CDER Office of Surveillance and Epidemiology: 2017 Update

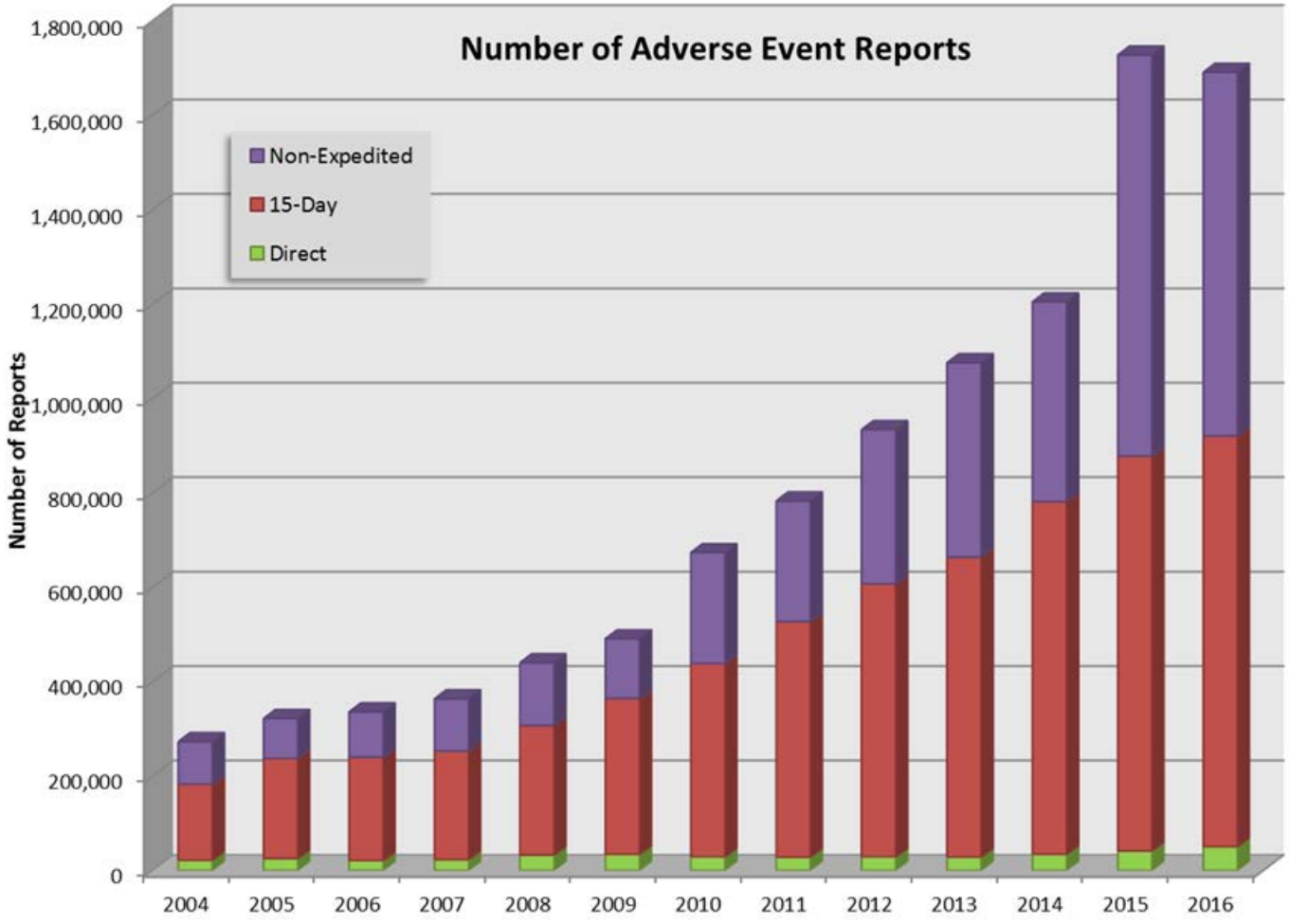
Gerald J. Dal Pan, MD, MHS
Director
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

FDA/CMS Summit
December 5, 2017

U.S. FOOD & DRUG ADMINISTRATION

Adverse Event Data

FDA Adverse Event Reporting System (FAERS)



Best Practices for Pharmacovigilance

FDAAA 2007 establishes requirement for 18-month/10,000 patient safety review.

"(D) preparing, by 18 months after approval of a drug or after use of the drug by 10,000 individuals, whichever is later, a summary analysis of the adverse drug reaction reports received for the drug, including identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number;

ARTICLES

Assessment of the Impact of Scheduled Postmarketing Safety Summary Analyses on Regulatory Actions

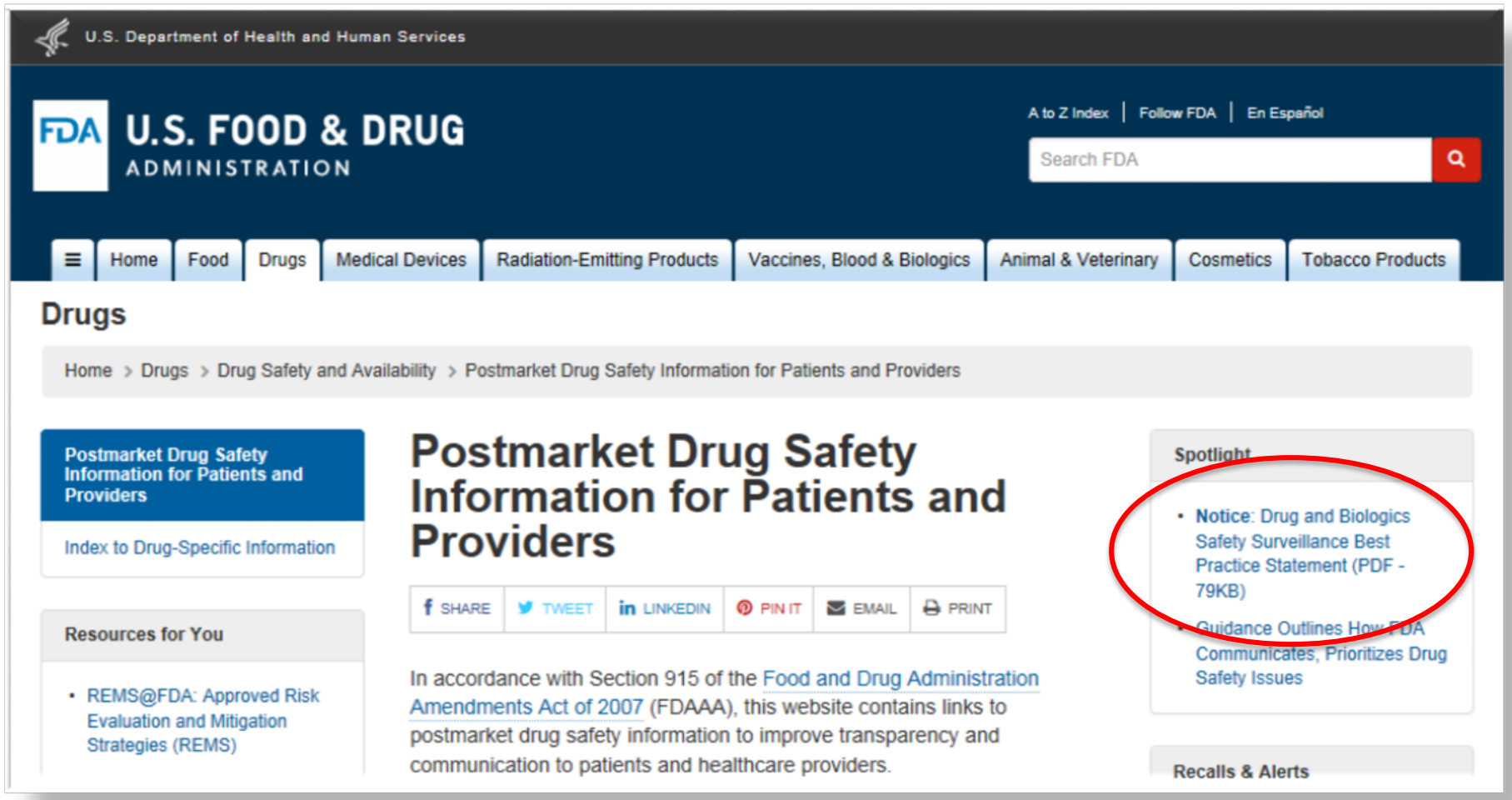
S Sekine[1,2], EE Pinnow[1], E Wu[1], R Kurtzig[1], M Hall[1] and GJ Dal Pan[1]

Impact analysis show that these reviews have little value.

21st Century Cures Act 2016 removes this requirement

(b) FAERS REVISION.—Section 505(r)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(r)(2)(D)) is amended by striking ", by 18 months" and all that follows through the semicolon at the end of the sub-paragraph and inserting "and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;".

Best Practices for Pharmacovigilance



Best Practices for Pharmacovigilance

Drug and Biologics Safety Surveillance Best Practice Statement
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
US Food and Drug Administration

The 21st Century Cures Act (the "Cures Act"), enacted on December 13, 2016, has the goal of advancing medical product innovation as well as ensuring patient access to safe and effective treatments as soon as possible. One of the provisions of the Cures Act includes a revision to a previous statutory requirement that generally required FDA to undertake routine safety analyses of drugs 18 months following approval or after 10,000 individuals have used the drug, whichever occurs later. See section 505(r)(2)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) before and after it was amended by the Cures Act. These assessments were largely redundant to our current surveillance practices at the Food and Drug Administration (FDA), were not an efficient use of FDA resources, and did not provide

Improved Access to Adverse Event Reports

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

News & Events

Home > News & Events > Newsroom > Press Announcements

FDA News Release

FDA improves access to reports of adverse drug reactions

New online tool makes it easier for users to search the FDA Adverse Event Reporting System

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

For Immediate Release September 28, 2017

Release

The U.S. Food and Drug Administration today launched a new user-friendly search tool that improves access to data on adverse events associated with drug and biologic products through the FDA's Adverse Event Reporting System (FAERS). The tool is designed to make it easier for consumers, providers, and researchers to access this information.

