non-interventional studies of treatment using real-world evidence. The workshop discussed the advantages and disadvantages of the use of negative controls for evaluating the safety and effectiveness of regulated medical products. Stakeholders held robust discussion and provided feedback on a causal inference framework and associated next steps.
- On April 11 and 12, 2023, the FDA conducted a two-day training and innovation event where Investigators from the Sentinel Operations Center discussed surveillance of adverse outcomes following medication use in pregnancy and discussed "First Trimester Exposure to Fluoroquinolones: A Case Study in Signal Identification." Staff from the Sentinel Innovation Center highlighted a general framework for developing computable phenotyping algorithms from electronic health records.
- On November 8, 2023, the FDA, under a cooperative agreement with the Duke Margolis Center for Health Policy, hosted the 15th Annual Sentinel Initiative Public Workshop. The workshop provided opportunities for attendees to discuss recent achievements and developments as well as engage with the broader community of patients, consumers, and scientific stakeholders.

The Sentinel System has proven to be a vital source of safety information that informs regulatory decision-making and expands our knowledge of how medical products perform once they are widely used in medical practice. Additional information on the Sentinel System can be found on the FDA Sentinel Initiative page and the Sentinel Initiative website.

Preventing Risks

OSE is fully engaged in preventing risks throughout a product's lifecycle. As part of the FDA preapproval process for new drug products, OSE reviews and determines the acceptability of proposed proprietary names for drugs and biological products to minimize medication errors associated with product proprietary name confusion. OSE also designates distinguishing suffixes for nonproprietary names of biological products.

443

Total Proprietary Name Reviews conducted from October 1, 2022 – September 30, 2023

Application Type	Receipts	Performance Goal Met (%)	Performance Goal Exceeded
IND	138	94	Yes
NDA/BLA	226	92	Yes
BsUFA IND	18	93	Yes
BsUFA BLA	40	97	Yes
ANDA*	21	94	N/A

Table 2: Proprietary Name Reviews from October 1, 2022 – September 30, 2023

***Note: Proprietary Name Reviews (PNRs) are not subject to GDUFA III but the performance is being tracked based on a 180-day review time frame.**

Fiscal Year (FY) 2023 (October 1, 2022, to September 30, 2023) user fee goals for the review of proprietary names are listed in Table 2. OSE met or exceeded all performance goals in FY 2023 for review of proprietary names for both BLA/NDAs and INDs.

OSE conducted 58 Nonproprietary Suffix Reviews from October 1, 2022 – September 30, 2023.

OSE reviews proposed container labels, carton labeling, Prescribing Information, patient labeling (including the Instructions for Use and Medication Guides), packaging, product design, and human factors submissions to minimize or eliminate hazards that can contribute to medication or use errors.

Work Type	No. Completed
Suffix review for 351(a) BLA	28
Suffix review for 351(k) BLA	20
IND	10

Table 3: Nonproprietary suffix review for biological products from October 1, 2022 – September 30, 2023

Human factors (HF) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system. OSE's HF program exists to enhance patient safety in the healthcare environment by focusing on the design of the user interface of medical products. By collecting data from

representative participants in simulated, though realistic scenarios, HF studies help FDA assess the effectiveness of proposed risk control measures in order to determine whether the design of the user interface supports the safe and effective use of the medical product.

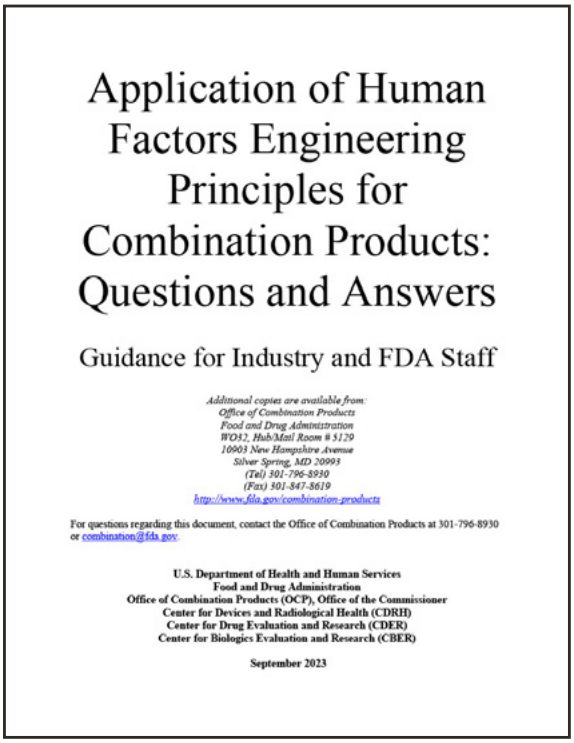
A use-related risk analysis (URRA) serves as the backbone of the human factors engineering process. Sponsors utilize URRAs to identify and characterize use-related risks associated with the medical product's user interface design, and the URRA helps to identify hazards that may require further risk mitigation strategies.

In FY 2023, OSE received 69 HF validation study protocols and 416 other HF submissions or consults, including HF validation study results reports, formal industry meeting requests, and use-related risk analyses.

OSE continues its involvement in the detection and prevention of medication errors after a product is approved. It is the CDER scientific lead for medication error pharmacovigilance, which includes surveillance planning, safety signal detection, assessment, and prevention of medication errors. OSE works collaboratively with other CDER offices to investigate medication error safety signals for marketed drug products, including nonprescription, prescription, generics, therapeutic biological products and biosimilars, to determine if regulatory action is needed to mitigate the errors. Postmarketing monitoring of medication errors helps assess the effectiveness of the Human Factors and Proprietary Name program and provides a feedback loop to inform premarket measures aiming to reduce medication errors.

OSE collaborates with external stakeholders, including patient safety organizations, other government agencies, international regulators, and researchers to understand the causes of medication errors, identify potential mitigation strategies, and identify effective interventions to prevent errors. In 2023, for example, OSE evaluated medication error reports concerning reported confusion between norepinephrine and nicardipine (premix bags) that resulted in patient harm. In collaboration with other FDA offices, the norepinephrine overwrap labeling was revised to minimize the risk of this particular issue recurring.

OSE provided key subject matter expertise to a final guidance published in September 2023 that provided information in a question-and-answer format on the application of human factors engineering principles to the development of combination products as defined under the regulations at 21 CFR part 3. This guidance discusses the definition of a combination product critical task, considerations for combination products due to interaction of drug and device constituent parts, training as part of the user interface, and HF validation data to support the combination product user interface that may be included in a premarket submission.



Application of Human Factors Engineering Principles for Combination Products: Questions and Answers

Guidance for Industry and FDA Staff

Additional copies are available from:
Office of Combination Products
Food and Drug Administration
WO32, Hub/Mail Room # 5129
10903 New Hampshire Avenue
Silver Spring, MD 20993
(Tel) 301-796-8930
(Fax) 301-847-8619
http://www.fda.gov/combination-products

For questions regarding this document, contact the Office of Combination Products at 301-796-8930 or combination@fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Combination Products (OCP), Office of the Commissioner
Center for Devices and Radiological Health (CDRH)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

September 2023

Risk Management

Risk Evaluation and Mitigation Strategies (REMS)

A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of a particular medication. Although all medications have labeling that informs health care professionals and patients about medication risks, only a few medications require a REMS. REMS are not designed to mitigate all the risks of a medication; rather, REMS focus on preventing, monitoring, and/or managing a specific serious risk by informing, educating, and reinforcing actions to reduce the frequency and/or severity of the event.

REMS may include a Medication Guide (MG), Communication Plan (CP), certain packaging and safe disposal technologies for drugs that pose a serious risk of abuse or overdose, and/or Elements to Assure Safe Use (ETASU). REMS with ETASU have additional requirements to mitigate risks, such as pregnancy tests to avoid prenatal exposure to a teratogenic drug. Manufacturers are required to assess the effectiveness of the REMS in meeting its risk mitigation goal.

In 2023, 11 REMS with ETASU were approved, 35 REMS were modified, and two REMS were released. The REMS Public Dashboard serves to improve data access and transparency, and also allows users to quickly visualize trends and locate details of the REMS programs. Data used in this dashboard are pulled from existing data files available on the REMS@FDA website. Users can create visualizations and charts for total and active REMS programs, REMS with ETASU, REMS modifications, revisions, and released REMS programs.

On the REMS Dashboard, the active REMS page now enables users to directly access materials via hyperlink for each active REMS, including the REMS document, patient brochures, enrollment forms, and training materials. Data refresh is now automated and updated weekly.

