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	**Prof. Dr. Frédéric Amant (0000-0002-5452-4905)**
Contributor name(s) (+ ORCID) & roles	**Dr. Daniela Annibali (0000-0001-8413-7669) – Research Manager** **Wout De Wispelaere (0000-0003-1147-7050) - PostDoc**
Project number [1] & title	G036824N - Overcoming resistance to anti-PD1 blockade in uterine leiomyosarcomas
Funder(s) GrantID [2]	D-2024-2939
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	Uterine leiomyosarcomas (uLMS) are rare tumors, characterized by an aggressive clinical behavior and high risk of hematologic spread. Currently, no highly effective therapeutic agents are available for these patients, which leads to a very poor prognosis and emphasizes the urgent need for new therapeutic options. The onset of immune checkpoint blockade (ICB) has transformed the therapeutic landscape in oncology, showing unprecedented responses in a variety of difficult-to-treat cancers. Despite research indicating a strong potential for ICB in uLMS, clinical trials showed these tumors do not respond to single-agent ICB. Recent insights gained in the resistance mechanisms against ICB have spurred the development of combination treatment strategies to increase the effectiveness of ICB. Our preliminary data indicate that the immunomodulatory effects of PI3K/mTOR inhibitors can be leveraged to enhance the effectiveness of ICB in uLMS. Therefore, the goal of this project is to combine integrated molecular analysis (single-cell RNA sequencing and multiplex immunohistochemistry) with patient-derived murine and explant models, to in detail characterize the immune-modulatory effects of PI3K/mTOR inhibitors in uLMS and test them in combination therapies with immune checkpoint inhibitors.

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 [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
DS1	Clinical Data retrieved from the patient records (KWS platform UZ Leuven), stored in a pseudonymised manner	☐ Generate new data ☒ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:	.xls	☒ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	N/A
DS2	Fresh tumor resections from LMS patients will be cut into small fragments and cryopreserved as viable tissue in fetal bovine serum (FBS) + 10% dimethylsulfoxide (DMSO)	Generate new data	Physical				Viable frozen tumor material from n=20 patients
DS3	Tumors harvested from humanized patient-derived xenograft models and tumor material from patient-derived explants will be formalin-fixed and paraffin embedded	Generate new data	Physical				n=150 biological samples (FFPE) from humanized PDXs and PDEs

DS4	Tumor material from humanized patient-derived xenograft models will be collected after sacrifice and flash frozen in liquid nitrogen	Generate new data	Physical				n=80 biological samples (FFPE) from humanized PDXs
DS5	Single-cell RNA/TCR sequencing of tumor biopsies collected from humanized patient-derived xenograft models and patient-derived explants	Generate new data	Digital	Numerical Textual	.fastq .bam .sam .mtx .tsv .csv .HDF5 .json	<10 TB	
DS6	Multiplex immunofluorescence analysis (MILAN-method) of tumor samples from humanized patient-derived xenograft models and patient-derived explants	Generate new data	Digital	Images Textual	.tiff .ome-tiff .csv	<100 GB	

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.	Clinical and personal data will be retrieved from the UZ Leuven Klinikal Werk Station (KWS) system by authorized personnel in the Gynecological Oncology Lab

[3] Add rows for each dataset you want to describe.

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: S67067 ☒ Yes, animal data; provide ECD reference number: XXXX ☐ Yes, dual use; provide approval number: ☐ No Additional information:
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: Patient-derived explants (S67067) Patient-derived xenograft models SS63799)
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:
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:

[4] See Glossary Flemish Standard Data Management Plan

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). *RDM guidance on documentation and metadata*.	All digital data and metadata accompanying physical data will be stored on the data management platform from KU Leuven ManGO. This platform allows researchers to store and manage their data via different clients such as ManGO portal, or SFTP clients. • **Storage** The data is stored securely in the data centers of KU Leuven. Of each file, two copies are stored: one in the datacenter in Heverlee, and one other in the datacentre of Leuven. • **Metadata** Data can be described in the platform by adding metadata (at the file or folder level) to provide context to the data and make the data findable via the search interface. Each dataset will include a metadata file which will contain: ○ Title and description of the dataset ○ Names and contact information of the data creators ○ Date of data collection ○ Anonymized identifiers of patients from which samples were derived ○ File formats and structure ○ Instructions for accessing and using the data and relationship between different data elements The structure of the ManGO platform ensures data adheres to the FAIR data principles.

