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Deliverable D7.3

Stakeholder Engagement Plan – Interim Implementation Report

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Abstract: This document contains the deliverable template in order to be used as a guidance for future releases of the deliverables.

In this part, a short abstract of the deliverable should be presented.

Disclaimer

Revision History

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Table of Contents

Index of figures

Index of tables

Glossary

Abbreviation	Full name
AIH	ALAMEDA (Digital Health) Innovation Hub
CoI	Community of Interest
ECT	Engagement Coordination Team
HCP	Healthcare professional
HRQoL	Health-Related Quality of Life
HTA	Health Technology Assessment
LCG	Local Community Group
PMSS	Parkinson’s, Multiple Sclerosis and Stroke
RIA	Research and Innovation Action
RRI	Responsible Research and Innovation
SME	Small and medium-sized enterprise
SwafS	Science with and for Society
Tx.y	Task no. x.y
WPx	Work Package no. x

Executive Summary

The deliverable D7.3 Stakeholder Engagement Plan – Interim Implementation Report is the second output of task T7.2 and it illustrates the stakeholder engagement activities carried out during the first half of ALAMEDA project's duration (M1-M18).

After having mapped, clustered and analysed the relevant stakeholders, their preferences, and degrees of influence upon and interest towards ALAMEDA's results a comprehensive stakeholder engagement strategy has been designed in D7.1.

Based on that the ALAMEDA consortium has collectively committed to perform a series of actions to reach out, consult and involve all those actors whose active participation and contribution is deemed necessary to move toward value based and technology-enabled healthcare systems delivering the highest possible quality to the patients with brain disorders.

Specifically, during the first reporting period, most of the actions have been focused on engaging with representatives of the ALAMEDA main categories of end users i.e., patients, healthcare professionals and caregivers. In this regard, the engagement strategy of ALAMEDA is particularly ambitious as it aims to take a step beyond mere consultation and have them on board as partners in the design, development and technology assessment. This is made possible thanks to the centrality attributed to the definition of a novel shared decision-making model in WP3 that has specified the principles by which doctors and patients decide to employ wearable and sensing devices, perform data collection, use personal assistance and/or conversational agent technology.

In order to achieve this goal, the WP7 - and specifically the Task 7.2 – has conducted a series of stakeholder engagement activities in close collaboration with WP3 leader and partners. Since the project's start, such activities have highly benefitted from the experienced capacity of partners such as FISM, who is guiding the end users', and specifically the patients', engagement effort following the guidelines of the RRI recently concluded project "MULTI-ACT". The constitution of the Engagement Coordination Team and the activation of the Local Community Groups, which early activities are reported in the present document, have marked the start of this journey aimed to collect and give prominence to the experiential knowledge of the disease which is unique to patients and their closest carers.

Moreover, the consortium relies upon an extensive network of relations and affiliations of its members to EU-level or international alliances and initiatives which will be extremely valuable to amplify the outreach and engagement impacts in the next phase. Furthermore, policy- and market-oriented stakeholder engagement activities are planned for the next 18 months in parallel with the progressive development of the ALAMEDA Innovation Hub which will position itself as a relevant multi-sided platform for knowledge exchange, development, testing and integration of novel solutions based on ALAMEDA results.

Last, the partners have initiated a series of contacts and exploratory meetings to create bridges with a vast panorama of projects and initiatives working on specific aspects and digital endpoints for the same diseases as ALAMEDA as well as deploying AI and big data solutions on other neurological diseases. Those projects, some of which already identified in D7.1, have expressed their preliminary interest in getting involved in bi- and multi-lateral exchanges during the months to come.

1. Introduction

1.1 Purpose of the document

The present deliverable D7.3 is part of the outputs of WP7 "ALAMEDA Innovation Hub and Ecosystem Development" which aims to set the basis for the use of the ALAMEDA project's results beyond the project through the design and development of the ALAMEDA Digital Health Innovation Hub as the project's multi-side market web-based information platform and the constitution of a broad and lively stakeholder community.

In order to amplify the opportunities for the project results to be adopted and reused, the project team has envisaged the need to deliver a comprehensive stakeholder engagement strategy aimed to mobilize the key stakeholders whose commitment will be pivotal to steer adoption and scale up.

Specifically, D7.3 is developed in the frame of the activities planned under the task T7.2 and contains the intermediate report illustrating the activities of stakeholder (including patient) engagement undertaken by the consortium during the first half of project's duration whereas most efforts were concentrated on the design and the development of the ALAMEDA platform and technical solutions. It will be followed by a final stakeholder engagement report, which will be presented in D7.8.

