

Joint Policy on Data Sharing, Intellectual Property and Publications

Revised 'Constitution' Principles (DRAFT)

Defining terms:

Consortium Experiment : A MalariaGEN-funded experiment using data and expertise from multiple investigators. This is agreed by the Project Management Committee and the funders as well as all the investigators taking part in the experiment.

Contributing Investigator : An investigator in MalariaGEN (included in the original grant proposal or invited to join by the Project Management Committee) contributing to a Consortium Experiment by submitting data and/or samples and expertise

Investigator's own analysis : Analysis by an individual investigator that is in some way facilitated by MalariaGEN. This may be through:

- a) Use of genotyping data funded by MalariaGEN
- b) Use of samples or clinical data funded by MalariaGEN
- c) A more tangential relationship, e.g. use of genotyping data already published by the Consortium.

Key principles:

1. 'Sovereignty of physical samples and clinical data contributed to the Consortium Experiments remains with the contributing investigator'

This means:

Physical DNA samples can only be used by the Consortium as follows:

- For Consortium Experiments of MalariaGEN
- *and, in addition only* with the permission of the contributing investigator
- *and in addition only* with national legal and ethical approval in the country of origin and in the country where the experiment takes place

The Contributing Investigator is responsible for ensuring:

- Appropriate informed consent is available for the experiments used
- Appropriate legal and ethical approval is obtained

The location of genotyping / analysis is responsible for:

- The physical safety and integrity of the samples, as well as maintaining security and confidentiality of information on behalf of the contributing investigator

The Contributing Investigator can:

- Recall the physical samples at any stage after the agreed experiments have taken place
- Use the samples for other additional purposes outside MalariaGEN
- Release the samples to the Consortium for an agreed period of time only (particularly if constrained by national guidelines)

2. 'Contributing investigators have immediate access to genotyping data generated on their samples'

3. 'Contributed phenotype data is only available for consortium experiments'

This means:

- When a contributing investigator makes phenotypic data available to the consortium that is only to be used for agreed Consortium Experiments.

4. 'Consortium Experiment results are made public unless they are being considered for IP protection'

This means:

- They will be made available in draft to all investigators contributing data or expertise in the consortium experiment prior to publication
- They will be made available to all MalariaGEN investigators once manuscript is in press
- They will be made publicly available on the website after publication
- The project management committee must investigate whether pursuing IP protection is an important option prior to publication (according to principle 8)

5. 'Investigators' own analyses will not be affected by the publications policy but will be cited on the MalariaGEN web-site after publication'

This means:

- The results of investigator's own analysis will be published according to the wishes of the investigators.

In addition:

- The Consortium will develop an acceptable policy for sharing pre-publication results to build synergy across the consortium and encourage 'peer advice'

However:

- Projects receiving funding from Grand Challenges must observe the terms and conditions of the Framework Agreement document in regard to guidelines for pursuing IP appropriately

6. 'Authorship of Consortium Publications will reflect the genuine contributions of MalariaGEN collaborators in accordance with normal academic practice'

There are two types of consortium publications:

- A. Whole Consortium publications: include the names of all MalariaGEN investigators and the names of their affiliation. The first 'Project Description' paper will be a MalariaGEN 'whole consortium publication'; as will other papers that relate to the workings of the group as a whole. This paper will be circulated prior to publication for review and comment. In

addition, significant contributions will be recognized by naming individuals as authors (and could be external to MalariaGEN).

- B. Consortium Subgroup publications: Results of Consortium Experiments will cite the name and affiliation of each member of MalariaGEN that contributes data or expertise to the publication. Additional names may be appropriate and details of authorship will be decided by a 'writing committee' established for each publication

7. 'The Consortium will wherever possible feed back results of scientific discovery to participating communities'

- Feedback and presentation of research progress and research results to participating communities in Malaria endemic countries is encouraged

8. 'The decision to patent before publishing results is taken by the Project Management committee for Consortium Experiments and by individual investigators for their own analyses'

However:

- All funded projects by the Grand Challenges programme must adhere to the guidelines for pursuing IP in accordance with the Framework Agreement

9. 'All results will be released directly into the public domain via publication and then the web-site unless IP protection is necessary to enhance technology transfer to developing countries'

IP protection should be sought when:

- Discovery is directly relevant to clinical application (diagnostic, drug, or vaccine)
- And: Highly likely to be immediately licensed out
- And: Shown to require IP protection as a stimulus for further development

10. 'In the unlikely event of royalties flowing from IP licenses, mechanisms will be sought to ensure that they flow to the appropriate participating communities, and not to investigators'

11. 'Patents will be licensed to non-profit organisations – except where a for-profit company is able to dedicate significantly more resources, however in this case steps will be taken to ensure global access is achieved'