
Towards strategies for the treatment and prevention of Henipavirus infections

A Data Management Plan created using DMPonline.be

Creator: Laura Vandemaele

Affiliation: KU Leuven (KUL)

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Principal Investigator: Laura Vandemaele

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Project abstract:

Henipaviruses, containing the WHO high-priority Nipah and Hendra viruses, pose an enormous threat to public health. Henipaviruses have been isolated from Pteropus fruit bats across Oceania, Asia, and Africa. Due to climate change and other factors, these areas will likely expand and enhance spillover events. Despite the high risk of a future henipavirus pandemic and the high case-mortality rate, no treatment is available for human use, indicating the urgent need for research and development. One major hurdle in henipavirus research and drug discovery is the requirement for a BSL-4 facility. As such, the discovery of a nonpathogenic henipavirus, Cedar virus (CedV), presents an opportunity to conduct henipavirus research in a non-BSL-4 facility. This project aims to establish a proficient and validated drug discovery and development pipeline for henipaviruses through a multi-disciplinary approach. To this end, we will develop in vitro and in vivo models, using CedV, which will promote the identification of small-molecule inhibitors of henipavirus replication. Moreover, these inhibitors will be used as tool compounds to identify druggable targets in the replication machinery of CedV, and contribute to the understanding of henipavirus replication. The outcomes of this PhD project will greatly contribute to henipavirus research and pave the way for the first antiviral drugs to treat and/or prevent henipaviral infection in humans, thereby increasing global pandemic preparedness.

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DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

- Not applicable

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Not applicable

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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)

During this project I will be generating new data.

I will not be working with personal data.

The type of data that I will be collecting is experimental and some are included in the list below:

- Antiviral compound screening experiments will produce excel files (.xlsx) with numerical data (1-100 MB)
- Virus titration will produce excel files (.xlsx) with numerical data (1-100 MB)
- RT-qPCR will produce numerical data with Roche LightCycler 96 with numerical data (1-100 MB)
- Protocols will be written in excel files (.xlsx; <100 MB)
- Experiment measurements and observations will be collected in excel files (.xlsx; <100 MB)
- Biological samples resulting from cells, viruses, animal tissues,... will be collected (physical; <6000 samples).
- Genetic sequences will be digitally generated (.fastq, <100 MB)
- Analysis of results from sequencing and the calculations will be stored in excel files (.xls; <100 MB)
- Graphs of experimental data will be generated in Graphpad software (.tiff; <1 GB)
- Manuscripts for publication of results will be written in word documents (.pdf; <100 MB)
- Western blot images will be generated with Image Lab (.mscn; <1 GB)
- High content images of antiviral screenings will be generated with the high content imagers (.tiff; <1 GB) and exported as excel files (.xlsx; <1 GB)

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)

1. All complete protocols containing data, or other data files, will be stored. Myself (Laura Vandemaele) and my supervisor Professor Johan Neyts has access to our OneDrive folders and will keep them for as long as necessary, and for a minimum of 5 years. Laura Vandemaele and Johan Neyts are the responsible people for data preservation and can be contacted by the FWO with questions of long-term preservation of the data. After finishing the PhD project, the folders are archived on our shared driver. They will stay there for a minimum of 10 years.
2. For storage of all our data we use cloud software (OneDrive, using a KULeuven license) for short to midterm storage and to share files with team members and collaborators. Our Onedrive has automatic back-up procedures to ensure that my data is not lost. For long term storage/archive we use a shared drive with automatic back-up procedures, maintained by the ICTS managers of the Rega institute. As far as storage capacity is concerned Onedrive has a 2 terabyte storage capacity which is more than enough for the data sets that I am storing as most files are between 1-100 MB. All my data will also be backed up to the shared drive which also contains back-up procedures (managed by ICTS) and has a very high storage capacity if necessary. Finally our Onedrive has a strong security policy for data storage with a multifactor authentication system ensuring the safety of our data. The shared drive is also very well secured by the ICTS managers of the Rega Institute. Myself (Laura Vandemaele) as well as my supervisor Professor Johan Neyts have access to this data.

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)

At this point, I have no reason to deviate from the principle of preservation of data and of the minimum preservation term of 5 years.

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)

All experimental animal work is/will be approved by the relevant ethical committees.

For the mouse and hamster experiments, we already obtained approved by the Ethical Committee for Animal Experimentation (KU/UZ Leuven) (mice: P104/2023, hamsters: P153/2023).

