**IDDO Data Access Application Form**

The Data Access Application Form is used to evaluate your proposal and make data access decisions.

**Please email** **dataaccess@iddo.org** **to request the IDDO Data Access Guidelines and the IDDO Data Use Agreement, which you should review before completing this form.** Your completed application form should address all ‘Review Considerations’ outlined in the Data Access Guidelines. Find out more in the ‘Accessing Data’ section of the  [FAQs](https://www.iddo.org/data-reuse/frequently-asked-questions).

Complete all sections of this form fully and return with all supporting documentation requested (such as relevant ethics approvals) todataaccess@iddo.org.

You **must** request in writing any subsequent changes to your Research Team, conflict of interest, changes to data variables or studies (additions and/or deletions), or changes to research objectives or methodology. Please email dataaccess@iddo.org to request any of these changes.

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| **SECTION A: LEAD APPLICANT / RESEARCH TEAM INFORMATION** |
| **Lead Applicant Details** |
| **Title** (Prof, Dr) |  |
| **First name** (given name) |  |
| **Surname** (family name) |  |
| **Position at employing organisation / institution** |  |
| **ORCID ID** [**https://orcid.org/**](https://orcid.org/) **or academic profile web address** | *[if no ORCID or URL, please attach a short academic CV]* |
| **Email** |  |
| **Employing Organisation/Institution** *Institution with a remit including health, research or academic pursuit, and with legal status to sign the* ***Data Use Agreement****.* |
| **Institution Name** |  |
| **Department (if applicable)** |  |
| **City**  |  |
| **Country** |  |
| **Has your institution reviewed and agreed to execute the Data Use Agreement if your application is approved?** | YES/NO(delete as appropriate) |
| **Co-applicants (Research Team)***Please list ALL individuals accessing data, including those at any other location(s) where the data will be accessed, cleaned or analysed. You must notify IDDO in writing of any later additions, and you must not share data with any additional individuals before we have reviewed and approved the additions. Add rows as necessary.* |
| **1. Name / Title**  |  |
| **1. Position / Role in analysis** |  |
| **1.Organisation/Institution** |  |
| **1. Location(s) where the data will be accessed/cleaned/analysed** |  |
| **2. Name / Title**  |  |
| **2. Position / Role in analysis** |  |
| **2. Organisation/Institution** |  |
| **2. Location(s) where the data will be accessed/cleaned/analysed** |  |
| **3. Name / Title**  |  |
| **3. Position / Role in analysis** |  |
| **3. Organisation/Institution** |  |
| **3. Location(s) where the data will be accessed/cleaned/analysed** |  |
| **Conflicts of Interest** *List details of any existing or perceived conflicts of interest (financial or non-financial) relating to how you or your co-applicants might use the data you are requesting (see* [*ICMJE.org for the definition of conflicts of interest*](http://icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html)*).* |
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| **SECTION B: RESEARCH PLAN**  |
| **Title of Proposed Research** |  |
| **Is this a re-submission of a previous application to IDDO that has already been reviewed?**  | *[If yes, provide the submission date of the previous application]* |
| **Summary of Research in Lay Language** *Suggested maximum 200 words* |
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| **Summary of Research Objectives and Scientific Value** *Suggested maximum 400 words**You can demonstrate the scientific value of your work by highlighting how your research objectives:* * *are in line with research areas highlighted by a published global research agenda*
* *address knowledge gaps of importance to those affected by related diseases*
* *benefit the wider public health community and contribute towards improving research capacity, policy and health in disease-affected communities*
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| **Primary and Secondary Outcome Measures** *Suggested maximum 200 words* |
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| **Proposed Methodology and Statistical Analysis Plan** *For each main outcome measure, please describe:** *analysis population*
* *measures of effect to be reported*
* *statistical methods with relevant details such as name of test/regression model*
* *inference method*
* *covariate adjustments*
* *subgroup analyses*
* *adjustment for multiple studies and assessment of heterogeneity*
* *model fit evaluations*
* *sensitivity analyses*
* *sample size/power considerations*
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| **Variables Required for the Analysis***Please list* ***all*** *the essential and desirable variables you require for the study (e.g. baseline parasitaemia, liver function test (ALT, ALP) at baseline and D28, etc.). As part of IDDO’s governance framework, please justify the need of the following variables in case they are required for your study.* * *Ethnicity*
* *Race*
* *Marital Status*
* *Education*
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| **Ethics** *Suggested maximum 300 words.**Provide details of any approvals required by your institution to undertake this work: list reference numbers of any approvals or provide clear evidence as to why no approvals are required (e.g. an extract of relevant the policy from your institutional ethics review board).**Please also give examples of which ethics guidelines you will be following to deliver this project (e.g. general guidance such as the CIOMS/WHO*[*International Ethical Guidelines for Health-related Research Involving Humans*](https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf)*, domain-specific guidance such as the FATML*[*Principles for Accountable Algorithms*](https://www.fatml.org/resources/principles-for-accountable-algorithms)*, or guidance specific to your type of research, such as the Nuffield Council on Bioethics*[*Research in Global Health Emergencies: Ethical Issues*](https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies)*; London, 2020 .* |
