MedDRA – An Introduction

Michael J. Klepper, MD
President and CEO
Integrated Safety Systems, Inc.
For lack of training, they lacked knowledge.

For lack of knowledge, they lacked confidence.

For lack of confidence, they lacked victory.

-Julius Caesar
Objectives

• To provide a basic understanding of MedDRA
• To show the differences between MedDRA and WHO-ART and the implications of these differences
• To be able to apply MedDRA to your daily work at Boehringer Ingelheim
Topics

• Rationale for MedDRA
• History of MedDRA
• Maintenance and Support Services Organization (MSSO)
• Regulatory Status of MedDRA
• MedDRA Dictionary
  – MedDRA basics
  – Hierarchy
  – Multi-axiality
  – MedDRA conventions
  – Coding examples using MedDRA

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Medical Dictionary for Regulatory Activities

Rationale for MedDRA
Rationale for MedDRA

• Established terminologies (WHO-ART, COSTART, etc.):
  – Lack specificity
  – Have limited data retrieval options
  – Unable to handle complex combinations of signs and symptoms (syndromes)
Rationale for MedDRA

• Need for global standardization
  – Across regulatory agencies
  – Across multinational pharmaceutical companies
  – Necessary throughout product lifecycle
  – Necessary for electronic data transfer
Rationale for MedDRA

– Avoids translation distortions/errors across countries
– Saves time
  • No need to cross-reference through lifetime of product
  • No need to translate
History of MedDRA
History of MedDRA

- 1989 - UK MCA identifies need for a single medical terminology to support new computer databases
- 1991 - ADROIT medical terminology created by UK MCA
- January 1993 - identification of need for a medical terminology to support European Community drug regulatory system
History of MedDRA

• 2Q 1993 - Working party set-up of European regulators and pharmaceutical industry representatives to evaluate wider applicability of MCA terminology

• November 1993 to October 1994 - Working party reviews and amends MCA terminology, now called MedDRA
History of MedDRA

• December 1993 - European Committee for Proprietary Medicinal Products approves MedDRA Project
• October 1994 - ICH recommends that MedDRA (version 1.0) should form basis of a new medical terminology
History of MedDRA

- November 1994 – ICH Steering Committee released a draft (alpha) version (version 1.1) of terminology for review and evaluation
- March 1995 – ICH working group evaluated the alpha test results and evaluated suggested changes
History of MedDRA

- February 1996 - MedDRA Version 1.5 released for review in US and Japan
- July 1997 – ICH approval of international terminology
History of MedDRA

- November 1998 – IFPMA (Trustee of ICH Steering Committee, holder of intellectual property) selected BDM International Inc. (a subsidiary of TRW Inc.) as the Maintenance and Support Services Organization (MSSO)
- March 1999 – MedDRA version 2.1 released

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The Maintenance and Support Services Organization

The MSSO
The MSSO

• To provide services to support MedDRA terminology including the following:
  – Maintenance
  – Distribution
  – Implementation
  – Ongoing development
  – To ensure terminology continues to evolve in response to user needs
The MSSO

• Management Board appointed by ICH Steering Committee
• Consortium of international companies
  – TRW Inc. – program management, system engineering, terminology maintenance
  – Quintiles Transnational Corporation – international network of medical and terminology experts
  – Stellar Business Systems – program management and strategic planning
The MSSO

– Cyntergy Corporation – international user support
– Ernst & Young – knowledge management expertise provider

• In December 2002, TRW Inc. merged with and became a wholly owned subsidiary of Northrop Grumman
www.meddramsso.com

Maintenance and Support Services Organization

Having worked side by side with international regulators and the pharmaceutical and biotech industries to develop and support MedDRA, the Maintenance and Support Services Organization (MSSO) was the logical choice to be the world's sole licensee and distributor of MedDRA subscriptions.

Our unique experience with MedDRA also makes us the logical choice for MedDRA support services, products, and initial assessment.

Wherever you are in the MedDRA implementation process, we have the experience and resources to help you complete the transition quickly and efficiently. The MSSO is staffed by medical and information technology experts with significant regulatory experience.

We look forward to helping you take advantage of the many efficiencies of this powerful new information tool.

