Deliverable 4.1

Trial and evaluation design framework

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List of abbreviations

Abbreviation	Full name
ILE	Independent Living Elderly
ICG	Informal Care Giver
D-ICG	Dedicated Informal Care Giver
FCG	Formal Care Giver

Version History

Version	Date	Changes	Organization

Lead partner(s) involved in deliverable

Lead partner	Date
KOR	

CO- Partner(s) involved in deliverable

Organization	Name person
AC	

Trial and Evaluation Framework Plan

This plan provides a structured approach to conducting trials, engaging end-users, and establishing evaluation specifications. Customizing each step according to the specific context of the trial will ensure a more tailored and effective framework.

1 Objective Definition

- **Purpose:** we first define the goal of the trial and evaluation : WP4 aims to provide evidence of the good performance of Solaria as well as the requirements for implementing Solaria in the daily life of the three end-user groups: seniors, informal care givers and healthcare professionals. This information aims to facilitate evidence-based improvement of the product.
- **Key Objectives:** clarify what needs to be achieved through end-user engagement and evaluation : the 'trial and evaluation design' includes the methods of the trial tests and the evaluation of results. For this task UC will be supported by SLG and FSL. The ethical aspects will be dealt by AC.

2 End-user Identification

- **Persona Profiling & Selection Criteria:** the Solaria project addresses the following four end-user target groups:
- **Elderly:** this target group lives independently at home or in serviced flats. They are not digitally skilled and, although still healthy and mobile, suffer from the isolation and loneliness of old age. They have the need of an easy-to-use communication tool that allows them to chat with family, friends, and with other informal care givers that regularly help them with basic housework. They also have the need to be in contact with healthcare professionals that assist them with certain conditions they might have. We use the abbreviation ILE (independent living elderly).
- **Informal Care Givers (ICG):** this target group consists of relatives and friends of the seniors. They are recipients of the Solaria system as they initiate video-calling and messaging with the seniors to keep a regular contact with them and be reassured. This group are also recipients of alert notifications (through lights, smoke, and CO2 detector alerts) and will possibly take care of the seniors. In many cases this group will influence the decision to buy the Solaria product.
- **Formal Care Givers (FCG):** this third target group is represented of formal care givers such as nurses, therapists, and physicians who periodically or non-periodically carry out medical checks on the elderly. This group are possible recipients of the seniors' health data for regular monitoring of the elderly's health status and possible disease diagnosis.
- **Tertiary users:** this target group is represented by private insurance companies and governmental health institutions that could promote Solaria and cover the cost for the elderly.
- In the field tests the 3 first end-user target groups will be involved.

3 Engagement Activities

- **Recruitment Strategy:** in WP D2.2 FSL developed a plan for recruiting end-users.
- **User Onboarding:** all end user partners (BONA, HLN & KOR) will prepare onboarding materials and sessions to familiarize users with the product.
- **User Support:** all end user partners (BONA, HLN & KOR) will establish channels for user support during the trial period, in cooperation with UC.

4 Trial Execution

- **Timeline:** we developped a schedule for the trial duration.

In total there are 4 iterations in the Solaria-project. Iterations 1 & 2 consist in 2 acceptance testing periods. In what follows we describe the two field trials in the 3 end-user organisations BONA, HLN & KOR.

Field trial 1 (iteration 3) : M16 until M20 of the project

The pilot tests will start with an iteration in Flanders & Switzerland at a small number of selected homes & assisted living apartments serviced by KOR (n=10), HLN (n=8) and BONA (n=5). This first trial on a smaller scale is to test the functionality, usability, and acceptance of the system. This first iteration will also test support for first installations & the increasing technical maturity of the system before the larger roll-out takes place during field trial 2.

During iteration 3 seniors (n≥30), informal care givers (n ≥20), healthcare professionals (n ≥10) and insurance experts (n≥2) recruited by KOR, HLN and BONA will participate in the field test. Seniors will be persons aged 65 and over with approximately similar proportions in gender, living independently at home or in serviced apartments. Questionnaires and interviews will be used for the evaluation of the field trial, results will be anonymized in order for users not to be identified. The results of the first field trial will be analyzed and presented in a report by FSL. The report will be discussed within the consortium at a Steering Committee (SC) meeting at the end of M20. The common derived conclusions will be incorporated into the system design and implementation.

