



MedDRA® Use at CDER

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Disclaimer :

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

Topics

- MedDRA Use
 - Post-marketing adverse events
 - AERS reports
 - Adverse event coding
 - Data retrieval and review
 - MedDRA upversioning
 - Pre-marketing adverse events
- MedDRA Training

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
- Enables medical accuracy and transparency in coding, with extensive, specific MedDRA terms

Why MedDRA (cont)?

- 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

MedDRA use in FDA Centers

CDER: Center for Drug Evaluation and Research

- Postmarket surveillance:
 - 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

MedDRA use in FDA Centers (2)

CDER: Center for Drug Evaluation and Research

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

MedDRA use in FDA Centers (3)

CDER: Center for Drug Evaluation and Research

- VAERS database in MedDRA since 2007; legacy data migrated

CFSAN: Center for Food Safety and Applied Nutrition

- CFSAN Adverse Event Reporting System (CAERS) database is coded in MedDRA since 2002

Is MedDRA Required at FDA ?

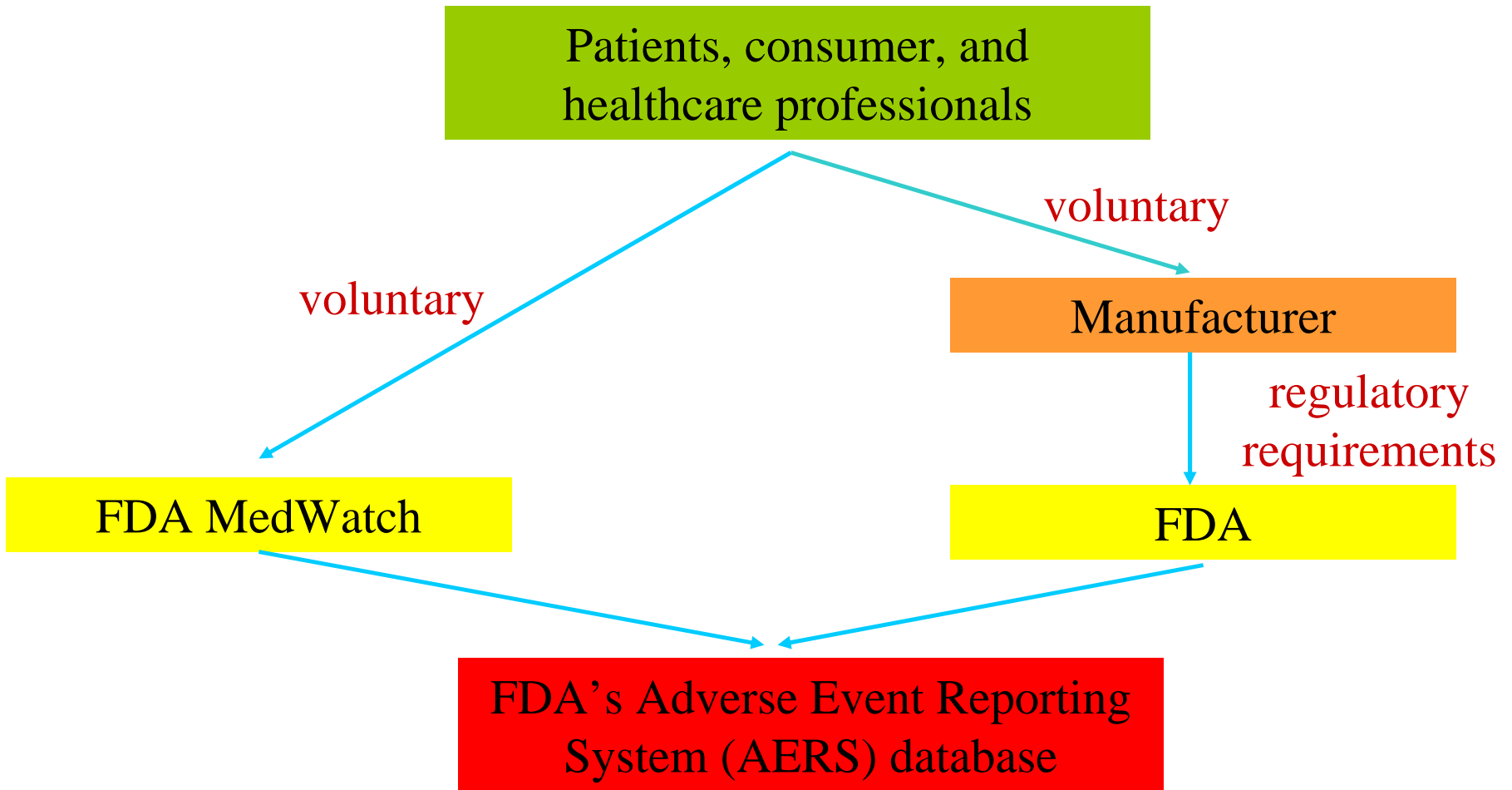
- MedDRA is not currently required at FDA
- However, most drug adverse event reports from manufacturers are received electronically, pre-coded in MedDRA
- In March 2003, FDA issued a proposed rule (*Safety Reporting Requirements for Human Drug and Biological Products*)
 - to require MedDRA for coding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



