FACILITATE

innovative medicines initiative

IMI2 Project ID 101034366
FACILITATE

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

WP6 – Communication and dissemination

D6.1 Communication, dissemination, and exploitation plan

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Table of contents

Document History 2
Definitions 3
Abbreviations 4
List of Figures 4
List of Tables 5
Executive Summary 5
1. Introduction 5
2. DiCEP in practice 8
2.1 DiCEP objectives 8
2.2 Key-messages 9
2.3 Target audiences of the DiCEP 10
2.4 Open access repositories 11
2.5 Management of the DiCEP 12
3. Communication and dissemination 12
3.1 Communication and dissemination strategy 12
3.2 Communication tools and objectives 14
3.3 Events 17
3.4 Dissemination tools 18
4. Exploitation and sustainability 20
4.1 Exploitation and sustainability strategy 20
4.2 Exploitation activities 21
4.3 Sustainability activities 22
5. Monitoring the implementation of the DiCEP 22
5.1 Key Performance Indicators 22
5.2 Monitoring tools 23

5.3 Monitoring reports 24
6. Publication policy 24
Annexes 29
ANNEX I. FACILITATE visual identity 29
ANNEX II. Social media strategy 31
ANNEX III. Monitoring report 33

Definitions

- **Participants** of the FACILITATE Consortium are referred to herein according to the following codes:
  1. **UNIMORE.** Università degli Studi di Modena e Reggio Emilia
  2. **VUB.** Vrije Universiteit Brussel
  3. **TUNI.** Tampereen Korkeakoulousaatio SR
  4. **EUPATI.** Stichting EUPATI Foundation
  5. **ACN**. Associazione Cittadinanzattiva Onlus
  6. **PN.** PRIVANOVA SAS
  7. **ODY**. Odysseus Data services SRO
  8. **ZEN.** Privredno drustvo Zentrix Lab Drustvo sa ogranicenom odgovornoscu Pancevo
  9. **INPECO.** Inpeco SA
  10. **BPE.** ADERA
  11. **AOU.** Azienda Ospedaliero Universitaria di Modena Policlinico
  12. **MUG.** Medizinische Universitat Graz
  13. **UJ.** Universytet Jagiellonski
  14. **IMR.** Institute for Medical Research, University of Belgrade
  15. **SCC.** Spitalul Clinic Colentina Bucuresti
  16. **PNZW.** St Antonius Hospital Gronau Gmbh
  17. **EURAC.** Accademia Europea di Bolzano
  18. **EURORDIS.** EURORDIS – European Organization for rare Diseases Association
  19. **SARD.** SANOFI Aventis Recherche et Développment
  20. **MED.** Mdsol Europe LTD
  21. **ABV.** Abbvie Inc
  22. **AZ.** AstraZeneca AB
  23. **BAY.** Bayer Aktiengesellschaft
  24. **PFZ.** Pfizer limited
  25. **TAK.** Takeda Pharmaceuticals International AG
  26. **ALM**. Almirall SA
  27. **SERV**. Institut de Recherches Servier
- **Linked third parties**.
  4.1 EUPATI IT. Accademia del Paziente Esperto EUPATI
  9.1 INPECO TPM. Inpeco TPM SRL
- **Grant Agreement**: (Including its annexes and any amendments) The agreement was signed between the beneficiaries of the action and the IMI2 JU for the undertaking of the FACILITATE project (Grant Agreement No. Project n° 101034366).

- **Project**: The sum of all activities carried out in the framework of the Grant Agreement.
- **Consortium**: The FACILITATE Consortium, comprising the above-mentioned participants.
- **Communication Working Group**: each partner will nominate 1 person who care about the Communication & Dissemination activities.
- **Consortium Agreement**: The agreement was concluded amongst FACILITATE participants for the implementation of the Grant Agreement. The agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
- **Deliverable review**: An evaluation procedure by one or more reviewers, which precedes the distribution of a deliverable (as defined in the Work plan) to the IMI2 JU.tium
- **Quality assurance**: All the planned and systematic activities implemented to provide adequate confidence that an entity will fulfill requirements for quality.
- **Quality policy**: A set of principles on which quality assurance procedures are based.
- **Risk**: Uncertainty that may significantly impact the execution or outcome of the project, and which effect may be negative – a threat risk, or positive – an opportunity risk.
- **Work plan**. Schedule of tasks, deliverables, efforts, dates, and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
- **WP 6 Leaders**: ACN and TAK will be responsible for the implementation of the WP6 strategy
- **WP 6 members**: ACN, UNIMORE, VUB, TUNI, EUPATI, PN, ZEN, AOU, MUG, UJ, IMR, SCC, PZNW, Eurac, EURORDIS, SARD, ABV, BAY, PFZ, TAK, ALM will actively participate in the WP6 activities.

Abbreviations

CommWG: Communication Work Group
CT: Clinical Trial
CommWG: Communication Working Group
DiCEP: Communication, Dissemination and Exploitation Plan
DP: Data protection
EDC: Expert Decision Committee
EU: European Union
ExCom: Executive Committee
GDPR: General Data Protection Regulation
H2020: Horizon 2020 programme
KPI: Key Perfomance Indicators
PMO: Project Management Office
RWE: Real world evidence
WP: Work Package
WPL: Work Package Leader

List of Figures

Figure 1: Examples of communication (left) and dissemination (right) activities
Figure 2: FACILITATE Logo
Figure 3: Communication/dissemination tracker

List of Tables

Table 1: Relation of the DiCEP to Project key documents and deliverables
Table 2: Keyword definitions. Source: EU glossary
Table 3: The target audience of the DiCEP
Table 4: Target audience, relevant messages, and methods
Table 5: FACILITATE public deliverables and guidelines
Table 6: Link of relevant EU-funded projects
Table 7: KPIs of Communication and Dissemination activities
Table 8: KPIs of Exploitation and Sustainability activities
Table 9: Reporting timeline

Executive Summary

The overall aim of FACILITATE is to enable the return of clinical trial data to study participants and other healthcare professionals involved in their care within a GDPR compliant and approved ethical/legal framework and to develop a new ethical, legal, and regulatory framework overcoming the current limitations and discrepancies between the European Member States.
FACILITATE places stakeholder engagement as one of the main objectives of the project and emphasizes the effective collaboration of multiple stakeholders. With the FACILITATE consortium forming a multidisciplinary, multistakeholder public-private partnership, bringing together patients, patient organizations, research and academic institutions, technological organizations, and industrial partners, effective communication across the whole spectrum of FACILITATE activities, is fundamental. Therefore, the first task of Work Package 6 is the preparation of a Communication, Dissemination, and Exploitation Plan (DiCEP) which presents the programme of activities aimed at informing and involving stakeholders and citizens at large of the project. Particular emphasis lies in engaging with patients and patient organizations as active stakeholders.
DiCEP defines the nature and goals of the communication and dissemination activities, their targets, the key messages of the project, a roadmap and the branding of the project, the roles and responsibilities of the partners, the communication tools that will be used, and a timeline of the activities.
This document has been drafted by the project coordinator and task 6.1 leader (UNIMORE), WP6 leaders (ACN and TAK), in strict collaboration with several other partners.

This document will serve as a “living document” throughout the project, guiding the communication and dissemination efforts carried out by the consortium, and will be periodically reviewed and updated anytime deemed necessary.

1. Introduction

This document represents deliverable “6.1-Communication, Dissemination and Exploitation Plan” of FACILITATE. According to the European Commission communication best practices and to the H2020 Manual (How to make full use of the results of your Horizon 2020 project[1]): “the beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public), strategically and effectively” (Article 38 of the grant agreement).

