Revisiting the neural bottleneck of information transmission in cochlear implant users

A Data Management Plan created using DMPonline.be

Creator: Elise Verwaerde

Affiliation: KU Leuven (KUL)

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Project abstract:

A cochlear implant (CI) is the most successful sensory-bionic prosthesis for the auditory rehabilitation of people with a profound hearing loss. However, overall CI outcome is highly variable across its users and auditory capabilities do not come close to those of normal-hearing listeners. CI users mainly perceive speech based on temporal envelope modulations (TEMs), and therefore it is crucial that TEMs are properly transmitted and encoded at different levels of the auditory system. Any encoding deficit in the auditory pathway negatively affects speech perception with the CI. Given that the electrode-neuron interface (ENI) is the bottleneck for auditory functioning with a CI, the neural transmission at the ENI is an imperative factor in CI outcome. It is therefore of great importance to assess how TEM encoding at the ENI affects neural transmission up to the auditory cortex. In this project, we will probe different neural aspects of TEM encoding from the ENI to the auditory cortex and develop and evaluate a diagnostic method for identification of temporal processing deficits in individual CI users. This new method will be evaluated in adults and children with a CI using objective electrophysiological measures. This project will enable clinicians to gain information about the neural ability to encode TEMs and improve CI outcome, especially in adverse listening conditions.

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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
Objective fitting - Admin	(Scanned image of) test forms	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☒ .pdf ☐ .docx ☐ .xlsx ☐ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☐ .rbadata ☐ .aseq ☐ .apr ☐ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☐ .csv ☐ .png ☐ .pptx	☒ < 100 MB (per participant) ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	9 pages per participant
Objective fitting - Admin	Informed consents + CI subject form	☒ Generate new data ☐ Reuse existing data	☐ Digital ☒ Physical	☐ Observational ☐ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☒ NA	☐ .pdf ☐ .docx ☐ .xlsx ☐ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☐ .rbadata ☐ .aseq ☐ .apr ☐ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☐ .csv ☐ .png ☐ .pptx	☐ < 100 MB ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	14 pages per participant

Objective fitting - Experimental	EEG Data	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .pdf ☐ .docx ☐ .xlsx ☐ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☐ .rbadata ☐ .aseq ☐ .apr ☒ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☐ .csv ☐ .png ☐ .pptx	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB (per participant ~ 50 GB) ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA
Objective fitting - Experimental	Experiment files	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .pdf ☐ .docx ☐ .xlsx ☐ .txt ☒ .apx ☒ .apf ☒ .js ☒ .xml ☒ .wav ☒ .rbadata ☒ .aseq ☐ .apr ☐ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☐ .csv ☐ .png ☐ .pptx	☐ < 100 MB ☒ < 1 GB (per year) ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA

Objective fitting - Experimental	EEG stimulation files	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .pdf ☐ .docx ☐ .xlsx ☐ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☒ .rbadata ☒ .aseq ☐ .apr ☐ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☒ .csv ☐ .png ☐ .pptx	☒ < 100 MB (per year) ☐ < 1 GB ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA
Objective fitting - Behavioral	Behavioral data	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .pdf ☐ .docx ☐ .xlsx ☐ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☐ .rbadata ☐ .aseq ☒ .apr ☐ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☒ .csv ☐ .png ☐ .pptx	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB (per participant ~ 5 GB) ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA

Objective fitting - Statistics	Analysis files MATLAB & R	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☐ .pdf ☐ .docx ☒ .xlsx ☒ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☐ .rbadata ☐ .aseq ☐ .apr ☐ .bdf ☒ .m ☒ .mat ☒ .R ☒ .tsv ☒ .csv ☐ .png ☐ .pptx	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB (per year ~ 30 GB) ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA
Objective fitting - Results	Figures/charts with results	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☒ .pdf ☐ .docx ☐ .xlsx ☐ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☐ .rbadata ☐ .aseq ☐ .apr ☐ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☐ .csv ☒ .png ☐ .pptx	☐ < 100 MB ☒ < 1 GB (per year) ☐ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	NA

Objective fitting - Administrative files	Information about protocol, study aims, methods, datasets, literature, ...	☒ Generate new data ☐ Reuse existing data	☒ Digital ☒ Physical	☐ Observational ☒ Experimental ☐ Compiled/aggregated data ☐ Simulation data ☐ Software ☐ Other ☐ NA	☒ .pdf ☒ .docx ☒ .xlsx ☒ .txt ☐ .apx ☐ .apf ☐ .js ☐ .xml ☐ .wav ☐ .rbadata ☐ .aseq ☐ .apr ☐ .bdf ☐ .m ☐ .mat ☐ .R ☐ .tsv ☐ .csv ☒ .png ☒ .pptx	☐ < 100 MB ☐ < 1 GB ☒ < 100 GB (per year) ☐ < 1 TB ☐ < 5 TB ☐ < 10 TB ☐ < 50 TB ☐ > 50 TB ☐ NA	Some files will be printed out, most will not.

