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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Keeping track of study data in multicenter trials

There are no results in trials without data. Data are what trials are about. No wonder investigators are protective of their data and stingy handing them out.

Usually the data center/coordinating center is the keeper of study data and, hence, the center responsible for protecting data against misuse and the center responsible for keeping track of who has them.

If data are shared during the trial, the sharing is usually limited to baseline data and then only with the investigator group. Hence, the task of keeping track of who has study data during the trial is easy but it gets more complicated when the trial is finished and when data are distributed to members of the investigator group and to others outside the investigator group.

The guidelines that follow concern issues of access during and after data collection.

Access during the trial

Guideline 1: Produce written policy on limits to data access during the trial; produce prior to the start of data collection; have policy reviewed and approved by study leaders

Guideline 2: The elements of the policy should include specification of who has access to interim treatment results and whether clinic personnel can see them
Comment: The usual norm is to limit access to members of the treatment effect monitoring committee\data and safety monitoring committee. Clinic personnel do not see interim treatment results.

Guideline 3: Restrictions on access should not include details regarding the design and methods of the trial
Comment: Research on human beings has to be free and open to sustain public trust. Hence, details of design and methods should be openly available.

Guideline 4: The written policy should be explicit as to whether presentation or publication of interim results is allowed and, if so, the circumstances under which allowed
Comment: The presumption is that such presentations or publications are proscribed; there should be compelling reasons to deviate from the presumption.

Guideline 5: Access to study data, if any at all, should be limited to the investigator group

Comment: The reason is obvious. There is no reward in doing trials if others, outside the investigator group, have access to study data before the people who collect them.

Guideline 6: Access, if any outside the coordinating center (Guideline 5), should be limited to baseline data; access sometimes also allowed in the investigator group to followup results for the control-assigned group of study subjects if a study objective is characterization of the natural history of disease

Guideline 7: The coordinating center/data center should keep a log of persons seeing interim treatment results; log should be subject to review by study officers, study sponsor, and study investigator group

Guideline 8: Policy (Guideline 1) should be explicit as to whether the sponsor receives interim treatment results
Comment: The presumption is that it does not; there should be compelling reasons to deviate from that path.

Guideline 9: Requests for study data should be reviewed by study officers and should not be supplied by the coordinating center without approval

Guideline 10: Requests from outside the investigator group should be denied unless the information is necessary for the safety or well-being of persons studied or for regulatory purposes

Access after the trial

Guideline 11: Produce document outlining policy on data access after the end of data collection; produce at or before the end of data collection; have policy reviewed and approved by study leaders

Guideline 12: Ensure that study investigators receive study data prior to persons outside the investigator group
Comment: It is obvious that those who collect data should be able to see them, analyze them, and publish them before they are given to others for their uses.

Guideline 13: Provide study investigators access to the full, identified, study dataset

Guideline 14: Require study investigators receiving study datasets to sign statements indicating that they will:
a. Not reveal identity of study subjects
b. Limit use to persons vetted by the recipient
c. Maintain a log of persons given access by them to datasets
d. Adhere to study policy and procedures regarding presentations and publications arising from use of study data

Guideline 15: Provide data to investigators (Guideline 12) as soon as practical after completion of data collection, consistent with final data harvests and editing

Guideline 16: If a dataset is provided to the sponsor, require assurances similar to those for Guideline 13

Guideline 17: Do not agree to data share outside the investigator group if doing so preempts investigator rights to be the first to analyze and report their results
Comment: To comply with this guideline, investigators have to be in charge of reviewing and vetting requests for data until they are finished paper writing. If data are handed over to a custodian for data sharing before that, the hand over should be with the condition that investigators have the right to review requests and to reject or forestall those that conflict with investigator rights to be first to analyze and report.

Guideline 18: If data are to be deposited with a custodian for data sharing, require information on how the custodian is funded and whether it profits from answering requests for data; do not deposit if unsatisfied with answers

Guideline 19: Do not deposit data with a custodian if the custodian's vetting procedures for requestors are seen as inadequate

Guideline 20: Do not deposit data for data sharing without assurance that the custodian:
a. Has adequate procedures and means to catalog users of study data
b. Will provide study investigators on request a list of persons or agencies to whom data have been provided and of proposed uses

Guideline 21: Do not deposit data if custodian is not willing to allow study investigators to contact recipients for details regarding use

Guideline 22: The coordinating center should maintain a log of persons or agencies having study data, of date supplied, and of data provided
Comment: The log is important should it be necessary to recall datasets because of errors.