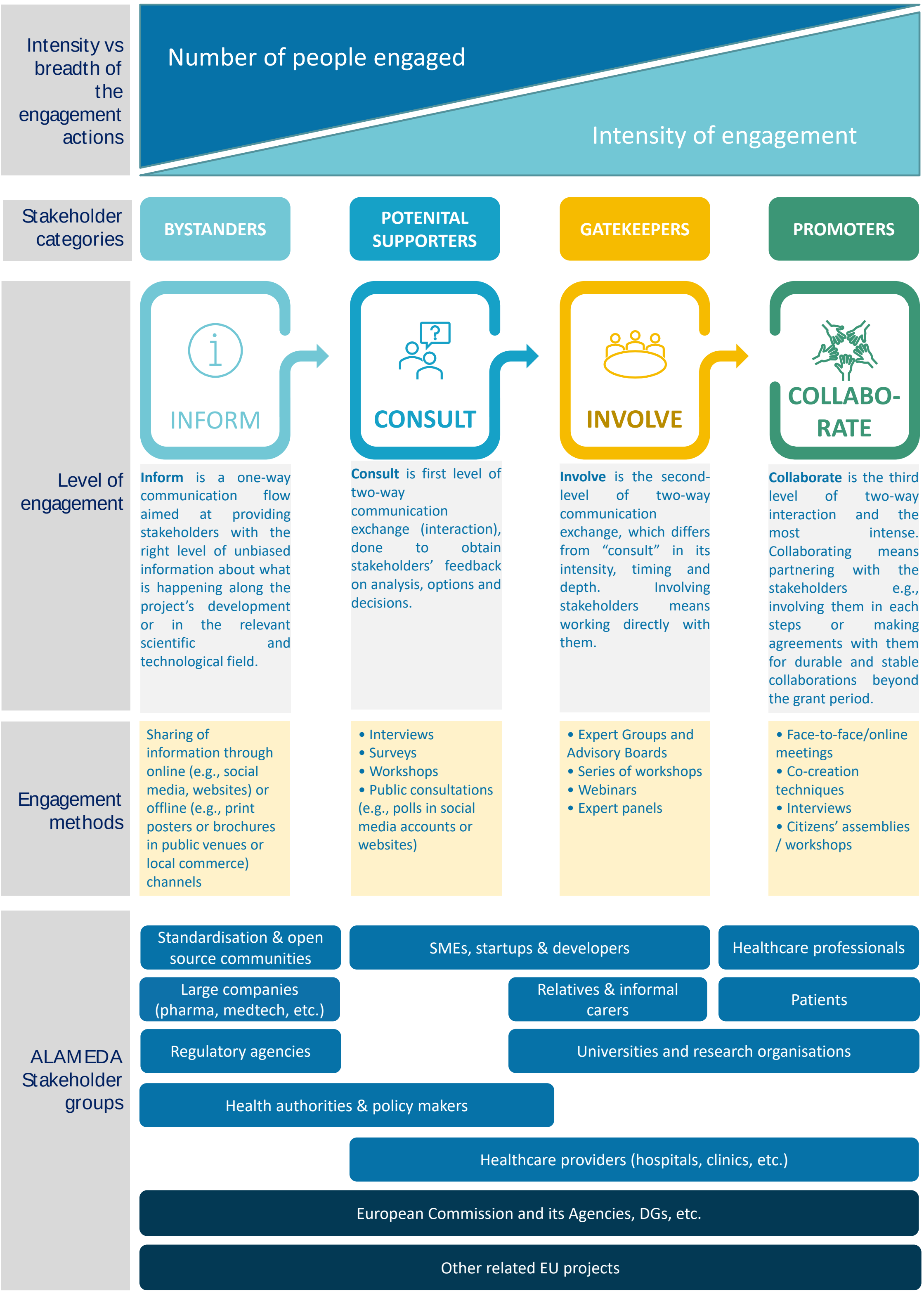
1.2 Deliverable structure

The deliverable D7.3 is structured into four main sections in addition to the present introduction (Section 1), the Summary and conclusions (Section 6) and the bibliographic references listed in Section 7:

- Section 2 provides a short recap of the stakeholder analysis and mapping carried out in D7.1.
- Section 3 contains the detailed reporting of the activities performed in order to engage successfully the ALAMEDA end users and specifically the patients and their communities.
- Section 4 presents the next steps and the indicators to be collected to support the reporting and assessment of the stakeholder engagement activities to be conducted along the next 18 months.
- Section 5 briefly illustrates the planned next steps to strengthen the stakeholder engagement capacity of the consortium and broaden its scope.

2. Stakeholder analysis

The design of an impact-driven stakeholder engagement strategy requires an accurate identification and analysis of the involved stakeholders. To this purpose, an in-depth mapping has been carried out in Deliverable D7.1 and is briefly summarised in Figure 1 below. Moreover, a preliminary analysis of the stakeholder categories - from the communication viewpoint - has been presented in the Dissemination Plan (Deliverable D8.2) too, with a view to support the elicitation of the most appropriate channels and tools for communication and outreach.



Stakeholder categories	BYSTANDERS	POTENTIAL SUPPORTERS	GATEKEEPERS	PROMOTERS
Level of engagement	INFORM **Inform** is a one-way communication flow aimed at providing stakeholders with the right level of unbiased information about what is happening along the project's development or in the relevant scientific and technological field.	CONSULT **Consult** is first level of two-way communication exchange (interaction), done to obtain stakeholders' feedback on analysis, options and decisions.	INVOLVE **Involve** is the second-level of two-way communication exchange, which differs from "consult" in its intensity, timing and depth. Involving stakeholders means working directly with them.	COLLABORATE **Collaborate** is the third level of two-way interaction and the most intense. Collaborating means partnering with the stakeholders e.g., involving them in each steps or making agreements with them for durable and stable collaborations beyond the grant period.
Engagement methods	Sharing of information through online (e.g., social media, websites) or offline (e.g., print posters or brochures in public venues or local commerce) channels	• Interviews • Surveys • Workshops • Public consultations (e.g., polls in social media accounts or websites)	• Expert Groups and Advisory Boards • Series of workshops • Webinars • Expert panels	• Face-to-face/online meetings • Co-creation techniques • Interviews • Citizens' assemblies / workshops

ALAMEDA Stakeholder groups

Standardisation & open source communities
SMEs, startups & developers
Healthcare professionals
Large companies (pharma, medtech, etc.)
Relatives & informal carers
Patients
Regulatory agencies
Universities and research organisations
Health authorities & policy makers
Healthcare providers (hospitals, clinics, etc.)
European Commission and its Agencies, DGs, etc.
Other related EU projects

Figure 1. ALAMEDA stakeholder engagement strategic framework

3. Engagement of the end users in the pilot countries

Despite the huge progress done and the impetus given by COVID-19 for countries to accelerate the adoption of digital health, it is largely acknowledged that challenges with the adoption, scale, and spread of health innovations still represent significant gaps in the evidence-to-practice cycle [1]. In the health innovation design process, a lack of attention paid to the needs of end-users, and subsequent tailoring of innovations to meet these needs, is deemed as one of the most likely reasons justifying the failed adoption of many promising innovations. Thus, in the recent years digital health developers and providers have been broadly exploring the best ways to keep the human element front and centre of digital health innovation process.

Furthermore, the engagement of end users unavoidably acquires centrality regardless the sector, as long as the innovation community is consistently shifting from a *product design* to a *service design* approach. When a technology (tool) includes a clearly stated, meaningful value proposition [2] for all users who must interact with the technology or the information it generates, the newly introduced technology can be used as a trigger for establishing new routines involved in providing care, and ultimately a re-configured service or even an improved treatment or care pathway.

