



**IMI2 Project ID 101034366
FACILITATE**

**FrAmework for CllnicaL trlal participants daTA reutilization
for a fully Transparent and Ethical ecosystem**

**WP6 – Communication and
dissemination**

D6.2 FACILITATE Website

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Document History

Version	Date	Description
V0.1	11/05/2022	ToC, Structure of the document with introduction (ZEN)
V0.2	21/05/2022	Section 1.1 and 1.2 (ZEN)
V0.3	08/06/2022	Update of the images and content (ZEN)
V1.0	28/06/2022	Stakeholders and general structure update, (ZEN)

Summary

The website represents a key communication channel in raising awareness of the project and informing partners about the outcome of the project, latest news, upcoming events etc. The website also serves as main repository for public project documents.

The D6.2 Website deliverable is a result of the work done in the context of Task T6.1. The objective of this deliverable is to present the features of the FACILITATE website. The FACILITATE website is administered and implemented by Zentrix Lab, leader of WP4. The supported material was provided by each partner individually and the content approved by all partners.

1. Introduction

Deliverable D6.2 summarizes the initial work carried out in Task T6.1. In this period, the main activity was to create a website. The website contains a general presentation of the project and its objectives.

The development of FACILITATE project begins and ends with stakeholders, so the website targets all different groups of stakeholders:

- Patients
- Clinicians & healthcare professionals
- Pharma companies
- Healthcare actors on a broader spectrum

The website visitors will find information about project advancements, outcomes, and potential impacts. They will also have access to publications, public deliverables and other outcomes, and information on activities planned by the project.

Versions in local languages are planned to facilitate the understanding for stakeholders who do not speak English.

1.1 Hosting and URL

The FACILITATE website is available at <https://facilitate-project.eu/>

1.2 Website presentation and Structure

- Homepage
- About
 - About FACILITATE
 - Why FACILITATE?
 - Work Packages
- Research Activities
- Stakeholders

Project ID 101034366 – FACILITATE – D6.2 Website Deliverable

- Patients
- Clinicians & Healthcare Professionals
- Pharma Companies
- Healthcare Actors on a Broader Spectrum
- Patients
- Resources
 - Main Deliverables
- Project Partners
- News & Events

1.2.1 Homepage

The homepage is the landing page where visitors can discover what the FACILITATE project is and for whom it is.

The homepage consists of several different sections that are listed below. Menu and footer remain the same on all pages.