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



How post-marketing adverse event reports get to FDA



What Type of Reports are in AERS?

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

FOR

- 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

FDA Evaluates Manufacturer-submitted MedDRA Coding

- FDA depends on many different companies to submit accurate and complete MedDRA coded reports
 - Reliance on coded data to perform analyses and generate important safety signals
- Inaccurate and/or incomplete coding: delayed, misdirected or missed safety concerns
- AERS Data entry contractor, PSI International, has a coding staff, performs Quality Assurance of Mfr coding

AERS and MedDRA Coding Standards

- ICH-Endorsed Guide for MedDRA Users:
MedDRA® Term Selection: Points To Consider
<http://www.ich.org/LOB/media/MEDIA5939.pdf>
 Designed to promote medical accuracy and consistency in term selection
 - 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-defined Mfr. Coding “Errors”

- Missed Concepts
 - All medical concepts described after the product is taken should be coded
 - Concepts not captured in coding are “missed”

- “Soft Coding”
 - MedDRA terms that most accurately reflect the reporter’s words should be selected
 - Selecting a term which is both less specific and less severe than another term that exists in MedDRA is “soft coding”

FDA Recommendations

- Organizations should utilize MedDRA specificity and avoid soft coding errors
 - Critical for later retrieval / signal generation
- FDA encourages organizations to follow *ICH MedDRA Term Selection Points to Consider*
 - Organizations should establish their own coding guidelines based on, and not conflicting with, the ICH PTC document

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

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)

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, HLG, and SOC levels
 - MedDRA OSE reaction groups
 - MedDRA SMQs
 - Customized retrieval strategy

Designated Medical Events (sample)

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

DMEs and MedDRA PTs (sample)

DME	PT terms (MedDRA 13.0)
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

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 HLGs), plus specific PTs from other sections
- Many topics overlap with current SMQs

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

AERS Search Screen

AERS v5.3 - [Search ISRs/Cases]

File Edit Actions Tools Options Window Help

Select Search Criteria
 Type of Search: ISRs Search Cases Search

Product

Select Products	Product(s)	Flag	Delete Lot #	Lot #
<input type="button" value="Interaction"/>				
<input type="button" value="Combination"/>				

Include Concomitant Products Include Combination Products

Reaction

Select Reactions	Reaction(s)	Level
<input type="button" value="Select SMQs"/>		

Search for reactions listed

ISR/Case #: Manufacturer Control #: FDA Received Date: From: To:

MM/DD/YYYY MM/DD/YYYY

Meddra Terms
Record: 1/1

AERS –SMQ Search Selection

AERS v5.3
File Edit Actions Tools Options Window Help

Select SMQ(s)

Standardised MedDRA Queries

SMQ Name	SMQ PTs	SMQ Details	Broad	Narrow
ACCIDENTS AND INJURIES (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
ACUTE CENTRAL RESPIRATORY DEPRESSION (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
ACUTE PANCREATITIS (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
ACUTE RENAL FAILURE (SMQ)	SMQ PTs	SMQ Details	<input type="radio"/>	<input checked="" type="radio"/>
ADVERSE PREGNANCY OUTCOME/REPRODUCTIVE TOXICITY (INCL NEONATAL DISOR	SMQ PTs	SMQ Details	<input type="radio"/>	<input type="radio"/>
CONGENITAL, FAMILIAL AND GENETIC DISORDERS (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
DISORDERS OF THE OFFSPRING (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
PREGNANCY COMPLICATIONS (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
REPRODUCTIVE TOXICITY (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
AGRANULOCYTOSIS (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
ANAPHYLACTIC REACTION (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
ANGIOEDEMA (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
ANTICHOLINERGIC SYNDROME (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
ASTHMA/BRONCHOSPASM (SMQ)	SMQ PTs	SMQ Details	<input checked="" type="radio"/>	<input type="radio"/>
BILIARY DISORDERS (SMQ)	SMQ PTs	SMQ Details	<input type="radio"/>	<input type="radio"/>

OK Clear Selection Close

Selecting a "parent" SMQ (which has ≥ 1 subordinate SMQ), will result in a search that includes all PTs from all the subordinate SMQ(s).

