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Abstract: This document describes the stakeholder engagement strategy of project ALAMEDA and defines the different types of stakeholders participating in the e-health ecosystem, as well as the different state-of-the-art methodologies for actor involvement.

Disclaimer

Revision History

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Glossary

Abbreviation	Full name
AIH	ALAMEDA (Digital Health) Innovation Hub
CoI	Community of Interest
ECT	Engagement Coordination Team
HCP	Healthcare professional
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 D7.1 is developed as a first output of task T7.2 which aims to map and analyse stakeholders, their preferences, and degrees of influence upon and interest towards ALAMEDA's results with a view to delivering a comprehensive stakeholder engagement strategy. Concrete efforts to engage a broad and diverse set of stakeholders is deemed crucial to build the foundations for new models, partnerships and institutional changes needed to move toward value based and technology-enabled healthcare systems delivering the highest possible quality to the patients.

The document contains a broad and detailed analysis of the relevant actors and main challenges and opportunities towards an effective stakeholder engagement strategy in a digital health research and innovation project such as ALAMEDA, as well as an initial list and assessment of the most relevant projects and networks the project team plans to establish synergies with.

It entails a thorough discussion of the different categories of stakeholders interacting in the digital health ecosystem and specifically in the digital brain health realm and to what extent they are potentially manifesting their interest in the expected project's outcomes as well as their power to shape and influence it.

For what end users (namely, patients, healthcare professionals and caregivers) are concerned, the engagement strategy of ALAMEDA is particularly ambitious as it aims to take a step beyond mere consultation and have them on board as design partners. This is made possible thanks to the centrality attributed to the definition of a novel shared decision-making model in WP3 that will specify 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 - will conduct a series of stakeholder engagement activities which are sketched in the present plan to secure a continuous involvement of the end users in the research, design, testing and evaluation of the technologies. Such activities highly benefit from the experienced capacity of partners such as FISM, who will be specifically guiding the patient engagement effort following the guidelines of the RRI recently concluded project "MULTI-ACT". The constitution of the Engagement Coordination Team and the Local Community Groups 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. Furthermore, policy- and market-oriented stakeholder engagement activities are planned and described for the second and third years of the project 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 authors explore and acknowledge 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. All those projects are identified as the potential members of a novel AI4Brain Community of Interest and bi- and multi-lateral exchanges have been initiated to explore interests and opportunities.

1. Introduction

1.1 Purpose of the document

The present deliverable D7.1 “Design of Stakeholder Engagement Plan” 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 in building the foundations for new partnerships and institutional changes to support the shift towards value-based healthcare models and sustainable, high quality health systems of the future.

Specifically, D7.1 is developed in the frame of the activities planned under the task T7.2 and contains the initial plan of stakeholder (including patient) engagement. It will be followed by a mid-term and a final stakeholder engagement report, which will be respectively presented in D7.3 and D7.8.

1.2 The strategic importance of stakeholder engagement for ALAMEDA

ALAMEDA aims at implementing a suite of smart services focused on improving care for patients with brain diseases. Using an Artificial Intelligence (AI) based healthcare support system, the project intends to enhance disease monitoring capacities and provide personalised rehabilitation and treatment assessments for patients with Parkinson’s, Multiple Sclerosis and Stroke (PMSS), to ensure that medical interventions are effective and that situations likely to worsen can be early detected and predicted.

This way ALAMEDA will materialise the triple aim of (value-based) digital health innovation: enhanced patient experience, improved health outcomes, and controlled health care costs.

Such ambitious goal requires the mobilisation of a huge variety of stakeholders interacting in the digital health innovation ecosystems which entails several elements of complexity potentially hindering their successful engagement:

- A highly regulated sector: regulatory barriers that obstruct the emergence of new professions, products and services with the effect of maintaining the status quo have been included in the list [1] of hindering factors that delay the implementation of disruptive innovations aiming to transform healthcare delivery processes such as ALAMEDA. Thus, the involvement of policy makers and regulators acquires crucial importance even in a proof-of-concept study in order to foster the appropriate conditions for deployment and scaling up.
- The presence of complex power dynamics to manage: another important obstacle relates to the lack of preparation among the involved agents or to the established interests of specific stakeholders and their fear of losing influence and power within the system [1].
- A generally low perception of the shared ownership of the research & innovation challenge which hamper the identification of common agendas and objectives.

For all the above reasons, ALAMEDA has gathered a considerable number of diverse interests and perspectives in the composition of the consortium and aims to expand its community of reference also building on the learnings obtained from previous projects run by some of its partners.

One of these in particular, MULTI-ACT, has set the basis for a paradigm shift in the empowerment of patients and their surrounding communities and we will exploit its knowledge and guidelines to build a strong end users (and specifically) patient engagement route along the whole project's duration.

Furthermore, the project plan foresees that a key component of ALAMEDA design and final outputs will be the launch of a multi-side market information platform, the ALAMEDA Digital Health Innovation Hub aimed to stimulate and support multi-stakeholder collaboration and nourish further development and testing opportunities by connecting innovation seekers and solvers (e.g., SMEs, startups and developers). The aim of the platform is:

- to integrate the information generated by the project and make them available to developers as an open source;
- to promote the research findings, guidelines and evaluation results to the broader academic audience and the relevant decision makers.

The ALAMEDA Digital Health Innovation Hub is going to represent the keystone legacy of the project beyond its end and a virtual place for open innovation to build upon and flourish around ALAMEDA's results.

1.3 Deliverable structure

The deliverable D7.1 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 detailed explanation of the stakeholder analysis and mapping methodology to be used in ALAMEDA and presents an initial plan for differentiating engaging methods depending on the stakeholders' degrees of interest and power.
- Section 3 makes a spotlight on the engagement of the end users and specifically the patients and their communities, which is central to the success of the digital transformation framework proposed by ALAMEDA and its shared decision-making model.
- Section 4 introduces the concept and the policy background motivations behind the constitution of the AI4Brain Community of Interest.
- Lastly, Section 5 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 24 months.

2. Stakeholder analysis

The design of an impact-driven stakeholder engagement strategy requires an accurate identification and analysis of the involved stakeholders.

The stakeholders that have a potential interest and/or influence in the expected results of ALAMEDA are depicted in Figure 1. A preliminary analysis of the stakeholder categories has been presented in the Dissemination Plan (deliverable D8.2) for what concerns the elicitation of the most appropriate channels and tools for communication and outreach.

In the present section, we take a step further to provide a more in-depth analysis of the roles in the digital health innovation ecosystems, interests, priorities and expectations of each category in order to devise the most appropriate ways to engage the necessary actors and competences and build a fertile ground for ALAMEDA results' use and exploitation of the scientific and technological knowledge that the project is generating.