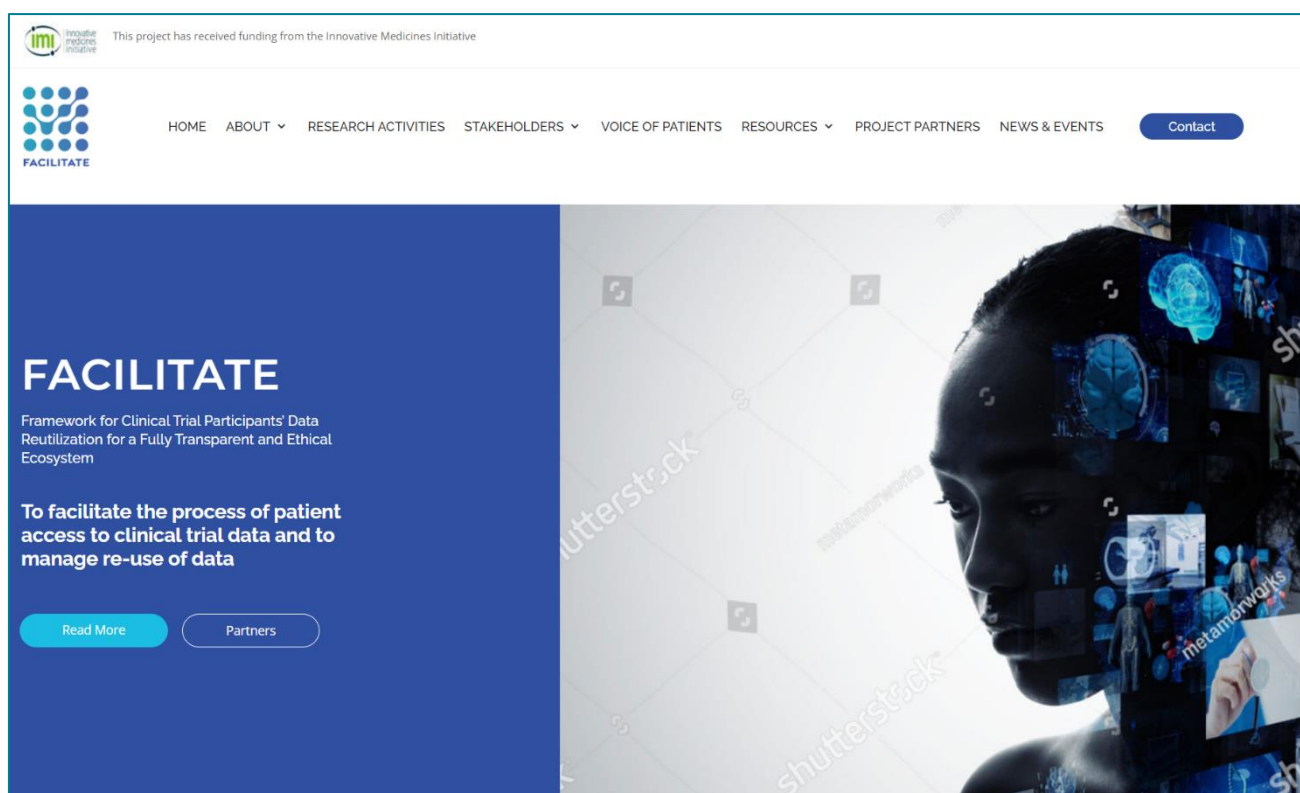


Figure 1. Homepage

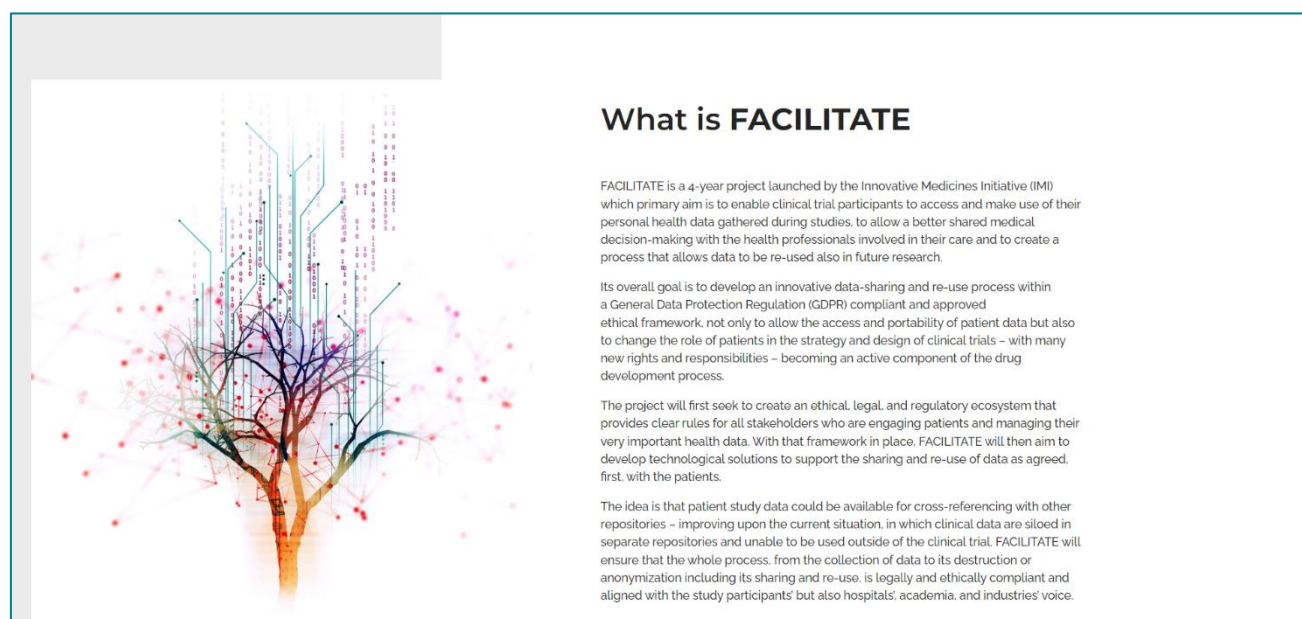


Figure 2. Homepage -What is Facilitate

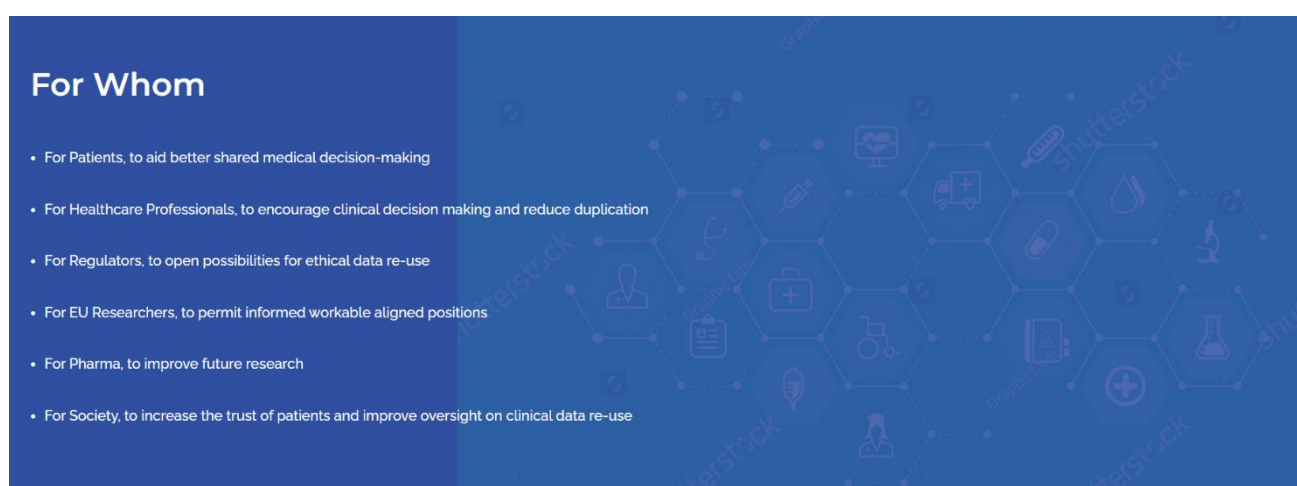


Figure 3. Homepage - For Whom

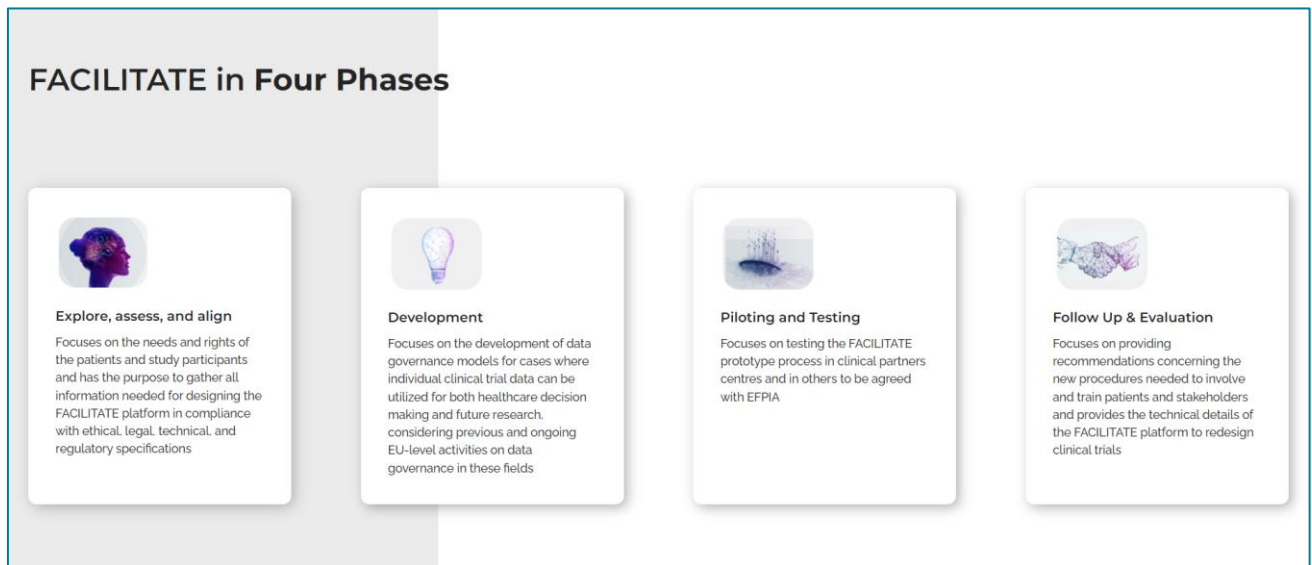


Figure 4. Homepage -Facilitate in Four Phases

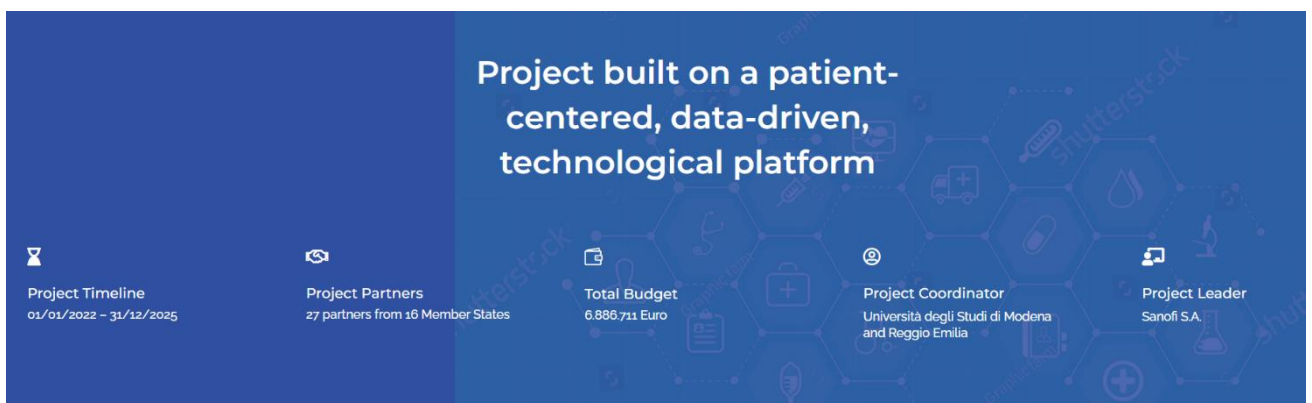


Figure 5. Homepage - Project Information

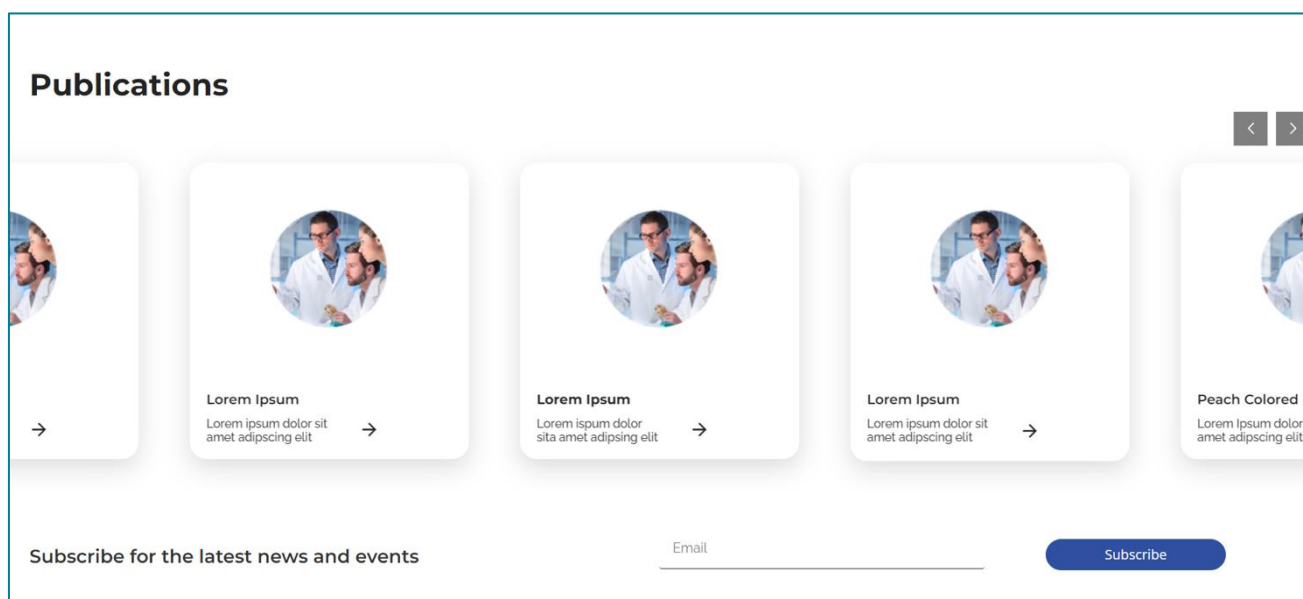


Figure 6. Homepage - Publications and Subscribe



Figure 7. Homepage - Partners

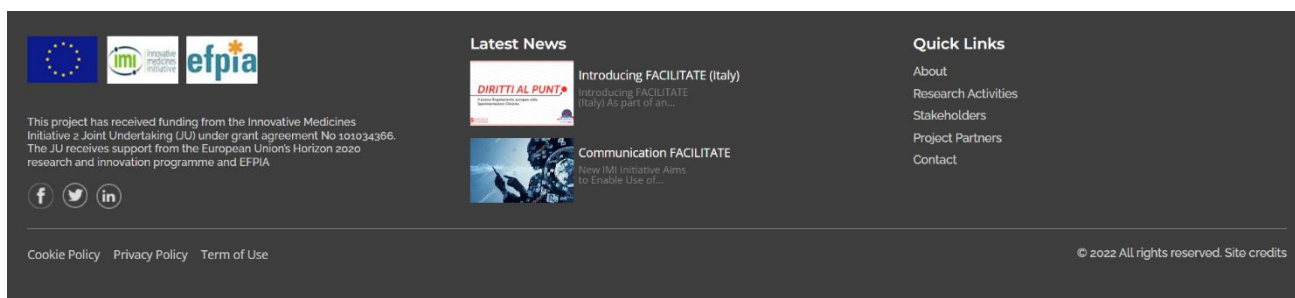
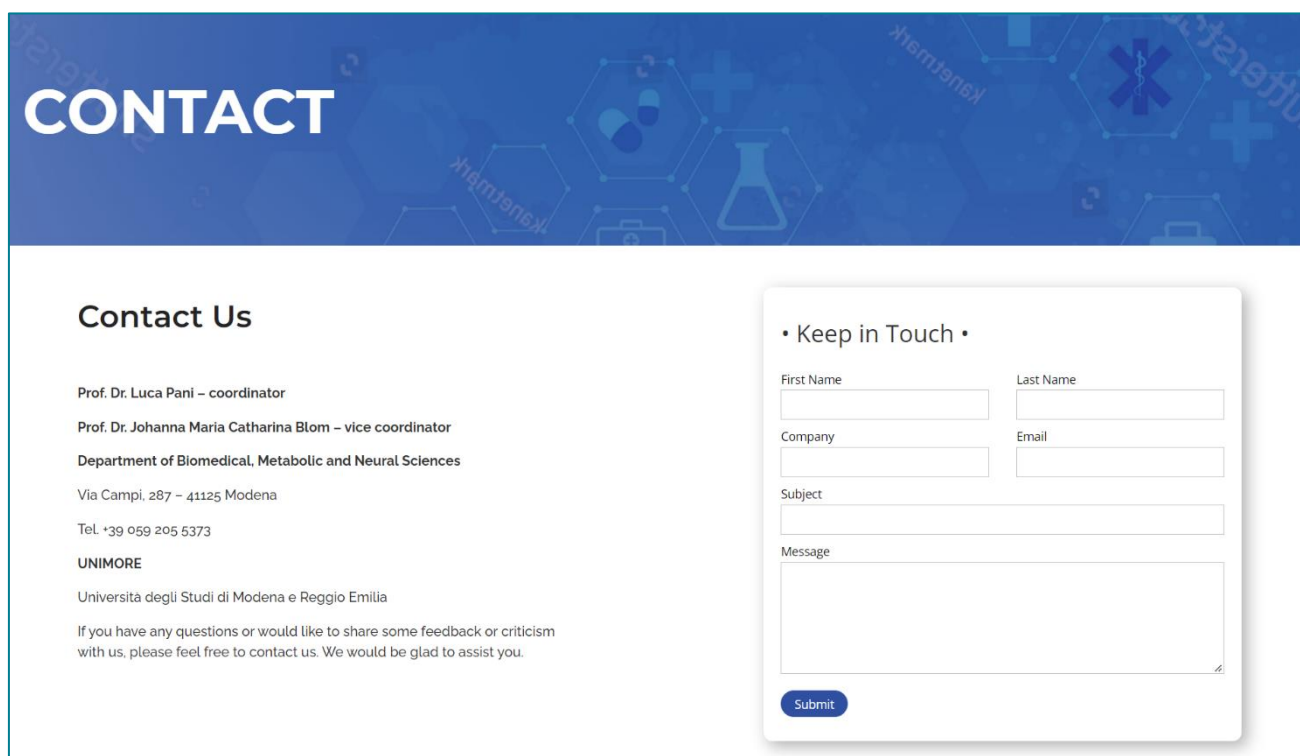


Figure 8. Homepage - Footer



CONTACT

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If you have any questions or would like to share some feedback or criticism with us, please feel free to contact us. We would be glad to assist you.

• Keep in Touch •

First Name

Last Name

Company

Email

Subject

Message

Figure 9. Contact page

1.2.2 About

The About section consists of three subpages:

- About FACILITATE
- Why FACILITATE?
- Work Packages

ABOUT FACILITATE

OBJECTIVES OF THE FULL PROJECT

- Implement best practice for handling personal data protection regulations
- Nurture the harmonization of an ethical and legal framework applicable to medical research in the Member States
- Deliver a prototype process for returning clinical trial data to study participants and to facilitate the conduct of health research projects, during and after the study
- Generate recommendations on which, when and how data should be returned to study participant
- Develop insights on how this data could be used in health care decision making and for future research
