

MedDRA Use at FDA

ASEAN MedDRA Workshop

March 19, 2010

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International Conference on Harmonisation of Technical
Requirements for Registration of Pharmaceuticals for Human Use



Disclaimer :

- The information within this presentation represents the views of the presenter, not necessarily those of the FDA.



Learning Objectives

At the end of session, participants will be able to:

- Describe the utilization of MedDRA at FDA
- Understand FDA's coding practices for postmarketing reports
- Describe strategy for data retrieval and analysis using MedDRA



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Topics

- MedDRA use in FDA Centers (general)
- MedDRA use in Center for Drugs (CDER)
 - Post-marketing adverse events
 - AERS reports
 - Adverse event coding
 - Data retrieval and review
 - MedDRA upversioning
 - Pre-marketing adverse events
- MedDRA Training



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Why MedDRA?

ICH initiative (M1)

- An international terminology for coding of medical information throughout the regulatory cycle (clinical trials Phase I-IV and post-marketing)
- Enables standardized communication of coded data between regulators and manufacturers/sponsors.
 - Example: MedDRA used in electronic transmission of Individual Case Safety Reports (ICSRs) following ICH E2B standards

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Why MedDRA (cont)?

- Enables medical accuracy and transparency in coding, since many and specific MedDRA terms
- MedDRA Hierarchy and other concept groupings (such as SMQs) allow for useful data retrieval and presentation
- Global ICH-endorsed guides for coding and data retrieval (ICH *Points to Consider* documents)
- Global version synchronization

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MedDRA use in FDA Centers

- Center for Drugs (CDER)
Center for Drug Evaluation and Research
 - uses MedDRA in pre and post marketing
 - FDA Adverse Event Reporting System (AERS) database is coded in MedDRA since 1997; legacy data migrated
- Center for Biologics (CBER)
Center for Biologics Evaluation and Research
 - VAERS database in MedDRA since 2007; legacy data migrated
- Center for Foods (CFSAN)
Center for Food Safety and Applied Nutrition
 - CFSAN Adverse Event Reporting System (CAERS) database is coded in MedDRA since 2002



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Is MedDRA Required at FDA ?

- MedDRA is not currently required at FDA
- However, most drug reports from manufacturers are received electronically, pre-coded in MedDRA
- In March 2003, FDA issued a proposed rule (*Safety Reporting Requirements for Human Drug and Biological Products*)
 - to require MedDRA for coding of post-marketing adverse event reports
 - rule is not final



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Use of MedDRA in CDER (1)

- November 1997: AERS launch, using MedDRA
 - Prior to this FDA coded AE reports in COSTART and entered them into the Spontaneous Reporting System (SRS)
 - Migrated 1.5 million records into AERS using COSTART to MedDRA mapping

- Over 3 million reports entered into AERS and coded in MedDRA since November 1997

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Use of MedDRA in CDER (2)

- In AERS, MedDRA is used to code:
 - The “events”
 - adverse events
 - medication errors
 - and/or product quality issues
 - Indications for use
- Data entry contractor (PSI International) has a coding staff
- Majority of manufacturer reports are submitted electronically pre-coded in MedDRA
 - Our coding staff performs QC on mfr. coding

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Use of MedDRA in CDER (3)

- Pre-approval clinical trials
 - Safety data submitted with new drug applications (NDA) are often coded in MedDRA
 - Medical officers and biostatisticians in CDER have increased their use of MedDRA in recent years
 - (More on premarketing MedDRA use later)

Post-marketing: The Adverse Event Reporting System (AERS)

Evaluation of Safety Issues: role of AERS and MedDRA

Many data sources are used (as applicable) for the evaluation of safety issues:

- Spontaneous adverse event reports (from AERS) is one source
- Epidemiologic data
- Medical literature
- Data from the NDA or BLA, other sponsor submissions
- Additional information from the sponsor, such as clinical trial data, postmarketing adverse event data, and/or datasets with specific data elements