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

I have no other issues related to the data management that are relevant to mention.

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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
		<i>Please choose from the following options:</i> <ul style="list-style-type: none"> • Generate new data • Reuse existing data 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> • Digital • Physical 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> • .por, .xml, .tab, .csv, .pdf, .txt, .rtf, .dwg, .gml, ... • NA 	<i>Please choose from the following options:</i> <ul style="list-style-type: none"> • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA 	
Protocols	Written protocols	New data	Digital	Other: descriptive	.docx .pdf	<100 MB	NA
Experiment measurements and observations	Measurements and observations (survival of mice/hamsters, body weight,...)	New data	Digital	Experimental	.xls	<100 MB	NA
Biological samples	All biological samples resulting from experiments (cells, viruses, animal tissues, RNA,...)	New data	Physical	NA	NA		<5000 samples
qPCR raw data	Files resulting from Roche LightCycler 96	New data	Digital	Experimental	.lc96p	<100 MB	NA
qPCR results	Excel files exported from Roche LightCycler 96 analysis software with calculations of viral RNA levels	New data	Digital	Compiled	.xls	<100 MB	NA

Sequencing raw data	Genetic sequences	New data	Digital	Experimental	.fastq	<100 MB	NA
Sequencing results	Analysis of results from sequencing + calculations	New data	Digital	Compiled	.xls	<100 MB	NA
Graphs	Graphpad software files with graphs resulting from analysis of data	New data	Digital	Software	.pzfx	<100 MB	NA
Graph images	Exported images from graphs made in Graphpad software	New data	Digital	Compiled	.tiff	<1 GB	NA
Manuscripts	Manuscripts for publication of results	New data	Digital	Compiled	.pdf	<100 MB	NA
Antiviral compound screening experiments	Results from antiviral compound screening with HCI	New data	Digital	Experimental	.xlsx	<1 GB	NA
Virus titration experiments	Results from virus titration experiments with HCI	New data	Digital	Experimental	.xlsx	<100 MB	NA
Western blot experiments	Images generated with Image Lab	New data	Digital	Software	.mscn	<1 GB	NA
High content images	Images generated with high content imagers	New data	Digital	Experimental	.tiff	<1 GB	NA

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:

I will reuse data of protein and gene sequences from databanks such as ncbi and uniprot.

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, animal data

All experimental work is/will be approved by the relevant ethical committees.

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.

- No

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.

- Yes

Yes, the project may lead to a novel compound development, for which IP rights may be acquired in the future.

Moreover, the established assays, animal models, and know-how will significantly contribute to Henipavirus research globally. Valorisation may be possible in

collaboration with major organisations (such as the BMGF, the Wellcome Trust, NIH, that all have provided substantial funding to our laboratory), by licensing to pharmaceutical companies or by setting up a spin-off (Johan Neyts is co-founder of former Okapi Sciences and more recently of AstriVax (www.astrivax.com) in which also PMV (Participatiemaatschappij Vlaanderen) invested.

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.

- No

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

IPR issues will, as has been the case in the past, diligently monitored and managed by the KU Leuven LRD (the TTO). At this moment, we did not identify legal issues.

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).

Daily labwork (protocols, calculations, results,...) will be documented in an online OneNote labbook which is continuously being backed up by KU Leuven servers. Additionally, original files with raw data and files with analysed data will be labelled and stored on servers controlled and backed up by the KU Leuven IT department.

The results of the experiment are also saved in our Onedrive server for data safety, for easy comparison between experiments and so our team members and collaborators can easily access the information.

For each experiment a protocol is prepared in excel containing:

1. An introduction section with background information about the experiment.
2. An experimental section explaining clearly every step of the experimental process and noting any variation in the conditions of the experiment at any point, as well as dates, incubation times, cell densities and any other detail necessary for experimental reproducibility
3. A results sheet depicting all the results of the experiment in detail
4. Finally a conclusion sheet which mentions a summary and explanation of the results as well any troubleshooting steps needed to further optimise the assay.

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.

- Yes

For microscopy imaging experiments: the Leica LASX software generates metadata files for all images, which will be stored together with the image.

All generated data/files will have a standard naming: i.e. date_name researcher_type of experiment. Structural metadata will for example

describe relations between different datasets and describe other characteristics of the experimental data. Administrative/descriptive metadata will provide information on for example when results were generated, when constructs were created, by whom and other technical information. Statistical metadata will describe processes that will be used to collect, process, or produce statistical data.

