FWO DMP Template - Flemish Standard Data Management Plan

Version KU Leuven

Project supervisors (from application round 2018 onwards) and fellows (from application round 2020 onwards) will, upon being awarded their project or fellowship, be invited to develop their answers to the data management related questions into a DMP. The FWO expects a **completed DMP no later than 6 months after the official start date** of the project or fellowship. The DMP should not be submitted to FWO but to the research co-ordination office of the host institute; FWO may request the DMP in a random check.

At the end of the project, the **final version of the DMP** has to be added to the final report of the project; this should be submitted to FWO by the supervisor-spokesperson through FWO's e-portal. This DMP may of course have been updated since its first version. The DMP is an element in the final evaluation of the project by the relevant expert panel. Both the DMP submitted within the first 6 months after the start date and the final DMP may use this template.

The DMP template used by the Research Foundation Flanders (FWO) corresponds with the Flemish Standard Data Management Plan. This Flemish Standard DMP was developed by the Flemish Research Data Network (FRDN) Task Force DMP which comprises representatives of all Flemish funders and research institutions. This is a standardized DMP template based on the previous FWO template that contains the core requirements for data management planning. To increase understanding and facilitate completion of the DMP, a standardized **glossary** of definitions and abbreviations is available via the following link.

1. General Project Information	
Name Grant Holder & ORCID	Elias Broeckhoven https://orcid.org/0000-0002-9758-684X
Contributor name(s) (+ ORCID) & roles	Kai Dallmeier (https://orcid.org/0000-0002-8117-9166), promotor Rik Gijsbers (https://orcid.org/0000-0003-0191-3904), co-promotor
Project number [1] & title	HepaHamster – Development and Characterization of a Novel Small Animal Model for the Study of Hepatitis B and D Virus
Funder(s) GrantID [2]	1S00525N
Affiliation(s)	X KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: ROR identifier KU Leuven: 05f950310

[1] "Project number" refers to the institutional project number. This question is optional. Applicants can only provide one project number.

[2] Funder(s) GrantID refers to the number of the DMP at the funder(s), here one can specify multiple GrantIDs if multiple funding sources were used.

Please provide a short project description	Chronic hepatitis B (HBV) and hepatitis delta virus (HDV) infections claim over 880.000 lives annually. Preclinical animal models are urgently needed to understand host-pathogen interactions and to search for effective treatments aiming at functional cure. However, a narrow host range restricts infections to humans and chimpanzees. Human NTCP has been identified as receptor for HBV and HDV cell entry. Unfortunately, heterologous expression of hNTCP is not sufficient to render mice susceptible. In lack of alternatives, HBV-transgenic mice, or mice transduced with AAV-HBV vectors are used as chronic models, whereby HDV superinfection requires extra suppression of overshooting innate responses. Overall, the translational value of mouse models remains limited. Supported by strong preliminary data, we aim to establish Syrian hamsters (Mesocricetus auratus) as a novel immunocompetent, small animal model for HBV and HDV infection; achievable by concomitant transduction of hamster livers with AAV vectors expressing HBV as helper virus, and hNTCP as receptor. Our HBV/HDV co-infection will be validated by the use of direct-acting antivirals (e.g. Myrcludex-B) and immunomodulatory drugs (IFNα). Our unique approach provides an unparalleled opportunity to investigate virus-host interactions and holds the promise to become a next-generation preclinical model for the study of interventions for human HBV and HDV infections.

2. 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 [3].

				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
		☐ Generate new data ☐ Reuse existing data	☐ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☐ Numerical ☐ Textual ☐ Model ☐ Software ☐ Other:		☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	
Protocols	Written protocols	New data	Digital	Other: descriptive	.docx .pdf	<100 MB	NA
Experiment measurements and observations	Measurements and observations (survival of mice, body weight, painscores,…)	New data	Digital	Experimental	.xls	<100 MB	NA
Biological samples	All biological samples	New data	Physical	NA	NA	NA	6000 samples

