

## 1. General Project Information

Name Grant Holder & ORCID	Maarten Dewilde (LTDA, PharmAbs) ( <a href="http://orcid.org/0000-0002-3138-281X">http://orcid.org/0000-0002-3138-281X</a> )
Contributor name(s) (+ ORCID) & roles	Abhishek Garg (LCSI; co-PI) ( <a href="http://orcid.org/0000-0002-9976-9922">http://orcid.org/0000-0002-9976-9922</a> ) Rik Gijssbers (LMVGT; co-PI) ( <a href="http://orcid.org/0000-0003-0191-3904">http://orcid.org/0000-0003-0191-3904</a> )
Project number <sup>1</sup> & title	C3/22/022 <b>Building a proprietary platform for DNA-antibody based therapeutics.</b>
Funder(s) GrantID <sup>2</sup>	C3/22/022
Affiliation(s)	<input type="checkbox"/> KU Leuven <input type="checkbox"/> <del>Universiteit Antwerpen</del> <input type="checkbox"/> <del>Universiteit Gent</del> <input type="checkbox"/> <del>Universiteit Hasselt</del> <input type="checkbox"/> <del>Vrije Universiteit Brussel</del> <input type="checkbox"/> <del>Other:</del> Provide ROR <sup>3</sup> identifier when possible: <a href="https://ror.org/05f950310">https://ror.org/05f950310</a>
Please provide a short project description	DNA-based antibody therapy seeks to administer the encoding nucleotide sequence, rather than the antibody protein. This antibody gene transfer can allow the body to produce its own genetic medicine, and presents an alternative to the complex production and frequent administration of conventional antibody protein therapy. We previously obtained therapeutic proof-of-concept in mice and several plasmid-encoded antibody formats, and demonstrated clinical feasibility in sheep and non-human primate. However, despite the significant progress made over the last years, the produced plasma antibody concentrations are too low and show too fast of a decay to grant this approach a broad clinical application. Improving <i>in vivo</i> antibody production is therefore the key focus of this project. We thereto aim to strengthen our proprietary platform for plasmid DNA-based antibody therapeutics by generating an immunomodulatory toolbox targeted at increasing <i>in vivo</i> antibody expression. This will be done by mapping the activated immune pathways after <i>in</i>

<sup>1</sup> "Project number" refers to the institutional project number. This question is optional since not every institution has an internal project number different from the GrantID. Applicants can only provide one project number.

<sup>2</sup> 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.

<sup>3</sup> Research Organization Registry Community. <https://ror.org/>

*vitro* and *in vivo* plasmid DNA administration. This will be followed by building a toolbox methodology for modulating the plasmid DNA-induced immunoregulatory responses, and its effects on *in vitro* and *in vivo* antibody expression will be assessed. The resulting immunomodulatory toolbox will contribute to the maturation of our proprietary and differentiating antibody gene transfer platform, by considerably broadening its application and competitive edge.

## 2. Research Data Summary

				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
1. Plasmid and transgene (antibody/protein) DNA sequences	(Annotated) plasmid DNA sequences, and DNA sequences of transgenes/antibodies to be cloned in the plasmids. Sequences will be processed and adapted with CLC Main Workbench software (Qiagen). Details of plasmid design/construction will be stored in the electronic lab notebook. Plasmids will be sequence verified (performed at LGC Genomics (.abi files) and stored in SnapGene (together with the engineered digital maps of the respective plasmids).	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input checked="" type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input type="checkbox"/> .pdf <input checked="" type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .clc, .gbk, .dna, .fasta, .tif, .abi <input type="checkbox"/> NA	<input type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input checked="" type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA
2. Plasmid	Plasmid DNA, stored either as purified	<input checked="" type="checkbox"/> Generate	<input type="checkbox"/> Digital	NA	NA	NA	50 vials

