

The controlled terminology in this spreadsheet represents the CDISC Glossary, produced by the CDISC Glossary team that 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. This year the Glossary team is introducing, for certain terms, the concept of "cluster" described below in the Definition metadata.

Column	Description
Code (<i>Column A</i>)	Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned to individual CDISC controlled terms.
Codelist Code (<i>Column B</i>)	Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned to the Glossary 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 Glossary codelist and its applicable term set.
Codelist Extensible (Yes/No/NA) (<i>Column C</i>)	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 (<i>Column D</i>)	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 (<i>Column E</i>)	Contains the externally reviewed and adjudicated, semantically distinct term for each Glossary-defined concept. Glossary 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 CDISC 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) (<i>Column F</i>)	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.

<p>CDISC Definition (Column G)</p>	<p>This column has the concise definition for a 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.</p> <p>a. In case multiple meanings can be attributed to the same term (depending on the context in which the term is used), the meanings can be listed and numbered to distinguish the definitions from each other.</p> <p>b. NOTE - The definition may contain a note that can be a clarifying comment on the definition, including usage, context, or domain knowledge related to the term.</p> <p>c. Source citation - Preferably the definition includes a source citation. The sources for definitions are cited (see "Reference Citations") in square brackets. Multiple sources are numbered 1., 2., 3., etc. Where the original source definition has been altered by the CDISC glossary team or 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.</p> <p>d. See also, compare to - The definition may contain related terms, which are designated by 'See also' or 'Compare to', in order to offer pointers to similar, dissimilar, related, or antonymous terms. See also is used to present related, published glossary terms with definitions that may help clarify the distinctions between related terms (i.e., belong to a related cluster/grouping).</p> <p>e. Cluster of terms - Indicating a cluster of terms is an important feature introduced recently in development and it groups a set of related words included in this clinical research glossary (e.g. monitoring, exposure, milestones, participant) so that a user can read them in relation to each other to understand nuances and distinctions in context. The intent is to enable clarity of communication through selection of the right word to convey the relevant meaning accurately. Clusters can be found in this Glossary by the root or overarching core term e.g. "monitoring" followed by a See Also statement containing "subject monitoring", "medical monitoring", "study monitoring", "trial monitoring", each with a unique NCI C-code.</p>
<p>NCI Preferred Term (Column H)</p>	<p>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.</p>
<p>Acronyms,Abbreviations,Initials</p>	<p>This tab lists acronyms, abbreviations, and initials (AAI) that are commonly used within the clinical development lifecycle. The letters of each AAI appear in Column A, with capitalization reflecting common usage. Column B lists the spelled-out name(s) that pertain to the AAI in the first column. In general, the spelled-out name in Column B is uncapitalized, unless it is an organization, office, or other type of proper noun. In some cases, the Glossary Team has added additional notes to Column B in those cases where further explanation or clarity may be warranted.</p>
<p>References</p>	<p>This tab lists references and URLs associated with the sources used to develop CDISC Glossary definitions.</p>

Current Version Link

The latest version of the CDISC Glossary is posted here:
<https://evs.nci.nih.gov/ftp1/CDISC/Glossary/>