Disease resolution mechanisms and interrelation with dysmetabolism in severe malaria

A Data Management Plan created using DMPonline.be

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Project abstract:

Malaria is a worldwide health problem with a high disease burden. More than 200 million clinical cases and 600000 deaths occur each year. Most of the lethality is due to malaria complications, such as cerebral malaria and malaria-associated acute respiratory distress syndrome. Metabolic disturbances are also highly associated with mortality. Current antimalarial treatment is based on highly efficient artemisinin combination therapies which have an extremely fast action. Despite the rapid killing of most of the malaria parasites in the body, many patients do not recover from the complications and die. This suggests that in those cases, the disease resolution process is failing. In this project, we will first apply high-end technologies to investigate the mechanisms of disease resolution in relation to the dysmetabolism in a mouse model of malaria. Furthermore, we will also use these high-end technologies in a clinical study with severe malaria patients. By obtaining better mechanistic insights into the disease resolution mechanisms, this project will reveal new possibilities for improved treatment of severe malaria.

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Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

Mouse data: parasitemia, clinical scoring, weights and a variety of analyses on fluid and tissue samples. Transcriptomics and metabolomics (LC-MS data) from core facilities. Patient data: enrollment+informed consent forms, clinical+analytic data (including metabolomics and transcriptomics). Manuscript files. All data are kept in lab books (on paper or electronically, e.g. in excel sheets, including statistical analysis (GraphPad,Prism)). Files from specialized equipment (e.g. flow cytometry, plate readers, Western blot and RNA-Seq) are also kept. Most samples are stored in -80°C. Patient PBMC samples are stored in liquid N2. Histology blocks are kept at room temperature.

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

Prof. P. Van den Steen
Storage capacity/repository
- Electronic files are kept on our central server, with regular (> daily) backup and safe storage at different sites (Gasthuisberg and Heverlee). Backups are also made on portable drives, which are disconnected from the web. We keep all files for at least 15 years. A well-organized file system for easy searching and tracing is present.
- Samples: -80° freezers and liquid nitrogen storage are present, with capacity to keep samples for 10 years. Freezer-Pro software is used for proper organisation. Histology blocks are kept for 10 years in our local repository.
- A closet in a locked office is used for storage of forms and data on paper.

What’s the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

No deviation.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

Patient informed consent and enrollment forms will be encoded and kept locally in a locked office by Prof. L. Ayong in Yaoundé, Cameroon. Researchers from KU Leuven or Glasgow University will never have access to the names of the patients, only Prof. Ayong will be able to de-code the forms and link the data to the patients (only in exceptional circumstances, e.g. in case of patients who decide to withdraw from the study after having given informed consent and after sample collection). Encoded forms will be provided to the involved KU Leuven researchers in electronic format and stored in a dedicated database in a password-protected folder in our central and fully protected KU Leuven server.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

No other issues.

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FWO DMP (Flemish Standard DMP)

1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .cvs,.pdf, .txt, .rtf, .dwg, .gml, ... • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
data files mouse experiments	Xls files containing the data from the described mouse experiments, and corresponding graphpad files for statistical analysis	Generate new data	Digital	Experimental	.xml and .pzfx and others	100 Gb	
Flow cytometry data	Flow cytometry data	Generate new data	Digital	Experimental	other	100 Gb	
scRNA-Seq	datafiles single cell RNA sequencing	Generate new data	Digital	Experimental	other	1000 Gb	
Instrument data files	Datafiles from specific instruments, e.g. imaging, plate readers	Generate new data	Digital	Experimental	other	100 Gb	

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

NA

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data
- Yes, animal data

Mouse experiments: ethical approval is obtained from the animal ethics committee (ECD) from KU Leuven. P049/2018, P052/2020, P084/2020, P087/2020, P159/2020, P018/2021.
Clinical study in Cameroon with malaria patients: we are in the process of applying for ethical approval from Ethics Committee Research UZ/KU Leuven (EC Research) and to the Comité National d'Ethique de la Recherche pour la Santé Humaine, from Cameroon.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

Patient data in Cameroon (name and clinical data) will be pseudonimized. The codes will be kept by Prof. Lawrence Ayong (head of the malarialogy unit in Centre Pasteur du Cameroun) in a closed locker.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- Yes

A contract has been established with the Centre Pasteur du Cameroon regarding the clinical data collection.
This includes co-ownership of shared data results. No other major restrictions.

