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

HORIZON 2020 PROGRAMME – TOPIC H2020-SC1-BHC-24-2020
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DELIVERABLE D6.2: Practical guidebook for the methodology of co-creation sessions

Lead Beneficiary: 6-ESE

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

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V3.0	**03/02/2023**	**Alice PERNOT [ESE]** **Alena BOGDANOVA [ESE]**	**Second submission of the D6.2 first update**

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1. Executive Summary

This deliverable describes the methodology for the co-creation sessions, as per reference to Description of the Action part A.

Deliverable work status

Deliverable	Completion status in %	Deviation	Data complete or to be updated
D6.2: Practical guidebook for the methodology of co-creation sessions	80%	Delivered at M3 and updated at M10 (one-month delay).	Updates planned at M24 and M48 following the small-scale pilots and the clinical trials.
Associated Deliverables	D6.1 - Coordination strategy for stakeholders' engagement D6.1 and D6.2 are deeply interconnected, since D6.1 presents the strategy tested in task and deliverable 6.2.		
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 consists of a guidebook which provides practical and detailed information on the conduction, moderation, analysis, reporting and synthesis across the focus groups and sites. This document also included the necessary support tools for the participants (information documents, informed consent, presentations). It specifies the following aspects for the Focus Groups: project presentation, Focus Group objective presentation, guideline for leading Focus Group discussions as well as recommendations for collecting users' feedback during the Focus Groups.
The second version of this deliverable, which was submitted at M10, presented the updates on focus groups results and small-scale pilots' methodology. It focused on co-creation sessions results from France, the Netherlands and Ireland, in which participants expressed their general interest in the platform, and highlighted points for improvement of the tool that they felt were very important, and on a small-scale pilots' methodology including guidelines for pilots' hosts (the Netherlands (DIAK), Belgium (KUL) and France (ESE and Institut Bergonié)). All partners involved in the small-scale pilots collaborated on the elaboration of this methodology and agreed to follow it.

This deliverable is connected to D6.1, since D6.1 presents the strategy tested in task and deliverable 6.2. This deliverable will be updated at M24, (March 2023) with information regarding the small-scale pilots results, and with link to the future clinical trials, and at M48 (March 2024 - end of the project) with some updates linked with the impact assessment.

The deliverable is associated to the specific objective O2 "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 O6 "Ensure proper engagement of all stakeholders (notably older patients and diversified caregivers) by co-designing the GerOnTe method" in its entirety. D6.2 presents a guidebook to best organise the organisation 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 80% as described in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218. The WP6 partners will update the D6.2 at M24 (March 2023) with information regarding the small-scale

pilots results, and with link to the future clinical trials, and at M48 (March 2024 - end of the project) with some updates linked with the impact assessment.

Justification for delay in deliverable submission

At M3, 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.

At M10, the objectives related to this deliverable have been achieved as scheduled in Annex 1 (Description of the Action Part A) of the Grant Agreement N°945218. This deliverable was updated at M10, with one-month delay (M9 was planned) in regard with the organisation of the small-scale pilot studies that was caused by the small delays related to the development of the application, which delayed the envisioned timeline by one month. As a consequence, and due to added demands from GERONTE project partners the HOLIS GV platform with all its modules originally planned to be ready by the end of December 2021 (M9) has been delayed and has been finalized in February (M11). Hence, pilots will take place from the beginning of March (M12) to mid-April (M13), and delay the submission of the D6.3 by one month (M13 instead of M12).

Data associated

The data (i.e. proofs of the meetings and of the activities (Focus Groups, Small-scale pilots) 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 stakeholder's 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 will take place in France, Ireland, Italy and the Netherlands. They aim to identify: end-users' requirements, elements for maximum usability and best design of the interface or the app. Several Focus Groups involving the different end users' categories are proposed. Such Focus Groups will be held in different countries involved in the project, France, Ireland, Italy, and the Netherlands. Small-scale pilots will take place in France, the Netherlands and Belgium and will test the app with small groups of end-users to identify any possible issues and allow us to resolve them.

A guidebook for the Focus groups

This deliverable will detail the common methods and tools for organising the co-creation sessions about the GERONTE app creation in the framework of the technical WPs 1 to 5. This deliverable will be a guidebook to be addressed to the host to the Focus Group explaining moderation of the discussion, collection of the participants' feedback and how to report the users' feedback to the consortium for further implementation in the GERONTE system. This document will also include the necessary support tools for the participants (information documents, informed consent, presentations). It will specify the

following aspects for the Focus Groups: project presentation, Focus Group objective presentation, guideline for leading Focus Group discussions as well as recommendations for collecting users' feedback during the Focus Groups. The guidebook will be updated at M9, M24 and M48.

Focus groups will allow for a flow of information to directly feed the building and design of the app, just as the focus groups take place 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 will be involved in three ways, focus groups of 5 to 10 people, one-on-one ideation sessions and surveys. Focus group 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 and the mapping of the care journey. DIAK, DCU, UBx and ESE will organise co-design focus groups and sessions with stakeholders in their countries and BOC will organize focus groups with three types of participants, in order to validate their QKPIs and map the patient journeys within each clinical site. MyPL will act as a facilitator in the co-design focus groups when possible and will propose prototypes or mockups for the focus groups. Stakeholders were identified according to the work done in WP1 and have 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.

Ethics requirements

Precise and detailed ethics requirements will be defined with the GERONTE Ethics and Data Manager before the start of focus groups in M6.
The Ethics and Data Manager will ensure legal and ethical compliance before we put it in writing for open access. This is the topic of the data management plan and the ethics management plan (WP8). We can 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.

Attainment of the objectives and explanation of deviations

The objectives related to this deliverable have been achieved in full and 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.

1.1. Executive summary – FR

En Europe, le système de santé est conçu autour d'une approche patient mono-maladie, qui n'est pas adaptée à la prise en charge des patients multimorbides, et entraîne une détection et une gestion

inappropriées des symptômes, un sous- et surtraitement, et des coûts inutiles. Le projet GERONTE propose un nouveau modèle de soins basé sur une approche multi-centrée sur le patient. Le modèle GERONTE sera démontré dans le contexte de la prise en charge de patients multimorbides dont la morbidité dominante est le cancer, car la fréquence du cancer augmente chez les patients âgés, tout comme l'incidence de la comorbidité, ce qui accroît les résultats du projet. De plus, la gestion du cancer est déjà multidisciplinaire, ce qui minimisera les étapes nécessaires à un changement d'approche. Une fois validé, ce modèle sera applicable à toute autre combinaison de morbidités avec ou sans cancer, donnant au concept un potentiel majeur de généralisation à l'ensemble de la population âgée.
Pour atteindre son objectif, le consortium GERONTE est constitué de cinq hôpitaux et universités spécialisés en gériatrie et/ou oncologie de cinq pays européens différents (UBx, DIAK, OUS, UCD, KUL), de deux universités réputées dans les études socio-économiques des systèmes de santé (BOC, DCU), de deux experts en informatique de santé (MyPL, UCD) et de deux associations compétentes dans l'engagement des parties prenantes (SIOG, ESE). Le projet vise à faciliter l'accès et l'échange de données sur les patients pour les professionnels de la santé ainsi que pour les patients et leurs aidants naturels ; à regrouper tous les professionnels de la santé dans des parcours de coordination des soins individualisés axés sur les patients ; à développer un outil d'échange de données avec une interface destinée aux professionnels de la santé et une autre pour les patients et leurs aidants.
L'objectif du WP6 est de prévoir un engagement proactif des parties prenantes dans le projet et de fixer une stratégie pour les sessions de co-création. Les sessions de co-création auront lieu en France, en Irlande, en Italie et aux Pays-Bas. Elles ont pour but d'identifier les besoins des utilisateurs finaux, les éléments permettant une utilisation maximale et la meilleure conception de l'application. Plusieurs groupes de discussion impliquant les différentes catégories d'utilisateurs finaux sont proposés. Ces groupes de discussion seront organisés dans différents pays impliqués dans le projet, à savoir la France, l'Irlande, l'Italie et les Pays-Bas. Des pilotes à petite échelle auront lieu en France, aux Pays-Bas et en Belgique et testeront l'application avec de petits groupes d'utilisateurs finaux afin d'identifier tout problème éventuel et de nous permettre de le résoudre.
Ce livrable détaillera les méthodes et outils communs pour organiser les sessions de co-création sur la création de l'application GERONTE dans le cadre des WPs techniques 1 à 5. Ce livrable sera un guide à l'attention de l'hôte du groupe de discussion expliquant la modération de la discussion, la collecte des commentaires des participants et la manière de rapporter les commentaires des utilisateurs au consortium pour une implémentation ultérieure dans le système GerOnTe. Ce document comprendra également les outils de soutien nécessaires aux participants (documents d'information, consentement éclairé, présentations). Il spécifiera les aspects suivants pour les groupes de discussion : présentation du projet, présentation des objectifs du groupe de discussion, lignes directrices pour l'animation des discussions du groupe de discussion ainsi que des recommandations pour la collecte des commentaires des utilisateurs pendant les groupes de discussion. Le guide sera mis à jour à M9, M24 et M48.
Les groupes de discussion permettront un flux d'informations qui alimentera directement la construction et la conception de l'application, tout comme les groupes de discussion nous permettent d'identifier et de classer les priorités afin de mieux discerner les besoins des utilisateurs finaux, tant au niveau de la conception que du contenu de l'application. ESE est en charge de la méthodologie et de la coordination et tous les partenaires ont collaboré sur D6.1 et D6.2, lors de réunions et des mises à jour régulières ont été envoyées pour examen. Les partenaires ont décidé d'aligner les sujets et les questions de leurs groupes de discussion lors des ateliers des mois 4 et 5, afin d'en faire bénéficier la construction de l'application. Les parties prenantes seront impliquées de trois manières : groupes de discussion de 5 à 10 personnes, sessions d'idéation individuelles et enquêtes. Les sessions de groupes de discussion pourront être remplacées par des sessions individuelles à la demande des participants. Les résultats attendus des groupes de discussion sur la co-conception sont la collecte des commentaires des utilisateurs finaux pour alimenter l'application et anticiper les risques et les problèmes.
Les résultats attendus des groupes de discussion par BOC sont la validation des QKPIs et la cartographie du parcours de soins. DIAK, DCU, UBx et ESE organiseront des groupes de discussion et des sessions de

co-conception avec les parties prenantes dans leurs pays et BOC organisera des groupes de discussion avec trois types de participants, afin de valider leurs QKPI et de cartographier les parcours de soins dans chaque site clinique. MyPL agira en tant que facilitateur dans les groupes de discussion de co-conception lorsque cela sera possible et proposera des prototypes ou des maquettes pour les groupes de discussion. Les parties prenantes ont été identifiées en fonction du travail effectué dans le WP1 et ont été divisées en 7 catégories pour éviter les biais et maximiser les résultats : Spécialistes du cancer, spécialistes de la comorbidité, infirmières, autres professionnels de la santé, patients, soignants et personnes âgées en bonne santé. Les parties prenantes pour les groupes de discussion du BOC ont été identifiées comme étant des associations de patients, des experts et des membres de sites cliniques ; ils seront impliqués dans les sessions des groupes de discussion.
Les exigences éthiques précises et détaillées seront définies avec le responsable de l'éthique et des données de GERONTE jusqu'au début des groupes de discussion dans M6. Le responsable de l'éthique et des données s'assurera de la conformité légale et éthique avant de la mettre par écrit pour le libre accès. C'est le sujet du plan de gestion des données et du plan de gestion de l'éthique (WP8). Nous pourrons produire une deuxième version mettant à jour cet aspect lorsque les obligations légales et éthiques auront été vérifiées et validées par le coordinateur (UBx). La collecte, le stockage et l'utilisation des données personnelles seront évalués pour vérifier la conformité aux normes légales et éthiques au niveau national et européen selon l'hôte du groupe de discussion avant les sessions, y compris la production et la validation d'un formulaire de consentement éclairé pour les participants.

1.2. Executive summary – ND

In Europa is het gezondheidssysteem ontworpen rond een patiëntgerichte benadering, die niet aangepast is aan de zorg voor multimorbide patiënten, en resulteert in onaangepaste detectie en behandeling van symptomen, onder- en overbehandeling en onnodige kosten. Het GERONTE-project stelt een nieuw zorgmodel voor, gebaseerd op een patiëntgerichte benadering. Het GERONTE-model zal worden gedemonstreerd in de context van zorg voor multimorbide patiënten met kanker als een dominante morbiditeit, omdat de frequentie van kanker toeneemt bij oudere patiënten, evenals de incidentie van comorbiditeit, wat de resultaten van het project verhoogt. Kankerbehandeling is ook al multidisciplinair, wat de stappen die nodig zijn voor een verandering van aanpak tot een minimum zal beperken. Eenmaal gevalideerd, zal dit model toepasbaar zijn op elke andere combinatie van morbiditeiten met of zonder kanker, waardoor het concept een groot generalisatie potentieel krijgt voor de bredere oudere bevolking.
Om dit doel te bereiken bestaat het GERONTE-consortium uit vijf ziekenhuizen en universiteiten die gespecialiseerd zijn in geriatrie en/of oncologie uit vijf verschillende Europese landen (UBx, DIAK, OUS, UCD, KUL), twee universiteiten die bekend staan om hun sociaaleconomische studies van gezondheidssystemen (BOC, DCU), twee experts in gezondheidsinformatie (MyPL, UCD) en twee verenigingen die gespecialiseerd zijn in het betrekken van belanghebbenden (SIOG, ESE). Het project heeft tot doel de toegang tot en uitwisseling van patiëntengegevens te vergemakkelijken voor zowel gezondheidswerkers als patiënten en hun informele zorgverleners; alle gezondheidswerkers te hergroeperen in patiëntgerichte geïndividualiseerde zorgcoördinatie trajecten; een instrument voor gegevensuitwisseling te ontwikkelen met één interface voor gezondheidswerkers en een andere voor patiënten en hun zorgverleners.

Het doel van WP6 is om proactieve betrokkenheid van belanghebbenden bij het project te voorzien en een strategie voor de co-creatie sessies op te stellen. Co-creatie sessies zullen plaatsvinden in Frankrijk, Ierland, Italië en Nederland. Het doel van deze sessies is om de vereisten van de eindgebruikers, de elementen voor maximale bruikbaarheid en het beste ontwerp van de app te identificeren. Er worden verschillende focusgroepen voorgesteld met de verschillende categorieën eindgebruikers. Deze focusgroepen zullen worden gehouden in verschillende landen die bij het project betrokken zijn: Frankrijk, Ierland, Italië en Nederland. Kleinschalige pilots zullen plaatsvinden in Frankrijk, Nederland

en België en zullen de app testen met kleine groepen eindgebruikers om eventuele problemen te identificeren en ons in staat te stellen deze op te lossen.

