STREAMLINED **GER**IATRIC AND **ON**COLOGICAL EVALUATION BASED ON IC **TE**CHNOLOGY FOR HOLISTIC PATIENT-ORIENTED HEALTHCARE MANAGEMENT FOR OLDER MULTIMORBID PATIENTS

DELIVERABLE D6.1: Coordination strategy for stakeholders' engagement

Lead Beneficiary: 6-ESE

Involved Beneficiaries: 1-UBx; 2-KUL; 3-DIAK; 7-MyPL; 8-BOC; 9-SIOG; 10-DCU

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Disclaimer and acknowledgement

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Version	Date	Author	Description of change
V1.0	30/06/2021	Marianne GROS [ESE] Eléonore LEHN [ESE]	First submission
V2.0	03/02/2023	Alice PERNOT [ESE] Alena BOGDANOVA [ESE]	Second submission

Table of Content

Executive Summary

This deliverable describes the Coordination strategy for stakeholders' engagement as per reference to Description of the Action part A.

Deliverable work status

Deliverable	Completion status in %	Deviation	Data complete or to be updated
D6.1: Coordination strategy for stakeholders' engagement	95%	Updates M24, M48	Some updates may be done at M24 and M48 following the small-scale pilots and the clinical trials
Associated Deliverables	D6.2 - Practical guidebook for the methodology of co creation sessions D6.1 and D6.2 are deeply interconnected, since D6.1 presents the strategy tested in task and deliverable 6.2. Although updates of D6.1 were not originally foreseen in the project, it was proposed by the partners to update D6.1, because of its strong link with D6.2 which was initially planned to be updated. D6.1 was therefore updated at M10, following the updates of the T6.2 after the organisation of the Focus Groups and the review of their results. The update of the D6.1 includes the ethical aspects that could not be added when it was submitted to M3 (at that time still under discussion in WP9), and the reflections on the methodology to be adopted for small-scale pilots. D6.1 may still be updated at M24 and M48, depending on the reflections in Task 6.2. This update will be decided by the WP6 members.		
Associated Objectives	O.2 - Develop the HolisTM GV tool for the GerOnTe model to be implemented O.6 - Ensure proper engagement of all stakeholders (notably older patients and diversified caregivers) by co-designing the GerOnTe method WP6 is strongly linked to project objective O6. WP6 core goal is the O6 objective "Ensure proper engagement of all stakeholders (notably older patients and diversified caregivers) by co-designing the GerOnTe method", and the deliverables of this WP are the main deliverables linked to O6. WP6 consists of 3 sub-objectives, each linked with specific tasks and deliverables as briefly described hereafter: O6.1 - The first subobjective of WP6 is to create Focus Groups in order to involve stakeholders' representatives in the co-development of GerOnTe tools (O2) and methods (O3) as well as its data gathering (O1) and recommendations (O5). This subobjective is achieved through Tasks 6.1,		

	6.2 and 6.3, as documented in D6.1, D6.2 and D6.3 and is intertwined with Task 6.6, which focuses on the ethical issues related to all stakeholders' involvement and to the GerOnTe intervention, as a crucial and crosscutting piece to ensure the success of the project. O6.2 - The second subobjective of WP6 is to provide training sessions before the clinical trials, to increase stakeholders' involvement. This subobjective is achieved through Tasks 6.4 and 6.5, and will be documented in D6.4 and D6.5. O6.3 - The third subobjective of WP6 is to study older people's acceptance of using a web-app (HolisTM GV) and providing personal data. This subobjective has been achieved through Tasks 6.3 and 6.6 (currently on-going until M60 of the project). WP6 is also linked to the objective O2 "Develop the HolisTM GV tool for the GerOnTe model to be implemented", and especially to the sub-objective "Build an ICT tool that is user-friendly for older patients and their informal caregivers (simple to install, right profile and information easily accessible, ergonomic addition of personal data)" in relation with WP2, as the tests and focus groups carried out as part of the development of Holis™ GV were also part of WP2.

Description of deliverable

This deliverable describes the strategy for the co-creation sessions to ensure appropriate stakeholders' engagement. This deliverable is connected to D6.2, since D6.1 presents the strategy tested in task and deliverable 6.2. Although updates of D6.1 were not originally foreseen in the project, it was proposed by the partners to update D6.1, because of its strong link with D6.2 which was initially planned to be updated.

The deliverable is associated to the specific objective #2 "Develop the HolisTM GV tool for the GerOnTe model to be implemented" since it contributes directly to ensuring the user friendliness of the developed tool through co-creation sessions organised with healthcare professionals, older patients and informal caregivers. In addition, the Deliverable is associated to the specific objective #6 "Ensure proper engagement of all stakeholders (notably older patients and diversified caregivers) by co-designing the GerOnTe method" in its entirety. D6.1 establishes the strategy for Focus Groups and Small-scale pilots creation which involved stakeholders' representatives in the co-development of GerOnTe tools (O2) and methods (O3) as well as its data gathering (O1) and recommendations (O5).

Attainment of the objectives and explanation of deviations

The objectives related to this deliverable have been achieved up to 95% as described in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218. The WP6 partners decided that the D6.1 may be updated to reflect the project evolution and its effects on the respective work.

Justification for delay in deliverable submission

The objectives related to this deliverable have been achieved on time and as scheduled in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218.

Data associated
The data (i.e. proofs of the meetings and of the activities conducted) associated to this deliverable are available in the annexes of this deliverable, or as annexes of the technical report for the first reporting period (resubmission).

Objectives for the tasks regarding stakeholders' engagement and ethical issues (WP6)

The objective of WP6 is to foresee proactive stakeholder engagement in the project and define a strategy for the co-creation sessions. Co-creation sessions took place in France, Ireland and the Netherlands. They aimed to identify: end-users' requirements, elements for maximum usability and best design of the interface or the app. Small-scale pilots took place in France, the Netherlands and Belgium and tested the app with small groups of end-users to identify any possible issues and allow us to resolve them.
This first version of the D6.1 detailed the aim and initial plan for the focus groups and the expert panels. It also gave a brief overview of the aim of the small-scale pilots and the stakeholders and partners involved in this task. Updates to the D6.1 are to be added at the same expected deadlines as the updates of the D6.2, since they are deeply interconnected. The first update of the D6.1 at M9, details the plan for the small-scale pilots, since their implementation began at M9 and reli ed heavily on the results of the previous co-creation sessions, i.e. the focus groups and expert panels. The first update also included the ethics and risk assessment presented in WP8 and following updates at M24 and M48 will detail additional changes of strategy and plans for co-creation sessions.

Focus groups

Focus groups allowed for a flow of information to directly feed the build and design of the app, just as the focus groups happen by allowing us to identify and rank priorities to better discern end-user' requirements, concerning both the design and the content of the app. ESE is in charge of the methodology and coordination and all partners collaborated on D6.1 and D6.2, during meetings and regular updates were sent for review. Partners have decided to align the topics and questions of their focus groups during workshops in months 4 and 5. Stakeholders were involved in three ways, focus groups of 5 to 10 people, one-on-one ideation sessions and surveys. Focus groups sessions might be replaced by individual sessions at participants' request. Expected results of the co-design focus groups are the gathering of end-users' feedback to feed the app and to anticipate risks and issues. Expected results of the focus groups by BOC are the validation of the QKPIs for the assessment and management of multimorbidity and the mapping of the care journey. DIAK, DCU, UBx and ESE organized co-design focus groups and sessions with stakeholders in their countries, BOC organized focus groups with the clinical sites to map the patient journey and will organize focus groups with different types of participants, in order to validate their QKPIs and map the patient journeys within each clinical site. MyPL acted as a facilitator in the co-design focus groups when possible and proposed prototypes or mockups for the focus groups. Stakeholders were identified according to the work done in WP1 and had been divided in 7 categories to avoid bias and maximize results: Cancer

specialists, Comorbidity specialists, Nurses, Other health professionals, Patients, Caregivers and Healthy Seniors. Stakeholders for BOC's focus groups were identified as patient associations and experts and members of clinical sites; they will be involved in focus group sessions throughout the duration of the project at different timepoint .

Expert Panels

DIAK, within the frame of WP1, has organized expert panels involving 39 health professionals of various backgrounds. The panels were divided in four rounds, each lasting four weeks, from April to August. In monthly surveys, experts were asked to provide their input on the relevance of various comorbidities. After the fourth round, DIAK organised one expert meeting involving health professionals to review and finalize the results and gather feedback from experts.
BOC, within the frame of WP3, and specifically Task 3.4 will involve an expert panel group composed of different stakeholders (e.g. clinicians, patient representatives, healthcare managers) to discuss and finalize the list of QKPIs for the evaluation of multimorbidity.