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

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

This project involves experiments on humans and is approved by the Ethic Committee *Ethische Commissie Onderzoek UZ/KU Leuven* (B3222021000506 / S65454).

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

Some basic information is gathered from the subject (name, gender, address, info on cochlear implant and etiology, speech perception, ...) though strictly limited to the absolute necessary data. Furthermore, the collected data are pseudonymised.
Privacy Registry Reference: G-2021-3488

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

Not at this moment. In case IP possibilities arise, we will contact the KU Leuven Research and Development Department to advise on necessary steps.

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.

- Yes

Some of the results obtained will be important for a VLAIO-project. In the agreement of this project, it is described that the actual submission of articles can be delayed (to allow for consideration of patent applications) by a few months.

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

NA

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).

New lab members will receive training on how to perform the experiments. They will also be informed about how and where to store and handle the collected data. Furthermore, standard guidelines and instructions are available as .pdf, .docx and/or .readme, stored on network drives. They contain best practices regarding the practical side of experiments as well as policies about how to treat the participants, how to handle and store sensitive information.
Despite being structured according to the standard BIDS format, the data is not easily shared across the lab. Personal information about the participants is restricted and only accessible by the PI. The PI also has the final decision about sharing the data, which is constrained by the protocol approved by the ethical committee and by the informed consent signed by the participant.

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

The data will be stored based on the existing BIDS structure, which is already used for neuroimaging and behavioral data (see also website bids.neuroimaging.io). We will use this data structure in order to have a uniform way of data arrangement across studies.

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

Where will the data be stored?

The data will be stored on KU Leuven administered drives (large volume storage) and on encrypted hard drives in the lab. In order to be able to analyze the data, some files will (temporarily) need to be stored on a portable hard drive of the Leuven University. Once analyzed, the raw data are again removed from the portable hard drive.

How will the data be backed up?

In the lab, 2 to 3 encrypted hard drives are used to back up each other. They are kept in a secure cabinet with restricted access.

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

We will store the data on external hard drives with a capacity of several TBs.

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

The lab policy ensures that the researchers only have access to the data from the project they are involved in. Furthermore, the data for longer term storage are kept on separate encrypted drives with 1) limited access (only a limited set of people have access) and 2) an overwrite and delete protection (based on read-write access) to ensure no data gets lost.
The sensitive personal data of the participants are pseudonymised and stored in a restricted database only accessible by the PI. Only few researchers can use the data (after permission) to answer the research questions mentioned in the approved protocol.

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

The estimated cost for data storage and back-up over the 4-year FWO project is around 700 Euros and will be covered by the FWO-grant working budget.

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...).

In accordance with the applicable law, the data of this study will be retained for 20 years (KB 30 juni 2004). These terms and conditions are also mentioned in the informed consent that is signed by the participant prior to their participation in the experiments.

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

The data are stored on several encrypted external hard drives. Personal data will, however, be kept in a restricted, secure database managed by the PI.

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

No additional costs would be expected during the retention period as the data will still be stored on the external hard drives.
As mentioned before, the hard drives cost around 700 Euros and are covered by the FWO-grant working budget.

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.

- Other, please specify:

It is to be decided if data will be made available.
However, neither the raw data nor individual data will be made available. If decided to make data available; to ensure scientific transparency the data can be made publicly available after publication of the results or shared with third parties if requested and after agreeing to a mutual information transmission agreement. To protect the patient's identity, we will only share the pseudonymized behavioral and/or EEG data. No data will be omitted.

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

Only a limited number of researchers will have access to the data. The data are pseudonymised, so even for the researchers, there is no recognizable link between the data and the participant themselves. The PI has the end decision to share the data, only within the constraints of the protocol approved by the ethical committee, the informed consent signed by the participant, and only after agreeing to a mutual information transformation agreement. If this is the case, the data is only used to address research questions mentioned in the protocol.

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, Intellectual Property Rights

- Yes, Privacy aspects

Whether data can be shared is to be decided and depending on the IP regulations. Personal information of the participant or the key to access this information is not shareable at any time.

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

The personal data is stored in a restricted database of the lab, only accessible by the PI. Experiment data is pseudonymised and stored in an encrypted storage medium.

When will the data be made available?

To be decided.

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

To be decided.

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

To be decided.

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

Not yet applicable.

6. Responsibilities

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

The researchers themselves have been instructed on how to collect and document the data.

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

The researchers themselves have been instructed on how to handle and store the data. Back-up of the data is arranged by the PI in the form of multiple encrypted storage media.

Who will manage data preservation and sharing?

The PI will manage data preservation and sharing through highly restricted overwrite and delete authorization. It is also the PI's decision which data are shared with other co-workers and how this will be arranged.

Who will update and implement this DMP?

The researcher herself carries some responsibility. The PI, prof. Jan Wouters, bears the end responsibility of updating and implementing this DMP.