

Ancillary and Sub-Study Data Access

1. Data that are collected under the core GRADE study protocol are owned by the study and are available to the study group at large for the purposes of proposing a paper or presentation based on analysis of study data, with approval by the Publications and Presentations Subcommittee (PPS). Similarly, data collected as part of a GRADE sub-study are owned by the study.
2. Ancillary study data are owned by the ancillary study investigators, but a copy of the data must also be provided to the GRADE research group.
3. The Ancillary or Sub-study investigators will have primary access to the data that are collected as part of an Ancillary or Sub-study for analysis and papers that are consistent with the Ancillary or Sub-study aims. As with all paper proposals, PPS approval is required before access to the data is provided.
4. Following publication of the main ancillary or sub-study results, other GRADE investigators may propose analyses using ancillary/sub-study data. These proposals must be reviewed and approved by PPS. The PPS will select the most qualified research group members for the writing group, thus ensuring that Ancillary and Sub-study members will have the opportunity to participate in these writing groups. Further, since PPS approves and tracks all GRADE papers, potential overlap between Ancillary or Sub-study manuscripts and new paper proposals will be avoided.
5. All Ancillary and Sub-studies will follow GRADE publications policy and all analyses and manuscripts generated from such studies must be reviewed and approved by the GRADE PPS.