Plan Overview

A Data Management Plan created using DMPonline

Title: PARAAT

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Project Administrator: Maarten Tol

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Template: LUMC data management plan

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Project abstract:

In dit door het LUMC-geïnitieerde multicenter retrospectieve onderzoek wordt in kaart gebracht hoe vaak een pancreasresectie na pancreasletsel wordt uitgevoerd. In Nederland is dit nog niet eerder uitgezocht, op een studie bij kinderen na. Amerikaanse multicenter retrospectieve studie rapporteerde over 4% en 17% resecties bij American Association for the Surgery of Trauma-Organ Injury Scale Grade I-II pancreasletsels [Biffle, J Trauma Acute Care Surg 2021]. Data uit VS, Canada, Australië en Israel geven aan dat het aantal resecties toeneemt tot 77-84% bij graad III, 79% bij graad IV en 62-73% bij graad V [Byrge, J Trauma Acute Care Surg 2018; Biffle, J Trauma Acute Care Surg 2021].
Voor zover bekend is in Nederland 1 retrospectieve studie uitgevoerd naar behandeling van pancreasletsel, in dit geval bij kinderen. Hierin werd bij 121 kinderen 1 staartresectie en 2 pancreasreparaties uitgevoerd [Spijkerman, Eur J Trauma Emerg Surg 2021].
Bekend is dat de pancreasstaart relatief gezien meer Eilandjes van Langerhans bevat dan de rest van de pancreas. Een resectie van de pancreasstaart kan leiden tot een hogere kans op het ontwikkelen van Diabetes Mellitus. Het is mogelijk om eilandjes te isoleren uit de pancreas en deze terug te geven aan de patiënt, een autotransplantatie.
Dit onderzoek heeft als primaire doel om in kaart te brengen hoe vaak een pancreasstaartresectie wordt verricht en wat de kenmerken zijn van de patiënt ten tijde van de ingreep. Dit om in vervolgstudies te bekijken of voorspeld kan worden welke patiënten baat zouden hebben bij vroegtijdige transplantatie van de Eilandjes van Langerhans.
Om deze reden includeren we alle patiënten die tussen 01-01-2012 en 31-12-2021 via de spoedeisende hulp van een van de deelnemende centra zijn opgenomen met letsel aan het pancreas. Van deze patiënten worden de karakteristieken in kaart gebracht en details over de behandeling. Zie ook 3.5. Alleen informatie verzameld tijdens de reguliere klinische zorg wordt hierbij gebruikt.

ID: 153862

Start date: 02-08-2022

Last modified: 11-06-2026

PARAAT

I. General information

I.1 Name of researcher responsible for DMP

Maarten Tol

I.2 Department of researcher responsible for DMP

Internal Medicine, LUMC

I.3 ORCID ID of researcher(s) responsible for DMP

Maarten Tol: 0000-0001-7064-2947

I.4 Supervisor(s) of project, if applicable

Prof. dr. Inger Schipper

I.5 If applicable for your study or project, please provide:

If one or more numbers are not applicable for your study or project, please add '/ ' in the appropriate text box.

ABR number	/
METC number	/
EudraCT number	/
GMO number	/
CCD application number	/

I.6 If applicable: list the partner organisation(s) involved in your study or project.

Amsterdam UMC, Radboudumc, UMC Utrecht, MUMC+, ErasmusMC, UMC Groningen, Isala ziekenhuis, Zuyderland MC, NWZ Alkmaar, Medisch Spectrum Twente, Elisabeth-TweeSteden Ziekenhuis, OLVG, Haaglanden MC, St. Antoniusziekenhuis

II. About this DMP

II.1 Date of first DMP version

2024-06-12

II.2 Consulted LUMC data stewardship expert(s)

Note: This field is a requirement for most funders. DMPs will only be reviewed by funders after you have consulted one of the LUMC data stewardship experts.

To request for review: see section 6.

The LUMC has both local DMP supporters at the departments and central data stewardship experts, both specialized in clinical data stewardship and translational and fundamental research. This DMP was reviewed by:

Name	/
Telephone number	/
E-mail address	/
Date of consultation (dd/mm/yyyy)	/

Name	
Telephone number	
E-mail address	
Date of consultation (dd/mm/yyyy)	

II.3 Changes made to an earlier version of this DMP

Part of DMP	Date of change (in dd/mm/yyyy)	Question number(s)	Adaptation(s) made
I. General information			
II. About this DMP			
1. Data collection			
2. Data documentation			
3. Data storage during your study/project			
4. Archiving data within the LUMC			
5. Data publication & reuse			

Remarks:

1. Data collection

1.1 What type of study or project will you conduct?

- Study/project with human participants: observational study

We use data collected in regular clinical care over a period of 10 years, which are all in the past.

1.2 Is your informed consent form according to the *LUMC-based CCMO model form*?

- My study has an exemption from asking informed consent. Please give details in the 'additional information' field
- No, please explain in the 'additional information' field why you don't use this standard

In all hospitals, we aim to use an opt-out procedure: participants are sent a letter that asks them to actively withdraw their consent if they do not want to participate by returning a form. In most hospitals, this opt-out procedure is agreed upon by the local research committee. In some hospitals, this is not the case, in that case we argue to not ask for consent at all, as 1) we may lose too many patients by not getting into contact with them, 2) introducing bias, 3) for all 300 patients it is too much work.

We use a version of the following text in Dutch:

Wij zijn van mening dat het vragen van uitdrukkelijke toestemming in dit geval niet in redelijkheid kan worden verlangd, omdat het benaderen van de groep patiënten door de grote omvang van de groep een onredelijke inspanning vergt. Voor dit multicenter onderzoek worden ruim 300 patiënten geïncludeerd die in de periode 01-01-2012 en 31-12-2021 zich hebben gepresenteerd op een SEH met traumatisch letsel van het pancreas. Deze blijven over het algemeen kort onder controle bij de behandelaar. De meeste patiënten zullen geen behandelrelatie meer hebben in het ziekenhuis van primaire opvang of behandeling. Hierdoor zal het regelmatig voorkomen dat de adresgegevens niet meer kloppen omdat het patiënten van lang geleden betreft. Daarnaast is er een substantieel risico op een niet te corrigeren vertekening van resultaten, die de resultaten van het onderzoek onbetrouwbaar zouden maken (consent bias). De incidentie van laaggradige pancreasletsels is groter dan van hooggradige pancreasletsels. Over het algemeen worden laaggradige pancreasletsels vaker conservatief behandeld en zijn er minder lange termijneffecten te verwachten. Het is onze verwachting dat patiënten die (nog) geen nadelige gevolgen hebben ervaren minder snel moeite zullen doen om toestemming te geven. Dit zal met name gelden voor jongere patiënten. Hierdoor kunnen de resultaten vertekend raken door middel van consent bias. De resultaten van dit onderzoek genereren nieuwe wetenschappelijke inzichten die geldend zijn voor een populatie groter dan de directie onderzoekspopulatie. Traumatisch pancreasletsel komt niet vaak voor en de populatie waaruit we kunnen putten is klein. Voor dit onderzoek willen we daarom alle patiënten met traumatisch pancreasletsel includeren. Deze redenen samen maken dat we willen verzoeken om in het geval de opt-out procedure niet gevolgd kan worden, ook geen informed consent procedure te hoeven volgen.

1.3 Describe what is mentioned in the informed consent about data sharing and re-use.

Data sharing and re-use are not mentioned in the opt-out letter.

1.4 How do you ensure that participants, who have withdrawn their informed consent, are

removed from the data and thus are not available for reuse? Do you have a procedure in place for this?

Directly after the local principal investigator receives a letter indicating withdrawal of informed consent, the Castor record is adapted to fit the new 'consent status'.

1.5 Describe what you will do to pseudonymize or anonymize your data: How will you pseudonymize, where will identifiable data be stored and who is responsible for managing this data during the study or project?

All participants are given a randomly allocated three-digit code, e.g. PARAAT_123. These codes do not reflect the hospital of inclusion or any patient data.
The identifying list is stored by the local principal investigator, preferably in a study list in the electronic health data software. Maarten Tol is responsible for managing overall data, local PI's are responsible for their own identifying list.

1.6 Which data assets do you create during your study/project?

We use clinical data.

1.7 Is one of the outcomes of your project software? You can think of scripts, modules, tools, an app, a analysis pipeline etc.

- No

1.8 How will you collect, create and/or capture your data? Briefly describe what you need to collect or access the data. Think about protocols, tools, equipment, hardware etc.

Clinical data will be collected from the local electronic patient file software system.

1.9 What is the size and format of your digital data? And what software do you need to collect, process and analyse these data sets?

** if you don't know the size estimate, you can give a range: < 1 GB, 1-10 GB, 10-100 GB, 100 GB - 1 TB, > 1 TB*

Stage	Specification of data set	Software choice	File format	Data size estimate*
Data collection	1. clinical data	EPD data in CastorEDC	not applicable	not applicable
Raw data	1	Export to R	.sav/.csv	<1 gb
Processed data	1	R	.sav/.csv	<1 gb
Results	1	R, microsoft word	.spv/.csv/.docx	<1 gb
Other...				

1.10 What is the estimated *total size* of the digital data you generate in this study/project? You can use the 'additional information' field for more details.

- 0-10 GB

1.11 Are there any non-digital data or outputs that the project will generate?

- No

1.13 Will the project use existing data?

- Yes

1.14 What kind of existing data will you re-use?
Please explain in the 'additional comment' field: the owner, origin and type of existing data

- Data from an existing external cohort, biobank or registry
- Care data from HiX or other electronic health records (EHR)

External registry: dutch national trauma registry, generic overview of national data regarding the same research question.

1.15 Is there an agreement or other legal document for the use of existing data?

- Yes

1.16 What kind of an agreement do you have for the use of existing data?

- Data transfer agreement (DTA/DSA/DUA/MTA)

2. Data documentation

2.1 How will files and folders be named and structured?

All datafiles will get a version number, clear labelling and date.
We will include a data dictionary with the data files.

2.2 How will versions and changes be handled?

If a new version is created, the number will increase with a decimal point (for small changes) and to the next full point for big changes.

2.3 Business metadata: What general metadata (standard) will be used to describe all data sets in your study/project ?
Please describe briefly how you will create this.

- Dublin Core

2.4 Technical metadata: Which field-specific metadata standard(s) will be used to describe and/or standardize data and variables? Please describe briefly how you will create this.

We will use SNOMED codes where possible. We will create a data dictionary in Excel, containing the variable names, labels, types, and options for all variables in the dataset. This dictionary will be stored in the study documentation and updated if needed. For Castor data, the data dictionary is exported from the structure in Castor and stored in the study documentation.

2.5 What supporting information and/or documentation will you create to enhance understanding of the data? Please describe briefly what is needed for peers to understand, work and/or reproduce the data.

The study protocol will be stored with the data.
A data dictionary (code book) will be available for the questionnaires and clinical data. It will be added after export of the data from Castor.

All syntaxes used in data cleaning and analysis (including annotation describing the goal of processing steps) will be stored to facilitate replication.

A readme.txt with a list of all available files and a description of their contents will be created at the end of the project, before archiving the data. We will also include the necessary software and tools needed for reuse and state what the conditions were of the data sharing agreements signed with all parties.

2.6 Please tick the box to confirm that you are aware of and adhere to the applicable rules and codes of conduct for your study or project:

- **General**
  - **VSNU Code of Conduct for Research Integrity**
  - **LUMC data management guidelines**
  - **LUMC privacy policy**
- **Human research:**
  - **General Data Protection Regulation (GDPR; in Dutch: AVG)**
  - **Medical Treatment Contracts Act (In Dutch: WGBO)**
  - **Medical Research Involving Human Subjects Act (In Dutch: WMO)**
  - **Quality Assurance for Research involving Human Subjects**
  - **Code of Conduct for Medical Research (e.g. GCP)**
  - **Code of Conduct Responsible Use of Human Tissue**
- **Non-human research:**
  - **Experiments on Animals Act**

Please add an explanation when needed in the 'additional information' field.