Field trial 2 (iteration 4) : M21 untill M29 of the project

The second and large pilot trial will involve a total of 90 seniors living independently in their homes in Flanders (n=70) and Switzerland (n=20). The seniors will be persons aged 65 and over and with similar proportions in gender. To investigate the performance of the Solaria technology in real life settings, the technology will be rolled out to the two countries and installed in at least 60 seniors' homes and serviced flats. For a duration of 12 months the systems will be in operation although the exact duration of the individual systems may vary depending on the requirements and any emerging issues in the ongoing project or the respective country. In addition to the seniors, also informal care givers (n≥40), healthcare professionals (n≥20) and insurance experts (n≥3) will be involved in trial 2. Questionnaires for the evaluation of Solaria technology will be in Dutch and German. Questionnaires will be designed by FSL and provided on-line to informal care givers and healthcare professionals, while short paper questionnaires will be provided to the elderly. When necessary, care givers will be instructed to support seniors in filling in the questionnaire. The questionnaires will be handed out in an envelope and collected via an envelope by the care givers to guarantee confidential treatment of the answers. Results will be anonymized. The following table summarizes user involvement during the testing of the Solaria technology.

M	WP/Task	Aims	Methods	Users	Country

	WP2 Acceptance testing Co-creation	Identify needs, requirements and expectations of end-users. Co-creation of the product. Review and adaptation of the prototype.	Focus groups, co-creation sessions, semi-structured expert interviews. Two prototypes tested.	Seniors (n≥20) informal care givers (n≥12) healthcare professionals (n≥8), insurance experts (n≥1).	BE, CH
	WP3&WP4 Field trial 1	Testing functionality, usability and acceptance. Review and adaption of the product.	Prototype testing in home settings, semi-structured expert interviews and on- line or paper questionnaires	Seniors (n≥30) informal care givers (n≥20) healthcare professionals (n≥10), insurance experts (n≥2).	BE, CH
	WP3&WP4 Field trial 2	Testing functionality, usability, acceptance, satisfaction and value Review and adaption of the product	Online or paper questionnaires, semi-structured interviews for the four target groups	Seniors (n=90) informal care givers (n≥40) healthcare professionals (n≥20) insurance experts (n≥3)	BE, CH

- **Feedback Mechanisms:** FSL has the lead in the development & implementation methods for users to provide feedback (surveys, focus groups, interviews).
- **Monitoring Usage:** we will track user interaction and usage patterns. This task will be covered by UC & CT.

5 Evaluation Specifications

- **Metrics Establishment:** all end user organisations (BONA, HLN, Kor) will define measurable metrics aligned with objectives (e.g., user satisfaction, task completion rate, time spent).
- **Data Collection:** all end user organisations (BONA, HLN, KOR) will determine the methods and tools for collecting relevant data. FSL (for the research part) & AC (for the data security) will help with this task.
- **Analysis Plan:** FSL will outline procedures for analysing collected data and deriving insights.

6 Documentation and Reporting

- **Data Compilation:** all end user organisations (BONA, HLN, KOR) will gather and organize all collected data, with the help of FSL.
- **Analysis:** FSL will analyse these data to draw conclusions based on predefined metrics.
- **Report Creation:** finally a comprehensive report will be generated by FSL highlighting findings, insights, and recommendations, in cooperation with alle end user organisations (BONA, HLN, KOR).

7 Iterative Improvement

- **Feedback Integration:** there are feedback-moments planned in M20 & M25. In these moments user feedback of all target groups will be integrated into product improvements.
- **Continuous Evaluation:** during the field trials there are also ongoing evaluations to ensure continual improvement. The final evaluation is foreseen in M30.

8 Resource Allocation

- **Budgeting:** in the financial plan there are enough resources allocated for all partners for conducting the trials and evaluations.
- **Team Assignment:** clear roles and responsibilities are assigned to the end user organisations involved in the process (BONA, HLN, KOR).

9 Ethical Considerations

- **Privacy and Consent:** we will ensure compliance with data privacy laws and obtain user consent for participation. This task will be covered by AC. In attachment of this deliverable the main principles are published by AC.
- **User Well-being:** all end-user organisations (BONA, HLN KOR) will prioritize user well-being and safety throughout the process.

