
RESCUE-ESR3.10

A Data Management Plan created using DMPonline

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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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1. General features of the project and data collection

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	

- Multicenter study

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

2. Data Collection

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

- Yes (please specify)

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

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

NA

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

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3. Legislation/ Data Protection Impact Assessment

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

Imaging 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

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.

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.

RIA server is used to access the data.

4. Data Storage and Backup

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.

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

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

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

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

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.

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

8. Data Sharing Statement

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

NA

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

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