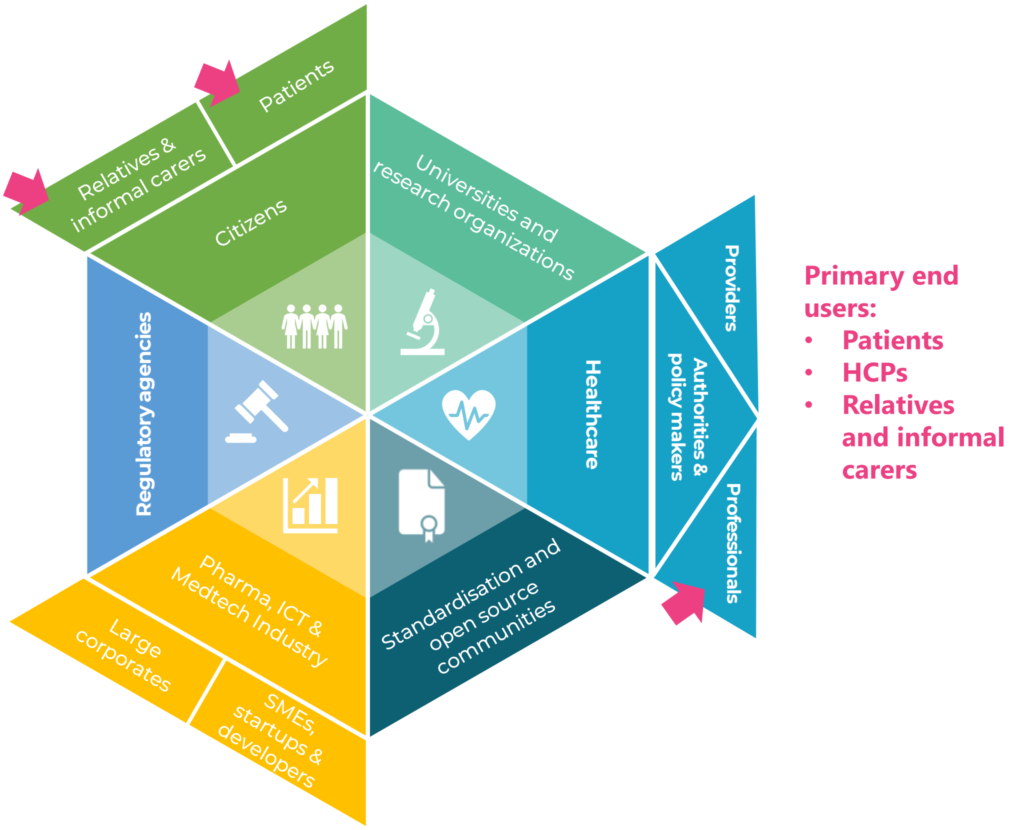


Figure 1. Key stakeholders and primary end users in ALAMEDA

From the very beginning of the ALAMEDA project, it has been evident that the core stakeholders to be involved in the research 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. Nonetheless, a series of other actors are instrumental to the success of the project and the exploitation of its results beyond its end. Thus, we are going to provide a concise analysis of each category following the methodology described hereafter.

2.1 Identification and mapping

The Stakeholders' analysis matrix is a tool (see Figure 2) for systematically identifying, selecting and analysing the stakeholders and their roles within the ALAMEDA project lifecycle. It is based on a simple matrix template that measures Influence vs. Power for each specific stakeholder group and/or individual.

Four broad stakeholder categories may be identified, these being:

- **Potential Supporters**: They typically demonstrate high influence capacity but lower than desired interest levels. Hence, it is important to make sure we engage with them, in a way that keeps them satisfied, consulting them about their needs, preferences and opinions and strengthens their support to the project. These stakeholders are sometimes overlooked because they have little or no influence on the final project's outcome and its implementation. However, they should be consulted as the project impacts them. They are generally consulted to better understand the potential effect that a project would have on them in the event of a large-scale adoption or because they have expertise in the area of interest. With time, some of them should become Promoters.
- **Promoters**: Are the groups/individuals who are the strongest "team" within our stakeholder groups. They exercise a high influence level while at the same time they are strongly and genuinely interested in contributing to the project success. We shall be closely collaborating with them to receive the highest possible valuable input.
- **Gatekeepers**: Are the groups/individuals who show great interest in the project but typically do not have much influence capacity. However, they act as strong promoters to the ALAMEDA project, and we shall be keeping them informed on all project aspects.
- **Bystanders (or indifferent)**: Are the groups/individuals that have neither high influence nor high interest in the project, and we certainly need to monitor their actions to make sure that we do our best effort to eventually turn them into *Gatekeepers*, by further engaging them with the ALAMEDA project.

Although originally aimed to provide guidance and support to the European Commission's officials involved in the EU policymaking cycle and the EU legislative process, the Better Regulation Guidelines toolbox [2] has a dedicated chapter on stakeholder engagement and offers a stakeholder identification tool containing some practical questions to guide the classification of stakeholders, most of which are valid regardless the ultimate aim of the engagement strategy. Here below an excerpt of those questions which prove useful to clearly identify which matrix category each stakeholder group is more likely to belong to.

Questions to examine the level of influence:

- Does the status of the stakeholder confer upon any particular legitimacy or relevance (*status test*)?
- Is the stakeholder's leadership regarded as personally influential (*VIP test*)?
- Is there evidence that this stakeholder has a wide popular following? How effective is the stakeholder in using press relations or new technology to publish views?
- What is the stakeholder's track record?
- Has the stakeholder successfully persuaded decision-makers in the past?

Questions to examine the level of interest:

- How close is the issue to the primary purpose/role of the stakeholder (*proximity test*)?
- How prominent is the core ALAMEDA objective on the stakeholders' agenda (*agenda test*)?
- What is the history of the stakeholder's involvement with this issue?
- How many of the stakeholder's active members are directly affected?

- At ‘worst case’ how affected might the stakeholder be?