Deze deliverable beschrijft de gemeenschappelijke methoden en instrumenten voor het organiseren van de co-creatie sessies over de GERONTE app in het kader van de technische WP's 1 tot 5. Deze deliverable zal een handleiding zijn voor de gastheer van de focusgroep met uitleg over de moderatie van de discussie, het verzamelen van de feedback van de deelnemers en hoe de feedback van de gebruikers te rapporteren aan het consortium voor verdere implementatie in het GerOnTe systeem. Dit document zal ook de nodige ondersteunende instrumenten voor de deelnemers bevatten (informatiedocumenten, geïnformeerde toestemming, presentaties). Het zal de volgende aspecten voor de focusgroepen specificeren: projectpresentatie, presentatie van de focusgroep doelstellingen, leidraad voor het leiden van focusgroepdiscussies en aanbevelingen voor het verzamelen van feedback van gebruikers tijdens de focusgroepen. De leidraad zal worden bijgewerkt op M9, M24 en M48.
Focusgroepen zullen een informatiestroom mogelijk maken die rechtstreeks de bouw en het ontwerp van de app zal voeden, net zoals de focusgroepen gebeuren door ons in staat te stellen prioriteiten te identificeren en te rangschikken om de vereisten van de eindgebruiker beter te onderscheiden, zowel wat het ontwerp als de inhoud van de app betreft. ESE is verantwoordelijk voor de methodologie en coördinatie en alle partners werkten samen aan D6.1 en D6.2, tijdens vergaderingen en regelmatige updates werden verstuurd ter beoordeling. De partners hebben besloten om de onderwerpen en vragen van hun focusgroepen op elkaar af te stemmen tijdens workshops in maand 4 en 5, ten voordele van de bouw van de app. Stakeholders zullen op drie manieren betrokken worden, focusgroepen van 5 tot 10 personen, één-op-één ideatie sessies en enquêtes. Op verzoek van de deelnemers kunnen focusgroep sessies worden vervangen door individuele sessies. Verwachte resultaten voor de co-design focusgroepen zijn het verzamelen van feedback van eindgebruikers om de app te voeden en om te anticiperen op risico's en problemen.
Verwachte resultaten van de focusgroepen door BOC zijn de validatie van de QKPI's en het in kaart brengen van het zorgtraject. DIAK, DCU, UBx en ESE zullen co-design focusgroepen en sessies organiseren met stakeholders in hun landen en BOC zal focusgroepen organiseren met drie soorten deelnemers, om hun QKPI's te valideren en de patient journeys binnen elke klinische site in kaart te brengen. MyPL zal waar mogelijk optreden als facilitator in de co-design focusgroepen en zal prototypes of mockups voorstellen voor de focusgroepen. De stakeholders werden geïdentificeerd op basis van het werk gedaan in WP1 en werden onderverdeeld in 7 categorieën om vooringenomenheid te vermijden en de resultaten te maximaliseren: Kankerspecialisten, Comorbiditeit Specialisten, Verpleegkundigen, Andere gezondheidswerkers, Patiënten, Zorgverleners en Gezonde Senioren. De stakeholders voor de focusgroepen van BOC werden geïdentificeerd als patiëntenverenigingen en -deskundigen en leden van klinische sites; zij zullen betrokken worden bij de focusgroep sessies.

Precieze en gedetailleerde ethische vereisten zullen worden bepaald met de GERONTE Ethiek- en Gegevensmanager tot de start van de focusgroepen in M6.
De ethiek- en gegevensmanager zal ervoor zorgen dat de wettelijke en ethische vereisten worden nageleefd voordat we het op schrift stellen voor open toegang. Dit is het onderwerp van het data management plan en het ethics management plan (WP8). We kunnen een tweede versie maken waarin dit aspect wordt bijgewerkt wanneer de wettelijke en ethische verplichtingen zijn geverifieerd en gevalideerd door de coördinator (UBx).
Het verzamelen, opslaan en gebruiken van persoonsgegevens zal voorafgaand aan de sessies worden getoetst op naleving van wettelijke en ethische normen op nationaal en europees niveau, afhankelijk van de focusgroep host, inclusief het opstellen en valideren van een informed consent formulier voor de deelnemers.

1.3. Executive summary – IT

In Europa il sistema sanitario è progettato sulle singole patologie – dunque poco adatto per la cura dei pazienti con multimorbidità – da qui derivano una gestione inappropriata dei sintomi, trattamenti insufficienti o eccessivi e costi evitabili. Il progetto GERONTE propone un nuovo modello di cura basato su un approccio incentrato sul paziente. Il modello GERONTE sarà testato su pazienti multimorbidi con il cancro come morbilità dominante, dal momento che l'incidenza del cancro aumenta nei pazienti più anziani in linea con l'incidenza delle comorbidità, aumentando così la significatività dei risultati del progetto. La presa in carico dei pazienti che soffrono di cancro, inoltre, segue già un approccio multidisciplinare, riducendo al minimo la necessità di introdurre cambiamenti radicali nel percorso di cura. Quando ne verrà validata l'efficacia, il modello GERONTE potrà essere replicato con qualsiasi altra combinazione di morbilità, che comprenda o meno il cancro, per cui le logiche sottostanti hanno un elevato potenziale di generalizzabilità con riferimento alla popolazione anziana in una prospettiva più ampia.

Per raggiungere i suoi obiettivi, il consorzio di GERONTE è costituito da cinque ospedali e università specializzati in geriatria e/o oncologia provenienti da cinque diversi Paesi europei (UBx, DIAK, OUS, UCD, KUL), due università rinomate per lo studio dei sistemi sanitari in una prospettiva socio-economica (BOC, DCU), due esperti in informatica applicata alla sanità (MyPL, UCD) e due associazioni specializzate nel coinvolgimento degli stakeholder (SIOG, ESE). Il progetto intende: i) facilitare l'accesso e lo scambio di informazioni relative ai pazienti tra diversi professionisti sanitari, così come tra i pazienti e i loro caregiver; ii) aggregare tutti i professionisti all'interno di un percorso di cura coordinato ed incentrato sui bisogni individuali dei pazienti; iii) sviluppare uno strumento di raccolta e scambio di informazioni con una duplice interfaccia, una rivolta ai professionisti sanitari e un'altra dedicata ai pazienti e ai loro caregiver.

Il WP6 è finalizzato a garantire il coinvolgimento proattivo dei diversi attori coinvolti nella progettualità e a definire una strategia per le sessioni di co-creazione. Le sessioni di co-creazione avranno luogo in Francia, Irlanda e Paesi Bassi e hanno lo scopo di identificare i requisiti degli utenti finali, gli elementi in grado di garantire massima fruibilità, nonché il miglior design dell'app. Si organizzeranno quindi diversi focus group con l'intento di ingaggiare diverse categorie di utenti finali. In particolare, questi focus group si terranno in diversi Paesi che partecipano al progetto, ovvero Francia, Irlanda e Paesi Bassi. Inoltre, verranno organizzati dei test pilota su piccola scala in Francia, Paesi Bassi e Belgio per testare l'app con gruppi ristretti di utenti finali, identificare eventuali problemi e risolverli in maniera tempestiva.

Questo deliverable dettaglierà le metodologie e gli strumenti più comuni da utilizzare per organizzare le sessioni di co-creazione strumentali allo sviluppo dell'app GERONTE nell'ambito dei WP da 1 a 5. Questo deliverable sarà una guida di cui gli organizzatori dei Focus Group dovranno tenere conto, che spiega come moderare la discussione, come raccogliere il punto di vista dei partecipanti e come riportare tali feedback al Consorzio affinché siano implementati nel sistema GERONTE. Questo documento includerà anche gli strumenti a supporto dei partecipanti (documenti informativi, consenso informato, presentazioni), specificando i seguenti aspetti: presentazione del progetto, presentazione dello scopo del Focus Group, linee guida per condurre il Focus Group, così come alcune raccomandazioni per raccogliere i feedback degli utenti durante gli incontri. Tale guida sarà aggiornata periodicamente, nei mesi M9, M24 e M48.

Il flusso di informazioni generate nei focus group alimenteranno direttamente la costruzione e la progettazione dell'app. Allo stesso modo, i focus group consentono di identificare e classificare le priorità per distinguere meglio le esigenze degli utenti finali, sia in termini di design sia di contenuto

dell'app. ESE è responsabile della metodologia e del coordinamento, mentre tutti i partner hanno contribuito ai deliverable D6.1 e D6.2 durante le riunioni e gli aggiornamenti periodici in cui si è proceduto alla revisione. I partner hanno deciso di allineare gli argomenti e le domande dei loro focus group durante i workshop organizzati nei mesi 4 e 5, a beneficio della costruzione dell'app. Gli stakeholder saranno coinvolti con tre possibili approcci: i) focus group da 5 a 10 persone; ii) sessioni di confronto individuale (one-to-one); iii) survey o questionari. I focus group potrebbero eventualmente essere sostituiti da sessioni individuali su richiesta dei partecipanti. I risultati attesi dai focus group finalizzati al co-design dell'app sono la raccolta di feedback degli utenti finali per alimentare l'app e anticipare rischi e criticità.

I risultati attesi dai focus group tenuti da BOC sono la validazione dei QKPI e la mappatura dei percorsi di cura. DIAK, DCU, UBx e ESE organizzeranno focus group e sessioni di co-design con le parti interessate nei loro Paesi e BOC organizzerà focus group con tre tipi di partecipanti al fine di convalidare i QKPI e mappare i percorsi dei pazienti all'interno di ogni struttura clinica . MyPL assumerà un ruolo di facilitatore nei focus group di co-design quando possibile e proporrà prototipi o mockup durante i focus group. Gli stakeholder sono stati identificati secondo il lavoro svolto nel WP1 e sono stati divisi in 7 categorie per evitare bias e massimizzare i risultati: oncologi, specialisti nelle principali comorbidità, infermieri, altri professionisti sanitari, pazienti, caregiver e anziani in buona salute. Gli stakeholder che saranno coinvolti nelle sessioni di focus group di BOC sono associazioni di pazienti, professionisti sanitari e varie organizzazioni attive a livello europeo ad es. società scientifiche.

I requisiti etici saranno definiti in modo preciso e dettagliato da parte dell'Ethics and Data Manager – ovvero un referente dedicato per GERONTE – prima dell'inizio dei focus group nel M6.

Tale responsabile assicurerà la conformità delle attività da un punto di vista legale ed etico prima di formalizzarle per iscritto e renderle accessibili al pubblico. Tale aspetto rientra nel piano di gestione dei dati e degli aspetti etici (WP8). Sarà quindi possibile produrre una seconda versione che aggiorna ed integra questi aspetti non appena gli obblighi legali ed etici saranno stati verificati e validati da parte di UBx nel suo ruolo di coordinatore delle attività.

Si effettuerà un assessment della raccolta, archiviazione ed uso dei dati personali secondo standard legali ed etici a livello nazionale ed europeo a seconda del focus group prima delle sessioni, compresa la stesura e validazione di un modulo di consenso informato per i partecipanti.

2. Introduction

2.1. GERONTE and its objectives

GERONTE is a 5-year research and innovation project (April 2021 to Mars 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

2.2. 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 to 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.

3. Preliminary points: GERONTE app co-design and other focus groups utility

3.1. Context of use

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 want 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.

E-Seniors, as leader of the Work Package 6 “Stakeholders’ engagement and ethical issues” will encourage a proactive engagement of stakeholders in the project beyond the validation and evaluation phase. This commitment will be implemented in co-creation sessions (focus groups and small-scale pilots) where the target users, older people and their carers, will be invited to discover the different elements of the GERONTE system and to express their requirements and expectations in this respect. Once the final GERONTE app prototype is ready, thanks to focus groups, small-scale pilots in real environments will be organised to test the usability of the system.

Focus groups are discussions or interviews, in small groups, between the focus group hosts, the technical partner and participants (who are GERONTE app potential end users), about their use and views on existing technological tools, their needs and expectations from the new care pathways and from the app, its content and its co-design.

Some of these focus groups will be replaced by or combined with individual interviews or surveys, either face-to-face, or by electronic means, and some will be group interviews, sometimes called focus groups, again, either face-to-face or by electronic means. If the people taking part agree through an informed consent form, these will be recorded and typed out (transcribed).

There will be 3 different types of focus groups, with:

- Université de Bordeaux, France (UBx) - within the framework of WP1 (T1.2)
- Stichting Diakonessenhuis, The Netherlands (DIAK) - within the framework of WP1 (T1.3)
- Dublin City University, Ireland (DCU) - within the framework of WP5 (T5.1)
- Università Commerciale Luigi Bocconi (BOC) - within the framework of WP3 (T3.4 and T3.5)
- E-Seniors, France (ESE) - within the framework of WP6 (T6.1)

Concerning the selection of the countries where the focus groups (and small-scale pilots) would be held, this choice was made prior to the project, during its creation, and with the partners who wished and had the means to organise such test phases. It should be noted that the purpose of having these specific countries (listed above) was also to co-create the Holis™ GV tool in the very countries where

it would be tested in clinical trials (France, Belgium and the Netherlands). This was to ensure that the tool would be tested and culturally adapted to the different countries where these clinical phases would take place, in order to ensure its best understanding and acceptance during the clinical trials.
For example, it was identified during the focus group phases that there were differences in the digitalisation of senior citizens, particularly between the Netherlands and France. France is indeed less digitalised, and these considerations were taken into account when creating Holis™ GV: the tool was made more accessible, more user-friendly and easy to handle and understand at first contact.
It should also be noted that DCU also conducted focus groups, although this was not originally foreseen in the project, as they wanted to test the methodology presented in the creation of the focus groups, in order to evaluate the relevance of their own actions in the project.

All focus groups were organised with the aim of co-creating the Holis™ GV tool, in order to ensure its accessibility and acceptance by the different testers in the different countries hosting clinical trials. The focus groups have no research purpose, and more specifically no purpose of collecting data, which could be used to establish statistics. This is why the choice of countries hosting the focus groups was based on the countries that would host the clinical trials.

The different types of focus groups are:

- **Within the framework of WP1:**
  - app co-design, to define the parameters and ergonomics of the GERONTE application
  - to define a dashboard of social and economic QKPIs (Quality Key Performance Indicators) for the management of multimorbid patients
  - to provide a literature review to inform the initial direction, involving international experts in geriatric oncology
- **Within the framework of WP3:**
  - app co-design, to define the parameters and ergonomics of the GERONTE application
  - to define a dashboard of social and economic QKPIs (Quality Key Performance Indicators) for the management of multimorbid patients
  - to map the patient journeys within the clinical trial sites while simultaneously highlighting specificities of different patient profiles due to multi-morbidities
- **Within the framework of WP5:**
  - app co-design, to define the parameters and ergonomics of the GERONTE application
  - to use the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS-CAT) framework to identify relevant constructs affecting the success, the failure, or the degree of implementation of the intervention in each site associated with effective implementation.
- **Within the framework of WP6:**
  - app co-design, to define the parameters and ergonomics of the GERONTE application

3.2. User's requirements for the GERONTE app co-design

Once those elements are identified, the technical team will try to identify the elements to include and exclude from the app before introducing mockups and gathering end-user feedback on these proposed

mockups. The introduction of mockups, ideas and prototypes will take place during focus groups through usability tests. These tests can take several forms, here are examples of some methods that might be used in the GERONTE focus groups:

- **Observational sessions:** End-users are given the studied feature or mockup to gather information on how they interact with it, detect issues in navigation or experience
- **5 second test:** consists of showing mockup to end users for five seconds, then asking questions, in order to gather information and metrics
- **Cognitive analysis:** Emotion-oriented question regarding visuals and interactions with the product, in order to gather information on how end-users feel about certain features
- **Satisfaction survey:** End-users are asked to rate features on usefulness, on a scale of 1 to 5

These tests allow for the evaluation of the co-design process and for the adaptation of the features if a need is detected. They will be conducted throughout the co-design process to ensure maximum use of the app.

The data collected in the GERONTE project in focus groups can be grouped in two main categories.

Participants in focus groups will give feedback on the app design, which includes:

- Baseline for the app's architecture
- Overall layout
- Color schemes
- Icons, icon placement, icon size
- Fonts, font size and placement
- Language and terminology used

Participants in focus groups will also give feedback on the functionalities, which includes:

- Notifications, alerts
- Amount of information available
- Amount of information end users have to provide
- Functionalities related to appointment management
- Functionalities related to health condition management
- Functionalities related to information management
- Functionalities related to user profile and settings
- Possible additional functionalities such as : advice of the day, activities etc

3.3. Focus groups co-design and development: MyPL approach

Based on product goals and requirements, GERONTE focus groups hosts (consortium partners) start with MyPL an iterative process of product design and development.

Adopted widely, the dual track agile methodology is a framework in product development that enables separating the effort to discover the problems to solve and their solutions from the effort of delivering working software. It consists of two tracks of activity: Discovery and Delivery. The main objective of the discovery track is to validate ideas of product quickly and efficiently while the purpose of the delivery track is to build, test and deploy production-ready code. So, in a nutshell, ideas are prototyped

in the discovery track and the results supply the delivery track. As shown in the figure 1, Discovery and Delivery tracks are repeated continuously through iterations that cover the product life.

