IMI2 Project ID 101034366 FACILITATE

FrAmework for ClinicaL trial participants daTA reutilization for a fully Transparent and Ethical ecosystem

WP6 – Communication and dissemination

D6.4 Report on Stakeholder Engagement 1

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Document History

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Definitions

A Stakeholder is defined for the purpose of this project as any individual or group that is affected by, who can influence or may have an interest in the outcomes of the FACILITATE project

Engagement. The term 'engagement' refers to all activities which will be carried out in synergy with various stakeholders across the WPs within FACILITATE. Consult, listen, co-create, understand, communicate, influence, negotiate, etc. with the broader objectives of satisfying their needs, gaining approval and support, or at least minimizing their opposition or obstruction [1]. It will be an iterative process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interest in a particular issue, for the dual purposes of creating a shared understanding and making relevant, transparent and effective decisions [2].

Terms of reference are generated separately for each expert stakeholder group to providea general description of involvement, and detail regarding responsibilities, expected input/commitment,

number/frequency/duration of meetings (as well as required notice of meetings), required feedback, timelines for feedback and benefits of involvement, and contactfor any queries/concerns in relation to the activity. It also discusses the process when members decide to drop out of the project. This help when engaging stakeholders and ensure they can make an informed decision regarding their involvement. The terms of reference will be updated throughout the project based on needs and in agreement with all stakeholders.

[1]. stakeholder_engagement_1st_edition_pgguidance_2014.pdf
[2]. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3371639/

Abbreviations

ACN. CITTADINANZATTIVA-Active Citizenship Network
CA. Consortium Agreement
CTR. Clinical Trial Record
EFPIA. European Federation of Pharmaceutical Industries and Associations
EU. European Union
EUPATI European Patients' Academy on Therapeutic Innovation
D. Deliverable
DAG. Digital Advisory Group (coordinated by EURORDIS)
DICEP. Communication, Dissemination and Exploitation Plan
ECT. Engagement Coordination Team
EDC. Expert Decision Committee
ENP. Italian EUPATI National Platform
ExCom. Executive Committee
EPF. European Patients' Forum
EURORDIS. Rare Diseases Europe
GDPR. General Data Protection Regulation
HTA. Health Technology Assessment
IMI. Innovative Medicines Initiative
IMI2 JU. Innovative Medicines Initiative Programme 2.
M. month
MEP. Member of European Parliament
MUG. Medical University of Graz
NDA. Non-Disclosure Agreement
PP. Project Partner
PL. Project Leader
PoC. Proof of Concept
PMO. Project Management Office
T. Task
TAK. Takeda
WP Work Package
WPL. Work Package Leader

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Executive Summary

This **report** gives an overview on how external and internal stakeholders have been and will be engaged in the project's activities, stakeholder engagement being the backbone of the whole project and an essential part of its successful accomplishment.

1. FACILITATE's stakeholders

FACILITATE aims to define and develop a working prototype process to return clinical trial data to study participants and to the secondary re-use of data:
The tools to be developed will be designed with patients and all relevant groups that work to serve them. To serve patients well, and through them to impact a wider civil society, we must also engage with the needs of academic research communities, government institutions, regulators, and pharma industries to enhance transparency and communication tools to foster trust in clinical research by the same patient community. This is the reason why the FACILITATE consortium is composed by academics, clinicians, patients' associations, pharma companies, healthcare professionals, software developers, clinical trials repositories processors and controllers, ethicists, lawyers and other active regulators etc. But the consortium's work will be constantly subjected to input from external stakeholders to broaden the range of people involved and the viewpoints so that this important goal can be built in a shared way.

According to these aims, stakeholder analysis has been carried out to identify

- the stakeholder groups and individuals that will ultimately affect, or will be affected by the process and outputs of the project
- those who are particularly interested in being engaged
- those who are likely to be influential and
- those that may provide the most useful input, (needs, shared values, and specific requirements) and are most likely to play a key role in using the results.

FACILITATE's Stakeholders include persons or groups having knowledge, interests and/or experience in clinical trials and the importance of the management of clinical trial data - during and after the trials - and/or experience in legal and ethical issue within them.
In line with the project needs, four **(4) key groups of stakeholders** have been identified:

Group 1: Patients (coordinated by EURORDIS-Rare Diseases Europe)

Patients' engagement in FACILITATE aims to develop a process to return clinical trial data to study participants, transforming the way patients will have access to clinical trial data in Europe. As a secondary aim, FACILITATE wishes to create a framework for trial data reuse in the medical research setting. For this aim as well, patients and patient group will be engaged.
The patients' involvement is coordinated by EURORDIS in collaboration with the European Patients' Academy on Therapeutic Innovation (EUPATI) and CITTADINANZATTIVA-Active Citizenship Network (ACN).

