INTRA-COCHLEAR BIOSENSOR FOR IN SITU MONITORING OF ELECTRODE-INDUCED INFLAMMATION

DMP 1S64622N

ADMIN DETAILS

Project Name: INTRA-COCHLEAR BIOSENSOR FOR IN SITU MONITORING OF ELECTRODE-INDUCED INFLAMMATION

Project Identifier: 3E190598 (onderzoeksportaal)

Grant Title: D-2021-1281

Principal Investigator / Researcher: Carmen Bartic; Nicolas Verhaert; Jolan Wellens;

Project Data Contact: Jolan Wellens, +32 475 89 49 35, Jolan.Wellens@kuleuven.be

Description: Neural implants such as Cochlear implants (CI's) and Deep brain stimulation systems have revolutionized the treatment of neural afflictions such as deafness and Parkinson's disease. Although successful, there are significant risks associated with implantation such as insertion trauma, foreign body reaction (FBR) and pathogen infection resulting in inflammation and reduced or loss of device function. Equipping neural implants with an additional biosensing functionality for inflammatory markers would give valuable information on the local implant environment, allowing for early diagnostics and guided drug treatment. Although several sensing principles have been demonstrated for relevant molecules in vitro, the transition to in vivo situations has been halted due to biofouling and stability issues. In this project, we will develop electrochemical sensing functionalities for different inflammatory markers such as hydrogen peroxide, pH, Tumor necrosis factor α (TNF-α) and Interleukin 6 (IL-6) with suitable properties towards implantation. We will improve the long term stability and sensitivity through incorporating antifouling zwitterionic polymers and using more suitable biorecognition elements (enzyme-free nanocatalysts, aptamers instead of antibodies for IL-6 and TNF-α). These sensors will be extensively characterized in vitro with model fluids and inflammatory cell culture models and if successful in vivo with a gerbil cochlea model.

Institution: KU Leuven

1. GENERAL INFORMATION

a. Name applicant

Jolan Wellens

b. FWO Project Number & Title

FWO project number: 1S64622N

Title: Post-implantation inflammation sensor for neural implants

c. Affiliation

KU Leuven

2. DATA DESCRIPTION

a. Will you generate/collect new data and/or make use of existing data?

- Generate new data

b. Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project.

Type of Data	Format	Volume	How created
(A) Microscopy images	.tiff, .jpg, .png	100 GB	Multiple imaging tools will be used to generate these data types: Optical techniques such as brightfield-, widefield-, confocal microscopy techniques, non-linear techniques and non optical techniques such as Atomic force and scanning electron microscopy.
(B) Data from electrochemical measurements	.DTA, .txt, .ASCII	25 GB	Using the integrated software of the potentiostat (Gamry Interface 1000) DTA files are generated which can be exported with Gamry echem software as txt files with parameters in separated columns. Metadata such as time/date, method, parameters, instrument settings are also stored in these files. Data from other potentiostats are saved as ASCII files.
(C) Data from contact angle and quartz crystal microbalance measurements. Data from UV/VIS or FTIR spectroscopy	.QSD,.txt, .png, . xlsx	20 GB	Data from QCM measurements is saved as .QSD and .txt files. Data from contact angle measurements are saved as .png files of water droplet with fitted contact angle displayed. Data from spectroscopy will be saved as .xlsx files.

(D) Analysis scripts and code for fitting echem data, and statistical analysis	.m(at), .py(w), .r , .dll	10 GB	Existing in-house scripts that are adapted; self-written code and statistics datasets
(E) Processed data	.xlsx, .txt,.mat,	5 GB	Processed data of all raw data sources described above will be stored in .xlsx, .txt or .mat format, depending on the type of data
(F) Metadata	.txt/.docx	1 GB	• see below, section 4
(H) Presentations, Protocols, reports	.ppt, .docx, .pdf	10 GB	Presentations will be saved as pdf or ppt files. Protocols and reports will be saved as .docx files

3. LEGAL AND ETHICAL ISSUES

a. Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.
No

b. Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)
No

c. Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?
NA

d. Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?
No

4. DOCUMENTATION AND METADATA

a. What documentation will be provided to enable reuse of the data collected/generated in this project?

