IMI2 Project ID 101034366 FACILITATE

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

WP6 – Communication and dissemination

D6.5 Report on Stakeholder Engagement 2

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Document History

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V0.1	11.11.2023	First draft
V0.2	21.11.2023 – 28.11.2023	Regular meetings every two weeks with core group and partly with all partners
V0.3	02.12.2023	Draft ready for reviewers
V0.4	06.12.2023	Feedback from reviewers
V0.5	15.12.2023	Feedback from SCom
V1.0	30.12.2023	Submission of final version

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 provide a

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 contact for any queries/concerns in relation to the activity. It also discusses the process when members decide to drop out of the project. This helpswhen engaging stakeholders and ensures 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)
DAG+ The expert group of patients made by the DAG members plus other selected non-rare diseases patients
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 second **report** on stakeholders' engagement gives an overview on how external and internal stakeholders have been engaged in the activities of the second year of FACILITATE, stakeholder engagement being the backbone of FACILITATE and thus an essential part of its successful accomplishment.

1. FACILITATE's stakeholders

FACILITATE aims to define and develop a prototype process to return individual clinical trial data to study participants and to the secondary 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 (that during the 2023 saw the entry of two new members, BMS and Roche) is composed of academics, clinicians, patients' associations, pharma companies, healthcare professionals, software developers, clinical trials repositories processors and controllers, ethicists, lawyers and other active regulators etc. Furthermore, the efforts, output and progress of the consortium will be constantly subjected to input from external stakeholders to broaden the range of people and their viewpoints so that important goals can be developed 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 individual clinical trial data in Europe. As a secondary aim, FACILITATE aspires 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 play a direct role in various work packages

within FACILITATE, ensuring that the identified methodologies align with the perspectives, requirements, expectations, and preferences of patients while adhering to ethical and legal regulations and the interests of various stakeholders. This also encompasses the methodological aspects essential for guaranteeing the 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 individual 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 thestudy 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 TAK)

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 to 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 (TAK) coordinates the industry's involvement.

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

FACILITATE will engage at all different levels and phases of the project with EU bodies and national healthcare stakeholders, patients' advocacy groups regulators, HTA bodies, and EU institutions to include their different perspectives in the development of the project. On a broader spectrum, this group of healthcare actors 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 and WP3 representatives from EURAC also proactively contributed to the work of the ECT.
The activities of the ECT 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 (see specification in Chapter 5).

- experts' involvement for the 4 groups of stakeholders (see specification in Chapter 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 for each of the four stakeholder groups mentioned above. This expert group is composed of people who have excellent knowledge and/or experience in the clinical trial ecosystem relevant to the respective stakeholder group and the related methodological, legal, and ethical issues.

These groups of experts have been (see Chapter 4) and 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. If feedback is needed on specific topics, it can be requested from individual experts or a subgroup of the expert group.

Level II

A wider list of stakeholders (see Chapter 4 for the details), composed of any person/groups interested in the activities of FACILITATE is being generated on a continuous basis. This group will be consulted throughout the distinct phases and tasksof the project through surveys, providing more quantitative feedback to the project. This group of stakeholders has been constantly updated/managed through the FACILITATE website and regularly receives the FACILITATE newsletter (see Chapter 5). Members can choose (or not) how they want to interact with the project, e.g., to participate in surveys or only to receive updates such as newsletters on project progress. All partners are asked to spread the word in their networks and at all events they participated in, 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 can be held throughout the project, as deemed necessary to get resolution on any cross-group issues that may arise. Meeting face to face, in a hybrid format allows for the most widespread 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 that the required expertise is present/available, based on the topics of concern being discussed at the roundtable.

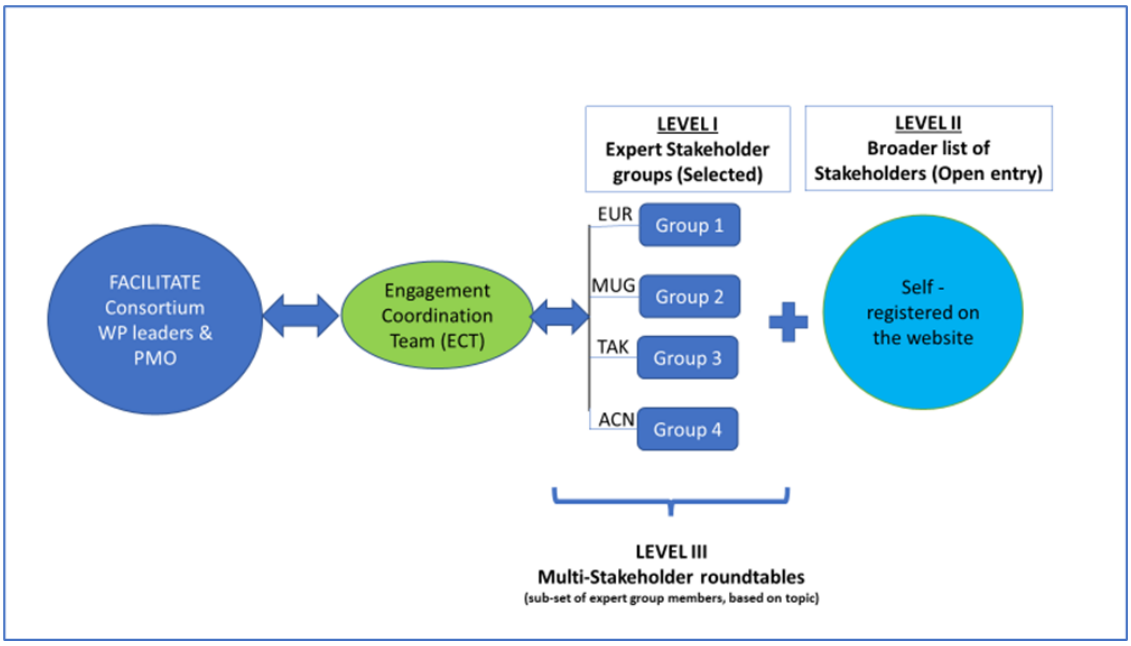


Figure 1. Relationship among the stakeholders' groups

4. External stakeholder recruitment progress and meetings in 2023

Level I Stakeholders - Expert groups

Group 1. Patients (Coordinated by EURORDIS):

The Patient Expert group comprises 24 participants, among rare (13) and non-rare disease (8) patients. The group includes existing members of the EURORDIS Digital and Data Advisory Group (DAG) and has been supplemented by additional members (DAG & additional members are the new group to be known as the DAG**+**). The DAG comprises 13 patient advocates (2 more than last year) nominated for a term of 3 years. This is a group of legal experts and patientexperts' volunteers who are experts (experienced) in terms of review of patient data usage.
The non-rare members were identified through a call out to the EUPATI graduate experts in Europe and through the partners networks based on an agreed profile outlined in the Terms of reference produced.

During 2023, three consultation meetings were held with the DAG and the DAG+:

1. **9th March 2023, DAG consultation on the Ethical Framework on Return and Re-Use of Data, produced in WP3.**

2. **16th of May 2023, first DAG+ consultation on Ethical Frameworks on Return and Re-Use of Data**
   Participants had the opportunity to provide written feedback in advance (3 weeks), which was then compiled and discussed during the live consultation. Then a 2-hour meeting online on the 16th of May 2023 - the First DAG+ Consultation on Ethical Frameworks for the Return and Re-Use of Data - was held. The meeting focused on several key aspects related to the ethical frameworks concerning the return and re-use of clinical trial data within the FACILITATE project. Below are the

main points discussed during the meeting.

Written Feedback and Live Consultation

A recurring theme was the need for participants to receive value in return for the use of their data in clinical trials. It was suggested that the return of data should include negative results, and concerns were raised about genome sequencing and variants of unknown significance.

Participants emphasized the importance of returning results from all investigations, including those that couldn't be returned during the trial.

Actionable Data

There was a discussion about how to define "actionable" data, with some suggesting that it should be defined by exclusion (what is not actionable) to ensure a more comprehensive approach. An alternative suggestion was to abandon the term "actionable" and instead return all data related to a participant's health.

Re-Use of Data

The use of the term "person" rather than "participant" was discussed, focusing on the broader impact of data use. Defining "public interest" and its relationship with "commercial interest" was considered important. Responsibility and accountability were emphasized as ongoing needs, and the definition of a clinical trial's scope was discussed.

Data safety, timing of consent requests, and the need for opting-in were highlighted.

Patients expressed a preference for opting-in rather than opting-out.

Participants recommended allowing the reuse of data for a specific period, not exceeding 5 years.

Detailed choices about sharing data were suggested, including defining categories of research to share data with and those to avoid.

Data safety remained a paramount concern.