- Ensure that the whole data process is legally compliant and aligned with the study participants' voice



AMBITION OF FACILITATE

- Avoid the current situation where, especially in Europe, data from clinical trials are siloed in separate medical systems islands without any possibility to be used beyond their original and often limited single-sided purpose
- Create new legal and ethical tools to allow patients' data to be accessed, used, and re-used, and clinical trials to be run
- Generate a partnership in which patients are at the centre of data governance thanks to advanced communication tools and participatory technologies
- Provide clear rules in a trusted ethical, legal, and regulatory ecosystem to strongly engage patients as data generators
- Bring effective and safer medicines faster at their approval date

Figure 10. About - About FACILITATE page

WHY FACILITATE

WHY FACILITATE

The current availability of both qualitative and quantitative health data is unprecedented in the history of mankind (i.e., 2.5 quintillion bytes/day which means 1.7 Mb per person/per second from 200 Billion connected devices by the end of 2020).



Soon technology-computing, connectivity and storage capacity will enable further availability of health data exponentially in two ways: increasing computerization and quantifying self and mobile-health.

Both these advances have potential issues. The increased computerization of medical processes and procedures would need to provide means to link data to information and to knowledge in a virtuous interchange while quantifying self and mobile-health, (i.e. the possibility for each person, healthy or not, to measure their medical condition through smartphones, wearable sensors and any other digitally reducible phenotypes) by becoming the primary source of health data that would need to be reconciled with data access, usage, portability, privacy and – in Europe – with GDPR compliance.

The present proposal aims at addressing in a solution-based methodology both issues.

The overall goal of this 4-years project is the development of a patient centered process prototype to allow the direct generation and the return of clinical trials data to study participants.

By putting the study participants at the very core of their data portability and secondary use the FACILITATE project will make it easier to integrate both local and pan-European implementations considering best practices and data protection regulations.

This prototype process will be delivered as part of the project alongside a robust business plan to ensure its sustainability to foster the harmonization of the legal framework applicable to medical research in different European Member States.

Figure 11. About - Why FACILITATE?

WORK PACKAGES

The FACILITATE project is in 4 Phases, but executed through delivery of 7 individual Work Packages (WPs) and one supplementary WP8:

Work Packages

» Work Package 1

WP1 relates to **Project management and Administration**. It will ensure that all the project objectives, tasks and deliverables are met on time and to budget. It will also help manage any risks on the project to ensure that the important objectives for patients and other stakeholders are delivered on.