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Japanese Maintenance Organization (JMO)

• Responsible for maintenance and distribution of MedDRA in Japan
Regulatory Status of MedDRA
Regulatory Status of MedDRA

• Implementation priority
  – Post-marketing surveillance
  – Clinical development
Regulatory Status of MedDRA

• Translations complete for:
  – Dutch (LLT level)
  – French (PT level)
  – German (PT level)
  – Italian (LLT level)
  – Portuguese (LLT level)
  – Spanish (LLT level)
  – MedDRA/J (Japanese) (LLT level)
Regulatory Status of MedDRA

• EMEA
  – MedDRA implemented in its EudraWATCH program
  – Mandatory MedDRA use:
    • January 2002 - single case safety reports received electronically
    • January 2003* - all ADR reporting
  – LLT level for electronic transfer of data
Regulatory Status of MedDRA

- FDA
  - Implemented MedDRA in Adverse Event Reporting System (AERS)
    - Historical data converted to MedDRA -1997
    - All new AEs now coded in MedDRA
    - Goal is to be paperless
  - March 2001, MedDRA use is recommended
  - March 2003, “The Tome” says that MedDRA will be mandated for AERS, but no exact date given for implementation
  - Reporting at PT level for all purposes

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Regulatory Status of MedDRA

• MHW “Kosheisho” (Japan)
  – MedDRA is official dictionary
  – Industry should use MedDRA for coding
  – Notification March 2004 that it is mandatory for all ADR reporting after 27 October 2003, and for other uses (such as Periodic Infection Report) after 01 April 2004
  – Report on PT level
The MedDRA Dictionary

MedDRA Basics
MedDRA Basics

- Includes:
  - COSTART (5th ed.)
  - WHO-ART (98:3)
  - J-ART (1996)
  - HARTS (Release 2.2)
  - ICD-9
  - ICD-9-CM (4th revision)
MedDRA Basics

• A terminology for coding all medical information obtained during all phases of development and marketing:
  – Symptoms
  – Signs
  – Diseases
  – Diagnoses
  – Indications
  – Investigations/Procedures
  – Medical/Social History
MedDRA Basics

• Types of Data Coded
  – Safety and efficacy data
  – Laboratory data
  – Medical history
    • Includes surgical and medical procedures
  – Family/social history
  – Physical examination data
# MedDRA vs. WHO-ART

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<thead>
<tr>
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<td>Lowest Level Term (LLT)*</td>
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* For WHOART, Included Term

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# MedDRA Versions

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<thead>
<tr>
<th>Version</th>
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<th>PT</th>
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</table>

Unchanged: SOC=26

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## MedDRA Versions

<table>
<thead>
<tr>
<th>Version</th>
<th>HLGT</th>
<th>HLT</th>
<th>PT</th>
<th>LLT</th>
<th>SSC</th>
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<td>16,751</td>
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</table>

MedDRA Term vs. MedDRA Code

• MedDRA Term = a word(s)
  – Example = Urticaria

• MedDRA Code = numbers representing each term
  – Example = Urticaria (term) = 10046735 (code)

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MedDRA Codes

• Unique number assigned to each term in the dictionary
• 8 digits
• Starts with 10000001, initially started alphabetically
• As terms added, codes assigned sequentially
• These are just identification numbers; they don’t reflect the relational organization of the data files (unlike WHO-ART)
# MedDRA Codes

<table>
<thead>
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<th>Term</th>
<th>Code</th>
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<td>Gastric haemorrhage (LLT)</td>
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<td>Gastric and oesophageal haemorrhages (HLT)</td>
<td>10017751</td>
</tr>
<tr>
<td>Gastrointestinal haemorrhages NEC (HLGT)</td>
<td>10017959</td>
</tr>
<tr>
<td>Gastrointestinal disorders (SOC)</td>
<td>10017947</td>
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</tbody>
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MedDRA Basics

• Non-current terms
  – Ambiguous, vague, misspelled, outdated terms
  – Terms derived from other terminologies that do not comply with MedDRA rules
  – Flagged as non-current
  – Non-current terms are located at the LLT level
MedDRA Basics

• Excluded from MedDRA
  – term qualifiers - frequent, rare, mild, severe (there are exceptions)
  – numerical values - potassium value of 3.0 mg/dL
MedDRA Basics