This has led to a progressive acknowledgement of the primary importance attached to end users' engagement, as recently recognised also in guidance documents made available by health authorities, payers and HTA agencies in order to support innovators in understanding what the health systems and providers are looking for when buying digital and data-driven technology for use in health and care, so that these principles of good practice can be built into the strategy and product development 'by design'. An example is provided by the recently updated UK 'Code of Conduct for Data-Driven Health and Care Technologies' which explicitly refers to end users' engagement as follows: "One of the best practical ways of getting to a clear value proposition is to research and define user needs thoroughly, and then involve users as much as possible in the whole life cycle of the product, through discovery, design, change and post-release review. Understanding the people and their specific needs will help with uptake and adoption of the technology or innovation being built, as well as clearly showing a commissioner or buyer the problem being solved." [3]

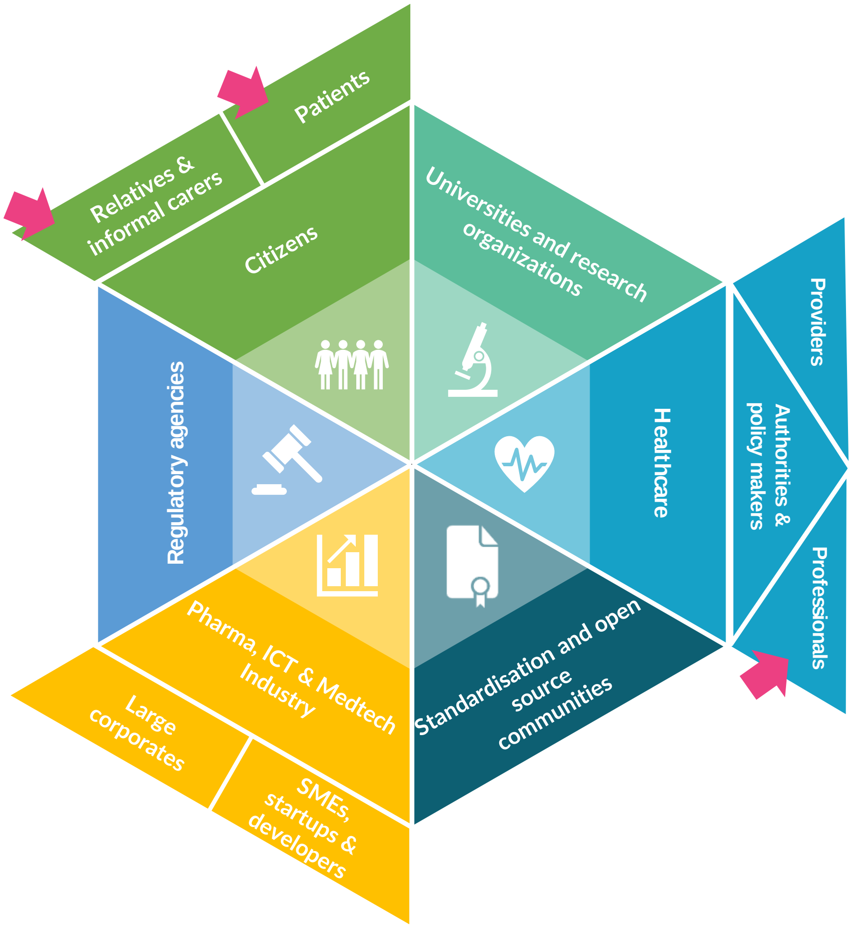
Furthermore, the approval of Regulation 2282/2021 (HTA Regulation) [4] has marked a renewed acknowledgement of patient engagement centrality. Within its new legislation frame, which entails a three-years transition period towards effective application as of 2025, Member States will have a new permanent framework for a European Cooperation on HTA and common rules to perform HTA jointly at the European level. The HTA Regulation also establishes quality standards for the joint work: among them, it requires the **systematic and timely participation of patient experts** in the procedures of the new Cooperation, especially in the main activities, such as Joint Scientific Consultations and Joint Clinical Assessments.

In ALAMEDA the primary end users are identified as follows:

Patients with Parkinson, Multiple Sclerosis and Stroke (PMSS): they will benefit from the individual personalized care based on AI decision making models that may be tuned to cover various aspects of brain diseases and a variety of medical care models, as well as methods to calibrate such models for individuals. Advanced data analytics and AI systems are being deployed in order to: (i) continuously monitor their health status and overall cognitive capacity; (ii) evaluate outcomes that matter to patients, such as fatigue, psychosocial status, anxiety and depression, quality of life, and satisfaction with the technology and tele-healthcare.

Healthcare professionals: The developed AI methods will be able to integrate and handle efficiently heterogeneous datasets and datasets with missing values (incomplete data). Different patients and outcomes will be monitored and recorded at different frequencies mainly due to the differences in their health status and the symptoms, enabling clinicians to design personalised monitoring plans. Further, medical doctors will be provided with bias-free information concerning the patients' life and disease related incidents, as inferred by the AI and monitoring process between the on-site clinical visits. Relapses have a major influence on clinicians' treatment decisions for patients with PMSS, therefore equipping clinicians with advanced tools for on-time prediction of relapse is of utmost importance to identify the most appropriate treatment, ensuring effective care for these patients over time. Monitoring motor function and sleep characteristics has the potential to predict the course of the disease, in particular the prediction of relapse or worsening that is fundamental for improving drugs and rehabilitative treatments efficacy, resulting in a better care and quality of life for the people affected by PMSS. For example, there are pointers in the PD case where sleep and motor incidents and their properties may help the clinical doctors towards decision concerning whether more drastic actions apart from drug administration should take place, early enough, before the quality of the patient's life will be severely downgraded.

Caregivers: The role of caregiving has a large socio-emotional impact that cannot be ignored. As this impact grows, families are looking for innovative solutions to help them balance the needs of patients with the demands of caregiving. There is encouraging and progressively increasing engagement of caregivers and their associations and networks in digital health and health innovation. A recent survey carried out on more than 700 caregivers in the US [5] found that the majority considered "very appealing" the opportunity to use digital health solutions. This included technology that provides "access to test results and other medical records in one place"; reliable information about the needs and conditions of patients"; and "tools to communicate directly with doctors and other care providers and coordinators". Digital health technology can indeed help address the adverse health complications that caregivers face by e.g., building communities for peer-to-peer interaction and support, assisting in managing everyday tasks and improving the ability for caregivers to monitor health and medications. Specifically, ALAMEDA intends to contribute to the latter objective, by providing a comprehensive, multi-sensor monitoring solution for individuals with brain disorders, deploying a great variety of sensors to monitor their physiological status, overall health and lifestyle aspects. The heterogeneous sensor data will be integrated in an intelligent manner, resulting in a comprehensive picture of the person's current status and its evolution over time, allowing the healthcare professionals to determine the best care approach in each case. Each sensing modality will be analysed separately, and their results will be integrated in a semantically meaningful manner, in line with the user requirements collaboratively defined by healthcare professionals, the informal caregivers, as well as the patients themselves during the first project's phase which is coming to its end. Their daily activities in terms of motor function will be monitored by wearables, while both they and their caregivers will be enabled to provide input about their fluctuating condition; input from caregivers will be especially important in cases in which the patients themselves do not have a complete realization of their condition, for example during their cognitive fluctuations, or when they manifest dyskinesias, of which they may not be aware.



