



Terms of Data Access

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A. DEFINITIONS

Access – transfer of Platform Data to an approved Data Requestor.

Application – information submitted for consideration by the Data Access Committee for the purpose of gaining access to Platform Data (see Application Form).

Data Contributor – any individual or organisation who has submitted Data included in the Platform.

Data Requestor – any individual or organisation requesting access to Platform Data.

Data Transfer Agreement (DTA) – an agreement between the Data Requestor and the Platform host institution (University of Oxford) to establish the terms and conditions of Data transfer.

Data Subject (or Subject) – an individual from whom Data have been collected or to whom Data relates.

Data Sharing Platform (the Platform) – a collection of data, managed by a governance and ethical framework to responsibly promote the availability of data for sharing in order to generate new knowledge.

Independent Data Access Committee (DAC) – a group of appointed experts who make decisions regarding applications for access to Platform Data.

Intellectual Property - all intellectual property, patents, trademarks, design registrations, copyrights, specifications, drawings, designs, data, database rights, information, ideas, methods, patterns, know-how and/or inventions including without limitation, testing and validation reports, process parameters and documentation, and regulatory registrations and supporting files, whether patentable or not, arising from or related to or useable in connection with the Platform data.

Inventory – an openly available list of all Data included on the Platform.

Platform Data (or Data) – demographic, health, biometric, genomic or other information on individuals, samples, medicines, communities, conditions or organisations submitted to the Platform.

Publication - any abstracts, reports, external communication, websites, presentations or other peer-reviewed scientific publications that contain outputs directly or indirectly related to the Data.

Research - any medical, biological, laboratory and research activities (including but not limited to scientific research, operational research, epidemiology, clinical research, program research, evaluations, retrospective program analysis etc.) involving the collection of information about a particular subject or research primarily and substantially aimed at understanding or treating any pathogen, disease or condition.

Research Outputs (or Outputs) - any information, data, and/or results generated in or arising from use or analysis of the Data.

Secretariat – the entity responsible for hosting the Platform including responsibility for the technical architecture, data curation, data security, data management and transfer, budget administration, and Platform website development and management. The Secretariat will support the development and execution of Platform proposals, policy and approvals and will support administration for the Data Access Committee.

Terms of Submission - A legal document executed between the data provider and data recipient (in this case the data contributor and Oxford who will hold the data), to agree the terms under which the data are submitted to the platform.

A. OVERVIEW

The WorldWide Antimalarial Resistance Network (WWARN) is a collaborative platform generating innovative resources and reliable evidence to inform the malaria community on the factors affecting the efficacy of antimalarial medicines. WWARN currently contains data on over 450 variables from over 400 malaria clinical trials. WWARN is part of the Infectious Diseases Data Observatory (IDDO), a multi-disease platform for data sharing and research collaboration based at the University of Oxford. Individuals who contribute data to the WWARN repository can decide between two data sharing models - retain decision-making power each and every time an analysis is done or delegate decisions about data access to the WWARN **Data Access Committee (DAC)**.

These Terms of Data Access are specific to datasets where access decisions were devolved to the DAC. Access to the other datasets is *not* regulated by these terms.

The WWARN Data Access Committee reviews, prioritizes and makes decisions regarding the approval of applications for access to platform data. This document describes the Terms of Data Access to WWARN data, and describes the basis on which the DAC will make decisions about applications for data access. This document is developed and amended by the DAC and provides the principles of access, details of eligibility for access, process for applications and decisions, and conditions for use of transferred datasets. This document forms the basis of the Data Transfer Agreement.

B. PRINCIPLES OF ACCESS TO PLATFORM DATA

While there is no internationally accepted policy framework to govern data sharing, WWARN has developed the following principles to guide the DAC's decision regarding access to data. The WWARN DAC will consider for approval applicants that propose to:

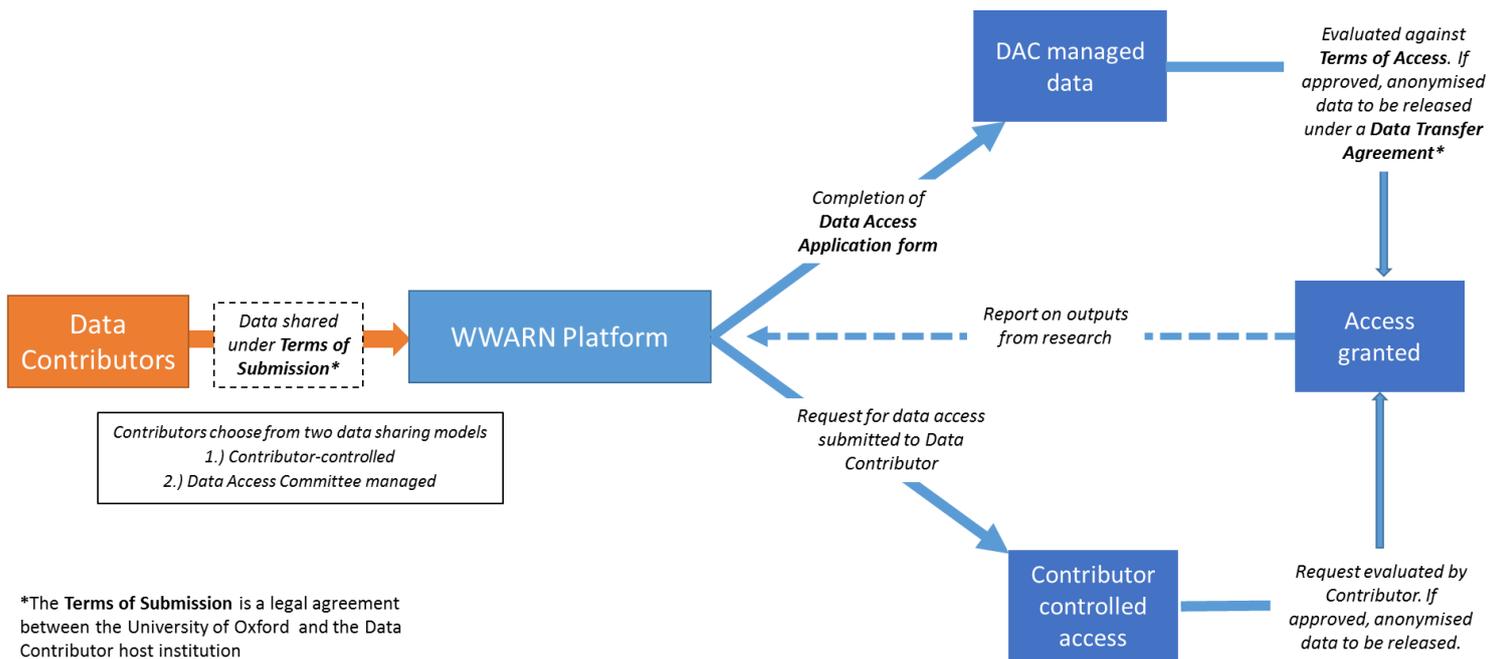
1. Deliver research that addresses knowledge gaps of importance to those affected by or at risk of emerging and poverty-related diseases;
2. Operate in a transparent manner and promote equitable collaboration which recognizes and protects the interests of those who generate the data;
3. Protect the rights and privacy of individuals and communities from whom the data originates;
4. Conduct research which contributes towards improving research capacity, policy and health in regions affected by or at risk of emerging and poverty-related diseases.

C. Process of Accessing WWARN Data

Published and unpublished data are submitted to the WWARN platform by the research, health and humanitarian communities under the Terms of Submission. Via these terms, contributors attest to their authority to submit the data, and their compliance with the necessary ethical and legal requirements. The WWARN Platform anonymises, curates and securely stores data. WWARN will make available on its website an Inventory listing which data is available to researchers. This Inventory will also indicate whether permission for access needs to be granted by the Data Contributor or by the DAC.

Requests for access to original and/or standardised data for studies that have devolved access decisions will be reviewed by an independent Data Access Committee. DAC members are nominated by the malaria research community. The DAC is chaired by TDR, the Special Programme for Research and Training in Tropical Diseases, hosted by the World Health Organization (WHO/TDR). Data will be sent to those approved by the DAC after the execution of a Data Sharing Agreement which outlines the terms of data use (see *Figure 1* below).

Figure 1: Process for data contribution and data access



*The **Terms of Submission** is a legal agreement between the University of Oxford and the Data Contributor host institution
 *The **Data Transfer Agreement** is a legal agreement between the University of Oxford and the Data Requestor host institution.

TERMS OF DATA ACCESS & USE

1. Terms of data access

1.1. Eligibility of the Requestor

Data is accessible to researchers working in a relevant field and who have a formal affiliation to an institution with a remit including health, research or academic pursuit, and with legal status which includes the scope to sign the Data Transfer Agreement. The Data Requestor will attest that sufficient funding and resources to perform the proposed research have been secured for this purpose. The DAC will consider potential impact of any conflicts of interest declared in the application.

1.2. Eligibility of the Research Proposal

Research proposals must be scientifically sound with adequate methodology to answer the question and should address a knowledge gap of value or potential value to malaria endemic communities, and/or to wider public health. The selected Data Subjects, populations and requested Data must be appropriate for the investigation.