[1] https://ec.europa.eu/research/participants/data/ref/h2020/other/comm/20210330_how-to-make-full-use-of-the-results-of-your-project_h2020_en.pdf

The valorization of the project is made up of communication, dissemination, and exploitation activities aimed to maximize the impact of the project results by optimizing their value, strengthening their impact, transferring them to different contexts, and using them in systems and practices at the local, regional, national, and European level. The DiCEP lays out dissemination, communication, and dissemination tools and strategies, providing a guideline for all the project partners to achieve the largest possible impact of the project. Rigorous dissemination and communication activities are a key part of any EU-funded project and, indeed, they should be the product of a shared effort provided by all partners and are related to key documents and deliverables of the project.

The Dissemination, Communication, and Exploitation Plan is drafted at an early stage of the project implementation (M6) and aims to provide a framework for all the partners, helping to effectively communicate and report all relevant activities and outcomes. While it is rooted in the initial Description of Action, it will be refined and updated throughout the project duration to reflect the project's progress and include possible new prospects.

Document	Access	Relationship to DiCEP
Grant Agreement Art. 38.1 – Communication activities by beneficiaries	Confidential	This article defines the obligations of EU funding beneficiaries concerning communicating the Project's results, herein included: ▪ obligation to promote the action and its results ▪ obligation and right to use the EU emblem ▪ disclaimer excluding Commission responsibility on communication activities related to the action
Grant Agreement Art. 29.1 – Obligation to disseminate results	Confidential	This article defines the obligation of EU funding beneficiaries of disclosing the Project's results to the public as soon as possible by appropriate means, including in scientific publications, in compliance with Art. 27 (results protection), Art. 36 (results confidentiality), Art. 37 (security) and Art. 39 (protection of personal data)
Grant Agreement Art. 28 – Exploitation of results	Confidential	This article defines the obligation of EU funding beneficiaries of taking measures to ensure results exploitation either directly or indirectly, in particular through transfer or licensing, up to 4 years after the period set out in Article 3 of the Grant Agreement
Consortium Agreement §7 – Results	Confidential	This section defines rules for dissemination/exploitation of individual/joint results deriving from the Project
Consortium Agreement §8 – Access Rights	Confidential	This section defines rules for access to background knowledge/technology/tools, and Project output results
Consortium Agreement §10 – confidentiality	Confidential	This section defines rules of confidentiality of information on scientific and technological outputs of the Project
Consortium Agreement, Annex XII – Communication guidelines	Confidential	This annex defines rules about permitted or prohibited communications, link guidelines, and third parties policy
Deliverable 1.7 – Data Management Plan - 1	Confidential	This deliverable defines the data management strategy for results dissemination and exploitation, including confidentiality under IP protection rules

Deliverable 6.2 – Project Website	Public	The Website is among the means of communication of the Project
Deliverable 6.3 – Stakeholder involvement plan	Confidential	This deliverable defines the strategy to involve stakeholders, and so which communication activities are related to the research purposes

Table 1: Relation of the DiCEP to Project key documents and deliverables

In a project like FACILITATE, with a high focus on patients' rights and public opinion and the exploitation of the FACILITATE Working Prototype both for research and outreach, "Dissemination and Exploitation" and "Communication" activities often share the same tools.

Keyword	Definition
Communication	*Communication on projects is a strategically planned process that starts at the outset of the action and continues throughout its entire lifetime, aimed at promoting the action and its results. It requires strategic and targeted measures for communicating about (i) the action and (ii) its results to a multitude of audiences, including the media and the public and possibly engaging in a two-way exchange.* FACILITATE results shall be communicated to a wide audience. Main activities are in common with dissemination and exploitation activities. In brief, these include project website; social media; leaflet; brochure; roll-up; Video; newsletters; workshops/focus groups.
Dissemination	*The public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including scientific publications in any medium*. Meant as the environment to address the project's results to specific target groups, the main tools for dissemination of the achievements of FACILITATE will be scientific conferences, scientific publications, policy briefs, and recommendations.
Exploitation	*The utilisation of results in further research activities other than those covered by the action concerned, or in developing, creating, and marketing a product or process, or in creating and providing a service, or in standardisation activities*. In FACILITATE, this term means to effectively use the research results for making them available to other researchers and other key stakeholders. FACILITATE's exploitation starts from the construction of the Business user cases (WP7) and will run until the development of the FACILITATE Working prototype, its validation, and widespread communication.
Intellectual Property Rights	*Legal rights are granted to people to protect their ideas. These rights include industrial property rights (e.g. patents, industrial designs, and trademarks), copyright (rights of the author or creator), and related rights (rights of performers, producers, and broadcasting organisations).*
Open Access	*The practice of providing online access to scientific information that is free of charge to the reader. In the context of Research and Innovation, open access typically focuses on access to 'scientific information', which refers to two main categories: peer-reviewed scientific research articles (published in academic*

	journals) and scientific research data (data underlying publications and/or raw data)

Table 2: Keyword definitions. Source: EU glossary

This deliverable represents the first version of FACILITATE DiCEP and constitutes a *live* document, which will be updated following the Project's evolution during its lifetime.

2. DiCEP in practice

2.1 DiCEP objectives

The effective and targeted communication and dissemination/exploitation of outputs from FACILITATE is crucial to ensure that results are understood and used for the protection of patients' interests by key audiences, including policymakers, the scientific community, and other stakeholders.

The principal objectives of the DiCEP are to:

- Build a **bridge between science and policy** through continuous dialogue and engagement between individuals involved in cutting edge scientific research and individuals involved in all stages of clinical trial governance;
- Channel **new knowledge to policymakers** on current open questions regarding the use of data from clinical trials and facilitate the exploitation of this knowledge in future research;
- Foster **stakeholder engagement** in FACILITATE, so that stakeholders can both contribute to shaping our research agenda and exploit results in their activities;
- Make FACILITATE data available via the **Open Access tools** for re-use and in particular for combination with other data sets, to promote the exploitation of results by other researchers;
- **Raise public awareness** with regards to the use and re-use of clinical trial data and provide insights into possible behavioural changes that can reduce chemical exposure and improve health and well-being;
- **Raise public awareness** of the role of FACILITATE activities in protecting the interest of patients involved in clinical trials.
- Communicate effectively with **citizens** to ensure their understanding of broader project objectives;

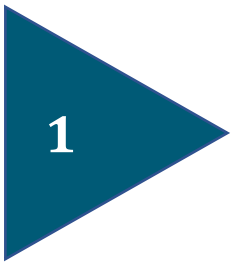
The common and shared understanding of these objectives results in dissemination, communication, and exploitation plan in line with work packages 6 and 7 operational objectives:

- [O6.1] Establish a website and all appropriate tools for communications purposes
- [O6.2] Establish a workable co-creation structure to enable timely input and collaboration, communication and dissemination structure and as well as implement it on a project basis, implementation according to project timelines
- [O6.3] Build a broad level of support and engagement adherence by and through active involvement of relevant stakeholders via events and surveys, discussions, advisory boards, or focus groups
- [O7.1] Define the FACILITATE business plan in terms of use cases, potential, benefits strategy requirements, and associated options ensuring patients' empowerment.
- [O7.2] Provide a clear and realistic business use plan ensuring the sustainability of the FACILITATE project outputs. Ultimately adoptions depend on the acceptability of the process of returning clinical trial data by stakeholders including industry partners, health care professionals, patients/patient organisations, and regulators/IRBs.

DiCEP activities are linked to the activities planned in the “Stakeholder involvement plan“ (D6.3).

2.2 Key-messages

The first step for an efficient communication strategy is to define key messages that have to be conveyed through various media, and that should stick with the audience after any encounter with the project’s communication.
In the following table, the essential aspects of our project are summarized so that they are ready for use at any time during the project’s lifetime.

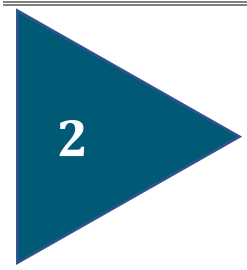


Benefits
The main benefits of FACILITATE are the following:

- align local and pan-European implementations and best practices for handling personal data protection regulations, taking into account not only the legal process but the applicable Stakeholders’ voice/opinion
- develop a pan-European prototype process to return clinical trial data to study participants

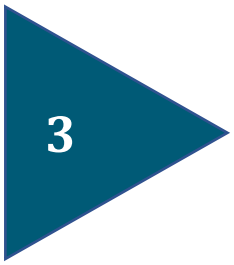
This project interconnects patients, caregivers, healthcare providers, clinical centres, hospitals, pharma companies, EU and national bodies, and people who are directly involved in clinical trials.