» Work Package 2

WP2 concerns the **Legal and Data Privacy framework**. It will develop the guidance documents necessary for primary and secondary use of patients' clinical data in compliance with GDPR – it must include privacy notices, consenting practice, rights management for re-use of the data, clauses for investigators contracts. WP2 members will engage with regulators, patient groups, data protection experts to ensure objectives of this WP are met.

» Work Package 3

WP3 is closely linked with WP2, but looks at the **Ethics, Standardization, and Regulatory framework**. This WP team will review and integrate technical and regulatory standards proposed by WPs 1 and 2 and provide recommendation aligned with the patients' voice – new standards will be developed if necessary and approval of these standards sought from the regulators.

» Work Package 4

WP4 concerns the **Technical Platform structure/design** that will be used to return data to patients and the **associated requirements**. It will develop a technology framework based on existing or new technologies and identify any potential technical issues. It will set up the process to be used in WP5.

» Work Package 5

WP5 relates to the **Technology Framework and Interoperability Solutions**. It will deploy a working prototype process to test that it is viable, to suggest overall direction, and to provide feedback (a working prototype demonstrating the feasibility for study participants to get access to their clinical study data).

» Work Package 6

WP6 relates to **Communication and Dissemination & Stakeholder Engagement** (see stakeholder pages for details of stakeholders involved). It will establish a FACILITATE project website and all appropriate tools for communications purposes to ensure awareness and updates as the projects develops. It will establish and implement a communication structure, conduct surveys with patients, Health Care providers, regulators etc to get their input and will establish and organise dissemination of the project results.

» Work Package 7

WP7 relates to **Business exploitation and sustainability**. It will establish a robust business plan to ensure sustainability and implementation of the project results. It will execute the business plan, including marketing of the project deliverables to the relevant end-users (all stakeholders as previously described).

» Work Package 8

WP8 concerns the 'ethics requirements' that the project must comply with under IMI2 JU rules.

Figure 12. About - Work Packages

1.2.3 Research Activities

This page presents the four phases of the methodology as well as our values.

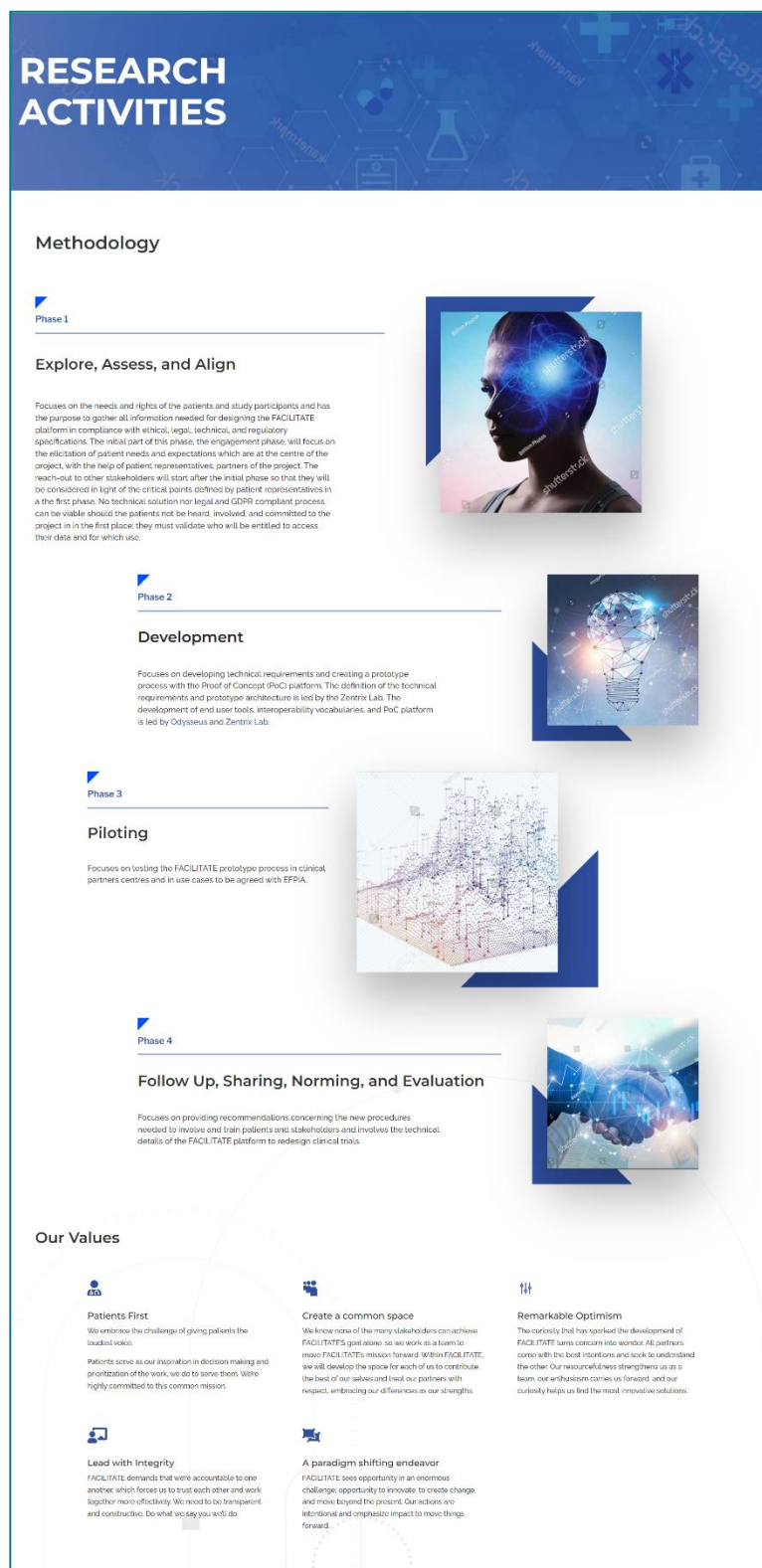


Figure 13. Research Activities page

1.2.4 Stakeholders

The FACILITATE project will work with four groups of stakeholders. The Stakeholders page contains subpages that display information about each stakeholder group separately. The right sidebar remains the same on all Stakeholders subpages.