[3]

	resulting from experiments (cells, bacteria, viruses, mouse tissues, …)						
Plaque assay images	Images taken from plaque assay plates	New data	Digital	Experimental	.png	<100 MB	NA
Plaque assay results	Excel files with raw data and analysis + calculations	New data	Digital	Compiled	.xls	<100 MB	NA
Flow cytometry raw data	Files resulting from LSRFortessa Flow Cytometer system	New data	Digital	Software	.fcs	<100 GB	NA
Flow cytometry analysis	Files for processing and visualizing flow cytometry data in FlowJo Software	New data	Digital	Software	.wsp	<100 MB	NA
Flow cytometry results	Excel files for calculations resulting from analysis in FlowJo Software	New data	Digital	Compiled	.xls	<100 MB	NA
IIFA results	Harmony	New data	Digital	Compiled	.txt, .xls	<100 MB	NA

	software files for high content imaging, and excel files for further analyses and calculations						
TCID50 results	Excel files with raw data and analyses of absorbance results with MTS	New data	Digital	Compiled	.xls	<100 MB	NA
EliSpot results	Files for ELISpots, ELISpot counting, and visualization images	New data	Digital	Compiled	.fcs, .xls, .tif	<1 GB	NA
Bioassay results	Excel files with raw data and analyses of bioluminescence	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	New data	Digital	Compiled	.tif	<1 GB	NA

	from graphs made in Graphpad software						
Manuscripts	Manuscripts for publications of results	New data	Digital	Compiled	.pdf	<100 MB	NA

GUIDANCE:
The data description forms the basis of your entire DMP, so make sure it is detailed and complete. It includes digital and physical data and encompasses the whole spectrum ranging from raw data to processed and analysed data including analysis scripts and code. Physical data are all materials that need proper management because they are valuable, difficult to replace and/or ethical issues are associated. Materials that are not considered data in an RDM context include your own manuscripts, theses and presentations; documentation is an integral part of your datasets and should described under documentation/metadata.
RDM Guidance on data

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)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.	☐ Yes, human subject data; provide SMEC or EC approval number: ☒ Yes, animal data; provide ECD reference number: ☐ Yes, dual use; provide approval number: ☐ No Additional information: All experimental work is/will be approved by the relevant ethical committees. For the in vivo experiments, we already obtained approval by the Ethical Committee for Animal Experimentation (KU/UZ Leuven) (P176/2022, P026/2022, P189/2024).

Will you process personal data[4]? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).	☐ Yes (provide PRET G-number or EC S-number below) ☒ No Additional information:
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 ☐ No If yes, please comment: Each workpackage can contribute to the valorization of the vaccine candidate: immunology and vaccine efficacy which will be assessed in all workpackages are needed for valorization.
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 to what data they relate and what restrictions are in place.	☐ Yes ☒ No If yes, please explain:
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 to what data they relate and which restrictions will be asserted.	☒ Yes ☐ No If yes, please explain: Intellectual property rights are in place for the vaccine candidates.

3. Documentation and Metadata

[4] See Glossary Flemish Standard Data Management Plan

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). *RDM guidance on documentation and metadata*.	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.
Will a metadata standard be used to make it easier to **find and reuse the data**? If so, please specify which metadata standard will be used. If not, please specify which metadata will be created to make the data easier to find and reuse. *REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.*	☒ Yes ☐ No If yes, please specify (where appropriate per dataset or data type) which metadata standard will be used: For flow cytometry and ELISpot, FCS files containing metadata will be generated and stored. If no, please specify (where appropriate per dataset or data type) which metadata will be created:

4. Data Storage & Back-up during the Research Project

Where will the data be stored? *Consult the interactive KU Leuven storage guide to find the most suitable storage solution for your data.*	☒ Shared network drive (J-drive) ☐ Personal network drive (I-drive) ☐ OneDrive (KU Leuven) ☒ Sharepoint online ☐ Sharepoint on-premis ☐ Large Volume Storage ☐ Digital Vault ☐ Other: 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 MVVD group. Additionally on an online sharepoint, only accessible for MVVD group, all manuscripts (drafts) will be stored for long term storage. The separate K-drive of KU Leuven will be used for long term storage of files and data from finished projects. Biological samples from experiments will be stored in freezers and registered in https://freezerpro.rega
How will the data be backed up? *WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS?*	☒ Standard back-up provided by KU Leuven ICTS for my storage solution ☐ Personal back-ups I make (specify) ☐ Other (specify) 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 ☐ No 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 (microscopy images, FASTQ files) 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. If no, please specify:
How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons? *CLEARLY DESCRIBE THE MEASURES (IN TERMS OF PHYSICAL SECURITY, NETWORK SECURITY, AND SECURITY OF COMPUTER SYSTEMS AND FILES) THAT WILL BE TAKEN TO ENSURE THAT STORED AND TRANSFERRED DATA ARE SAFE.* *Guidance on security for research data*	All data will be stored on a KU Leuven backed up server, for which access is only granted to the MVVD group members. This access is controlled by the head of our research group (Kai Dallmeier).
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.

