

## Call 2020-3-RIA-IMI-ECSEL- Joint Activity

### Information Session 18 June 2020 (remote)

### Questions and Answers

- 1) Q: Is any plan to publish more detailed information about the call, specifically more detailed scope  
A: No, there is no plan about that. Applicants are invited to check the Annex 7 of the ECSEL JU Work Plan 2020 and the Additional Call Information document – both available in the call's pages on the ECSEL website and Funding Portal
  
- 2) Q: What would be the evaluation method for this call what are the evaluation criteria, how do they differ from other ECSEL calls?!  
A: Same criteria as the other RIA calls. Applicants shall take into account when preparing the proposal, the ECSEL JU Work Plan 2020 and the Additional Call Information document. As explained in the presentation it is a RIA call with all the conditions (eligibility and evaluation) of a RIA call.
  
- 3) Q: What TRL activities are expected from the consortium?! Shall we think of it as another RIA and have research emphasis universities and research centers?!  
A: It is a RIA call, RIA calls have TRLs from 3-4 (eventually up to 5) so it is development it is not pure research and obviously consortia shall involve universities, research organizations but also SMEs and large enterprises.
  
- 4) Q: How many pilots are expected?!  
A: It is not completely clear what is meant by “pilots”. Probably it refers to “use cases” or maybe to the pilots involved in the “trials@home” project. There is a presentation of the project “trials@home”, which answers this question.
  
- 5) Q: Do we need to carry out clinical trials at home within the project or is the scope more related to development of future technologies to support the clinical trials at home such as infrastructure and services.  
A: The ECSEL projects should obviously focus on technology demonstrations as the call is focus on development of future technologies for remote clinical trials. Therefore, technologies demonstrators not necessarily clinical trials.
  
- 6) Q: What constitutes a clinical trial at home and a remote decentralized clinical trial  
A: see the presentation of the “trials@home” project

- 7) Q: Is a potential use case based on elderly care center an acceptable use case?! Where the elderly live or only spend daytime?!
- A: Probably not but it depends if it relates to technologies for conducting clinical trials at home probably yes
- 8) Q: What constitutes addressing 1) technical 2) regulatory 3) compatibility and 4) acceptability issues?! Are we right when we think that 1 is the main purpose but we need to account also for the issues 2-to 4 more?!
- A: Technology of course is the main part of the ECSEL project as it is about future technologies but obviously the consortium shall take into account also the points 2-3 depending on what is proposed as future technologies
- 9) Q: Is it possible to clarify the meaning of the patch to patch communication, from the call description
- A: It refers to means to communicate between different patches - for example patches that sense and patches that act
- 10) Q: The call description says *“running IMI JU project (Trails@Home) and complement to and extend the technology scan activity of the project which will identify barriers, enablers and data management for the Remote Decentralised Clinical Trials.”* Is it possible to elaborate on the type of collaboration and depth of involvement expected from us with the “trials@home” consortium members?! Is it exclusive?!
- A: There is a minimum requested collaboration: there should be some exchange of information between the two consortia (e.g. common workshops, events, publications). Collaboration is encouraged, there shall be some interactions between the two consortia/two projects though it is not clear what “exclusive” refers to.
- 11) Q: What does the identifying barriers and overcome the barriers identified refer to?! Is it enough to identify the barriers or also is the consortium expected to overcome the barriers identified?!
- A: This is related to the ambition of the project proposed. The more the better: if a consortium can identify the barriers and also overcome them even better.
- 12) Q: Clarify that is meant by technology scan activity?!
- A: refer to the presentation of the project “trials@home”.
- 13) Q: The call text reads *“In an end-to-end journey, aspects as quality and data integrity, security, connectivity, communication interface, stakeholders’ feedbacks such as patients, principal investigators, regulators, sponsors will be assessed over an broad technology range (available or with a validated proof-of-concept) in order to enable a seamless communication, data monitoring and collection from distant location for these RDCT.”* Are the expectations of the assignment defined exactly?!
- A: refer to the presentation of the project “trials@home”

- 14) Q: Indicate what period covers the maximum ECSEL funding in the call?! Is it the Q3/Q4 of the 2020 or is it circa 3 years 2021-2024  
A: see the call presentation. Maximum duration of the project is 3 years starting from 2021 until 2024
- 15) Q: We are running the EU-funded (3 Mio €) Innovation Project RealWorld4Clinic (<https://eit-health.de/en/realworld4clinic/>) under the umbrella of the EIT Health Knowledge and Innovation Community. The topic is highly related to “Trials@Home” and the ECSEL JU - IMI Joint Activity Call. We are interested in exploring the optimum way for a potential collaboration.  
A: Not a question but a proposal. As ways to improve the collaboration: join one of the proposals as a partner/consortium or wait until the selection procedure is finished and once the project(s) start look for more precise way to collaborate
- 16) Q: Clarifications on budget set up, eligible costs, management of the EU&national contributions  
A: This issue was addressed in the Call presentation – see the relevant slides
- 17) Q: In a project the use of augmented reality and artificial intelligence for telemedicine are contemplated in paediatric surgery for the treatment of tumors.  
A: This call is about the future technologies for remote clinical trials. If the project relates to this then it can be submitted to this call. Applicants are invited to check the documents when preparing the proposals (ECSEL JU Work Plan – Annex 7 and Additional Call Information Document).
- 18) Q: Is the call restricted to pharma/clinical trials or to medtech and new digital health care services?!  
A: There are no restrictions. Proposals focused on future digital technologies for clinical trials at home are eligible for funding in this call
- 19) Q: TELEREHABILITATION: Distributed rehabilitation at home service, monitored and managed remotely after an in centre training.  
A: The call is about technologies for remote clinical trials. Applicants are invited the check the call documents (ECSEL JU Work Plan – Annex 7 and Additional Call Information Document).
- 20) Q: What maturity level for the demonstrators is expected?!  
A: This is a RIA call so the expected TRL 3-4.
- 21) Q: Is clinical evaluation at home of implantable devices, such as periprosthetics, eligible in the context of Trials@Home?  
A: if related to development of digital technologies for trials at home, yes; see also the presentation of the project “trials@home”

