ETCTN Serious Adverse Event Reporting Information Page

1.   Introduction

The Cancer Therapy Evaluation Program-Adverse Event Reporting System (CTEP-AERS) is the safety system used to facilitate expedited Adverse Event (AE) reporting for all trials. CTEP-AERS covers all Rave and non-Rave trials conducted by the National Clinical Trials Network (NCTN), ETCTN, NCI funded Consortia, Cancer Centers, etc.

Since fall 2017, all newly activated studies for which CTEP holds the Investigational New Drug (IND) include a link between Rave and CTEP-AERS (Rave/CTEP-AERS integration), which relies on AEs being entered into Rave as they are known and sent to CTEP-AERS for evaluation for expedited reporting. This evaluation results in a recommended action to report or not report based on the protocol rules for adverse event reporting. Adverse events **must be** entered into Rave to initiate the ticket in CTEP-AERS; tickets **should not be** created manually in CTEP-AERS.

For additional information on adverse event reporting, review the NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs located on the CTEP website.

2.   Use of CTEP-AERS

2.1   Access

The CTEP-AERS application is located on a dedicated CTEP-AERS website.

2.2   Training

CTEP has developed a number of training and guidance resources on the use of CTEP-AERS.

- For general information on CTEP-AERS and links to other resources refer to the CTEP-AERS webpage

- CTEP-AERS WebEx Training Recording (scroll down to the Training section)

- CTEP-AERS Online Help

- The CTEP-AERS Training/Practice Website is located in the CTEP-AERS Training Environment

Training materials on the use of the Rave/CTEP-AERS integration are available on the CTSU members' website:

- CTEP Guidance for Recording Adverse Event Start and End Date in Rave is available in the Resources section> CTSU Operations Information>Guidelines & Procedures

- Expedited Safety Reporting Rules Evaluation User Guide is available in the Resources section>CTSU Operations Information>User Guides

- Training slides and/or video may be available in the protocol-specific Education and Promotion Materials section for those studies participating in the integration

3. For Questions and Support

For technical questions related to the use of CTEP-AERS, please contact the CTSU Help Desk:

- CTSU Help Desk: ctsucontact@westat.com or 1-888-823-5923

For medical-related questions that arise during the use of CTEP-AERS, please contact the CTEP-AERS AEMD Help Desk:

- AEMD Help Desk: aemd@tech-res.com or (301) 897-7497