Publicly Available Pharmacovigilance Resources

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Objective

• Provide useful publicly available resources to assist you in pharmacovigilance activities
Vaccine Adverse Event Reporting System (VAERS)

- General information regarding VAERS can be found at: http://vaers.hhs.gov/about/faqs

- Inquiries for vaccine adverse events can be conducted through WONDER

Source: Public Health Image Library
WONDER online databases utilize a rich ad-hoc query system for the analysis of public health data. Reports and other query systems are also available.

WONDER Systems
- AIDS Public Use Data
- Births
- Cancer Statistics
- Environment
  - Daily Air Temperatures
- Mortality
  - Underlying Cause of Death
    - Detailed Mortality
    - Compressed Mortality
  - Multiple cause of death (Detailed Mortality)
  - Infant Deaths (Linked Birth/Infant Death Records)
- Online Tuberculosis Information System
- Population
  - Bridged-Race Population (from NCHS)
  - Population (from Census)
  - Sexually Transmitted Disease Morbidity
  - Vaccine Adverse Event Reporting

Reports and References
- Prevention Guidelines (archive)
- Scientific Data and Documentation

Other Query Systems
- Healthy People 2010
- MMWR Morbidity Tables
- MMWR Mortality Tables

Denotes numerical data available to query or download

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http://wonder.cdc.gov/
FDA Vaccines Web Page

- General information on U.S. licensed vaccines
- Vaccine-related guidance documents
- Question and Answer documents
- FDA consumer updates
- www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm
Biologics Safety and Availability Page

- FDA/CBER posts notices about important adverse event reporting, recalls, shortages, and biological product deviations.

Medical Product Safety Alerts

- **MedWatch Safety Alerts**
  - Timely new safety information on drugs, devices, vaccines and other biologics
  - Actionable information that may impact treatment and diagnostic choices
  - Archived by year

- **Drug Safety Info Page**

http://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm
http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/DrugSafetyInformation/default.htm
Useful Guidances for Industry

• E2E Pharmacovigilance Planning Guidance


• Postmarketing Studies and Clinical Trials Guidance
  • (Postmarketing Studies and Clinical Trials Guidance—Implementation of Section 505(o)(3) of the Federal Food Drug and Cosmetic Act)
Vaccine Product Information: Prescriber Information

- Daily Med

http://dailymed.nlm.nih.gov/dailymed/about.cfm
Vaccine Product Information: Vaccine Information Statements

http://www.cdc.gov/vaccines/pubs/vis/
Advisory Committee on Immunization Practices (ACIP)

http://www.cdc.gov/vaccines/recs/acip/default.htm
Vaccine Safety Datalink (VSD)

- Group of geographically diverse HMOs conducting surveillance and hypothesis testing
- Information on VSD and VSD studies can be found at: http://www.cdc.gov/vaccinesafety/Activities/VSD.html
Mini-Sentinel and Sentinel

• **Mini-Sentinel**
  - 5 year pilot to design surveillance system and begin transition to increased use of active surveillance tools.
  - For more information: [http://www.minisentinel.org/default.aspx](http://www.minisentinel.org/default.aspx)

• **Sentinel**
  - An active electronic safety monitoring system to strengthen FDA’s ability to monitor post-market adverse events
  - [www.fda.gov/Safety/FDAsSentinelInitiative/default.htm](http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm)
FDA can require Post-Market Requirement studies under FDAAA

Status of these studies can be found at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm
Risk Evaluation and Mitigation Strategies (REMS)

• REMS may be required by FDA to ensure that benefits continue to outweigh risks

• For any product with a REMS, details can be found at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=REMS&utm_content=1
Post-marketing Drug & Biologics Safety Evaluations Page

- Summary findings from Comprehensive Safety Reviews (18 months post-approval)

Good Pharmacovigilance Practices

- Identifying and describing safety signals
- Investigating a signal through observational studies
- Interpreting safety signals
- Developing a pharmacovigilance plan

Questions?
FDAAA 2007

- FDAAA 2007 increased FDA authority to study and evaluate post-market events