AERS Search Result on Selected SMQ and Suspect Product

AERS - [Case Search Results]
 File Edit Actions Tools Options Window Help

Cases Found: Sort Results in Descending Order by Case Number

Rev.	Case #	# ISR	D/F	Suspect Product(s)	Reaction(s)	Out- come(s)	Age	Piv.	Exc.	Reason
<input type="checkbox"/>	3509108	1	D		NAUSEA,FATIGUE,DECREASED APP	LT,HO,R	29 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3550152	1	D		ENCEPHALOPATHY,JAUNDICE,ASCF	DE	9.88 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3560372	1	D		RENAL FAILURE,NAUSEA,DEPRESSI	DE	59 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3570227	1	D		ENCEPHALOPATHY,BRAIN OEDEMA	DE,LT,RI		<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3575839	1	D		RENAL FAILURE ACUTE,DRUG INEFF	DE,LT,RI		<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3601218	1	F		RENAL IMPAIRMENT	HO	30 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3613368	2	F		RENAL FAILURE ACUTE,GLOMERUL	HO	70 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3616046	2	F		ANURIA,HEPATITIS	HO	6 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3637177	1	F		ANURIA,HEPATITIS,CONVULSION	HO	6 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3642003	1	D		CYANOSIS,DISSEMINATED INTRAVA	DE,LT,Hi	86 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3729211	1	F		LYMPHADENOPATHY,DERMATITIS E	HO,OT	33 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3749867	1	D		ANION GAP INCREASED,BLOOD ALF	HO	68 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3777357	3	F		ACTIVATED PARTIAL THROMBOPLA	DE	87 YR	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3779158	1	D		HAEMODIALYSIS,HYPERSENSITIVT	LT,HO,D	42 YR	<input type="checkbox"/>	<input type="checkbox"/>	

View Image Batch Print More Save Case Series Send to Reports Close



Available Standard Reports

Available Standard Reports

STANDARD GROUPING 1 REPORT (1,3,4,7,8,9)
STANDARD GROUPING 2 REPORT (1,2,3,4,5,6,7,8,9,12)
STANDARD GROUPING 3 REPORT (1,2,3,4,5,6,7,8,9,10,12)
STANDARD TARGETED GROUPING 4 REPORT (8,9)
1 CASES BY GENDER AND AGE GROUP
2 CASES WITH POSITIVE DECHALLENGE AND RECHALLENGE
3 CASES BY YEAR AND QUARTER
4 CASES BY ISR TYPE
5 CASES BY REPORT SOURCE
6 CASES BY SUSPECT AND CONCOMITANT PRODUCTS
7 CASES BY COUNTRY AND REGION
8 ALL PREFERRED TERMS IN CASES
9 CASES BY PRIMARY SOC AND PT
10 LINE LISTING OF CASES
11 LINE LISTING OF CASES WITH NARRATIVE

Destination: Preview

Destination File Name

Run Reports

Cancel



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 in the new version
 - Replacing these PT codes in AE reports
- Upversioning of the MSSO MedDRA browser, FDA Coding principles, etc
- Information distribution to staff, training sessions



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

- MedDRA is the most used terminology in new drug safety data submissions
- May encounter data in another (older) terminology
- FDA recommends submitting data in a single terminology and integrated safety summary (ISS) in the same version of that terminology

Verbatim – LLT/PT Coding

Verification of 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

“Lumping” Specific Terms

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

Specific Terms

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

“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%)
- *Accomm 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 13.0

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.

