CTCAE v2.0 MedDRA v10.0

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 data submissions, with the Due Date of July 31, 2007, must submit these new codes.

CTCAE v2.0 Changes:
CTEP reviewed CTCv2 terms currently associated with MedDRA v9.0 preferred terms and codes and updated to appropriate MedDRA v10.0 lower level terms and codes.

Files Available from CTEP Website:
> **Text (.txt) file** The text file is a comma delimited file that includes the current list of CTC v2 terms and codes ("Adverse Events Category","AE/Supra-ordinate Term","MedDRA/ CTEP Term","MedDRA Code(v10.0)/ CTEP Code"). It can be used for importing the terms and codes directly into local databases.
> **Excel (.xls) file** The Excel file includes the current list of CTC v2 terms and codes ("Adverse Events Category","AE/Supra-ordinate Term","MedDRA/ CTEP Term","MedDRA Code(v10.0)/ CTEP Code").
> **Mapping Version Excel (.xls) file** This Excel file includes CTC v2 with both MedDRA 9.0 and MedDRA 10.0 terms and codes. It also includes a separate column to identify whether the term and code have changes between version 9.0 and 10.0.

5/10/2006