IMI WEB-RADR 2 Project and Overview of the SNOMED CT – MedDRA Mapping

Dr. Judy Harrison, Chief Medical Officer, MedDRA MSSO

European Industry MedDRA User Group Webinar
3 December 2019
IMI WEB-RADR 2 Project

• Funded by the Innovative Medicines Initiative (IMI)
  • Public-private partnership between the EU and industry association, EFPIA
  • Supports biopharmaceutical innovation in Europe

• WEB-RADR 2 seeks to build on mobile app functionality delivered in original WEB-RADR project
  • Enhance and expand access to app platform
  • Develop interoperability functions between regulatory and healthcare systems

• 18-month project (Sep 2018 – Feb 2020)
WEB-RADR Mobile Apps

HALMED
Agencija za lijekove i medicinalna preparate

bijwerkingen
centrumlareb

Yellow Card

DGPML
Diensten van de Pharmaceutische Gezondheidszorg

ADRA
Adresaten Diensten van de Receptenmedeling
## Project Structure

<table>
<thead>
<tr>
<th>General Assembly</th>
<th>General Advisory Board</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steering Committee</strong></td>
<td></td>
</tr>
<tr>
<td>WP1 – Governance, sustainability and project management</td>
<td></td>
</tr>
<tr>
<td>Mobile App Platform: Enhancement and technology adoption</td>
<td></td>
</tr>
<tr>
<td>WP2 – User needs and requirements</td>
<td></td>
</tr>
<tr>
<td>WP3 – Technology development</td>
<td></td>
</tr>
<tr>
<td>Mobile App Platform: Interoperability</td>
<td></td>
</tr>
<tr>
<td>WP4 – Terminology mapping and maintenance</td>
<td></td>
</tr>
<tr>
<td>WP5 – Connectivity to EHR databases</td>
<td></td>
</tr>
</tbody>
</table>

- ICH and SNOMED International
  - MSSO is ICH’s sub-contractor
Work Package 4

• WP 4 “Terminology Mapping and Maintenance”
• Co-leads: Patrick Revelle (MSSO) and Jane Millar (SNOMED International)
• Develop an initial bi-directional mapping between SNOMED CT and MedDRA
  • SNOMED-encoded EHR data converted to MedDRA for adverse event reporting
  • MedDRA-coded regulatory data feeding into clinical decision support systems
• Develop ownership, maintenance, licensing and distribution agreements between ICH and SNOMED International
## Term List for Mapping

- **List of Terms to Map (Bi-directional)**
  - 7,349 MedDRA LLTs
  - Derived from EMA and MHRA, UK reported terms
  - Includes adverse events, medical history, indications, and test names
  - All 27 SOCs represented
  - Included terms from EMA’s Designated Medical Event (DME) list

