IMI2 Project ID 101034366 FACILITATE

FrAmework for ClInicaL trIal participants daTA reutilization for a fully Transparent and Ethical ecosystem

WP6 - Communication anddissemination

D6.6 Report on Stakeholder Engagement 3

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Contents

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
ESG. Environmental, Social, Governance
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 Program 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
TLF. Trust Liaison Facilitator
WP Work Package
WPL. Work Package Leader

List of figures

Definitions

A Stakeholder is defined for the purpose of this project as any individual or group that is affectedby, 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 helps when 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/

1. Executive summary

This third report on stakeholders' engagement gives an overview of how external stakeholders have been engaged in the activities of the third year of FACILITATE. The assets are all related to establishing and implementing an effective communication to ensure continuous awareness and updates as the project develops; facilitating consultations with patients, healthcare professionals, pharmaceutical companies, and other stakeholders to gather their input; disseminating the project results effectively to reach a broader audience.

The 2024 discussions with expert stakeholder groups (online and written consultations, surveys, interviews) and public activities (such as webinars and congresses) continue to nourish the project's reflections and proposals and in some cases directly modify the documents produced (e.g., for D2.4) and provide input for future work.

A survey, involving more than 320 people, was carried out on one of the most recurring concepts that emerged in previous consultations, both external and internal: TRUST. Which confirmed the ethical and value-based approach of the project to what patients, but not only them, want in the management and return of data. The expert stakeholder groups were consulted on the results of this survey and on a new and important proposal to include a new professional figure (the Trust Liaison Facilitator, which is detailed in the following chapters) in the complicated pathway of clinical trials, receiving very rich input to build it as best as possible.

A successful way to talk to our stakeholders and above all to make the topic of data return and secondary use in clinical trials better understood externally was that of two public webinars: there was great interest (around 400 registrations for each) and interaction for both. Instant surveys at the end of the events told us that 70% had significantly or moderately increased their knowledge of the topics so they were a success given the "educational" objective we had set ourselves. Another success was the continuous growth of registered stakeholders through the website, which has now reached 410 people and is constantly being updated.

A great deal of work on communication materials - website restyling and updating, social media (the LinkedIn profile currently has almost 380 followers), glossary enrichment, podcasts, multilingual posters, brochures, and flyers, but also peer-reviewed articles and participation in external events - has been done throughout the course of 2024, since the work of involving stakeholders and disseminating the project results are closely linked and often overlapped. It is impossible to engage and interest stakeholders without effectively communicating the project's goals, progress, and milestones on a regular basis.

Patients' empowerment and inclusivity are key objectives of our present and future engagement, communication, and dissemination strategy, providing patients with new tools in an easy-to-understand language, and formats adapted to visible and invisible disabilities, available into the main European languages. These efforts further strengthen the FACILITATE project's impact, preparing the groundwork for its final outcomes.

2. FACILITATE’s stakeholders

The FACILITATE project develops a process prototype to return individual clinical trial data to participants and enable secondary data use, engaging patients, academic institutions, regulators, and the pharma industry to build trust in clinical research. External stakeholders, beyond the FACILITATE consortium, also include experts in clinical trials, data management, and ethical/legal issues.

The four main stakeholder groups are:

Patient Experts: coordinated by EURORDIS, with involvement from EUPATI and ACN, to ensure patient-centred methodologies.

Clinicians & Healthcare Professionals: coordinated by MUG, focusing on ethical and legal compliance in data processes.

Pharma Industry: coordinated by Takeda, until 2023 and now managed by BMS addressing consistent and transparent data sharing.

Broader Healthcare Stakeholders: coordinated by ACN, integrating perspectives from EU and national healthcare actors.

3. The Engagement Coordination team (ECT)

The four coordinators of the Stakeholder groups (EURORDIS, MUG, BMS, ACN) make up the **Engagement Coordination Team (ECT).** EUPATI and WP3 representatives from EURAC also partly contributed to its work.

The activities included:

- regular communication which takes place via monthly meetings as well as email correspondence
- mediation between the stakeholder groups and the consortium, as well as the other WPs which also rely on stakeholders' feedback as part of their 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.

4. Multilevel engagement

Within each group listed above, FACILITATE employs three levels of stakeholder engagement:

Level I: Expert groups (from 10 to 24 per stakeholder category) provide targeted feedback and review project progress (see Chapter 4).

Level II: A broader network of stakeholders is engaged/updated/managed through the FACILITATE website via surveys, newsletters, and regular updates (see Chapter 5 for the tools).

Level III: Multi-stakeholder roundtables (webinars) address cross-group concerns.

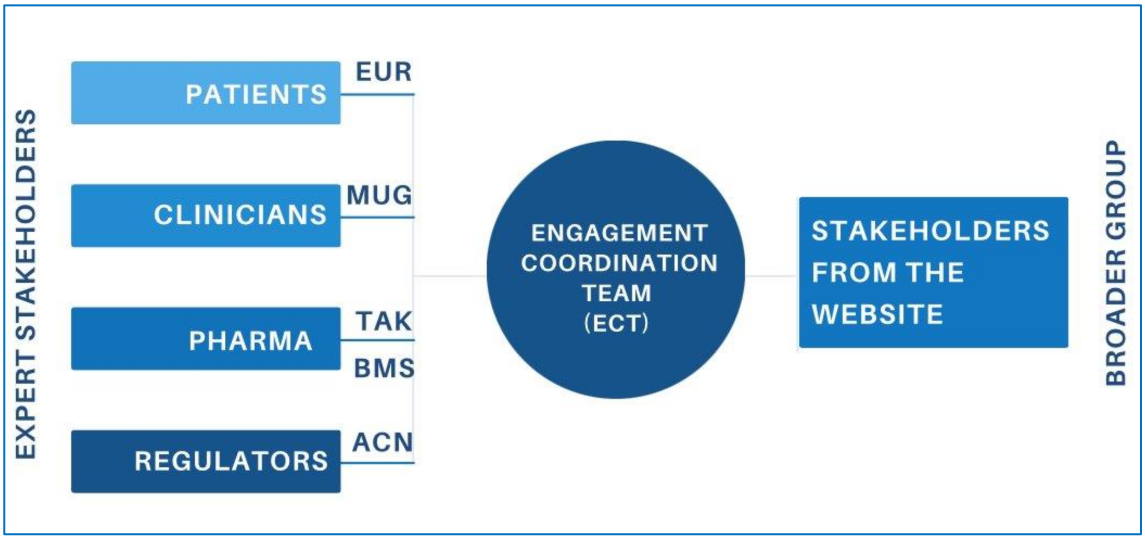


Figure 1. Relationship among the stakeholders' groups

5. Stakeholders' meetings in 2024

5.1 Level I Stakeholders - Expert groups

Group 1. Patient Experts DAG+

The Patient Expert group comprises 24 participants, among rare (13) and non-rare disease (8) patients.The group includes the members of the EURORDIS Digital and Data Advisory Group (DAG) and is supplemented by additional members (DAG & additional members are the new group to be known as the DAG+).

During 2024, the consultations were the following:

1. Survey: the role of trust in Return of Data (RoD) from clinical trials

Starting from the Clinical Trials Day 2024 (20 May 2024) until August 2024, the DAG+ group (together with the broader list of stakeholders) were invited to answer an online survey, conceived by WP3. They were asked to share their views and expertise to further investigate one of the strongest elements that has emerged within the previous project's research and consultations: TRUST. That is, trust in the overall clinical trial system and trust in the professionals involved have emerged as a pivotal element to explain participants' attitudes about data return in this context. When participating in a clinical trial, patient's trust might relate to different aspects. FACILITATE researchers identified a set of trust dimensions that has been asked to evaluate, rate, and discuss, including communication methods, transparency, the reliability of those closest to the participants, and the personnel involved, as well as add new elements that stakeholders consider to be missing.

The survey received 361 answers (multi-stakeholders): the findings provided a framework to improve participant engagement and overall trial and RoD success by addressing trust-related concerns (**Appendix 1**). In November and December, the results of the survey were the subject of three consultations with the DAG+ patient group, the group of clinicians and the companies group. All the stakeholders commented on the outcomes with interesting new considerations (see the details below for each group).

2. 5th November 2024 consultation of DAG+ on exploring the dimensions of trust and co-creating a new 'bridge' figure for patient-centric clinical trials, a Trust Liaison Facilitator

A DAG+ consultation meeting was held on 5th November 2024, to share insights on two topics:

a) the results of the **survey** around the role of trust in clinical trial systems (see above point 1)

b) the benefit of creating a new professional position (and a dedicated master's program) within the clinical trial environment. This new role, would be responsible for:

- enhancing process efficiency (by managing and streamlining administrative aspects of the clinical trial process; this role would enable physicians to focus more fully on participants and their needs)

- facilitating better communication among all stakeholders: physicians, clinical trial participants, sponsor, etc.

- providing support to clinical trial participants in navigating complexities of clinical trials, which may otherwise be overwhelming.

The proposal of the TLF comes from UNIMORE, but the need of this new role emerged from the work carried out within the project work and from various stakeholder requests, particularly from patients, who highlighted the importance of having dedicated support to navigate the complexities of clinical trials. TLF would enhance patient access to their clinical trial data, fostering trust necessary for effective data sharing and reuse key priorities of the FACILITATE consortium. It would also serve as a crucial bridge for communication among stakeholders, empowering patients with meaningful access to their health information.

Regarding point a)

The results were presented by one of the EURAC researchers responsible for drafting the survey. It confirmed patients' perspectives regarding access to their own data and the role of healthcare professionals in demystifying clinical trial information:

Patient Access to Data

One significant finding from the survey indicates that patients desire prompt access to their clinical trial data. This demand underscores a broader trend towards transparency in healthcare. By allowing patients to have access to their own data every time this does not damage the clinical trial blind, researchers can foster a sense of ownership and involvement in the trial process. This access aligns with the ethical principles of patient autonomy and informed consent, contributing positively to the overall trust in clinical research.

Seeking Explanations from Trusted Physicians

Another notable point is that patients feel empowered to being potentially able to seek explanations from medical professionals they trust, even when the data lacks a clear medical explanation for a lay person. This finding suggests that trust in healthcare providers plays a critical role in patient understanding and satisfaction. Patients value open lines of communication and reassurance from knowledgeable sources. Facilitating these discussions can enhance patient engagement, alleviate concerns, and improve overall perceptions of clinical trials.

The discussion about the survey results, brought to a broader reflection and highlighted key challenges and opportunities regarding the return of results to participants. These included:

Returning results in an organized yet flexible manner

- Providing results to participants in a way that is both organized and responsive to individual needs will require sponsors to invest resources and adapt their processes. Contracts between sponsors and trial sites will be necessary to achieve this, signalling a cultural shift in how clinical trials are conducted.

- Building trust hinges on presenting information in a format that participants can understand. While it may be administratively challenging, it is feasible and essential.

Contextualizing individual data

- Participants need their individual results presented within the broader context of the research. For example, understanding whether their results are "normal" and what deviations might mean requires comparison with other participants or study outcomes.

  - This approach ensures that results are meaningful and addresses the participant's expectations. As one participant expressed, "I was expecting after months of trial for my doctor to take a few minutes and discuss with me my outcomes."

Participant experiences with data sharing

A participant shared that, in a second trial, she only received a general statement about her results - "You had a very good outcome" - despite repeatedly asking for more detailed information. The lack of personalized feedback left her dissatisfied. This highlights the importance of tailoring explanations to meet participants' expectations without overwhelming them. While patients don't need medical training-level detail, they do expect meaningful and accessible information.

A researcher's perspective on data sharing

Another participant, a former researcher, reflected on how his perspective has changed now that he views trials as a patient. Returning data to patients is time consuming and resource intensive and these costs should be factored into the trial design.

These insights underscore the importance of balancing administrative feasibility with patient-centred communication to foster trust and engagement in clinical trials. As said, the survey's findings highlight critical aspects of trust in the clinical trial context, emphasizing the importance of timely data access and the role of trusted medical professionals in fostering understanding.

Technical recommendations

The discussion on the survey also revealed that it would be beneficial for the possible next consultation on the topic to focus its efforts on actual clinical trial participants rather than surveying the public. This targeted approach would yield more relevant data tailored to the specific experiences and concerns of trial participants. By adapting question phrasing to reflect more the actual context of current clinical trials, researchers could enhance the quality and applicability of the results. This specificity may lead to insights that drive improvements in patient engagement strategies and trial methodologies. For the FACILITATE IMI Project, refining the target audience for surveys will enable more meaningful data collection and ultimately facilitate stronger patient-researcher relationships.

Regarding point b) the emerged points from the patients were:

General need for the role

- Dedicated Role**:** Patient experts emphasize the importance of having a dedicated role in clinical trials to address challenges like recruitment, retention, communication, and participant needs. Currently, no one is specifically tasked with these activities, and they are often handled poorly or inconsistently.

- Structured Role: The role must be well-defined, structured, and supported by appropriate education and training, ensuring it doesn't become a catch-all position for unrelated tasks (e.g., administrative work).

Responsibilities of the role

- Improved communication
    a. Act as a key communicator between participants and the clinical trial team.
    b. Provide clear, evidence-based information to participants before and during the trial.
    c. Help participants understand processes, such as reimbursement for expenses, and avoid situations where participants face financial burdens due to miscommunication.
    d. Build trust by listening, providing feedback, and ensuring participants feel heard and supported.

- Facilitating practical needs
    a. Address logistical barriers like transportation or accessibility.
    b. Mitigate issues such as language barriers or lack of cultural sensitivity.

- Enhancing participant trust
    a. Proactively work to preserve trust, which is difficult to regain once lost.
    b. Act as a reliable, approachable team member participants can depend on.

- Clear role boundaries
    a. Avoid overlapping with medical professionals' responsibilities.
    b. Ensure that the role complements rather than competes with other team members.

Skills and qualifications

- Core Skills Needed
    a. Digital literacy and basic understanding of research methodology.
    b. Strong communication skills, including active listening and empathy.
    c. Knowledge of GDPR, privacy laws, and ethics.
    d. Cultural awareness and sensitivity to participants' diverse backgrounds.

- Education requirements
    a. A minimum of a bachelor's degree or equivalent life experience for training

eligibility.

b. A master's-level training program with practical, hands-on elements, such as collaboration with patient advocates, is recommended.

c. Specialization opportunities in areas like communication, cultural competence, and ethics.

Potential challenges

- Role expectations
    - The role may be perceived as a "do-it-all" position, requiring a broad set of skills and capabilities. This could lead to unrealistic expectations from both participants and the clinical trial team.
    - The absence of this key person due to illness or other reasons could create a gap in trial operations.
- Trust building
    - The role's success hinges on building trust within the team and with participants.
    - While a medical background is not deemed essential, the individual must have enough training to competently handle sensitive information and participant interactions.

Suggestions for role naming

- Alternative names for the role aim to reduce ambiguity and better reflect its purpose:
    - Participant Liaison
    - Facilitator (e.g., Clinical Research Participant Facilitator)
    - Avoid vague terms like "liaison," as it may not resonate with participants.

Training program features

- Content Suggestions
    a. Focus on clinical trial processes, ethics, communication, and cultural competence.
    b. Include input from patient advocates to ensure the training addresses real-world challenges.
    c. Offer longitudinal learning opportunities to enhance the skills of professionals over time.
- Ethics across cultures
    a. Include a course that addresses ethical considerations in culturally diverse contexts.
- Practical emphasis

   a. Training should be hands-on, with real-life case studies to ensure understanding and adaptability.

3. **November 2024, Written consultation on the Report on language to be inserted in privacy notices and informed consent forms - D2.4**

The group was invited to participate in a written consultation to share their thoughts and feedback on the Informed Consent Form (ICF) Guidance Document (WP2). This document was intended to provide guidelines on the essential content of the ICF for the return of individual clinical trial data to participants (RoIPD). Participants were asked to assist the consortium in identifying aspects they feel are missing, insufficiently addressed, or potentially redundant. The focus of this consultation is on what the ICF should include, as outlined in the document. While the primary emphasis is not on the language of the document - since it serves as guidance for those drafting the ICF and is not directly intended for trial participants - any ambiguous phrasing or unclear expressions can be flagged, with suggestions for improvement.

Results: Participants provided extensive feedback that has been incorporated into the D2.4 and raised important questions for further discussion as the project progresses. For example, one concern was the ambiguity in stating that “participants will need to be informed about why certain data can only be returned after the clinical trial.” This raises the question of whether there will be any data that will not be returned at all. If so, it might be necessary to explain why certain data cannot be disclosed.

Additionally, there are questions about potential limitations related to data comprehensiveness, accuracy, and the requirements for its interpretation. These points are slated for discussion during the General Assembly (GA) meeting in Madrid in January 2024.

Another topic is how to handle the section on data types. Participants suggested distinguishing between categories such as raw data, aggregated results, genetic data, and biomarkers. Each type’s implications for participants should be clarified, and additional resources, such as access to healthcare professionals or interpretation tools, could help participants better understand their data.

New elements added to the text following the consultation include:

- data security
- data retention
- making sure the texts are easy to read by using Flesch-Kincaid readability tests
- a paragraph on unforeseen or unexpected discoveries
- making clear who the data controller is.

