|  |
| --- |
| **The controlled terminology in this spreadsheet represents the CDISC Glossary produced by the CDISC Glossary team, which seeks to harmonize definitions, acronyms, abbreviations, and initials of commonly used clinical terms across the standards initiatives undertaken by CDISC to support clinical research. The purpose of the CDISC Glossary is to serve the community of clinical researchers by selecting and defining terms pertaining to clinical research, particularly eClinical investigations, sponsored by the pharmaceutical industry or a federal agency. Additional terminology will be developed on an ongoing basis. Future additions to the terminology set will be handled via the CDISC terminology change request and maintenance process.** |
| **Column** | **Description** |
| **Code** *(Column A)* | Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned to individual CDISC controlled terms. |
| **Codelist Code** *(Column B)* | Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned to the SDTM parent codelist names. This code is repeated for each controlled term (aka permissible value) belonging to a codelist.\*\*NOTE - light blue highlighting is used to identify the beginning of a new SDTM codelist and its applicable term set.  |
| **Codelist Extensible (Yes/No/NA)** *(Column C)* | Defines if controlled terms may be added to the codelist. This column is set as NA (Not Applicable) for the CDISC glossary since glossary terms are not necessarily meant for submission, but rather as a reference terminology.  |
| **Codelist Name** *(Column D)* | Contains the descriptive name of the codelist. As with the Codelist Code, the Codelist Name is repeated for each controlled term belonging to a codelist. |
| **CDISC Submission Value** *(Column E)* | Contains the approved, semantically distinct term for each Glossary-defined concept. Glossary terms are generally presented in lower case text. Only proper nouns are capitalized. The preferred term is chosen based on common usage, occurrence in a guidance regulation, or authoritative reference. |
| **CDISC Synonym(s)** *(Column F)* | This identifies the applicable synonyms for the CDISC Submission Value in Column E. A synonym is a concept that is semantically equivalent in contexts and usages with the term specified in the Submission Value column. |
| **CDISC Definition** *(Column G)*  | This identifies the CDISC definition for a particular Glossary term. Multiple meanings of the same term from different sources are numbered 1., 2., 3., etc.a. The definition may contain a note (begins with 'NOTE:') which may be a clarifying comment on the definition, including usage, context, or domain knowledge related to the term.b. The definition may also contain a source citation. The sources for definitions are cited (see "Reference Citations") in square brackets. Multiple sources for multiple definitions are numbered 1., 2., 3., etc. Where the original source definition has been altered by the CDISC glossary team, the citation begins with 'After.' Where the definition has been crafted from source text that is not itself a definition, the citation begins with 'After.' Where no source is listed, the definition is from the CDISC glossary team.c. The definition may also contain related terms, which begin with 'See also' or 'Compare to', in order to offer pointers to similar, related, or antonymous terms. |
| **NCI Preferred Term** *(Column H)* | This identifies the NCI preferred name for a term as identified in NCIt. \*\*NOTE - This column designates the human readable, fully specified preferred term corresponding to the NCI c-code, and is especially helpful for searching NCIt to get the entire concept with links to all instances of the term. |