

The CHERRIES Project has launched three healthcare territorial challenges and it is now looking for innovative solutions that can tackle them according to "Responsible Innovation" processes and methods, therefore following inclusive and participatory approaches during the implementation of such solutions.

For each challenge, CHERRIES will award one solution. Selected European innovators will:

- Co-develop and validate the solution with the challenge promoter
- Receive up to 50000€ to develop the solution over 10 months

<u>CHERRIES Murcia</u> is calling European companies to solve the "Early detection of progression in Multiple Sclerosis" challenge.

Below the answers to the questions received about the call (version of 31 March 2021).

Q.1. If a device takes measures multiple times in a day of course but it is not constantly monitoring like an IOT wrist watch, is this something you would consider in the application as it looks like you may only require constant monitoring devices?

A.1. This solution does not meet the specification requirements but can substantially enrich the clinical trial and the data derived from it but only if it is added to the required solution, focused on measuring daily physical activity. Our objective is to quantify the affectation / progression that MS produces in a totally passive way with respect to the patient.

Q.2. Using a cheaper and scalable approach with a cheap smartband and a tablet, and some sensors at home that don't even need an Internet connection, so we can combine all these technologies, make a more global analysis of the evolution of the person. Could an approach like this apply to the challenge? Could we even invite other patients' associations to join in the co-creation and testing phases?

A.2.

1. We are not looking for a sophisticated device. In fact we are waiting for a simple and robust device to monitor the patient in their daily physical activity. On the other hand, it is expected that the monitoring of cognitive status will be measured by questionnaires through the application, not through the device.

2. Regarding adding patients from other associations, we discarded it in the co-creation phase because this would increase the complexity of managing co-creation. However, we would be delighted to extend it to patients from other associations once it has been validated, so that the greatest number of people could benefit. That is why we offer these contact channels for the winning company among our services.

Q.3. - Do we need to include devices like tablets, smartphones if needed as part of the budget for any of the projects?

- Is it needed to have local support or to know local languages to apply to any of the challenges? If





so, can we subcontract a part of the budget for an already identified local company to help us with those tasks of co-creation?

A.3. A possible subcontracting from the third party – recipient to another entity is not explicitly mentioned but may not be forbidden. It has to strictly follow the national rules (legal and accounting practices in place) on procurement (including on business procurement) and to serve for the proper implementation of the activities, for which the financial support is granted. A detailed budget has to be annexed to the solution plan provides by any applicant.

Q.4. Is the intellectual property of what the developed solution will belong entirely to the company?

Is there any kind of licence or consideration/compensation, foreseen such as royalties to partners?

A.4. A pre-agreement will be made with the company within the co-creation agreement in which the agreed conditions are reflected. The aim is to value the inventive participation of all parties in order to strengthen a collaboration link.

Q.5. It is compulsory to use IoT and sensors, or is it possible to apply SW technologies with smartphones and tablets?

A.5. The idea of the original proposal was that the user would only wear a sensor element capable of collecting the requested information in the least invasive way possible. Some of these parameters such as heart rate or hand accelerometry are not usually available on smartphones and tablets, so the use of devices such as smartbands, smartwatches or even smartdots is suggested to collect the information. In order to upload the data to the cloud, since there is no need for online processing of the data, it is proposed to use a home gateway that downloads the data recorded throughout the day and sends it over the internet to the server used. This gateway can be configured around a smartwatch or tablet as long as no user intervention is required.

Q.6. Whether the solution should be integrated into the hospital's medical records and IT systems. This access is very restricted and difficulties arise in its implementation.

A.6. Any direct integration with the regional Health Institute SSIIs will be avoided as is usual in our innovation pilots. Data crossing will be done externally via downloads or gateways as agreed in the co-creation agreement. In addition to the co-creation agreement, a data processing commissioning contract will be signed between Regional Health Institute and the company detailing the terms of the agreed security approach.

