WWARN Policy on Data Use and Publication

Updated 16 April 2019

WWARN respects the right of researchers and institutions who collaborate and share data with WWARN. This document, which explains our Policy on Data Use and Publication, should be read in conjunction with the WWARN Terms of Submission.

If you have a query, please email the WWARN team at info@wwarn.org.

1.   Principle

1.1   WWARN supports researchers to meet the data access requirements of funders and journals. WWARN is an RE3Data registered repository. WWARN has developed an ethical and legal framework to protect the rights of the data owners and contributors to the WWARN Data Repository and of the research participants and their communities. The measures WWARN takes to secure shared data; how we ensure that the contributor retains, or delegates to the Data Access Committee, control and use of submitted data; and how WWARN use that data are all set out in the WWARN Terms of Submission. Every WWARN data contributor is required to accept these Terms of Submission before sharing their data with WWARN.

2.   Contributors' rights to publish data contributed to WWARN

2.1   Data Contributors are defined as the institutions and their authorised representatives (usually the corresponding author or principal investigator of the original study) who are responsible for submitting anonymised data, including individual patient data and meta-data, to the WWARN Data Repository.

2.2   Data Contributors retain the right to publish data that they have contributed to WWARN. Such data may be published without any involvement of WWARN. Contributors are asked to acknowledge use of specific WWARN analysis tools in any publication, for example the Parasite Clearance Estimator, using the form of words shown in Appendix 1a.

3.   WWARN's right to publish and refer to data contributed to WWARN

WWARN may use data in its Data Repository to produce several types of outputs as described below:

3.1   Data set curation

3.1.1   Data submitted to WWARN may be curated and a standardised data set generated using the WWARN data management and statistical analysis plan. The original data files, an audit trail of any changes made during curation and transformation, and the resultant data set are all available to the contributor and any individuals nominated by the contributor. These data sets may be analysed using the WWARN toolkit; WWARN should be acknowledged if any outputs are reproduced in a publication, using the form of words as shown in Appendix1b.

3.2   Study Summaries (WWARN data visualization tools)

3.2.1   The Study Summary provides a limited overview of the data and thus this will not influence the ability of a Contributor to publish the data elsewhere [1], since the results shown are similar to those usually published in a congress abstract. Please note: Detailed re-analyses of individual studies will not be published. Further details of the Study Summaries can be seen in Appendix 2.

3.2.2   Any relevant summary data suitable for presentation on interactive visualisation tools such as the WWARN Explorer or WWARN Surveyors will be incorporated. A Contributor has the right to decline permission for the Study Summary to be presented on the WWARN data visualization tools.

3.3   Data Inventory

Studies shared with WWARN will be listed in the WWARN inventory, which includes the study title and, if available, the associated publication PubMedID or other database identifiers (e.g. web of science). The data access option that the contributor has agreed to, i.e. DAC controlled or contributor controlled, will also be indicated in the inventory.

3.4   WWARN Study Group Individual Participant Data Meta-analyses

3.4.1   WWARN facilitates the formation of Study Groups to conduct specialised individual patient data (IPD) meta-analyses, for example, in relation to a particular drug, patient group or time span. Study Groups can be led by any individual with an interest in the field. This individual can consult the WWARN Data Inventory to identify datasets potentially eligible for inclusion in their Study Group IPD meta-analysis.

3.5.2   Contributors whose data are *Contributor Controlled* and are eligible for inclusion, will be contacted directly and provided with information about the intended IPD meta-analysis and invited to participate. If Contributors agree to be part of the Study Group, their data will be included in the pooled analysis, if eligible. Contributors who do not wish to have their data

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[1] Congress presentations or certain peer-reviewed publications may, rarely, require that results have never been in the public domain previously.

included in such an IPD meta-analysis should follow the refusal instructions provided in the contact email.

3.5.3 For studies that are Data Access Committee (DAC) Controlled, an application should be made to the independent Data Access Committee. Those requesting data will be required to list the datasets requested, how the data will be used, and how the original contributors will be credited. If the application for data is approved by the DAC, data will be released to the requestor under an agreement which secures the terms of use. Contributors of DAC-controlled data will also be given the opportunity to participate in any study group that includes their data.