10 Risk Management

- **Risk Identification:** in the proposal potential risks that could impact the trial and evaluation process are identified. We also foresee a contingency plan to counter eventual risks.

No	Risk	Prob	Impact	Prevention	Contingency plan
	Field Trial and Ethical Risks				
1	Not enough participants in target groups	Med	High: Sound and reliable evaluation impossible	Early end-user recruitment, clear information on project value and management of ethical and privacy	Recruit end-users from partners/stakeholders from outside of the consortium

				issues.	
2	Data privacy	Med	High: No confidence in solution, legal problems/no data	Open communication with end users on data security standards used and on implementation of GDPR regulation.	Use ISO 9241-210:2019 standard. Good preparation of trials in terms of addressing data privacy issues.
3	Ethical issues	Med	High: No confidence in solution, legal problems/no data	Open communication with end users on the drafting and implementation of ethical guidelines	Early draft of ethical guidelines and communication. Good preparation of trials in terms of addressing ethical issues.
4	Ongoing Covid-19 pandemic situation	Med	Low: Not enough seniors available for testing and co-creation	The system is envisioned for distant testing with minimized contacts.	Solaria used by end users with minimum external contacts.

Solaria Field Trial

Guidelines for the Participation Agreement and Privacy Notice

Objective of these guidelines: to provide instructions for field staff on how to effectively present and manage the Agreement and Privacy Notice with participants in the Solaria Field Trial.

1. Preparation

Understand the Documents - Ensure that all field staff have thoroughly read and understood the Agreement and the Privacy Notice, including its summary. Any questions or doubts can be directed to Magali Feys (magali@acontrario.law) and Jelle Cousyns (jelle@acontrario.law) of AContrario (the legal partner in the Solaria consortium).

2. Presentation of documents to participants

- *Setting the Context* - Start by explaining the purpose and the importance of these documents in protecting everyone's rights during the Solaria Field Trial.
  - Agreement: it formalizes the participation and defines the terms, conditions, rights, and responsibilities governing the relationship between Solaria and the Participant within the context of the Solaria Field Trial, seeking to foster clarity, trust and mutual understanding.
  - Privacy Notice: it explains how their personal data and information will be collected, used, and protected, emphasizing our commitment to their privacy and adherence to data protection laws.
- *Highlight Key Points* – Emphasize the most critical aspects of each document.
  - Agreement: you can focus on the fact that the participant receives a test license free of charge and that it is not guaranteed that the system will not have any bugs or defects; the duration of the agreement; the fact that participants will not be liable for accidental damages, but need to notify damages as soon as possible; etc.
  - Privacy Notice: you can utilize the summary of the Privacy Notice at the top of the document to provide an easily digestible overview.
- *Simplified Explanations* – Use simple language to explain the documents. Avoid legal jargon that may confuse the participants.
- *Interactive Q&A* - Encourage participants to ask questions. Answer clearly and patiently. If possible, offer general information related to the question. Do not speculate or provide incorrect details; if unsure of the answer, admit so and emphasize your commitment to finding the correct information. Where required, contact the relevant department or experts within the Solaria Consortium for a precise answer. This could be the

legal team of AContrario for contractual queries or the technical team of UCast for specific questions about the Solaria System.

3. Obtaining Signature and Consent

- *Signing the Agreement* - Ensure that the participant (or their authorized representative) signs two copies of the Agreement at the dedicated signing space. One copy should be kept by the participant, the other by your organization.
- *Explicit Consent Check-Box* – Ensure that the participant (or their authorized representative) tick the checkbox for consent for health data processing, found in the Participation Form at the bottom of both copies of the Agreement.
- *Acknowledgement for Privacy Notice* – Unlike the Agreement, participants do not need to sign the Privacy Notice. However, ensure to obtain a verbal acknowledgment that they have understood the Privacy Notice.

4. Document Management

Secure *Storage and Retention* - Ensure that your copy of the signed Agreement will be stored securely, in line with the internal organization policies or legal department's instructions. The Agreement must be retained for the duration of the Field Trial. On top, it is recommended to store the Agreement for an additional period of 5 years after the trial, in light of potential claims potential claims that might arise within the statute of limitations period.

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