ADCS Publications and Citation Policy

Overview of Publications Committee and Publication Policies

The ADCS Publications Committee (PC) shall consist of several (minimum of 3) members, whose remit is the administrative review of manuscripts for publications using or citing ADCS trial data. Evaluating the scientific merits of analyses or abstracts is beyond the scope of the PC. The ADCS PI and the Chair of the ADCS Internal Ethics Committee (IEC) shall be *ex officio* members of the PC. The Data and Sample Sharing Committee (DSSC) works closely with the Publications Committee to ensure that ADCS data sharing is recognized and appropriately acknowledged. The Administrative Core is responsible for providing support to both the PC and the DSSC.

ADCS principal investigators have first rights to author primary publications of ADCS trials. In addition, the ADCS Biostatistics and Data Management Cores are directly involved in primary data analyses of ADCS NIH-sponsored clinical trials.

Prior to publishing, all publications of the ADCS must be reviewed by the PC for adherence to authorship, human subjects, and conflict of interest issues.

Definition of Publication Types:

1. Primary Publications: Major publications refer to the first full-length reports on trials or new instruments in ADCS clinical trials. Instrument development papers that report on validity or reliability of assessment tools also fall into this category. Primary publications are likely to have high impact, therefore all issues associated with the publication process must be carefully scrutinized above and beyond the actual analysis of the data and production of manuscript text. Prior to the publication of the primary paper reporting efficacy results, publication of a subset of the data in which efficacy or safety are discussed is forbidden.

2. Secondary Publications: Secondary publications refer to all other publications of ADCS PIs that do not meet the above definition of "primary" and are generated within the ADCS. ADCS PIs will have priority access to data for secondary publications but will be asked to submit requests to the ADCS DSSC. The ADCS makes a distinction between two types of secondary papers:
    - Papers that involve analysis of drug or instrument efficacy or safety (or reliability and validity for instruments), and
    - Papers that address other issues.

3. Tertiary Publications: Tertiary publications refer to all publications beyond the primary manuscript and to publications arising from ADCS shared data whose authorship is initiated outside of the ADCS, but where the ADCS must be acknowledged for providing the data sets necessary for secondary analyses. The procedure for the development and completion for tertiary publications must begin with a proposal submission to the ADCS DSSC.
    - The ADCS will also facilitate the ability to share pre-randomization and de-identified curated electronic data, software tools, pipelines, and workflows employed to generate the derived data, including annotated descriptions and data dictionaries, and other valuable resources developed by the ADCS, while simultaneously protecting data from unauthorized access.
    - Public data sharing follows two timelines: one for pre-randomized data subjected to first-pass quality controls procedures (initial QC), and a second for derived and/or inspected data (curated) as outlined in the NDA Data Sharing Schedule.

Pharmaceutical companies and other sponsors may not have access to data from ADCS NIH trials until they have been published, with the exception of safety data that are the responsibility of a particular sponsor or blinded pre-randomization data (baseline, pre-treatment). Serious Adverse Event (SAE) data are made available under the guidelines of existing FDA requirements. Such data should not, however, be submitted for peer-reviewed publications without the express written consent of the ADCS.

- Anonymity of sites must be preserved in data presentation.

On Group Authorship

Authorship of ADCS clinical trial primary reports will include all site PIs. Site PIs whose site enrolls, randomizes, and then conducts the baseline visit on at least one participant meet the minimum qualification to be listed as study co-authors. Each site PI thereby attests to the veracity of the data from their site and to the proper conduct of the trial at their site. Site PIs who delegate the day-to-day operation of the trial to a junior investigator should allow the junior investigator to represent the site on the author list.

The first author will be the study PI, and the senior author will be the ADCS PI. In general, the main study statistician should be either the second or third in the author list. In addition, key members of the ADCS Coordinating Center should be listed as co-authors. The study PI should provide an attestation on the cover page of the manuscript that would presumably appear on the first page of a published article that he/she takes full responsibility for the content of the document and the conduct of the trial. The responsibility of authorship means that the project PI is responsible for circulating a draft of the manuscript to all co-authors with a reasonable turn-around time.

Secondary reports/publications must follow the same procedures as outlined for primary reports.

Publications should list in an appendix all participating site PIs and staff members who made significant contributions to the study. All ADCS protocols should make reference to this Publication Policy as a matter of principle and also to inform non-ADCS sites who participate in ADCS studies about this policy.

Conflict of Interest (COI):

All ADCS PIs provide disclosures (Regular or Special Disclosures) to the Internal Ethics Committee prior to each in-person ADCS Steering Committee meeting.

Description of potential or perceived conflicts of interest are of major concern to the ADCS given the heightened public scrutiny of clinical trials and Alzheimer's research. The ADCS must be sensitive to actual and perceived COIs in its publications. COIs exist for therapeutic agents and also potentially for assessment instruments that could have commercial value.

