

Data Sharing Agreement

1. Background

Over 1.45 billion people are infected with soil-transmitted helminths (STHs), including 845 million children, in some of the world's poorest communities. STHs are classified as neglected tropical diseases (NTDs) although the geographic reach is global. STHs reduce the body's ability to absorb nutrients and vitamins. This can exacerbate malnutrition and lead to anaemia, increased susceptibility to other infectious diseases, stunted growth and impaired cognitive development. As with many NTDs, STH is very much a disease of poverty.

To this end, DeWorm3's main goal is to establish the evidence necessary for informing global implementation guidelines in countries aiming to eliminate STH. This will entail a series of community trials to determine the feasibility of interrupting transmission of STH and, if successful, to develop an operational implementation plan to scale up the intervention.

Specific DeWorm3 project objectives include;

- demonstrate the feasibility of eliminating STHs using existing and intensified mass drug administration (MDA) strategies, specifically by leveraging existing lymphatic filariasis elimination platforms
- inform the guidelines, policies, and operational plans needed to successfully achieve STH elimination
- link qualitative and operational studies of the acceptability and feasibility of different strategies to ongoing field trials, guiding future implementation and scale-up plans

Community trials will be rolled out across Africa and Asia, with Benin, Malawi and India intended as first wave countries. These rigorous scientific trials will be undertaken in partnership with respective governments and research institutes, and supported by a committee of global experts. Commencement of the trials is expected in early 2017 where research activities will be integrated into existing STH programmes, implemented by national governments and partners. In addition to these trials, a number of additional activities will be conducted in India, Malawi, Benin, Ethiopia, Japan, Argentina, Kenya and other countries.

The findings of DeWorm3 will feed back to international organizations such as the World Health Organization, and will guide and inspire other global funders (including BMGF, DfID, USAID and CIFF) in informing subsequent funding and resource allocation. Most importantly it will benefit those suffering from the diseases, national governments with STH control programmes and the wider public in giving better understanding of how evidence-based science lies at the heart of global health and well-being.

2. Purpose of Data Sharing

To undertake a process of mathematically determining estimates for the interruption of STH transmission in target countries of Benin, Malawi and India. The provided data will be used to determine the course of Mass Drug Administration, Sample Size and Epidemiological Parameters of STH prevalence and intensity (*A. duodenale*, *N. americanus*, *A. lumbricoides*, *T. trichiura* and *S. mansoni*)

3. Data Owners

The requested DeWorm3 Data, described in section 5, will be provided by the Natural History Museum but remains the property of the domestic institution of the country of origin, whereby [Recipient Partner] agrees to the limited, non-exclusive use by the PI to conduct the research activities described in section 6.

4. Applicant/Recipient

The following party requests access Data Access at its sole risk and at no expense to DeWorm3 or the Owners of the mentioned data

Institution:
Authorized Representative:
Title:
Address:
Email Contact:

Recipients Principle Investigator:
Title:
Address:
Email Contact:

5. Requested Data

[Recipient Partner] requires access to the following data: [Describe]

6. Research Project

The Data described in section will be used by [Recipient Partner] for the following research activities: [Describe]

7. Non-Transferability & Confidentiality

This agreement is not transferable and the data provided is confidential. [Recipient Partner] agrees that substantive changes made to the research project and/or appointment of [Recipient Partner] of another principle investigator to complete it requires written approval by the Natural History Museum or execution of a new agreement in which the changes and/or new principal investigator are designated. [Recipient Partner] agrees to retain strict control over DeWorm3 data, to treat it as confidential with at least as much care as it would treat its own confidential information, but in no case less than a reasonable amount of care, and agrees not to transfer, share, sell or make DeWorm3 Data otherwise available to any other entity or individual without written consent from DeWorm3.

8. Non-Identification

Data provided by the Natural History Museum under this agreement will be stripped of all personal identifiers to the maximum extent possible, but the confined nature of some geographic areas from which the subjects were drawn, and the wealth of data available to them in publicly available records, could in certain instances make the individual identification of some subjects possible. To protect the confidentiality and privacy of these participants and their families, [Recipient Partner] agrees that effort whatsoever to establish the individual identities of any subjects from whom DeWorm3 Data were obtained. Any attempts to do so will be considered a material breach of this agreement, which may subject

[Recipient Partner] to legal action from the Natural History Museum, the domestic institution of the Data's country of origin or surveillance and research participants, their families, or relevant government entities.

9. Recipient's Compliance with IRB Requirements

[Recipient Partner] agrees to comply fully with all conditions imposed by [Recipient Partner], the Natural History Museum and/or the domestic institution of the Data's country of origin IRB and with the subjects' informed consent, as applicable. It is intended that [Recipient Partner] agreements herein shall inure to the benefit of the research subjects, as well as to the parties. [Recipient Partner] agrees to report promptly to DeWorm3 any proposed change in the research project and any unanticipated problems involving risks to subjects or others.