Small-scale pilots

The small-scale pilots involved a small group of 3 to 4 older people, in France, Belgium and the Netherlands and took place at the seniors' home environment and hospitals from M9 to M12. Their aim is to test the final prototype of the GERONTE app in a real-world environment, to validate the WP1 study questionnaires and to evaluate possible gender bias. MyPL lead of this task liaised with E-Seniors to update the D6.1 at M9 regarding their strategy for the small-scale pilots. DIAK, KUL, ESE and UBx were involved in the implementation of the pilots in their countries.

Ethics, risk assessment and gender considerations

The ethics and risk assessment were defined with the GERONTE Ethics and Data Manager, in compliance with legal and ethical standards at national and European level. This is the subject of the data management plan and the ethics management plan (WP8).
Regarding gender considerations, GERONTE is a project that keeps at its core the UN SDGs Agenda 2030. With regard to gender balance, we have considered the following goal SDG 5- Gender equality; achieve gender equality and empower all women and girls.
In the focus groups and small-scale pilots, an effort will be made to ensure the fairest possible representation among the patients, caregivers and health professionals recruited to participate in the various activities. However, the main focus will be on finding suitable candidates to participate in the tests, and particularly in the small-scale pilots. Indeed, within the framework of the small-scale pilots, the focus will be on candidates who will participate in clinical trials first.

Attainment of the objectives and explanation of deviations

The objectives related to this deliverable have been achieved up to 95% as described in Annex 1 (Description of the Action Part A) of the Grant Agreement N°945218.

Justification for delay in deliverable submission

The objectives related to this deliverable have been achieved on time and as scheduled in Annex 1 (Description of the Action Part A) of the Grant Agreement N°945218.

1. Introduction

1.1. The GERONTE project and its objectives

GERONTE is a 5-year research and innovation project (April 2021 to March 2026) funded by the European Union within the framework of the H2020 Research and Innovation programme. The overall aim of GERONTE is to improve quality of life - defined as well-being on three levels: global health status, physical functioning and social functioning- for older multimorbid patients, while reducing overall costs of care. To this end, GERONTE will co-design, test, and prepare for deployment an innovative cost-effective patient-centred holistic health management system, hereafter referred to as the GERONTE intervention. GERONTE intervention will rely on an ICT based application for real-time collection and integration of standardised clinical and home patient-reported data. GERONTE intervention will be demonstrated in the context of care of multimorbid patients having cancer as a dominant morbidity, and be versatile to any other combination of morbidities.

Objectives of the GERONTE project

O1: INFORMATION gather the stakeholders and data needed for patient-centred and multi-actor complex decision-making process and management
O2: **TOOLS** develop ICT tools for the GERONTE intervention to be implemented
O3: METHODS develop socio-economical methods for evaluating the impacts of the implementation of the GERONTE intervention
O4: **DEMONSTRATION** demonstrate in 16 study sites from three EU countries the feasibility and effectiveness of the GERONTE intervention
O5: **REPLICATION** develop recommendations for the replication of GERONTE best practices in all European health systems
O6: ENGAGEMENT engage all stakeholders by co-designing the GERONTE intervention

Objective of the Work Package 6

The objective of WP6 is to foresee proactive stakeholder engagement in the project and implement it in co-creation sessions, such as focus groups and one-on-one focus sessions as well as expert panels. Co-creation sessions are to allow for the end-users to discover the GERONTE project and model, and be able to give direct feedback on their expectations and requirements regarding the project.
The sessions aim to identify the elements that should be included or excluded from the app, in regards to content of the app and its design, in order to ensure maximum usability of the app by end-users, and therefore, the successful implementation of the app and the GERONTE model.

Once the final prototype of the GERONTE app was ready, small scale pilots in real world environments were organized to test the usability of the system with users prior to demonstration in RCT. Overall, this process of stakeholder engagement aims at making sure that GERONTE's technology is both useful and usable for the target users. Since WP6 focuses on end-users, it tackles the possible issues

regarding the usage of the GERONTE technology that might diminish the users' motivation to adopt the technology, as well as the related ethical issues.
This Deliverable details GERONTE strategy for all stakeholders' involvement related to the creation of the GERONTE app. The co-creation sessions took place in France, Ireland and the Netherlands, while the small-scale pilots took place in France, the Netherlands and Belgium. This deliverable, therefore, also aims to set the strategy for international partner cooperation. This first version of the D6.1 details the aim and initial plan for the focus groups and the expert panels. It also gives a brief overview of the aim of the small-scale pilots and the stakeholders and partners involved in this task.
As co-creation sessions are implemented along the duration of the project, we expect changes to the strategy and the plan for these sessions, and therefore, updates to the D6.1 will be added at the same expected deadlines as the updates of the D6.2, since they are deeply interconnected. The first update of the D6.1 at M9, detailed the plan for the small-scale pilots, since their implementation began at M9 and relies heavily on the results of the previous co-creation sessions, i.e the focus groups and expert panels. Following updates at M24 and M48 will detail additional changes of strategy and plans for co-creation sessions.

1.2. Rationale

In Europe, the health system is designed around a single disease patient approach, which is not adapted to the care of multimorbid patients, and results in inappropriate detection and management of symptoms, under and over treatment and unnecessary costs. The GERONTE project proposes a new model of care based on a multi-focused patient-centered approach. The GERONTE model will be demonstrated in the context of care of multimorbid patients having cancer as a dominant morbidity because cancer frequency increases in older patients as do incidences of comorbidity, which increases the project's results. Cancer management is also already multidisciplinary which will minimize the steps needed for a change of approach. Once validated, this model will be applicable to any other combination of morbidities with or without cancer, giving to the concept a major potential to be generalized for the broader older population. To achieve its goal, the GERONTE consortium is constituted of five hospitals and universities specialized in geriatrics and/or oncology from five different European countries (UBx, DIAK, OUS, UCD, KUL), two universities renowned in socio-economic studies of health systems (BOC, DCU), two experts in health informatics (MyPL, UCD) and two associations skilled in stakeholders' engagement (SIOG, ESE). The project will aim to facilitate access and exchange of patient data for health professionals as well as patients and their informal caregivers; to regroup all health care professionals in tailor-made patient focused individualized care coordination pathways; developing a data exchange tool with one interface directed at Health Professionals and another for patients and their caregivers.

This deliverable will help reach the KPIs set for WPs 1, 2, 3, 5 and 6, which are detailed in the Description of Action, part B, pages 6 to 9. The expert panels directly aim to fulfill the KPIs related to WP1 by involving health professionals and the focus groups will help fill-in the gaps of knowledge to reach these KPIs by gathering feedback from patients and caregivers. The co-design approach of the co-creation sessions and especially the focus groups will help reach the KPIs for WP2 since patients and health professionals will be directly involved in designing the app, which will ensure end-user

satisfaction. The focus groups will help WP3 achieve their KPIs, since BOC will be able through focus groups, to validate their QKPIs and map the different care pathways at the clinical sites and at EU level. The KPIs set for WP5 will benefit from the co-creation sessions, since the NASSS-CAT method will be applied throughout and help the analysis of the successes and failures. This deliverable will help reach the following KPIs set for WP6 by organizing the co-creation sessions in accordance to the requirements set in the KPIs.

2. Focus Groups coordination

2.1. Overview

2.1.1. Objectives and expected results

Objectives of focus groups

End user experience is paramount to the GERONTE project, because end users are at the core of both the new care pathways and the app we are endeavouring to create. Therefore, a co-design approach of the GERONTE application was deemed the most appropriate method of conception. The GERONTE project approach to co-design took place through co-creation sessions, especially Focus Groups at the stage of the conception and build of the app. Focus Groups were chosen because they allow for direct feedback from end-users and for targeted topics of focus in order to better adapt the project to the needs and expectations of its stakeholders. Those two aspects of the co-design approach were deemed most important by the GERONTE partner in order to build an app that is both useful and usable.

The focus groups and co-creation sessions were expected to allow partners to identify stakeholder needs and expectations towards the project and the app, as well as allow for a ranking of priorities for stakeholders, in order to best discern end-user requirements. Through focus groups and based on a first proposal of content by health professionals involved in the project (WP1) participants focused on questions regarding the information content of the app, whether it be general content or specific to a cancer type or comorbidity type.

