METHUSALEM D-2023-1864: THE DUODENAL MUCOSA: A KEY DETERMINANT OF MEAL-RELATED SYMPTOMS AND FOOD INTAKE.

A Data Management Plan created using DMPonline.be

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Project abstract:

Based on our own previous research, recent literature observations and emerging data from clinical trials, we propose an overall pathophysiological scheme that attributes key roles to increased mucosal permeability, triggered by local and systemic stressors, allowing luminal factors to maintain a vicious circle with activation of eosinophils and mast cells. The mucosal immune cell activation induces through local and systemic effects altered gastric sensorimotor function, altered gut peptide release and neuro-inflammation. These events induce impaired nutrient tolerance and upper gastrointestinal, systemic and psychological symptoms.

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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.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: N (ew data) or E (xisting data)	Indicate: D (igital) or P (hysical)	Indicate: Audiovisual Images Sound Numerical Textual Model SOftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
WP.1.A. Dataset budesonide trial (approved as S64291)	Symptom questionnaires Quality of Life questionnaires Psychosocial co- morbidity questionnaires Food Frequency questionnaires	New	D	Т	Redcap file, .txt, .xls	<1GB	Questionnaires are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.
	Personal data: sex, age, weight, length, medication, allergies, co- morbidities	New	D	Т	Redcap file, .txt, .xls	<1GB	Items are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.
	Duodenal biopsies	N	P, D	Other: biopsies during endoscopy	physical, .tif .czi	slides, tissue blocks and .tif .czi	Histology slides from duodenal biopsies. Widefield images acquired from the microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.

	Gene expression data	N	D	N/T	, •	1-10kB 1- 100MB 50- 100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Protein expression data	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A. txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Immunofluorescence microscopy images	N	D	I	.tif .czi	5-20MB 10- 50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.
WP.1.B. Dataset channel rhodopsin mice study	Neuronal imaging movies	N	D	I	.pst .inf .vws .txt .pxp .xls	1-	Live fluorescence microscopy image series generated using a calcium imaging technique are saved as outlook data files (.pst) in TillVision software with supporting technical metadata (.inf). Additional metadata are stored as .vws and .txt files. After analysis by Igor software, workspace files are saved as .pxp files, with results summarized in .xls files. The physical samples are discarded after analysis since the tissue is not suitable for further analysis anymore.

	3D renders, analysed and annotated images generated by image analysis programs like Imaris or alike	N	D	images	*.ims (Imaris)	5Tb		
	Summary data (text or spreadsheet format)	Newly generated after analysis	digital	Txt,xls	*.doc *.xls	300 Mb		
	Immunohistochemical stainings, Slides	N	Physical			4 boxes of 100 slides		
	Microscopic images: these images document immunohistochemical stainings for the previously recorded experiments	N	D	images	*.tif	500 Gb		
WP.1.C. Dataset low- grade mucosal inflammation alters gut peptide hormone release (approved as S66905)	ELISA data from plasma	N	D	Ν, Τ	.xls .txt	<100 MB	The Elisa software generates numbers of plasmal levels which are exported as xls or txt files	
WP.2.A. Dataset palmitoylethanolamide trial (approved as S65406)	Symptom questionnaires Quality of Life questionnaires Psychosocial co- morbidity questionnaires Food Frequency questionnaires	New	D	Т	Redcap file, .txt, .xls	<1GB	Questionnaires are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.	
	Personal data: sex, age, weight, length, medication, allergies, co- morbidities	New	D	Т	Redcap file, .txt, .xls	<1GB	Items are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.	
	Duodenal biopsies	N	P, D	Other: biopsies during endoscopy		slides, tissue blocks and .tif .czi	Histology slides from duodenal biopsies. Widefield images acquired from the microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.	

	Gene expression data	N	D	N/T		1-10kB 1- 100MB 50- 100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the
							TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Protein expression data	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Immunofluorescence microscopy images	N	D	I		5-20MB 10- 50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.
WP.2.B. Dataset corticotrophin releasing factor study (approved as S65020)	Duodenal biopsies	N	Р	Other: biopsies during endoscopy	physical	N.A.	Histology slides from duodenal biopsies

	Gene expression data	N	D	N/T	.txt, .xls, .png	1-10kB 1- 100MB 50- 100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Protein expression data	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Immunofluorescence microscopy images	N	D	I	.tif .czi	5-20MB 10- 50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in Imagel software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in Imagel software renders .tif files.
	Nutrient volume tolerance	N	N	N	.txt	10-20 MB	Text files of tolerated volume and associated satiation score
WP.2.C. Dataset obeticholic acid study (approved as S64643)	Symptom questionnaires Quality of Life questionnaires Psychosocial co- morbidity questionnaires Food Frequency questionnaires	New	D	Т	Redcap file, .txt, .xls	<1GB	Questionnaires are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.
	Personal data: sex, age, weight, length, medication, allergies, co- morbidities	New	D	Т	Redcap file, .txt, .xls	<1GB	Items are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.