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AERS

- FDA's post-marketing safety surveillance program for drug and therapeutic biologic products
- FDA uses AERS to monitor for new adverse events, medication errors, etc
- FDA staff in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) regularly examine the AERS database as part of routine safety monitoring
- When a potential signal of a serious risk is identified from AERS data, it is further evaluated



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Source of AE Reports Sent to CDER (1)

- Adverse event reporting is a voluntary process for healthcare professionals in the U.S.
- Healthcare professionals and consumers may send reports to manufacturers and/or the FDA (spontaneous reporting)
- Manufacturers are required to forward reports to FDA as per regulation



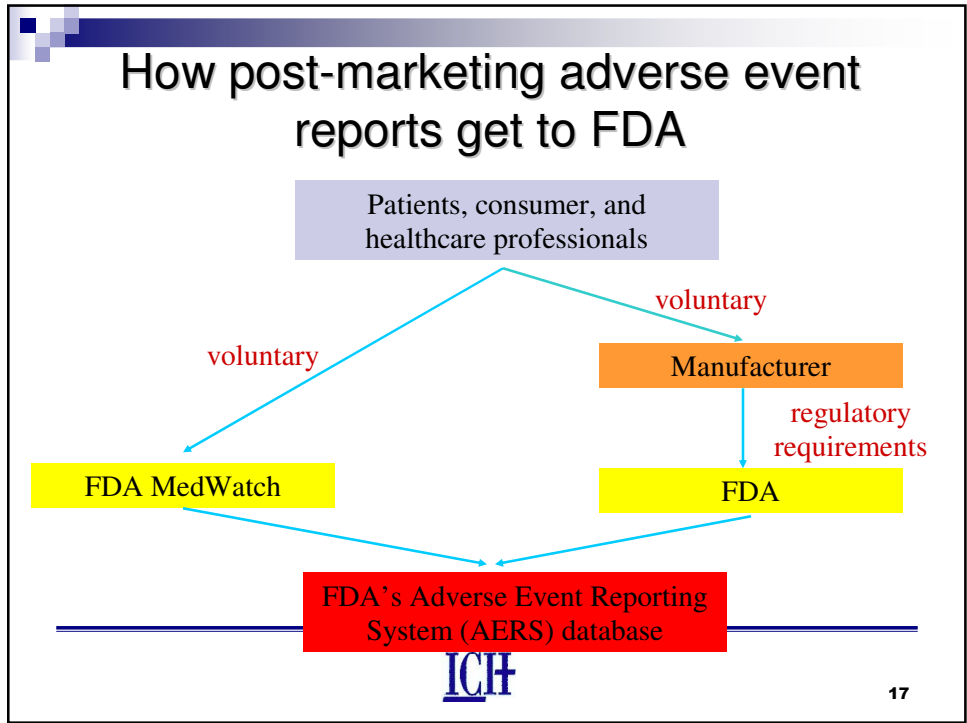
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Source of AE Reports Sent to CDER (2)

- Voluntary:
 - Direct to FDA by consumers and healthcare providers via MedWatch Program
 - ~5% of reports
- Mandatory:
 - Manufacturer regulatory requirement to report adverse events they become aware of to FDA
 - ~95% of reports



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- ## AE Reporting Requirements Drugs and Biologics
- Prescription drugs with or without approved applications, prescription biologics
 - 15-day reports (serious / unexpected)
 - Periodic reports (serious expected & all nonserious)
 - Only for products with approved applications
 - Quarterly for 3 years from approval, then annually
 - Nonprescription drugs without approved applications
 - 15-day reports (all serious)
-
- ICH
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Serious Adverse Event Regulatory Definition

Any adverse event occurring at any dose that results in any of the following outcomes:

- Death
- Life threatening
- In-patient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Important medical events based on appropriate medical judgment
 - may jeopardize the patient or subject and
 - may require medical or surgical intervention to prevent one of the other outcomes

Expected/Unexpected Adverse Event

- Expected:
 - Listed in current labeling, “labeled”

- Unexpected:
 - Not listed in current labeling, “unlabeled”

Adverse Drug Experience

- Any adverse event associated with the use of a drug in humans, whether or not considered drug related; includes adverse events from
 - use of drug in professional practice
 - drug overdose, accidental or intentional
 - drug abuse
 - drug withdrawal
 - any failure of expected pharmacological action

What Type of Reports are in AERS?

