Additional Call Information

ECSEL Call 2020-3 RIA, IMI – ECSEL joint activity

The specific conditions (scope and objectives) for the IMI – ECSEL joint activity call are described in "Annex 7 : Call 2020-3 RIA : IMI – ECSEL joint activity**"** of the ECSEL Work Plan 2020.

The topic of the call is "Next Generation Digital Technologies for Remote Decentralised Clinical Trials (RDCTs)". RDCTs represent a novel approach to operational clinical trials, which will move the key research activities away from typical clinical trial sites (e.g. hospitals and clinics) and closer to the study participant, for example via the use of home health nursing or telemedicine solutions.
The proposal(s) submitted to call 3 should deliver Next Generation Digital Technologies for RDCTs, that complement to or extent on the technology scan activity of the running IMI JU project "Trials@Home" that will identify barriers, enablers and data management for the RDCTs. The selected pre-competitive RIA project(s) resulting from ECSEL Call 3 should re-inforce the European Medical Technoloy sector and promote the collaboration with the IMI stakeholders.
Please refer to the following web pages for more information on Trials@Home:

- https://trialsathome.com
- https://www.imi.europa.eu/projects-results/project-factsheets/trialshome
- https://trialsathome.com/request-for-information/

In that respect, following additional call information applies to this call (Call 2020-3, RIA : IMI-ECSEL joint activity):

A. Technical, regulatory, compatibility and acceptability issues

In addition to "Annex 7 : Call 2020-3 RIA : IMI – ECSEL joint activity" of the ECSEL Work Plan 2020, the list of technical, regulatory, compatibility and acceptability issues that could be addressed also comprises:

- Integration and reuse of open/established IoT/Wearable and Ambient sensor platforms for data collection (easily integrate available devices)
- Integration and reuse of open/established data interoperability models and vocabularies, e.g. ontologies LinkedData (easily access and reuse available datasets, ensure interoperability across vendors, organizations, borders)
- Usability and Acceptance (extending "user friendliness", but referring to devices, comfort, durability, connectivity, battery life etc. and UI visualization dashboards, speech modalities, localization etc.)

B. Proposals to be submitted under this call could take into account the below expressed interest of the Trials@Home project on three aspects:

1. RDCT - patient engagement

i.e. trial awareness, information and alerts/reminders to patients, patient retention incentives, behavioral incentives, direct outreach / interaction with trial personnel, healthcare providers, satisfaction surveys, participant advisory board

This category of solutions enhances the operations of a "virtual care team" and improve engagement and connectivity with the study participants. In the conventional trial models of today, participant engagement relies heavily on the clinical trial sites, e.g. staff at brick-and-mortar clinics and hospitals. In a RDCT setting, the research professionals are no longer necessarily in the same physical location or even from the same organization, but somehow, they need to operate as a harmonious team. From the study participant's perspective, solutions are needed to build trust and to deliver a seamless experience where the virtual research team is all in the same loop and we can deliver both responsiveness and continuity and be able to develop relationships. Novel solutions that enable workflow coordination, information sharing and connectivity between all these stakeholders are needed.

Another novel solution type that could be useful is automated, AI-enabled journaling solutions for study participants. This could be a semi-structured (e.g. chatbot-based) or even free-format solution that would allow study participants to describe their experience in a more flexible and natural way. This could be combined with some AI to pick up key things, such as potential adverse events, identifying participants who are dissatisfied with their experience, etc. The journal entries could also be good material for the virtual care team in order to provide a more personalized experience.

2. **RDCT - data generation & collection**

i.e. patient reported outcomes, gathering of data in a formal clinical setting, acquisition management and operation of wearables & sensors, sample management, image management, gathering of real-life data, data (repository) management, source data verification, query management, data integrity, protocol and Good Clinical Practice (GCP) Deviations, access control, data transformation, data analytics, data integration, data interoperability in collection (reuse of open/established models/vocabularies), data visualization and analysis using AI toolbox.

Wearables represent a critical component for robust data collection with requirements for data integrity. The data capture market is already relatively saturated and good solutions are available to capture data directly from patients, using electronic diaries or sensor devices, as well as data capture solutions for the trial sites. However, in any given clinical trial, there are

typically a number of systems involved and they are often not integrated with each other. For example, one system may be used to capture data from patients and another one is used to capture data from the trial site. The data from these systems might then be combined in a back-end analytics system through integrations or batch data transfers, but it can be difficult to develop a “big picture” of what data has been collected and where, especially while the study is still ongoing. There are also various types of important metadata, such as timestamps for when the participant was consented into the study or to document the pathway through which they were introduced and onboarded into the study. New solutions that connect the data and metadata from various systems could bring additional value in the RDCT settings, where it is even more important to connect and centralize different data sources so that the relevant information is readily available to the research team and that operational issues can be detected in near real-time so that the team can intervene.

3. RDCT - close-out & reporting

i.e.AI in Clinical Study Report.