<u>Purpose of RoIPD:</u> an explanation of why returning individual clinical trial data is important, along with a definition of terms like RoIPD.

Risks and benefits: a chapter addressing potential risks and benefits associated with receiving clinical trial data. For instance, sensitive data might have emotional impacts on patients, and there is the potential for data misuse.

Costs and Constraints: clarifications regarding legal or practical constraints on using returned data, as well as any costs involved in accessing or receiving the data.

Ongoing communication: a recommendation to include a section on maintaining regular communication with participants about the status of their data during the trial, such as periodic updates on its availability.

Psychological support: acknowledgment of potential emotional or psychological effects on participants receiving sensitive health information. A new section could outline psychological support measures, such as referrals to counselling services or access to a support hotline, especially in the case of adverse findings.

4. Delphi consultation on Secondary Use of Clinical Trial Data

Conducted by WP1 for the definition of guidelines on the secondary use of CT data has now reached the conclusion of the first of three rounds. In the initial phase of the study, an expert panel formulated key questions for a comprehensive questionnaire. This set of questions was shared with stakeholders, including physicians, DAG+ members, and clinical trial experts, who contributed their perspectives. The insights gathered are now being analysed to guide the development of a second- and third-round questionnaire, aimed at fostering a shared consensus on best practices for the secondary use of clinical trial data.

5.2. Group 2. Clinicians & healthcare professionals

The Clinician Expert group comprises 11 members along with a diverse and highly specialized set of expertise across various medical and scientific disciplines. Their specializations include faculty members leading research and innovation in clinical and biomedical sciences, neurology, and neuroscience; cell biology and biotherapy (cellular research and biotherapeutic applications); vaccine research; geriatric oncology and palliative care; gastrointestinal malignancies; dermatology; psychiatry and mental Health.

During 2024 the consultations were the following.

1. Survey: the role of trust in Return of Data (RoD) from clinical trials

The Clinicians' group was also invited to participate in the survey (see point 1 in Group 1 consultations).

2. 7th November 2024 consultation on exploring the dimensions of trust and co-creating a new ‘bridge’ figure for patient-centric clinical trials a “Trust Liaison Facilitator”

A clinical experts consultation meeting (+ a following written consultation with the members who could not be present on the day of the meeting) was held on 7th November 2024, to share clinicians’ insights on the same topics addressed by the patients’ group:

a. the results of the survey around the role of trust in clinical trial systems
b. the benefit of creating a new position (and a dedicated master's program) within the clinical trial environment, that of Trust Liaison Facilitator (TLF).

regarding point a)

The main reflections that emerged are the following.

- The role and qualifications of the individual responsible for interpreting and sharing the data are critical. Trust and clarity in communication depend significantly on this person’s expertise and approach.
- Be mindful that returning data during the trial, if permitted by the research plan, should be handled with care. Simply providing raw data is unlikely to benefit the patient and may instead lead to confusion or even fear.
- A point to consider is how patients prefer to initiate interactions on data return. Should the contact be initiated proactively by the physician, or should there be a designated contact point where patients can reach out as needed? This distinction is crucial, as some patients may feel hesitant or shy, while certain physicians might be less accessible. Tailoring communication methods to accommodate these preferences can improve patient engagement and trust.

regarding point b)

Feedback on the proposed Trust Liaison role in clinical trials was generally positive, with clinicians seeing potential in streamlining processes and enhancing patient support.

- The role is seen as a bridge or buffer, supporting patients through their trial journey, beyond the traditional tasks of a Clinical Research Coordinator (CRC), who typically focuses on managing trial activities.
- The shift towards decentralized clinical trials (DCTs) presents unique challenges. Patients in these trials may be scattered geographically and often interact remotely via devices, making personal contact limited. Support personnel in this role must find ways to maintain engagement and support despite reduced physical or virtual contact. Managing patient adherence and providing necessary side-effect support in a decentralized setup is crucial, as these are factors known to affect retention.
- There is an interest in whether this role should cater to both primary and secondary care, with an emphasis on decentralizing some trials to primary care to reduce hospital strain. In the UK, for example, there is a strong push for trials to shift toward primary care settings to allow hospitals to focus on complex cases. This shift calls for versatile

support roles that can operate effectively across different care environments.

- Participants discussed whether this role should include regulatory support, particularly in managing documentation and reducing the need for amendments. Familiarity with regulatory requirements is valuable to avoid delays and streamline processes, ensuring the trial complies with ethical standards and meets regulatory needs. This aspect could make the role even more central to trial administration.
- There was consensus that maintaining a dedicated support figure could be cost-effective by reducing dropout rates, which often carry substantial costs. Part of the trial budget could cover this role as a small overhead, potentially offset by savings from improved patient retention and streamlined support. Deciding whether this should be a full-time role or integrated as an independent figure based on trial phase and complexity was also discussed, suggesting flexibility in staffing models based on trial needs.
- The role's impact on patient trust and quality of life was emphasized, especially considering findings from qualitative work with trial participants, clinicians, and pharmaceutical representatives. The ability to manage side effects, provide emotional support, and facilitate data transparency emerged as key factors in building trust and enhancing participant quality of life. These factors are essential for participant retention and satisfaction, particularly in longer or more demanding trials.
- There is interest in establishing a standardized role across Europe to ensure consistency in trial support. European initiatives, potentially through organizations like EUPATI, could lead efforts to create uniform role descriptions, training, and best practices, fostering a more cohesive trial support framework.
- The role discussed holds significant potential to improve patient experience, reduce trial dropout rates, and streamline trial processes, especially as clinical trials shift toward decentralized and primary care settings.

Some concerns:

- Concerns remain regarding the role's practical implementation, particularly in terms of administrative accountability and sustainability.
- Clinicians raised questions about the legal responsibilities of this role, particularly in patient interactions. Unlike research coordinators who face limitations (e.g., needing physician approval for tasks like patient appointments), this new role ideally would have fewer restrictions. However, defining accountability remains crucial, as responsibilities for this role differ significantly from traditional clinical or administrative roles. Moreover, these responsibilities could vary by country, depending on local laws and hospital practices, warranting thorough discussion.
- Who should hire and fund the Trust Liaison role is a significant issue. Hiring by a Contract Research Organization (CRO) might bias the role toward the promoter's interests, while hiring by hospitals or research teams could drive up trial costs, making this role impractical for smaller or less resourced teams. Clarifying these funding and employment aspects will be essential to maintaining balance and feasibility.

Suggestions:

- **Expand role to include both patient support and regulatory functions**. This dual focus can help reduce the regulatory burden on trial sites and address the participant's needs more comprehensively.
- **Tailor role based on trial phase and setting**. Flexibility is key, as early-phase trials with fewer participants may not require full-time support, while later-phase or decentralized trials might benefit from dedicated personnel.
- **Encourage funding models to sustain role as cost-effective**. Trial budgets should accommodate this role as a small, cost-saving overhead to enhance participant retention and streamline administrative tasks.
- **Promote European harmonization for role clarity and efficiency.** Regional initiatives should work toward harmonizing this role across institutions, ensuring smaller or less-resourced organizations have access to effective trial support frameworks.
- **Focus on building trust and quality of life**. Addressing these two critical elements could significantly improve participant retention and satisfaction, thus enhancing trial outcomes and data reliability.
- **Taking part to the digital revolution**. While the role could improve stakeholder communication, clinicians highlighted the current overload from increased digital communications. The Trust Liaison Facilitator should help streamline communication rather than add to it.
- **Patient information needs.** Flexibility in information-sharing is essential. Some patients may seek detailed clinical trial information, while others may prefer a more focused, outcome-oriented summary. Making information available on request would meet diverse patient needs and motivations.

Overall, the Trust Liaison Facilitator role holds promise but will require careful planning to balance support for participants with feasibility and role clarity within the clinical trial ecosystem.

The meeting concluded with a shared agreement on the need to harmonize training and professional standards across countries to enhance clinical trial coordination and success. Participants emphasized the importance of developing recommendations and guidelines that could serve as a quasi-standard to improve participant communication in clinical trials across Europe.

It was suggested that while extensive management structures often exist, their implementation should be tailored to the specific institutions conducting the trials. This approach allows institutions to leverage existing frameworks and structures, avoiding unnecessary hiring and financing challenges when additional personnel are not required. Furthermore, adding more communicators to a network must be approached cautiously, as it significantly increases the complexity of communication pathways.

Regarding the development of a European curriculum, participants proposed that

FACILITATE could define the detailed content, while individual institutions manage implementation. This strategy would enable integration with existing Continuing Education frameworks, which are often mandatory for medical professionals. Such an approach would streamline integration into current curricula, simplify funding for additional training units, and ensure better alignment with institutional practices.

- **Delphi consultation on Secondary Use of Clinical Trial Data**

As for the patients.

5.3 Group 3. Pharma industry/sponsors

The group, officially convening for the first time, includes members from pharmaceutical companies who are eager to provide input on the development of project activities. These members bring valuable experience from participation in similar initiatives, such as the Patient Data Access Initiative (PDAI), TransCelerate Data Return Initiative, and the Harvard Multi-Regional Clinical Trials Centre (MRCT) Return of Individual Trial Results Initiative.

Currently, the group consists of 5 to 6 members, but it remains flexible and open to ongoing updates and expansion. This adaptability ensures the inclusion of diverse perspectives and expertise as the project evolves.

During 2024 the consultations were the following.

1. **5th December 2024 consultation on exploring the dimensions of trust and co-creating a new 'bridge' figure for patient-centric clinical trials a "Trust Liaison Facilitator"**

A pharma experts consultation meeting was held on 5th December 2024, to share their' insights on the same topics addressed by the patients and clinicians' groups:

a) the results of the survey around the role of trust in clinical trial systems
b) the benefit of creating a new position (and a dedicated master's program) within the clinical trial environment, that of Trust Liaison Facilitator (TLF).

<u>Regarding point a)</u>
The discussion emphasizes several critical insights about the role of trust, data sharing, and industry reputation in the pharmaceutical sector:

1. **Predictability and confirmation**
   Much of the feedback aligns with expectations, affirming the challenges in implementation.
2. **Challenges in bridging the gap**
   While survey data indicate strong participant interest in accessing trial data, this interest

does not consistently translate into action. Barriers include user engagement, portal usability, and follow-through. Pilot initiatives are suggested to better understand and address these gaps.

3. **Variability across contexts**
   Engagement levels and trust-building efforts differ based on therapeutic areas and the nature of clinical trials. This underscores the importance of context-specific approaches rather than one-size-fits-all solutions.
4. **The link between trust and reputation**
   Trust in pharmaceutical companies remains critically low, even compared to other industries. Establishing evidence of the relationship between trust, engagement, and corporate reputation could be instrumental in driving organizational changes and improving stakeholder relationships. Companies must effectively communicate the value and impact of their work, both internally and externally, to ensure the broader goals of access to trials and medicines in underserved populations are met.
5. **Environmental, social, and governance considerations**
   Trust and reputation are increasingly tied to Environmental, Social, Governance (ESG) rankings, which influence both public perception and investor interest. There is an opportunity to integrate trust-building measures into ESG frameworks to demonstrate societal impact and enhance credibility. Detailed ESG reports are critical for driving change within pharmaceutical companies. These reports should not be superficial; they must include concrete actions and measurable outcomes to encourage more sustainable practices.
6. **Data Ownership, transparency, and predictability**
   A critical issue is the question of data ownership, with industry concerns about data sharing compounding the distrust. Simplified processes, like returning patient data (e.g., to children or oncology patients), can be an initial step toward rebuilding trust. The industry's reluctance to offer patients access to even basic trial data is a significant hurdle, but addressing this directly is key to bridging the trust gap.
7. **Collaboration, equity, and stakeholder relationships**
   Collaboration between industry, health organizations, and other stakeholders is crucial for improving trust and addressing health equity. These collaborations align with societal expectations and help create a more patient-centered environment.
   Highlighting efforts focused on health equity and transparent collaboration in reporting and marketing can reinforce a commitment to ethical practices and build stronger relationships with both patients and the public.
8. **Operational and communication gaps**
   Sponsors often overestimate patient understanding of clinical trial processes, which, combined with the introduction of new technologies (e.g., decentralization, real-world evidence), complicates engagement efforts.
   Simplifying communication and operational processes, particularly regarding patient data, and taking a risk-based approach to identify and prioritize populations for data access, could make a meaningful difference in improving engagement.

Focusing on tangible, incremental actions (such as returning patient data) can provide immediate benefits while laying the foundation for long-term trust-building.

9. **Infrastructure and health equity**
   Building infrastructure for clinical trials should not only benefit large pharmaceutical companies but should be accessible to academic sites and individual investigators, contributing to broader health equity. Infrastructure development should include a collective approach, with strategies for which trials to conduct in different regions. A data-driven, non-competitive model should guide these decisions, enhancing collaboration between organizations.
10. **Emergency preparedness**
    In emergency situations, like wars or pandemics, infrastructure should be built with preparedness in mind, ensuring access to both care and research.
11. **Global collaboration and equal access**
    Engaging a wide range of stakeholders, including regulators from various countries, is key to ensuring equal access to research and clinical trials worldwide. Collaborative efforts will reduce risk and increase fairness in access to innovative treatments.
12. **Actionable outcomes from discussions**
    It's important to move beyond just opening doors to new opportunities; there must be concrete actions taken based on these discussions, such as creating white papers or implementing recommendations to improve the system.
13. **Ongoing efforts and visibility**
    Continuous efforts are necessary to demonstrate the value of initiatives and increase awareness about their impact, especially within the pharmaceutical industry. Sharing success stories is vital to drive further change.

Regarding point b)

The conversation highlights the importance of fostering trust in clinical trials, emphasizing its role as a cornerstone for patient engagement and retention. Trust is seen as essential not only between patients and institutions but also internally within organizations and across stakeholders.

Key insights include

1. **Transversal role of trust professionals**.
   This proposed role spans multiple clinical trials within an institution, acting independently of specific sponsors to avoid conflicts of interest and ensure patient-centric care. It helps align patients with appropriate trials and addresses barriers to participation, including misunderstandings or logistical challenges.
2. **Collaboration across stakeholders**
   The role must integrate seamlessly with existing structures to enhance, not complicate, processes.
3. **Sustainability and funding**
   Sustainability is a recurring concern. The participants suggest embedding funding into

clinical trial budgets or leveraging collaborative models where multiple sponsors contribute to overhead costs. This ensures the role can be institutionalized rather than relying on short-term grants or "soft money."

4. **Impact on equity and access**
   The initiative is seen to address inequities in research participation, particularly in underrepresented communities.
5. **Need for clear definitions**
   To ensure success, the responsibilities of this role must be clearly defined and differentiated from other positions like study coordinators or navigators.

2. Delphi consultation on Secondary Use of Clinical Trial Data

As for the patients and clinicians.

5.4 Group 4. Healthcare actors on a broader spectrum

This group of various stakeholders is 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.

These stakeholders are continuously consulted also through a series of external events in which the consortium participates or organizes. In the last 3 years, the project has been presented at more than 30 international, national and local events (congresses, conferences, roundtables, training courses, panel sections, etc.).

Some initiatives included:

- the 14th International Congress on Human Genetics in Cape Town where the development of guidelines for the return of clinical trial data has been discussed and WP3 representative introduced the FACILITATE ethical framework and the role of patients, industry, researchers, and other stakeholders in developing it.
- An event dedicated to FACILITATE project in Portugal, launched from EUPATI for expert patients.
- An online event realized by ACN in Italy for members of civic associations to share the news of the FACILITATE work
- Other initiatives included Patients as Partners and the TransCelerate Data Return Initiatives (various workshops), as well as the Harvard Multi-Regional Clinical Trials Center (MRCT) Return of Individual Trial Results Initiative.
- Additionally, FACILITATE participated, among the others, in the DIA meeting 2024 and in the SCOPE Summit (more details about external event in Chapter 5).

Figure 2: Events with healthcare actors on a broader spectrum

5.5 Level II & Level III - Wider Stakeholder groups

Stakeholders' registration through the website

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. Once registered, each member will always be able to change his/her consent to be involved in the research activities. They regularly receive the newsletter with the project update and the invitation to events.

Let's FACILITATE Webinars

The realization of two public webinar - in April and in December 2024 - was a successful way to talk to and engage stakeholders and above all to make the topic of data return and secondary use in clinical trials better understood externally. Both webinars elicited a great interest, obtaining quite 400 registrations.

- **Let's FACILITATE Maximizing the societal benefit and lasting impact of clinical trials. Increasing stakeholder engagement and empowering participants to FACILITATE the effective return of clinical trial data - 19 April 2024**

  This first webinar saw the active participation of the project stakeholders themselves, who told in a roundtable why they thought facilitating was important and how it would impact on their lives and/or work activities, giving concrete examples. Alongside patient testimonials, we heard from clinicians, representatives from companies, and regulatory bodies (**Figure 3**).

Figure 3. First Let's FACILITATE public webinar on 19 April 2024

This varied panel ensured a comprehensive discussion that reflects the project's multidimensional impact and fosters collaboration among stakeholders. An instant survey at the end of the event revealed that 46% had significantly increased their knowledge of the topic (and 35% had moderately increased) so it was a success given the educational objective we had set ourselves (**Figure 4**). The webinar recording can be accessed on our website.