- Adverse Events
- Medication Errors
- Product Problems (with adverse events)

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- CDER: Drugs and therapeutic biologics, prescription + over-the-counter (OTC) products
- CBER: Tissue products, therapeutic blood products

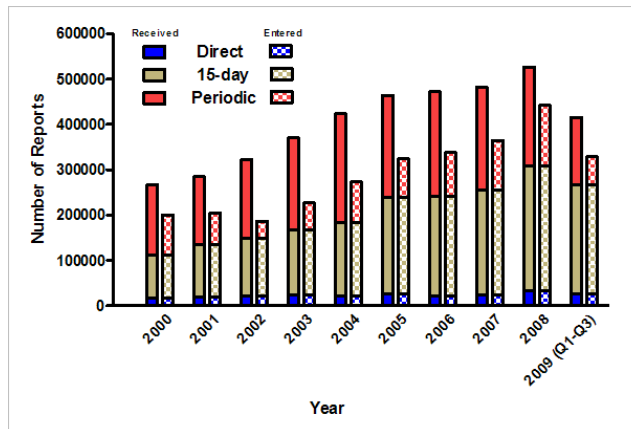
Electronic Submission (E-sub) of Individual Case Safety Reports (ICSRs)

- Follow ICH E2B standards
- Pre-coded in MedDRA
- Initiated in 2000, increasing every year
- As of end of 2009:
 - ~80% of total ICSRs from manufacturers are submitted to FDA as e-sub
 - ~50% of Periodic reports



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Reports Received (Solid Bars) and Entered (Checked Bars) into AERS by Type of Report: 2000 – 2009 (Quarter 3)



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AERS and MedDRA Coding Standards

- ICH-Endorsed Guide for MedDRA Users: *MedDRA® TERM SELECTION: POINTS TO CONSIDER*
 - Designed to promote medical accuracy and consistency in term selection
 - If more than one option, a “preferred option” is identified
 - Serves as a backbone for developing internal organization-specific coding guidelines
 - FDA Coding Principles for Postmarketing Adverse Event Reports
 - Harmonized with the ICH PTC document
 - FDA encourages firms to base their own coding guidelines on, and not conflict with, the ICH PTC document
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Why FDA Evaluates Manufacturer-submitted MedDRA Coding

- FDA depends on many different companies to submit accurate and complete MedDRA coded reports
 - Rely on coded data to perform analyses and generate important safety signals
 - Inaccurate and/or incomplete coding results in delayed, misdirected or missed safety concerns
 - FDA notes missed concepts and soft-coding issues
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Example of Accurate AE Coding

- Patient started treatment with SUSPECT DRUG in November 2009. He had a **fall** in December 2009 and developed **increasing confusion**. In January 2010 he **felt depressed** and complained of more falls. The SUSPECT DRUG was withdrawn. The symptoms improved.
- MedDRA coding:
PT Fall, PT Confusional state, PT Depressed mood



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Example of Soft Coding (1)

- A few days after *suspect drug* was started, patient experienced difficulty breathing. Chest CT scan one week later revealed bilateral pleural effusion. Respiratory failure occurred. Patient was placed on a respirator and treated; *suspect drug* was discontinued; patient recovered. Lung disorder was most likely due to the *suspect drug*.



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Example of Soft Coding (2)

- Soft Coded as
 - *PT Lung disorder*

- Should have coded
 - *PT Respiratory failure*
 - *(PT Pleural effusion)*

MedDRA Upversioning

- Scheduled upversioning of all AERS data
 - PT comparison between the 2 versions
 - Identification of PTs in the old version which are no longer in the new version
 - Mapping these PTs to an existing PT
 - Replacing these PT codes in AE reports