"Tools like the FDA Adverse Event Reporting System are critical to the FDA's ability to help ensure the greatest level of transparency and help patients and providers make safe use of drug and biologic products after they are approved by the FDA," said FDA Commissioner Scott Gottlieb, M.D. "The FDA is committed to fully informing patients and providers of adverse events reported with medical products and this enhanced portal now provides patients, doctors and others with easier access to the data they are interested in."

The new dashboard enables users to search for and organize data by criteria such as drug/biological product, age of the patient, type of adverse event, year the adverse event occurred, or within a specific timeframe. In addition to making it easier for consumers to search for adverse events reported with drug or biologic products, the FDA hopes the increased transparency will spur the submission of more detailed and complete reports from consumers, health care professionals and others, by making it easier for people to see other reports that the FDA receives, and search the database for similar observations.

Inquiries

Media

Lauren Smith Dyer
301-348-1888

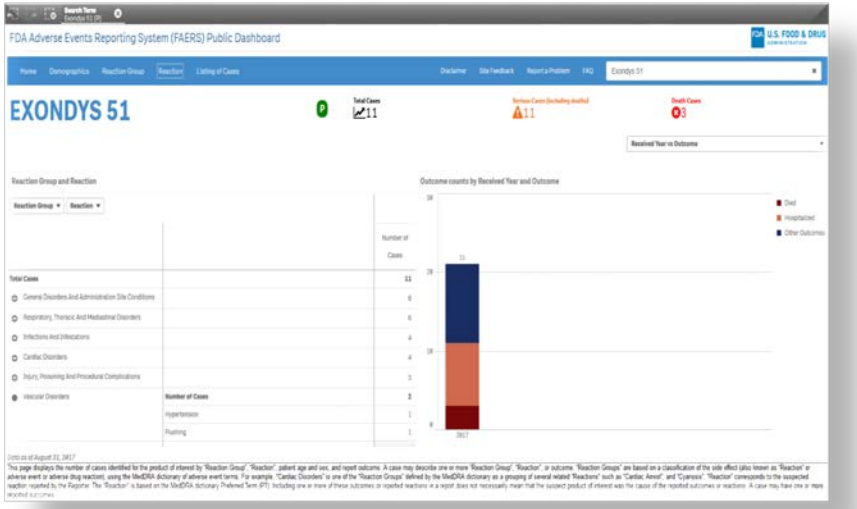
Consumers

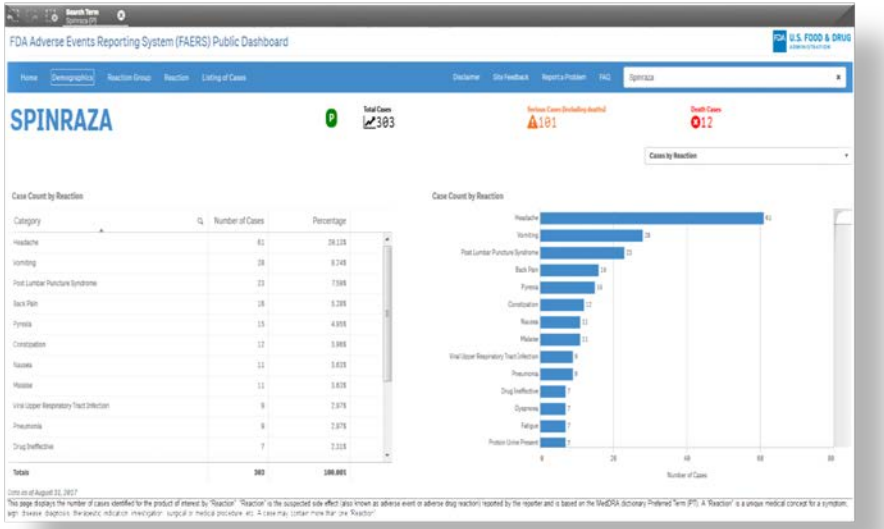
888-INFO-FDA

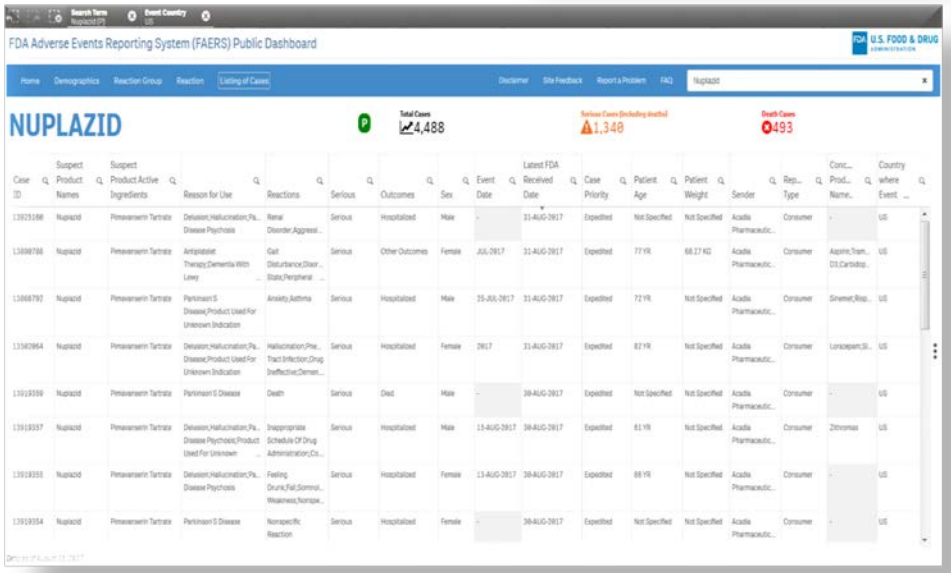
Follow FDA

Follow @US_FDA
Follow FDA
Follow @FDAmedia

Sample Dashboard Search







Media Article

CNBC

Search Quotes, News & Video

charles SCHWAB

HOME U.S. NEWS MARKETS INVESTING TECH MAKE IT VIDEO SHOWS MORE CNBC

BIOTECH AND PHARMACEUTICALS

HEALTH CARE | HOSPITALS | PHARMA | HEALTH INSURANCE | MODERN MEDICINE

Biotech stocks drop after FDA makes it easier for public to search for drug side effects

- Biotech stocks fell Friday, a day after the U.S. Food and Drug Administration made its database of side effects for medicines searchable.
- Sarepta Therapeutics, Ionis Pharmaceuticals, Biogen and Acadia Pharmaceuticals all traded lower after investors found reports on their drugs on the FDA's Adverse Events Reporting System.
- It is not clear whether the adverse events were caused by the medicines themselves, or were incidental, an analyst said.

Sarepta's Exondys 51, approved last year for certain patients with Duchenne muscular dystrophy, or DMD, had 11 reports of serious cases, including three deaths, according to FAERS.

Spinraza, a treatement from Biogen and Ionis for spinal muscular atrophy, or SMA, had 101 reports of serious cases, including 12 deaths.

And Acadia's Nuplazid, for patients with Parkinson's, had 1,343 serious case reports, including 493 deaths, FAERS reveals.

NLP and Machine Learning in FAERS

Journal of the American Medical Informatics Association, 0(0), 2017, 1–9
doi: 10.1093/jamia/ocx022
Research and Applications

Research and Applications

Development of an automated assessment tool for MedWatch reports in the FDA adverse event reporting system

Lichy Han,[1] Robert Ball,[2] Carol A Pamer,[2] Russ B Altman,[3,4] and Scott Proestel[2]

[1]Biomedical Informatics Training Program, Stanford University, Stanford, CA, USA, [2]Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD, USA, [3]Department of Genetics, Stanford University and [4]Department of Bioengineering, Stanford University

Corresponding Author: Scott Proestel, Division of Epidemiology, Office of Biostatistics and Epidemiology, FDA Center for Biologics Evaluation and Research, White Oak Building 71, Room 1260, 10903 New Hampshire Avenue, Silver Spring, MD 20993, USA. Phone: (240) 402-0396. E-mail: Scott.Proestel@fda.hhs.gov

Received 1 September 2016; Revised 30 January 2017; Accepted 24 February 2017

ABSTRACT

Objective: As the US Food and Drug Administration (FDA) receives over a million adverse event reports associated with medication use every year, a system is needed to aid FDA safety evaluators in identifying reports most likely to demonstrate causal relationships to the suspect medications. We combined text mining with machine learning to construct and evaluate such a system to identify medication-related adverse event reports.

Methods: FDA safety evaluators assessed 326 reports for medication-related causality. We engineered features from these reports and constructed random forest, L1 regularized logistic regression, and support vector machine models. We evaluated model accuracy and further assessed utility by generating report rankings that represented a prioritized report review process.

Results: Our random forest model showed the best performance in report ranking and accuracy, with an area under the receiver operating characteristic curve of 0.66. The generated report ordering assigns reports with a higher probability of medication-related causality a higher rank and is significantly correlated to a perfect report ordering, with a Kendall's tau of 0.24 ($P = .002$).

Conclusion: Our models produced prioritized report orderings that enable FDA safety evaluators to focus on reports that are more likely to contain valuable medication-related adverse event information. Applying our models to all FDA adverse event reports has the potential to streamline the manual review process and greatly reduce reviewer workload.