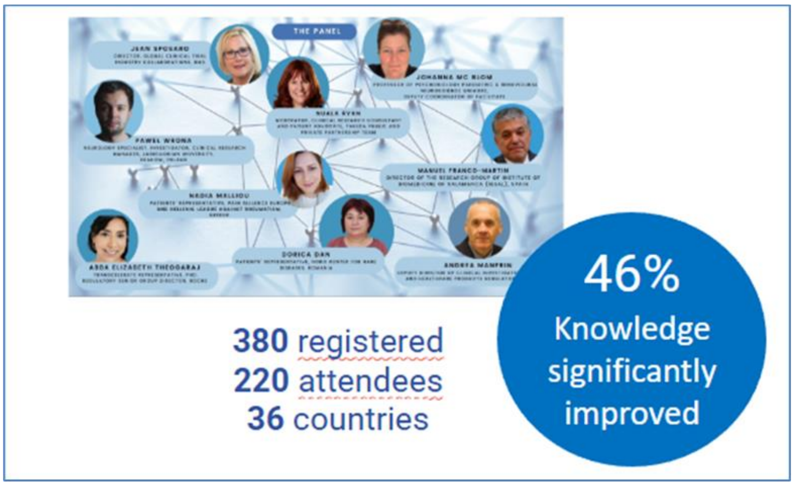


Figure 4. FACILITATE stakeholders first 2024 public webinar

Prior to the event, a campaign was run on FACILITATE's social media that spread the views of stakeholders, who were involved as speakers, on the topic of data return by capturing attention on the topic and inviting people to register for the webinar and the project's stakeholder pool (**Figure 5**).

This visionary project is crafting a ***participant-centric ecosystem*** *that respects, protects, and empowers patients by returning their data. It's about building bridges where walls once stood,* ***ensuring data flows securely to benefit all.***

Johanna MC Blom

Professor of Psychobiology Paediatric and Behavioural Neuroscience UNIMORE, Deputy Coordinator of FACILITATE

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

Sharing data with the beneficiaries of the clinical trial is a way to ***empower them*** *and to improve health equity, helping patients* ***better understand their health status after participating in clinical research.***

Dorica Dan

Patients' representative, NoRo Center for Rare Diseases, Romania

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

What is relevant to patients' participation in clinical trials is ***health and digital literacy****, given that patients might not be knowledgeable enough regarding what's explained and or discussed when consent forms are signed.*

Nadia Malliou

Patients' representative, Pain Alliance Europe and Hellenic League Against Rheumatism, Greece

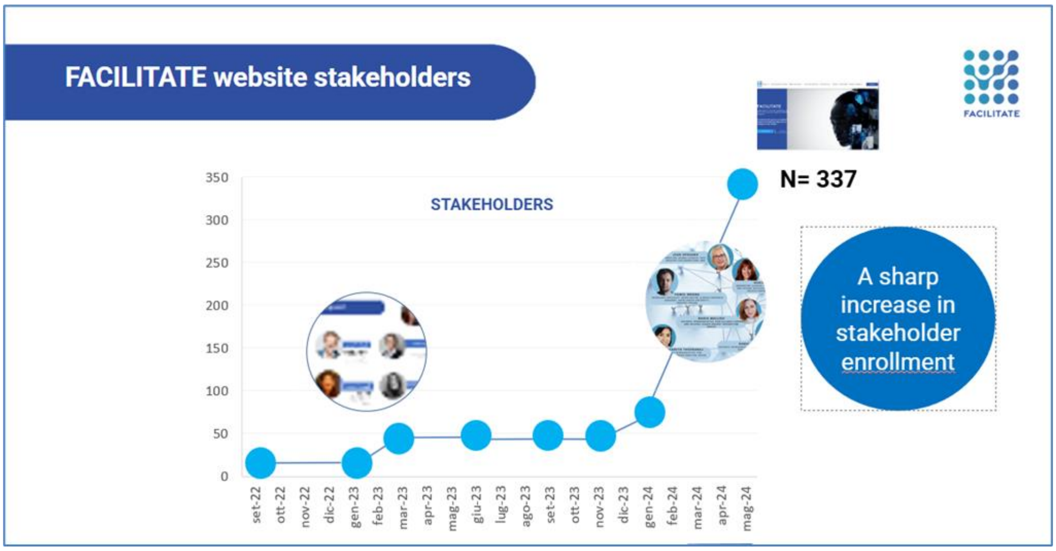
Through global cross-industry collaboration, we are partnering to optimize existing frameworks to identify quality, risk-based, ethical options for ***how, when and what types of individual health data*** *generated by study participants may be returned.*

Jean Sposaro

Director, Global Clinical Trial Industry Collaborations, BMS

Figure 5. Some speakers' statements for the social media campaign

The curve of stakeholders registered via the web, and therefore interested in receiving updates on the project, has soared, thanks also to the publicising and implementation of the webinars. After this first 2024 webinar we reached 337 stakeholders registered by the website (**Figure 6**).



FACILITATE website stakeholders

N= 337

A sharp increase in stakeholder enrollment

Figure 6. FACILITATE stakeholders register via website in May 2024

- **Let's FACILITATE Understanding the Secondary Use of Clinical Trial Data: perspectives from patients, clinicians, industry, and regulators.**

The second webinar has been realized next 11 of December 2024, with 341 registered participants and 130 attendees from 28 European and extra-European countries. Again, it was a roundtable open at the discussion with the public, with the aim of broadening knowledge on facilitation work but also on the meaning and importance of the secondary use of data.

The first panellist, a Professor of Pharmacology at the University of Modena and Reggio Emilia, Former Director General of AIFA, and member of the CHMP of the European Medicines Agency (EMA) shared his unique perspective on the potential and challenges of secondary data use. The CEO of the Clinical Research Data Sharing Alliance, gained insights into how clinical trial data can be repurposed to advance medical research, improve patient care, and inform evidence-based decision-making. We heard from 2 patient advocates, the Director of ALAN Maladies Rares Luxembourg sharing his unique perspective on the secondary use of clinical trial data and its value for patients; the co-founder, and board member of Sjögren Europe (Portugal), brought invaluable insights from her experience as a patient and advocate, making her a vital voice in our discussion. We brought the perspective of 2 clinician into the conversation with, for example, the director of the Research Group of Institute of Biomedicine of Salamanca (IBSAL), Spain. He offered insights on the opportunities and complexities around using clinical trial data beyond its original purpose, helping us understand the clinical impact this approach can bring (**Figure 7**).


Let's FACILITATE Public Webinar

Understanding the secondary use of clinical trial data

11 December, 2024
2:30 PM - 4 PM

http://facilitate-project.eu

SPEAKERS

JEAN SPOSARO
DIRECTOR, GLOBAL CLINICAL TRIAL INDUSTRY COLLABORATIONS, BMS

JOHANNA MC BLOM
PROFESSOR OF PSYCHOBIOLOGY PAEDIATRIC & BEHAVIOURAL NEUROSCIENCE UNIMORE, DEPUTY COORDINATOR OF FACILITATE

NUALA RYAN
MODERATOR, CLINICAL RESEARCH CONSULTANT AND PATIENT ADVOCATE, TAKEDA

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LUCA PANI
PROFESSOR OF PHARMACOLOGY UNIMORE, FORMER GENERAL DIRECTOR OF AIFA AND MEMBER OF THE CHMP OF THE EUROPEAN MEDICINES AGENCY (EMA)

AARON MANN
CHIEF EXECUTIVE OFFICER, CLINICAL RESEARCH DATA SHARING ALLIANCE, UNITED STATES

REBECCA SUDLOW
DATA PRIVACY AND SHARING ENABLING PLATFORM LEADER, ROCHE UK

MANUEL FRANCO-MARTIN
DIRECTOR OF THE RESEARCH GROUP OF INSTITUTE OF BIOMEDICINE OF SALAMANCA (IBSAL), SPAIN

ANA VIEIRA
PATIENT, SJÖGREN EUROPE CO-FOUNDER & BOARD MEMBER, PORTUGAL

DANIEL THEISEN
PATIENTS' REPRESENTATIVE, DIRECTOR OF ALAN – MALADIES RARES LUXEMBOURG

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

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Figure 7. Second Let's FACILITATE public webinar on 11 December 2024

During the webinar, space was left for direct questions from participants to the speakers, who showed a broad interest in the topics discussed. The webinar recording can be accessed

Concerning stakeholders' involvement, now - December 2024 - we have a total of **410 stakeholders enrolled through the website**, which is a great substantial increase compared to 2023 (and May 2024). We expect a further increase in the coming period because of the webinar. The composition of our broader list of stakeholders, is diverse and includes representatives of: health technology assessment (HTA) bodies, patients' associations, individual patients, academic researchers and general researchers, software developers, European umbrella associations related to health, caregivers/relatives, educational and advocacy actors, pharma/biotech company, clinical research center, contract research organizations (CRO) representative, ethical body, regulatory expert, EU institution, health research authority, public involvement manager etc.

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, discussions at conferences and through publications about the project, as better described in Chapter 5.

6. Stakeholder Discussion/engagement across WPs in 2024

The different WPs carried out various stakeholder engagement activities closely related to their deliverables. Here are the main activities divided by WP.

6.1 WP2 Legal and Data Privacy framework

WP2 conducted a second online consultation with four EDC(B) members on November 18, 2024, to gather their feedback on the development of the guidelines for ICF and privacy notice for RoIPD (D2.4). The discussion focused on the legal basis for RoIPD, the draft content of the ICF and privacy notice, and additional questions regarding the FACILITATE legal and ethical framework. WP2 also held a meeting with the Irish DPC on November 23, 2024, to further validate the proposed guidelines. The Irish DPC confirmed the suitability of using consent as the lawful basis for processing personal and the importance of having a distinct ICF and consent process to ensure that RoIPD is clearly separate from the clinical trial itself. As the outcomes reported in D2.7, both two consultations have provided valuable feedback on the work in progress of WP2 regarding RoIPD.

In the upcoming year, WP2 does not foresee any other engagement activities with external stakeholders apart from being informed by the FACILITATE stakeholder groups.

6.2 WP3 Ethics, standardization, and regulatory framework

Informative and engagement activities have been conducted after the exploratory survey on patient’s perception and trust about Return of data (ROD) for clinical trial data (in collaboration with WP6). Specifically, as detailed in chapter 4, a series of stakeholder consultations have been conducted over the months of November (with DAG+ and clinicians) and of December 5th (with pharmaceutical companies). Based on the results of the survey and of these discussions, a paper is currently under development.

A second batch of activities refers to D3.3 Ethical standards and guidelines No. 1: Return of individual participants’ data, and the D3.4 Ethical standards and guidelines No. 2, that has the overall aim to improve where possible the ethical principles and initial recommendations set out in D3.3. Both deliverables have been updated with input received from consultations in previous months and have been shared with the other working packages of FACILITATE to keep them informed and gain useful feedback.

6.3 WP4 Platform architecture design and requirements

In 2024, a few project conferences and HL7 Europe events have been attended (by ODY) to keep up to date with on-going developments and try out relevant prototypes for the FACILITATE RoIPD and SU use-cases. An important example in point was the IPS connection during the HL7 Europe WGM in Athens in January 2024, which focused on a prototype for IPS (International Patient Summary) data sharing leveraging HL7 FHIR and Smart Health Link technology.

In continuation of 2023, ODY participated in the first half of the year in the OHDSI CTWG (Clinical Trial Working Group) working on mapping CDISC SDTM data made available to this community by PHUSE and C-Path.

Throughout the year, WP2 connected with several XpanDH, Xt-EHR and xShare project events and its participants working on the European EHRxF (European Electronic Health Record Exchange Format).

6.4 WP5 Interoperability and standardization stakeholders’ engagement

In 2024, a few project conferences and HL7 Europe events have been attended to keep up to date with on-going developments and opportunities for the FACILITATE RoIPD and, initially, SU use-cases. In the context of WP5, events with interoperability experts and SDOs (Standards Developing Organizations) relevant to FACILITATE were:

- the Athens Digital Health Week 15-18 January 2024, including the HL7 Europe WGM, EuroVulcan2,
- and the FHIR Marathon, including connection sessions around the IPS (International Patient Summary).

This event also hosted an X-share event which explained the effort around the Yellow Button

(download functionality of EHR data for patients, still relevant to FACILITATE) and work planned around the IPS-R (Research) specification (relevant to the SU use-case).
Throughout the year, ODY has engaged on-and-off in conversations with interoperability experts and SDOs like CEN/TC 251 Health Informatics, CDISC, and the Pistoia Alliance with specific questions on the status and expectations for Clinical Trials and Life Sciences research or EHDS developments.

7. Communication and dissemination strategy

As previously described in more detail in deliverable D6.5, to provide a comprehensive communication and dissemination plan for 2024, different consultations inside the consortium were carried out at the end of 2023.

1. a dedicated workshop supervised by WP6 had been organized at the 2nd General Assembly (GA) held in Bordeaux, on 14-15 December 2023, with the aim of enhancing consortium involvement in FACILITATE dissemination activities. The workshop discussion suggested the need for:
    - improving the consortium's internal communication, with the addition of tools to deepen the topics covered in FACILITATE
    - intensifying stakeholders' outreach on the website and social media through user-friendly and multilingual tools by target audience (4 groups of stakeholders: patient, clinician, pharma, regulators; tools: publications in plain language, infographics, questions & answers, factsheets, glossary, etc.)
    - promoting training for stakeholders on the topics covered in FACILITATE, particularly those related to clinical trials, types of data, return of individual data to participants, secondary use of data, informed consent, etc.) with dedicated webinars, videos, and podcasts.
    - continuing updating the website with news, events, animated informational videos about the project, short articles in lay language, newsletters, etc.
2. In December 2023, an online survey for Consortium members had been implemented with the purpose to outline a communication strategy from legal, ethical, technological, and stakeholder engagement perspectives, fostering FACILITATE communication for 2024.The survey's analysis proposed different actions to enhance stakeholders' engagement and communication. The main suggestions included:
    - The proposal of new public general webinars to update on main topics related to return of CT data and secondary use with stakeholders' voice
    - The organization of meetings/consultations for the different groups of stakeholders (patients, clinicians, pharma, and regulators).
    - The definition of topics of interest to be explored for targeted audience of stakeholders in plain language and translated into the main European languages.

    - The participation in training courses and meetings for general stakeholders, external to the 4 groups (for instance, EU patients' rights day, MRCT webinars, PFMD events, TransCelerate initiatives, PEOF conference, etc.).
    - Planning FACILITATE achievements' presentation in the next international conferences.
    - Publishing scientific articles on peer reviewed journals, and multilingual articles in plain language about clinical trial data sharing and related topics on FACILTATE website.
3. Finally, the evaluations of the effectiveness of the activities carried out during the previous year that emerged from the monthly meetings of the WP6 working group were considered, with the proposals of new tools for stakeholders' involvement. This internal WP6 evaluation and the analysis of the outcomes in terms of engagement and empowerment of participants in clinical trials (CT) highlighted the need to strengthen some of the activities already underway and to implement new ones. In particular, the need was highlighted to:
    - enhance the involvement of stakeholders, particularly CT participants, on the issues of responsible data sharing, to improve qualitative and quantitative analysis on the needs and expectations related to the return of CT individual data and the secondary use of CT datasets.
    - further increase dissemination of project results through publication of scientific articles in peer reviewed journals and participation in local, national, and international public events dedicated to patient-centeredness in clinical research.
    - facilitate patient access to responsible CT data sharing topics through the FACILITATE website, with tools in plain language and translated into major European languages (from English to Italian, French, Spanish, German, Serbian, Dutch, etc).

In the light of the overall considerations, a communication and dissemination strategy for 2024 had been developed (those identified by the red star sticker are the new activities proposed for 2024) (**Figure 8, Table 1)**.

7.1. Website restyling and updating

At its launch, the FACILITATE website was designed with a static format, with information content on the project, its objectives, phases, mission, partners, and stakeholders' typology, with a special focus on the voice of the patient, which had a dedicated page.