Participants were also focusing on the technical aspects of the app, and were able to take part in the orientation of the design, through discussions around ICT use, behaviour and habits, needs and expectations, functionality prioritisation, functionalities of other apps and trends. Focus groups were to allow for a flow of information to directly feed the build and design of the app, just as the focus groups happen. Therefore, if elements previously expected to be or not be included in the app are identified, appropriate decisions towards either app content or design, can be made to maximise potential app use.

Focus group process reflection

Given the importance of the Focus groups in GERONTE, the methodology and coordination strategy are essential to the success of the overall project. E-Seniors as the lead of WP6 and with substantial experience in focus group organisation and moderation was in charge of the elaboration of the methodology and coordination.

In order to get the best results for all partners involved, they were consulted and collaborated throughout the elaboration of the strategy and methodology and they were able to give input according to their experience, needs and expectations. Regular meetings with partners either individually or in working groups were organised and regular updates on the deliverables were sent to the partners involved in the focus groups, for review and input.

Concerning the decision-making process regarding the role of these focus groups, it should be noted that the partners followed what had been foreseen during the preparation of the project, and with

reference to the Grant Agreement. Indeed, the Focus Groups were not intended for statistical purposes, but rather to allow each of the partners involved to collect data in order to best contribute to the co-creation of the tool. Indeed, as was foreseen by all partners when the project was drafted, Focus Groups are part of the mixed methods used for approaches and measures to evaluate the quality of care for people with multimorbidity. These methods are quantitative (Real World Data – RWD, eHR, questionnaire, PROMs and Patient-Related Experience Measures – PREMs) and qualitative (Focus Group, interviews, Delphi, observations). The Focus Groups with older people, patients and caregivers will therefore be fundamental for the identification of patients' expectations and priorities, and will be launched to list expectations of seniors and codesign guidelines, as part of the WP1 and WP6 tasks.

These Focus Groups were however discussed during preparatory workshops, internal to the WP6 partners, in order to work on the methodology of the co-creation sessions. These internal workshops consisted of short preparatory discussion sessions with the partners involved, which allowed to discuss and harmonise the methods that would be used for the Focus Groups, and to prepare a timeline for the preparation of the Focus Groups.

The technical partner, MyPL's input was particularly essential to the creation of the methodology and coordination strategy for focus groups, in order to take in consideration their specific technical needs and constraints, especially given the importance of their work on the outcome of the overall project. DIAK, DCU and UBx have all collaborated closely with E-Seniors to add input of experienced medical researchers and medical professionals, in terms of methodology but also ethical considerations.

Where possible, a harmonisation of focus groups involved in the co-design of the app, in regards to content, timeline and target groups, was decided. Such harmonisation would benefit both the build of the app and possible use of the data for potential academic publications from partners. Partners endeavored, when possible, to align the topics and questions of their focus groups during preparatory workshops in months 4 and 5.

Focus groups involved in the co-design of the app were conducted in three countries, France, Ireland and the Netherlands, by E-Seniors and Ubx for France, DCU for Ireland and DIAK for the Netherlands. Another type of focus groups will be conducted by BOC, the goal of this specific focus group is to validate the QKPIs identified by BOC.

BOC and MyPL will collaborate differently than other partners on the co-design of the GERONTE app. MyPL will have access to the list of topics in focus in BOC's sessions, and will be allowed to request results they think relevant to the build of the app. BOC may also organise focus groups for the specific purpose of helping in the co-design of the app.

For focus groups led by ESE, UBx, DCU and DIAK, stakeholders were identified in collaboration between all partners, according to the patient profile identified for the GERONTE project and the list of health professionals established in WP1. Inclusion and Exclusion criteria were decided on according to the constraints and needs of the project and partners professional input, in order to maximise results and avoid risks.

The partners decided on having specific focus groups categories of stakeholders, in order to get the best feedback possible and avoid bias and intimidation within the focus groups. For example, focus groups for health professionals were divided between clinicians and nurses and other health professionals, to ensure that no one category overpowers the others because of hierarchy or professional authority of any kind. Focus groups were organised in small groups of 5 people for patients and caregivers and health professionals and 10 people for the focus group session gathering

all categories of end-users. But where such focus group organisation was impossible either for health concerns, time concerns or explicit wishes of the participant, then one on one interviews were conducted as an alternative to focus groups. This allowed for flexibility regarding changing COVID-19 guidelines and the participants' various circumstances.
Additional to focus group sessions and in order to best co-design the GERONTE app, some of the participants from each category took part in one-on-one sessions, mostly ideation sessions for the technical partner to identify features to include or exclude from the app. After those one-on-one sessions, the technical partner worked on a prototype to study during the next focus group session. At the end of the focus group period for the co-design of the app (M10), a survey was sent to all participants to get one last round of feedback on the app before beta testing. The surveys represent one last chance for participants to be heard as freely as possible, as they are not moderated. The survey involved among other formats, open ended questions, multiple choices or opinion scales.
For focus groups led by BOC, the stakeholders and inclusion and exclusion criteria were identified by BOC, based on the needs and requirements of the project, on the work conducted by DIAK under WP1 (namely for the definition of the healthcare professionals to be involved in the analysis of the care pathway) as well as similar past experiences. For focus group related to the definition of the QKPIs for the assessment of multimorbidity (Task 3.4) and for the definition of new care pathways (Task 5.5) p atient associations were identified as stakeholder instead of patients directly because they facilitate the research process and avoid ethics concerns, as well as maximise representation of overall health care experience.

2.1.2. Expected results

The GERONTE care pathway is the general expected result. It is about redesigning the entire care pathway, the way in which we communicate with patients about their preferences for treatment and outcomes, the way that health care professionals involved in caring for older adults with multimorbidity and cancer communicate with each other and how we care for the patients during the subsequent oncologic treatment trajectory and follow-up. The applications are made to support this, and thus are an essential component.

The questions that we wanted to discuss with the focus groups are not just about the co-design of the app, but also about how they experienced their care process, how they feel that they could be given a more central role within their own care trajectory etc. While WP3 is mapping out the current patient journey, WP1 is about designing the future patient journey and what is needed to optimize that process.

The expected results of the focus groups are three-fold: the co-design of the GERONTE app, the validation of the QPKIs identified in the WP3 and the mapping of the patient's journey within the clinical site.
The co-design approach of the app aims to identify end-users' requirements, expectations and risks as well as to directly feed the build the GERONTE app with direct end-user feedback. By holding focus groups with the different types of end-users, we expected to be able to co-create a tool that they would use if not daily, then regularly in their healthcare journey.

We expected to be able to identify specific ICT requirements for maximized use, overall ICT experience and preferences to cater to targeted demographics, content required for health team use, limits/constraints of content access for health management. We also expected to be able to identify risks for drop in app use based on the collection of data on healthcare experiences, workload, emotional burden and overall habits in terms of ICT. Based on risk identification, we expected to be able to anticipate said risks and build features in the app to avoid such drop in use and therefore successfully maximize use of the app over time.

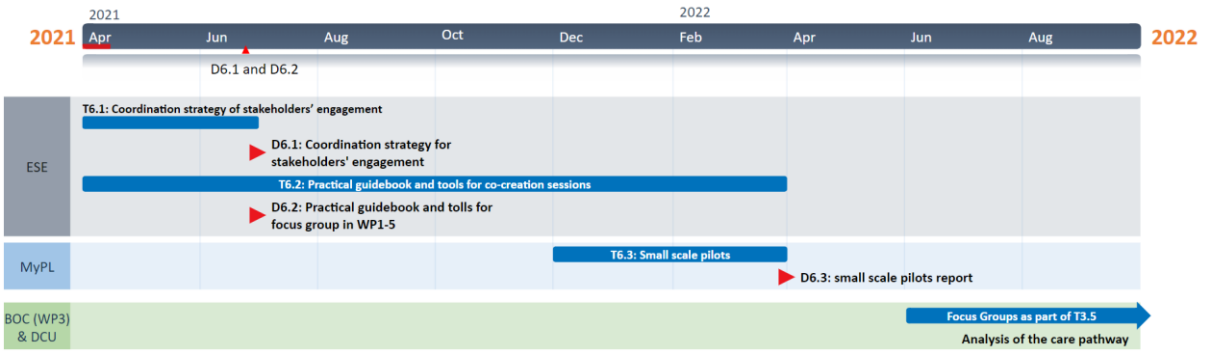
In terms of the validation of the QKPIs, we expect that the stakeholders involved in the focus groups will be able to give feedback and input of the QKPIs identified in WP3, in order to either refine them or validate them. We expect that the patient associations' wide experience will provide a wider representation of healthcare systems overall than individual patients and therefore, provide better and more reliable data.
BOC is also involved in mapping the patient journeys within each clinical site, through focus groups with experts from each sites. We expect that we will be able to map the patient's journey within the clinical sites thanks to the expertise and insights collected from clinical sites, through identifying the professionals involved, the coordination of the care process and the activities, the care settings and the sequence of activities.