### MedDRA LLT List

<table>
<thead>
<tr>
<th>Rank</th>
<th>MedDRA LLT</th>
<th>MedDRA code</th>
<th>MedDRA PT</th>
<th>MedDRA Primary SOC</th>
<th>Comment</th>
<th>Current Term</th>
<th>DME</th>
<th>Combined Term Counts</th>
<th>EMA Sourced Data Counts</th>
<th>MHRA Sourced Data Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nausea</td>
<td>10028813</td>
<td>Nausea</td>
<td>Gastrointestinal disorders</td>
<td>Yes No</td>
<td>17409 14204 12663</td>
<td>0</td>
<td>173086 13027 12805</td>
<td>0 1305 97 58 0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Fever</td>
<td>10016658</td>
<td>Pyrexia</td>
<td>General disorders and administration site conditions</td>
<td>Yes No</td>
<td>13949 10703 11653</td>
<td>0</td>
<td>138916 10685 11617</td>
<td>0 333 20 36 0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Vomiting</td>
<td>10047700</td>
<td>Vomiting</td>
<td>Gastrointestinal disorders</td>
<td>Yes No</td>
<td>130665 4827 9245</td>
<td>0</td>
<td>120571 4797 9173</td>
<td>0 1094 30 72 0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Headache</td>
<td>10019211</td>
<td>Headache</td>
<td>Nervous system disorders</td>
<td>Yes No</td>
<td>126861 14409 17451</td>
<td>0</td>
<td>125992 14383 17380</td>
<td>0 969 26 71 0</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Dizziness</td>
<td>10011573</td>
<td>Dizziness</td>
<td>Nervous system disorders</td>
<td>Yes No</td>
<td>92479 1813 7018</td>
<td>0</td>
<td>91734 1802 6979</td>
<td>0 745 13 39 0</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Death</td>
<td>10011906</td>
<td>Death</td>
<td>General disorders and administration site conditions</td>
<td>Yes No</td>
<td>79809 2 181</td>
<td>0</td>
<td>79155 2 181</td>
<td>0 154 0 0 0</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Lack of drug effect</td>
<td>10022610</td>
<td>Drug ineffective</td>
<td>Administration site conditions</td>
<td>Yes No</td>
<td>78689 25 923</td>
<td>0</td>
<td>78096 25 915</td>
<td>0 203 0 8 0</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Pneumonia</td>
<td>10035664</td>
<td>Pneumonia</td>
<td>Infections and infestations</td>
<td>Yes No</td>
<td>75348 13047 68907</td>
<td>0</td>
<td>74946 13024 6852</td>
<td>0 202 23 55 0</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Rash</td>
<td>10017984</td>
<td>Rash</td>
<td>Skin and subcutaneous tissue disorders</td>
<td>Yes No</td>
<td>78887 1525 6170</td>
<td>0</td>
<td>74630 1501 6098</td>
<td>0 1227 24 102 0</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Drug Ineffective</td>
<td>10011709</td>
<td>Drug ineffective</td>
<td>Administration site conditions</td>
<td>Yes No</td>
<td>71227 25 903</td>
<td>0</td>
<td>70951 25 903</td>
<td>0 176 0 0 0</td>
<td></td>
</tr>
</tbody>
</table>
Mapping Conventions

• Initial set developed
• Revised through project
• Will be available to users to understand how maps were created and to interpret results obtained

• Key principles
  • MedDRA LLT maps to Fully Specified Name (FSN) in SNOMED CT and vice versa
  • MedDRA v21.1 and SNOMED CT Jan 2019 International Edition
  • Only map current LLTs and active FSNs
  • Exact conceptual matches
• MedDRA LLT *Rhabdomyolysis* maps to SNOMED CT Rhabdomyolysis (disorder)

• Do not map to SNOMED CT Rhabdomyolysis (morphologic abnormality) as this concept refers to a pathological related finding rather than a clinical one

• SNOMED CT Rhabdomyolysis (disorder) maps to LLT *Rhabdomyolysis*
Additional Principles Covered

- NOS and unspecified MedDRA terms
- US and UK spelling variants
- Combination terms
- Test names and test results
- Specimen types
- Tumour types and stages
- Natural word order
- Punctuation marks
- Increased/high and decreased/low qualifiers
Mapping Teams and Process

- Dual independent mapping
- Quality assurance
- Knowledge of SNOMED CT and MedDRA required

**Team 1**
- Sandra Fielder (AbbVie) - Mapper
- Martin Menke (CSL Behring) – Mapper
- Sophie Reeve, Tamara Darwiche (MHRA) – Quality Assurance

**Team 2**
- Isabel Lázaro Salcedo (AEMPS) - Mapper
- Belen Castro (AEMPS) – Mapper
- Kine Toure Lam (AEMPS) – Mapper
- Debbra Scotti (Pfizer) – Quality Assurance

**Maintenance Organization Quality Assurance**
- SNOMED International – Donna Morgan, Krista Lilly
- MSSO – Ali Awan, Amanda Saunders, Judy Harrison
SNOMED International configured own mapping tool to accommodate MedDRA

Intended to support workflow
- Mappers
- Quality Review
- Maintenance Organization Quality Review