Starting in 2023, an initial reorganization of the Home page and the News and Events page was carried out, to highlight the new tools and the latest updates of the project and to dedicate

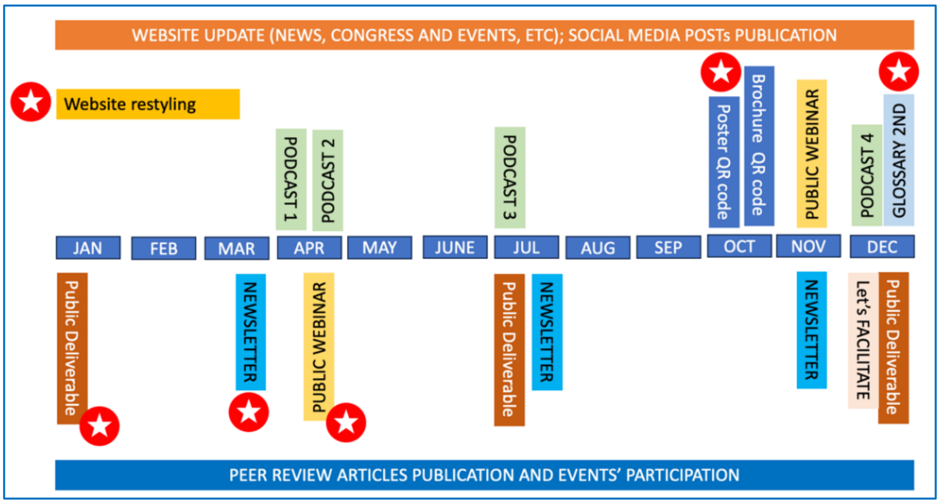


Figure 8. 2024 Communication and Dissemination Plan: timeline of main activities

Activities already underway

- Website updating
- Social media

New activities planned for 2024

- Website restyling
- Public Deliverables
- Publications on peer reviewed journals
- Glossary for patient (second part)
- Poster with QR code
- News
- Newsletters (brief and interactive version)
- Events
- Podcasts
- Public Webinars
- Let's FACILITATE report (ex-Newsletter long version)

Internal Communication

- Consortium Newsletter
- Publication Corner

Table 1. List of Communication and dissemination activities planned for 2024

its own section to news, newsletters, meetings, and events etc., to be updated regularly. To make people more aware of the impact of FACILITATE on health and research, to increase their knowledge about the world of clinical trials and data sharing, and to let them know the exact meaning of project-related terms we needed to provide patients with additional tools and make the website more easily accessible. Therefore, at the beginning of 2024, we modified and/or added more sections:

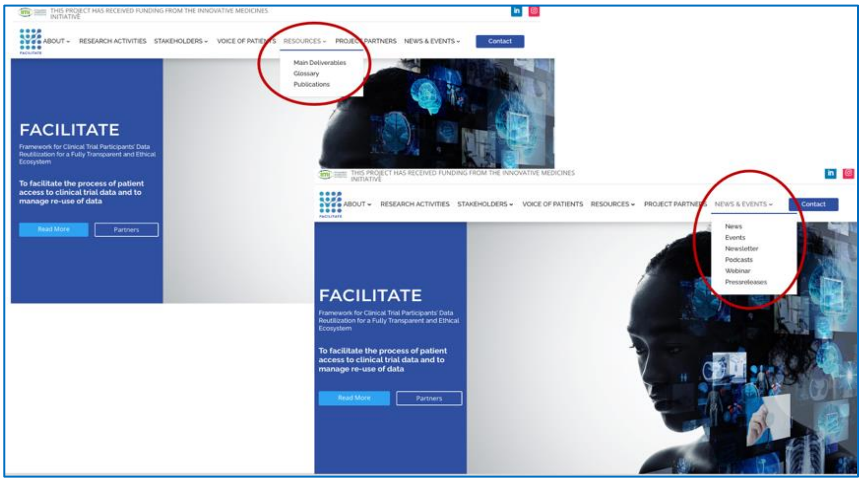
- the Home page was made dynamic, with highlights on the latest news (news, webinars, publications, glossary, podcasts, and newsletters) and content structured in such a way as to be more easily accessible by a wide audience (**Figure 9**).

Figure 9. Homepage restyling

- the Resources page, leading to the main deliverables, the publications, the glossary, and some new multilingual tools for patients and clinicians (posters, brochures, and flyers).
- the News and Events page, where all materials concerning communication to

stakeholders are regularly published: news, events, webinars, podcasts, newsletters, and press releases, all in plain language for a general audience and regularly updated (**Figure 10**).

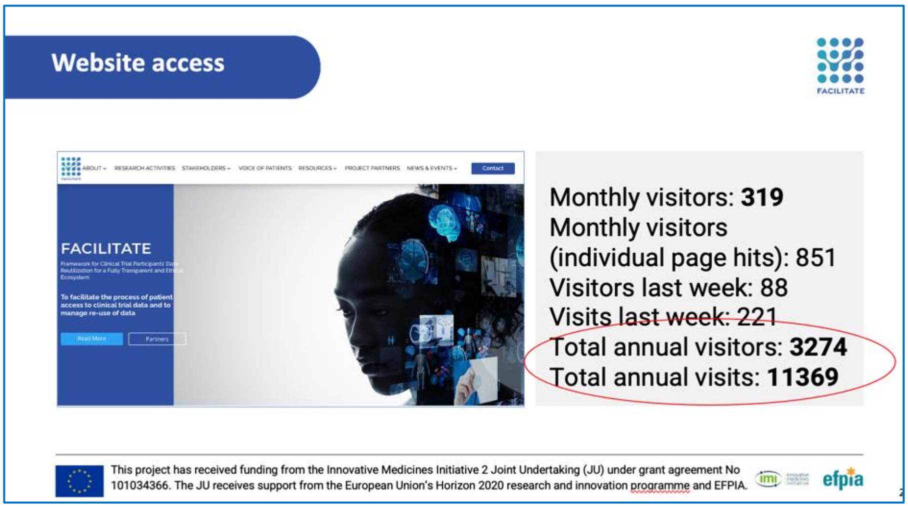
Some statistics was regularly carried out to verify the number of stakeholder accesses to the website. Currently, the number of annual accesses exceeds 11,000 (**Figure 11**).



Framework for Clinical Trial Participants' Data Reutilization for a Fully Transparent and Ethical Ecosystem

To facilitate the process of patient access to clinical trial data and to manage re-use of data

Figure 10. Resources and News and Events Content reorganization



Website access

Monthly visitors: **319**
Monthly visitors (individual page hits): 851
Visitors last week: 88
Visits last week: 221
Total annual visitors: **3274**
Total annual visits: **11369**

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Figure 11. Statistics of website access

7.2 Resources section

The Resources section leads to the main deliverables, the publications, the second part of the glossary. In January 2025 it will include some new multilingual tools for patients and clinicians (see below multilingual posters, flyers, and brochures).

7.2.1 Main Deliverables

The Main Deliverables page contains all the public FACILITATE deliverables approved by IHI so far (**Figure 12**)

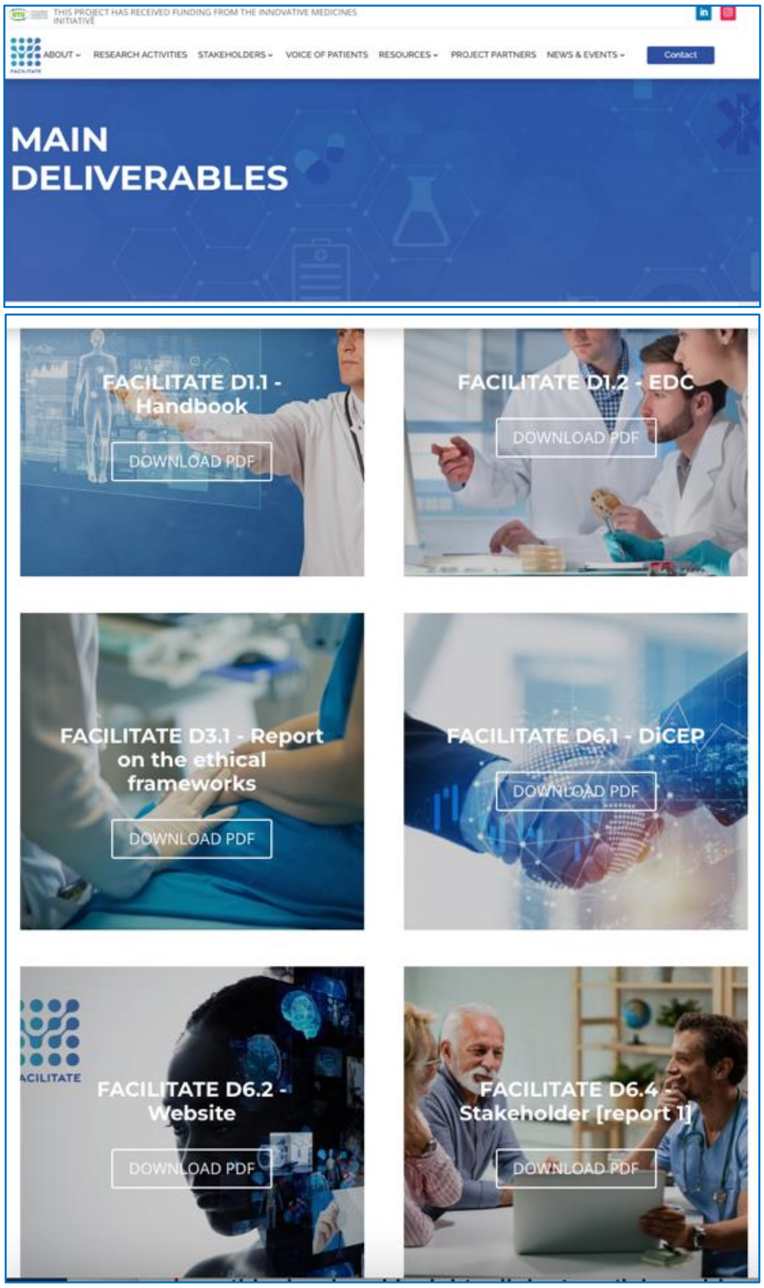


Figure 12. Main Deliverables page

7.2.2 Glossary (second part)

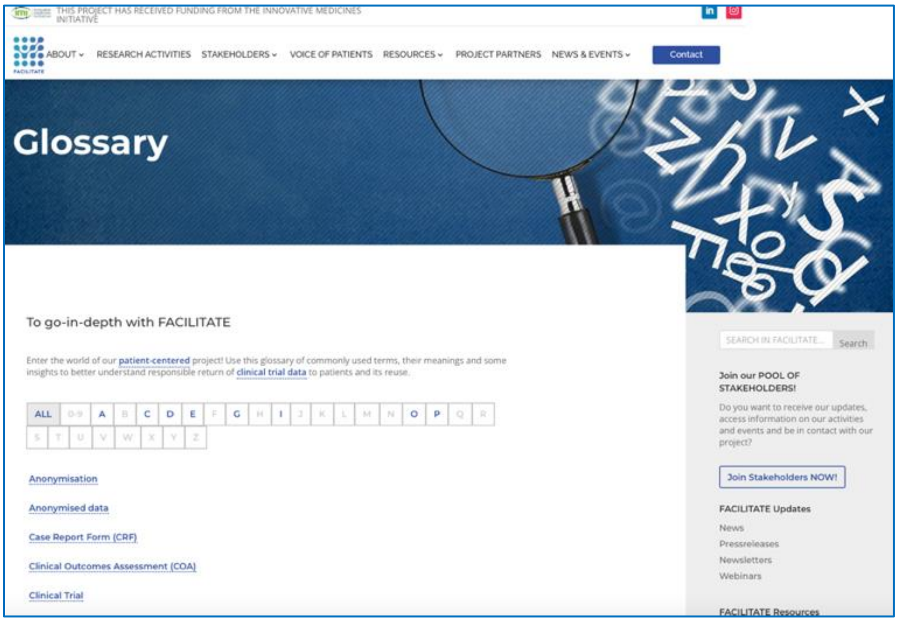
Although there are several plain language glossaries dedicated to clinical trials (a relevant example being the MRCT glossary that currently has done a huge amount of work collaborating with National Cancer Institute Thesaurus NCI thesaurus), we wanted to delve into the not-so-easy-to-understand terms that most recur on our website that are related to clinical trial data return to participants, secondary use, CT data sharing and patient-centeredness. Thus, a Glossary for patients (**Figure 13**) was launched last year with the first 20 terms, structured like described below (definition of the term with its source, infographics, synonyms, more glossaries (More resources), in-depth articles and useful tools (to go in depth).

A second part of the glossary has been realized in 2024 by a collaborative working group including UNIMORE, Cittadinanzattiva (ACN) and EUPATI Italy. This new section - to be published at the beginning of 2025 – will contain **35 new key terms** concerning clinical trial data sharing and reuse and patient-centeredness, which will be added to the other 20 terms already published on the website. The work followed the procedure outlined below:

- Selection of key terms
- Work on the selected terms, choosing the best definitions from different sources
- Approval of definitions and entire content with insights by UNIMORE/ACN/EUPATI group.
- Submission of glossary to the Communication Working Group (CommWG) for Consortium approval and integration of comments
- Submission of the final document for publication on the website (January 2025)

Among the main sources: MRCT already mentioned, the National Cancer Institute Thesaurus in addition to the glossary of CDISC, the clinical trial data standardization organization, along with other relevant institutions.

A third part with 30 more terms is planned for next year, and at the end of the project we expect to have a glossary including about 80-90 terms.



To go-in-depth with FACILITATE

Enter the world of our patient-centered project! Use this glossary of commonly used terms, their meanings and some insights to better understand responsible return of clinical trial data to patients and its reuse.

Anonymisation

Anonymised data

Case Report Form (CRF)

Clinical Outcomes Assessment (COA)

Clinical Trial

Join our POOL OF STAKEHOLDERS!

Do you want to receive our updates, access information on our activities and events and be in contact with our project?

FACILITATE Updates

News

Pressreleases

Newsletters

Webinars

FACILITATE Resources

Figure 13. Glossary on clinical trial data sharing and secondary use

7.2.3 Peer reviewed publications

The Publications page contains the peer-reviewed papers published by FACILITATE on relevant journals (6 so far and 2 ready to be submitted for publication) (**Figure 14**).

1. Staunton C et al. Ethical framework for FACILITATE: a foundation for the return of clinical trial data to participants. Front Med 2024; 11:1408600
2. Frimpong E et al. Need for Speed: Leveraging the Power of Functional Encryption for Resource-Constrained Devices Peer-reviewed Epublication, presented at the 9th International Conference on IoT, BigData and Security (IoTBDS'24)
3. Staunton C et al. Ethical and social reflections on the proposed European Health Data Space European Journal of Human Genetics. 2024;32: 498-505
4. Biasotto R et al. Public Preferences for Digital Health Data Sharing: Discrete Choice Experiment Study in 12 European Countries. J Med Internet Res 2023; 25: e4706
5. Blom JMC et al. The nexus of social alliances and diverse moral domains: a bedrock for participatory clinical research. Front Med 2023; 10:1250247
6. Mascalzoni D et al. Ten years of dynamic consent in the CHRIS study: informed consent as a dynamic process European Journal of Human Genetics. 2022; 30:1391-1397

Staunton C et al. Ethical framework for FACILITATE: a foundation for the return of clinical trial data to participants. Front Med 2024; 11:1408600

DOWNLOAD PDF

READ MORE

Frimpong E et al. Need for Speed: Leveraging the Power of Functional Encryption for Resource-Constrained Devices Peer-reviewed Epublication, presented at the 9th International Conference on IoT, BigData and Security (IoTBDS'24)

DOWNLOAD PDF

READ MORE

Staunton C et al. Ethical and social reflections on the proposed European Health Data Space European Journal of Human Genetics. 2024;32:498-505

SEARCH IN FACILITATE... Search

Join our POOL OF STAKEHOLDERS!

Do you want to receive our updates, access information on our activities and events and be in contact with our project?

Join Stakeholders NOW!

FACILITATE Updates

News
Pressreleases
Newsletters
Webinars

Figure 14. Peer-reviewed articles published on the website

7.2.4 Multilingual tools: Poster, Brochure, and Flyer

To increase stakeholders' interest, ensuring participation of all patients and caregivers and including vulnerable populations, a poster, and a flyer available in several European languages has been developed (**Figures 15, 16**). These materials feature a dynamic QR code that directs users to a brochure, which highlights the main FACILITATE topics in the corresponding language (**Figure 17**). All these information tools are designed with health literacy considerations in mind, including accessible fonts and formats to accommodate individuals with disabilities.

For participants seeking more detailed information about the project, another QR code on the information sheet links directly to the FACILITATE website, which is currently available in English. So far, 6 versions have been realized, in English, Italian, German, Spanish, French and Serbian (the layout of the latter three is in progress). As part of the pilot project, the Italian poster will be displayed in Italian at hospitals in Modena, while flyers will be distributed at pharmacies and family doctors' surgeries across the city. The QR code embedded in these materials will enable statistical analysis, offering detailed insights into the number of accesses to the three resources, along with information on locations and access times. Posters, Brochures, and Flyers will be available on the website and downloadable from January 2025.

A dedicated page entitled “Multilingual tools” in the Resources section will be set up, organized in two branches: one for the clinician and one for the patient. The first branch will contain the posters and flyers in the different languages to be displayed in the defined locations (hospitals, pharmacies, family doctors’ surgeries, etc). The second will contain the brochures available for patients to access key project information in their own language. The availability of these multilingual tools will be highlighted on the home page and through newsletters, news, and social media.

To ensure the widest possible dissemination of these multilingual tools to all stakeholders, particularly patients, an ad hoc campaign has been planned for next year with the involvement of institutions and patient associations directly or indirectly linked to the project (see 2025 Communication and dissemination plan).

FACILITATE
To be a protagonist in clinical research

Have you participated in a clinical trial and would like to know how the research data are managed?

A European initiative has been launched to facilitate participants' access to the clinical trial data collected during the study

Would you like to know more about how this project works and how you can be involved? Scan the QR code to enter the world of FACILITATE

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

FACILITATE
Sind Sie Protagonisten einer klinischen Studie?

Haben Sie an einer klinischen Studie teilgenommen und möchten wissen, wie die Forschungsdaten verwaltet werden?