Patients are part of the decision-making process. They are directly involved in activities within different work packages of FACILITATE, ensuring that the methodologies identified correspond to patient views, needs, expectations and preferences within ethical and legal framework allowed by regulations and interests of the different stakeholders, including methodological aspects necessary to ensure validity of data analyses.

Group 2: Clinicians & healthcare professionals (Coordinated by the Medical University of Graz - MUG)

FACILITATE aims to develop a working prototype process to return clinical trial data to study participants, ensuring that the whole data process, from the collection of data to its destruction or anonymization, including its sharing and re-use, is legally and ethically compliant and aligned with the study participants' but also hospitals, academia, and researchers' voice.

The clinicians and healthcare professionals' involvement are coordinated by MUG in collaboration with other universities, research organizations, clinical centers partners in the project to ensure the needs and requirements of these stakeholders are included in FACILITATE work, both in the development of the project and the resulting tools and recommendations.

Group 3: Pharma industry/sponsors (Coordinated by Takeda)

Sharing of clinical trial data has great potential to accelerate scientific progress and ultimately improve public health by generating better evidence on the safety and effectiveness of therapies for patients.[1] At present, however, the process is neither clear nor simple and is hampered by different regulations across countries. It is important that pharmaceutical industry is involved in the development of a consistent methodology/process for ensure that data shared with clinical trial participants is meaningful and carefully explained, and that all privacy, security, data integrity and patient safety protections are in place and comply with all laws, ethics committee approvals and organizational policies.

Takeda coordinates the industry's involvement in the project.

Group 4: Healthcare actors on a broader spectrum (Coordinated by ACN)

FACILITATE will engage at the different project steps, with EU bodies and national healthcare stakeholders, patients' advocacy groups regulators, HTA bodies, and EU institutions to include their different perspectives in the project development. This group of healthcare actors on a broader spectrum will be coordinated by the CITTADINANZATTIVA-Active Citizenship Network (ACN).

2. The Engagement Coordination team (ECT)

The four coordinators of the Stakeholder groups (EURORDIS, MUG, TAK, ACN) make up the **Engagement Coordination Team** (ECT). EUPATI also proactively contributes to the work of the ECT.

The activities of the ECT in these first months of work included:

- design and implementation of the Stakeholder Engagement Plan (Deliverable 6.3 of the project).
- regular communication which takes place via bi-weekly meetings as well as email correspondence
- mediation between the stakeholder groups and the consortium, as well as the other WPs that also rely on stakeholders' feedback as part of their work: especially in WP3's work on qualitative analysis (see specification in the paragraph 5).

[1] https://www.ncbi.nlm.nih.gov/books/NBK285999/

- experts' recruitment for the 4 groups of stakeholders (see specification in the paragraph 4).
- management of all communications and activities with members of their stakeholder groups, as well as deciding best methodologies for communicating.

3. Multilevel engagement

Within each group listed above, there are multiple levels of engagement, as detailed below:

Level I

In the last months of 2022, we have been working on putting together a smaller expert group of about 10 people that will involve all four stakeholder groups mentioned above. This advisory group is composed of people who have good knowledge and/or experience in the clinical trial ecosystem relevant to the respective stakeholder group and the related methodological, legal, and ethical issues.

This groups of experts will be consulted at various stages of the project to provide feedback and identify specific needs/requirements for each stakeholders group. The aim is to contribute to building the process structure and to periodically review the ongoing progress of the project. This will provide the necessary qualitative feedback. If feedback is needed on specific topics, it can be requested from individual experts or a subgroup of the expert group. This will be detailed in the Terms of Reference drafted for each group.

Level II

A wider list of stakeholders, composed of any person/groups interested in the activities of FACILITATE is being generated. This group will be consulted throughout the distinct phases and tasks of the project throughsurveys, providing more quantitative feedback to the project. his group will be consulted through surveys during the different phases and tasks of the project to obtain quantitative feedback on the project. This group of stakeholders will be constantly updated/managed through the FACILITATE website. Members can choose (or not) how they want to interact with the project, e.g., to participate in surveys or to receive updates such as newsletters on project progress.