- Information distribution to staff

- MSSO's *What's New Webinar*

CDER MedDRA Working Groups

- MedDRA Coding Working Group
 - Office of Surveillance and Epidemiology (OSE), CBER, Office of Compliance (OC)
 - AERS data
- MedDRA Coordinating Working Group
 - CDER level, broader issues
 - both pre and post marketing
- FDA representatives to ICH MedDRA PTC Working Group, CIOMS/MSSO SMQ Working Group and MedDRA Management Board



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AERS & Office of Surveillance and Epidemiology

- OSE Safety Evaluators are assigned product groups
- Monitor AERS reports for Adverse Events, Medication Errors, DME* events for their products
- Conduct AERS data review and analysis
 - Signal Identification
 - Signal Evaluation
 - Collaboration with other disciplines (OSE & CDER)
 - Recommendations regarding potential regulatory actions

- * Designated Medical Events (more later)



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AERS Data: Public Availability

- Freedom of Information (FOI)
 - AERS data can be released to public who request adverse event data
 - MedDRA coded data is included
- AERS Data Files available for public access
 - Quarterly web posting, but without a search tool
 - On FDA AERS website since 2004
- World Health Organization (WHO)
 - U.S. AERS data is sent quarterly to Uppsala Monitoring Center (UMC)/ WHO Programme for International Drug Monitoring AE database (Vigibase)



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Designated Medical Events (sample)

- | | |
|---|---|
| ■ Acute pancreatitis | ■ Liver failure/necrosis/
transplant |
| ■ Acute respiratory failure | ■ Pancytopenia |
| ■ Agranulocytosis | ■ Seizure |
| ■ Anaphylaxis / anaphylactoid
reactions | ■ Stevens-Johnson Syndrome |
| ■ Aplastic anemia | ■ Sudden death |
| ■ Blindness | ■ Torsades de Pointes |
| ■ Bone marrow depression | ■ Toxic epidermal necrolysis |
| ■ Deafness | ■ Thrombotic |
| ■ Disseminated intravascular
coagulation | thrombocytopenic purpura |
| ■ Hemolytic anemia | ■ Ventricular fibrillation |



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DMEs and MedDRA PTs (sample)

DME	PT terms (MedDRA 12.1)
Acute pancreatitis	Pancreatitis, Pancreatitis acute, Pancreatitis haemorrhagic, Pancreatitis necrotising, Pancreatic necrosis
Haemolysis	Haemolysis, Intravascular haemolysis, Haemoglobinaemia, Haemoglobinuria, Haptoglobin decreased
Product infectious disease transmission	Transmission of an infectious agent via a medicinal product, Transfusion-transmitted infectious disease, Product contamination microbial



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Safety Evaluator's Inbox; example

The screenshot shows the 'Incoming ISIRs' tab in the AERS v5.3.1 Risk Assessor Inbox. The interface includes a filter bar, a table of incoming ISIRs, and a list of associated MedDRA PTs.

ISIR #	ISIR Rev#	Criteria Code	N	M	Age	Suspect Product(s)	Reactions	Outcomes
077021-2-6	03/26/2007	SFE					BRYOCARDIAL INFARCTION	OT
097910-7	03/26/2008	SFE					EPILEPSY	OT
074747-4	06/18/2006	DNE					CONVULSION	OT
075011-1	06/26/2008	SFE			72 YR		BREATH/INCOHERENT/VENTILATION/RESPIRATORY PATG	OT
088500-9	06/18/2008	SFE			43 YR		BLINDNESS	DS
088600-0	06/17/2008	SFE			43 YR		BLINDNESS	DS
011906-4	03/18/2006	SFE			57 YR		INTRAVENOUS PHENORFIN/BLOOD PRESSURE IN	OT
074399-2	04/03/2006	SFE			66 YR		PULMONARY OEDEMA/EDSW	NO
019207-8	04/17/2006	DNE			39 YR		TONGUE TIGHTNESS/CONVULSION/ONPHARYNGO	OT
018013-7	06/05/2006	SFE					EPILEPSY	OT
0220780-7	06/17/2006	DNE			39 YR		TONGUE TIGHTNESS/CONVULSION/ONPHARYNGO	OT
0250120-9	07/10/2006	SFE			47 YR		CERVICAL PECTORAL CHEST PAIN	LT
0649737-X	04/27/2006	SFE			57 YR		ANGINA PECTORAL/ARTERIOSPASM CORONARY/8	OT
0758118-9	06/03/2006	DR			68.23 YR		TONGUE DISORDER/OXYGEN SATURATION DECR	OT
063020-1	02/20/2004	DR			72.12 YR		EQUIVOCAL/ECG/IRRITABLE/OT/CONSCIOUS/SPRO	OT
0631020-X	03/20/2004	SFE			72 YR		PAINFUL/ECG/8	OT