Consent

The engagement of patient organizations was seen as necessary to simplify the informed consent process and its content. The consent process needed to be explained in advance, allowing participants time to read, ask questions, and involve a family member or friend for support. Providing participants with a copy of the consent agreement was recommended.

The timing of consent requests for SU was considered, with a preference for obtaining consent when intermediary results were returned, and participants had already benefited from the trial. Oversight of the secondary use process was deemed necessary, with the EMA being perceived as most trustworthy by stakeholders.

Informed Consent

The complexity and length of informed consent forms were noted as intimidating for participants, and simplifying the language was encouraged.

The process should be explained in advance, and participants should be given time to read, ask questions, and involve others. Providing participants with a copy of the consent agreement was recommended. Participants should be encouraged to have a family member or friend present during the consent process for support.

Other Findings

Data from clinical trials, including unsuccessful ones, should be made available to prevent duplication of efforts and reduce the burden on both sponsors and participants.

3. 6th November 2023 Second consultation of the DAG+ on "vignettes" of the WP3

Vignettes are a set of situations/cases about the secondary use of CT data for which we would like participants' opinion and evaluation.

Also, this time the participants (all the members of the DAG+) had the opportunity to provide written feedback in advance (3 weeks), which was then compiled and discussed during the live consultation.

The point of this consultation was to try and put themself in each of the character's shoes and explore what questions they would have. What choices would they like to be given? What's missing or redundant in the process? etc.

Case 1: Y has an open attitude about sharing data for secondary purposes, and, at the same time, Y likes to put his medical experiences behind and move on with her life.

- Would you share your genetic data through broad consent? How broad? How narrow? - Should genetic data be treated differently from the rest of the clinical trial data?
- From your choices, what additional questions require answers?
- What other choices would you like to have, being in her position?

Case 2: X chooses to share her data only for research of treatment or therapy of chronic or serious illness. She excludes her data from being used for commercial purposes and she only authorizes the use by public institutions, not by private ones.

- Being in this case, would you consider these choices relevant? What other segmentation would you like to be available in relation to the type of results.

Case 3: Z chooses the secondary uses of his data according to research objectives and types of institutions (private/public). He also decides which categories of data he would like to share and which not to. He decides under which circumstances to be contacted about the requests for his data reuse and how often.

- Being in his shoes, would these be choices you would like to have? Are there other choices that you would find relevant?
- What types of data would you like to be able to choose from and share for secondary use (ex. bloodwork/genetic data/ imaging etc.) Are there types of data that should be considered sensitive? Should they be treated differently? How?

In all scenarios participants are being asked to consent to be contacted in relation to their clinical trial data and then recontacted for consenting after the trial has finished. Would this be a reasonable protocol to be applied in obtaining consent of secondary use purpose from clinical trial participants?

Results: The aim is to see these results as giving us the full range of options the platform we are building should cover. Then identify the technical capacity and more to deliver a solution which would cater for ALL types of patients (no matter how marginal their numbers are) during ANY period

of their lives.

Genetic data is highly sensitive and needs to be considered separately from other types of data. People showed concern about how one's data may influence the entire family. The general agreement is that more control, transparency, and safeguards need to exist when talking about genetic data.

The Purpose of the research is very important. Patients want to have a choice in the types of research they are sharing their data with, not just be informed about it.

Regarding types of institutions and private vs public, patients want to be informed. Some would require having a choice as well.

The issue of trust came across quite poignantly: "measures must be taken for me to be able to trust the system because if people don't trust the system they will, most likely, not share their data".

Patients all agree that the implications of giving **broad consent** need to be clearly explained to them. Opinions range from not considering it an option for them to wishing to be very well informed but not necessarily be offered a choice.

Timing of consent – The proposed suggestions in all three vignettes was to ask patients if they would like to be contacted in relation to the secondary use of their clinical trial data during the trial (not at the beginning) - and offer consent to be recontacted. Being presented with details about the secondary use of their clinical data as well as with the consent would happen after the trial has finished. Patients found this protocol the least stressful and the most probable to produce an informed and balanced decision.

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

The Clinicians group is now composed of 11 members: with generally extensive expertise in clinical trials, most of them served as PIs for several phases of a CT.

During 2023

A Clinical Experts Consultation Meeting was held on **8th November, 2023,** to share clinicians' insights on the practicalities of Return of Data to patients that have participated in a clinical trial.
The participants had the opportunity to provide written feedback in advance (3 weeks), which was then compiled and discussed during the live consultation.
Out of the total 11 clinical experts invited, 8 actively participated in the insightful discussions.
Following the session, a post-meeting questionnaire was distributed, and responses were received from 9 out of the 11 clinicians, providing valuable feedback and perspectives.
One key **takeaway** from the consultation is the acknowledgment that the Return of Data is generally considered good manufacturing practice (GMP) and is mandatory in most cases. This reflects a positive trend toward ensuring that patients receive pertinent information about their health.
However, the discussions also shed light on certain challenges associated with the Return of CT data. Some clinicians expressed concerns about the timing, noting that the data are sometimes provided too

late to be of substantial help. Additionally, there were observations that returning study data can be problematic without proper counseling or contextualization, potentially leading to confusion or misinterpretation.

Results

One of the questions posed to the parties involved was: **"When you participate in a clinical trial, do you usually return the individual data resulting from the study (test results, treatment received, study results) to the patients involved?** If not, what is the main reason for not doing this?"

From the responses received, resulted that, with one exception, medically significant or actionable results are **routinely reported** to the patients. However, when it comes to study-specific results, the routine practice is not to report them unless the patient explicitly requests this information or if the study protocol explicitly allows for such reporting. A comment highlighted the **timing issue**, noting that study data are often only made available at the conclusion of the trial. This limitation may diminish their utility for the patient.

It's crucial to acknowledge the **ethical and legal considerations** involved in reporting data to patients: the potential challenges in reporting non-validated data or findings that do not align with established treatment or diagnostic standards.

Question: If a data platform including all the patient data could be developed, do you think that this would be useful for you? And for the patients?

Answer: Opinions vary on the utility of a comprehensive data platform. While it could benefit research efforts by streamlining databases, concerns exist about potential burdens on physicians. From the patient perspective, counseling is deemed important, and there's a perception that a database might be confusing for them, especially in the case of genomic incidental findings, where mandatory counseling is recommended.

Question: Do you expect that a data-return platform would help you conduct your medical practice?

Answer: The consensus among participants is positive.

Question: If a data-return platform is to be established, would that burden your ability to conduct your medical practice?

Answer: There is a divergence of opinions on this matter, with some expressing concerns about potential burdens associated with the introduction of a data-return platform in their medical practice.

Question: Would you expect to be remunerated if you allocate more time to analyze clinical trial data brought by your patient?

Answer: Responses to this question were varied. While two participants expressed an expectation of remuneration, others emphasized non-monetary benefits or highlighted that this task is inherently part of physicians' duties.

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

The project already includes participation from numerous pharmaceutical industries and sponsors. Nevertheless, it actively seeks additional contributions from pharmaceutical companies through collaboration with other initiatives in the same domain, which involve a wide array of sponsor companies, as opposed to relying solely on a limited group of experts. In year 2 of the project this

included discussions with members that have been part of other similar initiatives such as thePatient Data Access Initiative (PDAI), TransCelerate Data return initiative, and Harvard Multi-RegionalClinical Trials Center (MRCT) Return of Individual trial Initiative. TransCelerate Data Return Initiative has 22 industry partners (only 5 overlaps with FACILITATE) so discussions and awareness initiatives-members have been encouraged to broaden the number of industry views that can be considered.

To ensure that any learnings from these projects can be incorporated in FACILITATE. During the face-to-face meeting in Paris presentations were made giving updates on these initiatives, thus raising further awareness. Also, FACILITATE participated to the DIA meeting in Boston In June 2023 and to SCOPE both organized by the lead of TransCelerate, Jean Sposaro.

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.

During 2023: throughout the year, there have been face-to-face meetings between individual project partners and regulators or external experts, often coinciding with the public events we participated in (see paragraph 5). However, a formal meeting of this group has not been convened yet, as we are waiting to have more well-defined project material agreed upon internally before engaging with these external stakeholders. As a result, these meetings are scheduled to take place in 2024.

FACILITATE has participated in a forum at the EULAR annual Congress in Milan: DATA MATTERS: keeping track of your health information" which was organized by the umbrella Rheumatology patient organization.

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 can 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. They receive regularly the newsletter with the project update and the invitation to events, like the **FACILITATE first webinar for stakeholders** - “Let’s FACILITATE A Project to Facilitate the Access to Clinical Trial Data and to Manage its Reuse” - that has been conducted on 27 January 2023 with 466 registered and 166 attendees, mostly patients or patient associations, pharma representatives and clinical researchers from different EU and extra-EU Countries (see chapter 5 for more details).

