Chinese MedDRA and WHODrug Meeting

6 September 2017, Beijing China

Agenda

• 9:00 – 12:30: MedDRA User Group Meeting
  – By MSSO

• 12:30 – 13:30: Lunch

• 13:30 – 16:30: WHODrug Meeting
  – By Uppsala Monitoring Centre (UMC)
MedDRA User Group Meeting

- 9:00 – 9:40 MedDRA and MSSO Update
  • Anna Zhao-Wong (MSSO)
- 9:40 – 10:40 MedDRA Coding Discussion
  • 朱丽琳 (Quintiles)
- 10:40 – 11:00 Break and Networking
- 11:00 – 11:40 MedDRA Feasibility Study by Jiangsu ADR Center
  • 马丹华 (江苏省ADR中心)
- 11:40 – 12:25 MedDRA and Traditional Chinese Medicine
  • 李庆娜 (西苑医院)
- 12:25 – 12:30 Questions and Answers

WHODrug Meeting

- 13:30 – 14:00 Introduction
- 14:00 – 15:00 Report from UMC

- 15:00 – 15:30 Break

- 15:30 – 16:00 Daily Challenges of Coding – An Interactive Session
- 16:00 – 16:15 Open Q&A Session
- 16:15 – 16:30 Wrap-up and Summary

Presenters: Anna Mattsson, Damon Fahimi and Mao Mao Soderberg
MedDRA and MSSO Updates
Anna Zhao-Wong, MD, PhD
Deputy Director, MSSO
MedDRA User Group Meeting, 6 September 2017

Topics

• Subscription rate reduction in 2017
• Removal of Chinese translation fee
• 2016 Chinese translation term review
  – Chinese linguistic convention
  – Quality control queries
• Unqualified Test Name Term List
• Condensed PTC documents in Chinese in 2017/2018
• Self Service Application
MedDRA Subscriber Profile and Subscription Rate Reduction in 2017

Quiz 1

• Which continent has the most number of MedDRA subscribing organizations?
  – Africa
  – Asia
  – Australia
  – Europe
  – North America
  – South America
Quiz 2

• Which country has the most number of MedDRA subscribing organizations?
  – Canada
  – China
  – Germany
  – Germany
  – United Kingdom
  – United States

Quiz 3

• When a sponsor’s MedDRA coding and AE reporting are done by a CRO, which of the following is correct?
  – Only the CRO needs a MedDRA subscription
  – Only the sponsor needs a MedDRA subscription
  – Both the CRO and the sponsor need MedDRA subscriptions
  – None of them need a MedDRA subscription
MedDRA Users Profile by Organization Type

- As of March 2017
  - 4,990 Subscribing organizations
  - 103 Countries
- Graph shows type of organizations (self identified)

MedDRA Users by Region and Top 25 Countries
2017 MedDRA Subscription Rates

- All subscription rates reduced at least 9-10%
- 2016 Commercial 2 subscription now divided into two levels:
  - New 2017 Commercial 2 rate
    - Revenue of $10-$20 Million USD reduced 50% to $2,765
  - New 2017 Commercial 3 rate
    - Revenue of $20-$500 Million USD reduced to $4,976
- As of January 2017, no more fee for Chinese MedDRA translation