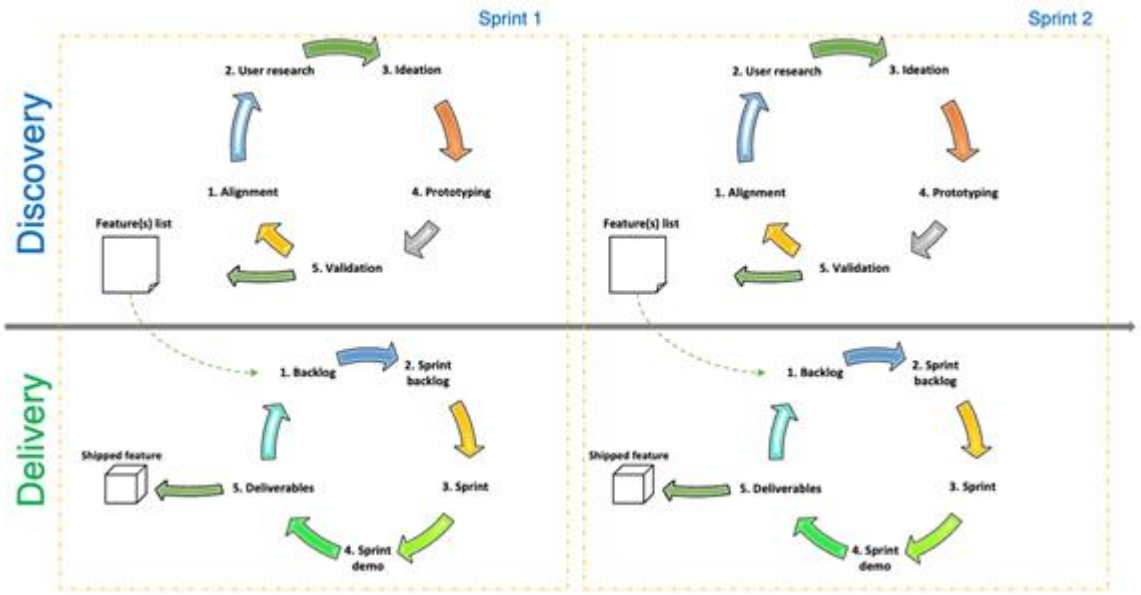


Figure 1: Dual track agile methodology

Discovery track

As a user-centric approach, the product discovery process has two distinct parts AKA spaces (as shown below).

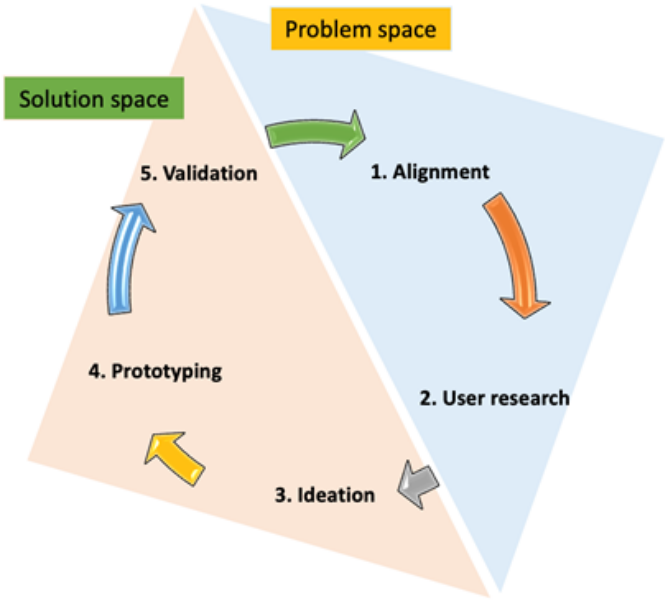


Figure 2 : Product discovery process

- **Problem space**: where the product team works on developing a profound understanding of users and their pain-points. Cultivating a deeper understanding of users helps product teams create products that customers want and need. The process enables the team to move beyond "nice to have" features towards building products that solve a problem and become a genuine necessity for the end users.
- **Solution space**: The product team will use the knowledge acquired from their interactions with the users – from the problem space- to build vital products that bring real value to the end-users.

Problem space

- **Alignment**

Where all stakeholders align over the outcome and the intent of the product or problems being solved. For the GERONTE project, the proposal document prevails. However, alignment sessions with involved WPs may be conducted if needed along the project.

- **User research**

The success of a given product ultimately depends on whether it can solve your user's pain points. So, our first step of building the GERONTE app will be understanding the struggles of our users.

- **Techniques for user research, validation, and prototyping**

The present part of the document will briefly describe methods that we may or may not be using depending on use cases along the project.

➔ ***Usability-Lab Studies***: participants are brought into a meeting room, one-on-one with a researcher, and given a set of scenarios that lead to tasks and usage of specific interest within a product.

➔ ***Field Studies:*** researchers meet with and study participants in their natural environment, - in hospitals for expert cases - where they would most likely encounter the product.

➔ ***Participatory Design***: participants are given design elements or creative materials in order to construct their ideal experience in a concrete way that expresses what matters to them most and why.

➔ ***Group studies***: groups of 3–12 participants are led through a discussion about a set of topics, giving verbal and written feedback through discussion and exercises.

➔ ***Interviews***: a researcher meets with participants one-on-one to discuss in depth what the participant thinks about the topic in question.

➔ ***Concept Testing***: a researcher shares an approximation of a product or service that captures the core of a new concept or product in order to determine if it meets the needs of the target audience; it can be done one-on-one or with larger numbers of participants, and either in person or online.

➔ ***User Feedback***: open-ended and/or close-ended information provided by a self-selected sample of users, often through a feedback link, button, form, or email.

➔ ***Desirability Studies***: participants are offered different visual-design alternatives and are expected to associate each alternative with a set of attributes selected from a closed list; these studies can be both qualitative and quantitative.

- ➔ ***Card Sorting***: a quantitative or qualitative method that asks users to organize items into groups and assign categories to each group. This method helps create or refine the information architecture of a site by exposing users' mental models.
- ➔ ***A/B Testing***: scientifically testing different designs on a site by randomly assigning groups of users to interact with each of the different designs and measuring the effect of these assignments on user behavior

3.4. Evaluation

Product designers perform usability tests to get users' feedback of the product. Product evaluation is a crucial step in product development which gives critical feedback of the product. MyPL will do so through small-scale pilots, which means bêta testing of the GERONTE app at the seniors' home environment, in order to track the possible difficulties in usage of the technology before launching the large-scale pilots.

In addition, these small-scale pilots will validate the WP1 study questionnaires (i.e. PROMs and PREMs, task 1.4) with the target users. Another goal is to "evaluate whether use of digital tools is gender-biased" and "understand sex differences in reporting symptoms with the GERONTE web-app and adapt criteria for intervention accordingly". These pilots enable us to address and evaluate this aspect. Pilots will be done with a small group of 3 to 4 older people, in France, Belgium and the Netherlands. 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, in charge of GERONTE app development, 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, KUL will liaise with the Netherlands and Belgium respectively.

4. Focus groups process overview

4.1. Targeted participants

Focus groups will involve 4 types of participants:

- Health professionals (physicians, specialists and oncologists, health care team for comorbidities, nurses, and other health professionals involved in the patient care pathway such as paramedics, psychologists, nutritionists, therapists, etc.)
- Patients (cancer profiles, comorbidities profiles, cancer gender profiles)
- Informal caregivers (family members or relatives or others, included in patient sessions or excluded from patient sessions)
- Healthy senior volunteers (non-frail and digitized seniors, who could also be or was informal caregivers)

These will take different amounts of time for different participants. Older people and informal caregivers, and health care staff will spend about between one hour and an hour and a half in total. This will usually be in one session, but can be scheduled to suit the needs of participants.

Participants will have the choice of engaging with a focus group, or an individual interview, as they prefer. Our experience is that some people prefer one or the other, and we can accommodate this.

4.2. Objectives

In order to co-design both the care pathways and the ICT tools in this project, through the use of Focus Groups we aim to:

- Gather feedback from end users on ICT use
- Gather feedback from end users on existing care pathways
- Gather feedback from end users on the design and build of the ICT tools developed in this project contemporaneously to its creation, in order to adapt it to end user requirements. End-user satisfaction is a crucial and necessary point to be proved before entering the market for the application's viability.

BOC, DIAK and DCU will be involved in focus groups to define the parameters and ergonomics of the GERONTE application, but not only.

BOC aims to define a dashboard of social and economic QKPIs (Quality Key Performance Indicators) for the management of multimorbid patients, by analysing care pathways according to the various phases of the care process: noticing the symptoms and first detection, assessment and diagnosis, treatment and care service definition, and service delivery and follow-up. This mapping activity will be done through multidisciplinary Focus Groups. MyPL will develop a clear graphic representation of the care pathways that can be added in the GERONTE app. The QKPIs will be detailed and linked to the various phases of the care pathway. BOC will do QKPIs assessment, but also co-designing of the app through their focus groups. MyPL will be involved in the co-design part.

DIAK will provide a literature review to inform the initial direction, and will be followed by a Delphi process which includes international experts in geriatric oncology. The output will be a core dataset of frailty data that can be used in the study. A parallel process will take place concerning patient preferences. This will begin with a literature review and progress to a Focus Group involving patients and their informal caregivers. This will inform the dataset for patient preferences that will be used, while assessing the presence of relevant gender differences.

DCU will use the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS-CAT) framework to identify relevant constructs affecting the success, the failure, or the degree of implementation of the intervention in each site associated with effective implementation. They will use focus groups to develop this process, building on the successful approach of Greenhalgh et al. DCU will work with project partners, clinicians, patients, carers, and other stakeholders, in a number of national or regional focus groups in Year 1, to co-create the structure and content of their logic model, the theory behind their realist evaluation, the tools, sources, methods, and approaches to be used to collect the necessary data, and an outline of the main constructs from CFIR expected to contribute to the implementation. All of this ensures a thorough and well-grounded process of evaluation, and serves to identify and bring necessary stakeholders on board in advance.

4.3. Focus groups hosts

The principal host will be responsible for the focus groups results quality control. Other researchers or partners involved must respect the activities duration specified in the protocol and report eventual problems.

Hosts for focus groups regarding app assessment are:

- Université de Bordeaux, France (UBx) - within the framework of WP1 (T1.2)
- Stichting Diakonessenhuis, The Netherlands (DIAK) - within the framework of WP1 (T1.3)
- Dublin City University, Ireland (DCU) - within the framework of WP5 (T5.1)
- Università Commerciale Luigi Bocconi (BOC) - within the framework of WP3 (T3.4 and T3.5)
- E-Seniors, France (ESE) - within the framework of WP6 (T6.1)

The Technical partner's involvement in the focus groups is essential to the collection of data, whenever possible MyPL will act as facilitator of the focus groups. When such participation is impossible the role will be filled by the host's own staff and MyPL will endeavor to attend the focus groups through virtual means, as a spectator.

4.4. Inclusion and exclusion criteria

Patients:

- **Inclusion Criteria:**
  - Age ≥ 70 years
  - Non-frail (Fried scale= 0) or Pre-frail (Fried scale = 1 or 2) condition
  - First stages of Cancer (1-2) or in complete remission or in partial remission for at least 6 months
  - Cancer types targeted in the overall project: Lung, Prostate, Breast, Colorectal
  - Multimorbid: defined as cancer plus at least one severe morbidity
  - Technology Acceptance

- **Exclusion Criteria**
  - Cognitive decline
  - Clinical unstable patients in the clinical judgment of the host
  - Terminal illness (life expectancy < 12 months)
  - Patients with a sensorial deficiency or with a certain level of motorial disability that, according to GERONTE partners, precludes the possibility to interact with GERONTE (i.e. deafness, blindness, paraplegia)
  - Subjects unwilling or unable to provide consent or unable to participate safely in the intervention program.
  - Patients with acute or uncontrolled psychiatric disease

Caregivers:

- **Inclusion Criteria:**
  - Age ≥ 18
  - Non-frail (Fried scale = 0)
  - Technology Acceptance
  - Caregiver to an older patient with Cancer and at least one comorbidity, regardless if patient is involved in the project or not

- **Exclusion Criteria:**
    - Subjects unwilling or unable to provide consent or unable to participate safely in the intervention program.
    - Caregiver with a sensorial deficiency or with a certain level of motorial disability that, according to GERONTE partners, precludes the possibility to interact with GERONTE (i.e. deafness, blindness, paraplegia)

Health Professionals:

- **Inclusion Criteria:**
    - Technology Acceptance
    - Practicing Health Professional dealing with patients with Cancer with comorbidities according to a list determined in WP1
    - Practicing in the healthcare centers identified and involved in the project

- **Exclusion Criteria:**
    - Subjects unwilling or unable to provide consent or unable to participate safely in the intervention program.

4.5. COVID-19 considerations

Due to the COVID-19 crisis, focus groups will be organised online via an online meeting tool such as Zoom, Microsoft Teams, Google Meet, etc. If the local situation allows it, focus groups could be organised face-to-face, in each partners' headquarters or in dedicated places.

Before participating in a face-to-face focus group, participants should have been vaccinated or have had a PCR test (with negative results) within the last 24 hours.

Participants should wear a new surgical mask (as a minimum) and have disinfected their hands.

The rooms provided for the participants should be cleaned, disinfected, and the moderators and facilitators should disinfect their hands and wear a surgical mask.

Hydro-alcoholic gel should be made available to participants, and a distance of one meter between each person should be respected. If this distance cannot be maintained due to the size of the premises, Plexiglas walls should be installed.

1 to 6 persons only should be present in the room of a face-to-face focus group.

5. Recruitment procedure

Recruitment will vary depending on the type of stakeholders and the partner acting as host. More participants than necessary will be recruited in order to ensure we reach the set minimum number of participants for focus groups throughout their duration. The set minimum is 5 participants for most focus groups, except for the focus group session common to all categories, for which the minimum is 10 participants.

5.1. Diakonessenhuis (DIAK, The Netherlands)

Patients and caregivers:

DIAK will recruit patients and caregivers through cancer patient associations and if available through caregiver associations. DIAK will list such associations and reach out to them in order to identify and recruit patients and caregivers to involve in the focus groups. DIAK will also place an advertisement in hospital clinics for participants, which will briefly explain the project and participant implication, as well as give directions on how to participate. DIAK will create a list of volunteers to participate in the project and select patients most relevant to take part in the focus groups according to the inclusion criteria. DIAK should keep the volunteer list in case of a drop in participants, for the duration of the focus groups.

5.2. E-Seniors (ESE, France)

Seniors:

E-Seniors has substantial experience in working with Seniors in a Focus Group setting, and has therefore, developed a streamlined process of recruitment and a network of Senior volunteers. The association will use this network to ask for volunteers for focus groups, through the use of the E-Seniors' mailing list, which goes out to past volunteers and participants of E-Seniors projects, and through the various E-Seniors social media platforms. E-Seniors will also present the project to trainees during our weekly training and workshops, especially to Seniors that meet the recruitment criteria set for the Focus Groups. A list of volunteers will then be established and the E-Seniors team will select volunteers according to the participation criteria. When volunteers have been selected, E-Seniors will ensure they sign the informed consent form and explain the project in more details before further involvement in the project. Volunteers who haven't been selected will be kept apprised of the project through the E-Seniors newsletter.

The procedure for identifying volunteers will be carried out by ESE with regards to project criteria: demographics (age, gender for equity, digitalization) and health situation (past and current) regarding cancer and comorbidities, experience as informal caregivers.
The procedure for recruiting volunteers will be carried out through ESE mailing list, social networks, ESE newsletter, discussion with ESE trainees during our weekly training, etc.
The focus groups will be one to one meeting, online meetings (via Zoom, Microsoft Teams or Google Meet) or face-to-face meetings at ESE headquarters.
The procedure for meeting ethics requirements (local and EC D9.1/D9.2) for ESE focus groups is the following:

- Following the FG protocol agreed by WP6 partners
- Informed consent form to be sent before the FG
- Anonymous identities to report the results
- No storage of personal or private data
- Approval from the CNIL before the start of FG
- Presence sheets to be signed by participants
- Other GDPR requirements is needed

5.3. Université de Bordeaux (UBx, France)

Patients:

UBx will endeavor to recruit patients both directly through health care centers involved in the project and through patient associations. UBx has experience with patient organizations and already has a network of partners among them. They will identify patient organizations working with the targeted type of patients and reach out to work with them in the recruitment of patients, through the sharing of a volunteer recruitment form. Such recruitment forms will explain the scope and goals of the project and the focus groups, and allow for participants to sign up. After signing up to volunteer, the patients will be contacted by UBx to ensure they meet the requirement for participation in the focus groups. UBx will select between 5 to 10 patients to take part in the focus groups, and keep a list of volunteers in case a participant wants to stop taking part in the focus groups. Patients who have not been selected to take part in the focus groups, will have the option to stay apprised of the advancement of the project, through a newsletter.