Now (November 2023) we have a total of **55 stakeholders enrolled through the website**, which is a substantial increase compared to the 15 of January 2023. The composition of our broader list of stakeholders, interested in receiving updates on the project, is diverse and includes:

1 Health Technology Assessment (HTA) bodies representative

9 Patients' Associations Representatives

14 Patients (comprising 3 EUPATI Fellows, 6 patients, and 3 Patient Representatives, individually)

9 Academic Researchers and General Researchers

2 Software Developers

2 Representatives of European umbrella associations related to health

2 Caregivers/Relatives

2 Representatives of educational and advocacy actors

3 Pharma/Biotech Company representatives

3 Clinical Research Centre representatives

1 Contract Research Organizations (CRO) representative

1 Ethical Body representative

1 Regulatory Expert

1 EU Institution representative

1 Health Research Authority representative

1 Public Involvement Manager

Targeted communication work is realized via social media and other channels. Stakeholders are being directed to the FACILITATE website through communication about the project on social media e.g., Twitter* and LinkedIn, discussions at conferences and through publications about the project, as described in Chapter 5. (*twitter has been eliminated as a communication channel after becoming owned by the American company X Corp). FACILITATE was added as "facilitate.project" on INSTAGRAM on 22 December 2023.

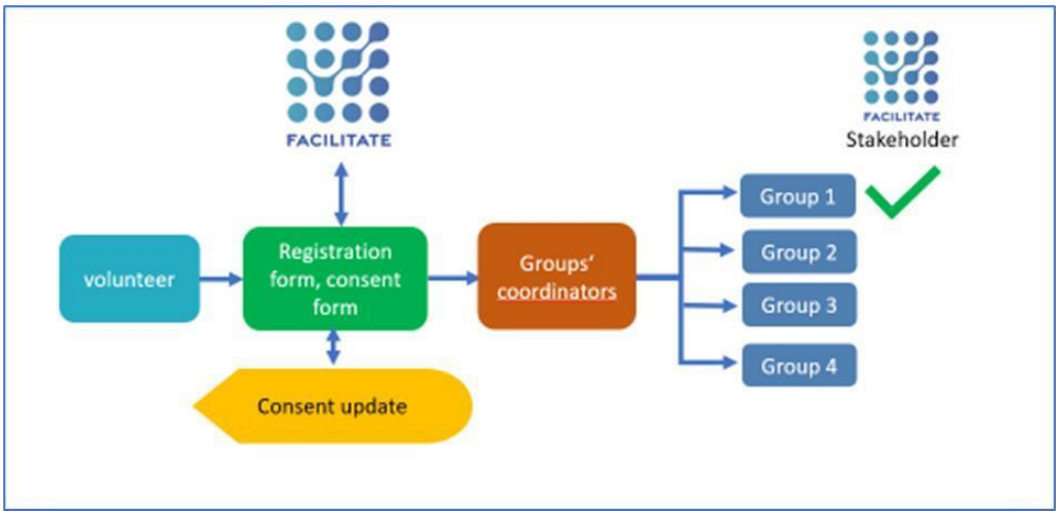


Figure 2. Stakeholders' registration process

5. Stakeholder Discussion/Engagement across WPs in 2023

WP2 Legal and Data Privacy framework

As required by D2.2 and D2.3, WP2 is tasked with consulting the Expert Decision Committee EDC(B) consisting of external legal and ethical expert and data protection authorities of certain Member States for feedback on the work that has been completed so far.
A meeting with EDC(B) (D2.2) had been scheduled for Dec. 11, 2023 (9-11 a.m.), and subsequently postponed to early 2024, with the provision that ad hoc pre-read materials would be sent to the experts containing an overview of the project, the prototype of the data return and reuse process, and the preliminary legal analysis conducted.
As for consultations with DPAs, they will be scheduled immediately after the EDC consultation and the outcomes will be reported in D2.3 (due in June 2024).
WP2 is also completing an additional and more detailed mapping of national legislation within priority countries with reference to the return and secondary use of data.
Finally, WP2, in cooperation with WP3, is finalizing a Glossary to promote the synergy between legal and ethical research that will be reported as an annex to D2.2. This Glossary is also linked to the one for the patient developed by WP6

WP3 Ethics, standardization, and regulatory framework

In the last year of WP3 works, there were multiple occasion to collaborate and interact between stakeholders:

1) INPECO collaborated with EURAC Research for the translation into a technical draft of the two processes for Return of Data (RoD) and Secondary Use (SU) described in D3.5 tables.

2) Organization and management of a virtual session with the Title: "Building a framework for clinical trial participants data reutilization for a fully transparent and ethical ecosystem: IMI FACILITATE

aims to understand and address what patients want" within the Patients' Engagement Open Forum (PEOF). In this context the FACILITATE project was presented and attention was also focused on the elaboration of the Secondary Use (SU) workflow. Lastly WP3 Vignettes were presented to a target of patients to help them navigate the main conundrums patients could face when consenting to the SU of their clinical trial data and gather their reactions and suggestions.

3) Collaboration with WP6 for the organization of the Clinical Expert group consultation meeting (see Chapter 4) to consider our RoD workflow and asked to react to it by sharing their opinions, asking for clarifications or indicate improvements.

4) Collaboration with WP6 for the management of the DAG+ consultations with patients. In this context our SU vignettes were used to gather patients' reactions, gather opinions, doubts, and suggestions from the members of this patient group.

5) After performing a wide exploratory and qualitative research phase, WP3 will concentrate on building a quantitative analysis using Conjoint Analysis.

WP5 Interoperability and standardization stakeholders' engagement

In the course of 2023, WP5 started work on Task 5.1, inventorying and assessing relevant developments and example solutions or approaches for the FACILITATE use cases.
After promising initial contact with participants in the now finished x-eHealth project [https://www.x-ehealth.eu/], this connection with EHRxF developments in Europe was continued by participating with several XpandH events [https://xpandh-project.iscte-iul.pt/]. The latest of these events is the EHRxF Expert Summit in Brussel on December 12.
Other relevant interoperability and standardization work is done in the (Euro)Vulcan project. This project is currently only partially looking at CT data (now with a track on standardizing the collection and reporting of AE data) but it offers good prospects for the future. Other standardization stakeholders are regularly engaged in the OHDSI Clinical Trial WG (which includes CDISK representation, for instance) and in incidental meetings with HL7, UNICOM/JIC and IHE representatives. The latter is relevant because of the recently published standard for consent management. Other engagements in this area were with co-panelists of the VUB HELT conference in April 2023: with them, insights and expectations were shared regarding the future of standard and/or social contract-based forms of consent management.

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 entire 2024 has already been approved and will be based also on the main results obtained by the various research groups, including 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 54 followers, Facebook 36 and LinkedIn 266 followers. For 2024, the

decision has been made to discontinue the use of Facebook, incorporating Instagram as an alternative social media platform for general audience. LinkedIn currently stands as the most suitable for project outreach via social media.

The workable structure, established to enable communication and dissemination, is composed as shown in Figures 3 and 4.

- The **University of Modena and Reggio Emilia (UNIMORE)** is responsible for supervising all activities concerning communication.
- The **Editorial Staff**, including around 10/12 people from:
    - **UNIMORE**, which takes care of the content and editing
    - **Cittadinanzattiva** - Active Citizenship Network (ACN) & Takeda, which are responsible for social media platforms
    - **Zentrix**, which created the website and the layout of some of the media for communication. Zentrix was responsible of the website update until spring 2023
    - **EDUNOVA** Inter-University Center UNIMORE, a service for website updates and webinars and podcasts' realization has taken over from Zentrix.

  The **Communication Working Group (Comm WG)** is composed of more than 29 persons people, and lists one person per partner of the project. Its main task is to approve the media for communication/dissemination and to support the activities of the Editorial staff.

Publication Corner

A **Publication Corner** at each Steering Committee meeting, with the objective to review and discuss on FACILITATE dissemination products (presentation to meetings, contribution to round tables, publications, etc.) has been implemented to track, follow up and plan the communication strategy. A folder has been created ad hoc in TEAMS (Communication and Dissemination/Publication Corner) to store documents and literature reviews.

Website update (https://facilitate-project.eu)

- **Home page:** A new section has been inserted at the opening to signal the latest updates (news, newsletters, tools, meetings, and events etc.) (Figure 5). The current proposal for early 2024 a new, is to add a more interactive Home page to highlight the main news.

