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Guidelines on Action Research for Large Scale Piloting

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Ref. No.:CWA 18123:2024 E

Contents	Page
European foreword	4
Introduction	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Abbreviated terms	10
5 Setting up the LSP project	10
5.1 General	10
5.2 Methodology	10
5.3 Assessment – KPIs	10
5.4 Resources	11
5.5 Developing protocols	11
6 Defining goals, objectives and interests	11
6.1 General	11
6.2 Steps to defining goals, objectives and interests	11
6.3 Relevance of defining objectives	13
6.4 Identifying interests	15
6.5 Constraints	15
7 Dividing roles and tasks	16
7.1 Identification of the key profiles — Stakeholders	16
7.2 Matching profile with tasks	17
7.3 Engagement strategies	18
8 Ethics in Action Research	18
8.1 Ethical approach to social sciences and applied social research	18
8.2 Legal and ethical clearance	19
8.2.1 General	19
8.2.2 Building up an Ethics Board	19
8.2.3 Legal compliance	20
8.2.4 Privacy and data protection	20
8.2.5 Ethical approval	21
8.2.6 General recommendations	21
8.2.7 Protecting vulnerable groups in practice	22
8.2.8 Procedures to engage participants	23
9 Training and mutual learning	25
9.1 General	25
9.2 Context of training and mutual learning	26
9.3 Identifying learning needs	26
9.3.1 Competency assessment	26
9.3.2 Stakeholders	26
9.3.3 Researchers	27
9.3.4 Defining learning objectives	27
9.4 Designing training and mutual learning activities	29

9.4.1	Types of activities.....	29
9.4.2	Essential considerations	30
9.4.3	Tailoring to needs.....	30
9.5	Implementing training and mutual learning activities	32
9.5.1	Planning and coordination.....	32
9.5.2	Evaluation and feedback.....	33
9.6	Promoting a culture of mutual learning by open communication.....	34
10	Dissemination	35
10.1	General	35
10.2	Targeted stakeholders and channels to reach them.....	35
10.3	Types of dissemination.....	35
10.4	Identification of events for dissemination	36
10.5	Ambassadors for dissemination.....	36
11	Continuous reflection.....	36
11.1	General	36
11.2	Organization of reflection meetings with different stakeholders	36
11.2.1	General	36
11.2.2	Define real objectives.....	37
11.2.3	Initiating meetings	37
11.2.4	Inclusivity and involvement	38
11.2.5	Facilitating the meeting.....	38
11.3	Collection of feedback to improve the LSP project.....	38
11.3.1	Revisit the LSP project goal.....	38
11.3.2	Stressing positive and negative aspects	39
11.3.3	Updating the risk management plan	39
11.3.4	Continual improvement process.....	39
11.3.5	Documentation and sharing	39
12	Celebration of successes, learning from mistakes.....	40
12.1	Celebrating Successes	40
12.1.1	Identification of successes.....	40
12.1.2	Acknowledgement of contributions	40
12.1.3	Keeping stakeholders informed of the achieved milestones.....	41
12.1.4	Sharing successes broadly.....	41
12.1.5	Integration into future planning.....	41
12.2	Recognizing achievements.....	41
12.3	Learning from mistakes	42
13	Sustaining change in practice.....	43
13.1	Early planning for sustainability	43
13.1.1	Sustainability objectives	43
13.1.2	Definition of the impact of the LSP project.....	44
13.2	Business modelling and planning.....	45
Annex A (informative) The training and mutual learning experience of the Pharon project		46
Annex B (informative) Ethics.....		52
Annex C (informative) Examples of types of projects which might use the premises of this CWA.....		55
Bibliography		58

European foreword

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Introduction

In the context of large-scale piloting, Action Research, also called Participatory Action Research (PAR), stands as an imperative process for addressing complex, dynamic, and multi-faceted problems. Its participatory nature allows for the active involvement of stakeholders who are often directly affected by the issues at hand, thereby fostering a deeper understanding and more sustainable solutions.

The inherent problem in large-scale pilots (LSP) lies in their scale and complexity. Such LSP projects often encounter issues like integrating diverse technologies, aligning multiple stakeholder objectives, ensuring ethical standards, and managing vast amounts of data. These challenges necessitate a robust, flexible approach that can adapt to evolving conditions and unexpected findings, which is where PAR plays a pivotal role.

Key stakeholders in this endeavour include not only researchers and pilot managers, whose expertise drives the LSP project's vision and execution, but also other parties relevant to the LSP project context, for example health and care providers, ethics boards (EB), and technology providers, whose collaboration is critical to the LSP project's success. Each brings unique insights that are crucial for identifying and unpacking the layers of the problem.

One of the current pressing challenges is ensuring the scalability and sustainability of the outcomes. As pilots grow in size and scope, the strategies developed should not only be effective in the short-term but also adaptable and durable. This requires a forward-thinking approach that considers future implications and builds on a foundation of ethical practice and stakeholder consensus.

Moreover, the competencies and skills required for stakeholders to conduct PAR should be outlined. This encompasses a range of abilities from technical know-how to collaborative competencies and ethical sensibility. These skills are necessary for a thorough understanding of the problems faced and the development of innovative, inclusive solutions.

Finally, establishing a framework for future research and collaboration is essential. This framework should facilitate the identification of new opportunities, foster continuous learning, and promote an environment where collaborative efforts can thrive, ensuring that the field of PAR remains at the forefront of innovation in large-scale piloting.

The idea for this CEN Workshop Agreement stems from the European Research and Innovation LSP project Pharaon that used the PAR approach in large scale pilots. A lack of guidance in this area was experienced, but at the same time the benefits that PAR brought were clearly visible.

This CEN Workshop Agreement has been developed as a guide for LSPs that conduct PAR in their LSP project. Due to the complexities of a large-scale, real world setting and of PAR as a time and resource intensive approach, it can be easy for LSPs to lose track of the process. Specific attention is needed to make sure that stakeholders are truly involved as co-researchers, which can be difficult especially for those who are inexperienced in working this way. By providing concrete actions to be taken in each step of the PAR process, this CEN Workshop Agreement aims to help LSPs navigate the difficulties of PAR.

Another pitfall of each PAR being very complex and context-dependent is that reports on PAR frequently fail to clearly describe the activities performed in the LSP project. This makes it nearly impossible to achieve the goal of building a learning community in which members can exchange their best practices and improve their scientific knowledge. By providing a standardized structure of PAR activities, this CEN Workshop Agreement can help ameliorate the consistency of PAR reporting.

While many trained researchers are likely familiar with participatory approaches similar to PAR, many stakeholders are likely new to conducting research. This CEN Workshop Agreement can serve as a document to familiarise them with the activities in a large-scale PAR project and help foster discussions about the nature of their involvement as co-researchers in the project. Some examples of projects where this CWA could be useful can be found in Annex C.

1 Scope

This CEN Workshop agreement defines Action Research and its role in large-scale pilots. It identifies the key stakeholders involved and outlines the necessary steps to conduct Action Research including, for example, setting up a project, training stakeholders and reflecting continuously. This CWA provides guidance on ethical considerations as well as addressing challenges and solutions like managing data, communication, and collaboration among stakeholders. It specifies ways to ensure the sustainability and scalability of the Action Research outcomes, as well as outlining the key competencies and skills required by the researchers and other stakeholders to conduct Action Research. The CWA establishes a framework for the identification of opportunities for future research and collaboration in this area. This CWA is mainly intended to be used by researchers and pilot managers but can also be useful to other involved stakeholders, like health and care providers, ethics boards, and technology providers.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp/>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

Action Research

Participatory Action Research

PAR

participatory, iterative process concerned with the development of practical knowledge in pursuit of worthwhile human purposes

Note 1 to entry: PAR seeks to bring together action and reflection, theory and practice, in collaboration with others, in pursuit of practical solutions to issues of pressing concern to people and, more generally, the flourishing of individual persons and their communities.

Note 2 to entry: The key elements include working in iterations of planning, action, and reflection, actively involving stakeholders as co-researchers and situating research in a community or in practice.

[SOURCE: Reason, P., & Bradbury, H. (Eds.). (2007). *The SAGE Handbook of Action Research: Participative Inquiry and Practice*. SAGE.]

3.2

Researcher

individual engaged in the conception or creation of new knowledge, products, processes, methods, or systems, and in the management of the projects concerned

Note 1 to entry: Researchers at all career stages across various fields, in both public and private sectors, irrespective of the nature of their appointment, employment, or the legal status of their employer are encompassed.

[SOURCE: Commission Recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, note added]

3.3

Stakeholder

individual or organisation representing a diverse array of actors who have a direct or indirect interest in the outcome and implementation of the developed solutions in an R&I project

Note 1 to entry: Stakeholders can include government agencies, regulatory authorities, technology regulators and manufacturers, financial institutions, non-profit associations, care facilitators, end-user organisations, etc.

Note 2 to entry: In R&I projects, stakeholders bring a practical and operational perspective to the project. Their primary objective is to ensure that the proposed solutions are viable, comply with applicable safety standards and regulations, and meet the needs and expectations of the industry and end-users. Stakeholders can provide expertise, funding, support, and resources to address the specific challenges and opportunities related to the project.

3.4

Internal stakeholder

member or group that is affected by a project and has a stake in its success

EXAMPLE Directors, department managers, project team members

Note 1 to entry: An internal stakeholder is directly involved in and has access to the decision-making process for the project.

Note 2 to entry: An internal stakeholder might be in charge of deciding what to do, allocating resources, and making sure the project aligns with the objectives of the company.

3.5

External stakeholder

member or group that is not affiliated with the leading company but is affected by the project's outcome or has an interest in it

EXAMPLE End-users, suppliers, government agencies, community organisations

Note 1 to entry: An external stakeholder does not directly oversee the project, but its participation and encouragement are crucial to its success.

Note 2 to entry: An external stakeholder might be impacted by the project's results and might have expectations regarding its deliverables and final products.

3.6

Stakeholder analysis

process of identifying stakeholders prior to the start of the project, classifying them based on their involvement, interest, and impact, and figuring out the most effective ways to involve and interact with each of these groups of people throughout the project's lifetime

3.7

Large-Scale Pilot

LSP

initiative for integrating key technologies into real-world applications and services

Note 1 to entry: Large scale pilot can have different pilot site with different purposes.

Note 2 to entry: If there are different pilots with the same purposes the local and the global KPIs can be merged.

[SOURCE: <https://digital-strategy.ec.europa.eu/en/policies/industrial-platforms>, notes added]

3.8

Goal

concise statement that outlines the desired outcome to be achieved over a longer period of time

Note 1 to entry: It is a broad statement that emphasizes the intended results and does not detail the methods used to accomplish them.

Note 2 to entry: The goal typically represents a broader statement that outlines the overall purpose of the research project.

3.9

Objective

specific, actionable targets that should be met within a shorter timeframe in order to attain a particular goal

Note 1 to entry: Objectives describe the actions or activities involved in accomplishing a goal.

Note 1 to entry: Within research the objective is more specific than the goal, indicating the particular focus and approach of a project.

3.10

Key Performance Indicator

KPI

quantifiable measure used to evaluate the success of an organization, employee, etc. in meeting objectives for performance

[SOURCE: Oxford Languages]

3.11

Local KPI

KPI that is specific to one pilot location

3.12

Global KPI

KPI that applies to all pilot locations

3.13

Vulnerability

particular situation or characteristic of a person that can place a person at greater or lesser risk of harm

[SOURCE: Gordon, 2020]

3.14

Exit strategy

ethical procedure to prevent end users from generating dependencies on the solutions or products they have been using during their involvement in the project, mainly when they are in vulnerable situations or frail conditions

4 Abbreviated terms

For the purposes of this document, the following abbreviated terms apply:

EB	Ethics Board
EU	European Union
GDPR	General Data Protection Regulation
IC	Informed Consent
KPI	Key Performance Indicator
LSP	Large-Scale Pilot
PAR	Participatory Action Research
SMART	Specific, Measurable, Achievable, Relevant, and Time-bound
SWOT	Strengths, Weaknesses, Opportunities, Threats

5 Setting up the LSP project

5.1 General

Undertaking LSP projects poses significant challenges for organisations and teams. The intricate nature, extensive scope, and resource demands necessitate meticulous planning and disciplined execution. Deploying a PAR approach can help address these complexities. First of all, through its iterative nature, PAR allows for adjustments and adaptations to the ever changing context in which the LSP takes place. Furthermore, by involving different stakeholders as co-researchers the problem at hand is addressed from a more holistic perspective, and the early involvement of all of these parties likely leads to a better solution. As all important stakeholders are involved early on, plans for sustaining the LSP project's achievements can be made throughout the LSP project, rather than just at the end. Still, both LSPs and PAR remain complicated, which is where the steps outlined in this CWA can assist.

5.2 Methodology

A robust methodology is the backbone of any successful LSP. The methodology should be inclusive, participatory, and iterative, ensuring the involvement of the relevant parties in shaping the research process and making it more responsive to their needs. Moreover, the steps of the PAR cycle (plan, action, observation, and reflection) should be defined in clear steps and iteratively repeated for continuous learning and improvement. The preparation and delivery of a clear communication plan is essential for maintaining transparency and fostering collaboration throughout the LSP project's lifetime, outlining the way in which information will be shared among stakeholders, including regular updates and feedback mechanisms.

5.3 Assessment - KPIs

The assessment of the LSP project's progress and outcomes is a critical element that should be integrated into the PAR methodology from the start. The evaluation framework should be meticulously designed to measure performance against the study objectives. To this end, a tailored set of indicators can be crucial for a nuanced assessment. The following points detail the structure of this framework:

- **Global and local KPIs:** A series of global KPIs that reflect the achievements against the shared objectives of all pilots, alongside potential local KPIs that are custom should be defined for the specific aims of each separate pilot. This approach ensures a holistic and focused assessment of both the individual progress and the collective milestones.

- **Early definition of metrics:** KPIs, both global and local, should be defined at the onset to serve as clear markers for gauging progress. Establishing these metrics early on paves the way for focused monitoring and enables agile responses to the evolving needs of the LSP project.
- **Integrated monitoring and feedback:** Integrated mechanisms for monitoring, impact assessment, and feedback that cater to both global and local KPIs should be established. Periodic meetings should address the progress of each pilot individually and the program collectively, encouraging knowledge exchange and alignment of efforts.

5.4 Resources

Effective management of resources is critical to the sustainability and success of large-scale PAR projects. Attention should be given to the comprehensive planning of resource allocation during the proposal phase: Budget should be allocated specifically for stakeholder engagement events, ensuring that these critical activities are well-funded and can be conducted effectively. A multifaceted reimbursement strategy that goes beyond financial compensation can be very well considered.

EXAMPLE Contributions can be acknowledged through skills development opportunities, allocated working hours, or formal recognition to incentivize and appreciate the commitment of all involved parties.

5.5 Developing protocols

The development of protocols is a strategic phase in PAR, providing a structured approach to LSP project execution and ensuring consistency and quality in the process. This includes the proper design of protocols that address all aspects of the LSP project's implementation. These protocols should be clear, detailed, and adaptable to the dynamic nature of PAR, subjecting these protocols to rigorous review and approval processes, engaging experts and stakeholders to ensure that they meet the LSP project's objectives and align with established ethical and legal standards, and ensuring that protocols are not only well-designed but also effectively implemented and monitored. The protocols should be reviewed regularly (e.g. during reflection meetings) and refined to respond to new insights and changing LSP project dynamics.

6 Defining goals, objectives and interests

6.1 General

This clause suggests a procedure on how to handle goals and objectives that follows the required steps to maximize the chances of the LSP project being successful. In PAR LSPs, stakeholders with different backgrounds and ideas come together to collaborate on a LSP project. This necessitates alignment between the groups, and discussions to work towards common goals. This step should take place at the start of the LSP project, to set a course together, and have a common idea to re-evaluate later on.

6.2 Steps to defining goals, objectives and interests

This subclause defines goals, objectives and interests for PAR. It covers aspects such as understanding the problem, considering stakeholders' needs, and setting e.g. SMART goals.

There are three LSP project phases to consider:

- a) **Phase 1: before LSP project implementation** at least the following aspects should be involved, starting with an initial stakeholder meeting:

- 1) Initial stakeholder meeting:

At the beginning of the LSP project, a meeting should be convened with all relevant stakeholders, including researchers, collaborators, and any parties involved. This should enable an open and

honest conversation during which each partner representative expresses their wishes and goals and listens to those of other partners. The expressed wishes and goals should be documented in a written setting. Specific attention should be given to giving voice to those who do not usually have it: minorities, discriminated audience, persons who have difficulties accessing or using technologies, etc. An inclusive methodology should offer different ways for all the stakeholders to express their expectations and be included in the LSP project development.

2) Timeframe for wishes and goals refinement:

A limited period should be given to all the stakeholders to define and structure the descriptions of their goals. This period enables institutions to refine and validate the first ideas documented in the initial meeting internally.

3) Second meeting: wishes and goals validation and adjustment:

Based on the documents produced during the refinement phase, the partners should ensure that the different goals expressed by each partner are compatible with each other. Another round of refinement might be needed at the end of this meeting upon decision of partners' representatives. Each party should also express their expectations regarding initially non-defined LSP project aspects such as tasks, timing, responsibilities, and contributions. This process should also include the definitions of the characteristics, needs, and expectations of the target audience to guide the LSP project's objectives. A (first) summary of results can be used to create a comprehensive plan to keep all relevant stakeholders involved from the very beginning to the end of the LSP project.

4) Testing assumptions:

The assumptions should be tested during an early stage, particularly if a small group from the target audience is involved when designing LSP project components (e.g. use cases). These assumptions should be tested on a larger scale early in the LSP project to prevent discovering later that the LSP project doesn't align with the target audience's expectations.

5) Stakeholder involvement plan:

A comprehensive plan should be created to keep all relevant stakeholders involved from the very beginning to the end of the LSP project.

- b) **Phase 2: during LSP project implementation** it should be recognized that defining and refining LSP project goals is an iterative process. The initial discussions and the goal-setting process should be revisited whenever necessary to realign with changing circumstances, new information, or evolving stakeholder interests.

During the LSP project implementation, each partner should monitor their activity and follow the **agile LSP project management methodology** to keep their activity consistent and adjust as much as possible to goal/wishes changes during the LSP project.

In this large-scale context, a federation structure is recommended: small groups work independently, with regular checks inside the groups. The regularity of the meeting should be decided collaboratively, and can be connected to timepoints, e.g. monthly, or to LSP project milestones, e.g. once an activity is completed. Between-groups checks are conducted less often, but also regularly, and sometimes on-demand, to share information about the LSP project realization (goals that change, become non-realizable, exceptional circumstances, adjustments to spread through the pilots, etc.).

LSP project-wide meetings should happen less frequently but still regularly enough to enable LSP project-level adjustments.

- c) **Phase 3: after LSP project implementation** the LSP project realization and success of goal achievements can be reflected further with the involvement of all the LSP project partners. In a final meeting, lessons learned should be documented and openly published to help the community and all partners involved to grow.

Each meeting should be adequately documented and should include at least the following aspects:

- Date and time;
- Participants;
- Scope of the meeting;
- List of arguments towards the Scope;
- Decisions (optional);
- The majority statement on the results of the meeting;
- Open issues and next steps.

6.3 Relevance of defining objectives

Undertaking LSP projects poses significant challenges for organisations and teams. The intricate nature, extensive scope, and resource demands necessitate meticulous planning and disciplined execution. Before embarking on a LSP project, it is paramount to gain a comprehensive grasp of its scope and intricacies. This entails precisely delineating objectives, essential resources, constraints, and potential risks. A meticulous analysis aids in establishing realistic expectations and identifying potential hurdles. This section focuses on the scope and research objectives of LSP projects and their impact in successfully tackling them.

To begin a research project, it is important to define the boundaries of the LSP project by conducting a scope analysis. This scope analysis will establish what should and should not be included in the LSP project. It is recommended to define the scope at the beginning of the research process to ensure that the LSP project goals and outcomes are realistic. When defining the research scope, the following factors should be considered:

- **Budget constraints and grant specifics:** Any financial limitations or grant funding specifics should be taken into consideration.
- **Proposed timeline and duration:** The expected duration of the research project should be determined.
- **Population of study and sample size:** The population intended to study and the proposed sample size should be specified.
- **Research methodology:** The planned research methodology should be described.
- **Inclusion and exclusion criteria:** Criteria for including or excluding certain aspects of the study should be defined.
- **Anticipated variables:** Any control, extraneous, or confounding variables that could impact the research should be identified and accounted for.

CWA 18123:2024 (E)

Research objectives, as in the specific goals the research aims to achieve, play a crucial role in guiding the research process. They provide a clear rationale for the research's pursuit and succinctly outline the LSP project's approach and purpose, aiding the research focus. The goal should be positioned at the end of the problem statement, just before the research objectives.

The research objectives not only help to define the scope and depth of the research by establishing the boundaries and extent of the LSP project but also contribute significantly to the overall research methodology design. Moreover, they play a pivotal role in enhancing existing knowledge, a task that is at the heart of academic research, thereby inspiring and motivating researchers and students alike.

There are two types of objectives: general and specific. Smaller goals are set to achieve the general objectives, which lead to fulfilling the larger objective. Specific objectives are the breakdown of the general objectives. The achievement of the specific objectives results in implementing the general objective.

Clear and precise formulation of research objectives is crucial as they serve as a guide for PAR. They help to choose the appropriate theoretical framework, create an effective research methodology with relevant methods, select the necessary tools and material resources, answer the research question, guide the development and analysis of the work, and define the validity of the hypothesis. In essence, objectives can be viewed as goals transformed into questions, and their proper formulation can greatly enhance the quality and success of the research study.

The research objectives should be defined and written once the research question has been stated and before the research has been defined (although they can be modified as the LSP project progresses). They should be adjusted to the available resources to become feasible and realistic.

The success of a research study relies heavily on creating practical and relevant research objectives. In order to formulate objectives that will lead to a successful study, it is essential to keep the following guidelines in mind:

- **Research objectives should be specific and clear**, leaving no room for ambiguity. They should align with the research questions or hypotheses and be measurable and achievable within the constraints of the study.
- **Action verbs that describe what is intended to be accomplished should be used.** Objectives should focus on measurable outcomes (by means of KPIs, set of quantifiable measurements of progress towards the intended outcomes of the LSP project) and prioritize the most crucial objectives for the study's success.
- **Objectives should be relevant to the research topic** and the study's overall purpose. The target audience should be considered, a time frame for achieving each objective should be set, and new information should be adapted as they emerge.
- **The importance of documenting the objectives in the research proposal, plan or protocol should be stressed.** This not only helps maintain focus throughout the study but also serves as a reference point, ensuring to stay on track and achieving the research objectives, leading to a successful research study.

By diligently applying the SMART criteria to the research objectives, the specific goal or objective to achieve can be effectively clarified, criteria for measuring success can be included, realistic and achievable objectives can be set, their relevance to the research can be ensured, and a timeframe for achieving each objective can be included. This structured approach is crucial in ensuring the objectives are well-defined and achievable, leading to a successful research study.

The research objectives should be revised and refined after their initial formulation. Feedback from peers, advisors, or mentors should be sought out to ensure they are well-constructed and aligned with the study objectives.

6.4 Identifying interests

In this step of the process the participants should explore the process of identifying interests in the context of the pilot stakeholders for PAR. This involves identifying stakeholder interests, aligning these with the LSP project goals, and managing potential conflicts of interest. The following points should be considered:

- **Mapping of interests:** The interests that all parties have in the LSP project should be mapped in a visual or written format.

EXAMPLE Those goals can be academic goals like scientific publications, technological goals like the implementation of new technology, commercial goals like entering new markets, or societal goals.

- **Collecting common values:** Common values that unite the LSP project stakeholders should be collected. This collection should be shared and can serve as a basis for working together effectively.
- **Identifying interests and values:** The interest and value identification process should have recurring discussions, surveys, or feedback sessions to gather insights and align LSP project goals with the stakeholder's perspectives and needs.
- **Conflict resolution mechanism:** As potential conflicts can arise throughout the whole LSP project period, a conflict resolution mechanism should be discussed and chosen. One option for this step is to present some conflict solution mechanism at the start of the LSP project (e.g. referee model, majority vote solution model, unity solution model). The result should be actively voted on. A no rejection vote is not recommended. The following step is to establish the chosen conflict resolution mechanism in LSP project specific aspects that can be used throughout the LSP project to address any new conflicts that can arise.

6.5 Constraints

Any major research project has to set section limitations, to ensure that all following activities will be within their described boundaries. Even though all relevant stakeholders will be addressed through the PAR approach it is mandatory to have a written set section boundary by the initiator or the funding agency.

The boundaries should at least cover:

- maximum time and staff involvement for the LSP project (Maximum person/months to be invested from each partner);
- legal constraints within the framework of the LSP project, compensation measures for non-realization of the LSP project tasks, recovery and mitigation actions in case of failure of one party;
- a mechanism of the financial resources (e.g. up to 1 Mio €);
- a higher-level, structured methodology for decision-making.

In many research projects there might be additional section boundaries but the aspects above are described as the minimum.

7 Dividing roles and tasks

7.1 Identification of the key profiles — Stakeholders

The success of PAR in LSP projects depends on getting a varied group of stakeholders involved early and effectively. A careful and organized approach should be chosen to include the wide range of views and skills that stakeholders offer due to the complex nature of research projects, requiring large-scale validations. The following points should be considered with regard to stakeholders to successfully perform PAR:

- **Early involvement:** To ensure the LSP project's integrity and relevance, it is crucial to involve all pertinent parties from the onset. This early engagement serves as a cornerstone for building a collaborative foundation, fostering a collective responsibility towards the LSP project goals and outcomes.
- **Stakeholder analysis and layering:** A comprehensive identification process should be undertaken to delineate the array of stakeholders, including but not limited to patients, citizens, healthcare professionals, social care professionals, researchers, private sector representatives, funders, and policymakers, depending on the context of the LSP project. A Stakeholder Onion Diagram can help to classify these parties into concentric layers, reflecting their influence and engagement from the core to the periphery.
- **Stakeholder grouping and prioritization:** After identifying the relevant stakeholders, these should be categorized in terms of their influence, interest, and levels of participation in the LSP project.
- **Ecosystem constitution:** The study group, representing a smaller version of the larger community of target groups, should be a balanced mix of the different groups identified. This team should be key in making decisions, guiding the research, and making sure that the various goals and viewpoints of the stakeholders work well together.
- **Defining expectations and roles:** Explicit expectations should be communicated, delineating the roles and responsibilities across the stakeholder spectrum. Each stakeholder's role should be defined not only by their positional capacity but also by the unique competencies and insights they contribute. This clarity can underpin the synergy within the consortium, enabling a cohesive and dynamic PAR process.
- **Developing a communication and engagement plan for each type of stakeholder:** The right strategy should be pondered to ensure the engagement and ongoing support of each of the stakeholder categories. To understand the stakeholders' motivation and proprieties, their alignment with the LSP project's priorities should be assessed, and a positive view of the LSP project should be fostered.

Stakeholders form an LSP, thus, are not mere participants but integral to the fabric of the research, each bringing invaluable insight, experience, and resources to the table. The roles they play can vary from direct involvement in the pilot studies to advisory and evaluative capacities, with a shared aim of enhancing the research's efficacy, scalability, and sustainability. A distinction can be made between internal and external stakeholders.

Based on the LSP project goals, this clause provides a global overview of the ecosystem at stake. It includes all actors which need to be approached to test and validate the LSP project concept, implement it, and ensure (some kind of) sustainability.

The following points can help within performing PAR:

- **Enlistment of the support of key organisational players early in the LSP project:** It can be beneficial to have the experience and insight of influential individuals within the organization or key stakeholders to guide the LSP project to a successful conclusion. In bringing them on board early on, the chance increases that they will support the LSP project.
- **Alignment of goals and plans among all stakeholders:** A stakeholder analysis can help to choose the right individuals to work with on the LSP project and guarantee that everyone knows exactly what success will entail and how they can contribute to it.
- **Resolve of conflicts or issues at an early stage:** Without a stakeholder analysis, there is a chance that key players for the success of the LSP project are not sufficiently motivated to participate or do not see its importance. Conducting a stakeholder analysis prior to initiating the LSP project can avoid such issues by allowing to properly assess the crucial people to involve, identifying possible conflicts and allowing for the time to address these, and involve these key players in the planning of the LSP project.

7.2 Matching profile with tasks

To match profiles with tasks, the following points should be considered:

- **Ascertain the necessary actions:** Identifying the various tasks that need to be completed is the first step in defining roles within the team. By knowing the number of tasks, these can more easily be assigned according to the total amount of work that needs to be done.
- **Identify the LSP project roles:** By analysing the LSP project's scope, objectives, stakeholders, and key actions, the relationship between the LSP project tasks and the LSP project roles should be established. Several methodologies can be used for this end, such as LSP project charters, a work breakdown structure, or a responsibility assignment matrix.
- **Assess team members:** The skills, interests, and availability of the team members should be assessed. This can be conducted through the screening of resumes, in an interview or survey, or through self-assessment. It is also important to understand and consider the team members' personalities, learning styles, and work preferences.
- **Determine any responsibility gaps:** After assessing pending tasks, these should be compared to the work that the members of the team are producing. This comparison can assist in locating any responsibility gaps.
- **Assign the LSP project roles:** The different criteria from the team members assessment (e.g. skills, interest, availability, etc) should be considered and crossed with the pending tasks. This can function as the basis for team realignment, allowing the assignment of workers to the most relevant roles, and to determine the distribution of responsibilities among them. Other dimensions, such as workload balance, diversity, and development, should also be considered, as well as the leveraging on approaches such as roles rotation to avoid worker burnout or stagnation.
- **Communicate the LSP project roles:** Once the roles have been assigned, this decision should be communicated. This communication should be conducted in a clear and consistent form, shedding light on the rationale behind the decision and the expectations of the role. The channel for this communication should be elected according to its relevance for the stakeholders under consideration (e.g. by email, through meetings, etc).
- **Consult the team members for feedback:** It should be determined whether the roles assigned are functional and foster teamwork by asking members of the team for their honest feedback and

by giving them the space to raise questions and voice concerns. This can encourage communication and foster positive team dynamics at work. These inputs can be collected through the scheduling of team meetings, individual meetings, or even anonymous surveys.

- **Monitor the roles and improve its assignment:** The efficiency of the role's assignment should be ensured, monitored, and adjusted when necessary, throughout the LSP project's lifetime. Surveys, indicators on performance and satisfaction, reports on status and issues, and good practices and lessons learned can be used for this analysis. Possible strengths, weaknesses, opportunities, and threats should be considered to facilitate improvements.

7.3 Engagement strategies

Providing stakeholders and LSP project supporters with a realistic and comprehensive timeline can help increase stakeholder engagement and support for the LSP project team's ongoing work.

Stakeholders can contribute to your LSP project more successfully if they are aware of the schedule, since being given a detailed timeline allows them to assess how and when they can contribute. Moreover, informing the stakeholders in advance will make them feel more involved and valued.

Maintaining the support and cooperation of external stakeholders throughout the LSP project requires effective communication and engagement.

8 Ethics in Action Research

8.1 Ethical approach to social sciences and applied social research

Ethics comprise the rules and guidelines that dictate acceptable conduct during the research process, ensuring that researchers act in a way that protects the rights of individuals and performs the due involvement of stakeholders. The research or experimentation conducted on / with human beings should adhere to basic ethical principles:

- respect for persons (autonomy) and people's capacity for decision-making;
- pursuit of the good by achieving maximum benefits and minimizing harm and wrongdoing;
- justice;
- fairness;
- responsibility;
- honesty;
- freedom;
- confidentiality;
- human dignity.

To accomplish this, it is important to employ methodologies that encourage interactive and effective communication among all LSP project researchers, regardless of their area of expertise. A practical example of an interactive ethical methodology can be found in Annex B which outlines the actions taken by the Pharaon project.

8.2 Legal and ethical clearance

8.2.1 General

In the context of PAR, ethics considerations and data management are essential to the integrity and credibility of the research. As such, some key aspects should be proactively addressed with a detailed and anticipatory strategy:

- **Ethics committee engagement:** Early engagement with respective ethics committees should be prioritised to secure approval before the commencement of the pilot. Timely approval is crucial to prevent delays and ensure that the LSP project adheres to the highest ethical standards from the outset. By securing the ethics committee's approval early on and embedding ethical considerations into the LSP project's foundation, the research is positioned to proceed smoothly without the hindrance of administrative or regulatory setbacks.
- **Legal and ethical compliance:** All legal and ethical requirements should be rigorously adhered to, including data privacy, informed consent (IC), and relevant regulatory frameworks. This commitment should be evident in all aspects of the LSP project's data management practices.
- **Ethical decision-making framework:** A comprehensive framework for ethical decision-making should be established, ingrained in the LSP project from its inception. This framework should empower stakeholders to make informed decisions that reflect ethical principles throughout the LSP project's duration. Here the Ethics Board (EB) plays a key role.

8.2.2 Building up an Ethics Board

The Ethics Board (EB) is a collective body which should ensure adherence to ethical and deontological principles in research involving humans, specifically participants, who may be in vulnerable situations.

It should oversee the storage, processing, and protection of sensitive personal data, ensuring the representation of perspectives, values, and needs of primary, secondary, and tertiary end users throughout the LSP project.

The mission and actions of the EB are framed and guided by an internal regulation, which should be in compliance with the GDPR. In this regard, the EB should:

- **develop procedures** to verify that ethical considerations are properly addressed throughout the LSP project, particularly in research, technological development, and pilot implementation involving participants who potentially are in vulnerable situations;
- **monitor strict compliance** with ethical and moral requirements across various LSP project phases, adhering to standards of integrity, honesty, and quality;
- **evaluate issues arising during the LSP project** that are not yet ethically regulated or clear, as well as those related to preferences, values, and needs of participants. The EB, in collaboration with the LSP project partners, should support the clarification of these issues;
- **initiate and/or review** processes, reports and outcomes in coordination with stakeholders.

EXAMPLE The ethics chair, the managerial structure of LSP project's EB, could include one partner, a primary or secondary end-user, and one external expert for each pilot site. These members should contribute their experience and knowledge to the LSP project.

Locally, EB members have the mission to ensure the legal and ethical compliance of procedures within LSP project's pilot implementation, particularly concerning human participants and personal data collection and processing. This process should take into account not only the legal frameworks of their

country or region but also the guidelines and recommendations provided by ethical project leaders over time. Any ethical issues raised during LSP project implementation should be reported to the ethics chair and the EB. Additionally, external experts should bring experience to the LSP project and help shape user requirements beyond the addressed use cases. Primary or secondary users should take the end-users' perspective to assess the impact of implemented ethical procedures or any gaps.

8.2.3 Legal compliance

The need to address legal compliance is a mandatory obligation for all parties involved in a LSP project, both those implementing the testing of technologies and those supplying the equipment/ solutions. Each party, within the limits of their responsibility, commitment, and liability, should be compliant with all regulatory requirements (national and international) in order to be part of a particular LSP project.

The following documents are commonly used to ensure ethical and legal compliance regarding participants engagement:

- The Nuremberg code (1947)
- Helsinki Declaration (2013)
- The Belmont Report (1979)
- The European Charter of Fundamental Rights (2016)

A short summary of those documents can be found in Annex B.2.

8.2.4 Privacy and data protection

Research involving personal information should comply with privacy legislation, particularly the GDPR, which harmonises data privacy laws and empowers EU citizens' privacy rights. Compliance with GDPR is fundamental for all the ethical principles of the LSP project. The GDPR, with an extended jurisdiction, applies to organisations processing personal data of EU residents globally (EU, 2016).

LSP projects should adhere to the seven key principles outlined in the GDPR, with a dedicated GDPR checklist to address specific LSP project needs. These seven data protection principles are:

- Lawfulness, fairness, and transparency;
- Purpose limitation;
- Data minimization;
- Accuracy;
- Storage limitations;
- Integrity and confidentiality;
- Accountability.

Noteworthy aspects include the “right to be forgotten”, where participants can request data erasure, and “privacy by design”, necessitating data protection integration from LSP project inception. An overview on how to handle consent within research and innovations is given in CWA 17933.

Consent is paramount, requiring a thorough explanation and understanding of the collected data. IC should be strengthened using clear and concise terms, offering an IC kit to pilot sites. Addressing incidental findings, especially in digital solutions not designed for diagnostics, involves case-by-case decisions by local ethics committees and the LSP project's EB, if applicable.

8.2.5 Ethical approval

Field trials for scientific purposes require the approvals of external EBs to be conducted and consequently be declared suitable for publication (ethical request). This verification procedure is essential to ensure that the protocol has been revised by a board of experts, without a conflict of interest, and that the methods and the way of assessing participants are ethical.

There is no standard protocol or list of documents for this request to the EB. Therefore, the research team should request the necessary information for the requirements from a responsible body as early as possible, to allow for sufficient time to prepare the request. The research teams can still expect to be asked for information about the LSP project and the principal investigator, the CV of the investigator and the core team, the research protocol, the tools and questionnaires (sometimes, translated into the local language), and the IC template.

For AR projects, the process for obtaining ethical approval might be challenging since objectives and methods are subject to change over the course of the LSP project. The following practical tips can help in that regard:

- knowing the responsible body and the expected waiting time for a reply;
- familiarisation with the procedures of request as early as possible (list of documents, CV forms, translation of questionnaires and IC Template adapted to the study);
- awareness that ethical protocols can be amended: Throughout implementation it is possible to contact the responsible body for updates on a previously approved protocol – this possibility should be explored before the first ethical request as it varies according to national legislation and case-to-case;
- indication of the open areas the study might present to the Ethical Committee when describing the study protocol, especially for the first time.

EXAMPLE The pilot activity will be decided after a comprehensive co-creation process; the technology to be used is under development – and might not meet the expected level of readiness; introduction of new partners/technologies through cascade calls; usage of non-validate questionnaires and the reason why.

If, in the early stages of the preparatory activities, a research team detects that an amendment might be needed in the future, or even a new ethical request, it should be considered in the timeframe of intervention. If it is not possible to predict, a timeline with some tolerance for setbacks should be advocated for. In doing so innovative and participatory research methods can be fostered.

8.2.6 General recommendations

The following four areas need to be addressed by pilots:

- Participants' human rights;
- Personal data privacy and security;
- Ethics committee requirements;
- Professional regulations.

They should not exclude other areas that can emerge during technology development or participant testing. Therefore, it is crucial to also consider international laws, general ethical principles, and obligations arising from both binding and non-binding agreements. A recommended procedure follows these steps:

- 1) **Analysis of all relevant national laws** involved to ensure compliance with ethical and legal regulations in the countries and regions where the LSP projects will take place;
- 2) **Alignment of these rules with LSP project methodologies**, focusing on human-centred design and integrating them with ethical principles and values, data protection rules, and privacy measures.

To achieve this, the key regulations of the countries involved can be detailed and categorized by areas of interest. The aim is to establish a comprehensive ethical-legal framework to ensure compliance in all aspects of technology development and LSP projects.

8.2.7 Protecting vulnerable groups in practice

Ensuring ethical conduct within pilot sites means combining the fundamental rights and freedoms of the participants in human research with the development of the LSP project’s own ethical guidelines. Working groups should reflect together on which principles, parameters, and values ought to be targeted in the scope of action, especially when working with vulnerable groups. Besides, it is important to actively contribute to the solution of social challenges that a determined LSP project can be related to.

Understanding the target groups and their contextual vulnerabilities is a starting point to defining values and principles within the scope of a LSP project. When it comes to LSP in the realm of PAR, it is important to engage stakeholders in the selection of the guiding principles. It is more complex when related to the testing of new technologies.

EXAMPLE 1 A pilot study where the target group are older people (65+) and where a new social media will be tested: LSP project partners can convey to define the following three values and principles: Equity, Justice, Autonomy.

Not only theoretical suggestions should be considered. The concept should be worked on and clarification on “potential risks” and “how to” accomplish the goals in the LSP project should be provided, Table 1 shows a practical example on how to be more pragmatic for the values chosen above.

Table 1 — Example on guidelines to protect vulnerable groups

Principle	Risk	Recommended Action	Guidance
Equity	Lack of access	Provide equipment and internet connection	Foster universal participation by providing all necessary equipment during the implementation period
Justice	Prejudice, stigmatization, discrimination	Prevent ageism	Avoid presuming older people are not interested in technology by default; involve older people in the decision-making process; be conscious of age-related stigmas; prefer inclusive terminology such as older adults/people instead of elders
Autonomy	Feeling incapable; Fear of using technology	Provide training (improvement on the digital literacy skills)	Enough training is recommended as part of the implementation,

Principle	Risk	Recommended Action	Guidance
			so people are actually able to interact with the solution; do not act passively in the face of e-divide

EXAMPLE 2 Values and principles are the opportunity to address societal challenges in the LSP project and their objectives:

- **Non-maleficence** emphasizes the obligation to avoid causing harm or injury to others. This involves taking proactive steps to prevent harm and minimize risks.
- **Beneficence** entails the duty to promote the well-being and welfare of individuals. This includes actively seeking to do good and acting in ways that contribute to the overall improvement of the situation for those affected.
- **Health maximization** focuses on prioritising actions and decisions that lead to the enhancement of health outcomes and overall well-being. It involves efforts to optimize health resources and interventions to achieve the best possible health outcomes for individuals and communities.
- **Efficiency** pertains to the responsible and effective use of resources to achieve desired outcomes. It involves maximizing the benefits obtained from available resources while minimizing waste, inefficiencies, and unnecessary costs.
- **Respect for autonomy** emphasizes the importance of honouring individuals' right to self-determination and decision-making. This principle acknowledges that individuals have the capacity and freedom to make choices about their own lives and healthcare, and it requires respecting their choices, preferences, and values.
- **Justice** involves the fair and equitable distribution of resources, benefits, and burdens within society. It requires treating individuals fairly and impartially, without discrimination or prejudice, and ensuring that everyone has equal access to opportunities, rights, and resources.
- **Proportionality** requires that the benefits of an action or intervention outweigh the potential harms or risks involved. It involves carefully balancing the interests and values at stake and ensuring that the level of intervention is proportionate to the desired outcome while minimizing any negative consequences.

8.2.8 Procedures to engage participants

8.2.8.1 Free and informed participation – the beginning of the collaboration

IC is a necessary element for the pilots, as a description of participant's right, complying with ethical, legal and deontological procedures.

In summary, to comply with current legislation, including the GDPR, the following topics are essential in an IC (WHO Research Ethics Review Committee, 2024):

- Introduction;
- Purpose of the research;
- Type of Research Intervention;

CWA 18123:2024 (E)

- Voluntary Participation;
- Procedures and Protocol;
- Description of the Process (data protection);
- Duration of the LSP project (and how long the data will be stored);
- Side Effects;
- Risks;
- Benefits;
- Reimbursements, if applicable;
- Confidentiality;
- Sharing the Results;
- Right to Refuse or Withdraw;
- Who to Contact;
- Certificate of Consent (tick boxes and signature).

Some procedures should be considered through the IC collection process, considering the following aspects:

- **Language:** inclusive, neutral and non-stigmatising language should be used;
- **Testing the template** with a representative of the target group not participating in the study to ensure it is understandable;
- **Training** the staff to in-person interactions.

Pilot partners should hold preparatory sessions to present the LSP project to end users. Afterwards, training should be provided to use the possible solutions made available in the pilot and clarification of any questions regarding participation should be provided. If the respondent agrees to participate in the LSP project, the IC should be signed before implementation can begin with the monitoring of people previously selected for this purpose.

8.2.8.2 Exit strategy - ending the collaboration

The exit strategy should always be considered in the LSP project termination to ensure that the LSP project results will remain to benefit the participants even after it is completed. Therefore, exit strategy is also called a project sustainability plan. An exit strategy defines a good end of an LSP project but can also consider the continuation of a solution after the end of an LSP project on a commercial, but also non-commercial basis. An exit strategy for a research or market validation LSP project is based on ethical considerations taking into account the involvement of end users. This can generate dependencies to the solutions or products they have been using during their involvement into the LSP project. It should be considered that these persons can be vulnerable. The lack of human contact at the end of the LSP project can also affect isolated people and should be considered.

Key questions for designing an exit strategy are:

- What should the exist strategy accomplish?
- What activities and results of the LSP project should be maintained once it is over?
- What exit strategy will be followed in the LSP project?
- What are the reasons for the LSP project termination?
- What early measures are required in the LSP project to ensure that the objectives of the exit strategy will be achieved?
- Who (partners, stakeholders) should implement actions and when?
- What are the indicators, monitor actions and results of the exit strategy?
- Who monitors the indicators and when?

9 Training and mutual learning

9.1 General

Within the framework of LSP projects, the collaboration between researchers and stakeholders is of paramount importance. For the successful deployment and implementation of innovative solutions in real-world settings, it is crucial to have not only a comprehensive understanding of technological complexities but also a keen awareness of the needs and expectations of end-users and the broader community.

This clause explores the key role of training and mutual learning as integral components in bridging the gap between researchers and stakeholders within LSP PAR projects. It highlights the essential need for a collaborative environment that actively encourages and formalises knowledge exchange and engagement. Such measures are essential to fully realize the potential of LSP initiatives:

- **Importance of collaboration:** Making sure that all relevant perspectives are included and stakeholders benefit from each other's expertise.
- **Comprehensive understanding:** Essential for grasping technological complexities.
- **Awareness of needs:** Understanding the expectations of end-users and the community.
- **Roles of training and mutual learning:** Serving as bridge builders between researchers and stakeholders by fostering a collaborative environment and encouraging formal knowledge exchange and engagement.
- **Challenges in collaboration:** The lack of familiarity and inherent differences in backgrounds, priorities, and objectives between researchers and stakeholders can hinder effective collaboration.
- **Invitation to stakeholders:** All stakeholders, including researchers, industry experts and policymakers, are encouraged to recognize the mutual benefits of a standardized approach to training and learning.
- **Opportunities for integration:** Collaborative efforts can facilitate the seamless integration of innovative technologies, enhancing safety, efficiency and effectiveness in LSP scenarios.

This clause serves as a guide, emphasizing the importance of training and mutual learning in LSP projects. It addresses the challenges arising from the unfamiliarity between researchers and stakeholders, the practical methods for overcoming these challenges to ensure a harmonious and productive collaboration. Annex A provides information on how this topic was handled within the Pharaon project.

9.2 Context of training and mutual learning

Researchers and stakeholders play key roles, each contributing unique perspectives and fulfilling distinct functions that complement each other. However, fundamental differences exist in their backgrounds, knowledge and objectives, aiming to facilitate effective collaboration.

Key differences:

- **Researchers** typically have an academic and technical focus, bringing innovation and scientific rigor to the LSP project.
- **Stakeholders** are oriented toward practical application, focusing on compliance with industry regulations and standards, policy alignment and the actual impact on the end-user.

Challenges in communication and mutual understanding: addressing the communication barriers that arise from these differences is crucial for the success of the LSP projects.

Dynamic interplay: the interaction between researchers and stakeholders creates a dynamic that benefits the LSP project through the following means:

- **Technical and deep understanding** brought by researchers with their insights into technology, data analysis, and scientific technologies.
- **Domain-specific knowledge and experience** offered by stakeholders, ensuring that the solutions are practical and meet end-user needs.

Importance of mutual learning and training: initiatives for mutual learning and training are vital for bridging the gap between theoretical research and practical application, ensuring that solutions are aligned with real-world needs.

Collaborative approach: emphasizing the significance of a collaborative approach between researchers and stakeholders highlights the potential for developing innovative solutions that are scientifically sound and practically valuable.

Following this introduction, Clause 9.4 summarizes recommendations for how to implement this collaborative approach effectively, showcasing the innovation that results from the convergence of expertise, knowledge, and experience between researchers and stakeholders.

9.3 Identifying learning needs

9.3.1 Competency assessment

Assessing the current competencies and skills of both stakeholders and researchers is a crucial step in identifying areas where training and mutual learning are needed. There are different options for conducting competency assessments for both groups.

9.3.2 Stakeholders

- **Surveys and questionnaires:** To self-assess their competencies and skills related to the LSP project's objectives. The questions should cover relevant areas such as domain knowledge, regulatory awareness, and technological literacy.

- **Interviews:** One-on-one or group interviews with key stakeholders to gain deeper insights into their competencies and experiences. These interviews can help identify specific areas of expertise and gaps in knowledge.
- **Observation:** To observe stakeholders in their work environments to assess their practical skills and competencies. E. g., if stakeholders are healthcare providers, observe their interactions with technology or patient care practices.
- **Document review:** To examine relevant documents, reports, and past LSP project outcomes to gauge the historical competencies of stakeholders. This can provide insights into their strengths and weaknesses.
- **Benchmarking:** To compare the competencies of stakeholders against industry or sector benchmarks to identify areas where they may be lagging or excelling.
- **Feedback and input:** To seek feedback and input from stakeholders (see Clause 9.4.3.4 for details on how to) on areas where they feel additional training or support is needed. This participatory approach can help in pinpointing specific training needs.

9.3.3 Researchers

- **Resume and qualification review:** To review the resumes, qualifications, and academic backgrounds of researchers to understand their formal competencies in the relevant fields for the LSP project (e.g. technology, healthcare, or data analysis in Pharaon project).
- **Portfolio assessment:** To evaluate the past research projects, publications, or innovations of researchers to assess their practical competencies and areas of specialization.
- **Peer review:** To engage in peer review or expert assessment of researchers' work to gauge their technical and research competencies. Peer review can provide valuable insights into their capabilities.
- **Skills assessment tests:** To administer skills assessment tests or simulations to researchers to assess their technical skills, problem-solving abilities, and familiarity with relevant tools and technologies.
- **Interviews:** To conduct interviews with researchers to discuss their research backgrounds, experiences and specific skills relevant to the LSP project.
- **Collaboration compatibility:** To assess researchers' abilities to collaborate effectively with stakeholders by examining their communication, teamwork, and interpersonal skills.

Once the competency assessments for both stakeholders and researchers are completed, the findings can be compiled into a comprehensive report. This report should highlight areas where additional training and mutual learning are required to bridge competency gaps. The assessment results can be used to design customised training programs and learning opportunities that address the specific needs of each group, facilitating a more effective collaboration in a LSP project.

9.3.4 Defining learning objectives

Clear and measurable learning objectives should be defined for effective training and mutual learning. These objectives should guide the development of training programs and ensure that the identified needs are addressed effectively. A framework for setting specific and measurable learning objectives for both stakeholders and researchers is detailed in Table 2 and Table 3.

Table 2 — Specific and measurable learning objectives for stakeholders

Objective	Learning Objective	Measurement
Improve technological literacy	Acquire proficiency in using digital tools and platforms for effective communication and data management.	Evaluation of the ability to use specified technologies through hands-on exercises, aiming for a minimum competency level.
Strengthen LSP project management skills	Develop LSP project management competencies, including planning, resource allocation, and progress monitoring.	Evaluation of the performance in simulated LSP project management scenarios, with a goal of achieving predefined LSP project milestones.
Enhance interdisciplinary collaboration	Foster effective communication and teamwork across diverse disciplines by participating in collaborative exercises.	Collect feedback on teamwork and collaboration from participants and monitor improved interdisciplinary interactions.
Enhance regulatory awareness	Gain a comprehensive understanding of relevant regulatory frameworks (e.g. in the healthcare and digitalisation sectors of the Pharaon project).	Evaluation of the knowledge through pre- and post-training assessments, with a target of achieving e.g. an 80 % or higher average score post-training.
Improve knowledge on LSP project's domain	Increase the stakeholders' knowledge in each domain (e.g. self-care, active and healthy ageing, etc), contributing to their capacitation and empowerment.	Evaluation of the knowledge through pre- and post-training assessments, with a target of achieving e.g. an 80 % or higher average score post-training.

Table 3 — Specific and measurable learning objectives for researchers

Objective	Learning Objective	Measurement
Deepen domain expertise	Gain a more profound understanding of the relevant topics of the LSP project topic, e.g. in Pharaon the learning objectives are focused on healthcare, aging and digitalisation.	Assessment of researchers' knowledge through pre- and post-training evaluations, with a target of achieving a significant increase in subject matter expertise.
Enhance technical proficiency	Improve the technical skills related to e.g. data analysis, technology, and digital tools.	Evaluation of researchers' technical proficiency through practical assessments, such as successfully using LSP project-specific software and tools.
Strengthen research methodologies	Refine the research design and data collection methodologies, ensuring the production of high-quality research outcomes.	Review the quality and rigor of research proposals and LSP projects, aiming for improvements in research methodologies.
Foster effective communication	Enhance the communication skills to effectively convey complex research findings to stakeholders and the broader team.	Evaluation of researchers' communication abilities through presentations, reports, and feedback from stakeholders on the clarity of research communication.

Objective	Learning Objective	Measurement
Promote cross-disciplinary collaboration	Develop, increase and/or improve the ability to collaborate across disciplines by engaging in joint research projects and interdisciplinary workshops.	Tracking the successful initiation and completion of cross-disciplinary research projects and assess the impact of joint workshops on collaboration.
Planning for sustainability	Enhance skills in business model development, including understanding intellectual property rights and identifying grant and financing opportunities. This is intended to ensure the sustainability of the solutions created by the LSP project after its completion.	Assessing the participants' ability to effectively develop a sustainability plan that can develop in real world actions aimed at delivering the solutions beyond the LSP project timeline.

9.4 Designing training and mutual learning activities

9.4.1 Types of activities

A variety of activities can promote a culture of mutual learning, collaboration, and co-creation between researchers and stakeholders, leading to more effective and impactful LSP project outcomes.

- **Joint workshops and seminars:** They can serve as a platform for mutual learning, as researchers can share their technical expertise, while stakeholders provide insights into practical needs and constraints. Researchers and stakeholders come together to discuss LSP project objectives, challenges, and potential solutions. Workshops can include hands-on activities, case studies, and interactive discussions.
- **Collaborative problem-solving sessions:** They join researchers and stakeholders to address real-world challenges faced by the LSP project. They encourage an open dialogue and brainstorming to explore innovative solutions that blend technical expertise with practical insights. This approach can lead to the co-creation of strategies and technologies that are more likely to succeed in real-world scenarios.
- **Co-creation workshops:** They join researchers and stakeholders to collaborate in the design and development of LSP project components. E. g., in a healthcare/telemedicine LSP project like Pharaon, stakeholders from healthcare facilities and researchers might co-create a user-friendly telehealth application. These workshops can involve iterative design and prototyping to ensure that the final product is aligned with both technical requirements and user needs.
- **Regular cross-functional meetings:** They provide opportunities for ongoing communication, knowledge sharing, and alignment of goals. Researchers can update stakeholders on LSP project progress and stakeholders can provide feedback and real-world insights.
- **Feedback loops:** Together with regular cross-functional meetings, the feedback loops also encourage continuous improvement. Researchers should actively seek feedback from stakeholders on LSP project developments, and stakeholders should feel empowered to provide input on design choices, usability, and effectiveness. This iterative feedback process enhances the co-creation of solutions that meet the evolving needs of both parties.
- **Joint research initiatives:** Where researchers and stakeholders collaborate on specific research questions or studies related to the LSP project's objectives. Researchers can leverage their analytical skills, while stakeholders contribute domain-specific data and expertise. This collaborative research can lead to valuable insights and solutions.

- **Training and capacity building:** To offer training programs and capacity-building sessions tailored to the needs of both researchers and stakeholders. E. g., in Pharaon project researchers can receive training on healthcare regulations and industry standards, while stakeholders can learn about emerging technologies and research methodologies. This mutual training enhances the knowledge base of both groups.

9.4.2 Essential considerations

There are a set of essential factors to consider when designing, planning, and executing the training and mutual learning activities.

- **Resource allocation:** The allocation of resources is needed for these activities. This should include budget considerations for training, facilitators, and technology tools if applicable.
- **Timing and frequency:** It is necessary to schedule the timing and frequency of these activities. E. g., workshops and seminars are scheduled monthly, quarterly, or as needed. Highlighting the importance of regularity can reinforce the commitment to ongoing collaboration.
- **Documentation and reporting:** Documenting the outcomes of these activities and how they relate to the LSP project's goals is mandatory. This documentation can serve as a valuable reference point and contribute to LSP project reporting and decision-making.
- **Scalability:** To consider addressing how these activities can be scaled to accommodate the evolving needs of the LSP project. Discuss strategies for adapting training and mutual learning as the LSP project progresses and requirements change.
- **Evaluation and feedback:** To mention the process for evaluating the effectiveness of these activities. It is necessary to explain how feedback from both researchers and stakeholders will be collected and used to make improvements.
- **Case studies or examples:** To help to include case studies or real-world examples of how these activities have been successfully implemented in similar LSP projects. This can provide practical insights and inspiration for LSP project stakeholders.
- **Responsibilities and roles:** To specify who will be responsible for organizing, facilitating, and coordinating these activities. Clear roles and responsibilities can help ensure smooth execution.
- **Adaptability to specific LSP projects:** To help to highlight how these activities can be adapted to suit the unique requirements and goals of different LSP projects. This flexibility is important as LSP project contexts can vary significantly.

9.4.3 Tailoring to needs

9.4.3.1 General

The adaptation of training and mutual learning activities to the specific needs and preferences of both researchers and stakeholders is essential to ensure engagement, effectiveness and overall success. The following considerations help to tailor the needs.

9.4.3.2 Understanding the diverse needs

Before designing training and mutual learning activities, it is crucial to gain a comprehensive understanding of the diverse needs within the researcher and stakeholder groups. This understanding can be achieved through different means:

- **Needs assessment:** to conduct a thorough needs assessment that involves surveys, interviews, and feedback sessions to identify specific areas where training and mutual learning can add value.
- **Stakeholder consultation:** to engage stakeholders in the planning phase to gather insights into their priorities, objectives, and preferred learning styles.
- **Researcher profiling:** to create profiles of researchers to better understand their academic backgrounds, technical competencies, and knowledge gaps.

9.4.3.3 Customised learning pathways

Once the needs are identified it is necessary to develop customized learning pathways for both researchers and stakeholders. These pathways should be tailored to their respective goals and learning preferences:

- **Flexible learning formats** to offer a variety of learning formats such as workshops, webinars, self-paced modules and peer-to-peer learning to accommodate different preferences.
- **Targeted content** to ensure that the content of training materials aligns with the specific areas of interest and relevance to the LSP project.
- **Individualized support** to provide opportunities for one-on-one consultations, mentorship, or coaching to address unique needs or challenges.

9.4.3.4 Feedback-driven adaptation

Continuous feedback loops are instrumental in tailoring training and mutual learning activities. To create mechanisms for ongoing feedback from both researchers and stakeholders is necessary:

- **Feedback surveys:** Feedback on the quality, relevance and effectiveness of training sessions and materials can be solicited regularly.
- **Feedback integration:** Feedback to refine and adapt future training and learning activities can actively be used to show stakeholders that their input is valued and acted upon.
- **Dynamic content updates:** Training materials can be kept dynamic by incorporating real-world examples, case studies, and emerging trends as suggested by participants.

9.4.3.5 Flexibility in scheduling

Researchers and stakeholders can have diverse schedules and availability. To accommodate varying time constraints is necessary:

- **To offer multiple time slots:** Training sessions can be scheduled at different times to accommodate participants in different time zones or with busy schedules.
- **To record sessions:** Recordings of training sessions can be made available for those who cannot attend live sessions.
- **To provide on-demand resources:** A repository of on-demand training resources and materials can be created that participants can access at their convenience.

9.4.3.6 Accessibility and inclusivity

It should be ensured that training and mutual learning activities are accessible and inclusive to all participants. Therefore, the following factors can be considered:

- **Language support:** Materials and resources can be provided in multiple languages or simplified languages if necessary.
- **Accessibility features:** It should be ensured that all digital resources are accessible to individuals with disabilities.
- **User-friendly technology:** User-friendly technology platforms and tools that are easy for all participants to navigate should be used.

9.5 Implementing training and mutual learning activities

9.5.1 Planning and coordination

Effective planning and coordination are essential when implementing teaching and mutual learning activities involving researchers and stakeholders. The following factors can be considered:

- **Needs assessment and stakeholder engagement:** A thorough needs assessment should be conducted to identify the specific learning needs of both researchers and stakeholders. Stakeholders should be engaged early in the planning process to gather insights into their preferences, availability, and expectations.
- **Clear learning objectives and curriculum design:** Clear and measurable learning objectives should be defined for each activity to guide content development and assessment. The learning objectives should be aligned with LSP project goals and the identified needs of both groups (details in Clause 9.3).
- **Curriculum design:** A curriculum that is shaped to the identified needs and preferences of researchers and stakeholders should be developed. A modular approach that allows participants to select topics of interest can be considered.
- **Resource allocation:** Resources should be allocated including time, budget, and personnel, based on the scale and complexity of the training and mutual learning activities. Access to necessary technologies, materials and facilities should be ensured.
- **Scheduling and timing:** A detailed schedule that accommodates the availability and time zones of participants can be created. Offering sessions at various times can be considered to cater to different schedules.
- **Technology and platform selection:** User-friendly technology platforms should be chosen for virtual training sessions, webinars, or collaborative tools. These platforms should be tested for compatibility and accessibility.
- **Expert facilitation:** Qualified facilitators or trainers with expertise in the subject matter and experience in conducting training for diverse audiences should be identified. Facilitators with guidance on participant engagement and interactivity can be provided.
- **Communication and notifications:** Clear communication channels should be established to keep participants informed about upcoming activities, materials, and expectations. Timely reminders and notifications about session details can be sent.

- **Participant feedback:** Mechanisms for collecting feedback from participants during and after each activity should be implemented. Feedback can be used to make real-time adjustments and improvements to subsequent activities.
- **Accessibility and inclusivity:** It should be ensured that all materials and activities are accessible to participants with diverse needs, including language preferences and disabilities. Inclusivity can be promoted by accommodating special requirements when necessary.
- **Evaluation and continuous improvement:** An evaluation framework to assess the effectiveness of training and mutual learning activities should be developed. Activities based on evaluation results and evolving LSP project needs should be reviewed and updated regularly.
- **Documentation and reporting:** Records of participant attendance, feedback, and learning outcomes should be maintained for documentation and reporting purposes. Reports summarizing the impact of training and mutual learning on LSP project outcomes can be set.

9.5.2 Evaluation and feedback

Evaluation and feedback are fundamental elements of the training and mutual learning process, enhancing their quality and effectiveness. In that regard the following aspects should be considered.

- **Formative and summative evaluation:** Both formative evaluations for continuous improvement and summative evaluations for overall outcomes assessment can be employed.
- **Learning assessment:** Participant progress can be regularly gauged in line with established learning objectives, utilizing diverse assessment methods.
- **Participant feedback:** Feedback from participants can be encouraged on content, format, and facilitation through anonymous channels.
- **Facilitator evaluation:** Facilitator or trainer performance can be assessed based on participant feedback and observed effectiveness. Constructive feedback can be provided to support professional growth.
- **Iterative improvements and continuous improvement cycle:** Evaluation results can be utilized to iteratively enhance content and delivery, responding to participant feedback and evolving LSP project needs. A continuous improvement cycle can be created that integrates feedback and evaluation findings into the planning and design of future activities, ensuring the overall quality of the training and mutual learning process is continually enhanced.
- **Feedback for tailoring:** Participant feedback and evaluation results can be used to tailor future training and mutual learning activities, ensuring alignment with evolving participant needs and preferences.
- **Monitoring participant engagement:** Issues related to participant involvement can be promptly addressed by monitoring their engagement and participation levels.
- **Impact assessment:** The influence of training and mutual learning on LSP project outcomes and collaboration between researchers and stakeholders can be evaluated. The contribution of acquired knowledge and skills can be analysed to LSP project success.
- **Transparency and communication:** Evaluation findings and improvements can be communicated to participants and stakeholders, demonstrating a commitment to quality while maintaining transparency in the process.

- **Documentation of results:** Records of evaluation results, participant feedback, and assessment outcomes can be kept. These records can be used to report on the effectiveness of training and mutual learning activities.

9.6 Promoting a culture of mutual learning by open communication

Open communication is the bedrock of successful mutual learning between researchers and stakeholders in LSP projects. In this regard the following aspects should be considered.

- **Shared vision and goals:** Participants should be encouraged to collectively define and articulate the LSP project's vision and objectives. Both researchers and stakeholders should share a common understanding of the LSP project's overarching goals.
- **Transparent information sharing:** Clear channels for sharing LSP project information, updates, and relevant data should be established. The timely dissemination of research findings and LSP project progress reports can be promoted.
- **Active listening:** Active listening during meetings, workshops, and discussions should be emphasized, fostering an environment where all voices are valued, regardless of background or expertise.
- **Feedback culture:** A culture of constructive feedback and open dialogue should be cultivated encouraging participants to provide feedback on ideas, proposals and LSP project activities.
- **Conflict resolution:** Mechanisms for addressing conflicts or disagreements respectfully and constructively should be developed providing conflict resolution and mediation resources when needed.
- **Accessibility and inclusivity:** It should be ensured that all communication platforms and materials are accessible to all participants, considering diverse needs and acknowledging the perspectives of underrepresented stakeholder groups.
- **Collaborative decision-making:** Researchers and stakeholders should be involved in decision-making processes regarding LSP project direction, resource allocation and prioritization, fostering joint ownership of decisions and outcomes.
- **Regular meetings and updates:** Routine meetings, progress updates, and discussion forums should be scheduled creating opportunities for participants to interact, share insights, and build relationships.
- **Information flow:** Clear pathways for information exchange between researchers and stakeholders should be established ensuring researchers have access to real-world insights and practical constraints, while stakeholders gain access to research findings and technical developments.
- **Trust building:** It should be recognized that trust is cultivated over time through consistent and transparent communication. Trust-building efforts should be prioritised as a foundational element of mutual learning.
- **Cultural sensitivity:** Cultural differences and communication styles should be kept in mind within the diverse group of participants, promoting cultural sensitivity and respect for varying perspectives.

- **Supportive leadership:** LSP project leaders and facilitators should be encouraged to exemplify open communication and collaborative behaviour, providing leadership training to enhance communication skills and mutual learning should be promoted.

10 Dissemination

10.1 General

Especially where LSP projects are financed with public funds, it is important to share the progress and results of an ongoing study. Good dissemination practices involve knowing that there are different types of audiences each with a preferred type of communication. The target audience varies from the scientific community to end-users, but also politicians and citizens. To maintain the sustainability of an LSP project, it is important to be able to keep the public informed and to evaluate the significance of the results.

LSP project exploitation activities should build upon the dissemination and communication plan by identifying and communicating the following important aspects:

- What kind of needs does the LSP project respond to?
- What kind of problem will be solved and why is the solution better than existing ones?
- What new knowledge will be generated and who can use such results?

The needs and point of view from the target audience should be researched, and a dissemination plan and activities should be prepared accordingly, following the recommendations below.

10.2 Targeted stakeholders and channels to reach them

The identification of targeted stakeholders should be tailored to align with the specific topic of each pilot program. The most appropriate methods should be discovered and utilized to effectively reach the intended audience, such as channels they are already familiar with. Communication should be conducted in a language that is easily understandable to a broad audience. For specialized audiences, such as those at scientific conferences, readers of daily newspapers, or attendees at fairs, the presentation style should be adjusted to suit their specific needs and understanding.

An in-depth investigation into the communication preferences and methods commonly used by the target audience is crucial. Potential channels for communication include a variety of platforms such as newspapers, academic journals, TV channels, fairs, and social media platforms as well as blogs and vlogs. One should distinguish between posts which are more on a serious note, and those which allow to keep the user constantly entertained and involved using visual posts. Blogposts and news articles can be more targeted to the stakeholders involved and end-users.

10.3 Types of dissemination

Dissemination can take on various forms and be executed through different channels. Channels should be selected that are already frequented by the targeted audiences to ensure effective reach. For creating impactful figures and videos the following recommendations should be considered:

- **Figures and texts** that are not only effective in conveying the intended message but also capable of capturing and maintaining interest can be developed.
- **Illustrations** can be employed where appropriate to enhance the understanding and appeal of the content.
- **Concise videos**, preferably no longer than five minutes, packed with essential information can be created. These videos are particularly suitable for platforms like YouTube or TV channels.

10.4 Identification of events for dissemination

The target audience for dissemination can be quite diverse, ranging from the scientific community to end-users, politicians, and general citizens. The varied interests and information needs of these groups should be recognized.

Effective dissemination practices require an understanding that there are different types of audiences, each with specific communication preferences. Identifying these audience segments and determining the most effective ways to reach them is key to successful dissemination.

When planning or participating in events the following can be considered:

- organizing or participating in joint events can be a strategic approach to reach a wider and more diverse audience;
- regularly scheduling events or publishing dissemination articles can help with sharing the progress of the LSP project consistently.

10.5 Ambassadors for dissemination

Appointing partners from successful case studies as dissemination ambassadors can significantly increase the reach and impact of these initiatives. By involving people who have actively participated in successful pilot projects as ambassadors, their first-hand experience and insights can be effectively used to inspire and inform a wider audience, and it can also help to avoid some difficulties. This strategy not only makes use of the ambassador's credibility, but also promotes an authentic and easy understandable dissemination process. Inviting participants who have been part of successful pilots to act as ambassadors for dissemination activities can be an effective way to leverage their experiences and insights for broader impact.

11 Continuous reflection

11.1 General

It's important to understand why certain continuous reflection strategies succeeded. Analysing the critical elements of success can provide valuable lessons that can be replicated or scaled up in future cycles of the research. The regular evaluation of the LSP projects' success should encompass a continuous reframing and evaluations, utilizing appropriate criteria and measurement techniques, to determine the contribution of the LSP project, showing evidence of what is succeeding and to identify and address gaps in a timely manner.

11.2 Organization of reflection meetings with different stakeholders

11.2.1 General

Continuous reflection is an essential pillar to effectively assess the progress of implementation during an LSP project. Only through carefully planned and structured reflections is it possible to obtain a real understanding of how a project is unfolding.

The continuous reflection process should encompass meticulously planned meetings, tailored to each type of stakeholder. In this context, stakeholders include everyone from research team members to the group supporting the LSP project's implementation, as well as the end-users of the project results and others considered crucial to the process.

Moderators of these meetings play a crucial role. Before the meeting, they should clearly communicate the objectives. During the meeting the moderators should raise participants' confidence and encourage participation. After the meeting, they should share the results with the participants.

The success of these meetings is intrinsically linked to the moderators' in-depth knowledge of the dynamics in which the participants are involved. Understanding the details of the work context enables formulating relevant questions and effectively grasping participants' knowledge and experience.

The methodology and the structure of meetings should be considered carefully. The research team should assess whether the necessary information can be obtained through more informal methods, such as informal conversations or phone calls. Meetings should not be a formality but an effective tool, adapted to the research needs, and beneficial for stakeholders.

Continuous reflection should result in practical and impactful actions. Ideas and suggestions from participants should be channelled into future projects. In summary, continuous reflection should be flexible, tailored to end-users, and lead to the adaptation of the project as needed, aligning with stakeholders' inputs. This practice should also be a crucial tool for implementing the PAR methodology that guides the research team.

11.2.2 Define real objectives

The definition of the objectives for each session should be closely tied to the stage that the LSP project is currently in (e.g. planning phase). In a phase preceding the beginning of the pilot, a comprehensive LSP project overview should be presented. This includes:

- articulating LSP project goals;
- offering a brief explanation of the use case creation process;
- sharing pre-validation results;
- delineating pilot implementation goals;
- outlining planned steps;
- specifying expected outcomes.

In cases where the group has actively contributed to prior stages, it should be explicitly demonstrated how their perspectives have been included in the LSP project, underlining the significance attached to their input. This consistent approach should be adhered to at every moment of the project.

In addition, the definition of meeting objectives should be explicit and, preferably, measurable, and achievable. This practice ensures precision and effectiveness in communication.

11.2.3 Initiating meetings

Sessions can be initiated, and their content proposed, by different stakeholders of the project. On one hand, the research team can define and pre-plan meetings in the initial project plan. These planned sessions essentially serve to assess the project, ensuring that pre-established indicators are being met and, from there, making decisions for adjustments in future iterations, if necessary. This type of action serves as a kind of internal audit to evaluate the ongoing activities.

On the other hand, these sessions can also be initiated by any of the stakeholders involved in the LSP project.

EXAMPLE During field visits by researchers in a retirement home, informal conversations with older adults or formal caregivers can uncover various “complaints” or suggestions for improvement. When such situations arise, it could be an opportunity to propose targeted meetings with the team or participants to collectively reach conclusions for improvement or potentially alter the intervention.

11.2.4 Inclusivity and involvement

When planning continuous reflection sessions, it's important to ensure the involvement of all relevant stakeholders. These stakeholders include members of the research team, the group supporting the LSP project's implementation, as well as the end-users of the project results and others considered crucial to the process. Engagement should be tailored individually to each group, considering their profile, motivations, and interests in the LSP project.

The means of involvement in activities are equally crucial and require careful consideration. While online sessions can effectively include those who are physically distant, they could pose challenges for individuals with lower digital literacy. The prioritization of face-to-face sessions is recommended for end-users of the project results. This preference isn't solely due to digital skills; it's because, in general, face-to-face interactions facilitate greater engagement, trust, and openness in communication.

11.2.5 Facilitating the meeting

This aspect is directly linked to ensuring effective discussions on various topics. Initially, it is crucial to understand the group dynamics and recognize the different power structures that might be at play. Individuals with leadership roles or seniority in the organization might be present in working groups, which can make some participants hesitant to share their real thoughts, worrying about potential negative consequences. To address these concerns, the following points should be considered:

- **Dynamic approaches** such as interactive online sessions, gamified surveys, or other strategies that focus on the content rather than who is presenting it should be explored. This can be tackled by using the “focus group” method. This approach prevents one person from dominating the discussion, encourages everyone on the panel to participate, and results in a set of prioritised opinions that truly reflect the group's preferences.
- The research team should assess whether **conducting meetings** is the best way to gather information from participants or if other approaches, like interviews, surveys, or even ethnographic techniques, should be explored.
- There are **numerous variables that affect how safe and at ease individuals feel** when engaging and taking part in social interactions. Several aspects should be considered in that context:
 - o **climate and environment** where the meeting is conducted: A welcoming and familiar space should be provided so that people don't feel uncomfortable or out of place. It should be ensured that everyone can access the meeting location.
 - o **room arrangement**: Seats arranged in a circle or around a table promote equality, conversation, and intimacy.
 - o **form of procedure** for the meeting: The group can set the rules as one of the first phases in the process so the participation can flow and people can truly feel invested in following them.

11.3 Collection of feedback to improve the LSP project

11.3.1 Revisit the LSP project goal

At the beginning of an LSP project, it is complicated to plan and to consider all the scenarios that may occur in its lifetime. Therefore, the output of this meeting can support the refinement of an overarching plan to reach the goals.

In this regard, revisiting the LSP project goals is an action that should always be carried out in the planning and replanning of all continuous reflection sessions, whether they are conducted formally or informally. Maintaining a constant focus on the goals can support the research team in concentrating on the project and in facilitating decision-making.

To revisit the LSP project goals the following points should be considered:

- the results of the reflection meeting should be clustered to highlight the most relevant points;
- the people in charge of analysing LSP project results should handle the analysis process considering the objective of the meetings;
- if necessary, the plan to reach LSP project objectives should be revised according to the discussion and action points.

11.3.2 Stressing positive and negative aspects

It is always important to discuss the things that are going well and that are not going well since these can also support the creation of a transparent and relaxed atmosphere among the LSP project partners.

Signalling and discussing negative aspects is a crucial point in the implementation of pilots as they can be so impactful that it leads to demotivation among the various teams involved. In this context, consideration should always be given, not only to the perspective of the research team but primarily to the team implementing actions on the “field”. Typically, those on the project front are the ones who understand the context better and can propose the best solutions. In that regard, the following points should be considered:

- The results should be organized to point out the positive and the negative aspects so as to outline the benefits that the LSP project may have;
- The list of negative aspects can be used to avoid repeating the same errors twice and creating stressful situations;
- The positive aspects should be valued and serve as the basis for best practices which can be used to improve the negatives;
- It can be considered whether positive aspects can be included not only in the list of best practices but also in the successes of the LSP project itself.

11.3.3 Updating the risk management plan

The collected feedback can be used to update the risk management plan. The results can be collected to outline the problems that occur in the LSP project and to draft possible solutions or to plan appropriate actions.

Reflection meetings can point out risks that were not anticipated at the beginning of the LSP project.

11.3.4 Continual improvement process

The meeting frequency should be aligned with the status of the LSP project. The frequency of the meetings should be aligned with the phases and the activities requested in the LSP projects. Similarly, the duration of the meeting needs to be planned accordingly, and the moderator should keep the time in mind throughout the meeting.

11.3.5 Documentation and sharing

The collected feedback as well as the update of the LSP project plan and risk management should be consolidated and shared with all the meeting participants. Participants need to have the opportunity to

revise and to update the text. The lessons learned from reflection meetings should be shared within the LSP project team, as well as externally to allow others to learn from the experience as well.

Identifying common tools for sharing documents, LSP project updates and data are crucial to stay connected and updated on the LSP project status. It is also important to consider the different backgrounds that participants may have, therefore tools should be selected that can be used easily by participants.

12 Celebration of successes, learning from mistakes

12.1 Celebrating Successes

12.1.1 Identification of successes

The acknowledgement of successes in PAR is as vital as the research itself. It not only motivates the team but also provides insight into what works, creating a roadmap for future actions. Successes should be pinpointed in the observation and reflection phases whether that be the attainment of specific objectives, the triumph of collaborative efforts, or breakthroughs in problem-solving. Recognizing these achievements helps to validate the approach and methodologies used.

Defining, evaluating, leveraging, and securing the LSP project success is needed to reinforce, validate and reward behaviour that is directly tied to it. This allows a higher comprehensive awareness of what is valued by stakeholders to reach success and managing accordingly to that understanding, enabling to adjust the LSP project as needed to achieve better results.

Identifying successes allows one to get a better understanding of the LSP project and the main levers that can affect their success (factors) and signalled a concomitant need to regularly reassess when LSP projects are considered successful (criteria and dimensions).

To understand what key areas, activities, or critical success factors are typically the most important ones needed for the LSP project to be successful, some researchers point out the way organisations prioritise its efforts and resources, make more informed decisions, and maintain a consistent course of action. Some criteria can include:

- relevance (is the LSP project doing the right things?);
- efficiency (how well are resources being used?);
- effectiveness (is the LSP project achieving its objectives?);
- impact (what difference does the LSP project make?);
- sustainability (will the LSP project benefits last?);
- coherence criterion (how does the LSP project fit with other LSP projects?).

12.1.2 Acknowledgement of contributions

Every participant's effort and input are valuable, and as such, should be recognised. This can be through verbal acknowledgments in meetings, formal awards, celebratory moments (e.g. having dinner together) or written commendations. Such recognition nurtures a culture of appreciation and encourages ongoing engagement.

Recognising achievements can boost enthusiasm and a sense of accomplishment, ensure positive developments, raise a holistic awareness of the success contributors and promote success-focused planning and action.

It should be clear from the beginning which goals the stakeholders are pursuing and how success can be evaluated, which outcomes are expected from the LSP project, and how these outcomes will contribute to the goals of the LSP.

12.1.3 Keeping stakeholders informed of the achieved milestones

If stakeholders are aware that milestones are being met, they are more likely to stay motivated and engaged during a long LSP project lifecycle, as it allows them to follow the progress of the initiative in real time. Furthermore, they will be more conscious of the amount of work that has already been completed.

12.1.4 Sharing successes broadly

Successes should be communicated across all stakeholder groups, including those less directly involved in the LSP project. Transparent communication through meetings, reports, or casual channels ensures everyone is informed and can celebrate the collective achievement.

Success provides individuals and organisations with a clear, shared and continually updated picture of what success means in the context of their efforts and the levels of success achieved in those efforts, considering the evolution of the definitions of success over time and the prospects for success. The main objective is to improve and ensure the success of LSP projects at maximum levels, acting accordingly.

12.1.5 Integration into future planning

The recognised successes should be used as a foundation for future planning. Building on what works sets a positive tone and creates momentum for ongoing improvement and innovation in the next cycle of PAR. Managing success should maximise efforts by considering the evolving stakeholders' needs and perspectives, knowing that they may change during the LSP project.

12.2 Recognizing achievements

Acknowledging accomplishments is pivotal in fostering a positive and motivating atmosphere within LSP projects. The following key aspects should be considered for recognizing and celebrating achievements:

- **Milestone evaluation:** Predefined LSP project milestones and performance metrics should be established to objectively assess progress. The successful attainment of these milestones should be evaluated and celebrated regularly.
- **Awards and certifications:** The offering of awards or certifications to individuals or teams that have made outstanding contributions or achieved significant LSP project milestones can be considered. A recognition program aligned with LSP project objectives and values can be created.
- **Public recognition:** LSP project achievements should be showcased through public announcements, press releases, and LSP project publications. The positive impact of the LSP project on the community, industry, or end-users should be highlighted.
- **Team celebrations:** Team celebrations, such as milestone parties, LSP project showcases, or awards ceremonies should be organized. These gatherings can be used as opportunities for team members to share their experiences and insights.
- **Knowledge sharing:** The sharing of best practices, success stories, and lessons learned should be encouraged within the LSP project community. A platform for participants can be created to exchange knowledge and experiences.

- **Continuous improvement:** It should be emphasized that recognizing achievements is part of a continuous improvement process. Lessons learned from past successes should be used to enhance future LSP project activities.
- **Individual and team recognition:** Both individual contributions and collaborative team efforts should be recognized. The achievements of cross-functional teams that have bridged the gap between researchers and stakeholders should be celebrated.
- **Flexibility in recognition:** Recognition efforts should be tailored to suit the preferences and cultural aspects of LSP project participants. It should be ensured that recognition methods are inclusive and accessible to all.
- **Documentation and legacy:** Records and documentation of LSP project achievements for historical reference should be maintained. A LSP project legacy should be created by capturing success stories, LSP project outcomes, and innovations.
- **Sustainability and impact:** The sustainability and long-term impact of LSP project achievements should be evaluated. It should be highlighted how these achievements contribute to the broader goals of the LSP initiative.

12.3 Learning from mistakes

Learning from mistakes is a powerful engine for growth in PAR. It involves creating a supportive atmosphere where feedback is encouraged, and failures are seen as opportunities for learning. Therefore, the following aspects should be considered:

- **Create a safe environment for feedback:** An environment where sharing and discussing errors is not only safe but is also seen as constructive should be fostered. Openness without fear of blame or reprisal is key to continuous learning and should be encouraged.

To enhance the outcomes and the opinions expressed, certain aspects should be encouraged to promote a safe environment for feedback:

- Each participant should be encouraged to share his understanding and learn from the different perspectives and sensibilities of the other participants, allowing them to gain insight into what is valued by each stakeholder.
 - A periodic reflection on the real state of the LSP project and its expected evolution should be promoted with the aim to improve LSP project monitoring and control.
 - In regular meetings each participant should be encouraged to openly express their opinions about problems and opportunities for improvement, in which the communication should be clear, available, and transparent, providing important learning opportunities for continuous improvement.
- **Identify and analyse mistakes:** During reflection, it's essential to candidly identify where things did not go as planned and what could be improved. A factual, blame-free analysis allows for an objective review of the mistakes.

Despite failure being accepted as a teachable moment, as a source of useful information, a review of some researchers suggests that this can be hard, from an emotional and cognitive point of view that make learning from failure difficult.

- **Learn and adapt:** The root causes of the mistakes should be understood. It should be analysed if it was a planning oversight, an execution misstep, or unforeseen circumstances. This insight helps in adapting strategies for the future.

Learning from what has worked well is not only very useful for the LSP project, in line with one of the aims of PAR but extends scientific knowledge at the same time.

- **Document learnings:** Detailed records of the lessons learned should be maintained. This documentation should act as a reference point to prevent repeating past mistakes and to inform future LSP project strategies.
- **Consider changes:** The action plan for the next cycle based on the learnings from past mistakes should be adjusted. This can mean altering strategies, approaches, or, if necessary, the goals themselves to better align with the realities encountered.