Key words: drug-related side effects and adverse reactions, supervised machine learning

BACKGROUND AND SIGNIFICANCE

The US Food and Drug Administration (FDA) receives more than 4000 medication safety reports every day, and the number of reports received each year has been increasing exponentially over the last decade. These reports are stored in a database known as the FDA Adverse Event Reporting System (FAERS), which has collected over 11 million reports since its inception in 1969.[1] In the United States, reporting these adverse events, medication errors, and product quality issues by health care professionals and consumers via the MedWatch program is voluntary, but it is mandatory for drug manufacturers.[2] The FDA uses these reports to detect safety issues that may not have been identified during pre-market clinical trials used as the basis for medication approval. Among the reasons for not detecting safety issues during pre-market evaluation are that the

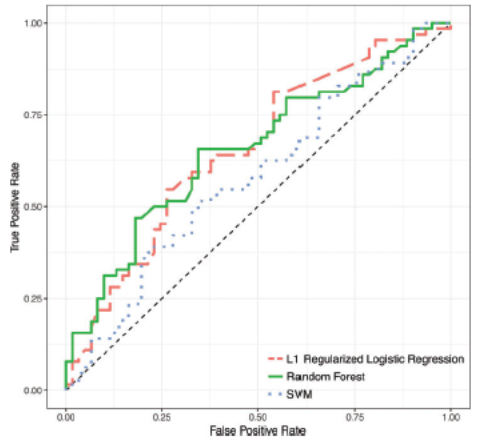


Figure 2. ROC curves for all classification models.

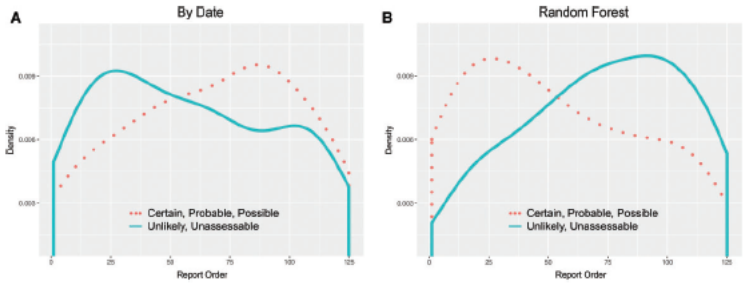


Figure 3. Comparison of report orderings in the held-out test set by (A) date and (B) random forest with assessments of *Certain*, *Probable*, or *Possible* vs assessments of *Unlikely* or *Unassessable*.

reporting systems, including the FDA Adverse Event Reporting System. Over the last decade, the number of adverse event reports has increased exponentially, resulting in a substantial workload for reviewers. Delays in detecting drug adverse events can have costly and detrimental effects on public health, and thus a system to identify reports most likely to contain information demonstrating causal drug events would be highly beneficial. Researchers have investigated such approaches using the US Vaccine Adverse Event Reporting System, in which extracted text features[16,17] were used with multiple classification algorithms to create an effective report classification model.[18–20]

The success of text classification in the Vaccine Adverse Event Reporting System and previous computational discoveries of new medication-related adverse events in FAERS[25–27] have generated significant interest in developing a classification system for FAERS. To accomplish this, we built models to classify and rank adverse event reports based on the likelihood of medication-related causality. In addition, we showed the potential utility of our models to assist manual adjudicators by shifting reports with a higher probability of medication-related causality to a higher priority in rank order.

For the first phase of this study, we chose to focus on reports with assessments of *Certain* to *Unassessable*, as they constituted

Can Social Media Generate Signals?

Drug Saf (2014) 37:343–350
DOI 10.1007/s40264-014-0155-x

ORIGINAL RESEARCH ARTICLE

Digital Drug Safety Surveillance: Monitoring Pharmaceutical Products in Twitter

Clark C. Freifeld · John S. Brownstein · Christopher M. Menone · Wenjie Bao · Ross Filice · Taha Kass-Hout · Nabarun Dasgupta

- English-language Twitter posts mentioning 23 medical products
- Identified posts resembling adverse events (proto-AEs)
- Vernacular internet terms translated to MedDRA
- Terms aggregated by MedDRA SOC
- 4,401 proto-AEs identified
- High correlation with FAERS at SCO level

Author's conclusion:

"Patients reporting AEs on Twitter showed a range of sophistication when describing their experience. Despite the public availability of these data, their appropriate role in pharmacovigilance has not been established. Additional work is needed to improve data acquisition and automation."

Source: Freifeld et al. Drug Saf 2014; 37:343-350

Methods Development

FDA

Pharmacovigilance from social media: mining adverse drug reaction mentions using sequence labeling with word embedding cluster features

RECEIVED 29 July 2014
REVISED 2 December 2014
ACCEPTED 4 December 2014
PUBLISHED ONLINE FIRST 9 March 2015

Azadeh Nikfarjam[1], Abeed Sarker[1], Karen O'Connor[1], Rachel Ginn[1], Graciela Gonzalez[1]

Evaluation of Facebook and Twitter Monitoring to Detect Safety Signals for Medical Products: An Analysis of Recent FDA Safety Alerts

Carrie E. Pierce[1] · Khaled Bouri[2] · Carol Pamer[2] · Scott Proestel[2] · Harold W. Rodriguez[1] · Hoa Van Le[1] · Clark C. Freifeld[1,3] · John S. Brownstein[1] · Mark Walderhaug[2] · I. Ralph Edwards[4] · Nabarun Dasgupta[1]

BMJ Open Utility of social media and crowd-sourced data for pharmacovigilance: a scoping review protocol

Andrea C Tricco,[1,2] Wasifa Zarin,[1] Erin Lillie,[1] Ba Pham,[1] Sharon E Straus[1,3]

Source: Nikfarjam et al. J Am Med Inform Assoc c 2015;22:671–681; Tricco et al. BMJ Open l (http://dx.doi.org/10.1136/bmjopen-2016- 013474); Pierce et al. Drug Saf 2017;40:317–331

