# The role of cerebral imaging in the diagnosis, management and prognosis of possible non-convulsive status epilepticus

*A Data Management Plan created using DMPonline.be*

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**Project abstract:**

Patient, problem or population: The diagnosis of non-convulsive status epilepticus (NCSE) is currently based on electroclinical data. The current gold-standard EEG criteria for the diagnosis of NCSE are known as the "Salzburg criteria". EEG patterns, which belong to the interictal-ictal continuum (IIC) only allow a diagnosis of possible NCSE. In these cases, it is recommended to treat with antiseizure medication (ASM), and confirm a diagnosis of NCSE only if clinic and EEG improves. This approach is problematic since patients who are not in NCSE will receive unnecessary treatment with potential side effects, and absence of response does not exclude refractory NCSE. In addition, it is unclear what a trial with ASM involves and over what time period this should be evaluated. In our study, we will select this group of patients with possible NCSE.
Intervention: We will obtain 18F-fluorodeoxyglucose positron emission tomography (FDG-PET), arterial spin labeling (ASL) MR imaging, and CT perfusion (CTP). We will determine which IIC patterns are associated with hyper-metabolism/-perfusion, which is an argument for ongoing ictal activity, and hypo-metabolism/-perfusion, which is consistent with an interictal state.

Deliverable 1. Cerebral imaging algorithm in possible NCSE.
Deliverable 2. New diagnostic criteria of NCSE based on cerebral imaging.
Deliverable 3: Guidelines for best management of
possible NCSE based on cerebral imaging.
Deliverable 4. Determination of the prognostic role of cerebral imaging in possible NCSE.

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## Application DMP

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**Questionnaire**

**Describe the datatypes (surveys, sequences, manuscripts, objects … ) the research will collect and/or generate and /or (re)use. (use up to 700 characters)**

The research will collect following datatypes:
- Medical information of participants gathered based on information within the medical record and clinical examination.
- Imaging information (DICOM files) of MR-FDG-PET and CT files.
- Electrographic information (EDF files) gathered from clinically indicated video-EEG's.

**Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)**

Clinical and EEG information are collected for clinical purposes. This includes data from the clinical file, and clinically indicated video-EEG. In addition, radiographic information will not be blinded and can be used clinically (CT and MR-FDG-PET). In accordance with UZ Leuven guidelines, this data is stored in a patient-specific manner.

Specifically, clinical information is stored in the KWS system at UZ Leuven. Radiographic information is stored in the PACS (CT and MR-FDG-PET) and MIM-server(MR-FDG-PET, list mode). EEG information from the video-EEG is stored on a dedicated server specific to UZ-Leuven, part of BrainRT.

In addition to these, aggregated pseudonymized data is securely stored on dedicated servers, ensuring the privacy and security of patient information while allowing for comprehensive data analysis. This information will be stored in:

- During research: Redcap, UZ Leuven server (access-protected)
- After research: Redcap, UZ Leuven server (access-protected)

M.D. Jeroen Gijs and prof. Dr. Wim Van Paesschen will have acces to the Redcap server and UZ Leuven server.

**What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)**

Not applicable (data will be preserved for at least 5 years).

**Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)**

REDcap is a secure web application for building and managing clinical data. M.D. Jeroen Gijs followed training for investigator and developer access to the REDcap project.

EDF files and DICOM/NIFTI files can not be stored within REDcap. They will be safely stored in a UZ Leuven server, where M.D. Jeroen Gijs and prof. Dr. Wim van Paesschen will have sole access to patient-specific data.

**Which other issues related to the data management are relevant to mention? (use up to 700 characters)**

Prof. Dr. Wim Van Paesschen and Prof. Dr. Nicolas Gaspard will perform blind annotation of pseudonymized EEG files. This process involves exporting the EEG data to Prof. Dr. Nicolas Gaspard at Erasme Hospital.

Please note that only pseudonymized EEG data will be exported for blind reading. Prof. Dr. Nicolas Gaspard will interpret these EEGs using the BrainRT software, identical to the one we utilize at UZ Leuven.

To ensure patient confidentiality, the EEG files will be stripped of any identifiable information. This includes the removal of video content and the anonymization of headers and metadata using a dedicated tool within BrainRT. Headers will only containt pseudonymized information (so that blind annotation in REDcap can be performed).