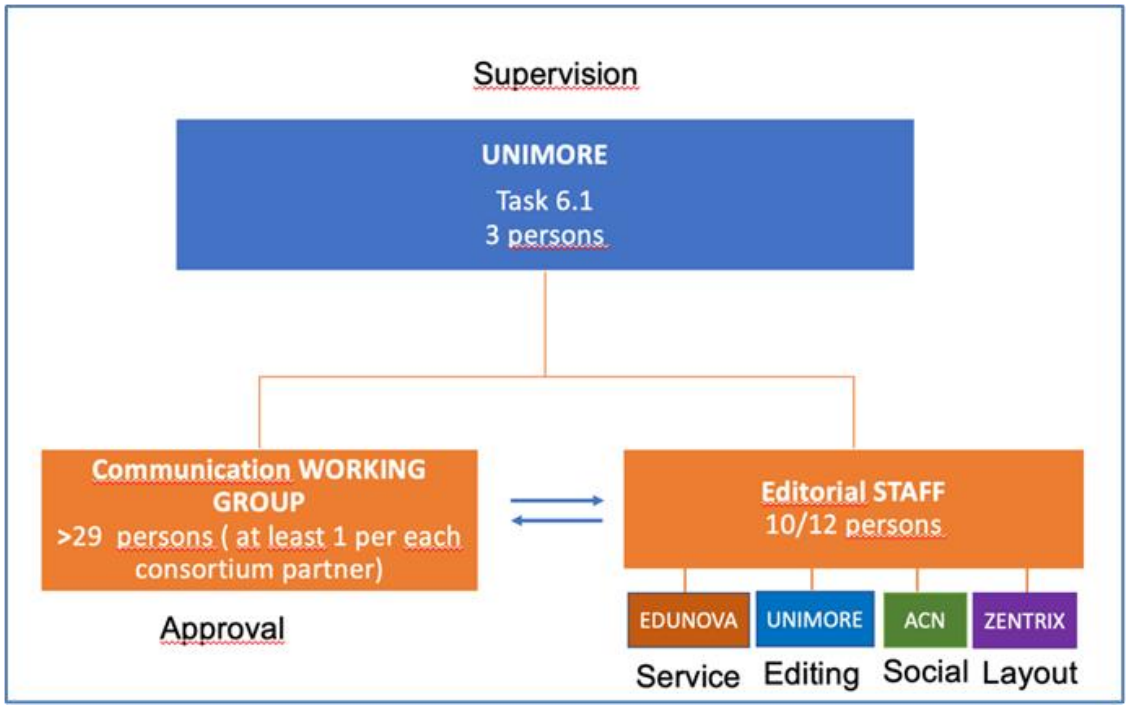


Figure 3. Organization of Communication and Dissemination Structure

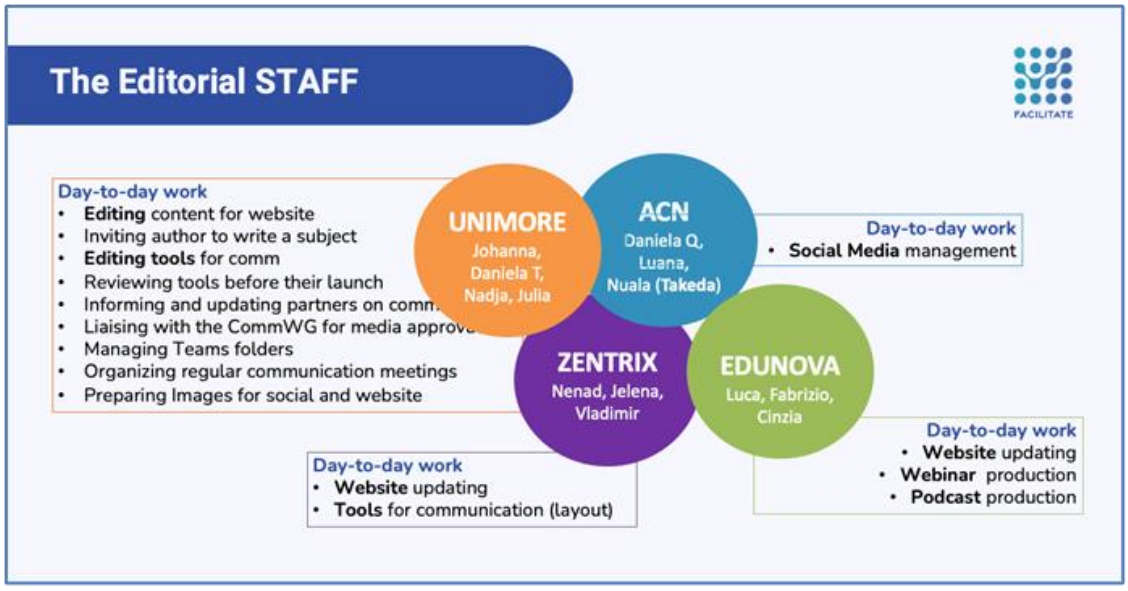


Figure 4. Organization and day-to-day activities of the Editorial Staff

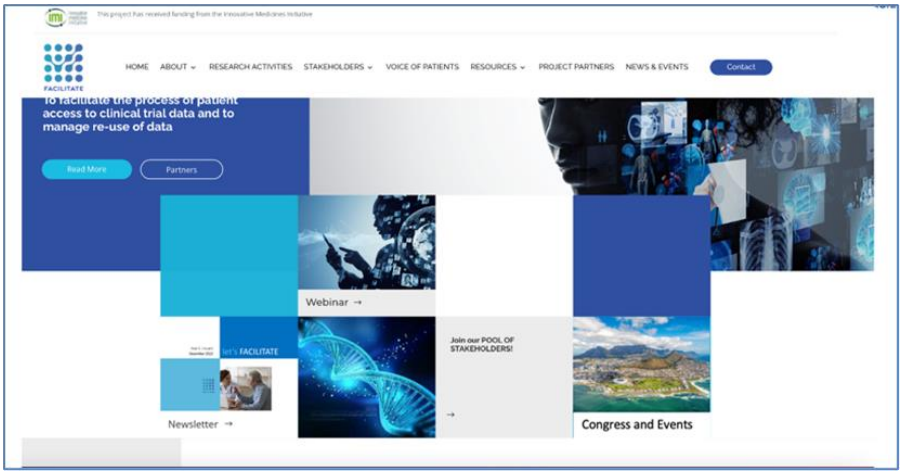


Figure 5. New section at the opening of the website Home page

- **News and Events page**

A reorganization of the page into 6 specific sections has been realized, organized as follows (Figure 6).

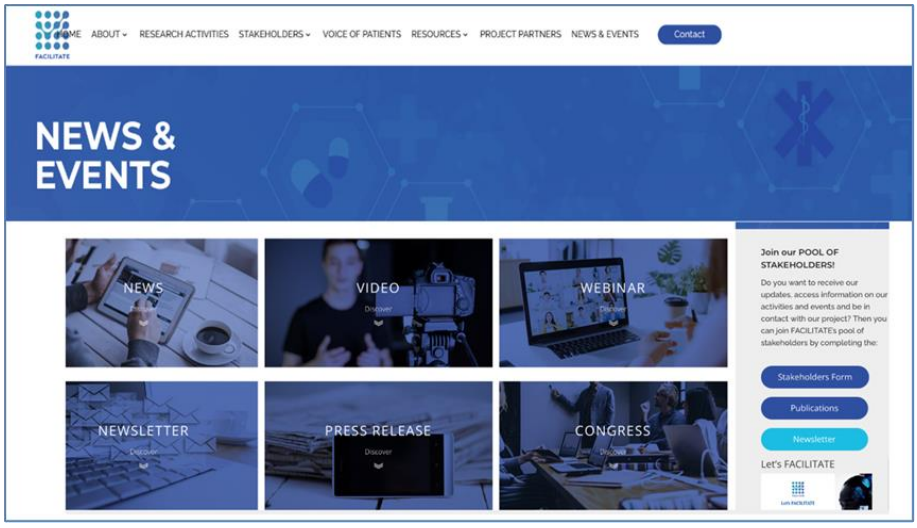


Figure 6. Reorganization of the News and Events page into 6 sections

- **Newsletter for stakeholders: "Let's FACILITATE"**

Four issues of Let's FACILITATE Newsletter have been published regularly on the website (Figure 7). The newsletter contains all updates on FACILITATE activities, with:

- an introduction signed by the Coordinator and the Project leader
- a column dedicated to a relevant topic of the project (Where we are)
- an in-depth look at some topic of interest (Focus on)
- reports of major FACILITATE dissemination events around the world (In the world)
- a list of major events of interest planned for the following months (Save the date)
- an alert about upcoming events, activities or tools organized and implemented by

FACILITATE, such as podcasts, webinars, glossary, etc. (Join the Event).
The newsletter is published regularly on the website and mailed to all consortium members and stakeholders who have registered. The publication is promoted on FACILITATE's social media with short video animations.