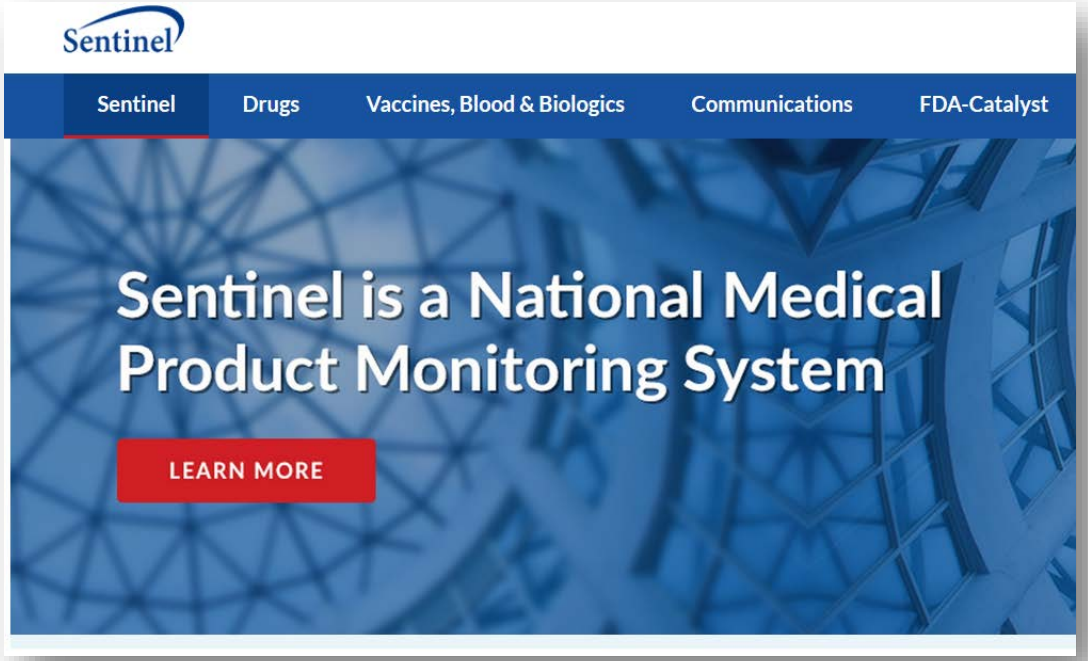
FDA U.S. FOOD & DRUG ADMINISTRATION

Sentinel

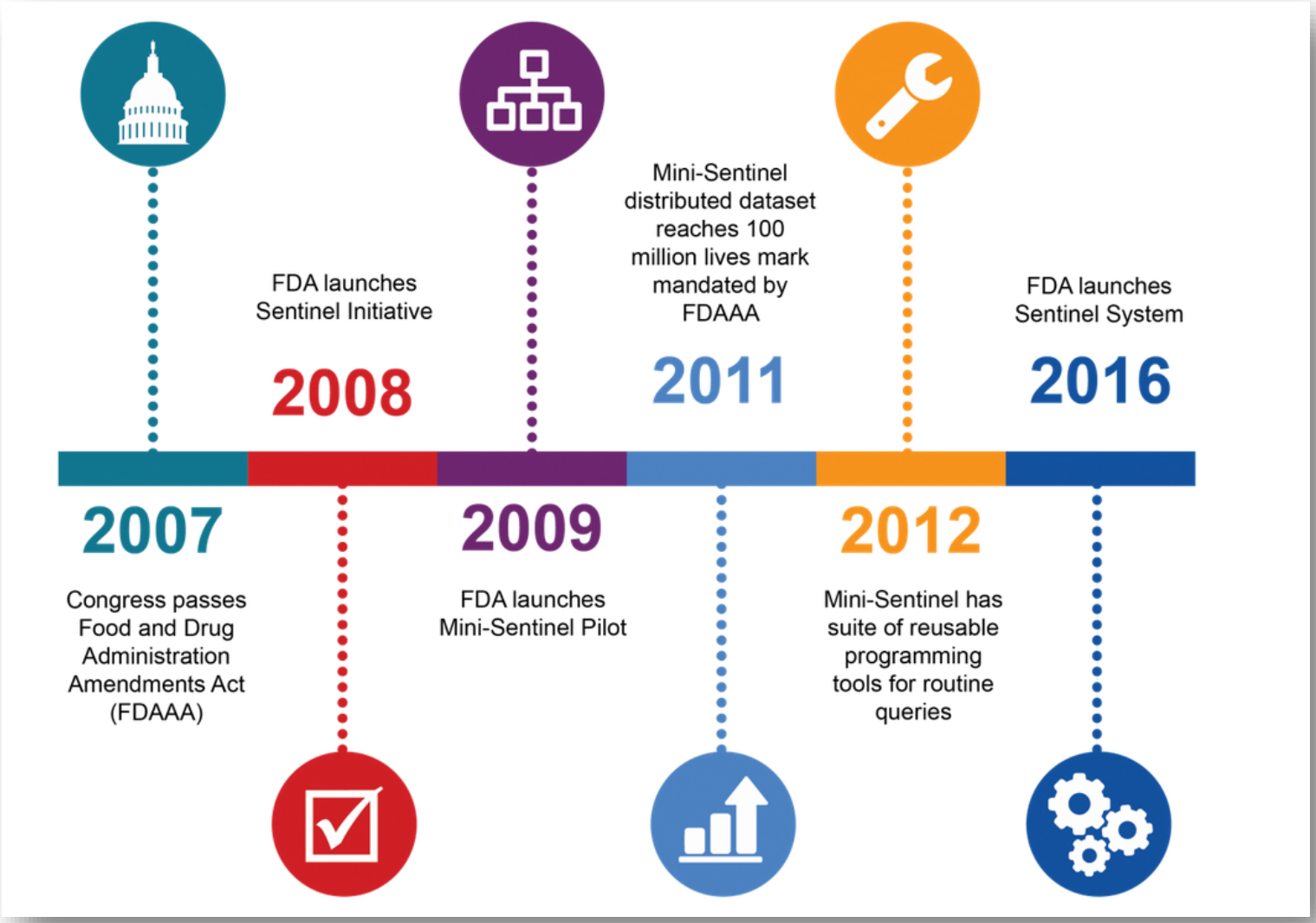
FDA Sentinel System

- National medical product monitoring system
- 17 data partners with 178 million members with pharmacy and medical coverage
- Distributed system where data partners retain physical control of data to protect privacy and security

www.sentinelinitiative.org/



Timeline



https://www.sentinelinitiative.org/background

Requirement to Consider Sufficiency of ARIA before PMR

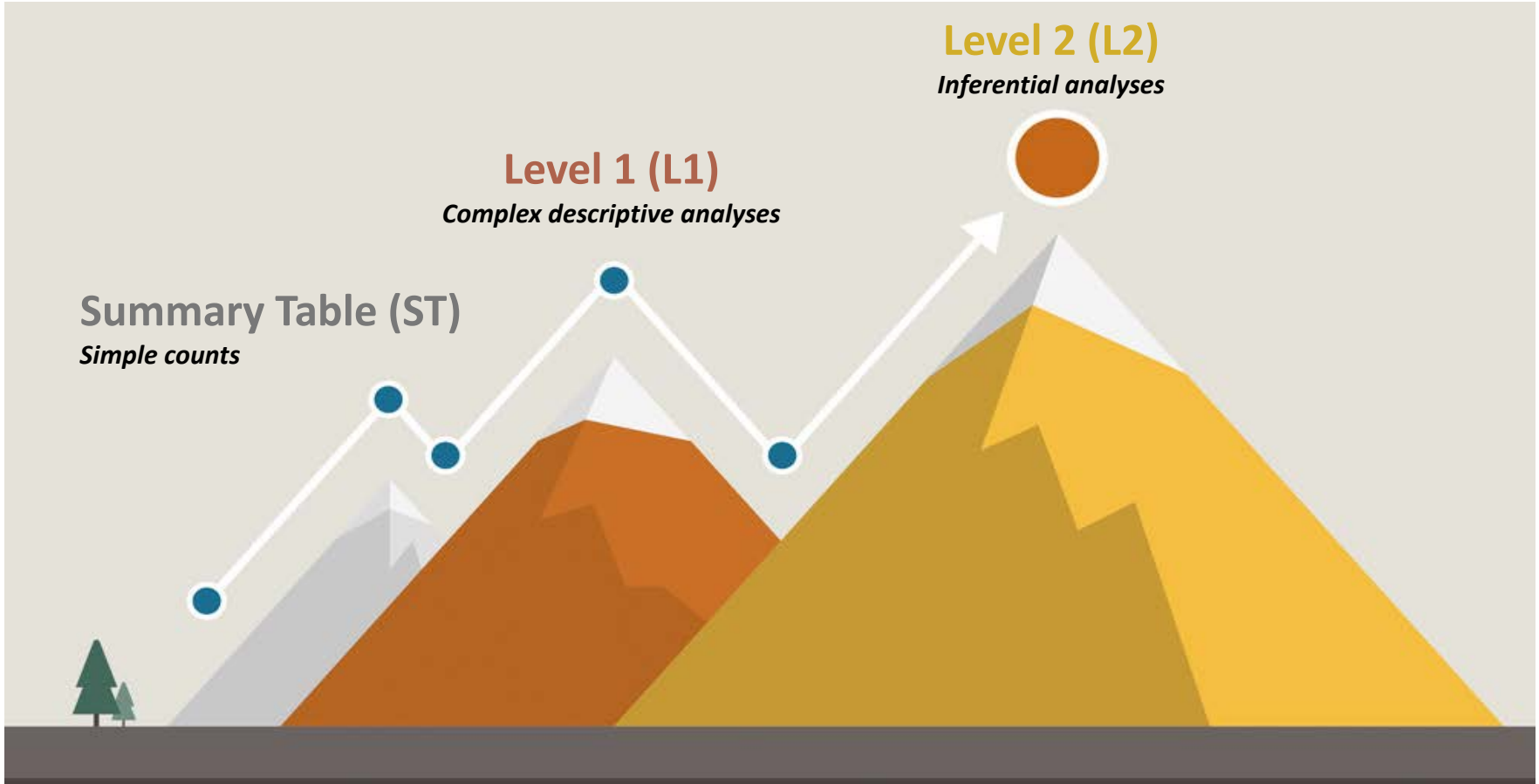
Section 905
Mandates creation of ARIA

Section 901
New FDAAA PMR authority

"The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the **active postmarket risk identification and analysis system** as available under subsection (k)(3) will not be **sufficient** to meet the purposes set forth in subparagraph (B)."

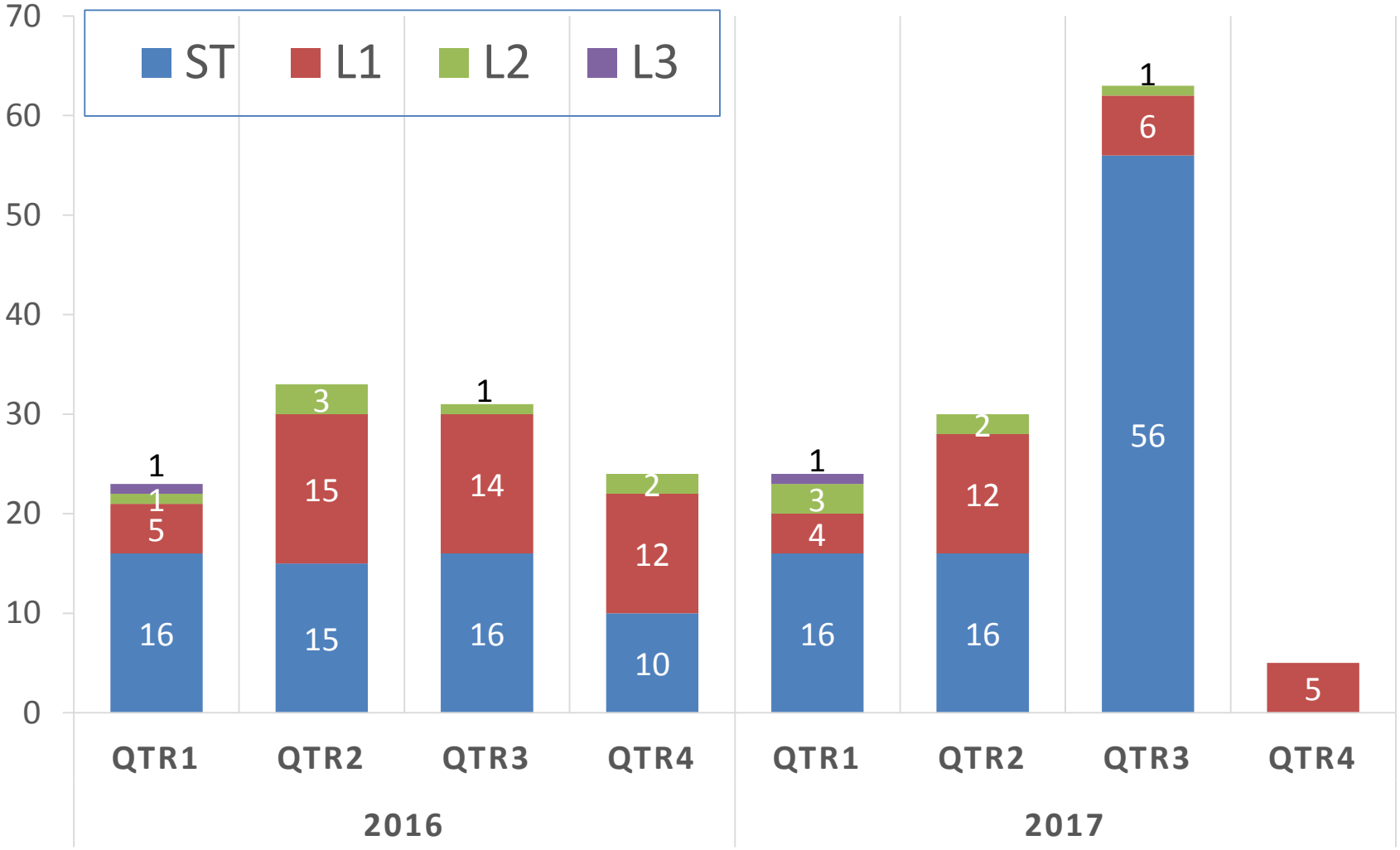
FDAAA = FDA Amendments Act 2007

Active Risk Identification and Analysis



Modular Programs: Validated, re-usable analytic tools that facilitate rapid safety analyses to be run on high quality electronic healthcare data