### 2017 MedDRA Subscription Rate Table

<table>
<thead>
<tr>
<th>MedDRA Subscription Types</th>
<th>2017 Annual Subscription Rates</th>
<th>Additional Rates for Japanese Translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority</td>
<td>$0 USD</td>
<td>$0 USD</td>
</tr>
<tr>
<td>Non-Commercial / Non-Profit</td>
<td>$0 USD</td>
<td>$660 USD</td>
</tr>
<tr>
<td>Commercial (Parent Company Annual Revenue or Turnover)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 0 (Annual Revenue &lt; $1 Million)</td>
<td>$717 USD</td>
<td>$895 USD</td>
</tr>
<tr>
<td>Level 1 (Annual Revenue $1-$15 Million)</td>
<td>$724 USD</td>
<td>$895 USD</td>
</tr>
<tr>
<td>Level 2 (Annual Revenue $15-$20 Million)</td>
<td>$3,705 USD</td>
<td>$895 USD</td>
</tr>
<tr>
<td>Level 3 (Annual Revenue $20-$50 Million)</td>
<td>$4,976 USD</td>
<td>$895 USD</td>
</tr>
<tr>
<td>Level 4 (Annual Revenue $50-$1 Billion)</td>
<td>$10,440 USD</td>
<td>$885 USD</td>
</tr>
<tr>
<td>Level 5 (Annual Revenue $1-$5 Billion)</td>
<td>$43,216 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 6 (Annual Revenue $5-$20 Billion)</td>
<td>$67,194 USD</td>
<td>$850 USD</td>
</tr>
<tr>
<td>Level 7 (Annual Revenue &gt; $20 Billion)</td>
<td>$74,620 USD</td>
<td>$890 USD</td>
</tr>
<tr>
<td>System Developer</td>
<td>$2,491 USD</td>
<td>$885 USD</td>
</tr>
</tbody>
</table>
MedDRA Chinese Translation
Term Review

Background

• MedDRA Chinese translation was first released in September 2009, V12.1
• It is updated twice a year with MedDRA English release
  – New terms
  – Translation changes requested by subscribers or the MSSO
• In 2016, MSSO conducted MedDRA term review of the Chinese translation
  – As part of an overall quality review of all of MedDRA translations maintained by the MSSO
Scope of the Term Review

- Accuracy of the term translation
- Consistency of the term translation
- Compliance with MedDRA Translation Rules and Conventions
- Develop Chinese linguistic conventions
  – Unique to Chinese translation

<table>
<thead>
<tr>
<th>English Term</th>
<th>Before Review</th>
<th>After Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion dependent anaemia</td>
<td>贫血输血依赖性贫血</td>
<td>输血依赖性贫血</td>
</tr>
<tr>
<td>Impaired driving ability</td>
<td>受损的传动力能力</td>
<td>驾驶能力受损</td>
</tr>
</tbody>
</table>

Summary of the Term Review

- Completed at end of 2016.
  – A total of 68,980 terms were reviewed
- 13% of the terms had translation changes
- All changes were implemented in v19.1 and v20.0

<table>
<thead>
<tr>
<th>English Term</th>
<th>Before Review</th>
<th>After Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Localized erythema</td>
<td>局限性红斑</td>
<td>局部红斑</td>
</tr>
<tr>
<td>HB-S disease with mention of crisis</td>
<td>血红蛋白 S 病有危象</td>
<td>提及危象的血红蛋白 S 病</td>
</tr>
<tr>
<td>Aortic stenosis congenital</td>
<td>主动脉瓣狭窄，先天性</td>
<td>主动脉狭窄，先天性</td>
</tr>
<tr>
<td>Influenza B virus IgA</td>
<td>B 型流感病毒 IgA</td>
<td>乙型流感病毒 IgA</td>
</tr>
</tbody>
</table>
Chinese Translation Term Review

- Established Chinese Linguistic Conventions
  - Help to maintain the accuracy and consistency of Chinese translation
  - Examples:
    - Anaesthesia: 感觉缺失
    - Hypoaesthesia: 感觉减退
    - Dysaesthesia: 感觉障碍
    - Paraesthesia: 异常感觉
    - Sensory abnormal: 感(知)觉异常
  - MSSO developed QC queries to maintain the quality of term translations
  - A living document maintained by the MSSO

Unqualified Test Name Term List
Unqualified Test Name Term List

- MSSO developed an unqualified test name term list
  - PT Blood glucose
  - These terms should never be reported as AEs
  - Intended for use in E2B test name field only
- Standardised, complete list of test name terms is a useful tool for checking data quality
  - Intended as recommendation only
  - Maintained by MSSO with each MedDRA release
  - Available now

List Available for Download

- Support Documentation page on MedDRA.org
- Spreadsheet of LLT/PT names and codes from Investigations SOC
  - >3,700 terms in v20.0
- Explanatory document
  - Purpose, uses, development of list
- Also available in Japanese on JMO website
List v 20.0