DNA	plasmid DNA (-20°C) or as frozen glycerol stocks of transformed bacteria (-80°C).	new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Physical				(2mL) in -80°C freezer, 200 vials (1.5 or 2 mL) in -20°C freezer.
3. Purified antibodies/ proteins	<i>In vitro</i> transfection experiments for expression of antibodies/proteins. Harvested cell culture medium containing the produced antibody/protein, and purified antibodies/proteins will be stored at -20°C.	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	NA	NA	NA	200 vials/tubes of 1 to 10 mL in -20°C freezer.
4. Cell lines	Different types of cell lines from mammalian origin (mouse, hamster and human), used for <i>in vitro</i> cell transfection experiments, reporter cell lines, screening of shRNA/miRNA,...	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	NA	NA	NA	100 vials/tubes of 1,5 or 2 mL in liquid nitrogen.
5. viral vectors	Different viral vectors (LV) will be generated to transduce target cells of interest. Vectors will be stored in a -80°C freezer at KU Leuven Viral Vector Core and monitored in dedicated databases (.xls file, KUL servers)	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	<input checked="" type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input type="checkbox"/> Compiled/ aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input checked="" type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg	<input type="checkbox"/> < 100 MB <input checked="" type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	20 eppendorf vials/tubes of 1,5 mL, each containing 50 µl of vector per prep, in

					<input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .xlsx <input type="checkbox"/> NA		-80°C freezer
6. Physical samples from <i>in vitro</i> experiments	Physical samples from <i>in vitro</i> experiments (e.g. cell medium after cell transfection)	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	NA	NA	NA	300 vials of 1,5 mL in -20 freezer.
7. Knock-out mice	Knock-out mouse strains are kept in the animal facility of KU Leuven. List of mice used for experiments is available in the LAIS system.	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	NA	NA	NA	Live mice in animal facility.
8. <i>In vivo</i> experimental data	Experimental details (treatment parameters, animal handling, observations...) will be written down in electronic lab notebook (eLabJournal, eLabNext, Eppendorf Group), raw data (e.g. body weight vs. time) will be stored as Excel files.	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input checked="" type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input checked="" type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .xlsx <input type="checkbox"/> NA	<input checked="" type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA
9. Mouse plasma	Plasma samples collected at different timepoints during in vivo gene	<input checked="" type="checkbox"/> Generate new data	<input type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	NA	NA	NA	1000 vials/tubes

samples	transfer experiments in mice.	<input type="checkbox"/> Reuse existing data					of 1,5 mL in -20°C freezer.
10. ELISA data	Enzyme-linked immunosorbent assays performed on different sample types (e.g. medium of <i>in vitro</i> transfected cells, plasma of treated mice) for quantification of transgene expression. Readout in excel files and data analysis in GraphPad prism.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input checked="" type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .pzf, .xlsx <input type="checkbox"/> NA	<input type="checkbox"/> < 100 MB <input checked="" type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA
11. Muscle samples	Mouse muscle samples collected after <i>in vivo</i> gene transfer.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	NA	NA	NA	300 vials/tubes of 1,5 mL in -80°C freezer.
12. mRNA and cDNA samples	mRNA will be extracted from different cell lines and conditions, and stored at -80°C. cDNA samples generated by reverse transcription of mRNA of <i>in vitro</i> cultured cells. cDNA will also be generated from mRNA from <i>in vivo</i> targeted tissue.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	NA	NA	NA	100 vials/tubes of 1,5 mL in -80°C freezer. 100 vials/tubes

							of 200 µL in -20°C freezer.
13. Gene expression data	Evaluation of transgene expression or target gene silencing in cell culture and <i>in vivo</i> in targeted tissue cells by (RT-)qPCR.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input checked="" type="checkbox"/> Compiled/ aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input checked="" type="checkbox"/> .csv <input type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .pzf, . xlsx <input type="checkbox"/> NA	<input type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input checked="" type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA
14. Reporter assay data	Reporter assay data performed on different sample types (e.g. medium of <i>in vitro</i> transfected cells, plasma of treated mice) for quantification of the Type I IFN and NFκB pathway. Readout in Excel files and data analysis in GraphPad prism.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input checked="" type="checkbox"/> Compiled/ aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .pzf, .	<input checked="" type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA

					xlsx <input type="checkbox"/> NA		
15. Cytokine array data	Cytokine array data performed on different sample types (e.g. medium of <i>in vitro</i> transfected cells, plasma of treated mice) for quantification of different secreted cytokines. Images (.scn) and quantifications in Excel files and data analysis in GraphPad prism.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input checked="" type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .scn, .xlsx, .pzf <input type="checkbox"/> NA	<input checked="" type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA
16. Flow cytometry data	Raw data of single cell phenotypes generated by flow cytometry (.fcs) or analysed via FlowJo (.wsp) and GraphPad prism.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input checked="" type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .fcs, .wsp, .p	<input checked="" type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA

					zf <input type="checkbox"/> NA		
17. Analyzed data, figures and statistical analyses	Analysis of raw data (excel data sheets with quantitative data and summary data), visualization of data in Excel and GraphPad Prism, and statistical analyses in GraphPad Prism. Presentation slides summarizing key findings of the project will be generated in Powerpoint.	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input checked="" type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input checked="" type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .pzf, .xlsx, .pdf, .tiff <input type="checkbox"/> NA	<input checked="" type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA
18. Protocols, experimental documentation, metadata, and manuscripts	Experimental protocols, details related to data collection/processing, and data collection/analysis particularities, will be stored in the electronic lab notebook (LTDA/PharmAbs), or Word (.docx) or Excel (.xlsx) files (LCSI), or Word and Excel files linked in an electronic lab notebook in OneNote LMVGT).	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input checked="" type="checkbox"/> Observational <input checked="" type="checkbox"/> Experimental <input checked="" type="checkbox"/> Compiled/aggregated data <input type="checkbox"/> Simulation data <input type="checkbox"/> Software <input type="checkbox"/> Other <input type="checkbox"/> NA	<input type="checkbox"/> .por <input type="checkbox"/> .xml <input type="checkbox"/> .tab <input type="checkbox"/> .csv <input checked="" type="checkbox"/> .pdf <input type="checkbox"/> .txt <input type="checkbox"/> .rtf <input type="checkbox"/> .dwg <input type="checkbox"/> .tab <input type="checkbox"/> .gml <input checked="" type="checkbox"/> other: .docx	<input checked="" type="checkbox"/> < 100 MB <input type="checkbox"/> < 1 GB <input type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> < 10 TB <input type="checkbox"/> < 50 TB <input type="checkbox"/> > 50 TB <input type="checkbox"/> NA	NA



					, .xlsx, .pdf, .one <input type="checkbox"/> NA		
<p>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.</p> <p>Existing data that will be reused are the following: protocols, DNA sequences of plasmids and transgenes (antibody/protein) and plasmid DNA (physical samples). All these data were previously generated in the labs of the PI and co-PIs, and are therefore available from this source (no external sources).</p>							
<p>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, please describe these issues further and refer to specific datasets or data types when appropriate.</p> <p><input type="checkbox"/> Yes, human subject data  <input checked="" type="checkbox"/> Yes, animal data  <input type="checkbox"/> Yes, dual use  <input type="checkbox"/> No</p> <p>If yes, please describe: All experiments in animals (mice) are approved by the Animal Ethics Committee of KU Leuven (project number P149/2022). Guidelines and rules from the HSE (Health, Safety and Environment) Department and the Animal Ethics Committee of KU Leuven will be followed.</p>							
<p>Will you process personal data<sup>4</sup>? If so, briefly describe the kind of personal data you will use. Please refer to specific datasets or data types when appropriate. If available, add the reference to your file in your host institution's privacy register.</p> <p><input type="checkbox"/> Yes  <input checked="" type="checkbox"/> No</p>							
<p>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.</p> <p><input checked="" type="checkbox"/> Yes  <input type="checkbox"/> No</p> <p>The research data that will be generated in this project hold great potential for tech transfer and valorization. The potential for commercial valorization will be continuously monitored and evaluated by the PharmAbs consortium IOF manager (Dr. Nick Geukens), and further steps in the valorization process will be done in close collaboration with KU Leuven Research &amp; Development (LRD). In this regard, all</p>							