Q.7. Prices and types of devices that could be used

A.7. There is a wide variety of devices available on the market, from different brands, and their prices vary: from 1600 euros to 90 euros. It is advisable to contact providers who may have open calls for clinical trials. Preferable requirements are the autonomy or battery life, as well as the speed of charging, looking for comfort and reduction of time without recording. The intensity of recording is weighted against the frequency of data update, as intense monitoring is required but not in real time. A weekly or even monthly data refresh would be acceptable.

Q.8. Monitoring

A.8. The intensity of logging is weighted against the frequency of data refreshment, as intensive but not real-time monitoring is required. A weekly or even monthly data refresh would be acceptable. To this end, the time without logging should be minimised by reducing battery charging times, with long





battery life and/or fast charging, and by reducing the time without a device in the event of an incident. The maximum recording surface should be obtained: 150 days for 30 patients.

Q.9. Data processing

A.9. The information must be presented in a specific way. It is preferable to collect pure sensor data; the more data and the more frequent, the better.

Q.10. In order to calculate the budget linked to the devices (watch, mobile phone, etc.): how many patients should be included in the pilot? For how long?

A.10. The study will be conducted on 30 patients for 150 days. The devices will remain the property of the company.

The budget is a lump sum based on what is justified by the companies. The idea is that the budget will not be used to pay for all these devices. However, the purchase of devices may be an eligible expense. A generic breakdown will be requested to monitor the expenses of the project.

Q.11. How is the cognitive part measured (when it affects the eyes)?

A.11. Following the study of the state of the art carried out prior to the launch of the challenge, it was decided to focus the monitoring on wrist movements because of the ease of recording alterations in gait and manual activities.

Q.12. Should the application offer an exercise (rehabilitation) plan to the patient?

A.12. The challenge is focused on the detection of progression, not on its treatment. However, if it is functional and interactive, it could be used later for cognitive rehabilitation, if these measures work.

Q.13. Is it possible to use companies' own devices if available?

A.13. Yes, the company's own technology can be used, there are no guidelines as to the type of devices to be used.

Q.14. Manual dexterity: incorporating the data into the company's AI models to obtain measurements. These models have to be trained beforehand to identify which movements have to be documented, what types of movements we want to study.

A.14. These patterns do not have to be defined. It is enough to know that the patient is making movements; that is already information: the frequency, the energy level, the duration or distribution throughout the day... There is a corpus of data but from very different sensorisations which make difficult to use as a training pattern for machine learning.

It is not defined in the literature what kind of movements correlate with patient training, independent of gait, progression of manual movements. This is something that we could define as a result of this study with the PROGRESS challenge.

Q.15. A lot of raw data will be collected, how will it be managed?

A.15. Experts in activity measurement will be in charge of predetermining the data to be studied.

Q.16. Bonus points for applications has been set up: what variables or criteria will add up to points in the application itself?

A.16. The scoring of the additional requirements is presented in the call itself (link https://www.cherries2020.eu/wp-content/uploads/2021/01/CHERRIES-Murcia Call-for-Solutions.pdf





) where it is described the maximum scoring limit for each optional requirement and how its value is calculated.

Q.17. When is the winner expected to be announced?

A.17. Estimated date of publication of the winning company: 21st of May 2021. Estimated start of cocreation: 3rd of June 2021.

Q.18. As of the psychological part, is it only contemplated to monitor the progress from physical symptoms not psychological ones?

A.18. The evolution of manual activity is a consequence of the patient's condition, recording physical activity by default, and passing on information are indicators of disease progression. It is also intended within this study to monitor the quality of life by means of the SF12 test.

Q.19. Is there any corpus of extra data to complement the models?

A.19. Some projects have a database. This type of experience is very new and there is no standard. Moreover, dynamic monitoring without specific effort required from the patient is difficult to compare.

Q.20. Regarding the questionnaires, they should be answered by the patients on a weekly basis. Do they fill them at home or at the Hospital? In case that they fill them at home, do the patients have access to a PC and Internet?

A.20. The complementary questionnaires to be given to patients are coordinated by the Neuroimmunology Unit at Santa Lucía Hospital, and are independent of the patients' movement monitoring. The patient can fill in the questionnaires at home or at the hospital, but they do not need Internet connection to do so.