All partners were asked to spread the word in their networks to encourage stakeholders to register on the website.

Level III Cross-group engagement

As well as consulting with the four stakeholder groups individually, a series of online multi-Stakeholder roundtables will be held throughout the project, but as deemed required to get resolution on any cross-group issues that may arise. There may be the possibility to have this meeting face to face, with a hybrid meeting to allow participation. Members attending these roundtables will come from members in level 1 engagement, but there will be flexibility in terms of member attendance from the expert group to ensure required expertise is present/available, based on the topics of concern being discussed at the roundtable.

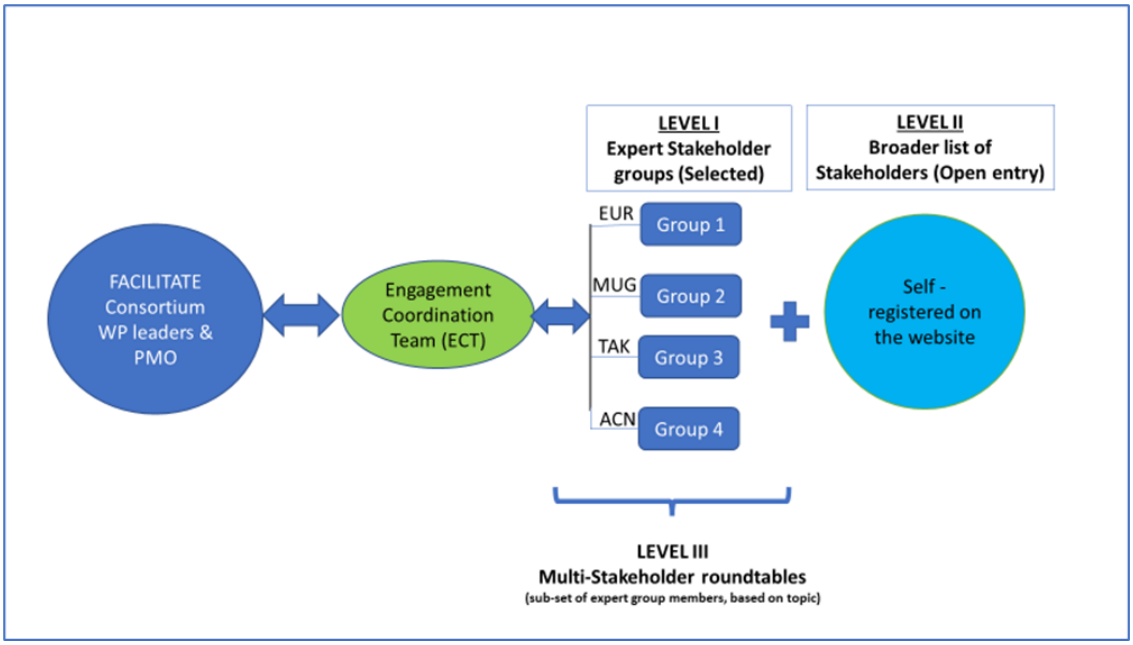

Figure 1. Relationship of the stakeholders' groups

4. External stakeholder recruitment progress

Level I Stakeholders - Expert groups

Group 1. Patients (Coordinated by EURORDIS):

The Patient Expert group comprises about twenty participants, among rare disease and non-rare disease patients.
The group includes existing members of the EURORDIS Digital and Data Advisory Group (DAG) and has been supplemented by additional members (to be known as the DAG**+**). The DAG comprises eleven patient advocates nominated for a term of 3 years. This is a group of legal experts and patient experts' volunteers who are expert (experienced) in terms of review of patient data usage.
The DAG**+** members were identified through a call out to all the EUPATI graduate experts in Europe and through the partners networks based on an agreed profile outlined in the Terms of reference produced. They should meet the following criteria:

- have participated in a clinical trial,
  - or are a healthcare provider of a person who has taken part in a clinical trial
  - and/or have knowledge and/or experience in legal and ethical issue within clinical trials
- are located anywhere in European Union (Switzerland and UK included)
- have good English fluency, to contribute to discussions and be able to review documents provided by the project for review and comment
- are committed to participate in the project for the duration, so that they can provide input through the initial design stages/use cases, right through to provision of final/guidelines/process for returning data to patients.
- ideally expert patients in the DAG+ will represent other non-rare disease patient groups (rare disease patients will be represented through the DAG), to ensure a wider patient representation.