- Granularity
- Specificity
Granularity

• More terms, more choices
• Need auto encoder
• Need browser
Coding Process

Verbatim Term

ARIS G

Autocode

Correct MedDRA Coded Term

No Match

Interactive Coding: MedDRA Browser

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Coding Process

• Remember:
  – An autocoder is just a tool
  – An autocoded result is not necessarily the right result!
Chest pain
(MedDRA 8.1)

- Ache across chest
- Chest abnormal feeling of
- Chest ache
- Chest aching
- Chest aching of
- Chest anxiety feeling of
- Chest burning
- Chest burning pain of
- Chest distress (NC)
- Chest distressed feeling
- Chest distressed feeling of
- Chest fullness
- Chest fullness of
- Chest heaviness
- Chest hot feeling of
- Chest pain
- Chest pain aggravated
- Chest pain exertional
- Chest pain NEC (NC)
- Chest pain precordial
- Chest pain substernal
- Chest pain with radiation to left arm
- Chest pain-L arm (NC)
- Generalised chest pain
- Generalised chest pains
- Generalized chest pain
- Nonspecific chest pain
- Other chest pain (NC)
- Pain chest
- Pain chest substernal
- Pain precordial
- Pain retrosternal
- Pain substernal
- Parasternal pain (excl organic)
- Precordial pain
- Retrosternal chest pain
- Retrosternal pain
- Sternal pain
- Substernal chest pain
- Substernal pain
- Thoracic pain
- Thorax pain
- Unspecified chest pain

Chest pain substernal
(WHO-ART 3Q01)

- Substernal pain
- Retrosternal pain
Specificity

- Terms
  - Medically more specific
  - More reflective of medical condition
Hepatitis viral
(MedDRA 8.1)
NC=non-current LLT

- Hepatitis in viral disease classified elsewhere (NC)
- Hepatitis viral
- Hepatitis viral NOS
- Hepatitis viral-like
- Other specified viral hepatitis with hepatic coma (NC)
- Other specified viral hepatitis with hepatic coma not elsewhere classified (NC)
- Other specified viral hepatitis without mention of hepatic coma (NC)
- Unspecified viral hepatitis with hepatic coma (NC)
- Unspecified viral hepatitis without mention of hepatic coma (NC)
- Viral hepatitis
- Viral hepatitis NOS
- Viral hepatitis not otherwise specified (NC)
- Virus hepatitis

Hepatitis viral
(WHO-ART 3Q01)

- Hepatitis A
- Hepatitis B
- Hepatitis C
- Hepatitis non-A non-B
- Virus hepatitis
Hierarchy
Definitions...

• System Organ Class (SOC):
  – Highest level of the hierarchy that provides the broadest concepts for data retrieval.

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Definitions...

- High Level Group Term (HLGT)
  - Subordinate only to SOCs and superordinate to descriptor for one or more HLTs.
Definitions...

• High Level Term (HLT)
  – Subordinate to HLGTS and superordinate descriptor for the PTs linked to it.
Definitions...

- Preferred Term (PT)
  - The PT represents a single unique medical concept.
Definitions...

• Lowest Level Term (LLT)
  – Has one of the following relationships to the Preferred Term (PT)
    • Synonym
    • Lexical variant
    • Quasi-synonym
26 MedDRA SOCs

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders

- General disorders and administration site conditions
- Hepatobiliary disorders
- Infections and infestations
- Immune system disorders
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
26 MedDRA SOCs

- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (including cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders
SSCs
Bone Marrow Depression and Secondary Immunocompromised State

HLGT
White Blood Cell Disorders

HLT
Neutropenias

PT
Neutropenia

LLT
Neutropenia complicated

SOC
Blood and lymphatic system disorders
MedDRA 7.0
Special Search Categories

- Arrest (Cardiac)
- Bone Marrow Depression
- Cardiac Ischaemia
- Haemorrhage
- Hypersensitivity Reactions
- Immediate Hypersensitivity and Anaphylactic Reactions
- Oedema
- Pain
- Premalignant Lesions
- Secondary Immunocompromised State
- Thrombosis
- Upper GI Bleeding/Perforation
- Vasculitis
MedDRA Special Search Categories