1.3. Ethics and other approvals

Whilst secondary data analysis does not always require ethics approval, the DAC will rely on Data Requestors to indicate that they have complied with all and any requirements for ethics and regulatory approvals required in their institutions or jurisdictions.

2. Terms of data use

2.1. Data Transfer Agreement

A Data Transfer Agreement (DTA) with Oxford University must be signed by the appropriate signatory from the Data Requestor's institution before Data are transferred to the Requestor.

The breach of any of the terms outlined in the DTA will result in a withdrawal of approval to access and/or use the Data and may result in recourse via the signatory institution.

2.2. Limitations of use

- 2.2.1. Data transferred to the Data Requestor shall be used solely for carrying out the Research stipulated in the application and described in the DTA;
- 2.2.2. Any change from the initial data access application including to the research objectives, protocol or collaborators, must be approved by the DAC in advance of implementation.

2.3. No onward transfer

- 2.3.1. Data may be accessed only by the individuals listed in the approved Data Access Application and may not be transferred to any other party(ies);
- 2.3.2. Data Requestors are responsible for securing the Data and shall not use or store Data on any system or at any facility outside of its control.

2.4. Protection of Data subjects and communities

- 2.4.1. Data Requestors must agree not to link the Data provided with any other information unless clearly described in the approved Data Access Application.
- 2.4.2. The Data Requestors shall not attempt to identify or contact any Data Subject, their family members or communities that contributed the data.

2.5. Intellectual property

- 2.5.1. The primary purpose of Data made available to requestors is to generate evidence that fills knowledge gaps of importance to those affected by or at risk of emerging and poverty-related diseases. It is not expected that commercial outputs will result from use of Data. Access to Data will be granted on the basis of this assumption.
- 2.5.2. Should a Data Requestor wish to pursue intellectual property claims or rights on any output resulting from use of the Data, the DAC has to be notified and the University of Oxford needs to be contacted to discuss relevant conditions and terms in advance of this pursuit.

2.6. Publication and transparency

- 2.6.1. A summary list of proposals received and the outcome of the review will be listed on the WWARN website.
- 2.6.2. Summary information on all accepted data proposals will be made publicly available through the WWARN website.

- 2.6.3. Data Requestors are expected to submit their Research Outputs to a peer-reviewed publication (or otherwise stated forum) within the timescale of the publication plan detailed in the approved Application.
- 2.6.4. Data users should take care to publish their results in a way that minimises the potential for stigmatisation. In cases where data users are concerned about the potential for stigmatisation for communities or populations, they should contact the data contributor for discussion. The DAC and/or the WWARN Secretariat can assist in this process.
- 2.6.5. Data are shared on the condition that all publications are published under open-access conditions or made otherwise openly available without cost or restriction.
- 2.6.6. All publication datasets generated as a Research Output will be submitted to the WWARN platform and made available through the WWARN data access process.
- 2.6.7. Any Research Output using Platform Data shall include due acknowledgement of each Data Contributor whose data were included in the analysis. Those who do not meet the requirements for authorship according to the [International Committee of Medical Journal Editors \(ICMJE\)](#) will be named as collaborators in the publication by-line, as described in the US National Library of Medicine MEDLINE® [authorship factsheet](#).
- 2.6.8. The Data Requestors will be provided with an inventory of available studies. In order to promote interaction between Data Contributors and Data Requestor, the first will be encouraged to share their contact details with those approved for access. Data Requestors will be provided with a list of the relevant Data Contributors to encourage interaction. Data Requestors are encouraged to contact Data Contributors for input on the analysis plan and manuscript drafts, and/or to explore potential collaboration.

Any Output using Platform Data shall include due acknowledgement of the WorldWide Antimalarial Resistance Network (WWARN) by the inclusion of WWARN in the acknowledgement section of the manuscript using the following statement:

“Data included in this analysis were obtained through the WorldWide Antimalarial Resistance Network (www.wwarn.org).”

- 2.6.9. Any other reference to names, logos, or any adaptation of Platform or Contributor trademarks requires prior authorisation of those entities.
- 2.6.10. Data Requestors should provide the Platform with a copy of all Outputs and Publications based on Platform Data within an acceptable timeframe and not later than one (1) month after the publication or public release of the Output or Publication.
- 2.6.11. The Secretariat and Data Contributors may, at their own discretion and in compliance with any applicable copyright, reproduce the Research Outputs, on their websites or other media with attribution to the Data Requestor(s).
- 2.6.12. If the approved Output of the proposed research has not been achieved within eighteen (18) months after gaining access to the Data, the DAC Secretariat will request a short project update from the Data Requestor.