



Experimental Therapeutics Clinical Trials Network

*Team Driven. Cancer Therapy Focused.*

National Cancer Institute at the National Institutes of Health

**TRIAL CONDUCT**

Intended for those at clinical sites  
conducting ETCTN trials

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# ETCTN Serious Adverse Event Reporting Information Sheet

## 1. Introduction

The Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS) is the entry point for expedited AE reporting for all trials. CTEP-AERS covers all Rave and non-Rave trials conducted by the Groups/NCTN, ETCTN, U01s, N01s, etc.

For information on adverse event reporting, please review the [NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD \(CTEP and CIP\) and DCP INDs and IDEs](#).

## 2. Use of CTEP-AERS

### 2.1 User Access

The CTEP-AERS application can be accessed at: <https://eapps-ctep.nci.nih.gov/ctepaers>

Please note that access to CTEP-AERS does not require a username or password.

### 2.2 User 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:  
[http://ctep.cancer.gov/protocolDevelopment/electronic\\_applications/adverse\\_events.htm](http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adverse_events.htm)
- CTEP-AERS WebEx Training Recording:  
<http://cbiit.webex.com/cbiit/ldr.php?RCID=7d45511f70f18982161c31724223b33a>
- CTEP-AERS Training Guide:  
[http://ctep.cancer.gov/protocolDevelopment/electronic\\_applications/docs/CTEP-AERS\\_Training\\_Guide.pdf](http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTEP-AERS_Training_Guide.pdf)
- CTEP-AERS Training/Practice Website: <https://betapps-ctep.nci.nih.gov/ctepaers/public/login>

## 3. For Questions and Support

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

- CTEP Help Desk: [ncictephelp@ctep.nci.nih.gov](mailto:ncictephelp@ctep.nci.nih.gov) or 1-888-283-7457

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

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