Nanomaterial enhanced immunotherapy for tumor treatment.

DMP C3/21/035

ADMIN DETAILS

Project Name: Nanomaterial enhanced immunotherapy for tumor treatment.

Project Identifier: 3M210428 (onderzoeksportaal)

Grant Title: C3/21/035

Principal Investigator / Researcher: Stefaan Soenen, Bella Manshian

Project Data Contact: Stefaan Soenen, +32 16 330 034, s.soenen@kuleuven.be

Description: The main aim of this C3 application is to facilitate the clinical translation of modern nanotechnology to explore new horizons in the treatment of cancer, continuing from recent groundbreaking results that demonstrated full tumor remission and lack of tumor relapse or metastasis in different murine tumor models. The unique ability of these nanomaterials (NMs), with their demonstrated activities against multidrug-resistant tumors and tumor initiating cells (TICs) as wellas their potent induction of immunogenic cell death (ICD) and ability to act as an adjuvant renders these particles perfectly suited to tackle some of the major issues remaining in tumor therapy. The current C3 aims at 1) enhancing GMP-certified production capacity of the nanoparticles of interest along with validation 2) of the nanoparticles combined with different immunotherapy regimens and 3) in different tumor models of interest. Along with the KUL LRD and external CROs paid through a Wellcome fund, appropriate tumor models and immunotherapy regimens have been defined, a business plan is being set up, and we are liaising with industrial partners. Together with clinical partners, we can then pave the way to incorporate this technology in the clinical pipeline of immunotherapy studies.

Institution: KU Leuven

1. GENERAL INFORMATION

a. Name applicant

Stefaan Soenen

b. FWO Project Number & Title

BOF project number: C3/21/035

Title: Nanomaterial enhanced immunotherapy for tumor treatment

c. Affiliation

- KU Leuven

2. DATA DESCRIPTION

a. Will you generate/collect new data and/or make use of existing data?

- Generate new data

b. Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project.

Type of Data	Format	Volume	How created
(A) transmission electron microscopy	.tif; ;jpegg	50 GB	TEM images of the synthesized nanomaterials that are to be used in this project The images will be put in folders with specific indication of the sample date and sample name in the subfolder names
(B) Dynamic light scattering (DLS)	.xlsx	1 GB	Dynamic light scattering data of the nanomaterials used in this project.
(C) IVIS Spectrum optical imaging	.tif, .PNG, .txt, .xlsx	1 GB	Optical imaging datafiles for all animal studies requiring luminescence and fluorescence imaging. The images and raw data are filed as series with .tif and .txt files in folders with unique identifiers in the folder name. An excel sheet will be kept to track the groups/animals and their individual scans taken and their corresponding folder name as well as a summarized analysed dataset.
(D) blood biochemistry results	.pdf	0.1 GB	.pdf files are generated by the device with all input (animal/date/parameters checked) and raw data for all parameters tested.

(E) ImageStream data	.cif, .rif, .daf	300 GB	Raw data of the ImageStream to analyze cell subpopulations will be stored as .cif files. Any analyzed data will be kept as .cif files while analysis templates are stored as .daf files. All data will be stored in folder with indication of the name and date of subjects and types of analyses
(F) immunohistochemistry data	.qptiff, OME	2 TB	Raw images of immunohistochemistry analysis will be stored as .qptiff files. Analysis templates and in-house generated scripts for data analysis will be stored as OME-compliant readouts.

3. LEGAL AND ETHICAL ISSUES

a. Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- No

b. 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, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

This project involves the use of mice as laboratory animals and we follow the guidelines and rules from the HSE Department (Health, Safety and Environment) and the Animal Ethics Committee at KU Leuven. Ethical permission for animal work were given for following ECDs by the Leuven animal ethics commission: approved (P146/2019 + P193/2021)

c. Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- Yes

Yes, any nanoformulation with potential therapeutic impact will be protected by us in collaboration with LRD. We have one pre-patent application submitted and plan to submit 2-3 more patent applications in the runtime of this project. This means that all data generated will only be accessible to the researchers involved in the work. Any other researchers will have to sign NTA/MTA aggreements via LRD and this will be discussed on a case to case basis. Once a patent has been approved, we will liaise with LRD to see which data can then become available to the broader public and which needs to be restricted.

d. Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. DOCUMENTATION AND METADATA

a. What documentation will be provided to enable reuse of the data collected/generated in this project?

All information regarding this study will be kept on central KULeuven large storage drives (L-drives) will be updated by a member of the research team every time new measurements take place.

The study outline describes the goal, purpose and objectives of the study and how the study will be performed practically.

Letters in brackets below refer to the table above (question 2b).

(A) and (B): Raw data nanoparticles properties will be kept in their original format. For organizational purposes, all TEM images of the same sample will be time-stamped, automatic indication of scale bar and will be placed in a folder with the name and data of sample generation. An accompanying pdf will be generated that describes the synthesis of the nanoformulations.

(C): Raw IVIS data will be stored for each condition with an automatically generated .txt file explaining the naming of the animals used, their group indication, treatments undergone, scan number, scan settings (time of exposure, camera settings, binning factor, f-STOP factor…), the name of the researcher acquiring the images and the name of the unique folder that carries all images and the text files. One such folder is generated for every individual scan performed.

(D): The blood biochemistry device generates .pdf files that provides the names and dates of acquisition of the individual subjects, along with the corresponding values for every parameter analysed.

(E): Raw .rif files with all channels for all acquired data will be stored. Compensated data (.cif) will be stored in the same folder. This will be accompanied by .daf files which outline the script used for analysis (selection of thresholds, gating, masks…) as well as any numerical data obtained in a table format linked within this .daf file. A corresponding .xlsx file will be kept to indicate which samples have been acquired, the exact conditions used during acquisition and which markers were used for staining. The names and dates of acquisition for all files will be indicated in the excel sheet.

(F): Histology data (.qptiff and .OME) will be kept as raw images, and an analysis pipeline (OME-compliant) that enables retrieval of numerical data from the images obtained. A corresponding excel sheet will be accompanying every folder to assign the images to a particular organ of a particular individuum and to detail the markers used in staining.

b. Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- Yes

We will follow the Dublin Core and Qualified DC metadata vocabularies to guarantee data interoperability allowing the exchange and reuse of data between researchers, institutions, organizations, countries, etc.

For each dataset, metadata will be always provided in a README file stored together with the data, including information such as title, creator, description, date of creation, data format, data type, data size, confidentiality type etc. There will be 4 levels of confidentiality (Public, Internal, Restricted, Confidential). Wherever possible the data will be shared following the Creative Commons CC-BY or CC0 licenses. In any case, obligation to protect results in

Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39 of the H2020-MGA, will be fulfilled.

5. DATA STORAGE AND BACKUP DURING THE FWO PROJECT

a. Where will the data be stored?

1. The time-stamped master copy of the data will be kept on the KULeuven central storage facility (L-drives). These data can then only be assessed by researchers working on the project by logging into their personal accounts from a work PC.

2. Physical data will be stored in a locked filing cabinet in a locked office in Gebouw De Nayer, KU Leuven, 3001 Leuven.

b. How is backup of the data provided?

The data will be stored on KULeuven L-drives for long-term storage which are mirrored servers with automatic daily back-up procedures.

c. 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

The central storage servers of KULeuven have sufficient space and additional space for project use can be purchased in 10 TB parts.

d. What are the expected costs for data storage and back up during the project? How will these costs be covered?

Costs of data storage will be supported by leftover overhead costs obtained through EU projects.

e. Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Please see question 5a.

6. DATA PRESERVATION AFTER THE C3 PROJECT

a. Which data will be retained for the expected 5-year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

After the end of the project, all data will be retained for the 5-year period expected by KU Leuven.

b. Where will the data be archived (= stored for the longer term)?

The data will be stored on the KULeuven long-term storage servers (L-drives) for 5 years, conform the KU Leuven policy.

c. What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

The costs will be covered by overhead leftovers available from EU projects. This will amount to approximately €1000/year.

7. DATA SHARING AND REUSE

a. Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- Yes

Please see question 3.c

b. Which data will be made available after the end of the project?

Data will only be made available in case of publications that require the publication/disclosure of the dataset.
In case data sharing is planned in the context of a publication, this will first be discussed with experts at LRD prior to publication to conform with all current standards regarding data protection and IP tech transfer.

c. Where/how will the data be made available for reuse?

- Upon request by mail

As explained above, the data is acquired to support IP applications and canthus not be widely shared without authorization. For any request we receive, LRD will be consulted regarding the legal requirements in sharing the information requested.

d. When will the data be made available?

- Upon publication of the research results

Data will only be made available to other researchers after publication of the research results or after obtaining the relevant patents. Any data to be made available will then first be discussed with LRD.

e. Who will be able to access the data and under what conditions?

As stated above, only requests via mail will be answered. Legal experts will be consulted when sharing data with researchers outside of the research group. A written agreement with the PI and LRD is necessary when sharing the data outside of the research groups.

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

None. Data preparation will be done by the researchers primarily involved in the project. Secure data sharing infrastructure is available at both universities, e.g. Belnet via KU Leuven. If costs occur, these need to be covered by the requesting party/-ies.

8. RESPONSIBILITIES

a. Who will be responsible for data documentation & metadata?

Prof. Dr. Stefaan Soenen
Dr. Bella Manshian

b. Who will be responsible for data storage & back up during the project?

Prof. Dr. Stefaan Soenen
Dr. Bella Manshian

c. Who will be responsible for ensuring data preservation and reuse?

Prof. Dr. Stefaan Soenen

d. Who bears the end responsibility for updating & implementing this DMP?

Prof. Dr. Stefaan Soenen