**Column Description of Annex A to G**

**Columns: “Level 1 Term”, “Level 2 Term”, “Level 3 Term”and “CodeHierarchy”**

Annex A to G have a hierarchical structure, apart from Annex B. These hierarchies of terms within the annexes are layed out by positioning each term per row in the respective column in regards to its position in the hierarchy (see example).

Annex B is an exception to this as there is no hierarchy, so only one single column named “Level 1 Term” is present.

Whereas for Annex [A, B, C, D, F, and G] each term occurs only once in the whole coding system, in Annex E terms may appear in multiple places at different levels within the hierarchy. To directly see the full hierarchy of each row and to be able to show terms in the browser under more than one parent term, a column “CodeHierarchy” has been introduced which shows all upper level codes as well as the respective code for the current row separated by a "|".

Example

* Nervous System = Level 1 Term
* Balance Problems = Level 2 Term below Nervous System
* Encephalocele = Level 3 Term below Brain Injury
* Cerebral Edema = Level 2 Term below Nervous System

Level 1 Term Level 2 Term Level 3 Term Code Definition Nervous System E01 Nervous System

Balance Problems E0101 A feeling of falling down ...

Brain Injury E0102 Damage to the brain.

Encephalocele E010201 Hernia of brain substance ...

Cerebral Edema E0103 A swelling in the brain ...

**Column:** **“Code”**

The column “Code” contains a unique code per term. The first time a new code is introduced, the code reflects the hierarchy of the term as well (e.g.: Encephalocele = E010201 -> E01(NervousSystem)02(Brain Injury)01(Encephalocele)). This code is fixed also for future revisions even though the code may be moved within the hierarchy. As in such cases the code itself does not reflect the hierarchy itself anymore, the “CodeHierarchy” column becomes essential to understand the current hierarchical structure of the Annex.

**Column**: **“Definition”**

A detailed definition of what the term is meant to represent.

**Column**: **“Non-IMDRF Code/Term”**

This column shall be used to show any links to other nomenclatures/terminologies adopted by the IMDRF AE working group. In the current state this is used to link the codes in Annex E to MedDRA Code and LLT (e.g. MedDRA:10049848:Balance disorder). The structure follows always the rule CodingSystem+:+Code+:+Term. Links to multiple nomenclatures/terminologies per IMDRF code will be possible and would be separated by a carriage return within the same spreadsheet cell.

**Columns: “Status”and “Status Description”**

The column “Status\*”specifies the current status or the change of the term and in regards to the previous version of each annex. The default is an empty cell, which corresponds to "active, no change to the previous version of the annex". All other states are selected from a fixed list and may be one of the following:

* + Not selectable
  + New
  + Retired
  + Moved
  + Modified (editorial)
  + Modified (technical)

The column \*Status Description\* gives more information on why the current status has been selected (e.g. why a term has been moved/deleted/revised/introduced or as in Annex E for the Level 1 Terms, that a more detailed investigation on the appropriate terms is requested).

Examples:

Not selectable | Please use more detailed term within hierarchy New | Term was added in on 17.04.2020 as there …

Retired | Term was inactivated on 17.04.2020 due to …

Moved | Term needed to be moved as … more appropriate. Please be aware that the code A010416 does not represent the current hierarchy anymore.

Modified (editorial) | Minor editorial change to the term and/or definition on 17.04.2020.

Modified (technical) | Term and/or definition was changed on 17.04.2020 due to …

**Columns: Primary Category and Secondary Category (Annex E only)**

These columns define the preferred location of the term in the hierarchy in case a code is positioned under more than one parent code.

**Maximum Field Length**

To help stakeholders build effective IT systems which remain compatible with future updates to the terminology, the IMDRF AE WG has defined maximum field lengths. The defined field lengths apply to the terms and definitions as they appear in English, and the same lengths apply to all annexes and to all levels in the hierarchy within the annexes. Individual jurisdictions may choose to specify a different length in their official languages, or review existing translations to fit the same limits.

The maximum field length for Terms and Definitions are defined below:

Term = 100 characters

Definition = 700 characters