PROJECT
i-PROGNOSIS: Intelligent Parkinson early detection guiding novel supportive interventions

GRANT AGREEMENT No.
690494

Memorandum of Understanding

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PROJECT ACRONYM	i-PROGNOSIS
PROJECT FULL TITLE	Intelligent Parkinson early detection guiding novel supportive interventions
Type Of Action	Research & Innovation Action (RIA)
Topic	H2020-PHC-21-2015 - Advancing active and healthy ageing with ICT: Early risk detection and intervention
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Duration	48 months
Project URL	www.i-prognosis.eu
EU Project Officer	Ramón Sanmartín Sola

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1 CONCERNED PARTIES

NAME	i-PROGNOSIS Consortium (see here)
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HEREAFTER CALLED	Inquirer

NAME	
CONTACT PERSON	
E-MAIL	
HEREAFTER CALLED	Supporter

2 INTRODUCTORY NOTE

This Memorandum of Understanding (hereafter: MoU) is an agreement that defines the framework of the negotiations between the partners of the i-PROGNOSIS project aforementioned (hereafter called: the inquirer) and a third-party organisation willing to support the project (hereafter called: the supporter). The purpose of this MoU is to outline the services that can be exchanged and actions to be performed by the different parties within a specific period of time. Actions and services taking place in the frame of this MoU are described under section 4 "Agreement".

3 THE i-PROGNOSIS PROJECT

The European Horizon 2020 research project i-PROGNOSIS seeks to promote the prognosis of Parkinson's disease through advanced analysis of behavioural data taken during user interaction with everyday smart devices (smartphones, smart watches, wristbands…). While no cure has been found to reverse Parkinson's yet, early diagnosis permits to slow down the progress of the

condition and proposes timely interventions to maintain a good quality of life for people living with the disease.

Smartphones present tremendous opportunities to improve people's health, including through the provision of non-pharmaceutical solutions. By building unobtrusive detection methods and supportive interventions, i-PROGNOSIS expects to rally the whole Parkinson's community – people living with the disease, families, carers, health professionals… – to its main objective: advancing the way Parkinson's disease is predicted and treated.

The i-PROGNOSIS consortium[1] includes 11 partners from 6 countries, all members of the European Union and is led by the Aristotle University of Thessaloniki, Greece. All partners have excellent experience and capabilities related to the project objectives and tasks in technological, health and healthy ageing policy domains. Medical partners of i-PROGNOSIS (listed below) are experts in Parkinson's and have experience in the roll out of health information technology (IT) programmes:

- UK: King's College Hospital - Dept. of Basic and Clinical Neuroscience,
- Germany: Technische Universitat Dresden - Dept. of Neurology,
- Greece: Aristotle University of Thessaloniki - Dept. of Neurology,
- Sweden: Karolinska Institutet - Dept. of Neurobiology, Care Sciences & Society.

3.1 THE i-PROGNOSIS GDATA STUDY

The GData (general data) study[2] collects data from a wide participant group including healthy volunteers and patients with Parkinson's disease in order to develop tests for the early detection of Parkinson's disease. The research focuses on the early identification of specific symptoms (motor and non-motor) which could accelerate a clinical diagnosis of the disease. Data is collected in an innovative and unobtrusive manner through the smartphone application iPrognosis (currently available on Android only through download from the Google Play Store).

3.2 THE iPrognosis MOBILE APPLICATION

The iPrognosis mobile application[3] is currently available for free on Google Play Stores in Germany, Greece, Portugal and the UK. By downloading the iPrognosis mobile application, all volunteers remotely participate in a clinical trial of a new kind through the provision of anonymized data (such as voice characteristics or typing patterns) collected from the daily use of their smartphone.

Unlike other symptoms tracking applications, iPrognosis does not require any specific action from the users and does not interfere with phones normal use or daily functioning. This permits the consortium to develop algorithms able to detect behavioural changes relating to Parkinson's. Eventually, a tool will be created that will screen for Parkinson's in daily living and lead to an early diagnosis with the help of your doctor.

To ensure the accuracy of the algorithm that will screen for Parkinson's and alert physicians, it is of utmost importance that the current prototype is used by a wide range of individuals, both persons

[1] More information about the i-PROGNOSIS consortium: http://www.i-prognosis.eu/?page_id=71
[2] More information about the i-PROGNOSIS GData study: http://www.i-prognosis.eu/?page_id=1772
[3] More information about the iPrognosis mobile application: http://www.i-prognosis.eu/?page_id=1985

living with Parkinson's and healthy individuals (controls). Only the massive participation of Europeans (preferably 40+) will permit to refine advanced analysis methodologies and machine learning algorithms able to detect behavioural changes relating to Parkinson's!

Complementarily to the app, engineers and neurologists are developing a number of web-connected everyday utilities (Internet of Things) with the objective to capture additional data that may relate to Parkinson's disease early symptoms. This is part of the SData (special data) study[4] to come. Personalised solutions to mitigate symptoms, facilitate physical exercise at home, and improve diet and sleep are also being explored as part of the i-PROGNOSIS supportive interventions[5] to sustain the quality of life of people living with Parkinson's over the course of the disease.