10. Publication

Prompt publication of the results of the research project is encouraged. [Recipient Partner] agrees to provide the Natural History Museum and the domestic institution of the Data's country of origin a copy of any abstract fourteen (14) days in advance of submission for publication and any manuscript or other formal public dissemination thirty (30) days in advance of submission for publication, in order to permit review and comment and to ensure compliance with the confidentiality requirement of this agreement and the limitations it imposes on the use of DeWorm3 Data provided.

11. Authorship

The Principal Investigator of DeWorm3 should be included as an author on all publications unless written exception is provided. If the research project involves a collaboration with other DeWorm3 co-investigators, [Recipient Partner] will include co-investigators as co-authors, as appropriate, on any publication.

12. Acknowledgements

[Recipient Partner] agrees to acknowledge the contribution of the Natural History Museum, the domestic institution of the Data's country of origin, and the Bill and Melinda Gates Foundation in any and all oral and written presentations, disclosures, and publications resulting from [Recipient Partner] analysis of DeWorm3 Data as follows:

"This manuscript is based on data collected and shared by the Natural History Museum and [Domestic Institution], DeWorm3 project with support from the Bill and Melinda Gates Foundation."

In addition, the manuscript or other documents produced will be reviewed by the DeWorm3 co-investigators (if any) or other DeWorm3 personnel, pursuant to section 10, for scientific content and consistency of data interpretation with previous DeWorm3 publications and [Recipient Partner] will use the applicable acknowledgement below.

If [Recipient Partner] agrees to incorporate significant comments from the review, [Recipient Partner] will use the following acknowledgement:

"This manuscript has been reviewed by DeWorm3 for scientific content and consistency of data interpretation with previous DeWorm3 publications and significant comments have been incorporated prior to submission for publication"

If [Recipient Partner] does not agree to incorporate significant comments from the review, [Recipient Partner] will use the following acknowledgement:

“This manuscript was not prepared in collaboration with the investigators of DeWorm3, and does not necessarily reflect the opinions or views of DeWorm3”

13. Non-Endorsement, Indemnification

[Recipient Partner] agrees not to claim, infer, or imply of the Natural History Museum or the domestic institution of the Data's country of origin endorsement of the Research Project, the entity or personnel conducting the Research Project or any resulting commercial product(s), except as described in section 12. To the extent permitted by law, [Recipient Partner] agrees to hold DeWorm3, and all other investigator(s) who generated DeWorm3 Data harmless and to defend and indemnify all such parties of all liabilities, demands, damages, expenses, and losses arising out of [Recipient Partner]'s use for any purpose DeWorm3 Data.

14. Accuracy of Data & Obligation to Notify

[Recipient Partner] agrees that DeWorm3 and other investigator(s) who generated DeWorm3 Data are not responsible for the accuracy of DeWorm3 Data provided. If [Recipient Partner] identifies an apparent error or inconsistency in any DeWorm3 Data received, [Recipient Partner] shall convey it to of the Natural History Museum and the domestic institution of the Data's country of origin, as soon as reasonably possible.

15. Amendments

Amendments to this agreement must be made in writing and be signed by authorised representatives of the Parties.

16. Termination

The Natural History Museum may terminate this agreement and any other such agreement with [Recipient Partner] if [Recipient Partner] is in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice by the Natural History Museum authorised representative of such default. The Natural History Museum reserves the right to terminate this agreement with immediate effect if any problems arise that in its opinion present an unacceptable risk to subjects or others. Upon termination of this agreement, [Recipient Partner] agrees to destroy all copies of DeWorm3 Data in [Recipient Partner]'s possession as soon as possible.

17. Disqualification, Enforcement

Failure to comply with any of the terms specified herein may result in disqualification of [Recipient Partner] from receiving additional DeWorm3 Data. The Natural History Museum and/or the domestic institution of the Data's country shall have the right to institute and prosecute any proceeding at law or in equity against [Recipient Partner] for violating or threatening to violate the confidentiality requirements or use limitations of this agreement, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement may subject [Recipient Partner] to legal action on the part of surveillance and research participants, their families, or relevant government entities.

18. Accurate Representation

[Recipient Partner] expressly certifies that the contents of any statement made or reflected in this document are truthful and accurate.

19. Prior Agreements

Executive and continued validity of this agreement is contingent upon [Recipient Partner]'s compliance with all terms and conditions of any and all other of [Recipient Partner]'s agreements with DeWorm3.

This agreement is entered into as of the last date indicated below by and between:

20. Signatures

EXECUTED by [Neil Greenwood] for and on behalf of)
THE TRUSTEES OF THE NATURAL HISTORY MUSEUM)
)

EXECUTED by [*insert name*] for and on behalf of)
[*insert name of Research Organisation*])
)