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| **Publication and Dissemination Plan** *Suggested maximum 300 words.**Provide a clear* ***timeline*** *for your research, including a date/s when you plan to submit publication/s and disseminate your findings (we will use this submission date to define the* ***Term*** *for data use in the* ***Data Use Agreement****, which lasts for two years).**Provide details of* ***plans for authorship/acknowledgement of data contributors****. Plans to publish and disseminate the research results must enable* ***open access*** *to the results.* |
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| **Collaboration and Knowledge Sharing** *Suggested maximum 300 words.**Provide details how you plan to involve data contributors (see* ***IDDO Data Use Agreement*** *clause 3.5.1). If you are requesting data from low-resource settings, please also include details of collaborative partnerships with these research communities and/or a strategy to share knowledge directly with regional/national health authorities.* |
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| **Funding** *Suggested maximum 100 words.**Provide confirmation that this research is adequately funded/resourced. Name the source or sources of funding.* |
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| **Scientific Review** *Suggested maximum 200 words.**If the project has been scientifically reviewed outside of your research team listed above, please provide details. This review could be by a funder/donor or review committee, or even another expert at your institution.*  *If this has not taken place, detail how your team has sufficient expertise/experience to deliver this work.* |
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| **SECTION C: DATA** |
| **Studies required***Use IDDO study IDs in the online inventory to list the studies you need data from.** Antimicrobial Resistance: <https://www.iddo.org/document/antimicrobial-resistance-data-inventory>
* Chagas Disease: <https://www.iddo.org/document/chagas-disease-data-inventory>
* COVID-19: <https://www.iddo.org/document/covid-19-data-inventory>
* Malaria: <https://www.iddo.org/document/malaria-data-inventory>
* Schistosomiasis / STH: <https://www.iddo.org/document/schistosomiasis-and-soil-transmitted-helminthiases-data-inventory>
* Visceral Leishmaniasis: <https://www.iddo.org/document/visceral-leishmaniasis-data-inventory>
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| **Data categories required***Select the relevant data domains that contain the variables you need to complete your analysis. We will transfer data in SDTM format, which consists of a series of data tables organised by the type of data – login in our online IDDO wiki for more information (*[*https://wiki.iddo.org*](https://wiki.iddo.org) *).* |
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| ***Meta data domains (always included)*** |
| ***TI*** | *Inclusion and exclusion criteria for the trial* | X |
| ***TV*** | *Schedule of planned trial visits* | X |
| ***TS*** | *Trial summary (e.g. name, associated PubMed ID, year)* | X |
| ***Domains commonly used for analysis*** |
| ***DM*** | *Demographics (e.g. age, sex, site, treatment arm)* | ☐ |
| ***DS*** | *Final status of each subject (e.g., Completed, Lost to Follow-up, Died)* | ☐ |
| ***IN*** | *Treatments and interventions: protocol-specified study treatment administrations* | ☐ |
| ***LB*** | *Laboratory data (e.g. haematology, clinical chemistry and urinalysis). This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains* | ☐ |
| ***MB*** | *Detection, identification, quantification, and other characterisations of microorganisms, excluding drug susceptibility testing* | ☐ |
| ***PC*** | *Pharmacokinetic data* | ☐ |
| ***PF*** | *Gene expression and genetic variation data* | ☐ |
| ***RS*** | *Clinical classifications of a subject's status (e.g. Glasgow Coma Scale (GCS) Score and the Paediatric Risk of Mortality (PRISM) Score) and determination of disease response to treatment (like the WHO Treatment Response for Malaria – ACPR, ETF, LTF, etc)* | ☐ |
| ***SA*** | *Signs, Symptoms, Medical History, Adverse Events* | ☐ |
| ***VS*** | *Vital signs (e.g. blood pressure, temperature, respiration, body surface area, body mass index, height and weight)* | ☐ |
| ***Other domains*** |
| ***AU*** | *The Audiometry Test Results (AU) Domain contains information about audiometric tests collected* | ☐ |
| ***CQ*** | *A findings domain that contains data for non-standardised COVID-19 Follow-up Questionnaire instruments*  | ☐ |
| ***DD*** | *A findings domain that contains the diagnosis of the cause of death for a subject.* | ☐ |
| ***ER*** | *Data collected to assess potential exposures to, or risk factors associated with, diseases by way of environmental contact or through participation in activities associated with risk* | ☐ |
| ***HO*** | *Data for inpatient and outpatient healthcare events (e.g. hospitalisation, nursing home stay, rehabilitation facility stay, ambulatory surgery)* | ☐ |
| ***PT*** | *Protocol-specified study treatment administrations, as collected (Exposure as Collected Domain)* | ☐ |
| ***MS*** | *Drug susceptibility testing data. This includes phenotypic testing and genotypic tests that provide results in terms of susceptible or resistant* | ☐ |
| ***MP*** | *Information about liver and spleen size* | ☐ |
| ***PE*** | *Physical examination data* | ☐ |
| ***PO*** | *Pregnancy outcomes* | ☐ |
| ***QS*** | *Questionnaires data* | ☐ |
| ***RP*** | *Physiological and morphological findings related to the male and female reproductive systems* | ☐ |
| ***SC*** |  A domain that contains information about a subject that is not collected in other domains  | ☐ |
| ***SK*** | *Skin findings (specific for PKDL studies)* | ☐ |

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