SWOG CANCER RESEARCH NETWORK

April 1, 2019

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: Medidata Rave – CTEP-AERS Integration

MEMORANDUM

The following activated protocols currently utilize the Medidata Rave – CTEP-AERS integration:

S1600	**S1619**	**S1802**
S1612	**S1706**	**S1815**
S1614	**S1801**	**S1900A**
S1714		

Prior to an updated section 16.1 of each protocol listed above please refer to the following:

For each study indicated above, all adverse events requiring expedited reporting must initially be reported on the Adverse Event Form in the appropriated Treatment Cycle folder in Medidata Rave. Once the adverse event is entered into RAVE, the Rules Engine will confirm whether or not the adverse event requires expedited reporting. The CTEP-AERS report must then be initiated directly from the Adverse Event Form in Medidata Rave. Do not initiate the CTEP-AERS report via the CTEP-AERS website. Sites are encouraged to confirm the Expedited Reporting Evaluation Recommendation with the reporting criteria outlined in the appropriate reporting table, and if included in the protocol the SPEER(s) and Section 16.1.f.

Expedited Reports via Medidata Rave:
In CTEP-AERS, click on “Help” to open the CTEP-AERS On-Line Help and choose the chapter “Submitting Reports for RAVE Users” for help in submitting expedited reports via Medidata Rave – CTEP-AERS integration.

If you have questions, you may contact the SWOG SAE Program at adr@swog.org

cc: PROTOCOL & INFORMATION OFFICE