Es wurde eine europäische Initiative gestartet, die den Teilnehmern den Zugang zu den im Rahmen von Forschungsarbeiten erhobenen Daten aus klinischen Studien erleichtern soll

Möchten Sie mehr darüber erfahren, wie dieses Projekt funktioniert und wie Sie sich daran beteiligen können? Scannen Sie den QR-Code und tauchen Sie in die Welt von FACILITATE ein

FACILITATE
E sei protagonista della ricerca clinica

Hai partecipato a uno studio clinico e vorresti sapere come vengono gestiti i dati della ricerca?

È stata lanciata un'iniziativa a livello Europeo per fare in modo che i partecipanti agli studi clinici possano accedere facilmente ai dati raccolti durante lo studio

Per sapere come funziona questo progetto e come potrebbe coinvolgerti, scansiona il codice QR ed entra nel mondo di FACILITATE

Figure 15. Poster with QR code in English (A), German (B), Italian (C)

FACILITATE

FACILITATE
To be a protagonist in clinical research

Have you participated in a clinical trial and would like to know how the research data are managed?

A European initiative has been launched to facilitate participants' access to the clinical trial data collected during the study

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WAS IST FACILITATE

FACILITATE ist ein vierjähriges europäisches Projekt, das sich mit der **verantwortungsvollen Nutzung von klinischen Forschungsdaten** befasst.

Ziel dieses **patientenorientierten** Projekts ist es, sicherzustellen, dass alle Bürger, die an einer klinischen Forschungsstudie teilnehmen, Zugang zu ihren individuellen Daten haben, die während der Studie gesammelt wurden.

Die Teilnehmer können so ihre Daten an ihren behandelnden Arzt und an andere Angehörigen der Gesundheitsberufe weitergeben.

Diese Möglichkeit stärkt die **Autonomie** des Einzelnen und erleichtert den Austausch von medizinischen Entscheidungen.

FACILITATE legt fest, **wann, in welchem Format und über welche Kanäle** Daten aus klinischer Forschung, die in Europa durchgeführt wurde, an die Teilnehmer zurückgegeben werden können.

DIE VORTEILE DER DATENRÜCKGABE

Für die Patienten
Verringerung von doppelten Untersuchungen oder Screening-Verfahren und Förderung gemeinsamer medizinischer Entscheidungen

Für Angehörige der Gesundheitsberufe
Förderung der medizinischen Entscheidungsfindung und Einsparung unnötiger Kosten durch erhöhten Zeitaufwand der Arzt-Patienten-Beziehung

Für die Aufsichtsbehörden
Eröffnet neue Möglichkeiten für die ethische (Wieder-)Verwendung von Daten und schafft Transparenz zum Nutzen der Gesellschaft

Für klinische Forscher in der Europäischen Union
Ermöglicht neue Wege für Sondierungsstudien, die zur Entwicklung innovativer therapeutischer Ansätze führen können

Für die pharmazeutische Industrie
Verbesserung der künftigen Forschung und Vereinfachung des Rekrutueringsprozesses für motiviertere Teilnehmer an klinischen Studien

Für die Gesellschaft
Erhöht das Vertrauen der Patienten und stärkt die Überwachung der (Wieder-)Verwendung von klinischen Daten

A

FACILITATE

FACILITATE
Sind Sie Protagonisten einer klinischen Studie?

Haben Sie an einer klinischen Studie teilgenommen und möchten wissen, wie die Forschungsdaten verwaltet werden?

Es wurde eine europäische Initiative gestartet, die den Teilnehmern den Zugang zu den im Rahmen von Forschungsarbeiten erhobenen Daten aus klinischen Studien erleichtern soll

Möchten Sie mehr darüber erfahren, wie dieses Projekt funktioniert und wie Sie sich daran beteiligen können? Scannen Sie den QR-Code und tauchen Sie in die Welt von FACILITATE ein

2

WHAT IS FACILITATE?

FACILITATE is a four-year European project focussing on the **responsible use of clinical research data**.

The aim of this patient-centred project is to ensure that all citizens participating in a clinical trial have access to their **individual data** collected during the study.

Participants can thus share their data with their treating physician and other healthcare professionals.

This possibility strengthens the **autonomy** of the individual and facilitates the sharing of medical decisions.

FACILITATE defines **which, when, in what manner and format, and through which channels** data from clinical research conducted in Europe can be returned to participants

THE BENEFITS OF RETURNING DATA

For patients
Reduces duplication of examinations or screening procedures and promotes shared medical decision-making

For health care providers
Encourages medical decision-making and saves unnecessary costs by increasing the time spent in the doctor-patient relationship

For regulatory authorities
Opens new possibilities for ethical (re)use of data, creating transparency for the benefit of society

For clinical researchers in the European Union
Enables new avenue for exploratory studies that can lead to the development of innovative therapeutic approaches

For the pharmaceutical industry
Improves future research and simplifies the recruitment process for more motivated clinical trial participants

For society
Increases patient confidence and strengthens monitoring of (re)use of clinical data

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

B

FACILITATE

FACILITATE
E sei protagonista della ricerca clinica

Hai partecipato a uno studio clinico e vorresti sapere come vengono gestiti i dati della ricerca?

È stata lanciata un'iniziativa a livello Europeo per fare in modo che i partecipanti agli studi clinici possano accedere facilmente ai dati raccolti durante lo studio

Per sapere come funziona questo progetto e come potrebbe coinvolgerti, scansiona il codice QR ed entra nel mondo di FACILITATE

CHE COS'È FACILITATE?

FACILITATE è un progetto Europeo quadriennale che si occupa della **condivisione responsabile dei dati della ricerca clinica.**

L'obiettivo di questo progetto - **centrato sul paziente** - è garantire a tutti i cittadini che partecipano a uno studio clinico la possibilità di accedere ai propri dati individuali raccolti durante la ricerca.

I **partecipanti** potranno così condividere i propri dati con il medico curante e con gli altri operatori sanitari.

Tale opportunità rafforza **l'autonomia** della persona e facilita la condivisione delle decisioni mediche.

FACILITATE definisce **quando, quali, in quale modalità e formato e attraverso quali canali** i dati delle ricerche cliniche condotte in Europa possono essere restituiti ai partecipanti

I BENEFICI DELLA RESTITUZIONE DEI DATI

Per i pazienti
Riduce la duplicazioni di esami o procedure di screening e favorisce la condivisione delle decisioni mediche

Per gli operatori sanitari
Incoraggia il processo decisionale medico e risparmia costi inutili, aumentando il tempo da dedicare alla relazione medico-paziente

Per le autorità regolatorie
Apre nuove possibilità di (ri)utilizzo etico dei dati, creando trasparenza a beneficio della società

Per i ricercatori clinici dell'Unione Europea
Consente di trovare nuove opportunità per studi eplorativi che potrebbero portare allo sviluppo di approcci terapeutici innovativi

Per l'industria farmaceutica
Migliora la ricerca futura e semplifica il processo di coinvolgimento dei partecipanti agli studi clinici, grazie alla loro maggiore motivazione

Per la società
Aumenta la fiducia dei pazienti nella ricerca clinica e rafforza la sorveglianza sul (ri)utilizzo dei dati clinici

C

Figure 16. Flyer with QR code in German (A), English (B), Italian (C)

FACILITATE

To be a protagonist in clinical research

FACILITATE

2

WHAT IS FACILITATE?

FACILITATE is a four-year European project focussing on the responsible use of clinical research data.
The aim of this patient-centred project is to ensure that all citizens participating in a clinical trial have access to their individual data collected during the study.
Participants can thus share their data with their treating physician and other healthcare professionals.
This possibility strengthens the autonomy of the individual and facilitates the sharing of medical decisions.

The right to access is a guarantee to obtain one's own data at one's own discretion, whenever possible, without compromising the results of the study

WHY FACILITATE? WHY NOW?

In recent years, the relationship between citizens and clinical research in Western countries has changed dramatically.
Patients are now more aware of the value of their data.
Moreover, the entire scientific community realized that Europe can only be competitive in medical research if the information accumulated over the course of studies can be returned and shared for the benefit of those who provided them.
The availability of digital technologies and artificial intelligence for data processing is a further incentive for responsible data sharing that ensures that increasingly equitable and inclusive health for citizens.

3

TODAY, WITHOUT FACILITATE

According to current European legislation, once a study has been completed and the data have been analyzed, all information collected during the trial must be anonymized and deposited in closed archives.
In addition, according to the regulations, within one year of the closure of the study, people who participated in the study might receive a summary of the overall results (lay summary), explaining in simple and understandable language the characteristics of the study, its objective, rationale, demographics, and efficacy and safety results.

TOMORROW, WITH FACILITATE

Clinical trial participants - patients and healthy volunteers - not only will receive the lay summary but can also access their own personal and health data if they wish and if this does not compromise the results of the clinical trial. Moreover, ey will be able to freely dispose of these data in all health-related decisions.

FACILITATE defines which, when, in what manner and format, and through which channels data from clinical research conducted in Europe can be returned to pa cipants

4

THE PATIENT'S VOICE

A survey conducted in 2023 by the Center for Information and Study on Clinical Research Participation (CISCRP), in which 11,793 people took part, revealed a strong need for more transparency. Participants requested to receive their individual data so that they can share them with their primary care physician or other health care providers.
In addition, the importance of communicating the clinical trial results to participants in simple and understandable language became clear.

"Sharing data with clinical trial participants strengthens their role and autonomy, improves equity, and helps patients better understand their own health status"
Dorica Dan, President of Romanian Patients' Associations RPWA e RONARD

Do you agree that...

89% ...it is important that all clinical trial volunteers receive individual medical data obtained from the research in which they participated so that they can share it with their treating physician and other health care professionals

89% ...it is important that all clinical trial volunteers receive the overall results of the clinical research in which they participated in simple, easy-to-understand language

What information would you like to receive?

67% My individual data obtained from the clinical study (procedures and test results)

65% A summary of the study results in plain language

58% Whether I received the drug or a placebo (substance with the same appearance as the drug, but containing no active ingredients)

CISCRP: Perception and Insights Study 2023. Global trends in public and patient attitudes about, and experienced with, clinical research

5

AN ACTIVE ROLE IN RESEARCH

The return of data gives citizens new rights and responsibilities and makes them active participants in the development of new therapeutic approaches. Reciprocity and trust between the actors involved in the different phases of the clinical trial are the key factors to achieve this.

"Promoting social alliance among people involved in clinical research means creating a shared sense of purpose, trust and collaboration, in which everyone feels valued and respected."
Prof. Johanna C. Blom, FACILITATE Coordinator

THE BENEFITS OF RETURNING DATA

For patients
Reduces duplication of examinations or screening procedures and promotes shared medical decision-making
For health care providers
Encourages medical decision-making and saves unnecessary costs by increasing the time spent in the doctor-patient relationship
For regulatory authorities
Opens new possibilities for ethical (re)use of data, creating transparency for the benefit of society
For clinical researchers in the European Union
Enables new avenue for exploratory studies that can lead to the development of innovative therapeutic approaches
For the pharmaceutical industry
Improves future research and simplifies the recruitment process for more motivated clinical trial participants
For society
Increases patient confidence and strengthens monitoring of (re)use of clinical data

6

THE ETHICAL PRINCIPLES

FACILITATE's first step was to define an ethical framework aligned with the needs of the individuals and compliant with the European Data Protection Regulation (GDPR). This framework provides clear rules for all actors involved in data management.
Listening to patients' needs and expectations was a key element in defining the ethical principles that govern the return of data. These include respect for the individuals and the community, transparency, autonomy, and inclusiveness.

FACILITATE has defined a new ethical and legal framework to meet the needs of citizens and all stakeholders involved in clinical research in Europe.

THE LEGAL FRAMEWORK

In parallel to the definition of ethical principles, FACILITATE outlined the legal framework for the development of guidelines for the return of clinical trial data and their reuse in clinical research, in accordance with European legislation.

7

GLOSSARY

Anonymized
Data from which personal information has been removed and which cannot be combined with other information to re-identify the person.

Clinical study data
All data -personal, demographic, and health information - collected at the time of enrollment and during the clinical trial until its completion.

Clinical trial
Clinical trials are research studies that test medical, surgical, or behavioral intervention in people. These trials are the primary way that researchers determine if a new form of treatment or prevention, such as a new drug, diet, or medical device, is safe and effective in people.
Clinical Trial Participant
Person who voluntarily engages in a clinical trial or research project. Participants can be healthy volunteers or people with a medical condition.

Data reuse
Also known as secondary use, this refers to the use of existing clinical trial data for purposes other than those for which they were collected.

GDPR
Acronym for General Data Protection Regulation is a European Union law on the protection of data and individuals with regard to the processing of personal data and the free movement of such data.

Lay summary
Summary of the overall results of a clinical trial, explaining in simple and easily understood language the characteristics of the study, its objective, rationale, demographic data, and efficacy and safety results.

Participation Autonomy
A fundamental ethical principle in clinical trials that emphasizes the right of individuals to make informed decisions about their participation.

Patient-centered
Any process, program, or decision in which the patient plays an active role as a meaningfully involved participant. Patient-centered means doing things WITH the patient - not FOR or TO the patient.

Reciprocity
Returning a good for a good received and compensating someone or a group for losses incurred in promoting the welfare of someone else or another group.

Social alliance
Voluntary collaboration among multiple entities that pool their resources, skills, and capabilities to address complex challenges, with the same values and ethical principles and a genuine interest in people and their well-being.

8

FACILITATE

Are you a person interested in clinical research and the return of individual data? Have you already taken part in a clinical trial and would you like to contribute to the project with your suggestions?

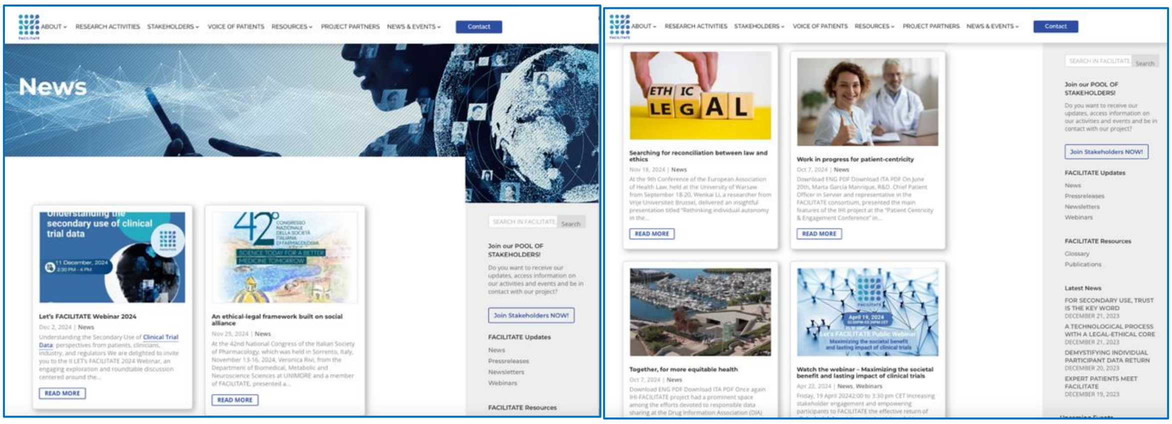
http//:facilitate-project.eu

Figure 17. English version of the Brochure with QR codes

7.3 News and Events section

7.3.1 News

The News page contains the main insights concerning FACILITATE, directly or indirectly (**Figure 18**): 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, webinars etc.



Let's FACILITATE Webinar 2024
Dec 2, 2024 | News
Understanding the Secondary Use of Clinical Trial Data: perspectives from patients, clinicians, industry, and regulators We are delighted to invite you to the II LET's FACILITATE 2024 Webinar, an engaging exploration and roundtable discussion centered around the...

An ethical-legal framework built on social alliance
Nov 25, 2024 | News
At the 42nd National Congress of the Italian Society of Pharmacology, which was held in Sorrento, Italy, November 13-16, 2024, Veronica Rivi, from the Department of Biomedical, Metabolic and Neuroscience Sciences at UNIMORE and a member of FACILITATE, presented a...

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FACILITATE Updates
News
Pressreleases
Newsletters
Webinars

FACILITATE Resources
Glossary
Publications

Searching for reconciliation between law and ethics
Nov 18, 2024 | News
At the 9th Conference of the European Association of Health Law, held at the University of Warsaw from September 18-20, Wenkai Li, a researcher from Vrije Universiteit Brussel, delivered an insightful presentation titled "Rethinking individual autonomy in the...

Work in progress for patient-centricity
Oct 7, 2024 | News
Download ENG PDF Download ITA PDF On June 20th, Marta Garcia Manrique, R&D, Chief Patient Officer in Servier and representative in the FACILITATE consortium, presented the main features of the IHI project at the "Patient Centricity & Engagement Conference" in...

