

## Updated Disease Codes for Protocols Approved prior to 10/1/04

CTEP will be updating IT applications (i.e., CDUS, AdEERS) Enterprise data systems by July 1, 2007 to MedDRA v10.0. CTEP has reviewed the lists of values for CTCv2.0; CTCAEv3.0, SDCv1.0, Legacy Disease Codes, Prior Therapy Codes and Pre-Existing Condition Codes. Values for CTCv2.0, CTCAEv3.0, SDCv1.0 and Legacy Disease Codes were updated.

As a result of CTEP's collaboration with caBIG, the Cancer Centers, the FDA, the MedDRA MSSO (Maintenance Service and Support Organization), and in compliance with the 2005 ICH Guidance on Data Transfer, we will be replacing Preferred Terms (PT) with Lowest Level Terms (LLT). **Note:** Because all PT codes also exist as identical LLT codes, the current PT code will be unchanged when represented as the LLT.

**All local systems must be updated to utilize these new codes. As of the July 1, 2007 CTEP will no longer accept the old codes. CDUS/CDS data submissions, with the Due Date of July 31, 2007, must submit these new codes.**

### Legacy Disease Codes Changes:

CTEP determined that Legacy Disease Codes that were not part of the Simplified Disease Classification would not be updated to MedDRA v10.0 codes. Only Legacy Disease Codes that are also part of the Simplified Classification will have updated codes.

### Files Available from CTEP Website:

**Text (.txt) file** The text file is a comma delimited file that includes the current list of Legacy Disease Codes (Category, Sub-Category, CTEP Term, and MedDRA codes). It can be used for importing the diseases and codes directly into local databases.

**Excel (.xls) file** The Excel file includes the current list of Legacy Disease Codes (Category, Sub-Category, CTEP Term, and MedDRA codes).

**Mapping Version Excel (.xls) file** This Excel file includes two worksheets. One worksheet labeled "Legacy Disease Mapping" includes the current list of Legacy Diseases with their Old MedDRA Code, New MedDRA Code and a column indicating whether the New MedDRA code has been updated from the Old MedDRA Code (Category, Sub-Category, CTEP Term, Old MedDRA Code, New MedDRA Code, Updated Code). The second worksheet labeled "Updated Codes Only" includes the same information but only for those disease codes that are being updated.