Figure 7. The four issues of the newsletter Let's FACILITATE, 3 in year 2 of the project

- **News**

The news section contains the main news concerning FACILITATE, directly or indirectly (Figure 8):

- participation in national and international congresses
- organization of dissemination events (training courses, focus groups)
- reporting of events of entities with which FACILITATE collaborates
- publications of interest to the project

Figure 8. News published on FACILITATE website

- **Congress and Events Calendar**

The Congress and Events page contains the updated calendar with major events of interest reported by project partners and/or identified by Editorial Staff. The Calendar provides access to a summary page with all event information and a link to the event website (Figure 9). The page is updated regularly.

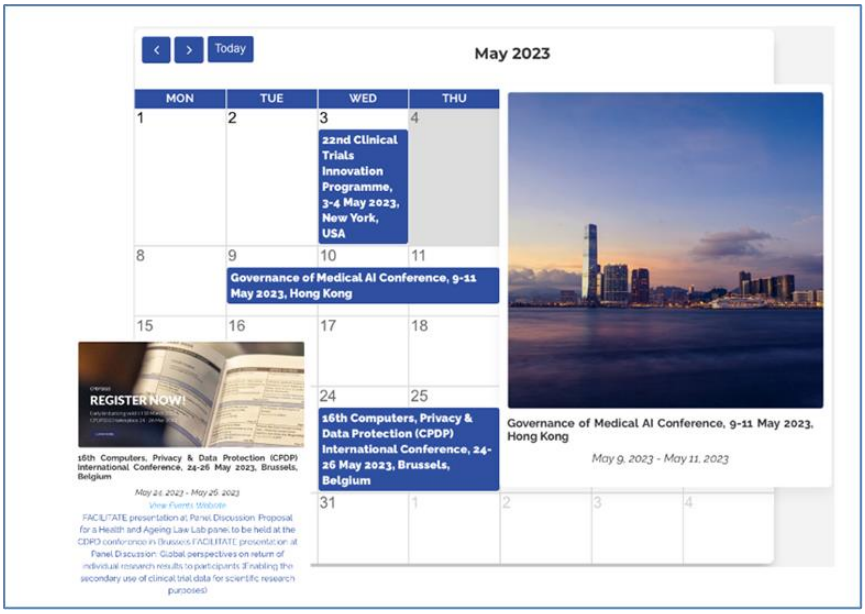


Figure 9. Congress and Events calendar page

- **Videos/Podcasts**

A series of 9 video podcasts (audio and video recordings, about 5 minutes each) has been planned (Figure 10), with the publication of individual episodes every two week, starting from January 2024. The work was conducted in collaboration with EDUNOVA. The first podcast has been recorded.

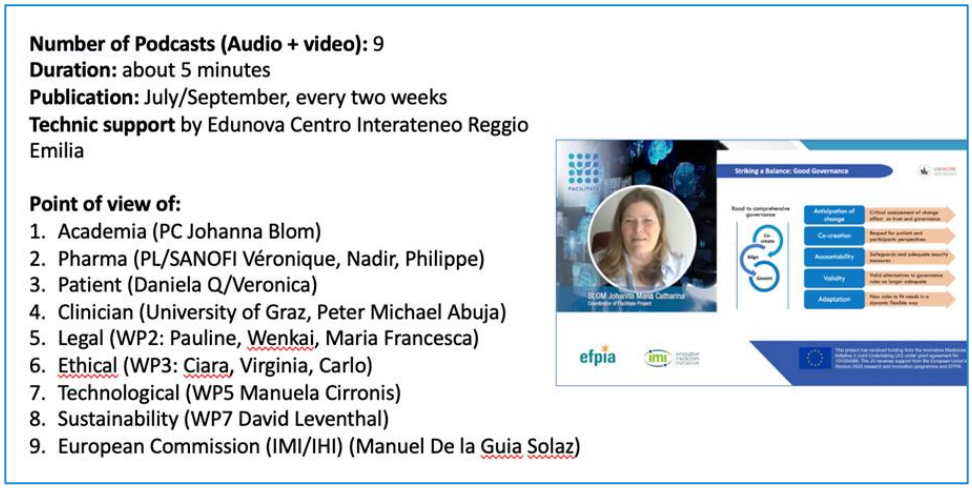


Figure 10. Podcast Editorial plan

- **Webinar**

FACILITATE first webinar for stakeholders - "Let's FACILITATE A Project to Facilitate the Access to Clinical Trial Data and to Manage its Reuse" - has been conducted on 27 January 2023, with the support of the EDUNOVA, with 466 registered and 166 attendees, mostly patients or patient associations, pharma representatives and clinical researchers from different EU and extra-EU Countries (Figure 11).

Main content of the webinar:

- introduction on the context in which the project was ideated and its importance in the landscape of current CT data return and reuse in the EU (Luca Pani).
- project's objectives, its mission, architecture, benefits for stakeholders and challenges (Johanna Blom and Véronique Poinsot).
- patient and other stakeholders' role as the main beneficiaries (Daniela Quaggia)
- legal and data privacy framework and associated challenges regarding the return of clinical trial data and their secondary use considering current European legislation (Pauline Granger)
- discussion on the two ethical contexts in which such individual trial data should be returned and re-used to meet the needs of the patient (Deborah Mascalzoni).