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: The ManGO platform allows users to design metadata schemas. Using these schemas, users of the ManGO portal have to fill in specific information accompanying their data-upload. Specific schemes will be designed for each datatype. ▫ Single-cell RNA seq data ○ Dataset title ○ Dataset description ○ File format ▪ Raw data: FASTQ ▪ Processed data: BAM/SAM, HDF5, CSV ▪ Metadata: CSV, JSON ○ Sample ID ○ Donor ID ○ Sample collection data ○ Sequencing platform ○ Read length ○ Sequencing depth ○ Library preparation protocol ○ Raw data processing software ○ Alignment reference genome ▫ Multiplex immunofluorescence data ○ Dataset title ○ Dataset description ○ File format ▪ Raw images: TIFF ▪ Processed images: OME-TIFF ▪ Metadata: JSON, CSV ○ Sample ID

	○ Donor ID ○ Sample collection date ○ Fixation method ○ Section thickness ○ Microscope model ▪ Objective ▪ Resolution ▫ For all physical datasets (e.g. FFPE and frozen tumor material) containers will be labelled with: ○ Project ID ○ Sample ID ○ Donor ID ○ Date of collection ○ Material type ○ Sample processing method • Fixation • Freezing ○ These physical samples will be accompanied by a metadata file in ManGO detailing the same information as the label on the physical container, with the addition of location where container is stored • Liquid nitrogen tank ID (flash frozen/viable frozen tissue) ▪ Rack number ▪ Box number ▪ Box position • Storage container ID (FFPE material) If no, please specify (where appropriate per dataset or data type) which metadata will be created:

3. 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 digital data (DS3 & DS4) will be stored on the data management platform from KU Leuven ManGO. - a REDCap-based system will be used as an electronic case report form to collect all clinical data. - an electronic lab notebook will be used to register and manage sample collection data and molecular analyses data
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 are stored securely in the data centers of KU Leuven. Of each file, two copies are stored: one in the datacenter in Heverlee, and one other in the datacentre of Leuven.
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 See above 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*	ManGo can only be accessed via KU Leuven accounts (after being granted permission) via the ManGO portal or through SFTP clients. The KU Leuven RDM-ICTS support team manages access and permission to the ManGO platform.
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	The expected costs for data storage are EUR 330.00/year. These costs have been accounted for in our application for this project at FWO.

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)

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): All digital data and metadata accompanying physical data will be stored on the data management platform from KU Leuven ManGO Archive.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	The expected costs for data storage are EUR 330.00/year. The costs of storage during the active years of the project are covered by the FWO grant. The following years, these costs will be covered as part of the Gynecological oncology lab running costs from running credits.

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:
If access is restricted, please specify who will be able to access the data and under what conditions.	Sequencing data will be submitted to the European Genome-Phenome Archive (EGA) and can be accessed after submission of a controlled data access (CDA) application

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: To protect patient privacy, sequencing data of patient-derived tumor material will be deposited in an access-controlled data repository.
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): European Genome-Phenome Archive ☐ 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?	Submission of data in EGA is free

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	Prof. Dr. Frédéric Amant Dr. Daniela Annibali Wout De Wispelaere
Who will manage data storage and backup during the research project?	Prof. Dr. Frédéric Amant Dr. Daniela Annibali Wout De Wispelaere
Who will manage data preservation and sharing?	Prof. Dr. Frédéric Amant Dr. Daniela Annibali Wout De Wispelaere
Who will update and implement this DMP?	Prof. Dr. Frédéric Amant Dr. Daniela Annibali Wout De Wispelaere