Primary end users:
- Patients
- HCPs
- Relatives and informal carers

Figure 2. ALAMEDA stakeholder categories with end users highlighted

3.1 Patient engagement in ALAMEDA: building on MULTI-ACT project legacy

As digital technology continues to evolve rapidly and healthcare providers and policymakers work hard to adapt, there is a high risk that the patient perspective may be lost. For this reason, ALAMEDA puts meaningful patient engagement at the top of its priorities and builds on the learnings of previous projects and experiences to ensure it is carried out in the most effective, participatory and purposeful way.

Specifically, ALAMEDA relies upon the participation of the Italian Multiple Sclerosis Society Foundation (FISM) as a key partner and former coordinator of the MULTI-ACT project.

MULTI-ACT is a three-year project funded within the H2020 Science with and for Society programme (May 2018 – April 2021). The aim is to increase the impact of health research on people with brain disorders by providing a framework and tools for multi-stakeholder health research initiatives (such as EU funded projects), allowing an effective cooperation of all the relevant stakeholders and the alignment of the results to the mission and agenda.

Over the last decade, patient engagement has become more important along with the democratization of health sciences. Patients started to be engaged not only in a passive role, but also as co-researchers. In fact, they can share with other stakeholders their own experience of the disease, which translates into a form of knowledge that integrates with and enrich scientific knowledge (experiential knowledge).

MULTI-ACT has developed a strategic Collective Research Governance and Sustainability Model (which is freely available and accessible via a handy digital toolbox) in the area of brain diseases by using Multiple Sclerosis as the first case study. The project foresees patients as a key stakeholder in the Health Research & Innovation (R&I) process. Hence, the project aims to contribute to the development of the "science with/of patient inputs" by providing guidelines for patient engagement in R&I (*with*) and by applying the patient-reported dimension in addition to the four research impact assessment dimensions (i.e., excellence, social impact, economic impact and adherence to the stated mission) of the MULTI-ACT model (*of*).

Specifically, for what patient engagement strategies and methodologies are concerned, MULTI-ACT has developed a set of guidelines which equip multi-stakeholder research initiatives with a tool to enable patient engagement actions into the R&I path at both program and project levels.

The guidelines propose a roadmap to capture 'experiential knowledge' of patients (i.e., knowledge gained through lived experience that researchers may not have), to better understand how to draw on their experience and use the experience constructively for co-creation purposes. This way, MULTI-ACT aims at leveraging both patients and other stakeholders' experience and at raising their ability to co-create and participate in decision making processes.

The MULTI-ACT guidelines indicate how to apply the project's patient engagement strategy within the activities of multi-stakeholder initiatives and are going to be used and contextualized in the frame of ALAMEDA.

3.2 Engagement Coordination Team meetings

As a first fundamental step, ALAMEDA has settled the Engagement Coordination Team (ECT) which, according to the guidelines, is meant at: "(i) creating commitment among the members and their community; (ii) moderating the dialogue between interdisciplinary and different (and sometimes competing) voices and experiences and settling a dispute resolution system; (iii) mitigating challenges such as ethical conflicts in protocol design, tokenism, power struggles, difficulties in recruiting different patients, additional time, cost; (iv) assuring that patients "feels valued" by facilitating team interaction and setting up an inclusive research environment" [6]. This path is already being undertaken by relevant international multi-stakeholder health research initiatives whose promoters have embraced the MULTI-CT model such as the International Progressive MS Alliance [7].

As for its composition, the ECT has been shaped in a way that ensures adequate representativeness to the three different disease-specific communities involved in ALAMEDA. Thus, it comprises: one patient and one clinician from each of the three disease domains considered in the project, an ethics expert, a representative of the technological partners from WCS and two representatives from FISM and WISE, respectively in charge of coordination and implementing the patient engagement strategy and overseeing the whole process of stakeholder engagement along the project. The following people have accepted[1]:

- Rachele Paolucci, person with MS
- Margherita Monti Bragadin, MS clinician
- Adrian Sion, stroke survivor
- Diana Dumitrascu, stroke clinician
- Foteini Skondra, person with PD and president of the Association of patients and carers PAR.KIN.S.ON (Greece).
- Natassa Bougea, PD clinician
- Dimitris Karamitros, WELLICS, technology expert
- Neringa Juceviciute, ethics expert
- Ludovico Pedullà, FISM, MULTI-ACT expert and responsible for the coordination of the patient engagement strategy across ALAMEDA
- Valentina Tageo, WISE, T7.2 task leader

The kick off meeting of the ECT has taken place on the 8th of September 2021 [8]. During the course of the online event (Figure 3), the participants have been provided with an in-depth introduction of the project's goals, ambitions and general stakeholder engagement principles as well as the explanation of the MULTI-ACT Patient Engagement Roadmap. The patient representatives were introduced to all research stages in which they could practically develop their contribution (design & plan, research execution, evaluation and translation to community) and were requested to reflect about their expectations towards the project's outcomes and the aspects of the research they feel they will be more likely able and feel comfortable to meaningfully contribute.

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[1] Specific provisions for collecting informed consent forms and authorization to image/voice usage for dissemination purposes are dealt with in WP1 by FISM, in collaboration with WISE and PLURIBUS.

Figure 3. First ECT virtual meeting held on September 8th, 2021

In order to operationalize the MULTI-ACT guidelines into the ALAMEDA context, a series of steps have been identified and agreed with the aim to translate the indications prescribed by the guidelines into feasible actions within the ALAMEDA work plan (Table 1).