Together, for more equitable health
Oct 7, 2024 | News
Download ENG PDF Download ITA PDF Once again IHI-FACILITATE project had a prominent space among the efforts devoted to responsible data sharing at the Drug Information Association (DIA)

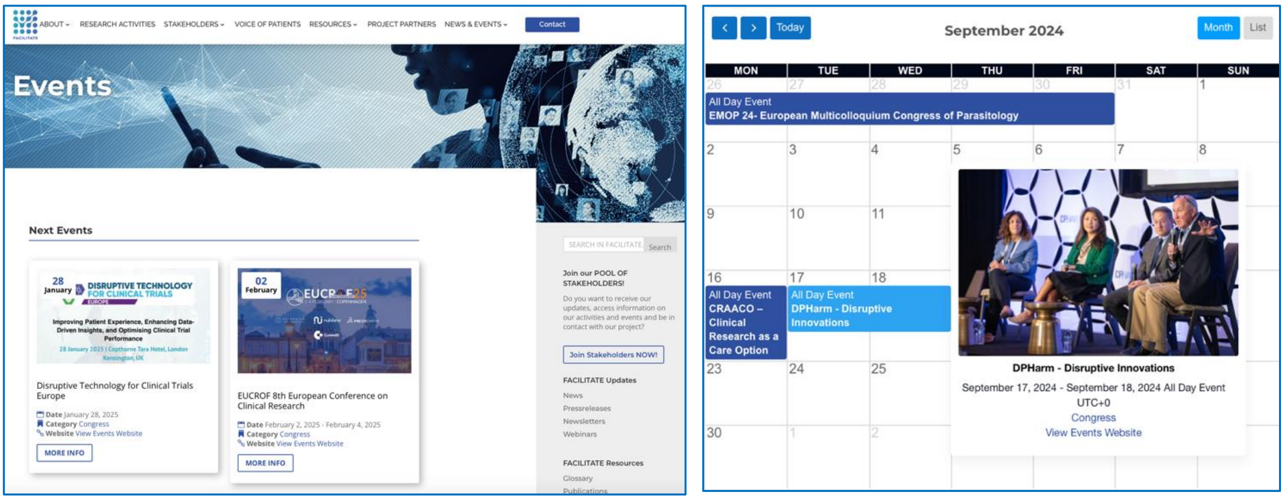
Watch the webinar – Maximizing the societal benefit and lasting impact of clinical trials
Apr 22, 2024 | News, Webinars
Friday, 19 April 20242:00 to 3:30 pm CET Increasing stakeholder engagement and empowering participants to FACILITATE the effective return of

Latest News
FOR SECONDARY USE, TRUST IS THE KEY WORD
DECEMBER 21, 2023
A TECHNOLOGICAL PROCESS WITH A LEGAL-ETHICAL CORE
DECEMBER 21, 2023
DEMYSTIFYING INDIVIDUAL PARTICIPANT DATA RETURN
DECEMBER 20, 2023
EXPERT PATIENTS MEET FACILITATE
DECEMBER 19, 2023

Figure 18. News page on the website

7.3.2 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 17**). The page is updated regularly.



Next Events

Improving Patient Experience, Enhancing Data-Driven Insights, and Optimising Clinical Trial Performance

28 January 2025 | Copthorne Tara Hotel, London Kensington, UK

Disruptive Technology for Clinical Trials Europe

Date January 28, 2025
Category Congress
Website View Events Website

EUCROF 8th European Conference on Clinical Research

Date February 2, 2025 - February 4, 2025
Category Congress
Website View Events Website

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FACILITATE Updates
News
Pressreleases
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Webinars

FACILITATE Resources
Glossary
Publications

September 2024

All Day Event
EMOP 24- European Multicolloquium Congress of Parasitology

All Day Event
CRAACO – Clinical Research as a Care Option

All Day Event
DPHarm - Disruptive Innovations

DPHarm - Disruptive Innovations
September 17, 2024 - September 18, 2024 All Day Event
UTC+0
Congress
View Events Website

Figure 19. Events page (sx) and calendar (dx) on the website

7.3.4 Meetings' and events' participation by FACILITATE members in 2024

A procedure has been put in place to facilitate the supervision of the Consortium's communication and dissemination activities, as reported in D6.5. The list below summarizes the main international events (European and non-European) in which consortium members participated as FACILITATE ambassadors.

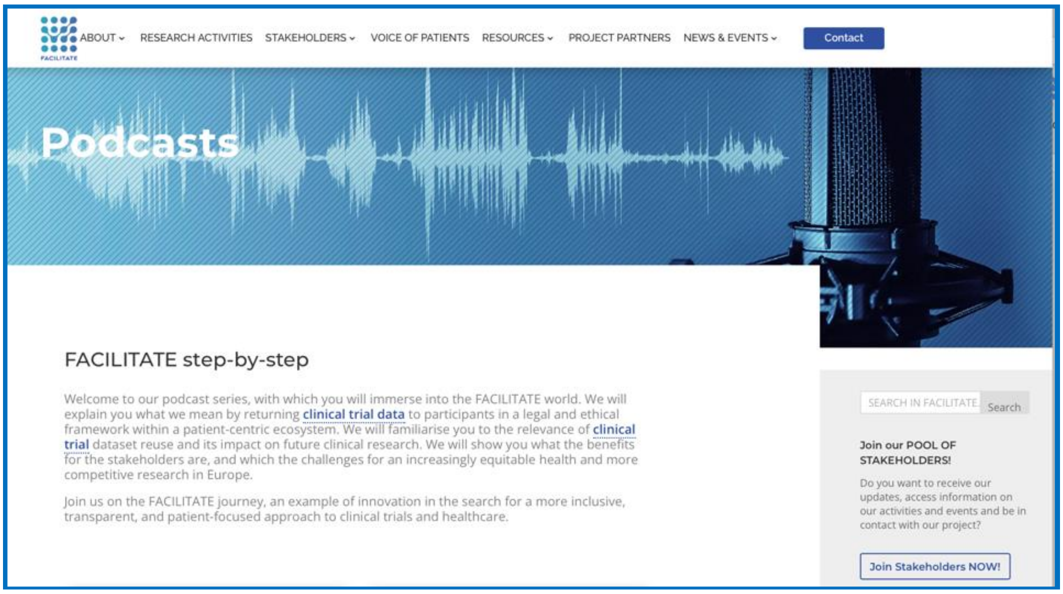
- **11 December 2024.** Let's FACILITATE online Webinar 2024 Understanding the Secondary Use of Clinical Trial Data: perspectives from patients, clinicians, industry, and regulators
- **20-21 November 2024.** The European project FACILITATE has been showcased by Nadir Ammour, co-leader of the FACILITATE project, at the 10th annual Clinical Monitoring & Patient Recruitment Retention Summit in Barcelona, with the topic: Advancing Patient Centric Clinical Trials: the case of IHI FACILITATE, returning clinical trial data to patients.
- **13-16 November 2024.** At the 42nd National Congress of the Italian Society of Pharmacology, which was held in Sorrento, Italy Veronica Rivi, from the Department of Biomedical, Metabolic and Neuroscience Sciences at UNIMORE and a member of FACILITATE, presented a poster entitled 'Embracing the healthcare digital revolution: pioneering an ethical and legal framework for clinical data return'.
- **29-30 October 2024.** Johanna Blom, UNIMORE, and Nadir Ammour, Sanofi –

FACILITATE Deputy Coordinator and Co-leader, respectively, have been invited to present the project achievements at the SCOPE Europe 2025 Summit in the multi-speaker panel: Innovation in Patient Engagement

- **18 October 2024.** Stefania Piras, EUPATI Italia, Accademia del Paziente Esperto, presented FACILITATE project at the meeting Health iconography Medical Humanities Festivals, Engagement of patients and caregivers in R&D which took plase in Alessandria, Italy. Her speech has been hosted in the Panel session “Transparency and collaboration: The Patient at the Center of Clinical Research.
- **18-20 September 2024.** At the 9th Conference of the European Association of Health Law, held at the University of Warsaw, Wenkai Li, researcher from Vrije Universiteit Brussel (VUB), delivered a presentation titled “Rethinking individual autonomy in the secondary use of health data for research: A legal and ethical analysis on informed consent”.
- **16-18 September 2024.** At the Clinical Research as A Care Option (CRAACO) Conference held in Philadelphia, Nadir Ammour, Global Lead, Clinical Innovation & External Partnerships, Sanofi and co-leader of the FACILITATE project, was the guest speaker in the panel Returning Participant's Individual Clinical trial Data.
- **20 June 2024.** Marta García Manrique, R&D. Chief Patient Officer in Servier and representative in the FACILITATE consortium, presented the main features of the IHI project at the “Patient Centricity & Engagement Conference” in London.
- **16-20 June 2024.** IHI-FACILITATE project had a prominent space among the efforts devoted to responsible data sharing at the 2024 Drug Information Association (DIA) Global Annual Meeting hosted in San Diego, with the active participation of Jean Sposaro (BMS) and David Leventhal (Pfizer).
- **11 June 2024.** Pawel Wrona, Neurology Specialist at the Jagiellonian University Krakow, Poland, participated to the 10th Conference for the International Clinical Trials Day, Warsaw
- **19 April 2024** Let’s FACILITATE Public Webinar. Increasing stakeholder engagement and empowering participants to FACILITATE the effective return of clinical trial data
- **20-22 March 2024.** The return of individual data to clinical trial participants as a means of patient empowerment was once again featured at the annual Patients as Partners in Clinical Research US Conference, which took place in Philadelphia.
- **28 March 2024.** Overview of TransCelerate’s Individual participant Data return (iPDR) Package, with the presentation of a comprehensive set of materials that provide general considerations to enable data return to clinical study participants.
- **11-12 March 202.** Pawel Wrona, Neurology Specialist at the Jagiellonian University Krakow, Poland, participated to the European Life After Stroke Forum in Dublin, Ireland

7.3.5 FACILITATE step-by-step podcasts series

Another tool developed to explain the role of FACILITATE, its impact on health and research, and the benefits to different stakeholders was a series of video podcasts entitled FACILITATE step-by-step (**Figure 20**). The first three episodes of our podcast series are available on the website in the Podcasts'page. In straightforward, easy-to-understand language, speakers explore what FACILITATE means - focusing on how clinical trial data is returned to participants in a legal, ethical, and patient-centered way within a collaborative ecosystem (**Figure 21**).



FACILITATE step-by-step

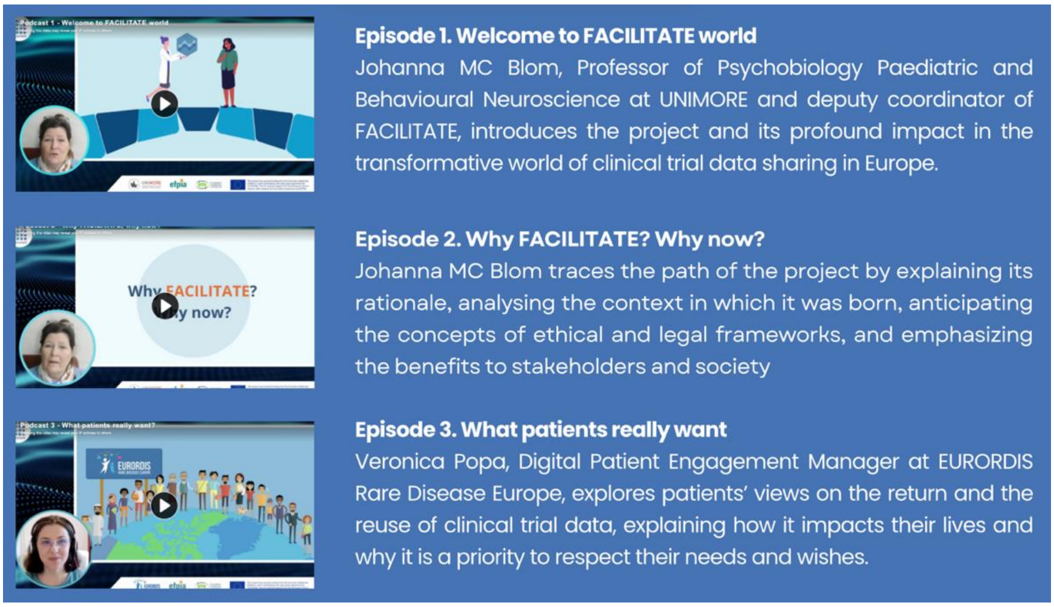
Welcome to our podcast series, with which you will immerse into the FACILITATE world. We will explain you what we mean by returning clinical trial data to participants in a legal and ethical framework within a patient-centric ecosystem. We will familiarise you to the relevance of clinical trial dataset reuse and its impact on future clinical research. We will show you what the benefits for the stakeholders are, and which the challenges for an increasingly equitable health and more competitive research in Europe.

Join us on the FACILITATE journey, an example of innovation in the search for a more inclusive, transparent, and patient-focused approach to clinical trials and healthcare.

Join our POOL OF STAKEHOLDERS!

Do you want to receive our updates, access information on our activities and events and be in contact with our project?

Figure 20. Podcast page on the website



Episode 1. Welcome to FACILITATE world
Johanna MC Blom, Professor of Psychobiology Paediatric and Behavioural Neuroscience at UNIMORE and deputy coordinator of FACILITATE, introduces the project and its profound impact in the transformative world of clinical trial data sharing in Europe.

Episode 2. Why FACILITATE? Why now?
Johanna MC Blom traces the path of the project by explaining its rationale, analysing the context in which it was born, anticipating the concepts of ethical and legal frameworks, and emphasizing the benefits to stakeholders and society

Episode 3. What patients really want
Veronica Popa, Digital Patient Engagement Manager at EURORDIS Rare Disease Europe, explores patients' views on the return and the reuse of clinical trial data, explaining how it impacts their lives and why it is a priority to respect their needs and wishes.

Figure 21. FACILITATE step-by-step series: presentation of the first three episodes

7.3.6 Podcast infographic

To make rather complex themes more comprehensible and focus the listener's attention on the key concepts of FACILITATE, in each podcast, the speaking voice was accompanied by a simple, cartoon-style infographic, with dialogues and animated effects (**Figure 20**).

Figure 22. An example of animated infographic realized for FACILITATE podcasts

7.3.7 Let's FACILITATE: a newsletter for stakeholders

At the end of the year 2023, at the General Assembly meeting in Bordeaux and thanks to face-to-face discussions with the consortium members on the means of communication, it was decided to change the format of the biannual newsletter for stakeholders to a more interactive and streamlined medium. In order not to lose information content that was nevertheless considered interesting, the old format was transformed into a larger annual report with a similar editorial plan as before (see Let's FACILITATE annual report for stakeholders ahead).

In February 2024, a new semi-annual newsletter format (3 pages) was launched for stakeholders with the link to the main news from the project, to be sent to consortium members, registered stakeholders, IMI-IHI, EDC and SAB members, etc. (**Figure 23**).

Year 3-Issue 1, February 2024

NEWSLETTER

Let's FACILITATE

LET'S FACILITATE WEBINAR

Join us for the Let's FACILITATE 2024 Webinar: an insightful overview and roundtable discussion of the project and its promising innovations to enable data return to clinical study participants. Do not miss this opportunity and save the date!

April 19, 2024
02:00PM-03:30PM CET
Let's FACILITATE Public Webinar
Maximizing the societal benefit and lasting impact of clinical trials
Register here

GLOSSARY FOR PATIENT

To go-in-depth with FACILITATE, enter our glossary, a new and useful tool to delve into the world of our patient-centered project. Use this selected list of words to better understand the meaning of some commonly used terms in clinical research and data sharing. Explore them to have an insight into the responsible return of clinical trial data to participants!

Go to glossary

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

01 / 03

Year 3-Issue 1, February 2024

Featured Panelists:
March 28, 2024
09:00AM to 10:00AM EST
Register here

TRANSCELERATE WEBINAR

Enabling Individual Participant Data Return (iPDR)

Prof Johanna Blom, IHI-FACILITATE Deputy Coordinator, has been invited to present the project and its implications in clinical trial data sharing scenario at the TransCelerate webinar on Individual Participant Data Return (iPDR) Package, a comprehensive set of materials that provide general considerations to enable data return to clinical study participants. Join the event!

PUBLICATION CORNER

FACILITATE carries on its dissemination mission with two publications on peer-reviewed journals. The first is a discrete choice experiment survey administered to a sample of residents in 12 European countries, investigating public preferences for digital health data sharing (Biasotto et al. 2023). The second explores the role of social alliance as fundamental for participatory clinical research, starting with initiative such as FACILITATE (Blom et al. 2023).

Go to publications

FACILITATE D3.1 - Report on the ethical frameworks
DOWNLOAD PDF
Go to Deliverables

FOLLOW THE PROGRESS!

FACILITATE's challenging path in the return of clinical trial data involves meeting predetermined targets, established from the beginning of the project. Advancement in the various topics of FACILITATE patient-centered research and achievement of legal, ethical and technological outcomes are now available on our website, a witness to the project's progress. Enjoy your reading!

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02 / 03

Year 3-Issue 1, February 2024

THE TIME IS RIPE

On November 29, at the Clinical Trials Europe 2023 meeting held in Barcelona, FACILITATE made a significant contribution to this important annual gathering. Prof Johanna Blom, Deputy Coordinator of the project, delivered a compelling presentation titled "Patient Engagement from a Data and Ethical Perspective."

Her address delved into critical ethical considerations surrounding patient centricity in clinical trials, highlighting issues that hold paramount importance in the context of the IHI project, such as:

- developing a feedback mechanism that actively involves patients and recognizes them as crucial stakeholders within the clinical trial framework.
- gaining insights into the effectiveness of clinical trials from the viewpoint of the patients: what works and what fails.
- evaluating the ethical implications of the clinical trials community making decisions for patients, possibly overstepping their autonomy.