Duodenal biopsies	N	P, D	Other: biopsies during endoscopy	physical, .tif .czi	slides, tissue blocks and .tif .czi	Histology slides from duodenal biopsies. Widefield images acquired from the microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.
Gene expression data	N	D	N/T	.txt, .xls, .png	1-10kB 1- 100MB 50- 100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
Protein expression data	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
Immunofluorescence microscopy images	N	D	I	.tif .czi	5-20MB 10- 50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.

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	ELISA data from plasma	N	D	N, T	.xls .txt	<100 MB	results from Elisa, Western blot for quantification of biological markers
WP.2.C. Human 3D enteroids (approved as S57826, S56978)	Phenotype of enteroids	N	D	T, N	.xls .tif	<1GB	
	Gene expression data	N	D	N/T	.txt, .xls, .png	1-10kB 1- 100MB 50- 100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Protein expression data	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Immunofluorescence microscopy images	N	D	1	.tif .czi	5-20MB 10- 50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.
WP.3.A. Dataset FODMAP elimination diet and reintroduction study (approved as S61692)	Symptom questionnaires Quality of Life questionnaires Psychosocial co- morbidity questionnaires Food Frequency questionnaires	New	D	Т	Redcap file, .txt, .xls	<1GB	Questionnaires are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.

age me alle	ersonal data: sex, ye, weight, length, edication, lergies, co- orbidities	New	D	Т	Redcap file, .txt, .xls	<1GB	ltems are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.
Du	uodenal biopsies	N	P, D	Other: biopsies during endoscopy	physical,	slides, tissue blocks and .tif .czi	Histology slides from duodenal biopsies. Widefield images acquired from the microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.
Ger	ene expression data	N	D	N/T	.txt, .xls, .png	1-10kB 1- 100MB 50- 100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
Pro dat	otein expression ata	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.

	Immunofluorescence microscopy images	N	D	1	.tif .czi		Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.
WP.3.B. Dataset MRI study with triggering FODMAP administration (approved as S66905, same number as peptide release study)	MRI file sets	N	D	I	MRI files	4.5 GB	DICOM, stored in Imaging Data Structure (IDS) format
WP.3.C. Dataset confocal laser endomicroscopy study (approved as S65735)	Symptom questionnaires Quality of Life questionnaires Psychosocial co- morbidity questionnaires Food Frequency questionnaires	New	D	Т	Redcap file, .txt, .xls	<1GB	Questionnaires are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.
	Personal data: sex, age, weight, length, medication, allergies, co- morbidities	New	D	т	Redcap file, .txt, .xls	<1GB	Items are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.
	Duodenal biopsies	N	P, D	Other: biopsies during endoscopy	nhysical	tissue blocks and .tif .czi	Histology slides from duodenal biopsies. Widefield images acquired from the microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.

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	Gene expression data	N	D	N/T	.txt, .xls, .png	1-10kB 1- 100MB 50- 100kB	Samples with reaction mix are transferred into 96 well plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficiency are saved as .png files The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Protein expression data	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.
	Immunofluorescence microscopy images	N	D	I	.tif .czi	5-20MB 10- 50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.
WP.3.D. Data set MRPGPRX2 study (also approved as S65735)	Protein expression data	N	D	N/T	.txt .xls	1-10kB 1- 100MB	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID laboratory in boxes with clear identification on shelves allocated to the research unit of Prof. Jan Tack.

	Immunofluorescence microscopy images	N	D	ı	.tir	5-20MB 10- 50MB	Widefield immunofluorescence images acquired with an Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in ImageJ software renders new .tif files. Confocal immunofluorescence images acquired with an LSM880 Zeiss microscope are saved as .czi files using Zeiss Black software. Processing in ImageJ software renders .tif files.	
		Calcium imaging movies	N	D	1	.pst .inf .vws .txt .pxp .xls	40-60MB 1- 100bytes 50- 250MB 1-25kB 0.1-5GB 10- 100MB	Live fluorescence microscopy image series generated using a calcium imaging technique are saved as outlook data files (.pst) in TillVision software with supporting technical metadata (.inf). Additional metadata are stored as .vws and .txt files. After analysis by lgor software, workspace files are saved as .pxp files, with results summarized in .xls files. The physical samples are discarded after analysis since the tissue is not suitable for further analysis anymore.
WP.3.F. Data set FUNDYSGWAS study (approved as S61548)	Symptom questionnaires Quality of Life questionnaires Psychosocial co- morbidity questionnaires Food Frequency questionnaires	New	D	Т	Redcap file, .txt, .xls	<1GB	Questionnaires are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.	
	Personal data: sex, age, weight, length, medication, allergies, co- morbidities	New	D	Т	Redcap file, .txt, .xls	<1GB	Items are filled out using the Redcap platform. Data can be extracted as .txt files which are converted into .xls files.	

