Spinal Cord Stimulation for Freezing of Gait in Parkinson's Disease
FWO DMP (Flemish Standard DMP)

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
		Please choose from the following options: Generate new data Reuse existing data	*Please choose from the following options*: Digital Physical	• Observational • Experimental • Compiled/aggregated data	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Informed consents forms	Signed ICFs	Generate new data	Physical	NA	NA	*NA*	A few ring binders (<3000 pages)
REDCAP data	Baseline characteristics and follow-up data (PROMs, clinical outcomes, outcomes from FOG-protocols, adverse events, etc.)	Generate new data	• Digital (REDCAP data)	• Observational • Experimental • Compiled/aggregated data	.xlsx .txt .csv	< 500 GB	NA
PROMs, questionnaires, MDS-UPDRS	NFOG-Q, C-FOG, MDS-UPDRS-III and IV.6, PDQ-39, LEDD, PAS, BDI, RBDSQ, daily questions	Generate new data	• Physical (All PROMs also have to be available on paper for the CTC monitor)	• Observational • Experimental	NA	NA	A few ring binders (<3000 pages)
FOG-video's	Video's of the FOG-provoking protocols	Generate new data	Digital	• Observational • Experimental	.mp4	< 2 TB	NA

FOG-annotations	Annotations of the video's (%TF, FOG characteristics)	Generate new data	Digital	• Observational • Experimental • Compiled/aggregated data	.eaf .psfx .csv	< 500 GB	NA
Axivity data	step duration (used to calculate step time variability), cadence, stride length, walking speed (for walking bouts >10s), turning speed, total daily step count, average gait bout duration, average gait bout intensity	Generate new data	Digital	• Observational • Experimental • Compiled/aggregated data	.csv .xlsx MATLAB files	< 100 GB	NA
ADPM data	Gait data during the FOG-provoking protocol	Generate new data	Digital	• Observational • Experimental • Compiled/aggregated data	.xlsx MATLAB files	< 100 GB	NA
STN-LFPs	BrainSense Timeline data and BrainSense Streaming data	Generate new data	Digital	• Observational • Experimental • Compiled/aggregated data	JSON files, MATLAB files	< 1 GB	NA
Spinal LFPs	NeuroSense data from Inceptiv	Generate new data	Digital	• Observational • Experimental • Compiled/aggregated data	JSON files, MATLAB files	< 1 GB	NA
Adverse event data	Safety reporting	Generate new data	• Digital (REDCAP data) • Physical (All adverse event data also have to be available on paper in the TMF for the CTC monitor)	• Observational • Experimental • Compiled/aggregated data	.docx .pdf .xlsx	< 1 GB	<1000 pages
Study documents	Trial Master File, containing essential study documents	Generate new data	Physical (all essential study docuemnts have to be available on paper in the TMF for the CTC monitor	NA	NA	NA	A few ring binders (<3000 pages)

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:

NA (Collect and generate new data, there will be no use of existing data)

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

As we will be working with personal data from human participants (which will be pseudonymised), approval by ethical committee is needed and will be obtained. An informed consent will be obtained from every participant, not only for study participation but also for long term preservation and data sharing within the group of collaborative researchers on this project.

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

Privacy Registry Reference: KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRivacy and EThical tool (PRET))

We will use pseudonymisation of data by referencing to patients with a unique number which is different from the hospital chart number.
Data will be stored on secured servers of KU Leuven, and the file listing the patient identifiers and the patient pseudonymisation numbers will be stored separately from the data. Only the PI and one substitute can access thepersonal data. Data viewing will be logged. Personal data will be kept for 10 years.

Short description of the kind of personal data that will be used: patient demographics, video's, PROMS, questionnaires and clinical data, gait data, neurophysiology data.

Privacy aspects concerning the video recordings:
As outlined in the study protocol (CIP), the at-home FOG-provoking-protocol will be recorded using two cameras and the videos are subsequently annotated, as is the gold standard for FOG assessment. Participants will be clearly informed during every FOG-protocol at what moments the cameras are actually recording, which is only in a limited timeframe during the execution of each task. For example, the cameras will not be filming between tasks; only the footage strictly necessary for the study is recorded. Since the videos will be reviewed exclusively by the primary researcher (PhD student Sara Smeets) and a subset of videos will undergo independent evaluation by a researcher from PRO-lab for verification purposes, patient privacy will be preserved. The researchers are bound by medical confidentiality and Good Clinical Practice (GCP) guidelines throughout the research process. Blurring the patient's face before annotating the video's would be inadvisable, as facial expressions play a critical role in assessing pauses in walking to distinguish freezing (e.g., akinetic freezing) from voluntary pauses; this distinction is often not apparent if the patient's facial expression is blurred. However, patients have the right to indicate on the ICF whether their videos may be published or used for other scientific purposes, and if so, their face will be pseudonymised (blurred) upon request. Upon completion of the study, all study data, including video recordings, will be stored for 10 years, conform the KU Leuven RDM policy. Prior to archiving the video recordings, participants' faces and identifiable elements in the environment (e.g., photos of individuals in home settings, other persons in the background) will always be blurred to respect the participant's privacy.

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

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

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).

