DMP title

Project Name EARLY DETECTION OF COPD EXACERBATIONS BASED ON NON-OBTRUSIVE DATA COMING FROM PATIENT-FRIENDLY WEARABLE BIOSENSORS - DMP title

Project Identifier 12ZW822N

Grant Title 12ZW822N

Principal Investigator / Researcher Heleen Demeyer

Description FWO senior post doctoral project that aims to 1) Validate wrist worn multi-sesor smartwatches in patients with Chronic Obstructive Pulmonary Disease 2) Investigate the impact of acute exacerbations on the biosensor signals 3) Investigate whether acute exacerbations can be early detected based on biosensor signals. This project is embedded in a multicenter project (collaboration between KULeuven and UGent).

Institution KU Leuven

1. General Information

Name applicant

Heleen Demeyer

Thierry Troosters (supervisor)

FWO Project Number & Title

12ZW822N

Title: EARLY DETECTION OF COPD EXACERBATIONS BASED ON NON-OBTRUSIVE DATA COMING FROM PATIENT-FRIENDLY WEARABLE BIOSENSORS

Affiliation

- KU Leuven

Heleen Demeyer is also affiliated to UGent as assistant professor. The project is multicenter (KULeuven - UGent).

2. Data description

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

- Generate new data
- Reuse existing data

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. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

Type of data	Format	How created
Clinical data (Phenotype)	Redcap --> .xls	Data on paper CRF. Coded data are transferred to the RedCap software.
Data from the accelerometer (Dynaport movemonitor)	.xls	Data are uploaded on the server of the company. On a regular basis the company provides us with an excell export containing all raw physical activity data. These exports will be stored at the network of KU Leuven and UGent.
Data from the wearable (Fitbit, Polar, Nonin pulse oximeter)	.xls	Information from smartwatches will be exported and saved on the sever of KU Leuven and UGent. Data of fitbit will be retrieved using the available API of fitbit. Data of Nonin and polar will be extracted per device and saved on the netwerk.
Patient answer on question in the smartphone application	.xls	Answers on the question about medication change will be logged on the back end of the smartphone application. Exports of the answer of the patients (and identification as an exacerbation) will be saved on the server of KU Leuven and UGent.

3. Legal and ethical issues

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.

- Yes

Privacy Registry Reference:G-2021-3148 (KU Leuven)

Short description of the kind of personal data that will be used:

Personal information will be collected for research purposes and consist of socio-demographical data (e.g. gender, date of birth, address), data on the health status (e.g. disease severity, medication intake, physical functioning, symptom experience) and biosensor data (steps/day, heart rate, hearte rate variabilty, oxygen saturation) via the informed consent procedure in agreement with the General Data Protection Regulation.

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)

- Yes

Approcal of EC: S62902
PRET G-2021-3148

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?

- No

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

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

1) A detailed protocol is available with a description on the test assessments. This protocol is available on the KULeuven and UGent network.

2) Detailed information about the coding will be included in Redcap. This logbook will be exported and saved on the network of both sites.

3) SAS program including development of new variables (e.g. calculation of physical activity outcomes, management of raw biosensor data).

4) A seperate codebook will be created for specific data management (i.e. analysis of heart rate variability based on the raw Polar data using Kubios software).

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

As indicated before, the following information will be available:

1) Protocol including manual of procedure and used questionnaires

2) Logbook developed in Redcap

3) Sas program with all information needed to understand development of new variables

4) Additional codebook with information missing in the previously mentioned Redcap logbook and/or SAS program.

5. Data storage and backup during the FWO project

Where will the data be stored?

The data will be stored on the university’s secure environment for private data. For part of the data this will be via RedCap.

Coded Fitbit data are saved on the fitbit website and exported on a regular basis using the Fitbit API.

How is backup of the data provided?

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

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: Sufficient space on J-drive and L-drive (research group / department).

UGent: Sufficient space on network

No high density data will be collected.

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

NA

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

The (exported) data will be stored on the university's secure envionment for private data.

6. Data preservation after the FWO project

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, ...).

Both raw data and finally processed data will be stored for at least the 5 year period after the end of the project.

Where will the data be archived (= stored for the longer term)?
Data will be stored on the university's central servers.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?
no additional cost is expected

7. Data sharing and reuse

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)?

- No

Which data will be made available after the end of the project?
The full anonymized dataset can be made available after publication of the data and upon request with one of the principal investigators of the present project. All new research questions will be submitted to the EC for approval.

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

- Upon request by mail

When will the data be made available?

- Upon publication of the research results

Who will be able to access the data and under what conditions?
Data of participants who granted permission will only be shared with research groups or third parties who submitted a written request to one of the investigators of this project and with whom a contractual agreement determines the terms and conditions of such sharing.

What are the expected costs for data sharing? How will the costs be covered?
No costs are expected. If any occur, they will be covered by the requesting parties.

8. Responsibilities

Who will be responsible for data documentation & metadata?
All researchers involved in the present project at different levels.

Who will be responsible for data storage & back up during the project?
Heleen Demeyer and Thierry Troosters

Who will be responsible for ensuring data preservation and reuse ?
Heleen Demeyer and Thierry Troosters

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