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:

Not applicable

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 below)
- Yes, animal data (Provide ECD reference number below)
- Yes, dual use (Provide approval number below)

Reference to several ethical committee approvals (including GDPR questionnaire if applicable): S57826, S56978, S61548, S61692, S64291, S64643, S65020, S65406, S65735. S66905

Mouse experiments: licensed to Pieter Vanden Berghe (P110_2020; P033_2022; P018_2022)

Will you process personal data? 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)

General description of the kind of personal data that will be used and their handling:

All data belo will be used as pseudononimized data. The file containing the link between the unique study number and the patient or subject ID (as used in the electronic patient file) and the name of the patient or subject is password protected and stored on the secured server of the UZ Leuven. This file also contains the contact details including E-mail and telephone number.

Data collected as pseudonimized data:

Age, sex, weight, length, medication, allergies, co-morbidities, medical history, symptom severity and frequency, food intake, responses to questionnaires regarding quality of life and co-morbidity.

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.

• No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keepdata 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).

All protocols (docx.file) and accompanying result files (.xlsx,.tif files) containing the key to identify the experimental samples are available on a shared drive from our lab managed by the KU Leuven and/or UZ Leuven. Only members from the team have access to these folders.

All ethical documents are available on the shared drive from the research groups involved.

An overview of the samples stored in the biobank is available on the shared drive from our research group.

For the microscopic image data that will be recorded: recording parameters (powers, excitation and emission wavelength), dimensions, image type, bit-depth, pixel sizes and microscope settings, will be stored. Either in a metafile accompanying the data (with identical filename) or embedded in the tiff header.

The experimental protocols, stimulation settings, temperatures of the physiological experiments that will be performed during this projected will be described in detail in a lab book and referred in a ReadMe text file that will accompany the recorded data. Similarly for the processed and analyzed data, all parameters used to arrive to the results are stored within the image format.

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.

No

Metadata standards are typically not used within our lab group. We do have a minimal set of requirements that will be followed in order to ensure standardization and possibility to reinterpret and reuse the data when necessary and permitted.

For the microscopic imaging data we do adhere to metadata standards:

Images will be stored in *.ome tiff format, which enables storing a multitude of microscope and recording parameters. For the more experimental imaging paradigms for which actual changes are made to the instrumentation, the metadata will be stored in accompanying txt or csv files.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- ManGO
- Other (specify below)
- Sharepoint online
- Digital Vault
- Shared network drive (J-drive)

All generated data are stored on the shared network drive platforms of the KU Leuven and UZ Leuven that are only accessible to the members of the research teams (only for PhD, postdocs, technicians not for master students). Big files such as images are stored on the sharepoint online drives.

Microscopy data: All original recordings and their metadata will be stored in one copy on external harddrives, which will be labeled by projectname, subproject, experiment, data and experimenter initials. Since most of the images are highly experimental and explorative, there is no need to keep a copy of the original data. However, upon first analysis the images that are judged of sufficient quality to derive conclusive data, will be analysed as saved on the researcher's computer with a backup either on a local external harddrive or via the LUNA network. Exchange of data between will happen via the LUNA network, which keeps track of versions and assures safe backups. Within an FWO IRI project (FBI, Pieter Vanden Berghe co-promoter), we are investigating future overarching datastorage and datamanagement solutions based on the IRODS / ManGo pipelines.

How will the data be backed up?

• Standard back-up provided by KU Leuven ICTS for my storage solution

Backup is secured daily on servers of the University and the University Hospital.

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

Yes

All groups involved have sufficient data storage capacity available.

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

Only the PIs are authorized to give access to the members of his/her team to the shared drives of the KU Leuven and/or the UZ Leuven.

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

The costs are considered to be budgeted within the working cost items of the project.

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All 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

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

- Large Volume Storage (longterm for large volumes)
- KU Leuven RDR

Data will be stored on archive drives of the university.

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

These costs are considered to be budgeted within the work costs of the project and maintained for longer duration by the PIs after the end of the project.

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.

• Yes, as restricted data (upon approval, or institutional access only)

Anonimized data can be made available for further analyses in line with the terms of the ICFs and following advice from the relevant local ethics committees.

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

The anonimized data sets can be shared within the TARGID research unit or shared upon request. In such case, data will be available after signing a data sharing agreement

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.

No

no restrictive factors

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

Other (specify below)

A specific repository will be chosen after the publication strategy is known as some journal request specific repositories.

When will the data be made available?

Upon publication of research results

Only after publication of the research results in a peer-reviewed journal.

Which data usage licenses are you going to provide?

If none, please explain why.

• Data Transfer Agreement (restricted data)

Data usage licences will be discussed with LRD before any licences are granted. Similarly, when DTAs or MTAs are discussed, this will always be after consulting and collaborating with LRD.

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

• Yes, a PID will be added upon deposit in a data repository

Depending on the data repository and the type of data that would be made available, a unique identifier will be added to the data set.

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

If shipment of data or material is required by an other study group abroad, after approval the costs of drafting of MTA/DTA and shipment itself will be covered by the requesting party.

Exchange of microscopic imaging data can be done via BELNET and no extra cost.

Responsibilities

Who will manage data documentation and metadata during the research project? Researchers who generate the data Who will manage data storage and backup during the research project? Researchers who generate the data Who will manage data preservation and sharing? The PIs of the respective research groups involved. Jan Tack will take the lead. Who will update and implement this DMP? Jan Tack