<sup>4</sup> See Glossary Flemish Standard Data Management Plan

	datasets generated within the current project will be reserved for at least 2 years after the end of the project for the launch of a spin-off company. Upon the launch of the spin-off company, KU Leuven will license commercial exploitation rights on the available proprietary knowledge and patent applications enabled by the results obtained in the current project to the spin-off company, and will provide access to relevant background IP and know-how to maximize the value of the spin-off company.
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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  Currently, there are no 3 <sup>rd</sup> party agreements that restrict exploitation or dissemination of the data we (re)use, but this can/will probably change during the course of the project.
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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  Currently, there are no other legal issues, such as IP rights and ownership, to be managed related to the data we (re)use, but this can/will probably change during the course of the project.

### 3. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep <b>data understandable and usable</b> , 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).	Detailed experimental protocols, the research progress and clear descriptions of obtained data, what they represent and how they were generated, will be collected in an electronic lab notebook (eLabJournal, eLabNext, Eppendorf Group at LTDA/PharmAbs; OneNote at LMVGT). Here, folders are provided for all subtasks of the project (folder structure: Project group > Project > Study > Experiment). In each folder, a new file will be made for each experiment, named with the data and subject, and including information on the responsible person (i.e. the person who created the file) as well as version tracking. Each experimental file will contain a section on the subject, objective and experimental design, used protocols, used and generated samples, results (a description of results and observation rather than all raw and analysed data) and conclusion. For each experiment, all raw and analysed data files, supplemented with a .pdf transcript of the experiment in the electronic lab notebook, will be stored in a folder on the shared server, using the same hierarchical folder structure as the electronic lab notebook. By using the same structure on the
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	<p>server and in the electronic lab notebook, contextual information on the experimentally obtained data can be easily searched and reused by a secondary analyst via the electronic lab notebook.</p> <p>For each peer-reviewed article, a separate folder will be made on the server, containing the latest word version and all raw and processed data used in the article. In addition, a separate file will be made in the electronic lab notebook for each article, containing clickable links to all metadata files of data that were used in that article, to facilitate tracing back of protocols, results and conclusions</p> <p>A physical sample inventory will be stored in freezers and all samples will be added to a digital inventory in the electronic lab notebook (with links to the experiments in which the samples are generated/used, and a link to the sample details).</p>
<p>Will a metadata standard be used to make it easier to <b>find and reuse the data</b>?</p> <p>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.</p> <p><i>REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.</i></p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>No uniform metadata standard is available for all different aspects of this project. Therefore, we will create a uniform system ourselves to enhance the use of secondary data. We will use the electronic lab notebook in which a number of predetermined topics have to be described for each experiment (Title/subject, Objective, protocol, results and conclusion). The electronic lab notebook facilitates searching for particular metadata through a search engine. By mimicking the folder structure of the electronic lab notebook in the server-based folder with the experimental data, linking of the metadata to the actual data will be facilitated. Folder names will be descriptive, and file names will have a clear meaning which include: date/date range of the experiment, project or experiment name/number, initials of author of the file, type of data and version number of the file.</p>