Most important data regarding this project will be kept on a shared secured box drive and will be updated by a member of the research team every time a new subject is enrolled and/or measurements take place.

Additionally all data will be backed up on the ZMB unit servers and a personal KU Leuven onedrive.

The names of the files will be structured in a comprehensible way: system studied/date/main parameters used.

In addition, data will be stored in a folder per experimental setup, the type of investigated system and the corresponding date. The analysis files will contain notes describing the analysis procedure and mention which original data files are included. A readme file describing the goal of the experiment and the analysis procedure will be stored in the folder where the data is saved. An index list correlating sample ID with sample properties and relevant experiments will be maintained.

b. Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

No

Metadata will be added to the stored data describing the experimental data, acquisition protocol and context within the project.

5. DATA STORAGE AND BACKUP DURING THE FWO PROJECT

a. Where will the data be stored?

Time-stamped copies of the data will be kept on a personal secured KU Leuven onedrive and ZMB server. Additionally most important data will be saved on a secured box shared between project partners.

b. How is backup of the data provided?

The data will be stored on a personal KU Leuven onedrive and ZMB server with automatic daily back-up procedures that allow for disaster recovery. Additionally backups are made on external hard drives.

c. 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

KU Leuven onedrive (Microsoft) allows for over one terabyte of data storage which surpasses the storage needs of the project. ZMB server offers also 1TB per user.

d. What are the expected costs for data storage and back up during the project? How will these costs be covered?

Costs of data storage within KU Leuven one-drive are covered by KU Leuven. Costs of data storage on existing computers/external hard drives are covered by the lab.

e. Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Researchers involved in the project and promotors will have access to the data during the research. Box drive access is only granted to these people. Backups will be made on password protected work computes and additional hard drives.

6. DATA PRESERVATION AFTER THE FWO PROJECT

a. Which data will be retained for the expected 5-year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

After the end of the project, all data will be retained for a minimum of 5-year period on the ZMB storage space. If needed, additional space on the KU Leuven Large Volume Storage (LVS) facility will be purchased by the promoter.

b. Where will the data be archived (= stored for the longer term)?

ZMB storage space and/or KU Leuven Large Volume Storage.

c. What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

Space on the ZMB server has been purchased by Unit members. Additional space on the KUL LVS will be paid from the promoter research grants (cost 129 euro/year for 5 TB).

7. DATA SHARING AND REUSE

a. Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

There are no legal restrictions or restriction related to IP potential.

b. Which data will be made available after the end of the project?

All data can be made available on an open repository, for example if requested by the editor or publisher of a scientific journal or via restricted access upon request of an individual (e.g. a researcher who intends to reproduce an experiment).

c. Where/how will the data be made available for reuse?

Upon request and after the agreement of the projects promotors, all data can be made available on a repository or via secured data sharing infrastructure (Belnet).

d. When will the data be made available?

Data will only be made available to other researchers after publication of the research results. And agreement of the (co-)promotors.

e. Who will be able to access the data and under what conditions?

As stated above, data can be made available on an open repository or upon request via email. A written agreement with the PI is necessary when sharing the data outside of the research groups.

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

None. Data preparation will be done by the researchers primarily involved in the project. Secure data sharing infrastructure is available at KULeuven, e.g. Belnet. If costs occur, these need to be covered by the requesting party/-ies.

8. RESPONSIBILITIES

a. Who will be responsible for data documentation & metadata?

The (co-)promotors of the project
Researcher: Jolan Wellens

b. Who will be responsible for data storage & back up during the project?

The (co-)promotors of the project
Researcher: Jolan Wellens

c. Who will be responsible for ensuring data preservation and reuse?

C. Bartic

d. Who bears the end responsibility for updating & implementing this DMP?

C. Bartic & J. Wellens