2.2. Role of the partners

E-Seniors as lead of WP6 is in charge of the coordination of the focus groups and their methodology. E-Seniors provided support and guidelines for the moderation of the focus groups, as well as coordinated the data between the host partners and the technical partner. E-Seniors was also in charge of the focus groups for healthy seniors in France, and moderated these focus groups themselves, as well as provided the data to the technical partner. E-Seniors also assisted UBx in the organization of their focus groups.
MyPL as the technical partner provided partners with lists of questions before the focus groups according to their sprint timeline and the focus group timeline. Each partner agreed to translate these lists before the focus groups when required. MyPL acted as a facilitator in the focus groups within the limits of their budget, in the event that MyPL could not act as facilitator, they attended the sessions virtually and were a simple spectator. In that event the facilitator would be a staff member of the partner organization. Given the need for feedback involved in the build of the app, all partners agreed to provide MyPL the data as soon as possible after each focus group session.
The partners recorded the focus group sessions and used tools to transcribe and translate the results, in order to gather feedback and transfer it as efficiently and as quickly as possible to MyPL.
UBx decided to organize focus groups with patients, caregivers and health professionals in France, on their own budget.
DCU also decided to organize focus with patients, caregivers and health professionals, on their own budget, they organized these focus groups in Ireland. They hired a full time PHD student to work on the project.
DIAK organized focus groups with patients and caregivers in the Netherlands. They did not hold focus groups with health professionals according to the focus group timeline, but instead organized two expert meetings. Those meetings still followed the moderation guidelines created in this WP.

BOC organized focus groups with experts from the clinical sites to map the patient journey from June until December 2022 and will organize focus group later on until the end of the project with three types of participants, patient associations representatives, experts both from the clinical sites involved in the project and at the EU-Level and clinical site participants such as health system experts, in order to validate the QKPIs they have identified in WP3. . These focus groups are organized by BOC on their own budget and will be conducted online or in person depending on the specific objective of the focus group. More details and information on the focus groups organised by BOC are in the Deliverables related to WP3, T3.5.

2.3. Timeline for the first year



2.4. Stakeholders involved

Because of the multi-focus of the app, several categories and sub-categories of stakeholders have been identified for focus group involvement. As they are all end-users of the app, they all should be involved in its co-design, in order to increase end-user representation and maximize use for each category of stakeholders.

The first category to have been identified were the **health professionals**. This category was identified on the base of the list established in WP1. That list identified all of the health professionals that should be involved in the clinical trials. It was decided by partners that the stakeholders identified by this list should also be represented in the focus groups, since stakeholders of the clinical trials and end-users of the app overlap.
After identifying all health professionals, partners agreed that for better end-user representation and therefore, better feedback for the app and overall results, sub-categories should be created.

Within health professionals, the first sub-category to have been identified were **oncologists and medical professionals** directly involved in cancer treatment. They represent a sub-category because of their unique knowledge and experience when it comes to cancer patients and treatment. The focus group session involving them as a specific category, focused on their end-user requirement specifically as cancer specialists, in terms of content, but also workload, ICT use and expectations of the app.

A second subcategory to be identified were **comorbidity specialists**, they were singled out as a category because they have a different experience with cancer patients than oncologists and their team. The focus group session involving them as a specific category, focused on their end-user requirement specifically as comorbidity specialists, in terms of content, but also workload, ICT use and expectations of the app.

A third subcategory of health professionals to be identified were **nurses**. They were identified specifically because they have a vastly different experience with cancer patients, than that of doctors. It was also decided to separate them from doctors, to avoid bias and problems with overpowering due to hierarchy or academic degrees. It was deemed essential to collect their unfettered feedback due to the importance of their work in the project and their significant workload. Nurses were deemed at a higher risk of dropout from both the project and app use, because of their workload and limited time. It is therefore essential that we get their feedback in order to create an app that is useful to them and doesn't add to their work, but facilitates it.

A fourth and final subcategory of health professionals regrouped **all health professionals that are involved in cancer patient care but not directly involved in the direct treatment** of either their cancer or their comorbidities. That category includes but isn't limited to, nutritionists, psychologists, and members of palliative care networks.

The second category of stakeholders identified is **patients**, they are to be the center of the new GERONTE health care pathways, and important end-users of the app.
The inclusion criteria for patient involvement in the focus groups was decided on the basis of the patient inclusion criteria of the clinical trials identified in WP1, in order to best identify their specific needs and requirements. The inclusion and exclusion criteria are detailed in the D6.2, section 3.d.
But all patients were older cancer patients with comorbidities, the latter defined as a patient with cancer and at least one other serious condition. When possible, the recruitment favored the specific four cancer profiles identified in the GERONTE project, lung, breast, colorectal and prostate cancer, since they are the topic of the clinical trials, but other types of cancers aren't an exclusion criterion.

The third category of end-users to be identified is **caregivers**. This category involves both formal and informal caregivers, without distinction, though consideration of the caregiver status were brought up during certain focus groups, in terms of workload and emotional load. The inclusion and exclusion criteria partners have agreed upon are details in D6.2, section 3.d. The criteria for caregivers is wider than that of patients because their age and background isn't specifically targeted in the project, only criteria of importance is their experience as a caregiver to an older multimorbid cancer patient. Partners were free to involve caregivers in the patient focus groups or keep them separate, caregivers were included in all of the common stakeholders focus group sessions.

The fourth category of stakeholders is **healthy seniors**. They were identified as stakeholders because their feedback gives a broader representation of senior ICT use in healthcare independent of health status. Their input was mostly required through one-on-one sessions, which was deemed best by the technical partner.

The fifth and last category of stakeholders identified for focus groups led by BOC,are : **patient associations, experts at EU and clinical site level and members of the clinical site**. These categories of stakeholders have been identified, because of their experience in patient representation or treatment, their wide knowledge of cancer patient experience, patient treatment, comorbidity patient experience and specific healthcare systems. They are instrumental in the validation of the QKPIs identified in WP3 and in the definition of new care pathway and heathcare models for the management of older multimorbid patients as part of Task 5.5 and its related D5.6.

3. Expert Panels

DIAK, within the frame of WP1, has organized expert panels involving health professionals. They took place from the months of April to August and were divided in four rounds, each lasting four weeks. DIAK has recruited 39 participants of different backgrounds in geriatric medicine or involved in cancer treatment for the four cancer types included in GERONTE (breast, prostate, lung and colorectal cancer), with a mean age of 47 and a mean of 17 years in clinical practice, for their panels. Among those 39 participants, 41% are males and 59% are females, 33 are physicians, 4 are nurses and the last 3 participants are from other health professions.
In a series of monthly surveys, these experts have been asked to provide their input on what comorbidities and aspects of intrinsic capacity are essential to include in the new GERONTE care pathway, on what patient profiles can be made, grouping patients that require similar care and decision making and on what to monitor in this group of patients at home using a self-monitoring application. They also gathered input on what health care professionals should be involved.

Suggested planning for the four rounds of the expert panels (M3):

The first round will consist of the following questions:
How important are the from literature-selected comorbidities or geriatric impairments in older patients with cancer (when making a treatment decision and for changing the care trajectory) 1-not important, 4-very important.
Non-essential multimorbidities and impairments will be excluded. DIAK will also ask their participants if they think certain impairments/ comorbidities are missing.

In the second round DIAK will introduce different patient profiles, based on the answers of the first round. DIAK will ask questions to find out if participants agree on the profiles, consider the profiles relevant and to learn why they are relevant per treatment modality. DIAK will also address what participants feel that is currently the biggest challenge in caring for older persons that both have cancer and comorbidity.

The third round will be used to further specify what exact information is needed from the selected comorbidities to determine the severity, which was mentioned in the previous rounds to be necessary. Besides that, participants will be asked what symptoms they would like to have self- monitored by patients at home in between their consultations, to serve as an indicator of functional decline, destabilization of comorbidity or adverse events. And participants will be asked whether these symptoms should be monitored continuously or only during active treatment and if they should be monitored in all patients or only in a group with a specific treatment- or cancer type.

In the fourth round DIAK will further examine the different aspects and the frequency of monitoring. And they will gather input on which healthcare professionals should be involved per profile.