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

Where will the data be stored?

All data will be stored on drives controlled and backed up by KU Leuven. Data with small volumes will be stored on the J drive, in a subfolder that can only be accessed by personnel of the Neyts lab. Data with large volumes (microscopy images) will be stored on the L drive of our team. For long term storage/archive: we use a shared K-drive with automatic back-up procedures of KU Leuven, maintained by the ICTS managers of the Rega institute.

Biological samples from experiments will be stored in freezers and registered in <https://freezerpro.rega>

How will the data be backed up?

The data will be stored on KU Leuven central servers (J/K/L drives). A back-up of the data on these drives will automatically be generated two times per day. Additionally, data will be mirrored and stored on a cloud-based service offered by KU Leuven (OneDrive), which is synced every 10 minutes.

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

All data with small volumes will be stored on the J drive controlled by KU Leuven. There is sufficient storage space foreseen (1.4 Tb) and this is constantly monitored by KU Leuven IT services. Data with larger volumes will be stored on a specifically allocated L drive of KU Leuven on which sufficient storage space is foreseen (10 TB) and which is also constantly monitored by KU Leuven IT services. The separate K-drive of KU Leuven will be used for long term storage of files and data from finished projects (200 GB). If needed, capacity of these KU Leuven drives can be increased at any time

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

All data will be stored on a KU Leuven backed up server, for which access is only granted to the Neyts lab members. This access is controlled by the head of our research group (Johan Neyts).

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

The costs of a KU Leuven server storage are: 415.2 euros/year for the J drive (1.4 TB), 1138.4 euros/year for the L drive (10 TB) and 22.768 euros/year for the K drive. The costs for data storage and backups are concerning the whole research group and are not specific for this project. Hence, the costs will be divided over all funding available by our group including the bench fee available by this project.

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...).

All generated data of this project will be stored in a folder on the network drive specifically designated for long term storage (K drive), which

is controlled and backed up by KU Leuven. Data will be retained for at least 10 years, conform the KU Leuven RDM policy.

Biological samples (RNA, tissues,...) will be stored in freezers (-80°C) until publication of the results. Relevant samples (virus stocks, cell lines) which can be reused in other projects will be preserved in freezers as long as possible.

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

All generated data of this project will be stored in a designated folder on the network drive specifically designated for long-term storage (K drive) backed up and secured by the KU Leuven. We do not wish or plan to deviate from the plan to store this data for a minimum of 10 years.

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

The costs of a KU Leuven server storage are: 415.2 euros/year for the J drive (1.4 TB), 1138.4 euros/year for the L drive (10 TB) and 22.768 euros/year for the K drive. The costs for data storage and backups are concerning the whole research group and are not specific for this project. Hence, the costs will be divided over all funding available by our group including the bench fee available by this project.

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.

- Other, please specify:

Yes all generated data will be used in published articles and in my PhD thesis. Upon publication, relevant raw data and experimental details will be made available in the KU Leuven data repository. Additionally, data might be made available upon reasonable request by mail.

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

Access may be restricted for some unpublished data such as the structure of compounds that have not yet been published. Access may be restricted to anyone who hasn't signed a non disclosure agreement. Data will be available on the KU Leuven research data repository (after publication) or by mail on individual basis to potential collaborators or interested researchers upon reasonable request, which will be assessed by the head of our research group Prof. Neyts

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

Access may be restricted for some unpublished data such as the structure of compounds that have not yet been published. Access may be restricted to anyone who hasn't signed a non disclosure agreement.

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

Data will be made available via the RDR, the KU Leuven institutional repository or by mail upon request.

When will the data be made available?

At the time of publication in a journal, or at the time of a conference, or at the end of the research project.

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

The use of specific data usage licenses is not yet known.

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 DOI will be available through RDR, but is not yet available.

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

Costs will be controlled by the research group and divided over all available funding and discussed with collaborators.

6. Responsibilities

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

The grant holder, Laura Vandemaele, this under the supervision of Prof. Johan Neyts

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

The grant holder, Laura Vandemaele, will be responsible for data collection, correct documentation and storage onto the KU Leuven servers, this under the supervision of Prof. Johan Neyts. The KU Leuven IT department will be responsible for maintenance and back up of the servers.

Who will manage data preservation and sharing?

Laura Vandemaele, Professor Johan Neyts and the ICTS managers of the Rega Institute

Who will update and implement this DMP?

Professor Johan Neyts bears the end responsibility of updating and implementing this DMP.