The Stakeholders subpages:

- Patients
- Clinicians & Healthcare Professionals
- Pharma Companies
- Healthcare Actors on a Broader Spectrum

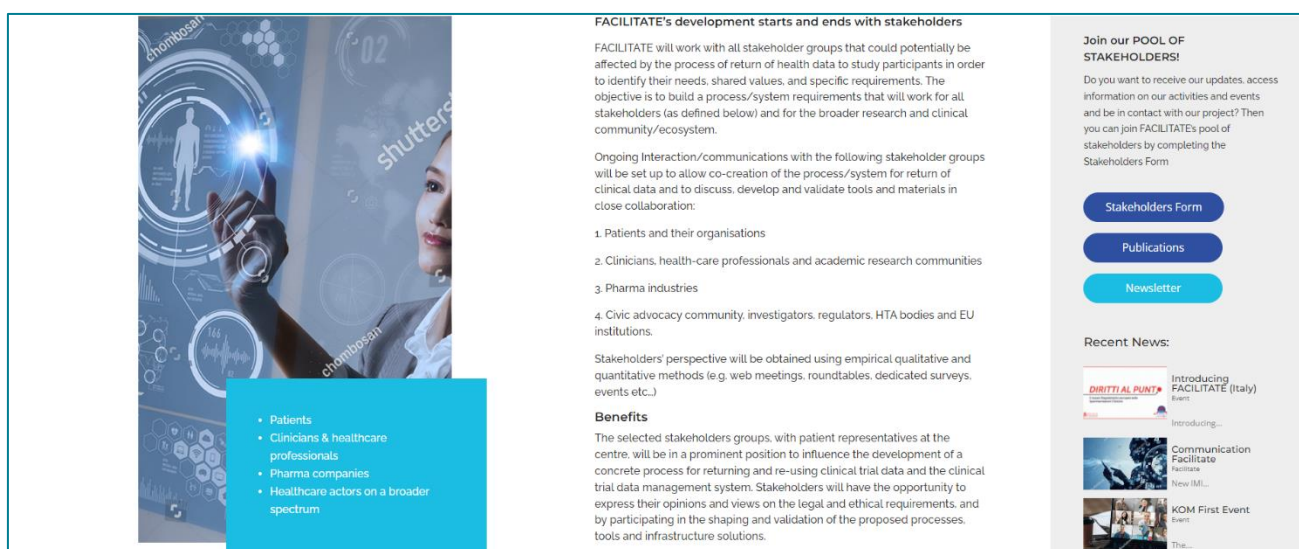


Figure 14. Stakeholders page

The Stakeholders Form button opens a new page displaying the stakeholder registration form.

Registration Form

Name

Surname

Email

Gender

Organization

Country of residence

I wish to engage with FACILITATE as:
Select the option that most applies to you and in context to the type of input you feel most comfortable giving to the project.

Note: This form should be completed only by a legally responsible individual. If you are unsure, please use other and specify.

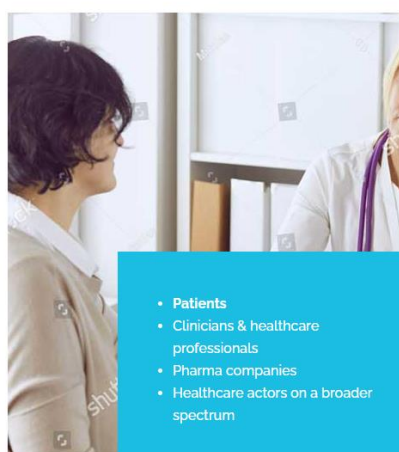
Patient

☐ I have read and agree with the FACILITATE Privacy

After registration through the stakeholder registration form, you will be included on the stakeholders' list of the FACILITATE project. We will then share news, activities, surveys, events, publications and updates regarding the project implementation. You are free to opt out at any time from the stakeholder list.

Submit

Figure 15. Stakeholders page - Patients subpage



- Patients
- Clinicians & healthcare professionals
- Pharma companies
- Healthcare actors on a broader spectrum

Patients' engagement in FACILITATE

FACILITATE aims to develop a process to return clinical trial data to study participants, transforming the way patients will have access to clinical trial data in Europe. We will engage Patients as stakeholders that play a central role at all levels in the FACILITATE project.

The patients' involvement is coordinated by the European Organisation for Rare Diseases (EURORDIS) in collaboration with the other patient advocacy and patient training organizations such as the European Patients' Academy on Therapeutic Innovation EUPATI EU, EUPATI Italy and CITTADINANZATTIVA – Active Citizenship Network (ACN).

Patients will be part of the decision-making process and be directly involved in activities within different work packages of FACILITATE, ensuring that the methodologies identified correspond to patient views, needs, expectations and preferences.

Figure 16. Stakeholders page - Patients subpage



Clinicians' engagement in FACILITATE

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

The clinicians and healthcare professionals' involvement is coordinated by the Medicine University of Graz – in collaboration with the other universities, research organisations, clinical centres partners in the project – to ensure the needs and requirements of these stakeholders are included in FACILITATE work, both in the development of the project and the resulting tools and recommendations.

Figure 17. Stakeholders page - Clinicians & Healthcare Professionals subpage



Companies' engagement in FACILITATE

Pharma Industries are working more and more with patients as partners in decision-making for their healthcare. Providing patients with appropriate access to their clinical trial data will help to facilitate this goal. However currently the process is not clear or simple and is hampered by varying regulations across countries. It is important that Pharma is involved in developing a *consistent* methodology/process for ensuring that data shared with clinical trial participants is meaningful and thoughtfully explained, and all privacy, security, data integrity and patient safety protections are ensured and comply with all laws, ethics committee approvals and organizational policies.

The involvement and feedback of Pharma Industries on this process is coordinated by Takeda for the FACILITATE project as part of its role in leading Stakeholder Engagement.

Figure 16. Stakeholders page - Pharma Companies subpage



- Patients
- Clinicians & healthcare professionals
- Pharma companies
- Healthcare actors on a broader spectrum

Healthcare actors' engagement in FACILITATE

The development of a working prototype process to return clinical trial data to study participants can be effectively addressed only by involving all the stakeholders.

This means that FACILITATE will engage also EU and national health stakeholders, civic advocacy community, regulators, HTA bodies, and EU institutions to include their different perspectives in the project development.


This group of healthcare actors on a broader spectrum will be coordinated by the CITTADINANZATTIVA-Active Citizenship Network (ACN).

