NCI Experimental Therapeutics Clinical Trials Network

A program of the National Cancer Institute of the National Institutes of Health

TRIAL CONDUCT
Intended for those at clinical sites **conducting** ETCTN trials

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 Medidata Rave and non-Rave trials conducted by the National Clinical Trials Network (NCTN), Experimental Therapeutics Clinical Trials Network (ETCTN), National Cancer Institute (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 Medidata Rave and CTEP-AERS as part of the Rave/CTEP-AERS integration; this integration relies on all AEs (routine or serious) being entered into Medidata 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 NCI and protocol rules for Serious Adverse Event reporting. Adverse events **must be** entered into Medidata Rave to initiate the expedited AE report 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 several 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; and
- 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; and
- 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 expedited AE reporting on integrated studies, 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