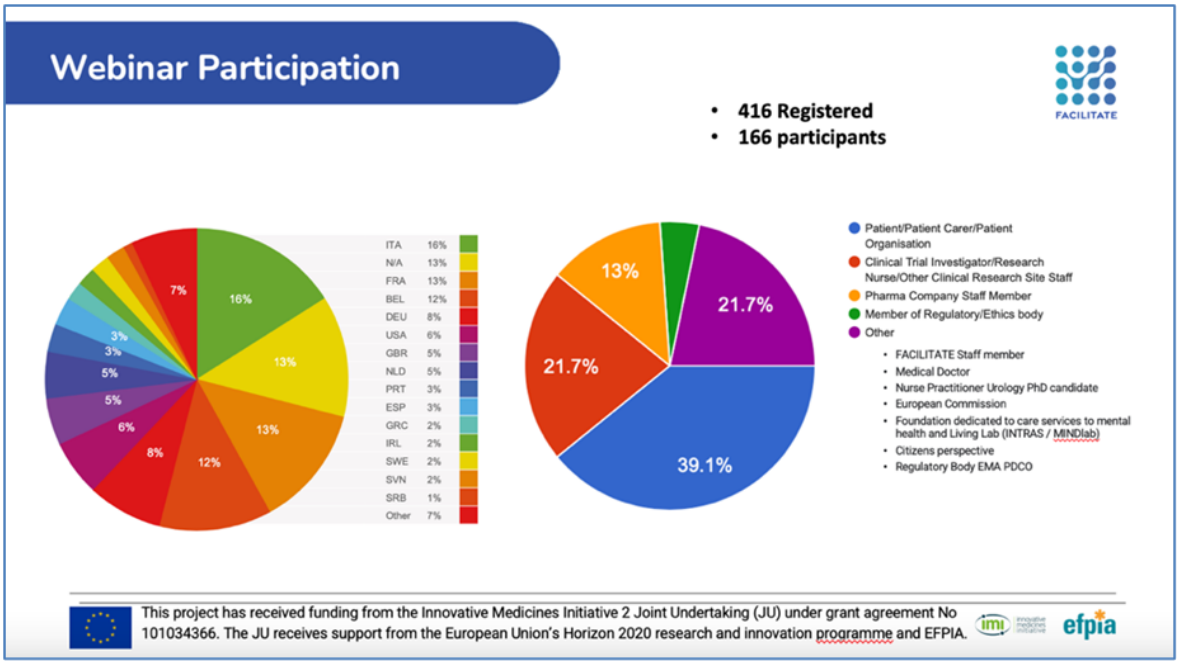


Figure 11. Attendees' data related to FACILITATE webinar

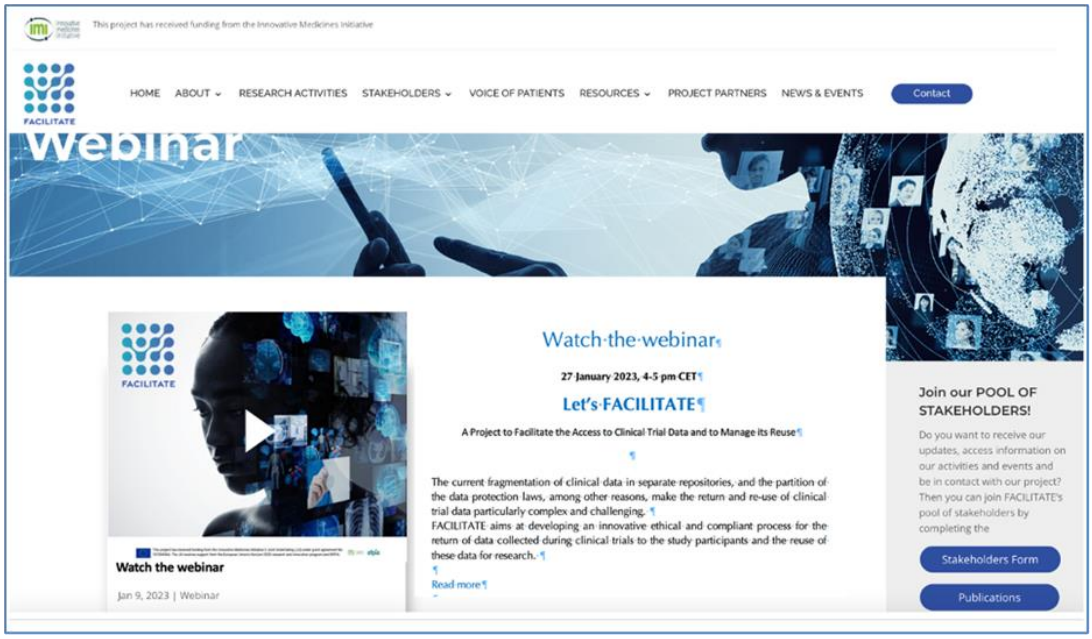


Figure 12. Website page for watching the recorded webinar

The webinar can be seen on the dedicated website page (https://facilitate-project.eu/category/webinar/) and at the following link: https://openmedia.edunova.it/w/dxVeGsiwbtV5Lr8cViGrB1

Resources page

Main Deliverables

Six public deliverables (D1.1 FACILITATE Handbook, D1.2 Expert Decision Committee, D3.1 Ethical framework, D6.1 DiCEP, D6.2 Website, D6.4 Stakeholders' engagement and Communication, dissemination pan [report 1]) have been published on the Resources' menu. The documents can be downloaded (Figure 13).

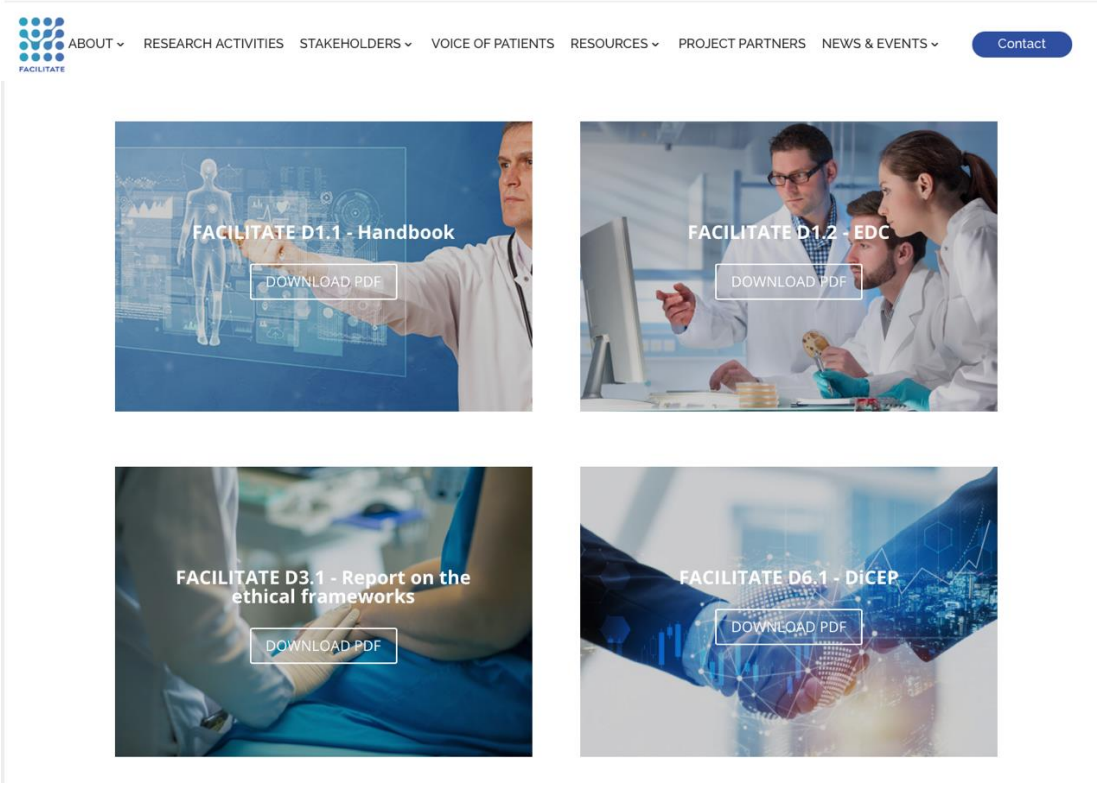


Figure 13. Main Deliverables page under Resources' menu

Glossary

A **Glossary for patients (First part)** has been realized by a collaborative working group including UNIMORE (WP6 and WP2) and EUPATI Italia and is harmonized with similar initiatives such as the glossaries from MRCT and TransCelerate.

The Glossary contains the main terms concerning clinical trial data sharing and re-use (to be updated). The work followed the procedure outlined below:

- Selection of the first term (at the end of work 20).
- Work on the selected terms (choice of the best UNIMORE or EUPATI definitions), and where necessary extending with WP2/WP3 term definions
- Approval by UNIMORE/EUPATI group of definitions and entire content with insights.
- Submission of glossary to CommWG for Consortium approval and integration of comments
- Submission of the final document to EDUNOVA for publication on the website (Figure 14)

This first part includes 20 terms. For each term, when necessary, insights have been provided (e.g., reporting links to other glossaries, ethical or legal insights, links to articles, videos, or patient guidelines, and so on) (Figure 15).

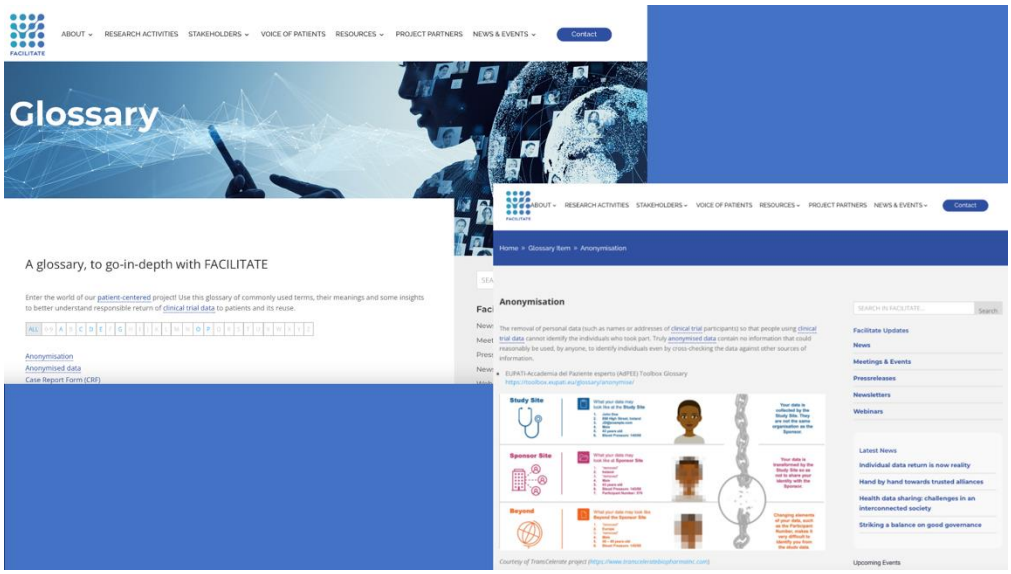


Figure 14. Glossary pages published on the Resources Session of the website

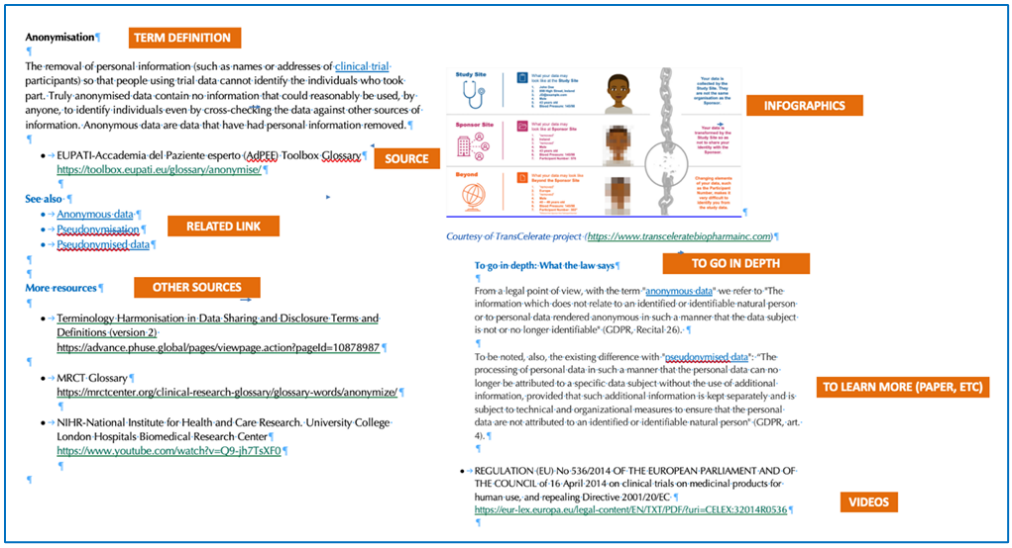


Figure 15. Glossary for patient: example of a term definition and in-depth sections