FACILITATE may change the future of research in Europe.

Figure 19. Stakeholders page - Healthcare Actors on a Broader Spectrum

1.2.5 Voice of Patients

VOICE OF PATIENTS



Patient needs and expectations at the centre of the project

- FACILITATE is a project built on a patient-centred vision: it focuses on the needs and rights of the patients who take part to a clinical trial to dispose of their own data
- FACILITATE main goal is to develop a process to return data originated from a clinical trial to study participants for their use and re-use
- Why the re-use of this data is so important for patients? Because it allows them to play a central role in clinical trials strategy and design and in the medical decision-making
- Today clinical trial data are siloed in separate repositories without any possibility to be used beyond their original single-sided purpose.
- FACILITATE aims to overcome this current limitation, transforming the way patients will have access to clinical trial data in Europe.
- How? By defining which, when and how clinical trial data should be returned to study participants and integrated in their individual health records files or applications
- The whole data process, from collection of data to its destruction or anonymization, including its sharing and re-use, will be legally and ethically compliant and aligned with the patient voice

Patients involved from the beginning

All technical solution and legal and ethical compliant process can be viable only if patients are heard, involved, and committed to the project from the first phase

In FACILITATE, patient needs, and expectations will be elicited with the help of patient representatives, which are partners of the project, through relevant interviews, surveys, or questionnaires

All the critical points and patient preferences will be defined by patient representatives and then addressed to other stakeholders

Patients will validate who will be entitled to access their data and for which use

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? Then you can join FACILITATE's pool of stakeholders by completing the:

[Stakeholders Form](#)


[Publications](#)

[Newsletter](#)


Recent News:



Introducing FACILITATE (Italy)
Event



Communication FACILITATE
Facilitate



KOM First Event
Event

Figure 17. Voice of Patients page

1.2.6 Resources

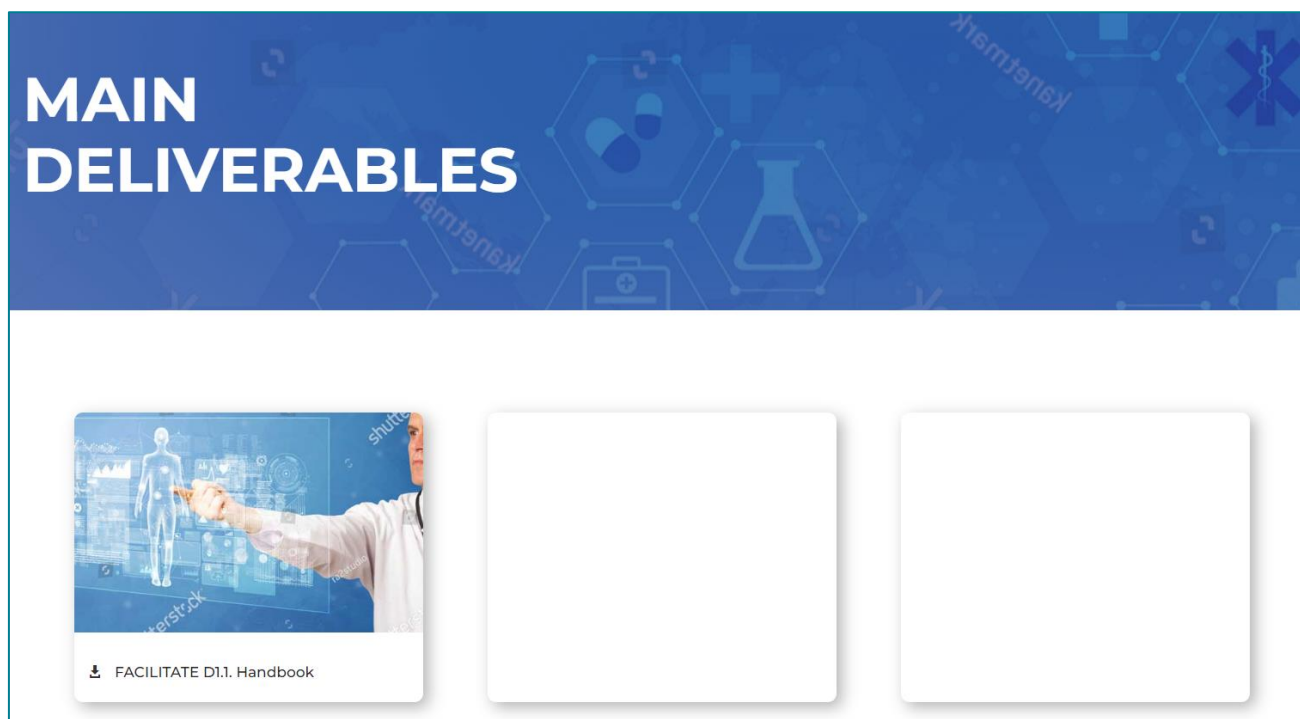


Figure 21. Resources - Main Deliverables page

1.2.7 Project Partners

Our Partners page shows a list of all project beneficiaries, by clicking on the logo of a partners, a new page opens with information about the selected entity and its role in the project. In addition, when the Partner's page is open, a click on the partner's logo redirects to the partner's website.