REMS Public Dashboard Web Statistics

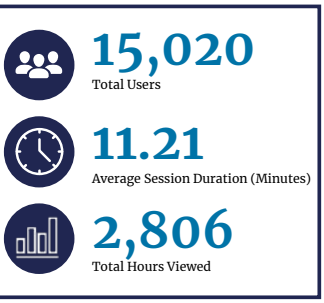


Figure 4: REMS Public Dashboard Wed Statistics

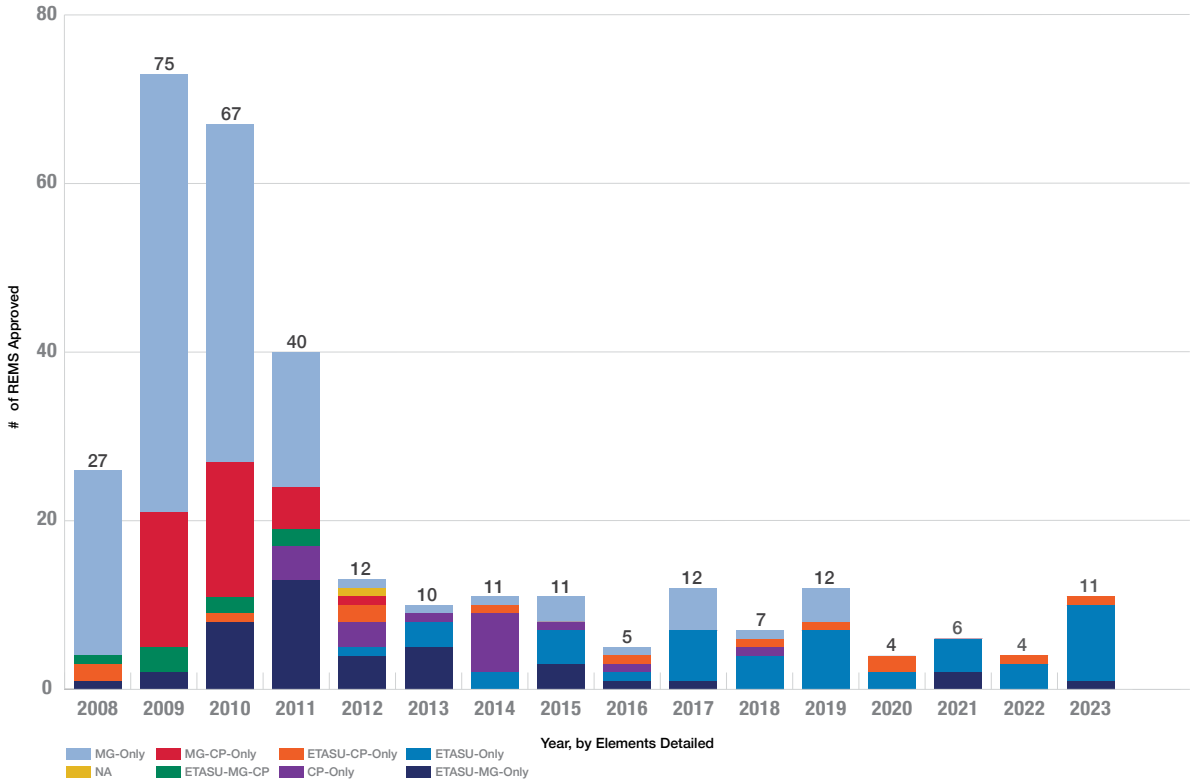
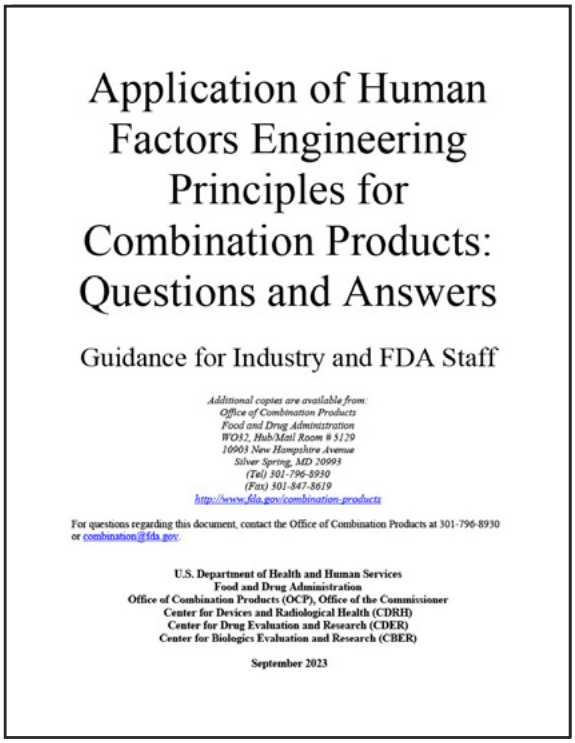


Figure 5: REMS Public Dashboard

Under certain circumstances, a REMS can be 'released' (i.e., is no longer required). In September of 2023, two REMS were released: Lotronex REMS and Alosetron REMS. Lotronex (alosetron hydrochloride) and approved generics are FDA approved for the treatment of severe diarrhea-predominant irritable bowel syndrome in women. Although safety risks for Lotronex and approved generics still exist, FDA determined the REMS for these drugs are no longer necessary to ensure the benefits outweigh the risks of ischemic colitis and serious complications of constipation.

OSE led the finalization of the guidance for industry entitled "Format and Content of a REMS Document." This final guidance, published in January 2023, describes the format of a proposed REMS document and incorporated extensive stakeholder feedback. The guidance finalizes the revised draft guidance issued in 2017 and announces the availability of the technical specifications document entitled "REMS Document Technical Conformance Guide."

OSE was the lead for the March 28 and 29, 2023, joint Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee Meeting to discuss the iPLEDGE REMS. The purpose of this meeting was to discuss proposed changes to the iPLEDGE REMS requirements to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of isotretinoin oral capsules for patients.



Application of Human Factors Engineering Principles for Combination Products: Questions and Answers

Guidance for Industry and FDA Staff

Additional copies are available from:
Office of Combination Products
Food and Drug Administration
WO32, Hub/Mail Room # 5129
10903 New Hampshire Avenue
Silver Spring, MD 20993
(Tel) 301-796-8930
(Fax) 301-847-3619
http://www.fda.gov/combination-products

For questions regarding this document, contact the Office of Combination Products at 301-796-8930 or combination@fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Combination Products (OCP), Office of the Commissioner
Center for Devices and Radiological Health (CDRH)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

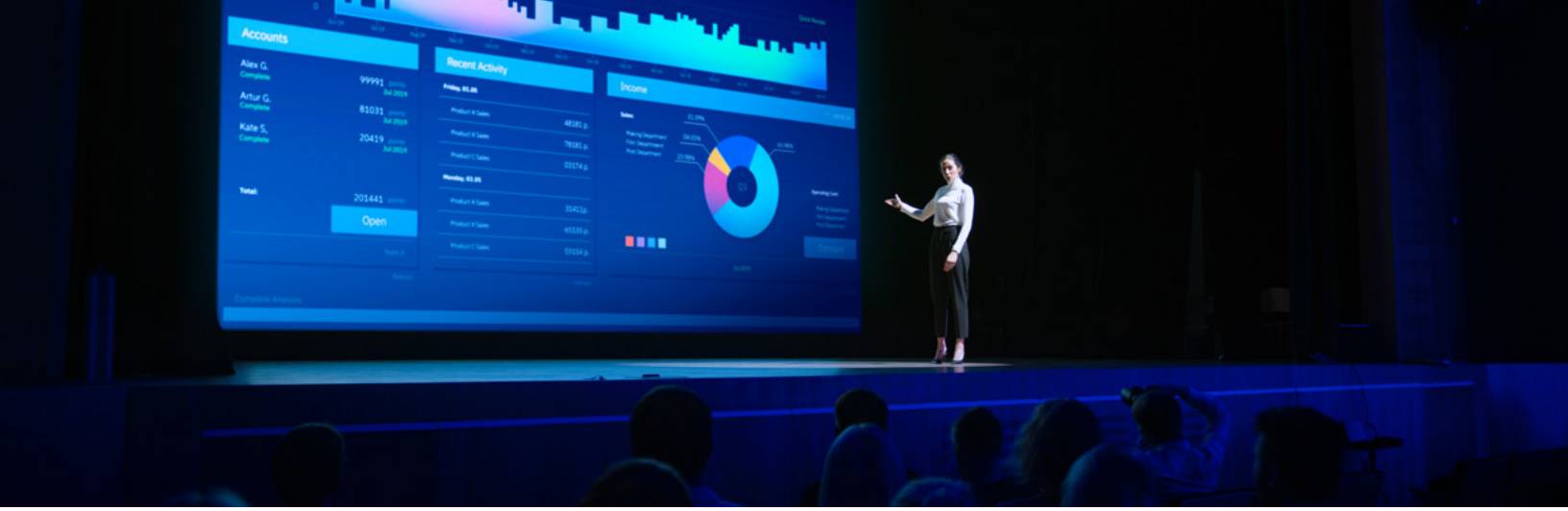
September 2023

Following the meeting, in November 2023, FDA notified isotretinoin manufacturers to modify the iPLEDGE REMS within six months for FDA review.