The export of EEG information will be conducted exclusively through Liquidfiles, a data-sharing tool specific to UZ Leuven, to further ensure

data security and privacy.
Specifically, clinical information is stored in the KWS system at UZ Leuven. Radiographic information is stored in the PACS and MIM-server. EEG information from the video-EEG is stored on a dedicated server specific to UZ-Leuven, known as BrainRT.

In addition to these, aggregated pseudonymized data is securely stored on dedicated servers, ensuring the privacy and security of patient information while allowing for comprehensive data analysis.

Radiographic and electrographic information can be pre-processed and stored in several ways. To keep a clear overview of these performed steps and radiographic output data, every dedicated folder contains a word document specifying pre-processing steps.

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## FWO DMP (Flemish Standard DMP)

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**1. Research Data Summary**

**List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.**

| | | | | Only for digital data | Only for digital data | Only for digital data | Only for physical data |
|---|---|---|---|---|---|---|---|
| Dataset Name | Description | New or reused | Digital or Physical | Digital Data Type | Digital Data format | Digital data volume (MB/GB/TB) | Physical volume |
| Clinical information (REDcap) | Clinically gathered information within REDcap, including eligibility, demographics, clinical presentation, evolution, treatment evolution, outcome, adverse events | New data | Digital | Observational | .csv | <100GB | / |
| Radiographic information (MRI,18FDG PET, CT, CT-perfusion) (UZL server, PACS/ MIM server) | Radiographic gathered data on 18FDG-PET-MR and CT-P | New data | Digital | Observational | .dcm .nii | < 10TB | / |
| Electrographic information (UZL server, BrainRT-server) | Video-EEG information | New data | Digital | Observational | .edf | < 10TB | / |

**If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:**

Not applicable.

**Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.**

- Yes, human subject data

Human subject data will be collected. This can be divided in 3 data types:
- Clinical information, prospectively collected. These examinations are performed as standard clinical practice. Video-data from video-EEG will not be stored.
- Radiographic information (18-FDG-PET-MR and Photon-countin CT-perfusion) prospectively collected (not standard clinical practice).
- Electrographic data (EDF format), prospectively collected and annotated.

We recieved approval from the Ethics Committee Research UZ / KU Leuven for our study s67933, including an interventional (CT and FDG-PET-MR) and observational (collection of clinical, electrographic information) subpart. Prospective collection of this data will only be performed after informed consent signed and agreed by the participant or the legal representative of the participant.

**Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific**

**datasets or data types when appropriate.**

- Yes

We will process personal data. All aggregated data will be pseudonymised. Following personal data are stored:
- Clinical information, prospectively collected: this data will contain personal information (age, weight, date of symptom onset, diagnosis, ...).
- Radiographic information: metadata in DICOM headers will have a date of birth, age, and weight.
- Electrographic data: metadata in EDF headers will have a date of birth.
Data of births will not be processed. Names and surnames will not be stored or processed. Other personal information (home adress, email adress,...) is not stored nor processed.

**Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.**

- No

At this moment there is no plan to commercially valorise this project.

**Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.**

- No

We only have a data transfer agreement with prof. Dr. Nicolas Gaspard for blind annotation of EEG data. This agreement does not restrict exploitation or dissemination of our data.

**Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.**

- No

**2. Documentation and Metadata**

**Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).**

- For REDcap data a codebook will be available on the REDcap server.
- For radiographic data a README.TXT or Word file will be created for documenting pre-processing steps. This Readme.txt or Word document will also contain a standard protocol for naming of files (for example patient pseudonymised id, scan type, and processing steps patient1_PET_c_SUV_.nii).

**Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.**

- No

- For REDcap data a codebook will be available on the REDcap server.

- For radiographic data a README.TXT or Word file will be created for documenting pre-processing steps. This Readme.txt or Word document will also contain a standard protocol for naming of files (for example patient pseudonymised id, scan type, and processing steps patient1_PET_c_SUV_.nii).
- Concerning metadata, all radiographic data will be stored in DICOM format. All electrographic data will be stored in EDF/EDF+ format. These are internationally recognized data formats.

**3. Data storage & back-up during the research project**

**Where will the data be stored?**

- Clinical data will be stored in the REDcap-allocated server.
- Radiographic and electrographic data will be stored in a firewall-protected UZL server, where only M.D. Jeroen Gijs en prof. Dr. Wim Van Paesschen will have acces to.
- In addition, clinical and EEG information are collected for clinical purposes. This includes data from the clinical file, and clinically indicated video-EEG. In addition, radiographic information will not be blinded and can be used clinically (CT and MR-FDG-PET). In accordance with UZ Leuven guidelines, this data is stored in a patient-specific manner.