Questions and Answers and Infographics

A Q&A section will be realized in the first months of 2024**,** about different items related to FACILITATE (I.e., role of patient in FACILITATE, legal framework, ethical framework, informed consent, restitution of individual health and /or CT data, reuse of data, etc.), with a pdf version to download. Some **Infographics** will be realized to provide easy-to-understand information on the project and its main achievements

Communication and dissemination tools

The communication and dissemination tools created for Consortium communication and dissemination activities (a general **Slide deck** on FACILITATE; a **Poster and Roll up** for congresses; a **Flyer;** a **Background** for speakers at webinars and podcast**),** to present FACILITATE at internal and external events with a coherent and well-defined image (Figure 16), have been generated and regularly updated.

Figure 16. Tools for communication and dissemination

Meetings' participation

A procedure has been put in place to facilitate the supervision of the Consortium's communication and dissemination activities, which involves different steps, as reported in Figure 17. A tracker form, to be filled in before and after, provides the main information about the event (Figure 18).

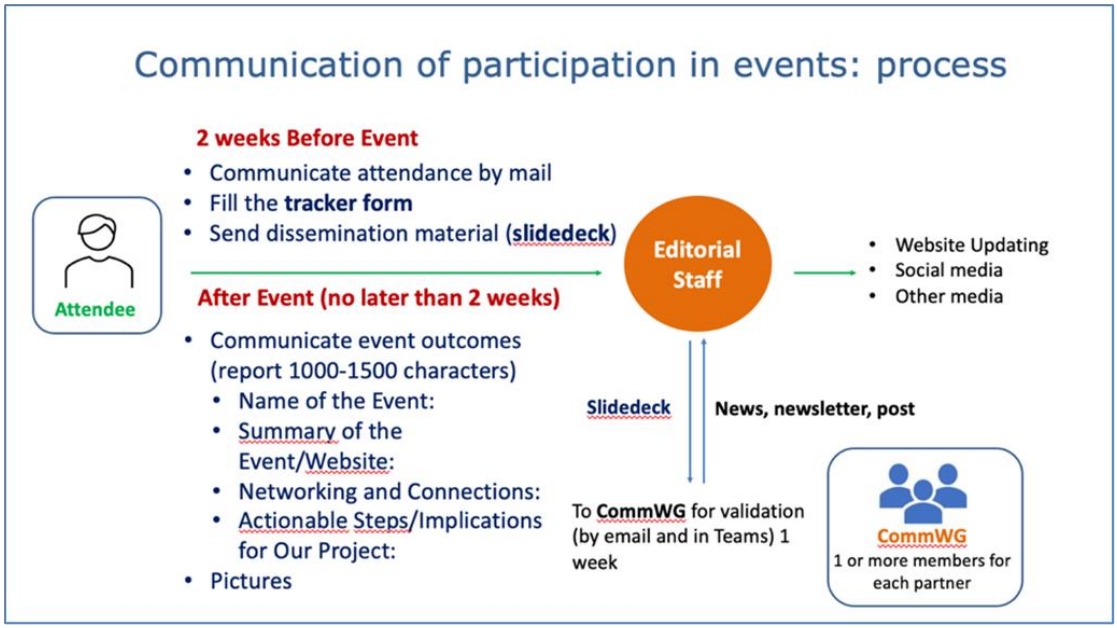
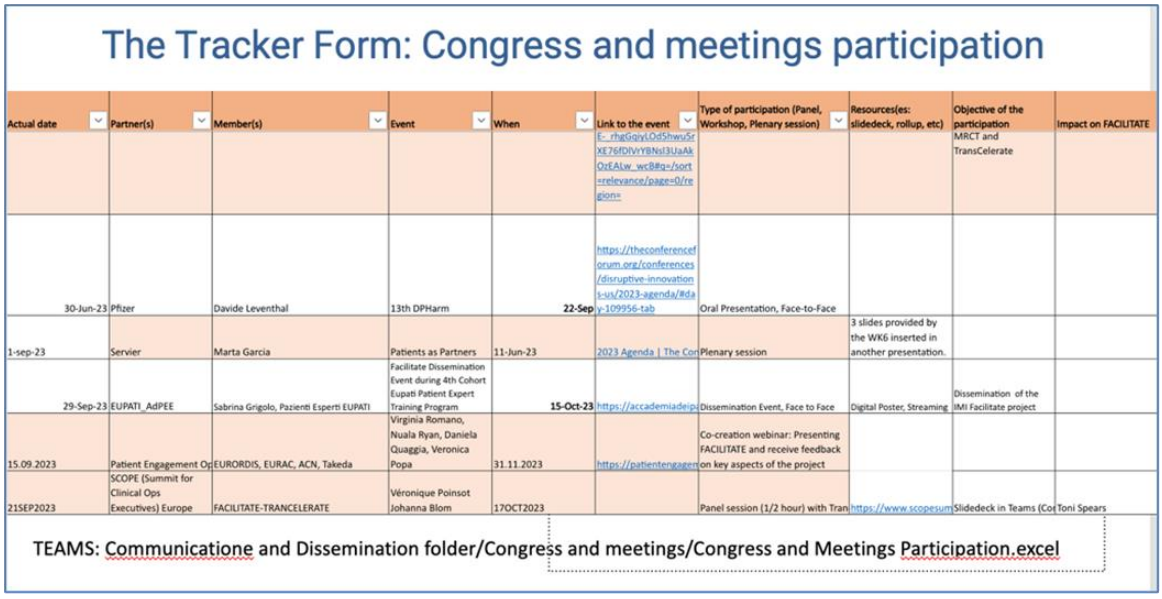


Figure 17. Procedure concerning events participation


The Tracker Form: Congress and meetings participation

Actual date	Partner(s)	Member(s)	Event	When	Link to the event	Type of participation (Panel, Workshop, Plenary session)	Resources(es: slidedeck, rollup, etc)	Objective of the participation	Impact on FACILITATE
					E-_rhqGqiyLOd5hwu5rXE76fDlVrYBNsI3UaAkOzEALw_wcB#q=/sort=relevance/page=0/region=			MRCT and TransCelerate	
30-Jun-23	Pfizer	Davide Leventhal	13th DPHarm	22-Sep	https://theconferenceforum.org/conferences/disruptive-innovations-us/2023-agenda/#day-109956-tab	Oral Presentation, Face-to-Face			
1-sep-23	Servier	Marta Garcia	Patients as Partners	11-Jun-23	2023 Agenda | The Con	Plenary session	3 slides provided by the WK6 inserted in another presentation.		
29-Sep-23	EUPATI_AdPEE	Sabrina Grigolo, Pazienti Esperti EUPATI	Facilitate Dissemination Event during 4th Cohort Eupati Patient Expert Training Program	15-Oct-23	https://accademiadeip	Dissemination Event, Face to Face	Digital Poster, Streaming	Dissemination of the IMI Facilitate project	
15.09.2023	Patient Engagement Or	EURORDIS, EURAC, ACN, Takeda	Virginia Romano, Nuala Ryan, Daniela Quaggia, Veronica Popa	31.11.2023	https://patientengagem	Co-creation webinar: Presenting FACILITATE and receive feedback on key aspects of the project			
21SEP2023	SCOPE (Summit for Clinical Ops Executives) Europe	FACILITATE-TRANCELERATE	Véronique Poinsot Johanna Blom	17OCT2023		Panel session (1/2 hour) with Tran	https://www.scopesum	Slidedeck in Teams (Co	Toni Spears

TEAMS: Communicatione and Dissemination folder/Congress and meetings/Congress and Meetings Participation.excel