13 Sustaining change in practice

13.1 Early planning for sustainability

13.1.1 Sustainability objectives

Granting the impact of research and innovation LSP projects after the end of funding is one of the main concerns of funding agencies. Typically, LSP project proposals are required to devote specific actions to the impact of the LSP project results on the society, and on how they can generate market opportunities and new discoveries and evidence. Furthermore, in most calls for LSP projects issued by funding agencies, a specific evaluation dimension focuses on impact. As an example, the Horizon Europe Standard Application Form asks for proposals that demonstrate:

- credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the LSP project;
- suitability and quality of the measures to maximize expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

To reach this goal an LSP project proposal, since its inception, should consider:

- the **clear definition of sustainability objectives and expected LSP project long-term impact**, also in terms of scale-up or adaptation of the solutions developed in the LSP project to another geographical context or to other user groups;
- **engaging with relevant stakeholders** like local communities, policy makers and other interested parties;
- implementing **ethical and sustainable data management practices** and ensuring data security, privacy, and compliance with relevant regulation in the field;
- raising awareness about **sustainability issues** related to the research within the dedicated team and among LSP projects participants.

The LSP project team should:

- conduct a **post-LSP project sustainability assessment**;
- engage in **educational outreach** to inform the broader community about the importance of sustainability;
- build a **communication plan** to involve potential future customers, e.g. public decision makers in the case of an exploitation pathway aimed at delivering a service to e.g. a public authority.;
- collaborate with **partners** who share a commitment to sustainability and can contribute expertise or resources.

13.1.2 Definition of the impact of the LSP project

To measure how the sustainability plan of a given LSP project will perform, one should take the following into consideration:

- **Market research and validation:** Typical tools should be adopted in this case. The conduction of surveys, interviews, and focus groups with potential participants/customers should be used to gather insights into their needs and preferences while testing the LSP project's minimum viable product with a selected group of early adopters to gather their feedback. Market trends, industry reports, and adjacent competitor offerings should be analysed to identify gaps and opportunities. Adjacent markets or product/service offerings that align with core competencies should be explored. The Technology Readiness Level (TRL) of the innovations that the LSP project would produce should be exactly defined.
- **Business model development:** The business model can be developed according to well established templates like the Canvas Model or the Lean Model. That way a clear definition of revenue streams, cost structure, scalability, and customer segments can be available.
- **Value proposition:** It should be sought to understand what LSP project results are most valuable to potential future public or private customers.
- **Intellectual property protection:** This should be developed with a strategy for licensing or intellectual property rights of all participating parties.
- **Granting and funding after LSP project ends:** Research funding opportunities from government agencies, foundations, and private investors can be needed along with the preparation of grant proposals or investment pitches that highlight expected objectives, impacts and corresponding financial needs. Funding can also include leveraging industry associations (e.g. organizing networking events).

The main expertise needed to conduct this activity is in the field of financial modelling, communication, market research and technical writing. These roles are typically missing in the case of researchers considering scientific publications as the sole output of the LSP project endeavours.

13.2 Business modelling and planning

There are many models that help to build a proper business plan. While some of them are very specific to the context of firms and start-ups, most of them can easily be adapted to the needs of an LSP project consortium seeking to find a path to the sustainability of LSP project results after LSP project ends. The most relevant templates are:

- Business Model Canvas;
- Value Proposition Canvas.

Another relevant element that can help to foresight the impact of an LSP project in terms of sustainability is the SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis. Even though that it is not a business model template per se, it can help to assess the internal and external factors influencing the possible business performance. It is usually used jointly with other templates to inform strategic decisions.

Annex A (informative)

The training and mutual learning experience of the Pharon project

A.1 Overview

Pharaon, standing for Pilots for Healthy and Active Ageing, is an ambitious European research and innovation project granted by the Horizon 2020 framework. Pharaon is assembled by 41 partners across 14 countries to develop digital solutions promoting active and healthy ageing. These are clustered at pilot sites in Italy, Netherlands, Portugal, Slovenia, and Spain (Murcia and Andalusia). All of them are aimed at emphasizing healthcare, aging lifestyle improvement, and digital literacy enhancement among older adults.

The key objectives of the Pharaon project are the following:

- Boosting independence, safety, and capabilities of individuals as they age, enabling them to continue residing in their homes;
- Diminishing undesired loneliness among older adults through various technological solutions;
- Facilitating mutual learning between researchers and stakeholders to better address the needs of aging populations and create effective solutions.

The core strategy of Pharaon to achieve the commitments is the deployment of cloud-based assistance systems to support older adults by integrating digital services, tools, interoperable open platforms, and devices. The initiative aims to validate the integrated solutions in LSP.

The validation is executed in two stages: pre-validation and LSP. An iterative approach guarantees evaluation reference from each pilot with active involvement of relevant stakeholders like patients, decision-makers, healthcare service providers, clinicians, researchers, and businesses for customisation, refinement, validation, integration, and update of the KPI indicators.

A.2 Training and mutual learning: identifying researchers and stakeholders

As it is stated in Clause 9, the collaboration between researchers and stakeholders is needed for an LSP success. The first step is to identify researchers and stakeholders. Researchers in the Pharaon project include the following categories:

- Gerontologists: researchers specializing in the study of aging, gerontology, and the physical, psychological, and social aspects of aging.
- Psychologists: psychologists specializing in aging-related issues, including cognitive decline, mental health, and emotional well-being.
- Clinical researchers: professionals conducting clinical trials and studies on medications, treatments, and interventions specifically designed for aging individuals.
- Epidemiologists: researchers who investigate patterns, causes, and effects of health and disease conditions in aging populations.
- Social scientists: researchers studying the social aspects of aging, including social isolation, community engagement, and quality of life.

- Healthcare researchers: experts in healthcare research who investigate healthcare systems, policies, and interventions relevant to older adults.
- Digital health researchers: specialists in the field of digital health, including telemedicine, wearable technology, and health informatics.
- Human factors experts: researchers focusing on human factors engineering to optimize the usability and safety of healthcare and digital tools for seniors.
- Data scientists: professionals with expertise in data analysis and machine learning, who work on data-driven insights and predictive analytics for healthcare outcomes in aging populations.
- Human-computer interaction researchers: human-computer interaction experts who focus on designing user-friendly digital interfaces and applications for older adults to improve digital literacy.
- Technology innovators: researchers and engineers developing innovative healthcare technologies, smart devices, and digital solutions tailored to the needs of older adults.
- Public health researchers: experts in public health who assess the impact of healthcare policies, interventions, and health promotion strategies on aging individuals.
- Education specialists: researchers with a focus on adult education, digital literacy training, and lifelong learning programs for seniors.
- Academic institutions: Faculty members and researchers from universities and research institutions specializing in aging-related fields.
- Policy analysts: experts in healthcare policy analysis and evaluation, providing insights into the regulatory and policy framework affecting aging healthcare and digital literacy.

Stakeholders in the Pharaon project include the following:

- National and regional government health departments: playing a crucial role in funding, regulating, and overseeing healthcare initiatives for aging populations.
- Healthcare providers: hospitals, clinics, and healthcare professionals are directly involved in delivering healthcare services to older adults.
- Aging advocacy organisations: national and regional organisations dedicated to advocating for the rights and well-being of older adults, e.g. Age UK in UK, ANCIANOS in Spain or FRATERNIDAD-FEYTS in France.
- Research institutions: academic and research institutions focusing on aging-related studies, digital literacy, and healthcare innovation.
- Pharmaceutical companies: developing medications and treatments for age-related diseases and conditions.
- Insurance providers companies: offering health and long-term care insurance policies relevant to older adults.
- Non-profit organizations: supporting initiatives related to aging, healthcare, and digital literacy for seniors.

CWA 18123:2024 (E)

- Healthcare professional associations: representing healthcare providers, caregivers, and healthcare workers who serve aging populations.
- Educational institutions: universities and educational organizations offering programs related to gerontology, healthcare management, and digital literacy education for aging individuals.
- Community centres: local community and senior centres that provide resources, social support, and educational programs for older adults.
- Care facilities for older adults: organisations operating nursing homes, assisted living facilities, and retirement communities.
- Older individuals and families: key stakeholders as they directly benefit from improved healthcare and digital literacy services.
- Regulatory authorities: government agencies responsible for setting regulations and standards related to healthcare, data privacy, and digital literacy.
- Technology companies and innovators: specializing in healthcare technology, telemedicine, wearable devices, and digital literacy tools for older adults.
- Technology regulators: agencies overseeing the safety and compliance of healthcare technology and digital tools.
- Financial institutions: banks and financial service providers offering retirement planning and financial management services for older adults.
- Telecommunications companies: providers of internet and communication services that enable digital access and connectivity for older adults.

A.3 Designing training curriculum – learning objectives

The design of learning objectives of researchers and stakeholders in the Pharaon project started with a first step of analysing the of background, knowledge, and objectives. The main differences between both groups were investigated and illustrated in Table A.1. It shows, researchers have a background and expertise rooted in scientific research, healthcare, and technology-related disciplines. Their knowledge is in hold advanced degrees in fields such as medicine, biomedical engineering, informatics, or gerontology. Their objective is advance knowledge through empirical research, develop innovative technologies, and contribute to the evidence-based practice of healthcare. Stakeholders in the telemedicine and older adult care project encompass a diverse array of actors, including government agencies, healthcare providers, senior living facilities, insurance companies, and advocacy groups. Their backgrounds vary widely, from policy and administration to clinical practice and financial management. Their primary goal is to ensure the successful implementation of telemedicine solutions, address regulatory compliance, and enhance the overall quality of care for older adults.

Table A.1 — Differences Background-Knowledge-Objective between researchers and stakeholders in illustrative examples of research-stakeholder collaboration on telemedicine and older adult care projects

Researchers	Stakeholders	Illustrative example
<p>Background: biomedical engineering, with experience on developing telehealth devices that monitor the vital signs of older patients remotely.</p> <p>Knowledge of medical devices, data analytics, and signal processing is instrumental in creating cutting-edge solutions.</p> <p>Objective: to enhance healthcare delivery, improve treatment outcomes, and contribute to the scientific understanding of aging-related health issues.</p>	<p>Background and knowledge: government healthcare agency focus on regulatory frameworks and funding allocation to support the integration of telemedicine into national healthcare systems.</p> <p>Objective: A senior living facility may prioritize the practical deployment of telehealth services to improve resident care. Hence, the stakeholder aims to bridge the gap between research outcomes and real-world application, with a strong emphasis on practicality, affordability, and adherence to healthcare standards.</p>	<p>Researchers develop a telemedicine platform for remote monitoring of chronic health conditions in older individuals. Researchers design the system, validate its accuracy, and conduct clinical trials to assess its effectiveness.</p> <p>Stakeholder like government healthcare agencies would assess the regulatory requirements for its use, allocate funding for widespread implementation, and collaborate with healthcare providers to ensure seamless integration into existing healthcare infrastructure.</p>

The previous analysis helped identifying the learning objectives for both groups, through specific learning goals and measurable mechanisms. Tables A.2 and A.3 summarize them.

Table A.2 — Specific and measurable learning objectives for researchers

Objective	Learning Objective	Measurement
Deepen domain expertise	focused on healthcare, aging, and digitalisation.	Assessment of researchers' knowledge through pre- and post-training evaluations, with a target of achieving a significant increase in subject matter expertise.
Enhance technical proficiency	To improve their technical skills related to e.g. data analysis, technology, digital tools.	Evaluation of researchers' technical proficiency through practical assessments, such as successfully using LSP project-specific software and tools.
Strengthen research methodologies	To refine their research design and data collection methodologies, ensuring the production of high-quality research outcomes.	Review the quality and rigor of research proposals and LSP projects, aiming for improvements in research methodologies.
Foster effective communication	To enhance their communication skills to effectively convey complex research findings to stakeholders and the broader team	Evaluation of researchers' communication abilities through presentations, reports, and feedback from stakeholders on the clarity of research communication

Objective	Learning Objective	Measurement
Promote cross-disciplinary collaboration	To develop, increase and/or improve the ability to collaborate across disciplines by engaging in joint research LSP projects and interdisciplinary workshops.	Tracking the successful initiation and completion of cross-disciplinary research LSP projects through specific assess the impact of joint workshops on collaboration.

Table A.3 — Specific and measurable learning objectives for stakeholders

Objective	Learning Objective	Measurement
Improve technological literacy	To acquire proficiency in using digital tools and platforms for effective communication and data management.	Evaluation of their ability to use specified technologies through hands-on exercises, aiming for a minimum competency level.
Strengthen LSP project management skills	To develop LSP project management competencies, including planning, resource allocation, and progress monitoring	Evaluation of their performance in simulated LSP project management scenarios, with a goal of achieving predefined LSP project milestones
Enhance interdisciplinary collaboration	To foster effective communication and teamwork across diverse disciplines by participating in collaborative exercises.	Collect feedback on teamwork and collaboration from participants and monitor improved interdisciplinary interactions
Enhance regulatory awareness	To gain a comprehensive understanding of relevant regulatory frameworks in the healthcare and digitalization sectors	Evaluation of their knowledge through pre- and post-training assessments, with a target of achieving e.g. an 80 % or higher average score post-training.

A.4 Lessons learned

The Pharaon case study illuminates several transferable best practices for other LSP:

- **engaging a diverse group of stakeholders** to garner a wide range of insights and experiences;
- **maintaining open communication channels** to ensure continuous exchange of knowledge and feedback;
- **adapting strategies based on real-time feedback** to ensure the solutions developed effectively meet the end-users' needs.

This case study demonstrates how a well-structured mutual learning framework significantly contributes to the success of LSP projects addressing societal challenges.

The Pharaon project has provided valuable insights into the implementation of training and mutual learning in the context of LSPs. Key lessons learned from this initiative include the following:

- **Importance of tailored training:** customised training programs were crucial in addressing the specific needs of diverse stakeholders. By tailoring the training to different groups, such as healthcare providers, policy makers, and technologists, the LSP project ensured that each participant acquired relevant skills and knowledge.
- **Continuous feedback loop:** the LSP project highlighted the importance of a continuous feedback mechanism between stakeholders and researchers. This approach enabled the adaptation of

training content and methodologies to better suit evolving LSP project needs and stakeholder feedback.