REMS requirements can be burdensome for prescribers, pharmacists, and patients because:

- Completion of REMS requirements is often done outside of stakeholders' clinical workflows.
- In some cases, manual processes are used, which can be costly and time-consuming for prescribers and pharmacists and can create delays or barriers to medication access for patients.
- Each REMS program is slightly different, potentially making it difficult to exchange information across REMS administrator systems, electronic health records, and pharmacy information management systems.

To address some of these issues, the FDA, under a contract with the MITRE Corporation and with stakeholders through an open community under the health data standards development organization Health Level Seven (HL7), is working to reduce the burden of REMS implementation and optimize patient outcomes by integrating REMS into prescribers' and pharmacists' clinical workflows. OSE has now advanced to Phase 1 of what is being called the REMS integration project and plans to transition from the planning to the execution phase of the HL7® REMS Integration Use Case.



Engaging Stakeholders

OSE engages multiple stakeholders by holding scientific meetings and public workshops, convening interagency workgroups, collaborating with international partners, and giving presentations at conferences. In 2023, OSE staff gave 83 presentations on a wide variety of topics, reaching thousands of students, researchers, as well as industry professionals in the U.S. and overseas. Presentations on topics such as the Sentinel System, FAERS, and the REMS Public Dashboard serve to improve stakeholder engagement and help users better understand and utilize tools developed by OSE.

9

OSE Super Office Director ***Gerald Dal Pan*** *gave nine presentations to international audiences.*

In Spring 2023, FDA collaborated with the Reagan-Udall Foundation for the FDA to hold two meetings seeking stakeholder input on important public health strategies to address the opioid crisis – one on "Understanding Fatal Overdoses to Inform Product Development and Public Health Interventions to Manage Overdose", March 8-9, 2023, and one on "Considerations for Buprenorphine Initiation and Maintenance Care", May 10-11, 2023.

On September 18-19, 2023, FDA, under a cooperative agreement with the Duke-Margolis Center for Health Policy, convened a public workshop as part of PDUFA VII commitments on postapproval pregnancy safety studies. The workshop addressed the development of a consistent and transparent approach to help decide when and what postapproval pregnancy safety studies might optimally be used to obtain timely evidence of safety for regulatory decision making. Participants heard from OSE staff regarding an overview of considerations to optimize the use of postapproval non-interventional pregnancy safety studies and a proposed draft framework for decision making.

OSE regularly exchanges information with international regulators on safety surveillance topics, adverse event reporting, medication error prevention and analysis, and other issues of common interest. The goal of these interactions is to collaborate on drug safety activities and support global harmonization on similar regulatory programs. In 2023, OSE exchanged information on more than 270 topics, including COVID-19 and artificial intelligence.

OSE is a member of the International Medication Safety Network (IMSN), an international network that promotes global safe medication practices to improve patient safety. At the October 2023, IMSN Annual Meeting, OSE led a session and panel discussion with international regulators and monitoring centers on opportunities for harmonization, research, and strategies to minimize the risk of medication errors.

Looking to the Future

In 2024, OSE will continue to be a world leader in pharmacovigilance, risk management, pharmacoepidemiology, and medication error prevention.

OSE will continue our responsibilities under the Prescription Drug User Fee Act VII, the Generic Drug User Fee Act III, and the Biosimilar User Fee Act III. OSE will continue using additional innovative strategies to quantify, understand, and confront the nonmedical use of opioids and stimulants through acquiring and analyzing diverse data sources and supporting external research to inform policy and regulatory decisions.

We will prepare for the award of the next Sentinel System contract, as we continue evaluating innovative approaches to increase the quality of analyses based on data in EHRs for safety assessments. The Sentinel Quarterly Newsletter will continue to disseminate knowledge and advance regulatory science. Furthermore, OSE will continue to explore novel methods, such as artificial intelligence, to increase the efficiency of our work, including processing the growing number of ICSRs submitted to FAERS.

OSE will continue to seek innovative and science driven approaches for REMS assessments. We will continue to support the Health Level 7 International (HL7®) CodeX® REMS Integration Use Case which aims to reduce the burden associated with REMS implementation by integrating REMS activities into the health care system. Looking to the future, the REMS Integration Use Case Community will test the REMS Integration Prototype via HL7® Connectathons (community testing opportunities), develop a REMS standard (HL7 FHIR Implementation Guide (IG)), and engage in real world testing.

We will strengthen our interactions with international regulatory partners to increase the exchange of information to support global harmonization on similar regulatory programs. These interactions enhance our surveillance activities and help inform emerging safety concerns.

