

MEMORANDUM

To: DAIDS Staff, CTU Primary Investigators, Site Leaders, Network Leadership, Network Operations Centers, Statistical and Data Management Centers, Non-Network Primary Investigators

From: Scott Proestel, M.D.
Acting Director, Office for Policy in Clinical Research Operations
Division of AIDS, NIH

Re: Mapping Strategy for Relationship Assessments Using Version 2.0 of the DAIDS EAE Manual

There has been considerable discussion inside and outside of DAIDS regarding how to “map” the relationship categories that exist within Version 1.0 of the DAIDS Expedited Adverse Event (EAE) Manual to the new categories that exist within Version 2.0. By way of background, Version 1.0 has five categories for assessing the relationship between the EAE and study agent, while Version 2.0 has only two. One of the primary reasons for mapping is to provide a consistent strategy for analyzing data from studies that initially reported under Version 1.0 and subsequently switched to Version 2.0.

An initial decision was made in March of this year to use a mapping strategy that grouped “Definitely Related,” “Probably Related,” “Possibly Related,” and “Probably Not Related” in Version 1.0 as being “Related” under Version 2.0, with the remaining term of “Not Related” in Version 1.0 mapping to “Not Related” in Version 2.0. However, significant concerns have been raised regarding the confusion that this strategy will create. Specifically, some networks plan to continue to use five categories of relationship assessment for toxicity management and study pause rules, in addition to the two categories of assessment for EAE reporting. In doing so, they will be mapping “Probably Not Related” as being “Not Related” for those purposes. Following discussions with the Network Leadership as well as the SDMCs, it has been decided that in order to reduce confusion, the relationship assessment mapping strategy for EAEs should be harmonized with the mapping strategy that will be used for toxicity management and pause rules. Please refer to the revised mapping strategy shown in the table below.

Some protocols have already incorporated the previous mapping strategy in which “Probably Not Related” is mapped to “Related.” However, the revised strategy listed below should be used for new protocols, and where reasonably feasible, should also be incorporated into ongoing protocols that switch to Version 2.0 of the DAIDS EAE Manual. I apologize for the confusion, but I believe that this revised approach will be best in the long run.

EAE Manual Version 1.0 EAE Manual Version 2.0

Definitely related	Related
Probably related	Related
Possibly related	Related
Probably not related	Not Related
Not related	Not Related

Please feel free to contact me regarding any questions.

Thanks,
Scott

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