Applications were reviewed by the ECT to ensure that they met the above criteria and successful applicants were then invited to take part in November 2022 and recruited based on:
- agreement to the terms of reference*,

- a declaration that there were no conflicts of interest and
- signature of a confidentiality agreement

As of December 2022, 8 members of the DAG+ have been recruited.

Patients/Patient groups have been already engaged during this first year and will continue to play a central role at all levels in the FACILITATE project.

The DAG has brought its insight in the rare patient focus group as part of the D3.5. The group has also participated at the Restitution meeting. The Digital and Data Advisory group will be engaged next month in offering feedback regarding FACILITATE's Ethical Framework.

Group 2. Clinicians & healthcare professionals (coordinated by MUG GRAZ)

The Clinicians group recruitment is ongoing. It will be composed of 5 up to 10 participants which:

- have worked at a site level in a clinical trial,
    - or be an expert that reviews/audits clinical trials
- be located anywhere in European Union (Switzerland and UK included)
    - It is noted that a spread of countries across the group participants is desired
- have good English fluency, to contribute to discussions and be able to review documents provided by the project for review and comment
- be representatives of varied types of sites, such as primary and secondary care centres
- have varied clinical indication experience, that may lend to discussion on varied use cases

For the qualitative research phase (see par 5) we contacted, explained the project, and in some cases directly involved: oncologists, otorhinolaryngologists, dermatologists, neurologists, head of Clinical Research Programming Unit (Gynecologic Cancer), orthopedists, cardiologists, vaccinologists.

Group 3. Pharma industry/sponsors (Coordinated by Takeda)

For the Pharma list of experts (Group 3), members that have been part of other initiative such as the Patient Data Access Initiative (PDAI), DataCelerate (part of TransCelerate), or Harvard Multi-Regional Clinical Trials Center (MRCT) Return of Individual trial Initiatives have been encouraged to participate, to ensure that any learnings from these projects can be incorporated in FACILITATE.

It is noted that this stakeholder group will be made up of both internal and external Pharma stakeholders. It is expected to have 6-10 members of this expert group.

For the qualitative research phase external Pharma stakeholders were identified to take part in interviews and focus groups related to the project. It also included members from the partner companies who are taking part in the project, but who themselves were not directly involved so were giving an independent view. - The project was explained, and potential challenges and risks discussed. This included representatives in various roles related to clinical data sharing such as Clinical Operations, Data Privacy, Data Transparency and Sharing. The following companies were involved: Janssen, BMS, Sanofi, Servier, Almirall, Pfizer, Regeneron and ProPharma Group.

Group 4. Healthcare actors on a broader spectrum (Coordinated by ACN)

This group will be flexible and engaged, when needed, at the different project steps, with EU and national health stakeholders, civic advocacy community, regulators, HTA bodies, and EU institutions

to include their different perspectives in the project development.

For the qualitative research phase (see paragraph 5) we contacted, explained the project, and in some cases directly involved: study coordinators, monitor, social scientist, academics (professors of: Clinical Trial Methodology, EU law with specific regulatory and compliance expertise in the field of clinical trials…) regulator, lawyer specialized in European health law and bioethics, specialized nurses, data managers, data protection officers, clinical research coordinators, ethic committee hospital pharmacists, phycologists, biobank experts.

The expert group members will follow the progress of the project from the start and will bring their knowledge and perspective to the project. This will consist of consultations along the entire project, including the input that will came from the other related work packages - mainly WP2 and WP3.

Level II - Wider Stakeholder groups

This broader stakeholder engagement is voluntary and only requires registration via the stakeholder form on the website. The registration data is used to build a database of stakeholders. Based on the selection of stakeholder type in the online registration form, engagement team coordinators enroll the participant in the appropriate stakeholder group. Once registered, each member will always be able to change his/her consent to be involved in the research activities. Now we have 17 registrations: 1 Health Technology Assessment (HTA) body, 6 Patient Associations, 2 Academic Researchers, 1 Software developer, 2 European health-related umbrella associations, 2 Caregivers/Relatives, 1 Representative of educational and advocacy actors, 1 Pharma/Biotech Company, 1 Head of prevention of corruption and transparency. Targeted communication work is planned via social media and other channels. Stakeholders are being directed to the FACILITATE website through communication about the project on social media e.g., Facebook, Twitter and Linked in, discussions at conferences and through publications about the project, as described in the paragraph 5.