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

Where will the data be stored?	<p>The time-stamped digital data will be stored in a project folder on the KU Leuven shared J-drive. The time-stamped digital (meta)data will be stored on the server of the electronic lab notebook (eLabJournal, eLabNext, Eppendorf Group), and a .pdf export of the electronic lab notebook experimental documentation will be made upon completion of the experiment to be saved in the project folder on the KU Leuven shared J-drive. This folder will be open for the lab members participating in this project, and is secured and backed-up by the ICTS service of KU Leuven. The researchers working on the project will have copies of the data files, as well as of the derived and compiled data stored on their personal computers.</p>
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	<p>Paper lab notebooks (in the LMVGT lab) are only used and kept in the L2 lab of the co-PI.</p> <p>Regarding the data pertaining to publications, the first author is responsible for storing all raw and processed data, and metadata, of the paper concerned in a subfolder on the KU Leuven shared J-drive. Next to this, all data underlying analyses/figures of the paper concerned will be stored together with the analysed data, tables, figures in the project folder in the electronic lab notebook (eLabJournal, eLabNext, Eppendorf Group) together with a detailed description of the performed analyses.</p> <p>The physical samples will be stored in the freezers of the labs of the PI and co-PIs. A digital overview of all stored samples will be available (either in an Excel file or in the sample inventory system of the electronic lab notebook).</p>
<p>How will the data be backed up?</p> <p><i>WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS? DESCRIBE THE LOCATIONS, STORAGE MEDIA AND PROCEDURES THAT WILL BE USED FOR STORING AND BACKING UP DIGITAL AND NON-DIGITAL DATA DURING RESEARCH.<sup>5</sup></i></p> <p><i>REFER TO INSTITUTION-SPECIFIC POLICIES REGARDING BACKUP PROCEDURES WHEN APPROPRIATE.</i></p>	<p>The digital data (saved on KU Leuven J-drive) will be stored on the university's central servers with automatic hourly back-up procedures (LTDA/PharmAbs, LMVGT). Backup copies will be made on hard drives and on a local RAID storage available in the office (LCSI).</p> <p>The data stored in the electronic lab notebook (eLabJournal, eLabNext, Eppendorf group) is replicated to 3 different data centers in real-time. Additionally, a full back-up of all data files is made every 24 hours. Data back-ups are stored as fully encrypted files to an external vault in case of an emergency and the necessity of a full recovery.</p> <p>Physical samples will be kept for 10 years post-project in the freezers of the project collaborators, with 2 vials of each crucial sample being stored in different freezers as back-up.</p>
<p>Is there currently sufficient storage &amp; 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.</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>KU Leuven provides sufficient storage and back-up capacity during and after the project. If necessary, the volume of the KU Leuven shared J-drive can be expanded with blocks of 100 GB at any time, for which budget is available.</p> <p>Sufficient freezer capacity is available in the different labs.</p>
<p>How will you ensure that the data are securely</p>	<p>Only lab members actively working on the project will have access to the KU Leuven J-drive (access is</p>

<sup>5</sup> Source: Ghent University Generic DMP Evaluation Rubric: <https://osf.io/2z5g3/>

<p>stored and not accessed or modified by unauthorized persons?</p> <p><i>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. <sup>7</sup></i></p>	<p>granted by the PI).</p> <p>In the electronic lab notebook (eLabJournal, eLabNext, Eppendorf group), only the people actively working on the project will be granted access to the experimental data of the project (settings by administrators for each individual lab member). Furthermore, after completion, experiments will be signed and locked into a read-only mode, which prevents further data modification, and a digital signature including time stamp is added to the experiment</p> <p>Secure storage of physical samples and paper notebooks is enabled by locking the laboratory doors when researchers are out of the office. Additionally, only people working in the LTDA/PharmAbs lab can access the lab by using a personnel card reader system, which only allows people working in the lab to enter.</p>
<p>What are the expected costs for data storage and backup during the research project? How will these costs be covered?</p>	<p>Data storage on the KU Leuven J-drive with backup will cost 519€ per Tb per year. Each eLabJournal Cloud license seat costs approximately 150€ per year. Costs will be covered by the laboratory or project consumables budget.</p>

## 5. Data Preservation after the end of the Research Project

<p>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...).</p>	<p>All generated research data (physical and digital; raw and processed) will be preserved for at least 10 years after the end of the project conform the KU Leuven RDM policy. The PI and co-PIs will decide on which research data will be kept past this timeframe.</p> <p>Exception: for biological samples it is not always possible to keep them for 10 years because of stability issues or because of expensive storage at very low temperatures. The PI and co-PIs will decide on which samples are considered valuable, difficult to obtain, likely to be reused and stable, and will preserve those biological samples. Samples that are easy to reproduce and those that are unstable will be discarded, but documentation and metadata related to these samples will be retained, and it will be indicated why these samples were discarded.</p>
<p>Where will these data be archived (stored and curated for the long-term)?</p>	<p>The digital data will be stored on the university's central servers (with automatic backup procedures) and paper lab notebooks will be kept in locked cabinets in the lab of the PIs concerned for at least 10 years, conform the KU Leuven RDM policy.</p> <p>The physical data will be stored in freezers in the labs of the PI and co-PIs for up to 10 years after the project (exception: see point 5.1).</p>
<p>What are the expected costs for data</p>	<p>Data storage on the KU Leuven J-drive with backup costs 519€ per Tb per year (current fee). Costs will be</p>

preservation during the expected retention period? How will these costs be covered?	covered by the laboratory budget.
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## 6. Data Sharing and Reuse

<p>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.</p> <p><i>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 &amp; RESTRICTED ACCESS. FOR MORE INFORMATION: <a href="https://wiki.surfnet.nl/display/STANDARDS/INFO-EU-REPO/#INFOEU-REPO-ACCESSRIGHTS">HTTPS://WIKI.SURFNET.NL/DISPLAY/STANDARDS/INFO-EU-REPO/#INFOEU-REPO-ACCESSRIGHTS</a></i></p>	<p> <input type="checkbox"/> Yes, in an Open Access repository  <input type="checkbox"/> Yes, in a restricted access repository (after approval, institutional access only, ...)  <input type="checkbox"/> No (closed access)  <input checked="" type="checkbox"/> Other, please specify:         </p> <p>The key findings of the project and their interpretation will be made available through publication of journal articles in established, peer-reviewed academic journals. Relevant data will be made available after publication upon reasonable request by email. These published data contain the results of processed data presented in tables.</p> <p>Data with valuable IP will be protected prior to publication. Unpublished data will be used for future grant applications/publications, and as such, can only be communicated privately to selected colleagues for as long as the IP potential has not been cleared by LRD. This is a precautionary measure to avoid compromising the IP potential of the work.</p> <p>Since the research data that will be generated in this project hold great potential for tech transfer and valorization, the datasets generated within the current project will be reserved for at least 2 years after the end of the project for the launch of a spin-off company. Upon the launch of the spin-off company, KU Leuven will license commercial exploitation rights on the available proprietary knowledge and patent applications enabled by the results obtained in the current project to the spin-off company, and will provide access to relevant background IP and know-how to maximize the value of the spin-off company.</p>
<p>If access is restricted, please specify who will be able to access the data and under what conditions.</p>	<p>Access to data, concerning ongoing, unpublished research, will be restricted to the researchers participating in the specific project as long as they are affiliated to KU Leuven. Once published, data will be accessible to all, either through reading the relevant paper, or upon reasonable request to the authors by email. For data shared directly by the PIs, a material/data transfer agreement (and a non-disclosure agreement if applicable) will be concluded with the beneficiaries in order to clearly describe the types of reuse that are permitted (usually under a CC BY-NC reuse license). Commercial-based requests will be</p>

	navigated in coordination between the involved (co-)PI(s) and KU Leuven LRD.
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.	<p> <input type="checkbox"/> Yes, privacy aspects  <input checked="" type="checkbox"/> Yes, intellectual property rights  <input type="checkbox"/> Yes, ethical aspects  <input type="checkbox"/> Yes, aspects of dual use  <input type="checkbox"/> Yes, other  <input type="checkbox"/> No </p> <p>The research data that will be generated in this project hold great potential for tech transfer and valorization. In this regard, datasets generated within the current project will be reserved for at least 2 years after the end of the project for the launch of a spin-off company. Upon the launch of the spin-off company, KU Leuven will license commercial exploitation rights on the available proprietary knowledge and patent applications enabled by the results obtained in the current project to the spin-off company, and will provide access to relevant background IP and know-how to maximize the value of the spin-off company.</p>
Where will the data be made available? If already known, please provide a repository per dataset or data type.	All digital data will be stored and be available for lab members using a shared network drive (KU Leuven J-drive) provided by the university. In addition, the relevant data will be made available to external people upon reasonable request by email. In case of data sharing outside KU Leuven, the universities' privacy and legal experts will be consulted prior to data sharing to regulate the data sharing process (e.g. data/material transfer agreement, non-disclosure agreement).
When will the data be made available?	<p>Data will only made available to other researchers after publication of the research results. No embargo will be foreseen unless imposed e.g. by pending publications, potential IP requirements (note: patent application filing will be planned so that publications need not to be delayed) or ongoing projects requiring data confidentiality. In those cases, datasets will be made available as soon as the embargo is lifted. Additional, non-published data can be made available for external researchers upon reasonable request (based on LRD contract).</p> <p>Furthermore, data with IP (potential) will be reserved and thus not shared for at least 2 years after the end of the project for the launch of a spin-off company.</p>
Which data usage licenses are you going to provide? If none, please explain why.	For data shared directly by the PIs, a material/data transfer agreement (and a non-disclosure agreement if applicable) will be concluded with the beneficiaries in order to clearly describe the types of reuse that are