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- Yes

A contract has been established with the Centre Pasteur du Cameroon regarding the clinical data collection.
This includes co-ownership of shared data results. No other major restrictions.

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

A datafile system is in place, in which the data of specific experiments are brought together in Excell files. These files contain a tab with a clear explanation on the purpose of the experiment, the different groups, treatments, sample number etc. The subsequent tabs contain data and graphs. Further processing of the data occurs in other specific software programs, e.g. Prism Graphpad. The datafiles relating to a specific experiment named with the date of the start of the experiment + type of experiment. These datafiles are logically ordered and fully searchable in our lab data system on the KU Leuven drives.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- No

A datafile system is in place, in which the data of specific experiments are brought together in Excell files. These files contain a tab with a clear explanation on the purpose of the experiment, the different groups, treatments, sample number etc. The subsequent tabs contain data and graphs. Further processing of the data occurs in other specific software programs, e.g. Prism Graphpad. The datafiles relating to a specific experiment named with the date of the start of the experiment + type of experiment. These datafiles are logically ordered and fully searchable in our lab data system on the KU Leuven drives.

3. Data storage & back-up during the research project

Where will the data be stored?

Storage capacity/repository
- Electronic files are kept on our central server, with regular (> daily) backup and safe storage at different sites (Gasthuisberg and Heverlee). Backups are also made on portable drives, which are disconnected from the web. We keep all files for at least 15 years. A well-organized file system for easy searching and tracing is present.
- Samples: -80° freezers and liquid nitrogen storage are present, with capacity to keep samples for 10 years. Freezer-Pro software is used for proper organisation. Histology blocks are kept for 10 years in our local repository.
- A closet in a locked office is used for storage of forms and data on paper

How will the data be backed up?

Electronic files are kept on our central server, with regular (> daily) backup and safe storage at different sites (Gasthuisberg and Heverlee). Backups are also made on portable drives, which are disconnected from the web.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

Highly secured central KU Leuven drives (shared drives, archive drives and large volume storage drives).
Additional Gigabytes or Terabytes can be obtained from the central KU Leuven ICTS services.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All research data generated during this project will be secured by the need for login, registration on datacenter/luna and use of u-number and password, which are also restricted. In case of potential IP establishment for one or more molecules developed in the project, the restriction will consist of omission of the molecule sequence and codenaming.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

Long-term data storage and costs will be managed by the principal investigator working in the project, Philippe Van den Steen. The cost for data storage is 520 Euro/terabyte/year, thus, the accumulated cost for 4 years is approximately 4160 euro. The costs will be covered by previous and current funding obtained by the host lab.

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

Yes, we will retain the mouse data for at least 10 years according to KU Leuven RDM policy, and clinical study data for 25 years according to CTC recommendations.

Where will these data be archived (stored and curated for the long-term)?

Data will be stored on the data server system of the KU Leuven (shared network J-drive for data that are in use, and archive drive K for older data).

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

Long-term data storage and costs will be managed by the principal investigator working in the project, Philippe Van den Steen. The cost for data storage is 520 Euro/terabyte/year. The costs will be covered by previous and current funding obtained by the host lab.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in a restricted access repository (after approval, institutional access only, ...)

All the data that are not under IP protection.

If access is restricted, please specify who will be able to access the data and under what conditions.

Access to external users will be evaluated and authorized by Philippe Van den Steen.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- Yes, Intellectual Property Rights
- Yes, Ethical aspects

Any datasets connected to IP, and any data containing personal information (clinical datasets).

Where will the data be made available? If already known, please provide a repository per dataset or data type.

KU Leuven RDR

When will the data be made available?

Upon publication of research results.

Which data usage licenses are you going to provide? If none, please explain why.

CC-BY 4.0 (data)
Data Transfer Agreement (restricted data)

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

A PID will be added upon deposit in a data repository. The data files may also be identified with DOI numbers.

What are the expected costs for data sharing? How will these costs be covered?

Local costs are minimal. Data transfer to external partners will be at the partners cost.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

PhD and postdoc researchers that will be working on this project will generate the data and are responsible for documentation, metadata, storage and backup, whereas the supervisor of the project has the end responsibility and manages long term preservation and sharing.

Who will manage data storage and backup during the research project?

The PhD and postdoc researchers that will be working on this project together with Philippe Van den Steen, PI of this project.

Who will manage data preservation and sharing?

Philippe Van den Steen

Who will update and implement this DMP?

The PhD and postdoc researchers that will be working on this project together with Philippe Van den Steen, PI of this project.