Read more

FACILITATE CONSORTIUM MEETS IN BORDEAUX

Two impactful days - 14 and 15 December 2023 - at the FACILITATE General Assembly were held in the lovely French city, filled with updates, workshops, discussions, and decisions that will shape our work ahead. Researchers highlighted the crucial role of communication and empowering individuals in the complex world of clinical trials, an essential topic for the FACILITATE consortium.

Follow us

pmo@facilitate-project.eu www.facilitate-project.eu

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

03 / 03

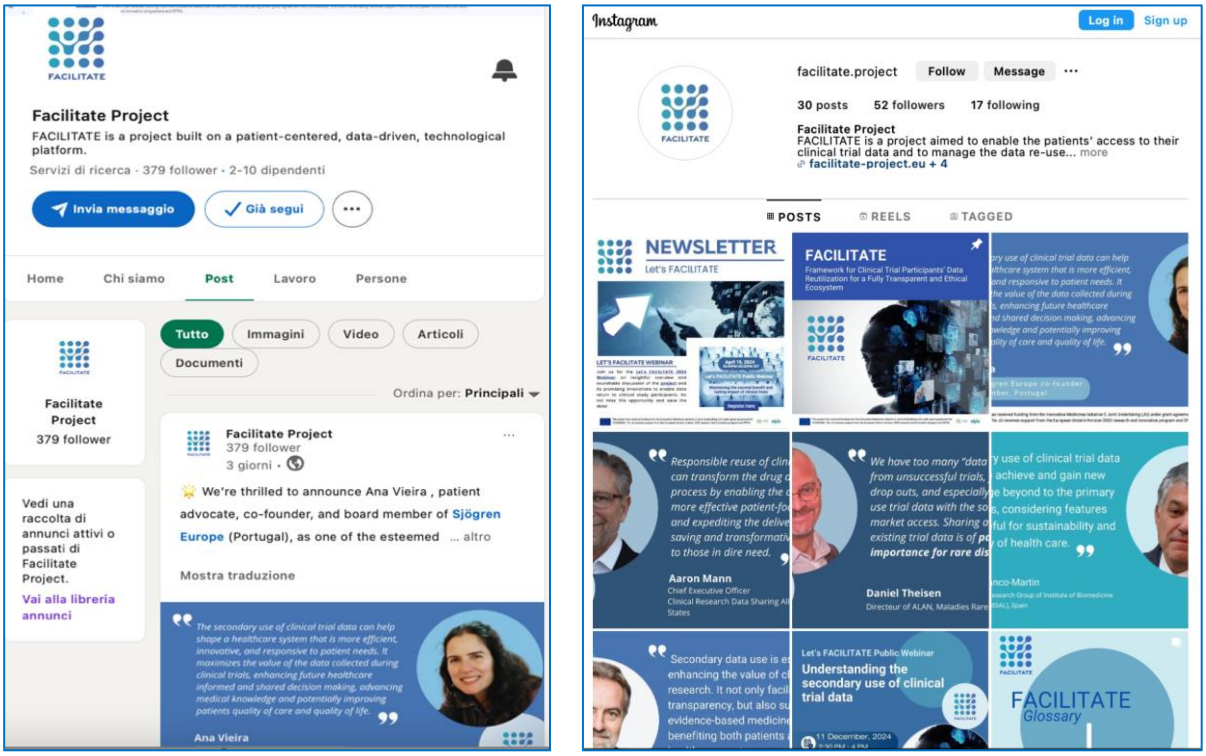
Figure 23. Short newsletter format for stakeholders (February 2024 issue)

7.3.8 Webinars

The two webinars conducted in 2024 and described above (for details, see chapter Level II & Level III - Wider Stakeholder groups, above) can be viewed on the webinars page.

7.4 Social media: LinkedIn and Instagram

Special effort has been devoted to strengthening communication through social media. The two currently active mediums - LinkedIn and Instagram – has been enriched with new content to engage stakeholders (**Figure 24**). The goals of FACILITATE, its social impact, benefits for different stakeholders, and challenges and opportunities for clinical research have been gradually explained. An important contribution was the publication of terms from the Glossary, which aimed to involve the audience in FACILITATE topics. Currently the project has **372** followers on LinkedIn and **52** on Instagram. The number is still low on Instagram, but we are planning in the coming year an ad hoc campaign in cooperation with the patient associations of EUPATI Italia-Accademia del paziente esperto and Cittadinanzattiva (ACN) to increase our followers.



Facilitate Project

FACILITATE is a project built on a patient-centered, data-driven, technological platform.

Servizi di ricerca · 379 follower · 2-10 dipendenti

Facilitate Project
379 follower
3 giorni ·

We're thrilled to announce Ana Vieira , patient advocate, co-founder, and board member of Sjögren Europe (Portugal), as one of the esteemed ... altro

Mostra traduzione

The secondary use of clinical trial data can help shape a healthcare system that is more efficient, innovative, and responsive to patient needs. It maximizes the value of the data collected during clinical trials, enhancing future healthcare informed and shared decision making, advancing medical knowledge and potentially improving patients quality of care and quality of life.

Ana Vieira

Vedi una raccolta di annunci attivi o passati di Facilitate Project.

Vai alla libreria annunci

facilitate.project

30 posts 52 followers 17 following

Facilitate Project

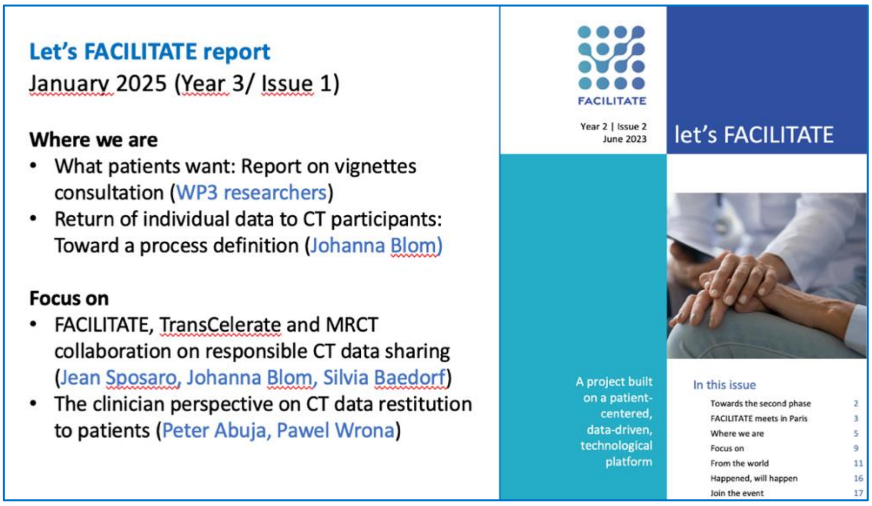
FACILITATE is a project aimed to enable the patients' access to their clinical trial data and to manage the data re-use... more

facilitate-project.eu + 4

Figure 24. FACILITATE social medium: LinkedIn (left) and Instagram (right)

7.5 Let's FACILITATE: annual report for stakeholders

As mentioned above, it was thought to use the old newsletter format to offer stakeholders an annual report on the Project - the Let's FACILITATE report - to be posted on the website in January-February 2025. In addition to containing an update on the main FACILITATE activities, two sections are provided - Where we are and Focus on -, where topics directly or indirectly related to the project are discussed (**Figure 25**).



Let's FACILITATE report

January 2025 (Year 3/ Issue 1)

Where we are

- What patients want: Report on vignettes consultation (WP3 researchers)
- Return of individual data to CT participants: Toward a process definition (Johanna Blom)

Focus on

- FACILITATE, TransCelerate and MRCT collaboration on responsible CT data sharing (Jean Sposaro, Johanna Blom, Silvia Baedorf)
- The clinician perspective on CT data restitution to patients (Peter Abuja, Pawel Wrona)

FACILITATE

Year 2 | Issue 2
June 2023

let's FACILITATE

A project built on a patient-centered, data-driven, technological platform

In this issue

Towards the second phase	2
FACILITATE meets in Paris	3
Where we are	5
Focus on	9
From the world	11
Happened, will happen	16
Join the event	17

Figure 25. Let's FACILITATE report: editorial plan for the January 2025 issue

7.6 Internal Communication

7.6.1 Consortium Newsletter

Comprehensive update of FACILITATE activities to all consortium members made use of semestral newsletters (2 issues, May 2024-December 2024). This newsletter is for internal use only and is sent by email to the entire consortium.

01/06

FACILITATE

Consortium Newsletter

FACILITATE

December 2024

Welcome to the last phase

Dear Consortium members, FACILITATE is now entering its final year of work. Many goals have been achieved and much remains to be done before the end of the project.

Here is a summary of the activities over the last few months, from spring until today, starting with the important milestone in June which saw all workpackages engaged in the **Mid-term Review.**

The submission of planned **deliverables** to IHI is proceeding smoothly, apart from some planned and unplanned delays, with the next deadline of December 24.

Highlights of this newsletter include the results of the **survey** on the role of the trust in the return of CT data and the launch of a **poster and flyer** in several European languages, with a dynamic QR code linking to a **brochure** with key topics in the corresponding language. No less significant are the activities that are underway to define consensus on best practices for the secondary use of CT data (**Delphi study**) and the proposal for the innovative role of the **Trust Liaison Facilitator**.

News from the

Mid-term review

On June 11 and 12, FACILITATE work package leaders met at the University of Modena and Reggio Emilia for IHI's Mid-term review (MTR). The meeting was very positive and fruitful. The reviewers congratulated the team for their efforts and commitments noting that the FACILITATE group is to be very dynamic and enthusiastic. The initial remarks emphasized the soundness of the work carried out in the first two and a half years of the project. Special appreciation went to the quality of the presentations and discussion, which highlighted the cohesion between the working groups. Some of the points raised were answered during the Q&A session. In particular, the reviewers expected more feedback from the stakeholder and asked that their involvement/engagement be described in more detail over the next 18 months.

The need for a clear mitigation process for the delays identified was also noted. Regarding the legal framework, the reviewers asked what the legal proposal would be for the advancement of the relevant legislation would look like.

Finally, the focus shifted to sustainability, with a request to outline the prospects for the end and post-project period. Further information can be found under the links below.

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Figure 26. Consortium Newsletter frontcover

7.6.2 Publication Corner

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

7.6.2 Other 2024 activities related to communication and dissemination

Throughout the year, the communication media for the dissemination of the project at national and international events have been regularly updated. They were available to the entire consortium (general slide deck on FACILITATE, flyers, roll-ups) with the changes and integrations that were gradually requested (new logos, new partners, new information etc.) and prepared presentations with specific content for the partners who requested them.

7.7 General considerations

Not all the initiatives that were suggested by the workshop and the survey at the end of 2023 have been realized in 2024, partly due to the high resources required for their implementation. Nevertheless, the activities carried out this year - from the second part of the glossary to the multilingual posters and brochures - allowed us to learn new approaches, establish new collaborations inside and outside the consortium, collect useful materials for the design of new media, and think of new tools to strengthen stakeholder involvement. No less important, the Mid-Term evaluation of FACILITATE in June was a useful opportunity to rethink the communication plan for the end of the project, especially in terms of:

- implementation of inclusive communication tools, which allow participation for all patients and caregivers, including vulnerable populations
- feedback from stakeholders and patient empowerment and engagement
- empowerment of patients on the issue of data return
- engagement with EU data sharing projects

In the light of these considerations, communication and dissemination proposals have been planned for 2025, to be realized together with the activities already in progress and those postponed from 2024.

7.8 2025 Communication and Dissemination plan

A communication and dissemination strategy has been developed for 2025 (the red star-symbol represents newly implemented activities) (**Figure 27**). The new proposals have patients' empowerment and inclusivity as a key objective, aiming to make the project known to the widest possible audience. The common denominator is the creation of patient tools in an easy-to-understand language and format, all translated into the main European languages (from English to Italian, German, French, Spanish, Serbian, Dutch).

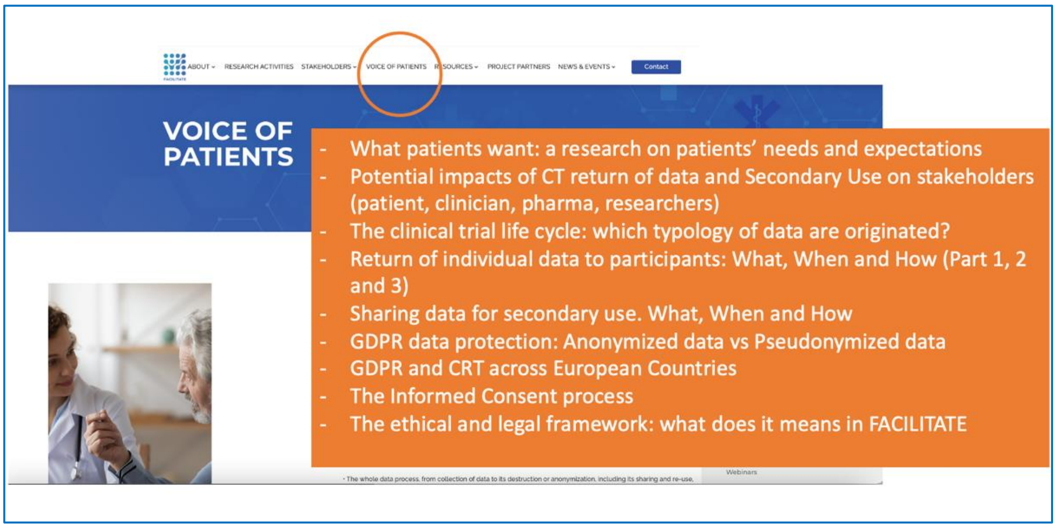
Figure 27. Timeline of the communication activities planned for 2025

The plan includes the following actions:

- Monitoring stakeholder access to FACILITATE project, particularly to website and its specific sections, with the aim of focusing communication efforts on the tools with the greatest interest.
- Strengthening the interaction with European and non-European entities active on FACILITATE related topics (e.g., MRCT, TransCelerate, CISCRP, EHDS, etc...), to implement collaborative communication and dissemination activities.
- Continuing the activities already underway, which have proven successful in terms of project communication, improving the quality and frequency of information if necessary.
    - Regular updating of the website and some restyling
    - Newsletters, internal for the Consortium and external for stakeholders with major updates
    - News on topics directly or indirectly related to the project
    - Publication of informative social media posts
    - Publication of articles in peer review journals (opinion papers, white papers, guidelines, original articles, etc.)
    - Publication of FACILITATE public deliverables on the website
    - New podcasts dedicated to legal framework, technological process for CT data return, secondary use of CT data and informed consent
    - Glossary with new terms pertaining to CT and responsible data sharing (third part)

- Implementing new activities and tools aimed at strengthening active patients' participation and discussion on return of CT data to participants, in plain language and translated into major European languages (English, Italian, French, Spanish, German, Serbian, Dutch) to grant the access to the widest possible patients' population. New proposals include**:**

- **Voice of Patients:** A series of multilingual short articles and/or infographics for the website, dedicated to a general audience regarding the main topics on responsible CT data sharing and ethical issues (**Figure 28**). These plain language articles will be designed in an easily accessible format and selected fonts and will be accompanied by appropriate iconography to allow for the greatest possible inclusiveness. The articles will be published in the Voice of Patients page on the website and highlighted in the Home page.



- What patients want: a research on patients' needs and expectations
- Potential impacts of CT return of data and Secondary Use on stakeholders (patient, clinician, pharma, researchers)
- The clinical trial life cycle: which typology of data are originated?
- Return of individual data to participants: What, When and How (Part 1, 2 and 3)
- Sharing data for secondary use. What, When and How
- GDPR data protection: Anonymized data vs Pseudonymized data
- GDPR and CRT across European Countries
- The Informed Consent process
- The ethical and legal framework: what does it means in FACILITATE

• The whole data process, from collection of data to its destruction or anonymization, including its sharing and re-use.

Figure 28. Some topics of interest on CT data sharing for the Voice of Patients section

- **Multilingual Publication extracts:** Short summaries in plain language from FACILITATE peer-reviewed publications (research articles, opinion paper, guidelines, etc.), available into at least 6 European languages. As for the short articles described above, these extracts will be designed in an easily accessible format and selected fonts and will be accompanied by appropriate iconography to allow for the greatest possible inclusiveness. They will be published in the Voice of Patients page on the website and highlighted in the Home page.
- **Questions and Answer:** A series of Q&A related to the project, organized by topics (role of stakeholders in the project, Clinical trial data return to participants, Informed Consensus, Legal issues, Ethical principles, etc.). Infographics will be realized to provide easy-to-understand information.
- **Infographic:** Some graphical presentation of concepts, data, information related to FACILITATE and responsible CT data sharing in 6 different European languages

- **Animated videos on Return/reuse of CT Data.** One or two short multilingual (6 main languages) animated videos on
    - FACILITATE role in return of individual CT data to participants.
    - Its impact on stakeholders’ life/work
- **Video-interviews to stakeholders.** A final video with short interviews with stakeholders (clinicians, patients, pharma representatives, regulators) on the impact FACILITATE could have on their life/work and what critical aspects still need to be addressed.
- **Other:** All activities related to Communication and Dissemination that will be necessary to achieve the objectives of the four final deliverables of WP6 (D6.7, D6.8, D6.9, D6.10) (See Chapter below.