- For patients: the project results will empower patients by returning their clinical trial data to them to aid better shared medical decision-making;
- For healthcare professionals: enriched healthcare data obtained during clinical care will aid clinical decision making and reduce duplication
- For EU research: giving patients control of their clinical trial data will open possibilities for ethical data re-use by enabling patients to donate their data;
- For regulators: exchanging opinions with counterparts from other countries and researchers to propose informed workable aligned positions;
- For pharma: improved patient retention as well as access to health data for future research;
- For society: increased transparency of clinical study and therefore increase the trust of patients and improved oversight on clinical data re-use.



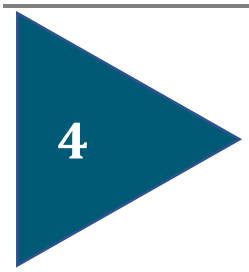
The three key elements of the project
The FACILITATE project aims to define and develop a working prototype process to return clinical trial data to study participants based on the following objectives:

- transform the way patients will have access to clinical trial data in Europe, allowing the portability of patients’ data.
- ensure that the whole data process, from collection of data to its destruction or anonymization, including its sharing and re-use, is legally and ethically compliant and aligned with the study participants’ but also hospitals, academia, and industries voice.
- define data governance models for clinical case use and on how this data is utilized in health care decision making and for future research.



The project in a nutshell

FACILITATE is a project built on a patient-centred, data-driven, technological platform. The main objective is the development of a new ethical, legal, and regulatory framework overcoming the current limitations and discrepancies between the European Member States enabling the return of clinical trial data to study participants and other healthcare professionals involved in their care within a GDPR compliant and approved ethical framework. FACILITATE will define which, when and how clinical trial data should be returned to study participants, including integration in, or interconnection with, patients' individual health records management files or applications. This avoids the current situation where clinical data are siloed in separate repositories without any possibility to be used beyond their original single-sided purpose. Having obtained consent on the data portability FACILITATE will re-use and cross-reference them with those contained in other repositories including RWE data captured across multiple settings and devices.



The basic philosophy of the project

Through research action, and participation of various stakeholders, FACILITATE's ambition is to change the current journey from source data to actionable and safe approval and bring more effective and safer medicines faster at their approval date. For this, the FACILITATE platform and its results will be presented in front of the European Medicines Agency and the National Competent Authorities Committees to show how a patient-centred data-driven approach can improve the entire process.

These are, of course, basic key messages. Further messages will emerge during the project, both regarding the research results and the outcome of stakeholders' involvement activities scheduled in Work Package 6.

2.3 Target audiences of the DiCEP

DiCEP activities are directed towards a wide range of internal and external audiences (stakeholders), including project participants. Two-way communication is sought, with valued inputs coming from stakeholders. The DiCep and stakeholder plan (D6.3) will be aligned.

Audience/Stakeholder	Communication/dissemination requirements
IMI JU.	FACILITATE project has received support and funding from IMI. The project needs to deliver its project progress, results, and future plans to IMI. In addition, IMI can support dissemination by promoting and communicating about FACILITATE through their own channels (website, newsletter, press, brochures, events, etc.).
Public health agencies and regulatory bodies	Engage with and keep periodically up to date on project progress through publications, public webinars, website updates.
Patient and disease-specific organizations	Establish frequent, efficient contact with the overarching patient and disease-specific organizations to keep them informed of FACILITATE's progress, findings, and major project developments via publications, webinars, website updates
Study participants	Specific requirements for participants in the study will be determined before recruitment for the research activities (not planned to perform specific CTs).
Health-care providers and clinical researchers	Engage with and keep periodically up to date on project progress through publications, public webinars, website updates.
Healthcare provider organizations	Engage with and keep periodically up to date on project progress through publications, public webinars, website updates.

Members of Ethics board	Engage with and keep periodically up to date on project progress through publications, public webinars, website updates. Targeted communications re: specific outputs on ethical and related issues from WP8, including the end of the project report.
Healthcare payers/insurers	Keep periodically up to date on project progress through publications, public webinars, website updates.
General public	FACILITATE will reach out to the general public to create awareness on the importance of return and reuse of the clinical trials' data and the project results.
Scientific community as universities and other academic institutions	The scientific community will be reached, for instance, at international conferences or symposia (by networking, poster, or oral communications) and via scientific publications.
Industry research and development key opinion leaders, pharma companies, and related institutions	Engage with and keep periodically up to date on project progress through publications, public webinars, website updates.
SMEs	Technological SMEs offering secured data exchange to patients
Related initiatives	Ongoing IMI2/H2020/HE and research projects that share research interests or other ongoing initiatives. They will be identified during the project life and connections will be established in pursuit of mutual benefit.
FACILITATE partners	Need to be updated on project activities and deliverables. Input sought from project partners on activities completed in the last quarter or where input from other WPs is needed. Project partners will update their own organizations on project activities and deliverables.

Table 3: The target audience of the DiCEP

2.4 Open access repositories

According to the guidance on open access, the appropriate measures to grant open access to all scientific publications resulting from FACILITATE will be adopted by the consortium. Each partner must ensure open access (online access for any user, free of charge) to all peer-reviewed scientific publications relating to their results. The Consortium will set up the FACILITATE Project community within a repository selected from the recommended lists of online archives provided by OpenAIRE and ROAR, in accordance with the Grant Agreement and the EU. Main deliverables, publications, guidelines, and open data will be deposited in the official repository of FACILITATE.

The project has an active page on the OpenAIRE website:
https://explore.openaire.eu/search/project?projectId=corda__h2020::5890aa6ec0b56e1b228b67f88e26f78b

The project coordinator is responsible to update the open access repositories. All the partners have to share the open access publications, research data, software, or other research data.

At the end of the project, a deliverable will be released to report on the Open Access activities [D6.10]. The consortium will follow the instructions set in the Guidelines on FAIR Data Management in H2020[2].

[2] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

2.5 Management of the DiCEP

The project's Communication, Dissemination, and Exploitation Plan is developed during the first 6 months of the project and is also presented to all partners during the project's kick-off meeting. Most of the partners are involved in its implementation, with few exceptions[3]. The GANTT of the DiCEP is available in **Annex I**.

WP6 Leaders (ACN and TAK) and the project coordinator (UNIMORE) are responsible for the implementation of the plan and its strategies. ZEN is in charge for website and dissemination material and EUPATI for the training activities. Many other Beneficiaries are actively involved in WP6 as VUB, TUNI, PN, AOU, MUG, UJ, IMR, SCC, PZNW, Eurac, EURORDIS, SARD, ABV, BAY, PFZ, TAK, and ALM.
The ExCom (Executive Committee) monitors the implementation of the plan (see deliverables D1.3-D1.4-D1.5-D1.6) through an annual report.

The DiCEP is developed by the Consortium partners. All partners shall appoint a person as the main contact for the communication and dissemination activities when the structure of the deliverable is set up. This group is called the "Communication Working Group" (CommWG): representatives have the right to validate content, according to the processes explained in par. 2.5.1

A distribution list (commwg@EU) will ensure that all partners are informed and are offered the opportunity to validate the content of any relevant news/information concerning the project's activities:

All activities performed during the implementation of the DiCEP are registered in the Teams repository and made available for the periodic reports.