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AERS Case Search Strategy

- Crucial: quality of submitted reports, quality of MedDRA coding

- Search: how inclusive or exclusive should it be?
 - Combination of MedDRA PT, HLT, HLTG, and SOC levels
 - MedDRA OSE reaction groups
 - MedDRA SMQs
 - Customized retrieval strategy



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OSE Reaction Groups

- Developed in 2001
 - No Standardized MedDRA Queries (SMQs) at that time
- Purpose: FDA internal consistency in retrieving MedDRA AE data for analysis of safety issues / pre-defined searched strategies
- Built with MedDRA grouping terms (HLTs and HLTGs), plus specific PTs from other sections
- Many topics overlap with current SMQs



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Standardized MedDRA Queries (SMQs)

- CIOMS/MSSO collaboration
 - Available in MedDRA since 2005
- Development, testing, maintenance
- Use in clinical and post-marketing setting, by regulatory agencies and pharmaceutical companies
- SMQs: global consistency in retrieving MedDRA AE data for analysis of specific medical concepts over time and multiple organizations

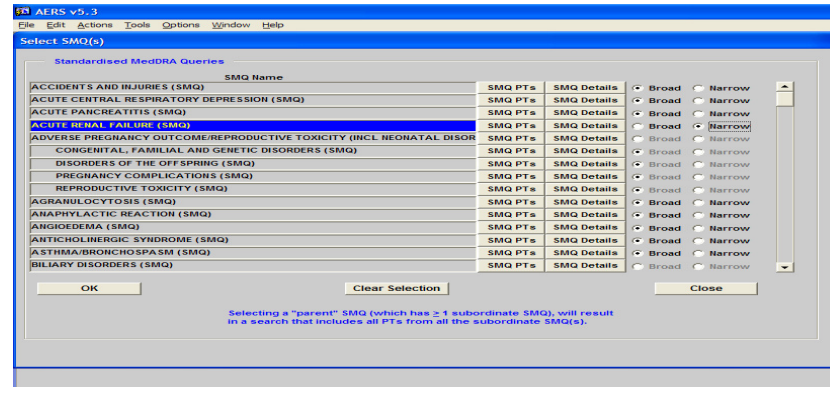


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AERS Search Screen

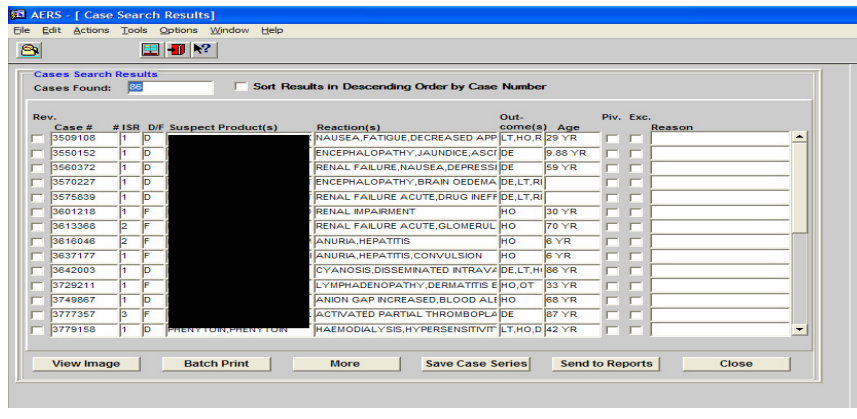
MedDra Terms
Record: 1/1

AERS –SMQ Search Selection



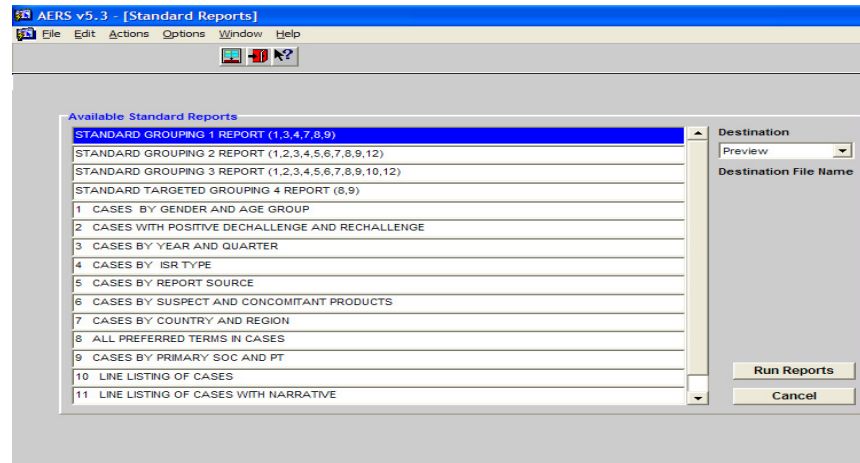
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Search Result on Selected SMQ and Suspect Product



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Available Standard Reports



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Developing a Case Series

- Search AERS database, published literature, and other sources
- Thorough database search strategies based on MedDRA terms
- Case definitions facilitate the development of the case series to provide reasonable evidence of a product related adverse event



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Evaluation of Cases - Principles

- Disease occurrence in expected time
- Absence of symptoms prior to exposure
- Positive dechallenge or rechallenge
- Consistent with pharmacological effects
- Consistent with known effects in the class
- Supporting evidence from pre-clinical studies, clinical trials
- Absence of alternative explanations



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AERS Strengths

- Includes all of U.S. and all U.S. marketed products