<p>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.</p> <p>EXAMPLE ANSWER: E.G. "DATA FROM THE PROJECT THAT CAN BE SHARED WILL BE MADE AVAILABLE UNDER A CREATIVE COMMONS ATTRIBUTION LICENSE (CC-BY 4.0), SO THAT USERS HAVE TO GIVE CREDIT TO THE ORIGINAL DATA CREATORS." <sup>6</sup></p>	<p>permitted, usually under a CC BY-NC reuse licence so that users can only share the work (while giving credit to the original data creators) but not change it or use it commercially.</p> <p>Commercial-based requests will be navigated in coordination between the involved (co-)PI and KU Leuven LRD, but since the research data that will be generated in this project hold great potential for tech transfer and valorization, the datasets generated within the current project will be reserved for at least 2 years after the end of the project for the launch of a spin-off company. Upon the launch of the spin-off company, KU Leuven will license commercial exploitation rights on the available proprietary knowledge and patent applications enabled by the results obtained in the current project to the spin-off company, and will provide access to relevant background IP and know-how to maximize the value of the spin-off company.</p>
<p><b>Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here.</b></p> <p>INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p>
<p><b>What are the expected costs for data sharing? How will these costs be covered?</b></p>	<p>We will minimize data management costs by implementing standard procedures e.g. for (meta)data collection, and file/sample storage and organization from the start of the project. The expected data management/sharing costs will therefore be minimal and will be covered by the laboratory budget of the project. For sharing physical samples, costs for sharing will be discussed with the receiving party on a case-by-case basis. Publication costs (open access) will be covered by the consumables budget of the project.</p>

## 7. Responsibilities

Who will manage data documentation and metadata during the research project?	The PI (Prof. Maarten Dewilde; LTDA/PharmAbs), the co-PIs (Prof. Abhishek Garg (LCSI), Prof. Rik Gijsbers (LMVGT)) and the project leader (Dr. Debby Thomas; LTDA/PharmAbs) will be responsible for documentation of data and metadata. Post-docs, PhDs and technicians will have the daily responsibility of
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<sup>6</sup> Source: Ghent University Generic DMP Evaluation Rubric: <https://osf.io/2z5g3/>



	record keeping of all data (digital, paper and physical samples). They will also be responsible for a correct and accurate data entry and recording of metadata.
Who will manage data storage and backup during the research project?	Post-docs, PhDs and technicians will have the daily responsibility of record keeping of all data (digital, paper and physical samples). They will also be responsible for a correct and accurate data entry and recording of metadata. The PI (Prof. Maarten Dewilde; LTDA/PharmAbs), the co-PIs (Prof. Abhishek Garg (LCSI), Prof. Rik Gijsbers (LMVGT)) and the project leader (Dr. Debby Thomas; LTDA/PharmAbs) will be responsible for data storage and backup during the project.
Who will manage data preservation and sharing?	The PI (Prof. Maarten Dewilde; LTDA/PharmAbs), the co-PIs (Prof. Abhishek Garg (LCSI), Prof. Rik Gijsbers (LMVGT)) will be responsible for data preservation and eventual reuse of obtained data, with support from the research and technical staff involved in the project.
Who will update and implement this DMP?	The PI (Prof. Maarten Dewilde; LTDA/PharmAbs) bears the end responsibility of updating and implementing this DMP.