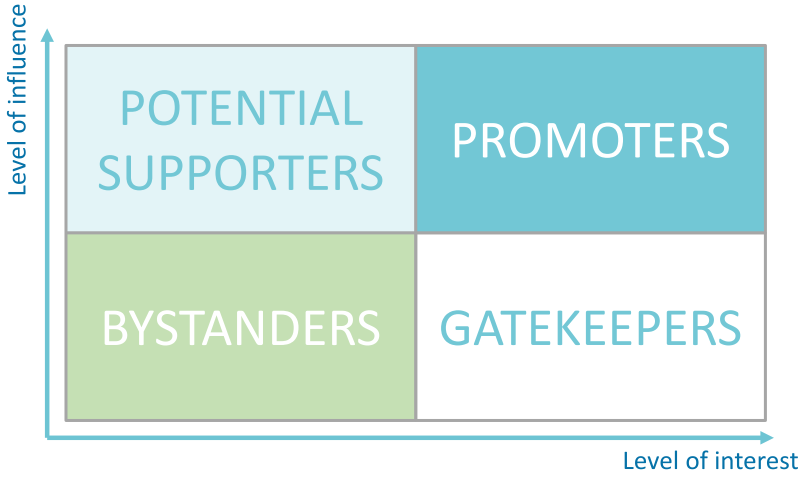


Figure 2. Stakeholder engagement matrix

After carefully considering the above questions, stakeholders can be placed in one of the four different matrix categories as illustrated in Table 1. The aforementioned tool is particularly useful to classify stakeholders and consequently assess the actions that need to be taken in order to trigger/enhance their engagement within the ALAMEDA project. However, it is important to stress that this is not to be considered as a strictly rigid classification because of the several nuances within each stakeholder groups as well as difference among country-level stakeholders (e.g., certain countries and regions may show a higher degree of innovation readiness and proactivity from their health authorities and healthcare systems).

At the beginning of the project the partners have also been provided by the T7.2 leader with a spreadsheet to collect relevant names of networks and organisations deemed important to monitor and interact with. Such list is a living document containing only organization-level generic data and is being complemented and integrated with the professional networks of each team members who committed to activate their own personal and organizational contacts so as to spread the word about the project, as well as enlarge the followers’ base in social media and the number of visits to the website as long as the project goes ahead. A preliminary list of selected relevant stakeholders including EU and international level networks is provided in section 2.2.

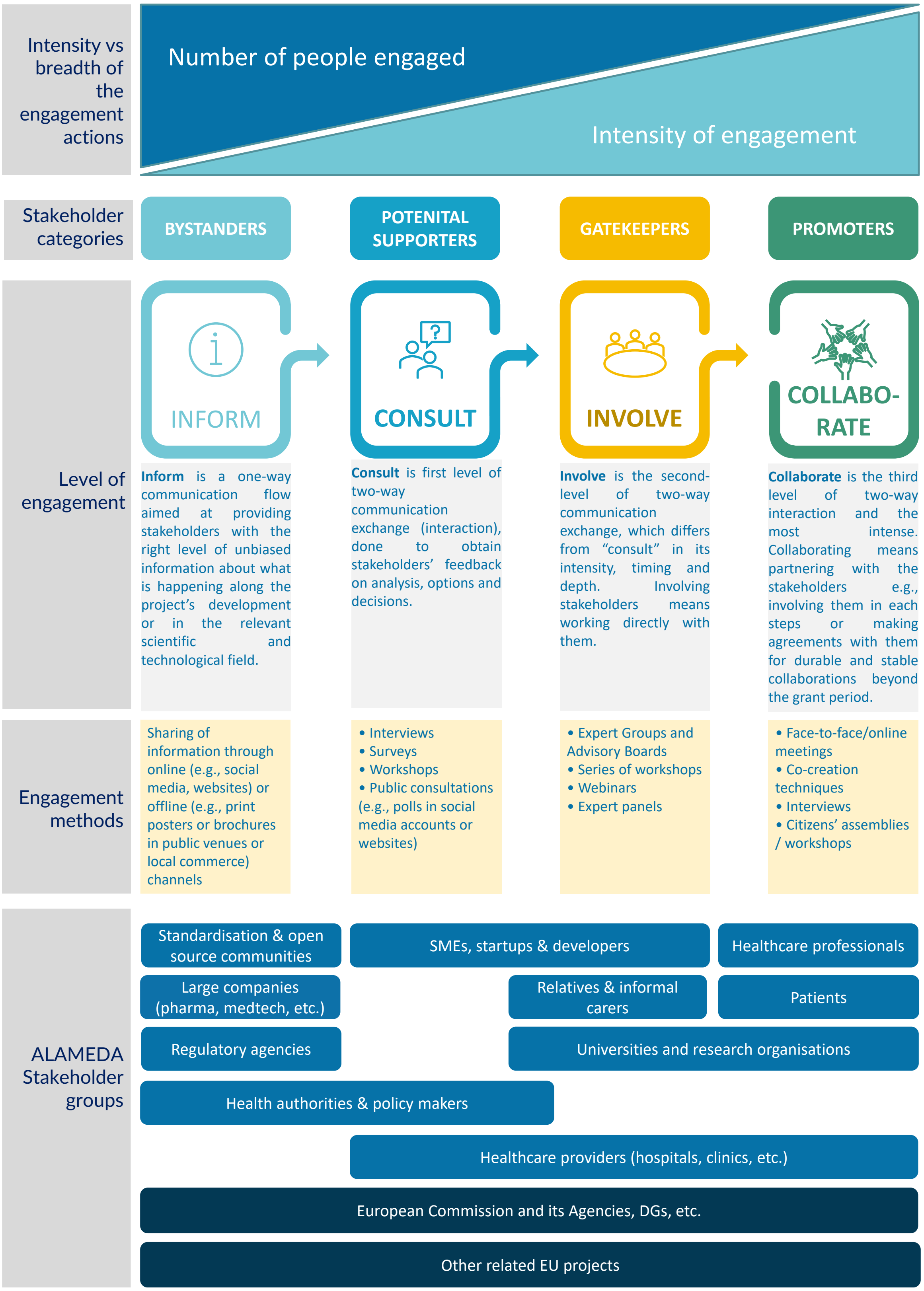
Table 1. Mapping of ALAMEDA stakeholders across the four matrix categories