Figure 18. Tracker form for events participation

2023 Meetings' participation by FACILITATE members

- **21 February 2023**: FACILITATE was presented at the Stakeholders' meeting in Cape Town, South Africa at the14th Congress on Human Genetics on 23 February 2023, within the Session Global perspectives on return of individual research results to participants.
- **23 February 2023:** FACILITATE was presented within the Session at the Global perspectives on return of individual research results to participants.
- **1 March 2023:** Johanna Blom - FACILITATE Deputy Coordinator - participated as a speaker at the 3rd International Conference on Rare Diseases: Greek Chapter, 2023, Athens in the Session "Flash Updates of RD Flagship Initiatives".
- **6-7 March 2023:** Privanova participated as a panellist in the fourth intersessional consultation of the Ad Hoc Committee to be held in Vienna, Austria, using this opportunity to disseminate the efforts done in FACILITATE.
- **15-16 March 2023:** Eurac Research hosted a face-to-face meeting in Bolzano to discuss the two ethical frameworks that WP3 is developing for the return of clinical trial data and for the secondary use of data.
- **21 March 2023**: the TransCelerate project co-hosted a workshop with EFPIA - European Federation of Pharmaceutical Industries and Associations in Basel, Switzerland, to collaborate on modernizing clinical trials and preclinical research while maximizing impact.
- **26 April 2023:** the Health & Ageing Law Lab (HALL) of Vrije Universiteit Brussel successfully hosted its inaugural Health, Law and Technology (HELT) symposium in Brussels (https://hall.research.vub.be/helt-2023-0). Deputy coordinator of the FACILITATE project, Johanna Blom, presented the FACILITATE and its relevance to the EHDS regarding the secondary use of health data for scientific research. Sebastiaan van Sandijk provided his expert insight regarding the interoperability of health data.
- **10 May 2023:** FACILITATE was present at the Medical AI and Data Governance, with Focus on

Genomics hosted at the Governance of Medical AI Conference in Hong Kong (9-10 May). Invited speakers: Deborah Mascalzoni, Uppsala University/Eurac Research, Johanna M.C. Blom, University of Modena and Ciara Staunton, Eurac Research

- **20 May 2023:** EUPATI-Portugal marked the International Day of Clinical Trials with a face-to-face event dedicated to the theme: “Space for Health Data". Among the Invited speakers, Ana Vieira, one of the expert patients involved and consulted in FACILITATE, shared the project and the importance of return of individual clinical studies data.
- **24-26 May 2023:** Two Expert Panels at the Computer Privacy and Data Protection (CPDP) meeting in Brussels: 1. Enabling the secondary use of clinical trial data for scientific research purposes; 2. The EHDS and secondary use of data: is it possible to balance individual interests with the ultimate need for data sharing to facilitate research? (Organized by VUB).
- **31 May-3 June 2023**: DATA MATTERS: keeping track of your health information" at the EULAR 2023 Congress in Milan.
- **25-29 June2023:** the DIA 2023 Global Annual Meeting | ILLUMINATE hosted in Boston industry, regulatory government, academics, and patients to network, problem-solve, and discuss global and local challenges facing the life sciences community (https://www.diaglobal.org/Flagship/DIA-2023)
- **22 September 2023:** David Leventhal (Pfizer) presented FACILITATE at the 13th face-to-face event held in Boston, MA, the 20-22 September.
- **15 October 2023:** EUPATI Italy held the face-to-face 4th Edition training course for the expert patient, where EUPATI presented FACILITATE project to their attendees.
- **17 October 2023:** Véronique Poinsot (Sanofi) and Johanna Blom (UNIMORE) were present at the Panel: "Demystifying Individual Participant Data Return to Modernize and Personalize Clinical Trials“ at Scope EU meeting held in Barcelona, Spain, on 17-18 October 2023.
- **24 October 2023:** Johanna Blom (UNIMORE) presented FACILITATE project at the APRE-Horizon IHI day, followed by a workshop on innovative European IHI project.
- **31 October 2023:** EURORDIS, EURAC, ACN, Takeda organized an interactive meeting with expert patients to discuss 3 vignettes about Use cases at the Patient Engagement Open Forum (PEOF) (31October-1 November).
- **29 November 2023:** Johanna Blom (UNIMORE) presented FACILITATE project at the meeting Clinical Trials Europe, Streamline & simplify your clinical trials, held in Barcelona, Spain the 29-30 November 2023.

Internal Communication

Comprehensive update of FACILITATE activities to all consortium members made use of quarterly newsletters (5 issues from May 2022 to September 2023) (Figure 19).

Figure 19. FACILITATE quarterly update issues

Stakeholders' Engagement and Communication & Dissemination strategy for 2024

A workshop supervised by WP6 has been organized at the 2nd General Assembly held in Bordeaux, on 14-15 December 2023, with the aim of fostering stakeholders' engagement and consortium involvement in FACILITATE dissemination activities.

Moreover, a Survey for Consortium members who can't be present Face-to-Face at the GA meeting has been implemented with the purpose to outline a communication strategy from legal, ethical, technological, and stakeholder engagement perspectives, fostering FACILITATE communication for 2024 (Figure 20).

The workshop discussion and survey's answers will be analyzed in January 2024 to define and implement the next Stakeholders' Engagement and Communication & Dissemination Plan.
Preliminary data suggest the need to:
- improve the consortium's internal communication, with the addition of tools to deepen the topics covered in FACILITATE
- intensify stakeholder outreach on the website and social media through user-friendly tools (e.g., infographics, questions & answers, factsheets, etc.)
- promote training for stakeholders on the topics covered in FACILITATE, particularly those related to clinical trials, types of data, secondary use of data, informed consent, etc.) with dedicated webinars, videos and podcast.
- Continuously updating the website with news, animated informational videos about the project, webinars and podcast

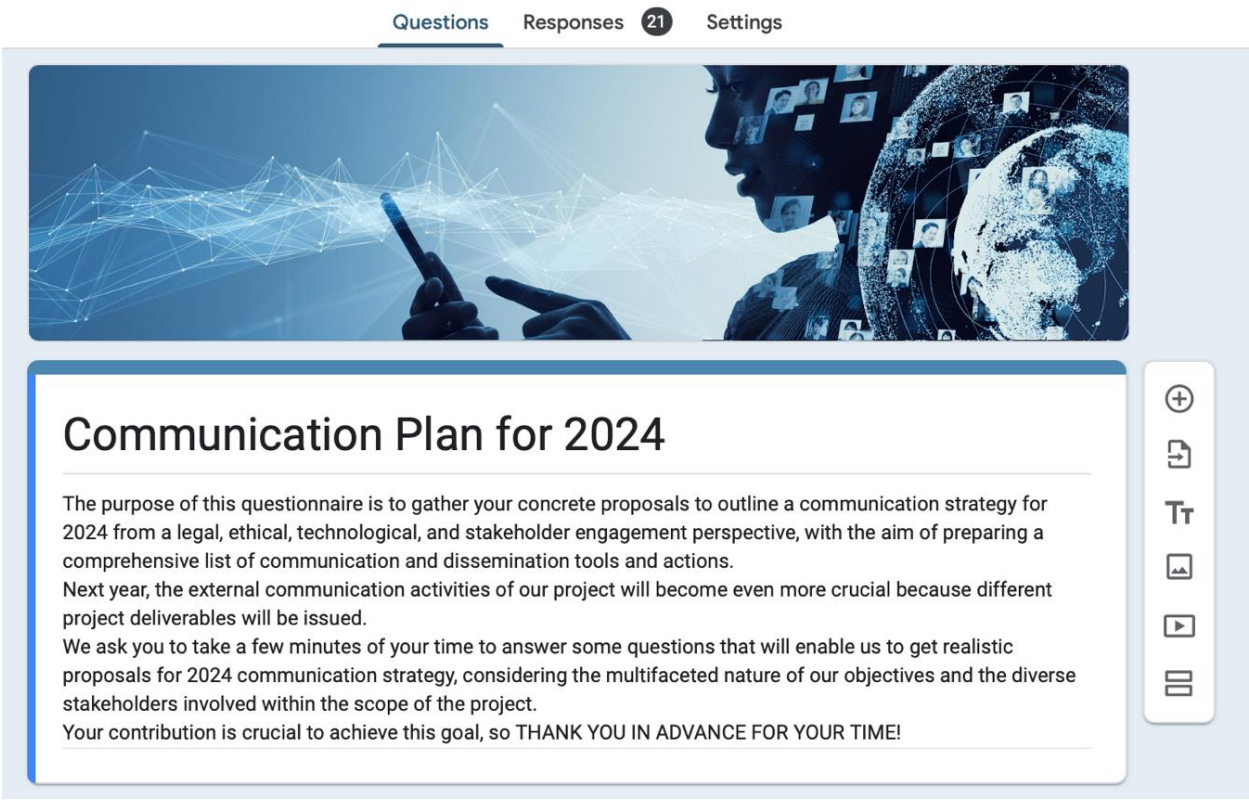


Figure 20. Survey on the Communication and Dissemination Strategy for 2024