Date: January 5, 2018
To: CDUS Submitters
From: Chief, Clinical Trials Operations and Informatics Branch, NCI, DCTD, CTEP
Subject: Conversion of CDUS Data from CTCAE v4.0 to CTCAE v5.0

To all CDUS Submitters,

The new CTCAE version 5.0 is now available. Effective **April 1, 2018**, all protocols will be converted to CTCAE v5.0 for both CDUS and CTEP-AERS reporting. Patient data submitted using CTCAE v4.0 **will no longer be accepted** by CTEP. The loading period beginning January 1, 2018 and ending March 31, 2018** (Q4 2017) will be the last quarter for which CTEP will provide support for data submitted using CTCAE v4.0.

Data Fields Affected and Summary of CTCAE Changes

The CDUS fields, "AE_Type_Code", "AE_Grade_Code" and "AE_Other_Specify" located in the Adverse Events, Baseline_Abnormalities, Late_Adverse_Events, and Phase1_End_Point_DLTS records, are affected.

The updates between CTCAE v4.0 and CTCAE v5.0 are:
- clarifications to grade descriptions
- clarifications to term definitions
- addition of terms and/or grades
- deletion of terms and/or grades
- Primary SOC changes due to MedDRA/MSSO SOC reorganization

CDUS protocols with a submission deadline of April 30, 2018, must submit data using valid codes from the CTCAE v5.0. To review the latest version of the CTCAE v5.0 documents, including a mapping document, refer to the following URL:
https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm#ctc_50

Timeline and Process for Conversion of Data for CDUS Complete Studies using CTCAE v5.0

The conversion of CTEP sponsored protocols currently submitting data in CTCAE v4.0 will begin the last week of March 2018. All CDUS-Complete Monitored studies will be converted to the latest version of the CTCAE once successfully loaded to the CTEP database **except** the following:

- CDUS-Complete Monitored studies with statuses of "Completed" or "Administratively Completed" as of March 31, 2018, conversion of data **will not be required**. However, a final CDUS submission using CTCAE v4.0 must be submitted by March 29, 2018.
- Active studies utilizing the CTEP-AERS/Rave Integration will receive further instruction in a separate communication.

 **Note: In order to allow adequate time for the activities involved in the conversion of data from CTCAE v4.0 to CTCAE v5.0, the CDUS loading period will end on Thursday, March 29, 2018. Any CDUS submitters who fail to successfully load their protocols by this date will have their protocols converted from CTCAE v4.0 to CTCAE v5.0 and will be required to submit all subsequent data using the latest version of the CTCAE.

Please keep in mind that once a protocol has successfully loaded and converted, any updates or changes to the data made during this loading period must use the latest version of the CTCAE.

If you have any questions or comments please contact the NCI CTEP Help Desk at ncictephelp@ctep.nci.nih.gov or by telephone at 301-840-8202.

Sincerely,
Nichelle Herriott on behalf of:

Mike Montello PharmD, MBA
CAPT (Ret.) USPHS
Chief, Operations and Informatics Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

Shanda Finnigan, MPH, RN, CCRC
Associate Branch Chief, Operations and Informatics Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute