Plan Overview

A Data Management Plan created using DMPonline

Title: Longitudinal (vision-related and general) Quality of Life of patients with uveitis in a tertiary care center

Creator: Martine Lamme

Principal Investigator: Martine Lamme

Data Manager: Martine Lamme

Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

The treatment of uveitis, which often involves long-term and aggressive measures, can have a great impact on the quality of life of a patient. Previous cross-sectional research on this subject found a profound negative impact of treatment on perceived quality of life, but does not follow up on the included patients. The Infection and Immunity cohort (I&I) of University Medical Center Utrecht aims to shift from ‘organ-based’ to more personalized treatment. This study proposes to determine the vision-related quality of life of patients with uveitis at inclusion in the I&I cohort and after at least one year of treatment. Furthermore, this study aims to assess the possible causes of changes perceived by patients.

ID: 68995

Start date: 01-02-2021

End date: 13-08-2021

Last modified: 26-05-2021

Copyright information:

The above plan creator(s) have agreed that others may use as much of the text of this plan as they would like in their own plans, and customise it as necessary. You do not need to credit the creator(s) as the source of the language used, but using any of the plan's text does not imply that the creator(s) endorse, or have any relationship to, your project or proposal

Longitudinal (vision-related and general) Quality of Life of patients with uveitis in a tertiary care center

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	N/A
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	N/A
Acronym/short study title	FU-QoL
Name Research Folder	xx-xxx_FU-QoL
Name Division	Heelkundige Specialismen
Name Department	Ophthalmology
Partner Organization	N/A
Start date study	Feb 2021
Planned end date study	August 2021
Name of datamanager consulted*	Dax Steins
Check date by datamanager	06-05-2021

1.2 Select the specifics that are applicable for your research.

- Monocenter study
- Use of Questionnaires
- Non-WMO
- Retrospective study

The Infection and Immunity Cohort (I&I) started in 2016 at University Medical Center Utrecht (UMCU). The goal of this cohort is to make a shift to personalized treatment rather than ‘organ-based treatment’. All (existing and new) patients who have been diagnosed with a (chronic) immunologic disease have been asked to enter the cohort. Among other more general questionnaires, the National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) was obtained from all patients with uveitis when they enter the cohort. For this retrospective study, we shall only include patients registered under the broad consent of this cohort (METC 16-011/C) who have filled in the NEI VFQ-25 questionnaire after one year.

2. Data Collection

2.1 Give a short description of the research data.

Research Objective: To determine the difference in perceived (vision-related and general health-related) Quality of Life in Uveitis patients, before and after, at least one year of using medication.

Study population: Patients with Uveitis, who are included in the I&I cohort, UMC Utrecht, the Netherlands.

Dataflow: For this study we shall reuse pseudonymized data from the I&I cohort. This includes the NEI VFQ-25/NL questionnaire (on paper, filled in twice by the patient). This data is entered into Castor and then exported to an Excel file (.xlsx). Additional patient data (which falls under this cohort) is derived from HiX (visual acuity, medication use, aetiology of uveitis, duration of uveitis). This data is entered into Castor and then exported to Excel. All analyses will be performed in SPSS.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	100	EPD (HiX)	Excel	Quantitative	.xlsx	0-10 GB
Human	100	NEI VFQ-25/NL Questionnaire	Castor EDC	Quantitative	.xlsx	0-10 GB
Human	100	METC 16-011/C	Castor EDC	Quantitative	.xlsx	0-10 GB

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospective study, we reuse pseudonymized data from the Infection & Immunity Cohort (METC 16-011/C)

2.3 Describe who will have access to which data during your study.

Type of data	Who has access
Pseudonymized data	Research team, datamanager
Direct identifying personal data	Research team, datamanager
Key table linking study specific IDs to Patient IDs	Research team, Datamanager

2.4 Describe how you will take care of good data quality.

1. Experimental data from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: Castor. In the eCRF, skips and validation checks are built in. Data collection will be frozen before analysis.

#	Question	Yes	No	N/A
1.	Do you use a certified Data Capture Tool or Electronic Lab Notebook?	X		
2.	Have you built in skips and validation checks?	X		
3.	Do you perform repeated measurements?	X		
4.	Are your devices calibrated?			X
5.	Are your data (partially) checked by others (4 eyes principle)?		X	
6.	Are your data fully up to date?	X		
7.	Do you lock your raw data (frozen dataset)	X		
8.	Do you keep a logging (audit trail) of all changes?	X		
9.	Do you have a policy for handling missing data?	X		
10.	Do you have a policy for handling outliers?	X		

2.5 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Data capture tool license fee			X
2.	Storage	X		
3.	Archiving	X		

1. License fee for using Castor

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

UMC Utrecht is and remains the owner of all collected data for this study. The data is collected in a relatively large patient group and can be very valuable for further, broader studies.

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

I will process personal data. I have consulted the division datamanager and I do not have to complete a full DPIA. I therefore fill out this DPIA light and proceed to 3.1.

3.1 Describe which personal data you are collecting and why you need them.

Which personal data?	Why?
Baseline characteristics (such as gender, age, location of disease, duration of disease)	To describe the study population
Clinical data (such as Best Corrected Visual Acuity, medication use, BMI, blood values)	To answer the secondary research question
Questionnaire data (answers to NEI VFQ-25/NL)	To answer the primary research question

3.2 What legal right do you have to process personal data?

- Other, please explain

Patients gave broad informed consent when entering the I&I cohort.

3.3 Describe how you manage your data to comply to the rights of study participants.

Right of Access	Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias.

The data are pseudonymized/anonymized and the key-linking table to re-identify patients is saved in a secure research folder with separate privileges determined by the relationship to the patient.

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal

data.

1. We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.
2. We make use of a certified Electronic Data Capture (EDC) tool (Castor). To send surveys, email address will be used in the EDC, but this is encrypted for the users in such a way that users can send emails to subjects without seeing the actual email address. No personal data other than email address will be used in the EDC.

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

We will not transport any personal data outside the UMCU network drives.

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. We will need < 50 GB storage space, so the capacity of the network drive will be sufficient. Paper questionnaires will be stored safely in a locked cabinet in a locked room in the UMC Utrecht.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

For the data collected in Castor, we have a data dictionary that's automatically created when a data export takes place. We do not use metadata standards yet.

5.2 Describe your version control and file naming standards.

We will distinguish versions by using the date, for example ddmmyyyy_documentname_v1.0_initials

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

Research data will be collected in an Excel spreadsheet / Castor and imported for statistical analysis in SPSS Statistics 25. The statistical analysis procedure will be explained further in a (future) publication of the study.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The data package will contain: the raw data, the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names, and a 'read_me.txt' file with an overview of files included and their content and use.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

Data and documentation needed to reproduce findings from this non-WMO study will be stored for at least 15 years.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. When the UMC Utrecht repository is available, the data package will be published here.

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

I do not yet have a PID. If the research were to be published or publicly archived, we will update this as soon as possible.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

The research data might be of interest for other researchers in longer follow up projects or other projects regarding quality of life.

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

- No, all data generated in this project will be made publicly available without any restrictions

To be determined.

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

To be determined.

8.4 Describe when and for how long the (meta)data will be available for reuse

- Other (please specify)

To be determined.

8.5 Describe where you will make your data findable and available to others.

To be determined.