Appendix 1: Organizational Structure

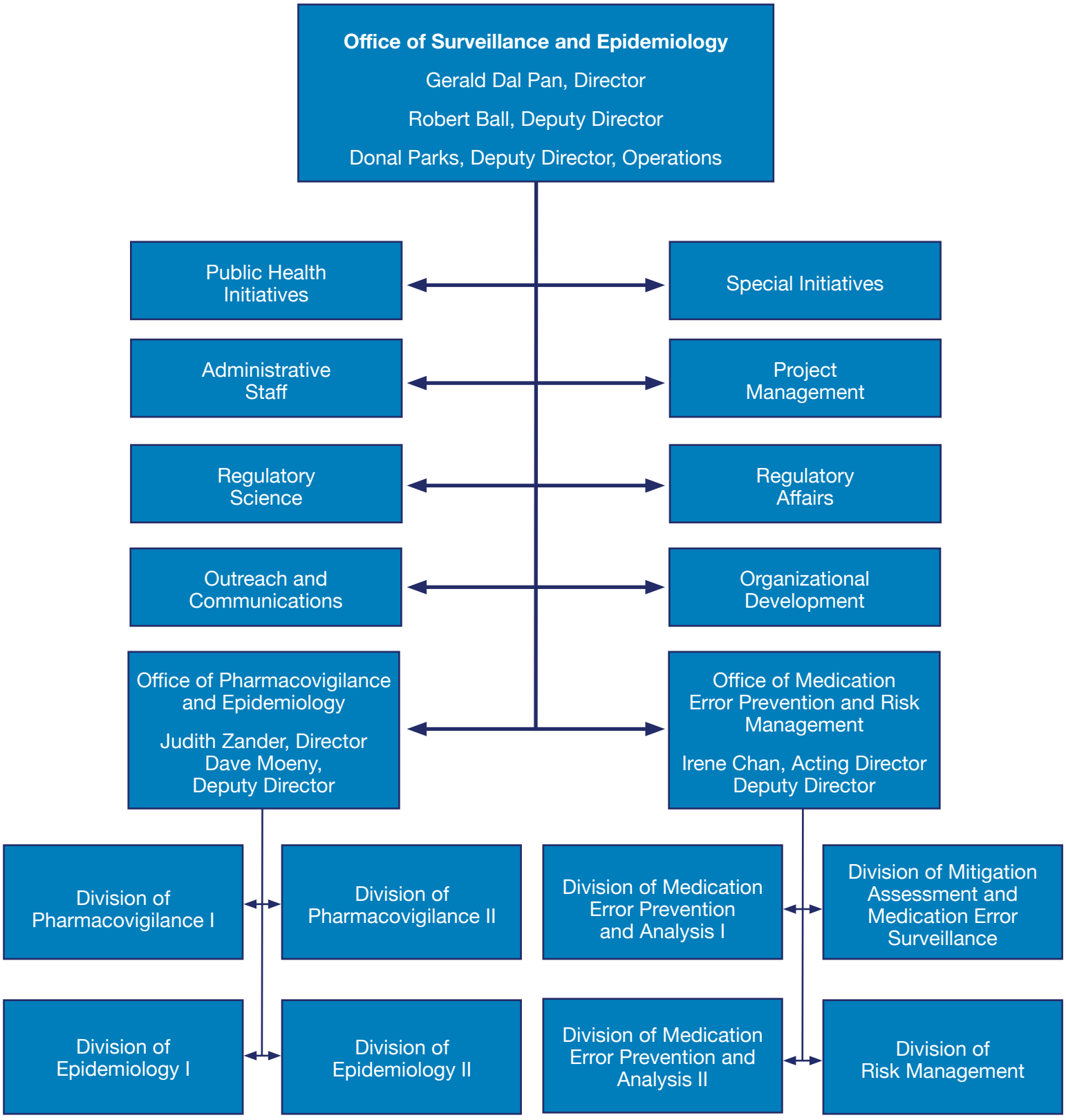


Figure 6: OSE Org Chart

Appendix 2: 2023 Publications

Contributors Bolded names represent OSE staff	Title	Citation
Vititoe SE, Govil P, Baglivo A, Beebe E, Garry EM, Gatto NM, Lasky T, Chakravarty A, **Bradley MC, Perez-Vilar S**, Rivera DR, Quinto K, Clerman A, Rajpal A, Frajzyngier V.	A descriptive cohort study of drug utilization patterns among patients hospitalized with Coronavirus disease 2019 in the United States, January 2021–February 2022	*Vititoe SE, Govil P, Baglivo A, et al. A descriptive cohort study of drug utilization patterns among patients hospitalized with Coronavirus disease 2019 in the United States, January 2021–February 2022. Open Forum Infect. Dis. 2023 Jul 7; 10(7).* doi: 10.1093/ofid/ofad339
Desai R, **Bradley MC**, Lee H, Eworuke E, Weberpals J, Wyss R, Schneeweiss S, **Ball R**.	A simulation-based approach to assess the potential impact of unmeasured confounding on study validity at the design stage of non-interventional studies	*Desai R, Bradley MC, Lee H, et al. A simulation-based approach to assess the potential impact of unmeasured confounding on study validity at the design stage of non-interventional studies. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 573.* doi: 10.1002/pds.5687
Apata J, Lyons JG, **Bradley MC**, Ma Y, Kempner ME, **Kim I, Eworuke E, Pennap D, Mosholder A**.	Assessing the risk of intentional self-harm in montelukast users: an updated Sentinel System analysis using ICD-10 coding	*Apata J, Lyons JG, Bradley MC, et al. Assessing the risk of intentional self-harm in montelukast users: an updated Sentinel System analysis using ICD-10 coding. J Asthma. 2023.* doi: 10.1080/02770903.2023.2293064
Mohamoud M, Cheng C, Ryan D, Kim I, Wu E, Muñoz M, Kortepeter C, Pinnow E, Dal Pan G.	Assessment of the impact of mandated postmarketing pediatric-focused safety reviews on safety-related regulatory actions 2013-2019	*Mohamoud M, Cheng C, Ryan D, et al. Assessment of the impact of mandated postmarketing pediatric-focused safety reviews on safety-related regulatory actions 2013-2019. Clin Pharmacol Ther. 2023 Apr 6.* doi: 10.1002/cpt.2900
Adimadhyam S, Hawrusik R, Seung Lee H, Jjingo JJ, Baumblatt J, Kempner M, Wiley M, Petrone A, Zhao Y, **Stojanovic D**, Eworuke E, **Ajao A**.	Association between race and COVID-19 outcomes in the United States (2020 – 2021).	*Adimadhyam S, Hawrusik R, Seung Lee H, et al. Association between race and COVID-19 outcomes in the United States (2020 – 2021). Poster presentation. 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 482-483.* doi: 10.1002/pds.5687
Fowler AC, Jacobo-Rubio R, **Xu J**.	Authorized generics in the US: prevalence, characteristics, and timing, 2010–19	*Fowler AC, Jacobo-Rubio R, Xu J. Authorized generics in the US: prevalence, characteristics, and timing, 2010–19. Health Aff. 2023 Aug 7; 42(8): 1071-1080.* doi: 10.1377/hlthaff.2022.01677
Perez-Vilar S, Karami S, Long K, Leishear K.	Cannabidiol exposures in the United States, National Poison Data System, July 2014–June 2021	*Perez-Vilar SA, Karami S, Long K, Leishear K. Cannabidiol exposures in the United States, National Poison Data System, July 2014–June 2021. Clin. Toxicol., 61(2): 123-130.* doi: 10.1080/15563650.2022.2156881
Dal Pan G, Li J, Concato J.	Case studies of FDA recently approved product applications using real-world evidence	*Dal Pan G, Li J, Concato J. The Evidence Base [Internet]. Case studies of FDA recently approved product applications using real-world evidence: an interview with Jie Li, Gerald Dal Pan and John Concato, FDA; 2023 Aug 16. Available from:* https: //www.evidencebaseonline.com/fda-case-studies-using-real-world-evidence/

Contributors Bolded names represent OSE staff	Title	Citation
Daubresse M, Seitz A, Meyer T, Ho A, Sivilus M, Geller AI, Lind JN.	Changes in pediatric emergency department visits and hospitalizations for unintentional exposures to oral prescription medications in the United States, 2010–2021	*Daubresse M, Seitz A, Meyer T, et al. Changes in pediatric emergency department visits and hospitalizations for unintentional exposures to oral prescription medications in the United States, 2010–2021. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 435.* doi: 10.1002/pds.5687
Jones CM, Olsen Y, Ali MM, Sherry TB, **Mcaninch J**, Creedon T, Juliana P, Jacobus-Kanto L, Baillieu R, Diallo MM, Thomas A, Gandotra N, Sokolowska M, Ling S, Compton W.	Characteristics and prescribing patterns of clinicians waivered to prescribe buprenorphine for opioid use disorder before and after release of new practice guidelines	*Jones CM, Olsen Y, Ali MM, et al. Characteristics and prescribing patterns of clinicians waivered to prescribe buprenorphine for opioid use disorder before and after release of new practice guidelines. JAMA Health Forum. 2023 Jul 7; 4(7).* doi: 10.1001/jamahealthforum.2023.1982
Phan, M, Cheng, C, Dang, V, Wu E, Muñoz M.	Characterization of pediatric reports in the US Food and Drug Administration Adverse Event Reporting System from 2010–2020: A cross-sectional study	*Phan, M, Cheng, C, Dang, V, Wu E, Muñoz M.Characterization of pediatric reports in the US Food and Drug Administration Adverse Event Reporting System from 2010–2020: A cross-sectional study. Ther Innov Regul Sci. 2023 Jun 23; 57: 1062–1073.* doi: 10.1007/s43441-023-00542-0
Naples JG, Mundkur M, Burkhart K, **Jones SC**.	Clinical harms associated with xylazine use in humans	*Naples JG, Mundkur M, Burkhart K, Jones SC. Clinical harms associated with xylazine use in humans. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 468.* doi: 10.1002/pds.5687
Sarpatwari A, Tessema FA, Mitra-Majumdar M, Been Lee S, Zakoul H, Brown BL, **Toyserkani GA, Oswell K, Hawkins Shaw KH, Zendel L, LaCivita C, Dal Pan GJ,** Avorn J, Kesselheim AS.	Communicating drug safety and safe use conditions in risk evaluation and mitigation strategy materials	*Sarpatwari A, Tessema FA, Mitra-Majumdar M, et al. Communicating drug safety and safe use conditions in risk evaluation and mitigation strategy materials. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 299-300.* doi: 10.1002/pds.5687
Eworuke E, Welch E, Haug N, Morgan C, Lee HS, Zhao Y, Huang TY.	Comparative risk of angioedema with sacubitril-valsartan versus renin-angiotensin-aldosterone inhibitors	*Eworuke E, Welch E, Haug N, et al. Comparative risk of angioedema with sacubitril-valsartan versus renin-angiotensin-aldosterone inhibitors. J Am Coll Cardiol. 2023 Jan 24, 81 (4): 321-331.* doi: 10.1016/j.jacc.2022.10.033
Howell BA, Black AC, Grau LE, Lin HJ, **Greene C,** Lee H, Heimer R, Hawk KE, D'Onofrio G, Fiellin DA, Becker WC.	Concordance between controlled substance receipt and post-mortem toxicology in opioid-detected overdose deaths: a statewide analysis	*Howell BA, Black AC, Grau LE, et al. Concordance between controlled substance receipt and post-mortem toxicology in opioid-detected overdose deaths: A statewide analysis. Drug Alcohol Depend. 2023;244: 109788.* doi: 10.1016/j.drugalcdep.2023.109788

