Brief overview of MedDRA and the Use of MedDRA for Data Analysis

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International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
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Brief overview of MedDRA and the Use of MedDRA for Data Analysis

MedDRA

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities
Objectives for Developing MedDRA

To support drug safety monitoring, by providing:

• An international multi-lingual terminology
• A terminology for use through all phases of development cycle
  o Clinical trials
  o Post-marketing
• Standardised communication between industry and regulators
  o Within regions and between regions
• Support electronic submissions of Individual Case Safety Report (ICSR)
• Tools to facilitate signal detection, management and aggregated data analysis
Brief overview of MedDRA and the Use of MedDRA for Data Analysis

Before MedDRA

- Difficulties to electronically communicate
- No harmonised terminology
  - Use of WHO-ART, COSTART, ICD-9, ICD-9 CM, HARTS etc
  - Use of own customised versions of these
  - Use of in-house developed dictionaries
- Inadequacies of previous terminologies
  - Not enough medical terms - low specificity
  - Not medically valid
  - Poor or no maintenance - addition of terms
  - Poor hierarchies hinder retrieval of grouped data
MedDRA History:

- **1990s** - No standard international medical terminology
- **1993** - Working party: Industry / EU regulators review & amend UK MCA terminology - “MEDDRA”
- **October 1994** - ICH adopted MEDDRA v1.0 as basis for international terminology – worked on by ICH M1 Expert Working Group
- **July 1997** - ICH agrees v2.0: new name “MedDRA”
- **March 1999** - MSSO opens and distributes v2.1
  - MSSO contracted by IFPMA in its capacity as trustee of the ICH Steering Committee
ICH Guidance – How to Use MedDRA?

• Establishment of the ICH MedDRA Points to Consider (PtC) Working Group in 1999

• ICH MedDRA Points to Consider Documents:
  o How to best classify the data? MedDRA Term Selection document
  o How to best retrieve and present the data? MedDRA Data Retrieval and Presentation document
  o Both updated with Users feedback for every release of MedDRA

MedDRA POINTS TO CONSIDER
http://www.ich.org
http://www.meddrasmsso.com
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MedDRA Governance: ICH MedDRA Management Board
MedDRA Management Board: Purpose & Responsibilities

• Oversees financial and technical operations of the MSSO
  - Examples: Review MSSO costs and fee structure
• Ensures the continued development and viability of MedDRA
• Ensures that MedDRA is easy to use and accessible to all
• Ensures MSSO is meeting the needs of users
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User Group

MedDRA Management Board (Six ICH parties, Canada, UK MHRA & WHO as Observer)

ICH Steering Committee

MSSO
Development Maintenance Implementation User Support Communication

JMO

User Communities
WHO
Regulatory Authorities
Regulated Industries
Other
WHO & MedDRA

• As of March 2008, MedDRA has been implemented in WHO’s Global Safety Database (Vigibase)
  o WHO National Centres can review data and conduct analyses in both WHO-ART and MedDRA
    - Data can be sent/entered in either MedDRA or WHO-ART
    - Reports generated in either MedDRA or WHO-ART

• With Vigibase containing >7 million ICSRs, it now provides a global repository of MedDRA-coded safety data:
  o Substantial tool for pharmacovigilance
  o Of significant benefit to global patient safety
WHO & MedDRA

• WHO Uppsala Monitoring Centre (UMC) has developed with ICH/MSSO a “bridge” for mapping from WHO-ART to MedDRA:
  o Allows conversion of legacy data from WHO-ART to MedDRA
  o Maintained current with every version release of WHO-ART and MedDRA
  o Does not work in the other direction since MedDRA is more granular than WHO-ART

• WHO UMC receives most of ICSRs coded in MedDRA
MedDRA for Data Analysis

- Allows for aggregation of reported terms in medically meaningful groupings
- Facilitates analysis of safety data
- Permits generation of lists AR/AE data in reports (e.g. tables, line listings)
- Assists to compute frequencies of similar AR/AEs
- Allows to analyze related data such as product indications, investigations, and medical and social history
MedDRA for Data Analysis – Examples

• EMA – European pharmacovigilance database EudraVigilance
  - Supports signal detection and data analysis by EMA and EU Regulatory Network
  - Good pharmacovigilance practices (GVP) – Module IX Signal Management
  - Guideline On The Use Of Statistical Signal Detection Methods In The Eudravigilance Data Analysis System
  - Facilitates transparency - publication of data used to review the safety of a medicine or active substance

http://www.adrreports.eu
## Brief overview of MedDRA and the Use of MedDRA for Data Analysis

