|  |  |
| --- | --- |
| **The terminology in this spreadsheet represents the MRCT Center Clinical Research Glossary and is intended for the general public to learn more about clinical research. The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) is a research and policy center with a dedicated team developing health literacy resources to support the creation of empowering participant-facing research communications.  The team at the MRCT Center heard from many people (including patient advocates, researchers, pharmaceutical and biotech leaders, and medical writers) that a plain language Clinical Research Glossary was needed for both the public to use, AND for research professionals who want to share clear and understandable research information with patients, participants, and caregivers.   The MRCT Center works with a diverse workgroup to develop all the definitions, and the team votes whether to move forward with a definition before it goes through CDISC Public Review. We welcome and include many different perspectives in our process. You can access the whole MRCT Center Clinical Research Glossary and all its content here:  https://mrctcenter.org/clinical-research-glossary/** | |
| **Column** | **Description** |
| **Code** *(Column A)* | Contains the unique alphanumeric code randomly generated by NCI Thesaurus (NCIt) and assigned to individual MRCT Center Clinical Research Glossary controlled terms. These codes are prefixed by the character 'C' and are also known as the NCI C-code. |
| **Codelist Code** *(Column B)* | Contains the unique alphanumeric code randomly generated by NCI Thesaurus (NCIt) and assigned to the MRCT Center Clinical Research Glossary parent codelist name. This code is repeated for each controlled term (aka permissible value) belonging to a codelist. These codes are prefixed by the character 'C' and are also known as the NCI C-code. \*\*NOTE - light blue highlighting is used to identify the beginning of a new MRCT Center codelist and its applicable term set. |
| **Codelist Extensible (Yes/No/NA)** *(Column C)* | Defines if controlled terms may be added to the codelist for data submission purposes. This extensibility value will be null (i.e., blank) for the MRCT Center Clinical Research Glossary since glossary terms are not necessarily meant for data 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 externally reviewed and adjudicated, semantically distinct term for each MRCT Center Clinical Research Glossary-defined concept. Terms are generally presented in lower case text. Only proper nouns are capitalized. The term is chosen based on common usage, occurrence in a guidance regulation, or authoritative reference. In general, the MRCT Center Clinical Research Glossary team chooses the most appropriate term based on common usage, be it the long name or a common acronym or abbreviation. This term will be listed first, followed by the corresponding long or short name in parentheses. Another use of the parentheses in the CDISC Submission Value column is to identify a context for which a general term may be used, to ensure that the term in the CDISC Submission Value column matches the granularity and context of the definition. |
| **CDISC Synonym(s)** *(Column F)* | Identifies the applicable synonyms for the MRCT Center Clinical Research Glossary Submission Value in Column E. A synonym is a concept that is semantically equivalent in contexts and usages with the term specified in the CDISC Submission Value column. |
| **CDISC Definition** *(Column G)* | Contains the plain language definition for a MRCT Center Clinical Research Glossary term. The term and definition are unique and given an NCI C-code for electronic exchange. The definition should be clear and easy to understand by the intended audience; the term to be defined is not included or used in the definition. |
| **NCI Preferred Term** *(Column H)* | 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. |