Stakeholder group	Matrix category	Interests in the project	Power (i.e., capacity to influence the project)
Patients (individuals)	Promoters	The patients are the ultimate beneficiaries of ALAMEDA project. The solution developed by ALAMEDA science and technology experts aims at providing them with more accurate assessment of their condition and corresponding evolution as well asthe response to treatment.	In the consortium, patientsare directly represented and taking part to different steps of the R&I work via their participation in the Engagement Coordination Team (ECT) and the Local Community Groups LCGs) as well as their inclusion in the pilots and within the research conducted in Task 3.3 concerning the socio-economic determinants of the diseases (see Section 3.1 for details). So far, their needs and preferences are being taken into account to design the use cases, discuss the variables to be measures and devices to be used (WP2) and settle a continuous shared decision-making process (WP3).
Patients (associations)	Promoters	Patients' association are coming together to ensure the promotion of the interests of patients who are at the heart of the development of digital health technologies and policies. Their main interests concentrate on sharing best patient-centric practice in digital health and ensuring the patient perspective is embedded in policy and government strategies supporting the introduction of technologies in care pathways. In some cases they are also directly funding and supporting research.	They are key actors in the ALAMEDA ecosystem of stakeholders due to their proximity to patients and their communities and their capacity to: (i) Promote understanding of the patient experience of digital health; (ii) Ensure patients are receiving the support needed to access and take the most advantage from digital health technologies; (iii) Inform policymakers on what good practices look like. Specifically, in ALAMEDA one of the pilots is led by a patients' organisation, the Italian Multiple Sclerosis Society Foundation (FISM), which thus has a central role in the development of the project's outcomes. FISM is also leading the patient engagement strategy of the project and guiding the activities of the ECT and the national LCGs in close cooperation with the other national pilot responsible partners.
Healthcare professionals	Promoters	Currently, assessment of function for brain disorders is based mostly on "snapshots" taken during clinical visits and subjective perception of patients' status during the period since their last visit. However, even well-validated instruments may miss overall trends due to variation within and across days, are vulnerable to variations among different clinicians, do not capture activities and function in real life settings, and tend to be biased toward more recent experiences. In addition, these types of assessments generally provide little help in predicting problems during early stages of a disorder, or in helping people and their clinicians detect upcoming periods of relapse in conditions such as MS or assessing the response to rehabilitation and treatment. For these reasons, the HCPs have very high stakes in ALAMEDA's potential results as it holds the promise to reduce these gaps by enabling better monitoring and early detection and prediction.	Healthcare professionals have a strong influential role on ALAMEDA as they are in the position to guide the design of the observational study and the identification of the key parameters to be measured as well as the most relevant questions the predictive analytics is expected to help answer. In ALAMEDA, healthcare professionals are directly taking part to the project's development via the participation of clinician bringing expertise in the three pathologies, respectively from NKUA (Parkinson's Disease), SUUB (Stroke) and FISM (Multiple Sclerosis).

Stakeholder group	Matrix category	Interests in the project	Power (i.e., capacity to influence the project)
Relatives and informal caregivers	Gatekeepers	Digital health technology can help address the adverse health complications that caregivers face by improving the ability for caregivers to monitor health and medications and assisting in managing everyday tasks. Innovative technologies also have the potential to help caregivers feel more organized and ultimately more in control.	Non-professional caregivers play an important and still underappreciated role in society and in the healthcare systems, juggling tasks both medical and mundane, and dealing with stress and burn out while doing it. Along with patients, their experiential knowledge of accompanying a person with a brain disease along his/her recovery, treatment or rehabilitation path is invaluable. For this reasons, informal caregivers are invited together with patients and healthcare professionals to take part to the ALAMEDA Local Community Groups. Furthermore, caregivers' networks and associations will be reached out via dissemination and communication actions.
Healthcare providers (hospitals, rehabilitation clinics, etc.)	Potential Supporters (likely to become Gatekeepers) and Promoters	The healthcare providers are and will increasingly be at the driving seats [3] in the digital transformation of the sector. Experts [4] suggest this could take different forms depending on their type of care (primary, specialised, acute, post-acute, or long-term care) the provider is delivering and the role each of them will strategically decide to play in the future digital healthcare ecosystems. Monitoring and assessment systems such as ALAMEDA have the potential to provide them the needed scientific evidence and technological assets to pursue the paradigmatic shift towards value base healthcare models thus allowing them to increase their return from the invested capital while delivering the patients a fully integrated experience centred on their needs. Overall, ALAMEDA will benefit healthcare professionals and providers by broadening the current panorama of diagnostic and monitoring tools available for clinical and healthcare practice.	In ALAMEDA, three clinical partners are participating directly in the project's execution from the solution co-design to its testing and evaluation. Though, they possess different profiles and play diverse roles in the care continuum for PMSS patients. FISM is a patient-driven research foundation acting as pilot leader for Italian site through its rehabilitation clinic for patients with MS. NKUA has joined the consortium and the pool of pilot sites via the Parkinson's Disease and Related Movement Disorders Outpatient Clinic, located in Aiginition University Hospital of Athens in Greece. SUUB is one of the largest hospitals in Romania and brings the expertise of their Neurology Department treatment patients suffering from a stroke. Beyond them, it is crucial to interact with a broader array of external healthcare providers in order to take into due consideration the diverse configurations of care pathways and roles of different types of healthcare providers.
Health authorities (payers) and policy makers (e.g., national/regional ministries of health)	Bystanders	Reimbursement pathways for digital health solutions are evolving at different speeds in different European markets. Germany, Sweden, and the United Kingdom are relatively mature markets where governments are promoting the digitization of care and have standardized reimbursement pathways. Elsewhere, pathways are either not yet established or present several regional differences.	As publicly funded health systems are the norm in Europe, reimbursement from one source—payers—tends to offer the greatest revenue potential and is the goal for the majority of companies developing digital health solutions. Thus, although their influence at a proof-of-concept stage, such as ALAMEDA's case is, is relatively low, it is crucial to gain a good understanding of potential future reimbursement pathways in order to design the most appropriate and feasible exploitation plans.
SMEs, startups and developers	Gatekeepers	Healthcare is a unique area for innovation where SMEs have a major part to play whether that be driving economic growth and creating jobs or reducing costs across	These include Consortium Partners (i.e., CATALINK, WELLICS, PLURIBUS, ENORA) as well as potential third-party providers that will exploit the

Stakeholder group	Matrix category	Interests in the project	Power (i.e., capacity to influence the project)
		increasingly cash-strapped healthcare systems dealing with ageing populations and the attendant increases in co-morbidities and chronic diseases. Research-intensive SMEs, technological start-ups and developers have the innovation capacity, creativity, and agility to develop faster and more efficient diagnostic and treatment methods are more in demand than ever. However, there is an increasing need for them to access to lively multi-stakeholder ecosystems, innovation testbeds and multi-sided market platforms such as the one the ALAMEDA Digital Healthcare Innovation Hub (AIH).	code and the software components of the ALAMEDA AI Toolkit through accessing the AIH. The AIH will provide developers with an official place to gather resources and engage with other developers to ask questions and discuss current source code developments, as well as investigate on further context- or organisation-specific developments of the software. It is thus specifically important to involve early in the AIH design process all those supply side actors that have a stake on the AIH so as to ensure it is conceived to embed the desired functionalities which will make of it the open and participatory ecosystem as planned in D7.1. They can provide key insights on the most advantageous features and services it should possess, and their engagement is pivotal to start creating the desired critical mass of stakeholders which will support its utility and sustainability beyond the project's end.
Universities, research organisations (including individual researchers)	From Gatekeeper to Promoters	Digital health centres, big data labs, and wearable-focused research facilities are becoming increasingly common at leading academic institutions across Europe. They have the knowledge and human capital as well as the infrastructure to efficiently generate evidence that will inform decisions and lead to positive outcomes for all the other stakeholders including patients, doctors, hospitals, insurers, regulators, and investors. For this reason, ALAMEDA attracts the interests of many research groups who are working on related or complementary innovation paths and looking to answer questions such as: (i) What are the most effective ways to incorporate new digital tools into health care? (ii) Will these solutions actually improve patient care? (iii) Is the process of implementing these tools worth the costs?	In an RIA-type of projects such as ALAMEDA, universities and research labs are the backbone of the innovation process bringing capacities, know-how and infrastructure. In particular, five large research entities based in four countries (ICCS, CERTH, UNIC, NTNU and UPB) are directly engaged as Promoters and responsible for the technological development of the augmented intelligence solutions put forward by the project. An increasing number of other public and private research organisations across Europe are working in the same still largely unexplored field: although they do not have a direct major influence on the project's execution their engagement is crucial to promote open and cross-border knowledge exchange. In this sense, researchers will be one of the core groups of stakeholders with the highest incentives to access and use the facilities made available by the AIH.
Standardisation and open source communities	Bystanders	The use of open standards and open source software provides a set of cost-effective, adaptable options for countries and regions. The growth of open ecosystems is expected to progressively reduce barriers of entry for new solutions, allow countries the flexibility to deploy customizable solutions to meet their needs, and provide key capacity-building opportunities for emergent entrepreneurs and technologists in the countries where these systems were being deployed. The philosophy of common goods and sharing that underlies open source naturally extends to the open exchange of data. This is accomplished through the promotion of open standards and interoperability approaches that allow the easier data exchange between systems.	From a patient's point of view, interoperability increases patient safety by increasing access to and the availability of clinical data thus the adoption of relevant standards is fundamental for ALAMEDA success. The existing connections between ALAMEDA's partners and relevant standardisation entities and communities, together with the contribution of Advisory Board members, are going to be exploited in order to develop and submit a standardisation proposal to the corresponding authorities so as to develop new International-level Standards in AI-related digital healthcare applications focusing on brain diseases.