Caregivers:

UBx will recruit caregivers through patient organizations, since caregivers are often represented along patients in such organizations. The recruitment methods through patient organizations is the same as patient recruitment.

Cancer Specialists and Comorbidity specialists:

UBx has an existing network of specialists they have past work and research experience with. They will use their existing network to recruit appropriate specialists to involve in the focus groups. Either by directly reaching out to them, or through the distribution of a call for volunteers in email form.

UBx is also in charge of identifying and selecting the health care centers involved in the GERONTE project, and will endeavor to also recruit specialists in those centers, through the circulation of a volunteer sign up form, accompanied by a project pamphlet explaining the project.

5.4. Dublin City University (DCU, Ireland)

Patients and Caregivers:

DCU plans to involve patient organizations they have worked with in the past, such as the cancer association, to identify patients that meet the criteria for focus group involvement and who volunteer to participate. After identifying those patients, explaining the project and scope of the focus groups, as well as making them sign an informed consent form, DCU plans to conduct some individual interviews before starting with the Focus Groups. DCU plans to recruit caregivers through the same process as their patient recruitment, since caregivers are often represented alongside patients among these organizations. DCU also plans to recruit patients and caregivers through an advertisement placed

in hospital clinics. The advertisement will briefly explain the aim of GERONTE and the involvement of participants, as well as give contact information to participate in focus groups. DCU will create a list of volunteers to participate in the project and select patients most relevant to take part in the focus groups according to the inclusion criteria. DCU should keep the volunteer list in case of a drop in participants, for the duration of the focus groups.

Medical professionals:

DCU will recruit medical professionals in the eight centers associated with the project, which provide cancer care to older people. They will use their existing network to recruit relevant medical professionals to involve in the focus groups via personal invitation.

Nurses and other health care staff:

DCU will recruit Nurses and other health care staff in the hospital associated with the project, St. Vincent's University Hospital. The DCU team will identify relevant nurses and medical staff to involve in the focus groups and invite them personally to participate.

5.5. Bocconi University (BOC, Italy)

Patient associations:

Bocconi will not be involving patients directly because the goal of their focus groups is better served by involving patient organizations. Since their focus groups do not require direct feedback from end-users and patient organizations would guarantee a greater generalizability of the takeaways of the study as well as avoid the complexities typically faced in the ethical space when sensible information is processed.

Bocconi has past experiences in partnering and working with patient organizations and associations, especially in a focus group setting. Therefore, reaching out to the representatives that are already known from previous collaborations would further speed up the recruitment due to the established professional relationships, while also ensuring greater commitment to the study. Bocconi has therefore, built on past experiences to establish a preliminary list of associations involving patients, their family members and caregivers, that are active at the European level that could be invited to take part into the FGs. They will reach out to organizations on their list to start their recruitment process and involve the organizations that volunteer to take part in their focus groups and who best fit in the project.

Healthcare professionals from the Clinical site:

Regarding ealth system experts, physicians, healthcare professionals from the clinical sites, BOC will rely on the support of GERONTE partners coordinating each clinical site, to identify and recruit participants.

Organizations active at the European level

Regarding Clinical experts at the EU-Level, Bocconi will identify relevant participants from already established professional relationships and past collaborations and reach out through email or phone call to inquire about participation.

6. Focus groups organization

6.1. Logistics

Please make sure that focus groups are gender balanced, respect a diversity of age & a diversity of socio-professional categories among participants.

Requirements for organising focus groups:

- Each focus group will be led in each host **partner's language** (Dutch, English/Irish, French and Italian) or **English for** focus groups involving **international participants** (BOC)
- At least **1 moderator** (active participant)
- At least **1 facilitator** (passive participant)
- Ideal number of participants = **5 seniors, informal caregivers, patients or health professionals** (max up to 8), **10 participants** for the focus group involving all categories of participants (max up to 13)
- Advised duration = **1h for seniors, informal caregivers and patients** (max **2h for health professionals**)
- Participants should sign an **informed consent form** allowing the consortium to process the data generated during focus groups, with a time to explain the context of the form and a time to answer questions before signature
- Participants should sign an **attendance sheet** at the beginning of the focus group session

6.2. Moderation and facilitation

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.
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.

One moderator and one facilitator per focus group per country will lead the discussions. DIAK, ESE, DCU, BOC and UBx will involve one of their staff members to ensure these roles.
For the ESE focus group, the technical partner MyPL will be the moderator. MyPL will try to attend the UBx, DIAK and DCU focus groups. Should MyPL be unable to be physically present during the focus group sessions, they will endeavor to attend the sessions through virtual means as an observer. MyPL attendance is important to collect the specific results they need to develop the GERONTE app.
BOC will involve the moderator and facilitator of their choice. MyPL will be given access to the list of topics for the focus groups organized by BOC and will be allowed to request results if relevant to the co-design of the GERONTE app.

6.3. Suggested plan for app co-design focus groups

Workshops for the practical organization of the focus groups will be held between the partners involved in the focus groups, in the two-month preceding the start of the focus groups in September. In those workshops the partners will endeavor among other things to collaborate on the specific topics and questions raised during focus group sessions, as well as a harmonized plan for focus groups. The following suggested plan for focus group sessions is the fruit of preliminary discussions between the partners and is in its first iteration, this plan will be refined and finalized during the workshops. The final version of the suggested plan will be circulated by ESE to all partners with practical support media for the organization and moderation of the focus groups before the start of the focus groups.

Focus groups will be designed to fit the needs and goals of both the host partners and the technical partner. They will be divided into two types of content and the part by the technical partner will take one of two forms, ideation sessions or usability tests.

1. **Welcoming participants** (5 min)
2. **Presentation of the focus group and rules** (10 min)
3. **Host questions** (20 min - 30 min)

- Questions on expectations of the app and the project
- Questions on needs from the project
- Questions on understanding of the project

4. **Technical partner questions and techniques**

   a. **Ideation session** (30 min - 40 min)

- Open ended questions on technology habits, use and preference
- Sentence suggestions like “when I use my phone, I don’t understand why...”
- Sessions around images
- Co-design user journey maps
- Roleplay games

   b. **Usability test** (30 min - 40 min)

Usability tests aim to test and validate ideas and prototypes for the app, here are examples of some methods that might be used in the GERONTE focus groups:

- **Observational sessions:** End-users are given the studied feature or mockup to gather information on how they interact with it, detect issues in navigation or experience
- **5 second test:** consists of showing mockup to end users for five seconds, then asking questions, in order to gather information and metrics
- **Cognitive analysis:** Emotion-oriented question regarding visuals and interactions with the product, in order to gather information on how end-users feel about certain features
- **Satisfaction survey:** End-users are asked to rate features on usefulness, on a scale of 1 to 5

5. **Conclusion of the focus group** (10 min)

- Review the discussion that took place
- Highlight certain points to be sure to be aligned
- Thank participants
- Ask for feedback = satisfaction questionnaire
- Inform about future actions of the project = pilots, final app, clinical trials

This is a temporary plan for focus groups, a general basis. It would be discussed during summer working groups with partners, and then adapted in regards with types of participants:

- Hp participants
- Patient participants (shorter sessions)

And also in regards with different focus groups aims:

- FGs for app design (Ubx, ESE, DIAK, DCU, MyPL)
- FGs for QKPIs assessment (BOC, DIAK)
- FGs for NASSS (DCU)

Other recommandations:

- Make users feel comfortable and safe
- Do not interrupt the user
- Give each user an equal opportunity to speak and equal importance
- Be patient and repeat the question/information if needed

Take notes and record all interactions, verbal and non-verbal

6.4. Suggested plan for focus groups related to the WP1

Patients

- What is wrong with the current system? / What should change in the new trajectory?
- What do you think is currently the biggest challenge, when you have both cancer and other disease considering care?
- What do you think that we should improve in caring for patients that have both cancer and other diseases?
- What was the biggest challenge that you had during your trajectory so far? / What would help you to make the trajectory easier?

Information needs/patient preferences/shared decision making

- Were you asked about your preferences?
- Do you feel like your preferences were sufficiently included in the decision making?
- Are there things that you felt healthcare professionals did not have enough time for/ not enough attention for?
- What could be done to improve the shared decision-making process in older patients with cancer and multimorbidity?

Monitoring/symptoms

- What words do you think we should use asking all these symptoms? / Are there symptoms/ words that you would rather not hear/answer to?
- Are there symptoms that are missing?
- Ask about the gender differences in symptoms

Self-management

- What topics definitely require self-management recommendations so you can try some things yourself, before you need to get in contact with a doctor? e.g. lack of appetite, staying active
- Was there information on what you could do with a complaint yourself missing during your current treatment?

Adherence

- What would motivate you to fill it out daily? Reminder? Toffee? Having a streak?
- What would motivate you to follow through with life style recommendations?
- What has motivated you in the past?
- What are the biggest pitfalls in your opinion to keep doing the self-management recommendations?

Caregivers

Preferably separate from the patients. Especially in this group, caregivers are good (sometimes better than patients) in indicating what symptoms their family/friend/parent/partner has or what changes.

- Were you involved in decision making and what was your role? What could be improved?
- Did you receive the information that you needed?

Feasibility of their help in filling out the application

- Would you be able to fill it out?
- Do you know the “patient” symptoms well enough?
- Would you have been willing to fill it out daily?
- What is the biggest challenge in this patient group?
- What was your biggest struggle in the trajectory so far?

Other questions

- Are there topics of which you received information too late/ in which you felt that you could have used some tips and tricks earlier? /
- In which you had to do a lot of effort yourself to get information about? Were there symptoms that were dealt with too late, because you didn’t know what you could do yourself first?

6.5. Transcription and translation of focus groups results

Each partner will transcript and then translate results collected from recorded focus group sessions.

Then, the results regarding the app design will be transferred to the technical partner MyPL and processed to go to the next ideation step.

7. Ethics and risk management

7.1. Data management and 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 open access. This is the object of the data management plan and the ethics management plan (WP8). We can 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.

7.2. Consent from local authorities regarding GDPR and/or ethical committees' approval

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 open access. This is the object of the data management plan and the ethics management plan (WP8). We can 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.

7.3. Participants consent

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 open access. This is the object of the data management plan and the ethics management plan (WP8). We can 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.

7.4. Risk assessment matrix

Table 1 – Risk assessment matrix

Risk assessment - GerOnTe Focus groups

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/weaknesses of/to particular stakeholder	Impact	Likelihood	Risk	Mitigation actions
Patients, seniors				
Lack of engagement due to mismanagement of expectations or project involvement	1	1	1	We will develop and provide 'Plain Language Statements' to explain the project and requirement for participation to patients and seniors. We will also support the written information with verbal or visual information (conversation and or presentation). At the start and end of each FG/ interview), we will need to provide opportunity for questions at relevant points (including before agreement to participate. Finally, we will ensure that all interviewer are trained in the GerOnTe co-design method (thanks to the handbook).
Loss of interest	2	4	8	Adherer to the content and time focused on co-design is meant to minimise the burden. We will also respectfully reiterate the aim and value of participation and appropriate number of times (not too much).
Lack of hindsight on app if	2	2	4	We will adhere to the aim of 3

involved too much				cycles to design the app (unless needed). Where additional design cycles are needed, we will consider adding extra time between FGs.
Shyness of response	3	2	6	Interview facilitator will be guided and trained to support: relaxed environment, group interaction, and management of group conversations to actively encourage contribution.
Risk of death during project	2	3	6	We will need to recruit a sufficient number of participants to account for participant attrition.
Over involved patients or caregivers/patients that don't understand the app/info on app	1	1	1	We will ensure the recruitment of sufficient number of participants to undertake additional FG (if necessary) to achieve FG objective. We will also provide a clear guide/ handbook on how to conduct FG. Software expert, or other GerOnTe Partner, with knowledge and training available to provide 'appropriate' level of support (without disruption the user-testing aspect' of the app)

Risk/weaknesses of/to particular stakeholder	Impact	Likelihood	Risk	Mitigation actions
Health professionals				

Added workload because of participation	**4**	**4**	**16**	**We will explain to the experts the importance of the project and the future benefit. We will also minimize the workload by working in a timely and efficient manner, and providing feedback on what is done with their input to demonstrate how they are contributing to the process. We will offer the opportunity of being acknowledged for their contribution in future publications.** **Finally, we will provide participants with a clear outline of requirement, value, and impact of involvement, and do our best to accommodate participants' needs around the timing, duration, frequency of interviews.** **Specifically for KUL/UZ Leuven: A workshop for health care professionals (members of the HPC) will be organised by MyPL prior to the testing phase during which the Holis digital tool will clearly be explained. There will be room for questions and guided initial testing.** **The Advanced Practice Nurse (APN) in KUL/UZ Leuven will ensure a smooth connection to the Holis digital tools in cooperation with MyPL. URL links and login details**

				will be exchanged and tested in advance. Testing of the Holis digital tool by health care professionals in KUL/UZ Leuven will always be done under the guidance of the APN. She will be more involved in the development process of the digital tools and already had some experience with Holis.
Lack of engagement due to mismanagement of expectations or project involvement	1	1	1	We will develop and provide 'Plain Language Statements' to explain the project and requirement for participation to health professionals. We will also support the written information with verbal or visual information (conversation and or presentation). At the start and end of each FG/ interview), we will need to provide opportunity for questions at relevant points (including before agreement to participate. Finally, we will ensure that all interviewers are trained in the GerOnTe co-design method (thanks to the handbook).
Loss of interest	2	4	8	Adherer to the content and time focused on co-design is meant to minimise the burden. We will also respectfully reiterate the aim and value of participation and appropriate number of

				times (not too much).
Lack of hindsight on app if involved too much	2	2	4	We will adhere to the aim of 3 cycles to design the app (unless needed). Where additional design cycles are needed, we will consider adding extra time between FGs.
Shyness of response	1	1	1	Interview facilitator will be guided and trained to support: relaxed environment, group interaction, and management of group conversations to actively encourage contribution.

Risk/weaknesses of/to particular stakeholder	Impact	Likelihood	Risk	Mitigation actions
Patients, seniors				
Less than 5 participants involved	3	4	12	We will need to ensure sufficient diversity in the remaining patients to gather relevant input nonetheless. We will recruit widely and sufficiently to ensure sufficient numbers, and accommodate participants needs around timing, scheduling, and method (FG, interview, in person, zoom)
Psychological difficulties of	3	3	9	To prevent any

involving a dead patient's relative				psychological difficulties, we will be sensitive to signals of impact of discussions and intervene if necessary, we will also organise the focus group discussions with two people to ensure sufficient possibility for observing and intervening. We will support open transparent pressure-free recruitment process, clear outline to potential participants of the nature of the interview, and topics that will arise, and allow time between providing project information and expression of interest.
Mismatch in data availability in different countries	2	1	2	We will put in place a careful recruitment process to identify the optimum place to recruit across the different countries.
Risk of trial specific data that would be hard to generalize	2	1	2	We will provide sufficient data on the project design to enable replication and where relevant understanding of context (to the interpretation and translation of findings).
Technical difficulties for organisators or for connection in case of an online focus group	2	4	8	Technical issues are always a risk when working with a digital tool. To avoid this as much as possible, URL links and login details were exchanged and tested in advance. In addition, MyPL was always ready to get to work immediately if a technical problem did occur.

				Meaning we will also develop and trail all plans and technology in advance. And we will confirm with participants to have an agreed method to contact one another in the event of issues on the day.

Risk/weaknesses of/to particular stakeholder	Impact	Likelihood	Risk	Mitigation actions
Health professionals				
Nurses: Risk of shyness if involvement in same FG than Doctors in same Hospital	3	4	12	To prevent that, we will allow opportunities for further elaboration outside of group sessions, and plan separate group sessions if necessary. Facilitator will provide a clear outline of the aims, including the value and need for multidisciplinary involvement and discussion. They will create open and balanced group dynamics, and support groups discussion and actively encourage involvement of all participants. Specifically for KUL/UZ Leuven: All health care professionals who will take part in the small-scale pilots already knew each other from previous

				collaborations or have met each other before. Given that the APNs in this case already had more experience with Holis digital tools than the participating doctors, we won't expect any shyness during the internal testing moments.
Risk of confirmation bias	3	4	12	We will ask open-ended questions to prevent this bias. Prior to the testing moments, health care professionals will be asked to look at the content and functioning of the Holis digital tools as objectively as possible. All feedback from the health care professionals will be discussed in group and a consensus between the different health care professionals was needed before it was communicated. Finally, facilitators can encourage consideration of alternatives at the outset of the FG and during group discussion.
Risk of glow of expertise / one expert overpowering group	3	5	15	Each expert meeting is preceded by survey rounds in which each person can provide their own input. Strong differences of opinion will therefore already be noted prior to the group meeting, allowing for a tailored

				approach. Doing the group meetings with multiple leaders, and tasking one of them with the job of making sure everyone is heard. A consensus between the different health care professionals will be needed before the feedback is communicated. Facilitator will provide a clear outline of the aims, including the value and need for multidisciplinary involvement and discussion. They will create open and balanced group dynamics, and support groups discussion and actively encourage involvement of all participants.
Mismatch in data availability in different countries	2	1	2	We will put in place a careful recruitment process to identify the optimum place to recruit across the different countries.
Risk of trial specific data that would be hard to generalize	2	1	2	We will provide sufficient data on the project design to enable replication and where relevant understanding of context (to the interpretation and translation of findings).
Technical difficulties for organisators or for connection in case of an online focus group	2	4	8	Technical issues are always a risk when working with a digital tool. To avoid this as much as possible, URL links and login details were exchanged and tested in advance. In addition, MyPL

				was always ready to get to work immediately if a technical problem did occur. Meaning we will also develop and trail all plans and technology in advance. And we will confirm with participants to have an agreed method to contact one another in the event of issues on the day.

7.5. Gender considerations

GERONTE focus group 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.

8. D6.2. Update 1 (MONTH 10): Co-creation sessions' results and guidelines for small-scale pilots

1.

8.1. Introduction

The D6.2 is a guidebook addressed to the host of the co-creation explaining moderation of the discussion, collection of the participants' feedback and how to report the users' feedback for the consortium for further implementation in the GERONTE system.

In order to co-design both the care pathways and the ICT tools in this project, through the use of co-creation sessions, the GERONTE consortium conducted 1-to-1 interviews and focus groups with health professionals, patients, and healthy seniors in order to:

- Gather feedback from end users on ICT use
- Gather feedback from end users on existing care pathways
- Gather feedback from end users on the design and build of the ICT tools developed in this project contemporaneously to its creation, in order to adapt it to end user requirements. End-user satisfaction is a crucial and necessary point to be proved before entering the market for the application's viability.

DIAK provided a literature review to inform the initial direction, followed by a Delphi process which included international experts in geriatric oncology. The output is a core dataset of frailty data that can be used in the study. A parallel process took place concerning patient preferences with Focus Group sessions involving patients. This informs the dataset for patient preferences that will be used, while assessing the presence of relevant gender differences.

DCU used the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS-CAT) framework to identify relevant constructs affecting the success, the failure, or the degree of implementation of the intervention in each site associated with effective implementation. They used focus groups and interviews to develop this process, building on the successful approach of Greenhalgh et al. DCU worked with project partners, clinicians, patients, carers, and other stakeholders, in a number of national or regional focus groups, to co-create the structure and content of their logic model, the theory behind their realist evaluation, the tools, sources, methods, and approaches to be used to collect the necessary data, and an outline of the main constructs from CFIR expected to contribute to the implementation. All of this ensures a thorough and well-grounded process of evaluation, and serves to identify and bring necessary stakeholders on board in advance.

ESE and the technical team tried to identify the elements to include and exclude from the app before introducing mockups and gathering end-user feedback on these proposed mockups. The introduction of mockups, ideas and prototypes took place during usability tests. These tests allow for the evaluation of the co-design process and for the adaptation of the features if a need is detected. They will be conducted throughout the co-design process to ensure maximum use of the app. The data collected in the GERONTE project in focus groups can be grouped in two main categories:

- Participants in focus groups will give feedback on the app design
- Participants in focus groups will also give feedback on the functionalities

Since the co-creation sessions are organized throughout the GERONTE system development until the validation phase, the guidebook and the tools are and still will be adapted as the project results move forward and therefore these outputs will need several iterations with information updated yearly, in line with the project outcomes, such as follows:

- Month 6 (September 2021), to be aligned with submission of data management plan: updates on focus groups organization (content, recruitment, ethics, etc.)
- Month 9 (December 2021): updates on focus groups results and small-scale pilots' methodology
- Month 24 (March 2023): updates on small-scale pilots results and link to clinical trials
- Month 48 (March 2024 - end of the project): updates on impact assessment

These first and second updates will therefore focus on co-creation sessions results in France, the Netherlands and Ireland, and on a small-scale pilots' methodology including guidelines for pilots' hosts (the Netherlands (DIAK), Belgium (KUL) and France (ESE and Bergonié)).

8.2. Co-creation sessions' main results in Ireland (DCU), The Netherlands (DIAK) and France (ESE)

8.2.1. Context of co-creation sessions

DCU conducted 1 co-creation session (focus/discussion groups) with clinicians and 1 co-creation session (1-to-1 interviews) with patients. The female patient lives at home on her own, with her family that lives nearby and are actively supportive if and when needed. The male patients have a high level of independence pre and post diagnosis, involved in social and physical activities, and a family support from their wife and family. The co-creation sessions for DCU were held online via Zoom.

DIAK had a group of 4 older patients (3 male and 1 female) with various cancer types (prostate, rectal and breast) and various stages of disease. None of them had received chemotherapy and they were all relatively fit. Participants were between 74-84 years old. Treatments that they had received or received were radiation therapy, surgery, targeted therapy and hormonal therapy.

ESE conducted 2 co-creation sessions, 1 interview with a group of 5 healthy seniors and 1 focus group (usability test) with 3 healthy seniors. The technical partner, MyPL, attended both sessions in the Paris ESE's headquarters. All participants were non-frail, fit and independant, and familiar with basic new technologies (ICTs). The gender dimension has been included.

8.2.2. Co-creation of the GERONTE care pathway

8.2.2.1. Case study: Strengths of the Irish care pathway

As a reminder, the GERONTE care pathway is the general expected result. It is about redesigning the entire national care pathways, 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 GERONTE applications are made to support this, and thus are an essential component. The questions that we want 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.

This is why DCU (Ireland) together with MyPL, the technical partner, asked questions during the co-creation sessions about how participating senior patients and health professionals feel about their national care pathway for cancer patients and in general. Here below find first the strengths of the care system according to participants, and then the recommendations they expressed for the GERONTE model to improve the situation.

The GERONTE solution will try to focus on everypoint mentioned below.

Table 2 - Strengths of the care pathway in Ireland

Strengths of the care pathway in Ireland
There is some integration between public and private healthcare partners to provide some preparatory care (taking bloods for instance) in advance of appointment to save time on the day of the consultation. A private company comes to the person's home and takes bloods so that the results are available at the subsequent consultations.
Communication between in-hospital specialists is good. Communication and decision-making between the in-hospital specialist consultants is effective.
The specialist departments and care currently provided within the services is good. • Centre of excellence (access to multidisciplinary care) and a user-friendly environment • Physical structure and aesthetically positive environment • Efficient care pathway • Professional and inclusive (with patients) decision-making • Able to provide information on personal health condition needs.
Communication regarding appointment was provided in: • By phone call • In written format through traditional postal methods • As reminder texts • The method of communication depended on the nature (purpose and seriousness/ significance) of the message to be communicated. • Specialist nurses called if the communication or upcoming appointment was potentially impactful. • Written communication and reminder text were sent for appointment. • The current communication (of health information and appointments) was considered sufficient, but additional information delivered through the GERONTE was considered helpful if it was in addition to existing methods of communication.
Support family involvement based on the patient's wishes and needs. Family support was valued by and beneficial to the patient. It was especially valuable and essential around: • Receiving information around diagnosis, treatment and after care • Managing and seeking healthcare support when issues arise.
Family was physically present for consultations. The inclusion of family in the provision of information was deemed essential as it would otherwise be difficult to take in the information. Support family involvement (information on what to watch for)in line with patient preferences. Support community health professionals to enable this through the provision of access to data, as they are key touch points for patients and their family.
Comprehensive information (regarding what would happen in their care needs) was provided by the clinicians. The current amount and timing of information around the care pathway (treatment and support care) was good. Information about diagnosis, treatment plan was comprehensive.
Once initial access to the services was gained the patient experienced care and follow-up that was proactive, streamlined and comprehensive. The provision of physical care and support immediately after care and treatment was good. These attributes of the care were valued.
Routine follow-up care was proactive and good Routine follow up was good

8.2.2.2. Case study: Improvements and recommendations for the GERONTE care pathway from Irish participants

The GERONTE solution aims at bringing a solution at the national and European level to improve care pathways and digital health monitoring. Here below are the points to be improved and other recommendations from the DCU co-creation sessions in Ireland.

Table 3 - Improvements and recommendations for the GERONTE care pathway from Irish participants

Improvements and recommendations for the GERONTE care pathway from Irish participants
Streamline access to geriatric and specialist care early
Enable data sharing between specialist to improve decision making and support when problem arise for the patient at home
Improve support to patient and family when problems arise at home
Embed early access to specialist (Gerontology) care to ensure older adults healthcare needs are recognised early and managed optimally.
The patient experienced significant difficulty: Being listened to; having their specific care needs recognised; accessing the relevant specialist care
Gerontology specialist care should be: systematically embedded in the GERONTE pathway; made available to Hospital-based clinicians and General Practitioners; supported and promoted by an ICT system that enabled the clinicals to make and prioritize referrals to Gerontology and specialist care, as early as possible, to prevent delayed care and the re-presentations.
Access to Gerontology care would support: Early and improved 'listening'; understanding of older adults' specific health needs.
Enable identification, collation, and sharing of the patient's hospital and community attendance and care needs. This would: provide a more complete picture of their health & well-being needs over time; enable improved and more timely decision-making by clinicians.
Enable and promote the community-based nurses and clinicians to support the patient when they experience problems or deterioration by providing access to certain patient data. This would require at a minimum access to a list of the patient's specific hospital-based contacts, clinicians, and supports and likely access to an overview of their health data/ care plan. It may be beneficial to: facilitate communication between the community team and the hospital team; identify and map the network of supports available based on the patients' profile
Access to support when problems arise at home
There were challenges and delays to the follow-up care when problems arose.
These impacted the patient's quality of life significantly, but once access to the right services were made, the problems were addressed comprehensively and compassionately.

As such, identification, referral and access to the right services in a timely manner were the issues (as opposed to the services themselves).
Being able to access records and results in advance of consultation to enable patient's decision making and preparation for the consultations. • Suggests access to results that are **'relevant' to their condition** (such as bloods monitoring their condition). This would enable the patient to monitor their condition and seek assistance or trigger action themselves (autonomy). • Access to **supportive information about the results** and **tailored information about what they mean** (in relation to their personal condition). Access should be via encryption and password. This would: enable understanding of their own results; provide patients with a source of scientifically sound information tailored to the patient's condition.
Improved system for time coordination when attending appointments as significant delays at appointments. Noted that there are likely important clinical demands that result in the delays. • Suggests a 'systematic log-in and ticket system' that notifies you where you are in the queue and about any delays. Such systems are currently in use in some other departments, but not in the oncology department. • This would: Reduce time 'spent waiting' in the chair, so that they can have a refreshment/ coffee while waiting; Reduce risk due to waiting around in general areas such as in 'Covid-times'; Be an added safety measure (if the ticket system had a logout system it would identify who was or was not in the building in the event of a critical incident/ fire)
An online real time booking system for consultant visits and blood tests would be a good solution.
The care pathway would ideally systematically prompt and support oncologists to involve geriatricians and other health professionals.
The current duration and volume of appointments, and the increasing demand on oncological and all other services requires this practical support.
Embed the routine screening of older cancer patient to ensure the systematic involvement of Geriatrician, allied and supportive care services where appropriate
Screening should trigger the involvement of all the relevant services such as: Geriatrician, specialist cancer nurses, pharmacists, physiotherapists, social workers, nutritionists, or psychologists.
Screening should occur at: • Diagnosis and treatment planning, to enables holistic decision making that considers the patient's baseline and the impact of the cancer and treatment • During treatment, to enable early intervention and involvement (with geriatric care and other services) and to prevent and respond to health deterioration • Post treatment to enable management of health changes due to accelerated ageing.
Screening would need to capture the patient's cognitive and functional status and benefit from family/ carer involvement (in line with patient's wishes). Develop a formal and comprehensive way to communicate information to patients and/ or family.
Contact time with patients is limited, and so cognitive and functional limitations may not be evident.
The complex and potent nature of cancer regimes results in complex and changing health information. Cancer and its treatment also impact on physical, cognitive and psychological functioning. Involvement

of the chosen family and relevant supportive care is needed to provide informational, emotional, practical support and monitoring.
Involve a case manager: Cancer treatment and pathways are complex and can cause significant short- and long-term health complications and rapid deterioration. To improve care, there needs to be a central point of contact, such as a case manager, to address the patient's and family's informational and support needs. The case manager would be able to direct and guide patients and family to the appropriate services, particularly when the patient experiences issues or deterioration. This will ensure that safe, quality, and cost-efficient care is delivered in a timely manner.
Address patient and family information needs in a more comprehensive way: Patient and family's informational needs are not met by the current system and are increasing in line with societal expectations and health literacy and the increased complexity of care. The current information provision levels do not meet patient or family needs or wishes or align with optimal timing or way of communication.
Have a central point for key health and treatment data. The patient and/ or family should have a central point/ repository with all their key health information available to them. This is needed to support patients and family when attending health appointments or when attending for emergency care. The contact detail for the case manager, and other key clinicians providing care to the should be available and up to day on this database.
Include the General Practitioner and broader Primary Healthcare Team, who will: enable patients and family to receive appropriate care from sources that are familiar and trusted to them. This is a prominent concern reported to healthcare professionals by patients and family; and enables General Practitioners to make decisions on when to manage, or refer, their patients.
Developing a communication system enables supportive care services and allied health professionals to communicate directly with patients and family. This will enable allied professionals to coordinate and plan patients' appointments so they can ensure designated appointments, with adequate time, that are tailored to the patient's information needs, and at a time convenient to the patient and their treatment.
Communicate specific and relevant health information, or concerns that the patient/ family raises, to the relevant health professional. To receive information that the patient inputs related to their domain of care (such as exercise diary, self-reported measures of well-being) to enable planning or intervention, enable other health professionals to communicate with and access them.

To these recommendations, Dutch participants, from the DIAK co-creation sessions, also suggested the following points:

- Symptoms: important to mention the 24 hours in the daily questions otherwise the time window is not clear (possibly also caused by the test environment and the delay between showing that it is a daily check-up and question)
- Patients would rather have all symptoms present and click on those that they have
- Communication about appointments is usually made well in advance (up to a few months)

8.2.3. Recommendations about the GERONTE Holis digital tool

Regarding the functionalities and needs for the GERONTE Holis application, participants in co-creation sessions in Ireland, the Netherlands and France made some recommendations to the co-creation sessions hosts. DCU, DIAK and ESE sent these remarks to the technical partners MyPL afterwards, so that it can integrate these changes or take them into account.

8.2.3.1. Observations during the usability tests

First, patients expressed their approval for the access to an emergency contact and cancer nurse specialist that is available on the Holis tool, with an accessible and responsive to call, and a mobile contact, important so that health professionals are available.

About the Maze, tested only with the Dutch participants: The program is too difficult to test in this population, they forget the questions, every screen needs a short question, and they don't realize that the actual app is different from Maze. They expressed mainly the problems with this testing environment, not with the app. Due to time limitations caused by the fact that DIAK's participants wanted to know each other before we could continue, DIAK only spent 45 minutes and most patients ended after the symptoms phase. But indirectly we noticed that they were sensitive to the positive feedback in the Maze environment.