8 2025 Strategic plan for developing recommendations and training guidelines (D6.7 - D6.8 - D.9)

As foreseen in the Grant Agreement, next year will most focus on the following activities, with proposed actions to implement them:

8.1. Developing Training Documentation and Recommendations (Task 6.3)

Lead: Active Citizenship Network (ACN); Partners: EUPATI Italy, EURORDIS, UNIMORE, EURAC, ABV, TAK; Timeline: Months 42–48.

1.1 Recommendations (Subtask 6.3.1); this subtask will produce two main deliverables:

a). Recommendations Document D6.7:
- Focused on overcoming the barriers and discrepancies between GDPR and ethical guidelines across EU Member States. Designed also as an advocacy tool for patients and their associations, culminating in a “Manifesto for the Right to Access Clinical Trial Data”.
Manifesto Goals:

- Provide accurate information.
- Increase awareness and understanding of the issue.
- Empower civic and patient associations, support healthcare systems, and advocate for healthcare professionals.
-

Planned Actions for Implementation:
- During the General Assembly in Madrid (January 2025), we will conduct a brainstorming session to outline key elements of the Manifesto.
 - Internal and external consultations:

- Regular discussions with project partners and targeted external consultations

- Engagement with patient and civic associations for feedback.

- Drafting the recommendations and Manifesto:

- Assign task leads to structure and refine content collaboratively.
  -Outreach to civic and patient associations:
- Goal: secure endorsements from at least 30 associations not already involved in the prototype process.

Actions: Host dedicated webinars, distribute targeted email campaigns, and use social media platforms to explain the Manifesto's importance.
Involve IMI Board and EFPIA representatives to ensure broad institutional reach.

a. D6.8 Workshop to present results:

Presentation to European Institutions and all the stakeholders:
Event: organize an advocacy event/ a final workshop within the framework of the MEPs Interest Group on "European Patients' Rights and Cross-border Healthcare," promoted by ACN to share the Manifesto and project outputs with the broader healthcare and patients' community.

8.2. Developing Training Guidelines (Subtask 6.3.2)

Lead: EUPATI Italy - Deliverable: D6.9
This subtask focuses on creating training guidelines in accessible, plain language to address:

1. Facilitate Prototype Process:
   - overview of its functionalities and use cases.
   - implementation planning (linked to WP7).
2. Educational Tools:
   - Topics: Informed consent, data sharing, and their importance in accelerating drug and medical device development.
   - Target audience: Patients, physicians, and the public to raise awareness about personal data management and reuse.

Planned Actions for Implementation:

Content Development:
o Collaborate with project partners to identify key topics and ensure materials are aligned with WP7.
o Integrate user-friendly formats like infographics, and FAQs to make materials widely accessible.

Stakeholder Consultations:
o Engage with patients, physicians, and patient associations to refine educational materials and ensure they address real-world needs.

Pilot Testing of Guidelines:
o Organize groups consultations or webinars to test materials with a sample audience.

Dissemination:
o Share finalized guidelines through project networks, partner websites, and public events.
o Develop targeted messaging to promote training materials and educational tools across Social Media:

With these actions, we aim to ensure the effective delivery of Task 6.3 outputs, fostering better understanding, awareness, and empowerment around the secondary use of clinical trial data.

9 Conclusions

The stakeholders' engagement & communication activities carried out in 2024 have advanced the project's objectives by fostering collaboration, gathering critical input, and disseminating results effectively. The structured engagement approach included consultations, surveys, and public events, which have enriched the project's reflections and shaped its outputs.

Discussions with expert stakeholder groups directly informed the project's deliverables and provided a strong foundation for future work. One highlight was a survey on the key theme of TRUST, involving over 320 participants. This confirmed the importance of an ethical, patient-centred approach to data management, aligning with stakeholders' expectations.

Public webinars also played a vital role, attracting around 400 registrations each and demonstrating their effectiveness in raising awareness about data return and secondary use in clinical trials.

The project's communication efforts also contributed to stakeholder engagement, with the FACILITATE website now boasting 410 registered stakeholders and the LinkedIn profile reaching nearly 380 followers. Diverse communication materials - including glossary, podcasts, multilingual posters and brochures, and peer-reviewed articles - helped convey the project's goals and progress to a broad audience.

Patients' empowerment and inclusivity are key objectives of our present and future communication and dissemination strategy, providing patients with new tools in an easy-to-understand language, and formats adapted to visible and invisible disabilities, available into the main European languages (from English to Italian, German, French, Spanish, Serbian, Dutch).

These endeavours underscore the vital connection between stakeholder engagement and effective communication.

Building and continuing working on the 2024 successes, the upcoming year will also focus on Task 6.3, dedicated to developing training documentation and recommendations. Key planned activities include:

- drafting a "Manifesto for the Right to Access Clinical Trial Data" and presenting it and project outcomes during an advocacy event within the MEPs Interest Group on "European Patients' Rights and Cross-border Healthcare."
- designing, testing, and disseminating plain-language materials on informed consent, data sharing, and the FACILITATE process.

These efforts will further strengthen the FACILITATE project's impact and prepare the groundwork for its final outcomes.

10. Appendix 1

10.1 Survey The role of trust in Return of Data (RoD) from clinical trials: results

Survey questions:

Q1 source of trust in order of importance in CT

Q2 general source of trust regarding RoD from CT

Q3 Preferred timing of RoD in CT

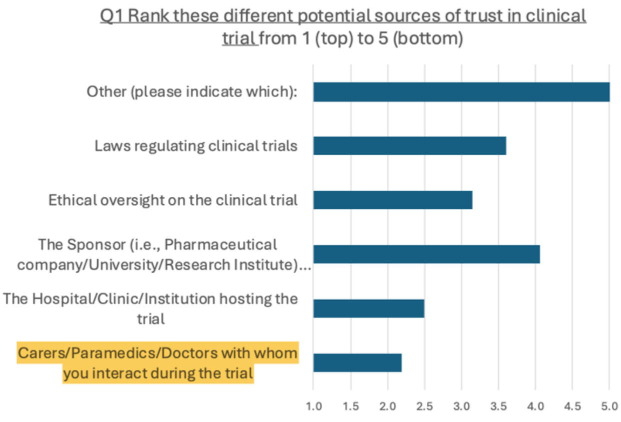
Q4 mode of delivery for RoD in clinical trials

Q5 willingness to participate in RoD

Q6 preference for subjects communicating data/results in RoD

Q7 effect of the type of data/results on preference for subjects involved in RoD

When participating in a clinical trial, patient's trust might be referred to different sources.
Please rank these different potential sources of trust by dragging them from the most relevant (i.e., 1, on top) to the least relevant and/or add any other you may need in the blank space.



Q1 source of trust in order of importance in CT

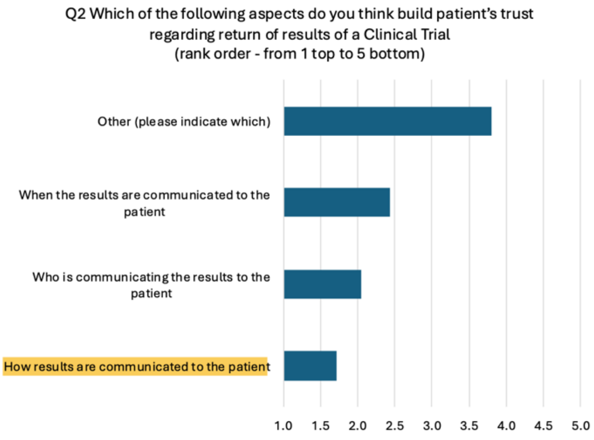
1. Trust in Those Subjects Closest to the Participant

The first graph highlights a pivotal factor in establishing trust: the influence of those who are closely connected to the participant, such as doctors, healthcare providers, or family members. Participants tend to trust the clinical trial when they know that someone close to them, or someone with direct personal influence, vouches for the process. The graph underscores the importance of interpersonal relationships and how they impact the trust that participants place in the clinical trial process.

Interpretation:

- Trust is not established in isolation but relies heavily on endorsements from individuals with whom participants interact with frequently.
- This suggests that involving local/known healthcare providers and ensuring they communicate effectively with potential participants could be a critical strategy for boosting trust.

Which of the following aspects do you think build patient's trust regarding return of results of a Clinical Trial?
Please rank these aspects by dragging them from the most relevant (i.e., 1, on top) to the least relevant and add any other you may need in the blank space.



2. Communication of Results

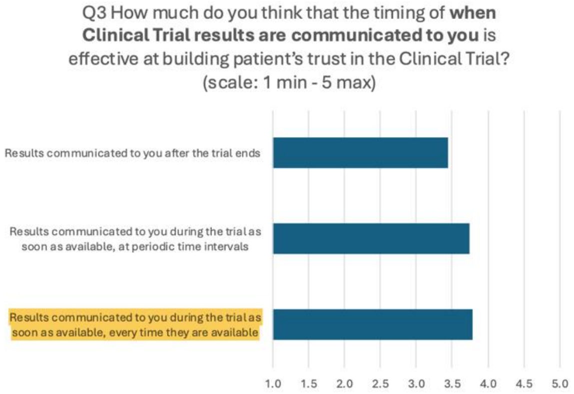
The second graph emphasizes the importance of how clinical trial results are communicated. It identifies that the mode of communication of results is the most trusted factor. Participants appreciate being kept up to date about the progress and results of the study.

Interpretation:

- communication mode builds trust, with participants favoring timely and accurate updates.
- The data suggest that clinical trial organizers should prioritize communication strategies, ensuring that results are shared in a proper manner to maintain participant trust.

Q2 general source of trust regarding RoD

How much do you think that the timing of when Clinical Trial results are communicated to you is effective at building patient's trust in the Clinical Trial?
Please rate each aspect on a scale from "not effective at all" (1) to "extremely effective" (5) at increasing trust.



3. Continuous Timely Updates

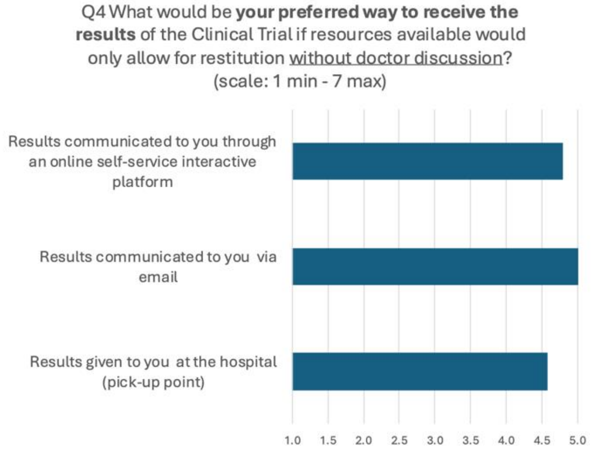
Continuing from the theme of communication, the third graph shows that participants prefer continuous and timely updates. A regular flow of information regarding the clinical trial's progress, potential risks, and any findings is a trust factor.

Interpretation:

- Continuous updates prevent feelings of uncertainty, which can undermine trust.
- A proactive communication strategy that ensures participants are regularly updated can enhance retention rates in clinical trials.

Q3 Preferred timing of RoD in CT

Imagine you are participating in a Clinical Trial. What would be your preferred way to receive the results of the Clinical Trial if resources available would only allow for restitution without doctor discussion?
Please rate your preference on a scale from "Dislike a great deal“ (1) to "Like a great deal“ (7).



4. Digital Communication as an Acceptable Method

The fourth graph shows that digital communication methods (e.g., email, patient portals, or apps) are generally accepted and trusted by participants. As the healthcare industry continues to adopt digital transformation strategies, this graph highlights that digital communication is not only acceptable but also a trusted method for conveying clinical trial updates.

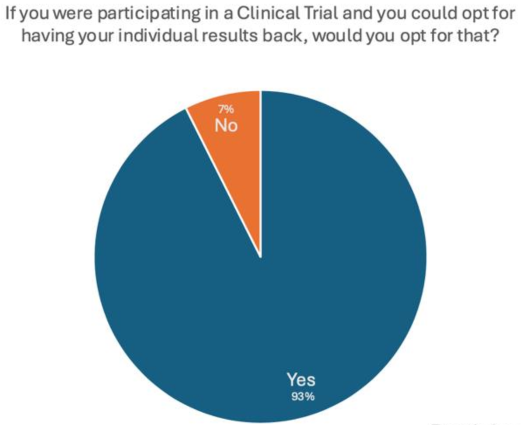
Interpretation:

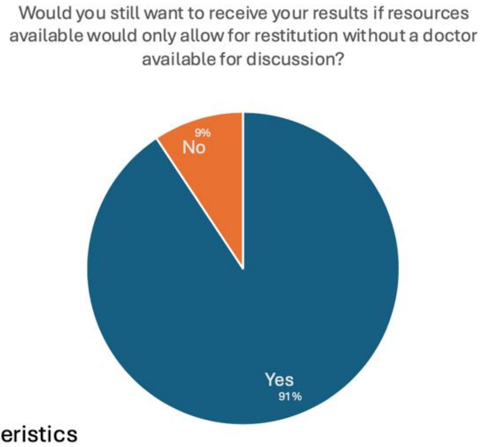
- Participants are comfortable with digital tools and platforms for receiving updates, indicating that digital-first strategies can be an effective method of building trust, especially when face-to-face communication is not feasible.

- This finding is particularly relevant in the context of remote or decentralized trials.

Q4 mode of delivery for RoD in clinical trials

Participant’s willingness to participate in RoD

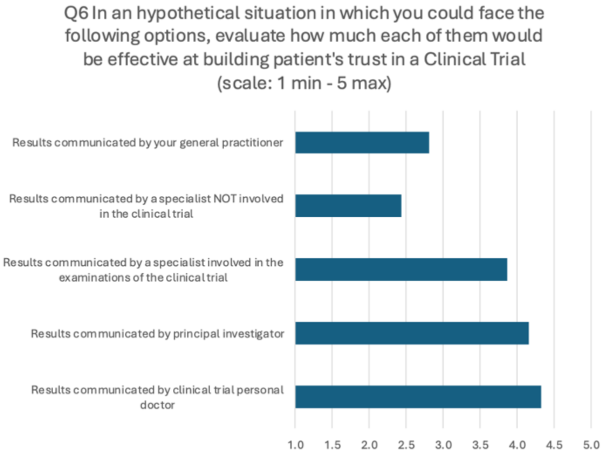




Participant’s characteristics
Sample:361
Average age: 53 (stdev: 10.75)

Q5 willingness to participate in RoD

In an hypothetical situation in which you could face the following options, evaluate how much each of them would be effective at building patient's trust in a Clinical Trial.
Please rate each aspect on a scale from "not effective at all" (1) to "extremely effective" (5) at increasing trust.



Q6 preference for subjects communicating data/results in RoD

6. Preference for Human Contact for Communication

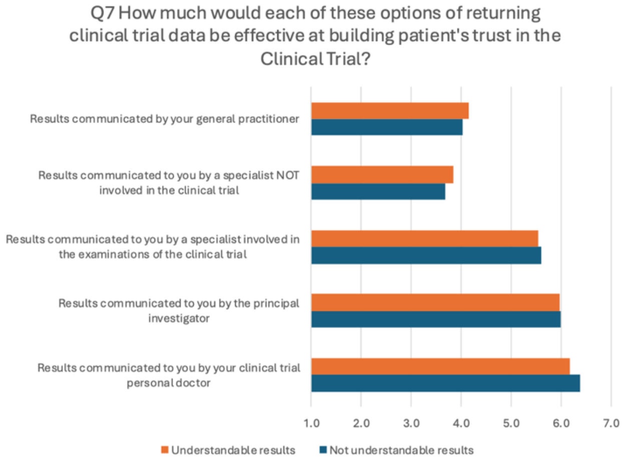
The sixth graph offers a complementary perspective, showing that while digital communication is accepted, the majority of participants like human contact for content updates. This suggests that trust can be further enhanced by incorporating personal interactions into the communication process, especially for sensitive information or significant updates regarding the trial.

Interpretation:

- While digital communication is efficient, there is still a need for personalized, human interaction.

- Organizers should blend digital communication with human interaction, ensuring that critical or sensitive information is conveyed in person or through direct human contact.

Imagine you are participating in a Clinical Trial and its results are (or: are NOT) understandable by you (i.e., you do need help in understanding their meaning). Facing the following hypothetical options, how much would each one of them be effective at building patient's trust in the Clinical Trial?
Please rate your preference on a scale from "Dislike a great deal" (1) to "Like a great deal“ (7).



Q7 effect of the type of data/results on preference for RoD

7. Preference for Trust in Personnel Involved in the Trial

The final graph highlights that participants place a greater deal of trust in the personnel involved in the trial especially when the trial is complex in terms of interpretation of the results. In such case an inversion effect appears to be in place, in which participants trust the personnel involved in the clinical trial even more than known medical professionals for the case the results of the trial are difficult to interpret.

Interpretation:

- Trust in personnel is a significant determinant of overall trust in the clinical trial.

- Ensuring that the personnel involved are not only competent but also approachable and transparent can greatly enhance participant engagement and satisfaction.