• Allows PTs which may have similar etiologies, that would otherwise go to different SOCs, to be grouped in the same category
  – Example: For a drug associated with increased bleeding tendency, it is important to find and group together for analysis and reporting purposes all bleeding-related adverse events
## MedDRA Special Search Categories

<table>
<thead>
<tr>
<th>8.1 PT</th>
<th>8.1 SSC</th>
<th>8.1 Primary SOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric haemorrhage</td>
<td>Haemorrhage</td>
<td>Gastrointestinal disorders</td>
</tr>
<tr>
<td>Haematuria</td>
<td>Haemorrhage</td>
<td>Renal and urinary disorders</td>
</tr>
<tr>
<td>Retinal Haemorrhage</td>
<td>Haemorrhage</td>
<td>Eye disorders</td>
</tr>
<tr>
<td>Haematoma</td>
<td>Haemorrhage</td>
<td>Vascular disorders</td>
</tr>
</tbody>
</table>
Standardised MedDRA Queries (SMQs)

- Eventually will replace SSCs
- Cooperative effort between CIOMS and ICH (MSSO)
- Groupings of MedDRA terms, ordinarily at the Preferred Term (PT) level, that relate to a defined medical condition or area of interest. Terms included in a given SMQ may relate to relevant signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data, etc.
Standardised MedDRA Queries (SMQs)

- Currently in Production (as of 11 Oct 2005)
  - Acute Renal Failure
  - Haemolytic Disorders
  - Hepatic Disorders
  - Rhabdomyolysis/Myopathy – first approved
  - Severe Cutaneous Adverse Reactions
  - Torsades de Pointes/QT Prolongation – first approved
Standardised MedDRA Queries (SMQs)

- **Awaiting Product**
  - Acute pancreatitis
  - Agranulocytosis
  - Anaphylactic reaction
  - Angioedema
  - Asthma/bronchospasm
  - Dyslipidaemia
  - Haematopoietic cytopenias
  - Lack of efficacy/effect
  - Lactic acidosis
  - Peripheral neuropathy

**Future SMQs:** 15 in Phase I Testing/Development
17 in Phase II Testing
13 in Future Development

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## SOC's MedDRA vs. WHO-ART

<table>
<thead>
<tr>
<th>MedDRA</th>
<th>WHO-ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and Lymphatic System Disorders</td>
<td>Red Blood Cell Disorders AND White Cell and RES Disorders AND Platelet, Bleeding and Clotting Disorders</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td>Cardiovascular Disorders, General AND Myo Endo Pericardial and Valve Disorders AND Heart Rate and Rhythm Disorders</td>
</tr>
<tr>
<td>Congenital, Familial and Genetic Disorders</td>
<td>Foetal Disorders AND Neonatal and Infancy Disorders</td>
</tr>
</tbody>
</table>
## SOCs MedDRA vs. WHO-ART

<table>
<thead>
<tr>
<th>MedDRA</th>
<th>WHO-ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ear and Labyrinth Disorders</td>
<td>Hearing and Vestibular Disorders</td>
</tr>
<tr>
<td>Endocrine Disorders</td>
<td>Endocrine Disorders</td>
</tr>
<tr>
<td>Eye Disorders</td>
<td>Vision Disorders</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>Gastro-intestinal System Disorders</td>
</tr>
<tr>
<td>General Disorders and Administrative Site Conditions</td>
<td>Body as a Whole, General AND Application Site Disorders</td>
</tr>
</tbody>
</table>

© ISS, Inc. 2005
## SOC MedDRA vs. WHO-ART

<table>
<thead>
<tr>
<th>MedDRA</th>
<th>WHO-ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatobiliary Disorders</td>
<td>Liver and Biliary System Disorders</td>
</tr>
<tr>
<td>Immune System Disorders</td>
<td>Collagen Disorders</td>
</tr>
<tr>
<td>Infections and Infestations</td>
<td>Resistance Mechanism Disorders</td>
</tr>
<tr>
<td>Injury, Poisoning and Procedural Complications</td>
<td>Poison Specific Terms (does not include injury)</td>
</tr>
<tr>
<td>Investigations</td>
<td>NONE</td>
</tr>
<tr>
<td>MedDRA</td>
<td>WHO-ART</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Metabolism and Nutrition Disorders</td>
<td>Metabolic and Nutritional Disorders</td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td>Musculo-skeletal System Disorders</td>
</tr>
<tr>
<td>Neoplasms Benign, Malignant and Unspecified (incl cysts and polyps)</td>
<td>Neoplasm</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td>Central and Peripheral Nervous System Disorders AND Autonomic Nervous System Disorders</td>
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</table>
## SOCs MedDRA vs. WHO-ART