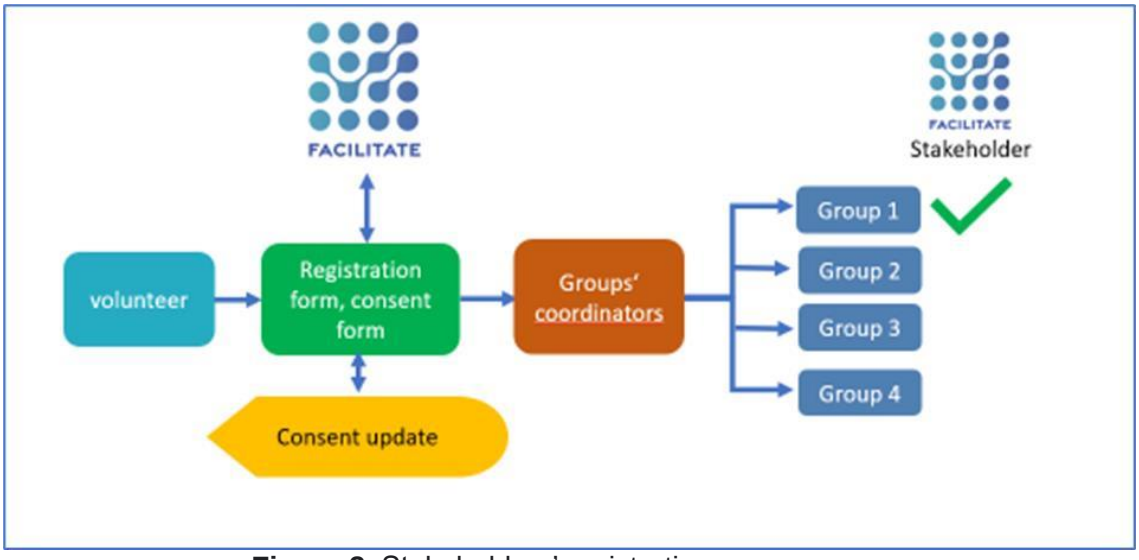

Figure 2. Stakeholders' registration process

5. First phase of Stakeholder Discussion/Engagement across WPs

The initial engagement phase focused on the elicitation of stakeholder needs and expectations.
Their perspective has been ascertained using empirical qualitative methods (**interviews, focus groups, restitution meeting roundtable**).

The initial qualitative research and interaction with external stakeholder took place between May and July 2022, before the formal level I groups were established. This was a first way to capture and interact with potential members of the groups, as they involve the same profiles: 1. Patients living with rare diseases, 2. Patients living with non-rare diseases, 3. Clinicians, 4. Industry, 5. Other expert and professions involved with clinical trials. These interviewees / focus groups' participants have been then invited to take part in the appropriate expert group, if they agree with all Terms of Reference for the group.

A) Qualitative research conducted by and in collaboration with the **Work package 3** (Ethics, standardization and regulatory framework) Leader EURAC:

First step: in-depth interviews

Four in-depth interviews were carried out with representatives from each of the stakeholder groups involved in the project. These interviews explored two key topics, that is the return of results to clinical study patients and the secondary us data. The purpose of interviews was to prepare the subsequent focus groups by highlighting some baseline issues about the phenomenon under investigation. Each participant was recruited by stakeholder representatives working in FACILITATE on the sole basis of having previously been involved in Clinical Trials either as a participant or a professional.
The interview was then oriented at exploring the clinical trial through the personal experiences and perspective of:

1. One patient directly involved (currently and/or in the past) in a clinical trial
2. One clinician
3. One pharma industry representative
4. One regulator

Patients' perspectives were central to the reflection while the insight we collected from institutional representatives were useful to fulfill an overall description of the clinical trials. This description covers:
The micro level:
(Patients sharing experiences and their reflections about them)

- Patient-researcher interaction
- Effective communication between relevant actors (patient, Principal investigator, general practitioner, physician, nurse, administrative personnel, other medical doctors, lawyers, patients' advocates)
- Issues and dilemmas concerning the Informed Consent Form
- Personal experience of the clinical trial before, during, after (reflections, emotions, doubts, unmet needs)
- Experience towards eventual restitution of results and requests to consent to secondary use

The macro level**:**
(Experts sharing experiences, opinions and perspective in the field)

- The issue of privacy
- The implication of the EU GDPR and its interpretations in different contexts
- The technological challenges and possible solutions of data sharing in the modern era

- Risks and benefits for scientific research
- Risks and benefits for patients

Experts' views were mainly used to complement patients' views and describing the clinical trial as a complex organizational process, its main steps, implications, and interconnections with other disciplines.