- Detection of events which were not seen in clinical trials
 - especially good for events with rare background rate, short latency
- Signal generation
 - one or more reports can trigger further evaluation of a possible safety signal
- Case series evaluation:
 - identification of trends
 - possible risk factors
 - clinical significance of emerging safety concerns



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AERS Limitations

- Underreporting
 - Duplicate reporting
 - Variable reporting quality, incomplete information
 - Reporting biases
 - Spontaneous reporting cannot be used to determine incidence of adverse events
 - Difficult to attribute events with high background rate, long latency
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AERS Search Topics (example)

- A new drug review at 18 months/ 10,000 prescriptions – all data
 - An area of concern for a drug, for example, blood dyscrasias
 - A specific scenario:
 - Drug X (a patch) and incorrect application
 - Drug Y and thyroid discoloration
 - Drug Z and hyperglycemia in the pediatric population
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AERS Search Strategy (example)

Drug X and blood dyscrasias - a search strategy

- Identify all reports and view all reported events in decreasing frequency
- Specific search on MedDRA terms: HLT *Marrow depression and hypoplastic anaemias*, PT *Bone marrow disorder*, PT *Biopsy bone marrow*, PT *Biopsy bone marrow abnormal*, PT *Reticulocyte count decreased*, PT *Reticulocyte count abnormal*, HLT *Neutropenias*, PT *Leukopenia*, PT *Lymphopenia*, PT *Thrombocytopenia*
- SMQ search: *Haematopoietic cytopenias* (SMQ)
- Review all reports with “Death” outcome and include any additional terms

Data Mining

- A statistical technique of searching a large database for associations at “higher than expected” frequencies
- Goal: to detect “higher than expected” drug and (MedDRA-coded) event pair frequencies for post-marketing reports
- Always need case evaluation of data mining signals
 - we do *not* assume that “higher than expected” means that there is a causal relationship

OSE use of Data Mining

- OSE desktop WebVDME (Empirica Signal) available since 2005
- Tool to identify unusual or unexpected product-event combinations
- Case report evaluation and other safety information accompany data mining result review



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Assessing Signals - Epidemiology