Table 1. Operationalisation of the MULTI-ACT patient engagement guidelines within ALAMEDA

Steps R&I path	Patient Engagement Activities suggested by the MULTI-ACT guidelines	ALAMEDA translation into action
DESIGN & PLAN	• Patients are **engaged** to suggest objectives, endpoints and outcomes of research. • Patients are engaged to define the relevance and acceptability of proposed research to patient community.	ECT local representatives act as bridge between project and local realities. ECT members are trained to outreach the relevant community. Members of ECT and LCG provide inputs and feedbacks on the prioritization of research items and when/how to seek for feedbacks and evaluations/validations.
RESEARCH EXECUTION	• Patients are engaged in the **development and monitoring of research at Project Level** (e.g., collaborating for ICT device development, for the enrolment to increase participation and decrease drop-down, to increase compliance with protocols and facilitate data collection…)	ECT and LCG members are eventually the first users of the ALAMEDA kit/demo testers. ECT members facilitate the communications between patients and technical partners.

EVALUATION	Patients are engaged in discussing in the multi-stakeholder team about **new methods to measure the impact of research and align results** to the mission/agenda. • Patients are engaged in **the assessment of new approaches** and products arising from research. • Patients are engaged in working with other stakeholders on research reports.	Patients, Informal caregivers, especially in LCG, are invited to evaluate the devices employed in ALAMEDA (usability, accessibility, safety...) the timing of use, their perspectives about simultaneous use of 1+ devices. The back-and-forth exchanges with non-medical stakeholders will provide valuable non-specialised insights to tech partners.
TRANSLATION TO COMMUNITY	• Patients are engaged in in **shaping the "translation strategy" of research results** to easy-to-use and easy-to-understand (lay) material and in communication activities to disseminate the research results • Patients are engaged in advocacy to leverage uptake of research results.	The ECT and LCG members are mobilised to support the communication and dissemination efforts via their local or national associations.

ALAMEDA held its second Engagement Coordination Team meeting in February 2022 (Figure 4). This was an important opportunity for us to share the outcomes of local engagement activities run so far at the level of pilot sites, discuss preliminary findings, and agree on next steps.

At that time the three Local Community Groups had been constituted in Italy, Romania and Greece, respectively including patients, caregivers and clinicians involved in the planning and delivery of care and rehabilitation services in three neurological disease domains of Multiple Sclerosis, Stroke and Parkinson's disease.

Among the topic discussed, the different consultation modalities and tools used in the three settings were described. While FISM (Italy) and SUUB (Romania) utilised individual interviews and focus groups as main methods, in Greece (NKUA) the team opted for using a remote and asynchronous feedback collection strategy (via email and online forms). Also, notable good practices have emerged e.g., in the selection of patients belonging to the Italian LCG where specific attention has been paid to gender balance as well as representativeness in terms of diversified personal profiles with different educational and professional background and family responsibilities.

The first iterations of the LCG engagement have been basically meant to gather the direct insights from their members on the questions to be asked via questionnaires with a view to pose stronger attention on symptoms and circumstances which, according to the experiential knowledge of patients with their conditions, may represent warning signs of potential worsening or relapse "red flags". In addition, preferences in relation to the user-interface interaction modalities, length and frequency of measurements, or the willingness to allow the capture of face image during the interactions so as to make emotional sensing and analytics possible, have been collected.

So far, the work done to involve patients has been much appreciated. Importantly, all patients have shown trust toward the team they are working along with. The patients/caregivers are reportedly willing to provide feedback and being involved in research, still some doubt arose regarding their perception of the added value of their contribution which makes in some cases patients hesitant about the necessity of their engagement.

In this regard, several ECT participants agreed that it may be too early to perceive a real return of engagement as the project is not mature enough to report tangible results to the LCG members. However, as a follow up action, the participants agree that it will be crucial to keep the LCG members constantly informed about progresses and make them aware of how their inputs are concretely helping shape the system. Also, giving them the chance to access the prototypes and demos and test the devices although they won't be among the patients recruited to take formally part to the study will be core to increase their comprehension and sense of utility.

Both in FISM and NKUA experience, the intermediation of the respective patient association has proven very valuable so far, both in ALAMEDA and other projects. SUUB is for the moment not connected to any association at local level, however the team id investing the chance to connect with the national Romanian association.

In general, it is clearly emerging the importance of adapting the engagement approach to local context, use existing channels and networks that already effectively work for patients and they feel comfortable with to informally share their lived experiences, such as Facebook groups, Whatsapp chats and others.

Figure 4. Second ECT virtual meeting held on February 2022

3.3 Local Community Groups: kick start and engagement in the design process

As anticipated above, the second step undertaken in the end user engagement strategy prompted by the ALAMEDA has been the constitution and activation of three Local Community Groups (LCGs). In the respective countries where ALAMEDA pilots are taking place i.e., Italy (Multiple Sclerosis), Greece (Parkinson's Disease) and Romania (Stroke). Such groups composed by 9-15 end users and animated by the respective patients and clinicians sitting in the ECT are meant to secure engagement at national and disease-specific level and provide valuable feedback as the research work progress.

Ad hoc informative materials in national languages have been produced to support this activity.

The three LCGs have held their first meetings during November 2021 and provided their preliminary inputs on the application of the project and its impact via questionnaires and live/online discussions. They have also participated proactively in the design phase by providing their preferences with regard to the data collection modalities and frequency, as well as the use of the proposed wearable and sensors. They are now actively engaged to support the research team in the next steps.

Alameda

Gruppi di Comunità Locali

Foglietto informativo

I Gruppi di Comunità Locali

Cosa stiamo facendo a Genova?

Tra Febbraio 2022 e Ottobre 2023, la Fondazione Italiana Sclerosi Multipla condurrà uno studio su 20 volontari con Sclerosi Multipla. Le informazioni raccolte creeranno una base dati da analizzare tramite intelligenza artificiale e sistemi di Machine Learning i quali, elaborando gli input provenienti direttamente dai pazienti, forniranno preziose indicazioni terapeutiche ai professionisti clinici.

Il fine ultimo è dimostrare che i dati raccolti e i modelli sviluppati dai ricercatori di ALAMEDA possano aiutare a prevedere gli episodi di ricaduta e recidiva della malattia e supportare gli specialisti sanitari nel disegno del percorso di cura e riabilitazione più appropriato.

ALAMEDA prende spunto dalle conclusioni raggiunte e gli strumenti messi a disposizione dal progetto **MULTI-ACT** terminato lo scorso aprile 2021.