Contributors Bolded names represent OSE staff	Title	Citation
Smith JC, Williamson BD, Cronkite DJ, Park D, Whitaker JM, McLemore MF, Osmanski JT, Winter R, Ramaprasan A, Kelley A, Shea M, **Wittayanukorn S, Stojanovic D,** Zhao Y, Toh S, Johnson KB, Aronoff DM, Carrell DS.	Data-driven automated classification algorithms for acute health conditions: applying PheNorm to COVID-19 disease	*Smith JC, Williamson BD, Cronkite DJ, et al. Data-driven automated classification algorithms for acute health conditions: applying PheNorm to COVID-19 disease. J. Am. Med. Inform. Assoc.* doi: 10.1093/jamia/ocad241
Wong HL, Zhang R, Lufkin B, Feng Y, Lo AC, Ngaiza M, Wernecke M, Ryan Q, **Vega A,** MaCurdy TE, Kelman JA, **Graham DJ**.	Disparities in erythropoiesis-stimulating agent use after changes in Medicare reimbursement and implementation of a risk evaluation and mitigation strategy	*Wong HL, Zhang R, Lufkin B, et al. Disparities in erythropoiesis-stimulating agent use after changes in Medicare reimbursement and implementation of a risk evaluation and mitigation strategy. Drugs Ther Perspect. 2023 Jan; 39: 29-39.* doi: 10.1007/s40267-022-00969-9
Stagner MK, Caro JC, **Dutcher SK, Moeny D,** Rosofsky R, Kiernan D, Shockro LA, Mai A, Pritchard JE, Lippmann SJ, Adhikari P, Hammill BG.	Diversifying the FDA's sentinel system with rigorous quality inclusion rules for the U.S. Medicaid population	*Stagner MK, Caro JC, Dutcher SK, et al. Diversifying the FDA's sentinel system with rigorous quality inclusion rules for the U.S. Medicaid population. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023.. Pharmacoepidemiol Drug Saf. 32(S1): 418.* doi: 10.1002/pds.5687
Freeman PR, **McAninch J,** Dasgupta N, Oyler DR, Slavov K, **Collins C,** Hargrove S, Freeman E, Miracle S, Slavova S.	Drugs involved in Kentucky drug poisoning deaths and relation with antecedent controlled substance prescription dispensing	*Freeman PR, McAninch J, Dasgupta N, et al. Drugs involved in Kentucky drug poisoning deaths and relation with antecedent controlled substance prescription dispensing. Subst Abuse Treat Prev Policy. 2023 Sep 1; 18(53).* doi: 10.1186/s13011-023-00561-y
Vititoe SE, Govil P, Baglivo A, Beebe E, Garry EM, Gatto NM, Lasky T, Chakravarty A, **Bradley MC, Perez-Vilar S,** Rivera DR, Quinto K, Clerman A, Rajpal A, Frajzyngier.	Drug utilization patterns among patients hospitalized with COVID-19 in the United States (January 2021 – February 2022)	*Vititoe SE, Govil P, Baglivo A, et al. Drug utilization patterns among patients hospitalized with COVID-19 in the United States (January 2021 – February 2022). Spotlight Poster Presentation. 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 450.* doi: 10.1002/pds.5687
Wu L, Gray M, **Dang O,** Xu J, Fang H, Tong W.	Enhancing drug labeling text mining and analysis with AI language modeling	*Wu L, Gray M, Dang O, Xu J, Fang H, Tong W. RxBERT: Enhancing drug labeling text mining and analysis with AI language modeling. Exp Biol Med (Maywood). 2023 Nov; 248(21): 1937-1943.* doi: 10.1177/15353702231220669
Yang F, Huang Y, Lerro C, **Liu W,** Fiero M, Feng Z, Kanapuru B, Patel T, Amiri-Kordestani L, Ison G, Fashoyin-Aje LA, Kluetz P, Singh H, Rivera D.	Enrollment representation of age, race, and ethnicity in ovarian cancer registrational clinical trials (2010-2020): an evaluation by the U.S. Food and Drug Administration	*Yang F, Huang Y, Lerro C, et al. Enrollment representation of age, race, and ethnicity in ovarian cancer registrational clinical trials (2010-2020): an evaluation by the U.S. Food and Drug Administration. J. Clin. Oncol. 2023 May 31; 41(16_suppl).* doi: 10.1200/jco.2023.41.16_suppl.e18527
Shoaibi A, Lloyd PC, Wong HL, Clarke TC, Chillarige Y, Do R, Hu M, Jiao Y, Kwist A, Lindaas A, Matuska K, McEvoy R, Ondari M, Parulekar S, Shi X, Wang J, Lu Y, Obidi J, **Zhou CK,** Kelman JA, Forshee RA, Anderson SA.	Evaluation of potential adverse events following COVID-19 mRNA vaccination among adults aged 65 years and older: two Self-controlled studies in the U.S. vaccine	*Shoaibi A, Lloyd PC, Wong HL, Clarke TC, et al. Evaluation of potential adverse events following COVID-19 mRNA vaccination among adults aged 65 years and older: two Self-controlled studies in the U.S. Vaccine. 2023 Jul 19; 41(32): 4666-4678.* doi: 10.1016/j.vaccine.2023.06.014

Contributors Bolded names represent OSE staff	Title	Citation
Toyserkani GA, Ewusie SB, Turk P, Quick J, Morrato EH.	Evolution of cross-sectional survey protocol quality over time: a case series of index U.S. REMS knowledge survey protocols (2007–2020)	*Toyserkani GA, Ewusie SB, Turk P, Quick J, Morrato EH. Evolution of cross-sectional survey protocol quality over time: a case series of index U.S. REMS knowledge survey protocols (2007–2020). Drug Saf. 2023 Sep 12; 46: 1073–1087.* doi: 10.1007/s40264-023-01344-x
Perez-Vilar S, Karami S, Wiley M, **Long K,** Martinez AI, **Leishear K,** Epperson M, **Radin R,** Greene P, **Mcaninch J,** Burk J.	Expanding capabilities for unapproved cannabis-derived product surveillance in the United States, TriNetX, July 1, 2018–June 30, 2022	*Perez-Vilar S, Karami S, Wiley M, et al. Expanding capabilities for unapproved cannabis-derived product surveillance in the United States, TriNetX, July 1, 2018–June 30, 2022. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 479.* doi: 10.1002/pds.5687
Perez-Vilar S, Karami S, Draper C, **Long K,** Barrett K, **Leishear K,** Nagavedu K, **Radin R,** Hoffman E, Greene P, Martinez AI, **Mcaninch J,** Kluberg SA.	Exploring the use of electronic health records (EHR) data for active safety surveillance of Epidiolex in PCORnet, July 1, 2018–July 1, 2022	*Perez-Vilar S, Karami S, Draper C, al. Exploring the use of electronic health records (EHR) data for active safety surveillance of Epidiolex in PCORnet, July 1, 2018–July 1, 2022. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 482-483.* doi: 10.1002/pds.5687
da Silva Macarenco A, **Toyserkani GA.**	Have REMS programs reached stable state 7 years post-approval?	*da Silva Macarenco A, Toyserkani GA.* Have REMS programs reached stable state 7 years post-approval? *Poster presented at: 2023 FDA Science Forum; June 13-14, 2023.*
Bradley MC, Cosgrove A, **Perez-Vilar S,** Eworuke E, Rosen E, Fuller CC, McLean LE, Perlin J, Poland RE, Sands KE, Rai A.	High dose dexamethasone for COVID-19 not common in a large US hospital network	*Bradley MC, Cosgrove A, Perez-Vilar S, et al. High dose dexamethasone for COVID-19 not common in a large US hospital network. Poster presentation. 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 198.* doi: 10.1002/pds.5687
Cotter S, Jones SC, Coquia S, Krefting I**, Mundkur M.**	Hypersensitivity reactions with ultrasound contrast agents in patients with a history of polyethylene glycol allergy	*Cotter S, Jones SC, Coquia S, Krefting I, Mundkur M. Hypersensitivity reactions with ultrasound contrast agents in patients with a history of polyethylene glycol allergy. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 471.* doi: 10.1002/pds.5687
Ngufor C, Yao X, Inselman JW, Ross JS, Dhruva SS, **Graham DJ,** Lee J-Y, Siontis KC, Desai NR, Polley E, Shah ND, Noseworthy PA.	Identifying treatment heterogeneity in atrial fibrillation using a novel causal machine learning method	*Ngufor C, Yao X, Inselman JW, et al. Identifying treatment heterogeneity in atrial fibrillation using a novel causal machine learning method. Am Heart J. 2023 Jun; 260: 124-140.* doi: 10.1016/j.ahj.2023.02.015