2.5.1 Content validation process

To ensure the quality and effectiveness of any communication activity (i.e., post on the website, post on social media, a tool), the validation process guarantees that the published information is previously validated by all Partners through the CommWG. The persons appointed in the CommWG are entitled to act as a validator of any type of content.
The validation request is shared 1 week before the publication if general project-related information will be published. If project results have to be published a validation time of 3 months has to be taken in consideration. The requester will add in the main objective "[Validation] Twitter/Facebook/Linkedin/Website content – deadline ___". In both instances, no answer in duly time will be interpreted as implicit validation by the Partner.

2.5.2 Patient involvement in the DiCEP management

Patients will be part of the decision-making process and be directly involved in activities within WP6, ensuring that the communication and dissemination strategy identified correspond to patient views, needs, expectations and preferences. The website will be translated in at least 5 European languages to facilitate the lecture for non-english speaking people.

3. Communication and dissemination

3.1Communication and dissemination strategy

Communication activities pursue the objective of reaching out to society and showing the impact and benefits of EU-funded projects, e.g., in addressing and providing possible solutions to

[3] (7) ODYSSEUS; (9) INPECO; (10) ADERA; (20) MDSOL; (22) ASTRAZENECA; (27) SERVIER

fundamental societal challenges. To this end, the focus is on informing and promoting the Project along with its results and achievements to multiple audiences, beyond the Project's own community. FACILITATE will pioneer a new concept in returning clinical trials' data to patients, and anticipates the innovative employment of the secondary use of data already generated.

Project partners shall aspire at acting together as much as possible in any **dissemination activity** to strengthen the Consortium identity and highlight its synergetic effort towards a common vision. In light of the highly multidisciplinary nature of FACILITATE, we foresee that most of the dissemination output will be jointly co-authored/co-presented. When carried out by individual partners, dissemination activities will be, whenever possible, framed within the wider context of ethical and legal objectives of FACILITATE.

The FACILITATE consortium has designed its communication/dissemination activities to achieve three primary inter-related objectives:

- promote EU-funded research;
- support and promote scientific and technological results, bridging dissemination and exploitation;
- establish a constructive and informed dialogue between science and society.

Dissemination activities will be supported by communication activities, as well as by communication material. Further, by helping in making results available for re-use and take-up, dissemination activities will also support exploitation and valorisation of the Project's results.

Figure 1: Examples of communication (left) and dissemination (right) activities

All communication/dissemination activities will clearly acknowledge EU funding [*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*] to promote EU commitment to innovation and to link the results under the unifying umbrella of FACILITATE. Whenever possible, dissemination results will target open access to maximise knowledge sharing.
On the website, a page will collect the publicable documents as open access publications and public deliverables. Confidental documents will be collected on TEAMS.

Communication efficacy assessment. Feedback from event participants (e.g., through questionnaires), from Consortium members involved in communication activities, and from popularity statistics stools (e.g., Twitter and Google Analytics) will help refine the communication/dissemination strategy, which will be regularly reassessed during focused communication meetings.

3.1.1 At the beginning of the project

At the initial phase, as no results will be available, the communication strategy will focus on raising project awareness among the stakeholders' community. When the first project results will become available, dissemination of project outputs will start and they will last until the end of the project.
The main activities at the beginning of the project are:

I. drafting press releases for IMI and partners before and just after the project start;
II. developing the website landing page, with preliminary information about the project's goals;
III. setting up the social media accounts;
IV. drafting a brief presentation of the project;
V. developing a project "corporate" image to ensure a unified project image;

3.1.2 Throughout the project's duration

I. ZEN will be responsible for uploading, updating, and maintaining the contents of the website. The website will be progressively enriched with information concerning the developments and achievements of the project;
II. Organizing dissemination tools like newsletters, brochures, templates, social media, introductory project posters, and slideshows to facilitate presentations at events and to support individual meetings, as well as the use of social media networks to raise awareness of the research and its results;
III. Press releases and social media campaigns addressed to the different stakeholders;

3.1.3 At the end of the project

I. All the partners will contribute to the dissemination of the results;
II. Updating open access repositories.

3.2 Communication tools and objectives

To promote the impact of the project on targeted end-users, the project must be broadly communicated and disseminated which will involve all activities by which project-related knowledge is provided to relevant stakeholders and other interested parties (including the general public) at local, national, European, and international level. The project dissemination activities will be targeted to make knowledge and the results of the project available to relevant stakeholders. The implementation of the dissemination and communication strategy is led by the WP6 and T6.1 Leaders, together with the active engagement and support of the entire consortium.

A varied portfolio of communication tools is developed to support communication and maximise the dissemination activities planned:

3.2.1 Project logo and visual identity

The **logo** of the FACILITATE project is depicted below (the selection between different options of the logo by the Consortium was closed on December 24th, 2021):

Figure 2. FACILITATE Logo

The FACILITATE logo highlights the connection between different data in the network and emphasises the creation of bridges between the different stakeholders, data repositories, and the solutions to provide those data to patients.

Two main colours have been defined to represent the project concept: the Light blue [#26ACC2 (RGB: 38 172 194)] and the second colour, Dark blue [#2F4FA1 (RGB: 47 79 161)]. They stand for the intensity of FACILITATE's networking, the darker, the more connected.

The logo should always be shown as clearly as possible and must not be overwhelmed by other visual elements. The logo and its components must never be altered or modified in any way. The logo is most effective when positioned on a clear background, which helps to protect its integrity. The logo should always be used in full. To keep a consistent project image, the FACILITATE logo available versions cannot be modified (font type or size, colours, etc.).

Several versions of the logo (that can be used alternatively according to the circumstances: print support, number of available colours, etc.) have been deployed and are available, including all graphics details, in **Annex II**. The logo versions are available to all the FACILITATE participants on Teams.

3.2.2 Digital and printed visual material

FLYERS – BROCHURES: All partners will contribute to producing the project's flyers in the relevant languages to inform all relevant target groups about the results and the deliverables of the project. Flyers or e-versions will be distributed through all relevant channels to all relevant stakeholders and target groups. Possible channels for the distribution of the flyers are seminars, conferences, meetings with stakeholders, and other relevant events. Flyers and Brochures will be also made available in pdf versions on the website.
ZEN with the support of ACN and UNIMORE will design and develop the English version of the project's flyer. After the finalization of the English version, partners will be in charge of translating it into the project's relevant languages.
Each partner will be responsible for distributing the flyer to as many people as possible.

POSTERS: The principal pictures of the project results in their different stages are worked out into posters that can be used in workshops, conferences, events, and other relevant dissemination activities, both online and in presence.

ROLL UP: A roll-up for the project dissemination in congresses, meetings, and other events to give visibility and image to the different events organized by the partners or those who attend as guests.

3.2.3 FACILITATE website

The FACILITATE **website** address is https://facilitate-project.eu/. The FACILITATE webpage will display public information about the project, the involved participants, contact information, deliverables, and related articles and news. At the beginning of the project, the website will only display basic information but over time the website will be fully established, full content will be available upon January 1st, 2022, and will be constantly updated from thereon. Deliverable D6.2 is dedicated to the website description and main functionalities.

3.2.4 FACILITATE social media profiles

Social media accounts – **Twitter**, **Facebook, Linkedin, and YouTube** are created and maintained to communicate about the project and its results, events, interviews, and also to drive traffic to the project's website. Contents will be developed in English, and, if needed, in other languages of the FACILITATE partners.

ACN will develop the project's social media profiles at the very beginning of the project and is supported by the coordinator regarding the profiles' visual aspects. ACN is responsible for the administration and maintenance of the project's social media profiles. UNIMORE will act as the second administrator.

Twitter	@imi_facilitate
Facebook	/imi_facilitate
Linkedin	https://www.linkedin.com/company/imi-facilitate/

The use of hashtags is fundamental for the effective use of social media. Each post should include: #IHI #FacilitateProject. The definition of the hashtags will be an ongoing process that will be updated at least twice a year. If the post is defined on the partner's account, the FACILITATE project must be included in the text @imi_facilitate.