After the fourth and last round of the expert panels, DIAK will gather and study the results of the expert panels. DIAK will then organize two expert meetings involving health professionals, in September and October, in order to review and finalize the results and gather feedback from experts.

Overview of the implementation and results of the expert panels

A panel of experts was established, including medical specialists, nurses and other health care professionals with a background in geriatric medicine or involved in cancer treatment for the four cancer types included in GerOnTe (breast, prostate, lung and colorectal cancer). DIAK aimed to include a full range of involved specialists, from different European, with variation in the degree of current involvement in geriatric oncology care as well as years in practice, and a representative gender ratio.

In a series of monthly surveys, these experts were asked to provide their input on the relevance of various comorbidities, and intrinsic capacity/frailty items for decision-making and care for each of these cancer types and the treatment modalities that are available for them. They also provided input on the multimorbidity profiles, composition of the health care professional consortium, as well as symptom monitoring and self-management (described elsewhere). Answers from each survey round were subsequently compiled, compared with findings from the literature reviews, and taken forward to the next survey for further fine-tuning. The questions addressed in each round are shown in Annexe 4 of the D1.1. As the questions pertained specifically to the development of the Geronte care pathway, we could not make use of pre-existing questionnaires. Thus, for each round we included those questions necessary to take the next step in the development of the care pathway, building on the input that was provided in previous rounds, or gathered through other sources as described throughout this deliverable.

Each round included between 32 and 40 participants across a range of different backgrounds (doctors, nurses) and a range of specialties (medical oncology, surgery, radiotherapy, pulmonology, urology, geriatrics, general practice). Respondents were from the following countries: Netherlands, France, Belgium, Norway, Italy, Denmark, Germany, Hungary, Cyprus, United Kingdom. Mean age was 47 years and respondents had a mean of 17 years in clinical practice. Detailed data on the composition of the expert panel in Round 1 can be found in Annexe 5 of the D1.1.

At the end of four survey rounds, an online meeting was planned with a selection of the expert panel – ensuring input from each relevant background, gender and specialty – to demonstrate how their input had been incorporated into the GerOnTe care pathway and Holis GV dashboard. The feedback they provided was included in the next steps of the development. Minutes of this meeting, which took place on 22-9-2021, can be found in Annexe 6 of the D1.1.

Table of the demographic data of the expert panel (also accessible in the Annexe 5 of the D1.1)

	n=	%

Male	16	41%
Mean age	47 years	
Years in clinical practice	17.1 years	
Profession		
Nurse	4	10%
Physician	33	85%
Other (research)	3	8%
Speciality		
Surgery	8	21%
Medical oncology	12	30%
Primary care	3	8%
Geriatrics	9	23%
Other hospital-based specialist /organ specialist	4	10%
Other specialty...	9	23%
Cancer type involved with*		
Breast cancer	9	23%
Colorectal cancer	13	33%
Lung cancer	7	18%
Prostate cancer	8	21%
All cancer types	12	31%
Which treatments do you provide to patients yourself?*		
Surgery	12	31%
Radiation therapy	5	13%
Chemotherapy	14	36%
Targeted and/or immune therapy	14	36%
Hormone therapy	14	36%
None	9	23%
Other, namely	7	18%

* multiple answers per participant possible
Total 39 respondents, anonymised, ROUND 1.

With each round of the survey, the experts received a summary of the input that was given in the previous round and then the survey was built from that. In this way, the panellists were informed about the evolution.

Further information on the Expert Panels is available in Deliverable 1.1.

4. Small-scale pilots coordination

The small-scale pilots aim to test the final prototype of the GERONTE app, with end-users in a real-world environment, in order to track the possible difficulties in usage of the technology before launching the large-scale pilots.

The small-scale pilots will also aim to validate the WP1 study questionnaires with the target users, a s well as evaluate the tool for possible gender bias, in order to rectify such potential bias by reaching a better understanding of sex differences in reporting symptoms with the GERONTE app.

MyPL, as the technical partner responsible for the development of the app, will specifically gather data on end-user impressions of the app, install time and experience, possible technical or logistical issues, and how to effectively avoid these issues.

The small-scale pilots will involve a small group of 3 to 4 older people, in France, Belgium and the Netherlands and will take place at the seniors' home environment from M9 to M12.

MyPL lead of this task, is in charge of the GERONTE app development and will provide all necessary technical support and provide the system prototypes and tablets for the testers. ESE will implement the piloting in France with UBx. DIAK and KUL will liaise with the Netherlands and Belgium respectively regarding the local implementation of the small-scale pilots in those two countries.

These pilots will be pre and post evaluated and all issues that could impact the clinical trial phase will be reported to the consortium.

MyPL as lead of this task and with the support of UBx will plan the implementation of the small-scale pilots in the three countries, based on results from the co-creation sessions. MyPL will liaise with E-Seniors in order to update the D6.1 at M9 regarding the strategy and coordination of the small-scale pilots. MyPL is also responsible for the deliverable linked to this task, which is the D6.3, the small-scale pilot report.

Update at M10:

This section has been updated with the information contained in D6.2. You can find more information about the coordination of small-scale pilots in D6.2, section 8.

4.1 Update on the Partners' involvement

MyPL's Product Management, Quality Management, and User Experience teams are the Stakeholders in Beta Testing and they closely monitor each and every move of the phase.

University of Bordeaux (UBx, France), E-Seniors (ESE, France), Diakonessenhuis (DIAK, The Netherlands), KUL (Belgium) will hire and liaise between MyPL and participants for better conduct of the beta testing.

MyPL as task leader will organize the work between the partners, coordinate the drafting of the protocol, its implementation, check that the timetable and content are respected, draft the minutes of the working meetings, ensure that they are validated by all the participating partners, and draft the final report to the commission (D6.3). In return, the partners involved undertake to respond to the task leader within a reasonable timeframe and according to the deadlines set, as well as to respect the commitments made regarding implementation. MyPL will lead this task and provide devices as well as any technical support the partners might need. A number of tablets have been provided by MyPL to FG partners; they will be reallocated to small-scale pilots at the end of the co-design phase ending at M9. MyPL will provide explanatory medium and materials at the direction of small-scale pilot participants so that they may understand the project and the small-scale pilot process. MyPL is working on the first version of feedback to ask the users. These feedbacks will evolve all along the pilot. MyPL is working on fake patient profiles for small scale pilots in France, DIAK agreed to review for medical accuracy. Also, MyPL is to draft the first version of the small-scale pilots and share it with DIAK & KUL.

DIAK and KUL will respectively liaise MyPL with participants in the Netherlands and Belgium. E-Seniors will liaise MyPL with senior participants while Bergonié will liaise MyPL with APN and HPC participants in France.

In France according to the proposal ESE will recruit up to 5 healthy seniors to test the app in their home environment. During the pilots with healthy seniors, no medical nor personal data will be collected as participants will be provided with the scenarios to fulfill and their account will be set up with email accounts provided by MyPL, unrelated to their personal data. They will be asked to input symptoms according to the provided profile everyday for the duration of the pilots. However, participants will be asked about their feedback regarding the usability of different features of the patient application. The feedback will be collected anonymously by ESE who will liaise with MyPL.

It was also decided that Bergonié in Bordeaux (France) would test the decision making dashboard and HPC dashboard with at least one APN and one HPC member. As this will give the most complete overview of the HOLIS platform possible. DIAK and KUL will also test the platform with at least one APN and one HPC member but KUL will not be conducting pilots with seniors.

DIAK (the Netherlands) & KUL (Belgium) approach of small-scale pilots will be different from the one adopted by UBx. DIAK will conduct the pilot with real patients. Accounts will be created for these patients to ensure anonymity of data reported by patients. Hence, allowing us to have accurate feedback from our target users.

KUL will test the Holis dashboards with their APN(s) and Geriatrician(s) without testing the patient app.

It was decided that DIAK would test the patient app on their patient's hardware (desktop, digital tablets or phone) depending on patient preference, with real patients to allow for insightful feedback that relates directly to the reality of their condition. Patients will input their real medical symptoms but anonymity is ensured by the use of fake profiles containing virtual personal data, therefore obscuring the link between symptom and real person.

○ 4.2 Update on the Targeted participants

End users (Healthy seniors, Patients, APNs and HPC members) who will actually use the HOLIS GV products are the Participants.

Targeted participants of the GERONTE small-scale pilots are seniors over the age of 70 and APNs and HPC members linked to the Institute Bergonié for France, to DIAK for the Netherlands and to KUL for Belgium.