Contributors Bolded names represent OSE staff	Title	Citation
Kim T, Brinker A, Croteau D, Lee PR, Baldassari LE, Stevens J, Hughes A, Tomaino J, deFonseka A, Altepeter T, **Kortepeter CM.**	Immune-mediated colitis associated with ocrelizumab: A new safety risk	*Kim T, Brinker A, Croteau D, et al. Immune-mediated colitis associated with ocrelizumab: A new safety risk. Mult Scler. 2023;29(10): 1275-1281.* doi: 10.1177/13524585231195854
Neyarapally GA, Millikan ED, Manzo C.	Implementation and integration of Risk Evaluation and Mitigation Strategies into the healthcare system	*Neyarapally GA, Millikan ED, Manzo C. Implementation and integration of Risk Evaluation and Mitigation Strategies into the healthcare system. Appl Clin Inform. 2023 Mar; 14(2): 354-355.* doi: 10.1055/s-0043-1767683
Ter-Minassian M, DiNucci AJ, Barrie IS, Schoeplein R, **Chakravarty A, Hernández-Muñoz JJ.**	Improving data capture of race and ethnicity for the Food and Drug Administration Sentinel database: A narrative review	*Ter-Minassian M, DiNucci AJ, Barrie IS, Schoeplein R, Chakravarty A, Hernández-Muñoz JJ. Improving data capture of race and ethnicity for the Food and Drug Administration Sentinel database: A narrative review. Ann Epidemiol. 2023 Oct;86: 80-89.e2.* doi: 10.1016/j.annepidem.2023.07.006
Mundkur ML, Muñoz MA, Ryan Q, Setse R, **Dutcher SK, Hernandez-Munoz JJ,** Epperson M, Hou L, Marshall, J, Sirsoninan EK, Whited EM, **Blum MD,** Maro JC.	Investigating potential differences in the safety profiles of biosimilars relative to originator products using a tree-based scan statistic	*Mundkur ML, Muñoz MA, Ryan Q, et al. Investigating potential differences in the safety profiles of biosimilars relative to originator products using a tree-based scan statistic. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 93.* doi: 10.1002/pds.5687
Palmer M, Kleiner DE, Goodman Z, Brunt E, **Avigan MI,** Regev A, Hayashi PH, Lewis JH, Mehta R, Harrison SA, Siciliano M, McWherter CA, Vuppalanchi R, Behling C, Miller V, Chalasani N, Sanyal AJ.	Liver biopsy for assessment of suspected drug-induced Liver injury in metabolic dysfunction-associated steatohepatitis clinical trials: expert consensus from the Liver Forum	*Palmer M, Kleiner DE, Goodman Z, et al. Liver biopsy for assessment of suspected drug-induced Liver injury in metabolic dysfunction-associated steatohepatitis clinical trials: expert consensus from the Liver Forum. Aliment Pharmacol Ther. 2024 Jan; 59(2): 201-216.* doi: 10.1111/apt.17762
Patel V, Salvatore T, Wyeth J, Kolejian S.	Medication errors and risk-mitigation strategies for COVID-19 emergency use authorization drug products	*Patel V, Salvatore T, Wyeth J, Kolejian.* Medication errors and risk-mitigation strategies for COVID-19 emergency use authorization drug products. *Poster presented at: 2023 FDA Science Forum; June 13-14, 2023.*
Slavova S, **McAninch J,** Dasgupta N, Oyler D, Freeman PR.	Methodological challenges for single versus polydrug classification of drug overdose deaths	*Slavova S, McAninch J, Dasgupta N, Oyler D, Freeman PR. Methodological challenges for single versus polydrug classification of drug overdose deaths. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 410-411.* doi: 10.1002/pds.5687

Contributors Bolded names represent OSE staff	Title	Citation
Andrade RJ, Aithal GP, de Boer YS, Liberal R, Gerbes A, Regev A, Terziroli Beretta-Piccoli B, Schramm C, Kleiner DE, De Martin E, Kullak-Ublick GA, Stirnimann G, Devarbhavi H, Vierling JM, Manns MP, Sebode M, Londoño MC, **Avigan M,** Robles-Diaz M, García-Cortes M, Atallah E, Heneghan M, Chalasani N, Trivedi PJ, Hayashi PH, Taubert R, Fontana RJ, Weber S, Oo YH, Zen Y, Licata A, Lucena MI, Mieli-Vergani G, Vergani D, Björnsson ES, IAIHG and EASL DHILI Consortium.	Nomenclature, diagnosis and management of drug-induced autoimmune-like hepatitis (DI-ALH): An expert opinion meeting report	*Andrade RJ, Aithal GP, de Boer YS, et al. Nomenclature, diagnosis and management of drug-induced autoimmune-like hepatitis (DI-ALH): An expert opinion meeting report. J Hepatol. 2023 Sep; 79(3): 853-866.* doi: 10.1016/j.jhep.2023.04.033
Bradley MC, Eworuke E, Senatore FF, Peters A, Beers E, Kolonoski J, Connolly JG.	Percutaneous transluminal septal myocardial ablation and common procedural complications before and after the approval of ablysinol	*Bradley MC, Eworuke E, Senatore FF, et al. Percutaneous transluminal septal myocardial ablation and common procedural complications before and after the approval of ablysinol. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 584.* doi: 10.1002/pds.5687
Sarpatwari A, Lu Z, **Toyserkani GA, Zhou EH, Oswell K, Hawkins Shaw KH, Zendel L, LaCivita C, Dal Pan GJ,** Kesselheim AS.	Physician perceptions of and experiences with risk evaluation and mitigation strategies: results from a national survey	*Sarpatwari A, Lu Z, Toyserkani GA, et al. Physician perceptions of and experiences with risk evaluation and mitigation strategies: results from a national survey. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 484-485.* doi: 10.1002/pds.5687
Simon GE, Shortreed SM, Johnson E, Yaseen ZS, Stone M, **Mosholder AD,** Ahmedani BK, Coleman KJ, Coley RY, Penfold RB, Toh S.	Predicting risk of suicidal behavior from insurance claims data vs. linked data from insurance claims and electronic health records	*Simon GE, Shortreed SM, Johnson E, et al, Toh S. Predicting risk of suicidal behavior from insurance claims data vs. linked data from insurance claims and electronic health records. Pharmacoepidemiol Drug Saf. 2024 Jan;33(1): e5734.* doi: 10.1002/pds.5734
Sarri G, **Liu W,** Zabotka L, Freitag A, Claire R, Wangge G, Elvidge J, Dawoud D, Bennett D, Wen X, Li X, Rentsch CT, Uddin MJ, Ali MS, Gokhale M, Déruaz-Luyet A, Moga DC, Guo JJ, Zullo AR, Patorno E, Lin KJ.	Prognostic factors of COVID-19: an umbrella review endorsed by the International Society for Pharmacoepidemiology	*Sarri G, Liu W, Zabotka L, et al. Prognostic factors of COVID-19: an umbrella review endorsed by the International Society for Pharmacoepidemiology. Clin Pharmacol Ther. 2023;114(3): 604-613.* doi: 10.1002/cpt.2977
Martinez AI, Burk J, Epperson M, Jjingo CJ, Baumblatt J, Seung Lee H, Zhao Y, **Stojanovic D,** Eworuke E, **Ajao A.**	Racial and ethnic differences in hospitalized and critical COVID-19 treatment, January 2021–April 2022	*Martinez AI, Burk J, Epperson M, et al. Racial and ethnic differences in hospitalized and critical COVID-19 treatment, January 2021–April 2022. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 208.* doi: 10.1002/pds.5687