MULTI-ACT ha sviluppato delle **linee guida per le organizzazioni di ricerca** per garantire il massimo coinvolgimento attivo di tutte le parti interessate nei programmi e progretti di ricerca in ambito sanitario.

In primo luogo, **ALAMEDA ha predisposto un organo di governanza partecipativa chiamato "Engagement Coordination Team" (ECT)**, composto da rappresentanti di pazienti e medici impegnati nel fornire pareri e suggerimenti ai ricercatori di ALAMEDA nel corso dei tre anni del progetto.

In secondo luogo, per assicurare che le caratteristiche specifiche di ciascuna malattia e del sistema di assistenza sanitaria nei tre paesi interessati siano tenuti in dovuta considerazione, ALAMEDA intende attivare dei **Gruppi di Comunità Locali, rispettivamente guidati dai pazienti e dai clinici che siedono nell'ECT come rappresentanti delle tre patologie in Italia, Grecia e Romania.**

Cosa sono i Gruppi di Comunità Locali?

Sono gruppi di volontari formati da 9-12 persone tra pazienti, familiari e/o caregivers, e personale sanitario chiamati a condividere opinioni ed esperienze e aiutare i ricercatori a disegnare un sistema di monitoraggio e raccolta di dati che sia flessibile ed adattabile alle circostanze ed esigenze di ciascun paziente, sempre nel rispetto della **privacy** e della responsabilità etica.

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Figure 5. Local Community Groups info sheet (Italian): sample pages 1 and 3

The outcomes of these meetings and preliminary engagement efforts are informing the detailed protocols of the pilots (WP6) and the shared decision-making model to be developed in WP3, in addition to provide information on system adaptation (e.g., obtrusiveness of the measurements, etc.) based upon their needs and comfort during the pilots and their daily living. In the next sections, the three groups and the different modalities of interactions with the end users put in place in each of them are described more in detail.

3.3.1 Local Community Group on Multiple Sclerosis (Italy)

The interactions with the LCG Italian members have been lively and with a strong role of the patients co-chairing the whole process.

It is important to note that in the case of MS, in addition to surveying the preferences and opinions of the LCG members about the devices, frequency of measurement, etc. an important discussion has been held with them around the identification and prioritisation of suitable endpoints that might act as warning signs of an incoming relapse. A summary of the output provided by the LCG's meetings is shown in Table 2, whilst the detailed outcomes of this reflections are reported in D3.2.

Table 2. Summary of the output provided by the Italian LCG

Rank	Domain	LCG members who decided to participate to specific Focus Group	Red flags identified
1	**Mobility**	2 PwMS (both men), 1 caregiver (famliar of PwMS with disability)	Balance, falls, muscle weakness and rigidity, sensorial deficit, slowened motor control
2	**Cognition**	4 PwMS (3 W, 1 M), both caregivers	Short-term memory deficit, concentration problems, cognitive lag, mental fatigue
3	**Emotional status**	1 PwMS (woman), 1 caregiver (famliar of PwMS with disability)	Stress, anxiety (irritability, worry), apathy, sadness/gloom, emotional fluctuations
4	**QoL/Daily living**	3 PwMS (2 W, 1 M), 1 caregiver (familiar of mother with MS)	Fatigue, decreased autonomy, apathy, isolation
5	**Sleep**	1 PwMS (man)	Awakenings, not restful sleep, bladder problems

During plenary meetings, a prioritization of the relevance of functional domains to monitor has been performed. Further, specific focus groups have been conducted in order to identify the "red flags" acting as warning signs of an incoming relapse and several questions, which will be delivered on daily basis to the ALAMEDA participants, have been developed. Importantly, LCG members decided to participate to the specific focus groups of interest. Expert health professionals also participated in order to support the group and answer possible questions, although – in line with MULTI-ACT guidelines - the process was guided by the patients.

Also, in addition to the information collected during the meeting a questionnaire was circulated among a broader group of end users including also patients interested in contributing though not taking part to the LCG. The questionnaire was mostly meant to complement the information gathered and oversee aspects such as the preferred data visualisation mode and interaction modalities with the devices.

Moreover, there was a consistent agreement on the need to have an interface for caregivers to be able to get feedback on the patients' status, help the patients remember to input the data, etc.

3.3.2 Local Community Group on Stroke (Romania)

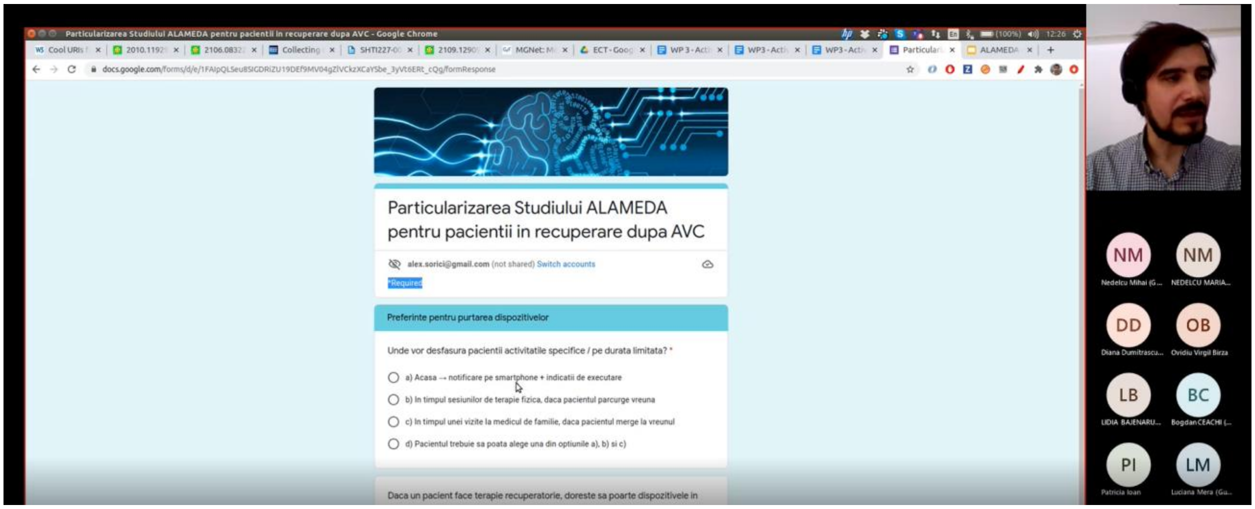
Stroke LCG members were presented with the devices and software applications to be used in ALAMEDA pilots. The overall conduction of the LCG activities has been handled by SUUB in collaboration with UPB, as it was seen advantageous to have a Romanian native technical partner directly involved in the design and development taking part into the engagement process.