<table>
<thead>
<tr>
<th>Term</th>
<th>Code</th>
<th>Level</th>
<th>Added in v20.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>17-ketosteroids urine</td>
<td>10000005</td>
<td>PT</td>
<td></td>
</tr>
<tr>
<td>17-hydroxy corticosteroid activity</td>
<td>10061618</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>2',5'-oligoadenylate synthetase test</td>
<td>10055845</td>
<td>PT</td>
<td></td>
</tr>
<tr>
<td>24 hour electrocardiogram</td>
<td>10073349</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>5-HIAA urine</td>
<td>10060014</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>5-hydroxyindoleacetic acid</td>
<td>100650342</td>
<td>PT</td>
<td></td>
</tr>
<tr>
<td>5-hydroxyindoleacetic acid in urine</td>
<td>10058872</td>
<td>PT</td>
<td></td>
</tr>
<tr>
<td>5' nucleotidase</td>
<td>10060986</td>
<td>PT</td>
<td></td>
</tr>
<tr>
<td>A/G ratio</td>
<td>10000037</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>Abdomen CT</td>
<td>10077423</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>Abdomen scan</td>
<td>10061636</td>
<td>PT</td>
<td></td>
</tr>
<tr>
<td>Abdominal CAT</td>
<td>10057781</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>Abdominal scan NOS</td>
<td>10000091</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>Abdominal wall biopsy</td>
<td>10000102</td>
<td>LLT</td>
<td></td>
</tr>
<tr>
<td>Abdominal X-ray</td>
<td>10061612</td>
<td>PT</td>
<td></td>
</tr>
<tr>
<td>Abdominal X-ray NOS</td>
<td>10050402</td>
<td>LLT</td>
<td></td>
</tr>
</tbody>
</table>

Condensed PT Documents in Chinese
**Points to Consider Documents**

- ICH-endorsed guides for MedDRA users
- MedDRA Term Selection: Points to Consider (MTS:PTC)
  - ICH MedDRA Coding guide
- MedDRA Data Retrieval and Presentation: Points to Consider (DRP:PTC)
  - ICH data analysis and visualization guide
- Recommended to be used as the basis for individual organizations’ coding and retrieval conventions

---

**Points to Consider Documents (cont)**

- Maintained and updated to synchronize with each MedDRA release
- Available only in English and Japanese
- Many examples in the English document are English specific – challenging to translate
- In response to users’ need of PtC guides in other MedDRA languages, PTC WG developed “Condensed PtC Documents”
Condensed PtC Documents

• Condensed versions of PtC documents now finalized
  – To be translated into all MedDRA languages except English and Japanese
  – Version independent; focus on general principles
  – Aim is to support adoption and consistent use of MedDRA worldwide
  – Removed language specific examples
  – Plan to make available in 2017/2018

• English and Japanese PtC documents will remain as full documents updated with each MedDRA release

Condensed PtC Documents Chinese Translation

• Step 1 – Initial translation
• Step 2 – Quality control review of the initial translation
  – If you are interested in being a peer reviewer, please contact me at anna.zhao-wong@meddra.org
  – Peer review qualification:
    • Minimum 2 years of MedDRA Coding experience OR minimum of 2 years data retrieval/analysis experience
    • Familiar with current PtC guides

• Step 3 – Finalization
• Step 4 – Release
MedDRA Self Service Application

Purpose

• Improve service by providing information to a global user community 24/7
Features

• Web-based application which allows:
  – Users to obtain their MedDRA ID
  – Retrieve primary Point of Contact
  – Points of contact to obtain subscription password information and MedDRA zip file passwords
  – Confirmation of MedDRA subscription with business partners
  – Download and print training certificates
• Launched in April 2017

Self Service Application

• URL: https://apps.meddra.org/selfservice/MSST_default.aspx
Paying Subscription by a Credit Card – Coming Soon

- Tired of bank wire transfer?
- Paying subscription by a credit card is coming
- Applicable to subscribers of lower commercial levels
- MSSO’s feasibility study is ongoing
- Would it benefit your organization?
Questions?