



Subject: Guidance for CTEP-AERS Reporting: Studies Utilizing the Rave/CTEP-AERS Integration – CTEP-AERS Reports Submitted Outside the Integration

Date: 4/28/2021

CTEP-AERS reports submitted directly in CTEP-AERS (outside the Integration) must continue to be managed/amended directly within CTEP-AERS. **Please do not ask your Site Staff to withdraw the original report and submit a new, duplicate report via the Integration.**

CTEP has been receiving requests from CTEP-AERS users to withdraw initial reports done outside the Integration so a new report can be submitted via the Integration. While we are appreciative of the desire to follow the proper process, this creates regulatory difficulties for CTEP.

Most of the Withdrawal requests are for CTEP-AERS reports which have already been assessed by CTEP and in some cases submitted to the FDA in an IND Safety Report. Withdrawing these CTEP-AERS reports and subsequently creating a new, duplicate CTEP-AERS report via the Integration triggers a new assessment by CTEP and in some cases a retraction of the previously submitted IND Safety Report and subsequent resubmission to the FDA.

Amendments (applies to CTEP-AERS Reports Submitted Outside the Integration only)

If corrections/changes/updates need to be made to the *Adverse Events* form in Rave, users can and should update as needed in Rave. Once a CTEP-AERS report has been submitted outside of the integration, however, the process to synchronize those changes between CTEP-AERS and Rave is manual as described below for this specific use case.

Use Case:

A CTEP-AERS report has already been directly submitted in CTEP-AERS (not through the Integration) for this patient/treatment course. If updates are required, do the following:

- **Rave:**
 - In the *Adverse Events* form in Rave make whatever changes/updates are required.
 - Run the Rules Evaluation via the *Expedited Reporting Evaluation* form.
 - If there is a recommendation to report/amend or you feel a CTEP-AERS amendment is needed, do **not** use hyperlink to move to CTEP-AERS.
- **CTEP-AERS:**
 - Log directly into CTEP-AERS: <https://ctepcore.nci.nih.gov/ctepaers/security/login>
 - In either the 'My Submissions' or 'Manage Reports' tab, select the previously submitted report, amend and submit.

Questions: contact the CTSU Help Desk at CTSUContact@westat.com.