- **Interdisciplinary approach:** the integration of various disciplines was pivotal in fostering a holistic understanding of the challenges and opportunities in active and healthy ageing. This interdisciplinary approach enhanced the collaborative spirit and enriched the learning experience for all participants.
- **Leveraging technology for training:** utilizing digital platforms for training and mutual learning proved effective in enhancing accessibility and engagement. This was particularly significant given the digital focus of the Pharaon project.
- **Measuring impact:** the LSP project underlined the need for clear metrics to assess the effectiveness of training programs. Regular assessments helped in fine-tuning the training modules and in validating the impact on LSP project outcomes.
- **Scalability and replicability:** the lessons from Pharaon are scalable and can be replicated in other LSPs. The strategies employed in this LSP project can serve as a blueprint for future initiatives aiming to integrate training and mutual learning in LSP projects.

The Pharaon project exemplifies the significant role of training and mutual learning in achieving the objectives of LSPs. The experiences and lessons from this LSP project can guide future LSPs in creating effective and impactful training programs. The integration of such programs into the fabric of LSPs not only enhances LSP project outcomes but also fosters a culture of continuous learning and collaboration among stakeholders and researchers. The Pharaon project stands as a testament to the power of combining technological innovation with targeted education and mutual learning to address societal challenges.

Annex B (informative)

Ethics

B.1 Iterative ethical methodology – Pharaon as an example

B.1.1 General

The Pharaon project, given its dimension and complexity, required an ethical analysis that goes beyond the compliance with European Union (EU) and Member States' laws and regulations on fundamental rights, data protection, and product liability directives. That is why a methodology to actively discuss ethical and societal challenges within the LSP project, using an interactive and iterative dialogue between the whole value-chain of stakeholders has been developed and now stands as a model to follow. For efficiency reasons, it was opted to pursue a pragmatic approach, providing a targeted and focused package of guidelines, tools, and a method (including checkpoint dates) to all the partners.

B.1.2 Pharaon model - an example

The Pharaon project showcases an outstanding example of a methodology that interconnects theoretical approaches of ethical research with the particularities of large-scale implementation of digital tools for health and social care. Through an iterative model of ethical analysis four dimensions were considered for developing a package of guidelines, tools, and checkpoints that can be used throughout the LSP project implementation (DANTAS et al., 2017).

The core of the methodology relies on the analysis and critical reflection processes regarding the safeguarding of participants/users following each of the dimensions: society, legal framework, technology, and people.

Society ought to be subdivided into three categories of transversal challenges: accessibility, gender, and safety. Accessibility in terms of digital accessibility, but also in terms of mobility, fostering participation, using simple and inclusive language etc. Tackling gender issues is another ethical commitment that practical measures should ensure, for example, looking for gender balance in all phases, providing representative data collection and analysis, using and promoting non-sexist language, prevent digital solutions from arising gender issues or perpetrating them. And also considering safety not only in face-to-face interactions but also in the digital arena and actively acting to prevent potential dangers, such as fake news, phishing, cyberbullying, data breaches, and fraud.

Legal framework refers to what is needed to comply with national and international legislation, assuring ethical, privacy, data protection and mostly the respect for the individual.

Technology is a dimension full of debates and reflections that need to be followed up in order to realize the most appropriate responses to current challenges. It was divided into five subclauses: training and education, building trustful artificial intelligence with user-centric design, health data, data governance and FAIR (findable, accessible, interoperable, reusable) principles, and incidental findings.

In training and education, the responsible research and innovation parameter should be highlighted as one of the key guidelines to achieve ethical alignment for LSP projects.

Another major and relevant concern in the field is how to ethically and responsibly develop artificial intelligence. There are many guidelines but just to mention one the European Commission stands behind ethics by design as a technique to address ethics concerns while solutions are being developed.

Health data have lots of specificities in the treatment and protection. Beyond that the progress in the healthcare innovation scenario depends on overcoming a siloed approach towards real-time

communications and interoperable systems with stakeholders' actual adherence. The European Health Data Space is an effort in that sense. Data governance and FAIR principles need to be reflected in each new LSP project as a way to legally and ethically address challenges and novelties. The same with the incidental findings which in health and social type of LSP projects may come up beyond anticipation, and they lead to discussions not only if the data should or should not be used, but how a person should be informed.

The last dimension is people and is organized into three topics: quality of life, older adults, and workforce. The first one refers to taking into account a comprehensive definition of well-being and quality of life for developing solutions and research in the areas of health and care, for example, the one from the Organization for Economic Co-operation and Development (OECD, 2023).

Pointing out older adults as target groups in a LSP project requires attention to many ethical aspects such as avoiding the stigmatization in output analysis, research/scientific biases, and the language. There is also the complexity of determinants that define older people as a vulnerable group without incurring false generalisations and age-based discriminations. In this sense, the IC and the ways of obtaining it play a pivotal role in the ethical success of a LSP project.

Two final aspects of people-related worries are e-inclusion and the workforce context and profile while implementing Information and Communication Technology-driven type of LSP projects.

Based on this extensive analysis and studies the iterative model has been tailored and a selection of tools has been developed for different publics and different levels of usage.

- Miniguide;
- Guidelines;
- User tips;
- Matrix for use cases;
- IC package;
- Procedures to obtain IC;
- Ethics dialogue.

B.1.3 Verification methodology of ethical compliance in Pharaon

The proposed methodology for verification involves a three-step multidisciplinary approach, composed of a legal analysis, the use cases elaboration, and the verification matrix for ethical compliance.

The legal framework was structured both in a broader sense, at the European level, and then, more specifically, concerning the national legislation for trial sites. To build the use cases and services a collection of data on expectations, habits and needs of users and carers set the ground for the scenarios. Besides, the technical possibilities and financial analysis are developed. Throughout the process to reach the final product the ethical recommendations are reviewed for compliance assurance. Finally, the verification matrix for ethical compliance is a tool used for ethical recommendations and concerns and crosschecks with the use case scenarios and services developed.

A final remark not only in terms of methodology verification but also implementation, is that it embodies major concerns for all parties involved in a LSP project, in other words, it cuts across the interests and outcomes of a LSP project and requires the commitment of a range of stakeholders.

B.2 Documents used to achieve legal and ethical compliance

B.2.1 The Nuremberg code (1947)

The Nuremberg Code, created in Germany in 1947, is a reference document in the history of research ethics. It consists of 10 fundamental principles in medical research, regarding: voluntary consent, societal beneficence, avoiding physical or mental injury, proportionality between risks and benefits, necessity, and the permanent right to withdraw. Although the Nuremberg Code has never officially been adopted as law, it has had a major influence on human rights law and medical ethics. Previous ethics codes focussed on the obligations of the investigator towards the research subjects. The Nuremberg Code reverses that logic, awarding the rights directly to the research subjects (EU, 2013).

B.2.2 Helsinki Declaration (2013)

The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. As a standard, this declaration is above other regulations. It was originally adopted in June 1964 in Helsinki, Finland, and has undergone seven revisions since (the most recent at the General Assembly in October 2013). The declaration is addressed primarily to physicians, however the medical association encourages others who are involved in medical research involving human subjects to adopt these principles.

B.2.3 The Belmont Report (1979)

The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, contains the basic ethical principles that should guide the ethical conduct of biomedical and behavioural research involving human subjects. Within this framework it sets 3 main protective principles to be followed: (1) Respect for Persons or Human Dignity; (2) Beneficence or Nonmaleficence; (3) Justice.

B.2.4 The European Charter of Fundamental Rights (2016)

Evidently, there is a strong connection between research ethics and human rights. Within the European regulatory framework, research ethics are like all European policy domains (to which Pharaon also aims to contribute), based on the explicit European commitment to human rights consolidated into legislation, in 2000, through the European Charter of Fundamental Rights (EU, 2016). By establishing a set of personal, civil, political, economic, and social rights, which all European legislation must be in line with, this Charter, recently updated in 2016, provides the legal basis for the most common values of the European Union. Following this perspective, it also applies to the European research policy, context and conduct, paving the way for important ethics guidelines to studies involving the participation of humans. From all the Charter's articles, some important principles are stressed out: Article 1 | Human Dignity; Article 3 | Right to the physical and mental integrity of the person; Article 6 | Right to liberty and security; Article 7 | Respect for private and family life, home and communications; Article 8 | Protection of Personal Data; Article 11 | Freedom of expression and information; Article 13 | Freedom of the Arts and Sciences; Article 21 | Non-discrimination; Article 25 | The rights of older adults.

Annex C (informative)

Examples of types of projects which might use the premises of this CWA

C.1 General

The implementation of pilot tests in projects with high Technology Readiness Levels (TRL) is a crucial step towards ensuring the success and efficiency of technological developments. Pilot testing serves as a bridge between the controlled environment of the laboratory and the complex realities of the real world. It allows for the validation of theoretical models, the identification of unforeseen variables, and the mitigation of risks before full-scale deployment. Efficiently conducted pilot tests also enable the identification and troubleshooting of potential issues that were not apparent during the lab-scale phase. This proactive approach can save considerable time and resources by preventing large-scale failures and ensuring that the technology is robust and reliable. Moreover, pilot testing facilitates stakeholder engagement and confidence building. By showcasing the technology's effectiveness and addressing any concerns through real-world demonstrations, stakeholders are more likely to support and invest in the technology.

In summary, the importance of conducting pilot tests in high TRL projects cannot be overstated. They are essential for validating technological innovations, identifying and mitigating risks, building confidence among stakeholders, and refining the product for successful commercialisation. Efficient execution of these tests is a critical factor in the journey from the lab to the market, ensuring that new technologies can achieve their intended impact in the real world.

C.2 The Ash-Cycle project: Integration of underutilized ashes into material cycles by industry-urban symbiosis

The AshCycle project (grant agreement number: 101058162) provides tools to reduce the amount of waste generated from the incineration of municipal solid waste, biomass, sewage sludge or combinations thereof by developing new utilization possibilities. The project will use exemplary pilot solutions of the Industrial-Urban Symbiosis concept by demonstrating novel methods to recover valuable elements from the ash. In addition, the aluminosilicate-rich minerals recovered from the ash will be tested as feedstock for companies in different value chains to obtain products for construction and wastewater treatment, leading to increased resource efficiency and circular economy. The mineral residues of the ash that remain after the recovery of the valuable elements will be used for the development of low-carbon recycled building materials and products. Another utilization perspective for the mineral residue is the development of alkali-activated composite adsorbents. The various recycling options are validated through laboratory-scale tests and product optimization. Subsequently, each product will be demonstrated in a large-scale. The pilot projects will take place in three main EU areas: Croatia and Slovenia, the Netherlands and Belgium, and Finland and Denmark, but also South Africa and Switzerland.

The following pilots are foreseen:

- extraction of phosphorus and rare metals from ashes;
- utilization of ashes in clay brick sector, concrete industry and alkali activation technology, and as SCM;
- carb-stone technology;
- use of ashes for earth construction;

- up-scaling of aggregate production from ashes.

The demonstration projects will serve as models for the successful implementation of the new solutions on the market and to improve the ability of society as a whole to accept new concepts, technologies, and processes. They are designed to serve as models with high replication and scaling potential.

C.3 The SWAG project: Next step towards everyday use of exoskeletons

Exoskeletons are a recent technology that allows someone with movement limitations to receive support with everyday movement. Think of the “robotic braces” that allow people with spinal cord injuries to walk. Technology keeps moving forward; nowadays there are ways to design those exoskeletons from textiles and other materials that can deform, so-called “soft robotics”. In other words, Soft Wearable Assistive Garments (SWAG). Those soft exoskeletons are much more comfortable to wear. This means that the use of such wearable robots at home or at work is getting closer. This way, people with for example walking problems can be assisted in everyday activities. In the new SWAG project (grant agreement number 101120408), 13 partners from across Europe work together to develop a fully soft exosuit that will support hip, knee, and ankle. It is dedicated to four different use cases: motion assistance for people with stroke or traumatic brain injury, occupational enhancement for workers, wellness training for improving fitness, and haptics for immersive virtual reality during training.

When developing such advanced technology, it is of utmost importance to very carefully look at what future users think of the envisaged exosuit and how it would be used. We are including end-users from the start of the project, with continuous involvement throughout the project. Starting with identifying user requirements for what people with a brain injury deem important when designing the SWAG exosuit, continuing with repeated testing of prototypes by brain injured patients as the exosuit takes shape step by step, and finalising with physical tests of the exosuit in (simulated) real life tasks, what the experience of the users is with the exosuit and whether it meets their expectations.

This will be done in an iterative way, testing subsequent versions of prototypes with end-users and providing feedback about end-user input to technical work packages for further development. This way of working fits well with PAR, and thus this CWA should be of added value for the project.

C.4 The GATEKEEPER project: Smart Living Homes - Whole Interventions Demonstrator for People at Health and Social Risks

Current efforts focused on identifying and addressing health and social risks early are primarily evident in clinical trial settings. Numerous healthcare systems across Europe, including those participating in the Gatekeeper project (grant agreement number 857223), have established approaches to categorize populations at risk according to their complexity level. In certain instances, this categorization relies on digitised health records, while in a few cases, it incorporates data from both primary and secondary care settings. Nevertheless, proactive implementation of risk prevention and management remains lacking.

The GATEKEEPER LSP planned and implemented various use cases across Europe, facilitating the implementation of digital solutions for early detection, intervention, and the support of risk stratification models.

Through a co-creation led and coordinated approach, the project fostered a strict collaboration among pilot sites, and engaging a wide user base to evaluate and contribute to understanding the key factors that differentiate successful solutions in the realm of health and social risk prevention, ultimately advancing the field active and healthy aging. The implemented use cases covered: Lifestyle-related early detection and interventions, chronic obstructive exacerbations management, diabetes: predictive modelling of glycaemic status, Parkinson’s disease treatment decision support system, predicting readmissions and decompensations in heart failure, multi-chronic older patient management including polimedication, primary and secondary stroke prevention.

The project developed an ecosystem made up of seamlessly integrated components that fosters collaboration, accelerates innovation, and ultimately enhances healthcare outcomes across Europe. The main components are: a dedicated data centre, a container platform, a federated services platform, a big data platform and an integrated web environment. The system constitutes a scalable trusted research environment for primary and secondary use of data, based on interoperability standards like Fast Healthcare Interoperability Resources.

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