- 22) Q: I like to have the full list of the Expression of Vision (EoV) submitted  
A: These EoV are confidential and therefore cannot be made public.
- 23) Q: Test bed for development of systems for distribution of medical samples and medicine health care by Unmanned Aerial Vehicles (UAVs)  
A: the same answer as for the Q#19. This call is about future technologies for remote clinical trials.
- 24) Q: What different types of patient inform consents are acceptable when it comes to e-Consent. And what is the best way to provide a patient ID stamp?  
A: see the presentation of “trials@home” project
- 25) Q: The need for integrated clinical and healthcare standards. Working with Standards Development Organizations (SDOs) and other standards related organizations.  
A: not clear what the question was
- 26) Q: Worries that pandemic escalation is not happening in China but US, Brazil, Russia and India and we should recognize and have our own target.  
A: not clear that the question was and note related to the present Call
- 27) Q: Social distancing doesn't seem to be the goal of this call. What is the goal of this call?!  
A: This call is not about COVID-19 but about development of the next generation technologies for remote clinical trials
- 28) Q: Being a Joint Undertaking is expected that ECSEL and IMI would select their own champions?! Is it fair to expect that?!  
A: No this is an open ECSEL JU call and everybody can apply (H2020 eligibility conditions apply).
- 29) Q: It is an ECSEL Call but based on an IMI JU project. Clarify the strategy of this call  
A: The selected project(s) in the ECSEL call will run independently but it is expected to see some interactions/collaboration between the two projects.
- 30) Q: How this programme can be beneficial for small and medium enterprises?! Which are the benefits and the advantages?!  
A: In general, the SMEs participating in the ECSEL JU projects perceive as beneficial the opportunity to work in an environment where the whole value chain is present and active (from large industry to RTOs). The ECSEL projects are fairly larger compare to H2020 project which allows for larger consortia where the SMEs can found easier a

suitable place for them. For more details, attendees are invited to check the ECSEL webpage and the Annual Activities Reports.

31) Q: Would all the presentations be made available?!

A: The presentations from ECSEL, “trials@home” project and AENEAS yes – will be posted on the ECSEL website. The presentations from the attendees give us permission to make them public.

32) Q: Is the 1:1.2 ratio to the realized over the entire consortium or for each individual participating partner?!

A: It is at project level. It is not mandatory it is strongly encouraged to make efforts towards it. It is a specificity of ECSEL and cannot be achieved per partner.

33) Q: How many EoV (expression of visions) have been submitted?!

A: This information is confidential and cannot be disclosed.

34) Q: Are applications such as implantable devices without pharmacological intervention eligible?!

A: Depends. If it is related to technologies for clinical trials at home yes.

35) Q: Is expected that the use cases are in line with the “trials@home” project use cases?!

A: see the presentation from “trials@home” project

36) Q: Are clinical centers expected to participate?!

A: Any organization can participate to ECSEL projects. Generally, the ECSEL projects include as much as possible the whole value chain (including the service providers and technology users) so in principle yes.

37) Q: For the trials hardware, sensors should be 100% finished or funding can be used to optimise devices and merge sensors data?!

A: Both options are open it depends on the project ambitions and targets.

38) Q: Will the session be recorded and made available?!

A: no

39) Q: The platforms could be made to feed the innovations to merge all the sensors?!

A: unclear question

40) Q: The project “trials@home” focuses on wearables. Are innovative point of care devices eligible to get information on critical biomarkers

A: Wearables are just one of the components. Point of care devices would be interesting but depends on the use cases solutions provided and how they fit into the project vision and the protocol developed. The pilot study itself focuses on diabetes.

- 41) Q: Could the project “trials@home” provide a contact point for the scanning team?!  
A: Check the project website; there is a dedicated page to submit inquiries related to the project (technologies will be fed into the scanning activity)
- 42) Q: How to realize the RDCT concept in case injectable drugs are tested?! Would the RDCT design elements be considering also for the various phases of the clinical trials.  
A: The RDCT can be incorporate in the clinical trials design not mandatory to use one over the other (complete remote over complete conventional). A hybrid version (remote couple of visit at the clinic but some collection of the data is done remote) is possible.
- 43) Q: Can a large company, mid-cap company participate in the call?!  
A: Yes
- 44) Q: What type of data standard for clinical trials are collected. Is there any work package working on this?!  
A: Yes, the project looks at different building blocks and there are groups looking at data capture and this data capture looks into getting data from electronic medical devices (e.g. medical history of a participant)
- 45) Q: In the Tech work package do you also look at the innovative security approaches?!  
A: yes, absolutely
- 46) Q: Would the technology gap analysis would be finished soon to take it into account for the preparation of the proposals to be submitted to this call by end of september  
A: The final gap analysis won't be finished before the end of the open call which runs for another 2 months until September and then some more time would be needed for the analysis of the results. But it might be possible to have some preliminary results from the scanning team before the call is closed. Liase with ECSEL team for further checks