INFORMATION FACILITATE/IMI EU PROJECT

https://www.facilitate-project.eu/

Clinical trials and studies generate vast amounts of high-quality data, yet it is rarely returned to the people taking part in the trial. Furthermore, the data is typically siloed in separate repositories and cannot be used for other studies.

The aim of new project FACILITATE is to develop a prototype of a **patient-centered, data-driven process that would allow innovative data sharing and the re-use and return of clinical trial data to study participants. The prototype process will be built within an approved ethical framework that respects the EU's General Data Protection Regulation (GDPR).**

FACILITATE's budget is almost EUR 7 million, coming from the EU and EFPIA companies. With a start date of 1 January 2022, it is the last Innovative Medicines Initiative (IMI) project to get underway.

The FACILITATE consortium comprises a wide range of stakeholders, including patients, healthcare professionals, software designers, processors and controllers of clinical trial repositories, ethicists, and lawyers. Together, they will build a trusted ethical, legal and regulatory ecosystem to provide clear rules for all stakeholders before engaging patients as data generators. Among other things, here the project will focus on asking study participants what they would need to feel part of a trusted ecosystem.

FACILITATE will then generate technological solutions to allow data to be shared and re-used, based on the 'empowered willingness' of patients. With patient consent, FACILITATE will be able to re-use and cross-reference data with data contained in other repositories including real world evidence (RWE) data captured across multiple settings and devices.

Ultimately, FACILITATE offers a concrete opportunity to modify the current healthcare paradigm, **by putting patient participation at the centre of the development of health research, and give patients the confidence to shift from a passive receiver of care to an active, responsible, and aware driver of their own health.**

FACILITATE is supported by the Innovative Medicines Initiative, a partnership between the European Union and the European pharmaceutical industry.

EUPATI'S ROLE IN FACILITATE PROJECT

The role of EUPATI would be to assist in producing guidelines and training on the outcomes of this project and to facilitate the input of EUPATI Fellows and EUPATI National Platforms where relevant

EUPATI will engage Certified Expert Patients, formed in its training course, and related organisations, to gather their point of view and different experience on the use of patients' data. This Group, will follow the progress of the project from the start and will bring their knowledge and perspective to the project.

EUPATI, ACN and EURODIS will be responsible for:

- ✓ preparing educational tools in a plain language for the general population about health-related ethical and legal aspects and issues
- ✓ (b) finalizing guidelines to simplify FACILITATE Process use by patients and caregivers;
- ✓ (c) advocate with the local and European Institution about the need to return clinical trials data to patients and reuse them in research activities in the Framework of the MEPs Interest Group «European patients' rights and Cross-Border healthcare (promoted by ACN, endorsed by about 100 associations across Europe)
- ✓ Project results and tools could also be shared with health stakeholders such as institutions, patients' and civic associations, professionals, volunteers.

AdPEE'S ROLE IN FACILITATE PROJECT

Workpackage 2 -Legal and Data Privacy Framework

Because of internal expertise, the EUPATI IT, as linked third party (EUPATI) will implement the following tasks:

T2.2 Develop legal texts (for privacy notices, informed consent forms, contracts)

suggestion: to provide feedback on the documents, plus involvement of EUPATI Fellows

ITALIAN EXPERT PATIENT CONTACT PERSON NEEDED

T2.3 Develop standards for the development of a study participants' portal for managing future research with their data and exercise their rights

suggestion: to provide feedback on the documents, plus involvement of EUPATI Fellows)

ITALIAN EXPERT PATIENT CONTACT PERSON NEEDED

AdPEE's Commitment - Workpage 2 – Role of Contact Person/Expert Patient

- ✓ Every 2-3 months calls between EUPATI and AdPEE to walk through the various Workpackages and coordinate

- ✓ people from EUPATI and AdPEE to be involved in emails/communication related to the project

- ✓ Time sheets - keep track of the time spent as well as on what (WP and task level).

Workpackage 6 – Communication and Dissemination

To update all WP6 members on activities to date/timelines in developing initial draft documents for:

- ✓ The FACILITATE Website
- ✓ The Stakeholder Plan
  - The draft plan will be sent AFTER the meeting, however plan to send out prior to the meeting a copy of the stakeholder form for review, which will be on the website
  - The Communications/Dissemination Plan
  - A draft of this will be sent out prior to the meeting with instructions on the input needed by partner
  - To initiate the process of receiving your feedback on these initial drafts and agreeing timelines for review

AdPEE's Commitment - Workpage 6

- ✓ Attend Calls with EUPATI and all WP6 members (bi-weekly)