Annex E and F: Health Effects Terms and Codes

- Based on FDA terms and refers to MedDRA
- Consists of IMDRF codes, terms and definitions
- 2 annexes
  - Annex E: Clinical Signs, Symptoms and Conditions
    (3 levels)
    (Structured according to Organ / Physiological system)
  - Annex F: Health Impact (3 levels)
    (e.g., death, hospitalization, unexpected medical intervention, wrong intervention due to incorrect diagnosis)

- Codes will be assigned after reviewing public comments. Coding principles will be the same as Annex A-D.
Annex E and F: Health Effects Terms and Codes

Injury and illness
- Serious, might lead serious
- Non-serious
- Events or No Health impact

Treatments
- Many types of Surgery
- Hospitalization
- Additional treatments
- No treatments

Status
- Death
- Not Recover
- Improve
- Recover
- No Patient Involved

Annex E
- Clinical Signs, Symptoms and Conditions

Annex F
- Health Impact
Annex E: Clinical Signs, Symptoms and Conditions

<table>
<thead>
<tr>
<th>No./ Category (Level 1) (Organs, Systems, Disorders, Concepts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Mental, Emotional and Behavioural Disorders</td>
</tr>
<tr>
<td>4. Immune System</td>
</tr>
<tr>
<td>5. Vascular System</td>
</tr>
<tr>
<td>6. Heart</td>
</tr>
<tr>
<td>7. Respiratory System</td>
</tr>
<tr>
<td>9. Ear and Labyrinth</td>
</tr>
<tr>
<td>10. Gastrointestinal System</td>
</tr>
<tr>
<td>11. Hepatic and Biliary System</td>
</tr>
<tr>
<td>12. Metabolism and Nutrition</td>
</tr>
<tr>
<td>13. Kidney and Urinary Tract</td>
</tr>
</tbody>
</table>
Annex E Coding system

• Categories are treated as Level 1 with codes but not used for reporting. Categories do not have definitions.
• Basic coding principle is the same as other Annexes.

E XX XX XX

- The Annex E excel file has a tab with all terms (LIST) and tabs for each category.
- For term which exists in a secondary place, its code is linked to the primary code.
Annex E: Special case for coding

◆ One term has one code.
  ➢ Some terms belong to two categories. In such case, the only code assigned to the term in the category taking priority is also applied to the same term in the other category.
  ➢ Other applicable category for the term is shown in the term list and the prioritized category is written in red and bold.

e.g.

Category 17. Skin and Subcutaneous Tissue

<table>
<thead>
<tr>
<th>Level 2 Term</th>
<th>Level 2 Code</th>
<th>Other Applicable Category</th>
<th>Level</th>
<th>Level 3 Term</th>
<th>Level 3 Code</th>
<th>Other Applicable Category</th>
<th>Level</th>
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</thead>
<tbody>
<tr>
<td>Skin Erosion</td>
<td>E17XX</td>
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<td>20. Injury</td>
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Category 20. Injury

<table>
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<th>Level</th>
<th>Level 3 Term</th>
<th>Level 3 Code</th>
<th>Other Applicable Category</th>
<th>Level</th>
</tr>
</thead>
<tbody>
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<td></td>
<td></td>
<td>Skin Erosion</td>
<td>E17XX</td>
<td>17. Skin and Subcutaneous Tissue</td>
<td>2</td>
</tr>
</tbody>
</table>

Not E20YYZZ
Instruction for commenting

- Please use the comment sheet to submit your comments.
- Comment:
  Please identify the issue clearly as to why the comment should support a change to the guidance or Annexes.
- Proposed Change:
  Please provide suggested change in order for comment to be understood for discussion.