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TO: ALL SWOG MEMBER, NCORP AND AFFILIATE MEDICAL INVESTIGATORS AND CLINICAL RESEARCH ASSOCIATES

FROM: SWOG Operations Office

RE: SAE Reporting System - CTEP-AERS Update

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MEMORANDUM

An updated version of CTEP-AERS has been released by NCI. Before, CTEP-AERS (and AdEERS prior) had over 20 different pathways for SAE reporting. Each pathway was based on the treatment the subject received (e.g. CTEP IND agents only, CTEP IND agent + surgery, non-CTEP IND agent + surgery + radiation, etc.), and each had slightly differing business rules affecting which questions were mandatory, optional, or not present on each report.

This CTEP-AERS update consolidates those 20+ reporting pathways into four. This consolidation not only creates a consistent experience within CTEP-AERS for you, the reporter, it also harmonizes CTEP-AERS and the CTEP AE database with the soon-to-be-piloted SAE reporting integration between NCI and Medidata Rave.

Most users will not notice a difference when using CTEP-AERS. No 'new' fields/questions have been added. A few fields/questions that were optional for certain pathways and mandatory for others are now mandatory for all. Other fields/questions that were not present on certain pathways are now present and optional on all.