Plan Overview

A Data Management Plan created using DMPonline

Title: RESCUE-ESR3.10

Creator: Saeed Arbabi

Principal Investigator: Saeed Arbabi, Dr. Peter Seevinck

Data Manager: Saeed Arbabi

Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Osteoarthritis is a major cause of disability worldwide. With an ageing population that becomes more obese the life-time risk of getting osteoarthritis is estimated at 25-40%. Pharmaceutical companies are actively searching for Disease Modifying OsteoArthritis Drugs (so-called DMOADS), though appropriate outcome measures that can identify patient benefits from a specific therapy are not available yet. New non-invasive imaging strategies that specifically address the modifying aspect of osteoarthritis are crucial to create a breakthrough for pharmaceutical companies to find new drugs and to guide clinical implementation in finding the right patient for the right therapy and subsequently monitor treatment. We think that the interaction of bone and cartilage in the joint plays an important role in selected patients (bone-phenotype) and that in another subgroup the vasculature is important in the development and progression of osteoarthritis (vascular phenotype). We will apply dedicated MRI sequences and spectral CT to image various aspects of knee osteoarthritis in order to grade the disease and find early markers to predict disease progression. Machine/Deep learning techniques will be used to provide detailed quantitative images that can be deduced from the complex-valued imaging data. Subsequently, machine learning algorithms will be used to translate these images in clinically applicable information regarding patients' phenotype and disease progression. Although sophisticated image analyses have been used previously to improve imaging of osteoarthritis, applications of machine learning algorithms to make both detailed images and clinical predictions for osteoarthritis is novel. With deep learning algorithms applied to imaging data we expect that complex interactions between subtle cartilage, bone, vascular and/or synovial tissue alterations can be identified as possible predictors for disease progression. The current concept reaches far beyond current image interpretation and it is anticipated that the method can be used to guide new therapeutic interventions, which will likely be different for different subsets (phenotypes) of patients. The project will lead to new MRI and CT based methods for imaging of osteoarthritis and vascular disease as potential predictors for disease progression, thereby creating a potential breakthrough in osteoarthritis research and care.

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Copyright information:

RESCUE-ESR3.10

1. General features of the project and data collection

1.1. Please fill in the table below. When not applicable, please fill in NA.

DMP version	23
ABR number	NA
METC number	NA
DEC number	NA
Acronym study title	Deep Learning Imaging to Value and Supervise Osteoarthritis Progression
Name Research Folder	RESCUE-COFUND_DMP_ESR3_10_Sept2019_v1_Arbabi
Name Division	Surgical Specialties & Imaging
Name Department	Orthopedics
Partner Organization	
Start date study	14-03-2019
Planned end date study	14-03-2023
Check date by datamanager	

1.2 Select the specifics that are applicable for your research (more than one option possible). If necessary, add text in the additional comment area.

- Multicenter study

Data is acquired as part of the TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.

2. Data Collection

2.1 Give a short description of the data for your research, including

- **the source of the data**
- **what tools you use for Data Capture**
- **the type of data, the size of the data**
- **the format of the data**

fully anonymized MRI and CT/PET images acquired in a study over time

Study subjects	Data Source	Data Capture Tool	File Type	Volume (records, MB, GB, TB..)	Format
Human	experimental data from human study	Medical Imaging device	DICOM data	around 20GB	dcm

2.2 Do you reuse data from other researchers or from the EHR?

- Yes (please specify)

We use anonymized data from TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.

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

Type of data	Who has access
Anonymized Imaging data	PI, research team

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

NA
Datasets used in our study are acquired, managed and anonymized by other research groups.

2.5 Specify costs involved in managing and storing your data.

NA
Datasets used in our study are acquired, managed and anonymized by other research groups.

2.6 State if intellectual property rights (IPR) are applicable on your data collection and state which agreements will be or are made.

NA
Datasets used in our study are acquired, managed and anonymized by other research groups.

3. Legislation/ Data Protection Impact Assessment

Will you be using personal data from the EPD, DNA, body material, images or any other form of personal data as described above?

1. **No, go to 4.1**
2. **Yes, go to next question**
3. **I am not sure, go to next question**

Answer = 1 -> skip this section and go to next question
Answer > 1 -> fill in this section and check with your datamanager (read guidance!)

Yes, we're using medical image data acquired as part of the TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.

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

Imaging data	

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

- An authorized datamanager processes care data for reuse on behalf of his/her function and I will receive pseudonimized

research data, so I will not ever see or process direct personal data myself

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

The data *are pseudonymized and the linking table to personal data is saved. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data.*

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

data are acquired as part of the TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study. read access is only given to authorized people on RIA.

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

RIA server is used to access the data.

4. Data Storage and Backup

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

ria.ds.umcutrecht.nl
we're using medical image data acquired as part of the TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study, that are put on RIA server.

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

we're using medical image data acquired as part of the TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study. Backup and all management strategies are taken by responsible research groups.

5. Metadata and Documentation

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

Data, metadata management are taken care of by other research groups responsible for the study.

5.2 Describe where you registered your research project, which standards you use for filenames and how you keep track of versions.

Project information can be found in the protocol and in this DMP for the original projects. (TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.)

6. Data Analysis

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

I will make an overview of datasets and analysis scripts, such that it is fully clear how the statistical analysis is performed. Peers will be able to repeat the analysis based on my overview.

7. Data Preservation and Archiving

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

Availability of data is stated on the projects DMPs. (TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.)
Source codes of the research can be published online on Github after UMC department consent.

7.2 Describe which archive or repository (include the link!) you will use for long-term archiving of your data collection once the project has ended and whether the repository is certified.

Availability of data is stated on the projects DMPs. (TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.)

7.3 Give the persistent identifier (the ISBN for your data) that you will use as a permanent link to your data collection.

I will update this plan as soon as I have the code.

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.

reuse of data is stated on the projects DMPs. (TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.)

8.2 Describe the related information that will be available with the data.

NA

8.3 Describe when the data or metadata will be available, under which criteria and for how long.

Availability of data is stated on the projects DMPs. (TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.)

8.4 Describe where you will make your data findable and available to others. A link to the data repository or a link to the data should be provided.

Availability of data is stated on the projects DMPs. (TOFA PREDICT clinical trial, ZODIAK study, EXTEND UP study, and APPROACH study.)