4 AGREEMENT

This agreement registers the interests, the common understanding and the cooperation between the inquirer and the supporter in the context of the deployment of the iPrognosis mobile application (hereafter the "iPrognosis app") in the frame of the i-PROGNOSIS project and its GData study implementation.

This agreement is entered into on DAY – MONTH 2018 by and between inquirer and supporter, which are the concerned parties, as described in section 1, individually referred to as "inquirer" and "supporter", collectively referred to as "parties".

The agreement concerns the submission of a medical study application to an ethical committee in the country of the supporter to allow the collection of GData in the concerned country. If the ethical application is successful, the data collection will take place in the country where the application was accepted in the frame of the i-PROGNOSIS GData study through the iPrognosis smartphone application that will be made available for free download via the Google Play Store. The final objective behind the submission of this ethical application remains the collection of a large amount of general data to refine machine learning algorithms able to screen for Parkinson's disease early symptoms. The inquirer expects, with the present agreement, to release the iPrognosis app in a new country and thus increase the number of 40+ individuals that will download and actively use the iPrognosis app.

The parties agree as follows:

4.1 ACTIVITIES/ROLE OF THE INQUIRER

a. The inquirer shall provide an example of application to an ethical committee for the GData study to the supporter to facilitate the application process and keep the workload to a minimum.

b. The inquirer offers large-scale assistance to the supporter during the application process in case of any arising questions as well as after the application is accepted.

[4] More information about the i-PROGNOSIS SData technologies: http://www.i-prognosis.eu/?page_id=67
[5] More information about the i-PROGNOSIS interventions: http://www.i-prognosis.eu/?page_id=61

c. The inquirer allows the supporter to become an ambassador of the i-PROGNOSIS project, e.g. acknowledgment of contribution on the project website, permission to put the project logo on the supporter's website to acknowledge participation.

d. The inquirer allows limited access to research data for the country the supporter has submitted an application to, in accordance with the i-PROGNOSIS Data Management Plan[6] and in compliance with the EU General Data Protection Regulation[7]. Raw data remain confidential. The use of shared data is embargoed until an i-PROGNOSIS consortium scientific publication involving such a dataset is released. The supporter may contribute to such a publication as co-author. Once the consortium will have published using the dataset (with or without the co-authorship of the supporter), the supporter will be able to use it for additional publications. In case the project consortium is not willing to publish about the concerned dataset, the supporter will be allowed to use it for any type of publication after the end of the project plus six months.

e. The inquirer will invite the supporter to participate in scientific publications, which will include description/analyses of data collected in the country of the supporter, as collaborating co-author(s), as well as popularised publications especially in the national language of the country where the iPrognosis app is expected to be released.

f. The inquirer will be happy to welcome the supporter (1 person only) to become part of the project's advisory board[8].

4.2 ACTIVITIES/ROLE OF THE SUPPORTER

a. The supporter will submit an ethical application to the competent authority of his/her country for the GData study and thus will release the iPrognosis mobile application in the name of his/her organisation for the i-PROGNOSIS consortium.

b. If the ethical application is accepted, the supporter will take care of the translation of the mobile app text-based contents into the national language. This applies in cases where the application is not yet available in the same language in another country. Translations can be done in-house by the supporter him-/herself and no professional translation is required from the inquirer. The supporter will receive a file from the inquirer which includes all text-based content in English, to be able to do so.

c. The supporter will not perform any study follow-up, including contacting and clinically examining participants, and no such option will be available in the iPrognosis mobile application for participants coming from the supporter's country.

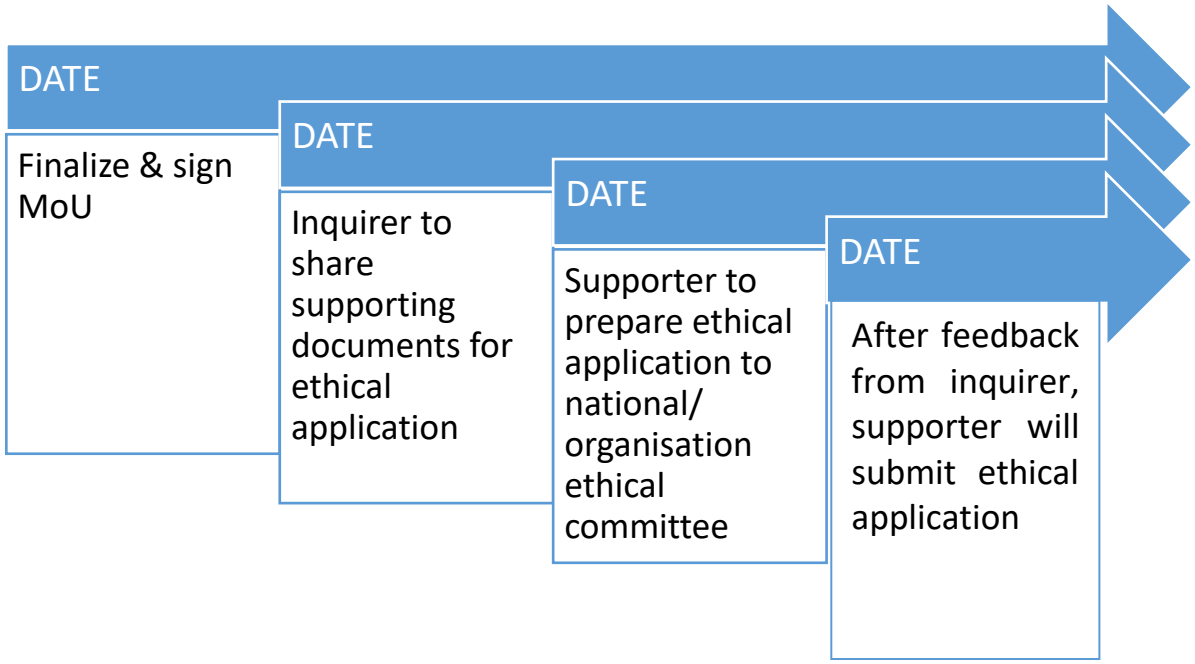
d. The supporter will be the main contact person for participants in the supporter's country and they will have to support participants by answering questions/inquiries. The supporter