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

Preferred Term (PT)	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%)
Vulvovaginal candidiasis	6 (3%)	5 (2.5%)
Dysgeusia	4 (2%)	0 (0%)

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

Adverse Events with a Rate of <2%

Preferred Term (PT)	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%)
Alanine aminotransferase 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%)

Adverse Event Profile*

High Level Group Term (HLGT)	Study Drug n (%)	Control n (%)
Gastrointestinal signs and symptoms	49 (24.5%)	40 (20%)
Gastrointestinal motility and defaecation 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 $\geq 2\%$

Data retrieval example:

Identify all Hepatobiliary adverse events in a dataset

A Search Looking at only Primary Hepatobiliary
SOC Will Miss ALL OF THESE AE's (and more)

Example

Hepatobiliary 1° SOC

- PT Jaundice hepatocellular
- PT Hyperbilirubinemia
- PT Jaundice cholestatic
- PT Liver disorder
- PT Hepatomegaly
- PT Hepatitis acute
- PT Cytolytic hepatitis
- PT Acute hepatic failure

Hepatobiliary 2° SOC

- PT Kernicterus
- PT Ocular icterus
- PT Yellow skin
- PT Jaundice acholuric
- PT Asterixis
- PT Coma hepatic
- PT Hepatic encephalopathy
- PT Radiation hepatitis

Primary SOC

- Nervous system disorder
- Eye disorders
- Skin and subcut tissue
- Blood and lymphatic system disorders
- Nervous system disorder
- Nervous system disorder
- Nervous system disorder
- Injury, poisoning....

Example (con't)

Combine 1° and 2° PTs to SOC *Hepatobiliary*

Hepatobiliary 1° SOC

- PT Jaundice hepatocellular
- PT Hyperbilirubinemia
- PT Jaundice cholestatic
- PT Liver disorder
- PT Hepatomegaly
- PT Hepatitis acute
- PT Cytolytic hepatitis
- PT Acute hepatic failure

Hepatobiliary 2° SOC

- PT Kernicterus
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- PT Hepatic encephalopathy
- PT Radiation hepatitis

Are we done?

Combine 1° and 2 ° PTs to SOC *Hepatobiliary*

Hepatobiliary 1° SOC

- PT Jaundice hepatocellular
- PT Hyperbilirubinemia
- PT Jaundice cholestatic
- PT Liver disorder
- PT Hepatomegaly
- PT Hepatitis acute
- PT Cytolytic hepatitis
- PT Acute hepatic failure

Hepatobiliary 2 ° SOC

- PT Kernicterus
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- PT Hepatic encephalopathy
- PT Radiation hepatitis

Uniaxial – no secondary associations

SOC *Investigations*

- PT Alanine aminotransferase increased
- PT Aspartate aminotransferase increased
- PT Blood bilirubin increased
- PT Alkaline phosphatase increased
- PT Liver scan abnormal

And there is more....

Combine 1° and 2 ° PTs to SOC *Hepatobiliary*

Hepatobiliary 1° SOC

- PT Jaundice hepatocellular
- PT Hyperbilirubinemia
- PT Jaundice cholestatic
- PT Liver disorder
- PT Hepatomegaly
- PT Hepatitis acute
- PT Cytolytic hepatitis
- PT Acute hepatic failure

Hepatobiliary 2 ° SOC

- PT Kernicterus
- PT Ocular icterus
- PT Yellow skin
- PT Jaundice acholuric
- PT Asterixis
- PT Coma hepatic
- PT Hepatic encephalopathy
- PT Radiation hepatitis

Uniaxial – no secondary associations

SOC *Investigations*

- PT Alanine aminotransferase increased
- PT Aspartate aminotransferase increased
- PT Blood bilirubin increased
- PT Alkaline phosphatase increased
- PT Liver scan abnormal

SOC *Surgical and medical procedures*

- PT Liver transplant

Lessons Learned

- Perform AE analyses on all levels of MedDRA hierarchy
 - Inclusion of all MedDRA levels in an AE Analysis Dataset submission, with verbatim AE term
 - Primary SOC and supplemental Secondary SOC(s) AE data display
 - Single version of terminology
- Use SMQs



MedDRA Training



MedDRA Training Courses/Resources

- Training
 - FDA is highly supportive of MedDRA training
 - Sound knowledge of MedDRA is critical for conducting effective safety review so signals are not missed
- Training courses
 - MSSO provides courses at CDER
 - MedDRA Introduction
 - MedDRA: Safety Data Analysis and SMQs
 - Internal experts provide additional training sessions
- MedDRA Resources
 - MSSO website
 - CDER Intranet website
 - Expert support

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