Stakeholder group	Matrix category	Interests in the project	Power (i.e., capacity to influence the project)
		Open source communities help answer critical development, implementation, and governance questions. These communities foster peer-learning between countries and users as implementation best practices and software improvements are captured and shared. Thus, they share many of the goals of the to-be AIH and it is important to keep them informed and share documented progresses of the project with them so as to ensure cross-fertilisation.	
Regulatory agencies	Bystanders	Whether it is software-as-a-medical-device (SaMD), artificial intelligence (AI), clinical practice technologies or consumer health technologies such as wearables, apps or fitness trackers, regulators must start revolutionizing their approaches to support innovation and implement new models to address technology, evaluate and authorise solutions to keep the pace of the market's growth. Projects such as ALAMEDA may contribute to settle evidentiary standards in a relatively novel field such as the application of AI-based models in the monitoring and assessment of brain related conditions.	Health regulatory authorities and bodies (e.g., medicines agencies, HTA bodies, notified bodies for medical devices) have limited power to influence the execution of the proof-of-concept study planned by the ALAMEDA team, however their activities and initiatives must be closely monitored.
Other related EU-funded and national projects	Depending on the consortium composition and project's status	Cohesion and collaboration-oriented activities across projects are strongly encouraged by the European Commission services and recognised of high value. See dedicated chapter (Section 4.1)	See dedicated chapter (Section 4.1)



Intensity vs breadth of the engagement actions

Number of people engaged

Intensity of engagement

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.	COLLABO-RATE **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 3. ALAMEDA stakeholder engagement strategic framework

After classifying the stakeholders across the four above mentioned quadrants and the respective four modalities of engagement, the next step is to determine the level and intensity of engagement that depends on time, resources, and stakeholder groups as well as the pre-existing ties and collaborations established by project partners before and outside the project itself. Therefore, it is advisable to think about these aspects well in advance. The main distinction in terms of intensity of engagement can be made between one-way and two-way communication flows. The latter implies a greater degree of exchange and contribution on the stakeholder's side; thus, it is usually more time-and resource-consuming and for this reason it tends to be directed to a narrower group of influential players. On the contrary, one-way informative activities usually address larger and less specialised audiences.

Finally, some engagement methods per stakeholder category are included as well in Figure 3 based on the authors' elaboration of the Australian Government Stakeholder Engagement Framework [5]. It is noteworthy that these methods are not exhaustive. Instead, they can serve as a springboard to think about additional methods that can be used as long as the project progresses. Also, there is no one right stakeholder engagement method and you may choose a number of methods at different stages of the process. Thinking about and selecting the most appropriate method of stakeholder engagement and the relevant tools and techniques to facilitate the engagement process can vary according to the situation, time, skills and resources. All engagement methods have their benefits and limitations and it is important to select the right one and review to ensure the method best fits the particular environment.

Adding another layer of complexity, stakeholder engagement should be guided by several principles. No matter these principles, an essential part of the engagement is having a clear rationale regarding why one should engage with a particular type of stakeholders. A summary of the guiding principles that can be useful for stakeholder engagement can be found in Table 2.

Table 2. General principles for effective stakeholders' outreach and engagement

Principle	Adherence
Purposeful	There has to be a clear goal for each stakeholder engagement
Inclusive	All relevant stakeholders have to be involved; it has to be easy for them to be involved
Timely	Stakeholders should be involved from the start and with an agreement on when and how to be involved
Transparent	Engagements have to be open and honest, with clear expectations, purposes, timing and methods
Respectful	The stakeholders' expertise, their needs and constraints should be acknowledged and respected

2.2 Preliminary selection of relevant external stakeholders

In the present section we preliminarily list a selected sample of relevant external stakeholders including EU level networks and associations we are constantly monitor and establishing bi- or multi-lateral interactions with as long as the project evolves.

Patient organisations and disease-specific networks:

- European Parkinson's Disease Association (EPDA), https://www.epda.eu.com/
- Stroke Alliance for Europe (SAFE), https://www.safestroke.eu/
- European Multiple Sclerosis Platform (EMSP), https://emsp.org/
- Multiple Sclerosis International Federation (MSIF), https://www.msif.org/
- Patient Reported Outcomes for MS (PROMS) Initiatives powered by the European Charcot Foundation, https://www.charcot-ms.org/initiatives/proms-1

- International Progressive MS Alliance, https://www.progressivemsalliance.org/
- European Brain Council (EBC), https://www.braincouncil.eu/
- European Patients Forum (EPF), https://www.eu-patient.eu/
- European Patients' Academy on Therapeutic Innovation (EUPATI), https://eupati.eu/
- National associations of patients with PMSS that are active in research, innovation and people empowerment such as e.g., the Asociación Parkinson Madrid (https://www.parkinsonmadrid.org/, Spain), active partner in the IDEA-FAST project (see section 4.1.4).