<table>
<thead>
<tr>
<th>Active Substances</th>
<th>SOC Codes</th>
<th>PTs</th>
<th>New EV</th>
<th>Tot EV</th>
<th>PRR (-)</th>
<th>PRR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Substance A</td>
<td>Blood</td>
<td>Thrombocytopenia</td>
<td>0</td>
<td>8</td>
<td>0.37</td>
<td>0.78</td>
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<td>Thrombotic Thrombocytopenic Purpura</td>
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<td>2.49</td>
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<tr>
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<td>Atrioventricular Block</td>
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<td>0.23</td>
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<td>Card</td>
<td>Atrioventricular Block Complete</td>
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<td>1</td>
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<td></td>
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<td>10</td>
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<td>2.46</td>
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<td>14.67</td>
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<td>Active Substance A</td>
<td>Card</td>
<td>Cardiac Failure Congestive</td>
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<td>5</td>
<td>0.21</td>
<td>0.65</td>
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<tr>
<td>Active Substance A</td>
<td>Card</td>
<td>Cardiogenic Shock</td>
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<td>1</td>
<td>0.25</td>
<td>1.75</td>
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<td>1</td>
<td>0.79</td>
<td>5.60</td>
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<td>Active Substance A</td>
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<td>Acute Myocardial Infarction</td>
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<td>1</td>
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<td></td>
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<td>0.07</td>
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<td>17</td>
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<td>0.21</td>
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<td>Card</td>
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<td>0</td>
<td>2</td>
<td>0.60</td>
<td>2.40</td>
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</table>
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Online access to suspected side-effect reports

On this website you can view data on suspected side-effects, also known as suspected adverse drug reactions for authorised medicines in the European Economic Area (EEA).

This data is presented in a format called a web report. Currently the data only relates to medicines approved through the centralised authorisation procedure.

News

Key information

- The information on this website relates to suspected side effects, i.e. medical events that have been observed following the use of a medicine, but which are not necessarily related to or caused by the medicine.

- Information on suspected side effects should not be interpreted as meaning that the medicine or the active substance causes the observed effect or is unsafe to use. Only a detailed evaluation and scientific assessment of all available data allows for robust conclusions to be drawn on the benefits and risks of a medicine.

- The European Medicines Agency publishes this data so that its stakeholders, including the general public, can access information that European regulatory authorities use to review the safety of a medicine or active substance. Transparency is a key guiding principle of the Agency.
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Number of individual cases by Age Group

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Specified</td>
<td>1,383</td>
<td>18.9</td>
</tr>
<tr>
<td>0-1 Month</td>
<td>2</td>
<td>0.0</td>
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<tr>
<td>2 Months - 2 Years</td>
<td>5</td>
<td>0.1</td>
</tr>
<tr>
<td>3-11 Years</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>12-17 Years</td>
<td>1</td>
<td>0.0</td>
</tr>
<tr>
<td>18-64 Years</td>
<td>3,334</td>
<td>45.6</td>
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<tr>
<td>65-85 Years</td>
<td>2,515</td>
<td>34.4</td>
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<tr>
<td>More than 85 Years</td>
<td>77</td>
<td>1.1</td>
</tr>
<tr>
<td>Total</td>
<td>7,317</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The number of individual cases identified in EudraVigilance for CAP is 7,317 (up to Apr 2012)

Number of individual cases by Sex

<table>
<thead>
<tr>
<th>Sex</th>
<th>Cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>4,441</td>
<td>60.7</td>
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<tr>
<td>Male</td>
<td>2,489</td>
<td>34.0</td>
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<tr>
<td>Not Specified</td>
<td>387</td>
<td>5.3</td>
</tr>
<tr>
<td>Total</td>
<td>7,317</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Number of individual cases by Geographic Origin (EEA/Non-EEA)

<table>
<thead>
<tr>
<th>Geographic Origin</th>
<th>Cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Economic Area</td>
<td>3,132</td>
<td>42.8</td>
</tr>
<tr>
<td>Non European Economic Area</td>
<td>4,177</td>
<td>57.1</td>
</tr>
<tr>
<td>Not Specified</td>
<td>8</td>
<td>0.1</td>
</tr>
<tr>
<td>Total</td>
<td>7,317</td>
<td>100.0</td>
</tr>
</tbody>
</table>

For the interpretation of the results, please refer to the key considerations at www.adreports.eu
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Choose how you want to see the number of individual cases identified in EudraVigilance for CAP (up to Apr 2012)

For the interpretation of the results, please refer to the key considerations at www.adreports.eu
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Contact Us!

Contact the ICH MedDRA Management Board
meddraboard@ich.org

ICH website: www.ich.org
MSSO site: www.meddramsso.com
MSSO Help Desk: mssohelp@mssotools.com
Thank You!