# Development of a clinical decision support system for diagnosing acute rejection and graft failure after kidney transplantation

*A Data Management Plan created using DMPonline.be*

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**Project abstract:**

Multiple non-invasive biomarkers for acute rejection (T-cell mediated rejection, TCMR; antibody mediated rejection, ABMR) and allograft failure after kidney transplantation have been proposed. The predictive value of one biomarker will very likely never be sufficient to accurately diagnose rejection or graft loss. In this project we fill a methodological gap in the research literature by combining the longitudinal features of several biomarkers into one multivariate joint longitudinal transition model in order to predict ABMR, TCMR and long-term allograft failure. First, we evaluate the predictive value of the biopsy history, eGFR, proteinuria and donor-specific HLA antibodies for acute rejection on a European cohort and validate the model on a US cohort. Next, the algorithm will be extended by including the longitudinal features of the 8-gene blood mRNA biomarker developed at KU Leuven, of urinary CXCL9 and CXCL10 levels and of polyomavirus type BK viremia. The diagnostic algorithm will be interpretable and is hypothesized to guide the need for
performing biopsies to detect rejection better and earlier than the current clinical approach based on serum creatinine and proteinuria. In the third phase of the project, we will integrate these longitudinal models with a competing risk model for the prediction of allograft failure.

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# FWO DMP (Flemish Standard DMP)

## 1. Research Data Summary

**List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.**

| | | | | 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 |
| | | *Please choose from the following options:*<br>• Generate new data<br>• Reuse existing data | *Please choose from the following options:*<br>• Digital<br>• Physical | *Please choose from the following options:*<br>• Observational<br>• Experimental<br>• Compiled/aggregated data<br>• Simulation data<br>• Software<br>• Other<br>• NA | *Please choose from the following options:*<br>• .por, .xml, .tab, .cvs,.pdf, .txt, .rtf, .dwg, .gml, …<br>• NA | *Please choose from the following options:*<br>• <100MB<br>• <1GB<br>• <100GB<br>• <1TB<br>• <5TB<br>• <10TB<br>• <50TB<br>• >50TB<br>• NA | |
| TEMPLATE | kidney transplant database UZ Leuven | Reuse existing data | Digital | Observational | .cvs | <1GB | |
| OPTN | American transplant registry | Reuse existing data | Digital | Observational | .sas7bdat | <100GB | |
| CTS | European kidney transplant database | Reuse existing data | Digital | Observational | .txt | <100GB | |
| | | | | | | | |

**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:**

* TEMPLATE: doi: 10.1111/tri.13964
* OPTN: https://optn.transplant.hrsa.gov/data/about-data/optn-database/
* CTS: https://www.ctstransplant.org/

**Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes, human subject data

* TEMPLATE: approved by Ethics Committee of the University Hospitals Leuven (S64006)
* OPTN: the Health Resources and Services Administration, US Department of Health and Human Services provides oversight to the activities of the OPTN contractor. OPTN's registry studies are institutional review board exempt.
* CTS: approved by the Ethics Committee of the Medical Faculty of Heidelberg University (No. 083/2005)

**Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes

* TEMPLATE: data are pseudonymised. Via a personal identification number, patients can still be identified by the managing hospital when in need for data cleaning or additional collection. During data analysis, the patient is however not identifiable by the researcher.
* OPTN, CTS: fully anonymous data.

**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/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

* OPTN: raw data are available upon data request from the Organ Procurement and Transplantation Network.
* CTS: raw data are available upon request to the Collaborative Transplant Study in accordance with the consents of the patients, the participating transplant centers and registries.

**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

## 2. Documentation and Metadata

**Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).**

* TEMPLATE: within the excel file, an extra tab is included, describing all variables (definition, units of measurement, values). This data is stored on the KU Leuven Onedrive servers.
As our data are sensitive patient data, these will not be shared in a repository. Data can be made available to third parties via a Data Transfer Agreement. All contracts with third parties are managed by the KU Leuven legal department (LRD) or the clinical trial center of UZ Leuven.
* OPTN: keeps codebooks (definition, units of measurement, values) of all variables included in every dataset in separate excel files. Kept by the OPTN.
* CTS: keeps codebooks (definition, units of measurement, values) of all variables included in every dataset in separate text files. Kept by CTS.

**Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.**

- No

* TEMPLATE: additional excel tab with description all variables is in place.
* OPTN, CTS: codebooks are available upon data request.

## 3. Data storage & back-up during the research project

**Where will the data be stored?**

* TEMPLATE: stored on KU Leuven Onedrive (with automatic back-up procedures).
* OPTN: stored on Ultraviolet (HPC cluster at NYU Langone Health).
* CTS: stored by CTS.

**How will the data be backed up?**

* TEMPLATE: standard daily back-up provided by KU Leuven ICTS.
* OPTN: standard back-up provided by HPC team NYU Langone Health.
* CTS: backed up by CTS.

**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

* TEMPLATE: KUL Onedrive offers a standard of 2TB for each user, which is sufficient for this project.

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

* TEMPLATE: only the researchers working on the project can access the data.

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

No extra costs are expected on top of the provided standard storage space by the KU Leuven.

## 4. Data preservation after the end of the research project

**Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).**

* TEMPLATE: data will be preserved for 10 years according to KU Leuven RDM policy.
* OPTN, CTS: data will be preserved for 10 years.

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

* TEMPLATE: KU Leuven Onedrive.
* OPTN, CTS: kept by organisation itself.

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

Additional on the standard data storage infrastructure (Onedrive) provided by the KU Leuven, no extra costs for data preservation are expected.

## 5. Data sharing and reuse

**Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.**

- No (closed access)

* TEMPLATE: raw data are only accessible by researchers involved in the project. Data can only be made available to third parties via a Data Transfer Agreement. All contracts with third parties are managed by the KU Leuven legal department (LRD) or the clinical trial center of UZ Leuven.
* CTS, OPTN: raw data are available on request to the organisation.

Data will be available in the form of publications or other dissemination of scientific work.

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

* TEMPLATE: only researchers working on the project have access to the raw data.

**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 in the comment section per dataset or data type where appropriate.**

- Yes, Privacy aspects

* TEMPLATE: sensitive patient data. Raw data can only be shared with a DTA, according to GDPR regulations.
* OPTN, CTS: raw data requests should be made to the organisation.

**Where will the data be made available? If already known, please provide a repository per dataset or data type.**

* TEMPLATE: raw data cannot be shared.
* OPTN, CTS: raw data requests should be made to the organisation.

**When will the data be made available?**

Upon publication of research results. Data will only be available in the form of publications or other dissemination of scientific work.

**Which data usage licenses are you going to provide? If none, please explain why.**

* TEMPLATE: No data usage license will be provided. Raw data can be shared with third parties only via a Data Transfer Agreement. All contracts with third parties are managed by the KU Leuven legal department (LRD) or the clinical trial center of UZ Leuven.

**Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.**

- No

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

* TEMPLATE: costs of data sharing will be negotiated in the DTA.
* OPTN, CTS: costs of data sharing have to be discussed with the organisation.

## 6. Responsibilities

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

Maarten Coemans

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

Maarten Coemans

**Who will manage data preservation and sharing?**

Maarten Naesens

**Who will update and implement this DMP?**

Maarten Coemans