Intended to capture all data related to the mapping within the tool
- No need for offline recording of mappings or related data (e.g., notes)
Mapping Status

- Test mapping of 760 terms (Feb – Mar 2019)
- Lessons learned meeting (April 2019)
  - Discuss process, teams, mapping tool and conventions
- Remaining terms mapped (May – October 2019)
Mapping Status (cont)

- Clean up and finalization (November 2019)
  - Consistency reviews
  - Confirm “unmappables”, e.g., medication error and product quality terms generally not in scope of SNOMED CT
  - Identify potential terms to be added to SNOMED CT to complete map
  - US/UK spellings represented in MedDRA to SNOMED CT map
  - Remove unqualified test name terms, e.g., LLT Blood glucose
    - Not informative and were a challenge to map

- Final map deliverables
  - MedDRA to SNOMED CT map
  - SNOMED CT to MedDRA map
Map Examples

- MedDRA to SNOMED CT

<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>10003083</td>
<td>ARDS</td>
<td>67782005</td>
<td>Acute respiratory distress syndrome (disorder)</td>
</tr>
<tr>
<td>10003846</td>
<td>AV block</td>
<td>233917008</td>
<td>Atrioventricular block (disorder)</td>
</tr>
<tr>
<td>10000059</td>
<td>Abdominal discomfort</td>
<td>43364001</td>
<td>Abdominal discomfort (finding)</td>
</tr>
<tr>
<td>10000075</td>
<td>Abdominal hysterectomy</td>
<td>116141005</td>
<td>Abdominal hysterectomy (procedure)</td>
</tr>
<tr>
<td>10000373</td>
<td>Accident automobile</td>
<td>426772002</td>
<td>Automobile accident (event)</td>
</tr>
<tr>
<td>10002781</td>
<td>Antiemetic supportive care</td>
<td>386495004</td>
<td>Vomiting management (regime/therapy)</td>
</tr>
<tr>
<td>10003193</td>
<td>Arteriovenous malformation</td>
<td>24551003</td>
<td>Arteriovenous malformation (morphologic abnormality)</td>
</tr>
</tbody>
</table>

- SNOMED CT to MedDRA

<table>
<thead>
<tr>
<th>SNOMED CT ID</th>
<th>Fully Specified Name</th>
<th>LLT Code</th>
<th>LLT Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>233985008</td>
<td>Abdominal aortic aneurysm (disorder)</td>
<td>10000054</td>
<td>Abdominal aortic aneurysm</td>
</tr>
<tr>
<td>116141005</td>
<td>Abdominal hysterectomy (procedure)</td>
<td>10000075</td>
<td>Abdominal hysterectomy</td>
</tr>
<tr>
<td>439888000</td>
<td>Abnormal cervical Papanicolaou smear (finding)</td>
<td>10065364</td>
<td>Papanicolaou smear abnormal</td>
</tr>
<tr>
<td>4854004</td>
<td>Acquired hemolytic anemia (disorder)</td>
<td>10055191</td>
<td>Acquired hemolytic anemia</td>
</tr>
<tr>
<td>32709003</td>
<td>Addiction (finding)</td>
<td>10001125</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>275735001</td>
<td>Baby 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

Nov 2019
Bi-directional Term Mapping Complete

Feb 2020
IMI Project Complete

March 2020
Alpha Test Period Begins
- Scope includes format and content
- Test Protocol Developed
- Regulatory, Industry, Vendor, Clinical Users, and Member country Testers Identified

Sept 2020
Alpha Test Period Ends

April 2021
Production Version of the Maps made available to licensed SNOMED/MedDRA Users
Volunteers Needed

• Seeking volunteers for alpha testing
• Provide feedback on format, content, release processes, and schedule

• Testing requirements
  • Have a defined use case
  • Be a SNOMED CT or MedDRA user
  • Have access to SNOMED CT encoded data

• If interested, please contact
  • Patrick Revelle (MedDRA MSSO) patrick.revelle@meddra.org
  • Jane Millar (SNOMED International) jmi@snomed.org
Thank you!