**How will the data be backed up?**

When using UZL REDCap, data is backed up as follows:

- The web server backup regime is specified below:
- An hourly backup, the last 6 versions of which are saved
- A daily backup, the last 7 versions of which are saved
- A weekly backup,  the last 6 versions of which are saved
- The database backup regime is specified below:
- A nightly cold backup of all databases
- One month’s storage of the nightly cold backups

When using UZL servers, data is backed up following an in-house protocol, we opted for a 'medium' backup protocol: 2 weekly and 48 hours backup.

**Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.**
**If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.**

- Yes

Currently we have 2 Terabyte (TB) of data storage in the UZL server. If this proves to be insufficient we will demand more data storage space.
We estimate to need 7 TB of data storage per year on UZL server.

**How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?**

Only prof. Dr. Wim Van Paeeschen and M.D. Jeroen Gijs will have developer access to the REDcap project.
Only prof. Dr. Wim van Paesschen and M.D. Jeroen Gijs will have access to the UZL server.

**What are the expected costs for data storage and backup during the research project? How will these costs be covered?**

We estimate we will need around 7 TB of hard disk space per year to save the imaging data. We estimated the total cost of our TBM-FWO project for 9 years (4 years of study plus 5 years after the end of the study) to be around €11340, based on a price of €180 per TB.

#### 4. Data preservation after the end of the research project

**Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).**

All collected data will be retained for at least 5 years.

**Where will these data be archived (stored and curated for the long-term)?**

Clinical data will be archived in REDcap.
Radiographic and clinico-electrographic data will be archived in the UZL server.
In addition, as radiographic data is not blinded this data is archived using standard clinical archiving protocols (PACS for CT, MIM-server, and dedicated server for list mode data for FDG-MR-PET) according to clinical practice in UZL. Clinical archiving protocol is meant to store clinically relevant data and might differ from our research protocol. We do not consider this to be a backup.

**What are the expected costs for data preservation during the expected retention period? How will these costs be covered?**

We estimate we will need around 7 Terabyte (TB) of hard disk space per year to save the imaging data. We estimated the total cost for 9 years (4 years of study plus 5 years after the end of the study) to be around €11340, based on a price of €180 per TB.

#### 5. Data sharing and reuse

**Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.**

- Yes, in a restricted access repository (after approval, institutional access only, …)

Our original imaging and annotated EEG data will be made available to researchers who provide a methodologically sound proposal.
Supporting Information:
Study Protocol
Statistical Analysis Plan (SAP)
Clinical Study Report (CSR)
Analytic Code
Time Frame:
data will be made available after publication of our results. There is no end date.

**If access is restricted, please specify who will be able to access the data and under what conditions.**

Our original imaging and annotated EEG data will be made available to researchers who provide a methodologically sound proposal.
To gain access, data requestors will need to sign a data access agreement.

**Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.**

- Yes, Privacy aspects

**Where will the data be made available? If already known, please provide a repository per dataset or data type.**

Currently the clinical, electrographic and radiological data is stored in a dedicated firewall protected UZ Leuven server and REDcap (as mentioned before).
After publication of our results, we will upload our data to the KU Leuven RDR depository.

**When will the data be made available?**

After publication of our results.

**Which data usage licenses are you going to provide? If none, please explain why.**

Creative Commons Attribution 4.0 International CC-BY-4.0

**Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.**

- No

Not applicable.

**What are the expected costs for data sharing? How will these costs be covered?**

Currently, we have not considered any costs for data sharing.
EEG data sets, and clinical information and processed images will demand relatively little storage.

**6. Responsibilities**

**Who will manage data documentation and metadata during the research project?**

M.D. Jeroen Gijs

**Who will manage data storage and backup during the research project?**

M.D. Jeroen Gijs, UZL, UZL REDcap

**Who will manage data preservation and sharing?**

M.D. Jeroen Gijs, UZL, UZL REDcap

**Who will update and implement this DMP?**

M.D. Jeroen Gijs

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## GDPR

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**GDPR**

**Have you registered personal data processing activities for this project?**

- Not applicable

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## DPIA

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**DPIA**

**Have you performed a DPIA for the personal data processing activities for this project?**

- Yes