

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

MEMORANDUM

To: Principal Investigators, NCORP Investigators, Clinical Research Professionals

From: Jenny Darcy, Statistics and Data Center

Subject: Pilot of Data Freezing in Rave for the A021501 and A021502 (ATOMIC) Trials

Date: August 15, 2018

The Alliance Statistics and Data Center (SDC) would like to pilot the use of the data freeze option within Rave. This will allow the data management team to freeze data after key data reviews (Eligibility Review and Case Evaluation) have been completed, and it will allow the Data Management staff to achieve the highest data management standards. The SDC recognizes that there may be a need to correct data after the key data reviews have occurred, and sites should first contact the study's Data Manager before updating any frozen data. This will allow the Data Manager to be aware of any changes after a key data review has taken place, and thus prompting a re-review of the corrected/updated data if necessary.

For the pilot, the Data Manager will freeze all baseline folder data after the Eligibility Review has been completed, freeze all treatment and follow-up folder data up to the point of the event that triggered the Case Evaluation, and, if the Case Evaluation was triggered by an event other than completion of all follow-up, freeze all treatment and follow-up folder data after all follow-up for the study has been completed.

We have selected A021501 and A021502 (ATOMIC) as pilot trials. As part of the evaluation of this pilot program, Alliance SDC staff will be contacting your site's Data Management staff and the Study staff to understand if freezing data along the way had any negative impact to work flow or efficiency.

Questions regarding this memorandum may be directed to the trial Data Manager and/or Central Monitor:

- A021501 – Pamela Fain Pribyl (fainpribyl.pamela@mayo.edu)
- A021502 – Tiffany Bainter (bainter.tiffany@mayo.edu) or Tiffany Schafer (schafer.tiffany@mayo.edu)