Patients could easily navigate between the various screens. If we read out loud the questions of adding symptoms they could click on the right screens and could indicate how severe the symptom was. However, it is not clear that "daily check-up" leads to adding symptoms.

Then, it didn't work to start with the test before they knew what the program would do. They had no idea what it was for or why they would fill it out. But they were happy to see that their "mission was completed".

Even though they told us beforehand that they were unlikely to use such an app, they expressed that they now use pen and paper to store the same information that we plan to have in the app. So difficult features like possibilities of enlarging a screen shouldn't be in the actual app, they did not know how to navigate back to the test.

8.2.3.2. Suggestions and recommendations

Participants are proactive people, familiar with new technology and with relatives/family members available to help them with digital health monitoring for instance. So, if the **time is limited** on the platform, it's fine for participants. They don't want to feel sick all the time. One person in the Netherlands had filled out symptom lists before and stopped after a week because she didn't like it and because she felt well capable of alarming herself in case something was wrong. So, the system has to be performant of course, but also functionalities must be "straight to the point", for example with **big and visual buttons** to go directly to the action the patient wants to execute. For instance, some participants would like to have a **"I am worried about my symptoms" button**. Other patients would like the Holis application to identify what to watch for and provide a **'symptom-checker like' button** to support decision on when and how to seek support, and also what is to be expected and considered 'normal' after treatment. This would enable their decision-making around what is to be expected and when and how to seek support (feedback on whether to seek healthcare support or not and what (healthcare contact) to seek support from).

They already also have their own systems on paper and excel on the computer, more in the Netherlands than in France for instance. But **they liked the graphs** on the application, because it shows them the progress of their health status. They all look for more information on their disease on the Internet, on their own, so they are also interested in getting more recommendations about how to deal with symptoms. Consultation was not discussed in the Netherlands and in France, but most patients reported that they keep a record of what was discussed in every single consultation since their diagnosis, either on paper in a word document/ excel sheet, so it would be good to provide the **opportunity to save these notes in the Holis application**.

All participants in Ireland, the Netherlands and France said that they will mainly use the Holis application **on their computer**, or maybe on their tablet if they have one. It needs to become part of their routine, **thanks to notifications** for instance, but not too much. Some of them already set an alarm to take their medication for example.

Participants think that **proactive information should come from the healthcare professionals' side** so that healthcare is updating the patients about their health. For instance, in Ireland, they thought of a newsletter type information, because Irish participants identify as being very much internally motivated to be healthy. As such, the utility of the app in 'keeping healthy' is very much around providing information that improves knowledge about what is happening about their health condition. Doing so, the Holis application would "save you going to the hospital unless you need to be there" according to patient participants, and all remotely.

In Ireland and France notably, currently communication about appointments is usually made well in advance (up to a few months). It would be a real improvement if the Holis application could keep track of all the appointment dates, times, preparation, and instruction that requires a robust personal system on the patient's behalf. This can be difficult for some patients or if very unwell. So, it would be useful if the Holis application could provide a **personalized record of appointments**. This personalized record would be 'additional' to and not replace the current system. Patients in Ireland recommended an '**encrypted system**' to send communication and appointments to the patient's mobile number as most people have a mobile.

Plus, in all host countries we observed that it would be essential for many older adults to have **support and training on the use of any technology** that they would benefit from. This should happen early on to promote use of the technology. The training and support should:

- Identify what the technology can do to help.
- Indicate the set-up and features that should be based on what the patient's needs and wants are. They may not wish to avail all features.
- **Provide direct support setting** it up so that it is **ready to use.**
- Provide demonstrations on how to use it and how to get support when difficulties arise.
- Recommend an 'encrypted system' to send communication and appointments to the patient's mobile number as most people have a mobile.

Having an online system where you put in your symptoms is really complete if it provides an **automated chat system** that feeds you through a tailored system based on your answers. This system could potentially be voice activated, as expressed by Irish participants. It would be helpful if the Holis application could support this (inclusion and access to patient data and advice) in line with the patient's preferences, literacy and access to technology. This functionality would complement the general information provided by the Holis application about the condition or treatment, the role and scope of healthcare provided, the contact points, the reason or significance of involvement of other services, such as palliative care, the facilities available on site, etc. Providing this information will address mis-

information that can occur when patients/ family don't have access to reliable sources of information, but also save patient time, and clarify and remove uncertainty and its associated stress.

Participating patients (and their family) also have personalized information needs about their specific condition or care pathway, such as:

- Their central point of contact (**case manager**, see above) / who is primarily responsible for their care
- Whom to contact in an **emergency**
- **Medication** regime, instructions and any updates related to this
- **Appointment** time, location and how to prepare for the appointment
- Access and parking options for appointment
- Common **side effects** of their treatment and how to manage them
- What to report to the health care team and when to seek health care
- Who will follow up care and what they need to do next.

The application should therefore enable patients and designated family members to flag changes or concerns in the patient's health condition.

8.2.3.3. Senior end-users' special requirements

Some recommendations made by senior participants in France concern the layout of the Holis application, which should be more user-friendly and easy to use for a 70+ senior patient. **The following elements must absolutely be adapted to senior end-users: size of font, aesthetic, vocabulary and sign-up process**.

Older people are generally interested in new technologies for the improvement of the quality of their life and/or the one of their relatives. However, when developing ICT solutions for this kind of users, it is crucial to keep in mind the **limits linked to aging**, as well as the fact that older generations had to adapt to technologies in a later moment of their lives and they might not feel confident in the use of particular devices.

Some of the most common issues linked to aging we need to consider, concern visual and hearing impairments or just low vision or progressive hearing loss. Thus, the interfaces of the developed solutions have the following requisites: **big characters, possibility to turn up the volume, video subtitles, no bright colors, simple and readable fonts**. Also limited mobility is a major concern for the developers of IT solutions. The proposed devices must be **light, easy to carry and reachable**.
We also need to consider some problems of social nature, such as the exclusion and isolation of seniors. Some of the users might live alone and have no opportunities to meet their relatives or friends. In this case, they wouldn't have any support in the use of a new IT solution. For this reason, it is suitable to **keep the device and the application as simple as possible** and also to **organize training sessions for the users**. The GERONTE solution must **encourage social interactions**, a tool for the seniors to keep in touch with their family, relatives and other people of their age, beside social services providers, health professionals and caregivers.
To avoid frustration regarding the GERONTE solution, it is essential to **focus on the acceptability of the GERONTE solution** we propose. The device has to be very simple and possibly similar to something seniors are familiar with (a remote control, a mobile phone, etc.). Furthermore, we must avoid solutions that may humiliate seniors, such as intrusive and unusual devices underlining the health and aging condition of the user. We also need to keep in mind that video cameras are problematic in terms of privacy and ethical issues, as well as acceptability.

8.2.3.4. Practical tips for next usability tests

Patients in the Netherlands and France preferred no or almost no open text boxes/questions on the Holis application: we need to **minimize the amount of questions** and we need to better combine and align the usability testing (knowing how to navigate in the application) with the content testing (we need to think: do the questions that we ask them make sense to them and are similar to the problems they experience?). It is not only the screens that we are testing, but also **whether they understand our questions and understand the purpose**. We need to develop easy and well understood examples, the content must make sense and be as clear as possible to test the format and the content. And the questions need to remain visible anytime.

Also, we should instruct patients that they need to fill it out as if they are currently receiving chemotherapy or therapy, to go back to that part of their disease. We also need to instruct them that they are **representatives of other older patients** who might be less fit and less active and have more problems.

It is preferable to only ask about features that will be in the actual application, because that will already take quite some time: for instance, the introduction to the project and the testing session takes time, because participating seniors and patients all have a serious disease and want to know each other's stories.

It is important to make patients understand the reason why we monitor their health and explain the relevance, as well as to show this system at the beginning of the trajectory, before they find their own system. This approach must be considered in the clinical trials the GERONTE consortium will conduct.

8.3. Small-scale pilots' guidelines

8.3.1. Small-scale pilots overview

8.3.1.1. Introduction

This deliverable 6.2 has been once submitted in M3 (June 2021) as requested in the grant agreement. This is an update to design guidelines in order for GERONTE partners to conduct small-scale pilots accordingly. Since the co-creation sessions are organized throughout the GERONTE system development until the validation phase, this guidebook and the tools will be adapted as the project results move forward and therefore these outputs will need several iterations with information updated yearly, in line with the project outcomes. These guidelines are one of the consequences of the strategy designed in T6.1, that fixes the specific goals and a timeline for all co-creation sessions (i.e. Focus Groups and small-scale pilots) that are hosted with the target end-users in France, Belgium and the Netherlands.

Small scale pilots are a milestone in the GERONTE project in order to assess the adoption of the HOLIS GV application by the platform users. Moreover, this task allows us to identify unforeseen difficulties and / or issues not only for the patient application but for HOLIS GV platform (Patient application + HPC Decision making dashboard + Care trajectory dashboard for the APNs).

Small-scale pilots are part of the WP6 “Stakeholders’ engagement and ethical issues” and the Task 6.3 entitled “Small-scale pilots”. This task is led by MyPL and pilots HolisTM GV at the seniors’ home environment, in order to track the possible difficulties in usage of the technology before launching the large-scale pilots. This task is therefore really linked to WP2 “Developing the tools for GERONTE”, also led by MyPL.

8.3.1.2. Objectives

This task’s main objective is to validate the HOLIS tools developed in the project’s co-creation phase. The HOLIS platform is made of three interconnected applications, the patient application, the care trajectory dashboard and the HPC decision making dashboard. Those three applications are directed at three different stakeholders: Patients, APNs and HPC members.

One of the goals of the pilots is to test the HOLIS GV platform on two levels, technical and usability/adoption. On the technical level pilots will aim to ensure that the workflow functions without any bugs. On the usability level the pilots aim to ensure that the platform is user friendly and that no major obstacles prevent users from accessing the HOLIS platform.

The pilots will also serve to test the WP1 study questionnaires with the target users, this will be done within the testing of the app as the study questionnaires directly fed the symptom monitoring and feedback questionnaires contained in the app.

Another goal of this WP is to “evaluate whether use of digital tools is gender-biased” this will be done by ensuring gender parity in recruitment as much as possible. Since healthy seniors will use factitious profiles and scenarios to report symptoms their data cannot be used to assess differences in symptom reporting, but the data from the pilot led with DIAK will be used to analyze if any difference in symptom reporting exists. Although the pool of participants will be small, therefore conclusions will be limited by the scope of the pilots.

8.3.1.3. 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.

8.3.1.4. 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.

8.3.1.5. 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)

8.3.1.6. 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

8.3.2. Recruitment procedure

8.3.2.1. 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.

8.3.2.2. 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.

8.3.2.3. 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.

8.3.2.4. 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.

8.3.3. Small-scale pilots process

8.3.3.1. MyPL's general approach

To implement this task, MyPL is adopting the "Dual Track Agile" methodology [1]. 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).

8.3.3.2. Small-scale pilots' timeline

Due to added demands from GERONTE project partners the HOLIS GV platform with all its modules originally planned to be ready by the end of December (M9) has been delayed and will be finalized in February. Hence, pilots are expected to take place from the beginning of March (M12) to mid-April (M13).

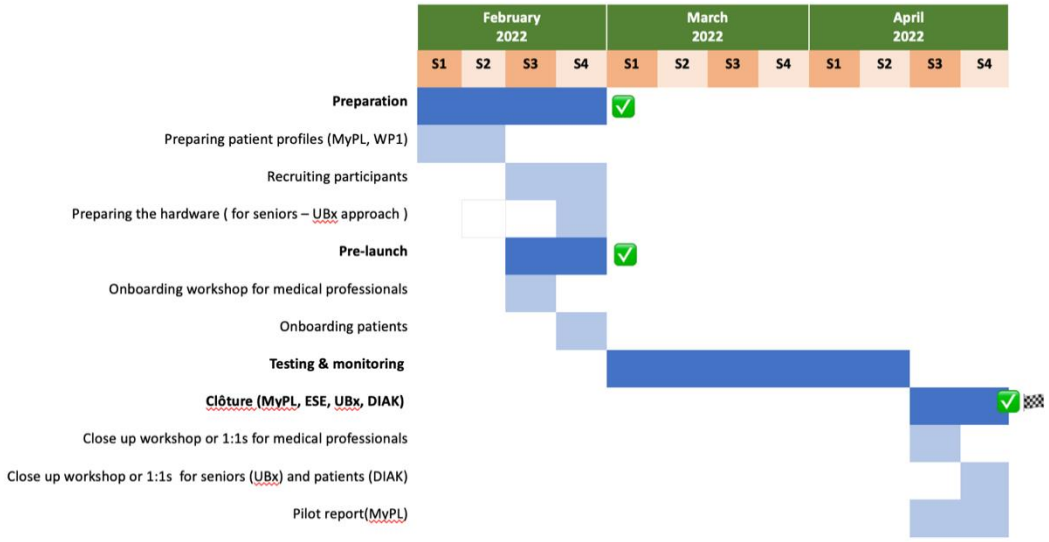


Figure 3 - GERONTE small-scale pilots timeline

8.3.3.3. Tools for beta testing

- **Hardware**:
  - Patients' application: participants will have the choice to use their own hardware for the pilots, or request to be lent a tablet, such device will be provided by MyPL as a loan.
  - "HPC decision making dashboard" and "Care trajectory dashboard" will be used in desktops within the hospitals.

- **Support system tool**: MyPL is using **Freshdesk** for the ticketing system. Every bug reported by the users will be automatically sent to our support team for fixing – as depicted in the picture below. Moreover, suggestions, feedback or prompt-in ideas from the users will be collected directly through our support system.

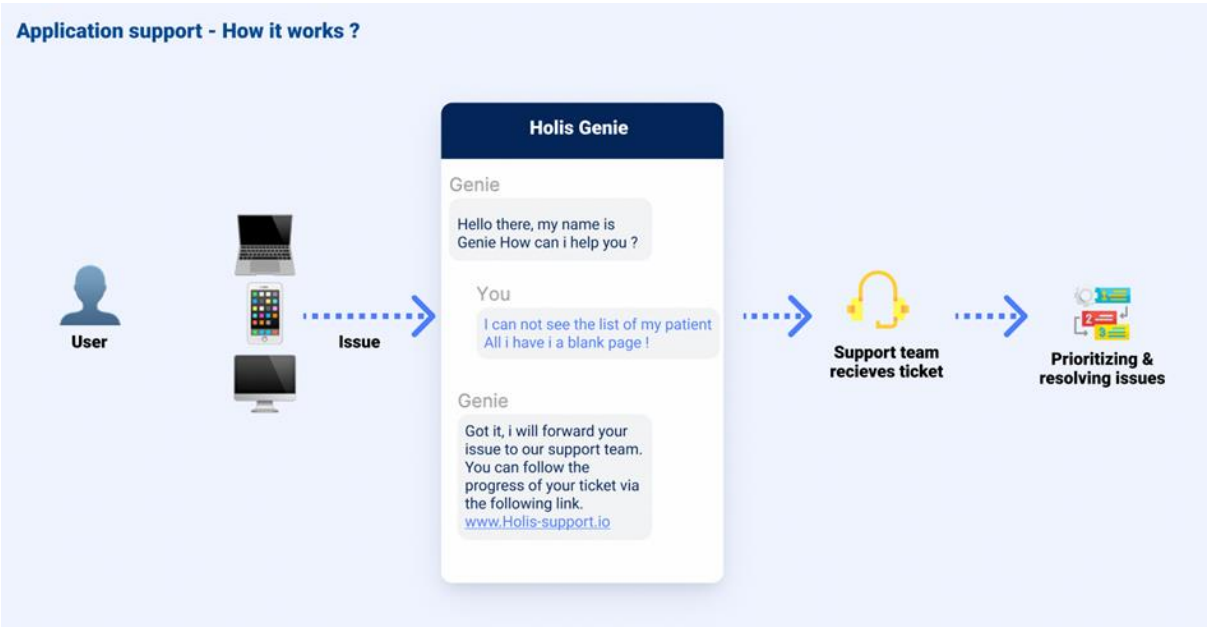


Figure 4 - Application support process by MyPL

Analytics: MyPL is using Hotjar in order to have a clear and global insight regarding the user experience. Moreover, all the surveys and questions asked will be sent via our analytic tool Hotjar.