Research infrastructures, clusters, and initiatives:

- EBRAINS Research Infrastructure, https://ebrains.eu/
- Human Brain Project, https://www.humanbrainproject.eu/
- European Brain Research Area (EBRA), https://www.ebra.eu/ (see section 4.1.5)
- National relevant research nodes such as FutureNeuro – SFI Research Centre for Chronic and Rare Neurological Diseases, https://www.futureneurocentre.ie/
- International Brain Initiative, https://www.internationalbraininitiative.org/
- Confederation of Laboratories for Artificial Intelligence Research in Europe (CLAIRE), https://claire-ai.org/
- Big Data Value Association (BDVA) / Data, AI and Robotics (DAIRO) aisbl Task Force 7 – Subgroup 3: Healthcare, https://www.bdva.eu/tf7-sg3-healthcare
- Candidate European Digital Innovation Hubs (EDIHs) having Life Sciences & Healthcare as one of their focus areas, https://s3platform.jrc.ec.europa.eu/digital-innovation-hubs-tool

Networks of Scientific Societies:

- European Academic of Neurology (EAN), https://www.ean.org/
- Federation of European Neuroscience Societies (FENS), https://www.fens.org/
- International Brain Research Organization (IBRO), https://ibro.org/about/
- European Federation of Neurological Associations (EFNA), https://www.efna.net/
- International Parkinson and Movement Disorder Society (MDS), https://www.movementdisorders.org/
- European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), https://www.ectrims.eu/
- European network for best practice and research in MS Rehabilitation (RIMS), https://www.eurims.org/
- European Stroke Organisation (ESO), https://eso-stroke.org/

In addition to the above categories, it will be of utmost importance to interact proactively with research groups, AI developers' communities, start-up and SME networks and accelerators as long as the work towards the launch of the AIH will advance and present them the prototype as soon as it will be available.

3. Engagement of the end users

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 [6]. 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 [7] 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." [8]

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 will be 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 based methods will be able to integrate and handle efficiently heterogeneous datasets and datasets with missing values (incomplete). 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. 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.

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 [9] 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.

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 risk that the patient perspective may be lost. For this reason, ALAMEDA put meaningful patient engagement at the top of its priorities and build 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 an 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.

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" [10]. 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 [11].

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 WELLICS 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 [12]. During the course of the online event, 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.

The subsequent step planned in the end user engagement strategy prompted by the ALAMEDA is 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 will 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 (Figure 4). The three LCGs have held their first meetings during November 2021 and provided their first inputs and concerns on the application of the project and its impact via questionnaires and live/online discussions. They are now actively engaged to support the research team in the next steps.

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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.

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.

03

Figure 4. Local Community Groups info sheet (Italian): sample pages 1 and 3

The outcomes of these meetings and preliminary engagement efforts are informing the design 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. They will be reported in more detail in the mid-term stakeholder engagement report (D7.3) due in month 18.

4. Establishing the AI4Brain Community of Interest

Despite the large number of promising experiments and proof-of-concept studies, large scale adoption of AI-powered healthcare support systems in the area of brain diseases is still lagging behind.

From a policy perspective, we expect that a novel stimulus will be certainly played by the upcoming Horizon Europe Partnership on Brain Health. As an important signal of political attention, France has announced that it will prioritise brain research during its upcoming EU presidency, aligning national strategies and working on the specific Brain Health partnership to be launched during the second half of Horizon Europe. As recently highlighted by Paweł Świeboda, CEO of EBRAINS and Director General of the Human Brain Project [13], the development and validation of "solutions to offer personalized brain health monitoring and intervention" will be one of the areas most requiring attention and focus along the design of the Roadmap for the Partnership on Brain Health.

On another note, a recent survey of users of AI technologies in healthcare, constituting of hospitals and other healthcare providers, carried out in the frame of the just released European Commission "Study on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the European Union" [14] provides an indication of the level of adoption of AI in the healthcare sector and the factors that may be affecting adoption and reveals that the technology most widely used or planned to use in the next three years is Patient Monitoring (72%) followed by Disease Diagnosis (61%), Medical Robotics (53%), Other (33%) and Genome Analysis (31%). The two top ranked among healthcare organisations are also the dominating area of application within healthcare among AI developers. Nevertheless, the report stresses that there are still considerable barriers to the adoption and upscale of AI-based solutions, such as the urgent need to develop clear legislation around the use of AI in healthcare and the ethical requirements to ensure transparency, verifiability and predictability of AI systems, the lack of benchmarking and certification systems, the still large reliance upon public funding of the research organisation developing AI solutions for healthcare, among others.

In order to translate insights into new technologies and solutions for healthcare, it thus gains increasing importance to establish broader alliances and identify complementarities and room for collaborations and synergies between ongoing projects working on specific aspects and digital endpoints for the same diseases as well as deploying AI and big data solutions on different neurological diseases. Moreover, the establishment of cross-disciplinary and cross-cultural initiatives have been shown to cultivate a common understanding and to support the transfer of technology into clinical practice. Lastly, uniting voices of different projects and bringing together diverse approaches around common issues is of crucial importance for the research community to increase their capacity to influence legislation and standardisation processes, seek novel opportunities for public-private collaboration and bring forward common needs and claims to the attention of the decision makers.

For all the above, we consider that the constitution of an informal **AI4Brain Community of Interest** initiated by ALAMEDA in collaboration with a number of other relevant EU projects would be a valuable contribution to the debate and foster knowledge exchange.

Here below a provisional list of related projects is provided. After having established a preliminary contact with each of them and investigated further the bi- and multi-lateral potential common interests and shared priorities, we will design a route for collaboration as well as a calendar of workshops and webinars. Furthermore, the ALAMEDA newsletter will host a dedicated section for the Community of Interest and will detail further purposes and modalities to join and engage. At the end of the project, we will also aim to produce a position paper with the largest possible support from the fellow projects of the Community.

4.1 Preliminary mapping of related brain digital health projects

4.1.1 Projects funded under the topic SC1-DTH-02-2020 with a brain health focus

Among the projects funded under the H2020 topic "SC1-DTH-02-2020 – Personalised early risk prediction, prevention and intervention based on Artificial Intelligence and Big Data technologies" three of them, including ALAMEDA, LETHE and BRAINTEASER targets the development of innovative AI based solution for neurological diseases.