All data and accompanying information will be stored exclusively on KU Leuven servers. The folder structure is organized according to experiment type and will be accessible by all researchers on the delegation log. We are using detailed lab notebooks. The data will be annotated during the acquisition phase of the experiments. All experimental work is prepared by extensive preparations, each step is logged. Standard operating procedures are written out in the lab and safely stored together with the experimental data in the same folders, to allow easy recovery of the metadata.
Metadata will be provided as readme, csv, word or excel files, containing all settings and technical descriptions of the experiment.

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.

- Yes

Metadata will be provided as readme, csv, word or excel files, containing all settings and technical descriptions of the experiment.
For the patient demographics and clinical data, metadata will be added to the database of the used statistical program (R, SAS and/or SPSS).
Neurophysiology data will be exported in Matlab, where metadata will be added.

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

Where will the data be stored?

Since we will be working with sensitive personal data, the data will be stored in the university's secure environment for private data and on the RedCap platform. We will use RedCap for active use of the data during the project.
All data are stored at the KU Leuven Onedrive, the KU Leuven Large Volume Storage L-drive, or the UZ Leuven servers (for clinical data). No data will be stored on local computers, etc.

How will the data be backed up?

The data will be stored on the university's central servers with automatic daily back-up procedures.

As we also use UZL REDCap, data is backed up as follows:
1. 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
2. The database backup regime is specified below:- A nightly cold backup of all databases- One month's storage of the nightly cold backups
3. Data restore, upon request

As we also use UZL REDCap, the following procedures for system recovery apply:
1. Systems are proactively monitored 24 hours a day, 7 days a week.
2. An emergency on-call service guarantees constant monitoring of the technical equipment, also outside office hours, but not at night. The on-call service is notified automatically in case of problems (between 7.00 - 23.00 hrs).
3. There are no fixed maintenance windows: a timely email is sent to inform the local IT Administrator of any planned maintenance or upgrades.
4. Any service unavailability, scheduled or unscheduled, is announced on the ICTS status page.
5. The web space is designed redundantly: in the event of system problems on one back-end server, all traffic is automatically diverted to another back-end server. The database platform is also designed redundantly.

Data that are not in REDCap (e.g. neurophysiology data, gait data, video's and video annotations) will be backed up regularly on an external hard drive, which is password encrypted and kept by the investigator in a locked down compartiment.

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

All KU Leuven personnel has access to 2 TB of data storage on OneDrive. As the estimated sizes of the datasets <2 TB, sufficient storage and backup capacity is available.
Our research group will have a L-drive with a capacity of 5 TB for active research data. As the estimated size of the dataset is <5 GB, sufficient storage and backup capacity is available.

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

The data will be stored in the university's secure environment for private data, only accessible with double authentication.
As we will also use UZ Leuven REDCap, physical access to the data centers is logged and restricted to authorized KU Leuven Information Technology (IT) personnel, using badge identification. At the clinical database level only study team members, monitors and auditors/inspectors for whom the Coordinating or Principal Investigator (as applicable) has requested project-specific eCRF access, are granted data access. Upon successful training completion each user is centrally assigned a user role, associated with predefined system/data privileges, in accordance with CR DM-WI-001. The gatekeeper for UZL REDCap is UZL CTC (ctc.datamanagement@uzleuven.be).

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

Data storage in the secure vault of KU Leuven is free up to 5TB. Beyond 5TB, the annual price for data storage is currently €569/5TB/year.UZL As the expected identifiable data is < 5TB, it can be stored for free on the central KU Leuven servers, but ample funding is available in case additional storage is needed. RedCap comes at a cost of +- €80 per year.
These costs will be covered by King Baudouin Foundation and FWO fundings we have already obtained for this project.

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 relevant data will be retained for at least 10 years after the end of the project.
Prior to archiving the video recordings, participants' faces and identifiable elements in the environment (e.g., photos of individuals in home settings, other persons in the background) will always be blurred (pseudonymised) to respect the participant's privacy.

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

The data will be stored on the university's central servers (with automatic back-up procedures) for at least 10 years, conform the KU Leuven RDM policy.

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

As the expected identifiable data is <5TB, it can be stored for free on the central KU Leuven servers.

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, …)

All data will be available on request after signing a data sharing agreement. The procedure for requesting access to data will be made available on the project website.

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

Access will be restricted to medical professionals who request access and sign a data sharing agreement. Access will be considered after a request is submitted explaining the planned reuse. Only uses for research purposes will be allowed and commercial reuse will be excluded.

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.

- No

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

Data will be available on request after signing a data sharing agreement. The procedure for requesting access to data will be made available on the project website

When will the data be made available?

Immediately after the end of the project. However, access will be restricted to medical professionals who request access and sign a data sharing agreement. Access will be considered after a request is submitted explaining the planned reuse.

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

Data sharing agreement.

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

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

No costs are expected. In case we decide to use Zenodo for sharing data on request, this would be free.

6. Responsibilities

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

The PI (Prof. Dr. Philippe De Vloo) and the PhD student (Dr. Sara Smeets)

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

The PI (Prof. Dr. Philippe De Vloo) and the PhD student (Dr. Sara Smeets)

Who will manage data preservation and sharing?

The PI (Prof. Dr. Philippe De Vloo) and the PhD student (Dr. Sara Smeets)

Who will update and implement this DMP?

The PI bears the end responsibility of updating & implementing this DMP.