FACILITATE members must actively engage with the project's social media profiles by following them and sharing relevant content with their respective networks. Their contribution in this area will help ensure that all key stakeholders are reached and that, consequently, FACILITATE messages are amplified and properly delivered.
The social media strategy is part of **Annex III.**

3.2.5 Videos

To enforce the project's dissemination, promotional videos will be developed and included on the website. Initially, three short videos (Project Coordinator, Project Leader, Patients) will introduce the project from different points of view. Furthermore during the lifetime of FACILITATE other videos will be developed following its main milestones. More specifically, basic videos are going to be produced:
- 3 short introductory clips,
- two along the project's key moments,
- one web doc for the final workshop.

3.2.6 Newsletter

FACILITATE will issue a quarterly newsletter to notify and update the project's progress and achievements and other aspects related to the project. An editorial board has been created with one member per WPs and countries who will contribute to identifying topics of interest, developing content, and reviewing the newsletter before its launch. A mailing list has been created to facilitate communication: editorial@facilitate-project.eu.

Internal FACILITATE newsletters will be distributed electronically by email and archivied on TEAMS. Public current and past newsletters will be available on the website and will be sent to the project partners, IMI officers, experts, associated collaborators, advisory boards members, and other people who have signed up to receive it (sign up option available in the newsletter and on the website, personal data of the subscriber will be treated accordingly to the GDPR).

3.2.7 Press releases

Press releases, prepared by the partners of the project, can be launched by its coordinator, accompanying major public achievements of the project, like public workshops and exhibition events. These press releases could also be translated and launched by partners in their own country. With these press releases, the project will be known not only among stakeholders but also in the wider realm of society.
A checklist will be distributed, where all partners can check all press releases planned, to have a full roadmap of the process.
Printed and online media can be used as a dissemination tool for our project. Information about the project can also be published in newspapers, magazines or online media addressed to the project's target groups.

3.2.8 Webinars

Webinars will be organized regularly, to inform the stakeholders about the project results.

3.3 Events

Conferences and workshops provide an excellent opportunity for specialists and non-specialists to meet each other, face-to-face, debate, and exchange information.
An interesting possibility is to co-locate these workshops with major events, organised by other stakeholders across Europe, to maximise exposure and attendance. The objective will be to sensitise local stakeholders and the public on the project's results.
Alternatively, each partner may present the project to specific target groups or organizations. Thus, providing detailed information about the project products and attracting organizations to use them.
The FACILITATE events are linked to the Stakeholder involvement plan (D6.3) and its research activities.
All partners can present the project progression during events. To ensure the quality, the presentations will be previously validated by all Partners through the CommWG.

The validation request is shared 1 week before the event if general project-related information will be presented. If project results have to be presented a validation time of 3 months has to be taken in consideration.

3.3.1 Workshops

Two workshops will be organized: (1) Ethical and Legal Expert Decision Committee (EDC(B)) workshop to discuss and align with DP authorities by EURAC at M36 (D2.7) and (2) project results presentation workshop by ACN at M46.

Event	M6	M12	M18	M24	M30	M36	M42	M48
EDC(B) workshop								
Result presentation workshop								

3.4 Dissemination tools

To provide clarity and to enhance the quality of the presented material, the consortium agrees that all dissemination activities should follow several important principles:

- To respect the Intellectual Property Rights (IPR) of all partners
- To respect and recognize the work of all partners by ensuring the proper reference of all relevant parties whose work is directly or indirectly mentioned in the proposed publication
- To promote transparency of procedures
- To protect confidential results
- To coordinate actions to avoid overlapping or duplication of dissemination activities
- To set criteria to distinguish between results suitable for dissemination and exploitable results
- To target the appropriate audiences
- Following Article 38.1.2 “Information on European Union (EU) funding – Obligation and right to use the EU emblem”, all dissemination material should mention the project name FACILITATE and GA number, as well as the IMI financial support to the project and the EU and IMI emblem
- Where appropriate, the project visual identity should be included
- Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results as well as open access to research data
- Any dissemination of results must indicate that it reflects only the author's view and that the EC is not responsible for any use that may be made of the information it contains.

The plan for the dissemination of the results of the project will answer: WHO (target audiences) will receive WHAT (key messages), HOW (methods), and WHEN (implementation and time planner).

Target audience (WHO)	Key messages/ content and goals (WHAT)	Main methods (HOW)	Frequency (WHEN)
Scientific community	The early phase of the project: Promotion of FACILITATE plans and the urgency/necessity of research. During the project and towards the end of the project we will disseminate results and progress updates.	Papers in high-impact journals: all publications resulting from the project will acknowledge IMI and the FACILITATE project, according to IMI and specific FACILITATE communication guidelines.	Periodically
		Presentations at scientific conferences and symposia	
		Publication of public deliverables on the project website	
European Commission, Local governments/authorities	Early and during the project: Progress updates regarding the entire project towards the end and after the project	Technical progress reports	Every 12 months
		Progress/update report including scientific results as well as the status regarding dissemination, exploitation, and policy/guideline development	

Policymaker organizations	The early phase of the project: Promotion of the project and awareness creation	Coordinator contacts, Personal invitations from Consortium partners to events and website; introduction website	Once
	Throughout and towards the end of the project: Laymen status updates regarding the project results	Updates through a specific section at the project website	Periodically
Stakeholders inclusive patients, clinicians & healthcare professionals, pharma industry/sponsors and Healthcare actors on a broader spectrum	Active involvement in the activities of FACILITATE	Stakeholder platform, meetings	Periodically

Table 4: Target audience, relevant messages, and methods

3.4.1 Publications

To give value to the ethical, legal, technological and socio-economic research generated from the project, a detailed publication plan will be provided taking into account their relevance to broad or specialized audiences and their open access and embargo policies. The consortium will adopt a gold open access model whenever possible and a green access model for any publication, respecting the publisher's embargo period.

3.4.2 Scientific and industrial conferences

The Consortium has identified and compiled a list of scientific conferences targeting broad and specialized audiences in the main scientific pillars of the Project and their branch disciplines, as well as industry-oriented events relevant to the technology pillars of the Project (AI, big data analysis, GDPR, and legal issues). The events list is shared through the FACILITATE Microsoft Teams and constantly updated. The table below reports the list of relevant events identified so far.

3.4.3 Main deliverables and guidelines

The Consortium has planned to deliver 56 deliverables during the implementation of FACILITATE. Some of these deliverables and guidelines are considered as public, useful for the public at large as well as for stakeholders.
The following deliverables will be published on a dedicated page of the website, as well as on TEAMS:

No.	Deliverable title
D1.1	Consortium handbook
D1.2	Expert Decision Committees establishment and management rules
D1.8	Scientific Advisory Board establishment and management rules
D2.6	Legal clauses
D2.7	EDC(B) workshop to discuss and align with DP authorities
D2.8	Outcome of consultations with local DP authorities
D2.9	Final legal report
D2.10	Guidance document for clinical studies
D3.1	Ethical framework
D3.2	Final set of guidelines
D3.3	Ethical standards and guidelines No. 1

D3.4	Ethical standards and guidelines No. 2
D3.7	Reutilization of data for returning and secondary use strategy
D6.1	Communication, dissemination and exploitation plan
D6.2	FACILITATE Website
D6.4	Report of the stakeholders involvement plan results No. 1
D6.5	Report of the stakeholders involvement plan results No. 2
D6.6	Report of the stakeholders involvement plan results No. 3
D6.8	Manifesto and project results presentation workshop
D6.9	Training guidelines
D6.10	Participation in the Open Research Data Pilot
D7.1	Report on stakeholders' needs and potential barriers

Table 5: FACILITATE public deliverables

3.4.4 EU and IMI2 official channels

The Consortium will benefit from existing tools provided by the EC or IMI2 concerning the dissemination of results:

- EC: Cordis, project results page
- EC: Horizon results platform
- IMI2: website (publication of project factsheet, success stories, newsletter) and social media (Linkedin and Twitter)
- IMI2/IHI Catalogue of tools

4. Exploitation and sustainability

4.1 Exploitation and sustainability strategy

Exploitation activities pursue the objective of effectively using the Project's results through scientific, economic, political, or societal exploitation routes aiming at turning research and innovation actions into a concrete value and impact for society in general. To this end, the main focus of exploitation activities is engaging with people/organizations within and outside FACILITATE to pursue a concrete use of research results, including, but not limited to, commercial use whenever applicable.