Sentinel ARIA Analyses (N=233)



From all FDA Centers, by date of distribution to Data Partners

10th Annual Public Workshop

https://healthpolicy.duke.edu/events/2018-sentinel-initiative-annual-public-workshop

Sentinel and PDUFA

PDUFA V Commitments

- Public stakeholder meeting ✓
- Fund 4 – 6 activities ✓
- Interim Sentinel Assessment ✓
- Final Sentinel Assessment ✓

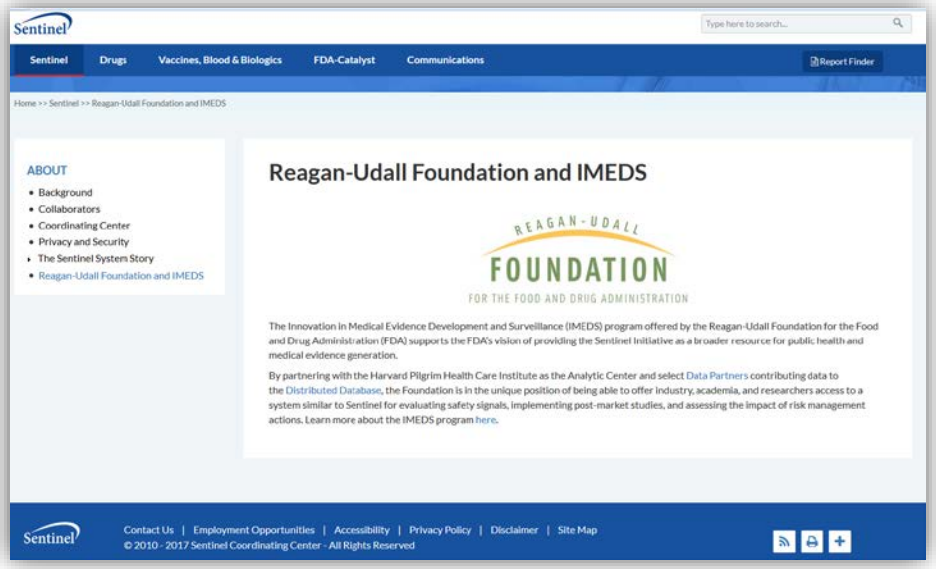
PDUFA VI Commitments

- Expand data sources and core capabilities
- Enhance communications with sponsors and public
- Evaluate additional ways to facilitate public and sponsor access to Sentinel
- Hold public stakeholder meeting
- Establish MAPPS and SOPPs for sponsor communication
- Integrate Sentinel into drug review
- Develop a comprehensive training program for review staff
- Report impact of Sentinel expansion and integration by FY2022

New Base Contract for Sentinel Coordinating Center

https://www.fbo.gov/index?s=opportunity&mode=form&id=ec59b8dbb36970e2912801aa2cfdd87d&tab=core&_cview=0

Making Sentinel Available to Others



- IMEDS shares the same analytic center at Harvard Pilgrim Healthcare as Sentinel
- IMEDS has the same analytic tools and similar database available to FDA
- IMEDS is publicly accessible
- Currently active with multiple analyses ongoing

https://www.sentinelinitiative.org/sentinel/reagan-udall-foundation-and-imeds

Real-world Evidence

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Real-World Evidence — What Is It and What Can It Tell Us?

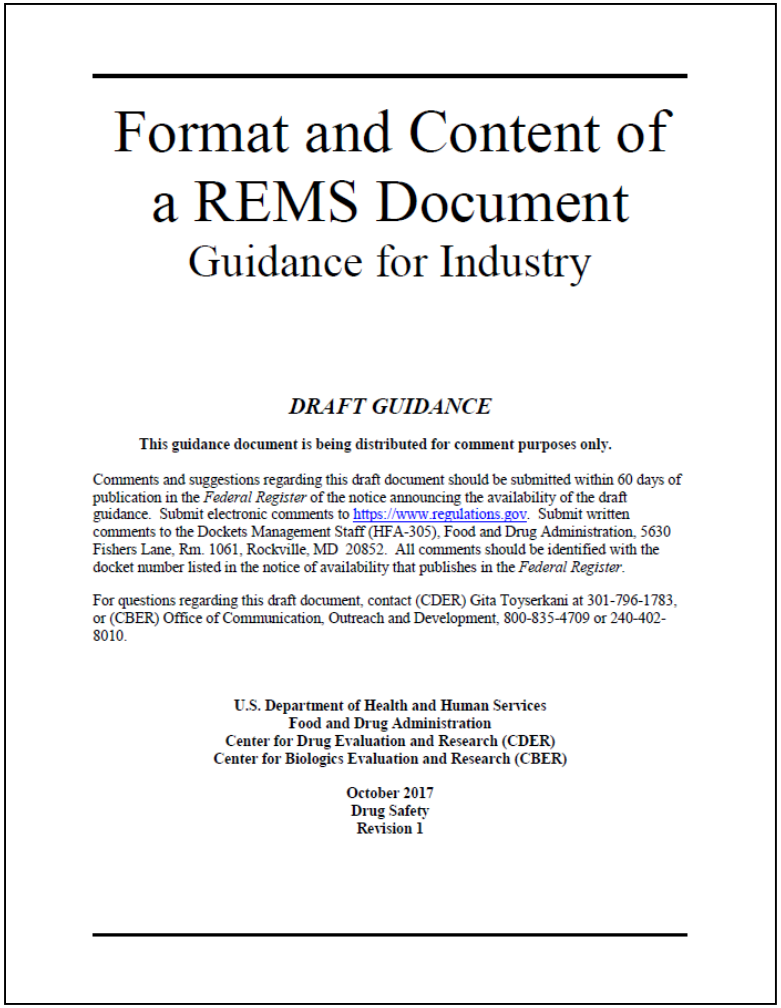
Rachel E. Sherman, M.D., M.P.H., Steven A. Anderson, Ph.D., M.P.P.,
Gerald J. Dal Pan, M.D., M.H.S., Gerry W. Gray, Ph.D., Thomas Gross, M.D., M.P.H.,
Nina L. Hunter, Ph.D., Lisa LaVange, Ph.D., Danica Marinac-Dabic, M.D., Ph.D.,
Peter W. Marks, M.D., Ph.D., Melissa A. Robb, B.S.N., M.S., Jeffrey Shuren, M.D., J.D.,
Robert Temple, M.D., Janet Woodcock, M.D., Lilly Q. Yue, Ph.D., and Robert M. Califf, M.D.

U.S. FOOD & DRUG ADMINISTRATION

Risk Evaluation and Mitigation Strategies

Format and Content of REMS Document

- Format and Content of a REMS Document
  - Revised draft guidance
- Includes a section for each participant
  - Who
  - What
  - When
  - With what



Format and Content of a REMS Document

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

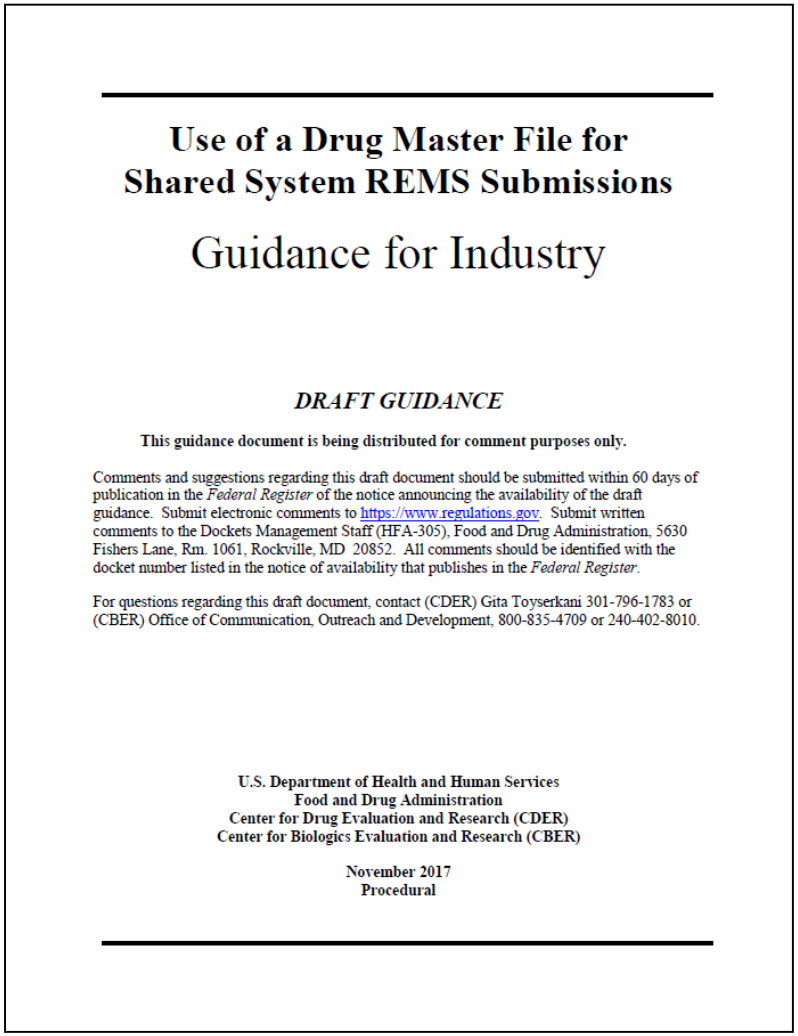
For questions regarding this draft document, contact (CDER) Gita Toyserkani at 301-796-1783, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2017
Drug Safety
Revision 1