- I'm aware of and adhere to the rules and codes of conduct that are applicable for my study.

2.7 Indicate which permits you will acquire for your study and add an explanation when needed in the 'additional information' field:

- Report the collection of (in)directly identifiable (research) data to the Data Protection Officer
- Letter of non-objection METC

3. Data storage during your study/project

3.1 Where will you store the different parts of your digital data? Please describe the storage location for each dataset that you defined in the table in question 1.9. Examples of storage options are given in the guidance.

Data set/type	Storage option
Results and figures	I-drive
Documentation	I-drive
Key files	Data Safe, EHR
Clinical Data	Castor EDC, exports in Datasafe

3.2 Please describe how backup and availability are guaranteed for each part of your data during the study/project.

Backup policy for LUMC network drives:
Every day a copy is automatically made of any changed files on the I and J disks . A full backup of all data is made once per week. IT&DI also makes monthly and quarterly backups so that earlier data can also be restored if necessary. DataSafes are also included in the LUMC backup policy. We can restore files up to four weeks ago from I and J disks (including DataSafe) and for older versions we need to contact the IT helpdesk.

Microsoft Office 365 guarantees file availability and provides a roll-back to a version up to a month earlier.

Castor EDC backups are made four times a day and stored at another geographical location by Castor. The backup files are kept for fifteen days. Reserve copies can be restored but this might add additional costs.

3.4 How will access to data be managed during the project?

Please specify for each storage device the tools and procedures that you use to ensure that only authorized persons have access to data. Outline roles and responsibilities for all activities during your project, e.g. data capture, metadata production, data quality, storage and backup. For collaborative projects you should explain the coordination of data management responsibilities across partners.

The coordinating researcher (Maarten Tol) will have full access. The local principal investigators only have access to their own data stored at their own hospital.
The principal investigator of the study (Inger Schipper) will also have full access. Medical student Samantha Scharringa will help collect the data, she will also have full access.

3.5 Do you have a plan or SOP for quality control of your data? Please explain briefly in the 'comment area'.

- No

3.6 Do you expect costs for storage and data management during the study or project?

- No

4. Archiving data within the LUMC

4.1 Which parts of your data will you select for long-term archiving? Please motivate why you would not archive (parts of) your data.

The raw, cleaned and analyzed data, just like the manuscript will be selected for long-term archiving.

4.2 What will you do to prepare your data for archiving within the LUMC? Describe how you intend to meet LUMC requirements.

We will store them with data that helps to identify what we did (e.g. codebook).

4.3 Will there be extra costs for this preparation?

- No

4.5 How long must your data be preserved? Please explain briefly in the 'additional information' field.

- Human research WMO/non-WMO: ≥ 15 years

4.6 Are there any requirements regarding the disposal of data?

- No

4.7 What are the requirements regarding the disposal of these data?
Describe how you will dispose of the data: how you will get approval, what people and/or tools you need, etc.

N/A

4.8 How will you ensure data and/or metadata findability and availability within LUMC for the long term?

My department has set up an overview of closed research projects. The department data steward is responsible for archiving data in a dedicated folder. The procedure and responsibilities are outlined in the departmental data stewardship SOP, which can be found in Zenya.

4.9 Do you have costs associated with long-term storage of your data?

- No

5. Data publication & reuse

5.1 Which parts of your data(sets) will you select for publication?

As of the current Data Sharing Agreements, there are no plans to make data(sets) available for publication.

5.2 Are there any restrictions placed on sharing/reuse of some/all of your data due to one or more of the following options? Briefly explain the restrictions.

- Research agreement

5.3 Will you publish your data open access or with restricted access?

- I will not publish my data

5.6 Please explain your reasons for not publishing your data.

As of the current Data Sharing Agreements, there are no plans to make data(sets) available for publication.

5.9 Where will you publish your (meta)data?

- I will not publish (meta)data outside LUMC

5.17 Who is responsible for your data and has authority to grant (additional) access to your data after finishing the study or project (e.g. for the long term)?

- PI of the study/project

6. Review request

6.1 Please tick the appropriate box.

- No review needed