Beyond academic research, the project outcomes may present commercial value. The consortium's expertise and technology under the frame of a fair long-lasting partnership, cover the following points:

- Agreements (*e.g.*, intellectual property rights agreements) with potential investors and end-user companies.
- Identification of potential markets.
- Systematic screening of publishable results before dissemination for intellectual property (IP) protection.
- Identification of strategies for potential market opportunities during the next five years after the project ends.

Commercialisation – Industry, and academia are not planning to commercialize a solution during the project. However, the process and associated tools will be defined to answer the needs, requirements, and expectations of the stakeholders' community, who can be the clients of a marketed solution derived from the outputs of the project.
In this respect, the sustainability plan will deploy a go-to-market analysis, identifying the economic potential of a marketable solution and, if needed, qualifying the potential additional resources needed to offer a technically and commercially viable solution.

4.2 Exploitation activities

4.2.1 Cross-fertilization with other EU-funded projects relevant for FACILITATE

The Table below is a preliminary analysis of the past and ongoing projects that can be relevant to FACILITATE, as listed in Annex A of the GA. This list will be updated during the project's lifetime.

Project/Initiative	Funding information	Linked Partner
PDAI (Patient Data Access Iniziative)		Pfizer
EUCROF (European CRO Federation)		
BBMRI ERIC	H2020	MUG, EURAC
SIENNA	H2020	EURAC
EHDEN	H2020-IMI2	ODYSSEUS
EHR2EDC	H2020-EIT Health	SANOFI
Governance of health data in cyberspace	Nordforsk	EURAC
AFFECT-EU	H2020	UNIMORE
HERMES	H2020-FET	UNIMORE
EASI	H2020	UNIMORE
SPIDIA4P	H2020	MUG
CY-Biobank	H2020	MUG
iBioStroke	H2020-ERA-LEARN	UJ
Instand-NGS4P	H2020	MUG
TENDER	H2020	VUB
PROTEIN	H2020	VUB
AI4HEALTHSEC	H2020	PN
PICASO	H2020	VUB
ACIDinCIBP	H2020-ERA-LEARN	AOU
H20	H2020-IMI2	SANOFI
HMA-EMA Joint Big Data Taskforce EMA/105321/2019	EMA	ADERA
EMA Regulatory Science to 2025 Strategic reflection	EMA	ADERA
DO-IT	H2020-IMI2	SANOFI

Table 6: Link of relevant EU-funded projects

4.2.2 FACILITATE Business Plan

A robust Business Plan will be created within the activities of WP7 that supports the design of the prototype process to ensure it is mature enough to pave the way for the development of a sustainable and effective platform after the end of the project. The Project is oriented to reach a Technology Readiness Level 3 – experimental proof-of-concept. Therefore, the Consortium will primarily concentrate on the non-commercial exploitation of the scientific results while technological outputs will be primarily protected using patents. Nonetheless, market opportunities must be evaluated for the long-term valorization of the Project's achievements.

This Business Plan will be implemented during the project including marketing of the solutions to relevant end-users. It will contain the following sections:

1) The Executive Summary,
2) The Business Description,
3) Market Analysis,
4) Competitive Analysis,
5) Sales and Marketing Plan,
6) Ownership and Management Plan,
7) Operating Plan,

8) Financial Plan,
9) Appendices and Exhibits.

4.2.3 FACILITATE Manifesto

As an advocacy tool for patients and their associations, a "Manifesto for the right to access to clinical trial data" to provide correct information, increase widespread awareness, sup the National Health Service and health professionals, and recreate empowerment on this issue, will be developed at the end of the project. The Manifesto will refer to the Recommendations provided as an outcome in T6.3.1, to define a possible space for such a 'European wide' process.
The Manifesto will be provided to the European Institutions with the direct involvement of the IMI Board and EFPIA representatives in the framework of an event of the MEPs Interest Group "European Patients' Rights and Cross-border Healthcare" promoted by ACN and supported by several civil society organizations and networks dealing with health.
It is expected that no less than 30 civic and patients' associations, not yet involved in the prototype process development, will sign the Manifesto (see KPIs).

4.3 Sustainability activities

4.3.1 FACILITATE business sustainability

From identified stakeholders' needs and possible implementation strategies, a final report detailing the optimal sustainability options and its implementation strategy [D7.3] will be identified. This report will qualify the requested next steps from the Proof of Concept (PoC) demonstration platform created in WP5, to define an operational platform that is functional to support the whole process and the associated tools developed throughout the project, as defined in WP 2 and 3 and in line with any regulatory or data protection guidelines that have been recommended The needs, barriers and risks identified in T7.1 and T7.2 will allow identification of the potential financial and/or expertise contribution required for the development of an operational platform/ associated tools, ultimately enabling market availability of a solution to all stakeholders.

4.3.2 Transition strategy in the healthcare system

For the EU health care systems to shift the focus to patient-centered outcomes, using existing resources more effectively and efficiently, the optimization of the overall care pathways in a continuum that goes from the (early)-diagnostic to the therapeutic approach is requested. FACILITATE aims at overcoming the present governance of individual "silos" variables and sets the scene for managing the entire clinical trial healthcare process.
By re-using and integrating data from different sources FACILITATE will allow Regulatory bodies to better understand how and when to authorize accelerated patient access to innovative pharmaceutical products. FACILITATE will thus profoundly impact EU citizens by its innovative approach to Clinical Trials and by doing so it will bring back the competitiveness of the Old Continent in the field of drug development, regulatory, clinical, and healthcare practices, and decision-making processes. The output is a concise document illustrating the platform capabilities and potentials to be submitted to decision-makers and healthcare professionals [D7.4].

5. Monitoring the implementation of the DiCEP

5.1 Key Performance Indicators

The KPIs related to the DiCEP have been divided into "Communication and Dissemination", and "Exploitation and Sustainability". A detailed list of indicators and methods is the following:

Communication and Dissemination

No.	Indicator	Measurable unit	Target
1	Planned peer reviewed publications	Number of items	10
2	Communication materials on the FACILITATE website	Number of communication materials	10 in at least 5 languages
3	Hits on the FACILITATE website	Number of hits	≈100 monthly
4	Downloads from the repository	Number of downloads	20
5	Social media followers on Twitter, Facebook and LinkedIn	Number of followers	100
6	Number of reports in non-scientific traditional media (TV/radio, non-scientific press)	Number of reports	5
7	Number of FACILITATE events (poster and oral communications)	Number of events	15
8	Direct engagement with end users, including through participation in (policy) workshops, events and participation in meetings	Number of end users engagements	50