Use of a Drug Master File for Shared System REMS Submissions

- Draft guidance issued November 2017
- Intended to improve efficiency



Use of a Drug Master File for Shared System REMS Submissions

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

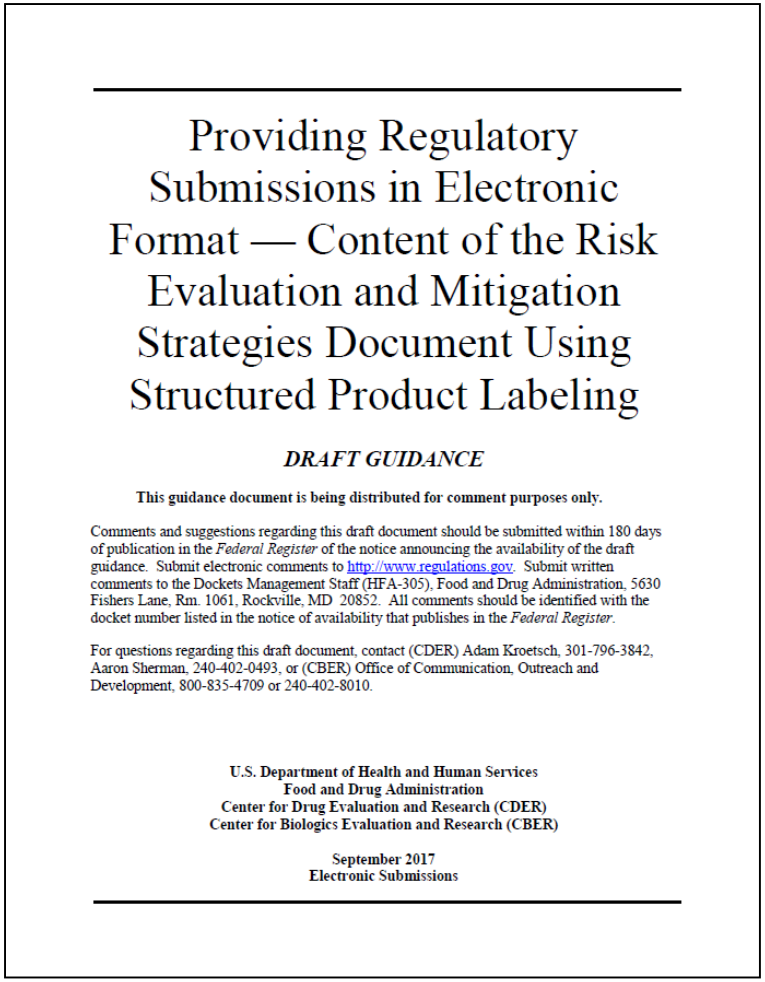
For questions regarding this draft document, contact (CDER) Gita Toyserkani 301-796-1783 or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2017
Procedural

REMS Document and Structured Product Labeling

- REMS into SPL format
  - Draft guidance
- Make REMS information available within existing healthcare systems and workflows
  - Easier sharing of information and incorporation in health information technology



Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

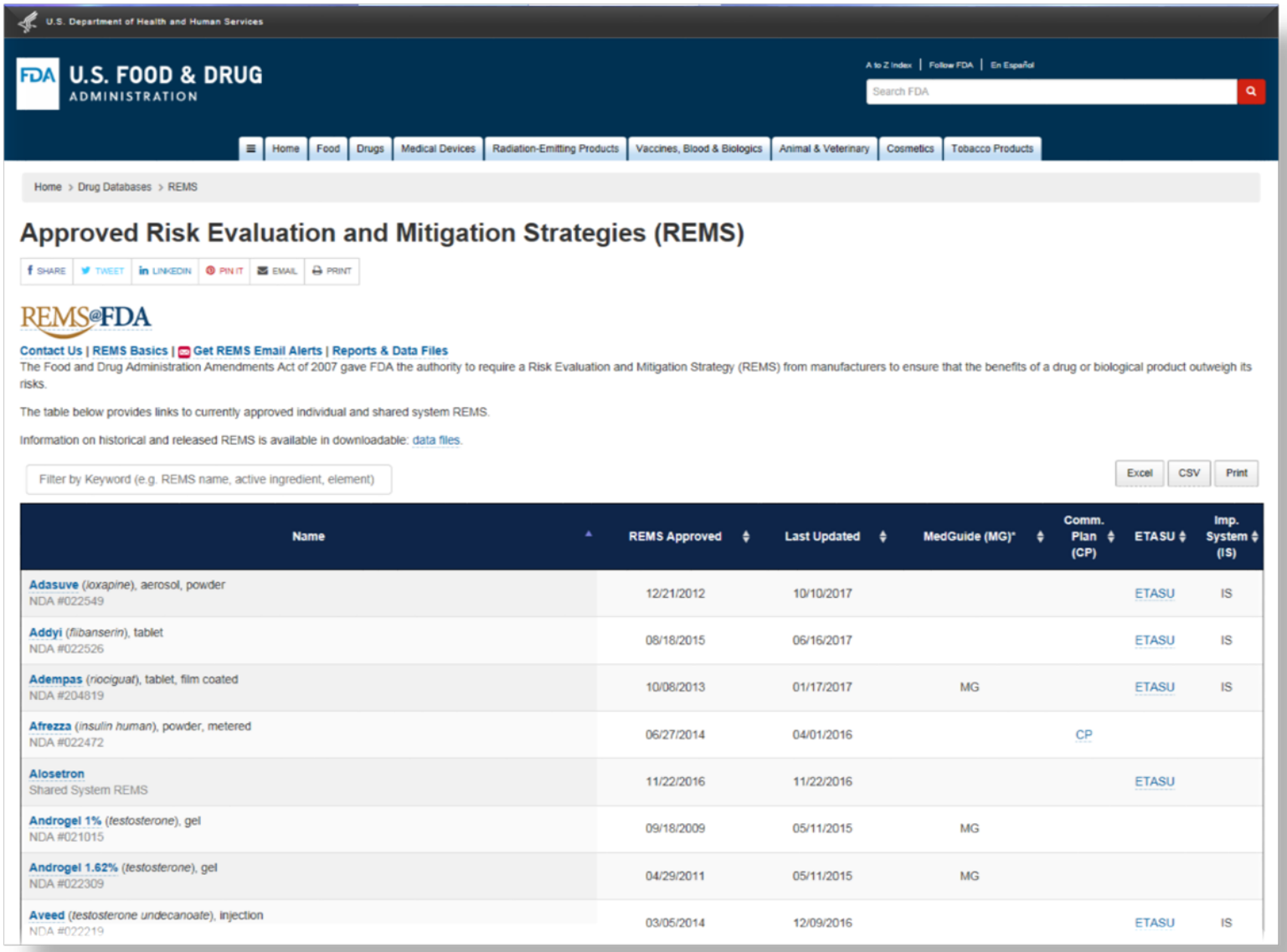
Comments and suggestions regarding this draft document should be submitted within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Adam Kroetsch, 301-796-3842, Aaron Sherman, 240-402-0493, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

September 2017
Electronic Submissions

REMS Website



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Home > Drug Databases > REMS

Approved Risk Evaluation and Mitigation Strategies (REMS)

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

REMS@FDA

Contact Us | REMS Basics | Get REMS Email Alerts | Reports & Data Files

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

The table below provides links to currently approved individual and shared system REMS.