Second step: focus groups
An extensive recruitment phase of 5 to 10 participants for each of the five Online Focus Groups (1. Rare patients (the DAG), 2. non-rare patients, 3. Clinicians, 4. Pharmaceuticals, 5. Other expert and professions involved with clinical trials) has been carried on and schedule 1-hour online meetings. All focus group participants were informed about the research goals and context, and a description of the project was circulated via e-mail before the focus group took place. All participants were recruited on the sole basis of belonging to one of the categories of actors involved in the project and of having been involved or exposed in at least one Clinical Trial.

Third step: Preliminary Results and restitution meeting
The researcher of EURAC summarized the findings of both semi-structured in-depth interviews and focus groups transcribed texts, which allowed researchers to identify a set of themes and issues relevant to stakeholders on the return of results and secondary use of data. The report does not intend to indicate what should be done or how but aims at describing the issues through the words of its main actors and aims at representing participants' views and expert reflections on those views. The plan is that this report will be made public in early 2023 and will be available through the FACILITATE website.

Fourth step: content analysis. Based on the previous steps, a report has been produced and shared back with all parties who took part in the interviews and focus groups. Going forward it will also help form the basis for work that the various WPs will do in the future.

B) WP2 Legal and Data Privacy framework
WP2 is conducting a mapping of the national laws regarding the return and secondary use of clinical trial data. This is being conducted with the help of relevant WP2 partners, including pharma industries and hospitals, etc. as internal stakeholders in form of questionnaires. WP2 is also proposing a glossary to be aligned with WP3 to promote the synergy between legal and ethical research.

Planned activity: WP2 envisages the feedback and comments from the stakeholders, especially the four expert groups on the legal research and the mapping of national laws, at various points where it is needed, on questions such as, whether the developed privacy notice and informed consent form are sufficiently comprehensible and easy to use by the patients and in the final guidance document for the clinical studies, whether there is a good balance of interests of all involved stakeholders, and whether there are overlooked technical challenges, etc. Additionally, WP2 partners will also proactively engage with a wider audience by disseminating the outputs through conferences and publications and interact with regulatory authorities as part of WP2 tasks.

C) WP3 Ethics, standardization and regulatory framework
The ethical framework on the future uses of clinical trial data for scientific research and the ethical framework on the return of clinical trial data (hereinafter referred to as "the ethical frameworks") have been developed through document analysis, literature review, and stakeholder engagement. Feedback on the developing framework was elicited through the bi-weekly WP3 meetings. The frameworks were circulated to WP2, 3 & 6 in advance of two separate meetings on the frameworks. In addition, the ethical framework on the future uses of clinical trial data for scientific research was circulated to all partners for consultation. This feedback is now being analyzed. This information will be made public as part of deliverable 3.1, the Ethical framework in 2023. In 2023, the frameworks will also be discussed at the

International Congress of Human Genetics, as well as with patient representatives. In addition, a consortium meeting is to be held in March 2023 to discuss these frameworks.

D) WP6 Communication and Dissemination

The Communication and dissemination task 6.1 participates in stakeholder involvement by promoting the project through various channels, some already active and being updated, others in the process of being implemented. A communication plan covering the first half of 2023 has already been approved and the communication strategy for the second half will be planned in early 2003. The latter will be based on the main results obtained by the various research groups and will include both already implemented and new tools.

The FACILITATE website has been implemented and the social media accounts - Facebook Twitter, and LinkedIn - have been active since July 2022 with regular posts about the project and involvement of the partners. Twitter has over 40 followers, Facebook 24 and LinkedIn 117 followers.

A workable structure to enable communication and dissemination has been established and organized as shown in Figure 3.

