Plan Overview

A Data Management Plan created using DMPonline

Title: Validity of web-based visual acuity in uveitis

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Template: UMC Utrecht DMP

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Validity of web-based visual acuity in uveitis

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)*	
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	
Acronym/short study title	EASEE_UVE
Name Research Folder	xx-xxx_EASEE_UVE
Name Division	DHS
Name Department	Ophthalmology
Partner Organization	N/A
Start date study	
Planned end date study	
Name of datamanager consulted*	Dax Steins
Check date by datamanager	15-01-2021

1.2 Select the specifics that are applicable for your research.

- Monocenter study
- Non-WMO
- Retrospective study

2. Data Collection

2.1 Give a short description of the research data.

Objective: Determining the reliability of a web-based visual acuity test in patients with uveitis.
Study population: Patients included in the registry ‘Ocular inflammation, METC 17-363’ who performed the web-based visual acuity test during the COVID-19 pandemic.
Data from April 2020 till September 2020 will be reused.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Humans	62	EPD (HiX) Easee (HiX)	Excel	Quantative	.xlsx	0-10GB

The web-based visual acuity test is incorporated in the EPD of the UMCU. See 'data handling' in the study protocol.

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospective study, we use data from HiX. For this study, it is not possible to get a pseudonymized dataset (e.g. from the RDP), because many variables are noted in the 'free text' of the anamnesis at the appointment. These variable need to be interpreted and seperated in different tables. It is also hard to link the right anamnesis to the vision test in the portal.

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

Type of data	**Who has access**
Direct identifying personal data	Research team with care relationship to patient, Datamanager
Key table linking study specific IDs to EPD Patient IDs (personal data)	Data manager and research team
Pseudonymized database in Excell	Research team, Datamanager

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

#	**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.	Time of datamanager	X		
2.	Storage	X		
3.	Archiving	X		
4.				
5.				

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.

An agreement on the intellectual property rights is laid down in the investigator initiated study agreement between the UMC Utrecht and Easee BV.

"The parties shall jointly own the results arising directly from the clinical studies. All intellectual property rights and know how owned by or licensed to any of the parties as defined below shall remain the property of the party or its licensor:

UMCU:

- Patient reported outcomes
- Patient selection
- Interpretation of data on pre-operative comorbidities influencing visual acuity results (i.e. visual acuity, adverse events)

Easee B.V.:

- Know how on how the technology will need to be technically integrated into existing IT infrastructure and data storage, such as API's, data formats and security protocols
- Expertise and know how on user experience and user interaction to ensure users are performing the tests according to the intended use and minimize the risks of misuse, abuse and/or suboptimal user experience
- Expertise and assistance in quality assurance and quality control allowing for use of the technology accord to relevant standards and regulations
- Insights and data on the user experience and results in various demographic groups and use cases encountered during user test sessions and the use of the product outside of the study."

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

We will use direct identifying data from the EPD. I have checked the full DPIA checklist 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?
EPD patient ID	To collect clinical data from the EPD
Study demographics	To describe the study population
Medical history of the eyes	To see if there is a correlationship between the medical history and the outcome of the visual acuity test.
Characteristics of uveitis	To see if there is a correlationship between the characteristics and the outcome of the visual acuity test.
Results from manifest and online visual acuity test	To answer the study question

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

- Other, please explain

Broad-specific informed consent. "Ocular inflammation registry 17-363''

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

We use broad informed consents where patients approve the use of clinical data by others than their treating physicians. The data is captured in Excel pseudonymized and the key (Excel ID and patient ID) is safed in a secured folder of the division.
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.

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

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.

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

Not applicable, data will not be transported outside of UMCU.

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 dossiers will be stored safely in a locked cabinet in a locked room in the UMC Utrecht. A project specific procedure is in place for access to the paper dossiers. Documentation of this procedure is stored in the Research Folder Structure.

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.

When importing the data from Excel to SPSS, the codebook is automatically generated from the column names. I will adapt the codebook to ensure it is understandable for everyone.When analysing in SPSS, every step will be safed in syntaxes, with the addition of the date.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version. Every month, we will move minor versions to a folder OLD. The major versions will be listed in a version document (projxVersDoc.txt), stating the distinguishing elements per listed version.

6. Data Analysis

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

I have written an analysis plan in which I state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan is stored in the project folder, so it is findable for my peers. During the research metadata will be generated, so peers will be able to repeat the analysis.

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 syntax to process the data, the syntax 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.

To be determined

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

To be determined

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.

To be determined

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