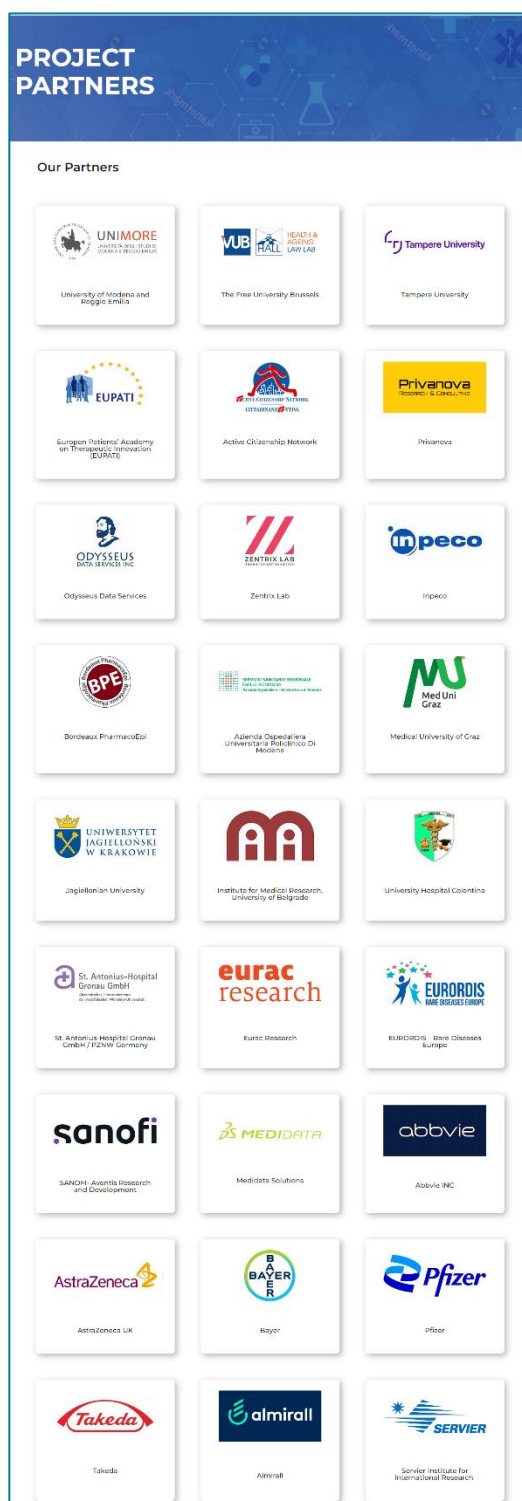


Figure 18. Project Partners page

1.2.8 News & Events

The News & Events page shows the latest news related to the FACILITATE project, as well as previous and upcoming events.

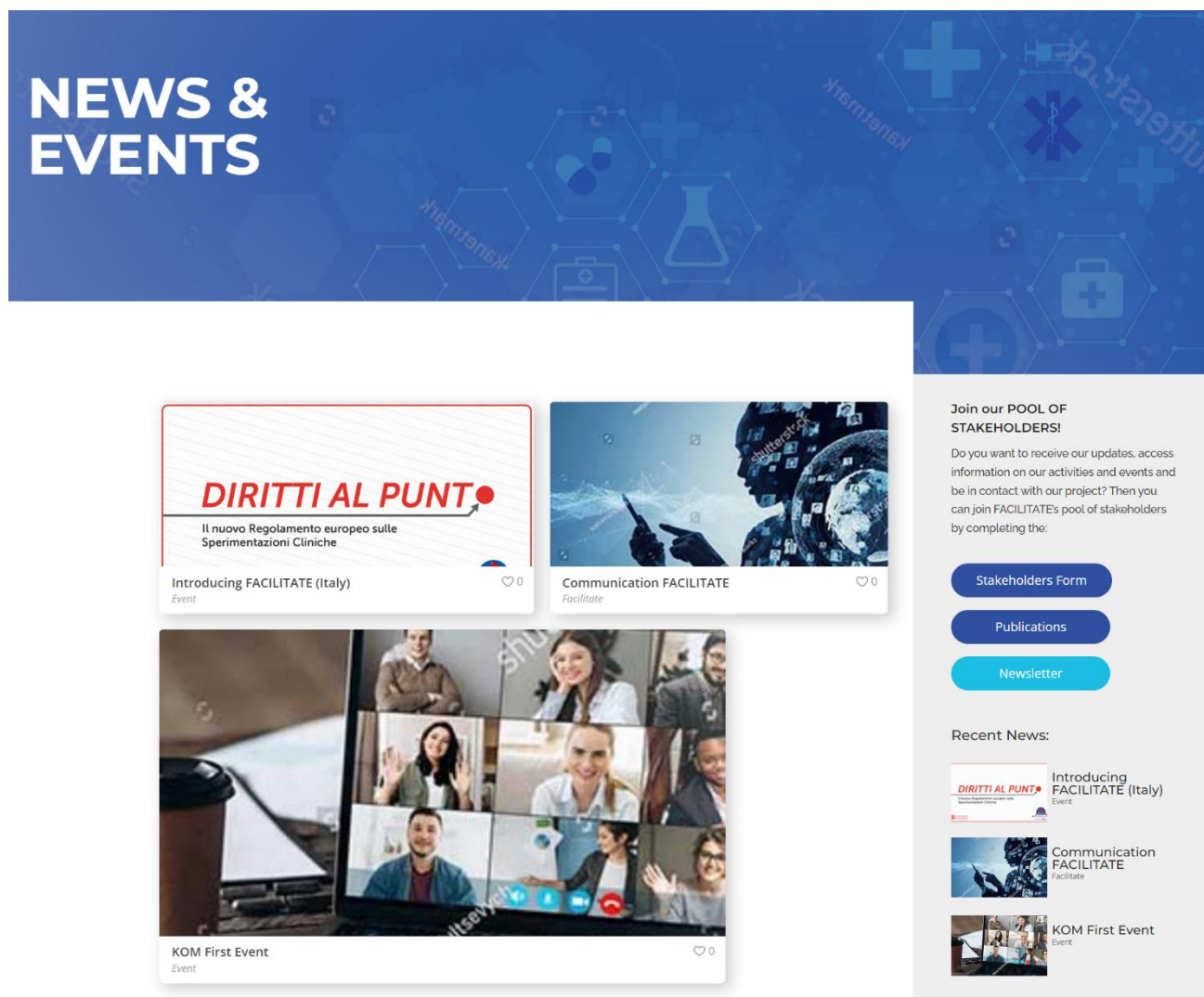


Figure 19. News & Events page

1.3 Activities after the public launch of the website

After the public launch of FACILITATE's website, ZEN will be responsible for uploading, updating, and maintaining contents of the website coming also from the partners.

Translations

The website will be available in five languages, English, French, German, Spanish and Serbian as main languages of the stakeholders. Translations will be available six month after its public launch.

User experience test

In the next weeks, FACILITATE's website will be tested by the partners and the stakeholders in all partner countries, as main targets. All partners will distribute the website among eventual stakeholders and provide them with the opportunity to participate actively to the project.

Updates

Updates of the website and a full check of its functionalities and appropriateness will take place every 2 months.

Once per month, and following FACILITATE's timeline, information on the advancements of the project's activities will be published. More specifically, the sections will be enriched with news and findings regarding:

- The ongoing research and engagement/policy actions
- The positive impact of the project through the Horizon Europe Program, in relation to all the stakeholders involved
- Events
- Training activities.