The participation of senior citizens (healthy seniors and patients) will allow us to:

- Test the whole HOLIS ecosystem. Indeed, the three applications are connected. For example, the 3 applications are connected:
    - The APN will trigger the creation of the patient's account through its application as well as that of the caregiver
    - The APN will set up the phone numbers that the patient should call in case of emergency and that the patient will find on his application
    - Depending on the treatment indicated by the APN on its application, a reporting system for the patient will be set up in the patient application (patients undergoing chemotherapy treatment will have different symptoms to report than those of a patient undergoing radiotherapy treatment)
- Test the usability of the application and get feedback on the functionalities. These requests will be made directly on the application or the patient will have a pop up asking for feedback. The content of these pop ups may change throughout the pilot. Frome will be as shown in the following slide.

In the same way as for the patients, the participation of the APNs and HPC members will allow us to:

- Test the entire HOLIS ecosystem.
    - Test the process of creating the patient profile, geriatric assessment, representation of the data on the dashboard.
    - The most important part is to test that the symptoms reported by the patients are well reported on the IPA dashboard.
- Test the usability of the application and get feedback on functionalities.
    - In the same way as with patients, these tests will allow us to get feedback from users.

Inclusion criteria for seniors

- Age: 70 years old or older
- Health/mental capacities: frailty scale = 0 is requested
- Technological skills: Willingness to interact with necessary equipment (tablet)

Exclusion criteria for seniors

- Age: under 70 years old
- Mental capacities: suffering from cognitive impairments or ailments preventing the use of a tablet on a regular basis.
- Health: frailty scale = <1 to be excluded
- Technological skills: Technophobe

4.3 Update on the recruitment procedure

E-Seniors (France)

Building on its existing database of active senior volunteers, E-Seniors will recruit up to 5 healthy seniors in France (Parisian region) to take part in the small-scale pilots, by asking for volunteers in their network and reaching out to senior's clubs and cancer patient associations. In case of drop out E-Seniors will recruit other participants to take part in the pilots. They will pick up the profile started by the previous participant and will be briefed individually on the app and pilot process.

E-Seniors will recruit through different channels like E-Seniors' mailing list, social networks pages (Facebook, LinkedIn, Twitter, Instagram), monthly newsletter. E-Seniors will also discuss with trainees during our weekly training in Paris. E-Seniors will also contact seniors who were involved in the co-creation process to propose further participation.

The GERONTE project will be presented to them and, for those who wish to participate, ESE will present the pilots' methodology.

When recruiting healthy senior volunteers, ESE will try to interest as many senior women as senior men in the GERONTE project, so that the results of the pilots are as accurate and real as possible. The gender dimension will thus be taken into account.

UBx (France)

UBx will recruit with the support of the Bergonié center, at least one nurse and one HPC member in order to test the usability of the HOLIS dashboard intended for medical professionals.

The participants will be recruited among the Bergonié staff or UBx and Bergonié's network of medical professionals, and will participate on a voluntary basis.

The GERONTE project will be presented to them and the appropriate documentation for participation will be prepared and explained to them before signature by UBx.

KUL (Belgium)

KUL will lead small scale pilots with APNs and Geriatricians.

They will recruit at least one APN and one HPC member among their staff on the basis of volunteering, in order to test the HOLIS dashboard intended for medical professionals.

Staff will be testing the dashboard on their work devices, no equipment will be provided to them by MyPL other than the HOLIS product.

DIAK (The Netherlands)

DIAK will lead small scale pilots with three types of participants, patients, nurses and geriatricians.

- Patients:

DIAK will aim to recruit 5 patients.

Patients already involved in the project at the co-creation stage will be reached out to again, and other patients will be recruited through the dissemination of flyers.

Patients will use the application in their own hardware (Desktop, digital tablet, or smartphone), but if they do not possess the appropriate digital equipment, MyPL is prepared to provide a tablet compatible with the app for the duration of the pilots.

- Medical professionals:

DIAK will recruit at least one APN and one HPC member in order to test the usability of the HOLIS dashboard intended for medical professionals. The participants will be recruited among the Diak staff on the basis of volunteering.

Staff will be testing the dashboard on their work devices, no equipment will be provided to them by MyPL other than the HOLIS product.

4.4 Update on the Small-scale pilots process

To implement this task, MyPL is adopting the "Dual Track Agile" methodology. Hence product development is split into two parallel tracks:

Discovery track where we adopt the following process:

- First interviews with end-users: in order to understand the users' mental models, pain points and how comfortable the seniors are with using apps on phones and digital tablets. This step has been conducted in the GERONTE project with ESE and WP1.
- User testing sessions: during which, we test the prototype being built and iterate till we have validated – with the end users- features. User testing has been conducted by DIAK, ESE and DCU
- Validation sessions: Daily design review meetings have been held with WP1 in order to hone the product and test prototypes.

Delivery track where we develop features that have been validated by users and agreed upon with WP6 partners and the GERONTE consortium.

Therefore, small-scale pilots in this case will be considered as a beta testing phase that will allow us to identify problems we haven't anticipated, fix bugs that may occur, and do some fine tuning.

The small-scale pilots will allow us to assess the interaction of end users with the application in its real environment.

MyPL will test the application with only minimum information required for the process that is "Cancer type" (as the symptoms asked to be reported depend on that information).

4.5 Update on the methodology of the feedback and analysis

During the pilots, users – patients, healthy seniors, APNs and Geriatricians- will be prompted to answer specific questions regarding specific features:

Feedback will be gathered via the Hotjar tool:

The feedback will be displayed in pop ups formats as depicted below.

The list of feedback will be prepared by MyPL with WP1 and will evolve along the pilots as we will implement solutions to bugs or usability issues that may arise.

Example of feedback asked:

- On a scale of 1 to 10 how would you rate your experience?
- On a scale of 1 to 10 how likely are you to recommend the HOLIS application?
- On a scale of 1 to 5 How useful is the "notification system" to you?
- On a scale of 1 to 10 how user friendly would you rate this feature?
- Tell us about your experience.

This feedback will allow us to assess some features, analyze the results and act accordingly.

5. Ethics and risks assessment

5.1. Data Protection

To be defined with the GERONTE Ethics and Data Manager.
We must be completely sure of the legal and ethical compliance before we put it in writing for the open access. This is the object of the data management plan and the ethics management plan (WP8). We will produce a second version updating on this aspect when legal and ethical obligations have been verified and validated by the coordinator (UBx).
Personal data collection, storage and use will be assessed for compliance with legal and ethical standards at national and European level depending on the focus group host prior to the sessions, including the production and validation of an informed consent form for the participants.

Update at M10:

Following the Ethics Management Plan (WP8), what was decided by the Ethics and Data Manager for the "Other research activities involving non-sensitive personal data collection or processing (WP1, WP3, WP5, WP6, WP7)", article 3.2.2, is the following:
"All research activities requiring stakeholder's engagement whether health seniors, onco-geriatric patients or health care professionals, as well as activities encouraging external communication to the general public and dissemination to stakeholders of the GERONTE outputs, require collection and

processing of minimal non-sensitive personal data that enable interested parties to be contacted (e.g. email, phone number, or postal address). Collection and processing of such data will be performed strictly in compliance with GDPR, 2018 and according to usual institutional practices of the Beneficiary of the linked third party designated as data controller."
All activities carried out in WP6 therefore followed this process of data collection and processing.

5.2. Risk assessment matrix

Risk assessment - GERONTE WP6 coordination strategy

Risk = impact X likehood					
Likehood	*Impact*				
	Incidental (1)	Minor (2)	Serious (3)	Major (4)	Catastrophic (5)
Frequent (5)	5	10	15	20	25
Occasional (4)	4	8	12	16	20
Seldom (3)	3	6	9	12	15
Remote (2)	2	4	6	8	10
Unlikely (1)	1	2	3	4	5