3.5.4 All contributors whose data are included in the Study Group analysis will have the opportunity to participate in the IPD meta-analysis, including contributing to the development of the statistical analysis plan, and writing and/or editing any resulting manuscript/s. A decision on the total number of authors who will be included on the resulting manuscript will be made by the Study Group at the outset of the collaboration. Typically, the Data Contributor of each dataset utilised will nominate two individuals to contribute to the study group, although the inclusion of additional individuals may be justified in large, complex, multi-centre studies. Those who fulfil the International Committee of Medical Journal Editors guidelines for authorship will be listed as authors on any publication that results from the study (see Appendix 3.1). All Data Contributors and individuals they nominate who do not meet the ICMJE criteria or do not wish to actively participate in the study group will be acknowledged in the resulting manuscript (see 3.5.6).

3.5.5 Details of publication authorship will be decided by the Study Group, as is expected in any publication with multiple authors. Depending on the nature and size of the study group, the group may decide on the most appropriate authorship model. Typically, this would be named as the WWARN XX IPD meta-analysis study group, with or without a named writing committee (see Appendix 3.2).

3.5.6 Contributors whose data are used in an IPD meta-analysis, but who do not participate actively in the study design, analysis or manuscript preparation will be acknowledged as Study Group Collaborators in the publication byline, as described in the US National Library of Medicine MEDLINE® authorship fact sheet. Study Group collaborators may cite any such publication in their CV and their name is indexed in Medline for the corresponding publication (see Appendix 4). Those who do not wish to be listed as Study Group collaborators may be acknowledged with or without their affiliation, or not acknowledged as preferred.

Appendices

1   Acknowledgements

   a.   *The statistical models used to estimate the parasite clearance measures and lag phase duration were fitted using the Parasite Clearance Estimator developed by the WorldWide Antimalarial Resistance Network (WWARN).*

   b.   *The data presented in X was analysed using tools developed by the WorldWide Antimalarial Resistance Network.*

2   Summary Data

2.1   Summary data normally includes details of the submitted study including: country, year, total patients enrolled and number of sample assays. High level calculations are also presented such as IC50 values or treatment success. Examples of displays shown in the graphs include:

   a.   Clinical data: Based on survival analysis to show the day 28 or 42 efficacy for that study.

   b.   Molecular data: Proportions of samples detected to carry mutations of interest along with the date, location of sample collection and names of investigators.

   c.   Pharmacology data: Scatter plot of drug concentrations over time or as a median (range) concentration on day 7, by treatment response (ACPR vs Treatment Failure).

3   Byline Authorship

3.1   The following are some extracts from the website of the *International Committee of Medical Journal Editors (ICMJE)*:

   a.   All persons designated as authors should qualify for authorship, and all those who qualify should be listed. The ICMJE recommends that authorship be based on the following 4 criteria: 1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND 2) Drafting the work or revising it critically for important intellectual content; AND 3) Final approval of the version to be published; AND 4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

   b.   When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms.

3.2   Some examples of WWARN study group authorships models

Study group: https://www.ncbi.nlm.nih.gov/pubmed/27221542
Study group with writing committee: https://www.ncbi.nlm.nih.gov/pubmed/30038039
Individual: https://www.ncbi.nlm.nih.gov/pubmed/30033231

4   Collaborators

4.1   The following is taken from the US National Library of Medicine MEDLINE® authorship fact sheet and adapted to the WWARN context.

a.   When a group name for a specific consortium, committee, study group, or the like appears in an article byline, the personal names of the members of that group may be published in the article text. This is referring to contributors as defined in 3.5.2 and 3.5.4. Such names are entered as collaborator names for the MEDLINE citation.

b.   Collaborator names are entered for a MEDLINE citation only when a group (corporate) author name is present for the citation. Collaborator names are included redundantly even if they have also been included as authors for the citation (because they also appear in the byline or are explicitly identified in the article as the authors). Collaborator names may also appear redundantly in the MEDLINE citation if they appear redundantly in the published article, such as when the collaborators are listed in the article by various subcommittees and an individual is a member of more than one subcommittee.

c.   If a personal name is entered in a PubMed search without a search tag, for example [au], all citations will be retrieved for which the name is an author or collaborator. A group author name entered without a search tag will retrieve citations with that name as an author occurrence as well as citations with the word(s) in any other field of the citation.

4.2   Further information on Description of the 'collaborator' status in MEDLINE® / PubMed® can be found at https://www.nlm.nih.gov/pubs/techbull/ma08/ma08_collaborators.html