5. 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...). *Guidance on data preservation*	☒ All data will be preserved for 10 years according to KU Leuven RDM policy ☐ All data will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans ☐ Certain data cannot be kept for 10 years (explain) 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)? *Dedicated data repositories are often the best place to preserve your data. Data not suitable for preservation in a repository can be stored using a KU Leuven storage solution, consult the interactive KU Leuven storage guide.*	☐ KU Leuven RDR ☒ Large Volume Storage (longterm for large volumes) ☐ Shared network drive (J-drive) ☐ Other (specifiy): The data, associated metadata and electronical labbooks will be stored on the K drive of KU Leuven with automatic back-up procedures for at least 10 years, conform the KU Leuven RDM policy.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	Costs to preserve data on the K drive will depend on the storage size at a specific moment in time as this can always be increased/decreased on demand, but are estimated at 11.4 euros/100 GB. This is paid annually and concern the whole research group. The costs will be divided over all funding available by our research group.

6. Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project? Please explain per dataset or data type which data will be made available. *Note that 'available' does not necessarily mean that the data set becomes openly available, conditions for access and use may apply. Availability in this question thus entails both open & restricted access. For more information: https://wiki.surfnet.nl/display/standards/info-eu-repo/#infoeurepo-AccessRights*	☐ Yes, as open data ☐ Yes, as embargoed data (temporary restriction) ☒ Yes, as restricted data (upon approval, or institutional access only) ☐ No (closed access) ☒ Other, please specify: The key findings of this project will be made available through publication in peer-reviewed journals. 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.	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. K. Dallmeier.
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 per dataset or data type where appropriate.	☐ Yes, privacy aspects ☐ Yes, intellectual property rights ☐ Yes, ethical aspects ☐ Yes, aspects of dual use ☐ Yes, other ☒ No If yes, please specify:
Where will the data be made available? If already known, please provide a repository per dataset or data type.	☒ KU Leuven RDR ☐ Other data repository (specify) ☐ Other (specify)

When will the data be made available?	☒ Upon publication of research results ☐ Specific date (specify) ☐ Other (specify)
Which data usage licenses are you going to provide? If none, please explain why. *A DATA USAGE LICENSE INDICATES WHETHER THE DATA CAN BE REUSED OR NOT AND UNDER WHAT CONDITIONS. IF NO LICENCE IS GRANTED, THE DATA ARE IN A GREY ZONE AND CANNOT BE LEGALLY REUSED. DO NOTE THAT YOU MAY ONLY RELEASE DATA UNDER A LICENCE CHOSEN BY YOURSELF IF IT DOES NOT ALREADY FALL UNDER ANOTHER LICENCE THAT MIGHT PROHIBIT THAT.* *Check the RDR guidance on licences for data and software sources code or consult the License selector tool to help you choose.*	☒ CC-BY 4.0 (data) ☐ Data Transfer Agreement (restricted data) ☐ MIT licence (code) ☐ GNU GPL-3.0 (code) ☐ Other (specify)
Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here. *INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.*	☐ Yes, a PID will be added upon deposit in a data repository ☐ My dataset already has a PID ☒ No
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.

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The grant holder, Elias Broeckhoven, will be responsible for data and metadata documentation and preservation.

Who will manage data storage and backup during the research project?	The grant holder, Elias Broeckhoven, will be responsible for data collection, correct documentation and storage onto the KU Leuven servers. The KU Leuven IT department will be responsible for maintenance and back up of the servers.
Who will manage data preservation and sharing?	The grant holder, Elias Broeckhoven, and the promotor and head of the research group (Prof. Kai Dallmeier) will share responsibility for ensuring data preservation and sharing.
Who will update and implement this DMP?	The grant holder, Elias Broeckhoven, and the promotor and head of the research group (Prof. Kai Dallmeier) will share responsibility for updating and implementing this DMP.