For what concerns BRAINTEASER an initial opportunity for collaboration and exchange of viewpoints has been provided by the "Open Co-Design" workshop organised by BRAINTEASER last 3rd of June 2021 to gather the needs and preferences of people living with MS and ALS from patient organisations and relevant stakeholders.

lethe	**LETHE: A personalized prediction and intervention model for early detection and reduction of risk factors causing dementia, based on AI and distributed Machine Learning**
Website	https://www.lethe-project.eu/
Short description	Dementia is the most severe expression of cognitive impairment, the main cause of disability in elderly people, currently affecting nearly 50 million individuals worldwide. LETHE is a Horizon 2020 project designed to prevent cognitive decline in an ageing population at an early time point by a multi-domain interventional lifestyle approach built on a person centred digital solution. In LETHE a broad approach to prevention of Dementia is built at the intersection of clinical and technological disciplines. LETHE is developing a data-driven risk factor prediction model for older individuals at risk of cognitive decline, novel digital biomarkers and a digital enabled intervention based on the evolution of the FINGER study [15].
Start/end date	01/01/2021 – 31/12/2024
Relevant contact persons	Project Coordinator: Sten Hanke, FH Joanneum (FHJ), sten.hanke@fh-joanneum.at General contact email: info@lethe-project.eu Dissemination manager: Matteo Colombo, i2Grow (i2G), m.colombo@i2grow.it

Brainteaser	**BRAINTEASER: Bringing Artificial INTelligencE home for a better cAre of amyotrophic lateral sclerosis and multiple SclERosis**
Website	https://brainteaser.health/
Short description	AI systems can be used to develop models able to predict the progression of multiple sclerosis and amyotrophic lateral sclerosis. While both are very complex, chronic and progressive degenerative neurological diseases, their clinical evolution, prognosis and therapies are different. In this context, the EU-funded BRAINTEASER project will develop a system of wearable sensors to enable prediction and advance clinical decision-making and prevention. Specifically, software and apps will be designed to embrace an agile and user-centred design approach, accounting for the technical, medical, psychological, and societal needs of the specific users. One main aim is to assist clinicians in suggesting interventions that can delay the progression of the disease.
Start/end date	01/01/2021 – 31/12/2024
Relevant contact persons	Project Coordinator: Maria Fernanda Cabrera Umpierrez, mf.cabrera@upm.es Scientific Coordinator: Barbara Di Camillo, barbara.dicamillo@unipd.it Dissemination Manager: Natalia Allegretti, natalia@echalliance.com Task leader for cross-project liaison: Dominika Suchonova, European Brain Council, comm@braincouncil.eu

4.1.2 Projects funded under the topic SC1-DTH-12-2020 with a brain health focus

Correlated to the above, another project has been funded under the same call and the topic "SC1-DTH-12-2020 – Use of Real-World Data to advance research on the management of complex chronic conditions" with a focus on complex brain disorders. A direct connection is favoured by the fact that both ALAMEDA and MES-CoBraD are led by two institutes of the National Technical University of Athens.

MES-CoBraD	**MES-CoBraD: Multidisciplinary Expert System for the Assessment & Management of Complex Brain Disorders**
Website	https://www.mes-cobrad.eu/

Short description	The EU-funded MES-CoBraD project aims to improve the diagnostic accuracy and therapeutic outcomes of complex brain disorders, such as epilepsy, dementia, and sleep disorders. The Multidisciplinary Expert System for the Assessment & Management of Complex Brain Disorders (MES-CoBraD) is an interdisciplinary project combining Real-World Data (RWD) from multiple clinical and consumer sources through comprehensive, cost-efficient, and fast protocols towards improving diagnostic accuracy and therapeutic outcomes in people with Complex Brain Disorders (CoBraD), as reflected in Neurocognitive (Dementia), Sleep, and Seizure (Epilepsy) disorders and their interdependence. To do this, it will combine real-world data from diverse populations from varying backgrounds through thorough, cost-efficient and fast protocols. The project will draw on expertise in medicine, engineering, computer science, amongst others, to ultimately help improve the quality of lives of those living with such disorders, as well as caregivers and society. It leverages RWD from diverse CoBraD populations across cultural, socioeconomic, educational, and health system backgrounds, with special attention on including vulnerable populations and minorities
Start/end date	01/04/2021 – 31/03/2024
Relevant contact persons	Project Coordinator: Dr Christos Ntanos, National Technical University of Athens (NTUA), School of Electrical and Computer Engineering, Decision Support Systems Lab Greece (EPU), cntanos@epu.ntua.gr

4.1.3 Projects funded under the topic SC1-BHC-06-2020 with a brain health focus

In the frame of the H2020 topic “SC1-BHC-06-2020 – Digital diagnostics – developing tools for supporting clinical decisions by integrating various diagnostic data”, we have identified one project focusing on brain health conditions (AI-Mind).

AI-Mind	**AI-Mind: Intelligent digital tools for screening of brain connectivity and dementia risk estimation in people affected by mild cognitive impairment**
Website	https://www.ai-mind.eu/project/
Short description	Besides time-consuming patient investigations with low discriminative power for dementia risk, current treatment options focus on late symptom management. What is now complex, labour-intensive, costly, and poorly predictive screening methods for mild cognitive impairment (MCI) shall be replaced by automated diagnostic screening tools. These are driven by artificial intelligence to address the urgent need for early accurate diagnosis and risk prediction. AI-Mind will disrupt the clinical setting and significantly impact patients’ and doctors’ diagnostic journeys. Physicians will have a supportive decision-making tool that is able to identify patients at risk of developing dementia with high probability.

Start/end date	01/03/2021 – 28/02/2026
Relevant contact persons	Project Coordinator: Dr. Ira Haraldsen, i.h.haraldsen@medisin.uio.no Generic contact email: contact@ai-mind.eu

Moreover, because of the centrality of sleep among the factors to be monitored in ALAMEDA, we consider of specific interest and relevance to closely follow and get in contact with the project "SLEEP REVOLUTION – Revolution of sleep diagnostics and personalized health care based on digital diagnostics and therapeutics with health data integration" which is striving to create new standardised guidelines for sleep medicine in the EU.

4.1.4 Relevant projects funded by the Innovative Medicine Initiative

Digital health innovation has acquired increasing importance and consequent funding streams in the Innovative Medicine Initiative. The three selected projects have been putting their efforts to address research questions closely connected to the ALAMEDA's objectives. Furthermore, we rely on direct contacts among the members of those consortia.

RADAR-CNS	**RADAR-CNS: Remote Assessment of Disease and Relapse – Central Nervous System**
Website	https://www.radar-cns.org/
Short description	The RADAR-CNS project aims to develop new ways of monitoring major depressive disorder, epilepsy, and multiple sclerosis using wearable devices and smartphone technology. The key goal of the project is to improve patients' symptoms and quality of life and also to change how these and other chronic disorders are treated. For all three disorders, patients often experience periods where their symptoms are manageable, followed by periods of deterioration and acute illness (relapse). Patient surveys have repeatedly highlighted the need to predict when relapses will happen and to improve the treatments which are available to stop them from occurring. Continuous remote assessment using smartphones and wearable devices provides a complete picture of a patient's condition at a level of detail which was previously unachievable. From RADAR-CNS – which is coming to its end – RADAR-base (Remote Assessment of Disease And Relapses) has emerged as an open source platform to leverage data from wearables and mobile technologies. The main focus of RADAR-base is seamless integration of data streams from various wearables to collect sensor data in real time and store, manage and share the collected data with researchers for retrospective analysis. In RADAR-CNS a consortium of clinicians, developers, researchers, patient organizations and EFPIA partners joined forces to transform care by leveraging sensor data from wearable devices like fitness trackers and smartphones. The

	combination of passively collected physiological data with active self-assessment via questionnaires and scheduled cognitive tests allows a comprehensive picture of the participant's health state.
Start/end date	01/04/2016 – 31/03/2022
Relevant contact persons	Project Leader & Leader Work Package 6 (Major Depressive Disorder) and Work Package 11 (Dissemination, Exploitation and Communication): Matthew Hotopf, King's College London, matthew.hotopf@kcl.ac.uk General contact details: https://www.radar-cns.org/contact