Table 7: KPIs of Communiction and Dissemination activities

Exploitation and Sustainability

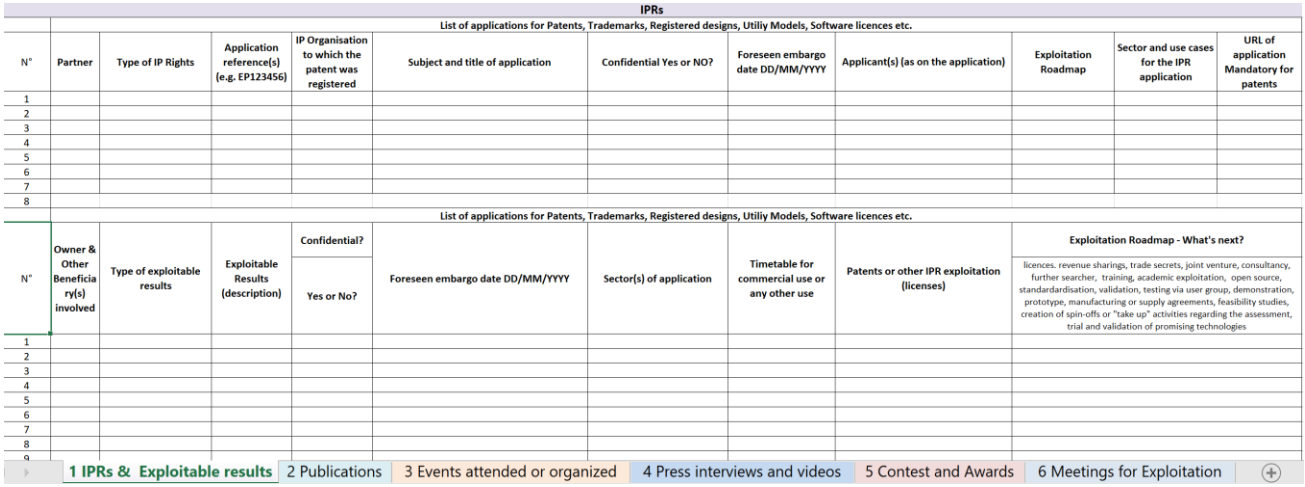
No.	Indicator	Measurable unit	Target
1	FACILITATE Business Plan	Business plan ready	1
2	FACILITATE Sustainability plan	Sustainability plan ready	1
3	FACILITATE Manifesto	Manifesto ready	1
4	FACILITATE transition strategy to the healthcare sector	Strategy ready	1

Table 8: KPIs of Exploitation and Sustainability activities

The list of KPIs will be updated during the project implementation, according to the ExCom decisions.

5.2 Monitoring tools

The PMO will keep track of the project's communication and dissemination activities for the IMI2 JU reporting. Participants, through their appointed Communication Working Group (see par. 2.5) will be asked regularly to provide information on any communication or dissemination activity related to FACILITATE they are involved in: this information should be entered directly into a general tracking table available in Teams. As needed, the PMO will collect and integrate all the available additional information on general communication or dissemination into the tracking table. Participants will be asked also to check the list of already reported activities, to ensure the completeness of the information.



IPRs

List of applications for Patents, Trademarks, Registered designs, Utiliy Models, Software licences etc.

N°	Partner	Type of IP Rights	Application reference(s) (e.g. EP123456)	IP Organisation to which the patent was registered	Subject and title of application	Confidential Yes or NO?	Foreseen embargo date DD/MM/YYYY	Applicant(s) (as on the application)	Exploitation Roadmap	Sector and use cases for the IPR application	URL of application Mandatory for patents
1											
2											
3											
4											
5											
6											
7											
8											

List of applications for Patents, Trademarks, Registered designs, Utiliy Models, Software licences etc.

N°	Owner & Other Beneficiary(s) involved	Type of exploitable results	Exploitable Results (description)	Confidential? Yes or No?	Foreseen embargo date DD/MM/YYYY	Sector(s) of application	Timetable for commercial use or any other use	Patents or other IPR exploitation (licenses)	Exploitation Roadmap - What's next?
									licences. revenue sharings, trade secrets, joint venture, consultancy, further searcher, training, academic exploitation, open source, standardardisation, validation, testing via user group, demonstration, prototype, manufacturing or supply agreements, feasibility studies, creation of spin-offs or "take up" activities regarding the assessment, trial and validation of promising technologies
1									
2									
3									
4									
5									
6									
7									
8									

1 IPRs & Exploitable results | 2 Publications | 3 Events attended or organized | 4 Press interviews and videos | 5 Contest and Awards | 6 Meetings for Exploitation

Figure 3: IPR, communication, dissemination tracker

5.3 Monitoring reports

To ensure the effectiveness of the communication and dissemination activities implemented throughout the project's lifetime and that the above key performance indicators are met, a monitoring system will be developed and set for this purpose.
Every year, all members of the CommWG asset are on par. 2.5 will be requested to prepare and deliver to the ExCom a brief report detailing the communication and dissemination activities implemented in that period. The following table indicates the dates of submission of internal communication reports for monitoring and assessment:

Reporting Period	Deadline
01/01/2022 - 30/11/2022	10/12/2022
01/12/2022 - 30/11/2023	10/12/2023
01/12/2023 - 30/11/2024	10/12/2024
01/12/2024 - 30/11/2025	10/12/2025
01/12/2025 – end of the project	Info to be part of the Final Report

Table 9: Reporting timeline

Once filled in, the templates described in par 5.2 from each partner will be sent to ACN and UNIMORE to develop the overall communication and dissemination report, synthesizing all partners' feedback and remark (**Annex 4**).

6. Publication policy

6.1 What is the project's authorship policy?

The project's authorship policy follows the generally accepted rules for academic publications, as per the International Committee of Medical Journal Editors (http://www.icmje.org/) / http://www.icmje.org/icmje-recommendations.pdf (citations marked in blue below)

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
2. Drafting the work or revising it critically for important intellectual content; and
3. Final approval of the version to be published; and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. These authorship criteria are intended to preserve the status of authorship for those who deserve credit and can take responsibility for the work.

1. Authorship positions and the Corresponding Author will be discussed, ideally, before the work is started, by respective Work Package Leads (WPL). The Executive Committee (ExCom) will mediate in case of conflict. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms.

   According to ICMJE, the corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer review, and publication process, and typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and gathering conflict of interest forms and statements, are properly completed, although these duties may be delegated to one or more co-authors. The corresponding author should be available throughout the submission and peer review process to respond to editorial queries in a timely way and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication.

2. All scientific publications stemming from the project should include the following authorship list- the statement "...*the FACILITATE Investigators*" and a full list of FACILITATE Investigators (by the institution) should be listed in acknowledgments for the main publications. For clarity, the full list of FACILITATE Investigators means the investigators who are involved in the relevant WP(s), and for other WPs this would be limited to Principal Investigators (PIs) who are mentioned in the DoA.

3. Co-authors must be kept informed. All individuals who meet the first criterion for authorship should have the opportunity to participate in the review, drafting, and final approval of the manuscript. The authorship criteria are not intended for use to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3: drafting the work or revising it critically for important intellectual content, and final approval of the version to be published.

4. All authors will reserve the right to withdraw from authorship at any time. All acknowledgments must be with the consent of the persons involved.

5. A person who has contributed to FACILITATE but does not meet all four criteria for authorship of the manuscript (see above) should be listed in the acknowledgments section of the same.

6. Free and comprehensive acknowledgment of individuals and groups who have given non-academic support should be done wherever possible (i.e. "*We gratefully acknowledge...*"). For FACILITATE those meriting acknowledgment are defined as/ having provided:

- materials or methods
- organisational support;
- clinical cases (but not otherwise involved);
- technical support;
- service lab support;
- patients and their relatives;
- funding bodies;
- internal peer review of manuscript or scientific advice;
- participated in writing or technical editing of the manuscript.

6.2 Reporting Scientific Communications

WP6 members with the support of the PMO will provide the FACILITATE participants with a semester updated list of the scientific publications produced within the Consortium. WPLs will be requested to inform the PMO about publication plans for manuscripts related to their respective work packages: draft title, intended authors, target journal, intended submission date.

6.3 What is the internal procedure for Publication review?

A partner may only disseminate any results if it has circulated the proposed dissemination to the other Beneficiaries by written notice at least 30 days in advance. Any beneficiary may object to proposed dissemination within 30 days of notification for general dissemination proposals if it can show its legitimate interest in relation to the Results would be significantly harmed. More details on the reasons for objections can be found in section 7.5.2 of the Consortium Agreement.

6.4 Acknowledgement

In line with the IMI FACILITATE Grant Agreement, all dissemination activities related to the FACILITATE Project (manuscripts, press articles, project websites, presentations, flyers, press releases, patents, etc.) must include the following elements:

1. The following phrase referring to the IMI/EU funding and the EFPIA contribution:
   "FACILITATE 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".

