DonoR-specific antilbodiES in cryo-bioPsIes and bRonchoAlveolar lavage fluid during rejecTIOn after luNg transplantation [Acronym: RESPIRATION]

A Data Management Plan created using DMPonline.be

Creators: Robin Vos, n.n. n.n.

Affiliation: KU Leuven (KUL)

Funder: KU Leuven (KUL)

Template: KU Leuven BOF-IOF

Principal Investigator: Robin Vos

Data Manager: Robin Vos, n.n. n.n.

Project Administrator: Robin Vos, n.n. n.n.

Grant number / URL: CELSA/23/034

ID: 203461

Start date: 01-10-2023

End date: 30-09-2025

Project abstract:

Survival after lung transplantation (LTx) is limited by chronic lung graft rejection.

Rejection diagnosis is currently based on histologic evaluation of lung tissue (biopsies, by bronchoscopic sampling) and assessment of antibodies directed against alloantigens (donor-specific anti-HLA antibodies, DSA) in blood, while bronchoalveolar lavage fluid (BALF) is used to rule out infection. Most centers therefore perform serial bronchoscopy (BALF and biopsies) and serum DSA (sDSA) measurements to monitor the transplanted lungs.

However, discrepancies between serological and histopathological findings are common, due to a “sponge effect”, whereby endothelial binding of circulating sDSA inside the vascular bed of the lungs (tissue-bound ‘graft’ DSA/gDSA) obscures detection of (unbound) sDSA in blood.

We therefore aim to **assess the presence of DSA within lung tissue (gDSA) and in BALF**, using prospectively collected biobanked lung samples from the Leuven and Prague Lung Transplant Programs.

We expect our findings may improve the diagnostic management of rejection after LTx.

Last modified: 11-12-2023

DonoR-specific antilbodiES in cryo-bioPsIes and bRonchoAlveolar lavage fluid during rejecTIOn after luNg transplantation [Acronym: RESPIRATION]

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: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Patient data	Clinical and demographic data associated with a patient	E	D	N, T	.ods .csv .xlsx .xls .docx .doc .pdf .txt .pzfx	<1GB	Not applicable
Biopsy data	Histologic data associated with a biopsy	E	D	N, T	.ods .csv .xlsx .xls .docx .doc .pdf .txt .jpeg .tiff .pzfx	<1GB	Not applicable
sDSA	Serum Donor-Specific Antibody data	E	D	N, T	.ods .csv .xlsx .xls .docx .doc .pdf .txt .jpeg .tiff .pzfx	<1GB	Not applicable
gDSA	Graft Donor-Specific Antibody data	N	D	N, T	.ods .csv .xlsx .xls .docx .doc .pdf .txt .jpeg .tiff .pzfx	<1GB	Not applicable
BAL DSA	BronchoAlveolar Lavage (BAL) Donor-Specific Antibody data	N	D	N, T	.ods .csv .xlsx .xls .docx .doc .pdf .txt .jpeg .tiff .pzfx	<1GB	Not applicable

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:

This project will use data previously obtained in other research projects (patient data, biopsy data, sDSA data). These data are stored on the access-restricted KU Leuven server of the BREATHE Lab, KU Leuven (GBW-0076_LTX), accessible by the PI and his designated collaborators. New data (gDSA, BAL DSA) will also be stored on the same server.

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)

Ethics approval for gDSA analysis in cryo-biopsies was already granted (S65867, CRYO-CARTA) as was approval for sDSA analysis within the scope of ongoing CLAD research by the PI (S51577, S57742).
All lung transplant recipients provide written informed consent at time of listing for lung transplantation to access and use their post-transplant clinical and biobanked data (including blood, BALF and lung biopsies) for clinical and scientific research purposes, per institutional protocol and in compliance with all applicable laws and regulations in both lung transplant centers, and research samples are stored in both transplant centers under local Biobank approval regarding ethics and biosafety issues (For KU Leuven BREATHE biobank: S63978). Transfer of samples from Prague to Leuven will occur under formal Material Transfer Agreement between both Institutions.

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)

Pseudonymized human subject data (S65867; S51577; S63978)

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- Yes

If data will be obtained of interest for valorization, IP restriction will be claimed. It is not clear from the start what novel data can be identified.

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.

- Yes

Material and Data transfer agreement and Research agreement between collaborating centers (University Hospitals Leuven/KU Leuven, Leuven, Belgium and Motol University Hospital, Prague, Czech Republic)

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 keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

Datafiles will be stored on an access-restricted KU Leuven server (J-drive: GBW-0076_LTX), in a project-specific source file, which enables logging of access, is back-uped on daily basis and alows for long-term storage.

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

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Shared network drive (J-drive)
- OneDrive (KU Leuven)
- Other (specify below)

Project-specific RedCap database to allow external imputation and storage of human data, from which datafiles are extracted which will be stored on Shared network drive (J-drive: GBW-0076_LTX) on KU Leuven server.

How will the data be backed up?

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

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

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

KU Leuven server is protected from unauthorized persons. Project-file access is restricted to the PI and his designated collaborators.

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

The costs are covered by BREATHE Lab (designated secured funding for data storage outside of the current 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

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

- Large Volume Storage (longterm for large volumes)
- Shared network drive (J-drive)

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

The costs are covered by BREATHE Lab (designated secured funding for data storage outside of the current 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)

Data can be obtained by researchers after request by the PI (R. Vos) or co-PI (B. Vanaudenaerde).

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

Scientific researchers can access the data after request and approval by the PI (R. Vos) or co-PI (B. Vanaudenaerde).

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

Please explain per dataset or data type where appropriate.

- Yes, privacy aspects
- Yes, intellectual property rights
- Yes, ethical aspects

IP only when applicable.

Where will the data be made available?

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

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

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.

- No

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

not applicable

Responsibilities

Who will manage data documentation and metadata during the research project?

PI (R. Vos), co-PI (B. Vanaudenaerde) and all designated researchers within the group that work on the project.

Who will manage data storage and backup during the research project?

PI (R. Vos) and co-PI (B. Vanaudenaerde)

Who will manage data preservation and sharing?

PI (R. Vos) and co-PI (B. Vanaudenaerde)

Who will update and implement this DMP?

PI (R. Vos) and/or co-PI (B. Vanaudenaerde)