Contributors Bolded names represent OSE staff	Title	Citation
Lo Re V, **Dutcher SK,** Connolly JG, **Perez-Vilar S,** Carbonari DM, DeFor T, Djibo DA, Harrington LB, Hou L, Hennessy S, Hubbard RA, Kempner ME, Juntz JL, McMahill-Walraven, Mosley J, Pawloski PA, Petrone AB, Pishko AM, Driscoll MR, Steiner CA, Zhou Y, Cocoros NM.	Risk of admission to hospital with arterial or venous thromboembolism among patients diagnosed in the ambulatory setting with COVID-19 Compared with influenza: retrospective cohort study	*Lo Re V, Dutcher SK, Connolly JG, et al. Risk of admission to hospital with arterial or venous thromboembolism among patients diagnosed in the ambulatory setting with COVID-19 Compared with influenza: retrospective cohort study. BMJ Med. 2023 Jun 6; 2(1).* doi: 10.1136/bmjmed-2022-000421
Graham DJ, Izurieta HS, Zhang D, Avagyan A, Lyu H, Weiderhorn R, Lu Yun, **Mosholder AD,** Smith ER, Zhao Y, Shangguan S, **Tsai H-T, Pennap D,** Sandhu AT, Wernecke M, MaCurdy TE, Kelman JA, Forshee RA.	Risk of severe COVID-19 in prevalent users of alpha-1 adrenergic receptor antagonists: a national case-control study of Medicare beneficiaries	*Graham DJ, Izurieta HS, Zhang D, et al. Risk of severe COVID-19 in prevalent users of alpha-1 adrenergic receptor antagonists: a national case-control study of Medicare beneficiaries. Am J Med. 2023 Oct; 136(10): 1018-1025.* doi: 10.1016/j.amjmed.2023.07.003
Hu M, **Wong HL,** Feng Y, Lloyd PC, Smith ER, Amend KL, Kline A, Beachler DC, Gruber JF, Mitra M, Seeger JD, Harris C, Secora A, Obidi J, Wang J. Song J, McMahill-Walraven CN, Reich C, McEvoy R, Chillarige Y, Clifford R, Cooper DC, Shoaibi A, Forshee R, Anderson SA.	Safety of the BNT162b2 COVID-19 vaccine in children aged 5 to 17 years	*Hu M, Wong HL, Feng Y, et al. Safety of the BNT162b2 COVID-19 vaccine in children aged 5 to 17 years. JAMA Pediatr. 2023; 177(7): 710–717.* doi: 10.1001/jamapediatrics.2023.1440
Konkel K, Reyes M, Diak IL, Cao K, **McCulley L.**	Serious skin injuries following exposure to unapproved mole and skin tag removers	*Konkel K, Reyes M, Diak IL, Cao K, McCulley L. Serious skin injuries following exposure to unapproved mole and skin tag removers. J Clin Aesthet Dermatol. 2023 Jan;16(1): 14-17.* PMID: 36743972; PMCID: PMC9891211.
Janiczak S, Wolf L, Muñoz M.	Severe cutaneous adverse reactions in Pirfenidone-treated patients: a case series	*Janiczak, S, Wolf, L, Muñoz, M.* Severe cutaneous adverse reactions in Pirfenidone-treated patients: a case series. *Poster presented at: American Thoracic Society International Conference; May 22, 2023; Washington, D.C.*
Korves C, Izurieta HS, Balajee AS, Zwain GM, Smith J, **Graham DJ,** Young-Xu Y.	Short-term effectiveness of bivalent COVID-19 mRNA booster vaccinations in the Veterans' Health Administration using self-controlled risk interval and test-negative case-control designs	*Korves C, Izurieta HS, Balajee AS, et al. Short-term effectiveness of bivalent COVID-19 mRNA booster vaccinations in the Veterans' Health Administration using self-controlled risk interval and test-negative case-control designs. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 79.* doi: 10.1002/pds.5687
Maro JC, **Nguyen MD,** Kolonoski J, Schoeplein R, Huang TY, **Dutcher SK, Dal Pan GJ, & Ball R.**	Six years of the US Food and Drug Administration's postmarket Active Risk Identification and Analysis system in the sentinel initiative: implications for real world evidence generation	*Maro JC, Nguyen MD, Kolonoski J, Schoeplein R, Huang TY, Dutcher SK, Dal Pan GJ, Ball R. Six years of the US Food and Drug Administration's postmarket Active Risk Identification and Analysis system in the sentinel initiative: implications for real world evidence generation. Clin Pharmacol Ther. 2023 Oct; 114(8): 815-824.* doi: 10.1002/cpt.2979
Simon GE, Cruz M, Shortreed SM, Sterling SA, Coleman KJ, Ahmedani BK, Yaseen ZS, **Mosholder AD.**	Stability of suicide risk prediction models during changes in health care delivery	*Simon GE, Cruz M, Shortreed SM, Sterling SA, et al. Stability of suicide risk prediction models during changes in health care delivery. Psychiatr Serv. 2024 Feb 1; 75(2): 139-147.* doi: 10.1176/appi.ps.20230172

Contributors Bolded names represent OSE staff	Title	Citation
Woronow D, Le H, Kortepeter C.	Statin associated immune mediated necrotizing myopathy (SA-IMNM) and subsequent use of non-statin LDL-C lowering drugs	*Woronow D, Le H, Kortepeter C.. Statin associated immune mediated necrotizing myopathy (SA-IMNM) and subsequent use of non-statin LDL-C lowering drugs. J Am Coll Cardiol. 2023 Mar; 81(8_Supplement): 1759.* doi: 10.1016/S0735-1097(23)02203-9
Apata J, Pennap D, Ma Y, Mosholder A.	Suicide poisoning mortality: a comparison of the national poison data system and centers for disease control national dataset	*Apata J, Pennap D, Ma Y, Mosholder A. Suicide poisoning mortality: a comparison of the national poison data system and centers for disease control national dataset. Inj Prev. 2024;30(1): 81-83. Published 2024 Jan 25.* doi: 10.1136/ip-2023-044940
Bautista PA, **Chai G, McAninch J,** Brown K.	Suspected falsified pill involvement in U.S. Poison Centers abuse cases 2019–2022	*Bautista PA, Chai G, McAninch J, Brown K. Suspected falsified pill involvement in U.S. Poison Centers abuse cases 2019–2022. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 245-246.* doi: 10.1002/pds.5687
Perez-Vilar S, Kempner ME, **Dutcher SK,** Menzin TJ, Woods C, Leishear K, Osterhout J, Adimadhyam S, **Adereti M,** Carruth A, Hansbury A, **Sandhu SK,** Lyons JG.	Switching patterns of immediate-release forms of generic mixed amphetamine salts products among privately and publicly insured individuals aged 15-64 years in the United States, 2013-2019	*Perez-Vilar S, Kempner ME, Dutcher SK, et al. Switching patterns of immediate-release forms of generic mixed amphetamine salts products among privately and publicly insured individuals aged 15-64 years in the United States, 2013-2019. Pharmacoepidemiol Drug Saf. 2023 Oct; 32(10): 1178-1183.* doi: 10.1002/pds.5661
Kangas L, Wolf L, Beganovic M, Kapoor R, Kidd J, McCartan K, Swank K, **Diak I.**	The Food and Drug Administration's (FDA's) safety surveillance of baricitinib and tocilizumab for COVID-19	*Kangas L, Wolf L, Beganovic M, et al.* The Food and Drug Administration's (FDA's) safety surveillance of baricitinib and tocilizumab for COVID-19 [abstract]. *Arthritis Rheumatol. 2023; 75 (suppl 9).*
Karami S, Ajao A, Wong J, Zhang D, Meyer T, Ding Y, Secora A, Major JM, Gill R, Chai GP, Zhao Y,McAninch J.	The impact of hydrocodone rescheduling on utilization, abuse, misuse, and overdose deaths	*Karami S, Ajao A, Wong J, et al. The impact of hydrocodone rescheduling on utilization, abuse, misuse, and overdose deaths. Pharmacoepidemiol Drug Saf. 2023 Jul; 32(7): 735-751.* doi: 10.1002/pds.5603
Mahesri M, Feldman WB, Sarpatwari A, Huybrechts KF, Wang J, Zhu Y, Hwang CS, Lee SB, Kesselheim AS, **Toyserkani GA, Zhou EH, Zendel L, LaCivita C, Dal Pan GJ,** Bykov K.	The impact of the removal of liver injury warning and liver testing requirement on ambrisentan use and liver function testing	*Mahesri M, Feldman WB, Sarpatwari A, et al. The impact of the removal of liver injury warning and liver testing requirement on ambrisentan use and liver function testing. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 478-479.* doi: 10.1002/pds.5687
Toyserkani GA, Lee J, Zhou EH.	The Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard: Improving transparency of regulatory activities	*Toyserkani GA, Lee J, Zhou EH. The Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard: Improving transparency of regulatory activities. Pharmaceut Med. 2023 Jul 8; 37: 349-353.* doi: 10.1007/s40290-023-00489-5
Zafari Z, Park JE, Shah CH, dosReis S, Gorman EF, **Hua W, Ma Y, Tian F.**	The state of use and utility of negative controls in pharmacoepidemiologic studies	*Zafari Z, Park JE, Shah CH, et al. The state of use and utility of negative controls in pharmacoepidemiologic studies. Am J Epidemiol. 2023 Oct 17.* doi: 10.1093/aje/kwad201

