MedDRA Update

MedDRA User Group Webinar
1 April 2020

Topics

• COVID-19 and MedDRA
• COVID-19 and the MSSO
• MedDRA Translations
• SNOMED-MedDRA Mapping
• MedDRA Website Chat Function
COVID-19 and MedDRA

COVID-19 Terms in MedDRA

• Pandemic prompted a need from users to code and report the infection
• PtC Working Group and the MSSO collaborated to produce a communication to users
  – Intended to inform users of existing terms and new terms being added to MedDRA
Recommendation

• Until Sept 2020, for verbatim reports of COVID-19 related events
  – Code using the existing terms available in MedDRA 23.0
• MSSO has added new terms to MedDRA and is adding more
  – These supplemental terms are viewable in the MedDRA Web-Based Browser (in the supplemental view)
  – Should not be used for coding or communication to other organizations since supplemental terms are not MedDRA terms yet

COVID-19 Terms Added to MedDRA

<table>
<thead>
<tr>
<th>Existing Terms</th>
<th>New Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLT Coronavirus infection</td>
<td>PT COVID-19</td>
</tr>
<tr>
<td>LLT Coronavirus test positive</td>
<td>PT SARS-CoV-2 test positive</td>
</tr>
<tr>
<td>LLT Exposure to communicable disease</td>
<td>PT Exposure to SARS-CoV-2</td>
</tr>
</tbody>
</table>

• Existing terms are more general, new terms are more specific
• MSSO is also considering related concepts such as quarantine, supply chain interruptions, etc.
• Users encouraged to submit change requests
COVID-19 and the MSSO

• Training
  – MSSO has cancelled all MedDRA face-to-face training worldwide through June 2020
    • Additional cancellations are possible
  – MSSO plans to provide additional webinars to fill the training void
    • MSSO adding more interactive components to webinars

• User Group Meetings
  – Cancelled in China and Europe
    • Replaced with webinars
  – US Meeting in June in Washington is still scheduled
COVID-19 Impacts to the MSSO (cont)

• MedDRA scheduled releases
  – No impact
• MedDRA Change Request Processing
  – No impact
• MSSO Help Desk
  – No impact
• Subscription Processing
  – No impact
• MSSO staff is very familiar and comfortable with working remotely

MedDRA Translations
MedDRA Translations

- MedDRA now available in 14 languages
  - Brazilian Portuguese was added in March 2020
    - All MSSO tools include Brazilian Portuguese in the user interface
  - Each translation includes all terms and user documentation

SNOMED CT – MedDRA Mapping
SNOMED-MedDRA Mapping

- Developed as part of the IMI’s WEB-RADR 2 project
- Based on frequently used MedDRA terms
- Independent maps MedDRA terms to SNOMED CT and SNOMED CT terms to MedDRA
- Currently undergoing an Alpha test
  - Looking for feedback on content and structure

Map Examples

**MedDRA to SNOMED CT map**

<table>
<thead>
<tr>
<th>LLT Code</th>
<th>LLT Name</th>
<th>SNOMED CT ID</th>
<th>Fully Specified Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>10003003</td>
<td>AR05</td>
<td>6775300000</td>
<td>Acute respiratory distress syndrome (disorder)</td>
</tr>
<tr>
<td>10003694</td>
<td>AV block</td>
<td>2338170000</td>
<td>Atrioventricular block (disorder)</td>
</tr>
<tr>
<td>10000059</td>
<td>Abdominal discomfort</td>
<td>4336400000</td>
<td>Abdominal discomfort (finding)</td>
</tr>
<tr>
<td>10000775</td>
<td>Abdominal hysterectomy</td>
<td>1161410000</td>
<td>Abdominal hysterectomy (procedure)</td>
</tr>
<tr>
<td>10000373</td>
<td>Accident automobile</td>
<td>4267720002</td>
<td>Automobile accident (event)</td>
</tr>
<tr>
<td>10002781</td>
<td>Antiemetic supportive care</td>
<td>3864950004</td>
<td>Vomiting management (regime/therapy)</td>
</tr>
<tr>
<td>10003193</td>
<td>Arteriovenous malformation</td>
<td>240510003</td>
<td>Arteriovenous malformation (morphologic abnormality)</td>
</tr>
</tbody>
</table>

**SNOMED CT to MedDRA map**

<table>
<thead>
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<th>LLT Code</th>
<th>LLT Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>2338500008</td>
<td>Abdominal aortic aneurysm (disorder)</td>
<td>10000054</td>
<td>Abdominal aortic aneurysm</td>
</tr>
<tr>
<td>1163100005</td>
<td>Abdominal hysterectomy (procedure)</td>
<td>10000075</td>
<td>Abdominal hysterectomy</td>
</tr>
<tr>
<td>4398800000</td>
<td>Abnormal cervical Papanicolaou smear (finding)</td>
<td>10065364</td>
<td>Papanicolaou smear abnormal</td>
</tr>
<tr>
<td>48540004</td>
<td>Acquired hemolytic anemia (disorder)</td>
<td>10065319</td>
<td>Acquired hemolytic anemia</td>
</tr>
<tr>
<td>32709003</td>
<td>Addiction (finding)</td>
<td>10000125</td>
<td>Addiction</td>
</tr>
<tr>
<td>91934008</td>
<td>Allergy to nut (finding)</td>
<td>10054959</td>
<td>Allergy to nuts</td>
</tr>
<tr>
<td>2757350001</td>
<td>Basal normal at birth (finding)</td>
<td>10029757</td>
<td>Normal baby</td>
</tr>
<tr>
<td>42284007</td>
<td>Bacillus Calmette-Guerin vaccination (procedure)</td>
<td>10072099</td>
<td>Tuberculosis immunization</td>
</tr>
</tbody>
</table>
Next Steps

- SNOMED International and ICH/MSSO will maintain the maps
  - Adjust to changes in both terminologies
  - Support requests for changes to existing mapped terms
  - Support requests for new terms to be mapped

MedDRA Website Chat Function
MedDRA website - Live chat feature

- New feature of MedDRA website
- Allows users to ask questions and interact with MSSO Help Desk staff
- Available when the MSSO global support team is online
- Users will be informed in the chat tool if staff are not available
  – Help Desk will follow up with any submitted questions
Thank You

Questions during the Q&A Session at the end of the webinar