- Putting case reports into a broader public health perspective
- Calculation of reporting rate in the exposed population – using denominator (drug use data)
- Compare to estimates of background occurrence rate in the general population
- Comparison of a similar period for similar or the same class of products
- Analyses of cases to identify population at risk
- Studying safety signals in population databases



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Pre-marketing Data Safety Review

New Drug Safety Review

- Adverse event (AE) and coding review
- Major sections of a safety submission review
 - Deaths
 - Serious adverse events (SAEs)
 - AEs related to dropouts/discontinuations
 - Common adverse events

Terminologies for Classifying AEs

- Medical Dictionary for Regulatory Activities (MedDRA) is the most used terminology in new drug safety data submissions
 - MedDRA not required for safety data submissions
 - ICH initiative and FDA standard for AEs
- May encounter data in an other (older) terminology
- FDA recommends submitting data in a single terminology and integrated safety summary (ISS) in the same version of that terminology



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Verbatim – LLT/PT Coding

Verify medical accuracy, consistency

Potential coding issues:

- Lumping dissimilar terms
 - Specific AEs all coded under an “umbrella” term
 - May obscure a safety signal under the lumped term
- Splitting similar terms
 - Splitting results in lower incidence
 - May minimize or mask a safety signal
- Miscoding



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“Lumping” Specific Terms (1)

- Face edema
 - Lip edema
 - Eyelid edema
 - Edema of hands
 - Foot edema
- Coding issue: all lumped to PT Oedema

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“Lumping” Specific Terms (2)

- | | |
|------------------|----------------------|
| ■ Face edema | PT Face oedema |
| ■ Lip edema | PT Lip oedema |
| ■ Eyelid edema | PT Eyelid oedema |
| ■ Edema of hands | PT Oedema peripheral |
| ■ Foot edema | |

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“Splitting” Similar Terms

- Splitting due to miscoding
“Stomach flu” and “Viral gastroenteritis”
- Appearance of “splitting” due to MedDRA granularity – issue of search strategy, not of coding
 - HLT Neutropenias vs. PT Neutropenia
(*HLT Neutropenias* contains PT *Agranulocytosis* PT *Autoimmune neutropenia* PT *Cyclic neutropenia* PT *Febrile neutropenia* PT *Felty's syndrome* PT *Granulocytopenia* PT *Granulocytopenia neonatal* PT *Idiopathic neutropenia* PT *Infantile genetic agranulocytosis* PT *Neutropenia* PT *Neutropenia neonatal* PT *Neutropenic colitis* PT *Neutropenic infection* PT *Neutropenic sepsis*)

Miscoding

- General term selected instead of specific
 - “Infection, expired due to salmonella sepsis”
miscoded to PT *Infection*
- Complex verbatim and miscoding
 - “Fall due to dizziness” –
miscoded to only PT *Dizziness*
 - “Acute renal failure due to cardiac arrest” -
miscoded to only PT *Cardiac arrest*

Data Retrieval: Grouping Terms

- Consideration of only individual AEs may result in missing groupings of AEs
(Example: Serotonin syndrome)
- Establish a case definition for a syndrome of interest

Data Retrieval: MedDRA Specificity

- A toxicity can manifest with multiple signs, each coded with a different Preferred Term
- Example:
 - These PTs may represent the same toxicity:
 - Vision blurred
 - Visual impairment
 - Accommodation disorder
 - Visual acuity reduced
 - Diplopia
 - Presbyopia

Data Retrieval: MedDRA Levels

Perform analyses on all levels of MedDRA hierarchy

■ PT*

- Vision blurred 2/200 (1.0%)
- Visual impairment 2/200 (1.0%)
- Diplopia 1/200 (0.5%)
- Visual acuity reduc. 1/200 (0.5%)
- Accommod disorder 1/200 (0.5%)
- Presbyopia 1/200 (0.5%)

■ HLGT

Vision Disorders
8/200 (4%)

All of these PTs are grouped in HLGT *Vision Disorders*. An AE analysis of HLGT *Vision Disorders* shows a higher percentage of events and appears higher up in a table sorted according to frequency