First authors and co-authors on **primary papers** may have industry relationships unrelated to the clinical trial in question that exceed $5,000 per annum either in the prior year and/or anticipated in the coming 12 months, as long as those industry relationships are fully disclosed in the publication.

The early involvement of the PC in efficacy/safety related secondary papers must be carried out in order to identify and manage any potential COI issues prior to the creation of a set of results or an initial draft manuscript. The **first author** of manuscripts involving **secondary analyses of efficacy or safety** must adhere to ADCS COI guidelines that stipulate a limit of $5,000 for relationships with involved company. The project leader from which the data on a secondary manuscript is based should be a co-author, as should the appropriate members of the ADCS Coordinating Center. If the potential first author has industry relationships that exceed $5,000 annually, a dialogue must occur between the author, the project leader, and the PC. If a

solution cannot be readily devised, the matter should be referred to the IEC for discussion and to the ADCS PI for a recommendation.

Co-authors on **secondary papers that involve safety or efficacy** may have relationships that exceed $5,000 per annum, as long as those relationships are fully disclosed in the publication.

Secondary papers that do not involve presentation of efficacy or safety data on compounds or instruments shall not have any restrictions on authors (first or co-authors) with respect to industry relationships. However, industry relationships of authors and co-authors must be fully disclosed in the publication. In addition, human subjects' issues must be carefully addressed in secondary publications.

COI issues which arise in the course of a major publication will initially be addressed by the PC with the first author or co-authors. In addition, the ADCS PI will also be consulted. If a resolution cannot be reached, the matter will be referred to the IEC for discussion and to the ADCS PI for a recommendation.

Publications Committee Role

The PC will be charged with the administrative review of manuscripts only and will not be tasked with evaluating the scientific merits of analyses or abstracts.

Exceptions: The PC does not intend to review manuscripts for scientific quality and acknowledges that ADCS data may be used to support publications with conflicting results. The PC has the right and authority to address and act accordingly on the following:

1. Failure to Follow Data Use Agreement: If users inadvertently violate the ADCS Data Use Agreement, it is likely that they will self-correct as infractions are discovered. If users willfully violate the Data Use Agreement, the sole sanction available to the ADCS will be to revoke access to ADCS data.
2. Fraudulent Use of Data: As soon as the PC becomes aware of any breach of the Data Use Agreement, immediate steps will be taken to address the breach and sanction those in violation. This may include discontinuing the user's data access and/or reporting the violation. Should the PC discover an attempt to publish data obtained fraudulently, the data users will be sanctioned through NIH communication with them or their academic supervisor(s).
3. Manuscripts of Insufficient Quality: If a review of a proposed manuscript reveals that it is egregiously poor in terms of language, writing, or sensible substance, the PC can recommend that the authors withdraw their submission if significant revisions are not made. Under such circumstances, the PC should refer the matter to the ADCS PI and the study PI. It is within the purview of the ADCS PI and study PI to withhold their approval of the manuscript until the proper revisions were made.

Publication Format

1. Primary Publications/Major publications are defined at the beginning of this document. Publication requirements follow:

    a. Within the context of the ADCS authorship policies outlined above (Section on "On group Authorship"), attribution of authorship should otherwise meet the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship and must be considered in all instances where ADCS data is primary to the manuscript. Arrangements for the proposed group authorship are needed with each journal when it is proposed.
    b. All manuscripts will acknowledge the support of NIA using the NIH grant number: U19 AG010483 for the ADCS (see Data Use Agreement) and funding by the ADCS in the support

acknowledgement section of the manuscript using language similar to the following: “Data collection and sharing for this project was funded by the Alzheimer's Disease Cooperative Study (ADCS) (National Institutes of Health Grant U19 AG010483).”

c. Manuscripts will be submitted to the PC for administrative review 30 days prior to submission, and the author will apprise the ADCS of acceptance or rejection. If accepted, the author will provide the full manuscript citation.
d. A copy of the manuscript will be provided to the ADCS upon publication of the manuscript. If permitted by the journal, a version of the article or link to the article will be uploaded onto the ADCS website.
e. Open Access policies for all ADCS publications with NIA funding must be followed.

2. Authors/investigators using ADCS data in <u>secondary or tertiary publications</u> are required to agree to the Data Use Agreement as well as the ADCS Publications Policy as outlined below:
    a. In order for the ADCS to track manuscripts which have utilized its data, for secondary or tertiary publications, it is preferable that the ADCS be appropriately named either as an author, by acknowledgement, or by key word.
        1. Appropriate wording can be considered such as: “Data used in the preparation of this manuscript/publication/article were obtained from the Alzheimer’s Disease Cooperative Study legacy database.”

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