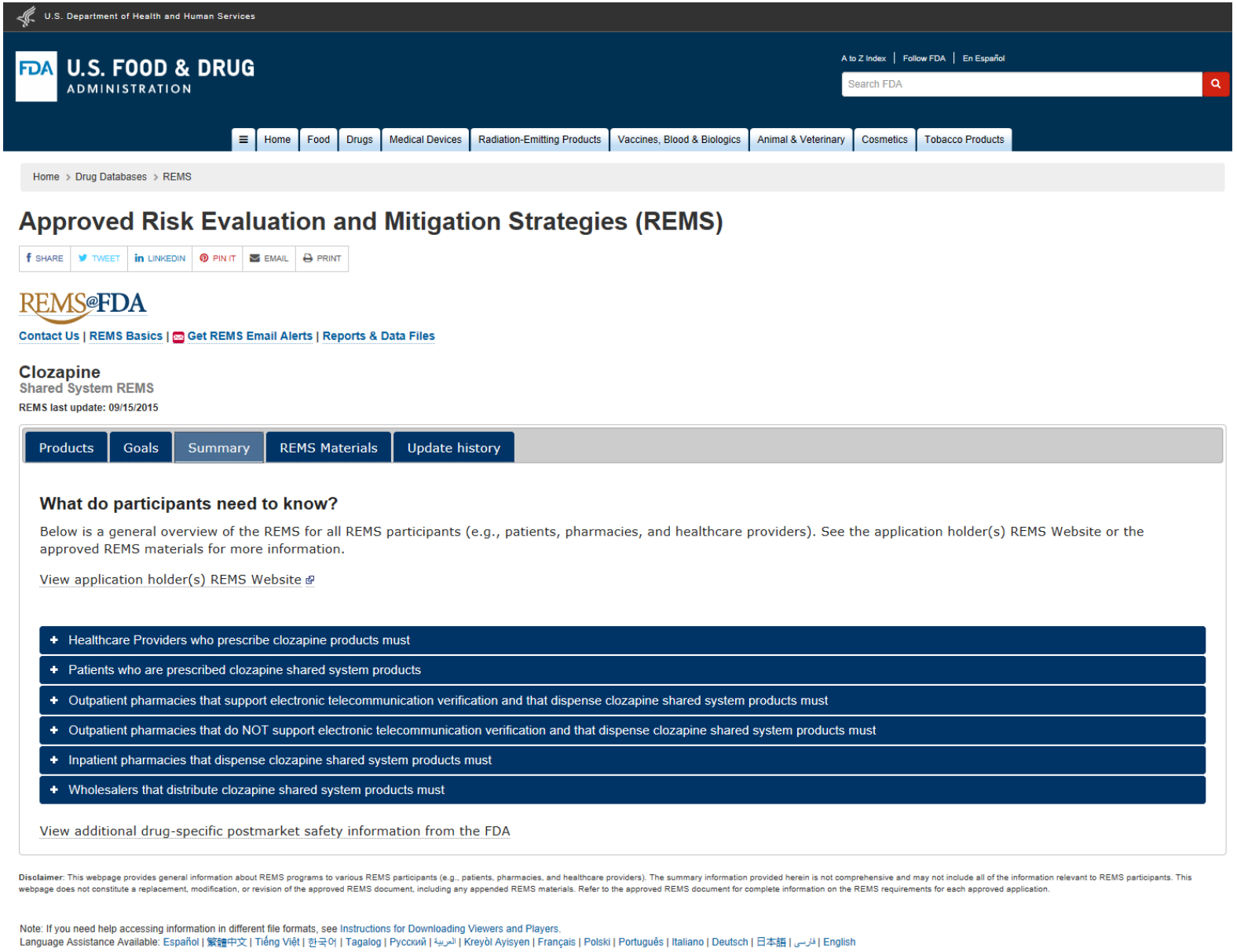
Information on historical and released REMS is available in downloadable: data files.

Filter by Keyword (e.g. REMS name, active ingredient, element)

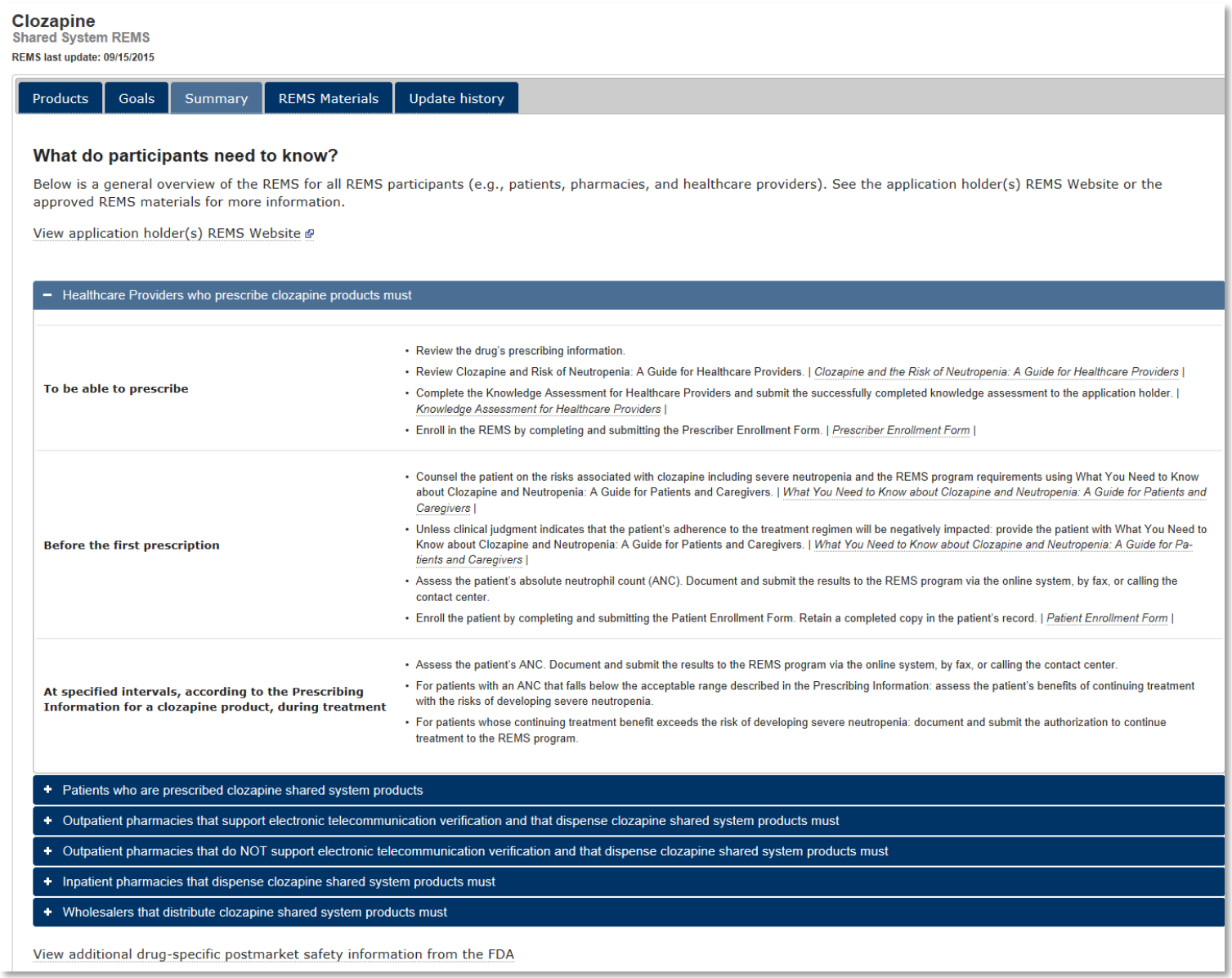
Excel | CSV | Print

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Adasuve (*loxapine*), aerosol, powder NDA #022549	12/21/2012	10/10/2017			ETASU	IS
Addyi (*flibanserin*), tablet NDA #022526	08/18/2015	06/16/2017			ETASU	IS
Adempas (*riociguat*), tablet, film coated NDA #204819	10/08/2013	01/17/2017	MG		ETASU	IS
Afrezza (*insulin human*), powder, metered NDA #022472	06/27/2014	04/01/2016		CP		
Alosetron Shared System REMS	11/22/2016	11/22/2016			ETASU	
Androgel 1% (*testosterone*), gel NDA #021015	09/18/2009	05/11/2015	MG			
Androgel 1.62% (*testosterone*), gel NDA #022309	04/29/2011	05/11/2015	MG			
Aveed (*testosterone undecanoate*), injection NDA #022219	03/05/2014	12/09/2016			ETASU	IS

Stakeholder Sections



Stakeholder Sections



Clozapine
Shared System REMS
REMS last update: 09/15/2015

Products | Goals | Summary | REMS Materials | Update history

What do participants need to know?

Below is a general overview of the REMS for all REMS participants (e.g., patients, pharmacies, and healthcare providers). See the application holder(s) REMS Website or the approved REMS materials for more information.

View application holder(s) REMS Website

− Healthcare Providers who prescribe clozapine products must

To be able to prescribe	• Review the drug's prescribing information. • Review Clozapine and Risk of Neutropenia: A Guide for Healthcare Providers. | *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* | • Complete the Knowledge Assessment for Healthcare Providers and submit the successfully completed knowledge assessment to the application holder. | *Knowledge Assessment for Healthcare Providers* | • Enroll in the REMS by completing and submitting the Prescriber Enrollment Form. | *Prescriber Enrollment Form* |
Before the first prescription	• Counsel the patient on the risks associated with clozapine including severe neutropenia and the REMS program requirements using What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers. | *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers* | • Unless clinical judgment indicates that the patient's adherence to the treatment regimen will be negatively impacted: provide the patient with What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers. | *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers* | • Assess the patient's absolute neutrophil count (ANC). Document and submit the results to the REMS program via the online system, by fax, or calling the contact center. • Enroll the patient by completing and submitting the Patient Enrollment Form. Retain a completed copy in the patient's record. | *Patient Enrollment Form* |
At specified intervals, according to the Prescribing Information for a clozapine product, during treatment	• Assess the patient's ANC. Document and submit the results to the REMS program via the online system, by fax, or calling the contact center. • For patients with an ANC that falls below the acceptable range described in the Prescribing Information: assess the patient's benefits of continuing treatment with the risks of developing severe neutropenia. • For patients whose continuing treatment benefit exceeds the risk of developing severe neutropenia: document and submit the authorization to continue treatment to the REMS program.

