CTEP Simplified Disease Classification Overview

The *CTEP Simplified Disease Classification* (CTEP SDC) v1.0 is a restructured, more intuitive classification of diseases, designed to meet the needs of CTEP while still allowing reporting based on the Medical Dictionary for Drug Regulatory Reporting (MedDRA) v6.0 disease terminology. It was developed to make reporting of clinical trials data more standardized and to facilitate uniform reporting by CTEP of its clinical trials activities.

Based on current clinical trials supported by CTEP, the CTEP SDC reduces the number of diseases from over 1,000 to just under 250 terms. It also reduces the number of groupings to about one-half the current categories and subcategories. This reduction is expected to improve the navigation of the disease hierarchy resulting in greater reporting consistency by broad disease groupings and individual diseases. It also introduces the World Health Organization's (WHO) terms for hematologic diseases, and provides a more simplified hierarchical organization of these terms.

The CTEP SDC is designed to uniquely identify the specific histologies for which CTEP conducts clinical trials, and groups these specific histologies into a hierarchy that conforms to the current organization of clinical oncology research. The CTEP SDC includes three levels, the lowest of which is the CTEP Disease Term, which is generally based on histology, but does not include concepts such as clinical stage or the extent of prior therapy allowable for patients who are eligible on a clinical study. This is a key distinction between the CTEP SDC and the currently used MedDRA terminology. MedDRA incorporates multiple clinical concepts into its disease terms (e.g., histology, stage, and/or prior therapy), creating a more comprehensive disease terminology, but one that prevents the coding of stage and prior therapy information as distinctive concepts. This, as well as the distinctive concept coding of molecular characteristics of cancers eligible on studies, is a future goal of the CTEP Enterprise System.

The CTEP SDC is available in the following formats:

Text (.txt) file The text file is a colon delimited file that lists the CTEP SDC codes and is used for importing the codes into user databases.

Excel (.xls) file The Excel file lists the CTEP SDC codes.

Mapping Version Excel (.xls) file The Excel mapping file provides the mapping of MedDRA Disease Terms to the CTEP SDC for use during a one-time conversion of disease information within the CTEP Enterprise System. In addition, each CTEP Disease Term is mapped to a single MedDRA term for use when reporting to the Food and Drug Administration.