* Examples utilize MedDRA version 12.0



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Frequency by MedDRA Levels

Preferred Term		HLT		HLGT		SOC	
Vision blurred	1%	Visual disorders NEC	2.5%	Vision disorders	4.0%	Eye disorders	4.0%
Visual impairment	1%						
Diplopia	0.5%						
Visual acuity reduced	0.5%	Partial vision loss	0.5%				
Accommodation disorder	0.5%	Refractive and accommodative disorders	1.0%				
Presbyopia	0.5%						

All of these PTs are grouped under HLGT *Vision Disorders*. An AE analysis of HLT *Visual Disorders NEC* shows a higher percentage of events and appears higher up in a table sorted according to frequency



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Adverse Event Profile with a Rate of $\geq 2\%$ *

Preferred Term	Study Drug n (%)	Control n (%)
Diarrhoea	32 (16%)	29 (14.5%)
Nausea	31 (15.5%)	25 (12.5%)
Headaches	20 (10%)	22 (11%)
Vomiting	18 (9.0%)	18 (9.0%)
Fatigue	7 (3.5%)	9 (4.5%)
Vaginal moniliasis	6 (3%)	5 (2.5%)
Dysgeusia	4 (2%)	0 (0%)

* Includes all adverse events with a rate of $\geq 2\%$

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Adverse Events with a Rate of $< 2\%$

Preferred Term	Study Drug n (%)	Control n (%)
Rash	3 (1.5%)	2 (1.0%)
Dry mouth	2 (1%)	3 (1.5%)
Vision blurred	2 (1%)	1 (0.5%)
ALT increased	2 (1%)	3 (1.5%)
Skin exfoliation	2 (1%)	1 (0.5%)
Visual impairment	2 (1%)	1 (0.5%)
Glossitis	1 (0.5%)	1 (0.5%)
Accommodation disorder	1 (0.5%)	0 (0.0%)
Visual acuity reduced	1 (0.5%)	0 (0.0%)
Memory impairment	1 (0.5%)	2 (1%)
Diplopia	1 (0.5%)	0 (0.0%)
Mucocutaneous rash	1 (0.5%)	0 (0.0%)
Presbyopia	1 (0.5%)	0 (0.0%)

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Adverse Event Profile*

High Level Group Term	Study Drug n (%)	Control n (%)
GI Signs and Symptoms	49 (24.5%)	40 (20%)
GI Motility conditions	32 (16%)	29 (14.5%)
Headaches	20 (10%)	22 (11%)
Vision Disorders	8 (4%)	2 (1%)
General system disorders NEC	7 (3.5%)	9 (4.5%)
Epidermal and dermal conditions	6 (3.0%)	3 (1.5%)
Fungal infectious disorders	6 (3%)	5 (2.5%)

* Includes all adverse events with a rate of $\geq 2\%$



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Lessons Learned

- Perform AE analyses on all levels of MedDRA hierarchy
 - Request that all levels of the MedDRA Hierarchy are provided
 - Request inclusion of all MedDRA levels in an AE Analysis Dataset

- Use SMQs



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AE MedDRA Data Display

Verbatim-LLT-PT-HLT-HLGT-Primary SOC-Secondary SOC(s)

AE Verbatim	LLT	PT	HLT	HLGT	Prim SOC	Sec SOC
Red at application site	Application site redness	Application site erythema	Application and instillation site reactions	Administration site reactions	General	Skin

MedDRA Training

MedDRA Training Courses/Resources

- Training
 - FDA is highly supportive of MedDRA training
 - MSSO provides courses at CDER
 - MedDRA Introduction
 - MedDRA: Safety Data Analysis and SMQs
 - Internal experts provide additional training sessions
 - Resources
 - MSSO website
 - CDER Intranet website
 - Expert support
-



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Acknowledgments

- Toni Piazza-Hepp
 - Chuck Cooper
 - Roger Goetsch
 - Lauren Y. Choi
 - Joe Tanning
 - Lisa Jones
 - Jake Kelsey
 - ...and others
-



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Questions / Discussion

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