+ Patients who are prescribed clozapine shared system products

+ Outpatient pharmacies that support electronic telecommunication verification and that dispense clozapine shared system products must

+ Outpatient pharmacies that do NOT support electronic telecommunication verification and that dispense clozapine shared system products must

+ Inpatient pharmacies that dispense clozapine shared system products must

+ Wholesalers that distribute clozapine shared system products must

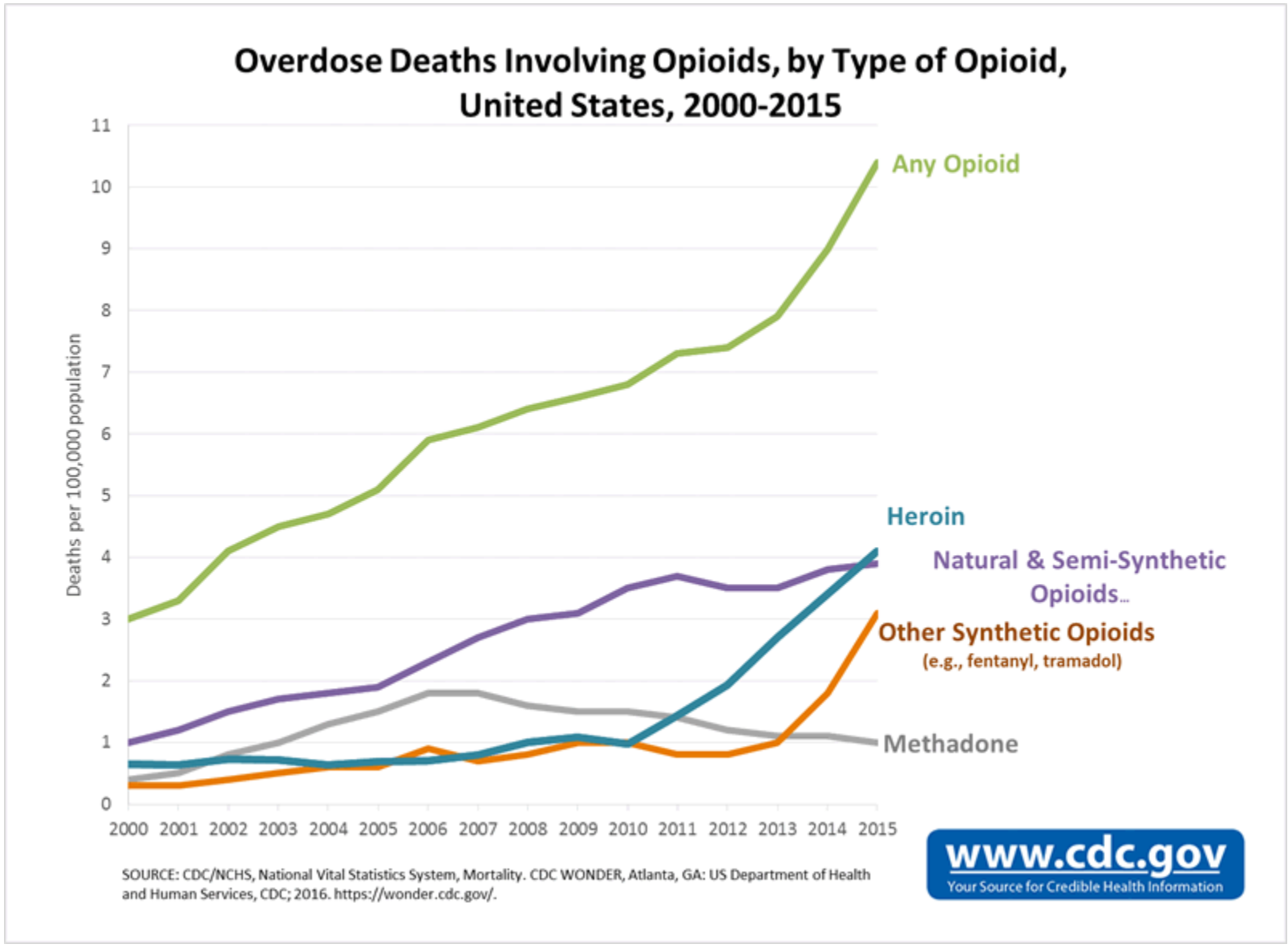
View additional drug-specific postmarket safety information from the FDA

Framework for Benefit-Risk Counseling to Patients About Drug with a REMS

- Part of REMS Integration Initiative
- Four Es:
  - Evaluate
  - Educate
  - Engage
  - Ensure

U.S. FOOD & DRUG ADMINISTRATION

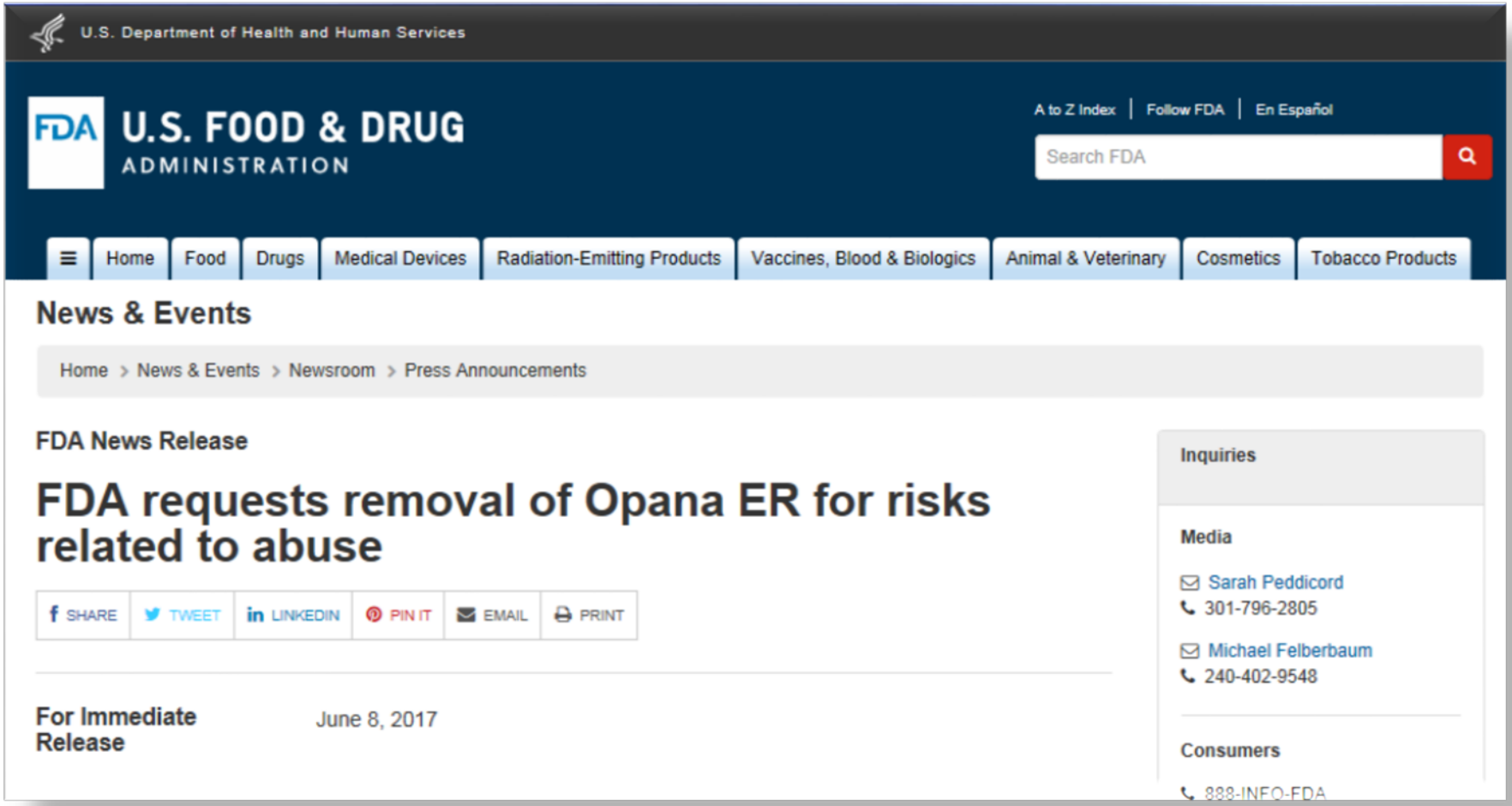
Prescription Opioid Abuse


Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2015
Deaths per 100,000 population
0
1
2
3
4
5
6
7
8
9
10
11
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015
Any Opioid
Heroin
Natural & Semi-Synthetic Opioids..
Other Synthetic Opioids
(e.g., fentanyl, tramadol)
Methadone
SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/.
www.cdc.gov
Your Source for Credible Health Information

Opioids

- A busy year!
- Six of seven Drug Safety and Risk Management Advisory Committee meetings 2017 concerned opioids
- Three public meetings:
  - Packaging, Storage, and Disposal Options To Enhance Opioid Safety--Exploring the Path Forward, December 11-12, 2017
  - Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities, July 10, 2017
  - Training for Opioid Analgesic Prescribers, May 9-10, 2017

Opana ER


U.S. Department of Health and Human Services
FDA
U.S. FOOD & DRUG
ADMINISTRATION
A to Z Index | Follow FDA | En Español
Search FDA
Home
Food
Drugs
Medical Devices
Radiation-Emitting Products
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Tobacco Products
News & Events
Home > News & Events > Newsroom > Press Announcements
FDA News Release
FDA requests removal of Opana ER for risks related to abuse
SHARE
TWEET
LINKEDIN
PIN IT
EMAIL
PRINT
For Immediate Release
June 8, 2017
Inquiries
Media
Sarah Peddicord
301-796-2805
Michael Felberbaum
240-402-9548
Consumers
888-INFO-FDA


FDA
U.S. FOOD & DRUG
ADMINISTRATION