<table>
<thead>
<tr>
<th>MedDRA</th>
<th>WHO-ART</th>
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<tr>
<td>Renal and Urinary Disorders</td>
<td>Urinary System Disorders</td>
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<tr>
<td>Reproductive System and Breast Disorders AND Pregnancy, Puerperium and Perinatal Conditions</td>
<td>Reproductive Disorders, Male AND Reproductive Disorders, Female</td>
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<tr>
<td>Respiratory, Thoracic and Mediastinal Disorders</td>
<td>Respiratory System Disorders</td>
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## SOCs MedDRA vs. WHO-ART

<table>
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<th>MedDRA</th>
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<td>Skin and Subcutaneous Tissue Disorders</td>
<td>Skin and Appendages Disorders</td>
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<td>Social Circumstances</td>
<td>NONE</td>
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<tr>
<td>Surgical and Medical Procedures</td>
<td>NONE</td>
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<tr>
<td>Vascular Disorders</td>
<td>Vascular (extracardiac) Disorders</td>
</tr>
</tbody>
</table>

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Caution:
Similar SOC nomenclature between MedDRA and WHO-ART does not guarantee similar mapping of the same verbatim or preferred term.
SOCs MedDRA vs. WHO-ART

• Examples
  – Hay fever
    • Immune system disorders (MedDRA)
    • Body as a Whole (WHO-ART)
  – Potassium low
    • Investigations (MedDRA)
    • Metabolic and Nutritional Disorders (WHO-ART)
• Examples (continued)
  – Meningitis
    • Infections and Infestations (MedDRA primary SOC, secondary SOC = Nervous system disorder)
    • Central and peripheral nervous system disorders (WHO-ART)
MedDRA New Categories

• Injury, poisoning and procedural complications
  – Broken ankle, injury to heart and lung, overdose, spinal cord injury, heat syncope

• Investigations
  – Blood alcohol excessive, renal scan NOS abnormal, low platelets, Gamma GT increased
MedDRA New Categories

• Social circumstances
  – Burglary victim, death of child, loss of employment, mid-life crisis, rape victim

• Surgical and medical procedures
  – Appendectomy, total knee replacement, routine vaccination
Multi-axiality
Multi-axiality

- A dictionary term may be represented in more than one System Organ Class
Multi-axiality

- Allows terms to be grouped by different classifications
- Allows retrieval and presentation via different data sets
- Allows an automatic assignment of predefined term groupings
Multi-axiality

- **PT**: Multi-Axial Primary Term
- **PT**: Multi-Axial Secondary
- **PT**: Singly Occurring Primary
- **SOC**: Primary SOC Term
- **LLT**: Non-current LLT Term
Multi-axiality

• Under Gastrointestinal Disorders (primary SOC)
  – PT Haematemesis = PT

• Under Vascular Disorders (secondary SOC)
  – PT Haematemesis= PT
Rationale for Primary SOC Use

• Decreases the risk of double counting of events in cumulative outputs (use of secondary SOC increases the risk)

• Provides for consistent representation of specific events between companies and regulators

• Allows secondary SOC allocations to be used for other type of scientific analyses
MedDRA Conventions
MedDRA Conventions

• Spelling
  – British English spelling is used at the PT level and above
  – American spellings are included at the LLT level
  – Examples: dyspnea - dyspnoea, hyponatremia - hyponatraemia, hemorrhage - haemorrhage
MedDRA Conventions

• Capitalization is used for the first letter of each term, proper names, and abbreviations
• Examples
  – Partial loss of vision
  – Charcot-Marie atrophy
  – AIDS
MedDRA Conventions

• Universally accepted abbreviations can be found at the LLT

• Examples
  – HIV (human immunodeficiency virus)
  – CBC (complete blood count)
  – CAD (coronary artery disease)
  – CHF (congestive heart failure)
MedDRA Conventions

• Natural word order is maintained at the PT level except when reversal of words allows similar terms to be grouped together