The LCG members were also well informed about the tasks that the pilot participants will be expected to undertake and, similarly to the other pilots, they were given the chance to express their preferences and debates on the different options available to "customise" the ALAMEDA pilot and specifically the data collection protocol for stroke.

As physical exercise at home is a crucial part of the rehabilitation program for a stroke survivor, there was unanimous agreement on the necessity for patients to wear the devices during all home physical exercise sessions.

This and several other aspects have been shared with LCG members to get their feedback in relation to their willingness to use the chatbot, the role to be attribute to the caregivers, etc.

The complete results of such consultations are reported in WP3 deliverables and has been extremely useful in designing the ALAMEDA data collection path with a view to maximise acceptance during the post-acute treatment and rehabilitation process.



Particularizarea Studiului ALAMEDA pentru pacientii in recuperare dupa AVC

alex.sorici@gmail.com (not shared) Switch accounts

*Required

Preferinte pentru purtarea dispozitivelor

Unde vor desfasura pacientii activitatile specifice / pe durata limitata? *

○ a) Acasa → notificare pe smartphone + indicatii de executare
○ b) In timpul sesiunilor de terapie fizica, daca pacientul parcurge vreuna
○ c) In timpul unei vizite la medicul de familie, daca pacientul merge la vreunul
○ d) Pacientul trebuie sa poata alege una din optiunile a), b) si c)

Daca un pacient face terapie recuperatorie, doreste sa poarte dispozitivele in

Figure 6. Alexandru Sorici (UPB) illustrating the questionnaire to collect patient preferences during the Romanian LCG virtual meeting held on November 5th, 2021

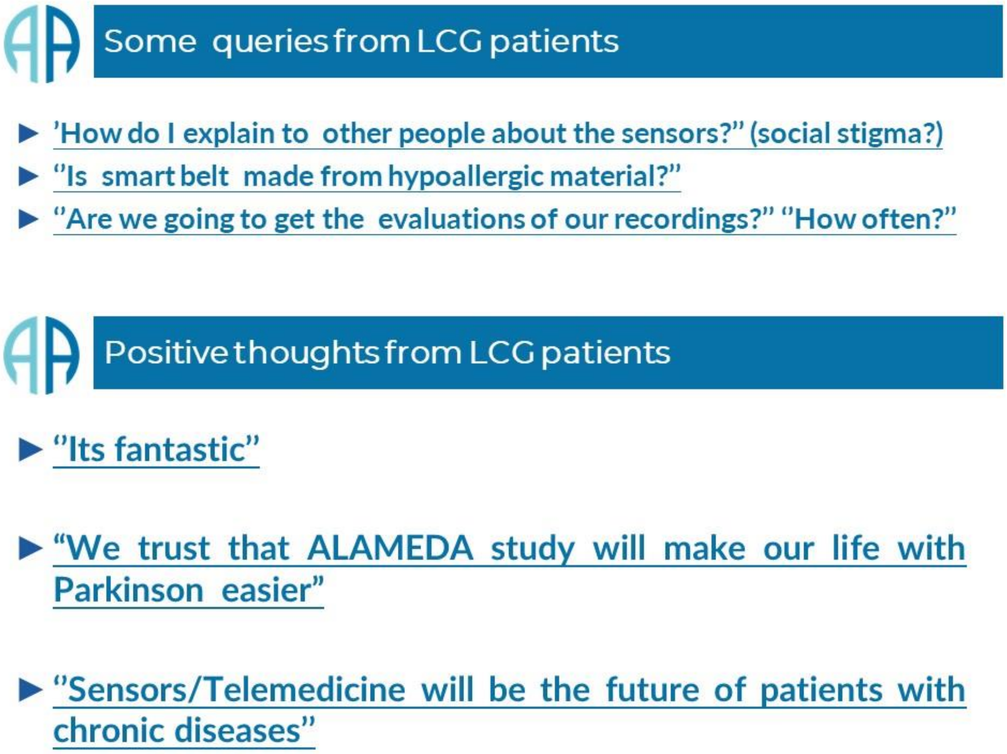
3.3.3 Local Community Group on Parkinson’s Disease (Greece)

As stated above, the Parkinson’s LCG in Greece chooses a slightly different engagement methodology. NKUA team members prepared an ad hoc questionnaire to get patient input on the data collection journey resulted which was composed by 27 closed questions to make easier for patients to fill it out.

15 patients with advanced Parkinson’s Disease answered the questionnaire and sent their answers via e-mail. These are not necessarily the patients that will be enrolled into ALAMEDA, but they have a similar profile.
More detailed information on the questionnaire and its outcome are provided in WP3 deliverables, however hereby we report the most relevant insights obtained:

- Patients expressed their preferences in relation to the study length but also their perspectives regarding the opportunity to be monitored for longer time: 53.3% of patients prefer 6 months as their maximum time to participate in the study, but a minority accept longer surveillance;
- Most patients (11/15, 73,3%) accept the more intensive surveillance, but the preferred time is quite variable and the preferred mode of interaction with the devices is quite variable;
- The patients were quite willing to have a bidirectional interaction with the devices and to get feedback and monitoring
- More than half do not want to wear electrodes on the forehead during sleep time

Overall, the results suggested that the planned data collection is deemed acceptable, although patients and caregivers have raised the issue that it may have to be tailored and “customized” for the individual patient. The extracts from the LCG discussions reported in Figure 7 showcase the generally positive reactions and attitudes but also the most frequently raised concerns around the risk of social stigmatization connected to the use of sensors and wearables, the acceptability of the devices and the wish expressed by patients to get feedback and be kept informed about the disease progress.



Some queries from LCG patients

- ’How do I explain to other people about the sensors?’’ (social stigma?)
- ‘’Is smart belt made from hypoallergic material?’’
- ‘’Are we going to get the evaluations of our recordings?’’ ‘’How often?’’

