

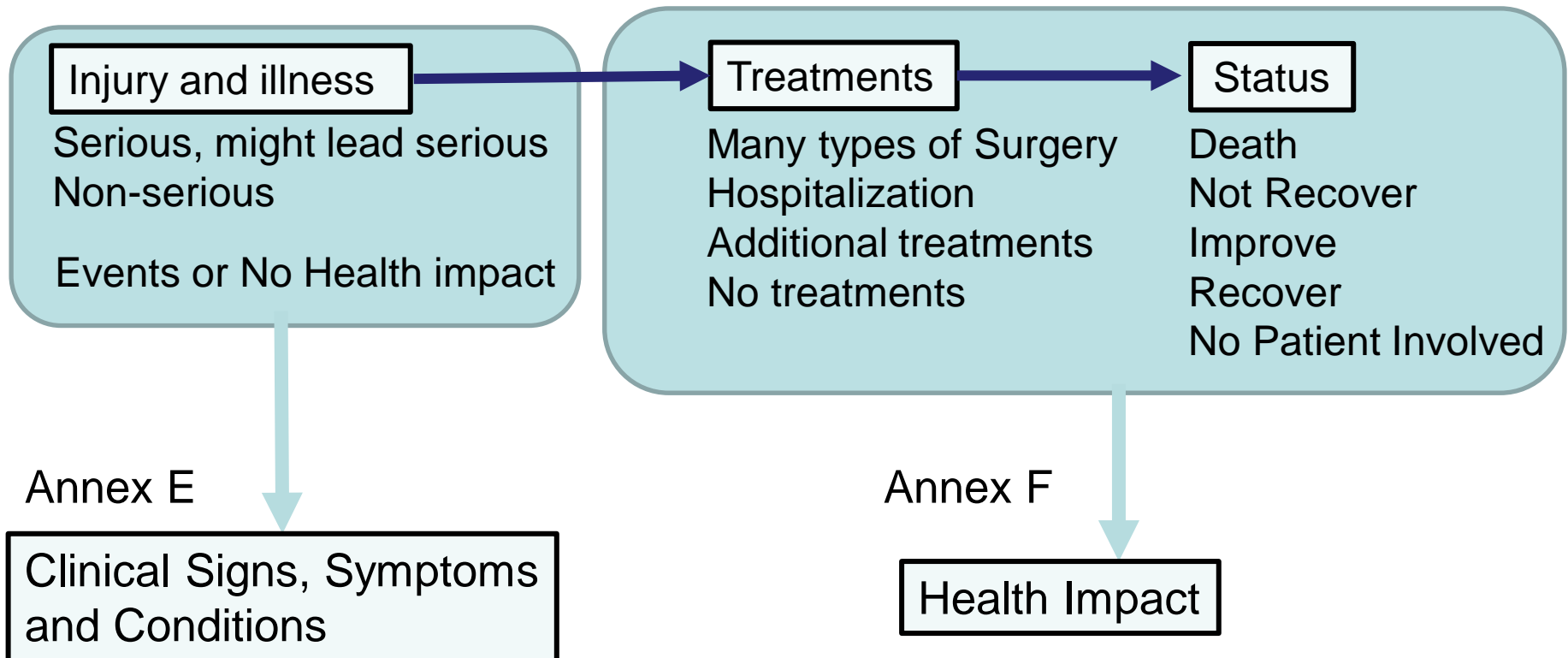


Annex E and F: Health Effects Terms and Codes

- 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





Annex E: Clinical Signs, Symptoms and Conditions

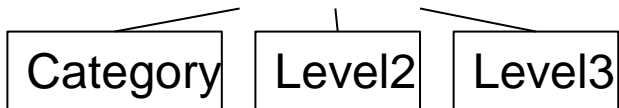
No./ Category (Level 1) (Organs, Systems, Disorders, Concepts)	
1. Nervous System	14. Reproductive System and Breast
2. Mental, Emotional and Behavioural Disorders	15. Pregnancy, Childbirth and the Puerperium
3. Blood and Lymphatic System	16. Musculoskeletal System
4. Immune System	17. Skin and Subcutaneous Tissue
5. Vascular System	18. Neoplasms Benign, Malignant and Unspecified
6. Heart	19. Infections
7. Respiratory System	20. Injury
8. Eye	21. Procedural Complications
9. Ear and Labyrinth	22. Investigations and Diagnostic Tests
10. Gastrointestinal System	23. General Disorders
11. Hepatic and Biliary System	24. Others
12. Metabolism and Nutrition	LIST (all terms in one sheet)
13. Kidney and Urinary Tract	



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 belongs 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

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Skin Erosion	<u>E17XX</u>	20. Injury	3				

Category 20. Injury

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Erosion	E20YY			Skin Erosion	<u>E17XX</u> Not E20YYZZ	17. Skin and Subcutaneous Tissue	2



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