

## IMI2 Call 3 – RADAR-CNS – Questions & Answers

### Consortium members

#### How do I find consortium partners?

As you must address all the issues in the call text, finding suitable partners is crucial.

As well as using your own networks, you can sign up and search the following partner search tools:

- <http://www.imi.europa.eu/content/partner-search>
- <http://www.fitforhealth.eu/>
- <http://www.imi-partnering.eu>

Get in touch with your local IMI contact point (SRG) and H2020 national contact point:

- [www.imi.europa.eu/content/states-representatives-groups](http://www.imi.europa.eu/content/states-representatives-groups)
- [http://ec.europa.eu/research/participants/portal/desktop/en/support/national\\_contact\\_points.html](http://ec.europa.eu/research/participants/portal/desktop/en/support/national_contact_points.html)

Don't forget to network on social media (e.g. IMI LinkedIn group)

#### Should the expertise on regulatory and medical-economics already be included in stage 1 of the proposal?

The consortium should be able to interact with regulators, payers and other stakeholders. EFPIA organisations have a lot of experience in this area which they can bring to the project, but the applicants should have a plan as to how they would use such expertise to influence these stakeholders.

#### Apple, Google and Amazon are rapidly innovating in this area. Given their overwhelming leadership in the digital sphere, should they be included?

In RADAR, the key question is what is the clinical significance of the data that can be measured, how does this signal propagate through the system to the right stakeholder so that the correct clinical action/decision can be taken. Organisations such as those mentioned have important expertise that could add to a consortium, and would definitely be welcome, but it must be emphasised that this is a clinical experiment.

#### Are there any specific regulatory bodies/expertise the public consortia should bring in - complementary to the EFPIA expertise?

Not specifically, and, while this is a European project, the results should apply globally so global expertise could be included, however, please read the IMI rules on eligibility carefully to ensure your consortium is eligible to be evaluated and to ensure the organisations in your consortium are eligible for funding.

- [IMI 2 Summary of most relevant provisions for participating in IMI2 actions](#)
- [IMI 2 Manual for evaluation, submission and grant award](#)

**EFPIA partners will be bringing data, analytics, devices etc - can the applicants learn more about what EFPIA will provide, since logically this would have a major impact on the applicants' proposal**

The input from the EFPIA companies will be fully described during the full proposal preparation at stage 2. During the stage 1 submissions, applicants should use the information available in the text and the webinar to prepare their submissions. Any specific questions can be emailed to [infodesk@imi.europa.eu](mailto:infodesk@imi.europa.eu). The questions and answers will then be published on the IMI website.

## **Observational studies & patient cohorts**

**What do you mean/expect exactly by “non-interventional/observational study”?**

A study where the way that patients receive clinical care is not changed. Only collecting data, and then observing clinical state changes and definitely not giving an intervention.

**The project has been described as a “clinical experiment” - does this mean it's an RCT?**

The studies are pragmatic and therefore do not need to be randomised, double blind, placebo controlled. A key difference is to include longitudinal data on the subjects, ie they would act as their own baseline.

**Can you give a range for the number of patients in the cohorts?**

The exact numbers of patients are being left to the applicants. However, applicants should consider the number of data points collected, the feasibility of recruitment, whether a single cohort or multiple cohorts would be needed etc. The study must be powered to meet the call objectives. Overall, larger cohorts in depression and MS are expected than in epilepsy.

**Would we need to be able to provide all patient cohorts – Depression, MS and Epilepsy - or will bringing one to the table be sufficient?**

Applicants must address all the objectives in the call text, so addressing all three disease areas is important. Applicants should note, however, that there is a stronger emphasis on depression and MS than epilepsy. There may also be opportunities to examine co-morbidities (eg MS/depression) to allow for efficient study design. In epilepsy, maybe a smaller cohort, or a targeted validation study of pre-existing biosignatures may be considered.

**Monitoring itself may change disease course in depression - does this need to be factored in to the design**

Yes, the goal is for observational studies, not those that would change the disease course. Therefore focus on quick questionnaires and passive data collecting.

**Regarding MS, what biological and/or clinical parameters would need to be collected?**

These have not been defined at this stage and will be clarified during the stage 2 full proposal preparation and trial design. However, the goal is to tie remote assessment signals with already established clinical measures. So the current methods scoring MS symptoms and exacerbations would be recommended.

### **Is it possible to focus only on elderly patients or does the population need to include all age groups?**

The study population should fairly represent the actual age distribution of the condition (which, for depression, is all ages), but should not include children. Note that the technology may be more likely to be accepted by younger patients.

## **Remote assessment tools**

### **Are remote assessment tools the starting point of the project?**

The starting point is to understand if and how data from passive devices can be used to track disease state. Data from physicians will have to be included (ie to identify the relapse). A question could be: do we need continuous data, or would periodic data be sufficient. For example, a solution may be to start with episodic data gathering, and then become more continuous in response to a signal.

Applicants should take a patient-centric view, and be broad based in thinking about sensors. ie don't see this as an avenue to push a single device, though this could be an aspect. It's best to be technology agnostic.

### **A significant number of the current techniques used in clinic are invasive - the call specifies non-invasive wearable devices - how flexible is the non-invasive requirement, keeping in mind the clinical relevance?**

The goal is to develop solutions that will be used by patients in the real world. Therefore non-invasive is important to ensure user acceptance. There is flexibility about what type of non-invasive devices can be used, eg commercially available, prototypes etc.

### **Regarding wearables, how do you manage the lack of certifications and precision/robustness of many of them when combining it with data provided from sanitized sources?**

Studies would be observational only; none of the devices will formally diagnose a patient. Therefore the regulatory requirement is quite different from a medical device and commercially available and experimental devices can be used, which could be formally validated at a later stage.

### **As the industry will bring in sensors etc, how open you are to the participation of research institutes and SMEs bringing in special expertise into this field.**

The call is very open on this point and would definitely welcome new sensors that would help address the clinical question. Note that there is a very strong preference for passive data gathering with non-invasive sensors.

### **The call text contains a list of parameters - sleep architecture, physical activity, speech, cognition, social connectivity etc. Is the set of technologies limited to these, or can it be expanded?**

These parameters have been identified as those that the companies think could be answer the clinical questions, however this list is not rigid. If an applicant knows that a subset of these measurements would be sufficient, then these could be used. Likewise, if additional necessary measurements can be obtained non-invasively, then these could also be included.

### **If an applicant developing remote EEG technology, could this be included?**

There is a strong preference is non-invasive technologies. If applicants can show that an EEG would meet requirements regarding usability, acceptability, cost then they could be considered. In the future, an adaptive approach could be considered, ie non-invasive sensors are initially used, and once an increased risk is detected, a slightly more invasive technology to be used. However, for this topic, the strong preference is for non-invasive technologies.

### **Could a game be used as a method of measurement?**

There is a strong preference for passive ways of measuring, however, if there is a quick game that people can play, this could be considered. Remember that the aim is to measure, and not change, disease state. Please also consider whether the measurement method can translate into everyday practice, ie would people play the game every day?

## **General**

**At the end of page 4 in the call text, it is written that “A key element of the RADAR Programme is coordination across all RADAR topics. This will require applicants to reserve some resource to support the coordination across different topics.” Can you please specify what should be achieved and when, and what resources should be reserved for this point?**

While topic 1 is currently a stand-alone topic, the intention is to ensure solutions that are developed in one RADAR topic can be shared across other topics. Therefore consortia members should be willing to share these results.