Contributors Bolded names represent OSE staff	Title	Citation
Sullivan, KM.	Three perspectives on non-traditional clinical roles in hematology/oncology pharmacy – FDA Oncology Safety Evaluator	*Sullivan, KM.* Three perspectives on non-traditional clinical roles in hematology/oncology pharmacy *– FDA Oncology Safety Evaluator. HOPA News. 2023; 20(1): 18.*
Fuller CC, Cosgrove A, Shinde M, Rosen E, Haffenreffer K, Hague C, McLean LE, Perlin J, Poland RE, Sands KE, **Pratt N, Bright P,** Platt R, Cocoros NM, **Dutcher SK.**	Treatment and care received by children hospitalized with COVID-19 in a large hospital network in the United States, February 2020 to September 2021	*Fuller CC, Cosgrove A, Shinde M, et al. Treatment and care received by children hospitalized with COVID-19 in a large hospital network in the United States, February 2020 to September 2021. PLOS ONE. 2023 Jul 11; 18(7).* doi: 10.1371/journal.pone.0288284
Van Metre Baum L, Madhav KC, Soulos PR, Jeffery MM, Ruddy KJ, Lerro CC , Lee H, **Graham DJ,** Rivera DR, Leapman M, Jairam V, Dinan MA, Gross CP, Park HS.	Trends in new and persistent opioid use in older adults with and without cancer	*Van Metre Baum L, Madhav KC, et al. Trends in new and persistent opioid use in older adults with and without cancer. J Natl Cancer Inst. 2024 Feb; 116(2): 316-323.* doi: 10.1093/jnci/djad206
Karami S, Asonye C, **Pinnow E,** Pratt V, **McCulley L, Dwumfour N, Zhou EH.**	Trends in pediatric nonprescription analgesic/antipyretic exposures during the COVID-19 Pandemic	*Karami S, Asonye C, Pinnow E, et al. (2023) Trends in pediatric nonprescription analgesic/antipyretic exposures during the COVID-19 pandemic. Clin Toxicol. 2023 Mar 4; 61(3): 190-199.* doi: 10.1080/15563650.2022.2158847
Thai TN, Winterstein AG, Suarez EA, He J, Zhao Y, Di Zhang D, **Stojanovic D,** Liedtka J, Anderson, **Hernández-Muñoz JJ, Munoz MA, Liu W,** Dashevsky I, Messenger-Jones E, Siranosian W, Maro JC.	Triple challenges–Small sample sizes in both exposure and control groups when scanning rare maternal outcomes in signal identification: A simulation study	*Thai TN, Winterstein AG, Suarez EA, et al. Triple challenges–Small sample sizes in both exposure andcontrol groups when scanning rare maternal outcomes in signalidentification: A simulation study. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 117.* doi: 10.1002/pds.5687
Davis SE, Zabotka L, Desai RJ, Wang SV, Maro JC, Coughlin K, **Hernández-Muñoz JJ,** Stojanovic D, Shah NH, Smith JC.	Use of electronic health record data for drug safety signal identification: a scoping review	*Davis SE, Zabotka L, Desai RJ, et al. Use of electronic health record data for drug safety signal identification: a scoping review. Drug Saf. 2023; 46: 725-742.* doi: 10.1007/s40264-023-01325-0
Mosholder A, Izurieta HS, Zhang R, Shangguan S, Lu Y, Akhtar S, Wernecke M, He J, Chillarige Y, Feng Y, Avagyan A, **Leishear K,** Forshee RA, MaCurdy TE, Kelman JA, **Graham DJ.**	Use of proton pump inhibitors and risk of severe COVID-19: a case-control study in US Medicare beneficiaries	*Mosholder A, Izurieta HS, Zhang R, et al. Use of proton pump inhibitors and risk of severe COVID-19: a case-control study in US Medicare beneficiaries. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 72.* doi: 10.1002/pds.5687
Konkel K, Oner N, Ahmed A, **Jones SC,** Berner ES, Zengul FD.	Using natural language processing to characterize and predict homeopathic product-associated adverse events in consumer reviews: comparison to reports to FDA Adverse Event Reporting System (FAERS)	*Konkel K, Oner N, Ahmed A, Jones SC, Berner ES, Zengul FD. Using natural language processing to characterize and predict homeopathic product-associated adverse events in consumer reviews: comparison to reports to FDA Adverse Event Reporting System (FAERS). J Am Med Inform Assoc. 2023 Dec 22;31(1): 70-78.* doi: 10.1093/jamia/ocad197

Contributors Bolded names represent OSE staff	Title	Citation
Adimadhyam S, Hou L, Dashevsky I, Zhang R, **Li Y, Bradley MC,** Eworuke E, Clerman A, Chin S, Ren Y, Seymour S, Quinto K, Maro JC, Busch R.	Using real-world data to evaluate comparative effectiveness cohorts of azithromycin relative to roflumilast in individuals with uncontrolled chronic obstructive pulmonary disease	*Adimadhyam S, Hou L, Dashevsky I, et al. Using real-world data to evaluate comparative effectiveness cohorts of azithromycin relative to roflumilast in individuals with uncontrolled chronic obstructive pulmonary disease. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 561.* doi: 10.1002/pds.5687
Li Y, Her M, Eworuke E, **Mohamoud MA, Hernández-Muñoz JJ, Kim I,** Thompson JW, Antoon JW, Connolly JG.	Utilization of beta-blockers among the pediatric population in the United States: A study in the FDA's sentinel system from 2008 to 2022	*Li Y, Her M, Eworuke E, et al. Utilization of beta-blockers among the pediatric population in the United States: A study in the FDA's sentinel system from 2008 to 2022. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 141.* doi: 10.1002/pds.5687
Woods C, Ho A, Dutcher SK, Ajao A, Hawrusik R, Schoeplein R, **Moeny D,** Huang TY.	Utilization of gonadotropin-releasing hormone agonist products in adolescents	*Woods C, Ho A, Dutcher SK, et al. Utilization of gonadotropin-releasing hormone agonist products in adolescents. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 319.* doi: 10.1002/pds.5687
Izulla P, Wagai JN, Akelo V, Ombeva A, Okeri E, Onyango D, Omore R, Fuller S, Khagayi S, Were J, Anderson SA, **Wong HL,** Tippett Barr BA.	Vaccine safety surveillance in Kenya using GAIA standards: a feasibility assessment of existing national and subnational research and program systems	*Izulla P, Wagai JN, Akelo V, et al. Vaccine safety surveillance in Kenya using GAIA standards: a feasibility assessment of existing national and subnational research and program systems. Vaccine. 2023 Sep 7; 41(39): 5722-5729.* doi: 10.1016/j.vaccine.2023.07.063
Eworuke E, Shinde M, Hou L, Paterson MJ, Jensen PB, Maro JC, Rai A, Scarnecchia D, **Dinci P, Woronow D,** Ghosh RE, Welburn S, Pottegard A, Platt RW, Lee H, **Bradley MC.**	Valsartan, Losartan and Irbesartan use in the USA, UK, Canada and Denmark after the nitrosamine recalls: a descriptive cohort study	*Eworuke E, Shinde M, Hou L, et al. Valsartan, Losartan and Irbesartan use in the USA, UK, Canada and Denmark after the nitrosamine recalls: a descriptive cohort study. BMJ Open. 2023 Apr 17. 13(4).* doi: 10.1136/bmjopen-2022-070985
Stagner MK, Caro JC, **Dutcher SK, Moeny D,** Rosofsky R, Kiernan D, Shockro LA, Mai A, Pritchard JE, Lippmann SJ, Adhikari P, Hammill BG.	Variation in mother-infant linkage rates by jurisdiction in US Medicaid data	*Stagner MK, Caro JC, Dutcher SK, et al. Variation in mother-infant linkage rates by jurisdiction in US Medicaid data. Abstracts of ICPE 2023, the 39th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Halifax, Canada, 25–27 August 2023. Pharmacoepidemiol Drug Saf. 32(S1): 45.* doi: 10.1002/pds.5687
Nadeau Nguyen M, Dores GM, Nayernama A, Jones SC.	Varicella zoster virus reactivation reported with Isatuximab use	*Nadeau Nguyen M, Dores GM, Nayernama A, Jones SC. Varicella zoster virus reactivation reported with Isatuximab use. J Chemother. 2023 Oct 6: 1-4.* doi: 10.1080/1120009X.2023.2266201

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
www.fda.gov

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993