Positive thoughts from LCG patients

- ‘’Its fantastic’’
- “We trust that ALAMEDA study will make our life with Parkinson easier”
- ‘’Sensors/Telemedicine will be the future of patients with chronic diseases’’

Figure 7. Examples of feedback from Greek LCG members

4. First steps towards an informal cross-project Community of Interest

As anticipated in D7.1, ALAMEDA partners consider the interaction with other projects highly beneficial and think that the activation of an informal cross-project Community of Interest would be a valuable contribution to the debate and foster knowledge exchange.

To this purpose we have established initial bilateral conversations with the following projects which were included in the preliminary mapping in D7.1:

- LETHE: ALAMEDA shares several touch points and common goals with LETHE, including its focus on the focus on enabling prediction of the onset and progress of a neurological disease, namely Alzheimer. The dissemination and stakeholder engagement team in ALAMEDA (WISE) is working together with the respective team in LETHE (Lisbon Council) to identify a series of events to be jointly targeted via either joint publications or the organisation of joint sessions or workshops. Furthermore, LETHE has agreed to take part to the informal CoI proposed by ALAMEDA (see D7.1) and initiate a series of activities such as recurrent webinars and the writing of a joint White Paper.

- IDEA-FAST: IDEA-FAST is a large IMI funded project aiming to identify digital endpoints that provide reliable, objective and sensitive evaluation of activities of daily life (ADL), disability and health related-quality of life (HRQoL) for the following neurodegenerative diseases, among which Parkinson’s Disease. ALAMEDA T7.2 Leader (WISE) and Coordinator (ICCS) have had the chance to meet the persons in charge of IDEA-FAST within our partner PLU and learn more in-depth their priorities, the current status of their work and potential touchpoints. At the core of IDEA-FAST, there is the necessity to identify the most promising measures and devices to assess sleep and fatigue. To this purpose they have been running a feasibility study which has just come to its end. During it digital measures have been compared with traditional measures. Criteria such as reliability, usability and acceptability have been assessed. Secondly, they planned to run a larger clinical observational study to evaluate the elicited subset of endpoints and devices during 30 months on 2,000 people. As fatigue is a critical symptom to be assessed for both ALAMEDA and IDEA-FAST, we have agreed to reconvene and discuss more in detail the chance to arrange a thematic workshop on fatigue digital endpoints.

- Our partner FISM has established contacts with both RADAR-CNS and MOBILISE-D projects as they are involved in both of them with different roles. We expect to arrange dedicated meetings with after summer.

5. Plans for the next 18 months

During the next 18 months, for what concerns the engagement of end users in the pilot sites, this will be continued under the supervision of the three pilot responsible partners FISM, NKUA and SUUB, always taking into consideration the MULTI-ACT guidelines as core directions, though allowing for flexible arrangements and adaptations to the specific national and local contexts, the configuration of the different healthcare systems and patient journeys (as detailed in D2.2) and the diverse needs and preferences of patients for what concerns meeting and contact modalities.

Specifically, periodic updates on the pilot progress will be provided to all the LCGs.

As discussed within the ECT, monthly informal meetings will be carried out in order to share achievements and drawbacks of the pilot implementation. Suggestions on how to maximise participants' adherence will be gathered. To this purpose, social media will also properly used, e.g., by creating social media pages in national languages (in addition to the official Twitter and LinkedIn project's handle) where participants, LCG members and researchers can share information and experience as the project evolves. This activity is being coordinated between WP7 and WP8, as responsible WP for communication and dissemination. A list of preliminary preferences on the social networks to be used (e.g., Facebook, Whatsapp, Telegram, etc.) has been compiled. In consideration of the different preferences, the choice of the platform to be used might vary across countries.

More in general, LCG members will be further mobilised in actions intended to increase information speading and outreach to the patient community as well as raise awareness on the role they can play within this project and the health innovation landscape in general. To this end, the connection with local and national patient association is deemed pivotal and will be exploited. For example, it is noteworthy that the Italian MS Society (and its foundation, FISM) has strong territorial roots and a consolidated presence at societal level, in fact, they have already hosted ALAMEDA at their Annual Scientific Congress 2022 recently held in Rome.

In fact, as foreseen in the DoA, the consortium has also planned to hold three pilot level workshops ideally either towards or after the end of the pilot execution period.

For what concerns the other stakeholder categories, the Exploitation Manager UNISYS, in collaboration with WISE and ICCS, is working on a calendar of actions to setup engagement activities, such as direct contacts, workshops and webinars with the potential third party vendors as well as other healthcare providers, research institutions and policy makers to pave the way for future use and exploitation of project's results, as soon as they will become available. This activity will also benefit of the interaction with other projects which status has been reported in the previous section above.

6. Summary and conclusions

The Deliverable D7.1 has set the departing point for the ALAMEDA stakeholder engagement strategy implementation whilst the present Deliverable D7.3 contains the activities reported so far.

From the very beginning of the ALAMEDA project, it has been apparent that the core stakeholders to be involved in the (co-)design and development work that the project entails are undoubtedly those who are identified in the Description of Action as the primary end users (and ultimate beneficiaries) of its results i.e., the patients, the Health Care Professionals (HCPs) and the caregivers.

Thus, the attention of Task 7.2 has focused on the activities highlighted in the Section 3 of the present Deliverable, namely the setup and activation of the Engagement Coordination Team and the first round of activities conducted with the Local Engagement Groups in each pilot site which has proven extremely valuable to guide the design of the data collection protocol of ALAMEDA and embed patients', health care professionals' and caregivers' preference in it.

The ECT and the LCGs will continue being the backbone of the end user engagement ALAMEDA strategy as they will help our research to design a shared decision-making model allowing truly personalised digital health technology experiences while securing comparability and reliability of research results. In this process, the role of health care professionals is equally pivotal to assess the actual clinician most burning needs the ALAMEDA system should be able to address and get their in-depth knowledge of organisational and procedural barriers as well as disease-specific aspects to make sure they are consistently taken into account.

As we now enter the second phase of ALAMEDA, a series of other actors are also instrumental to the success of the project and the exploitation of its results beyond its end. Those stakeholders have been identified and mapped in D7.1 and will now be prioritized also in connection with tailored communication and dissemination activities.

Last, ALAMEDA has opened fruitful dialogue channels with a selected group of ongoing projects working on specific aspects and digital endpoints for the same diseases (e.g., IDEA-FAST) as well as deploying AI and big data solutions on different neurological diseases (e.g, LETHE) and is in the process of agreeing upon mutually beneficial collaboration terms and plan joint activities.

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