	RADAR-AD Remote assessment of disease and relapse – Alzheimer's disease
Website	https://www.radar-ad.org/
Short description	In this project, the research team aims to investigate how mobile technologies can improve our understanding of Alzheimer's Disease. For example, these techniques might help to detect AD earlier in people with cognitive decline. Mobile technology also allows for a more personalized approach to AD treatment and care, so that people with this disease can live independently for longer. In addition, they also aim to identify "digital biomarkers" (electronic signals that give information about a person's health status) for AD. This creates new perspectives for the development of treatments against this progressive and debilitating condition. RADAR-AD also draws on the wealth of lessons and expertise from the RADAR-CNS project. Together these projects form a concerted effort in developing innovative ways to use remote measuring technology for the benefit of patients.
Start/end date	01/01/2019 – 30/06/2022
Relevant contact persons	Project coordinator: Dag Årsland, King'S College London, dag.aarsland@kcl.ac.uk General contact details: info@radar-ad.org

	IDEA-FAST: Identifying Digital Endpoints to Assess Fatigue, Sleep and 32ctivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases
Website	https://idea-fast.eu/

Short description	The aim of IDEA-FAST is to identify digital endpoints for fatigue and sleep disturbances that will provide a more sensitive, reliable measure of the severity and impact of these symptoms in a real life setting. They will do this by identifying the characteristics of fatigue and sleep disturbances and the digital endpoints that could quantify them. They will then select the digital devices and technologies that could measure and record these symptoms. They will also design a secure digital management platform to support the acquisition, storage and analysis of the data. All of this will be validated in a pilot study involving patients with neurodegenerative diseases (Parkinson’s disease and Huntington’s disease) and immune-mediated inflammatory diseases (rheumatoid arthritis, systemic lupus erythematosus, primary Sjögren’s syndrome, and inflammatory bowel disease).
Start/end date	01/11/2019 – 30/04/2025
Relevant contact persons	Project coordinator: Wan-Fai Ng, University Of Newcastle Upon Tyne, wan-fai.ng@ncl.ac.uk Dissemination manager: Veli Stroetmann, empirica Gesellschaft für Kommunikations und Technologieforschung Mbh, veli.stroetmann@empirica.com (PLURIBUS is a partner of IDEA-FAST)

4.1.5 Other relevant projects

Lastly, we acknowledge the importance of transversal policy-oriented dialogue and currently ongoing initiatives which will guide the future coordination work across the brain research community, namely towards the design of a common Strategic Research and Innovation Agenda and the consequent launch of the dedicated Horizon Europe Partnership on Brain Health, which will be launched presumably during the second half of the framework programme. For this reason, the EBRA Coordination and Support Action led by the European Brain Council (also involved in one of the ALAMEDA sister projects, BRAINTEASER) is particularly relevant. We will be seeking for a close interaction between the AI4Brain CoI and it so as to make sure the voices and needs from the research actors engaged in digital brain health and AI for brain projects are duly taken into account.

	EBRA: European Brain Research Area
Website	https://www.ebra.eu/
Short description	The European Brain Research Area project — EBRA — was created as a catalysing initiative for brain research stakeholders (researchers, clinicians, patients, governments, funders and public institutions) to streamline and better

	co-ordinate brain research across Europe while fostering global initiatives. The EBC-led Horizon 2020 project aims to reduce fragmentation in brain research and foster synergies through enhanced coordination of brain research efforts at the EU and global levels. In order to foster alignment and better co-ordination of research strategies across the European brain initiatives, a Shared European Brain Research Agenda (SEBRA) will be developed under the EBRA project. The SEBRA will focus on research opportunities and research and innovation gaps to be addressed in the field, priorities for action in the short and long term and research areas that would benefit most from cross – initiatives cooperation.
Start/end date	01/11/2018 – 31/10/2022
Relevant contact persons	Project Coordinator: Prof Monica Di Luca, European Brain Council, Monica monica.diluca@unimi.it

5. Reporting and evaluation of the engagement activities

Each stakeholder engagement activity carried out either via the Engagement Coordination Team and the Local Community Groups or other I is going to be reported in a mid-term and a final deliverable. In there we will analyse both qualitative and quantitative information related to the accomplishment of the objectives the engagement activity was intended for.

This activity is part of the task T7.2, thus the task leader WISE will centralise and analyse the relevant information provided by partners.

This will also serve to undertake strategic decisions and draw the roadmap for the post-project maintenance of the AI4Brain Community of Interest along with the other major exploitable results of the project.

6. Summary and conclusions

The Deliverable D7.1 sets the departing point for the ALAMEDA stakeholder engagement strategy implementation.

Based on the stakeholder analysis and mapping carried out, it emerges that predominant importance will be given to interact and synergise with the primary end users and their associations and networks. These activities have already kicked off following the patient engagement guidelines settled in the previous H2020 project "MULTI-ACT". Main achievements are represented by the setup of the Engagement Coordination Team and three country-level Local Community Groups i.e., groups of volunteers made up of 9-15 people including patients, family members and / or caregivers, and healthcare professionals called to share opinions and experiences and help researchers to design a monitoring and data collection system that is flexible and adaptable to circumstances and needs of each patient, always respecting privacy and ethical aspects.

The ECT and the LCGs will be 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. 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 be taken into account.

As a second relevant route for engagement, the present deliverable stresses the importance to support the effort of the exploitation-oriented tasks and respective leaders in attracting the interest of and liaise with SMEs, startups, developers as well as other researchers and research groups who will be the key beneficiaries of the ALAMEDA Innovation Hub as an open space for research, collaboration, development, and testing.

Last, ALAMEDA aims to open up a fruitful dialogue with a selected group of ongoing projects working on specific aspects and digital endpoints for the same diseases as well as deploying AI and big data solutions on different neurological diseases. This will be translated in a concrete effort to build a collaborative group named AI4Brain Community of Interest which all the identified projects will be invited to join. The Community will be a virtual space for learning exchange through workshops and webinars as well as the opportunity for like-minded experts to join efforts and voices culminating with the production of a shared Position Paper addressing the main challenges and expectations towards the upcoming Horizon Europe Partnership on Brain Health.

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