8.3.3.4. 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.

Figure 5 - Example of request for feedback: Screenshot from the Hotjar tool

8.3.3.5. Net Promoter Score

In order to assess the HOLIS performance, we gather users' feedback all along the pilots and make the necessary adjustments to meet users' satisfaction. The NPS is a score that will allow us to assess the general experience of the users. It is calculated based on the answers to following question:

"***On a scale from 1 to 10 how likely you are to recommend our application***". Users are then divided into three categories:

- **Detractors** – users who submitted a score from 0 to 6: Those are considered unhappy users.
- **Passives** – users who submitted a score from 7 to 8: Those are satisfied users but not enthusiastic.
- **Promoters** – Users who submitted a score from 9 to 10: those are loyal enthusiastic users

The NPS score is then calculated following the equation below:

NPS=% Promoters-% Detractors

There are two methods to interpret the NPS score:

- **Absolute method**: Generally, an NPS that is positive (NPS>0) is interpreted as a good score.
- **Relative method**: Comparing HOLIS NPS to other similar tools existing in the market.

Although there are several applications that provide symptoms monitoring for cancer patients, no NPS study is available. Therefore, we will adopt the Absolute method and in order to assess the impact of adjustments that have been implemented all along the pilots, we will launch two NPS studies, one at the end of the first week of use and another one at the end of the pilots and compare the scores.

8.3.3.6. Entry and exit criteria for beta testing

Apart from participants recruitment and prior to launching the beta testing, a set of criteria and conditions are to be met:

- Product ready: QA (Quality Assurance) testing has been performed and conclusive.
- User Manuals, Known Issues list are to be documented.
- Tools to capture bugs, feedback should be ready.

In order for the beta testing to be conclusive, following conditions are to be met:

- No Showstopper bugs in any of the HOLIS GV platform.
- All Major bugs discovered in the Beta Test phase should be fixed.

At the end of the beta testing, a “Beta summary” report is to be elaborated by MyPL and the beta testing is to be flagged as “Completed & Conclusive”.

8.3.3.7. Logistics

E-Seniors will assist MyPL in their contact with participants during the small-scale pilots and organize discussions around problems with the Holis application if the means deployed in the small-scale pilots are insufficient. E-Seniors and MyPL will also organize a briefing and debriefing session at the beginning and end of the small-scale pilots to inform participants.

MyPL will provide a tablet to each participant for the duration of the small-scale pilots (3 months), E-Seniors is responsible for liaising with seniors about returning the devices to MyPL.

The average time of use for symptom reporting according to the scenarios is 10 min/d, with a maximum of 20 min/d and a minimum of 5 min/d depending on the profile of the senior (these figures are given based on the interviews done previously with the seniors).

Senior participants will also be asked to send their impressions and opinion of the app directly through Holis, with an estimated implication of 10 minutes per week, totaling an hour and thirty minutes over the duration of the pilots.

Seniors will also be asked to test features and functionalities of the app with an estimated implication of thirty minutes per week, totaling three hours over the duration of the pilots.

Overall, with a two-hour introduction session and another two-hour session to wrap-up participation, senior participants implication in the small-scale pilots is estimated to take between thirteen and a half hours and twenty-three and a half hours, with an estimated expected average implication of sixteen and a half hours.

8.3.4. Suggested plan for small-scale pilots

8.3.4.1. Suggested plan in France

The role of the French partners is the following: ESE recruits the senior volunteers and coordinates with them their participation, MyPL provides the material and technical support for the Holis test, UBx (BERGO) participates in the identification of the needs for clinical and hospital expertise (if needed), in preparation for the implementation of the FRONE trial.

DIAK, KUL, MyPL and UBx (Bergonié) will analyze the potential challenges for end-users in using tools during the small-scale pilot phase – the risks are related to usage problems with the GERONTE system and these can be tracked with tasks that users should perform with the system. ESE will draft a list of tasks that users carry out with GERONTE during T6.3, and the tasks that users reported as problematic are considered as « risks » for which a solution for easier use should be proposed.

The planned course of the HOLIS pilot test for the **French partners** and participants is as follows:

Table 4 - The preparation phase of pilots in France

Task	Responsible
1. Recruitment of 5 seniors for the pilot to cover the 5 profiles of GERONTE	ESE
0. Recruitment of 1 APN and at least 1 member of the HPC (Geriatrician or Onco-Geriatrician) for the pilot, in order to test the whole HOLIS ecosystem	UBx
0. Preparation of the tablets for the patient application: the tablets will be pre-configured by the MyPL team to ensure that the tests will include the most used browsers: Chrome, Firefox, Opera and Internet Explorer	MyPL
0. Preparation of simulation profiles for the tests	MyPL & WP1
0. Preparation of test scenarios for each participant to cover at least the 5 multi-morbid profiles included in GERONTE	MyPL & WP1
0. Preparation of the first feedback to be requested from participants	MyPL & WP1
0. Sharing of simulation profiles and scenarios with APN and HPC	MyPL& UBx
0. Creation of emails for seniors to be used to connect to the application	MyPL
0. Creation of the hospital on the HOLIS application, as well as the account of the APN participating in the pilot	MyPL & UBx
0. A dedicated email support address for the HOLIS application	MyPL

Healthy seniors in France will use virtual patient scenarios to input symptoms so that they may test the patient application to the fullest. The scenarios will be prepared according to the patient profiles included in GERONTE and according to the different scenarios to be tested. The scenarios will be the subject of a preparation and validation phase with WP1.

The scenario described below serves as an example of a scenario that takes up the symptom escalation for seniors simulating a patient profile.

Table 5 - Example of patient scenario

Last name:	Ilisa
First name:	Dupont
E-mail:	lisa.dupont@gmail.com
Profile:	Cardiovascular, metabolic, pulmonary
Cancer type:	Breast cancer
Treatment:	Chemotherapy
Profile during treatment:	No alert

First connection made with ESE and MyPL during the workshop:

1. Go to your mailbox
2. Open your email sent by the HOLIS application
3. Copy the temporary password and click on the link - you will be redirected to the application
4. Paste the temporary password
5. Create your password - 8 digits
6. The MyPLwill explain to the participants how to use the application and answer the different questions

Usage scenario during the pilot (10min)

First day

1. Open the application on your tablet
2. Log in to the application and enter your password
3. Click on “My daily checkup”
4. Answer the question “Do you have nausea” = yes
5. Set the degree of severity to “Moderate”
6. Answer the question “Do you have difficulty breathing?” = No
7. Answer the question “Do you have diarrhea?” = yes
8. Set the degree of severity to “Moderate”
9. Answer the question “Do you have general pain?” = no
10. Answer the question “Do you have a fever?” = no

This scenario is repeated every day until the 7th day when you will have the “My weekly checkup” button displayed below the “My daily checkup” button

0. Click on my daily checkup and complete the scenario like the other days
0. After completing your “daily checkup”, click on the “my weekly checkup” button
0. Answer the question “Do you have a lack of appetite?”
1. Set the degree of severity to “Moderate”

0. Answer the question “Do you have difficulty sleeping?” = no

This scenario is repeated every week, after a month, you will have a third button displayed below the other two buttons “My monthly checkup”.

Table 6 - The pre-launch of pilots in France will include

<table>
<tr><th colspan="2">Tasks</th></tr>
<tr><td>1. Explanation workshop and handover of the HOLIS application - APN & HPC, organized by MyPL and UBx;

A one-week delay is foreseen to allow the APN and HPC members to get familiar with the application before starting the tests with the seniors who will simulate the patient profiles.</td><td>1. Explanation workshop and handover of the HOLIS application - APN & HPC, organized by MyPL and UBx;

A one-week delay is foreseen to allow the APN and HPC members to get familiar with the application before starting the tests with the seniors who will simulate the patient profiles.

Participants will have access through the link and code provided by the email address.</td></tr>
<tr><td colspan="2">0. Setting up a tool to evaluate the usability of the application and to get feedback from MyPL participants;</td></tr>
<tr><td colspan="2">0. Implementation of a support tool to allow participants (APNs and patients) to report bugs The tool will allow participants to report bugs via an email address (determine the most appropriate channel for seniors).</td></tr>
</table>

Start and progress of the pilots

Table 7 - Average time of use of HOLIS for APN

Tasks	Duration
1. Opening workshop and explanation of the pilots	2h
0. Handholding of the app	11h
0. Creation of the participants, 5 profiles	1h15
0. Decision making view for the participants profiles via HPC	25 min
0. Creation of the patient follow up for the participants	25 min
0. Preparation of the HPC evaluation meeting for the 5 profiles	1h15
0. Decision making during the HPC evaluation meeting view for the profiles	25 min
0. Follow up for the entry of symptoms for the 5	25min/day Total of 17h
0. Closing workshop	2h

Total	26h / 3,5 days

Table 8 - Average time of use of HOLIS for patients

Tasks	Duration
1. Opening workshop and handholding of the app	2h
0. Handholding of the app	1h
0. Average time for the entry of symptoms	10min/day 7h in total
0. Average time for the feedback from the app	10min/week 1h30
0. Average time for testing the consultation preparation features	25min/week 3h
0. Closing workshop	2h
Total	16h30

Table 9 - Average time of use of HOLIS by the geriatrician

Tasks	Duration
Opening workshop and explanation of the pilots	2h
Handholding of the app	1h
Geriatric diagnosis of 5 patients	1h15
Decision making of the treatment of the 5 profiles	25min
Decision making during the follow-up of the treatment	25min
Closing workshop	2h
Total	7h30

The testing and monitoring of pilots in France will include:

The patient application allows for symptom reporting at three frequencies (daily, weekly and monthly). The participants must respect this process according to the scenarios which will be transmitted to them.

The average time of use for symptom reporting according to the scenarios is 10min/day, with a maximum of 20 min/day and a minimum of 5 min/day depending on the profile of the senior (these figures are given based on the interviews done previously with the seniors).

The APN had to check that he/she receives the symptoms reported by the seniors (according to the scenarios) 25 min/day. The APN should run the scenarios that will exist throughout the pilot.

Table 10 - The testing will unfold as following

1. Adding patients at the beginning of the process	15 min per patient 1h15

2. Making a decision via the HPC decision making view	5 min per patient 25 min
3. Creating the patient follow up	5 min per patient 25 min
4. Preparation of the HPC evaluation meeting	15 min per patient 1h15
5. Making a decision during the HPC evaluation meeting view	5 min per patient 25 min

Concerning the monitoring, seniors will be able to call ESE directly and ESE will receive problems/questions from seniors. ESE will then address to MyPL the bugs and problems reported by the seniors directly in order to treat them in time by the MyPL support team. Difficulties reported by participants (APN and patients) will be analyzed and solutions discussed with the relevant MyPL & WP partners. Feedback from participants will be analyzed and discussed with the relevant partners.

To conclude the pilot phase in France, partners will proceed as follows:

- At the end of the pilot, all the bugs reported must have been dealt with and resolved MyPL
- The difficulties reported by the participants will be reviewed with the partners and an appropriate solution will be implemented after consultation MyPL
- The tests ensuring the Quality of the HOLIS system will be carried out MyPL
- A closing workshop and feedback with the APN will be conducted MyPL & UBx (2h)
- A closing workshop with senior staff, feedback and delivery of tablets MyPL & ESE (2h)
- A report including :
    - The list of difficulties raised and the solutions proposed and implemented.
    - The list of bugs reported and solved
    - Potential risks to be taken into account during the clinical study if any.
    - Performance indicators of the application
        - Average time of use to complete a mission/task (patient app)
        - Usability of the application (answering the question: is the application intuitive and easy to use?
        - This indicator will be calculated based on the feedback that will be asked to the participants.

8.3.4.2. Suggested plan in Belgium

Table 11 - The preparation of pilots in Belgium will include

Tasks	Responsible
Recruitment of 1 APN and at least 1 member of the HPC (Geriatrician or Onco-Geriatrician) for the pilot, in order to test the whole HOLIS ecosystem	KUL
Preparation of simulation profiles for the tests	MyPL & WP1
Preparation of the first feedback to be requested from participants	MyPL & WP1
Creation of the hospital on the HOLIS application, as well as the accounts of the APN participating in the pilot	MyPL & UBx
A dedicated email support address for the HOLIS application	MyPL

The pre-launch of pilots in Belgium will include:

- Explanation workshop and handover of the HOLIS application - APN & HPC MyPL & KUL – 2h
- Setting up a tool to evaluate the usability of the application and to get feedback from MyPL participants
- Implementation of a support tool to allow participants (APNs and HPC) to report bugs. The tool will allow participants to report bugs via an email address.

Table 12 - The testing and monitoring of pilots in Belgium will include

Tasks	Duration
The APN has to check that he/she receives the symptoms reported by the seniors (according to the scenarios). The APN should run the scenarios that will exist throughout the pilot	25 min/day
Adding patients at the beginning of the process	15 minutes / patient 1h15
Making a decision via the HPC decision making view	5 minutes / patient 25 minutes
Creating the patient follow up	5 minutes / patient 25 minutes
Preparation of the HPC evaluation meeting	15 minutes / patient 1h15 minutes
Making a decision during the HPC evaluation meeting view	5 minutes / patient 25 minutes

Concerning the monitoring, participants will be able to contact KUL directly. KUL will address to MyPL the bugs and problems reported by the participants directly in order to treat them in time.

Bugs reported by participants via KUL or via the email address that will be handled by the MyPL support team MyPL. Difficulties reported by participants (APN and patients) will be analysed and solutions discussed with the relevant MyPL & WP partners. Feedback from participants will be analysed and discussed with the relevant partners.

APN Scenarios:

The APN has a major role in the Holis application.

The APN has different objectives, including:

- adding patient information
- making a treatment decision with the consortium members
- activating treatment monitoring
- preparing the next meetings with the consortium on the evolution of the treatment every 3 months for one year
- participate in the decisions of these meetings

Each of these objectives deserves to be tested during the pilots, with its associated scenario.

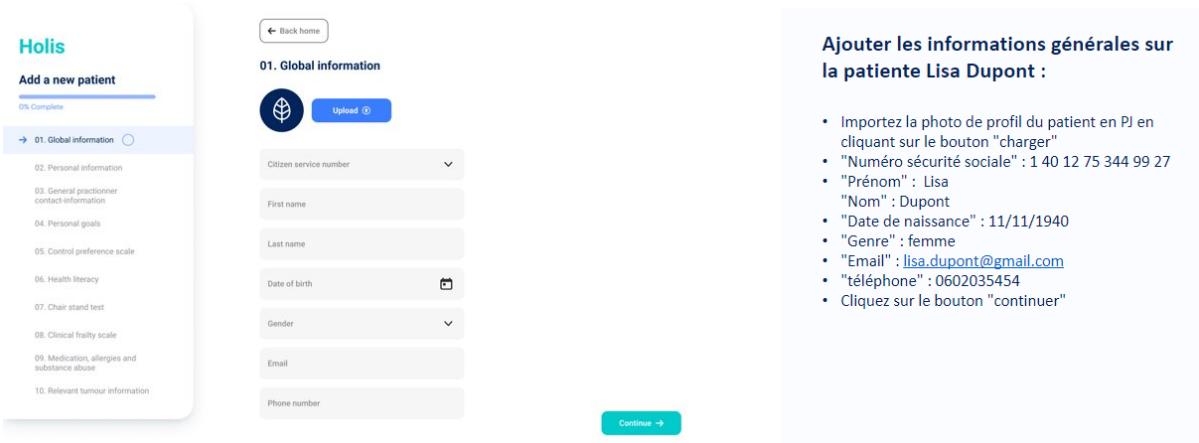


Figure 6 - Example: Scenario add information on a given patient profile

Geriatrician scenarios:

The objectives of the Geriatrician in Holis are:

- Assess the patient's health
- Make a decision on the treatment with the consortium members
- Make a decision every 3 months on the progress of the treatment

Each of these objectives deserves to be tested during the pilots, with its associated scenario.