• Examples
  – Gastric haemorrhage, Duodenal haemorrhage
  – Encephalitis cytomegalovirus, Encephalitis herpes, Encephalitis …
MedDRA Conventions

• Punctuation is limited to apostrophes in people’s names and hyphens in some terms
• Examples
  – Glaucoma steroid-induced
  – Stevens-Johnson syndrome
  – Fanconi’s syndrome
MedDRA Conventions

• NEC = Not Elsewhere Classified
  – When terminology does not allow for specificity of reported verbatim
  – Used for some HLGTs, HLTs, and LLTs
    • HLT: Coronary artery disorders NEC (vs. the specific: ischaemic coronary artery disorders)
    • HLGT: Eye disorder NEC
    • LLT: amnesia NEC
MedDRA Conventions

• NOS = Not Otherwise Specified
  – When reported verbatim is not specific
  – Only used in LLT terms
    • LLT: Adrenal insufficiency NOS, Neoplasm NOS
  – Eliminated from PTs in 2003 in Version 6.1
    (The NOS PTs were demoted to LLTs, and the equivalent non-NOS LLTs were promoted to PTs: 4,236 changes!)
MedDRA Conventions

• Numeric codes are 8 digit
• Start with first code of 10000001
• Initially assigned alphabetically by term
• New terms are assigned sequentially
• Codes are never reused
• “Codes” are not really coded information, do not reflect organization of dictionary: codes are just identification numbers
Coding Examples Using MedDRA 8.1
Coding Examples

• Example “low glucose” (verbatim)
  – Glucose low (LLT)
  – Blood glucose decreased (PT)
  – Carbohydrate tolerance analyses (incl diabetes) (HLT)
  – Metabolic, nutritional and blood gas investigations (HLGT)
  – Investigations (SOC)

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Coding Examples

- Example “hypoglycemia” (verbatim)
  - Hypoglycemia (LLT)
  - Hypoglycaemia (PT)
  - Hypoglycaemic conditions NEC (HLT)
  - Glucose metabolism disorders (incl diabetes mellitus) (HLGT)
  - Metabolism and nutrition disorders (primary SOC)
  - Endocrine disorders (secondary SOC)
Coding Examples

• Example “appendicitis” (verbatim)
  – Appendicitis (LLT)
  – Appendicitis (PT)

  -- Abdominal and gastrointestinal infections (HLT)
  -- Infections – pathogen class unspecified (HLGT)
  -- Infections and infestations (SOC) – primary SOC

  -- Intestinal infections (HLT)
  -- Gastrointestinal infections (HGLT)
  -- Gastrointestinal disorders (SOC) – secondary SOC

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Coding Examples

• Example “appendectomy” (verbatim)
  – Appendectomy (LLT)
  – Appendicectomy (PT)
  – Large intestine therapeutic procedures (HLT)
  – Gastrointestinal therapeutic procedures (HLGT)
  – Surgical and medical procedures (SOC)
Coding Examples

• Example “homeless” (verbatim)
  – Homeless (LLT)
  – Homeless (PT)
  – Housing circumstances (HLT)
  – Economic and housing issues (HLGT)
  – Social circumstances (SOC)
Garbage In = Garbage Out

- Bachache
- Death - worsened clinically by end of 4 hr rx
- Death (due to cardiac vs septic shock)
- Heme+ emesis
- Elevated CK=2022 (50-180)
“Thick Throat”

- Pharyngitis?
- Laryngeal edema?
### “Thick Throat”

<table>
<thead>
<tr>
<th>Verbatim Term</th>
<th>MedDRA Lowest Level Term</th>
<th>MedDRA Preferred Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharyngitis</td>
<td>Pharyngitis</td>
<td>Pharyngitis NOS</td>
</tr>
<tr>
<td>Laryngeal edema</td>
<td>Laryngeal edema</td>
<td>Laryngeal oedema</td>
</tr>
</tbody>
</table>
“Abnormal Potassium”

- MedDRA PT “Blood potassium abnormal NOS”
- What does this mean clinically?
  - Hypokalemia?
  - Hyperkalemia?
  - Hemolysis?
“Flintstone Feet”
Remember:
Irrespective of the Dictionary Used, the Quality of the Verbatim Term Drives the Coding Process!