Risk	Impact	Likehood	Risk	Mitigation measure
Changes in the partnership	2	1	2	Effective coordination and cooperation inside the partnership is ensured by the managerial structure and through the project work plan. The coordinator has extensive experience in coordinating large EU and national projects and managing the arrival of new partners in the project. In case of unforeseen events, other experienced persons among the partners specific tasks until the work with the new partners can be re-distributed.
Internal conflicts within the consortium	4	1	4	A comprehensive Consortium Agreement will be formulated by all partners. The coordinator will follow strict administrative guidelines and implement actions against partners failing to comply with procedures agreed upon in the CA. The coordinator will maintain an easily searchable record of all relevant correspondence among partners to aid the coordinator in resolving conflicts. The coordinator has

				experience in conflict management in European Projects. All partners have a track record of solving emergent problems in a collegial spirit.
Difficulties with the budget	2	1	2	The project proposal was thoroughly thought to provide an appropriate budget to each task and partner to achieve the project plan. Partners have the opportunity to discuss these issues freely with the coordinator at monthly meetings, for supervising the appropriate development of the project. The coordinator keeps regular communication with partners to discuss any potential financial barrier and tackle it as soon as possible. If a financial need arises in WP6, the issue will eventually be raised at a PSC meeting, and technical or financial support within the project may be proposed by the other partners.
Difficulties in carrying out activities	2	1	2	The partners will be in frequent contact to ensure that the activities are going well and to help other partners to prepare their activities if necessary. Activities will be organised in advance, during preparatory meetings, and partners can refer to D6.2 which will present the procedure for organising the different activities.
Irrelevant results	4	1	4	The results will be reviewed by all partners internally, and discussed at each stage to confirm their relevance or not. This frequent review and possible discussion with all members of the consortium should ensure the relevance of the results, or correct their trajectory if necessary.
Different styles of work	4	1	4	If the working styles are far too different, and this affects the quality of the work on the WP6, Partners are aware that the coordinator is available at any time for any complaint or dissatisfaction with the working plan in order to find solutions that can be

				discussed in extraordinary meetings by using video conference. Partners can also express and discuss their concerns to find appropriate solutions in General Assembly meetings.
Different working rhythm	4	1	4	The partners are required to inform the WP6 task leaders of their availability and working time in case of difficulties on their side. This should allow all partners to develop a work plan, updated in frequent meetings on WP6 tasks. The partners will complete this work plan by frequent email exchanges and reminders if necessary.
Excessive bureaucracy or in contrast neglect for formal requirements and documenting obligations	2	1	2	The partners are used to working in projects with particular bureaucratic demands and are able to adapt to different needs in terms of formal requirements. The different changes and demands will be monitored by the task leaders and if necessary by the coordinator, in order to be able to react to the specific needs.
Ignorance as regards to the customs of a different country	1	1	1	Each of the partners is composed of or works with specialists in medical issues, who can easily inform the consortium about the customs of the different countries involved in the project. These issues will be discussed as necessary within the consortium.
Improper distance in official relationships	1	1	1	Each of the partners is composed of partners who are used to interacting in a formal setting and who know how to interact in this kind of situation. The partners are also made up of medical professionals who are used to interacting with patients and can explain to others how to interact with such stakeholders. All problematic situations will be reported to the coordinator, who will answer them.
Misconceptions about mutual expectations of the partners at the	3	1	3	The early stages of the project will be subject to frequent and extensive discussions to ensure that mutual expectations are set that suit everyone.

commencement stage of the project				These discussions will be held with all the partners involved and the conclusions will be presented to all of them to ensure that all the project partners agree on the project's direction.
Distrust-fullness of the partners resulting in unwillingness to share know-how with others	2	1	2	Each of the partners is used to participating in national or European projects, where the principle of exchange is paramount. Each of the partners understands the importance of sharing their know-how with the others, or will be ready to adapt to different situations. This issue will also be discussed within the consortium if necessary.
Failure to safeguard the principle of mutual benefits for all partners in the consortium	2	2	4	The coordinator and WP leader will monitor the progress of the activities of the WP6 tasks, and will ensure at all stages that the principle of mutual benefit is respected for all partners in the consortium. If a breach is found, the partner will be able to raise the issue with the coordinator for discussion at a Consortium Board meeting.
Different understandings of the same concepts	3	1	3	All partners will make sure to discuss the different concepts of the tasks related to WP6 and its different activities in advance. This discussion will be repeated during the early stages of the project, to ensure that all partners have the same understanding of the same concepts, and can be repeated at other meetings if necessary.
Default of a partner on their obligations, including failure to perform tasks or untimely performance of tasks	5	2	10	The coordinator and WP leader will monitor the progress in all areas of the project closely against the project plan, goals, objectives, requirements, and quality standards of deliverables. Regular checks and WP and technical meetings will be held to ensure all partners are clear on the progress and targets. The coordinator or WP leader will call for an emergency meeting in order to re-establish the terms of the consortium agreement.

Lack of partner's personnel commitment to project implementation	4	2	8	The WP6 tasks leaders will keep track of deadlines and send reminders to partners through regular communication. If a partner does not meet a deadline, the leaders will inform the PO to explain the reasons for the delay and ask for an extension if needed. They will send a reminder to the partner and ask for a meeting with the partner if necessary, to propose mitigation measures. If the partner does not react, the coordinator will convene the Project Management Board in a video conference, where the case will be discussed and decided upon.
Country differences regarding legal procedures and organisational structures	4	1	4	All country differences will have to be taken into account during the preparation of the different activities, through a review of the different legal and ethical procedures existing in each country. If problematic differences arise, these will be resolved internally with the relevant stakeholders, and with the support of the consortium members.
Not addressing the needs and requirements of relevant stakeholders	4	1	4	At all stages of the activities, the partners will ensure that feedback from relevant stakeholders is taken into account, by asking for frequent feedback, which will then be considered by the partners. This feedback will be discussed jointly with the WP6 partners, if necessary, to review its relevance and ensure that it is taken into account where appropriate.

5.3. Gender considerations

GERONTE co-creation sessions hosts will analyse the eventual differences in gendered behaviour, regarding gender cancers (for instance breast cancer or prostate cancer). The impact on the end users will be also analysed considering the gender perspective. To ensure that the results of the project will benefit both genders equally, we will aim for an equal distribution in our datasets. While implementing

the AI of the GERONTE app tool solutions a particular care will be taken to ensure that the algorithms remain explainable, ethical, and free of gender (or any other) bias.

On a more general basis, GERONTE is a project that keeps at its core the UN SDGs Agenda 2030. With regard to gender balance, we have considered the following goal SDG 5- Gender equality; achieve gender equality and empower all women and girls. The gender angle will be a key element in the implementation of the focus groups and also in the target communication for the outreach for the app users, with the support of all partners and advisory board members.

Update at M10

As for KUL, gender equality was not taken into account when selecting suitable candidates to participate in the small-scale pilots. Health care professionals were asked to participate in the small-scale pilots based on their involvement in the GerOnTe project when the GerOnTe TWOBE clinical trial will start. Groups of participants were not homogeneous.

As for ESE, an effort was made to ensure the gender balanced approach to avoid any sex related bias. Initially, three women and two men were recruited to participate in the small-scale pilots. Eventually, one of the male participants had to urgently cancel his participation which led to certain deviations explained in detail in Deliverable 6.2.

As for DIAK, they aimed to recruit patients in a representative gender ratio. They conducted focus group meetings in which the challenges faced by older patients with cancer would be discussed as well as questions relating to the Holis GV application under development. For this purpose, they recruited non-frail or pre-frail patients aged ≥ 70 years, diagnosed with cancer (breast, lung, colorectal, prostate) in an early stage, in complete remission or in partial remission for at least 6 months; and with at least one additional comorbid condition. They were excluded if they had cognitive impairment impacting their participation, depressed mood or anxiety issues. Additionally, DIAK set out to recruit informal caregivers for these patients.

Demographics patients and caregivers for DIAK

	Country	Age	Gender	Cancer type
Patient 1	NL	85	Male	Colorectal cancer, stage IV
Patient 2	NL	78	Male	Prostate cancer, stage IV
Patient 3	NL	76	Male	Prostate cancer, stage I
Patient 4	NL	79	Female	Breast cancer, stage IV
Patient 5	NL	90	Female	Lung cancer, stage IV
Patient 6	IRE	76	Female	Colorectal cancer, stage IV
Patient 7	IRE	70	Male	Colorectal cancer, early stage
Patient 8	IRE	87	Male	Prostate cancer, stage unknown
Patient 9	IRE	85	Female	Colorectal cancer, stage IV
			Relation	
Caregiver 1	NL	70 +	Spouse	Prostate cancer, early stage
Caregiver 2	NL	70 +	Spouse	Prostate cancer, stage IV
Caregiver 3	NL	70 +	Spouse	Prostate cancer, stage unknown

As for DCU, and in regard with the co-design part of the focus groups, they actively sought to ensure and support gender equality and representation in the patient and health professionals.
For the patient, tests were conducted with slightly more females than males (6 females, 5 males).
For health professionals as a group, the focus groups were conducted with 26 females and 20 males, which is likely due to the high number of females working across the different health professions.