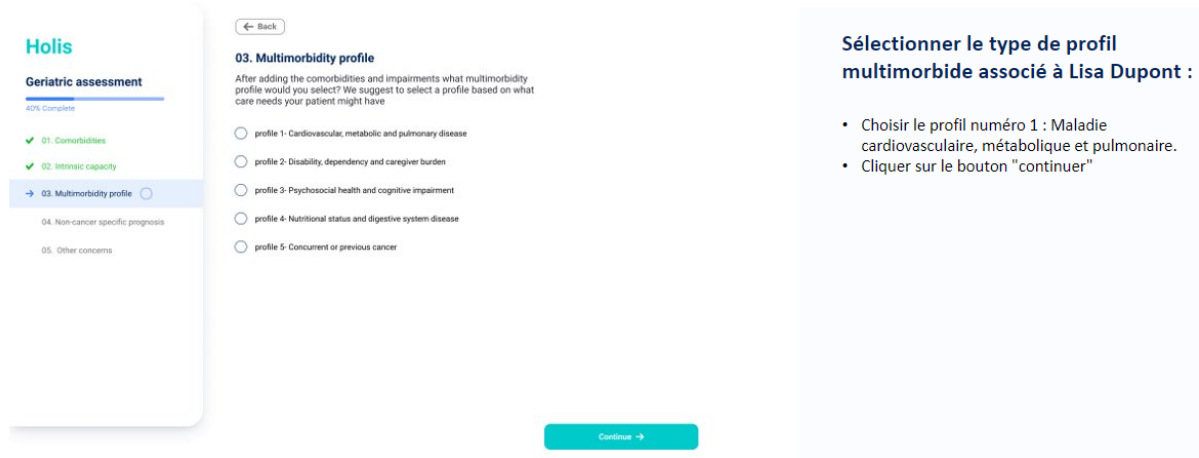


Figure 7 - Example: Assessing the patient's health

To conclude the pilot phase in Belgium, partners will proceed as follows:

- At the end of the pilot, all the bugs reported must have been dealt with and resolved MyPL
- The difficulties reported by the participants will be reviewed with the partners and an appropriate solution will be implemented after consultation MyPL
- The tests ensuring the Quality of the HOLIS system will be carried out MyPL
- A report including :
    - The list of difficulties raised and the solutions proposed and implemented.
    - The list of bugs reported and solved
    - Potential risks to be taken into account during the clinical study if any.
    - Performance indicators of the application

- Average time of use to complete a mission/task
- Usability of the application (answering the question: is the application intuitive and easy to use?
- This indicator will be calculated based on the feedback that will be asked to the participants.

8.3.4.3. Suggested plan in The Netherlands

With a previous literature review and multiple rounds of expert surveys, DIAK has established a list of symptoms that are relevant to monitor from a healthcare perspective. In the individual interviews (see co-creation sessions' results in The Netherlands as described here above in point 2.) that DIAK had with patients, they noticed that it was hard for them to express what symptoms they would want further self-management recommendations on or what symptoms they would definitely include in the symptom monitoring. Participants often felt that they had received enough information already. Therefore, DIAK would like to use the small-scale pilots to ask the same question again, after testing the Holis patient application, i.e., if there were any symptoms that they would have liked to receive self-management recommendations on. Maybe patients do have suggestions after seeing these examples. DIAK will ask actual patients this question, because they might have experienced bothersome or worrisome symptoms that they would recommend us to have self-management recommendations on.

Table 13 - The preparation of pilots in The Netherlands will include

Tasks	Responsible
1. Recruitment of 5 patients for the pilot to cover the 5 profiles of GERONTE	Diak
Recruitment of 1 APN and at least 1 member of the HPC (Geriatrician or Onco-Geriatrician) for the pilot, in order to test the whole HOLIS ecosystem	Diak
Preparation of the tablets for the patient application: the tablets will be pre-configured by the MyPL team to ensure that the tests will include the most used browsers: Chrome, Firefox, Opera and Internet Explorer	MyPL
Preparation of simulation profiles for the tests	MyPL & WP1
Preparation of test scenarios for each participant (patient, APN and HPC) to cover at least the 5 multi-morbid profiles included in GERONTE	MyPL & WP1
Preparation of the first feedback to be requested from participants	MyPL & WP1
Creation of emails for seniors to be used to connect to the application	MyPL
Creation of the hospital on the HOLIS application, as well as the accounts of the APN participating in the pilot	MyPL & UBx
A dedicated email support address for the HOLIS application	MyPL

Table 14 - The pre-launch of pilots in the Netherlands will include

Tasks

Explanation workshop and handover of the HOLIS application - APN & HPC MyPL & DIAK ○ A one-week delay is foreseen to allow the APN and HPC members to get familiar with the application before starting the tests with the seniors who will simulate the patient profiles.	2h
Explanation and handover workshop of the patient application - DIAK ○ At this stage, the patient profiles will already have been created by the APN (following the same real process). ○ Participants will have access through the link and code provided by the email address.	2h
Setting up a tool to evaluate the usability of the application and to get feedback from MyPL participants	
Implementation of a support tool to allow participants (APNs and patients) to report bugs. ○ The tool will allow participants to report bugs via an email address (determine the most appropriate channel for seniors).	

The testing and monitoring of pilots in the Netherlands will include:

The patients participating in the pilots in the Netherlands will use the patient application once, during a 45-minute session with a member of the DIAK staff. This member of staff will note all problems and questions from participants and relay them to MyPL.

Bugs reported by participants via DIAK or via the email address that will be handled by the MyPL support team. Difficulties reported by participants (APN and patients) will be analysed and solutions discussed with the relevant MyPL & WP partners. Feedback from participants will be analysed and discussed with the relevant partners.

To conclude the pilot phase in the Netherlands, partners will proceed as follows:

- At the end of the pilot, all the bugs reported must have been dealt with and resolved MyPL
- The difficulties reported by the participants will be reviewed with the partners and an appropriate solution will be implemented after consultation MyPL
- The tests ensuring the Quality of the HOLIS system will be carried out MyPL
- A report including :
  - The list of difficulties raised and the solutions proposed and implemented.
  - The list of bugs reported and solved
  - Potential risks to be taken into account during the clinical study if any.
  - Performance indicators of the application
    - Average time of use to complete a mission/task (patient app)
    - Usability of the application (answering the question: is the application intuitive and easy to use?
    - This indicator will be calculated based on the feedback that will be asked to the participants.

All bugs reported by participants are to be communicated to MyPL via e-mail as soon as they are received to ensure timely resolution.

8.3.5. Translation and report of small-scale pilots' results

Throughout the pilot process, the hosts (ESE, UBx=Bergonié, KUL and DIAK) will write reports based on the participants' feedback on the bugs in the application, or the least of their difficulties, as well as on the positive aspects of the pilots' experience. The hosts will feed back this information in the form of draft reports to MyPL and the coordinator on a regular basis.

At the end of the beta testing sessions conducted during the pilots, the final results from each country involved will be edited in the language of the participants and then translated into English by the partners. Then, KUL, DIAK, UBx (Bergonié) and ESE will send their reports in English to MyPL who will compile them into a final report of the small-scale pilots' results, corresponding to deliverable D6.3, due in month 12 (March 2022).

This report will be validated by the consortium partners.

8.3.6. Indicators to measure the results of small-scale pilots

Indicators are here defined to measure the results of the piloting phase and the impact of these results on the HOLIS' efficiency. They are described as follows:

- The list of difficulties reported and the solutions proposed and implemented
- The list of bugs reported and resolved
- Potential risks to be taken into account during the clinical study, if any are identified.
- Performance indicators of the application.
    - Average time of use to complete a mission (patient application)
    - Usability of the application (is the application intuitive and easy to use).

    - This indicator will be calculated based on the feedback that will be requested from the participants.

8.3.7. Gender balance in small-scale pilots

As per the specifications, MyPL should evaluate during the small scale pilots the following aspects:

- Whether use of digital tools is gender-biased
- Understand sex differences in reporting symptoms.

MyPL will ask all those involved in the small scale pilots (UBx, ESE, KUL and DIAK) to actually try to have gender representativity. As an example, by trying to involve 2 men / 3 women, rather than 1 man / 4 women for instance. This is the responsibility of those hosting the pilots to ensure such balance is respected.

To avoid gender bias, during co-creation sessions MyPL made sure to have a representative number of participants from both genders (first session: 2 men, 3 women, Second session: 2 men, 1 woman). Hence it allows MyPL to build a user experience and user interface that fits both genders. Moreover, ESE and DIAK will ensure recruiting a balanced team of participants.

Feedbacks asked regarding usability will be then compared based on the gender in order to reassess and act if needed. However, with such a small sample – 10 patients – conclusions would be rather speculative.

8.3.8. Protection of data and ethics requirements in the piloting phase

No collection of sensitive personal or medical data is foreseen in the context of this task. The participation of patients is not foreseen either.

ESE, DIAK, KUL and UBx will handle the personal data of their participants, including but not limited to their consent form, sign up information. This data will be kept during the life of the project and deleted according to RGPD regulation, unless participants decide to exercise their right of erasure or drop out of the project.

During the preparation phase, MyPL will take care of creating the email account for participants to use the application. Thus, no personal data will be collected. MyPL will conduct the pilots in such a way that (1) both administrative & medical data input are fictitious (hence alleviating this issue) & (2) have the application only share anonymized information from the pilots.

9. Conclusion

This guidebook is addressed to the host of the co-creation sessions explaining moderation of the discussion, collection of the participants' feedback and how to report the users' feedback for the consortium for further implementation in the GERONTE system.

Since the co-creation sessions are organised throughout the GERONTE system development until the validation phase, the guidebook and the tools will be adapted as the project results move forward and therefore these outputs will need several iterations with information updated yearly, in line with the project outcomes, such as follows:

- Month 6 (September 2021), to be aligned with submission of data management plan: updates on focus groups organisation (content, recruitment, ethics, etc.)
- Month 10 (January 2022): updates on focus groups results and small-scale pilots' methodology
- Month 24 (March 2023): updates on small-scale pilots results and link to clinical trials
- Month 48 (March 2024 - end of the project): updates on impact assessment

In V2 of this guidebook the results of the co-creation sessions were added, which include a comparison and analysis of the results as well as recommendations for the future HOLIS GV tool.

This update of the D6.2 also serves to set the methodology for the conduction of the small-scale pilots in all three partner countries (Belgium, France, the Netherlands). All partners involved in the small-scale pilots have collaborated on the elaboration of this methodology and agree to follow it.

The pilots will be followed by a report that makes up the D6.3. Given small delays in the development of the application that have pushed back the timeline for the pilots by a month, this report which was originally planned for M12 will be delivered at M13.

10. Annexes

10.1. ANNEX 1 – Focus groups anticipated timeline

TIMELINE FG	September 21					October 21					November 21				December 21			
	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Week 13	W 14	W 15	W 16	W 17	W 18
Health professionals																		
Cancer healthcare team																		
Health care team for co-morbidities																		
Nurses																		
Other health professionals																		
Patients																		
Informal caregivers																		
Common FG																		
Seniors-informal caregivers																		

10.2. ANNEX 2 – 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

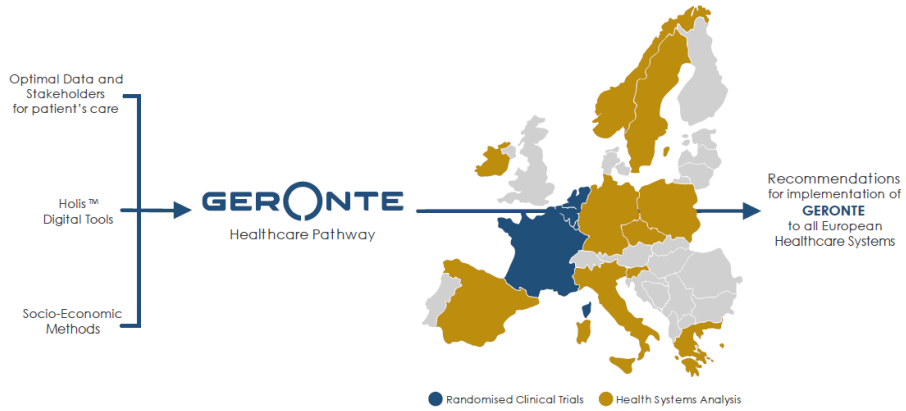
In this project comorbidity is defined as a patient with cancer presenting with at least one other serious disease.

Care Pathways

A care pathway is a multidisciplinary clinical governance tool for the mutual decision making and organization of care processes for a well-defined group of patients during a well-defined period. It is based on evidence-based practice for a specific group of patients with a predictable clinical course, in which the different tasks (interventions or episodes of care) by the professionals involved in the patient care are defined, optimized and sequenced.

10.3. ANNEX 3 – Presentation for focus groups (template)

GERONTE in A NUTSHELL



A CONSORTIUM OF 10 Partners

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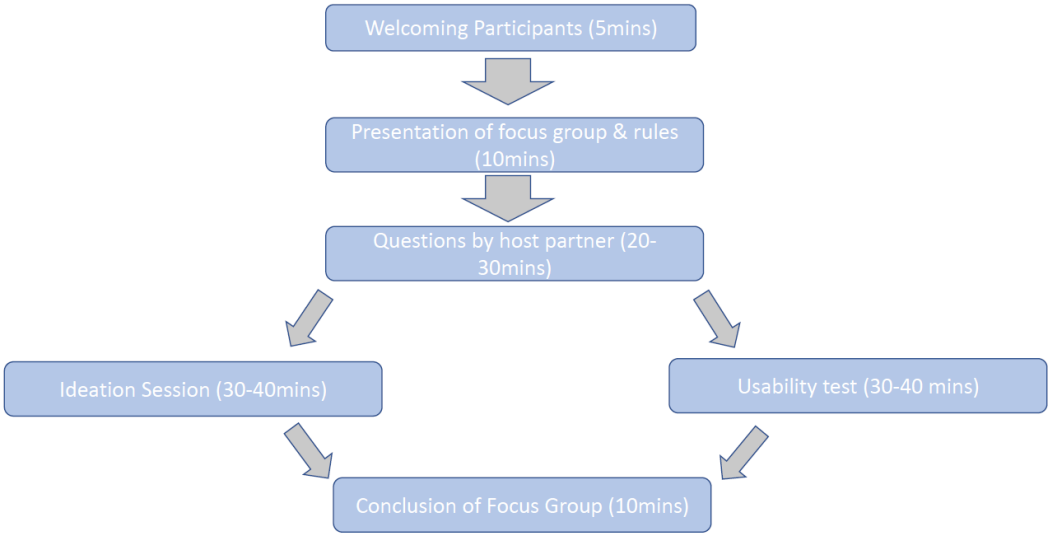
SUGGESTED PLAN FOR CO-CREATION FOCUS GROUPS*



*This suggested plan is in its draft version and will be finalized by M6 and concerns only focus groups involved in the co-design of the GERONTE app.

DETAILS ON SECTIONS OF CO-CREATION FOCUS GROUPS

- **Questions by host partner:** Questions on various topics including: expectations of the app and the project, understanding of the project, etc.
- **Ideation Sessions:** Use of a range of techniques to encourage ideation: Open ended questions on technology habits, use and preference, Sentence suggestions like, Sessions around images, Co-design user journey maps, Roleplay games
- **Usability tests:** Usability tests aim to test and validate ideas and prototypes for the app, here are examples of some methods that might be used in the GERONTE focus groups:
  - Observational sessions
  - 5 second test
  - Cognitive analysis
  - Satisfaction survey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The visuals are used for illustration purposes. Moreover, some of the icons used are downloaded from the Flaticon website, consulted on 31.01.2022, link: https://www.flaticon.com/

Support tool Freshdesk, see more information on the Freshdesk website, consulted on the 31.01.2022, link: https://freshdesk.com/lp/home?tactic_id=3387640&utm_source=Google-AdWords&utm_medium=FD-InsideEU-SE-Search-France-Brand_Shift&utm_campaign=FD-InsideEU-SE-Search-France-Brand_Shift&utm_term=freshdesk&device=c&gclid=Cj0KCQiAys2MBhDOARIsAFf1D1fJuI_J8k3dO4EkfY3Jtn6-Ns8eQ8JNm_7ws3shbnNl-sRccEgvkZUaAsfCEALw_wcB

See more information about the Analytics tool Hotjar on the Hotjar website, consulted on 31.01.2022, link: https://www.hotjar.com/usability-testing/

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