- The **University of Modena and Reggio Emilia (UNIMORE)** is responsible for supervising all activities concerning communication.
- The **Editorial Staff**, including around 10 people from the University of Modena, which takes care of the content and editing, Cittadinanzattiva - Active Citizenship Association (ACN) & Takeda, which are responsible for social media, and Zentrix, which is responsible for updating the website and creating the layout of the media for communication (Figure 4).
- The **Communication Working Group (Comm WG)** is composed of 27 people, one representing each partner of the project. Its main task is to approve the media for communication and to support the activities of the Editorial staff.

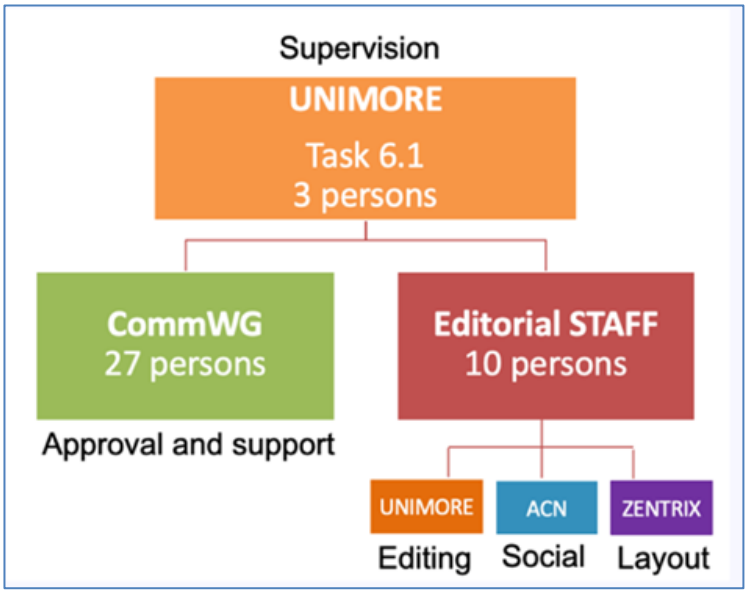

Figure 3. Organization of Communication and Dissemination Structure

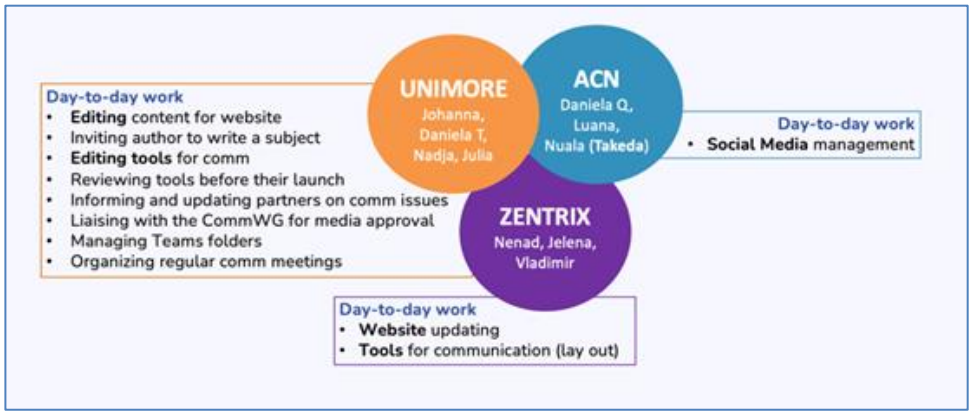

Figure 4. Organization and activities of the Editorial Staff

Tools for communication and dissemination

In the website **home page**

- a **Factsheet** to be downloaded, with the most relevant information about the project, has been realized. The same format, with the same general information, has been realized for every single partner to upload in each institutional website, with a section dedicated to partner's role in the project. The factsheet will be immediately visible when opening each partner's website by clicking on the logo.

- a button will be inserted to signal the latest updates (news, newsletters, tools, etc.)

A reorganization of the **News and Events page** has been planned, to be transformed into a more extensive section (Newsroom) containing the different media, organized as follows (Figure 5).

a. **Newsletters** for stakeholders, published bimonthly

b. **News** about FACILITATE and related themes, as pointed out by partners

c. **Congress** hosting/will host FACILITATE

d. **Press release** (the first will be "One year of FACILITATE")

e. **Animated video on FACILITATE** for stakeholders and for a general audience

f. **Webinar** for stakeholders and for a general audience: the first has been planned for 27 January 2023

g. **Podcast** for stakeholders and for a general audience

Figure 5. Reorganization of the Newsroom page

Regarding the Newsletter, which has been entitled "**Let's FACILITATE**", the first number has been published in December 2022 with the highlights of the first General Assembly of FACILITATE which took place in Modena, the 17 and 18 of November (Figure 6).