[6] The Open Data Management Plan of i-PROGNOSIS is available here: http://www.i-prognosis.eu/wp-content/uploads/2016/07/i-PROGNOSIS-690494_D5.1.pdf
[7] More information about data privacy in i-PROGNOSIS: http://www.i-prognosis.eu/?page_id=427
[8] More information about the i-PROGNOSIS Advisory Board: http://www.i-prognosis.eu/?page_id=349

may redirect participants to info@i-prognosis.eu in case of inability to respond to a participant's inquiry.

e. The supporter may make use of the inquirer's offered rewarding activities as described above (see section 4.1) and in accordance with the agreed Terms of Reference below (see section 4.4).

4.3 PROPOSED TIMELINE



Once/if the ethical application is accepted, the iPrognosis mobile app will remain available on the Google Play Store of the concerned country until the end of the GData collection period, that is to say until the end of October 2019.

4.4 TERMS OF REFERENCE

The supporter offers his/her services and expertise on a voluntary basis and is expected to remain in regular communication with the inquirer over the course of the project, ending 31 January 2020. Frequent correspondence (e-mail exchanges, conference calls, etc.) will be maintained between both partners mainly throughout the duration of the submission of the ethical application and the GData collection study.

Contributions

1. The inquirer does not require from the supporter to consult nor represent his/her organization of affiliation. The supporter is however expected to act pro-actively by raising any concern or issue that may hinder the approval of the ethical committee.

2. Upon request of the supporter, the inquirer will provide information (further to the template of application that will be provided proactively by the inquirer) that can be useful to submission of the ethical application.

3. The supporter will inform the inquirer in writing as soon as the ethical application is submitted and whenever the ethical committee will interact with the supporter.

4. The supporter will have no executive or decision-making authority and will act in a supportive manner. Recommendations brought up by the supporter will not be binding for the inquirer. However the project consortium will do its utmost to answer the needs and address the issues raised by the supporter.

5. For the success of the project the supporter is contributing to, public information (e.g. publications, dissemination material, etc.) will be explicitly identified as such and be made available to the supporter by the inquirer; the supporter is invited to disseminate them as widely as possible in case the ethical application is approved in his/her country. The inquirer cannot provide the supporter with financial support for the production of dissemination material and will not reimburse such costs at any point.

6. The contribution of the supporter will be publicly acknowledged in key publications and on the project website unless the supporter explicitly asks for her/his contribution to remain confidential.

Financial aspects

1. The inquirer will not grant the supporter any financial contribution but ensures the rewarding mechanisms agreed upon in the present memorandum of understanding and described in details under section 4.1.

Confidentiality

1. The supporter is aware that all documents shared with him/her are to be treated confidentially and are subject to a non-disclosure agreement between the inquirer and the supporter so that any project-related document cannot be shared with any third party unless the inquirer gives a formal authorization.

2. Information disclosed to the supporter (i.e. draft versions of project publications, key issues on which their feedback is sought, etc.) and the content of the discussions within the supporter must remain confidential, unless officially disclosed by the inquirer.

3. Meetings (incl. virtual ones) will be held under Chatham House rules and no reference to specific contributors will be recorded unless requested by one of the parties.

Property rights

1. The supporter ensures not to make content-related changes in the ethical application; all content belongs to the inquirer.

2. The supporter does not demand any ownership of data collected in the frame of the GData study; data collected remains the property of the individual they relate to who can -at any time- request access to their data and assert their right to be forgotten as recalled in the i-PROGNOSIS ethics and safety manual[9].

4.5 SIGNATURES

INQUIRER	**SUPPORTER**
Date:	Date:
Signature(s)	Signature(s)

[9] The first version of the ethics and safety manual of i-PROGNOSIS is available here: http://www.i-prognosis.eu/wp-content/uploads/2016/07/i-PROGNOSIS-690494_D1.2.pdf