Demographics patients, caregivers and health professionals for DCU

Type of interview Focus group (FG) or individual interview			**Total number of participants**	**Total number of patient**		**Total number of family members**	**Total number of nurses**			**Total number of medical doctors (oncologists, geriatricians)**		**Total number of**				
FG HP*	Indivi-ual HP*	Indiviv-idual patient/ family		Female	Male		Cancer nurse	Comm-Unity (non-cancer)	Nurse for Older adult care	Consultant	Non-consultant	Phar-macist	Physio-therapists	Nutri-tionist	Occupational therapist	Social worker
5	11	10	46 (26 females)	5	4	1 (male)	9	3	4	7	3	3	2	2	1	2
				In person 4 Zoom 2 Phone 3												
*HP Health professionals																

6. Follow-up and dissemination

The consortium valued the participation of participants in co-creation sessions and other focus groups by keeping them informed, through newsletters, workshops, social networks, etc.
We also disseminated and exploited focus groups and co-creation sessions results after the first year.

Stakeholders' engagement is the forte of Work Package 7 (Communication, dissemination and exploitation). In particular, WP7 is facilitating the engagement of its EU-wide network for the benefit of the early phase works of WP6 and thereby maximising its message and purpose. In this regard, WP7 has made its EU based network available to WP6 to be invited as per the required expertise: Cancer specialists, Comorbidity specialists, Nurses, Other health professionals. The selected experts have been invited from the WP7 network to establish the different co-creation sessions within WP6 namely: focus groups, Delphi panels, NASSS-CAT questionnaires and small-scale pilots. WP7 will also be involved in key stakeholder meetings to garner interest for expanding the messages resulting from the ongoing works of WP6. Lastly, WP7 will continue to support the stakeholder engagement process by inviting its EU experts to planning meetings and requesting data and other assistance as needed by WP6.

7. Conclusion

The coordination strategy for stakeholder engagement was discussed and agreed for and by the GERONTE consortium partners involved in the co-creation sessions of the GERONTE app and in the other focus groups organised within the project.

As some aspects of this coordination require more time, in particular the establishment of an ethical framework in line with local and European data protection regulations, this deliverable has been updated at M10, and may be updated at M24 and M48 .
At M10, the ethics requirements were added, in link with the Ethics Management Plan prepared by GERONTE's Ethics and Data Manager and reviewed and accepted by E-Seniors, the project coordinator and the other partners involved. The small-scale pilots methodology was also updated, as well as the gender considerations section and the overview of the implementation and results of the expert panels.

Furthermore, throughout the process of setting up the co-creation sessions, E-Seniors and the consortium partners involved will ensure that they remain flexible in order to place the users' requirements at the center of their concerns and strategy. Above all, the opinion and availability of the participants will be taken into account.
Therefore, the focus group and pilot hosts will place great emphasis on regular communication between the partners, general coordination with the project coordinator, and feedback from the participants.

8. Annexes

8.1. Annex 1: Glossary:

General Focus Group terms:

Focus groups
Focus groups are facilitated, and usually recorded, conversations, involving small groups of participants, one moderator and one facilitator. Discussion topics will range from ICT use, design of the app, its content and usability, to the participants' overall understanding of and expectations from project and app. Focus groups can also in the case of our project contain usability tests of mockups or features

1 to 1 interviews
Individual discussion with a moderator, a technician and only one potential end user.

Small-scale pilots
Type of software testing that verifies a component of the system or the entire system under a real-time operating condition. The purpose of the pilot test is to evaluate the feasibility, time, cost, risk, and performance of the GerOnTe tool with patients, in a real environment. "Small-scale" induces that one patient at a time will be involved.

Expert panels
Expert panels/monthly questionnaires based on the delphi panel method, will take place in four rounds and aim to reach consensus on which comorbidities and which geriatric impairments will alter the treatment decision or the care trajectory and are therefore relevant to know, gather and to share.

Questionnaires
Clinical and organisational Quality Key Performance Indicators (QKPIs) will then be defined, following a stepped approach and based on a structured consensus method (i.e. Delphi) bringing together experts from various clinical and organisational disciplines, to identify a short-list of professionals that should be involved and how they should communicate with one another within the GerOnTe model.

Moderator
The moderator's mission is to distribute the floor and channel the exchanges with benevolence and impartiality. He/she rules over the time allotted and distributes the floor fairly, in complete neutrality. As a true conductor of the focus group, he/she "moderates" tempers. To ensure that the debate is as fluid and interesting as possible, the moderator must intervene throughout the discussion, like a master of ceremonies. He or she must be calm and benevolent, but also neutral and firm. The smooth running of the debate rests essentially on his shoulders. In this respect, his or her greatest skill is undoubtedly diplomacy, to reframe the participants without offending them. If he/she must let the debaters express themselves, he/she must also be able to stop them. You also have to be able to set the pace and get the debate going again. There is nothing worse than a meeting that loses momentum

and intensity. The moderator will therefore have questions to get the conversation going again, concrete examples, and will try to bounce back on what is being said. A tip for this? Rephrase: "You mean that...", "You have just made an important point, can you say more? "etc.

Facilitator
The main function of the facilitator is to ensure that a meeting runs smoothly and achieves the desired objectives. As a multi-skilled person, he or she is able to take on several roles at once. The facilitator leads the meeting so that the participants stay awake and focused. He or she is also a mediator, ensuring communication between all the participants. To put them at ease and to ensure that the event runs smoothly, the facilitator also plays the role of architect. He or she is responsible for arranging the meeting room, preparing the table, adjusting the room's lighting, deciding where each participant should sit, etc.

Focus groups host
The host of a focus group is the GERONTE consortium partner who welcomes participants in a location predetermined by him/her, organizes the focus group in his/her country, recruits participants in his/her country, collects the results of the focus groups, transcribes them, translates them, and then passes them on to the technical partner who carries out the GERONTE app and to the other partners involved.

Technical terms:

Application
A computer program that is designed for a particular purpose.

Mobile Application
A mobile application or mobile app, is a computer program or software designed to run on a mobile device such as a phone, tablet, or watch.

Functionalities
Any or all of the operations performed by a piece of equipment or a software program.

Usability Test
Usability testing is a technique used in user-centered interaction design to evaluate a product by testing it on users.

Dashboard
Part of a device, a computer program, etc. that shows information and statistics (= numbers) about how the device, program, etc. is working, which you can use to control it.

End-User
The people that use or benefit from the end product of the project, in our case the web-based app and dashboard.

Mock-up

A plan of how a page of the dashboard or the app will look when it is finally created.

Layout
The way something is designed or arranged, in our case it concerns dashboard and app layout.

ICT
Information and communication technology.

Medical terms and positions:

Physicians
A medical doctor, especially one who has general skill and is not a surgeon.

Clinicians
A person qualified in the clinical practice of medicine, psychiatry, or psychology as distinguished from one specializing in laboratory or research techniques or in theory.

Oncologists
A doctor specialized in oncology, the branch of medicine concerned with the prevention, diagnosis, treatment, and study of cancer.

Cancer specialists
Cancer specialists include all medical specialists involved in cancer treatment, including but not limited to oncologists, radiotherapists, surgeons involved in cancer removal, urologists, pulmonologists.

Comorbidity specialists
Comorbidity specialists include all medical specialists involved in comorbidity treatment, including but not limited to endocrinologists, cardiologists, orthopedists and rheumatologists.

Paramedics
This category of health professionals gathers all professionals not included in the cancer or comorbidity specialists or nurses' categories, they include but aren't limited to, dieticians, physiotherapists, psychologists, occupational therapists or clinical pharmacists.

Advanced Practice Nurse
An advanced practice nurse who has additional education and training in how to diagnose and treat disease. Advanced practice nurses are licensed and certified by national nursing organizations. In cancer care, an advanced practice nurse may manage the primary care of patients and their families, based on a practice agreement with a doctor or system. Also called APN, NP, and nurse practitioner. This status does exist in all European countries.

Caregivers
In this project caregivers are caregivers of older multimorbid cancer patients. They provide daily or frequent care for the patients' needs whether medical or otherwise.

- **Formal caregivers:** Formal caregivers are paid for their services and have received training; this might be their profession or they might be a family member or a close one of the patient that has received training and is recognized officially as caring for the patient.
- **Informal caregivers:** An informal caregiver is usually a friend or a family member that cares for the patient without official status, pay or training.

Comorbidities

In this project comorbidity is defined as a patient with cancer presenting with at least one other serious disease.

Care Pathways

A clinical pathway is a multidisciplinary management tool based on evidence-based practice for a specific group of patients with a predictable clinical course, in which the different tasks (interventions) by the professionals involved in the patient care are defined, optimized and sequenced.

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