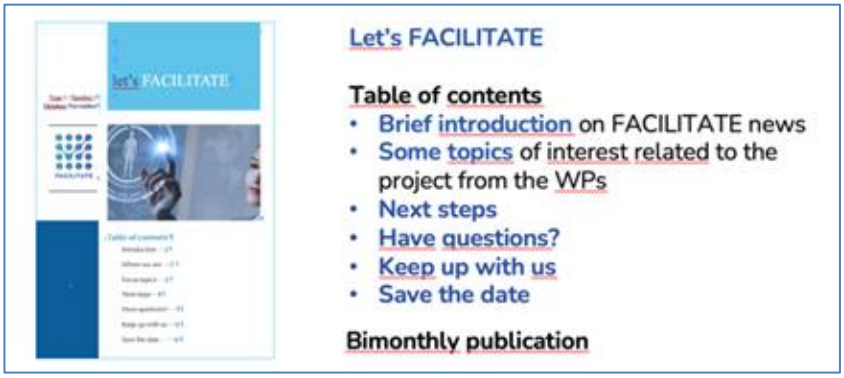

Figure 6. The first number of the newsletter Let's FACILITATE

For what concerns the updating of **The Voice of Patient** page, the following will be developed within March 2023s.

a. **Glossary** for patients and clinics, with the main terms concerning clinical trial data sharing and re-use (to be updated).

b. **Questions and Answers** on different items related to FACILITATE (I.e., role of patient in FACILITATE, legal framework, ethical framework, informed consent, restitution of data, reuse of data, etc.), with a version pdf for the download.

c. **Infographics** able to provide easy-to-understand information on the project and its main achievements

Other communication and dissemination tools, useful for the Consortium, to present FACILITATE at internal and external events with a coherent and well-defined image (Figure 7) has been developed: **Slide deck** on FACILITATE; **Poster and roll up** for congresses; **Flyer.**

Figure 7. Some of the tools for communication about FACILITATE

Meeting participation

As regards participation in congresses, FACILITATE will be present at the Computer Privacy and Data Protection in Brussels next May 2023, where a symposium and expert panel have been proposed, and at the Human Genetics Congress in Cape Town, South Africa, in February 2023.

6. Next steps in the other work packages starting in 2023

As described, the Engagement Coordination team (ECT) is in place for the project, and it liaised with all the WPs' leaders throughout the project to ensure all needs of the project in terms of stakeholder engagement are identified. WP Leaders should consider the stakeholder engagement they require at each task during their own regular WP meetings and relay this to the ECT team during the monthly WP6 calls to ensure planning and action regarding required stakeholder interactions.

WP4 Platform architecture design and requirements

- **Collaboration with key stakeholders** to define and prioritize the process of returning the data back to study participants, by co-creating the workflow and functionalities for the tools, and infrastructure that should enable access, approval, and data reuse (Task 4.1) [D4.1 Platform specifications and requirements M12- M18].

- **Engagement of the stakeholders** to validate the provided mockups, user stories, that will be used to finalize the stakeholders' requirements. Stakeholder involvement will be needed on Proof of Concept (PoC) process. WP2-3 is essential for technical & regulatory feasibility for WP4 and will form the foundation of the work. This will involve consensus on stakeholder priorities and potential trade-offs (WP3, WP4, WP5).

WP5 Technology framework and interoperability solutions

To involve stakeholders in design, prioritization and preparation of the PoC platform. This will

involve developing a user experience and intuitive end user tools for expressing the way in which patients want to share their clinical trial data and implementing diversified view and compliance control over the provided clinical trial data. It will ensure that returning of the clinical trial data to the patients is possible, and that patients are empowered to do this in a user-friendly manner. The developed process will facilitate privacy preserving technologies and harmonized processes that meet multi-dimensional requirements of the stakeholders, all relevant policies, GDPR compliances and other regulations.

WP7 Business exploitation and sustainability

- **Approval of FACILITATE business plan/use case strategy options** this includes a report on stakeholder needs and barriers for adoption of the process and associated tools developed through FACILITATE

- **Approval of FACILITATE** business sustainability and implementation strategy.