2. A link to the IMI website: http://www.imi.europa.eu
3. IMI, EU, EFPIA, and Associated Partners logos, available in Teams.
4. Some communication formats (e.g. short communications in peer-reviewed scientific journals) may not allow the inclusion of logos and web addresses. In these cases, the acknowledgment phrase will suffice.

To raise the project's profile and create awareness, the Consortium encourages the inclusion of a reference to FACILITATE in all publications from FACILITATE investigators, although publications may not be derived from the work done in FACILITATE:

"X, Y, and Z (authors) are members of the project FrAmework for ClInicaL trIal participants' daTA reutilization for a fully Transparent and Ethical ecosystem (FACILITATE). FACILITATE 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".

The inclusion of this acknowledgment in non-FACILITATE publications is encouraged but not mandatory. For clarity, the inclusion of the acknowledgment is mandatory for publications derived from FACILITATE-funded work.

6.5 Open Access

Each partner must ensure open access (OA) (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results in compliance with Article 29 of the Grant Agreement.

According to the Grant Agreement, this obligation includes:

1) as soon as possible and at the latest on publication, depositing a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;
   a) ensuring open access to the deposited publication — via the repository — at the latest:
   b) on publication, if an electronic version is available for free via the publisher or
2) within six months of publication in any other case.
3) ensure open access — via the repository — to the bibliographic metadata that identifies the deposited publication.

The bibliographic metadata must be in a standard format and must include all the following:

- the terms "Innovative Medicines Initiative 2"; "European Union (EU)" "Horizon 2020"; and “EFPIA”;
- the name of the action (FrAmework for ClInicaL trIal participants’ daTA reutilization for a fully Transparent and Ethical ecosystem), acronym (FACILITATE) and grant number (Innovative Medicines Initiative 2 Joint Undertaking No (Project n° 101034366);
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

For clarity, the open-access obligation in IMI projects includes both Gold and Green Open Access.

FACILITATE has a limited budget planned for open access publication costs amounting to 10.000 € held by UNIMORE. Therefore, it is encouraged, that in the first instance, partners explore other sources of funding for OA costs (internal funds, national grants, etc.). Open access publication funds will be allocated to the partners upon the decision of the Steering Committee, based on objective criteria:

1. Only publications directly linked to the DoA deliverables will be considered for funding from FACILITATE budget;
2. Publications in journals with a high impact factor or those within the top 3 journals in the respective specialty;
3. The Steering Committee will ensure that this budget is distributed fairly across WPs;
4. Consideration of the project duration, so that the fund is not fully spent well before the end of the project.

The above criteria are preferences, but specific cases may allow for exceptions from these. Unpredicted publication opportunities not covered by the DoA (including journals that may be addressed to a certain stakeholder group, industry journals, etc.) but with a supposedly high or valuable impact may be discussed and considered in agreement with the SC. In case the consortium submits to a high-impact conference that does not have open access as conference proceedings, the

value of the conference should be measured beforehand, and it should be agreed whether to submit or not.

In general, the publication policy will be updated when and where necessary, with the agreement of the SC.

Annexes

ANNEX I. FACILITATE visual identity

Reinforcing FACILITATE in a sustainable way is one of the core objectives of the DiCEP and the relevant activities foreseen. Hence, communication activities ensure that the project improves the visibility of its outcomes and results and builds foundations for long-term Public Relations (PR) management.
To this direction, the project's visual identity will be developed to contribute to the overall perception of the project and its uniform impression. It will include elements that will represent the project in a distinct and consistent way, such as the project's logo, fonts, templates, etc.).
Below, the key elements and principles of the project's visual identity to be always considered:

- In each template / document developed within the project, the project's title and agreement number should be mentioned. Project's logo should also be included in each page of the template / document.
- The EU logo and the disclaimer provided in the cover page of the Dissemination Plan should also be included in each template / document developed within our project to clearly show and highlight that this is an EU-funded project.
- In each project's template / document the logo's colors palette can be used for highlighting titles of sub-titles: Arial size 11 will be used for the development of texts of all word documents, while Arial size 18 will be used for the development of PowerPoint presentations.
- 1/1,5 line spacing will be applied in all cases.

For the development of documents (e.g deliverables format) and PowerPoint presentations, partners will use the templates made available in the project's repository.

LOGO different solutions

Project's logo is the most basic communication activity, as it will be the main image linked to our project. Furthermore, the development of our logo is essential in order to proceed with all the other dissemination activities.
4 different logos have been designed by ZEN and SARD. 41 people, at least one from all partners, voted. The votes were weighted resulting in one vote per partner. Logo number 4 was resulting the most successful.

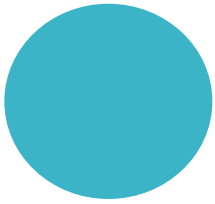
1)

2)

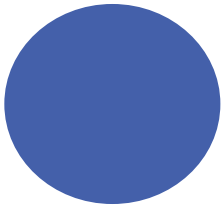
3) 4)

The colors palette used is the following:

Light blue
#26ACC2
RGB: 38 172 194



Dark blue
#2F4FA1
RGB: 47 79 161



ANNEX II. Social media strategy

Dissemination tool/channel	Target group	Frequency	Key Messages
Facebook	• Researchers/academia • Consortium and Scientific Advisory Board (SAB) members • Research institutions • Coordinators and researchers in sister-projects, both H2020 and publicly-funded • The European Commission (EC) • Patient associations • Pharma companies • Patients	**At least once every two weeks**	• The positive impact of the project through the H2020 Programme and how it is going to impact the society • Promotion of the FACILITATE working prototype • Distribution of information about FACILITATE • Promotion of the project's events • Relevant news on project topics (GDPR, Ethics, Technology innovation)
Linkedin	• Researchers/academia • Consortium and Scientific Advisory Board (SAB) members • Research institutions • Coordinators and researchers in sister-projects, both H2020 and publicly-funded • The European Commission (EC) • Patient associations • Pharma companies • Patients	**At least once every two weeks**	• The positive impact of the project through the H2020 Programme and how it is going to impact the society • Promotion of the FACILITATE working prototype • Relevant news on project topics (GDPR, Ethics, Technology innovation)
Twitter	• Researchers/academia • Consortium and Scientific Advisory Board (SAB) members • Research institutions • Coordinators and researchers in sister-projects, both H2020 and publicly-funded • The European Commission (EC) • Patient associations • Pharma companies • Patients	**At least once every two weeks**	• The positive impact of the project through the H2020 Programme and how it is going to impact the society • Promotion of the FACILITATE working prototype • Distribution of information about FACILITATE • Promotion of the project's events • Relevant news on project topics (GDPR, Ethics, Technology innovation)
	• Public authorities in the project's key-locations		• Distribution of information about FACILITATE

Dissemination tool/channel	Target group	Frequency	Key Messages
Partner organizations social media	• Local, national, and international policymakers • Research institutions • Coordinators and researchers in sister-projects, both H2020 and publicly-funded	**At least once per month**	• Promotion of the local and national policy councils and updates on the International Policy • The importance of supporting similar initiatives at the national/regional level • The positive impact of the project through the H2020 Programme and how it is going to impact the society and the research society • Promotion of the project's events • Re-post the posts of the project's social media
YouTube	• Researchers/academia • Consortium and Scientific Advisory Board (SAB) members • Research institutions • Coordinators and researchers in sister-projects, both H2020 and publicly-funded • The European Commission (EC) • Patient associations • Pharma companies • Patients	**Every time video content is available**	• Updates on the FACILITATE working prototype • Updates on the FACILITATE manifesto

ANNEX III. Monitoring report

The following index must be part of the report to be delivered annually:

- Period of reference
- Partners involved
- Communications actions
- Dissemination actions
- Exploitation actions
- Sustainability actions
- KPI status for Communication & Dissemination
- KPI status for Exploitation & Sustainability
- Comments for future activities and/or need to update the DiCEP